International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

Management of Bucco - Palatal Placed Impacted Maxillary Canine - Case Report

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Abstract: ***Rationale: The management of impacted maxillary canines depends on several factors. Among all teeth, maxillary canines are frequently impacted after the lower third molars. If there is enough space for the canine to erupt, a simple crown exposure followed by orthodontic management may be sufficient. However, in cases where adequate space is unavailable and the tooth is in an unfavorable position, surgical removal of the impacted canine may be necessary. Patient Concerns: The patient reported pain in the upper right front region of the jaw. Diagnosis: Based upon OPG and CBCT findings a final diagnosis of class LLL maxillary canine impaction was made. Treatment: The clinicians in this study used buccal split and palatal pull - out methods to manage impacted canine. Outcomes: The method used proved to be successful in treating bucco - palatally impacted canines.***

Keywords: Canine, Impacted, Surgical approach, Buccal, Palatal, Case report

1. Introduction

Tooth eruption alterations manifest as improper positioning within the oral cavity. Tooth impaction denotes a mature - rooted permanent tooth's failure to emerge. Among impacted teeth, maxillary canines rank high, particularly after third molars. [1]. Maxillary canines traverse a longer path in the jaw before emerging, with a higher prevalence in females [4, 5, 6]. Number of factors can be attributed to the impaction of maxillary canines. These factors can be generally classified as local or genetic, posing a hereditary influence [2]. Variations in placement of Impacted canine are - buccal, palatal, buccopalatal, or placed in arch [3]. Clinical and radiographic examinations aid in early detection, with CBCT being more effective than conventional radiography. Early detection is crucial due to potential complications such as root resorption, displacement, ankylosis, and cyst formation [6, 7, 8, 9].

This case presents a bucco - palatal impacted maxillary canine which was managed by the buccal split and palatal pull - out technique.

2. Case Report

A 27 - year - old female patient reported to the OMFS department with a chief complaint of pain in the upper right front region of the jaw. On eliciting history, the pain was dull aching, and continuous. Intraoral examination revealed deep disto - proximal caries associated with over - retained 53 and on palpation, a buccal bulge was observed in buccal mucosa. Further radiological investigation using an orthopantomograph revealed an impacted right maxillary canine (**Figure 1).**

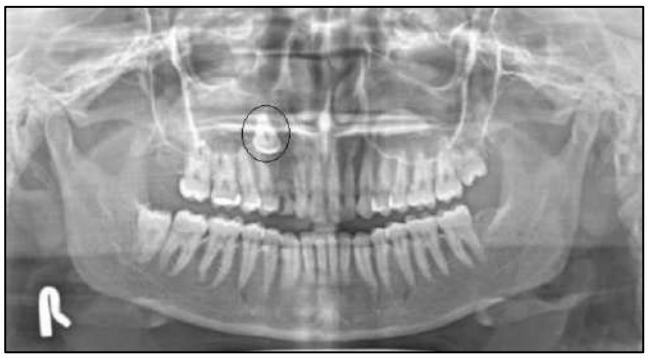

Figure 1: Orthopantomograph.

A Cone Beam Computed Tomography of the facial skeleton was done for the exact localization of the impacted right maxillary canine. The CBCT revealed a bucco - palatal position with the crown positioned palatally and the root buccally (**Figure 2).**

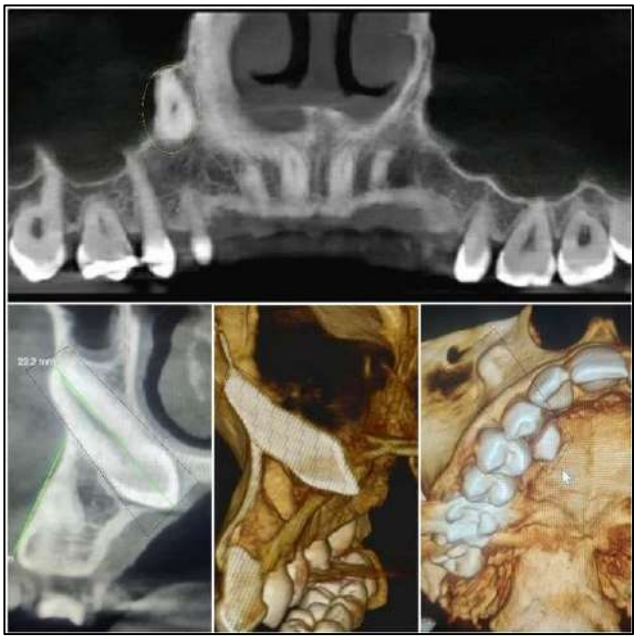

Figure 2: Cone Beam Computed Tomography.

Surgical extraction under conscious sedation was planned. After obtaining the anesthetist's fitness for surgery and written informed consent from the patient, the surgical procedure was carried out under conscious sedation.

Surgical Procedure:

Under conscious sedation, standard surgical scrubbing and draping was done.2ml of Lignocaine with 1: 2, 00, 000 dilution of adrenaline was used for an infraorbital nerve block of the right maxilla and anterior palatine nerve block, anesthetizing 11 - 15 and the associated palatal and Buccal mucosa. Local infiltrations were given labially in relation to 11, 12 and 13. A crevicular incision was given with respect to 12, 53, 24, 25 on buccal and palatal aspect with anterior releasing incision mesial to 12 and distal releasing incision distal to 25 bucally. A mucoperiosteal flap was reflected to expose the bone. Palatal bone guttering was done to completely expose the crown till the CEJ (**Figure 3).**

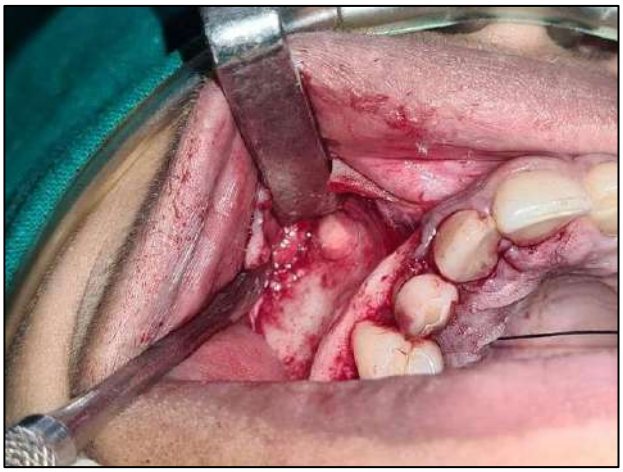

Figure 3: Exposure of palatally impacted crown.

This was followed by buccal guttering to expose the root (**Figure 4) (Figure 5).**

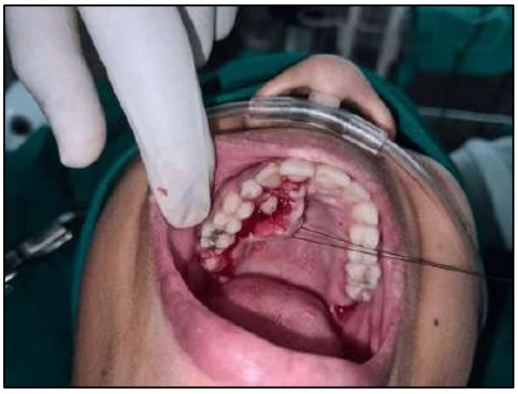

Figure 4: Exposure of buccally placed root

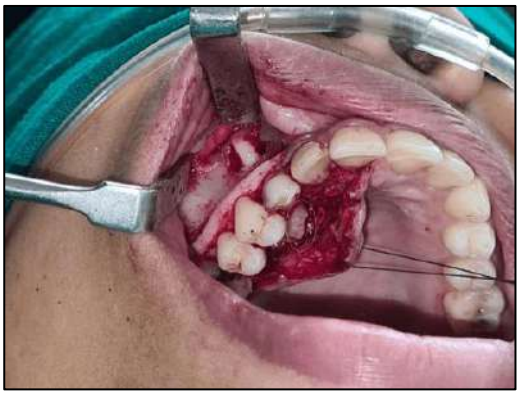

Figure 5: Complete Exposure impacted Canine

A horizontal split of the root was carried out at the apical 1/3rd level from the buccal side. The apical 1/3rd root was removed from the buccal aspect and palatal pull - out of the remaining tooth portion was carried out (**Figure 6).**

Figure 6: Extracted Canine

Haemostasis was achieved and closure was carried out using 4 - 0 vicryl suture (**Figure 7).**

Figure 7: Closure

Recovery was uneventful and the patient was stable. The patient was prescribed an analgesic and antibiotic regimen for 5 days. The patient was reviewed after 1 week and the healing was satisfactory.

3. Discussion

Tooth impactions, supernumerary teeth, oligodontia, infra - occluded teeth, taurodontism, and ectopic eruption of mandibular canines are examples of dental anomalies that affect a significant number of people worldwide and comprise a group of dental manifestations that are frequently examined in patients with maxillary impacted canines. [10] Because they are recognized earlier in the oral cavity, these dental anomalies may serve as risk markers for maxillary canine impaction and contribute to its early detection and treatment. [3]

There are various methods for the management of impacted canines. The method of management depends upon various factors such as the patient's age, stage of root formation, tooth position, presence of pathology, and general physical condition of the patient. The surgical method and orthodontic procedures used to treat impacted canines will differ based on the degree of impaction, horizontal overlap of the impacted tooth, canine angulation, and localized crowding.

No treatment is recommended if there is no evidence of resorption of neighboring teeth, absence of any pathology, or if there is presence of good contact between the lateral incisor and first premolar. In such cases patient is put on regular clinical and radiographic follow - up.

Surgical Exposure of the tooth followed by orthodontic treatment

If enough space is available or can be generated by orthodontic therapy, the affected canine is surgically exposed followed by orthodontic bonding. Controlled and planned traction forces can return the canine to its normal position in the arch. Orthodontic management is difficult with palatally impacted teeth. [1]

Surgical Removal of Impacted tooth

Teeth in an unfavorable position that is likely to cause issues in the future should be removed as soon as possible. When a patient is unwilling or unable to pay for orthodontic treatment, even teeth in a favorable position may have to be sacrificed. The surgical method differs depending on the canine's position and the type of impaction. Buccal flap elevation and bone guttering are all that is needed for a buccally displaced canine, and vice versa for a palatally displaced canine. In the case of bucco - palatal impaction, however, a single - sided approach is associated with the requirement for significant bone resection. [1] This can be reduced by employing the bucco - palatal technique proposed in the current paper. In bucco - palatally positioned oblique impactions, teeth are separated at the mid - root level from the opposing side. This shifts the center of rotation more cervically to the Level of cementoenamel junction or cervical root segment, as opposed to the typical center of rotation, which is positioned in the mid - root level, making removal easier.

A novel technique is described in this case report that is, the root is split in the mid - root region through the buccal aspect and the remaining part of the tooth is pulled out palatally.

4. Conclusion

Currently, not much literature on the approaches for surgical removal of canine is available. This case report has discussed the management of bucco - palatal impacted canine with buccal split and palatal pull - out technique. The positive outcomes obtained in this case prove that this approach is effective in the management of bucco - palatal impaction of Maxillary canines without any complications.

Informed Consent

The patient was provided with detailed information and an informed consent form was obtained.

Financial Support and Sponsorship

Nil

Conflicts of Interest

There are no conflicts of interest

References

[1] Kalyani P, Pendem S, Murugesan K: Buccal Split and Palatal Pull Out - A Novel Approach for Canine Impaction: A Case Report. J Clin Med Surgery.2022, 2: 1024.

[2] Sajnani AK, King NM: Prevalence and characteristics of impacted maxillary canines in southern Chinese children and adolescents [Internet]. Vol.5. Journal of Investigative and Clinical Dentistry.2014, 38: 44.10.1111/jicd.12027

[3] Herrera - Atoche JR, Agüayo - de - Pau MD, Escoffié - Ramírez M, Aguilar - Ayala FJ, Carrillo - Ávila BA, RejónPeraza ME: Impacted Maxillary canine prevalence and its association with other dental anomalies in a Mexican population. Int J Dent.2017, 10.1155/2017/7326061

[4] Dinu Ş, Todor L, Zetu IN,: Radiographic methods for locating impacted maxillary canines. Rom J Morphol Embryol.2022.10.47162/RJME.63.4.01

[5] El Beshlawy: Radiographic assessment of impacted maxillary canine position using CBCT: a comparative study of 2 methods. Egypt Dent J.2019, 10.21608/edj.2019.74780

[6] Masthoff M, Gerwing M, Timme M: Dental imaging - a basic guide for the radiologist. Rofo.2019.10.1055/a0636 - 4129
[7] Mitsea A, Palikaraki G, Karamesinis K, Vastardis H, Gizani S, Sifakakis I: Evaluation of Lateral Incisor Resorption Caused by Impacted Maxillary Canines Based on CBCT: A Systematic Review and Meta - Analysis. Children (Basel.2022,
[8] Tsolakis A. I., Kalavritinos M., Bitsanis E., Sanoudos M., Benetou V., Alexiou K., Tsiklakis K: Reliability of different radiographic methods for the localization of displaced maxillary canines. Am. J. Orthod. Dentofacial. Orthop.2018, 10.1016/j. ajodo.2017.06.026
[9] Guarnieri R., Cavallini C., Vernucci R., Vichi M., Leonardi R., Barbato E: Impacted maxillary canines and root resorption of adjacent teeth: A retrospective observational study. Med. Oral Patol. Oral.2016, 10.4317/medoral.21337
[10] Kolokitha OE, Balli D, Zarkadi AE, Gizani S: Association between maxillary canine impaction and other dental anomalies: radiological study of a mixed dentition children's cohort from an orthodontic clinic. Eur Arch Paediatr Dent.202324, 10.1007/s40368 - 023 - 00798 - y

Original Article

Efficacy for Lidocaine and Articaine in Inferior Alveolar Nerve Block - A Comparative Study

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Abstract

Aims: Compare the efficacy of 2% lidocaine with adrenaline (1:200,000) and 4% articaine with adrenaline (1:100,000) in inferior alveolar nerve block prior to extraction of bilateral teeth posterior to canine in interval of one week. **Methods and Material:** Thirty-five patients were selected for the study. Patients were divided into two different groups: Group 1 – (2% lignocaine with adrenaline (1:200,000)) and Group 2 – (4% articaine with adrenaline (1:100,000)) solution. The study variables for each anaesthetic agent were: onset of action and depth of anaesthesia. A pulp tester was used to demonstrate quantitative values and a visual analogue scale (VAS) was used for qualitative evaluation of the two anaesthetic drugs in 2 min cycle for 10 min with respect to test canine. Anaesthesia was considered successful when pulp tester value 64 was achieved in 10 min for both the anaesthetic agent. **Statistical Analysis Used:** The difference in the efficacy of lignocaine and articaine was analysed using Student's *t* test. Within group comparison of the response to the pulp vitality test and VAS over various time periods was analysed using repeated measures Analysis of Variance (ANOVA) with post-hoc Bonferroni test. **Results:** Data analysis showed statistical differences in onset and depth of anaesthesia between the two groups ($P < 0.05$). **Conclusions:** 4% Articaine with adrenaline (1:100,000) onset of action is faster and depth of anaesthesia is better compared to 2% lignocaine with adrenaline (1:200,000). Many previous studies reported onset of anaesthesia, but this study evaluates onset and depth of both the anaesthetic agent quantitatively and qualitatively.

Keywords: *Numerical value of anaesthesia, pain, pulp tester, visual analogue scale*

Introduction

In 1844, Horace Wells, a dentist, first introduced general anaesthesia. He inhaled nitrous oxide and got his tooth extracted.[1] In 1884, regional anaesthesia in the oral cavity was first performed by surgeon Halsted; he removed a wisdom tooth without pain. The synthesis of procaine in 1905 by Einhorn marked a significant advancement, which was the first ester-type local anaesthetic agent. In 1943, Löfgren synthesized lidocaine, which was the first modern local anaesthetic agent with improved efficacy and duration and less toxicity than procaine. Other amide local anaesthetics followed: mepivacaine (1960), prilocaine (1965), bupivacaine (1983), and articaine (2000).[2,3] Articaine differs from the amide local anaesthetic as it was derived from thiophene, and because it has a thiophene ring in its molecule instead of the usual benzene ring. The pharmacological characteristics of this anaesthetic are responsible for its main advantages. Substitution of the aromatic ring with a thiophenic ring increased the liposolubility of the drug along with its potency (1.5 times greater than that of lidocaine). Moreover, articaine is the only amide local anaesthetic containing an ester group in its molecular structure, thus allowing metabolisation of the drug both by plasma esterases and by liver microsomal enzymes.[1]

Despite extensive research in this field, no literature has been found correlating both quantitatively and qualitatively. The purpose of the study is the comparison of efficacy for 2% lidocaine with adrenaline (1: 200,000) and 4% articaine with adrenaline (1: 100,000) in inferior alveolar nerve block. This study is based on quantitative and qualitative criteria.

Material and Method

The study involved 35 patients (21 males and 14 females) with a mean age of 31.9 years (standard deviation (SD) = 7.41),

How to cite this article: Purkayastha RS, Joshi S, Nair K, Pawar S. Efficacy for lidocaine and articaine in inferior alveolar nerve block - A comparative study. Indian J Dent Res 2024;35:40-4.

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Received : 03-08-2023
Revised : 06-10-2023
Accepted : 19-10-2023
Published : 20-06-2024

Access this article online

Website: https://journals.lww.com/ijdr

DOI: 10.4103/ijdr.ijdr_678_23

Quick Response Code:

range from 18 to 40 years, who required bilateral extraction of permanent mandibular teeth posterior canine. Prior to procedures, all patients were provided with detailed information, and an informed consent form was attained. Approval was obtained from the Institute's Review Board and Ethics Committee (Registration Number: ECR/328/Inst/MH/2016). The inclusion criteria encompassed patients aged 18–40 years, classified as ASA 1 (systemically healthy), in need of bilateral mandibular tooth extraction posterior to the canine. Additionally, healthy canines without caries or periodontal disease were required. Exclusion criteria involved absence of canine, carious canine, acute infections, systemic diseases contraindicating extraction, allergies to specific local anaesthetics, immune compromise, unwillingness to participate, and poor motivation.

Detailed case histories and routine examinations were conducted for all participants. Adhering to stringent sterilization protocols, a split-mouth technique was employed for tooth extraction. Patients received both types of anaesthetic agents in separate appointments at weekly interval. The choice of local anaesthetic was randomized using a coin flip. To initiate testing, the tooth was isolated and dried using cotton rolls and an air syringe. A small amount of toothpaste was applied to the probe tip, positioned on the middle third of the tooth's facial surface. Ahead of injections, the experimental tooth and the contralateral canine underwent pulp testing during each appointment, ensuring baseline data and tooth vitality assessment.

After administration of anaesthetic agent in each group, stopwatch was set for an interval of 2 min at the end of which electric pulp tester reading and visual analogue scale (VAS) was noted [Tables 1 and 2, Figure 1a]. The electric pulp stimulation of the contralateral canine, which was not anesthetized, was used as a control to ensure that the equipment was working properly and that patients were responding adequately. The value of the initial sensation was recorded. The current rate was set at 9.0 mA, with (0) value to maximum value (64). Trained personnel, blinded to the anaesthetic solutions, were assigned to administer injections. A standard inferior alveolar injection, as described by Malamed, was administered with a 27-gauge needle and 5 mL disposable syringe. 2% Lidocaine with 1:200,000 adrenaline/4% articaine with adrenaline (1:100,000) was loaded into the 5-cc syringe, and the volume was adjusted to 3.6 mL each. On the side designated to receive the injection, after reaching the target area and performing aspiration, 3.6 mL of 2% lidocaine with 1:200,000 adrenaline/4% articaine with adrenaline (1:100,000) was injected. The pulp tester personnel were not present during the injections. A total injection of 3.6 mL of either 2% lidocaine with 1:200,000 adrenaline or 4% articaine with adrenaline (1:100,000) was administered on two consecutive appointments (1 week), respectively, as standard inferior alveolar nerve block. At 2-min post injection, test canine was pulp tested and the patient was asked about numbness of lip and assessed according to VAS [Table 1]. The cycle of testing was repeated every 2 min and all testing was stopped at 10 min post injection [Tables 1 and 2]. A maximum value of 64 was considered as a complete achievement of pulpal anaesthesia [Figure 1b]. Lip anaesthesia was considered successful when the subject felt numbness within 10 min. The time for onset of lip anaesthesia was recorded via VAS. Each patient was asked to rate the numbness they perceived during the testing procedure.

The ratings were:

1 – No numbness, 2 – Mild numbness, 3 – Moderate numbness, 4 – Numbness.

Result

Descriptive statistics were expressed as mean ± standard deviation (SD) for each group. The difference in the efficacy of 2% lignocaine with adrenaline (1:200,000) and 4% articaine with adrenaline (1:100,000) was analysed using Student's *t* test. Comparison of electric pulp tester and VAS reading over various time periods was analysed using repeated measures ANOVA with post-hoc Bonferroni test. In the above tests, *P* value less than or equal to 0.05 ($P \leq 0.05$) was taken to be statistically significant. The study population comprised 35 patients (21 males and 14 females), mean age 31.9 years (standard deviation (SD) = 7.41), range from 18 to 40 years, requiring bilateral extraction of permanent mandibular teeth posterior to Canine.

Comparison of the onset of action of the anaesthesia using the pulp tester between Group 1 (2% lignocaine with adrenaline (1:200,000)) and Group 2 (4% articaine with adrenaline (1:100,000)), at all the study time intervals, i.e., 2, 4, 6, 8 and 10 min, there was a statistically significant difference between the two anaesthetic solutions. Group 2 (4% articaine with adrenaline (1:100,000)) demonstrated high pulp tester scores as compared to

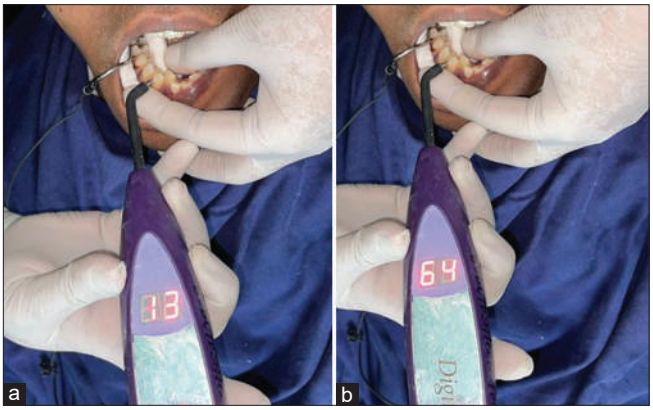
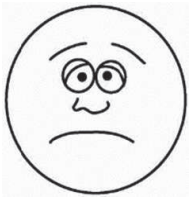
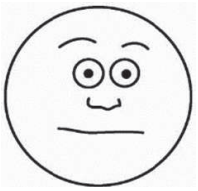
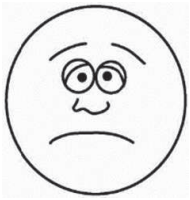
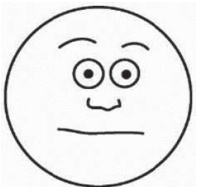
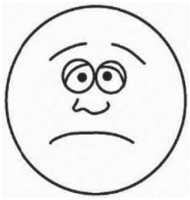
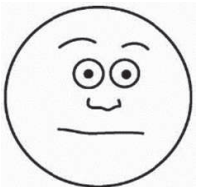
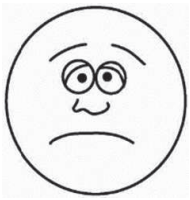
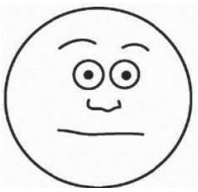
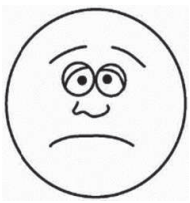
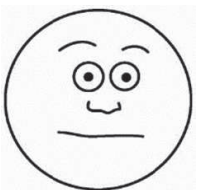


Figure 1 : (a) Electric Pulp Tester showing test Canine tooth result 2 minutes post injection. (b) Maximum value of 64 achieved 10 minutes post injection

Table 1: Table to evaluate using pulp tester access the onset of action of anesthesia using pulp tester

GROUP I/II	PATIENT	AGE	GENDER	MINUTES	PULP TESTING VALUES	VISUAL ANALOGUE SCALE
				2		
				4		
				6		
				8		
				10		

Table 2: Table to record numbness using visual analogue scales access numbness on visual analogue scale

Time in minutes	Visual analogue scale			
	1	2	3	4
2	 NO NUMBNESS	 MILD NUMBNESS	 MODERATE NUMBNESS	 COMPLETE NUMBNESS
4	 NO NUMBNESS	 MILD NUMBNESS	 MODERATE NUMBNESS	 COMPLETE NUMBNESS
6	 NO NUMBNESS	 MILD NUMBNESS	 MODERATE NUMBNESS	 COMPLETE NUMBNESS
8	 NO NUMBNESS	 MILD NUMBNESS	 MODERATE NUMBNESS	 COMPLETE NUMBNESS
10	 NO NUMBNESS	 MILD NUMBNESS	 MODERATE NUMBNESS	 COMPLETE NUMBNESS

Group 1 (2% lignocaine with adrenaline (1:200,000)). At the end of 10 min, complete anaesthesia was achieved with the 4% articaine with adrenaline (1:100,000); however, in 2% lignocaine with adrenaline (1:200,000), there was the moderate response of the tooth to the electric pulp tester [Table 3].

On comparing the depth of anaesthesia (lip numbness) using the VAS between Group 1 (2% lignocaine with

adrenaline (1:200,000)) and Group 2 (4% articaine with adrenaline (1:100,000)), at all the study time intervals, i.e., 2, 4, 6, 8 and 10 min, there was a statistically significant difference between the two anaesthetic solutions. The VAS score was higher in 4% articaine with adrenaline (1:100,000) group compared to 2% lignocaine with adrenaline (1:200,000) group. At the end of 10 min, complete numbness was achieved with the 4% articaine with adrenaline (1:100,000) [Table 4].

Discussion

4% Articaine with adrenaline (1:100,000) solutions achieve the highest level of anaesthetic potency and lowest systemic toxicity in all clinical situations. These are liposoluble, have high plasma protein binding rate, fast metabolization, fast elimination half time and low blood level. Articaine metabolizes in the liver and also in blood serum. It diffuses through tissues faster. Thus, articaine seems to be the local anaesthetic of first choice in tissues with suppurative inflammation, for adults, children (over 4 years), elderly, pregnant women, breastfeeding women, patients suffering from hepatic disorders and renal function impairment. The incidence of serious adverse effects related to articaine is very low. Toxic reactions are usually due to the use of excessive dose. To avoid overdoses, maximum recommendation dose must not be exceeded and aspiration test to be always performed prior to all local anaesthetic (LA) injections.[4]

Table 3: Comparison of the onset of action of the anesthesia using the pulp tester between Group 1-2% Lignocaine with Adrenaline (1:2,00,000) and Group 2-4% Articaine with Adrenaline (1:1,00,000)

Time period	Pulp Testing Values (Mean±SD)		*P* (Student *t*-test)
	Group 1	Group 2	
2 min	12.71±3.56	26.09±14.37	<0.001*
4 min	19.94±4.50	34.23±12.32	<0.001*
6 min	30.34±5.18	44.09±9.57	<0.001*
8 min	39.74±8.54	54.23±9.26	<0.001*
10 min	55.66±7.42	64.00±0.00	<0.001*

*$P \leq 0.05$ is considered as statistically significant

Table 4: Comparison of the onset of lip anesthesia using the Visual Analogue Scale between Group 1-2% Lignocaine with Adrenaline (1:2,00,000) and Group 2-4% Articaine with Adrenaline (1:1,00,000)

Time period	Visual Analogue Scale score (Mean±SD)		*P* (Student *t*-test)
	Group 1	Group 2	
2 min	1.86±0.36	2.20±0.41	<0.001*
4 min	2.00±0.00	2.74±0.44	<0.001*
6 min	2.40±0.50	2.97±0.30	<0.001*
8 min	2.91±0.28	3.34±0.48	<0.001*
10 min	3.23±0.43	4.00±0.00	<0.001*

*$P \leq 0.05$ is considered as statistically significant

Administering local anaesthetics in the oral mucous membrane often causes discomfort due to factors like injection speed, solution volume, tissue density and psychological factors. The acidic pH of anaesthetic solutions, such as lignocaine (pH ~3.5) and articaine (pH 4.0–5.5), significantly contributes to this discomfort.[5] At a higher pH, anaesthetic has a rapid onset of action and great potency. Articaine's distinct chemical structure, with a thiophene ring replacing the aromatic ring and an extra ester ring, results in higher liposolubility, potency and plasma protein binding compared to lignocaine. This leads to quicker onset, extended anaesthesia and better diffusion in bony tissue.[6]

The onset of action of an anaesthetic depends on a number of factors, such as the intrinsic properties of the drug substance used, and the anaesthetic technique employed. It is a known fact that the onset of action is directly influenced by the corresponding pKa value, smaller pKa values being associated to shorter latency. Accordingly, 4% articaine (pKa = 7.8) presents a shorter latency than 2% lidocaine (pKa = 7.9). The mean time taken by 4% articaine was 2–3 min as compared to 3 min for 2% lidocaine.[5] Diffusion rate is influenced by various factors, with concentration gradient being paramount. Higher initial anaesthetic concentration leads to faster molecule diffusion and quicker onset of action. Nerve fasciculi near the surface are termed mantle bundles; they encounter higher anaesthetic concentration and are swiftly blocked post injection.

Core bundles, situated closer to the nerve centre, experience delayed and lower concentration effects of local anaesthetic due to increased solution travel and barriers. As the anaesthetic diffuses, it dilutes in tissue fluids, with capillary and lymphatic absorption. Mantle fibres near the nerve surface innervate proximal areas, while core bundle fibres innervate distal points. For instance, an inferior alveolar nerve block affects molar vs. incisor and canine regions.

The central core theory states that the nerve on the outside of the nerve bundle supply molar teeth while the nerve and the inner supply the anterior teeth.[7] The anaesthetic solution may not diffuse into the nerve trunk to reach all the nerves to produce an adequate block even if deposited at the correct site. This theory may explain the higher experimental failure rates in the anterior teeth with Inferior Alveolar Nerve Block (IANB) but not posterior teeth.[1-3,8-11]

In the present study, the onset of anaesthetic action was demonstrated by means of electric pulp tester. Qualitative evaluation (subjective signs) was done using Moon's probe. 2 min post injection, test canine was checked with a pulp tester. The (quantitative evaluation) pulp tester readings were recorded in the interval of 2, 4, 6, 8 and 10 min. On comparing the onset of action of the anaesthesia using the pulp tester between Group 1 (2% lignocaine with adrenaline (1:200,000)) and Group 2 (4% articaine with adrenaline (1:100,000)), statistical analysis shows that at all the study time intervals,

i.e., 2, 4, 6, 8 and 10 min, there is a statistically significant difference between the two anaesthetic solutions. Group 2, i.e., 4% articaine with adrenaline (1:100,000) group shows high pulp tester scores as compared to Group 1 (2% lignocaine with adrenaline (1:200,000)). At the end of 10 min, complete anaesthesia is achieved with 4% articaine with adrenaline (1:100,000); however with 2% lignocaine with adrenaline (1:200,000), there was moderate response of the tooth to the electric pulp tester [Table 4]. Our results coincide with the existing literature, as faster onset of anaesthesia was observed with 4% articaine with adrenaline (1:100,000) group compared to 2% lignocaine with adrenaline (1:200,000) group, respectively.

In the present study, depth of anaesthesia was demonstrated by means of a VAS in which the patient was instructed to score intraoperative numbness. In the study to evaluate the numbness, VAS rating mentioned were: 1 – No Numbness, 2 – Mild Numbness, 3 – Moderate Numbness and 4 – Numbness. Patients were advised to rate according to the numbness they experienced in the time interval of 2, 4, 6, 8 and 10 min. At the same interval, the pulp tester determined the pulpal anaesthesia numerically. Pulpal anaesthesia is considered the highest depth of anaesthesia because the core nerve fibres on inferior alveolar nerve supplies canine pulp, verifying that local anaesthesia has diffused to the central neural fibres. On comparing of the depth of anaesthesia (lip numbness) using the VAS between Group 1 (2% lignocaine with adrenaline (1:200,000)) and Group 2 (4% articaine with adrenaline (1:100,000)) statistical analysis shows that at all the study time intervals, i.e., 2, 4, 6, 8 and 10 min, there was a statistically significant difference between the two anaesthetic solutions. Group 2, i.e., 4% articaine with adrenaline (1:1,00,000) group shows high pulp test scores as compared to Group 1 (2% lignocaine with adrenaline (1:200,000)). The VAS scores are higher in the articaine group as compared to 2% lignocaine with adrenaline (1:200,000) group. At the end of 10 min, VAS and pulp test values are much higher in 4% articaine with adrenaline (1:100,000) compared to 2% lignocaine with adrenaline (1:200,000) group, which indicate that 4% articaine with adrenaline (1:100,000) provides greater depth of anaesthesia compared to 2% lignocaine with adrenaline (1:200,000) [Tables 3 and 4].

Many previous studies reported the onset of anaesthesia, but this study evaluates onset and depth of both the anaesthetic agents quantitatively and qualitatively. Qualitative evaluation (subjective signs) was reported by the patient and noted by the observer using VAS and pulp tester was used for quantitative evaluation (numerical values) on the same side canine. The statistical values of both the anaesthetic drugs were correlated based on qualitative and quantitative criteria, which is a novel technique. On comparing both the anaesthetic drugs, statistical value shows that 4% articaine with adrenaline (1:100,000) is potent, effective and safe alternative to 2% lignocaine with adrenaline (1:200,000), in minor surgical procedure and is statistically significantly better as compared to the Lignocaine group.

Conclusion

In our comparative study, results showed 4% articaine with adrenaline (1:100,000) had a significant faster onset of action and better depth of anaesthesia when compared to 2% lidocaine with adrenaline (1:200,000). A clear difference between articaine and lidocaine was observed. An evidence-based approach to the current available literature suggests that articaine is an effective and well-tolerated anaesthetic for dental use when compared to lidocaine. Further studies on a larger group of population are recommended for greater authenticity of this relatively new drug in oral and maxillofacial surgery in India to make as popular and safer to be used as a routine anaesthetic agent in dentistry.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Kambalimath DH, Dolas RS, Kambalimath HV, Agrawal SM. Efficacy of 4% Articaine and 2% Lidocaine: A clinical study. J Maxillofac Oral Surg 2013;12:3-10.
2. Giovannitti JA Jr, Rosenberg MB, Phero JC. Pharmacology of local anesthetics used in oral surgery. Oral Maxillofac Surg Clin North Am 2013;25:453-65, vi.
3. Rahn R, Ball B. Local Anaesthesia in Dentistry: Articaine and Epinephrine for Dental Anaesthesia. 1st ed. Seefeld (Germany): 3M ESPE AG; 2001.
4. Nizharadze N, Mamaladze M, Chipashvili N, Vadachkoria D. Articaine - the best choice of local anesthetic in contemporary dentistry. Georgian Medical News 2011;(190):15-23. PMID: 21346262.
5. Malamed SF. Handbook of Local Anaesthesia. 7th ed. St Louis: Mosby; 2020.
6. Jain NK, John RR. Anesthetic efficacy of 4% articaine versus 2% lignocaine during the surgical removal of the third molar: A comparative prospective study. Anesth Essays Res 2016;10:356-61.
7. Kalia V, Supreet, Kaur R. Comparative evaluation of onset and duration of anaesthesia of 4% articaine versus 2% lidocaine with epinephrine 1:1,00,000 during exodontia. Indian J Compr Dent Care 2011;1:19-24.
8. Covino BG, Vassallo HG. Local Anesthetics: Mechanisms of Action and Clinical Use. New York: Grune and Stratton; 1976.
9. Malamed SF, Gagnon S, Leblanc D. Articaine hydrochloride: The study of safety of a new amide local anesthetic. J Am Dent Assc 2001;132:177-85.
10. Malamed SF, Gagnon S, Leblanc D. A comparison between articaine HCL and lidocaine HCL in pediatric dental patients. Pediatr Dent 2000;22:307-11.
11. Bagade SP, Joshi SS, Punamiya S, Malliwal A, Naik CS, Ansari A. To evaluate the Efficacy of Buprenorphine and 2% Lignocaine with adrenaline as postoperative analgesia following mandibular third molar surgery: A comparative study. Ann Maxillofac Surg 2021;11:236-40.

ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 05 | May - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

CLINICAL EVALUATION OF EFFECTIVENESS OF DIODE LASER AS AN ADJUNCT TO OPEN FLAP DEBRIDEMENT AS COMPARED TO OPEN FLAP DEBRIDEMENT ALONE IN THE PERIODONTAL TREATMENT OUTCOME OF PATIENTS WITH CHRONIC PERIODONTITIS – A SYSTEMATIC REVIEW

Dentistry

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ABSTRACT

Objective: The objective of this systematic review is to compare and clinically evaluate the adjunctive benefits of a diode laser (DL) to conventional open flap debridement (OFD) in the treatment of chronic periodontitis. **Background:** DL is an excellent soft tissue surgical laser, indicated for soft tissue curettage or sulcular debridement with an additional bactericidal effect. Studies have been conducted to determine the effect of DL as an adjunct to OFD. There is limited documentation regarding the clinical effectiveness to prove adjunctive effect of OFD in the surgical periodontal therapy. **Methods:** Only randomized controlled trials (RCTs) assessing use of DL only in continuous and contact mode on undersurface of flap post-conventional OFD for treatment of chronic periodontitis in the test group were considered. Studies published only in English language with follow-up periods of 3 and 6 months post-operatively and assessing probing pocket depth (PPD) and clinical attatchment level (CAL) as the outcomes were considered. A total of 6 RCTs were included in this systematic review. Cochrane Risk of Bias tool was used for assessing the risk of bias. **Results:** 3/6 studies concluded that DL significantly led to reduction in PPD or gain in CAL when used as adjunct to OFD. Whereas, other 3/6 studies concluded that DL did not significantly lead to reduction in PPD or gain in CAL when used as adjunct to OFD. **Conclusion:** DL can be used as an adjunct to standard treatments (OFD) of chronic periodontitis i.e; chronic periodontitis rather than as a replacement for standard treatments.

KEYWORDS

Open flap debridement, Periodontal flap surgery, Diode laser

INTRODUCTION:

Periodontitis is an opportunistic infection caused by an imbalance in the virulence factors of pathogenic microorganisms and host defence mechanisms, resulting in an immune-inflammatory response that can cause destruction of the periodontal ligament, alveolar bone with pocket formation and recession.[1] Pathogenic plaque micro-flora, host immune responses, and environmental factors play a major etiologic role and cause both direct as well as host-mediated tissue injury. Elimination or modification of these factors is the basic aspect of treatment, which arrests or controls the disease process. In addition, the aim is to regenerate the tissues and restore function with methods, which are predictable and achieve long-term benefits.[2]

Complete removal of bacterial deposits and their toxins from the root surface cannot be completely achieved by conventional nonsurgical mechanical therapy because of limited access to areas such as furcations, concavities, and developmental grooves and hence necessitating surgical intervention. Thus, flap surgery is an indication for deeper pockets, resulting in greater immediate pocket reduction and attachment gain.[3]

In recent years, various innovative adjunctive treatments have been developed to improve the clinical effectiveness of scaling and root debridement. Among the various new technologies offered, therapeutic diode laser treatment is one.[4] It promotes tissue healing and reduces edema, inflammation, and pain.[5] Laser-enhanced biostimulation has been reported to induce the intracellular metabolic changes, resulting in faster cell division, proliferation rate, migration of fibroblasts, and rapid matrix production. It has also been found to promote fibroblast maturation and proliferation, macrophage phagocytosis and lymphocyte activation.[8]

Light Amplification by Stimulated Emission of Radiation(LASER); have been used in periodontology to reduce periodontopathogenic bacteria,remove the pocket epithelium, and retard epithelial migration into the pocket. A significant reduction of periodontopathogenic bacteria has also been demonstrated, regardless of laser wavelength.[9]

The DL is a solid-state semiconductor laser that typically uses a combination of Gallium (Ga), Arsenide (Ar), and other elements such as Aluminum(Al) and Indium (In) to change electrical energy into light energy. The laser is emitted in continuous-wave and gated-pulsed modes, and is usually operated in a contact method using a flexible fiber optic delivery system. The reliable hemostasis achieved with diode lasers has made them a valuable tool during periodontal surgical procedures.[10]

DL with a wavelength of 810 nm or 910–980 nm, does not interact with dental hard tissues and therefore, is an excellent soft tissue surgical laser, indicated for cutting and coagulating gingiva and oral mucosa, and for soft tissue curettage or sulcular debridement with an additional bactericidal effect.[11]

Rationale :

Studies have been conducted to determine the effect of DL as an adjunct to OFD. Furthermore, various studies have described improved clinical outcomes by employing DL to de-epithelize the underneath lining of the mucoperiosteal flap and also facilitate considerable bacterial reduction.

Although there are studies analyzing the use of DL as an adjunct to OFD in patients with chronic periodontitis, there is limited documentation regarding the clinical effectiveness to prove adjunctive effect of DL in the surgical periodontal therapy.

There are no systematic reviews till date assessing the clinical effectiveness to prove adjunctive effect of DL in the surgical periodontal therapy.

Objective:

The objective of this systematic review is to compare and clinically evaluate the adjunctive benefits of a DL to conventional OFD in the treatment of chronic periodontitis, testing the hypothesis that adjunctive use of DL can improve outcomes of surgical periodontal therapy (OFD) as compared to OFD alone.

Focused Question:
Does DL as an adjunct to OFD has better clinical treatment outcome as compared to OFD alone in treatment of patients with chronic periodontitis in the age group of 20-65 years?

METHODS

Eligibility Criteria:
The PICO (patient, intervention, comparison, and outcome) strategy was followed in this systematic review which are key for designing all stages of an interventional systematic review.

Pico Analysis:
(P) Types of participants: Patients between age group of 20-65 years diagnosed with chronic periodontitis who have completed a cycle of non-surgical periodontal therapy (Phase – I) and present with residual pockets ≥ 5mm in atleast two quadrants.
(I) Types of interventions: DL as an adjunct to OFD as compared to OFD alone.
(C) Comparison between interventions: All possible comparisons between DL as adjunct to OFD with OFD alone in the treatment of chronic periodontitis.
(O) Type of outcomes measures: Clinical attachment level (CAL) gain, Probing Pocket Depth (PPD) reduction
(S) Types of studies: Only randomized controlled clinical trials (RCTs) were considered in the review.

Inclusion Criteria:
RCTs with split-mouth design assessing the clinical parameters- PPD and CAL/RAL, full text articles published in English till April 2023

Exclusion Criteria:
1. Studies assessing patients with habit of tobacco consumption, who are medically compromised or with systemic diseases or pregnant and lactating women, with history of periodontal surgery in past 6 months.
2. Studies assessing the parameters with multiple application of laser at the sites post-operatively

Information Sources:
PubMed, Cochrane Library, Google Scholar and EBSCOhost were employed as electronic databases. All databases were searched from years 2012-2023 with a personal computer.

Last electronic search was carried out on 30 April 2023.

Search Strategy:
Electronically the following search strategies were used in PubMed search builder.

Search terms and Boolean operators used were :
((Diode laser) AND (Open flap debridement)) AND (periodontitis)
Electronic search was carried out without any limits and language restriction to include all the possible clinical trials in the potentially relevant article search phase of the systematic review.

Selection Process:
Titles and abstracts of all relevant articles were screened was then narrowed down manually by the reviewer, When studies met the inclusion criteria or when insufficient data from abstracts for evaluating inclusion criteria were gained, the full article was obtained.

Data Collection Process:
A standardized specifically designed data extraction form was used to record data and a data chart was prepared from each included study, encompassing number of patients, clinical methods (assessment and treatment), follow-up duration and clinical outcomes (Table-2).

Data Items:
To assess the clinical outcomes of the interventions, Probing Pocket Depth (PPD) and Clinical Attachment Level (CAL) / Relative Attachment Level (RAL) were used as variables.

Study Risk Of Bias Assessment:
Cochrane Risk of Bias tool was used for assessing the risk of bias.

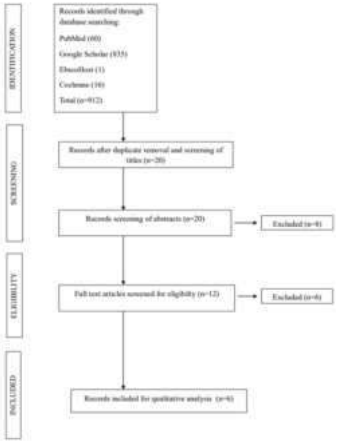
Majorly, seven domains (random sequence generation, allocation concealment, blinding of the outcome assessor, blinding of participants and personnel, incomplete outcome data, selective outcome reporting and other bias) were evaluated and included in a graph. The Risk of bias of the included studies were categorized accordingly:
(A) Low risk of bias if all domains were met.
(B) Unclear risk of bias if one or more domains were partly met.
(C) High risk of bias if one or more domains were not met
Two reviewers independently evaluated risk of bias of included studies. When disagreement between the two reviewers was detected, consensus was achieved by discussion with the third reviewer/statistical advisor.

Effect Measures:
PPD, CAL/RAL had to be expressed as mean difference in millimetres.

Synthesis Methods:
The search strategy provided a total of 912 articles. After assessing for eligibility criteria; 906 studies were excluded. 6 articles published from their earliest records were included in the present systematic review.

The flowchart of article screening and selection process is given in Figure 1

RESULTS



Study Selection: **Figure 1**

Table 1: Table Of Excluded Studies

AUTHORS and YEAR	STUDY DESIGN	REASON FOR EXCLUSION
Misra P, Kalsi R, Anand Arora S, Singh KS, Athar S, Saini A.(2023)[12]	RCT	1. Laser bio-stimulation done in non-contact mode 2. Multiple application of laser at the sites post-operatively
Roy S, Singh DK, Manohar B.(2022)[13]	RCT	1. DL used in non-contact mode 2. No post-operative follow-up at 3months
Shreya M, Harsh M, Surabhi J, Chandni P, Tanvi H, Santosh K.(2022)[14]	RCT	1.No post-operative follow-up at 6 months
Khan F, Chopra R, Sharma N, Agrawal E, Achom M, Sharma P.(2021)[15]	RCT	1. No post-operative follow-up at 6 months
Agarwal A, Saxena A, Gummaluri SS, Chaudhary B, Subramanyam S Sai K, Kumar G.(2021)[23]	RCT	1.No post-operative follow-up at 3 months
Dalvi S, Khetal N, Ansari S, Benedicenti S, Hanna R.(2021)[16]	Case report	1.Case report
Arvind N, Mamatha S, Srikala B. (2020).	RCT	1.PPD, CAL/RAL are not assessed
Shetty S, Shetty K, Alghamdi S, Almehmadi N and Mukherjee T. (2020)[9]	RCT	1.Granulation tissue is debrided using diode laser. 2.No mention of

		diode laser used on undersurface of flap
Karthikeyan J, Vijayalakshmi R, Mahendra J, Kanakamedala AK, Chellathurai BNK, Selvarajan S, Namachi vayam A. (2019)[3]	RCT	1. Multiple application of laser at the sites post-operatively
Heidari M, Fekrazad R, Sobouti F, Moharrami M, Azizi S, Nokhbatol foghahaei H, Khatami M. (2018)[18]	RCT	1.PPD, CAL/RAL are not assessed
Soliman MM, Sabra SM, Al-Shammrani AS, Sorour AA. (2014)[19]	RCT	1.Parallel-arm study 2.Non-surgical Periodontal therapy
Aena PJ, Parul A, Siddharth P, Pravesh G, Vikas D, Vandita A. (2015)[4]	RCT	1. No post-operative follow-up at 3 months
Sanz-Moliner JD, Nart J, Cohen RE, Ciancio SG. (2013)[20]	RCT	1.PPD, CAL/RAL are not assessed
Gokhale SR, Padhye AM, Byakod G, Jain SA, Padbidri V, Shivaswamy S. (2012)[21]	RCT	1. No post-operative follow-up at 6 months

Study Characteristics: Table 2: Table Of Included Studies

AUTHORS And YEAR	SAMPLE SIZE	COMPARISON AND INTERVENTION	OUTCOMES CONSIDERED FOR SYSTEMATIC REVIEW	MEASUREMENT OF PARAMETERS	FOLLOW-UP
Kolamala N, Nagarakanti S, Chava VK. (2022)[1]	15 patients, 30 sites	Control sites – Conventional OFD alone Test sites – Laser-assisted OFD (LA-OFD)(DL)	1.PPD 2.CAL/RAL	UNC-15 +Occlusal acryl ic stent - to stand ardize the measurements of clinical parameters	Baseline and 3, 6 months after surgery.
Doğan ŞB, Akça G. (2022)[22]	18 patients	Control sites - Modified Widman Flap and application of sham DL Test sites - Modified Widman Flap (MWF) and by applying active DL to the inside of the MWF.	1.PPD 2.CAL	UNC-15 +Occlusal acry lic stent - to stan dardize the measurements of clinical parameters	Baseline and 3, 6 months after surgery.
Rathod Swati et al. (2019)[25]	20 patients	Control sites – OFD Test sites –OFD + DL application	1.PPD 2.CAL	UNC-15 +Occlusal acryli c stent - to stand ardize the measurements of clinical parameters	Baseline and 3, 6 months after surgery.
Dr Nada Musharraf Ali1.(2019)[10]	16 patients	Control sites – OFD Test sites – OFD + DL application	1.PPD 2.CAL	UNC-15 +Occlusal acryli c stent - to stand ardize the measurements of clinical parameters	Baseline and 3, 6 months after surgery.
Jonnalagadda BD,Gottumukkala SNVS, Dwarakanath CD,Koneru S. (2018)[26]	23 patients	Control sites - CAPF: Conventional access periodontal flap LAPF - Laser assisted periodontal flap(DL)	1.PPD 2.RAL	UNC-15	Baseline and 3, 6 months after surgery.
Lobo TM, Pol DG.(2015)[2]	30 patients	Control sites – MWF technique Test sites – MWF + DL	1.PPD 2.CAL	UNC-15 +Occlusal acryli c stent - to stand ardize the measurements of clinical parameters	Baseline and 3, 6 months after surgery.

Risk Of Bias In Studies:

Figure-2 Overall Risk Of Bias Of Included Studies

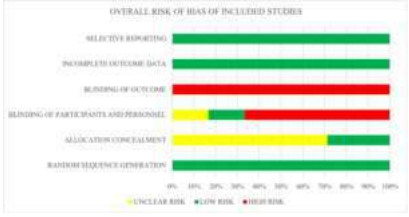


Figure-3 Risk Of Bias Of Individual Studies

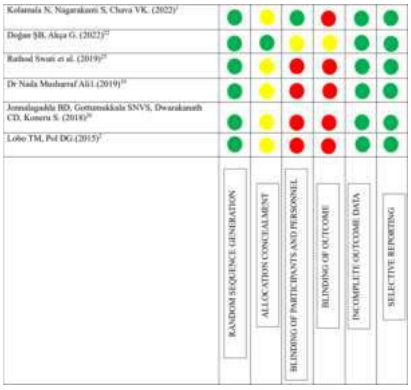


Table-3 Results Of Cal/ral

AUTHORS		Mean CAL/RAL		p-value
		CONTROL SITES	TEST SITES	
Kolamala N, Nagarakanti S, Chava VK. (2022)[1]	Baseline	9.26	9.53	0.413
	3 months	7.46	7.20	0.334
	6 months	0.83	0.83	0.001
Doğan ŞB, Akça G. (2022)[22]	Baseline	6.5 (5.00–7.30)	6.60 (5.11–7.04)	> 0.05
	3 months	2.57 (1.88–3.98)	2.68 (1.95–3.78)	
	6 months	2.54 (2.00–4.01)	2.71 (1.88–3.78)	
Rathod Swati et al. (2019)[25]	Baseline – 3 months	2.15 + 0.745	2.05 + 0.605	0.644
	3 months – 6 months	3.65 + 1.04	3.70 + 2.827	0.617
Dr Nada Musharraf Ali1.(2019)[10]	Baseline	6.2500 ± 1.00	5.8750 ± 0.95	0.968
	3 months	3.5000 ± 0.63	3.0000 ± 0.63	0.126
	6 months	3.3125 ± 0.62	2.7500 ± 0.47	0.014
Jonnalagadda BD, Gottumukkala SNVS, Dwarakanath CD, Koneru S. (2018)[26]	Baseline	9.23±1.31	9.08±1.43	0.6785
	3 months	7.45±0.71	7.69±1.11	0.5977
	6 months	7.24±0.64	7.24±1.20	0.9699

Lobo TM, Pol DG.(2015)[2]	Baseline	6.64±0.84	6.83±1.09	0.001
	3 months	4.87±0.63	5.23±0.79	
	6 months	4.75±0.47	5.18±0.78	

Table-4 Results Of Ppd

AUTHORS		Mean PPD		p-value
		CONTROL SITES	TEST SITES	
Kolamala N, Nagarakanti S, Chava VK. (2022)[1]	Baseline	7.00	7.40	0.271
	3 months	5.20	5.06	0.670
	6 months	5.20	4.40	0.005
Doğan ŞB, Akça G.(2022)[22]	Baseline	6.17 (4.92–7.02)	5.95 (4.95–7.04)	> 0.05
	3 months	3.72 (2.66–4.72)	3.69 (2.54–4.98)	
	6 months	3.85 (2.07–5.19)	3.79 (2.32–4.98)	
Rathod Swati et al.(2019)[25]	Baseline – 3 months	2.80 + 0.696	2.80 + 0.616	1.000
	3 months – 6 months	4.3 + 0.979	4.2 + 0.768	0.7210
Dr Nada Musharraf Ali1.(2019)[10]	Baseline	5.8125 ± 0.75	5.8750 ± 0.95	1.000
	3 months	3.1875 ± 0.54	3.0000 ± 0.63	0.382
	6 months	3.1875 ± 0.54	2.7500 ± 0.57	0.037
Jonnalagadda BD, Gottumukkala SNVS, Dwarakanath CD, Koneru S. (2018)[26]	Baseline	4.48±0.81	4.43±1.03	0.6647
	3 months	2.04±0.48	2.36±1.63	0.7063
	6 months	1.81±0.31	1.84±0.43	0.8802
Lobo TM, Pol DG.(2015)[2]	Baseline	6.08±0.91	6.02±0.81	0.001
	3 months	2.81±0.59	2.53±0.53	
	6 months	2.56±0.49	2.35±0.50	

RESULTS OF SYNTHESES:

Kolamala et al., 2022 [1] conducted a monocentric, triple-blind, split-mouth randomized clinical trial to evaluate the effect of DL as an adjunct to OFD in treatment of periodontitis in which control sites were treated with conventional OFD alone whereas test sites were treated with Laser-assisted OFD (LA-OFD). Clinical outcomes of sites showed a significant reduction in values of PPD and gain in RAL at 3 months and 6 months compared to baseline, and also significance was observed from 3 months to 6 months.

Doğan et al., 2022 [22] conducted randomized control split-mouth study to evaluate the post-operative discomfort and tissue response following the surgical periodontally treated sites. The control sites were treated with modified widman flap(MWF) by applying sham DL and the test sites were treated with MWF by applying active DL (810 nm –5; Picasso-AMD) to the inside of the MWF. No significant difference in reduction of PPD and CAL gain between control and test sites was observed at any time points post-operatively at 6 weeks, 3 months, and 6 months.

Rathod et al., 2019 [25] conducted a split mouth study in subjects diagnosed with chronic periodontitis. Control sites in this study were treated with OFD and the contralateral quadrant i.e. the test sites were treated with OFD and DL. The PPD in both the groups from baseline to 6 months was statistically significant. Control sites showed marginally greater reduction, this was not significant. The results showed statistically significant gain in RAL as compared to baseline in both sites. However, the difference in RAL in the two groups at the end of 6 months was statistically insignificant.

Dr Nada Musharraf Ali1 (2019)[10] conducted a double blinded, randomized, comparative, split-mouth clinical trial to evaluate the effect of 810nm DL in OFD as compared to conventional mechanical debridement in patients on Low dose aspirin. The control sites received Modified Widman Flap(MWF) surgery using conventional methods, whereas test sites received MWF surgery using 810nm DL as an adjunct. Clinical parameters considered for this review from this study are : PPD, RAL assessed at baseline, 3 months, and 6 months after surgery. There was a greater reduction in PPD (statistically significant at 3, 6 months) and greater gain in CAL(statistically significant) in the test sites when compared to the control sites.

Jonnalagadda et al., 2018 [26] conducted a split-mouth, randomized single-blinded clinical trial to compare postoperative healing and the clinical parameters of DL-assisted access flap surgery with access flap surgery alone. Clinical parameters considered for this review from this study are : PPD, RAL assessed at baseline, 3 months, and 6 months after surgery. In both the test and the control sites, conventional access flap surgery was performed. In the test sites, in addition, the inner surface of the flap was lased using semiconductor DL. Both groups showed a reduction in PPD and gain in RAL at 3 and 6 months, which were not statistically significant.

Lobo et al., 2015 [2] conducted a split-mouth study to evaluate the adjunctive benefit of a DL to conventional mechanical debridement in the surgical treatment of chronic periodontitis. The MWF technique was used in both control and test sites. In the test sites, a 940 nm DL unit was used as an adjunct. Both the sites showed a reduction in PPD and gain in CAL at 3 and 6 months, which were statistically significant. Risk of bias is overall low with regard to random sequence generation in all studies. Allocation concealment is unclear in all studies. Low risk of bias with regards to blinding of participants is assessed with four [1,10,22,26] out of six included studies, unclear with one study [25] and high with one study [2]. Risk of bias is low with regard to blinding of outcome in three studies [1,22,10] and high in three studies [2,25,26]. Risk of bias is overall low in all studies with respect to incomplete outcome data and selective reporting.

Heterogeneity in studies were due to different settings in each study with respect to power settings and wavelength of DL used. Also, time of exposure of soft tissue to laser differed in all studies.

DISCUSSION

Periodontal therapy is directed at disease prevention, slowing or arresting disease progression, regeneration of lost periodontal tissues, and maintaining the achieved therapeutic objectives. Longitudinal clinical trials of various conventional treatment techniques such as MWF and full-thickness flap procedure with or without osseous recontouring have shown to be effective in treating moderate-to-advanced periodontitis. Thus, flap surgery in deeper pockets results in greater pocket reduction and attachment gain.

In recent years, the use of laser therapy has been investigated as an alternative or adjunctive tool to conventional, mechanical procedures commonly employed in the treatment of periodontal and peri-implant diseases. Mechanical instrumentation of root surface for the reduction of bacteria and removal of soft- and hard-tissue deposits results in partial removal of pocket epithelium, which remains as the gold standard and healing by formation of a long junctional epithelium.

Lasers used in this regard have shown to retard epithelial downgrowth and help in formation of new connective tissue attachment. A significant reduction of periodontopathogenic bacteria has been demonstrated, regardless of laser wavelength.[27]

De-epithelialization with the laser retards epithelial downgrowth following periodontal surgery for up to 14 days longer than conventional flap techniques. This delay in epithelialization is due to laser-induced thermal necrosis of the wound margin and formation of a firm eschar that impedes epithelialization.[28] Whereas, it was found that a delay in onset of epithelial migration, not a decreased rate of migration, was responsible for the delayed epithelialization. It was speculated that the reduced inflammatory response retards the stimulus for epithelial migration by sealing the small vasculature and lymphatics and not allowing release of chemical mediators.[29]

Every laser has a different property and different tissue interactions, which depend upon the wavelength, power, waveform, tissue optical properties and tissue thermal properties. DL is an excellent soft tissue laser and is available in smaller cost-effective units. The radiation of DL shows greater absorption and less penetration than does Nd:YAG laser, especially in blood-rich tissue. Therefore, collateral damage with DL is less than with Nd:YAG or CO_2 laser.[30] The wavelength of DL is absorbed by the hemoglobin, which leads to tissue coagulation and

formation of charred layer. DL leads to thermocoagulation of the blood vessels, which is responsible for its hemostatic effect.[30]. The laser mode of antisepsis has several potential advantages over traditional biochemical antibiotics. A therapeutic dose can be delivered to a greater depth locally and leaves no residual concentration.[31] Laser radiation affects equally extracellular and intracellular pigmented pathogens and can access other privileged sites such as calculus and dentinal tubules. Laser antisepsis has no known systemic side effects, resistances, or negative interactions with other modes of therapy.[31] Laser energy also has the potential to breach the protective mechanisms of biofilms.[32]

The present systematic review analysed the outcomes of DL as an adjunct to OFD comparing the outcomes with OFD in patients with chronic periodontitis as there is limited research to conclusively evaluate the effectiveness of DL as an adjunct to OFD.

In all the included studies, the outcomes were assessed using custom made occlusal acrylic stents with grooves to standardize the UNC 15 probe angulation and position to determine PPD and CAL.

This systematic review indicated that DL didn't have an additive benefit on clinical paramaters of chronic periodontitis that were assessed i.e; PPD, CAL. Three (1,10,2)out of six included studies concluded that DL significantly led to reduction in PPD or gain in CAL when DL was used as adjunct to OFD. Whereas, other three (22,25,26) out of six included studies concluded that DL did not significantly lead to reduction in PPD or gain in CAL when DL was used as adjunct to OFD.

Gokhale et al[21] evaluated the efficacy of DL as an adjunct to mechanical debridement in periodontal flap surgery, on the basis of clinical parameters (plaque and gingival index, PPD and RAL) and microbiological analysis (subgingival plaque samples) of test and control groups. Results showed difference between the clinical parameters in the test and control groups did not reach a statistical significance. However, there was a statistically significant reduction in colony forming units (CFU) of obligate anaerobes in the test group as compared with the control group. The bactericidal effect of the DL was clearly evident by greater reduction of CFU of obligate anaerobes in the test group than in the control group.

Roy S et al [13] aimed to determine the efficacy of 940 nm DL exposure in combination with conventional periodontal flap surgery for the treatment of chronic periodontitis to evaluate postoperative discomfort and clinical parameters (visual analog scale (VAS) score ,gingival inflammation ,PPD, CAL, and sulcus bleeding index (SBI)) and concluded that DL as an adjunct to the surgical procedure can demonstrate appreciable benefits by increasing the CAL and minimizing the postoperative pain and the probing pocket, but such additional effects were not observed with gingival inflammation.

DL has proved to improve the gingival index, decrease probing pocket depth, bleeding on probing, bacterial content of periodontal pockets and improve the overall health of the periodontium. The keyword in the American Academy of Periodontology report is alternative, and the laser is used as an adjunct to standard treatments rather than as a replacement for standard treatments.[33]

Limitations:

1. The DL was used in different settings in each study with respect to power settings and wavelength. Also, time of exposure of soft tissue to laser differed in all studies.
2. Most of the studies did not blind the operator or outcome accessor, leading to potential performance and reporting biases.

Implications of the results for practice:

DL can be used as an adjunct to standard treatment of chronic periodontitis rather than as a replacement for standard treatment.

Policy:

This policy brief is based on the highlights of the studies considered in this systematic review which concludes that DL as an adjunct to OFD does not have additional benefits in the treatment of chronic periodontitis as compared to conventional surgical periodontal treatment(OFD).

Future research:

There remains a future scope for more randomized controlled studies to be conducted in multi-centers with a larger sample size and standardization of laser power settings for specific periodontal diseases which may lead to correctly assess the role of DL in the treatment of periodontitis.

CONCLUSION

Within the scope of the present systematic review, the use of DL as an adjunct to OFD did not significantly enhance the treatment outcome on the whole. Thus, the high investment cost for the laser equipment has to be weighed along with the proven clinical benefits.

Other Information

Registration And Protocol:

This systematic review was registered under the number CRD42023421858 in the PROSPERO database, created by the University of York, responsible for the registration and dissemination of systematic reviews and carried out according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

Support:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing Interests:

The authors declare no conflict of interest.

REFERENCES

1. Kolamala N, Nagarakanti S, Chava VK. Effect of diode laser as an adjunct to open flap debridement in treatment of periodontitis - A randomized clinical trial. J Indian Soc Periodontol. 2022 Sep-Oct;26(5):451-457.
2. Lobo TM, Pol DG. Evaluation of the use of a 940 nm diode laser as an adjunct in flap surgery for treatment of chronic periodontitis. J Indian Soc Periodontol. 2015 Jan-Feb;19(1):43-8.
3. Karthikeyan J, Vijayalakshmi R, Mahendra J, Kanakamedala AK, Chellathurai BNK, Selvarajan S, Namachivayam A. Diode Laser as an Adjunct to Kirkland Flap Surgery-A Randomized Split-Mouth Clinical and Microbiological Study. Photobiomodul Photomed Laser Surg. 2019 Feb;37(2):99-109.
4. Aena PJ, Parul A, Siddharth P, Pravesh G, Vikas D, Vandita A. The clinical efficacy of laser assisted modified Widman flap: A randomized split mouth clinical trial. Indian J Dent Res. 2015 Jul-Aug;26(4):384-9.
5. Sun G, Tunér J. Low-level laser therapy in dentistry. Dent Clin North Am 2004;48:1061-76,viii.
6. Mester E, Spiry T, Szende B, Tota JG. Effect of laser rays on wound healing. Am J Surg 1971;122:532-5.
7. Marques MM, Pereira AN, Fujihara NA, Nogueira FN, Eduardo CP. Effect of low-power laser irradiation on protein synthesis and ultrastructure of human gingival fibroblasts.Lasers Surg Med 2004;34:260-5.
8. Walsh LJ. The current status of low level laser therapy in dentistry. Part 1. Soft tissue applications. Aust Dent J 1997;42:247-54.
9. Shetty S, Shetty K, Alghamdi S, Almehmadi N and Mukherjee T. A comparative evaluation of laser assisted & conventional open flap surgical debridement procedure in patients with chronic periodontitis – a clinical and microbiological study- a pilot project. Int J Pharm Sci & Res 2020; 11(10): 4957-65.
10. Dr Nada Musharraf Ali1. "Open Flap Debridement Using 810nm Diode Laser and Conventional Surgery in Patients on Low Dose Aspirin– A Comparative Study". IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 12, 2019, pp 69-83.
11. Shah NK, Rai JJ, Dave DH and Patel JK: Deploying diode laser in periodontics: An evidence-based review. Adv Hum Biol 2018; 8:64-9.
12. Misra P, Kalsi R, Anand Arora S, Singh KS, Athar S, Saini A. Effect of Low-Level Laser Therapy on Early Wound Healing and Levels of Inflammatory Mediators in Gingival Crevicular Fluid Following Open Flap Debridement.
13. Roy S, Singh DK, Manohar B. Comparative evaluation of postoperative pain and tissue response in patients undergoing conventional flap surgeries with or without 940 nm diode laser exposure - A randomized clinical study. J Educ Health Promot. 2022 Dec 28;11:417.
14. Shreya M, Harsh M, Surabhi J, Chandni P, Tanvi H, Santosh K. Comparative Clinical And Microbiological Evaluation In Periodontal Flap Surgery With Diode Laser As An Adjunct To Mechanical Debridement Versus Conventional Mechanical Debridement: A Split Mouth Study. Journal of Positive School Psychology 2022, Vol. 6, No. 9, 3116-3127.
15. Khan F, Chopra R, Sharma N, Agrawal E, Achom M, Sharma P. Comparative evaluation of the efficacy of diode laser as an adjunct to modified Widman flap surgery for the treatment of chronic periodontitis: A randomized split-mouth clinical trial. J Indian Soc Periodontol. 2021 May-Jun;25(3):213-219.
16. Dalvi S, Khetal N, Ansari S, Benedicenti S, Hanna R. Utilization of 810 nm Diode Laser Treatment in Periodontitis as an Alternative to Surgical Debridement Approach. Photochem Photobiol. 2021 May;97(3):566-573.
17. Arvind N, Mamatha S, Srikala B. (2020). Effect of 810nm Diode Laser on Post-operative Pain Adjunct to Periodontal Flap Surgery. Indian Journal of Public Health Research & Development, 11(7), 91–96.
18. Heidari M, Fekrazad R, Sobouti F, Moharrami M, Azizi S, Nokhbatolfoghahaei H, Khatami M. Evaluating the effect of photobiomodulation with a 940-nm diode laser on post-operative pain in periodontal flap surgery. Lasers Med Sci. 2018 Nov;33(8):1639-1645.
19. Soliman MM, Sabra SM, Al-Shammrani AS, Sorour AA. A Study of the diode laser phototherapy for enhancing healing and reduction of microbial count in periodontal pockets within a Saudi community. J Dent Med Sci 2014;13:61-8.
20. Sanz-Moliner JD, Nart J, Cohen RE, Ciancio SG. The effect of an 810-nm diode laser on postoperative pain and tissue response after modified Widman flap surgery: a pilot study in humans. J Periodontol. 2013 Feb;84(2):152-8.
21. Gokhale SR, Padhye AM, Byakod G, Jain SA, Padbidri V, Shivaswamy S. A comparative evaluation of the efficacy of diode laser as an adjunct to mechanical debridement versus conventional mechanical debridement in periodontal flap surgery: a

clinical and microbiological study. Photomed Laser Surg. 2012 Oct;30(10):598-603.
22. Doğan ŞB, Akça G. Clinical Evaluation of Diode Laser-Assisted Surgical Periodontal Therapy: A Randomized Split-Mouth Clinical Trial and Bacteriological Study. Photobiomodul Photomed Laser Surg. 2022 Sep;40(9):646-655.
23. Agarwal A, Saxena A, Gummaluri SS, Chaudhary B, Subramanyam S Sai K, Kumar G. Clinical and microbiological evaluation of 940-nm diode laser as an adjunct to modified Widman flap for the management of chronic periodontitis: A 6-month randomized split-mouth clinical trial. J Dent Res Dent Clin Dent Prospects. 2021 Spring;15(2):133-139.
24. Comparison of Open Flap Debridement, with and without Diode Laser in the Management of Chronic Periodontitis: A Randomised Split Mouth Clinical Tria Journal of Clinical and Diagnostic Research. 2023 Jan, Vol-17(1): ZK04-ZK07.
25. Rathod Swati et al., 2019, Comparative evaluation of efficacy of diode laser as an adjunct to open flap debridement in the treatment of chronic periodontitis – a clinical and radiographic study. Int J Recent Sci Res. 10(01), pp. 30202-30207.
26. Jonnalagadda BD, Gottumukkala SN, Dwarakanath CD, Koneru S. Effect of diode laser-assisted flap surgery on postoperative healing and clinical parameters: A randomized controlled clinical trial. Contemp Clin Dent 2018;9:205-12.
27. Coffelt DW, Cobb CM, MacNeill S, Rapley JW, Killoy WJ. Determination of energy density threshold for laser ablation of bacteria. An in vitro study. J Clin Periodontol 1997;24:1-7.
28. Fisher SE, Frame JW, Browne RM, Tranter RM. A comparative histological study of wound healing following CO2 laser and conventional surgical excision of canine buccal mucosa. Arch Oral Biol 1983;28:287-91.
29. Moreno RA, Hebda PA, Zitelli JA, Abell E. Epidermal cell outgrowth from CO2 laser- and scalpel-cut explants: Implications for wound healing. J Dermatol Surg Oncol 1984;10:863-8.
30. Goharkhay, K., Moritz, A., Wilder–Smith, P., Scoop, U., Kluger, W., Jakolitsch, S., and Sperr, W. (1999). Effects on oral soft tissues produced by a diode laser in vitro. Lasers Surg. Med. 25, 401–406.
31. Harris, D., and Yessik, M. (2004). Therapeutic ratio quantifies laser antisepsis: ablation of porphyromonas gingivalis with dental lasers. Lasers Surg. Med. 35, 206–213.
32. Page, R.C., Offenbacher, S., Schroeder, B., Seymour, G., and Kornman, K. (1997). Advances in the pathogenesis of periodontitis: summaryofdevelopments,clinical implications and future directions, Periodontol. 2000. 14, 216–248.Convissar RA. The biologic rationale for the use of lasers in dentistry. Dent Clin North Am. 2004;48(4):771-794.

ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 05 | May - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

EFFECT OF ENAMEL MATRIX PROTEIN DERIVATIVE (EMD) AS AN ADJUNCT TO XENOGRAFT COMPARED TO XENOGRAFT ALONE IN THE TREATMENT OF INTRABONY DEFECTS IN SUBJECTS WITH CHRONIC PERIODONTITIS: A SYSTEMATIC REVIEW.

Dentistry

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ABSTRACT

Background: Enamel matrix derivative (EMD) has been widely used in periodontal regenerative treatment and the xenograft biomaterials show good biocompatibility and osteoconductivity of demineralized bovine bone matrix. So, to evaluate the improvement in clinical outcomes when Enamel Matrix Protein Derivative is used as an adjunct to Bovine-Derived Xenograft in intrabony defects of chronic periodontitis patients. **Material And Methodology:** In this systematic review, randomized controlled trials in subjects with periodontitis in the age group of 25-70 years were considered. An electronic search was made in PubMed, Google Scholar, and EMBASE databases. Studies concerning the use of a combination of enamel matrix derivative (EMD) and Xenograft compared with xenografts alone in periodontitis treatment were selected. **Result:** 4 studies were included in quantitative analysis after screening by two reviewers. Randomized controlled trials have indicated a significantly higher pocket reduction and clinical attachment level gain after the application of enamel matrix derivative (EMD) and Xenograft compared with xenografts alone. **Conclusion:** The use of enamel matrix derivative (EMD) as an adjunct to Xenograft provides significant results as compared to xenograft alone in intrabony defects of chronic periodontitis patients.

KEYWORDS

Enamel matrix protein derivative (EMD), Xenograft, Intrabony defects, Chronic periodontitis.

INTRODUCTION:

Periodontitis is an infectious disease that is caused by periodontal pathogenic bacteria and is characterized by pocket formation and attachment loss, ultimately affecting tooth survival.[5]

The bone replacement graft provides for regeneration through osteoconductive or osteoinductive processes and growth factors by inductive or cell-stimulating mechanisms.[1] The osteoconductive graft acts as a scaffold to support new tissue growth. The inductive process involves the graft or growth factor stimulating the host tissues to regenerate lost structures.[1]

Enamel matrix protein derivative (EMD), derived from developing porcine teeth consists of 90% amelogenins, with the remaining 10% primarily proline-rich non-amelogenins, tuftelin, tuft protein, serum, ameloblastin, amelin, and salivary proteins[3]. It induces the expression of cementogenesis - and osteogenesis-related genes in the mesenchymal cells, and has been used as an osteo-promotive agent for the regeneration of damaged periodontal support structures for >20 years.[1]

Demineralized porcine bone matrix (DPBM) is one of the most successfully used xenografts in various periodontal and implant surgeries including guided bone regeneration, alveolar ridge preservation, and sinus augmentation, and provides stable and reliable results clinically and radiographically. The good biocompatibility and osteoconductivity of demineralized bovine bone matrix, which is one of the most studied and accepted xenograft biomaterials. It has been widely used to improve the results of regenerative treatment in combination with EMD.

Thus, from both a biological as well as a clinical point of view, it would be pertinent to evaluate the combination of EMD and a bone graft as a treatment of advanced intrabony defects.

Protocol And Registration:

This systematic review is registered on the PROSPERO website: CRD420234929

This systematic review is according to PRISMA guidelines.

Focused Question

What are the clinical benefits of using a combination of enamel matrix derivative (EMD) and Xenograft compared with xenografts alone in subjects with chronic periodontitis with intrabony defects?

Population (P) – Subjects with chronic periodontitis

Intervention (I) – Combination of enamel matrix derivative (EMD) and
Xenograft Comparison (C) – Xenograft alone Outcome (O)- Reduction in probing pocket depth (PPD) and gain in clinical attachment level (CAL)

METHOD:

Inclusion Criteria: -

1. Randomized controlled trials comparing EMD + xenograft with xenograft alone
2. Studies with a mean follow-up period between 6 months and 4 years
3. Defect sites with pocket depth (PD) ≥5 mm & Intrabony defect depth ≥3 mm
4. Studies published in English language only from year January 2002 to May 2022
5. Patients with moderate to severe periodontitis

Exclusion Criteria: -

Review papers, In- vitro studies, animal studies, case reports, commentaries, and interviews.

Information Source:

A literature search was performed in PubMed, PMC, Google scholar, and EBSCO host databases for papers published from 2002 up to September 2022.

Search Strategy:

Papers published in the English language were selected for analysis.

Keywords used for study identification in all databases were "(enamel matrix derivative AND Xenograft) AND intrabony defect" and "(enamel matrix derivative) AND (xenograft) AND periodontal disease AND intrabony defect.

Selection Process:

1. Assessment of titles and abstracts

2. Assessment of full-text

Data Collection Process:
Data extraction sheet was prepared based on variables and the articles were analysed. Using data extraction sheet, the following data were collected: authors, year of publication, country, aim, tissue assessed, type of study, sample size, comparison group & control group, methodology, and conclusion. (Fig.1)

Data Items:
Variables for which data was sought included Periodontal disease, periodontitis, gingivitis, clinical attachment level, and pocket depth.

RESULTS:
Study Selection
A total of 1343 articles were found after electronic search. 1291 articles, which were of other languages and duplicates, were excluded leaving 52 articles. 42 articles were excluded after reviewing the abstracts leaving 10 articles .6 articles were excluded as they did not fulfil the eligibility criteria leaving 4 articles for this systematic review.

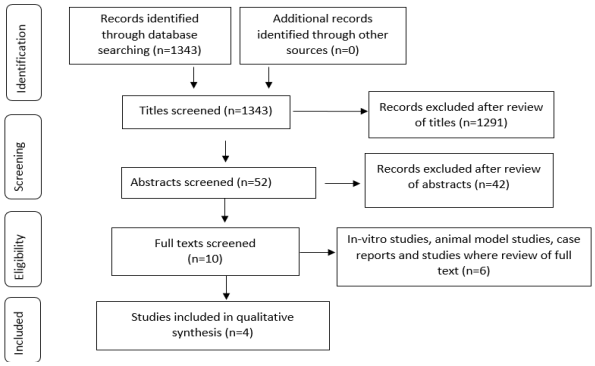


Figure 1- Flow Chart Of Literature Search Results And Study Selection

Study Characteristics
An overview of the included studies for the analysis is presented in Table 1.

Table 1: Studies Included In The Review:

Sr No	Author, Year	Title	Test Group	Control Group	Study Design	Follow Up	Results
1	Sculean.A. et al;2002	Clinical Evaluation of an Enamel Matrix Protein Derivative (Emdogain) Combined with a Bovine-Derived Xenograft (Bio-Oss) for the Treatment of Intrabony Periodontal Defects in Humans	Intrabony defect, were randomly treated with a combination of EMD + BDX	BDX alone	RCT	1 year	Both therapies led to significant improvements of the investigated clinical parameters.
2	Scheyer ET;2002	A clinical comparison of a bovine-derived xenograft used alone and in combination with enamel matrix derivative for the treatment of periodontal osseous defects in humans	Combination of EMD and BDX	BDX alone	RCT	6 months	The particulate anorganic cancellous bovine-derived bone xenograft used alone and in combination with enamel matrix derivative are effective for the treatment of human intrabony periodontal lesions
3	Lee JH, et al;2020	Adjunctive use of enamel matrix derivatives to porcine-derived xenograft for the treatment of one-wall intrabony defects: Two-year longitudinal results of a randomized controlled clinical trial.	DPBM with the adjunctive use of EMD	DPBM only	RCT	2 years	DPBM has been verified for biocompatibility and can be used as a scaffold to enhance the clinical and radiographic outcomes of periodontal regeneration of one-wall intrabony defects. In particular, the adjunctive use of EMD significantly reduced the postoperative discomfort
4	Lee JH.et al;2022	Long term stability of adjunctive use of enamel matrix protein derivative on porcine-derived xenograft for the treatment of one-wall intrabony defects: A 4-year extended follow-up of a randomized controlled trial	DPBM with the adjunctive use of EMD	DPBM only	RCT	4 years	The clinical, radiographic, and patient-reported outcomes were significantly improved when DPBM was used in the regenerative treatment, but no additional benefits were observed with the adjunctive use of EMD

Risk Of Bias In Individual Studies:
This assessment was conducted by using the recommended approach for assessing the risk of bias in studies included in Cochrane Reviews (Higgins 2011)[22] using the tool RevMan 5.0.

We used the two-part tool to address the six specific domains (namely: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and other bias). Each domain includes one or more specific entries in a Risk of Bias table. Within each entry, the first part of the tool involves describing what was reported to have happened in the study.

The second part of the tool involves assigning a judgment relating to the risk of bias for that entry: either low risk, unclear risk, or high risk.

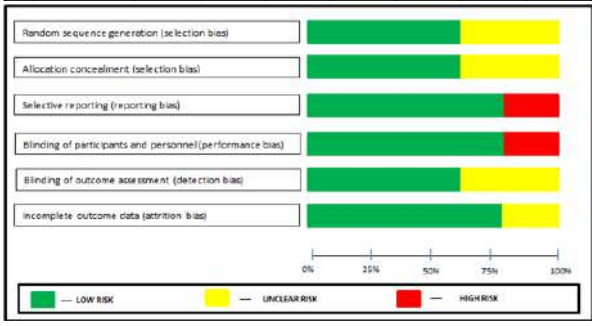
The domains of random sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting are addressed in the tool by a single entry for each study. We completed a Risk of bias table for each included study.

The risk of bias of the included studies is presented in Table 2, graph 1, and graph 2.

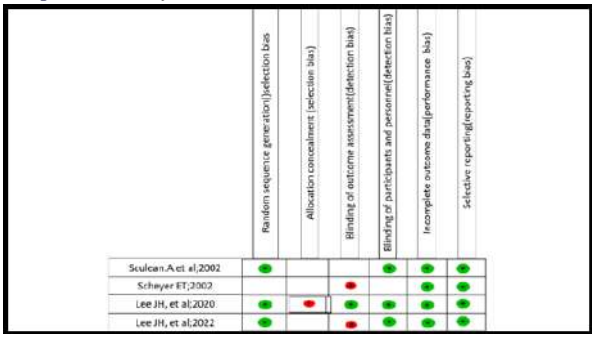
Table 2: Quality Assessment Of The Studies Included By Judging Risk Of Bias And Applicability Using Cochrane Risk Of Bias Tool For Randomized Controlled Trial

Sr no	Author /year	Type of study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome	Incomplete outcome data	Selective reporting
1.	Anton Sculean, et.al;2002	RCT	Low	Low	Low	Unclear	Unclear	Unclear
2.	Scheyer ET, et.al;2002	RCT	Low	Unclear	Unclear	Unclear	Low	Low

3.	Lee JH, Kim DH, et.al;2020	RCT	Low	Low	Low	Low	Low	Uncle ar
4.	Lee JH, Jeong SN;2022	RCT	Low	Low	Low	Low	Low	Uncle ar



Graph 1: Summary Of Risk Of Bias Assessment Of Selected Studies



Graph 2: Summary Of Risk Of Bias Assessment Of Individual Studies

DISCUSSION:

Periodontitis, an infectious disease characterized by progressive attachment and bone degeneration, may ultimately result in tooth loss if left untreated. Results from a national survey conducted in the United States in 2009 and 2010 demonstrated that over 47% of the adult population aged 30 years and above had periodontitis, distributed as 8.7%, 30.0%, and 8.5% with mild, moderate, and severe periodontitis, respectively. Regenerative periodontal surgery aims to predictably restore the tooth's supporting apparatus (i.e., root cementum, periodontal ligament, and bone) that has been lost following periodontal disease or trauma.[6]

Enamel matrix derivative (EMD) has been widely used in periodontal regenerative treatment, especially for contained intrabony periodontal defects. Among the bone grafting biomaterials that are successfully used as scaffolds with EMD deproteinized bovine bone mineral (DBBM) shows an additional improvement in clinical outcomes when combined with EMD and is considered effective especially in large or non-contained intrabony defects.

In the present review, studies in which xenograft was used along with other agents were excluded.

Matarasso M.et al, 2015 conducted a systematic review on Enamel matrix derivative and bone grafts for periodontal regeneration of intrabony defects. Concluded that the combination of EMD and bone grafts may result in additional clinical improvements in terms of CAL gain and PD reduction compared with those obtained with EMD alone. Lee JH et al (2019) shows that no statistically significant differences regarding any early clinical complication including dehiscence/fenestration, persistent swelling, spontaneous bleeding, and ulceration were observed between the control and test groups. Although these findings confirm the tendency of the adjunctive use of EMD to promote periodontal regeneration and reduce postoperative discomfort, it is difficult to definitively make this conclusion, given the data provided in the study.

Scheyer ET (2002), This study compared enamel matrix derivative (EMD) combined with a particulate anorganic cancellous bovine-derived bone xenograft (BDX) to BDX alone in the treatment of human intrabony defects. The results of this study demonstrate that both treatment modalities provide improvements in hard and soft tissue measurements that are statistically and clinically significant when compared to baseline. Furthermore, statistical analysis of the data revealed no significant differences between the treatment groups. Sculean A et al (2002), The results of this study have demonstrated that treatment of deep intrabony defects with both the combination of EMD + BDX and BDX alone may lead to clinically and statistically significant PPD reduction and CAL gain. No statistically or clinically significant differences in any of the investigated parameters were observed between the two treatments.

Limitations:

There are limited studies which is available. Also, there is a lack of data evaluating the long term follow up of the intervention. There can be selection bias as there is no consideration of multicentred clinical trials.

Implications Of The Results For Practice:

Xenografts can be used along with EMD in the clinical practice for the treatment of patients with moderate to severe periodontitis as they show positive results.

Future Research:

Studies can be carried out with different material combination with xenografts and EMD.

CONCLUSION:

Xenografts are biocompatible and can be used as a scaffold to enhance the clinical and radiological outcomes of periodontal regeneration of one-wall intrabony defects. In particular, the adjunctive use of EMD in combination with DPBM significantly reduced postoperative discomfort when compared with DPBM without EMD. DPBM is biocompatible and can be used as a scaffold to enhance the clinical and radiological outcomes of periodontal regeneration of one-wall intrabony defects, with greater knowledge and understanding of the biological effects that mediators such as EMD can produce, future outcomes in new levels of success and predictability.

Support:

No source of funding.

Conflicts Of Interest:

No conflicts of interest.

REFERENCES:

1. Lee JH, Kim DH, Jeong SN. Adjunctive use of enamel matrix derivatives to porcine-derived xenograft for the treatment of one-wall intrabony defects: Two-year longitudinal results of a randomized controlled clinical trial. J Periodontol. 2020; 91:880–889
2. Lee JH, Jeong SN. Long-term stability of adjunctive use of enamel matrix protein derivative on porcine-derived xenograft for the treatment of one-wall intrabony defects: A 4-year extended follow-up of a randomized controlled trial. J Periodontol. 2022; 93:231–238.
3. Scheyer ET, Velasquez-Plata D, Brunsvold MA, Lasho DJ, Mellonig JT. A clinical comparison of a bovine-derived xenograft used alone and in combination with enamel matrix derivative for the treatment of periodontal osseous defects in humans. Journal of periodontology. 2002 Apr;73(4):423-32.
4. Sculean A, Chiantella GC, Windisch P, Gera I, Reich E. Clinical evaluation of an enamel matrix protein derivative (Emdogain) combined with a bovine-derived xenograft (Bio-Oss) for the treatment of intrabony periodontal defects in humans. International Journal of Periodontics & Restorative Dentistry. 2002 Jun 1;22(3).
5. Matarasso M, Iorio-Siciliano V, Blasi A, Ramaglia L, Salvi GE, Sculean A. Enamel matrix derivative and bone grafts for periodontal regeneration of intrabony defects. A systematic review and meta-analysis. Clinical oral investigations. 2015 Sep;19(7):1581-93.
6. Miron RJ, Guillemette V, Zhang Y, Chandad F, Sculean A. Enamel matrix derivative in combination with bone grafts: A review of the literature. Quintessence Int. 2014 Jun 1;45(6):475-87.
7. Venezia E, Goldstein M, Boyan BD, Schwartz Z. The Use of Enamel Matrix Derivative in the Treatment of Periodontal Defects: a Literature Review and Meta-analysis. Critical Reviews in Oral Biology & Medicine. 2004;15(6):382-402.
8. Palmer RM, Cortellini P,Periodontal tissue engineering and regeneration: Consensus Report of the Sixth European Workshop on Periodontology. J Clin Periodontol 2008;35:83-86
9. Murphy KG, Gunsolley JC. Guided tissue regeneration for the treatment of periodontal intrabony and furcation defects. A systematic review. Ann Periodontol. 2003;8:266-302. 3.
10. Reynolds MA, Aichelmann-Reidy ME, Branch-Mays GL, Gunsolley JC. The efficacy of bone replacement grafts in the treatment of periodontal osseous defects. A systematic review. Ann Periodontol. 2003;8:227-265.
11. Shujaa Addin A, Akizuki T, Matsuura T, et al. Histological healing after nonsurgical periodontal treatment with enamel matrix derivatives in canine experimental periodontitis. Odontology. 2018;106:289-296.
12. Graziani F, Gennai S, Petrini M, Bettini L, Tonetti M. Enamel matrix derivative stabilizes blood clot and improves clinical healing in deep pockets after flapless periodontal therapy: a randomized clinical trial. J Clin Periodontol. 2019;46:231-240.
13. Esposito M, Grusovin MG, Papanikolaou N, Coulthard P, Worthington HV. Enamel matrix derivative (Emdogain) for periodontal tissue regeneration in intrabony defects. A Cochrane systematic review. Eur J Oral Implantol. 2009; 2:247-266.

14. Aspriello SD, Ferrante L, Rubini C, Piemontese M. Comparative study of DFDBA in combination with enamel matrix derivative versus DFDBA alone for treatment of periodontal intrabony defects at 12 months post-surgery. Clin Oral Investig. 2011; 15:225-232.
15. Jaiswal R, Deo V. Evaluation of the effectiveness of enamel matrix derivative, bone grafts, and membrane in the treatment of mandibular Class II furcation defects. Int J Periodontics Restorative Dent. 2013;33: e58-e64.

JIDA

Pediatric Dentistry

Assessment of Child, Parent and Operator Preferences towards the use of Papoose Board in Pediatric Dentistry: A Mixed Method Study

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Access this article online

Quick Response Code:

Website: jida.ida.org.in

DOI: 10.33882/jida.15.35477

How to cite this article: Bagul V., Katre A., Assessment of Child, Parent and Operator Preferences towards the use of Papoose Board in Pediatric Dentistry: A Mixed Method Study JIDA 2024; XVIII;34-38. https://doi.org/10.33882/jida.15.35477

Abstract

Introduction

Protective stabilization techniques and physical restraints may be required for when the traditional techniques of behaviour management are ineffective. A papoose board (PB) is a safe stabilization device that is highly effective in managing uncooperative or anxious children. However, in the current era, the child, parent and operator preferences towards the use of papoose board needs to be explored.

Material and Methods

A 12-point questionnaire was administered to child, parents and operator. Preferences to the use of papoose board were assessed quantitatively as well as qualitatively based on the images of papoose board usage shown. Quantitative data was expressed as frequency with percentage. Qualitative data was assessed through thematic analysis.

Results

30 children (3-12yrs) and their parents (11- Fathers; 19-Mothers), 15 operators were included in this study. Mean age of the children was 7.7 ± 2.6 yrs. 70% of children did not prefer the use of papoose board as they were scared and did not want to be tied up. 53.33% of parents preferred the use of papoose board as they thought of it as a protective device for their children. 46.66% of operators preferred the use of papoose board for unco-operative children.

Conclusion

Children did not prefer the use of papoose board but parents and operators preferred the use of papoose board.

Key Words

Behavior management; Papoose board; Physical restraint

Introduction

The primary goal of giving dental care to children is to make the experience as atraumatic as possible.[1] The child's acceptance toward the behavioral technique is a factor to consider other than the child's needs, urgency, and type of treatment at a particular time.[2] Problems arise when children are unwilling to cooperate during dental treatments, leading to the development of various behavioral management techniques.[1]

Paediatric dentists have to gain a good level of cooperation by applying various behaviour management techniques.[3] Various techniques enable the dentist to perform dental treatment on the child, and at the same time reduce anxiety and elicit the child's cooperation.[4] When dentistry is imperative, but anxiety-reducing techniques such as tell-show-do, voice control, behavior modification, or positive reinforcement are not effective, physical restraint may be required.[5]

Protective stabilization is the term utilized in dentistry for the physical limitation of a patient's movement by a person or restrictive equipment, materials or devices for a finite period of time in order to safely provide examination, diagnosis, and/or treatment.[6]

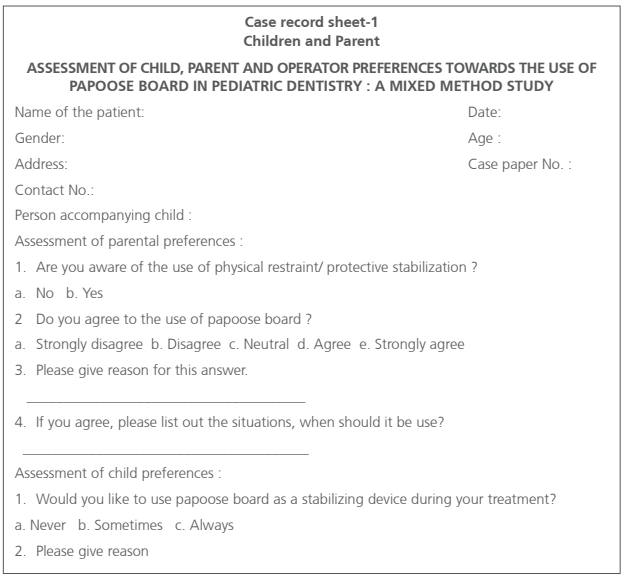
In pediatric dentistry, the use of papoose board is not uncommon.[7] A papoose board (PB) is a safe stabilization device with easy application technique, and it is highly effective in managing uncooperative children or anxious patients.[4,7] Deep touch pressure provided by a PB will help the patient reduce his or her anxiety level, and the patient will feel calm and secure during dental treatment and this method is classified as passive stabilization.[8]

An earlier study revealed that the PB appears to be well accepted by parents as a behavioural management technique in the condition that a proper explanation of its usage is given before its application.[1] However, there is scarcity of literature on the child, parent and operator preferences towards the use of papoose board. Thus, the aim of the study was to assess the child, parent and operator preferences towards the use of papoose board.

Material and Methods

This was a pilot mixed method study. The study was carried out between 1st and 25th of July, 2023 in the Department of Pediatric and Preventive Dentistry. Thirty children of three to twelve years reporting to the outpatient department and their parents and fifteen operators from the Department of Pediatric and Preventive Dentistry were the subjects for this study. Informed consent was obtained from the parents/guardians and operators before the study. Subjects with cognitive disabilities, whose general health condition would interfere with data collection and those who refused to give consent were excluded from the study. Basic demographic details were recorded for all subjects. A 12-point questionnaire divided into three sections was administered to all the study subjects. (Fig. 1 and 2) First section addressed for parental preferences, second section addressed for child preferences and third section addressed for operator preferences. Each section contained open-ended as well as closed-ended questions. 3 images of papoose board usage were shown to all the subjects prior to the administration of questionnaire by the investigator (not a subject in the study).

Fig. 1: Questionnaire Section 1 and 2



Case record sheet-1
Children and Parent

ASSESSMENT OF CHILD, PARENT AND OPERATOR PREFERENCES TOWARDS THE USE OF PAPOOSE BOARD IN PEDIATRIC DENTISTRY : A MIXED METHOD STUDY

Name of the patient: Date:

Gender: Age :

Address: Case paper No. :

Contact No.:

Person accompanying child :

Assessment of parental preferences :

1. Are you aware of the use of physical restraint/ protective stabilization ?

a. No b. Yes

2 Do you agree to the use of papoose board ?

a. Strongly disagree b. Disagree c. Neutral d. Agree e. Strongly agree

3. Please give reason for this answer.

_____

4. If you agree, please list out the situations, when should it be use?

_____

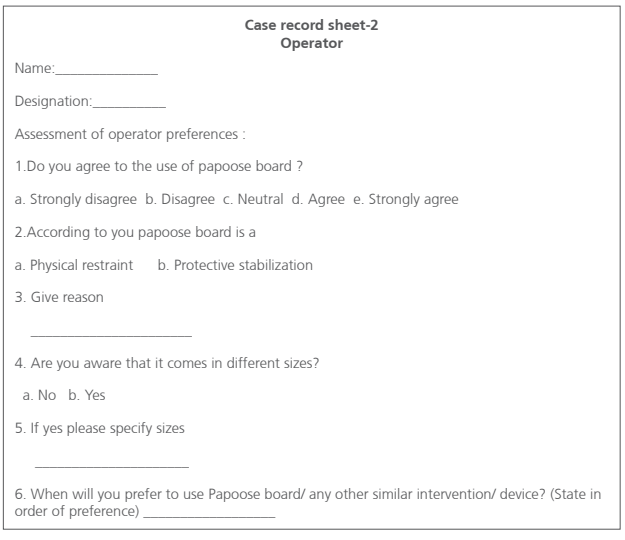
Assessment of child preferences :

1. Would you like to use papoose board as a stabilizing device during your treatment?

a. Never b. Sometimes c. Always

2. Please give reason

Fig. 2: Questionnaire Section 3



Case record sheet-2
Operator

Name:_____

Designation:_____

Assessment of operator preferences :

1.Do you agree to the use of papoose board ?

a. Strongly disagree b. Disagree c. Neutral d. Agree e. Strongly agree

2.According to you papoose board is a

a. Physical restraint b. Protective stabilization

3. Give reason

_____

4. Are you aware that it comes in different sizes?

a. No b. Yes

5. If yes please specify sizes

_____

6. When will you prefer to use Papoose board/ any other similar intervention/ device? (State in order of preference) _____

Parents awareness about the use of physical restraint/ protective stabilization was assessed as a binary categorical variable through question 1 as "Yes/No". Parental preferences towards the use of papoose board

were assessed through question 2 as a categorical variable based on a five-point Likert rating scale. The rating responses were 'Strongly disagree', 'Disagree', 'Neutral', 'Agree' and 'Strongly agree'. The reason for their response was assessed through question 3 qualitatively. Parents were asked to list out the situations for the use of papoose board in question 4.

Fig. 3: Children Preferences

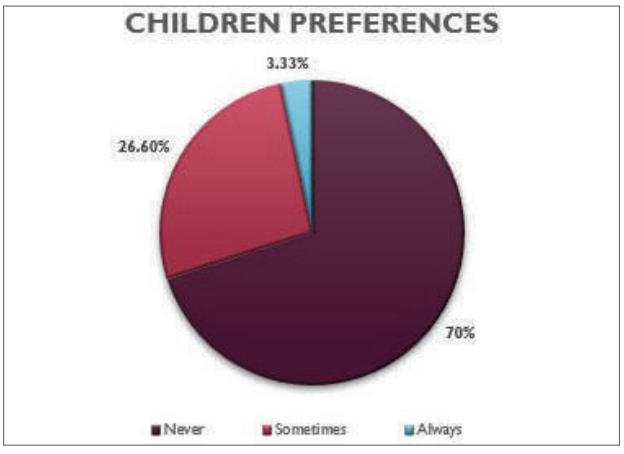
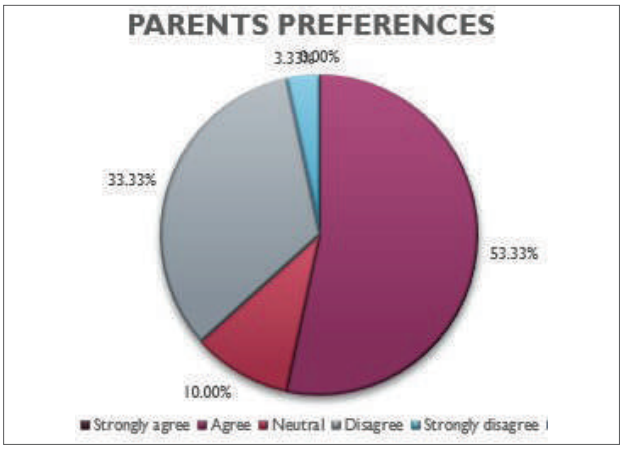


Fig. 4: Parents Preferences



Child preferences towards the use of papoose board during their treatment were assessed through question 1 based on a three- point Likert rating scale. The rating responses were 'Never', 'Sometimes', 'Always'. An open-ended question was asked specifying the reason for the response.

The third section assessed the operator preferences through question 1 towards the usage of papoose board based on a five-point Likert rating scale ranging from 'Strongly disagree' to 'Strongly agree'. Question 2 assessed the preferences regarding usage of papoose board as 'physical restraint' or 'protective stabilization' and an open-ended question was asked to specify the reason for the same. Question 3 and 4 assessed the awareness about different sizes of papoose board. Question 5 was an open-ended question wherein operator had to list out the situations for the usage of papoose board.

Categorical data such as age was assessed as mean with SD. Binary categorical variable were assessed as frequency with percentage. Qualitative data was assessed through thematic analysis.

Results

30 children aged 3-12yrs (Boys- 43.3%, Girls- 56.6%) and their parents (Fathers -36.6%; Mothers- 63.3%) were included in the study. Mean age of the children was 7.7 ± 2.6yrs. Out of 15 operators, 53.3% were faculty and 46.6% were postgraduate students.

70% of children never, while 3.33% always wanted to use papoose board during their treatment (Fig.3). Thematic analysis of children preferences generated one theme- (1) Restraint. (Table 1).

Fig. 5: Operator Preferences

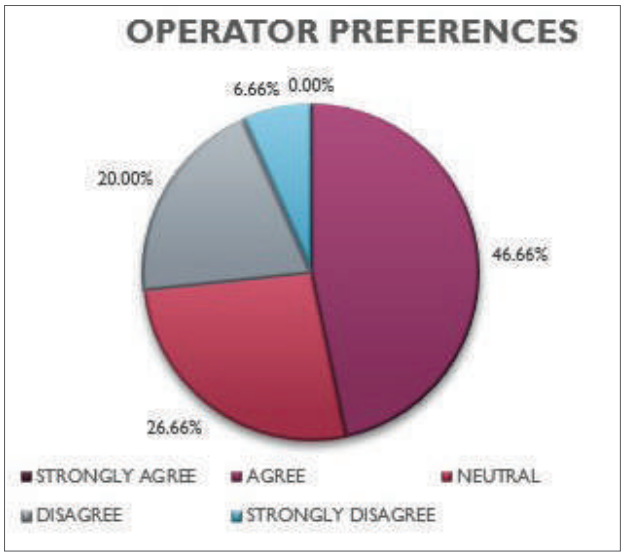


Table 1: Themes generated on thematic analysis for children

(1) Restraint	'I am scared'- Child no. 3
	'I don't want to be tied up'- Child no. 10
	'I don't like it'- Child no. 17

None of the parents were aware about the use of physical restraint/protective stabilization. 53.33% of parents agreed in contrast to 3.33% who strongly disagreed to the use of papoose board during treatment of their child (Fig. 4). Qualitative data was assessed thematically. The result of thematic analysis for parental preferences generated two themes: (1) Protective device for children (2) Child felt uncomfortable and tied up. (Table 2)

Fig. 6: According to operator papoose board is a?

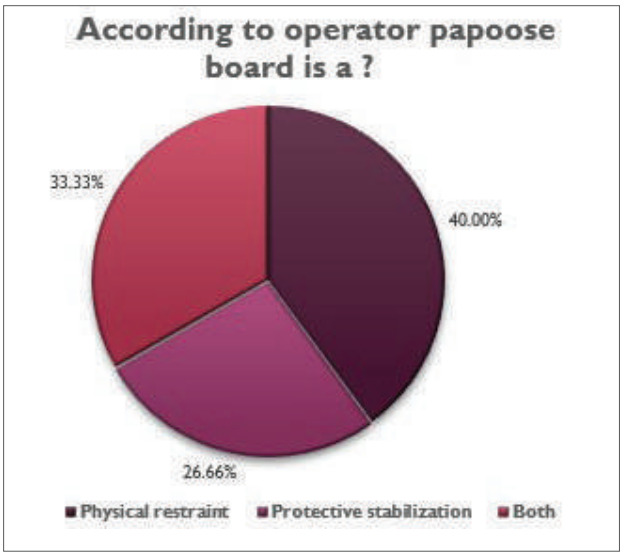


Table 2: Themes generated on thematic analysis for parents

Themes	Responses
(1) Protective device for children	'It will protect my child, no need to hold her'- Parent no.4 'For safety and to complete treatment if child is unco-operative'- Parent no.9
(2) Child felt uncomfortable and tied up	'Don't want to use anything which makes him uncomfortable'- Parent no.15 'Don't want child to feel tied up'- Parent no.21

Table 3: Themes generated on thematic analysis for operators

(1) Protective stabilization for unco-operative children	'Highly unco-operative children'- Operator no.1 'Stubborn children who are not anxious but still do not co-operate during the treatment'- Operator no.6 'When in case after behavior modification/ management fails, last resort'- Operator no.9
	'Children with special health care needs'- Operator no.11 'Highly disruptive patient, parent not willing for pharmacological measures of behavior management'- Operator no.14

46.66% of operators agreed in contrast to 6.66% who strongly disagreed to the use of papoose board. (Figure 5) 40% of operators considered papoose board as physical restraint while 26.66% considered it as protective stabilization (Figure 6). 40% of operators were aware about the correct sizes of papoose board. The result of thematic analysis of operator preferences generated a theme- (1) Protective stabilization for unco-operative children. (Table 3)

Discussion

The use of aversive conditioning has decreased over the past few years[9] but it may be considered as the last resort of non-pharmacological behavior management before switching to pharmacological behavior management in unco-operative children.[10] This decision has to be made by the operator in agreement with the parents. However, the preference of the child has not been considered in this decision-making process, hence this study is justified.

According to this study, children did not prefer the use of papoose board. This might be because children seemed to judge things by the way they look[11] and the thought of being tied up made them uncomfortable. Children thought of PB as a restraint in our study. This might be because most children did not understand the reason for the restraint, the difference between restraint and stabilization and whether PB would be a routine procedure during their future dental visits.[12] Some might even view PB as a punishment instead of a protective method.[13]

On the other hand, most parents preferred the use of papoose board for treatment of their child. Previous research also showed that parents agreed that placement of PB is necessary to perform dental treatment even though it may be stressful for their child.[1,4] In this study, majorityof parents considered PB as a protective device for children while some of them did not want their child to feel uncomfortable and tied up. Similar results were reported by a study conducted by Malik et. al in which some parents explained that the papoose board calmed their children, helped the dentist to complete the procedures, and made their experience less stressful. For others, the papoose board was a horrible and traumatizing experience, leading to feelings of guilt toward their children.[14]

Most of the operators preferred and few were neutral to the use of papoose board in this study. Nazzal et. al has reported similar results that the use of advanced behavioral management techniques, such as protective stabilization, was relatively high amongst operators.[3] According to this study, majority of operators considered PB as a protective stabilisation for unco-operative children or children with special health care needs. Newton et. al also reported similar results that a large proportion of practitioners felt that the use of physical restraint was appropriate with certain disabled patients.[10]

The actual procedure of papoose board usage was not shown. This may change the perspective of both children and parents on seeing/using the actual procedure.

Conclusion

Children did not prefer the use of papoose board as they thought it would make them feel tied up and uncomfortable.

The Papoose board appears to be well accepted and preferred by parents as a behavioral management technique in unco-operative children in view of child safety and stabilization.

Operators who considered PB as a protective stabilization appeared to prefer the use of papoose board in pediatric dentistry.

Acknowledgement

This is self-funded research. No external funding was received.

Conflict of Interest

There are no conflicts of interest

References

1. Mokhtar IW, Suhaimi ASM, Ahmad MS et al. The papoose board: parents' perception and attitudes of its usage in their child's dental treatment: J Dent Indones. 2019;26(3):133-139
2. Peretz B, Zadik D. Parents' attitudes toward behavior management techniques during dental treatment. Pediatr Dent. 1999;21(3):201–4.
3. Nazzal H, El Shahawy OI, Al-Jundi S et al. The use of behaviour management techniques amongst paediatric dentists working in the Arabian region: a cross-sectional survey study. Eur Arch Paediatr Dent. 2021;22(3):375-385.
4. Frankel RI. The Papoose Board and mothers' attitudes following its use. Pediatr dent. 1991;13(5):284-8.
5. American Academy of Pediatric Dentistry. Use of protective stabilization for pediatric dental patients. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2022:340-6.
6. Adair SM, Waller JL, Schafer TE, Rockman RA. 2004. A survey of members of the American Academy of Pediatric Dentistry on their use of behavior management techniques. Pediatr Dent. 26(2):159–66.
7. AAPD. Guideline on protective stabilization for pediatric dental patients. Am Acad Pediatr Dent. 2013;35(5):E169.
8. Chen HY, Yang H, Chi HJ, Chen HM. Physiologic and behavioral effects of papoose board on anxiety in dental patients with special needs. J Formos Med Assoc. 2014;113(2):94–101.
9. Crossley ML, Joshi G. An investigation of paediatric dentists' attitudes towards parental accompaniment and behavioural management techniques in the UK. Br. Dent. J. 2002; 192: 517–521.
10. Newton JT, Patel H, Shah S, Sturmey P. Attitudes towards the use of hand over mouth (HOM) and physical restraint amongst paediatric specialist practitioners in the UK. Int J Paediatr Dent. 2004 ;14(2):111-7.
11. Kantaputra PN, Chiewcharnvalijkit K, Wairatpanich K, Malikaew P, Aramrattana A. Children's attitudes toward behavior management techniques used by dentists. J Dent Child (Chic). 2007 ;74(1):4-9.
12. Makho R, Legare A, Bedos C, dos Santos BF. Understanding the lived experiences of children who have used papoose board for elective dental care.
13. Cusack P, Cusack FP, McAndrew S, McKeown M, Duxbury J. An integrative review exploring the physical and psychological harm inherent in using restraint in mental health inpatient settings. Int J Ment Health Nurs. 2018;27(3):1162-1176.
14. Malik P, Ferraz Dos Santos B, Girard F, Hovey R, Bedos C. Physical Constraint in Pediatric Dentistry: The Lived Experience of Parents. JDR Clin Trans Res. 2022 ;7(4):371-378.

Original Article

Evaluation of Dentist Perception of Platelet Rich Plasma (PRP) for Accelerated Tooth Movement - Cross Sectional Survey

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Submitted: 20-Nov-2023
Revised: 28-Nov-2023
Accepted: 14-Dec-2023
Published: 16-Apr-2024

Abstract

The current survey was conducted to assess the knowledge, awareness and perception of platelet-rich plasma (PRP) on accelerated tooth movement among dentist present in the state of Tamil Nadu. Tamil Nadu dentists were the subjects of the cross-sectional questionnaire survey. 500 participants completed self-administered questionnaires about their knowledge, awareness, and perception of PRP's effect on accelerated tooth movement. The Statistical Package for the Social Sciences (SPSS) (V 22.0) was used to do the statistical analysis. It computed the frequency distribution.The result showed that 466 (93.2%) had prior knowledge of PRP, whereas 34 (6.4%) had no previous experience with it. A total of 156 (31.2%) dentists were aware that PRP procedures are used for teeth rotation and canine retraction.15.2% of participants stated that PRP facilitates accelerated tooth movement.Therefore, results of the study show that the dentists were a little aware of PRP as an additional therapeutic strategy for accelerating tooth movement. More awareness required among the dentist regarding application and its benefits of PRP in accelerated tooth movement.

Keywords: *Orthodontics, platelet-rich plasma, tooth movement*

Introduction

One of the recently used local agents to speed up orthodontic tooth movement is platelet-rich plasma (PRP).[1] PRP was frequently used in the form of gel and made by combining PRP with extra ingredients like thrombin and calcium chloride.[2,3] PRP is composed of both natural fibrinogen and increased platelet counts. The most prevalent secretory granules in platelets are alpha granules. They are rich in proteins that are essential for primary hemostasis and wound healing, such as growth factors and chemokines.[4,5] Pure PRP (P-PRP), leukocyte-rich and platelet-rich plasma (L-PRP), pure platelet-rich fibrin (P-PRF), and leukocyte-rich and platelet-rich fibrin (L-PRF) are the four subtypes of platelet-rich concentrates. The first generation of autologous platelet concentrations in a small volume of plasma is platelet-rich plasma (PRP).

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DOI: 10.4103/jpbs.jpbs_1187_23

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How to cite this article: Nagappan N, Dcruz TM, Loganathan A, Gupte SH, Ali R, Karthik P, *et al.* Evaluation of dentist perception of platelet rich plasma (PRP) for accelerated tooth movement - cross sectional survey. J Pharm Bioall Sci 2024;16:S1591-93.

As a second-generation product, PRF has the benefit of being easier to prepare and having longer-lasting effects.

Variable growth factors and cytokines, including transforming growth factor β, vascular endothelial growth factor, interleukin, interferon, and tumor necrosis factor α, are abundant in platelet-rich concentrates. These traits facilitate their involvement in a wide range of biological processes, such as angiogenesis, inflammation, osteoblastogenesis, and osteoclastogenesis, which in turn promote bone regeneration and wound healing. There have been several attempts to quicken the orthodontic tooth movement rate. Every method has claimed to be better than the others in numerous studies, but the information about each method is still inconclusive.[6] These days, platelet-rich concentrates have shown promise in regenerative dentistry and oral surgery procedures like periodontal therapy, implantology, and tooth extraction in addition to orthodontics.

Since the 1980s, pharmacologic methods to quicken the movement of teeth in orthodontics have been studied in humans. Because pharmacologic approaches are more controlled, less invasive, and less expensive than other approaches, they may be superior if clinically proven to be effective. The potential for concurrent negative effects is still a problem, especially when systemic administration is involved.[7,8] Although, there are numerous methods for speeding up tooth movement. Recently, there has been increased focus on the connection between PRP and orthodontic tooth movement. In two recently published animal studies, Güleç *et al*. (2010) and Rashid *et al*. (2005) evaluated the effects of PRP on tooth movement. Both investigations found a positive correlation between the local PRP injection and the acceleration of orthodontic tooth movement.[1,9]

There is not any literature that describes dentists in Tamil Nadu's understanding of PRP's ability to accelerate tooth movement. The study's current goal was to assess Tamil Nadu dentists' knowledge, awareness, and perception of PRP's role on accelerated tooth movement.

Methodology

A cross-sectional descriptive questionnaire survey was distributed to practicing dentists in Tamil Nadu by means of an online Google form. A pilot study was used to decide on the sample size. The last sample size of 500 subjects had been determined after a pilot study. There were two sections to the questionnaire. The participant's name, age, gender, and years of dental practice were all inquired about in the first section. The understanding of PRPs and its use in orthodontics is covered in the second section.

Every participant filled out the three-month-long questionnaires between March and May of 2023. Following a brief explanation of the goals and objectives of the research, each participant in the survey has submitted an informed consent form. The current research's inclusion criteria comprise individuals who have earned a bachelor's degree in dentistry surgery (BDS). The study excluded the dentists who were unwilling to take part and incapable of providing informed consent.

Results

There were a total of 285 (57%) men and 215 (43%) women among the 500 study participants. Five hundred people participated in the study, of whom 200 (or 40%) were between the ages of 15 and 30, 150 (30%) were between the ages of 20 and 25, and 150 (30%) were between the ages of 25 and 30. Of the 500 survey participants, 466 (93.2%) had prior knowledge of PRP, whereas 34 (6.4%) did not have any previous exposure to it. Of the 500 study participants, 365 (73%) were knowledgeable about the process of extracting platelets from blood, and 150 (30%) were dentists who had personally handled and experienced the process. Four hundred fifty four (90.6) provided accurate answers about the use of PRP to promote bone maturation and wound healing, while 46 (9.4) provided inaccurate answers.

A wide range of 156 (31.2%) dentists were aware that PRP procedures are used for correcting teeth rotation and canine retraction. Fifteen point two percent of respondents reported that use of PRP during orthodontic treatment causes accelerated tooth movement.

Discussion

One of the most prevalent topics of concern at present is the mechanical low force and accelerated tooth movement used in orthodontics. The length of treatment has a negative impact on oral hygiene and gingival, alveolar, and root embrasure resorption. Several investigators endeavored to expedite tooth movement until Wilcko discovered a surgical method that diminished certain thin layers of an alveolar to provide a periodontal ligament-mediated acceleration in tooth movement. Most recent was Gulec e*t al*.[9] who used PRP injections to accelerate tooth movement.

The current objective of the study was to evaluate the knowledge, awareness, and its perception of Tamil Nadu dentists regarding the role and use of PRP in accelerating tooth movement. As a matter of the 500 study participants, 285 (57%) sample were men and 215 (43%) sample were women. Of the 500 survey

participants, 466 (93.2%) had prior knowledge of PRP, whereas 34 (6.4%) had no prior knowledge. PRP has demonstrated a wide range of benefits and uses in numerous dental specialties.[10] Previous research has shown that PRP preparation techniques have developed over time, with the goal of standardizing the process. In early attempts to prepare PRP, a mixture of 10,000 units of bovine thrombin and its 10 mL of 10% calcium chloride was used to activate PRP.[11-13]

It is no longer advised to activate with bovine thrombin because it has been shown to result in coagulopathy due to their cross-reactivity of human factor V antibodies with antibovine factor V antibodies. Therefore, it was suggested to use calcium chloride alone or autologous thrombin. Textor and Tablin demonstrated that, while it could take 20 minutes for PRP to activate, calcium chloride activation may be the affordable and efficient technique.[14,15] Based on the findings of Von Böhl *et al*., who reported that the majority of hyalinized areas were found lingually and buccally from the central plane rather than in the area of the central plane due to local stress and shear concentrations, this study recommended that intraligamentary injection at the distobuccal and distopalatal surfaces of the canine root. These areas needed to have rapidly bone metabolism with the goal to speed up orthodontic tooth movement. However, previous studies evaluated the advantages of local pharmacologic agent injection to accelerate tooth movement and it found one or two submucosal or gingival injection sites.[16-18]

The present investigation found that 156 (31.2%) dentists were aware that canine retraction and tooth rotation could be corrected with PRP procedures. Fifteen point two percent of participants said that PRP had accelerated tooth movement in a positive approach. The impact of PRP on the orthodontic tooth movement rate was assessed by Rashid A. *et al*.[1] and demonstrated that, in the current animal study involving local PRP injection, total maxillary tooth movement was significantly faster on the experimental side compared to the control side. Accelerated orthodontic tooth movement without any clinically or microscopic adverse effects that could be identified. Furthermore, Güleç *et al*.[9] reported that PRP increased orthodontic tooth movement by 1.4-1.7 times.

Conclusion

According to the present study, the dentists had a basic understanding of PRP as a supplementary therapeutic approach for accelerating tooth movement. Dentists need to be more knowledgeable about the use of PRP in orthodontic tooth movement and advantages in accelerated orthodontics.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Rashid A, ElSharaby FA, Nassef EM, Mehanni S, Mostafa YA. Effect of platelet-rich plasma on orthodontic tooth movement in dogs. Orthod Craniofac Res 2017;20:102-10.
2. Carlson NE, Roach RB Jr Platelet-rich plasma: Clinical applications in dentistry. J Am Dent Assoc 2002;133:1383-6.
3. Kao RT, Murakami S, Beirne OR. The use of biologic mediators and tissue engineering in dentistry. Periodontol 2000 2009;50:127-53.
4. Anitua E, Andia I, Ardanza B, Nurden P, Nurden AT. Autologous platelets as a source of proteins for healing and tissue regeneration. Thromb Haemost 2004;91:4-15.
5. Pietrzak WS, Eppley BL. Platelet rich plasma: Biology and new technology. J Craniofac Surg 2005;16:1043-54.
6. Long H, Pyakurel U, Wang Y, Liao L, Zhou Y, Lai W. Interventions for accelerating orthodontic tooth movement: A systematic review. Angle Orthod 2013;83:164-71.
7. Yi J, Xiao J, Li H, Li Y, Li X, Zhao Z. Effectiveness of adjunctive interventions for accelerating orthodontic tooth movement: A systematic review of systematic reviews. J Oral Rehabil 2017;44:636-54.
8. Yamasaki K, Shibata Y, Imai S, Tani Y, Shibasaki Y, Fukuhara T. Clinical application of prostaglandin E1 (PGE1) upon orthodontic tooth movement. Am J Orthod 1984;85:508-18.
9. Güleç A, Bakkalbaşı BÇ, Cumbul A, Uslu Ü, Alev B, Yarat A. Effects of local platelet-rich plasma injection on the rate of orthodontic tooth movement in a rat model: A histomorphometric study. Am J Orthod Dentofac Orthop 2017;151:92-104.
10. Marx RE. The biology of platelets and the mechanism of platelet-rich plasma. In. Marx RE, Garg AK. Dental and craniofacial applications of Platelet-Rich Plasma. 2005:3-30.
11. Dhurat R, Sukesh M. Principles and methods of preparation of platelet-rich plasma: a review and author's perspective. Journal of cutaneous and aesthetic surgery 2014;7:189.
12. Chahla J, Cinque ME, Piuzzi NS, Mannava S, Geeslin AG, Murray IR, *et al*. A call for standardization in platelet-rich plasma preparation protocols and composition reporting: A systematic review of the clinical orthopaedic literature. J Bone Joint Surg Am 2017;99:1769-79.
13. Whitman DH, Berry RL, Green DM. Platelet gel: An autologous alternative to fibrin glue with applications in oral and maxillofacial surgery. J Oral Maxillofac Surg 1997;55:1294-9.
14. Alsousou J, Ali A, Willett K, Harrison P. The role of platelet-rich plasma in tissue regeneration. Platelets 2013;24:173-82.
15. Textor JA, Tablin F. Activation of equine platelet-rich plasma: comparison of methods and characterization of equine autologous thrombin. Vet Surg 2012;41:784-94.
16. Von Böhl M, Maltha J, Von den Hoff H, Kuijpers-Jagtman AM. Changes in the periodontal ligament after experimental tooth movement using high and low continuous forces in beagle dogs. Angle Orthod 2004;74:16-25.
17. von Böhl M, Maltha JC, Von Den Hoff JW, Kuijpers-Jagtman AM. Focal hyalinization during experimental tooth movement in beagle dogs. Am J Orthod Dentofacial Orthop 2004;125:615-23.
18. Krishnan V, Davidovitch Z. Cellular, molecular, and tissue-level reactions to orthodontic force. Am J Orthod Dentofac Orthop 2006;129:1-32.

ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 04 | April - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

THE EFFECT OF LASER AS AN ADJUNCT TO NON-SURGICAL THERAPY IN THE TREATMENT OF PERI-IMPLANTITIS- A SYSTEMATIC REVIEW

Dentistry

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ABSTRACT

Peri-implantitis is an inflammatory process affecting the tissues around an already osseo-integrated implant, and it is becoming the most challenging problem in clinical implant dentistry. Peri-implant mucositis can be managed through non-surgical therapy, however the effectiveness of Laser an adjunct to non-surgical therapy in managing peri-implantitis is assessed through this systematic review. An electronic database search was carried out from Pub Med, Google scholar, Web of science, EBSCO host, Embase, Science direct. A total of only 4 articles were assessed as per the inclusion and exclusion criteria. Only randomized controlled clinical trials were included. Data extraction sheet was prepared and all 4 studies were analyzed with parameters including plaque index, peri-implant probing depth, bleeding on probing, suppuration, and radiographic marginal bone level. Laser application improves clinical signs of inflammation without significantly improving bone levels

KEYWORDS

peri-implantitis, laser, non-surgical therapy, supportive peri-implant therapy, mechanical debridement

INTRODUCTION

Peri-implantitis is an "inflammatory process" affecting the tissues around an already osseo-integrated implant, and it is becoming the most challenging problem in clinical implant dentistry.[1]

The differential diagnosis between peri-implant mucositis and peri-implantitis is based on evidence that alveolar bone loss following initial healing and bone remodelling has occurred and requires a radiographic evaluation of the bone level around dental implants over time. In the absence of initial radiographs and probing depths, radio-graphic evidence of bone level ≥3 mm and/or probing depths ≥6 mm in conjunction with profuse bleeding represents peri-implantitis.[2]

The current principles for the treatment of peri-implantitis were primarily derived from principles established for the therapy of periodontitis.[3] Traditionally, nonsurgical mechanical debridement (NSMD) is performed for the treatment of periodontal and peri-implant diseases. The goal in non-surgical therapy of peri-implant mucositis and peri-implantitis is to eliminate or significantly reduce the amounts of oral pathogens in the pockets around implants. The ideal goal of peri-implantitis would be the resolution of the disease (i.e.no bleeding on probing, no suppuration, no further bone loss)[4] The most common is a non-surgical approach, by mechanical debridement of the affected implants with plastic curettes. However, this conventional treatment has limitations in the resolution of peri-implant mucositis. Non-surgical periodontal therapy carried out with curettes can still result in incomplete removal of plaque, calculus and persistent probing depth, bleeding on probing, suppuration.

To overcome these limitations, different adjunctive therapies have emerged over the years, diode laser therapy being introduced recently. Lasers can effortlessly irradiate the entire surface, especially in irregular and rough areas where mechanical instruments cannot easily reach. They not only eliminate bacteria but also inactivate bacterial diffused toxins. The bio stimulatory properties of lasers yield improvement in peri-implant condition.[5]

Protocol And Registration:

The systematic review was conducted in accordance with the Preferred Reporting Items of Systematic Reviews (PRISMA) and Meta - analyses statement. PROSPERO acknowledgement receipt number [426067]

MATERIALS AND METHODS:

The systematic review was conducted in accordance with the PRSIMA guidelines.

Focused Question:

Does LASER as an adjunct to mechanical non-surgical periodontal therapy result in improved outcomes in terms of probing pocket depth and bleeding on probing compared to non-surgical periodontal therapy alone in subjects with peri-implantitis ?
Population (P) - periimplantitis

Intervention (I) – mechanical non-surgical periodontal therapy + LASER

Comparison (C) – mechanical non-surgical periodontal therapy alone.
Outcome (O)- absence of peri-implant probing depth >5 mmm, bleeding on probing and no further bone loss.

ELIGIBILITY CRITERIA:

1. Randomized controlled trials (RCT)
2. Studies including cases of osseointegrated dental implants affected by peri-implantitis as per case definition.
3. Original publications evaluating efficacy of LASER as an adjunct to non surgical mechanical debridement (NSMD) in peri-implantitis.
4. Studies using low level laser therapy , using diode laser, Er:YAG laser and diode laser, photobiomodulation therapy along with non-surgical therapy with and without adjunctive laser therapy and having a follow up of at least 6 months.
5. Studies reporting one or more clinical parameters including probing pocket depth (PPD), Bleeding on probing and marginal bone level.

Exclusion Criteria:

Review papers, In- vitro studies, animal studies, case reports, commentaries, interviews.

Information Sources And Search Strategy:

Databases search were MEDLINE/PubMed, Cochrane Central Register of Controlled trials (CENTRAL), EBSCO host, Science Open, Google Scholar and Open Grey databases up to and including Feb 2023. Literature searching for papers that reported the efficacy of adjunctive laser therapy in the treatment of periimplantitis.

Search Strategy:

The selection strategy was based on a combination of *types of studies* AND *disease* AND *therapy* using different combinations of Medical Subject Heading (MeSH) terms and free text words.

MeSH terms (italic) adopted for electronic database search were: "*randomized controlled trial*" "*Peri-implantitis*" OR "*Peri-implant*" OR "*Periimplpant*" OR "*Periimplantitis*", "*Peri-implant infection*"

OR "*Periimplant infection*" OR "*Peri-implant complication*" OR "*Periimplant complication*" OR ("*implant*" AND "*failure*") "*non surgical therapy*" OR "*non-surgical mechanical debridement*" OR "*non surgical periimplant therapy"* OR *"non surgical peri-implant therapy"* AND *"LASER peri-implant therapy"* "*adjunct LASER*" OR "*laser peri-implant*" OR "*laser periimplant*" OR **"***diode" OR "Er:YAG" OR "low level laser therapy" OR "photobiomodulation" OR "photobiostimulation".*

Study Selection:

1. Assessment of titles and abstracts

2. Assessment of full text articles.

Data Management And Collection Process:

Data extraction sheet was prepared based upon variables associated in the articles analyzed. Data regarding authors, year and country of publication, type of study, aim, clinical, radiographic and microbiologic parameters assessed, sample size, control group, intervention, methodology and conclusion.

Data extraction sheet was prepared based upon variables and the following data were collected:

Author, country, year of publication, study design, length of follow - up, no. of subjects, age, gender, type of NSMD, type and mode of delivery of laser, point of application, supportive peri-implant therapy, peri-implant probing depth, bleeding on probing, marginal bone levels.

The collected data was then transferred into evidence tables to provide an overview of the included studies and available data.

Data Items:

Variables for which data was sought included Peri-implantitis, peri-implant probing depth, bleeding on probing, marginal bone level.

RESULTS

Study Selection:

A total of 11,600 articles were found after electronic search, 8550 which were duplicates. Total articles screened were 3050, 2994 titles of articles were not fulfilling the eligibility criteria, after which 56 abstracts were analyzed. 45 articles were excluded after reviewing abstracts as the studies did not meet the inclusion criteria. A total of 11 full text articles were evaluated of which 7 articles did not fulfil the eligibility criteria and 4 articles were eligible for qualitative analysis.

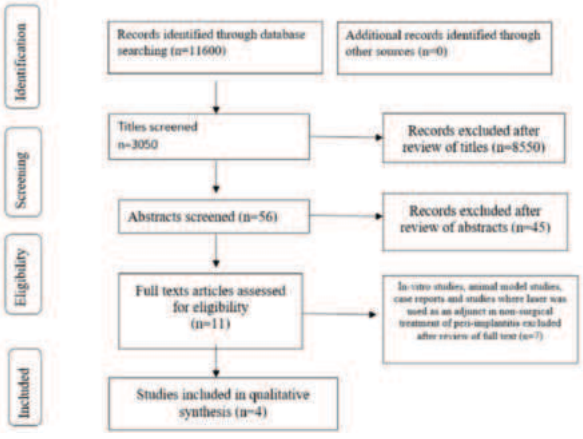


Figure 1- Flow Chart Of Literature Search Results And Study Selection

Studies Included For The Analysis.

Four studies were included for the qualitative synthesis. Out of the 4 studies, all 4 were randomized controlled trials. 3 out of the 4 studies suggest LASER group did not yield significant results when compared to control group. An overview of the included studies for the analysis is presented in **Table 1**.

First author, Year of publication	**Roccuzzo A et al 2022**	**Alqahatni F. et al 2020**	**Abduljabbar T et al 2017**	**Arısan V et. al 2015**
Study design	Single centered double blinded, parallel designed randomized controlled clinical trial.	Single centered, parallel designed randomized controlled clinical trial.	Single centered single blinded, parallel designed randomized controlled clinical trial.	Single centered, split mouth randomized controlled clinical trial.
Country	Switzerland	Riyadh	Saudi Arabia	Turkey
Sample size Population characteristics (no. of subjects, age, gender,)	No. = 25 Age >18 yrs Gender male- 13 female-12 Test group : smokers= 3 Non smokers= 9Control group Smokers=2 Non smokers=11	No.= 67 Male-31 Female-3 Test- 34 Maxilla-4 Mandible= 30 Control -31 Maxilla= 5 Mandible=28	No. = 63 Age 31- 58 years Gender Male= 63 Test: 32 patients 39 implants Control 31 patients 35 implants Delayed loaded platform switched implants	No.= 48 Age= 43-76years Male=3 Female=7
Periodontal diagnosis : Periimplant diseases	Peri-implantitis	Peri-implantitis	Peri-implantitis	Peri-implantitis
Interventions	Test: Mechanical debridement using titanium curettes and stainless steel curettes + diode laser setting : 810nm , 2.5 W, 50Hz 10ms 3x30s (90s per appointment) Control group : Mechanical debridement with non activated adjunctive diode laser.	Test group : 940-nm indium gallium arsenide phosphorous diode laser (Epic Biolase, Irvine, Calif).- 20 seconds at a constant distance of 15 mm and with a continuous wavelength (3.41 J/cm2 delivery with a 1.76 cm2 spot and average output of 0.3 W	Test : Mechanical debridement by plastic curettes + pulsed Nd : YAG laser 1064nm 60-120s.power 4W 80mJ, pulse width 350 milliseconds, 50Hz with air and water cooling. Control group: Mechanical debridement with plastic curettes.	Test group : Diode Laser wavelength of 810 nm (energy density, 3 J/cm2; power density, 400 mW/cm2; energy, 1.5J; and spot diameter, 1 mm) for a duration of 1 min in pulsed mode with a power level of 1W using a standard 400 lm delivery optical fiber tip.
Point of application	At days 0, 7 and 14 Supportive care: supramucosal prophylaxis at and oral hygiene monitoring at 3 mo and 6mo follow up.	Day 0, 2 ,7 Follow up at 3 and 6 months.	At baseline Follow up at 3 , 6 months.	Day 0 Follow up at 1 month and 6 months.

Clinical parameters	1.Plaque index 2.Bleeding on probing 3. Suppuration on probing 4. Periimplant probing pocket depth	1.Plaque index 2.Peri-implant probing depth 3.Bleeding on probing	1..Plaque index 2. bleeding on probing 3. probing depth	1.Plaque index 2.Peri-implant depth 3.Bleeding on probing
Radiographic parameters	Measurement of mesial and distal bone level.	Crestal Bone Resorption on mesial and distal aspects.	Crestal bone loss on mesial and distal aspects	Marginal Bone Level (MBL) on panoramic radiograph
Microbiologic parameters	*Aa, Pg, Tf, Td, Fn, Cr.*		-	*Aa, Pg, Pi, Sc, Tf, Cc, Cg, Ec, Fn, Pm, Sm, Td, Vp,*
Biomarkers	IL-1B, IL-10, MMP-8		-	

Risk Of Bias In Individual Studies

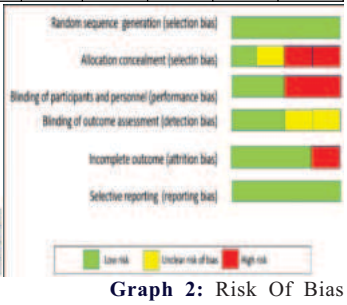
This assessment was conducted by using the recommended approach for assessing the risk of bias in studies included in Cochrane Reviews (Higgins 2011) using the tool RevMan 5.0.

The risk of bias of the included studied is presented in **Table 3**. **Graph 3** and **Graph 4** shows the assessment of risk of bias in individual studies and across studies respectively.

Table 3: Quality Assessment Of The Studies Included By Judging Risk Of Bias And Applicability Using Cochrane Risk Of Bias Tool For Randomized Controlled Trial

Sr no.	Authors (Year)	Type of study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome	Incomplete outcome data	Selective reporting
1	Roccuzzo A et al (2022)[8]	RCT	Low	Low	Low	Low	High	Low
2	Alqahatni F. et al (2020)[9]	RCT	Low	High	High	Unclear	Low	Low
3	Abduljabbar T et al (2017)[10]	RCT	Low	High	High	Low	low	Low
4	Arısan V et. al (2015)[11]	RCT	Low	Unclear	Low	Unclear	Low	Low

Graph 1: Risk Of Bias In Individual Studies



Graph 2: Risk Of Bias Across Studies

DISCUSSION:

The progressive loss of supporting bone beyond biological bone remodeling, if left untreated can lead to failure of implant. Traditionally, nonsurgical mechanical debridement (NSMD) is performed for the treatment of periodontal and peri-implant diseases.[2] The ultimate goal of this form of therapy is to debride the teeth and peri-implant surfaces from dental plaque/calculus and granulation tissues thereby reducing pathologic microbial load in gingival sulcus, facilitating healing.[3]

Peri-implantitis management remains unpredictable with no generally acceptable consensus and may require open flap surgery (resective and/or regenerative) as monotherapy, or as a second stage procedure, if the non-surgical treatment fails.[4] The present data questions the effectiveness of non-surgical therapy since only limited improvements in the main clinical parameters have been reported with high possibility of disease reoccurrence. Mechanical debridement by ultrasonic devices, curettage, air polishing, and remodeling the implant surfaces by implantoplasty together constitutes the non-surgical therapy for Peri-implantitis. Adjunctive therapy including antimicrobials, antiseptics, photobiomodulation have also improved clinical outcomes in peri-implantitis. In a review by Chala et al, adjunctive LASER therapy showed significant results in reducing inflammation during a short follow up period.

In the study by Abduljabbar et al (2017)[10], Nd: YAG laser was effective in reducing peri-implant soft tissue inflammation only in short term. The wavelength of 1064nm gets absorbed in epithelial lining of periodontal pocket, leaving the heard tissues unaffected. It also reduces the count of periimplant pathogenic bacteria, reducing expression of interleukin-1 beta and matrix metalloproteinases in the GCF of periodontitis patients. Due to potential of implant surface damage, Nd:YAG laser should be cautiously used under copious irrigation.

Alqahatni et al (2020)[9] concluded that LLLT resulted in no significant difference in marginal bone level up to 6 months follow up but showed improvement in peri-implant soft tissue healing even after 6 month follow-up. The results were not in accordance to those of the study by Abduljabbar et al which may be attributed to multiple laser application following NSMD. LLLT positively influences biological tissues by improving cell proliferation, nerve conduction and microcirculation. As reported by Khadra et al, LLLT stimulates mechanical strength at implant-bone interface.

Rocuzzo et al (2022)[8] in their randomized controlled trial showed significant reduction in PPD compared to baseline. Though bacterial counts of *Pg, Tf, Fn and Cr* decreased in laser group, clinical and radiographic outcomes did not show any statistically significant improvement. The split mouth study by Arsan et al(2015)[11] concluded that laser did not yield any additional positive influence on peri - implant healing when compared to control group.

CONCLUSION:

The results of this systematic review should be interpreted with caution. The effectiveness of LASER as an adjunct to mechanical debridement in improving clinical and radiographic parameters of peri-implantitis has limited evidence till date. Supportive peri-implant therapy with oral hygiene monitoring plays an important role in treatment of periimplantitis. Laser therapy under optimal power settings and copious irrigation should be carried out to avoid over heating of implant surfaces. Non-surgical mechanical debridement with or without laser therapy reduces clinical signs of inflammation without significantly improving bone levels.

REFERENCES:

1. Heitz-Mayfield, L., & Mombelli, A. (2014). The Therapy of Peri-implantitis: A Systematic Review. *The International Journal of Oral & Maxillofacial Implants*, *29*(Supplement), 325–345.
2. Roccuzzo, A., Klossner, S., Stähli, A., Imber, J. C., Eick, S., Sculean, A., & Salvi, G. E. (2022). Non-surgical mechanical therapy of peri-implantitis with or without repeated adjunctive diode laser application. A 6-month double-blinded randomized clinical trial. *Clinical oral implants research*, *33*(9), 900-912.
3. Darby, I. (2022). Risk factors for periodontitis & peri-implantitis. *Periodontology 2000*, *90*(1), 9-12.
4. Muthukuru, M., Zainvi, A., Esplugues, E. O., & Flemmig, T. F. (2012). Non-surgical therapy for the management of peri-implantitis: A systematic review. *Clinical Oral Implants Research*, *23*, 77-83.
5. Renvert, S., Roos-Jansåker, A. M., & Claffey, N. (2008). Non-surgical treatment of peri-implant mucositis and peri-implantitis: a literature review. *Journal of clinical periodontology*, *35*, 305-315.
6. Figuero, E., Graziani, F., Sanz, I., Herrera, D., & Sanz, M. (2014). Management of peri-implant mucositis and peri-implantitis. *Periodontology 2000*, *66*(1), 255-273.
7. Abduljabbar, T., Javed, F., Kellesarian, S. V., Vohra, F., & Romanos, G. E. (2017). Effect of Nd: YAG laser-assisted non-surgical mechanical debridement on clinical and radiographic peri-implant inflammatory parameters in patients with peri-implant disease. *Journal of Photochemistry and Photobiology B: Biology*, *168*, 16-19.
8. Alqahtani, F., Alqhtani, N., Celur, S. L., Divakar, D. D., Al-Kheraif, A. A., & Alkhtani, F. (2020). Efficacy of Nonsurgical Mechanical Debridement With and Without adjunct low-level laser therapy in the treatment of Peri-Implantitis: a randomized controlled trial. *Journal of Oral Implantology*, *46*(5), 526-531.
9. Arısan, V., Karabuda, Z. C., Arıcı, S. V., Topçuoğlu, N., & Külekçi, G. (2015). A randomized clinical trial of an adjunct diode laser application for the nonsurgical treatment of peri-implantitis. *Photomedicine and laser surgery*, *33*(11), 547-554.

EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 11
Issue: 5
180-185
Year: 2024

AN OVERVIEW OF PEMPHIGUS VULGARIS – A CASE STUDY AND IT'S TREATMENT STRATEGIES

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Article Received on 08/02/2024 **Article Revised on 28/03/2024** **Article Accepted on 18/04/2024**

ABSTRACT
Pemphigus vulgaris is a common autoimmune blistering disease affecting the oral mucosa and skin, in which oral mucosa is the initial site of presentation. Assessment of etiological factors, oral lesions along with cutaneous manifestations is hence vital for early diagnosis and treatment. In this article, a case of pemphigus vulgaris affecting both the oral cavity and skin is reported. A detailed review of the treatment modalities of pemphigus vulgaris and management of recalcitrant lesions is described in this article.

KEYWORDS: Pemphigus, Pemphigus vulgaris, Blistering disease, Auto-immune disorders.

INTRODUCTION
Pemphigus refers to a group of autoimmune, mucocutaneous blistering diseases, in which keratinocyte antigens are the target of the autoantibodies, leading to acantholysis and blister formation.[1,2] There are about 0.5 to 3.2 cases per 100,000 population reported each year, with the highest incidence between the 5th and 6th decade of life with a clear female prediliction.[3]

The major variants of pemphigus are pemphigus vulgaris, pemphigus vegetans, pemphigus foliaceus, pemphigus erythematosus, paraneoplastic pemphigus (PNP) and drug related pemphigus.[4] Among these, pemphigus vulgaris is the most common form, accounting for more than 80% of cases.[6] In majority of patients, painful mucous membrane erosions are the presenting sign and may be the only sign for an average of 5 months before skin lesions develop.[5]

A case report of pemphigus vulgaris affecting both oral cavity and skin along with a brief review of literature is reported here.

CASE REPORT
A 44-year-old female patient reported with the chief complaint of ulcers in the mouth and difficulty in chewing and swallowing since the past 5 months.

She started experiencing pain in the oral cavity 5 months ago after which she noticed the ulcers. The ulcers bled on brushing, with increased salivation in the morning. She also noticed a few skin lesions at this time. On having some ayurvedic medicine one month back, her condition worsened with appearance of genital lesions.

The patient reported to be under extreme stress since past 6 months due to her husband passing away and son being terminally ill. She was taking counselling sessions for stress and depression.

There was presence of a single blister on the left hand, one ulcerative lesion on chest and left shoulder, **(Figure 1)** five ulcerative lesions on areola of right breast and on areola of left breast. Ulcers on the breast and the left shoulder had well defined borders with erythematous base. The cutaneous lesions were tender on palpation and the blister was flaccid. Nikolsky's sign was negative.

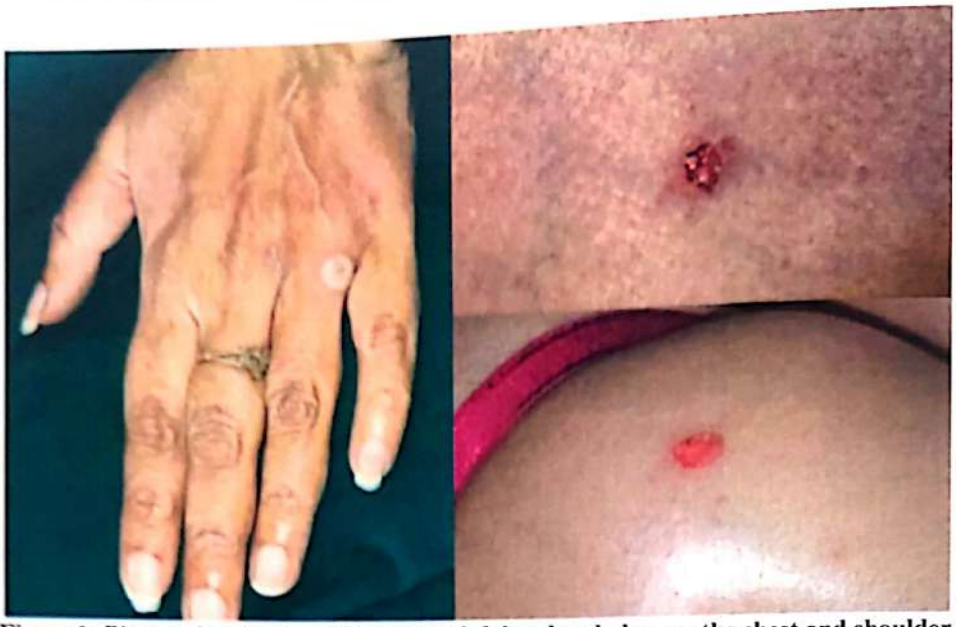

Figure 1: Picture showing flaccid blister on left hand and ulcer on the chest and shoulder.

On intraoral examination, there was presence of ulcerations and erosions on both buccal mucosae, extending from the commissural area to retromolar trigone including the posterior palatal area. **(Figure 2 and 3)** The tongue was coated and had presence of discrete ulcerations covered with pseudomembranous slough on the left and right lateral borders. **(Figure 3)** Lower labial mucosa had an erosive lesion with slight blood tinge. On the upper left labial mucosa, there was presence of a healing ulcer with an erythematous periphery. **(Figure 2).**

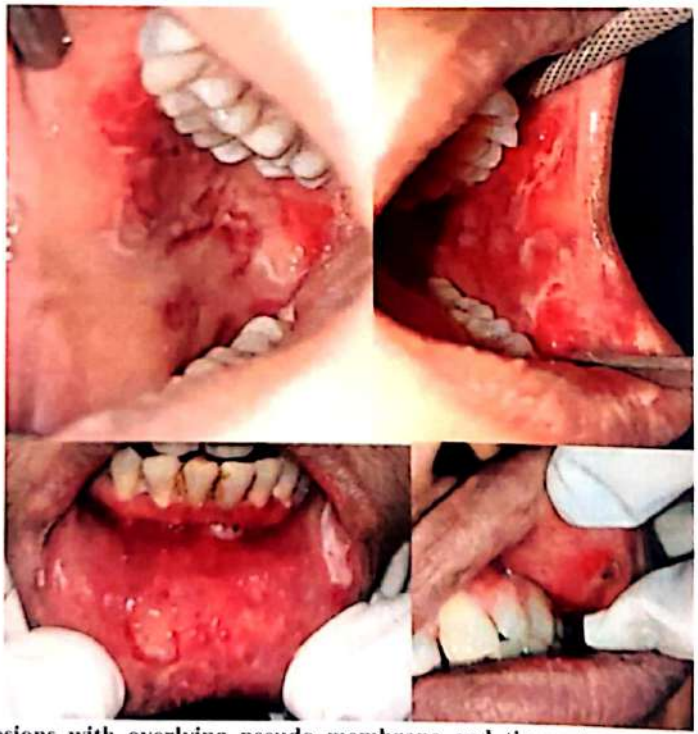

Figure 2: Ulcerative lesions with overlying pseudo membrane and tissue tags on the right and left buccal mucosae and lower labial mucosa and presence a healing ulcer with encrustation on upper labial mucosa.

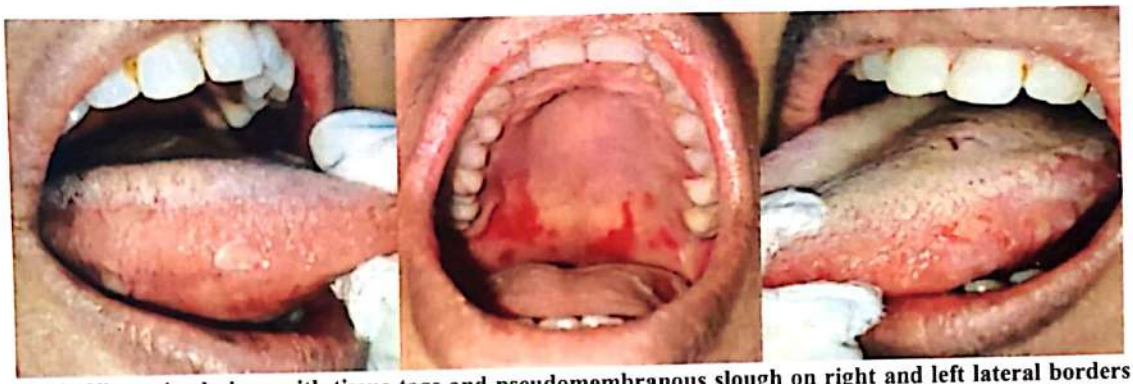

Figure 3: Ulcerative lesions with tissue tags and pseudomembranous slough on right and left lateral borders of tongue and erythema with posterior palate.

The lesions on buccal mucosae, labial mucosa and tongue were covered by whitish pseudo membrane with tissue tags and surrounded by erythematous periphery. There was bleeding from these lesions on even the slightest manipulation. Considering the oral and dermal manifestations, the condition was provisionally diagnosed as a muco-cutaneous blistering disease.

Due to the chronicity of the lesion, the gender of the patient, presence of thin flaccid easily rupturing blisters with tissue tags a differential diagnosis of Pemphigus Vulgaris was given. Since Nikolsky's sign was negative for cutaneous lesions and the patient being of middle age, bullous pemphigoid was considered as the second differential diagnosis.

The patient was adviced complete blood count, a desmoglin 3 autoantibody test to confirm pemphigus vulgaris and a thiopurine methyl transferase enzyme activity test (TPMT) for formulation of treatment protocol. Desmoglin 3 autoantibody test gave positive result with observed value above 200 which confirmed pemphigus vulgaris. TPMT levels and CBC values were within the normal range, except WBC count which was raised to 15,500 cells per cubic mm.

She was prescribed 10 mg tablet of Wyosolone to be taken four times a day for one week, and the dosage was tapered by reducing one tablet in each of the successive weeks for a total of 4 weeks. The patient was also prescribed an ointment formulation, which was a combination of Clotrimazole (antifungal), Neomycin (antibiotic) and Beclomethasone (steroid) 5mg for oral lesions three times daily along with supplementation of Vitamin D3 60,000 IU once a week. She was followed up every week for 4 weeks. The patient was adviced meditation and exercises to reduce stress.

At the end of 4 weeks, 80% of her lesions had resolved. **(Figure 4)** As the TPMT levels were within normal range. Tablet Azathioprine (immunosuppressant) was prescribed, with a dose of 50 mg for a day to start with to assess for idiosyncratic reactions or any side effects. The dosage was increased to 100 mg once a day per week for four weeks, as no adverse reactions were reported. At the end of 3 months there was complete resolution of the lesions and her quality of life improved significantly.

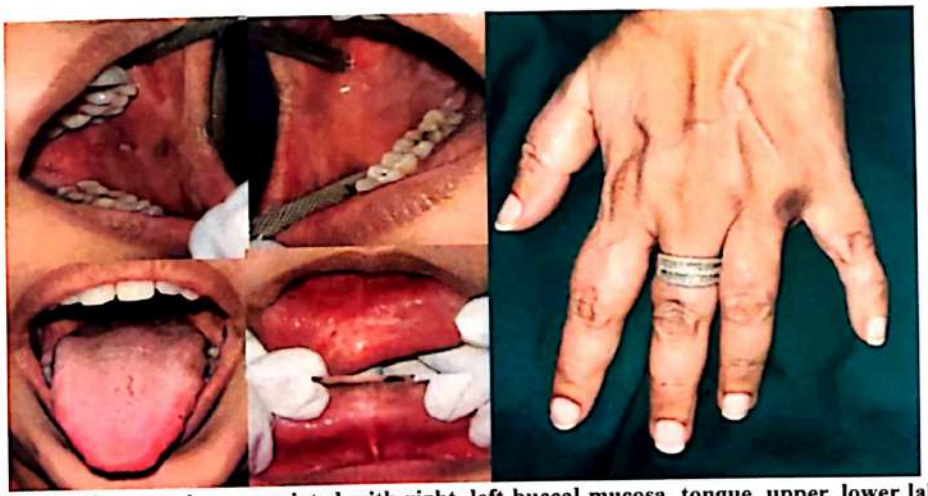

Figure 4: Healed lesions can be appreciated with right, left buccal mucosa, tongue, upper, lower labial mucosa and hand with presence of scar on hand.

DISCUSSION

The worldwide prevalence of pemphigus vulgaris is about 0.1 to 0.5% per million population per year.[8] The incidence of pemphigus, however, varies as per the geographic area and ethnic population. Literature reports suggest that the incidence of pemphigus vulgaris ranges from 0.76 to 16 per million population per year in Europe.[9] In India, the prevalence of pemphigus vulgaris is lesser than the rest of the world and is in the range of 0.09% to 1.8%.[10]

The classical lesion of pemphigus is a thin-walled bulla arising on otherwise normal skin or mucosa, which rapidly breaks and continues to extend peripherally, eventually leaving large denuded areas. This disease also exhibits positive "Nikolsky's sign" – the ability to induce peripheral extension of a blister and/or removal of epidermis as a consequence of applying tangential pressure with a finger or thumb to the affected skin, peri-lesional skin, or normal skin in patients affected with pemphigus.[11] **In this case, inspite of Nikolsky's sign** being negative for the skin lesions, desmoglin 3 test was positive. This suggests that the condition was not bullous **pemphigoid wherein Nikolsky's sign is commonly** negative. Hence there is a possibility for presence of hybrid lesions within pemphigus vulgaris cases which needs to be further investigated.

A detailed history is essential in distinguishing the lesions of pemphigus from those caused by acute viral infections such as herpes and EM (Erythema Multiforme). This is because a similar clinical picture can be seen in undiagnosed and/or untreated immunocomprised patients, suffering from RHS (Recurrent Herpes Simplex) infections in the form of atypical ulcers which lasts several weeks or months. Moreover, cytological presence of Tzanck cells may complicate the diagnosis.[12] Our patient did not give any positive history of compromised immunity like acquired immune deficiency syndrome or chemotherapy, organ transplant. Hence, RHS infection and EM were ruled out.

An early diagnosis is vital to patient management, when lower doses rendered for shorter periods can effectively control the disease. The treatment is administered in two phases: a loading phase, to induce disease remission, and a maintenance phase, which is further divided into consolidation and treatment tapering to improve quality of life.[13]

In cases of extensive oral lesions or involvement of other mucosa and skin, systemic corticosteroid therapy is initiated immediately. An initial dose of prednisone 0.5–2 mg/kg is recommended.[14] Our patient was prescribed a dosage of 10 mg tablet Prednisolone, four times a day for one week, which was tapered by reducing 1 tablet in each successive week for a total of 4 weeks.

The patient was also prescribed an ointment formulation of Clotrimazole (antifungal), Neomycin (antibiotic) with Beclomethasone (steroid) 5mg for local application on the oral lesions 3 times daily along with Vitamin D3 supplementation of 60,000 IU (international units) once a week.

Depending on the response to medication, the dosage was gradually decreased to the minimum therapeutic dose, once daily in the morning to minimize side effects. Adjuvants such as Azathioprine or Cyclophosphamide are added to the regimen to reduce the complications of long-term corticosteroid therapy.[15]

Azathioprine which was prescribed to our patient, is one of the main adjuvants used in PV (Pemphigus Vulgaris).[15,16] It is considered as a first-line adjuvant immunosuppressant according to the (European Dermatology Forum) EDF guidelines. The dosage varies between 1 and 3 mg/kg/day, based on the activity of the thiopurine methyltransferase (TPMT) enzyme, involved in the metabolism of the drug. When TPMT levels are high, normal doses of azathioprine (up to 2.5 mg/kg/d) are administered, while adults with PV and intermediate or low TPMT levels should receive a maintenance dose (up to 0.5–1.5 mg/kg/d). Azathioprine should not be used in patients with no TPMT activity. A dose of 50 mg/d could initially be administered, and if no idiosyncratic reactions occur, it can be increased after a week. In case of any idiosyncratic reactions, it should be discontinued.[17,18] The primary benefit of adjuvant azathioprine is its steroid-sparing effect.[15,19]

Azathioprine has been reported to require a lower cumulative corticosteroid (CS) dose for remission, with some investigators reporting superior steroid-sparing effect when compared to MMF (Mycophenolate mofetil) and cyclophosphamide.[15,20] When compared to steroid monotherapy, adverse events are significantly reduced with adjuvant azathioprine treatment without any compromise in the rate of clinical remission.[15,20]

As the TPMT levels were within normal range in the case reported here, Tablet Azathioprine (immunosuppressant) was prescribed to our patient, with an initial dose of 50mg once a week, as precautionary dose to assess for any idiosyncratic reaction. The dosage was increased to 100mg once a week for 4 weeks as no adverse reactions were reported. At the end of 3 months, there was complete resolution of lesions giving a much better quality of life for the patient.

A relapse is said to occur when there is appearance of ≥3 new lesions/month that do not heal spontaneously within 1 week, or by the extension of established lesions, in a patient who has achieved control of disease activity.[15] In an event of relapse, a Rituximab therapy was planned for the patient.

Rituximab is an anti-CD20 monoclonal humanized antibody, with the potential to reduce desmoglein autoantibodies and selectively deplete B cells.[21] [22]

Rituximab is indicated in patients who remain dependent on more than 10 mg prednisolone combined with an immunosuppressive adjuvant according to the EDF. Administration schedule in literature is either 1,000 mg IV every 2 weeks or 375 mg/m^2 every week.[23,24] The same dosage can be administered again in case of clinical relapses. A meta-analysis on treatment with rituximab in severe pemphigus showed remission in approximately 95% of the total patients.[21] Prophylactic infusion after complete remission does not seem to provide any additional benefit.[25] Rituximab does not eliminate the need for steroids or immunosuppressive agents, and most patients in published studies did use such therapy along with rituximab.[21]

Before the advent of corticosteroid therapy, pemphigus was fatal, with a mortality rate of up to 75% in the first year. It is still a serious disorder, but the existing 5% to 10% mortality rate is primarily due to the side effects of therapy.[26] Morbidity and mortality due to the chronic and fatal course of this condition can be reduced with early diagnosis and prompt treatment leading to complete resolution as reported in the present case.

REFERENCES

1. Kumar SJ, Nehru Anand SP, Gunasekaran N, Krishnan R. Oral pemphigus vulgaris: A case report with direct immunofluorescence study. J Oral Maxillofac Pathol, 2016 Sep-Dec; 20(3): 549. doi: 10.4103/0973-029X.190979. PMID: 27721634; PMCID: PMC5051317.
2. Grando SA. Pemphigus autoimmunity: Hypotheses and realities. *Autoimmunity,* 2012; 45: 7–35.
3. Shamim T, Varghese VZ, Shameena PM, Suddha S. Pemphigus Vulgaris in oral cavity. Clinical analyses of 71 cases. Med Oral Pathol Buccal, 2008; 13: 2622-6.
4. Arpita R, Monica A, Venkatesh N, Atul S, Varun M. Oral Pemphigus Vulgaris: Case Report. Ethiop J Health Sci., 2015 Oct; 25(4): 367-72. PMID: 26949302; PMCID: PMC4762976.
5. Fassmann, A., Dvořáková, N., Holla, L.I., Vaněk, J., & Wotke, J. Manifestation of pemphigus vulgaris in the orofacial region. Case report, 2003.
6. Lester William Burket, Greenberg MS, Glick M. Burket's Oral Medicine. B.C. Decker; 11th edition, 2003.
7. Robinson NA, Yeo JF, Lee YS, Aw DCW. Oral pemphigus vulgaris: A case report and literature update. Ann Acad Med Singapore, 2004; 33(Suppl): 63S-68S.
8. Karisetty B, Reddy KN, Lahkar M. Prevalence of Pemphigus vulgaris and Pemphigus Foliaceus in tertiary care hospital in India: an update. The Pharma Innovation Journal, 2013; 2: 68-72.
9. Huang YH, Kuo CF, Chen YH, Yang YW. Incidence, mortality, and causes of death of patients with pemphigus in Taiwan: a nationwide population-based study. Journal of Investigative Dermatology. 2012; 132: 92–97.
10. Kanwar AJ, De D. Pemphigus in India. Indian J DermatolVenereolLeprol, 2011; 77: 439-49.
11. Seshadri D, Kumaran MS, Kanwar AJ. Acantholysis revisited: Back to basics. *Indian J Dermatol Venereol Leprol.* 2013; 79: 120–6.
12. Banerjee I, Bhowmik B, Maji A, Sinha R. Pemphigus vulgaris - A report of three cases and review of literature. J Family Med Prim Care, 2018 Sep-Oct; 7(5): 1109-1112. doi: 10.4103/jfmpc.jfmpc_133_18. PMID: 30598970; PMCID: PMC6259552.
13. Rai A, Arora M, Naikmasur VG, Sattur A, Malhotra V. Oral pemphigus vulgaris: Case report. *Ethiop J Health Sci.,* 2015; 25: 367–72.
14. Toth GG, Jonkman MF. Therapy of pemphigus. *Clin Dermatol,* 2001; 19(6): 761–767.
15. Gregoriou S, Efthymiou O, Stefanaki C, Rigopoulos D. Management of pemphigus vulgaris: challenges and solutions. Clin Cosmet Investig Dermatol, 2015 Oct 21; 8: 521-7. doi: 10.2147/CCID.S75908. PMID: 26543381; PMCID: PMC4622091.
16. Schiavo AL, Puca RV, Ruocco V, et al. Adjuvant drugs in autoimmune bullous diseases, efficacy versus safety: facts and controversies. *Clin Dermatol,* 2010; 28: 337–343.
17. Anstey AV, Wakelin S, Reynolds NJ. British Association of Dermatologists Therapy, Guidelines and Audit Subcommittee. Guidelines for prescribing azathioprine in dermatology. *Br J Dermatol,* 2004; 151: 1123–1132.
18. Meggitt SJ, Anstey AV, Mohd Mustapa MF, Reynolds NJ, Wakelin S. British Association of Dermatologists' guidelines for the safe and effective prescribing of azathioprine *Br J Dermatol,* 2011; 165: 711–734.
19. Chams-Davatchi C, Mortazavizadeh A, Daneshpazhooh M, et al. Randomized double blind trial of prednisolone and azathioprine, vs Prednisolone and placebo, in the treatment of pemphigus vulgaris. *J Eur Acad Dermatol Venereol,* 2013; 27(10): 1285–1292.
20. Chams-Davatchi C, Esmaili N, Daneshpazhooh M, et al. Randomized controlled open-label trial of four treatment regimens for pemphigus vulgaris. *Arch Dermatol,* 2007; 57: 622–628.
21. Schmidt E, Goebeler M, Zillikens D. Rituximab in severe pemphigus. *Ann N Y Acad Sci.,* 2009; 1173: 683–691.
22. Eming R, Nagel A, Wolff-Franke S, et al. Rituximab exerts a dual effect in pemphigus vulgaris. *J Invest Dermatol,* 2008; 128: 2850–2858.
23. Kasperkiewicz M, Shimanovich I, Meier M, et al. Treatment of severe pemphigus with a combination of immunoadsorption, rituximab, pulsed dexamethasone and azathioprine/mycophenolate mofetil: a pilot study of 23 patients. *Br J Dermatol,* 2012; 166: 154–160.
24. Ahmed AR, Spigelman Z, Cavacini LA, et al. Treatment of pemphigus vulgaris with rituximab and

› Rev Esp Patol. 2024 Jan-Mar;57(1):15-26. doi: 10.1016/j.patol.2023.11.005. Epub 2023 Dec 30.

Linking inflammation and angiogenesis with fibrogenesis: Expression of FXIIIA, MMP-9, and VEGF in oral submucous fibrosis

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Affiliations + expand

PMID: 38246706 DOI: 10.1016/j.patol.2023.11.005

Abstract

Objectives: Interplay of Factor XIIIa (FXIIIa), a transglutaminase, responsible for cross-linking of matrix proteins, Matrix Metalloproteinase-9 (MMP-9), a gelatinase, and Vascular Endothelial Growth Factor (VEGF), an angiogenic inducer, were studied in relation to fibrogenesis and disease progression in oral submucous fibrosis (OSMF).

Material and methods: Immunohistochemical expression of markers was studied in 60 formalin-fixed paraffin-embedded tissue blocks of OSMF and 20 normal oral mucosal tissues. FXIIIa was studied quantitatively while MMP-9 and VEGF were assessed semi-quantitatively. Expression was compared with histopathological grades of OSMF.

Results: FXIIIa expression significantly increased in OSMF (p-value 0.000). However, expression decreased and cells became quiescent with increasing grades (p-value 0.000). MMP-9 (p-value epithelium 0.011, p-value connective tissue 0.000) and VEGF expression (p-value epithelium 0.000,

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Conclusion: FXIIIa may play a crucial role in initiation of fibrosis in OSMF. MMP-9 may have a diverse role to play in OSMF as a regulator of fibrosis. VEGF may show an angio-fibrotic switch and contribute to fibrosis in OSMF. These cytokines may show altered function and can contribute to fibrosis and chronicity of disease due to changes in the microenvironment. Tissue stiffness in OSMF itself creates an environment that enhances the chronicity of the disease.

Keywords: Angiogenesis; Angiogénesis; FXIIIa; Factor de Crecimiento Endotelial Vascular (VEGF); Fibrosis; Fibrosis submucosa oral; Matrix metalloproteinase-9 (MMP-9); Metaloproteinasa-9 de matriz (MMP-9); Oral submucous fibrosis; Vascular Endothelial Growth Factor (VEGF).

The Effect of Lycopene Administration in Periodontal Diseases: A Systematic Review and Meta analysis

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Abstract

Background: Lycopene is a dietary antioxidant which provides defense against oxidation. Oxidative stress may result in periodontal tissue damage. There is a positive relationship between lycopene consumption and reduction in the risk of development of degenerative diseases caused by free radicals, such as periodontitis and other diseases like cancer, cardiovascular diseases, asthma, arthritis, stroke, hepatitis. This systematic review discusses the studies conducted to assess the effect of lycopene in periodontal health. **Aim:** To evaluate the effect of lycopene in maintaining periodontal health. **Search Methods:** An electronic database search was conducted from the following databases: PubMed, EBSCO Host, Science Direct, EMBASE and Google scholar. **Selection Criteria:** Randomized controlled trials, experimental studies, case-control studies, and cohort studies published in peer reviewed journals in English language were included. Case reports, case series, animal model studies, in-vitro studies, studies where lycopene was combined with other antioxidants or with additional therapeutic methods and unpublished research were excluded. **Data Collection and Analysis:** Total 36451 results were obtained after database search. It included case- control studies, experimental studies, reviews and randomized control trials. Out of which, only six studies satisfied the selection criteria. Data extraction sheet was prepared & the studies were analyzed. **Results:** Out of the six studies analyzed, all were randomized controlled trial. **Conclusion:** Lycopene has been used widely as an antioxidant in the treatment of chronic diseases. However, Literature is deficient in the studies regarding the effect of lycopene on periodontal health.

Keywords: Antioxidants, carotenoids, gingivitis, lycopene, periodontal disease, periodontitis, tomatoes

Introduction

Oxygen is an indispensable element in life. Mitochondria utilizes oxygen to produce adenosine triphosphate which provides energy. Free radicals and oxidants, which are examples of reactive oxygen species (ROS), are produced during this process. These substances have a harmful as well as a beneficial effect.[1] They are also produced during the process of normal cell metabolism within the body. External sources such as medications, radiation, pollution, and cigarette smoke also generate ROS. Structural damage to the cells occurs due to higher concentrations of these substances.[2]

ROS are generated by polymorphonuclear leukocytes (PMNs) during phagocytosis in the process of oxidative burst, resulting in endothelial dysfunction and tissue injury. In inflammatory conditions, PMNs produce oxidative stress. The interendothelial junctions then open, allowing inflammatory cells to move through the endothelial barrier. This results in injury to the tissues along with the removal of pathogens and foreign particles. Chronic diseases such as periodontitis, rheumatoid arthritis, and cardiovascular disorders and degenerative conditions such as aging, autoimmune disorders, and neurodegenerative disorders develop due to this process of oxidative stress and tissue damage.[2,3]

Microorganisms, along with other contributing variables, are the primary cause of periodontal disease, which is a complex illness. One of the main causes is oxidative stress. Its involvement in the disease process, whether as a cause or a result, is unknown. A very mild form of periodontal disease is gingivitis, which manifests as inflammation of the gingiva. Gingivitis if left untreated can progress to the destruction of periodontal apparatus, mobility of the tooth, and ultimately tooth loss.[3]

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Received: 24-08-2023 **Revised:** 29-11-2023 **Accepted:** 24-12-2023 **Published:** 28-03-2024

Access this article online

Quick Response Code:

Website: www.jiaphd.org

DOI: 10.4103/jiaphd.jiaphd_189_23

How to cite this article: Sanadi RM, Mandavkar SA, Patil EA, Chaudhari SR. The effect of lycopene administration in periodontal diseases: A systematic review and meta analysis. J Indian Assoc Public Health Dent 2024;22:16-24.

Dietary supplementation of antioxidants may strengthen the defense system of the body and arrest the inflammatory process. However, as per the current guidelines of evidence-based practice, there is limited literature on dietary supplementation in individuals with periodontitis.[3]

Lycopene is a naturally occurring antioxidant of plant origin. It is a member of the class of substances known as carotenoids. The richest natural source of lycopene is the tomato. Highly unsaturated hydrocarbons are present in two unconjugated double bonds and 11 conjugated. It can reverse the damage of DNA produced by hydrogen peroxide (H_2O_2).[4] Lycopene has the highest quenching ability for singlet oxygen among the biological carotenoids, thereby preventing oxidation.[5]

The risk of developing chronic diseases and degenerative conditions brought on by free radicals, such as periodontitis, malignancies, cardiovascular diseases, respiratory diseases, cataract, arthritis, hepatitis, and stroke, is found to be reduced when lycopene supplementation is used. Due to its antioxidant property, lycopene has been studied enthusiastically. However, the number of studies examining the impact of lycopene supplementation on periodontal health is rather few.

Rationale

The microorganisms that have colonized the subgingival plaque can activate a host immunological response in periodontal diseases that can result in an excess of ROS. A number of biological processes, including the deterioration of periodontal fibers, alveolar bone resorption, and eventually tooth loosening and loss, are set off by this excess ROS generation, which also results in the release of inflammatory chemicals. Therefore, there is a lot of promise for treating periodontitis with the application of ROS-scavenging compounds. The administration of antioxidants can improve the therapy of periodontitis because excessive ROS produced by the host immune response exacerbates the illness. Lycopene is a biological antioxidant that works well by binding to molecules that undergo oxygen-mediated reactions. The formation of free radicals is modulated by lycopene, which is necessary to prevent the observed tissue destruction. Although lycopene is frequently used in oral medicine as an antioxidant, very few researchers have looked at how lycopene supplementation affects periodontal disorders when used as an adjunct to scaling and root planing (SRP). To analyze the evidence already in existence regarding the impact of lycopene administration on periodontal diseases when used as an adjunct to conventional periodontal therapy, the current systematic review was carried out.

Methodology

Registration and the study protocol

In this investigation, we adhered to the Preferred Reporting Items recommended for Meta-Analysis and Systematic Review (PRISMA) guidelines (http://www.prisma-statement.org, accessed on March 9, 2023). The PROSPERO entry for the current systematic review is CRD42023397857.

Research question

Based on the "PICOS" (PRISMA-P 2023) approach, studies about the impact of lycopene administration on periodontal disorders were chosen:

- P (population): Healthy subjects with mild-to-moderate periodontitis and moderate-to-severe gingivitis and subjects who have not received any antibiotics or antioxidant therapy in the past 3 months
- I (intervention): Systemic administration of antioxidant lycopene
- C (comparison): With other antioxidants with or without lycopene
- (Result): Healthy periodontium and reduced periodontal inflammation with a reduction in probing pocket depth (PPD) and clinical attachment levels (CALs).

Search technique and resource

To separate all available papers on lycopene administration, four Internet databases (ScienceDirect, Google Scholar, Web of Science, and PubMed) were searched using MeSH terms and its effect on periodontal diseases [Table 1]. A manual search in journals was also performed.

Focused question

Does lycopene administration has an effect on periodontal diseases?

Other research question

Does the use of lycopene prevent periodontal disease progression?

Principle objective

To assess how oral lycopene administration affects periodontal disorders.

Secondary objective

To examine how lycopene prevents the growth of periodontal disease.

Materials and Methods

Study design

This study examines the effectiveness of lycopene supplementation in periodontal disorders through a comprehensive review and meta-analysis of randomized controlled trials.

Table 1: Sources, information, and search techniques used

Database	Searched strategies	Results
PubMed	"Lycopene" OR "lycopenes" AND "periodontal" OR "periodontitis" OR "periodontics" OR "periodontically" OR "periodontal health"	6367
Science direct	"Lycopene" AND "gingivitis" "periodontal health" "periodontitis s"	5520
Web of science	"Periodontics" AND "lycopene" AND "antioxidants" OR "gingivitis"	3695
Google scholar	"Lycopene" AND "periodontal health" AND "periodontitis" AND "gingivitis"	20,869
	Total	36,451

Inclusion criteria

1. Randomized controlled trials
2. English-language full-text publications that have been published in peer-reviewed journals
3. Lycopene is used as an adjunct to oral prophylaxis
4. Studies include patients diagnosed with periodontitis and gingivitis.

Exclusion criteria

1. Case reports and case series
2. Research using animal models and *in vitro* testing
3. Studies in which lycopene was combined with other antioxidants or with additional therapeutic methods
4. Unpublished study.

Search strategy

Cohort studies, experimental studies, randomized controlled trials, and case–control studies that were published in English in peer-reviewed journals between November 1, 2022, and September 3, 2023, were included in the electronic database search conducted by Dr. Samiksha Mandavkar and Dr. Ekta Patil and revised by Dr. Rizwan Sanadi. The databases searched were PubMed, Web of Science, Google Scholar, and Science Direct.

These were the search phrases used:

- Lycopene AND Periodontal health
- Lycopene AND Periodontitis
- Lycopene AND Gingivitis
- Lycopene OR Gingivitis
- Lycopene OR Periodontitis
- Lycopene OR Periodontal health.

Selection of studies

The following process was used to choose the studies:

i. Evaluation of the titles and abstracts
ii. Evaluation of the entire text.

Data collection process

Based on the associated variables, a data extraction sheet was created, and the articles were examined. Using a data extraction sheet, the following information was gathered: year of publication, authors, sample size, country, aim, type of study, tissue examined, methodology, comparison group and control group, and conclusion.

Data items

Variables for which data were sought included periodontal disease, periodontitis, gingivitis, CAL, and pocket depth.

1. Periodontal disease: Periodontitis is defined as "an inflammatory disease of the supporting tissues of the teeth caused by specific microorganisms or groups of specific microorganisms, resulting in progressive destruction of the periodontal ligament and alveolar bone with increased probing depth formation, recession, or both"
2. Periodontitis: Inflammation of the supporting tissues of the teeth. Usually, a progressively destructive change leads to the loss of bone and periodontal ligament. An extension of inflammation from the gingiva into the adjacent bone and ligament
3. Gingivitis: Inflammation of the gingiva
4. CAL: CAL is the measure of the distance from the periodontal pocket depth to the cementoenamel junction
5. Probing depth: Probing depth is the distance from the gingival margin to the base of the sulcus or pocket with a calibrated probe.

Included studies for analysis

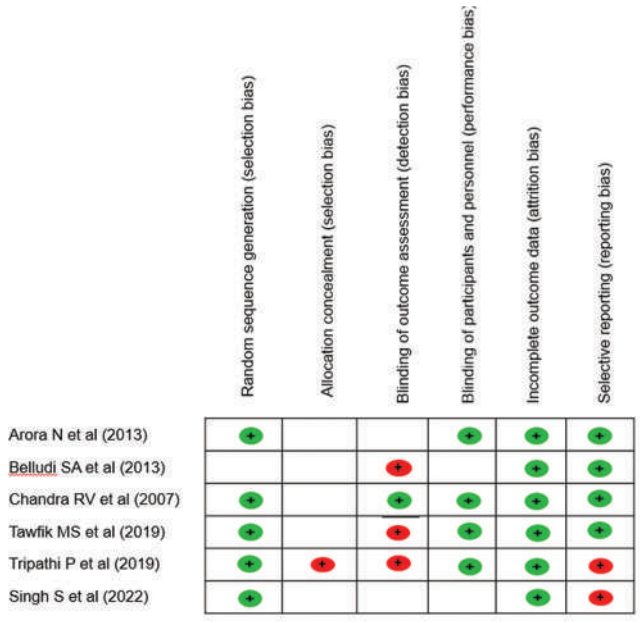
The qualitative synthesis included six investigations. Six studies were all randomized controlled trials. In all, six studies suggested lycopene has a role in maintaining periodontal health. Table 1 lists the details regarding the papers that were considered for the analysis.

Assessment of bias in included studies

This assessment was conducted using the recommended approach for assessing the risk of bias in studies included in Cochrane Reviews (Higgins 2011) using the tool RevMan 5.0.

We used the two-part tool to address the six specific domains (namely, random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and other bias). Each domain includes one or more specific entries in a risk of bias table. Within each entry, the first part of the tool involves describing what was reported to have happened in the study. The second part of the tool involves assigning a judgment relating to the risk of bias for that entry: either low risk, unclear risk, or high risk.

The domains of random sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting are addressed in the tool by a single entry for each



Graph 1: Risk of bias Assessment Summary

Table 2: Features of the studies that were part of the systematic review

Author AND year of publication	Country	Aim	Type of study	Sample size, comparison group, and control group	Methodology	Parameters	Conclusion
Singh *et al*., 2022[16]	India	To compare the effects of systemically prescribed lycopene as a monotherapy as an alternative to scaling and root planing in patients with chronic gingivitis	RCT	The participants were randomly assigned into two groups: The experimental group (*n*=50) control group (*n*=50)	The experimental group (*n*=50) received 10 mg of lycopene a day for 2 weeks, and the control group (*n*=50) received a placebo for 2 weeks	Periodontal parameters were recorded at baseline, 1st, and 2nd weeks, the sulcus bleeding index, plaque index, gingival index, and salivary uric acid level were measured	Lycopene seems to have a bright future as a treatment option for plaque-induced generalized chronic marginal gingivitis
Tripathi *et al*., 2019[3]	India	To investigate the influence of orally administered antioxidants (lycopene and green tea extract) on periodontal health and salivary UA levels in gingivitis patients as an adjunct to SRP	RCT	Thirty systemically healthy participants were divided as: test group (*n*=15) Control group (*n*=15)	Control group participants received full mouth oral prophylaxis, whereas test group participants received oral lycopene and green tea extract (CLIK®) for 45 days along with complete oral prophylaxis	Periodontal assessment was done at baseline, 1 hour after SRP. Clinical parameters such PI, SBI, and salivary UA levels were evaluated at baseline and 45 days after SRP	Lycopene with green tea extract seems to have an adjunctive prophylactic and therapeutic role in the treatment of gingivitis patients
Tawfik *et al*., 2019[5]	Egypt	To prepare SLMs encapsulating lycopene, and to assess their biochemical and clinical effects in the management of chronic periodontitis. Along with the assessment of PC levels in the gingival crevicular fluid were assessed at different time intervals	RCT	Sixteen chronic periodontitis participants were divided as Group I (*n*=8) Group II (*n*=8)	Group I was managed by SRP and local delivery of lycopene-loaded SLMs, while group II was managed by SRP only	Periodontal assessment was done at baseline. Clinical and radiographic measurements were reassessed at 1 and 6 months after therapy to evaluate the quantitative changes in the defect. 2 GCF samples thirty minutes apart were obtained from the same site at 1, 3, 7, 14, 21 and 30 days to assess PC levels using PC Assay kit	Locally delivered lycopene along with SRP have a protective effect over periodontal tissues and it decreases oxidative damage of protein in diseased periodontium compared to that of healthy periodontium
Belludi *et al*., 2013[4]	India	To evaluate the effect of lycopene as an adjunct to mechanical therapy in the management of periodontal disease (gingivitis and periodontitis)	RCT	Twenty systemically healthy participants were divided as Test group: (*n*=5), control group (*n*=5)	Test group (*n*=5) received, 4 mg lycopene/day for 2 weeks with oral prophylaxis (full mouth SRP completed within 24 h) and controls (*n*=5), receiving only oral prophylaxis	Pre- and post-therapeutic periodontal parameters were evaluated. Clinical parameters such as PPD, CAL, and BOP were recorded at baseline and 14 days after treatment	Lycopene show to be a promising treatment modality as an adjunct to full mouth SRP of the oral cavity in patients with moderate periodontal disease
Arora *et al*., 2013[6]	India	To evaluate the efficacy of systemic lycopene along with routine scaling and root planning in terms of changes in clinical parameters and levels of circulating TNF- α,	RCT	Forty-six chronic periodontitis patients were divided as Test group: (*n*=23) Placebo group: (*n*=23)	Test group received oral administration of lycopene (8 mg/day) × 2 months and Placebo group received oral	Periodontal parameters regarding PI, MGI, BOP, CAL gain, and PPD reduction were evaluated and peripheral blood samples and whole	Lycopene supplementation adjunct to SRP resulted in improved periodontal parameters. Salivary uric acid levels increased and salivary IL-1β

Contd...

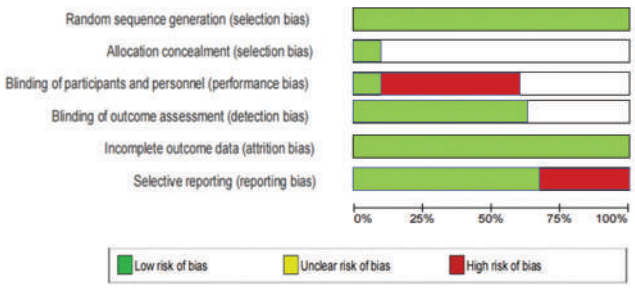
Table 2: Contd...

Author AND year of publication	Country	Aim	Type of study	Sample size, comparison group, and control group	Methodology	Parameters	Conclusion
		salivary IL-1β, and uric acid in chronic periodontitis			administration of placebo ×2 months	saliva were obtained at these points of time to measure the levels of IL-1ß, TNF-α, and uric acid using commercially available kits	levels decreased to a statistically significant levels after lycopene supplementation in management of periodontal disease
Chandra *et al*., 2007[18]	India	To compare the effect of systemically administered lycopene as a monotherapy and as an adjunct to SRP in gingivitis patients and salivary uric acid concentration	RCT	Twenty systematically healthy adults were divided as Test group (*n*=10) Control group (*n*=10)	Test group (*n*=10) received, 8 mg lycopene/day for 2 weeks Control group (*n*=10) received, placebo for 2 weeks	BI, plaque index PI, and GI were recorded at baseline, 1, and 2 weeks Salivary uric acid levels were assessed using commercially available reagent kit	Lycopene group showed statistically significant reduction in clinical parameters. There was a strong negative correlation between the salivary uric acid levels and percentage reduction in GI at 1 and 2 weeks in the lycopene group and nonlycopene group

UA: Uric acid, SRP: Scaling and root planning, SBI: Sulcular bleeding index, PI: Plaque index, SLMs: Solid lipid microparticles, PC: Protein carbonyl, PPD: Probing pocket depth, CAL: Clinical attachment level, BOP: bleeding on probing, TNF- α: Tumor necrosis factor alpha, IL-1β: Interleukin 1 beta, MGI: Modified gingival index, BI: Bleeding index, GI: Gingival index, RCT: Randomized controlled trial

Table 3: Risk of bias evaluation

Authors (year)	Type of study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome	Incomplete outcome data	Selective reporting
Singh *et al*. (2022)[16]	RCT	Low	Unclear	Unclear	Unclear	Low	High
Tripathi *et al*. (2019)[3]	RCT	Low	High	High	Low	Low	High
Tawfik *et al*. (2019)[5]	RCT	Low	Unclear	High	Low	low	Low
Belludi *et al*. (2013)[4]	RCT	Unclear	Unclear	High	Unclear	Low	Low
Arora *et al*. (2013)[6]	RCT	Low	Unclear	Unclear	Low	Low	Low
Chandra *et al*. (2007)[18]	RCT	Low	Unclear	Low	Low	Low	Low



Graph 2: Risk of bias graph

study. We completed a "risk of bias" table for each included study. The risk of bias in the included studied is presented in Table 2 and Graphs 1, 2.

Studies that were not included in the analysis

Five studies were excluded, of which two were narrative reviews, one was a cohort study, one was a survey, and one was a randomized controlled study, in which other antioxidants were used with lycopene. Information about the excluded studies is presented in Table 3.

Statistical analysis

The odds ratio with 95% confidence interval (CI) was calculated for dichotomous outcomes. A fixed effects model (Mantel–Haenszel method) was used if there was no heterogeneity ($P > 0.05$ or $I^2 \leq 24\%$), otherwise, a random-effects model (DerSimonian–Laird method) was used. All statistical analyses were performed using the RevMan 5.3 (Cochrane Collaboration, Software Update, Oxford, UK).

Evaluation of heterogeneity

The significance of any discrepancies in the estimates of the treatment effect of the different trials was assessed using Cochran's test for heterogeneity and the I^2 statistics, which describes the percentage of the total variation across studies that is due to heterogeneity rather than chance. Heterogeneity was considered statistically significant if $P < 0.1$. A rough guide to the interpretation of I^2 given in the Cochrane Handbook is as follows: (1) from 0% to 40%, the heterogeneity might not be important; (2) from 30% to 60%, it may represent moderate heterogeneity; (3) from 50% to 90%, it may represent substantial heterogeneity; and (4) from 75% to 100%, there is considerable heterogeneity.

Investigation of publication bias

To test for the presence of publication bias, the relative symmetry of the individual study estimates was assessed around the overall estimates using Begg's funnel plot. A funnel plot (plot of the effect size versus standard error) was drawn. Asymmetry of the funnel plot may indicate publication bias and other biases related to sample size, although asymmetry may also represent a true relationship between trial size and effect size.

Results

An electronic search turned up 36,451 items in all. Fifty-eight articles remained after 29,272 articles that were duplicates and articles in other languages were removed. Forty-eight items remain after 10 were excluded because they failed to meet the eligibility requirements. The flow chart of research selection and the outcomes of the literature search is shown in Figure 1.

Synthesis of result

Clinical attachment loss

Three studies containing data on 68 (n = 68) participants, of which (n = 34) participants were evaluated in the treatment group (lycopene) and (n = 34) patients were evaluated in the control group for the evaluation of the gain in CAL. In a meta-analysis, the standardized mean difference is used as a summary statistic when various studies employ different metrics to evaluate the same outcome. Therefore, before the results of the studies can be integrated to provide an aggregate pooled estimate, they must be standardized to a similar scale.

As shown in Figure 2, the standard deviation (SD). The mean difference is 0.52 (−1.63–2.68) and the pooled estimates favor the treatment group. This signifies that the gain in CAL on average is 0.52 times more in the treatment group as compared to controls, but this difference is not statistically significant (P = 0.51).

Among all the included studies, Arora N *et al.,* 2013,[6] had the highest weightage at the overall pooled estimate, whereas the lowest weightage was observed for Belludi SA *et al.*, 2013, [4] at the pooled estimate. The sample size (n) and variability are both directly and adversely correlated with the study's weight. The box represents the weight of each study, whereas the black horizontal line represents the 95% confidence limit. The bigger the size of the box, the more the weightage of the study at the pooled estimate, and the wider the horizontal line, the more the presence of variability and less weightage of that individual study at the overall pooled estimate.

By employing the random effect model, the I^2 statistic showed 93%, the heterogeneity for Tau^2 was 3.35, x^2 being $P < 0.00001$, and the overall effect for Z value being 0.48 (P = 0.63).

The funnel plot did exhibit substantial asymmetry, as shown in Figure 2, which suggested the presence of publication bias. The meta-analysis publication bias is demonstrated by the funnel plot's lopsided distribution and systematic heterogeneity of individual studies when compared to the standard error.

Begg's funnel plot in Figure 3 with 95% CIs demonstrates uneven distribution and systematic heterogeneity of individual studies when compared to the standard error of each research, indicating the presence of publication bias.

Probing depth

Three studies containing data on 68 (n = 68) participants, of which (n = 34) participants were evaluated in the treatment

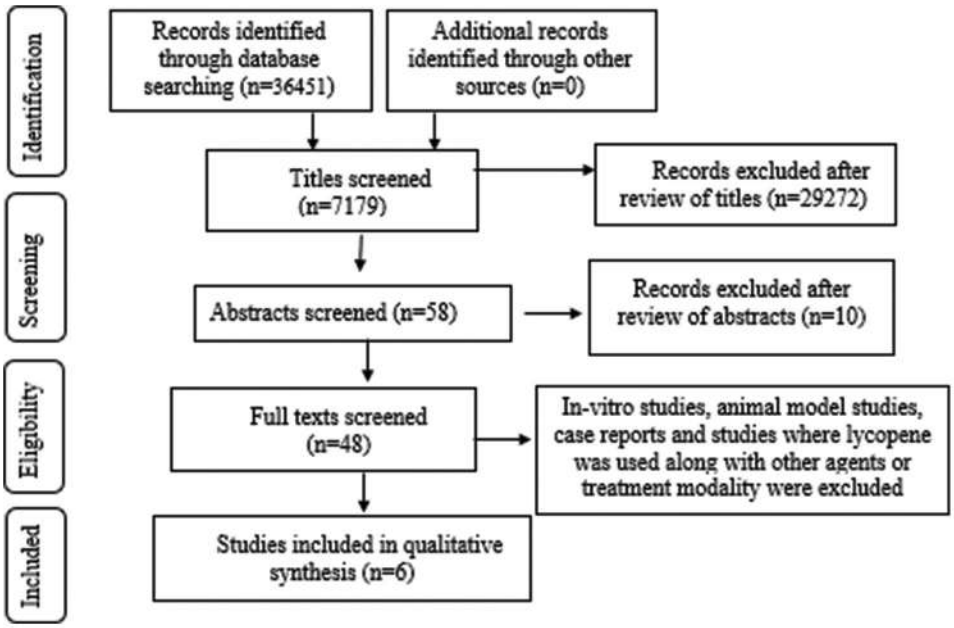


Figure 1: Results of a literature search and a flowchart for choosing a study

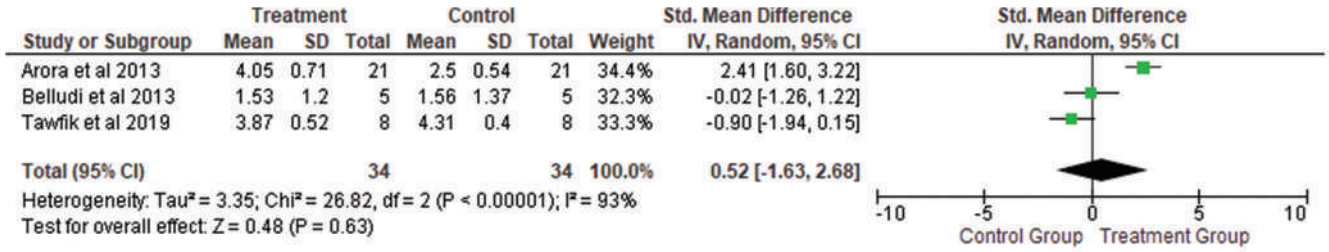


Figure 2: Forest plot showing the treatment group (lycopene) versus the control group with regard to the gain in clinical attachment level. CI: Confidence interval, SD: Standard deviation, IV: Intravenous

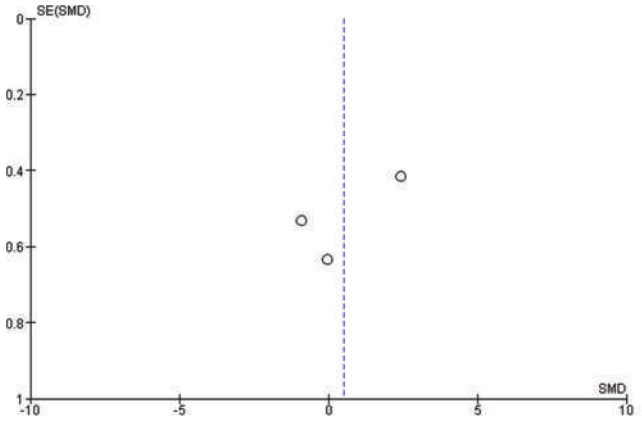


Figure 3: Begg's Funnel plot with 95% confidence intervals demonstrating uneven distribution and systematic heterogeneity

group (lycopene) and (n = 34) patients were evaluated in the control group for the evaluation of the reduction in probing depth (PD).

As shown in Figure 4, the SD The mean difference is −0.42 (−0.90–0.06) and the pooled estimates favor the control group. This signifies that the reduction in probing depth (PD) on average is 0.42 times more in the control group than the treatment group, but this difference is not statistically significant (P = 0.09). Both are more or less equal.

Among all the included studies, Arora N *et al*., 2013,[6] had the highest weightage at the overall pooled estimate, whereas the lowest weightage was observed for, Belludi SA *et al.*, 2013,[4] at the pooled estimate.

By employing the random effect model, the I^2 statistic showed 0%, the heterogeneity for Tau^2 was 0.00, x^2 being $P < 0.00001$, and the overall effect for Z value being 1.71 (P = 0.09).

Figure 5 illustrates a Begg's funnel plot with 95% CIs that show symmetric distribution and systematic heterogeneity of individual studies when compared with the standard error of each research, confirming the absence of publication bias.

As shown in Figure 5, the funnel plot did not exhibit any discernible asymmetry, showing that there was no publication bias. No publication bias was present in the meta-analysis, as evidenced by the symmetric distribution and systematic heterogeneity of individual studies compared to the standard error in the funnel plot.

Table 4: Characteristics of studies that were excluded

Author (year)	Reason for exclusion
Isola G, Polizzi A, Muraglie S, Leonardi R, Lo Giudice A (2019)	Randomized controlled trial which included other antioxidants with lycopene
Gupta S, Jawanda MK, Arora V, Mehta N, Yadav V (2015)	Narrative review
Levi Y (2015)	Narrative review
Linden GJ, McClean KM, Woodside JV, Patterson CC, Evans A, Young IS, Kee F (2009)	Cohort study
Wood N, Johnson RB (2004)	Survey

Discussion

Periodontitis is a multifactorial inflammatory condition which is predominantly caused by Gram-ve anaerobic microorganisms. These microorganisms release lipopolysaccharides which cause destruction of the periodontal tissues. Inflammation eliminates the stimuli that cause tissue damage, which leads to the healing of the periodontal tissues.[7-9]

ROS are known to play a role in the pathogenesis of a number of chronic inflammatory diseases and disorders, including periodontal diseases. By starting a chain reaction of free radicals, a range of ROS, including hydroxyl radicals and singlet oxygen, superoxide ion, hypochlorous acid, and H_2O_2, can cause tissue damage. The etiology of periodontitis is significantly influenced by the damaging nature of ROS.[10,11]

Treatment with medications that prevent the creation of free radicals or counteract their effects may be beneficial therapeutically since free radical generation seems to be crucial for the prevention of tissue deterioration. Antioxidant therapy has been proposed by numerous studies as a potential periodontal disease treatment strategy. Many periodontal chemotherapeutic medications are known to have an antioxidative effect against spontaneous oxidation in addition to their antiseptic and antibacterial properties.[12]

Lycopene, found abundantly in tomatoes, is the most potent antioxidant. In addition, it is said to have an antiapoptotic impact and to improve neutrophilic cells' capacity for phagocytosis and bacterial death. Lycopene reduces cell damage in a number of methods, including restricting the production of free radicals, stimulating the activity of

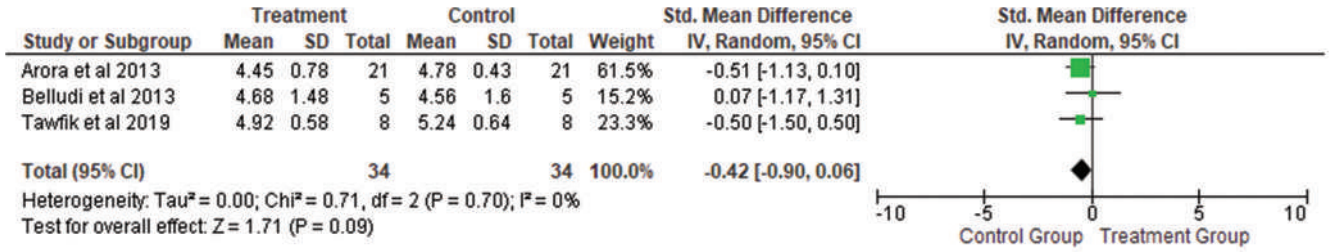


Figure 4: Forest plot showing the treatment group (lycopene) versus the control group concerning the reduction in probing depth. CI: Confidence interval, SD: Standard deviation, IV: Instrumental variables

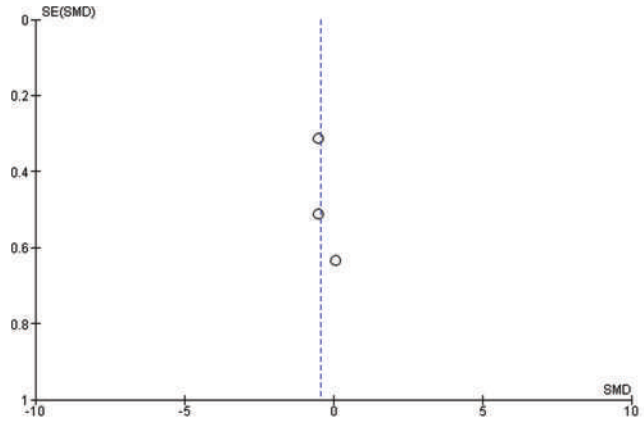


Figure 5: illustrates a Begg's funnel plot with 95% CIs that show symmetric distribution and systematic heterogeneity

repair enzymes, repairing oxidative damage, stimulating the activity of antioxidant enzymes, annihilating free radicals or their precursors, and reversing DNA damage brought on by H2O2.[13]

The results of the research that evaluated the impact of lycopene on periodontal health, including gingivitis and periodontitis, are summarized in the current systematic review. There are few research that examined the impact of lycopene on periodontal health alone. Because there is less evidence, animal studies, *in vitro* research, and case reports were not included. Studies that employed lycopene in combination with other drugs were not included in the current study.

Alpha-tocopherol, alpha-carotene, beta-carotene, and lutein all have lower antioxidant potencies than lycopene carotenoids. Lycopene has been used in combination with other antioxidants such as Vitamins A and E, green tea extract, and lutein, reported that the combination of antioxidants was substantially superior to the sum of individual effects. We have not included those studies, as we wanted to analyze the effect of lycopene alone on periodontal health. Levi Y, 2015,[14] and Gupta S, *et al*. 2015,[15] presented narrative reviews on the preventive role of lycopene in maintaining oral health.[6,16]

In a cohort study, Linden GJ, *et al*. 2009[8] found that among 60–70-year-old Western European men, low serum levels of many carotenoids, particularly beta-cryptoxanthin and beta-carotene, were linked to a higher prevalence of periodontitis.[8] According to a study by Wood N. *et al*. (2004)[9], periodontitis and congestive heart failure risk are related, and increased monthly tomato consumption (MTC) in those with periodontitis seems to have a beneficial impact on this association.[9,17] However, because of their poor level of evidence, these investigations were disregarded.

In a pilot investigation, Isola *et al*., 2019,[17] looked at the relationship between salivary and blood Vitamin C and antioxidant levels and coronary artery disease, gingival health, periodontitis, or both conditions.[2] However, as no study examined the single impact of lycopene on periodontal health, these results were disregarded. Characteristics of studies that were excluded are summarized in Table 4.

The qualitative synthesis included six studies. The six studies that were included were all randomized controlled trials.

Belludi *et al*.[4] evaluated the efficacy of systemic lycopene in conjunction with scaling and root planning in a randomized, placebo-controlled, parallel design, double-blinded trial and noted changes in clinical parameters and levels of the tumor necrosis factor, salivary interleukin 1 beta, and uric acid within chronic periodontitis. When the risk of bias was evaluated because this study was a randomized controlled trial, the lowest risk of bias was found.[4,6]

A potent antioxidant, lycopene is the main carotenoid present in tomato-based goods. Among the many carotenoids, it has the strongest singlet oxygen-quenching properties and is useful for shielding blood cells from NOO-radical damage. Therefore, Belludi SA, *et al*. (2013)[4] evaluated the impact of systemically delivered lycopene as an addition to SRP in individuals with gingivitis and periodontitis. However, a considerable risk of bias was found when the likelihood of bias was analyzed.[4,7]

For individuals with chronic gingivitis, Chandra RV *et al*. (2007)[18]. and Singh *et al.* (2022)[16] examined the effects of systemically prescribing lycopene as a monotherapy and as an alternative to SRP.[10,14] In a study by Singh S *et al.*, 2022[16], when the risk of bias was analyzed, a substantial risk of bias was found.[16]

Solid lipid microparticles containing lycopene were created by Tawfik *et al.* in 2019[5] and their biochemical and clinical effects on the treatment of chronic periodontitis were evaluated. An evaluation of the risk of bias revealed a substantial risk of prejudice.

In addition to SRP, Tripathi P *et al*., 2019,[3] investigated the effects of orally administered antioxidants (lycopene and green tea extract) on gingivitis patients' periodontal health and salivary UA levels.[12] However, a considerable risk of bias was found when the danger of bias was evaluated.

With the exception of two studies, there was a danger of bias because blinding, selective reporting, and allocation concealment of research participants were not done. The results of the mentioned studies may have been impacted by this. Lycopene has been utilized as an adjuvant to SRP in patients with gingivitis and periodontitis, according to the research analyzed, and it did influence preserving periodontal health.

For meta-analysis, three studies containing data on 68 ($n = 68$) participants, of which ($n = 34$) participants were evaluated in the treatment group (lycopene) and ($n = 34$) patients were evaluated in the control group for the evaluation of the gain in CAL and reduction in probing depth (PD). The pooled analysis report signifies that the gain in CAL on average is 0.52 times more in the treatment group as compared to controls, but this difference is not statistically significant ($P = 0.51$) for gain in CAL and the reduction in probing depth (PD) on average is 0.42 times more in the control group as compared to the treatment group, but this difference is not statistically significant ($P = 0.09$).

Any systematic review's accuracy is based on the number and caliber of the papers it includes. This reviews lack of a larger number of studies with large sample sizes, which would have allowed for more meaningful results from meta-analyses, was one of its key shortcomings. The comparison of lycopene analysis results from various research is another inherent drawback of reviews of diagnostic accuracy. The studies included lacked a larger number of sample sizes also in the methodology part randomization and blinding of clinical trials could have been more specified to avoid heterogeneity. In most cases, comparisons ought to be made using the same series of patients, the same reference standard, and the same patients. English-only articles only; non-English articles were excluded. More randomized controlled studies could still be undertaken in future, though.

Conclusion

Lycopene is a potent antioxidant and has the ability to quench singlet oxygen, and it can modulate the generation of free radicals, which is important for preventing tissue deterioration. It may also help as an adjunct to treat periodontal diseases. The results of this meta-analysis showed that there is a statistically significant gain in CALs after the administration of lycopene, whereas it is more or less equal when it comes to PPD. Lycopene has shown encouraging benefits when used to preserve periodontal health in people with gingivitis and periodontitis; however, there is little research on this topic and further studies need to be undertaken.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Pham Huy LA, He H, Pham Huy C. Free radicals, antioxidants in disease and health. Int J Biomed Sci 2008;4:89-96.
2. Mittal M, Siddiqui MR, Tran K, Reddy SP, Malik AB. Reactive oxygen species in inflammation and tissue injury. Antioxid Redox Signal 2014;20:1126-67.
3. Tripathi P, Blaggana V, Upadhyay P, Jindal M, Gupta S, Nishat S. Antioxidant therapy (lycopene and green tea extract) in periodontal disease: Apromising paradigm. JIndian Soc Periodontol 2019;23:25-30.
4. Belludi SA, Verma S, Banthia R, Bhusari P, Parwani S, Kedia S, *et al.* Effect of lycopene in the treatment of periodontal disease: A clinical study. J Contemp Dent Pract 2013;14:1054-9.
5. Tawfik MS, Abdel Ghaffar KA, Gamal AY, El Demerdash FH, Gad HA. Lycopene solid lipid microparticles with enhanced effect on gingival crevicular fluid protein carbonyl as a biomarker of oxidative stress in patients with chronic periodontitis. J Liposome Res 2019;29:375-82.
6. Arora N, Avula H, Avula JK. The adjunctive use of systemic antioxidant therapy (lycopene) in nonsurgical treatment of chronic periodontitis: A short term evaluation. Quintessence Int 2013;44:395-405.
7. D'Aiuto F, Nibali L, Parkar M, Patel K, Suvan J, Donos N. Oxidative stress, systemic inflammation, and severe periodontitis. J Dent Res 2010;89:1241-6.
8. Linden GJ, McClean KM, Woodside JV, Patterson CC, Evans A, Young IS, et al. Antioxidants and periodontitis in 60 70 year old men. J Clin Periodontol 2009;36:843-9.
9. Wood N, Johnson RB. The relationship between tomato intake and congestive heart failure risk in periodontitis subjects. J Clin Periodontol 2004;31:574-80.
10. Medzhitov R. Origin and physiological roles of inflammation. Nature 2008;454:428-35.
11. Brock GR, Butterworth CJ, Matthews JB, Chapple IL. Local and systemic total antioxidant capacity in periodontitis and health. J Clin Periodontol 2004;31:515-21.
12. Chapple IL, Matthews JB. The role of reactive oxygen and antioxidant species in periodontal tissue destruction. Periodontol 2000 2007;43:160-232.
13. Firatli E, Unal T, Onan U, Sandalli P. Antioxidative activities of some chemotherapeutics. A possible mechanism in reducing gingival inflammation. J Clin Periodontol 1994;21:680-3.
14. Levy Y. Oxidative stress, antioxidants and periodontal disease. Arch Oral Biol 2015;60:1461-2.
15. Gupta S, Jawanda MK, Arora V, Mehta N, Yadav V. Role of lycopene in preventing oral diseases as a nonsurgical aid of treatment. Int J Prev Med 2015;6:70.
16. Singh S, Gogoi A, Kumar A, Esha E, Jagnade R, Jain G, *et al*. A randomized, double blind, split mouth controlled clinical trial of systemically administered lycopene on periodontal health. J Oral Biol Craniofac Res 2022;12:22-6.
17. Isola G, Polizzi A, Muraglie S, Leonardi R, Lo Giudice A. Assessment of Vitamin C and antioxidant profiles in saliva and serum in patients with periodontitis and ischemic heart disease. Nutrients 2019;11:2956.
18. Chandra RV, Prabhuji ML, Roopa DA, Ravirajan S, Kishore HC. Efficacy of lycopene in the treatment of gingivitis: A randomised, placebo controlled clinical trial. Oral Health Prev Dent 2007;5:327-36.

ISSN Print: 2394-7489
ISSN Online: 2394-7497
IJADS 2024; 10(2): 246-252

www.oraljournal.com
Received: 16-01-2024
Accepted: 22-02-2024

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AOT mimicking a dentigerous cyst - unravelling a rare radiologic puzzle with review of literature

Dr. Sayali Nakhate, Dr. Deepa Das and Dr. Bhakti Patil Soman

DOI: https://doi.org/10.22271/oral.2024.v10.i2d.1948

Abstract
Adenomatoid odontogenic tumor or AOT is a slow-growing benign odontogenic neoplasm common in the maxilla and often misdiagnosed as Dentigerous cyst. But there are certain intricate radiographic features which are exclusively diagnostic to AOT. The more common variant is the follicular type of AOT, which involves an unerupted tooth, often mistaken as a dentigerous cyst. Here, we report a case of a 14- year-old girl, with an AOT, located in the anterolateral region of the maxilla associated with an impacted canine and premolar tooth. It was initially diagnosed as dentigerous cyst, due to clinical similarities. The reports of fine needle aspiration cytology and incisional biopsy were also suggestive of DC (Dentigerous Cyst). But the Cone beam computed tomography scan (CBCT) findings were in favour of AOT. Finally, the histopathological report after total excision was that of Adenomatoid Odontogenic Tumour, hence emphasizing the accuracy of CBCT in diagnosing large bony lesions. The case report highlights the importance of early diagnosis of odontogenic neoplasms, it's treatment and gives a review on the clinical characteristics of similar cases. Therefore, AOT should be considered as a differential diagnosis of unilocular lesions surrounding the impacted tooth in the anterior maxillary region.

Keywords: Adenomatoid odontogenic tumour, dentigerous cyst, benign jaw tumours, treatment of adenomatoid odontogenic tumours, cysts

1. Introduction
The term "AOT" was introduced for Adenomatoid Odontogenic Tumor by Philpsen and Birn and later adopted by the WHO (2005) in their "Histological typing of odontogenic tumors, jaw cysts and allied lesion [1]." AOT represents 3-7% of all odontogenic tumors hence is very uncommon [2, 3]. It is also called, "Two Third's Tumor" as it occurs in the maxilla in about 2/3rd cases, about 2/3rd cases in young females, 2/3rd cases are associated with impacted tooth and in 2/3rd cases the affected tooth is canine [4, 5].
Here, we report the case of a 14- year-old girl with an AOT located in the anterolateral region of the maxilla, associated with an impacted canine and premolar tooth. It was initially diagnosed as dentigerous cyst due to clinical similarities. The reports of fine needle aspiration cytology and incisional biopsy were suggestive of a DC (Dentigerous Cyst). But the Cone beam computed tomography scan (CBCT) findings were in favour of AOT. After total excision, the histopathological examination reported it to be Adenomatoid Odontogenic Tumor. Therefore, the importance CBCT in correctly diagnosing large bony lesions and their management is highlighted through this case report.

Report
A 14-year-old female patient came to the department of Oral Medicine and Radiology with a chief complaint of swelling in upper left front jaw since four months and pain in relation to it since one month. Four months ago, she noticed a lemon sized swelling in the upper left region of her face, for which she visited a local dentist and was informed of a retained deciduous tooth in the same region, which he extracted. Following the extraction, she noticed a slight regression in the size of the swelling. But after fifteen days, the swelling re-appeared and enlarged to the present size as before. As the swelling was asymptomatic, she did not seek treatment.

However, three months later, she started experiencing pain in same region. The pain was sudden in onset, dull aching and intermittent in nature. She gave history of occasional watery discharge from the left eye. Clinically she presented with gross facial asymmetry due to the swelling which was approximately 2x3 cm^2 in size on the left side of the face. [Figure 1] There was obliteration of the left nasolabial fold and the swelling was nontender, firm to hard in consistency with no associated lymphadenopathy.

Intraorally there was presence of an irregular gingival growth along the crest of the alveolar ridge of 23, 24 and 25 extending approximately 1mm below the level of the gingival crest. [Figure 2] The swelling was non-tender and soft to firm in consistency with no history of bleeding or discharge. On the buccal aspect of 24 and 25 region, there was a bony defect/ windowing palpable about 1cm above the crest of the ridge where it was soft on palpation.

The patient had reported with an orthopantomogram taken 4 months ago [Figure 3] before extraction of the retained deciduous tooth and it revealed a single unilocular well defined radiolucency in the left maxilla. It was extending superoinferiorly from left lateral border of orbit to 1cm below alveolar ridge of 24, 25 and anteroposteriorly from mesial of 21 to distal of 26, approximately 5x4 cm^2, with thin corticated borders which were not attached to any of the teeth. Internal structure appeared to be uniformly radiolucent with impacted 23 pushed to the left infraorbital margin and 24, 25 suspended inferiorly within the lesion.

The boundaries of the maxillary sinus could not be well appreciated. The lesion on the left maxilla was provisionally diagnosed as a benign odontogenic lesion. Differential diagnoses included Dentigerous cyst, Adenomatoid odontogenic tumour and Unicystic ameloblastoma.

On fine needle aspiration, a straw-colored fluid with a slight blood tinge was obtained, [Figure 4] which was reported as a mixed inflammatory aspirate.

A screening OPG and CBCT scan were taken. In the OPG, the lesion was of the same size as it was in the previous one, taken 4 months back and additionally, 24 was missing with marked external root resorption of 22 and 26. [Figure 5] CBCT scan revealed the presence of a peri-coronal expansile hypodense lesion occupying the left maxillary sinus. Anteroposteriorly the lesion measured 36.5 mm in maximum dimension, 40.5mm bucco palatally and 19.7mm supero-inferiorly. [Figure 6].

The hypodense lesion had well- defined thin corticated margins except on the medial side, where it was invading the left nasal cavity and involving the inferior turbinate. [Figure 7] The borders were not attached to the cemento- enamel junction of 23 or 25. Internal structure was uniformly hypodense with average gray values similar to that of surrounding soft tissues. Internally there were multiple pinpoint hyperdensities suspended peripherally within the lesion, about 6 in number. [Figure 8].

A distinct cystic lining could be appreciated, separate from the sinus wall which indicated that the lesion was not originating from the maxillary sinus. [Figure 9] There was superior displacement of the orbital floor in the left lateral infraorbital region. The buccal and palatal cortical plates had expanded and perforated. [Figure 10] External root resorption in relation to 23 and 26 were appreciated in CBCT also. [Figure 11].

On the basis of a hypodense lesion in the maxilla with pinpoint hyperdensities and impacted teeth 23 and 25 in a young female, a radiographic diagnosis of adenomatoid odontogenic tumour was arrived at.

An incisional biopsy was performed and histopathological staining revealed non keratinized stratified squamous epithelium of 2-3 cell layer thickness which was proliferating in certain areas. The sub adjacent connective tissue capsule had chronic inflammatory cell infiltration in the form of lymphocytes and few plasma cells along with dilated and engorged blood vessels. The remaining connective tissue capsule was predominantly fibrous with few odontogenic rests. A histopathological diagnosis of infected dentigerous cyst was reported.

Decompression of the lesion was planned, for conservative approach, after which an individual obturator with an open-ended stent was made with acrylic resin. The patient was instructed to clean the obturator three times a day using saline solution to avoid debris obstruction and infections. [Figure 12].

She was scheduled for radiographic follow-ups after an interval of three months. [Figure 13].

Six months post decompression, the diminished lesion was enucleated completely under general anaesthesia with an intraoral approach. The lesion came out in toto. [Figure 14] No bone graft was placed in the cavity. The impacted 25 was extracted. A radiograph of the specimen taken post-operatively revealed concentric radio-opaque rings. [Figure 15] The postoperative course was uneventful and no complications reported.

On histopathological examination, there was presence of thick fibro cellular connective tissue wall lined partly by thin odontogenic epithelium. There was epithelial proliferation in some parts in the form of arcading pattern. The subjacent connective tissue was loose, highly vascular and intensely inflammed. A couple of places in the section revealed epithelial proliferation in the form of rosettes and ductal pattern. [Figure 16] Areas of dystrophic calcification were also noted in the vicinity. The excised specimen was histopathologically reported as AOT.

Figure format

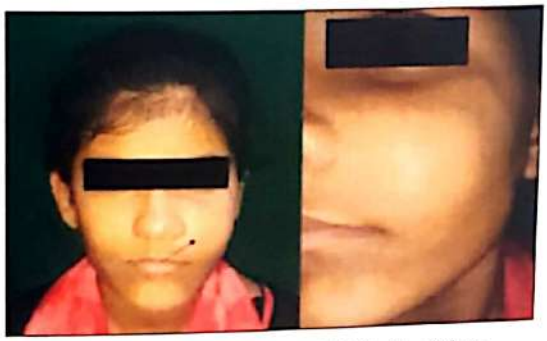

Fig 1: Extraoral swelling with left side of face

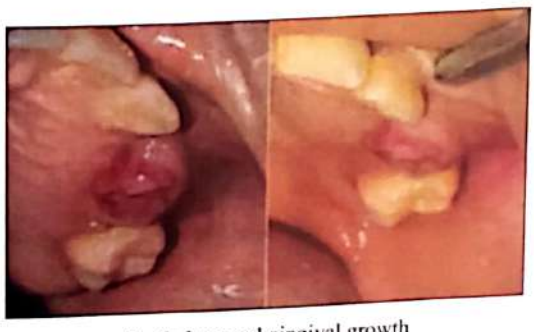

Fig 2: Intraoral gingival growth

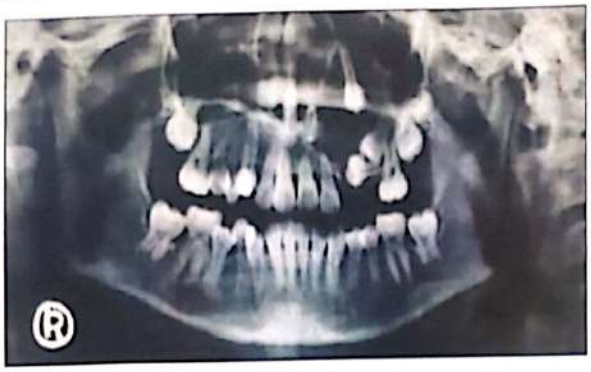

Fig 3: Pre-operative OPG of patient taken 4 months ago

Fig 4: Fine needle aspiration revealed straw coloured fluid with blood tinge

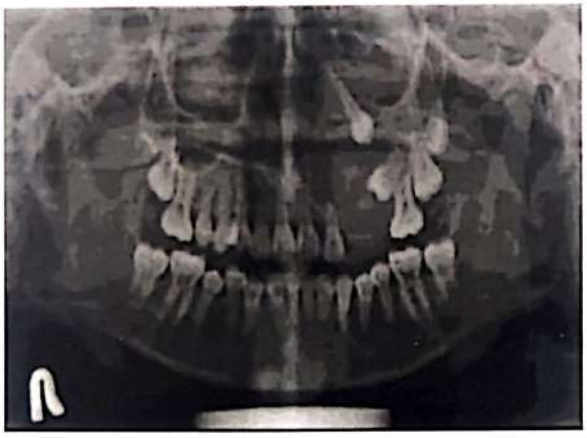

Fig 5: Screening OPG taken in our department.

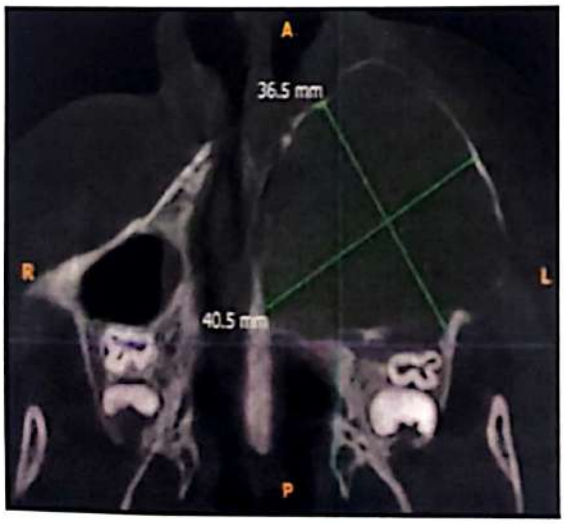

Fig 6: Dimensions on CBCT on axial section

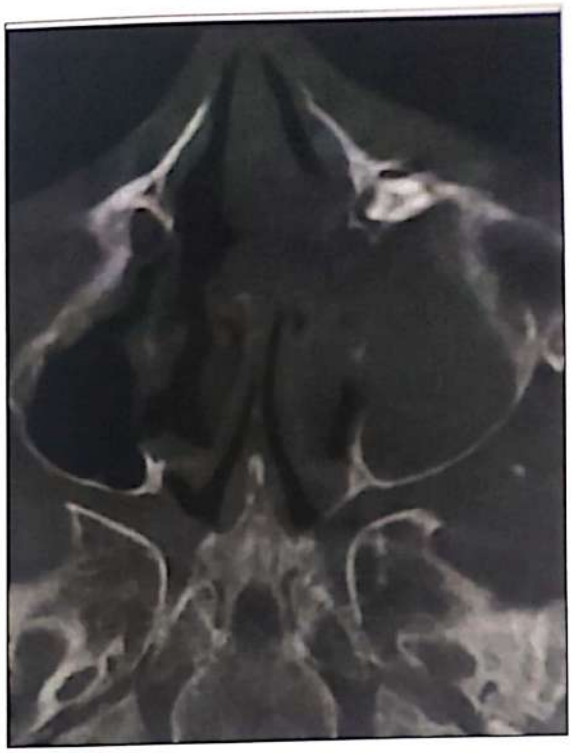

Fig 7: lesion invading the left nasal cavity

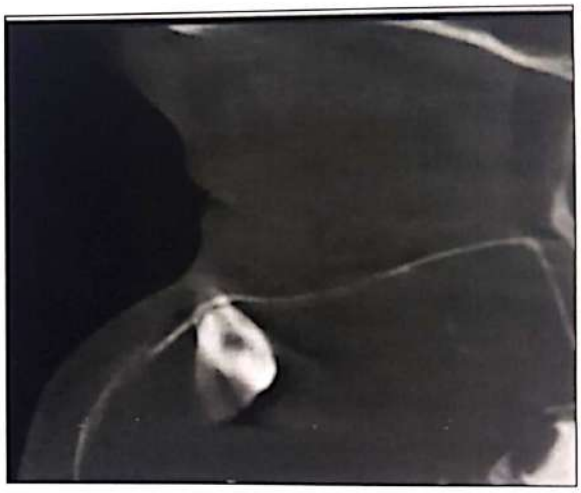

Fig 8: Pinpoint hyperdensities can be appreciated suspended peripherally within the lesion

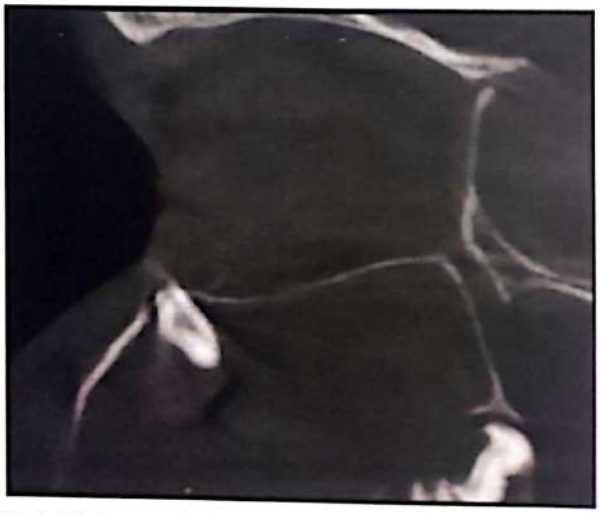

Fig 9: Distinct cystic lining separate from the sinus wall can be appreciated

Table 1: The clinical characteristics of the 20 AOTs associated with DCs along with the present case are summarized below:

Sr. No.	Reference	Age/Sex	Race	Year	Site	Radiographic features
1.	Valderrama [27]	16/F	Philippino	1988	Maxilla	Unilocular radiolucency surrounding the crown of tooth 14
2.	Warter *et al.* [28]	8/M	Nigerian	1990	Maxilla sinus	Unilocular radiolucency surrounding the crown of tooth 13
3.	Tajima *et al.* [29]	15/M	Japanese	1992	Maxilla	A well- defined radiopaque mass surrounding the crown of unerupted 28.
4.	Garcia-Pola *et al.* [30]	12/M	Spanish	1998	Maxilla	Unilocular radiolucency surrounding the crown tooth 23
5.	Bravo *et al.* [31]	14/F	Not stated	2005	Maxilla	Unilocular radiolucency surrounding tooth 23 crown
6.	Nonaka *et al.* [32]	13/F	Brazil	2007	Maxilla	Unilocular radiolucency with few radiopaque areas 23 and 24
7.	Chen *et al.* [33]	15/M	Chinese	2007	Maxilla	Unilocular radiolucency with impacted 23
8.	Sandhu *et al.* [34]	25/F	Indian	2010	Maxilla	Unilocular radiolucency with impacted 13
9.	J Baby John, Reena Rachel John [35]	38/F	Indian	2010	Maxilla	Unilocular radiolucency with impacted 27
10.	Khot and Vibhakar [36]	17/F	Indian	2011	Maxilla	Unilocular radiolucency with impacted 33
11.	Zama Moosvi [37]	13/F	Indian	2011	Mandible	Unilocular radiolucency with impacted 32
12.	Anita Dnyanoba Munde *et al.* [38]	20/F	Indian	2013	Mandible	Unilocular radiolucency with impacted 33
13.	Vikramjeet Singh *et al.* [39]	15/F	Indian	2012	Maxilla	Unilocular radiolucency with impacted 13
14.	Anshita Agarwal *et al.* [40]	15/F	Indian	2012	Maxilla	Unilocular radiolucency with impacted 23
15.	Sushruth Nayak *et al.* [41]	32/M	Indian	2012	Mandible	Unilocular radiolucency with impacted 43.
16.	Latti BR, Kalburge JV [42]	15/F	Indian	2013	Mandible	Unilocular radiolucency with impacted 33
17.	Harish Saluja *et al.* [43]	18/F	Indian	2013	Mandible	Unilocular radiolucency with impacted 43
18.	Shivesh Acharya [44]	14/F	Indian	2014	Maxilla	Unilocular radiolucency with impacted 13
19.	Ludmila De Faro Valverde *et al.* [45]	17/F	Unknown	2014	Maxilla	Unilocular radiolucency with impacted 23
20.	Majumdar *et al.* [25]	14/F	Indian	2014	Maxilla	Unilocular radiolucency with impacted 23
21.	Manjunatha *et al.* [26]	19/F	Indian	2015	Mandible	Unilocular radiolucency with impacted 34
22.	Present case	14/F	Indian	2022	Maxilla	Unilocular radiolucency with impacted 23, 25

Discussion

Adenomatoid odontogenic tumour, often described as the master of disguise, was first reported by Steen lands as epithelioma adamantium in 1905 [6]. Adenomatoid odontogenic tumour with its simple abbreviation AOT, was proposed by Philipsen and Birn [7].

AOT, according to WHO histological typing of odontogenic tumours, jaw cyst and allied lesions, has been defined as a tumour of the odontogenic epithelium with duct-like structures and with varying degrees of inductive changes in the connective tissue [8]. It accounts for only for 2.2- 7.1% of all odontogenic tumours [9]. AOT is commonly reported in females and has a characteristic tendency to occur in the anterior maxilla especially in the younger age group [10].

Philipsen *et al.*, categorized AOT into three variants (Follicular, extrafollicular, and peripheral). The 'follicular type' consists of a central lesion associated with an impacted tooth. The follicular type is the most common type accounting for 73% of cases. Another variant accounting for24% of the cases, is the 'extrafollicular type'. It has a central lesion, but is not associated with the tooth. The next one which is extraosseous in origin called the 'peripheral type' and accounts to 4.4% of cases [10].

The follicular variant of AOT is commonly misdiagnosed as DC, as both have an unilocular, well-defined radiolucency engulfing the crown of an impacted canine. Aspiration reveals straw coloured fluid to differentiate DC from the solid tumour. Follicular type of AOT extends apically beyond the cementoenamel junction (CEJ) [11] while the cystic lining of DC remains attached to the tooth at the cervical region [12].

In the present case, the attachment of the lining was slightly beyond the cementoenamel junction. Aspiration revealed the presence of straw-coloured fluid and therefore, it was difficult to clinically diagnose the lesion as AOT. Incisional biopsy taken from the posterior aspect was histopathologically diagnosed as an infected dentigerous cyst. The lesion was also associated with multiple unerupted teeth. All these features went in favour of dentigerous cyst. Hence, the misdiagnosis of infected dentigerous cyst was made.

The usual treatment for a dentigerous cyst is careful enucleation along with the removal of impacted tooth. But if eruption of the impacted unerupted tooth is considered feasible, the tooth may be left in place after partial removal of the cyst wall. This will permit the decompression of the cyst with reduction in the size of the bone defect. Patients may also need orthodontic treatment to assist eruption. Large dentigerous cysts may also be treated by marsupialization. [15] In this case, as the patient was a young female, aesthetics was an important factor, since the size of the bone defect was large. Hences, a decompression could have been planned.

The CBCT findings were suggestive of AOT, because of the presence of specks of calcification in the lesion. Other factors which went in favour of AOT were the age of the patient, gender, site of the lesion.

AOTs are odontogenic tumors which have the biological nature of benign tumors, without the local invasion. The most preferrable treatment of AOT as reported by many surgeons is complete enucleation with long-term follow up [16-20].

For smaller AOTs, surgical enucleation and complete curettage gives good prognosis. In case of younger patients with a larger AOT, during surgical enucleation or curettage, there is a risk of damage to adjacent anatomic structures in both jaws. Moreover, mandibulectomy and maxillectomy with simultaneous reconstruction of the surgical defect with fibular or other flaps is not appropriate during the stage of development of jaws. Guided tissue regeneration with a membrane technique and bone grafting proposed by some authors after complete removal of the tumor [21] have questionable long term effects.

The AOT has reported to have less recurrence rate. Only three cases recurred out of 750 reported by Philipsen and Reichart. [20, 10, 22] Hence, decompression or marsupialization holds key for younger patients with large AOTs.

The goal of treating large cystic lesions of the jaws is to minimize postoperative recurrence and preserve the shape and function of the jaws. Fenestration decompression is the

treatment that creates an opening to reduce pressure within a cystic cavity, inducing bone formation [23]. The rationale for fenestration decompression is to reduce the size of cystic lesions, avoiding total removal. Here, patients should be kept under regular follow up to observe changes in size of tumor and bone density [24]. If tumor size does not decrease, bone density increases by about 50% [23] or continues to grow, following which immediate surgical enucleation is done. Thus, overall damage is reduced though a second surgery is required.

In the present case, the large extensive bony defect was initially diagnosed as dentigerous cyst and differential diagnosis was an expansile AOT. Initial decompression of the lesion was planned. After six months when there would be slight decrease in size of the bony defect, complete enucleation was planned. After complete enucleation it was finally diagnosed as AOT.

AOT has been reported to occur in the mandibular anterior regions, sinus, posterior maxillary regions, in addition to the anterior maxilla [13, 25]. These findings imply that dental laminar remnants are most likely the progenitor cells for this benign odontogenic tumor.

There are still differing opinions regarding the histogenesis of AOT; hypotheses range from odontogenic cysts to the fully developed enamel organ, dental lamina, and/or its remnants [11, 25].

Envelopmental theory hypothesis proposes that AOT grows next to or into a nearby dental follicle while forming a cystic space [14, 25]. Hence in this case reported, AOT might have developed from the dental laminar remnants along with DC at the time of cyst expansion.

Very few cases of AOT have been reported that arise in association with DC. A systematic search of the English language medical literature revealed only 21 such cases so far and 15 cases occurred in the maxillary region, of which 12 cases were associated with impacted canine and 10 cases occurred in females belonging to the second decade of life. (25) Table 1 Summarizes the clinical features of 20 such cases in addition to the present case. (Table 1).

Conclusion

CBCT scan was a successful tool in diagnosing AOT inspite of the incisional biopsy report of DC. This emphasizes how crucial CBCT is for accurately diagnosing large bony lesions and how it must be considered before treatment planning. AOT and DC are both benign, encapsulated lesions. Conservative surgical enucleation or curettage is the treatment of choice and the prognosis is good along with consistent follow up. This case highlights the importance of clinical examination, CBCT scanning, grossing and meticulous histopathological examination to diagnose rare variants of neoplasms in the jaws.

Acknowledgements

Without the diligent work of Dr. Drishti Shah, Dr. Srishti Talkar and Dr. Surabhi Sharma, the treatment of this patient could not have been concluded.

Conflict of Interest: Not available.

Financial Support: Not available.

References

1. Kramer IR, Pindborg JJ. Histological Typing of Odontogenic Tumours, Jaw Cysts and Allied Lesions. Berlin: Springer-Verlag. WHO international histological classification of tumors No. 5; c1971.
2. Rajendran R, Shafer's Textbook of Oral Pathology. Rajendran R, Sivapathasundharam B, editors. 6th ed. Noida (India): Elsevier; c2009. p. 282-283.
3. Neville BW, Damm DD, Allen CM, Bouquot JE. Oral and Maxillofacial Pathology. 2nd ed. New Delhi (India): Elsevier; c2005. p. 621-625.
4. Garg D, Palaskar S, Shetty VP, Bhushan A. Adenomatoid odontogenic tumor - hamartoma or true neoplasm: a case report. J Oral Sci. 2009;51:155-159.
5. Vasudevan K, Kumar S, Vigneswari S. Adenomatoid odontogenic tumor, an uncommon tumor. Contemp Clin. Dent. 2012;3:245-247.
6. Mohamed A, Singh AS, Raubenheimer EJ, Bouckaert MM. Adenomatoid odontogenic tumour: Review of the literature and an analysis of 33 cases from South Africa. Int J Oral Maxillofac Surg. 2010;39:843-846.
7. Philipsen HP, Birn H. The adenomatoid odontogenic tumour. Ameloblastic adenomatoid tumour or adeno-ameloblastoma. Acta Pathol. Microbiol. Scand. 1969;75:375-398.
8. Reichart PA, Philipsen HP. Odontogenic Tumors and Allied Lesions. London: Quintessence Publications; c2004. p. 105-15.
9. Singh V, *et al.* Adenomatoid odontogenic tumour with dentigerous cyst: Report of a case with review of literature. Contemp Clin Dent. 2012;3(2):S244-247.
10. Philipsen HP, Reichart PA. Adenomatoid odontogenic tumour: facts and figures. Oral Oncol. 1999;35(2):125-131.
11. Ide F, Mishima K, Kikuchi K, Horie N, Kusama K. Development and growth of adenomatoid odontogenic tumour related to formation and eruption of teeth. Head Neck Pathol. 2011;5:123-132.
12. Latti BR, Kalburge JV. Dentigerous cyst associated with adenomatoid odontogenic tumour (AOT): A rare case report and review of literature. Med Sci. 2013;1(2):44.
13. Anita DM, Ravindra RK, Swapna S, Sunil S. Adenomatoid odontogenic tumour of the mandible arising from a dentigerous cyst: A case report. Res Rev J Dent Sci. 2014;2(1):87-91.
14. Batra P, *et al.* Adenomatoid odontogenic tumour: Review and case report. J Can Dent Assoc. 2005;71(4):250-253.
15. James RH, Edward E, Myron RT. Contemporary Oral and Maxillofacial Surgery. 5th ed. St. Louis: Mosby Elsevier; c2008. p. 453-459.
16. Mohamed A, Singh AS, Raubenheimer EJ, Bouckaert MM. Adenomatoid odontogenic tumour: Review of the literature and an analysis of 33 cases from South Africa. Int J Oral Maxillofac Surg. 2010;39:843-846.
17. Shetty K, Vastardis S, Giannini P. Management of an unusually large adenomatoid odontogenic tumor. Oral Oncol Extra. 2005;41:316-318.
18. Kalia V, Kalra G, Kaushal N, Sharma V, Vermani M. Maxillary adenomatoid odontogenic tumor associated with a premolar. Ann Maxillofac Surg. 2015;5:119.
19. Swasdison S, Dhanuthai K, Jainkittivong A, Philipsen HP. Adenomatoid odontogenic tumors: An analysis of 67 cases in a Thai population. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2008;105:210-215.
20. Liu M, Sun G, Hu Q, Tang E. Treatment for large adenomatoid odontogenic tumors: clinical analysis of 13 cases. Int J Oral Maxillofac Surg. 2018;47:1181-1186.
21. Blumenthal NM, Mostofi R. Repair of an intrabony

IJRAR.ORG E-ISSN: 2348-1269, P-ISSN: 2349-5138

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Comparison Of The Efficacy Of Commercially Available Polyherbal Gel versus Aloe Vera gel In Postsurgical Early Wound Healing After Conventional Flap Surgery In Patients With Stage III Grade A Periodontitis - A Randomized Controlled Trial.

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Abstract: Periodontal health is important for preventing dental and gingival diseases, preserving teeth and supporting overall health of an individual. Gingivitis is reversible with good oral hygiene. However, if left untreated, or if not controlled, gingivitis can progress to periodontitis which can provoke a destructive host response, leading to clinical attachment loss and ultimately possible tooth loss.Herbal formulations have been used in several forms in oral care such as mouthwash and dentifrice as it helps to reduce bleeding, inflammation, and swelling of the gingiva and is useful in the treatment of periodontal diseases. However, no studies have yet been reported on the comparative efficacy, of Polyherbal gel versus aloe vera gel, on periodontal postsurgical wounds during the initial wound healing period. Hence, a study to this effect in individuals suffering from Stage III Grade A periodontitis was conducted.

Key words: Early Wound Healing, Conventional Flap Surgery, Periodontitis

Introduction: Periodontal health is important for preventing dental and gingival diseases, preserving teeth and supporting overall health of an individual. Initial changes from health to plaque induced gingivitis may not be detectable clinically, but as gingivitis progresses to more advanced forms of this disease, clinical signs and symptoms become more obvious.[1] Gingivitis is reversible with good oral hygiene. However, if left untreated, or if not controlled, gingivitis can progress to periodontitis which can provoke a destructive host response, leading to clinical attachment loss and ultimately possible tooth loss. [2]

Periodontal therapy is initially directed at reduction of oral bacteria and associated calcified deposits by chemical plaque control methods which includes; use of chemical agents like chlorhexidine, thymol-listerine, phenol, eucalyptol, benzalkonium chloride, sodium and stannous fluoride etc. Mechanical plaque control methods which include use of tooth brushes, interdental brushes, interdental floss and scaling and root planingetc.[3]

The periodontal flap procedure is most frequently employed for pocket elimination/ reduction, particularly for moderate and deep pocketsDuring the post- surgical phase, there may be bleeding, pain, swelling and infection.[4]It has been shown that the early stages of post-surgical wound healing are associated with inflammation which, in turn, enhances biofilm formation.[5]If plaque formation is hindered, periodontal wounds heal faster and show less complications, while periodontal surgery at plaque-infected sites leads to lack of clinical improvements or even worsening.[6]The first seven days following periodontal surgery is the time period in which patients is unable to perform good oral hygiene with least efficiency due to pain on touch and due to the presence of sutures. During this period of inadequate oral hygiene management, effective chemical measures which can reduce bacterial plaque and improve the initial healing response can be prescribed. Antibacterials have been shown to reduce plaque formation and inflammation and improve healing and patient comfort when used after periodontalsurgery.[7]

However, the use of synthetic antibiotic has its own adverse effects such as drug toxicity, acquired bacterial resistance, drug interaction, and patient's compliance limit the use of systemic antimicrobials.[8] Therefore, a positive influence on the subgingival biofilm may be accomplished with high concentrations of antibiotics with a local delivery of the antimicrobial drug.[9]

With the ever-changing lifestyle, people have become health conscious and take all possible efforts to lead a healthy life. Today, people around the world are giving preference to natural drugs due to the, increasing realization of the side effects of allopathic medicines. There has been a change in worldwide fashion from synthetic to herbal medicine in recent times. Thus, it increases the demand of herbal drugs. Herbal formulations have gained popularity amongst such group of people who want to stay healthy and at the same time avoid unwanted side effects.[10]

Herbal medicine is also called as phytomedicine or botanical science and it is science of medicine that uses of seeds, berries, roots, leaves, bark or flowers of medicinal plants and their extracts for curing ailments. They are absolutely natural and devoid of side effects.[11] Herbal formulations have been tried for treatment of most systemic diseases and have yielded good results as compared to medicinal drugs. Also, with the increasing prices of prescription medicine, herbal medicines are often cheaper than their conventional medicinecounterparts.[12]

Several studies have documented the efficacy of Herbal formulations.[12] Due to their proven efficacy in the treatment of systemic diseases; they were used for treating dental problems and proved to be effective. Formulations are available in the market to treat different types of oral ailments like toothache, plaque and caries, pyorrhea and aphthae.

A well-documented scientific and clinical basis for the use of a Polyherbal formulation containing oils of Myristica fragrans, and extracts of Terminalia arjuna, Pterocarpus marsupium and Triphala is commercially available (Hiora- GA). These herbs have a soothing effect, astringent property, connective tissue healing properties along with antioxidant, antimicrobial and anti-inflammatory properties. The beneficial effects of Hiora GA can be attributed to the combined effect of the individual potent herbs.[13]

Aloe vera is a medicinal plant. It has immense properties of therapeutic benefits. It is widely known for its wound healing, analgesic, anti-inflammatory, antibacterial, antifungal, antiviral, antioxidant, and antitumor properties. It has been used in several forms in oral care such as mouthwash and dentifrice as it helps to reduce bleeding, inflammation, and swelling of the gingiva and is useful in the treatment of periodontal diseases. [14] However, no studies have yet been reported on the comparative efficacy, of Polyherbal gel versus aloe vera gel, on periodontal postsurgical wounds during the initial wound healing period. Hence, a study to this effect in individuals suffering from Stage III Grade A periodontitis was conducted.

Materials and Methods: The study was conducted in Department of Periodontology of a recognized dental from January 2019 to August 2020. Ethical clearance was obtained from the Institutional Ethical Committee before commencement of the study.

A total of fifty-four subjects diagnosed with Stage III Grade A periodontitis requiring periodontal flap surgery were included in the study.

GROUP-1 Polyherbal gel (27 subjects) 27 subjects were advised to apply Polyherbal gel 2-3 ml thrice daily for 7 days.

GROUP-2 Aloe vera gel (27 subjects) 27 subjects were advised to apply aloe vera gel 2-3 ml thrice daily for 7 days.

The subjects were selected on the basis of the following inclusion criteria: Systemically healthy, within the age range of 30-60 years of either sex. having probing pocket depth of ≥ 5mm and <7 after Phase I therapy, presence of horizontal bone loss as determined by Orthopantomography (OPG). The exclusion criteria were: Smokers & Tobacco chewers, pregnant women or lactating mothers and those using oral contraceptive pills, history of antibiotics or anti-inflammatory medication in past 3 months, history of any periodontal treatment in past 6 months, subjects with known drug allergy to any of the medication to be used in the study.

Clinical parameters assessed were: Plaque index, Modified Gingival Index, Visual Analogue Scale, Wound Healing Index. The surgical procedure was performed under local anaesthesia. Conventional periodontal flap surgery was carried out by raising full thickness flap at the selected surgical site. After thorough debridement and irrigation, interrupted sutures were placed at the interdental area. After thorough debridement and irrigation, interrupted sutures were placed with 3-0 black braided silk sutures at the interdental area.The subjects in group 1 were advised to apply Polyherbal gel 2-3 ml thrice daily for 7 days. The subjects in group 2 were advised to apply Aloe vera gel 2-3 ml thrice daily for 7 days. Post surgical assessment of clinical parameters was done at:7^{th}, 14^{th} and 21^{th} day post operatively.

Results: Data obtained was compiled on a MS Office Excel Sheet (v 2010). Data was subject to statistical analysis using Statistical package for Social Sciences (SPSS v 21.0, IBM).Normality of data was checked using Shapiro-Wilk test data followed a normal distribution hence parametric tests have been used for statistical comparisons.

Comparison of numerical values between the 2 groups was done using t test. For intra group comparison repeated measures ANOVA has been used followed by Tukey's Post Hoc test.Comparison of change in numerical values over time intervals from baseline or initial values between the 2 groups was done using t test.

For all the statistical tests, $p < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

Plaque Index(PI)

On inter group comparison,of the change in PI over a period of 21 days, it was found that at all-time intervalsthere was a no significant difference seen for the values between the two groups. **(Table 1)**

Modified Gingival Index (MGI)

On inter group comparisonof the change in MGI over a period of 21 days, it was found that the change from baseline to Day 7, baseline to Day 14 and baseline to day 21, Day 7- Day 14, Day 7- Day 2, Day14-Day 21at all-time intervals except between 7th to 21st daythere was a no significant difference seen for the values between the two groups as all p-Values are $p > 0.05$.There was a statistically significant in scores between7th to 21st dayas p-Value is 0.047 (<0.05) **(Table 2)**

Visual Analogue Scale (VAS) scores for pain

On inter group comparisonof the change in VASover a period of 21 days, it was found that at all-time intervals there was no significant difference seen for the values between the two groups. **(Table 3)**

Wound Healing Index (WHI)

On inter group comparisonof the change in Wound healing index over a period of 21 days, it was found that at all-time intervals there was a no significant difference seen for the values between the two groups.**(Table 4)**

Discussion: Plaque-induced Gingivitis is the most common form of inflammatory diseases affecting the periodontium.The most common complication of chronic gingivitis is progression to periodontal disease and tooth loss. So, progression of gingivitis should be prevented to avoid further consequences as gingivitis is a reversible disease.

Periodontal disease if left untreated, or if not controlled, it can provoke a destructive host response, leading to clinical attachment loss and ultimately possible tooth loss.[2] Treatment of periodontitis includes periodontal flap surgery.

After periodontal surgery, which is intended to treat periodontal pockets, prevention of bacterial contamination of the operated area is essential to prevent wound infection and create a favourable environment for the healing process.[6,15] It has been shown, that, the early stages of postsurgical wound healing

are dominated by inflammation which, in turn, enhances biofilm formation.[5,15]If plaque formation is hindered, periodontal wounds heal faster and show less complications while periodontal surgery at plaque infected sites leads to lack of clinical improvements or even worsening. [6] So, the present study was designed accordingly to get the real clinical effect which can be implemented in daily practice.The study was carried out for a period of 21 days to evaluate the early wound healing, plaque control, gingival inflammation and pain after conventional flap surgery post application of commercially available Polyherbal gel versus Aloe vera gel.

The parameters assessed in the study included the Plaque Index. It was used in the study to determine the efficacy of plaque control and oral hygiene maintenance of the patient. There was no significant difference in maintenance of oral hygiene between the two groups and the plaque scores remain unchanged between the groups.

The Modified Gingival Index was used in the study to assess gingival bleeding on probing along with visible signs of inflammation and thus recognize and record the presence of early to severe inflammatory gingival disease.On inter group comparison the change in Modified gingival index at all time intervals except between 7th to 21st daythere was a no significant difference seen for the values between the two groups.

Visual analogue scale scores were assessed on the 1st, 7th, 14th and 21th day post operatively. On inter group comparison of the change in Visual Analogue Scale over a period of 21 days, it was found that at all-time intervals there was no significant difference seen for the values between the two groups.

Wound Healing Indexwas assessed on the 7th, 14th and 21th day post operatively. On inter group comparisonof the change in Wound healing index over a period of 21 days, it was found that at all-time intervals there was a no significant difference seen for the values between the two groups.

Polyherbal gel and Aloe vera gel shows the synergistic action of the herbs and has several medicinal properties. From the results of the present study, we can assume that the beneficial effect of an herbal gel may be result in reduction in gingival inflammation, reduce pain, promotes wound healing thus arresting disease progression.

In the present study, there was mean reduction in values of PI, MGI, VAS Score and WHI index over a period of 21 Days in both the groups. Hence, present study suggested that Polyherbal gel and Aloe vera gel showed promising results with respect to early wound healing, plaque control, gingival inflammation and pain after conventional flap surgery.

Conclusion: From the results of the present study, it can be concluded that commercially available Polyherbal gel and Aloe vera gel were effective in postsurgical early wound healing after conventional flap surgery in subjects with Stage III Grade A periodontitis.

References:

1.Lindhe J, Hamp SE, Loe H. Experimental periodontitis in the beagle dog. Int Dent J 1973; 23: 432.

2. Kinane DF. Causationand pathogenesis of periodontaldisease.Periodontology 2000 2001; 25(1): 8-20.

3. Loe H. Oral hygiene in the prevention of caries and periodontal disease. Int Dent J 2000; 50(3):129-139.

4. Bakeen GS, Strahan JD. Effects of 1% chlorhexidine gel during the healing phase after inverse bevel mucogingival flap surgery. J Clin Periodontol 1980; 7: 20–25.

5. Susin C, Fiorini T, Lee J, De Stefano JA, Dickinson DP, Wikesjo UM. Wound healing following surgical and regenerative periodontal therapy. Periodontol 2000 2015; 68:83–98.

6. Nyman S, Rosling B, Lindhe J. Effect of professional tooth cleaning on healing after periodontal surgery. J Clin Periodontol 1975; 2:80–86.

7. Zambon JJ, Ciancio SG, Mather ML, Charles CH. The effect of an antimicrobial mouthrinse on early healing of gingival flap surgery wounds. J Periodontol 1989;60(1):31-34.

8. Golub LM, Lee HM, Lehrer G. Minocycline reduces gingival collagenolytic activity during diabetes. Preliminary observations and proposed new mechanisms of action. J Periodontol Res 1983;18:516–26.

9. Rams TE, Slots J. Local delivery of antimicrobial agents in the periodontal pocket. Periodontol 2000 1996; 10:139–59.

10. Prakash S, Shelke AU. Role of Triphala in dentistry. J Indian Soc Periodontol 2014; 18(2): 132–135.

11. Peddapalli H, Boggula N, Ramya D, Rashi KN, Rao PV. Therapeutic Potential of Piper betle: An Amazing Nature's Medicinal Reservoir. Chem Res J 2020; 5(3):62-75

12. Somu AC. Efficacy of a herbal extract gel in the treatment of gingivitis: A clinical study. J Ayurveda Integr Med 2012; 3(2):85–90.

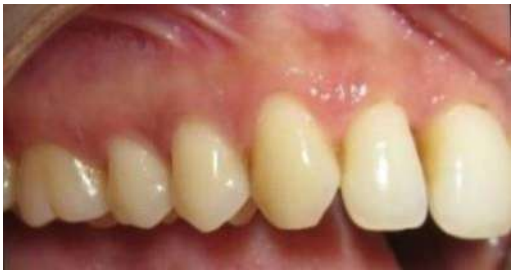
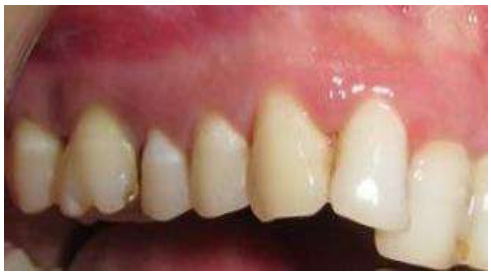
13. Gujjari S K, Divya S, Ali N M, Arora D, Gujjari A K. Effect of HIORA-GA gel on Periodontal surgical wound. Int J Curr Res 2015; 7(5):15741-15746.

14. Grindlay D, Reynolds T. The Aloe vera phenomenon: A review of the properties and modern uses of the leaf parenchyma gel. J Ethnopharmacol 1986; 16: 117-51.

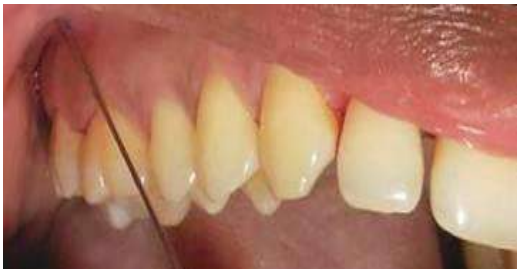
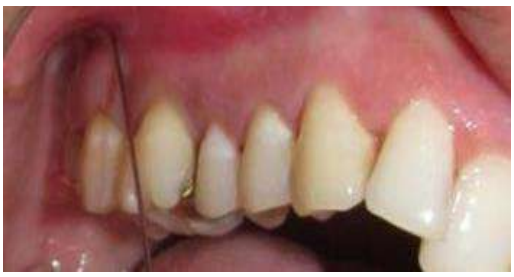
15. Daly CH, Highfield JE. Effect of localised experimental gingivitis on early supragingival plaque accumulation. J Clin Periodontol 1996; 23:160–164.

Surgical protocol

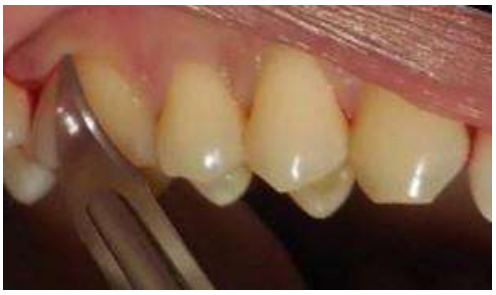
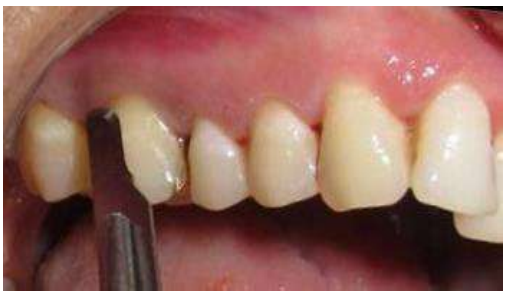
Group-1(Polyherbalgel) Group-2(Aloeveragel)

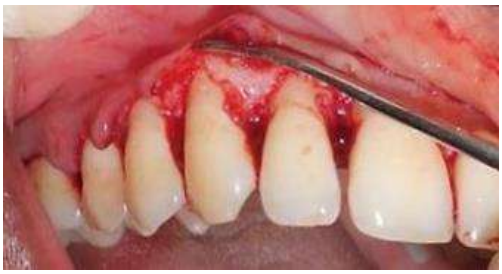
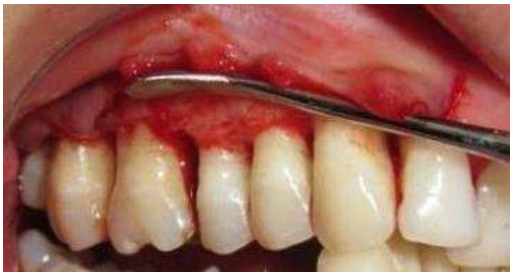
a) Baseline pre-operative photographs

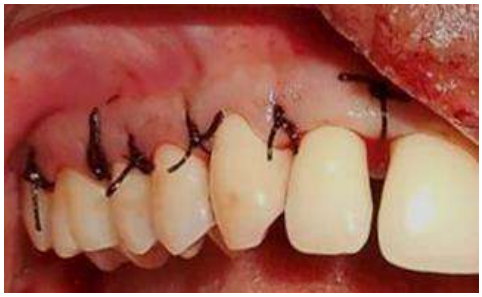
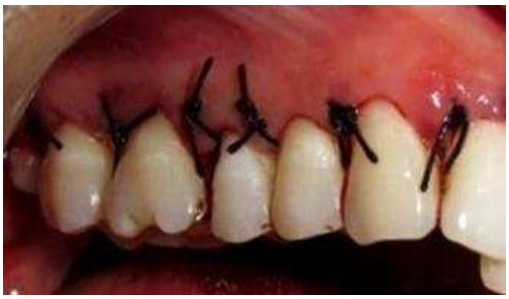
b) Administration of Local anaesthesia

c) Incision placement

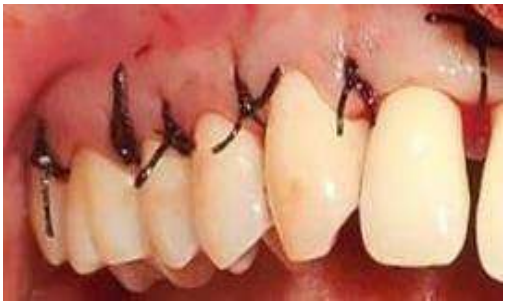
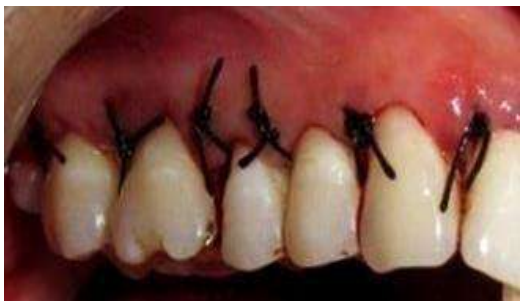



d) Flap reflection with periosteal elevator

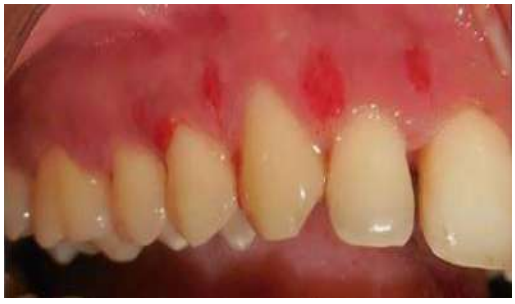
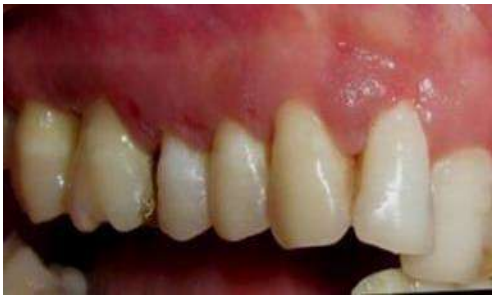



e) Flap approximation and suturing

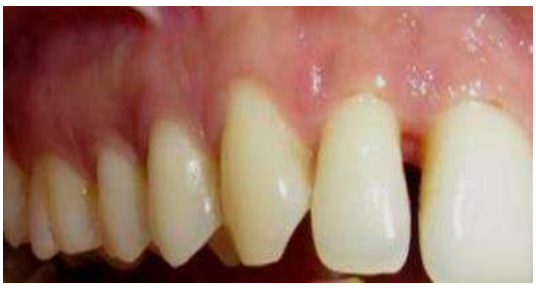
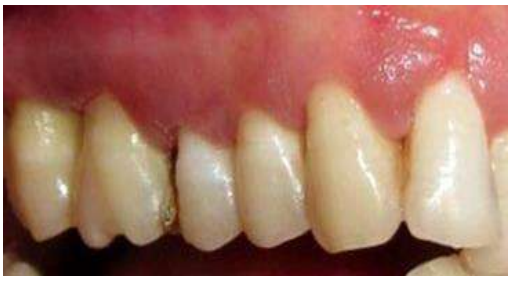
Post-Operative Follow-Ups

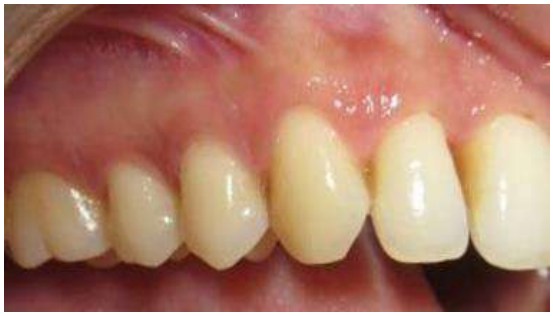
f) 1st day follow-up

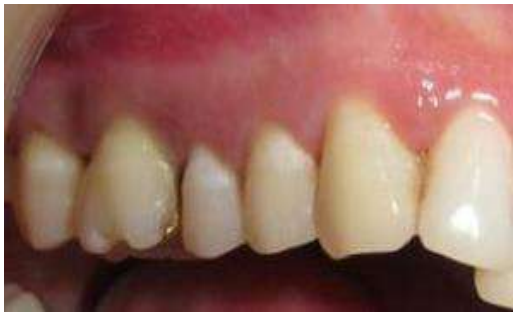



g) 7th day follow-up

h) 14th day follow-up





i) 21th day follow-up

Table 1:Intergroup comparison of changes in PI Score of Polyherbal Gel Vs Aloe Vera Gel over a period of 21 days

PI	PolyherbalGel	AloeVeraGel	P value
Baseline-Day7	-0.88±0.21	-0.87±0.28	0.413
Baseline-Day14	-0.03±0.13	-0.03±0.18	0.431
Baseline-Day21	0.01±0.14	0.03±0.18	0.399
Day7-Day 14	0.85±0.26	0.84±0.28	0.460
Day7-Day 21	0.90±0.18	0.89±0.28	0.477
Day14-Day21	0.05±0.16	0.05±0.15	0.466

Table 2:Intergroup comparison of changes in GI Score of Polyherbal Gel Vs Aloe Vera Gel over a period of 21 days

GI	PolyherbalGel	AloeVeraGel	P value
Baseline-Day7	-0.86±0.22	-0.78±0.32	0.151
Baseline-Day14	-0.02±0.13	-0.02±0.16	0.463
Baseline-Day21	0.07±0.19	0.03±0.15	0.240
Day7-Day 14	0.84±0.24	0.76±0.28	0.130
Day7-Day 21	0.92±0.22	0.81±0.26	0.047
Day14-Day21	0.09±0.24	0.06±0.07	0.270

Table 3: Intergroup comparison of changes in VAS Score of Polyherbal Gel Vs Aloe Vera Gel over a period of 21 days

VAS	Polyherbal Gel	AloeVeraGel	P value
Day1-Day 7	1.63±1.50	1.67±1.33	0.462
Day1-Day14	3.33±1.00	3.70±1.07	0.097
Day1-Day21	4.44±0.89	4.56±0.97	0.332
Day7-Day 14	1.70±1.20	2.04±1.40	0.176
Day7-Day 21	2.81±1.00	2.89±1.28	0.407
Day14-Day21	1.11±0.64	0.85±0.53	0.056

Table 4: Intergroup comparison of changes in WHI Score of Polyherbal Gel Vs Aloe Vera Gel over a period of 21 days

WHI	Polyherbal Gel	AloeVeraGel	P value
Day7-Day 14	0.37±0.49	0.30±0.47	0.286
Day7-Day 21	0.37±0.49	0.30 ±0.47	0.286
Day14-Day21	0.00±0.00	0.00±0.00	-

ISSN: 0976-3031

Available Online at http://www.recentscientific.com

CODEN: IJRSFP (USA)

International Journal of Recent Scientific Research
Vol. 15, Issue, 01, pp.4503-4511, January, 2024

International Journal of Recent Scientific Research

DOI: 10.24327/IJRSR

Research Article

COMPARATIVE EVALUATION OF DEPIGMENTATION USING CERAMIC SOFT TISSUE TRIMMING BUR VERSUS SCALPEL FOR TREATMENT OF PHYSIOLOGICAL GINGIVAL MELANIN HYPERPIGMENTATION: A RANDOMIZED CONTROLLED TRIAL

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DOI: http://dx.doi.org/10.24327/ijrsr.20241501.0845

ARTICLE INFO

Article History:

Received 18th December, 2023
Received in revised form 28th December, 2023
Accepted 15th January, 2024
Published online 28th January, 2023

Keywords:

hyperpigmentation, scalpel depigmentation technique, ceramic soft tissue trimming bur

ABSTRACT

Aims: The present trial aimed to comparatively evaluate depigmentation using ceramic soft tissue trimming bur versus scalpel for treatment of physiological gingival melanin hyper pigmentation. **Materials and Methods:** Subjects within the age range of 20-45 years of either sex, reporting to the Out Patient Department with chief complaint of blackish appearance of gums (physiological gingival melanin hyper pigmentation) were selected for the study. A total of sixty-two sites with physiological gingival melanin hyper pigmentation were selected by convenience sampling technique. **Statistical analysis used:** The results of the trial were analysed for statistical significance. **Results:** It was observed that this minimally invasive surgical technique with ceramic soft tissue trimming bur resulted in reduction of the gingival melanin hyper pigmentation with minimal bleeding, rapid wound healing and less post-operative pain and discomfort. **Conclusions:** It was concluded thatceramic soft tissue trimming bur was effective in the treatment of gingival melanin hyper pigmentation.

INTRODUCTION

A smile expresses a feeling of joy & success and can reflect self-confidence and kindness. Gingival health and appearance are essential components of an attractive smile, and removal of unsightly-pigmented gingiva is a necessity for a pleasant and confident smile.[1]

The gingiva color is described as coral pink. It is determined by several factors such as epithelial thickness, degree of keratinization, pigments within the gingival epithelium & the size and number of blood vessels.[2] Melanin, carotene, reduced haemoglobin, and oxyhemoglobin are the main pigments which contributes to the normal colour of the oral mucosa.[3]

Gingival pigmentation is the deposition of coloring matter, coloration or discoloration by a pigment pertaining to the gingiva .[4] Melanin, melanoid, carotene, reduced hemoglobin, soft keratin and oxyhemoglobin were identified as pigments.[5] Melanin, an aturally occurring brown pigment, contributes to the endogenous pigmentation of skin, gingiva and remainder of the oral mucous membrane.[6] Gingival melanin pigmentation may be multifactorial, physiological or pathological and it occurs in all humanraces.[7]Gingivalmelaninhyperpigmentation is caused due to excessive melanin deposition by the melanocytes that are primarily located in the basal and supra-basal layers of the epithelium.[8] Gingival melanin hyper pigmentation is one of the issues which determine the smile of an individual. Especially when it is associated with a gummy smile, it not only becomes an esthetic concern, but also a psychological concern for anindividual.[9]

Melanin hyperpigmentation can be attributed to both endogenous and exogenous factors. Endogenous factors include medical conditions such as Addison's disease, Peutz-Jegher's syndrome, Von Recklinghausen's disease (neurofibromatosis) etc.[10] The exogenous factors are heavy metals such as copper, mercury, silver, bismuth, arsenic, lead, and gold or some kind of tattoos like intentional amalgam or graphite.[11] Gingival depigmentation is a periodontal plastic surgical procedure whereby the gingival hyperpigmentation is removed or reduced by various techniques.[12] It can be carried out by various methods such as scalpel surgical technique, bur abrasion method, Electrosurgery, Cryosurgery, Lasers, Radiosurgery, chemical methods and methods aimed at masking the pigmented gingiva. (Free gingival graft, Acellular dermal matrix allograft).[13] Although various treatment modalities have been reported for depigmentation, the selection of the appropriate technique should be based on clinical experience and the individual operator's preferences. Most of the surgical modalities have disadvantages such as poor wound healing, post-operative pain, not acceptable to the clinicians or the patients, expensive, requires more clinical expertise and difficulty in controlling penetration depth. To overcome this, a

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new modality such as ceramic soft tissue trimming bur had thus been introduced.

Ceramic soft tissue trimming bur can often replace laser, electro-surgery and surgical blades. It is a flame shaped biocompatible hard oxide zirconia point bur with head size 15mm, head length 8mm and total length 25mm. This minimally invasive surgical technique with ceramic soft tissue trimming bur leads to minimal bleeding, less post-operative pain and discomfort, rapid wound healing. Ceramic soft tissue trimming bur culminates final refinement to the post-operative deepithelialized area.

The literature on the use of Ceramic soft tissue trimming burs in the treatment of gingival hyperpigmentation is very limited. Hence, the present study was conducted to comparatively evaluate gingival depigmentation using ceramic soft tissue trimming bur versus scalpel for treatment of physiological gingival melanin hyperpigmentation.

Aim of the Study

To comparatively evaluate depigmentation using ceramic soft tissue trimming bur versus scalpel for treatment of physiological gingival melanin hyperpigmentation.

Objectives of the Study

1. To evaluate depigmentation using ceramic soft tissue trimming bur for treatment of physiological gingival melanin hyperpigmentation.
2. To evaluate depigmentation using scalpel for treatment of physiological gingival melanin hyperpigmentation.
3. To comparedepigmentation using ceramic soft tissue trimming bur and scalpel for treatment of physiological gingival melanin hyperpigmentation.

MATERIALS AND METHODS

Study design was a Parallel arm, Randomized clinical trial. Subjects within the age range of 20-45 years of either sex, reporting to the Out Patient Department of Periodontology of a recognized dental college with chief complaint of blackish appearance of gums (physiological gingival melanin hyperpigmentation) were recruited for the study. A total of sixty-two sites with physiological gingival melanin hyperpigmentation were selected by convenience sampling technique. Approximately 26 sites per group completed the trial at the endpoint follow up, considering the attrition samples which lost on follow-up. Ethical clearance was obtained from the ethical committee of the institute. Subjects were explained aboutthenatureofthestudyindetailandinalanguagebestunderstood bythem. An informed signed consent was obtained from the subjects who were willing to participate in the study. A detailed case history was recorded. Subjects were randomly grouped as:

1. **Group A** (n=31, ceramic soft tissue trimmer used for depigmentation)
2. **Group B** (n=31, scalpel depigmentation technique)

Subjects of either sex between the age group of 20-45 years were included in the study. Systemically healthy and co-operative subjects with physiological gingival melanin hyperpigmentation (DOPI score 2 and 3) and with esthetic concern were included. Subjects with autoimmune or endocrine disorders were excluded from the study. Smokers, Pregnant and lactating mothers and subjects taking medications which may cause gingival melanin hyperpigmentation were also excluded.

Assessment of clinical parameters

The gingival melanin pigmentation was assessed by the Dummett-Gupta Oral Pigmentation Index (Dummett CO, Gupta OP, 1964)[19] from left first premolar to the right first premolar. The wound healing was assessed by Healing Index (Landry RG, Turnbull RS, Howley T 1988)[20] from left first premolar to the right first premolar region. The intensity of pain or discomfort was assessed by the Visual Analogue Scale (Matthews DC, McCulloch CAG 1993)[73] ranging from 0 (no pain) to 10 (severe pain).

METHODOLOGY

All the selected subjects received thorough scaling and root planing and were motivated to maintain good oral hygiene. Modified Bass technique of brushing were explained and demonstrated tothem. Photographs were taken for all subjects in the same dental set up with the same position with fixed magnification and distance (at base line,7th day, 1 month and 6 months).

Surgical protocol

The surgical procedure for Group A (Ceramic soft tissue trimming bur) performed was as follows:

1. Presurgical rinse and perioral scrubbing was performed.
2. Adequate local anaesthesia was obtained using 2% Lignocaine HCl with 1:80000 Adrenaline.
3. Ceramic soft tissue trimming bur was used in the high-speed revolutions per minute without water coolant spray to excise the pigmented layer of gingival epithelium.
4. Afterremovingtheentirepigmentedepitheliumwithcera micsofttissuetrimmer, the exposed surface was irrigated with saline and any remnant of pigmented tissue left over was removed.
5. The solution of Evion 400mg capsule was then applied to the post-operative surgical area.
6. Post-surgical instructions were given to all the subjects.
7. Subjects were advised to rinse with 0.2% chlorhexidine gluconate mouthwash twice daily for 15 days.
8. Ibuprofen 400 mg twice daily for three days was prescribed post operatively.
9. Subjects were recalled after 1week and post-surgical evaluation.
10. Post-surgical assessment of clinical parameters was done at 1week, 1month and 6months.

The surgical procedure for Group B (Scalpel Depigmentation Technique) performed was as follows:

1. Presurgical rinse and perioral scrubbing was performed.
2. Adequate local anaesthesia was obtained using 2% Lignocaine HCl with 1:80000 Adrenaline.
3. A Bard Parker handle with a No.15 blade was used to remove the pigmented layer.
4. The exposed surface was irrigated with saline and any remnant of pigmented tissue left over was removed.

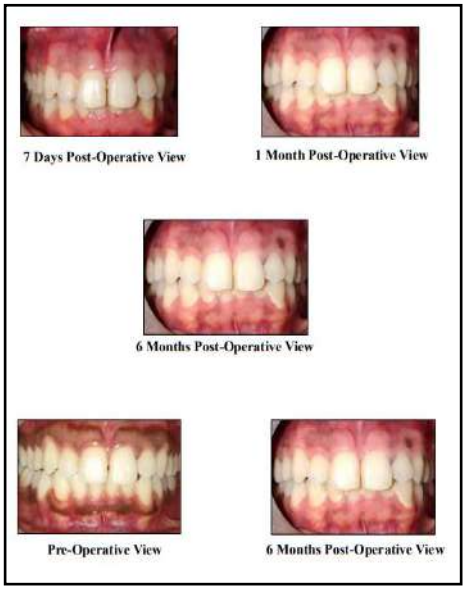
5. The surgical area was then covered with a periodontal dressing.
6. Post-surgical instructions were given to all the subjects.
7. Subjects were advised to rinse with 0.2% chlorhexidine gluconate mouthwash twice daily for 15 days.
8. Ibuprofen 400 mg twice daily for three days was prescribed post operatively.
9. Subjects were recalled after 1week and post-surgical evaluation.
10. Post-surgical assessment of clinical parameters was done at 1 week, 1 month and 6 months.

RESULTS

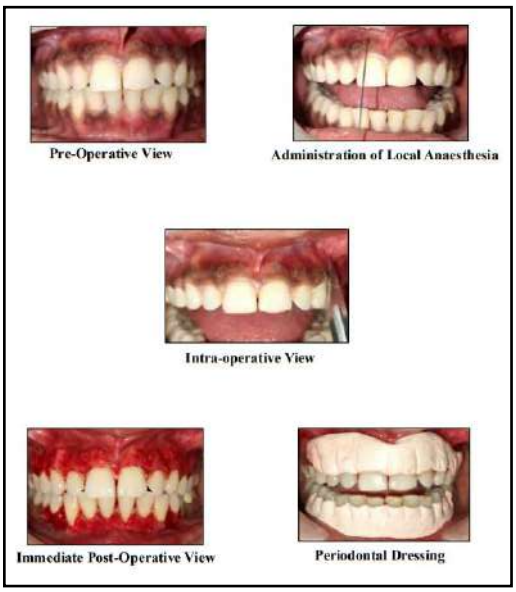
Subjects were recalled post-surgery at 7th day, 1 month and 6 months for follow-up. All of them were compliant and there were no dropouts from the study. Healing was uneventful in both the groups (Group A and Group B). The changes in the clinical parameters over 6 months were recorded. The data obtained was tabulated and subjected to statistical analysis.

Group A

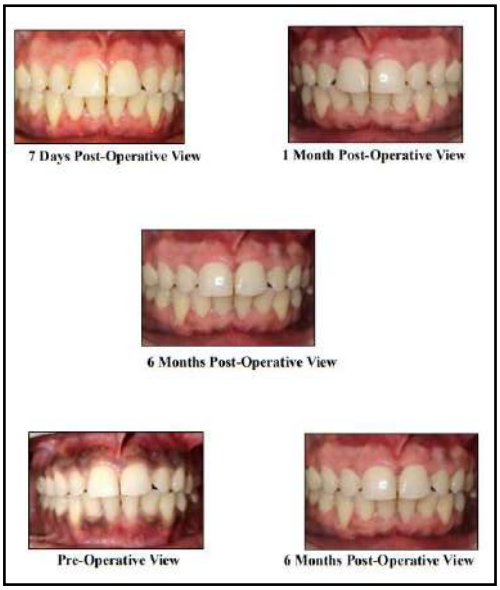
Group A (cont.)



Group B



Group B (cont.)



Statistical analysis

All data were entered into a computer by giving coding system, proofed for entry errors. Data obtained was compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States). Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data has been depicted.

Normality of numerical data was checked using Shapiro- Wilk test & was found that the data did not follow a normal curve; hence non-parametric tests have been used for comparisons. Inter group comparison (2 groups) was done using Mann Whitney U test. Intra group comparison was done using Friedman's (for >2 observations) followed by pair wise comparison using Wilcoxon Signed rank test. Comparison of frequencies of categories of variables with groups was done using chi square test.

For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

* = statistically significant difference (p<0.05)
** = statistically highly significant difference (p<0.01)
# = non-significant difference (p>0.05) … **for all tables**

Dummett-Gupta Oral Pigmentation Index (Dummett CO, Gupta OP, 1964) [23, 24]

The gingival melanin pigmentation was assessed using Dummett-Gupta Oral Pigmentation Index (Dummett CO, Gupta OP, 1964) [23, 24] at baseline, 7th day, 1 month and 6 months. On intragroup comparison, there was a statistically highly significant difference seen between the time intervals in both the groups (p<0.01) with higher values at baseline.

The mean DOPI values for Group A were: baseline (2.54 ± 0.508), 7th day (0.00 ± 0.000), 1 months (0.15 ± 0.368) and 6 months (0.15 ± 0.368) respectively. (Table-1, Graph-1) The mean DOPI values for Group B were: baseline (2.23 ± 0.430 mm), 7th day (0.00 ± 0.000), 1 months (0.00 ± 0.000) and 6 months (0.08 ± 0.272) respectively. (Table-1, Graph-1)

On intra group comparison the DOPI in Group A from baseline to 6 months was (2.38 ± 0.637) and in Group B was (2.15 ± 0.368) (Table-2, Graph-2a).

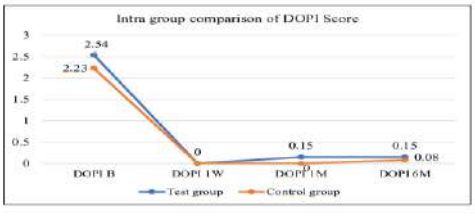
On intergroup comparison over a period of 6 months, the mean DOPI in Group A from baseline to 7th day was (2.57 ± 0.508) in Group A while (2.23 ± 0.430) in Group B. This difference between the groups was statistically significant (p=0.024) (Table-2, Graph-2a). The DOPI in Group A from baseline to 1 month was (2.38 ± 0.637) while (2.23 ± 0.430) in Group B. This difference between the groups was not statistically significant (p=0.213) (Table-2, Graph-2a). The DOPI in Group A from baseline to 6 months was (2.38 ± 0.637) while (2.15 ± 0.368) in Group B. This difference between the groups was not statistically significant (p=0.071) (Table-2, Graph-2a).

The DOPI in Group A from 7th day to 1 month was (0.15 ± 0.368) while (0.00 ± 0.000) in Group B. This difference between the groups was statistically significant (p=0.039) (Table-2, Graph-2b). The DOPI in Group A from 7th day to 6 months was (0.15 ± 0.368) while (0.08 ± 0.272) in Group B. This difference between the groups was not statistically significant (p=0.390) (Table-2, Graph-2b). The DOPI in Group A from 1 month to 6 months was (0.00 ± 0.000) while (0.08 ± 0.272) in Group B. This difference between the groups was not statistically significant (p=0.153). (Table-2, Graph-2b)

Table 1- Intragroup comparison of changes in DOPI Score over a period of 6 months

DOPI Score at Test Group	Baseline	7th day	1 month	6 months	P value
Mean	2.54	0.00	0.15	0.15	0.000*
SD	0.508	0.000	0.368	0.368	
DOPI Score at Control Group	**Baseline**	**7th day**	**1 month**	**6 months**	**P value**
Mean	2.23	0.00	0.00	0.08	0.000*
SD	0.430	0.000	0.000	0.272	

Graph 1 - Intragroup comparison of changes in DOPI Score over a period of 6 months



Healing Index (Landry RG, Turnbull RS, Howley T 1988) [11]

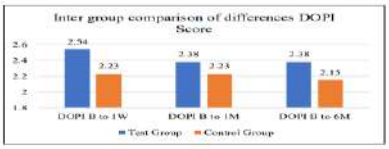
The woundhealing was assessed using Healing Index (Landry RG, Turnbull RS, Howley T 1988) at baseline, 7th day, 1 month and 6 months.

On intragroup comparison there was a statistically highly significant difference seen between the time intervals in both the groups (p<0.01) with higher values at 6 months. The mean woundhealing values for Group A were: 7th day (3.46 ± 0.508), 1 month (5.00 ± 0.000) and 6 months (5.00 ± 0.000) respectively. (Table-3, Graph-3) The mean wound healing values for Group B were 7th day (2.96 ± 0.871), 1 month (4.77 ± 0.430) and 6 months (5.00 ± 0.000) respectively (Table-3, Graph-3). On intragroup comparison the mean woundhealing values for Group A from 7th day to 6 months was (1.54 ± 0.508) and in Group B was (2.04 ± 0.871). (Table-4, Graph-4)

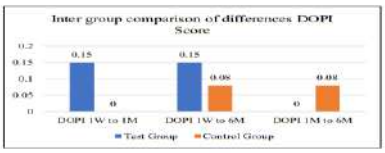
Table 2- Intergroup comparison of changes in DOPI Score over a period of 6 months

DOPI Score	Test Group		Control Group		P value
	Mean	SD	Mean	SD	
B to 1W	2.54	0.508	2.23	0.430	0.024*
B to 1M	2.38	0.637	2.23	0.430	0.213#
B to 6M	2.38	0.637	2.15	0.368	0.071#
1W to 1M	0.15	0.368	0.00	0.000	0.039*
1W to 6M	0.15	0.368	0.08	0.272	0.390#
1M to 6M	0.00	0.000	0.08	0.272	0.153#

Graph 2a- Intergroup comparison of changes in DOPI Score over a period of 6 months



Graph 2b- Intergroup comparison of changes in DOPI Score over a period of 6 months

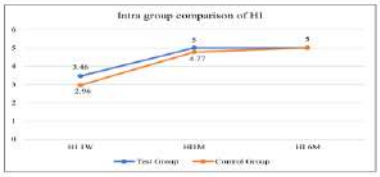


n intergroup comparison over a period of 6 months, the mean woundhealing values from 7th day to 1 month was (1.54 ± 0.508) in Group A while (1.88 ± 0.766) in Group B. This difference between the groups was not statistically significant (p=0.102) (Table-4, Graph-4). The mean woundhealing values from 7th day to 6 months was (1.54 ± 0.508) in Group A while (2.04 ± 0.871) in Group B. This difference between the groups was statistically significant (p=0.016) (Table-4, Graph-4). The mean woundhealing values from 1 month to 6 months was (0.00 ± 0.000) in Group A while (0.23 ± 0.430) in Group B. This difference between the groups was statistically significant. (p=0.010). (Table-4, Graph-4)

Table 3 - Intragroup comparison of changes in Healing Index Score over a period of 6 months

Healing Index Score at Test Group	7th day	1 month	6 months	P value
Mean	3.46	5.00	5.00	0.000*
SD	0.508	0.000	0.000	
Healing Index Score at Control Group	**7th day**	**1 month**	**6 months**	**P value**
Mean	2.96	4.77	5.00	0.000*
SD	0.871	0.430	0.000	

Graph 3 - Intragroup comparison of changes in Healing Index Score over a period of 6 months



Visual Analogue Scale (Matthews DC, McCulloch CAG 1993)[73]

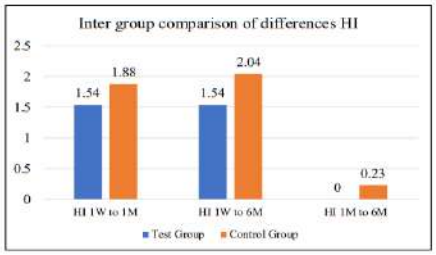
The intensity of pain or discomfort was assessed using Visual Analogue Scale (Matthews DC, McCulloch CAG 1993) at baseline, 7th day, 1 month and 6 months.

On intragroup comparison there was a statistically highly significant difference seen between the time intervals in both the groups ($p<0.01$) with higher values at baseline. The mean intensity of pain or discomfort for Group A were: baseline (0.15 ± 0.368), 7th day (0.00 ± 0.000), 1 month (0.00 ± 0.000) and 6 months (0.00 ± 0.000) respectively. (Table-5, Graph-3) The mean intensity of pain or discomfort for Group B were: baseline (5.46 ± 1.303), 7th day (1.69 ± 1.087), 1 month (0.27 ± 0.452) and 6 months (0.00 ± 0.000) respectively (Table-5, Graph-5). On intragroup comparison mean intensity of pain or discomfort in Group A from baseline to 6 months was (0.04 ± 0.196) and in Group B was (1.69 ± 1.087) (Table-6, Graph-6a)

Table 4- Intergroup comparison of changes in Healing Index Score over a period of 6 months

Healing Index Score	Test Group		Control Group		P value
	Mean	SD	Mean	SD	
1W to 1M	1.54	0.508	1.88	0.766	0.102#
1W to 6M	1.54	0.508	2.04	0.871	0.016*
1M to 6M	0.00	0.000	0.23	0.430	0.010*

Graph 4- Intergroup comparison of changes in Healing Index Score over a period of 6 months



On intergroup comparison over a period of 6 months, the mean intensity of pain or discomfort from baseline to 7th day was (0.04 ± 0.196) in Group A while (1.65 ± 0.977) in Group B. This difference between the groups was statistically significant (p=0.000) (Table-6, Graph-6a). The mean intensity of pain or discomfort from baseline to 1 month was (0.04 ± 0.196) in Group A while (1.65 ± 0.977) in Group B. This difference between the groups was statistically significant (p=0.000) (Table-6, Graph-6a). The mean intensity of pain or discomfort from baseline to 6 months was (0.04 ± 0.196) in Group A while (1.69 ± 1.087) in Group B. This difference between the groups was statistically significant (p=0.000) (Table-6, Graph-6a). The mean intensity of pain or discomfort from 7th day to 1 month was (0.00 ± 0.000) in Group A while (0.00 ± 0.000) in Group B. This difference between the groups was not statistically significant (p=1.000) (Table-6, Graph-6b). The mean intensity of pain or discomfort from 7th day to 6 months was (.00 ± 0.000) in Group A while (0.27 ± 0.452) in Group B. This difference between the groups was highly statistically significant (p=0.005) (Table-6, Graph-6b). The mean intensity of pain or discomfort from 1 month to 6 months was (0.00 ± 0.000) in Group A while (0.27 ± 0.452) in Group B. This difference between the groups was highly statistically significant (p=0.005) (Table-6, Graph-6b).

Table 5- Intragroup comparison of changes in VAS Score over a period of 6 months

VAS Score at Test Group	Baseline	7th day	I month	6 months	P value
Mean	0.15	0.00	0.00	0.00	0.000*
SD	0.368	0.000	0.000	0.000	
VAS Score at Control Group	Baseline	7th day	I month	6 months	P value
Mean	5.46	1.69	0.27	0.00	0.000*
SD	1.303	1.087	0.452	0.000	

Graph 5 - Intragroup comparison of changes in VAS Score over a period of 6 months

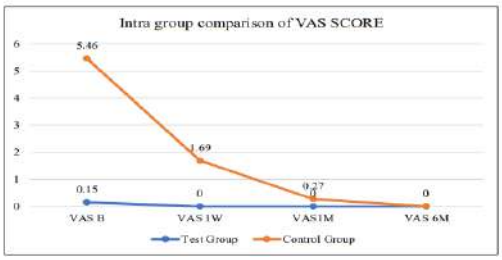
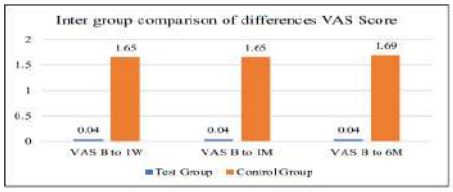


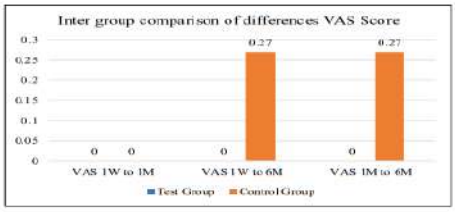
Table 6- Intergroup comparison of changes in VAS Score over a period of 6 months

VAS Score	Test Group		Control Group		P value
	Mean	SD	Mean	SD	
B to 1W	0.04	0.196	1.65	0.977	0.000**
B to 1M	0.04	0.196	1.65	0.977	0.000**
B to 6M	0.04	0.196	1.69	1.087	0.000**
1W to 1M	0.00	0.000	0.00	0.000	1.000#
1W to 6M	0.00	0.000	0.27	0.452	0.005**
1M to 6M	0.00	0.000	0.27	0.452	0.005**

Graph 6a- Intergroup comparison of changes in VAS Score over a period of 6 months



Graph 6b- Intergroup comparison of changes in VAS Score over a period of 6 months



DISCUSSION

Gingival health and it's appearance are pivotal components of a good smile. Gingival melanin hyperpigmentation is an aesthetic concern amongst many individuals with a high lip line and a gummy smile. Although, this does not pose a medical problem, demands for cosmetic correction of gingival melanin hyperpigmentation have become increasingly common in today's aesthetically driven world of dentistry.[74, 75]

Melanin pigmentation appear in the gingiva as early as 3 hours after birth.[76] Physiologic pigmentation is probably genetically determined, but Dummet CO (1971)[76] suggested the degree of pigmentation is related to mechanical, physical and chemical stimulation. Melanin hyperpigmentation may be associated with conditions like endocrine disturbances, Albright's syndrome, malignant melanoma, Peutz-Jegher's syndrome, Addison's disease and Von Recklinghausen's disease.

Gingival depigmentation is a periodontal plastic surgical procedure aimed at removing or reducing the hyperpigmentation. Since gingival depigmentation is a cosmetic procedure, the technique should be simple, less technique sensitive and minimally invasive.[77] Various depigmentation techniques include chemical exfoliation of the pigmented tissue, bur abrasion, scalpel surgery, cryosurgery, electrosurgery, gingival grafts, and laser[78] Most of these techniques involve removal of the full thickness of the epithelium and part of the papillary connective tissue layer. These techniques may result in harmful effects such as chemical burn, delayed healing, excessive pain and discomfort, bone necrosis and difficulty to control the depth of penetration.[70]

The selection of a particular technique for depigmentation should be based on experience of clinician, affordability of patient's and preferences. Hence, there is a need for a minimally invasive surgical gingival depigmentation technique. Therefore, the present study was conducted to comparatively evaluate depigmentation using ceramic soft tissue trimming bur versus scalpel for treatment of physiological gingival melanin hyperpigmentation.

In this study, sixty-two sites with physiological gingival melanin hyperpigmentation, having a DOPI score of 2 or 3 (Dummett CO and Gupta OP 1964) [23, 24] were selected. Twenty-six selected sites underwent depigmentation using Ceramic soft tissue trimming bur, whereas the remaining twenty-six sites underwent depigmentation using scalpel surgical technique. The surgical procedure was performed under aseptic precautions and subjects were recalled at 7th day, 1 month and 6 months postoperatively for follow up examination and assessment of clinical parameters.

Scalpel depigmentation technique, which was first illustrated by Dummet and Bolden (1963)[79]. Surgical bur abrasion method was first reported by Ginwalla et al (1966)[80] which involves de-epithelisation of pigmented areas of the gingiva by using high speed rotary instruments.

Ceramic soft tissue trimming bur is a rotating bur. It is a rotating scalpel for soft tissue which promotes coagulation with minimal bleeding. Ceramic soft tissue trimming bur point is made from a very hard and durable bio-compatible oxide material. They are made up of mixed ceramic composed of Zircon-dioxide partly stabilized by Yttrium and Aluminium ceramic. They are used at 300,000 rpm - 450,000 rpm without cooling. Here, the kinetic energy is converted to heat. It secures a nice and gentle cut.

The gingival melanin pigmentation index (DOPI) score was assessed using Dummett-Gupta Oral Pigmentation Index (Dummett CO, Gupta OP, 1964)[23,24] at baseline, 7th day, 1 month and 6 months. In the present study, on intragroup comparison there was a statistically highly significant difference seen for DOPI score at baseline as compared to 7th day, 1 month and 6 months ($p<0.01$) follow up. However, on intergroup comparison there was a statistically highly significant difference seen at baseline and 1 month in the Group A($p<0.01$). Test sites treated with ceramic soft tissue trimming bur showed slight or no pigmentation as compared to control sites treated with scalpel depigmentation technique over a period of 6 months. The findings of this study were similar to those reported by Goldar K et al (2020)[42]and Negi R et al (2019)[41]. Goldar K et al (2020)[42]stated thatceramic soft tissue trimmer showed delayed re-pigmentation index than rest all other procedures. Negi R et al (2019)[41] stated that DOPI scores were significantly reduced from baseline in sites treated with ceramic soft tissue trimmer bur and LASER.

The woundhealing was assesse dusing Healing Index (LandryRG, TurnbullRS, HowleyT 1988)[11]at baseline, 7th day, 1 month and6 months. In the present study, on intragroup comparison there was a statistically highly significant difference seen for wound healing index score at baseline as compared to 7th day, 1 month and 6 months ($p<0.01$) follow up. However, on intergroup comparison there was a statistically highly significant difference seen at 1 week and 1 month in the Group A($p<0.01$). In this study, sites treated with ceramic soft tissue trimming bur resulted in rapid wound healing as compared to scalpel depigmentation technique over a period of 6 months. The finding of this study was similar to those reported by Goldar K et al (2020)[42]and Negi R et al (2019)[41]. Goldar K et al (2020)[42]stated thatceramic soft tissue trimmer has a better healing index compared to other procedures. Negi R et al (2019)[41] showed ceramic soft tissue trimmer bur treated areas healed faster compared to LASER treated areas.

The intensity of pain or discomfort was assessed using Visual Analogue Scale (Matthews DC, McCulloch CAG 1993)[73] at baseline, 7th day, 1 month and 6 months. In the present study, on intragroup comparison there was a statistically highly significant difference seen for VAS score at baseline as compared to 7th day, 1 month and 6 months ($p<0.01$) follow up. However, on intergroup comparison there was a statistically highly significant difference seen at baseline, 1week and 1month in the Group B($p<0.01$). In this study, sites treated with ceramic soft tissue trimming bur resulted in minimal or no pain as compared to scalpel depigmentation technique over a period of 6 months. The finding of this study was similar to the study conducted by Goldar K et al (2020)[42]. Goldar K et al (2020)[42] showed ceramic soft tissue trimmer has a low pain index compared to other procedures. However, Negi R et al (2019)[41] stated that ceramic soft tissue trimming bur treated patients reported slight to moderate pain as compared to LASER.

The reappearance of melanin pigment after a period of clinical depigmentation is called as repigmentation. Repigmentation may be related to the technique used in depigmentation procedure and the race of the patient. The mechanism of re-pigmentation is explained by migration theory, according to this theory active melanocytes from the adjacent pigmented tissues migrate to treated areas, causing re-pigmentation. Re-pigmentation may also be attributed to the melanocytes which are left during surgery as stated by Ginwalla et al (1966).[80] These may become activated and start synthesizing melanin.

In this study, out of 26 sites treated with ceramic soft tissue trimming bur, 22 sites resulted in delayed repigmentation at 6 months as compared to scalpel depigmentation technique where 24 sites resulted in delayed repigmentation at 1 month and 6 months.

The pattern of recurrence with re-pigmentation was patchy in distribution and due to its mild intensity, the results were considered to be satisfying for the patients. Recurrence can be prevented by the entire removal of melanin including free gingiva and interdental papilla since repigmentation starts as a result of migrating melanocytes from free gingiva. Adequate

tissue removal may not be possible at the marginal gingiva and interdental papilla region due to close proximity of the adjacent teeth. Ginwallaet al80 reported re-pigmentation in 50% of their cases between 24 and 55 days.

Kawar NI et al (2021)[81] in a case report presented a simple non-invasive gingival sculpting depigmentation technique, using a combination of diamond burs and scalpels. They stated that gingival sculpting is minimally invasive procedure that which renders excellent esthetic results.

The findings of this study were similar to a systematic review and meta-analysis conducted by Gul M et al (2019)[72], where they assessed the most effective method for the management of physiologic gingival hyperpigmentation. They concluded that, surgical stripping has been the conventional treatment of choice, but the new techniques are equally effective or even better than conventional scalpel surgery when different parameters were assessed.

In this study, ceramic soft tissue trimming bur treated areas required minimal chair side time and effort with delayed repigmentation than scalpel depigmentation technique. The finding of this study was not in accordance with the study reported by Abdelmagyd HA et al (2019).[82] They stated that gingival depigmentation using scalpel method has an advantage of being effective and requires minimum time and effort with the lowest rate of repigmentation compared to laser and abrasion methods.

Thus, within the limitations of the present study, this minimally invasive surgical technique with ceramic soft tissue trimming bur resulted in reduction of the gingival melanin hyperpigmentation with minimal bleeding, rapid wound healing and less post-operative pain and discomfort. Hence, the use of ceramic soft tissue trimming bur might prove to be a boon in achieving aesthetic satisfaction.Occurrence of repigmentation needs to be assessed and comparative evaluation of repigmentation, evidence of repigmentation with ceramic soft tissue trimming bur versus scalpel depigmentation technique needs to be done are the limitations of the study.

CONCLUSION

The present study was conducted to comparatively evaluate depigmentation using ceramic soft tissue trimming bur versus scalpel for treatment of physiological gingival melanin hyperpigmentation.

A total of 52 sites with physiological gingival melanin hyperpigmentation and with esthetic concerns for the same were included in this study. 26 sites with gingival melanin hyperpigmentation were treated using ceramic soft tissue trimming bur in the Group A, whereas scalpel depigmentation technique was performed in the other 26 sites in the Group B. The clinical parameters were assessed at baseline, 7th day, 1 month and 6 months.

There was a statistically significant decrease in the pigmentation scores, wound healing index scores as well as the degree of pain and discomfort at 6 months as compared to the baseline scores.

Thus, within the limits of this study, it can be concluded that the effectiveness of ceramic soft tissue trimming bur in the treatment of gingival melanin hyperpigmentation is clinically favourable. This minimally invasive surgical technique with Ceramic soft tissue trimming bur is better than scalpel depigmentation technique as it causes minimal bleeding, rapid wound healing and less post-operative pain and discomfort as compared to scalpel depigmentation technique. Hence, the use of ceramic soft tissue trimming bur might prove to be a boon in achieving aesthetic satisfaction.

References

1. Doshi Y, Khandge N, Byakod G, Patil P. Management of gingival pigmentation with diode laser: Is it a predictive tool? Int J Laser Dent 2012; 2(1): 29 32.
2. Fiorellini JP, Kim DM, Uzel NG. Clinical features of gingivitis. In: Newman MG, Takei HH, Klokkevold PR, Carranza FA, (ed.). Carranza's Clinical Periodontology. St. Louis: Elsevier; 2012.p.112-113.
3. Dummett CO. Oral pigmentation: First symposium on oral pigmentation. J Periodontol 1960; 31: 356-360.
4. Almas K, Sadig W. Surgical treatment of melanin-pigmented gingiva; an esthetic approach. Indian J Dent Res 2002; 13(2): 70-73.
5. Dummett CO, Barens G. Pigmentation of the oral tissues: a review of the literature. J Periodontol 1967; 38(5): 369-378.
6. Ibusuki M. The color of gingiva studied by visual color matching Part II. Kind, location and personal difference in color of the gingiva. Bull Tokyo Med Dent Univ 1975; 22: 281–292.
7. Prasad D, Sunil S, Mishra R, Sheshadri. Treatment of gingival pigmentation: A case series. Indian J Dent Res 2005; 16: 171-176.
8. Murthy MB, Kaur J, Das R. Treatment of gingival hyperpigmentation with rotary abrasive, scalpel, and laser techniques: A case series. J Indian Soc Periodontol 2012; 16(4): 614-619.
9. Sanadi RM, Pillai MV, Chawla V. Gingival melanin depigmentation using cryotherapy: a case report. Global J Res Analysis 2019; 8(1): 459-461.
10. Cheraskin E. Diagnosis of pigmentations of the oral tissues. In: Dumette CO, consulting editor. First Symposium on Oral pigmentation. J Periodontol 1960; 31: 375-382.
11. Rawal YS, Burrell R, Hamidi SC, Kalmar JR, Tatakis DN. Diffuse pigmentation of maxillary attached gingiva: Four cases of the cultural practice of gingival tattoo. J Periodontol 2007; 78: 170-173.
12. Malhotra S, Sharma N, Basavaraj P. Gingival esthetics by depigmentation. J Periodontal Med Clin Pract 2014; 1: 79-84.
13. Lin YH, Tu YK, Lu CT, Chung WC, Huang CF, Huang MS, Lu HK. Systematic Review of Treatment Modalities for Gingival Depigmentation: A Random Effects Poisson Regression Analysis. J Esthetic Res Dent 2014; 26(3): 162-178.
14. Cicek Y, Ertas U. The normal and pathological pigmentation of oral mucous membrane: a review. J Contemp Dent Pract. 2003: 15; 4(3):76-86.
15. Moneim RA, El Deeb M, Rabea AA. Gingival pigmentation (cause, treatment and histological preview). Futur Dent J 2017 1; 3(1): 1-7.
16. Dummet CO, Barens G. Oromucosal pigmentation: an updated literary review. J Periodontol. 1971; 42(11): 726-736.
17. Bayindir F, Bayindir YZ, Gozalo-Diaz DJ, Wee AG. Coverage error of gingival shade guide systems in measuring color of attached anterior gingiva. J Prosthet Dent 2009; 101(1): 46-53.

18. Özbayrak S, Dumlu A, Ercalik-Yalcinkaya S. Treatment of melanin-pigmented gingiva and oral mucosa by CO2 laser. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2000; 90: 14-15.
19. Dummett CO. Oral tissue color changes (I). Quintessence Int. 1979; 10(11): 39-45.
20. Brown FH, Housten GD. Smoker's melanosis- A case report. J Periodontol. 1991; 62(8): 524-527.
21. Gorsky M, Buchner A, Fundoianu-Dayan D, Aviv I. Physiologic pigmentation of the gingiva in Israeli Jews of different ethnic origin. Oral Surg Oral Med Oral Pathol 1984; 58(4): 506-509.
22. Patsakas A, Demetriou N, Angelopoulos A. Melanin pigmentation and inflammation in human gingiva. J Periodontol 1981; 52 (11): 701-704.
23. Dummett CO, Gupta OP. Estimating the epidemiology of oral pigmentation. J National Med Assoc 1964; 56(5): 419-420.
24. Raman RA, Pratebha B, Jananni M, Saravanakumar R. Computerized Intensity Values to Objectivize Dummett–Gupta Classification of Physiologic Gingival Pigmentation. Clin Adv Periodontics 2015; 5(2): 140-145.
25. Hedin CA. Smoker's melanosis. Occurrence and localization in the attached gingiva. Arch Dermatol 1977; 113: 1533 -1538.
26. Hanioka T, Tanaka K, Ojima M, Yuuki K. Association of melanin pigmentation in the gingiva of children with parents who smoke. Pediatrics 2005; 116(2): 186-190.
27. Kumar S, Bhat SG, Bhat MK. Development in techniques for gingival depigmentation-An update. Indian J Dent 2012; 3: 213–221.
28. Peeran SW, Ramalingam K, Peeran SA, Altaher OB, Alsaid FM, Mugrabi MH. Gingival pigmentation index proposal of a new index with a brief review of current indices. European J Dent 2014; 8(2): 287-290.
29. Dummett CO. Oral tissue color changes. Ala J Med Sci 1979; 16: 274-283.
30. Roshna T, Nandakumar K. Anterior esthetic gingival depigmentation and crown lengthening: Report of a case. J Contemp Dent Pract. 2005; 6(3): 139-147.
31. Almas K, Sadiq W. Surgical approach of melanin pigmented gingival; An esthetic approach. Indian J Dent Res 2002; 13(2): 70-73.
32. Farnoosh AA. Treatment of gingival pigmentation and discoloration for esthetic purposes. Int J Periodontics Rest Dent 1990; 10: 312-319.
33. Thangavelu A, Elavarasu S, Jayapalan P. Pink esthetics in periodontics – Gingival depigmentation: A case series. J Pharm Bioall Sci. 2012; 4: 186-190.
34. Atsawasuwan P, Greethong K, Nimmanon V. Treatment of gingival hyperpigmentation for esthetic purposes by Nd: YAG laser: Report of 4 cases. J Periodontol. 2000; 71: 315–321.
35. Yeh CJ. Cryosurgical treatment of melanin pigmented gingiva. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1998, 86: 660-663.
36. Tamizi M, Taheri M. Treatment of severe physiologic gingival pigmentation with free gingival autograft. Quintessence Int. 1996; 27(8): 555-558.
37. Fowler EB, Breault LG, Galvin BG. Enhancing physiologic pigmentation utilizing a free gingival graft. Pract Periodontics Aesthet Dent 2000; 12: 193-196.
38. Hirschfeld I, Hirschfeld L. Oral pigmentation and method of removing it. Oral Surg Oral Med Oral Pathol 1951; 4: 1012-1016.
39. Pontes AE, Pontes CC, Souza SL, Novaes AB Jr, Grisi MF, Taba M Jr. Evaluation of the efficacy of the acellular dermal matrix allograft with partial thickness flap in the elimination of gingival melanin pigmentation - A comparative clinical study with 12 months of follow-up. J Esthet Restor Dent 2006, 18: 135-143.
40. Phillips GE, John V. Use of a subepithelial connective tissue graft to treat the area pigmented with graphite. J Periodontol. 2005; 76: 1572-1575.
41. Negi R, Gupta R, Dahiya P, Kumar M, Bansal V, Samlok JK. Ceramic soft tissue trimming bur: A new tool for gingival depigmentation. J Oral Biol Craniofac Res 2019; 9(1): 14-18.
42. Goldar K, Chaubey KK, Agarwal S, Agarwal T. Gingival depigmentation by gingival ceramic trimmer. Univ J Dent Sci 2020; 6(1): 43-48.
43. Lagdive S, Doshi Y, Marawar PP. Management of Gingival Hyperpigmentation Using Surgical Blade and Diode Laser Therapy: A Comparative Study. J Oral Laser Appl 2009; 9(1): 41-47.
44. Anoop S, Abraham S, Ambili R, Mathew N. Comparative evaluation of gingival depigmentation using scalpel and diode laser with 1 year follow-up. Int J Laser Dent 2012; 2(3): 87-91.
45. Grover HS, Dadlani H, Bhardwaj A, Yadav A, Lal S. Evaluation of patient response and recurrence of pigmentation following gingival depigmentation using laser and scalpel technique: A clinical study. J Indian Soc Periodontol 2014; 18(5): 586-592.
46. Butchibabu K, Koppolu P, Tupili MK, Hussain W, Bolla VL, Patakota KR. Comparative evaluation of gingival depigmentation using a surgical blade and a diode laser. J. Dent. Lasers. 2014; 8(1): 20-25.
47. Bhardwaj A, Uppoor AS, Naik DG. A comparative evaluation of management of melanin pigmented gingiva using a scalpel and laser. J Interdisciplinary Dentistry. 2014; 4(3): 135-139.
48. Sanadi R, Suthar N, Bhusari BM, Chelani L Gingival depigmentation using Scalpel technique versus laser technique: A case report. J Dent Med Sci 2015; 14(8): 38-40.
49. Maniyar M, Kukreja E, Gaikwad R. Comparative Evaluation of two treatment modalities for a patient with Pigmented Gingiva. J Indian Dent. Assoc. 2015; 9(6): 35-40.
50. Nagati RR, Ragul M, Al Qahtani NA, KS R. Clinical effectiveness of gingival depigmentation using conventional surgical scrapping and diode laser technique: a quasi experimental study. Glob J Health Sci 2017; 9(3): 296-303.
51. Suragimath G, Lohana MH, Varma S. A split mouth randomized clinical comparative study to evaluate the efficacy of gingival depigmentation procedure using conventional scalpel technique or diode laser. J Lasers Med Sci 2016; 7(4): 227-232.

52. Sagar G, Rajesh N, Kumar T, Reddy K K, Shankar B S, Sandeep V. Comparative evaluation of two surgical techniques using conventional scalpel method and diode laser for treatment outcome of depigmentation: 6 months follow-up study. J Dent Lasers 2016; 10: 2-9.
53. Prasad D, Sunil S, Mishra R. Treatment of gingival pigmentation: A case series. Indian J Dent Res 2005; 16(4): 171-176.
54. Mani A, Mani S, Shah S, Thorat V. Management of gingival hyperpigmentation using surgical blade, diamond bur and diode laser therapy- A case report. J Oral Laser Appl 2009; 9(4): 227-232.
55. Kathariya R, Pradeep AR. Split mouth de-epithelization techniques for gingival depigmentation: A case series and review of literature. J Indian Soc Periodontol 2011; 15(2): 161-168.
56. Gokhale ST, Vatsala V, Gupta R, Gupta I. Treatment of gingival hyperpigmentation by scalpel surgery and electrosurgery: a split mouth design. Indian J Dent Sci 2011; 3(4): 10-11.
57. Bhusari BM, Kasat S. Comparison between scalpel technique and electrosurgery for depigmentation: A case series. J Indian Soc Periodontol 2011; 15(4): 402-405.
58. Murthy MB, Kaur J, Das R. Treatment of gingival hyperpigmentation with rotary abrasive, scalpel and laser techniques: A case series. J Indian Soc Periodontol 2012; 16(4): 614-619.
59. Thangavelu A, Elavarasu S, Jayapalan P. Pink esthetics in periodontics–Gingival depigmentation: A case series. J Pharm Bioallied Sci 2012; 4(Suppl 2): S186-S190.
60. Pasupuleti K, Reddy R, Roopa D, Sahitya S, Swamy N. Aesthetic gingival depigmentation procedures: clinical and patient responses. J Stomat Occ Med 2012; 5: 28–37.
61. Kikani A, Parikh H, Sheth T, Nayak K. Aesthetic management of gingival hyperpigmentation by electrocautery with review of literature - A Case Report. J Ahmedabad Dent Coll Hosp 2011; 2(2): 99-104.
62. Mahesh HV, Harish MR, Shashikumar BM, Ramya KS. Gingival pigmentation reduction: A novel therapeutic modality. J Cutan Aesthet Surg.2012; 5(2): 137-140.
63. Deepa D, Chawla A, Srivastava P. Gingival Depigmentation By Scalpel, Diode Laser And Electrosurgery-A Case Report. Indian J Dent Sci 2013; 5(1): 62-64.
64. Kaushik N, Srivastava N, Kaushik M, Gaurav V. Efficacy of different techniques of gingival depigmentation; A comparative evaluation with a case report. Int J Laser Dent 2013; 3(2): 68-72.
65. Gupta G, Kumar A, Khatri M, Puri K, Jain D, Bansal M. Comparison of two different depigmentation techniques for treatment of hyperpigmented gingiva. J Indian Soc Periodontol 2014; 18(6): 705-709.
66. Varghese AI, Byju M, Abraham SS, Isac S, Anto A. Case Report Revel the pink-gingival depigmentation: report of two cases. Sch J Dent Sci, 2015; 2(2B): 159-162.
67. Sheel V, Purwar P, Dixit J, Rai P. Ancillary role of vitamin C in pink aesthetics. British Med J Case Rep 2015; 65: 27-31.
68. Narayankar SD, Deshpande NC, Dave DH, Thakkar DJ. Comparative evaluation of gingival depigmentation by tetrafluroethane cryosurgery and surgical scalpel technique. A randomized clinical study. Contemp. Clin. Dent. 2017; 8(1): 90-95.
69. Renganath MJ, Ramakrishnan T, Vidya Sekhar MN, Ebenezer M, Anithadevi S. Black to pink: A case report of treating gingival hyperpigmentation. Int J Cur Res Rev 2017; 9: 14-17.
70. Yussif NM, Rahman AR, ElBarbary A. Minimally invasive non-surgical locally injected vitamin C versus the conventional surgical depigmentation in treatment of gingival hyperpigmentation of the anterior esthetic zone: A prospective comparative study. Clin Nutr Exp; 24: 54-65.
71. Wagle SV, Agrawal AA, Sankhe R. Gingival depigmentation using scalpel. Biomed Biotechnol Res J 2018; 2(3): 223-225.
72. Gul M, Hameed MH, Nazeer MR, Ghafoor R, Khan FR. Most effective method for the management of physiologic gingival hyperpigmentation: A systematic review and meta-analysis. J Indian Soc Periodontol. 2019; 23(3): 203-215.
73. Matthews DC, McCulloch CA. Evaluating patient perceptions as short-term outcomes of periodontal treatment: A comparison of surgical and non-surgical therapy. J Periodontol. 1993 Oct; 64(10): 990-997.
74. Prasad S, Agrawal N, Reddy N. Gingival depigmentation: A case report. People's J Sci Res 2010; 3(1): 27-29.
75. Javali M, Tapashetti R, Deshmukh J. Esthetic management of gingival hyperpigmentation: Report of two cases. Int J Dent Clin 2011; 3(2): 115-116.
76. Dummett CO. Physiologic pigmentation of the oral and cutaneous tissues in the negro. J Dent Res 1946; 25: 421 32.
77. Lin YH, Tu YK, Lu CT, Chung WC, Huang CF, Huang MF, Lu HK. Systematic Review of Treatment Modalities for Gingival Depigmentation: A Random-Effects Poisson Regression Analysis. J Esthet Restor Den 2014; 26: 162–78.
78. Doshi Y, Khandge N, Byakod G, Patil P. Management of gingival pigmentation with diode laser. Is it a predictive tool? Int J Laser Dent 2012; 2 (1): 29-32.
79. Suchetha A, Shahna N, Bhat D, Mand AS, Sapna N. A review on gingival depigmentation procedures and repigmentation. Int J Applied Dent Sci 2018; 4: 336-41.
80. Ginwalla TM, Gomes BC, Varma BR. Surgical removal of gingival pigmentation. (A preliminary study). J Indian Dent Assoc 1966; 38(6): 147-50.
81. Kawar NI, Alrayyes SM, Khuzam M, Haddad JR, Tilwani SK. Gingival Sculpting: A Simple Gingival Depigmentation Technique Using Bur Abrasion and Scalpel Combined–A Case Report. Clin adv periodontics 2021; 11(3): 145-149.
82. Abdelmagyd HA, Al-Ahmari MM, Shetty SR. Treatment of gingival hyperpigmentation using different techniques. J Datta Meghe Inst Med Sci Univ 2019; 14(1): 50-55.

How to cite this article: Jain Priyanka P, Sanadi Rizwan M and Pol Kavita G. (2023). Comparative evaluation of depigmentation using ceramic soft tissue trimming bur versus scalpel for treatment of physiological gingival melanin hyperpigmentation: a randomized controlled trial. *Int J Recent Sci Res.15*(01), pp.4503-4511.

Review Article

Periodontal Disease a Possible Risk Factor for Osteoradionecrosis in Patients Undergoing Radiation Therapy – A Systematic Review

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Abstract

Background: Poor oral hygiene is one of the factor leading to periodontal disease. The effect of radiation therapy on periodontal health is dose dependent and is associated with poor periodontal health before radiotherapy initiation. Osteoradionecrosis, a serious dental complication is often seen in individuals undergoing radiation therapy; especially in individuals with poor oral hygiene.

Aim: To analyze the association of osteoradionecrosis with periodontal disease in oral cancer patients receiving radiation therapy.

Materials and methods: An electronic database search was performed at PubMed, Google Scholar, EBSCO Host, EMBASE and Science Direct from August 2021 to January 2022.

Results: Ninety-seven articles were identified on searching the electronic databases. Only two randomized controlled clinical trials and two case reports qualified for the qualitative synthesis. The included studies were assessed for the risk of bias.

Conclusion: Periodontal disease is a possible risk factor for osteoradionecrosis individuals with oral cancer undergoing radiation therapy. However there remains a need for conducting studies to further evaluate the association between osteoradionecrosis and periodontal disease.

Keywords: Oral cancer, Osteoradionecrosis, Periodontal disease, Radiation therapy

Key messages: Oral cancer patients undergoing radiation therapy may have difficulty in maintaining oral hygiene, thereby resulting in progression of periodontal disease. Proper oral hygiene maintenance protocol needs to be followed for patients with oral cancer undergoing radiation therapy.

Introduction:

Periodontal disease (Periodontitis) is an inflammatory condition of gums and the teeth supporting tissues.[1] It is characterized by the destruction of connective tissue and dental bone support subsequent to infection by microorganisms.[2] Periodontitis has been considered as a risk factor for Osteoradionecrosis (ORN).[1]

Radiotherapy (RT) is one of the mainstays of treatment for any type of carcinomas. For oral cavity cancer, RT is often used in the postoperative setting after surgical resection. ORN is still one of the most serious dental complications in cancer patients who receive RT, and often occurs in patients with poor oral hygiene.

ORN is defined as exposed irradiated bone tissue that fails to heal over a period of 3 months without a residual or recurrent tumor.[3] Marx, described ORN as "a complex metabolic and homeostatic deficiency of tissue that is created by radiation-induced cellular injury; microorganisms play only a contaminating role in ORN, and trauma may or may not be an initiating factor."[4]

The effect of radiation therapy on periodontal health is dose dependent. The local effect on periodontal tissue when high dose fraction of radiation is used, involves alterations in the cellularity, vascularity and reduced healing/remodeling potential of the periodontium.[5]

Rationale:

Radiation therapy is one of the most routinely performed treatment in cancer patients. This may lead to the radiation induced disease known as osteoradionecrosis. The patients suffering from oral cancer also have difficulty in maintaining oral hygiene, thereby leading to periodontal disease. However, to our knowledge, there is limited literature available that assesses the role of periodontal disease as possible risk factor for development of osteoradionecrosis in patients with oral cancer undergoing radiation therapy. The purpose of this study was to evaluate whether ORN is associated with periodontal disease in individuals with oral cancer undergoing Radiation Therapy.

Focused question: Is periodontal disease a possible risk factor for osteoradionecrosis in patients undergoing radiation therapy?

Another research question: Does treatment of periodontal disease in osteoradionecrosis patients undergoing radiation therapy reduce further complications?

Primary objective: To evaluate the association of periodontal disease as a possible risk factor for osteoradionecrosis in patients undergoing radiation therapy.

Secondary objective: To analyze the role of periodontal disease on osteoradionecrosis in patients undergoing radiation therapy.

Materials and methods:

Protocol and Registration: The protocol was registered at: https://.crd.york.ac.uk

Prospero Registration number: CRD42022302572

Study design: The present systematic review of case-control studies, cohort studies, randomized controlled trials, experimental studies and case reports was conducted to assess and analyze the existing evidence on role of periodontal disease on osteoradionecrosis in patients undergoing radiation therapy.

Inclusion criteria:

1. Case-control studies, cohort studies, randomized controlled trials, experimental studies and case reports.
2. Articles published in peer-reviewed journals in English.
3. Oral cancer patients undergoing radiation therapy.

Exclusion criteria:

1. Narrative and Literature Review articles
2. Animal model studies and in vitro studies
3. Head and neck cancer patients
4. Unpublished research.

Information sources & search strategy:

An electronic database search for case-control studies, cohort studies, randomized controlled trials, experimental studies and case reports published in English language in peer-reviewed Journals was conducted from the following electronic databases: PubMed, Google Scholar, EBSCO Host, EMBASE and Science Direct.

The following terms were used for search:

Periodontal disease "OR" Periodontitis "OR" Gingivitis "AND" Osteoradionecrosis "OR" Oral cancer "OR" Radiation therapy Periodontitis "AND" Osteoradionecrosis

Periodontal disease "AND" Radiation therapy "AND" osteoradionecrosis Oral cancer "AND" Periodontitis "AND" Osteoradionecrosis

Study selection:

Three reviewers participated in the study selection process and no duplicate data was extracted. Inter-observer reliability was achieved by calibration sessions until an almost perfect agreement was obtained. Hence there was no disagreement between the reviewers.

Study selection was carried out in two phases:

i. Assessment of titles and abstracts

ii. Assessment of full text.

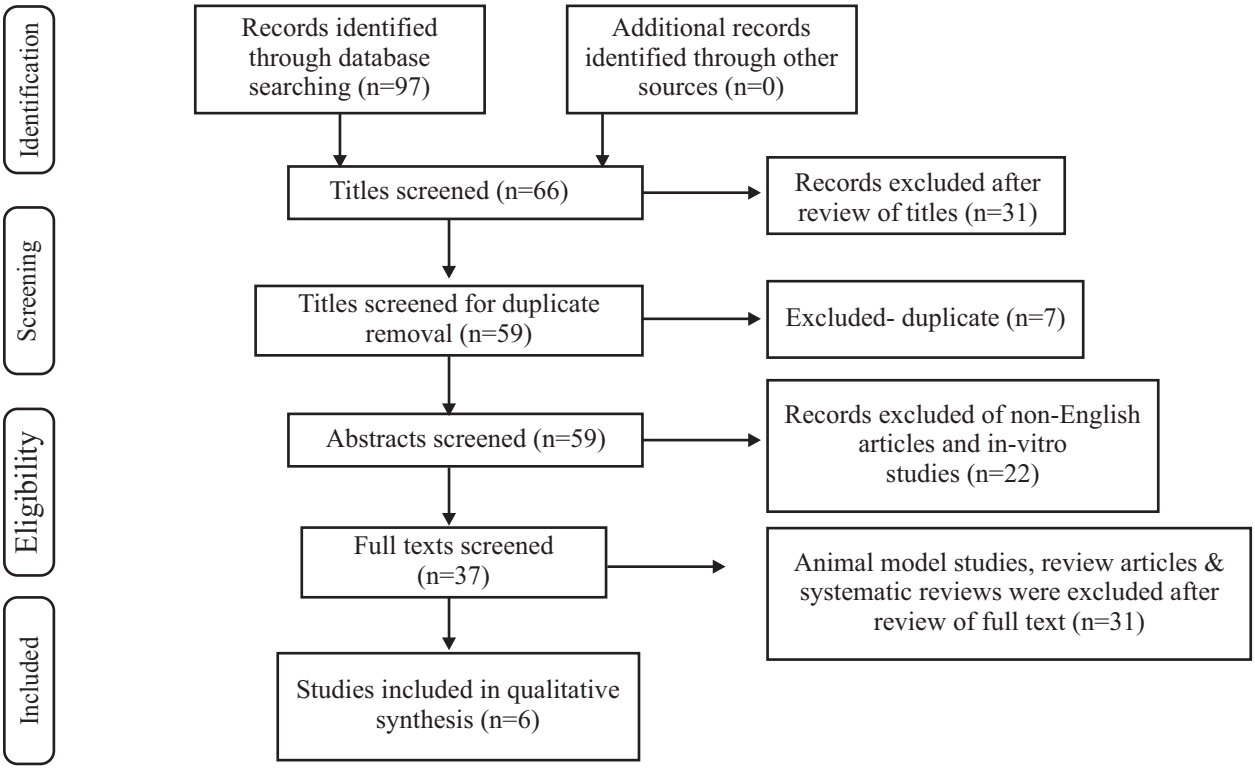
Data extraction process:

Data extraction sheet was prepared based on variables associated, and the articles were analyzed. Using data extraction sheet, the following data were collected: authors, year of publication, country, aim, type of study, sample size, comparison group and control group, methodology and conclusion.

Data items: Variables for which data was sought included Periodontal disease, Osteoradionecrosis.

1. **Periodontal disease (PD)** – Periodontal disease is defined as "an inflammatory disease of the supporting tissues of the teeth caused by specific microorganisms or groups of specific microorganisms, resulting in progressive destruction of the periodontal ligament and alveolar bone with increased probing depth formation, recession, or both."
2. **Osteoradionecrosis (ORN)** – Osteoradionecrosis is an inflammatory condition of bone that occurs after the bone has been exposed to therapeutic doses of radiation usually given for a malignancy.

Figure 1: Flow chart of literature search results and study selection



Results:

A total of 97 articles were found after electronic search. Thirty one articles were excluded after review of titles. After excluding duplicates, abstracts of 59 articles were screened. Subsequently, 22 articles were excluded as they were in different language other than English and were in vitro studies. Thirty one articles were excluded as they did not fulfill the eligibility criteria. Six articles were included for qualitative synthesis. Figure 1 shows the flow chart of literature search results and study selection.

Studies included for the analysis

Six studies were included for the qualitative synthesis. Out of the 6 studies, 2 were randomized clinical trials and 4 were retrospective cohort studies. Table 1 shows characteristics of the studies included in the systematic review.

Table 1: Characteristics of included studies:

Author and year of publication	Country	Aim	Type of cancer	Type of study	Sample size, comparison group & control group	Methodology	Conclusion
Satheeshkumar PS, Chamba MS, Balan A, Sreelatha KT, Bhatathiri VN, Bose T. (2010)[6]	India	1) To determine the effectiveness of triclosan in the management of radiation induced oral mucositis. 2) To compare the effectiveness of triclosan mouth rinse with conventional sodium bicarbonate mouth rinse	Oral cancer	Randomized Clinical trial	Twenty-four patients Test group: Triclosan 0.03% W/V mouthwash Control group: Sodium bicarbonate 2 mg mouth wash	Twenty-four patients who underwent radiation therapy for oral cancer and subsequently developed oral mucositis were included in the study. They were randomly allocated into two groups on noticing grade I mucositis (erythema). The	Triclosan mouthwash was found to be effective in reducing the severity of radiation-induced oral mucositis and helped in early reversal of symptoms during post treatment period.

To be Cont..

Table 1: Characteristics of included studies:

						study group was advised to use triclosan mouthwash containing triclosan 0.03% W/V and sodium bicarbonate 2 mg mouth wash for the control group. A weekly follow-up evaluation of body weight, food intake, pain and grading of mucositis were made during the radiation treatment period and post radiation treatment period.	

Studies excluded from the analysis: 6 studies were excluded as they were review articles. An overview of the excluded studies is presented in Table 2.

Table 2: Characteristics of excluded studies

Author (year)	Reason for exclusion
Madrid C, Abarca M, Bouferrache K (2010)[3]	Narrative review
Haroun K, Coblens OM (2019)[10]	Narrative review
Abed H, Burke M, Scambler S, Scott SE (2020)[11]	Systematic review

Author and year of publication	Country	Aim	Type of cancer	Type of study	Sample size, comparison group & control group	Methodology	Conclusion
Kojima Y, Otsuru M, Hasegawa T, Ueda N, Kirita T, Yamada S, et al (2021)[14]	Japan	To evaluate the risk factors for ORN including tooth extraction before RT.	Oral cancer	Retro-spective cohort study	Three hundred and sixty-six patients	Three hundred and sixty-six patients were investigated retrospectively with head and neck cancer who underwent RT exceeding a dose of 50 Gy at six hospitals between 2008 and 2018. All patients underwent panoramic radiographic examination, necessary tooth extractions as much as possible, oral hygiene	During RT for oral or oropharyngeal cancer, apical lesions, alveolar bone loss of more than 50%, and post-RT tooth extraction significantly increase the risk of ORN development, and extraction of the infected tooth or the tooth with a poor prognosis significantly reduces the risk.

To be Cont..

Table 2: Characteristics of excluded studies

						instructions, removal of dental calculus, and professional mechanical teeth cleaning by a dentist and dental hygienist before RT. Endpoints were the onset and timing of ORN, and background factors.	
Khoo SC, Nabil S, Fauzi AA, Yunus SSM, Ngeow WC and Ramli R et al (2021)[15]	Malaysia	To determine the predictors of osteoradionecrosis (ORN) which were associated with a dental extraction post radiotherapy.	Head and neck cancer	Retrospective cohort study	Seventy-three patients	A retrospective analysis of medical records and dental panoramic tomogram (DPT) of patients with a history of head and neck radiotherapy who underwent dental extraction between August 2005 to October 2019 was conducted. It was conducted in two university hospitals in Malaysia: Oral and Maxillofacial Surgery Clinic, University Kebangsaan Malaysia Medical Centre (UKMMC) and Faculty of Dentistry, University of Malaya (FDUM).	The prevalence of ORN following a dental extraction was 21.9%. Dental extraction of more than five years after RT, surgical removal procedure and the upper cortical line of mandibular canal being invisible were the predictors of ORN post extraction.
Foote RL, Loprinzi CL, Frank AR, O'Fallon JR, Gulavita S, Tewfik HH, et al (1994)[9]	United States	To determine whether a chlorhexidine mouthwash could alleviate radiation-induced oral mucositis.	Oral cancer	Randomized trial	25 patients Test group: Chlorhexidine mouthwash Control group: Placebo mouthwash	Patients scheduled to receive radiation therapy to include greater than one third of the oral mucosa were selected for study. Following stratification, they were randomized in a double-blind manner to receive a chlorhexidine mouthwash or a placebo	Chlorhexidine mouthwash might provide benefit for patients receiving radiation therapy to the oral mucosa, they provided strong evidence concluding that a chlorhexidine mouthwash is detrimental in this clinical situation.

To be Cont..

Table 2: Characteristics of excluded studies

						mouthwash. Both groups were then similarly evaluated for mucositis and mouthwash toxicity.	
Ito K, Takumi K, Meibom SK, Qureshi MM , Fujima N, Andreu-Arasa VC (2020)[4]	USA	To evaluate whether 18F-FDG PET/CT can predict ORN associated with periodontal disease in patients with oropharyngeal or oral cavity squamous cell carcinoma (OP/OC SCC) undergoing RT.	Oral cancer	Retro-spective cohort study	One hundred and five	One hundred and five OP/OC SCC patients treated with RT who underwent pretreatment F-FDG PET/ CT between October 2007 and June 2016 were retrospectively reviewed. A post-treatment diagnosis of ORN was made clinically based on presence of exposed irradiated mandibular bone that failed to heal after a period of three months without persistent or recurrent tumor. The maximum standardized uptake value (SUVmax) of periodontal regions identified on PET/CT was measured for all patients. Image-based staging of periodontitis was also performed using American Academy of Periodontology staging system on CT	Pretreatment F-FDG PET/CT identification of periodontitis may be helpful to predict the future development of ORN in patients with OP/OC SCC undergoing RT.
Chang C, Liu S, Muo C, Liao Y, Chiu K, Tsai C, et al (2022)[17]	Taiwan	To investigate how different timelines of various dental therapies were related to osteoradionecros is development under consideration of	Oral cancer	Retro-spective cohort study	Seven thousand one hundred and seven	A total of 7,107 oral cancer patients were enrolled, including 88 osteoradionecrosis patients treated with low radiotherapy dosages (<60 Gy)	Patients that were treated with high irradiation dosages (≥60 Gy) had a higher tendency to develop osteoradionecrosis if they received dental surgery during

To be Cont..

Table 2: Characteristics of excluded studies

	radiotherapy dosage in patients with oral cancer.		or high radiotherapy dosages (≥60 Gy), from the Longitudinal Health Insurance Database for Catastrophic Illness Patients of Taiwan. Cox proportional hazard regression was used to compare the osteoradionecrosis risk of various dental treatment time lines under different irradiation dosages.	radiotherapy. Those who were treated with low radiation dosages (<60 Gy) and received periodontal therapy during radiotherapy might have an increased risk in developing osteoradionecrosis.

Assessment of risk of bias in included studies

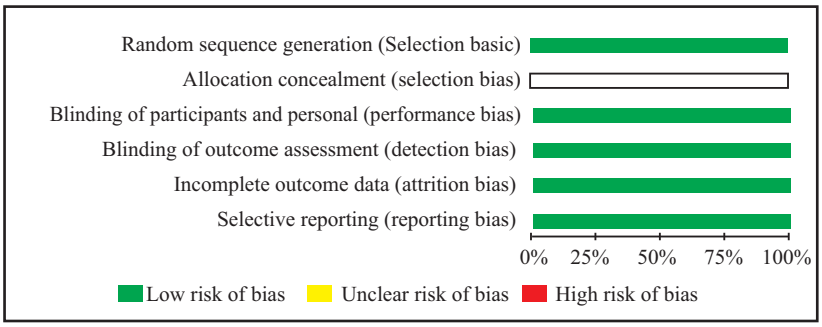
This assessment was conducted using the recommended approach for assessing the risk of bias in studies included in Cochrane Reviews (Higgins 2011) using the RevMan 5.0 tool for randomized controlled trials and Robin tool for non-randomized controlled trials (retrospective studies). We used the two-part tool to address the six specific domains (namely random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias). Each domain includes one or more specific entries in a risk of bias table. Within each entry, the first part of the tool involves describing what was reported to have happened in the study. The second part of the tool involves assigning a judgment relating to the risk of bias for that entry: either low risk, unclear risk or high risk. The risk of bias of the included studies is presented in Table 3 & 4 and Graphs 1, 2.

Table 3: Risk of bias assessment for RCT studies

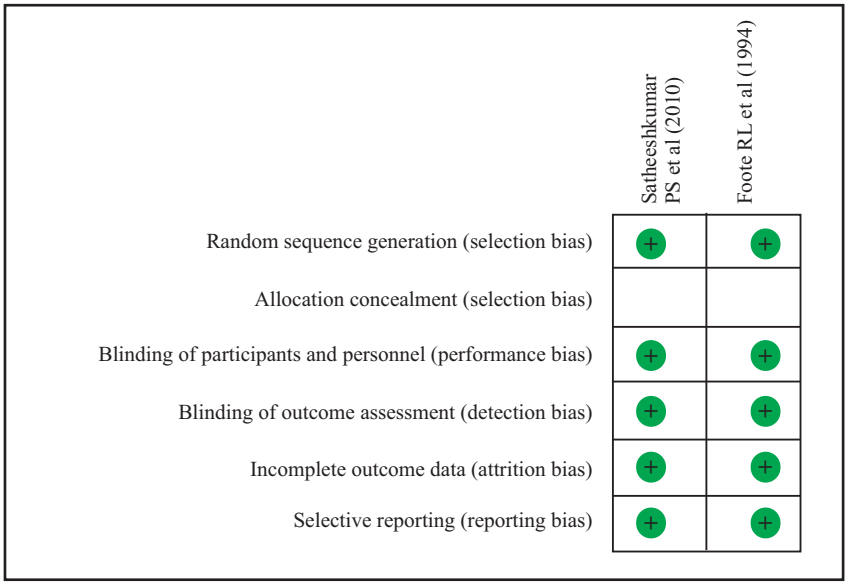
Sr No.	Authors (Year)	Type of study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome	Incomplete outcome data	Selective reporting
1	Satheeshkumar PS et al (2010)	RCT	Low	Unclear	Low	Low	Low	Low
2	Foote RL et al (1994)	RCT	Low	Unclear	Low	Low	Low	Low

Table 4 : Risk of bias assessment for Non-RCT studies

Sr No	Author (Year)	TYPE OF STUDY	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
1	Kojima Y et al	Retrospective cohort study	Yes	No	Unclear	Yes	No	Yes	Unclear
2	Khoo SC et al (2021)	Retrospective cohort study	No	No	No	Yes	Yes	Yes	Yes
3	Ito K et al (2020)	Retrospective cohort study	No	No	No	No	No	No	No
4	Chang C et al (2022)	Retrospective cohort study	No	No	No	No	No	No	No



Graph 1: Risk of Bias Assessment - Part 1



Graph 2: Risk of Bias Assessment - Part 2

Discussion

Osteoradionecrosis is bone death due to radiation. In a review by Singh A et al (2022)[13], it was stated that one of the alarming complication of radiation therapy of the head and neck region was osteoradionecrosis with clinical signs such as exposed bone area, formation of a fistula, mobility of tooth/teeth and/or spontaneous exfoliation of tooth/teeth. Hypoxia, hypovascularity and hypocellularity resulted due to radiation induced endarteritis for which hyperbaric oxygen therapy was used for osteoradionecrosis patients as well. Such conditions are favorable for the growth of anaerobic micro-organisms and thereby forming subgingival periodontal pocket formation hence suggesting periodontitis having role in osteoradionecrosis.

Xerostomia or dry mouth is a routinely observed side effect of cancer treatment, which is found most frequently among patients undergoing targeted radiotherapy especially in oral cancer patients. Dry mouth is also common among patients taking certain chemotherapy regimens (anti-sialagogue) known to decrease salivary secretion and thereby result in dry mouth. Even the available evidence is limited, with patients on certain drugs known to include salivary gland hypofunction.[16] Association of all these factors lead to poor oral hygiene and thereby result in periodontal disease. Therefore, periodontal disease is considered as a possible risk factor for development of osteoradionecrosis in patients undergoing radiation therapy.

The present systematic review outlines the observations of the studies that evaluated whether osteoradionecrosis is associated with periodontal disease in individuals having oral cancer and receiving radiation therapy. There were few studies available, which evaluated the role of periodontal disease on radiation induced osteoradionecrosis. In-vitro studies, animal studies, review articles were excluded as they provide low level of evidence.

Six studies were considered for qualitative synthesis, in which 2 studies were randomized clinical trials and 4 were retrospective cohort studies.

Satheeshkumar PS et al (2010)[6] assessed subjects who developed mucositis after they underwent radiation therapy for oral cancer. Twenty-four subjects were randomly divided into two groups, one receiving triclosan mouthwash and other

sodium bicarbonate mouthwash. They concluded that the severity of radiation-induced oral mucositis reduced after using Triclosan mouthwash.

Foote RL et al (1994)[9] included subjects who were scheduled to undergo radiation therapy. The subjects were randomized into two groups by double-blinding to receive either placebo mouthwash or chlorhexidine mouthwash. They concluded that in individuals undergoing radiation therapy chlorhexidine mouthwash might provide benefit in reducing oral mucositis.

Kojima Y et al (2022)[14] conducted a study to evaluate risk factor of tooth extraction before radiation therapy. They found out that oral problems such as caries, poor oral hygiene and periodontal disease were known to induce osteoradionecrosis, hence treatment of all these factors before radiation therapy is mandatory. One of the most common oral cancers is squamous cell carcinoma. Radiation therapy has been routinely used for treatment of oral cancer. Hence, an association of periodontal disease as a possible risk factor for osteoradionecrosis in patients undergoing radiation therapy can be suggested.

In a study by Khoo et al (2021)[15], individuals who underwent extraction after radiation therapy, who were at risk for development of osteoradionecrosis (ORN) were included. They stated that dental extraction of more than five years after RT, surgical removal procedure and the invisible upper cortical line of mandibular canal being were the risk factors of ORN post extraction. Hence, extraction of teeth due to severe periodontal destruction may contribute to development of osteoradionecrosis.

Ito K (2020)[1] studied one hundred and five oral cancer patients treated with RT who underwent pretreatment F-FDG PET/ CT. They performed image-based staging of periodontitis using American Academy of Periodontology staging system on CT. They concluded that pretreatment F-FDG PET/CT identification of periodontitis may be helpful to predict the future development of ORN in patients with oral cancer undergoing RT.

Chang C (2022)[17] studied 7107 patients treated with low radiotherapy dosages (<60 Gy) or high radiotherapy dosages (≥ 60 Gy) to compare the osteoradionecrosis risk of various dental treatment timelines under different irradiation dosages. They concluded that those who were treated with low radiation dosages (<60 Gy) and received periodontal therapy during radiotherapy might have an increased risk in developing osteoradionecrosis

The risk of bias was low for both the randomized clinical trials except for unclear allocation concealment. Based on the studies assessed, it was observed that poor oral hygiene leading to periodontal disease could be a possible risk factor for osteoradionecrosis. Hence, maintenance of oral hygiene and periodontal health is essential to minimize the risk of osteoradionecrosis in individuals undergoing radiation therapy for oral cancer. Also, they reported that chlorhexidine mouthwash was found to be effective in the periodontal management of patients suffering from osteoradionecrosis.

A scope for conducting randomized clinical studies in future may be helpful in establishing the association between periodontal disease and osteoradionecrosis. Further, the awareness of good oral hygiene maintenance among individuals, especially those undergoing radiation therapy for oral cancer has to be stressed upon to minimize the risk of osteoradionecrosis and its subsequent complications.

Conclusions

Periodontal disease develops very commonly in patients suffering from oral cancer because of difficulty in maintaining proper oral hygiene due to inadequate mouth opening. Radiation therapy is carried out in such patients as a treatment modality after chemotherapy is performed. This leads to development of osteoradionecrosis in few patients. Hence, it can be concluded that periodontal disease is a possible risk factor for osteoradionecrosis in patients undergoing radiation therapy.

Acknowledgements: Nil

References

1. Ito K, Takumi K, Meibom SK, Qureshi MM, Fujima N, Andreu-Arasa VC et al. Risk assessment of osteoradionecrosis associated with periodontitis using F-FDG PET/CT. Eur J Radiol 2020; 132(11): 1-6.
2. Yousef A, Jehani AL. Risk Factors of Periodontal Disease: Review of the Literature. Int J Dent 2014; (5): 1-6.
3. Madrid C, Abarca M, Bouferrache K. Osteoradionecrosis: An update. Oral Oncol 2010; (46): 471–74.
4. Jegoux F, Malard O, Goyenvalle E, Aguado E, Daculsi G, Bretagne V, et al. Early-stage pathogenic sequence of jaw osteoradionecrosis in vivo. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2010;109(2):173-83.
5. Irie MS, Mendes EM, Borges JS, Osuna LGG, Rabelo GD, Soares PBF. Periodontal therapy for patients before and after radiotherapy: A review of the literature and topics of interest for clinicians. Med Oral Patol Oral Cir Bucal 2018; 23(5): e524-30.
6. Satheeshkumar PS, Chamba MS, Balan A, Sreelatha KT, Bhatathiri VN, Bose T. Effectiveness of triclosan in the management of radiation-induced oral mucositis: A randomized clinical trial. J Can Res Ther 2010; 6(4): 466-72.

7. Yusof ZW, Bakri MM. Severe progressive periodontal destruction due to radiation tissue injury. J Periodontol 1993;64(12):1253-58.
8. Galler C, Epstein JB, Guze KA, Buckles D, Stevenson-Moore P. The development of osteoradionecrosis from the sites of periodontal disease activity: report of 3 cases. J Periodontal 1992;63(4):310-16.
9. Foote RL, Loprinzi CL, Frank AR, O'Fallon JR, Gulavita S, Tewfik HH, Ryan MA, Earle JM, Novotny P. Randomized Trial of a Chlorhexidine Mouthwash for Alleviation of Radiation-Induced Mucositis. J Clin Oncol 1994;12(12):2630-33.
10. Haroun K, Coblens OM. Reconstruction of the mandible for osteoradionecrosis. Curr Opin Otolaryngol Head Neck Surg 2019;27:401–6.
11. Abed H, Burke M, Scambler S, Scott SE. Denture use and osteoradionecrosis following radiotherapy for head and neck cancer: a systematic review. Gerontology 2020;37:102-9.
12. Verdonck HWD, Meijer GJ, Kessler P, Nieman FH, Baat CD, Stoelinga PJW. Assessment of bone vascularity in the anterior mandible using laser Doppler flowmetry. Clin Oral Impl Res 2009;20(6): 140-44.
13. Singh A, Huryn JM, Kronstadt KL, Yom SK, Randazzo JR and Estilo CL. Osteoradionecrosis of the jaw: A mini review. Front Oral Health 2022;3:98078.
14. Kojima Y, Otsuru M, Hasegawa T, Ueda N, Kirita T, Yamada S, Kurita H, Shibuya Y et al. Risk factors for osteoradionecrosis of the jaw in patients with oral or oropharyngeal cancer: Verification of the effect of tooth extraction before radiotherapy using propensity score matching analysis. J Dent Sci 2022;17(2):1024-1029.
15. Khoo SC, Nabil S, Fauzi AA, Yunus SSM, Ngeow WC and Ramli R et al. Predictors of osteoradionecrosis following irradiated tooth extraction. Radiat Oncol 2021;16(1):130.
16. Aranha V et al. Xerostomia in patients undergoing anticancer therapy. World J Adv Sci Res 2020;3(5): 1-15.
17. Chang C, Liu S, Muo C, Liao Y, Chiu K, Tsai C, et al. The impact of dental therapy timelines and irradiation dosages on osteoradionecrosis in oral cancer patients: A population-based cohort study. Oral Oncol 128 2022;105827: 1-8.
18. Lajolo C, Rupe C, Gioco G, Troiano G, Patini R, Petruzzi M, et al. Osteoradionecrosis of the Jaws Due to Teeth Extractions during and after Radiotherapy: A Systematic Review. Cancers (Basel). 2021 Nov;13(22): 5798.

Original Article

Comparative evaluation of the depth of penetration and postoperative pain associated with the use of continuous chelation using HEBP and standard irrigation protocol in the endodontic treatment of adult permanent nonvital teeth: A randomized controlled trial

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ABSTRACT

Aim: To evaluate and compare the apical depth of penetration and postoperative pain associated with the use of 9% 1-Hydroxyethylidene-1, 1-Bisphosphonate (HEBP) along with 3% sodium hypochlorite (NaOCl) as continuous chelation and standard irrigation protocol in endodontic treatment of adult permanent nonvital teeth.

Methods: In this parallel arm double-blind single-center randomized controlled trial, standard irrigation protocol was compared to continuous chelation protocol (HEBP/NaOCl combination) with respect to the apical depth of penetration of irrigant and the postoperative pain. Forty-six patients aged between 18 and 45 years presenting with nonvital teeth requiring root canal treatment were randomly divided into two groups ($n = 23$) based on irrigation regime. After the final irrigation protocol, the apical depth of penetration of the irrigant was evaluated using a radiovisiography and radiopaque dye. Postoperative pain levels were evaluated at 6 h and 24 h after treatment using the numerical rating scale.

Results: The results revealed that there was no statistically significant difference between the two groups in terms of the apical depth of penetration of the irrigant. While, with respect to postoperative pain, a statistically significant difference was found between the two groups at 24 h, with lower pain values observed in the continuous chelation group.

Conclusion: The use of soft chelating agents like HEBP in continuous chelation has the apical depth of penetration comparable to that of ethylenediaminetetraacetic acid (EDTA) in standard irrigation protocol with lower postoperative pain at 24 h. Therefore, HEBP with NaOCl in continuous chelation can be seen as a viable, economical, and less technique-sensitive alternative to the use of EDTA for an effective three-dimensional disinfection of the root canal system up to the apical third of the root, which can be easily incorporated into daily clinical practice.

Keywords: 1-Hydroxyethylidene-1, 1-Bisphosphonate, postendodontic pain, continuous chelation, etidronic acid, postoperative pain

INTRODUCTION

Endodontic treatment of nonvital teeth represents a microbiologic challenge for the clinician due to the heavy bacterial load present in the root canal system and hence a documented higher

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Submitted: 18-Jun-2022 **Revised:** 12-May-2023
Accepted: 09-Aug-2023 **Available Online:** 29-Dec-2023

Access this article online	
Website: https://journals.lww.com/eddt	Quick Response Code
DOI: 10.4103/endo.endo_157_22	

How to cite this article: Parekh JS, Vaidya MJ, Hegde VR. Comparative evaluation of the depth of penetration and postoperative pain associated with the use of continuous chelation using HEBP and standard irrigation protocol in the endodontic treatment of adult permanent nonvital teeth: A randomized controlled trial. Endodontology 2023;35:344-51.

incidence of postoperative pain and flare-up.[1,2] Studies have shown bacterial penetration into the dentinal tubules ranging from 200 ∝m to as high as 2100 ∝m in cases of nonvital teeth.[3,4] The inability of the endodontic instruments to eliminate these bacteria present in deeper depths of the dentinal tubules,[2] to adapt to the anatomical complexity of a root canal system,[5] and to clean the lateral canals, apical deltas, fins, webs, and transverse anastomoses; emphasizes the importance of chemical means of cleaning and disinfecting all areas of the root canal, especially in a nonvital tooth.[6,7]

The use of 17% ethylenediaminetetraacetic acid (EDTA) causes the inactivation of chlorine of sodium hypochlorite (NaOCl) and calcium ion sequestration in leading to decalcification of dentin up to 20–30 μm thus reducing the microhardness of root dentin.[8-13] The cumulative effect of all these factors is potentially capable of decreasing the fracture resistance of the tooth making it more prone to vertical root fractures.[14]

To overcome these drawbacks of EDTA, 1-Hydroxyethylidene-1, 1-Bisphosphonate (HEBP), also known as Etidronate, a weak chelating agent, is used in the concentration of 9% or 18%.[12,15] A combination of sodium hypochlorite (NaOCl) and HEBP irrigant, known as continuous chelation, can be used during chemo-mechanical root canal preparation and for final irrigation. HEBP has short-term compatibility with NaOCl, and does not affect the free chlorine content of NaOCl[16] thus, maintaining the proteolytic/antibacterial effects of the NaOCl. HEBP, being a calcium sequestering agent, prevents the accumulation of smear layer and hard tissue debris.[11,17,18]

Hence, this clinical study was undertaken to evaluate the effectiveness of continuous chelation, a combination of NaOCl with HEBP, on apical depth of penetration in the root canal system and in the clinical success of root canal treatment of adult permanent nonvital teeth.

MATERIALS AND METHODS

Study design

A parallel-arm double-blinded single-center randomized control trial design was used for the study. The trial was approved by the Institutional Ethics Committee and registered at the Clinical Trials Registry – India (CTRI/2021/03/032370). The study was conducted in accordance with the World Medical Association Declaration of Helsinki, the Institutional Ethical Committee, and the CONSORT guidelines (2010) for randomized control trials.

The sample size was determined using the mean and standard deviation values from the literature, and a total of 46 participants aged between 18 and 45 years were included in the study. All patients were informed regarding the benefits, risks, alternative treatment choices and about their right to withdraw from the study and that not participating in the study had no consequences regarding their treatment whatsoever. Informed consent was obtained from all patients.

Inclusion criteria

i. American Society of Anaesthesiologists Category I and Category II adult patients aged between 18 and 45 years
ii. Adult permanent asymptomatic nonvital teeth requiring endodontic treatment
iii. Teeth whose nonvitality was confirmed by electric pulp tester (EPT) and thermal sensitivity testing
iv. Feasibility of isolating the tooth with a rubber dam
v. Vertucci Type I and Type IV root canal anatomy
vi. Participants with the ability to understand the consent forms and the pain record scales.

Exclusion criteria

i. Nonvital tooth with periapical lesion
ii. Patients with preoperative pain (pain ranging from 1 to 10 on a numerical rating scale [NRS])
iii. Patients who had taken Nonsteroidal anti-inflammatory drugs or any other analgesic for pain within the last 4–8 h
iv. Teeth with calcified root canals and complex root canal anatomy
v. Periodontally compromised teeth
vi. Patient is not willing to give consent for the study
vii. Patients with known allergies to the materials used in the study.

For evaluation of the apical depth of penetration of irrigant

CONSORT flow diagram outlining the treatment methodology is represented in Figure 1. Forty-six participants with nonvital teeth requiring endodontic treatment were selected. After routine examination of the subjects, nonvitality of the tooth was confirmed using an EPT and thermal sensitivity test and asymptomatic status was recorded on a NRS, a preoperative digital imaging (radio visio graphy) was done. According to inclusion and exclusion criteria, the participants were randomly divided into two groups Group I (Control group): Standard irrigation protocol using 3% NaOCl and 17% EDTA, Group II: Continuous chelation using 9% HEBP with 3% NaOCl, using computer-generated sequence. Allocation concealment was ensured by picking up a nontransparent concealed envelope during randomization.

Tooth was then anesthetized using 1.8 ml of 2% lignocaine containing 1:80,000 adrenaline and isolated using a rubber

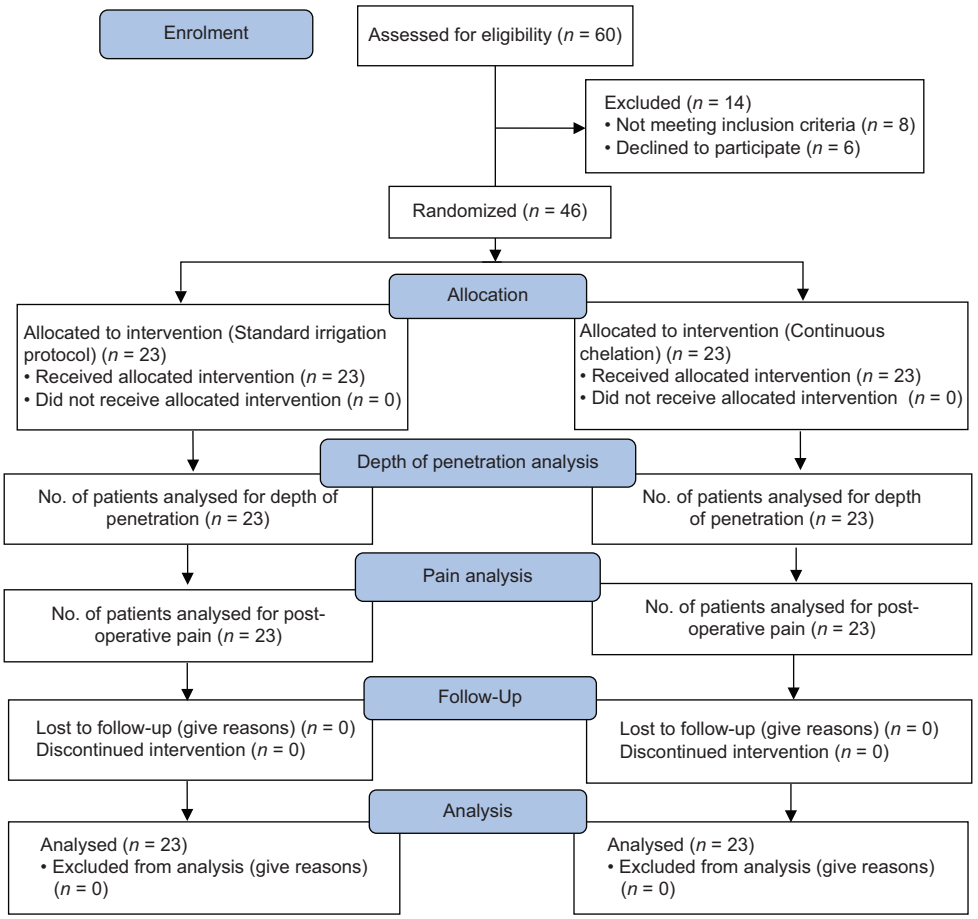


Figure 1: CONSORT flowchart

dam. Caries was excavated, and a preendodontic build-up was done if required. Access opening was completed and root canals were negotiated using K files #10 and #15. A glide path was established, and the working length was verified with an electronic apex locator. Rotary Pro Taper Gold nickel–titanium files upto F3 were used sequentially. Irrigation was performed using a 30-gauge side-vented needle, kept 1 mm short of the working length. The syringes loaded with the experimental irrigating solution were masked using color-coded tapes to ensure blinding.

- During the shaping and cleaning procedure, each canal was irrigated with 1 ml of 3% NaOCl (Group I) and 1 ml of 9% HEBP + 3% NaOCl solution (Group II) for 15 s after the use of each file. HEBP/NaOCl solution for continuous chelation protocol was prepared according to the manufacturer's recommendations, 10 ml of 3% NaOCl is to be used with two capsules of HEBP (each capsule consists of 0.42 g HEBP)
- After complete instrumentation and apical preparation of the canals, the tooth was irrigated with 20 ml saline to prevent interaction of the irrigant with final irrigating solutions, and to standardize the duration of action of the irrigants on the root canal.

In Group I

- Step I-Final irrigation protocol was performed with 3 ml of 3% NaOCl activated for 1 min, followed by the use of 1 ml of saline for 1 min
- Step II-3 ml of 17% EDTA was then used for 1 min, followed by 1 ml of saline for 1 min to avoid potential carry-over effects of the irrigant
- Step III-3 ml of 3% NaOCl was used for 1 min.

In Group II

- Step I – Final irrigation protocol was performed with 3 ml of 9% HEBP + 3% NaOCl for 1 min, followed by the use of 1 ml of saline for 1 min
- Step II – 3 ml of saline (instead of 17% EDTA used in Group I) was used for 1 min to ensure blinding. This was followed by irrigation with 1 ml of saline for 1 min
- Step III – 3 ml of 9% HEBP + 3% NaOCl was used for 1 min.

All the irrigants were activated using manual dynamic agitation. After the final irrigation protocol, each canal was irrigated with 1 ml of saline for 1 min and 1 ml of radio-opaque dye (Omnipaque) was injected into each canal. A digital radiograph was taken, and the penetration of

irrigant was evaluated in each group depending on the apical depth of penetration of the dye. A trained and calibrated examiner assessed the penetration. Radio-opaque dye was then removed using saline, and the canals were dried using paper points. Following this, the access cavity of the tooth was temporized using a temporary filling material (Cavit, 3ESPE). Each patient was prescribed topical anesthetic gel to be applied onto the tooth which was clamped for isolation in case of soft-tissue pain and discomfort.

For measuring the apical depth of penetration

Radiographic images were assessed with digital imaging software, and a line was drawn connecting the coronary landmark to the apical depth of penetration of irrigant. (Figures 2 and 3). In cases of molars, the percentage of canal penetrated by the dye was calculated. An index of penetration was calculated using the formula,

$$\text{Index} = \frac{\text{apical depth of penetration}}{\text{working length}}$$

For postoperative pain evaluation

Postoperative pain was recorded at 6 h and 24 h for both the groups using the NRS.

Statistical analysis

Descriptive statistics in mean and standard deviation of numerical data in each group were obtained. After assessing the normality of continuous data using Shapiro–Wilk test parametric and nonparametric tests were applied. For numerical continuous data following a normal distribution, intergroup comparison (2 groups) was done using unpaired *t*-test. Mann–Whitney *U*-test was applied for nonnormally distributed data. All data analysis was done at 95% confidence interval ($\alpha = 5\%$ and $\beta = 20\%$) and $P < 0.05$ was considered statistically significant.

RESULTS

Table 1 presents the baseline demographic data and tooth type information. The mean age (mean ± standard deviation) of the patients in Group I was 28.1 ± 7.4 years, and in Group II, it was 26.9 ± 6.7 years. There was no statistically significant age difference between the groups ($P > 0.05$). Distribution of gender and tooth type also showed statistically no significant difference among the two groups, with equal distribution of males and females and tooth type in both the groups ($P > 0.05$).

The mean working length for Group I is 19.71 and for Group II it is 19.63, the mean apical depth of penetration for Group I is 19.17 and for Group II is 19.23, mean index values for Group I is 0.971, while for Group II, it is 0.979, mean difference for Group I is 0.54 and Group II is 0.39 and mean percentage of apical penetration in Group I is 97.34 and Group II is 98.01.

With respect to postoperative pain experienced at 6 h and 24 h, a statistically significant reduction in pain was observed at 24 h between the two groups ($P < 0.05$). The mean postoperative pain at 6 h and 24 h is presented in Graph 1. In Group I, 56.5% of patients had no postoperative pain, 26.0% of patients reported mild pain, while 13% of patients reported moderate pain and one patient reported severe pain at 6 h; at 24 h 78.2% of patients had no pain, 17.3% of patients reported mild pain and only one patient reported moderate pain. In Group II, 69.5% of patients had no postoperative pain, 21.7% of patients reported mild pain, one patient

Table 1: Distribution of gender and of tooth type in Group I and Group II

	Group		Total	*P*
	Group I, *n* (%)	Group II, *n* (%)		
Gender				
Male	10 (43.5)	11 (47.8)	21 (45.7)	0.782
Female	13 (56.5)	12 (52.2)	25 (54.3)	
Total	23 (100.0)	23 (100.0)	46 (100.0)	
Tooth type				
Mandibular first molar	12 (52.2)	14 (60.9)	26 (56.5)	0.842
Mandibular premolar	11 (47.8)	9 (39.1)	20 (43.5)	
Total	23 (100.0)	23 (100.0)	46 (100.0)	

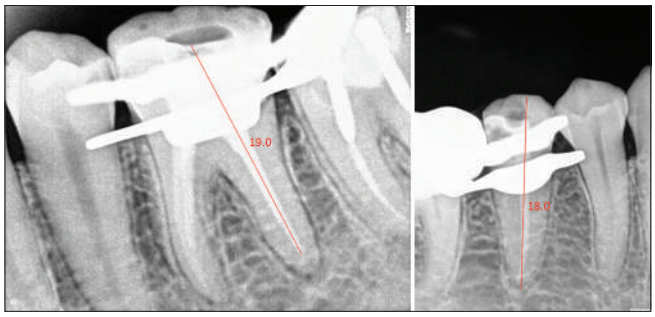


Figure 2: Measurement of depth of penetration of dye in Group I

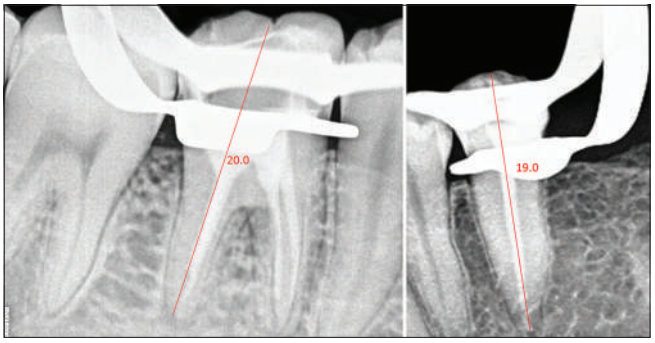
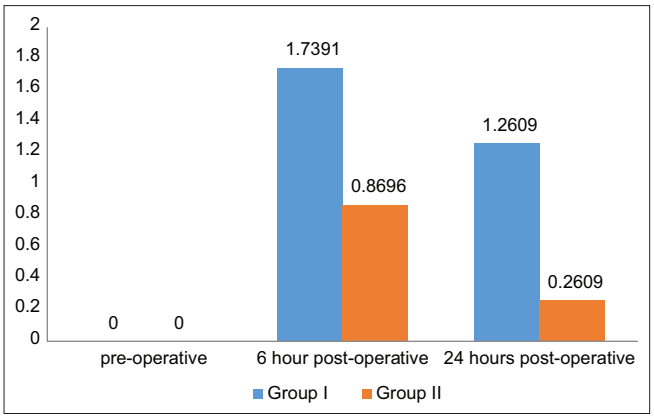


Figure 3: Measurement of depth of penetration of dye in Group II



Graph 1: Intergroup comparison of pain at different time period (6 h and 24 h) between Group I and Group II

reported moderate pain, and one patient reported severe pain at 6 h; at 24 h, 82.6% of patients had no pain, 13.0% of patients reported mild pain, and only one patient reported severe pain. Patients in Group II reported significantly lower Visual Analog Scale (VAS) scores compared with patients in the control group. The intragroup comparison revealed a statistically significant reduction in postoperative pain in both groups at the different time intervals recorded.

DISCUSSION

Dentistry has entered the era of "evidence-based decision making," where randomized controlled trials (RCTs) provide the essential evidence to practice evidence-based dentistry.[19] However, there is a lacuna of RCTs in endodontics evaluating the use of HEBP as an endodontic irrigating agent in continuous chelation protocol and comparing it with the apical depth of penetration of standard irrigation protocol. To the best of our knowledge, this is the first RCT evaluating the same.

HEBP or etidronic acid is a newer biocompatible chelating agent that can be used in combination with NaOCl and has adequate calcium chelating capacity.[20,21] HEBP was the first weak chelating agent proposed for use in a mixture with NaOCl during root canal preparation under the concept of continuous chelation, to simplify the irrigation protocol.[15] The HEBP/NaOCl mixture maintains the desired properties of both compounds for a short term.[15-17,22-24] It dissolves pulp tissue remnants,[23,25] exerts a strong antimicrobial effect against biofilms on the dentine surface[23] and inside dentinal tubules,[17] even in the presence of hard-tissue debris or a smear layer.[26-28] While the mixture of NaOCl and HEBP remains active for 1 h at room temperature,[16,29] its storage at a lower temperature maintains the free available chlorine for up to 7 h. In addition, Boessler *et al*.[30] described a possible reduction of torsional load on rotary instruments with the use of chelating agents like HEBP. The use of HEBP has also been shown to optimize the bond strength of epoxy resin sealer to dentine.[25,31]

Laboratory studies have revealed encouraging results for the use of HEBP as a root canal irrigant, especially due to its lower calcium ion sequestration, no adverse effect on microhardness, reduced erosional effects, and effective smear layer removal.[10,12,16,27,32-34]

Positive correlation between the higher incidence of postoperative pain and flare-up in teeth with necrotic pulp has been demonstrated by several studies[3,4,35-38] and potentially increased risk of extrusion of irrigants into the periapical tissues due to cementum or periapical resorption.[39,40] Mandibular molars and premolars have been reported to have a higher incidence of postoperative pain.[37,40,41] The fluid dynamics for irrigation also changes in these relatively narrow canals,[42] and therefore, nonvital mandibular premolars and molars with no radiographically detectable periapical lesions were endodontically treated in two visits with no intracanal medicament.[40,43]

In this study, 3% NaOCl was used as studies reported it to be associated with less intense and infrequent postendodontic pain than 5.25% NaOCl in treating mandibular molars with nonvital pulps.[40,44] with no effect on its antibacterial efficacy.[45] HEBP has a constant calcium-binding capacity, so its chelation effects depend on its concentration. Yadav *et al*.,[46] found that 18% HEBP and 17% EDTA had similar chelating capacities. Ulusoy *et al*.,[25] in their study, found no significant difference between 9% and 18% of HEBP in terms of smear layer elimination. Therefore, 9% HEBP was used in this study.

Each irrigant was activated using manual dynamic agitation for 1 min during the final irrigation protocol. Studies demonstrated that manual dynamic irrigation was significantly more effective than an automated-dynamic irrigation system, static irrigation, and passive ultrasonic irrigation system in the apical thirds.[47,48]

The limitations of available methods of investigation for a clinical study and ethical concerns owing to the high radiation and multiple exposures required for micro-computed tomography (CT) and cone-beam CT, radiographic studies using radiopaque dyes proposed for investigating and evaluating the penetration of irrigating solution inside the root canal system by Salzgeber and Brilliant,[49] Abou-Rass and Piccinino,[50] and Teplitsky *et al*.[51] have been used in this study.

To allow visualization of the infiltration of the irrigant into the root canal, Iohexol (Omnipaque) was used as contrast medium because it is a nonionic, monomeric, and water-soluble iodide solution with similar density and viscosity as 5.25% NaOCl, the low-osmolality agent which is readily available as a sterile, pyrogen-free, nontoxic solution and widely used in the medical field.[52,53]

The results of the present randomized control trial revealed that the apical depth of penetration of HEBP was as effective as EDTA. The mean percentage of apical penetration in Group I is 97.34 and Group II is 98.01. Since there is no clinical study in the literature, which evaluates and compares the effective apical depth of penetration of HEBP against EDTA, the results of this study cannot be directly compared to those of previous studies. However, *in-vitro* studies by Lottanti *et al*.,[32] Morago *et al*.,[27] Morago *et al*.,[18] and Kfir *et al*.[34] demonstrated the ability of HEBP to remove smear layer to be as effective as EDTA which is in accordance with this study and without the adverse erosive and calcium ion sequestration effects of EDTA on microhardness.

The results can be attributed to the lower surface tension of HEBP, which may increase its wettability, contact with dentinal walls, and penetration ability into the anatomical complexities of the apical third and the dentinal tubules,[54,55] reducing the chance of vapor lock. Continuous chelation protocol provides the added advantage of removing the smear layer during the instrumentation itself, thereby allowing the diffusion of NaOCl[15] and adequate time for tissue dissolving action.[4]

A clinical study provides the unique opportunity to assess allergic, immunologic, and postoperative pain response to a drug; besides, assessment of overirrigation. A standardized ten-point NRS was used to evaluate pain intensity as it is easier to use than a VAS, and more sensitive than a verbal rating scale,[56] and convenient as readings could be easily enquired over a telephone interview.

Postendodontic pain can occur within a few hours or a few days after endodontic treatment. According to a recent systematic review by Pak and White[57] the prevalence of pain during the first 24 h after root canal treatment is 40%, falling to 11% after 7 days. Therefore, in this study, the pain was assessed at 6 h and 24 h following instrumentation and canal irrigation, where the first reading at 6 h interval, was selected to determine the level of pain experienced by the patient after the effect of the local anesthesia had completely worn off,[58] while the maximum of 24 h was selected because the incidence and severity of postoperative pain are highest in the first 24 h and significantly decreases to minimal levels after 48 h postoperatively.[57]

The postoperative pain percentage at 24 h in Group I and Group II was found to be about 12.60% and 2.60%, respectively, which is a statistically significant difference at $P = 0.038$. This confirms that the postoperative pain at 24 h with HEBP in continuous chelation is considerably less compared to the control group.

However, at 6 h, no significant difference was observed between the two groups. The intragroup comparison further revealed a statistically significant difference in postoperative experienced by the participants at 6 h compared to readings taken at 24 h in both groups.

Results are in accordance with the previous study by Ballal *et al*.[59] The higher amount of pain experienced in the EDTA group could be attributed to the reduced antibacterial activity of NaOCl due to the presence of a smear layer, which adversely affects it.[27] The penetration of NaOCl into inaccessible areas such as fins, deltas, isthmus, and lateral canals is possible only after smear layer removal. However, the reduced tissue contact time (1 min) with NaOCl after EDTA rinse is insufficient for the complete dissolution of the pulpal tissue to occur.

Limitations

Studies to evaluate the long-term follow-up of the effect of continuous chelation protocol on radiographic healing as well are further required. Studies are required to evaluate the effect of HEBP on various preoperative pulpal and periapical 28 conditions as well as at more gradual time intervals. There are inherent limitations to a clinical study as against laboratory studies where more sophisticated, precise, and direct measurements of various parameters such as the detergent action or surface tension or wettability or smear layer removal at various magnification levels can be studied.

CONCLUSION

Within the limitations of the study, it can be concluded that HEBP in continuous chelation protocol has the adequate and comparable apical depth of penetration to that of EDTA in standard irrigation protocol, as confirmed by the penetration of the radioopaque dye. The use of HEBP in continuous chelation effectively reduced the postoperative pain recorded at 24 h compared to EDTA and the difference measured was statistically significant.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Onay EO, Ungor M, Yazici AC. The evaluation of endodontic flare-ups and their relationship to various risk factors. BMC Oral Health 2015;15:142.
2. Ince B, Ercan E, Dalli M, Dulgergil CT, Zorba YO, Colak H. Incidence of postoperative pain after single- and multi-visit endodontic treatment in teeth with vital and non-vital pulp. Eur J Dent 2009;3:273-9.
3. Nagaoka S, Miyazaki Y, Liu HJ, Iwamoto Y, Kitano M, Kawagoe M. Bacterial invasion into dentinal tubules of human vital and nonvital teeth. J Endod 1995;21:70-3.
4. Chivatxaranukul P, Dashper SG, Messer HH. Dentinal tubule invasion and adherence by *Enterococcus faecalis*. Int Endod J 2008;41:873-82.
5. Peters OA, Schönenberger K, Laib A. Effects of four Ni-Ti preparation techniques on root canal geometry assessed by micro computed tomography. Int Endod J 2001;34:221-30.
6. Haapasalo M, Shen Y, Wang Z, Gao Y. Irrigation in endodontics. Br Dent J 2014;216:299-303.
7. Park E, Shen Y, Haapasalo M. Irrigation of the apical root canal: Irrigation of the apical root canal. Endod Top 2012;27:54-73.
8. Grawehr M, Sener B, Waltimo T, Zehnder M. Interactions of ethylenediamine tetraacetic acid with sodium hypochlorite in aqueous solutions. Int Endod J 2003;36:411-7.
9. Mohammadi Z, Shalavi S, Jafarzadeh H. Ethylenediaminetetraacetic acid in endodontics. Eur J Dent 2013;7:S135-42.
10. Takhar K, Jindal N, Agarwal R, Rani M, Bansal S. Comparative evaluation of the effect of different endodontic irrigation protocols on the microhardness of root canal dentin: An *in vitro* study. Dent J Adv Stud 2021;9:128-32.
11. Bedir SS, Mossa H, Hassan AM. Etidronate as a weak chelating agent on root canal dentin: An update review. J Clin Diagn Res 2017;11:12.
12. Dineshkumar MK, Vinothkumar TS, Arathi G, Shanthisree P, Kandaswamy D. Effect of ethylene diamine tetra-acetic acid, MTAD™, and HEBP as a final rinse on the microhardness of root dentin. J Conserv Dent 2012;15:170-3.
13. Ari H, Erdemir A, Belli S. Evaluation of the effect of endodontic irrigation solutions on the microhardness and the roughness of root canal dentin. J Endod 2004;30:792-5.
14. Yassen GH, Eckert GJ, Platt JA. Effect of intracanal medicaments used in endodontic regeneration procedures on microhardness and chemical structure of dentin. Restor Dent Endod 2015;40:104-12.
15. Zehnder M, Schmidlin P, Sener B, Waltimo T. Chelation in root canal therapy reconsidered. J Endod 2005;31:817-20.
16. Biel P, Mohn D, Attin T, Zehnder M. Interactions between the tetrasodium salts of EDTA and 1-hydroxyethane 1,1-diphosphonic acid with sodium hypochlorite irrigants. J Endod 2017;43:657-61.
17. Arias-Moliz MT, Ordinola-Zapata R, Baca P, Ruiz-Linares M, Ferrer-Luque CM. Antimicrobial activity of a sodium hypochlorite/etidronic acid irrigant solution. J Endod 2014;40:1999-2002.
18. Morago A, Ruiz-Linares M, Ferrer-Luque CM, Baca P, Rodríguez Archilla A, Arias-Moliz MT. Dentine tubule disinfection by different irrigation protocols. Microsc Res Tech 2019;82:558-63.
19. Akobeng AK. Understanding randomised controlled trials. Arch Dis Child 2005;90:840-4.
20. Cobankara FK, Erdogan H, Hamurcu M. Effects of chelating agents on the mineral content of root canal dentin. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2011;112:e149-54.
21. Girard S, Paqué F, Badertscher M, Sener B, Zehnder M. Assessment of a gel-type chelating preparation containing 1-hydroxyethylidene-1, 1-bisphosphonate. Int Endod J 2005;38:810-6.
22. Tartari T, Bachmann L, Zancan RF, Vivan RR, Duarte MA, Bramante CM. Analysis of the effects of several decalcifying agents alone and in combination with sodium hypochlorite on the chemical composition of dentine. Int Endod J 2018;51 Suppl 1:e42-54.
23. Arias-Moliz MT, Ordinola-Zapata R, Baca P, Ruiz-Linares M, García García E, Hungaro Duarte MA, *et al.* Antimicrobial activity of Chlorhexidine, Peracetic acid and Sodium hypochlorite/etidronate irrigant solutions against *Enterococcus faecalis* biofilms. Int Endod J 2015;48:1188-93.
24. Tartari T, Guimarães BM, Amoras LS, Duarte MA, Silva e Souza PA, Bramante CM. Etidronate causes minimal changes in the ability of sodium hypochlorite to dissolve organic matter. Int Endod J 2015;48:399-404.
25. Ulusoy Öİ, Zeyrek S, Çelik B. Evaluation of smear layer removal and marginal adaptation of root canal sealer after final irrigation using ethylenediaminetetraacetic, peracetic, and etidronic acids with different concentrations. Microsc Res Tech 2017;80:687-92.
26. Arias-Moliz MT, Morago A, Ordinola-Zapata R, Ferrer-Luque CM, Ruiz-Linares M, Baca P. Effects of dentin debris on the antimicrobial properties of sodium hypochlorite and etidronic acid. J Endod 2016;42:771-5.
27. Morago A, Ordinola-Zapata R, Ferrer-Luque CM, Baca P, Ruiz-Linares M, Arias-Moliz MT. Influence of smear layer on the antimicrobial activity of a sodium hypochlorite/etidronic acid irrigating solution in infected dentin. J Endod 2016;42:1647-50.
28. Tejada S, Baca P, Ferrer-Luque CM, Ruiz-Linares M, Valderrama MJ, Arias-Moliz MT. Influence of dentine debris and organic tissue on the properties of sodium hypochlorite solutions. Int Endod J 2019;52:114-22.
29. Zollinger A, Mohn D, Zeltner M, Zehnder M. Short-term storage stability of NaOCl solutions when combined with Dual Rinse HEDP. Int Endod J 2018;51:691-6.
30. Boessler C, Peters OA, Zehnder M. Impact of lubricant parameters on rotary instrument torque and force. J Endod 2007;33:280-3.
31. Neelakantan P, Varughese AA, Sharma S, Subbarao CV, Zehnder M, De-Deus G. Continuous chelation irrigation improves the adhesion of epoxy resin-based root canal sealer to root dentine. Int Endod J 2012;45:1097-102.
32. Lottanti S, Gautschi H, Sener B, Zehnder M. Effects of ethylenediaminetetraacetic, etidronic and peracetic acid irrigation on human root dentine and the smear layer. Int Endod J 2009;42:335-43.
33. Emre Erik C, Onur Orhan E, Maden M. Qualitative analysis of smear layer treated with different etidronate concentrations: A scanning electron microscopy study. Microsc Res Tech 2019;82:1535-41.
34. Kfir A, Goldenberg C, Metzger Z, Hülsmann M, Baxter S. Cleanliness and erosion of root canal walls after irrigation with a new HEDP-based solution vs. traditional sodium hypochlorite followed by EDTA. A scanning electron microscope study. Clin Oral Investig 2020;24:3699-706.
35. Siqueira JF Jr. Microbial causes of endodontic flare-ups. Int Endod J 2003;36:453-63.
36. Alamassi BY. Endodontic postoperative pain: Etiology and related factors – An update. Int J Dent Sci Res 2017;5:13-21.
37. Mathew ST. Post operative pain in endodontics: A systemic review. J Dent Oral Hyg 2015;7:130-7.
38. El Mubarak AH, Abu-bakr NH, Ibrahim YE. Postoperative pain in multiple-visit and single-visit root canal treatment. J Endod 2010;36:36-9.
39. Farzaneh S, Parirokh M, Nakhaee N, Abbott PV. Effect of two different concentrations of sodium hypochlorite on postoperative pain following single-visit root canal treatment: A triple-blind randomized clinical trial. Int Endod J 2018;51 Suppl 1:e2-11.
40. Mostafa ME, El-Shrief YA, Anous WI, Hassan MW, Salamah FT, El Boghdadi RM, *et al.* Postoperative pain following endodontic irrigation using 1.3% versus 5.25% sodium hypochlorite in mandibular

molars with necrotic pulps: A randomized double-blind clinical trial. Int Endod J 2020;53:154-66.
41. Alí A, Olivieri JG, Duran-Sindreu F, Abella F, Roig M, García-Font M. Influence of preoperative pain intensity on postoperative pain after root canal treatment: A prospective clinical study. J Dent 2016;45:39-42.
42. Al-Muhammad J, Tomas S, Anselmet F. Modeling a weak turbulent flow in a narrow and wavy channel: Case of micro-irrigation. Irrig Sci 2016;34:361-77.
43. Bashetty K, Hegde J. Comparison of 2% chlorhexidine and 5.25% sodium hypochlorite irrigating solutions on postoperative pain: A randomized clinical trial. Indian J Dent Res 2010;21:523-7.
44. Verma N, Sangwan P, Tewari S, Duhan J. Effect of different concentrations of sodium hypochlorite on outcome of primary root canal treatment: A randomized controlled trial. J Endod 2019;45:357-63.
45. Frough-Reyhani M, Ghasemi N, Soroush-Barhaghi M, Amini M, Gholizadeh Y. Antimicrobial efficacy of different concentration of sodium hypochlorite on the biofilm of *Enterococcus faecalis* at different stages of development. J Clin Exp Dent 2016;8:e480-4.
46. Yadav HK, Tikku AP, Chandra A, Yadav RK, Patel DK. Efficacy of etidronic acid, BioPure MTAD and SmearClear in removing calcium ions from the root canal: An *in vitro* study. Eur J Dent 2015;9:523-8.
47. Dioguardi M, Crincoli V, Sovereto D, Caloro GA, Aiuto R, Illuzzi G, *et al*. Effectiveness of vapor lock effect removal in endo training blocks: Manual dynamic agitation versus passive ultrasonic irrigation. Appl Sci 2019;9:5411.
48. Pasricha SK, Makkar S, Gupta P. Pressure alteration techniques in endodontics – A review of literature. J Clin Diagn Res 2015;9:ZE01-6.
49. Salzgeber RM, Brilliant JD. An *in vivo* evaluation of the penetration of an irrigating solution in root canals. J Endod 1977;3:394-8.
50. Abou-Rass M, Piccinino MV. The effectiveness of four clinical irrigation methods on the removal of root canal debris. Oral Surg Oral Med Oral Pathol 1982;54:323-8.
51. Teplitsky PE, Chenail BL, Mack B, Machnee CH. Endodontic irrigation – A comparison of endosonic and syringe delivery systems. Int Endod J 1987;20:233-41.
52. Abrar S, Jaiprakash R, Mahala H, Naviwala GA, Ramugade M, Sapkale K. Comparative evaluation of efficacy of endodontic irrigant delivery to working length using conventional needle syringe, endovac and self-adjusting file system on prepared mesiobuccal canal of mandibular first molar by using radiographic contrast media: an in vivo study. Int J Dentistry Oral Sci. 2019 Dec 11;6:706-10.
53. Munoz HR, Camacho-Cuadra K. In vivo efficacy of three different endodontic irrigation systems for irrigant delivery to working length of mesial canals of mandibular molars. Journal of endodontics. 2012 Apr 1;38:445-8.
54. Giardino L, Estrela C, Generali L, Mohammadi Z, Asgary S. The *in vitro* effect of irrigants with low surface tension on *Enterococcus faecalis*. Iran Endod J 2015;10:174-8.
55. Giardino L, Del Fabbro M, Morra M, Pereira T, Bombarda de Andrade F, Savadori P, *et al.* Dual Rinse(®) HEDP increases the surface tension of NaOCl but may increase its dentin disinfection efficacy. Odontology 2019;107:521-9.
56. Hjermstad MJ, Fayers PM, Haugen DF, Caraceni A, Hanks GW, Loge JH, *et al.* Studies comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for assessment of pain intensity in adults: A systematic literature review. J Pain Symptom Manage 2011;41:1073-93.
57. Pak JG, White SN. Pain prevalence and severity before, during, and after root canal treatment: A systematic review. J Endod 2011;37:429-38.
58. Singh S, Garg A. Incidence of post-operative pain after single visit and multiple visit root canal treatment: A randomized controlled trial. J Conserv Dent 2012;15:323-7.
59. Ballal NV, Gandhi P, Shenoy PA, Shenoy Belle V, Bhat V, Rechenberg DK, *et al.* Safety assessment of an etidronate in a sodium hypochlorite solution: Randomized double-blind trial. Int Endod J 2019;52:1274-82.

Case Report

Pyogenic Granuloma in a Lactating Mother: An Unusual Case Presentation

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ABSTRACT:

Pyogenic granuloma is a non-neoplastic soft tissue overgrowth of skin or mucous membrane usually related to inflammatory etiology. It has various etiologic factors; upregulation of female steroid hormones is one of them. Here, we are reporting a case of pyogenic granuloma present on the left lateral border of the tongue in a lactating mother. Unlike the most pregnancy associated pyogenic granulomas, it did not undergo regression post parturition. The possible role of the hormones in the formation of pyogenic granuloma is also discussed here.

KEYWORDS: Pyogenic granuloma, pregnancy tumour, lobulated capillary hemangioma.

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Submitted: 03.10.2023, **Accepted:** 11.12.2023, **Published:** 26.12.2023

INTRODUCTION:

Pyogenic granuloma or pregnancy tumour is a non-neoplastic soft tissue overgrowth of skin or mucous membrane generally arising as a result of inflammatory reaction.[1,2] Hullihen in 1844 was the first one to describe Pyogenic Granuloma in English literature[3], but the introduction of the term "pyogenic granuloma" or "granuloma pyogenicum" was given by Hartzell in 1904.[4] According to many authors, the term 'pyogenic granuloma' is a misnomer, as there is no granulomatous reaction or no pus formation seen.[5] However, the term is still in use. Pyogenic Granuloma (PG) is usually found on the cutaneous or mucosal surfaces. Among the latter, it most commonly affects the oral cavity,[6]generally affecting the keratinized tissue.[7] It is predominantly seen on the gingiva and most often the gingiva of maxillary anterior region is affected.[8,9]It can affect other oral sites such as lip, tongue, and buccal mucosa. Here, we present a rather unusual case of PG of the tongue in a lactating mother.

CASE REPORT:

A 25-year-old lactating mother to a 14 months old infant was referred to the OPD with a swelling on left lateral border of the tongue. Patient first noticed a small growth on left lateral border of the tongue in the 2nd trimester of her pregnancy about 6 months back, which gradually increased to the present size. No history of associated pain and any other associated symptoms were present, except for a slight discomfort reported by the patient while eating food. Patient did not recollect any history of allergy to any medications. On inspection, a pedunculated growth of quadrangular shape with pinkish white colour and with an approximate size of 3x2x2 cm was present on left lateral border of the tongue extending up to the dorsum of the tongue. The surface of the lesion was rough on palpation and was firm in consistency with irregular borders. The growth was non tender, non-fluctuant and non- compressible. No discharge was present. Temperature over the lesion was normal. The

Access this article online

Quick Response Code:

Website: www.pjsr.org

DOI: doi.org/10.5281/zenodo.10432305

How to cite this article: Mhatre VS & Choudhari S. Pyogenic Granuloma in a Lactating Mother: An Unusual Case Presentation. PJSR. 2023;16(2):34-37.

inspectory findings of size and shape were confirmed with palpation and a provisional diagnosis of pyogenic granuloma was given (Figure 1).

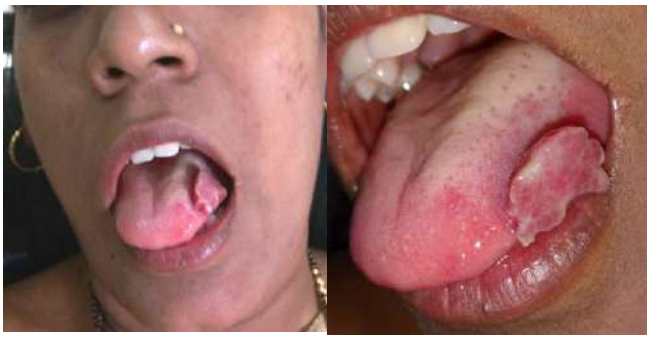

Figure 1: Pinkish white pedunculated growth measuring 3x2x2 cm present on left lateral border of tongue.

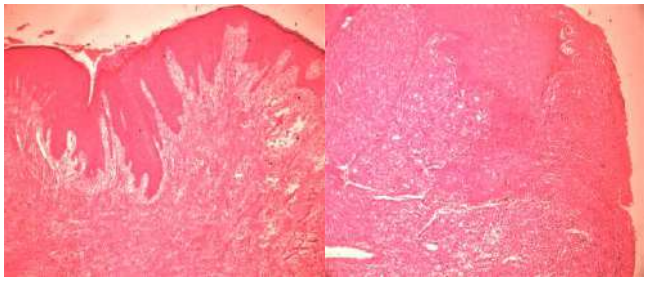

Figure 2: H & E stained section showing proliferated parakeratinized stratified squamous epithelium with underlying vascular connective tissue composed of inflammatory cell infiltrate.

Patient was advised to undergo excision of the lesion and was referred to the department of Oral Surgery for further treatment. After routine blood investigations in the department of Oral Pathology, an excisional biopsy of the lesion was performed under local anesthesia with due consent of the patient in the department of Oral Surgery. The tissue was sent for histopathological examination in the department of Oral Pathology.

A single bit of soft tissue specimen quadrangular in shape measuring 3x2x2 cm in size having irregular surface and firm consistency with reddish brown colour was received. Microscopic examination showed proliferated parakeratinized stratified squamous epithelium of varying thickness with an area of surface ulceration. Underlying connective tissue was composed of moderate chronic inflammatory cell infiltration and rich vascularity with endothelial cell proliferation confirming the diagnosis of pyogenic granuloma (Figure 2).

Excisional biopsy of the lesion was carried out and oral prophylaxis was done. Patient has not reported any recurrence for last six months after excision.

DISCUSSION:

PG is a tumour-like lesion, the pathogenesis of which is still unclear. It was initially considered to be a botryomycosis infection. Hence, the term 'pyogenic' was used. However, many authors believe that the etiology of PG is inflammatory in origin. Hence, PG is considered to be a kind of inflammatory hyperplasia. It is thought to arise as the reaction of tissues to minor injury or chronic irritation[10].These may include chronic irritation from dental calculus or retained teeth roots and trauma[12]. About one-third cases are associated with a history of traumatic injury, especially the extragingival PG[1,15]. Poor oral hygiene is a precipitating factor in many of the patients[1,15]. Certain drugs like cyclosporin have also been associated with the formation of PG[10]. The lesion in the present case started in the second trimester of pregnancy and continued to increase in size. An increased incidence of PG in pregnant women suggests a role of hormonal factors in the etiopathogenesis of this lesion. Hence, terms “pregnancy tumor,” “pregnancy epulis” and “granuloma gravidarum” are often used[7]. There is a striking predilection for gingiva in majority of pregnancy induced pyogenic granulomas (about 75% cases)[11,16]. The occurrence of the present case on the left lateral border of the tongue in a pregnant woman creates a rather unusual clinical presentation.

The lesion grossly appears as a solitary, red, pedunculated papule that is very friable. Less commonly, it may be a sessile plaque like lesion. It generally shows a rapid exophytic growth, with an ulcerated surface.[6]Sometimes, it shows a slow growth and takes weeks to months to reach optimal size[12]. It can occur in any age group; however, incidence is more common in females in second decade of life. Male-to-female ratio is 1:1.5[17].The colour of the lesion ranges from pink to red to purple depending upon the age of the lesion. Young PGs are red due to rich vascularity with prominent capillaries. As the lesion becomes old, it develops pink colour due to collagenization[1]. Present case showed a slower growth rate and a pinkish white colour rather than usual reddish pink colour, which suggests an old lesion.

In pregnancy, female steroid hormones may have a dual role on the pathogenesis of pyogenic granuloma. Due to the effect of the female steroid hormones- Estrogen and Progesterone, the concentration of angiogenic factors is increased and apoptosis of granuloma cells is reduced resulting in an enhanced angiogenic effect[18]. Increased levels of Estrogen hormone in pregnancy are responsible for increased production of vascular endothelial growth factor (VEGF) in the macrophages, an effect that is

antagonized by androgens may be related to the development of pregnancy tumour[19]. Progesterone functions as an immunosuppressant. It prevents an acute inflammatory reaction, but results in increased chronic tissue reaction, resulting clinically in an exaggerated appearance of inflammation. Usually, there is a regression of pregnancy tumour after parturition. The levels of VEGF are high in the granulomas in pregnancy and almost undetectable after parturition. This may be due to Angiopoietin-2 (Ang-2) causing blood vessels to regress in the absence of VEGF[7]. However, in this case, lesion continued to grow even after patient's delivery. It can be due to increased levels of hormone Prolactin which is responsible for persistent inflammation and is proangiogenic via the release of pro-angiogenic factors by leukocytes and epithelial cells[21]. This along with the irritation from the adjacent teeth could be the reason of non-regression and continued expansion of the lesion.

Histologically, two different types of pyogenic granulomas are found. One type shows presence of proliferating capillaries in a lobular arrangement. These lobules are surrounded by collagen fibres. This type is called as lobular capillary hemangioma (LCH) type PG[2]. The second type consists of highly vascular proliferation resembling a granulation tissue. This is called as non-LCH type of PG. The histopathologic examination in the present case was suggestive of non-LCH type of PG.

Excisional biopsy along with the removal of the irritant should be carried out to treat pyogenic granuloma. Recently, use of Nd:Y lasers has been proposed.

CONCLUSION:

Various etiologic factors such as trauma, chronic irritation, drugs, hormones etc have been implicated in the pathogenesis of PG. The female steroid hormones- Estrogen and Progesterone have a possible role in the formation of pyogenic granuloma and hormone Prolactin may be associated with continued expansion of the lesion post parturition in the present case. Hence, though PG is a non-neoplastic lesion, proper diagnosis, prevention and treatment should be instituted. Regular follow-ups should be carried out periodically to rule out recurrences and possible etiologies.

Financial Support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

REFERENCES:

1. Neville BW, Damm DD, Allen CM, Bouquot JE. Oral & maxillofacial pathology. 2nd Edn., WB Saunders, Philadelphia. 2002;437-495.
2. Vilmann A, Vilmann P, Vilmann H. Pyogenic granuloma: evaluation of oral conditions. Br J Oral Maxillofac Surg. 1986 Oct;24(5):376-82. doi: 10.1016/0266-4356(86)90023-9. PMID: 2945586.
3. Hullihen SP. Case of Aneurism by Anastomosis of the Superior Maxillare. Am J Dent Sci. 1844 Mar;4(3):160-162. PMID: 30749326; PMCID: PMC6055386.
4. Hartzell MB. Granuloma pyogenicum. J Cutan Dis Syph.1904;22:520-525.
5. Gonçales ES, Damante JH, Fischer Rubira CM, Taveira LA. Pyogenic granuloma on the upper lip: an unusual location. J Appl Oral Sci. 2010 Sep-Oct;18(5):538-41. doi: 10.1590/s1678-77572010000500019. PMID: 21085814; PMCID: PMC4246389.
6. Sarwal P, Lapumnuaypol K. Pyogenic Granuloma. 2022 Oct 23. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: 32310537.
7. Gondivkar SM, Gadbail A, Chole R. Oral pregnancy tumor. Contemp Clin Dent. 2010 Jul;1(3):190-2. doi: 10.4103/0976-237X.72792. PMID: 22114415; PMCID: PMC3220110.
8. Leal RM, Rodrigues AM, Mendonça AA, Chrcanovic BR. Oral pyogenic granuloma: Epidemiology of 171 cases. Rev Min Estomatol 2004;1:13-9.
9. Gordón-Núñez MA, de Vasconcelos Carvalho M, Benevenuto TG, Lopes MF, Silva LM, Galvão HC. Oral pyogenic granuloma: a retrospective analysis of 293 cases in a Brazilian population. J Oral Maxillofac Surg. 2010 Sep;68(9):2185-8. doi: 10.1016/j.joms.2009.07.070. Epub 2010 Apr 22. PMID: 20417014.
10. Sharma S, Chandra S, Gupta S, Srivastava S. Heterogeneous conceptualization of etiopathogenesis: Oral pyogenic granuloma. Natl J Maxillofac Surg. 2019 Jan-Jun;10(1):3-7. doi: 10.4103/njms.NJMS_55_18. PMID: 31205381; PMCID: PMC6563641.
11. Jafarzadeh H, Sanatkhani M, Mohtasham N. Oral pyogenic granuloma: a review. J Oral Sci. 2006 Dec;48(4):167-75. doi: 10.2334/josnusd.48.167. PMID: 17220613.
12. Al-Noaman AS. Pyogenic granuloma: Clinicopathological and treatment scenario. J Indian Soc Periodontol. 2020 May-Jun;24(3):233-236. doi: 10.4103/jisp.jisp_132_19. Epub 2020 May 4. PMID: 32773973; PMCID: PMC7307466.
13. Pilch BZ. Head and neck surgical pathology. Lippincott Williams & Wilkins, Philadelphia. 2001:389-390.
14. Macleod RI, Soames JV. Epulides: a clinicopathological study of a series of 200 consecutive lesions. Br Dent J. 1987 Jul 25;163(2):51-3. doi: 10.1038/sj.bdj.4806194. PMID: 3476134.
15. Eversole LR. Clinical outline of oral pathology: diagnosis and treatment. 3rd Edn., BC Decker, Hamilton. 2002:113-114.

16. Sternberg SS, Antonioli DA, Carter D, Mills SE, Oberman H Diagnostic surgical pathology. 3rd Edn., Lippincott Williams & Wilkins, Philadelphia. 1999;69:174.
17. Epivatianos A, Antoniades D, Zaraboukas T, Zairi E, Poulopoulos A, Kiziridou A, Iordanidis S. Pyogenic granuloma of the oral cavity: comparative study of its clinicopathological and immunohistochemical features. Pathol Int. 2005 Jul;55(7):391-7. doi: 10.1111/j.1440-1827.2005.01843.x. PMID: 15982213.
18. Yuan K, Wing LY, Lin MT. Pathogenetic roles of angiogenic factors in pyogenic granulomas in pregnancy are modulated by female sex hormones. J Periodontol. 2002 Jul;73(7):701-8. doi: 10.1902/jop.2002.73.7.701. PMID: 12146528.
19. Kanda N, Watanabe S. Regulatory roles of sex hormones in cutaneous biology and immunology. J Dermatol Sci. 2005 Apr;38(1):1-7. doi: 10.1016/j. jdermsci.2004. 10.011. Epub 2004 Dec 9. PMID: 15795118.
20. Ojanotko-Harri AO, Harri MP, Hurttia HM, Sewón LA. Altered tissue metabolism of progesterone in pregnancy gingivitis and granuloma. J Clin Periodontol. 1991 Apr;18(4):262-6. doi: 10.1111/j.1600-051x.1991. tb00425.x. PMID: 1856307.
21. Reuwer AQ, Nowak-Sliwinska P, Mans LA, van der Loos CM, von der Thüsen JH, Twickler MT, Spek CA, Goffin V, Griffioen AW, Borensztajn KS. Functional consequences of prolactin signalling in endothelial cells: a potential link with angiogenesis in pathophysiology? J Cell Mol Med. 2012 Sep;16(9): 2035-48. doi: 10.1111/j.1582-4934.2011.01499.x. PMID: 22128761; PMCID: PMC3822974.
22. Mills SE, Cooper PH, Fechner RE. Lobular capillary hemangioma: the underlying lesion of pyogenic granuloma. A study of 73 cases from the oral and nasal mucous membranes. Am J Surg Pathol. 1980 Oct;4(5):470-9. PMID: 7435775.

ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 12 | December - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

MUCO-EPIDERMOID CARCINOMA ON THE PALATE- A RARE CASE REPORT

Oral Medicine

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ABSTRACT

Mucoepidermoid carcinoma (MEC) is a malignant epithelial tumour. As the name implies, the tumour is composed of both mucous-secreting cells and epidermoid type cells in varying proportions. Most of the malignant neoplasms of the salivary gland occur in the parotid gland. Only a few have been well-documented in minor salivary glands. Epithelial neoplasms originating in the minor salivary glands account for approximately 15% of all salivary gland neoplasms. The following is a case report in which a 46-year-old lady presented with a painless swelling on the palate which was status quo for two years. Such lesions on the palate can be ignored or misdiagnosed if they are asymptomatic. Hence, this case report is an attempt to emphasize the need for early and prompt diagnosis of MEC to avoid complications and ensure better prognosis.

KEYWORDS

MEC- Mucoepidermoid carcinoma, Palatal swelling, Minor salivary gland tumours, Palatal tumours, Epithelial neoplasms.

INTRODUCTION

Mucoepidermoid carcinoma (MEC) is a malignant epithelial tumour, first studied and described as a separate entity by Stewart et al in 1945. As the name implies, the tumour is composed of both mucous-secreting cells and epidermoid type cells in varying proportions. [1] It accounts for <3% of all head and neck tumors. It occurs most frequently in adults during the fifth and sixth decades of life. [2],[3] About 5% of these tumors occur in patients younger than 18-year-old with women mostly affected. [2], [4], [5] About two-thirds of them arise within the parotid gland, and one-third arise within the minor salivary glands. When MEC arises in minor salivary glands, it can be located on the palate, retromolar area, floor of the mouth, buccal mucosa, lips, and tongue. Rarely, it can arise as primary jaw tumor or as laryngeal, lacrimal, nasal, paranasal, tracheal, or pulmonary tumor. Here we present a rare occurrence of mucoepidermoid carcinoma on the palate.

Case Report

A 46-year-old female patient came to the department with the chief complaint of a pea sized painless swelling on the palatal region 2 years ago. At that time, she was undergoing root canal treatment for a tooth adjacent to it and was adviced by the dentist that, it was an infective swelling which would subside after pus drainage. Since there was no change in the size of the swelling, ever since she noticed it, she reported to us. The patient had no positive history of any ill-healthy habit or any systemic illnesses

On examination, there was an oval, irregularly shaped mass, pink in colour, interspersed with erythematous areas, approximately 1x2 cm^2 in size in posterior palate on the right side. It extended from the mesial of tooth 17 to distal of 18, the surface of which was irregular. On palpation the mass was soft to firm, nontender and non- compressible with regular smooth borders. (Fig. 1) Patient had a metal bridge prosthesis from 16 to 18. Lymph nodes were not palpable. The soft tissue mass on the palate was provisionally diagnosed as a benign neoplasm and a differential diagnosis of minor salivary gland neoplasm was given.

Periapical pathology in relation to 16, 17 or 18 was ruled out with an intra-oral periapical radiograph. (Fig. 2) CBCT scan presented with only a homogenous hypodense mass in the posterior palatal region with no hyperdensities. (Fig. 3) A benign non-odontogenic neoplasm on the right posterior palate was given as the radiographic diagnosis. On performing fine needle aspiration biopsy of the mass, there was a reddish white aspirate. (Fig. 4)

An incisional biopsy was done and the specimen was examined histopathologically. (Fig. 5) Histopathological picture revealed cystic spaces with presence of mucous and epidermoid cells. In some of the cystic spaces, areas of degeneration were noticed in the centre. Intermediate cells were appreciated in few cystic areas. The cystic spaces were seen infiltrating the salivary gland tissue. (Fig. 6 and 7) Hence, the histopathological report suggested mucoepidermoid carcinoma of the posterior palate.

DISCUSSION

Most of the malignant neoplasms of the salivary gland occur in the parotid gland. Only a few have been well-documented in minor salivary glands. [5] Epithelial neoplasms originating in the minor salivary glands account for approximately 15% of all salivary gland neoplasms. [9][10] Mucoepidermoid carcinoma (MEC) is a malignant epithelial tumour reported to be more prevalent in females (approximately 1.5 times) as compared to males and the case reported here also is a 46-year-old female. It is commonly seen in the third to sixth decade of life. The most common site of its occurrence is parotid gland followed by the palate, retromolar area, and buccal mucosa. [6]

Among minor salivary glands, the tumor shows predilection to the hard and soft palate. [6][7] Palatal tumors are reported to be more benign than malignant. [8] MEC of the hard palate presents as a slow-growing, persistent, painless swelling which is soft in consistency. However, pain and pus discharge may be seen in lesion with secondary infection. Ulceration, resorption of underlying bone, numbness of adjacent teeth, tooth mobility, root resorption, and indurated/firm mass are the symptoms of advanced disease. In the present case, the lady had presented with a painless swelling on the palate which was status quo for two years. Such lesions on the palate can be ignored or misdiagnosed if they are asymptomatic. Further, late diagnosis of a similar lesion can cause extensive spread, with possibility of perforation of the hard palate and invasion into maxillary antrum or nasal cavity. [11]

Fortunately, in the present case, though the palatal swelling was asymptomatic, she grew anxious and reported to our department and was promptly diagnosed. Etiology of MEC is not known but prior exposure to ionizing radiation can be considered as a contributing factor since cases of MEC have been recorded after radiation therapy for thyroid carcinoma or leukemia. Tobacco either in chewing or smoking form has not been implicated as a causative factor of MEC. [12]

Histopathologically, the tumors are graded into low, intermediate, and high grade. A low-grade MEC presents as a slow-growing swelling with a characteristic size of <3 cm. Histologically, these tumors show predominance of mucous-secreting cells. They are partially encapsulated and contain cystic spaces filled with mucin, lined by mucus-secreting, intermediate, and epidermoid cells, whereas the high-grade tumors predominantly consist of epithelial cells, with few mucinous cells. These are rapid-growing tumors and have a tendency of local tissue invasion in early stages. In long-standing cases, distant metastasis to lungs is observed with an unfavourable prognosis. [13] The present case has features similar to low-grade MEC clinically as well as histopathologically as it was slow growing and consisted of cystic spaces filled with mucin, lined by mucus-secreting, intermediate, and epidermoid cells. This could possibly be the reason for asymptomatic nature of the case presented. Treatment of MEC depends on its aggressiveness and the extent of its spread. When the tumor is confined to the palatal mucosa with intact periosteum, wide excision of lesion along with underlying mucoperiosteum is advised. [14] When the tumor

infiltrates the periosteum with erosion of underlying bone, excision of lesion along with the underlying bone is indicated. Failure to detect lesion in its early stage leads to involvement of overlying maxillary sinus and the nasal cavity, requiring more extensive surgery including palatectomy, infrastructure maxillectomy, or extended maxillectomies.[15] Hence, to avoid such damage and extensive surgeries a prompt diagnosis and early treatment is necessary for MEC. Through this case an attempt is made to emphasize the need for early and prompt diagnosis of MEC to avoid complications and ensure better prognosis.

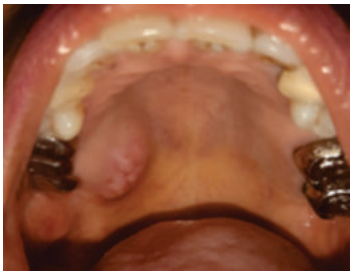

Figure 1: Clinical picture

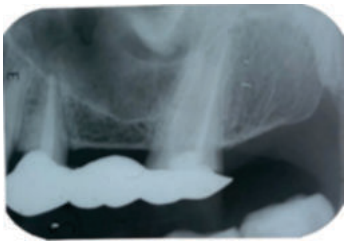

Figure 2: Intra-oral periapical radiograph ruling out odontogenic cause

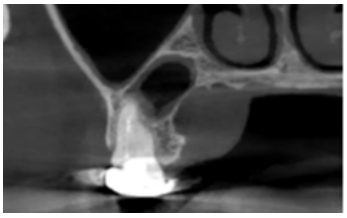

Figure 3: Coronal section of CBCT showing soft tissue enlargement

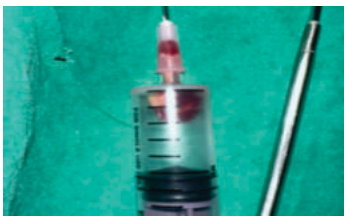

Figure 4: Fine needle aspiration biopsy

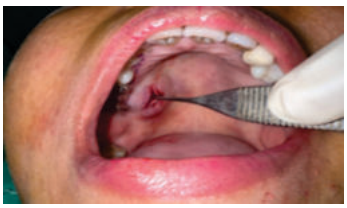

Figure 6 and 7: Histopathological picture.

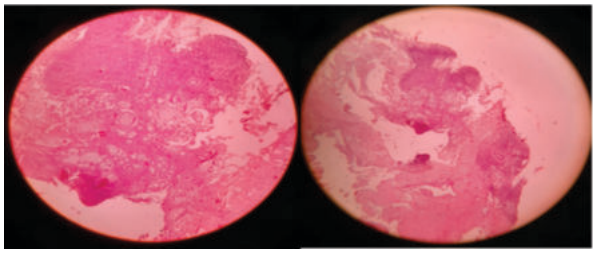

Figure 6 and 7: Histopathological picture.

REFERENCES

1. B Sivapathasundharam. Shafer's Textbook of Oral Pathology - E Book. Elsevier Health Sciences; 2016.
2. Jarde SJ, Das S, Narayanswamy SA, Chatterjee A, Babu C. Mucoepidermoid carcinoma of the palate: A rare case report. J Indian Soc Periodontol. 2016 Mar-Apr;20(2):203-6. doi: 10.4103/0972-124X.170828. PMID: 27143836; PMCID: PMC4847470.
3. Castro EB, Huvos AG, Strong EW, Foote FW., Jr Tumors of the major salivary glands in children. Cancer. 1972;29:312–7.
4. Hicks J, Flaitz C. Mucoepidermoid carcinoma of salivary glands in children and adolescents: Assessment of proliferation markers. Oral Oncol. 2000;36:454–60.
5. Luna MA, Batsakis JG, El – Naggar AK. Salivary gland tumors in children. Ann Otol Rhinol Laryngol. 1991;100:869–71.
6. Gill S, Mohan A, Aggarwal S, Varshney A. Mucoepidermoid carcinoma of hard palate. Indian J Pathol Microbiol 2018;61:397-8.
7. Munhoz Ede A, Cardoso CL, Tjioe KC, Sant'ana E, Consolaro A, Damante JH, et al. Atypical clinical manifestation of mucoepidermoid carcinoma in the palate. Gen Dent 2009;57:e51-3.
8. Moshy J, Owibomaingere S, Mwakyoma H. Intraoral minor salivary glands neoplasms; the pattern and management. Prof Med J. 2010;17:483–9.
9. Eveson JW, Cawson RA. Tumours of the minor (oropharyngeal) salivary glands: A demographic study of 336 cases. J Oral Pathol. 1985;14:500–9.
10. Waldron CA, El - Mofty SK, Gnepp DR. Tumors of the intraoral minor salivary glands: A demographic and histologic study of 426 cases. Oral Surg Oral Med Oral Pathol. 1988;66:323–33.
11. Flaitz CM. Mucoepidermoid carcinoma of the palate in a child. Pediatr Dent 2000;22:292-3.
12. Jakobsson PA, Blanck C, Eneroth CM. Mucoepidermoid carcinoma of the parotid gland. Cancer 1968;22:111-24.
13. Ritwik P, Cordell KG, Brannon RB. Minor salivary gland mucoepidermoid carcinoma in children and adolescents: A case series and review of the literature. J Med Case Rep 2012;6:182.
14. Moore BA, Burkey BB, Netterville JL, Butcher RB 2nd, Amedee RG. Surgical management of minor salivary gland neoplasms of the palate. Ochsner J 2008;8:172-80.
15. Truitt TO, Gleich LL, Huntress GP, Gluckman JL. Surgical management of hard palate malignancies. Otolaryngol Head Neck Surg 1999;121:548-52.

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Journal of Dental Problems and Solutions OPEN ACCESS JOURNAL

ISSN: 2394-8418 DOI: https://doi.org/10.17352/jdps

Research Article

Assessment of orofacial functions in children using 'off track' mobile application: A cross-sectional study

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Received: 21 November, 2023
Accepted: 04 December, 2023
Published: 05 December, 2023

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Keywords: Orofacial functions; Malocclusion; Children

Abstract

Introduction: Orofacial dysfunctions interfere with normal growth and development and may lead to multiple outcomes, including malocclusion. Assessment of Orofacial functions is thus critical in children.

Methods: 'Off Track', a mobile-based app was used for orofacial functional assessment. The domains assessed were breathing, swallowing, chewing, speech, sleep, and others. The dysfunctions in each domain and the 'Off Track' score distribution were represented as frequency with percentages. Fisher's exact test was used to detect the difference between the age groups. Unadjusted odds were estimated to assess the association between feeding history and breathing dysfunction, feeding history and sleep dysfunction, and breathing dysfunction and sleep dysfunction.

Result: The 'Off Track' scores 3, 4, 5, and 6 were recorded in 42.9%, 39.3%, 14.3% and 3.6% of the population, respectively. Most of the participants (89.29%) showed dysfunction in the breathing domain followed by swallowing (75%). The difference between the age groups was not significant ($p > 0.05$). Odd's ratios estimated for feeding history of the child and, mouth breathing and sleep dysfunction were not statistically significant.

Conclusion: Orofacial dysfunctions are widely prevalent in children and 'Off Track' may serve as a chairside user-friendly app-based screening tool to assess orofacial functions in children.

Abbreviations

OMD: Orofacial Myofunctional Disorder; KCPS: Karaduman Chewing Performance Scale; PEDI-EAT-10: Pediatric version of the Eating Assessment Tool; NOT-S: Nordic Orofacial Test Screening; MB: Mouth Breathing; SDB: Sleep Disordered Breathing

Introduction

Orofacial functions include many vital actions such as breathing, chewing, and swallowing, and they form the basis of social interaction in speech, emotional communication, and facial expressions [1]. Oral dysfunction can begin with the very first breath and with the very first feed [2]. It may also occur due to various genetic and congenital diseases, the existence of parafunctional habits, and/or as a result of trauma [3]. When oral dysfunction goes untreated, orofacial myofunctional disorders (OMD) can result. Orofacial myofunctional disorders include dysfunction of the lips, jaw, tongue, and/or oropharynx that interferes with normal growth and development or function of other oral structures, and the lack of intervention at critical periods may result in malocclusion and suboptimal facial development [4].

There is a close relationship between form and function. The development of malocclusion must be considered as a result of interactions among the genetically determined developmental

Citation: Patwardhan PP, Katre AN (2023) Assessment of orofacial functions in children using 'off track' mobile application: A cross-sectional study. J Dent Probl Solut 10(2): 016-020. DOI: https://dx.doi.org/10.17352/2394-8418.000123

factors and several external and internal environmental factors, including orofacial functions [5].

The impact of breathing, swallowing, chewing, normal resting position of musculature, and airway obstruction on the developing occlusion has been reported [4]. Hence early assessment of orofacial functions and dysfunctions is of paramount importance.

The use of electronic media is increasing day by day and there are several mobile-based applications being used as an aid in dental practice [6-10]. However, there is no mobile-based application available for assessment of orofacial functions to the best of our knowledge. A valid, reliable, economical, chairside, and easy-to-use tool for the orofacial functional assessment is thus needed. Thus, the aim of the study was to assess the orofacial functions in three to thirteen-year-old children using a mobile-based application – 'Off Track'.

Materials and methods

A cross-sectional study design was used. The study was carried out between the 7th and 14th of March, 2022 in the Department of Pediatric and Preventive Dentistry, YMT Dental College and Hospital, Navi Mumbai, India. As this was the first study using the app, no specific sample size was estimated. All children of three to thirteen years reporting to the outpatient department were screened. Children with any systemic disorders or craniofacial syndromes, children who were undergoing or had completed orthodontic treatment, children who did not cooperate with the examination and other procedures, and those whose parents refused to give consent were excluded from the study. The protocol was approved by the Institutional Review Board and Institutional Ethics Committee before the study commenced.

Informed consent was obtained from the parents or the guardians before the assessment. Basic demographic details (Name, age, gender, etc) along with the feeding history (Breastfeeding/bottle feeding/ both) of the children were recorded. Orofacial functions were assessed using 'Off Track'.

'Off Track' is an android-based application consisting of 6 domains of orofacial functions. Each domain contains a set of questions with categorical outcomes. The domains assessed are breathing, swallowing, chewing, speech, sleep, and others (posture, history of oral habits, height and weight of the child, etc). Breathing is assessed as a binary categorical variable through three questions based on a three-point Likert rating scale. The responses of yes/sometimes are considered as breathing dysfunction. Swallowing is assessed as a binary categorical variable through three questions. A response of 'Yes' for questions 2 or 3 or a response of 'No' for question 1 is considered as swallowing dysfunction. Chewing is also assessed as a binary categorical variable through three questions. A response of 'No' for any one question is considered as chewing dysfunction. Speech is assessed as a binary categorical variable through two questions. A response of 'Yes' for question 2 or a response of 'No' for question 1 is considered as speech dysfunction. Sleep is also assessed as a binary categorical variable through six questions. Even a single affirmative answer is considered sleep dysfunction. The parameters/questions in the app were framed following a pilot expert validation.

All the parameters assessed are parent/ self-reported or investigator-assessed. Based on the information fed in the app, an 'Off Track' score ranging from 0-6 is calculated by the app. Higher scores indicate dysfunction in multiple domains. The app also gives general recommendations for orofacial functional improvement. (Details mentioned in Annexure 1).

The dysfunctions in each domain were represented as frequencies with percentages. The 'Off Track' score distribution was also represented as frequency with percentages. Fisher's exact test was used to detect the difference between the age groups. Unadjusted odds were estimated to assess the association between feeding history and breathing dysfunction, feeding history and sleep dysfunction, and breathing dysfunction and sleep dysfunction.

Results

28 children participated in the study. 9 (32.1%) children belonged to the age range of 3-6 years and 19 (67.9%) children were in the age range of > 6-13 years (Table 1). The mean age of the participants was 8.79 + 0.98 years. 53.6% were males and 46.4% were females. 21.4% had an abnormal birth history (caesarean section) and 28.6% of the children had a history of both bottle feeding and breastfeeding.

The 'Off Track' scores of the participants ranged from 3 to 6. The scores 3, 4, 5, and 6 were recorded in 42.9%, 39.3%, 14.3%, and 3.6% of children, respectively. None of the participants had 'Off Track' scores of 0, 1 or 2.

Table 2 depicts the age and gender-wise distribution of the dysfunction detected in each domain. Most of the participants (89.29%) showed dysfunction in the breathing domain followed by swallowing (75%), chewing (64.29%), and sleep (60.71%). The least dysfunction was recorded in the domain of speech (21.43%). When the breathing and swallowing domains were assessed according to age, no significant difference was found between the groups ($p > 0.05$).

The estimated odds of having breathing dysfunction and sleep dysfunction in participants with a history of bottle feeding were 0.77 (0.0605 to 10.0043) and 1.11 (0.2054 to 6.0093) respectively. The odds of having sleep dysfunction in participants with breathing dysfunction were 3.56 (0.2816 to 44.8860), none were statistically significant (Table 3).

Table 1: Age and gender-wise distribution of the sample population.

Age (years)	Boys (n = 15) (53.6%)	Girls (n = 13) (46.4%)
3 to 6	4 (14.28%)	5 (17.85%)
> 6 to 13	11 (39.28%)	8 (28.57%)
N = 28		

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Table 2: Age and gender-wise distribution of orofacial dysfunctions.

Dysfunction	Age (years)	Boys	Girls	Total	
Breathing n1 = 25 (89.29%)	3 to 6	4 (16.00%)	5 (20.00%)	9 (36.00%)	x^2 = 1.591
	> 6 to 13	9 (36.00%)	7 (28.00%)	16 (64.00%)	
		x^2 = 0.231			
Swallowing n2 = 21 (75.00%)	3 to 6	3 (14.28%)	5 (23.80%)	8 (38.10%)	x^2 = 1.364
	> 6 to 13	8 (38.09%)	5 (23.80%)	13 (61.90%)	
		x^2 = 0.047			
Chewing n3 = 18 (64.29%)	3 to 6	3 (16.67%)	4 (22.22%)	7 (38.89%)	x^2 = 1.051
	> 6 to 13	6 (33.33%)	5 (23.80%)	11 (61.11%)	
		x^2 = 0.258			
Speech n4 = 6 (21.43%)	3 to 6	1 (16.67%)	2 (33.33%)	3 (50.00%)	x^2 = 1.116
	> 6 to 13	1 (16.67%)	2 (33.33%)	3 (50.00%)	
		x^2 = 1.257			
Sleep n5 = 17 (60.71%)	3 to 6	3 (17.65%)	4 (23.53%)	7 (41.18%)	x^2 = 1.619
	> 6 to 13	6 (35.29%)	4 (23.53%)	10 (58.82%)	
		x^2 = 0.007			
N = 28, $p > 0.05$					

Table 3: Association of feeding history, mouth breathing and sleep dysfunction.

	Mouth breathing	Sleep dysfunction
Bottle feeding*	OR = 0.7778	OR = 1.11
Breastfeeding only	(0.0605 to 10.0043)	(0.2054 to 6.0093)
	OR = 3.56 (0.2816 to 44.8860)	
* History of both bottle and breastfeeding		

Discussion

It may be possible to ensure early detection of any problem in the stomatognathic system by using reliable and valid screening of the orofacial functions in children. Children with neurological or anatomical problems have been assessed for orofacial functions in the past [11-13]. However, data on healthy children is lacking, hence, this study on three to thirteen-year-old children using a chairside tool - The 'Off Track' app. Children in the age group of 3-13 years were selected and analysed under 2 subgroups viz. 3-6 and > 6-13. This division was done according to the dentition present i.e., primary and mixed dentition, respectively.

There are various studies reported in the literature for the assessment of orofacial functions. Authors have used simple orofacial examination, appropriate tests (Mirror test/ water retention test) [5], or different tools like the Karaduman Chewing Performance Scale (KCPS), Pediatric version of the Eating Assessment Tool (PEDI-EAT-10), Nordic Orofacial Test Screening (NOT-S) protocol for the assessment [3]. However, there is no single tool that provides a comprehensive assessment of all the orofacial functions. 'Off Track' is a promising and easy-to-use chairside tool providing the overall assessment of the orofacial functions.

Breathing is a critical function of the human body. Mouth Breathing (MB) is a form of breathing that replaces nasal breathing and the aetiology is complex. Due to its various deleterious effects, mouth breathing has been a concern for healthcare professionals in various areas. Children with MB show skeletal as well as dental deformities such as backward and downward rotation of the maxilla and mandible, steep occlusal plane, and labially inclined upper anterior teeth [14]. Hence, assessment of breathing is crucial. The mirror test and the water retention test are among the breathing tests most cited in the literature [15]. The off Track app uses the water retention test along with the parent-reported indicators of mouth breathing. We found that the breathing domain showed the most dysfunction among all the domains. The prevalence of mouth breathing in children is highly variable ranging from 11% - 56% [16-19]. Adenotonsillar hypertrophy is the most common cause of mouth breathing in children [20] and children in the age group of 2 to 10 years are most commonly affected [21]. Mouth breathing can also result from nasal obstruction because of nasal inflammation in children. In the past few years, environmental degradation and air pollution have led to an increased prevalence of respiratory allergic diseases, and hence allergic rhinitis-related nasal obstruction has become more common [22], which may also lead to compensatory mouth breathing.

The swallowing domain was the second most common domain to show dysfunction. Atypical swallowing develops as a compensatory movement pattern when normal movement is inhibited and this tongue thrust swallow involves excessive perioral effort and the tongue exerts forward and/or lateral pressure into the teeth [4]. The off Track app uses the actual observation of lip movements while swallowing for assessment of the swallowing domain. It has been reported in the literature that atypical swallowing starts as a compensation mechanism for a pre-existing malocclusion (e.g., open-bite, spacing in the dentition, etc). [23]. Also, patients who present with malocclusions like posterior crossbite have an increased prevalence of atypical swallowing [5].

Odd's ratios estimated for feeding history of the child and, mouth breathing and sleep dysfunction were not statistically significant. According to a recent systematic review, breastfeeding is a protective factor against the development of mouth breathing (OR = 0.62; 95% CI: 0.41-0.93) and the likelihood of developing mouth breathing is 41% and 34% lower among children that were breastfed for more than 12 and more than 24 months, respectively [24]. A study done by Talib, et al. in 2017 [25] reports that breastfeeding has a protective effect on sleep-disordered breathing (SDB) while non-nutritive sucking has no effect on SDB. In our study, the population was either breastfed or had a combined history of bottle and breastfeeding. None of the children had a history of purely bottle feeding. This, along with the limited sample size may be the reason for our observations.

Age had no significant impact on any of the assessed orofacial functions. Most of the children were in the age range of > 6-13 years which may possibly have contributed to the same.

In our study, none of the participants had 'Off Track' scores of 0, 1 or 2. Our study was performed on the patients reporting for treatments with existing dental problems possibly affecting more than one functional domain.

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The 'Off Track' app has some inherent limitations. The sixth domain in the assessment collects information regarding unrelated parameters like posture, oral habits, height and weight of the children, and others, and a score is calculated, however, the impact of each of these parameters is not assessed. The recall bias encountered while questioning the parents regarding the history cannot be overlooked. Additionally, owing to this being a pilot study, a definite sample size estimation, calibration of the operator, etc. was beyond the scope of this research. We carried out expert validation of the questions framed in the app, however, content validity and criteria validity have yet to be evaluated. Additionally, agreement with specific functional parameters (Eg. PSG for determining sleep disturbances) was not a part of this pilot study.

Conclusion

The 'Off Track' app may serve as a simple, chairside screening tool to assess orofacial functions in children, with certain improvements. Future studies with adequate sample size may help substantiate our claims.

Acknowledgement

This is self-funded research. No external funding was received.

Ethics approval

Institutional Review Board and Ethics Committee,

Dr. G.D. Pol Foundation's YMT Dental College and Hospital, Navi Mumbai, India.

References

1. Bakke M, Bergendal B, McAllister A, Sjögreen L, Asten P. Development and evaluation of a comprehensive screening for orofacial dysfunction. Swed Dent J. 2007;31(2):75-84. PMID: 17695052.

2. Siegel SA. Aerophagia-induced reflux in breastfeeding infants with ankyloglossia and shortened maxillary labial frenula (tongue and lip tie). International Journal of Clinical Pediatrics. 2016; 5:6-8.

3. Ozturk S, Ozsin Ozler C, Serel Arslan S, Demir N, Olmez MS, Uzamis Tekcicek M. Orofacial functions and oral health: An analysis on children aged 5-8 years old. J Texture Stud. 2022 Feb;53(1):31-40. doi: 10.1111/jtxs.12628. Epub 2021 Sep 19. PMID: 34482536.

4. D'Onofrio L. Oral dysfunction as a cause of malocclusion. Orthod Craniofac Res. 2019 May;22 Suppl 1(Suppl 1):43-48. doi: 10.1111/ocr.12277. PMID: 31074141; PMCID: PMC6851783.

5. Ovsenik M. Incorrect orofacial functions until 5 years of age and their association with posterior crossbite. Am J Orthod Dentofacial Orthop. 2009 Sep;136(3):375-81. doi: 10.1016/j.ajodo.2008.03.018. PMID: 19732672.

6. Sharma H, Suprabha BS, Rao A. Teledentistry and its applications in paediatric dentistry: A literature review. Pediatr Dent J. 2021 Dec;31(3):203-215. doi: 10.1016/j.pdj.2021.08.003. Epub 2021 Sep 1. PMID: 34848924; PMCID: PMC8613071.

7. Patil S, Hedad IA, Jafer AA, Abutaleb GK, Arishi TM, Arishi SA, Arishi HA, Jafer M, Gujar AN, Khan S, Raj AT. Effectiveness of mobile phone applications in improving oral hygiene care and outcomes in orthodontic patients. J Oral Biol Craniofac Res. 2021 Jan-Mar;11(1):26-32. doi: 10.1016/j.jobcr.2020.11.004. Epub 2020 Nov 17. PMID: 33344158; PMCID: PMC7736984.

8. Zolfaghari M, Shirmohammadi M, Shahhosseini H, Mokhtaran M, Mohebbi SZ. Development and evaluation of a gamified smart phone mobile health application for oral health promotion in early childhood: a randomized controlled trial. BMC Oral Health. 2021 Jan 7;21(1):18. doi: 10.1186/s12903-020-01374-2. PMID: 33413304; PMCID: PMC7791794.

9. Scheerman JFM, van Meijel B, van Empelen P, Kramer GJC, Verrips GHW, Pakpour AH, Van den Braak MCT, van Loveren C. Study protocol of a randomized controlled trial to test the effect of a smartphone application on oral-health behavior and oral hygiene in adolescents with fixed orthodontic appliances. BMC Oral Health. 2018 Feb 7;18(1):19. doi: 10.1186/s12903-018-0475-9. PMID: 29415697; PMCID: PMC5803887.

10. Thakur JH, Subhadra HN, Jawdekar A. Evaluation of CRAFT as a Tool for Caries Risk Assessment in 3- to 6-year-old Children and its Validation against Alban's Test: A Pilot Study. Int J Clin Pediatr Dent. 2019 Nov-Dec;12(6):538-542. doi: 10.5005/jp-journals-10005-1698. PMID: 32440071; PMCID: PMC7229380.

11. Kaczorowska N, Markulak P, Mikulewicz M. Assessment of orofacial dysfunction in a group of Polish children with unilateral cleft lip and palate: A preliminary report. Adv Clin Exp Med. 2020 Nov;29(11):1331-1336. doi: 10.17219/acem/128187. PMID: 33269820.

12. Alaçam A, Çalık Yılmaz BC, Incioğlu AS. Assessment of orofacial dysfunction using the NOT-S method in a group of Turkish children with cerebral palsy. Eur Arch Paediatr Dent. 2020 Apr;21(2):215-221. doi: 10.1007/s40368-019-00475-z. Epub 2019 Sep 6. PMID: 31493279.

13. Hoang DA, Le VNT, Nguyen TM, Jagomägi T. Orofacial dysfunction screening examinations in children with sleep-disordered breathing symptoms. J Clin Pediatr Dent. 2023 Jul;47(4):25-34. doi: 10.22514/jocpd.2023.032. Epub 2023 Jul 3. PMID: 37408343.

14. Zhao Z, Zheng L, Huang X, Li C, Liu J, Hu Y. Effects of mouth breathing on facial skeletal development in children: a systematic review and meta-analysis. BMC Oral Health. 2021 Mar 10;21(1):108. doi: 10.1186/s12903-021-01458-7. PMID: 33691678; PMCID: PMC7944632.

15. Pacheco MC, Casagrande CF, Teixeira LP, Finck NS, de Araújo MT. Guidelines proposal for clinical recognition of mouth breathing children. Dental Press J Orthod. 2015 Jul-Aug;20(4):39-44. doi: 10.1590/2176-9451.20.4.039-044.oar. PMID: 26352843; PMCID: PMC4593528.

16. S Dhull K, Verma T, Dutta B. Prevalence of Deleterious Oral Habits among 3- to 5-year-old Preschool Children in Bhubaneswar, Odisha, India. Int J Clin Pediatr Dent. 2018 May-Jun;11(3):210-213. doi: 10.5005/jp-journals-10005-1513. Epub 2018 Jun 1. PMID: 30131643; PMCID: PMC6102427.

17. Felcar JM, Bueno IR, Massan AC, Torezan RP, Cardoso JR. Prevalência de respiradores bucais em crianças de idade escolar [Prevalence of mouth breathing in children from an elementary school]. Cien Saude Colet. 2010 Mar;15(2):437-44. Portuguese. doi: 10.1590/S1413-81232010000200020. PMID: 20414610.

18. Abreu RR, Rocha RL, Lamounier JA, Guerra AF. Prevalence of mouth breathing among children. J Pediatr (Rio J). 2008 Sep-Oct;84(5):467-70. English, Portuguese. doi: 10.2223/JPED.1806. Epub 2008 Sep 29. PMID: 18830512.

19. De Menezes VA, Leal RB, Pessoa RS, Pontes RM. Prevalence and factors related to mouth breathing in school children at the Santo Amaro project-Recife, 2005. Braz J Otorhinolaryngol. 2006 May-Jun;72(3):394-9. doi: 10.1016/s1808-8694(15)30975-7. PMID: 17119778; PMCID: PMC9443508.

20. Kim DK, Rhee CS, Yun PY, Kim JW. Adenotonsillar hypertrophy as a risk factor of dentofacial abnormality in Korean children. Eur Arch Otorhinolaryngol. 2015 Nov;272(11):3311-6. doi: 10.1007/s00405-014-3407-6. Epub 2014 Dec 10. PMID: 25490975.

21. Vogler RC, Ii FJ, Pilgram TK. Age-specific size of the normal adenoid pad on magnetic resonance imaging. Clin Otolaryngol Allied Sci. 2000 Oct;25(5):392-5. doi: 10.1046/j.1365-2273.2000.00381.x. PMID: 11012653.

Citation: Patwardhan PP, Katre AN (2023) Assessment of orofacial functions in children using 'off track' mobile application: A cross-sectional study. J Dent Probl Solut 10(2): 016-020. DOI: https://dx.doi.org/10.17352/2394-8418.000123

22. Lin L, Zhao T, Qin D, Hua F, He H. The impact of mouth breathing on dentofacial development: A concise review. Front Public Health. 2022 Sep 8;10:929165. doi: 10.3389/fpubh.2022.929165. PMID: 36159237; PMCID: PMC9498581.

23. Maspero C, Prevedello C, Giannini L, Galbiati G, Farronato G. Atypical swallowing: a review. Minerva Stomatol. 2014 Jun;63(6):217-27. English, Italian. PMID: 25267151.

24. Savian CM, Bolsson GB, Botton G, Antoniazzi RP, de Oliveira Rocha R, Zanatta FB, Santos BZ. Do breastfed children have a lower chance of developing mouth breathing? A systematic review and meta-analysis. Clin Oral Investig. 2021 Apr;25(4):1641-1654. doi: 10.1007/s00784-021-03791-1. Epub 2021 Jan 27. PMID: 33506425.

25. Al-Talib T, Koroluk LD, Vann WF Jr, Phillips C. The Impact of Non-nutritive Sucking on the Risk for Sleep-disordered Breathing in Children. J Dent Child (Chic). 2017 Jan 15;84(1):30-34. PMID: 28387187.

Citation: Patwardhan PP, Katre AN (2023) Assessment of orofacial functions in children using 'off track' mobile application: A cross-sectional study. J Dent Probl Solut 10(2): 016-020. DOI: https://dx.doi.org/10.17352/2394-8418.000123

Original Article

Do We Recognize a Prosthodontist? A Questionnaire-Based Survey

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Abstract

Loss of teeth impairs oral functions and masticatory efficiency and has a psychological impact on the patient. Not only missing teeth but also any defects of the face have important psychosocial implications for affected patients. Face has a unique role in social and emotional expression and communication, and most importantly, it is the reflection of oneself. Maxillofacial defects are deformities that affect an individual's physical and psychological health, resulting in serious psychiatric, familial, and social problems. In the earlier days, it was difficult to rehabilitate these patients on a consistent basis. Today, with the emergence of maxillofacial prosthodontics as a field, it is possible to restore the majority of them to normal form and function. The vista of prosthodontics is wide and encompasses various treatment modalities right from a simple conventional complete denture to advanced implant-supported and reconstructive procedures in all age groups right from infancy to geriatrics. A common man must be aware of the reach of a prosthodontist in terms of rehabilitation, as well as it is the responsibility of a clinician to consult a prosthodontist as per case demands. This questionnaire-based survey is to know the need, knowledge, awareness, attitude, and desire to consult a prosthodontist among the general public and general practitioners.

Keywords: Awareness survey, Prosthodontist, Education, General public, General practitioners.

Introduction

Teeth play a key role in the general wellness of an individual. Loss of teeth significantly impairs oral functions and masticatory efficiency and has a psychological impact on the patient. Rehabilitation of the patient is of utmost importance to improve their quality of life.

Not only missing teeth but also any defects of the face and associated structures, therefore, have important psychosocial implications on affected patients. Here a prothodontist plays a crucial role. A prosthodontist is a specialist who deals with the replacement of missing teeth and oral structures, dentures, or prostheses. The vista of prosthodontics is wide and encompasses various treatment modalities right from a simple conventional complete denture to advanced implant-supported prosthesis and reconstructive procedures in all age groups right from infancy to geriatrics.[1-3]

Patients with different educational and socioeconomic background may have varied awareness regarding the role and scope of a prosthodontist. As it is rightly said, awareness allows us to get outside of ours mind and observe it in action. It is the greatest agent of change and is important in each and every element of life.

Access this article online

Website:
www.jrad.co.in

DOI:
https://doi.org/10.53064/jrad.2023.14.6.425

With emphasis being placed on patient-mediated concerns in prosthetic treatment planning, understanding patient's knowledge and attitude toward the various prosthetic treatments and creating awareness among the general public could be a prospective tool in predicting successful treatment outcomes. Shreya Gupta, Sneha Mantri, and Abhilasha Bhasin had evaluated the knowledge and attitude of the general public toward the prosthodontic rehabilitation and utilization of dental services and concluded that 44% of the surveyed population had insufficient knowledge regarding the treatment options for missing teeth.[2,4-7]

Thus, the purpose of this study is to survey the need, knowledge, awareness, attitude, and desire to consult a prosthodontist among the general practitioners and general public.

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Received: Sep. 02, 2023; **Accepted:** Oct. 12, 2023; **Published:** Oct. 28,2023

How to cite this article: Mistry S, Banga P, Dole V, Jadhav P, Doshi R. Do We Recognize a Prosthodontist? A Questionnaire-Based Survey. J Res Adv Dent 2023;14(6):1-5.

Materials and Methods

Study setting

This study was a cross-sectional questionnaire-based survey conducted all over India.

A questionnaire with 33 QUESTIONS, 15 dedicated to the general practitioners and 18 dedicated to the General Public, was prepared and validated to analyze the awareness and knowledge of prosthodontists among the general practitioners and general public of India. The online survey was conducted through Google Forms.

Study subjects

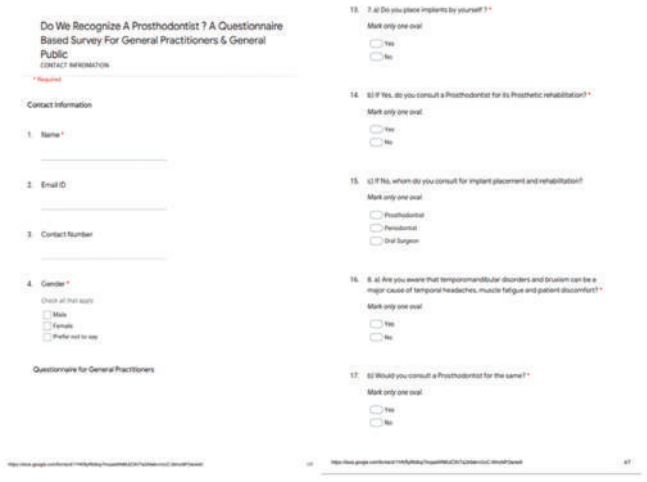
This study was 202 dental practitioners and 240 general public participated in this survey.

Methodology

In this study of a cross-sectional questionnaire-based survey, the targeted population were dentists (general dentist and specialist/consultant) and general public of India.

A survey through a online standard questionnaire with 38 questions, open as well as multiple-choice were questions delivered to dental practitioners and general public, out of which 15 questions for the dental practitioner and 18 questions for the general public. Questionnaire was formulated in Marathi, Hindi, and English language. The questionnaire comprised questions to assess awareness, knowledge, and significance of a prosthodontist among the general dental practitioners and general public of India. Adequate time was provided to fill the questionnaire.

The survey consisted of two different questionnaires with dedicated questions for general practitioners and general public. Collected data were tallied and sent for statistical treatment.


Do We Recognize A Prosthodontist ? A Questionnaire Based Survey For General Practitioners & General Public

CONTACT INFORMATION

Contact Information

1. Name *

2. Email ID

3. Contact Number

4. Gender *

Questionnaire for General Practitioners

13. 7. a) Do you place implants by yourself ? *

Mark only one oval

14. b) If Yes, do you consult a Prosthodontist for its Prosthetic rehabilitation? *

Mark only one oval

15. c) If No, whom do you consult for implant placement and rehabilitation?

Mark only one oval

16. 8. a) Are you aware that temporomandibular disorders and bruxism can be a major cause of temporal headaches, muscle fatigue and patient discomfort? *

Mark only one oval

17. b) Would you consult a Prosthodontist for the same? *

Mark only one oval

Results

A total of 440 participants responded out of which 202 were dental practitioners and 238 general public. The results of the very important and relevant questions of the survey are given in the following frequency tables.

Table 1: Do you know about prosthodontics as a specialty of dentistry?

	Frequency	Percent
No	60	25.1
Yes	179	74.9
Total	239	100.0

Table 2: Whom would you like your treatment to be done by?

	Frequency	Percent
General practitioner	52	21.8
Someone who is specialized in the field	187	78.2
Total	239	100.0

Table 3: Do you know there are fixed treatment options for replacing

	Frequency	Percent
	1	0.4
All missing teeth	59	24.7
Multiple missing teeth	53	22.2
Multiple missing teeth; all missing teeth	7	2.9
Single missing teeth	40	16.7
Single missing teeth; all missing teeth	9	3.8
Single missing teeth; multiple missing teeth	10	4.2
Single missing teeth; multiple missing teeth; all missing teeth	60	25.1
Total	239	100.0

Table 4: Are you aware that a missing eye/ear/nose/ digits can be replaced?

	Frequency	Percent
No	119	49.8
Yes	120	50.2
Total	239	100.0

Responses given by dental practitioner

In this study, the level of knowledge, awareness, and attitude about prosthetic treatment modalities has been evaluated. Prosthodontists usually consider factors such as the preservation of natural teeth and the maintenance of periodontal health as a priority, but patients tend to prioritize comfort in mastication and improvement of esthetics.[3] Therefore, it is vital to investigate patients' awareness, need, and demand for prosthodontic treatment options. To the best of our knowledge, ours could be the first Indian study that assessed those variables on prosthodontic options among general public and general dentist.

From the present study, it can be observed that the subjects were aware of various types of prostheses; this may be due to the increase in technology and media. However, the awareness about maxillofacial prosthesis and cleft lip and palate is less; this may be as the subject did not seem to the need replacement

Table 5: Would you be interested in an awareness program for more knowledge on different treatment options available for replacing missing teeth and parts of head, face, neck, digits, etc?

	Frequency	Percent
No	55	23.0
Yes	183	76.6
Yes; No	1	0.4
Total	239	100.0

Table 6: Do you feel the need to consult a prosthodontist?

	Frequency	Percent
No	39	19.3
Yes	163	80.7
Total	202	100.0

Table 7: Since how many years are you practicing dentistry?

	Frequency	Percent
<5 years	129	63.9
>15 years	5	2.5
10-15 years	18	8.9
5 to10 years	50	24.8
Total	202	100.0

Table 8: Do you consult a Prosthodontist for implants Prosthetic rehabilitation?

	Frequency	Percent
No	67	33.2
Yes	135	66.8
Total	202	100.0

Table 9: If No, whom do you consult for implant placement and rehabilitation?

	Frequency	Percent
	42	20.8
Oral surgeon	24	11.9
Periodontist	19	9.4
Prosthodontist	117	57.9
Total	202	100.0

Table 10: Are you aware of different treatment modalities in maxillofacial prosthodontics?

	Frequency	Percent
No	56	27.7
Yes	146	72.3
Total	202	100.0

Table 11: Do you consult a prosthodontist when you are approached by a patient requiring rehabilitation of the defects resulting due to maxillofacial carcinoma/trauma?

	Frequency	Percent
Before surgery	150	74.3
Nil	10	5.0
Post surgery	42	20.8
Total	202	100.0

of maxillofacial structures. The study suggests that in general, the dentist must spend more time on the chair side during examination and inform the patient about all the different types of prosthesis that a dentist can fabricate. Even though there is a scarcity of data regarding patient's needs and preferences in the field of prosthodontics, this study shows an increase in demand for fixed partial dentures by the individual with knowledge of the same. From the present study, it can be observed that most of the subjects were not aware of maxillofacial prosthesis.[4,5,8,9] This implies that persons whether male or female need motivation and education to help them know about various types of prostheses that they can get fabricated for themselves.

Discussion

Literature is replete with the fact that the importance of teeth for the general health and well-being of an individual is of paramount importance. The role of teeth in speech, mastication, and deglutition is irreplaceable. Hence, an appreciation of the need for the replacement of lost teeth which depend on knowledge and attitude of the individual about types and modes of artificial teeth replacement as well as the significance of a prosthodontist is required to be known. Hence, this study was conducted to evaluate the awareness, knowledge, and significance of a prosthodontist among the general dental practitioners and general public of India.

In this study, a total of 33 questions, 15 to the general practitioners and 18 to the general public, were prepared and validated to analyze the awareness and knowledge of the prosthodontists among the general practitioners and general public pan India. The online survey was conducted through Google Forms.

Various questions regarding the awareness of the different treatment modalities a prosthodontist encompass and, at the same time, the knowledge of the need of prosthodontist was asked to the general public and the general practitioners. Among the practitioners, it was observed that even though 80% of the general practitioners felt the need to consult a prosthodontist, only 45.7% of the practitioners did regularly consult a prosthodontist. Furthermore, the knowledge regarding different non-conventional treatment options was poor among the general practitioners. This showed the need of creating more awareness among the general practitioners for the vista of prosthodontics.[10-14]

On the contrary, the survey among the general public revealed that only 54.8% of them knew prosthodontics as a specialty. Furthermore, the awareness among the general public regarding the different arenas in prosthodontics was below average. The knowledge regarding the different fixed as well removable options to replace a missing tooth or teeth was found to be as low as 40%. A similar finding was found in a study conducted by Nadgere *et al*. who evaluated the prosthetic status and the prosthetic need of the people in Navi Mumbai. She concluded that as much as 85% of population were without any prosthesis.[6] About 60% of the general public were not aware that a missing eye, nose, ear, etc., can be replaced and rehabilitated by a prosthodontist. This was in line with the study conducted by Dahane *et al*. in 2021. They conducted a study wherein they evaluated the awareness and knowledge regarding maxillofacial prosthodontics among medical practitioners and concluded that only 10.9% were aware of maxillofacial prosthodontics as a branch of dentistry which deals with the restoration of maxillofacial defects.[15-18]

Only 38.9% of the population knew about geriatrics as a branch of prosthodontics and how it helps in treating the elderly. The importance of a prosthodontist in the rehabilitation of a patient suffering from mucormycosis post-COVID is still not known by many. The awareness and knowledge regarding this was found to be as low as 39.7% among the general public. This shows that there is a highly unmet need regarding the awareness and knowledge of the population of who a prosthodontist is and the need for prosthodontics.

In our survey, it was also noticed that 64% of the general population used social media platform for gaining knowledge and solutions regarding dental problems. Furthermore, social media advertising influenced 63.5% of the general population in selecting their treatment options. This clearly showed how social media played a role in motivating and educating the general public and influenced their treatment options. Lack of awareness of various prosthodontic treatment options among patients prevented them from utilizing treatment. Social media platforms, dental camps, and prosthodontic outreach programs are possible solutions to change the attitude, to spread awareness, and to provide knowledge about ways and means of artificial teeth replacement as concluded in our survey were similar to the study conducted by Gupta *et al*.[18-24]

Conclusion

Within the limitations of this survey, it can be concluded that the dentist should educate the patient about the different treatment options available in prosthodontic rehabilitation. The majority of the population was not aware of the missing parts of the face which could be prosthetically replaced, role of prosthodontist in head and neck cancer, and significance of geriatric dentistry. Knowledge about prosthodontics as a specialty was below average among general public. Awareness camps can be conducted to educate people on the type of replacement of teeth and maxillofacial structures that they can opt for. However, to further enhance the proficiency, efforts should be made to encourage the general public to be aware of the prosthodontic practice through continuous education programs. The prosthetic needs of the study population must be given high priority as there are many unmet needs and awareness. The focus of the dental outreach camps conducted should be oriented toward understanding the needs of the patients, their preferences and on improving the awareness and knowledge that they have about dental prosthesis. Furthermore, the awareness regarding multidisciplinary team approach involving the role of a prosthodontist along with other specialties should be encouraged among the general practitioners.

References

1. Sartawi S, Salim NA, Taim D. Awareness and treatment decisions on tooth wear among Jordanian dentists and prosthodontists: A cross-sectional survey study. Int J Dent 2020;2020:8861266.
2. Gupta S, Mantri SS, Bhasin A. Knowledge and attitude towards prosthodontic rehabilitation and utilization of dental services by central India population of Jabalpur city, India. Ann Med Health Sci Res 2018;8:12-5.
3. Jayasinghe UW, Harris MF, Parker SM, Litt J, van Driel M, Mazza D, *et al*. The impact of health literacy and life style risk factors on health-related quality of life of Australian patients. Health Qual life Outcomes 2016;14:68.
4. Imbery TA, Diaz N, Greenfield K, Janus C, Best AM. Quality of impressions and work authorizations submitted by dental students supervised by prosthodontists and general dentists. J Dent Educ 2016;80:1229-36.
5. Imbery TA, Greenfield K, Diaz N, Janus C, Best AM. Quantifying appointments, treatment time, impressions, and diagnostic data of cases staffed by general dentists and prosthodontists in a dental school clinic. J Dent Educ 2016;80:1219-28.
6. Nadgere JB, Doshi AG, Kishore S. An evaluation of prosthetic status and prosthetic need amongst people living in and around Panvel, Navi-Mumbai a survey. Int J Prosthest Dent 2010;1:6-9.
7. Dahane TM, Patel RM, Dubey SG, Mangal K. Awareness and knowledge of maxillofacial prosthodontics as a dental specialty amongst medical practitioners. J Evol Med Dent Sci 2021;10:608-12.
8. Gupta S, Mantri SS, Bhasin A. Knowledge and attitude towards prosthodontic rehabilitation and utilization of dental services by central India population of Jabalpur city, India. Ann Med Health Sci Res 2018;8:12-5.
9. Teja SV, Kumar VR, George VT. A survey to evaluate the awareness of various treatment modalities to replace missing teeth among patients visiting Kasturba hospital, Manipal: A prosthodontic perspective. World J Dent 2015;6:217-21.
10. Tulsani M, Nallaswamy D, Rupawat D, Devi S. Awareness of types of dental prosthesis among Indian population. Palarchs J Archaeol Egypt Egyptol 2020;17:1867-77.
11. Yosuef A, Fakiha Z. Awareness and attitudes of patients towards prosthetic rehabilitation of missing teeth at university dental hospital. Int J Dent Res 2017;7:17638-41.
12. Chowdhary R, Mankani N, Chandraker NK. Awareness of dental implants as a treatment choice in urban Indian populations. Int J Oral Maxillofac Implants 2010;25:305-8.
13. Nash KD, Pfeifer DL. Prosthodontics as a specialty private practice: Net income of private practitioners. J Prosthodont 2006;15:37-46.
14. Dings JP, Merkx MA, Maclennan-Naphausen MT, van de Pol P, Maal TJ, Meijer GJ. Maxillofacial prosthetic rehabilitation: A survey on the quality of life. J Prosthet Dent 2018;120:780-6.
15. Pisulkar S, Pakhan AJ, Godbole SR. Psychological considerations in patients with maxillofacial defects: A literature review. J Sch Adv Stud 2018;1:57-60.

16. Belkhode V, Sathe S, Nimonkar S, Godbole S, Kale S. Customized esthetic ocular prosthesis-a case report. J Sch Adv Stud 2018;1:29-32.
17. Beumer J 3rd, Curtis TA, Marunick MT. Maxillo Facial Rehabilitation: Prosthodontic and Surgical Consideration. 2nd ed. St. Louis: Ishiyaku EuroAmerica, Inc.; 1996.
18. Rumsey N, Harcourt D. Body image and disfigurement: Issues and interventions. Body Image 2004;1:83-97.
19. Karthikeyan I. A review on prosthetic rehabilitation of maxillofacial region. Anaplastology 2014;3:125.
20. Shinde DM, Godbole SR. Prosthetic rehabilitation of neurosurgical cranial defect using polymethylmethacrylate material-case report. Sch J Dent Sci 2019;4:32-7.
21. Shaheed R, Shukla S, Acharya S, Gopal U, Acharya N. Journey from fighters to survivors: Quality of life and mental status in cancer patients in a rural tertiary care hospital. J Clin Diagn Res 2019;13:XC01-4.
22. Gondivkar SM, Bhowate RR, Gadbail AR, Sarode SC, Patil S. Quality of life and oral potentially malignant disorders: Critical appraisal and prospects. World J Clin Oncol 2018;9:56-9.
23. Schoenbaum TR, Papaspyridakos P, Kim YK, Arce C, Knoernschild K. Clinician preferences for single-unit implant restoration designs and materials: A survey of the membership of the Pacific Coast Society for Prosthodontics. J Prosthet Dent 2023;2:10-12.
24. De Kok IJ, Redmond CC, Weintraub JA, Clark WA. Clinician perspectives on implementation of digitally fabricated complete dentures: A national survey of prosthodontists. J Prosthet Dent Dent 2023;1:65.
25. Wolfaardt JF, Brecht LE, Taft RM. The future of maxillofacial prosthodontics in North America: Part II-a survey. J Prosthet Dent 2022;127:351-7.

Microsurgical instruments for root end cavity preparation following apicoectomy

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ABSTRACT

Introduction-Root-end resection, also known as apicoectomy, is a widely recognized and accepted surgical approach aimed at preserving teeth afflicted with periradicularpathosis. In cases where nonsurgical endodontic retreatment is not viable or is declined by the patient, periradicular surgery becomes a crucial method for retaining affected teeth
Materials and Methods- The study sample comprised 80 consecutively treated teeth, involving 40 patients with a mean age of 45 years (ranging from 15 to 70 years).
Results- The overall results were excellent for pain assessment, as 91.4% teeth exhibited no painful symptoms .2.8% patients reported a permanent painful condition, with a pain score of 2.
Conclusion- The newly introduced retrotips prove to be highly effective for the preparation of root-end cavities. Root-ends prepared using this innovative sono-abrasive technique has demonstrated outstanding outcomes, as evidenced by excellent results observed during the one-year follow-up examination.

INTRODUCTION

Root-end resection, also known as apicoectomy, is a widely recognized and accepted surgical approach aimed at preserving teeth afflicted with periradicularpathosis. In cases where nonsurgical endodontic retreatment is not viable or is declined by the patient, periradicular surgery becomes a crucial method for retaining affected teeth. The primary objective of periradicular surgery is the regeneration of periapical tissues, restoring them to a healthy state. [1,2]The essential aspect of this surgical procedure involves the hermetic sealing of any potentially harmful agents within the confines of the root, preventing the risk of reinfection around the new apex. To achieve this objective, it is generally agreed upon that a 3 mm segment of the root end should be resected. Additionally, it is recommended to place a root-end filling, also known as retro filling, to an adequate depth. This comprehensive approach is designed to ensure the success of the procedure and contribute to the overall health of the periapical tissues. The conventional root end cavity preparation technique using rotary buts in a microhandpiece poses several problems to the surgeon: 1)Difficult access to the root-end, especially in case of limited working space. 2)Risk of lingual perforation of the root or cavity preparation when it does not follow the original root canal path. 3)Insufficient depth and retention of the root-end filling material 4)The root-end resection procedure exposes dentinal tubules 1 Isthmus tissue cannot be removed[-3],In the early 1990s, the challenges associated with conventional root-end cavity preparation were partially addressed with the introduction of micro instruments. The initial retro tips available had a smooth working tip and were powered by ultrasonic devices. More recently, a novel set of retro tips surfaced with diamond-coated tips, driven by a sonic hand piece. In a preliminary study, we assessed the intra-operative performance of these new retro tips, focusing on their applicability, access to the apex, and efficacy in root-end cavity preparation.[1,4]

PATIENTS AND METHODS: The study sample comprised 80 consecutively treated teeth, involving 40 patients with a mean age of 45 years (ranging from 15 to 70 years). This diverse patient group provides a comprehensive representation of individuals spanning various age ranges, contributing to the robustness of the study's findings. The inclusion of a broad age range allows for a more nuanced understanding of how the proposed techniques or interventions may apply across different demographics within the patient population. The distribution of the treated teeth is given in Table 1.

Table 1: Distribution of Treated Teeth

	Maxilla	Mandible	TOTAL
Incisors	35	15	50
Canines	7	4	11
Premolars	6	4	10
Molars	4	5	9
TOTAL	52	28	80

The retrotips used in the study were KaVo SONIC retro tips, manufactured by KaVo GmbH in Biberach, Germany. These tips are designed in left and right configurations and are available in two shapes: Flame- for cavity preparation, and T-form for undercut preparation .The tips are equipped with a 3 mm working length coated with diamond for enhanced durability and effectiveness. Additionally, a sterile cooling agent is delivered in proximity to the working tip. These retrotips are powered by a sonic handpiece operating at a high frequency, specifically the Ah-scaler SONIC flex from KaVo in Biberach, Germany. This detailed description outlines the specific features and characteristics of the instruments utilized in the study for root-end cavity preparation. All patients in the study underwent treatment following a standardized surgical protocol, the details of which have been previously reported (referenced as elsewhere) and are succinctly summarized in this article. Local anaesthesia was employed for all surgical procedures.The surgical steps included: 1) Flap Reflection: A buccal mucoperiosteal flap was reflected following either a sulcular or submarginal incision, with additional divergent release incisions as necessary.2) Apex Localization: The apex of the tooth was identified after removing the labial or buccal bone. This process was facilitated using a round bur in a slow-speed handpiece, which included sterile coolant for optimal conditions.3) Pathologic Tissue Removal: The soft tissue associated with periapical pathology was meticulously curetted to ensure thorough removal.4) Root-End Resection: A 3 mm segment of the root-end was resected perpendicular to the long axis of the tooth.5) Root-End Cavity Preparation: A root-end cavity with a minimum depth of 2 mm was prepared using the SONIC retro tips. The use of SONIC retro tips in the root-end cavity preparation is a notable aspect of the protocol, as mentioned in the previous sections. This technique aims to enhance the precision and efficacy of the root-end preparation during periradicular surgery.

Following the repositioning of the flap, primary wound closure was achieved using interrupted sutures. To monitor the progress and outcome of the surgery, periapical radiographs were taken at three specific time points: preoperatively, at the time of suture removal (10 days postoperatively), and during the 1-year follow-up examination.For the standardization of radiographs and to ensure consistent imaging conditions, an aiming device was customized. This device was individualized for each patient using a heavy-bodied impression material. The use of such a standardized imaging approach helps maintain consistency and accuracy in radiographic assessments across different time points, allowing for a reliable comparison of preoperative, postoperative, and follow-up images.

PARAMETERS FOR ASSESSING SUCCESS AND FAILURE: A COMPREHENSIVE ANALYSIS

After one year, the evaluation was based on anamnestic, clinical, and radiographic criteria. Each tooth treated surgically received scores for pain that is 0: No pain, 1: Mild pain (temporary), 2:Mild pain (permanent) , 3: Severe pain . The clinical manifestations were Score Definition 0 No clinical manifestations 1 Apical area tender to palpation 2 Apical swelling or tooth tender to percussion 3 Sinus tract or abscess . Radiographically, the size of the periradicular bone defect (S) was approximated using the formula: S = A/2 X B/2 X IJ (where A = length and B = height of radiolucency). The percentage of osseous regeneration (R) was calculated by comparing the 1-year radiograph with the postoperative radiograph using the formula: R = 100 - (Srecall X 100/SPoStop). Considering pain and clinical scores, along with the percentage of osseous regeneration, each treated tooth was categorized as successful, improved, or failing, based on the specifications outlined in Table 2.

Table 2: Healing Classification

CLASS	DEFINATION
Failure	Limited/Incomplete Healing: Osseous regeneration below 50% or a pain/clinical score of 2 or higher.
Improvement	Partial Healing: Osseous regeneration between 50-90% with pain and clinical scores both equal to 0.

SUCCESS	Complete Healing: Osseous regeneration exceeding 90%, accompanied by pain and clinical scores both equal to 0.

RESULTS

During the follow-up period, 10teeth were lost. The reasons for tooth loss included three patients moving away, five patients not attending the recall examination, and two teeth being extracted for reasons unrelated to periapical treatment. Out of the remaining 70 teeth, the postoperative healing process was uneventful.At the1-year follow-up examination, 64 teeth showed no adverse clinical manifestations, indicating a clinical score of 0. Only 4 teeth were tender to vestibular palpation, with a clinical score of 1. The overall results were excellent for pain assessment, as 64 teeth exhibited no painful symptoms (pain score = 0). Two patients reported a permanent painful condition, with a pain score of 2.

DISCUSSION

The present report focuses on analyzing the outcomes of periradicular surgery, specifically employing a novel retrotip for root-end cavity preparation. The advent of micro instruments has significantly transformed the surgical approach to root-end surgery, with various descriptive and experimental studies exploring the potential and efficacy of these retrotips. Despite this, there remains a scarcity of clinical follow-up studies. A singular experimental study was identified, utilizing sonic retrotips in an in vitro setting. This scanning electron microscopy study involved the preparation of root-end cavities using sonic tips, with a subsequent comparison to cavities created by burs in a conventional hand piece.[5] The incidence of root-face cracking was found to be low, with no significant difference observed between the two preparation techniques. However, there was a notable drawback in sonically prepared cavities, where marginal chipping was worse compared to cavities prepared conventionally.[6] Notably, this study reported a significantly higher occurrence of crack formation in the walls of root-end cavities prepared by ultrasonic tips compared to those made with a bur. Conversely, a separate report indicated no instances of root-face cracking after cavity preparation using ultrasonic retrotips at various power settings. Nevertheless, it was highlighted that, unlike bur-prepared root-end cavities, there was a consistent observation of chipping along all the ultrasonically prepared root-end cavosurface margins.[7]

A study reported a correlation between the frequency setting of ultrasonic retrotips and the incidence of root-face alterations. The study identified three types of cracks on resected root-ends: canal cracks, intradentin cracks, and cemental cracks. In cases where cracking occurred, the use of high-frequency ultrasonic root-end preparation was associated with a significantly higher number of canal cracks per tooth compared to a low-frequency preparation technique. To comprehensively understand the potential impact of cracks, further research is warranted. It should explore the likelihood of cracks occurring at various preparation depths and assess their implications on other variables, such as leakage. A particularly intriguing aspect would be to compare sonic instrumentation with ultrasonic instrumentation, specifically regarding the type and frequency of root-face alterations. The formation of cracks reaching the coronal aspect of the root-end filling raises concerns about compromising the benefits derived from the shape of the root-end cavity prepared by retrotips. Therefore, a more in-depth investigation into these aspects is crucial for a comprehensive understanding of the implications of root-face alterations in root-end surgery.[8,9,10]Studies have demonstrated that the use of micro instruments facilitates optimal root-end preparation, both in terms of dimension and direction. Root-end cavity preparations made with micro instruments exhibit more parallel walls and greater depth, enhancing retention capabilities. Importantly, these preparations closely follow the original root-canal system compared to those prepared with burs. Additionally, micro instruments enable the effective removal of any isthmus tissue that may be present between two canals within the same root. The advantages of microinstrumentation in achieving precise dimensions, direction, and adherence to the root-canal system highlight its efficacy in root-end surgery.[11,12]

The root-end resection can be executed in a more perpendicular manner to the long axis using sonic root-end cavity preparation. This approach helps prevent the creation of a bevelled root surface at the neo-apex. Findings from dye leakage and scanning electron microscopy studies on resected roots suggest that there might be a potential for leakage through exposed apical dentinal tubules. Therefore, employing sonic root-end cavity preparation not only allows for a more perpendicular root-end resection but also necessitates consideration of potential leakage issues through exposed dentinal tubules at the apical region.The reported success rates for periradicular surgery, employing conventional root-end preparation techniques, fall within a range of 50% to 70%. Due to variations in study designs, surgical approaches, follow-up durations, and success criteria, a direct comparison among these clinical studies proves challenging. Nevertheless, a consistent observation emerges: for a majority of teeth, the treatment outcome, when evaluated at the one-year follow-up, tends to remain stable thereafter. It is emphasized that

cases exhibiting partial or incomplete radiographic healing at the one-year follow-up, in the absence of adverse clinical findings, need not be considered for retreatment. From the clinician's perspective, such cases may be viewed as successes rather than failures.[13,14,15]

CONCLUSION

The newly introduced retrotips prove to be highly effective for the preparation of root-end cavities. They streamline the surgical process for treating root ends in cases where access is constrained, simplifying the procedure. Root-ends prepared using this innovative sonoabrasive technique has demonstrated outstanding outcomes, as evidenced by excellent results observed during the one-year follow-up examination.

REFRENCES

1. Carr GB: Advanced techniques and visual enhancement for endodontic surgery. Endo Report 7:6,1992
2. Fong CD: A sonic instrument for retrograde preparation. J Endod 19:374,1993 van Arx T, Kurt B, Ilgenst
3. Carr GB: Ultrasonic root end preparation. Dent Clin North Am 41:541, 1997
4. van Arx T, Kurt B, Ilgenstein B, et al: Preliminary results and analysis of a new set of sonic instruments for root-end cavity preparation. IntEndod J 31:32, 1998
5. Gutman JL, Saunders WP, Nguyen L, et al: Ultrasonic root-end preparation. Part 1. SEM analysis. IntEndod J 27:318, 1994
6. Gorman MC, Steiman HR, Gartner AH: Scanning electron microscopic evaluation of root-end preparations. J Endod 21:113, 1995
7. Waplington M, Lumley PJ, Walmsley AD, et al: Cutting ability of an ultrasonic retrograde cavity preparation instrument. Endod Dent Traumatol 11: 177, 1995
8. Sumi Y, Hattori H, Hayashi K, et al: Ultrasonic root-end preparation: Clinical and radiographic evaluation of results. J Oral MaxillofacSurg 54:590, 1996
9. Frank RJ, Antrim DD, Bakland LK: Effect of retrograde cavity preparations on root apexes. Endod Dent Traumatol 12:100, 1996
10. Layton CA, Marshall JG, Morgan LA, et al: Evaluation of cracks associated with ultrasonic root-end preparation. J Endod 22: 157,1996
11. Lloyd A, Jatmberzins A, Dummer PM, et al: Root-end cavity preparation using the Micro Mega Sonic Retro-prep tip: SEM analysis. IntEndod J 29295, 1996
12. Engel TK, Steiman HR: Preliminary investigation of ultrasonic root end preparation. J Endod 21:443, 1995
13. Hirsch JM, Ahlstrom U, Henrikson PA, et al: Periapical surgery. Int J Oral Surg 8:173, 1979
14. Mikkonen M, Kullaa-Mikkonen A, Kotllainen R: Clinical and radiographic re-examination of apicoectomlzed teeth. Oral Surg Oral Med Oral Path01 55:302, 1983
15. Lyons AJ, Hughes CE, Dixon EJ: A j-year audit of outcome of apicetomies carried out in a district general hospital. Ann R CollSurg Engl77:273, 1995

Original Article - Evaluative Study

Interest of Oral and Maxillofacial Surgeons Towards Specialised Training in Facial Aesthetic and Plastic Surgery in India - An Evaluative Study

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Abstract

Introduction: The Dental Council of India has included facial plastic surgery in the scope of practice of Oral and Maxillofacial Surgeons (OMFSs) in India. However, the knowledge and interests of these specialists towards facial plastic surgery are unexplored. **Materials and Methods:** A descriptive cross-sectional study consisting of a structured questionnaire tool with six domains and 46 questions was circulated amongst registered OMFSs in India. The study consisted of 950 participants. The data obtained from this questionnaire were coded and entered into Statistical Package for Social Sciences (SPSS) and a descriptive analysis was conducted. **Results:** The study yielded that only 33% of the participants were completely aware of facial fillers and 30.5% were aware of Botox procedure. However, there was complete awareness of blepharoplasty in 42%, cheiloplasty/palatoplasty in 65.8%, laser facial resurfacing in 23.7% and facial rejuvenation in 23.5% of the participants. **Discussion:** It was found that a high number of OMFSs felt that their exposure to plastic surgery during their post-graduation years was not sufficient.

Keywords: Facial aesthetics, facial plastic surgery, oral and maxillofacial surgery, oral surgeons, rhinoplasty

Introduction

Facial plastic surgery is an eminent branch of the medical sciences with a vivid historical background and established frontiers. It is one of the most emerging fields in medicine, owing to its ability to directly influence the patient's psychological state in terms of body image, self-esteem, confidence and quality of life.[1,2] In today's world, it has been demonstrated that taking, altering and posting selfies on social media can affect an individuals' self-esteem, confidence, body image perception and mood.[3] It is believed that high social images may be attributed to having presentable and pristine facial skin and tone, symmetry, lips and hair.[4] This also results in an increased popularity of facial plastic surgery amongst the masses with the current trend shifting towards non-surgical facial aesthetic procedures.[5,6]

Facial plastic surgery is typically performed by plastic surgeons who have specialised training and expertise in this field and may collaborate with other specialists such as dermatologists, otolaryngologists and oral & maxillofacial surgeons (OMFSs) to perform comprehensive facial rejuvenation and reconstruction procedures.[5] OMFSs form a significant portion of this cohort. Being primarily a dental speciality in India, the practice of OMFSs was limited to procedures such as extraction of impacted teeth and jaw-bone pathologies such as fractures and tumours until a few years.[7] In December 2021, the Executive Committee of the Dental Council of India allowed OMFSs to practice Facial Plastic Surgery. However, little data about the specialists' interest and preparedness for facial plastic surgery is found in the literature searches. A study conducted amongst plastic surgery residents and teachers in a renowned institute in

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Website: https://journals.lww.com/aoms

DOI: 10.4103/ams.ams_101_23

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Received: 08-06-2023 **Last Revised:** 29-08-2023
Accepted: 09-10-2023 **Published:** 19-12-2023

How to cite this article: Kumar V, Shome D, Mhatre P, Khot AJ, Gaunkar RB, Mhamunkar P. Interest of oral and maxillofacial surgeons towards specialised training in facial aesthetic and plastic surgery in India - An evaluative study. Ann Maxillofac Surg 2023;13:173-8.

India has concluded that the residents have lesser exposure to aesthetic surgery training than reconstructive procedures.[8,9] A similar study conducted among plastic surgery residents in the USA also showed that they felt least prepared in performing aesthetic procedures excluding breast reconstruction amongst all the sub-specialities.[10] This led to the highest number of residents pursuing some kind of fellowship in aesthetic surgery post-graduation.[11] This study aims to explore the agreement, inclination and interests of OMFSs in India towards facial aesthetic and facial plastic surgery.

Materials and Methods

A descriptive cross-sectional study was carried out in India amongst registered OMFSs from November 2021 to February 2023 and has been reported according to the STROBE guidelines.[12] Ethics approval (IEC/TEC/OC2101) was obtained from the Institutional Ethics Committee on 21 October 2021. Consent was waivered due to the nature of this study. A well-structured questionnaire tool consisting of six domains was created as a Google Forms sheet. Forty-five close-ended questions were formulated, separated into six different domains as follows:

i. Personal details
ii. Knowledge regarding specific facial cosmetic procedures and/or materials
iii. Relay and referral
iv. Current status of facial plastic surgery procedures
v. Exposure to facial plastic surgery
vi. Need for targeted skill-based training modules and advanced certified training in Facial Plastic Surgery.

The demographics and work experience of the respondents were recorded in the first domain.[13] The second section assessed the respondent's knowledge regarding current procedures performed by a practising facial aesthetic and facial plastic surgeon. The third section listed a series of scenarios in plastic surgery and the respondent was asked to choose from the list of specialists to whom they would refer the given case. The fourth section helped assess the share of plastic surgical procedures in their current practice. The fifth section evaluated their training in facial plastic surgery during post-graduation and the supplementary courses, if taken. The sixth section of the questionnaire assessed their attitude towards facial aesthetic surgery becoming a part of their daily practice. Doctors were contacted through the repository obtained from the Association of OMFSs of India. Some doctors were contacted independently through social apps. Some of the respondents were also obtained through snowball sampling. A pilot study was carried out among 30 subjects to check for the flaws and feasibility of the study. The prevalence of OMFSs for the awareness of Botox was computed to be 33.3%. On the basis of the pilot study, the sample size was determined.

$n = z^2pq/d^2z = 1.96$, at 95% confidence level

The sample size was calculated to be 946 rounded off to 950.

The data obtained from this questionnaire were coded and entered into Statistical Package for Social Sciences (SPSS) (SPSS Inc., version 17, IBM, Chicago, Illinois, USA) software.[14] Normality of the data was assessed before analysis using Shapiro–Wilk's test. A priori analysis was carried out setting α at 5% and β at 20%. Thus, the power of the study ($1-\beta$) is 80%. Descriptive analysis through frequency distribution was calculated and Chi-square test was applied. Unpaired *t*-test was computed to compare the responses of males and females. $P < 0.05$ were considered statistically significant.

Results

Out of the total 950 participants of the study, 44.68% were female and 55.32% were male. Geographically, 22.45% of the participants were based in South India, 18.12% in North India, 28.77% in West India, 18.76% in East India and 11.90% were based in Central India. 7.2% of the practitioners were academicians, 49.7% were private clinicians whereas 42.4% were both academicians and private practitioners. Of these, 55% of the participants had <5 years of experience; 32.6% had an experience of 5–15 years and 11.8% had an experience of >15 years, as depicted in Table 1.

The knowledge of the participants regarding specific facial cosmetic procedures and/or materials was assessed through the second section of the questionnaire, as depicted in Table 2. It was found that only 30.1% of OMFSs were completely aware, 45.3% were partially aware whereas 24% were unaware in knowledge pertaining to carrying out otoplasty procedures. For liposuction, it was found that only 25.9% were completely aware, 49.4% were partially aware and 24.1% were unaware. In context to the most commonly performed Botox procedure, only 30.5% of the participants were completely aware; whereas, for facial fillers, only 33% of the participants were completely aware with $P < 0.001$, showing a highly significant association. There was complete awareness of blepharoplasty in 42%, cheiloplasty/palatoplasty in 65.8%, laser facial resurfacing in 23.7% and facial rejuvenation in 23.5% of the OMFSs with a $P < 0.05$, which is considered statistically significant.

Exposure of the OMFSs to plastic surgery, as evaluated through the questionnaire is depicted in Table 3. Table 4 depicts the preference of Oral and Maxillofacial Surgeons for referral of their cases to OMFS, ENT surgeon, plastic surgeon, oculoplastic surgeon and dermatologist in certain clinical scenarios. It was found that greater percentage of referrals would be preferably made to OMFSs in cases of cleft lip/palate surgeries, facelifts, craniosynostosis, facial fractures, rhinoplasty, repair of lacerated/avulsed ear, defect correction after tumour excision and cancer of the oral cavity. In case of scar revision, 53.11% of the participants would make a referral to a general plastic surgeon whereas, in eyelid injuries, 42.36% of the participants would prefer an oculoplastic surgeon. However, for correction of microtia

or prominent ear, 35.40% of referrals would be made to OMFSs and ENT surgeons.

Spearman's coefficient correlation between the domains of knowledge, relay and referral, education and training and attitude amongst the speciality academician/clinician and sociodemographic variables is depicted in Table 5. Correlation is significant at the 0.05 level. The correlation test showed that there exists a negative correlation ($r = -0.272$, $P < 0.001$) between the attitude towards the future of facial plastic surgery and the gender of the participant. Whereas, in the case of the region of practice and the attitude towards the future of facial plastic surgery, a slightly positive correlation existed ($r = 0.090$, $P = 0.006$). The years of practice showed a positive correlation ($r = 0.097$, $P = 0.002$) and the type of practice also shows a strong positive correlation ($r = 0.168$ and $P < 0.001$) to the attitude towards the future of facial plastic and reconstructive surgery in India.

Table 1: Distribution of all categorical variables within the sample

Variable	*n* (%)
Gender	
Female	424 (44.68)
Male	525 (55.32)
Region of practice	
South	213 (22.45)
North	172 (18.12)
East	178 (18.76)
West	273 (28.77)
Central	113 (11.90)
Years of experience	
<5	525 (55)
5–15	311 (32.6)
>15	113 (11.8)
Type of practice	
Academician	69 (7.2)
Private clinician	475 (49.7)
Both	405 (42.4)

All values are expressed as frequency with percentages (in parentheses)

Discussion

The present study attempted to study the knowledge and interests of OMFSs towards facial aesthetic procedures in India. It concluded that only about a fourth of the OMFS were aware and knowledgeable about facial aesthetic procedures and a majority of the OMFS felt that their exposure to plastic surgery during their post-graduation years was not sufficient. Shetty and Bhat studied the recognition of OMFSs as dental professionals and their perceptions regarding cosmetic facial surgery in India. It was found that 94.4% of professionals in India agreed to refer patients for cosmetic facial surgery to OMFSs, if required. However, they were not up to date regarding the magnitude of the progress and recent developments in the various specialties.[15] These results are in agreement with our study which yielded that greater percentage of referrals would be preferably made to OMFSs in cases of cleft lip/palate surgeries, facelifts, craniosynostosis, facial fractures, rhinoplasty, repair of lacerated/avulsed ear, defect correction after tumour excision and cancer of the oral cavity.

Alamri *et al*., conducted a study on the perception and knowledge of facial plastic surgery among the healthcare professionals in Saudi Arabia. It was found that amongst the participants, 75.5% agreed that training in plastic surgery programme is a requirement to be a facial plastic surgeon. However, 24.5% of the healthcare professionals believed that plastic surgery training is not a requirement and 14.9% amongst those believed that only training in a maxillofacial programme would be sufficient.[16]

In an article reviewing the distribution of scope of practice for OMFSs in the United States of America, Davison *et al*., elaborated on the key issues regarding the practice of cosmetic surgery. The study concluded that no restrictions can be legally placed on the oral surgeons and more data would be necessary to effectively understand the capability of these professionals in practicing cosmetic surgery.[17] The present study observed a difference in the opinion of OMFSs regarding relay and referral in certain clinical scenarios, as equal referrals would also be made to general plastic surgeons, oculoplastic surgeons and ENT surgeons in this study. This necessitates the need for establishing a standard

Table 2: Knowledge regarding specific facial cosmetic procedures and/or materials

Cosmetic procedure	Responses			*P*
	Completely aware, *n* (%)	Partially aware, *n* (%)	Unaware, *n* (%)	
Blepharoplasty	401 (42)	502 (52.6)	46 (4.8)	0.032*
Rhinoplasty	492 (51.5)	457 (47.9)	0	0.866
Otoplasty	287 (30.1)	433 (45.3)	229 (24)	<0.001**
Cheiloplasty/palatoplasty	628 (65.8)	229 (24)	92 (9.6)	0.041*
Laser facial resurfacing	226 (23.7)	403 (42.2)	320 (33.5)	0.028*
Liposuction of face and neck	247 (25.9)	472 (49.4)	230 (24.1)	<0.001**
Facial rejuvenation	224 (23.5)	518 (54.2)	207 (21.7)	0.012*
Botox	291 (30.5)	545 (57.1)	92 (9.6)	<0.001**
Facial filler	315 (33)	542 (56.8)	92 (9.6)	<0.001**

Level of significance: *$P \leq 0.05$ is considered statistically significant, **$P \leq 0.001$ Highly significant association. All values are expressed as frequency with percentages (in parentheses); Statistical test used: Chi-square test

Table 3: Exposure in facial plastic surgery

Clinical scenario	Responses	Type of practice			*P*
		Academician, *n* (%)	Clinician, *n* (%)	Both, *n* (%)	
Were you formally trained in facial plastic surgery during your post-graduation residency?	Yes	45 (4.74)	79 (8.32)	122 (12.85)	<0.001**
	No	24 (2.53)	396 (41.73)	237 (24.97)	
	May be	0	0	46 (4.85)	
Do you feel you were sufficiently trained in this area during your post-graduation residency?	Yes	8 (0.84)	67 (7.06)	59 (6.22)	<0.001**
	No	26 (2.74)	358 (37.72)	324 (34.14)	
	May be	35 (3.69)	50 (5.27)	22 (2.32)	
Were any facial plastic surgery physicians involved with resident education at your post-graduation program?	Yes	32 (3.37)	155 (16.33)	36 (3.79)	0.041
	No	25 (2.63)	310 (32.66)	369 (38.88)	
	May be	12 (1.26)	10 (1.05)	0	
Did you have the opportunity to participate in cosmetic minor procedures (injections, lasers, chemical peels, hair transplant, etc.,) during your post-graduation residency training?	Yes	61 (6.43)	141 (14.86)	47 (4.95)	<0.001**
	No	8 (0.84)	331 (34.88)	358 (37.72)	
	May be	0	3	0	
Did you have the opportunity to participate in facial plastic reconstructive procedures during your post-graduation residency	Yes	33 (3.48)	227 (23.92)	214 (22.55)	0.007*
	No	24 (2.53)	248 (26.13)	191 (20.13)	
	May be	12 (1.26)	0	0	
Did your post-graduation program provide you with formal lectures in cosmetic facial plastic surgery topics?	Yes	48 (5.06)	136 (14.33)	178 (18.76)	<0.001**
	No	21 (2.21)	321 (33.82)	217 (22.87)	
	May be	0	18 (1.90)	10 (1.05)	
Did you have the opportunity to participate in cosmetic plastic surgery procedures during your post-graduation residency?	Yes	54 (5.69)	337 (35.51)	106 (11.17)	<0.001**
	No	15 (1.58)	138 (14.54)	299 (31.51)	
	May be	0	0	0	
Do you feel that facial plastic surgery should continue to be recognised as part of OMF Surgery?	Yes	62 (6.53)	465 (48.99)	405 (42.68)	0.061
	No	7 (0.74)	4 (0.42)	0	
	May be	0	6 (0.63)	0	
Do you feel that facial plastic reconstructive procedures are a vital part of your post-graduation residency training?	Yes	58 (6.11)	396 (41.73)	386 (40.67)	<0.001**
	No	11 (1.16)	28 (2.95)	5 (0.53)	
	May be	0	51 (5.37)	14 (1.47)	
Do you feel cosmetic minor procedures (injections, lasers, chemical peels, etc.,) are a vital part of Post-graduation residency training?	Yes	33 (3.48)	343 (36.14)	238 (25.08)	<0.001**
	No	26 (2.74)	24 (2.53)	47 (4.95)	
	May be	10 (1.05)	108 (11.38)	120 (12.64)	
Have you attended supplementary courses in facial plastic surgery after post-graduation?	Yes	19 (2)	318 (33.51)	231 (24.34)	<0.001**
	No	50 (5.27)	157 (16.54)	174 (18.33)	
	May be	0	0	0	
Will you be interested in taking a course in Facial Aesthetic Surgery?	Yes	65 (6.85)	406 (42.78)	367 (38.67)	<0.001**
	No	1 (0.10)	69 (7.27)	38 (4)	
	May be	3 (0.32)	0	0	
Does your institution have a facial plastic surgery fellowship?	Yes	6 (0.63)	57 (6)	49 (5.16)	<0.001**
	No	63 (6.64)	418 (44)	356 (37.51)	
	May be	0	0	0	
How would you describe your training for cosmetic minor procedures during your post-graduation residency	Independent administration	24 (2.53)	73 (7.69)	39 (4.11)	<0.001**
	Under supervision	8 (0.84)	244 (25.71)	112 (11.80)	
	No exposure	37 (3.89)	158 (16.65)	254 (26.76)	
Describe your training for facial plastic reconstructive procedures during your post-graduation residency	Independent administration	13 (1.37)	68 (7.16)	33 (3.48)	<0.001**
	Under supervision	45 (4.74)	287 (30.24)	189 (19.91)	
	No exposure	11 (1.16)	120 (12.64)	183 (19.28)	
Describe your training for cosmetic plastic surgery procedures during post-graduation residency	Independent administration	22 (2.32)	70 (7.38)	43 (4.53)	<0.001**
	Under supervision	37 (3.89)	274 (28.87)	98 (10.33)	
	No exposure	10 (1.05)	131 (13.80)	270 (28.45)	

Level of significance: *$P \leq 0.05$ is considered statistically significant, **$P \leq 0.001$ Highly significant association. All values are expressed as frequency with percentages (in parentheses); Statistical test used: Chi-square test. OMF: Oral and maxillofacial

Table 4: Relay and referral

Clinical scenario	Specialisation (*n*)				
	General plastic surgeon	OMFS	ENT surgeon	Oculoplastic surgeon	Dermatologist
Scar revision	504 (53.11)	379 (39.94)	0	0	66 (6.95)
Cleft lip/palate	169 (17.81)	718 (75.66)	21 (2.21)	0	41 (4.32)
Facelift	352 (37.09)	487 (51.32)	43 (4.53)	23 (2.42)	44 (4.64)
Craniosynostosis	282 (29.71)	575 (60.59)	70 (7.38)	0	22 (2.32)
Facial fractures	113 (11.91)	814 (85.77)	0	0	22 (2.32)
Rhinoplasty	193 (20.34)	433 (45.63)	301 (31.72)	22 (2.320	0
Double eyelid	260 (27.40)	300 (31.61)	0	389 (40.99)	0
Repair of lacerated/avulsed ear	249 (26.24)	329 (34.67)	281 (29.61)	90 (9.48)	0
Microtia/prominent ear	210 (22.13)	336 (35.40)	336 (35.40)	45 (4.74)	22 (2.32)
Defect after tumor excision	251 (26.45)	636 (67.02)	46 (4.85)	0	22 (2.32)
Cancer of the oral cavity	159 (16.75)	711 (74.92)	79 (8.32)	0	0
Eyelid injuries	205 (21.60)	252 (26.55)	90 (9.48)	402 (42.36)	0

All values are expressed as frequency with percentages (in parentheses). OMFS: Oral and Maxillofacial Surgeons, ENT: Ear, Nose and Throat Surgeons

Table 5: Spearman's coefficient correlation between domains of knowledge, relay and referral, education and training and attitude among the speciality academician/clinician and sociodemographic variable

Variable	Knowledge regarding specific facial cosmetic procedures	Relay and Referral	Education and training in FPRS	Attitude towards the future of FPRS
Gender				
r	0.074	0.021	−0.024	−0.272
P	0.022	0.515	0.463	<0.001*
Region				
r	0.238	0.049	0.066	0.090
P	0.002	0.131	0.042	0.006*
Year of experience				
r	0.281	0.240	0.098	0.019
P	<0.001	0.095	0.003	<0.001*
Type of practice				
r	0.177	0.012	0.273	0.019
P	<0.001	0.723	<0.001	0.049*

*Correlation is significant at the 0.05 level. FPRS: Facial plastic and reconstructive surgery

protocol in training and supervision of oral and maxillofacial surgery students as well as practicing surgeons to inculcate quality knowledge and high standard surgical skills in them.

Conclusion

This study demonstrated that the current knowledge of OMFSs in India has scope for improvement. However, the agreement, inclination and interest towards training in facial aesthetic procedures and facial plastic surgery are immense.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Quality-of-Life Outcomes after Cosmetic Surgery: Plastic and Reconstructive Surgery. Available from: https://www.journals.lww.com/plasreconsurg/Citation/1998/11000/Quality_of_Life_Outcomes_after_Cosmetic_Surgery.53.aspx. [Last accessed on 2023 Mar 13].
2. Castle DJ, Honigman RJ, Phillips KA. Does cosmetic surgery improve psychosocial wellbeing? Med J Aust 2002;176:601-4.
3. Shome D, Vadera S, Male SR, Kapoor R. Does taking selfies lead to increased desire to undergo cosmetic surgery. J Cosmet Dermatol 2020;19:2025-32.
4. Shome D, Kumar V, Van Der Hulst RR, Booi DI, Tandel H, Male SR, *et al.* Determinants of the influence and experiences of cosmetic and aesthetics profiling on interpersonal relationships among Indian patients. J Cosmet Dermatol 2023;22:275-83.
5. Chuang J, Barnes C, Wong BJ. Overview of facial plastic surgery and current developments. Surg J (N Y) 2016;2:e17-28.
6. Shome D, van der Hulst RR, Kumar V, Booi DI, Mhatre PD. Evolution and trends of facial plastic surgery and facial aesthetic procedures in India: From awakening to revival. Aesthet Surg J Open Forum 2023;5:ojad022.
7. Kolokythas A. What is the scope of practice of oral and maxillofacial surgeons? J Oral Maxillofac Surg 2021;79:267.
8. Sharma RK. Changing trends in plastic surgery training. Indian J Plast Surg 2014;47:162-6.
9. Welcome To DCI Portal. Available from: https://www.dciindia.gov.in/NewsSection.aspx?NewsType=Public%20Notice. [Last accessed on 2023 Mar 20].
10. O'Neill R, Raj S, Davis MJ, Abu-Ghname A, Reece EM, Winocour J,

et al. Aesthetic training in plastic surgery residency. Plast Reconstr Surg Glob Open 2020;8:e2895.
11. Braza ME, Adams NS, Ford RD. Perceptions of preparedness in plastic surgery residency training. Plast Reconstr Surg Glob Open 2020;8:e3163.
12. Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, *et al.* Strengthening the reporting of observational studies in epidemiology (STROBE): Explanation and elaboration. PLoS Med 2007;4:e297.
13. Ministry of Home Affairs | Government of India. Available from: https://www.mha.gov.in/en/page/zonal-council. [Last accessed on 2023 Aug 21].
14. IBM Corp. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.; 2017.
15. Shetty D, Bhat S. Recognition of oral and maxillofacial surgeons by dental professionals and their perceptions regarding cosmetic facial surgery-a questionnaire-based study. J Oral Maxillofac Surg 2019;77:2556.e1-7.
16. Alamri AA, AlJehani R, Alnefaie MN, Moshref S, Fida AR. Perception and knowledge of facial plastic surgery among health care professionals at tertiary care center, Jeddah, Saudi Arabia: Cross sectional study. Mater Sociomed 2019;31:125-9.
17. Davison SP, Hancock M, Sinkiat M, Enchill Z. Oral surgeons as cosmetic surgeons and their scope of practice. Plast Reconstr Surg 2019;143:872e-9e.

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Case Report

Pediatric Oral Malignancies of Mesenchymal Origin: Report of Two Cases and Literature Review

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Received: 20 November 2023

Published: 30 November 2023

Abstract

Oral pediatric malignancies are associated with diagnostic dilemmas and difficulties with respect to treatment and local control measures. Early detection and treatment are a pre-requisite to avoid significant morbidity and also improve the quality of life. The aim of this presentation is to report 2 cases of oral malignancies in a pediatric population which required a comprehensive clinical, imaging and microscopic assessment for accurate diagnosis and subsequent management.

Keywords*: Pediatric malignancies, Oral cavity, Sarcoma*

Introduction

Pediatric neoplasms of oral and maxillofacial region constitute a minor proportion of head and neck tumors but are associated with diagnostic dilemmas and difficulties with respect to treatment and local control measures. While cysts and tumors of odontogenic origin generally account for most of these lesions, emphasis should also be given to the non-odontogenic lesions that may affect the various parts of oral mucosa. Pediatric neoplasms could either be congenital or develop later in course of life and may include hamartomas, benign neoplasms and malignancies such as sarcomas. These neoplasms, especially if malignant pose difficulties in diagnosis and subsequent management thereby needing a comprehensive clinical, imaging and histopathological assessment for accurate diagnosis.

Cancer in children and adolescents represents a group of diseases considered rare, with an incidence of 0.01% in the age range of 0–19 years in developed countries and when compared to adult malignancies, it corresponds to 2–3% of all malignant tumors.[1] Malignant lesions of the oral cavity constitute a small proportion of all oral lesions in children and mainly include lymphomas (especially Burkitt) and sarcomas such as rhabdomyosarcoma, osteosarcoma and fibrosarcoma.[2] In addition, mucoepidermoid carcinomas of the oral cavity have rarely been reported in the pediatric and adolescent age groups. Generally most tumors have a low or intermediate grade and are often cured with surgery alone.[3]

Early detection and treatment are a pre-requisite to avoid significant morbidity and also improve the quality of life. The dynamic growth and development that is seen through the adolescence period should also be taken in consideration while determining the treatment plan. The aim of this presentation is to report 2 cases of oral

malignancies in a pediatric population which required a comprehensive clinical, imaging and microscopic assessment for accurate diagnosis and subsequent management.

Case Report

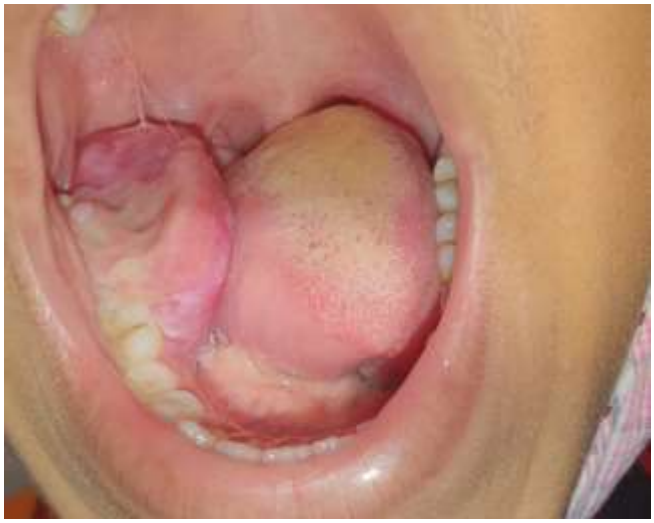

Fig 1: Aggressive soft tissue growth in the posterior mandibular region with displacement of involved teeth.

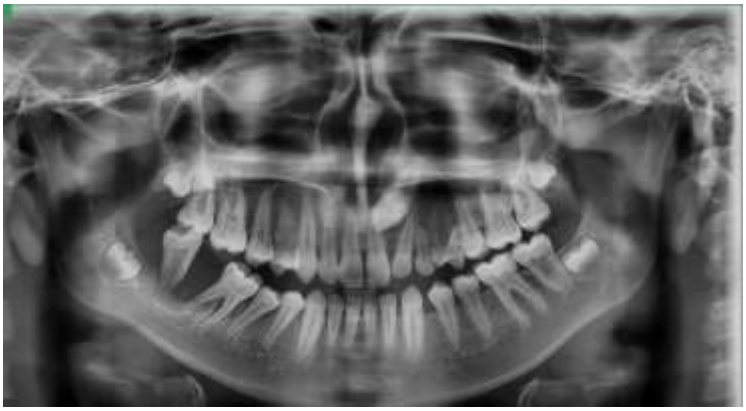

Fig 2: OPG showing large ill-defined expansile osteolytic lesion in relation to 46-48 region

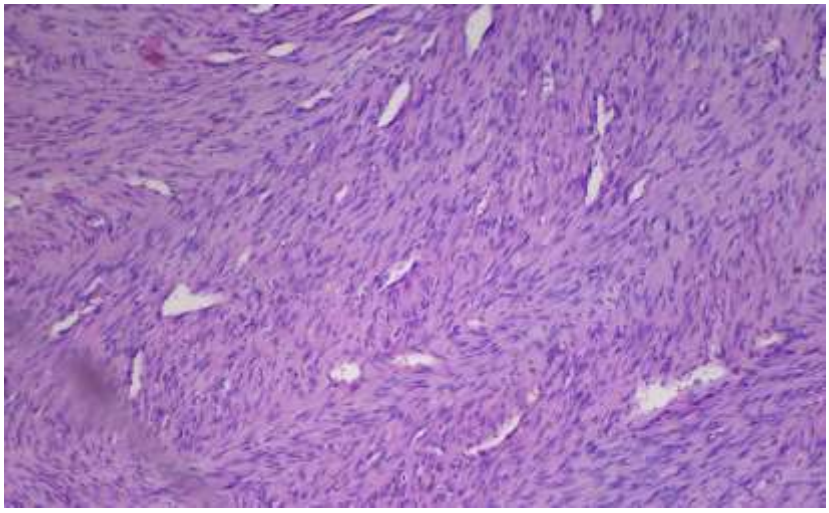

Figure 3: Photomicrograph (10x) showing spindle shaped neoplastic cells in interlacing fascicular arrangement

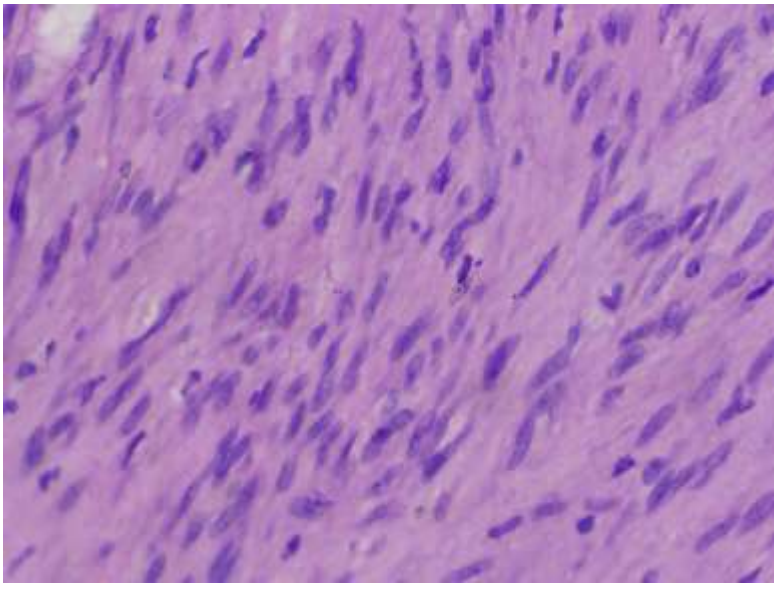

Figure 4: Photomicrograph (40x) showing spindle shaped malignant cells and elongated nuclei with round ends.

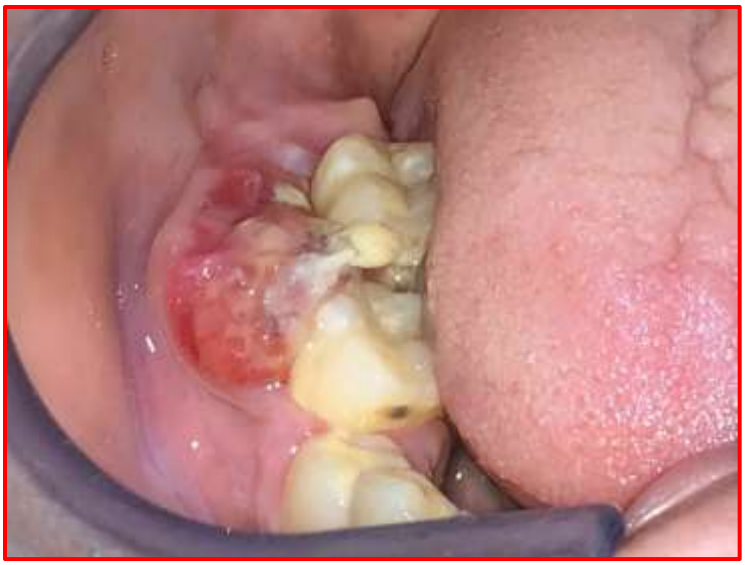

Figure 5: ulcerative lesion of the right posterior region of the jaw

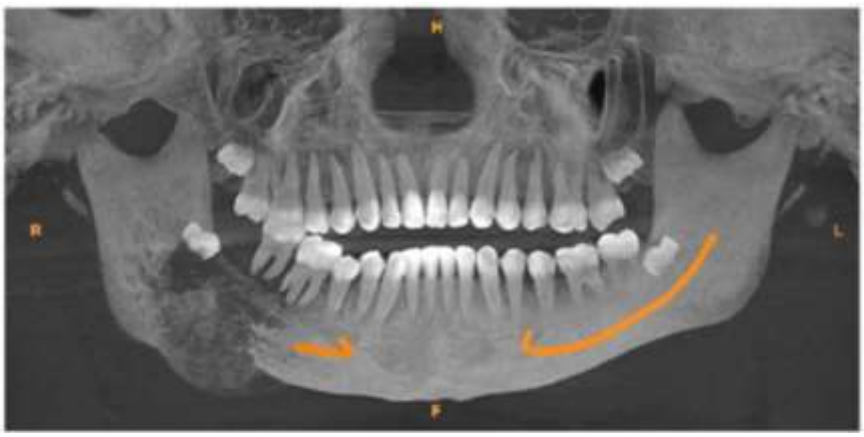

Figure 6: solitary large ill-defined expansile osteolytic lesion of mixed density in the right body and ramus of the mandible

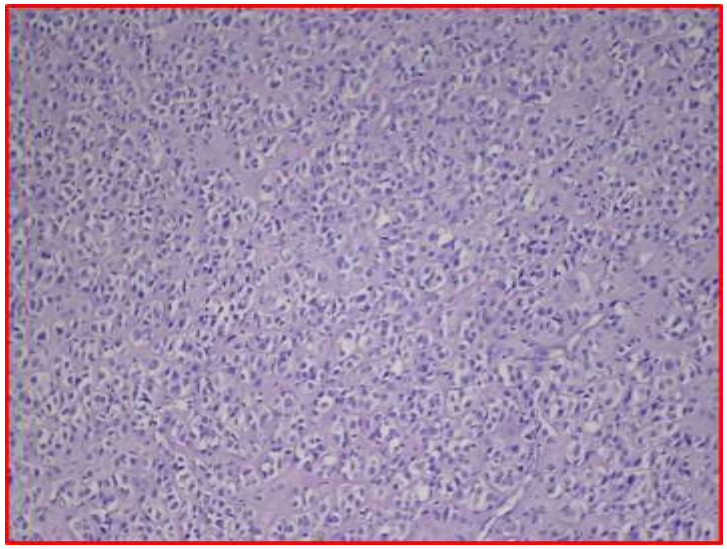

Figure 7: Sheets of malignant tumor cells separated by fibrous connective tissue septae and eosinophilic areas resembling tumor osteoid surrounded by malignant osteoblasts.

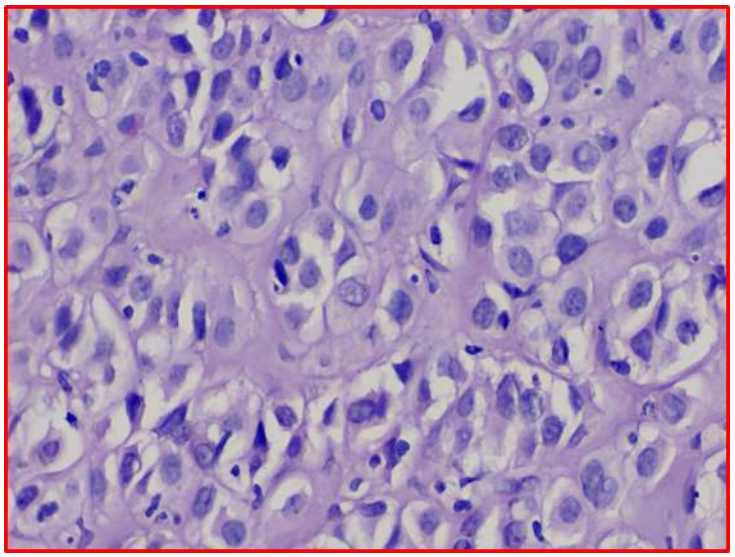

Figure 8: Clear cells- round to oval in shape with vesicular nuclei and clear cytoplasm with some binucleation resembling chondroid like areas

Case 1:

A 13- year old male patient presented with a painless rapidly enlarging growth of the right posterior region of jaw since 2 months. Intra-oral examination revealed a firm, non-tender reddish soft tissue mass in the right posterior mandibular region extending anteriorly from 45 to retromolar region posteriorly involving the buccal and lingual mandibular gingiva. Inferiorly the lesion extended till the floor of the mouth causing displacement of the tongue along with displacement of the associated teeth **(Fig 1).** Radiographically, an ill-defined osteolytic lesion of the right posterior mandible with buccal and lingual cortical plate expansion was noted **(Fig 2)**.

Incisional biopsy was performed which revealed a highly cellular connective tissue stroma composed of atypical spindle shaped cells arranged in streaming and interlacing fascicles interspersed with hypocellular and myxoid areas. The tumor cells were characterized by elongated spindle shaped nuclei with rounded ends and indistinct cytoplasm **(Fig 3 & 4)**. Malignant spindle cell tumor was considered as the diagnosis with differential diagnosis of leiomyosarcoma and malignant peripheral nerve sheath tumor. Immunohistochemical analysis of the lesional tissue showed positive staining for α- SMA and vimentin while being negative for S-100 and neuron specific enolase. Based on the findings, the final diagnosis was leiomyosarcoma. The patient was advised surgical management of hemimandibulectomy and referred to higher centre for further treatment.

Case 2:

A 14-year old female patient reported with an ulcerative lesion of the right posterior region of the jaw associated with mobility of teeth 46 and 47 since 1 month **(Fig 5)**. The patient was apparently normal 1 month back after which the lesion was noted. CBCT shows a solitary large ill-defined expansile osteolytic lesion of mixed density in the region extending from 46 to the right body and ramus of the mandible **(Fig 6)**. A provisional diagnosis of aggressive neoplastic lesion such as odontogenic myxoma and osteosarcoma was considered. Incisional biopsy was performed and the H and E stained sections shows sheets of malignant tumor cells separated by fibrous connective tissue septae. The malignant cells displayed atypical features such as cellular and nuclear pleomorphism, nuclear hyperchromatism and few bizarre shaped cells. Presence of eosinophilic areas resembling tumor osteoid surrounded by malignant osteoblasts was evident. In addition, the sections also showed a sub-population of clear cells which were round to oval in shape with vesicular nuclei and clear cytoplasm with some binucleation resembling chondroid like areas **(Fig 7 & 8)**. Special staining for

PAS and mucicarmine to rule out clear cell odontogenic carcinoma and intra-osseous mucoepidermoid carcinoma was negative. Based on these findings the final diagnosis was chondroblastic variant of osteosarcoma. Hemimandibulectomy was performed and the final diagnosis of the excised specimen was high grade osteosarcoma. Six month follow-up was uneventful.

Discussion

Leiomyosarcoma is a malignant mesenchymal neoplasm of smooth muscle origin accounting for 6 to 7% of all soft tissue sarcomas.[4] This neoplasm is rare in the oral cavity accounting for less than 0.06% of all oral malignancies with mandible being an unusual location owing to the paucity of smooth muscle in that region.[5] Intra-oral leiomyosarcoma occurs predominantly in males around the 4th decade of life with less occurrence in the younger age group.[6] Clinically, the lesion tends to appear as a painless, non-ulcerated mass of the soft tissues with rapid growth and devoid of any characteristic features and may resemble any oral malignancy (Izumi et al, 1995).[7] Microscopically, leiomyosarcoma is characterized by interlacing fascicles of atypical spindle shaped cells with abundant eosinophilic cytoplasm and indistinct cytoplasmic borders. The nucleus is centrally located with blunt cigar shaped ends (Lo Mozio, 2000).[8] Definitive microscopic diagnosis of the lesion is difficult owing to its similarity to other spindle cell malignancies and requires positive immunohistochemical findings for the confirmation of diagnosis. As per the existing literature the ideal treatment option for leiomyosarcoma includes surgical resection (hemimandibulectomy /hemimaxillectomy) with adjuvant radiotherapy and chemotherapy with regular follow up. Overall, the 5-year survival rate for primary LMS in the oral cavity is around 55% and the local recurrence is seen in 34% of cases (Ethunandan et al, 2007).[9]

Osteosarcomas (OS) is the most common primary malignant tumor of bone, nearly 6% of which occurs in the jaw mainly the mandible.[10] The most common histopathologic type is chondroblastic type in head and neck group and osteoblastic in extremity group.[10]. The varied radiographic appearance of this lesion highlights the importance of histopathologic analysis in the diagnosis of osteosarcomas. The diagnosis of osteosarcoma is based on recognition of osteoid production by tumor cells and depending upon the predominant type of extracellular matrix present, osteosarcomas are categorized histopathologically into osteoblastic, chondroblastic and fibroblastic subtypes. [11] Mardinger et al reported the highest prevalence for chondroblastic osteosarcoma (42%) followed by osteoblastic osteosarcoma (33%).[12] Histologic diversity of osteosarcomas

points to the fact that histology alone is insufficient for the diagnosis of osteosarcoma. Therefore, combined clinical, radiographic and histopathologic analysis before definitive diagnosis is necessary. Wide radical resection is the treatment of choice for osteosarcoma of jaws with clearance margins of 1.5–2 cm. Surgery and adjuvant chemotherapy and radiotherapy may be required sometimes. The presence of micrometastases decides the need of adjuvant therapy. In mandible, hemimandibulectomy is commonly preferred.[13]

In general, the treatment options for childhood oral cavity cancer include surgery, chemotherapy and radiation therapy either alone or in combination. The management of malignant tumors of the oral cavity depends on histopathology.[14] Multidisciplinary and multimodal approach to management and local control as well as preservation of the function should be the goal of any therapy.

Conclusion

Pediatric jaw malignancies are an uncommon occurrence that requires a comprehensive multidisciplinary and multimodal approach to achieve the long-term goals which includes tumor surveillance, maintaining normal facial skeletal and dental growth which may not cease until 18-21 years of age, preservation of normal speech and swallowing function and replacement of the missing dentition. Early diagnosis and treatment are a pre-requisite to avoid significant morbidity and also improve the quality of life. It is imperative that a thorough diagnostic work-up be carried out for pediatric oral neoplasms to aid in appropriate management and better prognosis.

References

1. Katanoda K, Shibata A, Matsuda T, Hori M, Nakata K, Narita Y, et al. Childhood, adolescent and young adult cancer incidence in Japan in 2009–2011. Jpn J Clin Oncol 2017; 24:1–10.

2.Tanaka N, Murata A, Yamaguchi A, et al.: Clinical features and management of oral and maxillofacial tumors in children. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1999; 88 (1):11-5, 1999.

3.Perez DE, Pires FR, Alves Fde A, et al.: Juvenile intraoral mucoepidermoid carcinoma. J Oral Maxillofac Surg 2008; 66 (2):308-11.

4.Pinheiro, J.J.V., Alves, S.M., Okuda, E., Jorge, W.A., Jaeger, R.G., Araújo, N.S. Primary leiomyosarcoma

of the mandible. A case report. Med Oral Patol Oral Cir Bucal 2007; 12:E56-9.

5.Yan, B., Li, Y., Pan, J., Xia, H., Li, L. J. Primary oral leiomyosarcoma: a retrospective clinical analysis of 20 cases. Oral Dis 2010; 16; 198–203.

6.Mesquita, R.A., Migliari, D.A., Sousa, S.D., Alves, M.R. Leiomayosarcoma of the buccal mucosa: a case report. Oral Maxillofac Surg 1998; 56:507–9.

7.Izumi, K., Maeda, T., Cheng, J., Saku, T. Primary leiomyosarcoma of the maxilla with regional lymph node metastasis: Report of a case and review of the literature. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1995; 80:310-9.

8.Lo Muzio, L., Favia, G., Mignogna, M. D., Piattelli, A., Maiorano, E. Primary intraoral leiomyosarcoma of the tongue: An immunohistochemical study and review of the literature. Oral Oncol 2000; 36:519-24.

9.Ethunandan, M., Stokes, C., Higgins, B., Spedding, A., Way, C., Brennan, P. Primary oral leiomyosarcoma:a clinico-pathologic study and analysis of prognostic factors. J Oral Maxillofac Surg 2007; 36:409–16

10.Durnali A, Alkis N, Cangur S, et al. Prognostic factors for teenage and adult patients with high-grade osteosarcoma: an analysis of 240 patients. Med Oncol 2013; 30:624.

11.Schajowicz F. Histological typing of bone tumours. 2nd ed. Berlin: Springer-Verlag; 1993.

12.Mardinger O, Givol N, Talmi YP, Taicher S. Osteosarcoma of the jaw- The Chaim Sheba Medical Center Experience. Oral Surg Oral Med Oral Path Oral Radiol Endod 2001;91: 445-51.

13.Chaudhary M, Chaudhary SD. Osteosarcoma of jaws. J Oral Maxillofac Pathol 2012; 16:233-8.

14.Sturgis EM, Moore BA, Glisson BS, et al.: Neoadjuvant chemotherapy for squamous cell carcinoma of the oral tongue in young adults: a case series. Head Neck 2005; 27 (9):748-56

Original Article

Multidimensional Indicators as Enablers on Perception of Facial Beauty and Appearance among Indian Population: A Descriptive Cross-Sectional Study

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Abstract

Background: Facial appearance has been a flagbearer of "beauty" since time immemorial. Perception of beauty is highly influenced by cultural, interpersonal, and intra-personal variations. **Objectives:** This study aimed to assess the perception of facial beauty and appearance through multidimensional influencing indicators among the Indian population, and to determine whether the physically attractive person possesses more personal and socially desirable traits than the comparatively less attractive individual. **Materials and Methods:** A study population of 474 with equal male and female population of Indian origin was selected. Their perception was assessed based on the prevalidated, self-administered questionnaire using a tool with five major multidimensional indicators. Six images were selected, three each of male and female subjects, and labeled as A, B, and C, in descending order of attractiveness. The multidimensional influencing indicator tool was self-administered to the participants and the responses were recorded individually. **Results:** Photograph A scored the highest out of the three grading scales in both males and females. **Conclusion:** The most attractive photograph, in both males and females, was deemed to be associated with higher scores of attractiveness and success.

Keywords: Aesthetics, cosmetic, facial image, interpersonal relationships, psychological impact, race

Introduction

Despite the old adage not to "judge a book by its cover," facial cues often guide first impressions, and these first impressions guide our decisions.[1] Many works have been devoted to assessing the validity of the natural selection hypothesis or beauty as a "certificate" of good phenotypic condition. Indeed, it has been documented that cultural, between-person, and intraperson differences influence attractiveness perception in various ways.[2] The phrase—"First impression is the last impression" implies to the general attractiveness of an individual and how it is perceived by the mass.

It is well established that humans have always preferred beauty over brains, and standards of beauty set by society can impact an individual's overall personality to an extent that is indescribable. The face is the part of the human body from which we infer the most information about others, such as gender, identity, intentions, emotions, attractiveness, age, or ethnicity. In particular, by looking at a face, we are able to immediately acquire a consistent impression of its attractiveness.[3–5] Still, we could have a hard time explaining what makes a face attractive to us. As a matter of fact, which variables determine attractiveness and their interactions are still poorly understood issues.

Access this article online

Quick Response Code:

Website: www.jcasonline.com

DOI: 10.4103/JCAS.JCAS_208_22

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How to cite this article: Kumar VA, Hulst van der RRWJ, Shome DD, Booi DI, Tandel HA, Mhatre PD. Multidimensional indicators as enablers on perception of facial beauty and appearance among Indian population: A descriptive cross-sectional study. J Cutan Aesthet Surg 2023;16:292-9.

The effect of a "beautiful face" can be observed in every aspect of life. In some cases, it has been observed that people with a beautiful face find it easy to get a job or a promotion than someone of the same caliber but less attractive. Beauty has always been associated with positive traits, which largely affects an individual's personal relationships and sexual life.[6]

Physical attractiveness has important social consequences. For example, beauty is associated with upward economic mobility, especially for women; attractive individuals are perceived to possess a variety of positive personality attributions.[7,8] In mock interviews, attractive people are more likely to be hired than less attractive individuals. This can be well understood from advertisements that promote "fairness," indicating that facial beauty can make life better.

The human face has been a source of great interest to psychologists and other scientists in recent years because of the extraordinarily well-developed ability of humans to process, recognize and extract information from other's faces.[9]

If attractiveness is a diffuse characteristic, it must possess at least two states, which are evaluated differentially. All research shows that this criterion is fulfilled: there are both attractive and unattractive people, and it is preferable, better advantageous, and more desirable to be pretty than to be ugly.[10]

The physical form of an individual's features majorly plays two roles, i.e., in functionality and in appearance. Therefore, the functional aspect of beauty majorly influences the appearance of an individual and exhibits a direct correlation.[9]

The quest for beauty has deep psychological roots in human beings and is as indispensable to them as any other quest. It has endowed our lives with an enjoyable depth of being without which it would be dull and drab. Our quest for beauty is as old as human civilization, and there was never a time when humans have been without it.[11]

On through literature review, few articles were found that delve into this topic, and there was an imminent scarcity of such studies performed on the Indian population. Hence the present study envisaged to assess the perception of facial beauty and appearance through multidimensional influencing indicators among the Indian population. It is aimed at determining whether the physically attractive person possesses more personal and socially desirable traits than the comparatively less attractive individual. It further intended to discern if the physically attractive individuals have better personal and professional life experiences and lead better life than the less attractive individual.

Materials and Methods

The current study was a descriptive cross-sectional study aiming to delve into the perception of facial beauty and appearance through multidimensional influencing indicators among the Indian population. It has been detailed in accordance with the STROBE guidelines, as prescribed by the EQUATOR Network. Ethical approval was obtained from the Institutional Ethics Committee of the Esthetic Clinics. Indian nationals aged 18 years and above, those willing to provide written informed consent, were included in the study. An equal number of participants were selected from four different cities in India (Mumbai, Delhi, Kolkata, and Hyderabad). A pilot study was conducted among 50 participants to sieve through the flaws and feasibility of the study. These were not recruited while constituting the final sample size. Based on the pilot study, the sample size was estimated to be 474, which was rounded off to 480 as the final sample (calculated through G* Power Software, maximum admissible error (d)—4.5%, power of study—80%, level of significance—5%). Individuals with intellectual incompetence or who were diagnosed as mentally challenged were excluded from the study. Stratified random sampling method was deployed to recruit the participants from each city.

The perception was assessed based on the prevalidated, self-administered questionnaire using a tool with five major multidimensional indicators viz: personal traits, professional traits, interpersonal interactions and experiences, occupational index, and professional hierarchy. The psychometric properties of the assessment tool were checked for reliability, which was measured using Cronbach's alpha and validity, including face validity and content validity ratio.

Twenty standardized digital photographs of college students (10 male and 10 female) were shortlisted based on the following criteria: (facial frontal view, nonchalant look, no make-up on lips, face and eyes, and no accessories). These photographs were assessed by two subject experts (facial plastic surgeon and cosmetic dermatologist) based on a facial attractiveness Likert-rating 1–6 (1 being least attractive and 6 being most attractive). Higher interrater agreement (Kappa statistic = 0.92) led to the final selection of six images (three male and three female) which were categorized and sorted into descending levels of attractiveness and were labeled as A, B, and C (i.e., A being most attractive and C being least attractive). These images were printed on life-size-like placards and were used for the study to generate responses. The multidimensional influencing indicator tool was self-administered to the participants. The responses were recorded individually.

The normality of the data was discerned by Shapiro–Wilk's test and Kolgromonov–Smirnov's test. Descriptive statistics and two-way analysis of variance (ANOVA) were applied through SPSS Software (Version 18.0, IBM, Chicago, Illinois, USA). The level of significance was set at $P < 0.05$. Figure 1 depicts the facial appearance of the females selected in the study and labelled A, B and C. Figure 2 depicts the facial appearance of the males selected in the study and labelled A, B and C

Table 1: Descriptive statistics showing the percentage distribution among male personality traits

Trait	Photograph A		Photograph B		Photograph C	
	Grading scale	*N*%	Grading scale	*N*%	Grading scale	*N*%
Selfish	1	30.6666667	3	37.33333	1	32
Creative	1	40	4	29.33333	2	30.6666667
Self-assertive	1	33.3333333	2	30.66667	1	36
Stable	1	37.3333333	3	29.33333	1	33.3333333
Emotional	2	34.6666667	2	26.66667	1	38.6666667
Dependent	1	34.6666667	2	26.66667	1	38.6666667
Safe	2	28	2	34.66667	2	37.3333333
Interesting	1	29.3333333	3	33.33333	5	37.3333333
Genuine	2	30.6666667	2	34.66667	4	34.6666667
Sensitive	1	36	3	33.33333	3	30.6666667
Outgoing	1	34.6666667	1	26.66667	2	38.6666667
Sexual	1	32	2	40	1	28
Permissive	1	33.3333333	3	32	3	34.6666667
Sincere	2	37.3333333	2	28	4	34.6666667
Warm	1	37.3333333	4	36	1	26.6666667
Sociable	2	32	1	40	3	28
Competitive	1	33.3333333	2	30.66667	1	36
Kind	2	38.6666667	2	36	2	25.3333333
Empathic	1	32	1	33.33333	1	34.6666667
Modest	2	33.3333333	5	30.66667	2	33.3333333
Strong	1	32	2	33.33333	1	34.6666667
Serious	1	30.6666667	1	40	2	29.3333333
Humorous	1	26.6666667	2	38.66667	5	34.6666667
Simple	1	37.3333333	27	33.33333	5	29.3333333
Poised	1	33.3333333	1	36	5	30.6666667
Bold	2	37.3333333	2	32	4	30.6666667
Sophisticated	2	34.6666667	1	34.66667	4	30.6666667
Capable	1	37.3333333	2	30.66667	3	32
Trustworthy	1	38.6666667	1	34.66667	4	26.6666667
Enthusiastic	1	37.3333333	2	28	5	34.6666667

Grading scale: 1 = Strong agreement, 2 = Agreement, 3 = Neutral, 4 = Disagreement, 5 = Strong disagreement

Results

The sample comprised of 480 participants, both male and female, of ages ranging between 20 to 35 years, with a mean age of 24.36 ± 2.25 for males and 26.14 ± 3.25 for females. Tables 1 and 2 depict the distribution of male and female personality traits for each photograph, respectively. The table shows that the most attractive male photograph A scored the highest out of the three on the grading scale. Photograph A scored the highest scores out of the three, followed by photographs B and C. Similar results were seen in the female photographs, as the most attractive photograph was deemed to be associated with higher scores of attractiveness and success.

Tables 3 and 4 represent the percentage distribution of socially desirable traits among males and females, respectively. Photograph A scored the highest scores in males, followed by comparable scores in photographs B and C. In females, photograph A scored highest, followed by photograph C and least score for photograph B.

Tables 5 and 6 represent the distribution of interpersonal relationships among male participants and the level of significance among both groups. All the traits were seen to be statistically significant, with photograph A scoring highly among both genders.

Tables 7 and 8 showcase the results of a two-way ANOVA analysis of the distribution of interpersonal relationships and distribution of occupational index, respectively, among the male and female photographs.

Discussion

Attraction and interpersonal interaction have been finely related to each other. An attractive demeanor results in more successful milestones being achieved.[12,13] Beauty and its various repercussions have been termed as a "status."[14] To further investigate this cult, the current study envisaged to comprehensively discern viewpoints, here clustered as "Multidimensional Influencing Indicators," comprising

Table 2: Distribution of personality traits in female participants

Trait	Photograph A		Photograph B		Photograph C	
	Grading scale	*N*%	Grading scale	*N*%	Grading scale	*N*%
Selfish	1	32	2	32	3	36
Creative	1	32	4	29.33333	2	38.6666667
Self-assertive	1	30.6666667	2	33.33333	1	36
Stable	1	34.6666667	3	33.33333	1	32
Emotional	1	33.3333333	2	29.33333	2	37.3333333
Dependent	1	38.6666667	2	26.66667	1	34.6666667
Safe	2	33.3333333	2	34.66667	2	32
Interesting	1	34.6666667	3	33.33333	5	32
Genuine	2	37.3333333	2	30.66667	4	32
Sensitive	1	34.6666667	3	33.33333	3	32
Outgoing	1	30.6666667	1	30.66667	2	38.6666667
Sexual	1	33.3333333	2	36	1	30.6666667
Permissive	1	33.3333333	3	32	3	34.6666667
Sincere	2	37.3333333	2	28	4	34.6666667
Warm	1	34.6666667	4	34.66667	1	30.6666667
Sociable	2	29.3333333	1	36	3	34.6666667
Competitive	1	33.3333333	2	30.66667	1	36
Kind		34.6666667	2		2	32
Empathic	1	33.3333333	1	36	1	30.6666667
Modest	2	33.3333333	5	32	2	34.6666667
Strong	1	30.6666667	2	33.33333	1	36
Serious	1	30.6666667	1	40	2	29.3333333
Humorous	1	32	2	38.66667	5	29.3333333
Simple	1	34.6666667	2	33.33333	5	32
Poised	1	36	1	30.66667	5	33.3333333
Bold	1	33.3333333	2	36	1	30.6666667
Sphisticated	1	33.3333333	3	32	3	34.6666667
Capable	2	37.3333333	2	28	4	34.6666667
Trustworthy	1	34.6666667	4	34.66667	1	30.6666667
Enthusiastic	2	29.3333333	1	36	3	34.6666667

Grading scale: 1 = Strong agreement, 2 = Agreement, 3 = Neutral, 4 = Disagreement, 5 = Strong disagreement

Table 3: Descriptive statistics showing the percentage distribution among male socially desirable traits

Trait	Photograph A		Photograph B		Photograph C	
	Grading scale	*N*%	Grading scale	*N*%	Grading scale	*N*%
Friendliness	1	36	2	30.66667	4	34.6666667
Self-happiness	1	34.6666667	3	32	4	33.3333333
Physical attractiveness	1	36	2	32	4	30.6666667
Passionate	1	36	3	33.33333	2	30.6666667
Good-listener	2	32	3	36	3	32
Leadership	2	34.6666667	2	32	5	33.3333333
Honesty	1	40	2	42.66667	2	44
Responsible	1	33.3333333	5	30.66667	2	36
Courageous	1	37.3333333	2	34.66667	2	28

Grading scale: 1 = Strong agreement, 2 = Agreement, 3 = Neutral, 4 = Disagreement, 5 = Strong disagreement

of personality and socially desirable traits, interpersonal interaction, occupational status, and professional hierarchical positions.

The viewpoints of males and females, though minorly disproportionate, are majorly targeted and streamlined into the subtle difference in interpretation of the word "beautiful" and "handsome." Though mutually exclusive terms, stereotypes point out a woman being adjudged as "beautiful" as opposed to "handsome" for a man. The results of this study were in tandem with Kumar[11], which showed no significant differences in the responses of either of the genders to the various stems.

An interesting phenomenon discussed in abundance by Dipboye *et al.*, popularly termed the "attractiveness

Table 4: Distribution of socially desirable traits in female participants

Trait	Photograph A		Photograph B		Photograph C	
	Grading scale	*N*%	Grading scale	*N*%	Grading scale	*N*%
Friendliness	1	36	2	28	4	36
Self-happiness	1	37.3333333	3	32	4	30.6666667
Physical attractiveness	1	34.6666667	2	36	4	29.3333333
Passionate	1	30.6666667	3	32	2	37.3333333
Good-listener	1	30.6666667	3	36	3	33.3333333
Leadership	1	30.6666667	2	33.33333	5	36
Honesty	1	36	2	30.66667	2	33.3333333
Responsible	2	37.3333333	5	30.66667	2	32
Courageous	1	37.3333333	2	34.66667	2	28

Grading scale: 1 = Strong agreement, 2 = Agreement, 3 = Neutral, 4 = Disagreement, 5 = Strong disagreement

Table 5: Distribution on Interpersonal relationships among male participants and level of significance with two-way ANOVA analysis

Trait	Most likely			Least likely			Two-way ANOVA analysis within the groups			
	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	DF	*F*-value	MS	Level of significance (*P*-value)
Get into a relationship easily?	80	60	40	10	30	19	8	100	140.8	<0.001*
Have a good married life?	75	56	45	16	36	22				<0.001*
Get divorced?	25	44	35	24	38	36				<0.001*
Have a better sexually active life?	80	63	47	20	40	32				<0.001*
Be infidel?	70	64	44	10	20	15				<0.001*
Be promiscuous?	65	55	46	14	36	27				<0.001*
Be a good parent?	70	56	50	20	44	31				<0.001*
Have a good social/friend circle?	80	58	49	16	29	18				<0.001*
Be a good son/daughter?	70	50	45	10	20	17				<0.001*

*$P < 0.05$ is considered statistically significant

Table 6: Distribution on Interpersonal relationships among female participants and level of significance with two-way ANOVA analysis

Trait	Most likely			Least likely			Two-way ANOVA analysis within the groups			
	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	DF	*F*-value	MS	Level of significance (*P*-value)
Get into a relationship easily?	87	75	60	15	24	24	8	307.9	83.74	<0.001*
Have a good married life?	71	65	58	18	32	32				<0.001*
Get divorced?	35	40	50	20	35	26				<0.001*
Have a better sexually active life?	86	73	60	12	30	22				<0.001*
Be infidel?	67	70	54	10	26	35				<0.001*
Be Promiscuous?	80	75	80	14	40	37				<0.001*
Be a good parent?	85	78	75	19	40	31				<0.001*
Have a good social/friend circle?	85	74	65	17	22	28				<0.001*
Be a good son/daughter?	80	75	68	20	25	37				<0.001*

halo effect," linked positive personality traits such as trustworthiness, genuineness, kindness, and empathy.[16] The results are incongruent with our study as we concluded, in the vital domain of personality traits, that the image of the person labeled as most attractive was indicative of being greatly trustworthy, interesting, strong, warm, empathetic, outgoing, and sexually permissive. Facial attractiveness was demonstrated to be directly proportional to genuineness, sincerity, capability, and enthusiasm.

Increased facial attractiveness pointed out characteristics of kindness, which were reflected in the study published by Hamermesh *et al*. Augmented facial beauty indicated a

Table 7: Distribution of occupational index among the male participants with two-way ANOVA analysis

Trait	Most likely			Least likely			Two-way ANOVA analysis within the groups			
	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	DF	*F*	MS	Level of significance
Get a job easily?	84	68	55	10	30	40	4	36.78	188.5	<0.001*
Make better progress in life professionally?	74	62	52	12	34	41				<0.001*
Be rich?	75	60	45	20	36	40				<0.001*
Earning more?	75	63	44	25	38	42				<0.001*
Get promoted?	70	60	40	20	35	48				<0.001*

*$P < 0.05$ is considered statistically significant

Table 8: Distribution of female participants among occupational index and level of significance seen with two-way ANOVA analysis

Trait	Most likely			Least likely			Two-way ANOVA analysis within the groups			
	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	Phot-A (*N*%)	Phot-B (*N*%)	Phot-C (*N*%)	DF	*F*	MS	Level of significance
Get a job easily?	86	80	65	20	30	40	4	168.2	76.90	<0.001*
Make better progress in life professionally?	80	78	63	25	30	45				<0.001*
Be rich?	82	76	60	25	30	35				<0.001*
Earning more?	80	78	70	25	35	40				<0.001*
Get promoted?	80	75	65	30	40	45				<0.001*

*$P < 0.05$ is considered statistically significant

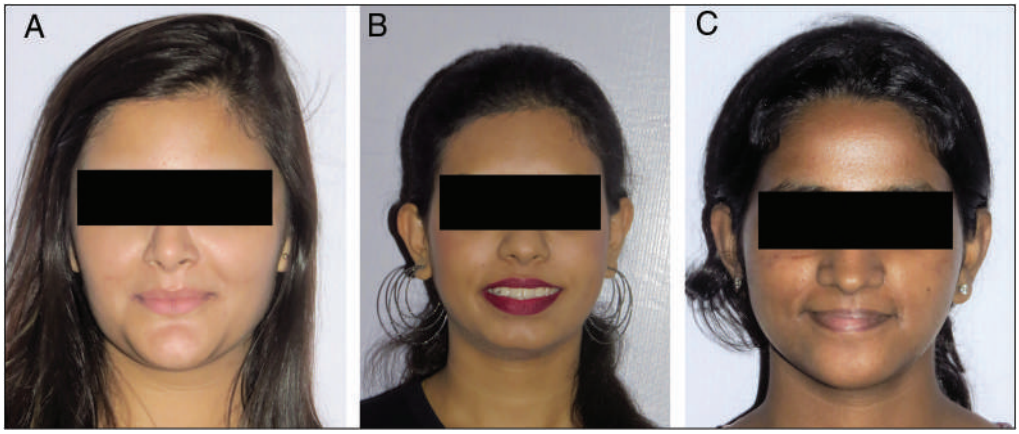

Figure 1: Facial appearance of the females in the study labelled A, B, C.

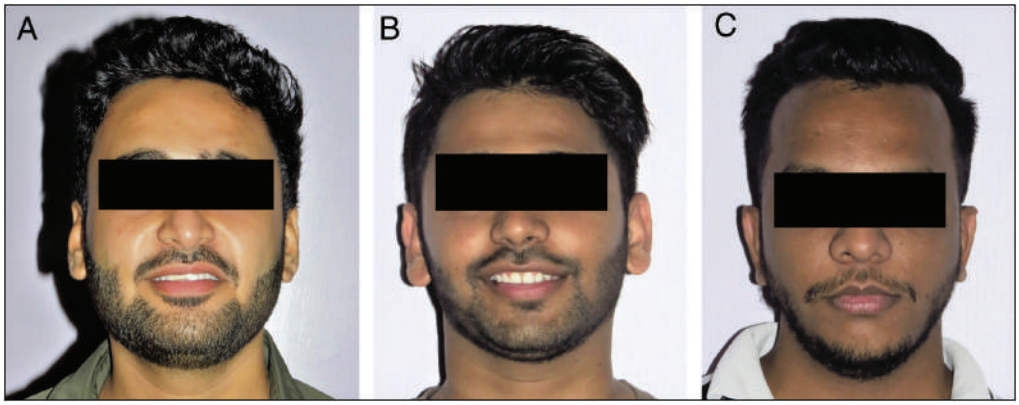

Figure 2: Facial appearance of the males in the study labelled A, B, C.

happier individual, in congruence with reports by others.[17] They also scored higher in the sexually permissive and interesting parameters.[18] Facial attractiveness also had a significant influence on mating behavior and friendships. Though this study did not assess any parameters on sexual permissiveness, it did show that the people were perceived to be more physically attractive and confident.

A meta-analysis conducted by Langlois *et al.*[20] equated increased facial attractiveness to greater social appeal and interaction, quipping that beauty and interpersonal competence go hand in hand. Others also reported congruent results with our study, inferring that facial attractiveness plays a crucial role in a person's social life.[21] The results of this study support the meta-analysis of increased social interaction and the building of social and self-confidence in the individual.

Socially desirable traits mirrored impeccably in attractive individuals, being more friendly, passionate, honest, and possessing leadership traits. Reports from Montepare and Zebrowitz[22] validated the stance of the reporting of the current study by fortifying that beauty was intertwined with constructs of intelligence and sophistication. However, there was no substantial relation established between intelligence and facial attractiveness, according to Mitchem and Zietch.[23]

Statistically significant ($P < 0.005$) findings in the subsets of interpersonal relationships have been reported in our study. The individual marked as most attractive was discerned to get into relationships easily and enjoyed a better sexual life. However, they were also labeled to be presumably more infidel, promiscuous, and had a propensity to divorce their partner. With the pursuit of pulchritude being not a trivial affair. Castillo and Petrie have also been vocal in their study regarding family dissolution and increased divorce rates among those perceived to have higher grades of facial attractiveness.[24] Further, greater mating behavior and promiscuity have been documented by Fisman, Iyengar, and Driskell.[25] However, the results were a takeoff to those published by Hamermesh and Abrevaya[26] and Little *et al.*,[27] which commented on depleted divorce rates and greater marital positivity with increased beauty scores. A plausible explanation to this could be attributed to Dorner's research which mentioned cognition and behavior as two seamless constructs which influence happier marriages, as compared to external physical pulchritude. Our research shows similar implications when it comes to the perception of beauty and the probable chance of the person being divorced, as almost a third of the participants saw the most attractive female being divorced.

Occupational and professional fields revealed that those with increased facial beauty tend to get professional placements and jobs easily and more rapidly, make better progression in careers, earn more and have greater chances of being promoted. Sala *et al.* [29] deliberating occupational prestige, write about the concept of "beauty premium" and justify that beauty pays. The results of our study were in conjunction with Langlois *et al*.[20], who also mentioned that increased facial attractiveness led to greater occupational competency. Hamermesh and Abrevaya further fortify our stance that personal beauty betters economic outcomes. Enhanced facial attractiveness also is related to positive hiring decisions and juror selections, adding the occupational benefit and increased job rankings during interviews. According to Stevenage and Luxen and Van de Vijver[30], they had higher chances of being hired. The presumed most beautiful image in our study was ranked as the highest office bearer (CEO) in a circumstantial professional hierarchy, as compared to the others with a muted beauty emanation.

While the functional aspect of beauty refers to the natural course of action in a specific role, attractiveness is the impact that is made through the impression of a person. The present study explores both these horizons of an ambiguous concept that "beauty" is. This has been done by accessing the functionality of the subject's appearance in relation to the established standards of beauty. The various parameters studied, such as friendliness, self-happiness, physical attractiveness, etc., and their effect on outcomes related to the job, opportunities, career, relationships, etc., throw light upon the unexplored side of beauty standards.

Conclusion

The concept of beauty and pulchritude, though often debated and scrutinized open, yields substantial evidence that the might of beauty has implications manifold. It channelizes arenas and vistas for personal and professional growth and rings the impending need for such principles to be effectively documented.

The current study presents a solution to the dogma surrounding the facets of beauty in the Indian subcontinent. It endeavors in assimilating a multidimensional, multifaceted, and totalitarian viewpoint about what is beautiful. Fatigue bias and central tendency bias were tried to be reduced by restraining the options to each stem. However, the descriptive nature of the study warranted lucid aggregation of thoughts.

The authors express their intent and desire for this study to be replicated in other study settings so as to establish a concurrent contemporary global standard for what is beautiful. We further impress upon the fact that the difference across various socioeconomic strata be discerned, and the idea of beauty among rural and urban populations be weighed.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Talamas SN, Mavor KI, Perrett DI. Blinded by beauty: Attractiveness bias and accurate perceptions of academic performance. PLoS ONE 2016;11:e0148284.
2. Ibáñez-Berganza M, Amico A, Loreto V. Subjectivity and complexity of facial attractiveness. Sci Rep 2019;9:8364.
3. Walker M, Vetter T. Changing the personality of a face: Perceived big two and big five personality factors modeled in real photographs. J Pers Soc Psychol 2016;110:609-24.
4. Little AC, Jones BC, DeBruine LM. Facial attractiveness: evolutionary based research. Philos Trans R Soc B Biol Sci 2011;366:1638-59.
5. Leopold DA, Rhodes G. A comparative view of face perception. J Compar Psychol 2010;124:233-51.
6. Hamermesh, Daniel S. Beauty Pays: Why Attractive People Are More Successful. Princeton: Princeton University Press, 2011.
7. Elder GHJ. Appearance and education in marriage mobility. Am Soc Rev 1969;34:519–33.
8. Holmes SJ, Hatch CE. Personal appearance as related to scholastic records and marriage selection in college women. Hum Biol 1938;10:65–76.
9. Buss DM, Barnes M. Preferences in human mate selection. J Pers Soc Psychol 1986;50:559–70.
10. Webster M, Driskell JE. Beauty as status. AJS 1983;89:140-65.
11. Kumar P. Concept of beauty in India. Int J Cosmet Surg Aesthet Dermatol 2002;4:261-4.
12. Cash TF, Kehr J. Influence of nonprofessional counselors' physical attractiveness and sex on perceptions of counselor behavior. J Counsel Psychol 1978;25:336-42.
13. Baker MJ, Churchill GA. The impact of physically attractive models on advertising evaluations. J Marketing Res 1977;14:538-55.
14. Webster M, Driskell JE. Beauty as status. AJS 1983;89:140-65.
15. Brewer MB. A dual process model of impression formation. In: Srull TK, WyerJr RS, editors. A dual process model of impression formation. Lawrence Erlbaum Associates, Inc; 1988. p. 1–36.
16. Dipboye R, Dhahani L. Exploring the effects of physical attractiveness in job applicant evaluations: Taking into account stimulus variability (March 7, 2017). Available at SSRN: http://dx.doi.org/10.2139/ssrn.2928874.
17. Hamermesh DS, Abrevaya J. Beauty is the promise of happiness? Europ Econ Rev 2013;64:351-68.
18. Koukounas E, Over R. Habituation of male sexual arousal: Effects of attentional focus. Biol Psychol 2001;58:49-64.
19. Scheib Joanna E, Gangestad Steven W, Randy T. Facial attractiveness, symmetry and cues of good genes. Proc R Soc Lond B 1999:266:1913-7.
20. Langlois JH, Kalakanis L, Rubenstein AJ, Larson A, Hallam M, Smoot M. Maxims or myths of beauty? A meta-analytic and theoretical review. Psychol Bull 2000;126:390-423.
21. Zhang D, Zhao Q, Chen F. Quantitative analysis of human facial beauty using geometric features. Pattern Recognit 2011;44:940-50.
22. Montepare JM, Zebrowitz LA. A social-developmental view of ageism. In: Nelson TD, editor. Ageism: Stereotyping and prejudice against older persons. The MIT Press; 2002. p. 77–125.
23. Mitchem DG, Zietsch BP, Wright MJ, Martin NG, Hewitt JK, Keller MC. No relationship between intelligence and facial attractiveness in a large, genetically informative sample. Evol Hum Behav 2015;36:240-247.
24. Castillo M, Petrie R. Discrimination in the lab: Does information trump appearance? Games Econ Behav 2010;68:50-59.
25. Fisman R, Sethi-Iyengar, Sheena S, Kamenica E, Simonson I. Racial preferences in dating: Evidence from a speed dating experiment (October 2004). Stanford GSB Research Paper No. 1871. Avaliable from: http://dx.doi.org/10.2139/ssrn.610589.
26. Hamermesh DS, Abrevaya J. Beauty is the promise of happiness? Eur Econ Rev 2013;64:351-368.
27. Little AC, Burt DM, Perrett DI. What is good is beautiful: Face preference reflects desired personality. Pers Individ Diff 2006;41:1107-18.
28. Hakim C. Erotic capital. Eur Soc Rev 2010;26:499-518.
29. Sala E, Terraneo M, Lucchini M, Knies G. Exploring the impact of male and female facial attractiveness on occupational prestige. Res Soc Stratification Mobility 2013;31:69-81.
30. Luxen MF, Van De Vijver FJR. Facial attractiveness, sexual selection, and personnel selection: When evolved preferences matter. J Organiz Behav 2006;27:241-55.

Original Research- Retrospective Study

Cost-effectiveness of the Flapless Insertion of Zygomatic Implants Using Dynamic Navigation - A Retrospective Study

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Abstract

Introduction: Zygomatic implants are an effective solution for rehabilitation of edentulous atrophic maxillae. However, the conventional technique of zygomatic implant placement is invasive, requires a longer healing period and is economically cumbersome. Therefore, the flapless technique of insertion of zygomatic implants using dynamic navigation system has been introduced. This study aims to compare the cost-effectiveness of flapless insertion of zygomatic implants using dynamic navigation to the conventional flap technique. **Materials and Methods:** The study participants were divided into two groups: Group A ($n = 20$) included patients treated by flapless insertion of zygomatic implants using dynamic navigation and Group B ($n = 20$) included patients treated with zygomatic implants using the flap technique. An analysis of the effectiveness of the implants was done using the concept of quality-adjusted prosthesis years, and an analysis of the costs was done by evaluating the treatment costs at each step. The data were collected, and analysis was done using IBM SPSS software. The Kruskal–Wallis rank-sum test was employed to analyse variations in costs and effects between the two groups. **Results:** The study showed that the distribution of costs varies across both the categories of the procedure. Group B shows lesser cost-effectiveness as compared to Group A. **Conclusion:** The technique of flapless insertion of zygomatic implants is cost-effective. However, further studies considering factors such as time and cost of productivity evaluating the cost-effectiveness should be conducted.

Keywords: Atrophic maxilla, cost-effectiveness analysis, dynamic navigation, flapless technique, zygomatic implants

Introduction

Missing teeth can be a significant challenge for patients, leading to a lack of self-esteem, difficulty in speaking and eating and overall lower quality of life.[1] Dental implants are an answer to this problem to a great extent. However, in an atrophied edentulous maxilla, placement of a conventional implant is met with difficulty.[2] Zygomatic implants have emerged as an effective solution for these cases, providing a stable and long-term replacement for missing teeth.

Zygomatic implants are a type of dental implants that are used to replace missing maxillary teeth when the maxilla is severely atrophied. They were introduced by Branemark for posterior maxillary anchorage as well as to expedite the process of rehabilitation.[3] They are longer and wider than traditional dental implants and are anchored in the zygomatic bone. However, the surgical technique used to place these implants can greatly affect the outcome and cost-effectiveness of the treatment. The traditional flap technique for zygomatic implant insertion involves making a flap incision in the periodontium, raising the flap and then drilling a hole in the zygomatic bone for the implant.[3,4] This technique is invasive and can cause significant trauma to the soft tissue and bone. In addition, the traditional flap technique has numerous drawbacks such as perforation and infection of the maxillary sinus, delayed post-surgical healing and injury to the ocular

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DOI: 10.4103/ams.ams_80_23

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Received: 27-04-2023 **Last Revised:** 07-08-2023
Accepted: 28-08-2023 **Published:** 23-10-2023

How to cite this article: Bhalerao A, Ayoub A, Marimuthu M, Wahab A, Kumar V. Cost-effectiveness of the flapless insertion of zygomatic implants using dynamic navigation - A retrospective study. Ann Maxillofac Surg 0;0:0.

nervous structures.[5] It requires a longer healing period and can result in further complications.

The flapless insertion of zygomatic implants is a minor surgical technique that involves placing the implants without the need for a flap incision.[6] It involves making a small incision in the gingiva, using a guide to direct the implant into the zygomatic bone and then securing the implant in place, throughout being guided by computer-assisted technology using a software to navigate the direction and angulation of implant placement.[7] This technique has been shown to be less invasive and less traumatic than the traditional flap technique and has the potential to be more cost-effective. A cost-effectiveness analysis is an important tool for systematically combining information about effective interventions with information about their costs. It highlights interventions that have the potential to reduce the burden of disease substantially.[8]

Therefore, this study aims to determine the cost-effectiveness of zygomatic implants using dynamic navigation. By doing so, it elaborates on the advantages, duration and complications as well as compares the financial cost with the health cost of both the techniques.

Materials and Methods

The present study followed a retrospective study design wherein the patients treated with zygomatic implants during the time period of October 2021–February 2023 were included. The approval for this study was obtained from the Institutional Review Board (IHEC/SDC/PhD/OMFS-1611/21/244).

Inclusion criteria

- Patients treated with zygomatic implants using dynamic navigation and followed up for a period of one year
- Patients treated with zygomatic implants using the flap or flapless technique and followed up for a period of one year.

Exclusion criteria

- Patients treated with any other kind of prosthesis
- Patients with a follow-up period of less than one year
- Patients with inaccessible or poorly documented data.

Within the review period, 74 patients were screened, and their data was subsequently evaluated, out of which, 18 were excluded due to a short review period and 16 were excluded due to inadequate documentation of the data. The selected sample was divided into two groups. Group A (n = 20) included patients treated by flapless insertion of zygomatic implants using dynamic navigation and Group B (n = 20) included patients treated with zygomatic implants using the flap technique. Demographic details and additional data regarding post-surgical complications and their subsequent management were also recorded.

The patients were evaluated at baseline and at three months postoperatively to assess several functional and psychological parameters related to their prosthesis. The assessment involved perceived chewing ability measured on the Visual Analogue Scale from 0 (worst possible outcome) to 10 (best possible outcome). The concept of quality-adjusted prosthesis years (QAPYs)[9] was used to determine the effectiveness of the intervention. QAPY is a concept derived from quality-adjusted life year, with values ranging from 0 (absent tooth) to 1 (prosthesis in perfect condition after one year). The QAPYs were calculated by considering the patient's degree of satisfaction according to function and aesthetics at three intervals: baseline, six months and one year after surgery.

The costs of the treatment included the basic tariff for radiographic investigations, diagnosis and treatment planning, implant material, surgical, prosthodontic and laboratory cost as well as operation theatre charges, drug costs and general anaesthesia costs. The cost of management of complications and maintenance charges post-surgery were also included in the study. This calculation was based on the average fee structure followed for each procedural step followed in India. All costs were recorded in Indian rupee (symbol: ₹; code: INR) for the year 2022.

Cost-effectiveness is expressed as a ratio of the difference in costs (i.e., incremental costs) divided by the difference in effects (i.e., incremental effects) between the two strategies, i.e., in patients treated with zygomatic implants using dynamic navigation with flapless technique and flap technique.

The Kruskal–Wallis rank-sum test was employed to analyse variations in costs and effects between the two groups. $P < 0.05$ was considered statistically significant. The bivariate distributions of mean total costs and QAPYs for both the treatment strategies were done and summarised in terms of two-way cost-effectiveness acceptability curves. For all statistical analyses, the Statistical Package for the Social Sciences (SPSS) (SPSS Inc., version 22, IBM, Chicago, Illinois, USA) software[10] was used.

Results

All the patients included in the study were in the age group of 40–60 years, with a mean age of 52.37 ± 3.42 years in Group A and 54.11 ± 2.12 years in Group B. In Group A, 65% of patients were male and 35% were female, whereas, in Group B, 55% were male and 45% were female. The imaging and diagnostic cost was ₹2524.90 (154.08) in Group A, whereas in Group B, it was ₹2530.25 (148.85). The material cost of implants for Group A was ₹94,620 ± 2813.61 and for Group B was ₹95,685 ± 2687.843. No statistical difference was seen in the diagnostic and material costs of both the groups ($P > 0.05$).

In Group A, no extra costs were needed for operation theatre, hospital management, general anaesthesia and drugs. These costs were required for Group B. Therefore, a significant difference was observed in the total operative costs of both the groups with a mean of ₹97,144.90 ± 2865.14 for Group A but ₹148,882 ± 2964.99 for Group B. This was statistically significant with $P < 0.05$. The total post-operative cost (complication management cost + maintenance cost) was ₹2810.30 ± 271.09 in Group A but ₹17,613.35 ± 2150.52 in Group B. This was statistically significant with $P < 0.05$. The total cost of procedure for Group A was

Table 1: The difference in average costs between Group A and Group B

	Mean	*N*	SD	SEM	Significance	
					One-sided *P*	Two-sided *P*
Diagnosis						
Group A	2524.90	20	154.078	34.453	0.394	0.788
Group B	2530.25	20	148.851	33.284		
Material costs						
Group A	94,620.00	20	2813.614	629.143	0.472	0.943
Group B	94,685.00	20	2687.843	601.020		
OT charges						
Group A	0.00	20	0.000	0.000	<0.001	<0.001
Group B	15,986.00	20	502.985	112.471		
Other hospital charges						
Group A	0.00	20	0.000	0.000	<0.001	<0.001
Group B	20,440.00	20	920.755	205.887		
GA charges						
Group A	0.00	20	0.000	0.000	<0.001	<0.001
Group B	12,540.50	20	275.251	61.548		
Drugs						
Group A	0.00	20	0.000	0.000	<0.001	<0.001
Group B	5230.50	20	150.559	33.666		
Total operative cost						
Group A	97,144.90	20	2865.140	640.665	<0.001	<0.001
Group B	148,882.0	20	2964.990	662.992		
Complication management cost						
Group A	1945.30	20	214.791	48.029	0.005	0.010
Group B	15,863.35	20	21,545.688	4817.762		
Maintenance cost						
Group A	865.00	20	143.435	32.073	0.107	0.214
Group B	885.00	20	143.435	32.073		
Total post-operative cost						
Group A	2810.30	20	271.098	60.619	0.003	0.006
Group B	17,613.35	20	2150.515	4807.661		
Total costs						
Group A	99,955.20	20	21,484.893	4804.168	<0.001	<0.001
Group B	166,495.35	20	22,761.836	5089.701		

OT: Operation theatre, GA: General anaesthesia, SD: Standard deviation, SEM: Standard error mean

₹99,955.20 ± 21,484.89 and ₹166,495.35 ± 22,761.84 in Group B. This was statistically highly significant with $P < 0.001$, as depicted in Table 1.

The QAPYs were calculated at baseline, six months and one year after the procedure. At baseline, the mean QAPY in Group A was 0.557, whereas in Group B, it was 0.516. At six months after procedure, the mean QAPY was 0.792 for Group A and 0.763 for Group B. At one year after the procedure, the mean QAPY was 0.856 for Group A and 0.864 for Group B.

The *P* value determined was <0.05 at baseline and six months. This was statistically significant. However, one year after the procedure, no significant difference was seen in the QAPYs of both the groups, as depicted in Table 2.

The average cost-effectiveness ratio is depicted in Table 3. The stochastic two-way analysis showed that the technique of flapless insertion of zygomatic implants is more cost-effective at ₹116,770.09/year as compared to the flap technique at ₹192,702.95/year.

Table 2: The average mean values of quality-adjusted prosthesis years for Group A and Group B

	Mean	*n*	SD	SEM	*P*
Baseline					
Group A	0.557	20	0.028	0.00620	<0.001
Group B	0.516	20	0.047	0.01057	
6 months					
Group A	0.792	20	0.053	0.01188	0.030
Group B	0.763	20	0.031	0.00703	
1 year					
Group A	0.856	20	0.036	0.00816	0.207
Group B	0.864	20	0.030	0.00682	

SD: Standard deviation, SEM: Standard error mean

Table 3: The cost-effectiveness for Group A and Group B

	Cost	Effect	Cost-effectiveness
Group A (flapless)	99,955.2 (2839.261)	0.856 (0.03)	116,770.09
Group B (flap)	166,495.35 (22,761.836)	0.864 (0.03)	192,702.95

Table 4: The Kruskal–Wallis hypothesis test

Null hypothesis	Test	Test statistic	Significant[a,b]	Decision
The distribution of cost-effectiveness is the same across Group A and Group B	Independent samples Kruskal–Wallis test	28.5	<0.001	Reject the null hypothesis

[a]The significance level is 0.050, [b]Asymptotic significance is displayed

The Kruskal–Wallis test [Table 4] showed that the distribution of costs is not the same across both the categories of the procedure. Group B shows lesser cost-effectiveness as compared to Group A, as depicted in Table 3 and Figure 1.

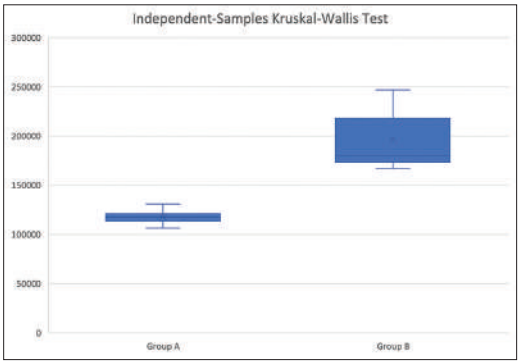

Figure 1: The boxplots of costs and quality-adjusted prosthesis year outcomes

Discussion

Placement of implants involves high costs and investments as compared to other oral rehabilitation modalities such as complete dentures and implant-supported dentures. The cost of investment is further higher in the flapless placement of zygomatic implants using dynamic navigation as compared to the conventional technique. However, this study showed that in spite of the greater cost at baseline, the technique of flapless insertion using dynamic navigation is cost-effective over the years in terms of QAPYs.

This study demonstrated that in Group A (flapless technique), the computer-aided dynamic navigation system gives relatively fast and accurate results as compared to Group B (flap technique). The operating time is significantly reduced and is nearly free of any morbidity or post-operative complications. The number of recalls and follow-up periods of the patient is also reduced. The patient is comfortable as no flap is raised and is ready to resume normal life in a short time of recovery. Overall, it was found that the patients in Group A saved time, adding to the total cost-effectiveness of the procedure.

Whereas, in Group B (flap technique), additional costs were incurred for the customisation of surgical template guides, general anaesthesia and operation theatre. Raising of the flap causes increased operative time, delays wound healing and causes post-operative pain and discomfort to the patient. The number of recalls is higher and the follow-up period is longer. This is challenging, not only physically but also mentally and emotionally. This is relevant to the scope of this study, as it affects the functionality and performance of the patient upon return to daily life, especially in terms of productivity and thereby affecting the 'costs' of this procedure.

The results of our study are in agreement with a similar study conducted by Ravidà *et al*.,[11] which concluded that computer-guided implant placement shows higher rates of survival and comparably lesser long-term cost as compared to non-guided implant placement. In a study conducted by Gebretsadik,[12] effectiveness of up to 94% was derived through analysis of a cumulative success rate in zygomatic implants placed through the conventional technique. Whereas, Wu *et al*.,[13] in their study, determined that the zygomatic implants placed through dynamic navigation showed an effectiveness rate of 98.64%.

An increased radiation exposure to the patient is an important drawback of implant surgeries, especially in those assisted by dynamic navigation as demonstrated by Kunzendorf *et al*.[14] However, the technique demonstrated in this study has an equal amount of radiation exposure to the patient in both the conventional technique and the flapless technique assisted by dynamic navigation. A pre-operative cone-beam computed tomography (CBCT) is taken to pre-plan the site and the position of the placement of the zygomatic implants, and the post-operative scanning is used to assess the accuracy of the achieved results. In dynamic navigation, the pre-operative CBCT is used to guide the placement of the zygomatic implant during surgery. This is achieved using the stereo-pair of cameras of the dynamic navigation system without exposing the patient to any harmful radiation during surgery. Hence, needless exposure of the patient to radiation is prevented.

The technique of flapless insertion of zygomatic implants requires intensive training, and a learning curve has to be taken into consideration while training students and young professionals. In a study conducted by Spille *et al*.,[15] the accuracy of implant placement by young professionals was

evaluated using dynamic navigation. It yielded a statistical significance in the accuracy of angle as well as position of the implants to the apex as compared to the entry point and angular deviations. Furthermore, there was a subjective improvement in handling the dynamic surgery system by these professionals. The study concluded that the technique of using dynamic navigation for implant placement requires the operator to be highly skilled. However, it can be learnt quickly and incorporated into daily clinical practice.

In a systematic review conducted by Ramezanzade *et al*.,[16] the technique of Dynamic-Assisted Navigational System in Zygomatic Implant Surgery was evaluated on the basis of accuracy and complications. The study yielded that the reliability and accuracy of dynamic navigation techniques in large randomised and prospective controlled studies do not meet the threshold of acceptability.

Therefore, it is suggested that further research in the form of randomised and prospective clinical studies be conducted to understand the gap in the literature in relation to the cost-effectiveness of zygomatic implants using both the conventional technique and the dynamic navigation technique.

Conclusion

The present study showed that the technique of flapless insertion of zygomatic implants is more cost-effective as compared to the conventional flap technique. Flapless insertion is a quick and accurate technique, with minimal post-operative complications. By having less operative time, the number of recalls and follow-up periods, it is not only cost-effective in terms of the costs incurred but also the time saved.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Nordenram G, Davidson T, Gynther G, Helgesson G, Hultin M, Jemt T, *et al.* Qualitative studies of patients' perceptions of loss of teeth, the edentulous state and prosthetic rehabilitation: A systematic review with meta-synthesis. Acta Odontol Scand 2013;71:937-51.
2. Esposito M, Worthington HV. Interventions for replacing missing teeth: dental implants in zygomatic bone for the rehabilitation of the severely deficient edentulous maxilla. Cochrane Database Syst Rev 2013;2013:CD004151. [doi:10.1002/14651858.CD004151.pub3].
3. Aparicio C, Manresa C, Francisco K, Claros P, Alández J, González-Martín O, *et al.* Zygomatic implants: Indications, techniques and outcomes, and the zygomatic success code. Periodontol 2000 2014;66:41-58.
4. Malevez C, Daelemans P, Adriaenssens P, Durdu F. Use of zygomatic implants to deal with resorbed posterior maxillae. Periodontol 2000 2003;33:82-9.
5. Chrcanovic BR, Abreu MH. Survival and complications of zygomatic implants: A systematic review. Oral Maxillofac Surg 2013;17:81-93.
6. Bhalerao A, Marimuthu M, Wahab A, Ayoub A. Dynamic navigation for zygomatic implant placement: A randomized clinical study comparing the flapless versus the conventional approach. J Dent 2023;130:104436.
7. Bhalerao A, Marimuthu M, Wahab A, Ayoub A. Flapless placement of zygomatic implants using dynamic navigation: An innovative technical note. Br J Oral Maxillofac Surg 2023;61:136-40.
8. Jamison DT, Breman JG, Measham AR. Cost-effectiveness analysis. In: Priorities in Health. Washington (DC): The International Bank for Reconstruction and Development/The World Bank; 2006. Available from: https://www.ncbi.nlm.nih.gov/books/NBK10253/. [Last accessed on 2023 Jan 27].
9. Probst LF, Vanni T, Cavalcante DFB. Cost-effectiveness of implant-supported dental prosthesis compared to conventional dental prosthesis. Rev Saude Publica 2019;53:s1518-8787.2019053001066. [doi:10.11606/s1518-8787.2019053001066].
10. IBM Corp. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp; 2017.
11. Ravidà A, Troiano G, Qazi M, Saleh MH, Saleh I, Borgnakke WS, *et al.* Dose-dependent effect of smoking and smoking cessation on periodontitis-related tooth loss during 10–47 years periodontal maintenance-A retrospective study in compliant cohort. J Clin Periodontol 2020;47:1132-43.
12. Gebretsadik HG. An update on the success rate of the zygomatic implant in Orofacial reconstructive surgery: A 20 years systematic review. Clin Surg J 2023;4:1–6.
13. Wu Y, Tao B, Lan K, Shen Y, Huang W, Wang F. Reliability and accuracy of dynamic navigation for zygomatic implant placement. Clin Oral Implants Res 2022;33:362-76.
14. Kunzendorf B, Naujokat H, Wiltfang J. Indications for 3-D diagnostics and navigation in dental implantology with the focus on radiation exposure: A systematic review. Int J Implant Dent 2021;7:52.
15. Spille J, Helmstetter E, Kübel P, Weitkamp JT, Wagner J, Wieker H, *et al.* Learning curve and comparison of dynamic implant placement accuracy using a navigation system in young professionals. Dent J (Basel) 2022;10:187.
16. Ramezanzade S, Keyhan SO, Tuminelli FJ, Fallahi HR, Yousefi P, Lopez-Lopez J. Dynamic-assisted navigational system in zygomatic implant surgery: A qualitative and quantitative systematic review of current clinical and cadaver studies. J Oral Maxillofac Surg 2021;79:799-812.

Review Article

Comparative evaluation of accuracy of different generations of electronic apex locator in determining the correct working length: A systematic review and meta-analysis

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ABSTRACT

Aim: Different approaches are used to determine the working length of the root canal. The current and most widely researched are the electronic apex locators (EALs). Since the early apex locators were developed in 1942, several generations had their qualities and shortcomings developed. Thus, a comparative evaluation of the accuracy of different generations of EALs in determining the correct working length: Systemic review and meta-analysis to analyze individual studies quantitively and draw conclusions on the best generation of apex locator currently used.

Materials and Methods: A comprehensive search was conducted on different electronic databases and by manual search. Studies comparing third and fifth generations with fourth-generation apex locators were subject to strict inclusion criteria followed by data extraction and meta-analysis.

Results: Following the meta-analysis, the accuracy is fifth>fourth>third generation of apex locators.

Conclusion: Analysis of individual studies quantitatively will give a better understanding of which devices to use to accurately determine the working length.

Keywords: Electronic apex locator, fifth-generation apex locator, fourth-generation apex locator, third-generation apex locator, working length determination

INTRODUCTION

The success of endodontic treatment largely depends on the precise determination of the working length of the tooth. Many methods such as radiology, tactile sensation, paper point method, and apical periodontal sensitivity have been practiced over the years. The development of the electronic apex locators (EALs) revolutionized such methods by offering better accuracy, constant chairside monitoring of working length and optimizing patient comfort, and preventing overpreparation and subsequent damage to periapical areas.[1-6] An electronic method for root length determination was first investigated by Custer in 1918. The idea was revisited by Suzuki in 1942 who found consistent values in electrical resistance between an instrument in a root canal and an electrode on the oral mucous membrane and speculated that this would measure the canal length. Sunada took these principles and constructed a simple device that used direct current to measure the canal length.[7] First-generation and second-generation apex locators were resistance and impedance-based. Third-generation apex locators were frequency-dependent comparative impedance type. Fourth-generations ratio-type apex locators determine the impedance at five frequencies. The fifth generations

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Submitted: 02-Jun-2022 **Revised:** 31-Jan-2023
Accepted: 15-Feb-2023 **Available Online:** 29-Sep-2023

Access this article online	
Website: https://journals.lww.com/eddt	Quick Response Code
DOI: 10.4103/endo.endo_145_22	

How to cite this article: Bhagat PS, Hegde VR, Kawle S, Jain PB. Comparative evaluation of accuracy of different generations of electronic apex locator in determining the correct working length: A systematic review and meta-analysis. Endodontology 2023;35:202-9.

were the dual frequency ratio type which determines the capacitance and resistance of the circuit separately.[8] Many studies compared the ability of various generations of EALs in determining root canal length. Most of these studies showed that EALs were accurate for canal length measurement, within a clinically acceptable range of ± 0.5.[4] Some studies indicated that the most recent generation of devices had enhanced accuracy, better patient acceptance, and greater ease of use for dentists[4,14,15] but other studies mentioned that some EALs of the third generation were more accurate than those of the fourth generation.[13,17,26]

Hence, the purpose of this systematic review and meta-analysis is to compare the accuracy (O) of the third- and fifth-generation apex locators (I) with fourth-generation apex locators (C) in determining the working length in teeth undergoing endodontic treatment (P).

MATERIALS AND METHODS

This review was carried out following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and is registered with Prospero no. −CRD42021256428. The schematic pattern of the protocol is shown in Figure 1.

Eligibility criteria

Inclusion criteria

The inclusion criteria for the selection of articles were as below:

1. Studies should have a direct comparison between different generations of an EAL
2. Studies should have defined statistical analysis
3. The study should be comparative, between two or more generations of EALs for effectiveness in getting the working length
4. A comparative study of any of the generations of EAL versus/against the control group for effectiveness in checking the working length
5. The study should show the importance of the working length in the endodontic procedures
6. The publications were in English or a foreign language, with full text available in either soft or hard copy.

Exclusion criteria

The exclusion criteria for not selecting the articles were as below:

1. Lack of clear description with regard to the specifications and comparisons of a different generation of EAL
2. Noncomparative study
3. Studies not having any justified conclusion
4. Studies having conclusions with any statistical significance
5. Publications were in the form of letters, commentaries, or narratives.

Study design

All studies were screened by reading the printed title and abstract. The choice of articles for inclusion in the systematic review was created by applying the inclusion and exclusion criteria below.

The full texts of those studies were known, and reference lists contained in this were also reviewed to appear for different probably relevant articles which may be incomprehensible throughout the initial search.

Literature search

A comprehensive search was conducted on electronic databases and by manual search. Four electronic databases, PubMed, net of information, EMBASE, and SCOPUS searched with the keywords EALs, fifth generation apex locator, fourth generation apex locator, third generation apex locator, and working length determination.

Boolean operators, such as "AND, NOT, OR," were used in the following ways to get a more refined output for the search. Working length AND EALs, third generation AND fifth generation apex locator, fourth generation apex locator, AND third generation apex locator OR fifth generation. The search lined all articles printed from 1990 to July 2020. Duplicate records were removed. Another search of the four electronic databases for reports of the outcome of medical procedure passageway retreatment was conjointly performed each prospective and retrospective clinical studies printed in Chinese or English language were enclosed.

Data collection

Characteristics of included studies and qualitative data were extracted in duplicate by two reviewers using predetermined and piloted extraction forms. Piloting of the forms was performed during the protocol stage until over 90% agreement was reached. Missing or unclear information was requested by the researchers.

Data extraction

Information on authors' names, year of publications, study design, sample, inclusion criteria, groups of intervention, type of treatment, follow-up period, type of (brand name) of the third-generation, fourth-generation, and fifth-generation apex locator, and outcome assessment/working length and result was independently extracted by two reviewers [Table 1]. Data regarding the included studies was also independently extracted by the reviewers based on a previously defined

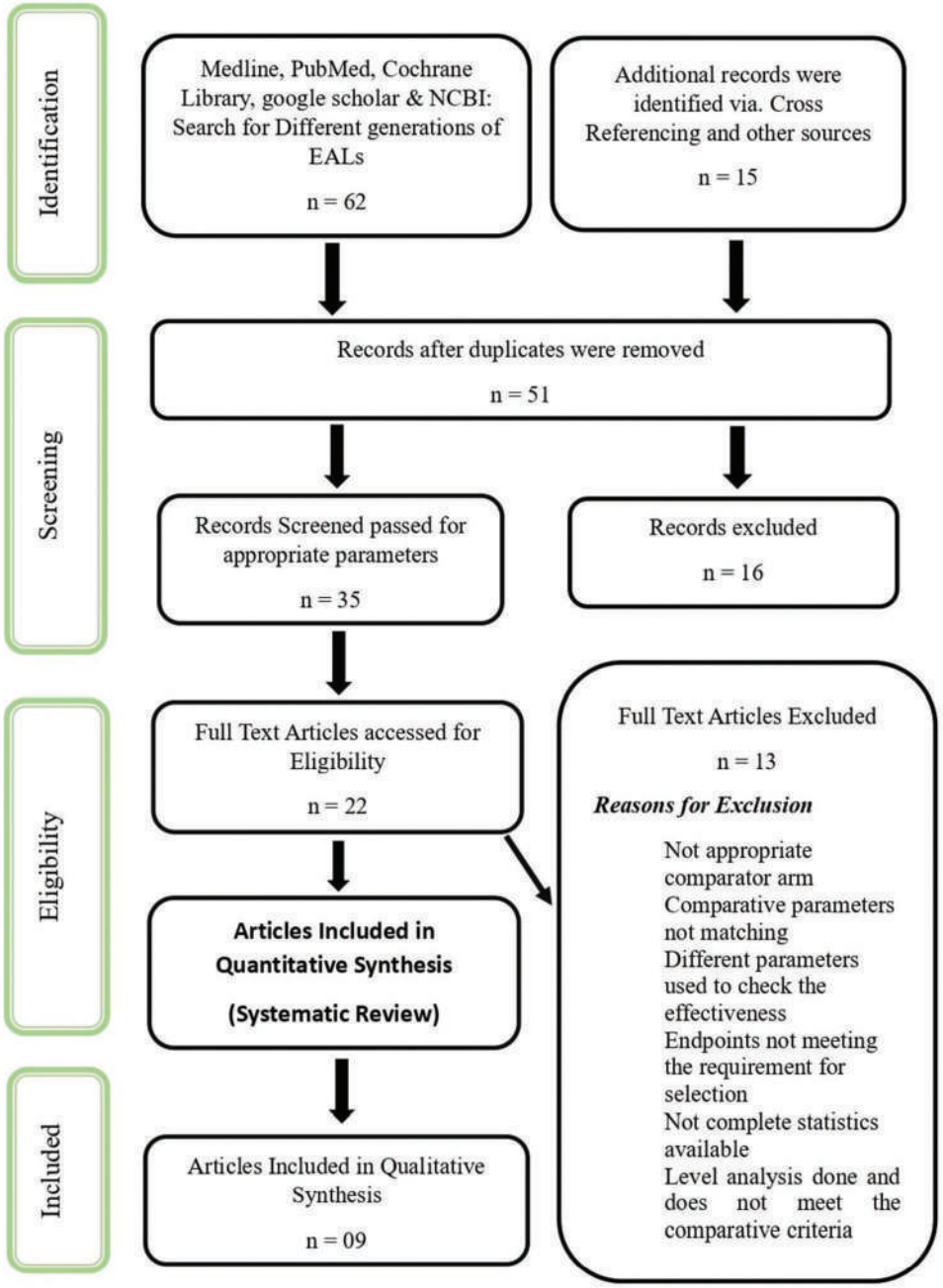

Figure 1: PRISMA flowchart

Table 1: Demographic details of included individual studies

Year of publication	Author	Sample size	Country	Type of teeth
2015	Swapna D *et al*.	31	Not specified	Single-root teeth
2018	Yolagiden M *et al*.[4]	35	Not specified	Mandibular premolars
2017	Saraf P *et al*.	90	Not specified	Multirooted teeth
2019	Kamath A *et al*.	20	Not specified	Maxillary first molars
2016	Saraswathi V *et al*.	40	Not specified	Maxillary central incisors
2011	Katia E *et al*.	40	Not specified	Premolars, canines, and incisors), with completely formed apices that were scheduled for extractions
2020	Abdelsalam N *et al*.	43	Not specified	Mandibular molars
2018	Piasecki L *et al*.[15]	54	Buffalo. New York	Mandibular molars
2017	Taneja S *et al*[14]	60	Not specified	Mandibular premolars

protocol in a specific form in the Microsoft Office Excel 2007 software (Microsoft Corporation, Redmond, WA, USA).

Risk of bias in individual studies

The risk of bias was assessed by the two independent reviews for *in vitro* studies included in the review and discrepancies were resolved by discussion and appropriate consultation with a third reviewer. The domains for risk assessment were graded as high, uncertain, or low risk, based on sample size, randomization, standardization of instrumentation, filling procedures, blinding, and statistical analysis. Thus, the overall risk for individual studies was assessed as low, medium, or high risk based on the domains and criteria. A medium-risk assessment was provided to the studies when one or more domains were found to be uncertain, with none at high risk [Table 2].

Risk of bias within studies

The risk of bias within the studies was evaluated independently by two review researchers. The studies were classified as low risk of bias, unclear, and high-risk bias. The following domains were assessed.

RESULTS

Synthesis of results

A narrative synthesis was provided for the findings obtained from the studies, mainly focusing on the intervention details (the types of apex locators – third, fourth, fifth generation), characteristics of the sample (tooth type), and outcome assessment (working length, etc.). The summaries of intervention effects for each study were provided by calculating standardized mean difference (for continuous outcomes). The heterogeneity of the previously mentioned characteristics was assessed using the Chi-square test (significance: 0.1) and I^2 statistics. If a high level of heterogeneity exists ($I^2=50\%$ or $P = 0.1$), the characteristics of the included trials were analyzed and sources of heterogeneity might be explained by subgroup analysis or sensitivity analysis. The possibility of a meta-analysis will be a chance to predict because this study includes all types of research designs, varying forms of interventions, different types of comparators, and varying characteristics of participants. However, if studies are sufficiently homogeneous in terms of design, intervention, comparator, and other characteristics, then probably further meta-analysis can be carried out.

Data analysis

After following the search strategy and application of selection criteria, 11 articles were selected for qualitative assessment. The cumulative mean difference was calculated for comparing the effectiveness of different generations of EALs. The

Table 2: Risk of bias assessment of individual studies

Study ID	Sample size calculation	Samples with similar dimensions	Teeth randomization	Standardization of instrumentation procedures	Standardization of filling procedures	Endodontic treatment performed by a single operator	Blinding of the observer	Statistical analysis carried out	Risk of bias
Swapna D *et al.*	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Medium risk
Yolagiden M *et al.*[4]	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Medium risk
Saraf P *et al.*	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Medium risk
Kamath A *et al.*	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Medium risk
Saraswathi V *et al.*	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Medium risk
Katia E *et al.*	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Medium risk
Abdelsalam N *et al.*	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Medium risk
Piasecki L *et al.* [15]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Medium risk
Taneja S *et al.* [14]	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Medium risk

heterogeneity among studies was assessed as per the values of I^2 and Cochrane Q to identify the statistical model to base applied; hence, fixed/random effect model (Mantel-Haenszel) was applied wherever indicated. Since there were five studies, publication bias was not assessed as more than five studies are required to detect funnel plot asymmetry. All the statistical analysis was performed using the Statistical Software review manager version 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark). We followed the PRISMA guidelines for the methodology. The study selection process is summarized in Figure 1. All the titles and abstracts were screened based on the stringent selection criteria. Subsequently, the full texts were assessed independently by the two reviewers. A total of nine studies over the past two decades met the inclusion criteria for full-text reading and all nine were included for further analysis.

Study characteristics

Nine articles were selected from the screening of the abovementioned number of articles by two independent reviewers. Following careful examination and discussion were conducted depending on the selection criteria by the reviewers. Any discrepancies in opinion were resolved by the third reviewer. Ultimately, nine articles were finalized for qualitative synthesis. Studies meeting the inclusion criteria underwent validity assessment and data extraction. The studies that did not meet the inclusion criteria were excluded. The data provided in the selected studies should contain and be recorded in Excel sheets under the headings: author, year of study, location, sample size, type of apex locators, outcome assessment, and author conclusions[Table 3]. The publication year of the studies varied from 2011 to 2021. The total sample size for all the included studies was 413 teeth. The tooth type when assess varied from single-rooted teeth[1,2,5,6,10] to multi-rooted teeth[3,4,8,10] in some of the studies. Most of the studies did not specify the study location discretely except one but were conducted in the department of conservative dentistry and endodontics. Two studies[1,3,4,6] were *in vivo*, one *ex vivo*,[2] and four studies[5,9-11] were *in vitro*.

When we assessed the types of apex locators a variety of different devices were used as mentioned further:

- Third generation–Root ZX,[1,9] Dentaport ZX,[3,4] I Root[3,4] Romipex,[3] Sybron endo mini,[3] Propex Pixi,[4] Mini apex locator[6]
- Fourth generation–Raypex 5[1,2,5,6] Root ZX mini[3,10,11]
- Fifth generation–Apex pointer^{+2}, Apex ID[2,10,11] Raypex[3,4,6,9] Apex NRG XFR.[5]

The outcome that we assessed was the working length accuracy of the apex locator after the placement of the intervention [Tables 1 and 2].

Meta-analysis

The meta-analysis was conducted on five studies which have data outcomes that could be used for analysis. The

Table 3: Characteristic details of included individual studies

Study design	Third generation	fourth generation	fifth generation	Outcome assessment method	Conclusion
In vivo	Root ZX	Raypex 5	-	WL	On analyzing the results of our study, it can be concluded that Raypex 5 was as effective as Root ZX in determining the minor diameter
Ex vivo	-	Raypex 5	Apex pointer + Apex ID Raypex 6	WL	All EALs showed an acceptable determination of the WL between the ranges of±0.5 mm except for the Apex pointer+device, which had the lowest accuracy Further studies may be beneficial especially to better evaluate the accuracy of the Apex pointer+
In vivo	Dentaport ZX, I Root Romipex Sybron Endo Mini	Root ZX Mini	Raypex 6	WL	The repeatability with that of apex locators is of great advantage, but the information gained from the radiographs cannot be obtained by any other means. Therefore, it is recommended that radiograph and apex locators are the best combinations in accurately determining the WL and the successful endodontics
In vivo	I Root, Dentaport ZX, Propex Pixi	-	Raypex 6	WL	The result of this study showed no significant difference among the groups, indicating they were as good as the radiographic method
In vitro	-	Raypex 5	Apex NRG XFR	WL	Neither of the two apex locators was 100% accurate in determining the WL
In vivo	Mini Apex locator	Raypex 5		WL	Under the *in vivo* conditions of this study, no statistically significant differences were observed between the Raypex 5 and the Mini Apex locator EALs
In vitro	Root ZX	-	Raypex 6	WL	Apical foramen blockage has a negative influence on the accuracy of apex locators that was more pronounced in Root ZX than Raypex 6
In vitro		Root ZX Mini	Apex ID	WL	The Root ZX Mini and CanalPro were precise for both root canal length and WL determination in mesial curved canals of mandibular molars, whereas the apex ID was accurate for the WL when using the 0.5 mark
In vitro		Root ZX Mini	Apex ID	WL	CanalPro showed highest accuracy in all conditions with accepted accuracy percentage above 90%

EALs: Electronic apex locators, WL: Working length

four studies were excluded due to the data reported that could not be analyzed (which was not in mean ± standard deviation format). The results of the forest plot are depicted in the figures. After the meta-analysis was conducted for the selected studies, the heterogeneity was analyzed based on I^2 values; hence, the fixed or random-effect model was applied.

When the working length accuracy of third generation versus fourth generation was assessed in two studies, the cumulative mean difference was −0.02 (confidence interval [CI]: −0.12, 0.08). The heterogeneity was not significant $I^2 = 41\%$, hence, we applied the fixed effects model. The mean working length accuracy shown by the fourth generation was higher than the counter group as seen in Figure 2.

The mean working length accuracy was assessed by comparing fifth generation versus fourth generation, the heterogeneity was not significant $I^2 = 16\%$, hence, we applied the fixed effects model. In three studies, the cumulative mean difference was 0.26 (CI: −0.11, 0.62). Thus, indicating the mean working length measured by the fifth generation was much accurate than the counterpart as seen in Figure 3.

DISCUSSION

This systematic review and meta-analysis were conducted following the standard protocol using the PRISMA guidelines to summarize and appraise all appreciated studies published within the past two decades with the research question to compare the effectiveness of the accuracy of different generations of EALs for the estimation of the working length targeting generation 3, generation 4, and generation 5 in patients undergoing endodontic treatment. Most of the studies had multirooted teeth as samples. Twenty-two studies were screened for eligibility and nine studies were finalized for qualitative synthesis based on the outcome data which could be analyzed. After that the meta-analysis was conducted for the five studies, the heterogeneity was analysed based on I^2 values; hence, fixed or random-effect model was applied. The results of the meta-analysis were depicted in Figures 2 and 3. The publication year varied over the past decade. Four studies were *in vitro* in study designs. The majority of the studies used Raypex 5 as fourth generation, whereas Apex ID[2,10,11] and Raypex[3,4,6,9] were the fifth-generation apex locators which were commonly used. The third-generation apex locators had a variety as mentioned in the methodology. The majority of investigations were comparative studies or evaluation studies, which did not directly compare the two techniques but, rather, performed a radiographic confirmation of the electronic method of working length determination. Different types of apex locators were used, and despite no significant difference being detected among them, they did produce inconsistent results due to the different electronic characteristics applied to each device. The majority of the studies had a medium risk of bias when we assessed the quality of included studies under different domains. The domains included were rated if the criteria were met with "Yes" and "No." None of the studies

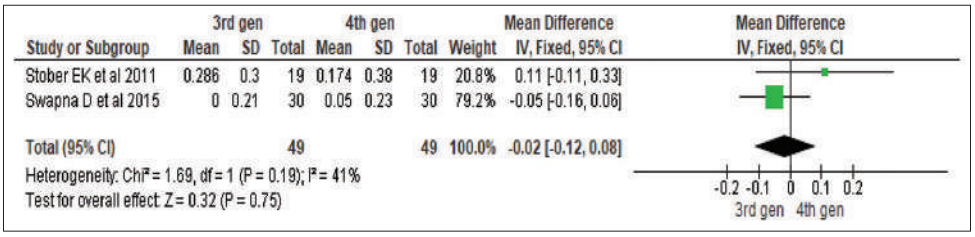

Figure 2: Forest plot 1 (Working length accuracy of fourth-generation vs. third-generation EALs). EALs: Electronic apex locators, CI: Confidence interval, SD: Standard deviation

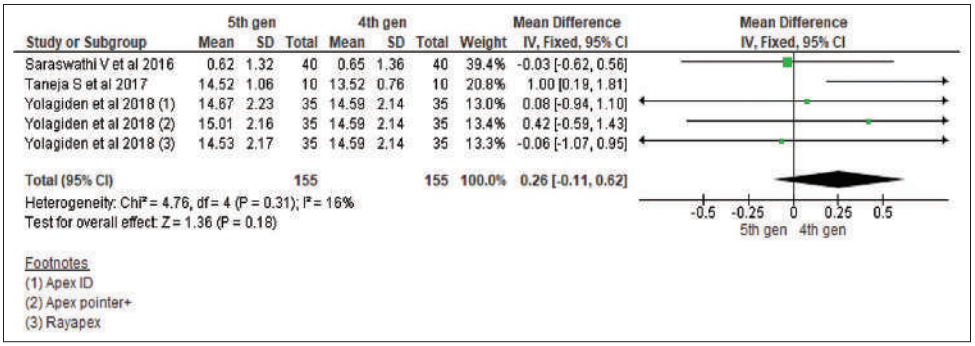

Figure 3: Forest plot 2 (Working length accuracy of fourth-generation vs. fifth-generation EALS). EALs: Electronic apex locators, CI: Confidence interval, SD: Standard deviation

had a high risk. Five studies were sufficiently homogeneous in terms of design, intervention, comparator, and other characteristics, then further meta-analysis was carried out.

A quantitative comparison was carried out between the third generation and fourth generations in which the fourth generation showed higher and better accuracy in determining the working length of the tooth under optimal clinical conditions. However, when a comparison was carried out between the fourth generation with the recent state-of-the-art fifth generation, the latter showed higher accuracy under optimal clinical conditions.

The heterogeneity was negligible; hence, we applied a fixed-effect model in both comparisons. The cumulative mean difference ranged from −0.02 to 0.26. The publication bias was not assessed due to less number of studies in each comparison. The designing and construction of the EALs by the manufacturers majorly influence the way in which the apex locator functions. The third-generation EALs use the two frequencies to measure the impedance in the canal. The disadvantage of this generation is sensitivity to canal fluid and the machine needs a fully charged battery,[12] fourth-generation EALs use a composite waveform of two signals, 0.5 and 4 kHz, the signals go through a digital to analog converter into an analog signal, which then goes through amplification and then to the patient circuit model.[13] A significant disadvantage of the fourth-generation devices is that they need to perform in relatively dry or in partially dried canals.[13] In some cases, this necessitates additional drying. Furthermore, in heavy exudates or blood it becomes inapplicable[9,14] and the fifth-generation EALs measure the capacitance and resistance of the circuit separately. It is supplied by a diagnostic table that includes statistics of the file. They have the best accuracy in any root canal condition (dry, wet, bleeding, saline, ethylenediaminetetraacetic acid [EDTA], and NaOCl).[8] These differences in operating mechanisms could impact the accuracy of the EALs under specific conditions.[13,15-17] However, studies by Hoer[27], Nekoofar[18], and Welk *et al*.[13], suggest that there is no impact of different operating mechanisms on the accuracy of the EALs. This could be attributed to the fact that most manufacturers do not define the exact nature of their devices nor how they operate electronically. Clearly, with the limited information provided by manufacturers, the classification of electronic devices used to measure canal length is a matter of controversy and ignorance.[18] Only third-generation or higher devices were included due to their better performances when compared with the first- and second-generation ones, that have previously been documented. Results of this systematic review revealed that the operating mechanisms of different generations of EALs did not influence the working length determination under ideal or optimal conditions which was in accordance with studies by Hoer[27], Nekoofar[18], and Welk *et al*.[13]. However, these findings were not found to be the same in clinical conditions such as the presence/absence of blood, pus, pulp tissue, NaOCl, and EDTA. Studies by Taneja S[14], Ebrahim[26], and Tsesis *et al*. [17] suggest that all apex locators were accurate when used with NaOCl irrigant but were less accurate in presence of blood and pulp tissue within the canal. On the contrary, Herrera *et al*. [24,25]and Tsesis *et al*. [17] demonstrated that the accuracy of apex locators is not influenced by the status of the pulp tissue (vital or necrotic).[24,25] Clinicians are most of the time challenged, when they come across situations like perforations, horizontal and vertical fractures, different apical diameters (open apex), calcified canals, curved canals, lateral and accessory canals, etc., which will pose a difficulty in determining the working length by EALs. There is controversy in the diagnosis of horizontal and vertical root fractures by EALs. Some studies have reported that EALs have the capacity to diagnose horizontal and lateral root fractures,[19,20] and other studies have indicated that horizontal fractures and perforation sites can be better diagnosed by EALs than vertical fractures. Few studies have investigated the ability of apex locators to detect root fractures and perforations.[21,22] Due to limited information on this subject, a general conclusion could not be achieved. More studies are required to quantify. The diameter of apical foramen may also influence the accuracy of EALs.[23-25] Studies by Herrera *et al*.[24,25], evaluated the performance of EALs in teeth with different apical diameters and found that the accuracy of apex locators reduced significantly with increasing apical diameter. Correlational analysis revealed that the presence of accessory canals and isthmuses in the apical region did not interfere with the precision of the different EALs. This could be due to the fact that it may be blocked by debris and/or organic tissues, thus preventing electrical communication that could interfere with the accuracy of the EALs.[16] Of the anatomic parameters evaluated, the presence of a lateral foramen negatively affected the accuracy of the EALs.[15] Other factors such as gender, age, type of tooth, or moisture seemed to have no influence on the working length determination by different EALs.

Drawback-One of the recommendations for future studies and a limitation of our study was that major randomized control trials were not a part of this review due to lack of availability.

Future scope-Under optimal clinical conditions, fifth-generation apex locators have better accuracy but the differences in Working length (WL) measurement between different generations of EALs are still unclear.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Renner D, Grazziotin-Soares R, Gavini G, Barletta FB. Influence of pulp condition on the accuracy of an electronic foramen locator in posterior teeth: An *in vivo* study. Braz Oral Res 2012;26:106-11.
2. Coolidge ED. Past and present concepts in endodontics. J Am Dent Assoc 1960;61:676-88.
3. Cruse WP, Bellizzi R. A historic review of endodontics, 1689-1963, part 2. J Endod 1980;6:532-5.
4. Yolagiden M, Ersahan S, Suyun G, Bilgec E, Aydin C. Comparison of four electronic apex locators in detecting working length: An *ex vivo* study. J Contemp Dent Pract 2018;19:1427-33.
5. Shanmugaraj M, Nivedha R, Mathan R, Balagopal S. Evaluation of working length determination methods: An *in vivo*/*ex vivo* study. Indian J Dent Res 2007;18:60-2.
6. Pratten DH, McDonald NJ. Comparison of radiographic and electronic working lengths. J Endod 1996;22:173-6.
7. Gordon MP, Chandler NP. Electronic apex locators. Int Endod J 2004;37:425-37.
8. Khadse A, Shenoi PR, Kokane V, Khode R, Sonarkar S, *et al.* Electronic apex locators-an overview. IP Indian Journal of Conservative and Endodontics; 2:35-40.
9. Stein TJ, Corcoran JF, Zillich RM. Influence of the major and minor foramen diameters on apical electronic probe measurements. J Endod 1990;16:520-2.
10. Green D. Stereomicroscopic study of 700 root apices of maxillary and mandibular posterior teeth. Oral Surg Oral Med Oral Pathol 1960;13:728-33.
11. ElAyouti A, Weiger R, Löst C. Frequency of overinstrumentation with an acceptable radiographic working length. J Endod 2001;27:49-52.
12. Kobayashi C, Suda H. New electronic canal measuring device based on the ratio method. J Endod 1994;20:111-4.
13. Welk AR, Baumgartner JC, Marshall JG. An *in vivo* comparison of two frequency-based electronic apex locators. J Endod 2003;29:497-500.
14. Taneja S, Kumar M, Sharma SS, Gogia H. Comparative evaluation of accuracy of three electronic apex locators in different simulated clinical conditions- an *in vitro* study. Ann Med Health Sci Res 2017;7:190-4.
15. Piasecki L, José Dos Reis P, Jussiani EI, Andrello AC. A micro-computed tomographic evaluation of the accuracy of 3 electronic apex locators in curved canals of mandibular molars. J Endod 2018;44:1872-7.
16. de Vasconcelos BC, Veríssimo Chaves RD, Vivacqua-Gomes N, Candeiro GT, Bernardes RA, Vivan RR, *et al. Ex vivo* evaluation of the accuracy of electronic foramen locators in root canals with an obstructed apical foramen. J Endod 2015;41:1551-4.
17. Tsesis I, Blazer T, Ben-Izhack G, Taschieri S, Del Fabbro M, Corbella S, *et al.* The precision of electronic apex locators in working length determination: A systematic review and meta-analysis of the literature. J Endod 2015;41:1818-23.
18. Nekoofar MH, Ghandi MM, Hayes SJ, Dummer PM. The fundamental operating principles of electronic root canal length measurement devices. Int Endod J 2006;39:595-609.
19. Goldberg F, Frajlich S, Kuttler S, Manzur E, Briseño-Marroquín B. The evaluation of four electronic apex locators in teeth with simulated horizontal oblique root fractures. J Endod 2008;34:1497-9.
20. Uzun O, Topuz O, Tinaz C, Nekoofar MH, Dummer PM. Accuracy of two root canal length measurement devices integrated into rotary endodontic motors when removing gutta-percha from root-filled teeth. Int Endod J 2008;41:725-32.
21. Ebrahim AK, Wadachi R, Suda H. Accuracy of three different electronic apex locators in detecting simulated horizontal and vertical root fractures. Aust Endod J 2006;32:64-9.
22. Azabal M, Garcia-Otero D, de la Macorra JC. Accuracy of the Justy II apex locator in determining working length in simulated horizontal and vertical fractures. Int Endod J 2004;37:174-7.
23. Saito T, Yamashita Y. Electronic determination of root canal length by newly developed measuring device. Influences of the diameter of apical foramen, the size of K-file and the root canal irrigants. Dent Jpn (Tokyo) 1990;27:65-72.
24. Herrera M, Ábalos C, Lucena C, Jiménez-Planas A, Llamas R. Critical diameter of apical foramen and of file size using the Root ZX apex locator: An *in vitro* study. J Endod 2011;37:1306-9.
25. Herrera M, Abalos C, Planas AJ, Llamas R. Influence of apical constriction diameter on Root ZX apex locator precision. J Endod 2007;33:995-8.
26. Ebrahim AK, Wadachi R, Suda H. *Ex vivo* evaluation of the ability of four different electronic apex locators to determine the working length in teeth with various foramen diameters. Aust Dent J 2006;51:258-62.
27. Hoer D, Attin T. The accuracy of electronic working length determination. Int Endod J 2004;37:125-31.

Review Article

Oral Cysticercosis: Importance of Early Diagnosis and Prevention

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Abstract

Cysticercosis is a result of parasitic infestation by *Cysticercus cellulosae*, the larval stage of the pork tapeworm, *Taenia solium*. Cysticercosis affects various organs including oral cavity and an accurate clinical diagnosis in oral cysticercosis is usually not established. English literature was reviewed and analyzed on oral cysticercosis from the year 1980 to December 2021 as found through standard electronic databases (PubMed, MEDLINE, and Scopus) using search words as cysticercosis; oral cysticercosis; neurocysticercosis; *C. cellulosae*; *T. solium*; treatment of cysticercosis; and prevention of cysticercosis. Forty cases of oral cysticercosis from 13 publications were analyzed. Cysticercosis can cause oral cystic swelling or nodules and these may be the only evidence of the disease. Tongue was the most affected site. It can lodge at multiple sites including brain and eyes where it can cause serious complications. Two cases of oral cysticercosis were reported to be having the involvement of the brain. This review emphasizes the importance of early diagnosis and prevention of oral cysticercosis which can have more serious systemic involvement. It is important to rule out the presence of the parasite in the brain or eyes through thorough investigations so as to avoid serious complications.

Keywords: Cysticercosis, *Cysticercus cellulosae*, neurocysticercosis, oral cysticercosis, *Taenia solium*, taeniasis

Introduction

Cysticercosis, the most common parasitic disease worldwide, results from infestation by the larvae of *Taenia solium*, *Cysticercus cellulosae*. It can lodge in various organs and tissues of the human body. Although it is endemic in developing countries,[1,2] its increasing incidence has also been reported in the Western countries with a prevalence of more than 50 million people affected worldwide.[3] Involvement of central nervous system by the parasite (neurocysticercosis) can turn fatal.[4] It may cause cystic swelling or nodules in oral cavity which may be the only evidence of the disease. Oral clinician can diagnose it early when cysticercosis involves oral cavity and can prevent its more serious systemic involvement. This review aims at discussing the natural history, etiopathogenesis, clinical course, and management of *T. solium* along with the importance of establishing the early and correct diagnosis of oral cysticercosis.

Received: 23-01-2023 **Revised:** 24-04-2023
Accepted: 27-04-2023 **Published:** 06-09-2023

Access this article online

Quick Response Code:

Website: http://www.jmau.org/

DOI: 10.4103/jmau.jmau_8_23

Methods

We have reviewed and analyzed the case reports, case series, and reviews on oral cysticercosis as found through standard electronic databases (PubMed, MEDLINE, and Scopus) and cross-references from the year 1980 to December 2021. The search was carried out using the keywords cysitcercosis; oral cysticercosis; neurocysticercosis; *C. cellulosae*; *T. solium*; treatment of cysticercosis; and prevention of cysticercosis. Articles contributing new dimension to diagnosis, treatment, and prevention of oral cysticercosis were included in the review and analyzed. Case reports of oral cysticercosis with the involvement of brain were also reviewed. Forty cases of oral cysticercosis from 13 publications were analyzed. This

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How to cite this article: Choudhari S, Dekate K, Deshpande SM, Dhumal S. Oral cysticercosis: Importance of early diagnosis and prevention. J Microsc Ultrastruct 0;0:0.

review discusses the natural history, etiopathogenesis, clinical course, and management of *T. solium* along with the importance of establishing the correct diagnosis of cysticercosis.

Review Results

The parasite and the disease

T. solium is an intestinal parasite which belongs to Phylum Platyhelminthes, class Cestoda, and order Cyclophyllidea. Its larval form is *C. cellulosae* which causes cysticercosis. Platyhelminthes exist in three phases: larval stage, adult worm, and an egg phase. Different hosts are required for these. For adult *T. solium*, humans serve as the natural definitive host, whereas for the larval form, pigs and human beings may act as an intermediate host. Infestation by adult tapeworm is taeniasis, whereas cysticercosis is caused by its larval form.[5] These forms of infection are distinct disease processes which have different treatment outcomes and prognosis.

The tapeworm has head, i.e., scolex, neck and caudal end, and proglottids. Scolex is globular in shape and has four suckers and rostellum arm with double row of hooklets. 40,000–60,000 eggs are contained in each proglottid. Larval forms are usually harbored by pigs; however, dogs, cats, and sheep may also serve as an intermediate host.[6] Adult *T. solium* inhabits human's small intestine. From the distal end of the worm, gravid proglottids are detached and passed with the feces, releasing 1000 of fertile eggs to the environment. Pigs may consume these through contaminated human feces and the life cycle of *T. solium* begins. Eggs then develop into larvae and from intestine larvae enter the bloodstream reaching various tissues and developing into cysts.[7] Humans when ingest undercooked and infected pork with *T. solium* cysts, the larvae grow into adult tapeworms in human intestine and thus humans develop taeniasis (human tapeworm infection). Human cysticercosis results from ingestion of eggs of *T. solium* through fecally contaminated vegetables, food, or water [Figure 1]. Reflux of the proglottid from the intestine into the stomach can release *T. solium* eggs in the gut which can result in cysticercosis. Thus, man becomes the intermediate host and human cysticercosis develops from larval form of the parasite.[8,9] Eggs develop into embryos which invade the intestinal wall and through bloodstream can reach various tissues.[1,10] In these tissues' embryos develop into larvae and become cysticerci or "bladder worm," a fluid-filled cyst.[11,12] Cysticerci encyst at various sites, most commonly subcutaneous tissue; striated muscles, brain, and ocular tissue.[7,13-15]

It takes 2–4 months to develop into cysticerci. The presence of parasite results in infiltration of neutrophils and eosinophils into surrounding tissues.[5] Cysticerci can remain latent for a period of 3–5 years. They may remain alive for years or degenerate and calcify. Colloidal stage is the first stage of involution of cysticerci, in which scolex undergoes hyaline degeneration. Next stage is the granular stage, the scolex gets converted into coarse mineralized granules, and the cyst wall thickens. At this stage, cysticercus is no longer viable.[16,17] After this, there is the development of granulomatous reaction which is followed by calcification. Duration of these stages depends on the host immune response.

Immune response of the host

The encystment of the larvae elicits a low initial host response. This phase is often asymptomatic. This phase may last for years. Clinical manifestations depend on cyst location and size. Clinically evident disease is actually produced by the host response evoked by the larval antigens released by degenerating cysts. This causes the release of inflammatory mediators and edema of the surrounding tissue. The encysted larvae generally die after the acute inflammatory phase, completing the degeneration phase, and often calcify.[18]

Clinical features

As per the review, cysticercosis was found to be common in parts of Africa and Asia, Mexico, and Central and South America. It commonly affects cerebral and subcutaneous tissues, skeletal muscle, eye, liver, lungs, and heart.[11,14,19] Clinical manifestation of the disease is usually due to functional disturbance of the infected tissue and inflammatory host response. Superficial lesions are readily detectable, but deep lesions remain undiagnosed unless and until clinical manifestations develop. Clinical effects depend on the organ or the tissue involved, host reaction, and larval burden.[5] Taeniasis being an intestinal infestation by the parasite presents usually abdominal discomfort, nausea, weight loss, and diarrhea. Headache, fever, and myalgia are the general symptoms. The involvement of brain and eyes is the most serious.[19,20] Neurocysticercosis is the most common helmenthic infection of the brain worldwide.[21] It is associated with substantial morbidity. Most frequent signs and symptoms of neurocysticercosis are meningitis, seizures, obstructive hydrocephalus, increased intracranial pressure, and mental disorders.[22,23] Paraesthesia or pain of lower extremity results from cysts in the spinal column.[13,18] In our review of forty cases of oral cysticercosis, two cases were reported to be having involvement of brain. Neurocysticercosis may be a risk factor for the induction of certain cancers.[24-26] Epidemiological studies have suggested an association between neurocysticercosis and occurrence of certain central nervous system tumors and hematological malignancies. Cerebral gliomas, astrocytomas, oligodendrogliomas, and multiple myeloma and leukemia are reported in patients with neurocysticercosis.[26-29] Immune suppression and chronic inflammation caused by cysticercosis and DNA damage, resulting from transfer of genetic material from parasite to the host are possible mechanisms playing role in tumorogenesis in patients with neurocysticercosis.[24,25] Eye involvement by cysticercosis can result in visual disturbances, proptosis, or loss of vision.[7] Cysticerci when involve muscles can cause myositis with fever, eosinophilia, and muscular pseudohypertrophy, which can later progress to atrophy and fibrosis. The involvement of subcutaneous tissues by cysticerci presents as firm, mobile nodules which are usually painless.[14]

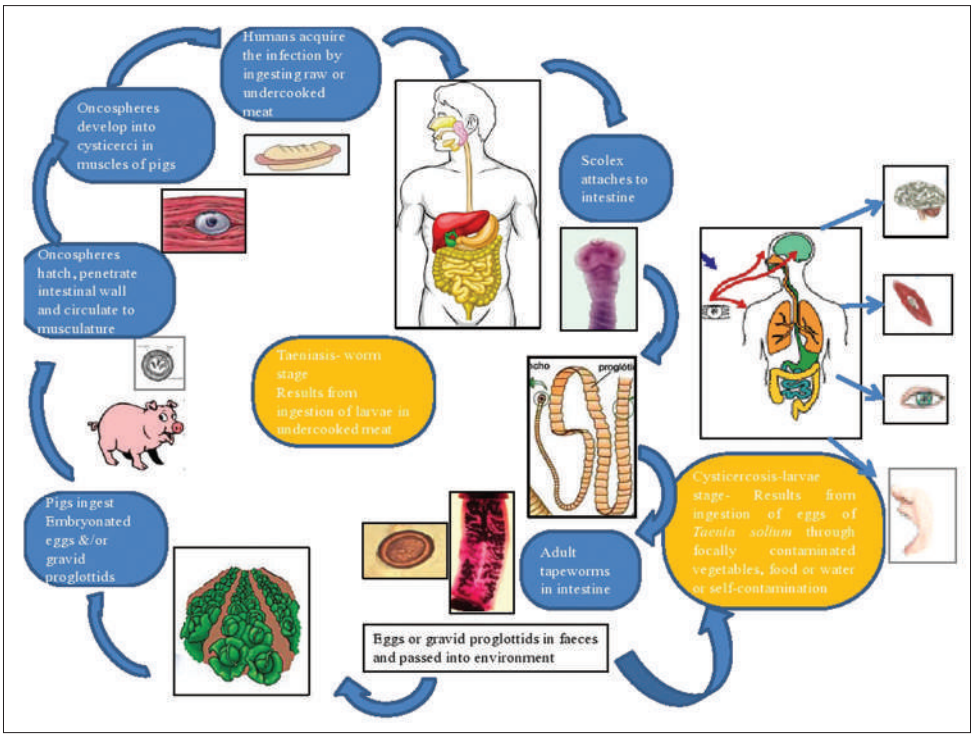

Figure 1: Taeniasis and cysticercosis: Pathogenesis

Oral cysticercosis

The involvement of oral cavity by cysticerci results in painless nodular swelling of the oral mucosa, and dentist may be the first person to diagnose it. The prevalence of 3.5% has been reported for oral cysticercosis.[5] Oral sites involved by cysticercosis are tongue, buccal mucosa, lips, floor of mouth, gingiva, soft palate, and tongue.[5,30-33] As per our review, tongue was found to be most commonly involved site. High muscular activity and metabolic rate of these muscles and high vascularity of tongue may explain its frequent involvement by cysticerci. Involvement of tongue can cause interference with tongue movement, resulting in discomfort during speaking and eating. Perioral sites include subcutaneous tissues of submental and submandibular region and neck midline.[5,34] Usually, patients with cysticerci present as painless swelling. However, secondary infection can result in pain.[35] Thus, cysticercosis should be considered in the differential diagnosis while examining solitary lesions in any patient from an endemic area.

Systemic involvement in patients with oral cysticercosis

Cysticercosis involves the brain, lungs, liver, heart and skeletal muscles, and subcutaneous tissues.[36] The patient with oral cysticercosis should be investigated to rule out systemic involvement. Oral cysticercosis has been reported with serious involvement of brain and eye.[37,38] Cysticercosis is a potentially fatal parasitic disease when involving the central nervous system (neurocysticercosis). In patients with oral cysticercosis, multiple foci of the presence of larval infestations at various sites have been reported.[37,39] In a series of 450 cases reported by Dixon and Lipscomb *et al*., in 1961, eight cases were reported to have foci in brain and with subcuticular nodules.[37] Cases of oral cysticercosis have been reported with multiple subcutaneous nodules in trunk, limbs, and face.[38,39]

Cysticercosis has also been associated with neoplastic tumors of brain and other systems.[24,26] The associated carcinogenic mechanisms discussed are chronic inflammation, genetic alterations, and change/modulation of host response associated with the parasitic infection. However, there is a scarce literature on oral cysticercosis with the occurrence of cancer.

Diagnosis

For diagnosing cysticercosis, radiologic imaging and laboratory tests can be used, but the final diagnosis can only be confirmed by histological examination. Plain film radiography may help in the diagnosis of soft-tissue involvement by revealing multiple calcified "puffed-rice" lesions.[6] However, as compared to radiographic examination, other imaging modalities such as ultrasonography, computerized tomography, and magnetic resonance imaging (MRI) are more effective in diagnosis.[40] MRI is very useful in detecting brain and spinal cord lesions. Imaging is also helpful for the detection of orbital involvement.

Serological tests such as enzyme-linked immunosorbent assay (ELISA), enzyme-linked immunoelectrotransfer blot (EITB) (western blot or immunoblot), and lentil lectin glycoprotein (LLGP)-EITB can be done for immunodetection of cysticercosis using sera, cerebrospinal fluid, and saliva. Although ELISA can give results with good sensitivity and specificity, but is not 100% sensitive.[41] Serological tests can detect antigens present in secretary products of live cysts or antigens related to viable cysticerci or adult tapeworms. Tests

for serum antibodies to the parasite are useful particularly for follow-up but are less effective for detection as people from an endemic area can have antibodies due to exposure and not due to established infections.[42] LLGP-EITB, which is an antibody detection test, is the test of choice for the clinical diagnosis of cysticercosis, whereas tests based on antigen detection such as ELISA-HP10 and B158/B60-ELISA are useful for follow-up of cases after treatment.[43,44] Eosinophilia, raised immunoglobulin E are also laboratory findings in patients with cysticercosis.[12]

Fine-needle aspiration cytology (FNAC) may be of help to the clinician in treatment planning by providing fast preoperative diagnosis in case of solitary nodule or swelling.[45,46] On FNAC, speck of pearly white material can be identified which microscopically shows larval fragments in an inflammatory background.[12,45] Cytological smears can be stained with Giemsa and Ziehl Neelsen (Z-N) stain. With Z-N stain, the parasite is found to be acid-fast.[47] Confirmative diagnosis of cysticercosis is provided by histopathological examination. On gross examination, cysticercosis appears as a well-encapsulated mass. Microscopically, a dense fibrous capsule surrounding a cystic cavity containing *C. cellulosae* is seen. Fibrous capsule shows double-layered membrane with an outer acellular, hyaline eosinophilic layer, and an inner layer with few cells. *T. solium* larvae are seen within the membrane. After the death of the larvae, cyst undergoes calcification. Concentric layers of dystrophic calcifications are seen in the capsule. A dense aggregate of eosinophils and leukocytes with the infiltration of lymphocytes, plasma cells, and histiocytes at the periphery is seen in the fibrous capsule surrounding the larvae.[45,48] Histological differential diagnosis for *C. cellulosae* includes Cysticercus bovis which can be differentiated by the scolex. In former, the scolex is globular and it has a double crown of rostellar hooklets, while in latter, the scolex is quadrangular and no rostum is found.

Histopathologic demonstration of the parasite or demonstrations of cystic lesion with scolex on MRI or computed tomography is the proposed absolute criteria for the diagnosis of cysticercosis. While the demonstration of positive cysticercal antibodies on serum enzyme-linked immunoblot or demonstration of anticysticercal antibodies or cysticercal antigens on ELISA have been proposed as diagnostic criteria for cysticercosis. However, improved, simple, cost-effective, and rapid diagnostic tests are required to detect *T. solium* carriers. DNA-based molecular diagnostics such as polymerase chain reaction (PCR) have been developed to detect parasites in fecal samples. PCR assays were reported to have 100% sensitivity in detection of Taeniasis.[49] However, these assays are expensive. Loop-mediated isothermal amplification assay has proved to be an easy, cost-effective, highly sensitive, and specific method for the detection of *T. solium* carriers,[50] but it needs validation on larger sample.

Management

The management of cysticercosis can involve surgery, chemotherapy, and supportive medical treatment. Number, size, and location of cysts affect the treatment. For lesion presenting as accessory symptomatic solitary cyst, simple surgical removal with periodic follow-ups is sufficient.[6,8,9,12,32,51] However, treatment of multifocal involvement by cysticerci and neurocysticercosis is difficult, controversial, and depends on clinical presentation. Management of cases with multifocal involvement depends on the number, location, and site of involvement, stage of the disease, and extent of host inflammatory response. The treatment involves antiparasitic drugs such as albendazole and praziquantel along with corticosteroids to control inflammation. The management of different forms of parenchymal neurocysticercosis involves treatment with antiparasitic drugs with corticosteroids and antiepileptic drugs. Extraparenchymal neurocysticercosis is treated surgically wherever possible with adjuvant antiparasitic and anti-inflammatory therapy.[32] Ocular, spinal lesions and lesions within ventricles are best treated by surgical resection.

Oral cysticercosis is best managed with surgical enucleation.[51,52] In cases of disseminated cysticercosis, patients who are symptomatic, and when surgery is not possible, anithelmenthic drugs are advised.

Risk Factors and Prevention

Risk factors for human taeniasis

Consumption of undercooked meat containing viable cysticerci.

Risk factors for human cysticercosis/neurocysticercosis

Poor personal hygiene may lead to self-infection, contamination of food, water, and household things. Even direct infection to another person is possible.

Prevention

Culture, religion, socioeconomic status, and level of education should be taken into consideration while adopting strategies for preventing tenasis and cysticercosis. Preventive efforts should be targeted to reduce pork tapeworm carriers, resulting in reduction of *T. solium* egg shedding. Adequate cooking of pork, effective fecal disposal, maintaining good personal hygiene, treatment and prevention of human intestinal infections so as to reduce the exposure to fecally derived eggs can prove very effective in controlling the infection. Stringent policies for quality control of beef and pork in slaughterhouses and markets are required. Improvement in sanitation and improved pig husbandry is also one of the useful preventive measures. Developing a vaccine against *T. solium* seems to be promising interventional measure but potential utility of it needs to be found out. Recently, a recombinant vaccine antigen, TSOL18 is developed which is found to be effective at reducing infection of pigs with *T. solium*.[53] This will ultimately help to reduce human cysticercosis. However, more research is required to improve the methods for preparing vaccine and also more field trials are required to prove their efficacy.

Conclusion

Diagnosis of oral cysticercosis remains clinically unsuspected in most of the cases due to nonspecific clinical presentation. Cysticercosis should be considered in the differential diagnosis while examining solitary nodular swelling in the oral cavity in patients from an endemic region. Cysticercosis is caused by ingesting food, vegetables, or water contaminated by *T. solium* eggs or through self-contamination. This parasitic disease is potentially eradicable by developing and adopting preventive strategies aimed at reducing the exposure to fecally derived eggs. Preventable measures include maintaining improved sanitation, good personal hygiene, adequate pork cooking, and adopting stringent pork inspection strategies. More efforts should be directed to develop large-scale production of the vaccine against *T. solium* and more field trials should be undertaken to test the efficacy of the vaccine so as to eradicate this disease.

Clinical significance

Oral clinician may play a significant role in the early detection of this parasitic entity, which can have more serious systemic involvement. Cysticercosis is fatal when it involves the central nervous system. The patient with cysticercosis of oral cavity should be investigated further to rule out serious involvement of brain, spinal cord, and eyes.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Garcia HH, Del Brutto OH. *Taenia solium* cysticercosis. Infect Dis Clin North Am 2000;14:97-119, ix.
2. Sawhney IM, Singh G, Lekhra OP, Mathuriya SN, Parihar PS, Prabhakar S. Uncommon presentations of neurocysticercosis. J Neurol Sci 1998;154:94-100.
3. Hawk MW, Shahlaie K, Kim KD, Theis JH. Neurocysticercosis: A review. Surg Neurol 2005;63:123-32.
4. Ong S, Talan DA, Moran GJ, Mower W, Newdow M, Tsang VC, *et al.* Neurocysticercosis in radiographically imaged seizure patients in U.S. Emergency departments. Emerg Infect Dis 2002;8:608-13.
5. Gadbail AR, Korde S, Wadhwan V, Chaudhary M, Patil S. Oral cysticercosis: Report of two cases with review of literature. Oral Surg 2010;3:51-6.
6. Meher R, Sabherwal A. Cysticercosis of the cheek. Intern J Trop Med 2005;2:1540-2681.
7. García HH, Gonzalez AE, Evans CA, Gilman RH, Cysticercosis Working Group in Peru. *Taenia solium* cysticercosis. Lancet 2003;362:547-56.
8. Saran RK, Rattan V, Rajwanshi A, Nijkawan R, Gupta SK. Cysticercosis of the oral cavity: Report of five cases and a review of literature. Int J Paediatr Dent 1998;8:273-8.
9. Pandey SC, Pandey SD. Lingual cysticercosis. Indian J Plast Surg 2005;38:160-1.
10. Castillo M. Imaging of neurocysticercosis. Semin Roentgenol 2004;39:465-73.
11. Romero de Leon E, Aguirre A. Oral cysticercosis. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1995;79:572-7.
12. Delgado-Azañero WA, Mosqueda-Taylor A, Carlos-Bregni R, Del Muro-Delgado R, Díaz-Franco MA, Contreras-Vidaurre E. Oral cysticercosis: A collaborative study of 16 cases. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;103:528-33.
13. Singhi P, Singhi S. Neurocysticercosis in children. J Child Neurol 2004;19:482-92.
14. Wortman PD. Subcutaneous cysticercosis. J Am Acad Dermatol 1991;25:409-14.
15. Strickland GT. Hunter's Tropical Medicine. 6th ed. Philadelphia: W.B. Saunders Co.; 1984. p. 783-6.
16. Rabiela MT, Rivas A, Flisser A. Morphological types of *Taenia solium* cysticerci. Parasitol Today 1989;5:357-9.
17. Sotelo J, Del Brutto OH. Brain cysticercosis. Arch Med Res 2000;31:3-14.
18. Kraft R. Cysticercosis: An emerging parasitic disease. Am Fam Physician 2007;76:91-6.
19. Flisser A, Plancarte A, Correa D, Rodriguez-Del-Rosal E, Feldman M, Sandoval M, *et al.* New approaches in the diagnosis of *Taenia solium* cysticercosis and taeniasis. Ann Parasitol Hum Comp 1990;65 Suppl 1:95-8.
20. Indira C, Ramesh V, Misra RS. Association of oral cysticercosis and post kala azar dermal leishmaniasis. Int J Oral Maxillofac Surg 1990;19:266-7.
21. García HH, Evans CA, Nash TE, Takayanagui OM, White AC Jr., Botero D, *et al.* Current consensus guidelines for treatment of neurocysticercosis. Clin Microbiol Rev 2002;15:747-56.
22. Lustmann J, Copelyn M. Oral cysticercosis. Review of the literature and report of 2 cases. Int J Oral Surg 1981;10:371-5.
23. Webb DJ, Seidel J, Correll RW. Multiple nodules on the tongue of a patient with seizures. J Am Dent Assoc 1986;112:701-2.
24. Khurana S, Dubey ML, Malla N. Association of parasitic infections and cancers. Indian J Med Microbiol 2005;23:74-9.
25. Del Brutto OH, Dolezal M, Castillo PR, García HH. Neurocysticercosis and oncogenesis. Arch Med Res 2000;31:151-5.
26. Herrera LA, Benita-Bordes A, Sotelo J, Chávez L, Olvera J, Rascón A, *et al.* Possible relationship between neurocysticercosis and hematological malignancies. Arch Med Res 1999;30:154-8.
27. Del Brutto OH, Castillo PR, Mena IX, Freire AX. Neurocysticercosis among patients with cerebral gliomas. Arch Neurol 1997;54:1125-8.
28. Herrera LA, Ramirez T, Rodríguez U, Corona T, Sotelo J, Lorenzo M, *et al.* Possible association between *Taenia solium* cysticercosis and cancer: Increased frequency of DNA damage in peripheral lymphocytes from neurocysticercosis patients. Trans R Soc Trop Med Hyg 2000;94:61-5.
29. Cavellani CL, da Silva AC, Ribeiro GK, Oliveira LF, Ferraz ML, Teixeira Vde P. Association between cysticercosis and neoplasia: A study based on autopsy findings. ScientificWorldJournal 2013;2013:895942.
30. Sharma AK, Misra RS, Mukherjee A, Ramesh V, Jain RK. Oral cysticercosis. Int J Oral Maxillofac Surg 1986;15:349-51.
31. Sah K, Grover N, Chandra S, Gulia S. Oral cysticercosis in a vegetarian female: A diagnostic dilemma. J Oral Maxillofac Pathol 2019;23:289-91.
32. Manikandan G, James V, Chandrasekaran C, Varghese SC. An atypical case of cutaneous cysticercosis in buccal mucosa. J Oral Maxillofac Pathol 2020;24:591.
33. Sethi G, Kaur D, Arora N, Sethi D. Lingual cysticercosis: A case series with review of literature. Indian J Otolaryngol Head Neck Surg 2021;73:116-9.
34. de Souza PE, Barreto DC, Fonseca LM, de Paula AM, Silva EC, Gomez RS. Cysticercosis of the oral cavity: Report of seven cases. Oral Dis 2000;6:253-5.
35. Mishra YC, Nadkarni N. Oro-facial cysticercosis. Ann Dent 1988;47:23-5.
36. Cysticercosis Biology. Centre for Disease Control and Prevention. Available from: https://www.cdc.gov/parasites/cysticercosis/biology.html. [Last accessed on 2023 Apr 23].
37. Dixon HB, Lipscomb FM. Cysticercosis: An Analysis and Follow-Up of 450 Cases. Privy Council, Medical Research Council Special Report Series No. 299. London: Her Majesty's Stationary Office; 1961.
38. Timoşca G, Gavriliţă L. Cysticercosis of the maxillofacial region. A clinicopathologic study of five cases. Oral Surg Oral Med Oral Pathol 1974;37:390-400.
39. Bedi TR, Pandhi RK, Bhutani LK. A case of cysticercosis cellulosae involving the oral cavity. Int J Dermatol 1974;13:188-9.
40. Richards F Jr., Schantz PM. Laboratory diagnosis of cysticercosis. Clin Lab Med 1991;11:1011-28.

41. Jay A, Dhanda J, Chiodini PL, Woodrow CJ, Farthing PM, Evans J, *et al.* Oral cysticercosis. Br J Oral Maxillofac Surg 2007;45:331-4.
42. Garcia HH, Harrison LJ, Parkhouse RM, Montenegro T, Martinez SM, Tsang VC, *et al.* A specific antigen-detection ELISA for the diagnosis of human neurocysticercosis. The cysticercosis working group in Peru. Trans R Soc Trop Med Hyg 1998;92:411-4.
43. Rodriguez S, Wilkins P, Dorny P. Immunological and molecular diagnosis of cysticercosis. Pathog Glob Health 2012;106:286-98.
44. Garcia HH, O'Neal SE, Noh J, Handali S, For the cysticercosis working group in Peru. 2018. Laboratory diagnosis of neurocysticercosis (*Taenia solium*). J Clin Microbiol 2018;56:e00424-18.
45. Shear M, Speight PM. Parasitic cysts. In: Shear M, Speight PM, editors. Cysts of the Oral and Maxillofacial Regions. 4th ed. Singapore: Blackwell Munksgaard; 2007. p. 192-5.
46. Mazhari NJ, Kumar N, Jain S. Cysticercosis of the oral mucosa: Aspiration cytologic diagnosis. J Oral Pathol Med 2001;30:187-9.
47. Kala P, Khare P. Fine-needle aspiration cytology as a diagnostic modality for cysticercosis: A clinicocytological study of 137 cases. J Cytol 2014;31:68-72.
48. Elias FM, Martins MT, Foronda R, Jorge WA, Araújo NS. Oral cysticercosis: Case report and review of the literature. Rev Inst Med Trop Sao Paulo 2005;47:95-8.
49. Mayta H, Gilman RH, Prendergast E, Castillo JP, Tinoco YO, Garcia HH, *et al.* Nested PCR for specific diagnosis of *Taenia solium* taeniasis. J Clin Microbiol 2008;46:286-9.
50. Nkouawa A, Sako Y, Nakao M, Nakaya K, Ito A. Loop-mediated isothermal amplification method for differentiation and rapid detection of *Taenia* species. J Clin Microbiol 2009;47:168-74.
51. Ribeiro AC, Luvizotto MC, Soubhia AM, de Castro AL. Oral cysticercosis: Case report. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;104:e56-8.
52. Singh A, Gautam P, Handa AC, Handa KK. Oral cysticercosis: A case series and review of literature. J Oral Maxillofac Surg 2018;76:2572-6.
53. Gauci C, Jayashi C, Lightowlers MW. Vaccine development against the *Taenia solium* parasite: The role of recombinant protein expression in *Escherichia coli*. Bioengineered 2013;4:343-7.

ISSN 2993-5407

Case Report

Translational Medicine : Open Access

Riga-Fede Syndrome : A Rare Case Report With Literature Review

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Submitted: 2023 July 25; **Accepted:** 2023 Aug 26; **Published:** 2023 Sep 15

Citation: Nagar, S. R., Deshmukh, Z. S. K., Fernandes, G., Bhandare, P. R., Shah, P. (2023). Riga-Fede Syndrome : A Rare Case Report With Literature Review. *Transl Med OA, 1*(2), 50-55.

Abstract

Riga-Fede syndrome is characterised as an ulcerative lesion that originates on the ventral surface of a neonate's tongue due to vigorous back and forth movements of the tongue over the precociously erupted mandibular anterior teeth. This condition has been receiving discernible attention as a progressing condition with escalating case reports over the years. The aetiology of this issue is not precisely deduced; however, there have been multiple treatment options discovered that have secured success with higher precision. The purpose of this research paper is to exhibit various case reports and aetiologies responsible for this disease, as well as an explanation of different treatment plans depending on the status of the tooth, that is, the mobility of the tooth and the precarious chances of aspiration. Moreover, radiographic study to visualise if it is a supernumerary or a primary regular tooth and if it is associated with hindrance in breast-feeding causing soft tissue injuries and the state of the child's health. A 28-day-old female infant was presented to the oral pathology clinic with a natal tooth exhibiting grade 2 mobility along with a lesion on the ventral surface of the tongue, leading to the clinical diagnosis of Riga-Fede disease. The treatment performed, consisting of the extraction of natal teeth, was selected as the treatment of choice over more conservative treatments for the rapid resolution of the lesion and the limited risk of inadequate nutrient intake since the tooth was interfering with the feeding process. Following the extraction of the tooth, it underwent microscopic studies to identify diverse changes associated with the erupted tooth. There was regular monitoring of the patient, and complete wound healing was observed after 4 weeks. The proposed treatment was successful, and the patient is still in follow-up without recurrence of the lesion after one year. This paper presents a concise review of the literature about neonatal teeth and their role in Riga-Fede disease.

Keywords: Riga-Fede Syndrome; Tongue; Oral Pathology

1. Background

A chronological sequence is generally associated with normal eruption that involves the eruption of lower anterior as the first primary tooth at around 6 months of age. Rarely, teeth can appear in the oral cavity at birth and these teeth are called natal teeth. Natal tooth/teeth are defined as those which are present at birth and neonatal tooth/teeth are those which are seen within 30 days of life in an infant's oral cavity. Teeth which erupt before the normal eruption time are often called as congenital teeth, predeciduous teeth, fetal teeth, dentitia pracoex, dens canntalis, infancy teeth, precocious dentition and although the cause is yet unknown, it is often attributed to . The prevalence of natal teeth is presently found to be between 1 in 2000 to 3500 live births with a general predilecition towards the female gender. The exact cause of such tooth / teeth is still unknown but factors such as infections, febrile and pyretic conditions, trauma during delivery, malnutrition, hormonal imbalance, environmental toxins, maternal exposure to chemicals and tooth germ anomalies often pose as associated risks. These teeth can cause ulcers on the ventral surface of the tongue, lip, and the mother's breast characterizes the rare pediatric condition called Riga-Fede Disease.

This disease appears as an ulcerated area on the ventral surface of the tongue (most common site in neonates and infants) as a result of a benign ulcerative process of the tongue and frenulum, owing to repetitive trauma caused by the process of eruption of the primary lower central incisors [2]. This lesion eventually progresses to an enlarged, fibrous lesion in the form of an ulcerative granuloma. The treatment depends on the tooth's

mobility and the risk of aspiration or swallowing; whether it is supernumerary or regular primary teeth; whether it is causing interference in breastfeeding; breast and oral soft tissue injuries; and the general state of child's health. The clinical characteristics of natal and neonatal teeth may resemble natural primary dentition or may be conical in shape but histologically it may show different enamel, dentin, cementum and pulp changes. Mostly they depict a hypoplastic enamel, dentin and pulp.

2. Case Presentation

A 28 days old female infant was referred to the Oral Pathology department for ulceration on the ventral surface of the tongue (13 mm diameter) and difficulty in suckling because of the natal teeth. Clinical examination revealed a tooth with sharp incisor edge and grade two mobility. The ventral surface of the tongue showed a 5 × 8 mm ulcer extending from under border of the tongue to lingual frenulum. Feeding and nutrition of the baby was getting affected (Figure 1). The extraction of natal teeth was selected as treatment of choice, over more conservative treatments, for the rapid resolution of the lesion and for the limited risk of inadequate nutrients intake. The extracted teeth underwent a macroscopic and microscopic examination except for the irregular spaces in the region close to the amelodentinal union and the histological ground section that revealed a thin enamel layer with varying degrees of mineralization to an absence of enamel in some regions.

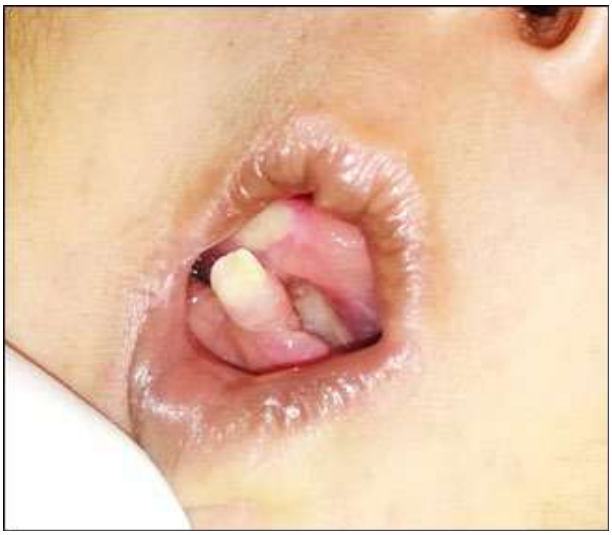

Figure 1: Ulceration on ventral surface of tongue in the index case

On ground sectioning of the tooth, it showed hypoplastic enamel with reduced thickness and loss of enamel at few places. There was presence of atubular osteodentin along with alterations in the atypical dispositions of dentinal tubules. Moreover, there existed irregular dentin in the cervical portions and interglobular dentin in the coronal region. The enamel rods showed a fish scale pattern and enamel spindles were seen focally. Predominantly tubular dentin was present. Dentinoenamel junction was not scalloped which was similar to deciduous teeth (Figure 2.1, 2.2, 2.3, 2.4). The complete healing of the lesion took 4 weeks; subsequently, the infant, revised at the 1-year follow-up visit.

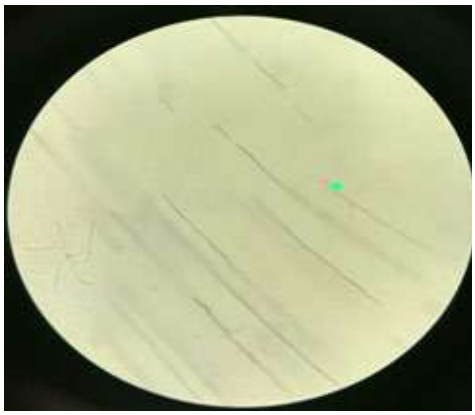

Figure 2.1: Ground section of neonatal tooth showing Enamel.

Enamel is the outermost layer of the tooth, constituting tightly packed mineralized crystals.

In neonatal teeth, the enamel may appear thin and poorly mineralized, with poorly defined crystals than in mature teeth. It also exhibits irregular surface with a substantial amount of hypoplasia and enamel anomalies.

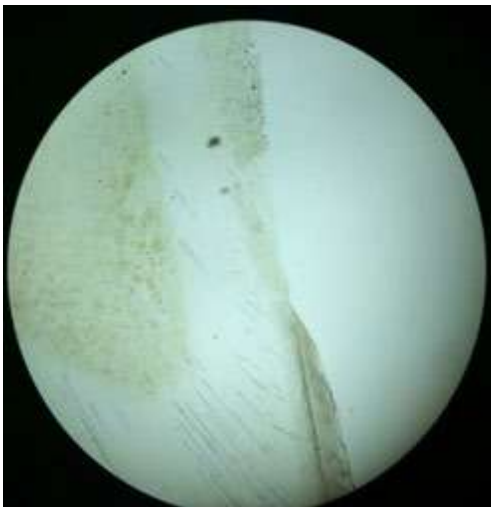

Figure 2.2: Ground section of neonatal tooth showing Dentin.

Dentin is the layer beneath the enamel, containing less inorganic content with greater porosity and leathery texture in contrast to mature teeth. The dentin in neonatal teeth may also show wider dentinal tubules (small channels that run through the dentin), indicative of rapid dentin formation, with higher amounts of mineralization.

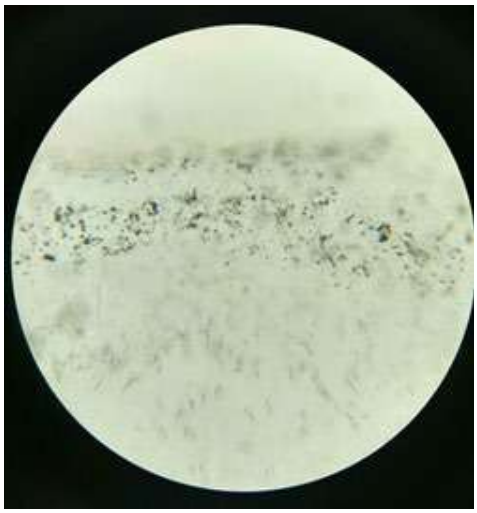

Figure 2.3: Ground section of neonatal tooth showing Tomes granular layer.

A specialized layer of zone called Tomes granular layer allocated at the interface between dentin and cementum in mature teeth, is a hypomineralized area of radicular dentin; formed due to coalescing and looping of the terminal ends of the dentinal tubules. In neonatal teeth, this layer may ill-defined and disorganized compared to mature teeth, since these teeth are under developed and the dentin layer is partially mineralized. This is because neonatal teeth are still developing, and the dentin layer is not fully mineralized. Subsequently, the Tomes granular layer is yet to be entirely functional, and the dentin formation may be incomplete or irregular.

Figure 2.3: Ground section of neonatal tooth showing Pulp cavity.

The dental pulp is the most vital part of the tooth structure, filled with vascular tissue, neural tissue and connective tissue.
In neonatal teeth, the dental pulp, is similar in structure and function to the pulp in mature teeth.
Nevertheless, in neonatal teeth pulp tissue may be more exposed and vulnerable as a result of thinner, disorganized enamel layer. In fact, this property can en route to subsequent infections and hypersensitivity to changes in the temperature or chemical irritation, due to its high density of nerve endings.

3. Histopathology

Histologically, Riga-Fede syndrome is characterized by ulcerated and inflamed tissue with mixed acute and chronic inflammation. It typically exhibits a superficial necrosis of the mucosa with an inflammatory infiltrate on the tongue and sometimes the lower lip. The acute inflammation consists of neutrophils, while the chronic inflammation is characterized by lymphocytes, plasma cells, macrophages, mast cells and a predominance of eosinophils. It is, therefore, a cause of eosinophilic ulcers. Atypical histiocytic granulomas may also be seen.

The surface of the ulcerated tissue may show areas of granulation tissue with proliferating fibroblasts and new blood vessels. In some cases, there may be signs of bacterial infection, with colonies of bacteria present in the tissue. Neutrophilic infiltration presents as an integral part of the ulcer and the surrounding tissue, which is a prime indication of inflammation. The epithelium encircling the ulcer is often hyperplastic, that is an increased number of cells. Moreover, there are a few noted cases which prove the chances of these lesions being permeated with bacteria or viral infections, which can be seen in microscopic examination [2].

Following the excisional biopsy, based on the clinicopathological findings, it is mandatory to deduce the syndrome from other differential diagnosis lesions affecting the tongue, to reach the ultimate solution.

Different Conditions Include

Infections	Malignancies	Blood dyscrasias	Neurological evaluation
Ulcerative Candidiasis Bacterial infections Fungal infections Tuberculosis Primary syphilis	Lymphoma sarcoma	Agranulocytosis (blood condition in which there are no white blood cells)	Riga Fede disease can be an early sign of a neurological or developmental problem.

It is important to note that histopathological features alone cannot be used to diagnose Riga-Fede syndrome. Clinical presentation and history are critical components in making a diagnosis. A thorough examination, including a medical and dental history, is essential to rule out other potential causes of oral ulcers and lesions.

In summary, the histopathology of Riga-Fede syndrome is characterized by ulcerated and inflamed tissue with mixed acute and chronic inflammation, with possible signs of bacterial infection. However, further studies are needed to better understand the histopathological features of this rare condition.

4. Discussion

Riga-Fede syndrome or disease (RFD) is a reactive traumatic mucosal disease that is characterised by recurrent oral mucosal ulcerations. The mandibular incisor teeth's repeated stress to the tongue during constant protrusive and retrusive movements causes it to grow. Although the symptoms can be seen right away after birth with natal and neonatal teeth, the ailment is most frequently seen in infants, and the start of the lesions typically coincides with the eruption of the primary teeth.

It is described as traumatic ulcerative granuloma with stromal eosinophilia (TUGSE) that appears in early life. Elzay proposed that TUGSE and Riga Fede illness might be regarded as a single entity because they share similar histologic characteristics and are frequently linked to a history of trauma. Riga Fede disease is nearly entirely limited to the tongue, whereas TUGSE has primarily been known to arise in late adulthood and is not restricted in location to the tongue but can also appear in the buccal mucosa, vestibule, gingiva, or palate. In the current review of the literature, 29 lesions were identified as ulcerations on the ventral surface of the tongue as a result of repeated trauma to the primary lower incisors, three lesions were identified on the dorsal surface of the tongue as a result of trauma to the upper incisors, and three lesions were identified on the lower lip. Seven patients experienced the symptoms within two months of delivery. These instances were all connected to (neo)natal teeth. The remaining 27 individuals, with a mean age of ten months and ages ranging from six to twenty-four months, began to experience lesions after the eruption of their lower incisors. The ratio of men to women seemed to be 1.8:1 [3].

Although the cause of the early eruption of these teeth is unknown, a number of conditions, including infections, nutritional deficiencies, fever, endocrine disorders, tooth germs in a superficial position, and osteoblastic activity in the vicinity of dental germs, have been linked to the condition. Furthermore, In Grave's disease, elevated maternal anti-TSH receptor antibody levels could lead to fetal hyperthyroidism and that could explain the premature dental eruption, it could also occur because of the exposure of mother to environmental toxins like polychlorinated biphenyls (PCB). More than 20 syndromes and abnormalities, including chondroectodermal dysplasia, congenital pachyonychia, Hallermann-Streiff Syndrome, craniofacial dysostosis, Pierre Robin Sequence, Sotos Syndrome, Syndrome of Wiedemann, and Meckel and Gruber Syndrome, may be linked to heredity and the natal and neonatal teeth. In addition to the trauma brought on by the teeth, Narang et al. listed the persistent traction created by tongue-tie as additional factor. Certain authors associate RFD exclusively with the neurological disease cerebral palsy. This is reflected in the classification by Domingo- Cruz et al who divided the disease into precocious and late. Precocious RFD occurs in the 0-6 months age and has no relation to any neurological diseases. Late RFD occurs post 6 months with the primary teeth as the causative factor and related to neurologic diseases as these patients have difficulty controlling their tongue movement/voluntary movements.

The majority of natal teeth are deciduous teeth that emerged prematurely, while some may be supernumeraries. It is more common in females than males, with an incidence of 1:2000 live births. The existence of natal and neonatal teeth may result in difficulties such as discomfort in breastfeeding, aspiration of teeth, breast nipple bruises, lingual ulcerations, and unwillingness to eat. According to Tang et al., trauma is simply one of several factors that contribute to the development of RFD. Viral and toxic substances may enter the traumatised area through the submucosa and cause an inflammatory reaction and tissue loss.Every mucosal surface in the oral mucosa can be impacted, although in cases that have been recorded, the tongue is the most frequently afflicted area. Ulcerations on the tongue's ventral surface's midline are the typical visual representation of oral lesions [4].

Histopathologically, Riga Fede disease is distinguished by an ulcerated mucosa with granulation tissue and a mixed inflammatory infiltration made up of lymphocytes, macrophages, mast cells, and a profusion of eosinophils the latter of which is the most typical of this entity. There are multiple treatment plans discovered as solution for riga-fede disease, all of which significantly focus onto terminate the source of trauma so healing can take place. The first and foremost option opted as a treatment plan for riga-fede disease has always been a conservative approach and if this initial remedy does not provide a full-fledged resolution, then extraction of the neonatal tooth is the treatment of choice. To begin with, a conventional conservative treatment relies on multiple aspects, which are to be considered such as inconveniences during breast feeding, interference during suckling, implantation and the degree of mobility, occurrence of traumatic lesions. Out of all the most significant

point to be notified is that if whether the tooth belongs to the natural dentition or if it's a supernumerary tooth, with the aid of radiographic findings. If it is diagnosed as a tooth of natural dentition, each of the above-mentioned treatment strategies are ought to be considered, unless any of this would cause injury to the new born.

Conservative treatment: these management options can be utilized alone or in combination.

• Firmly implanted – can be left in the arch instead of extraction, except when they interfere while feeding or are extremely mobile with a substantial risk of aspiration, lastly if it holds to be responsible for the occurrence traumatic lesions on the tongue of the new born.

• To prevent injury to the maternal breast while feeding, the incisal pointed edges can be smoothened, or masking the ragged incisal edges with composite resins, opting to different methods of feeding habits such as shifting to physiological nursing bottles with large holes in the nipple, placing a nasogastric tube.

• cellulose film or other protective dental appliance; oral disinfectant; corticosteroids; teething ring

If conservative treatment strategy fails to accurately resolve the condition or when the child is gravely malnourished or dehydrated then extraction is the treatment of choice to be essentially considered. Alternatively, excision of the lesion itself might be performed. An excisional biopsy is indicated if the injury persists even after the extraction of the natal teeth. In the case described, the lesion healed in fifteen days, requiring no biopsy. After one year the infant had the upper incisors and right side lower central incisor partially erupting. At the radiographic examination it was found that the permanent central incisors were with 1/3 of the mineralized crown. The close follow-up of the successor permanent tooth eruption is very important. Since destruction of the primary or natural teeth may subsequently jeopardize the relationship between the jaws and child can develop harmful tongue posture, subsequently routing to speech problems. Consequently, resulting in difficulties for the eruption of the permanent teeth [5]. Table1gives a summary of the literature regarding Riga-Fede disease.

Authors Name	Age	Gender	Tooth	Presentation	Treatment
Dr M Khaja Khalid Nawaz et al (6)	1 week(tooth present no lesion) 3 weeks (lesion observed)	Female	natal tooth	Ulceration on the ventral surface of the tongue, smooth reddish and replicates the tooth form.	Extraction of the tooth was opted as the treatment of choice
Mebin George Matthew (7)	20 days	Male set of twins	Natal mobile tooth in the mandibular anterior region	Circular Ulcer (1*1cm in one twin and 2*2 cm in other)on the ventral surface of the tongue	Extraction of the tooth
Luiz Evaristo Ricci Volpato et al (8)	1 month	Female	2 Natal teeth in the mandibular anterior region	Ulcerative lesion(8mm in diameter) on the ventral surface of the tongue	Left natal tooth extracted Right natal tooth covered with an increment of GIC
R.P.S. Mohan et al (9) Case 1	`30 days	Male	Natal left and right mandibular cental incisor	15*10mm on the internal mucosa of the lower lip	Selective grinding of the affected tooth with triamcinolone
R.P.S. Mohan et al (9) Case 2	42 days	Male	Natal left and right mandibular central incisors	25*25mm on the ventral surface of the tongue	Extraction and triamcinolone
R.P.S. Mohan et al (9) Case 3	34 months	Male	Natal left mandibular central incisor	20*15 mm on the ventral surface of the tongue	Selective grinding of the affected tooth with triamcinolone
R.P.S. Mohan et al (9) Case 4	15 months	Male	Natal right mandibular incisor	10*5mm on the ventral surface of the tongue	Selective grinding of the affected tooth with triamcinolone.
R.P.S. Mohan et al Case 5	20 months	Male	Natal left mandibular central incisor and right central and lateral incisor	8*5mm on the ventral surface of the tongue	Selective grinding of the affected tooth with triamcinolone.
R.P.S. Mohan et al (9) Case 6	30 months	Male	Natal left mandibular lateral incisor	2*3mm on the lateral left border of the tongue	Extraction and triamcinolone application.
R.P.S. Mohan et al (9) Case 7	46 months	Male	Natal right and left mandibular central incisor	3*5mm on the right lateral border of the tongue	Selective grinding of the affected tooth with triamcinolone.

R.P.S. Mohan et al (9) Case 8	34 months	Male	Natal right mandibualr central incisor	2*5mm at the tip of the tongue and the granulomatous tissue at the alveolar ridge	Selective grinding of the affected tooth with triamcinolone.
R.P.S. Mohan et al (9) Case 9	50 months	Male	Natal right and left mandibular central incisors	15*10mm at the ventral surface of the tongue	Selective grinding of the affected tooth with triamcinolone.

Table1. Summary of the literature regarding Riga-Fede disease:

5. Conclusion

Early detection of Riga Fede disease is recommended since such lesions may produce deformity or mutilation of tongue, dehydration, inadequate nutrients intake by the infant and growth retardation. Furthermore, these teeth are generally present in syndromic children and it is important to rule out this during diagnosis. The treatment in these cases often requires an interdisciplinary approach of paediatrician and maxillofacial surgeon as it is concerned with the child's health and future dentition. Extraction of the teeth may prove to be a good and viable treatment option in such cases since it can alleviate feeding. In case of mild to moderate irritation of the tongue, conservative treatment such as smoothing the incisal edge with an abrasive instrument is advocated. Alternatively a small increment of composite may be bonded to the incisal edge. In the present case, we performed extraction of the natal teeth and this offered improvement and normalization of feeding. In conclusion, as Riga Fede disease often mimics many oral malignant and benign disorders, the differential diagnosis is important [6-9].

List of Abbreviations

RFD: Riga-Fede syndrome or disease

Declarations

Ethics Approval and Consent to Participate

The article does not contain any studies with human participants or animals performed by any of the authors

Consent for Publication

The parent of the infant gave consent for publication of this case report and accompanying images.

Availability of Data and Materials

Not applicable

Competing Interests

All the authors declare the absence of a competing interests related to this study.

Funding

No funding obtained

Acknowledgements

Not applicable

References

1. Rao, R. S., & Mathad, S. V. (2009). Natal teeth: Case report and review of literature. Journal of oral and maxillofacial pathology: JOMFP, 13(1), 41.
2. Ceyhan, A. M., Yildirim, M., Basak, P. Y., Akkaya, V. B., & Ayata, A. (2009). Traumatic lingual ulcer in a child: Riga–Fede disease. Clinical and experimental dermatology, 34(2), 186-188.
3. Çavuş, Ş., & Özmen, B. (2017). Riga-F ede disease in the upper jaw in an infant. Dermatologic Therapy, 30(5), e12517.
4. Kumari, A., & Singh, P. K. (2019). Diagnosis of Riga–Fede Disease. The Indian Journal of Pediatrics, 86(2), 191-191.
5. Costacurta, M., Maturo, P., & Docimo, R. (2012). Riga-Fede disease and neonatal teeth. Oral & implantology, 5(1), 26-30.
6. Nawaz, M., Krishnamurthy, S., Sivaraman, G. S., & SivakumarS, N. N. (2016). Riga Fede Disease-A Case Report. JMSCR, 4(6), 11089-11091.
7. Mathew, M. G. (2022). Riga Fede disease in twins. BMJ Case Reports, 15(11), e252226.
8. Volpato, L. E. R., Simões, C. A. D., Simões, F., Nespolo, P. A., & Borges, Á. H. (2015). Riga-Fede Disease associated with natal teeth: two different approaches in the same case. Case reports in dentistry, 2015.
9. Mohan, R. S., Verma, S., Gill, N., & Singh, U. (2014). Riga-Fede disease (Cardarelli's aphthae): A report of nine cases. South African Journal of Child Health, 8(2), 72-74.

Section A-Research paper
ISSN 2063-5346

Comparative effectiveness of intra-alveolar Stevia extract powder versus amoxicillin trihydrate powder in healing of mandibular third molar extraction sockets among 18-45 year-old Indian adults - a split mouth randomized controlled trial.

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DOI: 10.48047/ecb/2023.12.si4.1703

Abstract

Background: Plant based compounds are gaining popularity in healthcare. Stevia, a plant based sweetener, has antihyperglycemic, antihypertensive, anti-inflammatory, antitumor, diuretic, anti-microbial and immunomodulatory effects. Its use as an antimicrobial agent in the extraction sockets of mandibular third molars has never been reported in the literature.

Aim and objectives: This study aims to find an answer to avert adverse effects related to post-operative oral antimicrobials and thus evaluates and compares the effectiveness of stevia with amoxicillin trihydrate used in sockets of surgically extracted impacted mandibular third molars.

Materials and methods: A split mouth randomised controlled trial was undertaken on 18-45 years old 40 healthy subjects with bilaterally impacted mandibular third molars ie, 80 surgical sites. After extractions, Group 1(n=40) received stevia extract powder and Group 2 received amoxicillin trihydrate powder in the sockets before suturing. Facial measurements, inter-incisal mouth opening, WBC counts, rise in axillary temperature, presence of suppuration, lymph node palpability, intra-oral erythema, wound dehiscence and pain were noted pre and post-operatively on days 1,3,7.

Results: There was no statistically significant difference ($p>0.05$) on inter-group comparisons in all variables except pain and facial measurements ($p<0.05$). There was no incidence of infection/overt inflammation in either group.

Conclusion: Intra-alveolar Stevia powder showed comparable antimicrobial effect as amoxicillin trihydrate powder and can be used to improve overall patient's comfort, avoiding systemic adverse effects of oral antimicrobials, following impacted mandibular third molar surgery.

Keywords: Stevia rebaudiana, impacted mandibular third molars, Intra-alveolar antibiotic, local antimicrobial agent.

Introduction

Although surgical extraction of impacted mandibular third molars is routinely undertaken procedure in Oral and Maxillofacial surgical practice, its possible intra and post-operative sequelae include (but are not limited to), bleeding, damage to adjacent tooth, pain, trismus, swelling, dry socket and infection of the surgical site. Given the incidence of post-operative infection in literature, use of routine antibiotic prophylaxis in patients undergoing such surgeries is considered unsubstantiated.[1] Use of antibiotic prophylaxis for reduction of infection related postsurgical complications, such as pain, trismus, delayed wound healing, and swelling have been discussed and debated.[2] Supporters of systemic antibiotics for such cases, consider oral route as the gold standard. Since amoxicillin is proven to be effective against common oral infection isolates, it has been used in most of the regimens.[3] However, systemic administration of an antimicrobial agent might not yield desired availability of the drug at the target site (due to poor bone penetrance) hence greater dosage or a drug with broader spectrum may be required in certain cases. Adverse effects of the drug per se, microbial resistance towards the drug, destruction of eco- niches e.g., intestinal microflora and their sequelae, makes local application of such agents, a better alternative especially in accessible areas such as mandibular third molar region.[4]

There seems to be a perpetual need for discovering new antimicrobial compounds with varying chemical structures and novel mechanisms of action due to an alarming increase in the incidence of new and re-emerging infectious diseases and development of microbial resistance to the antibiotics in current clinical use.[5]

A global shift towards discovery and application of plant based products for therapeutic use in humans cannot be understated. Plant extracts and phytochemicals with known antimicrobial properties can individually or as an adjunct, significantly aid therapeutic treatment regimens. Minimum side effects, ease of availability and cost-effectiveness are their major advantages .[5]

Stevia is one such natural product, extracts of which are widely used as sweetening agent. Recently, it has been proven to have antimicrobial activity and beneficial effects on human health.[6.7.8] Commercially available Stevia is an extract from the leaves of the plant Stevia rebaudiana. Dr. Moises Santiago Bertoni discovered Stevia in the 19th century. This plant belongs to Chrysanthemum plant species and is related to Lettuce, Marigold and Chicory. Stevia was used by Guarani Indians for sweetening tea, as well as making sweet treats. The chemical compounds that produce its sweetness are various steviol glycosides (mainly stevioside and rebaudioside), which are 200–300 times sweeter than sugar. Additionally, diterpenoids present in the leaves viz Manoyl oxide (anti-inflammatory and anti-parasitic), Labdanesclareol (anti-tumorous and cytotoxic), Phytosterols (cardiovascular advantages) have been reported.[6]

Stevia extracts are non-caloric and non-cariogenic, heat stable, pH stable, not fermentable, hence, generally used as a natural sweetening agent.[7] Stevia has low Glycemic Index & aids activation of beta cells of the pancreas which helps to evade blood sugar spikes[7,8]. Steviol Glycosides are poorly absorbed in the body and pass unaltered through the upper gastrointestinal

tract. In colon, steviol glycosides get converted to steviol, metabolized by the liver and are completely excreted in the urine. Hence there is no accumulation of Stevia in the body during and after metabolism. Stevia helps to improve the function of pancreas when taken on a regular basis.[7]

Preclinical and clinical studies have proven it to be non-genotoxic, non-mutagenic and encourage its therapeutic and pharmacological applications.[8]Genotoxicity and clinical toxicity even at dosage levels beyond 300 times the recommended dose, have been ruled out.[9] Since it has been approved and marketed as a sweetener, it is routinely and preferentially used over other artificial sweeteners currently. Other therapeutic benefits (apart from hypoglycaemic effect) reported are, antihypertensive, anti-inflammatory, antitumorogenic, antidiarrheal, diuretic, and immunomodulatory effects.[8] Topical application of stevia extract has yielded promising results in healing of abrasions, lacerations, blemishes and acne.[10]

Gamboa et al showed the antimicrobial activity of stevia extracts against oral microbial flora at MIC between 30-120mg/ml.[11] The antimicrobial spectrum of Stevia rebaudiana involves: Streptococcus mutans, Lactobacillus acidophilus, salmonella typhimurium, klebsiella pneumonia, eschericia coli, bacillus cereius, B. subtilis, S. aureus, M. letus, B. megaterium, S. marcensens, P. aeruginosa, E. coli, P. valgaris and fungi such as Candida albicans, R. oligosporus and A. niger.[11] These are the most commonly involved pathogens in infectious conditions in and around the oral cavity. Stevia extracts also exhibit antiviral activity and are potential rotavirus inhibitors.[12]

After a thorough review of literature, we did not find any clinical study using intra-alveolar stevia extracts as an antimicrobial agent. This split mouth study was thus designed to comparatively evaluate effects of Stevia extract powder vs amoxicillin trihydrate powder placed in third molar extraction sockets. This study tested the null hypothesis which states that 'Intra-alveolar Stevia extract powder is not an effective antimicrobial agent for healing of surgically extracted mandibular third molar wounds'.

MATERIALS AND METHODS

A Split mouth, randomized controlled trial was undertaken in the age group of 18-45years old healthy subjects, reporting to the dept. of Oral and Maxillofacial Surgery for surgical extraction of impacted mandibular third molars. Ethical clearance was obtained from the Institution's Ethics Committee (ref no. MUHS/PG/E-2/2254/2017). The trial was registered in CTRI-ICMR with reference number - CTRI/2020/08/027305.

Sample size was determined using the expected proportion of successful cases in each group values of which are estimated from literature & using the formula[13],

$$n = \frac{(Z_\alpha + Z_\beta)^2 [p(1-p) + q(1-q)]}{(p-q)^2}$$

where Z_α is the z variate of alpha error i.e. a constant with value 1.96, Z_β i.e. a constant with value 0.84,

A sample size of 40 subjects per group was thus computed for the present study. Since this was a split-mouth design, subjects with bilateral impacted mandibular third molars, indicated for surgical extractions were included and randomly assigned into one of the 2 groups by computer generated random numbers. A written consent was obtained from the subjects prior to commencing the study. One site was operated at once and a wash-out period of one month was diligently followed in all cases. Subjects, who were lost to follow-up or did not comply with post-operative instructions or did not report for the second site, were excluded. Patients with a

known medical history, an active infection elsewhere, and recent use of antimicrobial drugs (in the last 7 days), an immune-compromised state, pregnant or lactating mothers and uncooperative patients, mentally retarded patients were excluded from the study. Thus, a total of 42 subjects were initially recruited for this study. Two patients opted not to get operated on the second site, hence were excluded. The study thus evaluated 80 surgical sites in 40 subjects.

Pain was evaluated by 0-10 Visual Analogue Scale. Facial Swelling was assessed using two facial lines (in cm) using a flexible calibrated surgical scale.

- Line 1- The distance from tragus to the commissure of the mouth.
- Line 2- The distance from the lateral canthus of the eye to the gonion.

Mouth Opening was evaluated by measuring the distance between incisal edges of the upper and lower central incisors at maximum mouth opening in mm.

Absence of preoperative infection was ensured by normal white blood cell counts and axillary temperature. Facial measurements (mm) and inter-incisal mouth opening (mm) (to assess amount of swelling and trismus), WBC count, rise in axillary temperature (^{o}F), presence of suppuration and lymph node palpability (as indicators of surgical site infection), intra-oral erythema and wound dehiscence (to assess healing) and pain (VAS scores) were noted pre and post-operatively. Intra-operatively, length of the incision (mm) and amount of periosteal stripping (mm) (as indicators of surgical trauma) were also noted.

All subjects were operated under similar conditions by the same operating surgeon using standard operating aseptic protocol. After thorough irrigation, Group 1 subjects received intra-alveolar stevia extract powder (180mg) whereas, Group 2, received intra-alveolar amoxicillin trihydrate powder (500mg). Two 3-0 black silk interrupted sutures were placed in all 80 surgical sites. Pressure pack was applied on the surgical site, standard postoperative instructions were given, and routine analgesics (but not antibiotics) were prescribed to all subjects. All subjects were followed-up on postoperative days 1, 3 and 7 for evaluation of variables as stated above. WBC counts were evaluated only on the 3rd postoperative day.

Statistical Analysis

· Data obtained was compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States).

·Data was subjected to statistical analysis using the Statistical package for social sciences (SPSS v 26.0, IBM).

Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data has been depicted.

Normality of numerical data was checked using Shapiro-Wilk test & was found that the data for WBC count only followed a normal curve; hence Inter group comparison (2 groups) was done using t test (Table 1).

Normality of numerical data was checked using Shapiro-Wilk test & was found that the data for all other variables did not follow a normal curve; hence non-parametric tests have been used for comparisons. Inter group comparison (2 groups) was done using Mann Whitney U test. Intra group comparison was done using Friedman's (for >2 observations) followed by followed by pair wise comparison using Wilcoxon Signed rank test. Comparison of frequencies of categories of variables with groups was done using chi square test.

For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

RESULTS

The groups were demographically similar since a split-mouth study design was followed. A total of 80 surgical sites (in 40 subjects) were evaluated clinically preoperatively and postoperatively on 1st, 3rd and 7th days.

There was a statistically non-significant difference between the 2 groups for WBC count with t test ($p>0.05$, Table 1).

For all values in Table 2, there was a statistically non-significant difference between the 2 groups ($p>0.05$, Mann Whitney U test) except for, Line 2 on POD1 (1^{st} post-op day) ($p=0.010$), Pain on POD1 ($p=0.000$) and pain on POD 3 ($p=0.000$) with higher values in group 2 in all cases.

There was a statistically non-significant difference seen for the frequencies between the two groups ($p>0.05$) with Chi-square test (Tables 3a, 3b,3c,3d) for suppuration, wound dehiscence, erythema, lymph node palpability.

For all values, #= statistically non-significant difference, *= statistically significant difference and **= statistically highly significant difference

Table 1: Inter group comparison of values for WBC count (n=40 per group)

	Group	Mean	Std. Deviation	Std. Error Mean	T value	p value of t test
WBC count	1	7108.25	1317.536	208.321	.000	1.000#
	2	7103	1317.536	208.321		

Table 2: Inter group comparison of values (n=40 per group)

	Group	Mean	Std. Deviation	Std. Error Mean	Median	Mann-Whitney U value	Z value	p value of Mann-Whitney U test
Temp Preop (^{o}F)	1	97.775	.5839	.0923	98	800.000	0.000	1.000#
	2	97.775	.5839	.0923	98			

Temp POD1 (^{o}F)	1	97.715	.5668	.0896	97.7	800.000	0.000	1.000#
	2	97.715	.5668	.0896	97.7			
Temp POD 3 (^{o}F)	1	97.807	.5563	.0880	97.9	800.000	0.000	1.000#
	2	97.807	.5563	.0880	97.9			
Temp POD 7 (^{o}F)	1	97.825	.5852	.0925	98	800.000	0.000	1.000#
	2	97.825	.5852	.0925	98			
MO Preop (mm)	1	42.35	3.199	.506	42	800.000	0.000	1.000#
	2	42.35	3.199	.506	42			
MO POD1 (mm)	1	37.50	4.489	.710	37.5	623.000	-1.709	0.087#
	2	35.63	5.006	.792	36			
MO POD 3 (mm)	1	39.38	3.972	.628	40	655.500	-1.397	0.162#
	2	38.35	3.718	.588	38.5			
MO POD 7 (mm)	1	40.95	3.096	.490	41	776.500	-0.228	0.820#
	2	41.28	3.030	.479	40.5			
Line 1 Preop (mm)	1	115.18	9.120	1.442	118	800.000	0.000	1.000#
	2	115.18	9.120	1.442	118			

Line 1 POD1 (mm)	1	118.63	9.372	1.482	120	628.500	-1.653	0.098#
	2	122.13	9.318	1.473	125			
Line 1 POD 3 (mm)	1	117.20	8.936	1.413	118.5	657.000	-1.377	0.168#
	2	120.03	9.322	1.474	121.5			
Line 1 POD 7 (mm)	1	115.68	8.931	1.412	118	718.500	-0.785	0.432#
	2	117.03	9.133	1.444	119			
Line 2 Preop (mm)	1	107.00	9.816	1.552	108.5	800.000	0.000	1.000#
	2	107.00	9.816	1.552	108.5			
Line 2 POD1 (mm)	1	108.40	9.358	1.480	109	533.000	-2.573	0.010*
	2	112.58	10.270	1.624	114			
Line 2 POD 3 (mm)	1	107.63	9.591	1.516	109	611.500	-1.817	0.069#
	2	110.63	10.500	1.660	112			
Line 2 POD 7 (mm)	1	107.10	9.711	1.535	109	742.500	-0.555	0.579#
	2	108.08	9.900	1.565	109			
Pain Preop	1	0.33	1.859	.294	0.2	765.000	-0.341	0.733#
	2	0.18	1.738	.275	0.15			

Pain POD1	1	1.55	.932	.147	1	132.500	-6.534	0.000**
	2	3.98	1.310	.207	4			
Pain POD 3	1	.68	.656	.104	1	225.000	-5.837	0.000**
	2	1.85	.736	.116	2			
Pain POD 7	1	.23	.423	.067	0	720.000	-0.995	0.320#
	2	.33	.474	.075	0			
length of incision (mm)	1	30.48	4.904	.775	31	800.000	0.000	1.000#
	2	30.48	4.904	.775	31			
periosteal stripping (mm)	1	10.73	1.240	.196	11	800.000	0.000	1.000#
	2	10.73	1.240	.196	11			

Comparison of frequencies of categorical variables
A= Absent, P= Present
Table 3a: Suppuration

		group				
		1	2	Total	Chi square value	p value
suppuration	A	39	40	79		
	P	1	0	1	1.013	0.314#

Total	40	40	80		

Table 3b: wound dehiscence

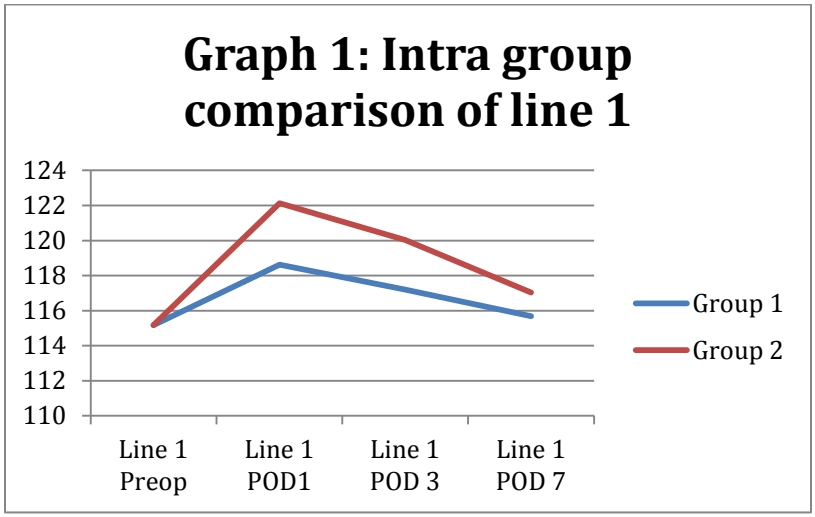
		group				
		1	2	Total	Chi square value	p value
wound dehiscence	A	39	40	79		
	P	1	0	1	1.013	0.314#
	Total	40	40	80		

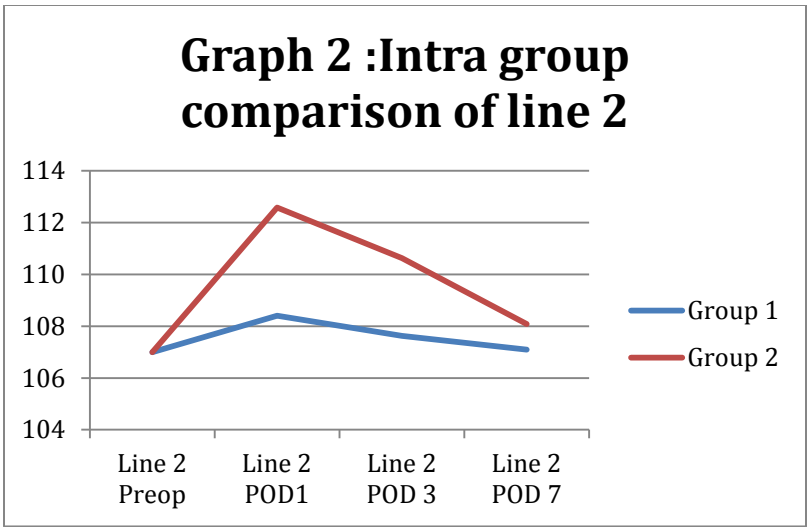
Table 3c: Erythema

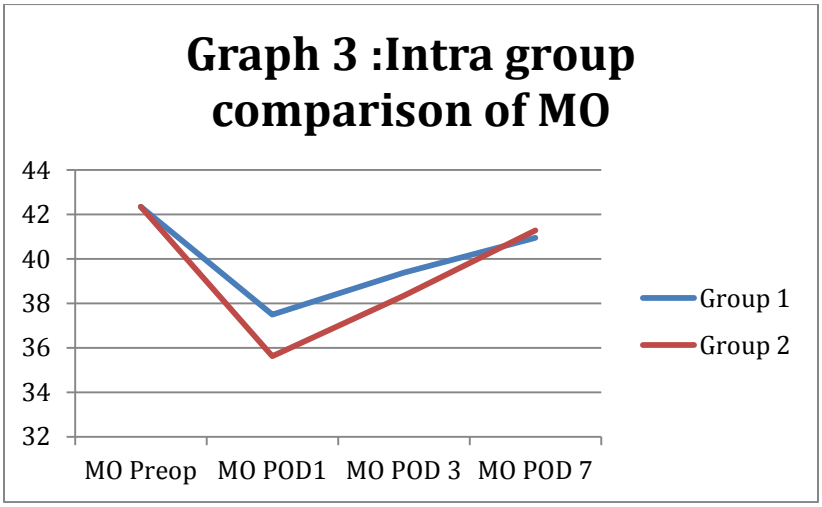
		group				
		1	2	Total	Chi square value	p value
erythema	A	39	40	79		
	P	1	0	1	1.013	0.314#
	Total	40	40	80		

Table 3d: lymph node palpability

		group				
		1	2	Total	Chi square value	p value
lymph nodes	Not palpable	40	40	80	---	---
	Total	40	40	80		







DISCUSSION

The reported frequencies of post-operative sequelae after third molar extraction surgeries are between 2.6 percent and 30.9 percent.[14]The spectrum of sequelae which range from postoperative infection, trismus, swelling and pain, depend on difficulty level of impaction, patient factors, surgical procedure, tissue handling, operating time, asepsis and medications prescribed/ administered [15,16]. The oral cavity houses maximum number of myriad of microorganisms. Hence, considering likelihood of postoperative infection and thereby, a compromised post-operative quality of life, systemic antimicrobial agents have been prescribed routinely, rather indiscriminately[17,18]. However, there is a risk of causing antimicrobial resistance and other systemic adverse effects due to these drugs.

This study was thus designed to avoid systemic antibiotic use and tested effectiveness of Stevia rebaudiana extract in comparison to Amoxicillin trihydrate powder, used in sockets of surgically extracted mandibular third molars, in subjects who did not show any preoperative signs of

locoregional infections. To the best of our knowledge, the use of Stevia extract for such a purpose has not been investigated and reported previously in the literature.

Standard operating protocols, standardized observer and similar difficulty level of impactions were ensured. Split mouth study design minimized inter-subject variability. So, the two groups were matched. It can also be noted that there is no statistically significant difference between the length of incision and periosteal stripping (p=1.000, Table 2). Thus, surgical trauma was also similar in both groups.

WBC counts, rise in axillary temperature, presence of suppuration and lymph node palpability were used as indicators of infection.
There was a statistically non-significant difference between the 2 groups for WBC counts with t test (p>0.05, Table 1).
There was a statistically non-significant difference between the 2 groups for axillary temperature with Mann-Whitney U test (p>0.05, Table 2). Even with Friedman's intra-group comparison, there was no significant difference in both groups for axillary temperature.
There was no clinically evident suppuration /lymph node palpability in both groups on all post-operative days. With chi square test, there was no statistically significant difference for suppuration and lymph node palpability (p>0.05, Table 3a, 3d) between the two groups.
The above suggest that Stevia has comparable anti-microbial effect as Amoxicillin. Gamboa et al and Tadhani et al have described antimicrobial properties of Stevia in details. [11, 19]
Evaluation of facial swelling was done using two facial lines as described. There was a statistically significant difference with Mann- Whitney U test on inter group comparison of line 2 (p=0.010, Table 2), with higher value in group 2 on POD1.
There was no statistically significant difference between 2 groups (p>0.05, Table 2) in mouth opening with Mann-Whitney U test. Intra-group comparison with Friedman's test for facial measurement lines (Graph 1,2) and mouth opening (Graph 3) did show statistically significant difference, with higher values in group 2 (ie, more facial edema) and lower values in grp2 (ie, greater reduction / more trismus). Post-surgical inflammatory response does lead to surgical edema and thereby a consequential decrease in mouth opening in all cases.
Pain as indicated by VAS Scores, shows a highly significant difference in two groups with higher values in group 2 on postoperative day 1 and 3, (p=0.000, Table 2, Mann- Whitney U test).
This denotes that Stevia not only helps in controlling the incidence of postoperative infection, but also, reduces inflammatory reaction, edema, and postoperative pain. Although, analgesic prescribed was the same in both the groups, Group 1 subjects were relatively more comfortable. The observed anti-inflammatory effect could be attributed to manoyl oxide [6], a diterpenoid content of Stevia rebaudiana. Stevia leaf extracts contain high amounts of folic acid, vitamin C and hence have radical scavenging (free radicals, hydroxyl radicals and superoxide anion) activities which promote wound healing. [11,19]
None of the surgical sites underwent wound dehiscence. There was no statistically significant difference with Chi square test (p= 0.314, Table 3b) between 2 groups.
Intra-oral erythema was comparable in the surgical sites in both groups and there was no statistically significant difference with Chi square test (p= 0.314, Table 3c) between 2 groups. Thus, wound healing was comparable and uneventful in both groups.
None of the subjects reported with any local or systemic adverse effects/drug reactions.

CONCLUSION

It can thus be concluded that the effectiveness of intra-alveolar stevia extract is comparable to that of intra-alveolar amoxicillin trihydrate powder for control of postoperative infection.

Stevia rebaudiana appears to offer a beneficial effect on the management of post-operative sequelae and improve overall patient's comfort in the postoperative period following impacted mandibular third molar surgery.

This is a simple and cost-effective method, which does not require additional skill or armamentarium and does not cause any adverse effects to the patient systemically and locally. Also, adverse systemic effects related to systemic antibiotic use can be avoided. The clinician does not have to rely on patient compliance as in with the use of oral antibiotics.

Limitations and future scope:

Present study included only healthy subjects due to ethical constraints. Future studies may be aimed at including patients with a medically compromised status.

Although this study was standardized to the maximum possible extent, similar studies with more variables and with larger sample size should be encouraged.

More complex inflammatory markers and/or culture methods could be used if adequate funding is available to execute such studies.

Conflict of interest:

No conflict of interest

Funding:

None

REFERENCES

1. Gopee P, Rikhotso E. Impacted mandibular third molars: the efficacy of prophylactic antibiotics and chlorhexidine mouthwash in preventing postoperative infections. SADJ 2017 Jun;72(5):213-218
2. López-Cedrún JL, Pijoan JI, Fernández S, Santamaria J, Hernandez G. Efficacy of amoxicillin treatment in preventing postoperative complications in patients undergoing third molar surgery: a prospective, randomized, double-blind controlled study. Journal of Oral and Maxillofacial Surgery. 2011 Jun 1;69(6):e5-14.
3. Carlier M, Noë M, De Waele JJ, Stove V, Verstraete AG, Lipman J, Roberts JA. Population pharmacokinetics and dosing simulations of amoxicillin/clavulanic acid in critically ill patients. Journal of Antimicrobial Chemotherapy. 2013 Nov 1;68(11):2600-8.
4. Zucchelli G, Sforza NM, Clauser C, Cesari C, De Sanctis M. Topical and systemic antimicrobial therapy in guided tissue regeneration. Journal of periodontology. 1999 Mar;70(3):239-47.
5. Cowan MM (1999) Plant products as antimicrobial agents. ClinMicrobiol Rev 12:564–582
6. Yadav SK, Guleria P. 2012. Steviol glycosides from stevia: biosynthesis pathway review and their application in foods and medicine. Crit Rev Food SciNutr 52:988–998
7. Bixa Botanical India. 2021. *Stevia Leaves Powder Stevia rebaudiana*. [online] Available at: <https://bixabotanical.in/products/stevia-leaves-powder-stevia-rebaudiana?variant=34002198069292&currency=INR&utm_medium=product_sync&utm_source=google&utm_content=sag_organic&utm_campaign=sag_organic&utm_campaign=gs-

2020-09-02&utm_source=google&utm_medium=smart_campaign&gclid=CjwKCAjw4_H6BRALEiwAvgfzqxCVZlxGvr9y9d-xNWf4J0cqT88_7QhCw2gdx68y1KRLB8PKJUBpvxoCCNoQAvD_BwE> [Accessed 19 February 2021].

8. Lemus-Mondaca R, Vega-Gálvez A, Zura-Bravo L, Ah-Hen K. Stevia rebaudianaBertoni, source of a high-potency natural sweetener: A comprehensive review on the biochemical, nutritional and functional aspects. Food chemistry. 2012 Jun 1;132(3):1121-32
9. Zhang Q, Yang H, Li Y, Liu H, Jia X. Toxicological evaluation of ethanolic extract from Stevia rebaudianaBertoni leaves: Genotoxicity and subchronic oral toxicity. Regulatory Toxicology and Pharmacology. 2017 Jun 1;86:253-9.
10. Contreras MS. Anticariogenic properties and effects on periodontal structures of Stevia rebaudianaBertoni. Narrative review. Journal of Oral Research. 2013 Oct 29;2(3):158-66.
11. Gamboa F, Chaves M. Antimicrobial potential of extracts from Stevia rebaudiana leaves against bacteria of importance in dental caries. ActaOdontológicaLatinoamericana. 2012 Oct;25(2):171-5.
12. de Oliveira AJ, Cordeiro LM, Gonçalves RA, Ceole LF, Ueda-Nakamura T, Iacomini M. Structure and antiviral activity of arabinogalactan with (1→ 6)-β-d-galactan core from Stevia rebaudiana leaves. Carbohydrate polymers. 2013 Apr 15;94(1):179-84.
13. Chow S, Shao J, Wang H. 2008. *Sample Size Calculations in Clinical Research*. 2nd Ed. Chapman & Hall/CRC Biostatistics Series. page 89.
14. Bui CH, et al. Types, frequencies, and risk factors for complications after third molar extraction. J Oral MaxillofacSurg 2003;61:1379-1389.
15. de Santana-Santos T, de Souza-Santos JA, Martins-Filho PR, da Silva LC, de Oliveira e Silva ED, Gomes AC. Prediction of postoperative facial swelling, pain and trismus following third molar surgery based on preoperative variables. Med Oral Patol Oral Cir Bucal 2013;18:e65–70.
16. Lago-Me´ndez L, Diniz-Freitas M, SenraRivera C, Gude-Sampedro F, Ga´ndara Rey JM, Garcı´a-Garcı´a A. Relationships between surgical difficulty and postoperative pain in lower third molar extractions. J Oral MaxillofacSurg 2007;65:979–83.
17. Sane VD, Gadre KS, Chandan S, Halli R, Saddiwal R, Kadam P. Is post-operative antibiotic therapy justified for surgical removal of mandibular third molar? A comparative study. Journal of maxillofacial and oral surgery. 2014 Jun 1;13(2):189-94.
18. Monaco G, Staffolani C, Gatto MR, Checchi L. Antibiotic therapy in impacted third molar surgery. European journal of oral sciences. 1999 Dec;107(6):437-41.
19. Tadhani MB, Subhash R. In vitro antimicrobial activity of Stevia rebaudianaBertoni leaves. Tropical Journal of Pharmaceutical Research. 2006;5(1):557-60
20. Gardana C, Simonetti P, Canzi E, Zanchi R, Pietta P. Metabolism of stevioside and rebaudioside A from Stevia rebaudiana extracts by human microflora. Journal of agricultural and food chemistry. 2003 Oct 22;51(22):6618-22.

frontiers | Frontiers in Dental Medicine

TYPE Opinion
PUBLISHED 01 August 2023
DOI 10.3389/fdmed.2023.1134294

OPEN ACCESS

EDITED BY
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RECEIVED 30 December 2022
ACCEPTED 29 May 2023
PUBLISHED 01 August 2023

CITATION
Kumar V, Sangle R, Jain R, Bhanushali N, Yadav S, Qureshi A, Tandel H and Mhatre P (2023) Allocating intricacies: pediatric oral health spotlight in the union health and well-being budget of India.
Front. Dent. Med 4:1134294.
doi: 10.3389/fdmed.2023.1134294

Allocating intricacies: pediatric oral health spotlight in the union health and well-being budget of India

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KEYWORDS

union health budget, Indian healthcare, oral health, national oral health comprehensive intervention program for children, national oral health program

Introduction

Healthcare in the union health and well-being budget

Health is a state of physical, mental, and social well-being and not just the absence of disease and infirmity. Healthcare services help reduce mortality rates, keep diseases in check, and raise life expectancy, which play a substantial role in the economic growth of a country (1). The Union Budget 2021 was prescribed for the first time with consideration to holistic health care and well-being, yet, as per National Health Profile (NHP) data of 2019, India spends just over 1% of its GDP on public health, which is drastically low considering the country's population, demographics, and ever-increasing disease burden (2). However, with increased awareness about healthcare in the post-pandemic era, this trend appears to be shifting. For the financial year 2022–23, Rs 2,23,846 crore was allocated towards healthcare in the budget presented, which was 137% higher than the preceding year (Rs. 94,452 crore) (3). The Union Budget 2023–24 has been called the first of "amrit kaal", or the elixir era, aims to achieve the goal of India becoming a developed country in the next 25 years. The Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Health and Family Welfare, and Finance ministries of India are responsible for allocating the entire Union Health Budget. For 2023–2024, the total budget for health across all three ministries is Rs. 1,06,654 crores. Of the total Union Health Budget, about 2.3% is allocated to pediatric healthcare (3).

Upgraded contrivances

The Prime Minister Atmanirbhar Swasth Bharat Yojana scheme

This scheme, with an outlay of 64,180 crores over 6 years, will consist of 15 health care emergency centers and two mobile hospitals, establishing critical care hospital blocks in 602 districts and 12 central institutions, strengthening national centers for disease control and its five branches and 20 metropolitan health surveillance units, providing support for health and wellness centers with integrated public health care labs in all districts and 3,382 block public

health units in 11 states, and the setting-up of nine bio-safety level three laboratories and four regional National Institutions for Virology (4).

Swachch bharat, swasth bharat

This scheme will be implemented with an allocation of 1,41,678 crores over a period of 5 years from 2021 to 2026, merging the Supplementary Nutrition Programme and the Poshan Abhiyan and is aimed at the cleaning of fecal sludge, wastewater treatment, source segregation of garbage, a reduction in the use of plastic, a reduction of air pollution, and bioremediation of all legacy dump sites while also improving the nutritional outcomes in 112 districts (5).

The Jal Jeevan Mission

This scheme will be implemented over 5 years with an outlay of 2,87,000 crores stressing the importance of clean water, sanitation, and a clean environment whilst providing the water supply in all 4,378 urban local bodies, 2.86 crores of household tap connections, and liquid waste management in 500 Atal Mission for Rejuvenation and Urban Transformation cities (6).

The Pradhan Mantri Swasthya Suraksha Yojana (PMSSY)

The budget allocated to establishing a new All India Institute of Medical Sciences (AIIMS) and refining the existing Government Medical Colleges has been reduced by Rs. 517 crores from last year (7).

The Pradhan Mantri Jan Arogya Yojana (PMJAY)

This scheme's budget allocation has doubled from Rs. 3,100 crores in 2020–21 to Rs. 6,400 crores in 2021–2022 (8). Through this scheme, the Government of India aims to establish a public health insurance fund for the economically weaker sections of society. It takes into account the inability of the population to access basic healthcare. However, no mention of oral health insurance has been made. This scheme especially lacks attention to pediatric health and, more so, to pediatric oral health.

The national AIDS and STD control programme

Unfortunately, the budget for this initiative remains unchanged at Rs. 2,900 crores (9). India, with 2–3 million individuals infected with HIV, requires significant attention and funds to manage highly prevalent STIs. In children, the Maternal-to-Child Transmission rate of HIV is about 40%–45%. The number of children enrolled in the HIV National Program are expected to be above one lakh but approximately only 30% of them are supposedly on Anti-Retroviral Therapy (10). Hence, this program is inadequate in achieving the required amount of resources and ensuring their proper distribution.

Figure 1 depicts the comparative analysis of the health care budget distribution between the years 2019–20 and 2021–22 across various health departments in India. Compared to the financial year 2019–20, the allocation of funds to the Department of Health and Family Welfare showed a significant rise. This trend was further observed in the allocation of the budget to the Department of Drinking Water and Sanitation. In the financial year 2021–22, a large sum of the Union Budget was allocated for the development and distribution of the COVID-19 vaccine.

India placed against its global contemporaries: the Ying and Yang

Total expenditure as a percentage of GDP in India is as low as 1.26%. It has been reported that India has one of the lowest public healthcare budgets in the world; countries like the United Kingdom, the Netherlands, New Zealand, Finland, and Australia spend over 9% of their total GDP on public healthcare, Japan, Canada, France, Germany, and Switzerland spend about 10%, and the United States 16%. In India, only 25% of the population has access to sanitation, and the use of diagnostic testing is almost in India. Though there has been a considerable increase in the Union Budget allocated to the healthcare sector from Rs 62,659.12 in 2019–20 to Rs 69,000 crore in 2020–21, there still seems to be scope for betterment (11). Out-of-pocket payments account for 70% of healthcare costs in India, whereas in the US these account for around 10%–12%.

Prioritising non-communicable diseases: need of the hour

In India, 63% of deaths are due to non-communicable diseases (NCDs) and 11% due to injuries. And yet the government spends less than 0.5% of its GDP on NCDs and so the states with high poverty levels have a low per capita expenditure on NCDs (12). When applied to the dental sector, this is especially true in cases of dental caries. According to a systematic review conducted by Shah et al., 49.6% of the children (approximately 100 million children) below the age of five years in India live with untreated dental caries. This substantially increases the burden of disease in the population and highlights the need for effective implementation of preventive strategies with early interventions such as fluoride application, pit and fissure sealants, etc., in the National Oral Health Policy (13).

The inverse care law: the Pandora's box

While the Indian healthcare sector is divided into public and private, the private healthcare segment in India is mainly focused

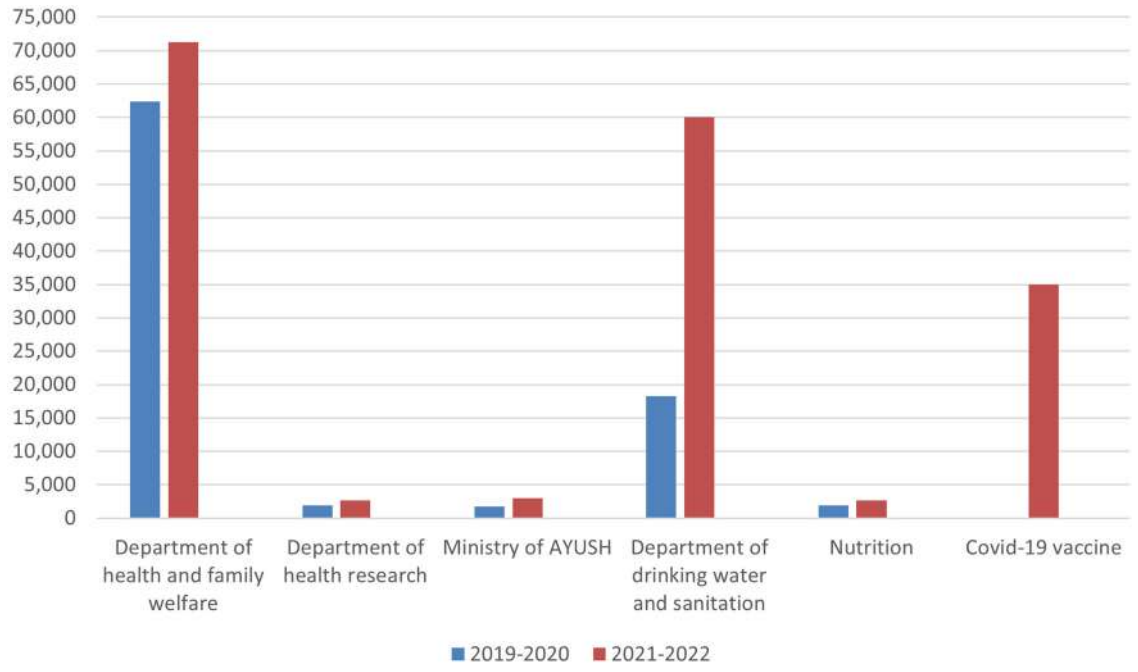

FIGURE 1
A comparative chart of the healthcare budget distribution between the years 2019–20 and 2021–22.

on urban centers, leading to the unequal distribution of services, with 75% of the healthcare infrastructure concentrated in urban areas where only 27% of the total Indian population resides. Only 11% of sub-centers, 13% of Primary Health Centers (PHCs), and 16% of Community Health Centers (CHCs) in rural India meet the Indian Public Health Standards (IPHS). Only one allopathic doctor is available for every 10,000 people and one state-run hospital is available for every 90,000 people. As per the 2017–18 budget announcement, 1,50,000 Health Sub Centers and Primary Health Centers are to be transformed into Health and Wellness Centers (AB-HWCs) by December 2022 to provide Comprehensive Primary Health Care (CPHC) to ensure healthcare for all (14). The PHCs in India are the primary point of contact for services regarding non-communicable diseases. Therefore, oral health promotion, check-ups, and appropriate referral as well as screening for chronic non-healing ulcers is an essential function of the PHCs (15).

Oral health: the "international neglect"

The Union Health and Well-Being Budget 2021 was announced for the first time as a holistic presentation of healthcare needs, assimilating and amalgamating traditional and modern healthcare delivery systems and needs. Whilst allocating significant funds toward the AYUSH (Ayurveda, Yoga, Unnani, Siddha and Homeopathy) framework, a disappointing zero percent of the GDP has been allocated towards oral and dental care needs. No distinct consideration was given to oral health care under the Union Budget 2021–22 despite the schema of the Common Risk Factor Approach proving a strong relationship between the departure from oral health and its myriad links with systemic illness.

Oral health is an integral component of general health yet oral diseases still remain a burden for developing countries like India, especially among the rural population (16). Amongst emerging countries, China enjoys a relatively favorable dental health status and, amongst high-income countries, South Korea exhibits the best dental health status (17). In India, poor oral health status maybe primarily attributed to ignorance among the masses. According to one study (Mathur 2021), 95% of adults in India suffer from gum disease, 50% of citizens do not use a toothbrush or toothpaste, and 70% of children under the age of 15 have dental caries (18), which proves that the burden of oral diseases is on the rise, with oral health being an issue of "international neglect" by policymakers (19). The capacity of the existing health system to overcome these challenges is uncertain; as shown in **Figure 2**, the budget allocation to oral health care seems negligible compared to other policies. There is no specific allotment for the oral healthcare of the pediatric population as the majority of oral diseases can be controlled if intercepted at this growing age. To improve the system and bring about a policy change, a systematic analysis of the existing oral health system is necessary.

National oral healthcare programme: the oral health delivery fabric of India – thrusting beyond boundaries

The NOHP is a stint of hope at acknowledging the gravity of oral health care. Praiseworthy initiatives like establishing 85

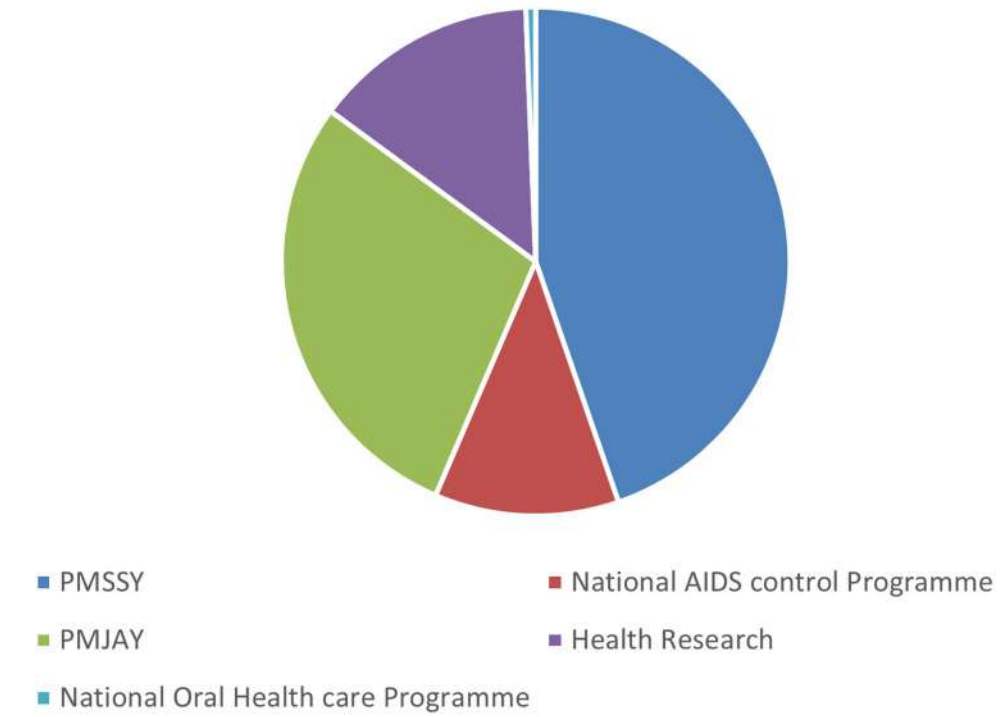

FIGURE 2
A pictorial representation of the major allocations in the healthcare budget.

Muskaan clinics providing free dentures to anyone above the age of 65 years is a part of the Danta Bhagya Yojane, the national oral health policy which was drafted in February 2021 as a part of this initiative. The policy has appreciated the importance of equity, integration, community participation, gender, prevention and promotion, and research which would help in addressing the oral disease burden in India. The Rashtriya Bal Swasthya Karyakram which is a milestone so set that appraising the overall quality of life of children which involves screening of children from birth to 18 years for defects at birth, diseases, deficiencies, and developmental delays. The National Cancer and Tobacco Control Program, National Rural Health Missions, and School Health Program are other budding prospects for efficient delivery of oral health to the population.

Centers for oral health care like the PGI Chandigarh launching the E-RCTC- a joint initiative of PGIMER Chandigarh and the Union to strengthen the National Control Tobacco Programme (NTCP) has been launched. The Maulana Azad Institute of Dental Science (MAIDS) which has fabricated the Mobile Dental Clinic Project and Antitobacco cell, Centre for Dental Education and Research (CDER) is a part of Cochrane Oral Health's Global Alliance and is the National Centre of Excellence for Implementation of the National Oral Health Programme and the World Health Organization (WHO) Collaborating Centre for Oral Health Promotion have also been devised. These schemes have the primary objective of narrowing the rural-urban gap in oral healthcare with a definite budget allocation for the same, thereby increasing the utilization of public oral health facilities and community-based awareness by at least 50% per district by 2030, establishing baseline data for the oral disease burden of the country by 2025, and reducing morbidity and mortality from them by 15% by 2030. To ensure a district-level electronic database of information on health system components by 2025 while integrating oral health information architecture and exchanges between district and primary health centers by 2030. The aims of these initiatives is to eventually strengthen the oral health care system. As no specific care or onus is given to children between 6 or 12 years of age, it becomes essential to gauge how to cease the sustained degradation of oral health care in places where access and resources are inadequate through a common risk factor approach.

Importance of pediatric oral health and incremental care

While many nations have seen improvements in a variety of oral health metrics, India has not. According to a biannual multi-centric oral health study undertaken by the Ministry of Health and WHO in India in 2007–2008, dental caries prevalence among 12-year-olds ranged from 23% to 71.5%. A systematic review that was released in 2018 indicated that 49.6% of Indian children under the age of six had untreated dental

caries (21). The number of children with untreated dental caries is roughly 10 crores if this percentage is extrapolated to children under the age of six. These figures imply that an incremental care method is more appropriate for a developing nation like India because it is periodic care which provides the children with priority dental treatment in a step-by-step manner. The procedure has its own benefits, although it is very occasionally used in complete projects. However, by identifying the needy, the treatment providers, the funding source, and using modern data processing techniques to collect and study the information, one can better understand the many factors involved, possibly make better predictions, and make better decisions about the allocation of resources to solve the problems in health care and achieve the maximum benefit of using the straightforward procedure of providing dental care incrementally to cover the children who will be the country's future citizens.

The role of the union budget of India and its influence on international agencies

The yearly upward trend in the allotment of funds to the healthcare sector is a crucial indicator of the progressive development in the country. A developing nation such as India serves as a template for international agencies as well as other developing nations to better understand the direct effects of increased financial aid on the incidence and prevalence of diseases in the population. Through the betterment in overall mortality and reduced burden of disease in the population, India serves as a great example to other countries and healthcare agencies to formulate an effective plan of action towards achieving global health.

Conclusion

The essence of this communication lies in the fact that there has been considerable progress in the Government's budget allocators and policymakers' consideration towards oral health and health, in general. Although an integral part of national upliftment, the oral health system of India is deficient in many aspects. The reorientation of oral health services is required to counteract the problems faced due to various oral diseases. Encouraging the system to bring about a change and help in providing attention to a systematic analysis of the oral health care system is necessary for the eradication of existing oral diseases.

About 50% of children in India under the age of six years live with untreated dental caries. This study throws light upon the need for the allocation of funds and the imposing of policies for the betterment of pediatric oral health and general oral health, and highlights the existence of numerous national health schemes devoted towards pediatric oral health such as Danta Bharat Yojna and Rasthriya Bal Swasthya Karyakram. The Union Health Budget allocates an average of 2.3% towards the pediatric health sector. However, the intricacies of this budget towards pediatric oral health is unknown. It is indeed high time to give due diligence to the importance of oral healthcare in India. The criticality and exigency of the deteriorating oral health status of children should not be undermined, as preventive care and pediatric oral care should be given as equal status as curative and restorative care.

The authors declare that this review is an independent opinion and that the authors do not support any particular government or political party or organization.

Author contributions

VK: Principle investigator and designing the study. RS: Protocol designing. RJ: Providing important intellectual content. NB: Providing important intellectual content. SY: Critical Revision of the study. AQ: Critical Revision of the study. HT: Critical Revision of the study. PM: Critical Revision of the study. All authors contributed to the article and approved the submitted version.

Acknowledgments

The authors wish to express their gratitude to Ridhima Gaunkar (Government Dental College and Hospital, Goa) and Jasleen Thakker (TPCT's Terna Dental College, Navi Mumbai) for their contributions towards addressing certain technical aspects of the article.

Conflict of interest

HT is employed by Suitradhaar Strategies Pvt Ltd.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

1. Lustig N. Investing in health for economic development: the case of Mexico. In: Mavrotas G, Shorrocks A, editors. *Advancing development: Core themes in global economics*. London: Palgrave Macmillan UK (2007). p. 168–82. (Studies in Development Economics and Policy). Available at: doi: 10.1057/9780230801462_10

2. Why budget 2021 is a good start for Indian healthcare? Financialexpress (2021). Available at: https://www.financialexpress.com/budget/why-budget-2021-is-a-good-start-for-indian-healthcare-2191007/ (Accessed March 11, 2023).

3. India budget | Ministry of finance | Government of India. Available at: https://www.indiabudget.gov.in/ (Accessed March 11, 2023).

4. PM Atma Nirbhar Swasth Bharat Yojana. Available at: https://pib.gov.in/Pressreleaseshare.aspx?PRID=1704822 (Accessed May 12, 2023).

5. Swachh Bharat Mission - Gramin. Department of drinking water and sanitation. Available at: https://swachhbharatmission.gov.in/SBMCMS/index.htm (Accessed May 12, 2023).

6. Mathur B. Union budget 2021 explained: Decoding the 137 Per Cent increase in health expenditure. NDTV-Dettol Banega Swasth Swachh India (2021). Available at: https://swachhindia.ndtv.com/union-budget-2021-explained-decoding-the-137-per-cent-increase-in-health-expenditure-56568/ (Accessed March 11, 2023).

7. Home: Pradhan Mantri Swasthya Suraksha Yojana (PMSSY). Available at: https://pmssy-mohfw.nic.in/ (Accessed May 12, 2023).

8. About PM-JAY - National Health Authority | GOI. Available at: https://nha.gov.in/PM-JAY (Accessed May 12, 2023).

9. National AIDS Control Programme V | National AIDS Control Organization | MoHFW | GoI. Available at: https://naco.gov.in/national-aids-control-programme-v (Accessed May 12, 2023).

10. Nath A. Pediatric HIV in India: current scenario and the way forward. *Indian J Public Health*. (2017) 61(2):124–130. doi: 10.4103/ijph.IJPH_314_15

11. Gupta I, Ranjan A. Public expenditure on non-communicable diseases & injuries in India: a budget-based analysis. *PLoS One*. (2019) 14(9):e0222086. doi: 10.1371/journal.pone.0222086

12. SCORE G. Rural Healthcare. Available at: https://iasscore.in/current-affairs/mains/rural-healthcare (Accessed March 11, 2023).

13. National Oral Health Programme (NOHP):: National Health Mission. Available at: https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=1044&lid=608 (Accessed March 11, 2023).

14. Basavaraj P, Singla A, Gupta R, Malhi R, Pandita V, Prasad M. Eliminating health disparities by implementation of oral health allocation in union budget – empowering change. *J PEARLDENT*. (2017) 8:16–31. doi: 10.5958/2229-4457.2017.00006.X

15. IPHS 2022 Guidelines | National Health Systems Resource Centre. Available at: https://nhsrcindia.org/IPHS2022/iphs-2022-guidelines (Accessed March 11, 2023).

16. Saekel R. Comparison of oral health Status in Asia: results for eight emerging and five high income countries or regions and implications. *Chin J Dent Res Off J Sci Sect Chin Stomatol Assoc CSA*. (2016) 19(4):191–206. doi: 10.3290/j.cjdr.a37144

17. CSR: Oral Health Awareness in India. Available at: https://thecsrjournal.in/csr-oral-health-awareness-in-india/.

18. Gururaj G. Injuries in India: a national perspective. *Burd Dis*. (2019).

19. Benzian H, Hobdell M, Holmgren C, Yee R, Monse B, Barnard JT, et al. Political priority of global oral health: an analysis of reasons for international neglect. *Int Dent J*. (2011) 61(3):124–30. doi: 10.1111/j.1875-595X.2011.00028.x

20. Rashtriya Bal Swasthya Karyakram (RBSK). Available at: https://rbsk.gov.in/RBSKLive/ (Accessed May 12, 2023).

21. Ganesh A, Muthu MS, Mohan A, Kirubakaran R. Prevalence of early childhood caries in India - A systematic review. *Indian J Pediatr*. (2019) 86(3):276–86. doi: 10.1007/s12098-018-2793-y

JIDA

Periodontology

Effectiveness of boric acid as an adjunct to scaling and root planing in the treatment of chronic periodontitis: A Systematic Review

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Access this article online

Quick Response Code:

Website: jida.ida.org.in

DOI: 10.33882/jida.15.34540

How to cite this article: Karnik S., Sah N. Effectiveness of boric acid as an adjunct to scaling and root planing in the treatment of chronic periodontitis: A Systematic Review, JIDA 2023; XVII; xx-xx
https://doi.org/10.33882/jida.15.34540

Abstract

Brief Background

Boric acid suppresses periodontal inflammation and diminishes alveolar bone loss. The objective of the study was to assess the effects of locally delivered 0.75% boric acid as an adjunct to scaling and root planing (SRP) as compared to SRP alone in treatment of subjects with chronic periodontitis.

Materials and Methods

An electronic search was made in the MEDLINE/ PubMed, CENTRAL, EBSCO, Google- Scholar and OpenGrey databases. Studies that reported the efficacy of boric acid in the treatment of chronic periodontitis were selected. The search strategy provided a total of 40 studies. After selection, data was extracted from 4 selected articles.

Results

4 studies were selected following independent screening by two reviewers. Due to considerable heterogeneity in the study design, a qualitative data analysis was performed. Randomized controlled trials have indicated significantly higher pocket reductions and clinical attachment gains following a combination of boric acid and SRP in comparison to scaling and root planing alone.

Summary and Conclusions

The local application of boric acid as an adjunct to SRP may result in significant improvement in periodontal parameters. Due to the highly heterogeneous data and some risk of bias, this data still needs to be interpreted with caution.

Key Words

Boric acid, Local drug delivery, Periodontitis, Scaling and root planing, Systematic review

Introduction

Periodontitis is an inflammatory response to microbial flora characterized by periodontal attachment loss and alveolar bone resorption which ultimately leads to tooth loss.[1] It has been shown that Porphyromonas gingivalis (Pg), Treponema denticola (Td), and Tannerella forsythia (Tf) are the most important species present in greater numbers in subgingival plaque of patients with periodontitis compared with healthy individuals.[2] The primary objective of periodontal therapy is the elimination of pathogenic organisms leading to resolution of inflammation and halting the disease progression.[3]

Mechanical therapy consisting of scaling and root planing is the gold standard nonsurgical therapy. However, mechanical therapy may fail to eliminate periodontal pathogenic species such as those invaded into periodontal tissues or in deep periodontal pockets because of limited access to the root surface.

Nonsurgical periodontal therapy is aimed to minimize or eliminate microbial biofilm using both mechanical and chemotherapeutic approaches.[15] This is achieved by means of local delivery of antimicrobial /pharmaco-potent agents using sustained-/controlled- release systems subgingivally, using numerous formulations as adjunct to mechanical debridement.[5]

Goodson et al. in 1979 introduced the concept of controlled release local drug delivery.[6] It eliminates problems associated with systemic therapy (such as drug toxicity and interactions and formation of resistant bacteria), limits the drug to its target site, and therefore, results in higher drug concentrations.

Till now, various antimicrobial agents have been used for local drug delivery in the treatment of periodontitis. Boric acid is one such which has been recently evaluated to be used locally in the treatment of chronic periodontitis.

Boron, a bioactive trace element with atomic number 5 and chemical symbol B, presents abundantly in the environment as boric acid and borate. It is frequently found in fruits, vegetables, and nuts. The supplementation of boron through diet in physiological amounts is known to influence numerous metabolic parameters.[7]

It has been demonstrated that boric acid suppresses periodontal inflammation and diminishes alveolar bone loss in experimental periodontitis in a ligature- induced rat model.[8] Recently, Luan et al[9] reported that a boron containing compound, AN0128, has both antibacterial and anti-inflammatory properties. They showed that the daily topical application of AN0128 (1%) in treating experimental- induced periodontitis resulted in reduced formation of an inflammatory infiltrate and bone loss in rats.[9] Boric acid was effective against Prevotella intermedia, Porphyromonas gingivalis, Eubacterium nodatum, and Treponema denticola.[12]

Boric acid increases osteogenic effects by stimulating osteogenic differentiation related marker gene synthesis during the proliferation and differentiation cycle in human bone marrow stromal cells.[26] Boric acid, along with osteoblasts, also affect the activity of osteoclasts.[10]

Although multiple studies have been conducted to find evidence on the therapeutic effects and benefits of boric acid, little is known about the use of this substance for periodontally diseased patients. Therefore, this systematic review was undertaken to evaluate the potentially beneficial effects of locally delivered boric acid as an adjunct to SRP during nonsurgical periodontal therapy in patients with periodontal disease.

Objectives

Primary Objective:

To assess the effects of locally delivered 0.75% boric acid as an adjunct to scaling and root planing (SRP)as compared to SRP alone in treatment of subjects with chronic periodontitis with respect to probing pocket depth (PPD) and clinical attachment level (CAL).

Secondary Objective:

To assess the effects of locally delivered 0.75% boric acid as an adjunct to scaling and root planing (SRP)as compared to SRP alone in treatment of subjects with chronic periodontitis with respect to plaque index (PI) modified sulcus bleeding index (mSBI), gingival index (GI), and patient reported outcome measures (PROMs).

Materials and Methods

The systematic review was conducted in accordance with the Preferred Reporting Items of Systematic Reviews (PRISMA) and Meta-analyses statement.[11]

The focused question was:

Does locally delivered 0.75% boric acid as an adjunct to scaling and root planing (SRP) improve the treatment results, in terms of Probing pocket depth and Clinical attachment level, compared to SRP alone in subjects with chronic periodontitis?

Eligibility Criteria –

The following eligibility criteria were entailed:

1. Randomized controlled trial (RCTs).
2. Original publications evaluating efficacy of locally delivered boric acid as an adjunct to SRP in treatment of chronic periodontitis.
3. Studies using local delivery device, either as gel or irrigation.
4. Comparative data available on SRP alone or locally delivered placebo as an adjunct to SRP.
5. Studies on human subjects.
6. Studies reporting one or more clinical periodontal parameters as outcome including probing pocket depth (PPD), clinical attachment level (CAL), plaque index (PI), gingival index (GI) and modified sulcus bleeding index (mSBI).
7. Studies published in English language only.

Exclusion Criteria –

Review Papers, In-Vitro Studies, Animal Studies, Case Reports, Commentaries, Interviews, Updates.

Information sources and search strategy -

An electronic search was made in the MEDLINE/ PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), EBSCO, Google- Scholar and OpenGrey databases up to and including Feb 28, 2021 for articles addressing the focused question.

The search strategy used was:

Types of studies: Longitudinal studies OR comparative study OR clinical trial OR controlled clinical trial OR randomized controlled trial.

Disease: Periodontitis OR periodontal diseases.

Therapy: (Boric acid) AND (subgingival curettage OR dental scaling OR root planing OR dental prophylaxis).

Study selection process -

Titles and abstracts of all identified reports were independently screened by two reviewers based upon the inclusion/exclusion criteria. Disagreement was resolved by discussion among the reviewers. Selected studies were then analyzed for data extraction.

Reviewers extracted data into specifically created excel spreadsheets. The collected data was then transferred into evidence tables to provide an overview of the included studies and available data.

The primary outcome variable was change in PPD and CAL. Secondary outcomes were changes in PI, mSBI and GI. Patient-reported outcome measures (PROMs) were also noted together with adverse events recording.

Risk of bias in individual studies -

Risk of bias of each included study was assessed using the recommended approach for assessing risk of bias in studies included in Cochrane Reviews (Higgins 2011).[4] It was based on random sequence generation, allocation concealment, blinding of participants & personnel, blinding of outcome assessors, incomplete outcome data addressed, free of selective reporting, free of other bias. Judgement of 'Yes' indicated low risk of bias, 'No' indicated high risk of bias, and 'Unclear' indicated unknown risk of bias. Risk of bias for each included study is presented in Table 3, Figure 2 and Figure 3.

Sr. No.		Saglam et al [13]	Singhal S et al [14]	Kanoriya D et al [15]	Mamajiwala A et al [16]
1.	**Random sequence generation**	Yes	Yes	Yes	Yes
2.	**Allocation concealment**	Yes	Yes	Yes	Yes
3.	**Blinding of participants & Personnel**	Yes-Participant blinding No - Operator blinding	Yes	Yes - Participant blinding Unclear - Operator blinding	Unclear
4.	**Blinding of outcome assessors**	No	Yes	Yes	Yes
5.	**Incomplete outcome data addressed**	Yes	Yes	Yes	Yes
6.	**Free of selective reporting**	Yes	Yes	Yes	Yes
7.	**Free of other bias**	No	Yes	No	No

Table 3: Risk of bias summary

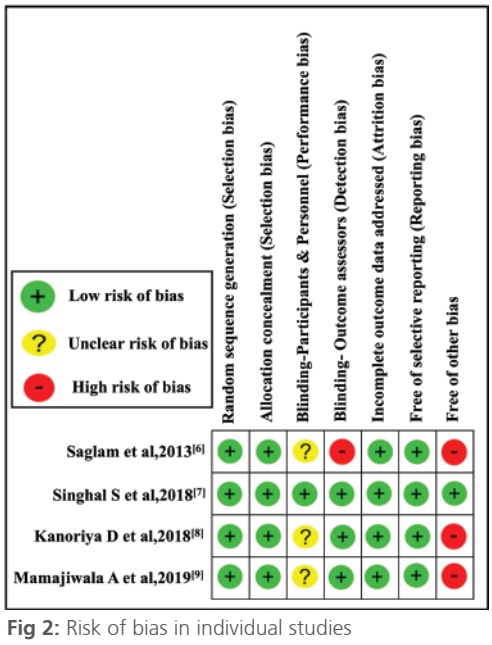

Fig 2: Risk of bias in individual studies

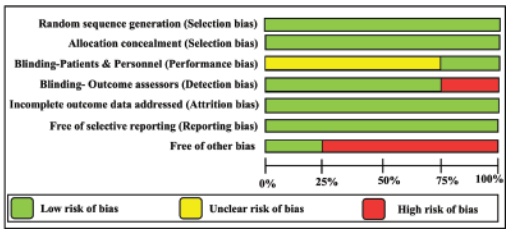

Fig 3: Risk of bias across studies

Results

Titles and abstracts of all identified reports were independently screened by two reviewers based upon the inclusion/exclusion criteria. The studies identified from the electronic database resulted in 40 studies. Full text reports were obtained and assessed independently and in duplicate for studies appearing to meet the inclusion criteria or with insufficient information in the title or abstract to confirm eligibility for inclusion. Finally, 4 studies were selected for full text assessment. Selected studies for this systematic review were analyzed for data extraction. Figure 1 is the flowchart that summarizes the article selection process. An overview of the existing studies is presented in Table 1. The excluded studies are presented in Table 2.

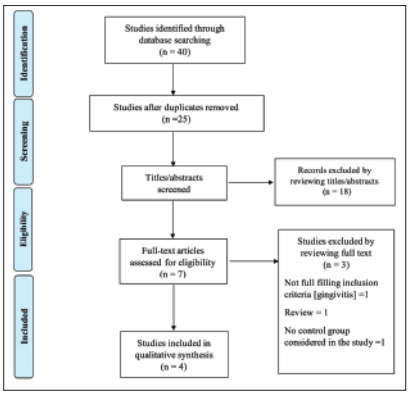

Fig 1: Flow chart of search strategy

First author, year of publication	**Saglam et al, 2013[13]**	**Singhal S et al, 2018[14]**	**Kanoriya D et al, 2018[15]**	**Mamajiwala A et al, 2019 [16]**
Study Design	Single-center, Single-masked (participants), Parallel-designed, Randomized placebo-controlled clinical trial.	Single center, Double-masked, Parallel-designed, Randomized placebo-controlled clinical trial.	Single center, Double-masked, Parallel-designed, Randomized placebo-controlled clinical trial.	Single-center, three-group, Parallel-designed, Randomized placebo-controlled clinical trial.
Population characteristics (no. of subjects, age, gender, country)	No.= 45 subjects; Age: 32-63years; Gender: Males-22 Females-23 Country: Turkey	No.= 64 subjects. Age: 30-50years; Country: India	No.= 42 subjects. Age: 25-55 years. Country: India	No.= 45 subjects Age: 18-55 years. Gender: Males-22 Females-23 Country: India
Inclusion criteria	1) ≥ 30 years old 2) ≥20 teeth 3) ≥8 sites with PPD≥5 mm.	buccal class II furcation defects in asymptomatic mandibular first molars, which are endodontically vital, along with a radiolucency in the furcation area, according to IOPA with PPD ≥5 mm, horizontal probing ≥3 mm following SRP.	1)systemically healthy 2)PPD ≥5mm or CAL ≥4 mm and vertical bone loss ≥3 mm on IOPAs. 3) ≥20 teeth	1)patients diagnosed with chronic periodontitis; PPD >5 mm post initial therapy and 2)systemically healthy patients.

First author, year of publication	**Saglam et al, 2013[13]**	**Singhal S et al, 2018[14]**	**Kanoriya D et al, 2018[15]**	**Mamajiwala A et al, 2019 [16]**
Periodontal diagnosis	Chronic periodontitis	Chronic periodontitis	Chronic periodontitis	Chronic periodontitis
Interventions	**Group 1**: SRP + saline irrigation **Group 2**: SRP + 0.2%chlorhexidine irrigation **Group 3**: SRP + 0.75%boric acid irrigation	**Group 1**: SRP +0.75% boric acid gel **Group 2**: SRP +placebo gel	**Group 1**: SRP +0.75% boric acid gel **Group 2**: SRP +placebo gel	**Group 1**: SRP +0.75% boric acid gel **Group 2**: SRP+1% chlorhexidine gel **Group 3**: SRP +placebo gel
Dosage form	Irrigation	Gel	Gel	Gel
Point in time of application	Once, at baseline after SRP	Once, at baseline after SRP	Once, at baseline after SRP	Once, at baseline after SRP
Follow up period (months)	1,3	3,6	3,6	3,6
Clinical parameters	PPD, PI, GI, CAL, BOP	RVCAL, RHCAL, PPD, PI, mSBI	PPD, PI, mSBI, CAL	PPD, GI, PI, mSBI, CAL
Microbiological parameters	Pg, Tf, Td (Quantitative analysis using PCR)	-	-	Aerobic flora (CFUs on blood agar)
Radiographic parameters	-	IBD	IBD depth (DDR%)	-
Patient reported outcome measures	No adverse reactions were reported.	No adverse reactions were reported.	No adverse reactions were reported.	No adverse reactions were reported.

Table 1: General characteristics of included studies

Sr. No.	Authors and year	Reason for exclusion
1.	Tasneem N [17]	Did not meet inclusion criteria [Included Gingivitis patients]
2.	Brignardello-Petersen [18]	Review
3.	Banerjee et al [19]	No control group used in the study

Table 2: Excluded studies with reasons for exclusion

Discussion

The present systematic review, aimed to evaluate the effectiveness of local antimicrobial agent boric acid in the management of chronic periodontitis.

All the studies[12-15] included in the present systematic review showed that boric acid as LDD showed significant improvements in the clinical periodontal parameters among the study groups. The boric acid group showed significantly greater PPD reduction and CAL gain at 3 and 6 months than the control group.[12,13,14] Also, the boric acid group demonstrated a significantly greater bone defect fill than the placebo sites at 6-month time interval.[13,14] Furthermore, studies have shown[12,15] that boric acid as an adjunct to SRP eliminated different species of bacteria, all of which are relevant in the treatment of chronic periodontitis.

Significant improvement in PI scores, suggested that patients had properly maintained the oral hygiene. The improved oral hygiene can be attributed to the Hawthorne effect.

GI and mSBI were the two indices chosen as markers of the gingival inflammatory process. The anti- inflammatory action of boric acid may be potential reason for improvement in the gingival inflammatory condition.

A study conducted by Luan et al[9] reported that boron-containing compound AN0128 has anti-bacterial activity

against Prevotella intermedia, Porphyromonasgingivalis, Enterococci, and Treponemadenticola. These results were contradictory to the results of the study conducted by Saglam et al[10], where they reported that boric acid irrigation did not have an additional advantage over the reduction of microbes. They proposed that 0.75% concentration of boric acid did not produce any cytopathic effect on periodontopathogens and thus was ineffective. The chances of washout of drug from the targeted site is higher with subgingival irrigation leading to an insignificant effect of boric acid on periodontopathogens in the study. However, the reduction in microbial count in the study by Luan et al[9] can be attributed to the use of a different vehicle for drug delivery.

Boric acid increases glutathione and other neutralizing agents of reactive oxygen species which prevents oxidative damage[19]. This fact validates the beneficial effect of local delivery of an agent with antioxidant property in the treatment of chronic periodontitis. Tepedelen suggested that boric acid has important therapeutic effectiveness, and could be used in the treatment of inflammatory diseases where oxidative stress and the wound-healing process play an important role[20]. Boric acid reduces the formation of DNA double- strand breaks caused by various agents (irinotecan, etoposide, doxorubicin, and H2O2), as well as improving the wound- healing process[21].

Boric acid application in the treated sites showed bone formation when analyzed radiographically at 6 months, suggesting an osseo-differentiation mechanism of boron[13,14]. According to Xu et al, in osteoporotic rats supplemented with dietary boron, an increase in the serum content of boron was found to stimulate bone formation and inhibit bone loss, thereby producing obvious therapeutic effects against osteoporosis.[22] Boron helps in the regulation of osteoblastic behaviour in MC3T3-E1 cells, and can provide novel usage in regenerative medicine.[23] Runt- related transcription factor- 2 (RunX2) is a transcription factor essential for osteoblast differentiation.[24] Hakki et al. observed that boron regulates the osteoblastic transcription factor RunX2 and bone morphogenetic proteins. Therefore, boron is a promising element for inducing osteogenesis.[23]

The major proteolytic enzymes (i.e., elastase, chymase, and cathepsin G) are serine proteases that degrade elastin and several other important proteins in the periodontium, including collagen, proteoglycans, and basement membrane components. The boron atom forms a tetrahedral B adduct, and thus inhibit serine proteases.[25]

All the studies, provided with the information that no treatment-related adverse events were reported.

One of the primary limitations of this analysis is the inclusion of RCTs published only in English. Despite significant heterogeneity, the data was pooled. The reviewers were unable to procure data from any ongoing trials. Hand searching of the relevant articles was also not carried out.

Conclusion

Within the limitations of this study, the current systematic review states the potential of adjunctive application of boric acid which resulted in a beneficial reduction of the probing pocket depth and clinical attachment gain. However, due to the heterogeneity of the data and several risks of bias, this evidence needs to be interpreted with caution.

Acknowledgement

None

Conflict of Interest

No conflicts of interests.

References

1. Page RC, Offenbacher S, Schroeder HE, Seymour GJ, Kornman KS. Advances in the pathogenesis of periodontitis: Summary of developments, clinical implications and future directions. Periodontol 2000 1997;14:216-48.
2. Holt SC, EbersoleJL.Porphyromonasgingivalis,Treponema denticola, and Tannerella forsythia: The "red complex", a prototype polybacterial pathogenic consortium in periodontitis. Periodontol 2000 2005;38:72-122.
3. Greenstein G, CatonJ.Periodontal disease activity: A critical assessment.JPeriodontol 1990;61:543-52.
4. Higgins JP,Green S.Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0(updated March 2011). The Cochrane Collaboration, 2011.
5. Elavarasu S, Suthanthiran TK, Naveen D. Statins.A new era in local drug delivery. J Pharm BioalliedSci 2012;4:248-51.
6. Goodson JM, Haffajee A, Socransky SS. Periodontal therapy by local delivery of tetracycline. J ClinPeriodontol 1979;6:83-92.
7. Uysal T, Ustdal A, Sonmez MF, Ozturk F. Stimulation of bone formation by dietary boron in an orthopedically expanded suture in rabbits. Angle Orthod 2009;79:984-90.
8. Demirer S, Kara MI, Erciyas K, Ozdemir H, Ozer H,AyS.Effects of boric acid on experimental periodontitis and alveolar bone loss in rats. Arch Oral Biol 2012;57:60-5.
9. Luan Q, Desta T, Chehab L, Sanders VJ, Plattner J, Graves DT.Inhibition of experimental periodontitis by a topical boron-based antimicrobial. J Dent Res 2008;87:148-52.
10. Gorustovich AA, Steimetz T, Nielsen FH,Guglielmotti MB. A histomorphometric study of alveolar bone modelling and remodelling in mice fed a boron-deficient diet.Arch Oral Biol 2008;53:677-82.
11. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A Petticrew M et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement, Syst Rev 4: 1.
12. Saglam M, Arslan U, Buket Bozkurt S, Hakki SS. Boric acid irrigation as an adjunct to mechanical periodontal therapy in patients with chronic periodontitis: A randomized clinical trial. J Periodontol 2013;84:1297-308.
13. SinghalS, Pradeep AR, Kanoriya D, Garg S, Garg V. Boric acid gel as local drug delivery in the treatment of class II furcation defects in chronic periodontitis: A randomized,controlled clinical trial.J Invest Clin Dent 2017;9:e12279.
14. Kanoriya, D., Singhal, S., Garg, V., Pradeep, A. R., Garg, S.,& Kumar, A.Clinical efficacy of subgingivally-delivered 0.75% boric acid gel as an adjunct to mechanotherapy in chronic periodontitis: A randomized, controlled clinical trial.J Invest Clin Dent 2017;9(1):e12271.
15. MamajiwalaA,Sethi KS, Mahale SA,Raut CP, Karde P A, Kale AM.Comparative evaluation of boric acid gel versus chlorhexidine gel in the treatment of chronic periodontitis: Randomized, placebo-controlled clinical study. ContempClin Dent 2019;10:457-64.
16. Tasneem N, AN Savitha, Jayaram P and AR Pradeep. Efficacy of 0.75% Boric Acid and 0.2% Chlorhexidine Subgingival Irrigation as an Adjunct to Scaling and Root Planing in the Treatment of Gingivitis. A Comparative Clinico-Microbiological Study. J Oral Biol 2019;6(2):1-5.
17. Brignardello-Petersen, R. Boric acid probably increases clinical attachment level and reduces probing depth and intrabony defect depth when used as an adjunct to scaling and root planing in patients with chronic periodontitis. J Am Dent Assoc 2017;148(9):e127.
18. Banerjee S, Mathur A, Shetty N, Makhijani B, Bali A, Manohar B. Subgingival Periodontal Pre-Treatment Irrigation with 0.75% Boric Acid as an Adjunct to Mechanical Periodontal Therapy in Localised Chronic Periodontitis. J Nepal SocPerio Oral Implantol 2019;3(5):9-120.
19. Ince S, Kucukkurt I, Cigerci IH, Fatih Fidan A, EryavuzA.The effects of dietary boric acid and borax supplementation on lipid peroxidation, antioxidant activity, and DNA damage in rats. J Trace Elem Med Biol 2010;24:161-4.
20. Tepedelen BE, Soya E, Korkmaz M. Boric acid reduces the formation of DNA double strand breaks and accelerates wound healing process. Biol Trace Elem Res 2016;174:309-18.
21. DemirciS, Dogan A, AydinS , Dulger EC, Sahin F. Boron promotes streptozotocin-induced diabetic wound healing: roles in cell proliferation and migration,growth factor expression, and inflammation.Mol Cell Biochem 2016;417:119-33.
22. Xu P, Hu WB, Guo X, etal.Therapeutic effect of dietary boron supplement on retinoic acid- induced osteoporosis in rats. Nan Fang Yi Ke Da XueXueBao 2006;26:1785-88.
23. Hakki SS, Bozkurt BS, Hakki EE. Boron regulates mineralized tissue associated proteins in osteoblasts (MC3T3- E1). J Trace Elem Med Biol 2010;24:243-50.
24. Franceschi RT, Ge C, Xiao G, Roca H, Jiang D. Transcriptional regulation of osteoblasts. Cells Tissues Organs 2009;189:144-52.
25. Hunt CD. Dietary boron: an overview of the evidence for its role in immune function. J Trace Elem Exp Med 2003;16:291-306.
26. Ying X, Cheng S, Wang W, et al. Effect of boron on osteogenic differentiation of human bone marrow stromal cells. Biol Trace Elem Res 2011;144:306-15.