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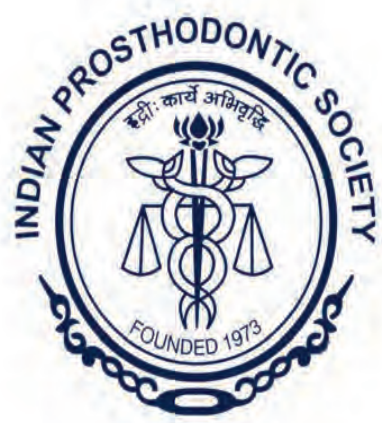

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To serve as a medium for continued prosthodontics education and quantitative scientific publications on clinical trials, basic science related to the biological aspects of prosthodontics, basic science related to prosthodontics techniques as well as orofacial pain that will ultimately improve the prosthodontics research and patient's health and psychological comfort.

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CASE REPORT

Controlling bias in research

Bias in clinical research depart the results systematically from the true values due to lack in standardization of protocol.[1] The high demand for publishing articles in the field of academics and acceptance of research that has positive results by the journals has made the researcher to hasten their research, and focus on desirable study outcome. As a consequence, errors in research are becoming inevitable that could be either systematic or random. A random error could be prevented by increasing the sample size, but Bias, a form of systematic error, is difficult to control as multiple factors are involved.[2] Bias can occur in the planning, data collection, analysis, and publication phases of research. Understanding research bias will help in controlling error in research and avoid suboptimal or potentially harmful treatments rendered to the patients/participants.

Bias differs according to the study design and the error increases when an inappropriate study design is selected for the research hypothesis. The research question that leads to a prospective study design is always better than a retrospective study, unless the research involves a rare disease or condition that requires a proof of concept retrospectively so that a long term research could be planned. Similarly, a randomized controlled trial with a standardized protocol has reduced bias than an observational study design. However, large volume of observational research are being conducted especially when a research is required in short-term for completion of an academic target especially with the graduates.

Among the observational study design, a Cohort conducted in prospective manner has better control of bias than the other observational study**.** Prospective study design begins from an exposure, or a disease or treatment followed up for a specific period; while a cohort can be retrospective when the disease or failure event in a specified cluster is followed back for the presence or absence of exposure. Another method of retrospective study that is undertaken to identify the cause or exposure to a disease is considered as a Case control study. Researcher often confuse with a retrospective cohort and a case-control study. To differentiate between a retrospective cohort and case-control; A retrospective cohort study identifies groups based on the intervention while a case-control study identifies the groups based on their outcome,[3] e.g., occurrence of failure with xenograft around the implant will be a Case control, whereas the effect of xenograft in implant treatment is Cohort. A retrospective design has the probability of high bias due to missing data collected from the patient.[4] Similar to case-control, a cross-sectional observational study also has the disadvantage of missing data. This type of study design is often used to evaluate the prevalence of an event through questionnaires and/or analyse the treatment and outcome at a single point of time. The researcher does not go back or follows an event, but defines the state of event during the specified time.

In contrast to the observational studies that only observe an event, experimental studies (clinical trials) tests a hypothesis. The occurrence of error is possible even with the clinical trial, but comparatively less due to equal distribution of compromising factor in both the control and the test groups due to randomization of population.[5] With the increased submission of research article to the journals, the authors should understand that clinical trial gets more weightage than an observational study design.

At preliminary phase, in search of the cause of a disease, the researcher recruits more exposed (test) than the unexposed (control) leading to an incorrect Measure of association. The selection bias due to the missing data of the patient related information can occur, especially in a retrospective study when data is collected from registries. Inappropriate definition of the eligible population, uneven diagnostic procedure, inaccurate sampling frame are few other reasons for selection bias. Selection bias occurs with the knowledge of the researcher and hence, blinding of patient recruitment is very essential to prevent bias. Allocation concealment is an essential aspect of randomized controlled trials that can avoid selection bias.[6]

Confounding bias can happen without the knowledge of the researcher; a hidden factor that is not considered when including a participant in a group,[7] e.g., to identify smoking as a cause of implant failure, participants included based on smokers and nonsmokers, and we often fail to consider the other risk factors like osteoporosis, diabetes etc., in inclusion criteria. There can be more chance of these confounding factors present in the test participants than the controls. In contrast, the clinical trial has an equal chance of these confounding factors distributed in both the test and control groups due to randomization of the sample, thus preventing incorrect association. A stringent inclusion and exclusion criteria's will help in choosing a homogenous sample and the right comparison group. The collection of data of all possible exposure or risk factors for the occurrence of a disease, a prolonged follow up is essential in preventing the occurrence of selection bias. Hence, a prospective study is always better when compared to retrospective study design to avoid missing data**.** Though selection bias cannot be avoided with observational study; the possible shortcomings should be mentioned as limitations, that would enable the readers to formulate a new research question to test a hypothesis.

During the course of the study, there are possibilities of patient not reporting back or does not prefer to answer a specific question. This nonresponse bias could be converted into an information by obtaining the demographic details of nonrespondent. In coherence with nonresponse bias, attrition bias occurs because of loss of participant due to complication of outcome. Comparing the demographic details of both the respondents and nonrespondents/lost participants, we can convert these biases into a specific demographic information that identifies the reason for nonresponse or loss of participant in the study.

Also, during the course of the study, an information bias can occur with open-ended or ill-defined pre and postoperative questionnaires and the conveying capacity of the investigator with interview based questionnaires to achieve their required outcome. Secondly, the collected information from a register or records can lead to information bias. Moreover, it is essential to use standardized questionnaires to avoid information bias. With the pandemic, the researchers started to use self-made questionnaire that is circulated through google forms. These questionnaires need to be validated using a sub-population of the main group, and later can be circulated for a research purpose. However, we commonly fail to validate the questionnaire and an ethical clearance is mandatory for a questionnaire study. When the patient's reported data are used, the trial design should mask the intent of the question in the structured interview and should use the validated scales for data acquisition. Similarly, a self-administered questionnaire with clear instruction is better than an interview in reducing the information bias. But, the possibility of low response rate is greater and can be managed as discussed in nonresponse bias. Other than the questionnaire study, the information bias also occurs in other observational studies and clinical trials due to nonstandardized equipment. This could be managed by use of standard measurement devices.

In an observer bias, the clinician sees only positive aspect of the test group because he is already aware of the participant group. Also, the clinician may perform the clinical procedure for the test group better than the control group. Blinding, either single, double or triple depending on the research question can reduce most of the biases. Participants also need to be blinded of the group to which they belong, to reduce the performance bias.

Detection bias, measurement bias and instrument bias due to a nonstandardized equipment and lack of training to investigator are few other types that occur in a quantitative analysis.[8] Recall bias occurs when both experiment and disease status are known at the time of study, and the clinician recalls the test (experiment) group more than the control group. A standardized protocol, training of the investigators, blinding, standardized instruments and a control that reveals standard measurement can reduce bias during analysis stage.

The study guidelines Strengthening the Reporting of Observational studies in Epidemiology for observational, Consolidated Standards of Reporting Trials for clinical trial and Consensus-based Clinical Case Reporting Guideline Development) for case report need to be used as a guide as the researcher formulates the research question. This would minimize errors that could occur due to investigators negligence.

Finally, the author should avoid publishing only selective results and hiding the negative aspects during the course of design to avoid publication bias. Also, the editor should avoid selecting publications based on affiliation of the authors causing publication bias.

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Review

To compare different non-surgical treatment modalities on treatment of obstructive sleep apnea: A systematic review and meta-analysis

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Abstract

The study aimed to assess the effect of mandibular advancement device (MAD) in patients with obstructive sleep apnea for reduction in 24-h mean blood pressure, sleep quality, Apnea Hypopnea Index (AHI), and patient compliance, compared to continuous positive airway pressure (CPAP), other interventions, or no treatment. Three different databases such as PubMed, EMBASE, and CENTRAL were searched using different search terms till July 2021 as per the inclusion and exclusion criteria. After inclusion of studies, data extraction including risk of bias assessment was done. For each study, we used odds ratio, mean difference, and 95% confidence interval to assess and synthesize the outcomes. The quality of evidence was evaluated as per the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE). Twenty-one randomized controlled trials were included: 497 patients in the MAD group, 239 patients in the CPAP group, and 274 patients in the sham group. In MAD-CPAP comparison, the results favored CPAP in the reduction of AHI of 3.48 (1.76-5.19). However, unclear results were found for sleep quality measured as Epworth Sleepiness Scale (ESS), patient compliance, and 24-h mean blood pressure. In MAD-sham comparison, the results favored MAD in the reduction of AHI of − 8.39 (−10.90–−5.88] and ESS of − 0.91 (−1.70–−0.12) and favored sham in terms of patient compliance while, unclear results for 24-h mean blood pressure. The GRADE score indicated that the quality of evidence is very low, low, and moderate for different outcomes. CPAP in comparison to MAD and MAD in comparison to sham showed a significant AHI reduction. However, patient compliance and 24-h mean blood pressure were not significantly different in MAD-CPAP or MAD-sham. Quality of evidence is very low and low when MAD was compared with CPAP and sham, respectively, for AHI.

Keywords: Continuous positive airway pressure, obstructive sleep apnea, oral appliance, systematic review and meta-analysis

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INTRODUCTION

Obstructive sleep apnea (OSA) is sleep-related breathing disorder. OSA if left untreated may lead to poor quality of life (QoL), increased chances of road traffic accidents, cardiovascular attack, endocrine, metabolic, urogenital, neurological other systemic disorders like hypertension.[1-3] The prevalence of OSA is 2%–4% in adult population.[4] Gold standard test to diagnose OSA is polysomnography through Apnea Hypopnea Index (AHI), which also indicates severity of OSA. Symptoms of OSA can be daytime and nighttime. Daytime symptoms include daytime sleepiness, morning headache, difficulty in concentration during daytime, awakening with dry mouth or sore throat, experiencing mood changes, and memory loss. Nighttime symptoms include apnea, gastroesophageal reflux disease, loud snoring during sleep, road traffic accidents, decreased libido, sexual dysfunction, and bruxism.[5-7] Treatment of OSA can be surgical or nonsurgical. Surgical management includes pharyngoplasty, uvulopalatopharyngoplasty, nasal surgery, tonsillectomy in adults, genioglossus advancement, maxillomandibular advancement, and adenoidectomy, but these are not acceptable to many patients[8] due to its invasiveness. Nonsurgical management includes continuous positive airway pressure (CPAP), oral appliances (OAs) like mandibular advancement device (MAD) and act as conservative treatment options.[9,10]

CPAP is used as therapeutic as well as diagnostic for OSA patient.[11-14] CPAP works to keep the airway open and therefore prevents airway collapse, improves quality of sleep, reduces mortality rate, reduces high blood pressure, and reduces sympathetic tone during daytime and nighttime.[15-20]

OA improves upper airway configuration and prevents airway collapse through alteration in positions of jaw and tongue.[21-24] OA for OSA patients can either be tongue retaining devices/MADs.[25] The mechanism of action is to protrude the lower jaw more anteriorly and pulls the genioglossus forward, which helps in forward movement of the tongue. This forward movement of the tongue creates more upper airway space, which reduces chances of snoring and improves symptoms of OSA.[25] These OAs are active and protrusion of the mandible can be titrated to various degree according to the need. These are named as MAD or mandibular-repositioning appliance.[26,27]

MADs are popular choice to patients as these are affordable, light weight, and easy to use than CPAP. CPAP is a complete assembly having mask which is attached to the patient's face.[28] This may not be easily acceptable by the patient. Therefore, MADs are recommended in mild-to-moderate obstructive sleep apnea cases.[28-30] This device also stated to eliminate compliance issues with CPAP and therefore may be a treatment of choice for CPAP-intolerant patients.[28]

Sham is nonactive MAD which can be given in upper or lower arch as placebo. Sham has similar design as active MAD or just in the form of a plate with no components attached to it, but unlike active MAD, these do not protrude mandible. Few studies showed no significant change in blood pressure and sleep quality between MAD and sham appliance.[1] Hence, to find the true treatment effect of these physical therapies and to avoid the effect due to possibility of regression to the mean or placebo effect, a comparison with sham is important.

Efficacy of these treatments in OSA was assessed by measuring AHI, sleep quality, blood pressure, snoring events, nocturnal oxygenation, QoL, neurocognitive behavior, and patient compliance. Hence, the aim of the study was to assess the effect of MAD in comparison with CPAP and sham or no treatment for reduction in 24-h blood pressure, sleep quality, AHI, and patient compliance.

METHODS

This meta-analysis was registered in PROSPERO[31] (CRD42020131068) and followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) system.[32] The following databases were searched: Cochrane Central Register of Controlled Trials (CENTRAL); MEDLINE (from 1946 onwards); and EMBASE. Only English-language articles were included without any restriction on date of publication to compare MAD with CPAP, sham, or no appliance in patients with OSA. Details of PICO of meta-analysis were

1. Population (P) was OSA.
2. Intervention (I) were MAD or mandibular-repositioning device, mandibular protrusion.
3. Comparison (C) were CPAP, sham, occlusal splints, or no appliance.
4. Outcomes (O) were reduction in 24-h mean blood pressure, sleep quality (Epworth Sleepiness Scale [ESS]), AHI and patient compliance.

Various search terms including MeSH and Emtree were used as per attached Supplementary Table 1 for different databases. These terms were then combined with different Boolean operator like "AND" or "OR" or "NOT." The authors (JV, PD, and BPS) have done search in these databases. Manual search of reference list of the included studies was also done by one author (PC). Duplicates were

removed in EndNote (version 19), and all articles were exported from EndNote to Covidence[33] for screening of abstracts and full text. Abstract followed by full-text screening was done by the two different reviewers (JV and PD) independently and the third reviewer (BPS) resolved conflicts for screening done by the two reviewers. After full-text screening, data extraction including risk of bias assessment was done in Covidence.

Criteria for study selection

Inclusion criteria for the study were randomized controlled trial (RCT), cross-over trial (first period data were taken), following the above-mentioned PICO criteria, and published in English.

Exclusion criteria for the study were duplicate studies, studies with data errors, irrelevant outcome, case report, letter to editor, conference proceeding, systematic review, or meta-analysis.

For the included studies, data extraction and risk of bias assessment were done in Covidence[33] by the two reviewers (JV and PD) independently and consensus was reached after. For any conflicts, the third reviewer (BPS) was consulted. Data extraction was done in data extraction form of all studies in five sections:

1. Identification details included sponsorship source, country, study setting, author, E-mail, and publication details
2. Methods included design of the study, aim of the study, duration of the study, ethical approval, key conclusions of the study, method of recruitment of patients, and null hypothesis
3. Population included inclusion criteria, exclusion criteria, any group difference, population description, total number randomized, withdrawals, and exclusion of patients
4. Intervention and comparison group included total number randomized, type of intervention and with device or appliance details, number of visits, duration of follow-up, and resource requirement
5. Outcome included AHI, ESS, 24-h mean blood pressure, and patient compliance.

Data analysis was finally filled in RevMan 5.4 software[34] for statistical analyses. For missing data, the corresponding author of studies was contacted.

Risk of bias assessment: It was done as per the Cochrane Handbook of Systematic Review[35] using RoB 1.0 (Risk of Bias 1.0) having following domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessor, incomplete outcome, selective outcome reporting, and other bias if any. Risk of bias assessment was selected for each domain as of low, high, or unclear risk of bias with supporting comments mentioned in the article.

A fixed-effects model was used for meta-analysis to generate forest plot using instructions as mentioned in the Cochrane Handbook of Systematic Reviews.[35] Heterogeneity was assessed using I^2 statistic; if I^2 value was >50%, it was considered substantial heterogeneity. Quality of evidence was assessed through the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) recommendation.[36,37]

RESULTS

Databases were searched till July 2021; out of 305 articles, 41 studies met the inclusion criteria after full-text screening. Twenty-one studies were included for meta-analysis because outcome values in 20 articles could not be synthesized quantitatively.[16,38-56] The study filtering process is depicted in PRISMA flowchart [Supplementary Figure 1].

Summary of characteristic of the included studies is presented in Table 1. Out of 21 studies,[17,19,22,23,57-73] 11 studies compared MAD and CPAP, while 10 studies compared MAD and sham.

In most studies, the follow-up period was 6–12 weeks, but only one longitudinal study[60] has 10 years of follow-up. Two studies are same except the study by Aarab *et al*.,[47] which was 1-year follow-up of Aarab *et al*.[16] Hence, these two studies were merged for risk of bias assessment.

Summary of risk of bias assessment and risk of bias graph is shown in Figure 1. In sequence generation, 70% of studies showed low risk of bias and 30% showed unclear risk of bias. Methods of sequence generation were computer-generated random number,[23,38,42,48,52-54,56,59,62,65,68,69,73,74] block randomization,[16,22,43,44,47,60,71] and block of four.[40,67] Many studies did not mention method of sequence generation.[17,19,39,41,45,46,50,51,57,58,61,63,64,66,70,72,75]

In allocation concealment, 27% of studies showed low risk of bias, 27% showed unclear risk of bias, and 45% showed high risk of bias. Methods of allocation concealment used were sealed opaque envelope,[16,23,47,52,65,66,68] telephonic allocation,[69] flipping card,[50] sequence of arrival,[48] software,[45] and method not mentioned.[17,19,20,22,38-44,46,49,51,53-55,58-64,67,70-73]

Table 1: Basic characteristics of included studies

Study	Design	Severity of OSA	Outcome	Period	Intervention			Sample		
					MAD	CPAP/sham	SHAM	MAD	CPAP	Sham
Banhiran 2018	Cross over	AHI >5	AHI ESS	12 weeks	AT-MAS (SomnoGuard AP; Tomed, Bensheim, Germany)	Transcend AUTO (Somnetics International, New Brighton, MN) with the pressure set at 5–15 cm H2O		43	43	
Mehta 2001	Cross over	Mild to moderate OSA	AHI	6 weeks	MAS was custom made	-	Lower dental plate used as control	12	-	12
Venderveken 2008	Cross over	Mild OSA	AHI ESS	1, 4 months	Soft SR-Ivocap Elastomer (Ivoclar, Vivadent AG; Schaan, Liechten-stein) and provides full occlusal coverage of both dental arches	-	Thermoplastic MAD used in this study was the SomnoGuard plus, a development product designed by Tomed Dr. Toussaint GmbH, Germany	-	-	-
Dal-Fabbro 2014	Cross over	Mild to moderate OSA	AHI ESS 24 h ambulatory blood pressure	4 weeks	Mandibular advancement appliances (the BRD) were individually constructed and installed	CPAP device (REMstar Plus; Respironics Inc., Murrysville, PA, USA)	The lower arch of the same MAD was used	9	17	13
Uniken venema 2020	Longitudinal follow-up study		AHI ESS	3 months, 1, 2, 10 years	Thornton Adjustable Positioner type-1 (AirwayManagement Inc., Dallas, TX, USA)	Breas PV10 (Molnlycke, Sweaden)	-	14	17	-
Petri 2008	Three armed, parallel group design	Mild to moderate OSA	AHI ESS	4 weeks	Type of intervention and its details (type of device/ material and method/ technique and treatment used): The appliances were one-piece, custom-made acrylic dental devices, the acrylic covering only the molars and premolars. The appliance was secured to these teeth by four stainless steel Adams clasps in each jaw. The MAA advanced the mandible to the most protrusive position without discomfort with a 5-mm vertical opening in front	-	The appliances were one-piece, custom-made acrylic dentaldevices, the acrylic covering only the molars and premolars. The appliance was secured to these teeth by four stainless steel Adams clasps in each jaw	33	-	30
Gotsopolous 2004	Cross over	Mild to moderate OSA	AHI ESS	4 weeks	Design features of MAS: Separate upper and lower acrylic appliances anchored onto dental arches and covering the occlusal surfaces of all the teeth. Two acrylisc flanges situated bilaterally on the buccal surface of the	-	Control device (inactive oral appliance)	36	-	37

Contd...

Table 1: Contd...

Study	Design	Severity of OSA	Outcome	Period	Intervention			Sample		
					MAD	CPAP/sham	SHAM	MAD	CPAP	Sham
					lower appliance in the molar region. Two 10 mm "LEWA" screw devices to enable advancement of the slots; this permitsincremental protrusion of mandible					
Nikolopolou 2017	Parallel study design	Mild to moderate OSA	AHI ESS	6 months	This oral appliance holds the mandible and tongue in a protruded position	REMstar Pro system was used (Respironics, Herrsching, Germany)	-	21	22	-
Andrean 2013	RCT	Mild to moderate	AHI ESS 24 h mean blood pressure	3 months	The active OA with mandibular advancement (OAa) was custom-made andof a monobloc design. The OAa protruded the mandible to 70%–75% of the patient's maximum mandibular protrusive capacity (>4 mm)	-	The OAc possessed the same feature as the active device except for the lack of any mandibular advancement (<0.5 mm)	36	-	36
Bamagoos 2019	Parallel study design	AHI>10 events/h with MAS therapy (cutoff of 5 events/h)	AHI ESS Arousal index	6 weeks	MAD (5 mad positions 0%, 25%, 50%, 75%, 100% with advancement in 4–12 mm range)	CPAP	-	17	17	
Blanco 2005	Cross over trial	AHI≥10/h	AHI ESS Compliance SF 36 FOSQ	3 months	Advanced group (Advanced mandible model OA)	-	Nonadvanced group (nonadvanced mandible model OA)	8	-	7
Deane 2009	Cross over trial	AHI≥10/h	AHI Compliance ESS Quality of sleep (arousal index) Subjective snoring frequency and intensity Side effects Patient satisfaction Appliance preference	1 month	MAS: Custom-made 2-piece device (Somnomed Ltd, Australia)	-	TSD: Nonadjustable silicon appliance constructed by injection molding (Aveo-TSD, Innovative Health Technologies, New Zealand)	11	-	11
Cantolla 2015	Randomized, placebo-controlled, double blinded, and crossover clinical trial	Mild-to-moderate OSA (≥5 AHI<30)	AHI Somnolence (ESS) Compliance Sleep characteristics Snoring	12 weeks	MAD The commercial device KlearwayTM (University of British Colum-bia, Vancouver, Canada)	-	Placebo device: The placebo device was the same KlearwayTM device but in centric occlusion and did not provoke mandibular advancement	39	-	38
El Solh 2011	Cross over trial	Confirmed diagnosis of OSA defined as AHI>5 by overnight polysomnography	AHI ESS	3 days	MAD: Mandibular advancement custom-made device	Combination therapy: Auto CPAP plus MAD-nasal CPAP mask and given aREMstar® CPAP	-	10	10	-

Contd...

Table 1: Contd...

Study	Design	Severity of OSA	Outcome	Period	Intervention			Sample		
					MAD	CPAP/sham	SHAM	MAD	CPAP	Sham
						machine (Respironics, Murrysville, PA)				
Ferguson 1997	Cross over trial	Mild to moderate OSA	AHI ESS Compliance Efficacy Side effects Preference	4 months	AMP	nCPAP: Therapy (nCPAP) is a highly effective treatment for OSA, 2 but there can be substantial problems with patient acceptance and long term compliance	-	10	10	-
Gagnodoux 2009	Cross over trial	AHI between 10 and 60 events/h	AHI Sleepiness (ESS, OSLER) Compliance Home sleep study HRQOL Cognitive tests Side effects Preference	8 weeks	MAD: Adjustable bi-bloc acrylic oral appliance (AMCTM; Artech Me´dical, Pantin, France)	CPAP: CPAP device (Sullivan S6EliteTM; Resmed, Bella Vista, NSW, Australia) equipped with a microprocessor and pressure monitor	-	30	29	-
Gagnodoux 2017	Cross over trial	AHI≥30	ESS Compliance AHI 24 h MAP RHI	2 months	MAD (AMO®, Orthosom, Beaucouzé, France). The MAD was custom made, consisting of an adjustable two piece acrylic OA (AMO®, Orthosom, Beaucouzé, France) with attachments of various sizes allowing mandibular advancement adjustment	-	The sham device consisted of the upper appliance only and did not advance the mandible	75	-	75
Goodoy 2017	Placebo controlled clinical trial	AHI≤5	AHI ESS PSQI FOSQ Beck anxiety and depression inventories Multiple sleep latency test PVT	1.5 year	MAD: BRD	-	Placebo: An open arch dental protection plate made of acetate with no effect on upper airway patency	15	-	15
Phillips 2013	Cross-over trial	AHI 10 events per h	24-h MAP 24-h ambulatory BP and central BP and arterial stiffness Neurolgical functional behavior and QOL using FOSQ SF-36 the ESS, and The AusEd driving simulator (Austral-asian Sleep Trials Network, Australia	1 month	MAD: Somnodent (SomnoMed Ltd., Sydney, Australia), a custom fitted and titratable two-piece device	CPAP (ResMed Autoset S8 (ResMed, Bella Vista, Australia)	-	56	52	-

Contd...

Table 1: Contd...

Study	Design	Severity of OSA	Outcome	Period	Intervention		Sample		
					MAD	CPAP/sham	SHAM	MAD	CPAP	Sham
			Side effects Compliance Treatment preference							
Randerath 2002	Crossover trial	AHI of 5/h minimum and 30/h maximum, mild to moderate OSA	AHI Sleep quality (arousal index, respiratory induced arousals) Compliance	6 weeks	ISAD: ISAD (IST; Hinz; Herne, Germany) is an OA for the noninvasive treatment of sleep-disordered breathing	CPAP: (Max II, MAP, Martinsried, Germany; Somnotron, Wein-mann, Hamburg, Germany; and Vector, Hoffrichter, Schwerin, Germany)	-	12	8	-
Tan 2002	Crossover trial	Mild to moderate OSA (AHI between 10 and 49 events/h)	AHI ESS Patient preference	2 months	MAS	nCPAP	-	10	14	-

OSA: Obstructive sleep apnea, CPAP: Continuous positive airway pressure, OA: Oral appliances, OAc: Control OA, OAa: Active OA, TSD: Tongue stabilizing device, ESS: Epworth Sleepiness Scale, SF 36: The short form-36, QOL: Quality of life, HRQOL: Health-related QOL, OSLER: Oxford sleep resistance, RHI: Reactive Hyperemia Index, MAP: Mean arterial pressure, PSQI: Pittsburgh Sleep Quality Index, PVT: Psychomotor vigilance test, BP: Blood pressure, FOSQ: Functional Outcomes of Sleep Questionnaire, MAS: Mandibular advancement splint, BRD: Brazilian dental appliance, MAD: Mandibular advancement device, AMP: Anterior mandibular positioner, nCPAP: Nasal continuous positive airway pressure, AHI: Apnea–Hypopnea Index, RCT: Randomized controlled trials, ISAD: Intra oral sleep apnea device, MAA: Mandibular adjustable appliance, AT: Appliance therapy

In blinding of participants and personnel, 65%, 20%, and 15% of studies showed low, unclear, and high risk of bias, respectively. In blinding of outcome assessor, 65%, 25%, and 10% of studies showed low, unclear, and high risk of bias, respectively.

In incomplete outcome data, 67%, 27%, and 5% of studies showed low, unclear, and high risk of bias, respectively. In selective outcome reporting, 32% and 67% of studies showed low and unclear risk of bias, respectively. Few studies mentioned trial registry number and published studies followed trial document.[17,23,38,48,52,57,60,65,68,71,73]

The GRADE score was very low, low, and moderate for different outcomes and for comparison of MAD-CPAP and MAD-sham or no treatment as shown in Table 2. The main reasons of downgrading of quality were indirectness, high risk of bias, and imprecision.

Forest plot comparing AHI between MAD and sham included nine studies having 237 patients in the MAD group and 233 patients in the sham group [Figure 2]. Out of nine studies, 5 studies[59,62,65,66,70] favored the MAD, but 4 studies[63,64,69,71] gave unclear result. Compared with sham, MAD significantly decreased AHI (weighted mean difference: 8.39, 95% confidence level [CI]: 10.90–5.88). Figure 2 also depicts comparison of AHI between MAD and CPAP. Two studies[17,58] favored CPAP and two studies[60,19] gave unclear results. Compared with MAD, CPAP significantly decreased AHI (weighted mean difference [WMD]: 7.77, 95% CI: 5.89–9.66).

Forest plot comparing 24-h mean blood pressure between MAD and sham included 113 patients in the MAD group and 116 patients in sham [Figure 3]. Three studies included for this outcome and showed unclear result. Figure 3 also shows comparison between MAD and CAPA and found unclear result (WMD: 0.50, 95% CI: −3.41~2.41).

Forest plot comparing ESS between MAD-sham included nine studies having 249 patients in the MAD and 248 in the CPAP groups [Figure 4]. Out of 9 studies, one study[73] favored MAD than sham, and the remaining 8 studies showed unclear result. In comparison to MAD and sham, MAD significantly reduces ESS (WMD: 0.91 CI: −1.70 ~ −0.12). Figure 4 also depicts forest plot of MAD-CPAP for ESS, in which 8 studies were included. For 3 months of follow-up, seven studies favored CPAP than MAD (WMD: 0.31, 95% CI: −0.38~1.01).

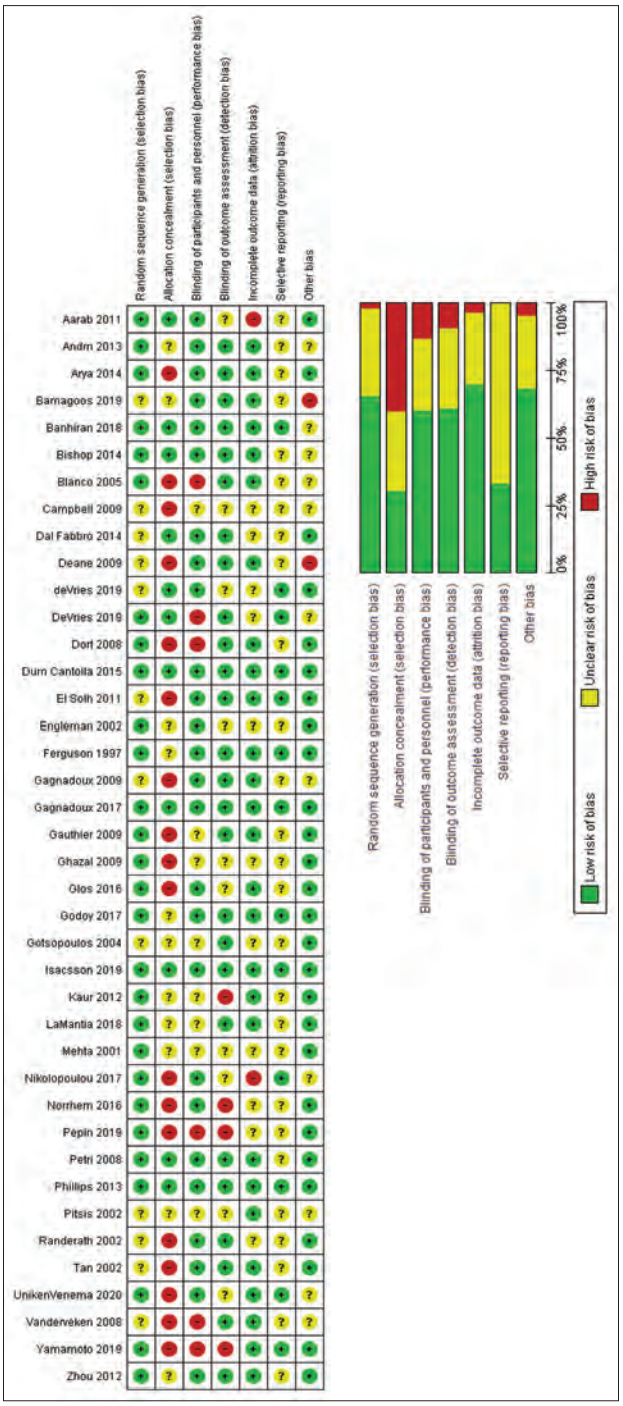

Figure 1: Risk of bias summary and risk of bias graph

Forest plot comparing patient compliance between MAD and sham showed 100 patients for MAD and 902 patients for sham group [Figure 5]. All three studies showed unclear results. Compared with MAD, sham significantly showed better patient compliance (WMD: 0.84 CI: 0.32–1.36) Figure 5 also shows comparison between MAD and CPAP with unclear result (WMD: 0.24, 95% CI: −2.27~2.74).

DISCUSSION

This meta-analysis compared MAD with CPAP, sham in obstructive sleep apnea patients for AHI, ESS, 24-h mean blood pressure, and patient compliance.

Most of the studies have at least one high risk of bias mainly in allocation concealment, blinding of participants, and outcome assessor. Many studies did not register

Table 2: Summary of finding table of MAD versus Sham or no treatment (above) and MAD versus CPAP (below) using GRADE approach

Patient or population: Individual with OSA
Intervention: MAD
Comparison: Sham or no treatment

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Risk with sham	Risk with MAD			
AHI	The mean AHI was 0	MD 8.39 lower (10.9 lower to 5.88 lower)	-	470 (9 RCTs)	⊕⊕◯◯ Low[a, b]
24 h MAP	The mean 24 h MAP was 0	MD 0.11 higher (2.81 lower to 3.04 higher)	-	229 (3 RCTs)	⊕⊕⊕◯ Moderate[c, d]
ESS	The mean ESS was 0	MD 0.91 lower (1.7 lower to 0.12 lower)	-	497 (9 RCTs)	⊕⊕◯◯ Low[e, f]
Compliance (h/night)	The mean compliance (h/night) was 0	MD 0.84 higher (0.32 higher to 1.36 higher)	-	190 (3 RCTs)	⊕⊕⊕◯ Moderate[g, h]

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI), [a]Downgraded by one level for serious risk of bias as majority of studies are unclear risk of bias contributed data, [b]Downgraded by one level for serious Indirectness due to various designs of MAD like monoblock and twin-block and nCPAP or standard CPAP, [c]Downgraded by one level for serious Indirectness due to various designs of MAD like Monoblock and Twin-block and nCPAP or standard CPAP, [d]Downgraded by one level for serious Indirectness due to various designs of MAD like Monoblock and Twin-block and nCPAP or standard CPAP, [e]Downgraded by one level for serious risk of bias as majority of studies are unclear risk of bias contributed data, [f]Downgraded by one level for serious indirectness due to various designs of MAD like Monoblock and Twin-block and nCPAP or standard CPAP, [g]Downgraded by one level for serious risk of bias as majority of studies are unclear risk of bias contributed data, [h]Downgraded by one level for serious indirectness due to various designs of MAD like Monoblock and twin-block and nCPAP or standard CPAP. CI: Confidence interval, MD: Mean difference, OSA: Obstructive sleep apnea, MBP: Mean blood pressure, ESS: Epworth Sleepiness Scale, AHI: Apnea Hypopnea Index, GRADE: Grading of Recommendations, Assessment, Development and Evaluation, MAP: Mean arterial pressure, RCTs: Randomized controlled trials, MAD: Mandibular advancement device, nCPAP: Nasal continous positive airway pressure, CPAP: Continuous positive airway pressure

Patient or population: Individual with OSA
Intervention: MAD
Comparison: CPAP

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Risk with CPAP	Risk with MAD			
AHI	The mean AHI was 0	MD 3.48 higher (1.76 higher to 5.19 higher)	-	91 (4 RCTs)	⊕◯◯◯ Very low[a, b, c]
ESS	The mean ESS was 0	MD 0.31 higher (0.38 lower to 1.01 higher)	-	434 (8 RCTs)	⊕⊕⊕◯ Moderate[d]
24 h MAP	The mean 24 h MAP was 0	MD 0.5 higher (2.41 lower to 3.41 higher)	-	108 (1 RCT)	⊕⊕⊕◯ Moderate[e]
Compliance (ease of use)	The mean compliance (ease of use) was 0	MD 0.31 lower (2.79 lower to 2.16 higher)	-	112 (2 RCTs)	⊕⊕◯◯ Low[f, g]

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI), [a]Downgraded by one level for serious risk of bias as majority of studies are unclear risk of bias contributed data, [b]Downgraded by one level for serious inconsistency as studies show 79% of I square, [c]Downgraded by one level for serious Indirectness due to various designs of nCPAP or high standard CPAP, [d]Downgraded by one level for serious Indirectness due to various designs of nCPAP or high standard CPAP, [e]Downgraded by one level for serious Indirectness due to various designs of nCPAP or high standard CPAP, [f]Downgraded by one level for serious inconsistency as studies shows 73% of I square, [g]Downgraded by one level for serious Indirectness due to various designs of nCPAP or high standard CPAP. CI: Confidence interval, MD: Mean difference, OSA: Obstructive sleep apnea, MAP: Mean arterial pressure, ESS: Epworth sleepiness score, MAD: Mandibular advancement device, CPAP: Continuous positive airway pressure, GRADE: Grading of Recommendations, Assessment, Development and Evaluation, AHI: Apnea Hypopnea Index, ESS: Epworth Sleepiness Scale, RCTs: Randomized controlled trials

prospectively in clinical trial registry which may lead to presenting selective outcome reporting for beneficial outcomes only. This leads to negative impact on certainty of evidence and future studies should focus on methodology for adequate allocation concealment, blinding, and trial registration.

Comparison of outcomes between mandibular advancement device and continuous positive airway pressure

In MAD-CPAP comparison, CPAP showed 3.48 times (ranged from 1.76 to 5.19 times) AHI reduction in comparison to MAD, but certainty of evidence is very low. CPAP is a device which creates pressure stent to open anatomical collapse of upper airway. It comes as an air pressure creating device with tube. The tube may be attached with nasal mask or face mask or simple nasal prongs. CPAP may show 24% better compliance (ranged from − 2.27 to 2.74) to MAD due to otorhinolaryngological reasons in nasal cavity and/or paranasal sinuses such as anatomical, physiological, or pathological. Other reasons of compliance with CPAP may be related to duration of use for effectiveness (>4 h use), side effects such as dermatitis, leakage from mask, claustrophobia, discomfort in nose, and rhinitis. Hence, patients who have mild-to-moderate OSA, not suitable for MAD treatment, or did not get improvement by MAD may take advise from sleep physician or dentist for CPAP. CPAP is also recommended

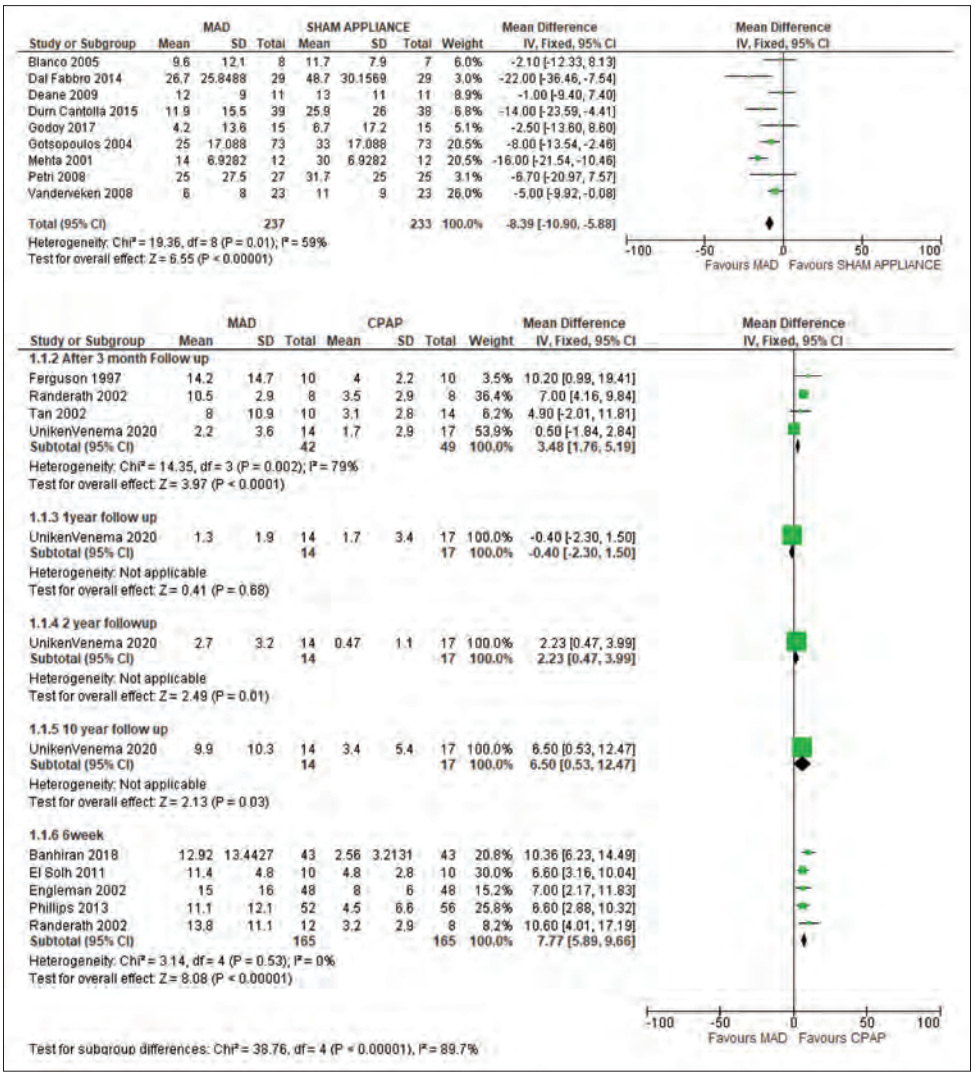

Figure 2: Forest plot interpretation of MAD-sham (above) and MAD-CPAP (below) for AHI. MAD: Mandibular advancement device, CPAP: Continuous positive airway pressure, AHI: Apnea Hypopnea Index

in patients with controlled epilepsy, edentulous, or poor dentition. In case of poor compliance, low adherence due to side effect, or higher cost of CPAP, MAD is a treatment of choice, especially in short term. A meta-analysis by Li *et al*.[76] showed a similar finding with significantly decreased AHI by CPAP over MAD, but no significant difference in ESS. Another meta-analysis by Schwartz *et al*.[30] showed significantly decreased AHI in CPAP group in comparison to oral appliance. A study of Schwartz *et al*. also showed significantly lower compliance of CPAP in comparison to MAD. Studies showed that MADs have better compliance and QoL than CPAP, which leads to favorable side effects, increased usage time, and low rate of withdrawal.[68]

Comparison of outcomes between mandibular advancement device and sham

In MAD-sham comparison, results favored MAD in reduction of AHI, ESS and favored sham for patient compliance and unclear results for 24-h mean blood pressure. MAD is a jaw-repositioning device that repositions the jaw by forwardly protruding mandible and hyoid bone, thus preventing upper airway collapse by contracting genioglossus and increasing retroglossal distance. It has been determined by videoendoscopic and magnetic resonance imaging studies that MAD primarily increases the upper airway volume at velopharyngeal level.[56] The forward advancement of the mandible elevates the base of the tongue and stretches the soft palate, thus helping in improving the air patency. This systematic review also found various designs of MAD, which might influence outcome values.

Earlier data suggest that inactive OA (sham) played a role in the treatment of OSA and may help in lowering AHI levels. However, various RCTs have concluded better efficiency of MAD over sham appliance or placebo.[57-63]

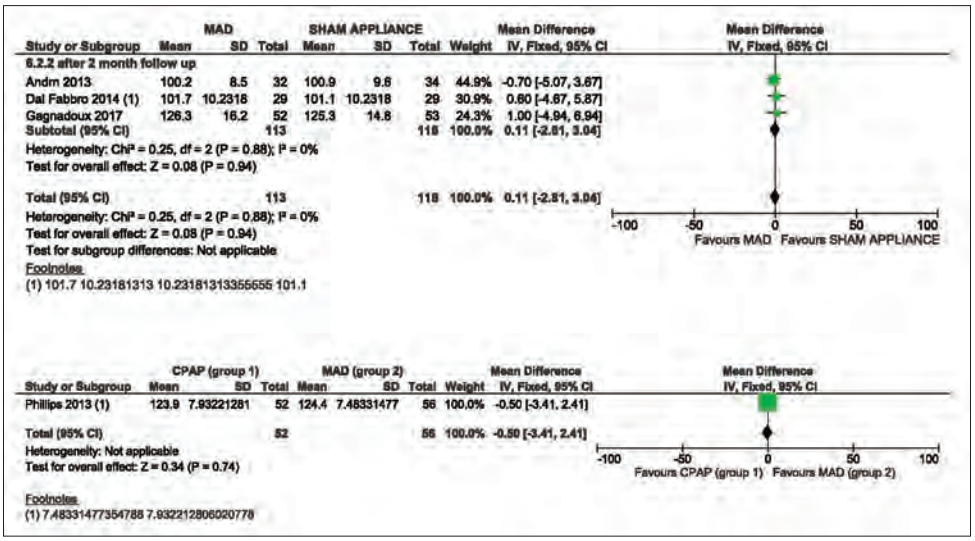

Figure 3: Forest plot interpretation of MAD-sham (above) MAD-CPAP (below) for 24-h mean blood pressure. MAD: Mandibular advancement device, CPAP: Continuous positive airway pressure

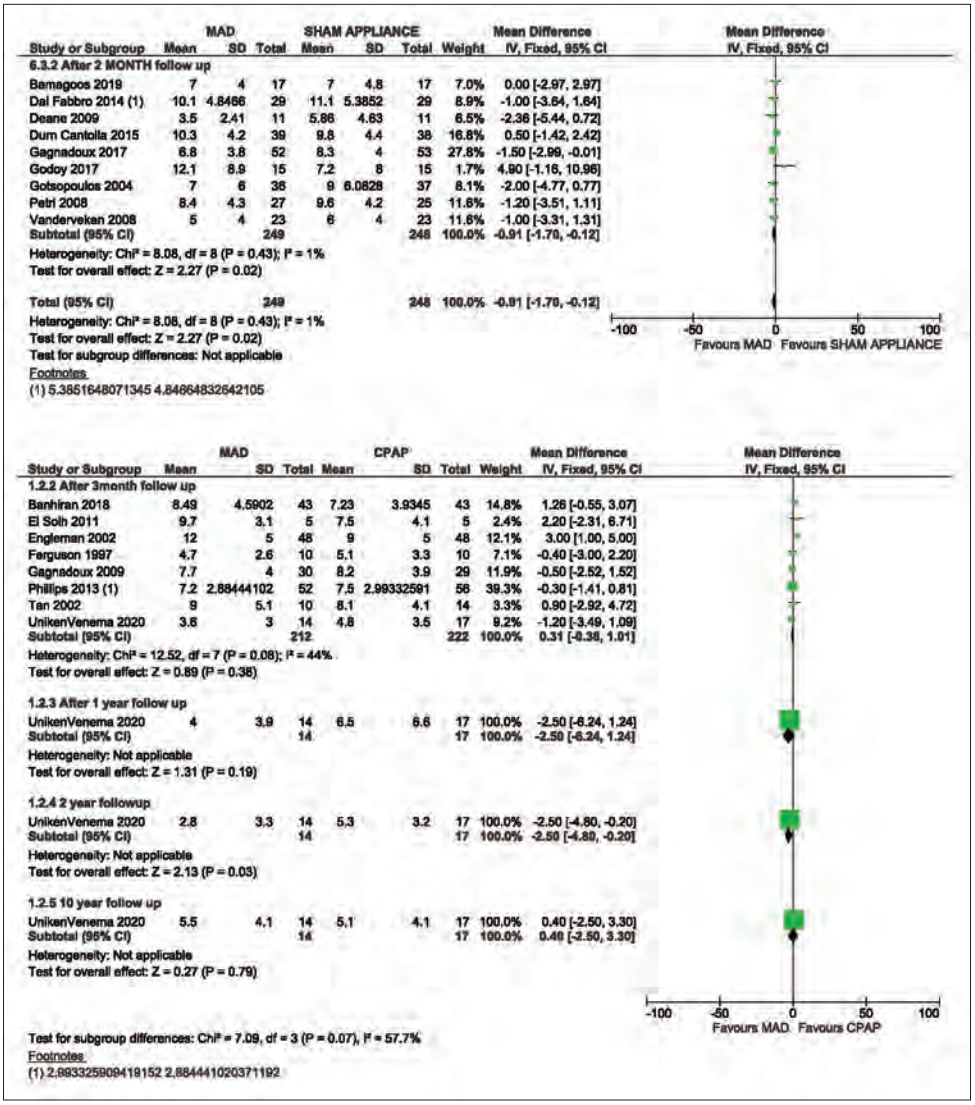

Figure 4: Forest plot interpretation of MAD-sham (above) MAD-CPAP (below) comparison for ESS. MAD: Mandibular advancement device, CPAP: Continuous positive airway pressure, ESS: Epworth sleepiness scale

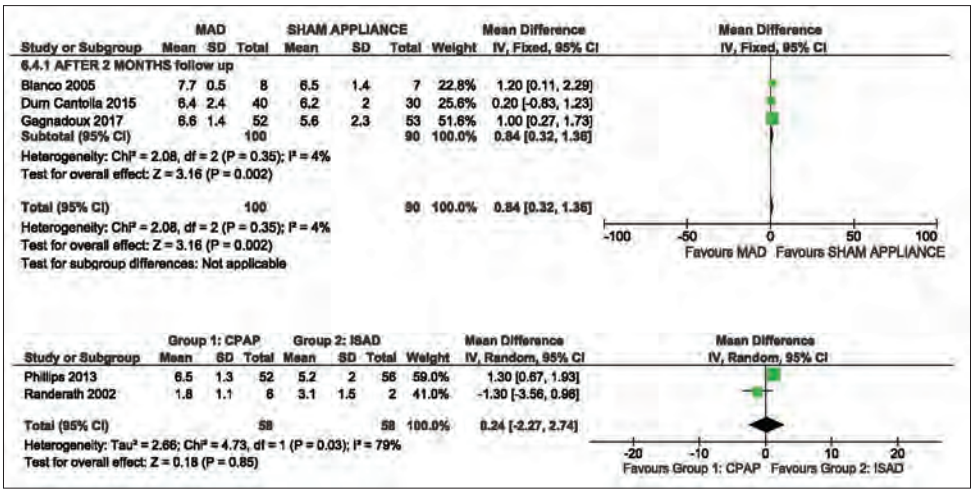

Figure 5: Forest plot interpretation for MAD-sham (above) MAD-CPAP (below) for patient compliance. Mandibular advancement device, CPAP: Continuous positive airway pressure

This study suggests the use of CPAP or MAD in mild-to-moderate OSA. For severe apnea, CPAP is still treatment of choice. For noncompliant patients with CPAP, MAD is recommended and vice-versa if feasible. However, patient education including anatomical, physiological, and pathological condition should be considered for effective treatment.

The GRADE results showed low or very low quality of evidence due to indirectness, high risk of bias in allocation concealment, blinding of participants, outcome assessors, and inconsistency due to heterogeneity in studies. Reason of indirectness was due to various designs of CPAP or MAD was used in different studies.

Various databases were searched: PubMed, CENTRAL, and EMBASE to search the relevant studies related to this meta-analysis. The results of this review are applicable to mild-to-moderate OSA patients with no restriction of gender and age range from 24 to 55 years.

However, there are certain limitations to the present analysis, which are as follows: (1) the number of included studies is limited; (2) individual studies differed in exclusion/inclusion criteria; (3) the courses and detail of therapy were varied; (4) the severity of OSA in patients varied between studies; and (5) pooled data were analyzed, as individual patient data was not available, precluding more in-depth analyses.

CONCLUSION

Continuous positive air pressure significantly reduces AHI in obstructive sleep apnea patients, but quality of evidence is very low in comparison to MAD. Patient compliance and 24-h mean blood pressure were not significantly different when MAD was compared to sham.

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Conflicts of interest

There are no conflicts of interest.

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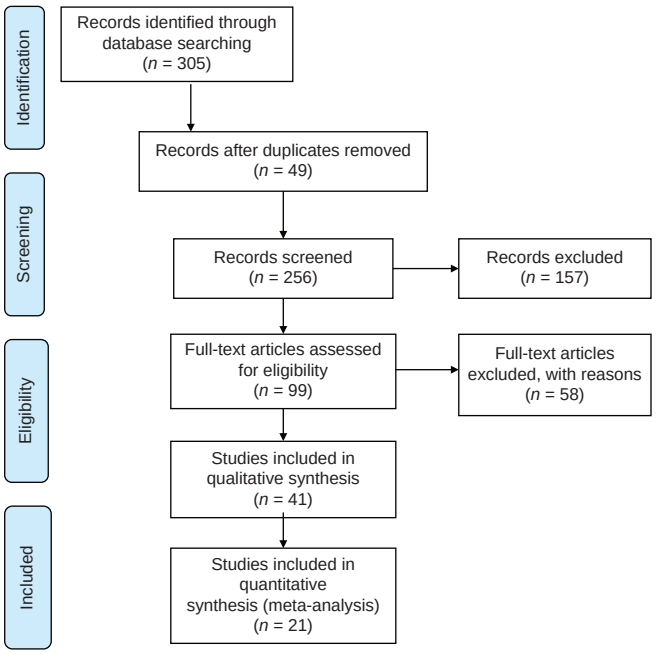
Supplementary Table 1: Search strategy for EMBASE, CENTRAL, PubMed

Search database	Search stratergy
EMBASE	("sleep disordered breathing"/exp OR "apnea, sleep" OR "apnoea, sleep" OR "nocturnal apnea" OR "nocturnal apnoea" OR "obstructive sleep apnea" OR "obstructive sleep apnea hypopnea syndrome" OR "obstructive sleep apnea syndrome" OR "obstructive sleep apnoea" OR "obstructive sleep apnoea hypopnoea syndrome" OR "obstructive sleep apnoea syndrome" OR "obstructive sleep-disordered breathing" OR "sleep apnea" OR "sleep apnea syndrome" OR "sleep apnea syndromes" OR "sleep apnea, obstructive" OR "sleep apnoea" OR "sleep apnoea syndrome" OR "sleep apnoea syndromes" OR "sleep apnoea, obstructive" OR "sleep disordered breathing" OR "upper airway resistance syndrome"/exp OR "upper airway resistance syndrome" OR "apnea" OR "apnoea" OR "periodic apnea" OR "periodic apnoea" OR "obstructive airway disease"/exp OR "obstructive airway disease" OR "upper respiratory tract obstruction"/exp OR "upper respiratory tract obstruction" OR "airway obstruction"/exp OR "airway obstruction" OR "obstructive apnea hypopnea index"/exp OR "obstructive apnea hypopnea index" OR "sleep apnea hypopnea syndrome"/exp OR "sleep apnea hypopnea syndrome" OR "upper respiratory tract disease"/exp OR "upper respiratory tract disease" OR "obstructive apnea"/exp OR "obstructive apnea" OR "breathing disorder"/exp OR "breathing disorder" OR "apnea"/exp OR apnea) AND ("sleep apnea device"/exp OR "sleep apnea device" OR "mandibular advancement device"/exp OR "mandibular advancement device" OR "sleep apnea appliance"/exp OR "sleep apnea appliance") AND ("positive end expiratory pressure"/exp OR "positive end expiratory pressure" OR "positive airway pressure mask"/exp OR "positive airway pressure mask" OR "bipap device"/exp OR "bipap device" OR "cpap device"/exp OR "cpap device" OR "tongue suspension device"/exp OR "tongue suspension device" OR "oral appliance"/exp OR "oral appliance" OR "oral appliance therapy"/exp OR "oral appliance therapy" OR "occlusal splint"/exp OR "occlusal splint") AND ("randomized controlled trial"/exp OR "randomized controlled trial" OR "noninferiority trial"/exp OR "noninferiority trial" OR "controlled study"/exp OR "controlled study" OR "controlled clinical trial"/exp OR "controlled clinical trial" OR "superiority trial"/exp OR "superiority trial" OR "equivalence trial"/exp OR "equivalence trial" OR "double blind procedure"/exp OR "double blind procedure" OR "crossover procedure"/exp OR "crossover procedure" OR "single blind procedure"/exp OR "single blind procedure")
CENTRAL	#1 (OSAHS):ti, ab, kw (Word variations have been searched) in Trials 208 #2 (OSAS):ti, ab, kw (Word variations have been searched) in Trials 3525 #3 (obstructive airway disease):ti, ab, kw (Word variations have been searched) in Trials 3486 #4 (obstructive apnea):ti, ab, kw (Word variations have been searched) in Trials 5346 #5 (obstructive sleep apnea):ti, ab, kw (Word variations have been searched) in Trials 5233 #6 (obstructive sleep apnoea hypopnea syndrome):ti, ab, kw (Word variations have been searched) in Trials 891 #7 (obstructive sleep apnoea hypopnea syndromes):ti, ab, kw (Word variations have been searched) in Trials 891 #8 (obstructive sleep apnoea syndromes):ti, ab, kw (Word variations have been searched) in Trials 2180 #9 (obstructive sleep apnoea syndrome):ti, ab, kw (Word variations have been searched) in Trials 2180 #10 (obstructive sleep apnoea):ti, ab, kw (Word variations have been searched) in Trials 5233 #11 (obstructive sleep apnoeas):ti, ab, kw (Word variations have been searched) in Trials 5233 #12 ("sleep apnoea hypopnoea syndrome"):ti, ab, kw (Word variations have been searched) in Trials 325 #13 ("sleep apnoea syndrome"):ti, ab, kw (Word variations have been searched) in Trials 2312 #14 ("sleep apnoea syndromes"):ti, ab, kw (Word variations have been searched) in Trials 2312 #15 ("sleep apnoea-hypopnea syndromes"):ti, ab, kw (Word variations have been searched) in Trials 0 #16 ("sleep apnoea/hypopnea syndromes"):ti, ab, kw (Word variations have been searched) in Trials 325 #17 MeSH descriptor: [Sleep Apnea, Obstructive] this term only 1844 #18 MeSH descriptor: [] explode all trees 0 #19 MeSH descriptor: [] explode all trees 0 #20 MeSH descriptor: [Sleep Apnea Syndromes] this term only 1216 #21 MeSH descriptor: [Sleep Apnea Syndromes] this term only 1216 #22 #1 or # 2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 962528 #23 #17 or #18 or #19 or #20 or #21 in Trials 2450 #24 #22 or #23 in Trials 950036 #25 (mandibular advancement device):ti, ab, kw (Word variations have been searched) in Trials 212
PubMed	(((((((((Obstructive sleep apnea AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Obstructive sleep apnea patients AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (obstructive sleep apnea syndrome AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Obesity Hypoventilation Syndrome AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Sleep Apnea, Obstructive AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Sleep Apnea, Central AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Sleep apnea AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND ((((Mandibular advancement device AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Mandibular advancement therapy AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Mandibular repositioning device AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Mandibular protrusion device AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND ((((((CPAP AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (continuous positive airway pressure AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Oral appliance therapy AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Occlusal splints AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Sham appliance AND ((randomized controlledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (No appliance AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND (((((Reduction in blood pressure AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Sleep Quality AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Sleep hygiene AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (AHI Index AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) OR (Apnea Hypopnea Index

Contd...

Supplementary Table 1: Contd...

Search database	Search stratergy
	AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter]))) AND ((randomizedcontrolledtrial[Filter]) AND (humans[Filter]) AND (english[Filter])))



Supplementary Figure 1: PRISMA flow diagram

Research

Comparative evaluation of tensile strength, tear strength, color stability and hardness of conventional and 1% trisnorbornenylisobutyl polyhedralsilsesquioxane modified room temperature vulcanizing maxillofacial silicone after a six month artificial aging period

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Abstract

Aims: Silicone elastomers, chemically known as polydimethylsiloxane used in maxillofacial rehabilitation, over a period of time, undergo degradation and discoloration once aged, thereby reducing clinical longevity. Many previous studies reinforced the maxillofacial silicone material with stronger materials to increase its mechanical properties. However, no studies have been conducted to evaluate all the primary properties using single reinforcing agent. This study was conducted to evaluate and compare the tensile strength, tear strength, color stability, and Shore A hardness of conventional and 1% trisnorbornenylisobutyl polyhedralsilsesquioxanes (POSS) modified room temperature vulcanizing (RTV) maxillofacial silicone after a 6 - month artificial aging period.

Setting and Design: *In vitro* comparative study.

Materials and Methods: Eighty-eight silicone samples were fabricated. Therefore for each parameter of tensile strength, tear strength, color stability and hardness, twenty two samples comprising of 11 samples of conventional RTV silicone (Group 1) and 11 for POSS modified RTV silicone (Group 2) were fabricated in stainless steel molds using ASTM D 412–06, ASTM D 624, and ASTM D 2240–15 Standards. Baseline measurements for Shore A hardness and color values were recorded. Samples were then exposed to 6 months of natural weathering process and evaluated for tensile and tear strengths, color stability (ΔE), and hardness.

Statistical Analysis Used: Paired and unpaired *t*-test.

Results: Intragroup and intergroup comparison was done using unpaired and paired *t*-test. At the end of 6-month aging period, the tensile strength and tear strength of POSS-modified RTV silicone were significantly

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higher than conventional RTV silicone ($P < 0.0001$ and $P = 0.00014$, respectively). Intragroup comparison of conventional group showed highly statistically notable changes in L, a, and b values ($P = 0.01631$, > 0.0001, and $= 0.0.0067$, respectively), whereas the POSS-modified RTV silicone showed statistically nonsignificant results in L, a, and b values' ($P = 0.91722$, 0.15174, and 0.10847, respectively) comparisons after aging. Intergroup ΔE value comparisons showed an extremely statistically difference ($P < 0.0001$) within the groups. Intergroup comparisons postaging hardness showed a high statistical difference between both the groups, indicating a significant increase in hardness in the conventional group ($P < 0.0001$). However, intragroup comparison for hardness values showed a statistically highly significant difference for Group 1 ($P < 0.0001$) and a nonsignificant difference ($P = 0.4831$) for Group 2.

Conclusion: After the simulated 6-month aging procedure, 1% NB 1070 trisnorbornenylisobutyl POSS-incorporated RTV maxillofacial silicone showed better tensile strength, tear strength, Shore A hardness and color stability as compared to conventional RTV silicone. Hence, trisnorbornenylisobutyl POSS is a potent cross-linking agent which enhances the primary mechanical properties of RTV silicone can result in in significant increase in the mean life expectancy of RTV silicone even after 6 months of weathering.

Keywords: A-2000 room temperature vulcanizing maxillofacial silicone, color stability, hardness, natural weathering, NB 1070 trisnorbornenylisobutyl polyhedralsilsesquioxanes, tear strength, tensile strength

INTRODUCTION

Maxillofacial prosthodontics is associated with rehabilitation of missing or lost stomatognathic and associated structures by fixed or removable auxiliary alternates.[1,2] Since decades, many different materials have been used for fabrication of maxillofacial prosthesis such as porcelain, natural rubber, gelatin, latex acrylics, and silicones in anaplastology. Among these material, methylmethacrylate resin is used extensively due to its durable nature.[3] However, acrylics have disadvantages of rigidity and polymerization shrinkage. This often leads to staining and unesthetic appearance and hence have been replaced by silicones as the choice for extraoral maxillofacial prosthesis. Silicones are flexible and soft as they mimic the soft tissues.[4] Pigmentation is done with intrinsic and extrinsic stains to mimic soft tissues. Competency of the silicone makes it clear at the corners, which merges smoothly with the adjoining soft tissues, giving an esthetically pleasing appearance. In spite of these advantages, degradation and discoloration are two major limitations associated with silicone maxillofacial prostheses. Once the prosthesis is delivered, it is exposed to light containing ultraviolet (UV) radiation, air that is polluted with dust and changes in atmospheric pressure, all resulting in wearing of silicone prosthesis.[5,6] While resting on human skin for extended period, perspiration and sebum get absorbed into the extraoral silicone prosthesis. However, UV radiation increases cross-linking, but breaks down bones of polymer matrix, lowers down the rate polymerization and degrades the silicone, all of which contribute to colour changes and material deterioration.[7-10] Hence to improve the longevity, many studies have reported use of stronger reinforcing materials. However this has seen limited success.

Silicone elastomers chemically known as polydimethylsiloxane, are widely used due to its unique properties of good consistency, high tear and elongation strength, longevity, good handling properties, improved intrinsic stainability and patient compliance. The essential properties of silicone elastomer depend on the degree of cross linking network, the type and density of filers in the silicone network. Cross-linking of elastomers further depends on type, nature and density of thermal initiator, type of fillers, the reinforcing material, curing temperature and polymerization method.[11-13]

Incorporation of polyhedralsilsesquioxanes (POSSs) as a reinforcing stabilizer and fortifying agent in elastomers has been reported.[14] POSS as a reinforcing agent contains nano-scale organic-inorganic components that form a 1.5 nm silica cage with eight pendant organic groups. This structure helps in more cross - linking and enhances mechanical properties.[15-17] Hybrid molecule will contain a 1.5 nm silica cage with eight pendant organic groups. POSS are hybrid nanoscale agent having to class of discrete organic inorganic hybrids particles.

Studies have concluded reinforving silicone with POSS cross-linker have enhanced mechanical properties.[16,17] Recently, a new interventional POSS named NB 1070 – TrisnorbornenylIsobutyl POSS (Hybrid Plastics, Hattiesburg, MS) has been introduced. It is a colorless liquid and is said to be the most biocompatible with silicone elastomers. Its resin solubility is maximum with

silicone elastomers. POSS moieties have been studied for cytocompatibility, antithrombogenicity, and biostability and hence is biocompatible and medical graded.[18] In addition to its biocompatibility and resin solubility, the liquid nature of NB 1070 may enable a complete homogenous dispersion into maxillofacial silicone, which can probably enhance the properties of interest in maxillofacial silicones. This formed the base for our study's research hypothesis.

A comprehensive search of literature databases yielded only one study conducted by Mohammad *et al.* on the effect of POSS on elongation strength, tear strength of room temperature vulcanizing (RTV) maxillofacial silicone. However, POSS used in this study was the powder form of tris - diimethylvinylisobutyl poss.[19] This study concluded that there was insignificant difference in the tensile strength of silicone at 0% and 5% concentrations of POSS. However, there was notable increase in tear strength of silicone at 1% concentration of POSS. Hence, 1% POSS was used to conduct the study.[19]

No studies have been conducted to compare the effects of POSS on color balance and hardness of maxillofacial RTV maxillofacial silicone. Furthermore, no study exists that has evaluated the properties of maxillofacial silicone after incorporating 1% trisnorbornenylisobutyl POSS. Neither there are studies, that have evaluated the effect of a single cross-linking agent or nanofiller particles on all the mechanical properties such as tensile strength, tear strength, Shore A hardness and color stability of maxillofacial silicone. Hence, this study was planned to measure and compare the effect of trisnorbornenylisobutyl POSS in 1% concentration on tensile strength, tear strength, color stability, and hardness of RTV silicone.

The null hypothesis states that addition of trisnorbornenylisobutyl POSS in 1% concentration in silicone elastomers will not significantly change the tensile, tear, color, and hardness properties of RTV maxillofacial silicone when compared to conventional unmodified RTV maxillofacial silicone.

MATERIALS AND METHODS

The study was conducted after obtaining necessary permission from Institutional Ethics Committee vide approval no: SVIEC/DN/DENT/BNPG/17018002. On the basis of a previous study by Mohammad *et al*.,[19] a minimum sample size derived for the study was 9 to achieve a mean reduction difference between 0% concentration and 1% concentration of POSS with standard deviation of 5.5 at 5% risk and 95% power. However, a sample size of 11 was considered for each parameter of tensile strength, tear strength, color stability, and hardness. Thus, the total sample size of 88 was achieved.

Stainless steel metal dumbbell shaped molds with dimensions of the tensile test bar and trouser shaped molds with dimensions of the tear test bar were made as per ASTM D 412-06 standards,[20] and ASTM D 624 standards,[21] respectively. Samples for color stability and hardness were made from stainless steel metal molds with wells of 30 mm × 06 mm, according to ASTM D2240-15 Standards,[22] were fabricated. All the metal mold assemblies consisted of three parts of 6 mm in dimensions of height, breadth, and thickness that were secured tightly in place by wrench screws.

Silicone samples were fabricated using RTV Maxillofacial silicone elastomer. Factor II A -2000 Part A and Part B (Technovent Ltd, UK) were weighed on an electronic balance. Six drops of Factor II Thixo (Technovent Ltd, UK) was added and the mixture was hand spatulated first and then mechanically mixed at 1000 rpm in a high speed mixture (Phillips, India). Intrinsic Pigments (P499, Technovent, UK) were weighed and added drop by drop in sequence of Intrinsic skin shade Biscuit (P415): 7 drops, Ochre (P416): 19 drops, Ivory (P417): 9 drops, Mushroom (P419): 4 drops, Tan (P412):9 drops, Light Buff (P413): 3 drops, Pink (P410): 13 drops and Dark Brown (P418): 4 drops to obtain appropriate skin color. The final mixed silicone was mixed in a vacuum mixing machine to avoid porosities in final mix. The mixture was dispensed into disposable plastic syringes to avoid air incorporation in the material. The silicone material was then dispensed in the stainless steel molds and was sealed completely with tightening of screws. For Group 2 samples, the same procedure was followed except that Factor II Part A was mixed with 1% concentration of NB 1070 trisnorbornenylisobutyl POSS (Hybrid plastics, Hattiesburg) to form reinforced Part A. To promote miscibility, the mixture was heated at 55°C for 15 min. Then, this mixture again was placed in a speed mixer for 2 min at 3000 rpm. The mixture was then placed in a refrigerator to cool for 1 h to prevent spontaneous curing. This modified Part A (15 g) was then mixed with A-2000 Part B (15 g) along with six drops of Factor II Thixo by spatula and then for 1 min at 1000 rpm in the speed mixture and pigmented conventionally. All stainless steel molds were coated with the talcum powder for easy retrieval of the samples.[23] Once the samples were cured, the excess flash of silicone was removed with sharp scissor or BP blade, respectively. Thus, 88 samples were made, which were free of porosities or any kind of defects.

Baseline measurements of color were made using a spectrophotometer (Premier Model: 5100, color scan, Rayscan Equipments and Services Pvt. Ltd.).[22] The samples were kept near densitometer using white background which measures the degree of light passing through or reflected by a subject. The wavelength reflected back was calibrated and the computer gave the L, a, and b readings.

Baseline measurements for hardness of both the groups were made using Shore A hardness durometer[24] (Tool Center, Digital). The measured hardness was determined by the depth of the impaling indenter under the load. The hardness values were expressed in Shore units (range, 0–100).

Eighty-eight samples were now subjected to artificial aging procedures.[22,25,26] Artificial sebum and acidic perspiration were prepared using reagents and methods as per routine methods.[8,16,27,28] For first 3 months, daily, all the samples were exposed to daylight exposure for 8 hours [Figure 1] followed by exposure to simulated sebum for 16 hours [Figure 2] followed by cleansing for 5 min using neutral soap solution. Further,daily for next 3 months, they were exposed to daylight exposure for 8 hours, followed by exposure to simulated acidic perspiration for 16 hours [Figure 3] and cleansing of samples for 5 min using neutral soap solution. Lastly all the specimens were exposed to dark storage for 24 hours at 50% ± 5% relative humidity by placing wet cotton saturated with distilled water between the samples [Figure 4]. The artificial aging protocol is summarized in Figure 5.

The four properties were now evaluated after the artificial aging procedure. Color values and hardness values were evaluated as per the methodology followed for baseline measurements. From the two values (baseline and after 6 months) ΔL, Δa and Δ b values were calculated. Color change ΔE was measured according to CIELab system using the formula $\Delta E = ([\Delta L]^2 + [\Delta a]^2 + [\Delta b]^2)^{1/2}$ formula. Further the mean ΔE was classified as per the 3 clinically relevant intervals as follows: ΔE <1 (undetectable color alteration); 1< ΔE <3.3 (clinically acceptable color alteration); and ΔE >3.3 (clinically unacceptable color alteration).[29] The color stability was also quantified and evaluated as National Bureau of Standards (NBS)[30] units by using the formula = ΔE × 0.92. The interpretation of the NBS values was: 0.0–0.5 as trace, 0.5–1.5 as slight, 1.5–3.0 as noticeable, 3.0–6.0 as appreciable, 6.0–12.0 as much and >12 as very much.

For evaluating tensile and tear strengths, the samples were fit in Universal Testing Machine (Tinius Olsen 10ST) with 1 KN load cell and measured at cross head speed of 51 mm/min. The tensile strength and percentage elongation were measured automatically by the software using formula Load = Stress (Nm^{-2})/Initial cross-sectional area (mm^{-2}). The tear strength was calculated using the following formula: Tear strength (n/mm) = Load failure in n/thickness of specimen in mm.[31,32]

Figure 1: Exposure of conventional and POSS-modified samples to UV radiations (day light). POSS: Polyhedralsilsesquioxanes, UV: Ultraviolet

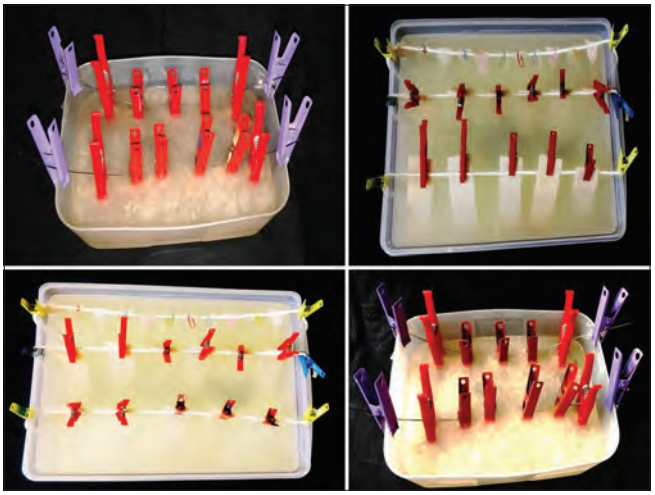

Figure 2: Exposure of conventional and POSS-modified samples to sebum. POSS: Polyhedralsilsesquioxanes

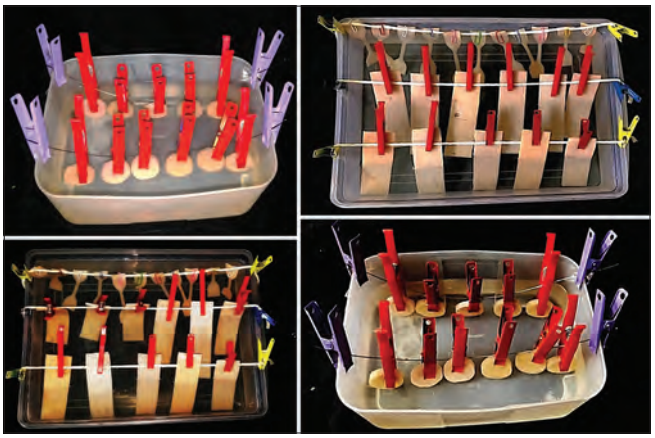

Figure 3: Exposure of conventional and POSS-modified samples to acidic perspiration. POSS: Polyhedralsilsesquioxanes

RESULTS

Tensile strength comparisons using unpaired *t*-test [Table 1] showed that Mean Tensile Strength of Group

2 (POSS-modified RTV silicone) is extremely statistically significant when compared to the mean tensile strength of Group 1 (Conventional RTV Silicone) $P < 0.0001$. Results of unpaired *t*-test for tear strength comparisons [Table 2] also showed that mean tear strength of Group 2 is extremely statistically significant when compared to the mean tear strength of Group 1 ($P < 0.0001$).

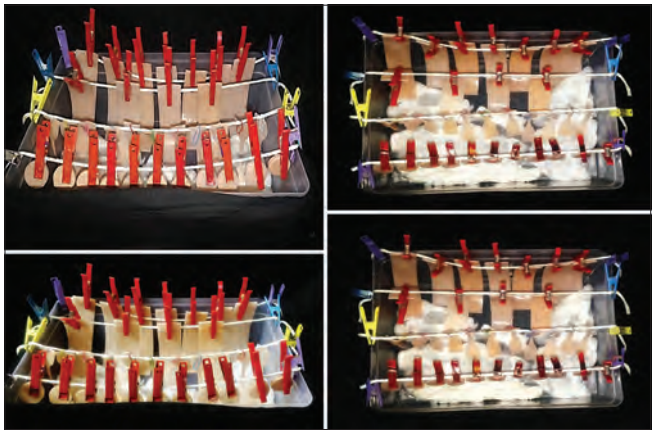

Figure 4: Exposure of conventional and POSS-modified samples to dark room condition. POSS: Polyhedralsilsesquioxanes

Color stability comparisons [Table 3] using unpaired *t*-test showed that the mean ΔE values of Group 2 (POSS-modified RTV silicone) were extremely statistically significant when compared to the mean ΔE values of Group 1 (conventional RTV silicone) ($P < 0.0001$). The ΔE values obtained were expressed and interpreted according to the NBS.[33] Accordingly, to the NBS units interpretation, the ΔE value for Group 1 (4.9174) is interpreted as appreciable change and ΔE value for Group 2 (1.189) is interpreted as slight change. As per clinical relevance classification,[29] ΔE for the Group 1 was 5.345, which was clinically unacceptable, and ΔE for the Group 2 was 1.293064, which was clinically acceptable.

The results of the hardness values for intergroup and intragroup comparisons are shown in Table 4. Baseline comparisons for mean Shore A hardness values of Group

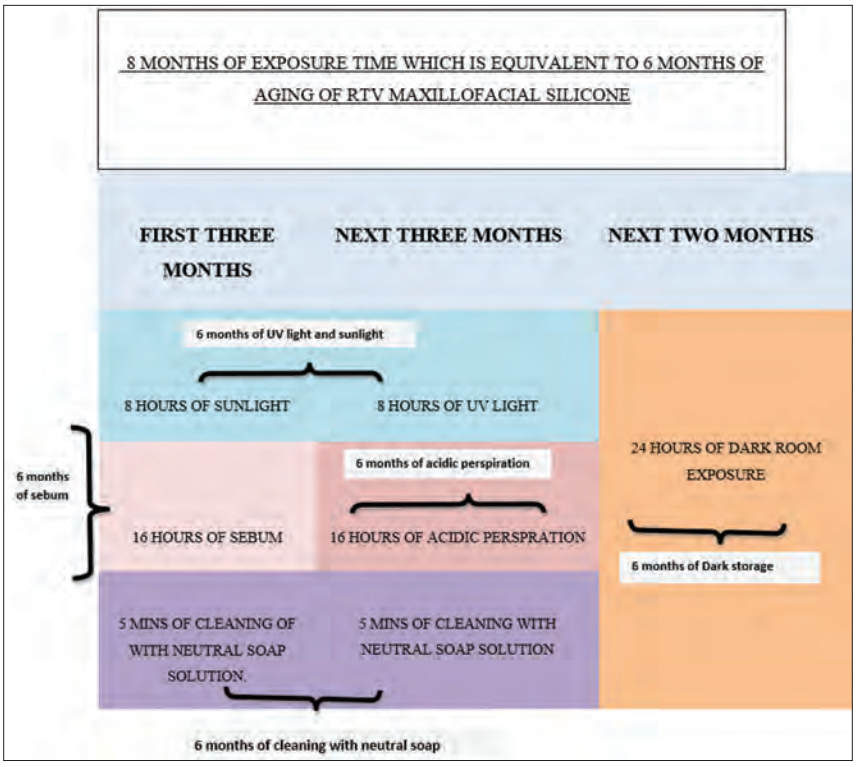

Figure 5: Form of exposure of all the samples which is equivalent to 6 months of aging of RTV maxillofacial silicone is given in tabular form below. RTV: Room temperature vulcanizing

Table 1: Summary statistics of the unpaired *t*-test comparison between conventional (Group 1) and polyhedralsilsesquioxanes modified (Group 2) room temperature vulcanizing silicone for tensile strength

Tensile strength (Mpa)	Group 1	Group 2	*T*	Df	Standard of difference	CI	*P*	Interpretation
Mean±SD	2.5536±0.6295	3.9391±0.5067	5.6866	20	0.244	0.8772-1.8937	<0.0001	Extremely statistically significant
SEM	0.1898	0.64824						
n	11	11						

SD: Standard deviation, SEM: Standard error of mean, CI: Confidence interval

Table 2: Summary statistics of the unpaired *t*-test comparison between conventional (Group 1) and polyhedralsilsesquioxanes modified (Group 2) room temperature vulcanizing silicone for tear strength

Tear strength (N/mm)	Group 1	Group 2	*T*	Df	Standard of difference	CI	*P*	Results
Mean±SD	42.2482±1.8786	56.0636±7.3757	6.0202	20	0.295	−18.6024–−9.0285	<0.0001	Extremely statistically significant
SEM	0.5664	2.2238						
n	11	11						

SD: Standard deviation, SEM: Standard error of mean, CI: Confidence interval

Table 3: Summary statistics of the unpaired *t*-test comparison between conventional (Group 1) and polyhedralsilsesquioxanes modified (Group 2) room temperature vulcanizing silicone of (ΔE) values after 6 months of aging

Color change (ΔE)	Group 1	Group 2	*T*	Df	Standard of difference	CI	*P*	Interpretation
Mean±SD	1.293064±0.6268555	1.293064±0.4815345	17.006	20	0.238	−4.5504017–−3.5560983	<0.0001	Extremely statistically significant
SEM	0.1890040	0.1451881						
n	11	11						

SD: Standard deviation, SEM: Standard error of mean, CI: Confidence interval

Table 4: Summary statistics of the inter- and intragroup comparison between conventional (Group 1) and polyhedralsilsesquioxanes modified room temperature vulcanizing silicone (Group 2) for shore A hardness at baseline and after 6 months of aging

Group	Mean	*T*	Df	Standard of difference	CI	*P*	Interpretation
Group 1: Baseline	19.8145	1.3149	20	0.362	−1.2320-0.2793	0.2034	Nonsignificant
Group 2: Baseline	20.2909						
Group 1: Postaging	26.01800	13.1511	20	0.433	−6.594–−4.788	<0.0001	Extremely statistically significant
Group 2: Postaging	20.32700						
Group 1: Baseline	19.8145	18.8194	10	0.298	−6.263–−4.937	<0.0001	Extremely statistically significant
Group 1: Postaging	26.01800						
Group 2: Baseline	20.2909	0.7283	10	0.217	−0.6421-0.3257	0.4831	Nonsignificant
Group 2: Postaging	20.32700						

CI: Confidence interval

1 and Group 2 were statistically nonsignifiant $P = 0.2034$. However, hardness values between the groups after 6 months of artificial aging were extremely statistically significant $P < 0.0001$. Intragroup comparisons (baseline vs. Post aging) was statistically significant $P < 0.0001$ for Group 1 and non significant for Group 2 $P = 0.4831$.

DISCUSSION

The importance of good looks for social expectance and success has always been overemphasized.[34] Patients having acquired or congenital craniofacial defects have non pleasing facial features that affect an individual's day to day, personal and social interactions. With maxillofacial rehabilitation, the patient's negative approach can be reviewed into a positive approach.[35]

In relation to extra oral defects, when it comes for the fabrication of prosthesis for maxillofacial defects, choice of material is utmost important to replicate the hard and soft tissues. The most favorable qualities include biocompatibility, translucence, color stability, texture, resistance to tear due to physical and chemical insults, and a tactile sensation of softness. Silicone elastomers are flexible and soft and are thermal insulators. They have good oxidative stability. Moreover, they can be pigmented to mimic soft tissues by intrinsic and/or extrinsic stains, which gives prosthesis life like natural appearance.[36]

The choice of the RTV silicone has been inundating. Studies have demonstrated high-temperature vulcanizing (HTV) silicones to be superior in terms of strength, hardness and stiffness than RTV silicone. The prime limitation of HTV silicone is its processing. HTV silicones are less translucent, have more stiffness, have low edge strength, and are very sensitive in processing[2,37-39] when compared to RTV silicone. Addition RTV silicones exhibit better mechanical properties apart from ease in fabrication of moulds, manipulation, intrinsic and extrinsic coloring. They are color stable and biological inert when compared to other silicones.[40]

Nevertheless, with any type of silicone, even with improved properties, there is no ideal silicone having all favorable properties which can increase the longevity of maxillofacial prosthesis.[41] Discoloration of prosthesis and deterioration over natural aging are the most serious problems associated with currently available maxillofacial silicones. Physical degradation of material properties results in difficulty in prosthesis repair and shortens life span of prosthesis up to 6 months. However, it also depends on patients' personal habit, climate, and environment, which leads to frequent change of prosthesis over short period of time.[42]

Since past few years, there were various attempts to reinforce the maxillofacial silicone due to its very short mean life expectancy. Various studies have evaluated reinforcements with medical fluids, titanium opacifiers, UV mineral based light protecting agent, nano oxides of titanium, zinc and cerium, UV stabilizers, titanium dioxide nanoparticles and nano ceramic fillers.[16,26,28,29,31,35] Reinforcing fibers of tulle, polyester, polyurethane, propylene, nano - reinforcements of zinc oxide, titanium, barium sulfate, silica and carbon nanotubes have also been reported to improve properties of maxillofacial silicone.[43,44] However, in accordance with all the previous studies, there is no single cross-linking or nanoparticles or oxides reinforcing agents used in a research which has evaluated all the primary properties of maxillofacial prosthesis. Taking all the above consideration, this study was conducted to evaluate the primary properties (tensile strength, tear strength, color stability, and hardness after 6 months of aging using a single reinforcing cross-linking material known as POSS).[19]

The POSS belongs to a class of compact three-dimensional architecture consisting of organic and inorganic compounds with cage dimensional structure with unlike degrees of symmetry, topologically equivalent to a sphere. POSS molecules are easily miscible with polymeric resins. POSS and resins form a soluble compound which forms single-phase material. Among the family of silsesquioxanes, the oligomeric composites can be bifurcated into two main groups: the fully dense POSS and the partially dense POSS. Fully dense POSS represents a fully compact closed architect with the silicone atoms placed apically. Partially dense POSS is an open cage with dangling Si-OH groups. Hence, the large variety of completely concentrated and partially concentrated POSS can refer to the general formula RnSinO1.5n.[45] POSS is a medically graded cross-linking agent. It has also been tested as a biomaterial and was first introduced in breast surgery. Its biocompatibility can be due to the foci of areas that are silicone rich with enhanced surface free energy. POSS molecules are not toxic in nature and cytocompatible.[46]

Hamza *et al.* in 2014 studied the flexural strength and color change of 4 commercially available interim materials modified with 1 wt% POSS and concluded that 1% POSS-incorporated samples did not show any significant differences in color stability with coffee.[47] A study conducted by Shi *et al.* in 2014 concluded that the thermal stability improved by cross - linking of POSS into new networks of polydimethylsiloxane (PDMS).[48] Chen *et al.* in 2010 studied the synthesis, intrinsic and extrinsic characterization of novel RTV silicone rubbers by addition of Vinyl - POSS as reinforcing cross - linking agents.[49] They concluded that the mixture was thermally stable thereby increasing mechanical properties. Stiffness of these RTV silicones improved because of the closed and open concentrated caged networks in PDMS matrix.[50]

Only one study by Mohammad *et al.* in 2010 evaluated the primary properties by incorporating POSS in different concentration (0%, 0.5%, 1%, 2%, and 5%) in RTV maxillofacial silicone and concluded that tensile strength did not differ between 0% and 5% concentrations of POSS, respectively. However, there was marked increase in tear strength of silicone at 1% concentration of POSS.[19]

State of the matter plays a crucial role in miscibility and homogeneous mixture of solutions. When solutions are made using compound of same state of matter, the final solution prepared would be more homogeneous than using compounds of different state of matter.[50] This formed major part for the research hypothesis and hence hypothesized that incorporation of liquid POSS agent may improve the primary properties of RTV silicone. In order to have complete homogeneous mixture and good miscibility and to ensure uniform dispersion of POSS particles into polymer matrix of RTV silicone, liquid NB 1070 trisnorbornenylisobutyl POSS was chosen.

The tensile strength of POSS-modified RTV silicone significantly increased than conventional RTV silicone after a natural aging for 6 months. The trends in the results for tensile strength and tear strength in the present study were similar with the results of the study conducted by Mohammad *et al.* in 2010, where the tensile strength was maximum at 1% dimethylvinyl isobutyl and tris-dimethylsilane isobutyl POSS concentration. The strength values were in accordance with the clinically accepted range (2.5–6.5 N/mm^2 or Mpa).[19] After incorporation of NB 1070 POSS in A - 2000 RTV silicone, the modulus of elasticity and yield stress decreased significantly both in tension and compression. In tension, the silicone with NB 1070 POSS yield at 14% strain and the modulus reduces with increase in POSS concentration.[50] The yield stress, however, decreases with increase in POSS concentration. In terms of cross-networking density, ideally for NB 1070 POSS-incorporated silicone, the yield stress would increase due to the greater cross - link density. However, this was not observed; the yield stress decreased with POSS loading, thus resulting in increase in resistance to tensile load.[51]

The tear strength of POSS-modified RTV silicone was significantly higher than conventional RTV after a natural aging for 6 months and was in accordance with clinically

acceptable values (26–60 n/mm).[29] Tear strength increased on the interaction between the NB 1070 POSS cross-linker and the polymer chains, respectively. NB 1070 POSS being readily miscible has good surface area to maximize the polymer/POSS interactions. Thus, the POSS modified A-2000 RTV silicone resulted in a polymer matrix that is able to withstand significant weathering conditions without deterioration and degradation. The silicone modification by the reinforcing material readily and effectively slides the polymer chains over POSS, thereby making the mixture, a more flexible network which enhances mechanical strength.[52]

Color change calculated as ΔE values for inter-group comparison showed highly statistically significant difference between the groups. POSS modified silicone showing less color change. In addition, ΔE comparisons were further evaluated on color interpretation indices viz. NBS standards and clinical acceptability index. This was done to identify if the samples that showed color change to statistically significant level were clinically acceptable or not. Both the indices interpreted color change in conventional group RTV silicone to be clinically discernible and evident. On the other hand, according to both indices, POSS-modified RTV silicone samples did not show clinically perceivable change in color, thus making it acceptable for clinical use even after 6 months of aging. A direct and indirect comparison of the color stability results obtained in the present study cannot be made with any of the studies available in literature. The present study is first of its kind to evaluate color stability in POSS incorporated maxillofacial RTV silicones.

The reason for high color stability of POSS-modified RTV silicone can be explained on the basis of its chemistry. Alkyl groups break the POSS cage at eight corners of silicone-oxygen bond. The structures of POSS have relative stronger Si-O bonds; however, C-H, C-C, and C-Si are significantly weaker. On exposure to a severe natural aging environment, including tropical heat, high-energy ion beams and oxygen plasma, only Si-O bonds can survive, while others undergo degradation and form volatile organic compounds. More importantly, the bonded Si-O bonds can further form a SiO2-like surface layer on the POSS etching and consumption. Due to exceptional oxidation resistance, POSS structured nano-composite is a promising material that can be utilized for manufacturing photo oxidative resistant materials. Hence, the POSS cage has shown the photo-oxidative stability to polymers through a passivation mechanism.[53,54]

Baseline comparison of hardness in both the groups showed statistically non-significant difference, indicating that the samples were equally soft at the beginning of the study. After 6 months of aging, there was high marked difference between both the groups, indicating a significant increase in hardness in the conventional group ($P < 0.0001$). On the other hand, intragroup comparison showed statistical non - significance for the POSS modified RTV silicone and statistically highly significant difference in the conventional silicone group. This means that POSS incorporation helps RTV silicone to retains its softness over 6 months period. Intergroup comparison at 6 months also showed marked significant change between the two groups with POSS-modified group showing lesser loss of softness as compared to conventional RTV silicone. The reason why hardness values did not alter significantly in the POSS modified group can be explained by the nature of POSS bonds in silicone. NB 1070 POSS moieties consist of stronger Si-O bond, which is not degraded even after exposure to environmental factors. The NB 1070 POSS is hydrophobic in nature; hence, the penetration of sebum, perspiration, and water in highly humid climate is significantly reduced. Due to strong Si-O bond, the leaching of the components of RTV silicone is reduced resulting in less rigid material and maintaining its flexibility.

Due to similarity of structure of NB 1070 POSS and maxillofacial RTV silicone, the bond strength remains stronger even after exposure to the natural environmental factors; hence, all the mechanical properties are maintained with little degradation.[47] Hence, NB 1070 is a potent reinforcing agent which has improved all the primary mechanical and physical properties of RTV silicone. Therefore, they null hypothesis is rejected for all the four parameters.

Literature exists on incorporation of various reinforcing agents but is scarce with respect to evaluation of effect of a single agent on all the primary properties viz., tensile strength, tear strength, color stability, and hardness. Further it may be noted that values for all the properties tested in the present study for conventional and POSS-modified RTV silicone were well within the clinically acceptable standards prescribed for clinical use of any maxillofacial silicone.

Results of these study though may not be immediately extrapolated to clinical situation; however, it has given pathways and avenues for further clinical research. The study has a few limitations. The effect of adhesives on the properties of the two groups was not evaluated. In future, the effect of adhesives and an aging time of more than 6 months can be evaluated as clinical studies making the study more externally valid.

CONCLUSION

Incorporation of 1% NB 1070 trisnorbornenylisobutyl POSS in RTV maxillofacial silicone shows a significant improvement in tensile strength, tear strength, and hardness and improved color stability as compared to conventional RTV silicone after the simulated 6-month accelerated aging procedure. Incorporation of 1% NB 1070 trisnorbornenylisobutyl POSS into RTV silicone improves properties and can prolong the life of maxillofacial RTV silicone.

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Conflicts of interest
There are no conflicts of interest.

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Research

Stability of implant–abutment connection in three different systems after fatigue test

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Abstract

Aim: Abutment screw loosening of implant-supported prosthesis causes a mismatch between the abutment and the implant. This screw loosening is influenced by the implant–abutment connection type, however, with contradictory results reported in different studies. The present study evaluates the stability of abutment–implant connections in three different systems before and after the fatigue test.

Settings and Design: Thirty implants (4.3 mm in diameter and 12 mm in length) were divided into three groups of 10: Implantium, Zimmer, and straight internal hexagonal connection (SIC) implants.

Materials and Methods: Two torques of 35 Ncm with an interval of 10 min were applied, followed by measuring removal torque value (RTV). The samples were re-torqued and then underwent a simulation of 1-year chewing clinical performance of dental implant under axial force of 400 N, with a frequency of 8 Hz (one million cycles). After fatigue test, the RTV was calculated and recorded.

Statistical Analysis: The mean RTVs obtained before and after cyclic load were analyzed by SPSS version 22 software using multivariate analysis.

Results: Significant differences in RTV and role of cyclic loading were found between SIC and Implantium groups ($P = 0.006$ and 0.021, respectively), as well as between Zimmer and SIC groups ($P = 0.032$ and 0.006, respectively), but not between Zimmer and Implantium groups ($P = 0.771$ and 0.248, respectively).

Conclusion: The type of connection could affect the screw loosening, the preload loss, and the implant component stability. SIC group revealed the highest RTVs before and after cyclic loading.

Keywords: Dental implant, fatigue, reverse torque, screw loosening

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INTRODUCTION

Replacing lost or missing teeth with implant has become the first treatment plan in many situations.[1] It is important to pay special attention to technical and biomechanical parameters along with esthetic issues. Unfortunately, most implant manufacturers do not discuss the potential

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problems with their designed connection systems.[2] Therefore, many studies have been conducted to achieve a precise and consistent connection between implant components.[3-6]

At present, the implant manufacturers fabricate two types of implant connections, including (1) butt joint or slip-fit joint with a completely passive connection and a small space between the implant and abutment and (2) conical interface connection designed based on friction fit. These two groups are divided into subcategories of internal hexagon, internal octagon, external hexagon, and other varieties.[7]

A screw is used to fix an abutment on an implant with the aid of a connection and helps to stabilize the abutment–implant system components. One of the greatest complications in cement/screw-retained prostheses is the screw loosening that causes the implant–abutment mismatch after occlusal loading of the prosthesis.[8,9] Due to the screw loosening, the combination of horizontal and vertical misfits causes a gap formation between the components, thereby resulting in bacterial plaque accumulation, nonadherence to health, gingivitis,[10,11] peri-implantitis, bone loss, and screw fracture.[12] One of the success factors in implants with a single prosthesis is the stability of their components. As oral function causes tendency for the abutment screw loosening, the torque plays an important role in the integrity of implant–abutment interface and may reduce the possibility of abutment screw loosening.[13] The screw torque value determines the preload level, which is distributed over the contact surfaces of the implant–abutment–screw threads, and some will be spent to overcome friction.[14] The stretching of implant and abutment screw threads creates a compressive force between the prosthetic components and holds them together.[15] In addition to preload, another major factor affecting the stability of implant and prosthetic components is the conical geometry between implant and prosthetic components in different abutment–implant connections.[16,17]

There are few studies evaluating the removal torque value after fatigue test in different implant–abutment interface designs, most of which compare the internal against the external designs. Therefore, the purpose of this study was to determine the removal torque value (RTV) in geometrically different internal connections of three different implant systems before and after the cyclic load test. The first null hypothesis was that there is no difference in RTVs, before and after cyclic loading, between three studied systems. The second null hypothesis considered that the cyclic loading has no effect on RTV in the three studied systems.

MATERIALS AND METHODS

In this experimental study (approved ethical No.394843), the sample size calculation in each group was defined in accordance with $d = 2.5$ and $\alpha = 0.05$. A total of 30 implants (4.3 mm in diameter and 12 mm in length) were categorized into three groups ($n = 10$): (a) Implantium with conical connection as 11° internal hexagon, (b) Zimmer (paragon) with conical connection as 8° internal hexagon, and (c) SIC with butt joint connection as internal hexagon with completely parallel walls. A computer-generated randomization was used in this study. The implants were mounted in the epoxy resin using the parallelometer in the mounting jig of chewing simulator CS (SD Mechatronik) to ensure the parallel placement of the implants and were standardized to perform subsequent cyclic loading.[18] This set has an elastic modulus of about 20 GPa, similar to the bone.[19] Prefabricated abutments were used to restore the coronal part. The antirotation standard abutments of corresponding system were applied for each of the three groups. To harmonize the conditions of applying force to the samples after mounting in the epoxy resin, the abutments were matched in height from the implant platform to the same length in the Milling Machine (Surveyor/Milling Machine Song Young). For torque application, the samples tightly closed in a clamp were placed under a force of 35 Ncm by a Cedar DID-4 digital torque meter (Sugisaki Meter Co., Ltd). After 10 min, the samples were re-torqued with a force of 35 Ncm according to the method specified by Khraisat *et al*.[20] in 2004 to achieve the maximum preload on the samples. After 2 min of the second torque, the RTV was measured and recorded based on the method described by Khraisat *et al*.[20]

The samples were then re-torqued according to the previous method. To create the moment arm for the loading process, identical hemispherical zirconia crowns were machined, sintered, and cemented over the implant–abutment assembly with polycarbonate cement. The models were then placed in the chewing simulator CS (SD Mechatronik) for the cyclic loading process. Jemt *et al*.[21] showed that most of abutment screw loosening occurs in the 1st year of function, and this then decreases over time, followed by an axial force of 400 N with a frequency of 8 Hz with 1-mm vertical and horizontal range of motion at a rate 1 mm/s to 1 million cycles. Artificial saliva was used to model oral conditions in the test environment. In the application of force to prevent damage to the device and to avoid the wear process in the head of the device and abutments, the simulator area was made of titanium grade 4. An axial load of 400 N with a frequency of 8 Hz was applied. Each of the samples was left in the device

for about 2 weeks to reach a millionth fusion cycle. This was the simulation of 1 year of clinical implantation.[22] After the fatigue test, RTVs of the samples were calculated and recorded by the digital torque meter, as described above. The mean RTVs before and after cyclic load were computed, and the data were inserted into the SPSS version 22 (IBM, NY, USA) software and then analyzed by one-way ANOVA and repeated-measures ANOVA tests. The RTVs before and after cyclic loading were evaluated.

RESULTS

In all samples, the RTV was reduced relative to the initial removal torque, and this reduced RTV was higher after the cyclic loading process. The mean RTVs are presented in Figure 1. Based on one-way ANOVA, there is a significant difference in the mean RTVs of abutment screw between the three groups before the cyclic loading process ($P = 0.006$). *Post hoc* Tukey's HSD showed no significant difference between Zimmer and Implantium groups ($P = 0.771$). There was a significant difference between SIC and Implantium groups ($P = 0.006$), as well as between Zimmer and SIC groups ($P = 0.032$) [Table 1]. Considering the difference in the groups before cyclic loading, a two-way analysis of covariance was performed to examine the intergroup difference after each cyclic load on each of the groups separately. It should be noted that the two-way analysis of covariance showed that there is no significant difference between Zimmer and Implantium groups ($P = 0.248$). Moreover, there was a significant difference between SIC and Implantium groups ($P = 0.021$), as well as between Zimmer and SIC groups ($P = 0.006$). The best results belonged to the SIC group, which showed a preload loss less than the other two groups. Reductions in RTV were observed in all three groups after cyclic loading.

To evaluate the effect of cyclic load on each of the groups separately, the repeated-measures ANOVA showed that there is a significant difference between the mean RTVs before and after the cyclic load process ($P = 0.019$). The interaction between implant type and cyclic load on RTV showed no significant difference ($P = 0.836$). The effect of system type on RTV revealed a significant difference between the three groups ($P < 0.001$) [Table 2]. Tukey's *post hoc* test showed no significant difference between Zimmer and Implantium groups ($P = 0.303$) but a significant difference between Zimmer and SIC groups ($P = 0.004$), as well as a significant difference between Implantium and SIC groups ($P < 0.001$) [Table 1].

Figure 1: Mean removal torque values before and after cyclic loading in studied groups

DISCUSSION

Studies on the types of implant–abutment connections have reported very different results, and each has done various tests on varied systems. In the present study, the presumed first null hypothesis was rejected as the RTV of abutment screws was lower in all groups than the primary RTV. Nevertheless, Ferreira *et al*.[23] showed that Morse Taper abutments have higher RTV than the initial torque due to cold soldering in the implant–abutment interface. The reason of different conclusion can be the implant system (Straumann ITI) or using one-piece abutments in their study. In agreement with the results of the present study, Sahin and Ayyildiz[14] examined the correlation between microleakage and screw loosening at implant–abutment connection. They reported a decrease in RTV relative to the initial torque in all specimens. In their study, the minimum and maximum RTVs were 9% and 14% in the Morse Taper samples. This value in the present study was estimated to be 10% in the SIC system with straight internal hexagonal connection (the lowest torque loss) using

Table 1: Tukey's *post hoc* test results of removal torque values before and after cyclic loading in the studied groups

Group	Before	After
Zimmer		
Implantium	0.771	0.303
SIC	0.032	0.004
Implantium		
Zimmer	0.771	0.303
SIC	0.006	0.000
SIC		
Zimmer	0.032	0.004
Implantium	0.006	0.000

SIC: Straight internal hexagonal connection

Table 2: Results of repeated-measure ANOVA test to evaluate the effect of cyclic load and implant type on the removal torque values

Variables	*P*
Cyclic load	0.019*
Cyclic load group*	0.836
Group	0.000*

*Significance level = 0.05

the equation of $\frac{\text{initial torque value - RTV}}{35} \times 100$, and the highest torque loss (about 20%) was in the Implantium group. The Zimmer group was positioned between the two groups.

The defined second null hypothesis was rejected as well. In the present study, the cyclic load process also reduced the RTV. Cho *et al*.[24] examined the effect of cyclic load on the screw loosening in internal hexagon and external hexagon systems. They reported that the RTV of abutment screw was less than the primary RTV in all samples, in line with the present study. In addition, they showed that the cyclic load process on all of their samples caused a significant decrease in the RTV of the abutment screw. The method used in their study was very similar to that in the present study, with the retightening process being considered with a time interval of 10 min from initial torque. This process led to an increase in RTV in both internal and external hexagon groups. The mean RTV in their study was 27 Ncm for the external group and 25 Ncm for the internal group. Compared with the present study, this value was 28 Ncm in the internal hexagon conical connections and 31 Ncm in the butt joint internal connection in the SIC group, which could be due to the design of the system. In fact, parallel walls with an appropriate space between the components will result in better assembly of parts, consequently spending less torque to overcome the friction between components, increasing preload values, and elevating RTV; the present results confirm this point. In another research, Kim *et al*.[25] investigated the RTV on five different connections and reported a reduction in RTV after cyclic loading in all samples, but this was not significant in some groups.[25] This amount of torque loss seems to be spent to overcome the friction between the components of the abutment–implant system. This issue has been investigated in the study of Haack *et al*.,[26] who reported that most torque values applied on the abutment screw are used to overcome the friction between components, and only 10% is spent to create preload. They stated that different material types could affect the torque loss. Therefore, this study used titanium screws.

In this study, there was a significant difference in the RTV between the SIC group and the other groups before and after cyclic loading. The SIC group showed a higher RTV than Implantium and Zimmer groups. This is because of the different connection types in these three groups. In the SIC group with parallel-wall internal hexagon connection, the component stability is obtained through the stretching of the abutment screw threads and the implant body, while the stability of the components in the other two groups is achieved through the friction between the abutment taper walls and the implant inner surface. Therefore, it can be concluded that the most torque values used in the SIC group are spent to create the preload, while the torque of the abutment screw in two other groups is distributed to create friction between the conical walls of abutment and implant and create preload in the abutment screw threads. This was also proved in the study of Cho *et al*.[24] This result merely indicates that *in vitro* screw loosening was less in the SIC group than in the other two groups. Other mechanical tests, such as joint opening, screw fracture, and marginal gap, as well as bacterial penetration tests, should be carried out for these connections to draw definite conclusion on the advantages and disadvantages of these connections.

Previous studies have shown that the implant–abutment connection gets degraded by the processes of wear and corrosion in the oral cavity, which contributes to loosening the connection during mastication. The glycoproteins in the oral fluids act as a lubricant and amplify these processes.[27] Therefore, we incorporated artificial saliva in the simulation to mimic the oral cavity environment better. The used chewing simulator had two moving axes that were controlled by programming software to simulate all the paths of masticatory movements. The axis's load and sliding motion was adjusted to best replicate the oral cavity conditions. Despite great efforts to ensure the highest study quality, there were also some limitations. It should be noted that statistical analyses are unable to express the exact clinical condition; therefore, the results should be interpreted with caution. The analyzed data regarding the RTV dispersion in the three groups studied before and after cyclic load showed that the distribution of data in the Implantium group is much greater than the other two groups. As statistical analyses use the mean of these data, they underestimate the abutment screw loosening which is one of the present study limitations. Regarding the results of this study and considering the limitations of this study, it can be said that the parallel-wall internal hexagon connection shows less screw loosening.

CONCLUSION

Despite the limitations of the current study, the following conclusions were drawn:

1. The type of implant–abutment connection affects the abutment screw loosening and the component stability
2. The parallel-wall internal hexagon butt joint connection in the SIC system showed the least screw loosening
3. The cyclic loading affected the removal torque value and the screw loosening and reduced the removal torque value.

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Conflicts of interest

There are no conflicts of interest.

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Research

Impact of complete mouth rehabilitation following Pankey Mann Schuyler versus HOBO Philosophy on Oral Health-Related Quality of Life using Oral Health Impact Profile-14: A randomized clinical trial

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Abstract

Aim: Aim of this in vivo study was to assess the impact of two rehabilitation philosophies namely; Pankey Mann Schuyler (PMS) & Hobo Twin Stage (HOBO) on Oral Health-related Quality of life (OHRQoL) using Oral Health Impact Profile (OHIP 14).

Settings and Design: This was a randomized clinical trial.

Material and Methods: This study was designed based on the PICOT model. 40 patients were selected who need to undergo complete mouth rehabilitation. The intervention performed was complete mouth rehabilitation therapy and the results were compared with that of no intervention. The outcome was assessed in terms of improvement in mastication, phonetics, esthetics and overall OHRQoL (OHIP-14) over a period of 01 year at intervals of 48 hrs, 01 mon, 6 mon and 12 months. Patients were unaware of the treatment philosophy being used and were given a questionnaire (OHIP-14); at baseline (pre-treatment) and 48 hrs, 1, 6 and 12 months after completion of treatment (post-treatment) to evaluate OHRQoL. The data was collected by independent reviewers blinded to the regimen followed making the participants and the outcome assessors blinded to the procedure.

Statistical Analysis: Independent Student's *t*-test and Chi-Square test were used for analysis

Result: Analysis illustrated significant differences in scores obtained pre-treatment and post-treatment in both groups at 12 months ($P < 0.05$). At 12 months, OHIP-14 scores showed a mean percentage change of 51% in Group A (PMS); ($P = 0.001$) and a mean percentage change of 49% in group B (Hobo).

Conclusion: Complete mouth rehabilitation therapy for management of generalized attrition or mutilated dentition is a viable and effective treatment option and brings about definitive improvement in Oral Health Related Quality of Life (OHRQoL) and overall health status of an individual.

Keywords: HOBO Twin Stage, Oral Health Impact Profile 14, Oral Health-related Quality of Life, Pankey Mann Schuyler, randomised clinical trial

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INTRODUCTION

"Two central goals of healthy people 2020 initiative are to attain high-quality, longer lives free of preventable disease disability, injury, and premature death; achieve health equity, eliminate disparities, and improve the health of all groups; create social and physical environments that promote good health for all; and promote quality of life, healthy development, and healthy behaviors across all life stages."[1] Oral care is one of the twelve important topics included in the leading health indicators.[2] Lately, the assessment of improvements in living standards, assessed considering the oral status is becoming an indicator of the overall health status of an individual and also being included as an important domain in public health programs.

There is a wide range of oral conditions that require attention and management, however, generalized attrition or wearing away of the teeth is one such condition in which the remaining natural teeth are mutilated or worn off. It may or may not alter the vertical dimension of patient but results in altered function, esthetics, and overall health status of the individual.

Management of such cases warrants a well-planned treatment protocol aimed at restoration of the lost tooth structure and maintains integrity of remaining dentition. Various treatment approaches and philosophies mentioned in the literature can be utilized in complete mouth rehabilitation of lost tooth structure that varies in terms of treatment sequence, treatment time, and use of instruments.

The term complete mouth rehabilitation applies to the restoration of teeth, with or without dental implants; with fixed dental prostheses in the maxillae and mandible.[3] Complete mouth rehabilitation produces a distinguished improvement in patient's life irrespective of the philosophy followed. However, comparison of outcome of various treatment philosophies has not been attempted. Earlier, there was a scarcity of objective measurement tools to evaluate the improvements in the quality of life after a particular treatment instituted.

However, today there is a far extensive scope with availability of various tools for the same.[4] Oral Health Impact Profile 14 (OHIP-14) is one of the instruments that dictates individuals perceptivity of oral health status on their well-being.[5] The OHIP consist of 14 questions formulated under seven domains based on Locker's scale [Figure 1].[5-7] Two most commonly employed philosophies for complete mouth rehabilitation are Pankey Mann Schuyler (PMS) and Hobo Twin Stage (HOBO).[8,9]

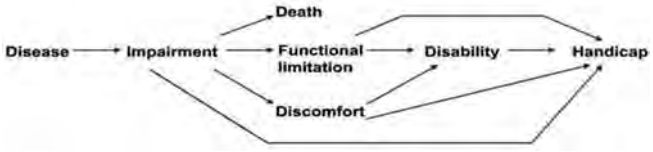

Figure 1: Locker's conceptual model of oral health

In PMS, area of freedom between CRCP and IP (<0.5 mm), anterior guidance determines restoration of anterior followed by lower posteriors. Wax patterns of upper posteriors are fabricated using functionally generated path technique to achieve simultaneous contact of all posterior teeth.[10] The absence of balancing side contact and group function on working side.[11] Fully adjustable articulator is not required.

Hobo-Twin-stage concept is a two stage methodical approach based on the theory of disclusion. First, anterior segment is removed and occlusal pattern of posterior teeth is fabricated keeping cusp angle same as that of standard value of effective cusp angle produced (condition I). Second, with anterior segment in position, morphology and guidance is established to create definitive disclusion (Condition 2).[12]

This randomized clinical trial aims to evaluate the impact of complete mouth rehabilitation therapy on Oral Health-Related Quality of life (OHRQoL) using OHIP-14.[13] The primary objective was to evaluate the influence of treatment on OHRQoL using short form of OHIP-14 measured on the Likert Scale.[14] The secondary objectives were to compare the impact of rehabilitation using PMS versus Hobo on the OHRQoL and to comment on the seven domains that result in summated OHIP-14 scores.

Null hypothesis was that that there will be no definitive improvements in patients, posttreatment and similar effect on OHRQoL would be obtained in both the groups (PMS and HOBO).

METHODOLOGY

Ethical clearance was obtained from the Institutional Ethical committee Review Board, Armed Forces Medical College, Pune, India, (IEC/2020/193 date July 15, 2020). Forty patients who reported to Department of Dental Surgery and Oral Health Sciences AFMC, Pune and needed to undergo complete mouth rehabilitation were selected to participate in the randomized clinical trial based on the inclusion and exclusion criteria. Patients with generalized attrition, severely mutilated dentition, multiple missing

teeth who complained of difficulty in chewing, and speech, pain, and generalized sensitivity were selected. Subjects with no wear facets or with single or few teeth missing were excluded from the study.

Based on the clinical and radiological findings, treatment plan was formulated and discussed with the patients. The PIS (patient information sheet) was provided, purpose of study explained and all participating patients were made to sign informed consent (ICF).

The sample size was calculated considering the power of the study as 80%, confidence interval at 95%, difference in group means to be 20%. Sample size of 40 was derived (i.e., 20 in each group) [Figure 2].

The selected forty patients were divided into two groups depending upon the mode of rehabilitation planned. Group A: Twenty patients who would be rehabilitated following PMS philosophy. Group B: Twenty patients who would be rehabilitated following HOBO Twin Stage philosophy. Based on the longest held occupation, measurement of social class was made. Patients were categorized according to the Modified Kuppuswamy Scale.[15] Patients were also categorized based on the age in two groups (Group A-20–40 years and Group B-40–60 years) and gender into male and female [Table 1].

Patients in each group were treated using standardized care based on treatment protocol but were blinded to the philosophy being followed. The protocol followed was the occlusal plane analysis, determination of existing vertical dimension, evaluation of loss of vertical dimension if any and need for restoration and occlusal splint therapy if required based on the assessment. Each patient from the group A was rehabilitated using PMS philosophy and Group B using Hobo Twin Stage philosophy following the standard treatment protocol. All operative treatment was conducted by postgraduates in prosthodontic clinics under similar working conditions with similar armamentarium and material. All the restorations were fabricated in the same dental laboratory to rule out any bias in the outcome.

OHRQoL was assessed based on OHIP-14 questionnaire which consists of 14 questions covered under seven domains namely functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The questionnaire was allocated by an independent research reviewer at starting point (pretreatment), 48 h, 1 month, 6 months, and12 months after intervention (posttreatment).[16]

The research reviewer and all patients were blinded to the group allocation, making it a double blind study. For each of the 7 domains with 14 OHIP questions, patients were assessed for the outcome of treatment on various aspects of life as mentioned earlier, in the preceding 12 months (at the intervals of 48 h, 1 month, 6 months, and12 months after the completion of

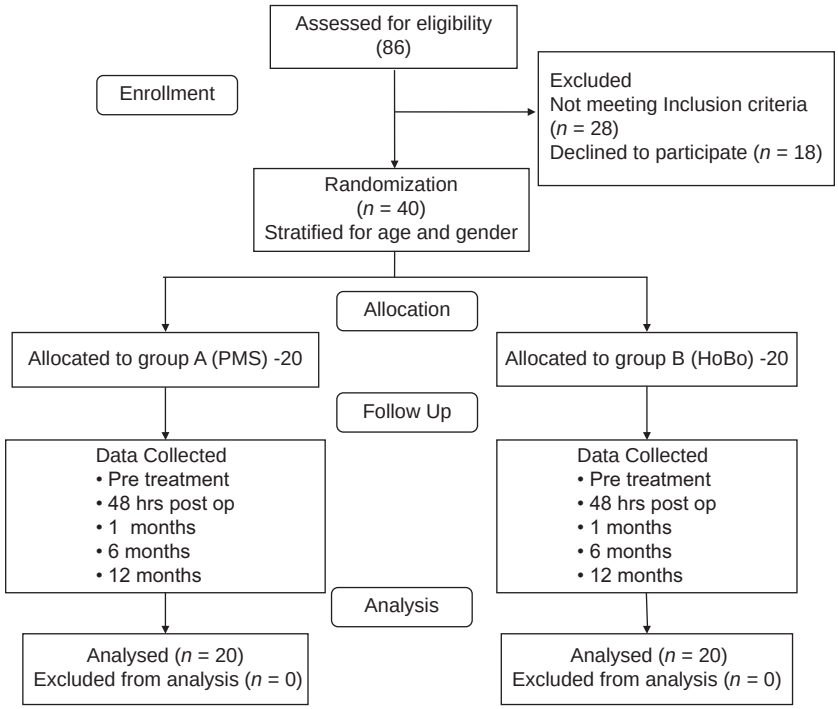

Figure 2: Flow diagram depicting patient selection and random allocation in two groups

Table 1: Baseline characteristics of study participants

	Patient demographics								
	Gender		Age		Social class				
	Male, *n* (%)	Female, *n* (%)	Mean (years)	SD	I, *n* (%)	II, *n* (%)	III, *n* (%)	IV, *n* (%)	V, *n* (%)
Treatment group									
PMS	18 (90)	2 (10)	47.8	6.37	2 (10)	12 (60)	4 (20)	0	2 (10)
HOBO	16 (80)	4 (20)	45	9.89	4 (20)	6 (30)	2 (10)	4 (20)	4 (20)

SD: Standard deviation, PMS: Pankey Mann Schuyler, HOBO: Hobo Twin Stage

treatment). Responses were recorded on a 5-point Likert scale and coded as 5 = "very often," 4 = "fairly often," 3 = "occasionally," 2 = "hardly ever" and 1 = "never." Impact of treatment on OHRQoL was used as the primary outcome measure. A collective report of negative impacts stating reduction in OHIP-14 score indicates an improved OHRQoL.

All the data were compiled in excel sheet and subjected to statistical analysis. ANCOVA was used for the repeated measures. Inter-group statistical differences in common variables were assessed using independent sample *t*-test and RMANOVA was used for intra-group statistical differences. Linear models and logistic regression (binary and ordinal) models were used to assess relationships between the treatment groups and mean summary OHIP-14 and OHIP-14 domain scores. Demographic variables (including age, gender, and social class) were considered as covariants. All variables recorded were presented by time-point and by treatment group. This study design was implemented to avoid any bias and to prevent any uncertainty in randomization process.

RESULTS

Oral Health Impact Profile-14 summary scores

Forty participants completed the randomized clinical trial after 12 months. Mean OHIP-14 scores for all participants were recorded and mentioned in Table 2. ANCOVA for repeated measures was applied fitted to OHIP-14 scores [Table 3]. The record of categorical variables is presented as n (% of cases), whereas continuous variables were depicted as mean and standard deviation among two study groups. Inter-group statistical comparison of distribution of categorical variables was assessed using the Chi-square test. Inter-group statistical comparison of means of continuous variables was assessed with Independent sample *t*-test. Fixed factors in the model were treatment group, time point, i.e., (before treatment, at 48 h, 1 month, 6 months, and 12 months), social class, age, and gender. Covariants used were starting point values and age. Two-level interactions between treatment group and each of time point, social class, gender and age were considered for inclusion. Statistical Package for the Social Sciences (SPSS version 21.0, IBM Corporation, USA) for MS Windows was used for analysis and $P < 0.05$ were considered to be statistically significant.

There was an interaction between treatment group and time-point ($P < 0.0001$). Therefore, any difference in OHIP-14 summary scores between groups over time was not the same. The group effect, time-point effect, and any of their two-level interactions cannot be interpreted in isolation. Groups were compared at each of the 4 timepoints separately. This analysis illustrated that Group A (PMS) technique had improved OHIP-14 scores compared to Group B (HoBo) by mean scores of 1.58 at 48 h, 1.12 at 1 month ($P = 0.014$), 1.02 at 6 months ($P = 0.004$) and 1.02 at 12 months. Group A exhibited better OHIP-14 scores with a percentage change of 51%, showing significant differences at 1 month posttreatment with *P* value (0.014) and at 6 months posttreatment with *P* value (0.004). Group B recorded percentage change of 49%. The model indicated that there was no difference in results between social classes ($P = 0.508$) or genders recorded ($P = 0.459$) or age ($P = 0.391$) [Table 3].

Oral Health Impact Profile-14 domains

Functional limitation

Pretreatment mean values for Group A (PMS) and Group B were 2.35. At 12 months, post treatment mean values for both the groups were 1.15 ($P = 0.001$). However, statistically significant differences in mean value were found at 48 h posttreatment ($P = 0.007$). Mean percentage change in scores over a period of 12 months was 50.66% in Group A and 49.21% in Group B which indicates more improvement in Group A by 1% as compared to Group B in this particular domain [Figures 3 and 4].

Physical pain

Pretreatment mean value was 3.10 for Group A (PMS) and 3.15 for Group B (Hobo). Posttreatment, mean value was 1.00 ($P = 0.001$) for both the groups. Mean percentage change in scores over a period of 12 months was 65.33% in Group A and 67.28% in Group B which indicates more improvement in Group B by 2% as compared to Group A in this particular domain [Figures 5 and 6].

Table 2: Inter-group comparison of mean pretreatment and posttreatment Oral Health Impact Profile-14 scores of cases studied

	n	0-h		48-h		1-month		6 months		12 months		Mean percentage change
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	12 months
Summary OHIP-A4 score												
Group A (PMS)	20	2.94	0.54	1.58	0.24	1.12	0.09	1.02	0.04	1.02	0.04	50.66
Group B (HOBO)	20	3.08	0.46	1.62	0.24	1.23	0.A6	1.09	0.09	1.03	0.04	49.21
P		0.379^{NS}		0.590^{NS}		0.014*		0.004*		0.520^{NS}		
Functional limitations score												
Group A (PMS)	20	2.35	0.33	2.00	0.32	1.35	0.23	1.15	0.23	1.15	0.23	50.66
Group B (HOBO)	20	2.35	0.56	1.70	0.34	1.30	0.25	1.25	0.26	1.15	0.23	49.21
P		0.999^{NS}		0.007*		0.520^{NS}		0.206^{NS}		0.999^{NS}		>0.05
Physical pain score												
Group A (PMS)	20	3.10	0.82	1.35	0.33	1.05	0.15	1.00	0.00	1.00	0.00	65.33
Group B (HOBO)	20	3.15	0.61	1.30	0.47	1.10	0.20	1.00	0.00	1.00	0.00	67.28
P		0.828^{NS}		0.699^{NS}		0.389^{NS}		0.999^{NS}		0.999^{NS}		
Psychological discomfort score												
Group A (PMS)	20	3.20	0.98	1.40	0.45	1.10	0.31	1.00	0.00	1.00	0.00	65.44
Group B (HOBO)	20	3.60	0.82	1.55	0.48	1.20	0.34	1.00	0.00	1.00	0.00	70.36
P		0.169^{NS}		0.315^{NS}		0.336^{NS}		0.999^{NS}		0.999^{NS}		
Physical disability score												
Group A (PMS)	20	3.45	0.81	1.95	0.48	1.25	0.4A	1.00	0.00	1.00	0.00	69.31
Group B (HOBO)	20	3.65	0.56	2.05	0.28	1.50	0.46	1.10	0.20	1.00	0.00	71.83
P		0.370^{NS}		0.427^{NS}		0.078^{NS}		0.036*		0.999^{NS}		
Psychological disability score												
Group A (PMS)	20	3.25	0.95	1.50	0.46	1.00	0.00	1.00	0.00	1.00	0.00	66.11
Group B (HOBO)	20	3.40	1.02	1.85	0.65	1.15	0.33	1.15	0.33	1.00	0.00	67.50
P		0.634^{NS}		0.057^{NS}		0.048*		0.048*		0.999^{NS}		
Social disability score												
Group A (PMS)	20	2.95	1.01	1.55	0.43	1.05	0.15	1.00	0.00	1.00	0.00	61.84
Group B (HOBO)	20	2.90	0.79	1.40	0.50	1.15	0.33	1.00	0.00	1.00	0.00	62.59
P		0.863^{NS}		0.3A5^{NS}		0.225^{NS}		0.999^{NS}		0.999^{NS}		
Handicap score												
Group A (PMS)	20	2.30	0.77	1.30	0.25	1.00	0.00	1.00	0.00	1.00	0.00	50.14
Group B (HOBO)	20	2.35	0.95	1.30	0.52	1.15	0.46	1.05	0.15	1.05	0.15	47.92
P		0.855^{NS}		0.999^{NS}		0.154^{NS}		0.154^{NS}		0.154^{NS}		

SD: Standard deviation, OHIP: Oral Health Impact Profile, PMS: Pankey Mann Schuyler, HOBO: Hobo Twin Stage, NS: Statistically nonsignificant. *Statistically Significant

Table 3: Mixed model analysis of covariance for repeated measures fitted to Oral Health Impact Profile-14 summary score

Effect (variable/interaction)	*F*	*P*
Treatment group	32.80	0.001***
Baseline score	24.20	0.001***
Time point	28.42	0.001***
Age	1.24	0.391 (NS)
Gender	0.96	0.459 (NS)
Social class	0.68	0.508 (NS)
Group × time point	26.49	0.001***

***$P<0.001$. NS: Statistically nonsignificant

Psychological discomfort

Pretreatment mean value was 3.20 for Group A (PMS) and 3.60 for Group B (HOBO). Posttreatment mean value was 1.00 ($P = 0.001$) for both groups. Mean percentage change in scores over a period of 12 months was 65.44% in Group A and 70.36% in Group B which indicates more improvement in Group B by 5% as compared to Group A [Figures 7 and 8].

Physical disability

Pretreatment mean value for Group A (PMS) was 3.45 and 3.65 for Group B (HOBO). Posttreatment mean value was 1.00 ($P = 0.001$) for both the groups. However, statistically significant differences in mean value were found at 6 months posttreatment with the *P* value (0.036). Mean percentage change in scores over a period of 12 months was 69.31% in Group A and 71.83% in Group B which indicates more improvement in Group B by 2% [Figures 9 and 10].

Psychological disability

Pretreatment mean score was 3.25 for Group A (PMS) and 3.40 for Group B (Hobo). Posttreatment mean value for psychological disability score was 1.00 ($P = 0.001$) for both groups. However, statistically significant differences in mean values were found at 1 month and 6 months posttreatment with the *P* value (0.048). Mean percentage change in scores over a period of 12 months was 66.11% in Group A and 67.5% in Group B which indicates more improvement in Group B by 1% as compared to Group A in this particular domain [Figures 11 and 12].

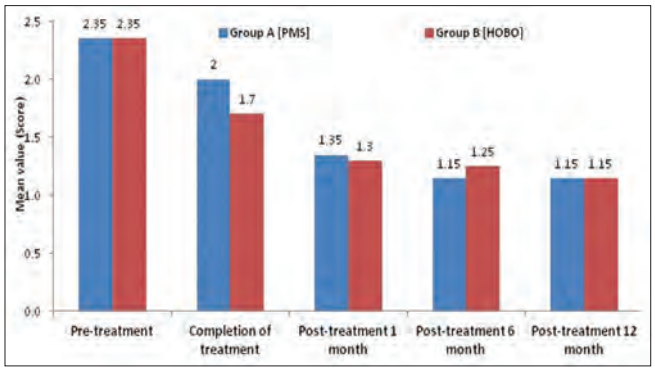

Figure 3: Inter-group comparison of mean pretreatment and posttreatment functional limitations score of cases studied

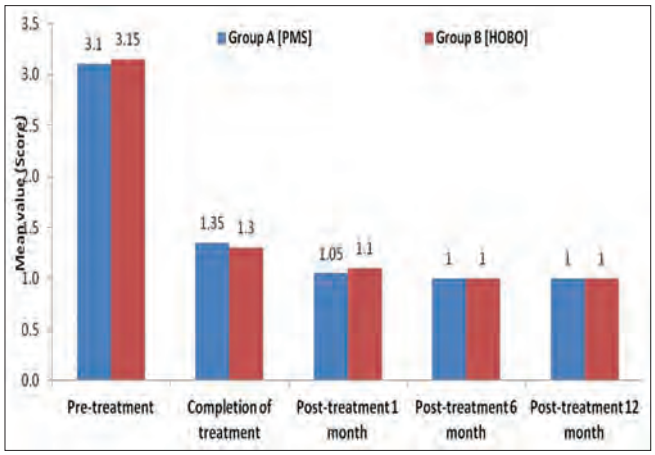

Figure 5: Inter-group comparison of mean pretreatment and posttreatment physical pain scores of cases studied

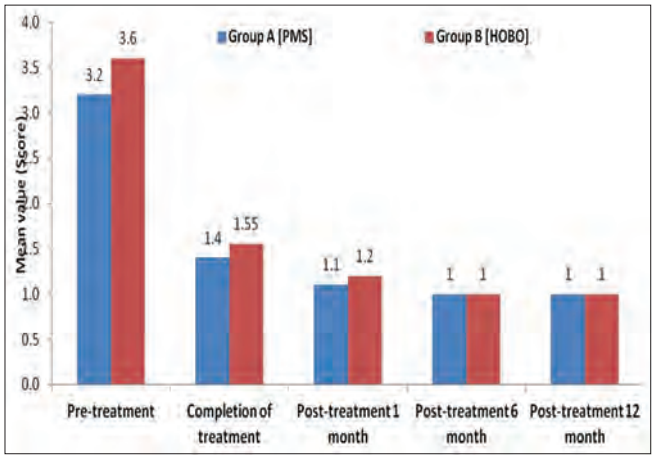

Figure 7: Inter-group comparison of mean pretreatment and posttreatment psychological discomfort score of cases studied

Social disability

Pretreatment mean value for social disability score was 2.95 for Group A (PMS) and 2.90 for Group B (Hobo). Posttreatment mean value was 1.00 ($P = 0.001$) for both groups. Mean percentage change in scores over a period of 12 months was 61.84% in Group A and 62.53% in Group B

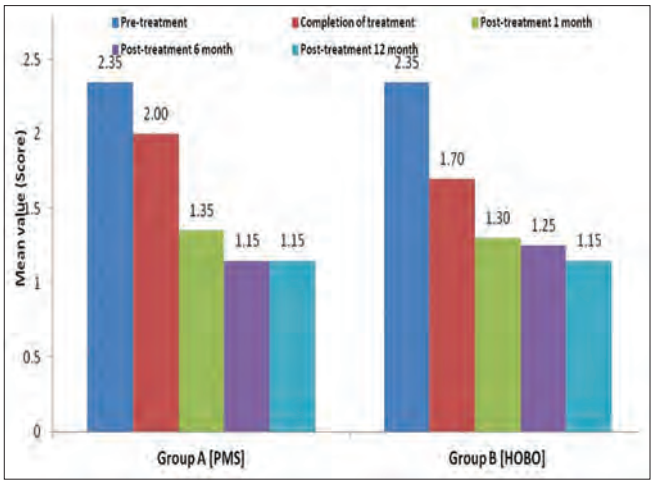

Figure 4: Intra-group comparison of mean pre- and post-treatment functional limitations score of cases studied

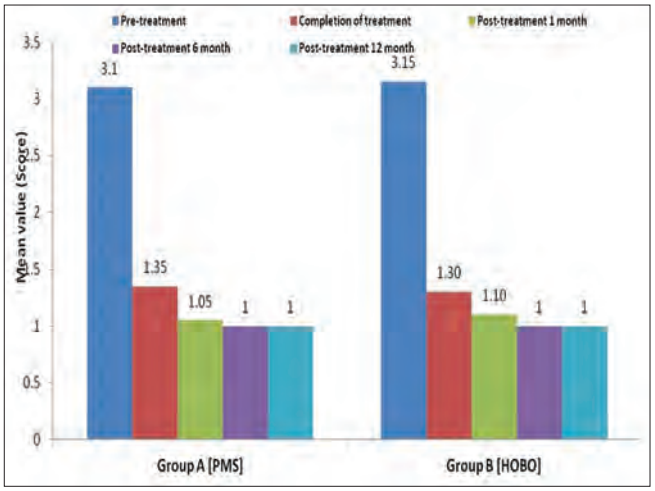

Figure 6: Intra-group comparison of mean pretreatment and posttreatment physical pain scores of cases studied

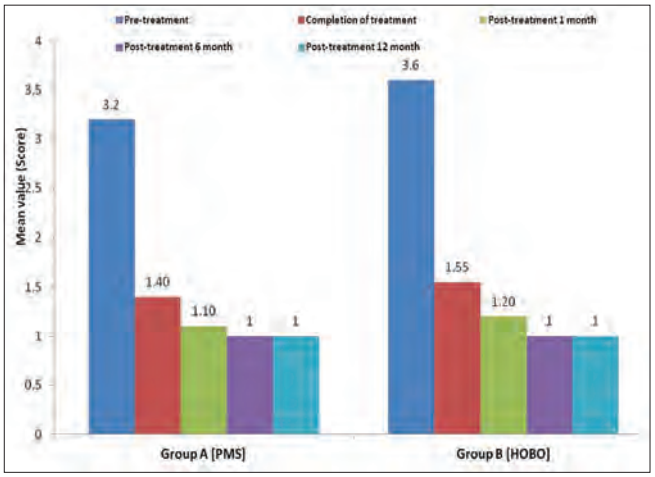

Figure 8: Intra-group comparison of mean pretreatment and posttreatment psychological discomfort score of cases studied

which indicates more improvement in group B by 1% as compared to Group A [Figures 13 and 14].

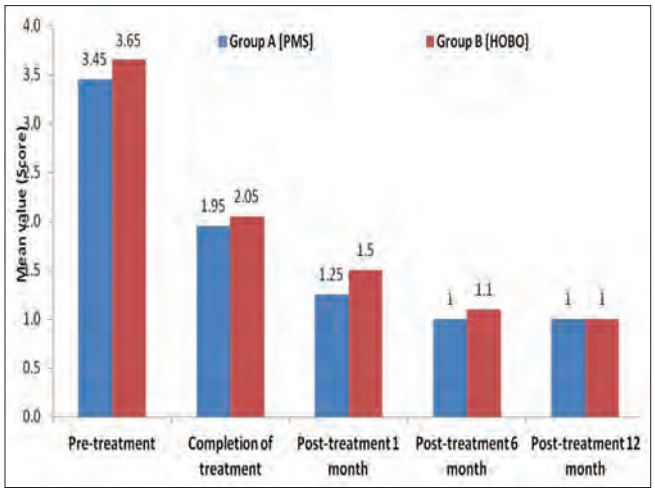

Figure 9: Inter-group comparison of mean pretreatment and posttreatment physical disability scores of cases studied

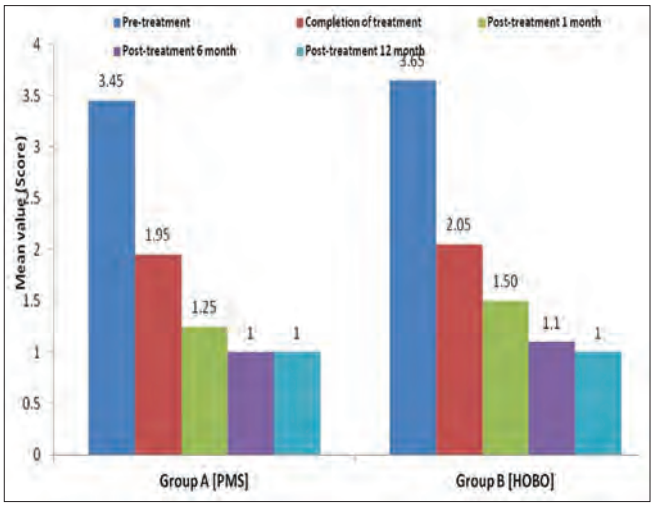

Figure 10: Intra-group comparison of mean pretreatment and posttreatment physical disability scores of cases studied

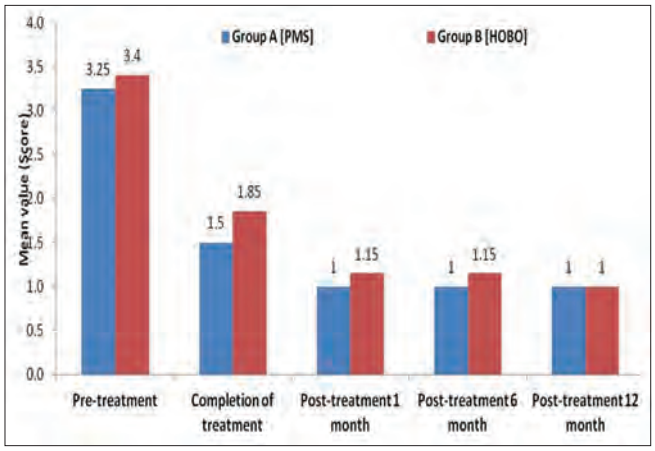

Figure 11: Inter-group comparison of mean pretreatment and posttreatment psychological disability scores of cases studied

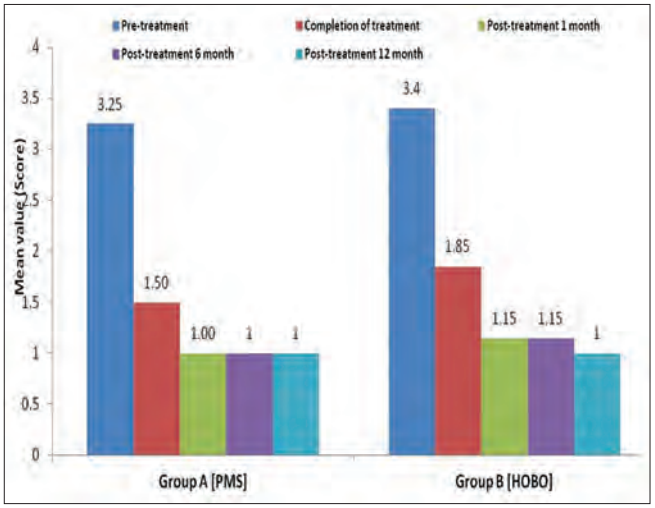

Figure 12: Intra-group comparison of mean pretreatment and posttreatment psychological disability score of cases studied

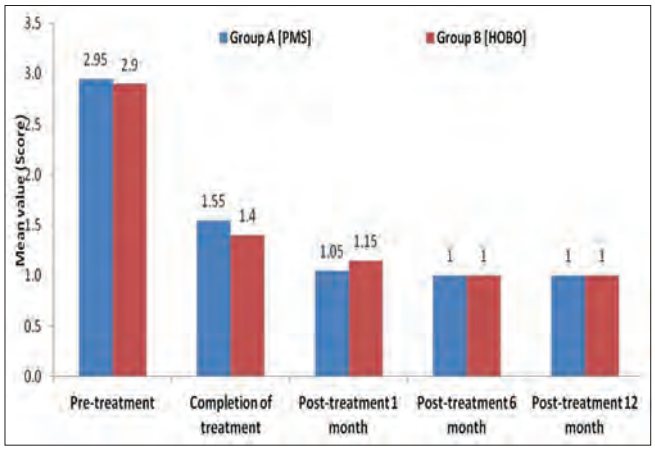

Figure 13: Inter-group comparison of mean pretreatment and posttreatment social disability score of cases studied

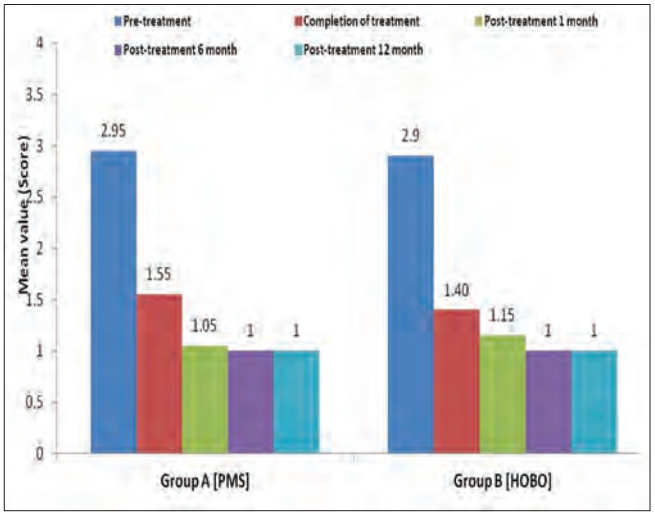

Figure 14: Intra-group comparison of mean pretreatment and posttreatment social disability score of cases studied

Handicap

Pretreatment mean value for handicap score was 2.30 for Group A (PMS) and 2.35 for Group B (Hobo). Posttreatment

mean value was 1.00 ($P = 0.001$) for Group A (PMS) and 1.05 Group B (Hobo). Mean percentage change in scores over a period of 12 months was 50.14% in Group A (PMS) and 47.92% in Group B (Hobo) which indicates more improvement in Group A by 3% as compared to Group B in this particular domain [Figures 15 and 16].

DISCUSSION

The life expectancy of individuals is approximately 78.6 years, based on the survey report of National Center for Health Statistics 2020. According to a report published by National Health and Nutrition Examination Survey, 63% of adults aging 18–64 years visit dental clinics in past years (2020).[17] Adult individuals visit the dental specialists for sensitivity of teeth or difficulty in mastication or compromised esthetics which is a result of loss of tooth surface material. The loss can be due to generalized attrition or mutilated dentition that is one of the most common dental diseases of adulthood which progresses till early old age among dentate individuals. The impact of such diseases on their daily life makes them considerably important.

Complete mouth rehabilitation of such patients is a challenging task as the clinical and symptomatic presentation is unique in every case and does not always fall into the defined category of diagnosis and treatment planning. Due to availability of numerous options in terms of philosophies, techniques and concepts, there are different schools of thoughts regarding the selection of treatment strategy for complete mouth rehabilitation. The mutilated dentition affects various aspects of life in the form of physical disability, psychological disability, functional limitation, pain, psychological discomfort, social disability and, handicap, thereby deteriorating the overall quality of life for an individual.[18] So the management aims at providing optimum levels of restoration in individual domains along with improvement in the overall quality of life.

Complete mouth rehabilitation creates a state of synchronous harmony between teeth and their periodontal structures along with para-oral structures such as muscles of mastication and Temporomandibular joint (TMJ), so as to result in optimum functional and biologic efficiency.[19] Meticulous assessment of the patient's occlusion, dietary habits and various disorders, is required to formulate a definitive diagnosis and establish a treatment planning.[9] Outcome and prognosis of the treatment is also affected by variables such as, Etiology, Clinical situation, Signs and symptoms, Treatment philosophy employed, age, gender, and socioeconomic status.[20,21]

This randomized clinical trial is an attempt to assess and compare the changes in oral health related quality of life (OHRQoL) at pre and post rehabilitation process under various domains. It also attempts to compare the effects between two most commonly utilized philosophies for full mouth rehabilitation i.e., PMS and HOBO Twin Stage in order to derive a conclusion whether any substantial amount of difference exists between various techniques used in terms of impact of the treatment on the overall OHRQoL with the help of a validated measurement tool; OHIP-14 (since no data exists comparing the effects of various treatment philosophies). This will guide the clinicians to adopt an appropriate rehabilitation philosophy for each patient. The scores have been summated at a considerable amount of follow up period of 12 months which gives patients an appropriate amount of time to

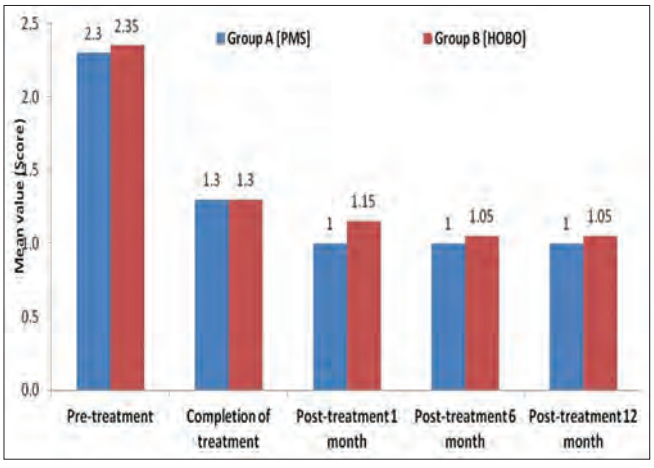

Figure 15: Inter-group comparison of mean pretreatment and posttreatment handicap score of cases studied

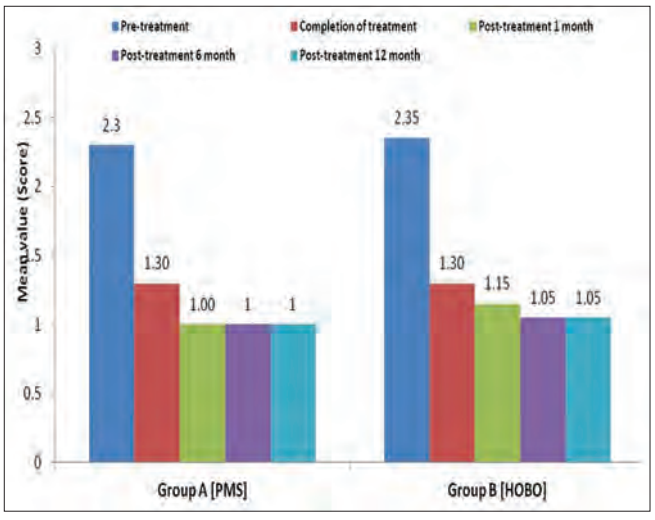

Figure 16: Intra-group comparison of mean pretreatment and posttreatment handicap score of cases studied

assess the outcome of the treatment instituted, considering various domains.

OHRQoL dictates the impact of oral status on everyday life and general health of the patient. OHIP is a tool that evaluates individuals perception of the well being based on impact of various oral disorders. The OHIP-49 used earlier was shortened from 49 to 14 items and these 14 questions were conceptually formulated that are based on Locker's theoretical model [Figure 1]. The other measurement tools used to assess OHRQoL are LORQV3, GOHAI.[22,23]

For each of the 14 OHIP questions, people were asked how frequently they had experienced the impact in the preceding 12 months. Responses were made on a 5 point Likert scale and coded 5 = "very often," 4 = "fairly often," 3 = "occasionally," 2 = "hardly ever" and A = "never." For this report, descriptive statistics were created by computing the mean of the coded response for each item which is described as the severity score for each item. OHIP-14 used in this study has been validated in various languages and it allows collection of informative data, which increases its reliability.[5]

Cases selected for this clinical trial were in which vertical dimension was maintained and space was available with the clinical symptoms of sensitivity and signs of generalized attrition. The occlusal scheme utilized was group function and full coverage PFM restorations were given.

In the clinical trial conducted, significant improvements were observed under all the seven domains of life postoperatively. The study shows that the pain relief was foremost followed by an instant and obvious change or improvement in the esthetics. The results of this study also validate that mastication, speech, social interactions and sleep improved measurably post dental treatment.

Patients in Group A and Group B showed boost in OHRQoL scores throughout the 12 month with marked improvement in 48 h and 1 month post treatment followed by gradual improvement in all the domains of OHIP-14. Thus, benefits of complete mouth rehabilitation therapy were highest at 48 h posttreatment which gradually stabilized over a period of 12 months.

These results strongly suggest that management of generalized attrition or mutilated dentition with complete mouth rehabilitation has definite impact on the physical, social and psychological levels thereby resulting in overall improvement in OHRQoL. It was also observed that the improvement is consistent regardless of the treatment philosophy employed for complete mouth rehabilitation; PMS or HOBO Twin stage.

PMS exhibits better cumulative results when compared with HOBO in terms of seven domains of OHIP-14. Out of the 7 domains assessed, PMS showed better results in functional limitation score and handicap score, whereas Hobo technique showed better values in terms of physical pain, psychological discomfort, physical disability, psychological disability, and social disability. This could be attributed to the fact that vertical dimension is restored and sequential therapy allows rebuilding of the masticating surfaces at the stage of temporisation. Furthermore, the occlusal surfaces are in perfect harmony with the anatomical structures due to utilization of Broadrick's occlusal plane analyzer for mandibular posterior segment and incorporation of functionally generated path for maxillary posteriors, thereby bringing the entire stomatognathic system in anatomical and functional (dynamic) harmony.

In the literature, previous randomized clinical trials conducted on children and partially dentate individual showed statistically significant positive differences post full mouth rehabilitation. However, the terms full mouth rehabilitation and oral rehabilitation have been interpreted as treatment with restorations and removable partial denture and shortened dental arch with adhesive resin-bonded bridge work.[24-27]

Strengths

The strengths of this clinical trial are as mentioned

1. Random allocation was done which eliminated the selection bias
2. Double-blind study (patient, research reviewer, and data analyst were blinded)
3. Follow-up with the OHIP-14 was done at multiple time lines not just pre- and posttreatment. Which gave the patients sufficient time to evaluate consistent improvements in quality of life
4. Further sources of bias were eliminated by carrying out clinical part of the therapy by operators at same treatment center and the laboratory procedures at same lab using similar materials
5. Patient reported outcome measures were recorded thus eliminating the reviewer's bias
6. Lack of comparative studies in the literature.

Limitations

The limitations of the present study are the unavoidable variables such as the clinical situation, age, gender, occupation, habits and patient's dietary habits that play an

important role in the occurrence as well as the prognosis and success of the therapy instituted.

Most pertinent point is that no two cases of mutilated dentition of generalized attrition are same in terms of amount of tooth surface loss; amount of vertical dimension discrepancy, available freeway space, space available for restoration, so actual comparison between different philosophies is not practically possible.

CONCLUSIONS

Patients with severely worn out dentition requiring rehabilitation can be managed with different philosophies and techniques available. However, it is observed that most commonly used philosophies are PMS and HOBO. Till today, there are no clear guidelines for the selection of the technique indicating superiority of results obtained with therapy or technique. This clinical trial is an attempt to achieve quantifiable results in terms of various domains of oral health leading to improvement in OHRQoL. The trial conducted exhibits following conclusive results.

1. FMR has definitive positive outcome posttreatment as compared to pretreatment (statistically significant)
2. PMS gives better results in two out of 7 domains, namely functional limitation score and handicap score, whereas Hobo technique showed higher values in terms of physical pain, psychological discomfort, physical disability, psychological disability, and social disability. Although HOBO shows better results in terms of five domains as compared to PMS which shows better results in two out of seven domains. These significant results shown by HOBO are at intermittent stage of the treatment and not at the final outcome stage
3. Overall improvement in OHRQoL based on assessment of seven domains of OHIP-14 was seen better with PMS.

The results of this clinical trial are in consonance with the advantages of the PMS Philosophy mentioned in the literature, namely maintaining patients vertical dimension, establishing occlusal morphology to achieve optimum occlusion. Hence, the results can be generalized to the population when treatment protocols are planned and executed.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Research

Comparative evaluation of enamel wear against monolithic zirconia and layered zirconia after polishing and glazing: An *in vitro* study

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Abstract

Aim: The aim of this study was to compare the wear behavior of human tooth enamel opposing monolithic zirconia and layered zirconia after glazing and polishing by a two-body wear mechanism using a wear simulator.

Settings and Design: This *In-vitro* study was done in Department of Prosthodontics, Sri Sai College of Dental Research, Vikarabad.

Materials and Methods: Zirconia specimens were divided into four groups (n = 15), Group monolithic glazed zirconia (MG), Group monolithic polished zirconia (MP), Group zirconia layered with E. max ceram and glazed (LG), Group zirconia layered with E. max ceram and polished without glaze (LP). Sixty human premolar teeth were subjected to wear test against the zirconia specimens using a Pin on Disc wear tester under a constant load of 5 kg (49 N) at 30 rpm for 10,000 cycles. The loss of enamel was recorded before and after the wear test and mean loss of height of tooth enamel after 10,000 cycles of wear was measured with a profile projector. The surface characteristics of all the four group zirconia specimens were evaluated qualitatively with scanning electron microscope.

Statistical Analysis Used: One way ANOVA, Tukey Post hoc.

Results: One-way analysis of variance test revealed that the mean loss of enamel of four groups was statistically different with $P < 0.001$. A further Tukey post hoc test revealed that the MP group had lesser mean scores than group LP, MG, and LG.

Conclusion: It was concluded that MP caused less wear to opposing natural teeth, and polished surfaces of both monolithic and layered zirconia showed less tooth wear compared to glazed surfaces of monolithic and layered zirconia.

Keywords: Enamel wear, layered zirconia, monolithic zirconia

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INTRODUCTION

Zirconia is used as an alternative to metal ceramics owing to its superior properties and esthetics.[1] In comparison to other dental ceramics, Zirconia has been reported

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to have superior qualities in terms of biocompatibility, dimensional and chemical stability and fracture resistance. Literature on ceramics has shown that they tend to be more abrasive to the opposing natural teeth when compared to other restorative materials.[2] Zirconia, as claimed by the manufacturers, has high strength and abrasive resistance, and therefore, its effect on the opposing teeth is to be investigated.

Wear of the teeth is influenced by various factors such as thickness of enamel, abrasiveness of the restorative material, and patient's oral habits. Studies have shown that surface finish and hardness of the restorative material are the two prime factors which affect the wear of the opposing teeth.[3] Therefore, there is a necessity to explore the suitable surface finish for zirconia restorations for them to function efficiently without any harm to the opposing natural teeth.[4]

The present study aimed to assess and compare the wear pattern of monolithic zirconia and layered zirconia on opposing natural teeth using a wear simulator following glazing and polishing.

MATERIALS AND METHODS

Fabrication of monolithic zirconia specimens

For the calculation of sample size, G power software was used. Keeping the power of the study as 90% and alpha error 5%, the sample size was calculated to be 15 per group. Institutional approval has not been considered as it is an *in vitro* study. Milled zirconia specimens prepared using computer-aided design-computer-aided manufacturing were used for the study. Sixty zirconia discs of dimensions 20 mm × 3 mm were milled (SIRONA in Lab MC X5) using an standard triangle language file. After milling, the specimens were subjected to sintering cycle at 1450°C (SIRONA in Fire HTC speed). The specimens acquired were distributed into four groups consisting 15 specimens each ($n = 15$) based on surface treatments [Figure 1].

- Group MG: Monolithic zirconia with glaze ($n = 15$)
- Group MP: Monolithic polished zirconia without glaze ($n = 15$)

Figure 1: Profilometer height measurement

- Group LG: Zirconia layered with E. Max and glazed ($n = 15$)
- Group LP: Zirconia layered with E. Max and polished without glaze ($n = 15$).

All the zirconia specimens were steam cleaned for 10 min, followed by ultrasonic cleaning and air-drying.

Layering of zirconia specimens

Zirconia specimens belonging to group zirconia layered with E. max ceram and glazed (LG) and group zirconia layered with E. max ceram and polished without glaze (LP) were layered. Prior to layering the specimens were sandblasted with aluminum oxide particles (50 μm) to increase surface roughness and enhance bond strength. After sandblasting, they were steam cleaned and air dried. Later Z-liner was applied to the discs and subjected to firing at 960°C. Porcelain powder dentin (IPS E. max Ceram) was mixed with adequate amount of modelling liquid and applied with the use of incremental brushing technique. Porcelain was added in excess on the zirconia discs to compensate for shrinkage. A thickness of 1 mm of ceramic layer over zirconia discs was attained and subjected to firing. To ensure that the porcelain layer on all the samples was flat and symmetrical, the samples were checked using an Iwanson's gauge.

Glazing of monolithic zirconia and layered zirconia disc specimens

Group monolithic glazed zirconia (MG) and group LG were subjected to glazing. IPS E. max Ceram Glaze paste and glaze liquid were mixed and applied in an even layer on the entire surface of the specimens followed by firing in a calibrated porcelain furnace (Ivoclar Vivadent Programat P310). Contents of IPS E. max Ceram shade and Glaze pastes include Silicone dioxide, oxides (Al_2O_3, ZnO_2, Na_2O, K_2O, ZrO, CaO, P_2O_5), glycerine, butandiol, and poly (vinyl pyrrolidone).

Polishing of monolithic zirconia and layered zirconia disc specimens

Polishing of group monolithic polished zirconia (MP) was done with Zi-finish range (Bredent UK). First, medium grit and fine grit Edenta Exa-Cerapol polishing wheels were used for 20 s at a speed of 3000 rpm. Once adequate smoothness was achieved, Zi-finish range prepolishers were used followed by polishers to gain high luster.

Polishing of group LP was done with polishing wheels and diamond paste. Medium grit followed by fine grit Edenta Exa-Cerapol polishing wheels was used for 20 s at a speed of 3000 rpm. After finishing, diamond paste (Renfert polish) was applied with a felt wheel to gain high luster. Finishing

and polishing procedure was done in a unidirectional manner and excess contact time and force was avoided during the polishing procedure to avoid heat generation.

Fabrication of teeth specimens

Sixty freshly extracted maxillary first and second premolars that are nondecayed and in good shape were disinfected and mounted with auto-polymerizing acrylic resin (length 15 mm and width 10 mm × 10 mm). The teeth specimens were randomly divided into four groups of 15 each to be tested against zirconia groups.

- Group I: To be tested against group MG
- Group II: To be tested against group MP
- Group III: To be tested against group LG
- Group IV: To be tested against group LP.

All the teeth specimens were viewed under profile projector (Metzer M profile projector) to assess the height before testing. The specimen's silhouette is enlarged and displayed on the projection screen via the projector. Because the image is magnified, the X-Y axis of the grid can be aligned with a straight edge of the part to be viewed or measured on this screen, making linear measurements easy to calculate. The teeth specimens were put on the profile projector's worktable in the proper order, and the X, Y, and Z axes were adjusted as needed, and the profile of each tooth specimen was drawn. From the height of the cusp tip to the base of the tooth, a vertical line was dropped. This height was used to determine the baseline height of that specific tooth.

Wear test

Wear test was carried out using pin on disc wear and friction test rig. The tooth specimens were inserted into the pin holder and the zirconia specimens were attached to the lower custom-made metal disc of diameter 165 mm and 5 mm thickness. To hold the test specimens, a provision was given in the center of the disc of dimensions 20 mm in diameter and 2-mm depth such that the specimens were securely seated in the rotating disc. Both the specimens moved in a rotational movement with a load of 5 kg (49N) at 30 cycles per minute for 10,000 cycles in the presence of distilled water.

The loss of height of all the tooth specimens after testing was determined using the profile projector (Metzer M profile projector) in reference to the baseline data [Figure 1]. To evaluate the wear patterns, test materials were assessed by Scanning electron microscope which produces signals on the interaction of the electrons and show the image with desired magnification (ZEISS ultra 55). A magnification of 500 × at 5.00 kV was chosen and surface roughness of each test specimen was recorded prior and after 10,000 wear cycles to analyze the influence of the material and the surface finish on the amount of enamel wear [Figures 2-5].

RESULTS

The loss of enamel height against zirconia groups was tabulated and subjected to statistical analysis. One-way

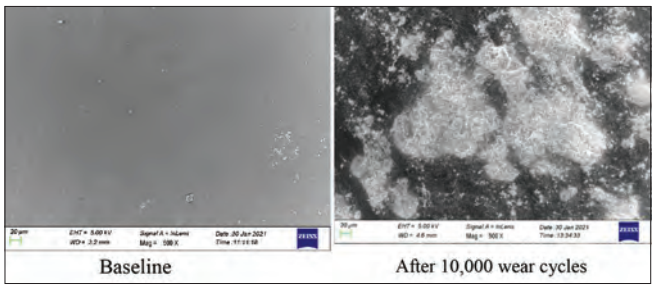


Figure 2: SEM images monolithic glazed zirconia. SEM: Scanning electron microscopy

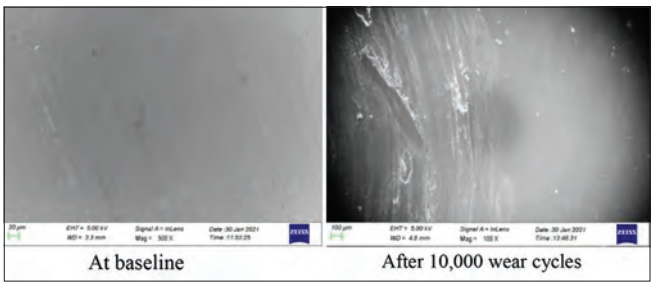


Figure 3: SEM images of polished monolithic zirconia. SEM: Scanning electron microscopy

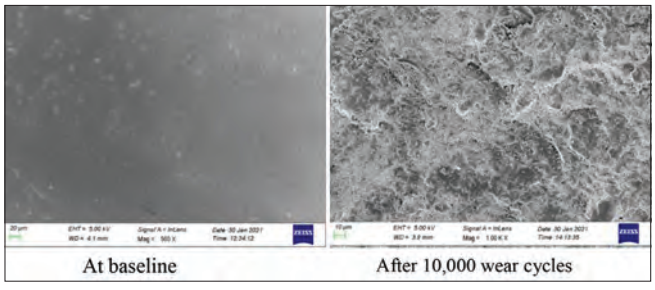


Figure 4: SEM images of layered glazed zirconia. SEM: Scanning electron microscopy

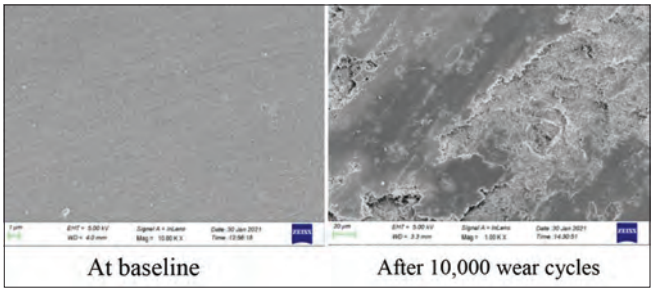


Figure 5: SEM images of layered polished zirconia. SEM: Scanning electron microscopy

analysis of variance test with Tukey's *post hoc* was performed to analyze mean loss of enamel height among four zirconia groups (MG, MP, LG, and LP) [Table 1 and Graph 1] and two within group categories (monolithic and layered) [Tables 2 and 3, Graphs 2 and 3]. The confidence intervals were set to 95% as $P < 0.05$ was considered statistically significant. The results revealed that Group II (teeth against MP zirconia) showed statistically significant lesser mean scores when compared to Group IV (teeth against LP zirconia), whose mean was comparable with Group I (teeth against MG zirconia) followed by Group III (teeth against LG zirconia), which showed greater mean score. Mean surface roughness values of zirconia groups before and after wear test were tabulated and analyzed [Tables 4, 5 and Graphs 4, 5].

DISCUSSION

Tooth enamel is a very hard, highly mineralized tissue that acts as a barrier to protect the tooth against mechanical and chemical insults but it can also be susceptible to wear. Enamel wear opposing restorative materials is a major concern as it is affected by various internal and external factors.[5] In the

Table 1: Comparison of mean loss of height of enamel in all the study groups

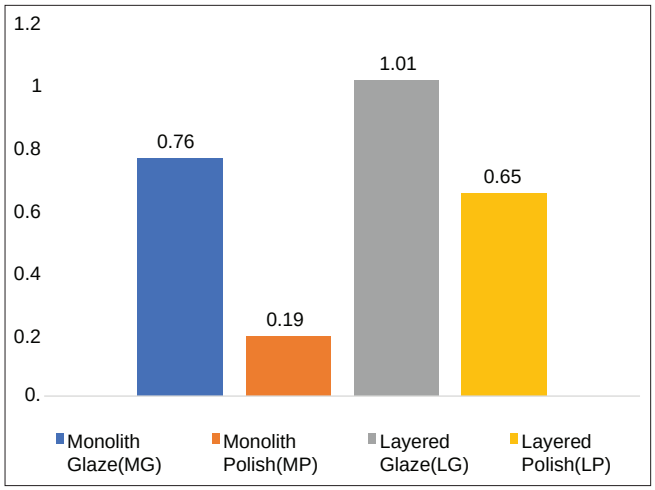
Group	Mean±SD	One-way ANOVA	Tukey's *post hoc*
GROUP I (MG)	0.76±0.17	<0.001	LG>MG=LP>MP
GROUP II (MP)	0.19±0.08		
GROUP III (LG)	1.01±0.11		
GROUP IV (LP)	0.65±0.10		

It was observed that four groups had statistically significant mean difference with $P<0.001$. SD: Standard deviation, MG: Monolithic glazed, MP: Monolithic polished, LG: Layered glazed zirconia, LP: Layered polished zirconia

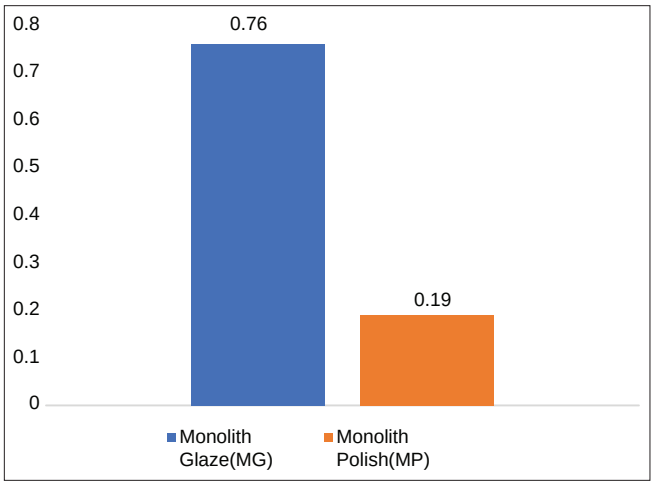
Table 2: Comparison of mean loss of height of enamel in Group I (teeth specimens against monolithic glazed zirconia) and Group II (teeth specimens against monolithic polished zirconia)

Monolith zirconia	Mean±SD		*P*
	Group MG	Group MP	
Enamel wear (loss of height)	0.76±0.17	0.19±0.08	<0.001

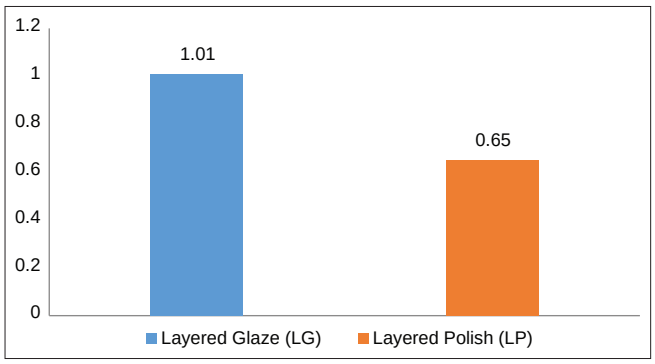
The test showed that there was a significant mean difference between the MG and MP specimens with $P<0.001$. MG: Monolithic glazed, MP: Monolithic polished, SD: Standard deviation



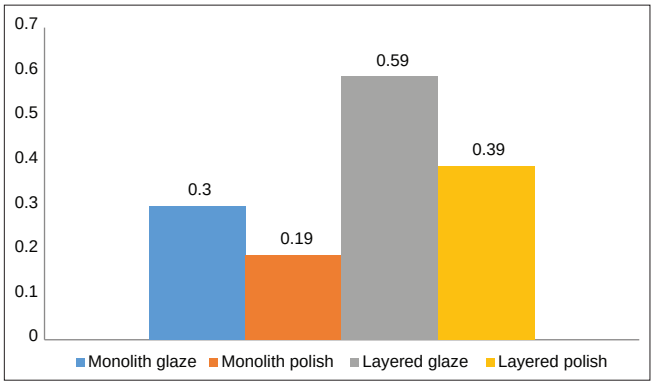
Graph 1: Graphical bar diagram representation showing mean loss of height after 10,000 wear cycles



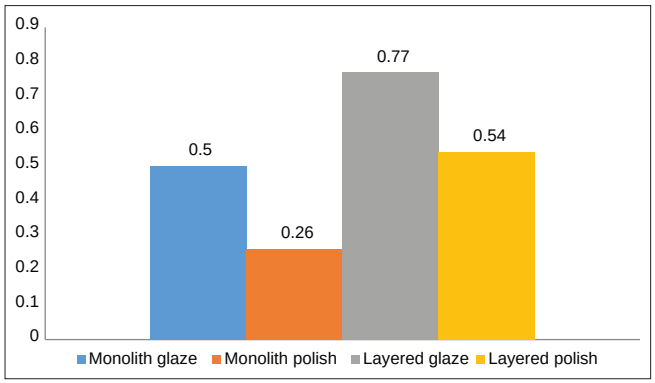
Graph 2: Graphical bar diagram representation showing mean loss of height after 10,000 wear cycles between monolithic glazed group (Group MG) and monolithic polished group (Group MP)



Graph 3: Graphical bar diagram representation showing mean loss of height after 10,000 wear cycles between layered glazed group (Group LG) and layered polished group (Group LP)



Graph 4: Graphical bar diagram representation showing surface roughness before wear test



Graph 5: Graphical bar diagram representation showing surface roughness after wear test

Table 3: Comparison of mean loss of height of enamel in Group III (teeth specimens against zirconia layered with E.max and glazed) and Group IV (teeth specimens against zirconia layered with E.max and polished without glaze)

Layered zirconia	Mean±SD		*P*
	Group LG	Group LP	
Enamel wear (loss of height)	1.01±0.11	0.65±0.10	<0.001

There was a significant mean difference between the layered glazed zirconia and layered and polished zirconia with $P<0.001$. LG: Layered glazed zirconia, LP: Layered polished zirconia, SD: Standard deviation

Table 4: Comparison of surface roughness in all the study groups before wear test

Group	Mean±SD	*P* One way ANOVA	Tukey's *post hoc*
Group MG	0.30±0.04	<0.001	LG>LP>MG>MP
Group MP	0.19±0.02		
Group LG	0.59±0.06		
Group LP	0.39±0.05		

A one-way ANOVA was performed to compare surface roughness in 4 different types of material. There was a significant difference between the mean surface roughness of the 4 groups. On further *post hoc* analysis, it was revealed that the LG group had significantly greater roughness than that of LP, MG, and MP, respectively. LP was significantly greater than MG and MP, respectively, while MG was significantly greater than that of MP. SD: Standard deviation, MG: Monolithic glazed, MP: Monolithic polished, LG: Layered glazed zirconia, LP: Layered polished zirconia

Table 5: Comparison of surface roughness in all the study groups after wear test

Group	Mean±SD	*P* One-way ANOVA	Tukey's *post hoc*
Group MG	0.50±0.05	<0.001	LG>(LP=MG)>MP
Group MP	0.26±0.06		
Group LG	0.77±0.08		
Group LP	0.54±0.06		

A one-way ANOVA was performed to compare surface roughness in 4 different types of material. There was a significant difference between the mean surface roughness of the 4 groups. On further *post hoc* analysis, it was revealed that LG group had significantly greater roughness than that of LP, MG, and MP, respectively. LP was equal to MG and group MP showed the lowest mean score. SD: Standard deviation, MG: Monolithic glazed, MP: Monolithic polished, LG: Layered glazed zirconia, LP: Layered polished zirconia

present study, enamel wear opposing the monolithic zirconia and layered zirconia was evaluated as each material differs in its properties and hence a different wear behavior occurs. Another important factor which affects the opposing enamel wear is the surface finish of the restorative material. The study was performed to check the difference in the enamel wear after glazing and polishing of monolithic zirconia and layered zirconia to ascertain which surface finish produces the least effect on the opposing enamel.

Glazing and Polishing have various advantages and disadvantages over each other. Glazing is highly esthetic and lustrous. Natural teeth shades can be matched with glazing which cannot be achieved by polishing. However, it is difficult to do, consumes much time, and takes better practice. Polishing on the other hand is easy to do, gives efficient results and less technique sensitive. However, the aesthetic value of polishing is lesser than glazing but the restoration can always be polished even after cementation which is not possible with glazing. Another disadvantage with glazing is that it tends to wear off with time in the functional regions revealing the underlying rougher ceramic surface which may harm the opposing dentition.

In the present study, Zi-finish range has been used to polish zirconia samples which makes surface polishing on zirconia much simpler. This includes prepolishers for smoothing and Polishers for high luster polishing. They are available in three shapes – lens, wheel, and pointed cone which make polishing more accessible in difficult regions like pits and fissures. Advantages of the new Zi-finish products include fast surface polishing of zirconia; two stage system of prepolish and polish, simplifies the work and reduces working time; can also be used with ceramic and nonprecious metals.

Study conducted by Mohammadi-Bassir *et al*. and Amaya-Pajares *et al*. showed that the porcelain polishing system produced higher surface roughness values in the range of 2.12–3.10 μ.[6,7] Research done by Mohammadi-Bassir *et al*. and Park *et al*. reported lower values, ranging between 0.08 and 0.9 μ after polishing with different zirconia polishing systems.[6,8] However, Vieira *et al*. Stated that the mechanical finishing and polishing methods were not able to provide a surface as smooth as the glazed surface.[9] A surface roughness test was performed in the present study before the test which showed surface roughness value of Ra-0.19 μ for the monolithic polished specimens, Ra-0.39 μ for the layered polished specimens, Ra-0.3 μ for MG, and Ra-0.59 μ for layered glazed zirconia. These findings were in conformity with the above studies.

Results showed that the wear was greater in Group MG compared to Group MP. Among the layered zirconia groups, Group LG showed greater wear compared to Group LP. Amidst all the groups tested Group LG showed the highest enamel wear whereas Group MP showed the lowest enamel wear suggesting that surface finish and the type of material has a role in the wear mechanism.

On qualitative analysis with scanning electron microscopy (SEM) in accordance to Kadokawa *et al.* and Ortega *et al.* Both MG specimens and layered glazed zirconia had more asperities with loss of glaze layer which might be a cause for increased wear among glazed groups.[10,11] The SEM image of MP showed a comparatively intact surface with mild roughening of the surface which might be the reason for relatively lower enamel wear compared to other groups. The SEM image of layered polished zirconia showed loss of surface finish but it appeared to be smoother compared to the monolithic glazed and layered glazed zirconia.

Between monolithic glazed and layered glazed group the surface of layered glazed zirconia appeared rough. In regards to the above findings, due to the damage of the glaze layer after repeated cycles, the surface tends to become rough thereby causing greater wear.

Test results showed that Layered and Glazed group showed significantly greater enamel wear (1.01 mm ± 0.11) compared to Monolithic Glazed group (0.76 mm ± 0.17), followed by Layered Polished group (0.65 mm ± 0.10) and Monolithic Polished group (0.19 mm ± 0.08) showed the least enamel wear among the groups tested indicating that the mechanical polishing of zirconia is the best method to reduce the antagonist wear. The results obtained were in conformity with the study done by Rosentritt *et al.*, Preis *et al.*, Wang *et al.*, Mitov *et al.*, and Park *et al.*[12-16] To substantiate these findings, surface roughness test was performed for the material specimens following the completion of the wear cycles. Surface roughness values obtained were: Monolithic glazed group (Ra-0.5 μ), monolithic polished group (Ra-0.26 μ), layered glazed group (Ra-0.77 μ), and layered polished group (Ra-0.54 μ). The rate of enamel wear may be correlated with the increase of the surface roughness among the test specimens during the wear simulation.

Previously conducted research showed the wear of enamel against zirconia through various study designs. *In vitro* studies conducted by Mitov *et al.*, Stawarczyk *et al.*, Elmaria *et al.*, Preis *et al.*, Wang *et al.*, Janyavula *et al.*, Mulay *et al.*, and Mundhe *et al.* have shown that polished zirconia produces less wear on enamel antagonists than glazed zirconia.[3,13-20] However, using a modified Leinfelder wear testing equipment, Shar *et al.* discovered that polished zirconia causes more enamel loss than glazed zirconia, and suggested that glazed zirconia should be preferable when the restoration opponent is natural tooth.[21] In contrast, Lawson *et al.*, Janyavula *et al.*, and Mitov *et al.* in their research determined that the polished surfaces of monolithic zirconia were smoother than glazed surfaces and showed a lower surface roughness than glazed and ground zirconia.[3,15,22]

The study's limitations are that, while enamel is a perfect antagonist, differences in natural substrate and storage media make it less practical and exact than synthetic materials, as stated by S D Heintze *et al.*[23] Furthermore, the outcomes obtained with nonstandardized enamel specimens were significantly variable. As proposed by Preis *et al.* and Attin *et al.*, this variance can be due to opposing inhomogeneity, tooth tissue with varied shape or thickness of enamel layers.[13,24] Steps involved in the fabrication of the specimens like sandblasting, layering, application of glaze and polishing were done manually. These factors alone or in combination may contribute to the inconsistencies.

Altogether, the type of restorative material and the surface condition have an influence on the wear potential of the restorative materials. When choosing a restoration, the wear behavior of the material against enamel should be considered as it is an irreversible damage. In order to preserve the enamel, it is essential that proper measures be taken. Chairside adjustments of the zirconia restorations leave a rough surface which in turn can be associated with increased enamel loss. This might be attributed to partial disruption of the glaze layer, incorporation of surface irregularities, etc. Therefore, it is essential that chairside polishing of the restoration is done, irrespective of the surface finish method, before the cementation of the restoration. In this way, zirconia can be effectively used against natural teeth. Several chairside polishing kits are available in the market, but the effectiveness and choice of the polishing agent are of question and stands as a further scope of the study.

CONCLUSION

Following observations might be concluded from the study taking in consideration its limits:

- On preevaluation: Surface roughness of specimens was found to be least in Group MP (Ra = 0.19 μ) followed by Group MG (0.3 μ), Group LP (0.39 μ), and Group LG (0.59 μ)

- Group MP caused the least wear of opposing enamel followed by Group LP, Group MG, and Group LG caused the highest wear
- Both Polished groups (MP and LP) caused lower wear compared to glazed groups (MG and LG)
- Both Monolithic groups (MP and MG) caused lower wear compared to layered zirconia groups (LP and LG).

Further studies may be required to conclude the relation between the surface roughness and the wear pattern.

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Conflicts of interest
There are no conflicts of interest.

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Research

Comparative evaluation of fracture resistance of anterior provisional restorations fabricated using conventional and digital techniques – An *in vitro* study

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Abstract

Aim: Comparative evaluation of the fracture resistance of anterior provisional crowns fabricated by conventional and digital techniques.

Settings and Design: Department of Prosthodontic, PGIDS, Rohtak, An *in-vitro* – Comparative study.

Materials and Methods: Thirty recently extracted maxillary central incisors were handpicked. Tooth preparation was done according to the principles of tooth preparation. A single-step impression technique was used for impression making of the prepared tooth and stone models were poured. Extracted teeth were divided into 3 groups (n = 10 each) based on provisional crown fabrication technique. A bis-acryl-based (Protemp 4 3M ESPE) resin was used to fabricate the provisional crowns by the conventional indirect technique. The rest of the stone models (20) were scanned using lab scanner (Dentsply Sirona InLab EOS X5). CAD/CAM provisional material (Dentsply Sirona multilayer PolyMethyl Methacrylate) PMMA disc was used for fabrication of provisional restoration through milling technique. 3D printed temporary provisional material (NextDent C&B resin) was utilized for 3D printed provisional crowns. Cementation of provisional crowns was done using eugenol free temporary luting cement (Templute, Prime dental). All cemented provisional crowns were subjected to load under Universal Testing Machine. The maximum load to produce fracture for each specimen was recorded in Newton (N).

Statistical Analysis Used: Shapiro–Wilk test was employed to test the normality of data. Kruskal- Wallis Test was used to compare the mean fracture resistance between all the groups. For intergroup comparison Mann-Whitney U Test was used.

Results: The mean fracture resistance of group I (Conventional technique) was found to be 558.8459700 ± 22.33 N; for group II (CAD/CAM technique) 960.8427200 ± 37.49 N and for group III (3D Printed technique) 1243.1774000 ± 68.18 N. Group I had the least fracture resistance value while group III showed maximum value.

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Conclusion: Provisional crowns fabricated using 3-D printing technique showed higher fracture resistance followed by CAD/CAM technique and conventional technique. Additive manufacturing of provisional crowns using 3-D printing technique could be considered a reliable and conservative method for the fabrication of stronger provisional restorations.

Keywords: Computer-aided design and computer/aided manufacturing technology, fracture resistance, provisional restoration, three-dimensional printing

INTRODUCTION

One of the most significant components of provisional, temporary, or interim restorations is meeting the patient's functional and aesthetic demands. They are of great significance, especially in those cases where longer duration of treatment is needed before delivery of the final prosthesis.[1,2]

According to Shillingburg, a provisional restoration should provide pulp protection of underlying prepared tooth from the external and internal noxious stimuli, protect periodontium, prevent supra eruption or mesial or distal tipping of tooth, and should be in harmonious occlusion and easy hygienic maintenance. They should be esthetically pleasing, biocompatible with the surrounding tissues such as the gingiva, should maintain the gingival health as well as emergence profile and should not induce any gingival pathosis. Proper marginal adaptation, low thermal conductivity, mechanical properties such as fracture resistance, strength, and wear resistance are the indispensable requirements of provisional restorations.[3]

One of the most common causes attributed to a failure of provisional restorations is the fracture of the prosthesis causing patient discomfort and economic loss. Fracture resistance is a mechanical property that describes the resistance of brittle materials to the catastrophic propagation of flaws under applied stress.[4]

The provisional restoration can be fabricated using the conventional chair-side method, in the laboratory on working casts, or more recently by the use of digital technology. Conventional technique fabrication includes prefabricated versus custom made which are further classified into direct, indirect, and direct-indirect methods. It has many disadvantages such as the production of exothermic heat, high residual monomer content, and more shrinkage resulting in dimensional discrepancies. It also affects the mechanical properties and fit of the prosthesis.[5]

Computer-aided design and computer-aided manufacturing system (CAD/CAM) have been introduced to simplify the method and eliminate the common errors associated with the conventional provisional technique; however, it has its own flaws.[6]

Recently, introduced additive system, i.e., three-dimensional (3D) printing system has superior qualities in the fabrication of provisional restorations, to overcome the demerits of previous techniques. Many studies have been done in the past comparing the provisional crown fabricated by conventional method and those fabricated using CAD/CAM milling technique on posterior teeth but lacks on anterior teeth, which are of utmost importance in esthetic zone.[5,6]

Therefore, this study aimed to compare the fracture resistance of anterior provisional crowns fabricated by conventional techniques and those fabricated by digital techniques.

MATERIALS AND METHODS

Thirty extracted maxillary central incisors of approximate anatomic crown length and mesiodistal dimensions were selected.

All the specimens were mounted in self-polymerizing acrylic resin using customized mounting mold and keeping the long axis parallel to mold using Ney surveyor. Specimens were divided into three groups of 10 each as follows:

- Group I: Provisional crown fabricated using conventional technique
- Group II: Provisional crown fabricated using CAD/CAM milling technique
- Group III: Provisional crown fabricated using 3D printed technique.

Preparation of the specimens

A tooth preparation kit (Shofu crown and bridge tooth preparation kit, India) was used for tooth preparation. It was done according to the principles of tooth preparation. Specimens were prepared for all ceramic full coverage crowns with shoulder finish line.

Impression making

To make the impression of the prepared tooth, a metal custom tray with perforations was made. The tray had similar dimensions to that of the acrylic block for accurate seating on the block. The tray had a space of 6 mm for the impression material. Polyvinylsiloxane impression material (AVEU™ gum putty, Made in Korea) was loaded in the custom tray and light body impression material (AVEU™ light body, Made in Korea) was loaded on the prepared tooth and single step impression was made. The loaded tray with putty impression material was placed on the acrylic block and a single-step impression was made. All the impressions were then poured in die stone (Ultra rock brown die stone; Kalabhai Karson Pvt. Ltd.) with the help of vibrator to avoid any void or bubble formation.

Fabrication of provisional crowns

Fabrication of provisional crowns by conventional method (Group I)

Before the commencement of tooth preparation, a putty index of the unprepared mounted tooth was made. Following the preparation of the mounted tooth, its impression was made using putty and light body impression material. Impression was poured using a vibrator and a die stone model was obtained. Cement space thickness was defined at 30 μm by applying the die spacer of the same thickness. Provisional restoration material Protemp4 TM was dispensed through dispensing tip into the preformed putty index, and thereafter, the index was seated over the stone model. For the exact seating of putty index onto the stone model, parallel vertical lines were scribed onto the stone model as well as in the putty index. Excess of provisional restoration material was removed using explorer and finishing and polishing of provisional restoration were done using acrylic finishing and polishing kit.

Fabrication of provisional crowns by milling technique (Group II)

The stone model was scanned with the help of a scanner (Dentsply Sirona In early-onset scoliosis [EOS] X5) [Figure 1a]. Surface tessellation language (STL) file of the scanned model was obtained [Figure 1b]. Designing of provisional crowns was done using EXOCAD software and. STL files of the provisional crowns were created [Figure 1c]. Cement space thickness was defined at 30 μm. Polymethyl methacrylate (PMMA) CAD disc was selected. Virtual sprue attachment was done. The. STL file of the designed data was fed into the milling machine (DentsplySironaInLab MC X5). Wet milling of the PMMA disc was performed [Figure 1d]. Later, sprue was removed from the milled disk. Finishing and polishing of the crowns were performed using an acrylic finishing and polishing kit.

Fabrication of provisional crowns by 3D printing (Group III)

The stone model was scanned with the help of a scanner (Dentsply Sirona In EOS X5) to generate a. STL file. The provisional restoration was designed using the EXOCAD software program. Cement space thickness was defined at 30 μm and the thickness of the build layer was kept at 0.05 mm. NextDent C and B resin was activated using an LC-3DM mixer [Figure 2a]. After activation, the resin was poured into a 3D printer

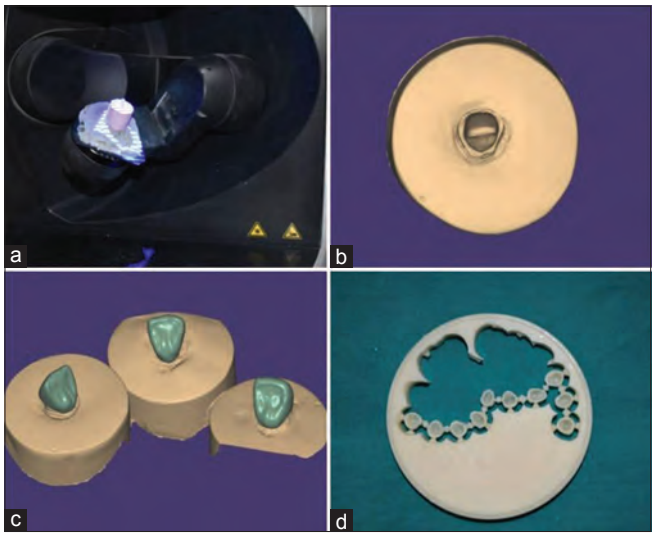


Figure 1: (a) Scanning of the stone die, (b) STL file of scanned stone die, (c) Designing of provisional crowns, (d) Milled provisional crowns, STL: Surface tessellation language

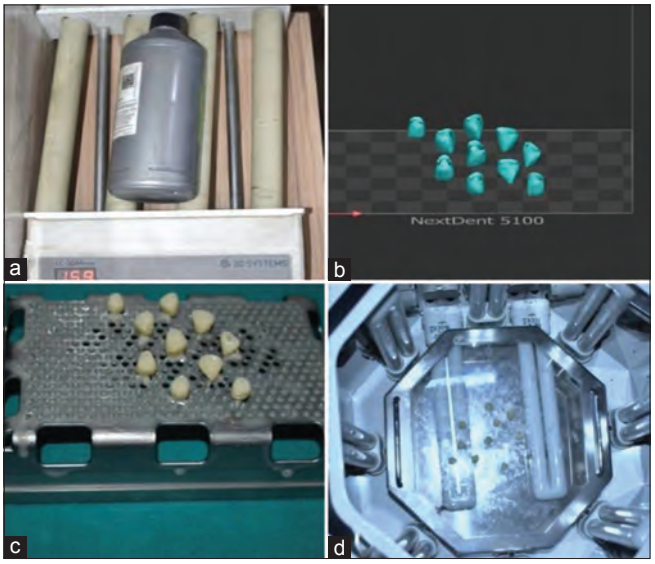


Figure 2: (a) Activation of NextDent C and B resin, (b) Orientation of provisional crown STL files on printing table, (c) 3D Printed crowns, (d) Post curing of 3D printed crown, 3D: Three-dimensional

container in the NextDent 5100 printer. The. STL file was generated and data fed to the NextDent 5100 printer [Figure 2b]. Objects were built layer-by-layer. The ultraviolet light (405 nm) cured each layer and hardened a thin layer of the polymer. The process continued until the completion of the full object with the layer thickness of about 50 μm with supporting structures [Figure 2c]. The printing cycle took about 30 min for partial curing of each provisional crown.

Postprocessing and curing of 3D printed provisional restoration was done. Supporting structures were removed. To remove and clean the uncured resin, printed crowns were cleaned with 96% isopropyl alcohol. The NextDent LC-3DPrint Box (wavelength 350–550 nm) was used for 30 min for postcuring of 3D printed resin materials to ensure that materials achieve full polymerization [Figure 2d].

Cementation of provisional crown

Finished and polished provisional restorations were evaluated for any voids, bubbles on the inner surface of the crown and any marginal inadequacy. TempluteTM (Prime Dental Products, India) noneugenol-based temporary luting cement was used for cementation. The entire inner surface of the provisional crown was coated with the mixed cement and the crown was placed on the prepared tooth with finger pressure to maintain constant pressure. After the initial set, excess cement was removed using explorer.

Mechanical testing of the specimens

A customized metal jig was fabricated to hold the specimen at 135° to the long axis of the tooth under universal testing machine. Fracture resistance tests of the specimens were performed using a universal testing machine (UNITEK 94100). Cemented specimens from all the Groups (I, II, and III) were loaded at 135° degrees to the long axis of the tooth simulating load during intercuspal movements. The load was applied 3 mm below the incisal edge on the center of the palatal surface of the cemented provisional crowns with a load applicator attached to the upper movable compartment of the machine with a crosshead speed of 1.0 mm/min [Figure 3]. Each specimen's maximal load to cause fracture was measured in Newton.

Statistical analysis

Data obtained were checked for normality using the Shapiro–Wilk test and it was found that the data followed a nonnormal curve; hence, nonparametric tests have been used for comparisons. Kruskal–Wallis test was used to compare the mean fracture resistance between all the groups. For intergroup comparison, Mann–Whitney *U*-test was used.

RESULTS

Descriptive statistics showed mean values, median and standard deviation of the effect of three techniques (Conventional technique versus CAD/CAM technique versus 3D printed technique) tabulated in Table 1 and drawn in the [Graph 1].

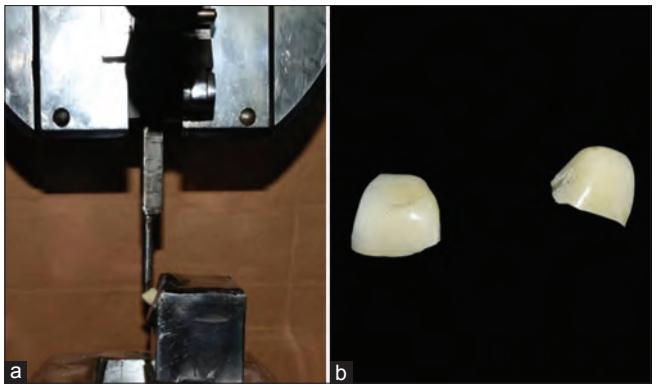
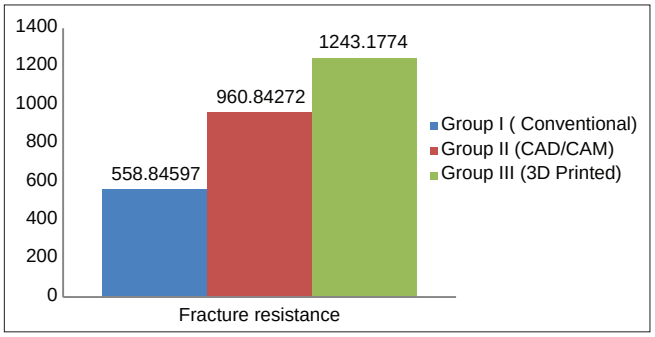


Figure 3: (a) Testing of specimen under Universal Testing Machine, (b) Fracture crown after testing



Graph 1: Fracture resistance of provisional crowns fabricated by conventional, CAD/CAM and 3D printed techniques. CAD/CAM: Computer-aided design and computer-aided manufacturing, 3D: Three-dimensional

Table 1: Mean value and standard deviation and median of Groups I, II, and III

	n	Mean±SD	Minimum	Maximum	Percentiles		
					25th	50th median	75th
Group I	10	558.8459700±22.33138645	524.343	585.347	535.843	562.6001	579.0566
Group II	10	960.8427200±37.49838928	905.320	1010.430	922.932	960.9181	989.4365
Group III	10	1243.1774000±68.18871764	1100.803	1330.774	1190.287	1255.4576	1288.4935
Strength	30	920.9553633±289.13683909	524.34330	1330.77400	578.1434750	960.9181	1140.563

SD: Standard deviation

The mean of Group I (provisional crown fabricated by conventional technique) was 558.84597 ± 22.33, whereas for Group II (Provisional crown fabricated by CAD/CAM milling technique) 960.84272 ± 37.49 and Group III (Provisional crown fabricated by CAD/CAM milling technique) was 1243.17740 ± 68.18. Group III showed the maximum mean fracture resistance of 1243.17N amongst all; whilst Group I showed the least fracture resistance of 558.84N. Statistically significant results and significant difference in mean fracture strength were found.

DISCUSSION

Provisionalization is an integral step in the treatment of fixed prostheses. Provisionalization's biological, mechanical, and esthetic criteria must be considered for success during the temporization phase of treatment. Various provisional materials have evolved over time regarding biologic, mechanical, and esthetic properties, which make them suitable in the specific area. The interim restoration is employed in-between from the time of tooth preparation till final cementation is done. To ensure a successful final restoration, a suitable fabricated provisional restoration is important, which becomes even more crucial in cases of full mouth rehabilitations. Provisional restorations are often utilized for relatively long periods (6–12 weeks) to monitor patient comfort and satisfaction.[5]

Provisional restorations are fabricated using a variety of techniques. The manual technique is further classified into direct, indirect, and indirect-direct techniques. Advancements in materials and technology aided the development of the CAD/CAM technique, which is further classified into additive and subtractive techniques. The subtractive technique is currently widely used in most modern dentistry facilities i.e., CAD/CAM. Due to ever-changing concepts and technology, we can now print the complex structure by additive technology as well, i.e., 3D printing, which is a quickly gaining attraction, employing a variety of resins. It is capable of simulating exact prostheses with minimal wastage of materials.[6] It is said to be less expensive and faster than milling. Stereolithography, digital light processing, selective laser sintering, and fused deposition modeling are some of the 3D printing techniques.[7-9]

An important requisite of the provisional restoration is that it should not deform under mechanical forces such as masticatory and parafunctional forces. Even though restorations are being planned to avoid failure, still fractures do happen, causing discomfort and financial loss to the patients. To ensure the clinical success, the mechanical strength attributes of provisional materials are critical and should be considered. Restoration fractures during function can be caused by various factors such as incorrect occlusion, bruxism, under contoured pontics, and trauma.[8,9]

There are confined studies that correlates and emphasize the mechanical properties such as fracture resistance of provisional restorations. The documented information is mainly available on marginal fit, fracture resistance; build layer effect done on the posterior tooth, but lacks on anterior tooth, which being in esthetic zone cannot be ignored. Therefore, the current research work was done to assess the fracture resistance of anterior provisional restoration fabricated by conventional and digital technologies.[10]

This study was conducted on recently extracted human maxillary central incisors for the advantage such as similar modulus of elasticity, hardness, and strength as teeth present in the oral environment. The selection of extracted maxillary central incisor, vertical mounting of the tooth into self-cure acrylic resin using Ney surveyor was done according to standardization as stated by Stappert *et al*.[11,12]

Group I versus Group II, (conventional technique versus CAD/CAM technique) showed that there was a statistically highly significant difference seen for the values between the Groups I versus II ($P < 0.01$) with higher values for Group II as compared to Group I. This result coincides with the finding of research conducted by Reeponmaha *et al*., Rayyan *et al*. and Abdullah *et al*. Reeponmaha *et al*. conducted a study to evaluate the fracture strength and fracture patterns of provisional crowns fabricated from different materials and techniques after receiving stress from a simulated oral condition. They concluded that provisional restoration fabricated using CAD/CAM techniques showed higher fracture resistance compared to conventionally fabricated monomethylacrylate resin.[1] Rayyan *et al*. conducted a study with the purpose to compare the color stability, water sorption, wear resistance, surface hardness, fracture resistance, and microleakage of CAD/CAM fabricated interim restorations with that of conventionally fabricated interim restorations. They concluded that CAD/CAM interim crowns showed better physical and mechanical properties than conventional or manually fabricated and may be used for long-term interim restorations.[13] Abdullah *et al*. did a study to compare the marginal gap, internal fit; fracture strength of CAD/CAM fabricated provisional restoration and concluded that CAD/CAM fabricated provisional crowns demonstrated superior mechanical properties than directly fabricated provisional restoration.[8]

Group I versus Group III, conventional technique versus 3D printed showed that there was a statistically highly significant difference seen for the values between the Groups I versus III ($P < 0.01$) with higher values for Group III as compared to Group I. The result coincides with the finding of a study done by Tahayeri *et al*. They evaluated the mechanical properties of 3D printed versus conventionally cured provisional material. Mechanical properties of 3D printed provisional restoration were found to be higher than that of the conventionally fabricated restorations.[13]

Group II versus Group III showed that there was a statistically highly significant difference seen for the values between the Groups III versus II ($P < 0.01$) with higher values for Group III as compared to Group II. The result coincides with the study done by Joshi *et al*. and Ibrahim *et al*. Joshi *et al*. performed the study to compare the physical and optical properties of provisional crown and bridge materials fabricated using CAD/CAM or 3D printing technology and concluded that milled PMMA has superior flexural strength and hardness compared to 3D printed resins.[12] Ibrahim *et al*. assessed the fracture resistance of interim restorations fabricated by 3D printing technique and milling technique. They concluded that interim crowns fabricated using the 3D printing technique showed higher fracture resistance compared to milled interim crowns under thermo mechanical loading.[14,15]

Based on the results of the present study, superior fracture resistance of Group III can be due to the following reasons:

a. The superior fracture resistance could be due to the layered nature of the 3D-printed structure and because of the chemical bonding between the layers. The increased values of the fracture resistance could also be due to the vertical building orientation of the 3D printed interim crowns employed in the present study and higher than horizontally printed specimen with layers parallel to load direction[16]
b. The higher fracture resistance could be attributed to the thin printed layer thickness used (50 μm) during the building process. The layer thickness could be an important contributor to the mechanical properties of samples. Lower the layer thickness, the more the layer to layer interfaces available; the better the degree of polymerization for each layer and the more mechanical performance is affected positively[16]
c. It could be attributed to the postcuring process of 3D printed crowns that was carried out in a special NextDent curing unit. The use of a postcuring technique on 3D printed crowns can improve fracture toughness and strength by increasing conversion and reducing the presence of residual monomers.[16]

The surface characteristic, topography of provisional not only affect the mechanical properties but also affects the color stability of provisional restorations. Song *et al*. compared the color stability of provisional restorative materials fabricated by 3D printing, dental milling, and conventional materials and concluded that all the three materials showed varied degree of discoloration with time. All the three materials showed initial excellent colour stability, but there was exponential or more rapid change in color after 8 weeks.[17] Coutinho *et al*. conducted a study on LuxaCrown, Protemp4, Heat cure PMMA to evaluate color stability of these three materials. They concluded that least color change was observed in heat cure PMMA followed by Protemp4 and highest difference was seen in LuxaCrown.[18]

The present study was novel as three provisional restoration materials selected were recent ones. The previous studies were done using the cast of die specimens and were mainly on the posterior tooth while the present study focused on anterior tooth region.

With in the limitations, the merits of this *in vitro* study were

Based on this study, clinical recommendations can be made that 3D printed restorations are more durable than the other two techniques. This study utilized extracted maxillary central incisors, which simulated the elasticity and other factors of natural teeth.

The present study compares the conventional technique to that of additive and subtractive manufacturing techniques, which has not been done previously to the best of our knowledge.

The present study includes postprocessing parameters of 3D printed crowns, which is an important parameter. Most of the studies regarding marginal fit comparison, internal fit comparison and fracture resistance and fracture pattern have been done mostly on posterior tooth whereas the present study compares of provisional restoration of anterior tooth region.

The limitations of the study are as follows

Extracted human maxillary incisors used had the disadvantage of variations in age and quality, thus compromising on the standardization of the bonded interface of cement and tooth. The periodontal ligament considerations were not taken into account. Acrylic resin was employed to embed the teeth, which had a different biomechanical position than the oral cavity and did not mimic the clinical situation.

The restoration was cemented with finger pressure, which is clinically applicable. The failure load was employed to assess the restoration's resistance alone, although in the oral environment, a variety of variables are present. Additional elements, including the physical and chemical stresses that the repair are exposed to over a long period of time in the clinic, may have an impact on the outcome.

Thermal variations are known to cause cracking and failure of the provisional restorations clinically. The cement used for luting the provisional crowns may impose surface changes on the crowns when it is subjected to thermal variations. Thermocycling with variable temperatures was not used in this investigation, which could have influenced the fracture resistance rating. The fracture patterns of the provisional crowns were not evaluated.

As a result, future research should evaluate the influence of the above-mentioned characteristics, as they may change the fracture resistance values and failure modality of the specimens. The use of artificial periodontal membrane to simulate the clinical condition could improve the research results further. Abutment mobility is a decisive clinical factor for the evaluation of failure load.

CONCLUSION

Within the limitations of this *in vitro* study, it can be concluded that:

1. Provisional crowns constructed using 3D printing technique showed higher fracture resistance followed by CAD/CAM technique and conventional technique
2. Additive manufacturing of provisional crowns using 3D printing technique could be considered a reliable and conservative method for the production of stronger provisional restorations
3. Fracture resistance of all the groups showed clinically acceptable values under mechanical loading.

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Conflicts of interest

There are no conflicts of interest.

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Research

Effect of silver nanoparticles on wettability, anti-fungal effect, flexural strength, and color stability of injection-molded heat-cured polymethylmethacrylate in human saliva

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Abstract

Aim: Aim of this study was to evaluate the effect of silver nanoparticles incorporated injection molded heat-cured polymethylmethacrylate resin on wettability, anti-fungal effect, flexural strength and colour stability in human saliva.

Settings and Design: An *In-Vitro* study with *In -Vivo* parameter

Materials and Methods: Rectangular and circular stainless-steel dies were fabricated according to ISO standardization 20795-1:2018 and ADA specification number 12. A total of 144 samples were prepared and divided into 4 groups with thirty-six samples in each group. Each of the 4 groups were subdivided into 3 subgroups based on concentration of silver nanoparticles as 0% in subgroup A, 0.05% in subgroup B and 0.2% in subgroup C. Group 1 samples evaluated wettability, they were assessed at 0, 7, 90 and 180 days after immersing in human saliva using goniometer. Group 2 samples evaluated antifungal effect, they were assessed against Candida albicans in Muller hinton agar plate enriched with 2% glucose. Group 3 samples evaluated flexural strength, they were assessed by using universal testing machine. Group 4 samples evaluated colour stability, they were assessed using UV spectrophotometer at 0, 3 and 7 days after immersing in human saliva.

Statistical Analysis Used: One-way ANOVA and Post- Hoc Tukey test were used to evaluate the significant differences in the mean values of the groups.

Results: Subgroup C samples with 0.2% Ag nanoparticles had better wettability, maximum antifungal property, highest flexural strength and good colour stability followed by subgroup B and subgroup A samples.

Conclusion: Injection molded denture base resin incorporated with 0.2% Ag nanoparticles could be used clinically as a denture base material for completely and partially edentulous patients.

Keywords: Antifungal effect, color stability, flexural strength, injection-molded resins, silver nanoparticles, wettability

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INTRODUCTION

Denture base resins used for fabricating removable prosthesis are polymethylmethacrylate (PMMA) was introduced in 1937.[1] Denture base resin has good esthetics, excellent biocompatibility, reliability, dimensional stability, absence of taste, odor, teeth adhesion, insolubility in body fluids, relative ease of manipulation, color stability, and low thermal conductivity.[2] The disadvantages are residual monomer toxicity and its effect on the oral tissues, the microbial colony with moderate-to-low mechanical properties that are susceptible to distortion and discoloration. The generation of cracks in denture base leads to fracture, which can also act as a point of entry for various bacteria.[3] High-impact injection molded PMMA was emerged in 1942 and provided better dimensional stability, wear strength, better deflection, and water sorption than conventional and reinforced PMMA.[4]

Wettability is affected by denture base resin to saliva contact. The degree of wetting is evaluated as the contact angle formed between liquid and solid. Human saliva has an important role to play in wettability with denture base resin. Denture base resins have influence toward the adhesion of *candidal* species. Nanoparticle incorporation exhibited enhanced mechanical, electrical, magnetic, and optical properties when compared with conventional PMMA. Various nanoparticles were incorporated in previous studies, but silver nanoparticles gained considerable attention because of its unique physical, biological, and anti-bacterial properties against Gram-positive and Gram-negative bacteria.[5] Flexural strength of denture base resin is one of the most important mechanical properties. The conventional PMMA has moderate flexural strength. By the addition of reinforcers flexural strength can be improved drastically. PMMA has a disadvantage of discoloration due to intrinsic and extrinsic staining from diet and habits. The use of high-impact injection-molded PMMA improves the physical properties of the denture base. This study evaluates the effect on wettability, anti-fungal effect, flexural strength, and color stability of injection molded heat-cured PMMA in human saliva with varying concentrations of silver nanoparticles.

MATERIALS AND METHODS

The study was approved by the Institutional Review Board (SRMDC/IRB/2019/MDS/No.202). The aim of this study was to evaluate the wettability, antifungal effect, flexural strength, and color stability of high-impact injection-molded PMMA reinforced with varying concentrations of silver nanoparticles in human saliva. The overall sample size was estimated to be 144. The samples were divided into four groups were and samples per group were 36. Each of four groups was again divided into 3 based on silver nanoparticle concentration. Rectangular stainless steel master die was fabricated according to ISO 20795-1:2018 with dimensions of 65 mm × 40 mm × 5 mm for evaluating flexural strength [Figure 1]. Circular stainless steel master die was fabricated according to ADA specification number 12 with dimensions 50 ± 1 mm × 1.0 ± 0.5 mm for evaluating wettability, antifungal effect, and color stability [Figure 2]. The samples were fabricated using this master die with high-impact injection-molded PMMA reinforced with silver nanoparticles at various concentrations [Figure 3]. All the samples were finished and polished using acrylic trimmers and sandpapers. The samples for flexural strength were cut into four strips of equal size measuring 65 mm × 10 mm × 5 mm [Figure 4].

Collection of unstimulated saliva

Unstimulated saliva from edentulous patients was collected by passive drooling method into a sterile container. Ten milliliters of the patient's saliva has been collected and was immediately stored in the freezer at 4°C to prevent bacterial growth and to prevent further degradation of salivary molecules. These salivary samples were used without further treatment for evaluating wettability and color stability.

Sample distribution

Group 1: Wettability

- Subgroup A-12 samples – 0% Ag nanoparticles (control group)
- Subgroup B-12 samples – 0.05% of Ag nanoparticles
- Subgroup C-12 samples – 0.2% of Ag nanoparticles.

Group 2: Antifungal effect

- Subgroup A-12 samples – 0% Ag nanoparticles (control group)
- Subgroup B-12 samples – 0.05% of Ag nanoparticles
- Subgroup C-12 samples – 0.2% of Ag nanoparticles.

Group 3: Flexural strength

- Subgroup A-12 samples – 0% Ag nanoparticles (control group)
- Subgroup B-12 samples – 0.05% of Ag nanoparticles
- Subgroup C-12 samples – 0.2% of Ag nanoparticles.

Group 4: Color stability

- Subgroup A-12 samples – 0% Ag nanoparticles (control group)
- Subgroup B-12 samples – 0.05% of Ag nanoparticles
- Subgroup C-12 samples – 0.2% of Ag nanoparticles.

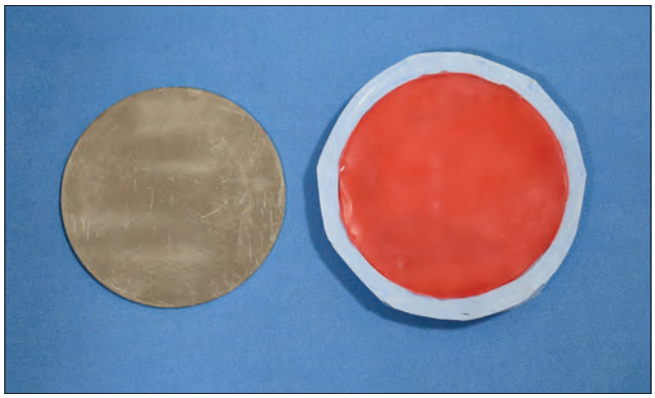


Figure 1: Wax pattern for Group 1, 2 and 4

Figure 3: Specimens for Group 1, 2 and 4

Test for wettability

The control and reinforced group samples were placed in human saliva (collected in vails) under optimum conditions for 0, 7, 90, and 180 days and were tested for wettability using goniometer. Goniometer has a CCD camera that captured and recorded the image of a droplet of test liquid which was placed onto the surface of the specimen using microsyringe and the image processed to determine the contact angle in two different positions and average was calculated.

Test for antifungal effect

The antifungal activity was evaluated using the Kirby-Bauer disk diffusion method against *Candida albicans*. Fabricated control and reinforced group samples were placed on Mueller–Hinton agar plates in petri dish incorporated with 2% glucose and were inoculated with the microorganisms at 37°C for 24 h. The antifungal activity of the control and reinforced specimens were evaluated by measuring the formation of the inhibition zone in millimeters around the samples after 24 h and were statistically analyzed.

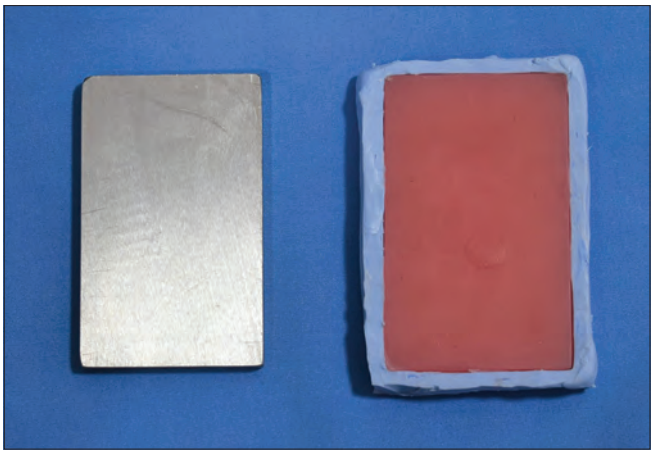


Figure 2: Wax pattern for Group 3

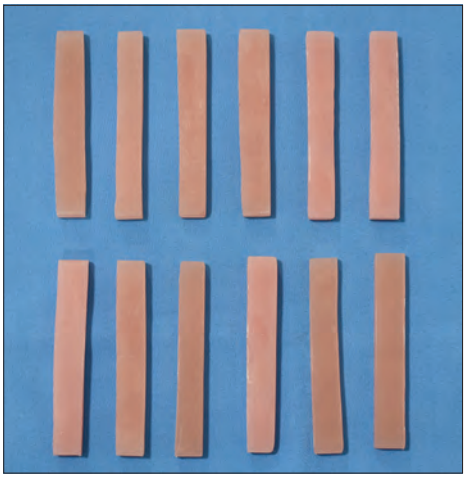


Figure 4: Specimens for Group 3

Test for flexural strength

The control and reinforced group samples were staged on Universal Testing Machine under 3-point loading for the evaluation of flexural strength. Load was being applied at the mid-point of the samples with crosshead speed of 5 mm/min. The maximal load before fracture was measured.

Flexural strength was calculated using the formula. $M = 3WI/2bd^2$ where, M = flexural strength (MPa), W = fracture load (N), I = test span distance between support points in mm, b = width of specimen (mm), and d = thickness of the specimen (mm)

Test for color stability

Fabricated control and reinforced group samples were immersed in human saliva collected from healthy individuals and stored for 7 days and tested using spectrophotometer. The evaluation was done before immersion, on the 3rd day and on the 7th day after immersion in human saliva. Distilled water was used as a negative

control medium. Images were taken under northern daylight on a clear day and color measurements were performed according to the Commission Internationale del'Eclairage L* a* b* uniform color scale. Measurements were taken on 3 different occasions and the mean values of L* (brightness), a* (red-green proportion), and b* (yellow–blue proportion) were calculated. The "corrected" L*, a*, b* values of each specimen were recorded as the baseline color readings before immersion in solution (T0-Dry). The posttreatment digital images of test specimens were obtained and analyzed to determine L*, a*, b* values of each specimen as mentioned previously. The total color change and ΔE of each test specimen were calculated using the equation. ΔE values ≤3.7 were considered to be visually imperceptible as well as clinically acceptable.

RESULTS

This study was done to investigate the effect of silver nanoparticles on wettability, anti-fungal effect, flexural strength, and color stability of injection-molded heat-cured PMMA in human saliva.

Wettability

The one-way ANOVA values for between and within the subgroup's comparison of the Group 1 samples are listed in Table 1. The sum of square value, the mean square value, and *F* value were found to be 123.656, 38.815, and 27.830 for the 0 day, for the samples stored for the 7th day the sum of square value, the mean square value and *F* value were found to be 298.669, 97.279, and 30.834, respectively. The sum of the square value, the mean square value, and *F* value for the samples stored for the 90th day were found to be 139.377, 3.345, and 0.832, respectively. The sum of square value, the mean square value and *F* value for the samples stored for the 180th day were found to be 234.607, 78.987, and 34.014, respectively. The significant difference was seen only on the 90th day with a value of 0.444 while other samples between and within the subgroups remained 0.

Table 2 shows Tukey *post hoc* honestly significant difference (HSD) multiple comparison values among the subgroups for wettability of Group 1 samples. The highest mean difference for subgroup A was found to be when compared with C and the value was 3.7758. The highest mean difference for subgroup B was when compared with C and the value was 1.2775. The highest mean difference for subgroup C was 1.2775. The standard error remained the same for all the subgroups.

Anti-fungal effect

Table 3 shows the Tukey *post hoc* HSD multiple comparison values for the antifungal effect of Group 2 samples. The highest mean difference for subgroup A was with the value of −22.667 when compared with B. Highest mean difference for subgroup B was with the value of 22.667 when compared with A. Highest mean difference for subgroup C was with the value of 27.417 when compared with A. The standard error remained the same for all the subgroups.

Flexural strength

Table 4 shows Tukey *post hoc* HSD multiple comparison values for flexural strength of Group 3 samples. The highest mean difference for subgroup A was −6.91833 when compared with subgroup B. Highest mean difference for subgroup B was 6.91833 when compared with. The highest mean difference for subgroup C was 9.99833 when compared with subgroup A. The standard error remained the same for all the subgroups.

Color stability

The one-way ANOVA values for between and within the subgroups comparison of Group 4 samples were listed in Table 5. The total sum of squares on the 0th, 3rd, and 7th days were 0.308, 0.310, and 0.318, respectively. The mean square value and F value on the 0 day were found to be 0.154 and 399549.453, respectively, and on the 3rd day, the mean square value and F value were found to be 0.155, and 1185201.538, respectively. The mean square value and F value for the samples stored for the 7th day were found to be 0.159, and 1147167.962, respectively.

Table 6 shows the Tukey *post hoc* HSD multiple comparison values for Group IV samples. The highest mean difference

Table 1: One-way ANOVA descriptive analysis between and within the subgroups for wettability (Group 1)

	Sum of squares	df	Mean square	*F*	Significance
0th day					
Between groups	77.631	2	38.815	27.830	0.000
Within groups	46.026	33	1.395		
Total	123.656	35			
7th day					
Between groups	194.557	2	97.279	30.834	0.000
Within groups	104.112	33	3.155		
Total	298.669	35			
90th day					
Between groups	6.690	2	3.345	0.832	0.444
Within groups	132.687	33	4.021		
Total	139.377	35			
10th day					
Between groups	157.975	2	78.987	34.014	0.000
Within groups	76.632	33	2.322		
Total	234.607	35			

on the 0th day was 0.2024583 for subgroup C when compared with subgroup A. The highest mean difference on the 3rd day was 0.2028417 for subgroup C when compared with subgroup A. Highest mean difference on the 7th day was 0.2056250 for subgroup C when compared with subgroup A.

Graph 1 represented the wettability values for the Group 1 samples. On the 0th day, 7th day, 90th day, and 180th-day subgroup A had maximum wettability, followed by subgroup B and subgroup C. Overall wettability was increased in all subgroups on all 4 days.

Graph 2 represented the values for the antifungal property of the Group 2 samples and it was found that subgroup C had the highest antifungal activity, followed by subgroup B and the least or nil antifungal effect was seen for subgroup A.

Graph 3 represented the values for the flexural strength of the Group 3 samples and it was found that subgroup C had the highest flexural strength, followed by subgroup B and the least flexural strength was seen in subgroup A.

The Graph 4 represented the color stability values for the Group 4 samples. On the 0th day, all the three subgroups had similar values. On the 3rd day, all the three subgroups had similar values. On the 7th day, subgroup C had the highest value and subgroups A and B had similar values. Overall, the was an increase in color change in all three subgroups on all the 3 days.

DISCUSSION

High-impact injection-molded PMMA was emerged in 1942 and provided better dimensional stability, wear strength, better deflection, and water-sorption than conventional heat-cured PMMA.[6] Comparing the properties of conventional denture base materials and injection molded materials, Parvizi *et al.* concluded that high-impact injection-molded PMMA had the best dimensional accuracy among conventional heat cure PMMA, high -impact injection-molded PMMA, and nylon injection-molded PMMA.[4] Although high-impact injection-molded PMMA is better than conventional heat-cured PMMA, it also suffers such demands as fracture of the prosthesis, water sorption on long-term usage, denture stomatitis due to candidal adhesion, and color

Table 2: Tukey *post hoc* honest significant difference multiple comparison values within the subgroups for the wettability (Group 1)

(I) Group	(J) Group	Mean difference (I–J)	SE	Significance	95% CI	
					Lower bound	Upper bound
Subgroup A	Subgroup B	2.4983*	0.42407	0.000	1.4577	3.5389
	Subgroup C	3.7758*	0.42407	0.000	2.7352	4.8164
Subgroup B	Subgroup A	−2.4983*	0.42407	0.000	−3.5389	−1.4577
	Subgroup C	1.2775*	0.42407	0.013	0.2369	2.3181
Subgroup C	Subgroup A	−3.7758*	0.42407	0.000	−4.8164	−2.7352
	Subgroup B	−1.2775*	0.42407	0.013	−2.3181	−0.2369

*The mean difference is significant at the 0.05 level. The error term is mean square (error)=1.079. SE: Standard error, CI: Confidence interval

Table 3: Tukey *post hoc* honest significant difference multiple comparison values for antifungal test (Group 2)

(I) Group	(J) Group	Mean difference (I–J)	SE	Significance	95% CI	
					Lower bound	Upper bound
Subgroup A	Subgroup B	−22.667*	0.558	0.000	−24.04	−21.30
	Subgroup C	−27.417*	0.558	0.000	−28.79	−26.05
Subgroup B	Subgroup A	22.667*	0.558	0.000	21.30	24.04
	Subgroup C	−4.750*	0.558	0.000	−6.12	−3.38
Subgroup C	Subgroup A	27.417*	0.558	0.000	26.05	28.79
	Subgroup B	4.750*	0.558	0.000	3.38	6.12

*The mean difference is significant at the 0.05 level. SE: Standard error, CI: Confidence interval

Table 4: Tukey *post hoc* honest significant difference multiple comparison values for flexural strength (Group 3)

(I) Group	(J) Group	Mean difference (I–J)	SE	Significance	95% CI	
					Lower bound	Upper bound
Subgroup A	Subgroup B	−6.91833*	0.52114	0.000	−8.1971	−5.6396
	Subgroup C	−9.99833*	0.52114	0.000	−11.2771	−8.7196
Subgroup B	Subgroup A	6.91833*	0.52114	0.000	5.6396	8.1971
	Subgroup C	−3.08000*	0.52114	0.000	−4.3588	−1.8012
Subgroup C	Subgroup A	9.99833*	0.52114	0.000	8.7196	11.2771
	Subgroup B	3.08000*	0.52114	0.000	1.8012	4.3588

*The mean difference is significant at the 0.05 level. SE: Standard error, CI: Confidence interval

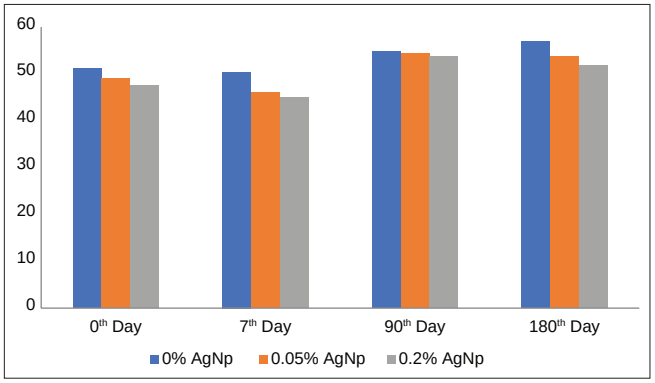
changes. Metal reinforcements can be used in high-impact injection-molded PMMA in a similar way that was carried out in conventional heat-cured PMMA. Such metal reinforcers used are nanoparticles.

Nanotechnology is a recently emerging field with extensive research in the characteristics of various nanoparticles that aid in dentistry as part of its treatment. Various nanoparticles were used as reinforcers in denture base materials. Silver nanoparticles were used for extensive experimentation in dentistry due to its optical property and antimicrobial effect. Few studies incorporated silver nanoparticles in conventional denture base materials and evaluated their properties. Sodagar *et al*. had reinforced silver nanoparticles in conventional heat-cured PMMA and showed improved results in terms of verifying the flexural strength.[7]

Apart from the evaluation of the flexural strength of silver nanoparticles reinforced high impact injection-molded PMMA, a few other properties of interest in this study were wettability, antifungal effect, and color stability. The wetting properties of the denture and the palatal mucosa occur through the adhesive forces (saliva) at the two interfaces which affect denture retention. Contact angle hysteresis is influenced by surface heterogeneity, surface roughness, surface deformation, and chemical contamination of water while rinsing.[8] Jaiswal *et al*. studied the wettability of conventional heat-cured PMMA in various artificial saliva and concluded all the artificial saliva had better wetting properties than distilled water.[9] The study by Farcasiu and Păuna compared the wettability of conventional heat-cured PMMA and injection-molded PMMA in natural and artificial saliva and concluded that injection-molded PMMA had the best wettability.[10] Zissis *et al*. verified the acrylic and nylon denture bases and concluded by stating that, the high-impact heat-polymerized PMMA denture base resin showed the best wettability with the least advancing and receding contact angle values.[11] He also mentioned that physical and mechanical properties would change when

Table 5: One-way ANOVA between and within the groups for color stability (Group 4)

	Sum of squares	df	Mean square	*F*	Significance
0 day					
Between groups	0.308	2	0.154	399549.453	0.000
Within groups	0.000	33	0.000		
Total	0.308	35			
3rd day					
Between groups	0.310	2	0.155	1185201.538	0.000
Within groups	0.000	33	0.000		
Total	0.310	35			
7th day					
Between groups	0.318	2	0.159	1147167.962	0.000
Within groups	0.000	33	0.000		
Total	0.318	35			

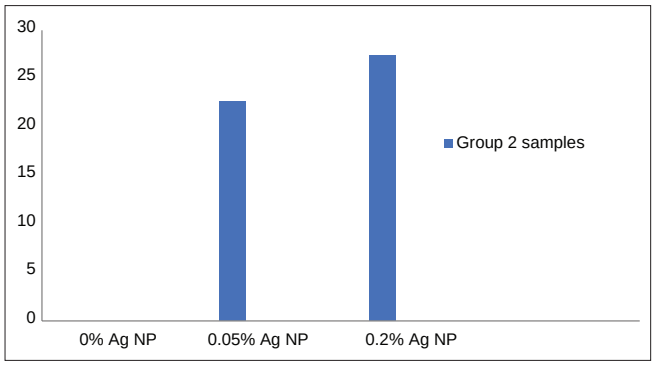


Graph 1: Graphical representation of wettability for Group 1 samples on 0, 7, 90 and 180 days

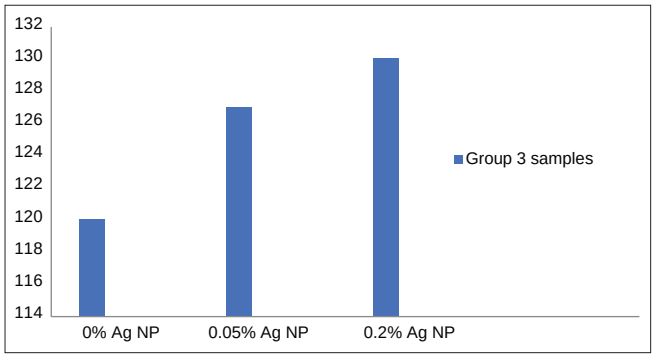
Table 6: Tukey *post hoc* honest significant difference multiple comparison values for color stability (Group 4)

Dependent variable	(I) Group	(J) Group	Mean difference (I–J)	SE	Significance	95% CI	
						Lower bound	Upper bound
0 day	Subgroup A	Subgroup B	−0.0128667*	0.0002536	0.000	−0.013489	−0.012244
		Subgroup C	−0.2024583*	0.0002536	0.000	−0.203081	−0.201836
	Subgroup B	Subgroup A	0.0128667*	0.0002536	0.000	0.012244	0.013489
		Subgroup C	−0.1895917*	0.0002536	0.000	−0.190214	−0.188969
	Subgroup C	Subgroup A	0.2024583*	0.0002536	0.000	0.201836	0.203081
		Subgroup B	0.1895917*	0.0002536	0.000	0.188969	0.190214
3rd day	Subgroup A	Subgroup B	−0.0127500*	0.0001476	0.000	−0.013112	−0.012388
		Subgroup C	−0.2028417*	0.0001476	0.000	−0.203204	−0.202480
	Subgroup B	Subgroup A	0.0127500*	0.0001476	0.000	0.012388	0.013112
		Subgroup C	−0.1900917*	0.0001476	0.000	−0.190454	−0.189730
	Subgroup C	Subgroup A	0.2028417*	0.0001476	0.000	0.202480	0.203204
		Subgroup B	0.1900917*	0.0001476	0.000	0.189730	0.190454
7th day	Subgroup A	Subgroup B	−0.0130583*	0.0001520	0.000	−0.013431	−0.012685
		Subgroup C	−0.2056250*	0.0001520	0.000	−0.205998	−0.205252
	Subgroup B	Subgroup A	0.0130583*	0.0001520	0.000	0.012685	0.013431
		Subgroup C	−0.1925667*	0.0001520	0.000	−0.192940	−0.192194
	Subgroup C	Subgroup A	0.2056250*	0.0001520	0.000	0.205252	0.205998
		Subgroup B	0.1925667*	0.0001520	0.000	0.192194	0.192940

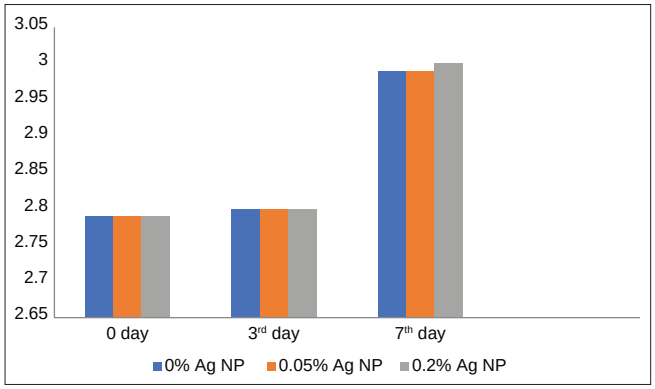
*The mean difference is significant at the 0.05 level. SE: Standard error, CI: Confidence interval



Graph 2: Graphical representation of antifungal effect for Group 2 samples



Graph 3: Graphical representation of Flexural strength for Group 3 samples



Graph 4: Graphical representation of Color stability for Group 4 samples on 0, 3 and 7 days

reinforcing materials were added. Hence, by adding silver nanoparticles to high-impact injection molding PMMA, there might be change in their wetting properties of the denture base resin.

The antifungal property of silver nanoparticles is highly appreciated in medical and dental fields. This can be used in denture bases to prevent the occurrence of denture stomatitis, which is considered because of the microbial biofilm adhesion on the porous denture material and accompanied by defective cleansing by saliva and poor tongue movements. The study by Aslanimehr *et al.* compared *candidal* adhesion in conventional heat-cured PMMA and injection-molded PMMA and concluded that there was significantly lesser adhesion of candida species in the surface of the denture in injection-molded PMMA due to less porous structure of the denture base resin.[12] Other ways to reduce candidal adhesion are the use of antifungal medications incorporated in denture base material to prevent the growth of *C. albicans* on the surface of the prostheses. The local drug delivery system directly delivers the drug at the site of infection decreases the risk of systemic side effects. A number of effective antifungal agents had been used, either topically or systemically, for the management of oral candidiasis. Amphotericin B, nystatin, various nanoparticles are common topical antifungal agents, whereas azoles such as fluconazole and ketoconazole are available for systemic antifungal treatment. The effect of conventional heat-cured denture base resin containing nano silver on *C. albicans* adhesion and biofilm formation had been reported by Wady *et al.* and concluded that silver nanoparticles had lesser candidal adhesion indicating its good antifungal property.[13] The study by Suganya *et al.* concluded a positive antifungal effect on silver nanoparticles reinforced conventional PMMA.[14]

The most important mechanical property of a denture base is flexural strength, and resistance to withstand masticatory forces. Reinforcers like nanoparticles change their spatial arrangement of molecules and get incorporated within the structure and improve its strength. The increased masticatory force beyond a certain limit leads to the formation of small cracks resulting in fracture of the prosthesis. High-impact injection-molded PMMA denture material has better mechanical properties than conventional heat-cured PMMA. Hamanaka *et al.* found that injection-molded thermoplastic denture base resins had better flexural strength compared to conventional heat cure PMMA.[15] Vallittu *et al.* concluded that higher flexural strength was seen for the injection-molding technique compared to the conventional method.[16] Nogueira *et al.* concluded that injection-molded PMMA had better dimensional accuracy compared to conventional heat cure PMMA.[17] Studies reinforcing injection-molded PMMA with fiber particles improved its properties. Various other reinforcing materials used were cyanoacrylate, metal wire, fibers, and woven glass. A study by Karacaer *et al.* compared injection-molded PMMA and convention heat-cured PMMA after reinforcing with E-glass fibers and concluded that reinforced injection-molded PMMA had better impact strength, transverse strength, and elastic modulus.[18] Flexural strength can also be increased in high-impact

injection-molded PMMA by metal reinforcements like in conventional heat-cured PMMA.

Color stability of denture base reinforced with nanoparticles is critical for the aesthetics of long-term restorations and had been previously studied *in vitro* for a variety of denture base materials. While denture base materials are vulnerable to water sorption and solubility, they can absorb or loose soluble components in the liquids, depending on their composition of saliva and this is the reason why the degradation occurs in materials leading to discoloration.[19] Color changes in denture base materials may be due to exposure to oral fluids, beverages, and denture cleaners. Color stability of provisional restoration using PMMA and bis-acrylic-based materials was evaluated by Gujjari *et al*., and concluded that PMMA was more color stable than bis-acrylic composite-based resin using ultraviolet spectrophotometer.[20] The study by Goiato *et al*., evaluated color stability and flexural strength of ocular prosthesis after reinforcing with ZnO_2, TiO_2, and Ba_2SO_4.[21] They concluded that color of the prosthesis was affected by concentration and type of material reinforced. In their study, TiO_2 had the best color stability and acceptable strength. Bohra *et al*. stated that conventional heat-cured resin had better stability than cold-cured resin.[22] The study by Shah *et al*. showed no color change in both nylon and acrylic PMMA denture base resin using conventional and injection molded techniques after immersion in denture cleansers.[23] In this study, silver nanoparticles were incorporated in various concentrations (0.05% and 0.2%) and evaluated for color stability on 0, 3, and 7 days. The procedure for evaluating color stability followed in this study was similar to the study by Gujjari *et al*.

Therefore, wettability, antifungal effect, flexural strength, and color stability were evaluated in this study after incorporating 0.05% and 0.2% silver nanoparticles in high-impact injection-molded PMMA and compared with the control group. The results showed increased wettability, positive antifungal effect, improved flexural strength, and negligible color changes in the denture base. Further scope of this study can be verified by clinical application and evaluation of the physical and mechanical properties for future use in the field of prosthodontics. Furthermore, varying the concentration of silver nanoparticles and the use of other nanoparticles may influence the results of the study.

CONCLUSION

Within the limitations of the study following conclusions were made:

- Subgroup C had slightly improved contact angle values than subgroup A and subgroup B throughout the storage periods, indicating that the incorporation of 0.2% of silver nanoparticles had significant changes in their wettability
- The maximum zone of inhibition was seen in subgroup C with the mean value of 27.42, followed by subgroup B with a mean value of 22.67 and the least antifungal effect in subgroup A, indicating that 0.2% of silver nanoparticles improved their antifungal effect
- High flexural strength was seen in subgroup C with the mean value of 130.0833, followed by subgroup B with the mean value of 127.0033 and the lowest flexural strength in subgroup A with the mean value of 120.085, indicating that reinforcement of silver nanoparticles with 0.2% showed a significant increase in flexural strength
- No change in color was observed in all the groups during the storage periods. This indicates that silver nanoparticles in 0.05% and 0.2% concentrations do not influence the color of the samples
- On comparing the various concentrations of Ag nanoparticles, subgroup C samples made with 0.2% Ag NP showed the highest wettability, antifungal effect, and flexural strength while the color stability remained almost unchanged, followed by subgroup B and subgroup A (control group) which had lesser values and least effective. Hence, it was concluded that high-impact injection-molded PMMA incorporated with 0.2% silver nanoparticles provided improved physical and mechanical properties in human saliva.

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Conflicts of interest
There are no conflicts of interest.

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Research

Surface roughness and marginal adaptation of stereolithography versus digital light processing three-dimensional printed resins: An *in-vitro* study

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Abstract

Aim: The aim of this study was to assess surface roughness and marginal adaptation of Stereolithographic versus Digital Light Processed three-dimensional (3D) printed provisional resins.

Materials and Methods: A 3-unit fixed partial denture (FPD) preparation was done on ideal model irrespective to 44–46. The Model was scanned and a 3-unit FPD was designed using 3-shape software. The STL file was transferred to two different 3D printers – Sprintray digital light processing (DLP) and Formlabs stereolithography (SLA). Eight samples were printed per group (total of 16 samples) using C and B temporary tooth-colored resin and cured according to the manufacturer's instructions. Marginal adaptation was checked for six surfaces per tooth for all the samples using a stereomicroscope. Surface roughness was also calculated for four samples from each group before and after polishing (pumice slurry + rouge and cotton buff) using a contact profilometer.

Results: The mean maximum marginal gap overall, was seen for the DLP group on the mesiobuccal surface of the first premolar, i.e., 178.8 ± 8.35 μm, while the minimal marginal gap was seen for the SLA group on the mesiolingual surface of first molar − 32.5 ± 7.07 μm. Furthermore, all the DLP samples showed a statistically significant higher mean marginal gap as compared to SLA samples ($P < 0.005$). All the samples showed surface roughness within the acceptable range. There was a statistically significant difference noted in Rz (roughness depth) before and after polishing ($P < 0.05$).

Conclusion: 3D printed temporary resin FPD via SLA showed a much better marginal adaptation (49.6 μm mean marginal gap for 46 and 106.8 μm for 44) as compared to those printed via DLP (101.8 μm mean marginal gap for 46 and 157.5 μm for 44). All the samples showed an acceptable surface roughness.

Clinical Relevance: 3D printed temporaries have shown good marginal fit and adaptation and are a viable choice in patients where temporaries has to be given for long term before a final prosthesis can be fabricated (especially for full mouth rehabilitations).

Keywords: Direct light projection, provisional restorations, stereolithography

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INTRODUCTION

The introduction of computer-aided design and computer-aided manufacturing (CAD/CAM) has revolutionized the field of restorative dentistry.[1] Prosthesis fabricated using CAD/CAM has several advantages such as reduced patient appointments, excellent tissue adaptation, and mechanical properties.[2-4] Digital manufacturing includes subtractive methods using computer-aided milling and additive method using 3-dimensional (3D) printing. Milling technologies have the inherent disadvantage of being unable to sculpt complicated details such as undercuts and intaglio geometry, as well as the ability to create only one unit at a time. Additive manufacturing, on the other hand, can render complicated geometry and has the potential to be considerably more resourceful as it does not involve the wear of rotary tools or wastage of materials.[5]

A total of seven additive manufacturing technologies were determined by the ASTM committee F42-Stereolithography (SLA), material jetting, material extrusion or fused deposition modeling, binder jetting, powder bed fusion, sheet lamination, and direct energy deposition.[6,7] In the SLA process, a build platform is immersed in liquid resin, which is subsequently polymerized by an ultraviolet (UV) laser. Each layer's cross-section is traced by the laser.[8]

The layer thickness can be customized by the user and dictates how much distance the build platform will drop into the photopolymer vat to allow the uncured resin to cover the previously cured layer. This process is repeated till the printing is complete.[9] The ASTM classifies digital light processing (DLP) into an identical category as SLA because their technologies are similar. The cross-section of object to be printed is projected by a matrix of microscopic mirrors with a semiconductor chip which is also known as a digital micromirror device. Some printers also use an arc lamp to project the image on the vat of liquid photopolymer through a DLP projector with a UV clear window under safe lighting. The printed object is rather drawn upward from the liquid resin than being submerged in this technique.[10,11] SLA and DLP are the most common technologies used in dentistry worldwide.

Recently, CAD/CAM technology has been extensively used to manufacture provisional crowns for patients via an indirect method.[12] Good quality provisional crowns are required to safeguard the prepared teeth and periodontal tissues.[13] They are also utilized to preserve the function and esthetics of the oral cavity. Internal fit and marginal adaptation are critical for any restoration's long-term clinical success.[14,15] Microleakage and plaque accumulation can be exacerbated by poor marginal fit, leading to cement disintegration, recurrent decay, and periodontal inflammation. As a result, extra attention should be paid to the marginal adaptation of restorations.[16,17]

The characteristics of the material such as marginal fit, hardness, and roughness affect the stability of color, in turn, influencing esthetic appearance, preservation of occlusal relationship, and bacterial adhesion which will lead to a biofilm formation. If the material used and the technique for fabrication of temporary crowns is adequate, the final result will be of superior quality and, hence, maintain the integrity of the periodontium.[18]

The aim of this study was to assess surface roughness and marginal adaptation of stereolithographic versus. DLP 3D printed provisional crowns. The null hypothesis stated that there is no difference between the surface roughness and marginal adaptation of provisional crowns fabricated by DLP or SLA 3D printers.

MATERIALS AND METHODS

Sample preparation

An ideal tooth preparation was done on a typodont model (NISSIN Typodont Jaw Model) with respect to the first premolar and molar, while the second premolar was removed to simulate a partially edentulous condition for fabrication of a fixed dental prosthesis (FDP). The preparations were evaluated by two different faculty members for the presence of undercut or any defect. The preparations were scanned by a Medit® Lab Scanner and files were exported in STL format and transferred to 3Shape® CAD software. A 3-unit FDP was designed and was transferred to two different types of 3D printers-Sprint Ray® (DLP) and Form Labs® (SLA). Eight samples per group were 3D printed (total of 16 samples) using NextDent C and B temporary tooth-colored resin. The build angle and layer thickness were rendered identical for both types of printers. The residual surface monomer was cleaned using 99.9% ethyl alcohol and support structures were clipped flush with the printed structure before polymerization using specific light cure units for the two printers according to the manufacturer's guidelines [Figure 1a-c].

Marginal adaptation

All the samples were seated on the ideal model without any internal surface modifications or adjustments. The typodont teeth were removed from the model for ease of recording. All the provisional FDP samples were evaluated under a stereomicroscope (LYNX, Lawrence Mayo) with ×2

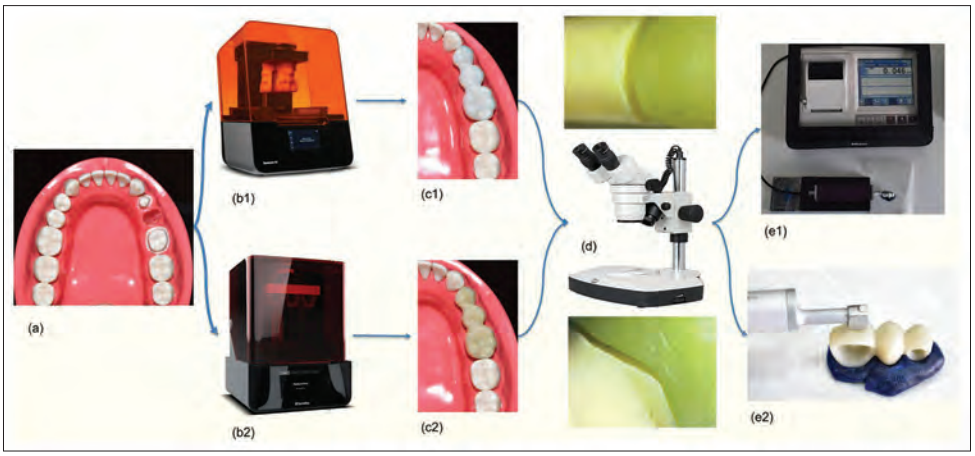

Figure 1: The sequential methodology of the study. (a) Tooth preparation, (b1): FormLabs printer, (b2): SprintRay printer, (c1): DLP sample, (c2): SLA sample, (d): Stereomicroscope, (e1): Contact Goniometer, (e2): Goniometer tip on sample. DLP: Digital light processing, SLA: Stereolithography

by a blinded reviewer for six surfaces per tooth-buccal, lingual, mesiobuccal, mesiolingual, distobuccal, and distolingual surfaces. A digital scale incorporated in the stereomicroscope software was used [Figure 1d].

Surface roughness

Four samples each from the two groups were randomly selected and were subjected to a surface roughness test by a contact goniometer (Ossila®) with a measurement accuracy of ±1° and a measurement range of 5°–180°. A droplet is placed on the substrate which is then gradually tilted. The advancing angle is measured at the front edge of the droplet just before the droplet becomes unpinned and starts to move. The receding contact angle is measured at the rear of the droplet before the trailing edge starts to move. Measurements were made both before and after surface polishing by pumice slurry, followed by rouge and a cotton buff [Figure 1e]. The values were evaluated by a blinded investigator and the same surface was chosen for all the samples (buccal surface) for roughness calculation.

Statistical analysis

All the values obtained were tabulated and coded in a spreadsheet and then transferred to IBM SPSS v23.0 software (IBM Corp. Armonk, NY). Due to the scaled nature of data, parametric tests were chosen. Unpaired/independent *t*-test was performed to find if significant differences are there between the two groups and the *P* value was calculated.

RESULTS

The group statistics of the marginal gaps seen on the six surfaces of both the abutments for all samples is summarized in Table 1. The mean maximum marginal gap overall was seen for the DLP group on the mesiobuccal surface of the first premolar, i.e., 178.8 ± 8.35 μm while the minimal marginal gap was seen for the SLA group on the mesiolingual surface of the first molar −32.5 ± 7.07 μm. The mean marginal gaps seen across the surfaces of the first molar were significantly less than that seen with the first premolar. Furthermore, all the DLP samples showed a statistically significant higher mean marginal gap as compared to SLA samples ($P < 0.005$).

The mean surface roughness (R_a) was 0.24 ± 0.07 μm for SLA samples and 0.28 ± 0.05 μm for DLP samples. There was no statistically significant difference between the two groups The difference in mean surface roughness values of the samples before and after polishing are displayed in Table 2 along with paired *t*-sample test.

DISCUSSION

The null hypothesis states that there was no difference between the DLP and SLA samples in the marginal adaptation and surface roughness. The null hypothesis was partially rejected as SLA samples showed a statistically significant difference in terms of marginal adaptation when compared with DLP samples ($P < 0.005$), but no difference was found between the surface roughness values. However, a significant reduction in roughness depth (R_z) was observed after polishing the samples ($P < 0.05$).

The clinical outcome of dental restorations depends highly on marginal adaptation.[17] In general, the precision of marginal fit is determined by tooth preparation, impression technique, restorative materials and technology used for fabricating them, and even on the luting cement. In the previous publications, the average discrepancy in the marginal fit has been reported

to be in the range from 177 to 400 μm for interim crowns.[18,19] McLean and Von[20] reported a marginal gap of 120 μm to be clinically acceptable while Boening *et al*.[21] claimed that a marginal gap between 100 and 200 μm lies within the clinically permissible range for a definitive prosthesis. In the current study, the DLP samples showed a mean marginal gap of 101.8 ± 11.42 μm for the first molar and 157.5 ± 13 μm for the first premolar. On the other hand, SLA samples showed much lower mean marginal gap values, i.e., 49.6 ± 10.9 μm for the first molar and 106.8 ± 15.22 μm for the first premolar. Although both groups showed values within the clinically acceptable range, SLA samples had statistically significant better marginal adaptation as compared to DLP samples ($P < 0.005$).

Previous studies[22,23] have already demonstrated that surface roughness significantly influences the extent of microbial adhesion to the denture base. The microbial attachment was increased on rougher surfaces, with roughness values ranging between 0.1 and 0.4 mm. Smooth interim restorations are essential to avoid biofilm accumulation and to maintain healthy periodontal tissues. The surface roughness values obtained in the current study lie in the threshold of clinical relevance, as described by Quirynen *et al*. and Bollen *et al*.[24,25]

Although there is no literature comparing SLA versus DLP technology in the construction of provisional crowns, studies comparing these technologies for the printing of 3D dental models are abundant. A study by Kim *et al*.[26] demonstrated that the models printed by SLA technique were more accurate in terms of measurement of teeth the arch as compared to the DLP technique; however, DLP was superior in precision. As the printers with SLA technology complete one layer by curing the resin point by point via laser projection, the slow space of the mirror reflecting the beam of laser is bound to generate the error. On the other hand, DLP technology is faster because it employs a projector to cure the material layer by layer, reducing the inaccuracy that comes with repetitive printing. When we examined the two processes, we found that the SLA technology, which uses a lower x-y resolution and thinner layer thickness, was more exact than the DLP technique, although it was less precise due to variations in the manufacturing technique. A recent systematic review[27] also demonstrated that models printed by SLA technology were more accurate but had a wider range of mean errors.

Table 1: Descriptive statistics of marginal gap seen on the six surfaces examined

Group statistics			
	SLA or DLP	Mean	Std. deviation
Marginal gap 44 buccal surface	SLA	0.1538	0.01408
	DLP	0.1975	0.01581
Marginal gap 44 lingual surface	SLA	0.1075	0.01282
	DLP	0.1712	0.01246
Marginal gap 44 mesiobuccal surface	SLA	0.2000	0.01195
	DLP	0.2788	0.00835
Marginal gap 44 mesiolingual surface	SLA	0.2087	0.01808
	DLP	0.2638	0.02326
Marginal gap 44 distobuccal surface	SLA	0.1775	0.02252
	DLP	0.2600	0.01069
Marginal gap 44 distolingual surface	SLA	0.1463	0.01188
	DLP	0.1837	0.00744
Marginal gap 46 buccal surface	SLA	0.0813	0.01246
	DLP	0.1600	0.01069
Marginal gap 46 lingual surface	SLA	0.0588	0.01458
	DLP	0.1125	0.00886
Marginal gap 46 mesiobuccal surface	SLA	0.0425	0.01035
	DLP	0.0837	0.01302
Marginal gap 46 mesiolingual surface	SLA	0.0325	0.00707
	DLP	0.0875	0.01282
Marginal gap 46 distobuccal surface	SLA	0.0400	0.00926
	DLP	0.0863	0.01188
Marginal gap 46 distolingual surface	SLA	0.0425	0.01165
	DLP	0.0813	0.01126

CONCLUSION

In this study, we did a comparative evaluation of marginal adaptation and surface roughness of SLA versus DLP 3D printed commercially available crown and bridge provisional restorative material. There was no difference in surface roughness between both techniques. Furthermore, the temporary restorations printed via SLA showed a significantly less marginal gap as compared to DLP ones. Future work utilizing the same methodology can be carried out clinically to provide a definitive protocol.

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Table 2: Paired samples *t*-test for surface roughness of various samples pre- and postpolishing

Paired samples test				
	Paired differences, mean (μ)±SD	*t*	df	Significant (two-tailed)
Pair 1: Roughness average SLA prepolishing - Roughness average SLA postpolishing	0.00020±0.00045	1.000	4	0.374
Pair 2: Roughness depth SLA prepolishing - Roughness depth SLA postpolishing	0.00780±0.00396	4.402	4	0.012
Pair 3: Roughness average DLP prepolishing - Roughness average DLP postpolishing	0.00020±0.00045	1.000	4	0.374
Pair 4: Roughness depth DLP prepolishing - Roughness depth DLP postpolishing	0.00640±0.00182	7.878	4	0.001

SLA: Stereolithography, DLP: Digital light processing, SD: Standard deviation

Conflicts of interest

There are no conflicts of interest.

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Research

Clinical evaluation of complete denture fabricated using two different final impression techniques on masticatory efficiency and oral health-related quality of life

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Abstract

Aim: To compare the effect of complete denture fabricated using selective pressure impression and functional impression technique on masticatory efficiency and oral health-related quality of life (OHRQoL) in patients with resorbed ridges.

Settings and Design: A randomized two arm, parallel group study.

Materials and Methods: Forty-eight participants with set inclusion and exclusion criteria were randomly allocated into two groups. Complete denture was fabricated in Group A and Group B using selective pressure and functional impression technique, respectively. The follow-up was done at 3 months. Masticatory efficiency was measured by color-changing chewing gum, and OHRQoL was assessed using the Geriatric Oral Health Assessment Index (GOHAI) Hindi Version.

Statistical Analysis Used: The Wilcoxon signed-rank test was applied to check the intergroup analysis for the GOHAI scores of both impression techniques. The Mann–Whitney U test was applied to compare intragroup analysis for masticatory efficiency and the GOHAI scores of both the techniques.

Results: A total of 45 participants completed the follow-up. The mean age of the total participants was 62.7 ± 3.8. No statistically significant difference ($P > 0.05$) was observed between the masticatory efficiency and post-GOHAI scores of both the impression techniques.

Conclusion: Selective pressure and functional impression techniques may be successfully used to fabricate complete dentures for patients with resorbed ridges.

Keywords: Chewing gum, dental impression technique, dental prosthesis, quality of life

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INTRODUCTION

In India, 34.5% of the total population is urban, and the rest resides in a rural setup.[1] Complete dentures would always remain a prime treatment modality for any resource-strained country. Complete denture rehabilitation aims to improve the patient's quality of life and masticatory

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efficiency. Therefore, research must be strengthened in this area to help the patients.[2] The quality of the denture in relation to satisfaction, comfort, stability, and chewing ability is totally dependent on the final impression.[3]

Selective pressure[4,5] and functional impressions[6] are well-accepted techniques for edentulous patients. In their randomized controlled trial, Hyde *et al*.[7] proved that patients preferred dentures fabricated using the selective pressure technique. They also emphasized the usage of silicone impression materials for final impressions. The oral health-related quality of life (OHRQoL) was also improved after wearing a denture made using addition silicone impressions.[8] Another suggested technique is functional impressions which accurately record and register mucosal resiliency along with denture base and functional margins.[9] The functional impression technique provides good results along with saving time. It is recommended for geriatric patients with old dentures, ill-fitting dentures, and clinically compromised conditions.[10] Yadav *et al*.[11] have also advised the use of the functional impression technique for better retention, stability, and support in Atwood's orders V and VI.

Although many authors recommend the functional impression, no study has compared it with an already established selective pressure impression technique in cases with resorbed ridges. Therefore, a gap exists in the literature. Many elderly patients with resorbed ridges in our day-to-day practice come for new denture fabrication, and their old dentures can be very well used for making a functional impression.

The study's primary objectives were to evaluate and compare the masticatory efficiency and OHRQoL of dentures fabricated with the selective pressure impression and functional impression techniques. The secondary objective was to evaluate the number of denture adjustment visits after a routine denture follow-up.

The null hypothesis stated that no difference exists in the masticatory efficiency and OHRQoL in complete dentures fabricated using selective pressure and functional impression techniques.

MATERIALS AND METHODS

A randomized two-arm, parallel-group study was conducted after approval from the institutional ethical committee with approval no. SVIEC/ON/DENT/BNPG17/D18004. A participation information sheet was given to all the participants, and informed consent was taken. The research work was carried out by the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. All dentures were fabricated between the periods of January 2018 to June 2019.

Using data values from a study done by Wegner *et al*.,[12] the sample size was calculated by 80% power and 95% confidence interval. A total sample size of 40 was determined and divided equally into 20 in each group. Considering the dropout ratio of 20%, another eight patients were added, making the final sample size 48.[12]

Following were the inclusion criteria

a. Age 60 years or above reporting to the department of prosthodontics for complete denture fabrication
b. Patients having a complete set of old dentures
    i. Having adequately extended peripheral borders and complaints of loosening due to resorption
    ii. Able to chew adequately though having worn out teeth
c. Patients with a resorbed ridge (American College of Prosthodontists (ACP) Class III and IV)[13]
d. Patients who could understand the questionnaire in Hindi.

Following were the exclusion criteria

Patients who refused to sign the consent form, had poor neuromuscular control, had pathological ridge defects, systemic problems, and patients with fractured or badly repaired old dentures were excluded from the study.

After assessment of eligibility, an orthopantomogram was taken. The least height of the ridge was measured to know the ridge status according to the ACP classification[13] using Adobe Photoshop [Figure 1]. Then randomization was done by a computer-generated method, and two groups were formed. This study was based on the parallel design compared to the crossover design because, in this design, patients will not have to stay without dentures during the wash-out period.

Random allocation was done by computer-generated sequence for all 48 patients. A single operator did all the

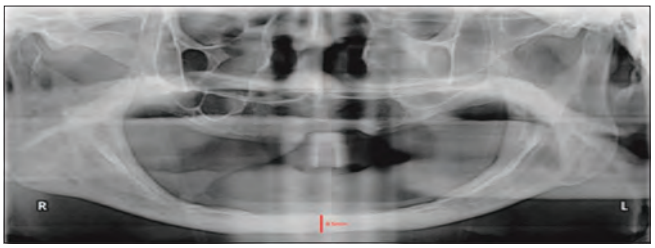

Figure 1: Measuring of the ridge height using adobe photoshop

procedures. In this study, evaluator and statistician were blinded.

The participants were divided into two groups. Group A complete dentures were made using selective pressure impression, and Group B complete dentures were made using the functional impression utilizing the patient's set of old dentures. The CONSORT flow diagram is shown in Figure 2.

The Hindi version of the Geriatric Oral Health Assessment Index (GOHAI) with a three-point Likert scale of "always-1," "sometimes-2," and "never-3" was used to assess the OHRQoL.[14] Pre-GOHAI questionnaire was administered to both the groups before starting any procedure.

In Group A, a preliminary impression was made using alginate in the metal stock tray, and the diagnostic cast was poured with type 2 dental stone. The maxillary arch spacer of 1 mm was adapted to the cast within the outline borders except in the area of the posterior palatal seal to provide space for the final impression. In the mandibular arch, 1 mm of the spacer was given on the crest and the slope of the alveolar ridge except in the buccal shelf-area.[15] The custom tray was fabricated using auto-polymerizing denture resin. Denture adhesive (Medicept LOT-10433) was applied on the border of the custom tray and kept aside for drying for 15 min as recommended by the manufacturer. Then a single-step border molding was done using heavy body silicone (Dentsply LOT-170925) in the upper arch and regular body silicone (Dentsply LOT-170329) in the lower arch. After giving relief holes, the final wash impression was made with light-bodied silicone Dentsply (LOT-170602) [Figure 3a].[8]

In Group B, labial, buccal and lingual extensions of old dentures were trimmed 1-2 mm short, so that functional depth gets recorded in tissue conditioner material. The tissue surface of the old existing denture was also trimmed approximately 2 mm to create space for the material. Tissue conditioner (Dentsply LOT-1709000863) was mixed according to the manufacturer's instruction and carefully applied on the tissue surface of the denture to avoid any air bubbles entrapment.[16] The denture was placed in the patient's mouth with firm pressure. The borders were molded by hand manipulation of the cheeks and lips. About 5 min were given for material to set in the old denture. The patient's tongue was directed to mold the lingual border in the mandibular ridge.[11] The denture was removed, rinsed with water, and evaluated [Figure 3b]. Later, dentures were given to the patient for functional usage, and proper home care instructions of not to soak the denture in any denture cleaning solution and store it in the air were given.[17] The patient was also instructed to clean the denture in plain running water after every meal and to use wet cotton or gauze to clean the fitting denture surface. The patient reported back after 1 day (within 48 h), and the denture was evaluated for well-rounded functional borders. Then the master cast was poured with Type 3 dental stone.

After getting the master cast in both groups, all the further clinical and lab steps were kept the same. The maxillomandibular records were mounted on a mean value articulator. Nonanatomical teeth (Prestodent; New India Dental Products, India) were used for both the groups

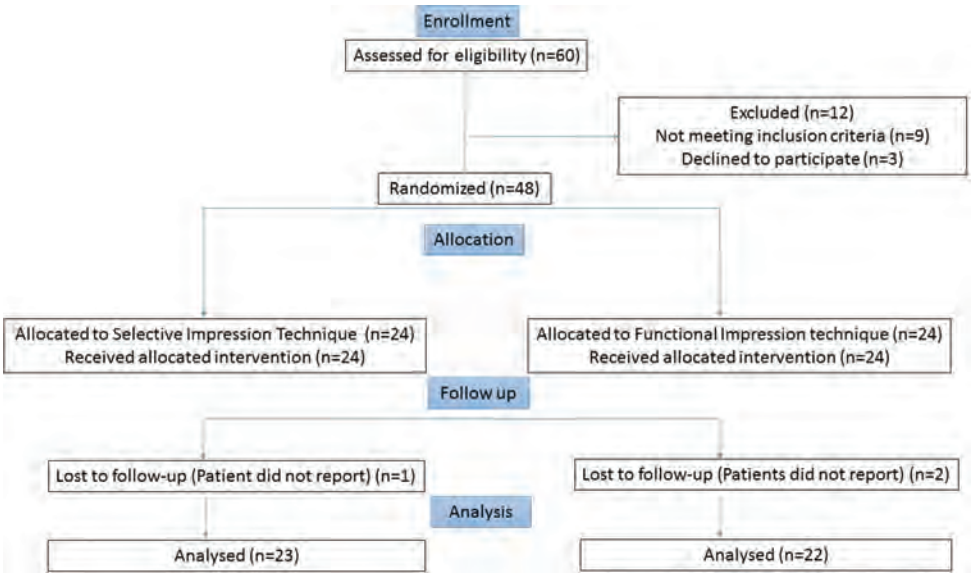

Figure 2: CONSORT flow diagram showing each phase of the study

because, in poor ridge foundation, the least movement was observed with nonanatomic teeth.[18] The denture insertion and routine postinsertion follow-ups were also maintained in both groups. The denture was used for 3 months,[10] and the patient was recalled to fill out the post-GOHAI questionnaire and evaluate masticatory efficiency.

Denture alteration visits within these 3 months of the adjustment period of the patients after routine follow-up visits were also observed as a secondary objective, as there could be more chances of sore spots corrections in resorbed ridges.

Various tools are available to check the OHRQoL. Ikebe *et al*.[19] concluded that the GOHAI was more sensitive than OHIP-14. The GOHAI consists of 12 questions, but the last 12th question cannot be applied to denture patients (How often were your teeth or gums sensitive to hot, cold or sweet foods?) was not included in the study. The same methodology of removing the last question was also applied by Shigli and Hebbal[20] in their study.

After filling out the post-GOHAI questionnaire, the color-changing chewing gum (Gumxylitol; lotte co., Ltd) was used in the patients.[21] The patient was told to chew 60 times, maintaining the rate of one per second. Afterward, chewing gum was wrapped in two polyethylene films and, with the help of two glass plates, flattened to 1.5 mm thickness. Color analysis was done by observing the changes before and after the mastication procedure.[21] A spectrophotometer and the color scale [Figure 4] developed by Hama *et al*.[22] were used to measure the values of color change. Halazonetis *et al*.[23] and Tarkowska *et al*.[21] stated that the masticatory efficiency could be evaluated safely using color-changing chewing gum.

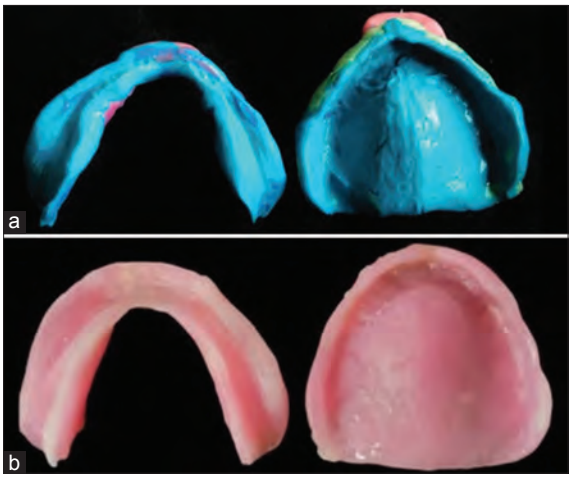

Figure 3: (a) Selective pressure impressions and (b) functional impressions

Statistical analysis

Wilcoxon signed-rank test was applied to check for the significant difference between the pre- and postscores of the GOHAI questionnaire for both the groups. Mann–Whitney U test was applied to compare both groups' GOHAI questionnaire postscores and masticatory efficiency. The data was analyzed with Statistical Package for Social Sciences (SPSS) for Windows, version 26.0 (IBM Corp., Armonk, N. Y., USA). Confidence interval was kept at 95%, and values of $P < 0.05$ was taken as statistically significant.

RESULTS

Out of 48 enrolled participants, 45 (23 participants in Group A and 22 in Group B) completed the study. One participant in Group A and two in Group B failed to report back after 3 months of the adjustment period.

The mean age of the total participants was 62.7 ± 3.8. Out of 45 participants, 88.9% of the patients were 61–65 years old. 4.4% and 6.7% of the patients belonged to the 66–70 and 71–75 years of the age group, respectively [Table 1]. Out of 45 patients, 26 were male and 19 were female. ACP class distribution of participants in Group A and B is shown in Table 2.

Table 1: Age distribution in Group A and B

Age (years)	*n* (%)	Mean±SD
61-65	40 (88.9)	62.7±3.8
66-70	2 (4.4)	
71-75	3 (6.7)	
Total	45 (100)	

SD: Standard deviation

Table 2: American College of Prosthodontists class distribution in Group A and B

Groups	ACP Class III (%)	ACP Class IV (%)	Total
Group A	20 (86.9)	3 (13.04)	23
Group B	18 (81.8)	4 (18.1)	22

American College of Prosthodontists

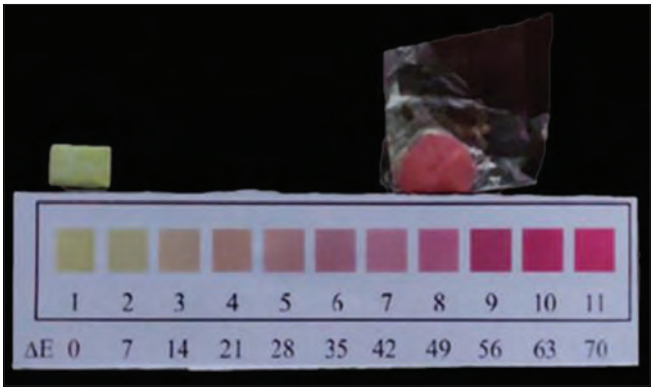

Figure 4: Color analysis of masticatory chewing gum using a color scale

The primary and secondary outcomes were analyzed, keeping a 95% confidence interval. The primary outcome was to evaluate masticatory efficiency and OHRQoL. The pre- and postscores on OHRQoL using the GOHAI questionnaire show a statistically significant difference ($P < 0.05$) for all the questions except question no. 9, 10, and 11 for both Group A [Table 3] and Group B [Table 4]. No statistically significant difference ($P > 0.05$) was observed between the post-GOHAI scores between Group A and B [Table 5]. No statistically significant difference ($P > 0.05$) was also observed between masticatory efficiency in Group A and B [Table 6]. The secondary objective was also nonsignificant as for routine denture adjustments, only one patient of Group A (selective pressure impression technique) reported for denture adjustment of the sore spot.

Table 3: Comparison of the pre- and post-geriatric oral health assessment index scores on oral health-related quality of life in Group A

Question number	GOHAI Score	Mean±SD	*Z*	*P*
1	Pre	2.17±0.491	−3.21	0.001*
	Post	2.48±0.511		
2	Pre	2.22±0.671	−3.50	0.0001*
	Post	2.30±0.635		
3	Pre	1.83±0.491	−1.80	0.05*
	Post	2.17±0.717		
4	Pre	2.13±0.757	−3.55	0.0001*
	Post	1.48±0.511		
5	Pre	2.17±0.650	−3.12	0.0001*
	Post	1.83±0.650		
6	Pre	2.09±0.596	−2.95	0.003*
	Post	1.04±0.209		
7	Pre	1.52±0.511	−1.83	0.05*
	Post	1.52±0.593		
8	Pre	2.52±0.665	−2.12	0.03*
	Post	1.61±0.499		
9	Pre	2.39±0.499	−0.71	0.7
	Post	1.52±0.593		
10	Pre	2.52±0.593	−1.89	0.8
	Post	1.22±0.422		
11	Pre	2.30±0.559	−2.97	0.6
	Post	1.57±0.507		

SD: Standard deviation. *Significant ($P<0.05$)

Table 4: Comparison of the pre- and post-Geriatric Oral Health Assessment Index scores on oral health-related quality of life in Group B

Question number	GOHAI Score	Mean±SD	*Z*	*P*
1	Pre	2.05±0.575	−3.16	0.002*
	Post	2.14±0.640		
2	Pre	2.45±0.739	−2.53	0.01*
	Post	1.32±0.477		
3	Pre	2.45±0.739	−2.33	0.02*
	Post	1.41±0.734		
4	Pre	2.59±0.590	−0.63	0.05*
	Post	1.23±0.528		
5	Pre	1.73±0.550	−2.64	0.005*
	Post	1.50±0.598		
6	Pre	1.45±0.596	−1.26	0.02*
	Post	1.09±0.294		
7	Pre	1.59±0.503	−2.71	0.005*
	Post	1.77±0.429		
8	Pre	2.91±0.294	−1.89	0.05*
	Post	1.23±0.429		
9	Pre	2.91±0.426	−0.44	0.9
	Post	1.23±0.528		
10	Pre	3.00±0.000	−1.0	0.6
	Post	1.00±0.000		
11	Pre	1.68±0.477	−2.82	0.7
	Post	1.41±0.503		

SD: Standard deviation. *Significant ($P<0.05$)

DISCUSSION

As both masticatory efficiency and OHRQoL after fabrication of dentures using two different techniques showed no significant difference, the null hypothesis was accepted.

Items 1-4 in GOHAI are based on trouble related to functional problems in swallowing, speaking, and eating. Both groups found a significant difference between patients' pre- and post-GOHAI scores related to these questions. Item no. 5 and 8 are related to pain and discomfort, showing a significant difference in both groups' pre- and post-GOHAI scores. Other items 6, 7, 9, 10, and 11 are based on psychosocial characteristics.

The statistically significant difference ($P < 0.05$) between the pre- and postscores of the GOHAI questionnaire was seen in all the questions except question no. 9, 10, 11. These items depict behavioral and psychological aspects. No significant difference was seen in these questions in the pre- and post-GOHAI scores of both the groups, probably because of the limitation of a complete removable prosthesis which will always persist and indirectly affect the patient's psychology. Patients' age, education, marital status, income, habits, attitudes, and the socioeconomic background will influence these responses.

There was no statistically significant difference ($P > 0.05$) between the masticatory efficiency and postscores of both the impression techniques for all the questions when evaluating the post-GOHAI questionnaire. Hence, both techniques may be equally acceptable for patients.

The result of this study suggests that the functional impression technique can also be seen as an effective alternative for making an impression in patients with resorbed ridges. The only prerequisite is the availability of an old set of dentures in acceptable conditions with peripheral borders and occlusion. If the extensions are improper, it will not lead to good results. Therefore, sound clinical judgment and skills are required regarding the existing condition of an old denture.

Table 5: Comparison of post-Geriatric Oral Health Assessment Index scores on oral health-related quality of life in Group A and B

	Groups	Mean rank	Sum of ranks	Mann-Whitney U	*P*
Post_Q1	Group A	22.24	511.50	235.5	0.6
	Group B	23.80	523.50		
Post_Q2	Group A	20.13	463.00	187.0	0.7
	Group B	26.00	572.00		
Post_Q3	Group A	19.61	451.00	175.0	0.6
	Group B	26.55	584.00		
Post_Q4	Group A	27.20	625.50	156.5	0.9
	Group B	18.61	409.50		
Post_Q5	Group A	17.11	393.50	117.5	0.7
	Group B	29.16	641.50		
Post_Q6	Group A	26.11	600.50	181.5	0.8
	Group B	19.75	434.50		
Post_Q7	Group A	18.22	419.00	143.0	0.9
	Group B	28.00	616.00		
Post_Q8	Group A	25.39	584.00	198.0	0.1
	Group B	20.50	451.00		
Post_Q9	Group A	28.63	658.50	123.5	0.9
	Group B	17.11	376.50		
Post_10	Group A	24.72	568.50	213.5	0.3
	Group B	21.20	466.50		
Post_11	Group A	28.22	649.00	133.0	0.1
	Group B	17.55	386.00		

Table 6: Comparison of masticatory efficiency using color-changing chewing gum in Group A and B

Groups	Mean±SD	Mean rank	Sum of ranks	Mann-Whitney U	*P*
Selective pressure impression technique	48.7±2.90	22.83	525.00	249.0	0.7
Functional impression technique	48.6±1.48	24.17	556.00		

SD: Standard deviation

The functional impression has an added advantage of giving psychologic comfort to the patients as they can pre-experience the comfort and stability of dentures with tissue conditioning material. This technique even provides prior judgment to a clinician about the results.

As there are no previous direct comparative studies on the above-said techniques and materials, the association between previous works of literature is difficult. However, the results of this study follow randomized control trial by Komagamine *et al*.,[24] where the selective pressure impression technique was able to establish early stability of new dentures with fewer postinsertion dentures adjustments. Many studies[25-27] and systematic reviews[3,28,29] have also presented no difference in patient satisfaction, mastication, and quality of dentures fabricated by simplified or traditional/conventional methods.

Sociodemographic variables play a significant role in influencing patient denture satisfaction.[30] In this study, all participants had the same socioeconomic background, as all visited an institute for their denture needs. 58% percent of Males and 42% of females were enrolled in the study. 89% of participants belonged to the 61–65 age group and 84% to ACP Classification III. Keeping all these variables into consideration, baseline balance was reasonably present. Nevertheless, comprehensive sociodemographic characteristics such as education, professional activity, marital status, socioeconomic status, and a span of edentulism along with patient's psychology can be addressed in future studies for better clinical applicability of results. Future studies can also report the minimal clinically significant difference associated with research involving patient denture satisfaction.

The limitation of the study is the small sample size. Longitudinal studies with more sample size can be conducted to support the results and reduce the baseline imbalances. Future studies can also assess the denture acceptance, adaptive skills, masticatory ability, and quality of life of a patient with poor neuromuscular abilities using the same or different impression techniques.

CONCLUSION

Selective pressure and functional impression techniques may be successfully used to fabricate complete dentures for patients with resorbed ridges.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Research

Evaluation of physical changes due to simulated loading on prosthetic screw supporting 4- and 6-unit implant prosthesis: An *in vitro* study

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Abstract

Aim: Screw loosening is a very common cause of failures in implant prosthodontics. In order to avoid screw fracture, it is imperative to understand the mechanical behavior of the screw and the dynamics it is subjected to intraorally. The present study was conducted to qualitatively evaluate and compare the morphological changes, surface defects, and cracks observed under a scanning electron microscope (SEM) in the prosthetic screw.

Settings and Design: Two Stainless steel edentulous mandible models were fabricated on the basis of all on four and all on six concepts by using CAD design. Screw retained prosthesis were fabricated for both the models and total number of 80 prosthetic screws were made up of Ti6Al4V.

Materials and Methods: Eighty prosthetic screws ($N = 80$) used in four- and six-unit implant-retained cast hybrid denture were subjected to cyclic loading of 1.5 million cycles and 3 million cycles, simulating a 5 and 10 years of usage, respectively. Once the simulated cycles had been completed in all subgroups, each prosthetic screw was inspected under SEM (×150–×1000) for any changes.

Statistical Analysis: The data thus obtained were statistically analyzed using SPSS 12.0 software and $P < 0.005$ was considered statistically significant.

Results: The study revealed statistically significant ($P < 0.005$) changes (like morphological changes, surface defects, crack initiation, and propagation) in the prosthetic screws after exposing them to predefined test conditions ($P < 0.001$).

Conclusion: It can be concluded that the prosthetic screws need to be changed after a period of clinical use of 5 years irrespective of the number of implants used for rehabilitation. Further, the tilt of the abutment and numbers of implants also contribute to the stresses on the implant-supported prostheses.

Keywords: All-on-4™, axial implant, implant-retained hybrid prosthesis implant-supported prostheses, scanning electron microscope, screw-retained hybrid denture, tilted implant

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INTRODUCTION

Dental implantology has undergone a revolutionary rebirth and rediscovery; therefore, implants are considered as the principal choice of treatment in selected cases.

After osseointegration is achieved around the implant, long-term clinical follow-ups have reported mechanical or biological complications.[1] One of the systematic reviews showed the survival rate of implant-supported single crowns and concluded that the overall incidence of abutment screw loosening was 7.3% in both external and internal type connections from 26 clinical studies included, while the incidence of abutment screw fracture was found to be 0.6%. Screw loosening may cause implant or screw fracture. In totaling, screw loosening or deformation also leads to micromotion at the implant–abutment interface when chewing.[2,3] Sones[4] reported that the failure of implant components principally, if abutment screws cannot be retrieved, might necessitate the disuse of the involved implant and require conversion or remake of the prosthesis.[5]

The mechanism of screw loosening has been described in two stages. Initially, external forces cause sliding between the thread, partially relieving the stretching of the screw and reducing preload. The second causes turning of the screw in an counterclockwise direction, which leads to loss of function. These nonperformances are due to metal fatigue and occur under repeated cyclic loading at levels below than the maximum strength of material.[6,7]

Many factors related to screw design and fabrication method may affect abutment or prosthetic screw loosening in metal-to-metal screw system; these primarily are related to preload. It was reported that the primary factor in screw loosening was not consistent; the following preload showed a difference and could affect the removal torque.[8,9]

The most common variables that influence the joint stability are the junction of implant–abutment where the contacting parts change when the screw is tightened. Being tightened together by the screw, the microroughness of all the metal contacting surfaces slightly flattens, and the microscopic distance between contacting surfaces decreases. As an outcome of this process called "settling," the screw loses part of its preload. Detorque value instantly after tightening is always lesser than the initial tightening torque.[10]

In additional, factors that affect abutment screw loosening include hex (internal hex system), height (or depth), platform diameter, surface condition, diameter of the screw, excessive bending, vibrating micromovement, microleakage, abutment diameter, surface coating, abutment connection, cement wash out, lateral cyclic loading, collar length, abutment angulations, inadequate tightening torque, retorque, reverse torque, and settling effect.[11,12]

On evaluation of newly placed abutment and screw assembly as observed by Hum. There is a percentage of initial torque loss, which is higher as compared to screws that have already undergone an application of initial torque. This torque loss is inherent in any bolted joints; it is a combined effect of bolts and is about 10% during the first 24 h after installation. This could be due to gasket creep, vibration in the system, thermal expansion, and elastic interaction during bolt tightening. Hence, previously tightened screws were observed to be unstable after the application of successive torque; if the abutment screw is exposed to excessive wear and is still in place, screw replacement is a good option. Hum had also introduced a technique to accurately locate the loose abutment screw and replace it with a new one.

MATERIALS AND METHODS

This study qualitatively evaluated and compared the physical changes in the prosthetic screw after 1.5 million and 3 million cycles that simulate 5 and 10 years of clinical usage.

Two stainless steel edentulous mandible models were fabricated on the basis of all-on-four and all-on-six concepts using computer-aided design [Figures 1 and 2]. Implant analogs were positioned and transmucosal abutments (ADIN implant company, Israel) to depict the four- and six-unit implant-supported hybrid prosthesis. Screw-retained

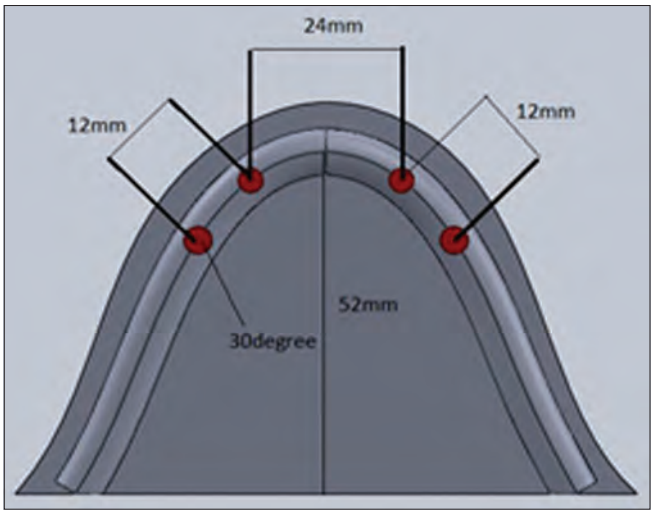

Figure 1: CAD design (ISP on four implants). CAD: Computer-aided design, ISP: Implant-supported prostheses

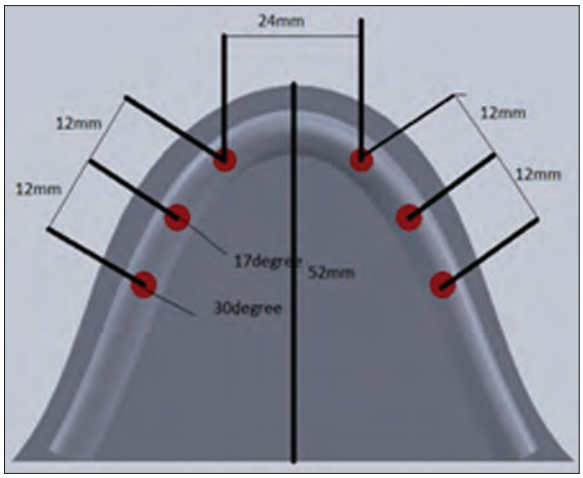

Figure 2: CAD design (ISP on six implants). CAD: Computer-aided design, ISP: Implant-supported prostheses

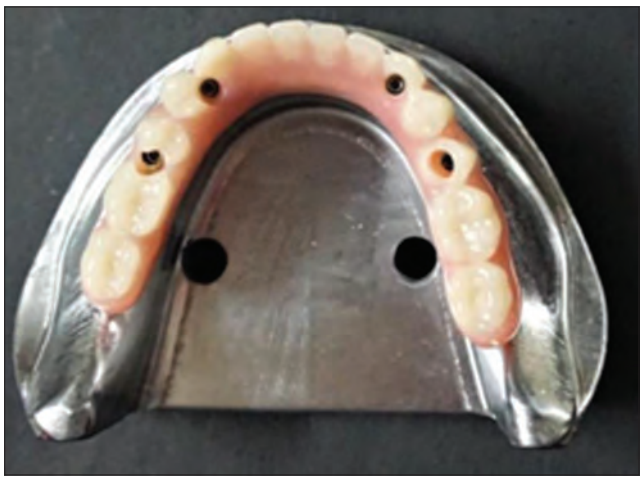

Figure 3: Stainless steel model of ISP on 4 implants with hybrid prosthesis. ISP: Implant-supported prostheses

Figure 4: Stainless steel model of ISP on 6 implants with hybrid prosthesis. ISP: Implant-supported prostheses

prostheses were fabricated for both the models [Figures 3 and 4]. A total number of 80 prosthetic screws were made up of Ti6Al4V. For the present study, there were two Group A and Group B, which were further divided into A1 and A2 and B1 and B2, based on the number of loading cycles. For each subgroup, different angulations were compared. For Group A1 and A2, there were two angulations. For Group B1 and B2, there were three angulations [Table 1].

Table 1: Distribution of samples

Groups	Sample size (*n*)	Sub groups	Sample size (*n*)	Number of loading cycles (million)	Years of intraoral usage (years)
A	32	A1	16	1.5	5
		A2	16	3	10
B	48	B1	24	1.5	5
		B2	24	3	10

Mandibular models were subjected to 1.5 million and 3 million cycles under a customized jaw simulator-cyclic loading machine [Figures 5 and 6]. In this machine, only vertical movement takes place and 100 N force is applied by maxillary dentulous model. Following these, all prosthetic screws were removed and replaced with a new set of screws and this process was repeated again. Once the stipulated cycles had been completed, each prosthetic screw was cleaned using acetone in ultrasonic cleaner for 10 min and then each prosthetic screw was inspected under a scanning electron microscope (SEM) from ×150 to ×1000 magnification [Model-JSM-6510 LVby JEOL USA, as shown in Figures 7-14] to evaluate the physical changes.

Null hypothesis

Clinical usage of 5 and 10 years, respectively, causes no physical changes in the physical screw, retaining a four- and six-unit implant-supported prostheses (ISP).

RESULTS

Models simulating ISP on 4 implants (Group A, $N = 32$) were further subdivided into two subgroups, i.e., A1, $N = 16$ and A2, $N = 16$ based on the number of cycles, i.e., 1.5 and 3 million, respectively [Table 1].

On subjecting the samples in Subgroup A1 ($n = 16$) [Table 2] to 1.5 million cycles, thirteen (81%) out of sixteen prosthetic screws showed physical changes (7 prosthetic screws were placed over 30° angulated implants and 4 prosthetic screws were placed over straight implants). One of the prosthetic screws (6.25%) showed loosening which was placed over an implant at angle of 30° as viewed under SEM (×150–×300).

On subjecting the samples in Subgroup A2 ($n = 16$) [Table 2] to 3 million cycles, all sixteen prosthetic screws (100%)

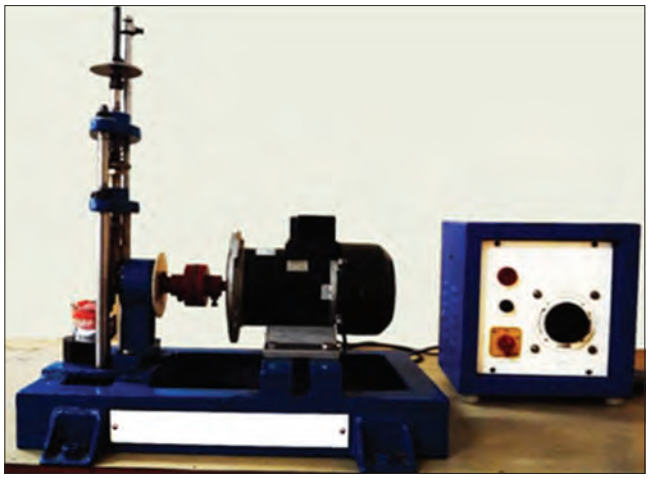

Figure 5: Customized cyclic loading machine

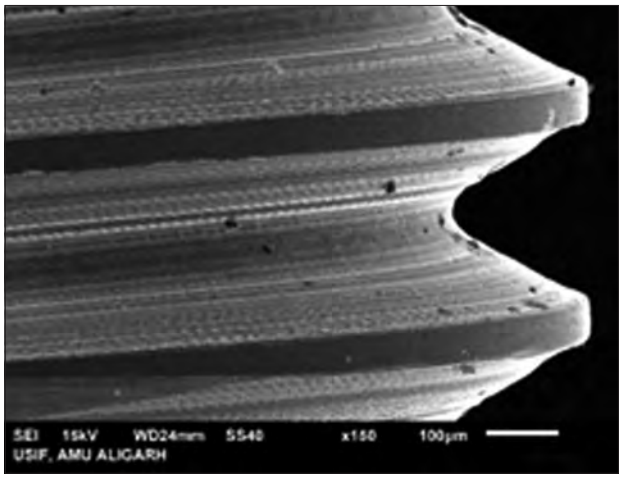

Figure 7: Before tightening the prosthetic screw (×150)

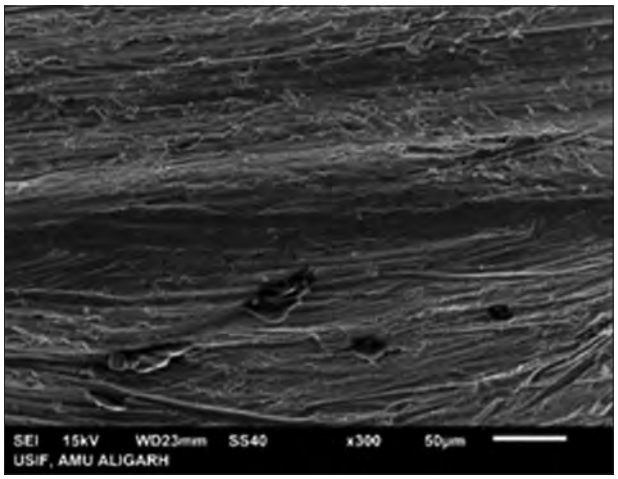

Figure 9: Physical changes in prosthetic screw – ISP on 4 implants after 5 years of usage (1.5 million Cycles) (×300). ISP: Implant-supported prostheses

showed physical changes (08 prosthetic screws were placed over 30° angulated implants and 08 prosthetic screws were placed over straight implants) and 4 prosthetic screws (25%) showed screw loosening (placed over 30° angulated

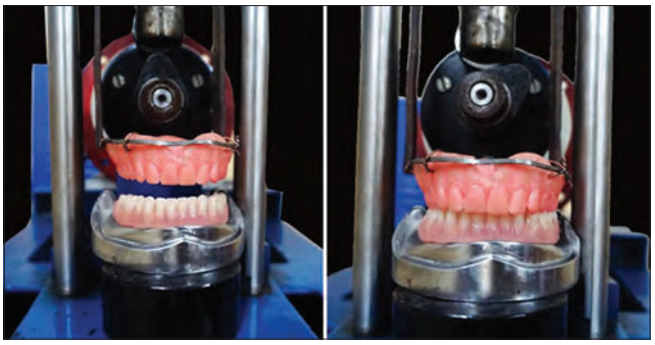

Figure 6: Prosthesis under cyclic loading

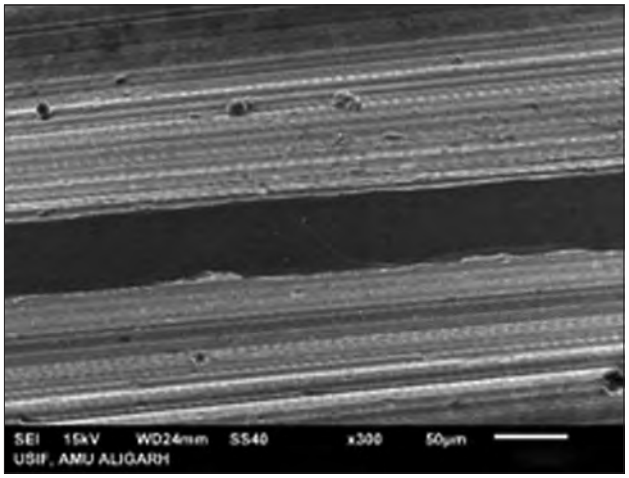

Figure 8: Before tightening the prosthetic screw (×300)

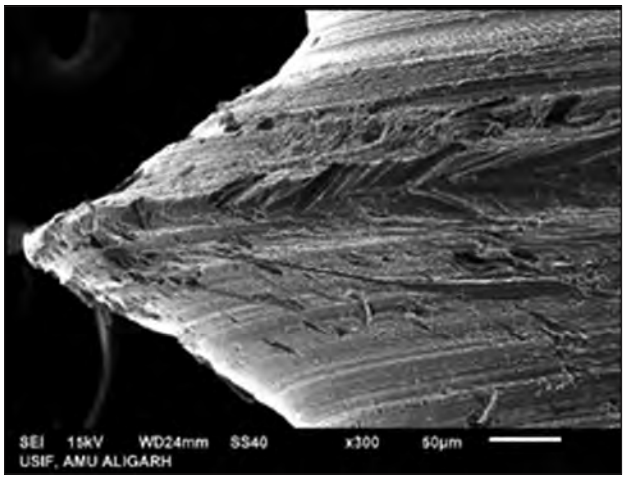

Figure 10: Physical changes in prosthetic screw – ISP on 4 implants after 10 years of usage (3 million Cycles) (×300). ISP: Implant-supported prostheses

implants) and 2 screws (12.5%) fractured (placed over 30° angulated implants) as viewed under SEM (×150–×1000).

On subjecting the samples in Subgroup B1 ($n = 24$) [Table 3] to 1.5 million cycles, eleven out of twenty-four prosthetic screws (45.83%) showed physical changes (06 prosthetic screws were placed over 30° angulated implants and 02

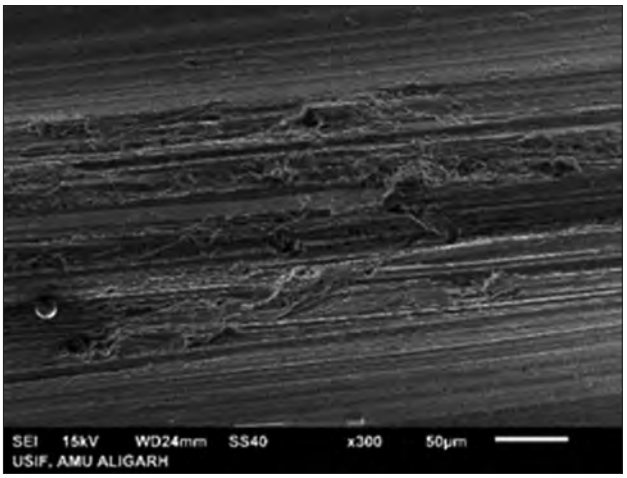

Figure 11: Physical changes in prosthetic screw – ISP on 6 implants after 10 years of usage (3 million cycles) (×300). ISP: Implant-supported prostheses

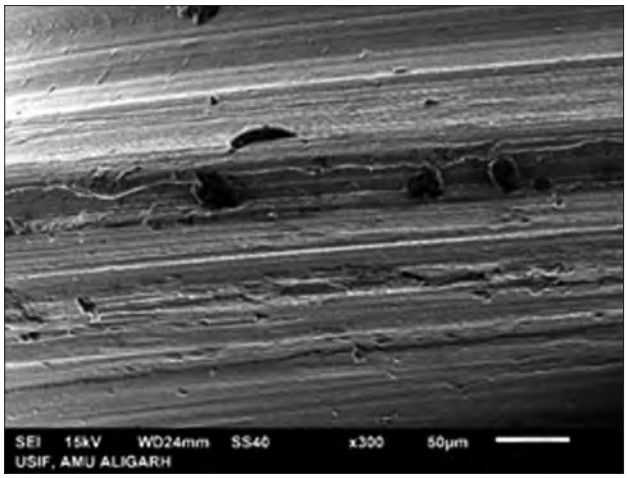

Figure 12: Physical changes in prosthetic screw – ISP on 6 implants after 5 years of usage (1.5 million Cycles) (×300). ISP: Implant-supported prostheses

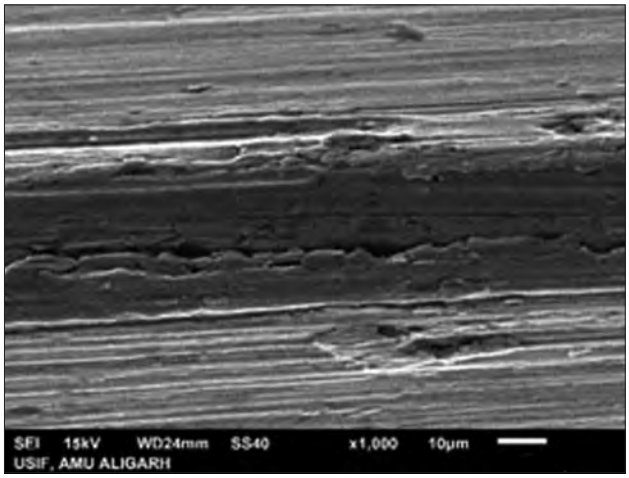

Figure 13: Physical changes in prosthetic screw - ISP on 6 implants after 5 years after 5 years of usage (1.5 million cycles) (×1000). ISP: Implant-supported prostheses

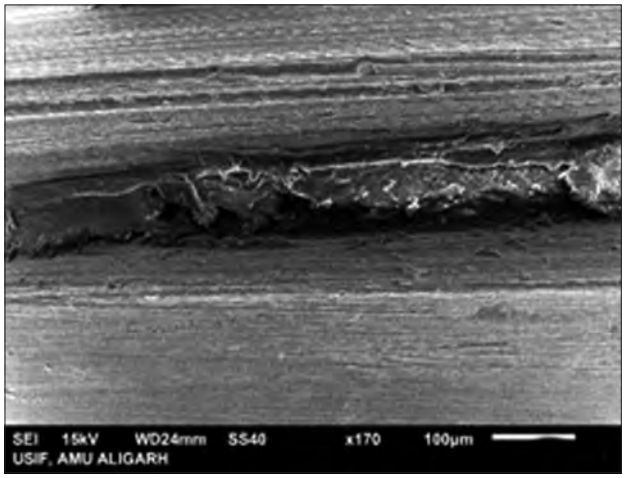

Figure 14: Physical changes in prosthetic screw – ISP on 4 implants after 5 years after 5 years of usage (1.5 million cycles) (×170). ISP: Implant-supported prostheses

prosthetic screws were placed over angulated implants at 17°) as viewed under SEM (×150–×1000).

On subjecting the samples in Subgroup B2 (n = 24) [Table 3] to 3 million cycles nineteen out of twenty-four screws (79.83%) showed physical changes (07 prosthetic screws were placed over 30° angulated implants and 03 prosthetic screws were placed over implants angulated at 17°) as viewed under SEM (×150–×1000). There was no loosening and fracture observed in ISP on six implants.

The data thus obtained were statistically analyzed using SPSS 12 software details-SPPS Inc., Chicago, IL, USA and $P < 0.005$ was considered statistically significant.

On comparing the statistical data of physical changes between ISP with four implants (Group A) which showed 81.25% changes to that of ISP with six implants (Group B) which showed 45.83% changes, there was a difference of 35.42% in physical changes which was statistically significant ($P = 0.003$). Therefore, from a mechanical point of view, an increase the number of implants from four to six when subjected to similar loading cycles (1.5 million), there were 35.42% ± 5.25% lesser physical changes in ISP with six implants as compared to ISP with four implants, also there were no loosening of screws or fractures observed.

On comparing the statistical data between physical changes in ISP with four implants at 1.5 million cycles (Subgroup A1) that shows 81.25% changes to ISP with four implants at 3 million cycles (Subgroup A2) that shows 100% changes, there was a difference of 18.75% in physical changes in the prosthetic screws which

Table 2: Number of prosthetic screws that underwent physical changes in implant-supported prostheses on 4 implants (Group A, *n*=32) after 1.5 million cycles (Subgroup A1, *n*=16) and 3 million cycles (Subgroup A2, *n*=16): At different angulation

Group A	Angulation	Total number of prosthetic screw tested	Number of loading cycles (lakhs)	Number of screws that underwent changes	Percentage of screws that underwent changes	*P*
Subgroup A1	0	8	1.5	4	50	0.141, NS
	300	8	1.5	7	88.5	
Subgroup A2	0	8	3	7	88.5	0.500*,
	300	8	3	8	100	NS

Chi-square test, Level of significance set at $P<0.05$. No significant differences were seen for the distribution of implants for different angulations for both the subgroups. *Sig: Statistically significant, NS: Nonsignificant

Table 3: Number of prosthetic screws that underwent physical changes in implant-supported prostheses on 6 Implants (Group B, *n*=48) after 1.5 million cycles (Subgroup B1, *n*=24) and 3 million cycles (Subgroup B2, *n*=24): At different angulation

Group B	Angulation	Total number of prosthetic screw tested	Number of loading cycles (lakhs)	Number of screws that underwent changes	Percentage of screws that underwent changes	*P*
Subgroup	0	8	1.5	2	25	0.064,
B1	170	8	1.5	2	25	NS
	300	8	1.5	6	62.5	
Subgroup	0	8	3	2	25	0.015*,
B2	170	8	3	2	25	N
	300	8	3	7	88.5	

*Significant at risk. Chi-square test, Level of significance set at $P<0.05$. For number of prosthetic screws that underwent physical changes in ISP on 6 Implants, for Subgroup B1, $n=24$, at 1.5 million cycles. No significant differences were seen for the distribution of implants for different angulation. For number of prosthetic screws that underwent physical changes in ISP on 6 Implants, for Subgroup B2, $n=24$, at 3 million cycles. Significant differences were seen for the distribution of implants for different angulation, the maximum percentage of screws that underwent changes were at 30° angulation as compared to 0° and 17°. *Sig: Statistically significant, NS: Nonsignificant, ISP: Implant-supported prostheses

though was not statistically significant ($P = 0.042$) but, from a mechanical point of view, an increase in the number of cycles from 1.5 million to 3 million there were 18.75% ± 5% more physical changes observed in the prosthetic screws that might have led to screw loosening or screw fracture as observed in one of the screws.

On comparing the statistical data between physical changes of ISP with four implants (Group A) that showed 100% changed to ISP with Six implants (Group B) that showed 79% changes, there were 21% differences observed in prosthetic screws which were not statistically significant ($P = 0.024$). As far as the mechanical aspect is concerned, an increase in the number of implants from four to six, and subjecting them to similar loading cycles, there were 21% ± 5.25% less physical changes in ISP with six implants.

On comparing the statistical data between physical changes of ISP with six implants at 1.5 million cycles (Subgroup B1) that showed 45.83% changes to ISP with six implants at 3 million cycles (Subgroup B2) that showed 79.83%, there were 33.33% differences observed in prosthetic screws which was again not statistically significant ($P = 0.0359$) but from a mechanical stand point there were more significant changes, it can therefore be inferred that the increased cyclic loading from 1.5 million to 3 million leads to 33.33% ± 5% more plastic deformation in the prosthetic screws [Tables 4 and 5].

DISCUSSION

Several *in vitro* studies have investigated the loosening of prosthetic screws.[7,13-19] The present study analyzes the prosthetic retaining screws submitted to dynamic cyclic loading after 5 and 10 years of clinical use, which made it possible to appreciate the physical changes of prosthetic screws that cause a significant effect on loosening of prosthetic screws.

In some of the causes of screw loosening, the most important causes are low preload due to inappropriate torque, ill-fitting screw and implant, vertical discrepancy on the abutment–implant, cyclic load on all components of the prosthesis, and excessive occlusal force.[19,20] The exact amount of torque on the screw is important for the ideal preload of the implant joint, which is the prosthetic abutment. The loosening or fracture of prosthetic screws is related to the difference of that of the implant–prosthetic abutment and the presence of a space between the implant connection and the prosthetic abutment, which may cause unfavorable stresses on the connecting components, implant, and bone.[21]

When a prosthetic screw is tightened, the screw becomes flattened [Figures 10 and 11] and a friction force or coefficient is generated around the screw which prevents loosening. Loosening of the screw is also related to the density of the bone that accepts the implant. This may account for the fact that the stability of the implant increases as the bone density increases. Consequently,

Table 4: No. of prosthetic screws that underwent physical changes in ISP on 4 implants (Group A, *N*=32) after 1.5 million cycles (Subgroup A1, *N*=16) and 3 million cycles (Subgroup A2, *N*=16): At different loading cycles

Group A	Angulation	Total no. of prosthetic screw tested	No. of loading cycles	No. of screws that underwent changes	% of screws that underwent changes	*P* value
Subgroup A1	00	08	1.5 lakhs	04	50%	0.141, NS
Subgroup A2	00	08	03 lakhs	07	88.5%	
Subgroup A1	300	08	1.5 lakhs	07	88.5%	0.500, NS
Subgroup A2	300	08	03 lakhs	08	100%	

Chi square test, Level of significance set at $P<0.05$. Ns: non significant, *sig: statistically significant. No Significant differences were seen for the distribution of implants for different loading cycles for both the subgroups

Table 5: No. of prosthetic screws that underwent physical changes in ISP on 6 implants (Group B, *N*=48) after 1.5 million cycles (Subgroup B1, *N*=24) and 3 million cycles (Subgroup B2, *N*=24): At different loading cycles

Group B	Angulation	Total no. of prosthetic screw tested	No. of loading cycles	No. of screws that underwent changes	% of screws that underwent changes	*P* value
Subgroup B1	00	08	1.5 lakhs	02	25%	NA
Subgroup B2	00	08	03 lakhs	02	25%	
Subgroup B1	170	08	1.5 lakhs	02	25%	NA
Subgroup B2	170	08	03 lakhs	02	25%	
Subgroup B1	300	08	1.5 lakhs	06	62.5%	0.500, NS
Subgroup B2	300	08	03 lakhs	07	88.5%	

Chi square test, Level of significance set at $P<0.05$. Ns: non significant, *sig: statistically significant. No Significant differences were seen for the distribution of implants for different loading cycles for both groups

prosthetic screw loosening is more frequent in case of implants in maxillary arch which is less dense than the mandible.[20,22,23]

There are few studies[7-9,18,24,25] to explain the causes of screw loosening, but none of them are conclusive. Almost all agree that loosening will not happen until the friction force between the threads is reduced by some external mechanism. In the present study, friction between the thread of prosthetic screw and multiunit abutment was affected by physical changes that push the coping against the abutment overtime, the screw threads of both abutment and prosthetic screw show surface deformation and reduce the normal friction force, and consequently, the cyclic load may rotate/loosen/fracture the prosthetic screw.

Theoretical analysis suggested that there is a linear relationship between the preload and torque applied. This relationship was reported by Bickford.[18]

$$Fp = T\,(P / 2\pi + \mu r / \cos\beta)^{-1}$$

(Fp = preload, T = torque, *P* = Screw pitch, μ = friction coefficient between prosthetic screw and abutment, *r* = minor radius of screw, β = thread half angle)

According to the above relation, preload depends on three factors: applied torque onto the prosthetic screw, screw geometry, and friction coefficient between prosthetic screw and abutment. If possible, the torque applied should impart the maximum preload that will not show any damage to the screw surface. The torque recommended by the manufacturer depends on the material of the screw, the shape of the screw, the type of thread, the material of the prosthetic component, and the surface finishing of the thread. In the present study, the recommended torque values of 20 N-cm for abutment screw and 15 N-cm for prosthesis screw were used.[26,21]

Various authors suggest applying a torque larger than the value recommended by the manufacturer as a means to avoid loosening. This practice is not advisable because as already discussed that preload should be in maximum limit to 80% of the tensile yield strength of the material in order to avoid screw strain and fracture during loading.[24]

The function of the friction coefficient is also somewhat conflicting: on one side, a low friction coefficient generates a higher preload for a given tightening torque; on the other hand, a low friction coefficient result in lower frictional forces opposing the opening torque. When the screws evaluated in this study were visually inspected, all of them appeared to be in good condition. The results of this study showed that, after 5 years of simulated clinical usage, 70% of prosthetic screws of ISP with four and six implants exhibited physical changes. Considering the plastic deformations observed in the screws [Figures 2, 5 and 7], it was noticeable that they present in areas in which there was more contact in between the prosthetic screw threads and the internal abutment screw threads. Continuous clinical usage creates plastic deformation (exhibited on the surface of screws) that causes crack initiation and this crack is responsible for the fracture nucleated at root of the implant threads. The fracture surfaces showed

dimples (microcavities), which is suggestive of ductile fracture. Near the site of crack nucleation, the dimples presented plastic deformations caused by the compressive stress due to opening and closing of the cracks.

ISP on four implants evidently showed that all the screws exhibited physical changes after 5 years of usage, which were more pronounced after 10 years of usage. It was also observed that physical changes were accompanied by screw loosening and fracture in ISP with four implants and the terminal implants were observed to be most affected by this, which could be attributed to the fact that these implants are placed at angle of 30 degree and the entire load is directed across the implant–abutment junction to the underlying fixture trough the screw which turned out to be the weakest link and hence underwent physical changes initially which even progressed to loosening as the duration of use increased and finally a few fractured. When evaluating the ISP with six implants, all the screws showed very minimal physical deformation as compared to the ISP with four implants. However, implants which were angulated at 30° showed the maximum physical changes.

During case selection, we have two choices that means either we increase the number of implants or tilt them depending on the clinical situation:

1. On increasing the numbers of implants, durability of prosthetic screw of ISP also increases, as observed in the study
2. On tilting, greater stresses are generated at implant abutment junction and these are deleterious when observed at the level of the abutment screw.

Hence, from a technical point of view, tilting of the abutments reduced the durability of prosthetic screw that retained ISP as shown in the present study. Therefore, to be on safer side, increasing the number of implants can help. However, according to the current literature, perception is to go from an all-on-four configurations with distal implants placed at an angle less than or equal to 30°, which is strongly not recommended according to our observations from the prosthetic screw point only.

CONCLUSION

Within the limitations of the study, the following conclusions can be drawn:

1. In rehabilitation of edentulous jaws with ISP (four and six implant configurations), tilting of implants to be avoided
2. Increasing the number of implants instead of tilting is more favorable as per observation of the present study, wherein it was evident that in increasing the tilt between 17 and 30 degree, the risk of prosthetic screw was very high
3. In any configuration of ISP with four or six implants, the prosthetic screw is to be replaced after a period of clinical use of 5 years/1.5 million cycles in order to have a more predictable outcome of the prosthesis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Do digital impressions have a greater accuracy for full-arch implant-supported reconstructions compared to conventional impressions? An *in vitro* study

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Abstract

Aim: The purpose of this study was to compare the accuracy of conventional implant impressions with digital impression techniques made using two different intraoral scanners.

Setting and Design: *In-Vitro* study.

Material and Methods: A scan of master cast containing four implants was made using two intraoral scanners: CEREC Primescan (Dentsply Sirona, USA) and 3Shape Trios (Copenhagen, Denmark) with PEEK scan bodies attached to the implants. Model was scanned ten times using different scanners. The accuracy of the chairside scanners was compared with highly accurate laboratory scanner. The scans were transferred into the software (Geomagic Control X 20, 3D Systems, Rock Hill, SC, USA) for analysis. The linear deviations and the angular deviations between the scans (scan of each model made using high-definition scanner and the master model scan) were calculated to determine the accuracy. Trueness was used as a parameter to compare the accuracy of different scanners (comparing test and reference).

Statistical Analysis: Analysis of variance was performed with Bonferroni's *post hoc* test for multiple group comparisons.

Results: Distribution of the mean overall absolute linear deviation was significantly lower in the conventional impression group compared to the CEREC Primescan scanner group and 3Shape Trios group ($P < 0.05$ for both). Distribution of the mean overall absolute linear deviation was significantly lower in the CEREC Primescan scanner group compared to the 3Shape Trios group ($P < 0.05$). Distribution of the mean overall absolute angular deviation did not differ between the three groups ($P > 0.05$ for all).

Conclusion: Conventional impressions showed significantly greater accuracy compared to the digital impressions made with both the above intraoral scanners for implant-supported restoration of an edentulous arch. In addition, the digital impressions with the CEREC Primescan scanner showed greater accuracy as compared to the 3Shape Trios scanner.

Keywords: Accuracy, digital impressions, edentulous arch

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INTRODUCTION

Dental implants are commonly used as an alternative to conventional partial or complete dentures for individuals with missing teeth, as they offer higher function, retention, and ease of use.[1,2]

Models made out of gypsum, poured from a physical elastomeric impression material, have been employed commonly to make implant-retained prostheses. To achieve an accurate prosthetic fit, the transfer of implant angulation and position is imperative.[3] Over the years, different techniques and materials have been used and evolved to improve and accurately replicate the implant position from the intraoral situation to the master cast.[4] If this step is not performed accurately, then it could lead to duplication of errors in the following steps of prosthesis fabrication.[5-10]

Digital implant dentistry has transformed the way impressions are recorded, and more importantly, the laboratory protocols followed thereafter. With the advent of digital impressions, the workflow of prosthetic reconstruction has been simplified by elimination of multiple steps such as tray selection and shipping to the laboratory. This has reduced the treatment time and has improvised patient compliance.[11-13]

A digital impression file eliminates storage issues as it is stored in digital library, which enables an efficient record keeping with a paper-free practice. Other than the learning curve in learning and using the new technology, there are financial limitations like the purchasing cost of an intraoral scanner. There are many scanners available for making digital impressions. These work on different image-capturing principles, and hence, their accuracies may not be the same.[14-18] The CEREC Primescan (Dentsply Sirona, USA) is an intraoral scanner that uses a white light for pattern projection onto an object; this concept is known as active triangulation. The images are captured in color continuously, eliminating the need of contrast spraying.[19] The Trios scanner (3Shape, Copenhagen, Denmark) is designed on the concept of confocal microscopy that records images from different positions in a continuous manner to create a 3D image. The latest model records color data without contrast spraying.[19] Accuracy has been described in the literature using two parameters such as trueness and precision (ISO 5725-1). Trueness describes the closeness to the actual dimensions of the object.[20-22] Precision is represented by the degree of reproducibility between repeated measurements.

Accuracy of scanners and conventional impressions have been previously described in the literature.[6-8] However, studies comparing the accuracy of the scanner with working on different principles that as optical triangulation and confocal microscopy on axial and tilted implants, used to restore edentulous arches, are still not reported adequately in the literature.

This study analyzes both the linear deviation and the angular deviation to evaluate the difference in the accuracy of conventional implant impressions and digital impression techniques made using these two different intraoral scanners.

MATERIALS AND METHODS

Fabrication of master model and master control STL files

Four dental implants, Bone Level Tapered 4.1 mm × 10 mm (RC, SLActive, Straumann AG, Switzerland, Basel), were placed in a sawdust model of an edentulous mandible. Anteriorly, implants were placed straight, and posteriorly, implants were placed at a 10° distal[11-13] angulation. This served as the master model [Figure 1].

Four scan bodies (Cares® RC Mono Scanbody, RC, BLT, Straumann, Basel, Switzerland) were then connected to the implants and tightened as recommended by the manufacturer [Figure 2]. The master model was scanned using a high-definition scanner (Artec 3D, Luxembourg, Europe) to obtain a STL file. This was the control STL file [Figure 3].

There were three study groups ($N = 30$):

1. Group A: Impressions made by conventional technique ($n = 10$)

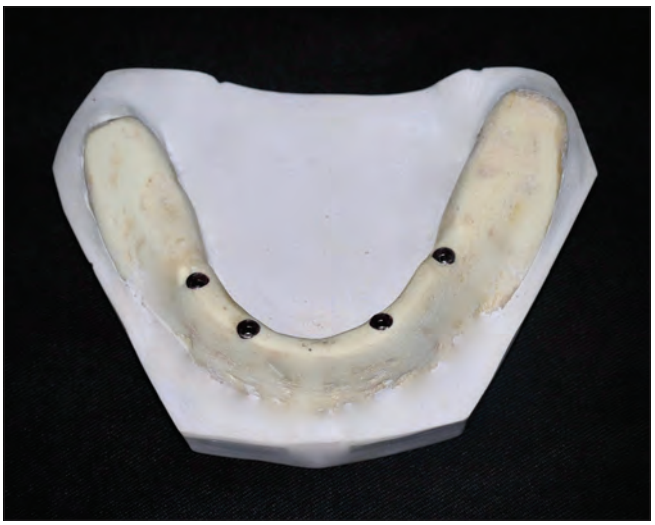

Figure 1: Sawdust model of an edentulous mandible with implants placed (control model)

2. Group B: Impressions made by intraoral scanner CEREC Primescan (Dentsply Sirona, USA) (n = 10)
3. Group C: Impressions made by intraoral scanner Trios 3Shape scanner (3Shape, Copenhagen, Denmark) (n = 10).

Group A

Using the open-tray impression technique, implant-level copings were fixed to the implants on the control/master model. Splinting of the open-tray impression copings was done using self-cure acrylic resin (Pattern Resin LS, GC America). Tray adhesive (Impregum; 3M ESPE, USA) was applied onto the intaglio surface of the custom tray. The impression was made only after drying the tray adhesive for 15 min. Using polyether impression material (Impregum; 3M ESPE, USA), ten impressions per group (A, B, and C) were made following standard procedure. The lab analogs were attached to the copings, and ten models were made. Scan bodies were fixed to each of the analogs, and each model was then scanned with the high-definition scanner (Artec 3D, Luxembourg, Europe), and the data, in the form of 3D images, were created and exported as an open-source STL file.

Group B

Using the scan bodies (Cares® RC Mono Scanbody, RC, BLT, Straumann, Basel, Switzerland), digital impressions were made with CEREC Primescan (Dentsply Sirona, USA), ten times, according to the manufacturer's instruction and exported as STL files [Figure 4].

Group C

Using the same scan bodies (Cares® RC Mono Scanbody, RC, BLT, Straumann, Basel, Switzerland) in place, ten digital impressions were made by the intraoral scanner 3Shape Trios (Copenhagen, Denmark) and exported as STL files [Figure 5].

Data analysis

All the scans were transferred into the metrology software (Geomagic Control X 20, 3D Systems, Rock Hill, SC, USA) for data analyses. Best fit algorithm was used; the tolerance was set at 1 μm; the control STL file of the master model [Figure 3] was superimposed to the four scan bodies and saved as a new STL file. This method was allowed for comparing the scan bodies only, minus the other irrelevant areas. As Ender and Mehl defined,[23] accuracy comprised the following two parameters: trueness depicts the degree of resemblance between the test scan and the scan taken by the scanner, while precision describes the variation between the test scans. The primary objective was, therefore, to ascertain and evaluate the accuracy, which includes trueness at the level of the scan bodies. Test scans and control scans were superimposed [Figures 6 and 7] using an algorithm with the tolerance set at 1 μm. Following this, a 3D comparison was made, calculating the linear [Table 1] and angular [Table 2] mean deviation from the mean positive and negative deviation using the methodology previously described by Papaspyridakos *et al.* (2016).[24]

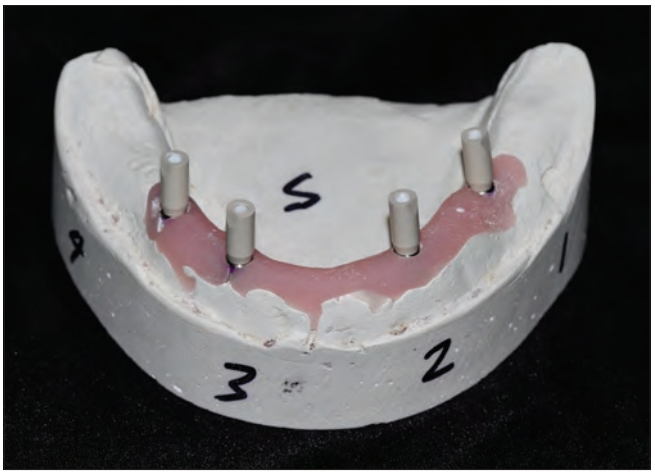

Figure 2: Scan bodies are attached to the analogs (Cares® RC Mono Scanbody, RC, BLT, Straumann)

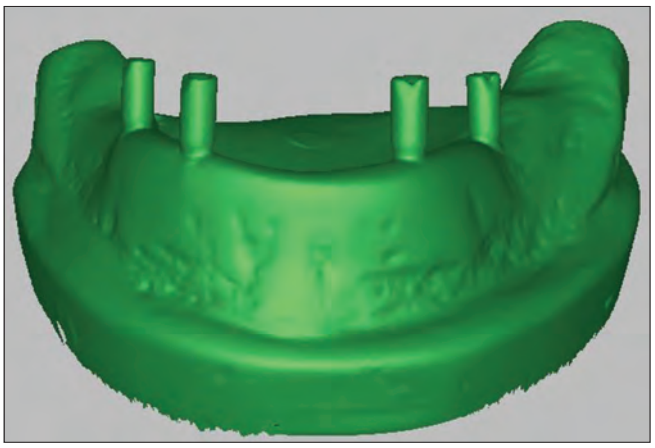

Figure 3: Control STL file

Figure 4: STL file created by CEREC Prime scanner

RESULTS

Distribution of the mean overall absolute linear deviation was statistically significantly lower in the conventional impression group as compared to the CEREC Primescan scanner and 3Shape Trios groups ($P < 0.05$ for both) [Table 3 and Figure 8].

Distribution of the mean overall absolute linear deviation was statistically significantly lower in the CEREC Primescan scanner group as compared to the 3Shape Trios group ($P < 0.05$).

Distribution of the mean overall absolute angular deviation did not differ significantly across the three types of scanner groups in intraoral model ($P > 0.05$ for all) [Table 4 and Figure 9].

Table 1: Distribution of the mean absolute linear deviations in different groups studied

Implant positions studied	Group A Conventional impression technique (*n*=10)		Group B Scan using CEREC Primescan (*n*=10)		Group C Scan using 3Shape Trios (*n*=10)	
	Mean	SD	Mean	SD	Mean	SD
A–B	0.059	0.038	0.095	0.038	0.073	0.047
B–C	0.038	0.037	0.127	0.057	0.248	0.107
C–D	0.061	0.023	0.057	0.031	0.050	0.037
A–D	0.020	0.060	0.226	0.063	0.316	0.129
A–C	0.131	0.048	0.173	0.029	0.217	0.061
B–D	0.113	0.041	0.174	0.034	0.351	0.046
Average	0.101	0.032	0.142	0.018	0.209	0.034

Absolute deviation in mm. SD: Standard deviation

Table 2: Distribution of the mean angular deviations in different groups studied

Implant positions studied	Group A Conventional impression technique (*n*=10)		Group B Scan using CEREC Primescan (*n*=10)		Group C Scan using 3Shape Trios (*n*=10)	
	Mean	SD	Mean	SD	Mean	SD
A–B	0.664	0.492	0.436	0.603	1.446	0.807
B–C	0.751	0.711	2.066	0.876	0.576	0.424
C–D	0.791	0.363	0.843	0.520	1.544	0.327
A–D	0.855	0.765	1.594	0.942	1.309	0.985
A–C	0.838	0.571	1.219	0.452	2.042	0.872
B–D	0.857	0.588	1.229	0.823	1.541	0.654
Average	0.793	0.329	1.231	0.309	1.409	0.752

Absolute deviation in degrees. SD: Standard deviation

Table 3: Intergroup statistical comparison of distribution of the mean absolute linear deviation in different groups studied

Intergroup comparisons (*P*)		
Conventional versus CEREC Primescan	Conventional versus 3Shape Trios	CEREC Primescan versus 3Shape Trios
0.012*	0.001***	0.001***

P-value by ANOVA with Bonferroni's *post hoc* test for multiple group comparisons. $P<0.05$ is considered statistically significant. *$P<0.05$, ***$P<0.001$. ANOVA: Analysis of variance

DISCUSSION

This study evaluated the linear and angular deviations produced by the three groups by comparing them to a master model which underwent scanning by a laboratory scanner (Artec 3D Space Spider, Luxembourg, Europe). Su and Sun compared the accuracy of 3ShapeTrios scanner and with a laboratory scanner by evaluating the precision

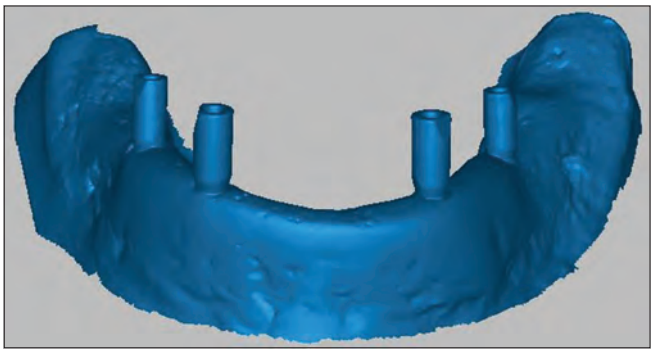

Figure 5: STL file created by 3Shape Trios

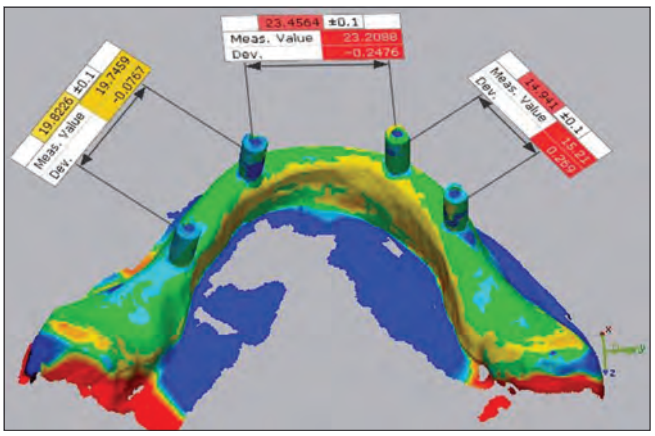

Figure 6: Superimposition and measurement of linear deviation

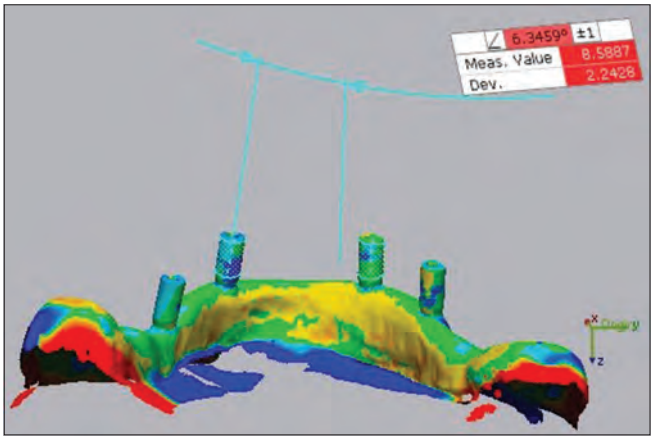

Figure 7: Superimposition and measurement of angular deviation

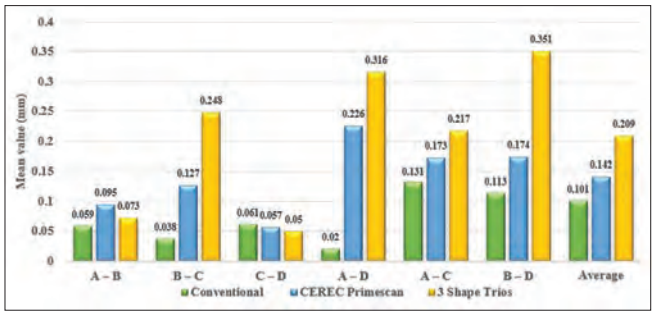

Figure 8: Distribution of the mean linear deviations in different groups studied (absolute deviation in mm)

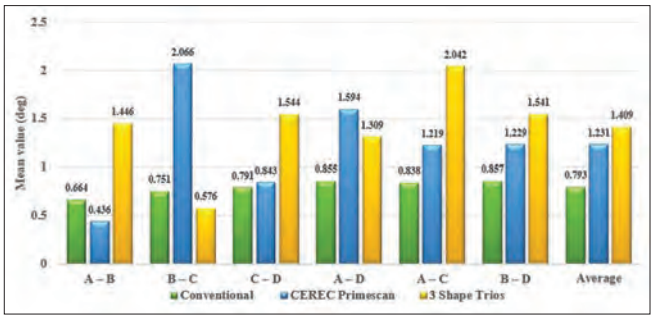

Figure 9: Distribution of the mean angular deviations in different groups studied (absolute deviation in degrees)

Table 4: Intergroup statistical comparison of distribution of the mean angular deviation in different groups studied

Intergroup comparisons (*P*)		
Conventional versus CEREC Primescan	Conventional versus 3Shape Trios	CEREC Primescan versus 3Shape Trios
0.355 (NS)	0.094 (NS)	0.999 (NS)

P-value by ANOVA with Bonferroni's *post hoc* test for multiple group comparisons. $P<0.05$ is considered statistically significant. NS – Statistically nonsignificant

between the two (Lava Scan ST). They found that the precision was significantly lower for 3Shape Trios, and the deviation was directly proportional to the number of teeth scanned during the procedure.[22]

The results of this study demonstrated the highest linear deviation for 3Shape Trios, followed by CEREC Primescan with the conventional impressions showing the least deviation in comparison to master model. A statistically significant difference was noted between the conventional impression group and CEREC Primescan ($P < 0.05$), between conventional impressions and 3Shape Trios, and between CEREC and 3Shape Trios ($P < 0.001$) groups regarding linear deviation. 3Shape Trios demonstrated the highest angular deviation at impression and scan level, followed by CEREC Primescan and conventional impression, respectively. Comparison of angular deviation at impression and scan level was found to be statistically insignificant in this research.

Digital impressions may have varied accuracy levels which largely depend on multiple factors such as scanning technique, size of the scan field, the angulation, number of implants, and the scan body fit.[25,26] The results of this study are in agreement with the studies conducted by Papaspyridakos *et al.* and Ender and Mehl where the authors conclude that there was statistically no significant difference observed between the accuracy of conventional and digital impressions.[23,24] However, studies conducted by Giménez *et al.* showed that the scanner recorded the first quadrant rather accurately, whereas for the second quadrant, the trueness significantly decreased.[27] Stimmelmayr *et al.* noted that there was a statistically significant difference in the scan body fit between laboratory analogs and implants.[28]

In this study, the conventional impressions were noted to be more accurate as compared to intraoral scans. This could be attributed to the fact that the open-tray splinted impressions have known to have a higher accuracy as compared to other impression techniques. Similar results were noted in several studies that reported high accuracy of open-tray splinting impression technique for internal connection implants.[29-32] The splinting of open-tray posts to each other does not permit any movement of the posts while making or retrieving the impression. Scan was made with high accuracy lab scanner. Furthermore, it has been observed that digital workflow has its own operator-based challenges. A study conducted by Giménez *et al.* reported that digital impression making has its own learning curve and the clinician needs adequate practice to reproduce or make precise intraoral scans.[33] This study compares both the liner deviation and the angular deviation of the impressions made using conventional method and digital intraoral scanners.

The limitations of this study are as follows: (i) owing to its *in vitro* design, this study oversimplifies impression making as the scans are recorded from a simplified model, where the implants were placed linearly; and (ii) intraoral scanning may show increased inaccuracies intraorally owning to the highly contrasting environments.[34]

The other difference lies in the stability of the surfaces scanned. The soft-tissue texture and form varies depending on the patient's jaw movements, thereby complicating the procedure of the scanning because it depends on the presence of reference points which are fixed (Andriessen *et al.*).[35] Similarly, it has been observed that an increase in interimplant distance along with a flat and dynamic mucosal surface results in an insufficiency of definitive reference points to enable accurate stitching Giménez *et al.*[33] In this

research, the implant positions were near to one another. The implication, therefore, would be that the interimplant distance is directly proportional to the scanning difficulty, and therefore, indirectly proportional to the accuracy. Clinically, biological factors such as saliva, gingival fluid, blood, breathing pattern, and movements of the tongue are some of the factors that contribute to reduction in accuracy.[34] Furthermore, the use of high-definition scanner for the master model and the conventional impression was a confounding factor in the study.

In addition, another limitation is that only a single implant system was used. Further studies should be carried out in a clinical setup with different implant systems and scanners of different technology specifications as well before clinical recommendations can be made for the treatment of an edentulous patient. Future studies should evaluate the accuracy of implants placed with higher angulation.

Pertaining to the clinical scenario, intraoral scanners show a great potential to physical impressions for implant prosthesis. However, for full edentulous situations, especially with a greater interimplant distance, a conventional open-tray impression with splinted impression posts may be the most accurate solution as the intraoral scanners do not get enough reference points in the edentulous arch and this leads to further inaccuracies. Furthermore, virtual images obtained can be printed or milled into physical models to draw a comparison with stone models which help establish a framework for the assessment of the clinical results. The ITI consensus statements also state that for edentulous impressions, the use of scans is not still recommended.[36]

CONCLUSION

The following can be concluded based on the research performed in this study:

1. The conventional impressions showed a high level of accuracy for implant-supported restoration of an edentulous arch
2. Digital impressions made using the scanner that works on optical triangulation principle and uses white LED light had a greater accuracy as compared to impressions made using the scanner working on the principle of ultrafast optical scanning and confocal microscopy
3. When all the three impression techniques were compared, conventional impressions showed significantly greater accuracy compared to the digital impressions made with both the above intraoral scanners for implant-supported restoration of an edentulous arch.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Case Report

Intraoral customized Z-spring-retained delayed surgical obturator for rare cases of bilateral subtotal maxillectomy

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Abstract

While dealing with a grave second wave of ongoing pandemic COVID-19, India also saw a surge in cases of COVID-19-associated mucormycosis, a systematic fungal infection caused by the Mucorales species. Mucormycosis is a highly angioinvasive, rapidly spreading fungal infection. In numerous cases of mucormycosis, bilateral subtotal maxillectomy was performed due to unpredictable and indefinable advancement of fungus clinically. Effective obturation of bilateral maxillectomy defect is a difficult task and as this is a relatively uncommon surgical problem, insufficient data are available on the construction of delayed surgical obturator for such cases. The aim of this article is to discuss the design of Z-spring-retained delayed surgical obturator which is easy to fabricate, easy to rectify, cost-effective, and comfortable for the patients compared to previous spring-retained obturators. This surgical obturator is retained through Z-spring made of 1.02 mm thick wire. Due to the thick gauge, this spring counters postsurgery trismus and develops the seal between the acrylic plate and dorsum of the tongue during deglutition thus helps the patient in taking a soft diet initially. Novelty in this case is the design of the spring, which makes it beneficial for both patient and prosthodontist.

Keywords: Delayed surgical obturator, maxillary carcinoma, mucormycosis, spring-retained obturator, total maxillectomy

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INTRODUCTION

While dealing with a grave second wave of ongoing pandemic COVID-19, India also saw a surge in cases of COVID-19-associated mucormycosis,[1] a systematic fungal infection caused by the Mucorales species. Mucormycosis is a highly angioinvasive, rapidly spreading fungal infection. Medications such as broad-spectrum antifungal agents such as amphotericin B and posaconazole and surgical intervention remain the mainstay for the management of mucormycosis. In numerous cases of mucormycosis, bilateral subtotal maxillectomy had to be performed due to unpredictable and indefinable advancement of fungus clinically. Effective obturation of bilateral maxillectomy defect is a difficult task and as this is a relatively uncommon surgical problem,[2] insufficient data are available on the construction of surgical obturator for such cases. Post removal of nasogastric tube, a surgical obturator should be provided as soon as possible to assist the

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patient in swallowing and speech as well as to reduce the psychological trauma of resection. Immediate surgical obturators often do not fit effectively as they are made using preoperative measurement and many times surgery is more extensive than planned. Therefore, it becomes essential to provide a functional delayed surgical obturator to the patient.

A 68-year-old male who was suffering from left sinonasal mucormycosis with palatal involvement and had undergone left subtotal maxillectomy with right inferior maxillectomy [Figure 1a] was referred to the prosthodontics department for fabrication of delayed surgical obturator 10 days after surgery. A multitude of factors come into play while rehabilitating a patient. As the wound was in the healing stage and the patient had periodontally firm mandibular teeth, a spring-retained delayed surgical obturator was planned until the defect stabilizes.

Expectations from this delayed surgical obturator were to obturate the defect, help the patient in deglutition of liquid, and semisolid diet postremoval of a nasogastric tube, improve speech, and counter trismus after surgery. Another expectation was to reduce psychological trauma to the patient. Although spring-retained obturators[3] have been used to treat total maxillectomy cases, the spring used is complicated in design, very flexible, difficult to fabricate, and difficult to rectify in the patient's mouth also the V-shaped arm of the spring impinges on the pterygomandibular raphe (especially in patients who are not having the third molar in the oral cavity) but we developed a simple Z-spring-retained customized obturator, which is easy to fabricate, easy to rectify, and does not impinge on soft tissues hence comfortable to the patient. In the previous spring-retained obturator, the spring design was similar for all the patients irrespective of different Different Vertical dimension at rest (VDR) for different patients. In Z-spring-retained obturator, the length of diagonal arm was decided according to the rest position of every patient (VDR). So that when the patient is in rest position, the spring is in passive condition and not putting any extra force on mandibular teeth and arch.

PROCEDURE

1. Preliminary impression of both maxillary and mandibular arch was made using an irreversible hydrocolloid compound (Zelgan, Dentsply, Gurgaon, India) [Figure 1b]. The patient was handled with utmost care while recording the impression, as the surgical wound was raw and fresh. Personal protective gear was used during the procedure, impressions and casts were disinfected using glutaraldehyde disinfectant, and instruments were properly autoclaved to reduce cross-contamination
2. After disinfection, the impression was poured in gypsum Type III material (Dental stone, Kalabhai Karson, Mumbai, India) [Figure 1c]
3. Record base was fabricated on maxillary cast using auto polymerizing resin (DPI, Rudrapur, India) and occlusal rim was made using modeling wax (Y-dents, Delhi, India). As it was decided not to exert masticatory forces on surgical site until primary healing, so record base was fabricated after completely blocking the defect area in the cast. Thus, the maxillary obturator did not require hollowing as it did not have any extension in a defect. Teeth arrangement was also delayed for the same reason of not putting masticatory forces on defect area in the healing phase
4. Jaw relation was recorded using a conventional method. First, Vertical dimension at rest (VDR) was recorded using the phonetics method which was 6.4 mm. Then, Vertical Dimension at occlusion was kept at 6.2 mm and the mandible was guided into centric relation using the chin point guidance method. Casts were mounted on a mean value articulator (Samit, Dento Kem, Faridabad, India). The purpose of this step was to record vertical dimension at rest and centric relation and fabricate the spring in this position so that spring is in passive position when the mandible is in rest position

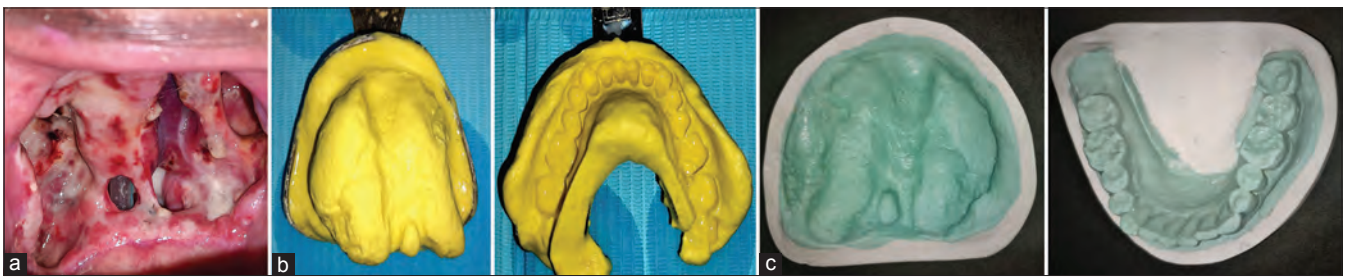

Figure 1: (a) Preoperative Intraoral view of unhealed total maxillectomy defect showing maxillary sinus, nasogastric tube, and turbinates, (b) impression of the total maxillectomy defect and mandibular arch made using irreversible hydrocolloid, and (c) cast of maxillectomy defect and mandibular arch poured in dental gypsum Type III

5. Spring fabrication: Nineteen-gauge (1.02 mm thick), hard, round, stainless steel orthodontic wire (Samit, Dento Kem, Faridabad, India) was used to fabricate the spring. The reason behind using a 19-gauge wire was to fabricate a spring which is self-supported, can counter trismus followed after surgery,[4] and does not fracture easily. Z-spring has three components: two horizontal arms, one diagonal arm, and two spring coils. The length of horizontal arms was decided to be 15 mm, as a small portion of this arm would be embedded in auto polymerizing resin. At the end of horizontal arm, two small loops were made to engage auto polymerizing resin. It was decided to fabricate coils of 4 mm diameter so that coils can be opened and closed comfortably. Distance between both horizontal arms of spring (length of diagonal arm) was decided according to the jaw relation of the patient. Two such springs were prepared [Figure 2a]
6. Mandibular record base fabrication: Adams clasp was constructed on both mandibular first molars and pin head clasp was constructed between canine and first premolar to provide retention to the mandibular denture base
7. Attaching Z-spring with both record bases: The lower end of the spring was attached to the bridge of Adams clasp and the upper end of spring was attached to the maxillary record base plate using autopolymerizing resin, thus, the obturator plate is in a suspended position [Figure 2b-d].

After finishing and polishing, a delayed surgical obturator was delivered to the patient. Pressure indicating paste was used to relieve all the pressure points. The patient and attendant both were instructed on insertion and removal of obturator. The patient was also instructed on how to clean both obturator and surgical site postmeal. Recall visits were kept after 24 h, 1 week, 2 weeks, 4 weeks, and 3 months for further adjustments as the defect shrunk very fast. After 3 months of follow-up, the Z-spring did not fracture, did not cause any soft-tissue trauma, and helped in maintaining mouth opening, i.e., countered trismus postsurgery. The patient was quite comfortable with obturator and had increased oral intake following insertion of obturator, which resulted in a 5 kg weight gain in 3 months. For a definitive obturator, a two-piece magnet retained hollow removable obturator or bar-retained fixed prosthesis attached to zygomatic implant would be planned based on the patient's physical condition, healing, economic condition, and preference.

BIO-MECHANICAL PRINCIPLE

Desired qualities in the spring were sufficient strength not to fracture under cyclic load, counter the trismus, flexible when in function, and passive in rest position. Keeping this in mind, 1.02-mm thick wire was used[4] and two coils were made which makes the spring both strong and flexible enough to serve the function. In rest position, Z-spring is not compressed and keeps the jaws separated similarly to the physiological rest position. Thus, it helps in

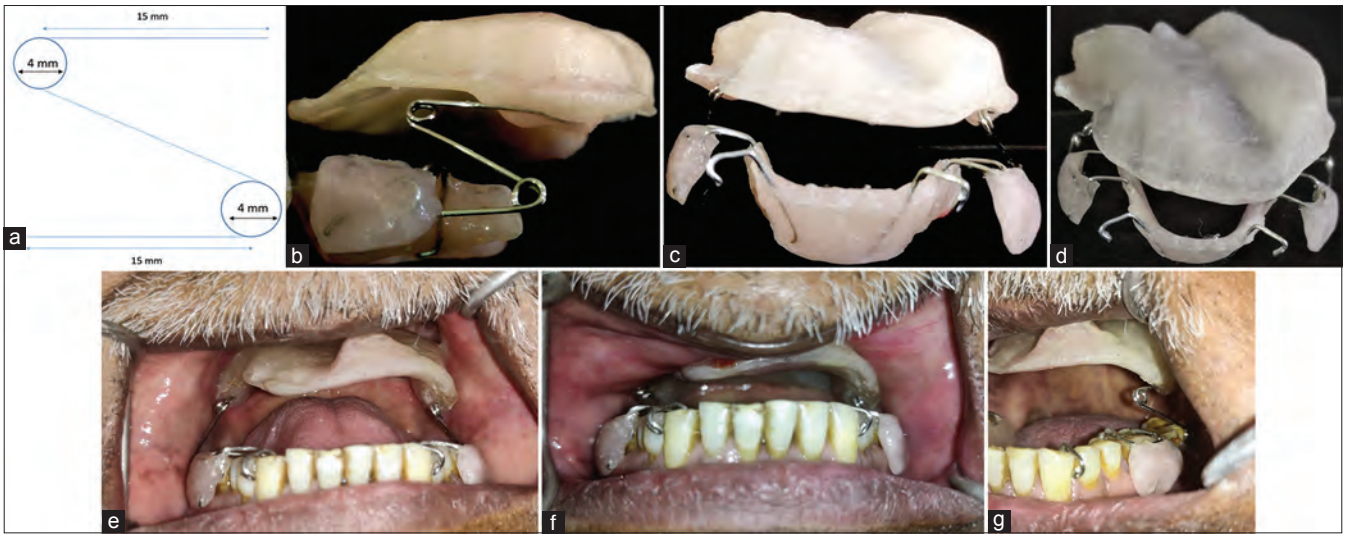

Figure 2: (a) Schematic diagram of Z-spring showing different parts of spring. Spring has two coils of 4 mm diameter each. The length of the two horizontal arms is 15mm. The length of diagonal arm decided according to VD at rest of patient, (b) side view of Z-spring obturator showing z-spring attached to maxillary and mandibular record base, (c) front view of Z-spring obturator showing retaining clasps and buccal acrylic button of mandibular denture base and tissue surface of maxillary obturator, (d) frontal view of Z-spring-retained obturator showing maxillary impression surface of obturator with minimal or no extension into defect thus not requiring hollowing, (e) postoperative intraoral view of seated obturator in the maximum opening of the mouth, (f) postoperative intraoral view of seated obturator in maximum closing of the mouth, (g) postoperative left lateral view of seated obturator during the opening of the mouth

counteracting trismus followed after surgery. Both the coils help in opening and closing movements. Both the coils act simultaneously and permit jaw movements.

DISCUSSION

There is limited data on delayed surgical obturator fabrication of the patients who have undergone bilateral total maxillectomy[5] as it is a relatively uncommon surgical process and creates defects that are difficult to rehabilitate prosthetically.[6] Lack of retention, support, and stability are common problems encountered while constructing prostheses for such patients.[7] Irrespective of the final treatment options available, the most immediate matter to be addressed is adequate nutrition in the postoperative phase.[8] Usually, wire-retained immediate surgical obturators are difficult to manage due to massive surgical defects and continuous contracture of the wound. Hence, a removable delayed surgical obturator is the best solution for such situations. Extraoral aid for retention can also be used for such cases but they are less esthetic and not preferred by young patients, hence, it becomes important to find different intraoral retentive means. One such successful obturator design is a spring-retained surgical obturator that is retained through spring, this spring develops the seal between the acrylic plate and dorsum of the tongue during deglutition [Figure 2e-g], thus, helps the patient in starting a soft diet right after removal of nasogastric tube. Although spring-retained obturators[3] have been used to treat total maxillectomy cases, the spring used is complicated in design, very flexible, difficult to fabricate, and difficult to rectify in the patient's mouth also the V-shaped arm of the spring impinges on pterygomandibular raphe (especially in patients who are not having the third molar in the oral cavity)[9] but we developed a simple Z-spring-retained customized obturator, which is easy to fabricate, easy to rectify, and does not impinge on soft tissues hence comfortable to the patient. In the previous spring-retained obturator, the spring design was similar for all the patients irrespective of different VDR for different patients. In Z-spring-retained obturator, the length of diagonal arm was decided according to rest position of every patient (VDR). Hence, when the patient is in rest position, the spring is in passive condition and not putting any extra force on mandibular teeth and arch.

In this obturator, we designed a Z-spring to connect the maxillary and mandibular denture base. This Z-spring is easy to fabricate and requires very less manipulation in the patient's oral cavity. The thickness of wire makes it a good choice postmaxillectomy as it counters trismus that follows surgery also it is flexible enough to permit mandibular movement. Such obturator was given in four patients and it required only a little effort in teaching insertion and removal of obturator to the patient. After 3 months of follow-up, the Z-spring did not fracture, did not cause any soft-tissue trauma, and helped in maintaining mouth opening, i.e., countered trismus postsurgery. The patient was quite comfortable with obturator and had increased oral intake following insertion of obturator, which resulted in an average 5 kg weight gain in 3 months. Masticatory forces, masseter muscular activity, duration of chewing cycle increases with increase in hardness of food,[10] as with this obturator patient was taking liquid and semisolid diet, it was easier to function due to softness of food and the obturator also did not require any kind of repair in the given time frame, thus saving procedure time and cost. Based on our practical experience while treating various patients with this obturator, the following indication, contraindication, and limitations of this obturator have been given. It would help clinicians in case selection.

Indication

- Periodontally firm mandibular teeth[11]
- Adequate mouth opening
- Manual dexterity

Contraindication

- Reduced mouth opening which hampers insertion and removal of obturator easily
- Mandibular edentulous arch or mandibular periodontally compromised teeth
- Exostoses are present in the mandibular arch as it causes discomfort to the patient
- Geriatric patients or patients with neurological disorders who do not have sufficient manual dexterity.

Limitation

Manual dexterity is required to insert and remove the obturator.

A short-term solution as spring may fracture in a definitive prosthesis.

CONCLUSION

This simple design can be useful to fabricate delayed surgical obturator in compromised total maxillectomy cases where sufficient retentive anatomic undercuts are not present. This design is a boon for such patients who want to avoid extraoral retentive aids to help retain the obturator in place.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given

his consent for his images and other clinical information to be reported in the journal. The patient understands that his name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Conflicts of interest
There are no conflicts of interest.

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IPS Member (Double room on Twin Sharing Basis)	13,000/-	20,500/-	24,500/-	5000/-
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