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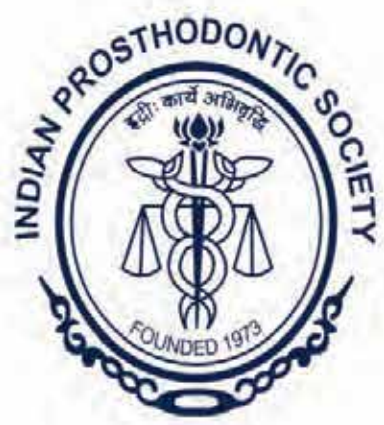

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To serve as a medium for continued prosthodontics education and quantitative scientific publications on clinical trials, basic science related to the biological aspects of prosthodontics, basic science related to prosthodontics techniques as well as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

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TIPS TO READER

BRIEF COMMUNICATION

Basics in statistics: Sample size calculation and descriptive data statistics

Statistics is a scientific approach for converting data into information. There are two types of data: descriptive and statistical data, and most often, researchers consider only the statistics of the measured outcome that were derived during the conduction of the study. It is essential to include statistical analysis for sample size calculation and the descriptive data when submitting a manuscript.

Sample population is the subset of participants from the target population, and an adequate number of participants is essential for obtaining appropriate statistical inferences. Selecting a convenient number of samples either due to the availability of limited participants or because of a lack of resources would be noninferential research. The sample size selection should be based on previous studies with similar characteristics. However, if a reference study is unavailable, we can conduct a pilot study before the main research to select an appropriate sample size. Sample size selection is influenced by the level of significance, the power of the study, the expected effect size, the underlying event rate, and the standard deviation of the population [Table 1].[1] The level of significance is to estimate the sample size based on a *P* value that is either <0.001 or <0.05, which is based on the confidence interval we are choosing, which is either 99% or 95%, respectively.[2] The power of the study is often represented as 1-β, where beta is the probability of failing to detect a difference when it is actually present. Often, the power of the study should be at least 80%, and if a larger sample size is planned for the conduct of the study, the power should be kept at 90%. The level of significance and the power of the study are selected by the researcher. However, the other three factors should be based on previous or pilot studies.

Table 1: Essentials of sample size calculation

Factors considered	Influence on sample size	Depending factor
Level of significance (*P*)	<0.001 - Increases sample size <0.05 - Decreases the sample size	Can be controlled by researcher
Power of study (1–β)	Above 90% - Increases sample size 80% - Decreases the sample size	Can be controlled by researcher
Effect size	Smaller the effect size - Larger the sample size	Mean of the data from reported research
Event rate	Smaller the event rate - Larger the sample size	Prevalence of disease condition, from reported data or existing disease distribution
SD	Homogenous/narrow SD - Smaller the sample size	SD from the previously reported data

SD: Standard deviation

Effect size is a relative difference in the mean value of the measuring outcome between the control and the study groups. For example, in a previously conducted study or pilot study, if the crestal bone loss in the peri-implant region in the control population is 1.5 mm and in the study population is 0.7 mm, the mean difference of both determines the effect size. If the effect size is small, the study population should be large, whereas the reverse is true when the effect size is large. The event rate is determined based on the prevalence of the condition/disease; if it is less, the sample should be increased. For example, to conduct a study on a failing implant, in the present scenario, the prevalence of the condition is <2%, and hence, we require a larger sample size. The standard deviation is based on the dispersion of the data among the participants from its average mean value. A smaller sample size is required for homogenous or less dispersed samples (narrow standard deviation) from its mean value. Event rate should be constantly evaluated during the process of the study, and if the prevalence of the condition is altered, the sample size should be altered accordingly at any stage of the study. Sample size determination should never be convenient, especially for a clinical study, and most journals make it mandatory to submit the sample size calculation. Furthermore, an adjustment of sample size is preferred in addition to the calculated size to compensate for the dropout of participants during the course of the study. If *n* is the number of samples derived from the sample size calculator and *b* is the dropout rate,

the adjusted sample size would be slightly more than the calculated sample size.

The data obtained from participants are divided into descriptive and inferential data, the former being the description of the population and the latter being the data extracted from the population. The statistics of descriptive data help prevent bias between the control and the study population. Descriptive data represent the average value or dispersion of value for each outcome. The mean, median, and mode are representations of descriptive data.[3] Furthermore, depicting the number or frequency of participants in each category is a form of descriptive data. Statistics from descriptive data help understand the presence or absence of bias between the control and the study population in their basic characteristics. For example, if the control and study populations are selected based on the quality of the anterior edentulous maxilla for placement of implants, the participants should not have varied characteristics based on age, sex, or gingival biotype. Furthermore, if the population varies between 30 and 40 years of age, we cannot have a mean test population closer to 30 years and a control population that is closer to 40 years. Hence, a researcher should perform statistics on descriptive data, so that the inference obtained from the research will be unbiased if there is no significant difference between the study and control populations in their basic characteristics.

Inferential statistics of descriptive data involve the comparative evaluation of two groups of data to determine the level of significance or *P* value. The descriptive data should have an inferential statistic, especially when performing a randomized control trial. The statistics of descriptive data between the control and the study groups will help in detecting the presence of bias during the randomization of participants between the groups. An unbiased RCT will not have statistical differences between the study and control groups.

Inferential statistical analysis of the test outcome should be performed by parametric and nonparametric tests [Table 2]. Parametric statistics are based on assumptions about the distribution of the population from which the sample was taken. Nonparametric statistics are not based on assumptions, and the data can be collected from a sample that does not follow a specific distribution or stringent criteria. The decision to use parametric or nonparametric tests often depends on whether the mean or median accurately represents the center of your data distribution sets.[4] For example, considering the values 10, 11, 11, 11, 13, 15, 18, and 20 as the data distribution for the interincisal distance measurement among the participants with deep bite in Class II division 2, the mean of this data distribution is 13.6 (average values), while the median is 11 (repeated occurrence of values). The type of statistics for this given data depends on the kind of analysis (qualitative or quantitative), the average value (mean or median), and the sample size. A parametric test is performed for a larger sample size, quantitative analysis, or when the mean more accurately represents the center of the data distribution. The nonparametric test is performed for a smaller sample size, qualitative analysis, or when the median accurately represents the center of the data distribution. Although the above factors are basic considerations, further decisions on using parametric or nonparametric tests should be confirmed by Shapiro–Wilk for smaller samples or Kolmogorov–Smirnov tests for larger samples. If there is no significant difference ($P > 0.05$) in either of the above tests, it indicates that the data are normally distributed and require a parametric test.

Table 2: Factors affecting the type of inferential statistical analysis

Factors	Parametric test is considered	Nonparametric test is considered
Sample size	Large	Small
Centre of data distribution	Mean	Median
Type of data	Quantitative	Qualitative

The field of research is moving toward a healthy competition, wherein publishing articles depend on the quality of research and manuscript writing. As already mentioned, the minor details in the manuscript, especially the quality writing and appropriate statistical information, add value to quality research.

Anand Kumar Vaidyanathan

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Systematic Review

Efficacy of implantoplasty in management of peri-implantitis: A systematic review

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Abstract

Aim: Peri-implantitis causes progressive loss of the supporting bony structure around the dental implant. Implantoplasty mechanically removes contaminated threads to achieve smoother implant surface thus reducing the bacterial load enabling fibroblastic growth to stimulate the healing effect. This Systematic review is done to appraise the outcome of implantoplasty on surface quality of Implant (roughness), biocompatibility of implants in peri-implantitis cases.

Settings and Design: The Settings of the studies are major online databases like PubMed, Scopus, and Cochrane online library. The design of the current study is systematic review of published qualitative studies.

Materials and Method: 37 articles were identified for the present review and systematic electronic literature search was done from August 2022 to January 2023, via PubMed, Scopus, Medline, and The Cochrane Library (Wiley) databases [PRISMA guidelines]. In vitro studies on implantoplasty for peri-implantitis were included for the review. 2 examiners independently selected based on the inclusion criteria and recorded the necessary data.

Statistical Analysis Used: Risk of bias assessment tool was evaluated with Newcastle Ottawa scale (NOS) and screened based on Selection, Comparability, and Outcome with the following categories: - maximum of 4, 2 and 4 points respectively. The observations were tabulated and analysed.

Results: Among the 8 selected studies, two studies reported no statistical difference between implantoplasty and control, one study proposed carbide burs were better than diamond burs, another study also suggested multilaminar burs were better than diamond and carbide. The Newcastle Ottawa scale (NOS) score for the quality of the included studies ranged from 6 to 8. Two of the studies had score of 6 points, eight had 7 points and one had 8 points.

Conclusion: Implantoplasty has been recommended as an efficacious treatment protocol for peri-implantitis that helps to diminish the inflammation and accompanied by a high success rate.

Keywords: Bone loss, dental implants, Newcastle–Ottawa scale, periodontitis, resective/regenerative therapy

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INTRODUCTION

Oral implants have proven to deliver an effective long-standing treatment option for the replacement of missing teeth.[1,2] Although this particular treatment option has high predictability and efficient outcome rates, meticulous constant maintenance and complication issues still do persist. Peri-implantitis is one such biological impediment that could result into detrimental effect on the long-term success of the implant procedure.[3] Peri-implantitis refers to a pathologic condition of the tissues surrounding the dental implants. It is typified by inflammation in the adjacent connective tissue resulting in progressive loss of supporting bony structure.[4] This condition occurs due to a disparity between the microbial load and the defense mechanism of the host or recipient.[5] The implant threads get exposed to the oral milieu and act as a favorable niche to bacterial adherence. This helps to promote the inflammatory process leading to progressive bone loss and in turn divulging more threads and permitting bacterial proliferation.[6] This inflammatory condition could result in failure and loss of the implant totally. Peri-implant disease can be categorized as peri-implant mucosal inflammation and peri-implantitis. The primary clinical features of this condition include increased probing depth, bleeding on probing, suppuration, injury to the adjacent bony structure, and finally, loss of the implant.[7]

Some of the risk factors that can be allied to the cause of peri-implantitis include chronic periodontitis cases, regular smoking, poor plaque control, and no preservation and poor maintenance after implant treatment.[8,9] The formation of biofilms and their composition is affected by surface properties inclusive of the surface topography, their chemical composition, and free energy on the implant surface. Such compounding factors such as surface roughness and various physiochemical characteristics make the dental implants vulnerable to bacterial adhesion and colonization.[10] Hence, the primary motive in treating a peri-implantitis case is the eradication of bacterial colonies, preservation of implant structure, enhanced esthetics, reduced bony defects, and finally, rejuvenation of lost bony structures. Re-osseointegration or healthy regeneration of the implant tissue requires actions such as control of inflammation, removal of bacterial biofilms *in toto,* and cleansing of the implant surface.[11] Surgical intervention that is carried out for peri-implantitis cases comprises open flap debridement, total elimination of granulation tissue, and decontamination of the exposed threads along with some resective procedures such as bone augmentation, and abolition of pocket are adapted to treat such cases.[12,13]

There are several methods for decontaminating the implant surfaces such as air-powder abrasion, ultrasonic and manual debridement with plastics or titanium curettes, implantoplasty, laser therapy, and titanium brushes. Certain chemical solutions applied are citric acid, hydrogen peroxide, cetylpyridinium chloride, tetracycline, ethylenediaminetetraacetic acid, chlorhexidine, etc., for the cleansing procedure.[14] Some other effective biofilm agents that have questionable responses included sodium bicarbonate and amino acid glycine.[15] Implantoplasty is done to smoothen the exposed implant threads with the help of diamond or carbide burs and thus favors diminishing the bacterial adherence thus facilitating fibroblastic growth and the healing process.[16,17]

Implantoplasty influences the mechanical properties and the technique resulting in excess metal debris at the surgical implant region. There is an increase in the activity of the inflammatory cells and cytokines cells, enhancement in the osteoclast activation, and abridged viability of gingival fibroblast when there is an accumulation of titanium particles and metal debris in the surrounding soft tissues.[18] This technique reduces the diameter and thickness of the implant. These factors along with bone loss owing to peri-implantitis upsurges the fracture risk of the implant.[19] It has been documented that unfavorable crown implant ratio, thinner implant that bends under high masticatory forces leading to fracture can be all due to severe bone loss.[20] Some studies have also reported that implantoplasty has the potential to imitate the *platform switch concept* in the recently adapted transmucosal surface by eliminating and polishing the implant threads and by lessening the diameter of the implant diameter in the most apical part of the exposed threads, which contacts the supporting bone.[21] There are many *in vitro* studies that have demonstrated the surface modification of rough implant discs (with diamond burs) failed to induce marked temperature increase or have an impact on surface biocompatibility with SaOs2 (cell line) osteoblast. The surface treatment augmented the hydrophilic nature of the surface that might be advantageous for re-osseointegration.[22,23] It has also been said that irrespective of the implantoplasty being executed or not, the longevity of implants treated for peri-implantitis was principally affected by the severity of bone loss present. Thus, it can be deduced that implantoplasty singularly cannot increase the probability of implant survival.[24] Therefore, this systematic review was planned with the aim to estimate and assess the outcome of implantoplasty on surface roughness and biocompatibility of implants in peri-implantitis cases.

MATERIALS AND METHODS

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [Figure 1].

Eligibility criteria

A total of 37 articles were identified for potential review. The inclusion criteria were the clinical as well as preclinical studies involving implantoplasty to treat peri-implantitis. *In vitro* studies assessing the proprieties of the implant surface were also included. Studies which had either incomplete datum and other adjuvant procedures along with implantoplasty that were used for peri-implantitis were excluded from the study. Studies having Newcastle–Ottawa Scale (NOS)[25,26] scores of <7 were also excluded.

Focused question

- Does the use of implantoplasty increase the biocompatibility of implants or not?

Search strategy

Systematic electronic literature search was conducted over 6 months, from August 2022 to January 2023, of the PubMed, Scopus, Medline, and the Cochrane Library (Wiley) databases. Articles written in English were selected and reviewed. The search term or keywords applied were the following: ((“peri-implant disease” OR “peri-implantitis” OR “peri-implant mucositis” OR) AND (“implantoplasty” OR “mechanical modification of the implant” OR “implant surface debridement”)).

Study selection and data extraction

Two independent examiners (DG and SB) decided on the studies to be selected as per the inclusion criteria and relevant data were extracted by them. Irrelevant studies were eliminated based on the article title and the abstracts. The third and fourth authors (NP and DP) assessed the studies to rule out duplications. Then, the full-text article of all the remaining studies was analyzed. Any difference of opinion was discussed to reach a conclusion by consensus.

Risk of bias assessment

The risk of bias was assessed for this study using the NOS[25,26] and screened under the following criteria:

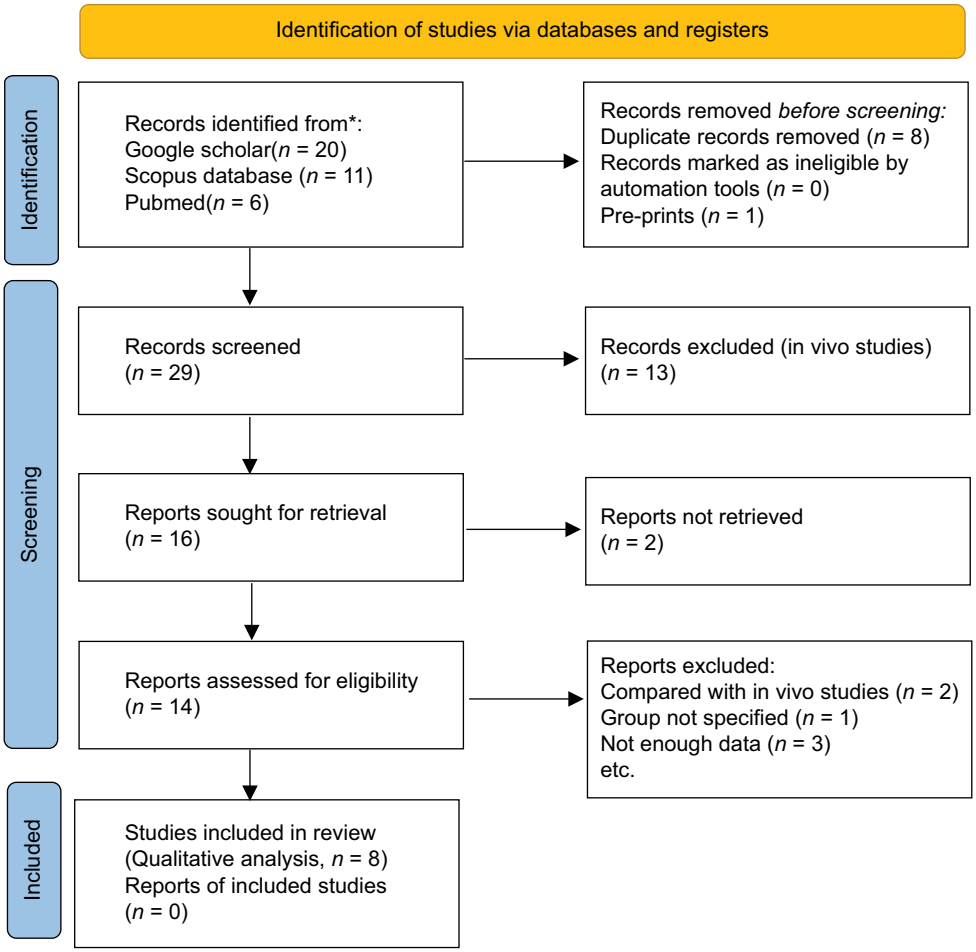

Figure 1: PRISMA Flowchart for the review. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

selection, comparability, and outcome. The categories were given a maximum of 4 points, 2 points, and 4 points, respectively. The included studies were qualified as "Good," "Fair," and "Poor" quality based on the total NOS score they achieved. Those studies having a NOS score of more than 7 were considered good-quality studies.

RESULTS

Study selection

After the removal of duplicates and studies with incomplete data and failure of revival (out of the total 37 articles that were included in the review), only eight studies were selected for the present systematic review [Table 1].

Studies characteristics

Out of the eight qualitative studies that were included here, three were from Switzerland, two from Spain, and one each from Brazil, New Zealand, and Norway. One study was done on titanium coins, one on titanium disks, and rest six were done on titanium implants of various companies and shapes. All eight studies were assessed on the terms of surface roughness which was considered one of the observational methods. Implant wall thickness was measured in one study, as well as operator observation and temperature change were observed in one study each. Seven out of eight studies were comparative studies and control group was present in three studies.

Maximum number of implants that were tested was "48" in two different studies by Camps-Font *et al.* and Beheshti Maal *et al.*[17] and least number of implants (22) tested were by Meier *et al.*

The main interventional element was diamond burs in five studies, tungsten carbide burs in four studies, silicon polisher in three studies, abrasive stones in two studies, unspecified rotatory instruments in two, and sandblasting, acid-etching, and anodizing technique in one study.

Two studies interpreted no statistical difference between implantoplasty and control, one study suggested carbide burs were better than diamond burs, and another study also suggested multilaminar burs were better than diamond and carbide. One another study found that diamond burs were better as compared to abrasive stones. Regarding the shape of the cutting instrument, it was found conical cutters had lowest mean roughness. Furthermore, for implant shape, it was found that internal hexagon and conical connection implants were more prone to fracture than external hexagon implants.

Risk of bias assessment

The NOS score for the quality of the included studies ranged from 6 to 8. Two of the studies had score of 6 points, eight had 7 points, and one had 8 points [Figure 2].

DISCUSSION

Peri-implantitis being an infectious disease surrounding the osseointegrated implants is characterized by loss of supporting bony tissues and inflammatory reactions including bleeding on probing. It has been reported to have a frequency in about 10% of implants and among 20% of patients after a period of 5–10 years postimplant treatment.[32] However, this prevalence varies contingent to the threshold of bone loss and/or probing depth. There are numerous clinical procedures to prevent and treat peri-implantitis cases, such as mechanical debridement, application of antiseptics or local/systemic antibiotics, and surgical interventions and regenerative measures.[33] There have been several researches that had attempted to combine and accumulate the data regarding such peri-implantitis cases in the past but have failed owing to the insufficient availability of information. Multiple efforts to combine the data of the available literature in a meta-analysis did not succeed in the past due to insufficient data.[34-37]

It has been documented that the adequate treatment strategy varies depending upon the case (whether it is mucositis adjacent to implant or peri-implantitis) and hence, no precise treatment method has been proven to be effective till date. Among the various number of treatment protocols for peri-implantitis, a comparatively

Figure 2: NOS scores of the studies included

Study name	Selection	Comparability	Outcome	NOS
Costa-Berenguer 2018[27]	●●○●	●●	●●	7
Meier 2012[28]	●●●●	○○	●●●○	7
de Souza Juniors 2016[29]	●●○●	●●	●●○○	7
Ramel 2016[30]	●●○●	●●	●●○○	7
Sahrmann 2019[31]	●●○●	●●	●●●○	8
Tawse-smith 2016[3]	●●○●	●●	●●○○	7
Octavi Camps Font 2020[19]	●●○●	●●	●●○○	7
Mehrnaz Behesti Maal 2020[17]	●●○●	●○	●●○○	6

Table 1: Summary of review and results of various studies

Author, Year	Origin country	Groups	Methodology	Intervention	Observation methods	Results	Interpretation
Costa-Berenguer *et al*. (2018)[27]	Spain	Implantoplasty- 10 Control- 10	screw-shaped titanium dental implants with external connection.	Tungsten carbide burs, silicone carbide polishers: Brownie and Greenie	Scanning electron microscopy (SEM) confocal microscope	Mean time 10 mins 48 sec Surface roughness 0.2 +- 0.02 , 0.75 +-0.3	No statistical difference in max resistance force
Meier *et al*. (2012)[28]	Switzerland	Single group – 22	Straumann implants	11 different rotatory instruments	surface roughness measuring device	arithmetic mean roughness (rz) averaged roughness (ra) high coefficient of correlation (P<0.001)	the conical cutters had the lowest mean roughness values compared to spherical carbide cutters
de Souza Juniors *et al*. (2016)[29]	Brazil	3 groups (12)– and compared with controls	Implants	diamond, tungsten carbide, multilaminar	The temperature was measured by a data acquisition system, rugosimeter	Temperature changes- no significant difference. Between control and intervention Implant surface roughness statistically significant difference	multilaminar bur took less time
Ramel *et al*. (2016)[30]	Switzerland	6 different sequence groups	6. Forty-two one-piece implants were embedded in epoxy resin blocks with 6-mm rough implant surface exposed	G1:3 DB: + 2 SPBG G2:3 DB: + Arkansas G3:3 DB: G4:3 DB: +1 SPG G5:5 DB: G6:5 DB: + 1 SPG	Surface roughness measurement - Each implant was scanned with a stylus profilometer	G1: 0.32±0.14 μm G2: 0.39±0.13 μm G3:0.71±0.22μm G4: 0.59±0.19 μm G5: 0.98±0.30 μm G6: 0.75±0.26 μm CP: 0.1±0.01μm CR: 1.94±0.47 μm	final surface roughness and treatment duration, the use of rotary diamond burs in decreasing roughness, followed by AS, appears to be an optimal treatment option
Sahrmann *et al*. (2019)[31]	Switzerland	Two groups of 15	Titanium implants were placed in the position of both first maxillary molars in models exposing 6 mm of their surface.	: Bud-shaped diamond burs Conical silicon carbide stones	Operators' Evaluation, Implant weight loss by precision scale and surface roughness measurement	G1: 0.76±0.14 μm G2: 0.38±0.15 μm Rz G1: 4.12±0.72 μm G2: 1.87±0.69 μm	a combination of abrasive stones and silicone polishers resulted in better gloss
Tawse-smith *et al*. (2016)[3]	New Zealand	Two groups 20 each machined and moderately roughened surfaces	grade IV titanium disks	Four different types of burs were used in the TPP: Shofu™ regular diamond, super-fne grit diamond, Brownie, Greenie	confocal laser scanning microscopy (CSLM),	Machined disc (G1) Before implantoplasty 4.00±0.52μm After implantoplasty 3.09±0.29μm Rough disc (G2) Before implantoplasty 4.50±0.4μm After implantoplasty 2.02±0.73μm	Surface roughness reduced in both groups
Octavi Camps Font *et al*. (2021)[19]	Spain	Three group (n=16) connection type. Half were controls	Screw-shaped titanium dental implants. Types: external hexagon, internal hexagon and conical.	The surface was moderately rough as a result of the sandblasting, acid-etching and anodizing techniques.	Implant wall thickness was recorded. All samples were subjected to a static strength test.	The mean wall thickness reductions varied between 106.46 and 153.75 μm.	Internal hexagon and conical connection implants seem to be more prone to fracture after implantoplasty.
Mehrnaz Behesti Maal *et al*. (2020)[17]	Norway	48 coins in 6 different rotatory bur sequence	On titanium coin	G1- CCB, red & white G2- CCB, red &white + AS G3- CCB, red & white + SC brownie+SC greenie G4- DSDC G5- DSDC + AS G6- DSDC + SC brownie + SC greenie	Immunostaining, Confocal microscopy	Surface roughness parameters were lower for the surfaces treated with experimental implantoplasty than for the SLA surface, and the sequence of carbide burs followed by silicone burs rendered the least rough surface of the test groups.	Carbide sequence better than diamond bur sequence

**AS: arkansas stone, DB: Diamond burs, SPBG: silicone polisher: Brownie & Greenie SPG: silicone polisher: Greenie, CCB: Carbide cutting burs, DSDC: Diamond sequence of decreasing coarseness, SC: Silicone cup

good percentage of success rates have been documented with the procedure of implantoplasty.[38]

Inflammation of the peri-implant tissues, owing to bacterial colonization, becomes a matter of primary concern among dental practitioners. This bacterial colonization on the implant surface facilitates in the etiopathogenesis of peri-implantitis thus leading to progressive bone loss and poor prognosis of the patient.[39] Hence, the eradication of bacterial contamination from the implant surface and discontinuing the development of bone resorption mutually increase the rate of implant survival. Among the various techniques to bring increase the longevity of the implant, mechanical alteration of the surface done in implantoplasty proposes to eliminate the irregularities and attain a smooth surface comprising viable cells that impedes bacterial adhesion.[40]

Azzola *et al*.[41] concluded from their study that the efficacy of implantoplasty to decrease plaque adherence and manipulating the formation of biofilm could be considered an initial proof of concept. This study demonstrated that implantoplasty produces less growth of biofilm and less mature biofilm as compared to untreated implants. Geremias *et al*.[42] demonstrated that implantoplasty reduces the rate of bacterial proliferation. They deduced that surface modification of implants affected by peri-implantitis, (either by implantoplasty or chemical decontamination), favors decreased collection of biofilm as compared to that of mechanical debridement. However, it has been observed that despite the substantial decrease in roughness accomplished with implantoplasty procedure, very minor irregularities remain on the treated implant surface, thus, favoring further bacterial colonization.[27] Ramel *et al*.[30] have stated in their study that various implantation etiquettes can produce differences in the surface roughness of the treated implants. Surface roughness and the composition of biomaterials used play an imperative role in the development process of biofilm. Since the surface structures represent the quality of the soft-tissue closure and adaptation around the implant, they should be manipulated cautiously so as to avert infections. This theory is applicable to the oral milieu owing to the fact that dental plaque formation remains a constant menace for periodontitis and peri-implantitis, in vulnerable individuals.[23]

There are several chemical disinfectants such as ethylenediaminetetraacetic acid, tetracycline, hydrogen peroxide, and chlorhexidine that can be allied with implantoplasty procedure, however, their advantages with the protocol remain debatable.[43] Studies were done by Matarasso *et al*. (2014)[44] and Schwarz *et al*. (2017)[45] found that implantoplasty has enhanced clinical outcomes along with regenerative methods for peri-implantitis cases. These studies have reported a long-term good outcome of surgical resective/regenerative therapy or advanced peri-implantitis. However, not much of scientific evidence is available eliciting the advantages of the combination of implantoplasty and regenerative therapy and it has been observed that implantoplasty might not be related with to the biological and/or mechanical complications of the disease condition.[46]

Costa-Berenguer *et al*. (2018)[27] demonstrated in their study that implantoplasty cause a slight decrease in the inner diameter of the implant and there is no noteworthy alteration in the fracture resistance of the implant with standard diameter. Gehrke *et al*.[47] observed a 32% reduction in implant resistance after the implantoplasty procedure was performed. This study suggested that implant wear substantially reduces the resistance to external forces while applying nonaxial loading. This is achieved due to the architecture of implant-abutment interface which alters the clinical performance and fracture resistance of the implant system following implantoplasty.

The present systematic review included studies that did not report about the biological and/or mechanical complications and it was evident that the success rate of implantoplasty was high. Two of the studies in the present systematic review informed specifically about the individuals with a history or periodontal lesion or periodontitis.[21,24] The outcome and prognosis of implantoplasty procedures for the treatment of peri-implantitis rely on various local and systemic factors. Consequently, its result might vary from one individual to another with or without a vital risk factor.

Implantoplasty thus has suggestively shown to reduce the fracture strength of implants with standard diameter external connection when there is a reduction in the body diameter of the implant. In cases of advanced peri-implantitis, both resective and/or regenerative procedures and implantoplasty trailed by surface decontamination produce decent osseointegration. However, it is important to sustain an adequate maintenance phase after the therapy including oral hygiene maintenance and removal of surface biofilm. Surgical and implantoplasty procedures for peri-implantitis have depicted positive outcomes but long-standing research work is necessitated to attain the dependability and validity of the treatment protocols.

Few of the limitations that could affect the outcome of the study included insufficient numbers of research works and their low number of samples. Second, owing to the limited

number of studies elucidating the parameters (surface roughness, biofilm formation, and biocompatibility) that were analyzed in this systematic review adequate information regarding the survival rate of the implants was not available. Third, since the literature that was published only in English language was considered for the present systematic review, there could be potential language bias in the information presented here.

CONCLUSION

Within the limitation of this systematic review, it can be concluded that:

1. Implantoplasty is recommended as a budding treatment option for peri-implantitis thus facilitating to reduce the inflammatory reaction followed by a high percentage success rate
2. Multilaminar burs or carbide burs with conical cutters were shown to cause less surface roughness
3. Implantoplasty has been found to reduce the fracture resistance of standard diameter dental implants with external connection when there is a reduction in the body diameter of the implant
4. Implants with internal hexagons and conical connections were found to be more prone to fracture when treated with implantoplasty.

However, stringent measures for good maintenance of the implant and the supporting structures are imperative for the long-term survival of the implant. It can be concluded that further research work is necessary, especially in clinical or *in vivo* situation, to predict the dependability, validity, and prognosis of the implantoplasty protocols.

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Conflicts of interest

There are no conflicts of interest.

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Systematic Review

Prevalence and severity of temporomandibular joint disorder in partially versus completely edentulous patients: A systematic review

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Abstract

Temporomandibular joint disorders (TMDs) following tooth loss may or may not be prevalent, but the risk of developing these disorders is always there due to changes in occlusion and vertical dimension, leading to changes in the disc-fossa relationship. The purpose of this systematic review was to evaluate the prevalence and severity of temporomandibular joint (TMJ) disorder in partially versus completely edentulous patients. An elaborated literature search was conducted in PubMed/Medline, Scopus, Web of Science, Lilacs, and Google Scholar databases including all articles about varied effects of partial and complete edentulism on the TMJ published from January 1, 2000, to January 1, 2022. After the meticulous screening, only publications which fulfilled the inclusion parameters were ultimately selected for full-text evaluation and tested for bias using the Joana Briggs Institute Appraisal tools for cross-sectional, case–control, and cohort studies. A total of 547 articles from various electronic databases and manual searches were found. After eliminating the duplicates and thorough screening, 13 studies were included for qualitative synthesis. Most of the studies demonstrated at least one or two signs of the presence of TMDs following tooth loss, the intensity/frequency of which increased in proportion to the number of missing teeth.

Keywords: Clicking, completely edentulous, condyle, crepitus, occlusion, partially edentulous, temporomandibular joint disorders, temporomandibular joint sounds

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INTRODUCTION

The temporomandibular joint (TMJ) is a synovial sliding-ginglymoid joint that is an intricate neural-muscular system working in harmony with the adjacent structures. It is also a three-point articulating joint, with the condyle-fossa being two points of contact and the dentition being the third. If one of these components is altered, the other two will also undergo secondary morphological alterations.[1]

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In the human body, the occlusion, craniosacral system, and functional systems are intricately intertwined in a dynamic equilibrium.[2] The phrase "temporomandibular disorder" refers to various conditions that clinically affect either the masticatory musculature, the TMJ and related tissues, or both.[3] Occlusion is believed to have a role in the etiology of temporomandibular joint disorders (TMDs).[4,5] Long-term loss of occlusal support can cause drifting of remaining teeth, changing occlusal contacts, and increasing the risk of TMDs.[6,7] Although many patients are able to adjust to condylar or occlusion positions that are not ideal when teeth are lost, especially posterior teeth, adaptive mechanisms set in to make up for the misalignment. If the joint's adaptive capacity is exceeded, other patients may develop degenerative joint disease.[8-10] Due to a change in the vector of force that alters biomechanical alterations during function and is followed by a change in the morphology of the glenoid fossa that alters in accordance with the dental pattern (if these changes occur), the morphology of the disc may be permanently altered.[11-14]

The rate of development of these disorders, if not timely rehabilitated in a partially edentulous population, may differ from that of the completely edentulous population, and the severity might also differ. This may further lead to pain and difficulty in mastication, thus affecting the overall health of the individual. Although studies have evaluated the presence of TMD following partial/complete tooth loss, no systematic review has been done comparing the prevalence and severity of TMD after partial or complete tooth loss. As a result, the purpose of this systematic review was to assess and compare the parameters. The null hypothesis stated that there would be no difference in both predominance and severity of TMJ issues between the group of people who were partially and totally edentulous.

MATERIALS AND METHODS

The present systematic review procedure has been registered under registration number CRD42022358477 at the National Institute of Health Sciences, International Prospective Register of Systematic Reviews database. The data were searched according to Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines.[15,16]

The review question "Amongst the elderly population with partially or completely edentulous arches what is the prevalence and severity of TMDs?" was formulated using patient, intervention, comparator, outcome, studies framework [Table 1] followed by an assembled search strategy, specifying inclusion and exclusion criteria, the identification and selection of studies, the evaluation of the quality of the research, the extraction of data and the creation of an evidence table, and interpretation.

The inclusion criteria included systematic reviews and meta-analysis, observational, and cross-sectional studies published in English from January 1, 2000, to January 1, 2022, involving patients of 35 years of age and above with partially (either or both maxillary and mandibular arches) and completely edentulous arches free of any systemic health condition without any prosthetic rehabilitation. Case reports, case series, articles in non-English languages, and research that did not meet the inclusion requirements were included under the exclusion criteria.

PubMed/Medline, Scopus, Web of Science, Google Scholar, and Lilacs databases were searched electronically along with a manual search of the references and citation analysis. For data search, the medical subject heading terms (MeSH) utilized were "temporomandibular disorders," "temporomandibular diseases," "TMJ changes after tooth loss," "missing posterior teeth," "partially edentulous," "completely edentulous," and "radiographic changes in TMJ following tooth loss." Following a rigorous screening of search results against eligibility criteria and data extraction, two independent reviewers (PR and PS) conducted a literature search. Two authors (DS and AS) independently assessed the bias risk in the included studies using a quality assessment checklist for cross-sectional studies, case–control studies, and cohort studies that was adapted from the checklist for Critical Appraisal by Joanna Briggs Institute. The third author (AS) was contacted in the event of a disagreement. A study was deemed to have a low risk of bias when the "yes" score was more than 70%, a moderate risk of bias when the "yes" score was between 50% and 69%, and a high risk of bias when the "yes" score was ≤49% for every article.[17,18] This scoring was finalized after consulting with all the authors. The studies that were included in the data extraction process were sorted and tabulated in chronological order. The summarized data from these included studies were listed.

RESULTS

Initial electronic and manual searches identified 547 studies (PubMed/Medline = 72, Scopus = 22, Web of Science = 15, LILACS = 34, Google Scholar = 132, and manual search = 272). Two independent reviewers (PR and PS) carried out the initial screening of titles and abstracts after the duplicates (n = 204) were eliminated. Full texts of 132 studies were acquired after a screening of the title and abstract. Following a full-text review, 43 papers

were included. Finally, after the risk of bias assessment and due to various other reasons, a total of 13 studies (8 cross-sectional, 4 case–control, and 1 cohort study) were included for qualitative synthesis. The selection process for the study is presented in Figure 1.

Since the present review aims to compare the prevalence and severity of TMDs in partially and completely edentulous patients, all the included studies were divided into partially (11 studies) and completely edentulous (2 studies) groups, respectively. A total of 2788 patients with missing teeth were examined either clinically or both clinically and radiographically for TMDs. In all the included studies, the clinical assessment was used as a diagnostic modality for assessing TMJ changes followed by 4 studies that had questionnaire and clinical assessment, 2 studies that reported radiographic along with clinical assessment, and 1 study that adopted logistic regression analysis for assessing TMJ changes following tooth loss. The clinical assessment involved the evaluation of Joint sounds, joint pain, muscle pain/tenderness, and mandibular deviation. For radiographic evaluation, Tallents *et al*.[19] used magnetic resonance imaging and Bertram *et al*.[20] used cone-beam computed tomography apart from clinical assessment for assessing TMJ changes following tooth loss.

In all the included studies, for both partially and completely edentulous groups, a strong association was found between missing teeth and the development of one or more than one symptom of TMDs, except for one study by Reshmi *et al*.,[21] which demonstrated a low prevalence of TMDs ($P = 0.064$) in partially edentulous patients. Among all the included studies, six reported[22-27] presence of abnormal TMJ sounds as one of the most common complaints of patients following tooth loss. Few of the studies also provided data on gender predilection in the development of TMDs after tooth loss. Four studies[21,25-27] concluded that females had more incidence of TMDs

Table 1: Patient, intervention, comparator, outcome, studies strategy

Elements	Contents
Population (P)	Patients of 35 years of age and above with partially (either or both maxillary and mandibular arches) and completely edentulous arches free of any systemic health condition and not wearing any prosthesis
Intervention (I)	Prevalence of TMDs in patients 35 years of age and above with partially and completely edentulous arches free of any systemic health condition and the severity they might develop if not timely rehabilitated
Comparator (C)	Prevalence and severity of TMDs in partially versus completely edentulous patients
Outcome (O)	Prevalence and severity of TMDs in patients with partially (either or both maxillary and mandibular) arches versus completely edentulous arches if not timely rehabilitated
Study design (S)	Cross-sectional, case–control, and cohort (prospective and retrospective) studies

TMDs: Temporomandibular joint disorders

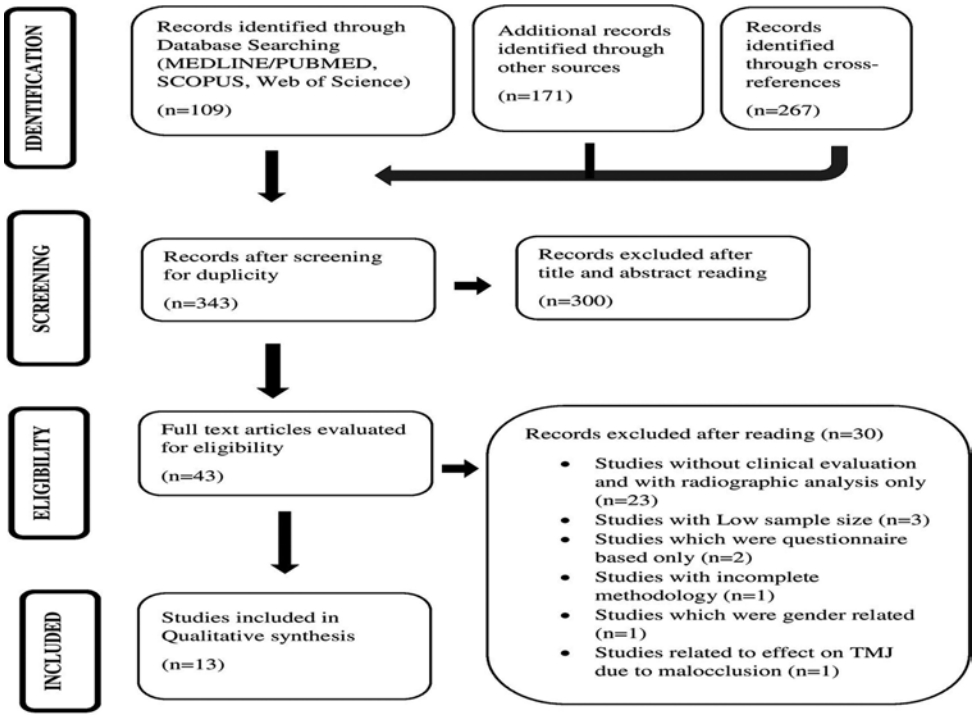

Figure 1: Study selection process

following tooth loss than males, while only one study[22] reported the opposite. Two studies having patients with partially edentulous arches compared TMD symptoms in Kenndy Class I versus Class II cases, in which one study concluded that patients with a Kennedy's Class I mandibular condition or a combination of Class I and Class II situation in the maxilla and mandible showed a higher prevalence of TMD,[21] whereas the other study concluded that contrary to the unilateral loss posterior tooth, the bilateral loss posterior tooth is associated with a more pronounced increase in cranial condyle displacement and condylar erosion.[20]

On the evaluation of the bias risk, it revealed that most of the cross-sectional studies (n = 4; 50%) exhibited a moderate bias risk overall; however, three studies (37.5%) had a low bias risk and one study (12.5%) had a high risk of bias. Similarly, among case–control studies, 2 studies demonstrated a moderate risk of bias, and 2 showed a low risk of bias. Furthermore, a moderate risk of bias was observed in one cohort study reported in this systematic review. A compilation of the extracted data from all of the included studies is depicted in Table 2.

DISCUSSION

The included studies' data supported acceptance of the null hypothesis of no difference in terms of prevalence and severity of TMJ disorders between the partially and completely edentulous group as it was observed from the included studies that the development of TMDs is a multifactorial entity and that not only loss of occlusal support, but, occlusal disharmony, emotional stress, masticatory muscle fatigue, parafunctional oral habits, traumatic injuries, hormonal influences, articular changes within the joint and malfunction of structures adjacent to TMJ can cause TMJ dysfunction in partially/completely edentulous patients.[22,28-30] This can further lead to the development of symptoms such as persistent masticatory muscle discomfort that radiates to the head and neck region.[30]

The confirmation of the possibility of the presence of any TMD symptoms better relies on a positive clinical dynamic/static test outcome;[31,32] therefore, low to moderate biased studies in which TMJ disorders were diagnosed via clinical examinations were preferably included for qualitative synthesis, except for one study in which the link between a number of independent factors and a categorical dependent variable was examined using logistic regression analysis. In addition, it determines the likelihood of an occurrence by fitting data to a logistic curve.[33]

Although there are studies that have found a low correlation between occlusal factors and the development of TMDs,[34-36] the included studies in the present systematic review have shown a strong prevalence of TMD following tooth loss. This can be explained according to the fact that in partially edentate patients, tooth loss or tooth wear may affect the occlusion and condylar posture at TMJ. Losing a tooth also causes the remaining teeth that are opposite and adjacent to shift, which results in early contact in centric and eccentric movements. Temporomandibular disorders and pain dysfunction symptoms may be brought on by this change in condylar posture over time, which may also cause structural alterations to the TMJ surfaces.[37] The impact of condylar position and loss of posterior teeth on temporomandibular disorders is still debatable, and little is known about the impact of the loss of anterior teeth and condylar position based on the research that is now accessible.[37,38] Complete edentulism is characterized by retruded contact position and the absence of intercuspation. Because of this, when the jaw closes, the position of the condyle-fossa in the mandibular fossa may change.[1]

Most of the included studies[19,21,23,24-27,39] recorded joint sounds for clinical assessment of TMJ following tooth loss which can be explained by researches done by various authors, concluding that joint sounds (clicking followed by crepitation and popping) are the most common sound symptom that arises from TMD.[23,40,41] As a result of friction between the condyle and the disc's posterior band, these articular noises are generated in TMJs that demonstrate disc displacement without reduction. Such a collision would make a single sound at the movement's maximum amplitude.[42] Some researchers believe that clicking can be a pause in the meniscus's forward gliding motion or it can also be related to sudden acceleration of condylar and internally displaced disc tissues.[43-46] According to others, clicks can also be attributed to fluid cavitation or can be found associated with a sudden movement of ligaments.[47,48] Crepitus is thought to be a symptom of osteoarthrosis, which is more common in patients who are edentulous, and other degenerative diseases of the articular surfaces, which are often brought on by aging.[46,49] According to Hwang *et al*. as indicators of anterior disc displacement with reduction and arthrosis, respectively, clicking and crepitation should be regarded as markers of morphological abnormalities.[50] However, according to a few authors, jaw sounds are common in the general/nonpatient population, and their clinical significance remains questionable; therefore, without discomfort or restricted jaw mobility, jaw sounds by themselves do not signify any TMJ issue.[42,51-53] Pain in

Table 2: Extracted data from all the included studies

Author/year	Study type	Sample size	Status of edentulousness	Diagnostic modality/ assessment used for evaluation of TMJ disorder	Outcomes (TMJ disorder) evaluated	Relevant findings
Tallents *et al*., 2002[19]	Case–control	345	Partially edentulous	Clinical and radiographical (MRI) assessment	Clinical evaluation of jaw pain, joint noise, and locking. radiographical evaluation of the TMJs for the presence or absence of disk displacement	Disk displacement was observed to be positively correlated with the absence of mandibular posterior teeth
Dulcić *et al*., 2003[39]	Cross-sectional	196 (male=68, female=128)	Partially edentulous	Clinical assessment	Clinical evaluation of the presence of one or more TMD symptoms - pain, crepitation, or clicking in the head and neck region	Regardless of sex, patients with more tooth loss in the supporting zones have a higher incidence and severity of TMD
Wang *et al*., 2009[12]	Cohort	741 (male=386, female=355)	Partially edentulous	Logistic regression analysis	Gender, age, the number of missing posterior teeth, and the number of quadrants with missing posterior teeth	The number of missing posterior teeth and the number of dental quadrants with missing posterior teeth both have an increased impact on TMD
Shetty, 2010[26]	Cross-sectional	100 (male=60, female=40)	Completely edentulous	Clinical assessment	Clinical evaluation of signs of joint sounds, joint tenderness, pain on mouth opening, muscle tenderness, deviation of the mandible on mouth opening, limitation during mouth opening, and referred pain	TMD symptoms were present in more than half of the asymptomatic patients. Additionally, 59% of the participants showed one or more TMD symptoms
Shet *et al*., 2013[25]	Cross-sectional	250 (male=99, female=151)	Partially edentulous	Clinical assessment	Joint sounds and joint tenderness	Subjects with greater tooth loss in the supporting zone have a higher incidence and severity of TMD and this can hasten the progression of degenerative joint disease
Falahi *et al*., 2016[24]	Case–control	200 (male=80, female=120)	Partially edentulous	Questionnaire-based and clinical assessment	Mouth opening, lateral excursions, deviations in the path of lateral excursions, presence or absence of clicking and crepitation, joint locking, condylar luxation, and pain in the TMJ and masticatory muscles	The number of occlusal support regions was found to be significantly correlated with the severity of TMD
Manchikalapudi and Polasani, 2017[54]	Case–control	140	Partially edentulous	Questionnaire-based and clinical assessment	Impaired mandibular movement, impaired or altered TMJ movement, muscle pain, joint pain, and pain in mandibular movements	While denture wearers displayed mild mandibular mobility restriction and mild pain during jaw motions, nondenture wearers displayed higher muscular soreness on palpation, clicking, and deviation of the jaw
Bertram *et al*., 2018[20]	Case–control (2 years)	210 (male=98, female=112)	Partially edentulous	Clinical and radiographic (CBCT) assessment	Radiographically evaluated for condylar morphology	A positive correlation was found between the degree of TMJ condylar erosion, the number of posterior teeth missing in each quadrant, and the bilateral position of posterior teeth missing

Contd...

Table 2: Contd...

Author/year	Study type	Sample size	Status of edentulousness	Diagnostic modality/ assessment used for evaluation of TMJ disorder	Outcomes (TMJ disorder) evaluated	Relevant findings
Chairunnisa and Sihombing, 2018[55]	Cross-sectional	100	Partially edentulous	Questionnaire-based and clinical assessment	Maximal mouth opening distance, TMDs function decline, and deviation, muscle pain, joint pain, and pain during mandibular movements	As the number of missing teeth increases, the incidence of TMDs also increases
Reshmi *et al*., 2018[21]	Cross-sectional	150	Partially edentulous	Questionnaire-based and clinical assessment	Limitations in movement, joint clicks, a feeling of tiredness or fatigue in the TMJ region, duration of symptoms, and the severity of symptoms	The prevalence of TMD among partially edentulous subjects was found to be low among the participants
Amin *et al*., 2019[22]	Cross-sectional	143 (male=78, female=65)	Partially edentulous	Clinical assessment	Facial pain, mouth opening, deviation, TMJ sounds, muscle tenderness	Signs of TMDs are more common in partially edentulous patients
Agustina *et al*., 2020[23]	Cross-sectional	113	Partially edentulous	Clinical assessment	Joint sounds (clicking, popping, and crepitation)	The degree of tooth loss is significantly correlated with TMJ clicking and crepitation
Zakir *et al*., 2020[27]	Cross-sectional	100	Completely edentulous	Clinical assessment	TMJ pain and sounds, mouth opening, and head, and neck muscles pain	During the first 5 years of edentulousness, TMJ problems were the most common

MRI: Magnetic resonance imaging, TMJ: Temporomandibular joint, TMDs: TMJ disorders, CBCT: Cone-beam computed tomography

the TMJ originates from the articular surfaces when the joint is overloaded. This can occur after tooth loss due to masticatory overloading. Mandibular movement immediately ceases when such pain is suddenly and unexpectedly felt (nociceptive reflex). However, over a due period, movement becomes limited and very deliberate (protective cocontraction).[10] Considering all these factors, apart from joint noises, all the included studies have assessed joint/muscle pain and tenderness, with few studies also assessing mandibular movements,[22,24,26,54,55] mouth opening,[22,24,26,27,55] and referred pain to head and neck region.[26,27,39]

The present study was limited by the inclusion of just a small number of studies examining the impact of tooth loss on TMJ in entirely edentulous patients. Furthermore, because there was a dearth of data, there was less research that linked radiographic analysis and clinical symptoms of TMDs. The same rationale prevented the inclusion of studies with large patient population and follow-ups. Future studies should include long-term follow-ups and a larger patient population. Studies correlating radiographs and clinical symptoms of TMDs following tooth loss are also required for a more precise outcome. More studies on the impact of TMJ after tooth loss in totally edentulous research to enable the scope of a meta-analysis should be undertaken to produce more precise information on this subject.

CONCLUSION

The following conclusions were drawn in accordance with the findings of this systematic review:

1. Effect of missing teeth on TMJ is always there and sometimes undergoes undiagnosed. This may be because these effects are frequently not clinically accompanied by pain. Although joint noises alone cannot be a determinant of TMD, other symptoms such as myofascial pain or any changes in mandibular movements should also be recorded for precise diagnosis
2. With an increase in the number of missing teeth, the severity of the negative impact on the TMJ also increases
3. In the case of partially edentulous patients, loss of posterior support has a more detrimental effect on TMJ than the loss of anterior
4. Being a multifactorial entity, complete loss of teeth alone cannot ensure the risk of the development of TMD. Other factors such as psychosomatic, physiological, anatomical, postural, and genetic should also be considered.

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Conflicts of interest

There are no conflicts of interest.

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Research

Comparative evaluation of circumferential crestal bone loss after 1 year of implant placement with flapless versus flap surgery using surgical template after immediate loading in the posterior mandibular region using cone-beam computed tomography: A randomized controlled trial

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Abstract

Aim: The study was aimed to evaluate circumferential crestal bone level after one year of implant placement with flapless versus flap surgery using surgical template after immediate loading in the posterior mandibular region using CBCT.

Setting and Design: The study was designed as a Randomized controlled trial.

Material and Methods: 32 implants were placed in single edentulous spaces in the mandibular posterior region after random allocation into two groups: Flap surgery (Group A) and Flapless surgery (Group B). Virtual implant planning was performed using Blue Sky Bio software, and static CBCT guided 3D printed surgical templates were fabricated for all participants of both the groups. Immediate non-functional temporization was performed. Circumferential crestal bone levels were assessed after surgery and one-year follow-up using CBCT and XELIS software. Vertical bone loss (VBL) and horizontal bone loss (HBL) was assessed on four sides: buccal, lingual, mesial and distal.

Statistical Analysis Used: Data was analyzed using Statistical Package for Social Sciences IBM Corp. Released 2017, IBM SPSS Statistics for Windows, Version 25.0. (Armonk, NY: IBM Corp.) and Graph Pad Prism 7.0 version. The level of significance was chosen <0.05. Chi square test was performed to assess the difference in the age in the two groups. Mann-Whitney U test was performed to compare the two groups for outcome measure. Graphically, quantile-quantile (Q-Q) plot was made using mean and standard deviation for normality verification of data.

Results: 100% survival rate and patient compliance was observed along the one-year follow-up duration. By using Mann-Whitney U test, statistically significant difference was found in the vertical bone loss among

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participants of Flap surgery (Group A) and Flapless surgery (Group B) on all the four sides after one year of implant placement. However, significant results were not obtained for the difference in the horizontal bone level.

Conclusion: Within the limitations of this study, vertical bone loss measured circumferentially was more positively correlated with the implants placed with flap surgery compared to flapless surgery after immediate loading in the posterior mandibular region after one year.

Keywords: Circumferential bone loss, crestal bone loss, flapless

INTRODUCTION

Extensive elevation of the flap for placement of dental implants has been the most widely accepted protocol which was designed by Brånemark *et al*.[1,2] Direct access and visibility of the field is one of the major advantages of flap reflection; furthermore, the procedures that require grafting or regenerative approach are possible only with flap elevation.[3] Disruption of blood supply to the supraperiosteal vessels during flap elevation is, however, a major concern as it leads to crestal bone loss.[4-8] Pain, discomfort, and risk of postoperative complications are other disadvantages that are associated with flap surgeries.[9] Placing the implant with a conservative approach without reflection of flap is becoming a popular approach among the clinicians. Flapless placement can be performed by removing a circular portion of soft tissue or by preparing the osteotomy site through mucosa.[10] Such minimally invasive procedure benefits the clinician as well as the patient by reducing the surgical time, lowering the postsurgical discomfort, and accelerating the recovery.[7]

Flapless approach becomes safer and predictable by digitally planning the implant position.[11-13] Implants placed with flapless technique when loaded immediately with a provisional prosthesis eliminate the need for a second-stage surgical procedure. Through the years, authors have emphasized comparable outcomes and survival rates with immediately loaded flapless implants.[14-16]

Implant placement done using stereolithographic surgical templates incorporating metal sleeves provides higher accuracy compared to free-hand placement.[17] Flapless surgeries performed using such three-dimensional (3D) guides would thereby enhance the outcomes by improving accuracy.

Implant success is more often related to the crestal bone loss around the implant following placement. Several studies in the literature have been performed to evaluate the bone loss using standard two-dimensional radiographic techniques. These allow for the assessment of bone loss only on the mesial and distal sides. Cone-beam computed tomography (CBCT) scans however can be used to determine the bone changes on all the four sides, i.e. buccal, lingual, mesial, and distal. A study conducted by Elsyad and Khirallah[18] aimed to evaluate such circumferential bone loss for splinted and nonsplinted implants. The assessment of circumferential bone loss for flapless surgeries using a guided approach has not been studied yet. Thus, the study aimed to provide insight into this breach in the literature. The null hypothesis was that both the techniques would have no difference in the crestal bone levels after 1 year of implant placement.

MATERIALS AND METHODS

This study was designed as a randomized controlled trial. Patients in need of rehabilitation of a single missing tooth in the posterior mandibular region were selected at the Prosthodontics Department of Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Nagpur, India. Ethical clearance number- SDKS/pg/syn/Prostho 2/2/2019.

The inclusion and exclusion criteria are shown in Table 1. The study participants were divided into two groups: Group A – flap surgery (control group) and Group B – flapless surgery (experimental group) comprising 16 participants (16 implants) in each group with equal number of male and female participants. The sample determination was based on a study by Job *et al*.[19] Sample size was determined by considering the mean difference of marginal bone loss (mm) as the main outcome measure.

The following assumptions were made based on a study by Job *et al*.:[19] The mean ± standard deviation (SD) in the conventional flap group is equal to 0.30 ± 0.22. The mean ± SD in the flapless group is equal to 0.05 ± 0.03. The mean difference (effect size) is equal to 0.25.

α error is equal to 1% (two-sided).

Power $(1-\beta)$ is equal to 90%.

Formula :

$$= \frac{(Z\alpha + Z\beta)^2 S^2}{(\mu 1 - \mu 2)}$$

$$\frac{(2.58 + 1.28)\ (0.004)}{(0.30 - 0.05)}$$

$$= 11.2 = 12$$

Required sample size (*n*) as per formula was equal to 12 per group. Assuming 20% losses to follow up in 1 year, effective sample size (*n*) was calculated to 14.4. As equal number of male and female patients were to be included in both the groups, per group 16 was selected as the sample size.

Flap surgery (Group A) – 8 male and 8 female participants.

Flapless surgery (Group B) – 8 male and 8 female participants.

Randomization was performed using a predetermined computer-generated random location plan with block size of 4 before the enrollment of participants.

Approval was obtained from the Institutional Ethical Committee (SDKS/pg/syn/Prostho 2/2/2019) and was registered with the Clinical Trial Registry, ICMR's National Institute of Medical Sciences (CTRI/2020/04/024424). Written informed consent in vernacular language was obtained from all participants.

All participants underwent single implant placement in the posterior mandibular region using CBCT-guided template.

Table 1: Inclusion and exclusion criteria

A. Inclusion criteria
Patients between 18 and 45 years of age
Patients fit for minor surgical procedures
Healthy periodontal condition
Partially edentulous patients missing one tooth in mandibular posterior region
Sufficient dimensions of alveolar ridge to place implant of minimum diameter 4 mm and length 10 mm
Presence of tripodal occlusal contact of natural teeth
Implants will be placed in healthy healed socket
Antagonist teeth should be healthy and nonrestored tooth
B. Exclusion criteria
Irradiation in the head-and-neck area <1 year
Poor oral hygiene
Pregnancy or lactation
Substance abuse
Psychiatric problems
Lack of opposing occluding dentition in the area intended for implant placement
Severe bruxism or clenching
Need for bone augmentation

After the preoperative assessment by superimposition of CBCT and laboratory scan of the diagnostic cast [Figure 1], virtual implant planning was performed using the Blue Sky Bio software program [Figure 2]. The planning was then imported to the 3D printer, and a customized tooth-supported CBCT-guided template was fabricated.

Implant surgery was performed under local anesthesia (lignocaine hydrochloride with 2% adrenaline 1:80,000) after an antibiotic prophylactic regimen and a 0.2% chlorhexidine mouth rinse. SuperLine Dentium implants (Dentium Co. Ltd, Suwon, Korea) of sizes ranging from diameter 4.0, 4.5, and 5 mm and length 10, 12, and 14 mm were used as per availability of bone. All implants were double-threaded, tapered, and sandblasted with large grits and acid etched.

For the control group, a full-thickness mucoperiosteal flap was reflected [Figure 3] and osteotomy was performed through the surgical template which had a metal sleeve to incorporate a pilot drill of diameter 2.2 mm [Figure 4]. Implant placement was done 0.5 mm subcrestally after sequential drilling with the help of insertion tool and torque wrench and tension-free primary closure was obtained.

For the experimental group, a circular portion of soft tissue was removed with the tissue punch [Figure 5]. CBCT-guided template was used and drilling protocol similar to that of the control group was performed.

After achieving insertion torque of more than 35 Ncm and radiographic verification, implants were slowly motor driven to its final position. Healing abutments were placed in position till the fabrication of temporary prosthesis. Immediate nonfunctional provisionalization was done using bis-acrylic material (AVUE temporary

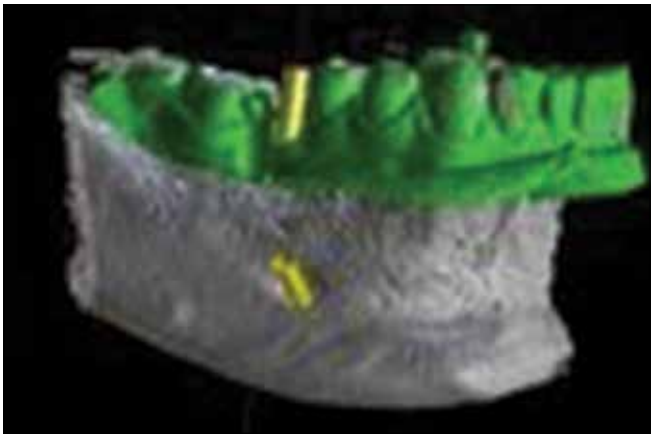

Figure 1: Superimposition of cone-beam computed tomography scan and laboratory scan of diagnostic cast

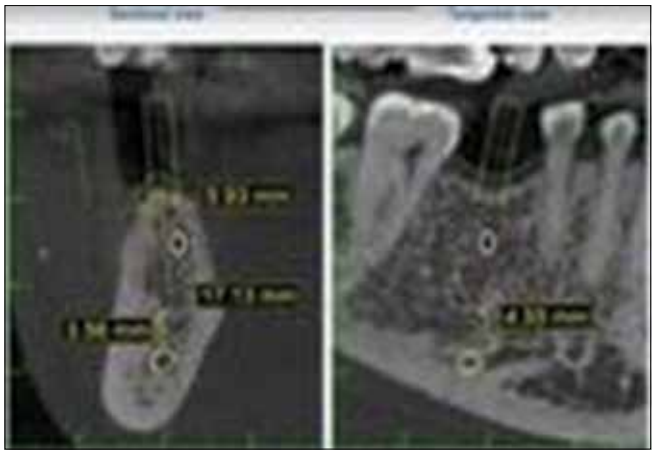

Figure 2: Virtual implant planning using Blue Sky Bio software

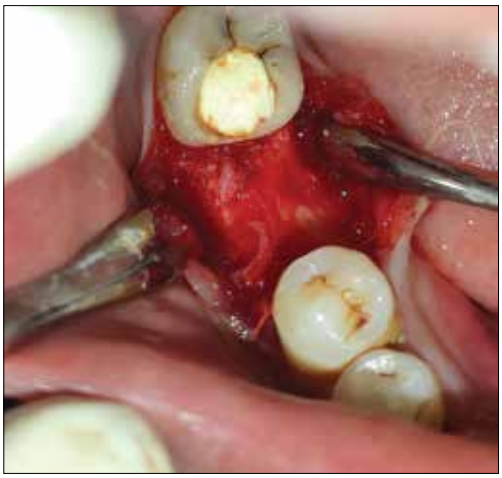

Figure 3: Full-thickness mucoperiosteal flap reflection (flap surgery Group A)

Figure 4: Drilling through the surgical template

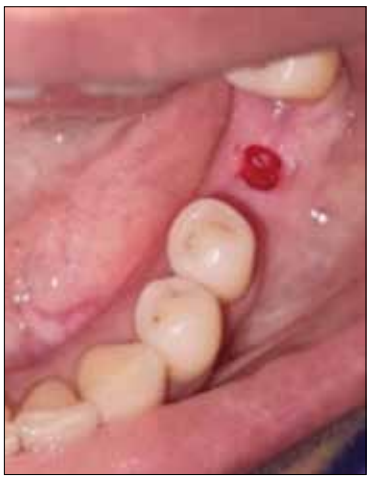

Figure 5: Circular portion of tissue removed in flapless technique (Group B)

crown and bridge material) for all implants of both the groups within 72 h. Postoperative antibiotics were prescribed. Participants were recalled for postoperative assessment after 3 days and after 10 days for suture removal. Similar prosthetic protocol was performed for both the groups. Definitive prosthesis was delivered after 3 months after proper evaluation of implant stability for all implants.

Crestal bone assessment was done with the help of successive CBCT taken immediately after the surgery with the healing abutments in position and 12 months postimplant placement using XELIS software. Vertical and horizontal crestal bone levels were determined at four sites: mesial, distal, buccal, and lingual. For evaluation, reference points were identified [Figures 6 and 7]. Point A was marked at the highest point of hard bone edge perpendicular to the long axis of implant, and Point B was identified at border of first bone-to-implant contact. A line from Point A was drawn perpendicular to the line through Point B, and the intersection was marked by Point C. The distance between Points A and C indicated the horizontal bone level (depicted in yellow), and the distance between the implant collar and Point B indicated the vertical bone level (depicted in red) [Figure 7]. Crestal bone levels were assessed at baseline just after surgery with healing abutments and 1 year after implant placement [Figures 8-11]. The difference between the crestal bone levels was calculated for baseline and 1 year. Negative values indicated loss while positive values indicated bone gain. Data were analyzed using the Statistical Package for the Social Sciences IBM Corp. Released 2017, IBM SPSS Statistics for Windows, version 25.0. (Armonk, NY, USA: IBM Corp.), and GraphPad Prism 7.0 version. The level of significance was chosen < 0.05. Chi-square test was performed to assess the difference in the age in the two groups. Mann–Whitney *U*-test was performed to compare the two groups for outcome measure. Graphically, quantile–quantile plot was made using mean and SD for normality verification of data. Linearity of the plot suggested normal distribution of data.

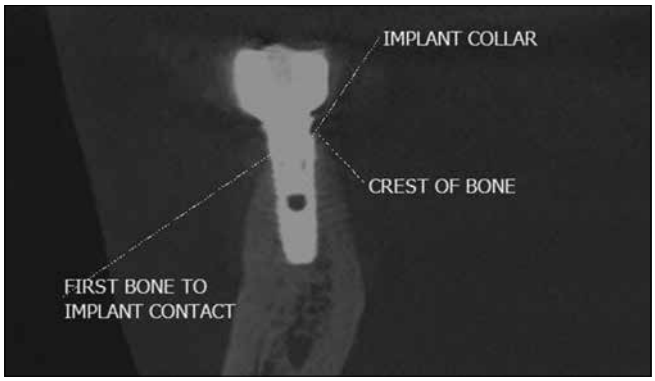

Figure 6: Reference points for measurement on cone-beam computed tomography (buccal and lingual side)

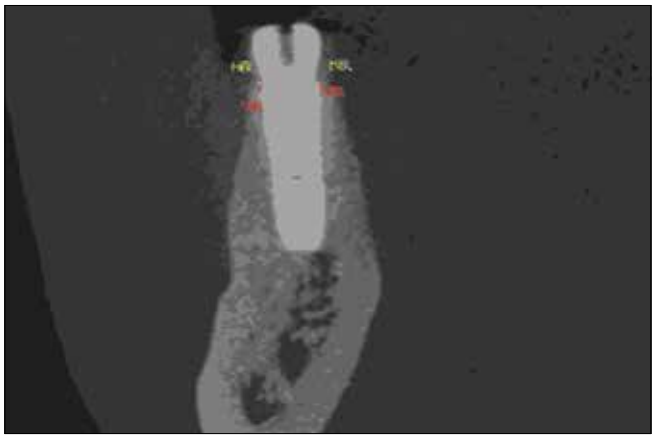

Figure 8: Cone-beam computed tomography measurements baseline just after implant surgery - buccal side and lingual side. Horizontal bone loss depicted in yellow and vertical bone loss in red

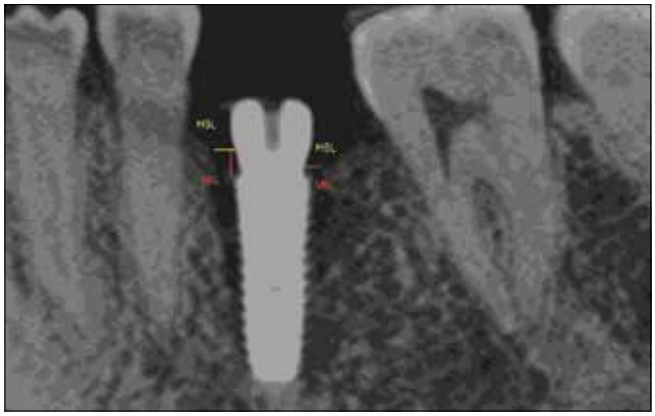

Figure 10: Cone-beam computed tomography measurements baseline just after implant surgery - mesial side and distal side. Horizontal bone loss depicted in yellow and vertical bone loss in red

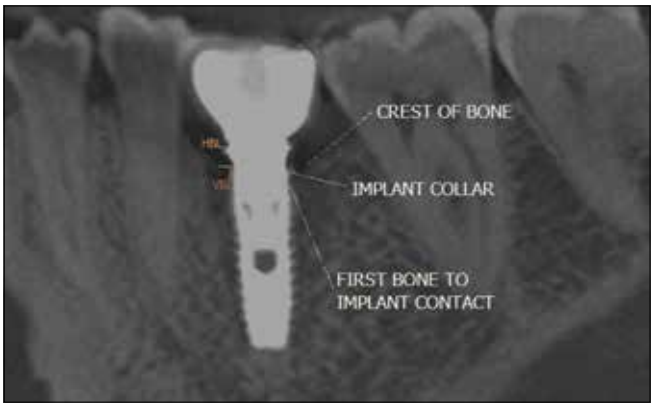

Figure 7: Reference points for measurement on cone-beam computed tomography (mesial and distal sides) horizontal bone loss depicted in yellow and vertical bone loss in red

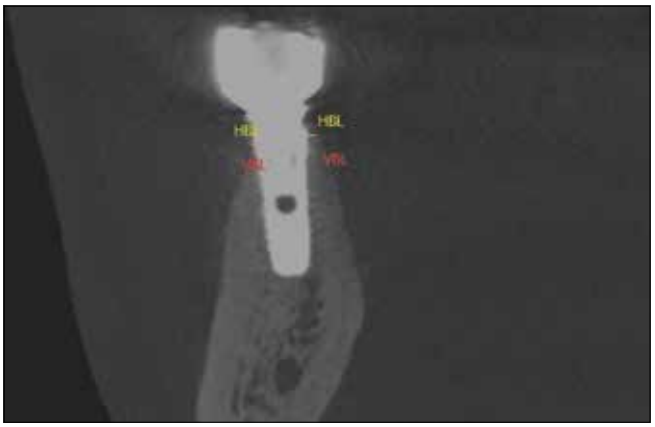

Figure 9: Cone-beam computed tomography measurements after 1 year of loading - buccal side and lingual side. Horizontal bone loss depicted in yellow and vertical bone loss in red

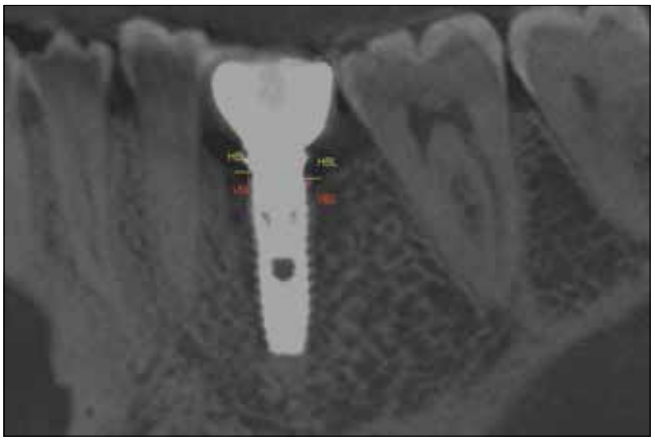

Figure 11: Cone-beam computed tomography measurement after 1 year of loading - mesial side and distal side. Horizontal bone loss depicted in yellow and vertical bone loss in red

RESULTS

A total of 32 implants (SuperLine Dentium) were inserted in 32 patients. Equal numbers of male and female participants were included in both the groups. All the patients reported for the recalls scheduled. A 100% survival rate was observed. By using Chi-square test, statistically no significant difference was found in ages of the patients of the two groups ($\chi^2 = 2.00$, $P = 0.36$, nonsignificant) [Table 2]. The difference in the buccal, lingual, mesial, and distal bone loss at baseline and 1-year follow-up is shown in Tables 3 and 4. By using Mann–

Whitney *U*-test, a statistically significant difference was found in the vertical bone loss (VBL) among participants of Group A and Group B on all the four sides after 1 year of implant placement [Table 3]. However, significant results were not obtained for the difference in the horizontal bone level after 1 year [Table 4].

DISCUSSION

Branemark's approach has been a breakthrough approach for all the clinicians in the field of implantology. Direct and easy access, superior esthetics, and desired regenerative procedure are few of the many benefits this approach provides.[20] Flapless implant placement has been an evolution that has progressed from the traditional approach trying to counter the disadvantages of flap elevation. Few authors have advocated that placing implants with a minimally invasive technique not only reduced the trauma but also maintains the tissue volume.[21-23] Cannizzaro *et al*.[14] have greatly emphasized the benefits of the flapless technique in terms of minimal trauma and better acceptability. This study was designed to assess the combined effect of CBCT-guided flapless surgery and immediate loading on the crestal bone for single implants. Nonfunctional loading was performed as it has more predictable outcomes compared to immediate functional loading protocol.[24] Predetermined computer-generated random location plan was used for randomization and participants were blinded from the allocation assigned.

Table 2: Distribution of patients according to their age in flap surgery (Group A) and flapless surgery (Group B)

Age group (years)	Flap implant surgery (Group A), *n* (%)	Flapless implant surgery (Group B), *n* (%)	χ^2
18–25	3 (18.75)	6 (37.5)	2.00
26–35	7 (43.75)	7 (43.75)	*P*=0.36 (NS)
36–45	6 (37.5)	3 (18.75)	
Total	16 (100)	16 (100)	
Mean±SD	36±7.12	34.12±6.62	
Range	25–45	23–44	

SD: Standard deviation, NS: Nonsignificant

Table 3: Comparison of vertical crestal bone loss in flap surgery (Group A) and flapless surgery (Group B) after 1 year

Vertical crestal bone loss (mm)	Flap implant surgery (Group A)	Flapless implant surgery (Group B)	*Z*	*P*
Buccal	−0.14±0.10	−0.06±0.07	2.30	0.02 (S)
Lingual	−0.14±0.13	−0.01±0.11	2.45	0.014 (S)
Mesial	−0.39±0.16	−0.19±0.24	2.30	0.021 (S)
Distal	−0.41±0.14	−0.20±0.19	3.02	0.002 (S)

S: Significant

Table 4: Comparison of horizontal crestal bone loss in flap surgery (Group A) and flapless surgery (Group B) after 1 year

Horizontal crestal bone loss (mm)	Flap implant surgery (Group A)	Flapless implant surgery (Group B)	*Z*	*P*
Buccal	−0.13±0.06	−0.11±0.08	0.98	0.33 (NS)
Lingual	−0.13±0.06	−0.10±0.06	1.43	0.16 (NS)
Mesial	−0.10±0.06	−0.11±0.13	0.32	0.74 (NS)
Distal	−0.14±0.08	−0.09±0.11	1.05	0.29 (NS)

NS: Nonsignificant

Various factors that influence the success and failure of any implant rehabilitation are the type of surgical technique, primary implant stability, and volume and quality of bone around the implant.[23] One hundred percent survival rate of solitary implants after 1 year was depicted in the results of this study regardless of the surgical technique. This is comparable with other clinical trials which depicted equal survival rates of both flapless and flap surgery groups.[25-31] Thus, flapless technique can be considered a reliable procedure for implant placement offering comparable survival rates.

However, implant success is not solely based on implant survival and should be assessed based on peri-implant conditions and bone-level stability.[29] Crestal bone loss is therefore an important factor which can guide the clinician to assess the peri-implant condition.[2,32]

Few studies have stated that bone loss with the flapless and flap elevation surgical techniques are comparable,[14,27,28,33] while other clinical trials reported that the flapless technique has significantly better outcomes.[10,19,29,34,35] Majority of these studies have focused on assessing the bone loss with the use of intraoral periapical radiographs. Only one study by Shamsan *et al*.[35] had assessed the crestal bone loss by using a CBCT. The use of CBCT is an acceptable method for measuring vertical bone height with precision.[36,37]

According to the results of the study, flap elevation affects the VBL significantly compared to flapless surgery. This finding is similar to the results of Kumar *et al*., 2018.[10] Kumar *et al*.[10] evaluated the 1-year VBL on the mesial and distal sides and observed a significant difference between the two groups. Similar significant findings were reported by Job *et al*.,[19] Naeini *et al*.,[29] Singla *et al*.,[16] and Shamsan *et al*.[35] Intact blood supply which maintains the nutrition to the flap is a critical factor for preventing the initial bone loss.[19,35]

Intact blood supply acts to preserve the bone tissues which benefits the healing and regeneration.[23] Furthermore, a positive healing environment for bone remodeling is achieved due to the intact periosteum.[38] Flapless surgery produces a significant reduction in the biologic width.[39] Results of the systematic review by Zhuang *et al*. in 2018,[38]

including results of 21 studies, concluded that crestal bone loss was significantly more with flap surgery compared to flapless.

Few studies have reported comparable outcome with both the techniques,[14,15,26-28,33,40-44] while few reported that flapless surgery can affect the bone more than flap surgery.[12,45] Difference in the outcomes could be because of the difference in the operating protocol. Few studies have used tissue punch,[10,23,33,43,46] while others have performed drilling directly through the mucosa.[12,14,25,28,31] Very few studies used computed tomography (CT)-guided surgical templates.[12,30,33,43,44,47,48] In these studies, CT-guided templates were only used for the flapless group while the flap surgery was done freehand after flap reflection. This study has used a guided procedure for both the groups. Freehand flapless surgery could be considered less accurate and lead to greater bone loss as shown in the findings of one study by Maló *et al*.[45] The difference in the results could also be attributed to the implant location. Few studies have only included maxillary region,[15,41,42] while others included were not specific to the region.[12,25,28,31]

Limitation of study

1. The study had a limitation in terms of follow-up of 1 year. Long-term observation period could provide a better insight in terms of the outcome measures for single as well as multiple implants
2. Only posterior implant placement was performed in the study; implant placement in anterior region should be evaluated further. The mandibular site of placement restricts the generalization of data for the implants placed in the maxillary arch
3. As only immediate loading protocol was used in this study, different loading protocols such as early loading and progressive loading could offer a discrete outcome
4. A smaller sample size of 32 patients was evaluated in this study. For the validation of the results on a large scale, a multicentric randomized control trial with larger number of participants should be performed.

CONCLUSION

Clinically, while deciding an approach for implant placement, it is important to understand the shortcomings and benefits of both the techniques. Clinicians are still hesitant while using flapless technique. As per the findings of the study, implants placed in the mandibular posterior region by flap implant surgery showed significantly more vertical crestal bone loss compared to flapless surgery after 1 year on immediate loading using CBCT. The horizontal bone loss was however comparable for both the techniques. Thus, it was concluded that flapless implant placement can provide results comparable to the conventional flap surgery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Comparative analysis on efficiency and accuracy of parallel confocal microscopy and three-dimensional in motion video with triangulation technology-based intraoral scanner under influence of moisture and mouth opening – A crossover clinical trial

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Abstract

Aim: The intraoral scanners are digital devices used to digitise the oral tissues. The accuracy of the intraoral scanners has been studied under different environmental conditions, but there might be differences that occur in the actual oral environment, which is still in question. The aim of the study was to evaluate the accuracy and efficiency of Parallel Confocal Microscopy and 3D in motion video with triangulation technology-based intraoral scanners under the influence of moisture and mouth opening.

Settings and Design: This was an Cross over clinical controlled study.

Materials and Methods: The controlled *in vivo* study included healthy subjects who were in need of CBCT for the purpose of locating the position of unerupted third molars before going abroad for a job. The subjects were exposed to scans in the upper and lower jaws with two intraoral scanners based on 3D motion video technology with triangulation (Medit) and parallel confocal microscopy (Trios) under the influence of two oral conditions, which were moisture (presence and absence of moisture) and mouth opening (30 mm and 50 mm, respectively). A total of 96 scans were obtained and superimposed individually over the reference CBCT scans to find the deviations in the Geomagic Rapidform (version 2020, USA) software. The efficiency of the scanners was calculated by recording the time taken and the number of images obtained after each scan.

Statistical Analysis Used: The significance was calculated by using the independent and paired sample *t* test in SPSS software (IBM, version 23).

Results: Based on the surface analysis, the trueness of the intra-oral scanners had statistically significant differences when compared between 3D in motion video technology with Triangulation and Parallel Confocal

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Microscopy ($P < 0.05$) whereas no statistical significance was observed in precision. There was a significant difference observed in the efficiency of the intra-oral scanners ($P < 0.05$).

Conclusion: There is a significant difference in the accuracy and efficiency of the intraoral scanners under the influence of oral conditions, such as different moisture levels and mouth opening conditions. 3D in motion video technology with Triangulation showed better results with the least deviation than Parallel Confocal Microscopy.

Keywords: Accuracy, digital impression, digitizers, efficiency, images captured, innovation, intraoral scanners, mouth opening, optical impression, oral fluids, precision, saliva, time taken, trueness

INTRODUCTION

Optical scanners are an integral part of digital manufacturing owing to the fact that digitization is the source of creating virtual models that can be used for the fabrication of dental prostheses by digital methods. The intraoral scanners, in particular, are preferred over conventional impressions due to their ease of use, better accuracy, elimination of several material consumptions, and increased patient comfort; the only disadvantage is the cost factor. One additional benefit of digital impressions is the ease of storage and retrieval of the data even after years, unlike stone models that can chip, break, or consume physical clinical or laboratory working space. The data capture of the intraoral scanners (IOSs) remarkably varies among different commercially available computer-aided design/computer-aided manufacturing systems. Several *in vitro* and *in vivo* studies have been carried out to test the performance of the IOSs, and they have concluded that clinically acceptable and relatively precise impressions can be made with IOSs when compared to manual impressions.[1] Any movement by the subject or error in the path of movement of the scanner by the operator while scanning will greatly affect the stitching of the images. Several factors such as illuminance,[2-5] presence of liquids,[6,7] scanning pattern,[8] scanning distance,[9] software updates,[10] preparation type and tooth geometries,[11] the distance between the abutment and the adjacent teeth[12] are said to affect the accuracy of IOSs.

Parallel confocal microscopy is used for IOS systems. This technique is used to acquire in-focus images from selected depths, a process known as optical sectioning (high-resolution optical images with depth selectivity). The parallel confocal microscopy intraoral system also works according to the principles of confocal microscopy and has a fast scanning time. A fundamental characteristic of this system is the variation of the focal plane without moving the scanner toward the subject being scanned. This system has the feature of telecentricity in the space of the subject being scanned, and it is possible to shift the focal plane while keeping telecentricity and magnification ratio.

Three dimensional (3D) in motion video technology with triangulation is able to capture moving objects. The scanner adjusts to the speed we want and is, therefore, able to follow along when the object is in motion. Meanwhile, picture-type scanning takes one picture per second. This means that the object must be held stationary to achieve the accuracy needed for good-quality images. Essentially, triangulation uses a 3-camera pattern to capture 3D imagery for this type of IOS. What makes triangulation useful is its ability to acquire high-speed data from materials we do not want to be in too much contact with, such as delicate or wet materials. In fact, triangulation principles have been widely used for centuries, but we are now beginning to really utilize them for industrial applications.

According to the present study, the trueness of the IOSs is the comparison done within the mouth opening conditions and the moisture conditions, whereas precision is the comparison between the 3D in motion video technology with triangulation and parallel confocal microscopy IOSs under different moisture and mouth opening conditions. Although we have different IOSs commercially available in the market, there is very little literature mentioning the significance of using a particular type of scanner for said intraoral or environmental conditions to avoid inaccuracies and increase the efficiency of the IOS. The study aims to compare the accuracy (trueness and precision) of two different technology-based IOSs (3D in motion video with triangulation and parallel confocal microscopy) and the efficiency, which is the time taken and the number of images obtained per scan; under different oral conditions, i.e., in the presence and absence of moisture and at two different degrees of mouth opening. The null hypothesis states that there is no difference between the two types of IOSs in terms of accuracy and efficiency.

MATERIALS AND METHODS

The clinical study was approved by the human ethics committee of the university (SRB/SDC/PROSTHO-1801/21/TH-031). All ethical guidelines specified by the WHO and the Declaration of Helsinki, 1954, were satisfied. All participants were briefed about the study, and they willingly signed informed consent forms.

Study design

A crossover clinical trial was conducted on six subjects. Each subject underwent four intraoral scans, which were full arch scans obtained from both the upper and lower arches of the subjects with two IOSs using 3D in motion video technology with triangulation (Medit i500) and parallel confocal microscopy (Trios 3) [Table 1] under 30 mm and 50 mm mouth openings and the presence and absence of saliva (total $n = 96$), which gave the accuracy of the scanners and the data on time taken and the number of images obtained was used to calculate the efficiency of the scanners, for which the data were extracted from the software while scanning under each condition. The sample size ($n = 96$) was calculated with G*Power software (Version 3.1.9.4) Mac OS X and windows XP/ vista/7/8 with a power of 95% and a high-intensity alpha error of 0.05.

Participants, eligibility criteria, and settings

Volunteers who needed a cone-beam computerized tomography (CBCT) scan to locate and determine the prognosis of their third molars without any symptoms before going abroad for a job were asked for their consent to participate in the study. They were screened for any calculus or debris and any deep caries lesions. The subjects had to have an average mouth opening of 50–55 mm. Six subjects, ranging in age from 20 to 25 years, took part in the study, and they were chosen at random from a pool of 20 other subjects. The eligibility criteria were as follows:

Inclusion criteria

Healthy controls with normal gait, stature, and build in the age group of 20–25 years of any gender with no history of systemic diseases who had a completely dentulous upper and lower arch, subjects with a complete eruption of all teeth until the second molars, mouth opening in the range of 50–55 mm, subjects with unerupted third molars without any symptoms, and subjects with normal viscosity of saliva with the normal flow were included in the study.

Exclusion criteria

Subjects with partial or complete edentulousness, restricted mouth opening, subjects who had restorations or replacements or had deep carious lesions; subjects with salivary gland disorder or with hypersalivation and xerostomia; subjects with thin or ropy saliva; subjects with noncarious lesions such as attrition, abrasion, or erosion were excluded from the study.

Intervention

The first part of the study was carried out in three steps: a CBCT scan; intraoral scanning under 30 mm and 50 mm mouth openings for the presence or absence of saliva using Medit and Trio IOSs; and the superimposition of intraoral scan data to CBCT data to evaluate the accuracy of IOS.

The second part of the study was carried out in two steps. The data entry was done after each intraoral scan, and the total number of images obtained and the scanning time were noted down from the display on the screen of the intraoral scanning software. The data were processed into an Excel sheet for statistical analysis, thereby defining the efficiency of the scanners.

Cone-beam computerized tomography scan

The subject was asked to remove any metal accessories in the head-and-neck region before proceeding with the CBCT preparation. The CBCT scan of the subject was made by making the subject stand upright with the chin resting on the chin rest. To avoid any head movements, the patient's head is locked in position. The laser point of the CBCT machine is made to coincide with the incisors of the patient using a thumbwheel. The subject is requested to maintain a still intraoral posture by not swallowing/grinding/moving during the exposure. The CBCT data were exported in DICOM format and converted into STL format with the help of online solutions. To maintain the standardization of the study, all the scans were done at the same time by the same operator.

Intraoral scan

Scanner preparation

To obtain a gold standard scan, the IOSs were calibrated using the calibration tool kit and as suggested by the manufacturer. The scanners were connected to the desktop

Table 1: Comparison of the different technology based intraoral scanners used in the study

Scanner	Manufacturer	Software technology	Light source	Version
Trios	3 shape	Parallel confocal microscopy	Laser	21.2.0
Medit i500	Medit	3D in motion video technology with triangulation	LED	V 2.4.6

3D: Three dimensional, LED: Light-emitting diode

computer with the software open to initialize the assisted calibration process. The tip of the IOS is inserted into the calibration object, and the calibration process is started from within the software. The process takes up to 3 min, during which the scanner runs through predefined motions and calibrates itself. Once the calibration is over, the object is separated from the scanner tip, and the scanner is ready for use. The calibration process is carried out after each scan, and the tips of the scanners are disinfected and sterilized according to the manufacturer's recommendation.

Preparing the subjects for intraoral scanning

Subjects were made to sit upright in a dental chair and asked to open their mouths to the fullest without resisting the free movement of the scanner. The scans were made with parallel confocal microscopy-based IOS followed by 3D in motion video technology with triangulation-based IOS under each condition. The whole procedure was done by a single operator and one observer at the same time for all the subjects under each condition for the standardization of the study. The observer was completely unaware of the scanner for blinding to eliminate bias.

Scanning under different degrees of mouth opening

All the subjects were made to sit in an upright position in a dental chair. They were instructed to rinse their mouths with plain water, swallow the pooled saliva, and open their mouths for scanning. The mouth opening was controlled and maintained at 50 mm with the help of the Boley's gauge. The gauge was positioned in the right quadrant while scanning the left quadrant and in the left quadrant while scanning the right quadrant. The same was done for a 30 mm mouth opening. To follow the scanning sequence, the scanning was carried out until the gauge stopped while the gauge was being replaced in the other arch and then continued in the other arch.

Scanning under different moisture conditions

The patients were given a cup of water to rinse and asked to swallow any pooled saliva completely and open their mouths for the presence of moisture. In the absence of moisture, the subjects are asked to open their mouths, and the saliva is completely suctioned with the help of suction and wiped all around the surfaces manually with a cotton roll. The cotton rolls were also used to isolate the mucosa from the surface of the tooth, and mild air was blown with the three-way syringe. The suction was constantly placed on the floor of the mouth.

Scanning pattern

The scans were made in the upper arch, followed by the lower arch. The occlusal surface of the tooth was covered, followed by the lingual and buccal surfaces, starting from the distal most molars and passing through the incisors to the other side molar for covering the surfaces in the said pattern. The soft tissue was retracted using fingers on the buccal side and a mouth mirror on the lingual side.

Superimposition of scans

For superimposition and surface analysis, the Geomagic Rapidform (version 2020, USA) was used. The CBCT scan was considered the reference scan, and the X, Y, and Z coordinates were determined to be fixed. The intraoral scans were imported one by one into the software and made to run through an initial fit and a best-fit algorithm [Figure 1]. The values of discrepancies that arose between the reference scan and model scan were measured and displayed by the software based on the root mean square (RMS) value [Figure 2], surface maximum deviation [Figure 3], and maximum deviation in the X, Y, and Z axes [Figure 4].

Statistical analysis

Statistical analysis was performed using SPSS software (Version 23.0. Armonk, New York: IBM Corp). Data collection was done with the help of the data collection sheets. Descriptive statistics (mean, standard deviation, and standard error) were carried out for each group. An unpaired *t*-test was carried out to find the significance between the groups (3D in motion video technology with triangulation and parallel confocal microscopy. A paired *t*-test was carried out to find the significance within subgroups of moisture (between the presence and absence of moisture) and mouth opening (30 mm and 50 mm).

RESULTS

The IOSs were compared for accuracy (trueness and precision) and efficiency (time taken and number of images). The results of the samples were analyzed for accuracy based on deviations observed from the results of superimposition between the reference scan and the experimental scans in surface analysis and specific points in molars, canines, and incisors in the X, Y, and Z coordinates in coordinate analysis.

Moisture conditions

The accuracy of the IOSs did not have any statistically significant difference when compared between the presence and absence of moisture (precision) [Table 2]. The accuracy of the intraoral scanners had statistically significant differences in the RMS value when compared between two systems of scanners (trueness) for lower scans with a $P < 0.05$. However, there was no statistically significant

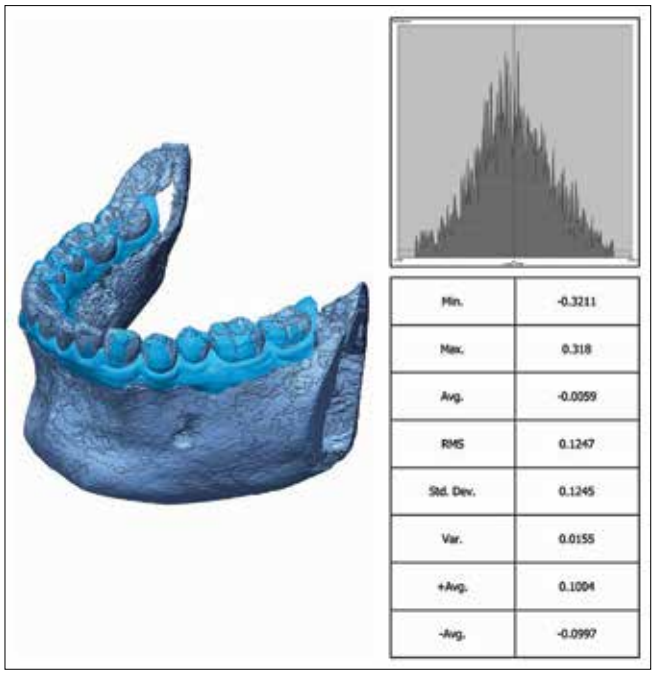

Figure 1: Image showing alignment of reference (CBCT) and sample data (IOS) after superimposition (best fit algorithm). CBCT: Cone-beam computerized tomography, IOS: Intraoral scan

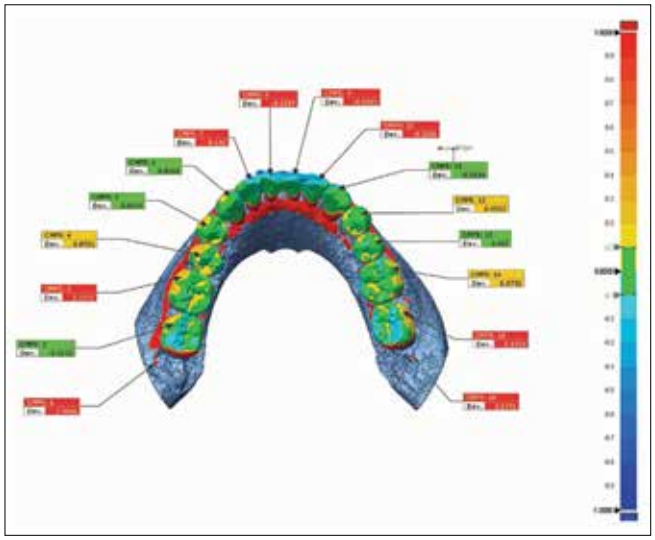

Figure 3: 3D compare image of surface analysis with maximum deviation values extracted by Geomagic software. 3D: Three dimensional

difference observed with the presence of moisture in the upper arch scan. The least deviations were observed in the 3D in motion video technology with the triangulation group under the presence and absence of moisture for both the upper and lower arch [Table 3].

Mouth opening

The accuracy of the IOSs did not show any statistically significant difference when compared between 30 mm of mouth opening and 50 mm of mouth

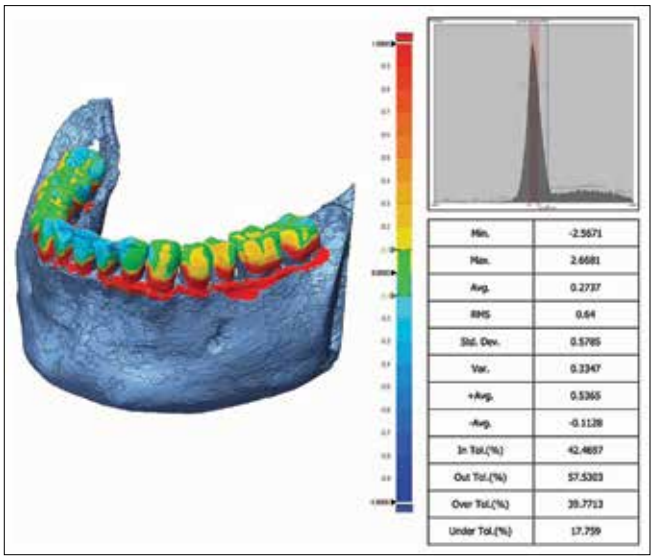

Figure 2: 3D compare image of surface analysis with RMS values extracted by Geomagic software. 3D: Three-dimensional, RMS: Root mean square

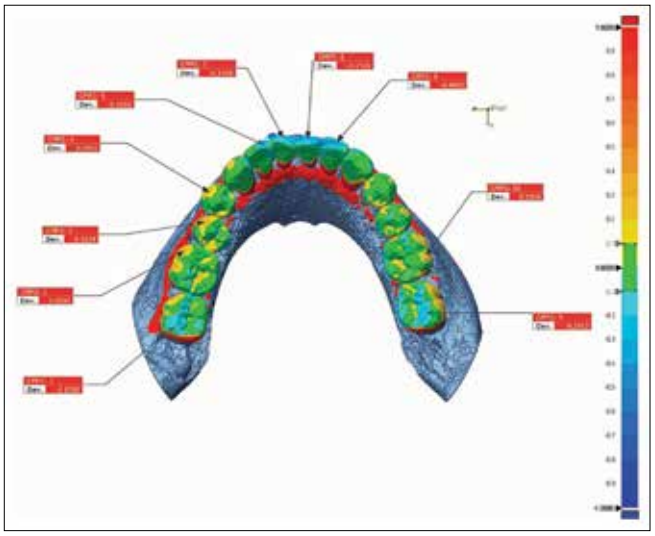

Figure 4: The deviations in X, Y, Z coordinate axis

opening (precision) [Table 4]. The accuracy of the intraoral scanners showed statistically significant differences when compared between the group's (i.e., Trueness) lower scan with 50 mm of mouth opening and the rest showing 3D in motion video technology with triangulation scan with better accuracy of the RMS value but statistically not significant [$P < 0.05$, Table 5].

Coordinate analysis

The analysis of sample results corresponding to X, Y, and Z coordinates showed no statistically significant difference in accuracy when compared between the mouth opening conditions and moisture condition. The coordinate axis analysis was done at five specific points, which were the right

Table 2: Comparison between the presence and absence of moisture based on deviations observed in surface analysis

IOS	Arch	Moisture conditions	Mean±SD	SE	CI		*t*	*P*
					Lower bound	Upper bound		
Parallel confocal microscopy	Upper	Presence of moisture	0.55±0.14	0.05	0.40	0.70	0.46	0.65
		Absence of moisture	0.60±0.17	0.07	0.42	0.78		
	Lower	Presence of moisture	0.42±0.14	0.05	0.27	0.57	0.02	0.97
		Absence of moisture	0.42±0.15	0.06	0.26	0.58		
3D in motion video technology with triangulation	Upper	Presence of moisture	0.41±0.13	0.05	0.26	0.55	0.37	0.71
		Absence of moisture	0.37±0.15	0.06	0.21	0.54		
	Lower	Presence of moisture	0.23±0.07	0.02	0.16	0.31	0.91	0.38
		Absence of moisture	0.20±0.04	0.02	0.15	0.25		

P value derived from paired sample *t*-test. 3D: Three dimensional, CI: Confidence interval, SE: Standard error, SD: Standard deviation, IOS: Intraoral scanner

Table 3: Root mean square value of deviation in moisture conditions between two technology-based intraoral scanner

Arches	Moisture conditions	IOS	Mean±SD	*P*
Lower	Presence of moisture	3D in motion video technology with triangulation	0.61±0.09	0.02*
		Parallel confocal microscopy	0.84±0.20	
	Absence of moisture	3D in motion video technology with triangulation	0.62±0.12	0.04*
		Parallel confocal microscopy	0.87±0.24	
Upper	Presence of moisture	3D in motion video technology with triangulation	0.94±0.20	0.08
		Parallel confocal microscopy	1.16±0.19	
	Absence of moisture	3D in motion video technology with triangulation	0.92±0.20	0.07
		Parallel confocal microscopy	1.17±0.23	

*Level of significance $P<0.05$. *P* value derived from independent *t*-test. 3D: Three dimensional, SD: Standard deviation, IOS: Intraoral scanner

Table 4: Comparison of the deviations observed in surface analysis between 30 mm mouth opening and 50 mm mouth opening conditions

Intra oral scanner	Arch	Mouth opening	*P*	SE	CI		*t*	*P*
					Lower bound	Upper bound		
Parallel confocal microscopy	Upper	30 mm mouth opening	0.59±0.15	0.06	0.42	0.75	0.39	0.70
		50 mm mouth opening	0.55±0.14	0.05	0.40	0.70		
	Lower	30 mm mouth opening	0.36±0.08	0.03	0.27	0.45	0.91	0.38
		50 mm mouth opening	0.42±0.14	0.05	0.27	0.57		
3D in motion video technology with triangulation	Upper	30 mm mouth opening	0.41±0.10	0.04	0.31	0.52	0.10	0.91
		50 mm mouth opening	0.41±0.13	0.05	0.26	0.55		
	Lower	30 mm mouth opening	0.21±0.06	0.02	0.14	0.28	0.56	0.58
		50 mm mouth opening	0.23±0.07	0.02	0.16	0.31		

P value derived from paired sample *t*-test. 3D: Three dimensional, SD: Standard deviation, CI: Confidence interval, SE: Standard error

Table 5: Root mean square value of deviation in mouth opening conditions (30 mm and 50 mm) between two technology-based intraoral scanner

Arches	Mouth opening conditions	IOS	Mean±SD	*P*
Lower	30 mm	3D in motion video technology with triangulation	0.97±0.17	0.14
		Parallel confocal microscopy	1.15±0.21	
	50 mm	3D in motion video technology with triangulation	0.61±0.09	0.02*
		Parallel confocal microscopy	0.84±0.20	
Upper	30 mm	3D in motion video technology with triangulation	0.94±0.20	0.07
		Parallel confocal microscopy	1.16±0.19	
	50 mm	3D in motion video technology with triangulation	0.94±0.20	0.08
		Parallel confocal microscopy	1.16±0.19	

*Level of significance $P<0.05$. *P* value derived from independent sample *t*-test. 3D: Three dimensional, SD: Standard deviation, IOS: Intraoral scanner

and left molars, the right and left canines, and one central incisor of the upper and lower arches [Tables 6 and 7].

Efficiency of the intraoral scanners

Statistically significant differences were found in the precision of the IOSs for time taken under mouth opening conditions and the trueness of the IOSs under moisture conditions. In terms of images obtained, there was a significant difference in the trueness of the IOSs under different mouth opening and moisture conditions [Table 8].

DISCUSSION

The effect of saliva and oral liquids on the accuracy of the IOSs is found to be significantly similar to the *in vivo* study done by Camcı and Salmanpour.[13] In surface

Table 6: Comparison of two different technology-based scanner based on the three-dimensional discrepancies observed between each intraoral scan and cone-beam computed tomography in the incisor, canine, and molar regions under the influence of the presence and absence of moisture

	IOS	Parallel confocal microscopy					3D in motion video technology with triangulation				
Arch	Coordinates and points	Mesiopalatal cusp M1 (R)	Mesiopalatal cusp M2 (L)	Cuspal tip C1 (R)	Cuspal tip C2 (L)	Incisal edge I1 (R)	Mesiopalatal cusp M1 (R)	Mesiopalatal cusp M2 (L)	Cuspal tip C1 (R)	Cuspal tip C2 (L)	Incisal edge I1 (R)
Upper	X coordinate										
	Mean±SD	−0.01±0.04	0.02±0.04	−0.02±0.02	0.01±0.01	−0.00±0.01	0.03±0.04	−0.02±0.02	−0.02±0.10	0.02±0.02	−0.00±0.01
	P	0.30	0.17	0.05*	0.03*	0.68	0.09	0.10	0.54	0.14	0.97
	Y coordinate										
	Mean±SD	−0.00±0.01	0.00±0.03	−0.00±0.03	−0.03±0.08	−0.01±0.03	0.00±0.02	0.00±0.03	−0.05±0.12	−0.00±0.05	−0.02±0.03
	P	0.34	0.67	0.54	0.38	0.26	0.53	0.89	0.31	0.68	0.19
	Z coordinate										
	Mean±SD	0.02±0.04	0.03±0.04	−0.04±0.06	−0.04±0.14	−0.06±0.11	−0.03±0.04	−0.11±0.15	−0.14±0.16	0.03±0.08	−0.03±0.17
	P	0.33	0.11	0.15	0.46	0.22	0.07	0.14	0.08	0.40	0.67
Lower	X coordinate										
	Mean±SD	0.00±0.03	0.00±0.02	0.00±0.00	−0.01±0.01	0.00±0.00	−0.03±0.03	−0.01±0.02	−0.00±0.02	−0.00±0.01	0.00±0.01
	P	0.94	0.56	0.07	0.06	0.07	0.03*	0.40	0.89	0.60	0.69
	Y coordinate										
	Mean±SD	0.00±0.04	0.00±0.02	−0.00±0.00	−0.01±0.01	−0.01±0.03	0.28±0.01	−0.00±0.02	0.01±0.02	−0.00±0.01	0.00±0.01
	P	0.78	0.51	0.03*	0.07	0.29	0.01*	0.47	0.27	0.77	0.47
	Z coordinate										
	Mean±SD	−0.00±0.03	0.00±0.05	0.01±0.01	0.03±0.04	0.04±0.08	−0.03±0.02	0.00±0.05	−0.00±0.05	0.00±0.03	−0.01±0.05
	P	0.74	0.78	0.07	0.10	0.27	0.01*	0.78	0.75	0.64	0.56

*Level of significance $P<0.05$. *P* value derived from independent sample *t*-test. 3D: Three dimensional, SD: Standard deviation, IOS: Intraoral scanner

Table 7: Comparison of two different technology-based scanner based on the three-dimensional discrepancies observed between each intraoral scan and cone-beam computed tomography in the incisor, canine, and molar regions under the influence of 30 mm mouth opening and 50 mm mouth opening conditions

	IOS	Parallel confocal microscopy					3D in motion video technology with triangulation				
Arch	Coordinates and points	Mesiopalatal cuspal M1 at 3	Mesiopalatal cuspal M2 (L) 14	Cuspal tip C1 at 6	Cuspal tip C2 (L) 11	Incisal edge I1 at 8	Mesiopalatal cuspal M1 (R)	Mesiopalatal cuspal M2 (L)	Cuspal tip C1 (R)	Cuspal tip C2 (L)	Incisal edge I1 (R)
Upper	X coordinate										
	Mean±SD	−0.04±0.07	0.07±0.14	−0.05±0.07	−0.00±0.02	0.00±0.02	0.05±0.13	−0.02±0.08	−0.02±0.10	0.01±0.01	0.00±0.00
	P	0.24	0.26	0.12	0.99	0.83	0.40	0.50	0.51	0.11	0.65
	Y coordinate										
	Mean±SD	−0.01±0.04	0.02±0.10	−0.04±0.11	−0.06±0.11	0.00±0.09	−0.01±0.05	−0.00±0.06	−0.04±0.13	−0.03±0.06	−0.01±0.03
	P	0.45	0.52	0.40	0.20	0.95	0.49	0.76	0.46	0.24	0.24
	Z coordinate										
	Mean±SD	0.04±0.08	0.08±0.14	−0.02±0.15	−0.12±0.20	−0.04±0.20	−0.02±0.10	−0.03±0.10	−0.11±0.15	0.02±0.08	−0.02±0.15
	P	0.29	0.20	0.76	0.21	0.63	0.57	0.40	0.14	0.52	0.68
Lower	X coordinate										
	Mean±SD	0.01±0.08	−0.00±0.03	−0.00±0.04	−0.00±0.03	−0.00±0.01	−0.05±0.05	0.01±0.04	−0.00±0.02	−0.00±0.03	0.00±0.01
	P	0.76	0.73	0.74	0.89	0.39	0.06	0.32	0.57	0.84	0.61
	Y coordinate										
	Mean±SD	0.00±0.06	−0.00±0.03	−0.01±0.03	0.00±0.03	−0.00±0.03	0.04±0.04	0.01±0.03	0.01±0.05	0.01±0.30	−0.01±0.02
	P	0.89	0.85	0.42	0.63	0.87	0.08	0.44	0.60	0.43	0.17
	Z coordinate										
	Mean±SD	−0.00±0.06	0.00±0.07	0.01±0.10	−0.00±0.15	0.02±0.09	−0.05±0.05	−0.06±0.07	−0.01±0.07	0.02±0.12	−0.11±0.15
	P	0.99	0.77	0.80	0.94	0.51	0.05*	0.11	0.71	0.68	0.14

*Level of significance $P<0.05$. *P* value derived from independent sample *t*-test. 3D: Three dimensional, SD: Standard deviation, IOS: Intraoral scanner

Table 8: Comparison of efficiency (time taken and images obtained) of two different technology-based intraoral scanners under the influence of different mouth opening (30 mm and 50 mm) and moisture (presence and absence) conditions

Arch	Oral conditions	Intraoral scanner	Time taken			Images obtained		
			Mean±SD	SE	*P*	Mean±SD	SE	*P*
Upper	30 mm mouth opening	3D in motion video technology with triangulation	59.16±12.02	4.90	0.28	1135.50±331.54	135.35	0.50
		Parallel confocal microscopy	71.16±23.34	9.53		1015.33±259.63	105.99	
	55 mm mouth opening	3D in motion video technology with triangulation	61.00±10.84	4.42	0.16	1338.66±257.68	105.19	0.52
		Parallel confocal microscopy	81.33±31.60	12.90		1212.33±394.13	160.90	
Lower	30 mm mouth opening	3D in motion video technology with triangulation	59.16±13.60	5.55	0.04*	1213.50±357.49	145.94	0.01*
		Parallel confocal microscopy	43.66±9.72	3.97		733.50±136.46	55.71	
	55 mm mouth opening	3D in motion video technology with triangulation	70.66±17.30	7.06	0.80	1424.33±331.90	135.49	0.04*
		Parallel confocal microscopy	68.16±15.91	6.49		1036.66±237.42	96.92	
Upper	Absence of moisture	3D in motion video technology with triangulation	55.00±11.94	4.87	0.79	1110.66±222.08	90.66	0.14
		Parallel confocal microscopy	57.33±17.15	7.00		901.66±237.00	96.75	
	Presence of moisture	3D in motion video technology with triangulation	58.33±8.35	3.41	0.11	1318.33±283.34	115.67	0.60
		Parallel confocal microscopy	81.33±31.60	12.90		1212.33±394.13	160.90	
Lower	Absence of moisture	3D in motion video technology with triangulation	52.66±10.55	4.31	0.44	1008.50±207.37	84.66	0.07*
		Parallel confocal microscopy	47.33±12.62	5.15		780.33±186.70	76.22	
	Presence of moisture	3D in motion video technology with triangulation	73.83±17.35	7.08	0.53	1478.00±285.33	116.48	0.03*
		Parallel confocal microscopy	67.66±15.53	6.34		1088.00±246.75	100.73	

*Level of significance $P<0.05$. 3D: Three dimensional, SD: Standard deviation, SE: Standard error

analysis, there was a significant difference in trueness but no significant difference in the precision of the IOSs under the influence of moisture conditions, which was in favor of the previous literature.[6] There was a significant difference in trueness, with the least deviations observed in 3D in motion video technology with triangulation than in parallel confocal microscopy, which was contrary to results published by Biagio Rapone,[14] where parallel confocal microscopy showed the least deviations when compared to the other two IOSs used in the study, yet 3D in motion video technology with triangulation IOS was not used in the study, making the results incomparable with the present study. 3D in motion video technology with triangulation showed the least deviations with an absence of moisture, irrespective of the arches, which may be due to 3D in motion video technology. The precision of both IOSs had lesser deviations in the lower arch and greater deviations in the upper arch, and this may be due to the fact that there is limited light exposure or direct light on the upper arch compared to the lower arch under any light conditions, the deviations in the first molars in the upper arch can be due to the parotid duct opening, and the lower arch can be due to the pooling of saliva in the posterior regions, and the tendency for inaccuracies to decrease from anterior to posterior in full arch scans. The deviations between the reference scan and the experimental scan were measured using superimposition techniques, and the analysis was carried out in two categories, namely surface analysis and coordinate axis analysis, to get the proper decision.

The coordinate axis analysis was done at five specific points, which were the right and left molars, the canine, and one central incisor of the upper and lower arches. The molars indicated the possible deviations that may arise in the posterior region; the canines indicated the possible deviations that may arise during the arch shift, and the incisors indicated the possible deviations that might arise in the anterior region. Also from the previous literature, the tooth types and geometries have shown to make a significant difference in the accuracy of the IOSs. There is a tendency for the inaccuracies to decrease from the anterior to the posterior in full arch scans.[15] In coordinate analysis, there is no significant difference in trueness but there was a significant difference in precision observed in the trios IOS in cuspal tips C1(R) and C2(L) in the X coordinate of the upper arch and in the Y coordinate of cuspal tip C1(R) in the lower arch. Increased deviations in the canine region can be because of the smoothness and regularity of the tooth surface of the canine and because deviations can occur during the arch shift.[15]

The accuracy values denoted the efficacy of the IOSs, whereas the efficiency of the IOSs was calculated based on the time taken and the number of images recorded and displayed by the software of the IOSs when the intraoral scans were taken.[16] With regard to the trueness of the time taken, there was no significant difference with the IOSs. The lowest measurements were observed in the absence of moisture, followed by the presence of moisture, irrespective of the IOS used suggesting that the absence of moisture helps in increasing the efficiency of both IOSs, supporting previous literature.[17-20]

Any movement during the scanning procedure can affect the flow of image capture. The major movements made by the patient during intraoral scanning would be mouth closure, which can be due to fatigue or restricted mouth opening. To evaluate the accuracy of the IOSs under

the influence of the mouth opening conditions, two measurements were taken: 50 mm, considering the average mouth opening of Indian adults, and 30 mm, considering the average tip diameter of both IOSs used in the study. The mouth opening was controlled with the help of a Boley's gauge. The movement of the subject's head was controlled by resting on the headrest of the chair and was monitored by the observer. Furthermore, subjects with normal height, stature, and build were selected to avoid inconsistencies. In surface analysis, there were significant differences in the trueness of the IOSs at 30 mm mouth opening, followed by 50 mm mouth opening in the lower arch and 30 mm mouth opening in the upper arch, and close to the significant value at 50 mm mouth opening in the upper arch. There was no significant difference observed in the precision of the IOSs. 3D in motion video technology with triangulation showed better accuracy values than trios. The lower arch, irrespective of the scanners, showed better accuracy than the upper arches. This may be because of the restrictions on opening the mouth; the free movement of the scanner in the upper posterior regions might be restricted, leading to more inaccuracies. In coordinate axis analysis, there is no significant difference in trueness but there is a significant difference in precision. Trios showed more negative deviations in both upper and lower arches, with all the coordinate axes X, Y, and Z indicating superiority toward 3D in motion video with triangulation technology.

The limitations of the study are that the subjects had ideal occlusions and sound tooth structure; partial or complete edentulousness or the presence of replacements and restorations might affect the accuracy of the scanners. Standard measuring and analyzing methods have to be used for 3D analysis. The study was performed with a single right-handed operator to avoid inconsistencies in results; this might cause errors that may arise due to operator fatigue. The study rejected the null hypothesis. With continuous improvements being made in the imaging principles of the intraoral scanners and the scanning techniques, the standards of the intraoral scanners can be raised in the near future.

CONCLUSION

Within the limitations of the study, there is a significant difference in the accuracy and efficiency of the IOSs under the influence of oral conditions such as different moisture levels and mouth opening conditions. 3D in motion video technology with triangulation showed better results with the least deviation than parallel confocal microscopy. The future scope of the study would be suggestions to use more standardized measuring techniques and subject-specific scanners, which will not have a great effect on any of the clinical variables. This can lead to great success in terms of the accuracy of digital impressions and help take digital dentistry to the next level.

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Conflicts of interest

There are no conflicts of interest.

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Research

Comparative evaluation of biological, mechanical, and patient-reported outcomes of angulated screw channel abutments versus multi-unit abutment-retained single-unit implant restorations in the anterior esthetic zone: An-*in vivo* study

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Abstract

Aims: The study aimed to evaluate biological, mechanical, and patient reported parameters associated with ASC abutments and MU abutments for the fabrication of screw retained implant crowns in the anterior esthetic zone.

Setting and Design: For the study, 20 patients were selected and implants were placed within the constraints of prosthetic envelope. Later, the screw retained crown was fabricated.

Materials and Methods: Biological parameters (including implant survival rate, marginal bone levels using cone beam computed tomography, and soft tissue assessment using periodontal indices) were measured at the time of crown placement and 1 year follow up. Mechanical parameter (screw loosening) was calculated using removal torque loss (RTL) values obtained at the time of crown placement and 1 year follow up. Patient reported parameters were evaluated using a questionnaire at 1 year follow up.

Statistical Analysis Used: All data were tabulated, statistically analyzed, and compared using SPSS version 23 IBM Corporation, Armonk, NY, USA.

Results: Implant survival was found 100% in both the groups. The marginal bone level reduced considerably in both the groups from baseline to 1 year follow up. The MU abutment group had slightly less marginal bone loss than the ASC abutment group. Additionally, there was no statistically significant difference between the two groups' periodontal indices at baseline and 1-year follow-up values. At baseline, the RTL value was substantially lower ($P < 0.003$) in the ASC abutment group than in the MU abutment group, however at the

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1-year follow-up, there was no statistically significant difference in RTL or screw loosening between the two groups. Patient-reported data showed no statistically significant difference.

Conclusion: Within the constraints of this study, it was suggested that both ASC and MU abutments provide equally promising results in terms of biological, mechanical, and patient-reported parameters in the anterior esthetic region for single screw-retained crowns.

Keywords: Angulated screw channel, implant, multi-unit abutment, screw-retained prosthesis

INTRODUCTION

Implant-supported fixed restorations are reliable means to rehabilitate partial or complete edentulism, overcoming the limitations encountered with conventional prosthetic options. Long-term success is determined not merely by osseointegration but additionally by functional and esthetic consequences.[1-3] Clinicians must evaluate biological and technical considerations when choosing among cement-retained and screw-retained prosthesis retention. Cement-retained prostheses are mostly preferred in esthetic zones to compensate for otherwise nonaxial positioning of implants to mask the unesthetic labial screw access hole. There are still certain constraints, such as the need for accurate implant placement for the ideal and esthetic location of the screw access hole to achieve a passive fit with a screw-retained prosthesis.[4-7]

The clinician can choose from a number of treatment options to improve the placement of implants in order to compensate for inadequate ridge anatomy, like ridge augmentation, changing the intended location of an implant, and implant placement with an angled trajectory, either with or without the use of implant guides.[8] With the emergence of angulated abutments, the angulated implant placement enables the insertion of an implant with greater dimensions in width and height, avoiding guided bone regeneration procedures, saving surgery times, and enabling cement-retained restoration easier to execute.[9,10]

The fabrication of screw-retained restorations in the anterior region necessitates breakthroughs in connecting abutments[11-14] like angulated or lateral screw channel abutments. Angulated screw channel (ASC) abutments with its Omnigrip screwdriver makes it possible to alter the angulation up to 28° with 360° rotational freedom. This abutment shifts the screw access hole palatally allowing esthetically oriented restoration, especially in anterior region. However increased treatment complexity, maintenance burden, incur additional costs with limited clinical trials have still limited its use in routine practice.[15-17] Multi-unit (MU) abutments can also bring the screw access hole palatally by changing the prosthetic screw direction. With definitive MU abutments, the soft tissue and titanium could adhere to one another more effectively, thereby minimizing bone resorption. It transfers occlusal stress from implant screw to MU abutment small screw which may cause rotation of the abutment. Hence, MU abutments with anti rotation features could be used for single implant restorations.[18,19]

In literature, only a few studies[15-22] using either ASC abutments or MU abutments for anterior screw retained crowns are documented. Most of these studies are case reports, *in vitro* studies, or comparative studies with conventional cement-retained restorations. To date, there is no *in vivo* comparison of ASC and MU abutments. Thus, this study elucidates the *in vivo* comparison of ASC and MU abutments in terms of biological, mechanical, and patient-reported parameters associated with these abutments.

The null hypothesis states that there is no difference between these abutments in terms of biological, mechanical, and patient-reported parameters.

MATERIALS AND METHODS

This study was carried out in the Department of Prosthodontics and Crown and Bridge. This study was registered at the Clinical Trials Registry of India (CTRI/2021/12/038506) on December 08, 2021. For the study, 20 patients were selected who needed solitary implant crowns in the maxillary anterior region. Following the acquisition of informed consent, patients were selected based on the inclusion and exclusion criteria listed below. A patient must fall within an age range of 18 and 60, maintain good oral hygiene and periodontal health, have adequate mesiodistal, buccolingual, and interocclusal space for an anatomic restoration, possess an infection-free implant site, and need a single prosthetic crown in the maxillary anterior esthetic zones (canine to canine). Exclusion criteria include patients with medical and general limitations for the surgical procedures, presence of active and uncontrolled periodontal diseases, history of local radiotherapy to the orofacial region, uncontrolled systemic

illnesses (uncontrolled diabetes, recent *myocardial infarction*, valvular prosthesis surgery, bleeding disorders, acute renal failure, and immunosuppression), patients taking intravenous bisphosphonates, psychiatric conditions, and chronic tobacco users.

Prior to prosthetic planning, patients were randomly allocated to receive ASC abutment (Group 1) and MU abutment (Group 2) [Figure 1] according to a parallel group design. After the compilation of the randomization lists, envelopes with random codes were opened sequentially by a nonstudy staff member. All implants were planned in accordance with the interventions assigned.

Phase 1

Preprosthetic phase-diagnostic impressions were made of both the arches using irreversible hydrocolloid (Plastalgin, Septodont, France) and casts were poured using dental stone (Type III, Ultrarock, Kalabhai). A diagnostic preview (via an arrangement of prosthetic teeth in wax) was used to establish the most esthetically pleasing and functionally viable tooth position. Over the duplicate cast, a diagnostic template was created and hollowed out to outline the prosthetic envelope [Figure 2] that the abutment must fit within. This prosthetic envelope was fabricated for each case using tooth color autopolymerizing acrylic resin.

Phase 2

Surgical phase and temporization – A standard aseptic surgical protocol was adopted for all the cases. A tapered endosteal root form implant (Genesis AKTIV, J. J. Implants, India) with an internal hexagonal connection was placed following standard osteotomy protocol by the same practitioner. The implant was inserted crestally or subcrestally to accommodate the angulated abutments (ASC [Dynamic abutment solutions, Spain] and MU [Genesis, J. J. Implants, India] abutments) in a way that it lies within the prosthetic envelope [Figure 3]. The cover screw was placed, the flap was sutured, and the implant was left submerged for 3 months. Implant position verified using radiograph. After 3 months, second-stage surgery was performed for the definitive prosthetic phase.

Phase 3

Definitive prosthetic phase – Open tray impression was made 2 weeks after second stage surgery with light body and putty addition silicone impression material (3M ESPE) for the fabrication of a single crown. Depending on the group assigned, a screw-retained porcelain-fused-metal direct metal laser sintering crown was made either on the ASC abutment or the MU abutment. The crown was then assembled onto the implants and as per the manufacturer's guidelines, the abutment and prosthetic screws were torqued [Figure 4]. The screw access hole was filled with a polytetrafluoroethylene tape followed by light-curing composite restorative material. The implant crown was made free from all contacts on the implant crown during excursion to the opposing side and also during protrusion.

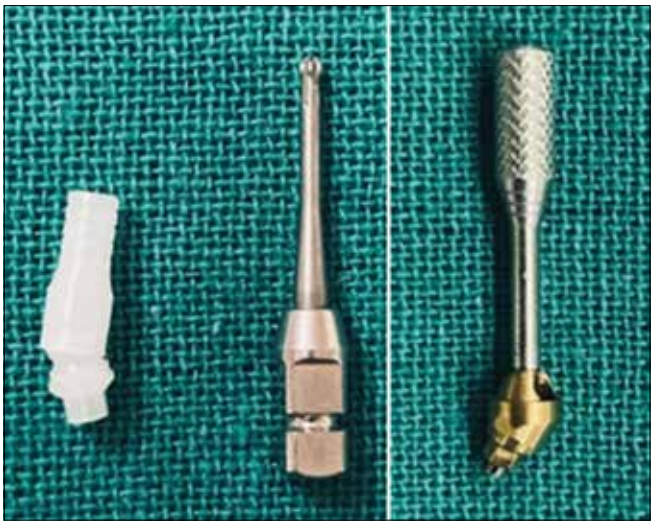

Figure 1: Angulated screw channel abutment with its prosthetic driver (right) multi-unit abutment (left)

Figure 2: Prosthetic envelope on duplicate cast

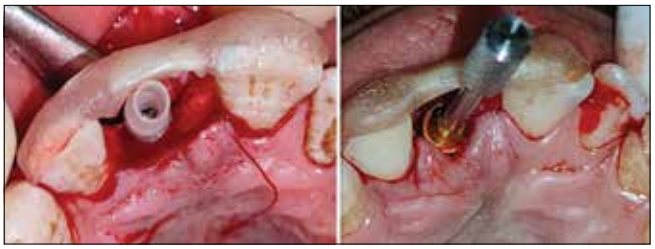

Figure 3: Angle correction verified intraorally with angulated screw channel (left) and multi-unit (right) abutments using prosthetic envelope

All the parameters were evaluated at the time of crown placement and 12 months after crown placement [Table 1]. Cone beam computed tomography used for estimating

Table 1: Biological, mechanical, and patient-reported parameters

Biological parameters	Mechanical parameters	Patient-reported parameters
Implant survival: Assessed after 1-year function Marginal bone level: Recorded using a CBCT radiograph at the time of prosthetic loading and 1-year follow-up Plaque accumulation: Using MPI Bleeding tendency: Using MSI Peri-implant inflammation: Using modified GI	Screw loosening: The abutment or prosthetic screw was tightened to 25 Ncm according to the manufacturer's recommendation using a customized digital torque meter. After 10 min, torque of 25 Ncm was reapplied. 10 min later of screw retightening, the RTV was measured by rotating the screwdriver in an anticlockwise direction. These readings were recorded at the time of prosthetic loading and 1-year follow-up and screw loosening was calculated using the following formula RTL ratio before loading $= \frac{\text{Tightening torque - removal torque before loading}}{\text{Tightening torque}} \times 100$ RTL ratio after loading $= \frac{\text{Tightening torque - removal torque after loading}}{\text{Tightening torque}} \times 100$ Screw loosening $= \frac{\text{Removal torque before loading - removal torque after loading}}{\text{Removal torque before loading}} \times 100$	A 1-year follow-up questionnaire consisting of 11 questions was used to evaluate the patient's feelings, functions, and esthetics. Patients rated their overall satisfaction on a 10-point scale from 0 to 10

RTL: Removal torque loss, MPI: Modified plaque index, MSI: Modified sulcus index, GI: Gingival index, CBCT: Cone-beam computed tomography, RTV: Reverse torque value

the marginal bone loss also helps assess the health of the implant, evaluating the bone quantity and quality changes, thus verifying secondary implant stability [Figures 5 and 6]. The compiled data were tabulated and assessed using statistical tests which include the paired *t*-test and Wilcoxon signed-rank test for within-group assessments and the independent *t*-test and Mann–Whitney test for between-group evaluations. The analysis was conducted using SPSS version 23 IBM Corporation, Armonk, NY, USA.

Figure 4: Final prosthesis screwed and screw access hole sealed

RESULTS

Comparing the marginal bone level, it was noticed that the mean marginal bone level significantly reduced in the ASC abutment group from baseline to 1-year follow-up ($P = 0.001$), and the mean marginal bone loss was estimated to be 0.51 mm. Likewise, the mean marginal bone level was significantly reduced in the MU abutment group from baseline to the 1-year follow-up ($P = 0.002$), and the mean marginal bone loss was estimated to be 0.39 mm. Although the estimated marginal bone loss was lower in the MU abutment group than the ASC abutment group, it was not statistically significant [$P = 0.449$, Table 2].

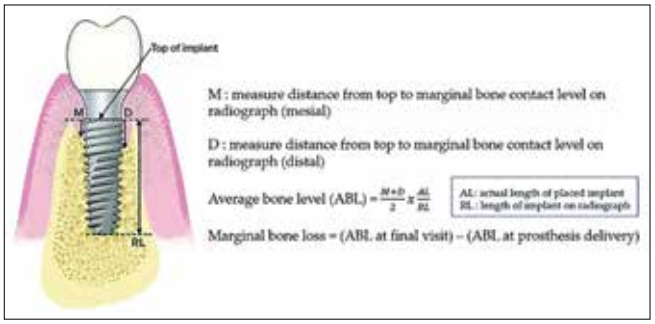

Figure 5: Calculation of marginal bone levels. ABL: Average bone level

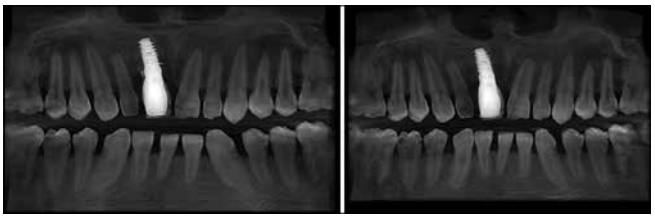

Figure 6: Cone-beam computed tomography assessment (right): At the time of prosthetic loading (left): At 1-year follow-up

Modified plaque index (MPI) values increased in both the groups from baseline to 1-year follow-up, although the rise was not statistically significant ($P = 0.564$ for the ASC abutment group and $P = 0.564$ for the MU abutment group). At baseline and 1-year follow-up, MPI was higher for the MU abutment group than the ASC abutment group, yet this disparity was statistically insignificant ($P = 0.735$ at baseline, $P = 0.782$ at 1-year follow-up). When comparing the modified sulcus index (MSI), it was found that the ASC abutment group had increased MSI values from baseline to 1-year follow-up while the MU abutment group had decreased MSI values from baseline to 1-year follow-up. The variances between the two groups, however,

were not deemed statistically significant (P = 0.317 for the ASC abutment group and P = 0.157 for the MU abutment group). MSI was found to be higher in the MU abutment group than the ASC abutment group at baseline whereas higher in the ASC abutment group than the MU abutment group at 1-year follow-up, which was statistically insignificant (P = 0.930 at baseline, P = 0.387 at 1-year follow-up). When comparing the gingival index (GI), it was shown that the MU abutment groups' GI values increased from baseline to 1-year follow-up, whereas the ASC abutment group's values decreased. However, these differences were statistically insignificant for any group (P = 0.705 for the ASC abutment group, P = 0.655 for the MU abutment group). GI was found to be lower in the MU abutment group than the ASC abutment group at baseline whereas higher in the MU abutment group than the ASC abutment group at 1-year follow-up which was statistically insignificant (P = 0.632, P = 0.970 at baseline, P = 0.632 at 1-year follow-up) [Table 3].

Removal torque loss (RTL) significantly increased within both the groups from baseline to 1-year follow-up (P = 0.001 for the ASC abutment group, P = 0.046 for the MU abutment group). When comparing mechanical parameters, the baseline RTL value was significantly lower in the ASC abutment group as compared to the MU abutment group (P = 0.003). RTL value in the ASC abutment group was lower at the 1-year follow-up than in the MU abutment group, but the variance was not statistically significant (P = 0.081). Screw loosening was higher for the MU abutment group than the ASC abutment group, and yet it was not statistically significant [P = 0.081, Table 4]. There was no statistically significant difference between the two groups' responses to any of the questions, revealing that both the groups were equally accepted by patients [Table 5].

DISCUSSION

The previous literature reveals no clinical studies of single-implant restoration using MU abutment. This may be due to high risk of prosthesis rotation and screw loosening. In this study, single MU abutment was taken as we hypothesized that if anti-rotational feature in MU is used with tight and proper proximal contacts, then MU abutment could prove to be an equally viable treatment option for single-unit implant restorations as ASC abutment. Since there were no statistically significant differences between the two groups for any of the parameters, the null hypothesis was accepted. First, the implant survival rate was evaluated among the biological parameters, and it was noticed that both the groups' overall implant survival rates were 100% as none of the 20 implants failed at the 1-year follow-up. Studies by Maló *et al*.,[23] Sánchez-Torres *et al*.,[24] and Hamudi *et al*.[25] on multiple MU abutments for implant-supported restorations proved a high implant survival rate. The studies by Pol *et al*.,[15] Wang *et al*.,[26] Tallarico *et al*.,[27] Anitua *et al*.,[28] and Shi *et al*.[29] show a similar high survival rate with ASC abutments. On the other hand, studies by Friberg and Ahmadzai[17] and Di Fiore *et al*.[30] showed slightly lower implant survival rates with ASC abutment than the present study. This might be result of longer follow-up period, more sample size, or posterior implant site.

Next, biological parameter is marginal bone loss. In accordance with Albrektsson *et al*.'s implant success defining guidelines marginal bone loss of <1.5 mm in the 1st year postinsertion is acceptable, as is marginal bone loss of <0.2 mm/year thereafter.[31] In this study, the

Table 2: Comparison of biological parameters (marginal bone level) in angulated screw channel group and multi-unit group at baseline and at 1-year follow-up

Group	Mean±SD		Mean marginal bone loss (mm)	*P*
	Mean marginal bone level at baseline (mm)	Mean marginal bone level at 1 year (mm)		
ASC group	2.21±0.54	(−) 2.72±0.62	0.51	0.001*
MU group	2.68±0.76	(−) 3.07±0.71	0.39	0.002*
P	-	-	0.449	

*Significant difference at $P \leq 0.05$. (−) symbol indicates a decrease in bone level from baseline. SD: Standard deviation, ASC: Angulated screw channel, MU: Multi-unit

Table 3: Comparison of periodontal parameters (modified plaque index, modified sulcus index, and gingival index) in angulated screw channel group and multi-unit group at baseline and at 1-year follow-up

Group	MPI			MSI			GI		
	At baseline (mean)	At 1-year follow-up (mean)	*P*	At baseline (mean)	At 1-year follow-up (mean)	*P*	At baseline (mean)	At 1-year follow-up (mean)	*P*
ASC group	0.82±0.60	0.09±0.54	0.564	0.73±0.47	0.82±0.62	0.317	1.27±0.65	1.18±0.60	0.750
MU group	0.90±0.57	1.00±0.82	0.564	0.80±0.79	0.60±0.70	0.157	1.20±0.92	1.30±0.68	0.655
P	0.735	0.782		0.936	0.387		0.970	0.632	

MPI: Modified plaque index, MSI: Modified sulcus index, GI: Gingival index, ASC: Angulated screw channel, MU: Multi-unit

Table 4: Comparison of mechanical parameters (removal torque loss and screw loosening) between angulated screw channel and multi-unit groups at baseline and at 1-year follow-up

Mechanical parameter	Mean±SD		*P*
	ASC	MU	
At baseline RTL	4.86±1.95	8.55±2.99	0.003*
1-year follow-up RTL	11.93±2.74	33.86±35.29	0.081
P	0.001*	0.046*	
Screw loosening	7.44±1.45	30.33±36.89	0.081

*Significant difference at $P \leq 0.05$. ASC: Angulated screw channel, MU: Multi-unit, SD: Standard deviation, RTL: Removal torque loss

Table 5: Comparison of patient-reported parameters at 1-year follow-up

	Mean±SD		*P*
	ASC	MU	
Q1	1.09±1.14	0.56±0.88	0.263
Q2	1.09±1.04	0.33±0.50	0.062
Q3	1.18±1.40	0.67±1.12	0.384
Q4	2.18±2.14	1.78±2.11	0.677
Q5	2.09±1.14	1.33±1.00	0.135
Q6	0.36±0.67	1.33±1.41	0.059
Q7	0.55±0.82	0.89±0.78	0.354
Q8	8.36±1.80	9.22±0.83	0.206
Q9	9.18±0.87	9.33±0.87	0.703
Q10	8.73±2.41	9.56±0.53	0.328
Q11	8.91±2.70	9.44±0.73	0.572

ASC: Angulated screw channel, MU: Multi-unit, SD: Standard deviation

average marginal bone loss in the ASC abutment group from baseline to 1-year follow-up was 0.51 mm. The observed bone loss was statistically significant ($P = 0.001$) and within the limit of implant success defining criteria by Albrektsson *et al.* These values recorded show a trend similar to previous studies but reflect slightly higher marginal bone loss values than the studies by Friberg and Ahmadzai,[17] Di Fiore *et al.*,[30] Tallarico *et al.*,[27] Pol *et al.*,[15] and Anitua *et al.*[28] The MU abutment group had a statistically significant mean marginal bone loss of 0.39 mm ($P = 0.002$). However, these values still fall within the implant success criteria established by Albrektsson *et al.*[31] Hamudi *et al.*[25] in a study reported almost similar readings after 3-year follow-up. At 1-year follow-up, marginal bone loss for the MU abutment group was slightly lower than for the ASC abutment group, but there was no statistically significant difference. It indicates that both the groups meet the implant success criterion in terms of marginal bone loss. In order to comprehend the changes in long-term marginal bone loss surrounding these abutments, longer follow-ups are required.

The next biological indicator is periodontal indices which are crucial for determining peri-implant health. In the current study, the ASC abutment group's MPI, MSI, and GI did not significantly change between baseline and 1-year follow-up. The MU abutment group's indices exhibited no significant changes at baseline and at 1-year follow-up. At baseline and the 1-year follow-up, there was no statistically significant difference in any of the indices between the ASC and MU abutment groups. It implies that both the groups had comparable peri-implant soft tissue alterations at the 1-year follow-up.

Under the mechanical parameters, screw loosening is assessed using RTL values. The RTL values increased significantly from baseline to 1-year follow-up in both the ASC and MU abutment groups. This suggests that significant RTL occurred in both abutments. When compared between the groups, the baseline RTL value was significantly lower ($P = 0.003$) in the ASC abutment group as compared to the MU abutment group. The RTL values before loading may be influenced by screw material, abutment-implant fit, torque device accuracy, and settling effect. Studies[32,33] suggest that screw tightening can cause a loss of 2%–10% of preload due to microroughness between implant and abutment surfaces. Therefore, it is suggested to tighten abutment screws again 10 min after applying the initial torque in order to reduce the settling effect and screw loosening. Retightening is more crucial for MU abutments to combat the settling effect and reduce screw loosening compared to ASC abutments.

However, there was no statistically significant difference in RTL at 1-year follow-up. This reveals that ASC resists better RTL than MU abutment initially, but after multiple retightening, both abutments show similar results at 1 year of function. The screw-loosening effect was similar for each group. In the MU abutment group, out of ten cases, two cases were reported with 100% screw loosening during the follow-up of 1 year. Proper investigation revealed the occurrence of porcelain fracture at the proximal contact area in both cases. These loose proximal contacts could have led to increased crown rotation and thereby screw loosening.

The present study did not investigate the angle of occlusal load on implant-retained restorations. The maximum angle correction achieved was 28° in the ASC abutment group and 30° in the MU abutment group. It was hypothesized in this study that there is no effect of angulation on screw loosening, which is in consensus with a study by Goldberg *et al.*[34] Conversely, a study by El-Sheikh *et al.*[35] stated that after dynamic loading, screw loosening increases with increasing abutment angulations and collar length. The variables such as type of implant-abutment connection, geometrical morphology, material used, abutment fabrication technique, design of screw and implant, type of restorations, and length of screw influence screw loosening.

Further studies are needed to investigate their effect on ASC and MU abutments to draw concrete conclusions.

Patient-reported parameters have always been noticeably underreported in research. Subjective assessment utilizing the patient's opinions of the esthetic outcome as determined by established questionnaires wherein patients reveal their level of satisfaction or disapproval. [Questionnaire 1]. Negative feeling evaluation showed a mean of 1.12 and 0.52 (closer to not likely) for the ASC and MU groups, respectively. Discomfort in function values revealed a mean of 1.23 and 1.33 (closer to not likely) for the ASC and MU groups, respectively. It was thus inferred that patients reported low negative feelings and low discomfort in function, which indicates better patient satisfaction for both the groups. Esthetic appearance shows a mean of a mean of 8.79 and 9.38 (closer to more likely) for the ASC and MU groups, respectively, which further show better patient satisfaction in terms of esthetics. This study revealed that patients' feelings, function, and esthetics were not dependent on the type of abutment.

Limitations of this study were its limited sample size and short-term follow-up. The high cost and limited documented clinical success rate of these abutments as single-unit implant restoration have restricted their application in day-to-day practice. Thus prospective studies with longer follow-ups and larger sampling sizes are required to comprehend the possible biological, mechanical, and patient-reported parameters, and draw concrete decisions about the superiority of either of abutments.

CONCLUSION

Within the constraints of this study, it can be stated that the ASC and MU abutments with anti-rotation features can be used as an effective alternative for screw-retained restorations in cases of nonaxially loaded implant with remarkable clinical outcomes after 1 year of function. To further validate the esthetic and functional efficacy of these abutments, it is essential to conduct *in vivo* research with a larger sample size and extended follow-up duration.

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Conflicts of interest

There are no conflicts of interest.

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QUESTIONNAIRE

Questionnaire 1

Feeling:

Q1. Have you ever experienced any feeling of shame or apprehension due to your implant cap?
प्रश्न1. क्या आपने कभी अपने इम्प्लांट कैप के कारण किसी शर्म या संकोच का अनुभव किया है?

Q2. Do you ever experience any decrease of self-confidence due to your implant cap?
प्रश्न2. क्या आपने कभी अपने इम्प्लांट कैप के कारण आत्मविश्वास में कमी का अनुभव किया है?

Q3. Do you still feel the absence of natural tooth?
प्रश्न3. क्या आप अभी भी प्राकृतिक दांतों की कमी महसूस करते हैं?

Function:

Q4. Are you reluctant to chew food with the implant cap?
प्रश्न4. क्या आप इम्प्लांट कैप के साथ भोजन चबाने में झिझकते हैं?

Q5. Do you find it harder to chew food after the implant cap is in place?
प्रश्न5. इम्प्लांट कैप लगाने के बाद क्या आपको खाना चबाना मुश्किल लगता है?

Q6. Have you experienced any changes in pronunciation of any word after placement of the implant cap?
प्रश्न6. क्या आपने इम्प्लांट कैप लगाने के बाद किसी भी शब्द के उच्चारण में किसी बदलाव का अनुभव किया है?

Q7. Have you experienced any change of taste while eating with your implant cap?
प्रश्न 7. क्या आपने अपने इम्प्लांट कैप के साथ भोजन करते समय स्वाद में किसी बदलाव का अनुभव किया है?

Esthetics:

Q8. Does the color of your implant cap matches with the color of your natural tooth?
प्रश्न 8. क्या आपके इम्प्लांट कैप का रंग आपके प्राकृतिक दांत के रंग से मेल खाता है?

Q9. Does the shape of your implant cap matches with shape of your natural tooth?
प्रश्न 9. क्या आपके इम्प्लांट कैप का आकार आपके प्राकृतिक दांत के आकार से मेल खाता है?

Q10. Does the color of the gums around your implant cap match with color of the gums around your natural tooth?
प्रश्न10. क्या आपके इम्प्लांट कैप के आसपास के मसूड़ों का रंग आपके प्राकृतिक दांत के आसपास के मसूड़ों के रंग से मेल खाता है?

Q11. Does the shape of gums around your implant cap match with shape of gums around your natural tooth?
प्रश्न11. क्या आपके इम्प्लांट कैप के चारों ओर मसूढ़ों का आकार आपके प्राकृतिक दांत के आसपास के मसूड़ों के आकार से मेल खाता है?

Research

Correlation of "K" plane to occlusal plane and three different ala-tragal lines in dentulous subjects with different skeletal forms: A cephalometric study

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Abstract

Aim: Orientation of the occlusal plane is an important clinical procedure for complete denture fabrication. An attempt had been made to reconstruct the occlusal plane using a different reference plane. The aim of this study was to find the correlation of the "K" plane to the occlusal plane and to assess the angular deviation between the K-plane to the occlusal plane (KO) with different skeletal forms.

Settings and Design: An *in vivo* observational study was conducted on dentulous subjects having Class I dental occlusion with different skeletal forms undergoing orthodontic treatment.

Materials and Methods: The study was conducted on 54 subjects aged 18–30 years. Metallic balls (3 mm in diameter) were attached to the desired landmarks, and a lateral cephalogram was taken for each subject. Cephalometric analysis was done using the Dolphin Imaging software, and the values obtained were recorded and subjected to statistical analysis.

Statistical Analysis Used: The values obtained were recorded and subjected to statistical analysis using simple descriptive analysis, Shapiro–Wilk test, Mann–Whitney *U*-test, and Pearson's correlation.

Results: A positive correlation was found between KO with a mean angular deviation of 8.59° ± 3.05°. The angle was found to be steeper in skeletal Class II subjects.

Conclusions: Clinical application of the K-plane to use as a reference plane to orient the posterior occlusal plane can enhance the treatment outcome for a removable prosthesis. The results of this study provide a theoretical foundation for the practical restoration of the occlusal plane in different skeletal forms.

Keywords: Ala tragal line, K-plane, lateral cephalogram, occlusal plane

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INTRODUCTION

Fabrication of a removable or fixed prosthesis requires the clinician to have a conscientious understanding of the components, structure, and qualities of the tissues that will support the proposed prosthesis. The occlusal plane is an average plane established by the incisal and occlusal surfaces of the teeth; in general, it is not a plane

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but represents the planar mean of the curvature of these surfaces (Glossary of Prosthodontic Terms-9).[1]

An accepted reference plane in an edentulous subject is to orient the occlusal plane to the Camper's plane; however, its application is still debatable. The main source of contention in this matter is disagreement about the precise location on the tragus (superior, middle, and inferior) to draw the ala-tragal line.[2]

Kattan *et al*.[3] introduced a new soft-tissue extracranial horizontal plane of the head, the "K" plane, which is based on fixed craniofacial points, and was found to be a reliable substitute for the Frankfort horizontal (FH) plane. The K-plane is delineated by soft-tissue nasion (SN) (anterior reference point) and the superior attachment of the ear (SAE) (posterior reference point). The nuchal line at the rear of the head, which divides the skull into the cranial and facial sections, was also discovered to be on the same level as the K-plane during the research.

The utility of the "K" plane to be used as an acceptable guide to determine the occlusal plane is not yet researched. The goal of this clinical study was to determine the relationship of the new reference plane (K-plane) to the occlusal plane. If this relationship was proven to be trustworthy and clinically perceptible, it would aid in orienting the occlusal plane in edentulous patients. Regardless of the occlusal relationship, a patient may have had when they had their full complement of teeth, the orientation of the occlusal plane changes with different skeletal forms. There are few studies employing cephalometry to compare differences in the occlusal plane in various skeletal forms.

The null hypothesis of this study was that there is no correlation of the K-plane to the occlusal plane (KO).

Therefore, the purpose of the research study was to find the correlation of the "K" plane to the occlusal plane and to assess the angular deviation between KO and K-plane to different ala-tragal lines with different skeletal forms.

MATERIALS AND METHODS

Study setting and source of data

The following study was carried out in the department of prosthodontics, and approval for the study was obtained from the Institutional Review Board and Ethics Committee (YEC2/2023/013); a total of 54 subjects who were willing to undergo orthodontic treatment were recruited based on the selection criteria and patient consent form. Eighteen subjects having either Class I, Class II, or Class III skeletal jaw relation were recruited for the study.

Study design

This was a cross-sectional study.

Sampling method

Simple random sampling was used.

Sample size

Sample size estimation was done using G*power software (Version 3.1.9.7, Faul *et al*., 2009, Germany, and the sample required in each to test the above-mentioned effect size at a 5% level of significance and 90% power will be equal to 18.

Therefore, the total sample size for the study will be equal to 54.

Inclusion criteria

1. Age group of 18–30 years
2. Full complement of permanent dentition (excluding third molars)
3. Dental Class I occlusion
4. Skeletal Class I, Skeletal Class II, and Skeletal Class III growth pattern.

Exclusion criteria

Subjects with:

1. Facial asymmetry
2. Developmental anomalies
3. History of trauma
4. Attrition of teeth
5. Temporomandibular joint pathologies
6. Extensive restorations and missing teeth
7. Previous history of orthodontic treatment
8. Periodontal disease, including periodontal pockets, trauma from occlusion, and pathological drifting of teeth
9. Presence of crowns and fixed dental prostheses.

Criteria for three different ala-tragal lines used in the study

1. Superior ala-tragal line (SAT): a line passing from the superior part of the tragus to the lower border of the ala of the nose (AN)
2. Middle ala-tragal line (MAT): a line passing from the middle part of the tragus to the lower border of the AN
3. Inferior ala-tragal line (IAT): A line passing from the inferior part of the tragus to the lower border of the AN.

Criteria for selection of skeletal patterns based on angles obtained after cephalometric analysis

Angular measurements were measured to know about the skeletal pattern of the patient; the angular measurements that were measured were:

1. Angle ANB
2. Yen angle
3. Wits appraisal.

The range at which the angles and measurements were categorized into different skeletal patterns was:

1. Skeletal Class I: Angle ANB (1.6°–3.1°), Yen angle (113°–123°), and Wits appraisal (−1 mm to 1 mm)
2. Skeletal Class II: Angle ANB (more than 3.1°), Yen angle (<113°), and Wits appraisal (more than 1 mm)
3. Skeletal Class III: Angle ANB (<1.6°), Yen angle (more than 123°), and Wits appraisal (< -1 mm or less than -1 mm).

Criteria for K-plane used in the study (K)

A line that is connecting the point on Superior attachment of the ear (SAE) to the point on soft tissue nasion (SN). Where SAE is the attachment of the superior part of the helix to the root of the scalp.

Method

The participants were asked to maintain a straight posture while holding their arms at their sides and focusing their eyes directly ahead at a faraway point. The superior-most and inferior-most sites of the tragus were marked with two lines. The tragus was divided into superior, middle, and inferior parts using the measurements made with a digital calliper in the aerospace over the distance between these two sites. On each subject, metallic balls (3 mm diameter) were adhered using a double-adhesive tape on the superior part of the tragus (ST), middle part of the tragus (MT), inferior part of the tragus (IT), lower border of the AN, SAE, and SN such that these points are visible on the radiograph as shown in Figure 1a and b.

Once the individual is in the cephalostat (Planmeca ProMax), a left lateral cephalogram is radiographed using a standard operating procedure with the mandible closed in the maximum intercuspation. On a cephalometric film (Kodak C-Mat Green Sensitive 8" ×10"), all lateral cephalometric radiographs were taken using a cephalostat. The exposure settings were 70 kVp, 10 mA, and 1 s. Ray's entrance occurs from the right to the left.

Radiopaque markers were seen on the lateral cephalogram at the designated landmarks as shown in Figure 2. The junction of the upper and lower incisal margins on the cephalogram, as well as the point on the mesiopalatal cusp on the upper first molar, were used to determine the occlusal plane. Cephalometric reference points were marked as shown in Figure 3 and Table 1. Angle ANB, Yen angle, and the distance for Wits appraisal were obtained using digital tracing using Dolphin Software (version 11.65, Patterson Dental Supply, St. Paul, MN, USA) to determine the subject's skeletal form.

The skeletal form of the subject and the angular deviation between KO, K-plane to SAT plane as shown

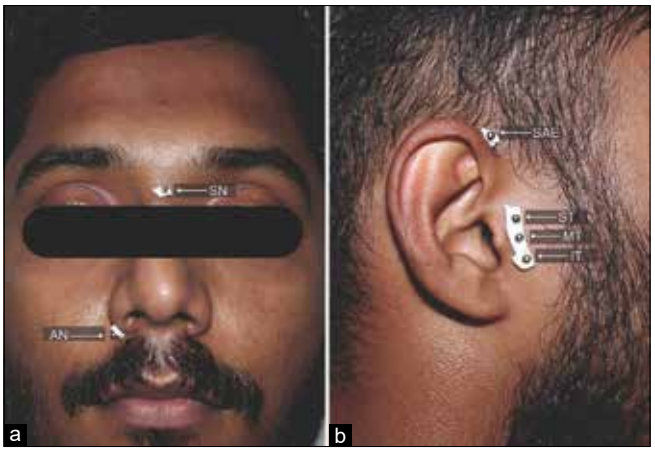

Figure 1: (a and b) Metallic balls placed on the landmarks. (a) Frontal view. (b) Lateral view. SAE: Superior attachment of the ear, ST: Superior part of the tragus, MT: Middle part of the tragus, IT: Inferior part of the tragus, SN: Soft-tissue nasion, AN: Ala of the nose

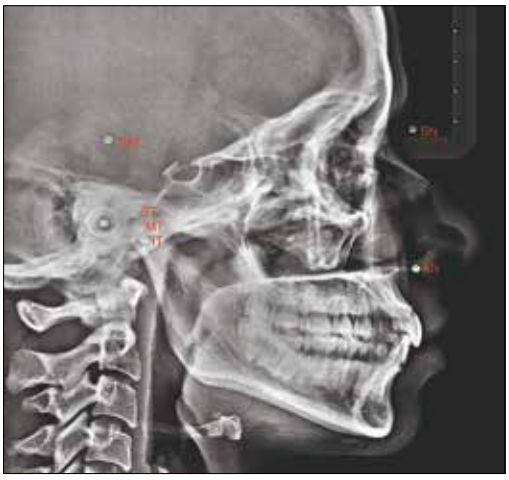

Figure 2: Lateral cephalogram showing radiopaque markers on the designated landmarks. SAE: Superior attachment of the ear, ST: Superior part of the tragus, MT: Middle part of the tragus, IT: Inferior part of the tragus, SN: Soft-tissue nasion, AN: Ala of the nose

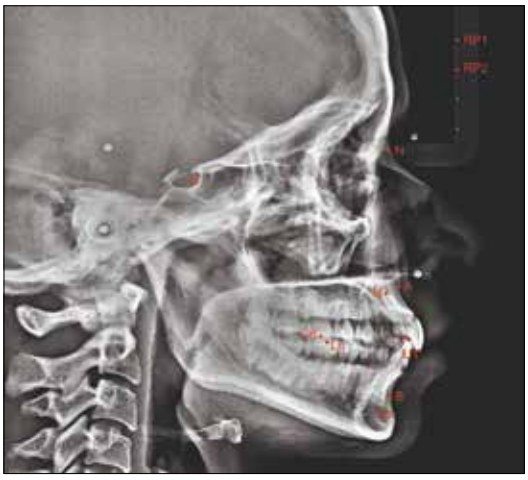

Figure 3: Cephalometric landmarks in the craniofacial region for the determination of skeletal form. Table 1 for the definition of landmarks

in Figure 4a and b, K-plane to MAT plane and K-plane to IAT plane as shown in Figure 5a and b were measured using information from 54 cephalometric radiographs and Dolphin imaging software (version 11.65, Patterson Dental Supply, St. Paul, MN, USA).

To determine the angular deviation between the K-plane and occlusal plane, the results obtained were collected and subjected to statistical analysis using simple descriptive analysis. When comparing various skeletal forms, the Shapiro–Wilk test was used to confirm the normality assumption. A nonparametric test, Kruskal–Wallis test, was performed to compare the KO, KSAT, KMAT, and KIAT planes in various skeletal forms. Pearson's correlation analysis was done to find out the correlation between the K-plane and three different ala-tragal lines to the K-plane and occlusal plane.

Table 1: Definition of cephalometric reference points used in the study

Abbreviations	Landmarks
RP 1	Calibration ruler for accurate reference for linear measurement magnification correction
RP 2	Calibration ruler for accurate reference for linear measurement magnification correction
Sella (S)	Centre of the pituitary fossa of the sphenoid bone
Nasion (N)	Junction of the frontal and nasal bones, at most anterior
Point A (A)	The deepest point on the curvature of the maxillary alveolar process
Point M (M)	Constructed point representing the center of the biggest circle that is tangent to the frontal, upper, and palatal surfaces of the maxilla
Point B (B)	The most anterior measure point of the mandibular apical base
Point D (D)	Centre of symphysis
Upper occlusal 6 (U6)	The point on the occlusal surface of the upper first molar
Lower occlusal (L6)	The point on the occlusal surface of the lower first molar
Upper central incisor tip (U1)	Adjacent midpoint of the maxillary central incisor
Lower central incisor tip (L1)	Adjacent midpoint of the mandibular central incisor

RP: Ruler point 1

Table 2: Descriptive statistics of cephalometric analysis showing the angulation between the K-plane and occlusal plane in dental Class I occlusion in different skeletal forms

	Mean±SD	Median	IQR
KO (angular measurements)	8.598±3.050	8.80	3.68

SD: Standard deviation, KO: K-plane to occlusal plane, IQR: Interquartile range

RESULTS

This study was carried out on a total of 54 subjects. These subjects were then subjected to cephalometric analysis. The results are statistically analyzed and then tabulated. The results obtained were measured in terms of degrees using the Dolphin Imaging software version 11.65 (Patterson Dental Supply, St. Paul, MN, USA).

The mean angular deviation between the K-plane and the occlusal plane in dental Class I occlusion was found to be 8.5° ±3.05° [Table 2].

The angular deviation between KO in Class I skeletal forms was 7.5 ± 3.2, Class II skeletal form was 10.2 ± 2.4, and in Class III skeletal form was 8.15 ± 3.6. Moreover, these values are found to be statistically significant ($P < 0.05$). The angular deviation between the K-plane to the superior, middle, and IAT lines is also found to be statistically significant [Table 3].

The angular deviation between the K-plane and SAT to KO was 0.522, the K-plane and MAT to KO was 0.586, and the K-plane and IAT to KO was 0.605 and was found to have a positive correlation ($P < 0.05$), where K-plane was kept as a constant plane [Table 4].

DISCUSSION

The null hypothesis was rejected as there was a positive correlation which was found between KO.

Rehabilitation of individuals who have lost all of their teeth is a tedious process because it calls for a thorough understanding of the biological and mechanical features of the stomatognathic system in an edentulous condition. For the best biomechanical and physiological success of the treatment outcome, establishing the plane of occlusion is one of the aspects to be taken into consideration.[4] The superior, middle, and IAT lines may all be taken into consideration to determine the plane of

Table 3: Descriptive statistics of cephalometric analysis showing the angulation between the K-plane to the occlusal plane and K-plane to three different ala-tragal lines in different skeletal forms

	Class 1		Class 2		Class 3		*P*
	Median	IQR	Median	IQR	Median	IQR	
KO (angular measurements)	7.5	3.2	10.2	2.475	8.15	3.675	0.002*
KS (angular measurements)	12	2	12.75	2.625	12.5	3.25	0.001*
KM (angular measurements)	9.1	2.4	10.3	2.65	9.5	2.575	0.000*
KI (angular measurements)	10.2	2.9	11.2	2.025	10.9	2.6	0.002*

*$P<0.05$ and is statistically significant. IQR: Interquartile range, KO: K-plane to occlusal plane

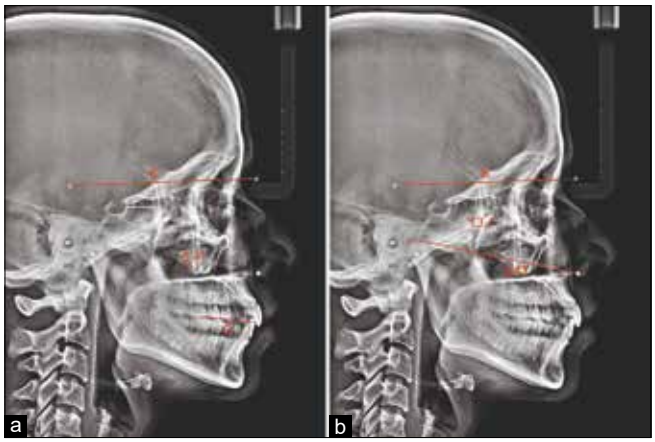

Figure 4: (a and b) Lateral cephalogram showing angular measurements. (a) Between the K-plane to the O plane. (b) Between the K-plane to the SAT plane. SAT: Superior ala tragal line

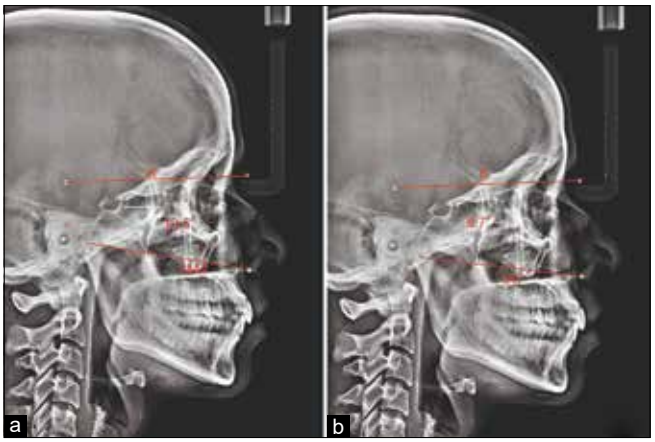

Figure 5: (a and b) Lateral cephalogram showing angular measurements. (a) Between the K-plane to the MAT plane. (b) Between the K-plane to the IAT line. MAT: Middle ala-tragal line, IAT: Inferior ala-tragal line

Table 4: Descriptive statistics of cephalometric analysis showing the correlation of the K-plane and three ala-tragal lines to the K-plane and occlusal plane in different skeletal forms using Pearson's correlation test

Variable	Pearson's correlation value	*P*
KS (angular measurements) - KO (angular measurements)	0.522	0.000*
KM (angular measurements) - KO (angular measurements)	0.586	0.000*
KI (angular measurements) - KO (angular measurements)	0.605	0.000*

*$P<0.05$ and is statistically significant. KO: K-plane to occlusal plane

occlusion, according to previous studies.[5,6] These planes are based on arbitrary landmarks, and the reliability to use and choose any of the three different ala-tragal lines is questionable and controversial.

Kattan *et al*.[3] found in his study that the K-plane is both reliable clinically and radiographically and can be utilized as a trustworthy reference plane. The K-plane, which is angulated at 0°–1° to the FH plane, has definitive and fixed craniofacial points, and its relationship to the occlusal plane and three different ala tragal lines has not been researched.

Hassouna *et al*.[7] concluded that the occlusal planes were found to have an impact on different skeletal patterns, wherein the variation in angulation of different occlusal planes had affected both the sagittal and vertical facial patterns. However, studies and literature support regarding the effect of different skeletal patterns on the orientation of the occlusal plane are scarce. Therefore, this study was undertaken to find out the correlation and angular deviation between KO and different ala-tragal lines having different skeletal forms.

The mean angular deviation between KO was found to be 8.5° ± 3.05°. Nirav *et al*.[8] analyzed and found that the mean angular deviation between different ala-tragal lines to the occlusal plane in dentulous subjects was 7.8° ± 4.55°. Subhas *et al*.[9] found that the mean angular deviation between the FH plane to the occlusal plane was 10.6°. According to the Glossary of Prosthodontics,[1] the angular deviation from the FH plane to the occlusal plane was 10°. The results of the present study indicate that the K-plane and occlusal plane are not exactly parallel; however, the values are consistent with those of earlier studies. Another cephalometric study by Sadr and Sadr[5] also inferred that there is no parallelism between the three different ala-tragal lines to the occlusal plane.

Kumar *et al*.,[10] in their study comprising both dentulous and edentulous subjects, concluded that the mean angular deviation from the FH plane to the occlusal plane was 10.6° and 10.35°, SAT to the occlusal plane was 7.05° and 7.35°, and the palatal plane to the occlusal plane was 6° and 6.55°, respectively.

In the present study, the angular deviation between the K-plane to SAT was found to be 11.35° ± 2.52°, which is in accordance with the study done by Kumar *et al*.,[10] who concluded that the angular deviation from the FH plane to SAT was 11°. Gandhi *et al*.[11] concluded in his study that the angular deviation between the FH plane to MAT and IAT was 14.3° and 10.7°, respectively. The values are in congruence with the present study, wherein the angular deviation between the K-plane to MAT was 10.8° ± 2.4° and K-plane to IAT was 10.2° ± 2.21°. It was discovered that the values obtained when measuring the angular deviation between the FH plane to the occlusal plane and FH plane to three different ala-tragal lines in various studies were equivalent to those obtained when measuring the angular deviation between KO and three different ala-tragal lines.[10,11]

When evaluated with various skeletal forms, it was found that the angular deviation between the K-plane and occlusal plane and three different ala-tragal lines was statistically significant [Table 3]. In addition, skeletal Class II patients were found to have a substantially greater angular deviation than skeletal Class I or Class III skeletal subjects; this conclusion is consistent with the research by Hassouna *et al*.[7] and Čelar *et al*.[12]

A positive correlation was found between the angular deviation of 'K' plane and three different ala-tragal lines to 'K' plane to Occlusal plane. This implies that when the K-plane is maintained as a constant plane, the angle varies positively and that when the value of one grows, the other similarly increases.

A reference plane that is based on fixed craniofacial points must be found to restore the occlusal plane in edentulous subjects as closely as feasible to the location of the previous natural teeth. The results of this study indicate that the K-plane, which is based on fixed anatomic landmarks, is clinically assessable, reliable, and repeatable and that it may be used as a reference guide to position the occlusal plane in patients who are completely edentulous.

Limitations of the study

1. Further studies comprising a larger sample size are required to truly assess the reliability of KO and K-plane to three different ala-tragal lines in different skeletal forms
2. The angular deviation in the present study is only researched in dental Class I occlusion. As the plane of occlusion varies with different head forms and different dental occlusion, further studies are required to analyze the angular deviation with these parameters
3. This study was carried out in subjects within the age group of 18–30 years. The use of the reference plane is to help us orient the occlusal plane in older individuals who are completely edentulous. Age changes were not taken into consideration in this study as it results in residual ridge resorption which led to a change in the inclination of the occlusal plane, thereby necessitating the arrangement of artificial teeth in their existing stomatognathic condition.

CONCLUSIONS

Within the limitations of this study, the K-plane can be used as a reference guide to orient the occlusal plane in completely edentulous individuals although there is no exact parallelism that exists between the K-plane and occlusal plane. Orientation of the occlusal plane should be done according to different skeletal patterns for completely edentulous patients.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Influence of wearing complete denture on the glycemic control, serum lipid, and proteins in patients with diabetes

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Abstract

Aims: The aim of this study was to assess the impact of prosthodontic rehabilitation on glycemic and lipid control in functionally and completely edentulous patients with diabetes.

Setting and Design: An *in vivo* study conducted with the intention of studying the potential link between edentulism and impaired masticatory efficiency with the nutritional status in diabetic patients.

Materials and Methods: A total of 20 diabetic patients based on the inclusion criteria were selected. They were rehabilitated using a removable prosthesis, and observations were made across three parameters – glycosylated hemoglobin (HbA1C), serum cholesterol (S col), and serum protein (SP) at three stages – baseline, 3 months, and 6 months posttreatment. This was done to gauge the impact of the prosthetic rehabilitation on their health due to an increased masticatory efficiency potentially causing changes in dietary patterns.

Statistical Analysis Used: •Inter group comparison (>2 groups) was done using one way ANOVA followed by pair wise comparison using post hoc test. •Intra group comparison was done using repeated measures ANOVA (for>2 observations) followed by post Hoc test. For all the statistical tests, $P < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error ati20%, thus giving a power to the study as 80%.

Results: Hba1c at the baseline had a mean value of 8.04%, which reduced to 7.87% at the 3-month stage and 7.38% at the 6-month stage. S col at the baseline had a mean of 151.6 mg/dL; at the 3-month follow-up, it was 166.5 mg/dL, and at the 6-month follow-up, it was 173.95 mg/dL. SP had a mean baseline value of 6.38 mg/dL, which progressed to 6.67 mg/dL at the 3-month stage and 6.97 at the 6-month stage.

Conclusion: Within the limitations of this study, it can be concluded that after 6 months of prosthetic rehabilitation in edentulous/functionally edentulous patients:

1. There was a reduction in HbA1c (8.04%-7.38%); however, it was found to be statistically insignificant at that stage
2. There was an increase in S col (151.6 mg/dL–173.95 mg/dL); it was found to be statistically significant

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3. There was an increase in SP (6.38 mg/dL–6.97 mg/dL); however, it was found to be statistically insignificant at that stage.

Keywords: Complete denture, diabetes, diet, mastication

INTRODUCTION

As per the latest data submitted by the International Diabetes Federation, an estimated 537 million adults are living with diabetes globally. The number is projected to be 643 million by 2030.[1-3] Periodontitis has been widely accepted as the 6th complication of diabetes, leading to premature loss of teeth and relying on artificial teeth. This, in turn, is accompanied with a great challenge in maintaining an effective masticatory mechanism, leading to crippling restrictions on diet.[4] Rehabilitation of edentulous areas not only restores esthetics but also oral function and chewing efficiency. However, lower masticatory performance is associated with patients with extensive loss of teeth, causing a restriction in diet due to avoidance of foods that are hard to chew.[5]

A controlled and balanced diet forms one of the fundamental means of managing and countering diabetes and hypercholesterolemia.[6] A high fiber and protein-rich diet with limited carbohydrates is recommended. The same may pose a challenge in edentulous patients as dietary fibers and proteins require a greater masticatory function to ingest.[6] Thus, rehabilitation and restoration of masticatory function should be of prime importance to provide the denture wearer the complete nutrition.[7]

To estimate the nutritional status, some critical parameters such as glycosylated hemoglobin (HBA1c), cholesterol, and serum proteins (SPs) can be measured. HbA1c, described as the glycated form of hemoglobin present in the blood, is accepted as a reliable indicator of the average blood glucose concentration in the preceding 6–8i weeks. It is, hence, considered a long-term indicator of diabetic control.[8] Cholesterol (S. L) is the main lipid found in the blood, bile, and brain tissue. It is also one of the most vital steroids in the body and a precursor to most steroid hormones. Gauging the levels of serum cholesterol (S col) may disclose changes in nutritional status and diet.[8] Proteins constitute the major position of the dissolved substances present in plasma. They are the basic structural component of the body. They consist of the enzymes present in the body and act as secondary sources of energy. Proteins are usually found in foods such as pulses meats and soy, which are challenging to ingest without effective mastication. Gauging the SP will indicate a change in the dietary patterns.[8]

Thus, the present study evaluated the impact of prosthodontic rehabilitation on glycemic and lipid control in functionally and completely edentulous patients with diabetes.

The objectives of this study were:

1. To measure the HbA1c, serum lipid levels, and SP of diabetic edentulous/partially edentulous patients before denture fabrication and insertion
2. To measure the HbA1c, serum lipid levels, and SP of diabetic edentulous/partially edentulous patients 3 months after denture fabrication and insertion
3. To measure the HbA1c, serum lipid levels, and SP of diabetic edentulous/partially edentulous patients 6 months after denture fabrication and insertion
4. To compare the values obtained from the above and study the impact of the insertion of the prosthesis.

MATERIALS AND METHODS

This was an *in vivo* study conducted in the department of prosthodontics and crown and bridge on a total of 20 patients (time-bound convenience sampling). Ethical approval granted from the Institutional Ethical Committee ABSMIDS ref no.- ABSM/EC/89/2021.

The patients selected for the study had to meet the following criteria:

1. Diabetic patient (HbA1c >6.5%) at the start of the study
2. Completely edentulous patient/functionally edentulous patients (<6 teeth present)
3. The state of the current dentition has been constant (without a history of the previous denture) for at least 3 months to obtain accurate baseline readings
4. The patient agrees to informed consent to be part of the study.

The selected patients were prosthodontically rehabilitated with a removable prosthesis (removable partial denture/complete denture) in the department of prosthodontics and crown and bridge, by postgraduate students. Routine blood testing for their HbA1c and serum lipid levels at three stages – pretreatment, 3 months posttreatment, and 6 months posttreatment were carried out. A semiautomated biochemistry analyzer (Agappe Mispa, Agappe Diagnostics, Kerala) was used for all tests. HbA1c measurement was

done using latex-enhanced immunoturbidimetry. The measurement of S col (total) and SPs was carried out using a standardized semiautomated high-throughput enzymatic analyzer.

The readings were tabulated and assessed to inspect the impact of the treatment. Patients were counseled regarding the chewing capabilities of the prosthesis and diet. Patients were encouraged to attempt to have foods they previously avoided due to challenges in chewing. They were counseled regarding nutrition and encouraged to test the capabilities of the prosthesis in a phased manner. Patients were asked to continue routine consultations with physicians for the treatment of diabetes and follow pharmaceutical protocol as advised.

All other factors were attempted to be maintained for the duration of the study.

Avoidance of confounding factors

Diabetes is a condition whose management is affected by a range of factors, including but not restricted to – nature diet, type of medication (pharmacokinetic and pharmacodynamic factors), activity, and psychological status.

In an attempt to study the impact of the factor of masticatory efficiency independently, the following measures were taken:

- Patients' medication (dosage and specific drug) was not changed (as per guidance by the physician) from 3 months before the study extending to the entire time period of the study
- Patients' dietary preferences were maintained (vegetarian/nonvegetarian diet); patients were encouraged to eat as per their natural desires as they gradually adjusted to the prosthesis over the period of the study
- All dentures were fabricated by postgraduate students in the same department using the same denture base resin (AcrypolR, Ruthinium group, Gujarat) and semi-anatomic teeth (Biorock, Brulon group, Gujarat) based on the arch size.

Statistical procedures

The sampling was done using time-bound convenience sampling for 2 years.

Data obtained were analyzed using the following:

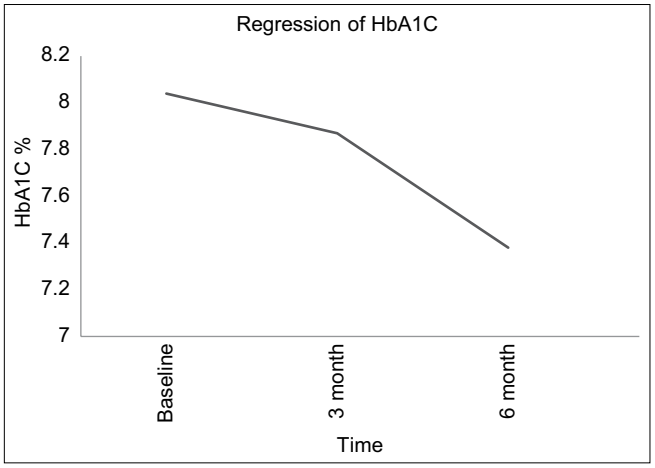
- Data were subjected to statistical analysis using the Statistical Package for the Social Sciences (SPSS v 26.0, IBM, Chicago, Illinois, USA)
- The normality of numerical data was checked using the Shapiro–Wilk test and was found that the data followed a normal curve; hence, parametric tests have been used for comparisons
- Intergroup comparison (>2 groups) was done using the one-way ANOVA, followed by pair-wise comparison using a *post hoc* test
- An intragroup comparison was done using repeated measures ANOVA (for >2 observations), followed by a *post hoc* test.

RESULTS

Table 1 shows the intragroup comparison of values of HbA1C, SP, S col, and weight, and the readings were taken at three intervals.

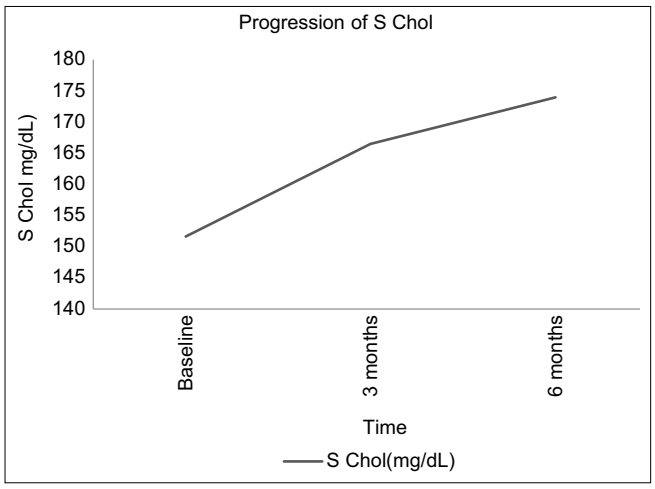
Hba1c at the baseline had a mean value of 8.04%, which reduced to 7.87% at the 3-month follow-up and 7.38% at the 6-month follow-up [Graph 1 shows regression and Table 2 shows intragroup comparison using the Tukey-HSD]. HbA1C is one of the most reliable methods of gauging long-term glucose control. The reduction from the baseline to the 6-month follow-up was found to be statistically insignificant by a slight margin ($P = 0.052$). The results can be attributed to a change in diet from the patient and a reduction in reliance of having softer foods (e.g., rice, fruit juices, and khichdi) which are carb rich and highly glycemic. Carbohydrates are digested faster by the body, and hence, the patient also tends to have a greater number of meals which can cause unhealthy spikes in the blood sugar, which have been found to be more harmful than a constant blood sugar albeit above normal values.

S col at the baseline had a mean of 151.6 mg/dL; at the 3-month follow-up, it was 166.5 mg/dL, and at the 6-month follow-up, it was 173.95 mg/dL [Graph 2 shows



Graph 1: Regression of glycosylated hemoglobin seen for 6 months

regression and Table 3 shows intragroup comparison using Tukey-HSD]. Edentulous patients and the geriatric population, in general, have been found to have high incidences of malnutrition; initial figures of the S col were on the borderline of normal, and as time progressed, the values shifted more toward the normal range. The results were found to be statistically significant. This can be attributed to better absorption of fats due to better masticatory efficiency and increased intake of food by the patients.



Graph 2: Progression of serum cholesterol seen for 6 months

SP had a mean baseline value of 6.38 mg/dL, which progressed to 6.67 mg/dL at the 3-month stage and 6.97 at the 6-month stage [Graph 3 shows regression and Table 4 shows intragroup comparison using Tukey-HSD]. Proteins and fibers are highly recommended for diabetics as alternative sources of energy for diabetics due to their lower glycemic index. The change increase in levels was found to be statistically insignificant. The increase can be attributed to the increase in the ability of patients to have tougher foods (meats, pulses, and soy). This can be further

Table 1: Intragroup comparison of values of glycosylated hemoglobin, serum protein, and serum cholesterol – readings taken at three intervals

	Time	*n*	Mean	95% CI for mean		Minimum	Maximum	*F*	*P* of RM ANOVA
				Lower bound	Upper bound				
HbA1c	1	20	8.040000	7.627946	8.452054	6.8000	10.4000	3.046	0.052#
	2	20	7.875000	7.461138	8.288862	6.7000	10.2000		
	3	20	7.380000	6.970134	7.789866	6.3000	9.4000		
SP	1	20	6.380000	5.930429	6.829571	4.9000	8.1000	2.197	0.120#
	2	20	6.670000	6.271688	7.068312	5.2000	8.0000		
	3	20	6.975000	6.564214	7.385786	5.6000	8.5000		
Serum cholesterol	1	20	151.65	144.91	158.39	136	187	8.416	0.001**
	2	20	166.50	158.40	174.60	142	211		
	3	20	173.95	164.45	183.45	148	230		

HbA1C: Glycosylated hemoglobin, SP: Serum protein, CI: Confidence interval, RM: Repeated measure. **=Statistically highly significant difference ($P<0.01$), #=Non significant difference ($P>0.05$)

Table 2: Intragroup pair-wise comparison of glycosylated hemoglobin using Tukey-honestly significant difference

Dependent variable studied	I time	J time	Mean difference (I–J)	SE	*P*	95% CI	
						Lower bound	Upper bound
HbA1c	1	2	0.1650000	0.2783331	0.825#	−0.504786	0.834786
		3	0.6600000	0.2783331	0.052#	−0.009786	1.329786
	2	3	0.4950000	0.2783331	0.186#	−0.174786	1.164786

CI: Confidence interval, SE: Standard error, HbA1C: Glycosylated hemoglobin

Table 3: Intragroup pair-wise comparison of serum cholesterol using Tukey-honestly significant difference

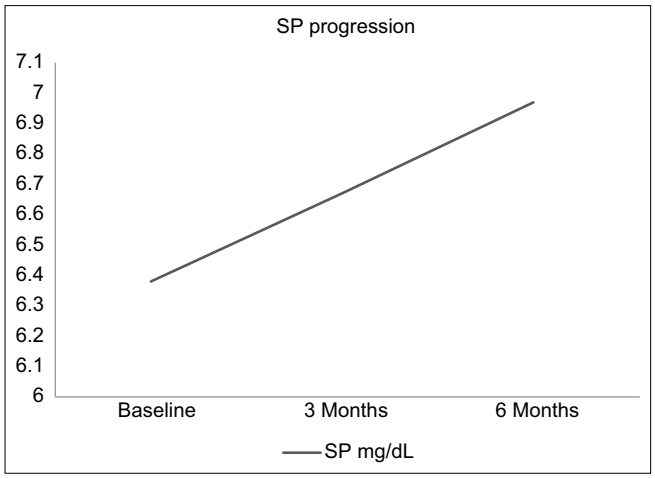
Dependent variable studied	I time	J time	Mean difference (I–J)	SE	*P*	95% CI	
						Lower bound	Upper bound
Serum cholesterol	1	2	−14.850*	5.534	0.025*	−28.17	−1.53
		3	−22.300*	5.534	0.000**	−35.62	−8.98
	2	3	−7.450	5.534	0.376#	−20.77	5.87

CI: Confidence interval, SE: Standard error. *=Statistically significant difference ($P<0.05$), **=Statistically highly significant difference ($P<0.01$), #=Non significant difference ($P>0.05$)

Table 4: Intragroup pair-wise comparison of serum protein using Tukey-honestly significant difference

Dependent variable studied	I time	J time	Mean difference (I–J)	SE	*P*	95% CI	
						Lower bound	Upper bound
SP	1	2	−0.2900000	0.2838689	0.566#	−0.973107	0.393107
		3	−0.5950000	0.2838689	0.100#	−1.278107	0.088107
	2	3	−0.3050000	0.2838689	0.534#	−0.988107	0.378107

SP: Serum protein, CI: Confidence interval, SE: Standard error. #=Non significant difference ($P>0.05$)



Graph 3: Progression of serum protein seen for 6 months

increased if an implant-supported prosthesis is used as they have been found to have a masticatory efficiency comparable to natural teeth.

DISCUSSION

Diabetes mellitus (DM) is a chronic disease characterized by poor control of blood glucose. This is caused by the impaired action of insulin, either due to a deficiency of insulin or the body's inability to effectively use the insulin it produces. Insulin is a regulator of blood glucose. Its impairment produces a state of hyperglycemia, meaning raised blood glucose – a common outcome of poorly controlled diabetes, and what eventually causes its several complications.[1-3,9]

The acute complications of DM include diabetic ketoacidosis, hyperosmolar hyperglycemic syndrome, hypoglycemia – loss of consciousness, seizures that occur due to skipped meals, excessive exercise, and excessive doses of antidiabetic medication.[9]

The chronic complications of DM caused lead to a state of chronic inflammation, which leads to the generation of free radical species. These lead to vascular injury and reduced blood flow, which affects various organs. Some of these are – cerebrovascular diseases such as stroke, retinopathy, and periodontitis causing premature loss of teeth, and cyclical vomiting syndrome conditions such as cardiac failure, hypercholesterolemia, nephropathy, neuropathy, and generalized slow healing. Hence, preventing complications, reducing the morbidity and mortality associated with diabetes, has clear implications on improving the overall quality of life of the patient.[9]

The cost-effectiveness and efficacy of nutrition therapy as parts of superior diabetic care are supported by strong evidence, by integrating it into the holistic management of diabetes apart from medical care. Diet counseling, for maintaining or improving glycemic control, improving risk factors for cardiovascular disease (e.g., blood pressure, lipids), and achieving weight management goals, within individualized treatment plans for all persons with DM and prediabetes as specified by the ADA, is recommended.[10-12] Reduction of the HbA1c values with nutritional therapy has been reported similar to or greater than what would be expected with medication treatment for type 2 diabetes.[6]

The impaired masticatory function may lead to inadequate food choice and, therefore, alter nutrient intake. A compromised masticatory efficiency will naturally lead to a decrease in intake of food that is tough to chew, which is generally protein- and fiber-rich food, or to swallowing of food without proper chewing which will cause malabsorption. This could lead to malnutrition and increased reliance on softer foods, generally carbohydrates and saturated fats which are harmful to diabetics.[7] The results of this study show that with an effective rehabilitation of masticatory apparatus, there could be a positive change in both choices of foods and overall nutritional status. This is consistent with the findings of a study by Suzuki *et al*., who found that simply dietary instructions and the fabrication of a new complete denture lead to improved protein intake and nutritional status. This can help limit disorders associated with improper diet.[7]

This study aimed to rehabilitate masticatory efficiency using removable complete dentures. A study by Allen and McMillan revealed that in the restoration of masticatory function, using a complete denture is 80% less efficient than natural.[13] Implant-supported full-mouth rehabilitation was found to result in better masticatory efficiency in an independent study.[14]

This study was carried out for 6 months with three tests taking place at the start of the study, at 3 months, and at 6 months. The first 2–6 weeks after the insertion of a new prosthesis are considered the adjustment period for the patient as the bone undergoes minor remodeling, and the patient gets used to a foreign body in the mouth. Since the patients in the study were all first-time denture wearers and had no history of previous prosthetic rehabilitation, it would be expected that they would take slightly longer to function with the dentures.[15]

The changes in the parameters tested were less marked comparing the results from the baseline to the 3-month test to the ones from the 3 months to the 6-month test.

This can be attributed to this initial adjustment period from the patient in the initial 20–40 days.[16]

A study to evaluate the nutritional status of edentulous patients pre- and postdenture insertion was conducted by Pandey *et al*., who showed results consistent with the current study, in which BMI, blood calcium, protein, HDL, Hb, and cholesterol levels were monitored before denture insertion and 3, 6, and 12 months after insertion. The changes in the counts before and after complete denture insertion were found to be statistically significant, and it was concluded that prosthetic rehabilitation of complete edentulism leads to an improvement in nutritional parameters.[17]

A study found a positive impact on nutritional status and BMI when comparing edentulous patients rehabilitated with dentures to those who have not.[18,19] Another factor that cannot be overstated is the aspect of mental health in the management of DM. With the restoration of teeth in edentulous patients, there is a reduction in embarrassment and an increase in confidence, which put the patient in a greater sense of peace and well-being. A well-made complete denture can truly change a person's life by bringing back a smile on their faces. Proper postoperative instructions and counseling are, hence, vital to keep the patients' spirits high and motivation to be healthier.[20]

A systematic review conducted suggested that denture wearers had reduced eating function when compared to dentate counterparts; however, wearing dentures had a positive impact on nutrition and enjoyment of eating.[21] Multiple studies have indicated a positive influence on the eating-related quality of life when comparing edentulous patients using complete dentures to edentulous patients without complete dentures.[22,23] There are studies in the literature that have found inconclusive links between masticatory efficiency and nutrition.[24]

With the study results, we could potentially consider masticatory rehabilitation as one of the factors to be taken in maintaining systemic health and considered in the holistic treatment of DM.

CONCLUSION

With the results of this study, it can be concluded that after 6 months of prosthetic rehabilitation in edentulous/functionally edentulous patients:

1. There was a reduction in HbA1c (8.04%-7.38%); however, it was found to be statistically insignificant at that stage
2. There was an increase in S col (151.6 mg/dL–173.95 mg/dL); it was found to be statistically significant at that stage
3. There was an increase in SP (6.38 mg/dL–6.97 mg/dL); however, it was found to be statistically insignificant at that stage.

Scope for further research

Further studies with a larger sample size and a longer follow-up will yield more accurate and valuable results.

Further studies can be conducted comparing the progress using different modalities of prosthodontic rehabilitation, for example, implant-supported prostheses and overdentures.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

An *in vivo* study to assess and compare the angular, linear, and depth deviation as well as the difference in bone density of implants placed using computer-aided design/computer-aided manufacturing fabricated three-dimensional guides versus the implants placed using bone pen kit in maxillary and mandibular ridges

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Abstract

Aim: The aim is to assess and compare angular, linear, and depth deviation and difference in bone density of dental implants placed using computer aided design/computer aided manufacturing (CAD/CAM) fabricated surgical guides versus implants placed using Bone Pen Kit. Till now, no original research exists in the search engines such as Pubmed, Google Scholar, Science Direct, and Research Gate on this kit.

Settings and Design: *In vivo*- Randomised control trial.

Materials and Methods: Twenty clinical cases were selected and split into two distinct groups. Group 1 involved the placement of 10 implants using CAD/CAM fabricated three dimensional guides and Group 2 involved the placement of 10 implants using Bone Pen Kit. Four deviation parameters were evaluated, which included: (a) Angular deviation, (b) Linear deviation at implant platform, (c) Linear deviation at implant apex, and (d) Depth deviation and difference in bone density before and after implant placement was also evaluated.

Statistical Analysis Used: SPSS software version 23 was utilized for the analysis of the data. The comparison was made using the Whitney test, and Wilcoxon signed rank test.

Results: When comparing angular deviation, the results indicated a statistically significant difference with a $P < 0.05$. The values observed for angular and linear deviation in Group 2 were significantly greater

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than those in Group 1. No statistically significant difference in depth and linear deviation was found at the implant platform among the two groups. Bone density before and after implant placement was significantly higher in Group 1.

Conclusions: (1) Angular and linear deviation at the apex in Group 2 exhibited higher values in comparison to Group 1, (2) No difference in depth and linear deviation at the implant platform was found among the two groups, and (3) There was no difference in change in bone density among two groups.

Keywords: Bone pen kit, computer-aided design/computer-aided manufacturing, guided implant surgery

INTRODUCTION

Advancements in oral implantology research have led to improved restorative options that are highly effective and reliable for patients with partial and complete edentulism. Improper implant site selection can significantly and frequently undermine the long-term predictability and success of long-term implant prosthesis.[1]

To achieve a successful treatment outcome, comprehensive presurgical planning is necessary. This planning entails careful consideration of anatomical and prosthetic factors to ensure proper implant positioning. When dealing with complex or compromised patients, relying solely on traditional periapical and panoramic imaging techniques, as well as visual inspection and clinical palpation, may not be adequate for optimal presurgical planning.[2]

The effectiveness of implants and prostheses supported by implants relies on the appropriate treatment strategy. A significant complication that can arise from implant failure is when the implant fixture is improperly positioned, resulting in failures in both the prosthetic component and the surrounding tissue, as well as an unsightly appearance. Employing a prosthetically driven approach to position implants is a fundamental notion that enhances the likelihood of achieving favorable outcomes in implant-supported prostheses.

With the advancements in dental implant technology, it is now feasible to virtually plan cases, minimizing errors and improving clinical results. It is even possible to create precise prosthesis that exhibit exceptional strength and in a wide range of materials, as well as computerized surgical guidance for quicker and less intrusive surgeries. The idea of stereolithography and computer-aided design/computer-aided manufacturing (CAD/CAM) technology can be combined to produce highly accurate surgical guide prototypes. This approach is based on accurate computed tomography (CT) scans of the bone anatomy, followed by the fabrication of computerized prototype surgical guides for implant placement based on mathematical three-dimensional (3D) models.[3]

A new concept for implant placement using BONE PEN KIT has been introduced in the field of implantology. This novel idea involving universally compatible drills has been recommended to enhance the accuracy of implant placement. Through the utilization of specialized drills, cups, and guide pins that help guide implant placement, the Bone Pen Guide Kit improves implant placement. It offers a simple approach for determining the size of the fixture as well as the size of the abutment in the future.

Thus, the aim of the present study was to assess and compare the accuracy of 3D positioning of dental implants placed using cone beam CT (CBCT)-generated surgical guides versus implants placed using Bone Pen Kit. This assessment and comparison were made on specific parameters such as angular deviation, depth deviation, linear deviation, and bone density before and after the placement of an implant. The null hypothesis postulated that the accuracy of implant placement would be comparable irrespective of the technique employed.

MATERIALS AND METHODS

Patient populations

A total of 20 patients having bilateral or unilateral partially edentulous ridges requiring single or multiple implants, regardless of gender, within the age range of 30–70 years were chosen.

Approval from Institutional Ethics Committee (University Ethics Committee (Medical) Swami Vivekanand Subharti University, Ref No: SMC/UECM/2021/246/154 was obtained before the study initiation. The research protocol, including study design, methods, and participant recruitment procedures, was thoroughly reviewed by the committee. The ethical implications and potential risks associated with the study were carefully considered during the evaluation process. Informed consent forms, information sheets, and other relevant study documents

were scrutinized to ensure compliance with ethical guidelines and regulations. The institutional ethics committee provided written approval, confirming that the study was ethically sound and in accordance with established ethical standards. All the implants in both groups were placed by a single operator, and no blinding was done. Patients with uncontrolled diabetes, recent myocardial infarction, and those undergoing intravenous bisphosphonate therapy were excluded from the study. In addition, patients who had undergone head-and-neck irradiation were also excluded from the study. Following clinical and radiographic evaluation, patients were subsequently divided into two groups:

- Group 1 – Implants placed using CAD/CAM fabricated 3D guides
- Group 2 – Implants placed using Bone Pen Kit.

Procedure

Assessment of implant site of Group 1

Preoperative radiographical assessment [Figure 1] along with clinical inspection [Figure 2a and b] was used to determine bone volumes and anatomic landmarks by CBCT investigation. A scan was performed to acquire CBCT data of the maxillary and mandibular jaws (Orthophos SL 3D, Dentsply Sirona). The obtained data were converted into Digital Imaging and Communications in Medicine File and also imported to the virtual implant planning software (Omega 3D). After the implant planning, a surgical guide devoid of stoppers but equipped with metal sleeves were meticulously created using the same software and subsequently printed using a commercial printable resin (Anycubic, photopolymer resin) in a 3D printer (Deplo Ackuretta) [Figure 3].

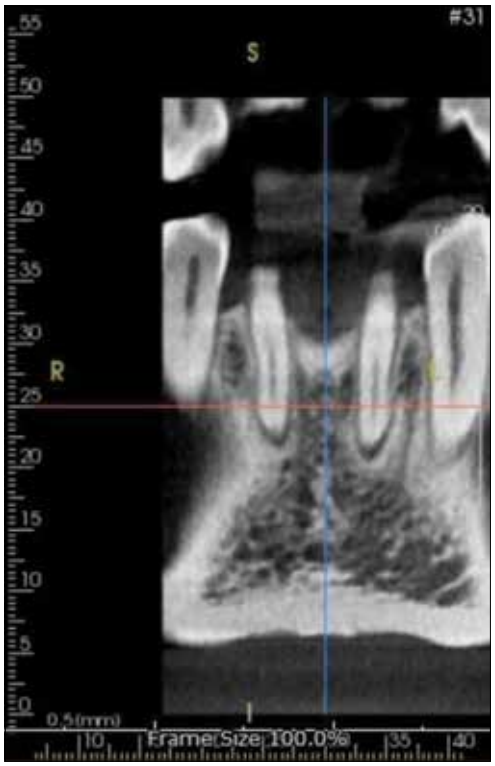


Figure 1: Preoperative cone beam computed tomography of Group I (computer-aided design/computer-aided manufacturing)

Surgical procedure of Group 1

The surgical site was prepared following a proper sterilization protocol, and anesthesia was administered using 2% lignocaine hydrochloride with epinephrine (1:200,000). The 3D printed guide was positioned at the intended implant placement site [Figure 4], and pilot drilling was performed with a lancet drill of 2.0 mm for the preparation of an osteotomy site of appropriate length [Figure 5].

Following implant placement, CBCT of the surgical site was performed [Figure 6]. Preoperative and postoperative CBCT were superimposed on each other for the evaluation of deviation parameters [Figure 7a and b].

The surgical procedure of Group 2

After preoperative radiographical assessment [Figure 8] along with clinical inspection [Figure 9a and b], preliminary steps were carried out similar to Group 1. Using the virtual implant planning software, a prosthetic implant plan was done. In Group 2, implants were placed using Bone Pen Kit [Figure 10]. The Bone Pen Kit included:

1. 2 Pen Drills (used in conjunction with the cups)
2. 5 Color-coded Cups in five diameters
3. 5 Color-coded Pins in five diameters to measure both vertical height and horizontal space.

A pen drill of appropriate length was selected and attached to the appropriate cup from the range of available cup diameters [Figure 11]. Coded pins were employed for the simultaneous measurement of both vertical height and horizontal space [Figure 12]. A latch-type shank was affixed to the handpiece of the implant motor, using a predetermined selected Drill guide width. The drill speed remained consistent across all patients, set at 800–100 rpm

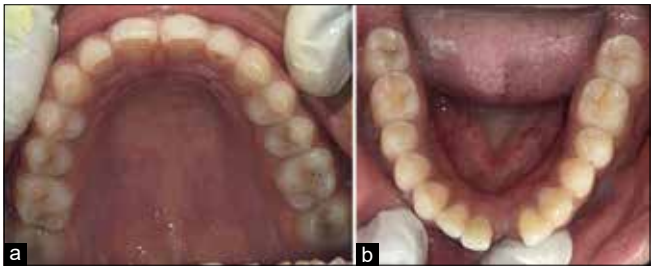


Figure 2: (a and b) Clinical intraoral view of Group I (computer-aided design/computer-aided manufacturing)

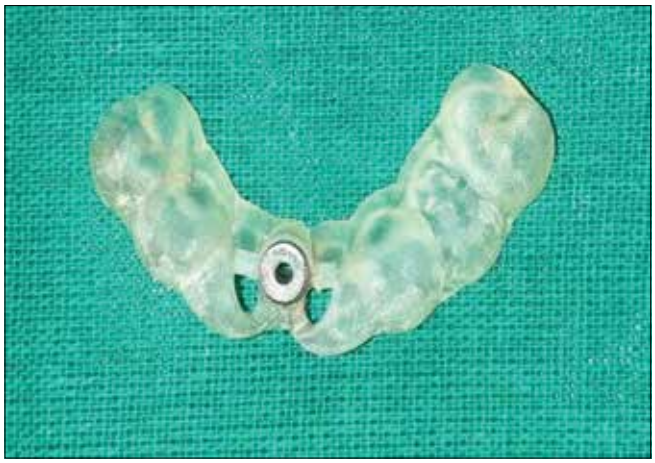


Figure 3: Computer-aided design/computer-aided manufacturing fabricated three-dimensional guide

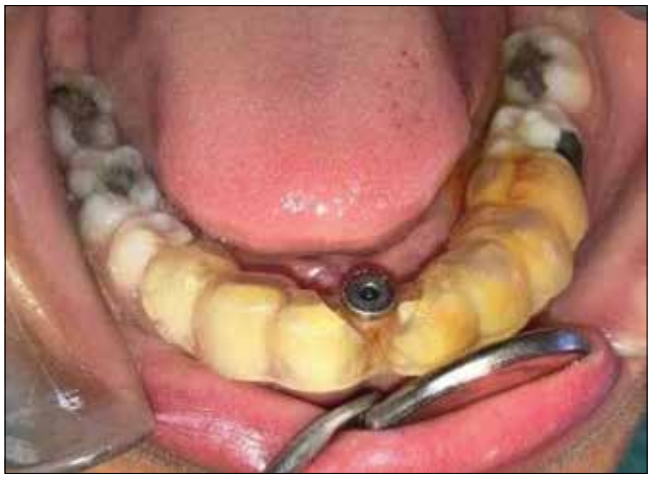


Figure 4: Adaptation of three-dimensional guide intraorally

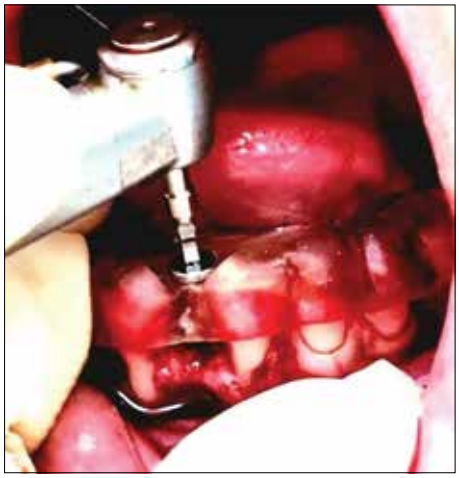


Figure 5: Pilot drilling through guide

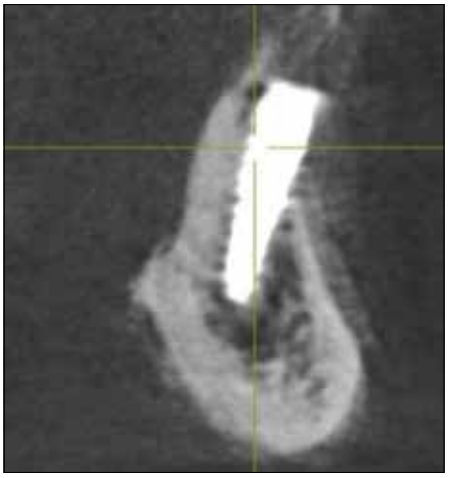


Figure 6: Cone beam computed tomography immediately after implant placement of Group I (computer-aided design/computer-aided manufacturing)

in D3 and D4 type bone and 1100–1200 rpm in D1 and D2 type bone, with a torque range of 35–40 Ncm, and irrigation was administered. Following the marking of site, a conventional 2.0 mm twist drill, commonly utilized for such procedures, was substituted, and the osteotomy site was prepared sequentially through conventional drilling methods.

Prosthetic phase for definitive prosthesis of Groups 1 and 2

After 3 months of implant placement, the implant site was uncovered, and a healing abutment was placed [Figure 13]. Patients were recalled after 2 weeks for implant impression [Figure 14]. After the fabrication of the prosthesis, the prosthesis fit and occlusion were checked and delivered to the patient [Figure 15].

Assessment of parameters

Pre- and postoperative CBCT scans were superimposed (Omega 3D software) and a 3D angle formed by the lines in dimensional space was measured, which determined the deviation that occurred between the virtually planned and actually placed implants. Four deviation parameters were evaluated between planned and placed implants which included: (a) Angular deviation, (b) Linear deviation at the implant platform, (c) Linear deviation at implant apex, and (d) Depth deviation [Figure 16]. For assessment of bone density: postoperative CT images were transferred to the Omega 3D software to determine bone density in Hounsfield units (HU). Measurements were done using this software through drawing region of interest in the axial images of the patient, a 1-mm area surrounding the implant, using all axial slices.

RESULTS

Differences between the mean and standard deviation of angular deviation, depth deviation, and linear deviation between the two groups were assessed. Angular deviation

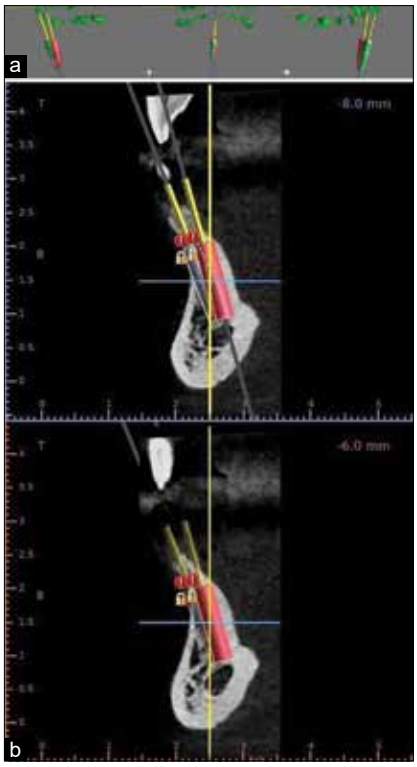


Figure 7: (a and b) Superimposed pre- and postoperative cone beam computed tomography of Group I

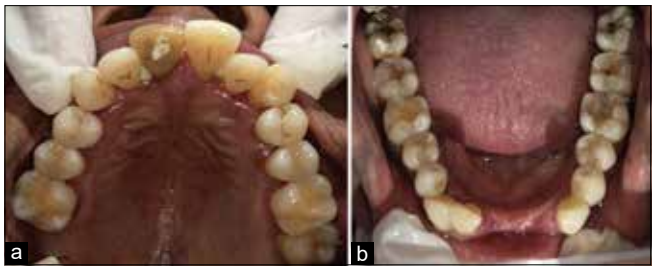


Figure 9: (a and b) Clinical Intraoral view of Group II (Bone Pen Kit)

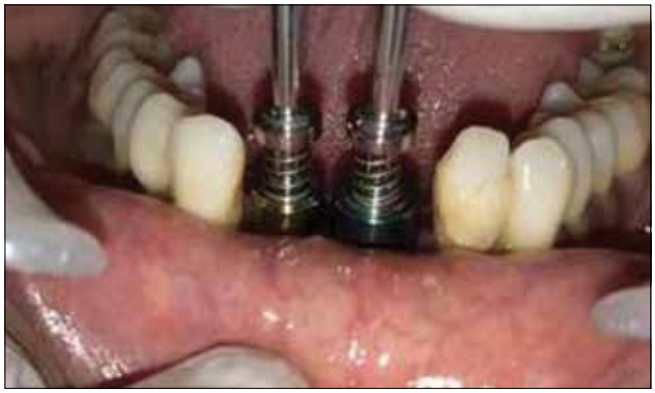


Figure 11: Pen drill attached to the cup of suitable diameter in Group II (Bone Pen Kit)

in Group 2 was significantly higher. It was 8.09° and 1.73° in Group 2 and Group 1, respectively. No difference in depth and linear deviation at the implant platform was

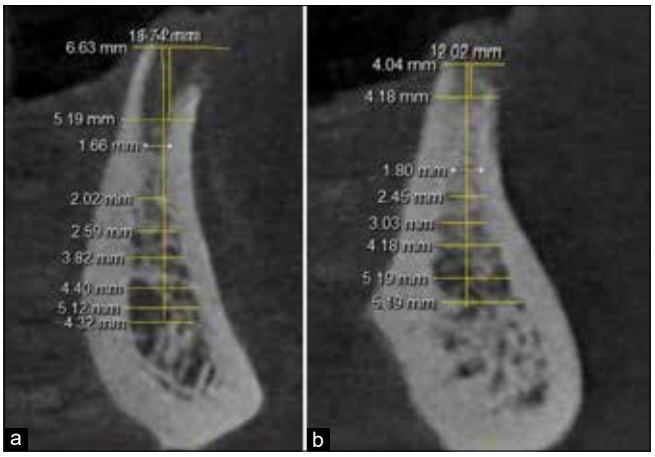


Figure 8: (a and b) Preoperative cone beam computed tomography of Group II (Bone Pen Kit)

Figure 10: Bone Pen Kit

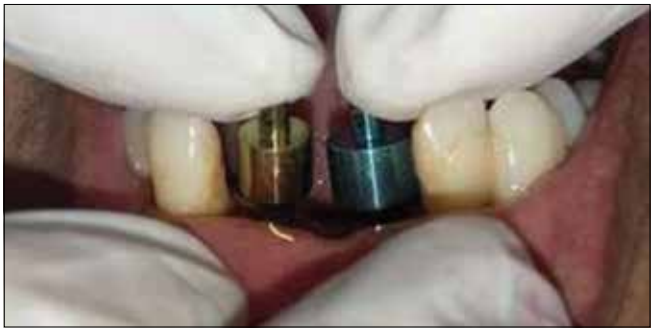


Figure 12: Color coded pins used to measure vertical and horizontal space in Group II (Bone Pen Kit)

found among the two groups. Linear deviation at apex in Group 2 was significantly higher, which was 4.72 mm as compared to Group 1, which was 1.2 mm. Bone density before and after implant placement was significantly higher in Group 1, which was 844.4 HU compared to Group 2, which was 635.8 HU. There was no difference in change in bone density among the two groups [Table 1 and Graph 1].

Differences between the mean and standard deviation of angular deviation, depth deviation, linear deviation, and

difference in the bone density between implants placed in the maxillary arch and mandibular arch in Group 1 were assessed using Mann–Whitney Test. No difference in angular deviation, depth deviation, linear deviation at the implant platform, and bone density before and after implant placement was found between the maxillary arch and mandibular arch in Group 1; however, linear deviation at the apex was significantly higher in the maxillary arch, which was 2.75 mm as compared to mandibular arch, which was 0 mm in Group 1 [Table 2 and Graph 2].

Differences between the mean and standard deviation of angular deviation, depth deviation, linear deviation, and bone density before and after implant placement in the maxillary arch and mandibular arch in Group II were assessed using Mann–Whitney Test. No difference in angular deviation, depth deviation, linear deviation, and bone density before and after implant placement at the apex was found between the maxillary and mandibular arch in Group II; however, linear deviation at the implant platform was significantly higher in the mandibular arch as compared to the maxillary arch. Linear deviation at the implant platform was 0.9 mm and 2.34 mm in the maxillary and mandibular arch, respectively, and bone density before implant placement was 551.8 HU and 719.8 HU in the maxillary and mandibular arch, respectively [Table 3 and Graph 3].

Differences between the mean and standard deviation of angular deviation, depth deviation, linear deviation, and bone density between implants placed in the maxillary arch of the two groups were calculated. There was no difference in angular deviation, depth deviation, linear deviation at the implant platform, and linear deviation at the apex between implants placed in the maxillary arch of the two groups [Table 4 and Graph 4].

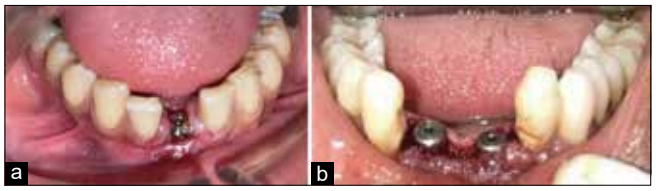


Figure 13: (a and b) Healing abutment placed 3 months after implant placement

Figure 15: Final prosthesis. Frontal view

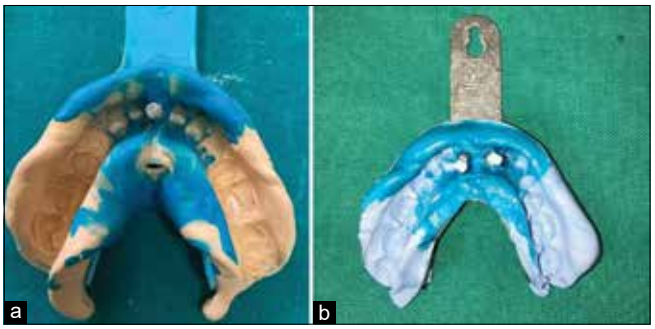


Figure 14: (a and b) Implant impression

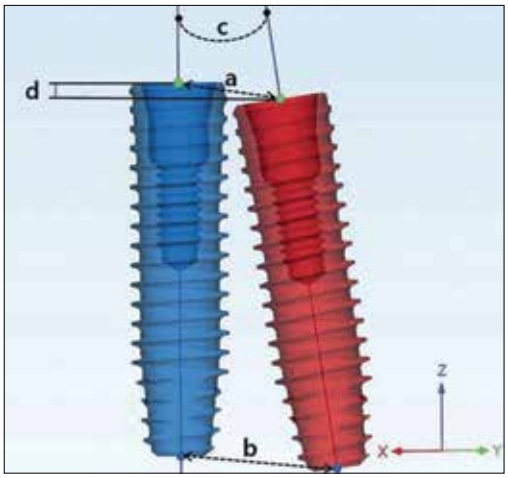


Figure 16: Four deviation parameters calculated between planned and placed implants. (a) Deviation at implant platform, (b) Deviation at implant apex, (c) Angular deviation, and (d) Depth deviation

Table 1: Difference between the mean and standard deviation of angular deviation, depth deviation, and linear deviation between two groups

Variable	Mean±SD		Difference	*P*
	Group I	Group II		
Angular deviation	1.73±1.26	8.09±6.15	−6.36	0.003*
Depth deviation	1.73±1.85	1.83±1.71	−0.10	0.684
Linear deviation (at implant platform)	0.50±0.81	1.62±1.33	−1.12	0.052
Linear deviation (at apex)	1.10±2.20	4.72±5.54	−3.62	0.023*
Bone density before implant placement	844.40±141.90	635.80±116.78	208.60	0.004*
Bone density after implant placement	1058.00±196.65	761.30±118.83	296.70	<0.001*
Change in bone density	213.60±72.24	125.50±129.86	88.10	0.199

*Significant difference at $P \leq 0.05$. Mann–Whitney test. SD: Standard deviation

Table 2: Difference between the mean and standard deviation of angular deviation, depth deviation, and linear deviation between implant placed in the maxillary arch and mandibular arch in Group I (computer-aided design and computer-aided manufacturing)

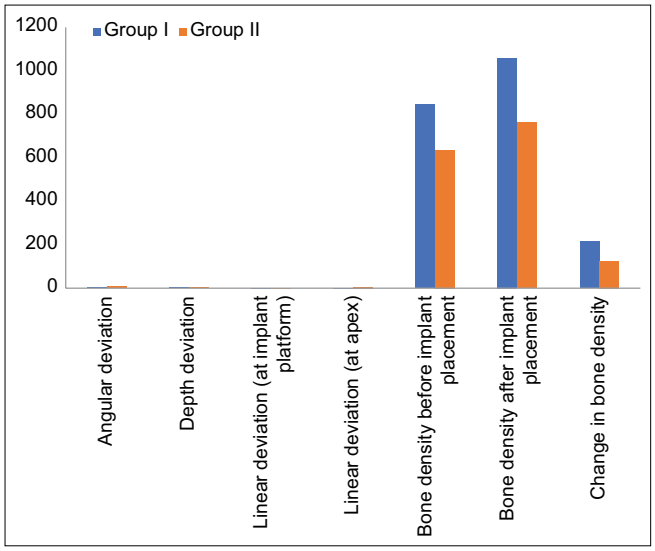
Variable	Mean±SD		Difference	*P*
	Maxillary arch	Mandibular arch		
Angular deviation	1.93±1.56	1.59±1.16	0.34	0.670
Depth deviation	3.15±2.14	0.78±0.85	2.37	0.067
Linear deviation (at implant platform)	1.05±1.10	0.13±0.20	0.92	0.184
Linear deviation (at apex)	2.75±2.90	0.00±0.00	2.75	0.018*
Bone density before implant placement	946.50±76.59	776.33±137.23	170.17	0.088
Bone density after implant placement	1193.00±170.03	968.00±167.22	225	0.136
Difference in bone density	246.50±105.12	191.67±36.32	54.83	0.285

*Significant difference at $P \leq 0.05$. Mann–Whitney test. SD: Standard deviation

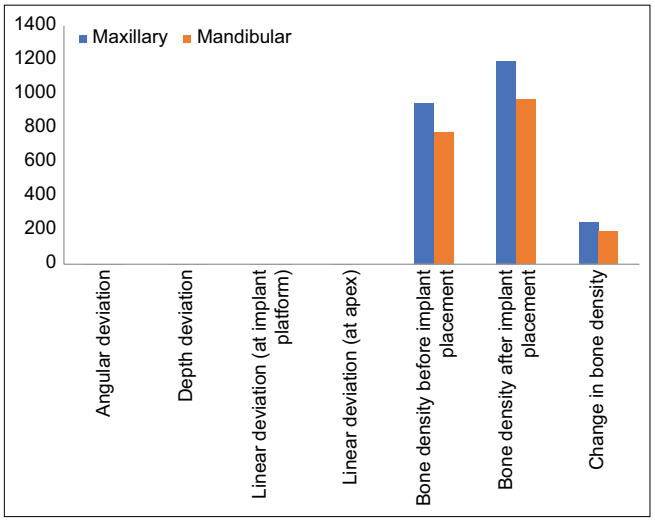
Table 3: Difference between the mean and standard deviation of angular deviation, depth deviation, linear deviation, and bone density between implant placed in the maxillary arch and mandibular arch in Group II (Bone Pen Kit)

Variable	Mean±SD		Difference	*P*
	Maxillary arch	Mandibular arch		
Angular deviation	9.50±7.43	6.67±4.99	2.83	0.602
Depth deviation	1.88±1.40	1.78±2.15	0.10	0.750
Linear deviation (at implant platform)	0.90±1.02	2.34±1.27	−1.44	0.045*
Linear deviation (at apex)	7.60±6.73	1.84±1.74	5.76	0.346
Bone density before implant placement	551.80±61.41	719.80±96.30	−168	0.028*
Bone density after implant placement	708.20±48.59	814.40±149.53	−106.20	0.249
Difference in bone density	156.40±96.40	94.60±162.06	61.80	0.602

*Significant difference at $P \leq 0.05$. Mann–Whitney test. SD: Standard deviation



Graph 1: Bar diagram of the comparison of angular deviation, depth deviation, the linear deviation, and Bone Density between two groups



Graph 2: Bar diagram of comparison of angular deviation, depth deviation, linear deviation, and bone density between the implants placed in maxillary and mandibular arch in Group I (computer-aided design/computer-aided manufacturing)

Differences between the mean and standard deviation of angular deviation, depth deviation, linear deviation, and bone density between the implant placed in the mandibular arch of each group were assessed using Mann–Whitney test. Angular deviation, linear deviation at the implant platform, and linear deviation at the apex were significantly higher in Group II and there was no difference in depth deviation or bone density before and after implant placement. The angular deviation was 1.59° and 6.67° in Group 1 and Group 2, respectively. Linear deviation at the implant platform was 0.13 mm and 2.34 mm in Group 1 and Group 2 respectively. Linear deviation at implant apex was 0 mm and 1.84 mm in Group 1 and Group 2, respectively [Table 5 and Graph 5].

Differences between the mean and standard deviation of bone density before and after implant placement in each group were assessed using Wilcoxon signed-rank test. An increase in bone density after implant placement was significant in each group [Table 6 and Graph 6].

Table 4: Comparison of angular deviation, depth deviation, linear deviation, and bone density between implants placed in the maxillary region of two groups

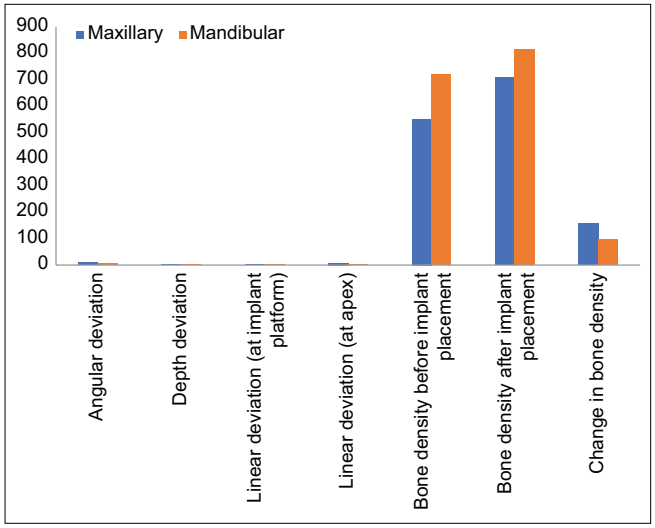
Variable	Mean±SD		Difference	*P*
	CAD-CAM	Bone Pen Kit		
Angular deviation	1.93±1.56	9.50±7.43	−7.57	0.086
Depth deviation	3.15±2.14	1.88±1.40	1.27	0.459
Linear deviation (at implant platform)	1.05±1.10	0.90±1.02	0.15	0.794
Linear deviation (at apex)	2.75±2.90	7.60±6.73	−4.85	0.268
Bone density before	946.50±76.59	551.80±61.41	394.70	0.014*
Bone density after	1193.00±170.03	708.20±48.59	484.80	0.014*
Difference in bone density	246.50±105.12	156.40±96.40	90.10	0.327

SD: Standard deviation, CAD-CAM: Computer-aided-design and computer-aided-manufacturing. *Indicates significant difference at $P \leq 0.05$

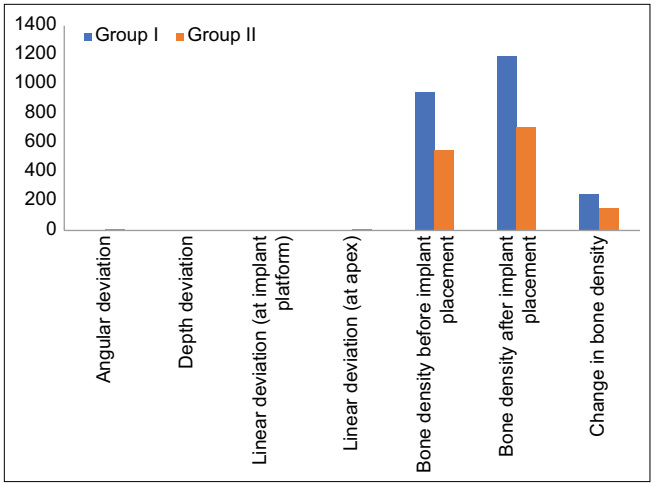
Table 5: Comparison of angular deviation, depth deviation, linear deviation, and bone density between implants placed in the mandible region of each group

Variable	Mean±SD		Difference	*P*
	CAD-CAM	Bone Pen Kit		
Angular deviation	1.59±1.16	6.67±4.99	−5.08	0.018*
Depth deviation	0.78±0.85	1.78±2.15	−1.00	0.356
Linear deviation (at implant platform)	0.13±0.20	2.34±1.27	−2.21	0.012*
Linear deviation (at apex)	0.00±0.00	1.84±1.74	−1.84	0.003*
Bone density before	776.33±137.23	719.80±96.30	56.53	0.175
Bone density after	968.00±167.22	814.40±149.53	153.60	0.144
Difference in bone density	191.67±36.32	94.60±162.06	97.07	0.360

SD: Standard deviation, CAD-CAM: Computer-aided-design and computer-aided-manufacturing. *Indicates significant difference at $P \leq 0.05$



Graph 3: Bar diagram of comparison of angular deviation, depth deviation, linear deviation, and bone density between implants placed in the maxillary and mandibular arch in group II (Bone Pen Kit)

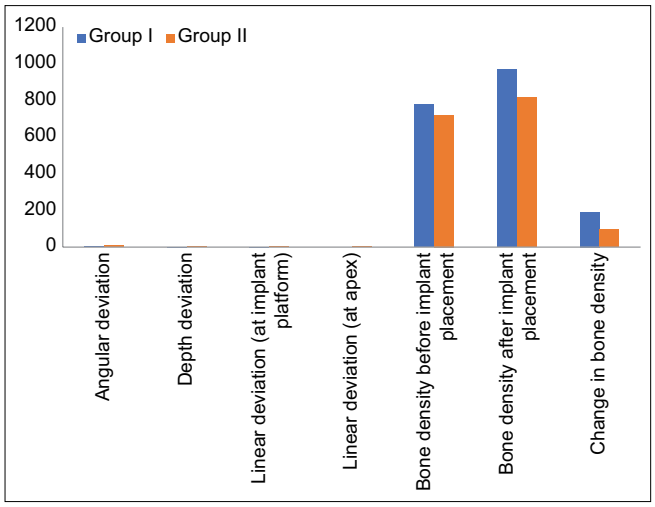


Graph 4: Bar diagram of the comparison of angular deviation, linear deviation, and bone density between implants placed in the maxillary arch of two groups

DISCUSSION

The null hypothesis, which stated that accuracy would remain consistent regardless of the variables under consideration, was partially rejected based on the specific variables examined. Accurate 3D positioning of the implant fixture, guided by prosthetic considerations, is considered critical for achieving a favorable long-term outcome in implant-supported prosthetic treatments.[4] Inadequate consideration of the superstructure during presurgical planning can lead to failures in implant-supported prosthetic treatments. Optimal functional and aesthetic outcomes can only be achieved through accurate implant placement, which is especially challenging in the confined space of the oral cavity. To enhance precision, a surgical guide can be used to provide detailed information on implant placement and ensure proper fit within the existing dentition or edentulous span at the time of surgery.[5]

The trend in dental implantology is to seek less traumatic surgical procedures to minimize patient discomfort. One such approach is the flapless surgical technique for implant placement, which has shown advantages in reducing



Graph 5: Bar diagram of comparison of angular deviation, depth deviation, linear deviation, and bone density between implants placed in mandibular arches of each group

Table 6: Difference between the mean and standard deviation of bone density before and after implant placement in each group

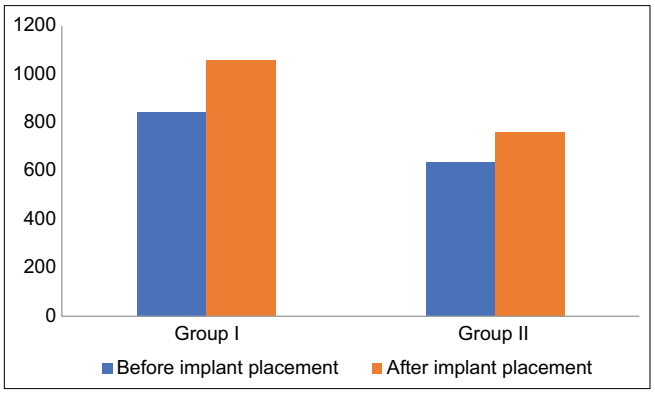
Group	Bone density, mean±SD		Difference	*P*
	Before implant placement	After implant placement		
Group I	844.40±141.90	1058.00±196.65	−213.60	0.005*
Group II	635.80±116.78	761.30±118.83	−125.50	0.005*

SD: Standard deviation. *Indicates significant difference at $P \leq 0.05$

surgical site morbidity and bone resorption. However, without direct visualization of the bone tissue, there is a risk of deviations in implant installation from the original treatment plan, which can negatively impact prosthetic rehabilitation success. To mitigate this concern, it is advised that flapless implant placement procedures must utilize surgical guides.[6]

According to a recent meta-analysis, guided implant placement demonstrated an accuracy of 1.2 mm at the crestal level and 1.5 mm at the apex of the implant. The average angular deviation was reported to be 3.8°.[7]

Nonetheless, this technique is not without disadvantages, which include the following: (1) The surgeon's limited visibility of anatomical structures; (2) Increased susceptibility to variances in implant alignment and depth during the placement process; (3) A reduced ability to manipulate the jawbone topography as necessary for prosthetic purposes. To assess the safety and effectiveness of computer-aided implant placement systems, various studies have consiguidely examined specific parameters of planned versus actual implant positions, including the linear deviation of the implant head and apex, as well as the angular deviation of the implant's long axis.[8]



Graph 6: Bar diagram of the comparison of bone density before and after implant placement in each group

A recent clinical trial revealed that fully guided surgery was the most precise, followed by partially guided surgery.[9] Conversely, freehand surgery showed a significant deviation from the ideal position. These findings were further supported by Smitkarn *et al*., who conducted a randomized clinical trial comparing freehand implant placement with computer-assisted implant surgery (CAIS).[4]

Majority of comparative studies on the accuracy of implant position between static CAIS and freehand techniques have been conducted *in vitro*. These findings were supported by Nickenig *et al*. who conducted a combined *in vivo*/*in vitro* study.[10]

There is a common misconception that sleeve-in-sleeve implant surgery can be performed due to the simplicity of the surgical steps. However, research has shown that the level of experience of the clinician is a crucial factor in the accuracy of implant placement, despite the systematic simplicity provided by the sleeve-in-sleeve concept.[11]

A new concept for implant placement using Bone Pen Kit has been introduced in the field of implantology. This relatively new concept with universally compatible drills has been proposed to help in better implant placement.

The kit contains cups and pins. Cups and pins with diameters of 6 mm, 7 mm, and 8 mm and color coding yellow, green, and purple [Figure 17], respectively, are used in the placement of implants in the anterior region and premolar region whereas cups and pins with wide diameters of 9 mm and 10 mm and color-coding purple, blue, and turquoise [Figure 18], respectively, are used in posterior regions including molars. Color-coded Pins are used to measure both vertical height and horizontal space.

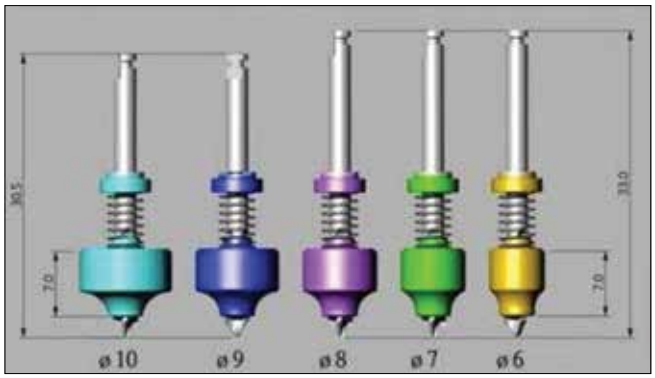


Figure 17: Five color-coded cups of diameter 6 mm, 7 mm, 8 mm, 9 mm and 10 mm

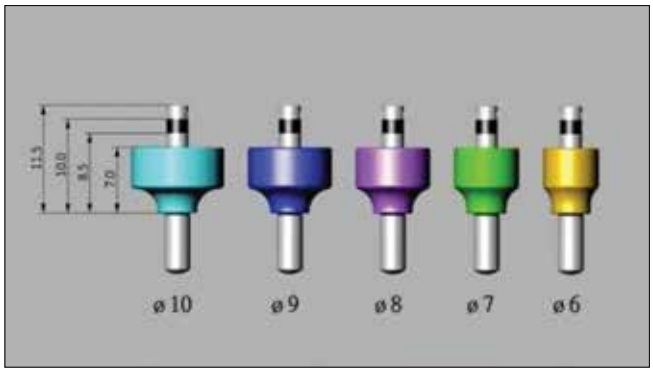


Figure 18: Five color-coded pins of diameter 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm to measure vertical height and horizontal space

In the present study, angular deviation in the Bone Pen Kit group was significantly higher than in the CAD-CAM group. There was no difference in depth deviation and linear deviation at the implant platform among the two groups. Linear deviation at the apex in the Bone Pen Kit group was significantly higher than in the CAD-CAM group. Bone density before and after treatment was significantly higher in the CAD-CAM group than in the Bone Pen Kit group. The deviation data obtained in this study is comparable to the deviations reported in previous clinical studies that utilized CT-guided implant placement techniques. One such study compared the linear and angular deviations of implants placed using fixed prototyped guides on mucosa or teeth and found that the mucosal guides resulted in linear deviations of 0.94 mm at the apex and 0.69 mm at the implant platform, with angular deviations of 2.71°. Another study that assessed linear and angular deviations in implants placed in fully edentulous patients found linear deviations of 1.68 mm at the implant platform and 2.19 mm at the apex, with an angular deviation of 4.67°.[6]

Unlike previous studies on guide-supported implant dentistry, the present study revealed variations in mean deviations. However, the present study demonstrated lower inaccuracy compared to Alevizakos *et al*.'s study, with a mean deviation in angulation of 2.2° ±1.1°, 0.6 mm ± 0.3 mm at the implant shoulder level, and 0.9 mm ± 0.4 mm at the implant tip level.[11]

Variations in the deviations observed between this study and the aforementioned studies could be attributed to the method utilized and the proficiency of the clinicians. It is well-known that the clinician's experience affects the treatment outcome. This claim is reinforced by the outcomes of the study, which revealed a definite learning curve. In a prospective, multicentric clinical trial with 2641 inserted implants, less experienced clinicians had a higher incidence of failure than experienced clinicians.[11]

Therefore, employing a surgical guide based on a guide improved the accuracy of implant positioning and enhanced treatment safety. Research has indicated that the proficiency of the clinician who installs the implants is a contributing factor, even when a surgical guide is employed. According to the research data, an angle deviation of 3° is deemed acceptable in terms of preserving anatomic structures, as well as preventing abutment loosening and ensuring passive fit. From this standpoint, the use of surgical guides is highly recommended for clinicians who possess limited surgical experience.[11]

Bone Pen Kit adheres to the principles of prosthetically driven implantology and offers a highly advantageous option that outperforms both surgical guides and free-hand implant placement. It assists in achieving 3D positioning of the implant, aligning it harmoniously with the desired orientation of the prosthesis. The Bone Pen Kit incorporates a spring action mechanism within its drill, enabling precise and controlled drilling to be accomplished.

In addition, this approach avoids the intricacies associated with guides, such as complex assembly, and is particularly suitable for patients with limited mouth opening.

In contrast to CAD/CAM fabricated 3D guides, which necessitate the adjustment of stoppers to determine the precise drilling length, the proposed method eliminates the need for additional technical components and reduces both cost and time requirements. Moreover, it offers a swifter and simpler procedure, devoid of complexities, and does not necessitate specialized training for implementation. Furthermore, Bone Pen Kit obviates the need for applying radiopaque markers during CBCT, thereby reducing both clinical and patient time commitments and minimizing the number of required patient visits.

Moreover, in contrast to surgical guides that are custom-made for each patient, the specialized drills, cups,

and pens included in the Bone Pen Kit are reusable due to their standardized dimensions derived from average values obtained from population data. In addition, when employing the Bone Pen Kit, the neighboring teeth themselves act as a guide in orienting the Bone Pen, facilitating prosthetically oriented implant placement.

CONCLUSIONS

Based on the limitations of this study, the following conclusions were made:

1. Angular and linear deviation in the Bone Pen Kit group was significantly higher as compared to CAD/CAM group
2. Linear deviation at the apex in the Bone Pen Kit Group was significantly higher as compared to CAD/CAM group
3. No difference in depth deviation and linear deviation at the implant platform among the two groups
4. There was no difference in change in bone density among the two groups
5. Bone Pen Kit is a reliable option and can serve as an asset in clinical set-ups lacking advanced digital technology (CAD/CAM, CBCT, 3D printers) and when the financial budget for treatment presents a barrier to such additional expenses
6. The Bone Pen Kit exhibits a favorable shelf life, demonstrating no signs of component degradation or wear. Furthermore, it is designed for reusability, is capable of enduring autoclaving processes, and possesses anti-rust properties
7. Despite offering numerous advantages, the utilization of the Bone Pen Kit is limited when it comes to completely edentulous patients, as the absence of reference teeth poses a challenge in accurately guiding its placement at the desired location.

However, in order to draw definitive conclusions, further *in vivo* long-term studies with larger sample sizes are required to evaluate the accuracy of the Bone Pen Kit in comparison to fully-guided implant placement, considering various deviation parameters.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Expression and ratio of receptor activator of nuclear factor kappa-B ligand and osteoprotegerin following application of *Nigella sativa*/bovine bone graft combination in posttooth extraction sockets

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Abstract

Aims: The aim of this study was to analyze the induction effect of a combination of *N. sativa* and bovine bone graft on the expression and receptor activator of nuclear factor kappa-B ligand expression (RANKL) and osteoprotegerin (OPG) on alveolar bone socket preservation on days 7 and 14.

Settings and Design: The research incorporated a posttest-only control group design. A total of 56 *Cavia cobaya* were divided into four groups: a control group, an *N. sativa* group, a bovine bone graft group, and a combined *N. sativa* and bovine bone graft group.

Materials and Methods: The lower incisors of the *C. cobaya* were extracted with material subsequently being applied to the resulting socket. After the 7th and 14th days, the experimental animals were terminated to enable observation of the socket. Following processing, the tissue was subjected to immunohistochemistry staining consisting of RANKL and OPG antibodies before being observed under a light microscope at × 400.

Statistical Analysis Used: Statistical analysis was carried out using the one-way ANOVA and Tukey's honestly significant difference tests.

Results: A combination of *N. sativa* and bovine bone graft reduced both RANKL expression and the RANKL/OPG ratio while increasing OPG expression in comparison to the other groups. In all the results obtained, the *N. sativa* and bovine bone graft combination was significant ($P < 0.05$) when compared to the control group on both the 7th and 14th days.

Conclusion: A combination of *N. sativa* and bovine bone graft reduced both RANKL expression and the RANKL/OPG ratio while increasing OPG expression.

Keywords: Bovine bone graft, medicine, *Nigella sativa*, osteoprotegerin, ratio of receptor activator of nuclear factor kappa-B ligand

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INTRODUCTION

Tooth extraction can result in the loss of alveolar bone which, in turn, might render the manufacture of dentures more difficult.[1,2] Consequently, it is necessary to attempt to lower the rate of postextraction alveolar bone loss. Socket preservation is a method used to slow the rate at which the alveolar bone's dimensions decrease after extraction.[3]

A material frequently utilized in socket preservation is a bovine bone graft.[4] However, if applied in isolation, this process may result in an inflammatory response which could compromise its efficacy.[5] Hence, another substance is required that will boost the effectiveness of the bovine bone graft while, simultaneously, reducing its inflammatory response. The active ingredient in *Nigella sativa*, thymoquinone, possesses anti-inflammatory and anti-osteoclastic properties.[6,7] The combination of these two substances was expected to have beneficial synergistic effects, which would slow the rate of bone loss.

The biomarkers that affect the homeostasis of osteoblastogenesis and osteoclastogenesis include the receptor activator of nuclear factor kappa-B ligand expression (RANKL) and osteoprotegerin (OPG). The affected area will be resorbed when the RANKL concentration is dominant. On the other hand, should OPG be dominant in the injury site, bone formation will be expected to occur.[8] Cytokines that are more numerous in the injured area also have an impact on the ratio of RANKL and OPG.[9] The production of RANKL will increase when pro-inflammatory cytokine levels such as interleukin (IL)-1 β, IL-6, and tumor necrosis factor (TNF)-α are dominant in the injured area. OPG production will also prove inevitable as a result of increasing expression of IL-10 in the injured area.[10-13] This study is expecting higher OPG levels and lower RANKL levels after *N. sativa*/bone graft application in the tooth socket, for which OPG is needed in the osteoblastogenesis process. Combining *N. sativa* into a bone graft combination was aimed to slow down the rate of osteoclastogenesis. The purpose of this study was to investigate the effect of administering a combination of *N. sativa* extract and bovine bone graft on the expression and ratio of RANKL and OPG in alveolar bone sockets on days 7 and 14.

MATERIALS AND METHODS

This research was approved by the Health Research Ethical Clearance Commission of our university, 524/HRECC. FODM/VIII/2022.

Animal preparation

The subjects of this research consisted of 56 guinea pigs (*Cavia cobaya*) that satisfied the following inclusion criteria: male, 3–3.5 months old, 300–350 g in weight, and in good health. The number of animal studies was determined by a previous similar study by Kresnoadi *et al*.[14] They were assigned in groups of 4–14 cages; each of which was 50 cm × 70 cm × 50 cm in dimension and acclimatized for a week by being isolated from loud noises, rain, and strong winds as part of their adaption process. High-fiber foods like corn were provided twice a day together with an unlimited supply of water. The experimental animals were then divided into four main groups: the control group, the bovine bone graft group, the *N. sativa* extract group, and the combination group (*N. sativa*/bovine bone graft) according to the treatments they were due to receive.

Nigella sativa preparation

N. sativa extract was obtained by means of maceration. A kilogram of *N. sativa* seeds was dried for 4 h by exposure to direct sunlight and subsequently crushed with a grinder, transferred to the extractor, and mixed with 2 L of 96% ethanol. The seeds were then placed in a shaker and agitated for 48 h before being filtered with a WH20 filter paper to produce a clear, dark liquid extract. To produce a viscous brown ethanol-free liquid at a temperature of 50°C–60°C, the *N. sativa* filtrate was placed into the evaporator to enable separation from the ethanol.

Bovine bone graft preparation

Bovine bone graft with a particle size of 150–350 μm/500 mg obtained from the tissue bank of Dr. Soetomo General Hospital, Surabaya, was subjected to a sterilization procedure using gamma irradiation 25 kGy.

Polyethylene glycol preparation

Polyethylene glycol (PEG) in gel form, obtained by mixing PEG 400 (diluent) and PEG 4000 (thickener) at a ratio of 4:1, was used as a carrier. Depending on the study group, the material was processed into four gel formulations: 25 g preparation of PEG gel for the control group, 24.5 g of PEG gel was combined with 0.5 g of *N. sativa* extract in the *N. sativa* group, 24.5 g of PEG gel and 0.5 g of bovine bone graft were combined in the bovine bone graft group, and 24 g of PEG gel was combined with 0.5 g of *N. sativa* extract and 0.5 g of bovine bone graft in the combination group. Each group contained a 2% active component.

Animal studies

A 20 mg/300-g body weight dose of ketamine (KEPRO, ZA, Denmark) was administered intramuscularly to the *C. cobaya*. The left mandibular incisor was then cleared

of food debris and carefully extracted with a needle holder to prevent tooth fracture. The extraction socket was subsequently irrigated with sterile distilled water and 0.1 mL of the material administered according to the study group. Finally, the socket was closed with DS12 3/8c monofilament polyamide suture, 12 mm, 6/0 met 0.7 (Braun VetCare SA, Rubi, Spain).

Immunohistochemical staining

On days 7 and 14, all members of the *C. cobaya* groups (28 *C. cobaya* on day 7 and 28 more on day 14) were terminated through the administration of a specific dose of 100 mg/cc of ketamine (KEPRO, ZA, Denmark). The mandible was then removed, fixated for 24 h in buffered formalin solution, and decalcified for 2 months in 10% ethylenediaminetetraacetic acid. Gradually diluted alcohol was used to dehydrate the subject before it is being removed with xylol and embedded in paraffin, which was then applied to the glass object after being cut to a thickness of 4 μm.

Alcohol and xylol were applied to deparaffinize the preparations. To observe RANKL and OPG proteins, monoclonal antibodies of RANKL (monoclonal antibody, Novus Biologicals® [12A668]) and OPG (monoclonal antibody, Novus Biologicals® [98A1071]) were administered to the preparations. 3,3'-Diaminobenzidine chromogen substrate was also added. The observation was focused on the apical third of the socket region, which was examined using a light microscope (Nikon Eclipse E100, Japan).

Statistical analysis

A Kolmogorov–Smirnov normality test and Levene's homogeneity test were both completed to analyze the acquired data, with the one-way ANOVA and Tukey's honestly significant difference tests subsequently being performed using the Statistical Package for the Social Sciences Software (SPSS) version 24 (SPSS™, Chicago, IL, United States).

RESULTS

Receptor activator of nuclear factor kappa-B ligand expression

On day 7, the control group recorded the highest expression of RANKL, while the combination group had the lowest [Figure 1]. These two groups both had a significant difference with $P < 0.000$. Other groups also showed a significant difference, including that between the control and bovine groups ($P < 0.000$), the control and *Nigella* groups ($P < 0.000$), the control and combination groups ($P < 0.000$), the bovine and *Nigella* groups ($P < 0.008$), and the bovine and combination groups [$P < 0.003$, Table 1]. However, there was no significant difference between the *Nigella* and combination groups. The immunohistochemical staining of each group is shown in Figure 2.

The RANKL expression immunohistochemical staining performed on day 14 is shown in Figure 3. On that day, according to the mean RANKL expression, the control group recorded the highest outcomes, whereas the *N. sativa* group registered the lowest [Figure 1]. The statistical analysis revealed a significant difference between the control and bovine groups ($P < 0.000$), the control and *Nigella* groups ($P < 0.000$), the control and combination groups ($P < 0.000$), the bovine and *Nigella* groups ($P < 0.000$), and the control and combination groups [$P < 0.000$, Table 2]. However, no significant difference between the *Nigella* and combination groups was identified.

Osteoprotegerin expression

Immunohistochemical staining of OPG expression on day 7 is shown in Figure 4. On that day, the combination group recorded the most numerous expressions of OPG, whereas the control group had the least [Figure 5]. On day 7, the statistical analysis revealed a significant difference between the control and bovine groups ($P < 0.000$), the

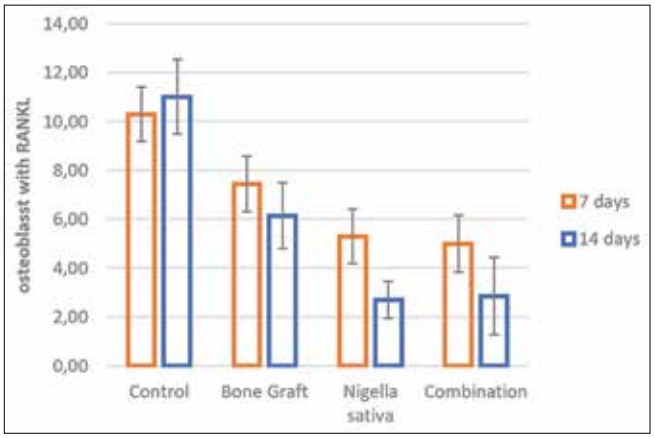

Figure 1: The mean and standard deviation of each group that represented the expression of RANKL from osteoblast cells. RANKL: Ratio of receptor activator of nuclear factor kappa-B ligand, *N. sativa: Nigella sativa*

Table 1: Receptor activator of nuclear factor kappa-B ligand expression on day 7

Group	Control	Bovine bone graft	*N. sativa*	Combination
Control		0.000*	0.000*	0.000*
Bovine bone graft	0.000*		0.008*	0.003*
N. sativa	0.000*	0.008*		0.964
Combination	0.000*	0.003*	0.964	

*Significant difference between groups. The *P* value of each group was established by means of a Tukey's HSD test. HSD: Honestly significant difference, *N. sativa: Nigella sativa*

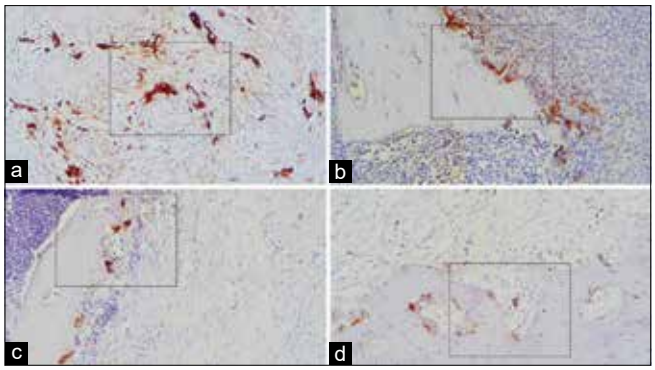

Figure 2: Ratio of receptor activator of nuclear factor kappa-B ligand (RANKL) expression on day 7. (a) Control group on day 7. (b) Bovine bone graft group on day 7. (c) *Nigella sativa* group on day 7. (d) Bovine bone graft and *Nigella sativa* combination group on day 7. Notice the cells inside the dash-line box: osteoblast cells that expressed RANKL was brown-stained; it could be seen near the margin of bone lining cells

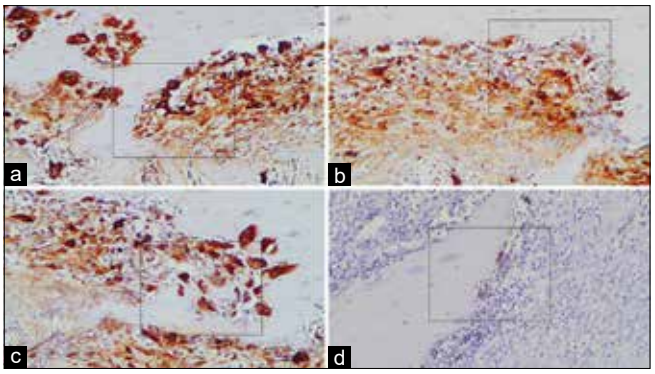

Figure 3: Receptor activator of nuclear factor kappa-B ligand (RANKL) expression on day 14with 100x magnification. (a) Control group on day 14. (b) Bovine bone graft group on day 14. (c) *Nigella sativa* group on day 14. (d) Bovine bone graft and *Nigella sativa* combination group on day 14. Notice the cells inside the dash line box: osteoblast cells that expressed OPG was brown stained; it could be seen near the margin of bone lining cells

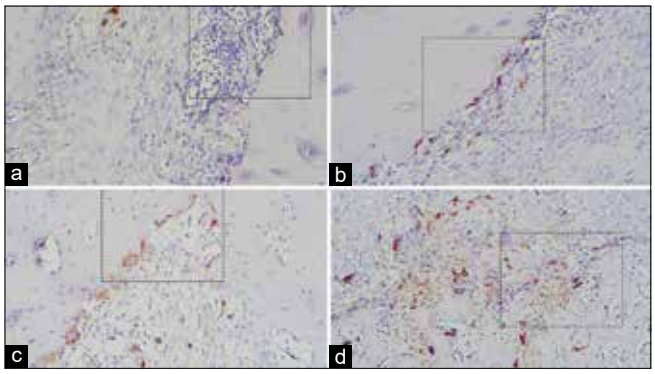

Figure 4: Osteoprotegerin (OPG) expression on day 7 with 100x magnification. (a) Control group on day 14. (b) Bovine bone graft group on day 14. (c) Nigella sativa group on day 14. (d) Bovine bone graft and Nigella sativa combination group on day 14. Notice the cells inside the dash line box: osteoblast cells that expressed OPG was brown stained; it could be seen near the margin of bone lining cells

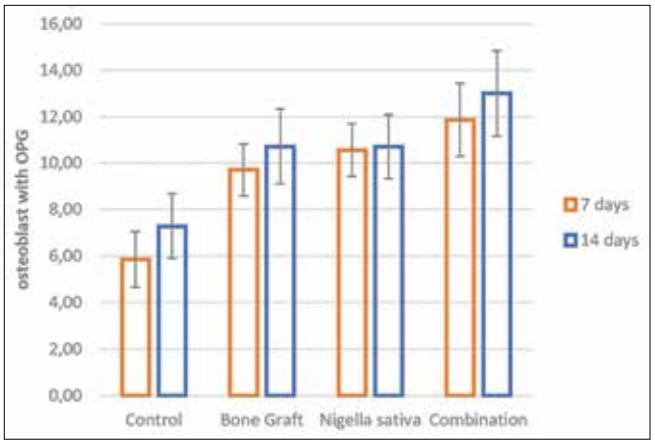

Figure 5: The mean and standard deviation of each group that represented the expression of OPG from osteoblast cells. OPG: Osteoprotegerin

Table 2: Receptor activator of nuclear factor kappa-B ligand expression on day 14

Group	Control	Bovine bone graft	*N. sativa*	Combination
Control		0.000*	0.000*	0.000*
Bovine bone graft	0.000*		0.000*	0.001*
N. sativa	0.000*	0.000*		0.997
Combination	0.000*	0.001*	0.997	

*Significant difference between groups. The *P* value of each group was established by means of a Tukey's HSD test. HSD: Honestly significant difference, *N. sativa: Nigella sativa*

control and *Nigella* groups ($P < 0.000$), the control and combination groups ($P < 0.000$), and the bovine and combination groups [$P < 0.021$, Table 3]. However, no significant difference existed between the bovine and *Nigella* groups or the *Nigella* and combination groups.

OPG expression on day 14 is shown in Figure 6. On that day, the combination group recorded the highest outcomes, whereas the control group had the lowest [Figure 5]. Statistical analysis revealed a significant difference between the control and bovine groups ($P < 0.002$), the control and *Nigella* groups ($P < 0.002$), and the control and combination groups [$P < 0.000$, Table 4]. However, no significant difference existed between the bovine and *Nigella* groups, the control and combination groups, and the *Nigella* and combination groups.

Ratio of receptor activator of nuclear factor kappa-B ligand/osteoprotegerin ratio

The value of the RANKL/OPG ratio was obtained by dividing the RANKL value by the OPG value. The balance between RANKL and OPG expression can be observed more precisely if the RANKL/OPG ratio is compared using only the RANKL and OPG as separate values. Figure 7 shows the average value of the RANKL/OPG ratio of each group. On day 7, the control group had the

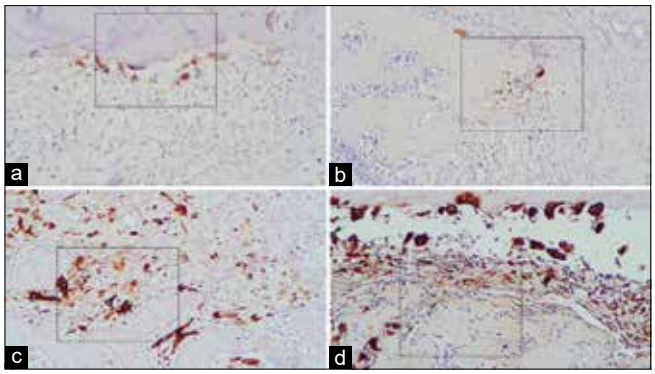

Figure 6: Osteoprotegerin (OPG) expression on day 14 with 100x magnification. (a) Control group on day 14. (b) Bovine bone graft group on day 14. (c) *Nigella sativa* group on day 14. (d) Bovine bone graft and *Nigella sativa* combination group on day 14. Notice the cells inside the dash line box: osteoblast cells that expressed OPG was brown stained; it could be seen near the margin of bone lining cells

Table 3: Osteoprotegerin expression on day 7

Group	Control	Bovine bone graft	*N. sativa*	Combination
Control		0.000*	0.000*	0.000*
Bovine bone graft	0.000*		0.596	0.021*
N. sativa	0.000*	0.596		0.259
Combination	0.000*	0.021*	0.259	

*Significant difference between groups. The *P* value of each group was established by means of a Tukey's HSD test. HSD: Honestly significant difference, *N. sativa: Nigella sativa*

Table 4: Osteoprotegerin expression on day 14

Group	Control	Bovine bone graft	*N. sativa*	Combination
Control		0.002*	0.002*	0.000*
Bovine bone graft	0.002*		10.000	0.052
N. sativa	0.002*	10.000		0.052
Combination	0.000*	0.052	0.052	

*Significant difference between groups. The *P* value of each group was established by means of a Tukey's HSD test. HSD: Honestly significant difference, *N. sativa: Nigella sativa*

highest average RANKL/OPG ratio value, whereas the combination group had the lowest. On day 14, the control group had the greatest mean RANKL/OPG ratio value, whereas the combination group had the lowest.

DISCUSSION

According to the results obtained, there was a statistically significant difference between the RANKL levels in the *N. sativa* group and those of the control group. In comparison to the control group, OPG levels in the *N. sativa* group were significantly higher. The expression of the RANKL/OPG ratio in the *N. sativa* group was statistically lower than in the control group due to a decrease in the RANKL levels and an increase in the OPG levels. This shows that the OPG value is greater than the RANKL value, which suggests that the bone apposition process

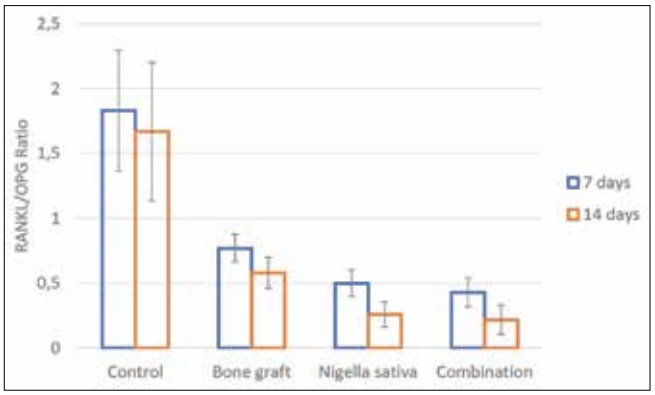

Figure 7: The mean and standard deviation of each group that represented the RANKL/OPG ratio from osteoblast cells. OPG: Osteoprotegerin, RANKL: Ratio of receptor activator of nuclear factor kappa-B ligand, *N. sativa: Nigella sativa*

can occur by suppressing the number of osteoclasts and increasing that of osteoblasts when thymoquinone, the active ingredient in *N. sativa*, is administered. This finding is consistent with that of research undertaken in 2017 by Arslan *et al*., who discovered that thymoquinone treatment enhanced the ratio of new bone per total defect area and new trabecular bone covered by active osteoblasts.[15] This finding is also supported by research conducted in 2022 by Baştuğ *et al*., who discovered that thymoquinone administration can increase the production of new bone, the quantity of osteoblasts, and the density of blood vessels.[16]

The results showed that only between the *N. sativa* group and the combination group did the expression of RANKL exhibit no significant differences on days 7 and 14, whereas the other groups presented such differences. This might be the result of the high anti-inflammatory properties of *N. sativa*, which can drastically reduce RANKL production when compared to the group that did not receive *N. sativa*. Nevertheless, the anti-inflammatory potential of the *N. sativa* and combination groups did not differ because they included the same amount of *N. sativa*, thereby yielding insignificant results.

Thymoquinone, which is present in *N. sativa* extract, has potent anti-inflammatory properties that can prevent the formation of RANKL. Moreover, it demonstrates the ability to decrease pro-inflammatory cytokines, including IL-1β, IL-6, TNF-, interferon-, and prostaglandin E2, while increasing anti-inflammatory cytokines like IL-10.[17] This is supported by research completed in 2015 by Wang *et al*., who established that the thymoquinone content of *N. sativa* could significantly lower IL-1β levels and inhibit nuclear factor kappa-light-chain-enhancer of activated B-cells activation caused by IL-1β, hence demonstrating

thymoquinone's potential to act as an anti-inflammatory.[18] Furthermore, Dwita *et al*.'s study revealed that the TNF levels may be dramatically reduced in comparison to those of a control group when a topical balm stick made from 10% *N. sativa* and 23.75% thymoquinone is applied.[19] The inflammatory mediator IL-6 from T-lymphocytes and monocytes could be suppressed by means of an oil extract from *N. sativa* with a high thymoquinone content, according to research undertaken by Koshak *et al*.[20] This is also consistent with the study results by Yousif *et al*., which showed that mice administered with *N. sativa* extract were able to increase their IL-10 levels in comparison to those of other groups.[6]

In a study conducted by Wirries *et al*., it was discovered that thymoquinone administration might enhance osteoblast differentiation and activate bone morphogenetic protein-2 (BMP2).[21] BMP2 is a cytokine that belongs to the transforming growth factor (TGF)-family of TGF's-β, which promotes bone development. BMP2 will bind to the cell membrane's Type I and Type II receptors (BMPR I and BMPR II), forming a complex that will phosphorylate the cytoplasm's receptor-activated Smad (R-Smad 1/5/8). SMAD 4 (Co-Smad), while activated, Smad will interact to create the Smad complex, which will then enter the nucleus to activate the production of the target genes runt-related transcription factor 2 (Runx2) and Osterix.[22]

Runx2 is a transcription factor that contributes to osteoblast differentiation. Research also demonstrates that Runx2 can control the expression of the OPG gene. The transcription of genes associated with osteogenesis, including OPG, is increased when Runx2 binds to the osteoblast-specific cis-acting element 2 (OSE2). This shows that Runx 2 also inhibits the formation of osteoclasts by increasing the production of OPG in addition to its ability to contribute to osteoblast differentiation.[23-25]

The results revealed that although the RANKL levels were much lower in the bovine bone graft group compared to the control group, they were still higher than those in the *N. sativa* group. While OPG levels were significantly higher in the bovine bone graft treatment group compared to the control group, they were lower than those in the *N. sativa* group. As a result, the RANKL/OPG ratio in the *N. sativa* group is lower than that in the bovine bone graft group. This could be due to the fact that bovine bone grafts include only proteins like BMP, which can aid osteoblastogenesis but lack anti-inflammatory characteristics. According to a study by Humidat *et al*., administering BBG alone has been shown to elevate the levels of TNF-α, which suggests that administering it may trigger a moderate inflammatory response.[5] Administering *N. sativa* produces contrasting results because, in addition to being able to activate BMP-2, its active thymoquinone content also possesses significant anti-inflammatory qualities that help reduce localized inflammatory reactions.[6,21]

This may also explain the no-significant difference result in the OPG levels between bone grafts and *N. sativa*, bone graft and combination, and *N. sativa* and combination, where active substances are present in each group that can boost BMP-2.[21] BMP-2 can activate the Runx-2 gene, which increases the transcription of genes associated with osteogenesis, including OPG when it binds to the OSE2.[23-25]

In comparison to the control group, administration of *N. sativa* together with bovine bone graft resulted in considerably reduced RANKL expression. When compared to the control group, OPG expression in the combination therapy group produced significantly higher results. The combined treatment group's RANKL/OPG ratio was much lower than that of the control group due to the combination of lower RANKL levels and higher OPG levels. This suggests that the administration of *N. sativa* and bone graft can reduce the number of osteoclasts, increase the number of osteoblasts, and induce the process of bone homeostasis toward bone apposition in postextraction alveolar bone sockets. This finding is in line with those of studies conducted by Rahmani-Moghadam *et al*.,[26] who discovered that treating mesenchymal stem cells with a mixture of thymoquinone and hydroxyapatite/alginate scaffolds can improve osteogenic differentiation.[2,9]

The results demonstrated that in comparison to the bone graft treatment group and the *N. sativa* treatment group, the combination of bone graft and *N. sativa* was capable of increasing the RANKL levels more significantly. The findings also indicated that joint administration of bone graft and *N. sativa* can reduce the OPG levels to a greater extent than either bone graft treatment or *N. sativa* treatment in isolation. As a result, the RANKL/OPG ratio of the combination group is lower than that of the *N. sativa* or bone graft groups alone. As observed in the expression of the RANKL/OPG ratio, which is lower in the combination group than its self-treatment counterpart, this demonstrates that the administering of a combination of these two components has a synergistic impact in suppressing the RANKL/OPG ratio. The administering of a mixture of these two substances can mutually assist them in achieving the desired outcome of reducing the RANKL/

OPG ratio due to this synergistic action. Bovine bone graft can increase BMP protein levels, an effect supported by *N. sativa*, while also reducing pro-inflammatory cytokine levels and increasing anti-inflammatory cytokine levels.[6,21,27] The value of the RANKL/OPG ratio in the combination group produced lower results than the individual treatment group by mixing these two ingredients.

This research will provide clinicians with new insights, in which giving additional active ingredients that can lower inflammatory reactions and support the process of bone osteogenesis may accelerate the process of bone regeneration following the administration of grafts in dentistry.

This study has limitations in terms of identifying the active components of *N. sativa*, which could affect the study's results. This is due to the fact that *N. sativa* itself contains a variety of active components that affected the study's findings, whereas the concentration used in this study was the 2% *N. sativa* extract. As a result, it is hard to determine which *N. sativa* active components had an impact on the study's outcomes. In addition, 2% *N. sativa* does not always have the same active component composition in every preparation, making it more challenging to control factors. It is suggested to use *N. sativa* active component like thymoquinone rather than *N. sativa* itself and to identify the thymoquinone percentage that gives the best result. Moreover, longer observation and more bone marker healing would be needed for future studies to fully understand the osteogenesis mechanism behind the *N. sativa* and bovine bone graft application.

CONCLUSION

N. sativa and BBG combination was able to reduce the level of RANKL, increase the level of OPG, and reduce the RANKL/OPG ratio after the tooth extraction procedure, which leads to osteogenesis acceleration.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Research

To determine the effect of plasma nitriding treatment 56 on screw loosening and surface topography of different 78 implant–abutment screw systems with and without thermocycling: An *in vitro* study

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Abstract

Aim: The aim of this study was to evaluate and compare the effect of plasma nitride-treated abutment screws of two different implant systems on screw loosening and surface topography with and without thermocycling.

Settings and Design: This was an *in-vitro* experimental study.

Materials and Methods: Fifty-two abutment screws (Group A: 26 Genesis and Group B: 26 Bredent) underwent plasma nitride treatment and were subdivided into two groups, one without thermocycling and one with thermocycling. Dynamic load was applied and detorque values were evaluated for determining the screw loosening using "independent t-test" with the help of IBM SPSS Statistics 20 and scanning electron microscopy was done to check for surface topography.

Statistical Analysis Used: Inter- and intragroup comparisons were done using independent t-test (SPSS: Statistical Package for the Social Sciences software version 20).

Results: Plasma nitriding treatment genesis implant system abutment screw showed more screw loosening ($P < 0.05$) and surface roughness as compared to bredent with and without thermocycling.

Conclusion: From the present study, it was shown that plasma nitride-treated abutment screws decreased the occurrence of screw loosening favoring the bredent implant–abutment system more than the genesis implant–abutment system.

Keywords: Abutment screw treatment, bredent implant system, genesis implant system, plasma nitride treatment, screw loosening

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INTRODUCTION

One of the main goals in dentistry is to restore the optimal form, function, and esthetics of the patient. With increase in the use of dental implants, there were more mechanical and biological complications as well.[1] Studies have shown 8%–45% of screw loosening occurs in implant-supported single crown cases.[2-6]

Screw loosening occurs when the clamping force between the implant and the abutment recedes the separating force acting in the screw joints. With reduced preload force, screw loosening results, which causes the system to become unstable or even break.[7-9] Failure to treat the loose abutment screw can further lead to fracture of the prosthesis, implant components, or the implant body, and bacteria may colonize and harbor in the open interface leading to crestal bone loss.

Many authors suggested that surface modification of implant–abutment screws improved its fatigue characteristics and lesser loosening torque and long-term anti-loosening performance as compared to uncoated implant–abutment screws.[10-13] Plasma nitriding is a technique where the metallic components are surface treated to increase the surface hardness and improve its wear and corrosion resistance properties. A study conducted by Sun *et al*. to determine the stability of dental implant–abutment screws derived a conclusion that the plasma nitride treatment enhances fatigue performance and anti-loosening properties, and reduces wear of the screw surface when compared to nontreated screws.[14]

The benefits of plasma nitride treatment of implant–abutment screws were established but the outcome of the surface treatment of different implant systems in oral conditions was not established. In this study, plasma nitride-treated implant–abutment screw with and without aging of 1 year was evaluated and compared for screw loosening and surface topography. The null hypothesis was that plasma nitride-treated implant–abutment screws that did not undergo thermocycling would show no difference on screw loosening and surface topography when compared with the ones that did.

MATERIALS AND METHODS

A sample size of 52 dental implant–abutment screws was determined and then divided into Group: A: 21 genesis implant system and Group B: 21 bredent implant system, as shown in Figure 1. The groups were further divided into two subgroups, with thermocycling and without thermocycling [Table 1]. Ethical committee number Ref. No. KIMSDU/IEC/02/2021, protocol number 245/2020-2021.

Figure 1: Abutment screws without plasma nitriding treatment (a) genesis aktiv implant system abutment screw (b) bredent implant system abutment screw

All the abutment screws were surface treated using plasma nitriding treatment (PNT) where a hollow cathode generates an arc discharge plasma, in which the electric field is accelerated and thus results in an effective ionization of the gas. The abutment screws were placed in a vacuum chamber for 3 h. The temperature of the chamber was adjusted to 550°C, the power bias was 700 V, the duty cycle was 20%, and the gas pressure in the vacuum chamber was 5 Pa. Figure 2 shows the abutment screws after PNT.

Thermocycling was done, where the group that did not undergo thermocycling were categorized as A1 and B1 to simulate the oral temperature and conditions, where water temperature of 6°C/60°C with 60 secs dwell time, 35 s intervals between water changes in 10,000 cycles simulating 1 year of oral environment[15] [Figure 3a and b] and 26 abutment screws did not undergo thermocycling and were categorized as A2 and B2.

Four *in vitro* models were established where implant specimen set (2 genesis and 2 bredent) was assembled and embedded into a cylindrical acrylic resin measuring 30 mm in diameter and 20 mm in height (ISO/FDIS 14801:2014) [Figure 4].

The abutment screws were tightened along with crown using castable abutment to 30 Ncm and retightened 10 min later.[16]

Using universal testing machine (Praj Metallurgiv Laboratory), dynamic load of 130N at 1 Hz with contact time of 0.2 s and loading cycles (1×10^5) was applied onto implants mounted to simulate the functional mastication at the center axis of the implant [Figure 5].

The detorque value was then recorded using digital torque gauge [Figure 6a and b].

Each loss ratio of removal torque was calculated using removal torque loss ratio formula.[17]

Single abutment screw was randomly selected for each group and was then observed under scanning electron microscopy (SEM) (Shivaji University, Kolhapur) for investigation of the surface changes that occurred at the implant–abutment screw surface after loading. The images of the threaded part were taken at magnifications of ×200, and ×500.

The analysis of samples for surface roughness was performed using ImageJ software which can display, edit, analyze, process, save, and print images. It calculates areas and pixel value statistics of user-defined selections and intensity-thresholded objects. It can create density histograms and line profile plots. It supports standard image processing functions such as logical and arithmetical operations between images, contrast manipulation, convolusion, Fourier analysis, sharpening, smoothing, edge detection, and median filtering. Quantitative analysis of the surface topography could hence be achieved.

Table 1: Sample size distribution

Group A	26 plasma nitrided genesis implant–abutment screw
Group B	26 plasma nitrided bredent implant–abutment screw
Group A1	13 plasma nitrided genesis implant–abutment screw without thermocycling
Group A2	13 plasma nitrided genesis implant–abutment screw with thermocycling
Group B1	13 plasma nitrided bredent implant–abutment screw without thermocycling
Group B2	13 plasma nitrided bredent implant–abutment screw with thermocycling

Figure 2: Abutment screws with plasma nitriding treatment (a) genesis aktiv implant system abutment screw (b) bredent implant system abutment screw

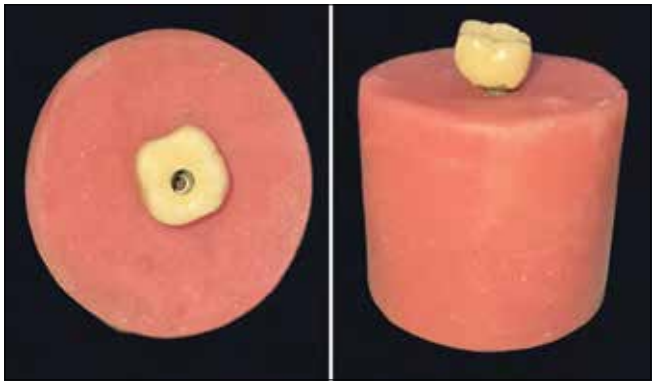


Figure 4: Implant assembly embedded in DPI self-cure acrylic resin

Statistical analysis

The results were evaluated and compared by independent *t*-test using Statistical Package for the Social Sciences (SPSS) software version 20 IBM. Descriptive statistics for removal torque loss and surface topography were expressed as mean ± standard deviation (SD). Intergroup and intragroup comparisons were made using independent *t*-test.

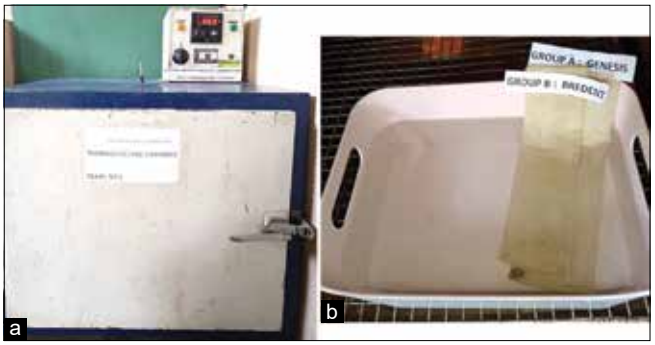


Figure 3: (a) Thermocycling unit (b) abutment screws undergoing thermocycling

Figure 5: Universal testing machine used for dynamic load testing

RESULTS

The values obtained after tightening the screw at 20 Ncm for initial untightened torque before loading and untightened torque after loading in all the groups (A1, A2, B1, and B2) are shown in Table 2.

The values of removal torque ratio before and after loading in Group A and Group B were obtained.

Intergroup comparisons of the values of removal torque ratio before loading were made and results were evaluated. The removal torque loss ratio was nonsignificant ($P > 0.05$) before loading in A1 and B1 as well as in A2 and B2, as shown in Table 3.

Intergroup comparisons of the values of removal torque ratio after loading were made and results were evaluated. The removal torque loss ratio after loading was highly significant ($P < 0.001$), where A1>B1 and A2>B2 indicating that screw loosening was higher in the genesis implant system than the bredent implant system, as shown in Table 4.

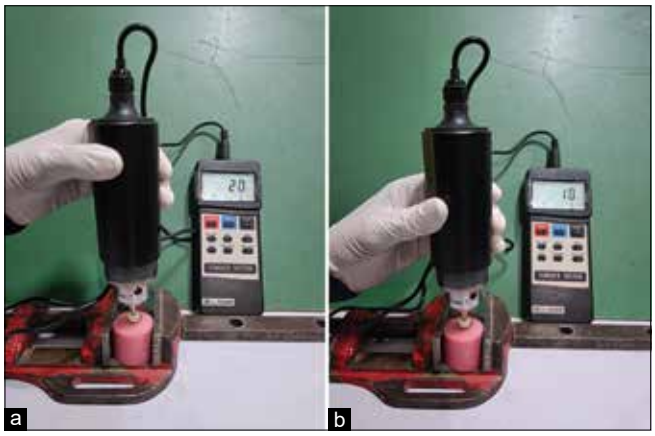


Figure 6: (a) 20n-cm tightening torque (b) initial loosening torque after loading, using digital torque gauge

The intragroup comparisons that were made of the removal torque loss ratio before loading in Group A and Group B using an independent *t*-test showed no significant difference, as shown in Table 5.

The intragroup comparisons that were made of removal torque loss ratio after loading in Group A and Group B using independent *t*-test showed a significant difference ($P \leq 0.05$) in loss of ratio of removal torque after loading among group A1 and A2 (A1 > A2) as well as B1 and B2 (B1 > B2), indicating that screw loosening was higher in groups without thermocycling as compared to those which underwent thermocycling, as shown in Table 6.

Graph 1 demonstrates the intergroup comparison of the loss ratio of removal torque after loading in two implant systems with and without thermocycling.

Graph 2 demonstrates intragroup the comparison of the loss ratio of removal torque before loading within each implant system with and without thermocycling.

The surface topography of the genesis implant–abutment screw without and with thermocycling using SEM at ×200, ×500 demonstrating the surface topography, respectively, are demonstrated in Figures 7 and 8.

The surface topography of the bredent implant–abutment screw without and with thermocycling using SEM at ×200, ×500 demonstrating the surface topography, respectively, are demonstrated in Figures 9 and 10.

The intergroup comparison of values obtained using ImageJ software on the surface roughness of the treated abutment screw showed the SD and mean values. A1 (mean: 90.97, SD: 32), B1 (mean: 86.63, SD: 34.25), A2 (mean: 94.27, SD: 32.29), and B2 (mean: 106.53, SD:

Table 2: The values obtained after tightening the screw at 20 N-cm for initial untightened torque before and untightened torque after loading in all the groups

Torque (N-cm)	Initial untightened torque				After 100,000 cycles untightened torque			
	Group A1	Group A2	Group B1	Group B2	Group A1	Group A2	Group B1	Group B2
20	17	18	17	18	8	9	9	10
20	18	17	17	17	8	8	10	11
20	17	17	18	17	8	8	10	11
20	18	18	17	18	8	9	9	10
20	18	17	17	18	7	7	9	11
20	18	18	17	17	9	9	10	10
20	16	16	18	17	6	8	10	10
20	18	16	17	16	8	7	10	11
20	17	18	17	17	7	9	9	9
20	18	18	17	17	8	8	10	10
20	16	17	18	17	7	8	10	9
20	18	17	17	18	8	9	9	11
20	18	17	17	18	7	8	10	10

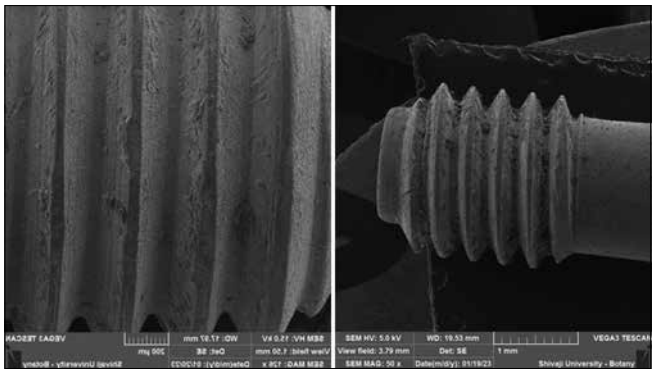


Figure 7: Scanning electron microscopy images demonstrating surface topography of genesis implant–abutment screw without thermocycling at ×200 and ×500, respectively

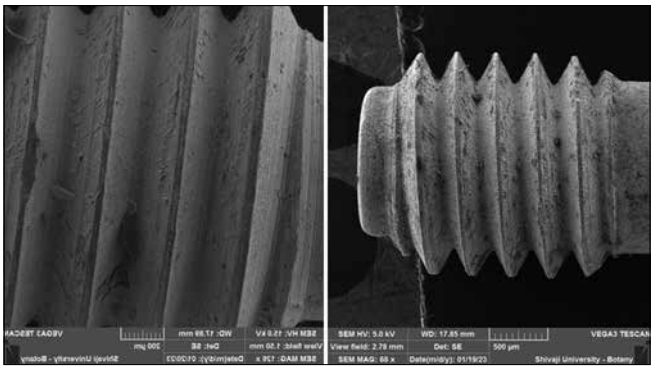


Figure 8: Scanning electron microscopy images demonstrating surface topography of genesis implant–abutment screw with thermocycling at ×200 and ×500, respectively

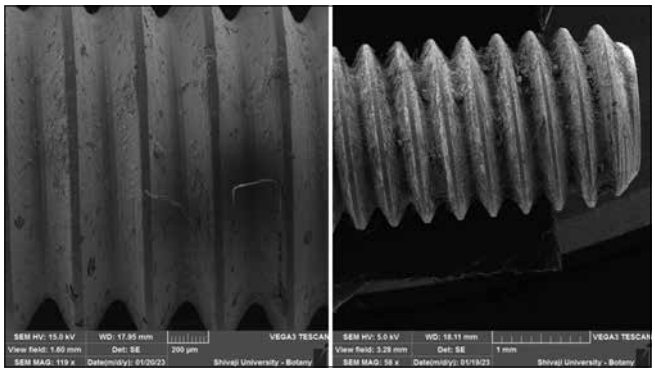


Figure 9: Scanning electron microscopy images demonstrating surface topography of bredent implant–abutment screw without thermocycling at ×200 and ×500, respectively

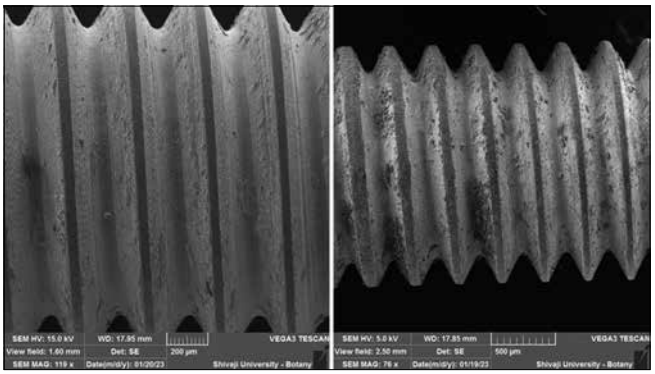


Figure 10: Scanning electron microscopy images demonstrating surface topography of bredent implant–abutment screw with thermocycling at ×200 and ×500, respectively

Table 3: Intergroup comparison of removal torque ratio before loading, with and without thermocycling using independent *t*-test

Aging	Subgroup	Mean±SD	Difference	*P*
Without thermocycling	A1	12.69±3.88	−1.16	0.360
	B1	13.85±2.19		
With thermocycling	A2	13.85±3.63	0.39	0.775
	B2	13.46±3.15		

SD: Standard deviation

Table 4: Intergroup comparison of removal torque ratio after loading with and without thermocycling using independent *t*-test

Aging	Subgroup	Mean±SD	Difference	*P*
Without thermocycling	A1	61.92±3.84	10.00	<0.001*
	B1	51.92±2.53		
With thermocycling	A2	58.85±3.63	10.00	<0.001*
	B2	48.85±3.63		

*Highly significant difference at $P<0.001$. SD: Standard deviation

Table 5: Intragroup comparison of removal torque ratio before loading, with and without thermocycling using independent *t*-test

Implant system	Subgroup	Mean±SD	Difference	*P*
Genesis system	A1	12.69±3.88	−1.16	0.441
	A2	13.85±2.19		
Bredent system	B1	13.85±3.63	0.39	0.721
	B2	13.46±3.15		

SD: Standard deviation

Table 6: Intragroup comparison of removal torque ratio after loading, with and without thermocycling using independent *t*-test

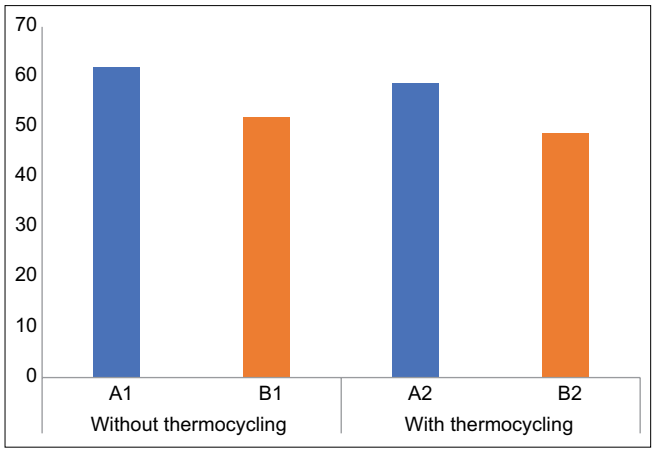
Implant systems	Subgroup	Mean±SD	Difference	*P*
Genesis system	A1	61.92±3.84	3.07	0.046*
	A2	58.85±3.63		
Bredent system	B1	51.92±2.53	3.07	0.019*
	B2	48.85±3.63		

*Significant difference at $P\leq0.05$. SD: Standard deviation

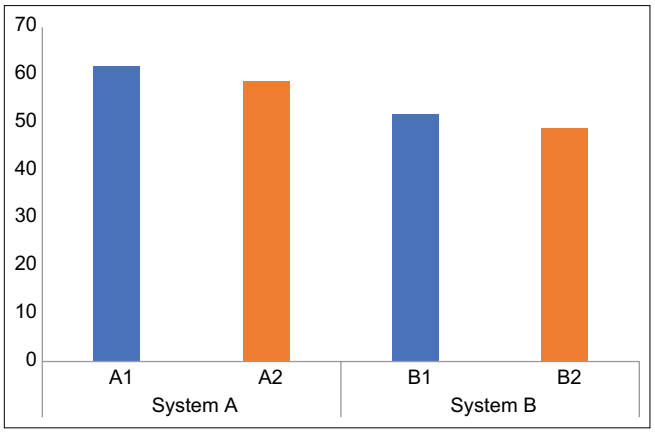
38.35), which shows that surface roughness of A1>B1 and A2>B2, as shown in Table 7.

The intragroup comparison of values obtained using ImageJ software on surface roughness of the treated abutment screw, where A1 (mean: 90.97, SD: 32), A2 (mean: 94.27, SD: 32.29), B1 (mean: 86.63, SD: 34.25), and B2 (mean: 106.53, SD: 38.35), which shows that surface roughness of A1>A2 and B1>B2, as shown in Table 8.

Graph 3 demonstrates the intergroup comparison of surface roughness of the implant system with and without



Graph 1: Comparison of ratio of removal torque loss after loading in two implant systems with and without thermocycling



Graph 2: Comparison of ratio of removal torque loss after loading in each implant system with and without thermocycling

Table 7: Intergroup comparison of surface roughness with and without thermocycling

Aging	Subgroup	Mean±SD
Without thermocycling	A1	90.97±32
	B1	86.63±34.25
With thermocycling	A2	94.27±32.29
	B2	106.53±38.35

SD: Standard deviation

Table 8: Intergroup comparison of surface roughness with and without thermocycling

Aging	Subgroup	Mean±SD
Without thermocycling	A1	90.97±32
	A2	94.27±32.29
With thermocycling	B1	86.63±34.25
	B2	106.53±38.35

SD: Standard deviation

thermocycling, where the x-axis determines the mean values and the y-axis determines subgroups.

Graph 4 demonstrates the intragroup comparison of surface roughness of the implant system with and without thermocycling, where the x-axis determines the mean values and the y-axis determines subgroups.

DISCUSSION

Single-unit implant-supported fixed prosthesis showed a maximum number of screw loosening by various authors and is, therefore, used in this study.[3] Pardel PB et al. stated that the preload should be 75%-80% of the elastic limit of the material or else it results in screw loosening.[18] Therefore, it is crucial to enhance the tightening torque retention and abutment screw preload force. Various studies reported that preload depends on the coefficient of friction between contacting surfaces (roughness of the surfaces, loading, hardness of screw threads, and the presence, quantity, and quality of lubricant on the surfaces.[11,19] In this study, the room-temperature-vulcanizing (RTV)% before loading in all the groups showed no significant difference.

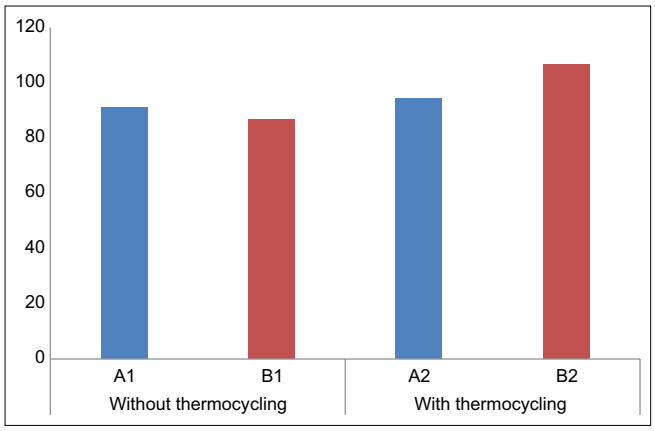
Yong-Hoon Jeong *et al.* used the electron beam physical vapor deposition method to prepare the surfaces of implant–abutment screws on titanium nitride and tungsten carbide films.[20] Elias *et al.* coated the implant–abutment screw with titanium nitride, titanium carbonitride, Teflon, and parylene.[13] The results indicated that uncoated screws had a higher opening torque for a given applied tightening torque. The conclusions drawn were that the coatings improved the performance of immediate fastening and long-term anti-loosening. However, the disadvantage was that the coatings would often fall off on loading.

Sun *et al.* used PNT on an implant–abutment screw as a coating to determine its long-term stability before and after treatment and concluded that PNT abutment screws decreased screw loosening and enhance fatigue performance.[14]

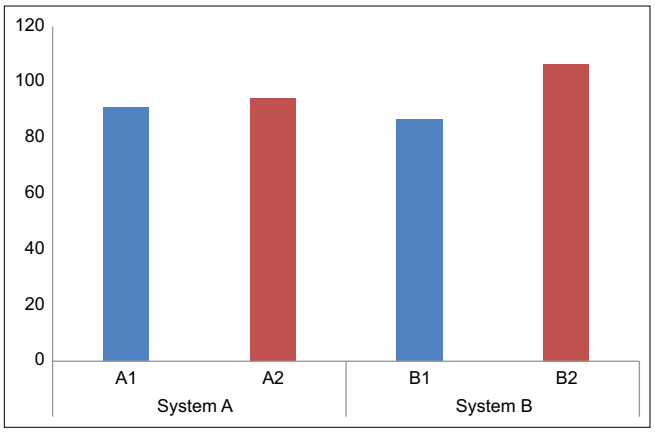
PNT is a surface modification method where the nitriding film shows even distribution on the material surface in close contact with the substrate, increasing its longevity. The nitriding treatment is known to improve the mechanical properties of the abutment screws.[14] All the samples underwent PNT.

The long-term effect of the PNT abutment screws in oral conditions was not tested. In this study, thermocycling was used to simulate the humidity and frequent thermal changes of the oral cavity caused by saliva and food intake. Ten thousand thermocycles are thought to represent an *in vivo* functioning time frame of 1 year of oral environment.[15]

Acrylic resin was used acrylic resin to be subjected to cyclic loading because acrylic resin has enough flexural strength



Graph 3: Comparison of surface roughness after loading in two implant systems with and without thermocycling



Graph 4: Comparison of surface roughness after loading in each implant system with and without thermocycling

and modulus of elasticity (3.4 × 105 lb/in. 2) is close to that of cancellous bone (3.6 × 105 lb/in. 2).[21]

Genesis Aktiv and bredent implant system were selected to be tested as they were the systems used in School of Dental Sciences, Krishna Vishwa Vidyapeeth Deemed to be University, Karad, Maharashtra.

Straight abutment was selected for this study as angled abutments are reported to have higher RTV ratio as compared to straight abutments[22,23] and its influence on the screw loosening would mask the effect of surface treatment to be tested.

Digital torque gauge instead of a hand torque wrench was used for tightening and removal of abutment screws in all the groups to achieve decimal precision for accuracy and standardization and to eliminate the possibility of deviations from exact torque value.[24,25]

In this study, the initial loosening torque was lower than the tightening torque (20 Ncm) before loading [Table 2]. This result coincided with the results obtained by studies that have shown lower loosening torque after tightening, the immediate torque loss rate of the thread joint is about 3%–20%.[26] As a result, the torque necessary to remove a screw is less than the torque initially used to place the screw. This can be due to the settling effect of the abutment during tightening. Therefore, abutment screws are suggested to be retightened after 10 min to reduce the settling effect[27-29] as done in this study.

The application of dynamic cyclic loading was to simulate the tooth contact duration of each masticatory cycle for over a period of 1 week. Furthermore, it is a reliable method to test the effect of mechanical fatigue on implant–abutment stability.[30]

The intergroup and intragroup comparisons of RTV% ratio after loading showed a significant difference, suggesting that the occurrence of the screw loosening process was higher with the genesis implant system (Group A) as compared to the bredent implant system (Group B). The bredent implant system abutment screws had longer and more number of threads as compared to that of the genesis implant system. Alkan *et al*.[31] preferred long screws with more number of threads, as the amount of screw loosening was lesser.

The intragroup comparisons showed the screw loosening was higher in groups that did not undergo thermocycling (A1 and B1) as compared to those that underwent thermocycling (A2 and B2), thereby rejecting the null hypothesis that there was no difference in screw loosening of PNT abutment screw with and without thermocycling.

Ten thousand thermocycles represent a timeframe of 1-year intraoral conditions.[15] In this study, the groups that underwent thermocycling showed a lesser RTV% ratio as compared to those that did not, which means that screw loosening was lesser with the thermocycling group after loading as compared to the groups that did not. The reason could be due to the influence of thermal stress on PNT abutment screws and their difference in the thermal expansion coefficient of the screw and implant body. The thermal stress caused by thermocycling was estimated to be lower than the yielding point as screw loosening occurrence was lower as compared to those that did not undergo thermocycling.[32] The results in this study contradict a report by Colpak and Gumus[33] where a decrease in the RTV% ratio was observed in reverse torque values of all groups after thermomechanical cycling, which indicates a decrease in the torque of the screws of both treated and untreated abutment screws. Coefficient of friction is

controlled by intrinsic metallurgic properties of the raw material and the manufacturing process, which determines the geometric design and quality of the surface finish.[34] Bredent system abutment screw was anodized by the manufacturer. This can be the other reason why the bredent group showed lesser screw loosening when compared to the genesis group.

The surface roughness values were obtained using ImageJ software as shown in histogram determined by SEM [Graphs 3 and 4]. The SEM images of the abutment screws were uploaded onto the software where the grayscale range of the images provides an overall quantitative results of the surface roughness of the screw. The surfaces of the implants appeared to be rough due to the presence of wear debris on the screw surfaces in both the genesis and bredent groups, which indicates that there was a slip in the thread contact surfaces, as shown in Figures 7-10.

Studies have shown that even untreated machined abutment screws also appear to have micro-roughness on the surface of the abutment screws that causes the presence of spots on the mating surfaces of the internal surface of the implant and abutment screw.[33] These spots, on tightening of the abutment screw, flatten causing a decrease in initial preload and initial RTV which results in a settling effect or embedment relaxation. Galling effect is a phenomenon where metal falls off on one and sticks onto the other surface, which is nondesirable. Hence, after loading, the surfaces of the abutment screws appeared rougher.

The surface morphology and microroughness of the implant and screw matching surface should be evaluated for nonstandard machining by the manufacturer, as it known to undergo changes throughout the service life of the implant system, before use as the micromotion can lead to wear of the screw surface caused by the external load.[34]

The screws that underwent thermocycling showed a lesser amount of mean surface roughness value as compared to the groups that did not undergo thermocycling, as shown in Table 7 and Graph 3. The mean surface roughness of genesis abutment screws also was seen to be higher than the bredent group, as shown in Table 8 and Graph 4. These results corroborated with the results of removal torque loss. Thereby, rejecting the null hypothesis that no differences were observed on screw loosening and surface topography of PNT abutment screws with and without thermocycling.

The surface treatment using PNT of the bredent implant–abutment screw showed better compatibility and results as compared to the genesis implant–abutment screw system.

CONCLUSION

The effect of PNT on commonly used genesis and bredent implant systems and comparing the screw loosening and surface topography of abutment screws with and without thermocycling after dynamic loading of the implant was investigated.

Within the limitations of the study, the following conclusions were drawn:

1. Screw loosening of plasma nitride-treated genesis and bredent dental implant system abutment screw was higher with groups that did not undergo thermocycling
2. Screw loosening was higher in the plasma nitride-treated genesis dental implant system as compared to bredent dental implant system
3. Surface roughness of plasma nitride-treated genesis and bredent dental implant system that underwent thermocycling showed more surface roughness when compared to those that did not undergo thermocycling
4. Surface roughness of the plasma nitride-treated genesis dental implant system showed more surface roughness when compared to the bredent implant system.

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Conflicts of interest

There are no conflicts of interest.

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Research

A comparative evaluation of antimicrobial property of traditional and three alternative disinfectants on irreversible hydrocolloid impressions: An *in vitro* study

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Abstract

Aim: The aim was to compare the efficacy of various herbal disinfectants on irreversible hydrocolloid impressions and to investigate the effectiveness of three herbal disinfectants and a chemical disinfectant against particular pathogens.

Settings and Design: *In vitro* -a comparative study.

Materials and Methods: The following methodology was followed to achieve the objectives. Four maxillary impressions were made for each selected patient with irreversible hydrocolloid impression material. The predisinfection swabs were taken from impression sites of teeth 17, 13, 27, and 23 (FDI system of tooth numbering). The impressions were immersed in all four different disinfectants such as 2% glutaraldehyde, Aloe vera solution, 50% neem oil, and apple vinegar solution, then the postdisinfection swabs were taken from the same sites 17,13,27,23 and then cultured onto sheep blood agar and examined for growth, and colony forming units (CFUs) of *Streptococcus viridans*, *Streptococcus mutans*, *Streptococcus sanguis*, and *Actinomyces viscosus*. The comparative analysis was done for the predisinfection and postdisinfection values in each study group.

Statistical Analysis Used: Descriptive analysis, Kruskal Wallis test, Mann Whitney post hoc test, Wilcoxon signed rank test.

Results: The results revealed that the mean CFUs of *S. viridans*, *S. mutans*, *S. sanguis*, and *A. viscosus* during postdisinfection samples were statistically significant when compared to predisinfection samples. Multiple comparison of the mean CFUs of all 4 microorganisms in the control group and in 50% Neem oil group was significantly lesser compared to *A. vera* and Apple Vinegar group.

Conclusion: CFUs of *S. viridans*, *S. mutans*, *S. sanguis*, and *A. viscosus* significantly decreased in the 50% neem oil group as well as the control group. As a result, 50% Neem oil was a viable option for disinfecting alginate impressions.

Keywords: *Actinomyces viscosus*, alternative disinfectants, glutaraldehyde, irreversible hydrocolloid, *Streptococcus viridans*

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INTRODUCTION

Infection control has assumed prime importance in dentistry. It is a matter of concern in prosthodontics as well, where impression materials are most commonly used. The majority of materials (casts and impressions) reveal the presence of various harmful bacteria.[1] The most frequently recognized opportunistic oral pathogens are *Streptococcus*, *Staphylococcus*, *Escherichia coli*, *Actinomyces*, Antitratus, *Pseudomonas*, *Klebsiella pneumonia*, and *Candida* species.[2] The most widely used chemical disinfectants are sodium hypochlorite and glutaraldehyde, both of which can have adverse effects such as skin irritation, and eye-watering.[3]

Consequently, it is essential to find a more natural alternative that would be equally effective in disinfecting while also being biocompatible with a wide range of pathogens.[4] According to the WHO, traditional herbal medicine can become alternative disinfectant materials because of their easily identified and safer ingredients, greater efficiency, and ease of availability. Some of the natural disinfectants used for disinfection are apple vinegar,[3] *Aloe vera* solution,[4] neem oil,[5] and lemon juice.[3]

This study aimed to compare the effectiveness of chemical disinfectants and three different herbal disinfectants such as Apple vinegar, 100% *A. vera*, 50% neem oil on irreversible hydrocolloid impressions and also found out the effectiveness of herbal disinfectants against particular microorganisms. The objectives were (1) to evaluate the antimicrobial effectiveness of irreversible hydrocolloid impressions disinfected with 3 herbal disinfectants, (2) to evaluate the antimicrobial effectiveness of irreversible hydrocolloid impressions disinfected with a chemical disinfectant, and (3) to compare the antimicrobial effectiveness of 3 herbal disinfectants with 1 chemical disinfectant. According to the null hypothesis, there is no discernible difference between the antibacterial properties of chemical and three herbal disinfection solutions.

MATERIALS AND METHODS

Method of collection of data

Ten cooperative dentate patients of the age group between 18 and 50 years who reported to the Department of Prosthodontics, Crown and Bridge, Bengaluru, were selected for the study, and ethical clearance was obtained approval no. 372/VOL-2/2021. Patients who had systemic disorders such as diabetes and renal disorders physically or mentally challenged and uncooperative patients were excluded. Study procedures were explained to the patient and they were included only, after obtaining the consent [Annexure 1].

For all selected patients, impressions were made and disinfected with 4 disinfectants, with 2% Glutaraldehyde as the control group and the test groups being *A. vera* solution, Apple vinegar solution, and 50% Neem oil against 4 different microorganisms (*Streptococcus viridans*, *Streptococcus sanguinis*, *Streptococcus mutans*, and *Actinomyces viscosus*).

Making of alginate impression

Four maxillary impressions were made for each selected patient with irreversible hydrocolloid impression material at intervals which was handled aseptically and in accordance with the manufacturer's instructions. After removal from the patient's mouth, the impression was rinsed slowly with sterile water and gently shaken to remove excess water.[1]

Culture and disinfection

Sterile cotton swabs were used to take the predisinfection swabs which simulate viable bacterial transfer. The swabs were collected from the impression sites of maxillary right and left second molar, and maxillary right and left canine teeth i.e., 17, 13, 27, 23 (FDI system of tooth numbering)[1] (17, 27–Parotid duct opening, 17, 13, 27, 23 - to include both anterior and posterior teeth for taking the disinfection swabs) [Figure 1]. The disinfectants employed in this investigation were commercially available at 2% glutaraldehyde, *A. vera* solution, and apple vinegar solution, with the exception of neem oil, which was freshly produced from neem seeds and diluted with sterile aqua dest diluent to make 50% concentrations,[5] thus making it ready for disinfection.

The impressions were then immersed in disinfectants of 2% Glutaraldehyde (Group A), *A. vera* solution (Group B), apple vinegar solution (Group C), 50% Neem oil (Group D) and were grouped as shown in Table 1. Following disinfection protocols, after 5 min, the impression was removed and rinsed with sterile water, and gently shaken to remove excess disinfectant. Similarly, all 10 selected patient's impressions were made, disinfected, and grouped

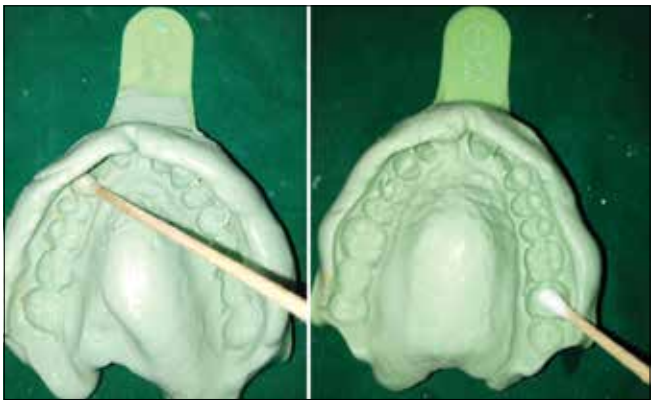


Figure 1: Predisinfection swabs in canine and second molar region

as mentioned in Table 1. Hence, a total of 40 impressions were made (10 × 4 groups = 40 samples). Then the postdisinfection swabs were taken from the same sites 17, 13, 27, 23 in the impression with sterile cotton swabs and labeled as in Table 1 and then cultured [Figure 2].

All predisinfection and postdisinfection cultures were plated directly onto sheep blood agar; cultures were incubated aerobically at 37°C for 24 h.[1] After incubation, all plates were examined for growth; only *Staphylococcus* species were seen where other organisms were absent [Figure 3]. As a result of this, it was decided that artificial strains of *S. viridans*, *S. sanguis*, *S. mutans* (*Lactobacillae* order), and *A. viscosus* (*Actinomycetales* order) would be cultured in the laboratory and the effect of the disinfectants of 2% Glutaraldehyde, *A. vera* solution, Apple vinegar solution, and 50% Neem oil checked.

To check for disinfection, for each disinfectant group, 20 blood agar plates were taken and were inoculated with the same microorganisms as predisinfection and postdisinfection samples. Similarly, for all disinfectant groups, same procedures were carried out and labelled as in Table 2. Thus, a total of 80 blood agar plates (20 × 4 = 80, 40 samples for predisinfection and 40 samples for postdisinfection) were obtained and incubated aerobically at 37°C for 24 h. After incubation, culture plates were checked for the growth of the mentioned microorganisms in both predisinfection and postdisinfection samples, and colony forming units (CFUs) were counted and this helped us to know the efficacy of the disinfectants [Figures 4-7].

The results obtained were then systematically documented in a form of a table. The comparative analysis was done for the predisinfection and postdisinfection values in each study group.

Table 1: Four disinfectant groups and patients

Group	A	B	C	D
1	A_1	B_1	C_1	D_1
2	A_2	B_2	C_2	D_2
3	A_3	B_3	C_3	D_3
4	A_4	B_4	C_4	D_4
5	A_5	B_5	C_5	D_5
6	A_6	B_6	C_6	D_6
7	A_7	B_7	C_7	D_7
8	A_8	B_8	C_8	D_8
9	A_9	B_9	C_9	D_9
10	A_{10}	B_{10}	C_{10}	D_{10}

Group A: 2% glutaraldehyde (control group), Group B: *A. vera* solution, Group C: Apple vinegar solution, Group D: 50% neem oil, Patients: 1–10. *A. vera: Aloe vera*

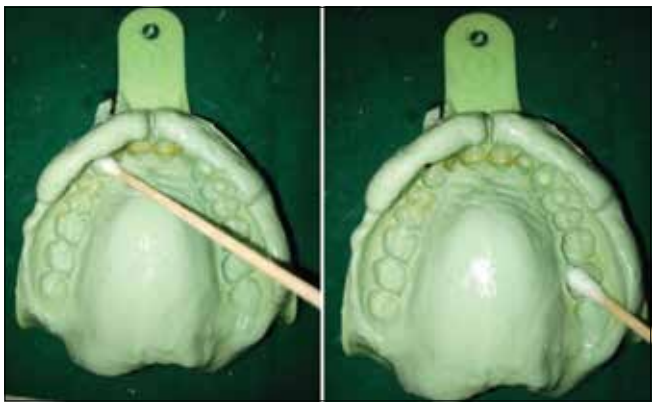


Figure 2: Postdisinfection swabs in canine and second molar region

RESULTS

A total of 40 impressions (sample size was estimated using the G*Power software version 3.1.9.4 (Heinrich-Heine-University, Düsseldorf, Germany) considering the effect, size to be measured [f] at 56%, power of the study at 80%, and the margin of the error at 5%, the total sample size needed are 40, normality was verified using one way ANOVA) were made for ten patients and disinfected with four different disinfectants. Then, predisinfection and postdisinfection swabs were taken for each impression, for a total of 80 swabs, which were cultured, examined for growth, and CFUs of all 4 microorganisms were counted.

Statistical analysis of the data (Statistical Package for Social Sciences [SPSS] for Windows Version 22.0. Armonk, NY, USA: IBM Corp., was used) was carried out using the Kruskal Wallis test followed by Mann–Whitney *post hoc* test to compare the mean CFUs of four microorganisms between 4 study groups. Wilcoxon signed Rank test was used to compare the mean CFUs of all four microorganisms between pre-and post-disinfection procedures in each study group. The level of significance was set at $P < 0.05$.

Figure 3: *Staphylococcus* growth in blood agar plate

Figure 4: Colony formation of *Streptococcus viridans*

Figure 5: Colony formation of *Streptococcus mutans*

Figure 6: Colony formation of *Streptococcus sanguis*

Figure 7: Colony formation of *Actinomyces viscosus*

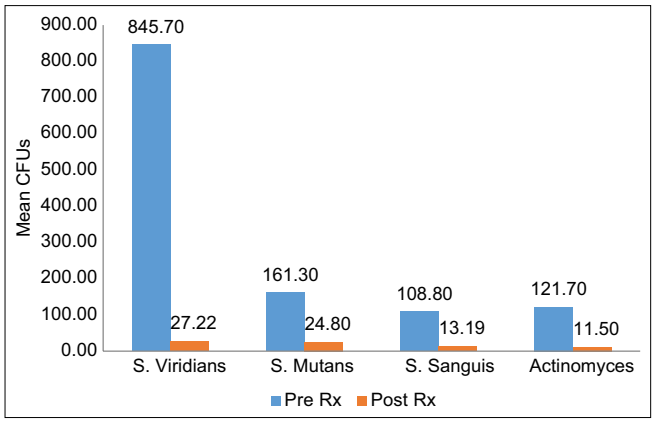
The test results showed significant growth of *Staphylococcus* species for predisinfection samples in all the groups whereas in postdisinfection samples for the control group (scanty/no growth), *A. vera* (present), apple vinegar (present) and 50% Neem oil group (scanty/no growth). This difference in the growth of *Staphylococcus* species between 4 groups in postdisinfection samples was a more significant reduction of microorganisms was seen in the control group >50% neem oil > *A. vera* > Apple Vinegar group.

In the control group (Glutaraldehyde), a significant reduction of mean CFUs was observed in the postdisinfection samples with respect to *S. viridans* > *S. mutans* > *S. sanguis* > *A. viscosus*. In 50% Neem oil group, a significant reduction of mean CFUs was observed in the postdisinfection samples with respect to *S. mutans* > *S. viridans* > *S. mutans* > *A. viscosus*. Similar results were obtained in both *A. vera* group and apple vinegar group were significant reduction of mean CFUs was observed in the postdisinfection samples with respect to *S. viridans* > *S. sanguis* > *A. viscosus* > *S. mutans*. All the pre and postdisinfection values are quoted separately and presented in the Graphs 1-4 for all four groups.

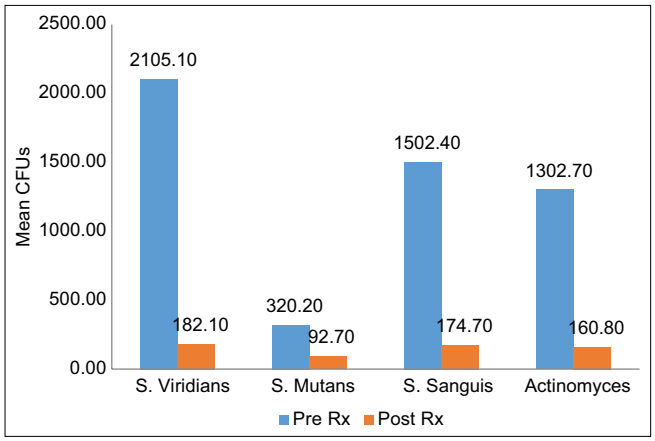
DISCUSSION

Dental workers, patients, and dentists are all exposed to numerous pathogenic bacteria through contaminated casts, materials, prostheses, and impression trays.[6] *S. viridans*, *S. sanguis*, *S. mutans*, and *A. viscosus* are frequent commensals in the oral flora and were chosen for this investigation.[4] Most chemical disinfectant solutions in routine use such as glutaraldehyde, sodium hypochlorite, and iodophor are irritants.[2] Consequently, they are detrimental to both health professionals and the environment.[4]

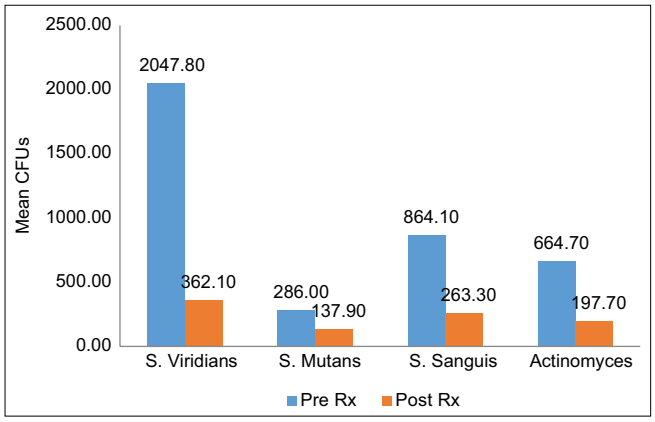
In the present study, alternative disinfectants used are *A. vera* solution,[4] 50% Neem oil[5] and apple vinegar solution[2] (Shelf life ~1–3 years). In this study, the control



Graph 1: Mean CFUs of different organism's b/w pre and post disinfection in control group. CFU: Colony forming unit



Graph 2: Mean CFUs of different organism's b/w pre and post disinfection in *Aloe vera* group. CFU: Colony forming unit



Graph 3: Mean CFUs of different organisms b/w pre and post disinfection in apple vinegar group. CFU: Colony forming unit

group (Glutaraldehyde) showed a microbial reduction of CFUs of *S. viridans*, *S. sanguis*, *S. mutans*, and *A. viscosus*. In a 2017 study, Devi and Himabindu determined the antimicrobial effectiveness of 0.5% sodium hypochlorite and 2% glutaraldehyde disinfection solutions against *S. aureus*, *Pseudomonas aeruginosa*, and *Candida albicans*. They

Table 2: Disinfectants and artificial strains of microorganisms

Disinfection	Disinfectant groups							
	Group A		Group B		Group C		Group D	
	Microorganisms							
	S. viridans		*S. viridans*		*S. viridans*		*S. viridans*	
	S. mutans		*S. mutans*		*S. mutans*		*S. mutans*	
	S. sanguis		*S. sanguis*		*S. sanguis*		*S. sanguis*	
	A. viscosus		*A. viscosus*		*A. viscosus*		*A. viscosus*	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	A_1	A_1	B_1	B_1	C_1	C_1	D_1	D_1
2	A_2	A_2	B_2	B_2	C_2	C_2	D_2	D_2
3	A_3	A_3	B_3	B_3	C_3	C_3	D_3	D_3
4	A_4	A_4	B_4	B_4	C_4	C_4	D_4	D_4
5	A_5	A_5	B_5	B_5	C_5	C_5	D_5	D_5
6	A_6	A_6	B_6	B_6	C_6	C_6	D_6	D_6
7	A_7	A_7	B_7	B_7	C_7	C_7	D_7	D_7
8	A_8	A_8	B_8	B_8	C_8	C_8	D_8	D_8
9	A_9	A_9	B_9	B_9	C_9	C_9	D_9	D_9
10	A_{10}	A_{10}	B_{10}	B_{10}	C_{10}	C_{10}	D_{10}	D_{10}

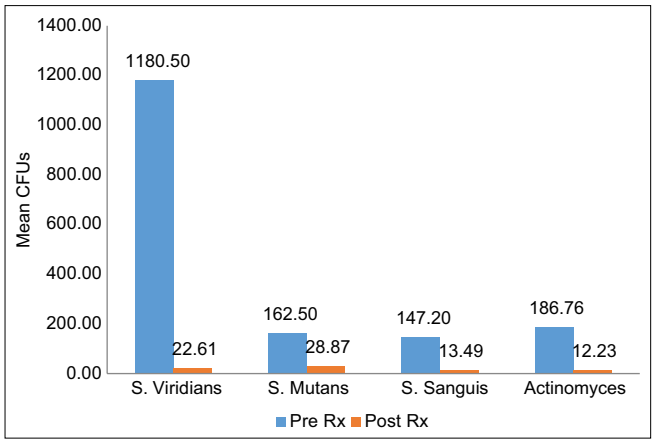
Group A: 2% glutaraldehyde (control group), Group B: *A. vera* solution, Group C: Apple vinegar solution, Group D: 50% neem oil, Patients: 1–10. *S. viridans: Streptococcus viridans, S. mutans: Streptococcus mutans, S. sanguis: Streptococcus sanguinis, A. viscosus: Actinomyces viscosus, A. vera: Aloe vera*

came to the conclusion that both disinfectant agents effectively disinfected alginate impressions.[7]

Apple vinegar is an astringent and a bactericide. When vinegar was employed in an ultrasonic cleaning system, Estrela *et al.* discovered that it had an antibacterial impact against *S. aureus*.[8] According to research by Ousaaid *et al.*, the functional qualities of apple vinegar may be related to the presence of organic acids and phenolic compounds.[9] In this study apple vinegar group (Group B) showed a microbial reduction of mean CFUs in the postdisinfection samples with respect to *S. viridans* > *S. sanguis* > *A. viscosus* > *S. mutans*. Zhang *et al.* studied organic acids in apple vinegar act as a disinfectant with a lasting effect to stop the growth of pathogenic bacteria.[10]

A. vera has strong antibacterial, antifungal, and antiviral effects.[4] Research by White suggests that 100% *A. vera* can be used as disinfectant and effective on oral microorganisms on the surface of the impression starting from the first 3 to 5 min.[11] As in this study, similar results were obtained in *A. vera* group (group C) which showed a reduction of growth and CFUs of tested microorganisms. Similar results were obtained in a study by Zimmerman and Sims, who are quoted in the article on the importance of *A. vera*, the growth of *S. aureus*, *S. viridans*, *C. albicans*, and Cornybacteria xerosis is inhibited by *A. vera*.[4]

Neem oil from neem seeds was used to inhibit the growth of *Salmonella typosa* and *Staphylococcus aureus* bacteria at concentrations of 50%, 75%, and 100%.[5] In this study



Graph 4: Mean CFUs of different organisms b/w pre and post disinfection in 50% neem oil group. CFU: Colony forming unit

50% Neem oil (Group D) was tested against *S. viridans*, *S. sanguis*, *S. mutans*, and *A. viscosus,* and significant antimicrobial efficacy was seen in postdisinfection samples. According to a study by Elavarasu *et al.* that neem oil is beneficial by slowing the growth of the microorganisms that cause plaque.[12] In the 50% Neem oil group, CFUs count and microbial growth in all tested microorganisms were less compared to other disinfectant groups.

Limitations

As it was done with a limited number of sample, a larger population can be taken for further clinical results. The standard strains employed in the test are representative of the oral microbiota, however, it is not recommended to extrapolate from their behavior in connection to the therapies considered to other elements of the intricate oral ecosystem. Also, future studies can be conducted with concentrated disinfectant solutions and other alternate disinfectants to assess their efficacy and also look into antifungal pathogens. The accuracy of the model after use of herbal disinfectants can also be studied. Despite these drawbacks, this work provides insight into a more effective technique for disinfecting impression materials using natural disinfectants.

CONCLUSION

From this study, the following conclusions were drawn:

- The most effective disinfectants for strains of *S. viridans*, *S. mutans*, *S. sanguis*, and *A. viscosus* were 50% neem oil > control group (2% glutaraldehyde) > *A. vera* > apple vinegar solution
- Within the limitations, it was concluded that 50% neem oil > control group (2% glutaraldehyde) > *A. vera* > apple vinegar solution are valid alternatives for the disinfection of alginate impression
- Keeping in mind the results of this study, alternative disinfectants can be future viable options to overcome the drawbacks of chemical disinfectants.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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ANNEXURE 1

Summary of results

Groups	*S. Viridans*		*S. Mutans*		*S. Sanguis*		*Actinomyces*	
	Predisinfection (CFU)	Postdisinf ection (CFU)	Predisinf ection (CFU)	Postdisinf ection (CFU)	Predisinf ection (CFU)	Postdisinfection (CFU)	Predisinfection (CFU)	Postdisinf ection (CFU)
Control	580.0	32.4	44.0	21.4	51.0	1.45	280.0	1.0
Control	62.0	27.8	380.0	156.0	52.0	2.45	26.0	26.0
Control	69.0	42.0	350.0	18.6	21.0	1.00	330.0	18.0
Control	698.0	45.6	11.0	1.0	410.0	31.00	56.0	36.0
Control	37.0	2.4	12.0	1.0	51.0	3.00	110.0	10.0
Control	2800.0	11.0	390.0	21.0	110.0	10.00	110.0	10.0
Control	4100.0	31.0	390.0	26.0	240.0	17.00	180.0	1.0
Control	37.0	25.0	12.0	1.0	51.0	3.00	110.0	10.0
Control	37.0	30.0	12.0	1.0	51.0	28.00	4.0	2.0
Control	37.0	25.0	12.0	1.0	51.0	35.00	11.0	1.0
A. vera	7600.0	660.0	55.0	45.0	76.0	62.00	350.0	250.0
A. vera	56.0	35.0	450.0	380.0	8500.0	820.00	550.0	450.0
A. vera	6000.0	420.0	550.0	55.0	42.0	21.00	5500.0	55.0
A. vera	850.0	76.0	250.0	20.0	41.0	31.00	5600.0	500.0
A. vera	54.0	38.0	680.0	45.0	55.0	41.00	410.0	35.0
A. vera	5400.0	400.0	310.0	30.0	110.0	20.00	240.0	190.0
A. vera	420.0	31.0	64.0	54.0	210.0	200.00	48.0	24.0
A. vera	65.0	55.0	420.0	220.0	5600.0	500.00	63.0	55.0
A. vera	520.0	50.0	63.0	48.0	210.0	22.00	46.0	24.0
A. vera	86.0	56.0	360.0	30.0	180.0	30.00	220.0	25.0
Apple vinegar	800.0	550.0	25.0	20.0	56.0	42.00	410.0	330.0
Apple vinegar	550.0	350.0	56.0	45.0	6700.0	780.00	350.0	250.0
Apple vinegar	5100.0	460.0	280.0	150.0	42.0	35.00	350.0	250.0
Apple vinegar	770.0	520.0	420.0	200.0	37.0	25.00	250.0	100.0
Apple vinegar	620.0	65.0	450.0	400.0	66.0	51.00	780.0	350.0
Apple vinegar	6200.0	600.0	380.0	55.0	260.0	200.00	610.0	350.0
Apple vinegar	42.0	35.0	550.0	54.0	540.0	360.00	3600.0	240.0
Apple vinegar	5500.0	550.0	280.0	150.0	200.0	620.00	55.0	28.0
Apple vinegar	850.0	460.0	89.0	65.0	450.0	220.00	62.0	54.0
Apple vinegar	46.0	31.0	330.0	240.0	290.0	300.00	180.0	25.0
50% neem oil	480.0	24.0	39.0	18.9	46.0	2.10	320.0	1.5
50% neem oil	69.0	35.0	450.0	210.0	52.0	2.40	36.0	17.0
50% neem oil	57.0	31.0	410.0	21.0	28.0	1.40	380.0	22.0
50% neem oil	720.0	35.0	25.0	1.1	340.0	31.00	48.0	24.0
50% neem oil	42.0	2.1	28.0	1.8	64.0	2.50	280.0	11.0
50% neem oil	2800.0	10.0	110.0	10.0	270.0	15.00	360.0	19.0
50% neem oil	7500.0	31.0	440.0	20.0	540.0	34.00	47.0	2.4
50% neem oil	48.0	21.0	35.0	2.0	42.0	2.50	350.0	21.0
50% neem oil	46.0	17.0	52.0	2.5	39.0	19.00	4.6	2.4
50% neem oil	43.0	20.0	36.0	1.4	51.0	25.00	42.0	2.0

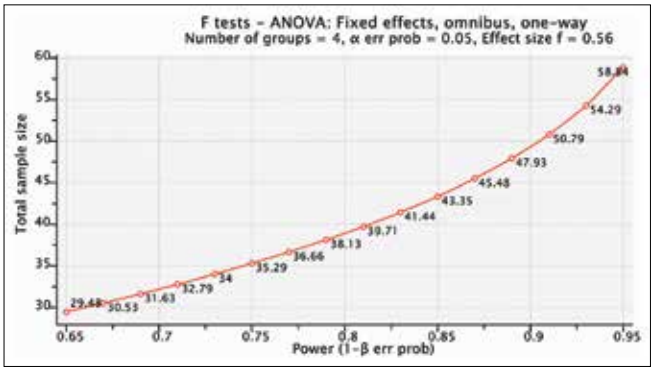
CFU: Colony forming unit, *A. vera: Aloe vera, S. viridans: Streptococcus viridans, S. mutans: Streptococcus mutans, S. sanguis: Streptococcus sanguinis*

Sample size estimation

The sample size has been estimated using the G*Power software version 3.1.9.4.

Considering the effect size to be measured (f) at 56%, power of the study at 80% and the margin of the error at 5%, the total sample size needed is 40. Each group will consist of 10 samples. (10 × 4 groups = 40 samples).

Power analysis curve



Customized esthetic wrought wire retainer in distal extension interim prosthesis: An alternate technique

The most affordable treatment for partial edentulism is acrylic removable partial dentures. Wrought wire retainers are a common type of partial prosthetic restoration on the prosthetic market, which is strongly influenced by the people's low financial resources. Only when the condition of the abutment tooth is suitably paired with the stiffness of the wrought alloy retainer is clinical success achievable. The area the arm that meets the teeth is significantly responsible for how stiff the arm is. Stiffness increases with the shift of measurement point toward the arm shaft which increases the load exerted on the tooth resulting in increased frictional force and wear to abutment teeth. Based on the period of usage of wire retained prosthesis, the amount of wear of lateral surface of tooth will be more. Canine and molar teeth of higher movability featured higher scale of wear if the retainer is active throughout its entire length.[1] When removable prosthesis is opposed to tooth, the distal extension tooth bearing segment has mucosal compressibility that is significantly higher during mastication, resulting in increased forces to the underlying bone.[2]

In the above distal extension scenario of definitive partial denture, the terminal abutment is subjected to Class I lever mechanism. If a conventional circumferential clasp is used as a retainer, the abutment will experience more torsional force as well as the circumferential clasp will compromise esthetics.[3,4] However, when a gingivally approaching clasp is used, the clasp tips to the mesial facial surface and disengage from the abutment, negating the torsional force that would otherwise be applied to it when dislodging forces are applied. It exhibits a Class II lever action.[3]

The circumferential clasp encircles >180° of primary abutment teeth, it will be prone to decalcification of the abutment teeth. Since the contour of the teeth gets over contoured, the self-cleansing property of the abutment teeth is lost. Whereas, in gingivally approaching clasp, the mode of retention is push type retention and only 3 point contact will be present on the abutment teeth which will enhance the retention and esthetics of the prosthesis. Therefore, the self-cleansing property is not lost.[5]

Thus, this manuscript presents an alternative technique using a gingivally approaching wrought wire retainer for improving retention, esthetics, and also lowering the wear of lateral surface of the abutment teeth, since the retainer's tip is the sole active element.

Technique and tips:

1. Case history recording followed by radiographic evaluation and diagnostic mounting was done. Maxillary diagnostic impression was made by alginate and a dual impression by Neil and Nairn technique was made for mandibular arch
2. Fabrication of custom tray for maxillary arch, followed by a single dual tray impression was recorded
3. Fabrication of temporary record base for each arch and jaw relation was recorded by Niswonger's method
4. A 21-mm gauge wire of length 15 mm was used for fabrication of clasp. The blunt end placed over the cervical 3rd of the tooth and the body of the clasp given a 90° bent just below the gingival margin. The clasp is adapted over the lateral slopes of the palate and terminates into two retentive loops [Figure 1]
5. This is followed by processing and finishing of the denture [Figure 2].

Financial support and sponsorship

Nil.

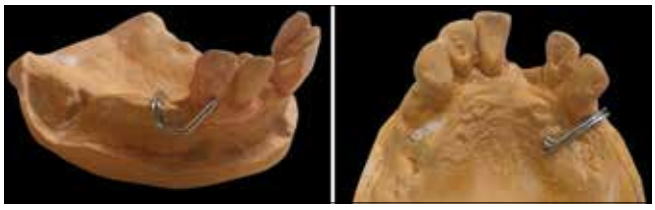


Figure 1: Retainer fabrication on master cast

Figure 2: Lateral view of clasp in maxillary interim partial denture

Conflicts of interest

There are no conflicts of interest.

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Brief Communication

Computer-aided design software-enabled preclinical prosthodontic training: A digital education technique

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Abstract

The prosthodontics preclinical training modules involve textbook-based two-dimensional (2D) ideal images and practicing on manikin models to emulate ideal tooth preparations and teeth arrangements. Relying solely on 2D images as objectives for preclinical exercises limits the trainee's creative skills to instructions of textbooks and clinical instructions received. With advancements in digital dentistry, dental trainees should have early exposure to the three-dimensional (3D) rendering of ideal preclinical objectives. A dental education technique using computer-aided design software and smartphones is described that will allow 3D rendering of ideal prosthodontic training assignments allowing early exposure to digital dentistry for dental training students.

Keywords: Computer-aided design software, dental education, digital dentistry, exocad

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INTRODUCTION

Conventional dental training curriculum consists of knowledge acquisition from textbooks, didactic lectures by tutors, and practice exercises on models and manikins to sharpen psychomotor skills. The prosthodontics preclinical training modules involve textbook-based two-dimensional (2D) ideal images and practicing on manikin models to emulate ideal tooth preparations and teeth arrangements. Relying solely on 2D images as objectives for preclinical exercises limits the trainee's creative skills to instructions of textbooks and clinical instructions received. Early exposure to digital training models in dental education will familiarize the dental trainees with advances in digital dentistry that can aid in developing and enhancing psychomotor skill acquisition.[1,2]

PROCEDURE

With technological advancements, where the final prostheses can be designed on software, dental trainees should have early exposure to the three-dimensional (3D) rendering of ideal preclinical objectives.

A typodont with ideal tooth preparations was made. The model was scanned using a dental laboratory scanner (Medit T500, South Korea), and stereolithography file was transferred to computer-aided design (CAD) software (exocad GmbH). The software provides a

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3D rendering of ideal tooth preparation [Figure 1]. In addition, a CAD model of maxillary and mandibular teeth articulated in a Class I occlusion was designed in the software [Figures 2 and 3]. A link providing access to the 3D preclinical objectives through CAD software was shared with the students. Link for preclinical prosthodontics training CAD view (to be downloaded and opened with exocad webview): https://drive.google.com/file/d/1AZUNVQFxdl0sFR4DBW6-OF_GfCXqzFHw/view?usp=share_link. Link for preclinical conservative training CAD view (to be downloaded and opened with exocad webview): https://drive.google.com/file/d/1aznEkmMYVeB23MOjn-SOT_Vxi9tQ-Kgt/view?usp=share_link. The link provides access to students through a web-based application – "Exocad Webview" (Exocad GmbH), enabling them to visualize ideal cavity preparation and teeth arrangement in 3D view using the software's features. The application works with any smartphone, has a simple and user-friendly interface, is free of charge, quickly loads almost any 3D mesh in a 3D viewer, and supports all open file formats. The CAD software-enabled view allows trainees to view the tooth preparations and ideal tooth arrangement in multiple planes and orientations.

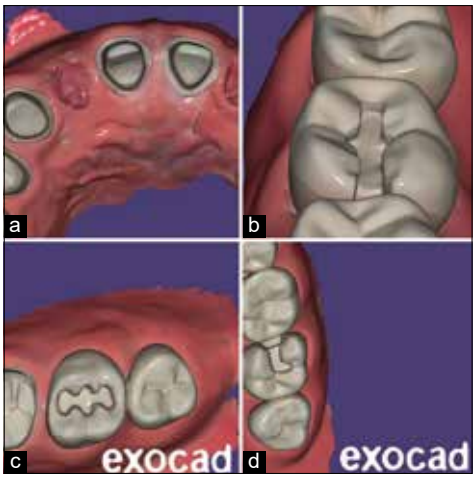

Figure 1: (a-d) Exocad view of various tooth preparations on typodont models as viewed in different planes

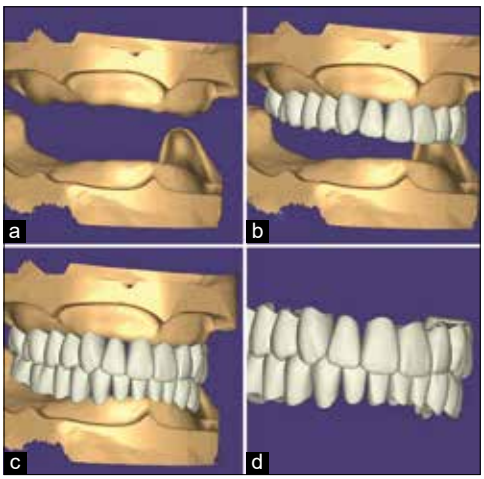

Figure 2: (a-d) Exocad view of edentulous maxillary and mandibular models with teeth arrangement in articulation

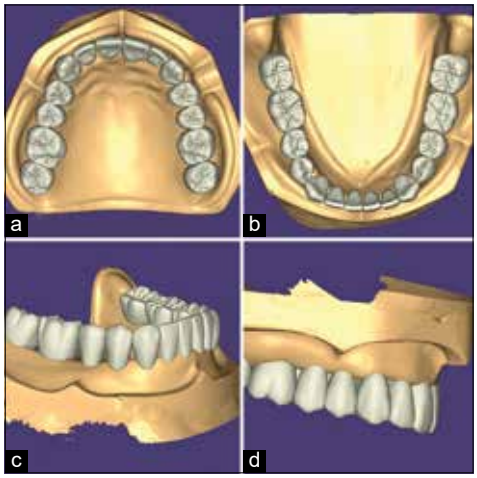

Figure 3: (a-d) Exocad view of maxillary and mandibular models with teeth arrangement viewable in any plane of choice

DISCUSSION

The 3D preclinical objective allows dental students to closely visualize each detail in different planes, an opportunity unavailable with traditional 2D images from textbooks. Early exposure to digital dentistry tools will make trainees more inquisitive about the profession. Existing evidence suggests that digital models and virtual simulators improve dental trainees' assessment capabilities and academic and clinical performances.[3-5] The teeth arrangement view, viewable on any smartphone with the ability to view the preclinical objectives in any plane of choice, provides students with a 3D rendering of the expected outcome. The ability to show or hide each layer, namely – maxillary or mandibular arches and teeth, enabled trainees to observe each component separately and in any orientation. Early exposure to digital dentistry's capabilities helps trainees gain firsthand access to advanced technology. The 3D view based on CAD software has an extremely logical and easy interface to use because the software emulates the analog work of a dental workflow. The access to 3D rendered objectives is limited to visualization in different planes, which remains a limitation of the technique, although the "view-only" option provides an opportunity to view learning objectives in a 3D view as against the earlier 2D images from textbooks. Moreover, dentistry being a skill-based specialty, would still require hands-on training in all aspects, and CAD-based training can only reinforce the existing system and cannot entirely replace the current

hands-on training modules of prosthodontic preclinical training. Academic institutions with digital training centers with licensed CAD software and artificial intelligence (AI) enabled simulators like MOOG simulators can allow trainees to further design and familiarize themselves with the advancements in digital dentistry, which will become a basic necessity in the near future. The inclusion of CAD software, virtual reality simulators, AI, and augmented reality technologies in academic curricula and the adoption of such training strategies by dental institutions and universities can strengthen the dental education systems.[6]

SUMMARY

A novel digital education technique using CAD software for preclinical prosthodontic training is described. The technique is cost-effective, straightforward, and can be used for large-scale use among any number of students as students view the 3D rendering in personal smartphones and do not require additional hardware or equipment. Digital tools like dental CAD software training must be included in the preclinical training curriculum as it will make dental training a digitally well-acquainted program for a technically savvy generation of dentists.

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Conflicts of interest

There are no conflicts of interest.

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