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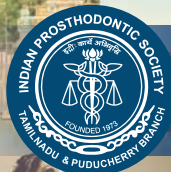
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Randomization in clinical research



Sampling is the process of selecting a small group from the entire population for research. Selection of sampling method based on the research question should align with the specific objectives and goals of the research; (1) Understand the characteristics of the population, including subgroups or clusters. (2) Assess the available resources, including time and budget. (3) Consider the level of precision needed for your study. Some methods may yield more precise estimates than others. (4) Evaluate the practicality of implementing the chosen sampling method in the context of your study. (5) To consult with statisticians or experts in research methodology when making decisions about sampling methods.

To attain an unbiased outcome, it is important to use a systematic selection process to ensure the samples include all characteristics that represent the actual population for which the research is conducted. The use of a larger number of dental graduates as a sample to find the incidence of dental caries may deviate the outcome, as they may be well aware of oral hygiene practice. This disproportionate selection of sample causes selection bias and hence sampling is an essential for any research.

Sampling methods are either probability (randomization) or nonprobability sampling. Probability is a random selection of participants so that any individual of the whole population has an equal chance to be included in the study, whereas in nonprobability sampling, the researcher deliberately selects the participants for his/her research goals.

Randomization/probability sampling is a crucial aspect of research design, as it helps minimize bias and ensures that the groups being compared are similar in their basic characteristics at the baseline. Here are some key considerations for randomizing samples in dental research so that the outcome of the research is more reliable:

- Select samples based on the research question before randomization: For example, to evaluate the effect of implants in improving brain activity, we need a population with the same mental characteristics in both control and study groups. A subset/subgroup from the sample can be selected based on the objective of the research, such as gender, age, or any other such criteria
- Allocation of participants with the use of appropriate randomization method:^[1,2]
 - Random sampling is done with the use of computers (computer-generated random numbers) and mathematical tables (random number tables) to generate sequences of participants that need to be included in the test and control groups. For example, to evaluate the effect of the implant on brain activity, use random number tables to select the required number of samples from the selected population
 - A systematic random sampling is performed when we have a defined sequence of populations. For example, the patient's unique identity number at the hospital can be used to collect data on oral manifestations caused by COVID-19. The researcher can recall every n^{th} number (like 5, 10, 15...) from the hospital data of such patients. This method is efficient and often more practical than simple random sampling when a defined list is available
 - Stratified random sampling ensures a precise balance by blocking or stratifying the systematically selected sample. In this method, a subgroup/subset based on age, sex, or educational level is stratified from the selected population. After stratification of the population, for example, based on sex, a simple random sampling is conducted under each stratum of male and female. This method ensures proportional representation for each stratum. For example, if age is a critical factor, use stratified randomization by dividing the participants based on age group (10–20; 20–30; 30–40, etc.), and later random sequence generation is done for each stratified group
 - Cluster random sampling is more practical to sample groups or clusters of individuals in a geographical region. This method is useful when

the population is naturally organized into clusters. For example, a questionnaire study especially requires clusters of samples based on geographic area. The population in India is divided into clusters such as Delhi, Chennai, and Mumbai. If one of the cities is selected, then all individuals within the selected clusters are included as the sample in this method.

- Allocation concealment is blinding the researcher or participant to minimize bias in the assignment of a group and in the assessment of its outcomes. This helps to prevent conscious or subconscious selection bias by researchers or participants. The researcher should employ specialized software or statistical packages that include randomization algorithms to automate the randomization process and ensure its integrity in allocating participants
- Tailor the randomization approach to fit the specific design of your dental research: Specific randomization strategies are required for different designs/research objectives (e.g., parallel groups, crossover, and factorial)^{3,4)}
 - In a parallel group randomization, each group receives a specific treatment that is comparable. This has a test group and a control group or more than two test groups undergoing parallel treatment
 - In crossover randomization, the groups are interchanged with the rendered treatment after a specific period. This confirms that the obtained outcome is not based on patient characteristics
 - Factorial randomization is when two different interventions that do not interfere with each other are assessed on the same participants.
- Ensure that the randomization process is ethical and transparent. Participants should be informed about the random assignment process and the possibility of being assigned to any group. Clearly document the randomization process, including the method used, any blocking or stratification criteria, and the allocation sequence
- After randomization, perform statistical analysis to confirm that the randomization was successful and that the groups are comparable at baseline. This can involve comparing demographic and clinical characteristics between groups to ensure there is no statistical difference between the groups.

A detailed sampling technique is less commonly mentioned in an article, except for a statement that a randomized sampling is done. The research is considered successful only when it is applicable to the entire population, and hence, researchers should be familiar and take an effort in use of appropriate sampling methods during the conduction of the research.

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A systematic review and meta-analysis of accuracy between protrusive interocclusal record and horizontal condylar guidance angle recording methods in dentulous patients

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Abstract

Aim: This systematic review and meta-analysis aimed to evaluate the accuracy of different methods used for measuring horizontal condylar guidance (HCG) angle in comparison with protrusive interocclusal record (IOR) for dentulous patients.

Settings and Design: The design involves systematic review and meta-analysis following the Preferred Reporting Items for Systematic Review and Meta-analysis guidelines.

Materials and Methods: An electronic search was carried out by two reviewers in the Google Scholar search engine and the EBSCO host, Cochrane Library, and PubMed/MEDLINE databases for quasi-experimental studies, *in vivo* studies, and cross-sectional studies published from January 2005 to February 2023 determining the HCG angle in dentulous patients.

Statistical Analysis Used: Meta-analysis was performed to evaluate the quantitative data.

Results: A total of 577 articles were identified, 29 analytical cross-sectional studies that fulfilled the eligibility criteria were included for qualitative synthesis and 26 studies were included for meta-analysis. A statistically significant difference was observed for the right and left HCG angles obtained by the panoramic radiograph method and cone-beam computed tomography (CBCT) method and for the right side HCG angle obtained by cephalogram method showing higher values than the protrusive IOR method. No statistically significant difference was observed for the left side HCG angle obtained by the cephalogram method and both the right and left side HCG angles obtained by the intraoral tracer method.

Conclusions: The panoramic radiograph, cephalogram, and CBCT obtained higher HCG angles in dentulous patients than the protrusive IOR method.

Keywords: Condylar guidance, cone-beam computed tomography, horizontal condylar guidance, interocclusal record, panoramic radiograph

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INTRODUCTION

The condyle and articular disc traverses the contour of the glenoid fossa to determine the condylar guidance.^[1-5] The condyle traverses the articular eminence when the mandible moves either protrusively or laterally from the centric point determining the condylar path.^[1-5] The accurate determination of condylar guidance is important to simulate the patient's temporomandibular joint and mandibular movement.^[6] Prosthetic rehabilitation of a single tooth, multiple missing teeth, and loss of vertical dimension need to be in association with the patient's stomatognathic structure for long-term and successful outcomes.^[7] Faulty determination of condylar guidance results in occlusal interferences.^[8] Various studies have described different methods to record horizontal condylar guidance (HCG) angle in dentulous patients.^[9,10] Most routinely, the clinician uses a protrusive interocclusal record (IOR) to transfer the HCG angle obtained from the patient to the articulator for the fabrication of the prosthesis.^[5,11,12] However, many studies reported the dimensional instability of the recording medium as a drawback with IOR.^[5,11,12] Radiographs are taken routinely for diagnostic purposes.^[13,14] Panoramic radiograph (orthopantomograph OPG) and cephalogram define temporomandibular joint as a curved glenoid fossa on temporal bone and round shape elevation of the articular eminence.^[15,16] However, both methods are two-dimensional imaging techniques and may cause some inaccuracies in the identification of landmarks and superimposition of structures.^[17] Many studies reported the use of panoramic radiograph and cephalogram for measuring HCG angle as the path traversed through the joint cavity by the condyle-disk assembly during a protrusive mandibular movement.^[18-20] Fan-beam computed tomography (CT) scan and cone-beam CT (CBCT) are three-dimensional imaging technique that generates higher resolution, multiplanar sections of temporomandibular joint without superimpositions.^[21,22] Various studies reported the use of CBCT and CT scan for measuring HCG angle.^[23-25] The structural as well as positional discrepancies observed in the lateral third of the condyle and fossa can be shown by transcranial radiograph.^[26] A study conducted by Shahidi *et al.* observed the difference between IOR and transcranial radiograph for measuring HCG angle.^[27] Different methods used to measure HCG angle in dentulous patients reported are axiography, electronic pantography and intraoral tracers.^[28-31] Luke *et al.* reported the occurrence of some clinical variability among radiographic and protrusive IOR methods for measuring HCG angle in their systematic review.^[18,32] The evidence on measuring HCG angle for dentulous patients by different methods is nonsummarized and inconclusive.^[32]

The present qualitative and quantitative analyses aimed to determine the accuracy between the protrusive IOR method and other different methods such as panoramic radiograph, CBCT, cephalogram, and intraoral tracer used for measuring HCG angle in dentulous patients. In order to simulate the stomatognathic structural balance for successful prosthetic rehabilitation, the clinicians will be able to select a convenient method of determining the HCG angle in dentulous patients. The null hypothesis was that no statistically significant difference would be found in the accuracy of protrusive IOR and various methods used for measuring HCG angle in dentulous patients.

MATERIALS AND METHODS

Protocol registration

The protocol for systematic review and meta-analysis with the code CRD42023401092 was registered at the Prospective Register of Systematic Reviews database^[32-35] and followed the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) 2020 guidelines.^[32,36-40]

Review question

The review question formulated according to the population, intervention, comparison, outcome, and study design (PICOS) framework^[41-44] was "Is there a difference in the accuracy of protrusive IOR method compared with other different methods used for measuring the HCG angle in dentulous patients?" The population was dentulous patients having all teeth intact whose HCG angle is measured using any method. The intervention was different methods such as panoramic radiograph, cephalogram, CBCT, digital methods, extraoral tracing, and intraoral tracing used to measure the HCG angle in dentulous patients. The comparison was a protrusive IOR method used to measure the HCG angle in dentulous patients. The outcome was studies that determined the accuracy of various methods used for measuring HCG angle in dentulous patients. The study design was quasi-experimental studies, *in vivo* studies, and cross-sectional studies measuring the HCG angle using any methods in dentulous patients.

Inclusion and exclusion criteria

Inclusion criteria included quasi-experimental, cross-sectional, and *in vivo* studies that evaluated the accuracy between protrusive IOR and other methods used for measuring HCG angle in dentulous patients. Full-text articles published from January 2005 to February 2023 in English were included.^[35] Exclusion criteria were studies published before 2005 other than in English, measuring

lateral condylar guidance, literature reviews, case series, *in vitro* studies, online surveys, and questionnaires.^[35]

Search strategy

Two reviewers (S.P. and J.I.) independently conducted an electronic search according to PICOS selection criteria for eligible studies, along with the presence of a third reviewer (J.N.) to solve any disagreements.^[32,35] The inter-rater reliability Cohen kappa score for both reviewers was 0.92.^[32,35] The systematic search was conducted in the Google Scholar search engine and EBSCO host, Cochrane Library, and PubMed/MEDLINE electronic databases using the following keywords, Mesh terms, and phrases along with the Boolean operators as shown in Table 1.^[35] The search strategy adopted in various databases is mentioned in Table 2. The search terms used in Google Scholar were accuracy, method, condylar guidance, dentulous patient, dentate patient, HCG, and sagittal condylar guidance.

Study selection and data extraction

Two reviewers (S.P. and J.I.) independently searched to critically assess the titles and abstracts of studies, followed by the removal of duplicate titles.^[32,35] After the removal of duplicate titles, the remaining article titles and abstracts were screened by both reviewers to exclude the irrelevant articles. Full-text articles were assessed and included, which met the eligibility criteria, whereas irrelevant articles were excluded from the study.^[32] An additional search of the reference list and citations of relevant articles was done. For qualitative synthesis, data extraction from included articles was done. Based on the homogeneity and quantitative data obtained, the articles were included for meta-analysis.^[45,46] Two reviewers independently performed the data extraction from the included studies with a Cohen kappa score of 0.92.^[32] The data extracted from the included studies were formulated in an Excel Microsoft spreadsheet as per the characteristics: study identification, country, age of the patient, sample size, intervention group, articulator model used, HCG angle right and left sides, and conclusion.^[35]

Risk-of-bias assessment

The 29 included studies were analytical cross-sectional studies. The risk-of-bias assessment was done using the Newcastle–Ottawa tool for cross-sectional studies.

The assessment criteria included eight items from three domains – selection, comparability, and outcome.^[47-49] For each domain, the scores were given, and the quality of the study was graded as poor, fair, and high.^[47-49] Quality assessment was made using the Review Manager software.^[35,50]

Meta-analysis

The quantitative data were extracted from the included studies to perform the meta-analysis.^[35] The forest plot was obtained using measured effects of mean, standard deviation, and total at a 95% confidence interval (CI) with $P < 0.05$ as statistically significant. To measure the heterogeneity, I^2 test was used. The random-effect model was used when the I^2 value was $>50\%$, and a fixed-effect model was used when the I^2 value was $<50\%$.^[51-55] To detect the publication bias, funnel plot was used.^[56]

RESULTS

Literature search

A total of 577 articles were retrieved, 21 from PubMed/MEDLINE, 1 from Cochrane Library, 49 from EBSCO host, and 506 from Google Scholar. A total of 75 duplicates were removed, 502 articles were screened, and 442 insignificant articles were excluded. Among 60 selected full-text studies, 31 studies were excluded (9 due to incomplete data provided and 22 due to data provided on edentulous patients).^[35] A total of 29 studies were included for qualitative synthesis, and 26 studies were included for meta-analysis. A PRISMA flowchart of the search results is represented in Figure 1.^[36,37]

Characteristics of included studies

The characteristic data of the 29 included studies are described in Table 3.^[1,3,5,9,10,23-25,27,28,30,31,57-73] In this review, 962 participants with an average age of 18–60 years were included. Among 29 included studies, 19 studies used Hanau Wide-View semi-adjustable articulator,^[1,3,9,10,23,25,57-60,63,65-73] 1 study used Hanau H2 semi-adjustable articulator,^[57] 2 studies used Denar Mark II articulator,^[27,61] 2 studies used Artex articulator,^[28,69] 1 study used SAM III articulator,^[5] and 1 study used Whipmix articulator.^[62] Among 29 included studies, 16 studies measured HCG angle using panoramic radiograph,^[1,3,5,9,10,24,58,60,62-66,69,70,72] 7 studies measured

Table 1: Terms used in search strategy as per population, intervention, comparison, outcome, and study design framework

Population	Intervention	Control	Outcome	Study design
Adult, dentulous patient, dentate patient	Panoramic radiograph, cephalogram, CBCT, interocclusal wax record	Protrusive interocclusal record, interocclusal wax record, IOR	Accuracy, HCG angle, horizontal condylar guidance angle, horizontal condylar guidance, sagittal condylar guidance	<i>In vivo</i> studies, cross-sectional studies, randomized control trial, clinical studies, nonrandomized trials

CBCT: Cone beam computed tomography, IOR: Interocclusal record\

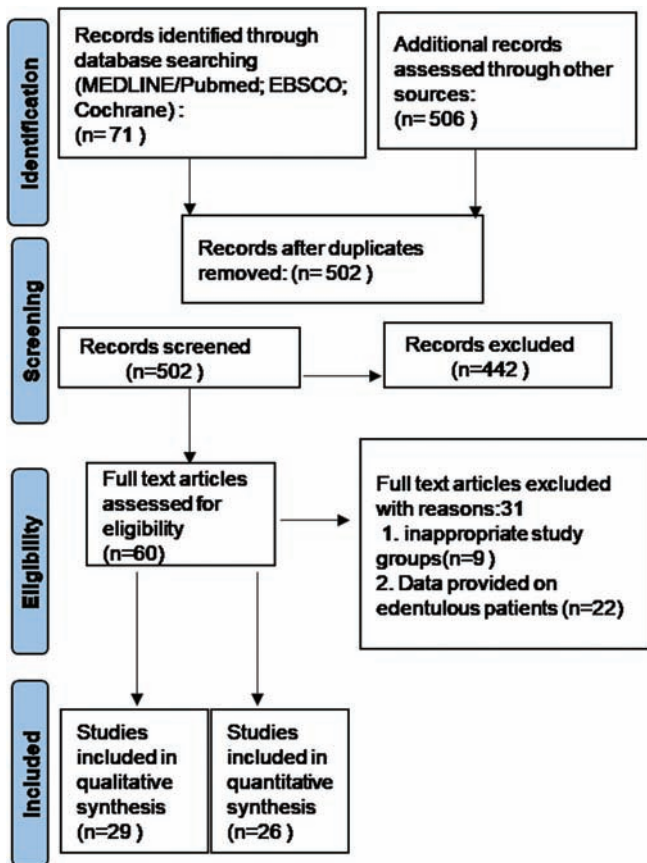


Figure 1: Preferred reporting items for systematic review and meta-analysis flow diagram

Table 2: Search strategy in different databases

Search strategy
Search strategy in PubMed was (((((Accuracy) AND Method) AND "Condylar guidance" OR "Horizontal condylar guidance" OR "sagittal condylar guidance") AND dentulous patient OR dentate patient)
Search strategy in Cochrane was (((((Accuracy) AND Method) AND "Condylar guidance" OR "Horizontal condylar guidance" OR "sagittal condylar guidance") AND dentulous patient OR dentate patient)
Search strategy in EBSCO was (((((Accuracy) AND Method) AND "Condylar guidance" OR "Horizontal condylar guidance" OR "sagittal condylar guidance") AND dentulous patient OR dentate patient)

HCG angle using CBCT,^[24,25,55,59,61,62,67] 7 studies measured HCG angle using cephalogram,^[1,59,60,67,68,71,73] 2 studies measured HCG angle using intraoral tracer,^[23,31] and one study each measured HCG angle using electronic pantograph,^[30] axiograph,^[28] CT scan,^[23] and transcranial radiograph^[27] in comparison to HCG angle obtained by protrusive IOR in dentulous patients. The right and left HCG angles were recorded from all studies. The sensitivity analysis was conducted for the right and left HCG angles.

Risk-of-bias assessment

The quality assessment of the analytical cross-sectional study was made using Newcastle–Ottawa assessment

tool.^[35,47-49] The study quality of 29 studies was good [Table 4].^[1,3,5,9,10,23-25,27,28,30,31,57-73]

Meta-analysis

Twenty-six studies were included for meta-analysis.^[1,3,5,9,10,23-25,31,57-73] Meta-analysis was conducted for panoramic radiograph, CBCT, cephalogram, and intraoral tracer methods.

Meta-analysis for right side horizontal condylar guidance angle

For the panoramic radiograph method, 16 studies were included.^[1,3,5,9,10,24,58,60,62-66,69,70,72] The I^2 value observed was 72%; hence, random-effect model was used. A statistically significant difference was seen ($P < 0.05$, pooled mean difference = 2.81 [1.8, 3.81], CI = 95%) as depicted in the forest plot [Figure 2].^[35] The HCG angle obtained for the panoramic radiograph method was higher than the protrusive IOR method.^[74] For the cephalogram method, seven studies were included.^[1,59,60,67,68,71,73] The I^2 value observed was 34%; hence, fixed-effect model was used. A statistically significant difference was seen ($P = 0.003$, pooled mean difference = 0.57 [0.20, 0.95], CI = 95%) as depicted in the forest plot [Figure 2].^[35] The HCG angle obtained for the cephalogram method was higher than the protrusive IOR method.^[74] For the CBCT method, seven studies were included.^[24,25,57,61,63,64,69] The I^2 value observed was 99%; hence, random-effect model was used. A statistically significant difference was seen ($P = 0.03$, pooled mean difference = 8.75 [0.68, 16.82], CI = 95%) as depicted in the forest plot [Figure 2].^[35] The HCG angle obtained for the CBCT method was higher than the protrusive IOR method.^[74] For the intraoral tracer method, two studies were included.^[23,31] The I^2 value observed was 65%; hence, random-effect model was used. No statistically significant difference was seen ($P = 0.57$, pooled mean difference = 1.46 [-3.60, 6.52], CI = 95%) as depicted in the forest plot [Figure 2].^[35]

Meta-analysis for left side horizontal condylar guidance angle

For the panoramic radiograph method, 15 studies were included.^[1,3,5,9,24,58,60,62-66,69,70,72] The I^2 value observed was 83%; hence, random-effect model was used. A statistically significant difference was seen ($P < 0.05$, pooled mean difference = 2.45 [1.14, 3.76], CI = 95%) as depicted in the forest plot [Figure 3].^[35] The HCG angle obtained for the panoramic radiograph method was higher than the protrusive IOR method. For the cephalogram method, six studies were included.^[1,59,60,67,68,73] The I^2 value observed was 66%; hence, random-effect model was used. No statistically significant difference was seen ($P = 0.91$, pooled mean

Table 3: Data extraction table of included studies

Study ID	Country	Age of the patient	Sample size	Intervention group	Articulator used	Condylar guidance value right side (mean and SD)	Condylar guidance value left side (mean and SD)	Conclusion
Uttaradi et al., 2022 ^[57]	India	20-30	20	CBCT	Hanau 96 H2	IOR: 37 (2.35) CBCT: 40.20 (2.57)	IOR: 35.40 (1.64) CBCT: 39.60 (1.26)	CBCT values were higher than clinical methods
Das et al., 2022 ^[58]	India	NR	20	Panoramic Radiograph	Hanau wide vue	IOR: 31.45 (4.43) OPG: 32.85 (6.50)	IOR: 31.05 (5.05) OPG: 32.55 (5.45)	R/G can be used as an alternative to IOR method
Jain et al., 2021 ^[59]	Malaysia	60-70	30	Cephalogram	Hanau wide vue	IOR: 28.83 (3.13) Cephalogram: 28.36 (2.78)	IOR: 28.83 (3.13) Cephalogram: 28.36 (2.78)	Lateral cephalogram provides the same measurement as the protrusive IOR OPG can be used to record CG
Keerthana et al., 2021 ^[60]	India	55-75	50	Panoramic radiograph	Hanau Wide-Vue	IOR: 34.85 (4.85) OPG: 38.77 (2.56)	NR	Any method can be used for measuring CG
Singh et al., 2021 ^[60]	India	20-45	82	Panoramic radiograph, lateral cephalogram	Hanau Wide-Vue	IOR: 34.08 (1.4) OPG: 35.16 (1.7)	IOR: 34.01 (1.2) OPG: 35.12 (1.6)	
Das et al., 2021 ^[25]	India	20-40	40	CBCT	Hanau Wide-Vue	IOR: 32.78 (2.64) CBCT: 35.43 (3.13)	Cephalogram: 34.67 (1.6) IOR: 35.18 (2.62) CBCT: 35.18 (2.62)	CBCT values higher than IOR
Naqash et al., 2020 ^[61]	Saudi Arabia	18-30	23	CBCT	Denar Mark II	IOR: 31.82 (4.53) CBCT: 38.12 (4.81)	IOR: 32.14 (4.32) CBCT: 38.96 (4.19)	Strong correlations were found between PR and CBCT techniques. CBCT values were 6°-7° higher than those obtained using the protrusive IOR
Dewan et al., 2019 ^[62]	India	20-41	30	Panoramic radiograph	Whipmix	IOR: 36.37 (9.42) OPG: 42.57 (7.60)	IOR: 35.85 (6.87) OPG: 42.71 (7.84)	IOR values for CG were less than panoramic radiographs
Amin et al., 2018 ^[63]	India	40-60	30	Panoramic radiograph	Hanau Wide-Vue	IOR: 30.83 (5.38) OPG: 35.53 (6.248)	IOR: 30.83 (5.38) OPG: 35.53 (6.248)	OPG higher than IOR values
Vadodaria 2021 ^[31]	India	24-40	30	CBCT, Jig method, intraoral tracer	NR	IOR: 27.43 (2.61) CBCT: 39.63 (1.96) Jig: 28.93 (2.72) Tracer: 30.77 (3.38)	IOR: 28.75 (3.01) CBCT: 40.50 (2.7) Jig: 29.69 (3.36) Tracer: 31.14 (4.17)	CBCT value were higher than clinical method
Prakash 2021 ^[64]	India	18-30	25	CBCT, panoramic radiograph	NR	IOR: 29.8 (4.44) OPG: 35.85 (4.21) CBCT: 30.96 (4.70)	IOR: 29.8 (4.44) OPG: 35.96 (4.23) CBCT: 31.13 (4.22)	OPG values were higher than CBCT. CBCT can be used as reliable method as clinical method
Katiyar et al., 2018 ^[65]	India	20-30	20	Panoramic radiograph	Hanau Wide-Vue	IOR: 34.05 (14.16) OPG: 34.8 (12.69)	IOR: 37.35 (14.13) OPG: 36.95 (11.3)	Due to reported inaccuracies of the IOR technique, the use of OPG as an alternative method is not difficult to perform and report positive clinical application
Ghods and Rasaeipour, 2018 ^[30]	India	26	50	Electronic pantograph	NR	Pantograph: 42.15 (5.35)	Pantograph: 41.18 (5.74)	Pantograph values were higher than conventional method
Kharzinejad et al., 2018 ^[66]	Iran		42	Panoramic radiograph	Hanau Wide-Vue	IOR: 33.9 (3.19) OPG: 35.88 (3.27)	IOR: 33.78 (3.22) OPG: 35.93 (3.27)	OPG higher than IOR values. OPG cannot be used as a reliable alternative diagnostic tool
Singh et al., 2017 ^[67]	India	20-40	30	Cephalogram	Hanau Wide-Vue	IOR: 31.30 (7.31) Cephalogram: 34.10 (6.41)	IOR: 31.80 (6.44) Cephalogram: 34.10 (6.41)	Radiographic method can be used to measure HCG; however, the protrusive method should be employed
Salemi et al., 2017 ^[64]	India	13-43	28	CBCT, panoramic radiograph	NR	OPG: 35.43 (3.0) CBCT: 33.49 (2.94)	OPG: 35.67 (3.36) CBCT: 33.94 (3.40)	CBCT and panoramic can be used instead of interocclusal record for adjusting condylar guidance in articulator
Kumar et al., 2018 ^[68]	India	20-35	20	Cephalogram	Hanau Wide-Vue	IOR: 32.60 (3.08) Cephalogram: 35.85	IOR: 32.92 (3.16) IOR: 34.51	Both methods can be used as no statistical significant difference was observed
Kwon et al., 2017 ^[69]	India	20-40	20	Panoramic radiograph, CBCT	Artex	Alu wax: 30.1 (6.7) OPG: 38.9 (9.0) CBCT: 35.4 (7.8)	Cephalogram: 35.85 Alu wax: 30.2 (6.3) OPG: 38.7 (6.4) CBCT: 36.8 (6.7)	OPG higher by 8°-9° than CBCT (5°-6°) than IOR values

Contd...

Table 3: Contd...

Study ID	Country	Age of the patient	Sample size	Intervention group	Articulator used	Condylar guidance value right side (mean and SD)	Condylar guidance value left side (mean and SD)	Conclusion
Galagali et al., 2016 ^[1]	India	20-40	120	Panoramic radiograph, cephalogram	Hanau Wide-Vue	IOR: 34.16 (6.83) OPG: 34.83 (6.44)	IOR: 34.16 (6.83) OPG: 35.7 (6.50)	Lateral cephalogram provides same measurement as protrusive IOR
Banasr et al., 2015 ^[70]	India	21-35	20	Panoramic radiograph	Hanau Wide-Vue	Cephalogram: 34.03 (6.63) IOR: 35.38 (5.14) OPG: 35.25 (4.25)	Cephalogram: 35.16 (5.85) IOR: 35.06 (6.08) OPG: 34.06 (4.58)	OPG can be used as a reliable method like interocclusal record for measuring CG
Godavarthi et al., 2015 ^[5]	India	20-30	20	Panoramic radiograph	Hanau Wide-Vue	IOR: 37.1 OPG: 40.55	IOR: 40.15 OPG: 34.75	OPG can be used as an alternative method to determine CG
Prasad et al., 2015 ^[28]	India	NR	30	Axiograph	SAM III, Artex	IOR: 33.25 (6.79) Axiograph: 42.12 (7.07)	NR	Axiograph has given higher values than Alu wax method
Acharya et al., 2015 ^[9]	India	20-30	20	Panoramic radiograph	Hanau Wide-Vue	IOR: 35.8 OPG: 33.75	IOR: 34.05 OPG: 34.25	OPG gave higher values than interocclusal record
Mishra and Palaskar, 2014 ^[71]	India	20-30	15	Cephalogram	Hanau Wide-Vue	IOR I: 28 (6.29) IOR D: 24.93 (5.92) C: 32.73 (5.92)	NR	Cephalogram values were higher than IOR. Indirect facebow transfer values obtained were higher than direct transfer
Shreshta et al., 2012 ^[23]	India	20-40	12	CT scan, intraoral tracer	Hanau Wide-Vue	IOR: 33.33 (7.75) CT: 43.83 (6.57) Jig: 29.16 (6.77) Tracer: 31.25±7.42	IOR: 33.64 (7.94) CT: 42.42 (6.06) Jig: 30.56 (7.02) Tracer: 30.83 (6.68)	CT scan showed higher HCG values than the clinical methods
Shahidi et al., 2012 ^[27]	Iran	20-41	30	Transcranial radiographs	Denar Mark II	IOR: 29.4 (4.5) R: 39.5 (5.7)	IOR: 30.2 (4) R: 38.8 (5.4)	Transcranial R/G can be used as an adjunct to interocclusal records
Prasad et al., 2012 ^[3]	India	20-40	75	Panoramic radiograph	Hanau Wide-Vue	IOR: 34.71 (5.27) OPG: 36.68 (4.69)	IOR: 35 (4.85) OPG: 38.18 (5.22)	OPG values were higher than IOR method of recording CG
Tannamala et al., 2012 ^[72]	India	20-41	10	Panoramic radiograph	Hanau Wide-Vue	IOR: 32.80 (5.01) OPG: 36.50 (3.75)	IOR: 32.10 (5.9) OPG: 35.50 (4.35)	OPG values were 4 degree greater than IOR values
Goyal and Goyal, 2011 ^[73]	India	19-35	20	Cephalogram	Hanau Wide-Vue	IOR: 32.75 (6.17) Cephalogram: 36.05 (7.54)	IOR: 34.75 (7.69) Cephalogram: 36.05 (7.54)	No significant difference found between IOR and cephalogram indicates replication of HCG value from the image of articular eminence

CT: Computed tomography, CBCT: Cone beam CT, HCG: Horizontal condylar guidance, IOR: Interocclusal record, NR: Not reported, OPG: Orthopantomograph, SD: Standard deviation

Table 4: Quality Assessment using Newcastle Ottawa tool for cross-sectional studies

Study Id	Selection			Ascertainment of risk factor	Comparability		Outcome		Total Quality score	
	Representativeness of case	Sample size	Non responders		Main factor	Additional factor	Assessment of outcome	Statistical test		
Study ID	*	-	*	**	*	-	*	*	7	Good
Uttaradi <i>et al.</i> , 2022 ^[57]	*	*	*	**	*	-	*	*	8	Good
Das <i>et al.</i> , 2023 ^[58]	*	-	*	**	*	-	*	*	7	Good
Jain <i>et al.</i> , 2021 ^[59]	*	*	*	**	*	-	*	*	8	Good
Keerthana <i>et al.</i> , 2021 ^[10]	*	*	-	**	*	-	*	*	7	Good
Singh <i>et al.</i> , 2021 ^[60]	*	*	*	**	*	-	*	*	8	Good
Das <i>et al.</i> , 2021 ^[25]	*	*	*	**	*	-	*	*	8	Good
Naqash <i>et al.</i> , 2020 ^[61]	*	*	*	**	*	-	*	*	8	Good
Dewan <i>et al.</i> , 2019 ^[62]	*	*	*	**	*	-	*	*	8	Good
Amin <i>et al.</i> , 2018 ^[63]	*	*	*	**	*	-	*	*	8	Good
Vadodaria 2021 ^[31]	*	*	*	**	*	-	*	*	8	Good
Prakash 2021 ^[64]	*	*	*	**	*	-	*	*	8	Good
Katiyar <i>et al.</i> , 2018 ^[65]	*	*	*	**	*	-	*	*	8	Good
Ghodsi and Rasaeipour, 2018 ^[30]	*	-	*	**	*	-	*	*	7	Good
Kharzinejad <i>et al.</i> , 2018 ^[66]	*	-	-	**	*	-	*	*	6	Good
Singh <i>et al.</i> , 2017 ^[67]	*	*	*	**	*	-	*	*	8	Good
Salemi <i>et al.</i> , 2017 ^[24]	*	*	*	**	*	-	*	*	8	Good
Kumar <i>et al.</i> , 2018 ^[68]	*	*	-	**	*	-	*	*	7	Good
Kwon <i>et al.</i> , 2017 ^[69]	*	*	*	*	*	-	*	*	7	Good
Galagali <i>et al.</i> , 2016 ^[11]	*	*	*	**	*	-	*	*	8	Good
Banasr <i>et al.</i> , 2015 ^[70]	*	-	*	**	*	-	*	*	7	Good
Godavarthi <i>et al.</i> , 2015 ^[5]	*	*	*	*	*	-	*	*	7	Good
Prasad <i>et al.</i> , 2015 ^[28]	*	*	*	**	*	-	*	*	8	Good
Acharya <i>et al.</i> , 2015 ^[9]	*	-	*	**	*	-	*	*	7	Good
Mishra and Palaskar, 2014 ^[71]	*	*	*	**	*	-	*	*	8	Good
Shreshta <i>et al.</i> , 2012 ^[23]	*	-	*	**	*	-	*	*	7	Good
Shahidi <i>et al.</i> , 2012 ^[27]	*	*	*	**	*	-	*	*	8	Good
Prasad <i>et al.</i> , 2012 ^[3]	*	-	*	**	*	-	*	*	7	Good
Tannamala <i>et al.</i> , 2012 ^[72]	*	*	*	**	*	-	*	*	8	Good

*Indicates positive finding and scored one. **Indicates positive finding and scored two

difference = 0.05 [-0.88, 0.99], CI = 95%) as depicted in the forest plot [Figure 3].^[35] For the CBCT method, seven studies were included.^[24,25,57,61,63,64,69] The I^2 value observed was 97%; hence, random-effect model was used. A statistically significant difference was seen ($P < 0.05$, pooled mean difference = 4.49 [1.18, 7.79], CI = 95%) as depicted in the forest plot [Figure 3].^[35] The HCG value for the CBCT method was higher than that for the protrusive IOR method. For the intraoral tracer method, two studies were included.^[23,31,35] The I^2 value observed was 64%; hence, random-effect model was used. No statistically significant difference was seen ($P = 0.82$, Pooled mean difference = 0.57 [-4.29, 5.43], CI = 95%) as depicted in the forest plot [Figure 3].^[35] The publication bias detected was low for all the methods used for measuring HCG angle compared with protrusive IORs in dentulous patients, as shown in the funnel plot [Figure 4].

DISCUSSION

A precise determination of the condylar guidance angle is needed to restore occlusion with fixed prosthesis within a stomatognathic harmony, maintaining correlation during centric and eccentric mandibular movements across the

condylar path and occlusal surface morphology. This systematic review and meta-analysis aimed to evaluate the accuracy of protrusive IOR compared with other different methods used for measuring HCG angle in dentulous patients.^[35] The null hypothesis was accepted for the intraoral tracer method and cephalogram method. No statistically significant difference was seen between the protrusive IOR method and intraoral tracer method for both right and left sides due to high heterogeneity due to less sample size, measures of outcome, and a lesser number of included studies with the quantitative data. The result was similar to a study done by Shreshta *et al.*^[23] showing no statistically significant difference between the protrusive IOR method and the intraoral tracer method.^[23] However, Vadodaria^[31] reported a statistically significant difference ($P < 0.001$) with a higher HCG angle obtained from the protrusive IOR method than the intraoral tracer method.^[31] For the HCG angle obtained by the cephalogram method for the left side, no statistically significant difference was observed. The difference in the result obtained for the left side HCG angle was due to a smaller number of included studies and different morphology of temporomandibular joint of included patients.

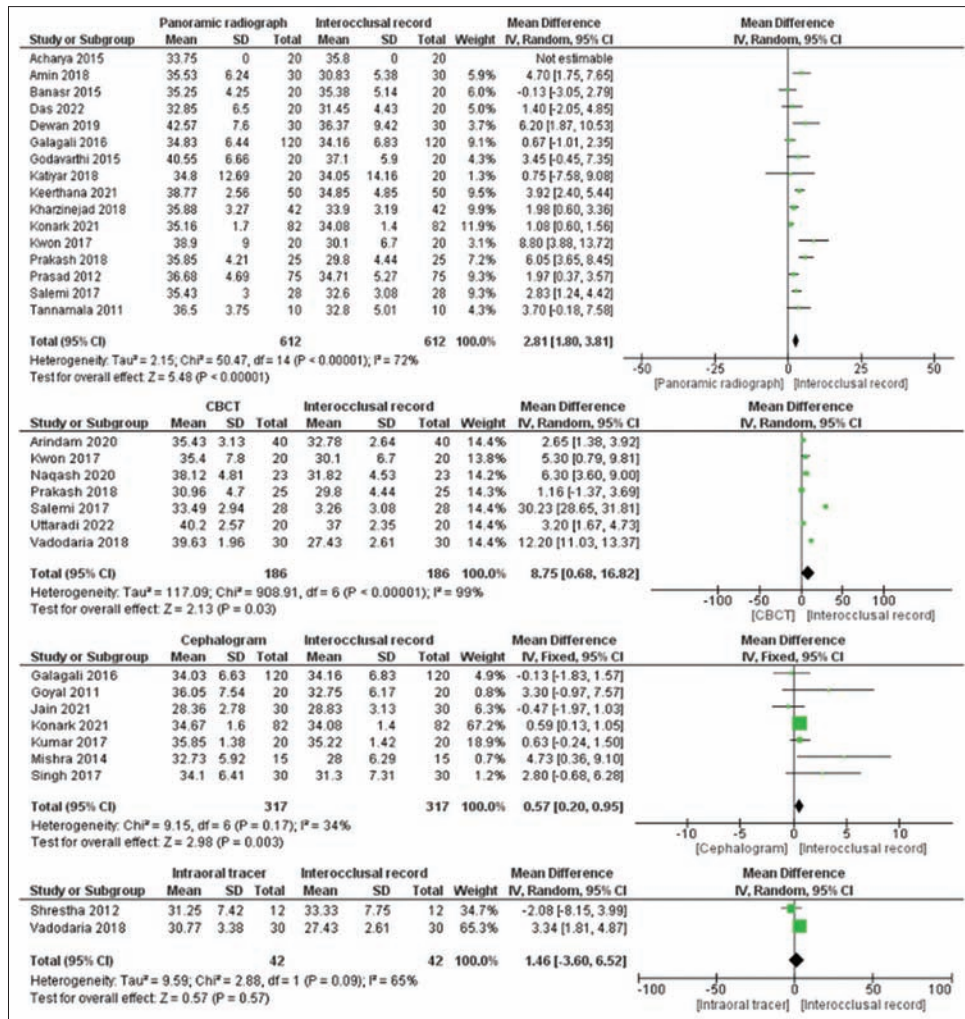


Figure 2: Forest plot comparing protrusive interocclusal record and intervention groups of Panoramic radiograph, cone-beam computed tomography, cephalogram, and intraoral tracer for the right side horizontal condylar guidance angle. CI: Confidence interval

The null hypothesis was rejected for panoramic radiographs, CBCT, and cephalogram methods. A statistically significant difference was seen for the panoramic radiograph method for both the right and left sides due to the larger number of included studies, ease of identifying the glenoid fossa, articular eminence, Frankfurt's horizontal plane, and obtaining the values from the radiographic images in comparison to inaccuracies obtained from IOR recording method, variations, and the inability of the clinician to guide the patient in protrusion.^[5,23] This result was similar to the studies done by Galagali *et al.*,^[1] Prasad *et al.*,^[3] Acharya *et al.*,^[9] Salemi *et al.*,^[24] Dewan *et al.*,^[62] Amin *et al.*,^[63] Prakash^[64] Kharzinejad *et al.*,^[66] and Banasr *et al.*^[70] reported a statistically significant difference and higher HCG angle from the panoramic radiograph method than the protrusive IOR method.^[1,3,9,24,62-64,66,70] However, studies done by Keerthana *et al.*,^[10] Godavarthi *et al.*,^[5] Das *et al.*,^[58] Singh *et al.*,^[60] Katiyar *et al.*,^[65] Kwon *et al.*,^[69] and Tannamala *et al.*^[72] showed no statistically significant difference between

the panoramic radiograph method and the protrusive IOR method.^[5,10,58,60,65,69,72]

A statistically significant difference was seen for the CBCT method for both the right and left sides due to higher resolution, three-dimensional, and clear images of condyle for measurement as compared to the protrusive IOR method. This result was similar to the studies done by Salemi *et al.*,^[24] Vadodaria^[31] Naqash *et al.*,^[61] and Prakash^[64] showing a statistically significant difference with a higher HCG angle obtained from the CBCT method than the protrusive IOR method.^[24,31,61,64] However, studies done by Das *et al.*,^[25] Uttaradi *et al.*,^[57] and Kwon *et al.*^[69] showed no statistically significant difference between the CBCT method and the protrusive IOR method.^[25,57,69]

A statistically significant difference was seen for the cephalogram method for the right side due to ease in the

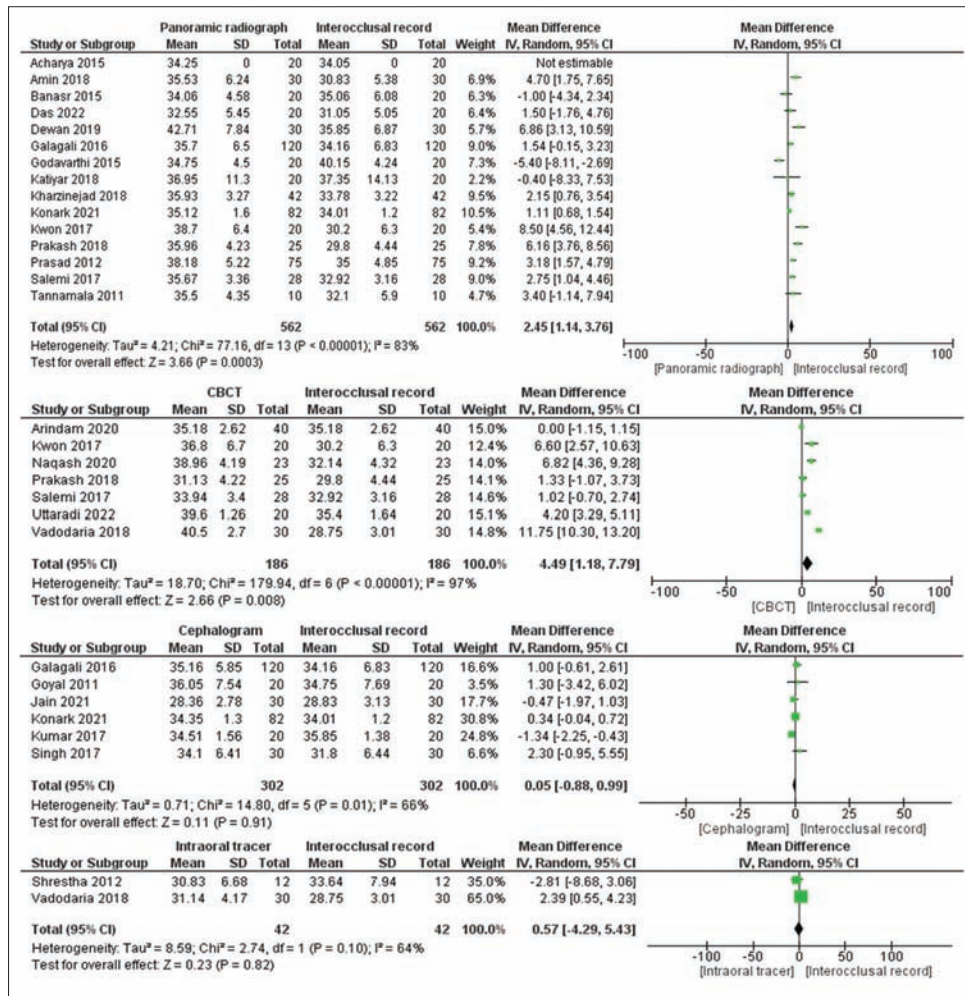


Figure 3: Forest plot comparing protrusive interocclusal record and intervention groups of panoramic radiograph, cone-beam computed tomography, cephalogram, and intraoral tracer for left side horizontal condylar guidance angle

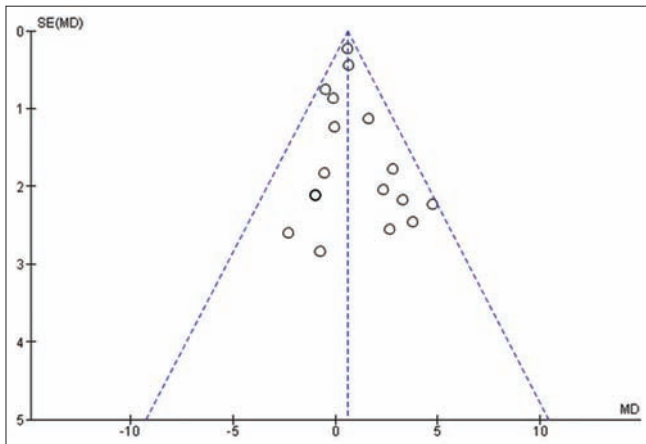


Figure 4: Funnel plot showing the publication bias

identification of bony landmarks for the measurement of HCG angle. This result was similar to the studies done by Galagali *et al.*,^[1] Singh *et al.*,^[60] Singh *et al.*,^[67] Kumar *et al.*,^[68] and Mishra and Palaskar^[71] showing a statistically significant difference with a higher HCG angle obtained

from the cephalogram method than the protrusive IOR method.^[1,60,67,68,71]

For rehabilitation of occlusal morphology and occlusion by prosthesis, the HCG angle obtained from the dentulous patient can be transferred to an articulator accurately by panoramic radiograph, CBCT, and cephalogram methods as compared with protrusive IOR method, giving a convenient choice of recording method to the clinician.

Some limitations could be considered in this systematic review. This review was carried out with studies published in English, analytical cross-sectional study design, and less number of included studies for different intervention groups. Differences in patient characteristics, operator experience, and equipment calibration were the potential sources of confounding bias that could have influenced the HCG angle measurement. To overcome these limitations, long-term randomized controlled clinical trials should be conducted on the present study topic for validated clinical results.

CONCLUSIONS

1. For both right and left side HCG angles, the panoramic radiograph method and the protrusive IOR method showed a statistically significant difference
2. For both right and left side HCG angles, the CBCT method and the protrusive IOR method showed a statistically significant difference
3. For the cephalogram method and the protrusive IOR method, a statistically significant difference was observed for the right side HCG angle and no statistically significant difference was observed for the left side
4. For both right and left side HCG angles, no statistically significant difference was observed between the intraoral tracer method and the protrusive IOR method
5. Higher HCG angle values were obtained from panoramic radiographs, CBCT, and cephalogram methods compared to the protrusive IOR method.

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Conflicts of interest

There are no conflicts of interest.

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Effectiveness of anterior repositioning splint versus other occlusal splints in the management of temporomandibular joint disc displacement with reduction: A meta-analysis

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Abstract

Background: Disc displacement with reduction (DDwR) is among the common disc disorders of temporomandibular joint (TMJ), which can be managed conservatively by splint therapy. Anterior repositioning splint (ARS) is the most commonly prescribed splint by dental practitioners, but not getting a normal disc-condyle relationship always and other side effects lead to need of comparing with other occlusal splints. This review will help in informed decision-making by clinicians in choosing an appropriate splint type for patients.

Aim: The aim is to compare the effectiveness of ARS in the management of DDwR with other occlusal splints for TMJ and muscle pain, TMJ noise, any adverse effects, regaining normal disc-condyle relationship.

Materials and Methods: We followed published protocol in the International prospective register of systematic reviews. Databases were searched till May 2023 using different search strategies as per the database. Title and abstract screening, followed by full-text screening and data extraction with risk of bias, was done by two independent reviewers in Covidence. Outcomes were reported as risk ratio (RR) or mean difference (MD) for dichotomous or continuous outcomes, respectively, using RevMan 5.4 (Review Manager 5.4) software. We used a random effect model for statistical analysis. Certainty of evidence was assessed using the Grading of Recommendation, Assessment, Development, and Evaluation Guideline Development Tool (GRADEpro GDT) software.

Results: A total of 1145 reports were found from a database search. After screening, four studies were included for systematic reviews. Other occlusal splints reported were sagittal vertical extrusion device and mandibular ARS, full hard stabilization splint of canine or centric stabilization type. Data of only two studies could be used for meta-analysis having 30 participants received ARS and 40 received other occlusal splints. We did not find evidence of any difference between ARS and other occlusal splints for TMJ clicking in short term (RR 1.25, 95% confidence interval [CI] 0.91-1.72) but a small difference in favor of other occlusal splint in long term (RR 2.40, 95% CI 1.04–5.55). No evidence of any difference was found between

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both treatments for TMJ pain in short term (MD-5.68, 95% CI-17.31–5.95) and long term (MD 0.00, 95% CI-2.86–2.86) and muscle pain in short term. The certainty of evidence for comparison of two treatments for different outcomes was of low or very low level.

Conclusion: Evidence is uncertain that other occlusal splints reduced TMJ clicking slightly in comparison to ARS. For the remaining outcomes, no evidence of any difference was found between the two splints and it may be biased due to selection bias, inadequate blinding of participants, and outcome assessor.

Keywords: Arthralgia, dummy splint, evidence-based medicine, joint disorders, occlusal splint, systematic review, temporomandibular disorders

INTRODUCTION

The temporomandibular joint (TMJ) consists of the condyle, glenoid fossa, articular disc, and associated musculature and ligaments. The articular disc is present between the condyle and glenoid fossa, which helps in rotation and sliding movement smoothly. Temporomandibular disorders (TMDs) were broadly categorized into intra-articular and extra-articular disorders.^[1] Disc displacement with reduction (DDwR) is one of the common TMDs.^[2-4] Due to various reasons, the articular disc during the closing of the mouth is displaced from its position, but it takes its original position during the opening of the mouth.^[5,6] This disorder is known as DDwR. After disc reduction during the translation of condyle, limitation in jaw opening is not found, but the movement of the mandible may not be as smooth as before.^[6] The main clinical finding of DDwR is TMJ noise,^[7] clicking being the most common complaint of the patient^[8] and the main reason for seeking treatment. Muscle and joint pain may also be associated with it. Optimal treatment for DDwR is of great clinical significance for dental specialists and has been classified as conservative and nonconservative (invasive). Among the conservative treatments, splint therapy is a commonly administered treatment modality. The objective of the management of TMD with splint therapy is to help in achieving a normal relationship of the glenoid fossa with the condyle having the articular disc at the correct position. This may help in the reduction of TMJ joint pain and noise and improve mandibular function.^[9] Among the wide variety of splints, anterior repositioning splint (ARS) is a commonly prescribed and used splint for DDwR.^[10-13] ARS allows the recapture of the disc, that is, it enables the repositioning of the mandibular condyle back onto the disc. It helps in the alleviation of joint noises and pain by helping the anterior position of the mandible rather than maximal intercuspation.^[14] However, indiscriminate long-term use of ARS can lead to irreversible changes in occlusion (posterior open bite) and rise in pain in the muscle (due to the protrusive position).^[15,16] Studies have

also reported reduced success rates in regaining of normal relationship of disc with condyle for long term.^[11,17-21] However, all available clinical evidence needs to be taken into consideration to draw a conclusion regarding the use of ARS in the treatment of DDwR. Furthermore, the problems associated with the long-term use of ARS mandates the need for assessment of other occlusal appliances in the treatment of DDwR and to compare their effectiveness with ARS.

With this background, we aimed to assess the clinical effectiveness of ARS in treating symptoms of DDwR when compared with other occlusal appliances. Furthermore, evidence has to be generated regarding its success in regaining the normal condyle-to-disc relationship and any treatment adverse effects. Thus, findings from the systematic review may help clinicians discuss the choice of splint with informed decision-making by patients with adequate justification for the proposed treatment plan in a particular clinical situation.

METHODOLOGY

Protocol was registered in PROSPERO (Registration number CRD42020176000)^[22] and is reported as per “Preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.”^[23]

The research question for systematic review was “In patients diagnosed with DDwR, is ARS more effective compared with other occlusal appliances in reducing TMJ noise, muscle pain, joint pain, and does it have any adverse effect?”

Population, Intervention, Comparison, Outcome (PICO) format for the systematic review was used to prepare search strategy for different databases:

1. Type of Population (P): Patients of any age, gender in which diagnosis of DDwR was made using research diagnostic criteria for TMDs or American Academy of Orofacial Pain,^[24] or diagnostic criteria for TMDs^[25]

- Presence of bilateral or unilateral clicking, popping, and/or snapping sounds in TMJ detected with palpation during various mandibular movements
 - Presence of bilateral or unilateral pain in the TMJ region.
2. Intervention (I): ARS
 3. Comparator (C): Other splints (OS) such as hard stabilization splint, soft stabilization splint, etc
 4. Types of outcome measures (O): TMJ pain, TMJ noise, muscle pain, adverse effects, if any
 5. Types of studies: Randomized controlled trials, quasi-randomized trials, or cross-over trials (first-period data were taken).

Exclusion criteria

1. Patients with congenital abnormalities and concomitant inflammatory or neoplastic conditions of TMJ, referred pain to TMJ due to other diseases, recent history of acute injury or any surgical treatment of TMJ and any form of therapy (including counseling, medication) administered concomitantly with splints. These patients were excluded as the inclusion of multiple conditions may have led to an invalid comparison
2. Studies that compare different types of intervention groups, studies that evaluate the effectiveness of splints after an initial active therapeutic intervention or concomitantly with other therapeutic interventions, reporting of data after definitive occlusal therapy, case reports, case series, reviews, conference proceedings, and abstracts.

Search strategy for databases and process of study selection

Three databases (Cochrane central register of Controlled Trials [CENTRAL], Medline [via PubMed], and Embase) were searched till May 2023 without any restriction on language and year of publication.

For each database, a comprehensive search strategy was developed for the identification of potentially eligible studies using various Boolean operators like “AND” or “OR” or “NOT.” Reviewer (BPS) conducted the search using different search strategies devised for different databases [Supplementary File 1]. The pool of retrieved articles was then transferred to reference management software (EndNote X9) to remove duplicates. After removing duplicates, articles were imported to Covidence for screening based on title and abstract initially, followed by full text by two independent reviewers (KM and BPS).^[26] Any difference of opinion or conflicts that arose between the two reviewers was resolved by discussion with other reviewers (RS and BT).

Data extraction and assessment of the risk of bias

Data extraction and risk of bias (RoB) assessment (using RoB 1.0 tool) were done in covidence by two reviewers (KM and BPS) independently in accordance with the Cochrane Handbook for systematic reviews of interventions.^[26] Any disagreements between the two reviewers was resolved by the third reviewer (RS).

Data extraction form was prepared and was checked for one definitely included study, one possibly included study, and one definitely nonincluded study. One reviewer modified the data extraction form and re-checked it. The form included the following details of each included study.

1. Identification of study: Study setting, country, sponsors, if any, publication details, E-mail of corresponding author
2. Method of study: Study design, objective, duration, ethical approval, null hypothesis, method of participant recruitment, follow-up, etc
3. Participants in the study: Inclusion and exclusion criteria, a diagnostic method used for DDwR, any baseline difference between groups, number of participants randomized, withdrawals or exclusion of participants with reasons
4. Intervention and comparison details of the study: Number of participants in intervention and comparison arm, type and details of intervention/comparator, follow-up, etc
5. Outcome included TMJ pain, TMJ noise, muscle pain, and adverse effects if any. The outcomes were divided as short term if follow-up was 3 months or less and long term if follow-up was more than 3 months.

Assessment of RoB was judged by RoB tool (RoB 1.0) after full-text screening.^[26] The tool comprised seven domains: Random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessor, incomplete outcome data, selective outcome reporting, and any other RoB. All domains were judged by two reviewers independently as low or unclear or high RoB with supporting annotation.

If any study required more information or clarification, one reviewer (KM) contacted the corresponding author of the study twice with a gap of 15 days if not responded by first E-mail. We judged unclear RoB for the concern domain if we did not get any response from the corresponding author. Cohen's Kappa (κ), measured through Covidence, to assess inter-rater reliability between the two reviewers, was found to be 0.84956. This indicates very good agreement between the reviewers KM and BPS.

Data analysis

Data were imported from Covidence to RevMan 5.4 for analysis.^[27] We used a random-effects model to obtain a forest plot. Heterogeneity was assessed using I^2 statistic. If the I^2 value was more than 50%, then it was considered substantial heterogeneity. Grading of Recommendations, assessment, development, and evaluation (GRADE) was done by GRADE pro software (GRADEPro GDT 2022).^[28,29]

RESULTS

A total of 1145 articles were retrieved upon searching the electronic databases till May 2023. Five hundred and thirty-nine duplicate articles were removed. Eighteen studies were excluded after full-text screening; wrong comparator (4), wrong intervention (5), wrong study design (1), wrong patient population (2), definition not as per protocol, (3) wrong outcome measure (1) and ongoing study (2).^[30,31] Four^[12,32-34] studies were included for systematic review after the screening stage. In these studies, ARS was compared with; canine-protected splint,^[12] sagittal vertical extrusion device (SVED) and mandibular anterior repositioning splint (MORA),^[32] and centric stabilization splint^[33,34] and soft splints.^[33] Table 1 presents the characteristics of the included studies. Eraslan *et al.*^[34] and Fayed *et al.*^[12] fulfilled all inclusion criteria, but data were not available in the form to be extracted and therefore could not be taken in meta-analysis. Hence, the

meta-analysis was done for the remaining two studies with the available outcomes.^[32,33] Figure 1 shows study flow diagram for the selection of studies as per PRISMA guidelines.

The quality of included studies was represented by RoB graph and summary in Figures 2 and 3, respectively. We judged 25% of studies^[32] with low RoB and 75% with unclear RoB for sequence generation.^[12,33,34] Kolmogorov–Smirnov test^[32] was used for sequencing of data. In most of the studies, the method of sequence generation was not mentioned.^[12,33] All studies were judged as unclear RoB for allocation concealment due to a lack of sufficient details about this domain. For blinding of participants and personnel, 25%^[32] of studies judged at low RoB as it mentioned double blind, 50%^[33,34] judged at unclear RoB as it did not mention blinding, and 25%^[12] of the studies judged at high RoB as pain may have been subjectively experienced by the participants due to knowledge of intervention and also personnel delivering treatment could not be blinded. For blinding of outcome assessor, 25%^[12] of studies were judged at low risk as the examiner was unaware of the treatment group and 75%^[32-34] studies were judged at unclear RoB as no mention of outcome assessors was made. For incomplete outcome data, 75%^[32-34] of studies were judged at low risk because outcome data of all participants was mentioned and 25%^[12] of studies were judged at high RoB as lost to follow-up without reason was found. For selective outcome reporting, 100%

Table 1: Basic characteristics of included studies

Study ID	Study design	Population	Sample size		Intervention	Comparison	Outcome	Follow up period
			ARS	Other				
Tecco, 2006 ^[32]	RCT	Disc displacement with reduction 28 males and 22 females 28.8 (14–63) years	20	20	Anterior repositioning splint: Acrylic ramp in the anterior palatal area, mandibular anterior teeth contact with the protrusive guiding ramp	MORA worn during daytime, SVED was worn at night MORA: Acrylic covers the occlusal and lingual surfaces of the mandibular posterior teeth, from the canines to the most distal molar bilaterally SVED: Anterior ramp is constructed behind the canine area and engages the anterior mandibular teeth, preventing mandibular movement in a posterior direction	TMJ pain TMJ clicking Muscle pain	3 months, 6 months
Fayed, 2004 ^[12]	RCT	Disc displacement with reduction 18–30 years	7	7	The anterior ramp of the ARS was developed into a smooth sliding surface. The ARS was adjusted to allow contacts on all the teeth, evenly and simultaneously, in the established advanced position	The CPS was adjusted to permit even centric occlusion contacts. In lateral excursions, the CPS provided canine rise	TMJ clicking	3 months
Devi, 2017 ^[33]	RCT	Disc displacement with reduction 18–55 years	10	20	ARS was given	Centric stabilization splint ($n=10$) Soft splint was given ($n=10$)	TMJ pain TMJ clicking	10 weeks
Eraslan, 2021 ^[34]	RCT	Disc displacement with reduction 18–60 years	20	20	ARS made of acrylic resin was given	Stabilization splint made of autopolymerizing acrylic resin was prepared and given	TMJ clicking	3 months

RCT: Randomized controlled trial, TMJ: Temporo-mandibular joint, CPS: Canine protected splint, SVED: Sagittal vertical extrusion device, MORA: Mandibular anterior repositioning splint, ARS: Anterior repositioning splint

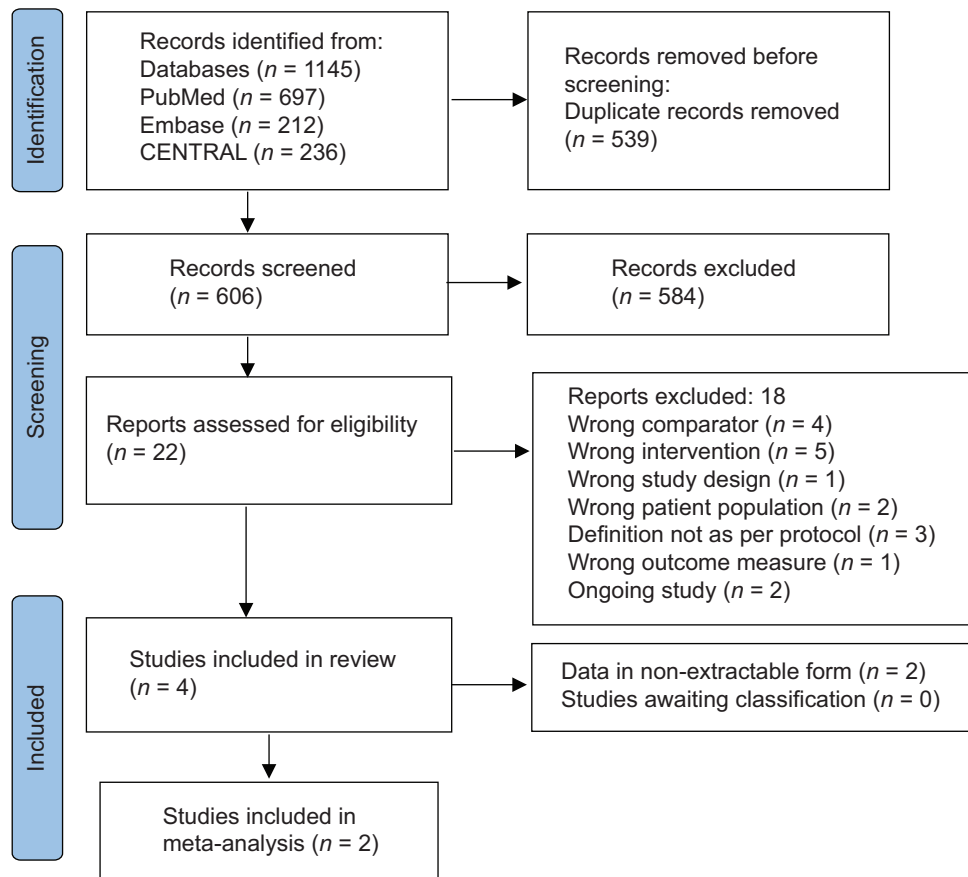


Figure 1: Preferred reporting items for systematic reviews and meta-analyses flow diagram

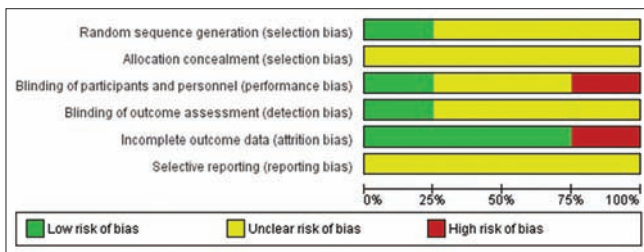


Figure 2: Risk of bias graph

of studies judged at unclear RoB as none of the studies were registered in an open-source database. Certainty of evidence was judged to prepare a summary of the finding table to inform-decision-making by dental practitioners using GRADE guidelines.

GRADE assessment showed very low or low certainty of evidence on comparison of ARS with other occlusal splints for different outcomes. The review quality was downgraded by one/two levels based on indirectness, inconsistency, limitation of study design, RoB, and imprecision [Table 2]. The random-effects model was used as there might be heterogeneity in regard to the usage of splints in different age, sex, and race groups and in different arches. Dichotomous and continuous data were measured using

risk ratio (RR) and mean difference (MD), respectively. 30 participants treated with ARS, 10 in Devi 2017^[33] and 20 in Tecco 2006.^[32] No evidence of any difference in TMJ clicking between ARS and OS in short term (RR 1.25, 95% confidence interval [CI] 0.91 - 1.72, $P = 0.17$, $I^2 = 0\%$, two studies; 60 participants), but evidence of a small difference was found in favor of OS in long term (RR 2.40, 95% CI 1.04–5.55, $P = 0.04$, one study; 40 participants) [Figure 4]. No evidence of any difference was found when ARS was compared to OS in DDwR for TMJ pain in short term (MD -2.15, 95% confidence interval [CI] -13.21-8.91, $P = 0.70$, $I^2 = 54\%$, two studies; 60 participants) and long term (MD 0.00, 95% CI -2.86–2.86, $P = 1.00$, one study; 40 participants) [Figure 5]. There was no evidence of any difference in muscle pain between ARS and OS in short term (RR 1.25, 95% CI 0.63–2.50, one study; 40 participants) [Figure 6].

DISCUSSION

The purpose of this review was to compare the clinical effectiveness of ARS with other occlusal appliances in treating symptoms of DDwR. The other occlusal splints (OS group) in the present systematic review were

Table 2: Summary of findings table of anterior repositioning splint versus other splints in the treatment of disc displacement with reduction using grading of recommendations, assessment, development, and evaluation approach

Patient or population: [Individuals with disc displacement with reduction]
 Setting: Hospital
 Intervention: [Anterior repositioning splint]
 Comparison: [Other splints]

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)
	Risk with [Other splints]	Risk with [Anterior repositioning splint]			
TMJ clicking short term	633 per 1,000	792 per 1,000 (576 to 1,000)	RR 1.25 (0.91 to 1.72)	60 (2 RCTs)	⊕⊕○○ Low ^{b,c}
TMJ clicking long term	250 per 1,000	600 per 1,000 (260 to 1,000)	RR 2.40 (1.04 to 5.55)	40 (1 RCT)	⊕⊕○○ Low ^{b,c}
TMJ pain short term	The mean TMJ pain short term was 0	MD 2.51 lower (13.21 lower to 8.91 higher)	-	60 (2 RCTs)	⊕○○○ Very low ^{a,b,c}
TMJ pain long term	The mean TMJ pain long term was 0	MD 0 (2.86 lower to 2.86 higher)	-	40 (1 RCT)	⊕⊕○○ Low ^{b,c}
Muscle pain short term	450 per 1,000	563 per 1,000 (284 to 1,000)	RR 1.25 (0.63 to 2.50)	40 (1 RCT)	⊕⊕○○ Low ^{b,c}

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; MD: Mean difference; RR: Risk ratio. Explanations: a. downgraded by one level for serious inconsistency as I2 is >30%; b. downgraded by one level for serious risk of bias as there are unclear risk of bias; c. downgraded by one level for serious imprecision as optimal information size is less; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation, RCTs: Randomized Controlled Trial, TMJ: Temporomandibular Joint. GRADE Working Group grades of evidence. High certainty: we are very confident that the true effect lies close to that of the estimate of the effect; Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect; Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

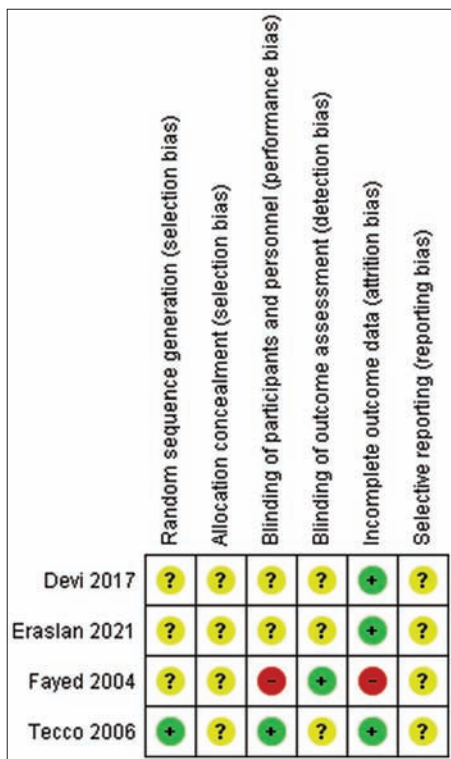


Figure 3: Risk of bias summary

canine protected splint (CPS), stabilization splint, SVED, and MORA.

The outcomes taken into consideration were TMJ pain, muscle pain, TMJ noise, and adverse effects; however,

we could not report on adverse effects as none of the included studies had reported regarding the same. In Devi et al.,^[33] 10 participants of ARS were compared with both 10 participants of centric stabilization splint and 10 participants of soft splint, as shown in Figures 4 and 5.

TMJ clicking is one of the common symptoms related to DDwR. The stiffness of elevator muscles causing TMJ clicking can be functionally recovered by removing the discrepancy between centric relation and maximum intercuspation.^[35] The results showed small evidence in favor of other splints when compared to ARS. This result is not in accordance with that reported by Al-Moraissi et al.^[36] where ARS lowered the incidence of clicking (moderate quality evidence) when compared to stabilization splint. It is possible that this difference, favoring OS group, may have resulted from reduced joint noises caused by expanding the TMJ space, allowing smooth translation of the condyle beyond disc surface inhomogeneity and positional aberrations to create a functional equilibrium within the stomatognathic system,^[37] or from achieving uniform contacts on all teeth with disocclusion of posteriors, which relaxes the elevator muscles resulting in reduced muscle tension.^[38]

Furthermore, in a study where joints were taken as units instead of patients, in the ARS group, the symptom of TMJ clicking got resolved in four out of five pretreatment joints compared to seven out of eight pretreatment joints in the CPS group.^[12] Occlusal splint therapy therefore helped to

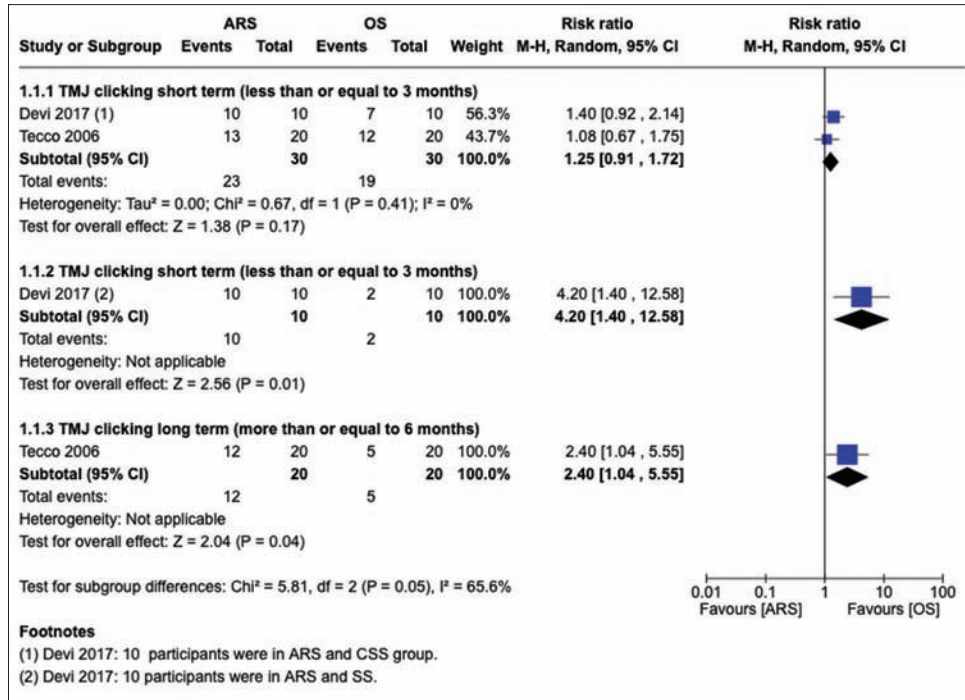


Figure 4: Forest plot comparison between anterior repositioning splint and other splint for tempero-mandibular joint (TMJ) noise (as TMJ clicking). TMJ: Temporo-mandibular joint, ARS: Anterior repositioning splint, OS: Other splint, CI: Confidence interval

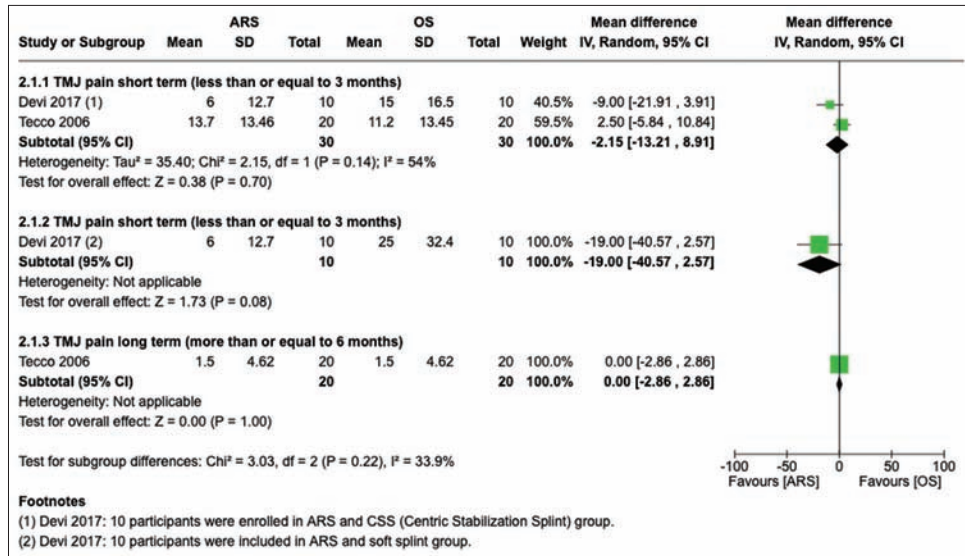


Figure 5: Forest plot comparison between anterior repositioning splint and other splint group for TMJ pain. SD: Standard deviation, IV: Intravenous, CI: Confidence interval, TMJ: Temporo-mandibular joint

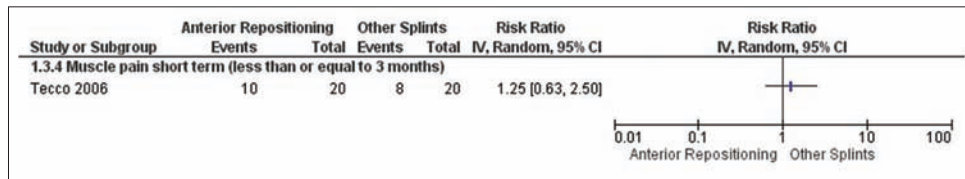


Figure 6: Forest plot comparison between ARS and OS for Muscle pain. IV: Intravenous, CI: Confidence interval

reduce TMJ clicking; however, it did not favor either of the two groups.

When TMJ pain in short term and long term was compared between ARS and OS, we found no evidence

of any difference. The result is not in accordance with that reported in the meta-analysis by Al-Moraissi *et al.*^[36] where ARS was found to be an effective treatment for arthrogenous TMD, but the quality of evidence was low.

This difference may be because ARS has been shown to reduce TMJ pain for anterior disc displacement by either reassembling the condyle anteriorly to recapture the displaced articular disc^[39,40] or by moving the anteriorly displaced articular disc backward in the therapeutic lower jaw position to restore normal disc condyle relation.^[41] Although uncommon, disc displacement could occur in directions other than the anterior, such as lateral, medial, or posterior.^[42] Hence, even the use of OS can help with TMJ pain relief by increasing occlusal stability, relaxing the muscles, deprogramming the mandibular posture, and changing the vertical dimension.^[43]

Muscle pain is the other common symptom of DDwR. On comparison of muscle pain between ARS and OS, the results did not find evidence of any difference. The result was not in accordance with Al-Moraissi *et al.*^[36] where they found that a hard stabilization splint (OS) achieved better results in myogenous TMD patients. This difference could be because of similar outcomes produced by all occlusal splints, such as relaxation of muscles by impeding parafunctional habits, protecting the teeth and jaws, normalization of periodontal ligament proprioception, change in jaw joint space and redistribution of condylar shear forces^[44,45]

Certainty of evidence using GRADE assessment showed low or very low quality of evidence because of downgrading the level of evidence. The reasons for downgrading the level of evidence were limitation in study design because sequence generation and blinding were not done adequately; inconsistency due to a high level of heterogeneity but reasons could not be explored due to a smaller number of studies; imprecision due to small sample size and wide CI crosses the line of no difference; indirectness due to various levels of protrusion used in fabricating anterior repositioning appliance.

None of the included studies were registered in the clinical trials registry, indicating bias in selective outcome reporting. As this might cause a negative impact on the quality of evidence generated, it is recommended that clinical trial registration should be emphasized and made mandatory for future clinical trials.

The differences observed between ARS and other occlusal splints in terms of TMJ pain, clicking, and muscle pain

might be attributed to variations in the main objective of utilizing different splints in each study, the subjective assessment of Visual Analog Scale scale, which may vary from patient to patient, and variations in the method of evaluation of TMJ clicking.

This systematic review includes a methodical technique and an extensive, transparent search strategy. We performed independent and duplicate eligibility evaluation and data extraction. Our emphasis was on patient-centred outcomes and we presented a summary of the finding table for certainty of evidence for chosen outcomes.

Limitations of the review

The current analysis has several limitations; (1) Due to language and database restrictions, less number of studies could be included in the review, (2) Exclusion, inclusion criteria, duration, and type of TMD varied among studies, so pooling of data could not be done for all studies, (3) Due to nonavailability of individual patient data, aggregate data were analyzed, impeding an in-depth analyses.

Future research

Randomized controlled trials, prospectively registered in an open-source database and conducted using an unbiased systematic approach, will be helpful in improving the quality of evidence on the topic under consideration.

CONCLUSION

Based on the findings from the present review, it can be concluded that OS showed a small difference in favor of ARS for TMJ clicking in patients with DDwR. For TMJ pain and muscle pain, no evidence of any difference was found between ARS and OS. Overall, we found insufficient evidence to judge that ARS is better than other occlusal appliances for the management of DDwR.

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Conflicts of interest

There are no conflicts of interest.

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- The style as well as bibliographic elements should be 100% accurate, to help get the references verified from the system. Even a single spelling error or addition of issue number/month of publication will lead to an error when verifying the reference.
- Example of a correct style
Sheahan P, O'leary G, Lee G, Fitzgibbon J. Cystic cervical metastases: Incidence and diagnosis using fine needle aspiration biopsy. *Otolaryngol Head Neck Surg* 2002;127:294-8.
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- If any of the bibliographic elements are missing, incorrect or extra (such as issue number), it will be shown as INCORRECT and link to possible articles in PubMed will be given.

SUPPLEMENTARY FILE

Supplementary file 1

Embase search strategy: “jaw disease”/exp OR “jaw disease” OR “jaw pain”/exp OR “jaw pain” OR “temporomandibular joint disorder”/exp OR “temporomandibular joint disorder” OR “dislocation”/exp OR dislocation OR “face pain”/exp OR “face pain” OR “arthralgia”/exp OR arthralgia OR “myofascial pain”/exp OR “myofascial pain” OR “sound”/exp OR sound OR “tinnitus”/exp OR tinnitus) AND (“mandibular advancement device”/exp OR “mandibular advancement device” OR “occlusal splint”/exp OR “occlusal splint.”)

PubMed search strategy: (((((((temporomandibular joint [MeSH Terms]) OR (craniomandibular disorders [MeSH Terms])) OR (((((((temporomandibular [Title/Abstract]) OR (temporo-mandibular [Title/Abstract])) OR (craniomandibular [Title/Abstract])) OR (cranio mandibular [Title/Abstract])) OR (jaw)) OR (mandib*)) OR (((tmj) OR (tmd)) OR (cmj)) OR (cmd)))) AND ((joint dislocations [MeSH Terms]) OR ((disc (displace * OR derange * OR dislocat * OR reduc*)) OR (disk (displace * OR derange * OR dislocat * OR reduc*)))))) OR (((temporomandibular joint [MeSH Terms]) OR (craniomandibular disorders [MeSH Terms])) OR (((((((temporomandibular [Title/Abstract]) OR (temporo-mandibular [Title/Abstract])) OR (craniomandibular [Title/Abstract])) OR (cranio mandibular [Title/Abstract])) OR (jaw)) OR (mandib*)) OR (((tmj) OR (tmd)) OR (cmj)) OR (cmd)))) AND (((facial pain [MeSH Terms]) OR (arthralgia [MeSH Terms])) OR (((“face pain”) OR (“orofacial pain”)) OR (“myofascial pain”)) OR (“joint pain”)))) OR (((temporomandibular joint [MeSH Terms]) OR (craniomandibular disorders [MeSH Terms])) OR (((((((temporomandibular [Title/Abstract]) OR (temporo-mandibular [Title/Abstract])) OR (craniomandibular [Title/Abstract])) OR (cranio mandibular [Title/Abstract])) OR (jaw)) OR (mandib*)) OR (((tmj) OR (tmd)) OR (cmj)) OR (cmd)))) AND (((sound [MeSH Terms]) OR (tinnitus [MeSH Terms])) OR (clicking tinnitus))) AND ((occlusal splints [MeSH Terms]) OR (((((((“oral splint*”) OR (“oral appliance*”) OR (“occlusal appliance*”) OR (“splint therapy”) OR (“dental splint*”) OR (“mandibular advancement splint*”) OR (“mandibular advancement device*”)))) AND (((((((randomized controlled trial [pt]) OR (controlled clinical trial [pt]) OR (randomized [tiab]) OR (placebo [tiab]) OR (drug therapy [sh]) OR (randomly [tiab]) OR (trial [tiab]) OR (groups [tiab]) NOT ((animals [mh]) NOT (humans [mh])))) Filters: English.

Central search strategy:

ID Search Hits.

#15 (“temporomandibular disorder”): Ti, ab, kw OR (TMJ disorder): Ti, ab, kw OR (TMD): Ti, ab, kw OR (disc displacement with reduction): Ti, ab, kw OR (arthralgia): Ti, ab, kw (Word variations have been searched) 7895.

#16 (occlusal splint): Ti, ab, kw (Word variations have been searched) 607.

#17 (anterior repositioning splint): Ti, ab, kw OR (ARS): Ti, ab, kw OR (splint): Ti, ab, kw OR (repositioning appliance): Ti, ab, kw (Word variations have been searched) 7819.

#18 (tmj pain): Ti, ab, kw OR (joint pain): Ti, ab, kw OR (muscle pain): Ti, ab, kw OR (tmj noise): Ti, ab, kw OR (TMJ clicking): Ti, ab, kw (Word variations have been searched) 41135.

#19 #15 AND #16 AND #17 AND #18 236.

Evaluation of marginal bone level, technical and biological complications between screw-retained and cement-retained all-ceramic implant-supported crowns on zirconia abutment: A systematic review and meta-analysis

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Abstract

Purpose: The purpose of this study was to evaluate the difference in marginal bone level, technical and biological complications between screw-retained and cemented all-ceramic implant-supported crowns fabricated on zirconia abutment at different follow-up periods.

Materials and Methods: Independent search was conducted in Cochrane Library, EBSCO, and PubMed/PubMed Central/MEDLINE databases and the Google Scholar search engine for prospective studies and randomized controlled trials published between January 2014 and June 2023 evaluating the marginal bone level, technical and biological complications between screw-retained and cemented all-ceramic implant-supported crowns fabricated on zirconia abutment. Meta-analysis was conducted to assess the quantitative data on the marginal bone level and biological complications.

Results: A total of eight studies were included for qualitative synthesis and six studies for quantitative synthesis. For marginal bone level, no statistically significant difference was observed ($P = 0.83$ and $P = 0.69$, respectively) during the follow-up period of 3 years and 5 years. For probing depth, the cemented group showed more amount of probing depth than the screw-retained group at a follow-up period of 3 years ($P < 0.05$) whereas no statistically significant difference was observed at a follow-up period of 5 years ($P = 0.73$). For bleeding on probing, the cemented group showed more probing depth than the screw-retained group at a follow-up period of 5 years ($P = 0.10$).

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INTRODUCTION

Prosthetic rehabilitation of single missing teeth with implant-supported fixed prosthesis became a predictable ideal treatment option for long-term successful clinical results.^[1-3] Titanium implants restored with either

cemented or screw-retained porcelain fused to metal crown was economical, durable successful treatment but had drawbacks of display of metal hue, ceramic chipping, and unaesthetic outcomes.^[4-6] To overcome

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Conclusion: The evidence suggests that the screw-retained group showed no statistically significant difference in marginal bone level, comparatively fewer biological complications, and relatively higher technical complications than the cemented group at different follow-up periods.

Keywords: Ceramic, computer-aided design/computer-aided manufacturing, marginal bone level, single implant, zirconia abutment

these limitations, custom-made computer-aided design (CAD)-computer-aided manufacturing (CAM) zirconia abutments are popularly used due to enhanced esthetic and mechanical properties, increased peri-implant emergence profile, reduced soft-tissue inflammation, reduced bacterial adhesion, enhanced soft-tissue integrity, and stabilization of marginal bone around the implant-supported restoration.^[7-11] However, Dini *et al.* in their systematic review concluded that zirconia abutment can be a favorable choice of implant abutment in the esthetic zone with the presence of unpredictable risk of fracture.^[12,13] All-ceramic implant-supported crowns on zirconia abutment can either be screw retained or cement retained.^[14] Cement-retained all-ceramic implant-supported crowns are cemented as a separate unit on the zirconia abutment. Screw-retained all-ceramic implant-supported crowns are fabricated as a one-piece hybrid-abutment-crown unit with a screw channel for screw tightening and loosening.^[15] Both types of reconstructions can be used for the single unit as well as for multiple unit prosthesis. Few studies reported that cement-retained all-ceramic implant-supported crowns showed the ease of fabrication and clinical and technical resemblance to tooth-borne reconstruction procedures but caused biological complications and peri-implantitis due to excess cement residue.^[16,17] To overcome certain disadvantages of cement-retained implant crowns, one-piece screw-retained all-ceramic implant crowns were used due to easy accessibility through the screw hole and elimination of luting cement.^[18] Few studies reported that marginal bone loss, biological, and technical complications was clinically more with cemented implant crowns.^[19] Few studies reported that cement-retained showed more marginal bone loss and biological and technical complications.^[20,21] Few studies reported no statistically significant difference between cement and screw-retained crowns on zirconia abutment in terms of biological, technical, and marginal bone level.^[22-24]

This systematic review aimed to evaluate the available evidence on the difference in marginal bone level and technical and biological complications between screw-retained and cement-retained all-ceramic implant-supported crowns fabricated on zirconia

abutment. The results obtained from this review would help the clinicians to make an appropriate decision for prosthetic rehabilitation of a single implant with zirconia abutment with either screw-retained or cement-retained all-ceramic implant-supported crowns for esthetically durable outcomes based on the clinical situations. The null hypothesis was that there would be no difference in the marginal bone level, technical and biological complications between screw-retained and cement-retained all-ceramic implant-supported crowns fabricated on zirconia abutment.

MATERIALS AND METHODS

Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines and Prospective Register of Systematic Reviews registration

The protocol registration with the CRD42021261601 code was done at the Prospective Register of Systematic Reviews (PROSPERO) database,^[25,26] and the present systematic review and meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines.^[27-32]

Review question

The following review question was formulated according to the Population, Intervention, Comparison, Outcome, and Study design (PICOS) framework:^[33-39] “Is there a difference between marginal bone level, technical and biological complications between screw-retained and cement-retained all-ceramic implant-supported crowns fabricated on zirconia abutment? The population was patients with single implant restored with screw-retained or cement-retained all-ceramic crown on zirconia abutment. The intervention was screw-retained all-ceramic implant-supported crown fabricated on zirconia abutment. The comparison was cement-retained all-ceramic implant-supported crown fabricated on zirconia abutment. The outcome was marginal bone level, technical and biological complications. The study design was randomized control trials and prospective studies.

Study selection criteria

Inclusion criteria included randomized controlled trials (RCTs) and prospective studies that evaluated

marginal bone level, technical and biological complications between screw-retained and cement-retained all-ceramic implant-supported crowns fabricated on zirconia abutment. Full-text human studies published in English between January 2014 and June 2023 were included. Exclusion criteria were clinical reports, *in vitro* studies, reviews, online surveys, and questionnaires not in English published before 2014. Studies done on single implant restored with screw-retained or cement-retained all-ceramic crown on titanium abutment were excluded.

Search strategy

Based on PICOS selection criteria and Cohen kappa inter-reliability score of 0.92 between the two independent reviewers (S. P. and J. I.), the advanced search for relevant studies was conducted with the presence of a third reviewer (J. N.).^[40] The advanced electronic search was conducted in the Cochrane Library, EBSCO, and PubMed/PubMed Central/Medline databases and the Google Scholar search engine using the following keywords, MeSH terms, and phrases coupled with Boolean operators (AND, OR, and NOT) [Table 1].^[41,42] For PubMed, Cochrane and EBSCO database search strategy used was ((((((zirconia abutment) AND all ceramic implant crown) AND screw retained) AND cement-retained) AND technical) AND biological) AND marginal bone) AND randomized controlled trial))))). The terms used for advanced search in Google Scholar were zirconia abutment, all ceramic implant crown, cement-retained implant crown, screw-retained implant crown, technical, biological, complications, marginal bone level, and randomized controlled trial.

Study selection and data extraction

Two reviewers (S. P. and J. I.) independently reviewed and assessed all the titles and abstracts of studies to remove the duplicates. The irrelevant articles from the remaining titles and abstracts were examined and deleted.^[41,42] The remaining full-text articles were examined for the degree of compliance and the irrelevant articles were excluded.^[41,42] The relevant eight studies were included from all the databases according to the selection criteria. Two reviewers (S. P. and J. I.) individually performed data extraction and mentioned the characteristics of eight included studies for all primary outcomes: study

identification, sample size, intervention group, control group, marginal bone level, biological complication, technical complication, follow-up, and conclusion in the Google Excel sheet.^[26,40]

Risk of bias assessment, quality assessment, and meta-analysis

The risk of bias (ROB) assessment for RCTs was done using the Cochrane ROB 2 tool and graded as high, low, or unclear from the scores of different domains of random sequence generation, allocation concealment, blinding of patients, outcome assessment, incomplete outcome data, and other biases.^[43,44] The Newcastle–Ottawa quality assessment scale of three domains selection, comparability, and exposure was used for prospective study design^[45,46] using Review Manager (RevMan) Version 5.4. The Cochrane Collaboration, 2020.^[47] The Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) assessment tool was used for the quality assessment of included studies.^[48] Based on the reported quantitative data from the included studies, a meta-analysis was performed.^[49]

RESULTS

Literature search

From different electronic database searches, a total of 195 articles were procured and 35 were duplicates among them. The remaining 160 abstracts were examined and 140 irrelevant articles were excluded. Full-text assessment of twenty eligible studies was done. Twenty full-text articles were screened, and 12 studies were excluded due to inappropriate outcomes. For the systematic review, eight studies were included. For meta-analysis, six studies were included [Figure 1].

Characteristics of included studies

The detailed characteristic data of eight included studies^[50-57] are listed in Table 2. Seven of the included studies were RCTs and one study was a prospective study. Six studies have reported data on marginal bone loss in terms of millimeters.^[50-57] Seven studies reported biological complications in terms of probing depth and bleeding on probing.^[50-52,54-57] Eight studies reported technical outcomes for ceramic chipping, loss of retention, loss of marginal adaptation, abutment fracture, and screw loosening. In

Table 1: Search terms used in search strategy as per Population, Intervention, Comparison, Outcome, and Study design framework

Population	Intervention	Control	Outcome	Study design
Adult	Zirconia abutment, all ceramic implant crown, screw-retained implant crown	Zirconia abutment, all ceramic implant crown, cement-retained implant crown	Technical, biological, complications, marginal bone level	Randomized control trials, clinical studies, prospective studies

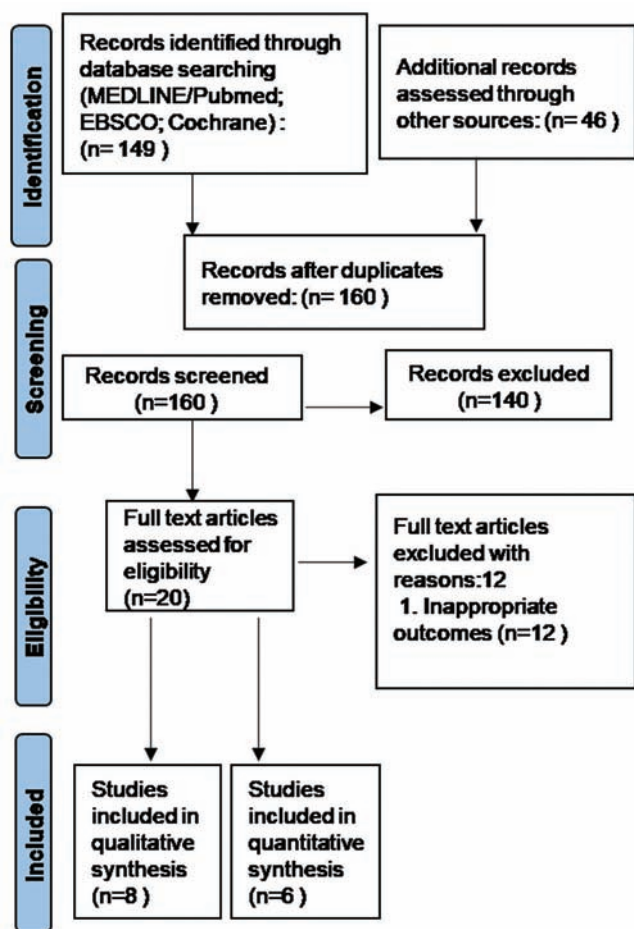


Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram

this review, 362 participants with a mean age of 49 years received 362 implants, of which 167 were restored with screw-retained all-ceramic implant crown and 195 with cement-retained all-ceramic implant crown on zirconia abutment. The follow-up period varied between 6 months and 11 years.

Risk of bias assessment

According to the Cochrane ROB 2 tool for RCTs,^[43] three studies^[52,54,55] showed a moderate ROB and four studies showed a low ROB^[50,51,53,56] [Figure 2]. The quality of one prospective study by Zembic *et al.* was good with a score of seven following the Newcastle–Ottawa assessment tool.^[57] GRADE assessment for marginal bone level, biological complications, and technical outcomes was done showing high quality for all the outcomes.^[48]

Meta-analysis

Heterogeneity measurement among the studies was done by the I^2 statistic method, where for $>50\%$ I^2 value random effect model was used, and for $<50\%$ I^2 value fixed effect model was used. Meta-analysis was conducted for six

studies at two different follow-up periods of 3 years and 5 years from the quantitative outcomes of mean, standard deviation, and the total number.^[58-61]

Meta-analysis for marginal bone level

The meta-analysis of marginal bone level comprised five studies.^[50,52-55] At follow-up period of 3 years, two studies^[53,54] were included and reported no statistically significant difference between both the groups ($I^2 = 90\%$, $P = 0.83$, confidence interval [CI] = 95%, pooled mean difference = 0.05 [−0.44, 0.54]), as depicted in the forest plot [Figure 3]. At follow-up period of 5 years, three studies^[50,52,55] were included and reported no statistically significant difference between both the groups ($I^2 = 77\%$, $P = 0.69$, CI = 95%, pooled mean difference = 0.05 [−0.19, 0.29]), as depicted in the forest plot [Figure 4].

Meta-analysis for probing depth

For biological complications, two subgroups of probing depth and bleeding on probing were analyzed. For probing depth, five studies^[40,52,54-56] were included. At follow-up period of 3 years, two studies^[54,56] were included and reported a statistically significant difference between both the groups ($I^2 = 0\%$, $P < 0.00001$, CI = 95%, pooled mean difference = −0.20 [−0.24, −0.16]), as depicted in the forest plot [Figure 3]. The positive association stated that the cement-retained group showed more amount of probing depth than the screw-retained group. At follow-up period of 5 years, three studies^[50,52,54] were included and reported no statistically significant difference between both the groups ($I^2 = 0\%$, $P = 0.73$, CI = 95%, pooled mean difference = 0.04 [−0.20, 0.29]), as depicted in the forest plot [Figure 4].

Meta-analysis for bleeding on probing

For meta-analysis of bleeding on probing, two studies^[50,55] were included and a statistically significant difference was observed between both the groups at a follow-up period of 5 years ($I^2 = 0\%$, $P = 0.10$, CI = 95%, pooled mean difference = −11.06 [−24.05, 1.92]), as depicted in the forest plot [Figure 4]. The positive association stated that the cement-retained group showed more amount of bleeding on probing than the screw-retained group.

Meta-analysis for technical outcomes

For technical outcomes, no quantitative data was obtained.

DISCUSSION

The developing era comprises different implant systems, implant-abutment connections, types of implant abutment, abutment to superstructure connection,

Table 2: Data extraction table for included studies

Study ID	Study design	Duration of the study	Sample size	Number of screw-retained zirconia abutment crowns on (intervention group)	Number of cement-retained zirconia abutment crowns on (control group)	MBL (mm) mean and SD	Biological complications		Technical outcomes			Follow-up	Conclusion
							Mean probing depth (mm) mean and SD	Mean bleeding on probing mean and SD	Ceramic chipping	Marginal Adaptation	Screw loosening		
Zembic <i>et al.</i> , 2015 ^[57]	Prospective	11 years	27	0	27	NR	CR: 3.4±1.1	CR: 0.3±0.3	NR	NR	SR: 17% CR: 17%	11 years	BC: No significant biological complications were reported at implant site between test and control group ^[57] Screw retained showed better clinical performance than cement retained in regards of technical and biological outcomes ^[56] BC: No statistically significant difference was observed between the two groups ^[51]
Cacaci <i>et al.</i> , 2017 ^[56]	RCT	36.9 months	114	53	61	NR	NR	SR: 0.5±0.1 CR: 0.7±0.1	NR	NR	NR	36 months	BC: No statistically significant difference was observed between the two groups ^[51] MBL: 5 years TC: 10 years
Thoma <i>et al.</i> , 2018 ^[51]	RCT	5 years	33	16	17	SR: 0.48 CR: 0.55	SR: 3.08 CR: 3.00	SR: 17% CR: 17%	SR: None CR: One crown	NR	NR	6 months	BC: No statistically significant difference was observed between the two groups ^[51] MBL: 5 years TC: 10 years
Amorfini <i>et al.</i> , 2018 ^[52]	RCT	10 years	32	16	16	SR: -0.29±0.23 CR: -0.15±0.09	SR: 3.3±0.4 CR: 3.1±1	SR: 0.4±0.3 CR: 0.4±0.4	SR: One case 3% CR: crown 3%	SR: None CR: One case 3%	SR: One case 3% CR: One case 3%	BC: No statistically significant difference was observed between the two groups ^[51] MBL: 5 years TC: 10 years	

Contd...

Table 2: Contd...

Study ID	Study design	Duration of the study	Sample size	Number of screw-retained zirconia abutment crowns on (intervention group)	Number of cement-retained zirconia abutment crowns on (control group)	MBL (mm) mean and SD	Biological complications		Technical outcomes			Follow-up	Conclusion
							Mean probing depth (mm) mean and SD	Mean bleeding on probing mean and SD	Ceramic chipping	Marginal Adaptation	Abutment fracture		
Heierle et al., 2019 ^[53]	RCT	3 years	34	17	17	SR: 0.5±0.35 CR: 0.7±0.34	NR	NR	SR: One minor case CR: One major case	SR: One case 3% CR: None	SR: One case 3% CR: None	3 years	MBL: No statistical difference 11% of overall technical complications was observed in both groups ^[53] MBL: No statistically significant difference was seen in the two groups BC: Catastrophic BC occurred in the CR group only High rate of catastrophic technical complications was seen more with screw retained than cement retained (15%) ^[54] MBL: CR more than SR group BC: No statistically significant difference was observed between the two groups TO: 15.4% for both the groups Relatively high in both groups ^[48]
Kraus et al., 2019 ^[54]	RCT	3 years	44	24	20	SR: -0.4±0.3 CR: -0.7±0.4	SR: 3.2±0.7 CR: 3.3±0.6	SR: 0.18 CR: 0.18	SR: None CR: One case minor	SR: Four case CR: Two case	SR: None CR: None	3 years	
Lamperti et al., 2022 ^[50]	RCT	5 years	34	17	17	SR: -0.20±0.4 CR: -0.34±0.31	SR: 3.2±0.5 CR: 3.2±0.6	SR: 33.3% CR: 37.2%	SR: One minor CR: Four minor One major	SR: None CR: One case minor	SR: Two cases CR: One case minor	5 years	

Contd..

Table 2: Contd...

Study ID	Study design	Duration of the study	Sample size	Number of screw-retained zirconia abutment (intervention group)	Number of cement-retained zirconia abutment (control group)	MBL (mm) mean and SD	Biological complications		Technical outcomes			Follow-up	Conclusion
							Mean probing depth (mm) mean and SD	Mean bleeding on probing mean and SD	Ceramic chipping	Marginal Adaptation	Screw loosening		
Kraus et al., 2022 ^[5]	RCT	5 years	44	24	20	SR: -0.4±0.4 CR: -0.4±0.4	SR: 3.5±0.6 CR: 3.5±0.8	SR: 27±15% CR: 43±36%	SR: One minor CR: Three minor	SR: Four case CR: Two case	SR: Four case CR: Two case	5 years	MBL: No statistical difference BC: PD showed no statistically significant difference between the two groups For BoP cement retained showed a higher value than screw retained TO: CR showed a higher rate 68.4% SR 22.7% ^[55]

BC: Biological complications, CR: Cement retained, MBL: Marginal bone level, NR: Not reported, RCT: Randomized control trial, SR: Screw-retained, TO: Technical outcomes, SD: Standard deviation, PD: Probing depth

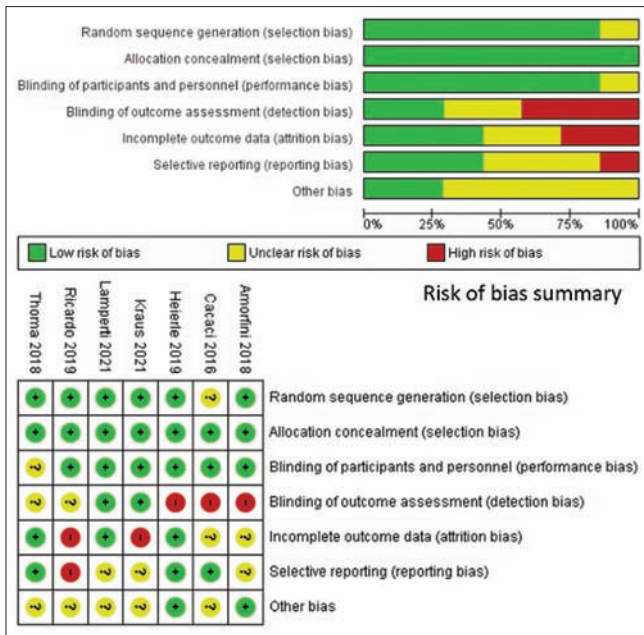


Figure 2: Graph for risk of bias and risk of bias summary

and various prosthetic materials. Due to the constant advancements in dental materials, zirconia has become an esthetic material of choice for implant abutments and superstructures. Titanium abutment along with porcelain fused to metal implant crowns either cement or screw-retained was the clinician’s choice. With the growing attribute of conversion into esthetic dentistry, zirconia abutments with all-ceramic cemented or screw-retained implant crowns are evolved and been used as a treatment option. However, the success of any treatment depends on its response to the surrounding mucosa, bone, opposing tooth, forces, and integration.^[3,51,53-55] After the evaluation of marginal bone level, technical and biological complications outcomes among all-ceramic cement or screw-retained implant crown on zirconia abutment, the type of retention to be used based on the clinical success rate can be decided. The present study analysis was conducted to compare the marginal bone level, technical and biological complications between screw-retained and

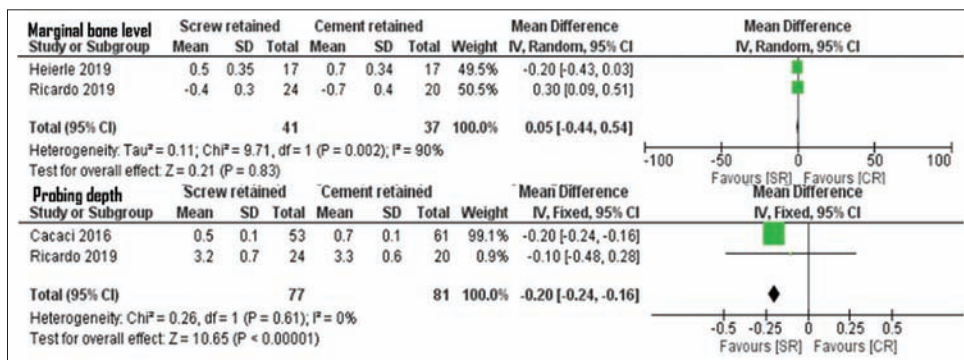


Figure 3: Forest plot for marginal bone level, probing depth, and bleeding on probing at 3-year follow-up period. SD: Standard deviation, CI: Confidence interval, IV: Intravenous

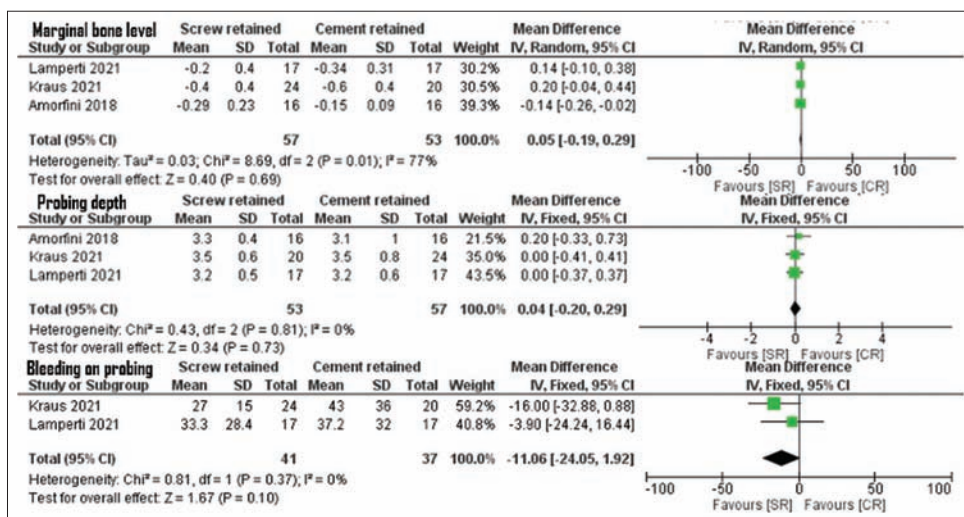


Figure 4: Forest plot for marginal bone level, probing depth, and bleeding on probing at 5-year follow-up period. SD: Standard deviation, CI: Confidence interval, IV: Intravenous

cement-retained all-ceramic implant crowns fabricated on zirconia abutment.

The mean marginal bone level is the distance measured from the implant shoulder to the bone crest at the mesial and distal aspects of the implant on radiographs in millimeters and calculated as a difference from the time of crown insertion till the follow-up period.^[50-55] For the marginal bone level, the null hypothesis was accepted. At 3 and 5 years of follow-up, there was no statistically significant difference in the marginal bone level between the two groups. This result was in accordance with the studies done by Thoma *et al.*,^[51] Amorfini *et al.*,^[52] Heierle *et al.*,^[53] Kraus *et al.*,^[54] and Kraus *et al.*^[55] reported no difference between the marginal bone level for cement-retained and screw-retained implant-supported all-ceramic crown on zirconia abutment measured at baseline and different follow-up period.^[50-55] Lemos *et al.*^[61] conducted a study to evaluate the role of plaque index in marginal bone loss between cement-retained and screw-retained implant crowns and stated no difference between both the groups. However, Lamperti *et al.*^[50] reported that marginal bone loss was more for the cement-retained group compared with the screw-retained group.^[50] No statistically significant difference was reported due to high heterogeneity, small sample size, shorter follow-up period, less number of included studies, biomechanics of prosthesis, and level of prosthesis.

Biological complications included probing depth and bleeding on probing. These parameters were recorded using a periodontal probe at six sites and mean values were calculated.^[50-57] For probing depth, the null hypothesis was rejected. At a follow-up period of 3 years, a statistically significant difference was observed with the cement-retained group showing more amount of probing depth than the screw-retained group. This result was in accordance with studies done by Kraus *et al.*^[54] and Cacaci *et al.*^[56] who reported more amount of probing depth for the cement-retained group than the screw-retained group at a follow-up period of 3 years.^[54,56] However, Lamperti *et al.*,^[50] Amorfini *et al.*,^[52] and Kraus *et al.*^[55] reported no statistically significant difference at a follow-up period of 5 years.^[50,52,55] The higher probing depth occurred due to cement remnants in the peri-implant sulcus leading to excessive tissue growth as a natural reaction to tissue irritation and the type of cement used.

For bleeding on probing, the null hypothesis was rejected. A statistically significant difference was observed with the cement-retained group showing more amount of bleeding on probing than the screw-retained group. This result

was in accordance with the studies done by Kraus *et al.*,^[54] Kraus *et al.*,^[55] and Cacaci *et al.*^[56] who reported higher biological complications with the cement-retained group than with the screw-retained group.^[54-56] However, studies done by Lamperti *et al.*,^[50] Thoma *et al.*,^[51] Amorfini *et al.*,^[52] and Zembic *et al.*^[57] reported no statistically significant difference between both the groups.^[50-52,57] The higher bleeding on probing occurred due to the presence of cement residues causing increased cellular response leading to gingival inflammation and a tendency to ooze out blood on probing.

Eight studies reported technical outcomes in terms of ceramic chipping, loss of retention, loss of marginal adaptation, abutment fracture, and screw loosening. A study done by Zembic *et al.*^[57] reported no technical complications with the cement-retained group.^[57] Studies done by Thoma *et al.*,^[51] Kraus *et al.*,^[54] and Cacaci *et al.*^[56] reported a higher rate of technical complications with the cement-retained group (68.4%) than with the screw-retained group (22.7%).^[51,54,56] A study done by Amorfini *et al.*^[52] reported the same rate of technical complications for both the groups (one case of ceramic chipping, one case of screw loosening in screw-retained crown, one case of abutment fracture, and one case of decementation in the cement-retained group).^[52] Studies done by Lamperti *et al.*^[50] and Heierle *et al.*^[53] reported an overall higher rate of technical complications in both the groups^[50,53] (11% at a follow-up period of 3 years^[53] and 15.4% at a follow-up period of 5 years).^[24,50] A study done by Kraus *et al.*^[54] reported higher catastrophic technical complications (>15%) for the screw-retained group than the cement-retained group at follow-up period of 3 years.^[54]

Screw-retained all-ceramic implant crown on zirconia abutment can be a choice of retention for prosthetic rehabilitation of the single implant which provides enhanced esthetic and successful outcomes by reducing marginal bone loss and less amount of biological complication due to direct veneering to zirconia abutment. However, frequent follow-up and care need to be undertaken to minimize technical complications. Thus, a clinician can opt for all-ceramic esthetic treatment options for a single implant crown with either screw-retained or cement-retained type of retention on an esthetic zirconia abutment. However, the choice of cement, proper removal of excess cement, and postcementation maintenance should be taken care of while opting for cement-retained all-ceramic implant crown for successful long-term results.

The limitations of this review and meta-analysis were the inclusion of fewer RCTs with varying follow-up periods

and the lack of quantitative data in any included studies for technical outcomes. To overcome these limitations, more RCTs should be included with results mentioned during the same follow-up periods. Thus, consideration should be given to recording the results at specific and different time intervals, and more clinical trials should be conducted on the current study topic.

CONCLUSIONS

The findings from this systematic review and meta-analysis can be concluded into the following:

1. For marginal bone level, no statistically significant difference was observed between the cement-retained and screw-retained groups at a follow-up period of 3 years and 5 years
2. Statistically higher amount of probing depth was observed for the cement-retained group than the screw-retained group at a follow-up period of 3 years
3. No statistically significant difference was observed for the cement-retained and screw-retained groups for probing depth at a follow-up period of 5 years
4. Statistically higher amount of bleeding on probing was observed for the cement-retained group than the screw-retained group at a follow-up period of 5 years
5. The evidence obtained for technical outcomes concludes that the cement-retained and screw-retained groups showed relatively higher rates of technical complications.

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Conflicts of interest

There are no conflicts of interest.

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Prosthetic rehabilitation of intraoral defects in patients with rhino-orbital-cerebral-mucormycosis: A systematic review

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Abstract

Aim: This study aimed to systematically review the frequency and type of intraoral prosthetic rehabilitation in patients with rhino-orbital-cerebral-mucormycosis (ROCM).

Settings and Design: Systematic review following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Materials and Methods: An electronic search was conducted in databases including PubMed, Web of Science, Scopus, and Google Scholar. Case reports that documented prosthetic rehabilitation following surgery in patients with ROCM were included. This review was registered under the International Prospective Register of Systematic Reviews CRD42021262284. Assessment of the quality of the included studies was done using the Joanna Briggs Institute Critical Appraisal Checklist for Case reports, which comprised of an eight-item checklist. The recorded observations were organized and subjected to analysis.

Statistical Analysis Used: Qualitative analysis was used.

Results: Among the 25 case reports, type IId defect was the most common. Three types of prosthetic treatments were rendered, with the obturator being the most common choice of rehabilitation, followed by implant-retained obturator overdenture and fixed implant-supported prosthesis. Patients undergoing implant-based rehabilitation exhibited a 100% survival rate for implants, with follow-up periods spanning from 6 months to 3 years. No prosthetic complications were reported in any of the included case reports.

Conclusions: The prevailing defect type identified was IId (48%), while the treatment of choice most frequently employed was an obturator (84%). However, with limited evidence available at present, further research is required to draw more definitive conclusions.

Keywords: Maxillectomy, obturator, overdenture, rhino-orbital-cerebral-mucormycosis

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INTRODUCTION

Mucormycosis, previously referred to as zygomycosis, is an opportunistic fungal infection attributed to a cluster of filamentous molds belonging to the *Mucorales* order. These

molds can be found in various environmental habitats such as soil, decomposing plant material, bread, and dust.^[1-4] It typically affects people who are immunocompromised or have an altered metabolic status. Common

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predisposing conditions include diabetes mellitus with or without ketoacidosis, hematologic malignancies, organ transplantation, iron overload, corticosteroid use, sustained trauma, prolonged neutropenia, and malnutrition.^[5,6] The most prevalent method of contamination is through inhalation of fungus spores followed by invasion along the arterial pathways, resulting in arterial thrombosis and tissue infarction.^[7,8]

According to its anatomical locations, mucormycosis can be divided into six types, including rhino-orbital-cerebral, pulmonary, cutaneous, gastrointestinal, disseminated, and uncommon sites. Rhino-orbital-cerebral-mucormycosis (ROCM) is the most common type, accounting for about one-third to one-half of all mucormycosis cases.^[9,10] The rhino cerebral type is often classified into categories 1 and 2. Type 1 is the rhino-orbital-cerebral form that can be extremely lethal, whereas type 2 is the rhinomaxillary form that is comparatively less fatal. ROCM has the propensity to invade the sinuses, followed by further extension into the palate, oral mucosa, bone, orbit, and brain.^[11] The initial manifestation of ROCM may be in the form of nonspecific symptoms with varying severity, such as fever, headache, nausea, and generalized weakness. Intraorally, this condition can manifest as changes in mucosal discoloration, swelling, ulcerations, superficial necrotic regions on the palate, bone exposure, and the development of dark eschar due to necrosis.^[12,13]

Dentists play a pivotal role in the early diagnosis of ROCM because an initial, nonspecific palatal ulceration could be the first presenting symptom of mucormycosis.^[12,14,15] As the lesions of mucormycosis occur primarily around the rhino cerebral areas involving facial tissues, maxilla, palate, and alveolar bone, surgical debridement and/or surgical resection become inevitable, but surgical procedures alone are insufficient. Prosthetic rehabilitation following surgery is essential as it helps improve masticatory efficiency, speech intelligibility, and also relieves psychological distress.^[16,17]

The research objectives of the systematic review are:

1. To determine the frequency of intraoral defects occurring in patients with ROCM as categorized by Brown's classification
2. To determine the type of prosthesis suitable for a particular class of intraoral defect.

Thus, the present systematic review aimed to synthesize the presently available evidence regarding the prosthetic rehabilitation options for intraoral defects occurring after surgical treatment of mucormycosis.

MATERIALS AND METHODS

Protocol and registration

The study protocol was registered on the International Prospective Register of Systematic Reviews website, Center for Reviews and Dissemination, University of York, with registration number CRD42021262284. It was developed following the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. The systematic review did not involve human or animal participants. Patient anonymity was maintained as we refrained from using names and images from the case reports in this systematic review.

Review question

The following PICOS question was used to frame the search strategy:

- Population: Patients with acquired intraoral defects occurring secondary to ROCM
- Intervention: Prosthetic rehabilitation with or without adjunct reconstructive surgery
- Comparison: Not applicable
- Outcome: Frequency and type of prosthesis given in intraoral defects as categorized by Brown's classification
- Study: Case reports, case series.

Information sources

All studies reporting on prosthetic management of mucormycosis were searched in electronic databases, including PubMed, Scopus, Web of Science, and Google Scholar, up to August 2022.

Eligibility criteria

Inclusion criteria

1. Age 18 years and above
2. Intraoral defects as a result of ROCM
3. Prosthetic rehabilitation of intraoral defect.

Exclusion criteria

1. Pediatric patients aged < 18 years
2. Sole extraoral defects as a result of ROCM
3. Communication defects
4. Articles which are not clearly mentioning about the type of defect and/or the prosthesis
5. Articles in language other than English.

Search strategy

The following search strategy was used: (Mucormycosis OR Mucorales OR Zygomycosis OR Black fungus) AND ("Rhino orbital cerebral" OR Rhinocerebral) AND (Prosthetic OR Prosthodontic OR Oral) AND (Rehabilitation), (Mucormycosis OR Mucorales

OR Zygomycosis OR Black fungus) AND (“Rhino orbital cerebral” OR Rhinocerebral) AND (obturator OR implants * OR prosthesis*).

Study design

The type of studies included for assessment comprised case reports. Evidence is scarce on ROCM due to its infrequent occurrence, challenges in diagnosis, complex diagnostic procedures, and geographical variations. The limited number of cases, coupled with diagnostic difficulties and research imbalances, collectively contribute to the absence of comprehensive data. Thus, due to the unavailability of high-quality experimental studies such as randomized controlled trials, case reports were included as they represent the best available evidence to guide clinical practice.

Data extraction and analysis

Two of the authors (S.W., R.S.M.) independently reviewed the titles and abstracts of all the articles that were obtained from the database after the search and selected those that complied with the inclusion criteria. Full-text review was done to weed out the articles according to the criteria and finally obtain articles that were included in the review. Both the reviewers then extracted the following data individually from the articles included in the study: first author, year of publication, demographic data (age and sex), description of the defect, any adjunct reconstructive surgery, categorization according to Brown’s classification, type of prosthesis, whether implant supported or not, type of implant if present, follow-up period, complications. For the studies that involved implants, data related to the type of implants and number of implants used were also collected. In case of any disagreement between the investigators, a third reviewer (A.Y.D.) was consulted to reach a consensus. The statistical data taken into account were mean and standard deviation for participants’ ages and absolute frequency and percentages for sex, defect type according to Brown’s classification, and type of prosthesis.

Risk-of-bias and quality assessment of the included studies

Two reviewers (N.K. and K.G.V.) autonomously conducted a risk of bias evaluation of the included studies to enhance the strength of the systematic review. The Joanna Briggs Institute (JBI) critical appraisal checklist was used for the quality assessment of the 25 studies. The JBI critical appraisal tool comprises eight questions based on specific criteria, in which each criterion received a response of “Yes,” “No,” “Unclear,” “Not applicable” and is summarized in Table 1.^[18] A score of one was assigned to a “yes” response and a score of zero was assigned to a “no” response.^[19]

To determine the inter-rater reliability, the collective Kappa scores computed from the data extracted by the two investigators (S.W., R.S.M.) were determined to be 0.82, denoting almost perfect agreement between the investigators.

RESULTS

Study selection and characteristics

A total of 240 articles were identified after the initial search of the PubMed, Web of Science, Scopus, and Google Scholar databases, of which 53 duplicates were removed. Titles and abstracts of the remaining 187 articles were assessed for potentially relevant studies that met the inclusion criteria, leaving 97 articles for full-text screening. Of these, 25 studies that satisfied the eligibility requirements were subsequently included in the systematic review [Figure 1]. The remaining articles were excluded due to a lack of enough information to classify the defect, no prosthetic rehabilitation, and not specifying the type of maxillofacial prosthesis provided. All the selected articles were case reports,^[20-41,43] and one study by Pandilwar *et al.* described two cases.^[42]

Risk of bias/quality assessment of the included studies

A total of 25 case reports were evaluated for quality assessment using the JBI Critical Appraisal Checklist for case reports to gauge their validity and credibility.^[18] Quality assessment of the included studies was based on eight criteria: (1) Clarity of patient demographic characteristics description. (2) Clarity and presentation of the patient’s history as a timeline. (3) Clear description of the patient’s current clinical condition on presentation. (4) Clear description of diagnostic tests, assessment methods, and their results. (5) Clear description of intervention (s) or treatment procedure (s). (6) Clear description of the patient’s post-intervention clinical condition. (7) Identification and description of adverse events or unanticipated events. (8) Presence of takeaway lessons in the case report. Each of the criteria received a response of either “Yes,” “No,” “Unclear,” “Not applicable” and was subsequently scored [Table 1]. The ratings from these were used to judge the risk of bias. Case reports with a score of eight were defined as high score studies, six and seven scores as medium, and five or less as low score.^[19] Six case reports were rated as high quality,^[23,25,26,28,30,42] 15 as medium quality,^[20,22,24,29,31,33-40,42,43] and four as low quality^[21,27,32,41] with a mean score of 6.6 ± 1.23 . However, no articles were eliminated from the review due to their low appraisal scores. The highest scoring criteria were the clear reporting of the treatment procedure of the patient and the existence of takeaway lessons from the case reports. The majority of case

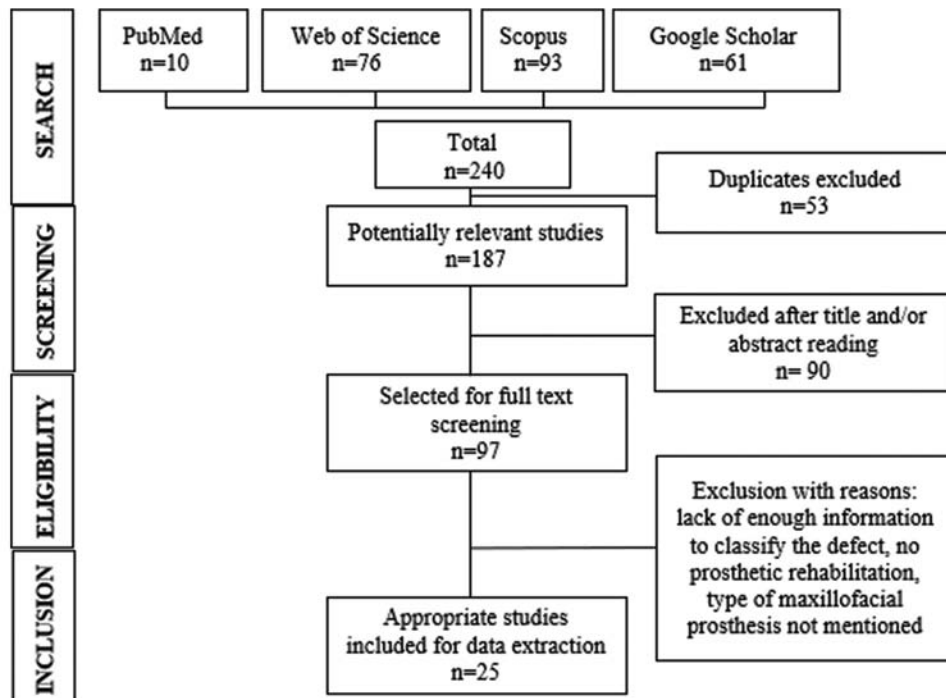


Figure 1: Flow diagram of search results from databases

Table 1: Risk-of-bias assessment of included studies using Joanna Briggs Institute critical appraisal checklist

S.No.	Author	1	2	3	4	5	6	7	8	Total score
1	Sykes LM, Sukha A., 2001 ^[20]	Y	Y	Y	Y	Y	N	N	Y	6
2	Schmidt BL <i>et al.</i> , 2004 ^[21]	Y	N	Y	U	Y	Y	N	Y	5
3	Shetty SR, Punnya VA., 2008 ^[22]	Y	Y	Y	Y	Y	Y	U	Y	7
4	Akhrass FA at al, 2011 ^[23]	Y	Y	Y	Y	Y	Y	Y	Y	8
5	Sujatha RS <i>et al.</i> , 2011 ^[24]	Y	Y	Y	Y	Y	N	N	Y	6
6	Doni BR <i>et al.</i> , 2011 ^[25]	Y	Y	Y	Y	Y	Y	Y	Y	8
7	Viterbo S <i>et al.</i> , 2011 ^[26]	Y	Y	Y	Y	Y	Y	Y	Y	8
8	Prasad K <i>et al.</i> , 2012 ^[27]	Y	N	Y	Y	Y	N	N	Y	5
9	Gowda ME <i>et al.</i> , 2013 ^[28]	Y	Y	Y	N	Y	Y	Y	Y	8
10	Faheemuddin M, Yazdanie N, Nawaz MS., 2014 ^[29]	Y	Y	Y	N	Y	Y	Y	Y	7
11	RJ Shah <i>et al.</i> , 2014 ^[30]	Y	Y	Y	Y	Y	Y	Y	Y	8
12	Naveen S <i>et al.</i> , 2015 ^[31]	Y	Y	Y	Y	Y	N	N	Y	6
13	Raval H <i>et al.</i> , 2016 ^[32]	Y	U	Y	N	Y	Y	N	Y	5
14	Arora A <i>et al.</i> , 2017 ^[33]	Y	Y	Y	Y	Y	Y	N	Y	7
15	Ramesh DN <i>et al.</i> , 2020 ^[34]	Y	Y	Y	Y	Y	Y	U	Y	7
16	Manjunath NM, Pinto PM, 2018 ^[35]	N	Y	Y	Y	Y	Y	N	Y	6
17	Salinas TJ <i>et al.</i> , 2019 ^[36]	Y	Y	Y	Y	Y	Y	N	Y	7
18	Inbarajan A <i>et al.</i> , 2018 ^[37]	Y	N	Y	N	Y	Y	Y	Y	6
19	Ikusika OF, Amole IO, Akinlade AA., 2018 ^[38]	Y	U	Y	Y	Y	Y	Y	Y	7
20	Mani UM <i>et al.</i> , 2019 ^[39]	Y	Y	Y	Y	Y	Y	N	Y	7
21	Srivastava D <i>et al.</i> , 2019 ^[40]	Y	U	Y	Y	Y	Y	N	Y	6
22	Kalluri M <i>et al.</i> , 2020 ^[41]	Y	U	U	N	Y	N	N	Y	3
23	Pandilwar PK <i>et al.</i> , 2020 ^[42]	Y	Y	Y	Y	Y	Y	N	Y	7
24	Pandilwar PK <i>et al.</i> , 2020 ^[42]	Y	Y	Y	Y	Y	Y	Y	Y	8
25	Gaur V, Patel K, Palka L., 2022 ^[43]	Y	Y	Y	Y	Y	Y	N	Y	7

reports lacked a comprehensive description of the clinical condition following the prosthetic rehabilitation. Those that were rated as low quality exhibited a deficiency in offering a coherent patient history description.

As the systematic review comprised mainly of case reports, the heterogeneity, absence of standardized methodologies,

and lack of control groups precluded the possibility of conducting a meta-analysis.

Summary of evidence

The data extracted from the 25 included studies are summarized in Table 2. The age of patients ranged from 22 to 67 years, with a mean age of 47.3 ± 14.84 years, of

Table 2: Characteristics of the included studies

Study	Age of patient	Sex	Description of defect	Any adjunct reconstructive surgery	Brown's classification	Type of prosthesis	Design of prosthesis	Whether implant-supported or not	Type of implants if present	Number of implants	Follow-up	Prosthetic complications
Sykes and Sukha, 2001 ^[20]	23	Female	Necrotic gingiva, swelling around the maxillary teeth	No	IId	Obturator	NR	No	-	-	NR	NR
Schmidt et al., 2004 ^[21]	47	Male	Small draining fistula involving the left maxilla	No	IId	Implant obturator-overdenture	NR	Yes	Zygomatic implant, endosseous implant	4 zygomatic implants, 1 standard endosseous implant	2 years	NR
Shetty and Punnya, 2008 ^[22]	65	Male	Palatal ulcer	No	IIC	Obturator	NR	No	-	-	1 year	NR
Al Akhrass et al., 2011 ^[23]	31	Male	Red papules in the left hard palate	No	IIb	Surgical obturator	NR	No	-	-	Death at 34 th postoperative day	NR
Sujatha et al., 2011 ^[24]	65	Female	Perforation in the anterior region of hard palate	No	IIa	Obturator	NR	No	-	-	NR	NR
Doni et al., 2011 ^[25]	49	Male	Palatal ulcer on right side of the palate	No	IId	Obturator	NR	No	-	-	Death in 30 th week due to renal complications	NR
Viterbo et al., 2011 ^[26]	22	Male	Median palatal ulcer with superficial bone erosion	No	IIa	Obturator	NR	No	-	-	NR	NR
Prasad et al., 2012 ^[27]	45	Female	Oval perforation of the hard palate	No	IIa	Obturator	NR	No	-	-	NR	NR
Gowda et al., 2013 ^[28]	52	Male	Left maxillectomy defect	No	IIb	Implant obturator-overdenture	Closed hollow bulb	Yes	Dental implants, magnet retained	3 implants	6 months	NR
Faheemuddin et al., 2014 ^[29]	49	Female	A large central maxillary defect, involving all of the hard palate and a part of the left antero-lateral ridge, sparing the soft palate beyond the posterior vibrating line posteriorly	No	IId	Obturator	NR	No	-	-	2 months	NR
Shah et al., 2014 ^[30]	48	Female	All maxillary teeth and alveolar ridge were missing	Reconstruction with buccal flaps	IId	Obturator	NR	No	-	-	1 year	NR
Naveen et al., 2015 ^[31]	47	Male	Necrotic ulceration of hard palate	No	IIId	Obturator	Open hollow bulb	No	-	-	NR	NR
Raval et al., 2016 ^[32]	22	Female	A necrotic mobile bony segment of the left maxilla along with palatal abscess	No	IIC	Obturator	NR	No	-	-	NR	NR
Arora et al., 2017 ^[33]	55	Female	Exposed, necrotic yellow-colored alveolar bone	No	IIIB	Interim Obturator	NR	No	-	-	6 months	NR

Contd....

Table 2: Contd...

Study	Age of patient	Sex	Description of defect	Any adjunct reconstructive surgery	Brown's classification	Type of prosthesis	Design of prosthesis	Whether implant-supported or not	Type of implants present	Number of implants	Follow-up	Prosthetic complications
Ramesh <i>et al.</i> , 2020 ⁽³⁴⁾	23	Male	Palatal ulcer	No	IId	Obturator	NR	No	-	-	1 year	NR
Manjunath and Pinto, 2018 ⁽³⁵⁾	NR	Female	Necrosed anterior maxilla with black discoloration of the hard palate	No	IIc	Interim Obturator	NR	No	-	-	1 year	NR
Salinas <i>et al.</i> , 2019 ⁽³⁶⁾	32	Female	Anterior maxillectomy defect	Microvascular (scapular and parascapular) free flap	IId	Implant-supported screw-retained metal-ceramic fixed prosthesis	NR	Yes	Endosseous implants	8 implants	3 years	NR
Inbarajan <i>et al.</i> , 2018 ⁽³⁷⁾	60	Female	Oronasal fistula on the left side of maxilla with defect extending into buccal vestibule on left side with adequate amount of alveolar ridge present	No	IIb	Obturator	NR	No	-	-	3 months	NR
Ikusika <i>et al.</i> , 2018 ⁽³⁸⁾	47	Male	Ulcerated foul-smelling palatal excoriation	No	IId	Obturator	Cast partial denture (Co-Cr framework)	No	-	-	5 months	NR
Mani <i>et al.</i> , 2019 ⁽³⁹⁾	64	Female	Foul-smelling discharge from upper left alveolus	Split thickness graft for repair of lateral wall of defect	IIId	Obturator	Closed hollow antral bulb and hollow prosthetic part	No	-	-	6 months	NR
Srivastava <i>et al.</i> , 2019 ⁽⁴⁰⁾	42	Male	Not mentioned	No	IIIb	Interim Obturator	NR	No	-	-	1 year	NR
Kalluri <i>et al.</i> , 2020 ⁽⁴¹⁾	65	Male	Large maxillary defect with oroantral communication	No	IId	Obturator	Closed hollow two-piece obturator	No	-	-	NR	NR
Pandilwar <i>et al.</i> , 2020 ⁽⁴²⁾	60	Male	Painful nonhealing wound of the palate along with unhealing extraction sockets in the maxilla	No	IId	Obturator	NR	No	-	-	NR	NR
Pandilwar <i>et al.</i> , 2020 ⁽⁴²⁾	67	Male	Grayish-colored bone, denuded of its mucoperiosteum seen on the left side of the maxillary alveolus and extending to involve the hard palate	No	IId	Obturator	NR	No	-	-	2 months	NR

Contd....

Table 2: Contd...

Study	Age of patient	Sex	Description of defect	Any adjunct reconstructive surgery	Brown's classification	Type of prosthesis	Design of prosthesis	Whether implant-supported or not	Type of implants if present	Number of implants	Follow-up	Prosthetic complications
Gaur et al., 2022 ^[43]	55	Female	Oroantral and oronasal communication	No	IId	Implant obturator-overdenture	NR	Yes	26 mm-long and 29 mm-long double pterygoid implants, 2 45 mm-long and 2 mm-long zygomatic implants, and 47.5 mm-long zygomatic implants, long and 14 mm-long polished bicortical screw implants	2 double pterygoid implants, 2 zygomatic implants and 2 bicortical screw implants	3 years	NR

NR: Not reported

which 13 were men (52%) and 12 were women (48%). One selected study did not provide the exact age of the patient but mentioned that it was an elderly female.^[35] The follow-up period differed considerably among the studies, ranging from 2 months to 3 years, with 10 studies not mentioning the follow-up period.^[20,23-27,31,32,41,42]

The majority of the articles (24%) reported that intraoral defects typically start as ulcers in the hard palate area in patients with mucormycosis.^[22,25,26,31,34] According to Brown's classification, type IId defects were the most common (48%).^[20,21,25,29,30,34,36,38,41-43] The reviewed studies included a total of three cases each of type IIa, IIb, and IIc (12% each),^[22-24,26-28,32,35,37] and two cases each of type IIIb and IIIc (8% each).^[31,33,39,40] Among these, three studies (11.5%) reported patients who underwent adjunctive reconstructive surgery before receiving prosthetic rehabilitation.^[30,36,39] Defects that required reconstructive surgery belonged to the categories IIIc and IId. They were reconstructed with split-thickness graft for repair of the lateral wall of the defect, microvascular (scapular and parascapular) flaps, and buccal mucoperiosteal flaps.

Three types of prosthetic treatments were found: removable (obturators), implant obturator overdentures, and fixed implant-supported prosthesis. The most commonly employed prosthetic restoration was an obturator, which was present in 21 of 25 patients (84%).^[20,22-27,29-35,37-42] Among the 21 obturators, there was one surgical obturator,^[23] three interim obturators,^[33,35,40] and the remainder were definitive obturators.^[20,22,24-27,29-32,34,37-39,41,42] This was followed by implant obturator overdenture in three of the cases (12%)^[21,28,43] and screw-retained metal-ceramic fixed prosthesis in one case (4%).^[36] Only five studies described the design of the prosthesis, which included one open hollow bulb obturator,^[31] one closed hollow bulb obturator overdenture,^[28] one modified obturator with a closed hollow antral part and hollow prosthetic part,^[39] one closed hollow two-piece obturator,^[41] and one obturator with cobalt-chromium framework.^[38]

Implant obturator overdentures were used to treat defects that fell under categories IIb and IId. The IIb defect was rehabilitated with an obturator on three dental implants and retained with the help of magnets.^[28] One case with IId defect received obturator overdenture on a cobalt-chromium bar cemented onto eight implants (two double pterygoid implants, two zygomatic implants, and two bicortical screw implants) and retained with the help of soft reline material.^[43] Another case of the IId category was treated with an implant obturator with overdenture on five implants (four zygomatic implants, and one standard

endosseous implant).^[21] Only one case reported by Salinas *et al.* with IId type defect underwent reconstructive surgery with a free flap followed by rehabilitation with fixed metal ceramic screw-retained prosthesis supported on eight endosseous dental implants.^[36] None of the included case reports described any kind of prosthetic complications.

DISCUSSION

ROCM faces a dearth of substantial evidence due to the rarity of the disease and geographical variations. Case reports have therefore been incorporated into the systematic review due to the lack of experimental research, such as randomized controlled trials. This systematic review aimed to determine the available treatment options for rehabilitating acquired intraoral defects caused by ROCM. Most of the studies employed various terms, including “limited”, “medial”, “partial”, “radical”, and “subtotal” to describe the extent of maxillectomy. However, few studies utilized established classification systems to define this extent. Hence, for the purpose of standardization, the intraoral defects in the studies included were classified using Brown’s classification system, which takes into account the horizontal and vertical extent of the defect, by correlating the clinical and radiographic findings in each case.^[44]

Brown’s classification (2010) takes into account both the vertical and horizontal extent of the defect. The vertical classification ranges from I to VI, with I referring to maxillectomy not causing an oronasal fistula; II – not involving the orbit; III – involving the orbital adnexae with orbital retention; IV – with orbital enucleation or exenteration; V – orbitomaxillary defect and VI referring to a nasomaxillary defect. The horizontal classification ranges from a to d, with “a” referring to a palatal defect only, “b” referring to $\leq 1/2$ unilateral, “c” referring to $\leq 1/2$ bilateral or transverse anterior, and “d” referring to $> 1/2$ maxillectomy.^[44]

The findings of this systematic review revealed that 12 out of 25 cases of intraoral defects in patients with ROCM belonged to category IId.^[20,21,25,29,30,34,36,38,41-43] In general, anterior maxillary defects have been reported to be less prevalent, but in this systematic review, class IId defect was found to be the second-most frequently reported defect, accounting for 12% of the cases of ROCM.^[22,32,35,45] This aligns with the findings outlined by Ali *et al.* in their literature review concerning prosthodontic rehabilitation for the same condition.^[46] Defects in categories IIa and IIb were discovered to occur with the same frequency as type IId defects (%).^[23,24,26-28,37] Of the 25 cases reviewed, it was found that Type IIIb and IIId defects were the

least prevalent, with only two instances of each category recorded.^[31,33,39,40]

The type of prosthetic rehabilitation provided varied depending on the type of impairment. For extensive defects such as category IId, Brown’s recommended treatment approach includes either surgical reconstruction or the placement of zygomatic implants. This is advised because achieving retention in such cases can be challenging due to the absence of suitable abutments, removal of natural undercuts, and alterations in the retaining anatomy.^[44,47] The present systematic review found that only three out of 12 IId category defects were rehabilitated with the help of implants^[21,36,43] and the remaining cases of the IId category were rehabilitated with the help of removable obturators.^[20,25,29,30,34,38,41,42] For the first case, a combination of four zygomatic and one standard endosseous implants was utilized by Schmidt *et al.* to retain an obturator overdenture prosthesis. He suggested using as many standard and zygomatic implants as dictated by the available bone, given the potential for implant failure in these patients.^[21] For the second case, Gaur *et al.* employed a combination of two zygomatic, four pterygoid, and two bicortical smooth surface one-piece implants due to a lack of keratinized mucosa and bone deficiencies.^[43] The third patient was successfully rehabilitated by Salinas *et al.* with a fixed metal–ceramic screw-retained prosthesis using a combination of microvascular flap reconstruction and endosseous implants.^[36]

Defects under the categories IIa, IIb, and IIc were rehabilitated using obturators, except for one defect in the IIb category, which was treated using a three-implant retained hollow bulb obturator overdenture with magnetic retention units.^[28] Gowda *et al.* utilized cobalt–samarium magnets in their design instead of the typical bar and clip due to limited space. The magnets effectively hold the prosthesis in place without causing lateral stress on the implant.^[28]

Type IIIb and IIId defects can result in loss of support for the orbital area, as well as the cheek and dental arch.^[44,47] Typically, in such defects, surgical reconstruction and the use of an implant are required to support a prosthesis, but this systematic review found that in three out of four cases, simple obturators were successful.^[31,33,40] In only one case, a split-thickness graft was used to repair the lateral wall of the defect, followed by rehabilitation with an obturator.^[39]

Among the cases reviewed, 84% of the patients were successfully rehabilitated with removable obturators without the use of implants.^[20,22-27,29-35,37-42] For patients with

ROCM, a maxillofacial prosthesis such as an obturator may be a preferred option over more invasive procedures like surgical reconstruction or implant placement. This facilitates routine inspections at the surgical site, which is crucial given the frequent recurrence observed in such cases.^[46,48,49] An obturator can serve as an effective and immediate solution for restoring function and esthetics, but multiple appointments may be necessary for adjustments as the surgical area heals.^[50]

Only five studies have explored the design of the prostheses, which includes one open hollow bulb obturator,^[31] three closed bulb obturators,^[28,39,41] and one with cast partial framework.^[38] The hollow bulb design is commonly used because it lightens the weight of the prosthesis and improves speech resonance.^[31] Mani *et al.* made further modifications to the hollow bulb design by also hollowing out the prosthetic part. This approach can reduce the overall weight of the prosthesis by over 33% and could be useful for patients with extensive defects where zygomatic or pterygoid implants cannot be placed.^[39]

Eight studies did not mention the follow-up period. Successful prosthetic results with no complications were reported from 2 months to 3 years.^[20,24,26,27,31,32,41,42] No prosthetic complications were reported in any of the studies, indicating that any damage that may have occurred was minor and could be corrected without requiring further surgical intervention.

The systematic review had limitations in that it only included case reports, which are the lowest level of evidence, for prosthetic rehabilitation of intraoral defects in patients with ROCM. In addition, some of the articles did not include follow-up information, which is necessary to evaluate the effectiveness of prosthetic rehabilitation. In the future, it may be helpful to have more comprehensive reporting on cases of rare diseases such as mucormycosis, as well as to use evaluation tools to assess the impact of treatment on the quality of life over extended follow-up periods.

CONCLUSIONS

Drawing from the results of this systematic review, which examined data from studies conducted up to August 2022, encompassing a total of 25 cases where patients with ROCM underwent prosthetic rehabilitation after surgery, the following conclusions emerged:

1. The most frequently encountered defect was type II in patients with ROCM
2. The systematic review findings indicate that the predominant choice for rehabilitating intraoral

defects in mucormycosis patients was an obturator with a hollow closed bulb used for three of the case reports. The four cases that underwent implant-based rehabilitation showed a 100% implant survival rate during the follow-up period, with no reported prosthetic complications. This underscores the viability of implants for utilization in mucormycosis patient care. Nonetheless, the current body of evidence, primarily consisting of case reports, remains constrained. Thus, there exists a clear need for further research to expand on the available evidence and offer more conclusive insights.

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Conflicts of interest

There are no conflicts of interest.

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A novel technique to detect cover screw location at stage two uncover surgery over conventional technique - A randomized controlled trial

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Abstract: **Aim:** The conventional technique of implant uncover using a blade and scalpel is associated with various drawbacks, including profuse bleeding, soft-tissue trauma, delayed healing, and patient noncompliance. Therefore, there is a need to explore the alternative approaches that offer improved accuracy and time efficiency during the cover screw location at the second stage of recovery. This study aims to assess the accuracy and time efficiency of a novel technique that utilizes an apex locator in comparison to conventional locating techniques for implant uncover.

Settings and Design: The study employed a simple randomized controlled trial with a sample size of 161.

Materials and Methods: The study employed apex locator (Woodpecker Woodpex III Gold 5th generation) in conjunction with a K-file (Mani k-file #10, 21 mm) for detecting the implant location. The accuracy of the novel technique was determined based on the values measured on the apex locator, with positive values indicating soft-tissue response and negative values indicating the cover screw (metal). The accuracy was cross-verified using radiovisiography (RVG). The clinician-based scoring was also done, considering RVG evaluation, amount of incision given, and ease of the procedure. The time required to locate the cover screw was recorded using a timer for both the novel technique and the conventional method.

Statistical Analysis Used: All the recorded values were statistically analyzed using the independent *t*-test ($P < 0.005$) with the SPSS software (version 23).

Results: The results revealed a significant difference in terms of incision given, ease of treatment, and time taken for the procedure ($P < 0.05$), while the accuracy of the novel technique was not disturbed ($P > 0.05$).

Conclusion: Based on the findings of this *in vivo* study, the use of an apex locator as an alternative to conventional methods for detecting cover screw location at the second stage of recovery is recommended. The novel technique demonstrated faster uncovering of implants without posing any risks to the surrounding tissues or implants.

Keywords: Apex locator, cover screw, implant dentistry, innovation, uncover

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INTRODUCTION

In recent times, dental implants have revolutionized modern dentistry, offering an effective solution for replacing missing teeth or providing support for dental prostheses. Advancements in implant dentistry owe much to improvements in implant systems, instruments, and placement techniques.^[1] Researchers in the field are increasingly focusing on less aggressive surgical procedures, shorter rehabilitation times, and faster osseointegration.^[2] Moreover, there is a growing interest in postoperative courses to promote faster tissue healing and better patient compliance.

Dental implant uncovering is a critical procedure where the top of the implant is exposed to allow for abutment attachment and crown placement after integration with the jawbone. The surgical protocols for implant uncovering can be broadly categorized into “Transmucosal technique” (one-stage surgery) and “Submerged technique” (two-stage surgery).^[3] Conventional implant uncovering using a probe, scalpel, and blade may result in soft-tissue trauma, pain, bleeding, delayed healing, and patient discomfort. To overcome these challenges, surgical lasers have emerged as a promising alternative in implantology, offering tissue preservation, reduced pain, lower risk of postoperative infections, and faster healing.^[4-7] Studies using soft-tissue diode lasers or erbium, chromium, yttrium, scandium, gallium garnet lasers for implant uncovering have reported positive results.^[8-11] However, thermal elevation caused by lasers can lead to undesirable side effects, necessitating a search for a safer approach.

The current research delved into the utilization of established clinical instruments, particularly the Apex locator, to tackle these challenges. The objective was to evaluate the feasibility of employing the Apex locator and a K-file for uncovering dental implants and to compare its effectiveness with the traditional cold scalpel technique. The null hypothesis stated that the Apex locator could not serve as a substitute for conventional methods in terms of accuracy and time efficiency when locating cover screws during the second phase of recovery. This study aimed to determine the viability of using the Apex locator as a precise, cost-effective, and patient-friendly approach for uncovering dental implants.

MATERIALS AND METHODS

The study adhered to the principles of the Declaration of Helsinki for the medical protocol and ethics and received approval from the University ethics review

board under ethical clearance number IHEC/SDC/PROSTHO-1904/22/054. Before participation, all patients were fully informed about the treatment details and provided informed consent by signing an agreement. The study assessed accuracy and time efficiency using apex locator values, digital intraoral periapical radiograph (IOPA), and a timer as the main parameters of evaluation. The parameters assessed were accuracy and time-efficiency assessment done using apex locator values, digital IOPA, and timer.

Two groups were evaluated for the study:

- Group 1: Novel technique using apex locator ($n = 80$)
- Group 2: Conventional scalpel blade technique ($n = 81$).

Sample size calculation

The sample size for the study was determined using G*Power 3.1.9.3 for Mac OS X[®], considering the previous literature by El-Kholey^[12] and aiming to maintain a power of 95%.

Selection criteria

Inclusion criteria

Single implant cases after 3 months of the healing period where the remaining natural dentition was healthy, implant should be completely covered by the soft tissue, both thick and thin biotype was included.

Exclusion criteria

Multiple or full mouth implant cases, cases with already exposed cover screw or prior placed healing cap or before 3 months of healing period, patients with compromised health and with known systemic disease were eliminated. Patients fitted with pacemakers, patients with a single piece or basal implant, and submerged implants covered by the bone were also eliminated [Figure 1].

Randomization and blinding

A total of 200 participants meeting the inclusion and exclusion criteria were initially screened, and from this pool, 161 individuals were assigned to their respective groups using a computer-generated randomization list obtained from randomizer.org. Importantly, neither the participants nor the assessors responsible for evaluating the outcomes had knowledge of the group assignments. Subsequently, the selected patients from both groups underwent the uncovering procedure.

Intervention

The patient need for the second surgery was divided into two groups: control group was recovery with conventional scalpel blade technique and in the experimental group Apex locator (Woodpecker Woodpex III Gold 5th generation) along with K-file (Mani k-file #10, 21 mm) was used during the implant uncovering to detect the implant location.

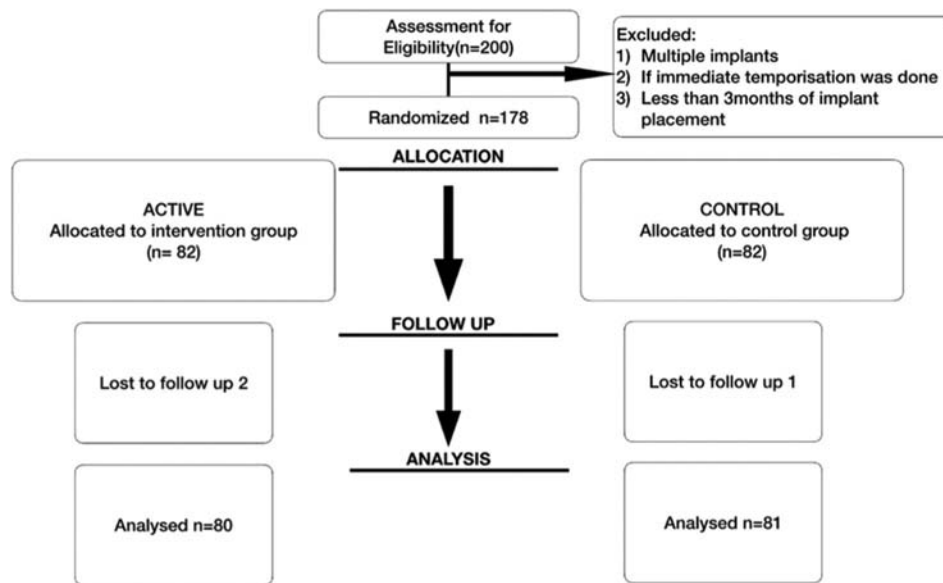


Figure 1: sample selection

After identifying the position of the cover screw head and confirming it with a radiograph, a small incision in the shape of a plus sign (+) was carefully made at the top of the area. This incision was performed to gently release the surrounding tissue and to facilitate the removal of the cover screw. Following the removal of the cover screw, a healing abutment was then inserted into place.

Outcome measure

Accuracy

The accuracy of the novel technique was determined based on the readings obtained from the apex locator. The positive values indicated soft-tissue response, whereas negative values indicated the presence of the cover screw (metal) [Figure 2]. Radiovisiography (RVG) images were taken and used as a reference for the approximate location of the cover screw [Figure 3]. The apex locator displayed green bars when the file approached the soft tissue surrounding the implant and red bars accompanied by a continuous beep sound when it neared the metallic cover screw part of the implant. The outcome measures were assessed through a scoring system provided to the clinician. The scoring scale included RVG evaluation, the amount of incision, and the clinician’s perspective [Table 1].

Time-efficiency

In the experimental group, the time taken from when the K-file was approached to the implant site until its confirmation in the radiograph was recorded using a timer. Conversely, for the conventional group, the time was recorded from the preoperative stage of using scalpel and blade to perform the procedure, and then, the postoperative RVG was taken for confirmation.

Table 1: Scoring scale for accuracy of the study

Scoring	Score 1	Score 2	Score 3
Radiographic	Away from the center	Within the center of cover screw	At the center
Incision (mm)	>10	5- 10	5 or less
Clinician’s perspective	Difficult	Moderate	Easy

Early wound healing score

Early wound healing score was assessed based on the clinical signs of re-epithelialization, clinical signs of hemostasis, and clinical signs of inflammation.^[13]

Statistical analysis

To validate the accuracy score, Cronbach’s alpha tool of measure was employed. The scoring ranged from 1 to 3, with score 1 representing “very poor,” Score 2 indicating “acceptable,” and Score 3 denoting “excellent.” To compare the two groups (experimental and conventional), the acquired values were tabulated in SPSS version 26.0, IBM, Armonk, NY, USA, and an independent *t*-test was conducted. This statistical analysis was used to determine if there were any significant differences between the two groups based on the accuracy scores.

RESULTS

On comparing the uncovering using an apex locator for patients to the patients managed with a blade, there was a significant difference between the two groups regarding both the accuracy and time-efficiency ($P < 0.05$). When accuracy was compared using the scoring criteria, there was neither significant difference using the radiographic evaluation aid ($P = 0.719$). However,

when it was compared in terms of incision required and clinician’s perspective, a significant difference was found between the two groups [$P = 0.001$, Table 2]. In terms of time taken to confirm the cover screw location, there was a statistical significant difference found between two groups 375.68 sec, the apex locator was found to be more time-efficient than the conventional technique [$P = 0.001$, Table 3]. No difference was found for early wound healing score. The early wound healing score was consistent across all samples in both groups, with scores falling within the range of 9–10. The maximum score of 10, indicating favorable and similar healing, was achieved by most individuals in both groups.

DISCUSSION

The rapid advancement of digital technologies has brought about a revolution in the various aspects of dentistry, presenting numerous advantages. However, when it comes to uncovering cover screws, traditional methods often lead to bleeding, soft-tissue trauma, and consume significant time. In response to this challenge, a novel technique was developed utilizing the widely available “Apex locator” from dental setups, resulting in promising outcomes and improved patient compliance. Originally used for detecting the working length of root canals, the Apex locator proved to be a valuable tool in uncovering dental implants. The study showcased that this technique facilitates more accurate localization of the cover screw within a shorter time frame, requiring minimal incision and offering greater ease for clinicians. With various techniques employed for second-stage surgery of submerged implants, this innovative approach utilizing the Apex locator demonstrates significant potential in enhancing the efficiency and effectiveness of the procedure.^[12,14] The use of a scalpel for incision or excision during surgery can lead to bleeding, pain, and discomfort for the patient, both during the procedure and in the postoperative phase. Furthermore, electrosurgery carries the risk of causing substantial damage to the implant surface, which may interfere with osseointegration and elevate the chances of implant failure.^[15]

In contrast, the conventional approach involves a time-consuming process of locating the center position of the cover screw using a probe and confirming it with

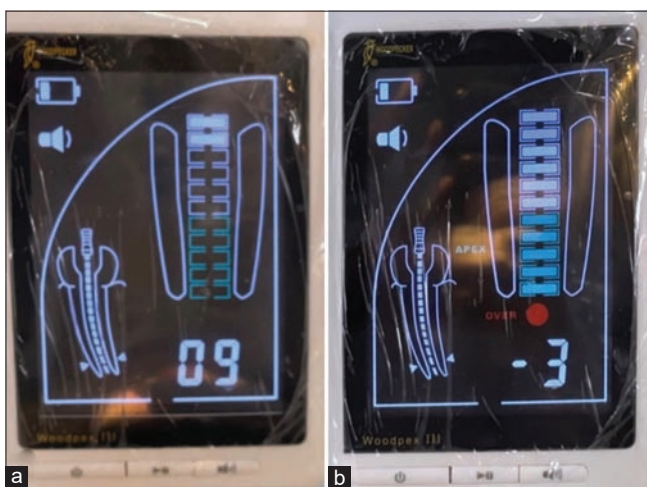


Figure 2: (a) Positive bars elicit soft tissue; (b) Negative bar elicit metal cover screw



Figure 3: (a) K file approaching implant cover screw (b) confirmation radiovisiography (c) postoperative recovery

Table 2: Comparison between implant detection and conventional technique for accuracy based on radiographic score, incision score, and clinician’s perspective (score)

Scoring	Group	Sample size	Mean±SD	SE	Mean difference	95% CI		t	P
						Lower	Upper		
RVG (radiographic score)	Group 1	n1=80	2.44±0.54	0.06	0.030	0.197	0.136	0.361	0.719
	Group 2	n2=81	2.47±0.52	0.05					
Incision (score)	Group 1	n1=80	2.11±0.63	0.07	0.445	0.245	0.646	4.39	0.001*
	Group 2	n2=81	1.66±0.65	0.07					
Clinician’s perspective (score)	Group 1	n1=80	2.61±0.53	0.05	0.729	0.546	0.913	7.86	0.001*
	Group 2	n2=81	1.88±0.63	0.07					

*Significant at 0.05, P value was derived from independent t-test. SD: Standard deviation, SE: Standard error, CI: Confidence interval, RVG: Radiovisiography

Table 3: Descriptive statistics for time-efficiency of the study

Group	Sample size	Mean±SD	SE	Mean different	t	P
Apex locator	n=80	29.13±1.3	0.144	375.68	43.99	0.001*
Conventional	n=81	384.82±76.8	8.59			

*Significant at 0.05; P value was derived from independent t-test.
SD: Standard deviation, SE: Standard error

multiple IOPAs. This method can be tedious and might result in decreased patient compliance due to the repeated need for X-rays and extended chair time. On the other hand, lasers present a range of potential benefits. They enhance visibility by promoting effective hemostasis, thereby minimizing trauma to both soft and hard tissues. Anesthetic injections and sutures become unnecessary with lasers, leading to reduced patient discomfort. Furthermore, lasers contribute to the prevention of local infections, inflammation, and postoperative pain, consequently promoting improved healing. In addition, the use of lasers shortens the time required before impressions can be taken. What's more, patients readily embrace this straightforward and comfortable technique, making it an appealing choice within the field of dental practice.^[16] In a study conducted by El-Kholey^[12] a 970 nm diode laser system was employed to uncover 23 implants in 15 patients. The outcomes of the study highlighted numerous benefits, including the removal of the necessity for a flap or sutures, the lack of postoperative discomfort, and swift tissue recuperation, facilitating prompt impression capture following the surgical procedure. These findings align with similar experiments and investigations that employed diode or alternative laser systems for the exposure of implants.^[17] The studies reached a consensus that soft-tissue lasers can be employed with efficacy and safety in second-stage implant surgery, presenting supplementary benefits when compared to conventional flap or punch methods. Nonetheless, the applicability of lasers for exposing implants could be restricted by inadequate keratinized tissue zones and accurate awareness of implant placement. Extensive research has been conducted to address worries about possible harm to the implant surface or nearby bone due to elevated temperatures generated during laser usage. The findings indicate that the diode laser, with its particular wavelength range, stands as one of the most secure options for utilization around implants, thus reducing the likelihood of undesirable outcomes.^[18,19] In the control group, second-stage surgery involved using conventional surgical instruments to expose the implant by excising a circular area of the tissues covering the implant, based on previous literature.^[20,21] Punch incisions were not used in this method, despite their simplicity, due to the concerns about possible deviation of the incision from the implant site. Arnabat-Domínguez *et al.*^[17] in their research

comparing laser and flap techniques in second-phase implant surgery, the authors proposed that employing the punch technique could potentially accelerate healing and decrease the duration needed for impression taking. This technique often avoids the requirement for sutures.

The current study utilized the apex locator to pinpoint the central location of a metal cover screw buried within the soft tissue. By tracking electrical resistance and identifying a sudden drop, the device aided in locating the precise center of the cover screw, facilitating its retrieval without any deleterious effect on implant surface. Therefore, the study refuted the null hypothesis and demonstrated the remarkable and meaningful application of the apex locator. The current investigation demonstrated that incorporating an apex locator during the second-stage implant surgery offers an economical and uncomplicated strategy. It diminishes surgical trauma, obviates the necessity for anesthesia, enhances surgical visibility by minimizing bleeding, minimize incision, and diminishes discomfort after the procedure. This innovative approach could significantly benefit both patients and clinicians in the field of implant dentistry.

CONCLUSION

The present *in vivo* study indicates that the apex locator can be a promising alternative to conventional methods for precisely and efficiently locating cover screws during the second stage of recovery. Its use resulted in faster implant uncovering, without posing any risks to the surrounding tissues or implants. These findings underscore the potential advantages of incorporating the apex locator as a valuable tool in implant dentistry, enhancing the surgical process and ultimately improving patient outcomes.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Effect of calcium and Vitamin D supplementation on residual ridge resorption in edentulous patients: An open-label randomized study

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Abstract

Aim: Complete dentures (CDs) are fabricated to rehabilitate the edentulous. Severe residual ridge resorption (RRR) compromises CD functionality, adversely affecting function, appearance, systemic health, and quality of life.

Settings and Design: The purpose of this study was to assess the benefit, if any, of calcium and Vitamin D supplementation on the rate of RRR. Retarding RRR would improve treatment prognosis and make CD fabrication less demanding.

Materials and Methods: This longitudinal, parallel, open-label randomized study was conducted in the Department of Prosthodontics of the institute. One hundred and fifty edentulous subjects underwent bone mineral density (BMD) assessment followed by CD fabrication to measure RR height and width with computerized tomographic (CT) scans. Subjects were randomized to oral supplementation group – S, given combined Vitamin D and calcium daily, and nonsupplementation group – NS. Subjects from both the groups were followed up with repeat BMD test and CT scan after 12 months. Mean BMD, RR height and width, and RRR values were collected, analyzed, and compared for the two groups using STATA 17.

Statistical Analysis Used and Results: Baseline mean T-score, RR height, and RR width were – 1.84, 22.30 mm, and 4.25 mm, respectively, for the sample. In both Groups S and NS, a statistically significant decrease in mandibular RR height ($P = 0.000$ for both) and width ($P = 0.027$ and 0.003 , respectively) was observed at 1-year follow-up. There was a statistically insignificant difference between Groups S and NS for mean BMD, T-score, RR height and width, and RRR at both baseline and 12-month follow-up. One-year RRR rate for Group S (1.30 mm) was insignificantly lesser than for group NS (1.33 mm).

Conclusion: Short-term oral calcium and Vitamin D supplementation was ineffective in reducing RRR and improving BMD.

Keywords: Absorptiometry, alveolar resorption, bone mineral density, calcium, dietary supplementation, dual-energy X-ray, Vitamin D

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INTRODUCTION

The world is aging rapidly. Aging inevitably results in increasing systemic and oral health problems. Although edentulism is reportedly declining in developed countries, it is still a major global health issue.^[1] The World Health Organization (WHO) pointed out that good oral condition is important for healthy aging, more so in the disadvantaged.^[2,3]

Edentulism (loss of all teeth) leads to functional and esthetic impairment, and psychological and social disability, besides affecting overall health.^[4] Loss of teeth from the jaw leaves behind a residual alveolar ridge (RR).^[5] Once an individual is rendered edentulous, he/she has to depend on complete dentures (CDs) for proper mastication and appearance.^[6] Such a prosthesis depends on the shape and size of the residual ridge for proper retention, stability, and function.^[7] A removable denture made by the very best clinician on a small residual ridge has high chances of failure.^[8,9] This happens because the resulting denture is ill-fitting or “floating” because of which it becomes nonfunctional.^[10-13]

Residual ridge resorption (RRR) is a chronic, progressive, and irreversible multifactorial process of alveolar bone depletion.^[14-18] The etiology of RRR is still not clear.^[19] It may be caused by local or systemic factors or a combination. These factors may be organized into four major categories: anatomic amount and quality of residual ridge; metabolic-bone formation and resorption factors; functional – (a) how long, how frequently, with what intensity and in which direction were forces applied to the residual ridge, (b) denture coverage area, and c) number, width, and form of teeth.^[20] RRR causes serious problems for the clinician in terms of making a well-functioning denture and in turn for the patient, who suffers from problems in mastication, nutrition, speech, appearance, and diminished quality of life. Methods advocated for reducing or preventing RRR include optimizing systemic health, modifying impression technique, using the neutral zone technique, employing broad denture base coverage, decreasing number of dental units or their buccolingual width, using monoplane teeth, applying the neutrocentric concept, increasing interocclusal distance at rest, retaining some teeth as overdenture abutments and/or instituting an implant supported prosthesis.^[21-23] Some of these have limited success in prevention, while others cannot be implemented in every patient.

Various researchers such as Jowsey, Stein and Beller, and Albanese reported that low calcium and Vitamin D levels

and a reduced calcium–phosphorus ratio were factors in generalized bone loss, and calcium supplementation may diminish such loss.^[24-26] Vitamin D aids calcium absorption from the alimentary tract and helps maintain blood calcium and phosphate concentration to ensure normal bone mineralization, growth, and remodeling. Many studies have shown that combined calcium and Vitamin D supplementation results in a reduction in fracture risk by improving bone quantity and quality.^[24-26]

Calcium is found in food, in supplements, and in some medications like antacids. All but 1% of the systemic calcium supply is stored in the skeletal system and dentition, where it is essential for structure and function.^[27] A decrease in calcium reserve may mean a reduction in bone mass and a corresponding reduction in bone strength.^[28,29]

However, no conclusive evidence exists regarding the effect of Vitamin D and calcium supplementation on alveolar resorption.^[30-32] Therefore, keeping in mind the positive outcomes of calcium and Vitamin D on quality and quantity of bone, this study was planned to assess the effects of fixed-dose calcium and Vitamin D supplementation on RRR in edentulous aging patients following prosthodontic rehabilitation with removable CDs. The null hypothesis was that calcium and Vitamin D supplementation has no effect on RRR in aging edentulous patients.

MATERIALS AND METHODS

The proposed design was a longitudinal, parallel, open-label randomized study with an allocation ratio of 1:1, prepared in conformance with CONSORT guidelines 2010. The participants of this study were edentulous patients, intervention comprised oral calcium and Vitamin D supplementation, the comparator group did not receive any intervention, and the outcome was reduction, if any, in RRR rate. The study was initiated after obtaining institutional ethical approval (Reference No. 1643/R. Cell-11) and clinical trial registry (CTRI/2017/09/009626). The target population for the study was aging completely edentulous subjects aged 40 years and above, visiting the Department of Prosthodontics of the institute for removable prosthodontic rehabilitation. The total sample size for a two-sided hypothesis with a power of 80% was approximately 150, including loss to follow-up of 20% ($Z\alpha = 1.96$, $Z\beta = 0.84$, $\sigma = 2$ mm, $\Delta = 1$ mm) by the formula $n = 2 \times (Z\alpha + Z\beta)^2 \times \sigma^2 / \Delta^2$; σ signifies standard deviation and Δ signifies significant change, i.e., $n = 2 \times (1.96 + 0.84)^2 \times 2^2 / 1^2 = 2 \times 7.84 \times 4 = 63$ subjects per group approximately [Figure 1].

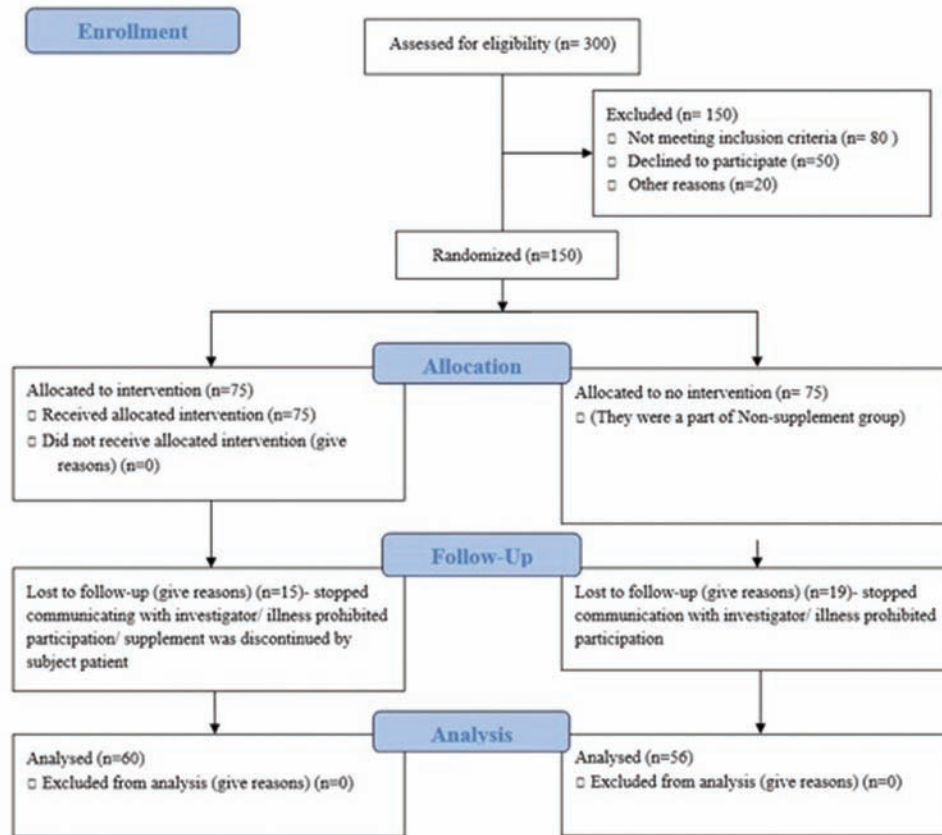


Figure 1: Consort flow diagram

Inclusion criteria were (1) completely edentulous patients who were nonsmokers and nonalcohol consumers aged 60 years or above, who were not under medication for any oral, metabolic, bone, kidney, or hormonal disorder, or previous calcium and/or Vitamin D supplementation; (2) all patients who were edentulous for more than 1 year, as residual ridge reduces in size most swiftly in the first 6 months, which gradually decreases to a steady rate; (3) Class I and 2 edentulous subjects with moderate alveolar ridge atrophy; and (4) subjects classified as philosophical as per MM house, as such patients recognize that they play an important part in the treatment. Such patients are more compliant with follow-up and instructions.

The exclusion criteria were 1) Patients on drugs that may interfere with Calcium or Vitamin D metabolism such as Biphosphonates, Levothyroxine, Phenobarbital, Phenytoin, Tiludronate disodium, Thiazide like diuretics, Antacids having aluminum and/ or magnesium content, mineral oil containing stimulant laxatives, Glucocorticoids, Orlistat, Cholestyramine and hormone replacement therapy. 2) Patients suffering from any oral, metabolic, bony, liver, kidney or hormonal disorder such as Osteitis Fibrosa, Paget's disease, Diabetes, Renal dysfunction, Hyper/Hypothyroidism, Hyper/hypoparathyroidism, Pituitary

gland dysfunctions, Prostatic or Ovarian Cancers etc. 3) Patients having smoking and/or alcohol drinking habit. 4) Patients on previous Calcium or Vitamin D supplements. 5) Previous denture wearers and patients with resorbed residual ridges or unfavorable ridge relations.

Written consent was obtained from all subjects. The age, gender, and duration of edentulism of the subjects were recorded, and data were anonymized. The subjects first underwent a dual-energy X-ray absorptiometry (DEXA) bone mineral density (BMD) test for calcium level of bone (g/cm^2 ; lunar DPX DEXA system). DEXA is considered the gold standard for BMD measurement.^[33-35] Following this, upper/lower CDs were constructed to satisfy the classification of acceptable fabrication criteria based on stability, retention, occlusion, articulation, and vertical dimension.^[36]

Cone-beam computerized tomography (CBCT) scans were made for quantitative analysis of mandibular residual ridge. CT scans of the patient were made with the CDs in position immediately postfabrication by paralleling the gantry tilt scan to the occlusal plane of the dentures.^[37-39] This was done to ensure that there were no dimensional variations because of angular discrepancies in the

subsequent scan. The occlusal plane was identified with the help of radiopaque inserts in the denture. Radiopaque markers (gutta-percha) were inserted at three points of interest in the mandibular denture (incisor and molar areas) to measure the height and width of residual mandibular ridge consistently and accurately in the same patient at baseline.^[40]

Postinsertion instructions and appointments were administered routinely, and the patients were asked to report regularly at 2-month interval for monitoring and checkup. Patients were randomized into two groups ($n = 75$ each; total sample size 150) with an equal number of male and female subjects, using block randomization with stratification protocol to avoid gender bias. A free online randomization sequence generator software was used for this open-label study. The first group (supplementation group – Group S) was given combined Vitamin D (500 i.u.) and calcium (1000 mg elemental) supplements (tablet Coxcal 500; Coxswain Healthcare) orally in two daily divided doses for 12 months; the second group (nonsupplementation group – Group NS) received no supplementation therapy during the study period. All patients were advised to take medicine in the morning and evening after meals. The study was conducted in an open-label manner. Patients were advised to maintain their diet and supplementation pattern rigorously throughout the study and their compliance was regularly monitored at 2-month intervals. Each patient was followed up with DXA and quantitative evaluation of the residual ridge by repeat CT scan 12 months after the first evaluation.

Mean T-score, BMD, RR height, and RR width values for the whole sample and different age and gender groups were obtained at baseline. The correlation of mean RR height and width with BMD and duration of edentulism at baseline, if any, was assessed. Demographic details of patients who completed the study were compiled. Mean BMD, T score, and RR dimension values for Groups S and NS at baseline and follow-up, with differences, if any, were evaluated. The mean RRR for both Groups S and NS was calculated and compared by subtracting mean RR dimension (mean of height and width in mm at earmarked three points) 1 year post denture fabrication from the initial dimension.

Statistical analysis

Statistical analysis was done with STATA version 17 (© 2024 StataCorp LLC, USA), and $P < 0.05$ was considered statistically significant. The variables were analyzed using mean, standard deviation, one-way analysis of variance test, Kruskal–Wallis equality-of-populations rank, Mann–

Whitney U -test with Welch correction, Wilcoxon signed rank test, Pearson's correlation coefficient, paired sample t -test, and independent-sample t -test with Welch correction.

RESULTS

Eighty males (53.33%) and 70 females (46.67%) were recruited, with there being 40 males and 35 females in both Groups S and NS. Baseline mean BMD, T-score, and mandibular RR height and width were 1.03 g/cm³, –1.84, and 22.30 mm and 4.25 mm, respectively [Table 1]. No statistically significant effect of age was observed on mean BMD, T-score, and RR width at baseline when tested at 5% level of significance, though RR height was found to significantly decrease with increasing age [Table 2]. Table 3 shows significantly lower mean BMD and T-scores for female subjects compared to males.

Mean residual ridge height significantly decreased with diminishing T-score/BMD [Table 4]. No significant correlation between duration of edentulism and mean RR height and width could be established [Table 5]. Thirty-four patients were lost to follow-up, with a sample attrition of 22.7%. The gender distribution and mean age of Group S and NS subjects who completed the study are given in Table 6.

Tables 7 and 8 show a statistically significant decrease in anterior, posterior, and mean residual ridge height as well as width, for both Groups S and NS, between baseline and 12-month evaluation appointments. However, for both the groups, there was an insignificant difference in mean BMD and T-scores between the two evaluations.

No statistically significant difference in mean BMD, T-score, RR height and width (anterior, posterior, and mean), and RRR (height and width) before or after supplementation could be seen between the two groups [Table 9]. One-year follow-up RRR (height) was found to be 1.30 and 1.33 mm for Groups S and NS, respectively; RRR (width) was found to be 0.36 and 0.46 mm for Groups S and NS, respectively.

DISCUSSION

WHO has classified edentulism as a disability, and India alone has 19% elderly edentulous population. No baseline data for edentulous Indian patients has been generated thus far. Efforts made to standardize treatment outcomes and eliminate confounding factors in the study included selecting subjects with the same attitude toward management, similar extent of RRR, and same ridge relation, i.e., Class I.^[4,6,40] Gutta-percha was used as a radiopaque marker because it has minimal toxicity and

minimal tissue irritability and is one of the least allergenic materials.^[40]

Occlusal stresses borne by the edentulous mandible are greater than the maxilla,^[7,15,19] with RRR rates being calculated as four times higher for the former.^[12] This may be because the hard palate also offers support for forces applied on the maxillary denture.^[8] To limit the number of

outcomes, and considering that mandibular resorption is more critical to the prognosis of complete dentures, it was decided to take RR measurements of the mandible only, and not of the maxilla.

Computed tomography and ultrasound are other means of density measurement. DEXA, which can be of peripheral or central type, is rapid, reliable, and most commonly used in clinical practice, being noninvasive and objective.^[34,35] It may be used to measure the BMD of entire skeleton or a region of interest.^[34,35] The BMD (g/cm^3) is compared to two norms: healthy 25–35-year-old adults of the same sex and ethnicity (T-score) and age-matched adults (Z-score). In 1994, the WHO defined osteoporosis as a T-score 2.5 SD or more below the young adult mean at any site (spine, hip, or mid radius). A T score 2.49–1.0 deviations below the young adult mean defines osteopenia. Normal bone density was described as a T-score ≥ -1.0 deviation of the adult mean.

Three-dimensional CBCT is used in dentistry for accurate pre- and postoperative qualitative and quantitative jaw bone analysis for implant placement, assessment of bone after distraction osteogenesis, and identification of various mandibular and maxillofacial bone deformities.^[37] This was used in the study for RR dimension measurement preferentially over conventional CT as the total radiation dose is reduced. Both single- and multi-slice CT scans may be used to measure RRR in edentulous and partially edentulous patients with the advantages of being painless, noninvasive, and accurate. Disadvantages include cost, radiation exposure, and risk of artifacts.^[38,39] Although varying from machine to machine and scanning parameters, the radiation dose of a CBCT scan is 3–6 times that of a digital panoramic radiograph.

The study sample with a mean age of 61.5 years had a mean BMD falling in the osteopenic range [$1.03 \text{ g}/\text{cm}^3$; T-score: -1.84 – Table 1]. An Indian study with mean age of men and women as 53.6 and 57.5 years, respectively, recorded BMD values and T-scores in the normal range.^[41] The difference could be because mean age of study sample was higher and subjects were edentulous in our study. The mean RR height and width for our study sample were

Table 1: Mean variable values for sample at baseline (n=150)

Variables	Mean±SD
Age (years)	61.52±9.85
Height (mm)	158.14±10.68
Weight (kg)	58.71±11.94
T-score	-1.84±1.21
BMD (g/cm^3)	1.03±0.10
Mean RR height (mm)	22.30±5.38
Mean RR width (mm)	4.25±1.46

BMD: Bone mineral density, RR: Residual ridge, SD: Standard deviation

Table 2: Variation in mean T-score, bone mineral density, and mean residual ridge height and width with age at baseline (n=150)

Age (years)	Mean±SD			
	T-score	BMD [#]	Mean RR height [#]	Mean RR width
40–44 (n=7)	-1.27±0.64	1.05±0.06	25.47±5.23	4.16±1.31
45–49 (n=10)	-1.98±1.22	1.01±0.08	24.16±3.90	3.94±0.94
50–54 (n=13)	-1.28±1.29	1.08±0.08	23.71±4.17	4.11±1.48
55–59 (n=19)	-1.94±0.87	1.02±0.09	22.40±5.87	4.81±2.19
60–64 (n=40)	-1.87±1.16	1.03±0.10	22.37±5.50	3.84±1.28
65–69 (n=24)	-2.14±1.44	1.01±0.12	21.66±6.09	4.68±1.38
70–74 (n=20)	-1.91±1.56	1.01±0.13	21.11±5.46	4.55±1.13
≥75 (n=17)	-1.77±0.88	1.04±0.08	20.91±4.92	3.95±1.41
P	0.6078	0.6551	0.0437	0.1672

[#]One-way ANOVA. Kruskal–Wallis equality-of-populations rank test. $P > 0.05$, not significant, $P \leq 0.05$ significant, $P \leq 0.001$ highly significant. BMD: Bone mineral density, RR: Residual ridge, SD: Standard deviation

Table 3: Variation in mean T-score, bone mineral density, and residual ridge height and width with gender at baseline (n=150)

Gender	Mean±SD			
	T-score	BMD [§]	Mean RR height [#]	Mean RR width [#]
Male (n=80)	-1.78±0.14	1.05±0.01	21.82±5.26	4.40±1.57
Female (n=70)	-1.90±0.13	1.00±0.01	22.86±5.50	4.08±1.31
P	0.05*	0.006*	0.517	0.300

[#]Mann–Whitney U-test with Welch correction. *Significant or highly significant. [§]Independent sample t-test. $P > 0.05$ not significant, $P \leq 0.05$ significant, $P \leq 0.001$ highly significant. BMD: Bone mineral density, RR: Residual ridge, SD: Standard deviation

Table 4: Variation in mean residual ridge height and width with T-score at baseline (n=150)

Variables	Mean±SD	
	Mean residual ridge height	Mean residual ridge width
Normal-T-score -1 – $+1$ (n=43; 28.7%)	23.63±4.73	4.14±1.13
Osteopenia-T-score -1 – -2.5 (n=69; 46%)	22.30±5.27	4.39±1.31
Osteoporosis-T-score ≤ -2.5 (n=38; 25.3%)	20.81±5.99	4.13±1.97
P	0.017	0.389

Kruskal–Wallis equality-of-populations rank test, $P > 0.05$ not significant, $P \leq 0.05$ significant, $P \leq 0.001$ highly significant. SD: Standard deviation

Table 5: Effect of duration of edentulism on mean residual ridge height and width for sample (n=150)

Duration of edentulism (years)	Mean residual ridge height	Mean residual ridge width
1-4	22.89±4.18	3.88±1.38
5-9	22.27±5.35	4.25±1.37
>10	22.07±6.04	4.44±1.64
P	0.966	0.535

Kruskal-Wallis, Pearson's correlation coefficient: Period versus height=0.10, Period versus width=0.014; $P>0.05$ not significant, $P\leq 0.05$ significant, $P\leq 0.001$ highly significant

Table 6: Demographic details of patients who completed the study (n=116)

Variables (n=116)	Group significant (n=60)	Group NS (n=56)
Age (mean±SD)	61.58±7.62	61.75±8.87
Gender, n (%)		
Male	28 (46.6)	35 (62.5)
Female	32 (53.3)	21 (37.5)

NS: Nonsupplementation, SD: Standard deviation

22.30 and 4.25 mm. A Saudi study evaluated RR height as the shortest height of the edentulous mandible on digital orthopantomogram between superior and inferior mandibular borders at fixed reference points, as described in the ACP classification.^[42,43] The authors recorded mean RR height as 24.57 mm for men and 21.62 mm for women which was in rough agreement with this study.

No statistically significant effect of age on mean BMD, T-score, and RR width at baseline was seen, though RR height was found to significantly decrease with increasing age. The BMD-age correlation was against previous findings such as those reported by Tremollieres and Ribot, who found that after BMD peaks in the twenties or thirties, it gradually reduces with age.^[5] The nonsignificant findings in our study may be attributed to narrow age group intervals.

Alveolar resorption is an inevitable, irreversible, and progressive phenomenon, implying a decrease in RR with increasing age (assuming an increasing duration of edentulism with increasing age).^[21] Aminah *et al.* found a positive correlation between age and reduced mandibular bone height in accordance with the findings of our study.^[22] Progressive age has been associated with depleted systemic health, nutrition intake, and BMD. No significant relationship between RR width and age was found probably because resorption first narrows the ridge and then reduces its height making it lower and broader in a cyclic fashion.^[23]

The study found no correlation between baseline RR height and width values and gender at baseline. BMD and T-scores were significantly higher for males. A study by

Table 7: Mean bone mineral density, T-score, and residual ridge height and width values for supplementation group (n=60)

Group S	Mean±SD		P
	1 st visit	Follow-up	
BMD (g/cm ³)	1.04±0.02	1.04±0.02	0.707
T-score [#]	-1.97±1.47	-1.94±1.28	0.520
Height (posterior) (mm)	20.02±1.21	18.84±1.20	≤.001
Height (anterior) [#] (mm)	20.71±5.03	19.33±4.65	0.000
Mean RR height (mm)	20.25±1.18	18.95±1.14	0.000
Width (posterior) (mm)	5.37±0.54	5.01±0.45	0.045
Width (anterior) (mm)	5.02±0.48	4.87±0.52	0.049
Mean RR width (mm)	5.25±0.43	4.89±0.37	0.027

[#]Wilcoxon signed rank test. Paired sample t-test. $P>0.05$ not significant, $P\leq 0.05$ significant, $P\leq 0.001$ highly significant. BMD: Bone mineral density, RR: Residual ridge, SD: Standard deviation, S: Supplementation

Table 8: Mean bone mineral density, T-score, and residual ridge height and width values for nonsupplementation group (n=56)

Group NS	Mean±SD		P
	1 st visit	Follow-up	
BMD (g/cm ³)	1.06±0.02	1.06±0.02	0.793
T-score	-1.67±1.36	-1.66±1.08	0.793
Height (posterior) (mm)	22.5±4.70	21.32±4.67	0.004*
Height (anterior) (mm)	24.03±5.02	22.37±5.14	0.000*
Mean RR height (mm)	23.01±1.14	21.67±1.15	0.000*
Width (posterior) (mm)	5.21±1.76	4.73±1.62	0.012*
Width (anterior) (mm)	4.41±0.29	3.88±0.34	0.019*
Mean RR width (mm)	4.95±0.32	4.48±0.28	0.003*

*Significant or highly significant. Paired sample t-test. $P>0.05$ not significant, $P\leq 0.05$ significant, $P\leq 0.001$ highly significant. BMD: Bone mineral density, RR: Residual ridge, SD: Standard deviation, NS: Nonsupplementation

Daly *et al.* reported an annual diminution in BMD which was 0.5%–0.7% more in women compared to men aged 60 years and above. This can be attributed to differences in skeletal size, peak BMD values, and postmenopausal effects.^[44]

A significant direct association of RR height was found with BMD and T-scores at baseline, though the relationship was insignificant for RR width. Aminah *et al.* established a significant correlation between the height of lower residual ridge and mandibular bone mass per unit volume ($r = 0.815$ with $\alpha = 0.048$).^[22] Studies conducted by Hirai and Xi among others also reported reduced skeletal bone density as a predisposing factor for reduced height of mandible.^[45,46] Alarming, 46% of subjects in our study were found osteopenic and 25.3% osteoporotic. Findings were in concurrence with a previous study done by the authors emphasizing need for large-scale osteoporosis management/prevention protocol implementation for the edentulous population.^[47]

No effect of duration of edentulism on RR width and height at baseline could be established. A study conducted by Jagdish and Patil in 2013 on 60 edentulous subjects

Table 9: Comparative mean bone mineral density, T-score, and residual ridge height and width in supplementation versus nonsupplementation group (n=116)

Variables	Mean±SD		P
	Group S	Group NS	
BMD-first visit (g/cm ³)	1.04±0.02	1.06±0.02	0.554
BMD-follow-up (g/cm ³)	1.04±0.02	1.06±0.02	0.573
T-score-first visit	-1.97±0.35	-1.67±0.34	0.548
T-score-follow-up	-1.94±0.31	-1.66±0.27	0.506
Height (posterior)-first visit (mm)	20.02±1.21	22.50±1.17	0.155
Height (anterior)-first visit (mm)	20.71±1.22	24.03±1.25	0.067
Mean RR height-first visit (mm)	20.25±1.18	23.01±1.14	0.106
Height (posterior)-follow-up (mm)	18.84±1.20	21.32±1.16	0.151
Height (anterior)-follow-up (mm)	19.33±1.12	22.37±1.28	0.084
Mean RR height-follow-up (mm)	18.95±1.14	21.67±1.15	0.105
Mean RRR (height*) (mm)	1.30±0.11	1.33±0.05	0.775
Width (posterior)-first visit (mm)	5.37±0.54	5.21±0.44	0.826
Width (anterior)-first visit (mm)	5.02±0.48	4.41±0.29	0.304
Mean RR width-first visit (mm)	5.25±0.43	4.95±0.32	0.580
Width (posterior)-follow-up (mm)	5.01±0.45	4.73±0.40	0.650
Width (anterior)-follow-up (mm)	4.87±0.52	3.88±0.34	0.129
Mean RR width-follow-up (mm)	4.89±0.37	4.48±0.28	0.397
Mean RRR (width) (mm)	0.36±0.14	0.46±0.13	0.605

*With Welch correction. Independent sample *t*-test. $P > 0.05$ not significant, $P \leq 0.05$ significant, $P \leq 0.001$ highly significant.

BMD: Bone mineral density, RR: Residual ridge, SD: Standard deviation, NS: Nonsupplementation, S: Supplementation

also showed no effect of period of edentulism on RR dimensions.^[48] Kovacic *et al.* showed similar RR height in patients edentulous for less and more than 1 year.^[49] Furthermore, patients edentulous for a greater duration of time report a decreasing rate of RRR, more so after 10 years of edentulism in the maxilla.^[50]

The study showed a significant decrease in mean RR height and width, for both the supplementation and nonsupplementation groups, between baseline and 12-month appointments. There was no change in mean BMD and insignificant improvement in T-scores for both the supplementation and nonsupplementation groups between these two evaluations. This implied an insignificant effect of supplementation on bone calcium levels between baseline and the 1-year appointment. As visualized by cone-beam computed tomography, RRR (height) in 1 year was 1.30 mm for supplementation and 1.33 mm for nonsupplementation group; RRR (width) was 0.36 and 0.46 mm for the two groups, respectively. Although nonsupplementation group RRR values were higher, the difference was insignificant. In other words, 12 months of Vitamin D and calcium oral supplementation failed to register a response. Kordatzis *et al.* compared resorption of the posterior lower residual ridge under CDs and two-implant-supported overdentures, immediately before and 5 years after intervention, by areal measurements using differential tomography. The average reduction in height was 1.63 mm for the complete denture group and 0.69 mm for the implant overdenture group.^[9]

Wical and Swoope compared the diet of patients with negligible residual bone resorption against those with severe resorption and found a positive correlation between low calcium and Ca/P levels with RRR. They suggested that these low levels appear to be contributory factors to resorption.^[30]

The results of this study did not substantiate the hypothesis that alveolar ridge resorption is retarded by Calcium and Vitamin D supplementation. This was not in alignment with a study conducted by Wical and Brussee, where the test group took fixed calcium and Vitamin D oral doses daily. Changes in height and outline of the alveolar ridge between two radiographs taken at and 1 year after extraction were recorded for both the test and placebo groups. Patients receiving supplementation had 36% less mean residual bone loss than the patients in the placebo group.^[31] An important difference between the Wical and Brussee study and our article was the timing of supplementation; while the former administered supplement since the time of extraction, the latter administered supplement to patients with well-healed residual ridges.

Shea *et al.*, in their study, reviewed the role of calcium supplementation in postmenopausal women and found that calcium has an insubstantial effect on BMD. They concluded that calcium given for two or more years can reduce the rate of bone loss but does not affect fracture risk.^[32] Their finding suggests that supplementation has a beneficial role if its duration is at least 2 years. On the other hand, oversupplementation of calcium has been reported to have an association with kidney stones, gastrointestinal disorders, cardiovascular disease, and prostate cancer.

Short-term oral calcium and Vitamin D supplementation was ineffective in reducing RRR and improving BMD. Investigators envisage that before rejecting the role of such supplementation in retarding RRR, future studies testing longer duration of supplementation with different formulations and dosage of Vitamin D and calcium, or stricter compliance measuring protocols, may be potentially helpful in retarding RRR. A large number of enrolled osteopenic and osteoporotic subjects could be a study limitation. Future perspective may focus on calcium and Vitamin D supplementation on subjects with normal BMD.

Through this open-label randomized study, reference mandibular RRR and RR height and width data have been created for the Indian edentulous population.

CONCLUSION

Short-term (12 months or less) oral calcium and Vitamin D supplementation could be ineffective in reducing alveolar ridge resorption rates and improving BMD.

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Conflicts of interest

There are no conflicts of interest.

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Comparative evaluation of masticatory efficiency, clinical performance, and patient satisfaction of single implant-retained mandibular overdenture versus conventional complete denture: A prospective *in vivo* study

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Abstract

Aim: The aim of this within-subject prospective clinical study was to investigate the scope of single implant mandibular overdenture by assessing its masticatory efficiency, clinical performance, and patient satisfaction compared to conventional complete dentures.

Settings and Design: Prospective *In Vivo* Study.

Material and Methods: This prospective *in vivo* study was conducted in the Department of Prosthodontics and Crown and Bridge, Christian Dental College, Ludhiana. A total of 12 completely edentulous patients received a single implant in the mandibular anterior midline region. After the healing period, the conventional maxillary and mandibular dentures were fabricated. 15 days post insertion of the conventional dentures, patients were evaluated for masticatory efficiency, clinical performance including retention and stability, and patient satisfaction. To evaluate the masticatory efficiency blue raspberry and original pink “Hubba Bubba tape gum” were used as a test food. Colorimetric analysis was done to assess variance of hue. To assess clinical performance, retention, and stability of the mandibular denture was recorded using a digital force gauge and was tabulated as per CU-modified Kapur’s criteria. OHIP-14 index was used to assess patient satisfaction. After evaluation of the parameters of conventional dentures, the denture was converted into an implant-retained mandibular denture by chairside conversion with locator attachments. 15 days post-implant loading, parameters of the implant retained mandibular overdenture were assessed again followed by statistical analysis.

Statistical Analysis Used: The masticatory efficiency was assessed using a paired *t*-test. The patient satisfaction was sequentially assessed with Wilcoxon signed rank test and thereafter paired *t*-test was used to compare between conventional complete denture and overdenture. Clinical performance was assessed using the Wilcoxon signed rank test.

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Results: The masticatory efficiency of single implant mandibular overdenture was higher than that of conventional complete dentures. The clinical performance of the overdenture was higher than that of the conventional denture. Stability being a time-dependent parameter might need longer follow-ups for further conclusions. Patient satisfaction with single implant retained overdenture was significantly higher than conventional complete dentures.

Conclusion: Single implant mandibular overdenture has improved masticatory efficiency, clinical performance, and patient satisfaction compared to conventional complete dentures.

Keywords: Clinical performance, masticatory efficiency, patient satisfaction, single-implant overdenture

INTRODUCTION

The World Health Organization's (WHO) report from 2022 states that adults who are 60 years of age and older experience complete edentulism on average by 23% around the world.^[1] More than 36 million patients have been estimated to be edentulous in the United States, and the prevalence of edentulism in India, as per the Study on Global AGEing and adult health by the WHO, is 16.3% and by the Dental Council of India in people aged 65–74 years old is 29.3%.^[2-4] The increase in edentulous patients worldwide has increased the need to restore them with a viable and affordable treatment modality.^[2]

Management of completely edentulous patients is challenging in moderately to severely resorbed ridges, especially in the mandibular arch.^[5] The introduction of titanium implants has enabled the rehabilitation of completely edentulous patients with endosseous implants as standard care.^[6] McGill and York's consensus specified the need for mandibular two-implant overdenture as the minimal first-choice treatment option for edentulous patients.^[5,6] In developing countries, two-implant overdenture costs at least 2.4 times more than conventional complete dentures.^[5-8] Passia and Kern's study on mandibular single-implant overdenture reports a cumulative implant survival rate of 96.6% over an average follow-up period of 37.3 months.^[9,10] A clinical study on mandibular single-implant overdenture with a follow-up of 10 years reported a 100% success rate.^[9,10] Ahmed Elawady *et al.* found a single-implant overdenture to be superior to a two-implant overdenture in terms of bone loss and implant failure rate.^[11] Coutinho *et al.* reported positive outcomes after a 5-year follow-up study on patient-related outcomes using mandibular single-implant overdenture.^[12,13] Passia *et al.* conducted a study on edentulous patients to assess the intraindividual chewing efficiency and observed an improvement in masticatory efficiency, irrespective of the number of implants.^[14]

Masticatory efficacy declines as a person becomes completely edentulous. A chewing efficiency of at least 25%

is considered sufficient for proper food digestion. Therefore, assessing the masticatory performance of completely edentulous patients after prosthetic rehabilitation becomes important.^[15,16] Studies conducted with single-implant overdenture have shown improvement in patient satisfaction, and in terms of masticatory efficiency, it provides varying results.^[8-14,17] Recent systematic reviews show improvement in masticatory efficiency with implant overdentures, despite the implant number, and have promising results even with single-implant overdentures.^[6,8,11,12,18,19] Single-implant mandibular overdenture is relatively less challenging and potentially less complicated for older populations.^[6,8,19]

To the author's best knowledge, there are limited studies comparing the intraindividual chewing efficiency, assessment of clinical performance, and patient satisfaction of a single-implant overdenture. One of the primary aims of single-implant overdenture treatment is to make overdenture treatment more affordable and provide a better quality of life for a wide spectrum of patients. Toward this direction, this study attempts to compare its clinical performance, masticatory efficacy, and quality of life versus conventional complete dentures. The study's null hypothesis was that a conventional complete denture and a single-implant-retained mandibular overdenture had identical masticatory effectiveness, clinical performance, and quality of life.

MATERIALS AND METHODS

The study obtained institutional ethical committee approval (Reference number: CDC/ERC/2020/13). Twelve completely edentulous patients of either gender and of varied age groups were selected for the study based on the inclusion criteria [Table 1].

Calculation of sample size

The sample size was calculated in accordance with the results of the prior study by Burns *et al.*^[20] The confidence range and margin of error for sample size calculation were 98% and 8%, respectively. A sample size of 12 was used in the present study using formula $n = Z_{\alpha/2}^2 P \times (1 - p) / d^2$,

where $Z_{1-\alpha/2} = 1.96$, is the standard normal deviate at type 1 error $\alpha = 0.05$.

The study's methodology and intended use were fully disclosed to the participants. Before the study's commencement,

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Completely edentulous nondenture wearers willing to participate in the study	<10 mm of alveolar bone height in the anterior mandible and <4 mm diameter
Patients who are physically and psychologically suitable for implant surgery	Absolute contraindication for implant placement
Patients with ACP type II and type III mandibular residual ridge were considered in the inclusion criteria	Recent stroke and myocardial infarction, valvular prosthesis surgery, immunosuppression, bleeding issues, active cancer therapy, drug abuse, psychological disease, and intravenous bisphosphonate use
Residual bone of minimum 15 mm length and 4.0 mm diameter	Neuromuscular coordination disorder
	History of head-and-neck radiation
	Bleeding disorder

ACP: American College of Prosthodontists

written informed consent to undergo treatment was obtained. An orthopantomographic assessment of the mandibular anterior edentulous space was done. Depending on available bone, an implant of appropriate length ranging from 10 mm to 11.5 mm (10 mm: $n = 8$; 11.5 mm: $n = 4$) and diameter of 3.5–4.5 mm (3.5 mm: $n = 7$; 4.0 mm: $n = 4$; 4.5 mm: $n = 1$) was placed in the mandibular anterior midline region. Three months later, each participant received a set of complete maxillary and mandibular dentures made by a single practitioner in accordance with a standardized prosthodontic process. Patients were recalled after 15 days of using conventional complete dentures to allow for settling in the newly fabricated dentures. Masticatory efficiency, clinical performance, including retention and stability, and patient satisfaction were assessed [Figure 1].

One week later, locator abutment was tightened on the implant at 25 Ncm [Figure 2].

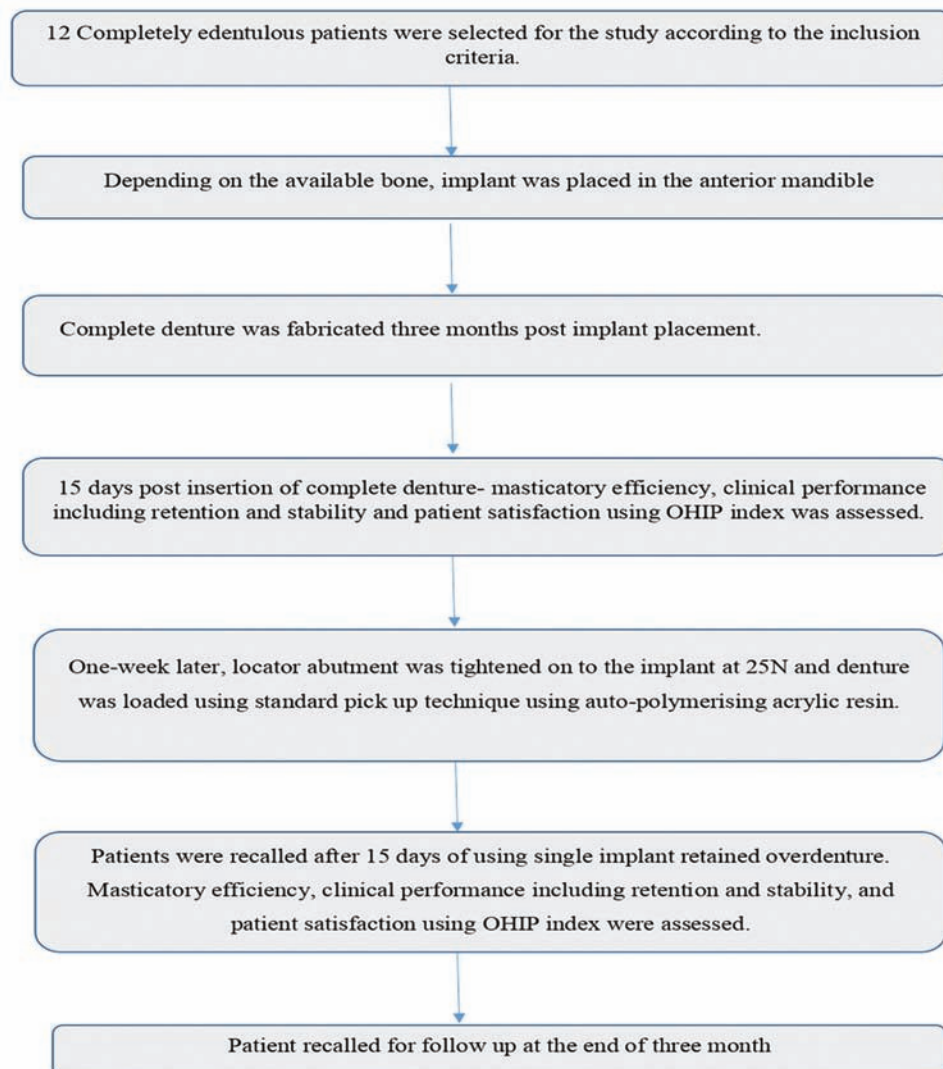


Figure 1: Schematic presentation of study design. OHIP: Oral health impact profile

A nylon cap and metal housing were incorporated at the tissue surface of the denture, according to the implant position by standard chairside pickup using autopolymerizing acrylic resin [Figure 3].

Patients were recalled after 15 days of using single-implant-retained overdenture. Masticatory efficiency, clinical performance, including retention and stability, and patient satisfaction were assessed. Follow-up was done at the end of 3 months.

Evaluation of masticatory efficiency

Although the sieve method is the gold standard for measuring masticatory efficiency, participants with impaired oral function may not always be able to break up test foods because their maximum biting strength may be lower than that needed to crush the test food.^[21] Therefore, the chewing gum test developed by Schimmel *et al.* was used in this investigation to measure the masticatory efficiency. Silva *et al.* displayed that the two-color chewing gum test was reliable for assessing the masticatory function of complete denture patients.^[22-24] It was evaluated based on their capacity for bolus-kneading by the ability to mix two colors.^[22-24]

The same operator asked each subject to chew the test food (Hubba-Bubba Tapes[®]) gums in the sour blue raspberry and original pink flavors of dimensions 30 mm × 18 mm × 3 mm for 25 cycles. The collected chewed-gum bolus was then manually pressed between two pieces of glass plates to create a wafer with a thickness of 1 mm. A digital camera was then used to take photographs of the wafer's both sides. A single JPEG file with a maximum size of 1000 pixels was created by joining both sides.^[22-26]

A freeware ViewGum (dHAL program) was used to conduct the colorimetric analysis. The hue value was determined, and the software first converted the images into the HSI color space [Figure 4]. The variance of hue (VOH) was statistically analyzed to compare the masticatory efficiency of single-implant overdenture to that of conventional complete denture using paired *t*-tests.

Evaluation of clinical performance: Retention and stability

Retention and stability were assessed using a digital force gauge (Lutron FG 20 kg). It has great resolution and precision, a measuring capacity of 20.00 kg/44.10 lb/196.10 N, and an overload capacity of 66 lb/30 kg.^[27] Measurements were tabulated based on CU-modified Kapur criteria.^[20] A tiny distal hook was used to join the “pull” end



Figure 2: Locator abutment tightened onto the single implant



Figure 3: Intaglio surface of mandibular single-implant overdenture

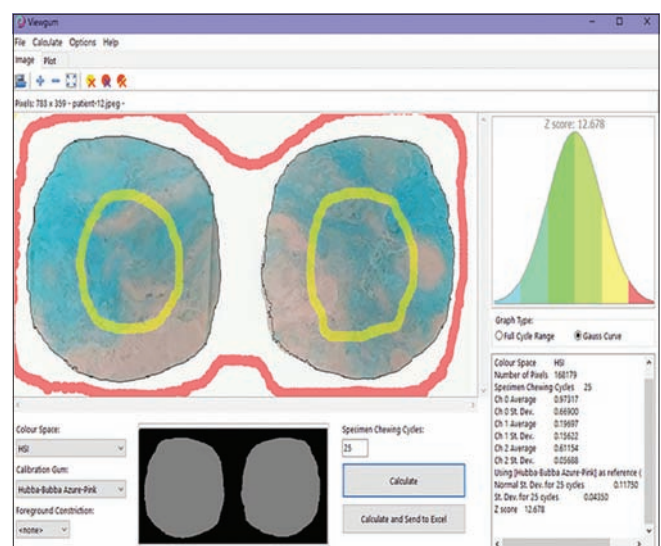


Figure 4: User interface in ViewGum software

of the force gauge to a 15 cm long piece of 19G stainless steel wire. The force gauge was used to pull the denture vertically, and the values were recorded when the denture was dislodged from residual ridge.^[20,28]

For evaluation of stability, the force gauge's end was placed near the canine on one side of the gingival embrasure of the denture and was pushed with a horizontal push force parallel to the plane of occlusion. The amount of force required to destabilize the denture was noted.^[20,28] The retention and stability values are then tabulated as per CU-modified Kapur's criteria for both conventional and single-implant-retained overdenture and then were statistically analyzed using Wilcoxon signed-rank test.

Patient satisfaction

Oral health-related quality of life (OHRQoL) was assessed using Oral Health Impact Profile (OHIP 14)^[29-31] Each patient was given the questionnaire, and the responses were statistically analyzed by the Wilcoxon signed-rank test.

RESULTS

Masticatory efficiency

The masticatory efficiency was evaluated statistically by paired *t*-test, in which the average VOH was calculated for 12 patients, and a comparison was made. The average VOH for complete denture patients was 0.492 ± 0.224 standard deviation (SD), $P = 0.001$, and *t*-test value 4.440, and for single-implant-retained overdentures were 0.202 ± 0.196 SD, $P = 0.001$, and *t*-test value 4.440. The paired *t*-test difference between a conventional denture and single-implant overdenture was 0.289 ± 0.226 SD, ($P < 0.05$) and $t > 1$, which shows that there is better mixing of different colored chewing gums with single-implant-retained overdenture in comparison to a conventional denture [Table 2].

Retention and stability

Clinical performance was assessed using the Wilcoxon Signed-Rank test, in which the retention and stability values were evaluated according to the CU-modified Kapur method. There was a statistically significant ($P = 0.001$) increase in retention and stability on the transformation of a complete denture to a single-implant overdenture. Retention scores of single-implant-retained overdentures (median = 2.00;

interquartile range [IQR]: 2.00–2.75) were higher than that of conventional complete dentures (median = 1.00; IQR: 1.00–1.00) [Table 3].

Stability score of single-implant-retained overdentures (median = 2.00; IQR: 2.00–2.00) was higher than that of conventional complete dentures (median = 1.00; IQR: 1.00–1.00) [Table 4].

Patient satisfaction

OHIP questionnaire is a universally accepted, reliable method for evaluating patients' satisfaction levels. The patient satisfaction OHIP scores in this study were higher for single mandibular implant overdenture [Table 5]. The mean score of conventional dentures was 41.00 ± 7.758 SD with $P < 0.001$, and that of single-implant overdenture was 22.33 ± 4.830 with $P < 0.001$. Total OHIP scores of single-implant-retained overdenture (median = 22.50; IQR: 18.25–25.50) was lower than that of complete denture (median = 42.00; IQR: 34.50–47.50), with a paired *t*-test difference of 18.667 ± 5.33 , $P < 0.001$, and *t*-test value 12.129, which signifies a higher level of satisfaction with single-implant overdenture in comparison to conventional complete denture [Table 6].

Statistical analysis

The masticatory efficiency and patient satisfaction of each participant with conventional dentures and implant-retained overdentures were compared sequentially using the paired *t*-test. Wilcoxon signed-rank test was used to determine the clinical performance, including retention and stability of conventional dentures and implant-retained overdentures. Normality of data was tested using Shapiro–Wilk test. The IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, N.Y., USA) was used to analyze the data with a significance level of 5%.

DISCUSSION

The prospective clinical study investigated the masticatory efficiency, clinical performance, and patient satisfaction of single-implant overdenture. Conventionally, there are various methods used for evaluating masticatory efficiency, which include the sieve method, the use of color-changing chewing gums, and subjective methods such as questionnaires.^[21,22] Schimmel *et al.*, for the first

Table 2: Hue score

Group	Mean hue score	Median	±SD	IQR	Mean difference	<i>t</i>	<i>P</i>
CD	0.492	0.509150	0.224	0.352100–0.717193	0.289±0.226	4.440	0.001*
OVD	0.202	0.067100	0.196	0.049350–0.401500			

* $P < 0.05$ significant, paired *t*-test. SD: Standard deviation, IQR: Interquartile range, CD: Complete denture, OVD: Overdenture

time, introduced the chewing gum Hubba Bubba, available in different colors.^[23,24] In this study, “raspberry-flavored azure blue” and “original pink” Hubba bubba gums were used.^[23-25] Schimmel *et al.* first introduced and validated the software ViewGum, a free and semi-automatic software computer program that is a good adjunct for studying masticatory efficiency with better speed and convenience.^[23-25] This study compared the masticatory efficiency of a conventional denture and single-implant overdenture depending on the ability of bolus formation and color mixing using the two-colored chewing gum and software ViewGum. The statistical paired *t*-test analysis

showed that the mean-VOH score was higher for complete dentures compared to single-implant overdenture, agreeing with the previous studies and concluding that masticatory efficiency was significantly improved in single-implant overdenture.

The clinical performance of the denture and overdenture was assessed by comparing the values for retention and stability using a digital force gauge which was tabulated as per CU modified Kapur’s criteria.^[20,27,28] The study results showed a significant improvement in retention and stability concerning single-implant-retained overdenture compared to conventional complete dentures.

In a similar study, two-implant overdentures were compared to conventional dentures by Burns *et al.* They stated that, even though conventional denture is a successful therapy, it might be possible to raise the level of clinical success for procedures with the implant-retained overdenture.^[20,28] The implant overdenture can offer much higher retention and stability than would otherwise be attainable with effective conventional treatment.^[20]

A recognized and helpful method for describing patient satisfaction is OHRQoL. The OHIP gives a subjective picture of the discomfort and disability of the patient.^[29-31] This study used OHIP-14 to assess OHRQoL. Patient satisfaction scores with single mandibular implant-retained overdenture were highly significant compared to conventional dentures 15 days postinsertion. Follow-up was done at the end of the 1st and 3rd months

Table 3: Retention score

Scoring	CD, n (%)	OVD, n (%)	CD versus OVD
Score 1	11 (91.7)		Z=3.276; P=0.001*
Score 2	1 (8.3)	9 (75.0)	
Score 3		3 (25.0)	
Total	12 (100.0)	12 (100.0)	
Median	1.00	2.00	
IQR	1.00-1.00	2.00-2.75	

*P<0.05 significant, Wilcoxon signed-rank test. IQR: Interquartile range, CD: Complete denture, OVD: Overdenture

Table 4: Stability score

Scoring	CD, n (%)	OVD, n (%)	CD versus OVD
Score 0	2 (16.7)		Z=3.357; P=0.001*
Score 1	10 (83.3)	1 (8.3)	
Score 2		11 (91.7)	
Total	12 (100.0)	12 (100.0)	
Median	1.00	2.00	
IQR	1.00-1.00	2.00-2.00	

*P<0.05 significant, Wilcoxon signed-rank test. IQR: Interquartile range, CD: Complete denture, OVD: Overdenture

Table 5: OHIP-14 score according to patient responses

Question	CD					OVD					Z	P	CD median	OVD median	CD IQR	OVD IQR
	1	2	3	4	5	1	2	3	4	5						
Q1	1	4	6	1	-	3	9	-	-	-	2.887	0.004*	3.00	2.00	2.00-3.00	1.25-2.00
Q2	2	2	7	1	-	6	6	-	-	-	2.667	0.008*	3.00	1.50	2.00-3.00	1.00-2.00
Q3	-	3	7	2	-	4	8	-	-	-	3.066	0.002*	3.00	2.00	2.25-3.00	1.00-2.00
Q4	-	1	7	4	-	5	7	-	-	-	2.980	0.003*	3.00	2.00	3.00-4.00	1.00-2.00
Q5	-	2	6	3	1	5	7	-	-	-	2.980	0.003*	3.00	2.00	3.00-4.00	1.00-2.00
Q6	1	1	5	4	1	5	5	2	-	-	2.850	0.004*	3.00	2.00	3.00-4.00	1.00-2.00
Q7	-	3	5	4	-	4	6	2	-	-	2.879	0.004*	3.00	2.00	2.25-4.00	1.00-2.00
Q8	-	3	5	3	1	5	6	1	-	-	2.877	0.004*	3.00	2.00	2.25-4.00	1.00-2.00
Q9	-	4	3	4	1	5	6	1	-	-	3.025	0.002*	3.00	2.00	2.00-4.00	1.00-2.00
Q10	-	5	4	3	-	5	6	1	-	-	2.565	0.010*	3.00	2.00	2.00-3.75	1.00-2.00
Q11	1	2	6	3	-	8	4	-	-	-	2.836	0.005*	3.00	1.00	2.25-3.75	1.00-2.00
Q12	1	2	8	1	-	7	5	-	-	-	2.889	0.004*	3.00	1.00	2.25-3.00	1.00-2.00
Q13	-	4	7	1	-	5	7	-	-	-	2.889	0.004*	3.00	2.00	2.00-3.00	1.00-2.00
Q14	2	4	4	2	-	8	4	-	-	-	2.913	0.004*	2.50	1.00	2.00-3.00	1.00-2.00

*P<0.05 significant, Wilcoxon signed-rank test. IQR: Interquartile range, CD: Complete denture, OVD: Overdenture

Table 6: Total oral health impact profile 14 score

Group	Mean OHIP14	Median	±SD	IQR	Mean difference	t	P
CD	41.00	42.00	7.758	34.50-47.50	18.667±5.331	12.129	<0.001**
OVD	22.33	22.50	4.830	18.25-25.50			

**P<0.001 highly significant, paired *t*-test. SD: Standard deviation, OHIP14: Oral health impact profile, IQR: Interquartile range, CD: Complete denture, OVD: Overdenture

to assess patient satisfaction, and the patients reported improved quality of life.^[30,31]

The fact that gum tends to adhere to the acrylic denture base is one limitation of the study. Coating a thin layer of petroleum jelly on the polished surface of the denture before chewing improved this to a small extent. This study had follow-ups at the end of 15 days and 3 months. The study by Schimmel *et al.* stated that patients' adaptation pattern to masticatory efficiency is time dependent; therefore, longer follow-ups are required to assess clinical performance and patient satisfaction.^[24] While the present study is a preliminary report or early evidence from a long-term study where the same patient will be assessed for various parameters for conventional removable, complete dentures and single-implant overdentures for at least 2 years. Therefore, the limited follow-up period for the present report is a limitation of the study and needs a further long-term study to assess the parameters with a larger sample.

CONCLUSION

Within the constraints of the study, it can be stated that a single-implant overdenture can be regarded as an effective treatment option for patients who are completely edentulous. It has a higher rate of clinical success than a conventional complete denture and is more affordable than an overdenture with two or more implants. The study has shown that masticatory efficiency improved with single-implant overdenture with better color mixing of two-colored chewing gum and bolus formation compared to conventional dentures. Improvement in clinical performance enhanced the patient's ability to adapt to the prostheses, gradually leading to overall progress in the quality of life and patient satisfaction.

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Conflicts of interest

There are no conflicts of interest.

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Comparison of the effect of zirconia and titanium abutments on peri-implant hard and soft tissues

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Abstract

Aim: The primary objective of this research was to assess and compare the impact of customized zirconia (Zr) and titanium (Ti) abutments, placed on early loaded dental implants, on both hard tissue (as measured crestal bone level) and soft tissue (as assessed by sulcular bleeding index [SBI], probing depth [PD], and Pink Esthetic Score [PES]), through clinical and radiographic evaluation.

Settings and Design: This research involved a sample of 15 patients who had partially dentulous mandibular arch. Within this group, a total of 30 implants were surgically placed. Specifically, each patient received two implants in the posterior region of the mandible, and the bone density in this area was classified as D2 type. In each patient, one implant was loaded with Zr abutment and the other was loaded with Ti abutment. The bone quality in the area of implant placement was Type D2. Two groups were created for this research. Each group consisted of 15 early loaded dental implants with customized Zr abutments and customized Ti abutments respectively.

Materials and Methods: Hard- and soft-tissue changes were evaluated in both the groups. Evaluation of crestal bone loss (CBL) with cone beam computed tomography and SBI, PD and PESs were evaluated by various indices at 2, 4, and 6 months postloading.

Statistical Analysis Used: After obtaining the readings, data were subjected to statistical analysis and comparison of quantitative data was done, paired *t*-test was used.

Results: The mean CBL in the Ti abutment is higher; the difference between the two groups was not statistically significant. SBI and PD for Zr were higher, but there was no statistically significant difference between the two groups. Zr had a higher PES than Ti abutment and the difference between the two groups was statistically significant. In the literature till date, the PES of Zr abutments were proven better for provisional restorations in implant prosthesis, but very few literatures support the same for the final implant restorations.

Conclusion: The study did not reveal a clear advantage of either Ti or Zr abutments over the other. Nevertheless, Zr abutments tended to produce a more favorable color response in the peri-implant mucosa and led to superior esthetic outcomes as measured by the PES.

Keywords: Customized zirconia abutment, hybrid abutment, titanium abutment

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INTRODUCTION

The field of dental implant has expanded significantly in the past few decades, bringing innovation with increasing the range of available treatments. One aspect of this advancement is specifically related to the prosthetic abutments. The prosthetic abutment attaches to the implant platform and serves as a connection point between the future superstructure or prosthesis and the fixture. In systematic reviews, titanium (Ti) has maintained a leading position as an abutment material. Due to their well-documented biocompatibility and mechanical characteristics, Grade 5 Ti alloys are typically used to create custom Ti abutments. However, the optical result may be harmed if the metallic color of Ti continues to shine through the mucosa. A dull gray shine through, even if placed sub gingivally, could make the soft tissue appear artificial.^[1]

The development of tooth-colored ceramic and personalized implant abutments is a result of consumer demand for extremely esthetic restorations. From an esthetic standpoint, especially for patients with thin, mucosal tissues, and customized zirconia (Zr) implant abutments are advised. Zr is superior to Ti, having less plaque accumulation with similar soft-tissue response, probing depths (PDs), bleeding on probing, and marginal bone level.^[2] Although, Ti abutments are still considered better mechanically and more reliable as compared to Zr when exposed to long term clinical function.^[1]

Literature provides very limited evidence on comparative clinical evaluation of customized Zr and Ti abutments. Hence, this *in vivo* research aimed to compare and evaluate the hard- and soft-tissue response around early loaded dental implants with customized Zr and Ti abutments.

MATERIALS AND METHODS

The Institutional Ethical Committee gave its Clearance under number IDST/IEC/2020-23/28. The Clinical Trial Registry of India received the study registration. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp. Released 2012 was used to estimate the sample size. Fifteen partly edentulous individuals (male and female) between the ages of 30 and 50 years had 30 dental implants implanted. Two groups were created for the investigation. Fifteen early loaded dental implants in Group 1 had a customized Zr abutment, while 15 early loaded implants in Group 2 had a customized Ti abutment. An appointment for diagnosis marked the beginning of the trial regimen. According to the inclusion, exclusion, and laboratory investigation criteria, all 15 patients were chosen.

Inclusion criteria

- Age 30–50 years
- Partially edentulous sites
- Extraction socket that has healed
- No occlusal disharmony
- Sufficient height and quantity of bone for implant placement
- COVID-19 (reverse transcription polymerase chain reaction report) negative
- Having good dental and general wellness.

Exclusion criteria

- Immunocompromised state
- Chronic bone diseases
- Psychiatric disorders
- Uncontrolled diabetes
- Pregnant or lactating females.

A thorough clinical examination, radiographic assessment involving the cone beam computed tomography (CBCT) was done [Figure 1]. All treatment options were thoroughly discussed with the patients. The relative advantages and disadvantages of implant treatment were informed. The surgical procedure was adequately explained and thereafter, a written consent was taken from all the patients.

After making diagnostic impressions with alginate, Type 2 dental stone was used to pour the cast, bite registration was recorded and semi adjustable articulator was used to mount the cast. With the help of vacuum forming machine, thermoplastic material was applied to the cast, and stents were made to direct the surgical drills during surgery.

A presurgical prophylactic dose of 2 g Amoxicillin 1 h before the surgery was prescribed to the patient. The patient was instructed to do intraoral rinses with 0.12% chlorhexidine after the surgical site was prepped with 5% betadine paint.

Local anesthesia (2% Lignocaine with 1:100,000 adrenaline) was administered using disposable syringe and a mid-crestal incision was given in mandibular posterior region with no. 15 BP blade [Figure 2]. Two releasing incisions were placed on the mesial and distal aspect to raise a full thickness mucoperiosteal flap. Surgical guide was then placed in position, and the initial osteotomy was performed using pilot drill. The complete osteotomy was obtained after using all the required surgical drills in the progressively increasing diameter. The depth of the osteotomy site was measured with the help of implant depth gauge.

Then, using an implant driver and a torque wrench, implants were placed [Figure 3] at the site of the osteotomy

with an insertion torque of 30–50 Ncm, according to the available bone density, healing abutments were attached and primary closure of the surgical site was achieved [Figure 4]. The healing abutments were then taken out and the closed tray impression copings were attached for making closed tray implant level impressions with the help of polyvinyl siloxane (putty and light body consistency) (Photasil DPI, India) impression material. At the end, healing abutments were reattached followed by postoperative instructions and medications were prescribed to the patient.

Final impression attached with lab analog was sent to the laboratory where the master casts were poured with Type IV Gypsum products and the scan bodies were attached to the cast followed by which the designing of the abutment was done according to the type of implants

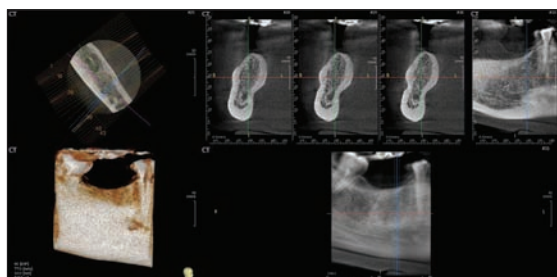


Figure 1: Preoperative cone beam computed tomography field of view



Figure 3: Implant placement done wrt 46, 47 region

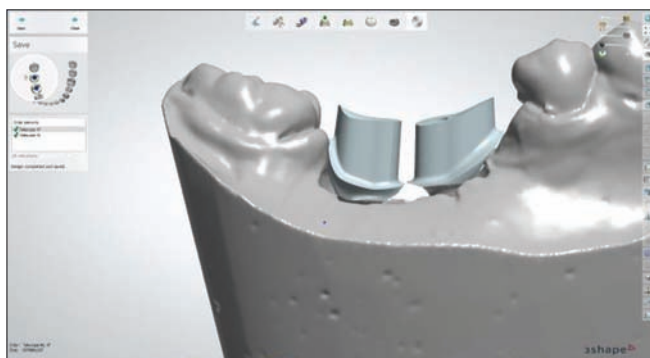


Figure 5: Designing of zirconia and titanium abutments wrt 46, 47

placed in the patient and milling of the abutments (Zr and Ti) were done with the help computer-aided-design/computer-aided-manufacturing software (3 Shape) [Figures 5 and 6]. The Porcelain Fused to Metal (DFML) crowns were also fabricated in the laboratory.

In the next appointment, the sutures were removed and customized Zr and Ti abutments were attached to the implants and were loaded functionally within a week [Figures 7 and 8].



Figure 2: Mid crestal incision and flap raised wrt 46, 47 region



Figure 4: Healing abutment attached and suturing done



Figure 6: Zirconia and titanium abutments

At the 2nd, 4th, and 6th months after loading, standardized follow-up exams were planned to evaluate both hard- and soft-tissue changes [Figure 9].

Crestal bone loss was assessed with CBCT (Papaya 3D Plus, Genoray Korea Japan) postoperatively at 0, 2, 4, and 6 months to assess the hard-tissue changes for both the groups. At 2, 4, and 6 months postloading PD, bleeding index (BI), Pink Esthetic Score (PES), which includes the mesio-distal papilla,

alveolar process deficiency, soft-tissue level, contour, color, and texture were all recorded to assess any change in both groups using the Hu-Friedy Colorvue plastic probe.

RESULTS

Data were collected and compiled methodically, converted from a pro forma with precoded fields to a computer, and a master table was created. The complete amount of data were thoughtfully distributed and displayed as separate tables and graphs.

Intergroup comparison of mean sulcular BI (SBI) at 2, 4, and 6 months was done using paired *t*-test. It was found that SBI for Group 1 is higher at recorded time intervals in comparison to Group 2. *P* value at 2 months was 0.650, at 4 months 0.825, and at 6 months 0.532, but the difference between the two groups was statistically not-significant [Table 1 and Graph 1].

Intergroup comparison of mean PD at 2, 4, and 6 months was done using paired *t*-test. It was found that PD for Group 1 is higher at recorded time intervals in comparison to Group 2. *P* value at 2 months was 0.906, at 4 months 0.748, and at 6 months 0.683, but the difference between the two groups was not statistically significant [Table 2 and Graph 2].

Intergroup comparison of mean PES at 2, 4, and 6 months was done using paired *t*-test. It was found that PES for Group 1 is higher at recorded time intervals in comparison to Group 2. *P* value at 2 months was 0.004, at 4 months



Figure 7: Zirconia and titanium abutment wrt 46, 47



Figure 8: Implant loading with porcelain fused to metal (DMLS) crowns wrt 46, 47

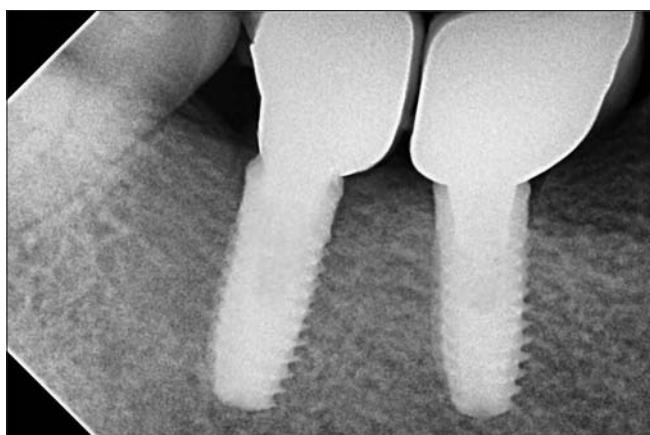


Figure 9: Postoperative IOPA X- ray wrt 46, 47

Table 1: Intergroup comparison of sulcular bleeding index

Groups	<i>n</i>	Mean	SD	<i>P</i>
At 2 months				
Group 1	15	0.7833	0.18581	0.650, NS
Group 2	15	0.7500	0.21129	
At 4 months				
Group 1	15	0.5333	0.18581	0.825, NS
Group 2	15	0.5167	0.22093	
At 6 months				
Group 1	15	0.2333	0.11443	0.532, NS
Group 2	15	0.2000	0.16903	

SBI: Sulcular bleeding index, NS: Not significant, SD: Standard deviation

Table 2: Intergroup comparison of probing depth

Group	<i>n</i>	Mean	SD	<i>P</i>
At 2 months				
Group 1	15	3.9500	0.33004	0.906, NS
Group 2	15	3.9333	0.42748	
At 4 months				
Group 1	15	3.4833	0.56273	0.748, NS
Group 2	15	3.4167	0.56432	
At 6 months				
Group 1	15	3.2500	0.60504	0.683, NS
Group 2	15	3.1667	0.49701	

PD: Probing depth, NS: Not significant, SD: Standard deviation

0.004, and at 6 months 0.008 and statistically significant difference was found in both the groups [Table 3 and Graph 3].

Intergroup comparison of mean crestal bone loss (CBL) at 2, 4, and 6 months was done using the paired *t*-test. It was found that mean CBL for Group 2 is higher at recorded time intervals in comparison to Group 1. *P* value at 2 months was 0.443, at 4 months 0.950, and at 6 months 0.170 and there was no significant difference in both the groups [Table 4 and Graph 4].

Obtained data showed bleeding on probing was higher for customized Zr abutment at recorded time intervals than customized Ti abutment, PD was less for customized Ti abutment compared to customized Zr abutment, PES was higher for customized Zr abutment at recorded time intervals and crestal bone loss was less for customized Zr abutment than customized Ti abutment.

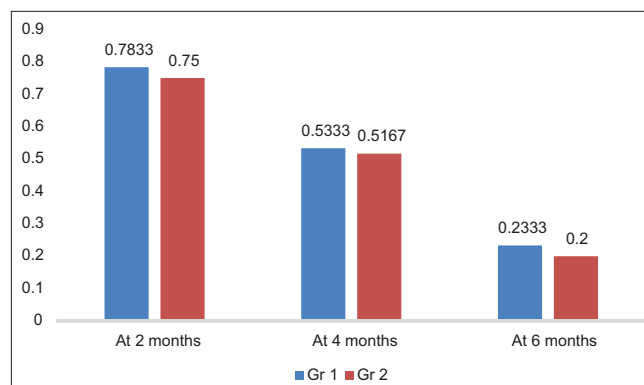
DISCUSSION

The objective of this *in vivo* study was to examine and assess the hard- and soft-tissue response to early loaded dental implants with custom-made Zr and Ti abutments.

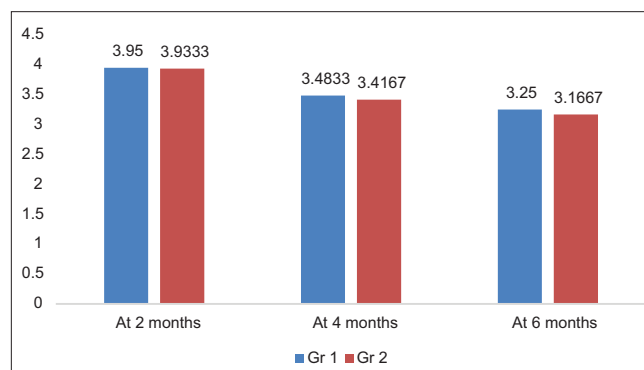
The CBCT was done to evaluate hard-tissue changes. The measuring tools used were provided within the Triana Software. Linear measurements were calculated using ruler tool to calculate distance on mesial and distal aspect to measure bone loss in coronal section and lingual and buccal

aspect in sagittal section, respectively. Bone measurements calculated on 0, 2, 4, and 6 months postloading of implants were compared by using this tool to calculate bone loss at a given time. The soft-tissue changes were evaluated by using Hu-Friedy Colorvue plastic probe for the both groups.

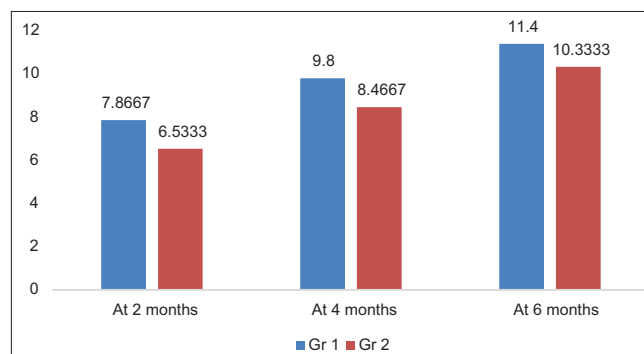
According to the study's findings, Group 1 (customized Zr abutment) had higher mean SBI scores than Group 2 (customized Ti abutment) at the recorded time points of 2, 4, and 6 months; however, there was no significant difference in both the groups. Because of the young junctional epithelium around the dental implants, initial



Graph 1: Intergroup comparison of sulcular bleeding index. SBI: Sulcular bleeding index



Graph 2: Intergroup comparison of probing depth



Graph 3: Intergroup comparison of Pink Esthetic Score. PES: Pink Esthetic Score

Table 3: Intergroup comparison of Pink Esthetic Score

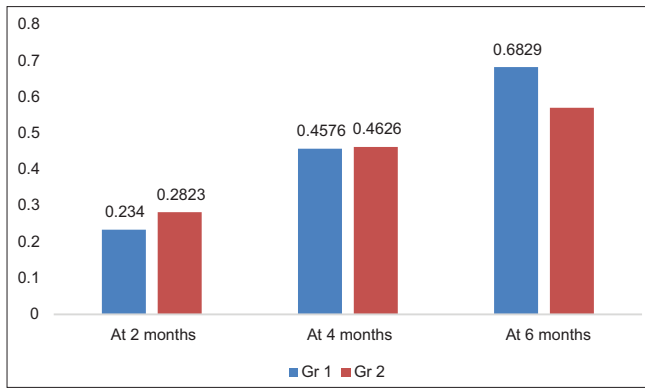
Group	n	Mean	SD	P
At 2 month				
Group 1	15	7.8667	1.12546	0.004 (significant)
Group 2	15	6.5333	1.18723	
At 4 months				
Group 1	15	9.8000	1.20712	0.004 (significant)
Group 2	15	8.4667	1.12546	
At 6 months				
Group 1	15	11.4000	0.91026	0.008 (significant)
Group 2	15	10.3333	1.11270	

PES: Pink Esthetic Score, SD: Standard deviation

Table 4: Intergroup comparison of crestal bone loss

Group	n	Mean	SD	P
At 2 month				
Group 1	15	0.2340	0.16211	0.443, NS
Group 2	15	0.2823	0.17769	
At 4 months				
Group 1	15	0.4576	0.18525	0.950, NS
Group 2	15	0.4626	0.24331	
At 6 months				
Group 1	15	0.6829	0.20007	0.170, NS
Group 2	15	0.5706	0.23524	

CBL: Crestal bone loss, SD: Standard deviation, NS: Not significant



Graph 4: Intergroup comparison of crestal bone loss. CBL: Crestal bone loss

bleeding on probing was greater, although this gradually subsided over time.

The percentage reduction in the SBI decreased more quickly in Group 2 (Ti) than in Group 1 (Zr) from the 2nd to 8th months and from the 4th to 6th months, although the difference was not statistically significant.

Sailer *et al.* concluded that there was more bleeding on probing at the prosthesis supported by Zr abutment in comparison to Ti abutment.^[3] However, Zembic *et al.*,^[2] Lops *et al.*,^[4] and Hosseini *et al.* (2013)^[5] reported no significant difference in BOP around Zr and Ti abutments.

Payer *et al.* evaluated SBI around two-piece Zr implants with Ti abutments for 24 months and concluded that there was no statistical difference among both the groups.^[6]

At the recorded time intervals of 2, 4, and 6 months, it was discovered that Group 2 (Ti) had lower mean scores for PD, but this difference between the two groups was once again not statistically significant. This may possibly be related to the initially immature junctional epithelium around the dental implants, which improve gradually overtime.

The percentage reduction in PD also showed a faster reduction from 2nd to 4th months and from 4th to 6th months in Group 2 (Ti) compared to Group 1 (Zr), but the difference was not statistically significant.

Sailer *et al.* and Carrillo de Albornoz *et al.* showed mean PD for Zr abutment (3.5 mm) was more than mean PD for Ti abutment (3.3 mm) at 1 year follow-up, but difference was not statistically significant between two groups.^[3,7]

In contrast Lops *et al.* reported that mean PD for Zr abutment was less than mean PD for Ti abutment, but difference was not statistically significant between two groups.^[4]

While considering the mean scores for PES, it was found that scores were considerably higher for Group 1 (Zr) at recorded time interval (2, 4, and 6 months) and there was a significant difference in both the groups.

The percentage increase in PES also showed a faster increase from 2nd to 4th months and from 4th to 6th months in Group 1 (Zr) compared to Group 2 (Ti) and the difference was statistically significant.

Payer *et al.* recorded PES to evaluate Zr and Ti abutments. The mean score for Zr abutments were higher after 24 months, showing a significant difference between the two.^[6]

Zembic *et al.* - Papilla Index, Hosseini *et al.* (2013) - Copenhagen Index Score, and Carrillo de Albornoz *et al.* - Implant Crown Aesthetic Index reported that no significant difference was found between the two.^[2,5,7]

Mean CBL was less for customized Zr abutment at recorded time intervals, but only for initial two follow-ups which were 2nd and 4th months. For the 3rd follow-up which was at 6th month, lesser CBL was found for customized Ti abutment than customized Zr abutment, but the difference between the two groups was nonsignificant.

Zembic *et al.*, Lops *et al.*, Hosseini *et al.* (2013), Payer *et al.*, and Carrillo de Albornoz *et al.* reported on interproximal CBL. Studies that were included reported no significant differences in CBL among both the abutments.^[2,4,7]

From observations, it can be deduced that the PD, bleeding on probing and CBL around implants were comparable with no statistical significant difference.

Significant difference was found in the PES among both the groups confirming the hypothesis that the Zr abutments can improve the esthetics around the dental implants compared to Ti abutment.

Furthermore, it was observed that the survival rate of early loaded implant was around 97% at 6 months. Occlusal loading 4–21 days after implant surgery is defined as “early loading.”

Pigozzo *et al.* stated that the overall survival rates were 97.5% for early loading at 1 year and 97.6% at 3 years.^[8] Ganeles *et al.* stated that implant survival rate is around 97% for early loading protocol at 12 months.^[9] Several studies supported early loading and stated that it is a good treatment alternative more esthetic and less time taking procedure.^[10]

Limitation of this study was the short follow-up period and sample size was small. Further investigations including a large sample size and a long follow-up period to enhance the significance of the conclusion concerning the use and predictability of the Zr abutment.

CONCLUSION

Following conclusions were made based on the limitations of this study:

1. SBI was higher for customized Zr abutment at recorded time intervals than customized Ti abutment, but there was no significant difference between both the groups
2. PD was less for customized Ti abutment at recorded time intervals than customized Zr abutment, but there was no statistically significant difference between both the groups
3. PES was considerably higher for customized Zr abutment at recorded time interval than customized Ti abutment with statistically significant difference among both the groups. It showed potential to improve the esthetics with Zr abutments and the overall quality of the soft tissue was also improved around implants
4. Crestal bone loss was less for customized Zr abutment, but only for initial two follow-ups which were 2nd and 4th months. At the 6th month, CBL was less for customized Ti abutment than customized Zr abutment, but the difference was statistically nonsignificant among both the groups.

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Conflicts of interest

There are no conflicts of interest.

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Effect of a centric stabilization splint on masticatory muscles in patients with temporomandibular disorders: An electromyographic study

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Abstract

Aim: Occlusal splint treatment is commonly used to treat a variety of temporomandibular disorders (TMDs), with efficacy ranging between 70% and 90%. Centric splints are effective in relieving muscular soreness in individuals with TMD. Electromyography (EMG) quantifies muscle activity and can be used as an accessory diagnostic tool to evaluate the efficiency of the splint on the masticatory complex. Electromyography is used for assessing patients with TMD and observing muscle electromyography. TMD patients have altered electromyographic (EMG) masticatory muscle activity because of its change in electrical activity index or because of the compensatory mechanism for the disorder. Therefore, this study serves to evaluate the efficacy of the centric stabilization splint on TMD using EMG.

Settings and Design: This cross-sectional study enrolled Ten TMD Patients with TMD, who underwent treatment with centric stabilization splint.

Materials and Methods: The study involved ten young adults with TMD aged 18–45 years who were recruited without regard to sex, religion, caste, or socioeconomic background. The participants were randomized to receive a flat-contact upper stabilization splint and pregelled EMG electrodes to assess the immediate impact of centric splints on TMDs. After 3 months of follow-up, muscle activity and muscle symmetrical activity were measured to assess improvement in the symptoms of TMD.

Statistical Analysis Used: The Shapiro–Wilk test was used to assess the normality of the variables' distribution using SPSS 26.0. Symmetrical activity and treatment response were investigated using the Wilcoxon signed-rank test.


Results: It showed an improvement in the temporalis, masseter, and sternocleidomastoid muscles' resting EMG activity. A statistically significant improvement was seen in the EMG activity of the bilateral temporalis, right masseter, right sternocleidomastoid, and left digastric muscles while clenching. The masseter, sternocleidomastoid, and digastric muscles all displayed significantly enhanced symmetrical activity ($P < 0.05$).

Conclusions: This research concludes that a centric stabilizing splint assists in relieving TMD symptoms. There was enhanced masticatory muscle activity both at rest and during function. Furthermore, there was

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an improvement in symmetrical activity of the masticatory muscles, which improved balance and enhanced the effective functioning of the masticatory complex.

Keywords: Centric splint, masticatory muscle, myalgia, orofacial pain, pain-related temporomandibular disorders, surface electromyography, temporomandibular disorders

INTRODUCTION

A wide range of clinical complications affecting the stomatognathic system, specifically the masticatory muscles, temporomandibular joint (TMJ), and surrounding tissues, are linked to temporomandibular disorders (TMDs).^[1,2] Mandibular movement abnormalities, joint sounds, and muscle and joint discomfort or pain are the primary symptoms and indicators of TMDs. The pain linked to TMJ dysfunction is characterized by its chronic, recurring, or persistent nature. It extends beyond the TMJ and masticatory muscles to potentially affect adjacent tissues, including the teeth, ears, neck, temples, forehead, and back muscles. Effective management of stomatognathic system TMD necessitates a holistic and methodical strategy. TMDs constitute over 30 conditions that affect the masticatory muscles and jaw joint, causing discomfort and dysfunction.^[3] Although symptoms may manifest at any stage of life, the highest incidence rate is observed among adults aged 20–40 years. There are numerous factors that can contribute to TMDs, such as jaw injury, bruxism, arthritis, malocclusion, and stress.^[2] Patients with TMDs that are linked to stomatognathic system problems may benefit from behavioral modifications, medication, physiotherapy, patient education, and removable appliances such as a centric occlusal splint. Based on the material, there are numerous varieties of splints, e.g., hard and soft splints. Occlusal splint therapy is a tried-and-true method of treating TMDs.^[4] Centric splints can effectively treat symptoms of TMJ pain and muscle myalgia.^[4] Centric stabilization splint reinstates the condyle-disk relationship, hence reducing muscle hyperactivity. The splint therapy can control tooth interference and mandibular movement. This will modify the muscle hyperactivity and balance the masticatory muscles. The depressor muscles (masseter, temporalis, and medial pterygoid) become overactive as a result of tooth interferences, which activate excursive movements resulting in mandibular deviation.^[5] Occlusal splint therapy reduces pain severity, increases mouth opening, and also increases synchronization between depressors and elevators of the mandible in patients with TMDs. To access this synchronization, EMG is used. Muscle electromyography (EMG) quantifies the electrical activity of muscles.^[5] It measures the electrical activity in

muscles using the nerve impulse firing potential. It is used to measure the muscle activity at rest and at function. It also evaluates the synchronicity of the right and left masticatory muscles. Therefore, EMG can be used to assess the improvement of bilateral muscle activity both at rest and at function in TMD patients after centric splint intervention.

As far as the authors are aware, there is a lack of EMG studies that simultaneously evaluate muscle synchronization and activity during rest and function in patients with TMD.^[6] Therefore, the objective of this investigation is to evaluate the masticatory muscular electrical activity in TMD patients before and after centric splint intervention using electromyography. The authors hypothesized the following: (i) patients with TMD would show abnormal masticatory muscle activity at rest and at function (pretreatment), (ii) the altered muscle activity would normalize posttreatment, and (iii) the synchronicity of the right and left masticatory muscles would improve posttreatment.

MATERIALS AND METHODS

This cross-sectional study was conducted in the department of prosthodontics and the study received approval from the institutional ethics committee, and each patient's informed permission was obtained being MAIDS/Ethical Committee/2016/3273.

Study procedure

Inclusion criteria

The research comprised patients with ages ranging from 18 to 45 years (both included). Without regard to sex, religion, caste, or socioeconomic background, patients were recruited. Selection criteria included the Research Diagnostic Criteria TMD (RDC/TMD) categorization with Axis 1 who were completely dentate or at least had adequate occlusal stops.

Exclusion criteria

Patients with limited mouth openings or those who had previously received occlusal appliances as therapy and orthodontics were also disqualified from the research.

Sample size calculation

The sample size was maintained in line with Al Quran and Kamal's 2013^[7] study, which used EMG to assess the immediate impact of centric splints on TMDs. Using formulas of comparison of two independent means with 0.05 and 0.2 as the initial values, the sample size was determined to be 10 patients or more, at the very least.

Centric splint fabrication

Ten young adults with TMD between the ages of 18 and 45 years volunteered to participate in this research. A flat-contact upper stabilization splint comprised heat-cured, strong acrylic resin. Jaw registration was done in centric relation, and the anterior teeth were kept apart by 2 mm. To provide broad and flat occlusal contact with the mandible in the central position, the hard splint was inserted, and occlusion correction was done accordingly to give flat contacts on splint.

EMG measurement (pretreatment)

Pregelged, sticky metal foil EMG electrodes were stuck on muscle to measure EMG. An earth electrode was placed on the left shoulder in the back region.

- For masseter, the most conspicuous region was positioned along a line connecting the angle of the mandible with the outer canthus of the eye [Figure 1]
- The electrodes for the temporalis muscle were positioned on the right side, slightly behind the hairline and near the muscle's anterior border
- The electrodes for the sternocleidomastoid muscle were stuck at the angle of the clavicle, near where the muscle attaches
- For the digastric muscle, they were attached to the anterior belly of the muscle, close to where the muscle inserts into the hyoid bone.

Using EMG electrodes, records of maximal clenching and rest were recorded for each muscle [Figure 2]. To



Figure 1: Electrodes placed at masseter muscle

measure synchronization, the balance between the right and left muscles was recorded and stored in BioJVA™ software [Figure 3].

To prevent muscular tiredness, the participants were given a 5-min break between each session of recordings. Each participant was instructed to perform a maximal clenching at the start until the maximum was obviously attained.

Follow-up and EMG measurement (posttreatment)

After 3 months of follow-up, the balance parameter, resting and maximal clenching muscle activity, and TMD symptom alleviation were assessed once more.

Statistical evaluation

To determine whether the variables followed a normal distribution, the Shapiro–Wilk test was done using SPSS 26.0 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, version 26.0. Armonk, NY, USA: IBM Corp) software. By determining the significance of variations in the EMG activity of all muscles and the balance of the following right and left muscles, the Wilcoxon signed-rank test was used to analyze symmetrical activity and treatment response.

RESULTS

Based on our research protocol, 10 participants were selected and given centric stabilization splints. The data were collected and analyzed using SPSS 26.0 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, version 26.0. Armonk, NY, USA: IBM Corp) software. The Shapiro–Wilk test was employed to determine the distribution's normality, and the box-plot graph was utilized to depict this normality, illustrated in Figure 4.

The muscle activity at rest was measured for all the patients before and after intervention with splint therapy. The electrical activity of muscles at rest improved after the treatment. This effect of the centric splint on the electrical activity of masticatory muscles at rest has been analyzed using the Mann–Whitney test in Table 1. On analysis, it was observed that the temporalis, masseter, and sternocleidomastoid Muscles' activity at rest showed a statistically significant improvement ($P < 0.05$).

The maximum volumetric clenching was measured using EMG for all the subjects before and after the splint therapy. It was observed that a significant improvement was pragmatic in all the muscles. The statistical evaluation was done using the Mann–Whitney test which is illustrated in Table 2. The analysis showed that the temporalis, right masseter, right

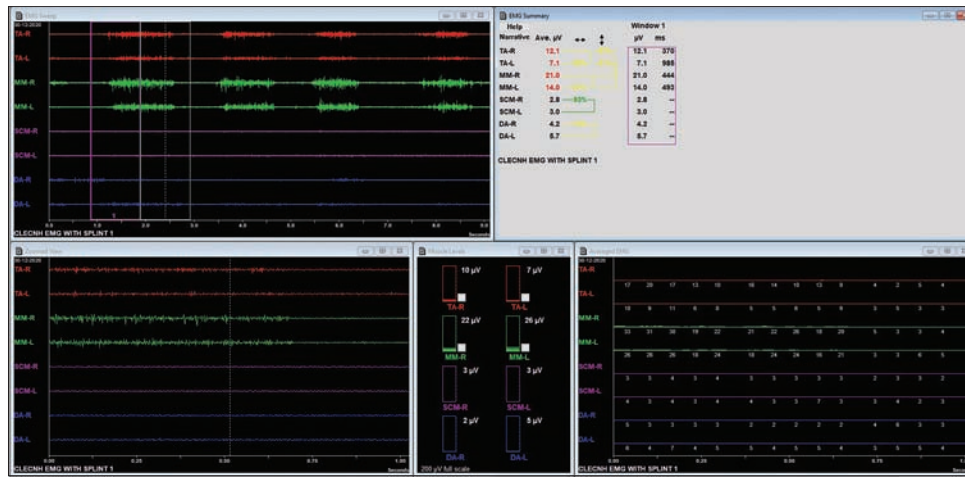


Figure 2: EMG (BioJVA™) machine



Figure 3: Data recorded in BioJVA™ software

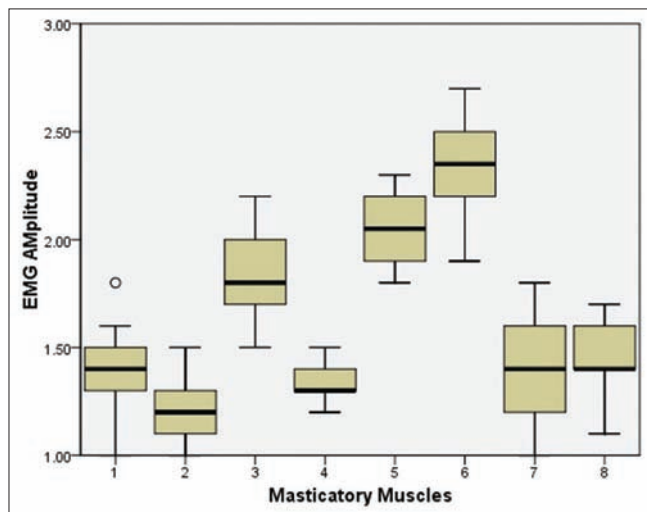


Figure 4: Box-plot chart after evaluating the distribution's normality using the Shapiro-Wilk test with a 95% confidence limit. X-axis: Group of masticatory muscle. Y-axis: EMG amplitude at rest. X-axis: 1-Right temporalis muscle; 2-Left temporalis muscle; 3-Right masseter; 4-Left masseter; 5-Left sternocleidomastoid; 6-Right sternocleidomastoid; 7-Right digastric; 8-Left digastric

sternocleidomastoid, and left digastric muscles' electrical activity during clenching showed a statistically significant improvement ($P < 0.05$).

The synchronization of bilateral masticatory muscle is crucial. It was observed that the synchronization between the muscles was improved when evaluated through EMG. The comparison of this synchronization was assessed and analyzed statistically using the Mann-Whitney test in Table 3. The balance between the right and left masseter, sternocleidomastoid, and digastric muscles improved significantly ($P < 0.05$).

DISCUSSION

The TMJ system encompasses the neuromuscular system around the TMJ and accompanying masticatory musculature. TMDs are divided generally as myogenous and arthrogenous.^[8] Pain in TMD may radiate to TMJ Area, facial region and behind the ears. It is accompanied by clicking joints, limited jaw opening, and disbalance in masticatory muscles, which may appear as severe muscular myalgia.^[9] A complete diagnostic evaluation utilizing RDC/TMD is needed for the most effective treatment of TMJ disorders.^[10] The noninvasive treatments for TMD include medication, physical therapy, occlusal splints, and cognitive-behavioral therapies.^[11] The best technique to cure TMD is to reinstate the proper disc-condyle interface. We normally employ a central stabilizing splint for this.^[12] The centric splint reduces myogenic pain and reverses symptoms of TMD. Electromyography (EMG) was performed to examine the electrical activity of muscles. The benefit of electromyography is that it is noninvasive, as it employs surface electrodes that are put over a respectable muscle on the surface of the skin.

Table 1: Mann–Whitney U-test showing intra-group comparison of electrical activity of masticatory muscles at rest

	Intra-group comparison of electrical activity of masticatory muscles at rest			P
	Paired differences of mean	95% CI of the difference		
		Lower	Upper	
RT - RT_S	-0.220	-0.467	0.027	0.075
LT - LT_S	-0.390	-0.582	-0.198	0.001
RM - RM_S	0.590	0.404	0.776	0.001
LM - LM_S	-0.030	-0.165	0.105	0.627
RSCM - RSCM_S	-0.240	-0.388	-0.092	0.005
LSCM - LSCM_S	-0.010	-0.305	0.285	0.941
RD - RD_S	-0.040	-0.332	0.252	0.764
LD - LD_S	0.180	-0.019	0.379	0.071

P<0.01 highly significant, P<0.05 significant, P>0.05 no significant. RT: Right temporalis, LT: Left temporalis, RM: Right masseter, LM: Left masseter, RSCM: Right sternocleidomastoid, LSCM: Left sternocleidomastoid, RD: Right digastric, LD: Left digastric, CI: Confidence interval, S_ : Patient wearing splint

Table 2: Mann–Whitney U-test showing intra-group comparison of electrical activity of masticatory muscles during clenching

	Intra-group comparison of electrical activity of masticatory muscles during clenching			P
	Paired differences of mean	95% CI of the difference		
		Lower	Upper	
RT_CLENCH - RT_CLENCH_S	11.530	10.067	12.993	0.002
LT_CLENCH - LT_CLENCH_S	10.020	7.115	12.925	0.003
RM_CLENCH - RM_CLENCH_S	11.720	10.455	12.985	0.002
LM_CLENCH - LM_CLENCH_S	-1.840	-4.083	0.403	0.096
RSCM_CLENCH - RSCM_CLENCH_S	-0.460	-0.932	0.012	0.050
LSCM_CLENCH - LSC_CLENCH_S	-0.160	-0.897	0.577	0.635
RD_CLENCH - RD_CLENCH_S	2.760	-3.146	8.666	0.318
LD_CLENCH - LD_CLENCH_S	-0.810	-1.120	-0.500	0.001

P<0.01 highly significant, P<0.05 significant, P>0.05 no significant. RT: Right temporalis, LT: Left temporalis, RM: Right masseter, LM: Left masseter, RSCM: Right sternocleidomastoid, LSCM: Left sternocleidomastoid, RD: Right digastric, LD: Left digastric, CLENCH: Muscles during clenching

Table 3: Mann–Whitney U-test showing comparison of symmetrical activity of masticatory muscles

	Comparison of symmetrical activity of masticatory muscles			P
	Paired differences of mean	95% confidence limits		
		Lower	Upper	
TEMP_PRE - TEMP_POST	6.107	-12.756	14.876	0.866
MAS_PRE - MAS_POST	2.316	-12.140	-1.660	0.005
SCM_PRE - SCM_POST	2.565	-34.502	-22.898	0.002
DIG_PRE - DIG_POST	3.054	1.891	15.709	0.018

P<0.01 highly significant, P<0.05 significant, P>0.05 no significant. TEMP: Temporalis muscle, DIG: Digastric muscle, SCM: Sternocleidomastoid muscle, MAS: Masseter muscle, _PRE: Before wearing splint, _POST: After wearing splint

EMG examination of masticatory muscles is of utmost importance for understanding the neuromuscular pathophysiology of TMD conditions.^[13-15] A full EMG examination should only be done using standardized (normalized) results.^[16-18] For early raw result

processing, normalization is important to allow effective statistical analysis.^[19] By comparing the muscle electrical potentials to the reference values, the muscular electrical potentials were standardized. Of the techniques studied, maximum voluntary gripping on these cotton rolls was proven to have the most consistent values and was hence used to measure EMG during clenching.^[20-22]

In this research, we compared patients before and after the splint therapy, through EMG. The findings demonstrate that before treatment, patients exhibited reduced resting and functional electrical activity of the masseter, sternocleidomastoid, and temporalis muscles. A previous study revealed that TMD patients' masticatory muscles were less effective and had decreased EMG activity which may reflect a reduction in muscular efficacy.^[14-17] TMD patients have lowered electrical potential; our results imply that a lower bite force is to be predicted. This electrical activity got improved with time. After follow-up of 3 months, There was Improvement in EMG Activity of the muscles.

Chaves *et al.*^[21] applied Axis I RDC/TMD to examine changes in TMD patients. Both at rest and during maximum clenching, raw and normalized EMG data were noted down. Contrary to our investigation, Chaves *et al.* observed no anomalies in TMD patients.

In our analysis, we identified an increase in synchronization of muscle activity in masseter, sternocleidomastoid, and digastric muscles ($P < 0.05$). This result was confluent with other studies.^[23-25] Berni *et al.*^[26] found that myogenous TMD patients had substantially decreased electrical activity in the masseter, temporalis, and suprahyoid muscles at rest, and that this activity was much more pronounced during maximum volumetric clenching recorded on parafilm in these patients. Similar to those results, Rodrigues *et al.*^[27] revealed that TMD patients displayed reduced masseter and temporalis EMG values at rest and volumetric clenching postures.

The current study's drawback, which is consistent with other investigations, was a lack of data on the precise assessment of the lateral pterygoid muscle activity.^[7] We did not, however, investigate every malocclusion-related factor that may possibly contribute to TMD. Another potential drawback of the research is that pain-related TMD may have both arthrogenous and myogenous etiologies, and EMG muscle activity may vary between the two groups. As a result, additional investigation is essential to validate the aforementioned statement.

CONCLUSIONS

The following results may be obtained from this clinical study:

1. A centric stabilizing splint assists in relieving TMD symptoms
2. The masticatory muscles' activity is markedly improved by the centric splint in TMD patients. In our study, it was found that the central stabilization splint improved rest and functional electrical activity, particularly in the temporalis, sternocleidomastoid, and masseter muscles
3. After treatment with the centric splint, there was an improvement in the synchronization of the masticatory muscles, which results in effective functioning of the masticatory complex.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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An *in vitro* assessment of optimizing implant positions in bilateral distal extension implant-assisted removable partial dentures: A microstress analysis

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Abstract

Aim: The aim of this study was to analyze and compare the stress distribution on dental implants in various positions when used with implant-assisted removable partial dentures.

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

Materials and Methods: A model representing a mandibular bilateral partially edentulous condition, with missing premolars and molars, was fabricated using epoxy resin. Two implants of similar diameter measuring 4.0 mm × 10 mm (Dentium, Korea) were inserted in the second molar and the second premolar region on either side of the model for comparing the biomechanical effect of various implant locations. Two types of loads 100N and 125N were applied vertically using universal testing machines in the premolar and molar regions. The loads on the implants beneath the cast partial denture were measured by physical stress analysis using a microstrain gauge.

Statistical Analysis Used: A comparison of maximum stress observed at the premolar versus molar regions due to the application of the 100N and 125N loads was done using the Mann–Whitney *U*-test.

Results: In physical stress analysis, obtained results were statistically analyzed, and the result was statistically not significant ($P = 0.435$ at 100N and $P = 0.718$ at 125N) in positional changes of implant.

Conclusion: In the current study, the statistical analysis of physical stress revealed no significant differences in stress values between the loadings at the premolar and molar regions. This suggests that the implant can be placed in either the premolar or molar region based on the availability of bone without affecting stress distribution.

Keywords: Implant-assisted removable partial denture, implant positions, Kennedy's Class I, physical stress analysis, strain gauge analysis

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INTRODUCTION

The demand for various partial denture prostheses is steadily rising. Several treatment options are available for rehabilitating partial edentulism, which include conventional fixed prostheses or implant-supported fixed prostheses.^[1] A well-designed removable partial denture (RPD) offers an affordable and widely accepted treatment option for patients with partial tooth loss. However, in cases of distal extension conditions (mandibular Kennedy's Class I or II situations), conventional RPDs can present challenges and uncertainties. Patients often experience difficulties with stability and retention, as the prosthesis may not adapt adequately, leading to periodontal issues in adjacent teeth and underlying bone resorption. Another prevalent concern is the occurrence of "Combination syndrome" observed in individuals wearing mandibular bilateral distal extension RPDs.^[2]

The placement of two implants is suggested as a beneficial approach to convert a Kennedy's Class I or II situation into a pseudo Kennedy's Class III condition. This transformation offers advantages in transmitting occlusal forces more favorably and preserving the vertical dimension at occlusion while ensuring stability and functionality.^[3] Ideally, for preventing denture displacement, the implant placement is recommended to be posteriorly at the second molar region. In cases where there is inadequate bone in this area, an alternative option is to position the implant more medially at the premolar region.^[4] The central inquiry of the present research revolves around assessing whether the choice of implant placement sites within the posterior jaw regions impacts the way stress is distributed. Hence, there was a need to explore whether the implant's position has any influence on the accumulation of stress around the implant fixture and the surrounding bone, with potential implications for future complications.

The Locator attachment is popular due to its dual retention properties, offering ease of placement in the oral cavity and a self-locating feature that allows it to adapt to nonparallel implants.^[5] Cobalt–chromium (Co–Cr) alloy is the material which is commonly used to construct cast partial denture (CPD) frameworks because of its corrosion resistance and high microhardness property.^[6–8] Hence, the use of Co–Cr CPD with Locator attachment is very popular in dental practice for implant-assisted removable partial denture (IARPD). As stress distribution through the implant is a critical element for the success of the treatment, the aim of this study was to assess stress distribution on the "Implant" to determine the biomechanically appropriate position for IARPD. The null hypothesis suggests that

there is no significant difference in stress levels based on the location of the implant in IARPDs.

MATERIALS AND METHODS

Study design and sample size estimation

This *in vitro* study was approved by the university curriculum development cell with registration number 02-D012-72845. The sample size was determined using G*Power 3.1.9.3 for Mac OS X® (Heinrich-Heine-Universität Düsseldorf, Germany) with a significance level of 0.05 and a power of 0.80 through a power analysis. Twenty-eight times application of two different loads on the model was performed and two readings based on location were achieved. The model underwent 28 repetitions of load application, resulting in two distinct readings based on location ($n = 28$ each group) under different loads.

Model preparation

To replicate a mandibular bilateral distal extension with missing teeth (#34–37 and #44–47), a model was created using commercially available epoxy resin (Lapox, Atul, India). Prefabricated edentulous silicone mold was employed to create a bilateral edentulous model. This involved blocking the posterior teeth using modeling wax. A thin layer of separating medium was applied, and epoxy resin (Lapox, Atul, India) was mixed with hardener according to the manufacturer's recommended ratio in a beaker. The mixture was then poured into the mold. The filled mold was left at room temperature for 24 h to allow the epoxy resin to set. A second pour was conducted on the same model using die stone (Kalabhai Kalrock, Laboz Inc., India) without the use of any wax blockout. This was done to create a dentulous model, which would serve as the foundation for producing a putty index, functioning as a location guide for the placement of implants. Two implants, measuring 4.0 mm × 10 mm (Dentium, Korea), were bilaterally inserted into the edentulous ridge following the proper drilling sequence. Utilizing a surveyor with a milling machine (BF2, Bredent), the implants were placed perpendicular to the occlusal plane. One implant was positioned at the second premolar region (mesial implant) and the other at the second molar region (distal implant) on both sides of the arch. Implant position was marked through a putty index already created before.

Fabrication of cast partial denture with attachment

Cingulum rest seat was prepared at the lingual aspect of the canine on both sides of the model. The model was scanned by the computer-aided machine (DWOS 3 series scanner, laser light), and cast partial design was planned virtually where the major connector was configured as

a lingual plate, which is in contact with the cingulum of the anterior teeth. From the digital library software (3D software – EXOCAD), a triangular-shaped canine rest was selected for both the sides and also a proximal plate (Guiding plane) was planned bilaterally on the distal area of canines. Lattice-type minor connectors were given on both sides. Virtually planned CPD was printed digitally by “additive manufacturing technique,” and Standard Tessellation Language file was fed to a 3D printing machine (SLM 125HL, Germany). Selective laser sintering machine (SLM 125HL machine) was used to build the 3D printed framework (Co-Cr framework, Wirobond C+). After finishing and polishing of metal partial denture, relief was given for Locator attachment. The occlusal surfaces of the distal extension areas were made of self-cure denture base material to simulate the occlusal plane. Locator attachments (D – 3.5 mm, H – 1 mm) (Zest Anchors, USA) were placed bilaterally at the premolar region and molar region. Pickup of the attachment on the partial denture was done for the premolar and molar regions by rapid repair material (Dentsply). After fabrication of the physical model proceeded to the laboratory for further procedures.

Strain gauge circuit

In the laboratory, the first planning of wiring of the resin model was done for physical stress loading. Spaces were created equally in buccal and lingual sides of the implant for the placement of “Mini Strain Gauge” (TML, Japan). Strain gauge was single axis type, length of 2 mm with 2.1 gauge factor, 120 Ohms resistance, foil type. Total 8 numbers of strain gauges were used for physical stress analysis [Table 1]. Mini strain gauges were affixed to both the labial and lingual sides of each implant (located at the second premolar and molar regions) in a vertical orientation at the crestal area using adhesive (CYN 202) [Figure 1]. Every strain gauge was affixed to the data acquisition system using a wired connection, enabling the software to monitor and record the stress values in the vicinity of the implant in response to the applied load. All the strain gauges are configured to a quarter bridge configuration, and in the data acquisition system, the bridge is completed with strain gauges. The system will be calibrated to get

accurate reading. In this system, tension will show +ve and compression will show as –ve.

Load application

Then, vertical loads 100N and 125N were applied bilaterally in the premolar and molar regions separately by universal testing machine (UTM). The S-shaped load cell was attached to the model with a pattern in order to distribute the load homogeneously. Application of load was based on previous literature.^[9,10] Load assessments were conducted on the abutment tooth, implants, and the residual ridge beneath the denture base using a UTM. This involved the application of a 100 N force followed by a 125 N force to simulate masticatory forces, directed vertically onto the occlusal table of molar region (distal location) and premolar region (mesial location) individually. These load measurements were repeated 28 times under two distinct conditions: first, with exclusive support from the bilateral mesial implant, facilitated by the attachment of a Locator attachment to the mesial implants, and second, with sole support from the bilateral distal implant, with a Locator attachment affixed to the distal implants. The unused implants were rendered inactive by ensuring that they no longer came into contact with the inner surface of the denture. The results were obtained in “Data Acquisition System” (microstrain, software: “LOAD CAM” model – MCS-1000), and the load-generated stress distribution was analyzed from a graphical representation in the software [Figure 2]. The test outcomes were presented in a graphical format, where each graph featured two sections. The upper portion displayed the collective results for the groups, while the lower section indicated the

Table 1: Location for wiring of mini strain gauge

Strain gauge number	Site of placement	Tooth region
Gauge 1	Labial side	Premolar region (3 rd quadrant)
Gauge 2	Lingual side	Premolar region (3 rd quadrant)
Gauge 3	Labial side	Molar region (3 rd quadrant)
Gauge 4	Lingual side	Molar region (3 rd quadrant)
Gauge 5	Labial side	Premolar region (4 th quadrant)
Gauge 6	Lingual side	Premolar region (4 th quadrant)
Gauge 7	Labial side	Molar region (4 th quadrant)
Gauge 8	Lingual side	Molar region (4 th quadrant)

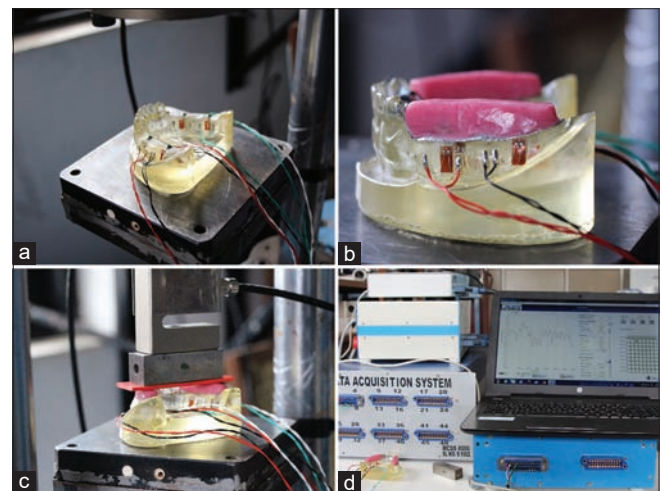


Figure 1: (a) Epoxy resin model was attached to all mini strain gauges, (b) metal frame of implant-assisted removable partial denture was placed, (c) application of load using load cell in universal testing machine, (d) data acquisition system was assessing the generated stress surrounding implant

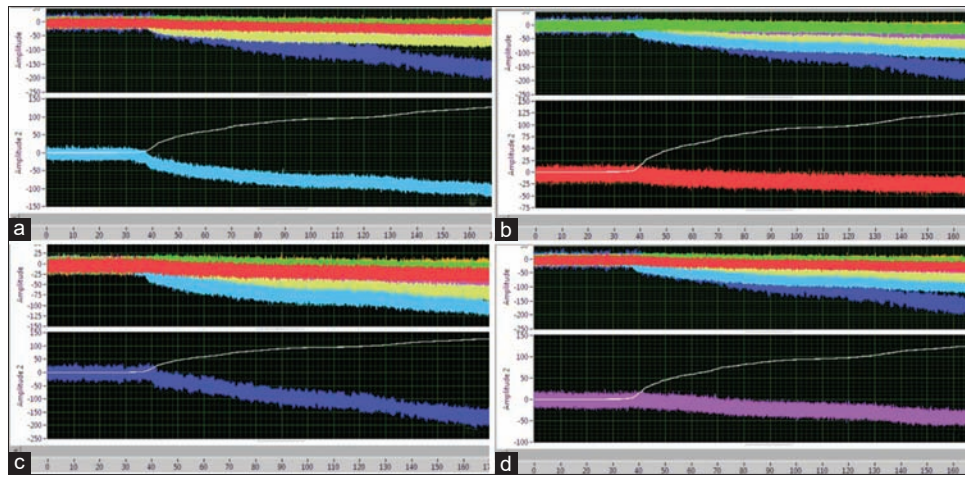


Figure 2: Graphical representation of microstress under load detected by mini strain gauge: (a) premolar (left), (b) premolar (right), (c) molar (left), (d) molar (right)

designated channels indicating different strain gauges. The measurement units were in strain, and the resolution was set at 1 microstrain. These graphs illustrated the relationship between strain and time.

Statistical analysis

All the collected data were recorded in a Microsoft Excel spreadsheet and later analyzed using SPSS for Windows (Statistical Package for the Social Sciences, SPSS, version 26.0, IBM Corp., Armonk, NY, USA). The results of the normality test Shapiro–Wilk’s indicated that the variables did not follow a normal distribution. Hence, nonparametric statistical analysis was conducted to analyze the data. The comparison of maximum stress observed at the premolar versus molar regions under the application of 100N and 125N loads was performed using the Mann–Whitney *U*-test.

RESULTS

Physical stress analysis was from the data derived from strain gauge. Values were obtained from graphs, entered in Excel pages, and statistically analyzed. The mean maximum stress observed at the premolar versus molar regions due to the application of the 100N and 125N load stress contours of IARPD (MPa) was compared. It was found that no statistically significant difference existed in mean maximum stress observed at the premolar versus molar regions due to the application of the 100N ($P = 0.435$) and 125N ($P = 0.718$) load stress contours of IARPD [Table 2]. The mesial implant, located in the premolar region, exhibited lower stress levels (median: 68) compared to the distal implant in the molar region (median: 75) under 100N load. Stress levels increased with a higher load 125N for both the mesial (median: 92) and distal (median:

Table 2: Comparing stress on two different implant sites by two different loads

Load	Implant site	n	Percentiles			P
			25 th	50 th (median)	75 th	
100 N	Premolar	28	67	68	68	0.435 [#]
	Molar	28	75	75	76	
125 N	Premolar	28	92	92	93	0.718 [#]
	Molar	28	102	102	103	

[#] $P > 0.05$ - not significant. *P* value derived from Mann–Whitney *U*-test

102) implants. However, since the difference in stress between these two implant locations was not statistically significant ($P > 0.05$), it suggests that the choice of implant location may not significantly impact implant placement decisions for individuals with IARPD. Instead, implant placement decisions can be based on bone availability in any suitable area.

DISCUSSION

The need for this study arises from the clinical complexity of selecting the optimal implant placement site in individuals with acquired resilience and periodontal disease. While the distal or molar region is commonly favored, certain cases involve limitations such as insufficient posterior bone volume. In such situations, the premolar region emerges as a potential alternative, given the similarity in stress distribution to the implant. Understanding the viability and effectiveness of this alternative treatment approach is crucial. Therefore, this study is essential to provide evidence-based guidance to clinicians facing these challenging clinical scenarios, ultimately improving treatment outcomes and patient care in the field of prosthodontics. This design showed strain around the neck of IARPD under both the loadings (100N and 125N) configuration. Stress was found little more in the molar region when compared to the premolar region, although

when it was statistically compared, the result showed that the difference was insignificant. In this complete scenario, natural teeth are always out of over stress which will help the prevention of existing remaining structures as said by Muller de Van.^[11] There is a minimum load on the rest area, thus it prevents load on natural tooth as it dissipates through implant, which supports the previous literature.^[12,13] The stress experienced by the distal implant in the molar area was higher than that of the mesial implant in the premolar region. This could be attributed to the distal implant's greater distance from natural dentition, as the load distribution in the mesial implant involves the natural teeth as well. Conversely, in the case of the distal implant, the load is primarily supported by the surrounding tissue, and once the implant is placed in the distal region, the area supported by tissue becomes constrained, leading to reduced stress distribution through the tissue. Instead, the implant and tooth act as abutments, minimizing stress transfer through the surrounding tissue.^[14,15] Clinically, however, there was no significant difference between the molar and premolar regions, indicating that both locations are viable for implant placement based on clinical requirements and availability, which aligns with findings in existing literature.^[16]

The Locator attachment system was selected for IARPDs due to its numerous advantages. Its resilient design enhances stability and ensures better force distribution during chewing, thereby reducing stress on both supporting implants and abutment teeth. Its self-aligning feature simplifies insertion and removal, ensuring patient comfort and convenience. With its low vertical profile, it contributes to an esthetically pleasing and streamlined prosthesis design. In addition, its compatibility with various implant systems adds to its treatment versatility. Overall, the Locator attachment system is a popular choice among clinicians and patients seeking stable, functional, and esthetically pleasing IARPDs. Finite element analysis is a valuable tool for stress measurement but comes with complexities, including the need for specialized software, computational resources, and validation. It relies on assumptions and can be time-consuming. Photoelastic analysis for stress distribution offers insights into stress patterns but is limited to 2D data and transparent materials and provides qualitative results. It is resource intensive for model fabrication and has scale limitations. Whereas, strain gauges operate based on the piezoresistive effect, where certain materials experience changes in electrical resistance when subjected to mechanical strain. These gauges are affixed to the surface of an object or structure to be tested, and when external forces are applied, causing deformation or strain in the object, the strain gauge also deforms, leading to a proportional change in its electrical resistance. This

small but measurable change was then processed using a Wheatstone bridge circuit to generate an electrical output signal directly correlated with the strain experienced by the object. The decision to use a strain gauge method over other stress evaluation techniques can be attributed to several factors. First, strain gauges offer a direct and highly sensitive measurement of mechanical strain, making them ideal for applications where precise stress and strain data are required. In addition, strain gauges are versatile and can be easily attached to a variety of surfaces and materials, allowing for a wide range of testing scenarios. Their nondestructive nature is another advantage, as they do not alter or compromise the structural integrity of the tested object.

Numerous previous studies focusing on the biomechanical aspects of IARPDs have consistently revealed enhanced denture stability and decreased stress on the residual ridge when utilizing supporting implants.^[17,18] Keltjens *et al.*^[19] reported that IARPD can also prevent underlying bone resorption, enhance retention and stability using attachments or healing caps, reduce stress in the supporting tooth, and provide comfort. Mijritsky *et al.*'s^[20] study reported that when implants are used, the need for buccal retentive arm clasps can be avoided at the esthetic zone.

In this study, only vertical loadings 100N and 125N of forces were tested, and rotational and lateral forces that are exerted on implants, attachments, and RPD framework were not incorporated. Future studies can be made on this lacuna with clinical research. The integration of digital dentistry and advancements in 3D printing technologies may also revolutionize the manufacturing process, making IARPDs more accessible and cost-effective for patients. As research continues to uncover the long-term clinical outcomes of IARPDs, their acceptance and application in prosthetic dentistry are expected to rise steadily, contributing to improved oral health and quality of life for patients. Exploring digital dentistry integration, patient-reported outcomes, and comparative studies is essential.

CONCLUSION

Although distal (molar) region is the best suitable area for the placement of implant in IARPD, in certain clinical conditions where posterior bone volume is not adequate for implant placement, the premolar region can be selected for the placement of the implant as there is no much difference of stress distribution to the implant. This treatment option will be very much effective where shortened dental arch concept is not applicable in order to

prevent the supraeruption of opposing teeth and IARPD will be much better choice than conventional. Future clinical research will be the confirmatory outcome of the present study.

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Conflicts of interest

There are no conflicts of interest.

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A comparative analysis of mechanical and optical behavioral patterns of translucent zirconia ceramics

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Abstract

Aim: This research aimed to assess and compare the translucency and mechanical properties of partially stabilized zirconia in contrast to lithium disilicate, particularly within the context of translucent zirconia.

Settings and Design: The experimental design entails examining fifty samples, with ten drawn from each of the five distinct categories of ceramic materials, as part of this in vitro study. Translucency is measured using the Konica Minolta CM-3600D spectrophotometer, assessing Delta E through Lab values against white and black backgrounds. Flexural strength is analyzed via a 3-point bend test on a universal testing machine, with a controlled crosshead speed set at 1 mm/min

Materials and Methods: The study included the five categories of ceramic materials, each consisting of ten samples: High-strength zirconia (Katana HT), translucent zirconia (e.max Zircad MT and Cercon ht ML), and lithium disilicate (Press MT and LT). The Konica Minolta CM-3600D spectrophotometer is utilized to measure the translucency parameter. This involves determining the color difference (Delta E) by comparing the L^*a^*b values against both white and black backgrounds. The flexural strength (FS) of zirconia and lithium disilicate materials was analyzed through a 3-point bend test, aiming to compare their respective strengths. The testing procedure was carried out on a universal testing machine with a controlled crosshead speed set at 1 mm/min. The FS was calculated using the formula $\sigma = FL/\pi R^3$ for circular disks, where σ represents the FS, F is the fracture load, L is the span length in millimeters, and R is the radius of the disk.

Statistical Analysis Used: The Student's t-test was employed for statistical analysis.


Results: The mean translucency parameter for e.max Press MT (6.33 ± 1.05) was significantly greater than all the specimens investigated. The Cercon ht ML exhibited a slightly higher translucency (2.18 ± 0.52) compared to e.max Zircad MT (1.49 ± 0.69), with a statistically significant difference ($P = 0.022$). Conversely, the FS of e.max Zircad MT (26.97 ± 2.06) was significantly greater ($P < 0.001$) than that of Cercon ht ML (23.25 ± 2.36). Notably, the Katana HT material demonstrated the highest load strength (32.92 ± 3.10), a statistically significant difference compared to its counterparts ($P < 0.001$).

Conclusions: Among the materials tested, lithium disilicate ceramics exhibited the highest translucency, with its MT variant demonstrating the lowest strength. Katana HT displayed significantly greater biaxial FS compared to translucent zirconia, surpassing even lithium disilicate. Translucent zirconia proved to be

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notably more translucent than high-strength zirconia. Within the category of translucent zirconia, e.max ZirCAD MT exhibited substantially higher FS than Cercon.

Keywords: Flexural strength, lithium disilicate, partially stabilized zirconia, translucency, translucent zirconias, yttria

INTRODUCTION

Following Land's introduction of the first feldspathic porcelain in 1903, zirconia garnered attention as an engineering ceramic in the 1970s and gained popularity among prosthodontists in the late 1990s.^[1-4] The presence of residual pores and impurities in zirconia, leading to the volumes with different refractive indices, surface optical scattering, and reduced translucency, necessitates their elimination to enhance the material's translucency.^[5-12] Despite this, 3 mol% yttria has traditionally been incorporated into dental zirconia to stabilize the tetragonal phase at the room temperature. The 3 mol% yttria-stabilized tetragonal zirconia polycrystal, exemplified by Katana HT, contains tetragonal zirconia, capable of generating a transformation zone that can act as a shield in the event of a crack occurrence.^[13] This transformative toughening process is integral to zirconia's exceptional fracture toughness in dental applications.

The initial version of 3Y-TZP dental zirconia faced the challenge of significant opacity. Alumina emerged as a contributing factor to the opacity of dental zirconia. During the sintering process, alumina is introduced as an aid to prevent pore formation in green-state zirconia. In addition, alumina segregates at grain boundaries, playing a role in stabilizing tetragonal zirconia. However, combining alumina with zirconia can lead to reduced in-line light transmission due to the differing refractive indices of the two materials.^[13] In the second iteration of 3Y-TZP utilized in dentistry, the alumina concentration was decreased from 0.25 wt% to 0.05 wt%. This adjustment resulted in increased translucency compared to the 3Y-TZP with higher alumina content. However, the reduced alumina in the 3Y-TZP with 0.05 wt% makes it more susceptible to low-temperature deterioration since there is less support for the tetragonal phase.^[14,15]

The concentration of yttria was increased to approximately 5 mol% in materials such as Cercon HTML, stabilizing them at an equilibrium of roughly 50% cubic and 50% tetragonal phases to enhance translucency.^[16-19] Despite being notably weaker than 3Y materials, these 5Y materials exhibited translucencies comparable to lithium disilicate glass ceramics.^[17] Engineering efforts

further reduced the cubic phase to approximately 30% in materials with a 4 mol% composition, such as e.max ZirCAD MT.^[11,18] Both 4 mol% and 5 mol% yttria-stabilized zirconia polycrystals (e.max ZirCAD MT and Cercon HTML) are commonly referred to as "translucent zirconia," despite their differing mechanical and optical characteristics.^[15,18]

The absence of a transformation-toughening mechanism in cubic zirconia diminishes its mechanical parameters.^[11,19] Zirconia flexural strength (FS) is influenced by hydrothermal degradation, characterized as low-temperature degradation, manifesting as the instability of traditional Y-TPZ in water and low temperatures over time.^[19] A correlation has been observed between low temperature deterioration and overall light transmission in materials, particularly in relatively thin restorations and variations in zirconia materials.^[19,20] While lithium disilicate is generally considered to have inferior mechanical properties compared to zirconia, it excels in translucency, offering a range of translucency levels and shades suitable for monolithic restorations while maintaining surface characterization.^[20] Microstructural frames indicate crystalline integration in a glass matrix, forming a glass ceramic with 70% crystalline lithium disilicate filler (IPS e.max; Ivoclar Vivadent AG).^[21,22] The exceptional translucency of lithium disilicate is attributed to the low refractive index of its crystals.^[23,24] Despite its fragility and low FS of about 360 MPa,^[23] lithium disilicate remains a viable option for specific esthetic applications.

This study aimed to comprehensively assess the translucency and FS of translucent zirconia in conjunction with lithium disilicate, specifically focusing on both the MT and LT variants. The existing literature lacks sufficient evidence for comparing FS and translucency among recently developed translucent zirconia and MT variants of lithium disilicate.^[17,20,24] In addition, there is a scarcity of research specifically examining translucency and FS within the translucent zirconia material itself. Our unique approach distinguishes this study, contributing to the current body of knowledge in this field. The null hypothesis posited that there would be no difference in translucency and FS among the three variants of zirconia, including lithium disilicate and translucent zirconia.

MATERIALS AND METHODS

This *in vitro* experimental study adhered to the ethical principles in research. While no human or animal participants were involved in this study, ethical principles were strictly observed. The study adhered to the standards set forth in the Helsinki Declaration of 1975, as revised in 2000. The approval for the study protocol was obtained from the Institutional Ethics Committee of Christian Dental College under the reference number Min No. CDC/ERC/2018/38. The study was designed to conduct a comparative analysis of the mechanical and optical behavioral patterns of translucent zirconia ceramics.

The study involved three zirconia products, encompassing two partially stabilized forms of translucent zirconia (4Y-ZP, e.max Zircad MT, and 5Y-ZP, Cercon ht ML), one high-strength zirconia (3Y-TZP, Katana HT), and two types of lithium disilicate (IPS e.max Press MT and IPS e.max Press LT from Ivoclar Vivadent AG), as detailed in Table 1. Each ceramic material, in shade A2, was prepared with ten specimens, segmented into round discs with a 15-mm diameter, and subsequently sintered or crystallized following the respective manufacturer's instructions.

To determine the necessary sample size for this study, a power analysis was performed using G * Power statistical software.^[25] The calculation of the sample size was based on an 80% desired power and a significance level of 0.05. For this analysis, a moderate effect size of 0.5 was assumed. The formula employed to calculate the sample size per group is expressed as:

$$n = 2 \times (Z\alpha/2 + Z\beta) 2 \times \delta 2 \sigma^2$$

where:

n represents the sample size per group.

$Z\alpha/2$ is the critical value for the desired significance level (0.025 for a significance level of 0.05).

$Z\beta$ is the critical value for the desired power (0.8).

σ is the estimated standard deviation of the outcome variable.

δ is the estimated standard deviation of the outcome variable.

Table 1: Attributes of the research material

Ceramic	Manufacturer	Type
3Y-TZP (Katana HT)	Dentsply Sirona Prosthetics	High-strength zirconia
4Y-PSZ (e.max Zircad MT)	Ivoclar Vivadent AG	Translucent zirconia
5Y-PSZ (Cercon ht ML)	Dentsply Sirona Prosthetics	Translucent zirconia
e.max MT	Ivoclar Vivadent AG	Lithium disilicate
e.max LT	Ivoclar Vivadent AG	Lithium disilicate

PSZ: Partially stabilized zirconia, HT: High translucent, MT: Medium translucent, LT: Low translucent, 3Y-TZP: 3 mol% yttria-stabilized tetragonal zirconia polycrystal

The estimated standard deviation for the outcome variable in the FS test was determined to be 10 MPa. Utilizing the previously mentioned formula, the required sample size for the FS test was computed as follows:

$$n = 2 \times (1.96 + 0.84) 2 \times (0.5) 2 (10) 2 = 9.98 \approx 10 \\ = 9.98 \approx 10$$

As a result, ten specimens per group were deemed necessary for the FS test. Consequently, a total of 50 specimens were included in this study for the FS test, with 10 specimens for each ceramic material.

Using a grinding machine (PSG-63DX; Okamoto), the specimens were meticulously crafted from each block employing a diamond wheel. Subsequently, they underwent a grinding process with surface grinding sheets (#100, #400, and #600) and were further polished with water-resistant abrasive papers #1000 and #2000 to achieve a uniform thickness of 2 mm. The thickness of each specimen was measured and confirmed using a digital caliper (external digital caliper; Bowers). Afterward, the specimens underwent a thorough cleaning process with distilled water through ultrasonic cleaning for 10 min and were then dried with compressed air. The final step involved measuring the specimens' dimensions using a Vernier caliper instrument (Aerospace 300 mm Digimatic Vernier Caliper, Measurement range: 0–300 mm, and Resolution: 0.01 mm).

Translucency assessment was conducted using a spectrophotometer (CM-3600D; Konica Minolta, Inc.) coupled with a color data application (Spectramagic NX; Konica Minolta, Inc.). The specimens were positioned against white and black backgrounds [Figures 1 and 2]. Prior to each measurement, the equipment underwent calibration using white and zero calibration tiles. Employing a 2-degree observer with a D65 illuminant and an 8-mm port, the readings were taken, and to mitigate the impact of air, a thin coating of glycerin was applied between the specimen and the background. Translucency (TP) was calculated based on the difference in the specimen's appearance against the white and black backgrounds using the following formula:^[26,27]

$$\Delta E = (L1 - L2) 2 + (a1 - a2) 2 + (b1 - b2) 2$$

Laboratory values against the white and black backgrounds were utilized to determine the color difference (ΔE). A universal testing machine^[28] (Model: WDW-52.5, serial number: 021034) with a crosshead speed of 1 mm/min performed a 3-point bend test. A specially designed

laboratory fixture [Figure 3] secured the circular specimens. The mechanism vertically loaded the specimen from the antagonist, slid it horizontally, and repeated the cycle. Test settings included a 20 N load, 0.4 Hz frequency, 2 mm sliding distance, 33% glycerin lubrication, and 300,000 testing cycles.^[29]

FS (σ) in MPa was calculated using the equation $\sigma = \frac{FR^3FL}{L^3}$, where F represents the fracture load, L is the span length in mm, and R is the radius of the disk.^[21,30] Statistical analysis involved a Student's *t*-test (unpaired) to compare the mean values between the two groups. If the assumptions of normality and equal variance were not met, appropriate nonparametric tests were applied. The results were reported as mean \pm standard deviation, along with *P* values.

RESULTS

Table 2 indicates a statistically significant difference ($P < 0.001$) in translucency observed between the two categories of zirconia with lithium disilicate and within the category of translucent zirconia. In Graph 1, the mean translucency parameter for e.max MT (6.33 \pm 1.05) and LT (3.61 \pm 0.59) was significantly greater than ($P < 0.001$) translucent zirconia, e.max Zircad MT (1.49 \pm 0.69) and Cercon ht ML (2.18 \pm 0.52) and the high strength, Katana HT (0.740 \pm 0.50). In terms of FS [Table 3], Katana HT (32.92 \pm 3.10) had the highest load strength ($P < 0.001$) than the translucent zirconia, E.max Zircad MT (26.97 \pm 2.06) and Cercon ht ML (23.25 \pm 2.36) and the lithium disilicate variants [Graph 2]. Even the Cercon ht ML, which had the lowest FS value among partially stabilized zirconia (PSZ), had a considerably higher mean value ($P < 0.001$) for FS than e.max LT (12.20 \pm 2.50) and e.max MT (9.49 \pm 2.03).

In Table 2 and Graph 1, when considering translucent zirconia, Cercon ht ML exhibited a slightly higher TP value (2.18 \pm 0.52) compared to e.maxZircad MT (1.49 \pm 0.69), with a statistical significance of $P = 0.022$. However, this significance level was lower in comparison to the flexural load values presented in Table 3 and Graph 2. Specifically, the FS of e.maxZircad MT (26.97 \pm 2.06) was found to be significantly higher ($P < 0.001$) than that of Cercon ht ML (23.25 \pm 2.36).

DISCUSSION

This research investigated the translucency and FS of three PSZ materials in comparison to their lithium disilicate counterparts. The null hypothesis was rejected for all



Figure 1: Specimen attached to black ring background



Figure 2: Specimen attached to white calibration background

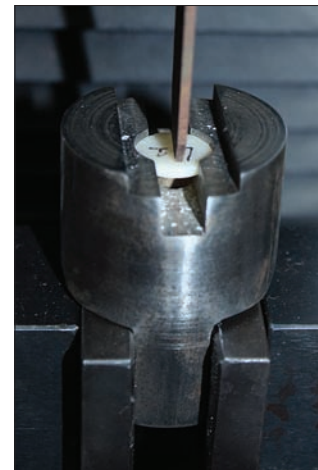


Figure 3: Biaxial strength testing in UTM: Flexural load application

the three types of zirconia when compared to lithium disilicate, as well as between e.max Zircad MT and Cercon ht ML. The examination of optical characteristics in newly developed translucent zirconia, high-strength zirconia, and lithium disilicate ceramics uncovered significant differences. In the category of translucent zirconia, Cercon ht ML demonstrated a slightly higher TP value (2.18 \pm 0.52)

Table 2: Mean and standard deviation in terms of translucency for each material

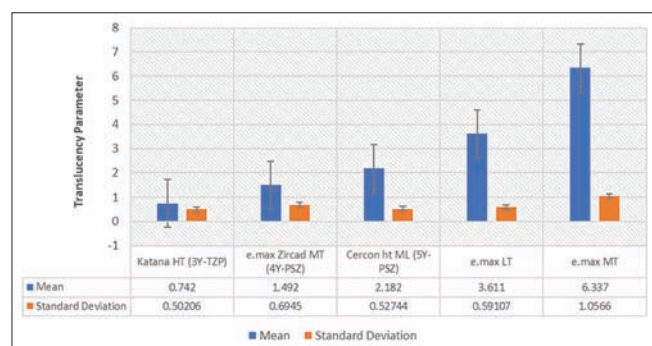
Brand	Mean±SD	95% CI for mean	Significant**	Minimum	Maximum
Katana HT (3Y-TZP)	0.74±0.50	0.38–1.10	0.001	0.12	1.76
e.max Zircad MT (4Y-PSZ)	1.49±0.69	0.99–1.98	0.001	1.00	2.78
Cercon ht ML (5Y-PSZ)	2.18±0.52	1.80–2.55	0.001	1.54	3.09
e.max LT	3.61±0.59	3.18–4.03	0.001	2.36	4.14
e.max MT	6.33±1.05	5.58–7.09	0.001	4.43	7.71

**Significance (*P* value). PSZ: Partially stabilized zirconia, HT: High translucent, MT: Medium translucent, LT: Low translucent, SD: Standard deviation, CI: Confidence interval, 3Y-TZP: 3 mol% yttria-stabilized tetragonal zirconia polycrystal

Table 3: Mean and standard deviation in terms of flexural strength for each material

Brand	Mean±SD	95% CI for mean	Significant**	Minimum	Maximum
Katana HT (3Y-TZP)	32.92±3.10	30.70–35.15	0.001	28.65	36.26
e.max Zircad MT (4Y-PSZ)	26.97±2.06	25.50–28.45	0.001	23.21	29.98
Cercon ht ML (5Y-PSZ)	23.25±2.36	21.56–24.94	0.001	18.89	26.85
e.max LT	12.20±2.50	10.40–13.99	0.001	8.15	15.91
e.max MT	9.49±2.03	8.03–10.94	0.001	6.78	12.09

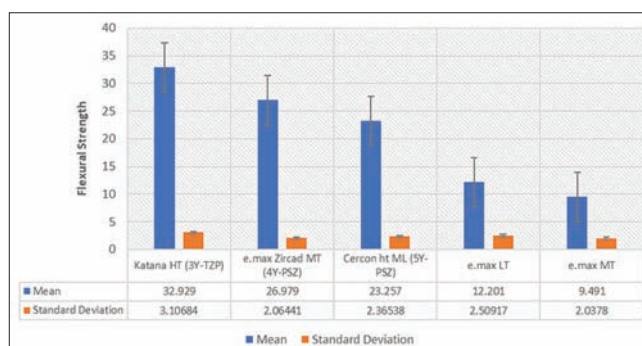
**Significance (*P* value). PSZ: Partially stabilized zirconia, HT: High translucent, MT: Medium translucent, LT: Low translucent, SD: Standard deviation, CI: Confidence interval, 3Y-TZP: 3 mol% yttria-stabilized tetragonal zirconia polycrystal

**Graph 1: Plot for translucency parameter of each materials**

compared to e.maxZircad MT (1.49 ± 0.69), with a statistically significant difference at $P = 0.022$. Conversely, the FS of e.maxZircad MT (26.97 ± 2.06) was markedly higher ($P < 0.001$) than that of Cercon ht ML (23.25 ± 2.36), as evidenced by the data presented in both Tables 2 and 3.

This indicates the level of significance of e.max Zircad MT in terms of FS was more significant ($P < 0.001$) than Cercon ht ML and comparatively less significant ($P = 0.022$) following TP values of Cercon ht ML, which was slightly higher than e.maxZircad MT. McLaren reported that surface-treated e.maxZircad MT showed much higher FS values ($P < 0.001$) than the three distinct 5Y-PSZ (Katana STML, Lava Esthetic and Argnez Anterior).^[30] This significant variance in the values was acquired due to the various types of surface treatment that 4Y-PSZ underwent (e.max Zircad MT). Given that no surface treatments were employed on any of the samples in this study, the difference in FS between e.maxZircad MT and Cercon ht ML was only moderate.

The least TP values were observed when using the white and black backgrounds with the high-strength Katana

**Graph 2: Plot for flexural strength parameter of each materials**

HT zirconia. Despite this, the translucent zirconia did not achieve the same level of translucency as the lithium disilicate material, although it was more translucent than the high-strength zirconia. As per the manufacturer's specifications, highly translucent zirconia, like Cercon ht ML, is characterized by an elevated yttria content ranging from 8 mol% to 10 mol%, leading to a fully stabilized cubic crystal structure.^[14,15,21,31]

Light scattering at the grain boundaries in the cubic phase was significantly reduced, primarily because the cubic phase of zirconia exhibits isotropic properties across various crystallographic directions.^[14,20] Therefore, the cubic phase appears more translucent. Because the translucent zirconia, e.max Zircad MT and Cercon ht ML were composed of 40%–45% tetragonal zirconia, and 50%–55% cubic zirconia, the transformation toughening of fully stabilized cubic phase was much lower than the partially stabilized cubic zirconia. Therefore, despite no discernible statistical difference, the optical properties of the Cercon ht ML material considered in this investigation were enhanced above those of e.maxZircad MT [Table 2].

All PSZ variations had biaxial FS values significantly more significant than their lithium disilicate equivalents. E.max Zircad MT's FS was higher than Cercon ht ML's in the translucent zirconia [Table 3]. A larger yttria concentration in Cercon ht ML stabilizes the zirconia materials, resulting in a microstructure with more cubic crystals and eliminating the toughening transition mechanism. The principal cause of these materials' lower FS and higher FS degradation is the absence of this process.^[32] The augmented grain size observed in cubic zirconia materials could be a contributing factor to the lower FS and flexural fatigue strength values. Smaller grain sizes, as seen in Katana HT and E.max Zircad MT, require higher applied stress for fracture initiation, while larger grain sizes may lead to diminished mechanical performance in both static and fatigue assessments. In addition, smaller grains can contribute to a reduction in the size of dislocations along the crystal grain boundaries, thereby enhancing the mechanical characteristics of the material.^[33-35]

Despite the marked differences observed in translucency and FS between the PSZ materials and lithium disilicate, it is crucial to acknowledge the study's limitations. First, the absence of surface treatments on the specimens may have influenced the results, as surface modifications can impact both the optical and mechanical properties of dental materials. Moreover, the study did not explore the effects of specimen aging, bond strength, enamel interactions, and material wear, which could offer additional insights into the long-term performance and durability of these materials. Future research endeavors should aim to address these limitations, providing a more comprehensive understanding of the clinical implications and performance of PSZ and lithium disilicate restorations.

In the broader context of available evidence, this study provides valuable insights into the field of restorative dentistry by comparing the optical and mechanical properties of PSZ materials and lithium disilicate. However, it is essential to clarify that this study does not constitute a systematic review. Conducting a systematic review that encompasses a broader spectrum of studies could yield a more comprehensive and robust evaluation of the available evidence. The study's findings bear significant implications for patient care and health policy. The superior translucency of lithium disilicate ceramics positions them as a suitable choice for highly esthetic restorations in anterior teeth, where a natural appearance is paramount. Conversely, the higher FS of PSZ materials makes them preferable for posterior restorations, emphasizing durability and resistance to occlusal forces. Dentists and clinicians should take these factors into consideration when selecting the most appropriate material for each clinical scenario.

Concerning the mechanisms at play, the study emphasized the impact of yttria concentration and crystal structure on the optical and mechanical properties of PSZ materials. The presence of fully stabilized cubic crystals in highly translucent zirconia resulted in decreased light scattering and enhanced translucency. A nuanced understanding of these underlying mechanisms can serve as a guide for the development of future zirconia materials with improved translucency and mechanical performance. This study may prompt some controversies, particularly in the context of choosing between PSZ materials and lithium disilicate for specific clinical applications. The decision-making process should involve a meticulous evaluation of the desired esthetic outcome, functional requirements, and the specific location of the restoration. Additional research and clinical studies are imperative to furnish more comprehensive evidence and address any controversies surrounding the selection of these materials.

Prospective avenues for future research in this collaborative effort might encompass a comprehensive comparison of various iterations of PSZ, incorporating newly developed ultra-translucent zirconia with glass integration. Delving into the impacts of surface treatments, aging, bond strength, and wear on the properties of these materials would offer invaluable insights for clinical applications. Furthermore, an exploration of the long-term clinical performance, survival rates, and patient satisfaction related to PSZ and lithium disilicate restorations would contribute to a deeper understanding of their effectiveness and provide essential guidance for treatment decisions.

CONCLUSIONS

In summary, this study revealed that translucent zirconia exhibits significantly higher translucency than high-strength zirconia. Among the translucent zirconia group, Cercon ht ML demonstrated slightly superior translucency compared to e.max Zircad MT, whereas e.max Zircad MT exhibited significantly higher biaxial FS than Cercon ht ML. In addition, both IPS e.max Press MT and LT ceramics displayed markedly higher translucency than all other specimens tested. Furthermore, high-strength zirconia exhibited stronger biaxial FS than translucent zirconia, while translucent zirconia demonstrated greater FS compared to extremely translucent lithium disilicate. Overall, these findings underscore the importance of selecting the appropriate ceramic material for specific clinical applications based on the considerations of translucency and FS properties.

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Conflicts of interest

There are no conflicts of interest.

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A comparative evaluation of internal and marginal fits of custom post and core fabricated using conventional and two digital techniques: An *in vitro* study

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Abstract

Aim: The purpose of this *in vitro* study was to comparatively evaluate the marginal and internal fits of cobalt–chromium metal custom post and core fabricated using a conventional technique with two digital techniques.

Settings and Design: The study was designed in an *in-vitro* study setting.

Materials and Methods: Five sets of custom post and core restorations were fabricated using the conventional (Group 1) and two semi digital methods (digital scanning of the resin pattern and computer aided additive manufacturing, and digital scanning of the silicone impression and subsequent computer aided designing [CAD] computer aided manufacturing fabrication) (Group 2 and 3). Marginal and internal fits of the posts were evaluated using a micro computed tomography scan at various points.

Statistical Analysis Used: A one way ANOVA test of the scores was made to evaluate the effect of different methods of custom post and core fabrication on marginal and internal fits. Bonferroni adjusted post hoc tests were conducted for intergroup comparison.

Results: Least marginal gap was reported in Group 3 ($82.5 \pm 14.36 \mu\text{m}$) followed by Group 1 ($110 \pm 25.19 \mu\text{m}$) and Group 2 ($112.5 \pm 26.75 \mu\text{m}$). Least internal gap at cervical, middle and apical as well as overall values were observed in Group 3 ($78 \pm 9.25 \mu\text{m}$, $72 \pm 7.79 \mu\text{m}$, $160 \pm 15.81 \mu\text{m}$, $103.3 \pm 4.43 \mu\text{m}$) followed by Group 1 ($113.5 \pm 25.35 \mu\text{m}$, $132.5 \pm 19.92 \mu\text{m}$, $502 \pm 74.63 \mu\text{m}$, $249.3 \pm 25.44 \mu\text{m}$) and Group 2 ($114.5 \pm 21.68 \mu\text{m}$, $133.5 \pm 19.57 \mu\text{m}$, $598 \pm 87.86 \mu\text{m}$, $282 \pm 28.91 \mu\text{m}$) respectively. The results of one-way ANOVA and Bonferroni adjusted post hoc tests for marginal gap did not show any statistically significant difference between the three groups ($P > 0.05$) but revealed statistically significant difference ($P = 0.02$) in internal gap values at the cervical, middle, and apical regions as well as overall internal gap region between the three groups.

Conclusions: Better marginal and internal fits were observed in custom post and core fabricated by digital scanning of the silicone impression and subsequent CAD as compared to those fabricated by the other two groups.

Keywords: Cobalt–chromium post and core, computer-aided designing and computer-aided manufacturing, custom post and core, digital method

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INTRODUCTION

Endodontically treated teeth have always been a challenge to restore.^[1] The difficulty of restoring such teeth drastically increases when the residual tooth structure is unable of supporting a restoration or satisfying the tooth's masticatory and esthetic needs.^[1,2] Custom posts and core restorations have become the primary treatment option to restore structurally compromised teeth, teeth that are exposed to high functional loads, or teeth requiring a modification in the emergence profile.^[3] Many factors influence the prognosis of such post and core restorations. The adaptation of posts to the root canal anatomy has been acknowledged as an important factor associated with the fracture resistance and survival of such teeth.^[4-6] Conventionally, custom post and cores are fabricated by either direct or indirect method followed by casting procedures.^[3]

The advent of computer-aided designing and computer-aided manufacturing (CAD-CAM) technology has greatly improved the accuracy and speed of prosthetic treatment when compared to conventional methods.^[7-11] The application of this technology to custom post and core fabrication definitely seems promising.^[12-15] These digital methods can be broadly classified as fully digital and semi-digital fabrication techniques.^[16-20]

The fully digital technique involves a direct digital scan or a dual digital scan with the help of scan posts, followed by computer designing and manufacturing of the custom post and core.^[19,20] The semi-digital technique involves a digital scan of a wax or resin pattern or a scan of the final impression of the post space followed by computer designing using specific CAD software and subsequent CAM fabrication.^[20-22] Thus, clinicians not having access to an intraoral scanner can still utilize the benefits of the digital workflow.^[22]

There are very few studies comparing the marginal and internal fits of custom post and core fabricated using semi-digital fabrication techniques to those fabricated by conventional techniques.^[17,19,20,22] Currently, there is no clear consensus as to which direct semi-digital fabrication technique provides a custom post and core with better marginal and internal fits.

Thus, the purpose of this *in vitro* study was to comparatively evaluate the marginal and internal fits of cobalt–chromium metal custom post and core fabricated using conventional technique and two semi-digital techniques using direct metal laser sintering (DMLS) for CAM. The null hypothesis was that there would be no difference in the marginal and

internal fits of custom metal post and core fabricated using a conventional technique with those fabricated using two digital techniques.

MATERIALS AND METHODS

This comparative *in vitro* study was conducted in the department of prosthodontics and crown and bridge of a dental college in collaboration with a micro-computed tomography (CT) center. Ethical committee approval TDCEC/45/2019 dated on 01/10/2019.

The sample size was calculated by considering the mean and standard deviation values ($0.118 \pm 0.066 \mu\text{m}$, $0.665 \pm 0.189 \mu\text{m}$, and $0.294 \pm 0.115 \mu\text{m}$) obtained from a previous study by Hendi *et al.*^[20] using G*Power software (Version 3.0.10). The level of significance (α error) was set at 5% and the power of the study ($1-\beta$) was set at 80% (0.80). The total sample size calculated was 9 (3 per group). A total of 15 samples (5 per group) were included in the present study to account for any loss of specimen.

Five freshly extracted noncarious, single-rooted mandibular first premolar teeth with relatively straight roots and completely formed apex of similar shape and size were selected. The teeth were washed and immersed in hydrogen peroxide solution to remove organic remnants. All remaining organic debris were removed with an ultrasonic scaler (UDS-P; WOODPECKER). Digital radiographs (Xios XG Select RVG Sensor; Dentsply Sirona) were taken to ensure a single canal, closed apex, and relatively straight root canals. Teeth were then decoronated 2 mm above cemento-enamel junction with a diamond rotary cutting instrument under water using a high-speed handpiece taking two points of reference (one point on the labial surface and one on the lingual surface).

The teeth were then endodontically treated following protocol. Biomechanical preparation was done using K-files and ProTaper endodontic hand files as per the manufacturer's instructions using the crown-down technique in the sequence of S1, S2, F1, and F2. First, the coronal and middle thirds of the canal were shaped using 10 and 15 No. K-files and S1, S2, and F1 ProTaper hand files, using a reciprocating back-and-forth motion. All pulp tissues were extirpated, and the canals were cleaned and shaped to obtain straight access to the middle and the apical third of all specimens. Apical preparation was done using 15 and 20 No. K-files and F2 ProTaper hand files. The canals were dried with size F2 paper points and were obturated using size F2 gutta-percha points and sealer by the warm vertical compaction technique.

Any excess coronal to the canal orifice was removed with a warm plugger post space prepared after 24 h. Post space length was kept constant at 10 mm for all teeth.^[7] Initially, no. 1, 2, and 3 Peeso reamers (MANI Peeso reamer; MANI, Inc.) were used to remove gutta-percha. Final post space preparation was done using ParaPost preparation drill No. 4 (ParaPost System Casting Technique Starter Kit; COLTENE). A tapered round bur (DIA-BURS TR 12; MANI, Inc.) was used to prepare a deep chamfer finish line of 1 mm width. Three groups were formed based on the method of fabrication of custom post and core.

Group 1 custom post and cores were fabricated by direct resin pattern using laboratory burnout post and pattern resin and casting the pattern using cobalt–chromium ingots. The ParaPost laboratory burnout tapered post No. 4 (ParaPost System Casting Technique Starter Kit; COLTENE) was tried in the prepared canal and evaluated for fit. The pattern resin was mixed in a ratio of 1:1 by weight, painted onto the burnout post, and inserted into the post space (GC Pattern Resin; GC). The cylindrical core pattern of 2 mm height was also built. All patterns were spruced and invested with a phosphate-bonded investment (ADENTAvest CB; Adentatec) and cast in an induction casting machine (Ducatron Serie 3; Ugin Dentaire) with Type 4 cobalt–chromium alloy (System NE; Adentatec).

Group 2 direct resin patterns were fabricated similarly to Group 1. These resin patterns were digitally scanned using a dental table-top scanner (Medit T300 Dental table-top scanner; MEDIT) [Figure 1]. The scanned data were compiled into an STL file for further digital fabrication. The custom posts and cores were fabricated with DMLS technology (EOSINT M 270; EOS GmbH) using a cobalt–chromium alloy powder



Figure 1: STL files of Group 2 custom post and cores

(Wirobond C+; BEGO GmbH and Co.) at 40 microns layer thickness.

For Group 3, the impression of post space was made using the No. 4 ParaPost plastic impression post (ParaPost System Casting Technique Starter kit; COLTENE) and addition silicone impression material (AVUE GUM; Dental Avenue). The light-bodied material was loaded inside the post space with the help of an intraoral tip. The plastic impression post was also painted with light-bodied material and inserted into the prepared post space. Putty consistency elastomeric impression material was loaded onto an impression material holder and was placed over the coronal portion of each tooth. The impressions were digitally scanned using a dental table-top scanner (Medit T300 Dental table-top scanner; MEDIT) to obtain digital virtual models [Figure 2]. Custom post and core were then designed using a CAD software (exocad 2.3 Matera Dental CAD software; exocad GmbH) (spacer thickness set to 0 microns) [Figure 3]. The custom post and cores were fabricated with DMLS with the same material and technique.

To ensure the standardization of procedure, a single operator performed all the above-mentioned procedures following the same protocol to fabricate the 15 custom posts and cores [Figure 4]. Laboratory-based micro-CT system with sub-micron spatial resolution (high aspect ratio tomography mode at 95 kV and 85 mA with a resolution of 14.5 μm, exposure time of 3 s) was used for scanning and image reconstruction (Carl ZEISS XRadia 520 Versa; ZEISS). Two-dimensional virtual slices were examined coronally. A compatible software (Dragonfly Pro Analysis Software) was used to measure linear distances to evaluate the internal fit and marginal fit of custom post and core [Figure 5].

Marginal fit of custom post and core was evaluated by means of marginal gap, which was taken as the vertical distance between the custom post and core and the tooth

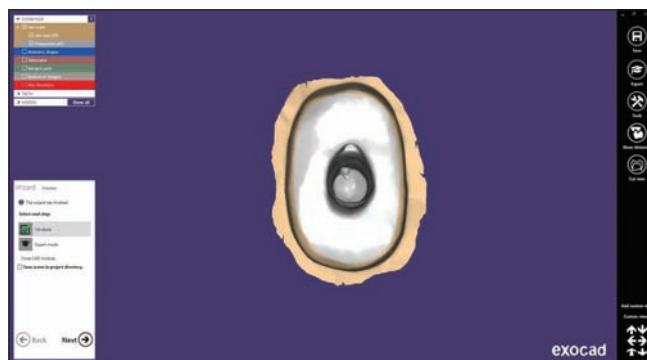


Figure 2: Digital virtual models of Group 3 custom post and cores

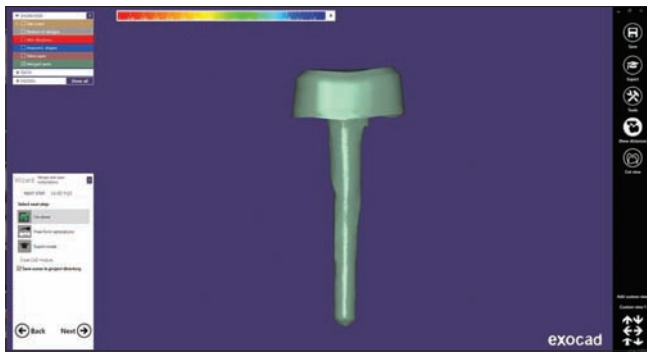


Figure 3: Digital designing of Group 3 custom post and cores using computer-aided designing software



Figure 4: Group 1, 2, and 3 custom posts and cores

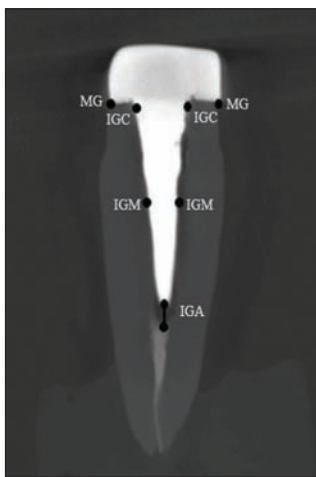


Figure 5: Points of measurement of marginal and internal fits. MG: Marginal gap, IGC: Internal gap (cervical), IGM: Internal gap (middle), IGA: Internal gap (apical)

at the margin at mesial, distal, buccal, and lingual aspects. Internal fit of custom post and core was evaluated by means of internal gap values measured at 3 levels: cervical, middle, and apical. Internal fit at cervical region was evaluated as the perpendicular distance between the custom post and core and the tooth as measured at the post and core junction at mesial, distal, buccal, and lingual aspects. Internal

fit at middle region was evaluated as the perpendicular distance between the custom post and core and the tooth as measured at the mid-point of the post at mesial, distal, buccal, and lingual aspects. Internal fit at apex was evaluated as the vertical gap between the custom post and core and the tooth as measured at the apex of the post space preparation.

The values obtained were entered into a Microsoft Excel spreadsheet and subjected to statistical analysis using the Statistical Package of the Social Sciences (SPSS) Software (IBM SPSS Statistics v20.0; IBM Corp). A one-way ANOVA test of the scores was made to evaluate the effect of different methods of custom post and core fabrication on marginal and internal fits. Bonferroni-adjusted *post hoc* tests were conducted for intergroup comparison.

RESULTS

The descriptive statistics for the three groups are shown in Table 1 and Figure 6. The results of one-way ANOVA and Bonferroni-adjusted *post hoc* tests for marginal gap did not show any statistically significant difference between the three groups ($P > 0.05$) [Tables 2 and 3]. Least marginal gap was reported in Group 3 ($82.5 \pm 14.36 \mu\text{m}$) followed by Group 1 ($110 \pm 25.19 \mu\text{m}$) and Group 2 ($112.5 \pm 26.75 \mu\text{m}$) [Table 2].

The results of one-way ANOVA revealed a statistically significant difference ($P = 0.02$) in internal gap values at the cervical, middle, and apical regions as well as overall internal gap region between the three groups [Table 2]. Least internal gap at cervical, middle and apical region was observed in Group 3 ($78 \pm 9.25 \mu\text{m}$, $72 \pm 7.79 \mu\text{m}$, $160 \pm 15.81 \mu\text{m}$) followed by Group 1 ($113.5 \pm 25.35 \mu\text{m}$, $132.5 \pm 19.92 \mu\text{m}$, $502 \pm 74.63 \mu\text{m}$) and Group 2 ($114.5 \pm 21.68 \mu\text{m}$, $133.5 \pm 19.57 \mu\text{m}$, $598 \pm 87.86 \mu\text{m}$) respectively [Table 2]. Least overall internal gap values were observed in Group 3 ($103.3 \pm 4.43 \mu\text{m}$) followed by Group 1 ($249.3 \pm 25.44 \mu\text{m}$) and Group 2 ($282 \pm 28.91 \mu\text{m}$) respectively. Bonferroni-adjusted *post hoc* tests showed a statistically significant difference in internal gap values between Group 1 and Group 3 ($P = 0.04$) and Group 2 and Group 3 ($P = 0.04$), and a statistically insignificant difference in internal gap values between Group 1 and Group 2 ($P = 1$) [Table 3].

DISCUSSION

As seen in the results of this study, the null hypothesis was partly accepted and partly rejected. The null hypothesis that there would be no difference in the marginal fit of custom post and core fabricated using conventional and two digital techniques was accepted. This study reported no significant difference in the marginal fit of the custom post and cores

Table 1: Descriptive statistics

Group 1					Group 2					Group 3				
Mesial	Distal	Buccal	Lingual	Mean	Mesial	Distal	Buccal	Lingual	Mean	Mesial	Distal	Buccal	Lingual	Mean
Marginal gap														
100	60	90	80	82.5	70	80	100	60	77.5	80	90	70	80	80
110	160	130	120	130	130	120	120	160	132.5	100	70	110	80	90
100	80	110	90	95	110	140	100	80	107.5	80	110	120	100	102.5
70	120	90	120	100	90	120	70	120	100	40	120	60	80	75
110	160	140	160	142.5	130	160	110	180	145	70	60	90	40	65
Internal gap: Cervical														
70	80	110	60	80	100	110	90	80	95	90	70	80	90	82.5
120	120	120	160	130	110	150	110	130	125	40	90	60	80	67.5
110	150	110	80	112.5	110	80	120	90	100	80	90	80	70	80
90	120	70	120	100	90	120	90	120	105	90	80	80	110	90
130	160	110	180	145	110	160	140	180	147.5	80	70	40	90	70
Internal gap: Middle														
100	190	190	140	155	180	140	100	200	155	110	40	80	90	80
120	150	130	150	137.5	130	150	120	170	142.5	40	90	40	80	62.5
190	120	100	90	125	90	90	190	150	130	80	90	80	70	80
110	110	160	190	142.5	160	190	90	110	137.5	40	80	110	40	67.5
90	90	120	110	102.5	120	110	90	90	102.5	80	70	40	90	70
Internal gap: Apical														
Group 1					Group 2					Group 3				
450					590					170				
520					650					180				
620					670					140				
430					630					150				
490					450					160				

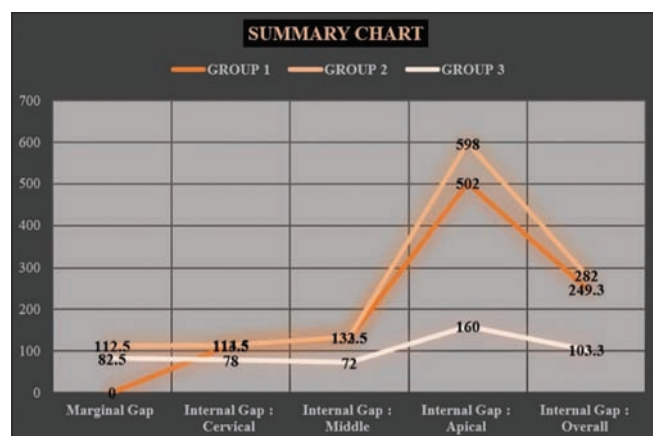


Figure 6: Results summary (in microns)

fabricated using the conventional technique and the two digital techniques. An apt reasoning to justify this result could be that there was the least distortion of both pattern resin and elastomeric impression material at the margin.^[3,19] This region was also relatively easy to record accurately as compared to the internal post space.^[3,19]

The null hypothesis that there would be no difference in the internal fit of custom post and core fabricated using conventional and two digital techniques was rejected. The custom post and core fabricated by scanning the elastomeric impressions reported better internal fit as

compared to those fabricated by the conventional direct method and by scanning the pattern resin custom post and cores. Better dimensional accuracy of addition silicone elastomeric impression materials could have led to better recording of the post space anatomy.^[20,22] The table-top laboratory scanner was able to better record the surface anatomy and details of the elastomeric impression as compared to pattern resin.^[20] The pattern resin custom post and cores could have distorted due to restricted flow, polymerization shrinkage while recording the internal anatomy of the post space leading to shorter posts and greater internal gap values.^[3]

Custom metal post and cores could be conventionally fabricated by direct and indirect techniques.^[3,6] Rayyan *et al.* and de Moraes *et al.* reported that custom post and cores fabricated with the direct technique presented better marginal and internal fits as compared to those fabricated using the indirect technique.^[3,6] The indirect technique presented a greater apical gap, probably due to increased laboratory steps and the material distortions.^[3,6] The present study has included the conventional direct technique of custom metal post and core fabrication as the control group (Group 1) in consideration of its better performance.

Digitalization has many advantages such as ease, reduction in chairside and prosthesis fabrication time, patient comfort,

Table 2: Summary statistics and one-way ANOVA

Dependent variable	Groups	Mean±SD	Minimum	Maximum	F	P
Marginal gap (microns)	Group 1	110±25.19	82.5	142.5	2.67	0.11
	Group 2	112.5±26.75	77.5	145		
	Group 3	82.5±14.36	65	102.5		
Internal gap: Cervical (microns)	Group 1	113.5±25.35	80	145	5.41	0.02*
	Group 2	114.5±21.68	95	147.5		
	Group 3	78±9.25	67.5	90		
Internal gap: Middle (microns)	Group 1	132.5±19.92	102.5	155	22.14	<0.001*
	Group 2	133.5±19.57	102.5	155		
	Group 3	72±7.79	62.5	80		
Internal gap: Apical (microns)	Group 1	502±74.63	430	620	58.72	<0.001*
	Group 2	598±87.86	450	670		
	Group 3	160±15.81	140	180		
Internal gap: Overall (microns)	Group 1	249.3±25.44	224.2	285.8	90.32	<0.001*
	Group 2	282±28.91	233.3	305.8		
	Group 3	103.3±4.43	100	110.8		

*Significant factor. SD: Standard deviation

Table 3: Bonferroni-adjusted post hoc tests: Intergroup comparison

Dependent variable	Group-wise comparison	Mean difference	SE	P	95% CI	
					Lower bound	Upper bound
Marginal gap	Group 1-Group 2	-2.5	14.40	1	-42.54	37.54
	Group 2-Group 3	30	14.40	0.18	-10.04	70.04
	Group 3-Group 1	-27.5	14.40	0.24	-67.54	12.54
Internal gap: Cervical	Group 1-Group 2	-1	12.64	1	-36.13	34.13
	Group 2-Group 3	36.50*	12.64	0.04	1.37	71.63
	Group 3-Group 1	-35.5*	12.64	0.05	-70.63	-0.37
Internal gap: Middle	Group 1-Group 2	-1	10.59	1	-30.43	28.43
	Group 2-Group 3	61.50*	10.59	<0.001	32.07	90.93
	Group 3-Group 1	-60.50*	10.59	<0.001	-89.93	-31.07
Internal gap: Apical	Group 1-Group 2	-96	42.49	0.13	-214.1	22.1
	Group 2-Group 3	438.00*	42.49	<0.001	319.9	556.1
	Group 3-Group 1	-342.00*	42.49	<0.001	-460.1	-223.90
Internal gap: Overall	Group 1-Group 2	-32.66	14.16	0.12	-72.01	6.69
	Group 2-Group 3	178.66*	14.16	<0.001	139.31	218.01
	Group 3-Group 1	-146.00*	14.16	<0.001	-185.35	-106.65

*Significant factor. SE: Standard error, CI: Confidence interval

reduced storage requirements, easy access to diagnostic information, and easy transfer of digital data.^[10-12,20] The application of this technology to custom post and core fabrication could possibly improve its marginal and internal adaptation mainly by better reproduction of surface detail, reduced cement film thickness, and negligible void formation, leading to better fracture resistance and overall prognosis of such restorations.^[13,14] Elimination of multiple laboratory steps could further improve the accuracy and reduce fabrication time.^[12-14]

The current technological limitation of intraoral scanners to fully record the depth of the post space and the inability of scan posts to record the internal anatomy of post space has dissuaded us from evaluating this method in the current study.^[16,20] On the other hand, the semi-digital methods can be easily adapted into clinical practice and can also be used by clinicians not having access to an intraoral scanner.^[20] The two semi-digital direct techniques of custom post and core fabrication evaluated in the current study were digital scanning of the resin pattern (Group 2) and digital

scanning of the elastomeric impression (Group 3). Both these semi-digital techniques could help eliminate many laboratory steps and thereby improve the ease, accuracy, and speed of manufacturing.^[20]

Different materials have been documented in literature for manufacturing of custom post and core such as zirconia, composite, glass fiber, and cobalt–chromium metal alloy.^[8,15,20,22] Most authors have used subtractive methods of CAD CAM manufacturing.^[19,20] This study has used DMLS which is an additive method of CAD CAM manufacturing for preparation of custom post and cores in both the semi-digital direct technique groups (Groups 2 and 3). The custom post and cores fabricated using DMLS method have been reported to provide similar fracture resistance and internal and marginal fits when compared to those manufactured using milling and conventional casting techniques.^[21] DMLS reports advantages such as better corrosion resistance and surface properties, less material waste, and fewer microporosities.^[21] Hence, this method was selected for fabrication of the custom post and cores.

Good marginal and internal adaptation and passive fit of post and cores to the root canal anatomy have been reported to be extremely essential for long-term success of custom post and core restorations.^[2-4] The apical portion of post and cores should contact the residual gutta-percha to prevent the ingress of saliva and bacteria.^[3] There are currently no clear guidelines to evaluate the adequacy of fit of posts.^[6] Therefore, this study has followed a previous study by de Moraes *et al.* to evaluate marginal and internal fits.^[6] Furthermore, an apical gap of >1 to 2 mm was considered unacceptable and categorized as poor fit and was associated with clinical complications.^[6]

This study utilized micro-CT images reconstructed in three planes to accurately view and measure the marginal and internal gap values at various points. Micro-CT scans have been known to exhibit high accuracy, better resolution, and detailed imaging with minimized metal scatter.^[23,24] The micro-CT system uses micro-focal spot X-ray sources and detectors with high resolution to produce three-dimensional reconstructed images with higher spatial resolution than CT imaging.^[21,25]

A lack of similarly conducted studies on custom metal post and cores fabricated using semi-digital techniques does not permit for a direct comparison of the results. A lack of standardized guidelines and techniques for assessing the internal and marginal fits of custom post and core as well as the plethora of material and scanner options used further prevents correlation of results.

The present study does have a few limitations. The *in-vitro* study design does not evaluate the impact of clinical factors such as saliva, limited mouth opening, and accessibility, on the accuracy of custom post and core fabrication. Hence, the results should be interpreted with caution. A lack of similarly conducted studies does not permit for a direct comparison of the results. Techniques to directly digitalize the post space have not been evaluated in the current study.

Evaluation of fully digital and semi-digital methods of custom post and core fabrication with respect to different materials and methods of CAD CAM manufacturing should be considered in future studies. A research lacuna was observed in this regard. Furthermore, standardization of point of measurement to evaluate the internal and marginal fits can help compare different materials and techniques accurately.

Overall, the advent of digital dentistry in the manufacturing of custom post and core has definitely ensured ease, accuracy, and faster fabrication of the custom post and

core. The CAM technology eliminated various laboratory steps and helped speed up the fabrication process. The direct scanning of the elastomeric impression followed by digital design and DMLS technique for custom post and core fabrication does seem to provide better internal and marginal fits among the three groups tested in the current study. However, the custom post and core fabricated in all the three groups showed internal and marginal fit values in the acceptable range.

CONCLUSIONS

1. Better internal fit was observed in custom post and core fabricated by digital scanning of the silicone impression and subsequent CAD as compared to those fabricated by casting the direct resin pattern and digital scanning of the direct resin pattern
2. This study reported no significant difference in the marginal fit of custom post and core fabricated by the conventional and two semi-digital techniques
3. Custom post and core fabricated in all the three groups showed internal and marginal fit values in the acceptable range
4. DMLS technology can be used successfully for manufacturing custom post and core restorations when using digital methods of CAD CAM fabrication.

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Conflicts of interest

There are no conflicts of interest.

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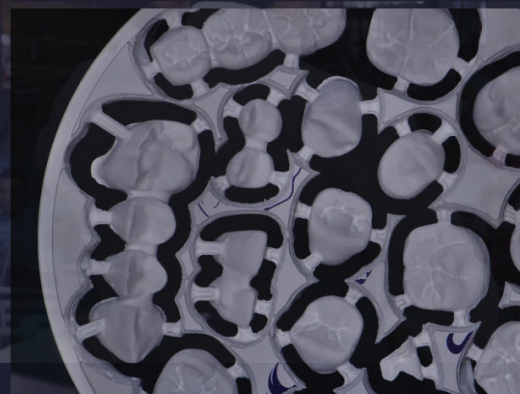
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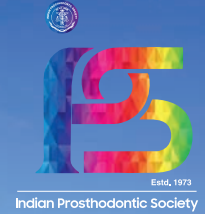
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