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3.1.3 Any other relevant information- Project Description

SYNOPSIS

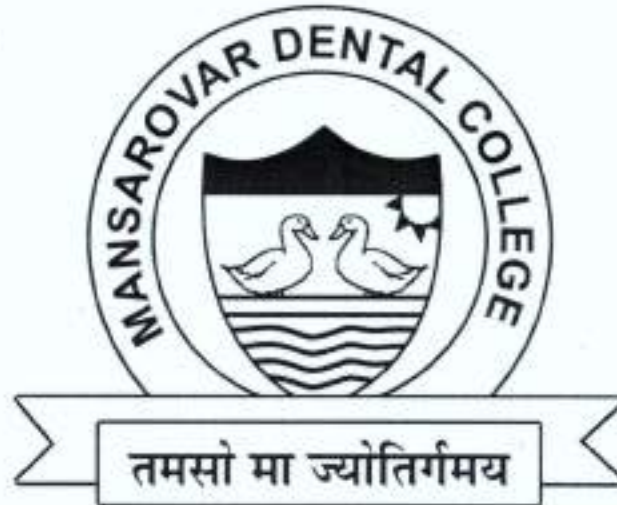
Title: “Efficacy of Finisher Gentlefile Brush, XP-Endo Finisher and Passive Ultrasonic Irrigation on the removal of an oil-based calcium hydroxide paste from the root canals: An *in vitro* study”

Submitted by:

Dr. Ojaswini Pawar

Under the guidance of:

Dr. Sagar Khanna



**Department of Conservative Dentistry
&
Endodontics**

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BHOPAL


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SYNOPSIS

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ENDODONTICS

“Efficacy of Finisher Gentlefile Brush, XP-Endo Finisher and Passive Ultrasonic Irrigation on the removal of an oil-based calcium hydroxide paste from the root canals: An *in vitro* study”

2020-2021


Dr. B. Gunidatta Nayak
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DETAILS OF THE PROJECT TO BE
SUBMITTED BY THE INDIVIDUAL
DESIROUS FOR CLEARANCE FROM
INSTITUTIONAL ETHICS COMMITTEE

SYNOPSIS/SUMMARY



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SYNOPSIS

Title	Efficacy of Finisher Gentlefile Brush, XP-Endo Finisher and Passive Ultrasonic Irrigation on the removal of an oil-based calcium hydroxide paste from the root canals: An <i>in vitro</i> study
Aims and Objectives	This <i>in vitro</i> study is designed to comparatively evaluate the efficacy of Finisher Gentlefile Brush, XP-Endo Finisher, and Passive Ultrasonic Irrigation to remove an oil-based calcium hydroxide paste from the root canals.
Study Centre	Mansarovar Dental College, Bhopal, Madhya Pradesh.
Duration of the Study	The preparation and collection of data will be spread over a period of time.
Introduction <p>The fate of endodontic therapy is determined by one of the most important factors which is thorough chemomechanical debridement of root canals.¹ Instrumentation of root canal in conjugation with irrigation has failed to achieve complete disinfection and cleaning.² Hence, the placement of intracanal medicaments to enhance disinfection comes into play. Calcium hydroxide (Ca(OH)₂) is one of the most widely used and accepted intracanal medicament for this purpose.³ One of the prime reasons being its mechanism of action of ionic dissociation into hydroxyl and calcium ions which on diffusing into dentinal tubules effectively eradicate microorganisms. It has gained popularity due to its effectiveness against majority of the endodontic microbes, tissue dissolving capacity, mineralization activity, and suppression of osteoclastic activities.⁴</p> <p>Various forms of Ca(OH)₂ are used which include aqueous-based and oil-based forms. They are available as powder form, mixed with distilled water or saline and also in injectable</p>	

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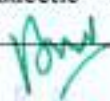
form, that are placed in the root canal using several techniques for few days to weeks. Metapex (META Biomed Co. Ltd, Chungcheongbuk-do, Korea) is an oil-based Ca(OH)_2 that consists of Ca(OH)_2 , silicone oil, and iodoform.⁵

It is mandatory that before the final procedure of obturation Ca(OH)_2 must be thoroughly removed from the root canal walls to facilitate complete adaptation of sealer and obturation materials to the canal walls.⁶ It has been shown in various studies that complete removal of Ca(OH)_2 from the canal walls is very difficult.⁷⁻¹⁵ These remnants of Ca(OH)_2 have been shown to prevent sealer penetration into dentinal tubules causing apical leakage, changes in physical properties of sealers, alterations in setting of sealers and reduced bond strength.¹⁶⁻²¹ There are various devices and techniques that are used to remove intracanal medicament from the canal walls, out of which passive ultrasonic irrigation (PUI) and XP-Endo Finisher have been evaluated the most in previous studies.⁷⁻¹⁵


Passive ultrasonic irrigation (PUI) is one of the popularly used irrigation technique, and is shown to be most efficacious to remove Ca(OH)_2 in previous studies.^{22,23} It is based on passive agitation of irrigant inside the root canal through an oscillating ultrasonic tip, and its mechanism of cavitation and acoustic streaming.^{24,25}

The XP-Endo Finisher (FKG Dentaire, La-Chaux-de-Fonds, Switzerland) is a novel instrument introduced into the market, which is based on the principle of shape memory of Max Wire Nickel-Titanium (Ni-Ti) alloy. The instrument is of ISO 25 size in diameter and has a taper of zero degree specially indicated for canals with complex morphology. The instrument has very high flexibility because it can achieve expansion upto 100-fold of an equivalent sized instrument or 6 mm of diameter in the last 10 mm of the file, when it is rotated. Initially the file is straight (M-phase or Martensite phase) when it is cooled at room temperature (20°), and on exposure of file to body temperature (35°) or inside the root canal it changes to a curve or sickle shape (A-phase or Austenite phase) caused due to its molecular memory. When

Study design	Prospective/ Retrospective Randomized/ Non-randomized Observational/ Comparative
Methodology (Materials & Methods) Material:	<ol style="list-style-type: none"> 1. 60 freshly extracted single rooted, human mandibular premolars with single canals. 2. Lab micromotor with straight handpiece (Marathon-4; Saeyang Microtech Co. Ltd, Daegu, Korea) 3. Wheel diamond disc on mandrel (Beego, Germany) 4. Dental operating microscope (Labomed PRIMA DNT; Labo America Inc., Fremont, CA) 5. Digital camera (Canon EOS1300D, Canon Inc., Taiwan) 6. X-Smart endomotor (Dentsply Maillefer, Ballaigues, Switzerland) 7. Syringe (DispoVan, Hindustan Syringes & Medical Devices Ltd., Faridabad, India) 8. 06, 08, 10, and 15 K-file (Dentsply Maillefer, Ballaigues, Switzerland) 9. ProTaper Universal rotary Nickel-titanium (NiTi) files (Maillefer, Dentsply, Ballaigues, Switzerland) 10. Ethylenediaminetetraacetic acid cream


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	<p>(Dolo; Prevest DenPro, Jammu, India)</p> <p>11. 3% Sodium hypochloride (NaOCl) (Hypo 5; Smyan Biomed India, Kolkata, India)</p> <p>12. 17% ethylenediaminetetraacetic acid (EDTA; Prevest DenPro, Jammu, India)</p> <p>13. Normal saline (NS; Abaris Healthcare Pvt. Ltd., Mehsana, Gujarat)</p> <p>14. ProTaper absorbent paper points (Sure-endo, Gyeonggi-do, Korea)</p> <p>15. Metapex; (META Biomed Co. Ltd, Chungcheongbuk-do, Korea)</p> <p>16. Roeko Endo-Frost spray (Coltene-Whaledent, Langenau, Germany)</p> <p>17. Orafill-G (Prevest DenPro, Jammu, India)</p> <p>18. XP-Endo Finisher (FKG Dentaire, La-Chaux-de-Fonds, Switzerland)</p> <p>19. Finisher Gentlefile Brush (MedicNRG Ltd, Kibbutz Afikim, Israel)</p> <p>20. Gentlefile handpiece (MedicNRG Ltd, Kibbutz Afikim, Israel)</p> <p>21. Ultra X-Ultrasonic Irrigation Device (Eighteeth, Jiangsu Province, China)</p> <p>22. Woodpecker UDS-E (Guilin Woodpecker Medical Instrument Co. Ltd, Guilin, Guangxi, P.R. China)</p>
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
	<p>23. Ultra X tip #25/0.02</p> <p>24. Razor Blade (TOPAZ; Harbans Lal Malhotra & Sons Pvt Ltd, West Bengal, India)</p>
Inclusion criteria	<ol style="list-style-type: none"> 1. Mandibular premolars with straight root 2. Teeth with single canal.
Exclusion criteria	<ol style="list-style-type: none"> 1. Teeth with open apices. 2. Teeth with calcified canals. 3. Teeth with resorption defect. 4. Teeth with carious lesion. 5. Teeth with fracture. 6. Teeth with previous restoration.
<p>Sample size:</p> <p>A total of 60 human mandibular premolars extracted for orthodontic or periodontal reasons with a single straight root and a patent root canal will be selected on the basis of radiographic evaluation. The teeth will be stored for two days at room temperature in 3% sodium hypochlorite (NaOCl) to remove organic debris following extraction. Eventually, the teeth will be scaled with ultrasonics, for removal of calculus or soft tissue debris. Teeth with any sign of immature apices, resorption, previous endodontic treatment, caries, calcification, previous restoration, cracks and fractures will be excluded from the study after radiographic verification in mesiodistal and buccolingual direction.</p> <p>Procedure planned:</p> <p>Then teeth will be decoronated to obtain a standardized root length of 16±1 mm using a diamond disc and water coolant. The apical patency will be established using a size #10K</p>	

file, this will be done by introducing the file in the root canal until visible at the apical foramen, observed under a microscope (Labomed PRIMA DNT; Labo America Inc., Fremont, CA) at x25 magnification. Working length (WL) will be determined exactly 1 mm short of the length that will be previously measured by the #10K file. The ProTaper Universal nickel-titanium (NiTi) Rotary system (Dentsply Maillefer; Ballaigues, Switzerland) will be used upto size F5 (#50/0.05 taper) using crown down technique for preparation of root canals with a torque and speed controlled electric motor as per manufacturers instruction. Copious irrigation will be done using 5 mL of 3% NaOCl by means of a 30-gauge side vented needle in a syringe, between successive instrumentation. Following the preparation, a final rinse of the root canal will be done using 5 mL of 17% of ethylenediaminetetraacetic acid (EDTA) solution and 5 mL of normal saline. The canals will be dried using sterile paper points. The prepared root canals will be filled with injectable calcium hydroxide Ca(OH)_2 (Metapex; META Biomed Co. Ltd, Chungcheongbuk-do, Korea), this will be done using special tips provided by the manufacturer. Complete filling of the root canals will be ensured with the help of radiographs taken mesiodistally and buccolingually. The coronal part of the canal will be sealed with a temporary filling material (Orafill-G; Prevest DenPro, Jammu, India). The samples will be stored at 37°C and 100% humidity for 1 week.

After removing the temporary filling material, a size #15K file will be introduced uptill the working length to loosen the Ca(OH)_2 and creating a space for the irrigation needle. The samples will be randomly divided into three experimental groups based on the Ca(OH)_2 removal technique ($n=20$).

Experimental groups and Ca(OH)_2 removal protocols:

Group 1 (Finisher Gentlefile Brush) - The root canals will be irrigated with 5 mL of 3% NaOCl by using a 30-gauge side vented needle in a syringe placed 1 mm from the WL with a flow rate of approximately 5 mL min^{-1} . The solution will be agitated for 1 minute by using


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the Finisher Gentlefile brush of tip size 0.25 mm placed 1 mm short of the working length in 7-8 mm up and down motion at a speed of 6500 rpm. Then the root canals will be flushed with 5 mL of 17% EDTA solution with a flow rate of approximately 5 mL min⁻¹, and the solution will be agitated with the Finisher Gentlefile brush for another 1 minute. Further the root canals will receive a final flush of 5 mL of normal saline. One Finisher Gentlefile brush will be used per specimen.

Group 2 (XP-Endo finisher) - A size 0.25 mm XP-endo finisher file will be mounted in a torque-controlled endodontic motor (X-Smart, Dentsply Maillefer, Ballaigues, Switzerland) set at 800 rpm and 1 Ncm. The file will be adjusted upto the WL using a rubber stopper while the file is still inside the plastic tube and will be cooled using a cold spray (Roeko Endo-Frost spray, Coltene-Whaledent, Langenau, Germany) which will make the file straight. Then the file will be removed from the plastic tube with slight lateral movement. The root canals will be irrigated with 5 mL of 3% NaOCl by using a 30-gauge side vented needle in a syringe placed 1 mm from the WL with a flow rate of approximately 5 mL min⁻¹. The XP-Endo finisher will then be inserted upto the WL and operated for 1 minute using slow and gentle 7-8 mm up and down motion. Then the root canals will be flushed with 5 mL of 17% EDTA solution with a flow rate of approximately 5 mL min⁻¹ and again instrumented with XP-Endo finisher for 1 minute. Finally, the root canals will receive a final flush of 5 mL of normal saline. One XP-Endo finisher will be used per specimen. Both NaOCl and EDTA solutions will be warmed to 37°C prior to application to allow the XP-Endo finisher file to work optimally when in austenite phase.³¹⁻³³

Group 3 (Passive Ultrasonic Irrigation) - Passive Ultrasonic Irrigation will be performed using Ultra X-Ultrasonic Irrigation Device (Eighteenth, Jiangsu Province, China) and a #25/0.02 Ultra X tip. The specimen will be irrigated with 3% NaOCl at a flow rate of approximately 5 mL min⁻¹, then the Ultra X tip will be inserted into the canal 1 mm short of

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the working length, and activated for 1 minute. This will be followed by irrigation with 5 mL of 17% EDTA solution at flow rate of approximately 5 mL min⁻¹ and agitated for 1 minute. Finally, the root canals will receive a final flush of 5 mL of normal saline. One ultrasonic tip will be used for 3 specimens.

Following irrigation, root canals will be dried with sterile paper points. Two longitudinal grooves on the buccal and lingual aspects will be prepared along the external surface at the maximum buccolingual diameter of the root to facilitate splitting of the root further exposing the instrumented root canal. This will be achieved using a diamond disc mounted on a handpiece under copious water cooling. This will be done with utmost precaution to avoid iatrogenic perforation of the canal space. Finally, by placing a razor blade in the buccal or lingual groove and gentle tapping of the blade the tooth will be split into two longitudinal halves.

IMAGE EVALUATION:


The appropriate half of each root with visible semi canal lumen having more amount of Ca(OH)₂ remnants will be selected. Images will be taken with the digital camera (Canon EOS1300D, Canon Inc., Taiwan) attached to a dental operating microscope (Labomed PRIMA DNT; Labo America Inc., Fremont, CA) at 25x magnification. The photographs will be coded to prevent identification of the specimens by the examiners. Two calibrated examiners who will be blinded to the experimental groups will score the images for the Ca(OH)₂ remaining in the canal according to the classification described by van der Sluis *et al.*:

Score 0: Root canal free of Ca(OH)₂.


Score 1: Less than half of the root canal filled with Ca(OH)₂.

Score 2: More than half of the root canal filled with Ca(OH)₂.

Score 3: Root canal completely filled with Ca(OH)₂.


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Remnants of Ca(OH) ₂ will be evaluated in coronal, middle, and apical third of all sections and the highest score observed will be recorded. Any disagreements between them will be reassessed with a joint discussion to reach an agreement on the score.	
Statistical Analysis Plan	
Depending upon the data obtained appropriate statistical analysis will be applied.	
Sponsorship (Yes/No)	No
Conflict of interest	None
Informed consent form in Hindi and English	Not applicable
Proposed Authors in the upcoming publication	Dr. Ojaswini Pawar Dr. Gurudutt Nayak Dr. Sagar Khanna Dr. Rahul Shrivastava Dr. Kasturi Roy
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Co-Guide/s	None


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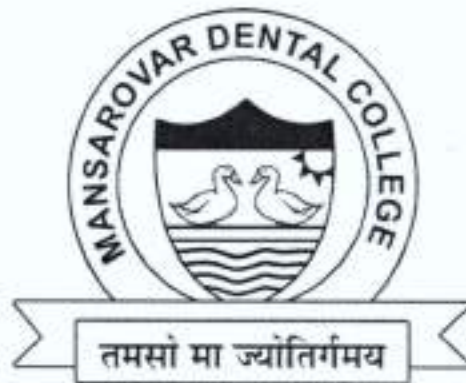
**Title: “CORRELATION OF UPPER AIRWAY SPACES AND
SOFT TISSUE PROFILE IN DIFFERENT FACIAL AND
SKELETAL TYPES”**

Submitted by:

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SYNOPSIS

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**DEPARTMENT OF
ORTHODONTICS & DENTOFACIAL ORTHOPAEDICS**

**“CORRELATION OF UPPER AIRWAY SPACES AND SOFT
TISSUE PROFILE IN DIFFERENT FACIAL AND
SKELETAL TYPES”**

2020-2021



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**DETAILS OF THE PROJECT TO BE
SUBMITTED BY THE INDIVIDUAL DESIROUS
FOR CLEARANCE FROM INSTITUTIONAL
ETHICS COMMITTEE**

SYNOPSIS/SUMMARY




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SYNOPSIS

TITLE	"Correlation of upper airway spaces and soft tissue profile in different facial and skeletal types".
AIM OF THE STUDY	The aim of this study is to find the correlation between the upper airway spaces and soft tissue profile in different facial types and skeletal types.
OBJECTIVES	Objectives of the study are:- <ol style="list-style-type: none">1. To find correlation between the upper airways with different facial and skeletal types.2. To find the soft tissue profile in relation to different facial and skeletal types.
STUDY CENTRE	Mansarovar Dental College, Hospital and Research Centre, Bhopal, Madhya Pradesh
DURATION OF STUDY	The preparation and collection of data will be spread over a specific period of time

INTRODUCTION:

The recent years have been marked by a search for new interrelations between the respiratory function and the risk of the development of malocclusions. The algorithms of early diagnostics and treatment have been developed for the same¹. Orthodontists deal with various kinds of malocclusions, which includes severe skeletal Class II and III deformities². The relationship between pharyngeal airway space and different craniofacial skeletal pattern morphology of patients, both anteroposterior (I, II, III skeletal Class) and vertical (dolichofacial, mesofacial, brachyfacial) has been discussed in the orthodontic literature for many years,


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due to their proximity and intimate association³⁻⁶. According to Muto et al⁷, craniofacial abnormalities, including mandibular retrognathism, short mandibular body length and backward/downward rotation, can lead to decreased pharyngeal airway. These findings indicate that nasopharyngeal obstruction may be related to changes in mandibular morphology⁸. Craniofacial growth and occlusion are influenced by many conditions including the respiratory function⁹. The upper airway is the first component of the significant structures, which provides respiration – one of the vital functions of the human body. Disturbed breathing function could lead to life threatening situations¹⁰. The discussion on the relationship between maxillofacial morphology and upper airway size and resistance has been continuing over a century. Narrowing of the pharyngeal airway passage caused by various etiological factors – especially in the nasopharyngeal area – results in mouth breathing^{11,12}. The study of upper airways and their relationship with mandibular position and size is extremely important in orthodontic diagnosis because of their association with obstructive respiratory disorders, especially sleep apnea. Indriksone et al², have determined a relationship between the size of the upper airways and the severity of malocclusion. The importance of lateral cephalometric radiographs in the evaluation of the morphology of soft and skeletal maxillofacial tissues and the diagnostics of airway pathology is unquestionable^{13,14}. Soft tissues play the primary role in the physical appearance and facial aesthetics. Various researchers have tried to relate the importance of soft-tissue aesthetics with orthodontic diagnosis and treatment planning. In recent years, it has been suggested that certain cephalometric standards relating the teeth to facial bones could ensure good facial form if adhered to the treatment goals. Most research demonstrates that soft tissues, which vary much considerably in thickness, are a major factor in determining patient's final facial profile¹⁵⁻¹⁷.

The aim of this study is to find the "Correlation between upper airway spaces and soft tissue profile in different facial and skeletal types"

STUDY DESIGN:

The study is planned to be conducted as an

- Retrospective, Randomised and Comparative type


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MATERIALS AND METHOD:

The study will be conducted as a Randomised control trial in the Department of Orthodontics & Dentofacial Orthopaedics, Mansarovar Dental College, Hospital & Research Centre, Bhopal, Madhya Pradesh. A total sample size of $N=120$ for this study will be obtained based on the power of study by statistical analysis. The Lateral cephalograms will be collected randomly from the records of Department of Orthodontics & Dentofacial Orthopaedics. Depending upon the VERT index¹⁸, which includes measurements of facial angle, facial depth, mandibular plane angle, lower anterior facial height and mandibular arch for different facial types.

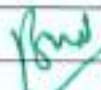
With regard to the VERT index,

- **Group I** - A negative value corresponds to a Dolichofacial type
- **Group II** - A positive value corresponds to a Brachyfacial type;
- **Group III** - If the value is zero, the patient will be classified as Mesofacial type

Depending on the ANB angle which gives the sagittal relationship of the jaw the skeletal types will be classified. ANB angle is measured as the difference between the SNA angle and SNB angle which gives the sagittal relationship of the maxilla and mandible respectively for different skeletal types.

- **Group IV** - ANB angle between 1° and 4° will be classified as skeletal Class I;
- **Group V** - ANB angle greater than 4° will be classified as skeletal Class II;
- **Group IV** - ANB angle less than or equal to 0° skeletal will be classified as Class III^{19,20}.

On the basis of these values, they will be placed in to their individual group of $n=40$ respectively. The parameters chosen for the cephalometric analysis in relation to the upper airway spaces and soft tissue profile will be traced and the tracings will be rechecked after 15 days of time to avoid errors. The measurements obtained from the tracings will be tabulated and the results will be obtained from the statistician by the necessary statistical analysis for the study.


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INCLUSION CRITERIA:

The study will include patients with :-

1. Age group between 12 years to 25 years
2. No previous history of any maxillofacial trauma or surgery
3. Patients without any craniofacial syndromes and abnormalities
4. No history of any clefts or conditions related to it
5. Any previous history of orthodontic treatment

EXCLUSION CRITERIA:

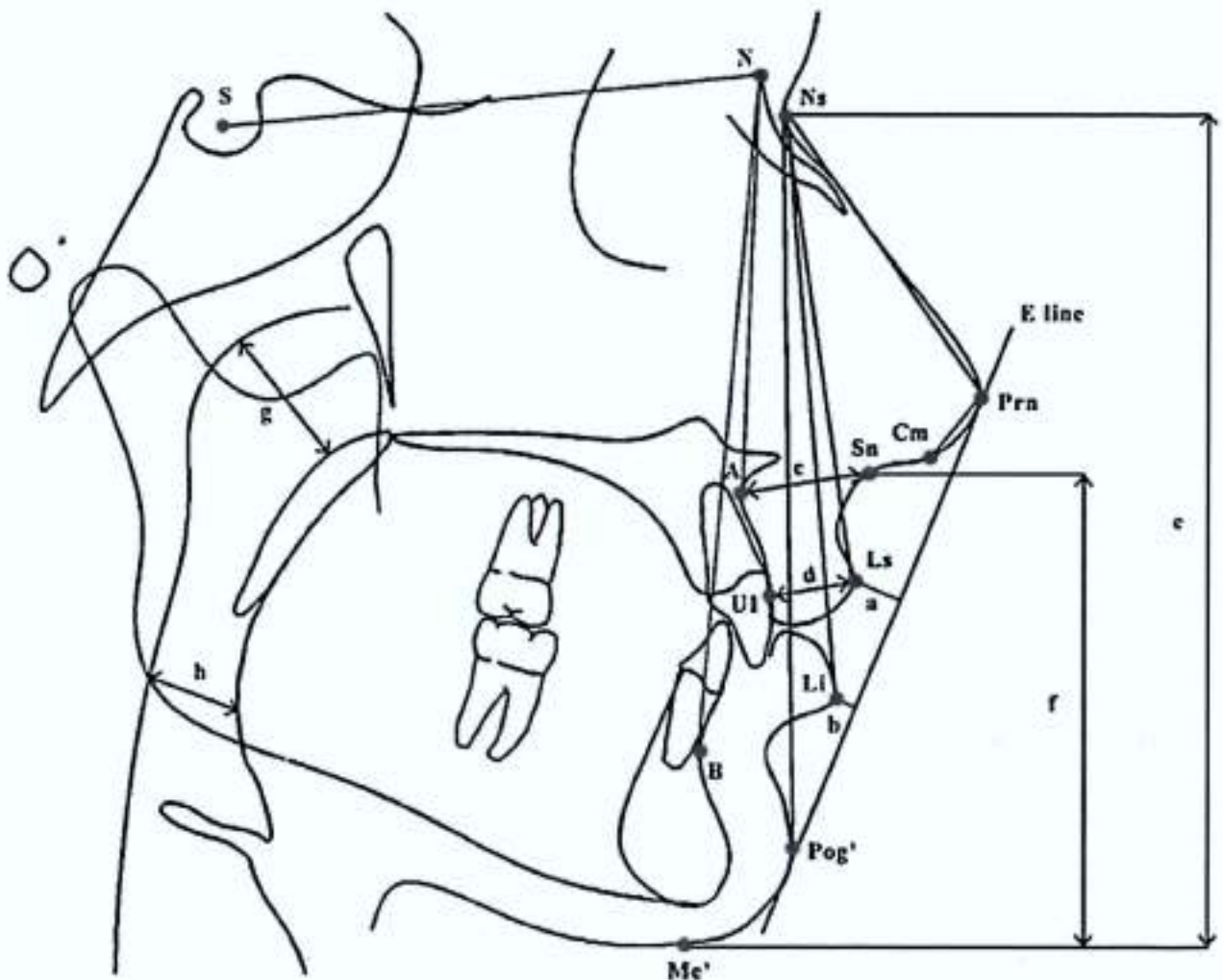
The study will exclude patients with :-

1. Age less than 12 years of age or greater than 25 years of age
2. Presence of previous history of maxillofacial trauma or surgery
3. Patients with any craniofacial syndromes and abnormalities
4. History of any clefts or conditions related to it
5. History of previous orthodontic treatment

PROCEDURE PLANNED:

- Subjects were positioned in the cephalostat with the sagittal plane at a right angle to the path of X rays, the Frankfort plane parallel to the horizontal, the teeth in centric occlusion, and the lips in repose.
- Patients were positioned within the cephalostat for lateral cephalometric projection. The nasal positioner was secured and referenced.
- Profile view of patient positioned within cephalostat for lateral cephalometric projection. The Frankfort plane was kept parallel to the floor.
- Lateral cephalograms will be taken from the records of Department of Orthodontics & Dentofacial Orthopaedics. Cephalometric tracings and measurements will be done depending upon the parameters that are to be taken into consideration.

CEPHALOMETRIC MEASUREMENTS:



Measurements: *SNA*- sagittal position of the maxilla; *SNB*- sagittal position of the mandible; *ANB*- sagittal jaw relationship; *Cm-Prn-Ns* - nose tip angle; *Ns- Prn-Pog'* - facial convexity; *Prn-Ns-Pog'* - nasomental angle; *Pog'-Ns-Ls* - upper lip-chin angle; *Pog'-Ns-Li* - lower lip-chin angle; *Ls-E (a)*,- distance from upper lip (*Ls*) to the E line (the line formed by connecting the *Prn* and *Pog'* points); *Li-E (b)* - distance from the lower lip (*Li*) to the E line; *A-Sn (c)* - upper lip thickness at point *A*; *UI-Ls (d)* - upper lip thickness at the maxillary central incisor; *TFH (e)* - facial height; *LFH (f)* - lower facial height; *UPW (g)* - width of the upper pharynx, measured as the distance from the point of the posterior outline of the soft palate to the closest point on the posterior pharyngeal wall; *LPW (h)* - width of the lower pharynx, measured as the distance from the intersection of the posterior border of the tongue and the inferior border of the mandible to the closest point on the posterior pharyngeal wall.

Bow

CEPHALOMETRIC LANDMARKS :

- **Point A** - The deepest point on the curve of the bone between the anterior nasal spine and dental alveolus
- **Point B** - The deepest midline point on the mandible between the infradentale and the pogonion
- **N (Nasion)** - The most anterior point of the frontonasal suture in the middle
- **S (Sella)** - The center of the sella turcica
- **B (Basion)** - The median point of the anterior margin of the foramen magnum
- **Or (Orbitale)** - the lowest point in the inferior margin of the orbit, midpoint between right and left images
- **Po (Porion)** (anatomic) - The superior point of the external auditory meatus
- **PNS (Posterior nasal spine)** - The intersection of a continuation of the anterior wall of the pterygopalatine fossa and the floor of the nose
- **ANS (Anterior nasal spine)** - The tip of the bony anterior nasal spine, in the median plane
- **UI** - The most labial point on the crown of the maxillary central incisor
- **Co (condylion)** - The most superior point on the head of the condylar head
- **Me (Menton)** - The most inferior midline point of the mandibular symphysis
- **Pog (Pogonion)** - The most anterior point of the bony chin in the median plane
- **Gn (Gnathion)** - This is the most anteroinferior point on the symphysis of the chin, and it is constructed by intersecting a line drawn perpendicular to the line connecting *Me* and *Pog*
- **Cm (Columella)** - The most anterior point on the columella of the nose
- **Ns** - Soft tissue Nasion
- **Prn (Pronasale)** - The most protruded point of the nasal apex
- **Sn (Subnasale)** - Midpoint of the columella base at the apex of the nasolabial angle
- **Ls (Labiale superius)** - Midpoint of the upper vermillion line

- **Li (Labiale inferius)** - Midpoint of the lower vermilion line
- **Pog'** - Soft tissue Pogonion
- **Me'** - Soft tissue Menton
- **PP2** – Posterior palate
- **Pp2'** – PP2 projection to pharyngeal wall
- **Tt** – Tongue tip
- **DI** – Dorsum of tongue
- **PAFM** – Anterior medium pharyngeal wall
- **PPFM** – Posterior medium pharyngeal wall
- **At** – Atlas Vertebra
- **H (Hyoid bone)** - The most superior and anterior point on the body hyoid bone
- **H'** – Hyoid projection into posterior laryngopharynx wall
- **C3** - 3rd cervical vertebrae
- **C3'** - 3rd cervical vertebrae projection into posterior laryngopharynx wall
- **PPFS** – Posterior Nasopharynx wall
- **E line** – Esthetic line or plane extending from soft tissue tip of the nose to the soft tissue tip of chin point


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The parameters to be evaluated in this investigation will be:

- *For facial type (VERT index)*

- **Angle of facial axis** – The intersection of Frankfort Horizontal plane with the facial plane (FH – N -Pog). Mean = $85.4^{\circ} \pm 3.7^{\circ}$
- **Facial depth** – The angle between the Basion – Nasion cranial plane and the Y axis (B-Na – S – Gn). Mean = $93^{\circ} \pm 3^{\circ}$
- **Mandibular plane angle** – Mandibular plane is a tangent to the gonial angle and the lowest point on the symphysis. It is related to the Frankfort Horizontal plane. Mean = $25^{\circ} \pm 5^{\circ}$
- **Lower anterior face height** - Angle formed by lines ANS-Xi and Xi-MP
- **Mandibular Arch** - Angle formed by lines Dc-Xi and Xi-MP

- *For skeletal type*

- **SNA angle** - Sagittal position of the maxilla – Angle formed between the SN plane and the Nasion to point A line. Mean = $82^{\circ} \pm 2^{\circ}$
- **SNB angle** - Sagittal position of the mandible - Angle formed between the SN plane and the Nasion to point B line. Mean = $80^{\circ} \pm 2^{\circ}$
- **ANB angle** - Sagittal jaw relationship – Angle formed between NA line and NB line. Mean = $2^{\circ} \pm 2^{\circ}$

- *For upper airway measurements*

- **Anterior base of cranium (S-N)** - Linear measurement between the Sella Nasion points
- **Maxillary length (PNS – ANS)** - Linear measurement between the Anterior nasal spine and Posterior nasal spine

- **Tongue height and length (Tt – DI)** - Linear measurement between the tip of the tongue and the highest point on the dorsum of tongue; (Tt – P) Linear measurement between the tongue tip and the lowest point of the soft palate
- **Mandibular length (Go – Me)** - Linear measurement between the gonion and menton points
- **Mandibular plane to hyoid length (MP – H)** - Linear measurement between the mandibular plane and the hyoid bone
- **Atlas to maxillary distance (At – PNS)** - Linear measurement between the Atlas and Posterior nasal spine
- **Superior pharyngeal space (PPFS – PP1)** - Linear measurement between the posterior nasopharynx wall and posterior palate 1
- **Median post palatal seal (PP2 – PP2')** - Linear measurement between posterior palate 2 and PP2 projection in to the posterior pharynx wall
- **Soft palate length (PNS – P)** - Linear measurement between the posterior nasal spine and the lowest point on the soft palate
- **Middle pharyngeal space (PPFM – PAFM)** - Linear measurement between the posterior medium pharynx wall and the anterior medium pharynx wall
- **Hyoid to 3rd vertebrae distance (H – C3)** - Linear measurement between the hyoid bone and the 3rd cervical vertebrae
- **Inferior pharyngeal space (H' – C3')** - Linear measurement between the hyoid projection to anterior laryngopharynx wall and 3rd cervical vertebrae projection into the posterior laryngopharynx wall
- **Posterior airway space (Ba-Go – Tt)** - Linear measurement between then basion gonion line to the tongue tip



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For soft tissue profile

- **Upper lip to E line** - Linear measurement between upper lip and E line
- **Lower lip to E line** - Linear measurement between lower lip and E line
- **Facial convexity ($N' - Prn - Pog'$)** - Angle between soft tissue nasion, pronasale and soft tissue pogonion
- **Nose tip angle ($Cm - Prn - Ns$)** - Angle between columella, pronasale and soft tissue nasion
- **Nasomental angle ($Prn - N' - Pog'$)** - Angle between pronasale, soft tissue nasion and soft tissue pogonion
- **Upper lip to chin angle ($Pog' - Ns - Ls$)** - Angle between Soft tissue pogonion, soft tissue nasion and labiale superius
- **Lower lip to chin angle ($Pog' - Ns - Li$)** - Angle between Soft tissue pogonion, soft tissue nasion and labiale inferius
- **Upper lip thickness at Point A ($A - Sn$)** - Linear measurement between point A and subnasale
- **Upper lip thickness at UI ($UI - Ls$)** - Linear measurement between the most labial part of the upper central incisor to labiale superius
- **Total facial height ($Ns - Me$)** - Linear measurement between soft tissue nasion to menton
- **Lower facial height ($Sn - Me$)** - Linear measurement between subnasale to menton
- **Upper pharyngeal width** - Linear measurement between the posterior outline of soft palate to the closest point on posterior pharyngeal wall
- **Lower pharyngeal width** - Linear measurement between the mandible and tongue intersection to the closest point on the posterior pharyngeal wall

DATA COLLECTION METHODS:

Values obtained from the tracings will be collected in the tabular form

METHODS OF MINIMIZING ERRORS:

After 15 days, the tracings will be repeated and difference will be calculated.

STATISTICAL ANALYSIS PLAN:

The difference of value $p < 0.005$ is considered to be significant

Sponsorship (Yes /No)	No
Conflict of interest	None
Informed consent form in Hindi and English	Not applicable
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Co-Guide	None


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SYNOPSIS

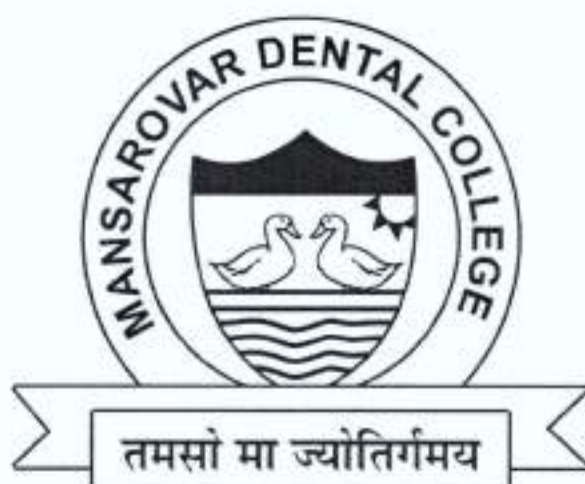
Title: “COMPARATIVE EVALUATION OF DIMENSIONAL STABILITY AND SURFACE HARDNESS OF TWO POLYVINYL SILOXANE INTEROCCLUSAL RECORDING MATERIAL AT VARIOUS TIME INTERVALS” - AN *IN VITRO* STUDY

Submitted by:

Dr. Ngangbam Johnson Singh

Under the guidance of:

Dr. Saurabh Shrivastava



Department of Prosthodontics , Crown & Bridge

MANSAROVAR DENTAL COLLEGE,

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NSM
Dr. P. Chandan Kumar
1/1/2024
Mansarovar Dental College
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DETAILS OF THE PROJECT TO BE SUBMITTED BY THE
INDIVIDUAL DESIROUS FOR CLEARANCE FROM
INSTITUTIONAL ETHICS COMMITTEE

SYNOPSIS/SUMMARY


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SYNOPSIS

TITLE	“COMPARATIVE EVALUATION OF DIMENSIONAL STABILITY AND SURFACE HARDNESS OF TWO POLYVINYL SILOXANE INTEROCCLUSAL RECORDING MATERIAL AT VARIOUS TIME INTERVALS” -AN <i>IN VITRO</i> STUDY
AIM	To evaluate dimensional stability of two different Interoclusal recording material i.e Jet bite (Coltene), Exabite II (GC) at different time interval i.e 1 hour, 24hours, 48hours
OBJECTIVES	<ol style="list-style-type: none">1. To evaluate the dimensional stability of Jet bite after 1 hour, 24 hour and 48 hours.2. To evaluate the dimensional stability of GC Exabite II after 1 hour, 24 hour and 48 hours.3. To compare and evaluate the dimensional stability of Jet bite and GC Exabite II after 1 hour, 24 hour and 48 hours.4. To evaluate the surface hardness of Jet bite after 1 hour, 24 hour and 48 hours5. To evaluate the surface hardness of GC Exabite II after 1 hour, 24 hour and 48 hours.



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	6. To compare and evaluate the surface hardness of Jet bite and GC Exabite II after 1 hour, 24 hour and 48 hours.
STUDY CENTRE	Mansarovar Dental College, Bhopal, Madhya Pradesh.
DURATION OF THE STUDY	The preparation and collection of data will be spread over a period of one and half year time
STUDY DESIGN	In Vitro Prospective Study.

INTRODUCTION

Success of prosthetic rehabilitation depends on several aspects out of which Bite registration is related to the precise mounting of cast in the articulator¹. According to Warren and Capp, the basic principle approach should be to make the interocclusal record at the correct occlusal vertical dimension, choosing an accurate, dimensionally stable recording material, and selecting an appropriate method of mandibular guidance². Many materials have been used for Maxillo-Mandibular registration procedure including modelling wax, acrylic resin, zinc oxide eugenol paste.

Wax has gained wide acceptance for interocclusal record transfer, however complete closure into wax is not easily achieved and rarely registers accurate incisal and occlusal forms of teeth³. Studies showed that waxes contain aluminium or copper particles which have flow rate of 2.5–22% at 37.5°C, So they are susceptible to distortion upon removal from the mouth⁴.

Acrylic Resin is most commonly used for interocclusal records in the fabrication of single stop centric occlusion records. Advantages of acrylic resin are accuracy and rigidity after setting and disadvantage is polymerization shrinkage ⁵.

Zinc oxide eugenol paste is a reliable interocclusal recording material, however it dehydrates cracks and sticks to the teeth or the portions of the record can be lost through breakage. Zinc oxide eugenol record once used for mounting is rarely used again also it is advisable to use minimum amount of zinc oxide eugenol to avoid excess flash ⁶.

Polyvinyl siloxane is an accurate interocclusal recording material. Currently Elastomeric material such as polyether and polyvinyl siloxane has been widely used for same purpose. When elastomeric interocclusal recording material are clinically used, flow characteristic of the mixed materials is necessary to reproduce surface details and in clinically reasonable time period they achieve solid like hardness to retain their shape and strength when articulated. The viscoelasticity of dental material is important in selection of suitable material for clinical application. However there is a "spring" to this elastomeric that can cause articulated casts to "open" in the centric closure position.

JET BITE is an Additional-silicone-based impression material for use in dentistry with an automatic mixing device. Material type ISO 4823, Type 1, high consistency Polyvinyl siloxane, addition-type. Polyvinyl siloxanes are biologically compatible with no known harmful reactions or secondary effects on patients and/or dental personnel. Impression materials are intended to set in the mouth of the patient; however, they should not remain in the mouth for more than twice the recommended setting time. Although they have high tear strength, care should be taken that no portion of the material remains in the interdental spaces or the sulcus.

EXABITE II NDS is an improved, addition reaction Vinyl Polysiloxane (VPS) impression material that has significant handling and advanced accuracy, extrudes easily, and sets hard quickly.

The present study will be undertaken with the following aim and objective to compare the dimensional stability and surface hardness of two different interocclusal recording material under constant load, assuming that there is no difference in stability.

METHODOLOGY (MATERIALS & METHOD):

STUDY SETTING -

This study will be conducted in the Department of Prosthodontics Crown & Bridge, Mansarovar Dental College, Bhopal.

MATERIALS AND METHODS:

Material using:-

- ▶ Stainless steel master die ADA specification no 19.
- ▶ Polyvinyl siloxane Exabite II NDS (GC).
- ▶ Polyvinyl siloxane Jet Bite (COLTENE).
- ▶ 4 × 4inch square glass slab.

INSTRUMENTS USING:

- ▶ Travelling microscope.
- ▶ Shore hardness tester (Durometer).

METHOD:-

- ▶ Standardized stainless steel die of 3 cm diameter as per ADA specification no 19 will be fabricated (3 cm diameter). 3 lines "A, B, C" lines will be inscribed on superior surface of die. Distance between "A & C" lines will be 5mm.
- ▶ Width of lines will be 0.20mm, Die has stainless steel ring that fits around the borders as a mold for impression material. Impression material used in this study will be Polyvinyl siloxane.
- ▶ Two different brands of Polyvinyl siloxane will be manipulated according to manufacturer instruction and sample will be prepared at room temperature.
- ▶ Die should be covered with a 4×4 inch square glass slab. Hand pressure will be applied over the glass slab for 5 sec till the metal ring is seen. This will be followed by application of 500g weight to further remove the excess material.
- ▶ Mold, stainless steel die and weight will be submerged in 37 ± 1 °C water bath to simulate ambient temperature. Each assembly to be remained in the bath till the material sets and additional 3 minute to ensure complete set of material. Metal ring will be removed from Stainless steel die and excess material will be removed using Bard Parker knife no.15. Sample will be

	<p>stored at room temperature in water proof container.</p> <ul style="list-style-type: none"> ▶ Prepared specimen will be in the form of disk measuring 0.3 cm thickness and 3 cm diameter with three parallel line with a distance of 2.5 mm on the surface, three lines will be named as A, B, C. ▶ Measurement of each sample will be taken between parallel lines A, C by means of Travelling microscope with 10 X magnification. ▶ Distance between the two parallel lines A and C will be measured at 4 fixed point. Reading will be recorded for all samples of each group for the interval of 1, 24, 48 hours. ▶ Means of distance between lines A, C of each sample will be compared to corresponding measurement of 500X 200 micrometer of stainless steel die measured using travelling microscope. ▶ Dimensional change will be calculated by formula. <p style="text-align: center;">Dimensional change% = $\frac{(X-Y)}{X} \times 100$</p> <ul style="list-style-type: none"> • X= standard measurement A-C in the die. • Y= observed measurement A-C in the samples. ▶ Same samples will be used to evaluate surface hardness of interocclusal recording material using shore
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<p>DATA COLLECTION TOOLS</p>	<p>hardness tester (Durometer). For testing the specimen depth indicator will be set to '0'. A light force with index finger is applied to the indenter for 3 sec and unit will be lowered on the sample until the pressure foot is in fully contact. Hardness value will be displayed on hardness tester. Four reading will be taken on four different site of a sample and mean value will be taken for statistical analysis.</p> <p>For the purpose of the study following tools will be used-</p> <ul style="list-style-type: none"> • Stainless steel die (ADA specification 19). • Travelling microscope. • Durometer (shore hardness tester).
<p>INCLUSION CRITERIA</p>	<ul style="list-style-type: none"> • Sample in form of disk measuring 0.3 cm thickness and 3cm in diameter with three parallel lines with distance of 2.5 mm on surface with no processing error.
<p>EXCLUSION CRITERIA</p>	<ul style="list-style-type: none"> • Samples with dimensional error. • Air voids in samples.



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DATA COLLECTION & METHODS

Data collection for Dimensional change

Dimensional change% = $(X-Y) \div X \times 100$.

STATISTICAL ANALYSIS PLAN

- One way ANOVA (one way analysis of variance)
- * • Multiple range (Tukey HSD- Honestly significant difference).

SPONSORSHIP

YES / NO

NO

CONFLICT OF INTEREST

None

**INFORMED CONSENT FORM IN
HINDI AND ENGLISH**

Not Applicable.

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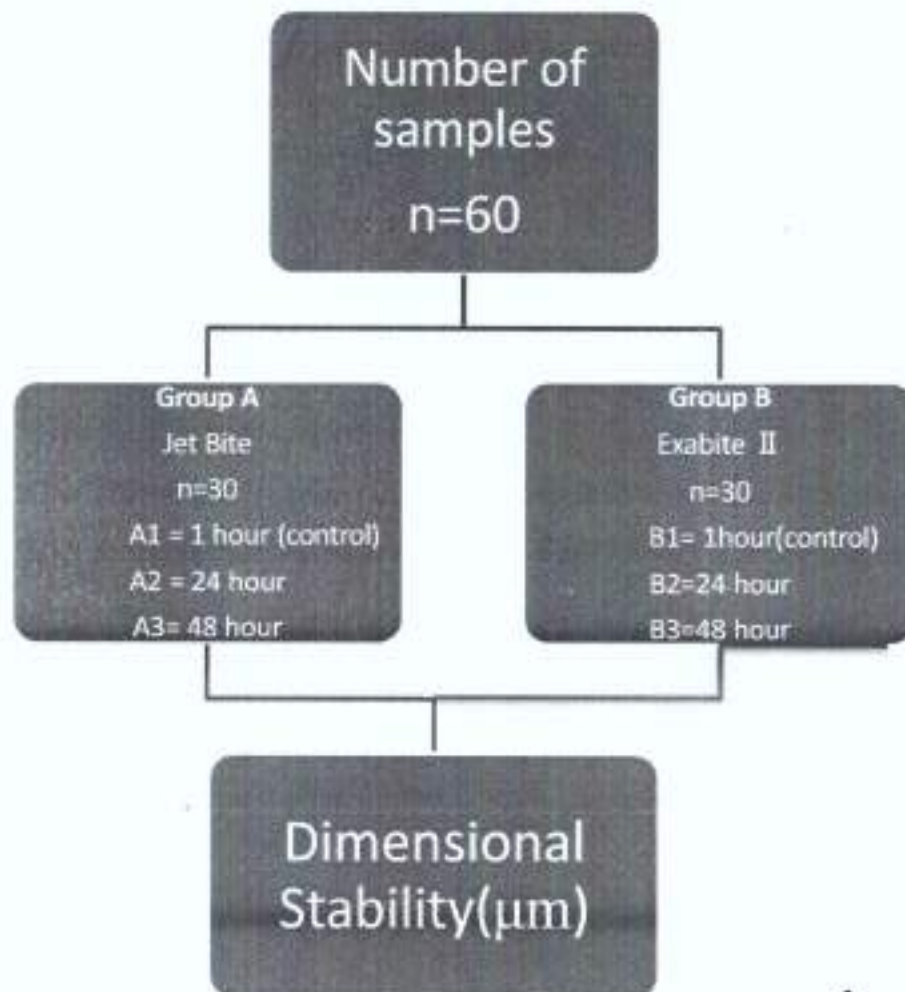

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MASTER CHART PROFORMA

Dimensional changes of two interocclusal recording material at various time interval

Duration	Group	Dimensional change in (μm)
1 hour	A1	
	A2	
	A3	
	B1	
	B2	
	B3	
24 hour	A1	
	A2	
	A3	
	B1	
	B2	
	B3	
48 hour	A1	
	A2	
	A3	
	B1	
	B2	
	B3	


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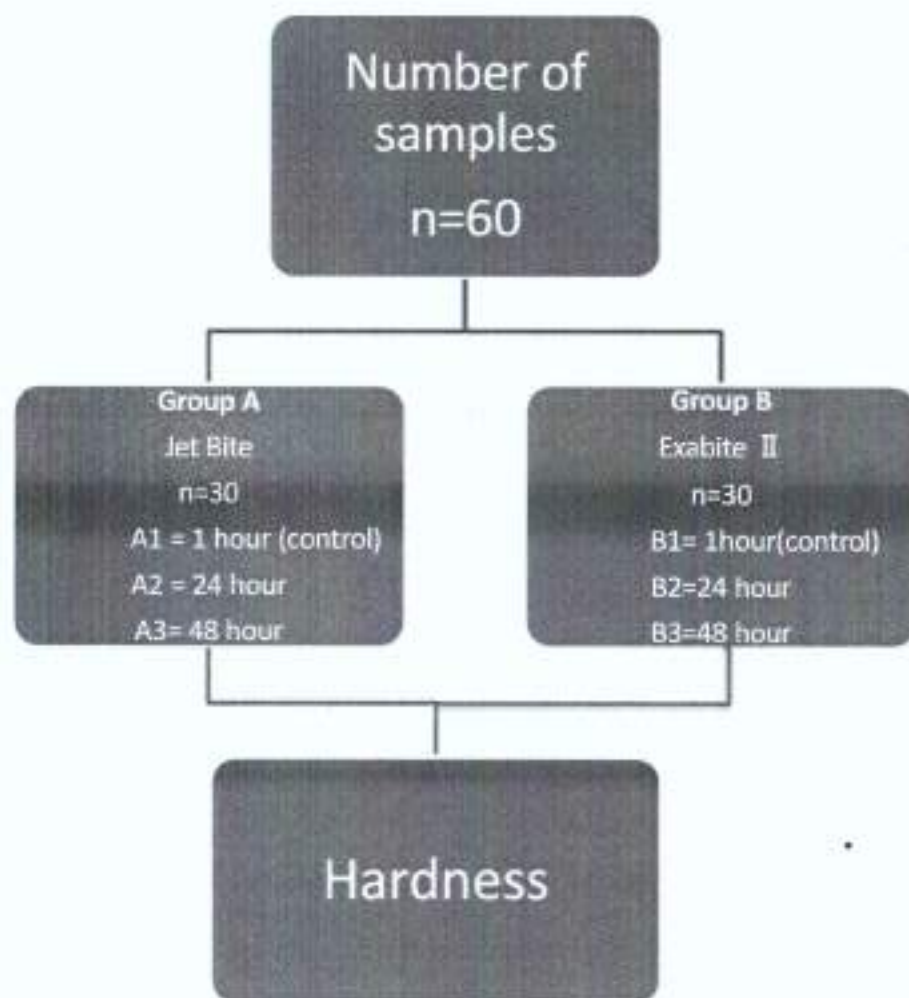
Bow
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Comparison of surface hardness of two interocclusal recording material at various time interval.

Duration	Group	Hardness
1 hour	A1	
	A2	
	A3	
	B1	
	B2	
	B3	
24 hour	A1	
	A2	
	A3	
	B1	
	B2	
	B3	
48 hour	A1	
	A2	
	A3	
	B1	
	B2	
	B3	



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SYNOPSIS

Title:

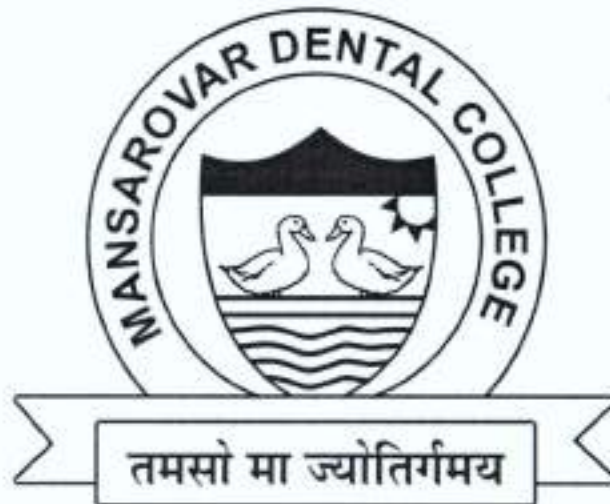
**“TO DETERMINE THE EFFICACY OF
PHOTODYNAMIC THERAPY AND EFFECT OF
SUBGINGIVAL APPLICATION OF OZONATED OLIVE
OIL AS AN ADJUNCT TO SCALING AND ROOT
PLANNING IN CHRONIC PERIODONTITIS:A
CLINICAL AND MICROBIOLOGICAL STUDY”**

Submitted by:


Dr. Vrushali nakhale

Under the guidance of:

Dr. Himanshu Khashu



Department of Periodontics


Dr. B. Ramdutt
Periodontist
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SYNOPSIS

**“TO DETERMINE THE EFFICACY OF
PHOTODYNAMIC THERAPY AND EFFECT OF
SUBGINGIVAL APPLICATION OF OZONATED
OLIVE OIL AS AN ADJUNCT TO SCALING AND
ROOT PLANNING IN CHRONIC PERIODONTITIS:A
CLINICAL AND MICROBIOLOGICAL STUDY ”**

**DR. Vrushali Nakhale
PG 1ST YEAR
2020-2021**

DEPARTMENT OF PERIODONTICS

**DETAILS OF THE PROJECT TO BE SUBMITTED BY THE
INDIVIDUAL DESIROUS FOR CLEARANCE FROM
INSTITUTIONAL ETHICS COMMITTEE**



**Dr. D. Govind Prasad
Principal
Maharaja Dental College
Bilalpur**

SYNOPSIS/SUMMARY

SYNOPSIS

Title	TO DETERMINE THE EFFICACY OF PHOTODYNAMIC THERAPY AND EFFECT OF SUBGINGIVAL APPLICATION OF OZONATED OLIVE OIL AS AN ADJUNCT TO SCALING AND ROOT PLANNING IN CHRONIC PERIODONTITIS:A CLINICAL AND MICROBIOLOGICAL STUDY
Aims and Objectives	<ol style="list-style-type: none">1.To evaluate the efficacy of Photodynamic therapy using photosensitizer Indocyanine green dye as an adjunct to SRP in the treatment of chronic periodontitis2.To evaluate the efficacy of ozonated olive oil as an adjunct to SRP in the treatment of chronic periodontitis3.To evaluate the efficacy of SRP alone4.To evaluate the efficacy of Photodynamic therapy and effect of subgingival application of olive oil as an adjunct to scaling and rootplanning in the treatment of chronic periodontitis
Study Centre	Mansarovar Dental College and Centre for Microbiology & Biotechnology institute, Bhopal, Madhya Pradesh.
Duration of the Study	1 year
Study Type	In vivo clinical and microbiological study
Study Design	A split mouth longitudinal study



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INTRODUCTION

Periodontitis is defined as an inflammatory disease of supporting tissues of teeth caused by specific microorganisms or groups of specific microorganisms, resulting in progressive destruction of the periodontal ligament and alveolar bone with periodontal pocket formation, gingival recession, or both.[1] Periodontitis is thought to be associated with anaerobic micro-organisms such as black-pigmented Porphyromonas species and Actinobacillus Actinomycetemcomitans (AA), in the subgingival plaque.[2] Among the available noninvasive therapies to achieve better plaque control, photodynamic therapy (PDT) and ozonated therapy (OT) are being widely recognized as two reliable techniques. PDT using low-level laser irradiation is known to selectively target the periodontal pathogens without potentially damaging the host tissues.[3] The reaction of a photosensitizer agent like indocyanine green (ICG), with laser light of appropriate wavelength in the presence of oxygen, helps in generating free radicals and singlet oxygen, which in turn damage DNA and cytoplasmic membrane of the pathogen.[4] Results of several clinical studies have acknowledged the beneficial effects of PDT in patients with chronic periodontitis.[5],[6],[7] Photodynamic therapy (PDT) has also emerged in recent years as a new noninvasive therapeutic modality for the treatment of various infections by bacteria, fungi, and viruses.[8] The unique properties, noninvasive nature, versatility, relatively little side effects, and adverse reactions make ozone therapy an effective tool in the treatment of periodontitis. Ozone therapy, amid its antimicrobial, analgesic, immunostimulating, immunomodulatory, and anti-inflammatory properties, it also oxygenates tissues, elevates their functional activity, and enhances their regeneration potential[9] The aim of the study was to evaluate the therapeutic effect of OT and PDT when used along with mechanical debridement in nonsurgical management of chronic periodontitis. The objectives of the study were (1) to assess and compare the periodontal status of patients following usage of OT and PDT along with conventional mechanical debridement in the management of chronic periodontitis at the end of 1 months and (2) to assess and compare the periodontal status of patients among the OT and PDT groups after 3 months following bi-monthly exclusive


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application of
 respective therapy repeated frequently without mechanical debridement in the
 management of
 chronic periodontitis the first appointment, a detailed case history of each patient
 was recorded to standardize
 the samples as chronic periodontitis patients as per the classification of
 periodontal diseases
 and conditions by the American Academy of Periodontology,[10] by assessing
 periodontal status of the patient
 using gingival index(GI) ,[11]plaque index(PI)probing pocket depth(PPD) , .[12]
 Full mouth SRP
 was performed in every case, following this, one of the quadrant of each case was
 rinsed with the photosensitizer(ICG dye) for PDT and in one of the quadrant
 subgingival application of ozonated oil was performed
 On the second appointment, i.e after 14 days reapplication of ICG and
 OZONATED olive oil was done. The photosensitizer dye was delivered using a 22
 gauge needle, guided along
 the bottom of the pocket by continuous horizontal movements to achieve a
 complete flushing of the pocket.
 Flushing with the photosensitizer was restricted to 30 s at each site[13] Following
 this, pockets were exposed to low-level laser light 810 nm at 0.5 W using an AMD
 Picasso diode
 laser equipment (AMD Lasers, LLC; 7405 Westfield Blvd, Indianapolis, IN,
 USA). The laser was delivered
 using a fiber-optic application having a tip of 10 mm length, with a default angle
 of 60°, and
 fiber core diameter of 400 µm. Irradiation settings employed the standard
 prescribed method of 0.5 W
 for 1 min in noncontact continuous wave mode.[13][14][15][16].Laser beam was
 guided like an ultrasonic
 probe from the pocket bottom to the gingivalmarginunder continuous horizontal
 movements in order
 to ensure that all areas of the pocket were irradiated.[16] Photosensitizer was then
 removed
 thoroughly by flushing with sterile water along with vacuum evacuation. Every
 care of isolation was advocated
 to prevent the material being contaminating the adjacent quadrants in the same
 arch. Following this,
 the other quadrant was prepared for OT. The patient was allowed to wash and
 gargle
 the mouth with normal water. For subgingival application of oil in the deepest
 selected periodontal pocket
 using a disposable 5-ml plastic syringe with a needle of 24G and of 0.55 diameter
 bend at the tip.
 The selected teeth were thoroughly dried and isolated carefully with cotton rolls,
 and then, oil was applied
 carefully subgingivally and interproximally until excess oil was observed from the
 gingival margin.


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	<p>This procedure was repeated for all teeth to be treated. The excess oil was removed with a cotton roll.</p> <p>Any side effects were noted, and supragingival deposits were removed at recall visits. Oil application was performed after initial SRP and at 14 day.</p> <p>After the completion of 1 and 3 month each of this 20 patient was recalled to estimate gingival index(GI),plaque index (PI) and probing pocket depth(PPD)</p>
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<p>Methodology</p>	<p>MATERIALS AND METHODS:The sample size was calculated as per formula:</p> $n = \frac{(Z_a + Z_p)^2 SD^2}{d^2}$ <p>In this study, total 60 sites from 20 patients will be enlisted from outpatient Department of Periodontics, Mansarovar Dental College Bhopal (MP), with clearance of ethical committee followed by informed consent from all patients who will be participating in this study.</p> <p>Systemic healthy patients diagnosed with chronic periodontitis (PPD>_ 5mm) and individuals who can maintain satisfactory oral hygiene after initial treatment were included.</p> <p>Patients will be categorized ,according to procedure, in three groups:</p> <p>Group I: Scaling and root planing only.</p> <p>Group II: Scaling and root planing & single episode of photodynamic therapy using indocyanine green dye</p> <p>Group III: Scaling and root planing &subgingival application of ozonated olive oil</p> <p>On first appointment all patient will receive full mouth conventional SRP and application of photodynamic therapy using photosensitizer indocyanine green dye it is delivered using blunt needle of 22 gauge guided along the bottom of the pocket, flushing with the photosensitizer was restricted for 30 sec then this pockets were exposed to low-level laser light 810nm at 0.5W using AMD picasso</p> <p>Diode laser in one quadrant and subgingival application of ozonated olive oil in the deepest selected periodontal pocket using disposable 5ml plastic syringewith a blunt 24 gauge needle of 0.55diameter bend at the tip then the teeth were thoroughly dried and isolated carefully with cotton rolls and then oil was applied carefully subgingivally and interproximally untill excess oil was observed from the gingival margin in another quadrant. Patient was recalled after 14 days.</p> <p>On second appointment reapplication of photodynamic therapy using photosensitizer indocyanine green and subgingival application of ozonated olive oil was done then patient was recalled after 15days.</p> <p>On third appointment that is at the end of 1 month clinical parameters such as gingival index(GI),plaque index(PI),probing pocket depth(PPD) were recorded</p>
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	<p>Microbiological analysis will be done by collecting GCF sample from the periodontal pockets with probing depth more than 5mm per quadrant. The samples will be collected from both control sites and test sites at baseline, 1, 3 and 6 months. Collection of GCF sample will be done using sterile endodontic paper point by inserting it for 20 seconds. The paper points will be carried in sterile vials containing 2-3 drops of 0.85% NaCl solution and will be sent to laboratory for detection of <i>Porphyromonas gingivalis</i> and <i>Aggregatibacter actinomycetemcomitans</i>.</p>
<p>DATA COLLECTION TOOLS</p>	<p>Mouth mask Gloves Head cap Mouth mirror UNC-15 probe Tweezer Cotton Kidney tray Hu-Friedy set of Gracy curettes (Hu-Friedy, USA) Ultrasonic scalers (EMS) Normal Saline 1% Methylene Blue Diode laser (Biolase Inc. USA) Biostimulation probe (Biolase Inc. USA) Protective eyewear ((Biolase Inc. USA) Endodontic paper points 0.85% NaCl solution Sterile vials.</p>
<p>Inclusion criteria</p>	<ol style="list-style-type: none"> 1. Age – 25 - 50 years 2. Periodontal pockets \geq 5mm of probing depth 3. Vital and asymptomatic teeth 4. Patient should demonstrate acceptable oral hygiene maintenance 5. Healthy systemic condition


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Exclusion criteria	<ol style="list-style-type: none"> 1. Pregnant or lactating females 2. Use of immunosuppressive agents 3. Smokers/chronic alcoholic patient 4. Patients who have taken systemic or local antibiotic therapy within preceding last 6 months 5. Active periodontal treatment within last 6 months 6. Allergy to methylene blue 7. History of phototoxicity.
Sample size	30 patients with 30 sites in each group hence a total of 90 sites will be evaluated in the study.
Data collection & method	<p>Intraoral examination will be performed for recording the following data (stent will be prepared for each tooth to be taken as reference point)</p> <ol style="list-style-type: none"> 1. Gingival Index (Loe & Silness) 1963 2. Plaque Index (Silness & Loe) 1964 3. Probing Pocket Depth(PPD) with UNC-15 probe 4. CAL: UNC -15 probe <p>Clinical parameter will be evaluated in both the test and control groups at baseline 1,3 and 6 month will be done.</p>
Microbiological analysis	<p>Collection of (GCF) sample will be done using Endodontic paper points and the sample will then be carried in sterile test tube vials containing 2-3 drops of 0.85% NaCl solution and will be immediately sent to laboratory.</p> <ul style="list-style-type: none"> • Lab Procedure:- <p>Growth conditions will be maintained at 37 °C in anerobic gas mixture containing 80% N₂, 10% CO₂, 10% H₂, and the culture medium which will be used is Modified Fries Agar/Broth Medium.</p>



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<p>Statistical Analysis Plan</p>	<p>All the required data will be obtained and statistical analysis will be done by SPSS version 23.0 IBM SPSS (IBM Inc. Chicago). Mean and standard deviation of each group will be calculated and as per requirement, both paired and unpaired t-test will be applied during statistical analysis. Same test can be applied for intergroup comparison. The significance level (p-value) will be set at 0.05 for all the parametric test. If required further statistical analysis will be applied if required in future.</p>
<p><u>ADDITIONAL POINTS FOR ALL EXPERIMENTAL STUDIES</u></p>	
<p>Sponsorship(Yes/No)</p>	<p>No</p>
<p>Conflict of interest</p>	<p>None</p>
<p>Informed consent form in English and Hindi</p>	<p>Consent in English:- MANSAROVAR DENTAL COLLEGE, BHOPAL (M.P.) CONSENT FORM NAME- _____ AGE/ SEX - _____</p>


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ADDRESS-
EMAIL ID-

MOBILE NO .-

I have been informed that Dr. Vrushali nakhale conducting a study for which GCF sample will be taken for laboratory testing. Along with this periodontal examination/systemic examination will also be done. I have been informed that I can withdraw myself at any stage of the study.

I have been explained the procedure and likely consequences of laboratory investigations and treatment procedures. I hereby accord my willingness to undergo the investigations and treatment procedures on my own risk.

Signature/ Thumb impression of patient/relative

Signature of Principal Investigator

Name of the patient/relative


Name of the Principal Investigator.

Consent in Hindi:-

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Proposed Authors in the upcoming publication	<p>Dr. Vrushali Nakhale Dr. Himanshu Khashu Dr. Richa Agrawal Gargava</p>
Principle Investigator	<p>Dr. Vrushali Nakhale Postgraduate Student, Department. of Periodontics, Mansarovar Dental College, Bhopal, Madhya Pradesh.</p>
Supervisor and Guide	<p>Dr. Himanshu Khashu Professor & Head, Department. of Periodontics, Mansarovar Dental College, Bhopal, Madhya Pradesh.</p>


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Co-Guide/s	Dr. Richa Agrawal Gargava Reader, Department. of Periodontics, Mansarovar Dental College, Bhopal, Madhya Pradesh.
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ANNEXURE III- CASE HISTORY PROFORMA

Patient Performa

Enrolment no.

OPD No.

Date:

Name:

Age/sex:

Address:

Phone No.

Occupation:

Education:

Height:

Weight:

BMI

Intra oral examination:



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Gingival index:

17	16	15	14	13	12	11	21	22	23	24	25	26	27

47	46	45	44	43	42	41	31	32	33	34	35	36	37

Plaque index:

17	16	15	14	13	12	11	21	22	23	24	25	26	27

47	46	45	44	43	42	41	31	32	33	34	35	36	37

Calculus score:

17	16	15	14	13	12	11	21	22	23	24	25	26	27
47	46	45	44	43	42	41	31	32	33	34	35	36	37

Probing pocket depth:


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17 16 15 14 13 12 11 21 22 23 24 25 26 27

47 46 45 44 43 42 41 31 32 33 34 35 36 37

Clinical attachment level:

17 16 15 14 13 12 11 21 22 23 24 25 26 27

47 46 45 44 43 42 41 31 32 33 34 35 36 37

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