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### MESSAGE

I would like to begin with a hope and desire that all our healthcare providers are safe in this unexpected battle against COVID-19 pandemic which has gripped the world and has cost so much in life & resources.

First of all, I would like to congratulate the Chief and associated Editors, Advisory Board comprising of Professors from various distinguished institutions, other faculty members and contributors, patrons and our beloved students and researchers associated with the Journal of Oral and Dental Health. It gives me tremendous delight to see this journal bringing up yet another issue. I want to specially congratulate **Mithila Minority Dental College & Institution** for its brilliant effort and statesmanship for making the Journal of Oral and Dental Health the official publication of L.N. Mithila University, Darbhanga.

It gives me immense pleasure to see the Journal in widespread circulation and benefitting numerous researchers and academicians in their quest for scientific temper and knowledge. This Journal and its issues are greatly benefitting Dental professionals and practitioners associated with the field of Dentistry and its allied post-graduate branches, thereby providing an overall enlightenment.

Today, Dentistry has evolved much since its inception and humble beginnings. The skeletal and aesthetic treatment & satisfaction of a patient often involves an interdisciplinary approach. As such, the Journal of Oral Dental Health through its collection of brilliant researches from all across the country, Epidemiological studies and data presented in its various issues boost a lot of confidence in young surgeons and Dentists alike.

I would conclude by wishing lots of success to the Editorial and Advisory Board in its present and future endeavours.

**Best wishes & regards,**

  
Surendra Pratap Singh

## MESSAGE FROM THE MANAGING DIRECTOR

—It is the supreme art of the teacher to awaken joy in creative expression and knowledge.

**Albert Einstein**

I am extremely happy and proud that a new issue of our esteemed Journal is being published. Our editorial team is continuously working hard to upgrade the quality of the publications. I am sure that these articles will be of extreme help to upgrade the knowledge of dental education.

Our faculties and post graduate students are getting an opportunity to publish their work which I am very happy about. And I came to know that even authors from many other Dental Colleges are contributing their articles. This I believe will be an excellent platform for sharing scientific thoughts.

With more and more original articles pouring in, I am sure that Journal of Oral & Dental Health will be one of the premium Journals in the field of Dentistry.

Wishing success and best wishes to the Editorial team.



**Imbesat Shaukat**

*Managing Director  
Mithila Minority Dental College & Hospital,  
Darbhanga, Bihar*

## MESSAGE FROM THE EDITOR IN CHIEF

Dear Readers,

Authors of various articles are appreciated to be chosen for publication in “Journal of oral & dental health”. However our priority of publication always remains towards innovative research work. Till date no concrete work has been done on prevention of spread of viral infection from patient to dental surgeon or vice versa.

So, scope is available for research & innovation. Hope authors take interest to go ahead with research on this aspect and bring shield of Protection.



**Dr. Arunachalam Sudheer,**  
Principal, Professor & Head, Prosthodontics and Crown & Bridge  
Editor in Chief  
Journal of Oral & Dental Health

Mithila Minority Dental College & Hospital  
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## MESSAGE FROM THE ADVISORY BOARD

*—Research is the creation of new knowledge!*

**- Neil Armstrong**

Greetings to one & all!

It gives me immense pleasure to welcome all avid readers to this inaugural edition of the Journal of Oral and Dental Health. This Journal is an official publication of the Mithila Minority Dental College & Hospital, Darbhanga (Bihar) affiliated to the State run Lalit Narayan Mithila University, Darbhanga, Bihar State (India) established and administered by the State Govt. of Bihar State and holds abundant potential to provide a platform for budding research professionals in Dental Sciences across the country and the South East Asian region.

In today's era of constant need of advanced technologies in every discipline, it has become imperative for young professionals and academicians alike to keep themselves updated with the latest scientific innovations & break through. This is only possible through a constant review of scientific literature and adopting a temperament of scientific research.

Every scientific breakthrough has been made possible only by inculcating a scientific temperament which promotes scientific curiosity & research in individuals. Research is a constant and dynamic pursuit of an idea and developing into a hypothesis, testing it through various methodologies which finally culminates into publishing it through various platforms.

A publication signifies the efforts of various individuals associated with an idea and the results and thus a scientific journal is a worthy platform which helps in showcasing these efforts. This journal, a culmination of efforts from stalwarts of various disciplines, will definitely prove to be wonderful opportunity for academicians as well budding professionals

My gratitude to the Founder Chairman of Mithila Minority Dental College & Hospital and the leadership of this journal, the Chief Patron – Acharya Shaukat Khail for his invaluable guidance. I thank the Patron of the Journal as well as Managing Director of MMDCH Mr. Imbesat Shaukat for getting me on board with this wonderful initiative. I thank the Editor in Chief, Dr. Rohit Miglani and the rest of the Editorial Board for their support.

I also take this opportunity to invite faculties in various dental institutes, clinicians, students, etc. to contribute to this journal by sending in their scientific studies and help enhance the scientific content of our discipline of dentistry.

Lastly, I congratulate the authors of the articles of this inaugural edition for successful publication of research.



Thank You

Regards

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# Comparison Of Palatal Morphology In Angle's Class I And Class II Malocclusions In Mithilanchal Population

## Abstract

**Objective:** To compare palatal morphology between Angle's Class I and Class II malocclusions in Mithilanchal population of Bihar.

**Materials and methods:** The study was done on 100 study models belonging to 50 (50%) male and 50 (50%) female comprising of 50 Class I and 50 Class II malocclusions meeting the inclusion criteria. The samples were collected from the pre-treatment records of the Department of Orthodontics. Mean values of each variable were calculated and compared between the two malocclusion groups. Independent sample t-test was performed to analyse the significant difference at  $P \leq 0.05$ .

**Results:** Palatal Index was found to be significantly larger in Class II malocclusion  $46.95 \pm 5.55$  (%) as compared to Class I malocclusion  $44.67 \pm 5.16$  (%). This was because of the deficient transverse development of maxillary arch in Class II malocclusion in relation to palatal vault development.

**Conclusion:** Palatal morphology varies between Angle's Class I and Class II malocclusions in Mithilanchal Population. This variation could be an important factor in diagnosis, treatment planning, and long-term stability of the orthodontic treatment.

**Keywords:** Angles's class I & Class II malocclusions; Palatal morphology; Mithilanchal.

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## INTRODUCTION

The palate is situated just below the maxillary sinus and the nasal cavity in the maxillary region and it is composed of hard and soft palates.<sup>1</sup> Hard palate contributes to the separation of the oral and nasal cavities.<sup>2</sup> It is associated with maxillary dentition and supports them.<sup>3</sup>

The morphology of palate plays an important role in defining the skeletal and facial pattern of an individual.<sup>4</sup> Due to its morphology and position, it is considered to be a key anatomical structure that determines skeletal patterns.<sup>5</sup>

A balanced face with proper occlusion has a superb relationship between its dental and osseous elements. Assessing and recognising the osseous or dental configuration of an arch is useful while planning treatment needs in any individual case.<sup>6,7</sup> Palatal morphology can be influenced by orthodontic treatment because orthodontic treatment mainly requires modifications in arch dimensions for the correction of the existing malocclusions.<sup>8</sup> Hence, analysis of osseous or dental arch dimensions are primary importance in orthodontic treatment planning.<sup>9</sup>



Based on individual's facial form, their arch form can be easily recognized. For example, brachiocephalic persons commonly have broad dental arches, whereas dolichocephalic persons have long or narrow dental arches and mesocephalic persons usually have paraboloid or average dental arches.<sup>10</sup>

The palatal depth, height and length are influenced by various factors, including the shape and size of the jaws and the type of malocclusion. One of the major goals of orthodontic treatment is the stability of the post-treatment results, as the arch shape appears to return to the original shape.<sup>11</sup>

In addition, normal palatal dimension values can be also used as a basis while studying oral developmental abnormalities<sup>12</sup>

Several reports shows Palatal dimensions can be influenced by ethnicity,<sup>13</sup> dietary regimes,<sup>14</sup> and environmental factors.<sup>6</sup>

Buschang et al. (1994) found greater palatal height and constricted maxillary dental arch in subjects with Class II division 1 malocclusion as compared to Class II division 2 malocclusion.<sup>15</sup> Nahidh et al. (2012) found that Class I subjects had larger palatal width and palatal depth as compared to Class II and Class III, while Class II subjects had larger palatal length. There are several literatures related to arch length and arch width on Indian subjects, however the investigations on palatal morphology (width, height and palatal index) are not readily available. Hence, the purpose of this study was to evaluate the palatal morphology in most common malocclusion groups namely Angle's Class I and Class II malocclusions in adult Mithilanchal population.

## MATERIALS AND METHOD

The aim of this study is to derive soft tissues norms for the Mithilanchal population. The present study is an observational, descriptive, cross-sectional study carried out on pre-treatment study models of patients who reported to Department of Orthodontics & Dentofacial Orthopaedics, Mithila Minority Dental College, Darbhanga, Bihar. The ethical approval was taken from Institutional Review Committee of the college. The study was carried out during November and December 2022.

Sample size was calculated to be 50 in each class of malocclusion. Inclusion criteria were: pre-treatment cast with Angle's Class I or Class II malocclusion with the subjects of age group 18-30 years. Poor grade study model, cases with cleft palate, missing or malformed permanent first molar were excluded. The sample consisted of study models of 50 females and 50 males.

In this study, the palatal width was measured between left and right first molars at the point of intersection of transverse fissure with the buccal fissure using digital Vernier caliper (Measuring range: 0-150 mm; Accuracy: 0.01 mm).<sup>16</sup> The

vertical distance between palatal depth and occlusal surface at first molar region was measured using metallic scale and depth rod of digital Vernier caliper. The vertical distance between depth of first molar fissure and height of palatal cusp of first molar was subtracted from this distance to obtain the height palate as described by Korkhaus.<sup>7</sup>

Palatal height index (PHI) calculated as:

$$PHI = \frac{PH \times 100}{PW}$$

Intra-observer variation was checked for korkhaus palatal height index on randomly selected 100 casts after seven days from the initial measurement. Kappa test showed substantial intra- observer agreement for measurements as the value was above 0.75. Statistical analysis was done using IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, N.Y., USA). Independent sample t-test was performed as the data was normally distributed as checked by Shapiro-Wilk test. Statistical level of significance was set at  $P \leq 0.05$ .



## RESULTS

Table 1 shows the comparison between Angle's Class I and Class II malocclusions and Table 2 the comparison of palatal width, height and palatal height index between the gender groups.

Parameters	CLASS	N	Mean	Std. Deviation	t- test	p-value
PALATAL	Class I	50	21.21	2.49	0.637	0.039*
	Class II	50	21.58	2.41		
PALATAL	Class I	50	47.34	2.42	1.427	0.130
	Class II	50	45.56	2.45		
PALATAL	Class I	50	44.67	5.16	0.244	0.006*

\* $P \leq 0.05$  significant t- independent test

INDEX (%)	Class II	50	46.95	5.55		
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Graph 1: Shows mean of palatal dimension between two malocclusions



Table 2: Comparison of palatal dimension among gender

Parameters	GENDER	N	Mean	Std. Deviation	t- test	p- value
PALATAL HEIGHT	Male	50	22.08	2.71	2.764	0.007*
	Female	50	20.76	2.00		
PALATAL WIDTH	Male	50	45.80	2.68	-.0581	0.562
	Female	50	46.10	2.47		
PALATAL INDEX (%)	Male	50	44.67	5.95	3.115	0.002*
	Female	50	46.95	5.22		

Mean values of palatal width in Class I and Class II division were  $47.34 \pm 2.42$  mm and  $45.56 \pm 2.45$  mm respectively; the difference was not significant. Mean values of palatal height in Class I and Class II malocclusions were  $21.21 \pm 2.49$  mm and  $21.58 \pm 2.41$  mm respectively; the difference was significant. Palatal height index in Class I and Class II malocclusions were

Palatal height was lesser in female compared to male with a significant difference. Palatal height was lesser in Class I malocclusion with significant difference.

Evaluation of arch dimensions is significant in diagnosis and treatment planning, and predicting the treatment outcome. Hence, it is essential for an orthodontist to be acquainted with usual growth and development of the dentition and dental arch.

In the present study, the palatal height index was  $44.67 \pm 5.16$  (%) in Class I and  $46.95 \pm 5.55$  (%) in Class II malocclusion. The average index value for Caucasian population is 42 (%). The present value for Class I malocclusion is in accordance with the Caucasian norms. Palatal height index is increased in Class II malocclusion due to the diminished transverse arch development with respect to the palatal height.

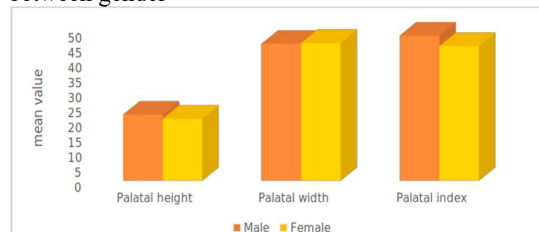
## CONCLUSION

Palatal width in Mithilanchal population has no significant difference in Class I malocclusion when compared to Class II malocclusion. Similarly, palatal width is lesser in male than the female samples. Palatal height is significantly increased in

$44.67 \pm 5.16$  (%) and  $46.95 \pm 5.55$  (%), respectively; the difference was significant.

\* $P \leq 0.05$  significant t- independent test

**Graph 2:** Shows mean of palatal dimension between gender



The mean values of palatal height in male and female were 22.08 mm and 20.76 mm respectively and the mean values of palatal height index in male and female were 48.55 mm and 45.06 mm respectively; the differences were statistically significant. Palatal width in male and female were 45.80 and 46.10 respectively; the difference was not significant.

## DISCUSSION

In the present study, palatal width was found to be greater in female compared to male with no significant difference. Similarly, palatal width was lesser in Class II compared to Class I with no significant difference.

males than in females and the palatal height index is significantly increased in males than in females.

Palatal morphology should be considered in diagnosis and treatment planning of different malocclusions as it can affect the treatment outcome and its stability.

**Conflict of Interest:** None.

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# A Surgical Re-Entry Study On The Effectiveness Of Autologous Platelet-Rich Plasma Gel And Bovine Porous Bone Mineral-Bio-Oss® In The Treatment Of Periodontal Intrabony Defects In Humans

## Abstract

**Aim:** To evaluate the efficacy of a combination of autologous Platelet-Rich Plasma (PRP) gel and Bovine Porous Bone Mineral (BPBM)-Bio-Oss® in the treatment of periodontal intrabony defects.

**Material and Methods:** A clinical trial was done in a total of 10 patients with the age group of 35-55 years having at least one intrabony defect. The effect of PRP gel and BPBM-Bio-Oss® on the clinical parameters like Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), Gingival Recession (GR) and Clinical Attachment Level (CAL) were evaluated. Radiographic bone levels and re-entry bone fill clinically were recorded.

**Results:** The results showed that there was statistically significant difference from baseline to 9 months, reduction in PPD up to  $6.60 \pm 1.43$  mm (73.3%), gain in mean CAL of  $4.70 \pm 0.76$  mm (27.4%), radiographic mean defect fill and defect resolution of  $4.04 \pm 1.77$  mm (86.5%) and  $3.12 \pm 1.06$  mm (66.5%) respectively. Surgical re-entry defect fill was 87.7% and defect resolution was 86.6%.

**Conclusion:** It was concluded that the combined technique with autologous PRP gel and bovine porous bone mineral-Bio-Oss® is an effective modality of regenerative treatment for periodontal intrabony defects. Further studies are necessary to elucidate the role played by PRP per se in different forms and in a combination therapy with various bone grafts in achieving these results.

**Key words:** intrabony defects; platelet-rich plasma; bovine porous bone mineral; regenerative periodontal therapy; surgical re-entry; Bio-Oss®

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## INTRODUCTION

Periodontal disease is regarded as the second most common dental disease worldwide after dental decay. Chronic periodontitis affects about 750 million people or about 10.8% of the world population as of 2010. And according to Global

Burden of Disease study (GBD, 1990-2017), severe periodontitis is the 6<sup>th</sup> most prevalent disease worldwide, with an overall prevalence of 11.2% and around 796 million people affected (Bernabe et al.2020). The prevalence of periodontal disease in

Indian population in the age group of 35-45 years was 89.6% (Shaju et al. 2011). Periodontitis being the major cause of tooth mobility and morbidity, the ultimate goal of periodontal therapy includes the arrest of progression of periodontal disease and the restoration of the lost supporting structures (cementum, periodontal ligament and alveolar bone) destroyed by the disease process. It finally results in achieving healthy and functional periodontium that aids in the long-term maintenance of the dentition (Marx. 2004).

Tissue Engineering is a highly promising field of reconstructive biology, is considered to be an attempt to regenerate the tissue/organ of the body. The biological events can take place in the laboratory or directly in the patient by combining three key elements; scaffolds or matrices, signalling molecule (Growth Factors) and the cells. Growth factors (GF's) are naturally occurring polypeptides that have the ability to regulate the key cellular events in tissue regeneration. These GF's have received a great deal of attention in the periodontal and craniomaxillofacial fields (Pieri et al. 2008). GF's are mitogenic (proliferative), chemotactic (stimulate directed migration of cells) and angiogenic (stimulate new blood vessels formation). Therefore, they appear to be critical in the wound healing process. Platelets have many functions beyond that of simple haemostasis. They contain important GF's including Platelet Derived Growth Factors (PDGF-AB & PDGF-BB), Vascular Endothelial Growth Factor (VEGF), Fibroblastic Growth Factor (FGF), Insulin-like Growth Factor (IGF), and Transforming Growth Factor- $\beta$  (TGF- $\beta$ ) in their  $\alpha$ -granules (Christgau et al. 2006). A concentrate of these platelets is obtained from the patient's own blood. Ultracentrifuge and gradient density cell separators are used to sequester and concentrate platelets; the autologous platelet-rich plasma (Appel et al. 2002). This PRP is activated by topical bovine thrombin and 10% calcium chloride to obtain a gel. The activated PRP gel is then placed in the osseous defects either alone or in combination with bone graft material (Lekovic et al. 2002), (Fabbro et al. 2011).

A variety of bone graft materials are available for use in periodontal regeneration. The autogenous bone graft have been referred to as the "gold standard" in osseous grafting procedures. However, the limited availability and the complications associated with the donor sites are its main disadvantages. Hence, allogenic materials (Freeze Dried Bone Allografts or Demineralized Freeze-Dried Bone Allografts), xenografts or alloplastic materials are being the mainstay of periodontal regeneration (Sculean et al. 2004). Xenografts fulfil most of the criteria of an ideal graft material. They are osteoconductive, readily available and are free of disease

transmission. The bovine porous bone mineral is a xenograft prepared by protein extraction of bovine bone, in which all inorganic components are removed, this result in a structure similar to human cancellous bone and has the ability to enhance bone formation in periodontal intrabony defects (Richardson et al. 1999).

## MATERIAL AND METHODS

### Patient Selection

A total of ten patients (2 males and 8 females) for the proposed study were selected from the Out Patient Department of Periodontology, Bapuji Dental College and Hospital, Davangere.

**Inclusion Criteria:** Patients in the age group of 35-55 years with a mean age of  $45 \pm 5$  years, in good systemic health with no contraindication to periodontal surgery, having at least one three walled intrabony defect with pocket depth of  $\geq 6$  mm in any one quadrant and with radiographic evidence of vertical/angular bone loss in the affected site. Patients not received any type of periodontal therapy for the past 6 months, not taking any immuno-suppressive Drugs like corticosteroids and with absence of any bleeding disorders. It was seen to that the, involved teeth were vital and asymptomatic.

**Exclusion Criteria:** Patients with one walled defects, suffering from any systemic diseases or with compromised immune system, allergic to tetracycline or chlorhexidine or any other medicine to be used in the study, taking any Drugs known to cause gingival enlargement. Pregnant and lactating mothers, smokers, those on anticoagulant therapy and endodontically treated teeth were excluded. Patients showing unacceptable oral hygiene compliance during or after the phase I therapy were also excluded.

All patients were given instruction as to the character and purpose of the study and signed an informed consent. The study design, consent and ethical committee clearance were approved by Rajiv Gandhi University Of Health Sciences, Bangalore, Karnataka, India.

### Pre-surgical Procedure

The Plaque Index (Silness & Loe. 1964) & Gingival Index (Loe & Silness. 1963) were recorded at baseline, 1 month, 3 months, 6 months and 9 months post-surgery. The following clinical parameters were recorded at baseline, 3 months, 6 months and 9 months post-surgery: 1. Probing Pocket Depth: Recorded with the help of Williams graduated periodontal probe from the crest of the gingival margin to the base of the pocket. 2. Clinical Attachment Level: Two measurements are used to calculate the CAL, the probing depth and the



distance from the gingival margin to the CEJ. The gingival margin could be at the CEJ, above or below the CEJ. 3. Gingival Recession: Measured as the distance from Cemento-Enamel Junction (CEJ) to the gingival margin. CAL & GR were measured using customized occlusal acrylic stent with guiding grooves and a silver point, which provided the fixed reference point (Lynch.1992).

Intra-oral periapical (IOPA) radiographs of the selected sites were taken using long cone paralleling technique and the radiographic evaluation was done at baseline, 6months and 9months post-surgery (Meffert et al. 1985) using the computer assisted image analysis. All the scanned radiographs were in RGB which was converted to a grey scale of 8 bytes. The brightness and contrast were auto adjusted uniformly for all the radiographs. After standardizing the radiographs, they were magnified at 10x, 20x and 50x. From these standardized and magnified radiographs, the linear measurements were recorded. Amount of defect fill was measured as initial distance from the CEJ to base of the defect minus 9months post-surgery distance from CEJ to the base of the defect. Defect resolution was measured as the initial distance between the crest of the alveolar bone to the base of the defect minus 9months post-surgery distance from alveolar crest to the base of the defect. Change in the alveolar crest height was measured as the initial distance from the CEJ to the alveolar crest minus 9months post-surgery distance from the CEJ to the alveolar crest. Clinical parameters that were recorded at surgical re-entry: 1. Mean bone defect fill, 2. Mean defect resolution & 3. Change in alveolar crest height.

Following initial examination and treatment planning, the selected subjects underwent phase I therapy, a thorough full mouth scaling and root planing were performed under local anesthesia followed by oral hygiene instructions. Occlusal adjustments were performed if trauma from occlusion was diagnosed. After 4-6 weeks, only those patients maintaining optimum oral hygiene were subjected to the surgical procedure (De Bruyckere et al. 2018).

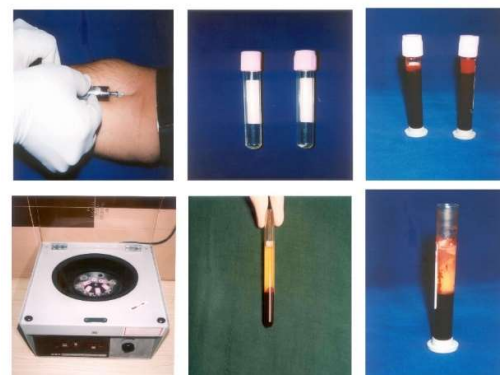
### Statistical Analysis

Results were averaged out (mean±standard deviation) for each parameter. The net difference between each pair of measurements was then calculated (pre and postoperative). The statistical evaluation of the changes from baseline to 9months was done using paired 't'-test. The level of statistical significance is often expressed as a p-value between 0 & 1. The smaller the p-value, the stronger the evidence that you should reject the null hypothesis. A p-value less than 0.05 (<0.05) is statistically

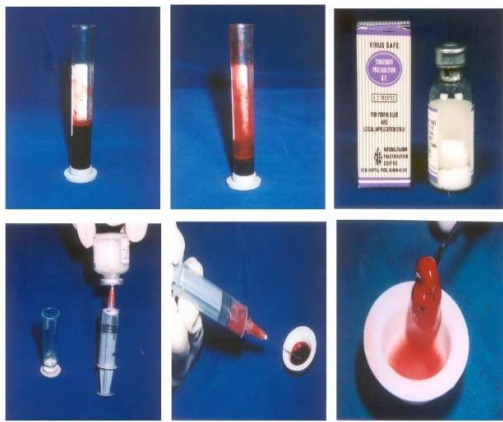
significant. A p-value higher than 0.05 (>0.05) is not statistically significant.

### PRP Preparation

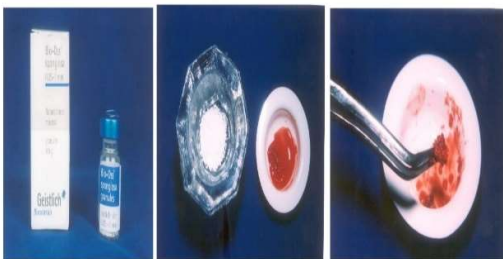
On the day of surgery, 10 ml of blood was drawn from the patient by venepuncture of the antecubital vein. Blood was collected in glass tubes (vacutainer) that contained 10% trisodium citrate solution as an anticoagulant. The tubes were placed into the centrifuge device, always ensuring that the tubes are counterbalanced as per the centrifuge manual. The glass tubes containing the blood were centrifuged at 1,300 rpm for 10 min, which resulted in the separation of whole blood into three basic fractions; Platelet-Poor Plasma (PPP) was on top of the preparation, Platelet-Rich Plasma (PRP) often called the "Buffy coat" in the middle, followed by the Red Blood Cell (RBC) fraction at the bottom. Two milliliters of the top layer corresponding to PPP was aspirated with a Pasteur pipette and discarded. The middle layer PRP was collected into another glass tube without anticoagulant in conjunction with the top 1-2mm of the RBC fraction, since the latter is also rich in newly synthesized platelets. The tubes were inserted into the centrifuge machine for another 10 minutes rotation at 2,000 rpm a 2nd centrifuge. This resulted in two layers, the upper layer of clear yellow supernatant serum, containing fibrinogen, with a very low concentration of platelets and the bottom layer often red tinged, consists of highly concentrated PRP or cPRP. The upper layer is discarded and the cPRP is drawn into a syringe and expressed into a sterile container. (Fig1.- 3.) Equal volumes (0.5ml) of sterile saline solution containing 10% calcium chloride ( $\text{CaCl}_2$ ) and 1000U/ml of thrombin is taken, cPRP is then added to this mixture in a ratio of 10:1, i.e., 1ml cPRP to 0.1ml thrombin- $\text{CaCl}_2$  solution, within 10 seconds a sticky gel is formed. This PRP gel can now be used alone or in combination with a bone graft in the ratio of 1:1, in the bone defects.



**Figure 1. (A) Drawing blood from antecubital region (B) Anticoagulant coated test tubes (C) Blood in the test tube (D) Centrifuge machine (E & F) After 1<sup>st</sup> centrifugation**



**Figure 2. (A) Test tube for 2<sup>nd</sup> centrifugation (B) PRP after 2<sup>nd</sup> centrifugation (C) Thrombin (D & E) Mixing thrombin & PRP (F) PRP gel**



**Figure 3. (A) BioOss (B) BioOss + cPRP (C) Cohesive mass of BioOss + cPRP**

### Surgical Procedure

Xylocaine 2% with aDrenaline (1:80,000) was used to anesthetize the operative site. After achieving adequate anesthesia, crevicular incisions were given on the facial and lingual/palatal sides reaching the tip of the interdental papilla using Bard-Parker (B.P.) knife-handle with blade No.12 and an interdental incision with No.11 blade. A full thickness mucoperiosteal flap was reflected using the periosteal elevator, taking care that the interdental papillary tissue was preserved or retained as far as possible. After reflection of the flap and exposure of osseous defect, the inner surface of the flap was curetted to remove the epithelium and granulation tissue, a thorough surgical degranulation of the infected tissue from the osseous defects was done (Fig. 4, 7 & 8) using Gracey curettes, 4R-4LColumbia and Universal Curettes (Hu-Friedy). Thorough root planing was done using hand instruments and ultrasonic scalers and the surgical site was then irrigated with normal saline. After open flap debridement was done the flaps were partially presutured. The required quantity of BPBM-Bio-Oss® bone graft was transferred to the dappen dish and mixed with the PRP gel obtained from the patient's own blood at a proportion of 1:1. A cohesive mass was obtained which was delivered into the osseous defect with light incremental pressure using the scoop of a Cumine scaler (Hu-

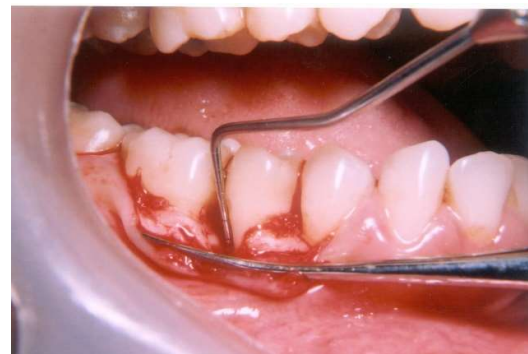
Friedy). The material was loosely packed from the base of the defect coronally, till the level of CEJ but overfilling or under filling of the defect was avoided. (Fig. 6 & 11) The presutured mucoperiosteal flaps were repositioned and secured in place using the black braided (4-0) silk sutures. Periodontal Dressing Coe-Pak™ (Cheshire et al. 1996) was placed over the surgical area. Post operative instructions were given to the patients. All patients were prescribed systemic Doxycycline HCl 200mg for first day followed by 100mg/day for 6days, combination of Ibuprofen (400mg) and Paracetamol (500mg) thrice daily for 3days and Chlorhexidine Gluconate (0.2%) (Soldner et al. 2019) mouth rinse twice daily for two weeks.



**Figure 4. Intra bony defect after debridement**



**Figure 7. Intra bony defect**

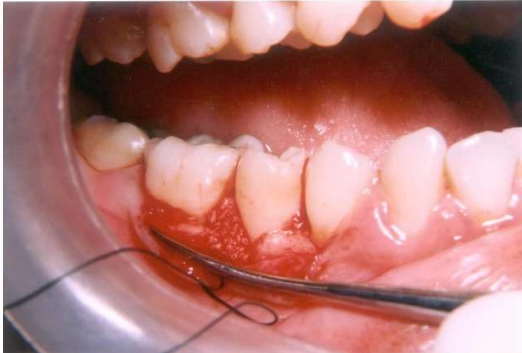


**Figure 8. Depth of intra bony defect**





**Figure 6. Defect fill with BioOss+ cPRP**



**Figure 11. Defect fill with BioOss+cPRP**

### Postsurgical Procedure

After one week following surgery, the periodontal Dressing and sutures were removed and the area was irrigated thoroughly with saline. Recall appointments were made, all clinical and radiographic parameters recorded at baseline were repeated at 1month, 3months, 6months and 9months post-operatively.

### Surgical Re-Entry Procedure

As described earlier the operative site was anesthetized, a full thickness mucoperiosteal flap was reflected; degranulation was not required. Clinical bone defect fill was measured. The site was irrigated with saline and the flaps sutured back with black braided (4-0) silk suture and a periodontal Dressing was placed which was removed after one week. (Fig 5,9, & 10)



**Figure 5. Surgical reentry at 9 months**



**Figure 9. Surgical reentry at 9 months**



**Figure 10. Surgical reentry at 9 months**

## RESULTS

The study was completed on all the patients. Healing of the experimental site was uneventful. There were no pre-, intra- or post-operative complications. Changes in PPD, CAL and GR are reported in Table1. Mean probing depth reduction of  $6.60 \pm 1.43\text{mm}$  (73.3%) was found, which was statistically highly significant ( $P < 0.001$ ). The gain in mean CAL was also significantly greater  $4.70 \pm 0.76\text{mm}$  (27.4%). There was change in mean gingival recession from baseline to 9months of about  $(-) 0.86 \pm 0.39\text{mm}$ ,  $(-) (10.7\%)$ .

The changes in radiographic evaluation are reported in Table 2. The experimental site at 9months presented with a mean defect fill of  $4.04 \pm 1.77$  (86.5%) which was statistically highly significant. Significantly higher mean defect resolution  $3.12 \pm 1.06$  (66.5%) and gain in mean alveolar crest height of  $0.66 \pm 1.25$  (16.2%) was found at 9months. (Fig 12-17)

The results of surgical re-entry are shown in Table3. Surgical re-entry evaluation showed statistically highly significant mean defect fill of  $6.00 \pm 1.83\text{mm}$  (87.7%). Mean defect resolution of  $5.80 \pm 1.69\text{mm}$  (86.6%) and gain in mean alveolar crest height of  $0.40 \pm 0.52\text{mm}$  (14.2%) was found.



**Figure 12. IOPA at baline**



**Figure 16. IOPA at 6 months**



**Figure 13. IOPA at 6 months**



**Figure 17. IOPA at 9 months**



**Figure 14. IOPA at 9 months**



**Figure 15. IOPA at baseline**

Clinical Criteria	Time Interval	Mean of criteria $\pm$ SD*	Difference from baseline	%	Significance (p**)
PPD	Baseline	9.00 $\pm$ 1.25			
	3 Months	4.50 $\pm$ 0.85	4.50 $\pm$ 1.18	50.0	t=12.1 p<0.001 HS***
	6 Months	3.10 $\pm$ 0.57	5.90 $\pm$ 1.20	65.6	t=15.5 p<0.001 HS
	9 Months	2.40 $\pm$ 0.52	6.60 $\pm$ 1.43	73.3	t=14.6 p<0.001 HS
CAL	Baseline	17.15 $\pm$ 1.58			
	3 Months	13.17 $\pm$ 1.38	3.98 $\pm$ 0.66	23.2	t=19.1 p<0.001 HS
	6 Months	12.79 $\pm$ 1.24	4.36 $\pm$ 0.82	25.4	t=16.8 p<0.001 HS
	9 Months	12.45 $\pm$ 1.25	4.70 $\pm$ 0.76	27.4	t=15.5 p<0.001 HS
GR	Baseline	8.03 $\pm$ 1.18			
	3 Months	8.91 $\pm$ 1.17	(-) 0.88 $\pm$ 0.37	(-) 11.0	t=7.52 p<0.001 HS
	6 Months	8.94 $\pm$ 1.16	(-) 0.91 $\pm$ 0.40	(-) 11.3	t=7.19 p<0.001 HS
	9 Months	8.89 $\pm$ 1.13	(-) 0.86 $\pm$ 0.39	(-) 10.7	t=3.16 p<0.01 S****

\*Standard Deviation  
 \*\*Students paired 't' test  
 \*\*\*HS - Highly Significant  
 \*\*\*\*S - Significant

**Table 1. Changes in mean Probing Pocket Depth (PPD), Clinical Attachment Level (CAL) & Gingival Recession (GR). (in mm)**



Radiographic Criteria	Time Interval	Mean of criteria±SD*	Difference from baseline	%	Significance (p**)
Mean Defect Fill	Baseline	8.48±1.44			
	6 Months	5.62±1.39	2.76±1.65	57.6	t=5.3 p<0.001 HS***
	9 Months	4.44±1.57	4.04±1.77	86.5	t=7.2 p<0.001 HS
Mean Defect Resolution	Baseline	4.63±1.02			
	6 Months	2.22±0.81	2.41±1.13	51.6	t=6.7 p<0.001 HS
	9 Months	1.51±0.43	3.12±1.06	66.5	t=9.6 p<0.001 HS
Mean Alveolar Crest Height	Baseline	3.85±1.12			
	6 Months	3.50±1.39	0.35±0.87	5.5	t=1.27 p=0.22 NS***
	9 Months	3.19±1.53	0.66±1.25	16.2	t=1.67 p=0.11 NS

\*Standard deviation

\*\*Students paired 't'-test

\*\*\*HS - Highly significant

\*\*\*\*NS - Not Significant

**Table 2. Mean Radiographic Changes at, 6 & 9 months. (in mm)**

Clinical Criteria	Time Interval	Mean of Criteria±SD*	Difference from Baseline	%	Significance (p**)
Mean Defect Fill	Baseline	10.10±2.23			
	9 Months	4.10±2.23	6.00±1.83	87.7	t=16.5 p<0.001 HS***
Mean Defect Resolution	Baseline	6.80±1.32			
	9 Months	1.20±1.32	5.80±1.69	86.6	t=12.4 p<0.001 HS
Mean Alveolar Crest Height	Baseline	3.40±1.26			
	9 Months	3.00±1.49	0.40±0.52	14.2	t=2.3 p<0.05 S****

\*SD - Standard Deviation

\*\*Students Paired 't' test

\*\*\*HS - Highly Significant

\*\*\*\*S - Significant

**Table 3. Surgical - reentry recordings. (in mm)**

## DISCUSSION

The use of both platelet-rich plasma & bovine porous bone mineral-Bio-Oss® individually for periodontal regeneration has been substantiated from the previous studies. The present study was to evaluate the efficacy of a combination of PRP gel & Bio-Oss® in the treatment of periodontal intrabony defects both clinically and radiographically. The conflicting data in the literature necessitates the need for such a study with surgical re-entry analysis. Histological study of the newly formed bone was not done, which could be one of the drawbacks of the study.

Based on the inclusion and exclusion criteria a total of 10 patients (2males & 8females) were selected for the study. According to the 2017 World Workshop on classification of periodontal diseases, Stage III Grade A type of periodontitis was considered for the study (Tonetti et al. 2018). Three wall bone defects were selected as they allow better containment, stability, increased blood supply to the graft and though to allow formation of the "space for osteogenesis" (Karaki et al. 1984).

Oral hygiene status was assessed by taking the Plaque Index (Silness & Loe. 1964) at baseline, 1month, 3months, 6 & 9months post-surgery. The PI

showed consistent reduction over the period of 9months. The mean PI score at baseline was  $2.33 \pm 0.46$ mm which measured  $0.90 \pm 0.13$ mm at 9months with a difference from baseline of  $1.43 \pm 0.43$ mm (61.4%). The reduction in PI score (Graph 1.) during the follow-up visits was highly significant.

Gingival Index (Loe & Silness. 1963) is considered to be a true reflection of gingival status in health and disease. It is more simple, easy and reproducible index and is used commonly in clinical periodontal research studies. The mean GI score (Graph 2.) at baseline was  $2.33 \pm 0.43$ mm and  $0.88 \pm 0.13$ mm at 9months, with the difference from baseline of  $1.45 \pm 0.45$ mm (62.2%). These findings were consistent with the findings of Chen et al. (1995) and Pietruksa. (2001). This reduction in GI score can be attributed to reduction in plaque and hence the reduction in gingival inflammation and subsequently resulting into tissue shrinkage.

Pocket depth resolution is a desirable outcome of periodontal regeneration and is the most important parameter in patient care for the clinician. The mean PPD at baseline was  $9.00 \pm 1.25$ mm which was reduced to  $2.40 \pm 0.52$ mm at 9months, the difference from baseline was  $6.60 \pm 1.43$ mm, with a reduction in PPD of 73.3%. These findings were consistent with Obarrio et al. (2000), Camargo et al. (2002) and Lekovic et al. (2002). The primary reason for reduction in PPD after the treatment can be attributed to the reduction in inflammation and shrinkage of the pocket wall. It can also occur due to combination of gain in CAL as well as because of post treatment gingival recession (Lekovic 2003).

The near perfect positive correlation between the gain in clinical attachment level and gain in bone height (Tonetti et al. 1993) has led to the use of CAL as an important outcome variable in regenerative studies. The mean CAL at baseline was  $17.15 \pm 1.58$ mm and at 9months was  $12.45 \pm 1.25$ mm. The mean gain in CAL was  $4.70 \pm 0.76$ mm (27.4%). Similar findings were recorded by Camelo et al. (1998) and Pietruska. (2001). The gain in CAL was attributed to resolution of tissue inflammation, reformation of collagen fibers, new attachment to the root surface and bone fill.

Monitoring the gingival recession may help explain the overall clinical picture and the factors affecting the regenerative response. Apical shift of the gingival margin is likely to reduce the regenerative capacity at a site thus affecting the final outcome (Machtei. 1997). The mean GR at baseline was  $8.03 \pm 1.18$ mm and at 9months was  $8.89 \pm 1.13$ mm, the difference was (-)  $0.86 \pm 0.39$ mm, (-) 10.7% of recession was found. The findings were consistent with those of Hartman et al. (2004). The slight GR that occurred at 3months was due to shrinkage of marginal gingiva post-surgery, following which



gingival margin position remained stable until 9th month.

Radiographic evaluation for the changes in alveolar bone was done as per the methodology explained by Meffert et al. 1985. Defect fill is a desirable outcome of any periodontal regenerative therapy. The mean defect fill was  $2.76 \pm 1.65$ mm (57.6%) and  $4.04 \pm 1.77$ mm (86.5%) at the end of 6 and 9months respectively which was statistically highly significant ( $P < 0.001$ ). These findings were in accordance with those of Camargo et al. (2002), Lekovic. (2002) and De Nicolo et al. (2015). The mean defect resolution at 6months and 9months post operatively was  $2.41 \pm 1.13$ mm (51.6%) and  $3.12 \pm 1.06$ mm (66.5%) respectively. These findings were in agreement with those of Camargo et al. (2002) and Lekovic. (2002). Following periodontal surgery there is remodeling of alveolar bone. The defect resolution occurs by defect fill as well as crestal resorption. Hence recording changes in the height of alveolar crest is important. There was a gain in alveolar crest height of 5.5% and 16.2% at 6 and 9months respectively.

Though surgical re-entry procedure causes a degree of ethical concern, the direct linear measurement is the primary and outstanding outcome variable of all regenerative procedures. It provides a direct visualization of the osseous defect changes (on alveolar crest as well as within the defect). At 9months re-entry the defect fill was recorded as 87.7% and the defect resolution as 86.6%. There was 14.2% increase in alveolar crest height Camargo et al. (2009).

In the present study favorable response were observed in all the clinical, radiological and surgical re-entry parameters that were recorded.

The potential mechanism of action of PRP is its sticky consistency due to its high fibrin content (Garg. 2018). The high fibrin content also works as a hemostatic agent aiding in stabilizing the graft material and the blood clot (Wikesjo et al. 1992). The PRP adheres to the root surface and impedes the apical migration of epithelial cells and connective tissue cells from the flap. The growth factors PDGF and TGF- $\beta$  in PRP promotes growth and differentiation of periodontal ligament cells and alveolar bone progenitor cells resulting in the clinical improvement observed. Hence the results demonstrated that PRP+BPBM-Bio-Oss® are capable of improving periodontal conditions and are successful in achieving the periodontal regeneration (Saleem et al. 2018). Since PRP utilizes patients own blood there is virtually no risk of disease transmission, making it a safe treatment modality. No antigenic reactions were observed in any of the patient, thereby indicating the safety of autologous PRP, the thrombin used for activation of PRP and BPBM-Bio-Oss®. Hence the advent and use of

these materials PRP+BPBM-Bio-Oss® represents a novel approach towards periodontal regeneration.

## CONCLUSION

The present study within its limits showed statistically significant, reduction in probing pocket depth, gain in clinical attachment level and increase in defect fill and defect resolution with the use of autologous PRP gel and BPBM-Bio-Oss® in periodontal intrabony defects. Further studies are necessary to evaluate the individual role played by PRP alone in various forms and with various combinations of bone grafts for periodontal regeneration, with histological study of the newly formed bone.

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# Bovine Porous Bone Mineral Bio-Oss® In The Treatment Of Periodontal Intrabony Defects In Humans - A Surgical Re-Entry Study

## Abstract

**Background:** Bovine porous bone mineral (BPBM)-Bio-Oss is a xenograft that has been successfully used in periodontal regeneration. The purpose of this study was to evaluate the efficacy of BPBM in the treatment of periodontal intrabony defects in humans and surgical re-entry examination to see the ability of BPBM to augment the bone at 9months.

**Material and Methods:** A clinical trial was done in a total of 10 patients with the age group of 35-55years, with pocket depth  $\geq 6\text{mm}$  and at least one intrabony defect. Re-entry surgeries were performed at 9months. Primary study outcomes were changes in probing pocket depth, clinical attachment level and defect fill.

**Results:** Significantly greater reduction in Probing Pocket Depth (PPD) of  $6.20 \pm 1.40\text{mm}$  (71.3%) was found, gain in mean Clinical Attachment Level (CAL) of  $4.16 \pm 1.05\text{mm}$  (25.8%) and radiographic mean defect fill and defect resolution were  $3.83 \pm 1.01\text{mm}$  (99.3%) &  $2.80 \pm 0.98\text{mm}$  (67.5%) respectively. Study presented with change in alveolar crest height of  $1.07 \pm 1.47\text{mm}$  (32.7%). Surgical re-entry defect fill and defect resolution were  $5.30 \pm 1.77\text{mm}$  (92.7%) and  $4.70 \pm 1.42\text{mm}$  (82.4%) respectively.

**Conclusion:** The results of this study indicate that BPBM-Bio-Oss is an effective material for regenerative treatment of periodontal intrabony defects. BPBM has the ability to augment the effects in reducing pocket depth, improving clinical attachment level and promoting defect fill.

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## INTRODUCTION

Periodontal diseases are among the most prevalent disease worldwide and are the major cause of tooth mobility and morbidity. Hence the objective of periodontal therapy includes the arrest of progression of periodontal disease and the restoration of the supporting structures (alveolar bone, cementum and periodontal ligament) destroyed by the disease process. It finally results in achieving a healthy and functional periodontium and aids in the long-term maintenance

of the dentition (Marx 2004).

Combination of various regenerative biological agents and techniques have attracted the interest of researchers in the field of reconstructive periodontal surgery. The periodontal regeneration requires an orchestrated sequence of biological events for its successful outcome. The different therapeutic modalities that attempt to enhance these biological events such as cell migration, adhesion, growth and differentiation have the potential to increase the success and predictability of periodontal regenerative procedures.

A variety of bone graft materials autografts, allografts, xenografts and alloplast are available for use in periodontal regeneration. Based on the

mechanism of action, bone grafts are (i) Osteogenic/Osteoproliferative, (ii) Osteoconductive, (iii) Osteoinductive, (iv) Osteopromotive. The autogenous bone grafts have been referred to as the "gold standard" in osseous grafting procedures. However, the limited availability and the complications associated with the donor sites are its main disadvantages. Hence, allogenic materials (Freeze Dried Bone Allografts or Demineralized Freeze-Dried Bone Allografts), xenografts or alloplastic materials are being the mainstay for periodontal regeneration (Sculen et al 2004). Xenografts fulfill most of the criteria of an ideal graft material there are two available sources of xenografts, anorganic bovine bone and the natural coral. They are osteoconductive, readily available and biocompatible. The bovine porous bone mineral is a xenograft prepared by protein extraction of bovine bone, which results in a structure similar to human cancellous bone and has the ability to enhance bone formation in periodontal intrabony defects (DeNicolo et al. 2015). Bio-Oss (Fig. 5) is a xenograft similar to human bone mineral in inner surface area, porosity, crystalline size and calcium to phosphorous ratio (Valdre et al 1995).

Bio-Oss bone graft material has a crystal size of 10-60nm similar to those of human bone and has a flexible bone structure. The particles of Bio-Oss are thin and look like tiny pallets fairly homogenous in size and shape. The overall porosity of Bio-Oss is upto 70-75%. The spongiosa structure which demonstrates the wide interconnective pore system of natural bone mineral help in invasion of new blood vessels followed by osteoblastic migration. The inner surface of Bio-Oss reaches to about 100m<sup>2</sup>/g which allows to achieve intimate contact with osteoblasts and pluripotential osteogenic cells. The compressive strength of Bio-Oss is 35MPa and modulus of elasticity is 11GPa which indicates that they are in the same range as that of natural bone. The osteoblasts recognize the surface of Bio-Oss as a bone layer consisting of biologic apatite and use that surface for deposition of new bone.

There are many reports on the use of BPBM-Bio-Oss in the regenerative treatment of periodontal intrabony defects in humans; the purpose of this study was mainly to evaluate the effectiveness of BPBM in defect fill and defect resolution at 9months by surgical re-entry. And to evaluate the effectiveness of BPBM on improving the clinical parameters like PPD, CAL, GR, and radiographic parameters like defect fill, defect resolution & alveolar crest height.



**Figure 5: BioOss Bone Graft**

## **MATERIAL AND METHODS**

### **Study subject and design**

The clinical trial was conducted in the Department of Periodontics. The study design, informed consent form and ethical clearance were approved by the University.

Human clinical trial was done on a total of 10 patients (2men & 8women) in the age group of 35-55years with a mean age of 45±5years. According to the 2017 World Workshop on classification of periodontal diseases, Stage III Grade A type of periodontitis was considered for the study (Tonetti et al. 2018). Systemically healthy patients with no contraindication for periodontal surgery having at least one three walled intrabony defect (Stavropoulos et al. 2010), with pocket depth of ≥6mm in any one quadrant and with radiographic evidence of vertical/angular bone loss, were included in the study. It was seen to that the involved teeth were vital and asymptomatic. Patients with one walled defects suffering from any systemic disease with compromised immune system, with bleeding disorders, allergic to tetracycline, chlorhexidine or any other medicine to be used in the study, taking immunosuppressive Drugs or any Drugs known to cause gingival enlargement, on anticoagulant therapy, pregnant, lactating mothers and smokers were excluded from the study. Patients were informed as to the character and purpose of the study and signed an informed consent form.

### **Presurgical therapy and measurements**

Following initial examination and treatment planning, the selected subjects underwent phase I therapy. A thorough full mouth scaling and root planing were performed under local anesthesia followed by oral hygiene instructions. Occlusal adjustments were performed if trauma from occlusion was diagnosed. 4 to 6 weeks following phase I therapy, periodontal re-evaluation was performed to confirm the suitability of the sites for the periodontal surgical study (De Bruyckere et al 2018). Custom made occlusal acrylic stents were used with guiding grooves which served as fixed



reference point for the position and angulation of probing (Lynch 1992). Prior to surgery the Plaque Index PI (Silness & Loe 1964) and Gingival Index GI (Loe & Silness 1963) were measured, with the help of Williams graduated periodontal probe, pocket depth was measured from the crest of the gingival margin to the base of the pocket. Two measurements are used to calculate the clinical attachment level: the probing depth and the distance from the gingival margin to Cemento-Enamel Junction (CEJ), the gingival margin could be, at, above or below the CEJ. Gingival recession was measured as the distance from CEJ to the gingival margin. Intraoral periapical (IOPA) radiographs of the selected site were taken using long cone paralleling technique. Figure 1A&1B. Shows the IOPA of the patients at baseline. The radiographs were evaluated using computer assisted image analysis. Amount of defect fill was measured as initial distance from CEJ to base of the defect minus 9months post-surgery distance from CEJ to the base of the defect. Defect resolution was measured as the initial distance between the crest of the alveolar bone to the base of the defect minus 9months post-surgery distance from alveolar crest to the base of the defect. Change in the alveolar crest height was measured as the initial distance from the CEJ to the alveolar crest minus 9months post-surgery distance from the CEJ to the alveolar crest.



**Figure 1A: Radiographic image at baseline, 6 and 9months**

**Radiographic Image  
Intrabony defect at baseline**



**At 9months post-surgery**

**Figure 1B: Radiographic image at baseline and 9months**

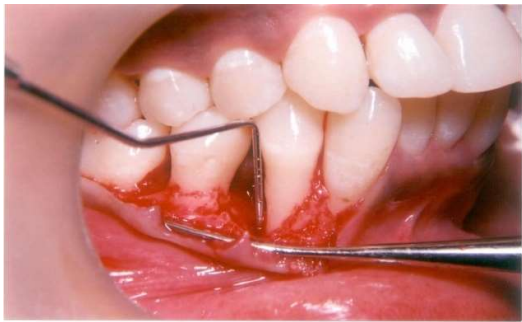
### **Surgical procedure and intrasurgical measurements**

The surgical procedure was performed under local anesthesia, Xylocaine 2% with aDrenaline (1:80,000). Buccal and lingual cervical incisions were given reaching the tip of the interdental papilla using Bard-Parker knife handle with blade No.12 and an interdental incision with No.11 blade. A full thickness mucoperiosteal flap was reflected using periosteal elevator. Taking care that the interdental papillary tissue is preserved or retained as far as possible. After reflection of the flap and exposure of the osseous defects, complete debridement of the defect as well as scaling and root planing were performed with the use of ultrasonic device and hand curettes, (Gracey curettes, 4R-4L Columbia and Universal curettes- Hu-Friedy). The inner surface of the flap was curetted to remove the epithelium and granulation tissue, followed by irrigation of the surgical site with normal saline (Figure2A, Figure4A). Measurements of the osseous defects were made using the same stents and probe. After open flap debridement, the flaps were partially presutured. The BPBM (Bio-Oss® Geistlich, Wolhusen, Switzerland) was delivered into the osseous defects using the scoop of a cumine scaler (Figure2B). The material was loosely packed with light incremental pressure from the base of the defect coronally till the level of CEJ but overfilling or under filling of the defect was avoided. The presutured mucoperiosteal flaps were repositioned and secured in place using the black braided (4-0)

silk sutures. Periodontal Dressing Coe-Pak™ was placed over the surgical area. Post-operative instructions, antibiotics (Doxycycline 200mg for 1<sup>st</sup> day followed by 100mg/day for 6days), analgesics (combination of Ibuprofen 400mg and Paracetamol 500mg thrice daily for 3days) and chlorhexidine gluconate (0.2%) (Solderer et al 2019), mouth rinse twice daily for two weeks were given to all the patients.



**Figure 2A: Bony defect**



**Figure 4A: Bony defect**



**Figure 2B: Carrying the BioOss**

### Postoperative care and measurement

After one week following surgery, the periodontal Dressing and sutures were removed and the area was irrigated thoroughly with saline. Recall appointments were made, PI and GI were recorded at 1, 3, 6 & 9months, measuring PPD, CAL & GR were repeated at 3, 6 & 9months. The radiographic measurements defect fill, defect resolution and alveolar crest height were made at 6 & 9months

post-surgery, Figure 1A&1B. Surgical re-entry and re-entry measurements were made at 9months. (Table1, 2, 3 & 4) Postoperative care included reinforcement of oral hygiene and professional plaque removal whenever necessary.

### Re-entry surgery

As described earlier the operative site was anesthetized, a full thickness mucoperiosteal flap was reflected; degranulation was not required. Clinical bone defect fill, defect resolution and alveolar crest height were measured. The site was irrigated with saline and the flaps sutured back with black braided (4-0) silk sutures and a periodontal Dressing Coe-Pak™ was placed which was removed after one week. In Figure 2A, 3, 4A & 4B baseline intrabony defect and the defect fill at 9months surgical re-entry respectively can be seen.



**Figure 2A: Bony defect**



**Figure 3: Surgical re-entry at 9months**



**Figure 4A: Bony defect**



**Figure 4B: Surgical re-entry at 9months**

### Statistical analysis

Clinical measurements of each parameter were averaged (mean  $\pm$  SEM). The net difference between each pair of measurements (pre and postoperative) was then calculated. The statistical evaluation of the changes from baseline through 9months was done using paired 't' test. The level of statistical significance is often expressed as a p-value between 0 & 1. The smaller the p-value; the stronger the evidence that you should reject the null hypothesis. A p-value < 0.05 is statistically significant. A p-value > 0.05 is not statistically significant.

## RESULTS

The study was completed on all the 10 patients. Healing of the experimental site was uneventful. PI score and GI score are recorded in Table 1. Reduction in mean PI score and GI score from baseline to 9months was found to be  $1.23 \pm 0.38$  (57.7%) and  $1.60 \pm 0.46$  (64.0%) respectively which was statistically significant. Changes in PPD, CAL and GR are reported in Table 2. Mean probing depth reduction of  $6.20 \pm 1.40$ mm (71.3%) was found, which was statistically highly significant ( $p < 0.001$ ). The gain in mean CAL was also significantly greater  $4.16 \pm 1.05$ mm (25.8%). There was change in mean gingival recession from baseline to 9months of about (-)  $0.57 \pm 0.76$ mm, (-) 7.6%. The changes in radiographic evaluation are reported in Table 3. The experimental site at 9 months presented with a mean defect fill of  $3.83 \pm 1.01$ mm (99.3%) which was statistically highly significant. Significantly higher mean defect resolution  $2.80 \pm 0.98$ mm (67.5%) and gain in mean alveolar crest height of  $1.07 \pm 1.47$ mm (32.7%) was found at 9 months. The results of surgical re-entry are shown in Table 4. Surgical re-entry evaluation showed statistically highly significant mean defect fill of  $5.30 \pm 1.77$ mm (92.7%), mean defect resolution of  $4.70 \pm 1.42$ mm (82.4%) and gain in mean alveolar crest height of  $0.70 \pm 0.48$ mm (23.2%) was found. The sample size used in this study is relatively small, one of the limitations of the study, but it is in the range adopted

by the vast majority of clinical periodontal regenerative studies in humans (Antezak et al. 1990). Histological study of the newly formed bone was not done, which could be one of the drawbacks of the study.

Clinical Criteria	Time Interval	Mean of Criteria $\pm$ SD*	Difference from baseline	%	Significance (P**)
Plaque Index	Baseline	$2.13 \pm 0.44$			
Gingival Index	1 Month	$1.73 \pm 0.34$	$0.04 \pm 0.17$	18.8	$t=7.44, P < 0.001$ HS***
	3 Months	$1.43 \pm 0.29$	$0.70 \pm 0.26$	32.9	$t=8.51, P < 0.001$ HS
	6 Months	$1.15 \pm 0.27$	$0.98 \pm 0.30$	46.0	$t=10.3, P < 0.001$ HS
	9 Months	$0.90 \pm 0.17$	$1.23 \pm 0.38$	57.7	$t=10.23, P < 0.001$ HS
	Baseline	$2.50 \pm 0.42$			
	1 Month	$2.08 \pm 0.31$	$0.42 \pm 0.24$	16.8	$t=5.53, P < 0.001$ HS
	3 Months	$1.73 \pm 0.22$	$0.77 \pm 0.32$	30.8	$t=7.61, P < 0.001$ HS
	6 Months	$1.33 \pm 0.24$	$1.17 \pm 0.31$	46.8	$t=11.9, P < 0.001$ HS
	9 Months	$0.90 \pm 0.13$	$1.60 \pm 0.46$	64.0	$t=11.0, P < 0.001$ HS

\*SD-Standard Deviation  
\*\*P-Students paired 't' test  
\*\*\* HS-Highly Significant

**Table 1: Mean Reduction in Plaque Index and Gingival Index**

Clinical Criteria	Time Interval	Mean of Criteria $\pm$ SD*	Difference from baseline	%	Significance (P**)
PPD	Baseline	$8.70 \pm 1.57$			
	3 Months	$4.70 \pm 1.16$	$4.00 \pm 1.41$	46.0	$t=8.9, P < 0.001$ HS***
	6 Months	$3.00 \pm 0.47$	$5.07 \pm 1.34$	65.5	$t=13.5, P < 0.001$ HS
	9 Months	$2.50 \pm 0.53$	$6.20 \pm 1.40$	71.3	$t=14.0, P < 0.001$ HS
CAL	Baseline	$16.12 \pm 1.27$			
	3 Months	$12.86 \pm 1.37$	$3.26 \pm 0.56$	20.2	$t=18.4, P < 0.001$ HS
	6 Months	$12.41 \pm 1.22$	$3.71 \pm 0.86$	23.0	$t=13.6, P < 0.001$ HS
	9 Months	$11.96 \pm 1.59$	$4.16 \pm 1.05$	25.8	$t=12.5, P < 0.001$ HS
GR	Baseline	$7.47 \pm 1.04$			
	3 Months	$8.20 \pm 1.11$	$(-) 0.73 \pm 0.60$	$(-) 9.8$	$t=3.85, P < 0.01$ S****
	6 Months	$8.23 \pm 1.15$	$(-) 0.76 \pm 0.74$	$(-) 10.2$	$t=3.25, P < 0.01$ S
	9 Months	$8.04 \pm 1.13$	$(-) 0.57 \pm 0.76$	$(-) 7.6$	$t=2.37, P < 0.05$ S

\*SD-Standard Deviation  
\*\*P-Students paired 't' test  
\*\*\*HS-Highly Significant  
\*\*\*\*S-Significant

**Table 2: Changes in mean Probing Pocked Depth (PPD), Clinical Attachment Level (CAL) & Gingival Recession (GR) (in mm)**



Radiographic Criteria	Time Interval	Mean of Criteria $\pm$ SD *	Difference from baseline	%	Significance (P**)
Mean Defect fill	Baseline	7.59 $\pm$ 1.27			
	6 Months	4.94 $\pm$ 1.10	2.65 $\pm$ 0.90	67.9	t=9.3, P < 0.001 HS ***
	9 Months	3.76 $\pm$ 1.24	3.83 $\pm$ 1.01	99.3	t=11.9, P < 0.001 HS
Mean Defect Resolution	Baseline	4.07 $\pm$ 0.98			
	6 Months	2.09 $\pm$ 0.65	1.98 $\pm$ 1.14	46.2	t=5.5, P < 0.001 HS
	9 Months	1.31 $\pm$ 0.43	2.80 $\pm$ 0.98	67.5	t=9.0, P < 0.001 HS
Alveolar Crest height	Baseline	3.52 $\pm$ 1.27			
	6 Months	2.86 $\pm$ 1.00	0.66 $\pm$ 1.37	21.8	t=1.52, P < 0.15 NS****
	9 Months	2.45 $\pm$ 1.22	1.07 $\pm$ 1.47	32.7	t=2.30, P < 0.05 S *****

\*SD-Standard Deviation  
\*\*P-Students paired 't' test  
\*\*\* HS-Highly Significant  
\*\*\*\*NS-Not Significant  
\*\*\*\*\*S-Significant

**Table 3: Radiographic changes at Baseline, 6 & 9 months (in mm)**

Criteria	Time Interval	Mean of Criteria $\pm$ SD *	Difference from baseline	%	Significance (P**)
Mean Defect Fill	Baseline	8.80 $\pm$ 1.93			
	9 Months	3.50 $\pm$ 0.97	5.30 $\pm$ 1.77	92.7	t=13.8, P < 0.001 HS***
Mean Defect Resolution	Baseline	5.70 $\pm$ 1.25			
	9 Months	1.00 $\pm$ 0.94	4.70 $\pm$ 1.42	82.4	t=17.4, P < 0.001 HS
Change in Alveolar crest height	Baseline	3.20 $\pm$ 1.14			
	9 Months	2.50 $\pm$ 1.08	0.70 $\pm$ 0.48	23.2	t=23.84, P < 0.01 S*****

\*SD-Standard Deviation  
\*\*P- Students paired 't' test  
\*\*\* HS-Highly significant  
\*\*\*\*S-Significant

**Table 4: Surgical Re - entry recordings (in mm)**

## DISCUSSION

Regeneration of the lost periodontium as a result of periodontal disease process has long been a desirable goal of periodontal therapy. A variety of bone grafting materials are available for use in periodontal reconstruction. Anorganic bovine bone xenograft- Bio-Oss has been successfully used in variety of periodontal applications including, ridge augmentation, sinus floor elevation, regeneration of periodontal intrabony defects and the guided bone

regeneration around the implants. Camelo et al (1998) in a histological study demonstrated the formation of new cementum, periodontal ligament and alveolar bone when periodontal intrabony defects were treated with Bio-Oss.

Three wall intrabony defects were selected because bone regeneration is believed to be improved with an increasing number of bony walls facing the root surface. Three wall bone defects allow better containment, stability and increased blood supply to the graft and thought to allow formation of the space for osteogenesis (Karaki et al 1984). The depth and width of osseous defects also affects the bone regeneration, wherein the deep narrow osseous defects always show better results than the shallow and wide defects. Data in the literature necessitates the need for surgical re-entry study, where we can visually analyze the quantity and quality of the new bone formed. Hence the aim of the study was to evaluate the efficacy of BPBM in the treatment of periodontal intrabony defects both clinically and radiographically.

Intra oral accessibility and plaque control during the presurgical phase were also evaluated and formulated into patient selection as these local and behavioral factors can influence the regenerative outcome (Schmitt et al 1997). Oral hygiene status was assessed by taking the Plaque index (Silness & Loe 1964) at baseline, 1, 3, 6 and 9months post-surgery. The PI score showed consistent reduction over the period of 9months. The mean PI score at baseline was 2.13 $\pm$ 0.44 which measured 0.90 $\pm$ 0.17 at 9 months with a difference from baseline of 1.23 $\pm$ 0.38 (57.7%). The reduction in plaque score was highly significant. These findings were consistent with the findings of Camelo et al 1998 & Nevis et al 2003. The mean GI score at baseline was 2.50.  $\pm$ 0.42 and 0.90  $\pm$ 0.13 at 9months with the difference from baseline of 1.60 $\pm$ 0.46 (64.0%). The reduction in Gingival Index score was highly significant similar to the findings of Bowen et al 1989, Chen et al 1995 & Pietruska 2001. GI score is considered to be a true reflection of gingival status in health and disease. It is more simple, easy and reproducible index and is used commonly in clinical periodontal research studies.

Pocket depth resolution is not only a desirable outcome of periodontal regeneration but also the most important parameter in patient care for the clinician. The mean PPD at baseline was 8.70 $\pm$ 1.57mm which was reduced to 2.50 $\pm$ 0.53mm at 9months, the difference from baseline was 6.20 $\pm$ 1.40mm (71.3%), which was statistically highly significant (p<0.001) reduction. These findings were consistent with those of Camelo 1998, Richardson 1999 & Pietruska 2001. The primary reason for reduction in probing pocket depth after the treatment can be attributed to the reduction in

inflammation and shrinkage of the pocket wall. It can also occur due to combination of gain in clinical attachment as well as because of post treatment gingival recession. Also, it is said that placement of a graft material into a defect may modify gingival tissue consistency and therefore impede penetration of periodontal probe without necessarily having induced any gain in clinical attachment (Lekovic 2003).

The near perfect positive correlation between the gain in clinical attachment level and gain in bone height (Tonetti et al 1993) has led to the use of clinical attachment level as an important outcome variable in regenerative studies. The mean CAL at baseline was  $16.12 \pm 1.27$  mm and at 9 months was  $11.96 \pm 1.59$  mm. The mean gain in CAL was  $4.16 \pm 1.05$  mm (25.8%) which was statistically highly significant ( $p < 0.001$ ). Similar findings were recorded by Camelo et al 1998, Lundgren et al 1999, Pietruska 2001. The gain in CAL was attributed to resolution of tissue inflammation, reformation of collagen fibers, new attachment to the root surface and bone fill.

Apical shift of the gingival margin is likely to reduce the regenerative capacity at a site thus affecting the final outcome (Machtei 1997). The mean GR at baseline was  $7.47 \pm 1.04$  mm and at 9 months was  $8.04 \pm 1.13$  mm, the difference was  $(-) 0.57 \pm 0.76$  mm  $(-) 7.6\%$ . These findings were consistent with those of Velasquez-Plata et al 2002 and Hartman et al 2004.

Radiographic evaluation for the changes in alveolar bone was done as per the methodology explained by Meffert et al (1985). Defect fill is a desirable outcome of any periodontal regenerative therapy. The mean defect fill was  $2.65 \pm 0.90$  mm (67.9%) and  $3.83 \pm 1.01$  mm (99.3%) at 6 months and 9 months post-operative respectively, showing statistically highly significant results, ( $p < 0.001$ ). These findings were similar to those of Lundgren et al (1999) and Pietruska (2001). The mean defect resolution was  $1.98 \pm 1.14$  mm (46.2%) at the end of 6 months post-surgery, which increased to  $2.80 \pm 0.98$  mm (67.5%) at 9 months post-operatively, showing statistically highly significant results. These findings were consistent with those of Camargo et al 2000 & Lekovic et al (2000). Following periodontal surgery, there is remodeling of alveolar bone. The defect resolution occurs by defect fill as well as crestal resorption. Hence recording changes in the height of alveolar crest is important. Gain in alveolar crest height of 21.8% and 32.7% after 6 and 9 months respectively was recorded which was statistically not significant.

Though surgical re-entry procedure causes a degree of ethical concern, the direct linear measurement is the primary and outstanding outcome variable of all regenerative procedures. It provides a direct

visualization of the osseous defect changes, on alveolar crest as well as within the defect. Although this additional procedure is performed for documentation and recording of clinical parameters, it also provides access for any needed revisionary treatment. The defect fill and defect resolution were 92.7% and 82.4% respectively, which was statistically highly significant. The gain in alveolar crest height was 23.2% which was statistically significant. In the present study favorable response was observed in all the clinical, radiological and surgical re-entry parameters. No post-operative complications other than those considered normal following any surgical procedure were noticed. Also, no antigenic reactions were observed in any of the patients indicating the safety of Bio-Oss.

## CONCLUSION

Based on the results of the present study it was concluded that a good defect fill and defect resolution at 9 months surgical re-entry were achieved by using BPBM-Bio-Oss for treating periodontal intrabony defects. Statistically significant, reduction in probing pocket depth, gain in clinical attachment level and increase in defect fill and defect resolution radiographically were seen. Further studies with larger sample size, studies on bone density, bone strength and histological study of BPBM-Bio-Oss® in periodontal regeneration in humans is needed.

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# A Comparative Evaluation Of Diode Laser Ablation Versus Scalpel Excision For Management Of Oral Leukoplakia

## Abstract

**Background And Purpose:** Oral leukoplakia is a potentially malignant disease with a malignant transformation rate between 0.6% and 20% requiring immediate attention. Therefore, for moderate to severe dysplasia, complete surgical resection is the treatment modality. This study aimed to evaluate two treatment modalities for oral leukoplakia by diode laser and scalpel surgery and to compare the results of these two procedures in terms of postoperative pain and functional disability.

**Materials And Methods:** A total of 30 patients with oral leukoplakia were recruited and randomized into blocks, divided into diode group and scalpel group. The visual analog scale (VAS) and Gorsky criteria were used to assess patients' pain and dysfunction in the first 3 days and 1, 2, and weeks after surgery, respectively, and were followed up regularly for 4 years for recurrence.

**Results:** The mean age was 38 years. The results showed that the diode group was significantly different from the scalpel group in terms of postoperative pain assessed using the paired "t-test" on the VAS scale and functional disability using the chi test. square. Over the next 4 years of diode follow-up, no one had a recurrence compared to two patients in the scalpel group.

**Conclusions:** Complete lesion regression with minimal patient discomfort was observed in patients treated with Diode compared to scalpel, suggesting that Diode Laser is a more effective method than conventional methods.

**Key Words:** Diode Laser, Leukoplakia, Scalpel Excision

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## INTRODUCTION

Oral cancer is one of the 10 most common cancers in the world with delayed clinical detection, poor prognosis, absence of disease-specific biomarkers and expensive treatments<sup>1</sup> Thus, among the of public health, oral cancer has a greater burden. Availability of Oral for visual inspection and availability of

clinically defined precursors (Leukoplakia, Erythema, And Oral Submucosal Fibrosis) for early detection and secondary prevention of squamous cell carcinoma SCC Provides the ideal opportunity that represents approximately 90% malignant, and despite different treatments<sup>2</sup>, the 5-year survival rate

is approximately 50%. Therefore, emphasis has been placed on early diagnosis and rapid treatment of these lesions improving the prognosis<sup>3</sup>. Oral leukoplakia is a common potentially malignant lesion with a variety of clinical manifestations, with an overall incidence ranging from 0.5% to 3.4 % and malignant transformed from 0.6% to 20%. These potentially malignant diseases (PMDs) cannot be distinguished from the early oral cancers by simple visual inspection, regardless of the expertise of the clinicians<sup>3</sup>. Many seemingly innocuous early oral cancer lesions are only observed clinically and not diagnosed, so several additional, non-invasive tools have been developed at the clinical and molecular level to identify the uncertain biology of oral lesions<sup>4,5</sup>. One such technique is vital staining, including toluidine blue, a basic metachromatic stain that stains acidic cellular component. Since cancer cells contain more DNA and RNA than normal epithelial cells, toluidine blue delineates malignant areas<sup>6</sup>. This is a simple, fast and cheap technique. In the current literature, various treatment modalities with varying success rates have been proposed. Drug therapy Use of vitamin A analogues (retinoids) and other antioxidants Vitamins and nutrients (i.e., Beta-carotene, vitamins C and E) have not been effective in well-designed prospective studies. The theory is that antioxidants help stabilize cellular free radicals (mainly unstable oxygen), which act as promoters of chromosomal mutations and carcinogenesis<sup>7</sup>. Question in chemoprevention is about toxicity upon administration and relapse after discontinuation. Therefore, surgical resection is the definitive treatment for moderate to severe cases<sup>7</sup>. Therefore, radical treatment is very important for the recurrence and malignant transformation of oral leukoplakia<sup>8</sup>. In various surgical treatments, laser technology helps improve the surgical approach and ultimate control of leukoplakia. CO2 lasers, Erbium family lasers, Neodymium: Yttrium Aluminum Garnet (Nd:YAG) lasers, and diode lasers are primarily used for tissue ablation, but primarily diode lasers due to of the portability and ease of use of the for small soft tissue Surgical, cost effective is gaining wide acceptance in the field of dentistry. Therefore, diode lasers are very commonly used in many surgical procedures and have many advantages such less scarring, less pain and less bleeding, and less risk of infection<sup>9</sup>. Many researchers have also found that diode lasers can be used to eliminate benign and potentially malignant diseases of the oral soft tissues. There are few studies in the current literature on the use of diode laser therapy. Support for potentially malignant diseases. Therefore, diode laser ablation of leukoplakia was chosen as the final treatment modality for treatment and compared to conventional scalpel excision. The aims and

objectives of this study were on the one hand to evaluate the efficacy, safety and acceptability of diode laser in the treatment of oral leukoplakia and to compare to conventional excision to scalpel, and on the other hand, the nature of the postoperative adverse effects, if when available, were associated with laser ablation and scalpel at consecutive follow-ups of 1, 2 and 3 weeks and 1 month, and were examined for recurrence during the 4-year follow-up period.

## MATERIALS AND METHODS

Patients with clinical diagnosis of leukoplakia were recruited in Department Of Oral & Maxillofacial Surgery in Mithila minority Dental College & Hospital Darbhanga Bihar, in a span of 2 years using convenient sampling after obtaining institutional clearance. The patients who were willing to participate, quit the habit, give consent, and with an age range between 20 and 60 years were included in the study. The patients who were not willing to stop adverse habits and to give consent, and with any other systemic diseases were excluded from the study [Figure 1]. Patients were advised to discontinue all the adverse habits and counseling was done, followed by complete physical head and neck examination and they were advised to use topical clotrimazole over the affected site for 1 week to manage and rule out any superadded candidiasis. After 1 week, punch biopsy was performed under local anesthesia prior to treatment. Leukoplakia patients with moderate to severe dysplasia were included in the study after clinical and histopathological confirmation. Informed consent was obtained before inclusion in the study. The lesions were classified according to the size. All surgeries were performed by the same surgeon and carried out under 2% lidocaine with 1:100,000 adrenalin. The patients were randomized into two groups. Block randomization was done considering factors such as age, gender, extent of lesion, and dysplasia to ensure balance between two treatment arms, that is, diode and scalpel. Randomly generated treatment allocation sequences were concealed in a sealed opaque envelope to eliminate bias. Group 1 was treated with diode laser ablation and the wound was left open for healing by secondary intention. Group 2 was treated with scalpel excision followed by 3/0 sterile mersilk suture used to heal by primary intention. Before starting the surgery, the lesional area was Dried with the help of gauze piece and toluidine blue staining was performed. The retention of stain regardless of the intensity was defined as “positive” test and absence of any stain was defined as “negative” test. After this procedure, the patients were infiltrated with local anesthesia and personal

protection barriers were used for both staff and patients under strict aseptic conditions.[3] Then the lesion was irradiated by diode laser K-Laser professional 6SE (diode laser) ( $970 \pm 15$  nm, 300 mm contact mode, 6 W) till the area changed to white, that is, photocoagulation (contact mode, pulse mode). Remnants of the ablated tissue were removed using sterile gauze dampened with saline solution. The procedure was carried out further till the desired depth of tissue was removed along with the surrounding 2 mm of the normal tissue. In the scalpel excision group, a wide and shallow excision was done covering the positive areas followed by sutures placed, and postoperative instructions were given and analgesic was prescribed. After 1 week, the patients were recalled for suture removal. All cases were examined in the first 3 days, and 1, 2, and 4 weeks after surgery by a third person who was blinded to the study. Clinical evaluation of postoperative complications such as bleeding, swelling, functional disturbance, and wound healing was done using visual analog score (VAS) and subjective evaluation was done according to Gorsky and Raviv (1992).[13] A VAS of 100 mm in length was used to evaluate the intensity of pain and swelling. This scale converted the visual analogical evaluation made by the patient into a numerical value: from 0 (corresponding to 0 mm on the VAS and showed no pain and no swelling) to 10 (100 mm on the VAS and showed unbearable pain and maximal swelling). Postoperative complications such as pain, bleeding, edema, and functional disturbances were graded 0–10 according to the following: •0–2: no postoperative complications •3–5: mild postoperative complications •6–7: moderate postoperative complications •8–10: severe postoperative complications The patients were continuously monitored periodically for 4 years to evaluate for any recurrences. Recurrence was a leukoplakia arising in the excised site as the first or within the borders of the treated area. To evaluate the recurrence rate in and around the surgical site, we included only patients with a minimum follow-up of 6 months. Data were analyzed using SPSS version 12.0 statistical package. A descriptive study was done for each variable. Student's t-test was carried out for comparison and Chi-square test for nonparametric variables. A total of 128 patients diagnosed with leukoplakia were screened for a period of 2 years. Among them, 98 patients were excluded as shown in Figure 1, and a total of 30 were included in this study. Of the 30 patients, 2 were females and the rest were males with a mean age of 38 years. Of these, 18 patients had single-site lesion with a high prevalence for buccal mucosa and 12 patients had bilateral lesion on retrocommisural area. Among 30 patients, 28 showed classical homogeneous leukoplakia with moderate epithelial

dysplasia and 2 showed speckled leukoplakia with severe epithelial dysplasia. All the patients were subjected to topical toluidine blue application which gave 100% sensitivity for the positive sites and also slightly adjacent to the clinically observed lesion in patients especially with inhomogeneous leukoplakia. The laser ablation group did not show difficulty while operating, and pain disappeared by the end of first week. In the scalpel group during excision, especially in few patients with wide lesions, there was difficulty in approximating the suture ends; postoperatively, in the first 3 days, there was severe pain, and at the end of 1 week 13% of patients still showed moderate pain. On comparing both the groups on 3rd and 7th days postoperatively, there was a statistically significant difference ( $P = 0.001$ ), suggesting that diode group experienced lesser pain. On 2nd and 4th weeks, both the groups experienced no pain [Table 1]. Bleeding was more in the scalpel group (60%), whereas in the diode group there was minimal to no bleeding. Edema occurred in both the groups in the first 3 days of postoperative follow-up. The diode group experienced comparatively less edema than the scalpel group in the subsequent visits, which showed statistical significance ( $P = 0.001$ ). Nevertheless, by the end of first week, edema was subsided completely in both the groups [Table 2]. Functional disorder occurred in some patients which was mainly in direct relation to the degree of pain and edema. On 3rd day comparison, there was statistical significance ( $P = 0.001$ ), suggesting that the diode group experienced less functional disturbances which returned to normal function with complete remission of lesion [Table 3], and there was no postoperative bleeding or scar formation and the lased area was soft on palpation and benefited with the treatment. At the end of 1 week, the scalpel group exhibited minimal functional disturbances signifying that diode laser ablation was more acceptable with minimal complications compared with scalpel. Gorski criteria showed that both the groups benefited despite modality, but the diode group showed 80% clinical remission within the first few days [Table 4]. Periodic follow-up was done for every 6 months till 4 years wherein none of the diode group showed recurrence, neither new lesions nor malignant transformation. Whereas in the scalpel group, 20% ( $n = 3$ ) of the patients showed recurrence of the lesion in the excised area [Table 5].

	Group	Mean	T	P
Day 3	Diode	4.60 $\pm$ 1.25	-6.50	0.001
	Scalpel	7.65 $\pm$ 0.5		
Week 1	Diode	0.12 $\pm$ 0.2	-7.65	0.001
	Scalpel	1.5 $\pm$ 0.5		
Week 2	Diode	0		
	Scalpel	0		
Week 4	Diode	0		
	Scalpel	0		

**Table 1: Pain**



	Group	Mean	T	P
Day 3	Diode	2.50 $\pm$ 1.5	-1.425	0.001
	Scalpel	3.50 $\pm$ 2.0		
Week 1	Diode	0.20 $\pm$ 0.2	1.851	0.007
	Scalpel	0		
Week 2	Diode	0		
	Scalpel	0		
Week 4	Diode	0		
	Scalpel	0		

**Table 2: Swelling**

	Group	Mean	T	P
Day 3	Diode	5.15 $\pm$ 1.5	-2.650	0.01
	Scalpel	6.50 $\pm$ 1.25		
Week 1	Diode	1.25 $\pm$ 0.5	-2.510	0.007
	Scalpel	2.15 $\pm$ 1.0		
Week 2	Diode			
	Scalpel			
Week 4	Diode			
	Scalpel			

**Table 3: Functional disturbances**

Clinical Indicator	Diode	Scalpel	Chi Square	P
Stage I 30-50% Improvement	0	1	4.105	0.215
Stage II 50% Benefit	1	1		
Stage III 70-80% Benefit	2	6		
Stage IV 90-100% Remission Of Sign Symptoms	12	7		
Stage 0 No Change	0	0		

**Table 4: Gorski criteria for subjective evaluation**

## DISCUSSION

In potentially malignant disorders, which are manageable with chemoprevention, toxicity is considerable and also relapse is common after discontinuing<sup>14,16</sup>. One such study using retinoic acid for oral leukoplakia showed that molecular abnormalities persist in few patients with clinical response, suggesting chemoprevention delays rather than preventing carcinogenesis<sup>17</sup>. Hence, surgical excision is recommended especially in oral leukoplakia with moderate to severe dysplasia according to Arruda et al<sup>17</sup>. As laser treatment offers many advantages in both intraoperative and postoperative periods, such as ultimate control of leukoplakia without any wound contractures, profound control over bleeding (hemostasis), healing, bactericidal effect, and improved patient compliance, it was selected as one of the treatment arms and compared with the conventional scalpel excision. It is also recommended that the patients must necessitate continued clinical monitoring following a surgical intervention to evaluate any reoccurrence or malignant transformation<sup>18</sup>. Among various lasers available, diode laser is cost-effective, user-friendly, and can be used in contact mode. Its active medium is a solid semiconductor with wavelength ranging from 800 and 980 nm which cannot be absorbed by the dental hard tissues. Hence, diode laser is safe for soft tissue surgeries and was used in our study<sup>19,21</sup>. Prior to surgical excision, vital staining procedure gives us the proposed lesional area to be excised. Hence, we have

performed preoperative vital staining with toluidine blue to reduce recurrences as it covers multicentric or microinvasive cancers. Chaudhary et al. in their study also showed high sensitivity value with respect to leukoplakia patients suggesting that prior vital staining is a valuable step for the selection of the area to be excised which is in accordance to our study. In this study, inhomogeneous leukoplakia presented a wide positive site for toluidine blue application and the rest presented no much difference to the clinically evident lesion. In this study, 100% sensitivity was observed which may be attributed to the lesser sample size. Laser ablation for leukoplakia is a promising treatment, as it is more effortlessly performed than excision with a knife and its power of penetration reaches to about 1.5 mm as seen in this study. Application of diode laser at 6 W in defocused continuous mode will increase the temperature of the affected tissues to above 50°C and less than 100°C. This temperature will cause protein denaturation. The sign of protein denaturation is blanching of treated mucosa. Denaturation of protein means destruction at the affected area of the diseased epithelium. In addition, cytotoxic protein subepithelial lymphocytes are all denatured due to its deeper penetration. Risk of secondary infection could be minimized with the help of denaturation which acts as a Dressing layer for the treatment site that may decrease pain. Due to the sealing of blood vessels and lymph vessels, ice packs should be applied to the treated area<sup>17</sup>. Regarding postoperative recovery, it was uneventful except pain and edema which disappeared at the end of first week in the diode group, but the scalpel group showed mild pain in 2 weeks' follow-up. Laser surgery has many advantages for both the surgeon and the patient, both during and after the operation and the surgeon has excellent visibility during the operation and this enables shortening of the operative time. Also, patients do not require a special method to stop bleeding after surgery and it is possible, as a rule, to leave the excised edges unsutured in the excision technique. This can be used even in patients who have a comprehensive lesion treated by an ablation technique without any Dressing on the wound and this keeps functional disorders to a minimum. Scalpel excision in comparison to laser ablation showed more discomfort and pain with significant difference in the first few days of therapy suggesting that laser ablation is superior to scalpel excision. According to Vasavi Krishnamurthy<sup>18</sup>, Laser -assisted ablation is a more precise treatment with less postop discomfort for leukoplakia; our study is in accordance with this study. Pulsed mode is more comfortable than continuous wave mode which was similar to a study done by Rolf Brochers<sup>19</sup>, and hence pulsed mode was used in our study. According to a case report by

Tatu et al., diode laser was performed for leukoplakic ablation at 7 W which establishes its efficacy in management of oral leukoplakia, and we followed the same method in this study which showed profound acceptance by patients in comparison to scalpel. There was no recurrence of lesion in the laser group within a span of first 3 months in our study, which supports the case reported by Prajwalit Kende et al., unlike a study done by Nilesh et al<sup>21</sup>. where reoccurrence was seen in two patients (n = 10). Ultimate control of leukoplakia is more important to reduce the risk. Hence, diode laser is a definitive technique with marked clinical improvement with high degree of patient acceptance in comparison to scalpel excision<sup>22,25</sup>. Marek and Smucle<sup>26</sup> concluded that malignant transformation of leukoplakia does occur even after laser ablation, and for this reason it is necessary to subject the patients to systematic follow-ups. Hence, we have done follow-up periodically once in 6 months up to 4 years. During this period, none showed neither recurrence nor malignant transformation with diode laser ablation which might be attributed to prior toluidine blue application for the selection of surgical site and precise handling of diode laser pulse mode application and also the location of the lesion. Whereas scalpel group, despite controlled measures, showed recurrence (20%) suggesting diode laser ablation is superior to scalpel excision. This may be attributed to the location of lesion and difficulty in excising wide lesions using scalpel. According to Nilesh et al<sup>11</sup>. and Ishii et al<sup>12</sup>. laser ablation was a more precise removal with less postop complication, which is in accordance to our study. Also, patients do not require a special method to stop bleeding after surgery and it is possible, as a rule, to leave the excised edges unsutured in the excision technique which was according to Hirano et al<sup>27</sup>. Ortega-Concepción et al<sup>24</sup>. in their review, concluded that diode laser, being a safe and effective method for the excision of soft tissue lesions, was validated in our study.

This can be used even in patients who have a comprehensive lesion treated by a vaporization technique without any Dressing on the wound and this keeps functional disorders to a minimum. According to a study done by Ioanina et al<sup>28</sup>. comparison of recurrence rate between different laser techniques such as CO2 laser, Nd: YAG laser, and potassium-titanyl-phosphate (KTP) in the lesional area was about 34.2%, 28.9%, and 17%, respectively, whereas this study did not show any recurrence among laser group. This may be attributed to the location of the lesion determining recurrences and malignant transformation. Mehana et al<sup>29</sup>. in a systematic review of 14 studies reported that surgery may reduce transformations to

malignancy of oral leukoplakia with dysplastic features, although it may not eliminate this risk completely despite complete removal using scalpel excision or laser vaporization. As the adjacent or peripheral epithelium may proliferate in the recurrence phenomenon, it is proposed that these epithelial tissues, which show clinically normal features, consist of highly active cells which are probably abundantly widespread in the basal cell layer. It has been accepted that “field cancerization” or “field change” of oral mucosal cancer is very important in explaining the presence of dysplastic cells adjacent to squamous cell carcinoma as well as potentially malignant disorders and recurrence following complete laser vaporization. There is correlation between location of lesion, dysplastic activity, adverse habits, gender, and presence of lesion for longer duration.

## CONCLUSION

Diode provides an alternative technique with marked clinical improvement and high degree of patient acceptance within the limits of this study. Because of good coagulation, patients’ surgical period with high-risk infections was reduced. Exceptionally precise tissue ablation at low power settings diode lasers is neither absorbed too much nor too little in water and hemoglobin, enabling precise char- free soft tissue ablation and hemostasis. The small portable size of the unit is of beneficial effect for the dentists. It is recommended that future studies can be carried out for evaluation of malignant transformation rate and reoccurrences with large sample size.

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# Evaluation Of Stress And Anxiety Among Dental Students In The Wake Of COVID-19 Pandemic—A Cross Sectional Study

## Abstract

### Aim:

This study aimed to evaluate anxiety and stress among dental under graduate and post graduate students who were due for appearing for the summer 2020 exams conducted by Maharashtra University of health sciences and provide guidance to combat this situation in Covid-19 era.

### Materials and Methods:

A questionnaire [English language] was distributed among the students. Participants gave their consent those willing to be part of the study. HAM-A and [GAD-7] scales were used for assessment of anxiety and stress levels among the students.

### Results:

110 students participated in the study. On comparison between PG and UG students based on HAM-A scale 44.8% PG and 30% UG students showed mild anxiety symptoms whereas 24.1% PG and 18.8% UG students had severe anxiety however the difference was statistically insignificant. On comparison between PG and UG students based on GAD-7 scale 3.4% PG and 18.8% UG students had minimal symptoms whereas 31% PG and 21.3% UG students had severe anxiety. However, the difference was statistically insignificant. On comparison gender wise overall by HAM-A scale girls were found to have a higher anxiety level than boys and the difference was found to be statistically significant.

### Conclusion:

Improving infection control measures have become a part and parcel for any health institution to maintain healthy environment, to alleviate anxiety among students and to boost their morale in this Covid-19 era.

### Keywords:

Covid-19, anxiety, HAM-A, GAD-7, dental students.

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## INTRODUCTION

WHO announced a public emergency in January 2020 which was officially named as COVID-19 on

Feb 2020 where, COVID-19 stands for corona virus disease that appeared in the year 2019. Corona virus is an enveloped virus known to have the property of mutation affecting the overall systems of our body

viz Respiratory, Hepatic, enteric and neurological system<sup>1</sup>.

### INDIA AND COVID-19:

India, being the second-largest populous country in the world, has been affected greatly due to the unprecedented situation arising out of the COVID 19 pandemic. It has been estimated that around 1 lakh cases were found to be diagnosed with COVID-19 by May 18<sup>th</sup> 2020 and by 11<sup>th</sup> July 2020, the cases almost totaled 8 lakhs. To control the spread of the viral disease, various guidelines and measures were undertaken in India viz. implementation of lockdown, social distancing and maintenance of hand hygiene, wearing of masks which were strictly followed. Implementing the following guidelines in India had an adverse consequence on the economy and the social well-being; however, it has been found to have a positive effect on the environment<sup>1</sup>. The current situation has affected human lives emotionally. The first reaction of this pandemic was fear among people about 'What to do?' and 'What not to do?' As of now, no specific medicine or vaccine is available to combat against the disease. Facts as well as unfounded reports without concrete evidence as well as outright mis- or false information resulted in an escalation of fear and a sense of uncertainty among the society. The frequency of the fear was also found to progressively increasing with some developing a paranoia of misconstruing every symptom as that of COVID 19 to also getting excessively anxious and getting tested for COVID despite the laying down of regulations stating exactly when to be tested. It was also observed that several people were found to misuse or hoard COVID specific critical medications that were prohibited for general use. This vicious cycle resulted in a massive burden of emotional distress and anxiety among people<sup>2</sup>.

### DENTISTRY AND COVID-19:

According to a published report<sup>3</sup>, dentistry has been greatly affected by COVID-19. Patient's oral fluids, dental unit surfaces and material contamination may act as a source of spread of the contagious disease to the dentist, his/ her assistant and the patient as well during daily clinical dental practice. Dentists are at major stress pertaining to covid-19 situation<sup>4</sup>. Dental students are also under pandemic radar especially during their exam times. Disaster associated emotional features are quite unique. For example, some students who are anxious students may also have depression. Besides majority of the population experiencing emotional distress due to the unprecedented and exhaustive situation would have been otherwise categorized as "Healthy" The vast

proportion of the population suffering from distress due to disasters were found to recuperate over a period of time with minimal or no interventions. These people are disturbed due to exposure to certain amount of stress whereas thirdly, a majority of people who are disturbed due to disaster associated stress might recovers spontaneously over time or with certain stress releasing inputs. So, it is very important to recognize this emotional impact emerging out of these crises and should be evaluated. Hence aim of the present study was to:

1. Evaluate anxiety and stress levels in dental under graduate (UG) and post graduate (PG) students appearing for BDS and MDS exams respectively in Summer 2020 (delayed due to Covid -19) conducted by MUHS [Maharashtra University of Health Sciences].
2. Comparative evaluation of HAM-A scale and GAD-7 scale among UG and PG students.
3. Comparative evaluation of HAM-A and GAD -7 scale gender wise among UG and PG students and
4. To compare overall difference of HAM-A and GAD-7 scale according to gender.

### MATERIALS AND METHODS:

After obtaining due institutional ethics committee clearance, 81 final year under graduate dental students and 29 final year post graduate dental students appearing for BDS and MDS Summer 2020 exams (delayed due to Covid-19) conducted by MUHS [ Maharashtra university of health sciences] respectively were selected for the study.

### STUDY DESIGN:

Informed consent was obtained from Final year UG and PG dental students. The use of Hamilton Anxiety Rating scale<sup>5</sup> assessed anxiety among students. The scale included 14 questions; that measures both psychic and somatic anxiety. Assessment of anxiety disorder was carried out by using Generalized Anxiety Disorder -7 scale. It included 7 questions describing symptoms experienced by the patients for past 2 weeks.

### SCORING

#### HAM-A SCALE:

0-Not present, 4- severe, total score range 0-56

Interpretation: Less than 17- mild severity, 18-24 mild to moderate severity, 25-30 moderate to severe.



### GAD-7 SCALE:

0- not at all sure to 3- nearly every day, total score range of 0-21.

Interpretation: 5- mild, 10- moderate, 15- severe.

Comparative evaluation among HAM-A and GAD-7 scales was carried out between UG and PG students. Also gender wise comparison of HAM-A and GAD-7 scale among UG and PG students and overall comparison was also carried out.

## RESULTS

### STATISTICAL ANALYSIS:

The data was analyzed using SPSS software v20. The data was analyzed using frequency distribution method and was presented as frequency and percentage

Question	0	1	2	3	4
1	2 (2.5)	6 (7.5)	21 (26.3)	30 (37.5)	21 (26.3)
2	1 (1.3)	9 (11.3)	16 (20)	27 (33.8)	27 (33.8)
3	14 (17.5)	16 (20)	13 (16.3)	22 (27.5)	15 (18.8)
4	13 (16.3)	10 (12.5)	18 (22.5)	25 (31.3)	14 (17.5)
5	8 (10)	15 (18.8)	27 (33.8)	23 (28.7)	7 (8.8)
6	11 (13.8)	19 (23.8)	21 (26.3)	15 (18.8)	14 (17.5)
7	24 (30)	21 (26.3)	15 (18.8)	13 (16.3)	7 (8.8)
8	16 (45)	20 (25)	11 (13.8)	8 (10)	5 (6.3)
9	43 (53.8)	14 (17.5)	17 (21.3)	6 (7.5)	0 (0)
10	47 (58.8)	16 (20)	8 (10)	7 (8.8)	2 (2.5)
11	31 (38.8)	26 (32.5)	12 (15)	7 (8.8)	4 (5)
12	40 (50)	17 (21.3)	16 (20)	5 (6.3)	2 (2.5)
13	34 (42.5)	19 (23.8)	15 (18.8)	7 (8.8)	5 (6.3)
14	25 (31.3)	13 (16.3)	25 (31.3)	11 (13.8)	6 (7.5)

**Table I: HAM-A Scale score distribution among PG students n (%)**

In HAM-A Scale among PG students, five students (17.2%) reported mild anxious mood, ten students (34.5%) reported moderate anxious mood, nine students (31%) reported severe anxious mood and five students (17.2%) reported incapacitating anxious mood.[Table I] In HAM-A Scale among PG students, one student (3.4%) reported no tension, four students (17.2%) reported mild tension, ten students (34.5%) reported moderate tension, nine students (31%) reported severe tension and five students (17.2%) reported incapacitating tension.[Table I].

In HAM-A scale among UG students, 2 students (2.5%) reported to be not anxious, 6 students (7.5%) reported mild anxious mood, 21 students (26.3%)

reported moderate anxious mood, 30 students (37.5%) reported with severe anxiety and 21 students (26.3%) reported incapacitating anxious mood.

In HAM-A scale among UG students, 1 student (1.3%) reported no tension, 9 students (11.3%) reported mild tension, 16 students (20%) reported moderate tension, 27 students (33.8%) with severe tension and 27 students (33.8%) reported with incapacitating tension.

Question	0	1	2	3	4
1	2 (2.5)	6 (7.5)	21 (26.3)	30 (37.5)	21 (26.3)
2	1 (1.3)	9 (11.3)	16 (20)	27 (33.8)	27 (33.8)
3	14 (17.5)	16 (20)	13 (16.3)	22 (27.5)	15 (18.8)
4	13 (16.3)	10 (12.5)	18 (22.5)	25 (31.3)	14 (17.5)
5	8 (10)	15 (18.8)	27 (33.8)	23 (28.7)	7 (8.8)
6	11 (13.8)	19 (23.8)	21 (26.3)	15 (18.8)	14 (17.5)
7	24 (30)	21 (26.3)	15 (18.8)	13 (16.3)	7 (8.8)
8	16 (45)	20 (25)	11 (13.8)	8 (10)	5 (6.3)
9	43 (53.8)	14 (17.5)	17 (21.3)	6 (7.5)	0 (0)
10	47 (58.8)	16 (20)	8 (10)	7 (8.8)	2 (2.5)
11	31 (38.8)	26 (32.5)	12 (15)	7 (8.8)	4 (5)
12	40 (50)	17 (21.3)	16 (20)	5 (6.3)	2 (2.5)
13	34 (42.5)	19 (23.8)	15 (18.8)	7 (8.8)	5 (6.3)
14	25 (31.3)	13 (16.3)	25 (31.3)	11 (13.8)	6 (7.5)

**Table II: HAM-A Scale score distribution among UG students n (%)**

In GAD-7 scale among PG students, two students (6.9%) were not at all sure about feeling nervous, eleven students (37.9%) felt nervous on several days, seven students (24.1%) felt nervous over half the days and nine students (31%) felt nervous nearly every day.

Question	0	1	2	3
1	2 (6.9)	11 (37.9)	7 (24.1)	9 (31)
2	0 (0)	10 (34.5)	8 (27.6)	11 (37.9)
3	2 (6.9)	8 (27.6)	10 (34.5)	9 (31)
4	6 (20.7)	12 (41.4)	6 (20.7)	5 (17.2)
5	7 (24.1)	14 (48.3)	1 (3.4)	7 (24.1)
6	5 (17.2)	9 (31)	8 (27.6)	7 (24.1)
7	3 (10.3)	10 (34.5)	8 (27.6)	8 (27.6)

**Table III: GAD-7 Scale score distribution among PG students n (%)**

In GAD-7 scale among PG students, ten students (34.5%) were worried for most of the days, eight students (27.6%) were worried about half the days and eleven students (37.9%) were worried nearly every day.[Table II]In GAD-7 scale among UG students, 8 students (10%) were not at all sure about feeling nervous, 42 students (52.5%) felt nervous on several days, 22 students (27.5%) felt nervous over half the days and 8 students (10%) felt nervous nearly every day.

Question	0	1	2	3
1	8 (10)	42 (52.5)	22 (27.5)	8 (10)
2	12 (15)	36 (45)	16 (20)	16 (20)
3	13 (16.3)	31 (38.8)	16 (20)	20 (25)
4	17 (21.3)	29 (36.3)	21 (26.3)	13 (16.3)
5	18 (22.5)	43 (53.8)	11 (13.8)	8 (10)
6	17 (21.3)	37 (46.3)	12 (15)	14 (17.5)
7	14 (17.5)	28 (35)	22 (27.5)	16 (20)

**TABLE IV: GAD-7 Scale score distribution among UG students n (%)**

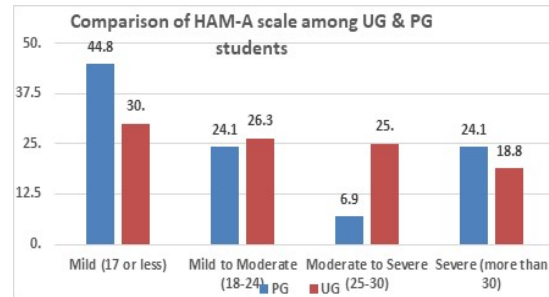
In GAD-7 scale among UG students, 12 students (15%) were not worried, 36 students (45%) were not being able to stop or control worrying on several days, 16 students (20%) were not being able to halt or control worrying over half the days and 16 students (20%) were not being able to stop or control worrying nearly every day. [Table IV]

According to HAM-A scale, 13 PG students (44.8%) showed mild anxiety, seven PG students (24.1%) showed mild to moderate anxiety, two PG students (6.9%) showed moderate to severe anxiety and seven PG students (24.1%) showed severe anxiety. Among UG students, 24 UG students (30%) showed mild anxiety, 21 PG students (26.3%) showed mild to moderate anxiety, 20 PG students (25%) showed moderate to severe anxiety and 15 PG students (18.8%) showed severe anxiety. However, this difference in anxiety (a/c to HAM-A scale) was not statistically significant ( $p=0.159$ ).

Anxiety	PG	UG	chi-square value	p value
Mild (17 or less)	13 (44.8)	24 (30)	5.178	0.159 (NS)
M - M (18-24)	7 (24.1)	21 (26.3)		
M - S (25-30)	2 (6.9)	20 (25)		
Severe (more than 30)	7 (24.1)	15 (18.8)		

chi-square test, NS: Non-significant

**TABLE V: Comparison of HAM-A Scale among PG and UG students**



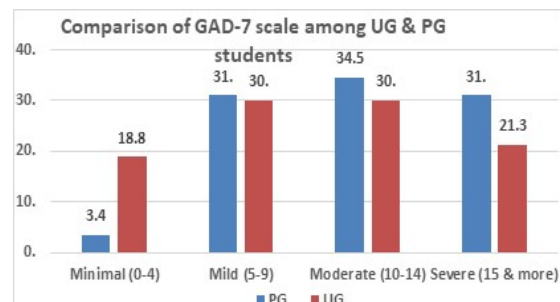
**FIG I: Comparison of HAM-A scale among UG and PG students.**

According to GAD-7 scale, one PG student (3.4%) showed minimal anxiety, nine PG students (31%) showed mild anxiety, ten PG students (34.5%) showed moderate anxiety and nine PG students (31%) showed severe anxiety. Among UG students, 15 UG students (18.8%) showed minimal anxiety, 24 PG students (30%) showed mild anxiety, 24 PG students (30%) showed moderate anxiety and 17 PG students (21.3%) showed severe anxiety. However, this difference in anxiety (a/c to GAD-7 scale) was not significant ( $p=0.222$ ).

Anxiety	PG	UG	chi-square test	p value
Minimal (0-4)	1 (3.4)	15 (18.8)	4.394	0.222 (NS)
Mild (5-9)	9 (31)	24 (30)		
Moderate (10-14)	10 (34.5)	24 (30)		
Severe (15 & more)	9 (31)	17 (21.3)		

Chi-square test, NS: Non-significant

**TABLE VI: Comparison of GAD-7 Scale among PG students and UG students.**



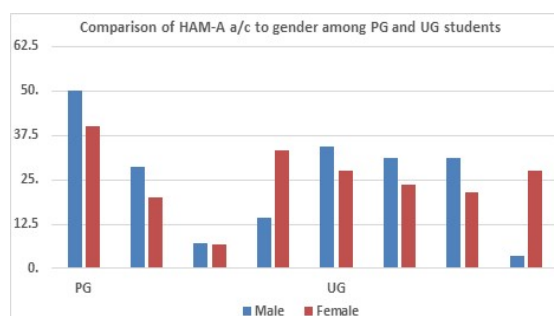
**FIG II: Comparison of GAD-7 scale among UG and PG students.**

According to HAM -A scale and GAD-7 scale among PG and UG students' gender-wise, the difference was not statistically significant.

	Gender	Mild	M - M	M - S	Severe	Total	$\chi^2$	p value
PG	Male	7 (50)	4 (28.6)	1 (7.1)	2 (14.3)	14 (100)	1.473	0.689 (NS)
	Female	6 (40)	3 (20)	1 (6.7)	5 (33.3)	15 (100)		
UG	Male	10 (34.5)	9 (31)	9 (31)	1 (3.4)	29 (100)	7.045	0.070 (NS)
	Female	14 (27.5)	12 (23.5)	11 (21.6)	14 (27.5)	51 (100)		

chi-square test, NS: Non-significant, M-M: Mild-Moderate, M-S: Moderate-Severe

**TABLE VII: Comparison of HAM-A according to gender among PG and UG students**

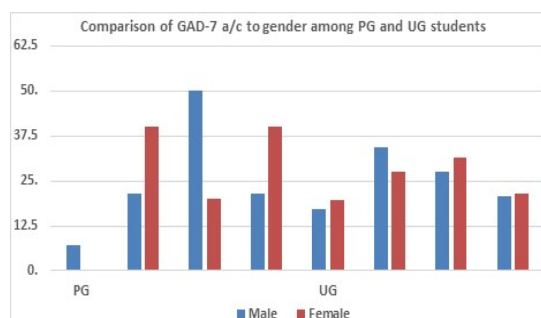


**FIG III: Comparison of HAM-A scale according to gender among UG and PG students.**

	Gender	Minimal	Mild	Moderate	Severe	Total	$\chi^2$	p value
PG	Male	1 (7.1)	3 (21.4)	7 (50)	3 (21.4)	14 (100)	4.571	0.206 (NS)
	Female	0 (0)	6 (40)	3 (20)	6 (40)	15 (100)		
UG	Male	5 (17.2)	10 (34.5)	8 (27.6)	6 (20.7)	29 (100)	0.455	0.929 (NS)
	Female	10 (19.6)	14 (27.5)	16 (31.4)	11 (21.6)	51 (100)		

chi-square test, NS: Non-significant

**TABLE VIII: Comparison of GAD-7 according to gender among PG and UG students**



**FIG IV: Comparison of GAD-7 scale according to gender among UG and PG students.**

According to HAM-A scale when compared gender-wise (overall) the difference was **statistically significant (0.050)**.

Gender	Mild	M - M	M - S	Severe	Total	$\chi^2$	p value
Male	17 (39.5)	13 (30.2)	10 (23.3)	3 (7)	43 (100)	7.694	0.050 (S)
Female	20 (30.3)	15 (22.7)	12 (18.2)	19 (28.8)	66 (100)		

chi-square test, S: Significant

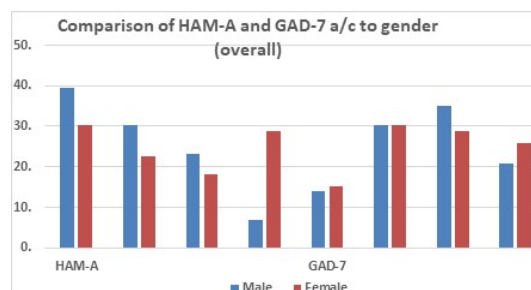
**TABLE IX: Comparison of HAM-A according to gender (overall)**

According to GAD-7 scale when compared gender-wise (overall) the difference was statistically insignificant.

Gender	Minimal	Mild	Moderate	Severe	Total	$\chi^2$	p value
Male	6 (14)	13 (30.2)	15 (34.9)	9 (20.9)	43 (100)	0.590	0.899 (NS)
Female	10 (15.2)	20 (30.3)	19 (28.8)	17 (25.8)	66 (100)		

chi-square test, NS: Non-significant

**TABLE X: Comparison of GAD-7 according to gender (overall)**



**FIG IV: Comparison of GAD-7 scale according to gender among UG and PG students.**

## DISCUSSION

Covid -19 pandemic has resulted into shock among the entire world population to such an extent that people need to reconsider their daily hygiene habits to contain the disease. Hence, its transmission is one of the worst nightmares experienced by the dental students leading to stress and anxiety<sup>7,8</sup>. Aerosols produced by routine dental procedures are responsible for transmission of the virus. Therefore, the students were afraid to take the exams. All the necessary measurements and precautions were implemented in the college as well as in the dental clinics that minimizes the spread of virus, since the participants were inexperienced, they were anxious to get exposed to the virus.

The present study being very first and one-of-a-kind to assess anxiety among dental students appearing for examination conducted by MUHS in Covid-19 pandemic. This study was conducted during August-September 2020. All the final year PG and UG

students appearing for exams were eligible for this study.

The questionnaire was completed by 110 students and the findings of this study suggest that both PG (34.5%) and UG (30%) students suffered from moderate anxiety. Also, female students were more anxious when compared with male students by HAM-A scale and the difference was found to be statistically significant. This is in contrast with a survey conducted in Bangladesh<sup>9</sup>. Since, HAM-A has a good internal consistency it is most frequently used scale. Both the scales were used for the present study since HAM-A focuses more on somatic symptoms of anxiety<sup>10</sup>. However, further studies are needed to assess the interrelation between somatic and anxiety symptoms.

To alleviate anxiety among the students, certain stress management tips were provided to them. It includes:

1. If the student is well prepared, then he/she may gain confidence level and hence can appear for exam without any anxiety.
2. Students should reach their respective departments early before exam and should prepare the patient according to the covid-19 guidelines and should follow the protocol.
3. Students should have a positive attitude and this can be achieved by having morale boosting mantras like “I can do this”
4. Students should concentrate on the pace of their exam.
5. Timing is the key.
6. Students must focus on calm breathing and positive thoughts.

Within the limitations of the present study, more sample size should be evaluated.

## CONCLUSION

To conclude, Covid-19 pandemic stems various psychosocial matters such as “normal people” prone to certain “extraordinary situations” such as anxiety, depression, biologic effects that includes sleep and appetite disturbances. This pandemic has affected the students worldwide physically as well as mentally. Hence it is our duty to increase their morale and gain a positive attitude among the students appearing for their exams either virtually or in practical. Hence this study is a gateway to the effects of pandemic on the students and how the situation should be managed in order to increase their confidence and morale

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# Evaluation Of Curcuma Oral Gel As An Adjunct To Non-Surgical Periodontal Therapy – A Clinical Study.

## Abstract

**Introduction** :- Herbal products have been long employed to improve the oral health by means of frequently used therapeutic procedures gargling and holding of medicated liquids in the mouth. Turmeric (*curcuma longa*) is one such novel product obtained from plants. In dentistry, it plays a role treating gingival and periodontal disease. The present study evaluates the efficacy of curcuma oral gel when used as adjunct to scaling and root planning.

**Material and Methods** :- 60 patients diagnosed with gingivitis, having pocket depth  $\leq 3$  mm and in good systemic health were selected by systematic sampling method and divided in two groups. In both groups scaling and root planning was done. In group A, Curcuma oral gel application was done while Group B was control group. Plaque Index (PI) and Gingival Index (GI) were recorded at baseline, 14 and 21 days.

**Results** :- PI and GI showed significant reduction in two groups after 14 and 21 days compared to baseline. On inter group comparison, both PI and GI showed significant reduction in group A at 14 and 21 days compared to group B ( $p < 0.05$ ).

**Conclusion** :- Curcuma oral gel was effective in treatment of gingivitis when used as adjunct to scaling and root planing for treatment of gingivitis patients.

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## INTRODUCTION

Gingivitis is a form of periodontal disease induced by bacterial plaque. It is an acute disorder of gingiva, affecting majority of populations in the world. It may or may not progress into periodontitis. Periodontitis manifests as inflammation of the gingival and the deeper periodontal tissues which may result into loss of supporting structures of tooth and finally the tooth. As bacterial plaque is the primary aetiological agent in gingivitis. Various treatment modalities have been attempted to control the plaque. Although, mechanical debridement with scaling and root planning is till date the gold standard, still many antimicrobial agents have been used to prevent the plaque accumulation and disease progression.<sup>1</sup>

A variety of oral antimicrobial agents are available such as tetracycline, minocycline, doxycycline, ornidazole, chlorhexidine etc. are available in the form of gels, paste, films, strips, and fibers.<sup>2-6</sup> These can be used for mouth rinsing, irrigation, systemic administration or local applications.<sup>7</sup> However, discolouration of teeth, unpleasant taste and allergic reaction can occur when these antimicrobial agents are used for a long period of time.

The traditional system of herbal medicine has been successfully used to treat a variety of chronic systemic ailments. Turmeric, neem, aloe vera, clove, cinnamon are among the common herbal products used in dentistry. Turmeric possesses anti-inflammatory, antioxidant, and antimicrobial



properties along with hepatoprotective, immunosuppressant, antiseptic, antimutagenic, and many more properties.<sup>8</sup>

Turmeric (*Curcuma longa*), one of the major spices, is being consumed in India and other Asian countries. It is the member of ginger family. The rhizome of *curcuma longa* is the most useful part of plant for culinary and medicinal purposes. The components of turmeric are curcumin, tumerone, atlantone, zingiberone, sugars, proteins, and resins. The active constituent is curcumin, which comprises 0.3-5.4% of raw turmeric.<sup>9</sup>

The anti-microbial and anti-inflammatory properties of *curcuma longa* can be used to manage gingivitis and to overcome the adverse effects caused by the antimicrobial agents. Till date, fewer research has been conducted to treat plaque-induced gingivitis by herbal medicine (turmeric gel). In the present study, the effect of *Curcuma* oral gel (*Curenex* gel) have been evaluated as an adjunct to scaling and root planing over period of three weeks for the management of gingivitis.

## MATERIALS AND METHOD

A total of 60 patients for this study were randomly selected by a systematic sampling method in which A total of 60 patients for this study were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics, Nair Hospital Dental College whose written consent and audio visual consent was taken prior to the study and if the patient was willing to discontinue the treatment procedure during the study, he or she was allowed to do so.

### Armamentarium

Mouth mirror, University of North Carolina-15(UNC-15) probe, Syringe, Local anaesthesia: 2% lignocaine Hydrochloride (HCl) with aDrenaline (1:100,000), Ultrasonic scaler, Curettes, *Curcuma* oral gel (*Curenex* gel™).

### Study design

The gingivitis patients having probing depth  $\leq 3$  mm were randomly divided into Group A and Group B by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

- a) Group A: Scaling and Root planing, followed by application of *Curcuma* oral gel.
- b) Group B: Scaling and Root planing alone.

The patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing.

### Clinical parameters

The following clinical parameters were recorded at baseline (day zero), 14 days and 21 days. The patients were advised to apply the gel post phase I therapy.

1. Plaque Index (P.I.) (TURESKEY-GILMORE-GLICKMAN MODIFICATION OF QUIGLEY HEIN<sup>10</sup>).
2. Gingival Index (G.I.) (LOE & SILNESS<sup>11</sup>).

## PROCEDURE

Following initial examination and treatment planning, the selected subjects underwent thorough scaling and root planing (SRP) with or without local anesthesia. If local anesthesia was required, then working site was infiltrated with 1ml of anesthetic solution with/without aDrenaline (1:200000). If any trauma from occlusion (TFO) was detected, it was relieved. A detailed instructions regarding self-performed plaque control measures was given. The patients in Group A were instructed to take a pea sized amount of gel on finger and apply to the gingiva twice daily and leave it for 10 minutes on affected area post phase I therapy, whereas Group B was used as a control group and only Scaling and Root Planing was done with or without local anesthesia. The clinical parameters were evaluated at baseline, 14 days and 21 days.

### Inclusion criteria

1. Age group between 20-55 years
2. Patients having gingivitis.
3. Patients in good systemic health
4. Patients having probing depths of  $\leq 3$  mm.
5. Patients who have not received any type of periodontal therapy in the past 6 months.

### Exclusion criteria

1. Patients suffering from any systemic diseases like bleeding disorder, diabetes mellitus and thyroid disorders.
2. Patients with a known history of allergy to *curcuma* oral gel or chlorhexidine gel.
3. Patients showing unacceptable oral hygiene compliance during/after the phase I therapy.
4. Patients taking any Drug known to cause gingival enlargement.
5. Pregnant and/or lactating mothers.
6. Patient on anticoagulant therapy and immunosuppressive Drugs like corticosteroids.

## OBSERVATIONS AND RESULTS

The present study evaluated the clinical efficacy of *Curcuma* oral Gel as an adjunct to scaling and root planing in gingivitis patients. The study consisted of 60 (37 males and 23 females) patients in the age group of 20 – 55 years having mean age of 34.82 years who were divided into two groups. Group A consisted 30 (17 males and 13 females) patients and Group B consisted 30 (18 males and 12 females) patients. Patients were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in

each group from the outpatient department of Periodontics.

Group A: Scaling and Root planing, followed by application of Curcuma oral gel.

Group B: Scaling and Root planing alone.

All patients were compliant. The overall results including baseline recordings with final outcomes are displayed in the form of tables for all the parameters.

## PLAQUE INDEX

### Effect of Ornidazole gel on Plaque Index (P.I)

		MEAN	SD	P* VALUE	POST-HOC TEST **
PI	BASELINE	3.3763	.9874	<0.01	BL>14DAY>21DAY
	14 DAY	2.0907	.8238		
	21 DAY	1.3793	.5354		

**Table 1: Plaque Index (P.I.): Data Summary (Group A)**

### Effect of Scaling and Root Planing on Plaque Index (P.I)

		MEAN	SD	P* VALUE	POST-HOC TEST **
PI	BASELINE	3.6597	.7533	<0.01	BL>14DAY>21DAY
	14 DAY	2.4327	.7075		
	21 DAY	1.5777	.5046		

**Table 2: Plaque Index (P.I.): Data Summary (Group B)**

		N	Mean	Std. Deviation	T	P* VALUE
PI(BL)	Curcuma gel(Group A)	30	3.3763	.9874	1.2453	0.11
	Scaling & Root Planing (Group B)	30	3.6597	.7533		
	Total	60	3.518	.8824		

		N	Mean	Std. Deviation	T	P* VALUE
PI(14DAY)	Curcuma gel(Group A)	30	2.0907	.8238	1.7115	0.046
	Scaling & Root Planing (Group B)	30	2.4327	.7075		
	Total	60	2.262	.7806		

		N	Mean	Std. Deviation	T	P* VALUE
PI(21DAY)	Curcuma gel(Group A)	30	1.3793	.5354	1.6898	0.048
	Scaling & Root Planing (Group B)	30	1.5777	.5046		
	Total	60	1.495	.5449		

**Table 3: Comparison of mean Plaque Index between Study groups (Group A and Group B)**

Since the Plaque Indices were observed repeatedly at three time points, repeated measures statistical

analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the plaque index between baseline, 14 day and 21 day in both the experimental groups. The P value was <0.05 for both experimental groups. (Table 1 and Table 2). (Table 3) show inter-group comparison of the mean plaque index. Unpaired t-test showed significant difference between two groups (p<0.05).

## GINGIVAL INDEX

### Effect of Ornidazole gel on Gingival Index (G.I)

		MEAN	SD	P* VALUE	POST-HOC TEST **
GI	BASELINE	1.572	.2605	<0.01	BL>14DAY>21DAY
	14 DAYS	.713	.2805		
	21 DAYS	.285	.1778		

**Table 4: Gingival Index (G.I.): Data Summary (Group A)**

### Effect of Scaling on Gingival Index (G.I)

		MEAN	SD	P* VALUE	POST-HOC TEST **
GI	BASELINE	1.6757	.1259	<0.01	BL>14DAY>21DAY
	14 DAYS	.857	.276		
	21 DAYS	.3817	.1842		

**Table 5: GINGIVAL Index (G.I.): Data Summary (Group B)**

		N	Mean	Std. Deviation	P* VALUE
GI(BL)	Curcuma gel(Group A)	30	1.572	.2605	0.06
	Scaling & Root Planing (Group B)	30	1.6757	.1259	
	Total	60	1.624	.2095	

		N	Mean	Std. Deviation	P* VALUE
GI(14Days)	Curcuma gel(Group A)	30	.713	.2805	0.049
	Scaling & Root Planing (Group B)	30	.857	.276	
	Total	60	.785	.2853	

		N	Mean	Std. Deviation	P* VALUE
GI(21Days)	Curcuma gel(Group A)	30	.285	.1778	0.04
	Scaling & Root Planing (Group B)	30	.3817	.1842	
	Total	60	.333	.186	

**Table 6: Comparison of mean Gingival Index between Study groups (Group A and Group B)**

Since the gingival Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the gingival index between baseline, 14 day and 24 day in both the experimental groups. The P value was <0.05 for both experimental groups. (Table 4 and Table 5). (Table 6) show inter-group comparison of the mean gingival index. Unpaired t-test showed significant difference between two groups ( $p < 0.05$ ).

## DISCUSSION

The present clinical study evaluates the efficacy of Curcuma oral Gel as an adjunct to scaling and root planing in management of gingivitis patients.

Gingivitis is a periodontal disease induced by bacterial plaque. Treatment of periodontal disease is routinely based on mechanical debridement of the tooth surface and appropriate and meticulous maintenance of oral hygiene. As an adjunctive approach, systemic or local administration of antimicrobials is used because of the microbial etiology of periodontal disease. Topical administration of chemotherapeutic agents in the form of mouthwashes, dentifrice or gels can be used effectively in controlling supragingival plaque formation and periodontal disease.<sup>12</sup>

The side effects of these chemicals have promoted the use of herbal products for this purpose. The anti-inflammatory activity of curcumin has been studied in various medical conditions and it has shown beneficial in the management of rheumatoid arthritis,<sup>13</sup> and enhances wound healing by promoting migration of fibroblasts in the healing site and by causing fibrosis of connective tissue.<sup>14</sup>

Very few studies have been done regarding the effect of curcuma gel as adjunctive anti-inflammatory agent in the treatment of gingival and periodontal diseases. The purpose of this study is to evaluate the efficacy of Curcuma oral Gel as an adjunct to scaling in management of gingivitis patients.

Patients with good systemic health and no contraindications to periodontal therapy were selected, since patients suffering from systemic diseases like uncontrolled diabetes mellitus or patients on immunosuppressive therapy, almost always show poor response to the periodontal therapy.<sup>15</sup>

Hormonal fluctuations in the female patient may alter the status of periodontal health and affect the treatment outcome. The most pronounced periodontal changes occur during pregnancy and lactation. Treatment considerations for pregnant patients with periodontal disease may include deferral of periodontal therapy until after parturition.<sup>16</sup> Hence, pregnant and lactating females were excluded from the study.<sup>16</sup>

In the present study the gingivitis patients having probing depth  $\leq 3$  mm were randomly divided into

Group A and Group B by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

Group A: Scaling and Root planing, followed by application of Curcuma oral gel.

Group B: Scaling and Root planing alone.

All the patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing with standard toothpaste and soft toothbrush. Clinical parameters like plaque index, gingival index were evaluated.

## CLINICAL PARAMETERS

**PLAQUE INDEX** (Turesky S. Gilmore N.D. and Glickman I. modification of QuigleyHein in 1970)<sup>10</sup> indicates the oral hygiene maintained by patient and is important because it can influence the periodontal outcome. Plaque scores were evaluated at baseline, 14, 21 days post phase I therapy.

### Experimental Group A

The mean plaque index score for patients in group A at baseline was  $3.38 \pm 0.99$  which was reduced to  $2.09 \pm 0.82$  at 14 days from baseline,  $1.38 \pm 0.54$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 1)

### Experimental Group B

The mean plaque index score for patients in group B at baseline was  $3.66 \pm 0.75$  which was reduced to  $2.43 \pm 0.71$  at 14 days from baseline,  $1.58 \pm 0.50$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 2)

### Comparison between the groups

When results of both groups were compared, statistically significant difference was observed. (Table 3) Thus, it can be concluded that in both groups, statistically significant reduction in plaque index was observed from the baseline to 21 days within the groups.

Statistically significant reduction in plaque index scores also observed when the both groups were compared with each other after 14 and 21 days. This demonstrates the efficacy of curcuma oral gel when used as adjunct to scaling and root planing.

A trend of progressive decline in plaque index scores over the duration of the study was seen. This could be due to antioxidant effects of curcuma oral gel and overall general improvement in periodontal

parameters. Similar trend in reduction of the plaque index was observed in a study conducted by Bhandari H, Shankwalkar GB (1980)<sup>17</sup> and Waghmare *et al.* (2011).<sup>18</sup>

**GINGIVAL INDEX (GI) (Loe & Silness 1963)<sup>11</sup>** is considered to be a true reflection of gingival status in health and disease. It is simple, easy and reproducible index and is used commonly in clinical periodontal research studies. Gingival index scores were evaluated at baseline, 14 and 21 days post-phase I therapy.

#### Experimental Group A

The mean gingival index score for patients in group A at baseline was  $1.55 \pm 0.26$  which was reduced to  $0.71 \pm 0.28$  at 14 days from baseline,  $0.85 \pm 0.18$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 4)

#### Experimental Group B

The mean gingival index score for patients in group B at baseline was  $1.68 \pm 0.13$  which was reduced to  $0.86 \pm 0.28$  at 14 days from baseline,  $0.38 \pm 0.18$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 5)

#### Comparison between the groups

When results of both the groups were compared, after 21 days statistically significant difference was observed between groups A and B. (Table 6) Thus it can be said that in both groups, statistically significant reduction in gingival index was observed from the baseline to 21 days within the groups. Statistically significant reduction in gingival index scores also observed when the both groups were compared with each other after 14 and 21 days. This demonstrates the efficacy of curcuma oral gel when used as adjunct to scaling and root planing. A trend of progressive decline in gingival index scores over the duration of the study was seen. This could be due to anti-inflammatory effects of curcuma oral gel and overall general improvement in periodontal parameters. This finding are similar to studies done by Suhag A *et al.* (2007)<sup>19</sup> and Mulikar S *et al.* (2013).<sup>20</sup>

#### Limitation of the present study:

At the end of the study, it has been observed that there have been certain aspects, which demand more detailed observation and elucidation of data and facts.

1) A larger sample size would have been preferable with a more long-term follow up.

2) An evaluation of microbiological parameters should have been carried out to know the minimal inhibitory concentration of the periodontal pathogens.

3) Paired or split mouth design would have excluded the influence of patients' specific characteristics and facilitated the interpretation of the study by minimizing the effects of inter-patient variability.

## CONCLUSION

The Clinical evaluation was suggestive of the fact that Curcuma oral gel was biocompatible with the tissues. It did not cause any biological complications and therefore could be safely used. The plaque and gingival index decreased in both the groups when compared within the groups. This indicates an overall improvement in oral hygiene status of patients. The reduction in plaque and gingival index score was statistically significant after topical application of Curcuma oral gel as compared to scaling and root planing alone when evaluated after 14 and 21 day. This demonstrates the efficacy of adjunctive use of curcuma oral gel over Scaling and root planing. Thus, it can be concluded that the adjunctive use of curcuma oral gel caused improvement in clinical parameters and can be used for treatment of gingivitis in patients. However, long-term studies to facilitate better understanding of the performance of curcuma oral gel for treatment of gingivitis in patients can be advocated in the future.

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# Comparative Clinical Evaluation Of Curcuma Oral Gel And Chlorhexidine Gel As An Adjuncts To Non-Surgical Periodontal Therapy – A Randomized Controlled Double Blinded Trial

## Abstract

**Introduction:** Topical chemotherapeutic agents used in the treatment of gingivitis are antimicrobial agents which help in plaque control, but there are adverse effects of these chemotherapeutic agents. This led to the search of herbal products which are highly beneficial and biocompatible. Turmeric (curcuma longa) is one such novel product obtained from plants. The present study evaluates the efficacy of curcuma oral gel with gold standard chlorhexidine gel when used as adjunct to scaling and root planing.

**Material and Methods :** 90 patients diagnosed with gingivitis, having pocket depth  $\leq 3$  mm and in good systemic health were selected by systematic sampling method and divided in 3 groups. In all 3 groups scaling and root planing was done. In group A, Curcuma oral gel application was done while in Group B Chlorhexidine gel application was done while Group C was control group. Plaque Index (PI) and Gingival Index (GI) were recorded at baseline, 14 and 21 days.

**Results :** PI and GI showed significant reduction in all three groups after 14 and 21 days compared to baseline. On inter group comparison, both PI and GI showed no significant difference in reduction of scores after 14 and 21 days ( $p > 0.05$ ).

**Conclusion :** Curcuma oral gel showed comparable efficacy as Chlorhexidine when used as adjunct to scaling and root planing for treatment of gingivitis patients.

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## INTRODUCTION

Gingivitis is inflammation of the gingiva which may or may not progress into periodontitis. Periodontitis manifests as inflammation of the gingival and the deeper periodontal tissues which may result into loss of supporting structures of tooth and finally the tooth. Bacterial plaque is the main etiological agent

in gingivitis and plaque control remains the ultimate focus for maintaining the periodontal health. Various treatment modalities have been attempted to control the plaque which includes personal and professional care to reduce the etiologic factors to decrease or eliminate inflammation. Mechanical debridement with oral prophylaxis is till date the gold standard,

still many antimicrobial agents have been used to prevent the plaque accumulation and disease progression<sup>1</sup>.

Number of antimicrobial agents shown better results with adjunct use of various local Drug delivery systems such as tetracycline fibers, metronidazole gel, minocycline ointment and minocycline microspheres, chlorhexidine chip, and doxycycline hyclate, without exposing the individual to systemic complications<sup>2</sup>.

Chlorhexidine is considered as gold standard in chemical plaque control due to its substantivity and has been used effectively in treatment of gingivitis over last 4 decades. But due to its adverse effects such as staining of teeth, desquamation, altered taste and mucosal burning, other active ingredients have also been investigated as an alternative for this agent<sup>3</sup>.

One such agent is Turmeric (*Curcuma longa*), which possesses anti-inflammatory, antioxidant, and antimicrobial properties along with hepatoprotective, immunosuppressant, antiseptic, antimutagenic, and many more properties<sup>4</sup>. *Curcuma longa* belong to traditional system of herbal medicine along with neem, aloe vera, clove, cinnamon. Turmeric (*Curcuma longa*), one of the major spices, is being consumed in India and other Asian countries. It is the member of ginger family. The rhizome of *curcuma longa* is the most useful part of plant for culinary and medicinal purposes. The components of turmeric are curcumin, turmerone, atlantone, zingiberone, sugars, proteins, and resins. The active constituent is curcumin, which comprises 0.3-5.4% of raw turmeric<sup>5</sup>.

*Curcuma longa* and chlorhexidine both have antimicrobial activity of which chlorhexidine is considered as gold standard in chemical plaque control. On the other hand, *Curcuma longa* is a herbal medicine and possesses additional anti-inflammatory benefit over chlorhexidine in management of gingival inflammation. Till date, there are fewer studies comparing Chlorhexidine gel and *Curcuma* oral gel topical application in patients with gingivitis. In the present study, the effect of topical application of the Chlorhexidine gel and *Curcuma* oral gel have been evaluated as an adjunct to scaling and root planing over period of three weeks in patients with gingivitis.

## MATERIALS AND METHOD

A total of 90 patients for this study were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics, Nair Hospital Dental College whose written consent and audio-visual consent was taken prior to the study and if the patient was willing to discontinue the treatment procedure during the study, he or she was allowed to do so.

### Armamentarium

Mouth mirror, University of North Carolina-15(UNC-15) probe, Syringe, Local anaesthesia: 2% lignocaine Hydrochloride (HCl) with aDrenaline (1:100,000), Ultrasonic scaler, Curettes, *Curcuma* oral gel (*Curenex gel*™), Chlorhexidine gel (*Hexigel*™).

### Study design

The gingivitis patients having probing depth  $\leq 3$  mm were randomly divided into Group A, Group B, and Group C by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

Group A: Scaling and Root planing, followed by application of *Curcuma* oral gel.

Group B: Scaling and Root planing, followed by application of Chlorhexidine gel.

Group C: Scaling and Root planing alone.

The patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing.

### Clinical parameters

The following clinical parameters were recorded at baseline (day zero), 14 days and 21 days. The patients were advised to apply the gel post phase I therapy.

1. Plaque Index (P.I.) (TURESKEY-GILMORE-GLICKMAN MODIFICATION OF QUIGLEY HEIN)<sup>6</sup>.
2. Gingival Index (G.I.) (LOE & SILNESS)<sup>7</sup>.

### Procedure

Following initial examination and treatment planning, the selected subjects underwent thorough scaling and root planing (SRP) with or without local anesthesia. If local anesthesia was required, then working site was infiltrated with 1ml of anesthetic solution with/without aDrenaline (1:200000). If any trauma from occlusion (TFO) was detected, it was relieved. A detailed instructions regarding self-performed plaque control measures was given. The patients were instructed to take a pea sized amount of gel on finger and apply to the gingiva twice daily and leave it for 10 minutes on affected area post phase I therapy, whereas Group C was used as a control group and only Scaling and Root Planing was done with or without local anesthesia. The clinical parameters were evaluated at baseline, 14 days and 21 days.

### Inclusion criteria

1. Age group between 20-55 years
2. Patients having gingivitis.
3. Patients in good systemic health
4. Patients having probing depths of  $\leq 3$  mm.
5. Patients who have not received any type of periodontal therapy in the past 6 months.

## Exclusion criteria

1. Patients suffering from any systemic diseases like bleeding disorder, diabetes mellitus and thyroid disorders.
2. Patients with a known history of allergy to curcuma oral gel or chlorhexidine.
3. Patients showing unacceptable oral hygiene compliance during/after the phase I therapy.
4. Patients taking any Drug known to cause gingival enlargement.
5. Pregnant and/or lactating mothers.
6. Patient on anticoagulant therapy and immunosuppressive Drugs like corticosteroids.

## Effect of Curcuma gel on Plaque Index (P.I)

		MEAN	SD	P* VALUE	POST-HOC TEST**
PI	BASELINE	3.4763	.99336	<0.01	BL>14DAYS>21DAYS
	14 DAYS	2.0330	.7668		
	21DAYS	1.3433	.5087		

**Table 1: Plaque Index (P.I.): Data Summary (Group A)**

## Effect of Chlorhexidine gel on Plaque Index (P.I)

		MEAN	SD	P* VALUE	POST-HOC TEST**
PI	BASELINE	3.8906	.94900	<0.01	BL>14DAYS>21DAYS
	14DAYS	2.2697	.6270		
	21DAYS	1.3403	.3522		

**Table 2: Plaque Index (P.I.): Data Summary (Group B)**

## Effect of Scaling and Root Planing on Plaque Index (P.I)

		MEAN	SD	P* VALUE	POST-HOC TEST**
PI	BASELINE	3.7263	.76036	<0.01	BL>14DAYS>21DAYS
	14DAYS	2.4993	.7171		
	21DAYS	1.6077	.5111		

**Table 3: Plaque Index (P.I.): Data Summary (Group C)**

		N	Mean	Std. Deviation	P* VALUE	POST-HOC TEST**
PI(BL)	Curcuma gel(Group A)	30	3.4763	.99336	0.15	A=B=C
	Chlorhexidine (Group B)	30	3.8906	.94900		
	Scaling &Root Planing (Group C)	30	3.7263	.76036		
	Total	90	3.7311	.88512		

		N	Mean	Std. Deviation	P* VALUE	POST-HOC TEST**
PI(14Days)	Curcuma gel(Group A)	30	2.033	.7668	0.043	(A=B)<C
	Chlorhexidine (Group B)	30	2.2697	.6270		
	Scaling &Root Planing (Group C)	30	2.4993	.7171		
	Total	90	2.2670	.7238		

		N	Mean	Std. Deviation	P* VALUE	POST-HOC TEST**
PI(21Days)	Curcuma gel(Group A)	30	1.3433	.5087	0.042	(A=B)<C
	Chlorhexidine (Group B)	30	1.3403	.3522		
	Scaling &Root Planing (Group C)	30	1.6077	.5111		
	Total	90	1.4300	.5751		

**Table 4: Comparison of mean Plaque Index between Study groups (Group A, Group B and Group C)**

Since the Plaque Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the plaque index between baseline, 14 days and 21 days in all the experimental groups. The P value was <0.05 for all the three experimental groups. (Table 1, Table 2 and Table 3). (Table 4) show inter-group comparison of the mean plaque index. One-way ANOVA test & Post-hoc Tukey's test showed significant difference between three groups (p<0.05).

## GINGIVAL INDEX

## Effect of Curcuma gel on Gingival Index (G.I)

		MEAN	SD	P* VALUE	POST-HOC TEST**
GI	BASELINE	1.623	.19235	<0.01	BL>14DAYS>21DAYS
	14DAYS	.735	.2776		
	21DAYS	.3077	.1647		

**Table 5: Gingival Index (G.I.): Data Summary (Group A)**



### Effect of Scaling on Gingival Index (G.I)

		MEAN	SD	P* VALUE	POST-HOC TEST**
GI					
	BASELINE	1.6533	.21746	<0.01	BL>14DAYS>21DA YS
	14DAYS	.7061	.32186		
	21 DAYS	.291	.18047		

**Table 6: GINGIVAL Index (G.I.): Data Summary (Group B)**

### Effect of Scaling & root Planing on Gingival Index (G.I)

		MEAN	SD	P* VALUE	POST-HOC TEST**
GI					
	BASELINE	1.6857	.17486	<0.01	BL>14DAYS>21DA YS
	14 DAYS	.8833	.28045		
	21 DAYS	.3817	.20806		

**Table 7: GINGIVAL Index (G.I.): Data Summary (Group C)**

		N	Mean	Std. Deviation	P* VALUE	POST-HOC TEST**
GI(BL)	Curcuma gel(Group A)	30	1.623	.19235	0.87	A=B=C
	Chlorhexidine (Group B)	30	1.6533	.21746		
	Scaling & Root Planing (Group C)	30	1.6857	.17486		
	Total	90	1.6851	.23486		
		N	Mean	Std. Deviation	P* VALUE	POST-HOC TEST**
GI(14Days)	Curcuma gel(Group A)	30	.735	.2776	0.048	(A=B)<C
	Chlorhexidine (Group B)	30	.7061	.32186		
	Scaling & Root Planing (Group C)	30	.8833	.28045		
	Total	90	.775	.301		
		N	Mean	Std. Deviation	P* VALUE	POST-HOC TEST**
GI(21Days)	Curcuma gel(Group A)	30	.3077	.1647	0.049	(A=B)<C
	Chlorhexidine (Group B)	30	.291	.18047		
	Scaling & Root Planing (Group C)	30	.3817	.20806		
	Total	90	.335	.1956		

**Table 8: Comparison of mean Gingival Index between Study groups (Group A, Group B, and Group C)**

Since the gingival Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the gingival index between baseline, 14

days and 21 days in all the experimental groups. The P value was <0.05 for all the three experimental groups. (Table 5, Table 6 and Table 7). (Table 8) show inter-group comparison of the mean gingival index. One-way ANOVA test & Post-hoc Tukey's test showed significant difference between three groups ( $p < 0.05$ ).

## DISCUSSION

The present clinical study evaluates and compare the efficacy of Curcuma Gel with Chlorhexidine Gel as an adjunct to scaling and root planing in management of gingivitis patients.

Bacterial plaque is the main causative agent for gingivitis and periodontitis and plaque control has an important role in the prevention of gingival and periodontal disease. Mechanical debridement of the tooth surface has remained standard of periodontal therapy; however the inability of patients to perform adequate mechanical plaque control has stimulated the search for alternate chemotherapeutic agents to improve periodontal health.

As an adjunctive approach, systemic or local administration of antimicrobials is used because of the microbial etiology of periodontal disease. Topical administration of chemotherapeutic agents in the form of mouthwashes, dentifrice or gels can be used effectively in controlling supragingival plaque formation and periodontal disease<sup>8</sup>. But the adverse effects of these chemicals such as staining of teeth, desquamation, altered taste and mucosal burning have promoted the use of herbal products for this purpose.

To the best of our knowledge, very few studies has been done to check the efficacy of Curcuma Gel with Chlorhexidine Gel as an adjunct to scaling in the treatment of gingival and periodontal diseases. The purpose of this study is to compare Curcuma oral Gel with Chlorhexidine Gel as an adjunct to scaling in gingivitis patients.

Patients with good systemic health and no contraindications to periodontal therapy were selected, since patients suffering from systemic diseases like uncontrolled diabetes mellitus or patients on immunosuppressive therapy, almost always show poor response to the periodontal therapy<sup>9</sup>.

Hormonal fluctuations in the female patient may alter the status of periodontal health and affect the treatment outcome. The most pronounced periodontal changes occur during pregnancy and lactation. Treatment considerations for pregnant patients with periodontal disease may include deferral of periodontal therapy until after parturition<sup>10</sup>. Hence, pregnant and lactating females were excluded from the study.

In the present study the gingivitis patients having probing depth  $\leq 3$  mm were randomly divided into Group A, Group B and Group C by a systematic sampling method in which every 5th subject was

selected and recruited alternatively in each group as follows:

Group A: Scaling and Root planing, followed by application of Curcuma oral gel.

Group B: Scaling and Root planing, followed by application of Chlorhexidine gel

Group C: Scaling and Root planing alone.

All the patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing with standard toothpaste and soft toothbrush. Clinical parameters like plaque index, gingival index were evaluated.

## Clinical parameters

**PLAQUE INDEX (Turesky S. Gilmore N.D. and Glickman I. modification of QuigleyHein in 1970)<sup>6</sup>** indicates the oral hygiene maintained by patient and is important because it can influence the periodontal outcome. Plaque scores were evaluated at baseline, 14, 21 days post phase I therapy.

### Experimental Group A

The mean plaque index score for patients in group A at baseline was  $3.48 \pm 0.99$  which was reduced to  $2.03 \pm 0.77$  at 14 days from baseline,  $1.34 \pm 0.51$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 1)

### Experimental Group B

The mean plaque index score for patients in group B at baseline was  $3.89 \pm 0.95$  which was reduced to  $2.27 \pm 0.63$  at 14 days from baseline,  $1.34 \pm 0.35$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 2)

### Experimental Group C

The mean plaque index score for patients in group B at baseline was  $3.73 \pm 0.76$  which was reduced to  $2.50 \pm 0.72$  at 14 days from baseline,  $1.61 \pm 0.51$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 3)

## Comparison between the groups

When results of all the groups was compared after 14 and 21 days no statistically significant difference was observed between group A and B, but both the

groups had statistically significant reduction in plaque index score when compared to group C. (Table 4) Thus it can be said that in all groups, statistically significant reduction in plaque index score was observed from the baseline to 21 days within the groups. After 14 and 21 days both group A and group B had statistically significant reduction in plaque score as compared to group C. This demonstrates the efficacy of curcuma gel and chlorhexidine gel when used as adjunct to scaling and root planing.

The significant reduction in plaque score in group A and group B compared to group C may be because of antioxidant activity of curcuma gel and antiplaque activity of chlorhexidine gel. Similar trend in reduction of the plaque index was observed in a study conducted by Bhandari H, Shankwalkar GB (1980)<sup>11</sup> and Waghmare *et al.* (2011)<sup>12</sup>

**Gingival Index (GI) (Loe & Silness 1963)<sup>7</sup>** is considered to be a true reflection of gingival status in health and disease. It is simple, easy and reproducible index and is used commonly in clinical periodontal research studies. Gingival index scores were evaluated at baseline, 14 and 21 days post-phase I therapy.

### Experimental Group A

The mean gingival index score for patients in group A at baseline was  $1.62 \pm 0.19$  which was reduced to  $0.74 \pm 0.28$  at 14 days from baseline,  $0.31 \pm 0.16$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 5)

### Experimental Group B

The mean gingival index score for patients in group B at baseline was  $1.65 \pm 0.22$  which was reduced to  $0.71 \pm 0.32$  at 14 days from baseline,  $0.29 \pm 0.18$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 6)

### Experimental Group C

The mean gingival index score for patients in group B at baseline was  $1.69 \pm 0.17$  which was reduced to  $0.88 \pm 0.28$  at 14 days from baseline,  $0.38 \pm 0.21$  at 21 days from baseline. There was statistically significant difference between baseline, 14 days & 21 days follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 21 days follow-up ( $p < 0.05$ ). (Table 7)

### Comparison between the groups

When results of all the groups was compared after 14 and 21 days no statistically significant difference was observed between group A and B, but both the groups had statistically significant reduction in plaque index score when compared to group C. (Table 8) Thus it can be said that in all groups, statistically significant reduction in gingival index score was observed from the baseline to 21 days within the groups. After 14 and 21 days both group A and group B had statistically significant reduction in gingival index score as compared to group C. This demonstrates the efficacy of curcuma gel and chlorhexidine gel when used as adjunct to scaling and root planing.

A trend of progressive decline in gingival index scores over the duration of the study was seen in group A and B compared to group C. This could be due to anti-inflammatory effects of curcuma oral gel and substantivity property of chlorhexidine gel. This finding are similar to studies done by Mulikar S et al (2013)<sup>13</sup>

### Limitation of the present study:

At the end of the study, it has been observed that there have been certain aspects, which demand more detailed observation and elucidation of data and facts.

- 1) A larger sample size would have been preferable with a more long-term follow up.
- 2) An evaluation of microbiological parameters should have been carried out to know the minimal inhibitory concentration of the periodontal pathogens.
- 3) Paired or split mouth design would have excluded the influence of patients' specific characteristics and facilitated the interpretation of the study by minimizing the effects of inter-patient variability.
- 4) Among the patients enrolled in the study, not all patient were regular for followup. There were Dropouts which were accounted for my enrolling new patients.

### CONCLUSIONS

The present study suggest that there was an overall decrease in plaque and gingival index in all the three groups when compared within the groups, over the 21-day study period. The plaque and gingival index scores were significantly lower for both curcuma oral gel and chlorhexidine gel as compared to scaling and root planing alone when evaluated after 14 and 21 days. Both gels were biocompatible with the tissues. They did not cause any biological complications and therefore could be

safely used. But, there were no statistically significant differences between curcuma oral gel and chlorhexidine gel the groups. Thus it can be suggested that curcuma oral gel and chlorhexidine gel may help reduce gingival inflammation and both gels can be used for treatment of gingivitis in patients. Long term evaluation of the sites is recommended to evaluate the sustainability of the results.

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# Comparative Evaluation of Efficacy of Potassium Nitrate in Toothpaste and Mouthwash Form in the Treatment of Dentinal Hypersensitivity. A randomized clinical trial.

## Abstract

**Introduction :** Dentinal hypersensitivity (DH) is one of the most commonly encountered dental problems. Characterized by pain of short duration arising from exposed dentin. Potassium Nitrate toothpaste has been used as a desensitizing agent to treat dentinal hypersensitivity. However fewer studies has been done to evaluate the desensitizing efficacy of potassium nitrate used in the form of mouthwash. The present study evaluates the efficacy of potassium nitrate in toothpaste and mouthwash form in the treatment of dentinal hypersensitivity.

**Material and Methods :-** Forty patients were selected with sensitive teeth and randomly divided into two groups by a systematic sampling method. In group I, toothpaste containing 5% potassium nitrate while group II receives mouthwash containing 3% potassium nitrate. The parameter were recorded at baseline, Week 2 and Week 4.

**Results :-** Within the groups there was an overall decrease in dentinal hypersensitivity in both groups after week 2 and week 4 compared to baseline. On inter group comparison, there were no statistically significant differences between the groups. ( $p>0.05$ ).

**Conclusion :-** Rinsing twice daily with a 3% potassium nitrate mouthwash or brushing twice daily with a 5% potassium nitrate toothpaste may help reduce discomfort arising from dentinal hypersensitivity.

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## INTRODUCTION

Dentinal hypersensitivity (DH) is one of the most commonly encountered dental problems. It can be particularly uncomfortable and unpleasant for patients and can dictate types of foods and Drinks ingested. Patients may describe the condition as dull or sharp, vague or specific and intermittent or constant. Dentinal hypersensitivity can be described clinically as an exaggerated response to non-noxious stimuli and is characterized by pain of short duration arising from exposed dentin in response to stimuli, typically thermal, evaporative, tactile, osmotic, or

chemical & which cannot be ascribed to any other dental defect or pathology.<sup>1</sup>

The disease is prevalent in the patient with the age range of 20-50 years. However, it is more prevalent in the patient with the age range of 30-40 and more prevalent in female individuals that would probably be related to their dental hygiene and dietary habits. The condition may affect any tooth, but it most often affects canines and premolars.<sup>2-6</sup>

Hypersensitivity is usually caused by loss of enamel covering due to attrition (para functional habits), abrasion (improper brushing technique), erosion



(dietary components, gastric disorders). Dentin exposure due to gingival recession, chronic trauma from faulty restoration, following iatrogenic removal of cementum during root planing and curettage can lead to sensitivity. Following the application of citric acid to remove smear layer and surgical periodontal treatment may also contribute to hypersensitivity.<sup>7</sup>

However most hypersensitive teeth are accompanied by gingival recession and cervical abrasion presumably resulting from periodontal disease, periodontal therapy, or improper brushing habits. Attempts to reduce dentine hypersensitivity have been aimed at either reducing the excitability of the nerve fibres within the pulp or occluding the open dentinal tubules. Various agents have been used as desensitizers for hypersensitive teeth including silver nitrate, fluoride, formaldehyde, strontium chloride and potassium nitrate.<sup>8-10</sup> Dentifrices containing potassium ions have been shown by several clinical studies to be effective in reducing dentine hypersensitivity. Potassium ions are thought to act by blocking the action potential generated in intradental nerves.<sup>11,12</sup> Potassium nitrate is used either as a toothpaste or as a mouthwash. And, there is always a dilemma regarding whether it is effective when delivered as toothpaste or as a mouthwash. The studies which compare the effectiveness of toothpaste and a mouthwash are rare. This study is designed to compare the effectiveness of desensitizing toothpaste and a mouthwash, both containing potassium nitrate for the treatment of dentinal hypersensitivity.

## MATERIALS AND METHOD

A total of 40 patients for this study will be randomly selected by a systematic sampling method in which every 5th subject will be selected and will be recruited alternatively in each group from the outpatient department of Periodontics, Nair Hospital Dental College, Mumbai. Written consent as well as video consent will be taken prior to the study and if the patient is willing to discontinue the treatment procedure during the study, he or she will be allowed to do so.

## STUDY DESIGN

Fourty patients were be selected with sensitive teeth and randomly divided into group I and group II by a systematic sampling method in which every 5th subject will be selected and will be recruited alternatively in each group as follows:

Group I: Those receiving toothpaste containing 5% potassium nitrate.

Group II: Those receiving mouthwash containing 3% potassium nitrate

The study was a randomised open labelled group design with three study visits: baseline, Week 2, and Week 4.

## Clinical Parameter

The study was a randomised open labelled group design with three study visits: baseline, Week 2 and Week 4. The participants teeth were subjectively assessed by means of a VAS(Visual Analogue Scale). The VAS is a 10-cm line with the anchor words “no pain” (0 cm) and “intolerable pain (10 cm)” at the opposite ends. Each participant were asked to place a vertical mark on the VAS to indicate the intensity of his or her level of sensitivity after receiving stimuli. The parameter will be recorded at baseline, Week 2 and Week 4.

## Sensitivity Assessment

To assess tooth sensitivity, a controlled air stimulus (evaporative stimulus) and cold water (thermal stimulus) were used. Scoring of tooth sensitivity was done first by using controlled air pressure, from a dental unit syringe applied 1 cm away from the affected teeth to determine the participant’s baseline response and followed by thermal stimuli i.e. application of ice-cold water after 5 minutes to the exposed dentin surface. The parameter were recorded at baseline, Week 2 and Week 4.

## Procedure

All patients were given oral hygiene instructions after oral prophylaxis. Patients were advised to use a new soft brush for brushing. Patients were randomly divided into group I and group II. Patients under group I were given self-applied toothpaste to be used twice daily and were instructed to brush with allocated toothpaste for 2-3 minutes for 4 weeks. Patients under group II were given a self-use mouthwash to be used twice daily and were instructed to use brush with regular toothpaste for 2-3 minutes twice daily, followed by rinsing with 10ml of water for 1 minute and then using 10ml of the allocated mouthwash for 1 min before spitting out for 4 weeks. All patients were recalled after 2 weeks and 4 weeks for follow up and were evaluated for sensitivity.

## INCLUSION CRITERIA

- 1) Patients with gingival recession having dentinal hypersensitivity.
- 2) Systemically healthy patients
- 3) Patients age between 25-55 years with chronic periodontitis.
- 4) Cooperative patients who can be motivated to maintain good oral hygiene.
- 5) Patients with at least one sensitive tooth with a VAS score of  $\geq 4$ .
- 6) Patients who consented to participate in the study

## EXCLUSION CRITERIA

- 1) Subjects with history of treatment for dentin hypersensitivity.
- 2) Patients with poor periodontal condition.
- 3) Patients having systemic debilitating disease.
- 4) Patients giving a history of allergy to potassium nitrate.
- 5) Caries or restoration in the area of hypersensitivity.
- 6) Patients with orthodontic appliance, crowns, bridges in the area of sensitivity.

## OBSERVATIONS AND RESULTS

The present study evaluate and compare the clinical efficacy of potassium nitrate desensitizing mouthwash and toothpaste in the treatment of dentinal hypersensitivity. The study consisted of 40 (24 males and 16 females) patients in the age group of 20 – 55 years having mean age of 34.82 years who were divided into two groups. Group A consisted 20 (13 males and 07 females) patients and Group B consisted 20 (11 males and 9 females) patients. Patients were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics.

Group I: Those receiving toothpaste containing 5% potassium nitrate.

Group II: Those receiving mouthwash containing 3% potassium nitrate

All patients were compliant. The overall results including baseline recordings with final outcomes are displayed in the form of tables for all the parameters.

Air stimulus (VAS-A)	GROUP	N	MEAN	SD	t	p-value
Baseline	Group I	20	6.3	1.38	0.595	P=0.556
	Group II	20	6.05	1.28		
Week 2	Group I	20	5.7	1.03	0.330	P=0.744
	Group II	20	5.6	0.88		
Week 4	Group I	20	5	0.65	0.680	P=0.501
	Group II	20	4.85	0.78		

(p < 0.05 - Significant\*, p < 0.001 - Highly significant\*\*)

**Table 1. The mean VAS scores for the two treatment groups after receiving air stimuli (VAS-A) at baseline, at week 2 and at week 4.**

Since inter-group comparison of the mean air stimuli (VAS-A) for group I and group II done at baseline, at week 2 and at week 4. Unpaired t-test was used

for parametric test showed no significant difference between two groups (p>0.05).(Table 1).

Cold water stimulus (VAS-C)	GROUP	N	MEAN	SD	t	p-value
Baseline	Group I	20	6.6	1.19	0.941	P=0.353
	Group II	20	6.25	1.16		
Week 2	Group I	20	6.2	0.89	1.463	P=0.152
	Group II	20	5.8	0.83		
Week 4	Group I	20	5.45	0.69	1.485	P=0.146
	Group II	20	5.15	0.59		

(p < 0.05 - Significant\*, p < 0.001 - Highly significant\*\*)

**Table 2. The mean VAS scores for the two treatment groups after receiving Cold water stimuli (VAS-C) at baseline, at week 2 and at week 4.**

Since inter-group comparison of the mean Cold water stimulus (VAS-C) for group I and group II done at baseline, at week 2 and at week 4. Unpaired t-test was used for parametric test showed no significant difference between two groups (p>0.05).(Table 2).

Air stimulus(VAS-A)	Time interval	MEAN	SD	F	p-value
Group I	Baseline	6.3	1.38	7.494	<0.01
	Week 2	5.7	1.03		
	Week 4	5	0.65		

Air stimulus(VAS-A)	Time interval	MEAN	SD	F	p-value
Group II	Baseline	6.05	1.28	7.626	<0.01
	Week 2	5.6	0.88		
	Week 4	4.85	0.78		

Cold water stimulus(VAS-C)	Time interval	MEAN	SD	F	p-value
Group I	Baseline	6.6	1.19	7.441	<0.01
	Week 2	6.2	0.89		
	Week 4	5.45	0.69		

Cold water stimulus (VAS-C)	Time interval	MEAN	SD	F	p-value
Group II	Baseline	6.25	1.16	7.662	<0.01
	Week 2	5.8	0.83		
	Week 4	5.15	0.59		

**INTRA-GROUP Comparison of the visual analogue scale score in terms of {Mean (SD)} at different time intervals in group I and Group II**

Table 7

GROUP	Variables	Time pair	T	p-value
Group I	VAS-A	baseline vs Week 2	1.79	0.2387
		baseline vs Week 4	3.87	<0.0009
		week 2 vs Week 4	2.08	0.1254
Group II	VAS-A	baseline vs Week 2	1.43	0.47290
		baseline vs Week 4	3.82	<0.001
		week 2 vs Week 4	2.39	0.0610
Group I	VAS-C	baseline vs Week 2	1.34	0.5587
		baseline vs Week 4	3.85	<0.0009
		week 2 vs Week 4	2.51	0.04497
Group II	VAS-C	baseline vs Week 2	1.59	0.3503
		baseline vs Week 4	3.89	<0.0008
		week 2 vs Week 4	2.30	0.07528

### Bonferroni's post-hoc analysis

Since the Visual Analog Scale (VAS) score were observed repeatedly at three time points, repeated measures statistic analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the VAS score between baseline, week 2 and week 4 in both the experimental groups. The P value was (<0.05) for both experimental groups. (Table 3 to Table 6). One-way ANOVA test & Bonferroni's post-hoc test showed significant difference within the groups from baseline to week 4 ( $p < 0.05$ ).

## DISCUSSION

The present clinical study evaluate and compare the clinical efficacy of potassium nitrate desensitizing mouthwash and toothpaste in the treatment of dentinal hypersensitivity.

During practice, dental professionals are frequently faced with patients suffering from dentin hypersensitivity (DH). DH is characterized by short, sharp pain that arises from exposed dentin in response to a stimulus including thermal, osmotic, mechanical, electrical, or chemical stimuli, and cannot be ascribed to any other form of dental defect or pathology<sup>13</sup>. The intensity of the pain may range from minor discomfort to the severe disturbance of daily activities.<sup>14</sup>

Dentinal Hypersensitivity (DH) reportedly peaks during the third and fourth decades of life and present in 10%–30% of the general population, with a higher incidence among females.<sup>15-18</sup> periodontal disease, active periodontal therapy, gingival recession, and erosive toothwear that exposes dentin are etiologic and predisposing factors related to DH.<sup>19</sup>. The management includes directed therapy to interfere with the mechanism of DH temporarily or permanently. Currently, two main approaches are used in the treatment and prevention of DH: tubular occlusion and blockage of nerve activity. For these purpose various strategies have been implicated that includes lasers, ions and salts, fluoride iontophoresis, dentin sealers, periodontal soft tissue grafting, and homeopathic medications<sup>17</sup>.

Mouthwashes Toothpastes and toothpastes containing desensitizing ingredients are the most common products for treatment of DH. They are considered as first-line approach to treat DH because of simple, noninvasive and cost-effective.<sup>20</sup>.

Very few studies have been done comparing the clinical efficacy of potassium nitrate desensitizing mouthwash and toothpaste in the treatment of dentinal hypersensitivity. The purpose of this study is to evaluated and compare the clinical efficacy of potassium nitrate desensitizing mouthwash and toothpaste in the treatment of dentinal hypersensitivity. In present study forty patients were be selected with sensitive teeth and randomly divided into Group I and Group II by a systematic sampling method in which every 5th subject were selected and recruited alternatively in each group as follows:

Group I: Those receiving toothpaste containing 5% potassium nitrate.

Group II: Those receiving mouthwash containing 3% potassium nitrate

The study was a randomized open labeled group design with three study visits: baseline, Week 2, and Week 4. The participants teeth sensitivity were subjectively assessed by means of a VAS (Visual Analogue Scale). To assess tooth sensitivity, a controlled air stimulus (evaporative stimulus) and cold water (thermal stimulus) were used. The parameter were recalled at baseline, at week 2 and at week 4.

### Clinical parameters

**Air Stimulus** Tooth sensitivity was assessed by means of a VAS (Visual Analogue Scale) when air stimulus was used. The parameter were recalled at baseline, at week 2 and at week 4.

### Experimental Group I

The mean Air stimulus score (VAS-A) for patients in Group I at baseline was  $6.3 \pm 1.38$  which was reduced to  $5.7 \pm 1.03$  at week 2 from baseline,  $5 \pm 0.65$  at week 4 from baseline. There was statistically significant difference between baseline, week 2 & week 4 follow-up ( $p < 0.05$ ). Bonferroni's post-hoc test showed significant reduction in Air stimulus score (VAS-A) from baseline to week 4 follow-up ( $p < 0.05$ ). (Table 3 and Table 7)

### Experimental Group II

The mean Air stimulus score (VAS-A) for patients in Group II at baseline was  $6.05 \pm 1.28$  which was reduced to  $5.6 \pm 0.88$  at week 2 from baseline,  $4.85 \pm 0.78$  at week 4 from baseline. There was statistically significant difference between baseline, week 2 & week 4 follow-up ( $p < 0.05$ ). Bonferroni's post-hoc test showed significant reduction in Air stimulus score (VAS-A) from baseline to week 4 follow-up ( $p < 0.05$ ). (Table 4 and Table 7)

**Cold water stimulus** Tooth sensitivity was assessed by means of a VAS(Visual Analogue Scale) when cold water stimulus was used. The parameter were recalled at baseline, at week 2 and at week 4.

### Experimental Group I

The mean Cold water stimulus score (VAS-C) for patients in Group I at baseline was  $6.6 \pm 1.19$  which was reduced to  $6.2 \pm 0.89$  at week 2 from baseline,  $5.45 \pm 0.69$  at week 4 from baseline. There was statistically significant difference between baseline, week 2 & week 4 follow-up ( $p < 0.05$ ). Bonferroni's post-hoc test showed significant reduction in Cold water stimulus score (VAS-C) from baseline to week 4 follow-up ( $p < 0.05$ ). (Table 5 and Table 7)

### Experimental Group II

The mean Cold water stimulus score (VAS-C) for patients in Group II at baseline was  $6.25 \pm 1.16$  which was reduced to  $5.8 \pm 0.83$  at week 2 from baseline,  $5.15 \pm 0.59$  at week 4 from baseline. There was statistically significant difference between baseline, week 2 & week 4 follow-up ( $p < 0.05$ ). Bonferroni's post-hoc test showed significant reduction in Cold water stimulus score (VAS-C) from baseline to week 4 follow-up ( $p < 0.05$ ). (Table 6 and Table 7)

### Comparison between the groups

When results of two groups were compared, no statistically significant difference was observed. (Table 1 and Table 2) Thus, it can be concluded that in two groups, statistically significant reduction in Dentinal Hypersensitive was observed from the baseline to week 4 within the groups. However, there was no statistically significant difference observed when the two groups were compared with each other. This demonstrates that both the treatment modalities result in comparable reduction in the Dentinal Hypersensitive of the patients.

Studies have found that toothpastes containing 5% potassium nitrate and mouthwash containing 3% potassium nitrate both significantly decreased sensitivity, despite the different application procedure. They act by increasing the potassium ion concentration adjacent to the dentinal nerve terminals, there is depolarization and activation of nerve fibers. A prolonged period of depolarization results in inactivation of the action potential. Divalent cation solutions stabilize the nerve membrane without changing the membrane potential. This potassium nitrate toothpastes/mouthwashes must be used for a minimum of 4 weeks, twice daily to bring about a reduction of sensitivity.<sup>12,20</sup> Similar trend in reduction of the sensitivity was observed in a study conducted by Pereira et al. (2001)<sup>21</sup> and Sunita et al (2012)<sup>20</sup>

**Limitations:** In the present study, no control group or placebo was included, abrasive components of toothpaste can also bring about tubule occlusion, thus there is possibility of biased results. More numbers of clinical trials done over a larger population are essential in future to find out best treatment strategy.

## CONCLUSIONS

The present study suggest that there was an overall decrease in dentinal hypersensitivity in both groups as demonstrated by two assessment methods, over the 4-week study period. The sensitivity scores were significantly lower for both toothpaste and mouthwash in response to air stimuli and thermal stimuli at 2 and 4 weeks. But, there were no statistically significant differences between the groups. Thus it can be suggested that rinsing twice daily with a 3% potassium nitrate mouthwash or brushing twice daily with a 5% potassium nitrate toothpaste may help reduce discomfort arising from dentinal hypersensitivity. Long-term evaluation of the sites is recommended to evaluate the sustainability of the results.

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# Evaluation of Ornidazole Gel as an Adjunct to Non-surgical Periodontal Therapy – A Clinical Study

## Abstract

**Introduction:** Topical chemotherapeutic agents used in the treatment of gingivitis are antimicrobial agents which help in plaque control. The present study evaluates the efficacy of Ornidazole gel when used as an adjunct to scaling and root planning.

**Material and Methods:** 60 patients diagnosed with gingivitis, having pocket depth  $\leq 3$  mm and in good systemic health were selected by systematic sampling method and divided into two groups. In both groups scaling and root planning was done. In Group A, Ornidazole gel application was done while Group B was the control group. Plaque Index (PI) and Gingival Index (GI) were recorded at baseline, 2 and 4 weeks.

**Results:** PI and GI showed a significant reduction in two groups after 2 and 4 weeks compared to baseline. On inter-group comparison, both PI and GI showed a significant reduction in group A at 2 and 4 weeks compared to group B ( $p < 0.05$ ).

**Conclusion:** Ornidazole gel was effective in the treatment of gingivitis when used as an adjunct to scaling and root planning for the treatment of gingivitis patients.

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## INTRODUCTION

Gingivitis is a form of periodontal disease induced by bacterial plaque. Plaque removal play important role in controlling and prevention of this disease. Conventional treatment of periodontal diseases includes periodic mechanical debridement of plaque by scaling and curettage from tooth surfaces and repeated topical or systemic administration of antibacterial agents. The effectiveness of conventional treatments is limited by the lack of accessibility to bacteria in the plaque.<sup>1</sup>

The systemic use of antibiotics raises a number of issues. A prolonged administration increases the risk of problems such as antibiotic resistance<sup>2</sup> and adverse Drug reactions like nausea, diarrhea and pseudomembranous colitis.<sup>3</sup> As a result of these matters, studies focused on localized systems of Drug delivery for the treatment of periodontal diseases. This approach leads to higher

concentrations of the Drug at the target sites, minimizing the potential systemic side effects.<sup>4</sup>

Local system Drug delivery for periodontal diseases may be carried out with fibers, films, microparticles, strips paste and gels made of biodegradable or non-degradable polymers and have been proposed as effective methods to administer antimicrobial agents in periodontal.<sup>5</sup>

One such agent is Nitroimidazole group of compounds. It acts by inhibiting DNA synthesis. It works on the principle that inactive form passively diffuses into cells where it is activated by chemical reduction. The nitro group gets reduced to anionic radicles which causes oxidation of DNA leading to strand breakage and cell death. Hence, it has both anti-microbial and mutagenic effect. This effect is primarily seen on obligate gram negative anaerobes like *P. Gingivalis*, *P. Intermedia*, *Fusobacterium*,

*Selenomonas sputigina*, *Bacteroides Forsythus* and the gram-positive anaerobes like *Peptostreptococcus*, and *C. Rectus* which are implicated in periodontal disease. Ornidazole and metronidazole are two such Drugs belonging to nitroimidazole group.<sup>6,7</sup>

Ornidazole is bactericidal at lower concentration and is active against anaerobic bacteria, which are responsible for periodontal disease.<sup>6</sup> Till date, fewer research has been conducted to treat plaque-induced gingivitis by Ornidazole gel. In the present study, the effect of Ornidazole gel have been evaluated as an adjunct to scaling and root planing over period of four weeks for the management of gingivitis.

## MATERIALS AND METHOD

A total of 60 patients for this study were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics, Nair Hospital Dental College whose written consent and audio-visual consent was taken prior to the study and if the patient was willing to discontinue the treatment procedure during the study, he or she was allowed to do so.

### Armamentarium

Mouth mirror, University of North Carolina-15(UNC-15) probe, Syringe, Local anaesthesia: 2% lignocaine Hydrochloride (HCl) with adrenaline (1:100,000), Ultrasonic scaler, Curettes, 1% Ornidazole gel (Clorni gel™).

### Study design

The gingivitis patients having probing depth  $\leq 3$  mm were randomly divided into Group A and Group B by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

Group A: Scaling and Root planing, followed by application of Ornidazole gel.

Group B: Scaling and Root planing alone.

The patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing.

### Clinical parameters:

The following clinical parameters were recorded at baseline (day zero), 2 week and 4 week. The patients were advised to apply the gel post phase I therapy.

1. Plaque Index (P.I.) (TURESKEY-GILMORE-GLICKMAN MODIFICATION OF QUIGLEY HEIN<sup>8</sup>).
2. Gingival Index (G.I.) (LOE & SILNESS<sup>9</sup>).

### Procedure:

Following initial examination and treatment planning, the selected subjects underwent thorough scaling and root planing (SRP) with or without local anesthesia. If local anesthesia was required, then

working site was infiltrated with 1ml of anesthetic solution with/without adrenaline (1:200000). If any trauma from occlusion (TFO) was detected, it was relieved. A detailed instructions regarding self-performed plaque control measures was given. The patients in Group A were instructed to take a pea sized amount of gel on finger and apply to the gingiva twice daily and leave it for 10 minutes on affected area post phase I therapy, whereas Group B was used as a control group and only Scaling and Root Planing was done with or without local anesthesia. The clinical parameters were evaluated at baseline, 2 week and 4 week.

### Inclusion criteria

1. Age group between 20-55 years
2. Patients having gingivitis.
3. Patients in good systemic health
4. Patients having probing depths of  $\leq 3$  mm.
5. Patients who have not received any type of periodontal therapy in the past 6 months.

### Exclusion criteria

1. Patients suffering from any systemic diseases like bleeding disorder, diabetes mellitus and thyroid disorders.
2. Patients with a known history of allergy to ornidazole gel.
3. Patients showing unacceptable oral hygiene compliance during/after the phase I therapy.
4. Patients taking any Drug known to cause gingival enlargement.
5. Pregnant and/or lactating mothers.
6. Patient on anticoagulant therapy and immunosuppressive Drugs like corticosteroids.

### Observations and results

The present study evaluated the clinical efficacy of Ornidazole gel as an adjunct to scaling and root planing in gingivitis patients. The study consisted of 60 (34 males and 26 females) patients in the age group of 20 – 55 years having mean age of 34.82 years who were divided into two groups. Group A consisted 30 (18 males and 12 females) patients and Group B consisted 30 (17 males and 13 females) patients. Patients were randomly selected by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group from the outpatient department of Periodontics.

Group A: Scaling and Root planing, followed by application of Ornidazole gel.

Group B: Scaling and Root planing alone.

All patients were compliant. The overall results including baseline recordings with final outcomes are displayed in the form of tables for all the parameters.

## PLAQUE INDEX

### Effect of Ornidazole gel on Plaque Index

#### (P.I)

		MEAN	SD	F	P <sup>+</sup> VALUE	POST-HOC TEST **
PI	BASELINE	3.5097	.9694	56.006	<0.01	BL>2week>4week
	2 week	2.124	.8117			
	4 week	1.3793	.5289			

**Table 1: Plaque Index (P.I.): Data Summary (Group A)**

### Effect of Scaling and Root Planing on Plaque Index (P.I)

		MEAN	SD	F	P <sup>+</sup> VALUE	POST-HOC TEST **
PI	BASELINE	3.7597	.7525	75.9279	<0.01	BL>2week>4week
	2 week	2.4993	.7171			
	4 week	1.641	.5154			

**Table 2: Plaque Index (P.I.): Data Summary (Group B)**

		N	Mean	Std. Deviation	T	P <sup>+</sup> VALUE
PI(BL)	Ornidazolegel(Group A)	30	3.5097	.9694	1.1158	0.135
	Scaling & Root Planing (Group B)	30	3.7597	.7525		

		N	Mean	Std. Deviation	T	P <sup>+</sup> VALUE
PI(2week)	Ornidazolegel(Group A)	30	2.124	.8117	1.8981	0.031
	Scaling & Root Planing (Group B)	30	2.4993	.7171		

		N	Mean	Std. Deviation	T	P <sup>+</sup> VALUE
PI(4week)	Ornidazolegel(Group A)	30	1.3793	.5289	1.9406	0.029
	Scaling & Root Planing (Group B)	30	1.641	.5154		

**Table 3: Comparison of mean Plaque Index between Study groups (Group A and Group B)**

Since the Plaque Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the plaque index between baseline, 2

week and 4 week in both the experimental groups. The P value was <0.05 for both experimental groups. (Table 1 and Table 2). (Table 3) show inter-group comparison of the mean plaque index. Unpaired t-test showed significant difference between two groups (p<0.05).

## GINGIVAL INDEX

### Effect of Ornidazole gel on Gingival Index (G.I)

		MEAN	SD	F	P <sup>+</sup> VALUE	POST-HOC TEST **
GI	BASELINE	1.6497	.1685	287.4397	<0.01	BL>2week>4week
	2 week	.783	.3043			
	4 week	.301	.159			

**Table 4: Gingival Index (G.I.): Data Summary (Group A)**

### Effect of Scaling on Gingival Index (G.I)

		MEAN	SD	F	P <sup>+</sup> VALUE	POST-HOC TEST **
GI	BASELINE	1.6523	.1796	201.2762	<0.01	BL>2week>4week
	2 week	.7397	.3049			
	4 week	.405	.2234			

**Table 5: GINGIVAL Index (G.I.): Data Summary (Group B)**

		N	Mean	Std. Deviation	t	P <sup>+</sup> VALUE
GI(BL)	Ornidazolegel(Group A)	30	1.6497	.1685	0.0593	0.476
	Scaling & Root Planing (Group B)	30	1.6523	.1796		

		N	Mean	Std. Deviation	t	P <sup>+</sup> VALUE
GI(2week)	Ornidazolegel(Group A)	30	.783	.3043	1.9922	0.026
	Scaling & Root Planing (Group B)	30	.9397	.3049		

		N	Mean	Std. Deviation	t	P <sup>+</sup> VALUE
GI(4week)	Ornidazolegel(Group A)	30	.301	.1796	2.0774	0.021
	Scaling & Root Planing (Group B)	30	.405	.3049		

**Table 6: Comparison of mean Gingival Index between Study groups (Group A and Group B)**

Since the gingival Indices were observed repeatedly at three time points, repeated measures statistical analysis was done. The parametric tests (post – hoc test, ANOVA for three or more groups) were chosen for statistical analysis. There was a significant decrease in the gingival index between baseline, 2 week and 4 week in both the experimental groups. The P value was <0.05 for both experimental groups. (Table 4 and Table 5). (Table 6) show inter-group comparison of the mean gingival index. Unpaired t-test showed significant difference between two groups ( $p < 0.05$ ).

## DISCUSSION

The present clinical study evaluates the efficacy of Ornidazole gel as an adjunct to scaling and root planing in management of gingivitis patients.

Gingivitis is a periodontal disease induced by bacterial plaque. Treatment of periodontal disease is routinely based on mechanical debridement of the tooth surface and appropriate and meticulous maintenance of oral hygiene. As an adjunctive approach, systemic or local administration of antimicrobials is used because of the microbial etiology of periodontal disease. Topical administration of chemotherapeutic agents in the form of mouthwashes, dentifrice or gels can be used effectively in controlling supragingival plaque formation and periodontal disease.<sup>5</sup>

Ornidazole belongs to nitroimidazole group of compounds. Acts by inhibiting DNA synthesis. It works on the principle that inactive form passively diffuses into cells where it is activated by chemical reduction. The nitro group gets reduced to anionic radicles which causes oxidation of DNA leading to strand breakage and cell death. Hence, it has both anti-microbial and mutagenic effect.<sup>6</sup>

Ornidazole is bactericidal in nature and active against anaerobic bacteria, which are responsible for periodontal disease.<sup>6</sup> Very few studies have been done regarding the effect of ornidazole gel as adjunctive anti-microbial agent in the treatment of gingival and periodontal diseases. The purpose of this study is to evaluate the efficacy of Ornidazole gel as an adjunct to scaling in management of gingivitis patients.

Patients with good systemic health and no contraindications to periodontal therapy were selected, since patients suffering from systemic diseases like uncontrolled diabetes mellitus or patients on immunosuppressive therapy, almost always show poor response to the periodontal therapy.<sup>10</sup>

Hormonal fluctuations in the female patient may alter the status of periodontal health and affect the treatment outcome. The most pronounced periodontal changes occur during pregnancy and lactation. Treatment considerations for pregnant patients with periodontal disease may include deferral of periodontal therapy until after

parturition.<sup>11</sup> Hence, pregnant and lactating females were excluded from the study.

In the present study the gingivitis patients having probing depth  $\leq 3$  mm were randomly divided into Group A and Group B by a systematic sampling method in which every 5th subject was selected and recruited alternatively in each group as follows:

Group A: Scaling and Root planing, followed by application of Ornidazole gel.

Group B: Scaling and Root planing alone.

All the patients following Phase I therapy were given oral hygiene instructions and taught Bass method of tooth brushing with standard toothpaste and soft toothbrush. Clinical parameters like plaque index, gingival index were evaluated.

## CLINICAL PARAMETERS

**PLAQUE INDEX (Turesky S. Gilmore N.D. and Glickman I. modification of QuigleyHein in 1970)<sup>8</sup>** indicates the oral hygiene maintained by patient and is important because it can influence the periodontal outcome. Plaque scores were evaluated at baseline, 2 week and 4 week post phase I therapy.

### Experimental Group A

The mean plaque index score for patients in group A at baseline was  $3.51 \pm 0.97$  which was reduced to  $2.12 \pm 0.81$  at 14 week from baseline,  $1.38 \pm 0.53$  at 4 week from baseline. There was statistically significant difference between baseline, 2 week and 4 week follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 4 week follow-up ( $p < 0.05$ ). (Table 1)

### Experimental Group B

The mean plaque index score for patients in group B at baseline was  $3.76 \pm 0.75$  which was reduced to  $2.50 \pm 0.71$  at 2 week from baseline,  $1.64 \pm 0.52$  at 4 week from baseline. There was statistically significant difference between baseline, 2 week and 4 week follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 4 week follow-up ( $p < 0.05$ ). (Table 2)

### Comparison between the groups

When results of both groups were compared, statistically significant difference was observed. (Table 3) Thus, it can be concluded that in both groups, statistically significant reduction in plaque index was observed from the baseline to 4 week within the groups.

Statistically significant reduction in plaque index scores also observed when the both groups were compared with each other after 2 week and 4 week. This demonstrates the efficacy of ornidazole gel when used as adjunct to scaling and root planing.

A trend of progressive decline in plaque index scores over the duration of the study was seen. This could be due to antimicrobial effects of ornidazole gel and overall improvement in periodontal parameters. Similar trend in reduction of the plaque index was observed in a study conducted by Noyan U et al. (1997)<sup>12</sup> using metronidazole gel, who demonstrated slight reduction in the plaque index.

**Gingival Index (GI) (Loe & Silness 1963)<sup>9</sup>** is considered to be a true reflection of gingival status in health and disease. It is simple, easy and reproducible index and is used commonly in clinical periodontal research studies. Gingival index scores were evaluated at baseline, 2 week and 4 week post-phase I therapy.

### Experimental Group A

The mean gingival index score for patients in group A at baseline was  $1.65 \pm 0.17$  which was reduced to  $0.78 \pm 0.30$  at 2 week from baseline,  $0.30 \pm 0.16$  at 4 week from baseline. There was statistically significant difference between baseline, 2 week and 4 week follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 4 week follow-up ( $p < 0.05$ ). (Table 4)

### Experimental Group B

The mean gingival index score for patients in group B at baseline was  $1.65 \pm 0.18$  which was reduced to  $0.94 \pm 0.30$  at 2 week from baseline,  $0.40 \pm 0.22$  at 4 week from baseline. There was statistically significant difference between baseline, 2 week and 4 week follow-up ( $p < 0.05$ ). Post-hoc Tukey's test showed significant reduction in plaque index score from baseline to 4 week follow-up ( $p < 0.05$ ). (Table 5)

### Comparison between the groups

When results of both the groups were compared, after 4 week statistically significant difference was observed between groups A and B. (Table 6) Thus it can be said that in both groups, statistically significant reduction in gingival index was observed from the baseline to 4 week within the groups.

Statistically significant reduction in gingival index scores also observed when the both groups were compared with each other after 2 week and 4 week. This demonstrates the efficacy of ornidazole gel when used as adjunct to scaling and root planing. A trend of progressive decline in gingival index scores over the duration of the study was seen. This could be due to antimicrobial effects of ornidazole gel and overall improvement in periodontal parameters. This finding are similar to studies done by Bhavin P et al. (20014).<sup>7</sup>

### Limitation of the present study:

At the end of the study, it has been observed that there have been certain aspects, which demand more

detailed observation and elucidation of data and facts.

- 1) A larger sample size would have been preferable with a more long-term follow up.
- 2) An evaluation of microbiological parameters should have been carried out to know the minimal inhibitory concentration of the periodontal pathogens.
- 3) Paired or split mouth design would have excluded the influence of patients' specific characteristics and facilitated the interpretation of the study by minimizing the effects of inter-patient variability.

## CONCLUSIONS

The Clinical evaluation was suggestive of the fact that Ornidazole gel was biocompatible with the tissues. It did not cause any biological complications and therefore could be safely used. The plaque and gingival index decreased in both the groups when compared within the groups. This indicates an overall improvement in oral hygiene status of patients. The reduction in plaque and gingival index score was statistically significant after topical application of ornidazole gel as compared to scaling and root planing alone when evaluated after 2 week and 4 week. This demonstrates the efficacy of adjunctive use of ornidazole gel over Scaling and root planing. Thus, it can be concluded that the adjunctive use of ornidazole gel caused improvement in clinical parameters and can be used for treatment of gingivitis in patients. However, long-term studies to facilitate better understanding of the performance of ornidazole gel for treatment of gingivitis in patients can be advocated in the future.

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# Two-Dimensional And Three-Dimensional Methods Of Diagnosing Obstructive Sleep Apnea- A Review

## Abstract

Obstructive sleep apnea is a common disorder pertaining to the field of orthodontics, sleep medicine, and ENT specialty. In many instances, the patient may be unaware of his/her airway problems and may turn up to the dentist for some other treatment. Apart from clinical case history and record taking it is utmostly important that the dentist examines and diagnoses upper airway obstructions, if any and advise his patient for proper treatment. There are several methods of diagnosing OSA which are available today due to advanced medical technology eg polysomnography, rhinometry, pharyngometry, Cine CT, Cine MRI, CBCT, lateral cephalogram etc. Each process has its merit and demerits. It largely depends on the clinician's decision, patient's feasibility and economic condition on which method of diagnosis should be considered. For dental surgeons and orthodontists, specially, lateral cephalogram tracing, CBCT of upper airway and thorough examination of adenoids provide a good method of diagnosing patients with airway obstruction.

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## INTRODUCTION

One of the many diseases occurring during sleep is called as SLEEP DISORDERED BREATHING. SDBs are abnormal breathing pattern during sleep resulting from various factors like blockage of airway, age, sex, diet and underlying disease resulting in often arousal from sleep and sometimes snoring<sup>1</sup>. There are four types of SDBs ie, Apnea, Hypopnea, Hypoventilation And Respiratory effort related arousals (RERAs). Apnea is complete cessation of breathing where airflow is less than 20 % of baseline for at least 10 seconds. Hypopnea is partial cessation of breathing with greater than 30 % reduction of airflow for atleast 10 seconds and oxyhaemoglobin desaturation of greater than 3-4%.

Respiratory effort-related arousals (RERAs) are episodes during which breathing and oxygenation are maintained at the expense of a great increase in respiratory efforts. Sleep hypoventilation is expressed by a reduction in only the oxygen level or an increase in the carbon dioxide level without measurable changes in breathing patterns evident in the airflow monitor. There are three types of sleep apnea:

- Obstructive sleep apnea which occurs Due to collapse of upper airway tract there is partial blockage of breathing but respiratory effort is normal.

- Central sleep apnea where the respiratory centre in lower brain stem is affected and respiratory effort is reduced/absent. It may or may not have blockage of airway eg, Cheyne-stokes respiration( heart failure) , narcotic induced medications (opioids), iatrogenic( side effect of positive airway pressure therapy), genetic ( congenital central hypoventilation syndrome/CCHS)
- Mixed sleep apnea

#### Apnea-Hypopnea Index (AHI INDEX)

It is sum of episodes of apnea and hypopnea per hour of sleep. Range of sleep disorder is as follows: less than 4: normal; 5-15: mild; 16-30: moderate; >30 : severe<sup>2</sup>

**Respiratory Distress Index (RDI)** It is sum of AHI AND RERAs per hour of sleep. It is Categorized same as in AHI .

OSA is defined as either More than 15 apneas, hypopneas, or RERAs per hour of sleep (i.e., an AHI or RDI >15 events per hour) in an asymptomatic patient, or More than 5 apneas, hypopneas, or RERAs per hour of sleep (i.e., an AHI or RDI >5 events per hour) in a patient with symptoms (e.g., sleepiness, fatigue, inattention) or signs of disturbed sleep (e.g., snoring, restless sleep, respiratory pauses). OSA syndrome applies only to the latter definition. In both situations, more than 75% of the apneas or hypopneas must have an obstructive pattern<sup>3</sup>.

**SLEEP CYCLE:** There are 4 stages of sleep<sup>2</sup>:

**Stage 0:** person is awake and conscious

**Stage1:** dozing stage where person is not fully conscious

**Stage 2:** unequivocal sleep (mostly non rapid eye movement / NREM sleep) (OSA SYMPTOMS OCCUR COMMONLY IN THIS STAGE)

**Stage 3:** deep sleep transition; where interplay between REM AND NREM sleep occurs(about 20-30% of sleep time is REM and rest is NREM)

**Stage 4:** cerebral sleep

#### EPIDEMIOLOGY OF OSA

At 5 events/h apnea-hypopnea index (AHI), the overall population prevalence ranged from 9% to 38% and was higher in men ( males: 13-33% and females:6 -19%). It increased with increasing age and, in elderly groups (> 50 yrs) ,was as high as 90% in men and 78% in women. At 15 events/h AHI, the prevalence in the general adult population ranged from 6% to 17%, being as high as 49% in the advanced ages.

## APPLIED ANATOMY OF UPPER AIRWAY:

**Upper airway is divided in three parts:**

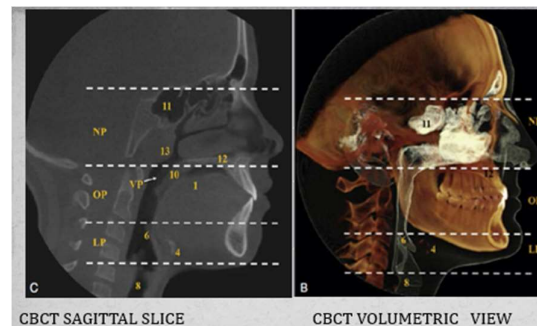
**i)Nasopharynx-** Nasopharynx extends from behind the nasal turbinates to the level of hard palate. Adenoids (pharyngeal tonsils) affect the nasopharyngeal patency.

**ii)Oropharynx -** extends from soft palate to upper border of epiglottis. *Divided in two parts :*

**a)Velopharynx/retropalatal pharynx-**which lies behind the soft palate extending from the hard palate to the caudal margin of the soft palate

**b)Retroglossal part-** from caudal end of soft palate to upper border of epiglottis. Uvula, soft palate, tonsils, and tongue posture may affect the oropharyngeal patency

**iii)Hypopharynx-** extends from epiglottis to level of division of larynx and esophagus. Position of tongue and hyoid bone may affect its patency.. the three parts as seen in acbt slice is shown below (fig 1). Pharyngeal soft tissues exhibited two periods of accelerated change (ages 6 to 9 years and 12 to 15 years) and two periods of quiescence (ages 9 to 12 years and 15 to 18 years).



**Fig 1. MPR and volume rendered CBCT slices representing anatomic upper airway (NP is nasopharynx, OP is oropharynx, LP is laryngopharynx, VP is velopharynx)**

#### ADENOIDS:

In a child the adenoids ( lymphatic tissue) is very active and it gradually grows reaching its peak at around 8-10 yrs of age after which it gradually involutes into almost half its size. Due to various circumstances relate to cell mediated immunity the adenoids can proliferate or fail to involute leading to airway obstruction.

**Adenoid hypertrophy (enlarged adenoids)** is the unusual growth (hypertrophy) of the adenoid (pharyngeal tonsil) first described in 1868 by the Danish physician Wilhelm Meyer (1824–1895) He described a long term adenoid hypertrophy that will

cause an obstruction of the nasal airways leading to mouth breathing and nasal voice . In 1872 Tomes coined the term "adenoid facies" to mouth breathers taking Meyer's hypertrophy hypothesis as a guide. Later on Todd and Broadbent supported and after thorough research the symptoms associated with mouth breathing came to be known as " long face synDrome" in field of orthodontics<sup>4</sup>

### HYOID BONE:

Hyoid bone is located below the mandible and only bone without any articulation to any other bone; its position affects patency of hypopharynx and oropharynx. Upto 18 yrs of age the hyoid bone grows in a forward and downward direction due to forward movement of mandible, growth of tongue, increase in length of cervical spine, excessive fat deposition etc. The hyoid to mandibular plane distance( H-MP) is increased in restricted in upper airway patients [The H-MP distances averaged  $12 \pm 5$  mm in the normal people,  $18 \pm 3$  mm in the snorers group, and  $24 \pm 7$  mm in OSA patients]

### UPPER AIRWAY IN DIFFERENT SKELETAL PATTERNS:

Mandibular retrognathia and vertical excess are often associated with airway problems. subjects with ClassII mandibular retrusion had the lowest airway values. In the Class III mandibular protrusion group—the highest oropharyngeal volume, nasal airway volume, and minimum axial cross-sectional areas are seen. The nasal volume is lower in the Class II mandibular retrusion group, compared with Class I subjects, Vertical Airway length is greatest in class III people and airway is placed most anteriorly in class II patients.

Vertical growers have narrow airway both AP and laterally, so the minimum cross section area and air volume is also small indicating possible obstruction. Since dimensions of pharyngeal airway is small, to avoid obstruction and maintain patency the maxilla or mandibular growth pattern are often retruded and the hyoid bone is also more downwardly postured as a compensatory mechanism<sup>4</sup>.

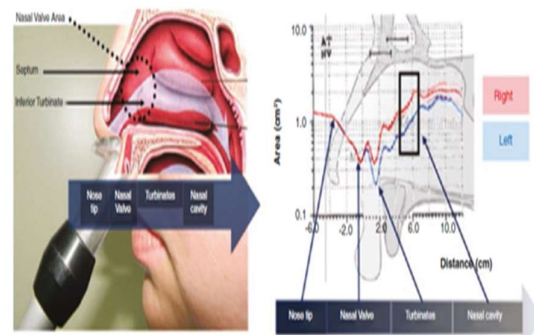
### DIFFERENT METHODS OF DIAGNOSING AIRWAY ARE:

- ✓ AcousticRhinometry
- ✓ Pharyngiometry
- ✓ Rhinomanometry
- ✓ Nasopharyngolaryngoscopy
- ✓ Muller's Maneuver
- ✓ Drug Induced Sleep Endoscopy(DISE)

- ✓ Dynamic Sleep Magnetic Resonance Imaging( MRI)
- ✓ Cine MRI
- ✓ Cone Beam Computed Tomogram( CBCT)
- ✓ Cardiovascular CT ( Cine CT)
- ✓ 2d Lateral Cephalogram
- ✓ polysomnography

### ACOUSTIC RHINOMETRY

AR was introduced by Hilberg and associates in 1985 as an objective method for examining the nasal cavity .This technique is based on the principle that a sound pulse propagating in the nasal cavity is reflected by local changes in acoustic impedance. AR is a simple, fast (approximately 30 seconds), and noninvasive technique that became widely accepted in a short period. It gives accurate measurement of anterior nasal cavity but posterior nasal cavity and pharyngeal part are not well measured in this process<sup>3</sup>.( fig 2)



**Fig 2. Acoustic rhinometry to measure nasal airflow geometry and airflow rate**

The sound wave penetrates the cavities and is reflected on the different nasal structures or their irregularities and detects the change in impedance. The most interesting data are the "minimum cross-sectional areas 1 and 2 (MCA1 and MCA2)". MCA1 corresponds anatomically to the area at the nasal valve level (bounded by the caudal margin of the upper lateral cartilage and the nasal septum), which has the greatest resistance in the normal nose. MCA2 corresponds to the area at the level of the head of the inferior turbinate.

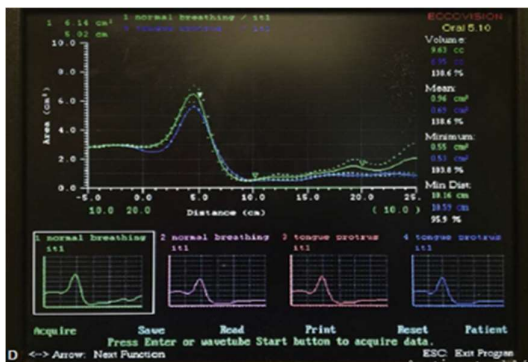
### PHARYNGOMETRY

Pharyngometry provides a noninvasive assessment of the dimensions, structure, and physiologic behavior of the UA from the oral cavity to the hypopharynx while the patient breathes. Computer processing of the incident and reflected sound waves

from the airways provide an area distance curve that represents the lumen from which minimal cross-sectional area and volume can be derived. This dynamic test measures the dimensions of the airway through the oral cavity and 25 cm down the pharynx<sup>5</sup>. (fig 3 and fig 4)



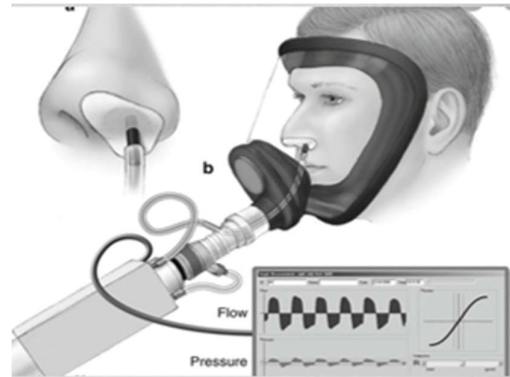
**Fig 3. Patient positioned with pharyngometer inside oral cavity**



**Fig 4. Digital screenshot showing volumetric measurements using pharyngometry**

## RHINOMANOMETRY

It is Mostly used by ENT specialists. It aims to objectively evaluate nasal obstruction. There are different types of rhinomanometry (RMM), active anterior RMM being the one most frequently used. This evaluates nasal airflow in inspiration and expiration by detecting potential obstructions and/or resistance. Airflow pressure checked before and after giving vasoconstrictor Drug, to check the mechanical obstruction and vasomotor obstruction respectively. Most common mechanical obstruction is deviated nasal septum and vasomotor one being inferior turbinate hypertrophy<sup>6</sup>. (fig 5)



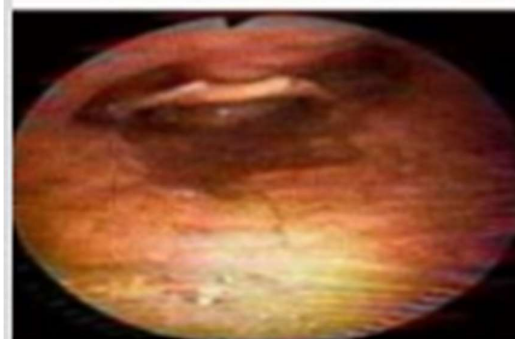
**Fig 5. Schematic diagram showing rhinomanometry airflow measurements**

## NASOPHARYNGOLARYNGOSCOPY

It is Mostly used by ENT specialists. It aims to objectively evaluate nasal obstruction. There are different types of rhinomanometry (RMM), active anterior RMM being the one most frequently used. This evaluates nasal airflow in inspiration and expiration by detecting potential obstructions and/or resistance. Airflow pressure checked before and after giving vasoconstrictor Drug, to check the mechanical obstruction and vasomotor obstruction respectively. Most common mechanical obstruction is deviated nasal septum and vasomotor one being inferior turbinate hypertrophy.

## MULLER'S MANEUVER

Fiberoptic nasopharyngoscopy with **Muller's maneuver** was first described by Borowieck and Sassin (1983). It is designed to see the collapsed sites of upper airway during the inspiration with closed mouth and nose leading to the negative pressure (40cm/H<sub>2</sub>O) in the chest and lungs. Introducing a flexible fiber-optic scope into the hypopharynx to obtain a view, the examiner may witness the collapse and identify weakened sections of the airway<sup>7</sup>. The patient is asked to breath with pinched mouth and nose and tested with fibreoptic A positive value suggests OSA and positive correlation with AHI. (fig 6 and Fig . 7)



**Fig 6. Resting airway as visualized by fibre-optic endoscope**





**Fig. 7. severe airway collapse during Muller's Manoeuvre**

A study conducted on both awake and sleeping patients using this maneuver graded the obstruction by viewing the oropharynx( both velopharynx and retrolingual collapse). Results showed that in retropalatal area collapse was more with muller's maneuver than induced sleep ({mean value+SD}  $3.13 \pm 0.99$  and  $2.75 \pm 0.46$ , respectively,  $p= 0.234$  ) whereas the retrolingual collapse was more in sleep induced patients ( $0.63 \pm 1.06$  and  $2.63 \pm 1.30$ , respectively,  $p= 0.005$ ) HENCE, though muller's method is useful, it can underestimate the extent of retroglossal collapse.

## DRUG INDUCED SLEEP ENDOSCOPY

Drug-induced sleep endoscopy (DISE) has been introduced by Croft and Pringle in 1991. Drug-induced sleep endoscopy (DISE) has been introduced as an alternative to conventional endoscopy for more accurately representing patterns of collapse during the sleeping state<sup>8</sup>. Conventional endoscopy and DISE detect retropalatal collapse equally well, but DISE may identify retrolingual, hypopharyngeal collapse more accurately and also lateral pharyngeal wall collapse more specifically.

## PRINCIPLE OF DISE

- the patient is laid down in a supine position on the operating table. The patients had basic cardiorespiratory monitoring (pulse oximetry, blood pressure, and electrocardiogram).
- The target depth of sedation is the transition from consciousness to unconsciousness (loss of response to verbal stimulation), in practical terms, when the patient started to snore and choke. Propofol (1.5mg/kg) for dose dependant sedation is administered . Dose of atropine is (0.6mg/kg) to reduce saliva is also added
- Once the patient has reached a satisfactory level of sedation, a flexible endoscope lubricated with lidocaine 2% gel is introduced into the nasal cavity. The lateral pharyngeal

wall, soft palate, tongue base and larynx are observed. The sites generating snoring and/or obstruction were assessed.

## Classification Of AIRWAY OSTRUCTION IN DISE ( The Lwptl System)

structure	pattern	comment
Lateral wall (Lw)	LS	Collapse at level of Salpingopharyngeal folds
	LV	Collapse at level of velum
	LH	Collapse at level of hypopharynx
	LSVH	combined
Palate(P)	PHL	High palatal collapse( muscular and aponeurotic part of soft palate)
	PL	PL is collapse of distal part of soft palate
	LvPl	Lvpl is circular palatal collapse, due to lateral wall collapse
Tongue BASE(T)	TH	High tongue base collapse above level of epiglottis
	TL	Low tongue base collapse at or below level of epiglottis
	THL	Collapse of whole tongue base
Larynx (L)	L1	Collapse of larynx except due to tongue base collapse
	L0	No collapse

In OSA patients, collapse of lateral wall is 93.3%, highest at level of velum followed by low palatal collapse (60%) , circular collapse (33.3%), low tongue collapse (13%), TH and PHL both (6.6%) and L (3.3%).

## Dynamic Sleep MRI

Dynamic sleep MRI has advantages of dynamic nature, the ability to evaluate the airway in a multiplane fashion. Dynamic magnetic resonance imaging (MRI) allows real-time characterization of upper airway collapse in sleeping subjects with obstructive sleep apnea (OSA). The three structures (planes ) we can study in MRI are retroglossal pharynx plane (RG), Retropalatal plane (RP) and Lateral pharyngeal wall (Lw). The RG and RP collapse is studied in sagittal sections whereas LPW is studied in axial sections<sup>9</sup>

## PRINCIPLE

- Subjects are laid in supine position in to magnetic coils with orbito-auricular plane at 90 angle to the horizontal plane. Airtight earplugs were inserted into the external auditory canal to minimize noise disturbance. Sleep MRI images are obtained with rapid MRI 2D multi-slice fast low-angle shot (FLASH) sequence The technical parameters are :

echo	Repetition time	Flip angle	matrix	Section thickness
1.73 ms	2.74 ms	6 degree	1.0 x 1.08	8mm

- The imaging time per slice for this sequence is 0.5 s. 100 consecutive images were obtained as a single section, with total imaging time of 50 s, where each image represents 0.5 sec.
- Usually patients with mild OSA (ahi< 10) shows single plane blockage (RP) whereas

patients with severe OSA (AHI>30) SHOW MULTIPLANE BLOCK ( RP+ RG+ LPW). There is a strong correlation between AHI and LPW collapse ( $b = 51.8$ ,  $p < 0.001$ ) the MRI “real time movie” during sleep has a higher reliability in detecting retropalatal blockage (96 %) than detecting retroglossal obstructions (85%).

## CINE MRI

CINE MRI is a modified version of MRI which was first used in study of cerebrospinal fluid (CSF) flow pattern in the brain ventricles during each heartbeat (systole and diastole). Later on, bowel movements, airway patency etc hollow structures were also examined with it.

## PRINCIPLE

- A fast gradient-echo sequence is used to create the cine MR images. Technical parameters included 8.2/3.6 (repetition time msec/echo time msec), an 80° flip angle, and an 8-mm section thickness.
- One hundred twenty-eight consecutive cine MR images are obtained at the same midline sagittal location in approximately 2 minutes. These images were obtained in the midline sagittal plane and in the transverse plane at the base of the tongue and displayed in a cine format to create a real-time “movie” of airway motion.
- Areas checked- oropharynx, nasopharynx, hypopharynx, adenoids etc during sleeping or awake patients. The change in airway diameter (narrowing) is greatest in the distal oropharynx and hypopharynx in OSA patients ( $p < 0.01$ ) and size of adenoids is also comparatively larger than normal person (13.46mm vs 7.36mm sagittal length)

## CBCT

Conventional CT SCAN was introduced in 1972 by G.N. Hounsfield. Arai et al in Japan and Mozzo et al in Italy independently developed CBCT which was first marketed in EUROPE in 1996 (NEW TOME 9000) and then introduced in US IN 2001. CBCT is a medical imaging modality that has been applied in different fields of medicine (e.g., cardiac imaging, radiotherapy). Although CT technology is a hard tissue- oriented imaging tool, with the use of DICOM (Digital Imaging and Communications in Medicine) it is possible to study 3D structures of hollow and soft tissue also. CBCT is very popular in orthodontics and has brought 3D radiography to clinical orthodontics as it defines the boundaries between tissues and empty spaces with high spatial resolution and less effective radiation dose when compared to conventional CT<sup>10</sup>.

## PRINCIPLE

This imaging technique is based on a cone-shaped X-ray beam centered on a 2-D detector that performs one rotation around the object, producing a series of 2-D images. These images are re-constructed in 3-D using a modification of the original cone-beam algorithm developed by Feldkamp *et al.* in 1984.

## SEGMENTATION

The boundaries of the area we want to assess has to be fed into computer by either of 3 methods ie, Machine/automatic, Manual and Semi manual. Manual process is very hectic whereas machine process is less accurate hence semimanual method is often used. The reliability of result by CBCT mainly depends on two things which are .ACCURACY OF SEGMENTATION and Field of view (FOV).

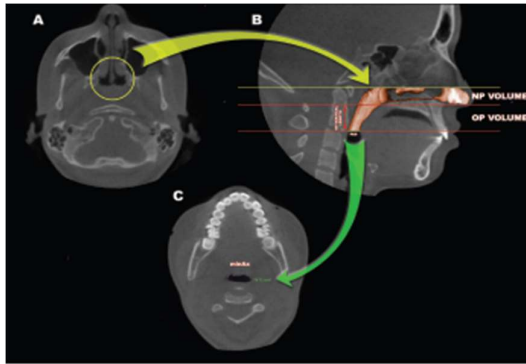
A traditional medical CT exposes the patient to a radiation dose of 124.9 to 528.4 microSv for the mandible and 17.6 to 656.9 microSv for the maxilla (depending on the volume imaged and operational settings of the CT). In contrast, CBCT needs 36 microSv to 50.3 microSv to provide a good amount of information. With an electron beam medical CT (EBCT) imaging system, to image the vocal cords, it needs 0.17 rem, which is equivalent to a 170 microSv exposure.

## AREAS OF AIRWAY MEASURED IN CBCT

The parameters measured for airway in CBCT are :-

- 1) THE NASAL PASSAGE volume(NP)
- 2) The oropharyngeal volume (OP)
- 3) The PAS (posterior airway space)- the most constricted space behind the base of tongue
- 4) Min Ax- the cross sectional area corresponding to PAS on axial slice
- 5) Vertical length OP

The greatest variability in UA is seen in the upper border of nasopharynx and lower limit of oropharynx where as the oral cavity and nasal cavity are more or less constant in their boundary<sup>11</sup>. The nasal passage, on the sagittal plane, was delimited from the last slice before the nasal septum joins the posterior wall of the pharynx and the lower boundary was determined by the palatal plane. The upper boundary of the oropharynx is the lower limit of NP and the lower one is the parallel to the plane that goes through the lowest anterior point of the second cervical vertebra (C2) (fig. 8)



**Fig 8. A.** axial slice in CBCT showing upper limit of nasopharynx where nasal septum fuses with posterior wall of pharynx (yellow line and circle) , **B.** upper limit of oropharynx and lower limit of nasopharynx (red line and green line) , **C.** axial slice showing minimum cross section area (min Ax) at PAS.

**The most common CBCT machines used were:**

- iCATH (Imaging Sciences International, Hatfield, PA)
- CB MercuRay™ (Hitachi Medical, Tokyo, Japan)
- NewTom 3G (ImageWorks, Elmsford, NY)
- Picasso Master 3D CBCT systems (VATECH, Seoul, Republic of Korea)

#### DIFFERENT PARAMETER OF CBCT :

According to a detailed study by Ogawa et al<sup>12</sup>, the OSA patients have reduced parameters when compared to non OSA patients. Mean value of Minimum cross section area was 45.8mm<sup>2</sup> in OSA subjects vs 146.9mm<sup>2</sup> in non OSA subjects.

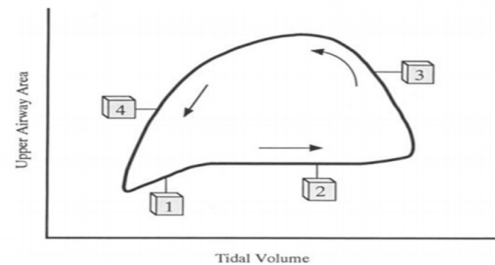
FOV (cm)	TUBE CURRENT(Ma)	TUBE POTENTIAL (Kvp)	SCANNING TIME (SEC)	RESOLUTION	VOXEL SIZE
13-30.5	2-15	110-120	10-40	0.25-0.6	3.527 x 3.527 pixels to 1024 x 1024 pixels

#### CINE CT

Ultrafast (Cine) CT scanning provides cross-sectional millisecond tomography, and therefore combines digital imaging and high resolution. It is mainly used in cardiovascular investigations but has also been used to study the airway structures<sup>13</sup>

#### PRINCIPLE

Cine CT is an fast alternative to conventional CT. It records the UA at 8mm thickness cross sections for retropalatal, retroglossal areas, the lateral pharyngeal walls ,the minimum airway cross section etc throughout the cycle of inspiration and expiration ( the tidal volume). Hence it is a dynamic process.(fig. 9)



**Fig 9.** Schematic diagram of the changes in upper airway area in an apneic patient as a function of tidal volume during the respiratory cycle . phase 1 is early inspiration, phase 2 is inspiration, phase 3 is early expiration and phase 4 is late expiration

Studies show that when compared to normal people, patients with OSA show obstruction at the distal aspect of the retropalatal or retroglossal part (MinCA in OSA is 41.3mm<sup>2</sup> vs 81.9mm<sup>2</sup> in non OSA), the airway at MCA in OSA patients is elliptical with major axis as the mediolateral length and minor axis as AP length . Airway muscles are more distensible (stretches more) during inspiration and early expiration in OSA patients . The airway was narrowest at end of expiration denoting collapse in OSA patients.

#### AIRWAY ANALYSIS USING LATERAL CEPHALOGRAM

The lateral cephalogram, a standardized sagittal X-ray of the head and neck, is perhaps the most commonly used of the above tests, especially by dentists. It is a simple, economical, readily available, and reproducible way to diagnose upper airway obstruction. some of the most notable cephalometric parameters are McNamara's line<sup>14</sup> and Fujioka's adenoid-nasopharyngeal ratio<sup>15</sup> although various other linear and area measurements have also been advocated.

#### 2D Vs 3D AIRWAY ANALYSIS

**The party balloon explanation** proposed by Graber, Varnsdall states that though volumetric measurement is most useful, it cannot be always used to compare the rate of distortion from normal tissue because if the distortion (collapse) occurs such that the total volume of airway remains same, then the findings will show false negative result<sup>1</sup>. Hence, linear measurement should always accompany 3 D analysis in all cases. (fig 10)



**Fig. 10. Party balloon explanation by Graber et al. two balloons of same volume but different shapes show how our airway can be different showing same total volume of space, which is undetected by 2D analysis only.**

**The advantages and disadvantages of 2D lateral cephalogram is presented in the table below as follows:**

ADVANTAGES	DISADVANTAGES
1.It is much cheaper than 3D scans	1.Cephalograms are good at properly identifying hypertrophied soft tissues (high sensitivity). However, they show less specificity in detecting an OSA case because it cannot check the overall nasopharynx.
2.Clinician expertise	2.Lateral cephalogram are good at detecting hypertrophied adenoidal than pharyngeal changes except McNamara's line which is consistent because it involves adenoids.
3.Lateral cephalogram is the gold standard radiogram for assessing upper airway in 2D	3.Adenoids have simple 3D anatomy when compared to complex airway, hence information loss and discrepancies in its 2D compression (Lat. Ceph.) is also less .
4.It is an excellent diagnostic tool for screening purpose of airway obstruction apart from clinical examination and questionnaires.	
5.Results of lat ceph helps the clinician to decide wheather to go for further specific ENT investigations or not	

### MC NAMARA'S AIRWAY ANALYSIS

In 1984, Mc Namara published his norms after taking sample of 111 untreated well balanced occlusion . The average value of upper pharyngeal airway is 17.4+/- 3.4 mm, values less than 5mm points to possible airway obstruction. For this, patient should not be swallowing while taking radiograph because the soft palate takes on the appearance of an inverted V, as the tensor and levator

veli palatini muscles pull the palate upward and backward during closure. Lower pharynx dimension is 11.3+/- 3.3mm. Values greater than 15-16 mm detects a large tongue, dialeted airway, enlarged tonsils<sup>14</sup>.( FIG. 11 A and B)

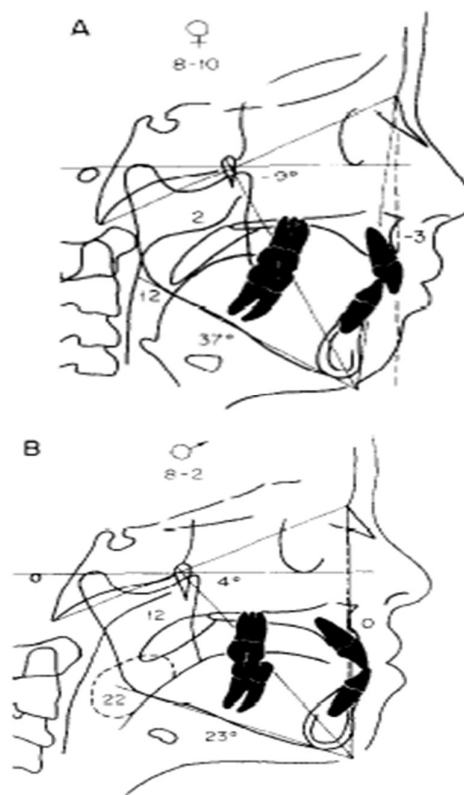
### STEPS IN MEASURING:

**Step 1:** Define the posterior pharyngeal wall, the soft palate, and the posterior border of the tongue.

**Step 2:** Bisect the distance from posterior nasal spine to the tip of the soft palate. Measure te closest distance from the anterior half of the soft palate to the posterior pharyngeal wall. ( Mc Namara's line)

**Step 3:** Identify the intersection point between the posterior outline of the tongue and the inferior border of the mandible (near the gonial angle).

**Step 4:** Measure the distance from this intersection point to the posterior pharyngeal wall



**Fig 11. A. Tracing of 8 yr old girl with class II relation showing airway; B. tracing of 8 yr old boy with skeletal class III relation showing airway**

### Adenoidal- Nasopharyngeal Ratio

This ratio was proposed by Fujioka et al, THE RATIO= A/N, variable according to age ( sex different is NS) (fig 12)





Fig 12A. Adenoidal measurement- “A” represents distance from A’ point of maximal convexity, along inferior margin of adenoid shadow to line B, Drawn along straight part of anterior margin of basiocciput ; “A” is measured along line perpendicular from point A’ to its intersection with B

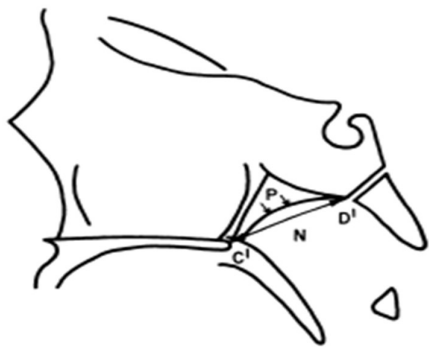


Fig. 12B. nasopharyngeal measurement. “N” is distance between C’ , posterior nasal spine to D’ , anteroinferior edge of sphenobasioccipital synchondroses. In case of ambiguity, D’ can be the point where margin of lateral pterygoid plate P meets the posterior roof of bony nasopharynx

The mean AN ratio increased from 0.33 at age 1.5 months to 0.55 at age 1 year 3 months, and reached its highest value, 0.59, at age 8 years 6 months. The AN ratio gradually decreased from this peak value to 0.52 at age 12 years 6 months and then diminished sharply to 0.38 at age 15 years 6 months<sup>15</sup>

## COMMON 2D AIRWAY MEASUREMENTS BY GRABER, VARNSDALL,VIG

Grabber gave 15 parameters for measuring soft tissue including airway length ,width, tongue position, tongue length and width, position of hyoid bone etc<sup>1</sup>, (fig 13)

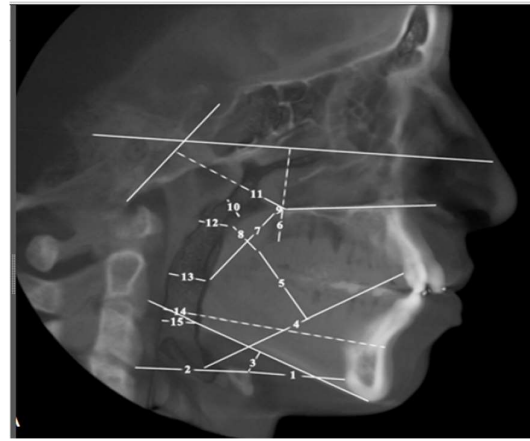


Fig 13. Graber’s measurements of airway

## POLYSOMNOGRAPHY

Polysomnography, also called a sleep study, is a comprehensive test used to diagnose sleep disorders. Polysomnography records your brain waves, the oxygen level in your blood, heart rate and breathing, as well as eye and leg movements during the study.

The recordings include electroencephalography (EEG) , electrooculography (EOG) , electromyography (EMG) and electrocardiography (ECG). Apart from this saturation level of blood (SpO<sub>2</sub> ), respiratory effort , heart rate and pulse are also studied. (fig. 14)

Polysomnography is gold standard and can be done in home or hospital set up. Different levels of sleep study are as follows:

**Level 1:** gold standard, attended PSG and full intervention possible

**Level 2:** unattended full PSG, all test done but complete intervention not possible

**Level 3:** only cardiorespiratory study done with airflow, SpO<sub>2</sub>, respiratory effort and EEG are studied

**Level 4:** only airflow and saturation level are measured



Fig 14. Patient undergoing level 2 polysomnography sleep study



## CONCLUSION

Obstructive sleep apnea is a sleep disorder involving mainly the upper airway tract, its morphology and various abnormalities. Upper Airway analysis to assess the morphology of pharyngeal spaces should always be performed besides clinical examination and history taking to diagnose the area of obstruction accurately. There are several ways of assessment starting from 2D cephalogram to 3D imaging like MRI and CBCT. 2D cephalograms is useful as a screening purpose for possible upper airway obstruction where as 3D scans are useful for a detailed investigation. Each technique has its own merits and demerits and it largely depends on the orthodontist or ENT specialist to decide which technique will give a accurate diagnosis. As different literature follows different methods, very few standardized protocols of measurements exist. Hence it is advisable to use a multidisciplinary, comprehensive 2D and 3D approach of measurements instead of following just a single technique blindly so that a more specific diagnosis and treatment planning can be done.

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# Remineralizing Agents: A Narrative Review

## Abstract

Dental caries is a complex disease that results from an imbalance between the demineralization and remineralization processes. As such, a promising preventive measure is to shift the balance in favor of remineralization. Remineralizing agents offer an opportunity to reverse the early-stage caries process, thus halting the progression of the disease process. In this narrative review, we discuss the demineralization-remineralization equilibrium, as well as old and new remineralizing agents.

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## INTRODUCTION

According to Fejerskov and Nyward (2004), dental caries is defined as a complex disease, caused by an imbalance in the physiologic equilibrium between tooth mineral and biofilm fluid.

Dental caries is the most common infectious disease in children. It is characterized by a progressive demineralization and loss of dental hard tissues, owing to acids produced by the bacteria present in dental plaque.

In 1998, McIntyre et al, showed how the initial demineralization of tooth enamel is a reversible process, and that it occurs alongside a process of remineralization, maintaining a balance between the two. However, at low pH, created by bacterial acids, this equilibrium may shift to favor the demineralization process.

Dental caries is an infectious disease of the dental hard tissues, leading to dissolution and loss of the enamel and dentine to acids produced as metabolic by-products of the causative bacteria.

Dental enamel is not a homogenous crystal structure, and is composed of crystal of varying chemical compositions, ranging from carbonated apatite, to hydroxyapatite and fluorapatite. Enamel remineralization is the natural process by which partially dissolved apatite crystals are reformed, into larger, stronger crystals, which show greater resistance towards dissolution by acids.<sup>(1)</sup>

Remineralizing agents are chemical compounds which aim at accelerating the remineralization process in noncavitated carious lesions, thus preventing future cavitation of the surface enamel and, by extension, also preventing the requirement for invasive treatment, while also making the enamel more resistant towards future carious lesions.

These usually act by accelerating, or otherwise aiding the remineralization of subsurface carious lesions, thus shifting the demineralization-remineralization cycle in favor of remineralization.

## **Demineralization-Remineralization Cycle (McIntyre et al, 1998)**

### **Demineralization**

The surface mineral content of enamel is composed of hydroxyapatite, which is in equilibrium with an environment which is saturated with calcium and phosphate ions.

At or below a pH of 5.5, it becomes reactive towards acidic Hydrogen atoms. These ions react with the phosphate in the environment, forming hypophosphate. As this causes an imbalance in the phosphate content between the enamel surface and its environment, the hydroxyapatite dissolves, to provide more phosphate ions, to restore the balance.

### **Remineralization**

Remineralization is the natural process of formation of new crystal structures, in subsurface demineralization, by calcium and hydroxide ions, aided by fluoride ions, resulting in a more acid-resistant crystal formation. <sup>(1)</sup>

At physiological conditions, the oral fluids (saliva, biofilm fluid) have calcium (Ca) and phosphate (Pi) in supersaturated concentrations with respect to the mineral composition of enamel and, as a result, these ions are continually deposited on the enamel surface or are redeposited in enamel areas where they were lost. <sup>(2)</sup>

If the pH is restored to neutral, the demineralization can be reversed, as the phosphate ion content becomes sufficient to restore the equilibrium. In this situation, partly-dissolved hydroxyapatite crystals may be rebuilt. <sup>(3)</sup>

The degree of remineralization depends on the inorganic ion concentration of the surrounding pellicle, and saliva. <sup>(4)</sup>

The surface and subsurface enamel absorbs and holds minerals and fluoride, which are present in the plaque fluid, and enhance the regrowth of partially dissolved crystals. Following fluoride incorporation into the enamel, results in larger crystal, which are significantly more resistant towards acid dissolution than regular hydroxyapatite crystals. This is the reason remineralizer white spot lesions are significantly less reactive towards acidic environments than normal hydroxyapatite. <sup>(3)</sup>

### **Role of Saliva in the Remineralization Process**

Reduction in the salivary flow rate/volume results in an increased potential for the development of dental caries.

Conversely, increasing the salivary flow rate/volume has proven to enhance the remineralization of white spot lesions.

Protective properties of saliva, which are enhanced on stimulation include:

- Salivary clearance.
- Buffering capacity.
- Degree of saturation with respect to tooth mineral.

Salivary proteins also play a major role in remineralization. Salivary glycoproteins participate in pellicle formation, while phosphoproteins regulate calcium saturation of the saliva. The pellicle offers the enamel resistance to dissolution in acidic environments. Early pellicle glycoproteins (acidic proline-rich proteins and statherins) attract calcium ions. <sup>(5)</sup> The ability of the saliva to remineralize demineralized enamel crystals stems from its ability to supply bioavailable calcium and phosphate ions to the tooth. At physiological pH, unstimulated and stimulated parotid, submandibular, and whole saliva are supersaturated with respect to most solid calcium phases. However, precipitation of calcium phosphate phases in saliva normally does not occur, due to the presence of salivary proteins, particularly statherin <sup>(6)</sup> and proline-rich phosphoproteins <sup>(7)</sup>. The proposed mechanism of action is that the segments of the proteins containing phosphoserine residues, in particular the statherin sequence, bind to calcium and phosphate ion clusters, preventing growth of the ion cluster to the critical size required for precipitation and transformation into a crystalline phase<sup>(8)</sup>.

This critical stabilization of calcium and phosphate ions by salivary phosphoproteins ensures that the ions remain bioavailable to diffuse into mineral-deficient lesions to allow for remineralization of demineralized crystals, while preventing surface deposition in the form of calculus. However, net remineralization produced by saliva is small and is a slow process, with a tendency for the mineral gain to be in the surface layer of the lesion due to the low ion concentration gradient from saliva into the lesion <sup>(9)</sup>. Recently, van der Veen et al. (2007) and Mattousch et al. (2007) examined white-spot lesions with quantitative light induced fluorescence following removal of orthodontic appliances. The majority of the lesions were stable, with no measurable signs of regression even after two years. They concluded that new remineralization systems were necessary to achieve effective lesion regression<sup>(10)(11)</sup>.

## Requirements of an Ideal Remineralizing Agent <sup>(5)</sup>

- Diffuses into the subsurface, or delivers calcium and phosphate into the subsurface.
- Does not deliver an excess of calcium.
- Does not favor calculus formation.
- Works at an acidic pH.
- Works on xerostomia patients.
- Boosts the remineralizing properties of saliva.
- For novel materials, shows a benefit over fluoride.

## Indications for Remineralizing Agents [Zero, 2006]

- An adjunct preventive therapy to reduce caries in high-risk patients
- Reduce dental erosion in patients with gastric reflux or other disorders
- To reduce decalcification in orthodontic patients
- To repair enamel in cases involving white-spot lesions
- Orthodontic decalcification or fluorosis or before and after teeth whitening and to desensitize sensitive teeth.

## Fluorides

Fluoride is the cornerstone of the non-invasive management of non-cavitated caries lesions, but its ability to promote net remineralization is limited by the availability of calcium and phosphate ions <sup>(12)</sup>. Fluoride ions can Drive the remineralization of extant non-cavitated caries lesions if adequate salivary or plaque calcium and phosphate ions are available when the fluoride is applied. For fluorapatite or fluorhydroxyapatite to form, calcium and phosphate ions are required, as well as fluoride ions. Several authors have now shown that enamel remineralization in situ and the retention of fluoride in plaque are dependent on the availability of calcium ions.<sup>(12)</sup> Hence, on topical application of fluoride ions, the availability of calcium and phosphate ions can be the limiting factor for fluoride retention and net enamel remineralization to occur, and this is highly exacerbated under hyposalivation conditions. <sup>(13)</sup> When adequate levels of calcium and phosphate ions are together with the fluoride ions, it has been shown in vitro that this combination can produce substantial remineralization of lesions of enamel and even those penetrating the underlying dentin in pH-cycling experiments.<sup>(14)</sup> Therefore, the challenge now is to achieve this clinically, since salivary remineralization of enamel promoted by topical fluoride (particularly high concentrations)

has been shown to give rise to predominantly surface remineralization <sup>(14)(15)</sup>. Surface-only remineralization does little to improve the aesthetics and structural properties of the deeper lesion. Ideally, a remineralization system should supply stabilized bioavailable calcium, phosphate, and fluoride ions that favor subsurface mineral gain rather than deposition only in the surface layer. <sup>(16)</sup> If fluoride is present in the biofilm fluid, and the pH is not lower than 4.5, hydroxyapatite (HA) is dissolved at the same time that fluorapatite (FA) is formed. <sup>(14)</sup>

The net result is a decrease in enamel dissolution, since a certain amount of calcium and phosphate ions, which was lost as HA, is recovered by enamel as FA. This mineral gain as FA during the pH Drop has not been considered as remineralization but rather as a decrease in demineralization because the mineral re-deposited is different from that which was lost. Furthermore, FA is deposited on the surface layer of enamel while HA is dissolved from the subsurface.

This indirect effect of fluoride reducing enamel demineralization when the pH Drops is complemented by its natural effect on remineralization when the pH rises enhancing the re-deposition of calcium and phosphate ions present in the biofilm fluid on demineralized enamel. If the demineralized enamel is cleaned by brushing, saliva is able to remineralizer it, but in the presence of fluoride this effect is enhanced. As a result, small amounts of calcium and phosphate ions lost by enamel during the pH Drop can be more efficiently recovered if F is still present in the oral environment (biofilm fluid or saliva) after the cariogenic challenge. This effect should be considered natural, not induced, because it occurs irrespective of patient compliance or dentist intervention if, for example, a fluoride-dentifrice is being used and fluoride is made available to the oral cavity.

By acting on the dynamics of the caries process, fluoride is very effective in slowing down the progress of caries lesions. However, since it does not have a direct effect on the etiological factors responsible for the disease (biofilm and sugar), it will not avoid it, and invariably the disease will leave scars on teeth, clinically visible or not. <sup>(2)</sup>

## Effect of Fluorides on Carious Lesions

Since fluoride enhances enamel remineralization, its clinical use to repair early caries lesions was advocated (“fluoride therapy”). However, the effect of fluoride in the dynamics of the caries process and its success in controlling caries should not be confused with its arrestment or reversal effect on caries lesions. Furthermore, it should be emphasized

that shallow demineralized enamel areas remineralize faster than deep ones.

Change in enamel lesions from a whitish to a shiny appearance was previously explained in terms of wear and polishing of the dull, partly dissolved surface of the active lesions, rather than re-deposition of mineral lost. However, the porosity of the deeper parts of the lesions was reduced, suggesting a partial remineralization of the lesion body. Therefore, the presence of a surface layer does not prevent subtle alterations at the crystals level inside the caries lesions after removing the biofilm accumulated on the enamel surface. However, while subsurface lesions remineralize in vitro within weeks, years are required for a complete remineralization in vivo. Therefore, if the biofilm accumulated on the enamel surface presenting non-cavitated active caries lesions is controlled by brushing with a fluoride-containing dentifrice, the lesions can not only be arrested, but also partially repaired. Even cavitated lesions can be arrested.

Any “remineralizing therapy” should follow two fundamental principles:

1. Dental biofilm, the necessary factor responsible for carious lesions, should be controlled by toothbrushing.
2. Fluoride should be used either to arrest existing lesions or to reduce the progression of new ones. <sup>(2)</sup>

These act on topical mechanisms, including:

- By inhibiting the demineralization process at the crystal surfaces.
- By promoting the remineralization process at the crystal surfaces, and forming more acid-resistant crystals in the process.
- At high concentrations, by also inhibiting bacterial enzymes.

In the absence of saliva and plaque in-vitro, fluorides in 1ppm concentration have shown increased mineralization of natural and artificial white spot lesions, over a 4-week period. <sup>(5)</sup>

The calcium-fluoride like material deposited when fluoride is applied topically has been associated with the beneficial effect of fluoride against erosive and abrasive lesions. The thickness of this calcium-fluoride like layer might be increased with the application of higher-concentration fluoride agents.

## Brushite

Brushite has been added to products such as dentifrices <sup>(17)</sup> in an attempt to enhance the remineralization of enamel subsurface lesions. Brushite is one of the more soluble crystalline calcium phosphate phases; however, remineralization of subsurface lesions in vivo and slowing of caries progression in clinical trials have not been shown. <sup>(16)</sup>

## Bioactive Glass

Bioactive glass (Bioglass®) was invented by Dr. Larry Hench in the 1960s. It acts as a biomimetic mineralizer matching the body's own mineralizing traits while also affecting cell signals in a way that benefits the restoration of tissue structure and function.

Bioactive glass formulations commonly used in research studies contain 45 wt% SiO<sub>2</sub> 4.5 wt% Na<sub>2</sub>O and CaO and 6 wt% P<sub>2</sub>O<sub>5</sub>. The network breakdown of silica depends upon the concentration of SiO<sub>2</sub> and is time dependent. Thus, keeping the silica below 60 wt% and maintaining a high CaO/P<sub>2</sub>O<sub>5</sub> ratio guarantees a highly reactive surface. <sup>(18)</sup>

Calcium sodium phosphosilicate (NovaMin) is an agent that is claimed to release calcium and phosphate ions intraorally to help the self-repair process of enamel. It is used extensively as a desensitizing agent, but the chemical reactions that occur may promote apatite formation enhancing remineralization. <sup>(19)</sup>

A variation on the use of crystalline calcium phosphates is the use of solid calcium sodium phosphosilicates, referred to as bioactive glasses. One of the first bioactive glasses developed was 45S5 Bioglass, which contained 45% SiO<sub>2</sub>, 24.5% Na<sub>2</sub>O, 24.5% CaO, and 6% P<sub>2</sub>O<sub>5</sub> (Cao and Hench, 1996). This glass has been studied for its ability to assist osteogenesis <sup>(20)</sup> and repair periodontal bone defects. <sup>(21)</sup> For dental applications, this calcium sodium phosphosilicate glass is marketed under the name of Novamin. It has been studied in vitro and clinically as a treatment for dentin hypersensitivity, with the proposed mechanism being the physical occlusion of dentin tubules. <sup>(22)</sup> Novamin has also been claimed by the manufacturers to have applications in enamel subsurface remineralization, although no publications supporting this claim could be found. <sup>(16)</sup>

Bioglass® in an aqueous environment immediately begins surface reaction in three phases, leaching and exchange of cations, network dissolution of SiO<sub>2</sub> and precipitation of calcium and phosphate to form an apatite layer. The critical stages for glass surface reactions are the initial Na<sup>+</sup> and H<sup>+</sup>/H<sub>3</sub>O<sup>+</sup> ion exchange and de-alkalinization of the glass surface layer is quite rapid, within minutes of implantation and exposure to body fluids. The net negative charge on the surface and loss of sodium causes localized breakdown of the silica network with the resultant formation of (silanol) Si (OH) groups, which then repolymerize into a silica-rich surface layer. Within 3-6 h in vitro, the calcium phosphate layer will crystallize into the carbonated hydroxyapatite (CAP) layer, which is essentially the bonding layer. Chemically and structurally, this apatite is nearly



identical to bone and tooth mineral. These Bioglass® surface reactions from implantation to formation of 100-150 µm CAP layer takes 12-24 h. When bioactive glass comes in contact with saliva, it rapidly releases sodium, calcium, and phosphorous ions into the saliva that are available for remineralization of the tooth surface. The ions released form hydroxycarbonate apatite (HCA) directly. They also attach to the tooth surface and continue to release ions and remineralize the tooth surface after the initial application. These particles have been shown to release ions and transform into HCA for up to 2 weeks. Ultimately, these particles will completely transform into HCA.<sup>(23)</sup>

NovaMin adheres to exposed dentin surface and forms a mineralized layer that is mechanically strong and resistant to acid. There is continuous release of calcium over time, which maintains the protective effects on dentin.

The NovaMin Technology was developed by Dr. Len Litkowski and Dr. Gary Hack. Currently available products in the market are NovaMin: SootheRx, DenShield, NuCare-Root Conditioner with NovaMin, NuCare-Prophylaxis Paste with NovaMin, and Oravive.

### Calcium Carbonate Carrier – SensiStat

The SensiStat technology is made of arginine bicarbonate, an amino acid complex, and particles of calcium carbonate, a common abrasive in toothpaste. The arginine complex is responsible for adhering the calcium carbonate particles to the dentin or enamel surface and allows the calcium carbonate to slowly dissolve and release calcium that is then available to remineralize the tooth surface.

The SensiStat Technology was developed by Dr. Israel Kleinberg of New York. The technology was first incorporated into Ortek's Proclude desensitizing prophylaxis paste and later in Denclude.<sup>(23)</sup>

### Dicalcium phosphate dihydrate

Inclusion of dicalcium phosphate dihydrate (DCPD) in a dentifrice increases the levels of free calcium ions in plaque fluid, and these remain elevated for up to 12 hours after brushing, when compared to conventional silica dentifrices.

Calcium from DCPD was incorporated into enamel and detected in plaque 18 hours post-treatment after brushing with a DCPD dentifrice which fosters improved remineralization of teeth in combination with fluoride.

### Xylitol

The use of chewing gum carrying xylitol increases salivary flow rate and enhances the protective properties of saliva. This is because the concentration of bicarbonate and phosphate is higher in stimulated saliva, and the resultant increase in plaque pH and salivary buffering capacity prevents demineralization of tooth structure. Moreover, the higher concentration of calcium, phosphate, and hydroxyl ions in such saliva also enhances remineralization. Miake et al. observed that xylitol can induce remineralization of deeper layers of demineralized enamel by facilitating calcium ion movement and accessibility.<sup>(23)(24)</sup>

Xylitol has the ability to:

- Reduce dental plaque formation
- Make plaque less adhesive
- Neutralize plaque acids by decreasing the production of lactic acid
- Reduce the levels of *S. mutans*
- Reduce cavities by up to 80%
- Demonstrate significant long-term reduction in caries (88-93%)
- Assist in the remineralization of tooth enamel
- Reduce gum tissue inflammation
- Help with Dry mouth and bad breath.

### Nano Hydroxyapatite

The application of nano-hydroxyapatite (HA) in the repair of early caries lesion has received considerable attention.

Accumulated evidence has demonstrated that the size of the calcium phosphate crystal plays an essential role in the formation of hard tissues and has a significant influence on its intrinsic properties, including solubility and biocompatibility.<sup>(25)(26)</sup> An in vitro study demonstrated that well-sized nano-apatite particles could simultaneously repair and prevent initial erosive lesions in enamel compared with conventional HA crystals that are hundreds of nanometers in length.<sup>(27)</sup> The size of HA has been suggested to influence remineralization and to play a key role in its mechanism of action.

Nano-HA promotes preferential remineralization of the outer enamel caries lesion, but full remineralization is not achievable under neutral conditions, while under acidic conditions nano-HA can significantly accelerate the rate, depth of penetration, and extent of remineralization of artificial incipient lesions.<sup>(28)</sup>

A study was done to determine the effect of nano-hydroxyapatite concentrations on initial enamel lesions under dynamic pH-cycling conditions. It was concluded that nano-hydroxyapatite had the potential to remineralize initial enamel lesions. A

concentration of 10% nano-hydroxyapatite may be optimal for remineralization of early enamel caries.<sup>(23)</sup>

### **Amorphous calcium phosphate (ACP)**

The ACP technology was developed by Dr. Ming S. Tung. In 1999, ACP was incorporated into toothpaste called Enamelon and later reintroduced in 2004 as EnamelCare toothpaste. There is modest evidence for Enamelon™ for its caries inhibitory action.

This macromolecule was developed by the American Dental Association Health Foundation. It is prepared using low temperature methods, and can be modified to create hybrids which contain silica or zirconia.

When applied topically, it is thought that ACP hydrolyses under physiological temperatures at a pH of 7.4 to form octacalcium phosphate and an intermediate, and then surface apatite.

The ACP technology requires a two-phase delivery system to keep the calcium and phosphorous components from reacting with each other before use. The current sources of calcium and phosphorous are two salts, calcium sulphate and dipotassium phosphate. When the two salts are mixed, they rapidly form ACP that can precipitate on to the tooth surface. This precipitated ACP can then readily dissolve into the saliva and can be available for tooth remineralization.

An inherent technical issue with Enamelon™ is that calcium and phosphate are not stabilized, allowing the two ions to combine into insoluble precipitates before they come into contact with saliva or enamel. This is unlike Recaldent™, which has the casein phosphoproteins to stabilize calcium and phosphate.

### **Limitation**

The surface actions of ACP reduce surface porosity and thus render such sites less likely to undergo subsurface remineralization.

Single phase ACP systems are formulated without water, to keep the ACP from reacting to form apatite.<sup>(5)</sup>

### **Alpha-tricalcium phosphate**

It is used in products such as Cerasorb, Bio-Resorb, and Biovision. Tricalcium phosphate (TCP) has also been considered as one possible means for enhancing the levels of calcium in plaque and saliva. Some small effects on free calcium and phosphate levels in plaque fluid and in saliva have been found when an experimental gum with 2.5% alpha-TCP by

weight was chewed, when compared to a control gum without added TCP.

### **Beta Tricalcium Phosphate (TCP)**

Alpha tricalcium phosphate is a breakdown product of enamel.

Beta tricalcium phosphate can be synthesized by heating a mixture of calcium carbonate and calcium hydrogen phosphate at 1000°C for 1 day. After milling, we obtain crystals of 0.01-5µm in size.

These crystals may be incorporated into oral care products, to provide bioavailable calcium in plaque and saliva.<sup>(5)</sup>

Beta-TCP was combined with 5,000 ppm F (NaF) and evaluated for the remineralization potential of subsurface enamel lesions via an in vitro remineralization/demineralization pH cycling dental model. Using surface and longitudinal micro hardness measurements, the TCP-SLS plus 5,000 ppm F system was found to significantly boost remineralization of subsurface enamel lesions, with micro hardness values increasing up to 30% greater than fluoride alone.<sup>(29)</sup>

### **Limitation**

Formation of calcium-phosphate complexes, or calcium fluoride (in the presence of fluorides), if used in concentrations greater than 1%.<sup>(5)</sup>

### **To prevent interactions with Phosphate**

Incorporation of ceramic particles (TiO<sub>2</sub>), to limit the interaction between Ca and PO<sub>4</sub>, and to increase their stability in solutions/suspensions.

### **To prevent interactions with F**

Organic coatings, such as surfactants (Sodium Lauryl Sulphate), carboxylic acids (fumaric acid), polymers, or copolymers, inhibits the interaction of Ca with F ions.<sup>(5)</sup>

It best functions at neutral, or slightly alkaline pH. Slight increase in surface micro hardness was seen after application on bovine enamel.

Effects on human enamel are yet to be seen.<sup>(5)</sup>

### **Enamelon**

Enamelon consists of destabilized calcium and phosphate salts with sodium fluoride. The calcium salts are separated from the phosphate salts and sodium fluoride by a plastic divider in the center of the toothpaste tube.

## Limitation

Calcium and phosphate are not stabilized, allowing the two ions to combine into insoluble precipitates before they come into contact with saliva or enamel.<sup>(5)</sup>

## Dicalcium phosphate dehydrate (DCPD)

This material has been used in some fluoride dentifrices to attempt to enhance on the remineralizing effects of the fluoride component. Inclusion of DCPD in a dentifrice increases the levels of free calcium ions in plaque fluid, and these remain elevated for up to 12 hours after brushing, when compared to conventional silica dentifrices.<sup>(5)</sup>

## Casein Phosphopeptides

Dairy products are linked with good oral health, since they have been shown to have anticariogenic properties in numerous model systems<sup>(30)(31)(32)(33)</sup>. These properties have been attributed to calcium, phosphate, and casein<sup>(32)(34)</sup>. The ability of bovine milk to remineralize enamel subsurface lesions has been demonstrated in vitro by McDougall (1977) and Mor and Rodda (1983). Casein is the major protein group found in milk and accounts for approximately 80% of the total protein (Aimutis, 2004). In milk, casein exists in micelles that stabilize calcium and phosphate ions. The ability of casein to stabilize calcium and phosphate ions resides in sequences that can be released as small peptides (casein phosphopeptides) by partial enzymic digestion. This has led to the development of a remineralization technology based on casein phosphopeptide-stabilized amorphous calcium phosphate complexes (CPP-ACP)<sup>(35)(36)</sup> [Recaldent® CASRN691364-49-5] and casein phosphopeptide stabilized amorphous calcium fluoride phosphate complexes (CPP-ACFP).<sup>(37)(38)(39)</sup> These complexes have been incorporated into commercial sugar-free chewing gums [Trident Xtra Care (Americas), Recaldent (Japan)] and dental cream [Tooth Mousse and Tooth Mousse Plus (Europe and Australia), MI Paste and MI Paste Plus (Japan and Americas)].

## Recaldent (CPP-ACP nanocomplexes)

This formulation contains multiphosphorylated peptides known as casein phosphopeptides (CPP), derived from milk caseins that form complexes with amorphous calcium phosphate (ACP) denoted as CPP-ACP. The food group most recognized as exhibiting anticaries activity is dairy products (milk, milk concentrates, powders and cheeses).<sup>(35)</sup>

Using in vitro, animal and in situ caries models, the components largely responsible for this anticariogenic activity have been identified as bovine milk caseins, calcium and phosphate.<sup>(30)(35)</sup> Casein, which is known to interact with calcium and phosphate (Reeves and Latour 1958), is a natural food component and therefore is an obvious candidate for an anticariogenic food and toothpaste additive, however this is precluded by its organoleptic properties and the very high levels required for activity.<sup>(30)(40)</sup> Using a human intra-oral caries model Reynolds (1987) showed that digestion of caseinate with trypsin did not destroy the protein's ability to prevent enamel sub-surface demineralization. Tryptic peptides of casein were found incorporated into the intra-oral appliance plaque and were associated with a substantial increase in the plaque's content of calcium and phosphate. It was concluded that the tryptic peptides that were responsible for the anticariogenic activity were the calcium phosphate sequestering phosphopeptides.<sup>(41)</sup>

These peptides are 10% w/w of caseinate and through their multiple phosphoserine residues sequester their own weight in calcium phosphate to form colloidal complexes (Reeves and Latour 1958; Swaisgood 1982). Since the CPP are not associated with the unpalatability (Swaisgood 1982) or allergenicity (Ametani et al. 1987; Elsayed et al. 2004) of the caseins and furthermore have the potential for a specific anticariogenicity at least ten times greater on a weight basis, their potential as a food and toothpaste additive is considerably better than that of the intact proteins. The CPP can be prepared as complexes with ACP referred to as CPP-ACP complexes or Recaldent.<sup>(40)(41)</sup>

This technology was developed by Eric Reynolds and co-workers at the University of Melbourne, and has since been incorporated into chewing gums (such as Recaldent gum™ and Trident White™) and tooth crèmes (GC Tooth Mousse™ and MI Paste™). A formulation with incorporated fluoride to a level of 900 ppm (GC Tooth Mousse Plus™, MI Paste Plus™).

This protein nanotechnology combines specific phosphoproteins from bovine milk with forming nanoparticles of amorphous calcium phosphate (ACP). The precise ratio is 144 calcium ions plus 96 phosphate ions and 6 peptides of CPP.

The casein phosphopeptides (CPP) are produced from a tryptic digest of the milk protein casein, then aggregated with calcium phosphate and purified by ultrafiltration. Under alkaline conditions the calcium phosphate is present as an alkaline amorphous phase complexed by the CPP. The nano-complexes form over a pH range from 5.0 to 9.0. Under neutral and alkaline conditions, the casein phosphopeptides stabilize calcium and phosphate ions, forming

metastable solutions that are supersaturated with respect to the basic calcium phosphate phases. The amount of calcium and phosphate bound by CPP increases as pH rises, reaching the point where the CPP have bound their equivalent weights of calcium and phosphate.

### Action on demineralized enamel

The CPP have a marked ability to stabilize calcium phosphate ions in solution.<sup>(36)</sup> Under alkaline conditions, pH 7–9, the  $\alpha$ S1-CN (59-79) and  $\beta$ -CN (1-25) peptides, maximally bind 21 and 24 Ca and 14 and 16 Pi ions per molecule in the respective ACP complexes to produce a maximum loading of 24 mol Ca/mol peptide (Cross et al. 2005). The amount of calcium and phosphate bound by the CPP was observed to increase as the pH increased towards pH 9.<sup>(41)</sup>

CPP binds to certain plaque bacteria and also localize ACP within dental plaque biofilms.

The material is pH responsive, with increasing pH increasing the level of bound ACP and stabilizing free calcium and phosphate, so that spontaneous precipitation of calcium phosphate does not occur. This provides an anti-calculus action.

Recaldent may influence the properties and behavior of dental plaque through (1) binding to adhesin molecules on mutans streptococci and thus impairing their incorporation into dental plaque, (2) elevating plaque calcium ion levels to inhibit plaque fermentation; and (3) providing protein and phosphate buffering of plaque fluid pH, to suppresses overgrowth of aciduric species under conditions where fermentable carbohydrate is in excess.

There is a strong correlation between remineralization and the concentration of the neutral ion pair  $\text{CaHPO}_4$ . By stabilizing calcium phosphate in solution, the CPP maintain high-concentration gradients of calcium and phosphate ions and ion pairs into subsurface lesions, an effect which explains the high rates of enamel subsurface remineralization which can be achieved when these products are used in solutions, gums, lozenges and crèmes.

The neutral ion species gain access to the subsurface lesion through a porous enamel surface. This is the reason arrested white spot lesions should have a surface etching treatment before remineralization with Recaldent products. Such a treatment, either alone or combined with gentle pumicing, will remove approximately 30 microns of surface enamel, but will not cause further mineral loss from the subsurface zone of the white spot lesion.<sup>(5)</sup>

Reynolds EC et al., performed a study in 2003 and showed that when CPP-ACP was present in a

mouthwash, it resulted in the increase of calcium and phosphate levels in supragingival plaque.

Kanako Yamaguchi et al., carried out an in vitro study in 2005 on bovine enamel and concluded that CPP-ACP paste prevented demineralization. The paste also increased remineralization of enamel as compared to the other paste that was CPP-ACP free. Maki Oshiro et al., used CPP-ACP paste on bovine teeth in 2007 to demonstrate its remineralizing potential. Bovine teeth were cut into blocks. Few of the specimens were placed in lactic acid (demineralizing solution) and were then placed in artificial saliva. Remaining specimens were stored in CPP-ACP paste solution and they were then placed in demineralizing solution and artificial saliva. Scanning electron microscopy (SEM) was utilized to observe morphological features and it revealed that the specimens which were treated with CPP-ACP first, showed little morphological changes as compared to the remaining specimens and so it was concluded that CPP-ACP has the ability to prevent demineralization.

Christos and George in 2007 carried out an in vitro study on human teeth to demonstrate the effect of CPP-ACP commercial paste on demineralization and remineralization. They used multiple internal reflection-Fourier transform infrared spectroscopy (MIR-FTIR) for analysis and concluded that the presence of CPP-ACP agent on dentine caused decreased demineralization and increased remineralization when compared with the surfaces of dentine where CPP-ACP agent was not applied. CPP-ACP complexes have been shown to reduce induced caries activity in specific-pathogen-free rats orally infected with *Streptococcus sobrinus* 6715WT-13.<sup>(35)</sup>

Solutions of CPP-ACP complexes at pH 7.0, applied to the animals' teeth twice daily, significantly reduced caries activity with 1.0% w/v CPP-ACP producing a 55% reduction relative to the distilled water control.

CPP-ACP at 0.5–1.0% w/v produced a reduction in caries activity similar to that of the 500 ppm F solution.<sup>(35)</sup>

A 1.0% CPP-ACP complexes pH 7.0 solution was demonstrated to prevent enamel demineralization in the human in situ caries model.<sup>(40)</sup> In this model two exposures of the CPP-ACP complexes solution per day produced a  $51 \pm 19\%$  reduction in enamel mineral loss relative to the control enamel and increased plaque calcium and inorganic phosphate contents by 143% and 160% respectively.

CPP was also found in the treated plaque at a level of  $2.4 \pm 0.7$  mg/g. The level of the CPP was determined by competitive ELISA using an antibody that recognizes both  $\alpha$ S1-CN (59-79) and  $\beta$ -CN (1-25). Electron micrographs of immunocytochemically stained sections of the

plaque revealed localization of the peptide predominantly on the surface of microorganisms but also in the extracellular matrix.<sup>(36)</sup>

A randomized controlled caries clinical trial was conducted to investigate the radiographic progression and regression of dental caries in adolescent subjects chewing a gum containing CPP-ACP complexes over a 24-month period. 2,720 subjects were randomly assigned to either a test or control group. All subjects received accepted preventive procedures, including fluoridated water, fluoridated dentifrice and access to professional care. The test group received a sugar-free gum containing 54.4 mg CPP-ACP complexes while the control group received an identical gum without CPP-ACP complexes. Subjects were instructed to chew their assigned gum for 10 min 3 times/ day, with one session supervised on school days, over the 24-month study period. The CPP-ACP complexes gum slowed progression of carious lesions compared with the control gum. Subjects chewing the CPP-ACP complexes gum experienced 53% more regression than those chewing the control gum. Whereas those chewing the control gum experienced 19% more progressions than those chewing the CPP-ACP complexes gum over the 24-month period. In conclusion, chewing gum containing 54.4 mg CPP-ACP complexes significantly slowed progression and enhanced regression of dental caries in a 24-month clinical trial relative to a normal sugar-free gum.<sup>(42)</sup>

### Indications for CPP-ACP <sup>(43)</sup>

1. CPP-ACP can be used to remineralize early carious lesions.
2. It has the ability to counteract the action of acids in cases of erosion.
3. It has been proposed that CPP-ACP has an edge over fluoride tooth paste when it comes to neutralizing acids in the oral cavity.
4. CPP-ACP can also block the dentinal tubules and in turn can reduce the sensitivity.
5. CPP-ACP alone or its combination with fluoride can be utilized as a prophylactic agent before the bonding of orthodontic brackets.

Remineralization of enamel subsurface lesions *in situ* has recently been demonstrated using a variety of delivery vehicles for CPP-ACP complexes including mouthwash, sugar-free chewing gum and lozenges (Shen et al. 2001; Reynolds et al. 2003; Cai et al. 2003; Iijima et al. 2004). Overall, this model has been extensively used to demonstrate the ability of CPP-ACP complexes to prevent enamel

demineralization and promote remineralization.  
<sup>(44)(45)(46)</sup>

The study by Bailey et al. (2009) examined 45 individuals, with 408 white-spot lesions immediately after orthodontic therapy, who were randomly assigned to either a dental cream containing 10% CPP-ACP treatment or a placebo cream treatment. They were instructed to apply the products twice daily for 12 weeks after normal oral hygiene procedures (they were supplied with dentifrice containing 1000 ppm F as NaF). The participants also received supervised fluoride mouth rinses. Following initial assessment, lesions were assessed at 4, 8, and 12 weeks. The lesions were scored for lesion severity and activity according to the International Caries Diagnosis and Assessment System II (ICDAS II) criteria (<http://www.ICDAS.org>). At 12 weeks, 31% more of the ICDAS code 2 (white spot visible when wet) and code 3 (loss of enamel surface integrity) lesions had regressed with the CPP-ACP cream compared with the control treatment (Odds Ratio = 2.3,  $p = 0.04$ ). In both treatment groups, active lesions were more likely to regress than inactive lesions (Odds Ratio = 5.07,  $p < 0.001$ ). It was concluded that significantly more post-orthodontic white-spot lesions regressed with the CPP-ACP cream treatment over a 12-week period.<sup>(47)</sup>

A clinical trial by Rao et al. (2009) compared the efficacy of three dentifrices: (1) 2% CPP and calcium carbonate, (2) 1190 ppm fluoride as sodium monofluorophosphate, and (3) a placebo. One hundred fifty schoolchildren were randomly assigned to use one of the dentifrices for 2 years. At the end of the study, it was found that the 2% CPP/calcium carbonate dentifrice significantly reduced caries experience relative to the placebo dentifrice, with a slightly better efficacy than the 1190-ppm fluoride dentifrice. Over 70% (72.3%) of the children remained caries-free using the CPP/calcium carbonate dentifrice compared with 53.2% using the fluoride paste and 31.1% using the placebo at 24 months. Since CPP/calcium carbonate in the presence of salivary phosphate would spontaneously form CPPACP, it is likely that the efficacy of this dentifrice was at least in part related to the remineralizing properties of CPP-ACP. The efficacy may also be partly due to the ability of the CPP-ACP to inhibit enamel demineralization.<sup>(40)</sup>

### Mechanism of Action for CPP-ACP

The mechanisms of action of CPP-ACP need to be considered at a location inside the enamel subsurface lesion, as well as at the surface of that lesion. The CPP-ACP and CPP-ACFP have been determined to be amorphous electro neutral



nanocomplexes with a hydrodynamic radius of  $1.53 \pm 0.04$  nm and  $2.12 \pm 0.26$  nm, respectively (Cross et al., 2004, 2005). From the size and electro neutrality of the nanocomplexes, it would be expected that they would enter the porosities of an enamel subsurface lesion and diffuse down concentration gradients into the body of the subsurface lesion (Cochrane et al., 2008; Reynolds et al., 2008). Recently, it has been shown, with confocal laser microscopy and fluorescently labelled anti-CPP antibodies, that CPP was present inside a CPP-ACP remineralizer enamel subsurface lesion. Once present in the enamel subsurface lesion, the CPP-ACP would release the weakly bound calcium and phosphate ions<sup>(48)</sup>, which would then deposit into crystal voids. The release of the calcium and phosphate ions would be thermodynamically Driven. The CPPs have a high binding affinity for apatite; hence, on entering the lesion, the CPPs would bind to the more thermodynamically favored surface of an apatite crystal face. Interestingly, the CPPs have been shown to prefer binding to the (100) and (010) faces of hydroxyapatite crystals, such that crystal growth would be allowed to continue only at the hydroxyapatite (001) plane or along the c-axis, which is the pattern of crystal growth during amelogenesis.<sup>(49)</sup> Hence, the CPPs, once bound to apatite crystals in the enamel subsurface lesion, may have an important role in regulating anisotropic crystal growth and also inhibiting crystal demineralization.<sup>(50)</sup>

When CPP-ACP is provided with a low background of fluoride, electron microprobe analysis has shown that the mineral formed in the enamel lesion is consistent with hydroxyapatite, and when fluoride is present, the mineral is consistent with fluorapatite or fluorhydroxyapatite (Cochrane, 2008). The demineralized enamel crystals contained numerous voids (central defects), whereas the voids (central defects) following remineralization with CPP-ACP showed substantial occlusion. The diffraction patterns of this newly formed mineral were consistent with those of apatite.

The CPP-ACP nanocomplexes have also been demonstrated to bind onto the tooth surface and into supragingival plaque to significantly increase the level of bioavailable calcium and phosphate ions. A randomized, double blind, cross-over in situ study was conducted to measure calcium and phosphate incorporation into plaque after 5 days of rinsing with either water, 2% CPP-ACP, 6% CPP-ACP, or destabilized calcium and phosphate. The plaque calcium and phosphate levels following rinsing with the water and the destabilized calcium and phosphate rinses were similar, whereas both CPPACP rinses resulted in significantly higher incorporation of calcium and phosphate ions. When the plaque CPP levels were determined with

competitive ELISA, it was found that 3 hours post-exposure to CPP-ACP, there remained a 4.6-fold higher peptide content than the baseline levels. Electron microscopic analysis of immunocytochemically stained thin sections of supragingival plaque samples showed that the CPP-ACP nanocomplexes were localized in the plaque matrix and on the surfaces of bacterial cells, confirming the work of Rose (2000), who showed the CPP-ACP nanocomplexes bound to *Streptococcus mutans* and model plaque to produce a reservoir of bioavailable calcium ions. These results are also consistent with those of Schüpbach et al. (1996), who showed the CPP to inhibit binding of *mutans streptococci* to saliva-coated enamel in vitro and in animal studies.<sup>(51)</sup>

These authors suggested that CPP-ACP incorporates into pellicle and plaque and results in an ecological transition of the bacterial population, which, together with the remineralizing capacity of the CPP-ACP, modifies the plaque's cariogenic potential.<sup>(16)</sup>

The method of binding CPP-ACP into plaque has been hypothesized to be due to calcium cross-linking<sup>(52)</sup>, and/or hydrophobic and hydrogen-bond-mediated interactions. Using acid and alkali extraction, to help distinguish between these mechanisms of binding, investigators found that the majority of the bonds localizing CPP in the plaque were hydrophobic and/or hydrogen-bond-mediated interactions between the CPP and bacterial cell/pellicle surfaces, since the peptides were released predominantly by alkaline extraction. These results are consistent with the proposed 3D structure of the CPP-ACP nanocomplexes showing calcium and phosphate ion clusters encapsulated by the surface-bound CPP. The surface-bound CPP molecules display a hydrophobic patch on the surface of the nanocomplex that may be responsible for the binding and localization of the complexes at the tooth surface. In a randomized, controlled, mouth rinse trial, a rinse containing 2.0% CPP-ACP nanocomplexes plus 450 ppm fluoride significantly increased supragingival plaque fluoride ion content to  $33.0 \pm 17.6$  nmol F/mg Dry wt of plaque when compared with  $14.4 \pm 6.7$  nmol F/mg Dry wt of plaque attained by the use of a rinse containing the equivalent concentration of fluoride ions (Reynolds et al., 2008). Although marked increases in plaque calcium, phosphate, and fluoride were found, calculus was not observed in any of the study participants, indicating that the plaque calcium, fluoride, and phosphate remained stabilized at the tooth surface by the CPP as bioavailable ions and did not transform into a crystalline phase.<sup>(51)</sup>

The release of calcium, phosphate, and fluoride ions by the CPP localized in plaque would be Driven thermodynamically, as described above. However,

this process in dental plaque would be promoted by low pH. As the pH of plaque decreased by bacterial acid production, then this would facilitate the release of calcium, phosphate, and fluoride ions from the complexes. The CPP in plaque could act as a sink for salivary calcium, phosphate, and fluoride ions to increase the ionic content of plaque when the plaque pH again rises if the peptides remain intact. However, plaque peptidases and phosphatases can degrade the phosphopeptides. The dephosphorylation of the phosphoserines of the CPP by phosphatases substantially reduces the ability of the peptides to bind calcium and phosphate ions. From the immunolocalization time-course study of CPP in plaque, the half-life of CPP in plaque was calculated to be 124.8 min. Furthermore, casein has been shown to be hydrolyzed by salivary sediment bacteria in a similar timeframe; hence the decrease in detection of the CPP in plaque is likely to be attributable to the enzymic digestion of the peptides to fragments not recognized by the antibodies used for the assay. Cross et al. (2005) have shown that the full-length CPPs are required for maximal stabilization of calcium and phosphate ions; therefore, enzymic hydrolysis of the CPP in plaque would reduce their stabilization capacity. It should be noted that the enzymic breakdown of the CPP has been shown to produce a plaque pH rise through the production of ammonia. Hence, this process may contribute to the inhibition of demineralization and promotion of remineralization observed *in situ*/ *in vivo* by the CPP-ACP.<sup>(51)</sup>

The released calcium, phosphate, and fluoride ions at the enamel surface will participate in a variety of equilibria to form a range of calcium phosphate species, depending on the pH and fluoride availability as described by Cochrane et al. (2008). The process of diffusion into a subsurface lesion must be an overall electro neutral process.

Therefore, diffusion potential into an enamel subsurface lesion can be characterized by the activity gradient of the neutral ion pair,  $\text{CaHPO}_4$ , into the lesion. As the neutral ion pair diffuses down its activity gradient into the lesion, unimpeded by the charges in plaque, pellicle, and the enamel, it will dissociate along its diffusion path to produce calcium and phosphate ions, capable of depositing into crystal voids promoting crystal growth. In the case of CPP-ACFP, fluoride would then also be provided that would allow the formation of the neutral species  $\text{CaH}_2\text{FPO}_4$  and  $\text{HF}_0$  to diffuse down activity gradients to dissociate and accelerate growth of a fluoride-containing apatite.<sup>(38)</sup>

The mineral gained by enamel subsurface lesions during *in situ* treatment with CPP-ACP has been acid-challenged to determine its relative solubility. These studies found that the CPPACP- produced mineral was more acid-resistant than the non-CPP-

ACP-treated lesions. The CPP-ACP-treated lesions tended to lose mineral only upon acid challenge below the remineralizer zone compared with the control lesions, which lost mineral throughout the lesion. These results are consistent with the production of a more stable mineral phase (e.g., hydroxyapatite or fluorapatite, as shown by electron microprobe analysis) that has a lower solubility than a calcium-deficient carbonated apatite of normal tooth enamel.<sup>(44)</sup>

## CPP-ACFP nanocomplexes

The Amorphous Calcium Phosphate (ACP) technology is a destabilized calcium and phosphate system that has been developed and commercialized. It is based on destabilized amorphous calcium phosphate, where a calcium salt (e.g., calcium sulphate) and a phosphate salt (e.g., potassium phosphate) are delivered separately (e.g., from a dual-chamber device) intra-orally or delivered in a product with a low water activity.<sup>(53)</sup> As the salts mix with saliva, they dissolve, releasing calcium and phosphate ions. The mixing of calcium ions with phosphate ions to produce an ion activity product for amorphous calcium phosphate that exceeds its solubility product results in the immediate precipitation of ACP or, in the presence of fluoride ions, amorphous calcium fluoride phosphate (ACFP). In the intra-oral environment, these phases (ACP and ACFP) are potentially very unstable and may rapidly transform into a more thermodynamically stable, crystalline phase (e.g., hydroxyapatite and fluorhydroxyapatite). However, before phase transformation, calcium and phosphate ions should be transiently bioavailable to promote enamel subsurface lesion remineralization.<sup>(38)</sup>

Casein phosphopeptides containing the cluster sequence- Ser(P)-Ser(P)-Ser(P)-Glu-Glu- bind fluoride as well as calcium and phosphate, and thus can also stabilize calcium fluoride phosphate as soluble complexes. These complexes are designated CPP-ACFP. Studies of such nano-complexes based on the casein alpha-S1 peptide fragment 59-79 have revealed a particle size of some 2 nm and stoichiometry of one peptide to 15 calcium, 9 phosphate and 3 fluoride ions.

A dentifrice containing CPP-ACP with fluoride provides remineralization which is superior to both CPPACP alone and to conventional and high fluoride dentifrices. However, Tooth Mousse (without fluoride) remineralizer initial enamel lesions better when applied as a topical coating after the use of a fluoride dentifrice.

CPP can stabilize high concentrations of calcium, phosphate and fluoride ions at all pH values from 4.5 up to 7.0, and is able to remineralizer enamel

subsurface lesions was observed at all pH values in this range, with a maximal effect at pH 5.5.

At pH values below 5.5, CPP-ACFP produces greater remineralization than CPP-ACP, and the major product formed when remineralization is undertaken with CPP-ACFP is fluorapatite, which is highly resistant to acid dissolution.<sup>(5)</sup>

An ACFP-forming dentifrice has been tested in a clinical trial studying high-caries-risk patients post-head and neck irradiation. In this study, the dentifrice forming ACFP was superior to the fluoride-alone dentifrice in lowering root caries increment; however, there was no significant difference in coronal caries increment between the two products.<sup>(54)</sup>

Chow et al. (2000) have investigated the ability of two solutions immediately mixed together and then used as a mouth rinse to promote remineralization of enamel subsurface lesions, using an in situ remineralization model. One solution contained calcium ions and the other fluoride and phosphate ions, such that when mixed together and with saliva they would immediately form an amorphous calcium fluoride phosphate phase. The solution used by Chow et al. (2000) contained higher concentrations of calcium and fluoride ions than phosphate ions, and hence the precipitate that formed has been referred to as a “calcium fluoride-like” phase. However, in the presence of phosphate in the solution, as well as in saliva, it is likely that some phosphate would have incorporated into the initial amorphous phase that formed as previously described (Christoffersen et al., 1988; LeGeros, 1991). The two-solution rinse promoted more remineralization of enamel subsurface lesions than the fluoride-alone rinse in this study.

This work, along with that of Vogel et al. (2008), who showed that pre-rinsing with a Ca solution significantly enhanced plaque fluoride retention from a separate fluoride rinse, confirms the important role of externally applied bioavailable calcium in enhancing the intra-oral retention of fluoride and promoting enamel subsurface lesion remineralization.

Although some of these published papers suggest that the destabilized ACP/ACFP technology may have efficacy in preventing caries progression, some authors have expressed concern with the destabilized nature of the product that forms intra-orally with this technology. The destabilized ACP/ACFP may transform to poorly soluble phases in the mouth, and, in so doing, may act to promote dental calculus. The formation of fluoride-containing apatite intra-orally would sequester available fluoride ions, thereby reducing their ability to promote remineralization of subsurface enamel lesions. It is likely, though, that some of the ACP/ACFP phases that are produced intra-orally

may be stabilized by the phosphoproteins in saliva, pellicle, and plaque that are not at full stabilization capacity. This may explain the bioavailability of these technologies in the presence of saliva and the positive in situ model results. However, long-term randomized controlled caries clinical trials of the destabilized ACP/ACFP technologies need to be conducted to demonstrate efficacy in preventing coronal caries and safety by the lack of dental calculus promotion with long-term use.<sup>(55)</sup>

## Ion Exchange Resins (IERS)

IERS have been appreciably acknowledged by researchers, due to their all-around properties as Drug delivery vehicles. Studies in the past have revealed that IERS are equally suitable for Drug delivery technologies, such as controlled release, transdermal, nasal, topical, and taste masking. Ion exchange resin provides a controlled release system, which supplies calcium, fluoride, phosphate, and zinc ions, to promote remineralization. Torrado et al evaluated a dentifrice containing a mixture of ion exchange resins and concluded that inclusion of calcium phosphate ion exchange resins helps promote remineralization.

In resin infiltration technique, low viscosity tri-ethylene glycol dimethacrylate resin with a sufficiently high (>200cm/s) penetration coefficient is applied on the white spot lesion after acid etching with 15% hydrochloric acid gel for 2 minutes, which halts the progression of the lesion.<sup>(56)</sup>

## Ozone

Ozonated water, when given in conjunction with CPP-ACP, has shown a slight improvement in amount of increase in mineral content of artificially demineralized enamel, however, the results so far have been insignificant, and this requires further research, before its utility in the remineralization process can be definitively established.<sup>(57)</sup>

## Silver Nanoparticles (Ag-Nano)

Ag-Nano treatment promoted remineralization of deciduous tooth enamel with initial caries-like lesion and bactericidal activity.

While the remineralization was less than that shown by CPP-containing agents, it showed 100% reduction in cariogenic bacteria.<sup>(58)</sup>

## Limitation

Black discoloration of teeth, over time, after application.

## Calcareo Fluorica

Calcareo Fluorica (calc-f) or fluoride of lime ( $\text{CaF}_2$ ) has been used for the treatment of various dental problems as it contains mineral salts that play role in the mineralization of teeth and bone.

Teeth treated with Calc-f tablets, on artificial carious lesions, showed increased surface hardness, when compared to teeth not treated with this medicine.<sup>(59)</sup>

## Self-Assembling Peptides

Recent developments in tissue engineering, material sciences and stem cell research offer considerable potential to dental therapies. Peptide treatment for early caries lesion is the area of current research. Peptide treatment significantly increases net mineral gain due to a combined effect of increased mineral gain and inhibition of mineral loss. Rationally designed  $\beta$ -sheet-forming peptides P114 that self-assemble themselves to form three-dimensional scaffolds under defined environmental conditions have been shown to nucleate hydroxyl apatite de novo and to have potential applications in mineralized tissue regeneration, mimicking the action of enamel matrix proteins during tooth development. Results suggest that a single application of P114 can be beneficial in the treatment of early caries lesions and that self-assembling peptides are candidate materials for mineralized tissue regeneration and repair.

Anionic P114 is a rationally-designed self-assembling peptide. Self-assembling peptides undergo well-characterized hierarchical self-assembly as three-dimensional fibrillar scaffolds in response to specific environmental triggers, offering a new generation of well-defined biopolymers with a range of potential applications. At certain peptide concentrations P114 switches from a low viscosity isotropic liquid to an elastomeric nematic gel ( $\text{pH} < 7.4$ ) then the anionic groups of the P114 side chains would attract  $\text{Ca}^{++}$  ions, inducing de novo precipitation of hydroxyl apatite inducing mineral deposition in situ.

P114 is safe, non-invasive and acceptable to patients. The treatment differs from other 'filling without Drilling'. The use of a biomimetic peptide such as P114 has the additional advantage of effecting 'natural' repair by regenerating the mineral itself. P114 is a well-tolerated treatment, and currently designed to test 'next generation' peptides to accelerate the repair process, thus making 'filling without Drilling' a reality.

In a recent study by Schlee et al. also proved that when P114 is applied to the tooth the peptide diffuses into the subsurface microproes and forms a 3D scaffold which is made up of small fibers these

scaffold mimes proteins found in teeth development and supports hydroxyl apatite crystallization around it to regenerate tooth enamel over a period of three months, another invitro study which evaluated the efficacy of the newly introduced self-assembling peptide P114 (Curodont™) for regenerating demineralized tooth tissue on smooth surface also showed significant results based on test and control group after 8 and 12 weeks.<sup>(60)</sup>

## CONCLUSION

Remineralizing agents provide a potential avenue for the management of tooth demineralization, especially that caused by dental caries. This can lead to a paradigm shift in the management of these diseases; from limiting the damage caused, by excavation and restoration; to, one day, potentially reversing the hard tissue destruction, followed by minimal restorative management.

Since the demineralization of enamel had been identified as a reversible process, the search has been ongoing for an ideal remineralizing agent, which could not only mitigate the damage caused by dental caries, but possibly reverse it.

Several synthetic and naturally-derived materials have been tried for this purpose, and many of these have shown a lot of promise as remineralizing agents. Perhaps, using multiple such agents in conjunction with each other may prove more beneficial in obtaining remineralization.

Fluorides were the first such agents, used for the remineralization of enamel. While fluoride ions play an integral part in the demineralization-remineralization process, helping in the long-term repair of subsurface demineralization; they take years to take effect in vivo, and are of limited use in cavitated lesions.

Among new materials, casein phosphopeptide-containing materials seem to show the greatest promise in terms of remineralization of cavitated and noncavitated lesions.

Although several of these remineralizing agents have shown quite a bit of promise, with their current level of effectiveness, they still remain just an adjuvant to conventional, more invasive methods for the management of dental caries.

However, with the leaps and bounds being made in the world of research in this field, the day may not be very far, when we will finally have discovered an ideal remineralizing agent.

An ideal remineralizing agent would completely change our approach towards dental caries management; thus, making it not only simpler for the dental practitioner, but also more easily acceptable by the patients.



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# Antimicrobial Photodynamic Therapy Colors of Light - Review Article

## Abstract

Photodynamic therapy (PDT), also known as photo radiation therapy or phototherapy involves the use of a photoactive dye (photosensitizer) that is activated by exposure to light of a specific wavelength in the presence of oxygen. The transfer of energy from the activated photosensitizer to available oxygen results in the formation of toxic oxygen species, such as singlet oxygen and free radicals. The reactive chemical species can damage proteins, lipids, nucleic acids, and other cellular components. Applications of PDT in dentistry are growing rapidly in the treatment of oral cancer, bacterial and fungal infection therapies, and the photodynamic diagnosis (PDD) of the malignant transformation of oral lesions. PDT also represents a novel therapeutic approach in the management of oral biofilms. Disruption of plaque structure has important consequences for homeostasis within the biofilm. Studies are now leading toward selective photosensitizers, since killing the entire flora leaves patients open to opportunistic infections. The oral cavity is especially suitable for photodynamic antimicrobial chemotherapy (PACT) because it is relatively accessible to illumination.

**Keywords:** Antimicrobial, Photosensitizers, Photodynamic Therapy, Periodontitis, Peri-Implantitis

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## INTRODUCTION

Photodynamic therapy (PDT) involves the use of low power lasers with appropriate wavelength to kill micro-organisms treated with a photosensitizer Drug. PDT could be a useful adjunct to mechanical as well as antibiotics in eliminating perio pathogenic bacteria.<sup>1</sup> Most high-level lasers exhibit bactericidal effects by thermal denaturation or direct ablation or destruction of bacterial cells and have been applied in nonsurgical or surgical periodontal and peri-implant therapies.<sup>2</sup>

Besides damaging the bacterial cells, the use of high level lasers results in irreversible thermal damage to the surrounding periodontal tissues, excessive ablation or thermal coagulation, carbonization or necrosis of the root, the gingival connective tissue, the bone and the pulp tissues, depending on the type of laser employed.<sup>2</sup>

Since the beginning of the 1990s, the application of light energy has been considered as a novel treatment approach in periodontics. In general, the use of lasers has been proposed as a new technical modality in the treatment of periodontal diseases. Dental lasers have been used as an effective means of decontamination of periodontal pockets over a period of 20 years.<sup>3</sup>

This method was first used in 1990 for the treatment of cancer. It was determined that its use stimulates autophagy (a method of cell catabolism, which leads to the destruction of abnormal cells) in resistant cancer cells or precancerous cells. In this method, wavelengths between 650- 900 nm which are within the visible red light and near infrared, and have great influence on biological tissue are used.<sup>4,5</sup>

## HISTORY

### Phototherapy (Origin of PDT)

Phototherapy began in Ancient Egypt, Greece, and India but disappeared for many centuries and was rediscovered by western civilization at the beginning of the twentieth century.<sup>6</sup>

Oscar Raab 1990 realized that the interaction between acridine (a dye) and visible light in the presence of oxygen killed paramecia.<sup>7</sup>

Tappeiner and Jodlebauer 1904 coined term “photodynamic” reaction for a biologic system that required oxygen, a light-absorbing sensitizer, and light.<sup>7</sup>

Dobson & Wilson 1992 showed that low-level helium–neon laser irradiation with toluidine blue O or methylene blue was effective for killing *P. gingivalis*, *F. nucleatum*, *A. actinomycetemcomitans* and *S. sanguinis*.<sup>8</sup>

Wilson et al. 1993 investigated bactericidal effect on microorganism in cell suspension (P.g., F.n. and A.a.) and shows that low doses of laser light are effective at killing bacteria.<sup>9</sup>

Atieh 2010 after a systematic review and meta-analysis concluded that the combined use of PDT with conventional SRP may provide additional improvements in CAL, PD and other clinical measures in the treatment of chronic periodontitis.<sup>10</sup>

Betsy et al. 2014 evaluated the potential of antimicrobial photodynamic therapy (aPDT) as an adjunct to scaling and root planing (SRP) in the treatment of chronic periodontitis. The result of this study showed that aPDT acts as a beneficial adjunct to SRP in nonsurgical treatment and management of chronic periodontitis in short-term.<sup>11</sup>

Carvalho VF et al. 2015 conducted randomized controlled clinical trial was designed to evaluate the efficacy of the photodynamic therapy (PDT) in the treatment of residual pockets of chronic periodontitis patients.<sup>12</sup>

Raut et al., 2018 conducted randomized control and showed significant reduction in PD, CAL and BOP in the test group as compared to control group after 6 months. Anaerobic culture of plaque samples of test group also revealed a significant reduction of microorganisms in comparison with control group.<sup>13</sup>

Sukumar K et al. 2020 conducted a study to evaluate the clinical and antimicrobial efficacy of multiple application of PDT as an adjunct to scaling and root planing in management of moderate periodontal pockets. Outcomes suggested that adjunctive multiple applications of PDT to SRP had showed significant reduction in periodontal pathogens over SRP alone.

## COMPONENTS OF PDT

Photodynamic therapy basically involves three nontoxic elements: visible innocuous light, innocuous photosensitizer and oxygen.<sup>15</sup>

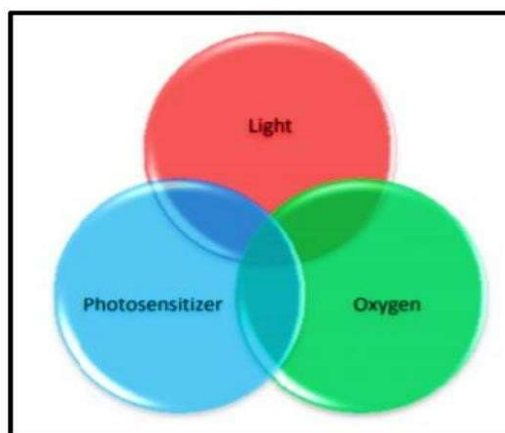


Figure 1: Components of PDT<sup>15</sup>

### LIGHT

In PDT, a light source is necessary to activate the photosensitizer.<sup>16</sup> In the past, a variety of light sources such as argon lasers, potassium titanyl phosphate (KTP) and Nd:YAG were used for photosensitizer activation. At present, diode lasers which have a number of advantages like cost effectiveness, portability and user friendliness are used predominantly.

**Argon/dye lasers:** It is most widely used systems, and standard source for clinical PDT. The argon/dye laser systems are capable of delivering from 1 to 7W of continuous wave (CW) 630nm light energy. High-power argon/dye laser systems were used in earlier trials for the application of PDT to malignant disease.<sup>18</sup>

**Metal vapour lasers:** Other types of laser systems that were utilized were generally variations of the argon/dye laser system. The gold vapour laser generated a wavelength of 627.8nm with sufficient power for clinical or experimental PDT studies, but with a pulsed output, at a repetition frequency of 5-15kHz.<sup>1</sup>

**KTP: YAG/dye lasers:** KTP:YAG/dye laser are combination system by Laser scope. The Laser scope 800 series KTP:YAG features operation at 1064nm and at the frequency-doubled phase allowing utilization of a quasi-CW (25kHz) laser beam at 532nm. The 532nm wavelength was delivered via fiberoptic connections to a dye laser head, which was capable of pumping a specially designed dye laser system producing a beam at 630nm (600 series dye module).<sup>20</sup>

**Diode lasers:** Diode laser system composed the attribute of the new generation of laser systems in medical field and was a miraculous advance in technology for PDT. Diode lasers is a solid state of semiconductor made of aluminum, gallium, arsenide and occasionally indium, which produces laser wavelength, ranging approximately 810 nm to 980 nm. The advantages of this system was it is compact and utilizing 120V power and an air-cooling system.<sup>18</sup>

**Non-laser light sources:** In light emitting diodes (LEDs) light is produced by a solid-state action called electroluminescence. LED is designed as the semiconductor layers on a substrate emit light all the way around the layered structure, and the LED structure is placed in a small reflective cup so that the light from the active layer will be reflected toward the expected exit direction.<sup>21</sup>

## PHOTOSENSITIZER

Photosensitizing agents / photosensitizers are dyes composed of molecules and is capable of absorbing light energy and using it to promote chemical reactions in cells and tissues when exposed to light.

### The following are the desirable properties of the photosensitizer:

- High binding affinity for the given microorganism,
- Broad spectrum of action,
- Low binding affinity for mammalian cells to avoid the risk of photo destruction of host tissues,
- Low propensity for selecting resistant bacterial strains,
- Minimal risk of promoting mutagenic processes,
- Low chemical toxicity,
- Have an excellent photochemical reactivity,
- Only be toxic in the presence of light,
- Preferable retention by target tissue,
- Rapidly excreted from the body,
- Non -toxic and activated upon illumination.

### The basic structure of photosensitizers.

Tricyclic dyes with different meso-atoms: Acridine orange, Proflavine, Riboflavin, Methylene blue, Fluorescein, Erythrosine

### Tetrapyrroles:

Porphyrins and derivatives, Chlorophyll, Phylloerythrin, Phthalocyanines

**Furocoumarins:** Psoralen and its methoxy derivatives, Xanthotoxin ,Bergaptene<sup>16</sup>

## Based on generations

### First-generation photosensitizers:

Photofrin derivatives, Hematoporphyrin derivatives

### Second generation photosensitizers:

5-Aminolevulinic Acid, Benzoporphyrin Derivative, Lutetium ,Texaphyrin ,Temoporfin , Tinethyletiopurpurin, Telaporfin sodium<sup>17</sup>

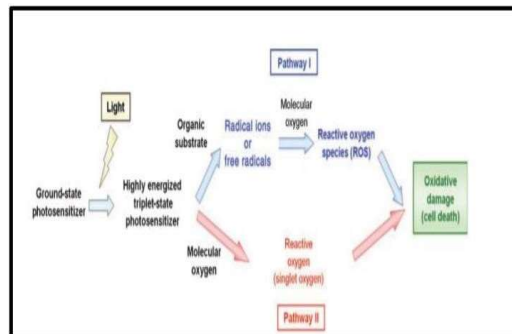
## OXYGEN

After one week following surgery, the periodontal Dressing and sutures were removed and the area was O<sub>2</sub> is recognized to be the main mediator of photo inactivation of cells sensitized with most clinically used photosensitizers. In 2002, the production of O<sub>2</sub> during PDT was detected for the first time by direct measurements in vivo. This highly reactive form of O<sub>2</sub> reacts with many biological molecules and causes damage that may be lethal for cells. The type II mechanism (O<sub>2</sub> mechanism) is generally considered to be dominant in PDT. The presence of sufficient O<sub>2</sub> is required for O<sub>2</sub> production in tissues.<sup>23</sup>

Reactive oxygen species (ROS) encompasses other reactive species which are not true radicals but are withal efficient to radical formation in the intra- and extracellular environments.

### Mechanism of action

After irradiation with light of a specific wavelength (lasers), the photosensitizer at ground state is activated to a highly energized triplet state. The prolonged lifespan of the triplet state that enables the interaction of the excited photosensitizer with the surrounding. molecules, and it is generally acquire the generation of cytotoxic species produced during photodynamic therapy occurs in this state.<sup>25</sup>



**Figure 2:** Mechanism of photodynamic antimicrobial reactions at the molecular level<sup>28</sup>



## **The triplet-state photosensitizer follows two different pathways (type I and II) to react with biomolecules.**

Type I reactions involve hydrogen electron-transfer reactions between the excited state of the photosensitizer and an organic substrate molecule of the cells, which produces free radicals and radical ions. These free-radical species are highly reactive and interact with endogenous molecular oxygen to produce highly reactive oxygen species such as superoxide, hydroxyl radicals and hydrogen peroxide, which are harmful to cell membrane integrity and result in irreparable biological damage.

In the type II reaction, the triplet – state photosensitizer reacts with oxygen to produce a highly reactive state of oxygen, known as singlet oxygen with a large number of organic substrates due to its high chemical reactivity, inducing oxidative damage and ultimately lethal effects upon the bacterial cell by damaging the cell membrane and cell wall. Singlet oxygen has a short

–term in biological system that causes limited shift of singlet oxygen from its site of formation leading to a localized response and making it ideal for application at localized sites without affecting distant molecules, cells or organs.

Microorganisms including viruses, bacteria, protozoa and fungi are killed by singlet oxygen. Because of the short life time singlet oxygen have short migration from its site of formation and the sites of initial cell destruction by photodynamic therapy are closely related to the localization of the photosensitizer. Thus, the reaction takes place within a limited space resulting in a localized response and make it ideal for application at localized sites without affecting distant molecules, cells or organs.

## **Mechanisms of Tissue Damage**

**Reactive oxygen species may cause damage to various cellular and extracellular tissues by causing:**

**Protein damage :-** Protein folding or unfolding, Protein fragmentation and polymerization reactions, Protease degradation of the modified protein, Formation of protein radicals, Formation of protein-bound ROS.

**Lipid peroxidation:-** It is metabolic process in which reactive oxygen species result in the oxidative deterioration of lipids. This may significantly affect cell membrane structure and function. Most effective at activating this process is the hydroxyl radical and also peroxynitrite anion.

**DNA damage :-** Mechanisms of DNA damage by peroxynitrite and hydroxyl radicals include: Strand breaks, Base pair mutations (purine and pyrimidine bases), Conversion of guanine to 8- hydroxy guanine which is measured as a marker of DNA damage as the nucleoside 8- hydroxy deoxyguanosine, Deletions, Insertions, Nicking and Sequence amplification.

## **ANTIMICROBIAL PHOTODYNAMIC THERAPY IN PERIODONTITIS**

Biofilm in oral cavity causes two of the most prevalent diseases, dental caries and periodontal diseases. An effective approach of periodontal therapy is to change the local environment to abolish the growth of periodontal pathogens. PDT is even efficacious against antibiotic resistant bacteria. Photodynamic antimicrobial chemotherapy could be an ideal complement to conventional scaling and root planing. It implement a rapid and painless procedure that allows the clinician to kill bacteria, suppress virulence factors left behind after scaling and root planing. This procedure is used during initial and maintenance therapy for the treatment of periodontitis.

During inflammation there is venous stagnation and diminish oxygen consumption by tissues. This reduction in oxygen level and change in pH may elevate the growth of anaerobic species. In such condition, PDT may improve tissue blood flow in the microcirculatory system and decrease venous congestion in gingival tissues. Moreover, PDT may improve oxygenation of gingival tissues by 21-47 per cent.<sup>30</sup>

De Oliveira et al. 2009 conducted randomized clinical result showed that PDT and SRP demonstrated similar reductions in the tumor necrosis factor- $\alpha$  and RANKL levels at 30 days.<sup>31</sup> Chondros et al. 2009 conducted a clinical trial in patients with chronic periodontitis and concluded no significant differences in terms of PPD, CAL, and the amount of plaque were seen, but the BOP was significantly reduced in the group of treatment by SRP and PDT.<sup>32</sup> Monzavi A et al. 2016 conducted a study to test the efficacy of adjunctive PDT with ICG compared with scaling and root planing (SRP) alone in chronic periodontitis treatment, found that PDT as an adjunctive approach yielded complete resolution of inflammation and significant reduction in periodontal pocket depth.<sup>33</sup>

## **PDT IN PERI - IMPLANTITIS**

Peri-implant disease may be defined as a pathologic condition including inflammatory and other kinds of lesions affecting the soft and/or hard tissues surrounding a dental implant. Peri- implantitis is characterized by a severe inflammatory process involving both mucosa and bone around the

implant. This represents the most diffuse cause of long-term implant failure.

Bone destruction, peri-implant pockets, bleeding on probing, the possible presence of exudate, and loss of supporting tissue are involved in peri-implantitis.<sup>34</sup>

Haas et al. 2000 investigated the clinical effects of treatment of antimicrobial photodynamic therapy (toluidine blue O + diode laser) in combination with guided bone regeneration using autogenous bone grafts showed improvements in the bone defect after a mean observation period of 9.5 months.<sup>35</sup> Dortbudak et al. 2001 reported that treatment of peri-implantitis with the application of the photosensitizer toluidine blue alone resulted in significant reductions of *Prevotella intermedia* and *Aggregatibacter actinomycetemcomitans* compared to baseline values.<sup>36</sup>

## PDT IN ENDODONTICS

The goal of endodontic treatment is to eliminate pathogenic bacteria which are the major problems in therapy treatment of infected root canals and periapical healing. Because of the complex structure of root canal system, the complete elimination of microorganisms still presents a major challenge and enables resistance to irrigation and mechanical cleaning of root canals.<sup>37</sup>

Bonsor et al. compared the antimicrobial efficacy of PDT to 2.5% NaOCl in the initial root canal treatment and concluded that both treatment modalities resulted in highly significant bacterial load reduction compared with baseline measurements. PDT application yielded 91.3% reduction of bacteria load, whereas 2.5% NaOCl led to 80.9% reduction.<sup>38</sup>

Fimpe et al. investigated the photodynamic effects of methylene blue on *Actinomyces israelii*, *F. nucleatum*, *P. gingivalis* and *P. intermedia* in experimentally infected root canals of extracted teeth and found up to 80 % reduction of colony-forming unit counts.<sup>39</sup> Xu et al. in an in vitro study, assessed the synergistic effect of methylene blue and red light on human gingival fibroblasts and osteoblasts. They sensitized both cell types with 50 µg/mLMB followed by exposure to red light at 665 nm for 5 min with an irradiance of 10, 20, and 40 mW/cm<sup>2</sup>. The results showed that light at 20 and 40 mW/cm<sup>2</sup> with MB had modest effects at 24 h on osteoblasts, whereas sodium hypochlorite completely eliminated cells.<sup>40</sup>

## CONCLUSION

Antimicrobial photodynamic therapy seems to be a unique and interesting therapeutic approach towards the treatment of periodontitis and peri-implantitis. The results of a number of in vitro studies clearly demonstrate the effective and efficient bactericidal effect of antimicrobial photodynamic therapy.

However, sufficient clinical and microbiological data that support the superior effects of the adjunctive use of photodynamic therapy have not been demonstrated in vivo or clinically in either periodontal or peri-implant therapies. The discrepancy in the results obtained from previous clinical studies may be a result of the differences in treatment conditions and parameters. Therefore, further in vivo and clinical studies are necessary to determine the optimal conditions of this novel therapy. Also, further randomized long-term clinical studies and meta-analyses are necessary to demonstrate the beneficial effects of antimicrobial photochemical therapy and their real advantages in comparison with conventional methods. Antimicrobial photodynamic therapy may hold promise as a substitute for currently available chemotherapy in the treatment of periodontal and peri-implant diseases.

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# Clinical Guidelines and Management of Ankyloglossia with 1-Year Follow Up: Report of 2 Cases

## Abstract

Over the past decade, there has been an exponential increase in the number of children diagnosed and treated with ankyloglossia, a condition where the lingual frenulum attaches near the tip of the tongue (anterior tongue-tie) or at the root of the tongue (posterior tongue-tie) and may be short, tight and thick. There have been immense controversies regarding clinical significance of this condition. Recent studies suggest that speech, solid feeding, and sleep difficulties may be linked to restricted tongue function. This article presents the latest evidence on the diagnosis and management of tongue-tie.

**Key Words:** Tongue-Tie, Tongue-Tie Division, Ankyloglossia, Frenulum, Frenectomy, Temporomandibular Joint

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## INTRODUCTION

The tongue is a highly mobile organ made up of longitudinal, horizontal, vertical, and transverse intrinsic muscle bundles. The extrinsic muscles are the fan-like genioglossus which is inserted into the medial part of the tongue and the styloglossus and hyoglossus into the lateral portions [1]. The lingual frenulum is a dynamic structure, formed by a midline fold in a layer of fascia that inserts around the inner arc of the mandible, forming a diaphragm-like structure across the floor of mouth. This fascia is located immediately beneath the oral mucosa, fusing centrally with the connective tissue on the tongue's ventral surface. The sublingual glands and submandibular ducts are enveloped by the fascial layer and anterior genioglossus fibers are suspended beneath it. Lingual nerve branches are located superficially on the ventral surface of the tongue, immediately deep to the fascia. The lingual frenulum is not a discrete midline structure. It is formed by dynamic elevation of a midline fold in the floor of mouth fascia [2].

Tongue-tie, or ankyloglossia, is a condition in which the lingual frenulum may either be attached too close

to the tip of the tongue [3] and too far forward towards the inferior alveolar ridge, or it may be attached in a more posterior position on the tongue and the floor of the mouth, but be so short as to impede movement. When the tongue is lifted, the tip of the tongue may form a heart shape [4]. In large cross-sectional studies of the condition in newborns, the prevalence has ranged from 4% to 10% [7]. Boys are affected more than girls, with the sex ratio being about 2:1. There is no clear ethnic predilection.

[8]. Ankyloglossia is also found associated in cases with some rare syndromes such as X-linked cleft palate syndrome [11], Kindler syndrome [12], van der Woude syndrome [13] and Opitz syndrome [14].

TABLE 1: Kotlow's classification.

Type	Movement of the tongue
Clinically acceptable, normal range of free tongue movement	Greater than 16 mm
Class I: Mild ankyloglossia	12 to 16 mm
Class II: Moderate ankyloglossia	8 to 11 mm
Class III: Severe ankyloglossia	3 to 7 mm
Class IV: Complete ankyloglossia	less than 3 mm

## Classification Of Tongue-Tie



## TONGUE-TIE IMPACT IN SPEECH AND ORAL DEVELOPMENT

One of the first symptoms of tongue-tie in adults is poor oral health. When the tongue has limited mobility, it becomes difficult to remove food and debris from the teeth after eating. Tongue-tie can also cause a gap between the bottom front teeth. Adults with tongue-tie may experience frequent cavities, gum inflammation, gum disease, bad breath, and other oral health problems.

Another major symptom of tongue tie in adults is temporomandibular joint (TMJ) dysfunction. When the tongue is unable to move in a full range of motion, the mouth naturally adapts to cope. One of the ways the mouth copes is by swallowing incorrectly. Normally, the tongue will push food around in the mouth to the back to swallow but when a tongue-tie is present, this cannot happen. Instead, people with tongue-tie have food move around in their mouth when they eat. This can lead to incorrect swallowing. With consistent incorrect swallowing, teeth can come misaligned and the jaw will develop incorrectly. The misaligned teeth and jaw development issues can cause an imbalance in the jaw joints which results in TMJ disorders. TMJ disorders can lead to serious symptoms like frequent headaches and migraines, jaw, neck, and back pain, clicking and popping jaw, and much more [16].

Localization of the frenulum insertion on the gingiva seemed to be of importance for gingival sequelae because insertion of the lingual frenulum in the area of the papilla had the highest association with gingival recession [15].

An abnormally low position of the tongue may cause mandibular prognathism with maxillary hypodevelopment due to an exaggerated anterior thrust leading to Class III malocclusion [22]. Whereas, somewhat higher position of tongue in the mouth may lead to tongue thrust causing posterior or anterior open bite. Moreover, excessive forces while retrusion of tongue by patient may cause blanching of tissues, gingival recession, and midline diastema in lower central incisors.

Speech problems can occur when there is limited mobility of the tongue due to ankyloglossia. The difficulties in articulation are evident for consonants and sounds like “s, z, t, d, l, j, zh, ch, th, dg” [17] and it is especially difficult to roll an “r”. These articulation problems are, however, less common than tongue-tie itself, and children and adults characteristically use various compensatory techniques of mouth opening and tongue movements [18]. Tongue-tie restricts the physiologic movements of the tongue and results in various functional, behavioral and speech abnormalities along with the development of frontal and lateral

lisps. Tongue-tie may cause problems which may exist since birth such as breastfeeding and swallowing to problems which may persist through lifetime such as dysarthria, mechanical problems, and social issues [19].

## CASE REPORTS

Case Number 1. A 17-year-old female patient reported to the Department of Periodontics in Mithila Minority Dental College, Darbhanga with chief complain of bleeding gums and dull pain. Oral examination of the patient revealed swollen gums and calculus deposits with ankyloglossia with thick, short frenulum, restricted tongue protrusion, and lifting of the tip of the tongue.



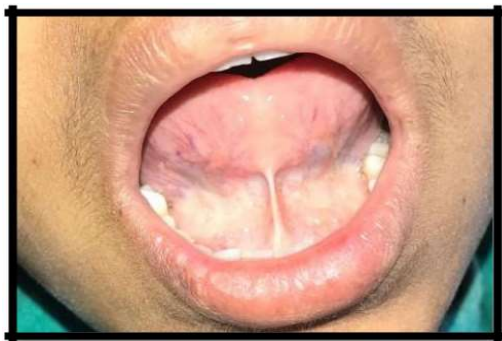
Figure:1 (Pre Operative)



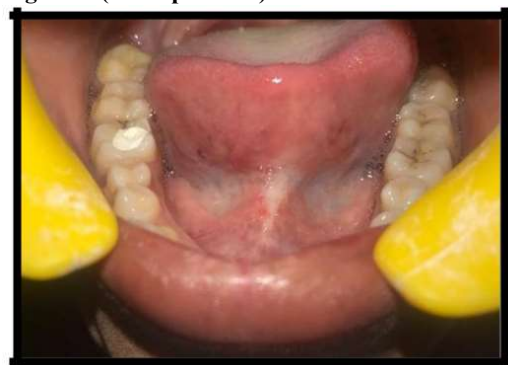
Figure:2 (Post Operative)

Case Number 2. An 18-year-old male patient reported to the Department of Periodontics in Mithila Minority Dental College, Darbhanga with chief complain of continuous dull pain and bad breath from mouth. Oral examination of patient revealed calculus deposits with stain. Also, ankyloglossia with restricted tongue movements were also observed.





**Figure:1 (Pre Operative)**



**Figure:2 (Post Operative)**

## CLINICAL MANAGEMENT

In first cases, frenum attachment was revised by frenectomy. A topical anesthetic was applied to the underside of the tongue following which block anesthesia was given. After achieving objective symptoms, a suture was passed at the middle of the tongue to control its movements, and two hemostat was used to clamp the frenum: one at the under surface of the tongue and another at the floor of the mouth avoiding salivary gland duct. Incision was placed above and below the hemostats to release the complete frenum by 15 No. Blade. On achieving homeostasis, the area was sutured with 4-0 Nylon Suture. The patients were discharged with postoperative instructions.

In second case, a topical anesthetic was applied to the underside of the tongue following which block anesthesia was given. Frenum was removed by using diode lasers. Nylon 4-0 Sutures was placed. After achieving homeostasis, patient was discharged with postoperative instructions.

In both cases, post-operative analgesics and antibiotics were prescribed. After 10 days, sutures were removed.

## RESULTS

Preoperative and postoperative scores were recorded. After 1-year follow up, significant improvement in symptoms of ankyloglossia was

observed. Free tongue movement increased from 9, and 8 mm to 14, and 15-mm. Speech also significantly improved.

## CONCLUSION

Diode provides an alternative technique with marked clinical improvement and high degree of patient acceptance within the limits of this study. Because of good coagulation, patients' surgical period with high-risk infections was reduced. Exceptionally precise tissue ablation at low power settings diode lasers is neither absorbed too much nor too little in water and hemoglobin, enabling precise char-free soft tissue ablation and hemostasis. The small portable size of the unit is of beneficial effect for the dentists. It is recommended that future studies can be carried out for evaluation of malignant transformation rate and reoccurrences with large sample size.

## DISCUSSION

Anatomical definition of ankyloglossia consists of descriptions as well as absolute measurements. Descriptions include the attachment of the frenulum to the tongue, the attachment of the frenulum to the inferior alveolar ridge, the elasticity of the lingual frenulum, and the appearance of the tongue when lifted. Absolute measurements include the length of the lingual frenulum when the tongue is lifted as well as the free tongue length [15].

Ankyloglossia can be divided into partial or complete ankyloglossia. Partial ankyloglossia is the presence of a sublingual frenulum which changes the appearance and/or function of the infant's tongue because of its decreased length, lack of elasticity or attachment too distal beneath the tongue or too close to or onto the gingival ridge. Complete ankyloglossia is a condition in which there is extensive fusion of the tongue to the floor of the mouth which is extremely rare [16].

Appearance of the tongue could be abnormal in some individuals. Improper chewing and swallowing of food could increase the gastric distress and bloating, and snoring and bed wetting at sleep are common among tongue tied children. Malocclusion like open bite due to thrust created by being tongue tied, spreading of lower incisors with periodontitis, and tooth mobility due to long-term tongue thrust are associated problems. It also affects self-esteem because it has been noted clinically that occasionally an older child or adult will be self-conscious or embarrassed about their tongue tie.

There is a wide difference of opinion regarding its clinical significance and optimal management. In many patients, ankyloglossia is asymptomatic, and

the condition may resolve spontaneously, or affected children may learn to compensate adequately for their decreased lingual mobility. Patients should be educated about the possible long-term effects of tongue tie, so that they may make an informed choice regarding possible therapy. The tip of the tongue should be able to protrude outside the mouth without clefting and should be able to sweep the upper and lower lips easily, without straining. When the tongue is retracted, it should not blanch the tissue lingual to the anterior teeth and should not put excessive forces on the mandibular anterior teeth. The lingual frenum should not create a diastema between the mandibular central incisor.

Patients should be asked to pronounce certain words which start with "I," "th," "s," "d," and "t" to check the accuracy of the word pronunciations. If a defective speech is observed, after postoperative wound healing, referral to a speech therapist is mandatory for speech modification. Postoperative tongue muscle exercises like licking the upper lip, touching hard palate with the tip of tongue, and side-to-side movements should be explained to the patient for enhanced tongue movements.

## CONCLUSIONS

Recent studies suggest that speech and feeding may be linked to restricted tongue function. It is important that accurate information and guidance is given to patients and that accurate information and guidance is given to parents with regard to the indications and potential benefits of tongue tie management.

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# Compound Odontoma Associated with Maxillary Anterior Crowding: Case Report

## Abstract

Odontomas are benign tumors containing all the various component tissues of the teeth. It is the most common odontogenic tumor, representing 67% of all such tumors. Most of these lesions are asymptomatic and are often detected incidentally on routine radiographs. Morphologically, odontomas can be classified as complex, which present as irregular masses containing different types of dental tissues, or as compound, which exhibit superficial anatomic similarity to even rudimentary teeth; the latter are also known as denticles. Herein, we report a case of compound odontoma, located in the anterior maxilla of a 13-year-old male patient. The lesion had caused crowding of the maxillary permanent incisors, with mild dilaceration with respect to tooth 11, resulting from the presence of the lesion. The treatment of choice was surgical removal of the lesion, followed by histopathological examination to confirm the diagnosis.

**Keywords:** Compound odontoma, hamartoma, odontogenic tumor, impacted tooth

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## INTRODUCTION

The term odontoma (or “odontome”) was originally used by Paul Brocain 1867 to describe all odontogenic tumors.<sup>1</sup> He defined the term odontoma as “tumors formed by the overgrowth of transitory or complete dental tissues.” Odontomas are now considered hamartomatous odontogenic lesions as they comprise both epithelial and ectomesenchymal components, having morphologically normal cells with defective structural organization.<sup>2</sup>

Odontomas are included in the World Health Organization (WHO) classification of head and neck tumors as a group of lesions affecting the odontogenic epithelium, containing odontogenic ectomesenchyme, with or without hard tissue formation.<sup>3</sup>

The WHO classifies odontomas into compound and complex odontomas. Complex odontomas are less common than the compound variety, and the latter

occur more commonly in the maxilla, having a predilection for the incisor-canine region without a sex-based predilection.<sup>4</sup> Complex odontomas are more common in the mandibular posterior region and exhibit a female predilection.<sup>5</sup> However, rarely, lesions may exhibit features of both compound and complex odontomas. Compound odontomas may be associated with impacted permanent teeth, and surgical removal is the treatment of choice. The prognosis is favorable with few cases of relapse.<sup>6</sup> This study aimed to report a case of compound odontoma associated with crowding of the permanent anterior teeth. The treatment of choice was surgical removal of the lesion, followed by histopathological examination to confirm the diagnosis

## CASE REPORT

- A 13-year-old male patient visited the department of pediatric dentistry with a chief



complaint of irregularly placed upper front teeth. His medical history was non-contributory.

- ▶ The patient had no history of orofacial trauma. There was no family history of anterior crowding.
- ▶ On intraoral hard tissue examination, maxillary anterior crowding was observed, with an unusual spacing between teeth 11 and 12.



**Figure 1. Intraoral clinical findings – Frontal view**



**Figure 2. Intraoral clinical findings – Occlusal view**

- ▶ Palpation revealed no swelling or tenderness. An occlusal radiograph was obtained, which revealed the presence of multiple small radiopaque tooth-like structures distal to the root of 11, located at the middle-third level of the root, surrounded by a narrow radiolucent area. Additionally, mild dilaceration was observed with respect to 11, likely caused by the presence of the lesion.



**Figure 3. Occlusal radiograph showing multiple tooth-like structures, as well as mild dilaceration with respect to 11.**

- ▶ Based on the history and clinical examination, a provisional diagnosis of cemento-ossifying fibromas was made. The differential diagnoses included periapical cemental dysplasia and complex odontoma.
- ▶ These tooth-like structures were carefully excised under local anesthesia.



**Figure 4. Perioperative image – Incision**



**Figure 5. Perioperative image – Flap reflection**



**Figure 6. Perioperative image – Enucleation of the lesions**



**Figure 7. Perioperative image – Verification of no remaining lesions**



- After the enucleation of all lesions, the incised flap was sutured in position.



**Figure 8. Postoperative image after the suturing of the incised flap**

- The specimens were then sent for histopathological analyses, which confirmed the diagnosis of compound odontoma.



**Figure 9. Postoperative image of the enucleated lesions**



**Figure 10. Histopathological image revealing rudimentary tooth-like structures**

- Thus, correlating the clinical, radiographic, and microscopic findings, compound odontoma was diagnosed.

- The patient was kept on regular follow-up, and his postoperative course was uneventful. He was subsequently referred to the department of orthodontics for the correction of his crowding.

## DISCUSSION

Paul Broca defined the term “odontoma” as “tumors formed by the overgrowth of transitory or complete dental tissues.”<sup>7</sup> They are mixed tumors, consisting of both epithelial and mesenchymal cells that present a complete dental tissue differentiation.<sup>8</sup>

The etiology of odontomas remains unknown, local trauma, infection, family history and genetic mutation have been suggested as possible causes. In our case no syndromes were evident and no episode of previous trauma was reported by the patient and family.

Studies have shown that most odontomas occur on right side of the jaw, which was also observed in the present case.<sup>9</sup> The average age of occurrence is 20.3 years whereas our patient was much younger at 13-year-old.<sup>10</sup> Considerable controversy exists over this tumor’s sex distribution. While some studies consider odontomas to be more common in women than in men,<sup>11</sup> others consider them to be similarly distributed between both sexes.<sup>12</sup> Our patient was a boy.

Clinically most odontomas are asymptomatic. They seldom cause swelling, pain, suppuration, bony expansion, and displacement of teeth. Odontomas can measure anywhere from a few millimeters to several centimeters in their greatest dimension.<sup>13</sup>

In 1914, Gabell, James, and Payne grouped odontomas according to their developmental origin: epithelial, composite (epithelial and mesodermal), and mesodermal.<sup>14</sup>

In 1946, Thoma and Goldman classified them as follows:<sup>15</sup>

- Geminated composite odontomas: two or more typically well-developed teeth fused together.
- Compound composite odontomas: more or less rudimentary teeth.
- Complex composite odontomas: calcified structures bearing no great resemblance to the normal anatomical arrangement of dental tissues.
- Dilated odontomas: the crown or root part of a tooth shows a marked enlargement.
- Cystic odontomas: an odontoma that is normally encapsulated by fibrous connective tissue in a cyst or in the wall of a cyst.

According to the WHO, odontomas can be classified into three groups:<sup>16</sup>

1. Complex odontoma: when the calcified dental tissues are simply arranged in an irregular mass bearing no morphologic similarity to rudimentary teeth.

2. Compound odontoma: composed of all odontogenic tissues in an orderly pattern, resulting in many teeth-like structures, but without morphologically resembling normal teeth.
3. Ameloblastic fibro-odontoma: consists of varying amounts of calcified dental tissue and dental papilla-like tissue, the later components resembling an ameloblastic fibroma. The ameloblastic fibro-odontoma is considered an immature precursor of complex odontomas.

In the present case, the enucleated specimen was sent for histopathology to rule out ameloblastic fibro-odontomas and onto ameloblastomas since these bear a striking resemblance to common odontomas, especially on radiographic examination.

## CONCLUSION

We have presented a case of a compound odontoma associated with permanent anterior crowding and mild dilaceration. Our case highlights the importance of identifying and managing this condition prior to the orthodontic correction of its resultant malocclusion.

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# Management Of Ellis Class-III Fracture: A Case Series

## Abstract

Coronal fractures of permanent dentition are the most frequent type of dental injury. Fractured anterior teeth are usually treated with conventional post and core and crown techniques, after being treated endodontically. If the original tooth fragment is retained following fracture, the natural tooth structures can be reattached using adhesive protocols. The fiber-reinforced post makes the reattachment of the crown esthetically possible with minimal preparation and reduces the possibility of tooth fracture during function. This paper presents the therapeutic approach of reattachment of the crown fragment to the tooth at the cervical and middle third levels.

**Keywords:** Fiber-reinforced, Coronal fractures, minimal preparation, reattachment.

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## INTRODUCTION

Crown fractures are the most common consequence traumatic injuries that mainly occur in the anterior teeth, especially the maxillary incisors (because of its position in the arch), whereas the mandibular central incisors are less frequently involved. It is estimated that a quarter of the population suffers from a minimum of one dental traumatic injury related to coronal fractures of the anterior teeth before the age of 18 years, the most common of which are attributed to falls, high-impact sports, and motor vehicle accidents.<sup>1</sup>

Dental injuries usually affect only a single tooth; however, certain trauma types such as automobile accidents and sports injuries involve multiple tooth injuries. One of the options for managing coronal tooth fractures when the tooth fragment is available and there is no or minimal violation of the biological width is the reattachment of the dental fragment. Reattachment of fractured tooth fragments can provide good and long-lasting esthetics because the tooth's original anatomic form, color, and surface texture is maintained. It also restores function, provides a positive psychological response, and is a

relatively simple procedure. Patient cooperation and understanding of the limitations of the treatment is of utmost importance for good prognosis.<sup>2</sup>

## CASE REPORT - I

A 15-year-old male patient came to the Department of Conservative Dentistry and Endodontics, with the chief complaint of fractured upper front teeth. Patient gave the history of complicated crown fracture of the maxillary right central incisor during sports activities one day before and there was no history of unconsciousness at that time. The patient's medical history was non-contributory. The fractured tooth fragment was recovered by the patient at the site of the injury and brought to the department in a handkerchief. The fractured fragments were kept in normal saline during the entire period before reattachment in the department. Vitality – false response to heat and cold test. The percussion test showed a negative response. Clinical and intraoral examination revealed that the crown of the right maxillary central incisor was split into two parts and

a fracture that extended horizontally in the middle portion [Figure 1]. The radiography image revealed the fracture in the middle third of upper right central incisor involving enamel, dentin, and extending into pulp [Figure 2]. Periapical radiographs revealed an intact periodontal ligament space, complete root formation, absence of any luxation injury, no root fracture in relation to tooth and bone fracture. Final diagnosis – Complicated crown fracture involving enamel, dentine and pulp (Ellis class III fracture) wrt 11. On examination, the treatment options were presented to the patient and guardian,

- including removal of fractured segment followed by restoration with post and core with crown
- reattachment of the tooth fragment
- extraction of the tooth and restoration of the site with fixed partial denture or an implant-retained crown.

After some deliberation about the advantages, disadvantages, prognosis, and cost of every treatment option, the patient opted to have the tooth fragment reattached. It is important to note that the reattachment option was presented only after confirming that the fragment was in good condition [Figure 3] and that it fits reasonably well on the fractured tooth.



**Fig 1 - Initial intraoral view**



**Fig 2 - Pre-operative radiograph**



**Fig 3 - Fractured fragment**



**Fig 4 - Obturation**



**Fig 5 - Post space preparation**



**Fig 6 - Fiber post cementation**





**Fig 7 - Reattachment of fragment**



**Fig 8 - Post-op**

## PROCEDURE

technique. Copious irrigation of the root canal was intermittently done with sodium hypochlorite and normal saline. An access cavity was modified with round bur w.r.t. 11. Working length was determined with 50 No. H file using digital radiographic method. After working length determination, biomechanical preparation was done till 70 No. H file using the Step-back Calcium hydroxide was placed as an intracanal medicament and the access cavity was temporized. The patient was recalled after 2 days. On the next visit, the teeth were asymptomatic. The Calcium hydroxide intracanal medicament was removed from the canals with the help of H- files and normal saline. The canal was Dried with absorbent point and master cone was selected. Then the tooth was obturated with Gutta percha points and AH plus sealer using the cold lateral compaction technique. (Figure - 4) On next visit, Post space made wrt 11 with passo reamers no. 6 leaving 5 mm gutta percha for apical seal and the post space was confirmed radiographically (Figure – 5). Glass fiber post was selected and fit was tried then canal surface was cleaned and the post surface by acid etched with 37% phosphoric acid then was rinsed and Dried.

The canal was refined with the color-coded Drills, if need be. The canal is conditioned with self-curing primer and adhesive. The self-adhesive resin cement (G-CEM Link Ace) was backfilled into the canal space with a syringe tip. Thin film of cement was then applied to the post and seated immediately. The post was then immediately light cured from three directions (Figure -6). A hole was prepared in the fractured tooth fragment and then etched with 37%

phosphoric acid, rinsed, blot Dried, and bonding agent was applied. Subsequently, resin cement (G-CEM Link Ace) was used to fill the hole in the tooth and the prepared grooves into the coronal fragment. The fragment was carefully seated on the remaining tooth and light cured (Figure – 7). During curing, firm and stable finger pressure was applied to the coronal fragment to closely oppose it to the tooth. After curing, excess composite was removed with a diamond finishing bur. Afterward, final polishing was done (Figure – 8).

Follow-up examinations were carried out at 4-month interval. The tooth remained normal in esthetics and function.

## CASE REPORT- II

An 18-year-old male patient came to the Department of Conservative Dentistry and Endodontics, with the chief complaint of broken upper front teeth 2 days back. Patient gave the history of fall on handpump. The patient's medical history was non-contributory. The fractured tooth fragment was mobile and partially attached to the gingiva (Figure 9). The fractured fragments were kept in normal saline during the entire period before reattachment in the department. Vitality – false response to heat and cold test. Clinical and intraoral examination revealed that the crown of the right maxillary central incisor has Ellis class III fracture, separated fragment was lost. Whereas Ellis class III fracture w.r.t. 22, where the fracture fragment was mobile and loosely attached to gingiva. The radiography image revealed the fracture in the middle third of upper right central incisor involving enamel, dentin, and extending into pulp. Periapical radiographs revealed an intact periodontal ligament space, complete root formation, absence of any luxation injury, no root fracture in relation to tooth and bone fracture. Final diagnosis – Complicated crown fracture involving enamel, dentine and pulp (Ellis class III fracture) w.r.t. 11&22. On examination, the treatment options were presented to the patient and guardian,

- including removal of fractured segment followed by restoration with post and core with crown (Figure 10).
- reattachment of the tooth fragment (Figure 13).
- extraction of the tooth and restoration of the site with fixed partial denture or an implant-retained crown.

Same treatment protocol was followed in case 2 as above case. Follow-up examinations were carried out at 4-month interval. The tooth remained normal in esthetics and function.

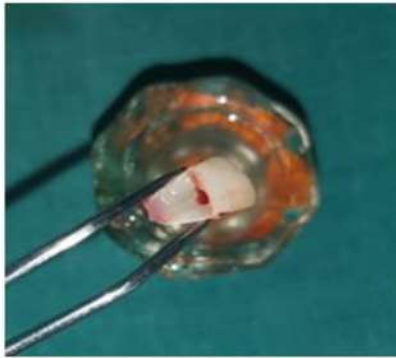




**Fig 9 - Initial Intraoral view**



**Fig 14 - Isolation**



**Fig 10 - Fractured fragment**



**Fig 15 - Post-op**

## DISCUSSION

With advancement in dental bonding technology, it is now possible to achieve excellent results with reattachment of the dislocated tooth fragments provided that the biologic factors, materials, and techniques are logically assessed and managed.<sup>3</sup> The use of natural tooth substance clearly eliminates the problems of differential wear of restorative material, unmatched shades, and difficulty of contour and texture reproduction associated with other techniques. Treatment plan can be made after evaluation of the periodontal, endodontic, coronal, and occlusal status. Other factors that might influence the choice of the technique include the need for endodontic therapy, extension of fracture, quality of fit between fragments, and the fracture pattern.<sup>4</sup>

Badami et al. have shown neither the bevel nor the material used could obtain the original fracture resistance of the tooth. Specimens prepared with chamfer and bonded had a fracture resistance of 40%–60%, with internal dentin groove, and over contour, it reached around 90%. The highest fracture resistance was obtained by chemically cured composite followed by light-cured resin and least by only dentin-bonding agent.

The pulp chamber was used for increasing the surface area for composite bonding and without the use of post.<sup>5</sup> Amir et al., in 1986, showed that the space provided by pulp chamber may be used as an inner reinforcement, thus avoiding any excess preparation of teeth. The direction of the fracture line is an important aspect in reresstorability, and it has a direct bearing on the prognosis of teeth. The fracture line was in a favorable direction in the cases



**Fig 11 - Matter cone**



**Fig 12 - Post space prepared**



**Fig 13 - Master cone**

undertaken.<sup>6</sup> Extensive damage of the tooth structure and missing fragment warrants reinforcement using fiber posts followed by crown. However, in our case reports, the fractured fragment was in sound condition and exhibited good fit over the radicular portion, so reattachment using fiber post was considered to be the best treatment option.<sup>7</sup> A bevel with flowable composite further improved the fracture strength. Conventionally, cast metal post and core were used for fracture reattachment. The newer variety of nonmetallic posts is made of either ceramic or fiber-reinforced materials such as carbon, quartz, or glass in an epoxy matrix. Tooth-colored fiber posts have

several advantages. They are more esthetic, bonded to tooth tissue, modulus of elasticity similar to that of dentin, and have less chances of fracture. Using glass fiber post with composite core and with recent advances in adhesive techniques and materials, one can create a monoblock, a multilayered structure with no inherent weak interlayer interfaces. The unique advantage of this system is that it reinforces the teeth structure through this concept. Therefore, the integrity of the final endodontic restorative continuum monoblock approaches that of the original healthy tooth itself.<sup>8</sup> An additional use of fiber posts is that it helps to distribute the stress to remaining radicular dentin. Luting the fiber posts with resin cement not only reinforces the tooth but also helps in achieving higher bond strengths of the fractured segments. It also minimizes the inclusion of air voids are easy to use and predictable. In apical areas light-cured luting resin cement may result in incomplete polymerization; hence, dual curing systems prove to be the most suitable material as they would allow polymerization even in those areas which would otherwise have left uncured due to the inability of light to reach in deeper areas.

Resin-based sealers are used to obturate the teeth planned for restoration with glass fiber posts as eugenol-based sealers may inhibit the set of resin cements.<sup>9</sup>

If the fracture line is supragingival, the procedure for reattachment will be straightforward. However, when the fracture site is subgingival or intraosseous, orthodontic extrusion with a post retained crown may be necessary.<sup>10</sup> Alternatively, surgical techniques such as electrosurgery, elevation of tissue flap, clinical crown lengthening surgery with removal of alveolar bone, and removal of gingival overgrowth for access to the fractured site are all viable methods for bonding fractured component. It has been suggested that whenever the fracture site invades the biologic width, surgery should be performed with minimum osteotomy and osteoplasty.<sup>11</sup>

However, in cases with minimal biologic width invasion, the organism is able to restore the biologic

width by itself provided assiduous plaque control is done. The prognosis of the reattached teeth would also depend on the fitness, contour, and surface finishing of the subgingival restoration.<sup>12</sup> If the invasion of biologic width is minimal, satisfactory esthetics and function can be achieved, without conventional flap surgery, however, requiring long-term follow-up. In some cases, crown lengthening is required to keep the restorations on definite margins. The success rates of reattached fragments have been seen to be up to 90% based on the parameters of periodontal, pulpal, and color harmony for a follow-up period of up to 24 months.<sup>13</sup>

## CONCLUSION

Several aspects govern the choice of a technique or the association of materials for fragment reattachment. Reattachment proved to be a successful technique in the present case reports for restoring aesthetics and function.

However, because few long-term studies have been reported in the literature, the patient should be informed of possible interim nature of the treatment. For traumatized patients with broken teeth, pain relief and immediate aesthetic restoration fragment reattachment fulfil the treatment goal.

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# Multidisciplinary Prosthodontic-Perio management for retention enhancement in elderly patient with complete denture by Frenectomy: A Case Report

## Abstract

Maxillary labial and buccal frenum are considered as normal anatomic structures in the oral cavity. The frenulum is defined as a thin membrane attached to the alveolar mucosa and periosteum which limits lip movement. However, they may exist intraorally as a thick broad fibrous attachment and/or become located near the crest of the residual ridge, thus interfering with proper denture border extension resulting in inferior denture stability, retention and overall patient satisfaction. This case report highlights the importance of clinical examination and treatment planning which may mandate preprosthetic surgery prior to fabrication of a new conventional complete denture. Adequate patient satisfaction with conventional complete dentures can be significantly increased after frenectomy.

**Keywords:** Frenectomy; Preprosthetic surgery; Complete denture; Treatment planning; Retention.

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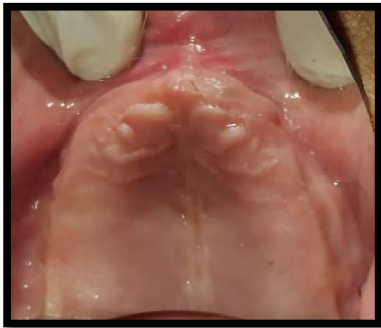
## INTRODUCTION

In this age of preventive dentistry and sophisticated methods of replacing teeth, such as with dental implants, conventional complete dentures still remain a viable method of treatment for many patients<sup>1</sup>. For edentulous patient, successful denture therapy is influenced by the biomechanical phenomenon of support, stability and retention. The successful construction of removable complete denture mainly depends on preoperative evaluation of the supporting hard and soft tissue structures and their proper preparation<sup>2</sup>. Preparation of the denture-bearing area can at times involve surgical alteration of the anatomic structures; alternatively, depending on the needs of the patient<sup>1,3</sup>. The maxillary labial frenum develops as remnants of the post-erect ectolabial band connecting the upper lip tubercle to the palatine papilla. This can be detrimental if the fibrous attachment is thick and

wide or located near the peak of the residual ridge, thereby disrupting the expansion of accurate denture limits so that stability and retention, and patient satisfaction are low. High attachment of the frenulum causes problems, for example, maxillary midline diastema due to thickening or hypertrophy or extensive fibrous frenulum tissue that will block orthodontic movement, block plaque release, cause tension and gingival recession<sup>4</sup>. Any abnormalities in the size and location of the frenulum can cause functional and esthetic problems which requires surgical excision. Frenectomy involves the complete removal of the frenulum, including its attachments to the underlying alveolar process<sup>5</sup>. In this case report, the patient had a high maxillary frenulum for which had gone surgical process so that it could not interfere with denture resistance and retention<sup>6</sup>.

## CASE REPORT

A 52-years-old male patient reported to the Department of Prosthodontics, Crown and Bridge at Mithila Minority Dental College and Hospital, Darbhanga with a chief complaint of loosening of maxillary complete denture. The patient was healthy and independent with hypertension that was medically controlled. The patient was not happy with the existing prosthesis and was not totally satisfied with a previous denture made by his dentist four years earlier. His major complaint with the first and second prostheses was loosening of maxillary complete denture while speaking. Multiple chair side hard and soft relines were performed over the previous year to enhance the retention and stability of the existing maxillary complete denture but the patient was not satisfied. Patient was explained about the implant supported overdenture but because of financial limitations he wanted a conventional CD. Upon intraoral examination of the maxilla, the labial frenum appeared as thick/multiple fibrous bands giving them a “fan-shape”.



**Fig.1 Patient intra oral view showing high labial frenum attachment in the maxillary arch**

The vestibules were considered shallow because of the frenum anatomy; otherwise, the rest of the soft tissues appeared within normal limits. The edentulous ridge appeared broad, rounded, and covered by firm soft tissue. The patient was informed about the high frenum attachment as a causative factor for denture looseness.

Therefore, he was advised about the surgical removal of frenum called “frenectomy” before a new denture fabrication. Before the patient was referred to the periodontics department, the existing soft liners on the maxillary complete denture was removed and a new chair side hard reline was performed which shows the significant amount of relief (labial and buccal notches) needed to accommodate the frenum after the chair side reline procedure. After the hard reline, clinical evaluation of occlusion and vertical dimension for the existing removable prosthesis found to be adequate.

However, during subsequent visits patient was still complaining about the maxillary denture looseness at different time of day while he was speaking. Then the patient was referred to the periodontist to perform the frenectomy. At the time of appointment for frenectomy, the treating prosthodontist was available to utilize the existing denture as a stent to support and stabilize the tissue attachments in the new position. Because of the existence of broad frenum and shallow vestibules, the periodontist decided to perform the frenectomy with the Z-plasty technique because of its usefulness in such situation where simultaneous frenum elimination and vestibule lengthening can be achieved.



**Fig.2 Buccal frenum excision and vestibule deepening with the Z-plasty technique.**

When simultaneous frenum excision and vestibule deepening with the Z-plasty technique were completed, and after final suturing, a soft denture reline material was placed on the existing denture and carefully inserted into the patient’s mouth.



**Fig.3 Final Suturing**

A gentle border molding was performed before the denture was removed from the mouth and then the excess reline material was trimmed around the borders. According to previously suggested protocol, the patient was instructed to keep the denture in place for the next 24 hours including sleep time and to minimize the in-out placement of the denture during the initial stages of healing (normally



the first 3 - 5 days). The sutures were removed after 7 days. During post-surgical week one and two, the initial soft denture reline material was replaced with new material twice. On the third post-surgical week, a different denture reline material was used and left in place for an additional three weeks. The definitive maxillary complete denture (Fig.4) construction was initiated six weeks following the surgical frenectomy procedure.



**Fig.4 Complete denture fabricated after 6 weeks**

The full mouth rehabilitation of the patient was achieved following the proposed treatment plan and the rendered treatment was performed according to classical recommendations in text books and literature for delivering such prosthodontic therapy. The final complete maxillary denture had longer border extensions. Post-treatment follow-up appointments indicated that the patient was fully satisfied with the final treatment outcome (Fig.5).



**Fig.5 Happy and satisfied patient**

Currently, it has been over a year since the treatment was completed and the patient is functioning well with the denture.

## DISCUSSION

Frenulum attachment inside the oral cavity develops with age; therefore, it varies from person to person. Frenulum attachment is categorized as abnormal if it inflicts pathological issues and complications in the

oral cavity, such as gingiva recess, centralis diastema, and it prevents adequate oral cleaning, prevents retention of prostheses, distracts orthodontic care, and, therefore, leads to psychological disturbances<sup>7</sup>. The stability and retention of a removable denture prosthesis, whether complete or partial, are affected by four force components that were described more than 50 years ago by Sir Wilfred Fish surface tension at the prosthesis intaglio-tissue interface, atmospheric pressure, occlusal forces, and peripheral neutral zone forces. The neutral zone is that area in the oral cavity where buccinator and orbicularis oris muscle inward forces are equal to outward muscle forces generated by the lateral borders of the tongue. These four components may become disruptive to a removable prosthesis if misdirected, or they may be very powerful retentive and stabilizing forces if properly directed. A fifth force could easily be added to the above list: disruptive dynamic tissue forces. This report describes such a disrupting force in the form of the buccal frenum<sup>8</sup>. This clinical report supports that pre prosthetic surgery is sometimes helpful for enhancement of complete dentures, thus preventing patients from going through a more expensive and time-consuming treatment with dental implants<sup>6</sup>.

## CONCLUSION

From the management of this case, it was concluded that a careful examination and an appropriate treatment plan provided more satisfactory denture results. The frenectomy procedure is an effective treatment to restore aesthetic function and also the stability of denture.

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# Management of Grade III Furcation Defect in Maxillary First Molar through Mesio Buccal Root Radisection: A Case Report

## Abstract

A challenging clinical dilemma faced by dentists is the endodontic-periodontal combined lesion, which presents difficulties in establishing a differential diagnosis and predicting a prognosis. Diagnosis can be challenging, requiring an accurate understanding of the underlying causes to select the appropriate treatment. The management of these lesions requires both endodontic and periodontal therapy, with root resection therapy being a viable treatment option for preserving multirooted teeth afflicted with furcation involvement. This case report examines a patient with an endo-periodontal lesion in a maxillary molar and reviews the root resective therapy used alongside endodontic treatment. Additionally, the literature on endodontic and periodontal treatments is discussed, providing insight into the treatment strategy and role of root resection in addressing this issue.

**Keywords:** *Endodontic-Periodontal Lesion; Furcation involvement; Root resection; Radisection.*

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## INTRODUCTION

The ultimate goal of restoring an endodontic issue is to ensure a functional and healthy dentition that provides lifelong comfort. Modern advances in dental procedures, such as root resection, are assisting clinicians in achieving this objective. According to the American Academy of Periodontology, root resection is the process of removing one or more of a tooth's roots at the furcation level, while still retaining the crown and remaining roots in functioning condition [1]. It's essential to differentiate root resection from crown resection, where the former involves removing the root at the cemento-enamel junction with an intact coronal portion. While crown resection involves hemisection, trisection, or bicuspidization of the crown in a multirooted tooth where both the root and associated crown portion may be removed or retained, depending on the case [2].

Root resection therapy has been discussed in endodontic literature for over a century [3]. Weine [4] suggests that the therapy is most appropriate in

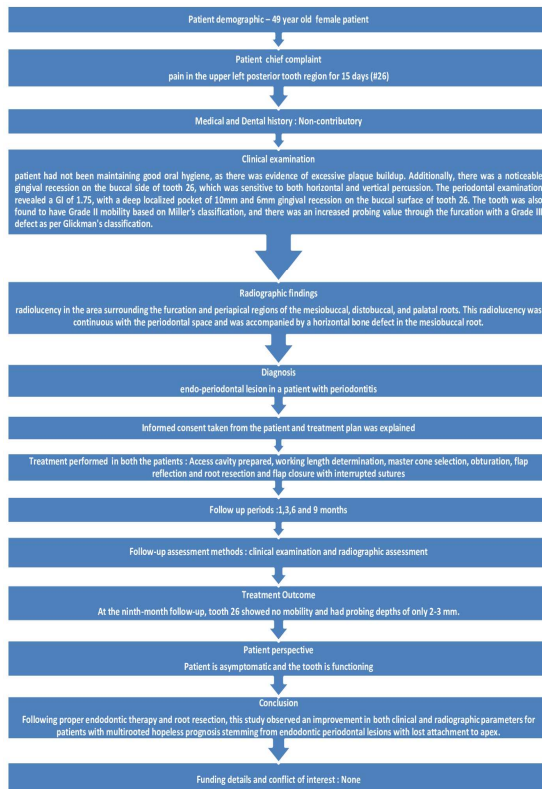
situations wherein a single root of a multi-rooted tooth is affected by severe bone loss, root exposure due to dehiscence, untreatable endodontic issues such as perforations, instrument separations, or vertical root fractures that are limited to a single root, and extensive carious lesions affecting the furcation areas and single root of the multi-rooted teeth. Success rates have varied among authors with some reporting a success rate of over 90% [5] while others as low as 30% [6]. Shin-Young Park et al conducted a retrospective study and reported that root resection for periodontal issues had better outcomes as compared to non-periodontal reasons. They also mentioned that the survival rate of resected teeth was higher when bone support greater than 50% remained [7]. Hence, to achieve success in root amputation procedures, selecting the appropriate cases is of utmost importance.

This case report examines root resective therapy and its correlation with endodontic management as a potential treatment for endo-periodontal lesions in

patients with periodontitis in the maxillary molar region. To develop a successful treatment regimen, the author reviewed pertinent endodontic and periodontal literature and evaluated the approach and significance of root resection. The paper explores the treatment strategy and the role of root resection in addressing the issue.

## CASE REPORT

This case report was written in compliance with the Preferred Reporting Items for Case Reports in Endodontics 2020 guidelines [8].



### Flowchart 1: PRICE 2020 Flowchart

A 49 year old female reported to the Department of conservative dentistry and Endodontics with the chief complaint of pain in the upper left posterior tooth region for 15 days. The pain was intermittent in nature and aggravated by mastication and food impaction. The medical and dental history of the patient was non-contributory. During the intraoral examination, it was observed that the patient had not been maintaining good oral hygiene, as there was evidence of excessive plaque buildup. Additionally, there was a noticeable gingival recession on the buccal side of tooth 26, which was sensitive to both horizontal and vertical percussion. The periodontal examination revealed a GI of 1.75, with a deep localized pocket of 10mm and 6mm gingival recession on the buccal surface of tooth 26. The tooth was also found to have Grade II mobility based on Miller's classification, and there was an increased

probing value through the furcation with a Grade III defect as per Glickman's classification.

The rest of the patient's dentition had no evidence of caries and had normal periodontal probing measurements. However, radiographic findings revealed radiolucency in the area surrounding the furcation and periapical regions of the mesiobuccal, distobuccal, and palatal roots. This radiolucency was continuous with the periodontal space and was accompanied by a horizontal bone defect in the mesiobuccal root.



**Fig 1: Pre-operative Radiovisiography (RVG)**

The diagnosis was an endo-periodontal lesion in a patient with periodontitis, and no other risk factors were present. Treatment planning was done taking into consideration that the tooth was nonvital with a grade III furcation involvement (mesiobuccal root) as well.



**Fig 2: Pre-operative clinical image of buccal side with class III furcal defect.**

The root canal treatment was planned and explained to the patient. Informed consent was obtained from the patient. The tooth was anesthetized using 2 ml of lidocaine containing 1:200,000 epinephrine and isolated with a rubber dam. The access cavity was prepared using round diamond bur (Mani Inc, Japan), and deroofting of the pulp chamber was done using Endo z bur (Dentsply, USA). Three distinct orifices were located using DG (David Green) 16 explorer (Dentsply, United Kingdom) i.e. mesiobuccal, distobuccal, and palatal. MB2 (mesiobuccal) canal was absent. The canals were

first negotiated by ISO #10 K (Mani Inc, Japan) file. Working length determination was done using Root ZX mini apex locator (J Morita, India) which was confirmed by radiovisiography (RVG).



**Fig 3: Working Length determination**

The glide path was established using manual preparation till ISO # 20 k- file. Canals were instrumented using NeoEndo Flex rotary files (Orkam Healthcare India Pvt Ltd.) till 20, 0.06. During instrumentation, canals were irrigated with 2.5 ml 5% sodium hypochlorite [Neelkanth (zodenta), India] followed by saline solution (Infutec Healthcare Ltd, India), and RC-Help containing 17 % Ethylene diamine tetra acetic acid (MEDA BIOMED CO.Ltd, Korea) was used as a lubricant. Final irrigation was done using 2 ml of 2% Chlorhexidine gluconate. A master cone radiograph



**Fig 4: Master Cone Selection**

was taken and canals were Dried using a paper point. Obturation was done using corresponding size gutta-percha and AH Plus sealer (Dentsply, Switzerland). The post-endodontic restoration was done using composite resin.



**Fig 5: Obturation**

Following initial diagnosis, non-surgical periodontal therapy was performed using a combination of patient motivation and thorough oral hygiene instruction, as well as a complete scaling and root planing treatment. In addition, patients were instructed to use a 0.12% chlorhexidine mouthwash twice daily during the non-surgical phase. After three months, a significant reduction in plaque and gingival index scores were observed, although periodontal measurements remained unchanged. Consequently, surgical intervention was recommended to address the furcation defect. Local infiltration anesthesia was administered and a full-thickness flap was raised on the buccal side from teeth 25 to 27.



**Fig 6: Flap reflection and root resection**

The granulation tissue was removed, and debridement was performed at the site of the defect using Gracey's curette 11/12 and 13/14. The root surface was thoroughly scaled and planned, as there was a severe bone loss beyond the apex of the mesiobuccal root, and the furcation involvement was noticeable during the operation. Therefore, it was necessary to perform mesiobuccal root resection and odontoplasty, which removed all undercuts. The flap was then repositioned and secured with 5-0 monofilament suture.



**Fig 7: Amputated mesiobuccal root**





**Figure 8: Flap closure with interrupted sutures**

Post-operative RVG was taken (fig. 9) and post-surgical instructions included using a postsurgical brush to clean the surgical site for two weeks and utilizing mouthwash for three weeks. Sutures were removed after ten days, and the patient was advised to visit the dentist regularly at 1, 3, 4, and 6 months.



**Fig 9: Post-operative RVG**



**Fig10: 9 months follow up**

At the ninth - month follow-up tooth 26 showed no mobility and had probing depths of only 2-3 mm.

## DISCUSSION

Combined endodontic-periodontal lesions affect both pulpal and periodontal tissues simultaneously, leading to severe and rapid destruction of supporting tissues beyond the tooth's apex. For such cases, the prognosis is usually deemed hopeless [9]. Different therapeutic methods have been developed to address molars affected by furcation involvement. These approaches consist of both nonsurgical and surgical mechanical cleaning, furcation plasty, tunneling techniques, regenerative therapy, and resective surgical procedures. Root resection, the removal of a root at the furcation or apical to it

without removing the crown, typically on maxillary molars [10], was selected as the treatment of choice for this patient after root canal treatment. This procedure was first introduced by Farrar and has been utilized to treat Class II and III furcation-involved molars. Root-resection therapy aims to eliminate the plaque-retentive niche and establish a morphology that facilitates good oral hygiene [11]. Rosenberg et al. [12] suggest that root resection may be indicated for grade II or III horizontal furcation involvement with minimal vertical bone loss, severe caries extending into the root or furcation area, endodontic perforation, or a root fracture affecting only one root. The literature reports varying survival rates for root resective therapy, with Svardström and Wennström [13] and Hamp et al. [14] reporting failure rates of 11% and 8%, respectively, over 10 years. Carnevale et al. found a tooth loss rate of only 6% in a 10-year study of 175 molars treated with root resection [15]. However, Langer and Bühler [16, 17] observed a less favorable 10-year outcome, with 32-38% of teeth failing over the observation period. Blomlöf et al. [18] recorded a survival rate of 68% for root-resected molars over 10 years. Dannewitz et al. [19, 20] reported failure rates of 40% and 38.6% in two studies conducted in 2006 and 2016, respectively. High failure rates were attributed to questionable prognosis for teeth selected for root resection and the use of root resective therapy in molars with advanced periodontal disease not amenable to regenerative approaches. A retrospective study over 30 years found a cumulative survival rate for root-resected molars of 98.9% after 5 years, 90.6% after 10 years, 68.9% after 15 years, 43.6% after 20 years, and 34.9% after 25-30 years. After the root resection, the chances of lower molars surviving were close to 80% even after a 20 year period, whereas the majority of maxillary molars were lost following the removal of the palatal root.

Currently, dental implant procedures are becoming more popular in clinical practice as an alternative to resective therapy for managing molars with advanced furcation involvement. Research indicates that the long-term survival of implants and root-resected molars after a 10-year period in the molar region is not significantly different. For instance, Hermann and his colleagues found no significant difference in survival rates between the two procedures [21]. Another study by Fugazzotto and his team reported a 15-year cumulative success rate of 96.8% for root-resected molars and 97% for molar implants [22]. However, some studies have reported higher failure rates and post-treatment complications associated with root-resected molars compared to molar implants. For example, Kinsel et al. [23] reported a 15.9% and 3.6% failure rate for root-resection therapy and single implants respectively, while Zafiroopoulos et al. [24] found 32.1% of post-treatment complications in hemisected molars and 11.1% in molar implants over a period of 4 years. It can be challenging to

draw a direct comparison between the effectiveness of respective therapy and molar implant treatment due to the lack of studies addressing the issue of treatment selection in the available literature.

## CONCLUSION

Root resection is a method utilized to conserve molars that are afflicted with furcation involvement. This approach requires a multidisciplinary approach, making it essential to carefully select the cases and plan the treatment accordingly. Failure to do so can lead to an unsuccessful procedure. When encountering a combined lesion that could stem from either primary periodontal or primary endodontic roots, a two-fold approach is needed involving both root canal treatment and periodontal therapy. Endo-periodontal lesions can be experienced by those with or without pre-existing periodontal diseases, as the destruction of the periodontal tissue can affect the root canal [25, 26]. Prognosis is heavily influenced by the condition of the periodontal tissue, as patients with periodontal diseases experience significant changes in oral ecology. It is important to keep in mind that endodontic treatment is only effective towards the endodontic component, meaning that periodontal lesions require additional treatment [27]. In cases of advanced furcation involvement, root resection is a viable option for long-term survival, specifically when only one root is affected. Following proper endodontic therapy and root resection, this study observed an improvement in both clinical and radiographic parameters for patients with multirrooted hopeless prognosis stemming from endodontic periodontal lesions with lost attachment to apex.

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# Management Of Severely Resorbed Mandibular Residual Ridge: A Case Report

## Abstract

Resorption of mandibular ridge is chronic, progressive and irreversible in nature which leads to loss of sulcular depth, decreased lower facial height and loss of vertical dimension. There are numerous hormonal, metabolic and neurological disorders which affects the denture adaptability. The complex neuromuscular control makes the denture passive and it ultimately leads to loss of retention and stability in complete denture. Hence mandibular ridge resorption becomes a challenging scenario for a dentist during fabrication of complete denture. The neutral zone concept plays an important role in overcoming the challenges of mandibular ridge resorption. The neutral zone is the area where outward forces from tongue is nullified or neutralized by inward forces from lips and cheeks during the functional movements. Apart from conventional method, the neutral zone technique is an alternative approach to construct complete denture. The aim of this technique is to construct a denture that is shaped by muscle function and is in harmony with surrounding oral structures. This article presents a case report which describes a technique for improving the stability of mandibular complete denture in severely resorbed mandibular ridges.

**Keywords:** Neutral zone, Mandibular ridge resorption, Complete denture, Retention and stability

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## INTRODUCTION

Mandibular ridge resorption is a multifactorial, biomechanical disease that is chronic, progressive, irreversible, and cumulative, resulting in sulcular depth loss, vertical dimension loss, and decreased lower facial height. The lingual plate resorbs the mandibular ridge, allowing more space for tongue movement and leading to tongue enlargement over time. On the contrary, the cheek and lip muscles lose tonicity as we age.<sup>1</sup>

Due to complex neuromuscular control, the denture becomes passive, causing difficulties in impression-making, mastication, and swallowing, resulting in loss of retention and stability in complete dentures. As a result, residual ridge resorption presents a difficult scenario for a clinician during complete denture fabrication.<sup>2</sup>

Complete dentures are primarily mechanical devices, but because they function in the oral cavity, they must be designed to be compatible with normal neuromuscular function. When all of the natural teeth have been lost, there is a void within the oral cavity that can be filled with a denture. The neutral zone is the potential denture space in which the forces of the cheeks and lips pressing outward are balanced by the forces of the cheeks and lips pressing inward on the denture.<sup>3</sup>

Our goal is to identify and use the forces generated by muscle function in order for them to have a positive impact on denture stability. This is only possible if we are aware of the neutral zone and position the teeth and develop the denture's external surfaces in such a way that all of the forces exerted

are neutralised and the denture maintains a state of equilibrium.<sup>4</sup>

The goal of this article is to present cases with resorbed ridges that were treated with the neutral zone technique for the fabrication of a successful and stable mandibular complete denture with a severely resorbed ridge.<sup>5</sup>

## CASE REPORT

A 70-years-old female patient reported to the Department of Prosthodontics, Crown and Bridge at Mithila Minority Dental College and Hospital, Darbhanga with a chief complaint of difficulty in chewing food due to missing maxillary and mandibular teeth. Patient had been edentulous and non-denture wearer since last 10 years. The medical history of patient revealed that she was diabetic, hypertensive and was under medication for the same. On clinical examination, the maxillary residual ridge was rounded and well formed (order iii) but the mandibular ridge was unfavourable due to high degree of resorption (Atwood's order v – low and well rounded). On TMJ examination, no clicking sound was heard, there was no tenderness present and there was no bilateral deviation was present and the neuromuscular coordination was excellent.

## OBJECTIVES OF THE TREATMENT:

The objectives of the treatment are fabrication of complete denture with stable mandibular denture using modified impression technique and neutral zone recording in patients with severely resorbed mandibular ridge.

## CLINICAL STEPS:

The primary impression was made in stock trays using impression compound. The primary impression was immediately poured with dental plaster (Gypsum II) and primary cast were made. The acrylic special tray was fabricated on primary cast. Maxillary border molding was done using green stick compound and secondary impression was made using zinc oxide eugenol material. Mandibular secondary impression was made by admixed technique using 3 parts by weight of impression compound and 7 parts by weight of green stick compound. The secondary was poured using dental stone and denture bases was made of cold cure acrylic resin. Occlusal rim were fabricated on denture bases.

On next visit, patient was instructed to sit in upright position. The maxillary rim was inserted inside patient's mouth and parallelism was verified using

fox plane. The mandibular occlusal rim was also inserted inside the patient mouth and was checked for extension and stability by guiding the patient to perform mandibular movements. Once the record bases were stabilized, two prominent points were marked on the tip of nose and tip of chin. The vertical dimension at rest (VDR) and vertical dimension at occlusion (VDO) was determined between these two points.

In this case VDR was 7.2 mm and VDO was 6.9 mm. Once the VDO was determined, the modelling wax in the canine - premolar region of mandibular occlusal rim was replaced by acrylic resin vertical stops. The remaining portion of mandibular occlusal rim was replaced by admixed material. The admixed material was manipulated in the patient's mouth by asking the patient to perform various mandibular movements (swallowing, suckling of mouth, pronouncing vowels) which helps in molding neutral zone space. The occlusal rim was fused at centric relation position and rims were articulated in a mean value articulator. Then putty index was made around mandibular occlusal rim. Then after that admixed material and acrylic stop of mandibular rim was replaced by wax occlusal rim. The teeth arrangement was done exactly following the putty index. After teeth arrangement try in was done of the waxed-up denture and patient was asked to perform all the functional movements.

This was done to confirm the stability of the denture during functional movement. Then denture was processed in conventional manner and final finishing and polishing was done to maintain the contour of polished surface. The mandibular denture was again evaluated with the putty index before the final denture insertion. The denture was inserted and verified for retention, stability, support and occlusion. The patient was comfortable and satisfied by the final prosthesis. Periodic recall visits were scheduled to verify the retention, support, stability and occlusion of the complete denture.



**Fig 1: Patient intra oral view showing severely resorbed mandibular ridge.**





**Fig 2: Admixed impression technique for mandibular ridge.**



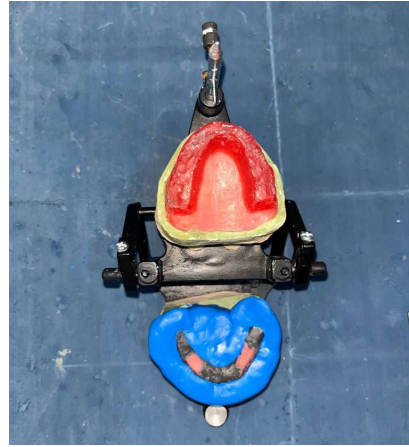
**Fig3: Acrylic resin stops in canine premolar region.**



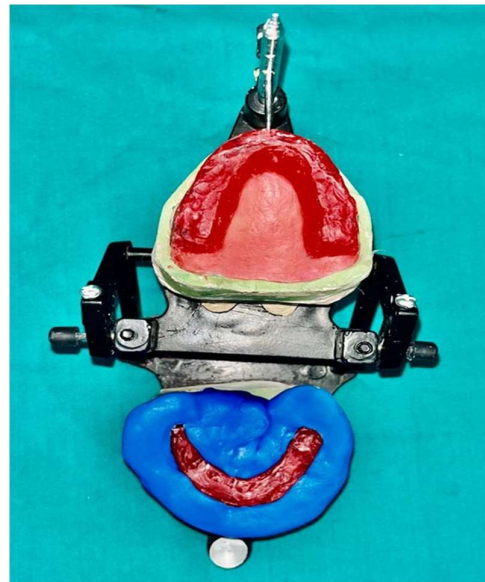
**Fig 4: Admixed material placed in remaining portion.**



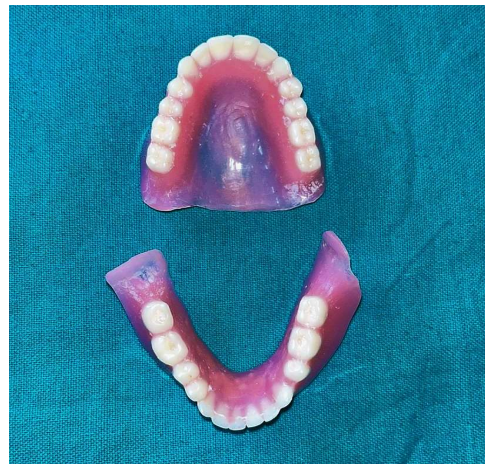
**Fig 5: Neutral zone moulding**



**Fig 6: Putty index around mandibular occlusal rim.**



**Fig 7: Admixed material replaced by wax occlusal rim.**



**Fig 8: Final finished and polished denture.**



**Fig 9: Happy and satisfied patient**

## DISCUSSION

Stable mandibular dentures are difficult to provide for patients with severely resorbed mandibular ridges. This problem can be avoided by making dentures with contours that complement the neutral zone. The neutral zone technique is used to create a denture with muscle balance.<sup>6</sup> The neutral zone approach employs the neutral zone to determine proper tooth placement following resorption. Many people believe that the maxillary anterior teeth should be placed near the natural anterior teeth's position. This technique for shaping all polished denture surfaces is sufficiently adaptable that dentists can incorporate it into their standard denture techniques.<sup>7</sup> The dentist can make impressions as well as vertical and centric relation records. The recorded neutral zone's width, shape, and position are unique and reproducible. They are, however, affected by a variety of conditions, such as various impression materials, different functional movements, different techniques, different vertical dimensions, different muscle tones, the period of edentulism, uncontrolled transitional tooth extraction.<sup>8</sup>

The width and shape of the recorded neutral zones could differ statistically significantly between materials and methods and this may explain why the result in this case differed slightly when the polished surface form and tooth position in the processed denture were reassessed. It's especially interesting to compare denture polished surface contours created with traditional methods to those created with the neutral zone methods described in this article.<sup>9</sup>

## CONCLUSION

The application of the neutral zone concept in denture fabrication, since the 1930s, it has been advocated. The neutral zone is an alternative technique for building complete systems. Dentures

on severely atrophied ridges. It is especially useful when dental implants are not an option.<sup>10</sup> The neutral zone's goal is to build a denture in muscle balance, as muscular control will be the primary stabilising and retentive factor during function. Although the technique is relatively simple, increased chair time and laboratory costs must be considered. This technique may result in a more stable and retentive complete lower denture as well as a shorter treatment time. For patients with severely resorbed ridges and/or mandibular defects, time is saved in comparison to conventional treatment.<sup>11</sup>

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# Surgical Management of Advanced Oral Submucous Fibrosis

## Abstract

**Background:** Severe oral submucous fibrosis (OSMF) poses problem with maintenance of oral hygiene, detection of malignancies and maintenance of nutrition. Surgical treatment includes release of fibrous bands with or without reconstruction for the raw area and postoperative physiotherapy.

**Methods:** All cases with OSMF who underwent surgical management at our institute were included in our study. The demographic data, preoperative interincisal distance, local examination was recorded. All patients underwent contrast enhanced computed tomography scan of head and neck to rule out hidden malignancy. All cases underwent OSMF band release with or without reconstruction. All patients were instructed for vigorous mouth opening exercise. All patients were followed up to 6 months and further divided into two groups depending upon whether they followed physiotherapy advice or not. Results: 13 patients of age group 18-47 years were included in our study. Male to female ratio was 1.6:1. Preoperative mean interincisal distance was 7.5 mm whereas post-operative it was 19.5 mm. Patients who had followed mouth opening exercise were having a mean increase of 15 mm more as compared to those who did not. Conclusions: Even after surgical management of severe OSMF, mouth opening exercise remains the key factor for maintenance.

**Keywords:** Oral Submucous Fibrosis, Surgical Management Of Advanced Oral Submucous Fibrosis, Mouth Opening Exercise

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## INTRODUCTION

Oral submucous fibrosis (OSMF) is an insidious onset chronic disease that involves any part of oral mucosa and occasionally the pharynx and upper third of esophagus. It is characterized by a juxta epithelial inflammatory reaction followed by fibroelastic changes in the submucosa and epithelial atrophy, which leads to stiffness of the oral mucosa causing trismus, burning sensation in oral cavity, oral discomfort leading to inability to eat<sup>1</sup>. OSMF is

a very old disease. The great Indian surgeon Sushrut had mentioned about disease called “**Vidari**” the symptoms and signs of which had close resemblance to OSMF. In 1952, Schwartz described the clinical features and named it as “**Atrophia Idiopathica Mucosa Oris.**” In 1953, Joshi named it as “oral submucous fibrosis.” Prevalence of OSMF in India is estimated to be approximately 5 million<sup>2</sup>. Known etiological factors include habitual areca nut



chewing specifically, those using lime. Tobacco which has been contemplated as one of the causes is associated more so with squamous cell carcinoma. Nutritional deficiencies like chronic iron and vitamin B complex deficiency have also been suggested<sup>1</sup>. OSMF also has a significant mortality rate because it is a premalignant condition and malignant transformation has been noticed to be around 3-7.6% of cases.<sup>3</sup> Many medical and surgical modalities are available for treatment. But in severe trismus, surgical intervention is the only answer. Surgery consists of bilateral fibrotic band release with/without bilateral coronoidectomy with/without reconstruction modalities<sup>4</sup>. The role of mouth opening exercises cannot be overemphasized. Insufficient physiotherapy accounts for one of the major causes for the recurrence of OSMF after surgery or after other treatment modalities along with non-stoppage of the habit. Insufficient physiotherapy, mainly resulting from negligence and postoperative pain, hampers effective postoperative effectiveness and beneficial results. Although several studies have been performed to assess the effectiveness of operative management for treatment of OSMF, very limited studies have been done to assess the effectiveness of operative intervention along with postoperative physiotherapy in adjunct to it. The purpose of our study was to emphasize the importance of mouth opening exercises in the treatment of OSMF.

## METHODS

Patients with mouth opening of less than 15 mm (Advanced OSMF), who underwent surgical management, were included in our study between September 2021 to January 2023 in the Department of Oral & Maxillofacial Surgery in Mithila Minority Dental College & Hospital Darbhanga Bihar. Patients with coexisting oral malignancy were excluded from our study. Patient's demographic data, habit of areca nut and tobacco chewing, preoperative mouth opening and CECT of head and neck to rule out hidden malignancies were documented. Patients were subjected to surgical intervention and followed by mouth opening exercise. Patients were followed up to 6 months and inter incisor distance was measured by vernier caliper and noted. Surgical intervention included bilateral release of fibrotic bands and bilateral coronoidectomy with or without flap reconstruction. Surgery was done in general anesthesia with fiberoptic assisted nasal intubation. Fibrous bands were incised from angle of mouth up to retromolar trigone by use of knife and hemostasis was achieved with the use of electrocautery. Mouth was forced open to maximum possible width. Coronoid process

was exposed from posterior end of incision and removed with the help of chisel and hammer. Interincisal distance was measured after coronoidectomy per operatively. In few patients, raw area was kept to epithelize secondarily and, in few patients, we used flap to cover the raw area. Patients were given Ryle's tube feeding and it was continued for 7 days. After the oral mucosa healed, the patients were given oral feeding. Wooden block or jaw key or rubber block or bunch of wooden spoons of ice-cream was used to keep the mouth open. The entire study population was followed up at regular intervals for 6 months and further divided into two groups depending upon whether they followed physiotherapy advice or not. The interincisal distance was measured during follow up.

## RESULTS

Total 13 patients of age group between 18-47 years were studied. 8 were males and 5 were females and male to female ratio was 1.6:1. Six patients were in the age group between 18-27 years and 4 patients belonged to age group between 28-37 years and the rest 3 belonged to age group between 38 to 47 years. Among them three patients underwent excision of fibrous band with coronoidectomy and raw area was covered by bilateral nasolabial flap. Four patients underwent excision of fibrous band with coronoidectomy and bilateral buccal pad fat was used to cover raw area. Six patients underwent excision of fibrous band with coronoidectomy and raw area was kept uncovered

Reconstruction	Group A	Group B	Total
Bilateral Nasolabial Flap	2	1	3
Bilateral Buccal Pad Of Fat	1	3	4
Allowed To Heal By Secondary Intention	1	5	6
Total	4	9	13

**Table 1: Reconstructive methods used in two groups**

	Pre Operative (Mm)	Intra Operative (Mm)	Post Operative (Mm)
Group A	7	31	12
Group B	8	30	27

**Table 2: Mean interincisal distance in two groups**

All patients were advised mouth opening exercise and close follow up maintained for 1 year. Amongst 13 patients, 9 patients had followed mouth opening exercise and 4 did not follow mouth opening exercise. Group A included those patients who followed mouth opening exercise. Group B included those patients who did not follow mouth opening exercise. In group A, mean preoperative interincisal distance was 7 mm, mean intraoperative interincisal distance was 31 mm and mean postoperative inter

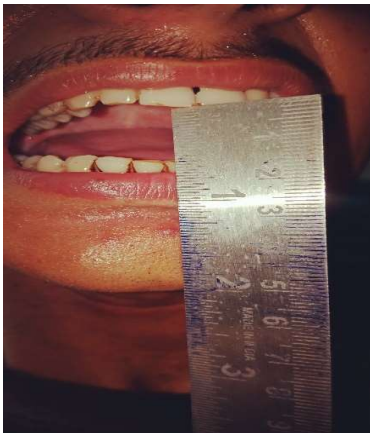
incisor distance at the end of 1 year was 12 mm. In Group B mean preoperative interincisal distance was 8 mm, mean intraoperative interincisal distance was 30 mm and mean postoperative interincisal distance at the end of 1 year was 27 mm.



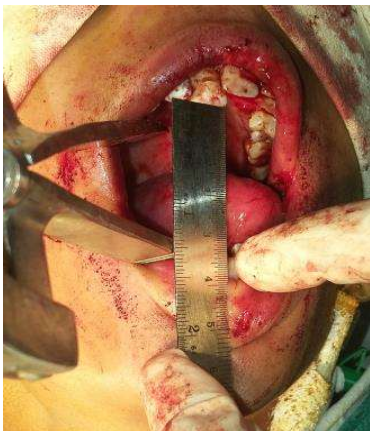
**Post Operative Photograph**

## DISCUSSION

Treatment for oral submucous fibrosis is mainly symptomatic, because the etiology of the disease is not fully understood, and it is progressive. Conservative treatment includes multivitamins, intralesional injections of steroids and hyaluronidase.<sup>4</sup> Such treatment will give temporary relief from symptoms like burning sensation. In a study performed by Borle et al it was stated that intralesional injections can aggravate the process of fibrosis formations<sup>5</sup>. Severe OSMF causes severe trismus and it affects the oral hygiene and even makes early diagnosis of malignancy difficult. It will not respond to conservative management. Surgical treatment OSMF is advisable in these patients. Surgical treatment includes surgical excision of fibrous bands with coronoideotomy. Majority surgeons prefer to cover this raw area by use of flaps like nasolabial flap, buccal pad of fat, free radial forearm free flap, collagen sheet, or full thickness skin graft<sup>6-10</sup>. Almost all studies have mentioned the advantages of different flaps over others. OSMF is a chronic disease and chances of recurrence of trismus are very high. Epithelization of raw area takes few weeks. To maintain mouth opening, patient requires vigorous mouth opening exercise until epithelization takes place. Due to pain, majority of patients do not follow mouth opening exercise and fibrosis again takes place. Most studies are focused on the type of flap they have used to cover the raw area. Importance of role of post-operative mouth opening physiotherapy exercise has not been addressed. In our study, a total of 13 patients with severe OSMF underwent surgical excision of fibrous bands with coronoideotomy with a variety of different reconstructive measures and we found that average preoperative interincisal distance was 8 mm and even intraoperatively we could achieve 31 mm. But in follow up to 1 year, in 4 patients who did not follow mouth opening exercise, mean interincisal distance was 12 mm which is again near to preoperative interincisal distance. In contrast, those



**Pre operative photograph with mouth opening**



**Intra Operative Photograph**



patients who followed mouth opening exercise were able to maintain the interincisal distance of 27 mm which is near to intraoperative mouth opening. Our study is intended to emphasize the importance of vigorous postoperative mouth opening physiotherapy in order to maximize the outcomes and benefit of the patient which is irrespective of the type of reconstructive method used. But due to inadequate number of cases, statistical significance of this objective could not be satisfied. The following studies have results in comparison to the present study, thereby reemphasizing the importance of physiotherapy in patients with oral submucosal fibrosis. Vijayakumar et al conducted a prospective clinical trial on 15 patients with OSMF grade 2 and 3 in which they found that a statistically significant increase in mouth opening by 6.26 mm after regular mouth opening exercise and ultrasound therapy<sup>11</sup>. In a study done on 64 patients by Thakur et al in which adjunct mouth opening exercises and micronutrient supplementation were prescribed for OSMF and noted that both should be given as first line treatment of OSMF<sup>12</sup>. In a study done by Cox et al, they compared the outcomes of physiotherapy exercise, local injection of hyaluronidase with steroids, in which they found that physiotherapy improved oral opening ( $p < 0.0005$ ), but not oral pain, while no clear improvement was seen in untreated patients as well as patients managed by injection<sup>13</sup>. They suggested that physiotherapy can be readily used to improve OSMF in communities with otherwise, limited health resources. In a study done by Kale et al, they found that adequate mouth opening of 43 mm at 6 months was achieved by surgical intervention followed by vigorous mouth opening physiotherapy exercise in the single patient that was included in their case report<sup>14</sup>.

## CONCLUSION

Whatever be the surgical approach of managing severe OSMF, physiotherapy in the postoperative period remains the integral part of maintaining the mouth opening achieved preoperative

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# Radix Entomolaris- A Case Report

## Abstract

Thorough knowledge and understanding of the anatomy of the root canal are very important, failure of which would lead to incomplete debridement, disinfection, and obturation of pulp and ultimately lead to failure of the entire treatment. One excellent example of anatomical variation is of Radix Entomolaris (additional distolingual root ) seen in the mandibular first molar. In these 2 case reports, the first mandibular molar with three roots and four canals is discussed.

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## INTRODUCTION

For a clinician, knowledge of the macrostructure and internal anatomy of canal plays a very important role in the success of Root canal treatment. A successful endodontic treatment includes locating the root canal orifice, chemomechanical cleaning and shaping of the root canals before obturating the canal with three dimensional hermetic seal. First molars has two-root two mesial and one distal canal. Mostly, the mesial root has two separate root canals which terminate in two distinct apical foramina but sometimes the mesial roots often merge at the root tip to terminate in one single foramen. The distal root typically has one kidney-shaped root canal. Radix entomolaris is an additional third root, seen most commonly in mandibular first molar. Carabelli, was the first one to introduce this in the literature. This additional root is seen on the distolingual side in mandibular molars. Carlsen and Ilexandersen first identified and described the external root morphology complexity as buccal or lingual supernumerary root. When present, complete diagnosis and treatment plan is necessary to avoid the chance of missed canal and treatment failure.<sup>1,2,3,4</sup>



**Fig 1: Clinical images of extracted mandibular molars with a radix entomolaris or paramolaris. (A) first molar with a radix entomolaris [distolingual view (left), lingual view (right)]. (B) radix entomolaris on a third molar (lingual view). (C) first molar with a separate radix paramolaris (buccal view). (D) first molar with a fused radix paramolaris (buccal view). [Courtesy JOE (2007);33;59]**

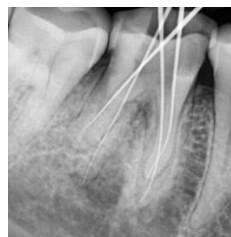
## CASE 1

A 28 year-old female patient reported to department of conservative dentistry and endodontics in Mithila minority dental college with a chief complaint of pain in lower- right posterior tooth region of jaw since few days. Clinically, the lower right first molar

tooth was restored and was tender on vertical percussion. No significant tooth mobility was present. Radiographically, periapical radiolucency was seen in relation to distal roots (Figure 1a). One extra root was seen on the distal side. The additional root was seen on the distolingual aspect of the tooth. The tooth showed no response on electric pulp testing. A confirmatory diagnosis of chronic apical periodontitis with respect to lower right first molar was made. The tooth was anesthetized. After doing the Access cavity preparation, DG 16 endodontic explorer was taken and two mesial canal orifices (mesiobuccal, mesiolingual) and one distal canal orifice (distobuccal) were located. On further exploration another orifice was found on distolingual part. Orifice enlargement was done with the help of gates glidden Drills Mani Inc., Japan) and access cavity of more or less trapezoidal shape was established to appreciate the additional distolingual root. The root canals were explored with a K-file ISO number 10 and radiographic length of the root canals were determined (Figure 1b). Biomechanical preparation was carried out using the NeoendoS rotary files (Dentsply, Switzerland) in all the canals with intermittent irrigation using 1% sodium hypochlorite. Root canals were obturated with Pro Taper gutta percha points and AH plus sealer (Dentsply, Switzerland). Post endodontic restoration was performed using type 2 Glass ionomer cement.(Figure 1d).



**Fig : 1 (a)**



**Fig : 1 (b)**



**Fig : 1 (c)**

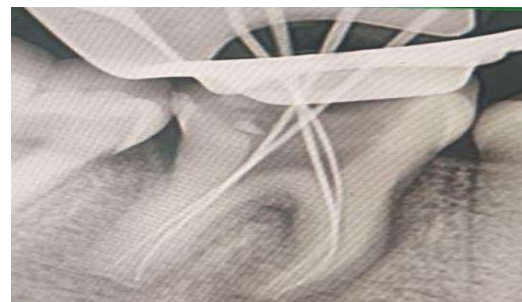


**Fig : 1 (d)**

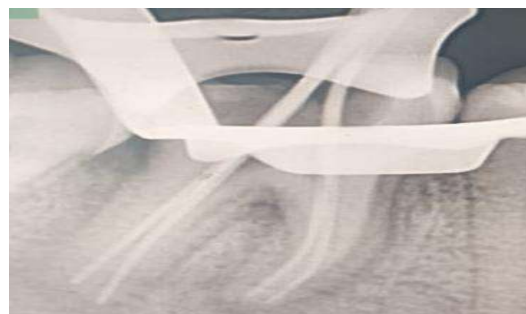
## CASE 2

A 17-year-old male patient came for endodontic treatment of mandibular right first molar in the department of Conservative Dentistry And Endodontics. After clinical examination the tooth was deeply carious and was diagnosed with

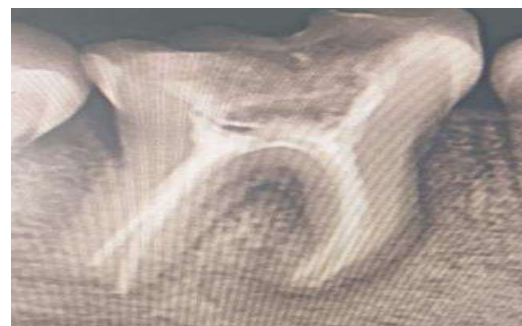
irreversible pulpitis. No radiographic sign of periapical pathology was visible in mandibular first molar. After administering local anaesthesia access opening was done in the same manner with endo-access bur and DG 16 endodontic explorer was used for searching for the orifices. First endodontic file introduced into the canal was K- file 10. Disto-lingual canal orifice was found a short distant from distal root canal orifices. The working lengths were determined of all the canals. They were cleaned with 2.5% sodium hypochlorite along with EDTA and shaped with k- file up to no. 30 in both mesial canals and no.40 in distally present canals, canals were filled with calcium hydroxide, patient was recalled after 3 days. At next appointment patient was asymptomatic. Master cone radiograph revealed proper fitting of gutta percha cones. Canals were Dried with paper point and obturation done by using zinc- oxide eugenol-based Sealer under rubber dam isolation.



**Working Length w.r.t. 46**



**Master Cone w.r.t 46**



**Obturation w.r.t. 46**

## DISCUSSION

Anatomical variations are an appreciable characteristics of mandibular First molar. Majority of mandibular first molars are two rooted, one medial and one distal root, but sometime additional disto lingual root may be encountered, known as Radix entomolaris. It has a prevalence of >30% in Mongoloid group and <5% in people of Italian population.<sup>5,6,7</sup> RE can be classified into four different types depending on the location of its cervical part .<sup>8,9</sup>(i) Type A: the RE is located lingually to the distal root complex which has two cone-shaped macrostructures. (ii) Type B: the RE is located lingually to the distal root complex which has one cone-shaped macrostructures. (iii) Type C: the RE is located lingually to the mesial root complex. (iv) Type AC: the RE is located lingually between the mesial and distal root complexes. Each type has a subclassification to allow for the identification of separate or nonseparate RE. An alternative classification of RE by De Moor et al. describes the curvature of the root or the root canal and is based on the work of Ribeiro et al.<sup>10,11</sup>

(i) Type 1: a straight root or root canal. (ii) Type 2: a curved coronal third which becomes straighter in the middle and apical third. (iii) Type 3: an initial curve in the coronal third with a second buccally oriented curve which begins in the middle or apical third. On clinical examination, Radix entomolaris presents with a bulbous crown and an extra cusp (tuberculum paramolare), or a more prominent occlusodistal or distolingual lobe. These findings along with a cervical prominence or convexity can indicate the presence of an additional root. Other diagnostic tools such as magnifying loupes, an intraoral camera, or a dental microscope may be useful in this respect. In 90% of the cases the third root is visible in routine radiography. A “hidden” RE can be viewed by an unclear outline of the distal root contour or the root canal. However, it may still be missed due to its slender dimensions occasionally. Taking radiograph from different angulation, horizontal projections, the standard buccal-to-lingual projection, 20 degrees from the mesial and 20 degrees from the distal reveals all the basic information regarding the anatomy of the tooth . Cone-beam computed tomography has emerged as a useful tool to aid in diagnosis of complex root canal anatomy.<sup>12,13</sup> Other than relying solely on radiographic method, obeying “law of symmetry “also helps in reaching to the additional canal. Once the straight line access has been established, proper shape of the access opening which is in general triangular for mandibular molars, should be modified to trapezoidal in outline. Care must be taken to prevent gouging of the dentin in

search for canal as this may weaken remaining tooth structure and thereby compromise the structural integrity of tooth and loss of peri cervical dentin.

## CONCLUSION

The oral health care professionals should be aware of this variation in anatomy of permanent mandibular first molars. The initial diagnosis is of utmost importance, to facilitate the endodontic procedure and to avoid treatment failures. Proper radiographic interpretation along with different angulation help in identifying accurate number of roots and their morphology. Once diagnosed, the conventional triangular cavity should be modified to a trapezoidal form distolingually to locate the orifice of the additional root. Other than endodontics, Radix entomolaris may pose difficulty during extraction and orthodontic procedure. Tooth should be thoroughly luxated during extraction, as distolingual root is exceptionally smaller and is more prone to fracture. During orthodontic procedure, presence of distolingual root and its curvature makes tooth movement difficult.

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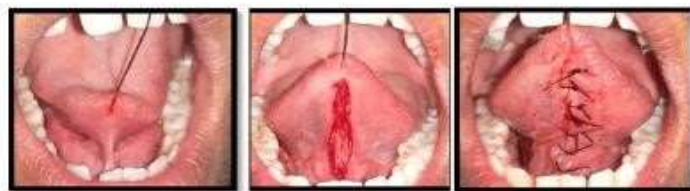


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