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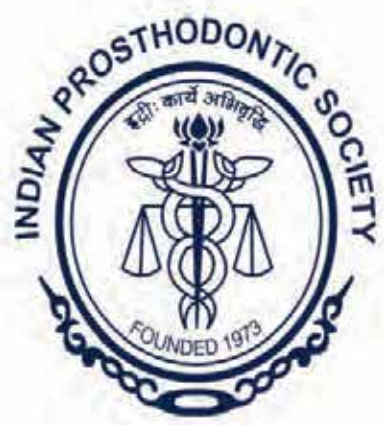

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The Journal of Indian Prosthodontic Society is the official publication of The Indian Prosthodontic Society. Published quarterly, this journal serves as a platform for the exchange of interesting case reports, scientific studies, literature reviews and valuable tips for the common benefit of the prosthodontics community. The journal also aims to bring evidence-based dentistry to the forefront and highlight its importance.

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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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REVIEWERS, 2021

Editorial

Greetings from the editorial board.

As the new Editor-in-chief, I acknowledge the former editors for their stupendous effort in establishing an identity for the *Journal of Indian Prosthodontic Society*. "Success does not happen overnight; it happens with hard work and team support," and the path to reach the present status was supported by the Past Presidents and Secretaries of the Indian Prosthodontic Society. I take this opportunity to share some historical events that led our Journal to reach the current position.

Dr. Kashyap Bhargava became the first editor of the official publication at the inception of Indian Prosthodontic Society in 1973. He and his successors, *Dr. Kickeri, Dr. Ajay D Lal, Dr. D.V. Nadigir,* and *Dr. Veena Subba Rao* published journals at periodic intervals. *Dr. Suhashini Nagda* (1998–2008) initiated the quarterly publication and registered our Journal with the Register of Newspaper of India, Indian National Scientific Documentation center, National Institute of Science Communication, Information Resources, and Abstracts on Hygiene and Communicable diseases. She was instrumental in attaining the ISSN number and subsequently to index our journal by Google Scholar, Index Copernicus, and Scopus. She also commenced the installation of website in the year 2003–2004. *Dr. Ravindra Savadi* (2009–2012) launched the reviewers' database and the journal was indexed by PubMed-Central during his tenure. *Dr. Shilpa Shetty* (2013–2015) improvised the journal by refining the review process, and *Dr. Gopi Chander* (2015–2021) streamlined the reviewers' database. During his term, the journal was indexed by PubMed-Medline and Web of Science, and his innovative ideas led to many competitive-based publications under the various titles. The editorial board, since 2000, also conducted periodic seminars and workshops to uplift the knowledge and skill of the editors and reviewers.

Currently, the volume of manuscripts submitted has increased immensely and the editorial board assures to publish the quality manuscripts to improve the citations. The journals are assessed and ranked by various measures, and the impact factor is one such measure that is highly valued. The impact factor is calculated based on the number of citations per manuscript that was published in the preceding 2 years. Personally, I wish to have a commendable impact factor for our journal and that depends on the quality of manuscripts and transparent review process. My humble request to all the authors to help me in achieving this goal by submitting their high-quality original research and systematic reviews for peer review and acceptance.

I welcome suggestions and looking forward to work for you.

V. Anand Kumar

Editor-in-Chief, The Journal of Indian Prosthodontic Society

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Review

The soft tissue esthetic outcome with and without immediate provisionalization in immediate implants: A systematic review and meta-analysis

Priyanka Vaibhav Sutariya, Shruti Parthiv Mehta, Hemil Hitesh Upadhyay, Mansoorkhan Rafikahmed Pathan, Surbhi Ravi Patel, Yashpreetsingh Amarjitsingh Bhatia

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Abstract

Aim: This systematic review and meta-analysis aimed at checking influences of immediate provisionalization on the primary esthetic outcome by Pink Esthetic Score (PES) as well as other secondary soft tissue outcomes such as bleeding on probing, probing depth, plaque index, mesial papillary recession, distal papillary recession, and midfacial mucosal recession of the peri-implant mucosa around immediately placed implants in the anterior maxilla.

Setting and Design: This systematic review and meta-analysis was evaluated using the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines.

Materials and Methods: The relevant studies were found in the databases such as MEDLINE (PubMed), the Cochrane Central Register of Controlled Trials, Science Direct, and Google Scholar. The search was restricted to studies published in English only, with no time constraints. A second hand search was conducted on individual journals and study reference lists. The Evidence Project risk-of-bias tool was used to assess the risk of bias in included studies. The level of evidence was determined using the GRADEpro GDT: GRADEpro Guideline Development Tool (software). McMaster University, 2020 (developed by Evidence Prime, Inc.,)

Statistical Analysis Used: The statistical meta-analysis was conducted by using Review Manager (RevMan) (Computer Program). Version 5.4. Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration, 2020.

Results: Nine studies were finalized. Seven studies were selected out of nine in the meta-analysis for PES. The results of the current meta-analysis for primary outcome observed that immediate implant placement (IIP) followed by immediate provisionalization improves the esthetic outcome, with forest plot favoring immediate provisionalization and demonstrating a statistically significant difference (mean difference [MD] $=1.54$, [95% confidence interval (CI): 0.82–2.27], $P < 0.0001$). Statistically insignificant result was observed for secondary outcomes; bleeding on probing (MD $= 4.00$, [95% CI: -1.15–9.15], $P = 0.13$), probing depth (MD $= 0.17$, [95% CI: -0.13–0.48], $P = 0.26$), plaque index (MD $= -1.00$, [95% CI: -7.56–5.56], $P = 0.77$), mesial papillary recession (MD $= -0.10$, [95% CI: -0.31–0.10], $P = 0.33$), midfacial mucosal

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recession (MD = −0.47, [95% CI: −1.01–0.07], P = 0.09). However, for distal papillary recession (MD = −0.32, [95% CI: −0.50–−0.13], P = 0.0007), the result was statistically significant with forest plot favoring immediate provisionalization.

Conclusion: When the implant is placed in the esthetic zone, IIP with immediate provisionalization provides the best gingival (pink) esthetics.

Keywords: Anterior maxilla, immediate implant placement, immediate provisionalization, pink aesthetics

INTRODUCTION

Replacing missing teeth has become one of the most critical requirements for restoring appearance and function.[1] Patients increasingly demand restorations that are functional as well as esthetic. Replacing missing teeth with the implant-supported fixed prosthesis in the esthetic zone is a well-known treatment method. Esthetic implant restoration mimics natural teeth in all aspects.[2] The clinician should know various concepts and techniques to attain a good implant esthetic outcome.[3] Due to the growing demand for immediate esthetics, practitioners led to a focus even further by providing restorations immediately following implant placement.[4]

Preserving alveolar bone and interproximal soft tissues following tooth extraction remains a challenge to achieve optimum esthetic. It is prudent to preserve the socket dimensions, shape, and gingival tissue height.[5] With rising patient needs and expectations, efforts were made to decrease the total treatment time by placing implants immediately following tooth extraction. Placing implants immediately to replace teeth in the esthetic zone has become a commonly used strategy for treatment. When compared to conventional implant placement, immediate implant placement (IIP) reduces the healing time while maintaining a high success rate.[6]

Various surgical factors affect the level of crestal bone and soft tissue around the immediate implant, which influences the final esthetic outcome.[6] Factors that influence implant esthetic outcome are the medical status of the patient, smoking habits, lip line, gingival biotype, soft tissue anatomy, the width of edentulous span, restorative status of neighboring tooth, infection at the site of implant placement, bone level at the adjacent tooth, bone anatomy of alveolar crest, and patient's esthetic expectations.[7] Abutment materials also influence peri-implant tissue color. When compared to metal abutments, ceramic abutments improve color matching between soft tissue around the implant and natural teeth.[8] Excess cement around the implant–mucosal interface causes bleeding when probed. Excess cement must be removed after the cementation procedure to prevent peri-implant inflammation.[9] If there is a sharp edge of provisional restoration remains, then it might irritate the peri-implant mucosa and cause inflammation. Connective tissue grafts are frequently used in conjunction with IIP and provisionalization to improve the soft tissue outcome and reduce peri-implant mucosal recession in the esthetic zone.[10] Over the last decade, IIP with immediate restoration has grown in popularity.[6] Immediate provisional restoration may improve the soft tissue contour in the immediate postextraction site, resulting in superior esthetic results.[11]

Esthetic indices are the tools for evaluating hard and soft tissue based on implant esthetic outcomes. One such tool to evaluate implant esthetic outcomes is Pink Esthetic Score (PES).[12] Peri-implant mucosa can be assessed with the help of PES after the implant treatment. PES is determined by seven factors: the mesial papilla, the distal papilla, the soft-tissue level, the soft-tissue contour, the alveolar process deficiency, the soft-tissue color, and the texture.[13]

The provisional fixed dental prosthesis provides several advantages right from treatment planning at the diagnostic stage to the luting of final restorations. It helps to assess occlusal, functional, and esthetic parameters at the time of diagnosis, ultimately helping to identify an optimal treatment outcome, before the final prosthesis is delivered. It provides a template to define contour, esthetics, proximal contacts, and occlusion of the final restoration. It can also be an essential tool in the psychological management of patients with aesthetic concerns to visualize the final results of the treatment.[14] Provisional restorations are designed to stabilize and/or function for a limited time and then must be replaced with a permanent prosthesis.[15]

Implant-supported interim restorations are a practical and necessary component of a successful implant restoration, especially in cases where the peri-implant gingiva in the esthetic area must be preserved and

require manipulation.[16,17] Immediate provisionalization replaces the natural contours of the teeth and supports the gingival architecture during the healing process, thus improving the overall prognosis of the treatment.[18] A thin buccal bone plate with a thin gingival biotype and exposure of peri-implant mucosa and future prosthesis when smiling or speaking are all common risk factors in the esthetic zone.[16] By understanding the nature of the tissue biotype, the clinician can employ appropriate surgical and periodontal procedures to reduce alveolar resorption and create a more favorable environment for implant placement.[19]

There have been mixed results regarding the esthetic benefits of immediate provisional restoration of dental implants in peri-implant tissue. The impact of provisionalization on peri-implant mucosal changes has been studied in recent studies, but no specific data were reported for an esthetic outcome. As a result, the purpose of this systematic review was to compare the esthetic outcome of implants placed immediately with and without immediate provisionalization in the maxillary anterior region. The null hypothesis for this systematic review was that there would be no difference in the aesthetic outcome of the soft tissue with immediate provisionalization compared to nonprovisionalization in immediately placed implants in the esthetic zone.

MATERIALS AND METHODS

Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines were used to conduct the current systematic review.[20] The research question formulated for the study was "Does immediate provisionalization have any influence on aesthetic outcome of the peri-implant mucosa around immediately placed implants in the anterior maxillary region?" The research question for the study was formulated based on population/participants, intervention, comparison, outcome, time, study design (PICOTS) structure.

This translated to:

- Population/participants: Anterior maxilla (at least between maxillary first premolars)
- Intervention: IIP with immediate provisionalization
- Comparison: IIP with and without immediate provisionalization
- Outcomes: (A) Primary outcome: Esthetic outcome with PES; (B) Secondary outcome: Soft-tissue outcome (bleeding on probing, probing depth, mesial papillary recession, distal papillary recession, midfacial mucosal recession, plaque index)
- Time: Studies that evaluate esthetic outcome at least 12 months after functional loading of implants
- Study design: Randomized controlled clinical trials (RCTs), prospective and retrospective clinical studies performed in humans.

Search strategy

Using the MESH terminologies, "Aesthetics, Dental Implants, Single-Tooth, Maxilla," an electronic search of various databases such as the National Library of Medicine (MEDLINE-PubMed), The Cochrane Central Register of Controlled Trials, Science Direct, and Google Scholar was performed. Other terminologies used for searches were "Immediate provisionalisation, Immediate implant placement, Peri-implant tissue, and Aesthetic outcome." These terminologies were searched with the Boolean operator "AND" and "OR." In addition to an online search, a hand search of review and clinical study bibliographies was performed on the topic of "immediate implant provisionalisation."

Inclusion and exclusion criteria

In the current systematic review, studies that met the following criteria were included.

1. Conducted on human participants
2. Full-text articles published solely in the English language
3. Include soft tissue and aesthetic outcome
4. Include IIP
5. Include immediate provisionalization
6. Include single implant placement in the anterior maxilla
7. Minimum follow-up period of 1 year
8. The implant must be placed at least from the premolar-to-premolar region
9. Minimum or no flap elevation during implant placement.

Studies were excluded if:

1. It was an *in vitro* study
2. The study was published other than the English language
3. Delayed implant placement was carried out
4. The study did not include soft tissue and esthetic outcome
5. If provisionalization was done in the posterior maxillary region
6. Follow-up <1 year
7. Presence of periodontal disease
8. Nonclinical studies, reviews, case reports, letters to editors, and technical notes were excluded from this systematic review.

Data collection and extraction

The data collection form for intervention reviews developed by Cochrane was used in the present study by two different authors (HU, MP) for data collection and extraction.[21] Data for primary and secondary outcomes were extracted from the included study. The following study data were gathered from each included study (based on inclusion and exclusion criteria): (1) author and year of publication; (2) type of study and randomization method; (3) control and treatment groups; (4) the size of the patient and implant samples; (5) the arch in which the implant is placed; (6) the timing of implant placement; (7) the time of provisionalization; (8) the follow-up period; and (9) the treatment outcome.

The titles and abstracts of the research were verified for possible inclusion by three independent authors (YB, HU, and SP). The authors then retrieved the full texts of all studies for independent review. All disagreements were resolved by discussion. Moreover, if an agreement could not be reached, another two investigators (PS, SM) resolve the conflict.

Quality assessment of included studies

"The Evidence Project risk-of-bias tool" was used to check the study rigors in both RCTs and non-RCTs.[22] The tool evaluated the validity and randomization of the studies. To assess the risk of bias, eight domains were used: (1) cohort, (2) control or comparison group, (3) prepost intervention data, (4) random assignment of participants to the intervention, (5) random selection of participants for assessment, (6) follow-up rate of 80% or higher, (7) comparison groups equivalent on sociodemographics, and (8) comparison groups equivalent on outcome measures at the baseline.

Statistical analysis

The variations in soft tissue esthetic outcomes with and without immediate provisionalization in immediately placed implants were investigated through meta-analysis. The differences in Mean (mean difference [MD]) values reported for esthetic outcome with 95% confidence interval (CI) were considered effective measures. *P* value was used to check the significance of the result between the two groups. If the $P < 0.05$, then there was a statistically significant difference in esthetic outcome when compared immediate provisionalization with nonprovisionalization in immediately placed implants. To analyze these effects and create a forest plot, Review Manager (RevMan) (Computer Program). Version 5.4. Copenhagen: The Nordic Cochrane Centre, Denmark, The Cochrane Collaboration, 2020. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2020 was used.

Data were collected from studies of different geographic regions. Thus, assuming heterogeneity of population exists, a random effect model was chosen for meta-analysis of included studies.

Summary of findings

To create the "Summary of findings" table, GRADE criteria were used to evaluate evidence quality, and the GRADE profiler (GRADEpro GDT) was used to import information from Review Manager 5.4. It was also used to evaluate the evidence's reliability, incompleteness, inaccuracy, and publication bias. The GRADE pro-GDT [Software] was used to generate the evidence profile table (Developed by Evidence Prime, Inc. Available from gradepro.org). The Medical Information Network Distribution Service, a Japanese GRADE education center, provided us with advice on how to use the GRADE system. Two reviewers (PS and SM) discussed the possibility of bias and agreed with the final decision.

RESULTS

Study selection

The initial electronic database search identified 213 possible publications. 46 were removed based on duplicate records (26) and full text not available (20). The remaining 167 articles were screened. From these 167 articles, 96 were excluded after evaluating their title and abstract. Following a full-text review of the remaining 71 articles, 62 were ruled out due to inclusion and exclusion criteria. As a result, the final nine articles were chosen for this systematic review [Figure 1].

Characteristics of included studies

Table 1 depicts the characteristics of the nine studies. There were four RCTs, four prospective studies, and one retrospective study among the nine included studies. The nine studies included 404 patients and 435 implants with a follow-up period of a minimum of 1 year [Table 1].

Risk of bias within studies

All nine studies have a low risk of bias (100%). In Figure 2, green color denotes Yes. Red color denotes No. Yellow color denotes Not applicable/Not reported [Table 2 and Figure 2].

Primary outcome

Meta-analysis 1: Esthetic outcome with and without immediate provisionalization by Pink Esthetic Score

A total of seven studies evaluated esthetic outcome with immediate provisionalization from which two studies compared the esthetic outcome with and

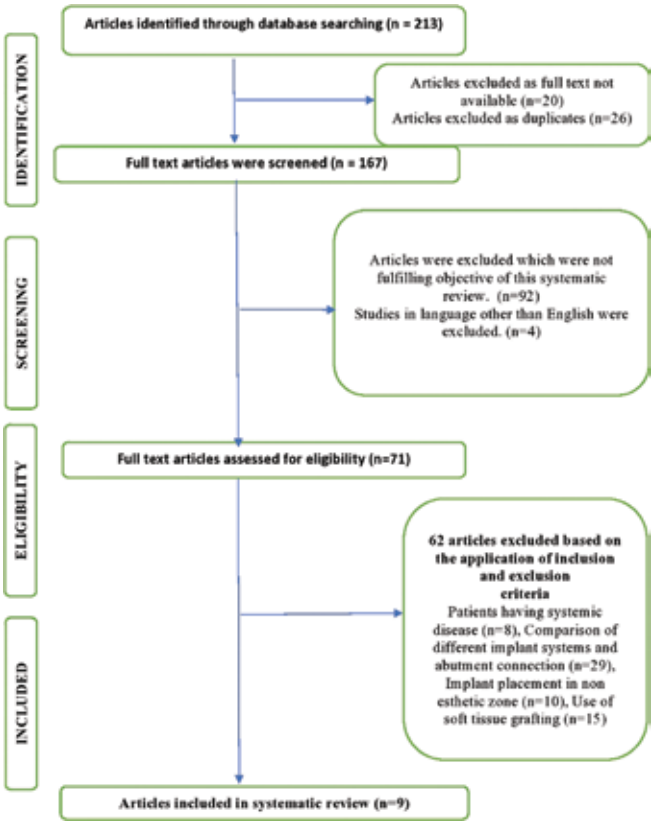

Figure 1: Study selection

Figure 2: Graphical representation of quality assessment of risk of bias in included studies

without provisionalization. All implants were placed and provisionalized immediately after extraction. These studies evaluated/included 365 immediately placed implants with provisionalization with a minimum 1 year of follow-up. All the studies calculated esthetic outcomes by PES with the scores 0, 1, and 2. The higher the score, the better the esthetics. In the meta-analysis performed on the PES [Figure 3], a statistically significant difference was observed ($P < 0.0001$) with favorable PES when the implant was placed immediately and provisionalized (MD = 1.54, [95% CI: 0.82–2.27]). Heterogeneity was high ($I^2 = 83\%$) because only two studies had a comparison group out of 7 studies.

Secondary outcome

Meta-analysis 2: Bleeding on probing with and without immediate provisionalization

Two studies calculated bleeding on probing with provisionalization. From which, only one study calculated bleeding on probing compared with and without immediate provisionalization. In the meta-analysis performed on bleeding on probing [Figure 4], statistically insignificant difference ($P = 0.13$) was found in bleeding on probing when provisionalization was done or not done after IIP (MD = 4.00, [95% CI: −1.15–9.15]).

Meta-analysis 3: Probing depth around implants with and without immediate provisionalization

Three authors have evaluated probing depth is immediately placed implants and provisionalization, from which two studies calculated probing depth compared with and without immediate provisionalization. It was calculated in millimeters. In the meta-analysis performed on probing depth [Figure 5], statistically insignificant difference ($P = 0.26$) was found with high probing depth when the implant was placed immediately and provisionalized (MD = 0.17, [95% CI: −0.13–0.48]). Heterogeneity was moderate ($I^2 = 73\%$).

Meta-analysis 4: Plaque index around implants with and without immediate provisionalization

Two studies had evaluated plaque score in immediately placed implants and provisionalization, from which one study calculated plaque score compared with and without immediate provisionalization. It was calculated in percentage (%). In the meta-analysis performed on plaque index [Figure 6], statistically insignificant difference ($P = 0.77$) was found in plaque index when provisionalization was done immediately after implant placement and when provisionalization was not done (MD = −1.00, [95% CI: −7.56–5.56]).

Table 1: Characteristics of the included studies

Author	Study design	Outcome	Number of implants	Arch	Timing of implant placement	Gingival biotype	Time period after which data were collected	Measurement site	Pink Esthetic Score (mean±SD)
De Rouck *et al.*[23]	RCT	Soft tissue dimension, probing depth, bleeding on probing, implant survival, patient esthetic satisfaction	49	Maxillary anterior region	Immediate	Thick	3, 6, 12 months	Clinical	-
Cosyn *et al.*[24]	Prospective study	PES	30	Maxillary anterior region	Immediate	Thick gingival biotype	3-year follow-up	Clinical	10.48±2.47
Hartlev *et al.* (2014)[25]	Prospective study	PES	68	Maxillary anterior region	Immediate	-	Mean follow-up 33 months	Clinical	Mean: 9.9
Van Nimwegen *et al.*[26]	Retrospective study	Bleeding on probing, PES	51	Maxillary anterior region	Immediate		5-year follow-up	Clinical	7.35±1.23
Noelken *et al.* (2018)[27]	Prospective study	PES	37	Maxillary anterior region	Immediate	All	1-, 2-, 5-year follow-up	Clinical	11.7±2
Arora *et al.* (2018)[28]	RCT	Probing depth, PES	40	Maxillary anterior region	Immediate		12-month follow up	Clinical	Group A: 11.1±2.08 (immediate provisionalization) Group B: 10.3±2.23 (without provisionalisation)
Furze *et al.*[16]	RCT	PES	20	Maxillary anterior region	Immediate	-	3, 12, 36 months	Clinical	Group 1: 8.1±1.6 (with provisionalization) Group 2: 5.5±1.93 (without provisionalisation)
Groenendijk *et al.* (2020)[29]	Prospective study	PES	100	Maxillary anterior region	Immediate	-	1-year follow-up	Clinical	12.081±1.633
Wang *et al.*[30]	RCT	3D-ridge change: Bone crest Bone thickness Ginviva volume	40	Maxillary anterior region	Immediate	Thick	12-month follow-up	Clinical	-

PES: Pink esthetic score, RCT: Randomized controlled clinical trial, 3D: Three-dimensional, SD: Standard deviation

Table 2: Results for quality assessment of risk of bias in included studies

Study	Cohort	Control or comparison group	Pre/post intervention data	Random assignment of the participants to the intervention	Random selection of participants for assessment	Follow-up rate of 80% or more	Follow-up (%)	Comparison groups equivalent on sociodemographic	Comparison groups equivalent at baseline on disclosure	Risk of bias
De Rouck *et al*.[23]	Y	Y	Y	Y	Y	Y	94	NR	NR	Low
Cosyn *et al*.[24]	Y	N	Y	N	Y	Y	83	NA	NA	Low
Hartlev *et al*. (2014)[25]	Y	N	Y	N	Y	Y	81	NA	NA	Low
Van Nimwegen *et al*.[26]	Y	N	Y	N	Y	Y	80	NA	NA	Low
Noelken *et al*. (2018)[27]	Y	N	Y	N	Y	Y	90	NA	NA	Low
Arora *et al*. (2018)[28]	Y	Y	Y	Y	Y	Y	100	NR	NR	Low
Furze *et al*.[16]	Y	Y	Y	Y	Y	Y	95	NR	NR	Low
Groenendijk *et al*. (2020)[29]	Y	N	Y	N	Y	Y	98	NA	NA	Low
Wang *et al*.[30]	Y	Y	Y	Y	Y	Y	95	NR	NR	Low

NA: Not available, NR: Not reported

Meta-analysis 5: Mesial papillary recession around implants with and without immediate provisionalization

Three studies have evaluated mesial papilla in immediately placed implants and provisionalization, from which two studies calculated mesial papilla compared with and without immediate provisionalization. It was calculated in millimeters. In the meta-analysis performed on mesial papillary recession [Figure 7], statistically insignificant difference (P = 0.33) was observed in mesial papillary recession when the implant was placed immediately and provisionalized and when provisionalization was not done after implant placement (MD = −0.10, [95% CI: −0.31–0.10]). Heterogeneity was low (I^2 = 35%).

Meta-analysis 6: Distal papillary recession around implants with and without immediate provisionalization

Three studies have evaluated distal papilla in immediately placed implants and provisionalization, from which two studies calculated distal papilla compared with and without immediate provisionalization. It was calculated in millimeters. In the meta-analysis performed on distal papillary recession [Figure 8], a statistically significant difference (P = 0.0007) was observed with the low distal papillary recession when the implant was placed immediately and provisionalized (MD = −0.32, [95% CI: −0.50–−0.13]). Heterogeneity was low (I^2 = 0%).

Meta-analysis 7: Midfacial mucosal recession around implants with and without immediate provisionalization

Three studies have evaluated midfacial mucosa in immediately placed implants and provisionalization, From which two studies calculated midfacial mucosa compared with and without immediate provisionalization. It was calculated in millimeters. In the meta-analysis performed on midfacial mucosal recession [Figure 9], statistically insignificant difference (P = 0.09) was found in midfacial mucosal recession when the implant was placed immediately and provisionalized and when no provisionalization was done after implant placement (MD = −0.47, [95% CI: −1.01–0.07]). Heterogeneity was high (I^2 = 89%).

Summary of findings

GRADEpro software was used to generate quality of evidence [Figure 10]. Total nine studies included in this meta-analysis for primary (esthetic outcome) and secondary aesthetic outcome (bleeding on probing, plaque index, probing depth, mesial papillary recession, midfacial mucosal recession, and distal papillary recession) gave data of 404 patients. The trials included in the present meta-analysis provided mean and standard deviation for all aesthetic outcomes. Thus, chances of missing summary statistics, which introduce bias and imprecision,

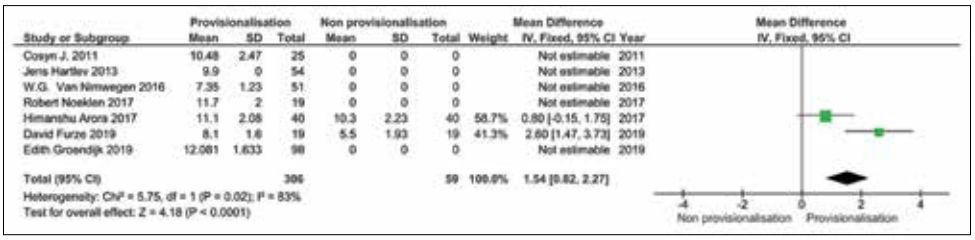

Figure 3: Forest plot for aesthetic outcome with and without immediate provisionalization

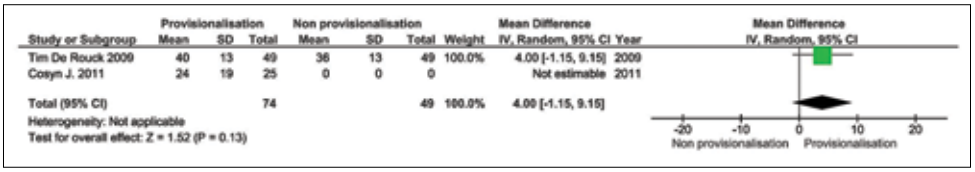

Figure 4: Forest plot for bleeding on probing with and without immediate provisionalization

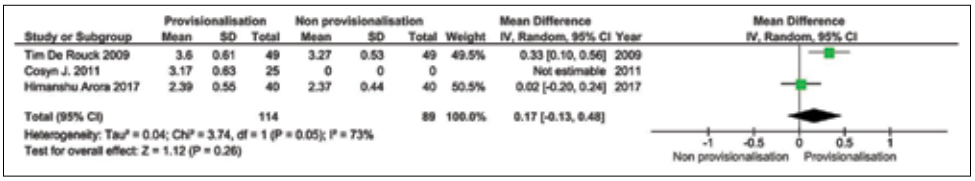

Figure 5: Forest plot for probing depth with and without immediate provisionalization

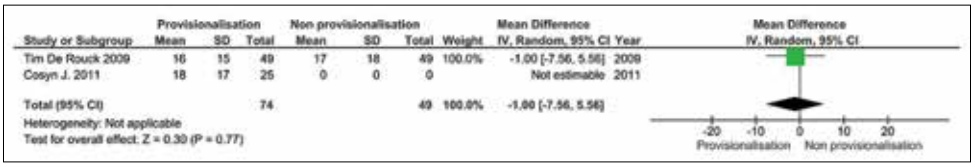

Figure 6: Forest plot for plaque index with and without immediate provisionalization

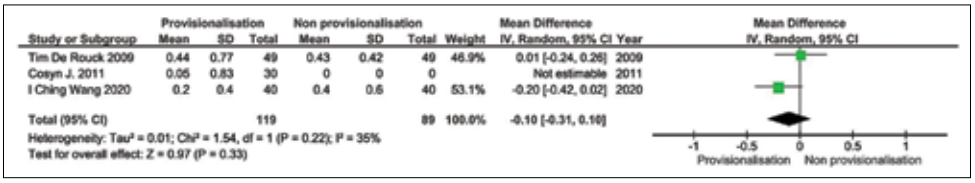

Figure 7: Forest plot for mesial papillary recession with and without immediate provisionalization

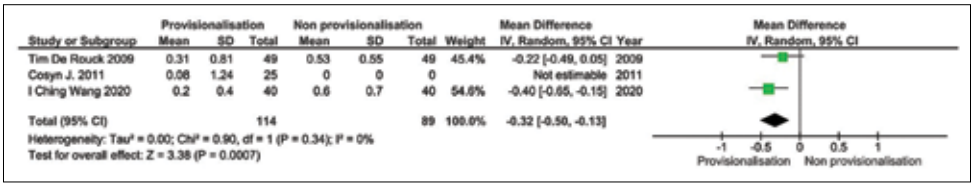

Figure 8: Forest plot for distal papillary recession with and without immediate provisionalization

are less in the present meta-analysis. According to the GRADE criteria, all nine studies included did not show inconsistency or indirectness, but although imprecision was present, the GRADE profiler (GRADEpro GDT) software determined that studies were at low risk of bias and generated moderate level of evidence. All the findings of included studies showed consistent results of immediate provisionalization for the esthetic outcome of peri-implant mucosa. These findings showed a positive influence of immediate provisionalization on peri-implant tissue.

DISCUSSION

The interim treatment phase is usually the longest and the most challenging.[31] The objective of this phase is to contour

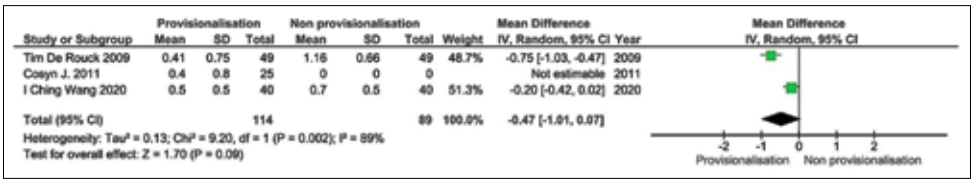

Figure 9: Forest plot for midfacial mucosal recession with and without immediate provisionalization

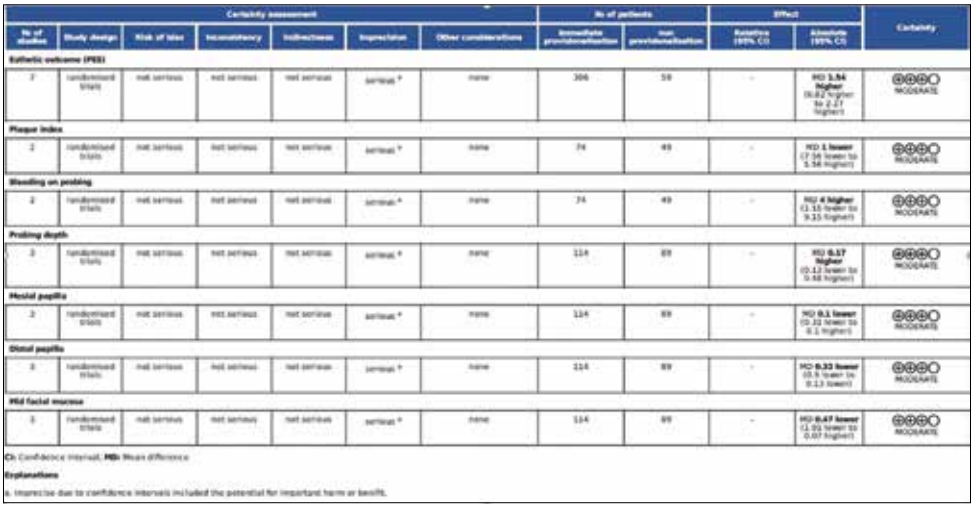

Figure 10: Summary of findings

the peri-implant mucosa before taking the final impression. An application of a provisional phase is preferable in the esthetic zone.[32] However, it is time-consuming and might require additional cost. The structure of peri-implant tissue is affected by provisional restoration.[33] Implant-supported provisional restoration can alter the peri-implant mucosal architecture's emergence profile. It also aids in the development of interdental papillae. It has been suggested that the technique of immediate placement and provisionalization offers advantages for the aesthetic outcome of single tooth anterior implant restoration.[34] Because of improved implant surface treatment and a good knowledge of implant healing, IIP has become a predictable process.

IIP has a number of benefits, including fewer surgical procedures, shorter treatment times, and higher patient satisfaction. There are also disadvantages such as mid-facial recession, papillary height loss, and crestal bone loss.[35] Wittneben *et al*.[32] used digital analysis to look at changes in mucosa profile pre- and post-soft tissue conditioning with implant provisional restoration using the dynamic compression technique. A significant difference was discovered when the structural changes in the mucosa and the emergence profile were compared. When compared to the original profile of the healing abutments, the change was more than doubled. Hence, it is essential to implement the distinct provisional phase. There are different techniques available for the generation of peri-implant tissue by provisional restoration. One of the most common methods is the "Dynamic Compression Technique".[36] This procedure begins by applying pressure to the soft tissue to guide and "squeeze" it into the proper posture. The interim restoration is then gradually lowered to allow soft tissue to fill in. This will help to grow peri-implant tissue and improve pink esthetics. A recent systematic review was done by the author Kinaia *et al*.,[35] in which the author has evaluated soft-tissue outcome around immediately placed implants, but the esthetic outcome was not evaluated. As a result, the present systematic review sought to check the influence of immediate provisionalization on peri-implant tissue in immediately placed implants in the esthetic zone.

This systematic review included seven studies that showed implant esthetic outcomes with PES. These studies showed that implant esthetic outcome is better when the implant was immediately placed and provisionalized in the anterior maxilla (MD = 1.54, [95% CI: 0.82, 2.27]). This is because provisional restoration molds the gingiva according to the contours of the restoration. Hence, this will improve the peri-implant esthetics, which will lead to an increase in PES. There was also statistically insignificant difference in bleeding on probing, probing depth, mesial papillary recession, midfacial mucosal recession, and plaque index

when provisionalization was performed immediately after implant placement versus when provisionalization was not performed immediately after implant placement in the maxillary anterior region. However, a highly significant difference was seen in distal papillary recession with less recession when immediate provisionalization was done after implant placement (MD = −0.32, [95% CI: −0.50, −0.13]).

Several factors influence the overall prognosis of the treatment plan, including (1) selection of patient, (2) position of tooth, (3) root position of adjacent teeth, (4) biotype of gingiva, tooth shape and the crestal bone height, (5) osseous anatomy of the implant site, (6) implant position, and (7) facial anatomy. Provisional implant restorations are important tools for restorative dentists to make an attempt to obtain the best aesthetic result for implant restorations.[3]

Noelken *et al*.[27] found that with IIP and provisionalization technique, implant region with facial bony inadequacies could be handled effectively with favorable esthetic results and stable marginal bone levels. After a 12-month follow-up, the success rates, marginal bone levels, and esthetic results of their study demonstrate proof of principle for preserving marginal bone height with immediately placed and provisionalized implants. Concerning soft tissue change following implant placement, De Rouck *et al*.[6] came to the conclusion that papilla levels could be managed predictably. Interproximal tissue levels are thought to be related to neighboring tooth connective tissue contacts and bone levels. Nariman *et al*.[37] concluded that if the tooth is extracted atraumatically, preserving the papillae and the bone and provisionalized immediately, the esthetic contour of the tooth is maintained, which is comparable with the natural tooth. Chandra Sekar *et al*.[38] concluded that IIP and loading could achieve predictable esthetic results than delayed placement.

Apart from the positive findings of immediate placement with provisionalization, there are also some limitations. Lack of control over the implant's final position, difficulty achieving primary stability, inadequate soft tissue coverage, difficulty to inspect all areas of the extraction site for defects or infections, and difficulties preparing the osteotomy due to the drill's movement against the extraction site's walls are all disadvantages of IIP.[39] If primary stability is lacking, then it is difficult to immediately provisionalize the implants.[40-42] If implant site is lacking soft and hard tissue, the optimum esthetic outcome might not be achieved and may require soft and hard tissue grafting procedures.[43] All the factors that influence the esthetic outcome should be checked thoroughly before planning the IIP and restoration.

In the present systematic review, articles published in the English language only were included; thus, data from studies published in other languages could not be compared. Although data on the soft tissue esthetic outcome with immediate provisionalization in IIP in the anterior maxilla have been published with acceptable conclusive findings, still well-conducted RCTs with long-term follow-up are needed to derive absolute evidence for the treatment.

CONCLUSION

We found moderate-quality evidence for positive esthetic outcomes of peri-implant mucosa with immediate provisionalization and IIP in the anterior maxilla. Moderate-quality evidence for soft tissue outcomes indicates that IIP with immediate provisionalization protocol is beneficial when the implant is placed in the esthetic zone. It minimizes soft tissue changes and molds the peri-implant tissue to the provisional restoration's contours. In patients with thin and scalloped gingival biotypes and bony defects, soft and hard tissue augmentation procedures should be performed to improve the esthetic outcome. To achieve the best esthetic result in implant treatment, the right surgical procedure, restorative procedure, and clinical experience are all important.

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Conflicts of interest
There are no conflicts of interests

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Review

Current scenario on adhesion to zirconia; surface pretreatments and resin cements: A systematic review

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Abstract

Several methods have been proposed to increase bonding of zirconia with resin. However, we are still to find the Holy Grail. A systematic literature review was performed through PubMed on international literature from January 2000 to May 2021 with relevant Medical Subject Headings terms. 56 articles were found to be relevant. Of all the different methods proposed, mechanochemical pretreatment of zirconia surface with alumina oxide and use of 10-methacryloyloxydecyl dihydrogen phosphate were found to be most effective as per majority of studies. New methods that require further research also surfaced.

Keywords: Resin cement, surface pretreatment, zirconia

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INTRODUCTION

In the second half of the 20th century, dentistry faced challenges as to meet the escalated esthetic needs. With the advent of glass ionomer cement and composite resins, esthetic dentistry reached a new height. Similarly, metal-ceramic restoration slowly lost its popularity and the time had come for a metal-free era. With the introduction of zirconia in dentistry, bigger possibilities emerged in the field of indirect restorations. However, from the start of the new millennium, a new question had arrived – how to bond the zirconia restorations to the tooth.

In the past 20 years, innumerable researches have been conducted to establish a possible solution for achieving a predictable bonding between tooth and zirconia. However, a single method is yet to be declared the "gold standard." The aim of this article is to systematically review the various studies dealing with zirconia bonding and to draw a conclusion as to which method is the best to date.

MATERIALS AND METHODS

This study was performed through the search engine PubMed on international literature. Studies published from January 2000 to May 2021 were searched. Keywords were zirconia, ceramic surface treatments, zirconia adhesion, MDP, bond strength test, resin bonding. These Medical Subject Headings (MeSH) were used individually or in combination. The literature search was performed by two independent reviewers.

The inclusion criteria were English language publication, *in vitro* studies, reviews, studies performing micro/macro, and shear/tensile bond strength tests. The exclusion criteria were case reports, clinical trials, studies with less than five

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samples, and studies without thermocycling and moisture storage. Any disagreement regarding the eligibility of the studies was resolved through discussion. Only articles pertaining to dentistry were considered.

RESULTS

The search carried out in PubMed identified 63 articles primarily. After screening the titles and abstracts, 45 articles were selected as relevant.

Then, with other MeSH or keywords, following results were obtained [Table 1].

Of the total 90 articles, 22 were repetition. Sixty-eight articles were finally selected and read, along with their relevant references. Twelve articles were further excluded and 56 articles remained.

DISCUSSION

Bonding to traditional silica-based ceramics, employing mechanical and adhesive retention, is well researched and bond strengths are predictable. While hydrofluoric acid (HF) etching along with methacryloxypropyl trimethoxysilane (MPS) application is a commonly recommended method for roughening the surface of silica-based ceramics and increasing their wettability,[1] zirconia is a polycrystalline nonetchable material.[2-6] Owing to its chemical inertness, cementation of zirconia indirect restorations has been problematic over the years. Thus, researchers have attempted to come up with various methods to overcome this handicap. This article aims to review all such employed techniques.

Factors that are assessed when considering adhesion of zirconia to any substrate are zirconia surface pretreatment, resin cement used, artificial aging, and the bond strength test performed and are discussed accordingly.

Zirconia surface pretreatment

Majority of the studies agree that zirconia surface needs to be modified before applying the luting cements since all the pretreatments increased bond strength. In this review, pretreatment techniques are classified into three groups:

- Mechanical
- Chemical
- Mechanochemical.

Table 1: Results obtained with other Medical Subject Headings/keywords

Keywords	Total received paper	Total selected paper
Zirconia surface treatment effect on bond strength	14	8
Zirconia-resin cement bond strength with thermocycling (*in vitro*)	31	20
Zirconia adhesion review	54	17
Total	99	45

All studies are equivocal on the need of a contaminant-free surface before any treatment. Most studies started the surface conditioning by polishing zirconia with paper sprays or milling cutters of silicon carbide. Ultrasonic cleaning before conditioning is also considered a beneficial method.[7-21] Several solutions were used that include distilled water, alcohol, acetone, and ethanol.

Mechanical

These methods aimed to modify the zirconia surface so as to either roughen it to enhance micromechanical retention or deposit various compounds (mainly silica) on its surface so as to make it suitable for bonding. They are discussed subsequently.

Sandblasting

Sandblasting with alumina particles increased bond strength by increasing surface energy, wettability, roughness, and the appearance of hydroxyl groups, which facilitate bonding with the primer/universal adhesive/cement.[10,13,15,20,22-24] Particles with size ranging from 25 to 110 μm at 0.5–4 bar for 10–20 s were used.[25-27] Bond strength was not affected by varying particle size despite the difference in surface roughness created.[28-31] However, an increase in particle size and pressure has long been associated with the formation of microcracks and weakening the mechanical properties of zirconia.[11,13,21,32-39] It has also been reported that sandblasting before sintering caused fewer phase transformations than after sintering. However, sandblasting before or after sintering had no influence on adhesion.[18,19]

Recent *in vitro* studies report that airborne particle abrasion (APA) may have a deleterious effect on the zirconia surface due to the creation of microcracks which might reduce the flexural strength.[40] Moreover, the tetragonal phase of Y-TZP is converted to the monoclinic phase with volume expansion (4%–5%) under the high stresses caused by this abrasion, and this unique transformation can produce different types of damage that affect the structural integrity and material reliability.[41,42] While this process may result in an increase in the crack propagation resistance of Y-TZP for a certain period, functioning as a toughening mechanism,[43] the presence of the unstable and stressful monoclinic structure makes the zirconia in this phase fragile, thus increasing the fracture tendency over longer term. The tetragonal (t)-monoclinic (m) phase

transformation is directly related to abrasive particles' size.[44]

Silica coating

Zirconia has silica-free surface and possesses relatively nonpolar surface. They are more chemically stable than silica-based ceramics, so traditional silane treatment is not usually effective on zirconia.[45] Silica coating techniques have been explored to convert silica-free into silica-rich zirconia surface for utilizing the chemical bonding provided by silanization.

Silicoater[45] technology is a method to impregnate silica pyrolytically on a substrate surface, followed by application of silane, before bonding using resin cement. However, it proved to be too expensive and complex and thus commercially nonviable.

Tribochemical silica coating (i.e., Rocatec or CoJet systems) (TSC) is a commonly used commercial technique in which zirconia surface is air abraded with alumina particles that have been coated with nano-silica, resulting in the impregnation of nano-silica into the zirconia surface. Studies have shown that tribochemical silica coating followed by silanization has resulted in enhanced initial bond strengths between zirconia and resin materials.[46-50] However, it is not clear whether it was caused by silica coating or the surface roughening effect of air abrasion.

Some studies have shown that similar effects were obtained with tribochemical silica coating/silanization and regular air abrasion with alumina particles on improving zirconia–resin bond strengths, thus indicating tribochemical silica coating only provided air–abrasion effect for creating surface roughness.[48,51] It has also been reported that tribochemical silica coating does not provide stable resin–zirconia bond strength,[52] probably because silica was not strongly attached to zirconia surfaces. EDXS analysis and SEM studies showed that the silica coated on zirconia surface could be cleaned away by ultrasonication in water or pressurized water spray,[53] indicating that no stable chemical bond was formed between silica and zirconia. The silica was probably deposited on the zirconia surface via weak physical force, such as Vander–Waals forces, which might not be strong and stable enough in a clinical situation.

On the other hand, for some researchers, TSC showed better bond strength than conventional sandblasting, favoring long-term stable adhesion.[11,22,38,39,54]

It has also been reported that when zirconia was air abraded with aluminum oxide (Al_2O_3) (110 lm), it resulted in higher roughness values, but air abrasion protocols with silicon dioxide (SiO_2) (110 lm; Rocatec) promoted better adhesion to 10-methacryloyloxydecyl dihydrogen phosphate (MDP)-based resin cement.[55]

Air abrasion with alumina is essential to obtain durable bonding of resin cement to highly translucent partially stabilized zirconia and yttria-stabilized tetragonal zirconia polycrystals (Y-TZP). Different air abrasion conditions affected the bond strength of resin cement, in the case of Y-TZP air abraded with 50-μm alumina at 0.2 MPa and 30-μm alumina at 0.12 MPa. When alumina air abrasion was used to treat the inner surface of zirconia crowns, even with larger particles, the system behaved as a bonded crown, promoting a higher fatigue resistance for the cemented crowns.[56]

There are other methods for silica coating such as modification of zirconia surface by utilizing flame treatment with tetraethoxy silane containing butane as fuel gas,[57] gas-phase chloro-silane pretreatment,[58] and sol–gel process silica coating.[59] However, further investigations into these techniques are required before clinical recommendation.

Laser

The application of lasers to the surface of zirconia is based on the same principle as sandblasting, i.e., obtaining a rough surface and increasing its wettability that allows micromechanical retention with the resin.[16] Different types of lasers have been described (Er:YAG, Nd:YAG, Yb:YAG, CO_2), with different parameters of power, energy intensity, distance, and duration. Most of the studies concluded that the application of laser did not increase the bond strength compared to sandblasting and did not obtain acceptable adhesion values,[8,12,15,60] due to the appearance of microcracks on the surface of the zirconia, leading to a phase transformation and weakening of mechanical properties.[60] Therefore, laser is not currently considered a valid mechanical pretreatment tool.[8,15] However, there have been reports where application of Er, Cr:YSGG laser with adjusted parameters on zirconia appeared to be useful as a nondestructive surface treatment method.[44]

Acid etching

It is well-established fact that unlike glass ceramics, acid etching is not effective for polycrystalline ceramics such as zirconia and alumina as they did not undergo significant structural change after HF acid etching.[61]

Hence, silanization and acid etching are not effective on zirconia because it is inert and without glassy matrix on which these agents act.[62]

Plasma spraying

Plasma has been used to increase the surface energy and alter the surfaces of the substrates without affecting their structural properties. However, the application of oxygen or argon plasma did not obtain good adhesion values after artificial aging, which added to the appearance of impurities on the surface of zirconia and indicated its susceptibility to hydrolytic degradation.[21,63,64]

Selective infiltration etching

It is based on the principle of heat-induced maturation and grain boundary diffusion and transforms the relatively smooth nonretentive surface of Y-TZP into a highly retentive surface. It also creates a three-dimensional retentive feature where the adhesive resin can infiltrate.[65]

Studies reported that selective infiltration etching (SIE), based on ceramic infiltration by molten silica and other oxides, and subsequent removal with HF acid create micromechanical irregularities that enhance the zirconia to resin bonds.[65-67] However, as creator of the SIE method stated "... SIE requires an investment of time and effort in order to achieve the required surface properties, and remains sensitive to the handling procedure during every step of the technique."[67]

Other methods such as ceramic coating,[26] fusion sputtering,[68] nanostructured alumina coating,[39] and titanium dioxide tube incorporation[69] were used, but more research is needed for them to be of any practical use.

Chemical

At present, following compounds are known to chemically bond to zirconia:

a. MDP containing zirconia primer
b. Primers composed of other monomers
c. A universal adhesive.

MDP monomer can make a chemical bond with metal oxides, such as zirconium oxide.[70,71] Researchers have found that adhesion between 10-MDP and zirconia was not only ionic bonding but also hydrogen bonding.[72]

The adhesives that contain chemical promoters are known as "Universal adhesives." Most of these universal adhesives contain 10-MDP at different concentrations and on application to zirconia after sandblasting increased adhesion and have even been proposed to replace mechanical conditioning and the need for primer application.[10,73] However, hydrolytic degradation of 10-MDP causes a decrease in adhesion over time in all its application forms, compromising the adhesive protocol.[36,74-76]

Application of luting and priming agents containing the adhesive monomer MDP provides better bond strength to zirconia than do other systems. However, some studies concluded that MDP in ceramic primer is effective for bonding zirconia and a luting agent does not necessarily have to contain an adhesive functional monomer when appropriate priming agent that contain such monomer is used. However, the strength and durability were not sufficient to satisfy the clinical requirements of retention, if the restorations were retained only by chemical bonding systems. Additional mechanical retention was still necessary.[77] Hence, combination of mechanical and chemical pretreatment appeared particularly crucial to obtain durable bonding to zirconia.[78] A recent study has also opined that combination of micromechanical and chemical surface treatment is a prerequisite for increasing adhesion to zirconia.[79]

Second to micromechanical roughness, adhesion strength was significantly increased by the adhesive system used. It has been proposed that the use of MDP-containing primers with resin composite cement containing the MDP monomer is required to enhance the bonding efficiency.[44] Hence, primers that contain MDP monomer should be used with resin cement even if it contains the same.[78,80,81]

Mechanochemical

Researchers have found that combined mechanical (TSC) and chemical (silane/MDP-containing ceramic primers) surface pretreatment of zirconia improved the bond durability of composite cement bonding to zirconia.[82] When zirconia was air abraded with Al_2O_3 (110 μm), it resulted in higher roughness values, but air abrasion protocols with SiO_2 (110 μm) promoted better adhesion to MDP-based resin cement.[55] Regarding the type of particle, studies found similar bond strength values between Y-TZP specimens subjected to airborne abrasion with conventional alumina particles and silica-coated alumina particles.[83,84] However, after 6 months of aging, silica-coated zirconia surfaces presented a higher bond strength,[84] which may be because conventional alumina particles are sharp and hard, whereas silica-coated alumina particles are softer and smoother, being less aggressive on the ceramic surface and facilitating the chemical bond. One study also reported that silica coating, irrespective of the use of primer or universal adhesive, provided significantly higher microshear bond strength values than other methods (sandblasting, laser).[85]

Although sandblasting can modify the surface of the zirconia, when used alone, it has been found to be ineffective in increasing adhesion to zirconia, and a chemical surface conditioner is required to make it stable in

the long term.[22,26,39,44] These chemical conditioners contain various molecules found in primers, adhesives, or cement. Surface conditioning methods, particularly physicochemical conditioning methods, tend to increase the bond strength values for resin-based cements to zirconia.[86]

The use of APA with 50 μm Al_2O_3 before sintering and the application of primer-containing MDP seem to be valuable methods for durable bonding with zirconia. APA with 50 μm Al_2O_3 after sintering induced the highest (t-m) phase transformation.[79]

One recent study concluded that the best treatment to promote greater bond strength to zirconia is to associate tribochemical treatment with self-adhesive resin cement containing a functional phosphate monomer.[87]

Resin cement

Evaluation of shear bond strength of different cements used with zirconia indicated that zinc phosphate and conventional and modified glass ionomer cements are not able to form a lasting bond with zirconia; only resin cement and resin cement-containing MDP monomer show good results even after aging.[88] It was also seen that bond strength of glass ionomer cements and conventional Bis-GMA-based composites is significantly lower, especially after aging by thermocycling. Only resin cement and resin cement-containing MDP monomer withstand thermocycling, with the latter achieving a higher bond strength.[70] Similar results were also obtained on evaluating the shear bond strength of five cements, before and after long-term stocking (2 years) and thermocycling at 37500 cycles. The results revealed that Bis-GMA-based cements lack long-term stability. The efficiency of different surface treatment, i.e., sandblasting with aluminum oxide (Al_2O_3) at 50 μm and silanization was also studied and found that surface treatments improve the initial bond strength, but their effect decreases with time. Only resin cements with phosphatic monomer have shown high adhesion values and reliability after thermocycling in association with sandblasting.[89]

The cements used in various studies for luting zirconia can mainly be divided into three types - Self-adhesive cements, cements containing 10-MDP, and Bis-GMA cements (which are neither self-adhesive nor contain 10-MDP). Bis-GMA cements showed lower adhesion values than the other two groups but better results in hydrolytic degradation.[22,90] A lot of studies have reported the synergistic effect on applying a 10-MDP primer, especially with self-adhesive resin cement.[13,91,92] Non-MDP-containing self-adhesive resin cements showed increased bond value with MDP-containing primer to zirconia ceramics. However, as per some studies, the bond strength of MDP-containing self-adhesive resin cements was not affected significantly by the use of zirconia primer due to the saturation of this molecule.[92] Hence, more studies are required to find the ideal resin cement although there is consensus on the need for prior mechanical surface conditioning to increase their adhesive values.[32,39,60,90] More studies regarding cement degradation following artificial aging are also required.[25,90]

Silanization and acid etching are not effective on zirconia because it is inert and without glassy matrix on which those substances act. For cementing zirconia restorations, the best procedure seems to be the combination of sandblasting with aluminum oxide (Al_2O_3) at 50 μm and resin cements-containing esteric organophosphate monomer (MDP).[62] However, during air abrasion with Al_2O_3 particles, large particles (>110 μm) and under high pressure (>3 bar) should be avoided, and an effective chemical component should be used[93] as air abrasion leads tetragonal to monoclinic (t-m) phase change on the surface of zirconia that in the long term can be detrimental to the restoration, not only because of the defects it creates[40] but also because of the low-temperature degradation suffered by zirconia.[94]

Artificial aging

This review is based on *in vitro* studies and so clinical guidelines cannot be established. Saliva contamination or parafunctional habits that negatively affect adhesion have not been accounted for.[95] Moreover due to variability in study designs contradictory results have been found. Hence, more dedicated studies are required to standardize specific techniques and to simulate clinical conditions for predictable results in zirconia bonding.

Majority of the articles selected for this review used liquid storage and thermocycling for artificial aging. These two methods in combination allow the evaluation of hydrolytic degradation and *in vitro* hydrothermal aging.[86,95]

Various liquids were used for storage from distilled water to artificial saliva. Storage in a liquid medium significantly reduced adhesion. However, among the studies with thermocycled groups, great variation was seen in the number of cycles, thus making it impossible to compare the results.

However, certain recommendations must be considered for any studies and reviews:[1] Studies should include a control group with no treatment, to more effectively assess the pretreatment tested.[2] It is necessary to standardize

the artificial aging method used to compare the results in a more effective way.[27]

Tests

Due to the lack of an international standard, different types of tests have been used to assess the bond strength between zirconia and resin cement. Due to its ease of use, macroshear test was most commonly performed. Otani *et al*.[96] described the macro tests (macroshear and macrotensile) as those that presented more heterogeneity in the distribution of stress and loads due to the greater adhesion area tested. On the other hand, the micro tests (microshear and microtensile) showed less variation and higher adhesive values due to a smaller adhesion area and less possibility of finding defects in the cementing. Tensile bond strength was found to be more sensitive in detecting differences in bonding effectiveness of different surface treatments after aging.[52] Many proposed[97] that failure analysis based on fractographic principles should assist researchers to correctly interpret the fracture phenomena.

CONCLUSION

The clinical success of a zirconia restoration is strongly dependent on the quality and durability of the bond between restoration and resin cement. A durable and strong bond requires zirconia surface changes for mechanical retention and chemical adhesion. New methods to increase bond strength between resin cement and zirconia need further investigations. This paper reviews various methods which have been used to enhance zirconia–resin cement bond strength, published in last 21 years. After reviewing the literature, we found:

a. There has to be a standard protocol for aging and thermocycling to standardize the examination
b. In spite of some studies being contradictory, Al_2O_3 sandblasting remains the best surface treatment method to date
c. Mechanochemical surface pretreatment provides the best adhesion
d. The best procedure for zirconia cementing is combination of sandblasting with 50 μ Al_2O_3 particle and then applying self-adhesive resin cement containing 10-MDP
e. SIE and application of low fusing glassy porcelain methods are promising, but more studies and simplification are needed.

For bond strength evaluation and stability and to establish standardized clinical protocols, more studies are required.

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Research

A comparative clinical trial for evaluating the posterior palatal seal developed from the conventional method and a novel functional swallow method

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Abstract:

Aims: The aim of this *in vivo* study was to compare the influence of posterior palatal seal (PPS) developed from the conventional method and a novel functional swallow method on the retention of custom tray and heat cure denture base.

Settings and Design: This was a nonrandomized crossover clinical trial.

Materials and Methods: Twenty patients requiring maxillary complete dentures were selected. In Group 1, for all twenty patients, the PPS was developed with the conventional functional method during border molding and a conventional cast scoring was performed before processing the denture base. In Group 2, for all the twenty patients, the PPS was developed with a novel functional swallow method and the master cast was "not" scored before processing the denture base. The retention was objectively measured using a dynamometer after border molding and also after processing the denture base for both groups.

Statistical Analysis Used: Independent Student's *t*-test and paired *t*-test were used for analysis.

Results: The mean retention value of Group 2 was significantly higher ($P < 0.001$) than Group 1 at border molding and after denture base processing. Within Group 1, the retention value significantly increased ($P < 0.001$) from border molding to the denture base stage, whereas within Group 2, there was no significant change ($P > 0.001$) between the stages.

Conclusions: Within the limitations of the study, the novel functional swallow method of establishing the PPS demonstrated higher retention than the conventional method both during border molding and after processing the denture base.

Keywords: Border molding, conventional method, denture base, functional swallow method, posterior palatal seal, retention

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INTRODUCTION

Despite conflicting theories found in the literature pertaining to the method of recording the posterior palatal seal (PPS), its' importance cannot be refuted.[1,2] Literature is abundant with a description of various methods to establish the PPS.[3-6] According to education surveys conducted across the globe, the arbitrary cast scoring technique is the most commonly followed.[7,8] However, according to Winkler, arbitrary method is considered the least accurate because the denture retention cannot be verified until the insertion appointment.[9] Winkler also proposed the conventional scoring method which involves locating and transferring the PPS boundaries using a trial denture base and scoring the PPS area on the master cast.[5] All scoring methods have the potential to overcompress the PPS area and hence considered nonphysiological.[5] A recent study investigated the efficacy of PPS obtained by employing conventional master cast scoring. The PPS retention was assessed subjectively by applying tipping forces on the palatal surface of the anterior teeth of the processed maxillary denture. The study had a small sample size and concluded that conventional scoring can be safely used to develop the PPS.[10]

The PPS can also be established by functional and semi-functional methods which do not support scoring. In the functional method, the patient participates in molding of the PPS, whereas in the semi-functional method, the dentist performs the molding of the PPS.[11] Among functional methods, the fluid wax technique is considered most physiologic as it does not cause overcompression of the PPS tissues.[12] The drawbacks of the technique are it is time consuming, complex and that the waxes may not sufficiently displace the soft palate due to inadequate strength. Furthermore, waxes are not dimensionally stable during impression procedure or cast pouring.[13] The "Ah" functional technique is also used conventionally to develop the PPS during border molding.[14] However, this method may not displace the PPS area adequately as the soft palate can return to the nondisplaced position before the molding compound may have hardened. This may lead to an inadequate posterior seal.[15] Several semi-functional methods have been recommended recently. Here, the PPS is molded using materials such as wax or resin within the PPS boundaries of the completed final impression surface.[13,15,16] These methods can be time-consuming, technique sensitive, and also have the potential to cause excessive displacement of the posterior seal area.[16] Hence, it is clear that there is no consensus among the proponents of scoring and nonscoring methods.

A novel nonscoring "functional swallow" method can be a useful alternative to the existing methods. It utilizes a low fusing compound and the swallowing forces inherent to every individual to displace the soft palate functionally when the head is flexed forward.[17] Very few studies have assessed the magnitude of retention developed from the various PPS methods and notably those comparing scoring and nonscoring methods.[1,18,19]

This study aimed to evaluate and compare the conventional method (with conventional cast scoring) and a novel functional swallow method (without cast scoring) in developing the PPS by measuring the magnitude of forces required to dislodge their corresponding border molded custom trays or heat-processed denture bases. The research employed the less explored approach of applying dislodging forces through the anterior part of the denture base in an outward and upward direction using a dynamometer.

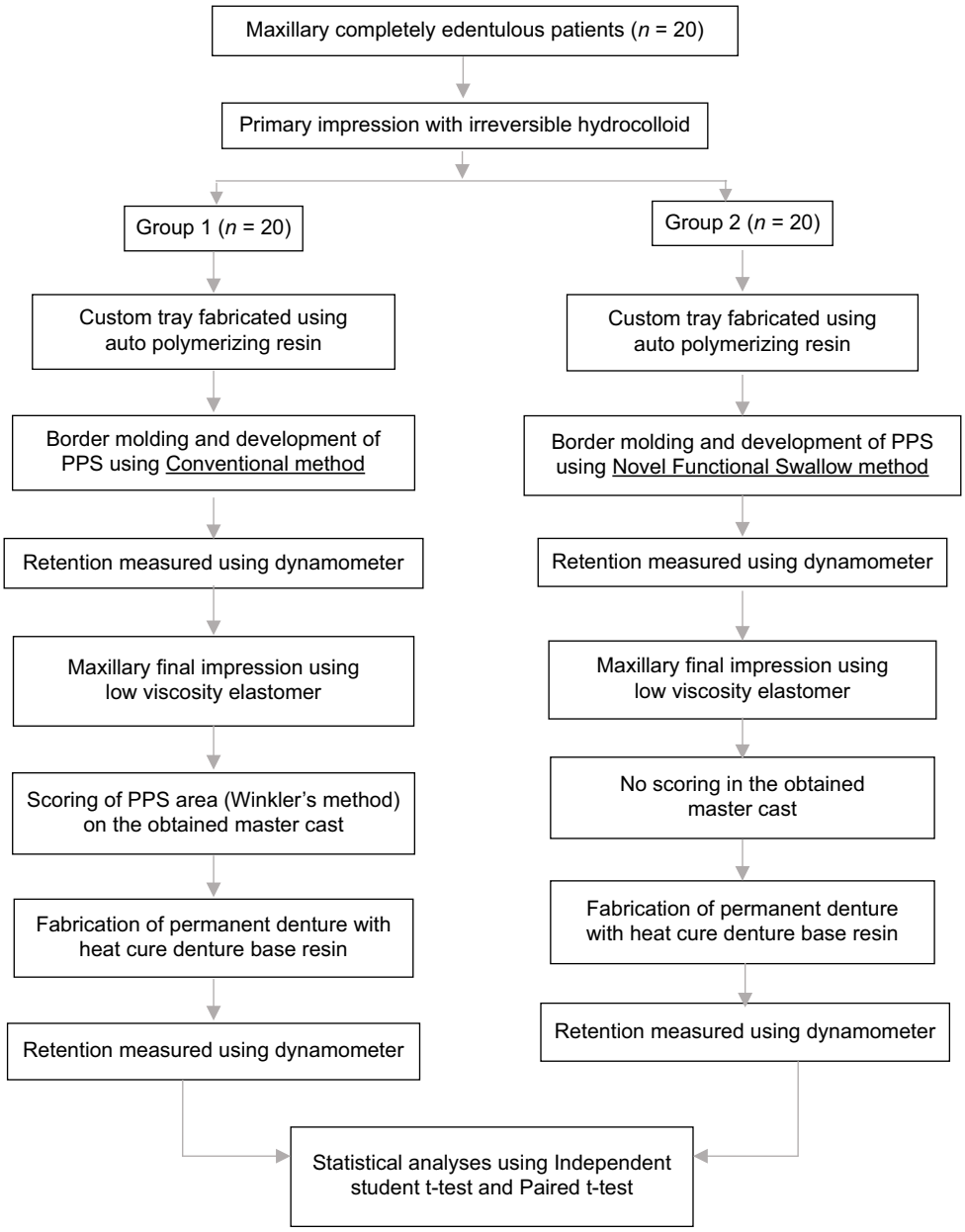
The null hypothesis was that the retention of border-molded tray or the heat-processed base fabricated from the conventional method of developing PPS will be similar to the retention of border-molded tray or the heat-processed base fabricated from the functional swallow method.

MATERIALS AND METHODS

The University Ethics Committee approved the trial (EC-2019/PG/31) to compare the efficacy of a conventional method versus a novel method in developing the posterior palatal seal. This clinical trial [Table 1] was conducted as per TREND (2004) guidelines for a period of 13 months from December 2018 to February 2019. The study was conducted according to the ethical principles of the Declaration of Helsinki (2013). Twenty maxillary completely edentulous patients who reported to the department of prosthodontics, crown, and bridge for complete denture treatment were selected. Informed consent was obtained from both male (11) and female (09) patients who were in the age group of 45–75 years. Inclusion criteria were patients with complete maxillary edentulous arch and at least 6 months postextraction, old denture wearers for at least 6 months, well-rounded, healed, edentulous ridges, firmly attached mucosa with no signs of inflammation, normal salivary flow, and with Class I or Class II type of soft palate anatomy based on House's classification[20] and patients who provided signed informed consent participated in the study.

Exclusion criteria included patients with Class III type soft palate, high vaulted palate, severe hard tissue undercuts,

Table 1: Study flowchart



bilateral tuberosity undercuts, presence of palatal tori, severely resorbed maxillary edentulous arch, history of neuromuscular disorders, and velopharyngeal dysfunction. Patients with the presence of irritated or abused mucosa, xerostomia, history of medication that could alter quality and quantity of saliva, and severe oral manifestations of any systematic diseases and patients with spinal problems and who could not bend forward were excluded from the study.

Based on the two interventional methods, the study had two groups. Group 1 ($n = 20$) comprised all twenty patients who underwent the conventional method of recording the PPS, whereas Group 2 ($n = 20$) comprised all twenty patients who underwent functional swallow method to record the PPS. All the clinical procedures were carried out by a single investigator.

Border molding procedure

The primary impression was made for every patient with an irreversible hydrocolloid (Neocolloid, Zhermack) and a cast obtained in plaster. On the primary cast, a 2 mm thickness of wax spacer was adapted uniformly all over with tissue stops. The spacer was kept 2 mm short of the periphery and also short of the demarcated PPS. Two autopolymerizing resin (DPI RR Cold Cure, Mumbai) custom trays were fabricated for each participant [Figure 1]. The handle was positioned symmetrically across the midline derived on the cast. The handle dimensions were standardized to 18 mm

length, 12 mm width, 6 mm thickness, and tilted labial with an angle of about 45°. Using a round tungsten carbide bur, a circular vent of 4 mm diameter was made in the midline placed 5 mm from the top of the handle [Figure 2]. The maxillary border molding procedure was performed twice for each patient using a low fusing compound (DPI Pinnacle Tracing Sticks, India). The PPS was incorporated as described below.

Identification and development of PPS

The anterior and posterior vibrating lines were identified intraorally and marked with an indelible marker. The anterior vibrating line was marked through the Valsalva maneuver and the posterior vibrating line by asking the patient to say "Ah" in a nonvigorous fashion. These marked lines were transferred to both the custom trays. The PPS was developed employing the conventional "Ah" functional method (Group 1) with one of the custom trays and by the novel functional swallow method (Group 2) with the other [Figure 3] as described below.

Conventional method

Combination of conventional functional and conventional scoring is commonly used in Asian countries.[21] It involved applying softened low fusing compound onto the demarcated PPS of the custom tray and asking the patient to say "Ah," a few times until the compound hardened.[14] The PPS thus created was assessed by tucking the tray handle from its inner side with a finger.[22] The procedure was repeated until satisfactory PPS was obtained. The final PPS was established on the master cast by the scraping method, as described by Winkler.[5] It involved marking and transferring the anterior and posterior boundary of the PPS area using the resin trial base. The PPS was scored on the master cast with a scraper. The medial palatal raphe area was scored to about 0.5 mm and the area from the midline to hamular notch on both sides between posterior and middle thirds was scored to a depth of 1–1.5 mm.

Novel functional swallow method

Initially, the patient was trained to lean forward, bend the head down till the chin touched the chest, and then swallow, with the instruction to keep the tongue against the palate during the swallow. The angle between the Frankfort plane and horizontal plane was 45° when the head was bent forward to the trained position [Figure 4]. A stick of low fusing compound was softened using a flame and applied on the demarcated PPS section of the other custom tray. The added compound was heated uniformly using an alcohol torch, tempered in hot water, and placed in the patient's mouth. The tray was supported on either side with fingers and the patient was asked to bend forward and swallow at least two times as practiced before. The patient was instructed to return to normal posture and

Figure 1: Primary cast with custom trays

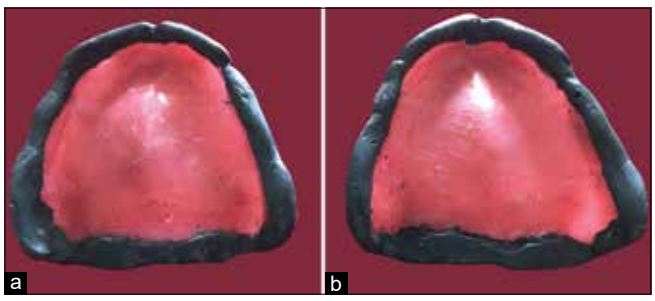


Figure 3: Posterior palatal seal developed from (a) conventional method and (b) novel functional swallow method

Figure 2: Vent placed in the custom tray handle of specific dimensions

Figure 4: Patient position to record posterior palatal seal with novel swallow method

swallow once again. The efficacy of the PPS was assessed by tucking the tray handle on its inner side. The procedure was repeated till satisfactory PPS was achieved. The green stick that appeared beyond the boundaries of the PPS was cut and finished using a sharp B.P blade.

Measurement of retention

The retention was evaluated using a pull-type analog dynamometer device [Figure 5]. All the retention measurements were made by a second investigator who was blinded about the study protocol. The c-shaped hook of the dynamometer engaged the vent hole of the handle snugly from its inner side. The reading was recorded in Newton.

Before recording the retention values, the patient was asked to wet the mouth with water and the custom tray was placed in the mouth for about 2 min. The patient's head was stabilized such that the Frankfort horizontal plane was parallel to the horizontal. The c-hook of the dynamometer was engaged into the vent of the handle and the device was pulled with one hand in an outward–upward direction perpendicular to the angulated handle [Figure 6]. Furthermore, a finger of the nonoperating hand was placed near the posterior part of the custom tray to prevent the tongue from resisting the tray dislodgment.

Measuring the retention of custom tray post border molding

The border-molded custom trays with the PPS established from both methods (Group 1 and Group 2) were evaluated separately. A total of three readings were taken for each method in every patient.

Fabrication of heat-processed bases

Post border molding, the maxillary final impression was made using a low viscosity elastomer (elite HD+, Zhermack S.p.A., Italy) for both the methods [Figure 7]. The master casts were poured into Type III gypsum [Figure 8]. Whereas a PPS scoring procedure on the master cast through a trial base was followed for the conventional technique (Group 1), the master cast obtained from the functional swallow technique (Group 2) was not scored [Figure 8]. A 2 mm thickness wax sheet was adapted uniformly on all master casts and heat-polymerized bases [Figure 9] were obtained by employing the compression molding technique. The bases were finished and a handle was made for each processed base using autopolymerizing acrylic resin. The handle was made to the specific dimensions and a circular vent was placed as described before.

Measuring the retention of heat-processed denture base

Heat-processed bases from both methods (Group 1 and Group 2) were evaluated for retention separately. Using the dynamometer, a total of three readings were taken for each method in every patient.

Figure 5: Analog-type dynamometer

Figure 6: Measurement of retention

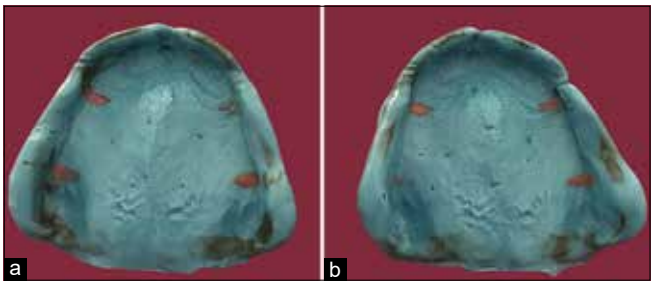


Figure 7: Final impression with posterior palatal seal developed from (a) conventional method and (b) novel functional swallow method

RESULTS

The force required to dislodge the custom tray after border molding and after processing the heat cure denture base was measured in newton. This measured force was considered as the retention value. These values were obtained for both Group 1 (PPS obtained by conventional method) and Group 2 (PPS obtained by functional swallow method). In Group 1, for each of the twenty patients, three retentive values were recorded with the custom tray and the mean was obtained. A total of 20 values were derived. The group mean was calculated which indicated retention after border molding [Table 2]. A similar mean value was calculated for Group 2 patients after border molding [Table 2]. Again three retentive values were measured with each heat cure base for each patient in Group 1 and the mean was determined, generating another twenty values. The

group mean representing retention with heat cure base was computed [Table 3]. Similarly, a mean retentive value was obtained for Group 2 after processing the heat cure base [Table 3].

Independent Student's *t*-test revealed higher mean retention values of Group 2 (PPS obtained by functional swallow method) than Group 1 (PPS obtained by conventional method) both during border molding [$P < 0.001$, Table 2] and after denture base processing [$P < 0.001$, Table 3]. Student's paired *t*-test showed that within Group 1, the mean retention value after denture base processing was significantly higher [$P < 0.001$, Table 4] than that during border molding. Student's paired *t*-test within Group 2 disclosed that there was no significant change in mean retention value [$P > 0.001$, Table 5] from the stage of border molding to heat cure denture base stage.

DISCUSSION

The philosophy behind any method used for recording PPS effectively lies in its ability to create sufficient displacement of the soft tissues within the physiological limits which will aid in creating a seal between the denture and the soft tissue during functional movements.[23] The "Ah" sound is not only used to mark the vibrating lines but also used frequently as a functional method to displace the soft palate during border molding with low fusing compound among Asian countries. In spite of its popularity, the "Ah" functional method has not been documented as a technique. Since the "Ah" functional method may not be consistent in developing a posterior seal, it is augmented by the conventional scoring procedure on the master cast. For the same reason, the conventional method in the present study combined the two. The nonscoring functional swallow method may be a simple alternative to the existing methods that are either inaccurate, cumbersome, or technique sensitive. The functional swallowing forces of the tongue that is inherent to an individual can displace the soft palate when the head is flexed forward. Due to the head flexion, the soft palate assumes a passive downward and forward position.[24] The soft palate may be easy to displace when it is passive. The swallowing function elevates the tongue to bring about an intimate contact between the custom trays carrying the softened low fusing compound with the passive soft palate. This helps to achieve a more efficient seal during border molding. Low fusing impression compound was used in this trial as it is easy to manipulate, commonly used, and also dimensionally stable during cast pouring procedures.

The physiologic fluid wax method[5] also recommends the patient's forward head flexion of 30° and the use of mouth temperature wax to establish the PPS. Training the patient to flex the head to 30° requires the cumbersome use of an angle measuring device. Furthermore, in this method, the patient's tongue has been positioned against the lower anterior teeth during the recording procedure. This position takes the tongue away from the posterior palatal area and does not aid in establishing the seal. In the present technique, the patient's head was bent down till the chin touched the chest or was close to it. At this point, the Frankfort horizontal plane made an angle of 45° to the horizontal. This position not only placed the soft palate

Table 2: Mean retentive values obtained after border molding between groups

Group	*n*	Mean	SD	Mean different	*t*	*P*
Group 1	20	14.38	6.41	−7.65	−7.360	<0.001*
Group 2	20	22.03	8.72			

*Statistically significant, mean retentive was compared using Student's *t*-test (*t*). Group 1: PPS by conventional method, Group 2: PPS by novel functional swallow method, SD: Standard deviation, PPS: Posterior palatal seal

Table 3: Mean retentive values obtained after conversion to heat processed base between groups

Group	*n*	Mean	SD	Mean different	*t*	*P*
Group 1	20	16.45	6.73	−6.10	−5.907	<0.001*
Group 2	20	22.55	8.66			

*Statistically significant, mean retentive values were compared using Student's *t*-test (*t*). Group 1: PPS by conventional method, Group 2: PPS by novel functional swallow method, SD: Standard deviation, PPS: Posterior palatal seal

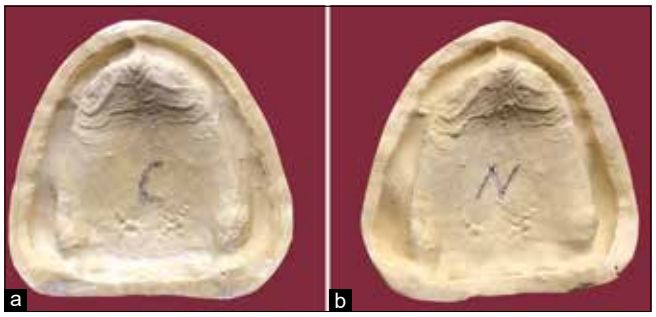


Figure 8: Posterior palatal seal area on master cast (a) scoring using conventional method and (b) nonscoring novel functional swallow method

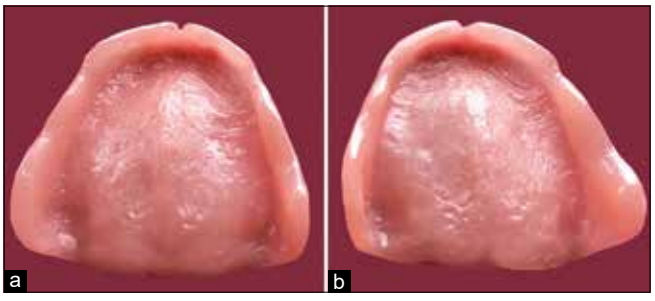


Figure 9: Heat-processed bases. (a) Conventional method and (b) novel functional swallow method

Table 4: Mean retentive values within Group 1 obtained after border molding and subsequent conversion to heat cure bases

Group	*n*	Mean	SD	Mean different	*t*	*P*
Group 1 – after border molding	20	14.38	6.41	−2.08	−9.128	<0.001*
Group 1 – after conversion to heat processed base (with cast scoring)	20	16.45	6.73			

*Statistically significant, mean retentive values were compared within Group 1 using paired *t*-test (*t*). Group 1: PPS by conventional method, SD: Standard deviation, PPS: Posterior palatal seal

Table 5: Mean retentive values within Group 2 obtained after border molding and subsequent conversion to heat cure bases

Group	*n*	Mean	SD	Mean different	*t*	*P*
Group 2 – after border molding	20	22.03	8.72	−0.53	−1.831	0.08
Group 2 – after conversion to heat processed base (without cast scoring)	20	22.55	8.66			

Mean retentive values were compared within Group 2 using paired *t*-test (*t*). Group 2: PPS by novel functional swallow method, SD: Standard deviation, PPS: Posterior palatal seal

in a passive, downward and forward position, but was also easy to achieve during the clinical procedures for the patient without assistance from an angle measuring device. Hence, the head was flexed to 45° in the present study.

The retention efficacy of complete dentures can be measured by subjective methods, clinical-objective methods, and purely objective methods. The most reliable among them is the objective measurement of denture base retention using the dynamometer.[25]

Various studies have evaluated the influence of patient factors,[26] denture adhesives,[27] and the type of PPS[1,19] on the magnitude of maxillary denture retention. These studies have quantified the denture retention by attaching a dynamometer to the geometric center of maxillary denture base through a metallic hook so as to generate a measurable dislodging force in a vertical or oblique direction. However, vertical pulling forces through the center of the denture may not simulate the denture dislodging pattern during function. This is due to the fact that the maxillary denture dislodgement pattern during function occurs through tipping or rotational forces causing dislodgement at the posterior end.[1,18] This dislodgement force is in an outward and upward direction.[28] Hence, vertical dislodgement forces were avoided in the present study.

Chandu *et al*. studied the influence of different methods of recording PPS by directing outward–upward rotational forces to the posterior end of the denture base.[19] They attached the hook to the posterior end of the denture base and used cumbersome equipment for measuring retention. The influence of tongue reflex to resist the denture base dislodgement from the posterior end during measurement of retention was not considered. In the present study, it was ensured that the tongue was kept away from the custom tray and the denture base during retention measurements by the operator's hand. Also, in contrast to previous studies, the tipping forces from the dynamometer was applied to the anterior end of the denture base in an upward and outward direction. This is analogous to the chairside clinical verification of PPS where tipping forces are applied on the inside of the tray handle on the border molded tray.[22]

The magnitude of retention of the custom tray after border molding in Group 2 (novel functional swallow method) was higher by about one and half times ($P < 0.001$) than that of Group 1 (conventional method). This may be due to passive positioning of the soft palate during anterior flexion of the head and hence a more superior palatal displacement achieved by low fusing compound. The mean retention of heat cure bases after processing was also significantly greater ($P < 0.001$) in Group 2 than in Group 1. It may be due to a more accurate soft palate displacement achieved by functional swallowing forces when compared to hypothetical cast scoring. This was in agreement with a previous study,[19] which found higher retention of heat cure bases when the PPS was recorded with a nonscoring method as against different scoring methods. However, the study did not divulge the specifics of their functional technique.

An accurate PPS not only improves retention of the denture base but also compensates for processing shrinkage.[13] Within Group 1, the mean retention value was the least at the border molding stage which significantly increased ($P < 0.001$) after the base was processed. This probably proves that scoring of the master cast may be essential when the "Ah" functional method is used to create the PPS during border molding. Among Group 2, the difference in the mean retention value from the border molding stage to the denture base processing stage did not change much. This was perhaps due to the master cast not being scored in the PPS area. Despite not scoring the master cast, the retention remained unchanged and higher than Group 1 after processing. This probably confirms a better compensation of curing shrinkage by the functional swallow method when compared to the conventional method.

The limitation of this study was that the retention was assessed only by measuring the dislodging force of the

denture base. Functional retention and patient satisfaction scores were not determined. The present study followed a nonrandomized crossover design. A randomized control trial comparing the efficacy of the two methods of establishing PPS along with patient satisfaction scores can further substantiate evidence and perceptions.

CONCLUSIONS

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

1. Between the two methods of recording the PPS, the nonscoring functional swallow method exhibited higher retention than the conventional method both during border molding and after conversion to heat cure denture base
2. In the conventional method, scoring of the master cast helped to increase the degree of retention from the border molding stage to the denture base stage
3. Although the master cast was not scored, the functional swallow method achieved greater retention
4. The nonscoring functional swallow method can be a practical alternative to the conventional scoring method.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that her name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Evaluation of clinical and radiographic outcome of friction fit conical abutment system in implant-supported dental prostheses: An *in vivo* study

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Abstract

Aim: The purpose of this clinical study was to analyze the clinical feasibility of friction fit conical abutment system in implant-supported fixed dental prostheses as an alternative to cement and screw retention.

Settings and Design: This was an *in vivo* longitudinal study.

Materials and Methods: A total of 10 prostheses were designed as 3- or 4-unit fixed dental prostheses supported by two implants. All the subjects selected were evaluated for pocket probing depth (PPD) and marginal bone loss at the time of implant placement (T1), at the time of placement of friction fit prostheses (T2), and 12 months after placement of friction fit prostheses (T3). Marginal bone loss at T2 and T3 was measured with respect to bone levels at T1 and T2, respectively. The patient satisfaction was assessed at T2 and T3 using FDI clinical criteria and scoring system (modified by Monaco *et al*.).

Statistical Analysis Used: Shapiro–Wilk test was employed to test the normality of data. Paired sample t-test was performed for quantitative variables.

Results: A total of twenty implants were inserted in ten partially edentulous spaces; the average patient age was 50.2 years. No significant difference was seen between T2 and T3 for PPD. Comparison of marginal bone loss using paired *t*-test showed a statistically highly significant difference at T2 and T3 with higher value at T2. No prostheses were dislodged during postprosthetic follow-up. The survival rate was 100% for both the abutments and implants. No change in surface luster was observed 12 months following prosthetic rehabilitation in any case. No prostheses or framework fracture was reported and all patients were satisfied with the prosthesis received.

Conclusions: Friction fit conical abutment system can act as a novel approach for the retention of implant-supported fixed dental prostheses.

Keywords: Alternate retention, computer-aided design and computer-aided manufacturing, friction fit

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INTRODUCTION

The longevity of restoration is the key objective of a successful treatment plan and so it is with implant-supported prosthetic rehabilitation. A successful treatment plan demands meticulous adherence to established protocols. The implant and prostheses are technique and material sensitive. One of the areas of concern is the abutment-prosthesis junction.[1] Implant-supported prosthetic reconstructions can either be screw retained or cement retained or a combination of both.[2,3] Although there are many advantages to either approach, inherent risks and drawbacks which negatively affect the long-term success of the implant-supported prosthesis become predominant.[4]

Screw-retained implant prostheses have an inherent lack of esthetics with a channel cast in metal or a compromised strength of the superstructure around the access hole. In addition, the problems of screw loosening and plastic deformation arise due to biomechanical overload. Subsequently, the restoration becomes mobile as the screw loosens, leading to an inflammatory reaction or a screw fracture.[5,6] Cement-retained implant prostheses are associated with peri-implantitis attributed to residual excess cement.[7,8] Residual excess cement can be eliminated by using a screw-retained cemented prosthesis or a combination implant crown in which screw access hole is on the occlusal surface of prosthetic crown which is extraorally cemented to abutment allowing removal of excess cement. Thereafter, the assembly is retained through screw. Although this technique allows the elimination of residual cement, it leaves the occlusal, usually functional cusp/fossa area to be restored with a composite that is more susceptible to wear and abrasion, thereby compromising occlusal contacts. Moreover, with multiple units, this technique becomes more difficult.[9]

To overcome the aforementioned shortcomings of the screw- or cement-retained implant prosthesis, friction fit implant-supported dental prosthesis that uses a tapered cone design to retain the coping on the abutment by surface friction can be designed. The conical coping is retained on conical abutment by surface contact. Tapered cone design creates friction when the prosthesis is completely seated over the abutment. The tapered attachment design ensures complete seating of the prosthesis as the diameter of the coping is greater than the diameter of the abutment.[10-12]

The aim of this clinical study was to analyze the clinical feasibility of friction fit conical abutment system in implant-supported fixed dental prostheses as an alternative to cement and screw retention. The objective is to analyze the clinical outcome by evaluating the health of peri-implant tissues over time by assessing the pocket probing depth (PPD), clinical parameters, and complications in terms of esthetic and functional properties[13] and radiographic outcome by evaluating the peri-implant bone changes (marginal bone loss) to demonstrate the feasibility of the friction fit conical abutment system as a novel approach for the retention of the prostheses.

MATERIALS AND METHODS

The study was approved by the Institutional Ethical Committee (RUHS-CDS/EC/2017/Proposal/001). All partially edentulous patients registered in the Department of Prosthodontics were assessed for implant-supported prostheses. Ten partially edentulous cases were selected following the inclusion criteria. All sites had opposing natural dentition. A total of ten prostheses supported by two implants were designed. All the subjects selected were evaluated at the time of implant placement (T1), at the time of placement of friction fit prostheses (T2), and 12 months after placement of friction fit prostheses (T3). The implant system used in the study was NobelReplace Conical Connection Implant System (Nobel Biocare).

The study included healthy subjects of 18 years and above with no temporomandibular joint pathosis, normal maxillomandibular relationship, sufficient interarch space, sufficient bone volume, and physically or psychologically fit for implant-supported fixed dental prostheses. Subjects with recent myocardial infarction, bleeding disorder, psychiatric disorder, undergoing intravenous bisphosphonate treatment, uncontrolled diabetes, pregnant women, and chronic smokers were excluded from the study. Prior to the study, the approval of the Institutional Ethical Committee (RUHS-CDS/EC/2017/Proposal/001) and informed consent of each participant were obtained. The participant data were formulated and used for research purposes.

Surgical phase

Surgery was performed by one experienced operator. All patients were operated under local anesthesia (2% lignocaine with 1:100,000 adrenaline). The osteotomy site was prepared as recommended by Branemark to minimize trauma to the bone and thereby prevent necrosis of the bone.[14] Cover screws were placed and flaps were approximated to achieve complete closure using simple interrupted and/or simple mattress lock sutures using a 3-0 braided nonresorbable silk suture. The patients were called for the postoperative checkup after 24 h and then

after 10 days of surgery for suture removal. Delayed loading protocol was followed for the study. After completion of the requisite period of 6 months for the bone to implant integration, second-stage surgery was performed and per-mucosal attachments were placed for the formation of the gingival collar.

Prosthetic phase

Irreversible hydrocolloid impression material (Zelgan 2002 Alginate; Dentsply) was used to make primary impressions. Impressions were poured immediately with Type 3 Dental Stone (Kalstone; Kalabhai Karson Pt Ltd.) to obtain primary cast for custom tray fabrication. A minimum window (1.5 cm^2) was prepared over the area of the implant to allow clearance for manipulation of the impression coping in the custom tray. Implant-level open-tray impression was made with polyvinyl siloxane impression material (Photosil; DPI) [Figure 1]. A master cast with implant analogs was created. A vinyl polysiloxane (GI-MASK Automix; Coltene/Whaledent Private Ltd.) was used to simulate soft tissues. After try-in of implant verification jig [Figure 2], the master cast with embedded implant analogs was sent for scanning, designing, and milling of abutment and superstructure/coping.

Three consecutive phases are involved in computer-aided design and computer-aided manufacturing (CAD/CAM) production: scanning, designing, and milling. Scanning: the master cast with implant analogs was digitally scanned by an extraoral scanner (Identica T500; MEDIT). Designing [Figure 3]: 2° conical titanium abutments were designed using CAD software (DentalCAD; Exocad GmbH) and were made parallel to each other. The abutments were allowed a uniform 2° axial taper to allow for complete seating and yet provide sufficient resistance form. The custom abutments were designed to be parallel and had the desired subgingival emergence profiles and heights. Milling: the customized implant abutments were created by the CAM device (ME-300HP; TDS Biotechnology Co. Ltd.) in accordance with the virtual design.

After milling, abutment try-in was done to ensure a complete fit of customized abutments over implants [Figure 4]. Thereafter, customized titanium abutments were completely seated on the master cast and digitally scanned with Extraoral Scanner (Identica T500; MEDIT) for designing the prosthesis [Figure 5]. Superstructure/prosthesis was designed directly over abutments [Figures 6 and 7]. It was ensured that to achieve friction fit, zero cement space was left after milling (the outer diameter of the abutment was the same as the internal diameter of the superstructure),

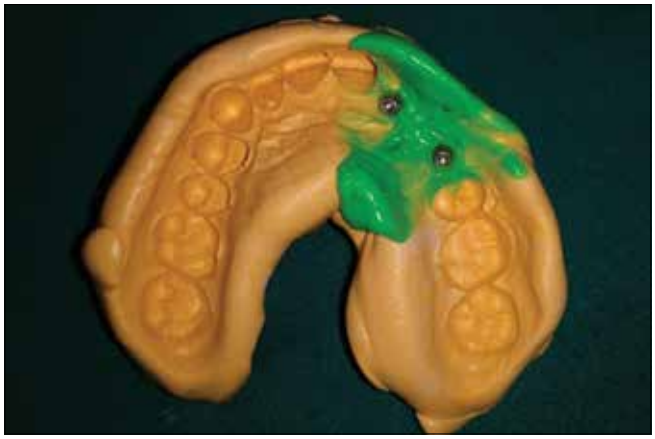

Figure 1: Implant-level open-tray impression

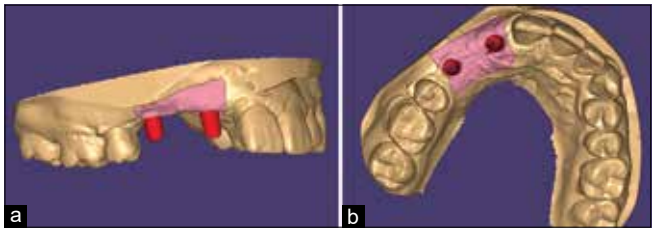

Figure 3: Abutment design using exocad DentalCAD software abutment design. (a) Lateral view, (b) occlusal view

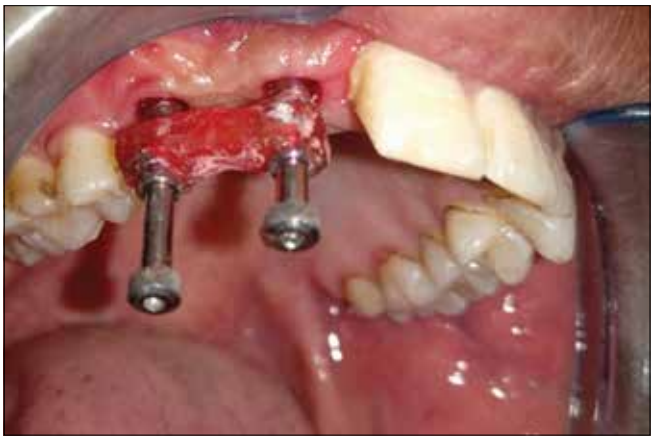

Figure 2: Try-in of implant verification jig

Figure 4: Customized milled abutment *in situ*

and a 2° axial taper was given. Thereafter, the superstructure was milled (ME-300HP; TDS Biotechnology Co. Ltd.). The abutments were tightened with a torque ratchet and superstructure was placed over abutments. Activation of friction fit attachment was achieved by biting force in posteriors and by gentle tapping with the handle of mouth mirror in case of anteriors. Implant-protected occlusion was ensured for all prostheses. Lateral tipping using a wood stick or lateral rocking of the prosthesis using forceps with silicon coating could be used for retrieving the prosthesis.[15,16]

Examination

Clinical parameters

PPD was evaluated at the time of prosthesis placement (T2) and 12 months after prosthesis placement (T3) using plastic instruments to avoid scarring and/or damage to the implant surface. Peri-implant PPD was measured using a plastic periodontal probe from the gingival margin to the bottom of the pocket at mesial, distal, facial, and lingual/palatal side with a pressure calibration stop of 0.25 N (TPS probe; Ivoclar Vivadent AG).[17,18]

Radiographic parameters

Radiographic analysis of the peri-implant bone was done by the cone-beam computed tomography (CBCT) (CS3D-9000; Carestream Dental LLC). CBCT radiographs were taken for measurements of the quality and quantity of bone in the peri-implant area, immediately following implant placement (T1), at prosthesis placement (T2), and 12 months after prosthesis placement (T3). The analysis was done using a measuring tool inbuilt in the CS3D-9000 CBCT machine software.

Change in the crestal bone level (linear measurements of bone loss around the implant) was measured in millimeters using CBCT. Navigation was done on the multiplanar screen to show the precise reformatted panoramic and sagittal view of the implant. The bone loss around the implant was assessed by a line drawn on the mesial, distal, buccal, and palatal image on the collar margin of the implant to the alveolar crest, using software tools [Figures 8-11].[19] Mean marginal bone loss was obtained by dividing the sum of marginal bone loss of mesial, distal, buccal, and palatal sides by four.

Data obtained were compiled on a spreadsheet (MS Office Excel 2010; Microsoft Corp.). Data were subjected to statistical analysis using the statistical software program (IBM SPSS Statistics, v20.0; IBM Corp.). Descriptive statistics such as mean and standard deviation for numerical data have been depicted. Paired sample *t*-test was performed for quantitative variables. For all the statistical tests, $P < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

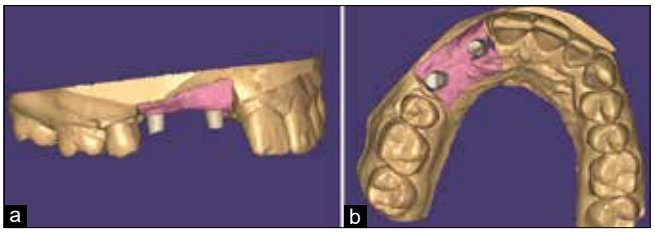

Figure 5: Scanned image of milled abutment. (a) Lateral view, (b) occlusal view

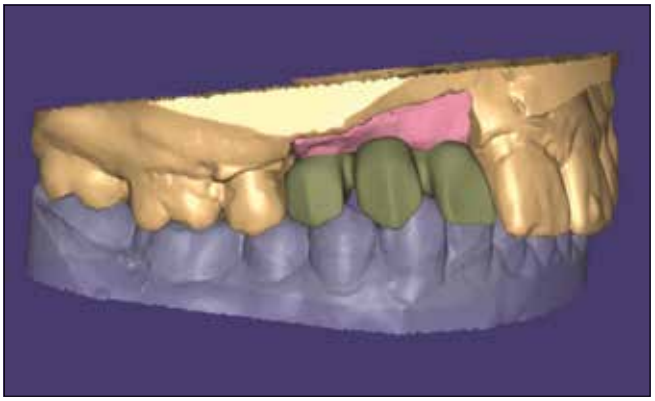

Figure 6: Prosthesis design using exocad DentalCAD software

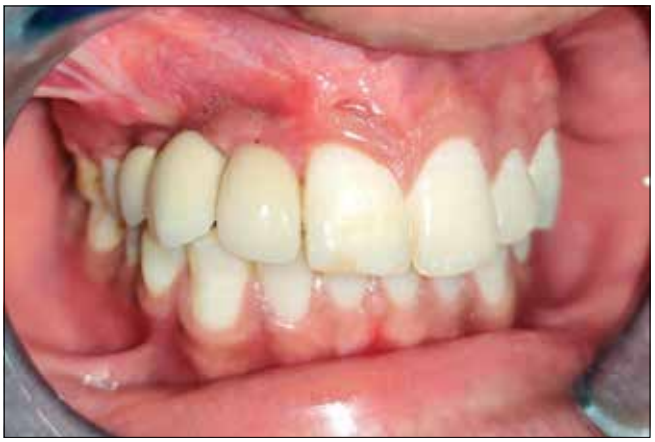

Figure 7: Milled superstructure with layered porcelain *in situ*

RESULTS

Clinical evaluation

Pocket probing depth

The mean value of PPD was 1.66 mm with a standard deviation of 0.20 at T2 and 1.69 mm with a standard deviation of 0.23 at T3. Results showed no significant difference between T2 and T3. Furthermore, the surface-wise result showed a statistically nonsignificant

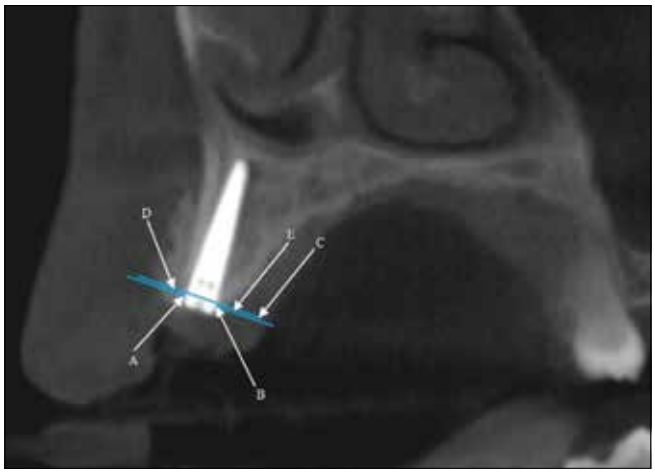

Figure 8: CBCT MARGINAL bone-level determination. (A) Bone crest buccally, (B) bone crest lingually, (C) line passing through implant shoulder buccolingually, (D) vertical distance between A and C, (E) vertical distance between B and C

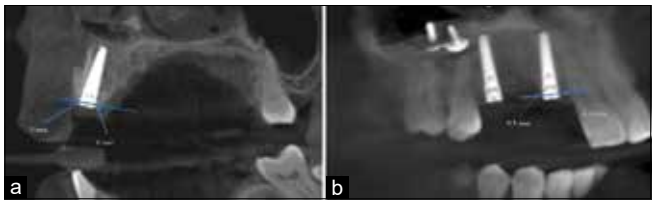

Figure 10: Marginal bone level at T2. (a) Faciolingual, (b) mesiodistal

Table 1: Statistical comparison of pocket probing depth (paired *t*-test)

	Mean	*n*	SD	SEM	Mean difference	SD of difference	*T*	*P* of paired *t*-test
Mesial T2	2.35	20	0.59	0.13	−0.10	0.31	−1.45	0.163[#]
Mesial T3	2.45	20	0.60	0.13				
Distal T2	2.25	20	0.44	0.1	−0.15	0.37	−1.83	0.083[#]
Distal T3	2.40	20	0.50	0.11				
Facial T2	1.00[a]	20	0.00	0.00	-	-	-	-
Facial T3	1.00[a]	20	0.00	0.00				
Lingual T2	1.05	20	0.22	0.05	−0.05	0.22	−1.00	0.330[#]
Lingual T3	1.10	20	0.31	0.07				
Average T2	1.66	20	0.20	0.05	−0.02	0.08	−1.45	0.163[#]
Average T3	1.69	20	0.23	0.05				

*All values are non significant. SD: Standard deviation, SEM: Standard error of mean

difference between T2 and T3 with a higher value at T3 [Table 1].

Radiographic evaluation

Marginal bone loss

Mean marginal bone loss was assessed before and after functional loading. Mean marginal bone loss at T2 represents bone loss before loading (between T1 and T2), while the mean marginal bone loss at T3 represents bone loss after functional loading (between T2 and T3). The mean values of marginal bone loss were 0.26 mm with a standard deviation of 0.08 at T2 and 0.12 mm

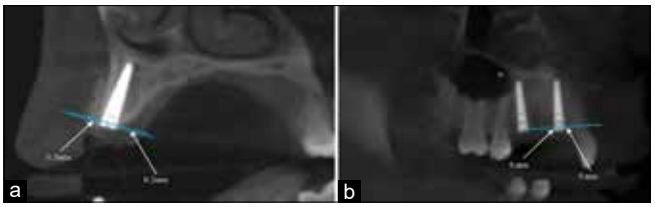

Figure 9: Marginal bone level at T1. (a) Faciolingual, (b) mesiodistal

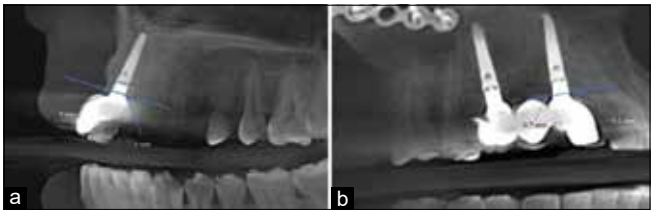

Figure 11: Marginal bone level at T3. (a) Faciolingual, (b) mesiodistal

with a standard deviation of 0.05 at T3. Comparison of marginal bone loss using paired *t*-test showed a statistically highly significant difference at T2 and T3 with higher value at T2 (0.26 mm ± 0.08). The above comparison indicates the marginal bone loss that occurred before functional loading was significantly higher than after loading [Tables 2 and 3]. Comparison of mesiodistal and faciolingual bone loss using paired *t*-test showed a highly significant ($P = 0.000$) difference at T2 and T3 with higher value at the mesiodistal surface [Table 4].

Prosthetic evaluation

No prostheses were dislodged during postprosthetic follow-up. Clinical parameters and complications were evaluated in terms of esthetic and functional properties according to FDI clinical criteria and scoring system modified by Monaco *et al.* [Table 5].[13,20] No change in surface luster was observed in any cases at T3 (12 months after placement of friction fit prostheses). No prostheses and framework fractures were reported and all patients were satisfied with the prosthesis received.

DISCUSSION

The friction fit abutment system achieves retention by principles of transition fit. The transition fit is used where accuracy is important, but where a small amount of clearance or a small amount of interference is acceptable and it results in size to size fit.[21-27] A friction fit is dependent on the accuracy at the prosthesis abutment interface and increases as the area of contact increases. Friction is maximum when the coping is fully seated on the abutment.[10-12,28]

This is, to the best of our knowledge, the first protocol that investigated the performance of friction

Table 2: Marginal bone level at T1, T2, and T3

Subjects	Implants (location wise)	Marginal bone level (mm)		
		At the time of implant placement (T1)	At prosthesis placement (T2)	12 months after prosthesis placement (T3)
1	12	+0.1	−0.175	−0.225
	14	+0.1	−0.15	−0.2
2	12	+0.075	−0.25	−0.35
	21	+0.25	0	−0.125
3	36	+0.25	0	0
	38	+0.175	0	−0.05
4	46	+0.125	0	−0.15
	48	−0.5	−0.875	−0.95
5	12	+0	−0.325	−0.45
	22	+0.3	−0.025	−0.125
6	32	+0.3	+0.025	−0.075
	42	+0.325	+0.025	−0.125
7	16	+0.9	+0.7	+0.525
	18	−0.175	−0.35	−0.45
8	34	−0.075	−0.425	−0.5
	36	+0.15	−0.225	−0.325
9	26	+1	+0.7	+0.575
	28	+0.25	−0.075	−0.25
10	45	+1.6	+1.325	+1.15
	47	+0.325	+0.075	−0.075

+: Alveolar crest above collar margin of implant, −: Alveolar crest below collar margin of implant

Table 3: Statistical comparison of marginal bone loss (paired *t*-test)

	Mean	*n*	SD	SEM	Mean difference	SD of difference	*T*	*P* of paired *t*-test
T2	0.26	20	0.08	0.02	0.14	0.09	7.28	0.000**
T3	0.12	20	0.05	0.01				

**Highly significant. SD: Standard deviation, SEM: Standard error of mean

Table 4: Statistical comparison of marginal bone loss (paired *t*-test) (mesiodistal vs. faciolingual)

	Site	*n*	Mean±SD	SEM	*T*	*P* of paired *t*-test
T2	MD	20	0.35±0.09	0.02	6.83	0.000**
	FL	20	0.17±0.07	0.02		
T3	MD	20	0.20±0.07	0.02	8.93	0.000**
	FL	20	0.04±0.04	0.01		

**Both values are highly significant. SD: Standard deviation, SEM: Standard error of mean, MD: Mesiodistal, FL: Faciolingual

fit conical abutment system in 3- or 4-unit fixed dental prosthesis supported by two implants. The present study was developed and carried out using methods that had been used in previous studies that examined the friction fit retention but with notable changes. Previous studies comprised three components (abutment-coping-superstructure) prosthetic assembly, where friction fit connection exists between abutment and coping and coping was then luted to the superstructure, while the present study design comprised two-component (abutment-superstructure) prosthetic assembly, where coping is an inherent part of the superstructure and friction fit connection exists between abutment and superstructure. In the present study, CAD-CAM-milled 3- or 4-unit metal-ceramic fixed dental prostheses were fabricated directly over the paralleled customized abutments instead of prefabricated abutment and coping, which were utilized in previous studies [Figure 12].[10,29-31] This eliminates the need for the dentist to choose prefabricated stock abutments and make them parallel intraorally. CAD-CAM abutments, on the other hand, are already parallel to each other with optimized height and emergence profile.[16]

In the present study, customized titanium abutments with 2° axial tapers were designed using CAD software (DentalCAD; Exocad GmbH) and were made parallel to each other. In one of our cases, abutment angle correction was >30 and it was compensated by using a multiunit abutment. This was done as retention of friction fit conical abutment system depends on the area covered. The more the area, the more will be retention.[28] Implant placement parallel to each other keeps the screw access hole occlusally and utilizes all axial surfaces for retention [Figure 13]. If the implants are not placed parallel to each other, it will result in shifting of screw access gingivally, thereby reducing the axial wall and thus the area covered by the superstructure [Figure 14].

Nardi *et al.* found the retention of friction fit prostheses to be directly proportional to the height and diameter of the abutment. The retentive strength of friction fit prostheses was found to be comparable with values reported for commonly used cement.[28] One advantage of the friction fit abutment system is the ease with which the clinician may retrieve the prosthesis to assess periodontal health and conveniently execute professional oral care.[16,32] In the present study, the prostheses were found to be acceptable

Table 5: Clinical parameters and complications in terms of esthetic and functional properties (as modified by Monaco *et al.*)

Properties	Parameters	T2	T3
Esthetic properties			
Surface luster			
1	Surface luster comparable to enamel	10	10
2	Slightly dull, not noticeable if covered with film of saliva		
3	Dull, cannot be masked by saliva film		
4	Rough surface, unacceptable plaque retentive surface		
Functional properties			
Framework fracture			
1	No	10	10
4	Yes		
Veneer fracture			
1	No	10	10
2	Yes, color wear in the occlusal portion (Grade 1: Polishable)		
3	Yes, chipping (Grade 2: Repairable)		
4	Yes, severe chipping/delamination (Grade 3: Replacement)		
Patient response			
1	Entirely satisfied	10	9
2	Satisfied		1
3	Minor criticism of esthetics; no adverse effect		
4	Completely dissatisfied and/or adverse effect, including pain		

1: Clinically excellent/very good, 2: Clinically good, 3: Clinically sufficient/satisfactory, 4: Clinically unsatisfactory

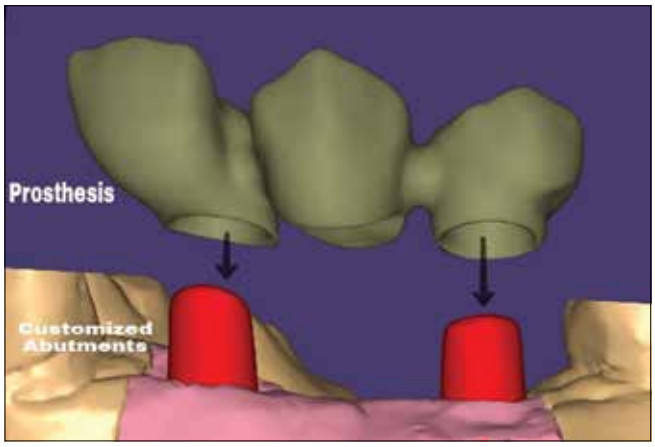

Figure 12: Two-component prosthetic assembly

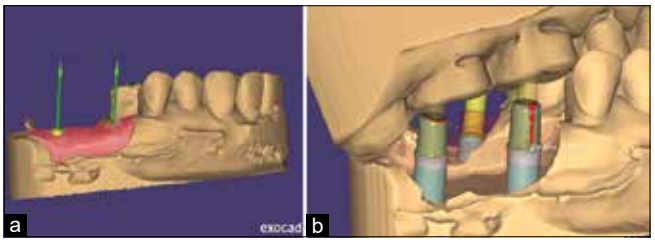

Figure 13: Implant placement parallel to each other keeps the screw access hole occlusally and utilizes all axial surfaces for retention. (a) Implant placed nearly parallel to each other, (b) occlusal screw access hole

on clinical parameters with 100% patient satisfaction in terms of retention and soft-tissue response.

Radiographic evaluation of marginal bone loss was done using CBCT. The amount of marginal bone loss was measured buccally, lingually, mesially, and distally using the inbuilt software of CBCT machine (CS3D-9000; Carestream Dental LLC) as conventional radiographs (periapical and panoramic) are two-dimensional and give no information about the alveolar bone quality and quantity.[33,34] Marginal bone loss assessment has been regarded as a critical criterion to assess implant success. The accepted implant success criteria are 1–1.5 mm of bone loss during the 1st year of loading and <0.2 mm annually thereafter.[35-37] Comparison of marginal bone loss using paired *t*-test showed a statistically highly significant difference at T2 (0.26 mm ± 0.08) and T3 (0.12 mm ± 0.05) with a higher value at T2. This can be attributed to surgical crestal bone trauma at the time of implant placement. These findings were in agreement with the study by Chou *et al.*[38] and Kline *et al.*[39] Marginal bone loss in the present study was 0.12 ± 0.05 mm during the 1st year of loading, which is less than the threshold specified in the success criteria.

In clinical parameter, PPD was recorded in the present study. The PPD results of the present study were in concordance with the results of the studies conducted by Degidi and Bressan, which also reported a nonsignificant difference in PPD at postprosthetic follow-up.[10,30]

The survival rate was 100% for both the abutments and implants. The frictional fit was viable, and even after 12 months of loading, a 100% prosthesis survival rate was achieved without prosthetic complications. These results were in concordance with the study conducted by Degidi *et al.*, which also reported similar results.[10] No change in surface luster was observed 12 months following prosthetic rehabilitation in any case. No prostheses or framework fracture was

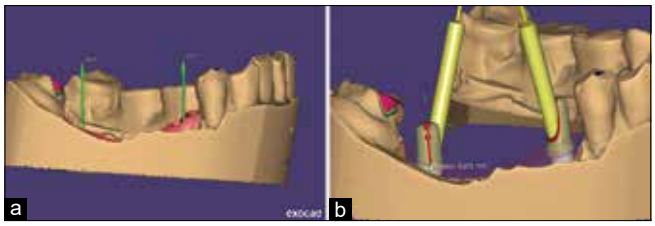

Figure 14: Implants placed nonparallel to each other will result in shifting of screw access gingivally, thereby reducing the axial wall and thus the area covered by the superstructure. (a) Implants placed nonparallel to each other, (b) shifting of screw access hole gingivally

reported and all patients were satisfied with the prosthesis received. No prostheses were dislodged during postprosthetic follow-up. However, to validate these findings, further long-term studies with a larger sample size are required.

CONCLUSIONS

Within the limitation of the present study, the friction fit abutment-prosthesis connection showed a 100% survival with encouraging data of PPD and marginal bone loss endorsing the reliability of friction-retained prosthesis without compromising the periodontal status. Thus, the friction fit conical abutment system can act as a novel approach for the retention of implant-supported fixed dental prostheses.

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Conflicts of interest.

There are no conflicts of interest.

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Research

A randomized controlled twelve month clinical study on the evaluation of success rate of endodontically treated teeth restored with metal poly-fiber posts and dentin posts

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Abstract

Aim: To compare the 12 month clinical performance of metal polyfiber post and dentin post systems in endodontically treated teeth.

Settings and Design: Department of Prosthodontics, KMSDCH, SVDU, Randomised Controlled study.

Materials and Methods: Thirty-six teeth that satisfied selection criteria were randomly allocated and treated in the two intervention groups – metal fiber post with composite core and dentin post with composite core. Patient characteristics with respect to gender, tooth guidance, type of tooth, and mobility amount of tooth structure left were recorded. The primary outcome of tooth loss and the secondary outcomes of recurrent caries detected at the crown margin, de-cementation of crown, and fracture of the core, post, and root were recorded at baseline, 3, 6, and 12 month follow up.

Statistical Analysis Used: Chi Square test.

Results: Thirty-six teeth in 17 patients (10 males and 7 females) were treated using metal fiber post (18 teeth) and dentin post (18 teeth). No loss of tooth was seen at the end of 3, 6, and 12 months. The secondary outcomes also showed no recurrent caries at margin and no fracture of core, post, and root in both the groups at the end of 3, 6, and 12 months. One case of de-cementation was observed in both the groups at the 12-month period. Periodontal and periapical conditions showed no clinical and radiographic signs at any of the follow-up periods in both the groups.

Conclusion: This twelve month randomized controlled clinical study concluded a similar success rate for endodontically treated teeth restored with crowns on both metal fiber post with composite core and dentin post with composite core.

Keywords: Crown de-cementation, dentin post, endodontically treated teeth, loss of tooth, metal polyfiber post, randomized control trial, root fracture

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INTRODUCTION

The best standard of care following endodontic treatment when a tooth lacks adequate structure to bond a conservative endocrown is to lute or bond a post with a composite core buildup primarily to provide adequate retention and resistance form to retain the definitive crown. Such restorations need a careful selection of the endodontic post system which has always been determined by experience and practicality of the practitioner. However, with increased clinical research, it has been that the decision to treat a tooth endodontically should be determined by the amount and nature of remaining tooth structure that would be able to support a definitive crown and in cases where a full-coverage restoration is the decision, and then, the practitioner has a choice of various post and core materials and post designs to retain an overlying crown.

The use of posts was originally only for retaining a crown in cases where reduced coronal structure remained[1] and was glorified to reinforce the remaining tooth.[2] With time, various authors hypothesized that the posts should have rigidity that be close to dentin in order to favorably dissipate the occlusal forces along the long axis of the tooth.[3-5] Metallic posts lack this unique requirement and moreover produce catastrophic fractures of roots. Posts therefore have been developed with a modulus of elasticity that mimics that of dentin. Most studies advocate the use of glass fiber posts for long-term success in restoring endodontically treated teeth as they are esthetic and resistant to corrosion and produce less unfavorable root fractures. In the past few years, material research has been directed toward obtaining materials with biomimetic properties. None of the premanufactured post systems meet all ideal biomechanical properties.

Metal polyfiber posts (SpirapostPFS, DMG, NJ, America) and dentin posts are two novel post types that have been innovated but less used in clinical scenarios. The metal polyfiber post is made up of stainless steel wires of surgical grade twisted around natural colored biocompatible polyfiber strands. Being self-adaptive, these innovative metal polyfiber posts fit the canals as if they are customized for the case. They adapt easily even in cases with curvatures, involve very less of dentin removal, and make a mechanically strong structure. Further, the coronal part of the post can be angulated according to the need of the long axis of the tooth to provide unhindered core buildup and adequate resistance form. The manufacturers claim 100% biocompatibility and ease of remove if retreatment is necessary.[6] Munoz *et al.* in 2007[7] evaluated the effect of cyclic loading on teeth restored with metal fiber posts and concluded that the new fiber metal post was able to resist functional and parafunctional forces when subjected to a loading force and in fact able to resist higher fatigue forces. Therefore, metal polyfiber post presents a clinical alternative to conventional rigid posts. Mastoras *et al.* inferred that the metal polyfiber system provided significantly increased post retention when compared with the fiber post.[8]

Biological dentin posts made from natural, extracted teeth present a feasible option for the strengthening of the root canal, thus presenting the potential advantages of low dentin stress, along with preservation of dentin walls. These posts being adhesively bonded to tooth dentin show greater retention compared to premanufactured posts and provide an economical option for restoring endodontically treated teeth. Case reports on the use of dentin posts to restore endodontically treated teeth exist in literatures.[9,10] Kathuria *et al.* concluded that teeth restored with dentin posts exhibited better fracture resistance than those restored with fiber-reinforced composite posts.[11]

In vitro studies indicate that the metal fiber post and dentin post are better than other post systems. Being lately introduced clinical behavior and success rates of the metal polyfiber post and dentin post are still lacking. Hence, there existed a need for a randomized control clinical study to evaluate the fracture resistance of these two post and core systems in endodontically treated teeth for a 12-month clinical observation period. The null hypothesis proposed in the study is that both the posts (metal polyfiber post and dentin post) do not differ in the success rates as compared with the primary and secondary outcomes for an observation period of 1 year.

METHODOLOGY

The study was conducted in the Department of the Prosthodontics and Crown and Bridge. Ethical approval for the study was granted by the Institutional Ethics Committee, SV vide no SVIEC/ON/DENT/BN-PG12/012116. All the patients who reported to the Department of Prosthodontics and Crown and Bridge for post endodontic rehabilitations were screened for the need of post and core restorations. The endodontically treated teeth were evaluated for inclusion and exclusion criteria which were set for the study. All eligible participants were informed of the nature of the study using the participant information sheet in their own language. A signed informed consent form in a language that the patient understood was obtained. The basic information recording patient details, operatory details, and primary

and secondary outcomes at 3, 6, and 12 months was recorded in a pro forma.

On the basis of data values obtained from the study done by Naumann *et al.*,[12] a sample size was obtained by using nMaster software (version 2.0) at 95% confidence interval and 80% power. A total sample size of 30 was arrived at which was divided equally into 15 in each group. Further considering a 20% dropout in the study, a final sample size of 36 was achieved.

The patients who reported to the Department of Prosthodontics in the period extending for 9 months (January to September) were screened and recruited in the study. This study was done on the 17 participants and 36 endodontically treated teeth adhering to the following inclusion and exclusion criteria. All patients received post and core treatment followed by crown placement as indicated for the case and were on a period of observation of 3, 6, and 12 months.

Inclusion criteria

1. Any teeth with an adequate root filling with no evidence of endodontic failure
2. Two or more cavity walls remaining
3. Symptom-free canal filling with a minimum apical seal of 4 mm
4. Healthy periodontium with no evidence of bleeding on probing with at least 75% periodontal support as seen on radiograph
5. Teeth with a minimum of 2 mm of coronal healthy tooth structure above gingiva or if lesser than that should be increased by a crown-lengthening procedure to get 2 mm of healthy crown structure
6. Residual root canal thickness at the orifice of more than 1 mm
7. Willingness to return at the intervals of at least 1-year evaluation.

Exclusion criteria

1. Potential abutments for fixed or removable prosthesis
2. Lack of adequate posterior support, defined as the absence of all molar teeth
3. Any obvious occlusal interference or fremitus affecting the tooth to be restored
4. Missing teeth in opposite arch
5. Patients with parafunctional habit (bruxism)
6. Patient who refuse crown-lengthening procedure
7. Pregnant patient.

The study being a randomized control design, the cases included were randomized using a computer-generated sequence of random numbers to the intervention group of metal fiber and control group of dentin posts. The generated randomized sequence was as follows 2 1 2 2 2 1 2 2 2 1 1 1 2 1 1 1 1 2 2 1 1 1 2 2 1 1 2 1 1 2 1 2 1 1 1 1 with "1" being metal polyfiber post group and "2" being dentin post group. The allocation details were sealed in an opaque envelope which was only opened after the period of 1-year evaluation prior to tabulating data for statistical evaluation. The group assignment for every tooth in the patients as decided by the sequence of random numbers was maintained by the department sister. The patient was also blinded to the groups under which their teeth were being treated.

In the study recruitment period of 9 months, 49 patients who were candidates for post and core restorations were screened for the inclusion and exclusion criteria. Of these, 13 cases were excluded, of which 9 did not satisfy inclusion criteria and 4 patients refused to participate. The remaining 36 cases were randomized for equal distribution into metal polyfiber post group and dentin post group (18 each). The summary of this study design is presented as a CONSORT flow diagram in Figure 1.

At the baseline, a routine examination was performed to record demographic details, tooth type, tooth mobility,[13] functional status on the basis of degree of attrition,[14] type of tooth guidance as combined anterior/canine guidance, canine guidance, and group function. Prior to the post placement, impressions were made of each tooth to document the amount of hard tissue loss according to the tooth restorability index.[15] Need for crown lengthening for ferrule was evaluated using a periodontal probe. A circumferential 2-mm ferrule was considered favorable, otherwise a surgical crown-lengthening procedure was done. Post space preparation was done using routine protocols of instrumentation, radiography, and principles of restoration of endodontically treated teeth.

For preparing dentin posts, the following method was followed to ensure standardization. In a clear acrylic block, three different post space preparations were done with the help of number 1, 2, and 3 Peeso drill (Hi-Rem over fiber post system, Italy). Dentin posts were prepared from healthy maxillary and/or mandibular canine or single-rooted premolar teeth which were freshly exacted for periodontal or orthodontic reasons or dis-impaction which were noncarious and had no evidence of cracks. Patients whose teeth were used for the study purpose provided consent to use their teeth for research purpose. The teeth were kept in 10% formaldehyde for 7 days and then sterilized in a Class B autoclave at 121°C for 15 min as per CDC guidelines[16] and decoronated after sterilization.

Debris and soft tissue were removed from the extracted tooth and sectioned longitudinally into two halves along the root canal with the high-speed air rotor [Figure 2]. The pulp tissue was removed from the canal. Dentin block was prepared out of each section and shaved with the flat taper fissure bur [Figure 3] to closely fit the shape of the previously prepared post spaces prepared using different sizes of Peeso reamers in the plexiglass block [Figures 4 and 5]. Dentin post thus prepared was of the size of Peeso reamer, and these were used as per requirement of diameter and length in patients. Posts thus prepared were sterilized using autoclave cycle of 121°C for 15 min and kept ready before use in patients.

All root canals receiving metal polyfiber and dentin posts were minimally prepared to allow passive insertion of the posts [Figure 6]. Fit and extension of the posts were confirmed radiographically. The selected posts were disinfected with a glutaraldehyde disinfectant and cemented using flowable dual-cure Duolink composite luting cement (Bisco Inc., Schaumburg, Illinois, US) [Figures 7 and 8]. Light-cure composite buildup was done using Bis-Core core buildup dual-cure composite (Bisco Inc., Schaumburg, Illinois, US) [Figure 9]. All teeth received full-coverage crowns luted with resin-modified GIC luting cement [Figure 10]. Maintenance instruction was given to each patient, and they were placed on a regular checkup and follow-up. A baseline intraoral periapical radiograph was taken once the crown was cemented [Figure 11]. The patient was recalled at 3-, 6-, and 12-month interval to evaluate the primary and secondary outcomes of post endodontic restoration [Figures 12-14]. The primary endpoint was loss of tooth for any reason and the secondary endpoints were recurrent caries detected at the crown margin,[17] de-cementation of crown, fracture of the core, fracture of the post, and fracture of the root.

During every follow-up, the clinical examination was performed by one calibrated blinded examiner (RS). However, blinding for radiographic interpretation could not be done. Follow-up examinations were performed with a dental probe and mirror to detect marginal gap formation of the restorations. Fracture of core in case of de-cementation of crown was evaluated clinically. Radiograph was taken in every recalled interval time to exclude the possibility of radiographic symptoms of root and post failure and periodontal and periapical lesions. Codes were assigned according to the outcomes by the examiner. The collected data were entered in the Excel sheets and tabulated and subjected to statistical analysis using Graph Pad Prism 9 Software, San Diego, California, America.

RESULTS

The demographic details of the patients included in the study and tooth characteristics are summarized in Table 1.

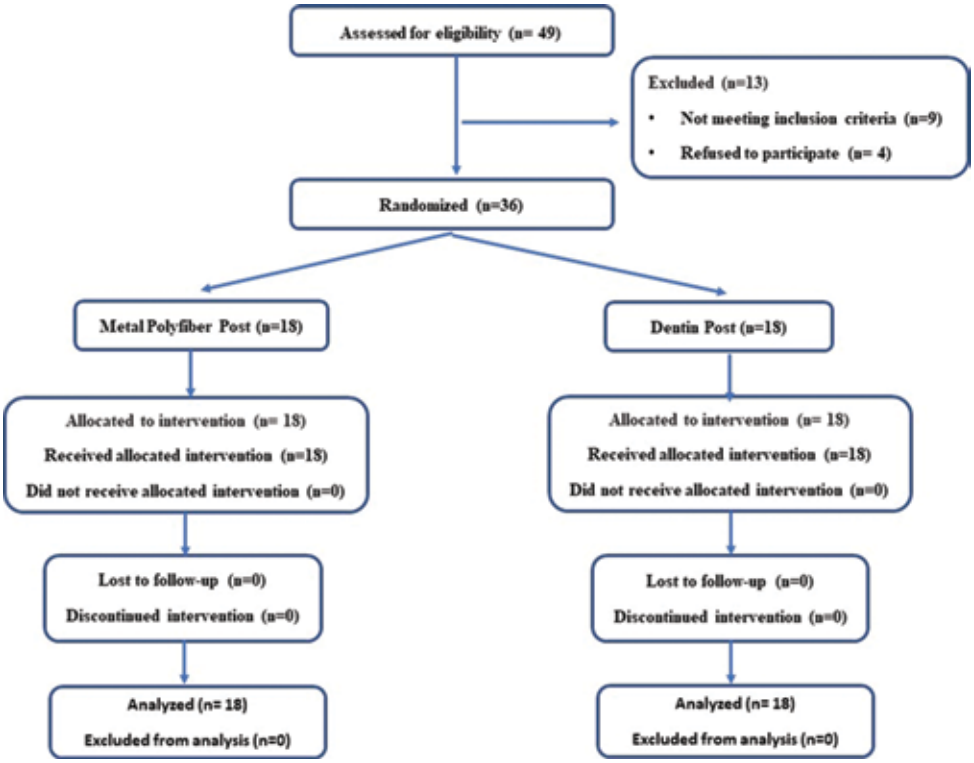

Figure 1: CONSORT flow diagram of the study design and flow of participants in various phases of the study

Figure 2: Sectioning of tooth

Figure 4: Plexiglass with different post spaces prepared

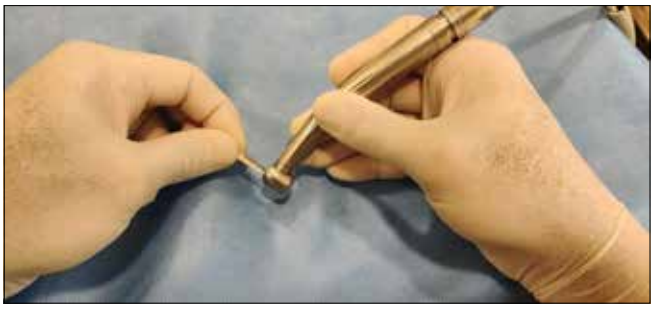

Figure 3: Shaving of dentin to prepare post

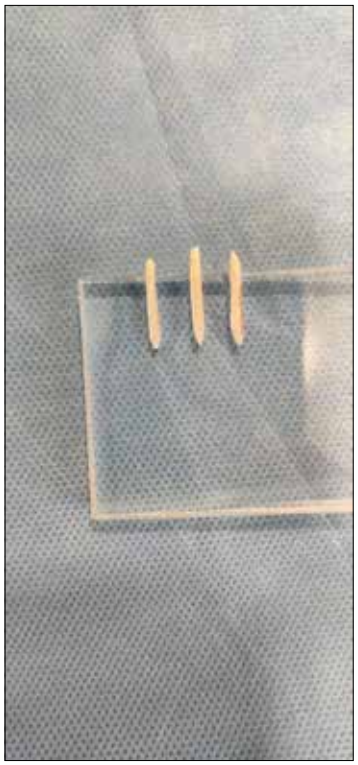

Figure 5: Dentin posts made of different sized custom fit to the plexiglass post spaces

A total of 36 patients with a mean age of 39 years for the metal polyfiber post group and 47 years for the dentin post group were recruited in the randomized control trial. Most of these teeth were incisors (38.88%) followed by premolars (33.33%) and an equal number of canines and molar teeth (13.15%). Majority of these teeth were restored with metal-ceramic crowns (72.22%). Metal restorations were around 25%, and all-ceramic crowns were 0.02%. All the patients were available for follow-up at 3-, 6-, and 12-month follow-up. The observations made for the primary and secondary outcomes are summarized in Table 2. None of the teeth in either group at all the three time intervals showed loss of tooth, recurrent caries detected at the crown margin, and fracture of the core or post or root. Two cases of crown de-cementations were reported at the end of 12 months, one in each group though. No post or core or root fracture was seen, and re-cementation after evaluating dynamic occlusion was done. Results of the Chi-square test for de-cementation using GraphPad Prism 9 software [Table 3] showed a statistically insignificant difference between the groups at different time intervals. Radiographic interpretations were not a part of outcome analysis but were done as protocol to evaluate the presence or absence of root fracture and development and/or progress of periodontal and periapical lesion if any. Nevertheless, radiographic assessments also did not show any new or change in periapical or periodontal tissues at the end of the time intervals. No symptoms of pain or any form of discomfort were reported by the patients. As there was no difference in the primary and secondary outcomes, any statistical evaluation of these observations was not done. On the basis of these results, the null hypothesis was accepted, indicating that there was no clinical or statistical difference in the success rate of endodontically treated teeth receiving restorations over either dentin post or metal polyfiber post.

Table 1: Demographic and tooth characteristics for the two groups

Characteristic	Metal polyfiber post (*n*=18), *n* (%)	Dentin post (*n*=18), *n* (%)	Total (*n*=36), *n* (%)
Gender			
Male	10 (55.56)	11 (61.11)	21 (58.33)
Female	8 (44.44)	7 (38.89)	15 (41.66)
Age (years) (mean)	39	47	43
Tooth guidance			
Anterior-canine	3 (16.67)	2 (11.11)	5 (13.88)
Canine-canine	6 (33.33)	6 (33.33)	12 (33.33)
Group function	9 (50)	10 (55.55)	19 (52.77)
Attrition			
0	9 (50)	4 (22.22)	13 (36.11)
1	3 (16.67)	5 (27.78)	8 (22.22)
2	1 (5.56)	2 (11.11)	3 (0.08)
3	5 (27.78)	7 (38.89)	12 (33.33)
Tooth type			
Incisor	7 (38.89)	7 (38.89)	14 (38.88)
Canine	1 (5.56)	4 (22.22)	5 (13.15)
Premolar	6 (33.33)	6 (33.33)	12 (33.33)
Molar	4 (22.22)	1 (5.56)	5 (13.15)
Tooth mobility			
0	18 (100)	18 (100)	36 (100)
I	0	0	0
II	0	0	0
Final restoration			
Metal	3 (16.67)	6 (33.33)	9 (25)
Metal ceramic	14 (77.78)	12 (66.67)	26 (72.22)
All ceramic	1 (5.56)	0	1 (0.02)
Tooth restorability index			
Score 0	1 (5.56)	2 (11.11)	3 (0.08)
Score 1	3 (16.67)	2 (11.11)	5 (13.88)
Score 2	5 (27.78)	6 (33.33)	11 (30.55)
Score 3	9 (50)	8 (44.44)	17 (47.22)
Need for crown lengthening for ferrule			
Yes	8 (44.44)	5 (27.78)	13 (36.11)
No	10 (55.56)	13 (72.22)	23 (63.88)

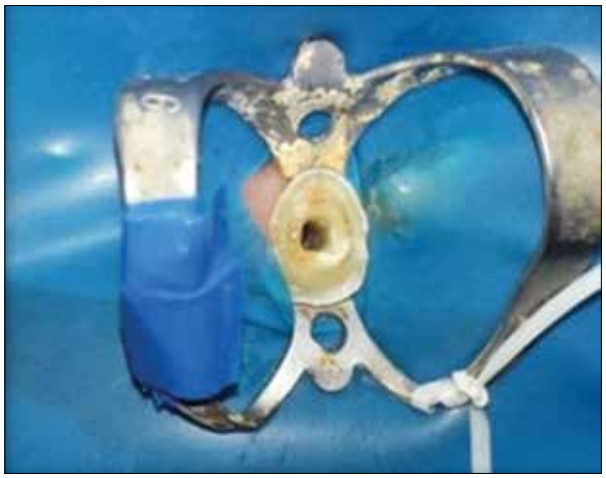

Figure 6: Post space preparation

Figure 7: Cemented metal polyfiber post

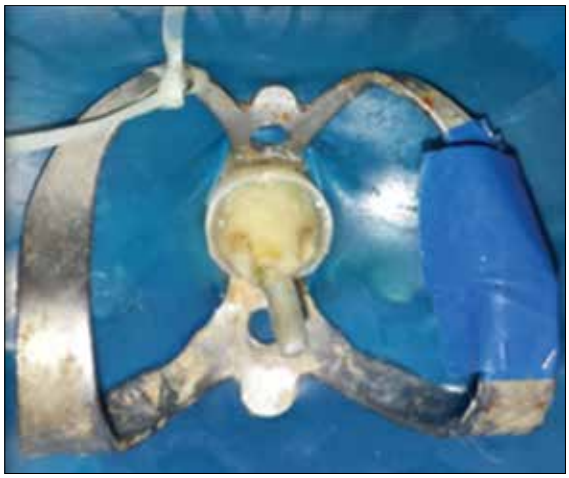

Figure 8: Cemented dentin post

DISCUSSION

Pulpless teeth survive the brunt of masticatory load if the access cavity opening has been conservative, and/or loss of tooth structure due to caries and resorption is minimal. In spite of these, evidence does exist to demonstrate pulpless teeth to be more prone to fracture than vital teeth.[18,19] It has also been observed that posterior teeth are more prone to cervical third and unfavorable fractures due to the nature of oblique stresses that act on them.[20] Engineering principles indicate that natural teeth with integral coronal and radicular structures perform best clinically. With endodontically treated teeth, these forms are affected and hence they may not perform to their fullest extent as a vital tooth may. Protection of such a weakened tooth is enhanced by an extra-coronal restoration. Many a time, the remaining tooth structure may not be adequate enough to retain a crown, thus indicating a post and core for long-term success. A post and core system is primarily needed to provide adequate structure to give retention to the crown. However, it should be done such that the load-bearing ability of the endodontically treated teeth is not jeopardized and thus failures are not invited. The adequacy and clinical efficiency of restorations post endodontic treatment have dictated the long-term success and survival of nonvital teeth.

Figure 9: Composite core buildup

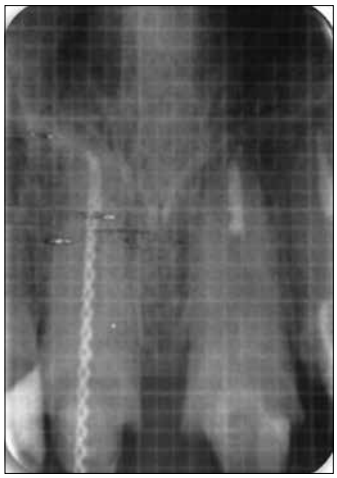

Figure 10: Baseline radiograph

Figure 11: Luted metal-ceramic crowns

Figure 12: Three-month observation

The cast metal post and core is extremely strong but stiff and increases the possibility of a nonvital tooth to be fractured.[21] In addition, the esthetics and time-consuming techniques are added disadvantages. Hence, prefabricated metallic post systems, which are less stiff and more practical to use, came up which eventually were replaced by fiber-reinforced posts, with claims made that the glass, quartz, and carbon fiber post have properties close to dentin.

This study was planned as a randomized control design with inclusion criteria set as periodontally healthy teeth with successful endodontic treatment, adequate bone support with presence of at least 2 mm of ferrule tooth structure above the gingiva with 2 or more cavity walls, and with thickness of 2 mm dentin after tooth preparation.[22] These criteria ensure better prognosis and long-term success of the post and core treatment, strength of the root, and reduction of root fracture. The concept that remaining dentin needs to be preserved is a very vastly researched topic. Most studies conclude at least 1.5 mm to 2 mm of ferrule height and 1 mm of axial healthy dentin with or without crown lengthening as minimum requirements for adequate ferrule effect and resistance to fracture.[23,24]

Success rate of endodontically treated teeth as abutments is reported to be 95% for single crowns, 89% for fixed partial denture and 77% for removable partial denture.[25-27] These stresses lead to fracture of teeth which are weakened by endodontic therapy and post placement. Vertical fractures occur in root-filled teeth fitted with posts, especially in those functioning as terminal abutments or as abutments for fixed or removable partial denture.[25,28] Hence, abutment teeth and patients in whom past or present history of bruxism and/or excessive attrition were also not included in the study due to excessive masticatory loads and presence of little remaining coronal dentin.[3,29]

Metal polyfiber and dentin posts were included in this trial as there are only *in vitro* studies that exist that evaluate the strength of teeth restored with them. Metal polyfiber posts were used as provided by the manufacturer. Commercial production of dentin post is not available, hence either they have to be produced manually or through CAD-CAM technology. The possibility of using CAD-CAM to produce dentin post was evaluated. However, there was not much success and feasibility found in the same. Hence, the

Figure 13: Six-month observation

Table 2: Primary and secondary outcomes in the two groups

Outcome	Time (months)	Metal polyfiber post		Dentin post	
		A, *n* (%)	B, *n* (%)	A, *n* (%)	B, *n* (%)
Loss of tooth	3	18 (100)	0	18 (100)	0
	6	18 (100)	0	18 (100)	0
	12	18 (100)	0	18 (100)	0
Recurrent caries detected at crown margin	3	18 (100)	0	18 (100)	0
	6	18 (100)	0	18 (100)	0
	12	18 (100)	0	18 (100)	0
De-cementation of crowns	3	18 (100)	0	18 (100)	0
	6	18 (100)	0	18 (100)	0
	12	17 (94.45)	1 (5.55)	17 (94.45)	1 (5.55)
Fracture of the core	3	18 (100)	0	18 (100)	0
	6	18 (100)	0	18 (100)	0
	12	18 (100)	0	18 (100)	0
Fracture of the post	3	18 (100)	0	18 (100)	0
	6	18 (100)	0	18 (100)	0
	12	18 (100)	0	18 (100)	0
Fracture of the root	3	18 (100)	0	18 (100)	0
	6	18 (100)	0	18 (100)	0
	12	18 (100)	0	18 (100)	0

Table 3: Result of the Chi-square test for de-cementation of the crown

Group X time	De-cementation of crown		Total
	A	B	
Metal polyfiber post at 3 months	18	0	18
	17.67 (0.01)	0.33 (1.33)	
Metal polyfiber post at 6 months	18	0	18
	17.67 (0.01)	0.33 (0.33)	
Metal polyfiber post at 12 months	17	1	18
	17.67 (0.03)	o. 33 (1.33)	
Dentin post at 3months	18	0	18
	17.67 (0.01)	0.33 (0.33)	
Dentin post at 6 months	18	0	18
	17.67 (0.01)	0.33 (0.33)	
Dentin post at 12 months	17	1	18
	17.67 (0.03)	0.33 (1.33)	
Total	106	2	108

χ^2=4.075, df=5, P (χ^2>4.075). Group A: Absence of clinical mobility of crown, Group B: Presence of clinical mobility of crown or patient comes with the crown

manual method of preparing dentin post was adopted. The method was devised to produce high-quality sterilized and standardized dentin post. Sterilization guidelines followed were such that bond strength and physical properties of dentin were not affected.[30]

Figure 14: Twelve-month observation

The luting resin also acts as a force buffer allowing favorable stress distribution. Dual-cure resin cement produces a hybrid layer that is essential to ensure good sealing for the post and core restoration and also to enhance post retention.[31-33] Good compressive strength, esthetic and adhesive properties similar elastic modulus were reasons to use composite resin as the core buildup material.[34-36] The methodology used to evaluate the outcomes was similar to those followed in previous well conducted clinical trials and retrospective studies.[37]

Results revealed that there was 100% success with respect to performance of both post and core systems for the primary outcome over 1-year period of evaluation. No tooth in both the groups showed tooth loss. In the absence of similar studies clinical on metal polyfiber post and Dentin post available in the literature, a strict comparison with other studies is not possible. However, similar primary outcome measures have been reported with other post and core systems in other studies.[22,37] These studies concluded that glass fiber post and core systems show a high success rate in restoration of endodontically treated teeth. They attribute such performance to the properties of post to be similar in modulus of elasticity and biomechanical behavior similar to dentin. On similar lines, it can be deciphered from the results of the present study that the use of metal fiber post and dentin post would not result in tooth loss for a period of 1 year when careful selection and treatment of endodontically treated teeth is done.

The secondary outcomes included in this study were those that could directly or indirectly be an outcome of post placement. The biomechanical behavior of the post and core influences the behavior of cement, the cement bond to the tooth structure and to the crown. If a post is similar in properties to dentine, it is bonded to the remaining tooth forming a monoblock making it more favorable for the biomechanical behavior of the crown and luting agent. Thus, inadequate post and core properties and a biomechanical disadvantage if present in the system can

manifest as loss of marginal integrity if the luting agent in the cervical margin, post or core or root fracture, cement microcracks, and crown de-cementation. Results of the secondary outcomes of recurrent caries detected at the crown margin, fracture of the core, fracture of the post, fracture of the root are similar to results obtained from Preethi *et al*.[37] and Grandini *et al*.[38] Although these studies did not evaluate the post type used in the present study, similarity in results could have been accorded as the post properties were similar, especially with glass fiber post. Grandini *et al*.[38] in their prospective study reported 9% of the crowns to have been de-cemented over 12-month period. However, no plausible reason for the same has been mentioned. In the present study, crown de-cementation was observed in around 5.55% of the cases which is lesser to that in previous studies.[37,38]

Ancillary analysis like multivariate analysis could have been done if different success rates would have been observed. Difference in the success rate was not observed in 1-year period, in spite of multiple confounding factors such as tooth location, tooth type, tooth guidance, tooth restorability index, need for crown lengthening for ferrule and final restoration type. Hence, the effect of these confounders on the results was not evaluated.

On analysis of results and after extrapolating the possible reasons for the specific outcomes, it can be concluded that both metal polyfiber post and dentin post behave in the same manner with respect to the primary and secondary outcomes when observed for period of 1 year. Both metal polyfiber and dentin post have similar biomechanical behavior and properties close to dentin. Metal polyfiber post has a structure like interproximal brushes that entangle with the resin cement in the post space. Contrasting a classic post, the metal polyfiber post does not have 2 separable or discrete interfaces between the post, cement, and dentin. The resin cement mechanically interlocks at different planes around the polyfiber strands, thus creating a metal and fiber-reinforced post which is which adheres to the root dentin.[8]

Teeth restored with solid dentin posts exhibit biomechanical properties similar to dentin. The microstructure of dentin is complex with a modulus of 13–18 GPa that differs according to locations and directions. The unique structure of dentin, it's ability to absorb shock and distribute stress uniformly provides a mechanism that inhibits crack propagation.[39] The resemblance in structure and properties of dentin post to radicular dentin may permit similar biomechanical behavior. It lets the tooth to exhibit similar movements and flexion under stress. It functions as a shock absorber and conducts only a small load to the dentinal walls. Therefore, this similarity between post dentin and root dentin coupled with good adhesion shall increase the fracture resistance of the tooth.[8,9]

This study was planned as a randomized control trial with stringent design, evaluation criteria, and internal validity. Being a randomized controlled trial conducted on Indian patients, the result of the study bears good external validity for clinical application to restore endodontically treated teeth that need post and core restorations. However, adequate consent and information of the entire procedure should be provided to the patients, especially when dentin posts are used. However, there were limitations in the study. The observation period was kept as 12 months. This observation period may not be considered as an optimum time for follow-up. Although, it is also not too less an observation period in a randomized control trial. Previous studies do exist where observation period has been limited to 12 months.[40] Furthermore, systematic reviews do include studies that have been observed for a minimum period of 12 months.[41,42] Furthermore, the use of dentin from extracted teeth may be unacceptable to patients. This can be resolved through adequate sterilization protocols, adequate consents, and standardized manufacture of preformed dentin posts. Future long-term studies should be planned to evaluate the clinical behavior of metal polyfiber post and dentin post. Endocrowns have today become a viable treatment possibility with advances in material and adhesion sciences.[43,44] Future comparison of metal polyfiber posts and CAD-CAM dentin posts with endocrowns shall help us come out with better clinical recommendations.

This study is an efficacy study in contrast to an effectiveness study proving equal efficacy of metal polyfiber post and dentin post over 1-year observation. An effectiveness study can also be planned in the future to determine the versatility of the post with respect to patient preference, dentist convenience, and cost analysis.

CONCLUSION

It can be concluded from this randomized controlled study that both the posts, metal polyfiber and dentin post in conjunction with composite cores, exhibit a high 1-year success rate in restoration of endodontically treated teeth.

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Conflicts of interest
There are no conflicts of interest.

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Research

Effect of multiple reuse of commonly used implant analogs on the changes in the distance between internal threads: An *in vitro* study

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Abstract

Aim: To assess the effect of multiple reuse of implant analogs of three different materials (SS, Ti, Al) on the changes in the distance between internal threads of implant analog by using two die materials at different time intervals (0, 3rd, 6th, 9th, and 12th).

Settings and Design: An *in vitro* study.

Materials and Methodology: Three commonly used implant analog materials (stainless steel, titanium, and aluminum) and two Type– IV die stone materials (Kalrock and Zhermack Elite) were used to make the samples. A total of sixty implant analogs (20 each), sixty corresponding abutments (20 each) and 720 screws (240 each) were taken, which includes stainless steel, titanium, and aluminum manufactured by Adin, Genesis, and Equinox/Myriad plus, respectively. In addition, silicone (light body consistency) was used to make an impression for the internal thread of implant analogs. The obtained samples were tested for changes in the internal threads of implant analogs while reusing the implant analogs at the interval of times (0, 3rd, 6th, 9th, and 12th) using a stereomicroscope at ×50. Here, the measured values at "0" interval were considered the control group.

Statistical Analysis Used: The values obtained were statistically analyzed using One way ANOVA, independent t test, and dependent t test for multiple comparisons.

Results: Based on the results obtained, the overall comparison of the mean distance between threads 1–2, 3–4, and 5–6 on the replica of internal threads of the stainless steel, titanium, and aluminum implant analog materials at 1–2 has more decrease in distance from 0 to 12th intervals, at 3–4 has less amount of decrease in distance than thread distance at 1–2 from 0 to 12th intervals, and at 5–6 has very less decrease in distance than thread distance at 1–2 and 3–4 from 0 to 12th intervals. On order the mean distance reduction between threads is more at 1–2, followed to that less reduction at 3–4 and very less reduction at 5–6. This

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infers that the amount of increase in the distance between the internal threads of implant analog at 1–2 has more followed by 3–4 and 5–6, respectively.

Conclusion: From the study, the following inferences are drawn: That the aluminum implant analog internal threads have more amount of increase in the distance between threads followed by stainless steel and titanium. Hence, among the three materials, titanium implant analogs were most efficient for reuse.

Keywords: Abutment, aluminum, implant analog, internal threads, reuse, stainless steel, titanium

INTRODUCTION

There were many more treatment procedures in dentistry today, but dental implants involve scientific innovation, analysis, understanding, and application in clinical practice. Dental implants are considered the most significant innovation of the present generation. A dental implant is a replacement for the root (or) roots of a tooth.

The contact between abutment and implant platform was a key factor because it reduces the load over the abutment screw, warranting these components high efficiency. Strain induced due to misfit can cause changes in screw geometry.

The success of a screwed connection was directly related to the preload reached during torque and the maintenance of this preload with the time. It was suggested that the screw loosening originates from the separation between the screw and abutment surfaces and the high-level stresses generated over the screws.[1] This was done at the time of final prosthesis fabrication in the laboratory. Multiple tightening and loosening of abutment screw by the laboratory personnel can cause change in internal threads of implant analogue. This further leads to abutment screw loosening on the implant.

Abutment screw loosening is recognized as a common complication with implant restorations which occurs on functional loading. When the abutment is fixed by tightening the screw, threads of the screw and the internal threads of the implant and implant analogs can get deformed. Extensive research has been carried out on the deformation of abutment screw, but changes on the internal threads of implant analog have not been studied till now.

The purpose of the present *in-vitro* study is to assess the effect of multiple reuse of implant analogs of three different materials (stainless steel, titanium, aluminum) on the changes in the distance between internal threads of implant analog by using two die materials at different time intervals (0, 3rd, 6th, 9th, and 12th).

MATERIALS AND METHODS

A total of sixty implant analogs, sixty corresponding abutments and 720 screws were taken, which includes 20 each Stainless steel (Adin Dental Implants), Aluminum (Equinox/myriad plus Dental implants) and Titanium (Genesis/Aktiv Dental implants) manufactured implant analogs by different companies. Two different companies (Kalabhai and Zhermack) of die stone materials were used to mount the implant analogs. All these materials were procured through the open market. IRB number for the above said study is 08607201801. Ethical commitee Gitam Dental College Regd. No. EC/NEW/INST/2021/1522.

A total of 60 implant analogs and corresponding abutments of different materials (each material 20 in number), including stainless steel, titanium, and aluminum were bought from the open market. The time intervals included in the study were 0, 3rd, 6th, 9th, and 12th. In these intervals, the '0' time interval values were considered control group values.

At "0" interval (i.e., without embedding the analog into the die stone)

To maintain the four standard points for measuring any parameter on the implant analogue an acrylic die of square shape was prepared by using the clear autopolymerizing acrylic resin. In this, acrylic die acts as a keyhole and implant analog acts as a key [Figure 1]. Hence, the acrylic die holds the implant analog and then marked the A, B, C, and D marks at the midpoint of each side of the square on this acrylic die. The implant analog was then placed in the acrylic die and then transferred the markings on to implant analog [Figure 2].

Internal threads

After that, for evaluating the internal threads implant analogs at "0" interval, (i.e., before placing the abutment) an impression was made using an addition silicone (light body consistency) which acts as a replica for the internal threads of implant analog. The impression material (base paste and catalyst paste) was manipulated following the manufacturer's instructions and loaded into the 5 ml syringe. With the help of a syringe, the material was carried

to the implant analog and injected with a 1.2 mm wide-bore needle into the implant analog [Figure 3]. An impression for internal threads of the implant analog was made. After polymerization of the impression material, the "A" mark was transferred onto the impression at the collar end. This was the position used to measure the distance between threads for every sample. Then, it was carefully removed from the implant analog without any distortion. This was made for every sample. The impression retrieved was then evaluated for measuring the distance between the threads at 1–2, 3–4, 5–6, i.e., from collar end to apical end at the marked position by using a stereomicroscope at ×50 by an image processing software [Figures 4 and 5]. Then, the values were tabulated and evaluated.

After "0" interval, the putty index with mold space obtained was used to fill with die stone material into which the implant analog was inserted by using a dental surveyor. This was done to position the implant analog at the center of the mold space filled with die stone. This same procedure was done for all three materials (stainless steel, titanium, and aluminum) of implant analoge and then obtained samples (die stone block with implant analog) were left untouched for 24 h. Then, each sample was taken and corresponding abutment was connected to implant analog by hand torqueing the abutment screw with the hex driver and torque wrench of about 10 Ncm. In each sample, the abutment screw was tightened and loosened about four times as the laboratory personnel approximately tightens and loosens the screw for four times during the fabrication of prosthesis. After every interval, the screw was discarded, and the new screw was taken for tightening the abutment to the implant analog.

After this, for evaluating the implant analogs internal threads, an impression was made using addition silicone (light body consistency). The base paste and catalyst paste of impression material was manipulated following the manufacturer's instructions and loaded into the 5 ml syringe. With the help of the syringe, the material was carried to the implant analog and injected with a 1.2 mm wide-bore needle into the implant analog and an impression

Figure 1: Customized acrylic die with markings of (A-D)

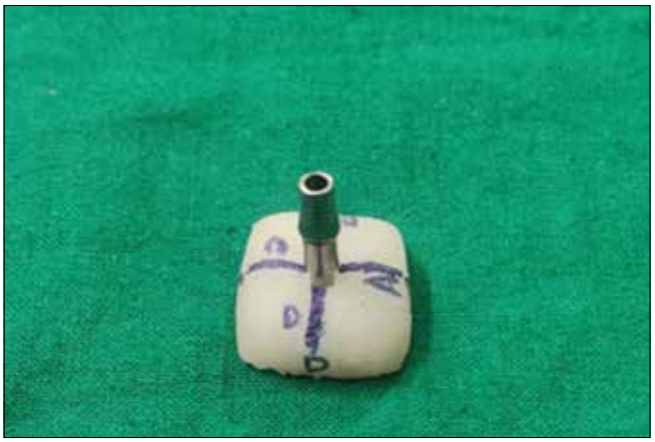

Figure 2: Implant analog and abutment assembly placed in acrylic die and transferring the marks

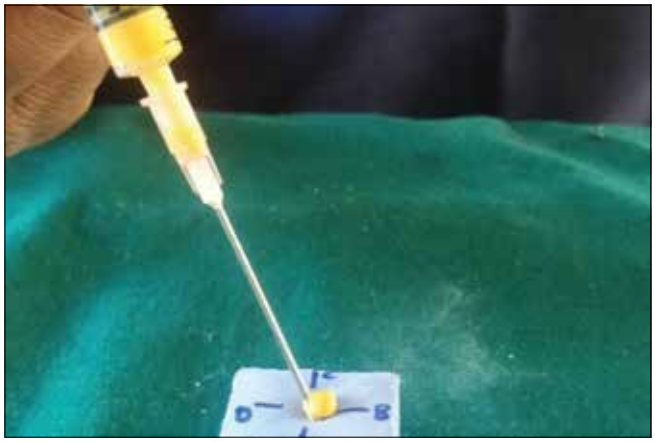

Figure 3: Impression for internal threads of implant analog with addition silicone (light body consistency)

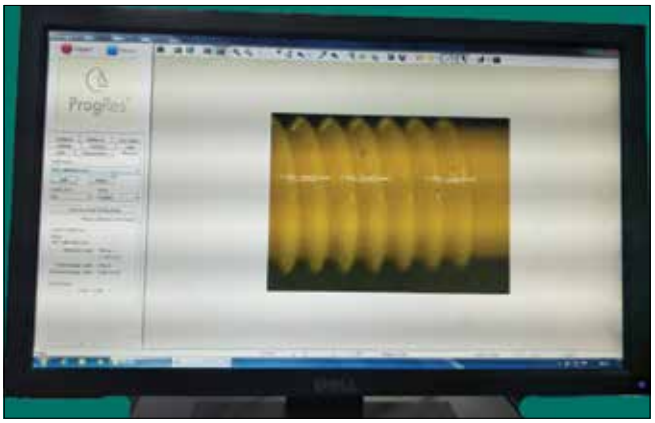

Figure 4: Distance between threads on replica measured using stereomicroscope and visualized in monitor by using Progres software

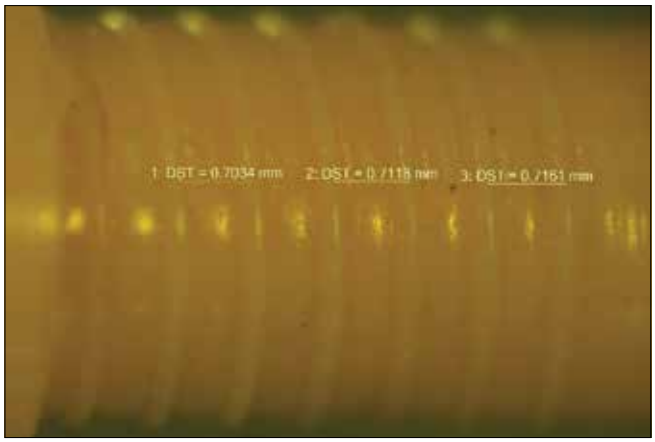

Figure 5: Distance between threads on replica (from their highest points)

for internal threads was made. After polymerization of the impression material, it was carefully removed from the implant analog without any distortion. This was done for every sample. After that, the implant analog was retrieved from the die stone block by breaking the block mechanically with a chisel and hammer. Placing the chisel at the side adjacent to the implant analog placed in the die stone block without touching it and then hammering over the chisel mechanically makes the block break and retrieves the implant analogue. This was done for every sample, and the implant analogs were retrieved. The procedure for the first interval was completed. The same procedure was done for the 2nd and 3rd intervals.

After the 3rd interval, the impressions made for internal threads of implant analogs (replica) were used to measure the distance between the threads. These values were evaluated the same as the samples tested at 0 interval by using the stereomicroscope at ×50 by an image processing software. The values were tabulated and were further evaluated. This was the same procedure done at the every three intervals and the samples were measured and the values were tabulated and were compared with the control group at 6th, 9th, and 12th time. After the fabrication of samples, relevant testing and recording of data were performed, followed by appropriate statistical analysis.

RESULTS

The comparison of mean distance between thread on replica at 1–2 of three different materials (stainless steel, titanium, and aluminum) in two die materials (Group A and Group B) at different time intervals (0, 3rd, 6th, 9th, and 12th) [Table 1] in which for the Aluminum at "0" interval the mean distance between thread on replica at 1–2 has 0.72 mm and 0.72 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between thread on replica at 1–2, i.e., at 12th interval the mean distance between thread on replica at 1–2 has 0.57 mm and 0.57 mm of Group A and Group B, respectively. For the titanium at "0" interval, the mean distance between thread on replica at 1–2 has 0.73 mm and 0.73 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between thread on replica at 1–2, i.e., at 12th interval, the mean distance between thread on replica at 1–2 has 0.67 mm and 0.67 mm of Group A and Group B, respectively. For the Stainless steel at "0" interval the mean distance between thread on replica at 1–2 has 0.70 mm and 0.70 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between thread on replica at 1–2, i.e., at 12th interval, the mean distance between thread on replica at 1–2 has 0.59 mm and 0.59 mm of Group A and Group B, respectively [Table 1].

The overall comparison of the mean distance between thread on replica at 1–2 of Group A and Group B of SS, Ti, Al material shows there is gradual decrease in the values has the time interval increases.

- For Al — 0 interval >3rd interval >6th interval >9th interval >12th interval
- For Ti — 0 interval >3rd interval >6th interval >9th interval >12th interval
- For SS — 0 interval >3rd interval >6th interval >9th interval >12th interval [Table 1].

The comparison of mean distance between thread on replica at 3–4 of three different materials (stainless steel, titanium, aluminum) in two die materials (Group A and Group B) at different time intervals (0, 3rd, 6th, 9th, and 12th) [Table 2] in which for the aluminum at '0' interval the mean distance between thread on replica at 3–4 has 0.72 mm and 0.72 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between thread on replica at 3–4, i.e., at 12th interval the mean distance between thread on replica at 3–4 has 0.59 mm and 0.59 mm of Group A and Group B, respectively. For the titanium at "0" interval the mean distance between thread on replica at 3–4 has 0.73 mm and 0.73 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between thread on replica at 3–4, i.e., at 12th interval, the mean distance between thread on replica at 3–4 has 0.68 mm and 0.69 mm of Group A and Group B, respectively. For the stainless steel at "0" interval, the mean distance between thread on replica at 3–4 has 0.70 mm and 0.70 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between thread on replica at 3–4, i.e., at

12th interval, the mean distance between thread on replica at 3–4 has 0.62 mm and 0.62 mm of Group A and Group B, respectively [Table 2].

The overall comparison of the mean distance between thread on replica at 3–4 of Group A and Group B of SS, Ti, and Al material shows that there is gradual decrease in the values as the time interval increases.

- For Al — 0 interval >3rd interval = 6th interval >9th interval >12th interval
- For Ti — 0 interval >3rd interval = 6th interval >9th interval >12th interval
- For SS — 0 interval >3rd interval = 6th interval >9th interval >12th interval [Table 2].

The comparison of mean distance between thread on replica at 5–6 of three different materials (stainless steel, titanium, aluminum) in two die materials (Group A and Group B) at different time intervals (0, 3rd, 6th, 9th, and 12th) [Table 3] in which the aluminum at '0' interval the mean distance between threads on replica at 5–6 has 0.72 mm and 0.72 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between threads on replica at 5–6, i.e., at 12th interval, the mean distance between threads on replica at 5–6 has 0.60 mm and 0.60 mm of Group A and Group B, respectively. For the Titanium at '0' interval, the mean distance between threads on replica at 5–6 has 0.73 mm and 0.73 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between threads on replica at 5–6, i.e., at 12th interval, the mean distance between threads on replica at 5–6 has 0.70 mm and 0.70 mm of Group A and Group B, respectively. For the stainless steel at '0' interval, the mean distance between threads on replica at 5–6 has 0.70 mm and 0.70 mm of Group A and Group B, respectively. For further intervals, there was a decrease in the mean distance between threads on replica at 5–6, i.e., at 12th interval, the mean distance between threads on replica at 5–6 has 0.63 mm and 0.63 mm of Group A and Group B, respectively [Table 3].

The overall comparison of the mean distance between threads on replica at 5–6 of Group A and Group B of SS, Ti, and Al material shows there is gradual decrease in the values has the time interval increases.

- For Al — 0 interval >3rd interval = 6th interval >9th interval >12th interval.

Table 1: Comparison of three different implant analog materials (stainless steel, titanium, aluminum) in two die materials (Group A and Group B) with mean distance between threads on replica at 1 and 2 at different intervals (0, 3rd, 6th, 9th and 12th) by one-way ANOVA

Groups	Time intervals	Al		Ti		SS		*F*	*P*	Pair wise comparisons		
		Mean	SD	Mean	SD	Mean	SD			SS versus Ti	SS versus Al	Ti versus Al
Group A	At 0	0.72	0.00	0.73	0.00	0.70	0.00	-	-	-	-	-
	At 3rd	0.66	0.01	0.72	0.00	0.62	0.01	308.0073	0.0001*	0.0001*	0.0001*	0.0001*
	At 6th	0.65	0.00	0.71	0.01	0.61	0.00	2916.7775	0.0001*	0.0001*	0.0001*	0.0001*
	At 9th	0.60	0.02	0.70	0.00	0.60	0.00	269.5104	0.0001*	0.0001*	0.0001*	0.0001*
	At 12th	0.57	0.00	0.67	0.01	0.59	0.00	479.8794	0.0001*	0.0001*	0.0001*	0.0001*
Group B	At 0	0.72	0.00	0.73	0.00	0.70	0.00	-	-	-	-	-
	At 3rd	0.66	0.01	0.72	0.00	0.63	0.01	728.6510	0.0001*	0.0001*	0.0001*	0.0001*
	At 6th	0.65	0.00	0.71	0.00	0.61	0.00	9405.7610	0.0001*	0.0001*	0.0001*	0.0001*
	At 9th	0.61	0.02	0.70	0.00	0.60	0.00	255.3360	0.0001*	0.0001*	0.0001*	0.0001*
	At 12th	0.57	0.00	0.67	0.01	0.59	0.00	645.8130	0.0001*	0.0001*	0.0001*	0.0001*

*$P<0.05$. SS: Stainless steel, Ti: Titanium, Al: Aluminum, SD: Standard deviation

Table 2: Comparison of three different implant analogue materials (stainless steel, titanium, aluminum) in two die materials (Group A and Group B) with mean distance between threads on replica at 3 and 4 at different intervals (0, 3rd, 6th, 9th and 12th) by one-way ANOVA

Groups	Time intervals	Al		Ti		SS		*F*	*P*	Pair wise comparisons		
		Mean	SD	Mean	SD	Mean	SD			SS versus Ti	SS versus Al	Ti versus Al
Group A	At 0	0.72	0.00	0.73	0.00	0.70	0.00	-	-	-	-	-
	At 3rd	0.66	0.01	0.72	0.00	0.63	0.01	436.7894	0.0001*	0.0001*	0.0001*	0.0001*
	At 6th	0.66	0.00	0.72	0.00	0.63	0.01	612.0379	0.0001*	0.0001*	0.0001*	0.0001*
	At 9th	0.63	0.02	0.71	0.00	0.62	0.01	175.5022	0.0001*	0.0001*	0.0014*	0.0001*
	At 12th	0.59	0.00	0.68	0.01	0.62	0.01	414.5442	0.0001*	0.0001*	0.0001*	0.0001*
Group B	At 0	0.72	0.00	0.73	0.00	0.70	0.00	-	-	-	-	-
	At 3rd	0.66	0.00	0.72	0.00	0.64	0.00	1261.4840	0.0001*	0.0001*	0.0001*	0.0001*
	At 6th	0.66	0.00	0.72	0.00	0.64	0.00	1802.3940	0.0001*	0.0001*	0.0001*	0.0001*
	At 9th	0.64	0.01	0.71	0.00	0.63	0.00	670.6690	0.0001*	0.0001*	0.0008*	0.0001*
	At 12th	0.59	0.00	0.69	0.01	0.62	0.00	798.1950	0.0001*	0.0001*	0.0001*	0.0001*

*$P<0.05$. SS: Stainless steel, Ti: Titanium, Al: Aluminum, SD: Standard deviation

Table 3: Comparison of three different implant analogue materials (stainless steel, titanium, aluminum) in two die materials (Group A and Group B) with mean distance between threads on replica at 5 and 6 at different intervals (0, 3rd, 6th, 9th and 12th) by one-way ANOVA

Groups	Time intervals	Aluminium		Titanium		Stainless steel		*F*	*P*	Pair wise comparisons		
		Mean	SD	Mean	SD	Mean	SD			SS versus Ti	SS versus Al	Ti versus Al
Group A	At 0	0.72	0.00	0.73	0.00	0.70	0.00	-	-	-	-	-
	At 3rd	0.67	0.01	0.73	0.00	0.65	0.01	290.2515	0.0001*	0.0001*	0.0001	0.0001*
	At 6th	0.67	0.01	0.72	0.00	0.64	0.01	421.6835	0.0001*	0.0001*	0.0001*	0.0001*
	At 9th	0.64	0.02	0.72	0.00	0.64	0.01	162.2086	0.0001*	0.0001*	0.0145*	0.0001*
	At 12th	0.60	0.00	0.70	0.01	0.63	0.01	697.2230	0.0001*	0.0001*	0.0001*	0.0001*
Group B	At 0	0.72	0.00	0.73	0.00	0.70	0.00	-	-	-	-	-
	At 3rd	0.67	0.00	0.73	0.00	0.65	0.01	486.9990	0.0001*	0.0001*	0.0001*	0.0001*
	At 6th	0.67	0.00	0.72	0.00	0.64	0.01	739.2860	0.0001*	0.0001*	0.0001*	0.0001*
	At 9th	0.65	0.01	0.72	0.00	0.64	0.00	575.8240	0.0001*	0.0001*	0.0014*	0.0001*
	At 12th	0.60	0.00	0.70	0.01	0.63	0.01	804.6250	0.0001*	0.0001*	0.0001*	0.0001*

*$P<0.05$. SS: Stainless steel, Ti: Titanium, Al: Aluminium, SD: Standard deviation

- For Ti — 0 interval = 3rd interval >6th interval = 9th interval >12th interval.
- For SS — 0 interval >3rd interval >6th interval = 9th interval >12th interval [Table 3].

From the results obtained, the titanium implant analogue has major difference in distance between the threads from the 6th interval and the stainless steel implant analogue has major difference in distance between the threads from the 3rd interval and the aluminum implant analog has major difference in distance between the threads after the 1st interval. Hence, the titanium implant analogs can be reused for six times, stainless steel implant analogs can be reused for three times and aluminum implant analogs to be used only once.

DISCUSSION

Abutment screw loosening is recognized as a common complication with cemented and screw retained implant restorations and which occurs on functional loading. When the abutment is fixed by tightening the screw, threads of the screw and the internal threads of the implant can get deformed. Extensive research has been carried on the deformation of abutment screw but changes on the internal threads of implant analogs on reuse have not studied.[2] Hence, the present study was carried out in this context but on the internal threads of implant analogs.

The internal threads of the implant analog are a part of the dense metal body, which is not easily subjected to deformation. However on repeated screw tightening and loosening, there is a chance of creation of friction between the screw threads and internal threads of implant analog. The coefficient of friction is controlled by the manufacturing process and is affected by metallurgical properties of the components, design, and quality of the surface finish. Investigators have suggested that repeated tightening of screws removes small irregularities on the contacting surfaces which was due friction.[3] This causes the micromovement.

Micromovement is defined as a movement of a tooth, prosthesis, or implant system component <100 μm that is not observable or subject to measurement *in-vivo* by ordinary means. In most implant systems, the exchange of fluids, in both directions, takes place at the level of the marginal bone crest and is considered to be a factor for chronic inflammation and marginal bone loss. Thus, during function and under occlusal loading, micromovement between abutment and implant will create a volumetric variation in the inner volume of the implant system.

Almost all implant abutment connections are retained and stabilized by screws. A screw is a mechanism that converts rotational motion to linear motion, and torque (rotational force) to a linear force. Preload is the technical term for the tension caused by tightening the screw that holds the assembled parts together. As long as the external loads on a joint don't exceed the preload, the screw is not subjected to any motion and will not become loose.

As described in the results, the thread distance at 1–2 on the replica of the implant analogue decreases, which shows that there is an increase in the distance between the internal threads of the implant analog. The reason is that there is an increase in the frictional contact between the internal threads of the implant analog and the threads of the screw and also stresses increase in the form of preload which causes the wear of the contacting surfaces of the threads while screw tightening and loosening repeatedly. This makes wobbling and misfit of the abutment or final prosthesis.

The friction created between the contacting surfaces such as internal threads and the screw threads at repeated

cycles causes the fretting wear. Fretting wear is a special wear process that occurs at the contact area between two materials under load and subject to minute relative motion by vibration or some other force. Fretting tangibly degrades the surface layer quality producing increased surface roughness and micropits, which reduces the fatigue strength of the components.[4] Soft materials often exhibit higher susceptibility to fretting than hard materials of a similar type. The hardness ratio of the two sliding materials also has an effect on fretting wear. This was the reason to which the Aluminum implant analogs internal threads has more wear followed by stainless steel implant analogs and titanium implant analogs.

The reason for increase in the internal thread distance between two threads of implant analogue was because of the compressive forces (preload) and clamping effect (tensile force creates a compressive force in the joint) which were developed due to screw tightening. This influences the joint stability, is how the contacting parts change when the screw is tightened. After being tightened together by screw, the microroughness of all the metal contacting surfaces slightly flattens and the microscopic distance between the internal thread pattern increases.[5]

As the thread distance at 3–4 in the replica of the implant analog decreases, which shows that there is an increase in the distance between the internal threads of the implant analog. As the thread distance at 5–6 in the replica of the implant analog decreases, which shows that there is an increase in the distance between the internal threads of the implant analog.

On comparing the mean distance between the threads 1–2, 3–4, 5–6 on the replica of internal threads of implant analogue the mean distance between the threads at 1–2 has more decrease from 0 to 12th intervals, at 3–4 has less amount of decrease in distance than thread distance at 1–2 from 0 to 12th intervals, and at 5–6 has very less decrease in distance than thread distance at 1–2 and 3–4 from 0 to 12th intervals. This infers that there is more amount of increase in the distance between the internal threads of implant analog at 1–2 followed by 3–4 and 5–6, respectively.

The reason was at the collar end of the implant analog, i.e., at internal threads 1–2 there is a passage of all the thread patterns of the screw (from apical end to the screw head) while tightening and loosening. This causes more frictional wear at the internal threads 1–2 of the implant analog. When compared with the internal threads at 1–2, the internal threads at 3–4 has a passage of the middle third and apical end thread pattern of the screws while tightening and loosening which causes a minimal frictional wear than at the internal threads 1–2. When comparing the internal threads at 5–6 with other threads, here only the apical thread patterns of screw will pass through it while tightening and loosening which causes very minimal frictional wear than the other two internal threads (1–2,3–4) and also there is more amount of preload forces at the 1–2 internal threads compared to 3–4 and 5–6 internal threads may be the possible reason.

A study by Y. Sameera, Rathika Rai stated that the internal threads of the dental implant are part of a dense metal body and hence, it was not subjected to deformation easily. As implant alloy hardness is greater than prosthetic screw hardness, the surface alterations to implant were fewer than those observed on prosthetic screw.[5]

On comparing with the above study, in the present study, there is a change in the internal threads of implant analog because here the screw was tightened and loosened for about four times at every interval, this is done for 12 intervals and for every interval, the old screw was discarded and new screw was taken for the next interval. The results obtained in the study clearly states that on repeated tightening and loosening the fretting wear occurs due to friction between the mating surfaces and the distance between the threads on the replica of implant analog is decreased, which infers that there is an increase in internal threads of implant analog. In this the aluminum material softer than the stainless steel and titanium, this was the reason for aluminum has more fretting wear followed by stainless steel and then titanium.

CONCLUSION

The following conclusions were drawn based on the results obtained in the present *in vitro* study which was conducted to assess the effect of multiple reuse of implant analogs of three different materials (stainless steel, titanium, aluminum) on the internal thread discrepancy were.

- From the results obtained, the titanium implant analog has major difference in distance between the threads from the 6th interval and the stainless steel implant analog has major difference in distance between the threads from the 3rd interval and the aluminum implant analog has major difference in distance between the threads after the 1st interval. Hence, the titanium implant analogs can be reused for six times, stainless steel implant analogs can be reused for three times and aluminum implant analogs to be used only once
- On comparing materials the aluminum implant analog internal threads has more amount of increase in the

distance between threads followed by stainless steel and titanium. In between the two die materials, no difference was observed.

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Conflicts of interest

There are no conflicts of interest.

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Research

A comparative evaluation of stress distribution between an All-on-Four implant-supported prosthesis and the Trefoil implant-supported prosthesis: A three-dimensional finite element analysis study

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Abstract:

Aim: The primary aim of this study is to analyse the stress distribution between an ALL ON FOUR implant supported prosthesis and the TREFOIL implant supported prosthesis with 3D finite element models.

Settings and Design: An *in vitro* perspective

Materials and Methods: Two mandibular three-dimensional Finite Element Models were constructed by the CREO version 5 software, in which Model A depicts a mandible with ALL ON FOUR implant supported prost hesis and Model B will depict TREFOIL implant supported prosthesis. Model A contains four implants, two anterior straight and posterior tilted implants (30˚), a bar and denture containing acrylic teeth. In Model B, it contains three straight implants and a prefabricated compensatory bar with standardised dimensions. To evaluate and compare the stress distribution between the bone and implant interface, one deleterious cantilever load of upto 300 N is applied on the second molar bilaterally and simultaneously. Another full bite biting load of 150 N is given bilaterally and simultaneously on the central groove of premolars and molars.

Statistical Analysis Used: The results of the simulations obtained were analysed in terms of Von Mises equivalent stress levels at the bone -implant interface.

Results: The results of loading 1 showed that the maximum Von Mises stress was recorded in the anterior implant region of the Trefoil system (Model B) when compared to All on four concept. The results of loading 2 showed that the maximum Von Mises stress were recorded in the anterior implant region Trefoil system (Model B) when compared to All on four concept.

Conclusion: This invitro study concludes that All on Four implant supported prosthesis showed better stress distribution when compared to the Trefoil concept.

Keywords: All-on-Four, bone–implant interface, finite element analysis, Trefoil concept

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INTRODUCTION

Edentulism is a condition or a state where there is complete or partial loss of teeth in the oral cavity.[1] Elderly individuals are the most commonly affected with complete edentulism and are in need for adequate oral rehabilitation for their general healthy well-being and good quality of life.[2] A continuous debate in the literature is going on about the increasing and the decreasing rate of edentulism, and it has been stated that the total rate of edentulism is on a steady decrease in developed countries, while it is on a drastic increase in the developing countries. The enormous developments in dental care have declined the rate of edentulism.[1]

The most commonly followed treatment of choice for edentulism is the removable complete denture,[2] which is a cost-effective option that aids to regain the masticatory function and the lost esthetics. Maxillary complete denture has better retention and stability when compared to mandibular denture.[3,4] This compromised retention and stability of mandibular denture is due to its anatomical restrictions, such as the influence of tongue[3] and less denture bearing surface area compared to maxilla. Hence, the need for fixed solution in the treatment of edentulism, especially in the mandibular arch, is quite essential, which is aided by the emergence of dental implants.

The success of implant-supported prosthesis is influenced by various factors, and one of the key factors is the quality and quantity of available bone.[5,6] In long-term edentulism, there is reduced bone height and volume, which impairs precise placement of implants. In conventional implant rehabilitation with highly resorbed mandible, patients have to undergo highly technique-sensitive procedures such as extensive grafting[7] or nerve repositioning. To overcome these clinical limitations, the concept of tilted implant came into existence.[6]

Dr. Paulo Maulo's introduced the concept of All on Four in 1989, in which two anterior straight implants and two tilted posterior implants along with multiunit abutments for rehabilitation.[8] The tilting of the posterior implants was up to 45° and was very useful when there is reduced posterior bone height. This increased the bone-to-implant contact, thereby enhancing stress distribution, preventing injury to the underlying vital structures, increasing the anteroposterior (AP) implant spread, and minimizing the cantilever.

The major limitation in this technique is the surgical complications such as nerve injury and accumulation of stress in the tilted implants,[9,10] which can lead to a doubtful long-term prognosis. The improvisation and evolution of technology pertaining to implant design, surface texture, innovative techniques have reduced the number of implants required for rehabilitation and its subsequent limitations. The usage of minimal number of implants and graft-less procedures has reduced the postsurgical trauma and pain, cost, and instruments required and provides ease of operation.[6]

One such recently evolved concept in full arch mandibular rehabilitation is the Trefoil system which was introduced by Dr. Kenji W. Higuchi . This system consists of three straight implants , a prefabricated compensation bar and various components such as a round abutment , two framework discs , a screw disc and a clinical screw.[6,11] The prefabricated bar has adaptive joints which aid in the compensation of vertical, horizontal, and angular misfit.

Irrespective of different treatment concepts, one of the key factors for determining the decision on which concept to be opted is based on the amount of biomechanical stress[12] that is transferred to the bone–implant interface which plays a crucial role in long-term prognosis of the prosthesis. For the purpose of understanding the stress distribution, an *in vitro* engineering tool becomes handy which is known as the finite element analysis (FEA). FEA is three-dimensional (3D) tool used to simulate a physical phenomenon using numerical mathematic technique referred to as the finite element method (FEM). This method divides the complex mechanical model into smaller subunits and facilitates the researchers to predict and verify the stress distribution in the potential bone–implant interface.[12,13] With this objective in mind, this study was done to compare the stress distribution between All-on-Four implant concept and the Trefoil concept under two loading conditions using the FEA.

MATERIALS AND METHODS

The study was approved by the Institutional Review Board for ethics committee is MADC/IRB-XXVI/2018/411. Two mandibular 3D finite element models, Model A and Model B depicting the All-on-Four implant concept and Trefoil implant concept, respectively, were constructed using the CREO version 5 software, and the analysis was performed using the ANSYS R20 [Table 1].

The various steps involved in the FEA studies were preprocessing, processing (loading protocol),

Table 1: Models used in the study

Model A	Model B
Mandibular model with All-on-Four implant system	Mandibular model with the Trefoil implant system

and postprocessing (solution to linear equations). Preprocessing includes the geometric model construction which is aided by reverse engineering or computer aided design (CAD) software. This involves the conversion of geometric model into finite element model by providing data for defining the individual material properties and boundary conditions.

The model of the mandible was obtained from the digitally scanned computed tomographic (CT) images and then was converted into geometric models. The final mandibular dimensions of the bone were 20 mm in height, 10 mm in width, and 153 mm in length. The thickness of the cortical bone was 2 mm, and the cancellous bone was present internally. After construction, these models were converted into finite element model. The dimensions and the images of the implants, bar, and prosthetic components were used for the virtual modeling.

For Model A – All-on-Four implant concept

Materials required

1. Four Nobel Biocare implants of size – 4.3 mm × 13 mm
2. Customized titanium bar of size – 5.5 mm wide, 4 mm thick, and 90 mm long.

Site of implant placement

1. Two anterior, straight implants placed around the lateral incisor region
2. Two posterior, 30° tilted implants placed in the second premolar region.

Abutments

1. Two straight abutments for the anterior implants
2. Two multiunit abutments for the posterior implants.

The straight and the multiunit abutments were fixed to the anterior and distal implants, respectively. The customized bar is placed over the implants. The length of cantilever (18 mm) is kept 1.5 times the AP implant spread. Then, an acrylic denture containing acrylic teeth, from second molar to second molar, is screwed over the bar with a prosthetic screw [Figure 1].

For Model B – Trefoil implant concept

Materials required

1. Three Trefoil implants of size – 5 mm × 11.5 mm
2. Prefabricated titanium bar of size – 5.5 mm wide, 5.5 mm thick, and 86 mm long.

Site of implant placement

1. One straight implant placed along the midline
2. Other two straight implants placed anterior to the mental foramen.

Distance between the implant should be 7.3 mm and the interforamen distance is 22 mm. A round abutment in placed over the implant and one framework disc is placed above it. The prefabricated bar is placed over the framework disc which is then followed by the placement of framework disc, screw disc and an acrylic denture with acrylic teeth. This entire assembly is screwed using the clinical screw.

Table 2: Young's modulus and Poisson's ratio for the various components with reference[17,20,29,34]

Components	Modulus of elasticity (MPa)	Poisson' s ratio
Cortical bone	13.7-16	0.3-16
Cancellous bone	1.37-16	0.3-16
Titanium	115-16	0.35-16
Acrylic resin - denture base	1.96-34	0.3-34
Acrylic resin - artificial teeth	2.94-34	0.3-34

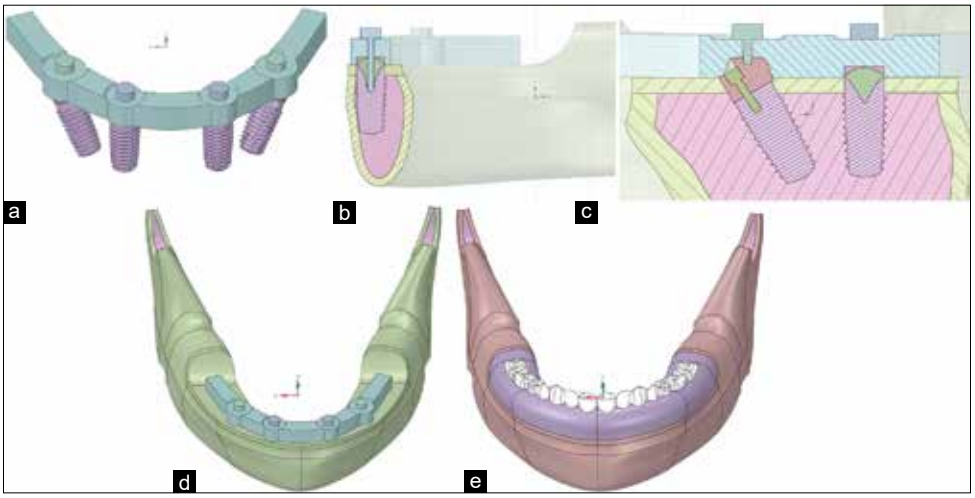

Figure 1: (a) Three-dimensional view of the implants and framework of the All-on-Four implant system; (b) Cross-sectional view of the anterior implant in All-on-Four implant system; (c) Cross-sectional view of the angulated distal implant in the All-on-Four implant system; (d) Three-dimensional view of the All-on-Four implant system with the framework; (e) Three-dimensional view of the completed All-on-Four implant system model - Model A

The AP spread in the trefoil system is fixed as the bar is prefabricated. The AP implant spread is 8.7 mm, and hence, the cantilevered bar is 14.5 mm [Figure 2].

The material properties that were used in the fabrication of the models include the Young's modulus and the Poisson's ratio [Table 2]. After the construction of geometric models, meshing is carried out for the purpose of detailed analysis and measuring the stress after the loading conditions [Figure 3]. All materials used in the models were considered to be isotropic. The boundary conditions were delineated after the meshing process and were defined particularly at the peripheral nodes of bone with no degree of movement in any of the directions [Tables 3 and 4]. In both models, implants were osseointegrated with the surrounding cancellous and cortical bone, and bone–implant interface was considered as a rigid junction.

The meshed images were analyzed in the ANSYS R20 software (Pennsylvania, United States). Von Mises stress was the principal stress that was obtained after the loading, and it is the most commonly used stress metric. The loading protocol includes a posterior cantilever load (loading 1)which is a bilateral and simultaneous vertical static load of 300 N which is applied on the cantilever portion exactly on the central groove of the second molar and a full mouth biting load (loading 2) which is a bilateral and simultaneous vertical static load of 150N applied on the central grooves of the occlusal surfaces of the first and second premolars. After loading, the maximum Von Mises stress values pertaining to the implant, bone, and the prosthetic screws were tabulated.

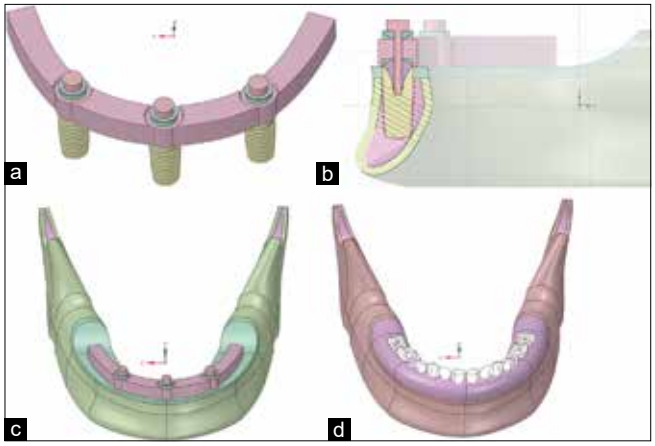

Figure 2: (a) Three-dimensional view of the implants and framework of the Trefoil concept; (b) Cross-sectional view of the implant in Trefoil concept; (c) Three-dimensional view of the Trefoil concept with the framework; (d) Three-dimensional view of the completed Trefoil Implant system - MODEL B

RESULTS

The various interpretations regarding the stress values can be visualized using the different color coding provided from blue (minimal stress) to red (maximum stress). The results showed the critical zones with their respective stress behaviors. The values of maximum Von Mises stress at the level of implant, bone, and framework level were obtained.

Loading 1 results (bilateral cantilever load)

A load of 300 N was applied bilaterally and simultaneously on the cantilever on both the models A and B [Figures 4 and 5]. The results showed that the maximum von Mises stress was recorded in the Trefoil system (Model B) when compared to All-on-Four concept. The maximum stress was recorded at the bone level of Model A and B being 43.4 and 48.36 MPa, respectively. The maximum stress found at the implants was around 73 and 165.9 MPa for Model A and B, respectively. In the framework also, the maximum stress was observed in the Trefoil system than the All-on-four [Tables 5-7].

Loading 2 results (full mouth biting load)

A full mouth biting load of 150 N was applied on the central grooves on the occlusal surfaces of the premolars and molars [Figures 6 and 7]. The results of this loading showed that the maximum von Mises stress were recorded in the Trefoil system (Model B) when compared to All-on-Four concept. The maximum stress was recorded at

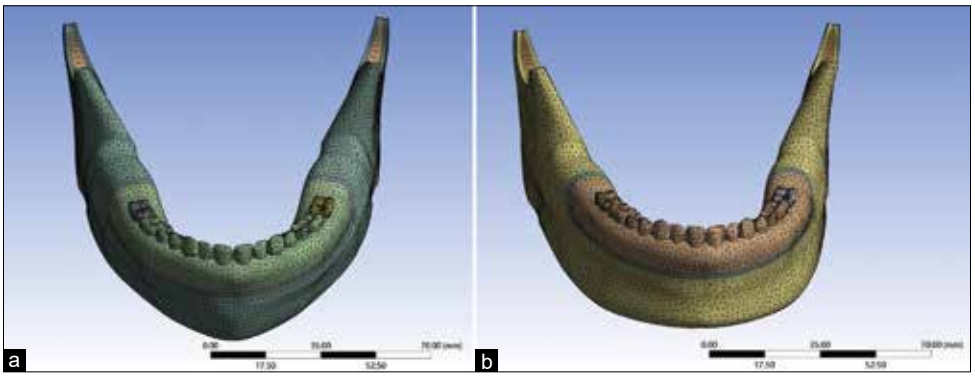

Figure 3: (a) MODEL A - meshing complete; (b) MODEL B - meshing complete

Table 3: Model A - All-on-Four - number of nodes and elements used

Total number of elements used	Total number of nodes used
189,062	350,877

Table 4: Model B - Trefoil concept - number of nodes and elements

Total number of elements used	Total number of nodes used
169,073	317,356

Table 5: Von Mises stress (MPa) at the bone, implant, and framework after loading 1 in Model A - All-on-Four

All-on-Four	Framework	Implant	Bone
Anterior	245	20.4	11.4
Posterior	255	73	43.4

Table 6: Von Mises stress (MPa) at the bone, implant, and framework after loading 1 in Model B - Trefoil concept

Trefoil	Framework	Implant	Bone
Anterior	1593	165.9	48.36
Posterior	834	29.45	26.5

the bone level of Model A and B being 21.8 and 26.9 MPa, respectively. The maximum stress found at the implants was around 65 and 71.3 MPa for Model A and B, respectively. In the framework also, the maximum stress was observed in the Trefoil system than the All-on-Four [Tables 8-10].

DISCUSSION

The rehabilitation of edentulous alveolar ridges was commonly done by removable complete denture prosthesis, which had certain disadvantages in terms of retention and stability, especially in case of mandibular denture.[3,4] To eliminate these problems and to provide a functional and a satisfactory treatment to the patient, fixed implant-supported prosthesis came into existence. Over the decades, many concepts and techniques for implant-supported full arch rehabilitation have been successfully introduced, and in the present-day scenario, rehabilitation procedures can be done with minimal implants in resorbed ridges also. This concept of rehabilitation with minimal implants has reduced the patient's postoperative pain and avoid injury to the underlying vital structures.[6]

Among the various concepts, All-on-Four implant system for the mandibular arches has been ruling for the past few decades.[9] The All-on-Four implant concept uses four implants where two implants are placed straight and anteriorly and the other two are placed posteriorly and are angulated. Recently, the concept of All-on-Three came into existence, the Trefoil concept which uses three straight implants and a prefabricated compensatory bar to rehabilitate

Table 7: Comparing the maximum von Mises stress (Mpa) at the bone, implant, and framework after loading 1 in both the Model A and B

Type of model	Framework	Implant	Bone
All-on-Four	255	73	43.4
Trefoil	1593	165.9	48.36

Table 8: Von Mises stress (Mpa) at the bone, implant, and framework after loading 2 in Model A - All-on-Four

All-on-Four	Framework	Implant	Bone
Anterior	38.5	14.2	1.8
Posterior	121.9	65	21.8

Table 9: Von Mises stress (MPa) at the bone, implant, and framework after loading 2 in Model B - Trefoil

Trefoil	Framework	Implant	Bone
Anterior	432.8	71.3	11.2
Posterior	139.5	52.1	26.9

Table 10: Comparing von Mises stress at the bone, implant, and framework after loading 2 in Model A and B

Type of model	Bone	Implant	Framework
All-on-Four	21.8	65	121.9
Trefoil	26.9	71.3	432.8

the mandible. The prefabricated bar has a compensatory mechanism to match the vertical, horizontal, and angular misfit. This concept also allows immediate loading.

Upon literature search, there was not much evidence or correlation regarding the biomechanical stress or strain for these the All-on-Four and the Trefoil implant concepts. In terms of choice of treatment modality, it is necessary for the rehabilitating prosthodontist to have a wider knowledge in regard to the biomechanical behavior of each and every system apart from the patient-related factors.[6]

FEA was used as a tool for the analysis since various studies showed evidence of solving greater biomechanical domains and can accurately provide us with the inferences.[14,15] Geng *et al*. suggested that 3D FEA studies aided in understanding biomechanics of implant dentistry in a much better way and the bone–implant interface, implant prosthetic connection, and multiple implant prosthesis.[14] Trivedi stated that FEA has many advantages when compared to studies done with real models and also added that these studies are repeatable and there is no ethical considerations for study designs.[13] Pesqueira *et al*. suggested among the various methods for evaluating stress, FEA has the advantages of evaluating and analyzing new configurations of implants, prosthetic components, and their associated materials.[12]

The mandibular bone model was obtained by converting the scanned CT images into geometric

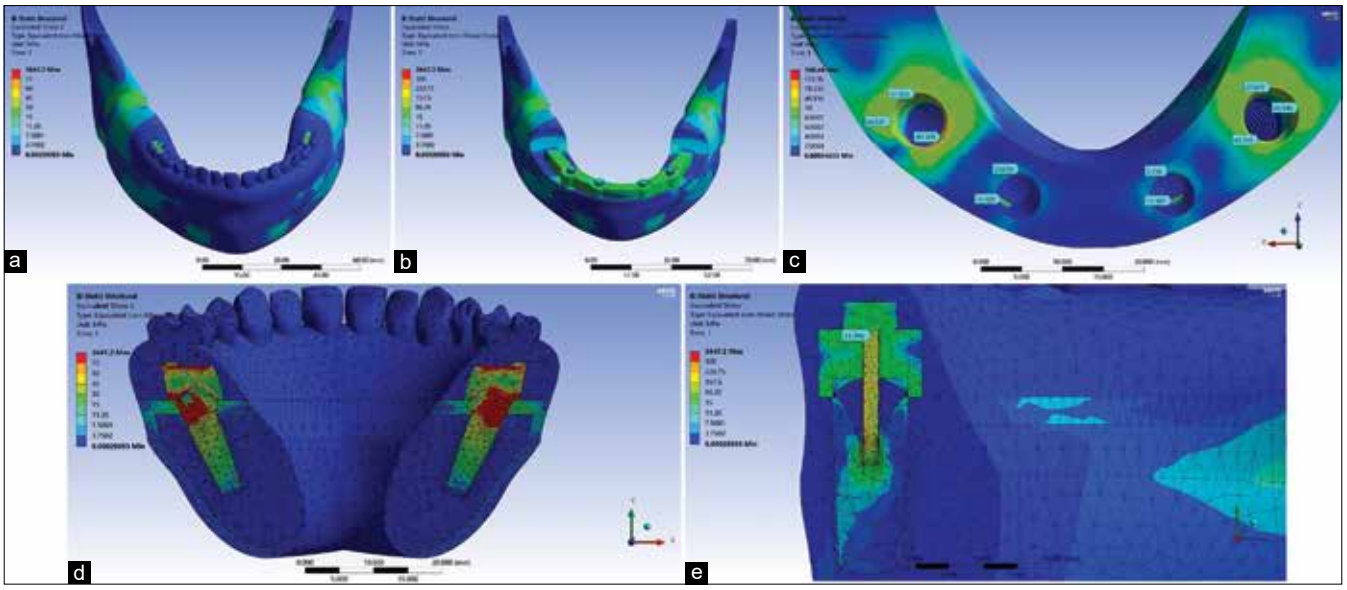

Figure 4: (a) Model A (All-on-Four) in response to load 1, stress distribution at the level of the denture; (b) Model A (All-on-Four) in response to load 1, stress distribution at the level of framework; (c) Model A (All-on-Four) in response to load 1, cross-sectional view distal to the posterior implant; (d) Model A (All-on-Four) in response to load 1, stress distribution at the bone level; (e) Model A (All-on-Four) in response to load 1, cross-sectional image along the center of the implant

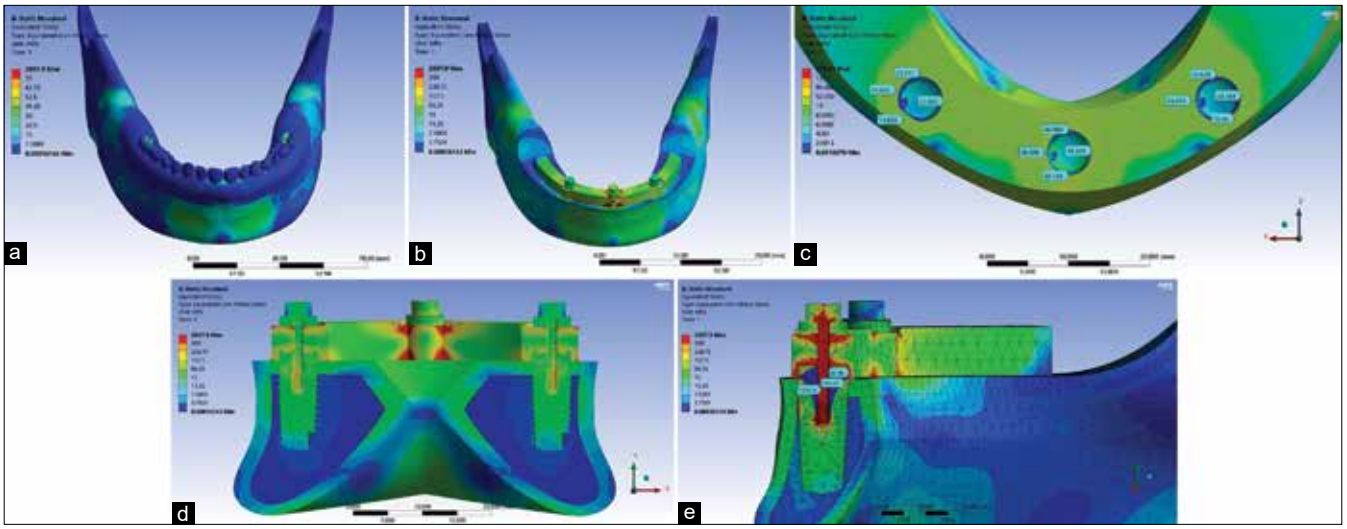

Figure 5: (a) Model B (Trefoil concept) in response to load 1, stress distribution at the level of the denture; (b) Model B (Trefoil concept) in response to load 1, stress distribution at the level of framework; (c) Model B (Trefoil concept) in response to load 1, cross-sectional view distal to the posterior implant; (d) Model B (Trefoil concept) in response to load 1, stress distribution at the bone level; (e) Model B (Trefoil concept) in response to load 1, cross-sectional image along the center of the implant

models and altered in way to make it parametric.[16] All-on-Four and Trefoil implant concepts were taken into consideration for the comparison as these are two concepts provide full arch rehabilitation with minimal number of implants and can avoid extensive surgical procedures such as nerve repositioning and grafting procedures.[6]

The dimensions of the implants and the bar used in All-on-Four and the Trefoil concept were decided based on the dimensions of the implants and prefabricated bar of the Trefoil concept as the dimensions were standardized in the Trefoil concept. The dimensions were kept nearly similar in both the models as the implant diameter and the bar thickness were important factors through which the stress distribution occurs.[17,18]

All-on-Four implant system contains two anterior straight and two posterior tilted implants. The angulations of the posterior implants were kept as 30°. According to Sannino, there was a negligible difference in the maximum von Mises stresses between the angulations of 15°–30°.[16,19,20]

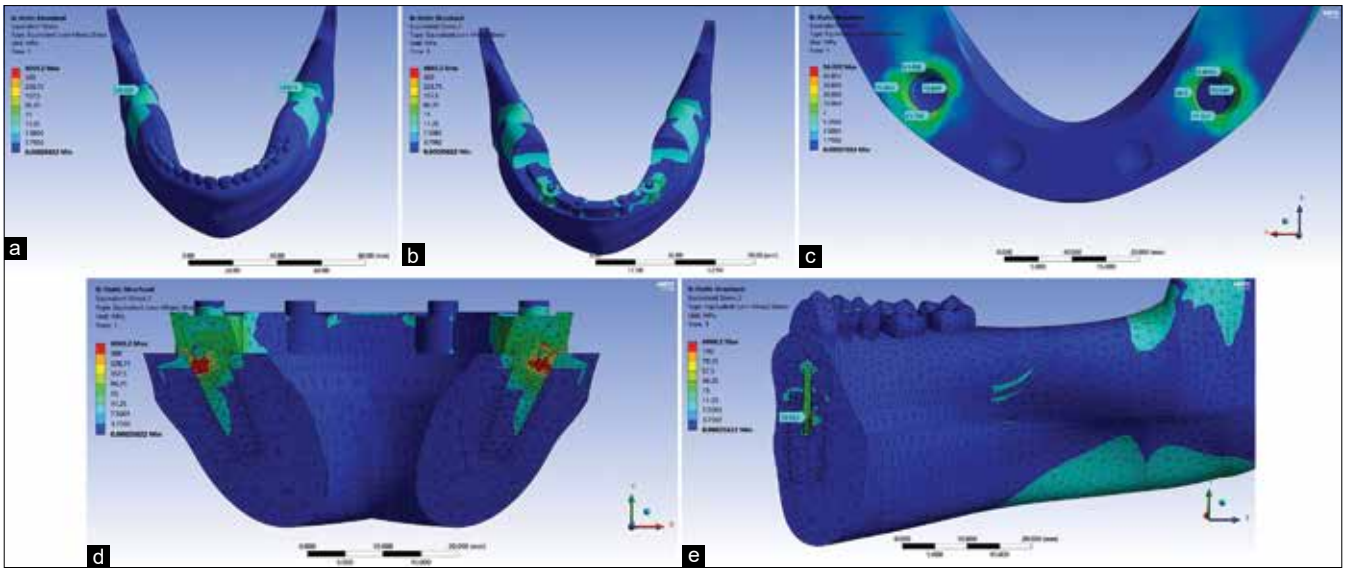

Figure 6: (a) Model B (All-on-Four) in response to load 2, stress distribution at the level of the denture; (b) Model B (All-on-Four) in response to load 2, stress distribution at the level of framework; (c) Model B (All-on-Four) in response to load 2, cross-sectional view distal to the posterior implant; (d) Model B (All-on-Four) in response to load 2, stress distribution at the bone level; (e) Model B (All-on-Four) in response to load 2, cross-sectional image along the center of the implant

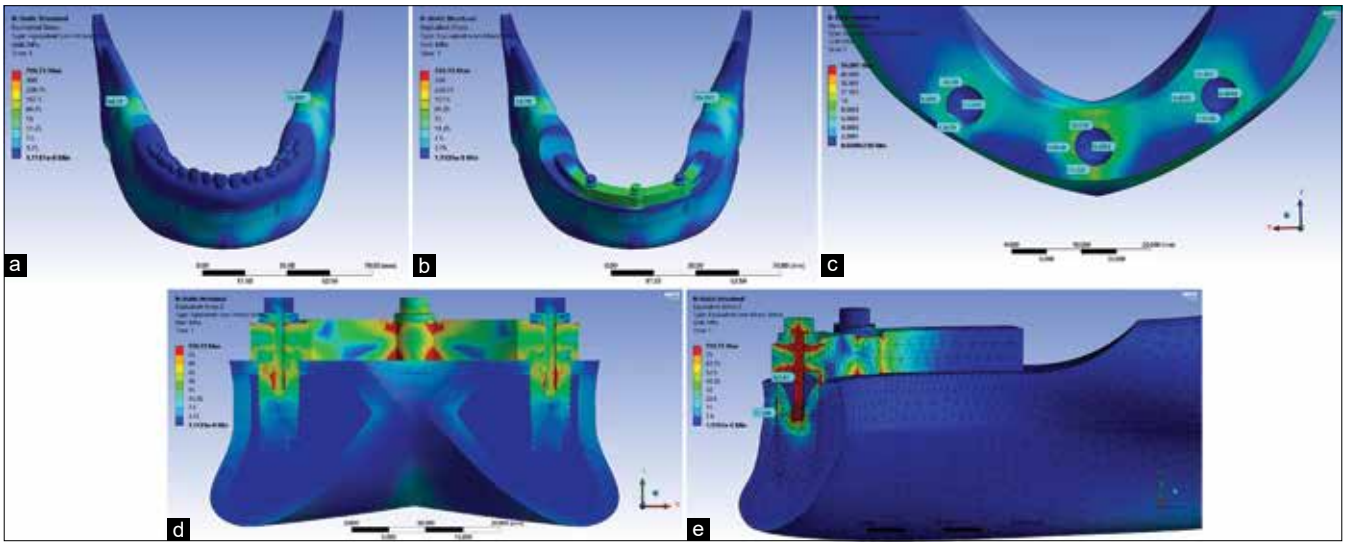

Figure 7: (a) Model B (Trefoil concept) in response to load 2, stress distribution at the level of the denture; (b) Model B (Trefoil concept) in response to load 2, stress distribution at the level of framework; (c) Model B (Trefoil concept) in response to load 2, cross-sectional view distal to the posterior implant; (d) Model B (Trefoil concept) in response to load 2, stress distribution at the bone level; (e) Model B (Trefoil concept) in response to load 2, cross-sectional image along the center of the implant

Studies done by Ozan *et al*., Liu *et al*., and Lofaj *et al*. also suggested that 30° tilted implant delivers less stress on the surrounding structure.[21-25]

In full arch mandibular rehabilitation with minimal implants with opposing natural teeth, one of the major factors that can induce greater biomechanical stress is the load in the cantilever region. Hence a cantilever load of 300N was chosen.[8,15] Following this, a full mouth simultaneous posterior biting load of 150 N was given to simulate the normal masticatory force.[16,26,27]

According to the results of both loading condition in Model A (All-on-Four), the maximum von Mises stress was recorded in the distal implant region. Liu *et al*.[21] in All-on-Four study suggested that the stress was maximum at the distal bone–implant interface due to the close proximity of load application. Lima *et al*.,[28] Saleh Saber *et al*.,[29] Sanino *et al*.,[16] Kumari *et al*.,[30] Horita *et al*.,[10] Deste and Durkan,[31] and Oh *et al*.[32] suggested that the maximum stress that occurred in the implant is also due to the fact that a vertical load is acting on an inclined implant.

According to the results obtained in Model B (Trefoil concept) after subjected to both loadings, maximum stress was recorded in the anterior implant region and amount of stresses was higher than the maximum Von Mises stress recorded in All-on-Four implant concept. The Trefoil concept has shown more stress concentration at the bone, implant, and framework interfaces with respect to the anterior implant.[33,34] The increased stress in the anterior implant region can be due to the fact that all three implants are placed straight because of which the cantilever or the inclined loads are not well tolerated by these implants. During the load application, when the load was given over the posterior cantilever, there was high stress in the anterior implant which could be due to a pivoting action in the anterior implant when load was given posteriorly. Another possible reason for anterior stress concentration is the lever action taking place with the posterior implant as the fulcrum and the anterior displacement load occurring due the cantilever loads.[35-37]

The Trefoil system also has a compensatory mechanism to compensate for the irregularities in implant position; however, since the study is a FEA study, the ideal implant positions are considered. The system accommodates for deviations of 4° angulation, horizontal deviation of 0.4 mm, and vertical deviation of 0.5 mm for passive fit.[38] In an *in vitro* study, prefabricated framework showed a passive fit comparable to prosthesis designed with CAD/computer-aided manufacturing even when implants were not exactly parallel.[39] In this study, the framework bar along with all its components was fixed to the implants which were parallelly positioned with no deviations. Passive fit was incorporated in the FEA model.[38-41]

Aouini *et al.* studied the prefabricated Trefoil framework and found that it matched a large proportion of patient mandibles studied for mandibular morphology.[38] The Trefoil system mandates that the implants are placed with the help of the system guide template so that the mandibular anatomy confirms to the prerequisites of the system in the implant placement sites.[39] Hence, the framework of Trefoil system matching the curvature of the patient mandible did not influence the study.[38-40]

On comparing the biomechanical behavior between the two treatment concepts, the Trefoil concept has shown more stress concentration at the bone, implant, and framework interfaces with respect to the anterior implant region. Since the number of implants is minimal, there is lesser surface area for bone anchorage in spite of its increased diameter, and hence, the bone anchorage is less, leading to improper force dissipation.[42] The lesser AP spread in the Trefoil concept also leads to deleterious effect on the bone and implant interface.[35]

The less stress distribution in All on Four concept was due to increased number of implants, tilted posterior implants and increased bone to implant contact which inturn increased the surface area and reduced the cantilever length due to the increased AP implant spread.[10,16,26-31] On the another hand, the occlusion given also greatly influences the biomechanical success of both All-on-Four and Trefoil concept. Implant-protected occlusion has to be given for the long-term success of the implant-supported full mouth rehabilitation.[43]

Clinical implication

The All-on-Four and the Trefoil concepts are viable treatment alternatives for patients with severely resorbed mandible. All-on-Four concept proves to be better than Trefoil concept in terms of biomechanical stress distribution.

Limitations of the study

1. In FEA, the oral conditions cannot be exactly simulated in the models
2. In FEA, the implants are considered to be 100% osseointegrated.

CONCLUSION

Within the limitations of the study, the following conclusions are made:

1. All-on-Four system has a better stress distribution than the Trefoil concept under both cantilever and full biting loading conditions
2. In the All-on-Four system, the stress concentration occurs in the tilted posterior implant and it is comparatively lesser than the stress in the Trefoil system
3. In the Trefoil concept, the stress concentration occurs in the anterior implant which is far greater than the stress in the All-on-Four system.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Effectiveness of Vitamin D along with Splint therapy in the Vit D deficient patients with Temporomandibular disorder-A Randomized, double-blind, placebo-controlled clinical trial

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Abstract

Aim: The purpose of this study is to comparatively evaluate the Vitamin D supplementation and stabilization splint therapy in patients exhibiting temporomandibular disorders (TMD).

Settings and Design The study design was double-blinded, parallel-group, randomized and placebo-controlled trial conducted in patients with low Vitamin D and TMDs, which were allocated to two groups, Study group S + D (Stabilization splint with Vitamin D supplementation) and Control Group S (Stabilization Splint with placebo drug).

Subjects and Methods: Thirty-six participants of 18–45 years of age gap with Vitamin D deficiency and TMD were included in the study. Preoperative values of Vitamin D levels in ng/ml, comfort mouth opening (CMO) in mm, maximum mouth opening (MMO) in mm, temporomandibular joint (TMJ) tenderness (grading 0–3), Visual analog scale score (VAS Score 0–10 cm), and total energy (TE) integral values of both left and right TMJ's in Hertz (Hz) were recorded using joint vibration analysis All the values of CMO, MMO, TMJ Tenderness and VAS were recorded at each follow-up at 1st week, 1st month, 2nd month, and 3rd month, respectively. Postoperative Vitamin D levels and TE of both TMJs were recorded at end of 3 months.

Statistical Analysis Used: For intergroup comparison, Mann–Whitney *U*-test and Pearson Chi-square tests were done. For Intragroup comparison, Wilcoxon signed rank test was used for comparison.

Results: In Intergroup comparison, a significant difference was seen in CMO, VAS score and MMO ($P < 0.05$) but not among mean values of TE of right and left TMJ, and Vitamin D levels ($P < 0.05$). In both groups, there were significant statistical variations in CMO, VAS score, MMO, and TE integral before and after treatment in the right and left TMJs ($P < 0.05$).

Conclusions: The study concludes centric stabilization splint helps in improving symptoms of TMD patients and Vitamin D supplementation provided faster relief in those cases.

Keywords: 1, 25 dihydroxy 20 epi Vitamin D_3, joint vibration, occlusal splint, temporomandibular disorders

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INTRODUCTION

The temporomandibular joint (TMJ) and its associated neuromuscular system are the two fundamental components of the temporomandibular system. The American Academy of Orofacial Pain broadly classifies temporomandibular disorders (TMD) into myogenous or muscle-related TMD, and arthrogenous or joint-related TMD.[1] The clinical features of TMD include pain in the temporomandibular region or muscles of mastication; radiation of pain to the face, behind the eyes, shoulder, neck and/or back; headaches and dizziness; tinnitus or ear-ache; clicking, locking or deviation of jaw; restricted jaw opening; clenching of teeth; and sensitivity of apparently healthy teeth without any oral disease. The most common symptom for which patients seek medical attention is pain in the associating region.[2] Patients with TMD who do not experience pain, may complain of popping, clicking and crepitus sounds, at the TMJ during joint movement. TMD has a multifactorial etiology. Several theories, including mechanical displacement, biomedical, trauma, osteoarthritis, muscle theory, neuromuscular, psycho-physiological and psychosocial theory, have been proposed to explain the etiology of TMD.[3] The factors can be classified as predisposing factors, initiating factors and perpetuating. Predisposing factors increases the risk of developing TMD such as genetic factors. Initiating factors like trauma are acute reasons for TMD and at last, perpetuating factors are those factors which delay the healing process. Among perpetuating factors, systemic mineral or vitamin deficiency plays an important role. Vitamin D deficiency has been associated with poor muscle strength and poor physical performance. Recently, it has been linked with TMJ Disorders.[4] Thus, it can be either a predisposing or perpetuating factor in manifestation of TMJ Disorder. Vitamin D supplementation in patients who had deficiency, should improve symptoms of TMD.[4] The most effective treatment for TMJ issues necessitates a thorough diagnostic examination using research diagnostic criteria/TMD (RDC/TMD). Along with RDC/TMD, an objective method such as evaluating joint vibrations using joint vibration analysis (JVA) can provide to be a very useful and significant diagnostic tool by reducing the chance of individual bias. An ideal therapeutic approach for TMD should focus on ameliorating the main signs and symptoms of this condition. Conservative management for TMD includes medication, occlusal splints, physiotherapy, interventions based on cognitive-behavioral approaches, and self-management strategies.[5] Despite its advantages, evidence for the comparative effectiveness of surgical and conservative intervention to reduce short-term pain in atherogenic TMD is still controversial and inconclusive.[5] The definitive treatment for TMD is to reinstate a normal disc-condyle relationship. For this, we usually use centric stabilization splint.[5] The centric stabilization splint has been reported to resolve myogenic pain, restricted mouth opening, and TMDs. Stabilizing splints help in stabilizing physiologically static and dynamic occlusion, relax the tensed masticatory muscles, and reduce the physiological stress in joint structures. The multimodal treatment plan of combined Vitamin D supplementation and Splint therapy can be implemented in TMD patients to evaluate their response. There is a lack of knowledge in associating Vitamin D with splint therapy in improving the comfort and quality of life in patients exhibiting TMD. The effectiveness of Vitamin D has not yet been established as a supplementary treatment in TMD. Thus, the null hypothesis of this study is that there is no significant difference in combining Vitamin D supplementation along with Splint therapy in patients exhibiting TMD.

Objectives

The current study aims at giving a diagnosis-based treatment plan to patients with TMD along with Vitamin D deficiency. The purpose of this study is to comparatively evaluate the role/effectiveness of Vitamin D supplementation along with stabilization splint therapy in the treatment of patients exhibiting TMDs. The diagnosis was based on both clinical symptoms using RDC/TMD and JVA.

SUBJECTS AND STUDY DESIGN

This was a double-blind, randomized, parallel-group, and placebo-controlled clinical trial carried out at the Department of Prosthodontics in Maulana Azad Institute of Dental Sciences, New Delhi.

Ethics

The Institutional Ethical Committee approved the study with informed consent was taken for each patient. For reference, Ethical Committee Number is MAIDS/Ethical committee/2016/3273.

Controlled trial registration

The trial was registered in Clinical Trial Registry under ICMR. The protocol (CTRI Number: CTRI/2020/10/028748), can be accessed through the following link: http://ctri.nic.in/Clinicaltrials/pdf_generate.php?trialid = 47731andEncHid = andmodid= andcompid=%27,%2747731det%27.

Inclusion and exclusion criteria

Inclusion criteria

Patient's age ranging from 18 to 45 years (both included) were included in our study. Patients were

recruited irrespective of sex, religion, caste, or socioeconomic status. RDC/TMD classification among Axis 1 with Group II patients were selected which was further verified using JVA[6] whose Vitamin D levels were <30 ng/ml[7] and were fully dentate or at least had sufficient occlusal stops, no more than two posterior teeth missing in each quadrant (excluding third molars) were selected.

Exclusion criteria

Completely edentulous patients or patients with no posterior occlusal stops were excluded from the study. Patents having reduced mouth opening or patients who had undergone previous treatment with occlusal appliances were also excluded from the study. Patients undergoing Orthodontic treatment and patients with pain because of systemic disease (e.g., rheumatoid arthritis, etc.) were also excluded from the study.

Sample size

The sample size was kept in accordance to the study done by Mazzetto *et al*.[8] in 2007 who evaluated the effect of low intensity laser application in TMD's. The sample size was calculated using formulae of comparison of two independent means with α set at 0.05 and β at 0.2. A minimum number of 16 patients per group were to be needed to obtain a significant difference in the treatment and control group. It was decided to keep a sample size of 20 participants per group (including 25% of drop out). Thirty-six participants completed the study with dropout of 4 participants (2 from each group).

Study procedures

Step 1: Screening of patients

Proper informed consent was taken from the patient. After he/she gave consent, then only the enrollment of the participant in the study was done. Preoperative blood tests were done for Vitamin D levels. Patients with levels <30 ng/ml and TMD and who come under our inclusion criteria were included in the study [Figure 1]. For randomization, random number table sequence generated by SPSS Statistics for Windows, version 26.0(SPSS Inc., Chicago, III., USA) and was used to allocate patients in study group S + D and control group S. The participants with even number in table were selected for study group S + D and participants with odd number were selected for control group S. For randomization concealment, participants in study group were given Vitamin D supplements in sealed envelope and control group participants were given placebo drug in sealed envelope. Patients who were excluded from study were also given appropriate treatment for TMD.

Step 2: Preoperative examination

Preoperative baseline values of inter-incisal comfortable mouth opening (CMO) and maximum mouth opening (MMO) were measured in millimeters. TMJ tenderness was recorded on scale of 0–3 in which, 0 depicted no pain on palpation; score 1 denoted mild pain; score 2 for moderate pain; and 3 for severe pain. Pain score was assessed on a visual analog scale (VAS) of 0–10 cm. Total energy (TE) integral values of TMJs of either side in Hertz (Hz) were obtained by a JVA record.

Step 3: Joint vibration analysis record

JVA sensors (BioJVA™, BioResearch) were placed over the patient's TMJs, and sensor wires were attached to the amplifier [Figure 2]. The patient was trained to get synchronized with metronome (The video instructions how to open and close mouth) on laptop. Both side TMJ vibrations were recorded as the patient followed the metronome of opening and closing movements. During closing, the patient was instructed to make only light contacts. A summary of the procedure was stored in the software provided by BioJVA™ [Figure 3].

Step 4: Bite registration and splint fabrication

Impression of the maxillary and mandibular arch was taken in irreversible hydrocolloid and were poured in Type III Gypsum product. Bite Registration was done at centric relation using VPS material (CADBITE, IVOCLAR). Models were mounted with dental plaster on HANAU Wide-Vue 183-2 articulator using a HANAU Spring bow and the patient's bite registration record. Wax-up of the splint was done using modeling wax. It was processed in clear heat cure resin. Full coverage splint was fabricated covering the entire arch and it fitted the occlusal and incisal surfaces of maxillary or mandibular teeth. The choice of arch was made on clinical condition like remaining tooth in each arch, periodontal support of each arch and the preference of patient was also considered. The thickness of splint ranged between 2 and 3 mm. Splint was retrieved and polished.

Step 5: Vitamin D supplementation

Group S + D patients were given Vitamin D tablets 60,000 IU once a week for 8 weeks. Control group S patients were given placebo drug for the same time period. Vitamin D supplements and placebo drugs were packed in a sealed envelope imprinted with a random table number, which were given to the patients by a third person to ensure double-blinding. This procedure was done along with randomization. The study was double-blinded so that neither the researcher nor the participants were aware, whether the patient was in the study group or control group.

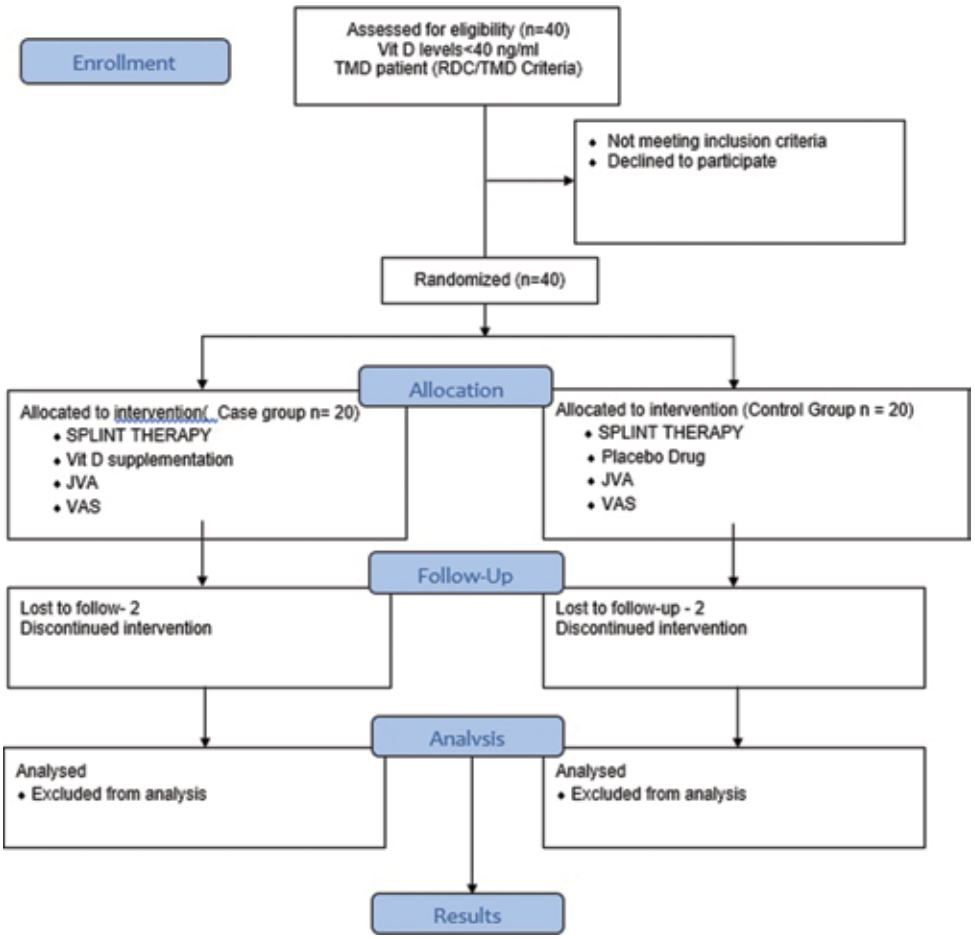

Figure 1: CONSORT flow diagram of trial

Figure 2: Joint vibration analysis sensors placed on temporomandibular joint along with amplifiers

Step 6: Splint insertion and follow-ups

Retention of the splint was checked and occlusal interferences were adjusted using 40 um articulating paper. Uniform contacts were verified in centric and canine-guided occlusion was given in splint. Follow-up done at 1st week, 1st month, 2nd month, and 3rd month after therapy. After the last follow-up, again blood tests were done to determine the Vitamin D levels.

Step 7: Statistical analysis

When the data obtained were under normal distribution, further inter-group and intra-group comparison was done.

Intergroup comparison

MannWhitney *U*-test was used to calculate significant intergroup differences of mean values of CMO, VAS pain score, MMO and TE of right and left TMJs before and after therapeutic intervention. The intergroup comparison of TMJ tenderness was done using Pearson Chi-square test.

Intragroup comparison

Friedman test was used for comparison of change with subsequent follow-up visits within each group. Wilcoxon signed-rank test evaluated the significance of difference in the CMO, VAS pain score, MMO and TE values of right and left TMJs to assess the treatment response and evaluate the improvement in subsequent follow-up.

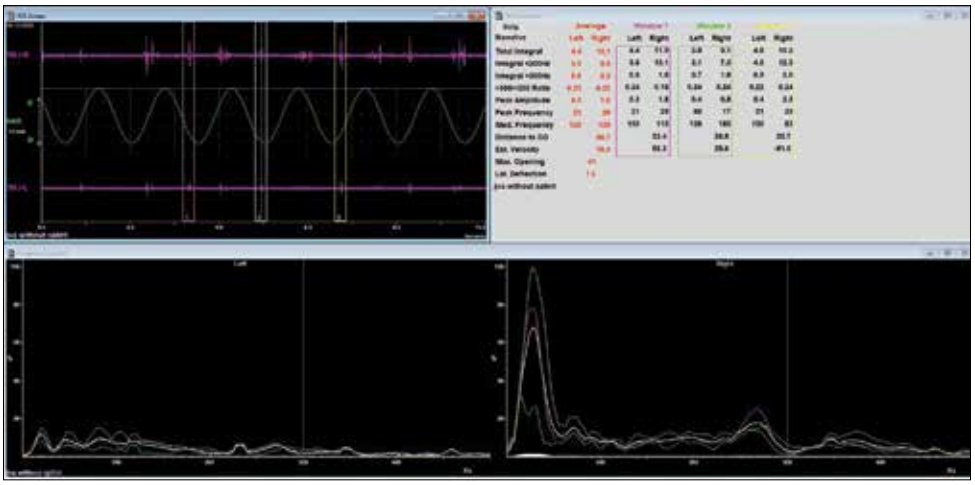

Figure 3: Temporomandibular joint vibrations recorded in the software

RESULTS

After randomization, 18 patients were allocated to each group. Baseline demographic variables of both groups such as CMO, VAS score, MMO, and TMJ tenderness score along with total integral energy (TE) of both the TMJ s are organized in Table 1.

Intergroup comparison

On comparing the mean of CMO, VAS Score, and MMO among two groups between delivery of splint and after 1 month of therapy, significant difference was seen ($P < 0.05$) [Tables 2-4]. Between all follow-ups, there was no significant difference was evident in mean values of TE of right and left TMJ between two groups [Tables 5 and 6]. On comparing means of Vitamin D levels at end of 3 months after therapy, significant difference was seen ($P < 0.05$) among two groups [Table 7].

Intragroup comparison

In both groups, there were significant statistical variations in CMO, VAS score, MMO, and TE integral before and after treatment in the right and left TMJs. Between follow-ups, there were significant statistical variations in CMO, VAS score, and MMO [Tables 8-10]. Statistically significant differences were seen between follow-up visits in TE integral of right TMJ in Group CS + D and TE integral of Left TMJ in both the groups [Tables 11 and 12]. Moreover, statistical difference was seen in Vitamin D levels before and after drug therapy in Group CS + D [Table 13].

Graphs were used to show the changes in tenderness grading as therapy progressed [Figures 4 and 5]. In Figure 4, it is depicted that at the time of diagnosis, 11 participants had Grade 3 tenderness and 7 participants had grade 2 tenderness, but at the end of 3 months, 12 participants had grade 1 tenderness and 6 of them had Grade 0 tenderness.

In Figure 5, it is depicted that at the time of diagnosis, 10 participants had Grade 3 tenderness and 8 participants had Grade 2 tenderness, but at the end of 3 months, 10 participants had Grade 1 tenderness and 8 of them had Grade 0 tenderness.

DISCUSSION

This trial was conducted to compare the Vitamin D supplementation and stabilization splint therapy in patients suffering from TMD using both JVA and VAS.

On comparing the mean of CMO, VAS score, and MMO among two groups, statistically significant difference were observed between delivery of splint and after 1 month of therapy which shows significant improvement. Stiesch-Scholz *et al*.[9] stated that increase in active mouth opening of 8.05 mm causes a significant reduction in pain during splint therapy. Pain reduction in group was evident after 1st follow-up where-as in control group, it was seen after 2nd follow up. This difference was significant and is because of Vitamin D supplementation. Hence, the null hypothesis was rejected. In this clinical trial, change in CMO was 2.11 mm for S + D group, 2.01 mm for S group, change in MMO was 3.11 mm for S + D group, 2.8 mm for S group.

Both therapy group patients showed improvement after 1 month of splint delivery and were consistent in both the groups as Stabilization splint therapy was given. Sato *et al*.[10] stated that Stabilization splint therapy gives 13% more successful results than other splints. Similar studies has been performed by Minakuch *et al*.[11] and

Table 1: Baseline characteristics of both group and control group

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
CMO (mm) at time of diagnosis	37.67±4.9 (26-46)	38.61±2.25 (35-43)	0.74
MMO (mm) at time of diagnosis	40.44±4.9 (30-48)	40.67±2.1 (38-44)	0.95
TMJ pain (Scale 0,1,2,3)	2.31±0.502 (2-3)	2.31±0.5 (2-3)	0.31
VAS score (0–9)	7.61±0.6 (6-8)	7.67±0.59 (7-9)	0.78
Serum Vitamin D levels at start (ng/ml)	25.11±1.7 (21.7-28.5)	24.83±1.89 (21.0-28.6)	0.64

*$P<0.05$, based on Chi-square and Mann–Whitney U test. SD: Standard deviation, S + D: Centric stabilization Splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, CMO: Comfortable mouth opening, MMO: Maximum mouth opening, TMJ: Temporomandibular joint, VAS: Visual Analog Scale

Table 2: Mean comparison of comfortable mouth opening

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	37.67±4.9 (26-46)	38.61±2.25 (35-43)	0.742
At 1st week	39.78±4.5 (30-48)	40.06±2.38 (36-44)	0.050*
At 1 month	41.67±3.29 (35-49)	41.78±2.15 (38-46)	0.188
At 2nd month	43.22±3.26 (36-50)	43.00±2.19 (38-48)	0.226
At 3 months	44.39±3.24 (36-50)	44.33±1.94 (40-48)	0.041*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 3: Mean comparison of maximum mouth opening

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	40.44±4.9 (30–48)	40.67±2.1 (38–44)	0.952
At 1st week	43.22±5.18 (36–52)	42.39±2.06 (38–46)	0.031*
At 1 month	44.44±3.05 (40–50)	44.50±2.59 (40–52)	0.379
At 2nd month	46.28±2.84 (41–52)	45.17±1.42 (42–48)	0.040*
At 3 months	47.11±2.61 (41–52)	45.94±1.58 (42–48)	0.076

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 4: Mean comparison for visual analog scale score

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	7.61±0.6 (6-8)	7.67±0.59 (7-9)	0.783
At 1st week	6.78±0.7 (6-8)	6.72±0.57 (6-8)	0.028*
At 1 month	6.00±1.02 (4-8)	6.00±0.76 (5-8)	0.345
At 2nd month	5.06±0.8 (4-7)	5.33±0.68 (4-7)	0.882
At 3 months	4.06±0.8 (3-5)	4.61±0.69 (3-6)	0.057*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

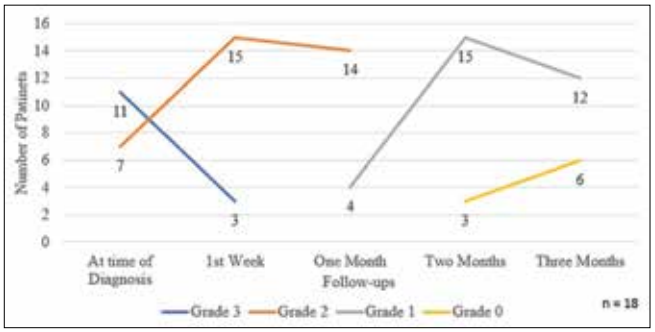

Figure 4: Graphs of how gradation of temporomandibular joint pain on palpation varies in Group S + D

Suvinen and Reade[12] which stated that the stabilization splints have a greater edge above other type of splint design. In this study, stabilization splint therapy was given to both groups keeping in mind the previous quoted literature.

In both the groups, there was a reduction in TMJ tenderness and muscle pain, resulting in increased MMO. This finding is consistent with study of Block *et al*.[13] in which he concluded that after 1 month of occlusal splint therapy, more than 73% of patients experience symptom remission because of correct condyle-disk relationship which alleviates the symptoms and reduce the muscle tenderness resulting in increased MMO.

After analyzing the pain score, S + D group showed the best response to therapy. In our study, the VAS Score decreased from 7.61 to 4.06 in group S + D, and 7.67 to 4.61 in group S. Both the group patients showed improvement in VAS Score in 4–8 weeks of therapy with consistent improvement. Best results were seen between 1st week and end of 3rd month ($P < 0.05$) in both the groups. Ekberg *et al*.[14] found that muscle myalgia decreases significantly after 6 weeks of duration and so does

Table 5: Mean comparison for total integral energy right temporomandibular joint (Hertz)

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	15.22±7.50 (2.3-29.2)	12.41±9.45 (3.9-34.0)	0.171
At 3 months	14.52±7.32 (1.8-28.6)	10.82±6.92 (3.4-28.4)	0.165

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 6: Mean comparison for total integral energy left temporomandibular joint (Hertz)

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	12.32±6.07 (2.3-22)	10.45±9.67 (3.3-39.1)	0.203
At 3 months	10.42±5.45 (2.2-21)	7.29±6.81 (2.0-28)	0.077

*$P<0.05$ significant, $P>0.05$=Insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 7: Mean comparison for serum Vitamin D levels

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	25.11±1.7 (21.7-28.5)	24.83±1.89 (21.0-28.6)	0.64
At 3 months	33.56±2.79 (27.9-39.1)	26.11±2.08 (21.9-30.2)	0.02*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 8: Wilcoxon signed-rank test for comfortable mouth opening

Groups	Group S + D	Group S
P difference between at time of Diagnosis and 1st week	0.512	0.917
P difference between 1st week and 1 month	0.040*	0.037*
P difference between 1 and 2 months	0.069	0.685
P difference between 2 and 3 months	1.000	0.820
P difference between at time of diagnosis and 3 months	0.05*	0.002*

$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 9: Wilcoxon signed-rank test for maximum mouth opening

Groups	Group S + D	Group S
P difference between at time of Diagnosis and 1st week	0.031	0.092
P difference between 1st week and 1 month	0.126	0.018*
P difference between 1 and 2 months	0.023*	0.114
P difference between 2 and 3 months	0.343	0.246
P difference between at time of diagnosis and 3 months	0.023*	0.002*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 10: Wilcoxon signed-rank test for Visual Analog Scale score

Groups	Group S + D	Group S
P difference between at time of Diagnosis and 1st week	0.126	0.352
P difference between 1st week and 1 month	0.140	0.052
P difference between 1 and 2 months	0.020*	0.049*
P difference between 2 and 3 months	0.092	0.102
P difference between at time of diagnosis and 3 months	0.035*	0.032*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

VAS Score because of reduction in muscular myalgia in specifically inferior lateral pterygoid muscle.

Both groups of patients demonstrated a downgrading of TE value of the right TMJ. Similar results were found for TE value of left TMJ. Statistically significant differences were found between 1st week and end of 3rd month signifying improvement and reduction in both the joints vibrations ($P < 0.05$). Stabilization splints has been proved in reducing TMJ vibrations. Garcia *et al*.[15] noted that the

Table 11: Wilcoxon signed-rank test for total integral energy right temporomandibular joint

Groups	Group S + D	Group S
P difference between at time of diagnosis and 3 months	0.049*	0.098

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 12: Wilcoxon signed-rank test for total integral energy left temporomandibular joint

Groups	Group S + D	Group S
P difference between at time of diagnosis and 3 months	0.002*	0.042*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 13: Wilcoxon signed-rank test for serum Vitamin D levels

Groups	Group S + D	Group S
P difference between at time of diagnosis and 3 months	0.002*	0.08

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

vibrations are decreased when mandible is advanced by a mandibular advancement device. Splints causes a forward rotation of the condyle favouring a softer movement during its reduction. In our study, vibrations were decreased in both the groups mostly because of correct condyle-disk relationship permitting softer movements.

Tenderness in TMJ was relieved in both the groups because of stabilization and distribution of forces. Similar studies were found by Kovaleski and De Boever[16] who showed reduction in pain within 2 months of splint therapy.

After analyzing the Vitamin D levels, best response was seen with S + D group, obviously because of 60,000 IU Vitamin D capsules which were given to all the participants in Group S + D. In our study, the Vitamin D levels increased from 25.11 to 33.56 ng/ml and 24.83 to 26.11 ng/ml in group S + D and Group S respectively which was statistically significant ($P < 0.05$). On comparing *P* values between 1st week and end of 3rd month, the difference was significant in group S + D. Park[7] conducted a systematic analysis to see if there was a relation between Vitamin D and osteoarthritis (OA). Vitamin D, according to Park, may help to prevent joint pain. Patients suffering from TMD who have low Vitamin D may benefit from this treatment. Systemic review of Kui *et al*.[17] culminated that the literature is present to link Vitamin D deficiency and TMD but clinical trials or placebo-controlled trials are not there to prove so. Hence, keeping the above statement in mind, this placebo-controlled clinical trial was planned. The current

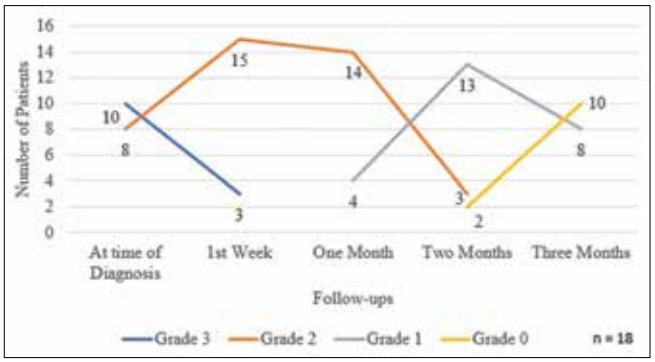

Figure 5: Graphs of how gradation of temporomandibular joint pain on palpation varies in Group S

study had a small sample size, but it was seen that Vitamin D hastens the treatment and gives a quick relief from symptoms of TMD. In future studies, larger sample size and inclusion of more parameters is herewith suggested.

CONCLUSIONS

Following conclusions can be withdrawn from this clinical study:

1. Centric stabilization splint helps in improving mouth opening, reduction in VAS scale, decrease in TEs of both right and left TMJ, and reduction in TMJ tenderness in TMD patients
2. Patients with TMD and Vitamin D deficiency should be supplemented with Vitamin D along with splint therapy to provide faster relief in symptoms.

Acknowledgment

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Declaration of patient consent

The authors declare that they have obtained consent from patients. Patients have given their consent for their images and other clinical information to be reported in the journal. Patients understand that their names will not be published and due efforts will be made to conceal their identity but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

A randomized controlled trial for evaluation of bone density changes around immediate functionally and nonfunctionally loaded implants using three-dimensional cone-beam computed tomography

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Abstract

Aim: The aim of this study was to compare and assess bone density changes around immediate functionally and nonfunctionally loaded implants.

Settings and design: *In vivo* comparative study

Materials and Methods: Sixty participants selected based on the predetermined inclusion and exclusion criteria received single tooth implants in mandible under two implant loading protocols: Immediate functionally loaded (IFL) and immediate nonfunctionally loaded (INFL). Randomization was done by computer-aided simple randomization procedure. Self-tapering, aggressive SLA implants were placed in the single tooth edentulous sites of mandible in both the groups. Three-dimensional cone-beam computed tomography (3D CBCT) was taken at baseline, 3 and 6 months postimplant placement. Quantitative analysis of the bone density was performed using 3D CBCT in three areas around the implants at crestal, middle, and apical regions of implants.

Statistical Analysis Used: Quantitative data were summarized as mean ± standard deviation. Statistical analyses were performed using the SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA) by unpaired *t*-test.

Results: Bone density changes after implant placement in IFL group from baseline to 3 months were; crestal region (314.18 ± 71.69), middle (278.23 ± 70.17), apical (274.70 ± 59.79) and changes from 3 to 6 months were; crestal (−105.55 ± 39.60), middle (−114.80 ± 41.46), apical (−141.88 ± 69.58). Bone density changes after implant placement in INFL group from baseline to 3 months were crestal region (199.42 ± 47.97), middle (56.91 ± 10.39), apical (200.98 ± 67.43) and changes from 3 to 6 months were; crestal (−194.38 ± 75.30), middle (−204.40 ± 63.75), apical (−191.28 ± 62.33).

Conclusions: It was concluded that INFL implant group showed better bone density when compared to IFL implant group.

Keywords: Bone density, dental implant, immediate loading, stability

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INTRODUCTION

Prolonged healing durations of 3–6 months serves as the basis of success associated with conventional loading (CL) or delayed loading protocols. The rationale is to keep the implant in an uninterrupted environment during the healing period.[1] The concept of immediate loading came into existence mostly due to the increased treatment time and prolonged period of edentulousness associated with the CL protocol. In addition, reduced bone density has been observed around the delayed loaded implant after the 3–6 months period due to the lack of functional stimulation during the healing period. These studies concluded that mechanical bone stimulation serves as one of the key factors in the regulation of bone remodeling.[2-5]

Immediate and early loading of dental implants as a technique is gaining popularity gradually owing to drastically reduced treatment periods and minimal discomfort attributed to the periods of edentulism. Copious histological and histomorphometric studies have shown that the osseointegration with immediately loaded implants is comparable to that with delayed loaded implants. Piattelli *et al.* in their study reported that, as the bone is loaded post the initial healing period, the peri-implant bone changes from a fine trabecular pattern to coarser and denser trabecular pattern, especially in the crestal half of implant interface.[6] This ossification process around implants, improves the support for the final prosthesis. However, literature pertaining to assessment of alterations in mineral bone density around implants and the comparison between different loading protocols are scarce.

Immediate loading protocols are dependent on a high primary stability which in turn is affected by a multitude of factors such as the quality and density of the available bone, as well as, the design, shape and surface characteristics of the implant. As concluded by various studies, immediate loading of dental implants can be accomplished successfully.[7] Furthermore, there might not exist a significant difference in parameters such as marginal bone levels with different loading protocols. Marginal bone levels are determined by implant surface modifications, design, implant position, surgical technique employed, and implant-abutment configuration.

In the long-term, greater resistance to occlusal forces can be achieved with an increased bone density around the implants, more so when considering the immediately loaded implants. However, there is a scarce reporting of literature concerning the quantitative assessment of bone mineral density (BMD) changes around implants, especially immediately loaded implants. Various tools can be utilized for such an assessment. One of the valid and widely used methods of assessing BMD at various skeletal sites is dual energy x-ray absorptiometry (DEXA).[8,9] However, cross-sectional imaging isn't an option extended with DEXA. Consequently, its applicability for implant placement is low. Other conventional imaging modalities being 2 dimensional, such as digital panorams, radiovisiography, cephalometric and tomographic images don't offer the possibility of accurate measurements of bone width and height. Hence, alternate computing tools, such as three-dimensional cone beam computed tomography (CBCT) and computerized axial tomography (CT) have been utilized to measure BMD in the oral cavity.[10]

The present study was conceptualized to determine whether there exists a difference in the quantitative radiographic bone density changes around implant as measured using CBCT scans, under the demanding conditions of immediate functional and nonfunctional loading. The null hypothesis was that no difference would be found in the alveolar bone density between immediate functionally and immediate nonfunctionally loaded (IFL and INFL) implants.

MATERIALS AND METHODS

Source of data

This prospective study progressed over the course of 2½ years in Department of Prosthodontics, Crown and Bridges, Faculty of Dental Sciences, King George's Medical University, Lucknow, U.P. and ethical clearance was obtained (Reference Code: 84th ECM IIA/P11).

Sample size

Sample size was calculated using the following formula:

$n = 17\ \sigma^2/\Delta^2 + 1$

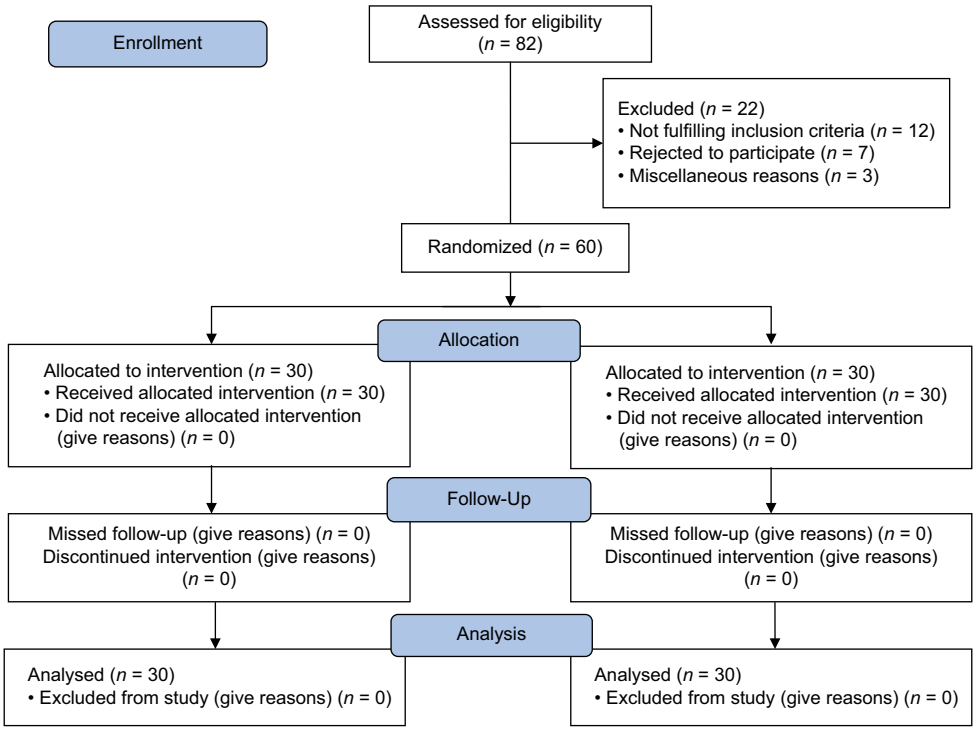
n = Sample size

σ = Standard deviation (SD)

Δ = Difference in effect of two interventions.

Study design

This was a randomized, prospective, longitudinal and *in vivo* comparative study. Eighty-two subjects were assessed for eligibility, out of which sixty subjects were enrolled for the study fulfilling the following inclusion and exclusion criteria [Flow Chart 1]:



Flow Chart 1: CONSORT 2010 flow chart

Inclusion criteria

1. Edentulous area in the posterior mandible with a single tooth missing
2. Healthy patient with no systemic conditions, good oral hygiene and consenting to participate
3. Subjects aged >18 years
4. Subjects with bone volume of more than 10.0 mm in height and 7.0 mm in width as evidenced on a preoperative CBCT scan
5. Subjects having implant stability quotient (ISQ) value of stability more than 60 during implant surgery.

Exclusion criteria

1. Systemic conditions which are contra-indications to the surgery, such as uncontrolled diabetes, presence of immunosuppressed state, history of head and neck cancer, patients on anticoagulants, and patients on oral/intravenous aminobisphosphonates
2. Patients needing regenerative bone techniques prior to implant insertion
3. Patients with diseases pertaining to oral cavity
4. Missing antagonistic teeth in the opposite maxillary arch.

The patients fulfilling study criteria were randomly divided by computer aided simple randomization into two groups, each consisting of thirty patients:

- Group I - Self-tapering SLA implants subjected to IFL was control group
- Group II - Self-tapering SLA implants subjected to INFL was test group.

Clinical procedure

Meticulous clinical and radiographic analysis was carried out for the preoperative evaluation of each subject. Bone anatomy was evaluated prior to implant placement using CBCT (CS9300 carestream, Atlanta, GA). Height and thickness of the bone was evaluated using the resultant DICOM files and implant dimensions were decided accordingly for each subject. The self-tapering, aggressive SLA implants of Tag Dental, Noga Medical, Israel were planned to be used in the present study as they have good initial stability and short healing period.

Following routine surgical protocol, prophylactic dose of antibiotic was given to the patients 1 h prior to surgery, followed by anesthetizing locally using articaine with adrenaline (1:100,000). A mid-crestal incision along with two lateral releasing incisions was given in fully healed single edentulous sites and a full-thickness flap was raised. Sequential osteotomy following manufacturer's recommendations was done. Equi-crestal placement of implants followed by torquing using a manual wrench (35 Ncm) was done to achieve primary implant stability. ISQ values were recorded using RFA (Osstell, Integration Diagnostics, Göteborg, Sweden) using a transducer placed on the fixtures. Stimulation of the elements using a sinusoidal wave causes vibration of the beam. RFA values

are recorded as ISQ on a scale from 1 to 100. Implants could only be loaded immediately (within 48 h after implant placement) by means of a single provisional resin crown when their mean ISQ recorded was equal to or more than 60. A prefabricated titanium abutment was prepared and screwed on the implant followed by placement of a provisional resin crown (Protemp, 3M) on the abutment. Occlusion was carefully evaluated using articulating paper (40 μ) (Arti-Check micro-thin, Bausch, Nashua, USA). As these tear resistant papers are coated with blue ink on one side and red on the other, the same paper can be used to evaluate centric as well as eccentric contacts by alternating the two colors. In the IFL group (n = 30), only light static contacts during maximum intercuspation as compared to adjacent natural teeth were established wherein during centric contact adjacent natural teeth had heavier contacts as compared to the centric primary contact on the implant crown [Figures 1-4], and any undue overloading was avoided. In the INFL group (n = 30), no contacts during maximum intercuspation or during eccentric movements were left [Figures 5-8]. Hence, in INFL group there wasn't any contact between the rehabilitated implant crown and the antagonist tooth at all times, making the implant loaded nonfunctionally. Postprovisionalisation, oral hygiene maintenance instructions, anti-inflammatory drugs (ibroprofen 500 mg BD for 5 days) and antibiotic (amoxicillin 500 mg TDS for 5 days) were prescribed. All subject were recalled after 1 week for evaluation of surgical site and removal of sutures. The provisional crowns were left in place for a period of 6 months and subsequently replaced by PFM crown. At 3 months appointment, a fresh CBCT was recorded for each patient, in both groups, which was repeated again at 6 months appointment. Detailed radiographic evaluation was done at baseline, 3 months and 6 months. Thereafter, quantitative analysis of bone density was performed in both the groups using CBCT in three areas i.e., crestal, middle and apical region of implants.

Assessment of bone density

DICOM files obtained using software (CS 3D imaging) were used for bone density assessment of each subject.

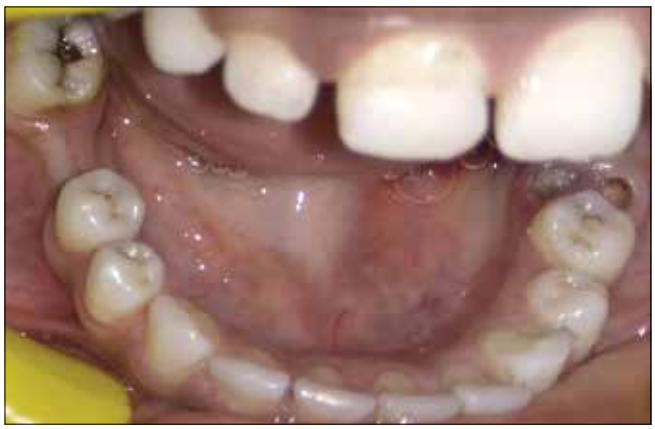


Figure 1: Preoperative photograph of immediate functionally loaded group

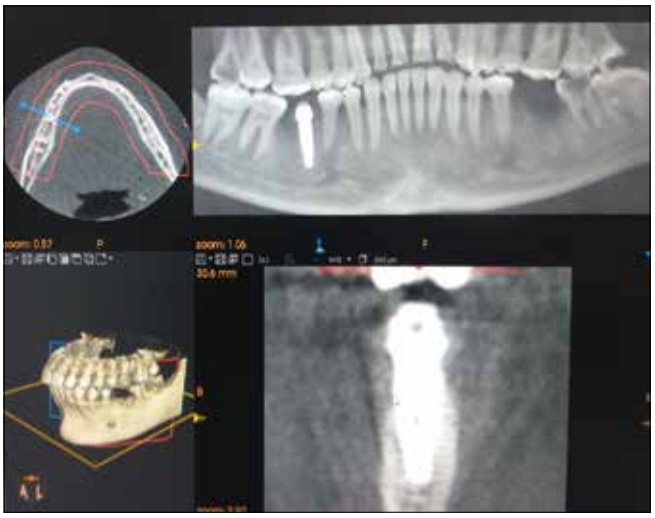


Figure 2: Preoperative assessment of bone by cone beam computed tomography

Figure 3: Clinical photograph with abutment

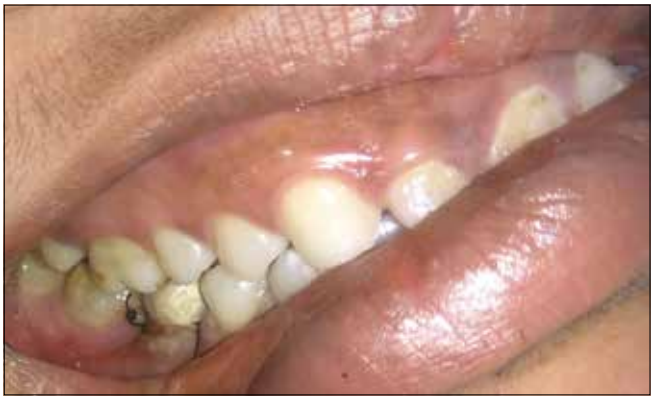


Figure 4: Clinical photograph with Prosthesis

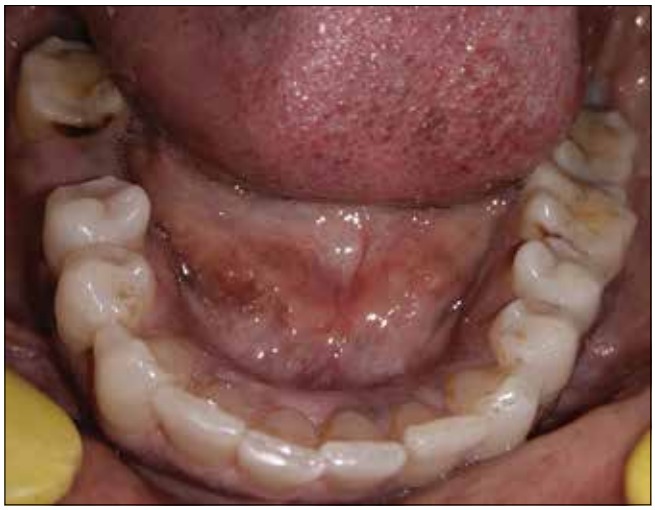


Figure 5: Preoperative photograph of immediate nonfunctionally loaded group

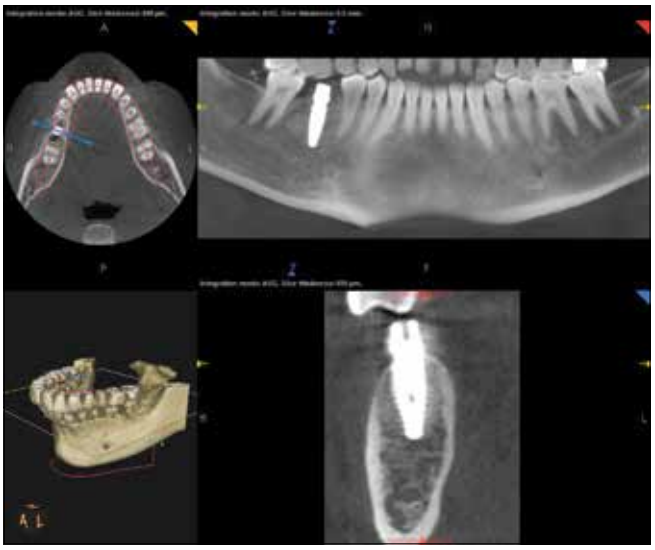


Figure 6: Preoperative assessment of bone by cone beam computed tomography

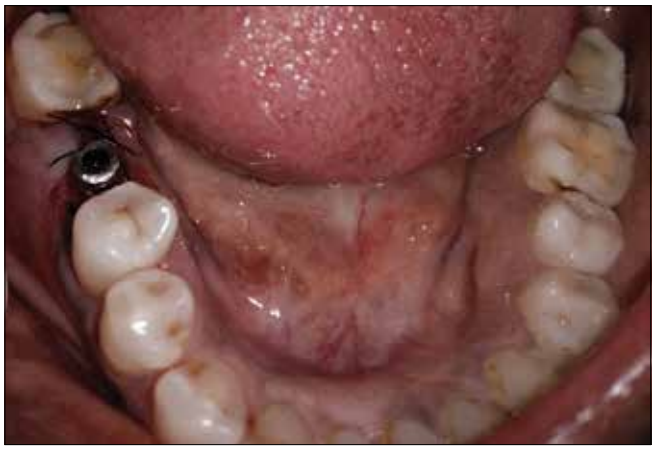


Figure 7: Clinical photograph with abutment

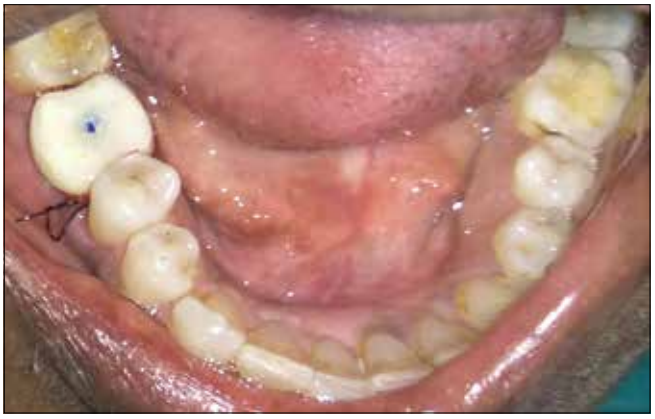


Figure 8: Clinical photograph with prosthesis

By moving the pointer from one region to another on the monitor, this software automatically provide the changes in the values in numbers. The values of the bone around each implant were measured in three areas around the implants at crestal, middle and apical region of implants.

Statistical analysis

The results were analyzed using descriptive statistics and making comparisons among various groups. Quantitative data was summarized as mean ± SD. Statistical analysis was done using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA) using unpaired *t*-test.

RESULTS

Implants in both groups were placed from January 2018 to January 2020. All data were recorded till July 2020. Baseline characteristics of two groups were statistically similar like gender, age, implant lengths and implant diameter and it did not affect the outcome of the present study.

Intragroup bone density measurements revealed that INFL group showed lesser bone density changes when compared to IFL group at the three levels i.e., crest, middle and apical, at the predetermined time intervals [Table 1].

Intergroup comparison of bone density changes at the crestal region showed significant differences at baseline to 3 months ($P < 0.001$) and 3–6 months ($P < 0.001$) [Table 2].

In the middle region the significant differences were found between both group from baseline to 3 months ($P < 0.001$) and 3–6 months ($P < 0.001$) [Table 3].

In the apical region significant differences were found between both group from baseline to 3 months ($P < 0.001$) and 3–6 months ($P < 0.005$) [Table 4].

Overall the significant differences were found between IFL and INFL group in bone density changes from baseline to 3 months ($P < 0.001$), 3 months to 6 months ($P < 0.001$)

with INFL group showing lesser bone density changes when compared to IFL group [Table 5].

DISCUSSION

In implant dentistry, starting from preoperative evaluation and examination to the actual surgical procedure to be followed and finally the prosthetic planning, including the loading protocol, the precise time of loading as well as the maintenance of the implant in the long run, is all dependent on the bone density.[11] The results of the present study stated that bone density was better maintained in INFL group when compared to IFL group. Therefore null hypothesis of the study was rejected. Bone density changes occurring during the course of this study were analyzed using 3D CBCT. Problems of projection geometry, superimpositions and total absence of the third dimension of bone depth, makes 2-D imaging not 100% accurate and reliable.[12,13] Hence, to improve the accuracy of bone density assessment, 3D CBCT was used in the present study.

Prosthetic restoration of an implant can be done either using conventional loaded protocol or immediate or early loaded protocol. Romanos *et al*. showed that following immediate loading of threaded implants, a bone-to-implant contact is established similar to that of conventionally loaded implants.[14-16] Also, immediate loading protocol reduces the overall treatment time as well as the cost, along with reducing the surgical exposures by eliminating second stage surgery. Hence, immediate loading approach has emerged as a more superior protocol with wide patient acceptance. Immediate prosthetic rehabilitation following implant placement can be accomplished either functionally or nonfunctionally.[17]

In the present study, subjects were divided into two groups on the basis of loading. Bone density was assessed at crestal, middle and apical region of the implant for both groups at periodic intervals of 0, 3 and 6 months postimplant placement and immediate rehabilitation. The CBCT measure of bone of implant in the both IFL group and INFL group showed decreased mean bone density at 3 months compared to baseline; however the mean bone density increased from 3 months to 6 months. The decrease in bone density at 3 months postimplant placement, in both groups, can be explained by formation of initial weaker and less mineralized woven bone after implant osteotomy. Thereafter, an increase in mean bone density values noted with both groups from 3 months to 6 months illustrates the conversion of less mineralized woven bone to highly mineralized and organized lamellar bone.[18] In the present study, significant bone changes have been observed at the apex after implant placement in both IFL and INFL groups. On intergroup comparison, the bone density in the apex region was found to be significantly reduced in IFL group compared to INFL group. This could be attributed due to the stress created by the immediate functional loading of the implant in IFL group used in the

Table 1: Mean bone density in the crestal, middle and apical region after implant placement in immediate functionally loaded and immediate nonfunctionally loaded group at predetermined time intervals

Timeline	Crestal	Middle	Apical
	IFL Group		
Baseline	1541.20±406.17	1438.05±400.29	1242.82±376.82
3 months	1227.02±422.10	1159.82±417.01	968.12±368.69
6 months	1421.40±389.97	1364.22±386.59	1159.40±362.85
	INFL Group		
Baseline	1507.00±427.00	1433.17±426.52	1237.62±406.83
3 months	1307.58±438.74	1239.22±433.36	1036.63±400.43
6 months	1413.13±427.48	1354.02±430.12	1178.52±407.17

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded

Table 2: Intergroup comparison of overall bone changes in the crestal region after implant placement between immediate functionally loaded and immediate nonfunctionally loaded group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	314.18±71.69	199.42±47.97	7.29	<0.001
3-6	−105.55±39.60	−194.38±75.30	5.72	<0.001

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

Table 3: Intergroup comparison of overall bone changes in the middle region after implant placement between immediate functionally loaded and immediate nonfunctionally loaded group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	278.23±70.17	56.91±10.39	5.11	<0.001
3-6	−114.80±41.46	−204.40±63.75	6.45	<0.001

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

Table 4: Intergroup comparison of overall bone changes in the apical region after implant placement between immediate functionally loaded and immediate nonfunctionally loaded group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	274.70±59.79	200.98±67.43	4.48	<0.001
3-6	−141.88±69.58	−191.28±62.33	2.90	<0.005

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

Table 5: Intergroup comparison of overall bone changes after implant placement between immediate functionally loaded and immediate nonfunctionally loaded test group

Timeline (months)	IFL±SD	INFL±SD	*t*	*P*
Baseline-3	289.04±69.03	198.12±57.41	9.61	<0.001
3-6	−120.74±53.75	−196.69±66.85	8.40	<0.001

IFL: Immediate functionally loaded, INFL: Immediate nonfunctionally loaded, SD: Standard deviation

present study.[19] Bone density changes in the apex postimplant placement is consistent with the study by Tavitian *et al*.[20] INFL group also showed lesser bone density changes in the middle region as compared to the IFL group at all times. Also, the crestal bone density changes was found to be significantly higher in the IFL group compared to INFL group. Stress concentration usually is highest at the crestal bone-implant interface.[21,22] The higher bone density changes at the crest in IFL group compared to INFL group can be attributed to increased crestal bone loss along with higher crestal bone demineralization seen with IFL implants.[23] Along with that, lateral forces exerted on IFL group may also be an attribute to the higher bone density changes as compared to INFL group where no contacts were present in the prosthesis.[24] Overall intergroup comparison of the IFL and INFL at all regions, showed significant differences in bone density changes from baseline to 3 months ($P < 0.001$) and 3 months to 6 months ($P < 0.001$) with IFL group showing greater bone density changes as compared to INFL group from baseline to 3 months (289.04 ± 69.03 and 198.12 ± 57.41 respectively) and 3 months to 6 months (-120.74 ± 53.75 and -196.69 ± 66.85 respectively). Immediately provisionalised implants have varying degrees of micromotion depending on their loading protocol; functionally or nonfunctionally. Lesser degree of change in bone density from baseline in INFL group compared to IFL group can be attributed to comparatively smaller micromotion in INFL implants than IFL implants.[25,26]

Limitation

- The sample size of both groups was small and study lack more reliable split mouth design
- Long term, multi-centric studies with larger sample sizes and a longer follow up period are suggested for future research
- The result of study should not be extrapolated for all type of implants.

CONCLUSIONS

Within the limitation of the present study, we concluded that INFL implant group showed lesser bone density changes when compared to IFL implant group and it was statistically significant. INFL implant improves the bone density of the patients. Bone density is one of the important factors affecting the overall success of treatment. Hence, quantification analysis of bone density is essential.

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Conflicts of interest

There are no conflicts of interest.

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Research

Comparison of patient satisfaction between complete dentures fabricated using "conventional" and "cephalometric angular reconstruction" vertical dimension procedures: A multicenter randomized clinical trial

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Abstract

Aim: In Prosthodontics, during complete denture fabrication, conventional methods employed to determine occlusal vertical dimension require patient co-operation. Hence, the aim of the present study is to evaluate the clinical effectiveness of the 'cephalometric angular reconstruction' procedure in the calculation of these lost dimensions.

Settings and Design: Multicentric randomised clinical trial conducted in four dental hospitals.

Materials and Methods: Fully edentulous people who came to the hospitals for complete denture treatment were recruited into the study. Those who fulfilled the inclusion criteria were randomly assigned to two groups; Group 1: Dentures fabricated using a 'conventional' procedure and Group 2: Dentures fabricated using 'cephalometric angular reconstruction'. The patient's level of satisfaction was assessed on a scale of 1 to 5; 1-dissatisfaction to 5-excellent. The confounding factors that can influence the satisfaction were also recorded.

Statistical Analysis Used: The distribution of patient's satisfaction was assessed using Chi-square test, whereas the difference between the two groups was evaluated using Mann–Whitney test.

Results: There was no significant difference either in the vertical dimension determined ($P = 0.465$) or the patient's level of satisfaction ($P = 0.943$) between the two groups. There was no influence of confounding factors considered in the present study on the satisfaction levels. There was no difference in the distribution of satisfaction levels based on the dentist's quality assessment ($P = 0.243$).

Conclusion: Complete dentures fabricated using cephalometric angular reconstruction procedure of vertical dimension determination were equivalent with respect to patient satisfaction, compared to those made using a conventional method. Hence, the new method can be clinically recommended during denture fabrication.

Keywords: Cephalometrics, complete dentures, occlusion, vertical dimension

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INTRODUCTION

The vertical dimension of occlusion (VDO) refers to the measurement in the vertical plane that establishes the relation between the maxilla and mandible when occluded.[1] It is of great biological importance as it plays a vital role in mastication, speech, appearance, and functioning of surrounding tissues.[2-4] In completely edentulous individuals, VDO is lost, and reconstituting the occlusal support is essential during prosthodontic rehabilitation. As the association between morphology and function is inseparable, an increase in this dimension prevents muscular relaxation, whereas a decrease causes over-relaxed musculature.[5-8] Hence, to avoid the disturbance in neuromuscular tone, precise measurement of VDO is essential. Many methods based on preextraction data, intra-oral measurements, profile tracing, rest position, swallowing, phonetic, neuromuscular perception, and craniometrics values are described in the literature.[5,9-14] Although there are many advances, clinical judgment based on experience alone is considered to play a significant role in the assessment of this important component during the construction of dentures. In routine clinical practice, the conventional technique of determining the vertical dimension at rest and positioning VDO to establish 2–3 mm of interocclusal rest space is employed. Another traditional technique based on anatomical landmarks and facial proportions is also used clinically. All these techniques require patient co-operation, and additionally, are extremely subjective. Hence, attempts were made to implement other standardized methods of calculating the lost facial dimensions.

In recent times, cephalometric analysis has gained much popularity in this field. Information pertinent to the role of cephalometrics in prosthodontic diagnosis, treatment planning, and prognosis is evident in the literature.[15-18] Many software programs are also being developed to calculate VDO using computer-assisted cephalometrics.[19,20] These methods are based on the skeletal landmarks that are not affected by edentulism.[21-29] The accuracy, and the reliability of angular and linear measurements and correlations, led to the development of regression equations.[30,31] In a study, based on multiple regressions, five angular and two linear cephalometric landmarks with weak to moderate positive and negative correlations were observed, yielding satisfactory results.[30] However, complexity is the major barrier to apply this technique clinically because most prosthodontists seldom use cephalometric techniques and analysis. To overcome this, an easy and simple method of cephalometric angular reconstruction that combines both the concepts of facial proportions and cephalometrics has been tested in contemporary dentulous individuals.[31] The positive results led to the framing of simple linear regression formulae. Thus, cephalometrics showed a lot of scope in this arena because of the positive observations in the preliminary studies.

The reconstructed VDO, in people with lost facial dimensions, influences the success of the prosthesis. This is because the tolerance, stability, esthetics, function, and phonetics of any prosthesis change based on the determined maxillomandibular relations. Hence, any deviation of the VDO affects all these aspects, in turn impacting the satisfaction of persons wearing these dentures. As there is no clinical trial that has compared the clinical effectiveness of determining VDO using cephalometric approach, the present multicentre randomised trial has been planned to determine the difference in the overall satisfaction of persons wearing complete dentures fabricated using "conventional" and "cephalometric angular reconstruction procedures."

MATERIALS AND METHODS

Ethical clearance

The present clinical trial is registered at the Clinical Trials Registry, India, with the registration number CTRI/2021/05/033585. A total of four dental institutes participated in the clinical trial. The institutional ethical committees of all the participating institutes approved the study protocol. The ethical approval number of the primary and leading center is IEC/NDCH/2020/P-48. Ethical approval numbers of other centers are PMNMDCH/1968/2020–21; Rc. No. 99/Academic/GDCH/Kadapa/2020; MDC_R_088429. Informed written consent was obtained from all the participants prior to screening for possible inclusion. All the participating investigators took part in an online meeting before the inclusion of the first patient to predefine and standardize the methodology and ensure uniform treatment outcome.

Trial design

This was a multicentre, parallel-group, equivalence, triple-blind trial with restricted randomization and an allocation ratio of 1:1 conducted in India (four centers).

Participants

All the participants attending the outpatient department of the four dental institutes (centers) were recruited based on the following eligibility criteria.

- Completely edentulous persons with Class I skeletal pattern (The Class I skeletal pattern was determined using the YEN angle, [Figure 1], which is based on the

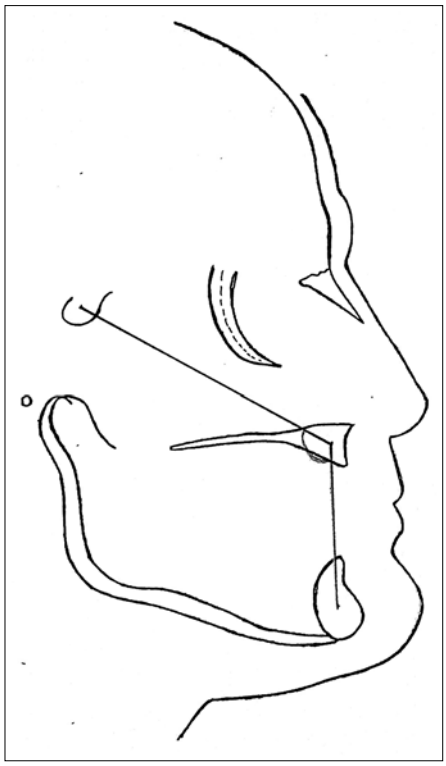

Figure 1: Yenn angle considered in the present study

landmarks midpoint of sella, the midpoint of premaxilla, and center of the largest circle that is tangent to the internal inferior, anterior and posterior surfaces of the mandibular symphysis, measured at the midpoint of the premaxilla. If this angle was between 117 and 123 degrees, it was considered as Class I skeletal pattern)
- Age range of 50–80 years
- Who gave their written informed consent to participate in the study.

Those with craniofacial malformations, facial asymmetries, or cleft palate were excluded from the study.

The study took place in the Departments of Prosthodontics in four dental institutions of India from December 2020 to June 2021.

Interventions

All the standard steps involved in the fabrication of complete dentures were followed for every participant, irrespective of the group. One postgraduate student in each center performed all the clinical procedures. In addition, they were trained and calibrated to determine the vertical dimension using either conventional or angular reconstruction procedures. That trained student recorded the vertical dimensions of all the participants in a centre. The details of the interventions for each group are mentioned below.

Group 1: The anatomical landmarks method was considered for determining the vertical dimension at rest. The Willis guide was used to measure the distance from the pupils of the eye to the rimaoris and the distance from the columella to the lower border of the mandible. When these measurements are equal, the jaws were considered at rest. Then, by establishing 2–3 mm of interocclusal rest space, the VDO was calculated.

Group 2: The cephalogram was obtained and placed on the view box with the patient's image facing the right. The four corners of the radiograph were taped to the view box. The matte acetate film was placed over the radiograph and taped securely to the radiograph and the view box. With a sharp 3H drawing pencil, the required reference landmarks, Nasion (N), Anterior Nasal Spine (ANS), Porion (P), and Gonion (G) were marked, as represented in Figure 2. These points were joined as shown in Figure 3 to form angles; N-ANS-G (by joining the landmarks N, ANS, and G) and P-G-ANS (by joining the landmarks P, G, and ANS). Then, using the formulae "N-ANS-Gnathion (Gn) (in degrees) =1.271 N-ANS-G (in degrees) +24.83" and "P-G-Gn (in degrees) = 0.987 P-G-ANS (in degrees) +35.93," the two angles were determined (where Gn is point Gn) and reconstructed on the tracing[31] [Figure 4]. The intersection of the two angles was marked as Gn [Figure 5]. The distance between ANS and the reconstructed point Gn was considered as the VDO in cephalogram [Figure 6]. The distance between N and ANS ($\dot{x}$); as well as ANS and reconstructed Gn ($\dot{y}$) was measured on the tracing [Figure 7]. The clinical distance between N and columella ($\dot{x}$) of the patient was measured, and using the formula $\dot{x}/\dot{y}$= x/y, the clinical distance between columella and Gn (y) was determined and considered VDO [Figure 7].

Immediately after insertion of fabricated complete dentures, all the participants were evaluated by respective investigators in each center. A questionnaire, which was divided into three parts, was used for assessing the outcome. In the first part, the dentist assessed the quality of the dentures; a rating scale of 1–5 was used, where 1-poor quality and 5-excellent quality. In the second part, the patients answered the questions regarding gender, age, level of education, marital status (married, divorced, single, or widowed), self-supporting lifestyle (1-ability to live by themselves, 2-supported by their families, and 3-able to live alone), smoking habits, period of tooth loss, and the number of previous complete dentures worn. In the third part of the questionnaire, patients rated their complete dentures, depending on the level of satisfaction. The patients rated using a scale ranging from 1 to 5 (where 1 – dissatisfaction and 5 – excellent).

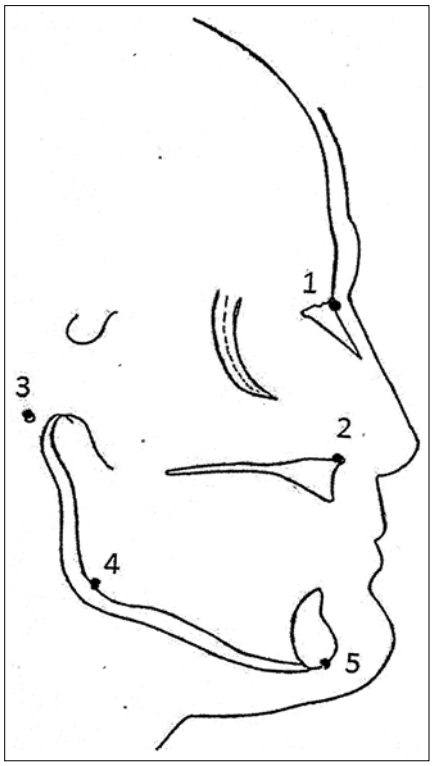

Figure 2: Landmarks considered in the present study; (1) Nasion; (2) Anterior Nasal Spine; (3) Porion; (4) Gonion; (5) Gnathion

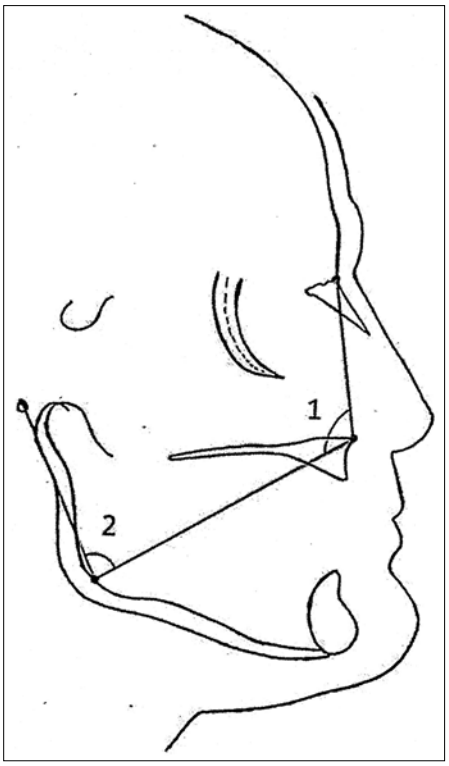

Figure 3: N-ANS-G and P-G-ANS (1) Angle formed between Nasion, Anterior Nasal Spine, Gonion (2) Angle formed between Porion, Gonion, Anterior Nasal Spine

Outcomes

The patient satisfaction on a scale ranging from 1 to 5 (1 – dissatisfaction to 5 – excellent) was considered the primary outcome measure. On the other hand, the dentist rating the denture quality from 1 to 5 (1 – poor quality and 5 – excellent quality) was considered the secondary outcome. There were no changes in the outcomes after the trial commenced.

Sample size

Based on the pilot study findings done on 12 participants (6 for each group), with 5% significance level and a power of 90%, considering patient satisfaction scale as the primary outcome measure, a sample size of 236 (118 in each group) was necessary. So, a final sample of 240 (120 in each group) was determined. To recruit this number of patients, a 6-month inclusion period was anticipated. No interim analysis was performed.

Randomization

The randomization was stratified by centers (four dental institutions) with a 1:1 allocation. Restricted randomization, i.e., block randomization was employed in the present study with multiple block sizes of 4 and 6. The table of random numbers was used to generate the random allocation sequence. Sequentially numbered opaque-sealed envelopes were used as mechanism for the allocation concealment. Determination of whether the participant should be given dentures using the conventional method or angular reconstruction procedure was done after enrolment, and initials steps of primary and secondary impressions, and fabrication of occlusal rims was completed. The appropriate numbered envelope was opened at the main center, and information given to other centers, during the jaw relation procedure. A professor in the main center (unrelated to the study) generated random allocation sequence, and assignment of participants to interventions. The enrollment of participants was done by the four investigators individually in their respective centers. The participants, the outcome assessors, and data analysts were blinded to the allocation.

Statistical analysis

The statistical analysis was carried out using SPSS 17.0 version for Windows (Chicago, III, USA). The level of significance was set at 0.05 level. Descriptive statistics regarding confounding factors like age, gender, level of education, marital status, self-supporting life style, smoking, period of tooth loss, and number of previous dentures worn was represented in number and percentage. The difference in the distribution of patient's satisfaction based on the various confounding factors considered was determined using Chi-square test. The difference in

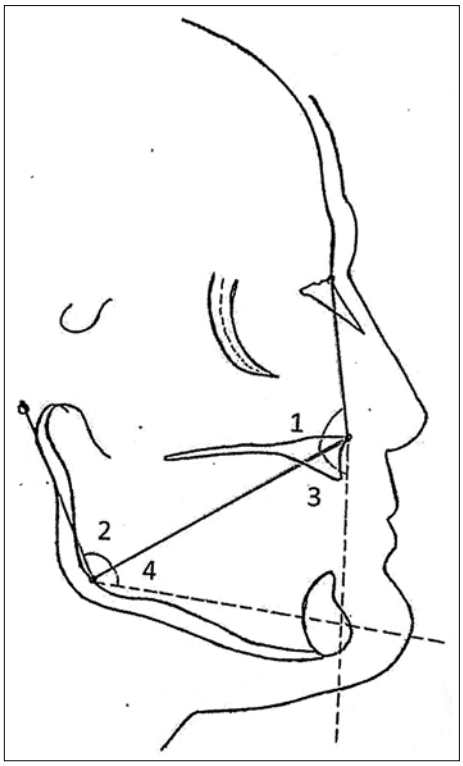

Figure 4: Determined angles N-ANS-Gn and P-G-Gn (1) Angle formed between Nasion, Anterior Nasal Spine, Gonion (2) Angle formed between Porion, Gonion, Anterior Nasal Spine (3) Angle determined between Nasion, Anterior Nasal Spine, Gnathion (4) Angle determined between Porion, Gonion, Gnathion

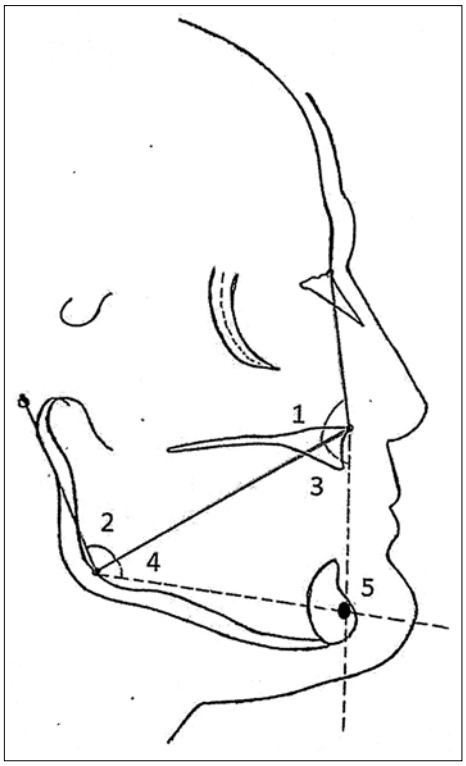

Figure 5: Reconstruction of point Gnathion

the distribution of patient's satisfaction based on center and dentist's assessment was tested using Chi-square test. The difference in the patient satisfaction scale between the two groups was assessed using Mann–Whitney test. The difference in the VDO between the two groups was assessed using unpaired *t*-test.

RESULTS

The details of the enrolment, number of participants who were randomly assigned to two groups, who received the intended treatment, and who were analyzed for the primary outcome is represented as a participant flow diagram [Figure 8]. The required number of participants could be recruited in the specified period of 6 months. The demographic characteristics of the participants are represented in Table 1. The mean age of the participants was 63.87 (range: 50–80), and among them, 136 were male and 104 females. The patient's level of satisfaction ranged from 3 to 5 (median: 4). The mean N-ANS-G obtained in the angular reconstruction group was 92.19 ± 3.54, whereas mean P-G-ANS was 89.53 ± 4.54. There was no significant influence of confounding factors on the level of satisfaction reported by complete denture wears [Table 2]. There was no

Table 1: Demographic characteristics of the participants *n*=240

	n (%)
Age (years)	
≤65	158 (65.83)
>65	82 (34.17)
Gender	
Male	136 (56.67)
Female	104 (43.33)
Level of education	
Illiterate	74 (30.83)
Primary school	61 (25.42)
Middle school	48 (20.00)
High school	27 (11.25)
Intermediate/diploma	22 (9.17)
Graduate	6 (2.50)
Professional degree	2 (0.83)
Marital status	
Married	221 (92.08)
Divorced	2 (0.83)
Single	5 (2.08)
Widowed	12 (5.00)
Self-supporting life style	
Ability to live by themselves	221 (92.08)
Supported by their families	14 (5.83)
Able to live alone	5 (2.08)
Smoking habit	
Yes	92 (38.33)
No	148 (61.67)
Period of tooth loss (months)	
≤12	125 (52.08)
>12	115 (47.92)
Number of previous dentures worn	
0	176 (73.33)
1	64 (26.67)

Represented as number (Percentage)

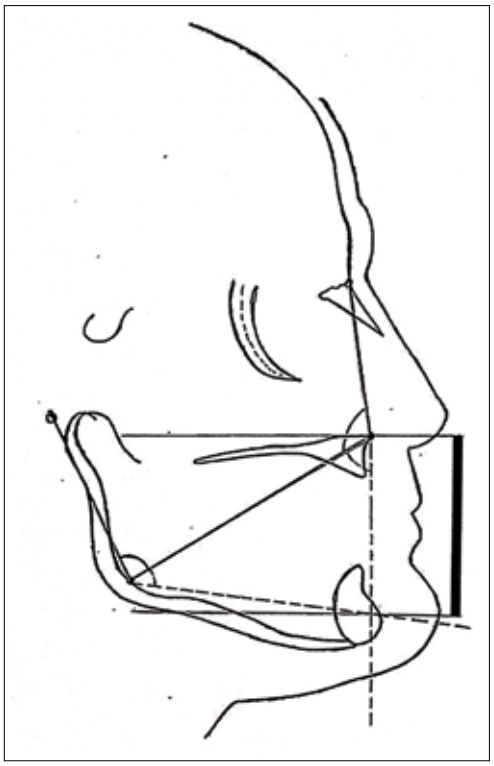

Figure 6: Reconstructed vertical dimension of occlusion in cephalogram

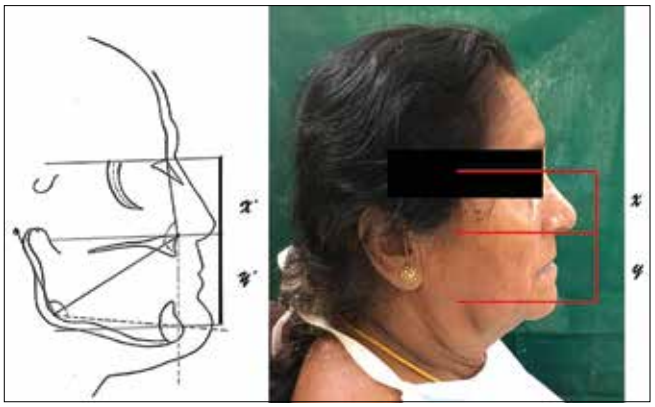

Figure 7: Clinical determination of vertical dimension of occlusion

difference ($P = 0.943$) in the patient's level of satisfaction between the conventional and angular reconstruction groups [Table 3]. Even, there was no influence of center on the difference in the level of satisfaction between the groups [Table 3]. The distribution of satisfaction levels based on dentist assessment also showed no significant difference ($P = 0.243$), which is depicted in Table 4. The VDO determined based on the two considered methods also showed no significant difference ($P = 0.465$), the details of which are represented in Table 5.

DISCUSSION

In recent times, prosthodontics has advancements in techniques and materials, but clinical steps for the determination of VDO could not evolve for preciseness. In edentulous people, because of the absence of posterior teeth, there will be a loss of VDO. The restored dimensions should be the same as probably what existed before the edentulous situation, as correct registration of VDO has biological importance.[2-6] However, the major problem with the existing methods is that the muscles controlling the mandible become tense when the mechanical recording devices are placed in the mouth. In addition, the physiological methods employed show variation in measurements between sittings and within the same sitting. Thus, failure in determining the VDO might cause many kinds of problems such as temporomandibular joint disorders, muscular dysfunction, atrophy, alveolar bone resorption, a trauma of soft tissue, disturbance in phonetics, esthetics, swallowing, and chewing.[6] Specifically, the VDO, if it is greater, causes trauma to supporting tissues, phonetic problems, disturbance in temporomandibular joint and esthetics, whereas low VDO decreases the masticatory efficiency and esthetics. So, proper establishment of VDO is important to improve the function and esthetics, and thus the patient's quality of life.[26] Measures to avoid indiscriminate increase or decrease in this value are important.

Standard measurement established through radiographic techniques and cephalometric analyses, which are easy, accurate, convenient, economical, and individualized, can be a useful additional tool in prosthodontics, if proved to be effective. A study reported maximum correlation between VDO inferior (lower facial angle from the G point to the ANS and the chin point) and the gonial angle.[27] The regression formulae derived in that study were encouraging in the field of Prosthodontics. Still, the major drawback was that the formulae proposed were based on a single cephalometric dimension that can influence the accuracy of the measurement. To surpass this, multiple regression equations derived by considering six angular and four linear cephalometric measurements were proposed.[30] However, for this, the dentist needs to invest more time in completing the analysis. Later, a simple cephalometric angular reconstruction method was tested on dentulous people and proved to be accurate.[31] The reconstruction of the facial dimensions through angles reported statistically significant positive correlations, which can be due to the fact that the human face follows precise dimensions. Hence, the present study was planned to determine the clinical effectiveness of the angular reconstruction method in edentulous people by comparing the satisfaction levels of people wearing complete dentures fabricated using the vertical dimensions predicted by cephalometrics to those with the conventional method. There was no difference

Table 2: Effect of confounding factors on complete denture wearer's level of satisfaction

	Level 3	Level 4	Level 5	*P*
Age (years)				
≤65	30 (19)	61 (38.6)	67 (42.4)	0.349 (NS)
>65	17 (20.7)	38 (46.4)	27 (32.9)	
Gender				
Male	24 (17.6)	57 (41.9)	55 (40.5)	0.682 (NS)
Female	23 (22.1)	42 (40.4)	39 (37.5)	
Educational level				
Illiterate	12 (16.2)	32 (43.2)	30 (40.6)	0.589 (NS)
Primary school	13 (21.3)	23 (37.7)	25 (41.0)	
Middle school	12 (25.0)	21 (43.8)	15 (31.2)	
High school	6 (22.3)	10 (37.0)	11 (40.7)	
Intermediate/diploma	3 (13.6)	11 (50.0)	8 (36.4)	
Graduate	0	1 (16.7)	5 (83.3)	
Professional degree	1 (50.0)	1 (50.0)	0	
Marital status				
Married	41 (18.6)	94 (42.5)	86 (38.9)	0.238 (NS)
Divorced	0	1 (50)	1 (50)	
Single	3 (60.0)	0	2 (40.0)	
Widowed	3 (25.0)	4 (33.3)	5 (41.7)	
Self-supported life style				
Ability to live by themselves	42 (19.0)	92 (41.6)	87 (39.6)	0.148 (NS)
Supported by their families	2 (14.3)	7 (50.0)	5 (35.7)	
Able to live alone	3 (60.0)	0	2 (40.0)	
Smoking habit				
Yes	18 (19.6)	35 (38.0)	39 (42.4)	0.681 (NS)
No	29 (19.6)	64 (43.2)	55 (37.2)	
Period of tooth loss (months)				
≤12	26 (20.8)	46 (36.8)	53 (42.4)	0.342 (NS)
>12	21 (18.3)	53 (46.1)	41 (35.6)	
Number of previous dentures worn				
0	33 (18.8)	72 (40.9)	71 (40.3)	0.785 (NS)
1	14 (21.9)	27 (42.2)	23 (35.9)	

Represented as number (Percentage). NS: Nonsignificant

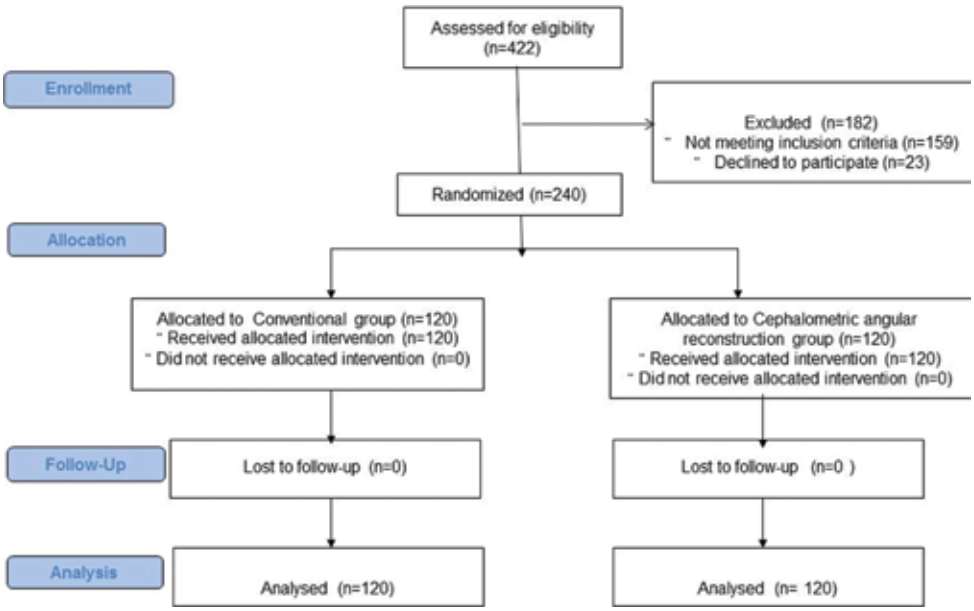

Figure 8: Participant flow diagram

either in the vertical dimension values determined as well as the in the satisfaction levels between the two groups. This shows that the angular reconstruction method can be employed clinically.

The famous artist Leonardo Da Vinci gave simple ratios for drawing the face, which was applied to complete denture construction by Ivy.[32-34] The facial dimensions follow simple proportions, and this concept of harmonic faces

Table 3: Complete denture wearer's satisfaction based on centre

Centre	Level 3	Level 4	Level 5	*P*
1	12 (20.0)	21 (35.0)	27 (45.0)	0.423 (NS)
2	9 (15.0)	23 (38.3)	28 (46.7)	
3	13 (21.7)	25 (41.7)	22 (36.6)	
4	13 (21.7)	30 (50.0)	17 (28.3)	
Group	**Mean±SD**	**Median**	**Range**	***P***
		Centre 1 (*n*=60)		
1	4.23±0.77	4	3–5	0.854 (NS)
2	4.26±0.78	4	3–5	
		Centre 2 (*n*=60)		
1	4.30±0.75	4	3–5	0.904 (NS)
2	4.33±0.71	4	3–5	
		Centre 3 (*n*=60)		
1	4.13±0.78	4	3–5	0.886 (NS)
2	4.17±0.75	4	3–5	
		Centre 4 (n=60)		
1	4.1±0.71	4	3–5	0.723 (NS)
2	4.03±0.72	4	3–5	
		Total sample (*n*=240)		
1	4.19±0.79	4	3–5	0.943 (NS)
2	4.20±0.78	4	3–5	

Represented as Number (Percentage). NS: Nonsignificant, SD: Standard deviation

Table 4: Cross tabulation of dentist assessment and wearer's level of satisfaction

Dentist/wearer	Level 3	Level 4	Level 5	*P*
4	10	31	33	0.243 (NS)
5	37	68	61	

Represented as Number (Percentage). NS: Nonsignificant

Table 5: Outcome measures considered in the present study

	Level		
	Level 3	**Level 4**	**Level 5**
	Group 1		
Weare's satisfaction	24	49	47
Dentist assessment	0	41	79
	Group 2		
Wearer's satisfaction	23	50	47
Dentist assessment	0	33	87
Vertical dimension of occlusion determined			
Groups	**Mean±SD**	**Range**	***P***
1	66.52±4.22	59.1-73.4	0.465 (NS)
2	66.91±4.11	59.1-73.1	

Represented as number. NS: Nonsignificant, SD: Standard deviation

can be utilized for the rehabilitation of lost dimensions. Research and clinical experience have revealed a close interdependence of facial proportions.[35-37] In the early stages of research, it has been observed that nasal height (N to ANS) accounts for 43% of the total facial height (N to Gn). In another study done on harmonious individuals, total facial height has been divided into 45% and 55% of nasal height and dental height, respectively. Later, in another study, the population has been divided into three facial types based on the growth pattern; normal, retrognathic, and prognathic. It has been observed that the upper facial height varied very little between the three facial patterns, whereas on the other hand, lower facial height has been found to be 56%, 59.5%, and 54.1% of total facial height in normal growth pattern, retrognathic and prognathic groups respectively. The proportion of middle and lower third the proportion of middle and lower third was proposed to be 0.8. Thus, the literature has proved a definite correlation between various facial dimensions, which led to the development of an instrument called a golden ruler. In another study, the face has been divided into four proportions and the ratio used for prosthesis construction. In the present study, for the conventional method of denture preparation, Willi's gauge was employed. The Pupil-rima oris distance has been considered to be equal to chin-nose distance, which is also based on facial proportions. That might be the reason for the similar vertical dimensions obtained in both methods. In almost all the cases, the level of patient comfort was satisfactory. This is the "comfort zone concept" that emphasizes VDO to be in a range instead of a fixed point.[38] Because of this adaptive capacity, small dispersions were acceptable and did not influence muscle activity. A study observed that the increase in VDO could change the extent of mandibular trajectory during swallowing only if the increase was more than 3 mm.[39]

The major drawback/limitation of cephalometrics is the need for a radiographic setup, which might not be available in all dental clinics, and additionally, the radiation exposure. Another drawback is the influence of racial differences[40] and the need to frame separate formulae for other populations based on the same theoretical principle. Thus, generalizabilty is a significant issue. However, there are many advantages of the angular reconstruction procedure considered in the present study. The landmarks selected were simple and could be marked easily. Using four cephalometric points, reconstruction of another point, Gn was done efficiently; there was ease in calculation, construction, and application. Angular variables were minimally affected due to problems of magnification and distortion when compared with the linear measurements. The patient's acceptability is another crucial factor in the success of this technique. Further studies on the clinical application of angular reconstruction procedure for partially edentulous people requiring removable partial dentures and dentate individuals undergoing orthodontic treatment are indicated. In addition, usage of radiographic markers for increasing the accuracy of transferring the cephalometric measurements to actual measurements is also indicated.

CONCLUSION

Based on the limitations of the present study, the cephalometric angular reconstruction procedure has been proved to be successful and can be suggested as an equivalent to standard methods of recording the VDO. It can be suggested as an alternative to patients with neuromuscular problems, those unable to co-operate for the conventional methods of recording the vertical dimension and in scenarios, which demand reduction of the time spent in contact with patients.

Registration

The study is registered at the Clinical Trials Registry, India, with the registration number CTRI/2021/05/033585.

Protocol

The full detailed protocol can be downloaded from the Clinical Trial Registry.

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Conflicts of interest

There are no conflicts of interest.

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Zygomatic implant-supported prosthetic rehabilitation of a patient with Brown *et al*. Class II c maxillary defect: A clinical report

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Abstract

The genesis of acquired maxillary defects poses a significant challenge when it comes to rehabilitating a patient prosthetically. These defects lead to functional and esthetic impairment, affecting the quality of life of an individual. This clinical report describes a satisfactory zygomatic implant-supported overdenture rehabilitation of a patient who underwent subtotal bilateral maxillectomy after an industrial accident. The result shows zygomatic implant-supported overdenture as a viable, predictable, and economical treatment option for a patient with an extensive maxillary defect.

Keywords: Attachments, maxillary defect, overdenture, zygomatic implant

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INTRODUCTION

After pathological ablation, chemical debridement, trauma, or failed reconstructions, a maxillary defect presents a significant challenge in reconstruction and prosthetic rehabilitation. Maxillectomy performed to excise the necrosed maxillary tissue leads to mastication, swallowing, speech, and esthetics problems.[1] The reconstructive or rehabilitation-based Brown and Shaw classification of maxillary defects divides the defect into vertical and horizontal components. The vertical component (I-IV) denotes the extent of unilateral defect, whereas the horizontal component (a-d) qualifies the extent of palate and alveolus involvement.[2] Several surgical reconstruction options, such as crestal onlay grafts, modifications of osteotomies with grafting, inlay grafting, and microsurgical revascularized flap, have been employed to reconstruct the maxillary defects. However, the surgical procedures are considered invasive; the results can be unpredictable and incomplete in rehabilitation.[1,3] In scenarios where reconstruction is not possible, prosthetic rehabilitation is the only way out.

In recent years, reconstruction with a combination of soft-tissue flaps and alloplastic implants, distraction osteogenesis, tissue engineering,[4] and rehabilitation with conventional obturators, two-piece obturators,[5] or implant-supported obturators[6] have been employed for the significant maxillary defects.

The prosthetic rehabilitation with zygomatic implants, introduced by Branemark System in 1988, presents

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a more straightforward approach in such complex situations. Zygomatic implants have been indicated in patients with atrophy of the maxilla, maxillary resection, complications after grafting procedures, congenital or acquired maxillary defects, and infeasibility to place conventional endosteal implants.[1,7,8] The length of available zygomatic implants varies from 30 to 52.5 mm and is either straight or angulated with an external hex connection. Zygomatic implant passes through the three or four layers of cortical bone providing stability and sufficient length for implant placement.[9] This clinical report demonstrates a satisfactory rehabilitation of a patient with Brown *et al*. Class II c maxillary defect with a zygomatic implant-supported overdenture.

CASE REPORT

A 32-year-old male patient was referred from the department of oral and maxillofacial surgery for the rehabilitation of a large maxillary defect after maxillectomy. The patient gave a history of an industrial accident that had led to the deposits of molten plastic in the oral cavity. The biopsy report confirmed avascular necrosis and osteomyelitis of the maxilla, for which, the patient underwent debridement of the necrosed maxillary tissue. The maxillary resection left a large bilateral maxillary defect and communication between the sinuses, nasal, and oral cavity.

Extraoral examination revealed severe loss of upper lip support, poor facial esthetics, nasal twang, and speech impairment. Intraoral examination showed bilateral loss of palate, maxillary alveolus, maxillary teeth, oro-antral, and oro-nasal communication [Figure 1].

The entity of the defect, the uncertain outcome of surgical reconstruction, and the economic constraints of the patient were taken into consideration. After a thorough clinical examination and cone-beam computed tomography (CBCT) evaluation, prosthetic rehabilitation with zygomatic implant-supported overdenture was proposed. The Blue-Sky Bio Software (Blue Sky Software, United States) was used to plan the implant's tentative angulation, diameter, and length. A free-hand surgical procedure was planned because of lack of supporting structure to stabilize a surgical template [Figure 2]. A vestibular incision was given to expose the body of zygoma and osteotomies were prepared on both zygomas. A bilateral Quad-zygoma-implant configuration was modified to the placement of zygomatic implants 45 degrees (32.5 mm × 4 mm) (Branemark System Zygoma, Noble BioCare, Switzerland), 2 on the right and 1 on the left side due to the lack of insufficient malar bone and torque achieved on the left side.

Multiunit abutments (Nobel Zygoma, Noble BioCare, Switzerland) were connected to the implants after 3 months. An open tray definitive impression with polyvinylsiloxane impression material (GC-Flexceed®, GC, India) was made and poured in Type IV gypsum (Kalabhai Kalstone, Kalabhai Karson, India) [Figure 3 left and right]. A circular anteroposterior bar was planned to splint all the implants together for the distribution of load cross-arch stabilization of the prosthesis along with burn out Preci-clix plastic 2.25 mm male PA attachments (CEKA Preci-Line, Belgium) to aid in the retention. To verify the design, a mock-up pattern resin framework with attachments was tried intraorally [Figure 4a]. The verified assembly was cast into a rigid metallic framework and checked intraorally as well as radiographically [Figure 4b left and right]. The wax occlusal rims were fabricated on the record bases for the interocclusal record, teeth arrangement, and trial were done to verify function [Figure 5], esthetic, and phonetics. The standard

Figure 1: Intraoral examination

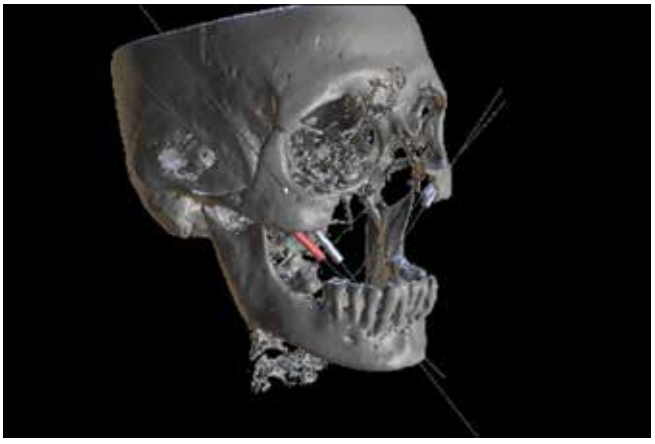

Figure 2: Treatment planning with Blue Sky Bio Software

protocol for maxillary complete denture fabrication was followed and acrylized with embedded CEKA Preci-clix female attachments, (CEKA Preci-Line, Belgium) on the denture intaglio surface [Figure 6a]. The finished and polished maxillary overdenture was inserted [Figure 6b]. The prostheses demonstrated optimal retention and stability during speech and mastication. The patient's response was satisfactory concerning speech, swallowing, mastication, and esthetics [Figures 7 and 8]. Postinsertion instructions were given, emphasizing insertion, removal, and hygiene of the prosthesis.

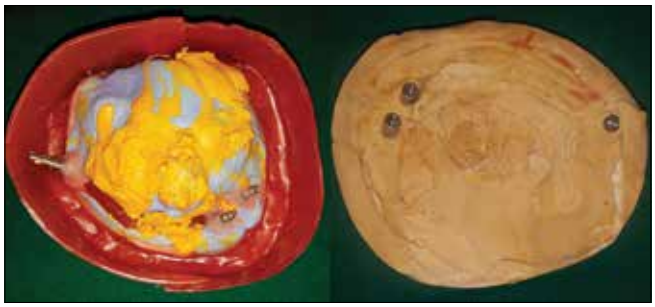

Figure 3: Definitive impression and master cast

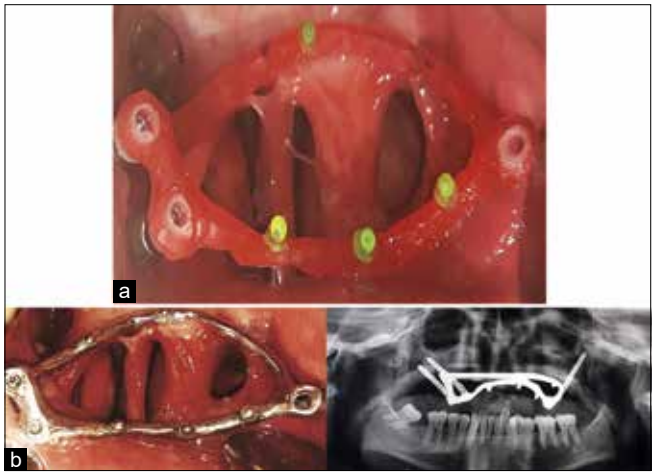

Figure 4: (a) Mock-up framework with PRESICLIX male attachments (b) Cast metallic framework with attachments (intraoral and radiograph)

Figure 5: Intraoral trial of prosthesis after teeth arrangement

DISCUSSION

The acquired maxillary defect, unlike congenital defects, leads to abrupt physiological and cosmetic changes. The quantity of tissue resected leads to functional, emotional, and social impacts on the patient. Various reconstruction and prosthetic rehabilitation options are available with their own set of merits and demerits.

Surgical reconstruction is often associated with postoperative morbidity, multiple revision surgeries, and unpredictable outcomes[1,9] and still warrants the removable prosthesis to restore the dentition and function.

The rehabilitation of Brown and Shaw[2] maxillary defects with the vertical component (II-IV) and the horizontal component (b-d) limits the feasibility of the conventional approach with obturator prosthesis, mainly due to the lack of supporting structures. The limitations of surgical reconstruction and impracticality of rehabilitation with conventional obturator designs, the plan to rehabilitate the patient with Brown *et al*. Class II c was paved with zygomatic implant-supported overdenture.

Zygomatic implants, introduced by Branemark, are indicated in patients with the atrophic maxilla, congenital defects, who have undergone maxillary resection, and bone grafting procedures are not feasible. The two main design configurations[7] for the use of zygomatic implants are (1) two zygomatic implants, one on each side bilaterally with two or more endosteal implants in the anterior maxilla and (2) "Quad approach" advocates two zygomatic implants on each side bilaterally in the posterior maxilla.[3] The clinical scenario in discussion presented a lack of anterior axillary bone, and therefore, the "Quad approach" configuration was planned. The CBCT evaluated showed insufficient zygomatic bone on the left side for the placement of two implants. Hence, the approach was modified by placing a single zygomatic implant on the left and two zygomatic implants on the right side.

The implants were splinted together to distribute the load and prevent overload of a single zygomatic implant on the left side.[1] The vast extension of the palatal defect limits the use of a single cross arch bar, and therefore, an anterior circular bar was milled to achieve the stability of the planned prosthesis.

The attachment systems available aid in the retention of the prosthesis. CEKA Preci Clix[10] is a stud type attachment system with a small head male attachment (2.25 mm Φ). Unlike Hader bar and clips, this attachment system requires

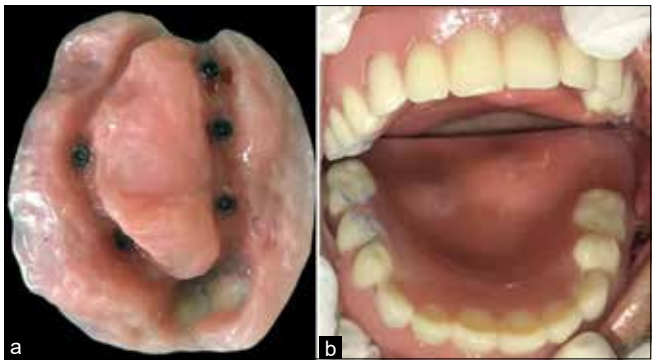

Figure 6: (a) Intaglio surface of overdenture with embedded female attachments (b) palatal view

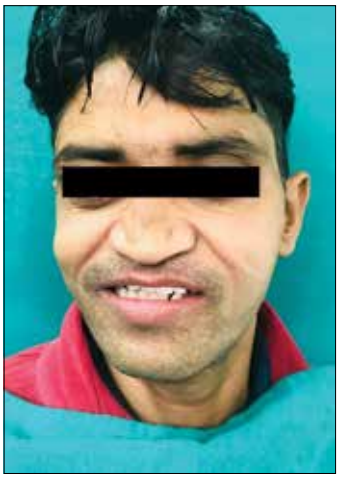

Figure 7: Frontal view (after prosthesis insertion)

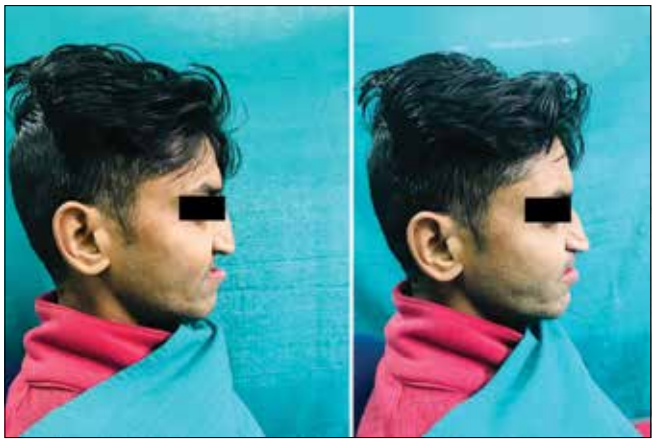

Figure 8: Profile view (before and after prosthesis insertion)

only 4 mm of the vertical space. The small head size and limited vertical space requirements allowed the sufficient bulk for the planned overdenture prosthesis and limited the risk of fracture of acrylic material. In addition, the female attachment allows better retention (yellow 2.5 lbs) and engages all around the male, thus increasing the area of retention. The sectional cuts provided in the female attachment allow greater flexibility and compensated for nonparallel male attachments on zygomatic implants. However, the female attachments are subjected to wear and may require replacement in future. The casting of the entire assembly with male attachments ensured rigidity, enhanced retention and was economical to the patient.

Opting for a zygomatic implant-supported overdenture with customized framework design makes hygiene maintenance and access much easier for the patient. Therefore, this approach represents a promising and adaptable treatment option to rehabilitate the large maxillary defects.[1,3]

SUMMARY

The presented treatment demonstrates an interdisciplinary approach for a maxillectomy patient. Zygomatic implants constitute a practicable and predictable approach for supporting a removable prosthesis in patients with the resected maxilla. This option is proven to be a better alternative to osseo-cutaneous flap surgery with endosseous implant-supported obturator in terms of retention, support, function, and esthetics. Thus, zygomatic implant-supported overdenture renders an efficient and economical approach in patients with large or subtotal maxillectomy defects.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the journal. The patient understands that his name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Fixed screw-retained interim restorations with immediate implant placement in esthetic zone: A case series with six different techniques

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Abstract

Postextraction immediate implant placement in the esthetic zone is a common treatment modality. Immediate fixed interim restoration following immediate implant placement may provide excellent esthetic results to the patients and boost the clinicians' confidence. This paper demonstrates a series of six different techniques used to fabricate the customized screw-retained interim restorations following immediate implant placement with partial extraction therapy in the maxillary anterior esthetic zone. The techniques have utilized a putty index, polycarbonate shell crown, patients' existing crowns (prosthetic or natural), or laminate veneer, or fabricated in the laboratory based on the specific clinical situation. Advantages and limitations of each technique including alternative techniques or materials have been discussed. Excellent esthetic results were obtained with all six techniques using the screw-retained immediate interim restorations following partial extraction therapy and immediate implant placement.

Keywords: Immidiate implant, implant esthetics, interim restoration, provisional restoration

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INTRODUCTION

Postextraction immediate implant placement in the esthetic zone has gained popularity amongst clinicians as it boosts patient satisfaction to a greater extent.[1,2] Advanced periodontitis, unrestorable caries, fractures, and traumatic injuries are the common reasons of immediate extraction of the maxillary anterior teeth. In any of these clinical situations (especially in traumatic injuries) the unsalvageable tooth or teeth usually required to be extracted. This may give tremendous psychological trauma to the patients, especially if it is in the esthetic zone (maxillary or mandibular anterior region). Such clinical situations need urgent replacement of the missing tooth/teeth. Immediate dental implant placement following extraction of such unsalvageable tooth/teeth is not a new concept and many clinical techniques and procedures have been well evidenced.[1,2] The advantages of single surgical procedure, that minimizes the overall treatment time, have encouraged clinicians to immediately

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insert the implant fixtures into extraction sockets.[1] However, various risk factors which may compromise the predictability of the esthetic results should be assessed in detail before commencing treatment procedures.[2] Sometimes, significant tissue alterations could be observed at the surgical site which compromises clinical outcomes.[3]

Immediate implant placement with immediate fixed interim restoration in the esthetic zone results in excellent short-term treatment outcomes in terms of implant survival and minimal change of peri-implant soft- and hard-tissue dimensions.[4] The volumetric facial contour changes of immediately placed implants with and without immediate interim restorations were studied in 40 participants and concluded that the restorations showed better volume preservation in the esthetic zone at 1-year follow-up.[5] Another similar study compared facial mucosal levels with and without immediate interim restorations and concluded that mid-facial mucosal marginal level and papilla height changes were minimal within groups, and no significant differences were found between the two groups.[6] A systematic review was carried out on four studies with immediate implant placement, five studies with immediate implant restoration, and four studies with immediate loading.[7] The authors concluded that immediately placed, restored, or loaded single-tooth implants in the esthetic zone result in similar hard and soft tissue changes compared with conventional protocols.

There are mixed results in the literature regarding the short-term and long-term peri-implant soft- and hard-tissue changes after immediate fixed interim restorations following immediate implants. Although postextraction bone remodeling will occur irrespective of the timing of the implant placement, the time saved with immediate placement and fixed immediate restoration indicated the attractive treatment option with high subjective and professional overall satisfaction.[1,2,8] Despite the satisfactory option, the maxillary anterior region still presents a challenge for clinicians because of the inherent difficulties encountered in the interim restorations and harmonious incorporation of the definitive prosthesis into patient's dentogingival complex.[9] The maxillary ridge has facial cortical bone that is more vulnerable to resorb as compared with the mandibular facial cortical bone because of the inherent difference in the bone density and the bone resorption pattern. Surgical and restorative techniques that can reduce the loss of hard and soft tissues that often accompany implant placement are desirable. The use of a customized interim restoration will provide a mechanism to assist the clinician in achieving the preservation of hard and soft tissue.[10]

Different techniques have been demonstrated for single unit immediate interim restorations using resin materials[10] or patient's own crown.[11] This paper demonstrates a series of 6 different techniques used to fabricate customized screw-retained interim restorations following immediate implant placement in the maxillary anterior esthetic zone. The techniques have utilized a putty index, polycarbonate shell crown, patients existing crowns (prosthetic or natural), or laminate veneer or fabricated in the lab based on specific clinical situation.

TECHNIQUES

Six different techniques in six different patients have been described for fabricating a fixed screw-retained interim restorations onto the immediate implants placed in the fresh extraction sockets in the maxillary anterior esthetic zone. All patients were treated by partial extraction therapy (also known as the socket-shield technique).[12,13] All implants had achieved optimal primary stability of more than 35 NCm to place immediate restorations which was measured with an adjustable torque-wrench (BioHorizons) during the surgery. All crowns were kept out of functional occlusion (in both centric and eccentric occlusion) by 32 μm using multi-layered shim-stocks to avoid premature overloading during the osseointegration period.

Technique 1: putty index and bis-acryl resin

A 35-year-old woman reported with a history of repeated dislodgement of her prosthetic crown on the maxillary right central incisor. The tooth was endodontically treated 17 years ago and had a postcore and crown restoration. The clinical and radiographic examination revealed that the tooth was unrestorable and was indicated for extraction. A polyvinyl siloxane putty index (Affinis; Coltene) was fabricated with the existing crown that was anatomically intact before the extraction [Figure 1a]. Partial extraction therapy followed by an immediate 4.2 mm × 15 mm sized tapered implant (BioHorizons) placement was carried out under local anesthesia. A screw-retained polyetheretherketone (PEEK) based interim abutment was placed on the implant [Figure 1b] and the hole was created in the putty index corresponding to the abutment screw access hole [Figure 1c]. The abutment screw access hole was closed with the Teflon tape and an interim abutment was picked up using a Bisacryl resin (Protemp 4; 3M ESPE) [Figure 1d]. The interim abutment was then attached to the laboratory analog and flowable composite resin (Z350 XT Flowable, 3M ESPE) was added to fill up the voids and the emergence profile was shaped using composite finishing kit. The interim restoration was finished and polished [Figure 1e] and screwed onto the implant [Figure 1f].

Technique 2: polycarbonate shell crown with bis-acryl resin

A 27-year-old woman reported with a history of trauma, leading to a fracture of her right maxillary central incisor [Figure 2a]. The root of the fractured tooth was removed with partial extraction therapy and a 3.8 mm × 15 mm sized tapered implant (BioHorizons) was placed. A PEEK-based interim abutment was placed [Figure 2b]. The polycarbonate shell crown (3M ESPE) of the most appropriate size was selected from the available stock [Figure 2c] and tried over the abutment for possible adjustments and fitting. The crown was perforated so that interim abutment popped out through it. An abutment-screw access hole was closed with a Teflon tape and a Bisacryl interim material (Protemp 4; 3M ESPE) was filled inside the polycarbonate crown and some of the material was injected over the abutment to prevent voids. Alternately flowable composite resin can be used and cured through the shell crown. The screw was loosened completely to retrieve the interim crown. After polymerization, the excess resin that leaked out of the crown contour was trimmed off. The voids were filled-up with flowable composite resin [Figure 2d]. The restoration was finished and polished using composite finishing and polishing discs (Soflex, 3M ESPE) [Figure 2e] and the interim crown screwed onto the implant [Figure 2f].

Technique 3: prosthetic (all ceramic) crown conversion

A 55-year-old man reported with a dislodged prosthetic crown on the maxillary left canine [Figure 3a]. The tooth was endodontically treated 12 years ago and restored with an all-ceramic Lithium-Disilicate (IPS e. max) crown. Since the remaining tooth structure was nonrestorable, the tooth was removed with partial extraction therapy and 4.2 mm × 15 mm sized tapered implant (Biohorizons) was placed immediately. The PEEK interim abutment was placed on the implant [Figure 3b] and the crown was adjusted and perforated corresponding to the abutment screw access hole [Figure 3c]. The abutment was then picked up with Bisacryl resin (Protemp 4;

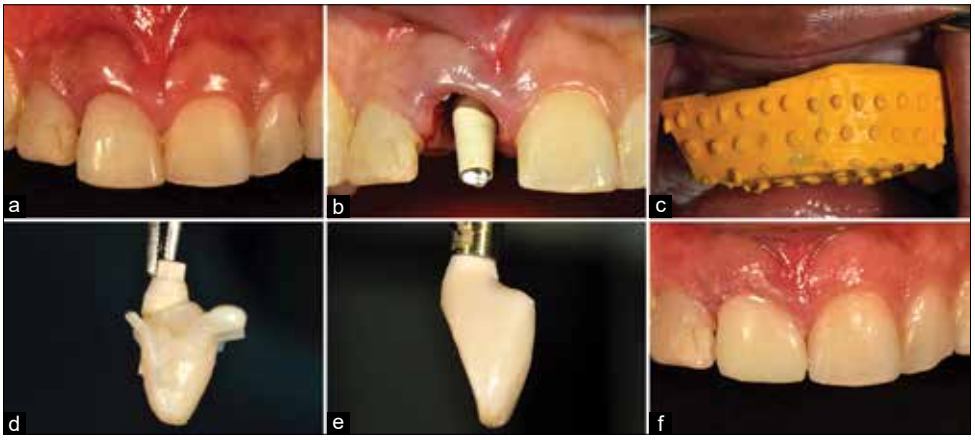

Figure 1: (a) Pretreatment view of the patient. (b) Immediate implant placed along with screw-retained polyetheretherketoe interim abutment. (c), Pick up of crown with putty index. (d), Picked-up unfinished crown. (e), Finished and polished crown. (f), Posttreatment view

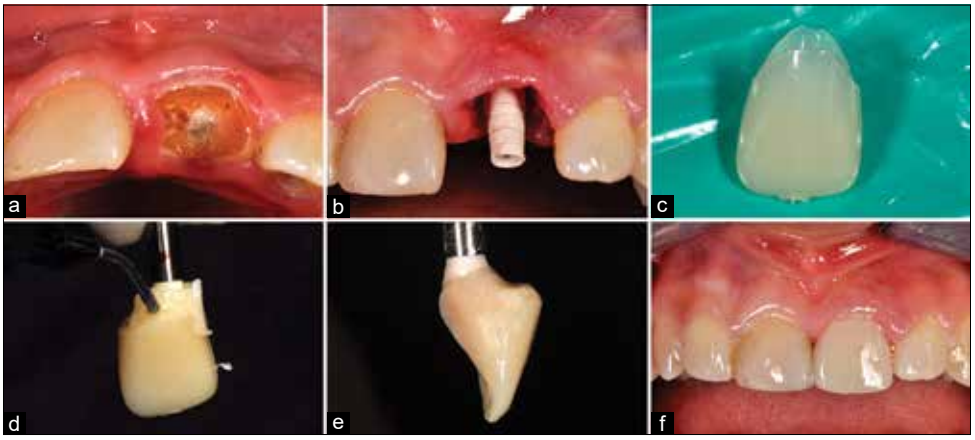

Figure 2: (a), Pretreatment intraoral view indicating fractured tooth at the gingival level. (b), Immediate implant placed along with screw-retained polyetheretherketoe interim abutment. (c), Polycorbonate shell crown for pick up. (d), Picked-up unfinished crown. (e), Finished and polished crown. (f), Posttreatment view

3M) as described in technique 3 [Figure 3d and e]. The finished and polished crown was screwed onto the implant [Figure 3f].

Technique 4: laminate veneer conversion

A 42-year-old woman reported with a veneered tooth that was fractured at gingival level during a car accident [Figure 4a]. The Lithium-Disilicate (IPS e.max) veneer was intact. Since the tooth was nonrestorable, the partial extraction therapy was carried out with the remaining root and 4.2 mm × 15 mm sized tapered implant (BioHorizons) was placed immediately in the socket. A PEEK interim abutment was placed over the implant [Figure 4b]. The veneer was carefully separated from the bonded tooth by trimming the tooth portion from the palatal aspect using the diamond rotary instruments [Figure 4c] and positioned onto the interim abutment. The height of the abutment was trimmed to accommodate the veneer [Figure 4d]. The intaglio surface of the veneer was sequentially treated with hydrofluoric acid etchant, the silane coupling agent, and the bonding agent in conventional manner. The abutment screw access hole was closed with Teflon tape and the flowable composite resin (Z350 XT Flowable, 3M ESPE) was injected in the gap between the veneer and the abutment and on the palatal side of the abutment. The flowable composite resin was light polymerized and the whole interim crown was unscrewed and placed on the laboratory analog [Figure 4e]. The excess resin was trimmed off, finished, and polished [Figure 4f] and the crown was screwed onto the implant [Figure 4g].

Technique 5: natural crown conversion

A 46-year-old male visited with a concern of traumatic injury to anterior teeth resulted in the fracture of his maxillary right central incisor at gingival level and partial fracture of left central incisor [Figure 5a]. Since the rest of the root portion of the right central incisor was nonsalvageable, the partial extraction therapy was carried out followed by immediate 4.2 mm × 15 mm sizes tapered implant placement (BioHorizons). The Titanium interim abutment was placed [Figure 5b]. The broken natural crown was trimmed from the palatal aspect to keep the facial surface intact [Figure 5c] and positioned in relation to the interim abutment. The height of the abutment was trimmed to accommodate

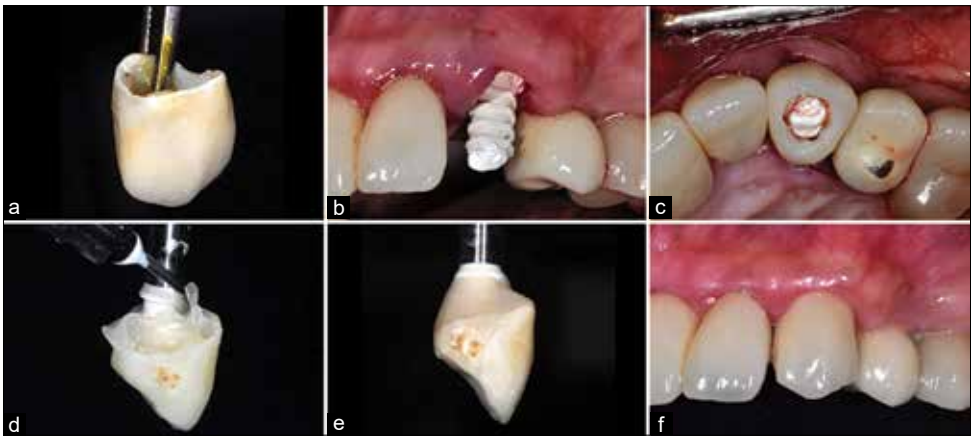

Figure 3: (a), Patient's dislodged all-ceramic crown. (b), Immediate implant placed, and screw-retained polyetheretherketoe interim abutment adjusted to fit the crown. (c), All ceramic crown adjusted and perforated for abutment screw access. (d), Minor modifications done on the picked-up unfinished crown. (e), Finished and polished crown. (f), Posttreatment view

Figure 4: (a), Pretreatment intraoral view indicating fractured tooth at gingival level. (b), Immediate implant placed along with screw-retained polyetheretherketoe interim abutment. (c), Patient's laminate veneer. (d), Veneer and interim abutment adjusted. (e), Picked-up unfinished crown. (f), Finished and polished crown. (g), Posttreatment view

the crown [Figure 5d]. The crown was sequentially treated with a phosphoric acid etchant and a bonding agent and subsequently picked up along with the interim abutment using flowable composite resin similar to technique 4 [Figure 5e]. After finishing and polishing [Figure 5f], the interim crown was screwed onto the implant [Figure 5g].

Technique 6: laboratory fabricated or indirect

In situations, where the patient can wait for couple of days to receive fixed interim restoration or already using removable partial denture, a laboratory fabricated interim restoration can be planned. The maxillary right central incisor of a 65-year-old male was fractured at the cervical level [Figure 6a]. The root was removed with partial extraction therapy and an implant (Biohorizons) of size 4.2 mm × 15 mm was placed immediately in the socket [Figure 6b]. A closed tray (alternately open tray can be used) impression of the implant was made [Figure 6c]. The final stone cast was fabricated, and an interim crown was fabricated with composite resin in the laboratory [Figure 6d]. The interim crown was screwed onto the implant [Figure 6e].

DISCUSSION

All the screw-retained interim restorations were replaced with functional definitive restorations after 4–6 months of osseointegration period. All provisional crowns revealed esthetically pleasing peri-implant mucosal contour without any clinically evident difference between any 2 techniques [Table 1]. Even though all patients were treated by partial extraction therapy,[12,13] the restorative techniques remain the same for conventional extraction and immediate implants placement (with or without bone grafts). The advantages and limitations of each technique are summarized in Table 1. Anterior tooth extractions typically require the execution of single-unit prostheses using composite resins or polymers like Bisacryl resins. In the first technique, the putty index was used to copy the external surface form of the crown. In situations of damaged crown structure, a waxed-up cast can be used to prepare the index. The use of thermoformed sheet can be another alternative option for the putty index [Table 1]. However, it needs an extra step of fabrication of a stone cast for the adaptation of the thermoformed sheet. The second technique utilized a polycarbonate shell

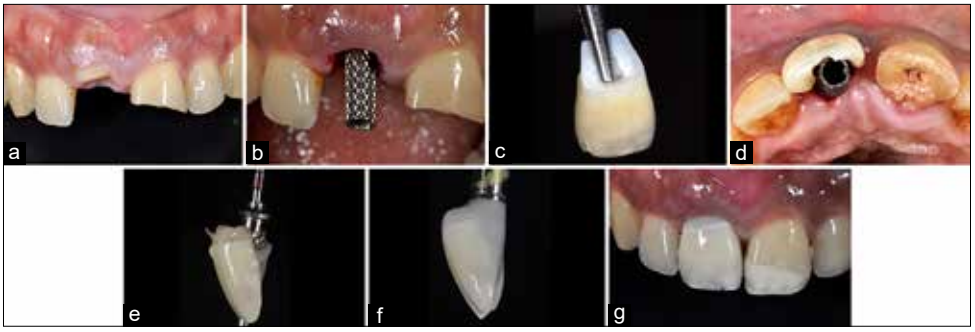

Figure 5: (a), Pretreatment intraoral view indicating fractured tooth at the gingival level. (b), Immediate implant placed along with screw-retained interim abutment. (c), Coronal portion of patient's fractured natural tooth. (d), Natural crown portion and interim abutment adjusted. (e), Picked-up unfinished crown. (f), Finished and polished crown. (g), Posttreatment view

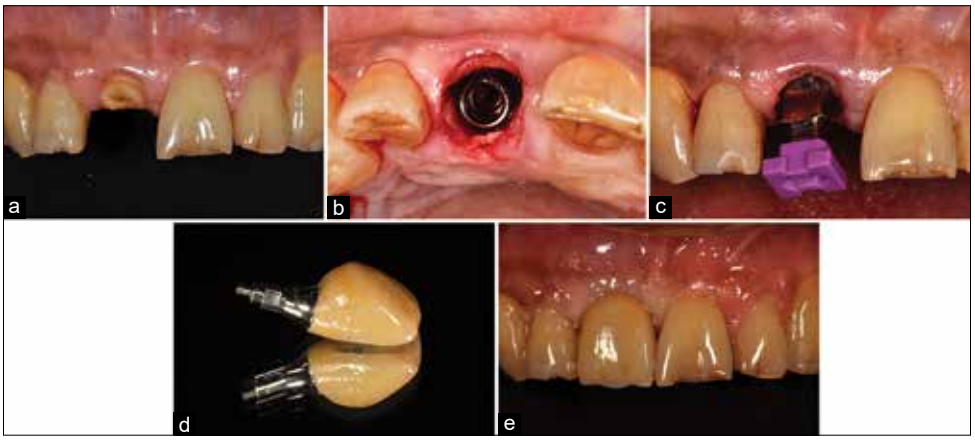

Figure 6: (a), Pretreatment intraoral view indicating fractured tooth at the gingival level. (b), Immediate implant placed. (c), Impression coping placed. (d), Finished and polished crown fabricated completely in lab. (e), Posttreatment view

Table 1: Different techniques used to fabricate interim restorations onto immediate implants with their alternatives, advantages, and limitations

Techniques used	Alternative techniques or materials	Advantages	Limitations
Technique 1: Putty index and Bisacryl resin		Quick	No visibility during pick up of interim restoration Need waxed-up cast if tooth anatomy not intact
	Thermoformed template	Transparent with good visibility during pick up of interim restoration	Need duplicated cast to adapt the thermoformed sheet
Technique 2: Polycarbonate shell crown with Bisacryl resin	With flowable composite resin	Quick Varieties of sizes and shapes available Well finished and polished surface	Need to keep in stock Need careful finishing
	Cellulose-acetate crown forms	Quick	Need to keep in stock Limited sizes or shapes available
Technique 3: Prosthetic crown conversion		Esthetic Quick	Limited to the specific patient who need extraction of tooth with prosthetic crown
Technique 4: Laminate veneer conversion		Esthetic Quick	Limited to the specific patient who need extraction of tooth with the veneered crown
Technique 5: Natural crown conversion		Esthetic Quick	Limited to specific patient who needs extraction of tooth with natural crown
Technique 6: Lab fabricated or Indirect		Reduced chair time Well-formed, finished, and polished restoration	Need additional impression procedure Cannot be immediately restored need to wait for consuming Lab cost involved

crown, available in stock. Alternately transparent flexible Cellulose-Acetate crown forms can be used. These crown forms need to be removed after polymerization.

The resin-based interim restorative materials, however, may not always provide promising esthetic results. Use of patient's original crown portion, (natural crown or restored either with prosthetic crown or laminate), if can be used, may provide good esthetic results as the original tooth shape and color is maintained.[11] This may also boost the patient's confidence. The use of coronal portions of patients' original teeth has been utilized for immediate implant interim restorations in technique 3 (with all-ceramic crown), technique 4 (with veneered crown), and technique 5 (with natural crown). Excellent esthetic results were achieved, and patients left home with their own original coronal portion fixed onto the implants. In some clinical situations, the patient can return for the interim restoration within 24–72 h after surgery and thus, the laboratory fabricated interim restoration can be planned. The laboratory fabricated interim crown was described in technique 6 that has provided excellent esthetic results [Figure 6e].

The alternative options to the fixed interim restorations could be any of the following including the removable partial dentures, Essix retainers, or bonding the resin-tooth to adjacent teeth. However, to maintain the hard and soft tissue form and esthetics, fixed interim restoration can be preferred. The cement-retained implant interim restorations can also be used alternatively. However excessive cement, if logged in the crestal region, could be potential irritant to the healing tissues. Occlusal consideration is an integral parameter of any implant treatment. This becomes even more critical especially with the maxillary anterior region as the contours of are important aspect of the anterior guidance in mandibular movements.

Partial extraction therapy was used to treat all six patients.[12.13] Recent developments involving partial root retention minimize the negative effects of extraction and offer enhanced buccal tissue contour in these cases.[13] However, each step of the treatment from tooth extraction to the definitive restoration should be performed meticulously to achieve a good esthetic outcome. One of the most critical parameters in immediate implant placement is primary stability. Fixed interim restoration can only be tried in situations where the primary stability of the implant is in clinically acceptable limits (usually more than 35 NCm). The selection of relatively longer implants may facilitate increasing primary stability in such situations. In most of the patients described, we have used 15 mm length of the implants for the same reason.

SUMMARY

This report demonstrated six techniques using screw retained immediate interim restorations following partial extraction therapy and immediate implant placement. The fabrication techniques have utilized a putty index, polycarbonate shell crown, patients' existing crowns (prosthetic or natural), or laminate veneer or fabricated in the laboratory based on the specific clinical situations. Excellent esthetic results were obtained in all six patients treated.

Declaration of patient consent

The authors declare that they have obtained consent from patients. Patients have given their consent for their images and other clinical information to be reported in the journal. Patients understand that their names will not be published and due efforts will be made to conceal their identity but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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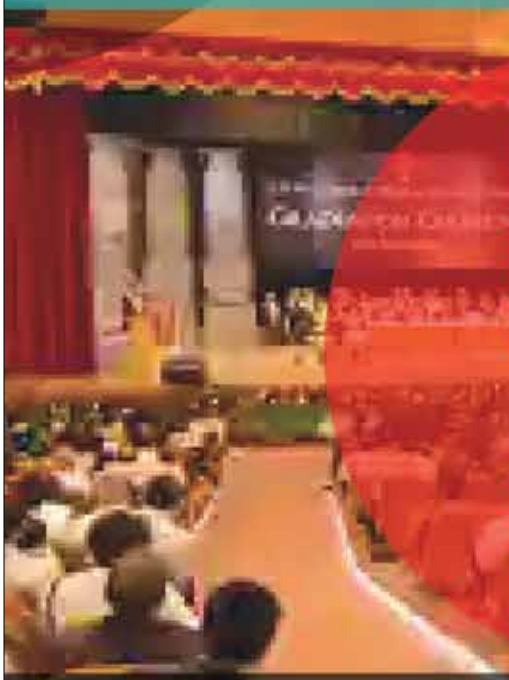

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