Editorial

An overview of statistics for dental research: Prosthodontic perspective

Clinicians often lack knowledge in statistical analysis; however, his/her inputs form a major role in enhancing the quality of research, especially in identifying relevant statistics for the obtained data based on the research objective. The statistician's expertise in dental research will be limited due to their lack of understanding of clinical and nonclinical trials. An inapposite communication of our requirement and the statistician's underexposure to our subject will result in skewed results. This editorial intends to provide an overview of statistics for different situations in dental research for the clinicians to have a basic knowledge in statistics for designing their research framework. The basis to perform statistical analysis depends on the research hypothesis, type of data, number of variables, and the test of normality.

A hypothesis is stated as either a null (there is no difference between cause and effect) or an alternate (there exists a difference between cause and effect) hypothesis that plays a vital role in suggesting the *P* value to choose the correct statistical method as discussed in our previous editorial.

The data collected by conducting research are categorized as, namely, qualitative (nominal or ordinal) and quantitative (interval or ratio).[1]

- Nominal data are categorical and qualitative, which are based on factors such as gender (male/female) and habits (smoking/nonsmoking), and they do not provide any quantitative value
- Ordinal data are also categorical; however, they are in between quantitative and qualitative data (e.g., ranking/grading based on education level and economic status). It could be confused with ratio data
- Interval data are the numerical type that has precise and continuous data (e.g., peri-implant bone loss/resonance frequency analysis (RFA) values at various stages of osseointegration). They can have negative data or positive data but lack a true zero
- Ratio is also numerical data, which ranks data and is continuous (e.g., total number of implant failures). They have a true zero value (e.g., the number of participants presented with crestal bone loss up to 1.5 mm is the representation of ratio data; while measuring a crestal bone loss to find the average bone loss is the representation of an interval data). Unlike the qualitative (nominal and ordinal) data, both the quantitative (interval and ratio) data have equal intervals.

The number of variables in the study also plays a role in the type of statistical analysis. A study with a single variable is the evaluation of therapy at a single point of time, where only one type of data (e.g., measuring crestal bone loss) is collected from several participants. A study with two or more variables can be either a comparison of pre- and postoperative data of therapy or assessing a postoperative effect based on age, sex, and economic level. In the former, there are two variables of pre- and postoperative effect, whereas the latter compares one variable (therapeutic effect) with several variables such as age and sex. With multiple variables, the researcher should know whether the data collected for each variable will be qualitative or quantitative. Even if the data are quantitative, the test of normality suggests the requirement of parametric or nonparametric statistical analysis.

The test of normality is commonly performed by methods such as the Shapiro–Wilk test for a study with small sample size and the Kolmogorov–Smirnov test for a study with a larger sample size. If there is no significant difference ($P > 0.05$) in either of the above tests, indicate that the data are normally distributed and require a parametric test.[2] However, normality tests such as D'Agostino's K-squared test, Jarque–Bera test, Anderson–Darling test, Cramér–von Mises criterion, Lilliefors test, and Pearson's Chi-squared test are available for precise interpretation.

Research may require multiple statistical tests to interpret the obtained data. We would like to make the readers understand better with examples to know the type of statistical analysis of different research objectives [Table 1].

Table 1: Statistical tool for data analysis

Number of variables	Type of data in one variable	Type of data in the second variable	Parametric or nonparametric	Statistical analysis
Single variable	Quantitative	-	Parametric	*t*-test for single mean
Single variable	Qualitative	-	Nonparametric	Chi-square test for goodness of fit
Two variables	Nominal (two groups)	Quantitative	Parametric	Independent sample *t*-test
Two variables	Nominal (two groups)	Ordinal/quantitative	Nonparametric	Mann–Whitney *U*-test
Two variables with equal samples	Quantitative	Quantitative	Parametric	Paired sample *t*-test
Two variables with equal samples	Ordinal/quantitative	Ordinal/quantitative	Nonparametric	Wilcoxon signed-rank test
Multiple variables	Nominal (>2 groups)	Quantitative	Parametric	ANOVA
Multiple variables	Nominal (>2 groups)	Ordinal/quantitative	Nonparametric	Kruskal–Wallis test
Two variables for correlation	Quantitative	Quantitative	Parametric	Pearson correlation coefficient
Two variables for correlation	Quantitative	Qualitative	Nonparametric	Spearman rank correlation
Two variables for association	Qualitative	Qualitative	Nonparametric	Chi-square test

Although this editorial stated with several examples of quantitative data, the analysis should be further confirmed by the test of normality and Shapiro–Wilk/Kolmogorov–Smirnov test, and if $P > 0.05$, a nonparametric analysis has to be conducted even for a quantitative data.

- A research objective with a single variable; recording the RFA values for evaluating the implant stability of several participants during placement to obtain a mean will be considered continuous quantitative data of a single variable. This methodology would require a *t*-test of a single mean for a parametric analysis
- A research objective with a single variable, but the samples are categorized based on RFA values, such as 1–10 implant stability quotient (ISQ) value as Grade I and 1–20 ISQ value as Grade II, the data obtained are ordinal (qualitative) data (the difference between two grading may not be equal and hence cannot be considered ratio [quantitative] data. The participant with a score of 10 in Grade I and the participant with a score of 11 in Grade II have a difference of only 1 score, whereas within the grade will present with a difference of 9. There is no equal difference between the participants between and within grading and hence will be considered qualitative data.). This objective is also a single-variable study, but with qualitative data that require the Chi-square test for nonparametric analysis
- A research objective with two variables; to find the relation/association between the intercanthal distance and intercanine distance, a correlation analysis should be performed and not a *t*-test. In this objective, the intercanthal distance (quantitative) and intercanine distance (quantitative) are two independent variables, and the values obtained will be continuous quantitative data, requiring a parametric analysis like Pearson correlation analysis. A similar research objective wherein to find the relationship between the different maxillomandibular relationships (qualitative) and the intercanine distance (quantitative), a combination of qualitative (Class I, II, and III maxillomandibular relations depicting ordinal data) and quantitative (measurement depicting continuous data) data will be obtained. Hence, a nonparametric test like the Spearman rank correlation test will be used. When both variables are qualitative, as in establishing an association between the gender (male/female) and jaw positions (Class I, II, and III), a nonparametric analysis like the Chi-square test of independence should be performed
- A research objective with two variables; evaluating the mean bone loss (quantitative) in the anterior edentulous space based on sex (qualitative), one variable is nominal (male/female), and the second variable is continuous (crestal bone loss in the anterior edentulous space). These two variables are independent of each other, and hence, an unpaired (independent) sample *t*-test is performed if the data are normally distributed. If the data are not normally distributed, it becomes nonparametric, and a Mann–Whitney *U*-test should be done
- A research objective with two variables that are dependent on each other would be similar to the pre- and postoperative assessment of crestal bone loss. Both variables of quantitative and are dependent of each other. This should be evaluated by the paired (dependent) *t*-test for parametric analysis if normality is even, while a Wilcoxon signed-rank test should be used for nonparametric analysis if the normality is unevenly distributed. An example of qualitative dependent variables is the assessment of economic wellness before and after prosthetic rehabilitation
- A research objective may require a comparison within and outside a variable. For example, the assessment of crestal bone loss between different categories of diabetes and within each category of diabetics at different time periods requires the one-way ANOVA for parametric and the Kruskal–Wallis for nonparametric analysis.

These are a few examples of the most common statistical analysis that can be correlated to their own research as shown in Table 1.[3,4] There are more number of statistical methods for systematic reviews and survival analyses. The editorial aimed at enumerating the type of statistical analysis for commonly used research objectives in prosthodontics that could be useful for upcoming researchers. Statistics is a vast subject, and it is mandatory that the researcher undertakes basic training in statistics to coordinate with the statistician for effective interpretation of obtained data.

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Systematic Review

Survival of tooth-implant connections: A systematic review and meta-analysis

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Abstract

Implant-supported prostheses have considerable biomechanical advantages in partially edentulous patients when compared to other prosthetic options. Given the steady drop in the frequency of patients reporting with complete edentulism, it is not unusual to see situations where teeth and implants can be splinted to provide support for fixed prostheses. A tooth implant prosthesis differs majorly from an implant-supported prosthesis in terms of force dissipation and design. The aim of this systematic review was to compare the survival rates of tooth-implant-supported prostheses with fully implant-supported and fully tooth-supported prostheses. Using the appropriate search terms, PubMed, Google Scholar, and other indexed journals were used to search the English-language literature. According to the review protocols and the PICOS inclusion criteria, the pertinent studies were chosen. The screening of appropriate studies, evaluation of study quality, and data extraction were carried out independently by two reviewers. The pooling of survival data by prostheses failure, implant failure, and marginal bone loss was used in the meta-analysis. The cumulative data of all included studies indicated that tooth-implant-supported prostheses showed a 5-year survival rate of 77%–84% and a 10-year survival rate of 72%. The pooled risk ratio for prostheses failure and implant failure was 0.99 and 1.76, respectively. These results were not statistically significant ($P > 0.05$). The pooled standard mean difference for marginal bone loss was 0.59, and the results were statistically significant ($P < 0.05$). A tooth-implant-supported fixed partial denture (FPD) has a similar survival rate when compared to implant-supported FPD or T-FPD.

Keywords: Fixed dental prosthesis, implant-tooth, survival

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INTRODUCTION

The occurrence of complete edentulism among patients has shown a consistent decline in recent years, coinciding with a growing demand for fixed dental prosthetic rehabilitation. The introduction of endosseous implants proved to be a game changer in the world of prosthodontics. Historically and conventionally, fixed partial denture (FPD) has either derived support completely from two teeth or two implants. However, it is not uncommon to come across cases where implants can potentially be splinted to natural teeth to provide support for an FPD. This is commonly seen in Kennedy Class I and Kennedy Class II situations. When the distribution, condition, or number of the natural teeth

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that is still present makes it difficult to restore the mouth with conventional fixed prostheses, teeth can be joined to implants to achieve this.

A combination of implant and tooth support for FPD is suitable, according to Belser *et al*.[1] In 1986, Ericsson *et al*. stated that an endosseous implant may be utilized as an extra abutment to natural teeth for FPD.[2] This implant can be used as an abutment for standard single-tooth implant prostheses, or it can be coupled with a neighboring natural tooth to support a fixed partial denture.[3]

To withstand the biomechanical forces applied to the tooth/restoration at the crestal bone region, a natural tooth's support structures are better constructed. The presence of enamel and dentine, the periodontal membrane, the nerve and blood vessel complex, the biomechanical design of the tooth root and material, and the inherent characteristics of the surrounding bone reduce the risk of occlusal overload to the natural tooth system. However, this is not true for dental implants. The periodontal ligament acts as a shock-absorbing cushion in the natural tooth, while in implants, there is no such interface present as there is functional bony ankylosis between the implant and the surrounding bony architecture. The junctional epithelium and the connective tissue complex are far more fragile around the dental implant. Differences in the biological width, vascularity, and pressure sensitivity are also noted between implants and the natural tooth.[4] There is an absence of a periodontal ligament around an osseointegrated implant and whenever there is splinting of two structurally different components, one with a periodontal ligament, i.e. the tooth, and one without the periodontal ligament, i.e. the dental implant, there will be an unequal force dissipation. This unequal force dissipation can be attributed to the lack of any sort of micromovement around a dental implant. On application of 0.1 N of force, a natural tooth with a healthy periodontal ligament exhibits mobility of 50–200 μ, whereas this displacement is less than 10 μ for an implant.[1]

It was suggested that nonrigid connectors (NRCs) be used in their place because the difference in mobility raised concerns about whether it was possible to rigidly attach natural teeth to implants.[5] The implant will support more of the occlusal load if the connection is rigid, with the natural abutment serving as a cantilever. This may result in increased crestal bone loss.[6] Contradictory to the above-mentioned disadvantages of a rigid connector, prostheses that used an NRC reported a higher rate of failure.[2]

The major advantage of tooth-implant-supported fixed partial dentures (TI-FPDs) over implant-supported FPDs (I-FPD) is the increased proprioception provided by natural teeth abutments owing to the presence of periodontal ligament, which gives patients more chewing comfort. "The tactile perception of PDL is 8.8 times greater than implant abutments."[7] Long-span edentulous gaps, cantilever portions, and teeth with decreased periodontal support and increased mobility can all benefit from the use of TI-FPD.[6] In addition, they could be used in anatomically restricted areas like those with insufficient alveolar bone, close vicinity to the maxillary sinus, and close proximity to the inferior alveolar nerve canal.[8-10] Such anatomic complexities demand for additional surgical procedures which could be contraindicated or refused by the patient for financial and other reasons. Moreover, exodontia, bone augmentation procedures, or additional risks that are associated with implant placement can be avoided with TI-FPDs. Prostheses deriving support from tooth and implant are significantly more economical than superstructures solely supported by implants. The unique proprioception provided by the periodontal ligament can prevent occlusal overload in tooth implant-supported prostheses.

The main objective of this systematic review was to determine the survival rate of an FPD deriving support from both the implant and a natural tooth.

MATERIALS AND METHODS

A comprehensive systematic review and meta-analysis were carried out. This study followed the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA 2020),[11] the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0, and 4th Edition of the JBI Reviewer's Manual"[12] and was registered at PROSPERO under registration code CRD42022340274.

Population, intervention, comparison, and outcome

- Population: Studies including edentulous participants more than 18 years' age group
- Intervention: Studies including edentulous patients in which rehabilitation is done using TI-FPD in the maxillary or mandibular arches
- Comparison: Studies including edentulous patients in which rehabilitation is done using only I-FPD or only fixed tooth-supported prostheses (T-FPD) in the maxillary or mandibular arches
- Outcome: Studies providing information about the survival of both types of prostheses in terms of the

number of prostheses failed or survived. Additional outcomes include changes in periodontal clinical parameters such as clinical attachment loss, probing depth, plaque index, gingival index, marginal bone loss, and any other related outcomes.

Inclusion criteria

Randomized controlled trials (RCTs) or quasi-experimental studies, nonrandomized trials, longitudinal studies, studies with full-text articles, studies providing a numeric value or sufficient information to calculate at least one of the outcome measures previously mentioned, only studies published in English, and studies published until January 2023 were included.

Exclusion criteria

Studies where participants did not give informed consent, studies involving removable prostheses, studies with any comparison group other than only implant-supported and only tooth-supported prostheses, review articles, case studies, *in vitro*, animal, and studies that only provide an abstract were excluded.

Search strategy

Studies were chosen in accordance with the review protocol's PICOS inclusion criteria. To find studies that might be eligible, two reviewers assessed the titles and abstracts. A third reviewer was approached for any questions.

The primary outcomes measured were the mean survival rate in the intervention and control groups. The PRISMA for conducting a meta-analysis was followed. The electronic data resources consulted for the elaborate search were PubMed, Google Scholar, and Directory of Open Access Journals (DOAJ). Searches were conducted on all articles published through January 2023, regardless of the language of the publication. The following keywords and MeSH terms were entered in the advanced search option with Boolean operators.

A concept table was prepared based on the PICOS criteria of the review question, and the search strategy was formulated according to it [Table 1].

Search strategy in PubMed

((tooth-implant-[All Fields] AND supported [All Fields]) AND (fixed [All Fields] AND ("prostheses and implants" [MeSH Terms] OR ("prostheses" [All Fields] AND "implants" [All Fields]) OR "prostheses and implants" [All Fields] OR "prostheses" [All Fields]))) AND ("mortality" [Subheading] OR "mortality" [All Fields] OR "survival" [All Fields] OR "survival" [MeSH Terms]).

Entry terms used in Google Scholar

1. Tooth-implant-supported prostheses
2. Survival.

The above-mentioned was the final search history for the databases accessed till January 2023.

Selection of studies

Each study's title and abstract were examined and evaluated critically by two separate reviewers. The methods used to apply the selection criteria included integrating the search results to eliminate duplicate entries, looking at titles and abstracts to eliminate articles that were obviously irrelevant, retrieving the full texts of articles that might be relevant, grouping and binding multiple articles from the same study, looking at the full texts of the articles to determine how closely the studies complied with the eligibility criteria, and establishing connections with other studies.

Data extraction

Data were independently gathered by two reviewers from the included studies after focusing on the articles from all the databases. Disagreements were once more settled through conversation. Where there were differences, the third reviewer oversaw a consensus discussion to resolve them. A list was formulated based on the data that were extracted. The main items of this list were authors, year and title of study, country, study design, sample size, age group of the participants, gender, radiographic findings, clinical findings, survival rate, outcomes, results, and other items. All included studies were meticulously and accurately analyzed to extract information about the publication and study, participants, settings, interventions, comparators, outcome measures, study design, statistical analysis and

Table 1: Concept table

Population	Intervention	Comparison	Outcome	Study design
Adults with partial edentulism	Tooth-implant-supported prostheses	Implant-supported prostheses OR Tooth-supported prostheses	Survival Implant failure Marginal bone loss Plaque index Clinical attachment loss Probing depth	RCT Quasi-experimental studies Non-RCT Retrospective studies

RCT: Randomized controlled trial

results, and all other pertinent information (funding and conflicts of interest). For each of the individual primary outcomes, data extraction was completed and accurately recorded in the Excel sheets.

Critical appraisal of retrieved studies (risk of bias)

For nonrandomized studies, ROBINS-I[13] checklist was used to perform the quality assessment.

Meta-analysis

Depending on the number of studies providing similar outcomes at the same follow-up interval, a meta-analysis was conducted. The number of events causing survival or failure of prostheses was used as effect sizes for the evaluation of cumulative risk ratios or hazard ratios. The pooled risk ratio was calculated using the fixed model for prostheses failure and marginal bone loss, while the random-effects model was used for implant failure. $P < 0.05$ was considered statistically significant.

RESULTS

Study selection

The primary electronic database look-up on PubMed/MEDLINE, Cochrane Library, and DOAJ revealed 2040 titles. Out of these, 1511 records were excluded. Two independent reviewers chose 256 pertinent titles from the abstracts; after screening them, 45 were assessed for eligibility. The articles not fitting the inclusion criteria were excluded. The reviewers examined and discussed 16 articles before choosing them for full-text analysis. The chosen studies' references were manually investigated; however, no additional papers were discovered. After prescreening, application of the inclusion and exclusion criteria, and handling of the PICO questions, 11 studies were included in the quantitative synthesis [Figure 1].

Study characteristics

The systematic review included 16 studies. Table 2 depicts the characteristics of 12 studies where the comparison is done between TI-FPD and I-FPD. Table 3 includes two studies where a comparison is done between TI-FPD and tooth-supported prostheses. Table 4 gives the characteristics of three studies where no comparison group is present.

Among the included studies, six studies were conducted in Sweden, four in Germany, four in Switzerland, and two in Belgium. From all the studies, 1097 patients in total were included. All the participants were in the 20–88 years' age group. Implant survival and stability, failure rate, implant complications, marginal bone level, and clinical parameters like plaque index were the outcomes that were measured in these studies.

Survival rate

The cumulative data of all included studies indicated that TI-FPD showed a 5-year survival rate of 77%–84% and a 10-year survival rate of 72%.

Risk of bias

Quality assessment of included studies was done according to the ROBINS-I tool[13] for nonrandomized clinical studies. The risk of bias was assessed across seven domains – confounding bias, selection bias, misclassification bias, bias due to deviation from intended interventions, bias due to missing data, bias due to selective reporting of results, and overall bias [Table 5].

Out of the included 16 studies, seven studies[8,9,14-18] showed low risk, four studies[18-21] showed moderate risk, whereas five studies[8,16,22-24] showed high risk of bias.

Among the studies with high risk, confounding bias and selection bias were high, which led to high risk among these studies. For studies with moderate risk, bias due to missing data was high, which led to moderate risk among these studies. The risk of bias has been summarized in the traffic light plot [Figure 2] and the summary plot [Figure 3].[25]

Meta-analysis

Meta-analysis was conducted among studies that provided data on the survival or failure of the prostheses irrespective of the follow-up period. Most of the studies had a mean follow-up of 5 years [Table 6].

A quantitative assessment was done on the following parameters:

1. Prostheses failure
2. Implant failure
3. Marginal bone loss.

Effect sizes

Effect sizes are quantitative measures of the strength and direction of an intervention's influence over a given outcome. When studies that evaluate the same outcome do so in different ways, the standardized mean difference is used as a summary statistic. In this case, standardizing the study results to a consistent scale is required before they can be combined.

Prostheses failure

Nine studies[9,14,16,17,19,23,24,26,27] evaluated fixed prostheses failure between TI-S FDP and I-S FDP. The pooled risk ratio was 0.99 [0.71 and 1.38], indicating that the risk of prostheses failure was less with TI-FPD-supported compared to only implant-supported FDPs. This difference was not statistically significant ($P > 0.05$). The heterogeneity (I^2) value was

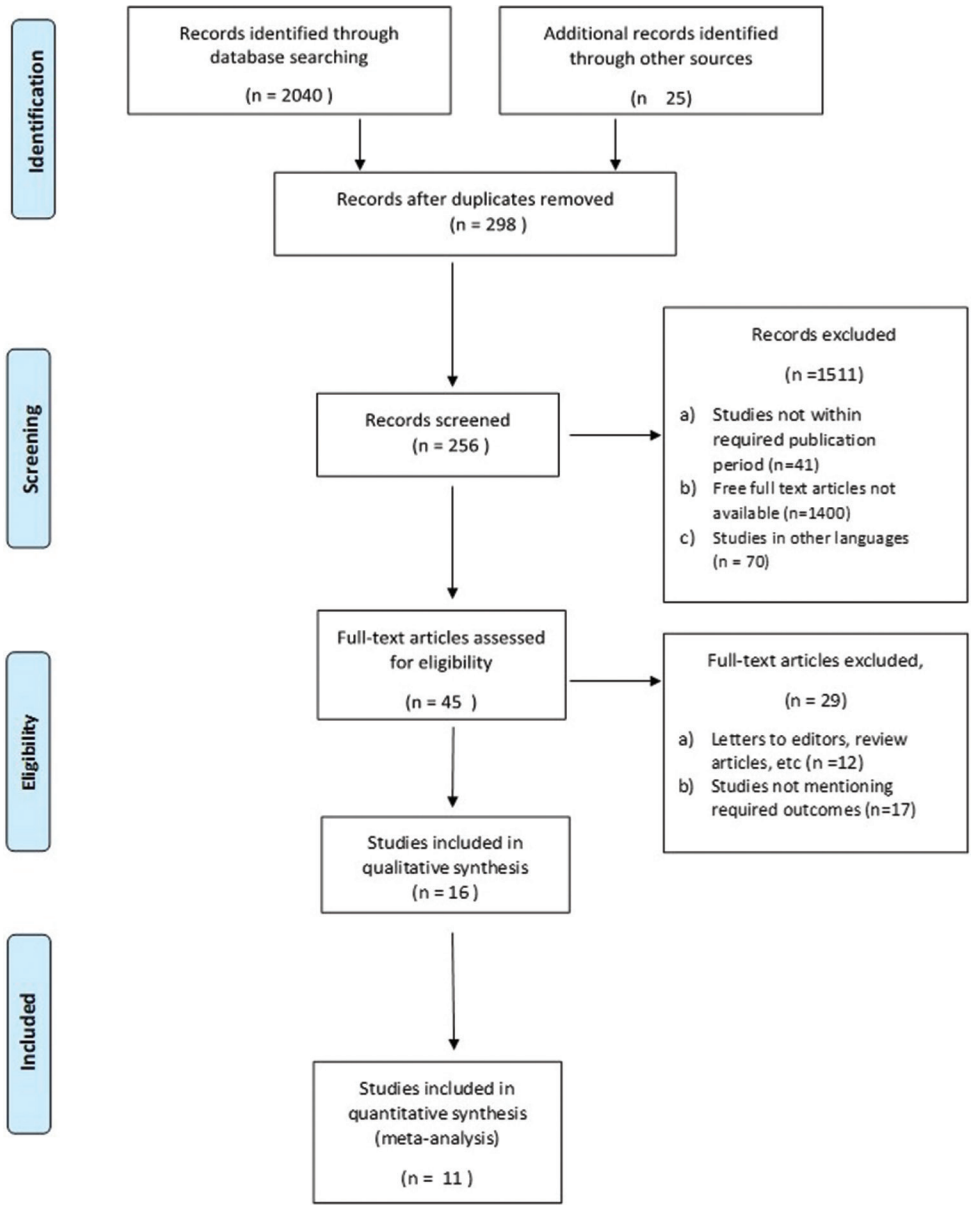

Figure 1: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart

moderate, i.e. $I^2 = 41\%$. Hence, the fixed-effects model was applied to obtain the pooled risk ratio [Figure 4].

Implant failure

Four studies[14,22,23,26] evaluated implant failure between TI-S FDPs and I-S FDPs. The pooled risk ratio was 1.76 (0.32 and 9.96), indicating that the risk of implant failure was greater with TI-FPD compared to only I-FPD. These results were not statistically significant ($P > 0.05$). Heterogeneity was high ($I^2 = 68\%$); hence, the random-effects model was used [Figure 5].

Marginal bone loss

Three studies[8,19,23] evaluated marginal bone loss between TI-S FDPs and I-S FDPs. The pooled standard mean difference was −0.59 (−0.81 and −0.36), indicating that marginal bone loss was greater in the comparison group, i.e. implant-supported as compared to. These results were statistically significant ($P < 0.05$). Heterogeneity was high ($I^2 = 98\%$), and a fixed-effects model was applied to obtain the pooled risk ratio [Figure 6].

DISCUSSION

Several articles on TI-FPD have been published in recent years. These articles include case–control studies, prospective or retrospective cohort studies, case series, case reports, studies using animals or *in vitro* models, narrative reviews, and systematic reviews. These articles have produced contrasting findings and opposing viewpoints. To

Table 2: Characteristics of studies comparing tooth-implant-supported and implant-supported prostheses

Study ID	Country	Study design	Sample size	Age (years)	Gender	Follow-up	Outcomes assessed	Survival rate (%)
Gunne, 1991[19]	Sweden	Longitudinal study	23 patients, 69 FPD	Mean: 57.7	Eight males, 15 females	3 years	Implant survival, bridge stability, mobility of teeth, marginal bone levels, plaque, gingivitis, pocket depth, and attachment levels	-
Olsson, 1994[24]	Sweden	Prospective	23 patients, 69 implants	Mean: 58	-	5 years	Implant survival, bridge stability, mobility of teeth, marginal bone levels, plaque, gingivitis, pocket depth, and attachment levels	5 years: 88
Gunne, 1999[23]	Sweden	Prospective	23 patients, 46 FPD, 69 implants	-	-	10 years	Stability, implant stability, BOP, sensory function, and marginal bone level	
Bragger, 2000[14]	Switzerland	Prospective	80 patients	Mean: 55.7	53 females, 32 males	4–5 years	Plaque index, gingival index, probing pocket depth, attachment level, and BOP	98.2 survival rate
Hosny, 2000[20]	Belgium	Prospective	18 patients	37–65	All females	14 years	Implant complications, prostheses failure, tooth fracture, and marginal bone level	-
Lindh, 2000[8]	Sweden	Prospective	26 patients, 95 implants	49–84	15 females, 11 males	3, 6, 12, 24 months	Plaque, probing depth, bleeding, marginal bone level, and implant survival	IG: 96 CG: 95
Naert, 2000[9]	Belgium	Prospective	644 implants	20–79	-	15 years	Survival and success	IG: 94.92 CG: 98.41
Romeo, 2004[24]	Italy	Prospective	250 patients, 759 implants	20–67	106 males, 144 females	7 years	Survival and success	90.60
Bragger, 2005[26]	Switzerland	Prospective	89 patients	28–88	34 males, 55 females		Survival and success	I-I type: 54.5 I-T type: 50
Bragger, 2010[27]	Switzerland	Prospective	84 patients, 175 FDPs	-	-	Mean: 11.31 years	Implant survival	-
Rammelsberg, 2012[16]	Germany	Prospective	132 patients, 166 FDP	21–83	-	Mean: 2 years, 4 months	Implant survival	-
Rammelsberg, 2020[17]	Germany	Prospective clinical study	434 FDP	Mean: 60.8	-	Mean: 4.26 years	Failure rate	5 years: 77–84 10 years: 72–77

FDPs: Fixed dental prostheses, FPD: Fixed partial denture, BOP: Bleeding on probing, IG: Implant group, CG: Control group

Table 3: Characteristics of studies comparing tooth-implant-supported and tooth-supported prostheses

Study ID	Country	Study design	Sample size	Follow-up	Outcomes assessed	Survival rate (%)	Conclusion
Bragger, 2000[14]	Switzerland	prospective	80 patients - three groups	4–5 years	Plaque index, gingival index, probing pocket depth, attachment level, and BOP	98.2 survival rate	Favorable clinical conditions were found at tooth and implant abutments after 4–5 years of function. Loss of FPDs over 4–5 years occurred at a similar rate with mixed, implant-, or tooth-supported reconstructions
Beur, 2015[15]	Germany	Prospective	44 patients, 49 FPD	36 months	Survival, pocket depth	IG: 96.3 CG: 95.5	It can be concluded that tooth-implant-supported FDPs exhibited promising clinical performance. No difference in periodontal parameters compared to tooth-supported FDPs was found

FDPs: Fixed dental prostheses, FPDs: Fixed partial dentures, BOP: Bleeding on probing, IG: Implant group, CG: Control group

the authors' knowledge, this is the only systematic review comparing TI-FPD with I-FPD as well as completely tooth-supported prostheses.

The purpose of the systematic review was to determine the success rate of fixed prostheses deriving support from both implants and teeth in patients who needed to replace missing teeth. After a thorough screening of the available literature, 16 studies were selected for the systematic review. Twelve studies had an implant–implant-supported prostheses as the control group,[8,9,14,16,17,19,20,22–24,26,27] three studies were conducted without having any comparison group,[18,21,28] while two studies had tooth–tooth-supported prostheses as the control group.[14,15] All of these studies measured the survival of the TI-FPD. The parameters used to measure the survival of TI-FPD were marginal bone levels, probing depth, attachment levels, bleeding on probing, stability of the prostheses, prosthetic failure, tooth mobility, and fracture. The cumulative data of all included studies indicated that TI-FPD showed a 5-year survival rate of 77%–84% and a 10-year survival rate of 72%–77%.

Table 4: Characteristics of studies with only tooth-implant-supported prostheses

Study ID	Country	Study design	Sample size	Age (years)	Gender	Follow-up	Outcomes assessed	Number of prostheses failed	Survival rate (%)	Reasons for failure	Conclusion
Lindh, 2001[28]	Sweden	Retrospective single group	111 patients, 185 implants	45–87	41 females, 40 males	3 years	Implant survival	-	3 years: 95.4	Implantitis, intrusion of the tooth, carious lesions, abutment screw loosening, and fracture of the abutment	The tooth-implant-supported prostheses using the Brånemark System are in the short term, an equally predictable treatment, as the completely implant-supported prostheses concerning implant survival and loss of marginal bone. When combining implants and teeth, a rigid form of connection should be used to prevent tooth intrusion
Nckenig, 2005[21]	Germany	Retrospective single group	83 patients, 84 implants	22–61	-	4.73 months	Survival	2/84	5 years	Not mentioned	Technical complications of implant-supported FPDs are dependent on the different bridge configurations. When using rigid functional connections, similarly favorable values will be achieved as in the case of solely implant-supported FPDs
Chrcanovic, 2020[18]	Sweden	Retrospective single group	85 patients, 96 FPD	-	-	10.5 years	Survival	20	5 years: 90.7 10 years: 84.8 15 years: 69.9 20 years: 66.2	Bruxism, loss of abutments, and cantilevers	Although combined tooth-implant-supported FDPs are an alternative treatment option, this study has found that across 20 years of service, nearly 35% of the prostheses may fail

FDPs: Fixed dental prostheses, FPDs: Fixed partial dentures

Gunne *et al.* conducted a split-mouth study in 1992 comparing the survival of TI-FPD with I-FPD. Twenty-three bridges derived support from both the implant and the tooth, while 23 bridges derived support from both the implant and the tooth. The patients were kept on a follow-up for 3 years.[19] According to Albrektsson, a lack of implant mobility is one of the key factors for success and should be gauged only after the superstructure has been removed.[29] In this study, the implant mobility was assessed without retrieving the prostheses although they concluded that implant survival was the same for both types of bridges.[19] The 5-year survival rate of 88% was reported. Bridge stability was found to be 89% for I-FPD and 91% for TI-FPD. One of the factors that the authors considered to measure the failure of the implant was sensory disturbances. Sensory disturbances commonly relate to nerve injury during the surgical part of the treatment. Nerve injuries are complications, and they seldom indicate the failure of the implant treatment.[23] They concluded that implants and teeth can be connected successfully without having any detrimental effect on either the tooth or the implant.[23]

Hosny *et al.*, in 2000, concluded a 14-year follow-up study evaluating TI-FPD. No implant mobility, fracture of any implant component, and prosthetic complications were observed. They concluded that joining teeth with implants for fixed prostheses had no detrimental effect on long-term survival. This particular study can have a low statistical power owing to its small sample size of just 18 participants and its cross-sectional nature.[20]

A comparative intraindividual split-mouth study was conducted in 2000 on 26 patients with bilaterally missing maxillary posterior teeth. They were treated with two different designs of FPD, namely, I-FPD and TI-FPD. The patients were monitored at intervals of 3, 6, and 24 months. The density of the bone in the affected area is one of the most crucial factors in determining the success of the implant; however, the type of bone in which the implants were placed is not mentioned. TI-FPD and I-FPD, both reported a similar failure rate. Although the survival rate of the control group was high, the follow-up period was too short to draw effective conclusions on actual long-term survival rates.[8]

Brägger *et al.* concluded a 5- and a 10-year follow-up reporting the survival of TI-FPD. The 5-year survival rate for TI-FPD was 98.2%.[14] This study had 111 patients with 186 implants.The survival rate of TI - FPD was compared with I-FPD as well as T-FPD. There was extreme heterogenicity in the sample size of the three groups which

Table 5: Risk of bias

Study ID	Confounding bias	Selection bias	Misclassification bias	Bias due to deviation from intended interventions	Bias due to missing data	Bias in the measurement of outcomes	Bias due to selective reporting of results	Overall bias
Gunne, 1991[19]	Serious	Low	Low	Low	Low	Low	Low	Moderate
Olsson, 1994[22]	Serious	Serious	Low	No information	Low	Moderate	Low	Serious
Gunne, 1999[23]	Low	Low	Serious	No information	No information	Moderate	No information	Serious
Bragger, 2000[14]	No information	Low	Low	Low	Low	Low	Low	Low
Hosny, 2000[20]	Low	No information	Low	Low	Serious	Low	Low	Moderate
Lindh, 2000[8]	Serious	Serious	Low	No information	Low	Serious	Low	Serious
Lindh, 2001[28]	Low	Low	Low	Low	Low	Low	Low	Low
Naert, 2000[9]	No information	Low	Low	Low	Low	Low	Low	Low
Romeo, 2004[24]	Low	Serious	Low	Serious	Serious	Moderate	Low	Serious
Bragger, 2005[26]	No information	No information	Low	Low	Low	Low	Low	Moderate
Nickenig, 2005[21]	Low	Low	Low	Low	Low	Low	Low	Low
Bragger, 2010[27]	Low	No information	Serious	No information	Low	Moderate	Serious	Serious
Rammelsberg, 2012[16]	Low	Low	Low	Low	Low	Low	Low	Low
Beur, 2015[15]	Low	No information	Low	Low	Serious	Low	Low	Moderate
Chrcanovic, 2020[18]	Low	Low	Low	Low	Low	Low	Low	Low
Rammelsberg, 2020[17]	Low	Low	Low	Low	Low	Low	Low	Low

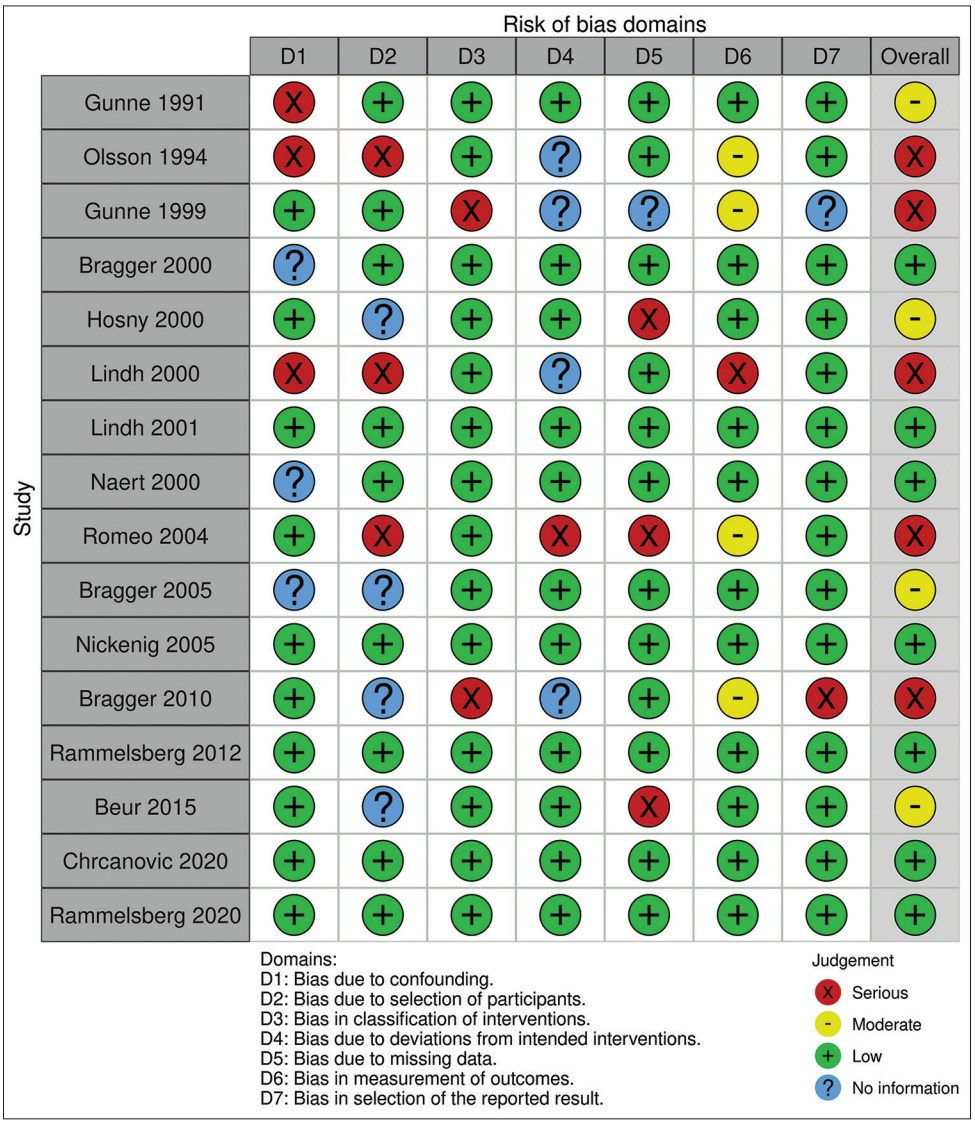

Figure 2: Traffic light plot

Table 6: Data for meta-analysis

Study ID	Number of prostheses failed		Number of implants failed		Bridge stability		Marginal bone loss	
	Tooth implant	Only implant	Tooth implant	Only implant	Tooth implant (%)	Only implant (%)	Tooth implant	Only implant
Gunne, 1991[19]	5 years: 2/69	5 years: 5/69			3 years: 91.3	82.60	2 years: 0.3±0.1	2 years: 0.7±0.2
Gunne, 1999[23]	2/23	4/23	10 years: 2/69	10 years: 6/69	10 years: 85	80	10 years: 0.5±0.6	10 years: 0.7±0.7
Bragger, 2000[14]	1/18	1/40	1/19	1/84	-	-	-	-
Hosny, 2000[20]	No failures				-	-	-	-
Lindh, 2000[8]	2	2			-	-	24 m: −0.09±0.52	24 m: −0.42±0.55
Naert, 2000[9]	10/339	1/305			-	-	-	-
Romeo, 2004[24]	3/31	12/295			-	-	-	-
Bragger, 2005[26]	10 years: 11/22	10 years: 15/33	5/22	1/69	-	-	-	-
Bragger, 2010[27]	10 years: 1/20	10 years: 0/9			-	-	-	-
Rammelsberg, 2012[16]	9/48	34/91			-	-	-	-
Rammelsberg, 2020[17]	8/155	8/213			-	-	-	-

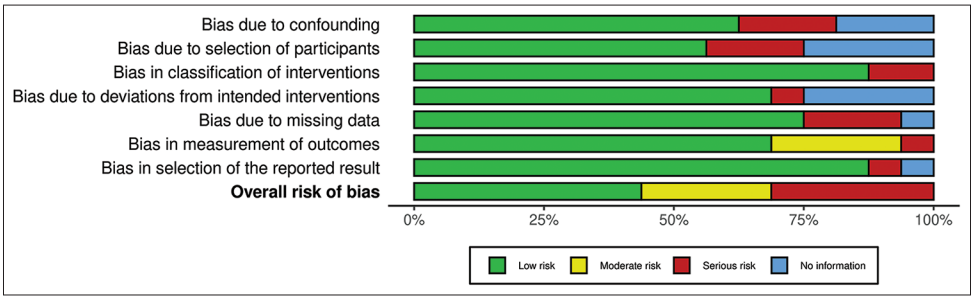

Figure 3: Summary plot

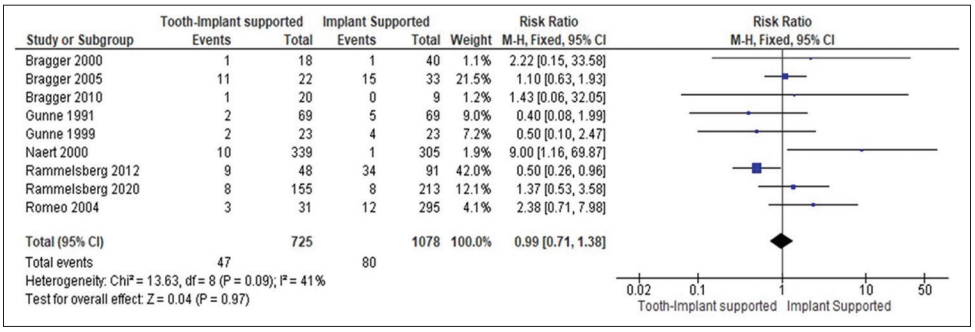

Figure 4: Meta-analysis of prostheses failure

could potentially alter results. TI-FPD had a noticeably higher failure rate. A 50% survival rate of TI-FPD was reported. While TI-FPD experienced more statistically significant technical failures, I-FPD experienced fewer biological complications.[26]

Lindh *et al.*, in 2001, retrospectively studied the survival rate of TI-FPD. One hundred and eleven patients with 185 implants were included in the study. The implant survival rate was found to be 95.4% after 3 years. They also mentioned the use of two different types of connectors to splint teeth and implants; this can potentially introduce some bias in the overall survival rate of implants. Although the survival rate of 95% is excellent, the follow-up duration is still relatively short.[28]

Romeo *et al.* investigated the long-term success and survival of prostheses that derived support from both the implant and the tooth. They reported a survival rate of 91%.[24]

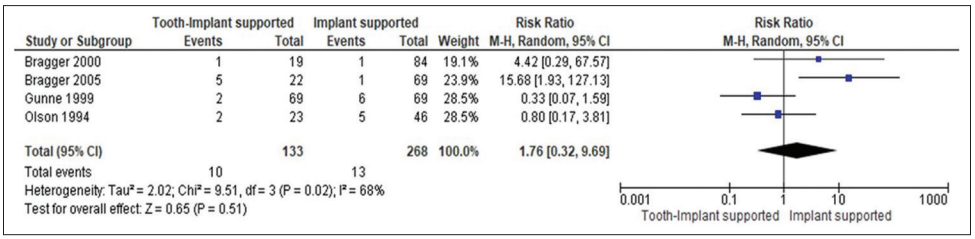

Figure 5: Meta-analysis of implant failure

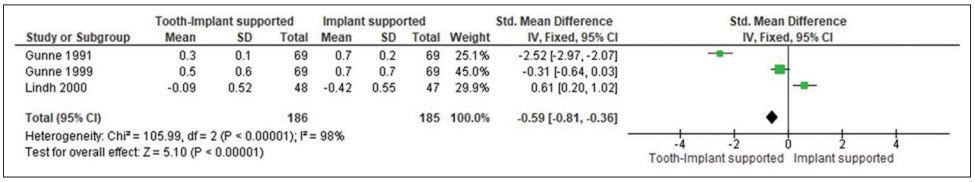

Figure 6: Meta-analysis of marginal bone loss

Although most of the above-mentioned studies reported a greater failure for the TI-FPD, the difference in survival was not statistically significant. Another important parameter that was discussed in some of the studies was marginal bone loss. Three studies[9,20,24] evaluated marginal bone loss between TI-FPD and I-FPD. Marginal bone loss was significantly greater in I-FPD. The majority of these studies concluded that the survival of a TI-FPD is similar to that of an I-FPD or T-FPD, and it can be a viable treatment option whenever indicated.[8,9,14,16,17,19,20,22-24,27] Only one study conclusively indicated a higher percentage of biological and technical complications.[26]

Four studies[14,22,23,26] evaluated implant failure between TI-FPD and I-FPD. The pooled risk ratio suggested that the probability of implant failure was greater with TI-FPD compared to I-FPD. These results were not statistically significant ($P > 0.05$).

A few of the included articles also discussed the material aspects and the prosthetic outcomes of FPD deriving support from both the implant and the tooth. Nine studies[9,14,16,17,19,23,24,26,27] evaluated fixed prostheses failure between TI-S FDP and I-S FDP. The risk of prostheses failure was less with TI-FPD compared to I-FPD although this difference was not statistically significant.

Nickenig *et al.* contrasted the technical and biological failures in TI-FPD utilizing two distinct retention techniques. In most cases, the implant abutments were surgically placed in the posterior mandible which frequently has a high bone density when compared to the maxilla. The question is whether the high survival rate reported in this study can be extrapolated to implants placed in the maxilla, which tend to have lower bone densities. They also reported an increased number of complications in screw-retained prostheses than in cement-retained prostheses.[21]

Beuer *et al.* compared the clinical survival of a three-unit zirconia TI-FPD with T-FPD, and they also discussed the prevalence of biological and technical issues. They were rehabilitated with zirconia and then subsequently veneered with porcelain and cemented with glass ionomer cement. The experimental group only had provisional restorations placed on their natural teeth rather than temporary bridges connecting them to the implants, which was one of the study design's limitations. It is possible that a small dimensional change can occur between the implant and the tooth during the fabrication of the final restoration. They concluded that zirconia-based FPDs supported by tooth implants and tooth support exhibited comparable clinical performance with similar survival rates.[15]

In a cohort study done in 2021 by Rammelsberg *et al.*, the failure and chipping rates of ceramic and metal-ceramic I-FPDs were assessed over the long term. The likelihood of chipping for prostheses was as follows after 5 years: 3%, 39%, and 18%, respectively, for metal fused to ceramic-fixed dental prostheses with a high noble metal framework.[17]

Chrcanovic *et al.*, in 2020, analyzed technical complications and risk factors for failure for TI-FPD. The prostheses were monitored for 10 years and ranged in span from 2 to 13 prosthetic units. They also compared the implant survival in bruxers and nonbruxers. The major drawback of this study was that the participants who were included in the bruxer group were not given a conclusive diagnosis of bruxism. In addition, there was a lack of information regarding biological aspects such as oral hygiene, bleeding during probing, and probing pocket depth. Comparing bruxers and nonbruxers, bruxers showed a significantly

higher rate of prosthetic failure. Eight of the failed prostheses with implant failures were smokers. Thus, these failures cannot be completely attributed to a TI-FPD. The estimated cumulative survival rate of the prostheses was 90.7% (84.6–96.9) and 84.8% (76.8–92.9) at 5 and 10 years, respectively.[18]

A similar systematic review was published in 2020 comparing the survival rate of TI-FPD with I-FPD. In the authors' knowledge, this is the only systematic review that compares the survival rate of a TI-FPD not only with I-FPD but also with T-FPD.[30] The current review also discusses the marginal bone loss that takes place with a T-I FPD.

There are some limitations to the current systematic review, despite an accurate screening process which might affect the outcomes. The main downside is the complete absence of RCTs. There is also an irregularity in the frequency of published literature. Due to this, it is very challenging to compare the current findings to those that have already been published in the literature. There is also a severe heterogenicity in aims, sample size, implant systems, types of connectors used, design, and material of the prostheses. The follow-up period, which ranges from 6 months to up to 14 years, also varies greatly. Since the majority of these studies were carried out in institutional settings, it is possible that the results cannot be applied to routine dental care.

CONCLUSION

Given the limitations of this systematic review and meta-analysis, the following conclusions can be drawn.

1. The survival rate of TI-FPD and tooth–tooth I-FPD is similar
2. There is no statistically significant difference in prostheses failure with TI-FPD and I-FPD
3. Between TI-FPD and I-FPD, there is no statistically significant difference in implant failure
4. There is an increased marginal bone loss in I-FPD than in TI-FPD.

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Conflicts of interest

There are no conflicts of interest.

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Systematic Review

Evaluation of accuracy between extraoral Gothic arch tracing and various other methods assessing horizontal condylar guidance angle in completely edentulous patients: A systematic review and meta-analysis

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Abstract

Aim: The aim of this systematic review and meta-analysis was to determine the accuracy of different methods of measuring horizontal condylar guidance (HCG) angle in comparison with extraoral Gothic arch tracing for completely edentulous patients.

Settings and Design: This was a systematic review and meta-analysis following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Materials and Methods: Two reviewers searched the EBSCOhost, Cochrane Library, and PubMed/MEDLINE databases and the Google Scholar search engine for *in vivo* studies, randomized controlled trials, cross-sectional studies, and quasi-experimental studies published from January 2005 to December 2022 on various other methods of determining HCG angle in completely edentulous patients compared with extraoral Gothic arch tracing method.

Statistical Analysis Used: Meta-analysis was conducted from the reported quantitative data.

Results: A total of 513 articles were obtained from different electronic databases, of which 22 studies were included for qualitative synthesis and 20 studies were included for meta-analysis. For the right side, a statistically significant difference was observed for panoramic radiograph ($P < 0.05$, pooled mean difference = 5.08 [2.17, 7]) and cephalogram ($P < 0.05$, pooled mean difference = 10.65 [8.81, 12.49]), whereas no statistically significant difference was observed for cone-beam computed tomography (CBCT) ($P = 0.41$, pooled mean difference = 4.39 [−6.10, 14.87]) and protrusive interocclusal wax record ($P = 0.92$, pooled mean difference = −0.45 [−9.62, 8.72]) as compared with extraoral Gothic arch tracing method. For the left side, a statistically significant difference was observed for panoramic radiograph ($P < 0.05$, pooled mean difference = 5.07 [1.95, 8.18]) and cephalogram ($P < 0.05$, pooled mean difference = 10.24 [8.65, 11.83]), whereas no statistically significant difference was observed for CBCT ($P = 0.31$, pooled mean

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difference = 4.05 [−3.74, 11.84]) and protrusive interocclusal wax record ($P = 0.72$, pooled mean difference = −1.21 [−7.86, 5.43]) as compared with extraoral Gothic arch tracing method.

Conclusion: The cephalogram and panoramic radiograph obtained higher HCG angles in completely edentulous patients than extraoral Gothic arch tracing.

Keywords: Accuracy, clinical, condylar guidance, edentulous, method, radiograph

INTRODUCTION

Complete edentulism due to local, systemic, and physiological factors results in a continuous resorption process leading to loss of vertical dimension, loss of functional efficiency, and disturbance in stomatognathic structures.[1] Harmonious coordination between the condylar path, mandibular movement, and occlusal morphology of teeth determines the longevity of a complete denture prosthesis.[2-4] The mandibular guidance generated by the condyle and articular disc traversing the contour of the glenoid fossa represents the condylar guidance.[5,6] Condylar guidance, the determinant of the occlusion obtained directly from the patient, is the most accurate reference point.[7] Inaccurate transfer of condylar guidance values on the articulator causes occlusal interferences during mandibular movements.[8,9] Horizontal condylar guidance (HCG) is obtained from the protrusive movements, and lateral condylar guidance is obtained from lateral movements.[10-12]

Extraoral tracers or intraoral tracers are widely used for Gothic arch tracing or arrowhead tracing to obtain HCG angle through set protrusive interocclusal record (IOR) on semi-adjustable articulators. It is one of the oldest methods and provides a reproducible mandibular border movement in horizontal plane and so has been used as a comparison group.[13,14] However, few studies reported higher HCG values obtained from Gothic arch tracing and stated that it aids to develop precise occlusion without any interference,[15] whereas few studies reported lesser accuracy due to lack of neuromuscular coordination, instability of denture bases, and higher complexity with Gothic arch tracing.[16-18] Few studies reported that interocclusal recording medium can affect the accuracy due to differences in composition, properties, compressibility, hardness, dimensional stability, accuracy, fine reproduction of details, and elastic recovery.[19,20]

Radiographic methods such as panoramic radiographs, cephalogram, and cone-beam computed tomography (CBCT) have been used for determining HCG angle.[20-22] The condylar guidance angle was determined by the intersection of two reference lines, first Frankfort horizontal plane (orbitale to porion) and second from the most superior point on an articular eminence to the most inferior point on an articular tubercle determining the mean condylar path inclination.[23,24] These bony reference points are identified and traced on two-dimensional and three-dimensional radiographs to measure HCG angle. However, differences were obtained between cephalogram, CBCT, and panoramic radiograph due to variations in resolution, contrast ratio, method of calculation, and clarity.[25,26]

Digital methods such as electronic facebow, digital tracers, kinesiography, and axiography use ultrasonic sensors to measure HCG angle in three dimensions displayed on the computer.[27-29] Luke *et al*. carried out a systematic review on radiographic techniques and protrusive IOR and reported the occurrence of some clinical variability among both methods.[30] No clear evidence has been reported on which method is accurate to determine the HCG angle in completely edentulous patients.

Therefore, the aim of this systematic review and meta-analysis was to determine the accuracy between extraoral Gothic arch tracing and other different methods used for measuring HCG angle in completely edentulous patients. This will give clinicians a choice of simplified, accurate, and convenient methods to determine the HCG angle from the patient for obtaining balanced occlusion without occlusal interferences for prosthetic rehabilitation in completely edentulous patients. The null hypothesis was that no statistically significant difference will be observed in the accuracy of measuring HCG angle between extraoral Gothic arch tracing and various other methods that are used in completely edentulous patients.

MATERIALS AND METHODS

Protocol registration

According to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines,[31-37] this systematic review and meta-analysis was conducted and registered at the Prospective Register of Systematic Reviews database under the code CRD42022283974.[38,39]

Review question

The following focused review question was formulated according to Population, Intervention, Comparison, Outcome, and Study design (PICOS) framework:[40-42] "Is there a difference in the accuracy of other different methods as compared with extraoral Gothic arch tracing used for measuring the HCG angle in completely edentulous patients?" The population was completely edentulous patients with healthy ridges above 35 years of age. The intervention was studies determining HCG angle using panoramic radiograph, cephalogram, CBCT, CT scan, digital methods, intraoral tracing, and interocclusal wax record in completely edentulous patients. The comparison was studies determining HCG angle using extraoral Gothic arch tracing through set protrusive IOR in completely edentulous patients. The outcome was HCG angle in completely edentulous patients. The study design included was *in vivo* studies, cross-sectional studies, randomized controlled trials, and quasi-experimental studies.

Inclusion and exclusion criteria

Inclusion criteria included *in vivo* studies, cross-sectional studies, randomized controlled trials, and quasi-experimental studies that evaluated the accuracy of other different methods compared with extraoral Gothic arch tracing used for measuring HCG angles in completely edentulous patients. Full-text studies published in English between January 2005 and December 2022 were included.[43] Human studies were included. Case reports, case series, reviews, questionnaires, surveys, and *in vitro* studies not in English published before 2005 were excluded.[43]

Search strategy

An advanced search of articles was conducted according to PICOS selection criteria. Two reviewers (S. P. and J. I.) conducted the search independently with the opinion of a third reviewer (J. N.) for any disagreements.[43] The Cohen kappa statistics was used to check the reliability and rate of agreement between the two authors. The Cohen kappa score of 0.90 indicates a perfect agreement between the two authors.[44] The following keywords, Mesh terms, and phrases coupled with Boolean operators (AND, OR, and NOT), as shown in Table 1, were used to conduct the advanced articles search in the following electronic databases: EBSCOhost, Cochrane Library, PubMed/MEDLINE, and Google Scholar. Article search was carried out in different databases using the following search strategy, as mentioned in Table 2.[43] The search terms used in Google Scholar were accuracy, method, condylar guidance, edentulous patient, HCG, sagittal condylar guidance, Gothic arch tracer, panoramic radiograph, cephalogram, and CBCT.

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

Population	Intervention	Control	Outcome	Study design
Adult, completely edentulous patient, complete denture wearers	OPG, cephalogram, CBCT, interocclusal wax record	Extraoral Gothic arch tracing, GT, protrusive IOR, extraoral tracing, hight tracers	Accuracy, HCG angle, horizontal condylar guidance angle, horizontal condylar guidance, condylar guidance	*In vivo* studies, cross-sectional studies, randomized control trials, clinical studies, nonrandomized trials

CBCT: Cone-beam computed tomography, HCG: Horizontal condylar guidance, GT: Gothic arch tracer, IOR: Interocclusal record, OPG: Panoramic radiograph

Table 2: Search strategy used in different databases

Name of the database	Search strategy
PubMed	((((Accuracy) AND Method) AND "Condylar guidance" OR "Horizontal condylar guidance") AND edentulous patient)
Cochrane	((((Accuracy) AND Method) AND "Condylar guidance" OR "Horizontal condylar guidance") AND edentulous patient)
EBSCO	((((Accuracy) AND Method) AND "Condylar guidance" OR "Horizontal condylar guidance") AND edentulous patient)

Study selection and data extraction

Two reviewers (S. P. and J. I.) independently reviewed and assessed the titles and abstracts of each study with the opinion of a third reviewer (J. N.) to solve any disagreement, and duplicates were removed.[38,43] After the removal of duplicates, the title and abstract were examined and irrelevant articles were excluded.[43] Full-text articles that met the eligibility criteria were assessed and the irrelevant articles were excluded. The references and citations of relevant articles were also assessed.[45,46] After narrowing it down to 22 included articles, the data extraction was done independently by two reviewers (S. P. and J. I.).[43] The following characteristics of the included studies were tabulated in the evidence table in the spreadsheet (Excel; Microsoft Corp.) for all outcomes: Study identification, country, sample size, comparison group, interventional group, articulator model used, condylar guidance values right and left side, and conclusion.[43]

Risk of bias assessment

The 22 included studies were *in vivo* studies. The Newcastle–Ottawa tool, a modified version of the case–control study scale, was used by two reviewers (S. P. and J. I.) for the quality assessment of included studies.[43] The assessment criteria include eight items from three domains. Selection (first domain) includes representativeness of the cases, sample size, nonrespondent, and ascertainment of risk factors. Comparability (second domain) includes study

controls for the most important factor and study controls for any additional factor.[47-49] Outcome (third domain) includes ascertainment of method and statistical test.[47-49] For each domain, the scores were given and the quality of studies was graded as poor, fair, and high.[47-49]

Meta-analysis

The statistical analysis of the systematic review was done using Review Manager (RevMan) Version 5.4. The Cochrane Collaboration, 2020.[50] 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. The I^2 test was used to measure the heterogeneity. If the $I^2 > 50\%$, random effect model was applied. If the $I^2 < 50\%$, fixed effect model was applied.[51-55] To detect the publication bias, funnel plot was used.[54]

RESULTS

Literature search

A total of 513 articles were obtained from an electronic database search, of which 22 were duplicates. A total of 491 abstracts were screened and 422 not relevant to the topic were excluded.[43] Sixty-nine articles were eligible for full-text assessment. After the screening of full-text articles as per the selection criteria, 47 articles were

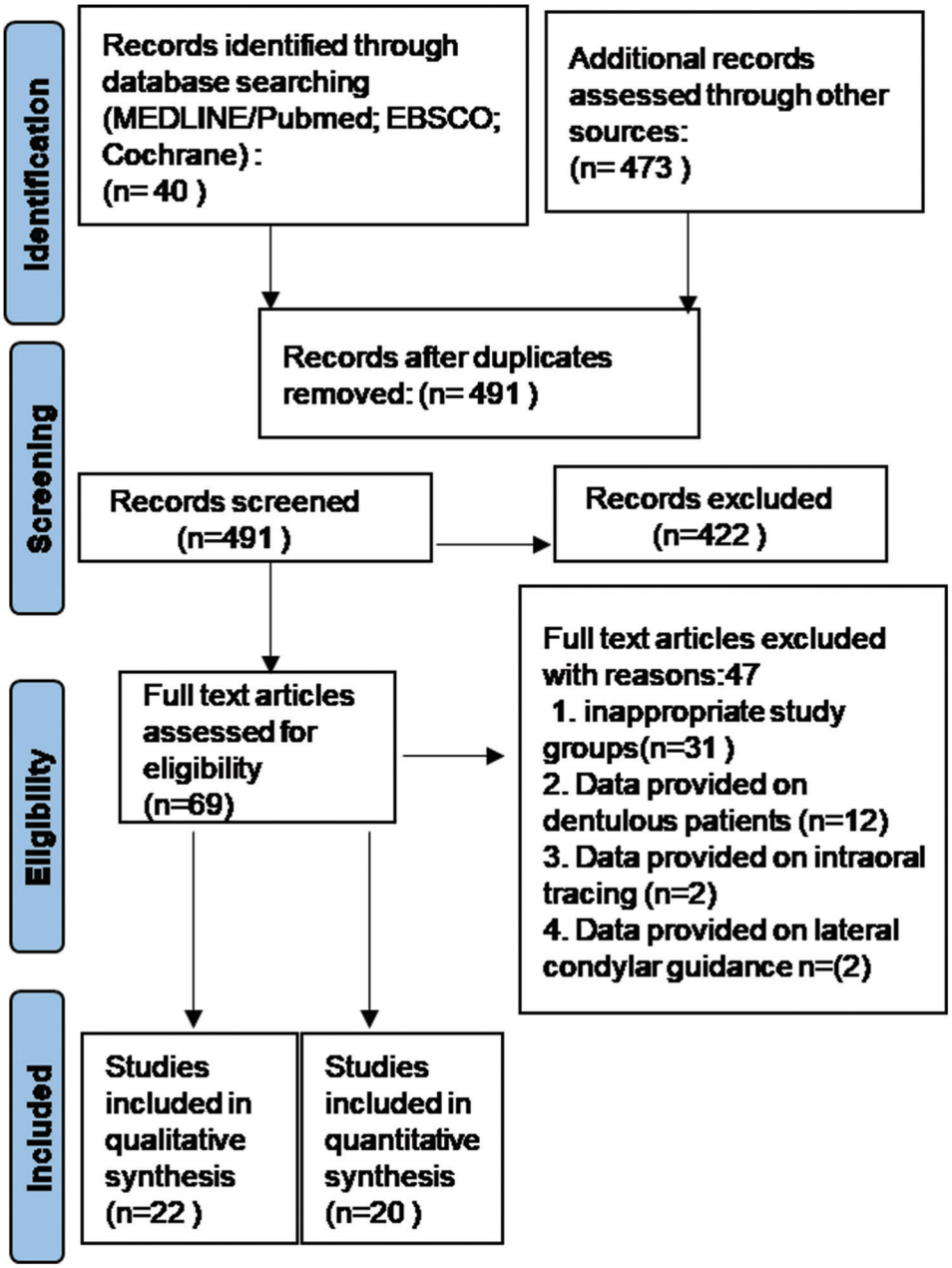

Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram

Table 3: Characteristic data extraction table of included studies

Study ID	Country	Age of the patient	Sample size	Comparison group	Interventional group	Articulator used	Condylar guidance value right side, mean (SD)	Condylar guidance value left side, mean (SD)	Conclusion
Verma *et al.*, 2022[56]	India	Above 40	20	Protrusive plaster IOR using hight extraoral Gothic arch tracing	CBCT, lateral cephalogram, OPG	Hanau Wide Vue	GT: 27.75 (8.19) Cephalogram: 37.40 (4.63) OPG: 35.05 (4.96) CBCT: 33.95 (5.06)	GT: 27.25 (7.34) Cephalogram: 37.40 (4.63) OPG: 33.35 (5.12) CBCT: 33.85 (6.04)	R/G method gave higher values than clinical. Method cephalogram more than OPG than CBCT than tracer
EL-Ghiaty *et al.*, 2022[57]	Egypt	50–60	12	Protrusive IOR using extraoral Gothic arch tracing method	CBCT, protrusive interocclusal wax record	Bio Art, Hanau Wide Vue	GT: 36.14 (4.98) IOR: 26.57 (3.95) CBCT: 26.57 (3.95)	GT: 30.71 (2.81) IOR: 21.63 (4.14) CBCT: 18.74 (3.78)	Wax protrusive record can give more practical values than other methods
Sharma *et al.*, 2022[58]	India	50–70	15	Bite registration material for IOR using extraoral tracer	CBCT, protrusive interocclusal wax record	Hanau Wide Vue	GT: 22.33 (3.77) CBCT: 44.60 (3.97) IOR: 35.87 (4.749)	GT: 25.67 (5.67) CBCT: 44.47 (5.59) IOR: 36.33 (5.192)	CBCT gave more value than other two methods
Kumar *et al.*, 2022[59]	India	50–70	30	Protrusive plaster IOR using hight extraoral Gothic arch tracing	CBCT panoramic view, CBCT cross-sectional view	Hanau Wide Vue	GT: 26.67 (2.58) CBCT P: 29.33 (3.65) CBCT Cephalogram: 31.24 (2.90)	GT: 27 (2.64) CBCT P: 29.52 (3.51) CBCT Cephalogram: 31.63 (3.28)	CBCT viable alternative method than Gothic arch method
Abdeen *et al.*, 2022[60]	Egypt	60–70	12	Printed tracing with protractor using Gothic arch tracing	CBCT, protrusive interocclusal wax record	Hanau Wide Vue	NR	NR	Protrusive wax record with semi-adjustable articulator and Hanau equation is more practical than other methods
Ambata, 2021[61]	India	55–75	50	Protrusive plaster IOR using hight extraoral Gothic arch tracing	OPG, lateral cephalogram	Hanau Wide Vue	GT: 23.46 (6.59) OPG: 30.90 (2.99) Cephalogram: 34.36 (3.39)	GT: 24.02 (5.220) OPG: 31.66 (2.93)	Lateral cephalogram gave more value than wax than OPG. Lateral cephalogram can be used as an alternative
Shetty *et al.*, 2021[62]	India		20	Protrusive plaster IOR using hight extraoral Gothic arch tracing	Axiograph, OPG	Girrbach Dental	GT: 33 (7.50) OPG: 36.50 (7.72) A: 25.65 (2.03)	GT: 27.75 (9.52) OPG: 32.50 (9.45) A: 25.55 (2.06)	Axiographic technique also can be used as an alternative technique to panoramic radiographic and Gothic arch tracing
Keerthi *et al.*, 2020[63]	India		22	Protrusive plaster IOR using hight extraoral Gothic arch tracing	OPG	Hanau Wide Vue	GT: 17.04 (6.61) OPG: 22.12 (7.2)	GT: 19.18 (8.12) OPG: 23.17 (7.66)	OPG gave higher value than clinical method
Mittal *et al.*, 2020[64]	India	45–65	15	Protrusive IOR using extraoral Gothic arch tracing method	OPG	Hanau Wide Vue	GT: 35 (4.98) OPG: 33.27 (5.43)	GT: 30.07 (5.13) OPG: 30.93 (4.90)	OPG can be a reliable aid to measure horizontal condylar guidance for programming of articulator[30,64]
Jerath *et al.*, 2019[65]	India		15	Protrusive plaster IOR using hight extraoral GT	CBCT, interocclusal wax record	Hanau Wide Vue	GT: 31.31 (2.83) IOR: 26.80 (2.14) CBCT: 33.09 (4.65)	GT: 31.10 (2.49) IOR: 27.8 (2.30) CBCT: 33.81 (3.45)	CBCT gave highest value than tracer than wax records
Bhandari *et al.*, 2018[66]	Nepal		25	Protrusive IOR with ZOE paste using hight extraoral GT	OPG	Hanau Wide Vue	GT: 21.32 (5.31) OPG: 24 (6.24)	GT: 21.08 (5.55) OPG: 24.48 (4.96)	OPG higher than IOR values. OPG can be used to calculate the condylar guidance value
Amin *et al.*, 2018[24]	India	40–60	30	Protrusive plaster IOR using hight extraoral Gothic arch tracing	OPG	Hanau Wide Vue	GT: 24.20 (7.06) OPG: 29.10 (9.13)	GT: 24.20 (7.06) OPG: 29.10 (9.13)	OPG higher than IOR values
Khalikar *et al.*, 2017[67]	India	50–60	10	Protrusive IOR using extraoral Gothic arch tracing method	OPG	Hanau Wide Vue	GT: 29.5 (4.7) OPG: 25.8 (4.26)	GT: 31.03 (3.29) OPG: 26 (4)	OPG and protrusive records may be used as a reliable guide to measure horizontal condylar guidance angle[30,67]

Contd...

Table 3: Contd...

Study ID	Country	Age of the patient	Sample size	Comparison group	Interventional group	Articulator used	Condylar guidance value right side, mean (SD)	Condylar guidance value left side, mean (SD)	Conclusion
Kumari *et al.*, 2016[68]	India		10	Protrusive silicone IOR using hight extraoral Gothic arch tracing	OPG	Hanau Wide Vue	GT: 25.70 (3.40) OPG: 37.10 (8.26)	GT: 25.40 (3.59) OPG: 38 (9.56)	OPG not reliable tool for measuring condylar slopes
Patil *et al.*, 2015[69]	India		10	Protrusive IOR using extraoral Gothic arch tracing method	OPG	Hanau Wide Vue	GT: 18.50 (4.11) OPG: 17 (3.43)	GT: 20 (4.08) OPG: 17.30 (4.73)	Gothic arch tracing gave similar readings as shown by the radiographic landmarks and can be used as a successful clinical method[30,69]
Acharya *et al.*, 2015[70]	India		20	Protrusive IOR using extraoral Gothic arch tracing method	OPGs	Hanau Wide Vue	GT: 26.50 OPG: 30.35	GT: 26.75 OPG: 29.50	OPG gave higher values than IOR
Godavarthi *et al.*, 2015[7]	India	40–65	20	Protrusive IOR using extraoral Gothic arch tracing method	OPGs	Hanau Wide Vue	GT: 38.62 OPG: 36.6	GT: 38.05 OPG: 34.17	IOR gave higher values than OPG method. OPG can be used as an alternative method to determine CG
Shah *et al.*, 2014[71]	India		24	Protrusive IOR by jetbite using extraoral Gothic arch tracing	OPGs	Hanau Wide Vue	GT: 30.42 (6.06) OPG: 38.54 (4.18)	GT: 32.38 (8.55) OPG: 41.88 (1.16)	R/G higher value than tracing. No correlation was obtained between both techniques
Shetty *et al.*, 2013[72]	India		15	Protrusive IOR with bite registration material at JR stage using hight extraoral Gothic arch tracing, IOR at try-in stage	OPGs	Hanau Wide Vue	GT: 12.73 (11.08) OPG: 37.13 (5.40) IOR: 24 (11.83)	GT: 13.47 (9.87) OPG: 35.13 (4.79) IOR: 21.67 (10.63)	OPG higher than other method
Shah *et al.*, 2013[73]	India		20	Protrusive interocclusal plaster record using extraoral Gothic arch tracing	OPGs	Hanau H2 and Hanau Wide Vue	GT: 35.45 (4.69) OPG: 37.9 (3.89)	GT: 37.35 (5.17) OPG: 38.9 (5.22)	OPG gave higher value than Hanau Wide Vue than Hanau H2
Thakur *et al.*, 2012[74]	India	45–65	28	Protrusive interocclusal plaster record using extraoral Gothic arch tracing	Interocclusal wax record	Hanau Wide Vue	GT: 22.93 (7.15) IOR: 21.64 (6.24)	GT: 23.93 (6.9) IOR: 21.28 (7.02)	Gothic arch tracing gave a higher value than interocclusal wax record
Nandini *et al.*, 2005[75]	India		10	Protrusive IOR using extraoral Gothic arch tracing method	Cephalometrics, Chandra tracer, intraoral tracer, functiograph, checkbite	Hanau articulator	NR	NR	Articulator values were higher than cephalometric value. Intraoral tracer than functiograph than Chandra tracer than checkbite than hight tracer

CBCT: Cone-beam computed tomography, GT: Gothic arch tracer, IOR: Interocclusal record, NR: Not reported, OPG: Panoramic radiograph, SD: Standard deviation

excluded (31 due to inappropriate study groups, 12 due to data provided on dentulous patients, 2 studies due to data on intraoral tracing technique, and 2 studies due to data provided on lateral condylar guidance).[43] For qualitative synthesis, 22 studies were included. For the meta-analysis, 20 studies were included. The articles' search result in the PRISMA flowchart is depicted in Figure 1.

Characteristics of included studies

The detailed characteristic data of 22 included *in vivo* studies are mentioned in Table 3.[7,24,56-75] In this review, 325 participants with an average age of 45–60 years were included. Among 22 included studies, 2 studies were conducted in Egypt,[57,60] 1 in Nepal,[66] and 19 in India.[7,24,56,58,59,61-65,67-75] Twenty-one studies have reported the use of Hanau Wide Vue semi-adjustable articulator,[7,24,56-61,63-75] and one study each reported the use of Hanau H2 semi-adjustable articulator,[71] Girrbach Dental articulator,[62] and Bio Art articulator.[57] Fifteen studies measured HCG angle using panoramic radiograph,[5,56,61-73] six studies measured HCG angle using CBCT,[56-[60,65] three studies measured HCG angle using cephalogram,[56,61,75] six studies measured HCG angle using IOR,[57,58,60,65,74,75] one study measured HCG angle using axiograph,[62] and one study measured HCG angle using functiograph and intraoral tracer techniques.[75] The right and left HCG angles were reported for all included studies.[7,24,56-75]

Risk of bias assessment

The Newcastle–Ottawa assessment tool, a modified version of the case–control study scale, was used for the quality assessment of the analytical cross-sectional study.[47-49] The study quality of 20 studies[7,24,56-71,73,74] was good and 2 studies[72,75] was fair, as shown in Table 4.

Meta-analysis

Twenty studies were included for meta-analysis.[7,24,56-59,61-74] The quantitative data which were obtained for right and left side HCG angles from four methods – panoramic radiograph, CBCT, cephalogram, and the interocclusal wax record – were compared with extraoral Gothic arch tracing for meta-analysis. A total of 15 studies were included for panoramic radiograph,[7,24,56,61-64,66-73] 2 studies for cephalogram,[56,61] 5 studies for CBCT,[56-59,65] and 4 studies[57,58,65,74] for interocclusal wax record.

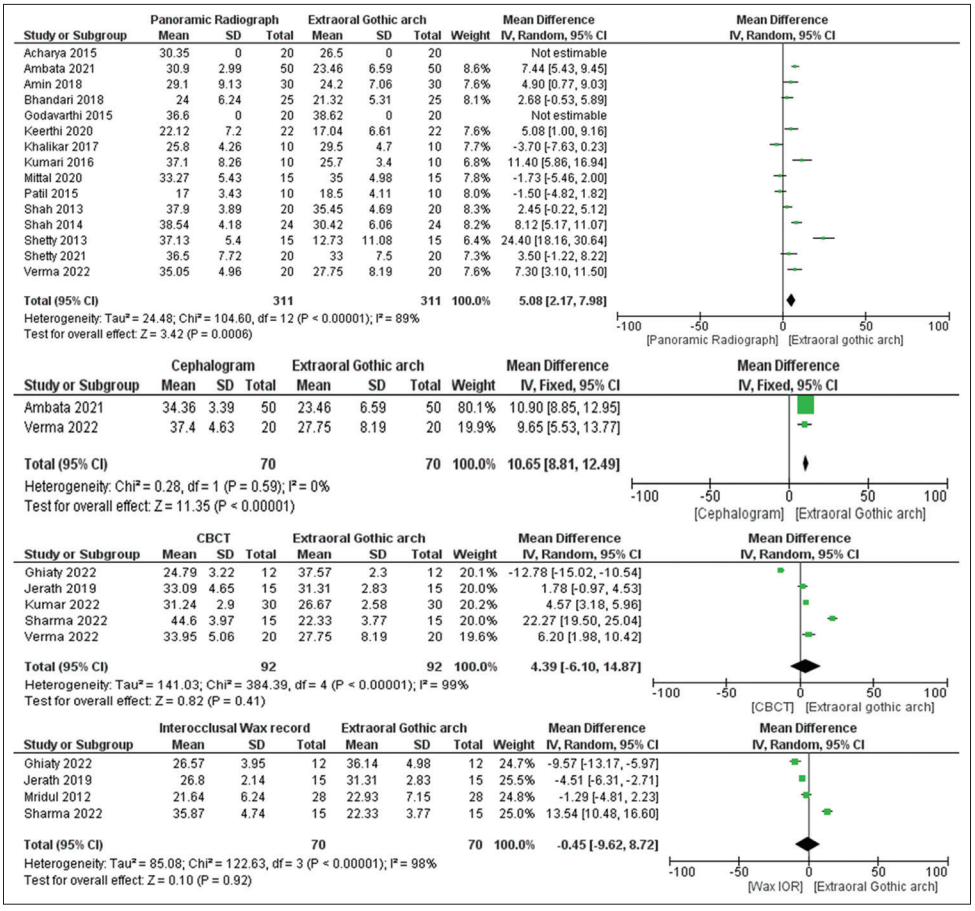

Figure 2: Forest plot comparing protrusive interocclusal record using extraoral Gothic arch tracing and intervention groups of panoramic radiograph, cephalogram, cone-beam computed tomography, and interocclusal wax record for right side horizontal condylar guidance angle

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

Study ID	Selection				Comparability		Outcome		Total score	Quality
	Representativeness of case	Sample size	Nonresponders	Ascertainment of risk factor	Main factor	Additional factor	Assessment of outcome	Statistical test		
Verma *et al.*, 2022[56]	*	-	*	**	*	-	*	*	7	Good
EL-Ghiaty *et al.*, 2022[57]	*	*	*	**	*	-	*	*	8	Good
Sharma *et al.*, 2022[58]	*	-	*	**	*	-	*	*	7	Good
Kumar *et al.*, 2022[59]	*	*	*	**	*	-	*	*	8	Good
Abdeen *et al.*, 2022[60]	*	*	-	**	*	-	*	*	7	Good
Ambata, 2021[61]	*	*	*	**	*	-	*	*	8	Good
Shetty *et al.*, 2021[62]	*	*	*	**	*	-	*	*	8	Good
Keerthi *et al.*, 2020[63]	*	*	*	**	*	-	*	*	8	Good
Mittal *et al.*, 2020[64]	*	*	*	**	*	-	*	*	8	Good
Jerath *et al.*, 2019[65]	*	*	*	**	*	-	*	*	8	Good
Bhandari *et al.*, 2018[66]	*	*	*	**	*	-	*	*	8	Good
Amin *et al.*, 2018[24]	*	*	*	**	*	-	*	*	8	Good
Khalikar *et al.*, 2017[67]	*	*	*	**	*	-	*	*	8	Good
Kumari *et al.*, 2016[68]	*	-	*	**	*	-	*	*	7	Good
Patil *et al.*, 2015[69]	*	-	-	**	*	-	*	*	6	Good
Acharya *et al.*, 2015[70]	*	*	*	**	*	-	*	*	8	Good
Godavarthi *et al.*, 2015[7]	*	*	*	**	*	-	*	*	8	Good
Shah *et al.*, 2014[71]	*	*	-	**	*	-	*	*	7	Good
Shetty *et al.*, 2013[72]	*	-	-	*	*	-	*	*	5	Fair
Shah *et al.*, 2013[73]	*	*	*	**	*	-	*	*	8	Good
Thakur *et al.*, 2012[74]	*	-	*	**	*	-	*	*	7	Good
Nandini *et al.*, 2005[75]	*	-	-	*	*	-	*	*	5	Fair

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

Meta-analysis for right side horizontal condylar guidance angle

For the panoramic radiograph, the random effect model was applied as the I^2 value was 89%.[43] A statistically significant difference was observed between the two methods ($P < 0.05$, pooled mean difference = 5.08 [2.17,7], CI = 95%), as stated in the forest plot [Figure 2].[43] HCG angle obtained from the panoramic radiograph was higher than extraoral Gothic arch tracing. For the cephalogram, the I^2 value obtained was 0%, so the fixed effect model was applied. A statistically significant difference was observed between the two methods ($P < 0.05$, pooled mean difference = 10.65 [8.81, 12.49], CI = 95%), as stated in the forest plot [Figure 2]. HCG angle obtained from the cephalogram was higher than extraoral Gothic arch tracing. For CBCT, the I^2 value obtained was 99%, so the random effect model was applied. No statistically significant difference was observed between the two methods ($P = 0.41$, pooled mean difference = 4.39 [−6.10, 14.87], CI = 95%), as stated in the forest plot [Figure 2]. For the protrusive interocclusal wax record, the I^2 value obtained was 98%, so the random effect model was applied. No statistically significant difference was observed between the two methods ($P = 0.92$, pooled mean difference = −0.45 [−9.62, 8.72], CI = 95%), as stated in the forest plot [Figure 2].[43]

Meta-analysis for left side horizontal condylar guidance angle

For the panoramic radiograph, the I^2 value obtained was 90%, so the random effect model was applied. A statistically significant difference was observed between the two methods ($P < 0.05$, pooled mean difference = 5.07 [1.95, 8.18], CI = 95%), as stated in the forest plot [Figure 3].[43] HCG angle obtained from the panoramic radiograph was higher than extraoral Gothic arch tracing. For the cephalogram, the I^2 value obtained was 0%, so the fixed effect model was applied. A statistically significant difference was observed between the two methods ($P < 0.001$, pooled mean difference = 10.24 [8.65, 11.83], CI = 95%), as stated in the forest plot [Figure 3]. HCG angle obtained from the cephalogram was higher than extraoral Gothic arch tracing. For CBCT, the I^2 value obtained was 98%, so the random effect model

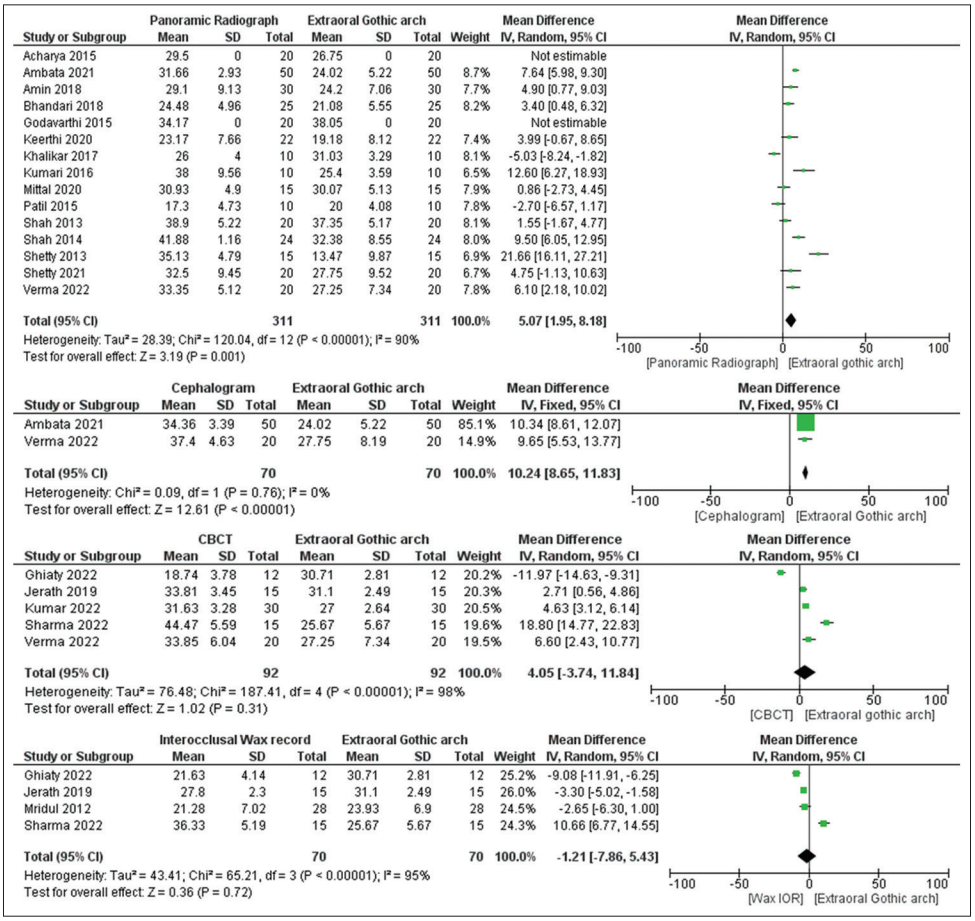

Figure 3: Forest plot comparing protrusive interocclusal record using extraoral Gothic arch tracing and intervention groups of panoramic radiograph, cephalogram, cone-beam computed tomography, and interocclusal wax record for left side horizontal condylar guidance angle

was applied. No statistically significant difference was observed between the two methods ($P = 0.31$, pooled mean difference = 4.05 [−3.74, 11.84], CI = 95%), as stated in the forest plot [Figure 3].[43] For the protrusive interocclusal wax record, the I^2 value obtained was 95%, so the random effect model was applied. No statistically significant difference was observed between the two methods ($P = 0.72$, pooled mean difference = −1.21 [−7.86, 5.43], CI = 95%), as stated in the forest plot [Figure 3].[43]

DISCUSSION

Accurate determination of condylar guidance angle is a necessity for coordinated and harmonious mandibular movements within the envelope of motion which is a unique entity for every individual. Hight extraoral Gothic arch tracer consists of a central bearing point and central bearing plate. The protrusive mandibular movements are recorded with an interocclusal recording medium and transferred to an articulator to measure the HCG angle obtained from the patient. This systematic review and meta-analysis was conducted to compare the extraoral Gothic arch tracing with CBCT, cephalogram, panoramic radiograph, and interocclusal wax record used for measuring HCG angle in completely edentulous patients.

The null hypothesis was accepted for the intervention group of CBCT and interocclusal wax record. No statistically significant difference was observed for both right and left HCG angles obtained from CBCT and interocclusal wax record compared with extraoral Gothic arch tracing. This result was in accordance with the study done by Kumar *et al*.[59] showing no statistically significant difference between CBCT and extraoral Gothic arch tracing and the study done by Sharma *et al*. showing no statistically significant difference between extraoral Gothic arch tracing and interocclusal wax record.[58] However, studies done by Verma *et al*. and Jerath *et al*. reported higher values from CBCT than clinical methods.[56,65] The study done by Jerath *et al*. reported lesser values for the interocclusal wax record than extraoral Gothic arch tracing.[65] However, a study done by Thakur *et al*. reported higher values from extraoral Gothic arch tracing than interocclusal wax record.[74]

The null hypothesis for the intervention group cephalogram and panoramic radiograph was rejected. Cephalogram and panoramic radiograph showed comparatively higher statistically significant values than extraoral Gothic arch tracing. This result was in accordance with studies done by Verma *et al*. and Ambata showing significant differences between cephalogram and extraoral Gothic arch tracing.[56,61] However, a study done by Nandini *et al*. reported no statistically significant difference between cephalogram and extraoral Gothic arch tracing.[75] Studies done by Kumari *et al*., Shah *et al*., and Shetty *et al*. reported statistically higher values from panoramic radiograph than extraoral Gothic arch tracing.[68,71,72]

The overall results obtained were due to the different methodologies used for measuring HCG angle. The accuracy of extraoral Gothic arch tracing varied due to the complex arrangement of hight extraoral tracer, the compressibility of the underlying tissues, the stability of the temporary record bases, the precision of the patient to perform various mandibular movements on the tracing plate, and differences in elasticity, rigidity, flow, accuracy, compressibility, setting time, thickness, and dimensional stability of interocclusal recording medium.[56,59,65] The interocclusal wax record obtained using Aluwax is an easy method to record protrusive mandibular movements for patients.[57,58,65] However, errors can occur during the laboratory transfer to the articulator, distortion of wax, uncoordinated mandibular movements of the patient, and inappropriate recording methods by the clinician. For the radiographic determination of the HCG angle, the angle was obtained by the intersection of two reference lines and was measured with a protractor. However, errors in measurement can occur due to improper identification of bony landmarks and inappropriate measurement by clinicians.[56,59,61,65,70,73] The differences in the HCG angles obtained can be due to the limitations reported by the studies such as the use of **s**maller sample size, the influence of condylar pathway by the overlapping structures, the use of two-dimensional lateral cephalometric image, errors due to manual tracing method, errors based on individual judgment, radiographic distortion, distortion due to head position and reference plane orientation, magnification errors, and projection errors.

For measuring the HCG angle in a completely edentulous patient, the clinician can opt for a cephalogram and panoramic radiograph as an alternative, convenient, accurate method to record, measure, and transfer the HCG angle for programming the semi-adjustable articulator to obtain balanced occlusion devoid of occlusal interferences during mandibular movements in a complete denture. Limitations of this review included the inclusion of only analytical cross-sectional studies, and studies published in English only. The quantitative analysis results were obtained from different studies with different comparison groups resulting in a smaller number of included studies for cephalogram, CBCT, and interocclusal wax record. For more specific results, studies comparing only two methods should be included. To overcome these limitations, new

clinical trials should be conducted on the present topic and should be included to obtain higher validated results. Further reviews can be conducted between any two methods to get comparative results.

CONCLUSION

The conclusions that can be drawn from the findings of this systematic review and meta-analysis are as follows:

1. Higher HCG angles were obtained from cephalogram and panoramic radiograph when compared with extraoral Gothic arch tracing in completely edentulous patients with statistically significant difference for both right and left HCG angles
2. Based on the mean difference and number of studies included for meta-analysis, it can be concluded that the panoramic radiograph is the best method to obtain higher and more accurate HCG angle in completely edentulous patients as compared with extraoral Gothic arch tracing.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Systematic Review

Clinical outcomes of implant-supported prosthetic rehabilitation of severely atrophic maxilla: A systematic review

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Abstract

Aim: The purpose of this systematic review is to evaluate the clinical outcomes for the various methods of rehabilitation of a severely atrophic maxilla with the help of implant-supported fixed prosthesis.

Materials and Methods: The relevant publications published between 2013 and 2022 and written only in English were identified using an electronic search. The primary research question for this study was developed based on the PICO framework, which stands for population, intervention, control, and outcomes which was "What are the clinical outcomes of implant-supported prosthetic rehabilitation in patients with severely atrophic maxilla?" The relevancy of the articles was confirmed by examining their titles, abstracts, and complete texts to determine whether they satisfied the requirements for inclusion. Utilizing specialized study design-related bias assessment forms, the risk of bias was evaluated.

Results: The database search resulted in 1568 results; however, 1529 of them were eliminated because of insufficient, duplicate, or missing data. Additionally, manual searching yielded 11 articles. After 50 full-text papers were assessed for eligibility, 17 articles were eliminated. Thus, 33 studies in total are included in the current systematic review. Risk of bias analysis and GRADE evidence analysis were performed. Data were found to be heterogeneous and thus meta-analysis could not be done and narrative synthesis is presented.

Conclusion: The patient's condition and the clinician's expertise play a role in taking the decision on choice of technique for the fixed implant-supported rehabilitation of the severely atrophic maxilla. A high success and survival rate is produced by the majority of fixed implant-assisted prostheses despite the biologic and prosthetic problems. A single approach cannot be recommended as the gold standard. The choice is dependent on the patient's biological factors as well as the clinician's expertise. The included studies were assessed using GRADE criteria. The quality of evidence is low-medium. Therefore, to better comprehend the clinical effectiveness of the treatment alternatives, more well-designed randomized controlled trials with longer follow-up period are required.

Keywords: Dental implant, fixed prosthesis, implant failures, patient satisfaction, prosthetic complications, pterygoid implant, severely atrophic, zygomatic implant

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INTRODUCTION

Improving oral rehabilitation with osseointegrated implants is a strategy to minimize the mechanical instability of conventional complete dentures and its negative psychological and social repercussions. However, the loss of alveolar bone significantly impeded the treatment of edentulous people. The need to insert osseointegrated implants on resorbed bone locations, particularly in posterior regions, necessitated studies to create methods to utilize the existing bone to fix implants.[1-3]

When managing the edentulous upper jaw, the atrophic maxilla poses a substantial treatment challenge. While the placement of implants continues to be the preferred method of action when more traditional prosthetic procedures have failed, the ability to successfully offer an implant-based long-term solution may be severely hampered by a lack of accessible bone. The possibility for a terrible clinical scenario upon failure of whichever remedy is supplied emphasizes the significance of long-term success.[2]

The dental rehabilitation of an atrophic maxillary arch often represents a challenge. Implant placement followed by fixed prosthesis is a reliable option for such patient to aid in the retention and stability of the prosthesis. There are many studies done regarding the success of this treatment approach; however, systematic reviews of the clinical outcome of such implant-supported fixed prosthesis have not yet been done.

MATERIALS AND METHODS

The review was carried out utilizing the suggestions from the Preferred Reporting Items for Systematic Reviews and Meta Analyses statement checklist [Figure 1]. The International Prospective Register of Systematic Reviews protocol was used to organize, carry out, and record this systematic review.

Primary research question

What are the clinical outcomes of implant-supported prosthetic rehabilitation in patients with severely atrophic maxilla?

PICO question

Patients with severely atrophic maxilla (P) who were rehabilitated using implant-supported fixed prosthesis (I) were evaluated to achieve the clinical outcomes (O).

Search strategy

The relevant English-language papers published between 2013 and 2022 were found using an automated algorithm in the scientific databases of Elsevier (Scopus), the National Library of Medicine PubMed, and Google Scholar. Using controlled lexicons, all databases (Medical Subject Headings terms in PubMed), free text, and terms

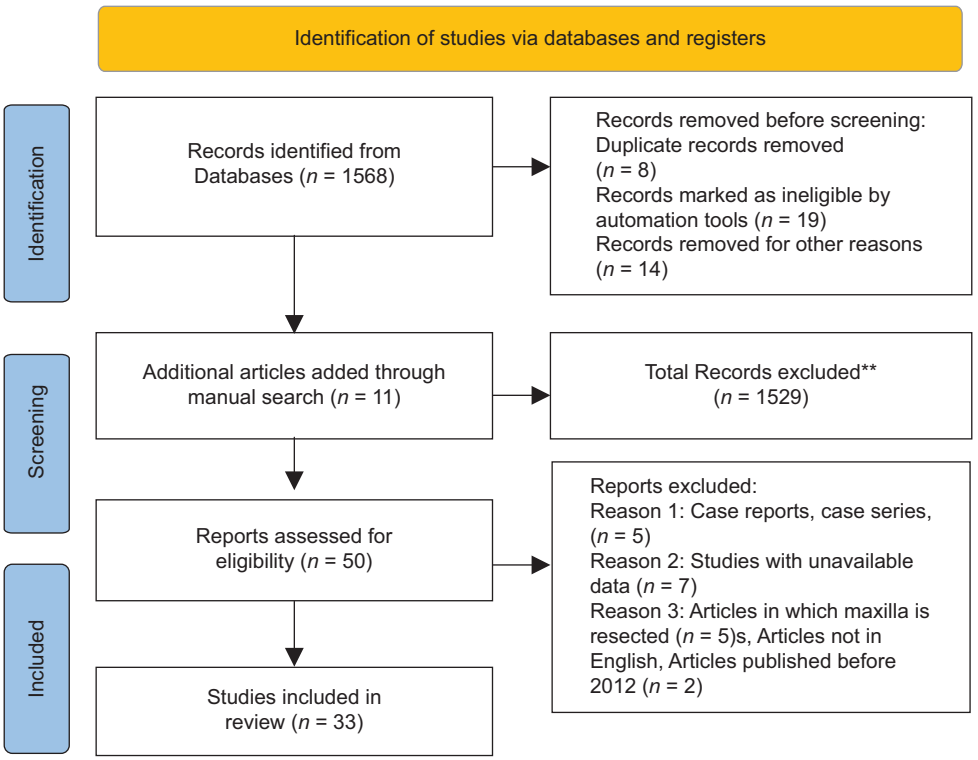

Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart

in the titles and/or abstracts were searched. Keywords were used to develop search methods for each division of the PICO question, which were divided and then combined using the Boolean operations AND and OR. Other research that might be of interest were found by searching for pertinent references in works from these journals. The Review's Registration ID is CRD42022341464, and it was submitted to PROSPERO International Prospective Register of Systematic Reviews.

Study selection

In vivo studies evaluating the outcomes of implant-supported rehabilitation of severely atrophic maxilla were included in this review.

Inclusion criteria

The research considered in this systematic review comprised pilot studies, randomized controlled trials (RCTs), cross-sectional studies, retrospective studies, prospective studies, and longitudinal studies on patients with implant-aided rehabilitation of severely atrophic maxilla published between 2013 and 2021.

Exclusion criteria

Case reports, systematic reviews, meta-analyses, narrative reviews, publications before the year 2013, case reports with patients having resected maxilla, literature reviews, books, reports, letters to the editor, and studies with unavailable data were excluded from this review.

Data synthesis [Figure 2 and Table 1]

Two reviewers independently cross-checked the data gathered after one reviewer (R1) collected information on the included research. Each included study's methodology (number and type of implants used), sample characteristics (sample size), publication information, characteristics related to outcomes such as demographic details, survival rates, prosthodontic complications, and other clinical outcomes were all systematically collected.

Outcomes and variables

The outcome measures were:

Failure of a prosthesis refers to the planned prosthesis that was unable to be implanted, the loss of the prosthesis as a result of implant failures, or the replacement of the definitive prosthesis for any cause. Any mechanical problem that renders the implant ineffective, such as implant fracture or deformation of the implant-abutment connection, is referred to as implant failure. This includes implant movement, stable implants that must be removed due to infection or slow marginal bone loss, or any other type of implant failure, any biological or prosthetic issues at the donor or recipient locations, such as persistent postoperative discomfort, etc.

Risk of bias assessment [Table 2]

Utilizing specialized study design-related bias assessment forms, the risk of bias was evaluated. Criteria were divided into six main groups based on factors such as randomization, blinding, outcome data, and baseline characteristics of the sample.[4] To assess the risk of bias, each study criterion was given one of three ratings: "yes" (low risk of bias), "no" (high risk of bias), or "unclear" (cannot find the information or uncertain about the possibility of prejudice). One reviewer evaluated the possibility of bias, while the other double-checked it.

DISCUSSION

Bone resorption has always been triggered by the loss of one or more teeth leading to loss of functional stimulus, and it can be influenced by a variety of variables including age, gender, diabetes, smoking, osteoporosis, the type of prosthetic rehabilitation, previous lost implants, the amount of time that has passed since implant rehabilitation, and others. There is a consistent and predictable resorption that varies depending on the area such as, in the maxillary jaw, it is primarily horizontal and centripetal. A condition known as "alveolar atrophy" is

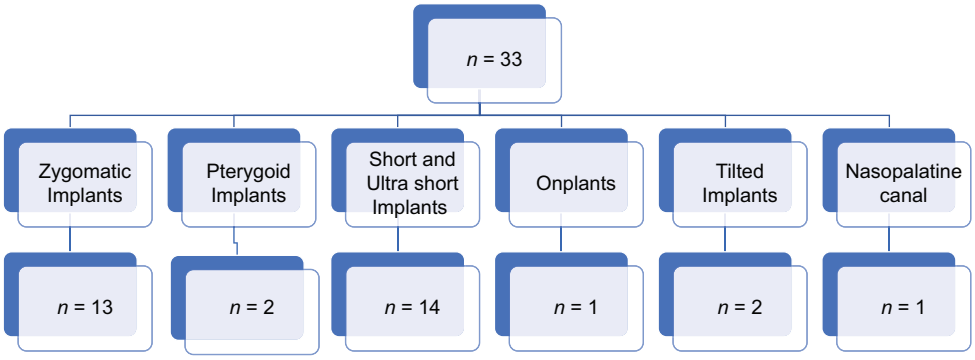

Figure 2: Data synthesis

Table 1: Data extraction

Name of author/ year of references	Sample size	Number of implants	Success rates (%)	Surgical complications	Prosthetic complications	Relevant findings
Yates *et al*., 2014[2]	*n*=25	43	86	Failure to integrate exposed threads, incorrect positioning, chronic discharging sinus with symptoms	Not reported	When direct alveolar support for traditional implants is absent, zygomatic implants provide a relatively measured method of replacing the missing upper dentition. Each instance might ultimately be restored to the intended prosthesis by changing the final design
Maló *et al*., 2013[34]	352	1542	98.2	Sinus infections, oroantral communication, peri-implant pathology	101 fractures of prosthesis, loosening of prosthetic components, prosthetic and abutment screw loosening	It is possible to restore function to one to four zygomatic implants using the All-on-4 concept to treat severely atrophic maxillae
De Santis *et al*., 2015[5]	*n*=44	102	93.1	Not reported	Screw loosenings, screw fractures, porcelain veneer fractures	Short implants are a good way to simplify and speed up the healing process, but more thorough follow-up research is needed
Fernández *et al*., 2014[30]	*n*=80	244	99.6	Orosinusal fistula vestibular cortical fenestration implant loss sinusitis, subcutaneous malar emphysema infraorbital nerve paresthesia	Not reported	Zygomatic bone offers a predictable anchorage for fixed prosthesis in patients with severely resorbed maxilla
Aparicio *et al*., 2014[20]	*n*=22	172	97.71	Peri-implant infection and dissolution of palatal bone	Fractured framework, loosening of screws, fracture of screws, fractured occlusal material, uncomfortable and bulky prosthesis leading to disconnected abutments	For the treatment of severely atrophic maxilla, a predictable approach is fixed implant-supported bridges
Rodríguez-Chessa *et al*., 2014[21]	*n*=29	67	79.1	Zygomatic fixation failure	Speech and phonetics impaired	Proper position and distribution of implants are important factors for success
Peñarrocha *et al*., 2014[16]	*n*=13	78	84.6	Lack of osseointegration sensory alterations surgical trauma	Not reported	One potential location for anterior implant-supported rehabilitation of the atrophic maxilla is the nasopalatine canal
Curi *et al*., 2015[1]	*n*=56	238	99	Bone loss up to 1.21 mm, failure to osseointegrate	Not reported	In individuals with partial or total edentulism, pterygoid implants provide good stabilization for bone-anchored prostheses
Taschieri *et al*., 2015[35]	*n*=41	53	100	Not reported	Not reported	In cases of low bone height, short implants can be thought of as a possibility for the rehabilitation of edentulous jaws
Felice *et al*., 2015[38]	*n*=20	34	100	Not reported	Not reported	Short implants (5–6 mm) have similar outcomes as compared to 10 mm implants placed with sinus lift
Maló *et al*., 2015[10]	*n*=43	172	95.7	Peri-implant pockets	Provisional prostheses fracture, abutment screw loosenings	Further investigations regarding long-term performance of rehabilitations using short-length implants are required
Esposito *et al*., 2015[12]	*n*=28	178	100	Buccal dehiscence	Implant failure due to denture overload	For the rehabilitation of an edentulous, atrophic maxilla, shorter implants may be a better, more affordable, and more rapid option than longer implants in augmented bone
Heuberer *et al*., 2016[17]	*n*=5	10	0	Not reported	Detaching from the palatal bone at the time of prosthetic loading	Use of Onplant system is not recommended in adult patients
Dos Santos *et al*., 2016[24]	*n*=1	4	100	Not reported	Not reported	Treatment of atrophic maxilla rehabilitation with anchoring in the zygomatic region was a success

Contd...

Table 1: Contd...

Name of author/ year of references	Sample size	Number of implants	Success rates (%)	Surgical complications	Prosthetic complications	Relevant findings
Nedir *et al*., 2016[36]	*n*=12	37	91.9	Peri-implantitis	Not reported	Short tapered implants with reduced thread pitch can be placed with good stability in atrophic maxilla using OSFE
Nedir *et al*., 2017[37]	*n*=12	37	91.9	Peri-implantitis, implant failure	Not reported	Predictable results can be achieved with 8 mm implants in conjunction with OSFE while lack of bone coverage does not affect the success rate
Pieri *et al*., 2016[32]	*n*=101	221	95.8	Peri-implant mucositis, bone loss,	Minor veneer and porcelain fractures, fracture of ceramic cusp, abutment screw loosening,	Although both treatments have equal results, short implants have fewer surgical problems and less morbidity than normal implants
Chen *et al*., 2016[41]	*n*=16	25	100	Not reported	Not reported	Simultaneous sinus floor elevation and short placement
Agliardi *et al*., 2017[9]	*n*=15	60	100	Perforation of sinus membrane, compromised healing, soft-tissue recession, oroantral communication, sinusitis	Not reported	A potential therapeutic option could be the immediate rehabilitation of a severely atrophic maxilla using zygomatic implants alone or with conventional implants. Reductions in biological expenses, treatment time, and morbidity are advantages
Balan *et al*., 2017[31]	*n*=18	29	100	Not reported	Not reported	Select patients may benefit from zygomatic implants, which significantly reduced the duration of rehabilitation and minimized side effects
Araújo *et al*., 2017[3]	*n*=37	129	98.4	Paresthesia of infraorbital nerve, acute infection, chronic pain, oroantral communication, bruising, suture dehiscence, sinusitis	Not reported	A dependable choice for the treatment of severely resorbed maxilla is zygomatic implants
Coppedê *et al*., 2017[8]	*n*=42	273	98.9	Dehiscence irritation inflammation soft-tissue complications	Not reported	A predicted option for the atrophic maxilla is zygomatic paired with conventional implants via the extrasinus procedure, providing full-arch screw retained prosthesis
Menéndez-Collar *et al*., 2018[33]	*n*=32	187	100 (axial) 98.5 (tilted)	Related to donor site in case of autogenous grafting, to sinus surgery, sinusitis, loss of graft, and perforation of the sinus membrane	Not reported	One therapeutic benefit of tilted implants is that they have a shorter cantilever, which allows for ideal load distribution. By providing anchorage for multiple cortical, longer fixations enhance the surface area of bone–implant contact and implant primary stability. For patients with atrophic maxilla, fixed restorations supported by axial and tilted implants may be an effective therapeutic option
Wagner *et al*., 2018[7]	*n*=18	72	97.2	Not reported	Not reported	Short (3 mm×8 mm) or ultrashort (4 mm×5 mm) implants are a viable and cost-effective treatment option for rehabilitation of atrophic maxilla

Contd...

Table 1: Contd...

Name of author/ year of references	Sample size	Number of implants	Success rates (%)	Surgical complications	Prosthetic complications	Relevant findings
Gürlek *et al*., 2019[42]	*n*=23	54	100	Not reported	Decementation and porcelain chipping	Suggests that bone-level 4–6 mm implants provide with similar outcomes as regular longer implants
Yalçın *et al*., 2020[6]	*n*=45	141	94.33	Infection peri-implantitis sinusitis wrong prosthetic rehabilitation oroantral fistula buccal abscess	Fractures of prosthetic components	Similar to endosteal implants, zygomatic implants might cause clinical problems. Zygomatic implants can aid in prosthetic rehabilitation, either by themselves or in combination with endosteal implants
Nave and Queralt, 2020[19]	*n*=102	206	97.57	Sinusitis	Not reported	In patients with severe maxillary atrophy, immediate rehabilitation using zygomatic implants has been shown to be a quick and predictable treatment option with a high survival rate and few biological side effects. It might be regarded as the gold standard
Almahrous *et al*., 2020[40]	*n*=60	-	-	Non-osseointegrated implant, peri-implant bone loss, pain and discomfort when tightening the abutment-implant, progressive bone loss	Implant unusable prosthetically	Significant differences between the two therapies may be shown in the treatment of sinus bone atrophy, which required BGS as opposed to CAIS, as well as peri-implantitis and bone craterization at one year. The other PROMs did not, however, show any statistically significant differences between BGS and CAIS at placement or after a year
Borgonovo *et al*., 2020[23]	*n*=23	98	100	Peri-implant mucositis	Not reported	For the immediate rehabilitation of the atrophic maxilla, extrasinus zygomatic implants have a high success rate with little to no complication
Amato *et al*., 2020[13]	*n*=55	146	99.3	Not reported	Abutment screw loosening, mobility of prosthesis	The use of extra-short (5 and 6 mm) and short (6.5 mm) implants, whether or not they are splinted to standard-length implants (4 mm×4 mm ultrashort implants), is recommended in the article as a less expensive and time-consuming method than invasive ones
Felice *et al*., 2020[15]	*n*=1	6	100	Not reported	Not reported	The use of extra-short (5 and 6 mm) and short (6.5 mm) implants, whether or not they are splinted to standard-length implants (4 mm×4 mm ultrashort implants), is recommended in the article as a less expensive and time-consuming method than invasive ones
Malchiodi *et al*., 2020[39]	*n*=23	50	94	Peri-implantitis	Not reported	SPS implants offer predictable long-term results when used for prosthetic rehabilitation
Aparicio *et al*., 2021[22]	*n*=122	488	-	Soft-tissue-related complications, vascular compression, erosion of mucosa leading to exposure of implant, soft-tissue dehiscence	Not reported	The risk factors associated with the quadruple zygoma method can be reduced by evaluating the anatomical variances among patients and then modifying surgical procedures and implant configuration

SPS: Sintered porous surfaced, CAIS: Computer-aided implant surgery, BGS: Bone graft surgery, PROMS: Patient-reported outcome measures, OSFE: Osteotome sinus floor elevation

Table 2: Risk of bias assessment table

Bias domain	Source of bias	2	42	5	30	20	21	16	1	34	37	38	24	12	17	24	36	32	41	9	31	3	8	33	7	42	6	19	40	23	13	15	39	22
Selection bias	Random sequence generation	NA	NA	NA	NA	NA	NA	NA	NA	NA	Y	Y	NA	Y	NA	NA	Y	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Y	NA	NA	NA	NA	NA
	Allocation concealment	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	N	NA	N	NA	NA	N	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	NA	NA	NA	NA	NA
Performance bias	Blinding of participants and personnel	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	N	NA	N	NA	NA	N	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	NA	NA	NA	NA	NA
Detection bias	Blinding of outcome assessment	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	N	NA	N	NA	NA	N	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	NA	NA	NA	NA	NA
Attrition bias	Incomplete outcome data	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Reporting bias	Selective reporting	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Other bias	Anything else, ideally prespecified	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Risk of bias	Low, unclear, high	Low	High	Low	Low	High	High	Low	Low	Low	High	High	High	High	Low	Low	High	High	Low	Low	Low	Low	Low	Low	Low	Low	High	Low	Low	Low	Low	Low	High	Low

Y: Yes, N: No, U: Unclear

caused by a moderate-to-severe loss of alveolar bone as a result of tooth loss, which may make achieving an appropriate implant-supported rehabilitation difficult or impossible.[5] For the purpose of clarification, this systematic review considered the included studies under Stage 5 and Stage 6 of alveolar bone resorption as per the Cawood and Howell's Classification (1988).

Conventional dental implants are insufficient in cases of advanced maxillary bone resorption to guarantee a fixed prosthesis and adequate anchoring. Autogenous, alloplastic, onlay bone graft, maxillary sinus augmentation, LeFort I osteotomy, and other methods or procedures to address maxillary bone deficiency issues require multiple surgical interventions, prolonging the prosthetic process, failing of the graft, perforating sinus membrane, and infections.[6] Numerous techniques have been documented in the literature for effective prosthetic restoration in these circumstances, including sinus grafting, other bone augmentation procedures, and various implant lengths, including zygoma implants and ultrashort implants.[7]

Type of implants used

In the literature, a variety of implants have been utilized to successfully restore the severely atrophic maxilla. Although many studies have been conducted for combining treatment protocols for the same, it has been found that the zygomatic bone offers a predictable anchorage for fixed prosthesis in most of the cases. The "Father of Dental Implantology," Dr. Per Ingvar Branemark, originally introduced zygomatic implants in 1998. It is advised that zygomatic implants implanted using the extrasinus technique be used in conjunction with conventional or regular implants to support full-arch, screw-retained prostheses as a prospective therapeutic option for the atrophic maxillae.[8] Reductions in biological expenses, treatment time, and morbidity are the advantages.[9]

The pterygoid region also serves as a potential for support along with the zygomatic and conventional implants. Linkow first suggested pterygoid implants in 1975, and JF Tulasne first explained the procedure in 1992. Longer posterior cantilevers and other prosthetic procedures may cause problems such fracture of screw and prosthesis, loss of marginal bone, and failure of implant osseointegration. The pterygomaxillary, pterygoid, and tuberosity areas have been recommended to prevent these issues.[1]

One more revolutionary concept of All-on-Four concept was developed by Maló *et al*. in 1998[10] to get beyond the maxilla's anatomical restrictions, which make it difficult to treat without using a complicated technique. Four anterior implants are inserted as part of the protocol to support a full-arch prosthesis in an edentulous jaw. The fact that for patients prosthetic rehabilitation with All-on-Four technique resembles natural dentition experience, as opposed to stark contrast between those with complete denture rehabilitation, may lead us to conclude that All-on-Four rehabilitation is a superior alternative to removable rehabilitation, such as complete denture, for restoring muscular function in edentulous patients.[11] For the prosthetic reconstruction of atrophic jaws, the idea of supporting a full-arch fixed prosthesis on just 4 implants has proven to be a reliable treatment choice. However, significant bone atrophy in edentulous posterior maxillae can make implant rehabilitation more difficult.[6]

Investigators have also evaluated short implants for atrophic jaws. The definition of term "short" implants is rather controversial. Some authors define short implants as those with a planned intra-bony length of 8 mm or less, while others define short implants as those with a length range from 7 to 10 mm. The minimum implant length that can be utilized in a clinical setting, however, is rapidly decreasing, and today, implants as short as 4 mm are being used.[12] When used in conjunction with sinus augmentation procedures for prosthetic restoration of the posterior maxilla, recent studies compared the outcomes of short (7 mm to 8 mm), extra-short (6.5 mm), and ultrashort (4 mm) implants with implants of conventional length and found that in augmented sinuses, ultrashort implants had implant survival rates that were comparable to those of standard implants.[6,13,14] The cumulative survival rates for implants of all lengths – standard, short, extra-short, and ultrashort – were equal. Even 4 mm ultrashort implants with a diameter of 4 mm may be a viable choice to restore a specific edentulous atrophic maxilla 1 year after loading.[15]

Another treatment approach is placement of implants in the nasopalatine canal as an anatomic buttress as reported in a study by Peñarrocha *et al*. in 2014.[16] Implant placed in this canal resulted in favorable outcomes. Scher originally detailed the procedure for implant insertion directly in the nasopalatine canal in 1994, and Misch later referenced it in his 1999 textbook.

Heuberer *et al*. in 2016[17] studied on the Onplant system. Unfortunately, it resulted in 100% failure in all implants resulting in loss of implant, thus rendering the Onplant type of implant unfit for rehabilitation purposes.

Basal bone refers to the cortical bone that is located beneath soft bone. The majority of the face's muscles adhere to

this bone. These implants are supported by the basal bone, which is thicker and undergoes almost little remodeling, providing the implant screw with great stability and strength. Basal implants were first utilized by Dr. Jean-Marc Julliet in 1972. Dr. Gerard Scortecci, a French dentist, developed specialized instruments for this treatment in the middle of the 1980s in addition to improving the basal implant technique that had previously been used. Because basal implants lack the various components that conventional implants have, they are also referred to as single-piece implants. Although many clinicians are still skeptical about basal implants' long-term success, the idea of them as an alternative to traditional implants has gained popularity throughout the past 20 years. These implants are supported by the basal bone, which is thicker and undergoes almost little remodeling, providing the implant screw with great stability and strength.[18]

Subperiosteal implants, initially introduced by Dahl in 1940, are an older form of dental implants. Since then, a number of procedures for implanting subperiosteal devices have been studied. Numerous articles have explained how maxillary dentures anchored by subperiosteal implants can successfully regenerate atrophic maxillary ridges in a single step.

Survival rates

The survival rates of zygomatic implants average between 97% and 100% in the selected studies. In most studies, implant failure occurred due to various reasons such as peri-implantitis, peri-implant bone loss, infection, and sinusal infections.[19] In patients with severe maxillary atrophy, immediate rehabilitation using zygomatic implants has been shown to be a quick and predictable treatment option with a high survival rate and few biological side effects. It might be regarded as the gold standard. Pterygoid implants along with zygomatic implants and conventional implants are also a viable treatment with high survival rates. One study shows that it is not advised in adult patients to use the Onplant system[17] as the survival of these types of implants is 0%. Although both treatments have equal results, short implants have fewer surgical problems and less morbidity than normal implants.[20] Due to their high success rate, short implants may be an effective, more rapid less expensive alternative to longer implants in enhanced bone for edentulous atrophic maxilla rehabilitation.[11] However, further research about the long-term performance of rehabilitations employing short-length implants is necessary.

Surgical complications

Although various complications were encountered in the studies, the overall success of the implants and prosthesis were found to be satisfactory. In studies where rehabilitation is done by the zygomatic implants and its variations, the most common surgical complication was found to be sinusitis. A significant number of reports of sinus issues were caused by ZI difficulties that had been present for a while. The removal of ZI due to recurrent sinusitis and more significant issues with intraoral soft tissue have also been documented by other writers. Lack of contact between the implant and the remnant alveolar crest, which would have allowed for connection between the sinus and oral cavities, may be the cause of the issue.[20] Zygomatic implants are said to have the potential to produce pathologic symptoms that develop in the maxillary sinuses, particularly if they are positioned intrasinusally; however, most patients do not experience these changes, and when they do, they typically remain asymptomatic.[18] Peri-implantitis or peri-implant mucositis along with bone loss and soft-tissue-related complications were also the complications in a large number of studies.

Nonosseointegrated implant, peri-implant bone loss, pain and discomfort when tightening the abutment-implant, progressive bone loss, dehiscence, irritation, and inflammation of soft tissue were also reported to be few of the biological complications of the rehabilitation using zygomatic implants. Prospective studies have shown that oroantral fistula, buccal abscess, paresthesia of infraorbital nerve, acute infection, chronic pain, oroantral communication, bruising, suture dehiscence, loss of graft, and perforation of the sinus membrane may also be surgical complications in case of standard implants in conjunction with the zygomatic implants.[2,3,5,7,8,17,20-31]

Prosthetic complications

Many of the studies have provided with the prosthetic complications to be fractures of prosthesis, loosening of prosthetic components, prosthetic and abutment screw loosening as frequent complications.

In the rehabilitation of atrophic maxilla with the zygomatic implants, tilted implants, and standard implants, fractured framework, loosening of screws, fracture of screws, fractured occlusal material, and uncomfortable and bulky prosthesis leading to disconnected abutments.[20] Abutment screw loosening and mobility of prosthesis postrehabilitation with short and ultrashort implants[13] were also suggested. Pieri *et al.* in 2016[32] had minor veneer and porcelain fractures, fracture of ceramic cusp, and abutment screw loosening in their study. Many of the authors did not mention any problems with the delivered prosthesis during the follow-up period. In the study conducted by Maló *et al.* in 2015[10] on the All-on-4

design for short implants, they reported that 7 provisional prostheses fractures and 6 abutment screw loosenings between 2 and 36 months of follow-up occurred. Following the repair of the fractures and tightening of the abutments, the occlusion was readjusted. Throughout the course of the study's follow-up, all circumstances remained stable. There were no new issues reported.

Other mechanical complications that were suggested by the authors were impaired speech and phonetics, implant failure due to denture overload, detachment from the palatal bone at the time of prosthetic loading, decementation, porcelain chipping, and fractures of few prosthetic components.

Summary [Table 3]

The rehabilitation of the maxilla has benefited greatly from scientific and technical advancements for patients. Present-day total edentulous individuals with significant maxillary atrophy have some rehabilitation options, including conventional implants, reconstruction of the bone, or zygomatic implants.[20] A key element in minimizing potential difficulties is the observation of patient anatomical variations and subsequent customization of surgical techniques and implant sections/designs to each patient's anatomy.[21] Extrasinus zygomatic implants have a good success rate with little, if any, problems when used for the rapid rehabilitation of the atrophic maxilla. The studies did, in fact, provide accurate and credible information regarding the survival and success rates of extrasinus zygomatic implants. However, it is evident that additional research on the longevity of implants after 5 years or beyond is required.[22] In cases where tilting of the implants is required, the therapeutic benefit is that they have a shorter cantilever, which allows for ideal load distribution. By providing anchorage to several cortices, longer implants enhance the surface area of bone–implant contact and implant primary stability. For patients with atrophic maxilla, fixed restorations supported by axial and tilted implants may be a viable therapeutic choice.[33,34] Short implants or ultrashort implants should be taken into consideration as a treatment option for the rehabilitation of edentulous jaws in cases with low bone volume, despite the limitations of the studies.[35-39] When selecting a course of therapy, it is important to take into account the absence of surgery and postsurgical issues because there could be negative consequences from augmentation operations. To better comprehend the clinical effectiveness of the treatment alternatives, more well-designed RCTs contrasting the usage of short implants against augmentation operations with longer follow-up will be helpful.[40-42] When unpredictable augmentations are an aspect of an alternate treatment strategy, basal implants can be the treatment of choice in terms of limiting time and patient recalls.[18,43] However, more studies regarding long-term follow-up of this technique are required. Recent advances have made it possible to successfully restore the severely atrophying, edentulous anterior maxilla in a single stage using either customized porous titanium or customized PEEK subperiosteal implants. To ascertain the long-term functional stability of these implants, higher sample sizes and longer follow-up times are advised in research.[44]

Table 3: GRADE evidence[45]

Name of author/year of reference	Study design	Quality of evidence
Yates *et al*., 2014[2]	Observational	Low
Maló *et al*., 2013[34]	Observational	Low
De Santis *et al*., 2015[5]	Observational	Low
Fernández *et al*., 2014[30]	Observational	Low
Aparicio *et al*., 2014[20]	Observational	Low
Rodríguez-Chessa *et al*., 2014[21]	Observational	Low
Peñarrocha *et al*., 2014[16]	Observational	Low
Curi *et al*., 2015[1]	Observational	Low
Taschieri *et al*., 2015[35]	Observational	Low
Felice *et al*., 2015[38]	RCT	Moderate
Maló *et al*., 2015[10]	Observational	Low
Esposito *et al*., 2015[12]	RCT	Moderate
Heuberer *et al*., 2016[17]	Observational	Very low
Dos Santos *et al*., 2016[24]	Observational	Low
Nedir *et al*., 2016[36]	RCT	High
Pieri *et al*., 2016[32]	Observational	Low
Chen *et al*., 2016[41]	Observational	Very low
Nedir *et al*., 2017[37]	RCT	High
Agliardi *et al*., 2017[9]	Observational	Low
Balan *et al*., 2017[31]	Observational	Low
Araújo *et al*., 2017[3]	Observational	Low
Coppedê *et al*., 2017[8]	Observational	Low
Menéndez-Collar *et al*., 2018[33]	Observational	Low
Wagner *et al*., 2018[7]	Observational	Low
Gürlek *et al*., 2019[42]	Observational	Low
Yalçın *et al*., 2020[6]	Observational	Low
Nave and Queralt, 2020[19]	Observational	Low
Almahrous *et al*., 2020[40]	RCT	High
Borgonovo *et al*., 2021[23]	Observational	Low
Amato *et al*., 2020[13]	Observational	Low
Felice *et al*., 2020[15]	Observational	Low
Malchiodi *et al*., 2020[39]	Observational	Low
Aparicio *et al*., 2021[22]	Observational	Low

RCT: Randomized controlled trial

The percentage of variation between trials that is attributable to heterogeneity rather than chance was calculated using the I^2 statistical analysis. Due to heterogeneous data, meta analysis could not be performed.

CONCLUSION

The selection of the various methods that are described over the years for the implant-supported rehabilitation of the severely atrophic maxilla is subjective to the

patient's conditions and the clinician's skills. Most types of implant-supported prostheses yield a high survival and success rate. The prosthetic complications such as screw fracture or loosening, and biologic complications such as sinusitis and peri-implantitis, although few, can be overcome with proper follow-up, and a stable prosthesis can still be achieved in such cases. As the treatment planning depends upon the respective individuals, no one technique can be considered a gold standard. There is, however, a requirement of future clinical and randomized control trials, with longer follow-up period for the correct decision-making while rehabilitating a severely atrophic maxilla.

Known facts

- There are various methods of rehabilitating a patient with severely atrophic maxilla with implant-supported fixed prosthesis
- In cases where bone augmentation procedures are not possible, treatment options such as zygomatic, pterygoid, short, or tilted implant-supported prosthesis can be considered
- The long-term clinical outcomes of such procedures have not been explored and further studies are required for the same.

Additions from this systematic review

- Zygomatic implants have a high success and survival rate
- Rehabilitation with the shorter diameter implants and tilted implants also yields good prosthetic results and stability
- Major biological complications include sinusitis and peri-implantitis, and the prosthetic complications vary from screw loosening to prosthesis fracture. However, these complications can be managed to achieve long-term results
- The treatment of choice is subjective to the patient's conditions and the clinician's skill. An informed decision should be made for the planning of type of implants and the prosthesis.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

The effect of food supplements on completely edentulous women rehabilitated with complete dentures: A randomized controlled trial

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Abstract

Aim: Neglected oral health is a major issue, especially in women of developing countries, leading to early loss of teeth which may further lead to malnutrition, degradation of overall health, and increased chances of osteoporosis. Thus, the aim of this study was to assess the effect of food supplement on masticatory performance, nutritional status, electromyography (EMG) (masseter and temporalis), and bone mineral density (BMD) among women rehabilitated with complete denture.

Settings and Design: Hospital based randomized controlled trial.

Materials and Methods: A randomized controlled trial with 106 women of 45–65 years rehabilitated with complete denture (56 received food supplement and 50 did not receive food supplement) and 52 healthy control was conducted. The outcomes were assessed at baseline and 3 and 6 months of follow up (after complete denture fabrication). Outcomes were measured via masticatory performance, nutritional status (hemoglobin, serum calcium, albumin, and Vitamin D level), EMG of masseter and temporalis muscles, and BMD.

Statistical Analysis Used: Friedman's analysis of variance test was used as a nonparametric test, and the Statistical Package for the Social Sciences version 21.0 at a significance level of 0.05 was used for statistical analysis.

Results: A statistically significant change was observed during follow up for the group with food supplement for BMD, EMG, and masticatory performance. When biochemical parameters were assessed during follow up, no statistically significant change was observed for both groups (with and without food supplement), except for serum calcium level in group which received food supplement.

Conclusion: It was found that the magnitude of effect was remarkably meager in food supplement group which could be perhaps due to less time given for follow up period. Longer duration of trials would yield better results.

Keywords: Bone mineral density, edentulism, electromyography, loss of tooth, masticatory performance, women

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INTRODUCTION

The World Health Organization considered loss of natural tooth or edentulism a disability, which not only affects oral and general health status but also affects quality of life.[1] Although it is an important aspect, it is still an often-overlooked or neglected public health issue, especially for women.[2] Edentulism causes poor chewing efficiency which ultimately leads to malnutrition, degradation of overall health, and increased chances of osteoporosis apart from marked hormonal and metabolic alteration due to menopause influencing calcium metabolism among women, thus leading to osteoporosis.[3] Edentulism is not only responsible for low food intake but also related to selective food consumption, especially with development of a tendency toward intake of soft diet resulting in unbalanced diet or undernourishment. Soft food usually is rich in fat and has low content of micronutrients.[4] There is a decreased intake of protein-rich diet, fruits, and vegetables leading to nutritional deficiency, dietary inadequacies, and debilitation.[5]

With loss of teeth, there is loss of neuromuscular control of the masticatory apparatus. Masticatory apparatus is involved in crushing of food particles into simpler form, which is helped by various facial muscles. Out of several factors, edentulism is one major factor, which affects masticatory performance and a decrease in masticatory performance has been reported in completely edentulous subjects.[6] Electromyography (EMG) of masticatory muscles (like masseter and temporalis) during masticatory movement is important to know effect on chewing cycle but has not been studied for completely edentulous women extensively. A decrease in EMG activity in osteoporotic dentate females was observed in one of the studies.[7] This decrease in masticatory performance in completely edentulous subjects leads to decreased intake of a variety of foods leading to malnutrition,[8] but yet none of the studies has correlated masticatory performance and nutritional status in completely edentulous women.

Thus, the aim of this study was to find out the effect of food supplement in completely edentulous women rehabilitated with complete denture on their masticatory performance, nutritional status, EMG (masseter and temporalis), and bone mineral density (BMD). It was hypothesized that rehabilitation of oral health with complete denture and use of food supplement in edentulous women might improve their overall health and also help in preventing osteoporosis.

MATERIALS AND METHODS

Study design

The study was a parallel-group randomized controlled trial with blinding of participants and outcome assessor. The institutional ethic committee approved the study (977/R cell-11), and the trial was registered in the Clinical Trials Registry of India with registry number CTRI/2014/10/005112. The study was conducted at a tertiary care center in the northern part of India after taking written informed consent from participants. Randomization was done using computer-generated random number (simple randomization) into with and without food supplement group (by author NS). Control group included matched complete dentate females. Allocation concealment was done using sequentially numbered opaque-sealed envelopes. The author (KK) did enrollment of patients, and another author (MK) assigned participants to different groups. All randomized participants were rehabilitated with tissue-supported removable complete dentures. Participants who were given food supplement were not allowed to discuss their treatment with another group. Outcome assessor (SK) was not aware of the treatment given to patients. Sample size was calculated by using ClinCalc using alpha 1%, power of 80%. Reporting guideline for this study is Consolidated Standards of Reporting Trials (CONSORT).

Participants

Female edentulous patients visiting the department of prosthodontics for fabrication of denture were enrolled after fulfilling inclusion and exclusion criteria.

Inclusion criteria

1. Females in the age range of 45–65 years
2. Class I complete edentulous cases (between 2 and 6 months of edentulism)[9]
3. No history of partial/complete denture wearing

Exclusion criteria

1. Any systemic or infectious disease/malignancy
2. Orofacial motor disorder
3. Osteoporosis
4. Taking any food supplement or any kind of restrictions in the diet
5. Psychiatric disorder/dementia, etc.

Exclusion criteria were based on history/medical records of patients. Female attendants with participants who fulfilled all inclusion and exclusion criteria but had all teeth were included as matched control. Matched control participants were subjected to all investigations (nutritional,

EMG, masticatory performance, and BMD) after taking written informed consent.

Intervention

Out of 181 recruited participants, 158 (56 and 50 participants received food supplement or not, respectively, and 52 attendants were healthy matched control) were finally included in the study. Thirty-one participants were excluded as they did not meet the required inclusion criteria. All participants went through the process of fabrication of tissue-supported complete denture and their basic sociodemographic and clinical characteristics were recorded. Participants in food supplement group were advised food supplement (Geria Gold Saffron, Hexagon Nutrition) 1 sachet (25 g) in a lukewarm water (glass of water of 200 mL) per day for 3 months. The composition of food supplement is presented in Supplementary Table 1. This food supplement was chosen as it matched the nutritional components recommended by National Institute of Nutrition, Hyderabad, and approved by funding agency. Other intervention group did not receive any food supplement. After 2 weeks of complaint-free period from postinsertion, baseline values of outcomes were recorded inclusive of biochemical investigations for nutritional outcome (albumin [ALB], hemoglobin, Vitamin D, and calcium); surface EMG of masseter and temporalis muscle; masticatory performance using fractional sieving method; and BMD by dual-energy X-ray absorptiometry (DEXA). Follow-up recording of outcomes was done at 3 and 6 months after baseline recording.

The clinician (BPS) having 8 years of experience in complete denture fabrication did all the clinical procedures in order to avoid interobserver discrepancies. Complete denture was fabricated using selective pressure final impression technique (zinc oxide eugenol) and bilateral balanced occlusion using a semi-adjustable Hanau Wide Vue 183-2 Articulator (Whip Mix Corporation, Fort Collins, USA). Heat-cured acrylic resin (Trevalon, Dentsply India Pvt. Ltd., Bangalore, India) with compression molding technique was used for denture fabrication.

Methods

Assessment of masticatory performance

The masticatory performance was assessed by fractional sieve test using peanut (3 g) as the test food which was developed by Manly and Braley[10] and modified by Kapur and Soman.[11] Participants were instructed to masticate peanuts (20 chewing strokes) and then spit out particles into beaker. They were also asked to rinse their mouth with water and again spit it in the same beaker.[10,12] Peanut particles were stirred gently using a glass rod so that the stuck particles of peanut can get separated. This was then poured and passed through a US standard mesh sieve of 1700 micrometer opening (number 10, standard test sieve, Dual Manufacturing Company, Ludhiana, India). The residue which was settled in the sieve was collected in a beaker, while the filtrate was collected into test tubes which were then centrifuged at 1500 rpm for 3 min.[13] The volume of both filtrate and residue was recorded and the procedure was repeated at 3 and 6 months of follow-up. Masticatory performance was calculated by $F \times 100/F + R$, where *F* and *R* were volume of filtrate and residue respectively.

Assessment of electromyography

Needle EMG signals were recorded with patients sitting in a comfortable office-like chair, arms extended along body and hands placed on thighs. Muscle activity was evaluated by means of EMG recordings of masseter and temporalis muscles on both sides during maximal intercuspation. The surface was cleaned with alcohol and ethyl chloride. Disposable monopolar needle electrodes were inserted into the ventral region of masseter muscle and the anterior portion of temporalis muscle to record signals.[14] EMG signals were made up of superimposed motor unit action potentials.

Assessment of nutritional status

It was recorded by biochemical investigations of the participant's blood serum.

Hemoglobin

It was done to check nutritional deficiency (of iron, Vitamin B12, and folate) in blood with colorimeter by cyanomethemoglobin method using hemoglobin kit (Bio Lab Diagnostics (I) Pvt. Ltd., Boisar, Maharashtra, India).

Serum calcium

This test measured level of calcium in blood. It is used to assess and manage disorders affecting calcium metabolism. It was measured by Arsenazo method using calcium (Arsenazo) kit (Beckman Coulter, Inc., CA, USA).

Serum albumin

This test measured amount of albumin in blood. It was measured by using bromocresol green by ALB colorimetric assay kit (Elabscience, Houston, Texas, USA).

Vitamin D

Serum 25(OH) D concentrations were estimated by radioimmunoassay (DiaSorin Inc., Stillwater, MN 55082-0285, USA; kit, normal range 9.3–37.9 ng/mL). The sensitivity of this assay was 1.5 ng/mL, the within-run coefficient of variation (CV) was 10.5%, and the total imprecision CV was 8.2% at 22.7 ng/mL.

Evaluation of bone mineral density

Total body BMD was assessed using Lunar Prodigy Advance DEXA system (analysis version: 12.30) (GE Healthcare, Madison, WI, USA).

This randomized controlled trial was ended after achieving the goal of sample size and length of follow-up.

Statistical analysis

Since assumptions of repeated measures analysis of variance (ANOVA) were not met, therefore Friedman's ANOVA test was used as a nonparametric equivalent to repeated measures ANOVA, to test several related samples assuming that the underlying variable has continuous distribution. The Mann–Whitney *U*-test was used as a nonparametric equivalent to the *t*-test for two independent samples. $P < 0.05$ was considered significant. Wilcoxon signed-rank test with Bonferroni correction was used as a nonparametric *post hoc* test for the domains whose result was found to be statistically significant. $P < 0.0167$ was considered significant for this test. Since the assumptions of independent sample *t*-test were not met, comparison between patients provided with food supplementation and those who were not given any food supplementation was done using Mann–Whitney *U*-test, which is nonparametric equivalent of independent sample *t*-test.

RESULTS

The baseline characteristic is presented in Table 1. One hundred twenty-nine participants were randomized into with and without food supplements. Follow-up was done at 3 months and 6 months. At 3 months of follow-up, 15 participants were lost, and at 6 months of follow-up, 8 participants were lost due to reasons mentioned in CONSORT flow diagram [Figure 1]. A statistically significant change was observed during follow-up for the group with food supplement for BMD, EMG, and masticatory performance ($P < 0.01$). While, in another group, no change was observed for BMD, but a statistically significant change was observed for EMG and masticatory performance [Table 2]. When both groups (with and without food supplement) and control groups ($P < 0.01$) were compared together, no statistically significant change was observed [Table 3] except for BMD ($P < 0.01$) at all time intervals. When nutritional outcomes were assessed with the period of time, no statistically significant change was observed for both groups (with and without food

Table 1: Baseline sociodemographic characteristics of control and intervention groups

	With food supplement (*n*=67)	Without food supplement (*n*=62)	Control group (*n*=52)
Age (years)	50.5±8.85	51.3±7.9	49.6±7.95
Education			
High school and below	43	39	32
Above high school	16	12	14
Graduation and above	8	11	6
Marital status			
Married	58	57	49
Unmarried	1	0	0
Widow	8	5	3
Duration of edentulism (months)	3.2±1.75	2.9±1.95	NA
BMI	21.3±3.1	22.1±2.9	20.5±1.4

BMI: Body mass index, NA: Not available

Table 2: Comparing changes in outcomes at follow-up from baseline

	Median *Z*-score (IQR)			*P*
	Baseline	First follow-up	Second follow-up	
With food supplement				
BMD	−2.30 (1.90)	−2.10 (1.92)	−2.10 (1.80)	<0.01
EMG temporalis (right)	−0.19 (1.19)	−0.11 (1.23)	0.02 (2.20)	<0.01
EMG Temporalis (left)	0.48 (0.27)	0.50 (0.16)	0.72 (2.01)	<0.01
EMG Masseter (right)	−0.24 (0.61)	0.03 (0.29)	0.04 (1.30)	0.07
EMG Masseter (left)	−0.30 (1.30)	0.08 (0.56)	0.21 (1.75)	<0.01
Masticatory performance	0.10 (0.97)	0.08 (1.01)	0.02 (1.12)	0.04
Without food supplement				
BMD	−2.10 (3.30)	−1.90 (2.95)	−2.10 (3.3)	0.16
EMG Temporalis (right)	−0.06 (1.46)	−0.0682 (0.79)	0.2828 (0.48)	0.03
EMG Temporalis (left)	0.49 (0.27)	0.4554 (0.16)	0.4920 (2.09)	<0.01
EMG Masseter (right)	−0.34 (2.12)	0.068 (1.28)	0.059 (1.32)	<0.01
EMG Masseter (left)	−0.07 (1.37)	0.15 (2.35)	0.17 (2.36)	<0.01
Masticatory performance	−0.002 (1.76)	0.104 (1.18)	−0.264 (1.29)	<0.01

IQR: Interquartile range, BMD: Bone mineral density, EMG: Electromyography

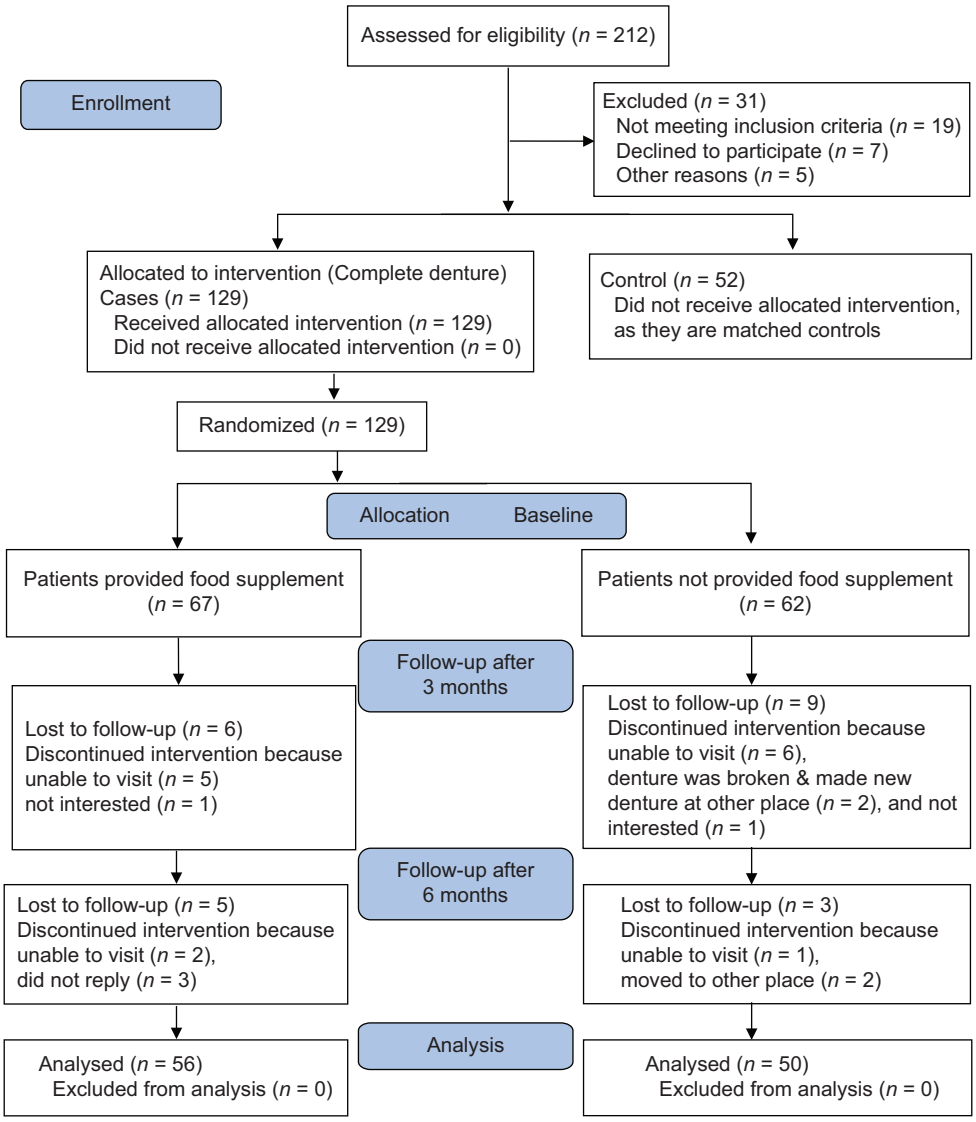

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram

supplement), except for calcium in group which received food supplement [Table 4]. While no statistically significant change was observed for albumin, hemoglobin, Vitamin D, and calcium when both groups (with and without food supplement) and control groups were compared together [Table 5].

DISCUSSION

In this study, effect of food supplement was assessed among completely edentulous women rehabilitated with complete denture. It was hypothesized that after providing food supplement and rehabilitating with complete denture, overall health of edentulous women might improve. However, we have not observed any significant difference in the mentioned outcomes. At baseline, sociodemographic characteristics were similar in intervention and control groups. It showed minimization of confounding variables such as age, duration of edentulism, and body mass index (BMI). This minimization of confounding variables is supported by predefined clear inclusion and exclusion criteria.

Electromyographic recordings of both sides of masseter and temporalis were done at baseline and follow-up in this study. It has been observed[15] that with an increasing age, there is a decrease in thickness of masseter and temporalis muscles and also reduction in muscle strength. Although previous studies have shown that after dental rehabilitation, there was an increase in masseter muscle thickness,[16,17] but in this study, no statistically significant difference was observed for EMG when both groups (with and without food supplement) and control group were compared together. In one study,[17] 3-month follow-up showed

Table 3: Comparing outcomes among three groups at baseline and follow-up

Outcomes	Median *Z*-Score (IQR)		
	Baseline	First follow-up	Second follow-up
EMG Temporalis (right)			
Control	-0.11 (1.59)	-0.11 (1.59)	-0.11 (1.59)
With supplement	-0.19 (1.19)	-0.11 (1.23)	0.02 (2.20)
Without supplement	-0.06 (1.46)	-0.07 (0.79)	0.28 (0.48)
P	0.09	0.15	0.68
EMG Temporalis (left)			
Control	0.23 (0.90)	0.23 (0.90)	0.23 (0.90)
With supplement	0.48 (0.27)	0.50 (0.16)	0.72 (2.01)
Without supplement	0.49 (0.27)	0.46 (0.16)	0.49 (2.09)
P	0.06	0.14	0.21
EMG Masseter (right)			
Control	0.09 (1.81)	0.09 (1.81)	0.09 (1.81)
With supplement	-0.24 (0.61)	0.03 (0.29)	0.04 (1.30)
Without supplement	-0.34 (2.12)	0.07 (1.28)	0.06 (1.32)
P	0.31	0.50	0.85
EMG Masseter (left)			
Control	-0.21 (0.91)	-0.21 (0.91)	-0.21 (0.91)
With supplement	-0.30 (1.30)	0.08 (0.56)	0.21 (1.75)
Without supplement	-0.07 (1.37)	0.15 (2.35)	0.17 (2.36)
P	0.94	0.63	0.54
Masticatory performance			
Control	0.05 (1.51)	0.05 (1.51)	0.05 (1.51)
With supplement	0.10 (0.97)	0.08 (1.01)	0.02 (1.12)
Without supplement	-0.002 (1.76)	0.10 (1.18)	-0.26 (1.29)
P	0.74	0.99	0.95
Bone mineral density			
Control	-0.60 (1.53)	-0.60 (1.53)	-0.60 (1.53)
With supplement	-2.30 (1.90)	-2.10 (1.92)	-2.10 (1.80)
Without supplement	-2.10 (3.30)	-1.90 (2.95)	-2.10 (3.30)
P	<0.01	<0.01	<0.01

Table 4: Comparison of nutritional outcome in with and without food supplement groups at follow-up

Nutritional outcomes	Median *Z*-score (IQR)			*P*
	Baseline	First follow-up	Second follow-up	
With supplement				
Albumin	0.00 (1.25)	0.00 (0.80)	0.00 (1.00)	0.24
Hemoglobin	0.38 (1.38)	0.41 (1.22)	0.00 (1.27)	0.69
Vitamin D	-0.17 (0.81)	-0.22 (0.57)	-0.21 (0.55)	0.30
Calcium	-0.17 (1.17)	0.00 (1.13)	0.09 (1.18)	0.01
Without supplement				
Albumin	0.00 (1.08)	-0.20 (1.60)	-0.33 (1.50)	0.06
Hemoglobin	-0.36 (1.45)	-0.18 (1.05)	-0.27 (1.05)	0.22
Vitamin D	-0.19 (1.09)	-0.23 (1.04)	-0.23 (0.72)	0.16
Calcium	0.14 (1.43)	0.25 (1.38)	0.00 (1.50)	0.88

a statistically significant difference in masseter muscle thickness after rehabilitation with complete denture, but it was conducted on male patients with sample size of 12, and study design was controlled before and after. Maybe if more time (more than 12 months) is given for a follow-up, different results would be observed. A statistically significant difference was observed when groups (with and without food supplement) were compared individually. This study corresponds to a study by Carletti *et al*.[18] which stated that remarkable improvement was observed in muscles of

Table 5: Comparison of nutritional outcomes among with and without food supplement groups with control group at follow-up

Biochemicals	Median *Z*-score (IQR)		
	Baseline	First follow-up	Second follow-up
Albumin			
Control	-0.018 (1.64)	-0.018 (1.64)	-0.018 (1.64)
With supplement	0.00 (1.25)	-0.00 (0.80)	0.00 (1.00)
Without supplement	0.00 (1.08)	-0.20 (1.60)	-0.33 (1.50)
P	0.931	0.754	0.893
Hemoglobin			
Control	0.04 (1.92)	0.04 (1.92)	0.04 (1.92)
With supplement	0.38 (1.38)	0.41 (1.22)	0.00 (1.27)
Without supplement	-0.36 (1.45)	-0.18 (1.05)	-0.27 (1.05)
P	0.941	0.904	0.837
Vitamin D			
Control	-0.42 (1.15)	-0.42 (1.15)	-0.42 (1.15)
With supplement	-0.17 (0.81)	-0.22 (0.57)	-0.21 (0.55)
Without supplement	-0.19 (1.09)	-0.23 (1.04)	-0.23 (0.72)
P	0.930	0.776	0.746
Calcium			
Control	-0.23 (1.59)	-0.23 (1.59)	-0.23 (1.59)
With supplement	-0.17 (1.17)	0.00 (1.13)	0.09 (1.18)
Without supplement	0.14 (1.43)	0.25 (1.38)	0.00 (1.50)
P	0.811	0.857	0.777

mastication (temporalis, masseter, and medial and lateral pterygoid) among patients with edentulism after wearing new prosthesis. Similar results were also observed by Müller *et al*.[19] who advocated the use of denture on both arches, and observed a gain in masseter muscle thickness after 6 months. When Zuccolotto *et al*.[20] compared EMG activity of temporalis and masseter muscles after using sliding plates among edentulous patients, a significant increase was observed, which corresponds to the result of this study. Piancino *et al*.[21] reported EMG activity among edentulous participants and observed that anterior temporalis was larger with old denture than in other conditions. In a systematic review,[22] it was also reported that muscular (temporalis and masseter) activity improved among edentulous subjects after implant treatment. It becomes difficult to compare and generalize the result of this study as there are few studies which have observed EMG activity of temporalis muscle on edentulous women.[22]

Masticatory performance did not show a significant improvement with time in food supplement group than without food supplement group. This could be due to the fact that participants who were taking food supplement may have relied on food supplement rather than on routine food items. Moreover, routine food items trigger activity of masticatory muscles perhaps thereby an improvement in mastication was observed in group which did not receive food supplement.

Due to decrease in bite force and masticatory performance, there is a negative impact of ageing on masticatory activity.

These hinder food chewing and may result in impaired digestive process, nutritional status, and overall health. Few studies[18,23] have shown remarkable improvement in mastication after the use of denture, which could be due to increased occlusal support after dental prosthesis,[18] which is also evident in this study. Although, when masticatory performance was evaluated between the groups, no change was observed. This could be perhaps due to the fact that food supplement had no role in mastication. Because participants of both groups were denture wearers, hence masticatory performance was not affected by food supplement.

In the present study, nutritional outcome was measured by levels of hemoglobin, Vitamin D, calcium, and serum albumin. Out of several markers for assessment of malnutrition, albumin, a serum hepatic protein and one of the most abundant proteins found in blood, is widely used by the clinicians, which is also considered a better predictor of malnutrition as compared to subjective global assessment and BMI.[24]

As mentioned earlier that after tooth loss, older adults avoid hard food items and go for softer food, which generally lack protein, micronutrients, and fiber. In this study, it was observed (after asking the diet consumed before and after wearing denture from participants) that higher protein consumption was missing. Moreover, majority of participants were consuming plant-based protein rather than animal protein, which are less digestible and contain less proportion of amino acids required for growth of the body.[25] This could be the reason of low albumin levels. However, in a recent study, this theory was discarded.[26] Rather authors suggested that no matter what protein source is, it does not affect muscle mass and strength of an individual.[26] In the present study, albumin level was not significantly different within groups, which may be due to no remarkable difference in protein intake before and after complete denture.

Furthermore, it was also observed that participants who received food supplement were relying more on food supplement rather than on routine food items. In a study,[27] it was observed that dietary protein is considered a crucial factor in assessing serum albumin. The authors further observed that nutritional supplement could only be favorable in participants who have low albumin levels (less than a normal range of 3.4–5.4 g/dL).[27] This study showed a similar finding that there was no difference in albumin levels after providing food supplement.

Vitamin D levels were found to increase in both groups. However, a significant rise was observed in group with food supplement, since they were consuming Vitamin D as supplement. An average time taken in a healthy individual to raise the level after taking supplement for Vitamin D is 2–3 months,[28] and this could be a reason for low level of Vitamin D at baseline. In the group without food supplement, it may take longer time as no dietary instructions were given nor change in lifestyle or Vitamin D-rich diet was advocated.

Calcium levels were also observed to be different in both groups. The group which did not receive any food supplement showed a statistically significant difference. This could be due to participants relying more upon food supplement and not consuming calcium-rich diet.

It was observed that the group which received food supplement showed a statistically significant difference in BMD. It was found that Vitamin D supplementation reduces tooth loss in the elderly and increases BMD.[29] A statistically significant difference was also observed between groups. It was observed that either Vitamin D with calcium or calcium alone is considered a basic treatment in managing osteoporosis, bone loss, or fractures.[30,31] Hence, BMD was found to increase which is relatable to our study. In a meta-analysis, an association between Vitamin D, calcium, and BMD was also found.[32] The authors have observed changes in BMD after rehabilitation with complete denture, but studies on with food supplement were not found so far.[33]

In this study, not much change in nutrient levels was observed in both groups as dietary counseling was not provided to patients either before or after recruitment. Moreover, changing dietary habits with types of food consumed may be a multifactorial adaptation process that takes much longer than a year for a measurable effect.[34] In addition, dietary counseling can improve fruit and vegetable intake in an edentulous individual.[35] Thus, a randomized controlled trial in which patients are followed for a longer period of time and in which they are given specific individual dietary counseling might maximize the possibility of dietary improvement.[2] In this study, patients were recruited who visited a hospital for complete denture fabrication. Hence, generalizations of the study finding need to take this point into consideration. This study adds evidence in scientific literature that food supplement may not be the best choice to give each completely edentulous patient after rehabilitation with complete denture. Regular use of complete denture itself may be sufficient enough to improve nutritional status.

CONCLUSION

It was observed that majority of outcomes were not changed significantly for food supplement group than

without food supplement group in completely edentulous women rehabilitated with complete denture.

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Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: Composition of food supplement

Nutritional facts	Units	Per 100 g powder (approximate)	Per serving 25 g powder (approximate)
Caloric content	kcal/kJ	457/1913	114/478
Calories from fat	kcal/kJ	153/641	38/160
Nutrients			
Total carbohydrates	g	55	13.75
Dietary fiber	g	1	0.25
Sugar	g	0	0
Protein	g	21	5.25
Total fat	g	17.00	4.25
Saturated fats	g	10.57	2.64
Monounsaturated fatty acid	g	4.28	1.07
Poly unsaturated fatty acid	g	0.71	0.18
Trans fat	g	0	0
Cholesterol	mg	0	0
Vitamins			
Vitamin A	IU	2000	500
Vitamin D	IU	200	50
Vitamin C	mg	40	10
Vitamin E	mg	10	2.5
Niacinamide	mg	10	2.5
Vitamin B2	mg	3	0.75
Vitamin B6	mg	2	0.5
Vitamin B1	mg	1.2	0.3
Folic acid	µg	200	50
Vitamin K	µg	70	17.5
Vitamin B12	µg	2	0.5
Minerals			
Calcium	mg	600	150
Phosphorus	mg	475	119
Magnesium	mg	200	50
Iron	mg	14	3.5
Zinc	mg	10	2.5
Iodine	µg	75	19
Herbal extract			
Dry extracts equivalent to			
Glycyrrhiza glabra	mg	2000	500
Withania somnifera	mg	2000	500

Original Article

Accuracy of models of partially edentulous arches obtained by three-dimensional printing: An *in vitro* study

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Abstract

Aim: The aim of this study was to evaluate the accuracy of models of partially edentulous arches obtained by three-dimensional (3D) printing.

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

Materials and Methods: Fifteen partially edentulous models were evaluated, using two methods of measuring dimensions: virtual, using the Standard Tessellation Language files of the models and software (control group), and physical, through printing the models and digital caliper (test group). For both methods, measurements were made regarding the dimensions of the teeth (width and length – buccal/lingual or palatal/occlusal) and distances between the teeth.

Statistical Analysis Used: For the variable of linear measurements (width and length) and distances between teeth of the same hemiarch, the Wilcoxon test was used, while for the variable between opposite hemiarches, the paired *t*-test was used.

Results: In the evaluation of the linear measurements, a significant difference was observed only when the width of the molar tooth was analyzed ($P = 0.014$). When the buccal length was measured, all teeth had linear measurements provided by the virtual method that was lower than the physical ($P = 0.000$), as well as the lingual/palatal length in incisors ($P = 0.003$) and molars ($P = 0.009$) and in total ($P = 0.001$). As for the analyses between teeth, no difference was identified between the measurements provided by the virtual method compared to the physical one.

Conclusions: The 3D printer used to print partially edentulous models provided linear distortions in the teeth but without changes in the distances between teeth of the same hemiarch and between teeth of opposite hemiarches.

Keywords: Accuracy, dental arch, dental models, digital dentistry, partial-arch, three-dimensional printing

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INTRODUCTION

The use of the digital workflow in dentistry has gained increased acceptance in clinical practice. Performing intraoral scanning directly on the patient or scanning conventional plaster models allowed the digitization of the dental situation.[1] With this technology, the scanned dental arches can be stored as a three-dimensional (3D) surface file, in Standard Tessellation Language (STL).[2] Thus, it is possible to realize a fully digital workflow, incorporating computer-aided design, and computer-aided manufacturing (CAD/CAM).[3]

In this context, rapid prototyping, also known as 3D printing or manufacturing by addition, is often used in areas such as dental prostheses, oral and maxillofacial surgery, oral implant dentistry, orthodontics, endodontics, and periodontics. In oral rehabilitation, CAD/CAM systems and rapid prototyping have been used for years to manufacture inlays, onlays, crowns, fixed partial dentures, implant prostheses, and maxillofacial prostheses.[4] Recently, they have also been used in stages for the manufacture of removable prostheses, including removable partial dentures (RPDs). In these cases, the implementation of the digital workflow in the construction of the structure of the RPDs took place mainly in the scanning and planning of the prosthesis,[5] but it still has limitations related to the digital processing of the prosthesis base. Therefore, a partially digital workflow is usually used, with the need to print the working model for processing the prosthesis base.

However, the accuracy of printed models depends on factors, such as the acquisition and processing of images of the hard and soft tissues of the mouth and processes involved in the manufacture and postprocessing of these materials. Furthermore, models obtained by various printing techniques are affected by polymerization shrinkage.[1,6] For this reason, recent studies have evaluated the accuracy of full-arch dental models fabricated using different 3D printing technologies. A systematic review by Etemad-Shahidi *et al*.[6] indicated that the accuracy of full-arch dental models obtained by 3D printing ranged between <100 and >500 μm, with most of the evaluated models being clinically acceptable. Despite this, the authors emphasized that models considered clinically acceptable for orthodontic purposes, for example, may not be acceptable for dental prosthetic work or other procedures requiring high accuracy.

However, no studies were found in the literature that specifically evaluated the accuracy of printed models of partially edentulous arches for the purpose of making removable partial dentures with a partially digital flow, which requires accurate models for the laboratory processing steps of the prosthesis. In this sense, the present study aimed to evaluate the accuracy of a 3D printer for printing partially edentulous models. The null hypothesis (H0) consists of the lack of accuracy of the 3D printer for the printing of partially edentulous models. The alternative hypothesis (H1) indicates that the printing process leads to linear distortions in the partially edentulous model.

MATERIALS AND METHODS

This is a cross-sectional study, which was based on the guidelines of STROBE (The Strengthening the Reporting of Observational Studies in Epidemiology).[7] The digital archive bank of STL files from a Dental Prosthesis Laboratory, with the patients' names blinded, was evaluated in the search for files of partially edentulous arches that presented at least 1 incisor, 1 canine, 1 premolar, and 1 molar. Files that showed significant coronal destruction and whose scanning was not performed satisfactorily were excluded, to present a fully complete model. This study was submitted to the Research Ethics Committee (CEP) of the Federal University of Rio Grande do Norte (UFRN), approved with protocol opinion number 4.745.226.

Materials and models' fabrication

A total of 15 files were selected, included in the sample, and submitted to two methods: (V) virtual, control group and (P) physical, test group of this study. The physical models were made from a printer an Anycubic Photon Mono SE (Anycubic, Shenzhen, Guangdong, China) and printing resin for models (PrintaX, OdontoMega, Ribeirão Preto, São Paulo, Brazil), using LCD technology, with the following parameters: layer height (0.05), amount of fixation layer (6), base fixation/bottom exposure time (25–40 s), normal exposure time/exposure time (2–3 s), and with orientation of horizontal printing, being evaluated 3 months ± 15 days after printing; while the virtual ones were evaluated by the GOM Inspect 2019 software (GOM GmbH – Schmitzstraße, Braunschwei, Germany).

Analysis of the accuracy

Initially, the measurements were standardized, considering the tooth and the distances between teeth, for both methods (V and P). For the tooth, measurements of width at which the anterior teeth were measured from the mesioincisal to distoincisal angle and the posterior teeth, from mesioocclusal to distoocclusal angle. Visualized through lateral [Figure 1a] and occlusal view [Figure 1b]. As for the length, the incisors were measured from the cervical to the incisal edge; the canines, from the cervical to

the point of union of the two buccal edges; the premolars, from the highest point of the buccal cusp to the highest point of the lingual or palatal cusp; on molars, from the highest point of the distobuccal cusp to the highest point of the mesiolingual or mesiopalatal cusp [Figure 1c-g].

For the distances between teeth, the distances between teeth of the same hemiarch and the distances between teeth of opposite hemiarches were measured, considering as a reference point the apex of the highest cusp (molars) and the apex of the palatine or lingual cusp (premolar). These distances between teeth still had the coding of the teeth involved, being: 1 (incisor), 2 (canine), 3 (premolar), and 4 (molar), in the distances between teeth of the same hemiarch: 1-3, 1-4, 2-3, 2-4, 3-4, and 4-4 [Figure 1h] and opposite hemiarches: 1-1, 1-3, 1-4, 2-2, 2-3, 2-4, 3-3, 3-4, and 4-4 [Figure 1i].

Then, an examiner (L. M. C. M. D.) was subjected to calibration. The examiner applied the virtual measurement method to 10 models, using the "straight line" measurement tool of the Tool of the GOM Inspect 2019 software (GOM GmbH – Schmitzstraße, Braunschwei, Germany), and after 15 days, the physical method, with the aid of a digital caliper, as described by Aly and Mohsen,[8] with a precision of 1 μm, considering the measurements described above.

The agreement between the methods was obtained using the Interclass Correlation Coefficient (ICC), the ICC mean and the standard deviation at a significance level of 95%, considering as no agreement (0), poor (0.1–0.20), weak (0.21–0.40), moderate (0.41–0.60), substantial (0.61–0.80), almost perfect (0.81–0.99), or perfect (1).[9] The concordance between the two methods was evaluated, obtaining a Kappa value of 0.864 (distance between teeth of the same hemiarch), 0.855 (distance between teeth of opposite hemiarches), physical method (width: 0.975; buccal length: 0.961; occlusal length: 0.983), and virtual method (width: 0.980; buccal length: 0.987; occlusal length: 0.988).[10]

With the examiner precalibrated, the data collection of the variables of this study began, using the same methods and means reported for calibration. The models were randomly randomized considering the method (V and P). Then, the collection was submitted in two different time periods: (T1) 15 models and (T2), after 15 days (wash-out period), the same models were evaluated to blind the examiner so that he would not remember the answers previously collected.

Statistical analyses

The statistical software IBM SPSS (Statistics V22.0; IBM Corp - Armonk, New York, United States) was used for

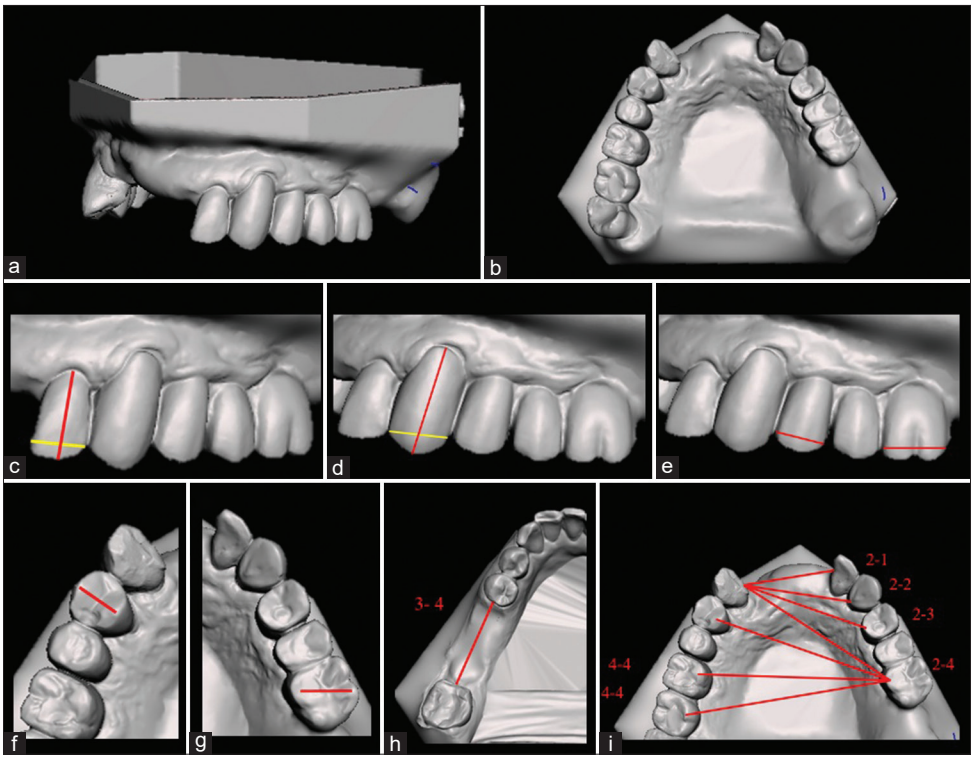

Figure 1: Measurements performed by the virtual and physical method. (a) Virtual model overview– lateral view, (b) Virtual model overview– occlusal view, (c) Measurement per tooth (incisor) in width (yellow line) and length (red line), (d) Measurement per tooth (canine) in width (yellow line) and length (red line), (e) Measurement per tooth (premolar and molar) in width (red line), (f) Measurement per tooth (premolar) in length (red line), (g) Measurement per tooth (molar) in length (red line), (h) Measurement of distance between teeth of the same hemiarch, (i) Measurement of distances between teeth of opposite hemiarches

data tabulation and analysis. The nonnormality ($P < 0.05$) was observed when the linear measures (per tooth) and distances between teeth of the same hemiarch of the models were measured by the physical and virtual methods. Therefore, the Wilcoxon test ($P < 0.05$) was used to evaluate the effect of the impression on the accuracy of the linear measurements provided by the two tested methods, both when the tooth was considered the subject and the distances between teeth of the same hemiarch. When evaluating the distances between teeth of opposite hemiarches, the data showed normal distribution ($P > 0.05$), allowing the paired *t*-test to be performed, with a statistical significance of $P < 0.05$.

RESULTS

Fifteen partially edentulous models were evaluated, consisting of 60 teeth, 15 of which were incisors, canines, premolars, and molars (each). Measurements consisted of 63 distances between teeth of opposite hemiarches, distributed in 9 possibilities of crossing between the evaluated hemiarchs, and 26 distances between teeth of the same hemiarch in 6 measurement possibilities.

In the evaluation of the linear measurements, per tooth, between the physical and virtual methods, a significant difference was only observed when the width of the molar tooth was analyzed ($P = 0.014$). When the buccal length was measured, all teeth had linear measurements provided by the virtual method that was lower than the physical ones, impacting the total assessment, which disregards each tooth individually ($P = 0.000$). This was also observed when measuring the lingual/palatal length in incisors ($P = 0.003$) and molars ($P = 0.009$) and in total ($P = 0.001$) [Table 1]. As for the analysis between teeth of opposite hemiarches [Table 2] and of the same hemiarch [Table 3], no difference was identified between the measurements provided by the virtual method compared to the physical method.

DISCUSSION

The null hypothesis (H0), which consists of the lack of accuracy of the 3D printer for the materialization of partially edentulous models, and the alternative hypothesis (H1), which indicates that the printing process leads to linear distortions in the partially edentulous model, were fully accepted. In the present study, it was observed that the linear measurements of molar teeth width and buccal and/or lingual/palatal length of all teeth underwent statistically significant changes. However, no statistically

Table 1: Linear measurements of the partially edentulous models by the physical and virtual method per tooth and the total

Measurements	*n*	Method/tooth											
		Incisor, med (Q25–75)		*P*	Canine, med (Q25–75)		*P*	Premolar, med (Q25–75)		*P*	Molar, med (Q25–75)		*P*
		Physical method	Virtual method		Physical method	Virtual method		Physical method	Virtual method		Physical method	Virtual method	
Width	15	5.80 (5.06–7.55)	5.82 (5.23–7.69)	0.638	6.69 (6.38–6.98)	6.82 (6.49–7.40)	0.320	6.77 (6.41–7.46)	6.65 (6.44–6.97)	0.211	10.31 (9.65–11.24)	10.26 (8.86–10.90)	0.014*
Length													
Vestibular	15	7.98 (7.31–9.70)	8.55 (7.68–9.66)	0.004*	9.24 (8.41–9.98)	9.55 (8.52–10.39)	0.002*	7.77 (7.09–8.36)	8.04 (7.67–8.68)	0.005*	6.95 (5.70–7.78)	7.02 (5.88–8.01)	0.020*
Lingual/palatine	15	8.84 (8.10–9.64)	9.11 (8.23–9.79)	0.003*	9.03 (8.35–9.81)	8.67 (8.25–9.74)	0.865	4.74 (4.08–5.47)	4.82 (4.11–6.74)	0.147	5.04 (4.50–6.23)	6.76 (4.68–7.38)	0.009*
Occlusal	15	999 (999–999)	999.00 (999.00–999.00)	1.000	999.00 (999.00–999.00)	999.00 (999.00–999.00)	1.000	5.02 (4.39–6.10)	4.82 (4.58–6.15)	0.551	7.73 (7.26–9.16)	8.02 (6.68–9.11)	0.532

Measurements	*n*	Method/tooth					
		Total, med (Q25–75)		*P*			
		Physical method	Virtual method				
Width	60	6.95 (6.26–9.21)	6.96 (6.29–8.75)	0.132			
Length							
Vestibular	60	7.94 (7.11–9.13)	8.31 (7.47–9.49)	0.000*			
Lingual/palatine	60	7.0 (4.93–8.98)	7.75 (5.43–9.17)	0.001*			
Occlusal	60	504.82 (6.57–999.00)	504.90 (6.52–999.00)	0.877			

*Statistical significance. Med (Q25–75): Median (quartile 25–75), *P*: Wilcoxon test

significant difference was identified in the evaluations between teeth, either from the same hemiarch or between opposite hemiarches.

In this context, the accuracy of models for making partially removable prostheses is important, since the printed models can be used to design and/or plan the metallic structure. This model is critical to the adaptation to the patient's oral tissues to avoid tooth movement and discomfort, which may result in the patient not using this type of prosthesis.[11] The correct functioning depends on an acceptable adaptation of the RPDs.[12] Changes to the printed model, therefore, may compromise the accuracy of these steps.

As in previous studies, the virtual models in STL were used as a control group, while models made by 3D printing were used as a test group.[13,14] In the present study, linear measurements of the width and length of the groups of teeth evaluated were performed due to the importance of these measures, especially for the planning stage of the components of removable partial dentures, which are important for issues such as the guide plane and undercut areas. The increased molar width found in this study may result in a maladaptation of a retention or opposition clip, for example, if made from one of these models, may be larger than necessary. Furthermore, changes in the buccal and lingual/palatal length of the teeth can also interfere with the guide plane of dental elements, staples, and larger connectors. In this study, these lengths in the printed models showed significant distortions, which can influence the adaptation and, consequently, the success of the rehabilitation treatment.

In addition, measurements between teeth were evaluated which are also relevant during the planning of prosthetic components. The measurement between teeth of opposite hemiarches is relevant because it may be related to larger connectors which occupy the entire patient's arch, just as the distance between teeth of the same hemiarch may be related to components such as the saddle, which may occupy only a hemiarch. In this study, it was observed that the evaluations between teeth did not present statistically significant changes, which may indicate these structures alone would not be influenced by the distortions found in the models. This is advantageous data when referring to the use of printed models for removable partial dentures since the dimensional accuracy of the complete arch is necessary for the adequate seating of the metallic structures that conventionally involve the two hemiarches.

Therefore, several factors may have influenced the distortions found in this study. A systematic review published by Etemad-Shahidi *et al*.[6] indicated that 3D printing techniques affect the accuracy of printed models, with stereolithography (SLA) and digital light projection (DLP) being the printing technologies with the highest accuracy. The study by Tsolakis *et al*.[15] showed that DLP 3D printers have greater accuracy for printing dental models than LCD (liquid crystal display). The study by Venezia *et al*.,[16] in turn, found that SLA technology had less distortion when compared to LCD and DLP. In this study, an LCD printer was used, and this printing technique could be one of the factors that contributed to the observed distortions.

In addition, another factor that can influence the accuracy of printed models is the material of choice. The study by Al-Qarni and Gad[17] evaluated three types of printed resin,

Table 2: Distances between teeth of opposite hemiarches in partially edentulous models measured by physical and virtual method

Distances between opposite hemiarches	Measurement method, average (SD)			
	n	Physical	Virtual	*P*
1–1	1	17.44 (0)	17.72 (0)	-
1–3	2	33.22 (0.32)	32.88 (1.32)	0.718
1–4	7	49.67 (7.47)	49.11 (7.23)	0.656
2–2	1	34.21 (0)	34.07 (0)	-
2–3	2	43.22 (0.59)	42.94 (0.31)	0.405
2–4	6	48.61 (10.34)	48.77 (10.30)	0.533
3–3	9	41.48 (8.30)	40.57 (7.01)	0.107
3–4	19	49.84 (7.28)	50.70 (6.30)	0.502
4–4	16	54.18 (5.25)	54.20 (5.11)	0.957
Total	63	48.11 (9.40)	48.18 (9.18)	0.867

1: Incisor, 2: Canine, 3: Premolar, 4: Molar, SD: Standard deviation, *P*: Paired *T*-test

Table 3: Distances between teeth of the same hemiarch in partially edentulous models measured by physical and digital method

Distances between the same hemiarch	Measurement method, med (Q25–75)			
	n	Physical	Virtual	*P*
1–3	1	-	-	-
1–4	2	25.90 (16.75–22.09)	32.21 (17.29–31.02)	0.180
2–3	2	16.95 (12.58–12.84)	17.04 (12.75–12.81)	0.655
2–4	4	37.78 (21.89–44.40)	38.85 (22.06–44.82)	0.465
3–4	15	21.99 (19.83–23.35)	20.10 (16.30–23.20)	0.221
4–4	2	22.47 (16.31–17.40)	19.62 (14.01–15.42)	0.180
Total	26	22.02 (17.87–27.54)	20.33 (17.06–23.96)	0.459

1: Incisor, 2: Canine, 3: Premolar, 4: Molar, *P*: Wilcoxon test, Med (Q25–75): median (quartile 25–75)

and it was observed that the material used influenced the accuracy of 3D printing. In this study, impression resin for models (PrintaX, OdontoMega, Ribeirão Preto, SP, Brazil) was used, which may also have influenced the accuracy of dental models. Furthermore, print orientation can also impact accuracy. Revilla-León *et al*.[18] evaluated impression of occlusal devices with orientations of 0°, 45°, 70°, and 90°, and it was observed that the impression orientation of 0º presented the highest precision among the tested groups. To avoid this bias, all models in this study were printed with the 0° orientation (horizontal).

Other factors that can also impact the accuracy of printed models are time and storage conditions. Lin *et al*.[13] indicated that 2-week storage time after impression affected the accuracy of full-arch models, while Yousef *et al*.[19] observed that fully dentate models stored under light exposure for 3 months were less accurate than those stored in closed boxes for the same period of time. In this sense, measuring the models after 3 months ± 15 days of storage, combined with exposure to light, may have contributed to the distortions found in the present study.

Despite the statistically significant differences observed in this study, it is not possible to state that this will have clinical implications of misfit in prostheses made from these 3D printing models, requiring clinical studies to make RPDs from printed models and evaluate the fit, and clinically rehabilitative success. A systematic review[5] indicated that the digital technique for making structures for removable partial dentures is accurate, with clinically acceptable misfits (<311 μm).

As a limiting aspect of this study, there is the use of only one 3D printer, a printing resin, and a printing orientation of only 0°. Therefore, future studies are needed to assess the impression accuracy of partially edentulous models made from other materials and impression methods, as well as clinical trials to assess whether the distortions found in dental models have a clinical impact.

CONCLUSIONS

Although this *in vitro* study was carried out with only one 3D printer, one type of resin, and one impression orientation, the results can contribute to the planning of removable partial dentures, since it was verified that the distortion in the size of the teeth can influence the clasps of retention. However, as there was no change between the hemiarches, components such as the saddle and the major connector would not suffer interference. Based on the results found and the limitations of this study, it can be concluded:

1. Partially edentulous models made from 3D printing may present significant linear distortions of the teeth, especially in the width of the molar teeth and buccal and/or lingual/palatal length of the dental elements
2. 3D printing does not seem to significantly change the measurements between teeth of the same hemiarch and of opposite hemiarches of the printed partially edentulous models.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

An investigation of the effects of topical sunscreen protection products under natural weather conditions on intrinsic color stability in maxillofacial silicones

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Abstract

Aim: The relatively short lifespan of maxillofacial prostheses (ranging from 3-24 months) is mostly a result of colour instability of silicone elastomers caused by ultraviolet (UV) radiation, requiring frequent remakes. An improvement in colour preservation could result in fewer remakes, thus saving time and money for both clinician and patient. In the quest for a suitable colour protection method, sunscreen protection products were considered; the most recent study on this subject was carried out in 1994, albeit using a low protection factor. The aim of this research was to determine if there is value in using topical sun protection products on extraoral silicone prostheses to prevent colour degradation.

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

Materials and Methods: Three commercially available sunscreen products were studied, Riemann P20, Boots Soltan, and Garnier Ambre Solaire all with a sun protection factor of 50. A total of 144 silicone elastomer samples were produced using a Caucasian (light) shade 1.2 ($n = 72$) and dark skin shade 3.2 ($n = 72$) from the Technovent Ltd. Reality Shade range. Each shade group ($n = 72$) was divided into three groups to be subjected to outdoor weathering ($n = 24$), indoor ($n = 24$), and dark storage ($n = 24$). Within each environmental group, samples were divided into groups of six samples ($n = 6$) to receive the three sunscreens plus a control group with no sunscreen. The CIEL* a* b* formula was used to obtain the color measurements.

Statistical Analysis Used: One way ANOVA test and Tukey's HSD test for multiple comparisons was used to analyse the data.

Results: The ΔE values had changed for all samples throughout the aging process.

Conclusion: Soltan showed promising results in protecting the dark-shaded samples in the outdoor environment only.

Keywords: Color change, maxillofacial prosthesis, pigments, silicone elastomer, sunscreen

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INTRODUCTION

Maxillofacial prosthetics have been used for many centuries to treat the esthetic – and in some cases functional – aspects of a range of defects caused by neoplasms, trauma, and congenital factors[1] but gained recognition and warranted further research following the First World War.[2]

Silicone elastomers have been found in recent decades to display the properties desired for the manufacture of such prostheses, namely, ease of work, ability to mimic facial skin surface and color, biocompatibility, and material properties, e.g., good tear and flexural strength.

A well-constructed prosthesis further addresses psychological aspects, not being recognized immediately among the general public as a prosthesis wearer. This requires a good fit of the prosthesis and realistic appearance, both in shape and color.[3] The margins of the prosthesis should blend in with the surrounding skin tissue, hiding the silicone boundaries, thus resulting in a natural appearing face that should not warrant staring, allowing the patient to accept their new appearance. A successful prosthesis should enable a patient to be socially accepted and lead a normal life.[4-6]

It is important to provide patients with prostheses that stay color stable for as long as possible, as degradation of this aspect of prosthetic rehabilitation is the first indicator that the device is an artificial object.

One major drawback of silicone elastomers is their tendency to degrade relatively quickly, depending on the frequency of wear, patient handling, environmental factors, retention method, and cleaning regime.[7] The fine margins are easily torn or damaged if not handled carefully, biofilm buildup from insufficient cleaning can degrade and discolor the tissue-facing surface of the prosthesis, while disinfection solutions can damage the material integrity.[8]

However, the majority of prosthesis replacements are due to color fading, a common problem among the profession, limiting the effective lifespan of the device and requiring remakes, thus costing time and money for both NHS Trust and patient.[9]

Coloring is achieved both intrinsically and extrinsically, and both methods are subject to color degradation, although more evidence of intrinsic color failing can be found in literature and will be discussed in this paper.[8,10-17]

Improvements can be made to increase color stability with the use of certain nano opacifiers, ultraviolet (UV) absorbers, photoprotective agents, and use of inorganic pigments and metal oxides;[9] some of these have been reported to be effective.[16,18-21]

Intrinsic coloring refers to pigments that are added before the curing process and thus become incorporated within the silicone matrix on polymerization. Colors can be layered to replicate the natural appearance and depth of skin.[7] In addition, flocking (small fibers) can be added at this stage, to break up the uniformity of the color and provide a three-dimensional effect. The different colored rayon fibers that constitute flocking allow multiple refractions, transmissions, and reflections between and within the fibers that visually recreate the subtle tones of cutaneous tissue.[22] Intrinsic colors have proven to have more longevity compared to extrinsic coloring.[23] When working with a clear base silicone, pigments are added either in premixed skin tones or starting with arrange of single colors; the method used may depend on the reconstructive scientist's preference and/or skill.

Although many factors contribute to the degradation of prostheses, color change has been described as the single most reason for remakes; moreover, UV light has been identified as one the main factors, resulting in photodegradation causing the absorption of photons and effectively changing the molecular structure.[11,12,14,15,24-27] Silicone materials absorb the energy of UV radiation, resulting in the breaking of polymer chains, production of free radicals, and subsequently, atomic weight loss.[28] These free radicals can then further degrade the material in terms of strength, flexibility, and color.[28]

Consequently, research is ongoing in attempting to find a suitable protection method against color degradation caused by sunlight and attempts have been made to incorporate UV-light absorbing, stabilizing, and opacifying agents into the silicone at the prepolymerization stage, to improve light fastness.

This study seeks to investigate the efficacy of commercially available sunscreen applied to prostheses as part of a patient's daily routine to prolong the life of these custom-made devices, as an easy and cost-effective solution to color preservation.

MATERIALS AND METHODS

The study was approved by the Manchester Metropolitan University Ethics Committee (2021-32756-26602) and University Hospitals Dorset.

Initially, a pilot study was carried out to determine the minimum required thickness of samples, where $P < 0.4$ when sample measurements were taken against black and white backgrounds; this value was reached at 6 mm [Figure 1] and thus eliminated the requirement to measure each sample against different backgrounds. A total of 33 circular discs (Ø35 × 6 mm) were made of carving wax and invested with white Type IV dental stone (GC Fujirock EP Premium) in an aluminum flask. After setting, the wax was eliminated, and the molds were sprayed with a separating medium (Medimold). Silicone M511 (Reality Series, Technovent Ltd.) shades 1.2 (Caucasian) and 3.2 (dark skin) were mixed with M514 Anti Slump Agent (Technovent Ltd.) at the ratio of 0.45 g per 40 g of silicone, to avoid porosities. Weight measurements were performed using a digital scale. The silicone was catalyzed with M511 Part B (Technovent Ltd.), mixed with a centrifugal mixer for 30 s at 3,300 revolutions per minute, and repeated three times, to prevent heat build through friction, potentially partially curing the material.

The molds were then packed and left to cure at room temperature for 24 h, until a total of 72 silicone discs for each shade had been produced. After removal from the flasks, the specimens were carefully removed and washed with water and soap and then trimmed with scissors. The samples were randomly assigned to 24 groups [Figure 2].

The sample size $n = 6$ per group was based on previous published studies in the field of color stability investigations;[13,16,20,21,29-31] in addition, section 6 of ASTM G24-13 recommends a minimum of six samples.[32]

The obtained data were averaged within each group ($n = 6$) and compared among groups by using one-way analysis of variance (ANOVA) with the Tukey's *post hoc* honestly

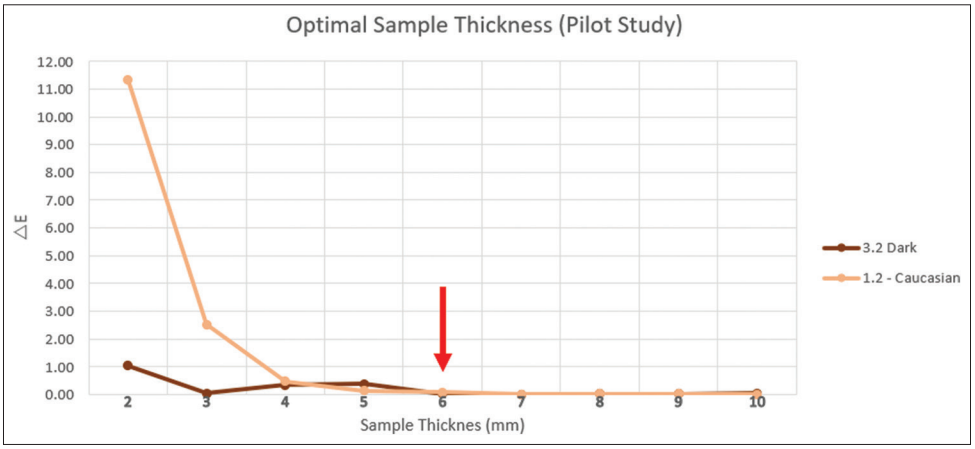

Figure 1: Pilot study results of required sample thickness; the red arrow depicts optimal sample thickness of 6 mm

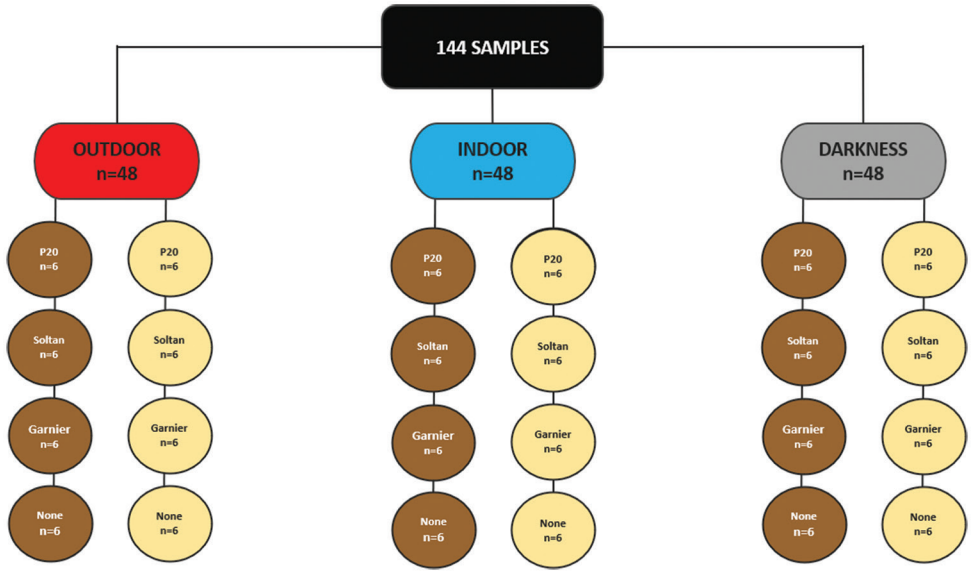

Figure 2: Sample group arrangement

significant difference (HSD) test (a = 0.05). Microsoft Excel was used for the analysis.

All samples were left to post cure for 24 h. Samples to be exposed to the outdoor environment (n = 48) were mounted on a reinforced glass plate, whilst samples stored indoors (n = 48) and in complete darkness (n = 48) were mounted in clear plastic boxes; water-based medical adhesive (Secure Silicone Adhesive B-400, Technovent Ltd.) was used to attach the samples to their respective backgrounds.

The weathering chamber was manufactured according to ASTM G 24-05 (2013) guidelines for the samples exposed to natural weathering conditions.

Three commercially available sunscreen products were studied, Riemann P20 Sunscreen Lotion, Boots Soltan Protect and Moisturise Suncare Lotion, and Garnier Ambre Solaire Protection Lotion, all with sun protection factor (SPF) of 50. A total of 144 silicone elastomer samples were produced using Caucasian shade 1.2 (n = 72) and dark skin shade 3.2 (n = 72) from the Spectromatch Reality Shade range. Each shade group (n = 72) was divided into three groups to be subjected to outdoor weathering (n = 24), ambient (n = 24), and dark storage (n = 24). Within each environmental group, samples were divided into four groups (n = 6) to receive the three sunscreens plus a control group with no sunscreen. The CIEL* a*b* formula was used to obtain the color measurements. Samples were cleaned every morning for 6 months and the sunscreen re-applied; to ensure consistent quantities of sunscreen were being applied, a blunt needle syringe was used to dispense a 0.02-g drop of each substance onto the samples, which was then spread evenly across using an oval-shaped spatula. A colorimeter (BELEY 8 mm Digital Precise Portable Color Analyzer Colorimeter) was used to record L* a* b* values at the beginning of the study and every consecutive 7th day. As the research was conducted during the pandemic, a spectrophotometer was not available for weekly use; colors were measured with a spectrophotometer at the start of the study, at the halfway point, and at the end, recording L* a* b* values. Every morning, all samples were cleaned using first an oil-based face cleanser with a soft sponge followed by soap, to remove any oil remnants from the cleanser, and left to dry for 30 min before returning to their respective environments.

After the final timescale measurements, all samples were steam cleaned, to remove any potential contaminants, and further readings were taken to finalize the study.

A summary of daily weather data in Swindon, Wiltshire, for the period of outdoor weathering was recorded during this study from the Met Office [Table 1].

RESULTS

The color stability of all test groups was adversely affected by natural outdoor weathering, indoor and darkness storage, and application of sunscreen. Effect of highly visible color change was perceived by various individuals without the use of color measures.

A one-way ANOVA was performed to compare the effect of topical sunscreen on color change ($\triangle$E), for combinations of two different silicone shades (dark shade: 3.2; light shade: 1.2) and three different environments (outdoor, indoor, and darkness). Tukey's HSD test for multiple comparisons found that the mean value of $\triangle$E was significantly different between each shade in each environment and the control group ($P < 0.05$) [Table 2].

The ΔE values had changed for all samples throughout the aging process [Figures 3 and 4]; the highest ΔE values were found in the outdoor environment (mean $\triangle$E >10 for P20), where the dark shade displayed generally higher ΔE than the light shade, while the group with no sunscreen showed a mean $\triangle$E <1. For both the indoor and darkness environments, this trend was reversed, and the light shade showed more change than the dark shade.

Figure 5 shows that there was a higher rate of color change at week 1 in the dark shade groups (maximum $\triangle$E = 19.61, outdoor, Garnier) compared to the light groups (maximum $\triangle$E = 2.09, outdoor, Garnier), and in most cases, groups

Table 1: Mean daily weather data April–September 2021

2021	Min Temp °C	Max Temp °C	Mean Temp °C	Total Sunshine hours	Total Global Radiation (KJ/m2)
April	1.4	11.7	6.6	6.9	17166.5
May	6.3	14.5	10.4	8.8	16345.4
June	11.6	20.0	15.8	8.1	16240.6
July	13.8	22.6	18.2	8.1	18678.6
August	12.2	19.5	15.8	9.6	13315.1
September	12.1	20.4	16.2	4.8	11551.1

Table 2: Statistical analysis

Source of variation	Environment	Shade	SS	*df*	MS	F	*P*-value	F crit	Significant
Between groups	Outdoor	3.2 - Dark	91.948	3	30.649	7.540	0.00145	3.0984	Yes
Between groups	Outdoor	1.2 - Light	121.423	3	40.474	42.714	0.00000	3.0984	Yes
Between groups	Indoor	3.2 - Dark	1.450	3	0.483	5.196	0.00812	3.0984	Yes
Between groups	Indoor	1.2 - Light	8.294	3	2.765	8.302	0.00088	3.0984	Yes
Between groups	Darkness	3.2 - Dark	101.448	3	33.816	6.167	0.00384	3.0984	Yes
Between groups	Darkness	1.2 - Light	22.858	3	7.619	4.892	0.01038	3.0984	Yes

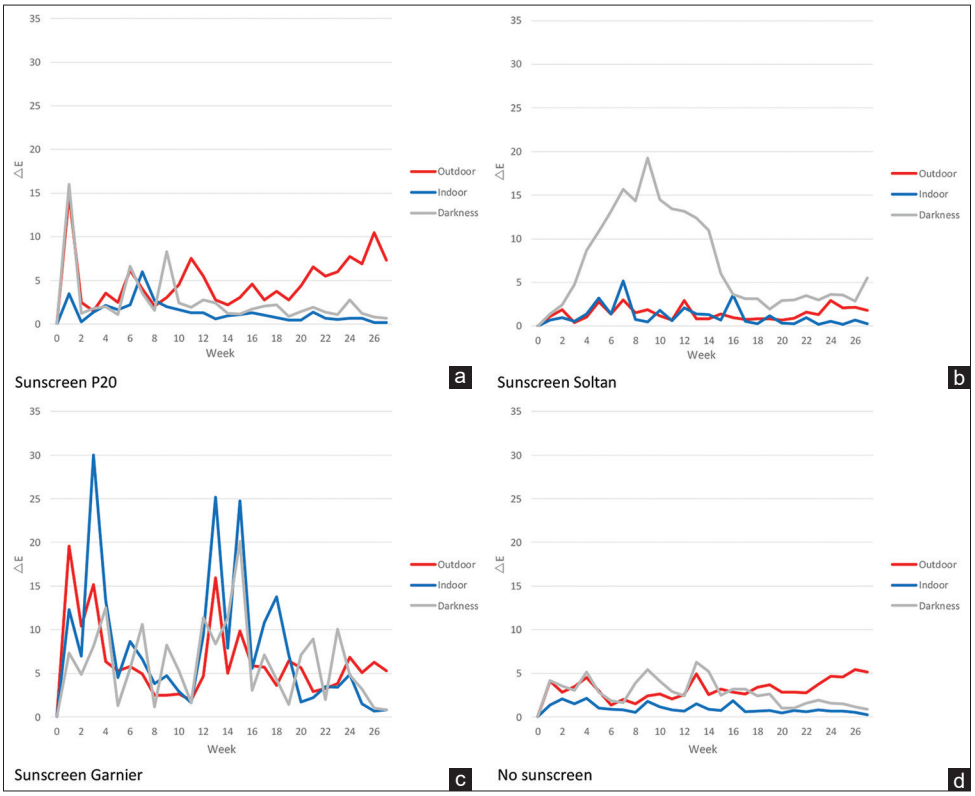

Figure 3: (a-d) Dark shade (3.2) ΔE over time, comparing different surface treatments and environments

stored in darkness showed less color change than groups in the outdoor and indoor environments. However, the Soltan group for the dark shade shows a significantly smaller △E than the nontreated group but only in the outdoor environment (Soltan group △E = 2.19, none group △E = 5.39).

The difference between the groups before and after steam cleaning was minimal (△E <0.5); this reduced the likelihood that the △E increases in the samples were a result of contamination, affecting the colors.

DISCUSSION

Due to the COVID-19 pandemic, weekly access to a spectrophotometer was restricted; previous studies have highlighted the superiority of this machine, which is commonly used for color studies.[33,34] To record frequent and regular color changes, a colorimeter was used on a weekly basis, and spectrophotometers at the beginning, midway, and end point of the project. Technical machine issues occurred at the end point, as can be observed in Figure 6, rendering spectrophotometer data unusable. However, as measurements between the two machines correlated closely until this point, the colorimeter readings therefore were considered appropriate for the continuation of this study. A previous study by Leow *et al.* used a colorimeter and found it successful.[17] In addition, Gehrke *et al.* found that the two types of measuring devices are comparable.[35]

Although the study design was not identical, the results of this study correlate closely with Bryant *et al.*'s findings in 1994, who tested three commercially available SPF 15 sunscreens (Faces Only, Native Tan, and Photoplex) on MDX 4-4210 silicone, opacified with talc and colored to a skin shade using red, rust, yellow, and brown nylon flock.[36] Although the previous study had found sunscreen

Figure 4: (a-d) Light shade (1.2) ΔE over time, comparing different surface treatments and environments

to be ineffective in color preservation, the current study assumed advancements in sunscreen protection agents and better UV protection with SPF 50 during the past 28 years since Bryant *et al.*'s study. Within their study, samples were tested for 300 h under artificial UV light and a control group in darkness; CIEL* a* b* measurements were taken with a spectrophotometer. In the current study, samples were tested over 4392 h creating a larger comparison, albeit using a colorimeter. Bryant *et al.*'s groups showed significant color changes, and they concluded that none of the sunscreens provided effective color protection; indeed, two of the sunscreens showed even greater △E values than the nontreated group.[36] Whilst this study attempted to improve the study design of Bryant *et al.*, it showed similar results for two of the three tested sunscreens; both P20 (chemical sunscreen) and Garnier (physical sunscreen) reflected the results found in the original study. However, Soltan (physical sunscreen) performed less detrimentally, and showed promising results under some conditions (△E < 3, and △E was less significant than the control (no-sunscreen) group in the outdoor environment for the dark shade).

Kuehni and Marcus created the first significant scale for the perceptibility and acceptability of small color differences; their research found that the average CIEL* a* b* color for 50% of observers, under controlled conditions, to perceive a color difference, was one unit.[37] ΔE values between 0 and 2 represent imperceptible color differences, while values in the range of 2–3 represent color differences that are perceptible by 50% of the population. Values of ΔE >3 are visually perceptible and clinically unacceptable. Paravina *et al.* further developed this research and concluded a 50:50% perceptibility and acceptability threshold for light skin tones as 1.1 ΔE and 3.0 ΔE, and 1.6 ΔE and 4.4 ΔE for dark skin tones.[38] Based on this, a commonly accepted threshold for research has been set at 3.0 ΔE.[10,21] This scale is summarized with the data of this study in Figure 7, showing the dark shade groups generally underwent a greater color change than the light shade groups, particularly in the outdoor environment, showing △E >3. Similar results were reported by Veli, who investigated the color degradation of two different skin shade silicones invested in Type II and Type III dental stone before and after polymerization, using M511 maxillofacial silicone, colored with Spectromatch Pro colorants; her results concurred that all light shade samples showed significantly less △E than the dark shade.[39]

It is possible that the lighter shade groups showed less color change because the relatively large amount of white pigment – compared to shade 3.2– acted as an opacifier. However, as all sunscreen-treated groups for the lighter shade show higher color change than the groups that received none, even in dark storage, it should be considered

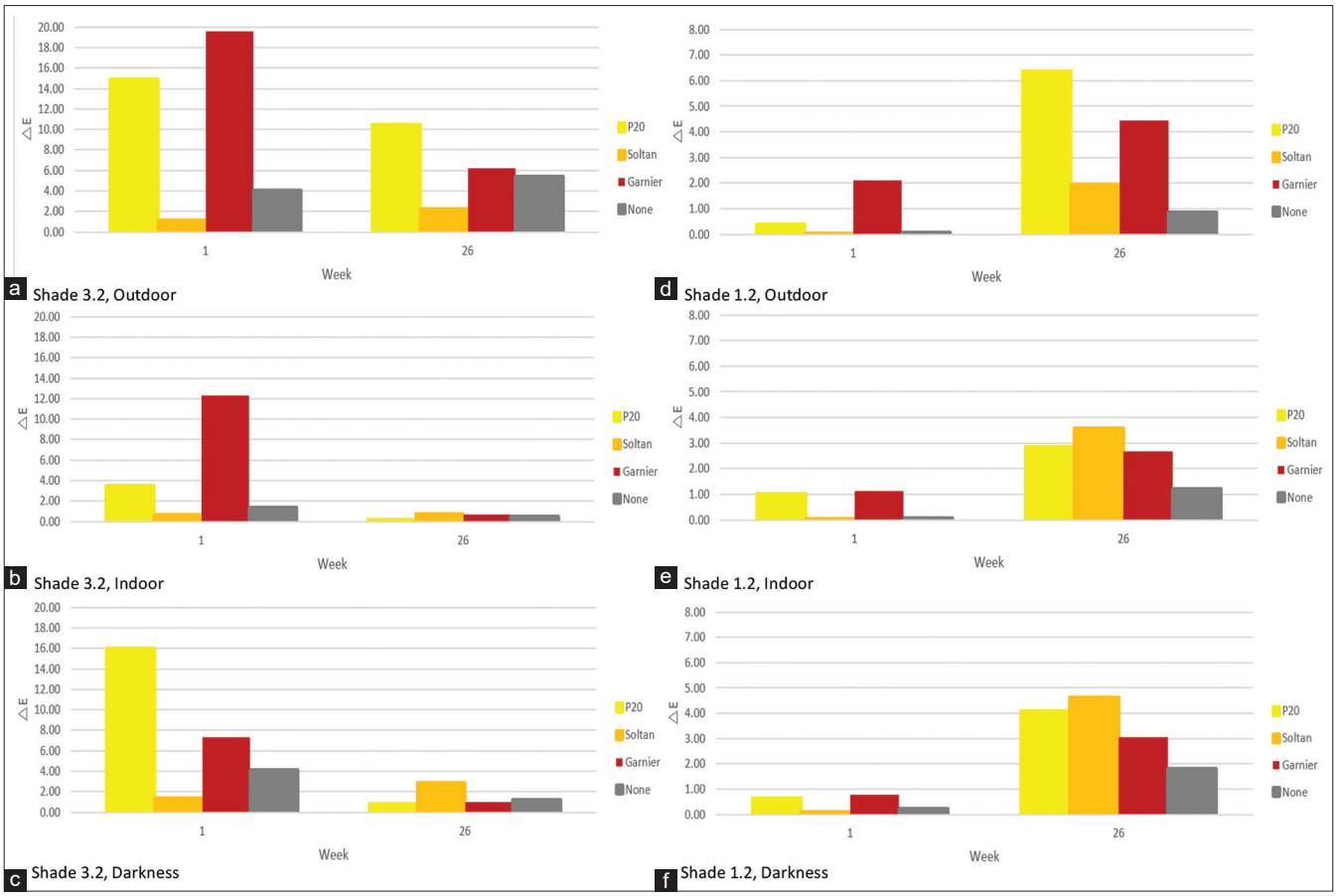

Figure 5: (a-c) Shade 3.2, (d-f): Shade 1.2; ΔE week 1 and week 26; samples treated with P20 and Garnier showed large ΔE for shade 3.2 after the 1st week of environmental exposure, for all three environments, which later stabilized. However, nontreated samples showed a similar trend

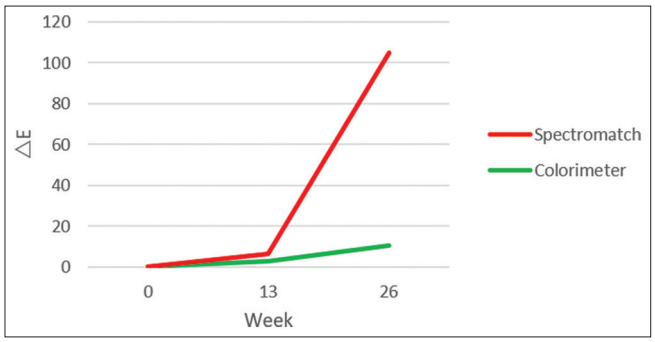

Figure 6: Mean data of ΔE shows the error discrepancy at week 26 between spectrophotometer and colorimeter readings

that factors other than UV radiation were responsible for the color change.

The dark storage groups were adversely affected despite the lack of UV radiation, indicating that a nonphotosensitive chemical reaction may have taken place; this was also discovered by Cifter *et al.*[40] They tested colored Cosmesil M511 maxillofacial silicone elastomer using five different colored investment stones (plus an aluminum mold to produce control specimens) to produce 120 rectangular samples; a total of 60 samples were cured at 100°C for 1 h, while another 60 were cured at room temperature. This differs from this current study, where samples were cured at room temperature over 24 h. Cifter *et al.*'s measurements were taken before dark storage, using a spectrophotometer, and again after 6000 h of dark storage. Although samples in this current study were exposed to their environments for a shorter amount of time (4392 h), similar results were recorded. Cifter *et al.* found that △E exceeded perceptible thresholds, concluding that both the polymerization temperature and the color of the investment stone had a significant effect on the color change over time, including white stone, as was used in this current study.

It was suggested that this first (inherent) type of color change occurs because of changes to the physical and mechanical properties caused by internal factors within the silicone elastomer chain.

Results of this study follow the trend shown by Cifter *et al.*, expressed by △E in the differing variations in the L* a* b* values; they found that, when white molding stone was used (as was for this study) together with polymerization

at 100°C, the yellowing of the silicone samples (expressed by an increase in the b* values) increased significantly after dark storage of 6000 h. Although in this study, samples were cured at room temperature, there is a strong correlation between these findings [Figure 8].

Outdoor storage, in contrast, shows a different trend in L* a* b* values [Figure 8]; both shades displayed darkening (negative values of L*); however, while the dark shade shows minimal △E in a* and b* values for sunscreen-treated groups, the light shade shows an increase △E in red (a*; which is, as per CIEL* a* b* formula, associated with a decrease in green), while the negative values of the b* values denote an increase in blue, (associated with a decrease in yellow). By the process of deduction, it could be assumed that dark storage promotes yellowing of silicone, through some loss of the blue spectrum, while light exposure (and associated rise in temperature) represents a loss of yellow, thus enhancing the blue color notion.

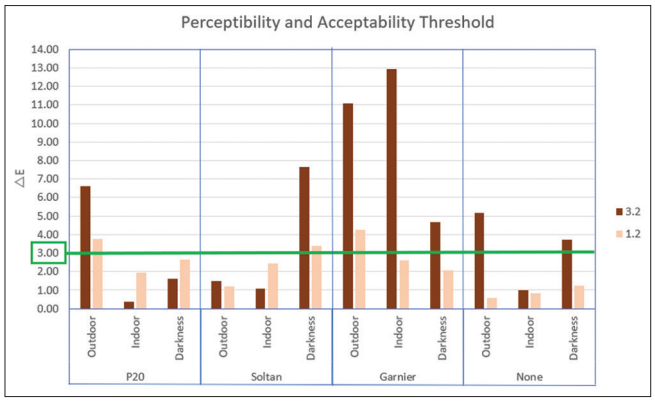

Figure 7: Mean ΔE data against perceptibility and acceptance threshold; green line depicts clinical acceptance at ΔE =/<3

As the mean △E for the b* value for shade 3.2 for the nonsunscreen-treated group was much higher than for the sunscreen-treated groups (△E <0.05), it could further be assumed that the sunscreen helped stabilize the colorimetric aspect in these pigment-rich samples; however, the sunscreen-treated groups were also significantly affected by darkening (ranging from △E L* values-2 [Soltan] to -4.4 [P20]), resulting in clinically unacceptable overall △E results. Therefore, for future research, it may be worth investigating the cause of the darkening effect, in finding a suitable, sunscreen-related method of protecting silicone from color degradation.

Further study should investigate the effectiveness of Soltan, as it appeared to be effective in protecting the samples from color degradation in the outdoor environment. Figure 9a confirms that this applied to each sample in the groups, indicating a reliable effect. Although not successful in all environments (e.g., indoor environment Soltan mean △E = 0.72> no sunscreen mean △E = 0.49), the breakdown of the group shows

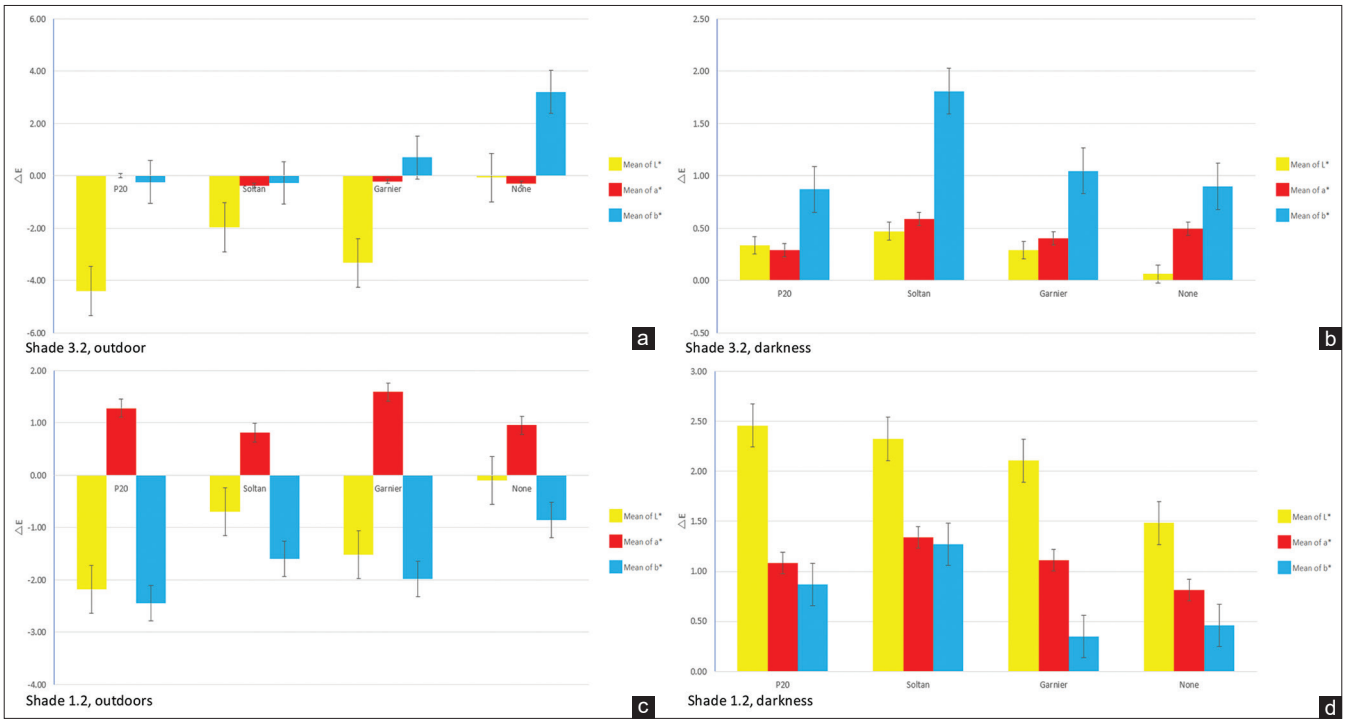

Figure 8: (a and b) Outdoor, (c and d) Darkness; ΔE demonstrating mean decrease in L* values = lightning effect on outdoor samples, and increase in mean b* values = yellowing of samples in dark storage

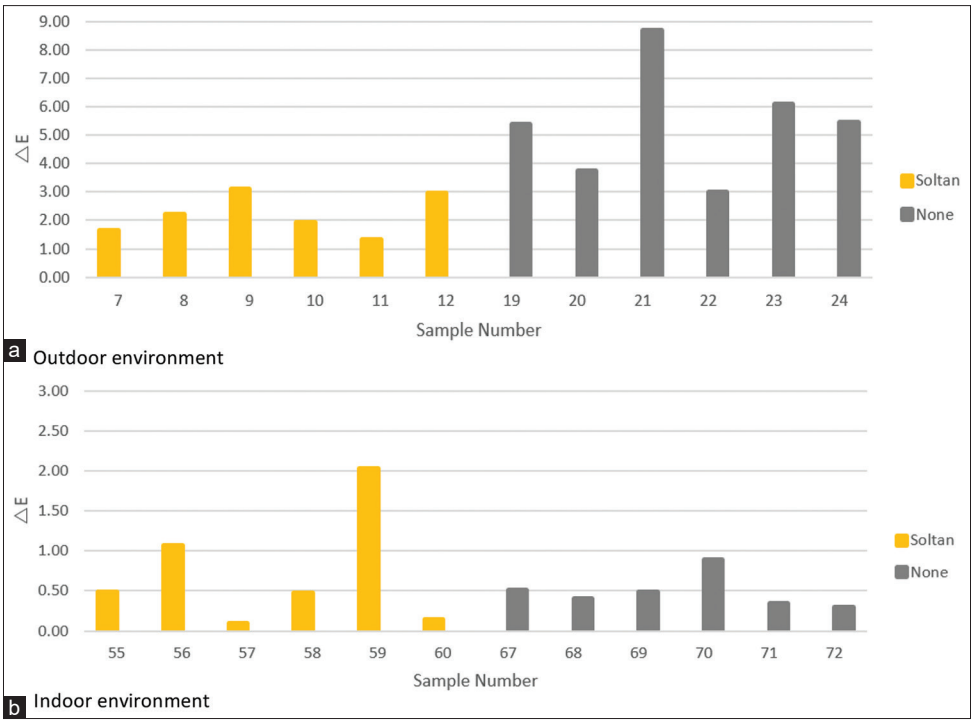

Figure 9: (a and b) Breakdown of groups Soltan and no sunscreen, (a) showing that the mean ΔE difference in the outdoor environment was not caused by outliers but reflected a consistently significant result, (b) showing that some samples in the Soltan group showed effectiveness versus the no sunscreen samples

that there were variations between the samples, which may be indicative of a potential solution for silicone color degradation [Figure 9b].

This study was conducted under nontemperature-controlled conditions, due to limitations of available equipment and travel restrictions during the pandemic; although weather data were collected for the duration of the study, it is not known to what temperatures the samples may have risen to, particularly in the outdoor environment, behind glass; it may be possible to establish a link between certain pigments being more prone to degradation under increased temperature, while other pigments may be more sensitive to UV light. A temperature-controlled study could open new research avenues.

Further limitations to this study include the lack of inclusion of nonpigmented samples; in retrospect, it may have been insightful to observe if the sunscreens had left any noticeable color changes; future studies would benefit from adding this additional control to the sample ranges.

The silicone tested was supplied prepigmented, with the pigment-to-silicone ratio unknown; future research may be beneficial in testing varying pigment-to-silicone ratios, alongside varying pigment colors.

The use of anti-slump agent may have had an influence on the color and could be tested specifically in future research.

As only one type of silicone elastomer was tested, it is not known if other types may react differently to topical sunscreen application; furthermore, different sunscreens could be tested, from the vast range available.

However, as one sunscreen has shown promising results, it appears prudent to continue research in this field of color preservation, to find a suitable product, saving time and money for both patients and NHS Trusts.

CONCLUSION

The hypothesis was mainly rejected, as only one of the tested sunscreens provided effective color protection to silicone elastomer M511, in only one environment and shade. In general, the study showed that the sunscreen deteriorated the pigments faster than natural weathering. This follows previous findings of Bryant *et al.*, who concluded that sunscreens have a similar detrimental effect on prosthetic materials as cosmetics (e.g., foundation, facial powders), namely causing an uncontrolled colour change. Therefore, from the findings of this study, patients should be encouraged to apply sunscreen to their skin but are advised to avoid applying sunscreen to their prosthesis. However, further research into the possible

color-protective properties of Soltan sunscreen should be considered.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Original Article

Comparative evaluation to study the effect of implant support on complete fixed dental prosthesis fabricated with peek framework when implants placed in all-on-4 and all-on-6 situation, by strain gauge analysis and finite element analysis – An *in vitro* study

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Abstract

Aim: To evaluate and compare the strain development and distribution of maxillary implant-supported complete fixed dental prosthesis (ISCFDP) with computer-aided design-computer-aided manufacturing milled PEEK BIO-HPP superstructure when placed using All-on-4 and All-on-6 situation using a strain gauge and finite element analysis (FEA).

Setting and Design: This is an *in vitro* study to evaluate and compare the stress minimization and strain developed at implant in premolar and in two clinically simulated situation of All-on-4 and All-on -6 ISCFDP

Materials and Methods: The study involved converting a human skull into. stl format to create 3D-printed stereolithography models with a modulus of elasticity closer to bone. Implants were placed in two models (M1 nad M2) in incisor, premolar, and pterygoid regions. A fixed dental prosthesis framework was fabricated on both models, and strain gauge sensors were attached.

Statistical Analysis Used: Descriptive and analytical statistics were done. The normality of data was analyzed by the Shapiro-Wilk test.

Results: The results obtained were tabulated and it showed strain around the neck of ISCFDP under 100N configuration in strain gauge analysis. Stress was found more in the molar region when compared to the premolar region. This design showed that the largest stress around the neck of ISFDP under 100 N load was found more in the premolar region when compared to the molar region due to the reduction of stresses in the pterygoid region in FEA.

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Conclusion: In the present study, strain gauge analysis at 100 N for loading at the premolar and molar region shows the reduced strain on tilted implants in All-on-6 situation due to stress dissipation to the terminal pterygoid implant using strain gauge.

Keywords: Finite element analysis, implant-supported complete fixed dental prosthesis, pterygoid implant, strain gauge analysis

INTRODUCTION

The prosthetic rehabilitation of the atrophic maxilla is quite challenging since maxillary bone exhibits a centripetal mode of resorption accompanied by pneumatization of the maxillary sinus.[1]

All-on-4 technique, by Paulo malo brought a phenomenal change in the year 1996 to address full mouth rehabilitation for atrophic maxilla. This had limitations for having an appropriate cantilever A-P spread and short arch prosthesis.[2] To overcome this, shorter implants were in practice to provide support in the framework at the cantilever end.[3]

The shorter implants not only converted short arch prosthesis to conventional prosthesis but also provided support to the prosthesis.[4]

The pterygomaxillary region has proven to be a better anatomical area for the placement of implants with a good success rate, as it exhibits the least resorption.[4,5]

With the advent of multiunit abutments and the tilted implant concept, pterygoid areas were considered for placement of implants and provided support in full mouth rehabilitation cases.[6]

The purpose of this *in-vitro* study is to evaluate and compare the stress distribution of implant-supported maxillary complete fixed dental prosthesis when placed using the All-on-4 protocol with terminal cantilever and All-on-6 protocol with the support from terminal pterygoid implants by strain gauge and finite element analysis (FEA).

MATERIALS AND METHODS

Model preparation

A human skull was subjected to cone-beam computed tomography (CBCT), and the DICOM file was converted into. stl format to make a 3D printed model having a modulus of elasticity closer to bone through fused deposition modeling acrylonitrile butadiene styrene, Aaron Industries Corporation, AAROPRENE®, Gujarat, India, [Figure 1a-c]. These two 3D printed models (M1, M2) will serve as a standard for comparing the stress distribution on All-On-4 implant-supported complete fixed dental prosthesis (ISCFDP) and All-on-6 ISCFDP. Both models were coated with occlude spray (Diaswiss S. A, Switzerland) and subjected to Table top scanner (Shining 3D, India). The scanned images of M1 and M2 were superimposed on the computed tomography (CT) scan of 3D printed M1 and M2 for standardization of implant angulation in both models. A surgically guided stent (ANYCUBIC SLA UV-Curing 3D Printer Resin-B07G35CC1V, China) with sleeves for accommodating implant drills was printed [Figure 1a-c]. Ethical committee number Kcds/Ethical Comm/032/2020-2021.

Virtual planning of implant position

Virtual planning was done to select the size of the implant in terms of diameter and length through CBCT data obtained from the patient.

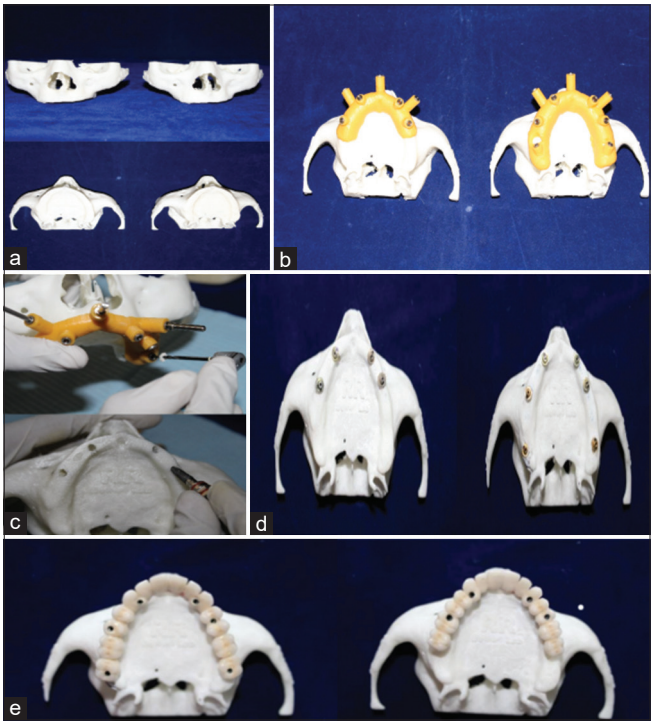

Figure 1: (a) Two 3D printed models M1 and M2 (b) surgical guide printed on M1 and M2 (c) Implant placement (d) Multiunit abutments of appropriate collar height were placed on M1 and M2 (e) Fixed dental prosthesis framework is fabricated on both M1 and M2

Implant placement

In M1, using the surgical guide, two straight implants measuring 3.3/11 were placed at the incisor area, and two tilted implants measuring 3.75/13 were placed at the premolar area [Figure 1a-c]. In M2, the implants were placed the same as M1, along with two tilted implants measuring 3.75/16 mm were placed in the maxillary tuberosity area.

Fabrication of implant-supported complete fixed dental prosthesis

To establish a restorative platform for the prosthesis, a multi-unit abutment (Multi-unit Abutment, BioLine®) was placed on each implant in both M1 and M2 [Figure 1d]. Multi-unit scan bodies (Multi-unit Scan bodies, BioLine®) were placed on each implant, and both the models M1 and M2 were subjected to model scanning (Shining 3D – Table top scanner, Hangzhou, China). Peek framework was designed (Exocad GmbH, Darmstadt, Hessen, Germany) and was printed (Shining 3D ACCUFAB-D1S dental 3D printer, China) on both M1 and M2 followed by ceramic (Vintage Art, Shofu Inc.) layering [Figure 1e].

Strain gauge analysis

Attatching strain gauge sensors

In the laboratory, the buccal and lingual sides of the implant were bonded with a total of 10 strain gauges (TML JAPAN), which were equally spaced [Figure 2a-c].

Multi-stranded wires (TRI-COM Cables, U. S. A) with thin coatings, responsible for the electrical connections, were attached on the external surface, connecting the strain gauge sensors to an electrical signal conditioning unit (Data Acquisition System).

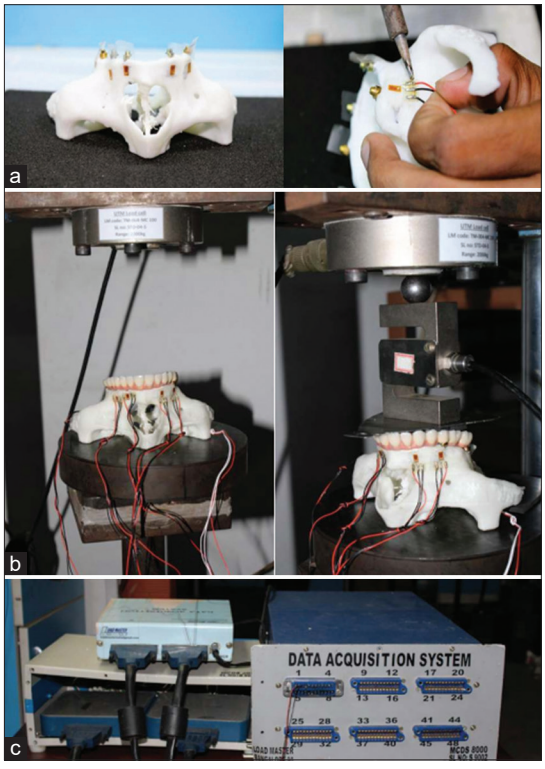

Figure 2: (a) Strain gauge sensors are placed on both the models M1 And M2 at the neck of each implant. (b) Vertical load applied bilaterally on model and developed up to 100N (c) Data acquisition system to determine strain values

Loading conditions

Compression test was done to analyze the strain developed around each implant in both M1 and M2. A metal plate was kept on the model with ISCFDP for the uniform area of contact throughout. Both M1 and M2 were subjected to a vertical load of 100N for seven times using a universal testing machine (Model MCS 1000). The magnitude of strain on each strain gauge was recorded in units of micro strain [Figure 2a-c].

Finite element analysis

Meshing procedure

The simulated model of the maxillary jaw with implants and superstructure fabricated was scanned to obtain the image for FEM meshwork [Figure 3a and b]. The FEM meshwork has definite elements and nodes. The mesh model of the maxillary jaw created had an appropriate elastic modulus of bone and adjacent structures. This was subjected to appropriate masticatory load to evaluate stress concentration on two models of an All-on-4 situation and All-on-6 situation, and the data were tabulated [Tables 1 and 2].

Loading conditions

For the FEA, a vertical load of 100 N was applied bilaterally on each framework in M1 and M2. The load was divided equally on the posterior teeth to compensate for the difference in the number of teeth in the frameworks of the groups.

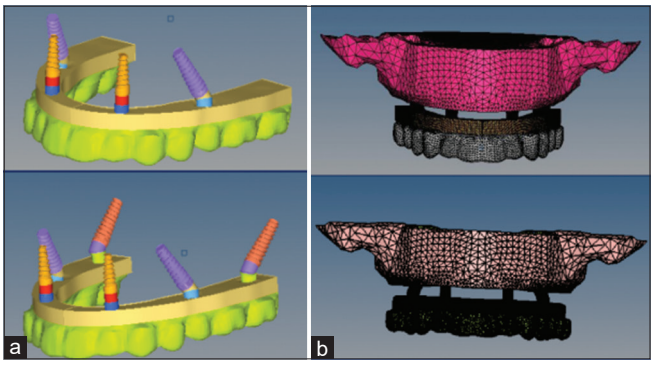

Figure 3: (a) Virtually designed 3D solid geometries of M1 and M2 model with implants and implant-supported complete fixed dental prosthesis (b) Mesh generation for both M1 and M2 using Ansys 18.1 software

Stress analysis

The FEA was performed using Ansys18.1software (Ansys, Inc. Canonsburg, Pennsylavania). Cortical and cancellous bone stress, implant stress, framework stress, and overall deformation of the framework on 100N load application were evaluated.

RESULTS

The results obtained were tabulated in strain gauge analysis. 100 N vertical load was applied in different positions in M1 and M2 [Figure 2b]. Each test was repeated seven times as the sample size obtained was seven. Values obtained from the graph were subjected to statistical analysis and tabulated in different sets [Tables 3 and 4].

In FEA, 100 N load was applied virtually in different positions, and maximum principle stress was obtained. The *P* value is equal to 0.05 [Table 5]. There is a significant difference between the All-on-4 system and All-on-6 system concerning peek [Tables 1 and 2]. The mean maximum overall stress observed in M1 v/s M2 [Figure 4a and b] due to the application of 100N load was compared. It was found that there a marginal significant difference existed in mean maximum overall stress observed at M1 v/s M2 due to the application of load on the PEEK maxillary ISCFDP.

Table 1: Model description: Number of elements and nodes

Model description	Elements	Nodes
All on 6	689,283	932,842
All on 4	642,270	869,263

FEA: 100 N load was applied virtually in different positions and maximum principle stress was obtained. FEA: Finite element analysis

Table 2: Stress distributed at 100N load in M1 and M2 using finite element analysis

100 N load/stress results	Peek	
	All on 4 system	All on 6 system
Overall deformation	0.097397	0.00827
Overall stress (Mpa)	42.5866	19.2165
Cortical stress (Mpa)	35.1339	17.4645
Cancellous stress (Mpa)	1.85663	1.51403
Implant stress (Mpa)	53.4681	13.631
Frame stress	7.71444	2.56453
Anterior implant stress (MPa)	25.1218	13.631
Posterior premolar implant stress (MPa)	53.4681	11.5376
Posterior molar implant stress (MPa)	-	9.47419

DISCUSSION

It is well known that prosthetic rehabilitation of the atrophic maxilla is quite challenging.[1] All on 4 technique, by Paulo Malo brought a phenomenal change in the year 1996 where in two straight implants were placed in the maxillary anterior region, and two tilted implants in the premolar region with accepted cantilever beam, favoring biomechanics of short arch prosthesis.[7] The limitations of this All-on-4 in terms of biomechanics were cantilever A-P spread and short arch prosthesis.[8,9] Meanwhile, the use of shorter implants to provide support in the framework of the cantilever was also in practice to convert the short arch prosthesis to a normal prosthesis.[5,6,10] Several studies have shown that the pterygoid region is resistant to resorption due to multiple muscle attachments, which provide torso frictional forces.[3,11,12] Further, with the advent of multi-unit abutments, a prosthesis can be envisioned with an excellent anchorage from the pterygoid region.[12] Implants placed in the posterior maxilla have been discussed as pterygoid plate implants, tuberosity implants, and pterygomaxillary implants. The structures that offer support for implant placement are the tuberosity of the maxillary bone, the pyramidal process of the palatine bone, and the pterygoid process of the sphenoid bone.[11,12]

Pterygoid implants are an alternative for treating patients with atrophic posterior maxilla because they have great success rates, comparable amounts of bone loss to conventional implants, few problems, and positive patient acceptability.[7-9]

Table 3: Numbering and positional placement of strain gauge in M1

Gauge number	Position	Region	Microstrain	Strain
Gauge 1	Buccal side	Premolar region (1st quadrant)	493	0.000493
Gauge 2	Labial side	Incisor region (1st quadrant)	146	0.000146
Gauge 3	Labial side	Incisor region (2nd quadrant)	52	0.000052
Gauge 4	Buccal side	Premolar region (2nd quadrant)	221	0.000221

Table 4: Numbering and positional placement of strain gauge in M2

Gauge number	Position	Region	Microstrain	Strain
Gauge 1	Buccal side	Molar region (1st quadrant)	238	0.000238
Gauge 2	Buccal side	Premolar region (1st quadrant)	69	0.000069
Gauge 3	Labial side	Incisor region (1st quadrant)	59	0.000059
Gauge 4	Labial side	Incisor region (2nd quadrant)	74	0.000074
Gauge 5	Buccal side	Premolar region (2nd quadrant)	169	0.000169
Gauge 6	Buccal side	Molar region (2nd quadrant)	232	0.000232

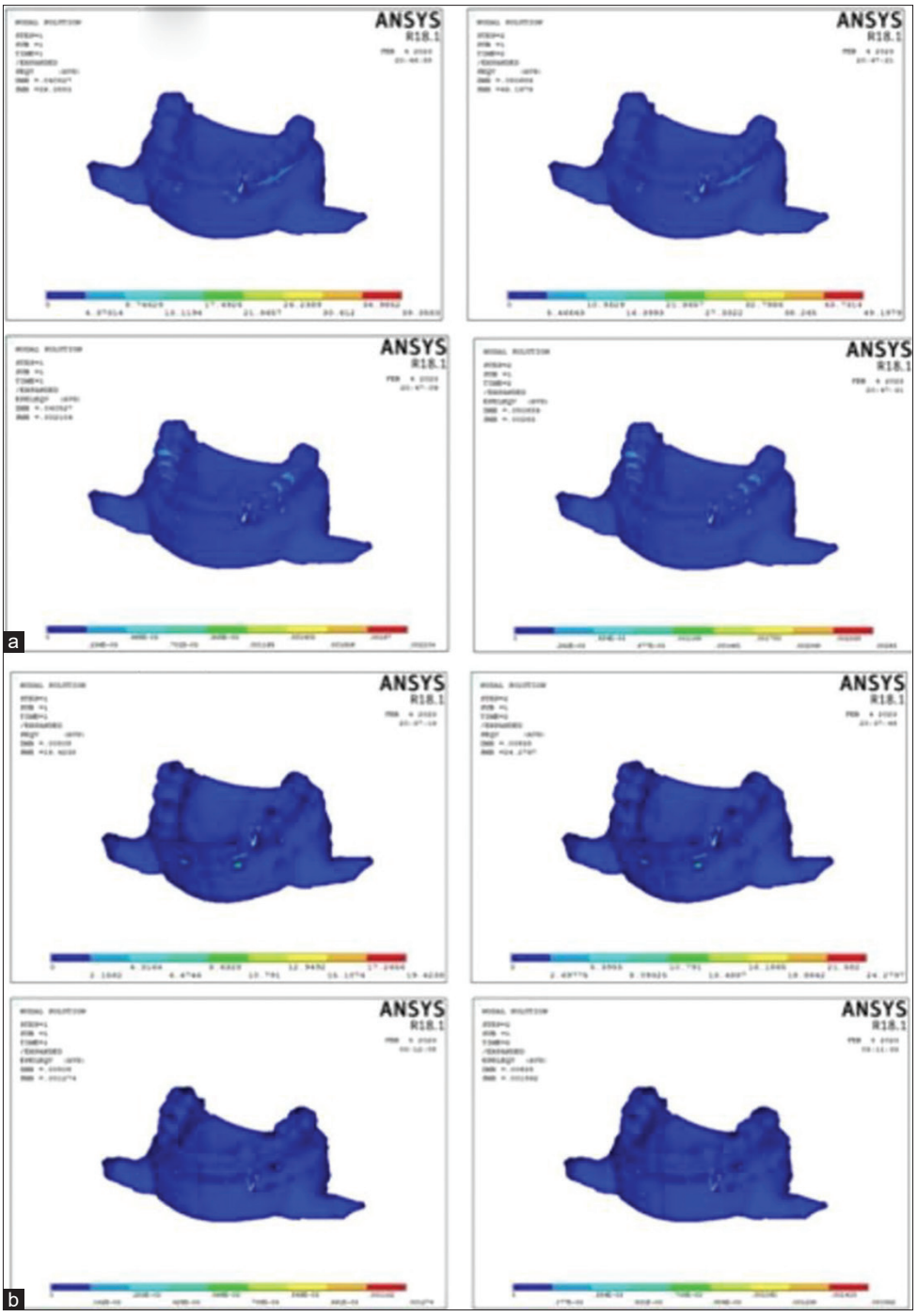

Figure 4: (a) Overall maximum stress in M1 (b) Overall maximum stress in M2

Hence, in this study, the pterygoid region is utilized for the placement of implants for overcoming the limitation of All-on-4 techniques by comparing and evaluating the stress distributed and strain developed beneath ISCFDP in All-on-4 and All-on-6 situations using strain gauge and FEA

Physical model

This design showed strain around the neck of ISFDP under 100N configuration. Stress was found a little more in the molar region when compared to the premolar region, although when it was statistically compared result showed that the difference was insignificant.

Finite element model

This design showed that the largest stress around the neck of ISFDP under 100 N load was found more in the premolar region when compared to the molar region due to the reduction of stresses in the pterygoid region.

Table 5: *P* value of 100N in M1 and M2

100N load mean strain results	Peek		Statistic		
	All-on-4 system	All-on-6 system	Mann–Whitney *U*	*Z*	*P*
Mean	228.00	140.17	30	2.45567	0.0364
SD	189.71	83.51			
Median	183.50	121.50			

Observation: The *P* value is nearly equal to 0.05. Inference: There is a significant difference between the all-on-4 system and the all-on-6 system concerning peek. SD: Standard deviation

Strength of the study

Tilted implants are alternative without need of bone grafting. An implant in the posterior area aids in support to a cantilever beam, due to this, there is less deformation observed. Peek as a superstructure there is proven reduction of stresses to the bone through the implant.

Limitations of the present study and scope for future research

In this study, only a vertical load of 100N was tested and rotational and lateral forces that are exerted on implants and framework was not incorporated. The present study was done on the maxillary model. Further study can be done in the mandibular model.

CONCLUSION

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

- In All-on-4 situation, the tilted implants placed in the premolar region exhibited more stress than the straight implants placed in the same situation
- In the present study, statistical comparison of strain gauge analysis at 100 N for loading at premolar and molar regions revealed the reduction in strain developed on the tilted implants placed at the premolar area when placed in an All-on-6 situation due to dissipation of stress to the terminal pterygoid implant using a strain gauge
- Implants placed in All-on-6 situation had a better distribution of stress than implants placed in All-on-4 situation
- Peek framework in All-on-4 situations had higher stress than All-on-6 situations
- In FEA, when a load of 100 N was applied, the stress was seen higher in the neck of ISCFDP of the premolar region when compared to the molar region.

M1 and M2

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Original Article

Patient acceptability of a wheel chair recliner developed to perform dental procedures at wheelchair itself: A cross-sectional study

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Abstract

Aim: Transfer from a wheelchair and discomfort in dental chair are two important barriers for access to dental care among wheelchair-bound patients. The authors have devised an automated wheelchair recliner that helps to mimic the dental chair functioning at wheelchair itself. The aim of this study was to analyze the performance and acceptability of wheelchair recliner among wheelchair-bound patients.

Settings and Design: Tertiary care settings, cross-sectional design.

Materials and Methods: A total of 100 wheelchair-bound adult patients (aged >21 years) were evaluated for acceptability of the recliner. The patients were assessed using eight-item covering patient comfort/acceptability related to positioning, reclining, repositioning, fear of falls, joy, discomfort, perception regarding dentist's discomfort, and use in future on a scale of 0–4 with 0 indicating least satisfying and four indicating most satisfying experience. Overall, patient experience was graded as poor, fair, good, very good, and excellent. The Chi-square test was used to compare the results.

Statistical Analysis Used: IBM Stats package 21.0 was used. Mean ± standard deviation, Numbers/percentages and Chi-square test were used to compare results. The confidence level of the study was 95%.

Results: The age of patients ranged from 22 to 83 years (mean age 52.26 ± 18.58 years). Majority were males (58%) and had temporary (60%) disability. On a 4-point scale, the mean scores of patients ranged from 2.47 ± 1.23 (positioning) to 3.40 ± 0.74 (intent to use in future). Overall experience was rated as good to very good by 77% of patients. No significant association of age, sex, or type of disability was seen with overall patient experience.

Conclusion: The acceptability rates were good to very good among wheelchair-bound patients and were unaffected by their age, sex, and type of disability.

Keywords: Disability, geriatric, satisfaction, special care, wheelchair recliner

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INTRODUCTION

Providing dental care to wheelchair-bound patients is a challenging task as the patients have various fears related to transfer from wheelchair to dental chair. Most of the

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dental practices generally do not have specialized facilities for patient transfer from wheelchair to dental chair. The accompanying caregivers are also mostly untrained for this task and are frightened of possible injuries during this process.[1] Transferring from wheelchair to dental chair is a complex process requiring specialized skills and a thorough assessment of patient's medical status, mobility level, endurance, ability to balance, and comprehend the given commands and factors that could motivate him for such transfer.[2]

Transferring into dental chair and overcoming the discomfort on the dental chair remain to be the most important factors affecting the access to dental care among wheel-chair bound patients.[3] A possible alternative to this is the treatment of a wheelchair-bound patient on wheelchair itself. However, this alternative also has ergonomic issues on the part of dental practitioners.

To overcome this difficulty, the most viable alternative is to develop such aids that help offer dental treatment in the wheelchair itself without compromising the ergonomic issues and facilitating the easy accessibility of required dental instruments. To meet this objective, several alternatives have been offered by different workers from time to time, namely, development of modified dental chair to ease the accommodation of wheelchair-bound patients,[4] wooden lifts,[5] using a specialized reclinable wheelchair,[6] etc. However, most of these aids are costly, lack mass scalability, and have limited patient acceptability.

To overcome this issue, the authors developed an innovative wheelchair recliner that helps provide the dental care to the patient in the wheelchair itself. This innovation is a simple DC battery-operated portable device that enables to convert the wheelchair into a working dental chair at demand and also overcomes the ergonomic issues [Figures 1 and 2].

The success of an innovation could be gauged if it helps to fulfill the need of the patient. In this article, we describe the patient acceptability, experience, and feedback on this novel innovative attempt.

MATERIALS AND METHODS

The present study was carried out as an extended part of a research project funded by the Department of Science and Technology and was approved by the institutional ethics committee (vide Letter No. 949/Ethics/R. Cell, Ref. No. 80th ECM II-A/P8).

The assessment was made on 100 wheelchair-bound patients with the Glasgow Coma Scale >12 requiring short-term dental procedures (not lasting more than 30 min), mainly prophylactic procedures, scaling, and Class 1 fillings visiting outpatient departments of the faculty of dental sciences, were included in the study, and were offered facility to avail treatment in the wheelchair itself without requiring transfer to dental chair using the reclining device developed by the authors.[7] Sample size estimations for this descriptive study were made at 95% confidence and 10% precision error using the formula $n = z^2 [p (1 - p)]/e^2$ (where $P = 0.5$ for descriptive studies with no proposed hypothesis, z is a constant with value 1.96 at 95% confidence, and $e = 0.10$ at 10% precision error), the calculated sample size was 96. After making a contingency provision of 5% and rounding off, we proposed a sample size 100.

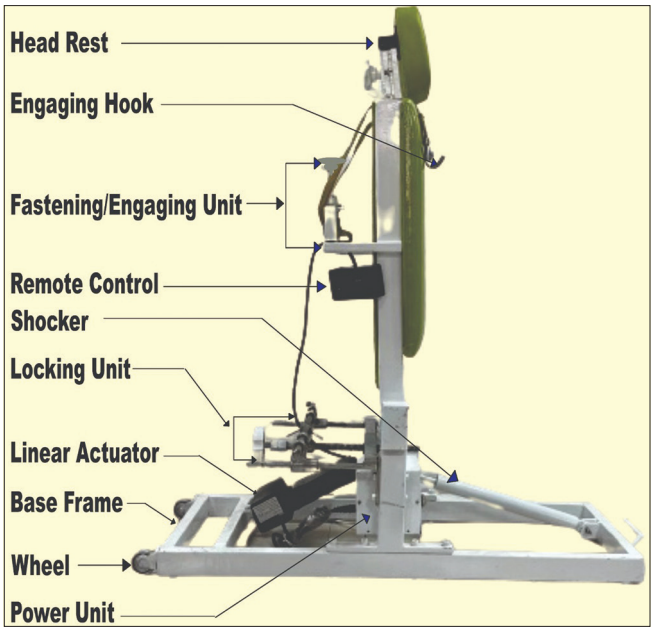

Figure 1: Wheelchair recliner

Patients unwilling to participate in the study, mentally unstable patients or those supposed to have procedures longer than 30 min were excluded from the assessment. At the time of enrolment, age, sex, and type of wheelchair dependence (permanent disability/temporary dependence) were noted. Permanent disability was defined as the physical condition of the patient where wheelchair dependence was lifelong (permanent lower limb disability, paraplegic/hemiplegic, and stroke patients requiring wheelchair support). In contrast, temporary dependence was defined as the physical condition where the patient was wheelchair dependent for a short period (such as patients having lower limb fractures, having undergone surgical procedures that require immobilization for a limited period).

Patient's feedback was collected on an eight-item structured inventory that assessed feeling while the positioning

Figure 2: Recliner being placed under wheelchair and tilting the wheelchair to enable the dentist to provide dental care at wheelchair itself

of recliner, feeling while being reclined, feeling during repositioning, fear of fall during positioning/reclining/repositioning, idea of wheelchair conversion into dental chair, discomfort during the entire procedure, noticing discomfort felt by the doctor during the procedure and intent to recommend this utility for use in a dental practice while treating wheelchair-bound patients. For all the items, the responses were collected on a 5-point Likert scale, where the most negative response was scored 0 and the most positive response was scored as 4. Total scores were obtained by summing the item scores for all the eight items.

The overall experience of patients was also assessed as – Poor, fair, good, very good, and excellent.

Data analysis

Data were analyzed using IBM SPSS ver. 21.0, IBM SPSS Statistics Inc., Chicago, Illinois, USA. Item-wise scores have been shown in numbers/percentages and mean scores. Total scores have been shown as mean ± standard deviation. The overall experience has been depicted as numbers/percentages. Gender and age differences for overall experience were compared using the Chi-square test. The confidence level of the study was 95%.

RESULTS

The age of patients ranged from 22 to 83 years. Maximum number of patients were aged between 21 and 40 years (33%), followed by 41–60 years (32%), 61–80 years (26%), and >80 years (9%), respectively. The mean age of patients was 52.26 ± 18.58 years. Majority of patients were males (58%). There were 60 patients having temporary wheelchair dependence, whereas 40 had permanent dependence [Table 1].

Item-wise scores on feedback inventory showed 50% or more responses with scores 3 and 4 for all the items. Among different items, the maximum number of 3/4 were obtained for the items use in the future (85%), followed by enjoyment (74%), repositioning (72%), discomfort (66%), fear of fall (64%), dentist's discomfort (56%), reclining (54%), and positioning (50%), respectively. There were only three items on which score 0 was accorded by some patients – these included reclining (8%), positioning (7%), and fear of falls (2%), respectively. Mean item-wise scores ranged from 2.47 ± 1.13 (positioning) to 3.40 ± 0.74 (use in future). For four-item, mean scores were above 3; these included repositioning (3.15 ± 0.85), enjoyment (3.10 ± 0.81), discomfort (3.03 ± 0.85), and use in the future (3.40 ± 0.74). For the other four items, mean scores ranged from 2.47 ± 1.13 (positioning) to 2.86 ± 0.99 (fear of fall). The total mean score was 23.42 ± 3.11 out of a maximum possible 32. The median score was 24 [Table 2].

Overall, subjective experience was reported to be good/very good by 77% of patients. There were 2% of patients who reported it as poor and 3% reported it as excellent. There were 18% of respondents who found it to be fair [Table 3].

No significant difference in overall subjective experience was seen among patients in different age groups, between two sexes and between the temporary and permanent nature of disability [Table 4].

DISCUSSION

An innovation to decrease the inconvenience of patients through the help of indigenous efforts is the mainstay of health-care delivery system. However, it is ultimately the patients who decide whether these innovations are useful and acceptable in the form being delivered to him. In the present study, an attempt was made to develop a wheelchair recliner that could help resolve the problems of wheelchair-bound patients seeking dental care. Incidentally, the wheelchair-bound patients reportedly give heightened importance to oral health as they tend to use their mouth as a "third hand," however, accessibility to dental care is a big barrier for them.[3] Among various factors related to accessibility to dental care, transfer from wheelchair and discomfort in dental chair emerge as issues of concern for these patients.[3] Innovations

Table 1: Age and sex profile of the study population

Characteristic	*n* (%)
Age (years)	
21–40	33
41–60	32
61–80	26
>80	9
Mean age±SD (range)	52.26±18.58 (22–83)
Sex	
Male	58
Female	42
Type of wheelchair dependence	
Temporary	60
Permanent	40

SD: Standard deviation

Table 2: Item-wise scores on feedback inventory

Item number	Item	Score					Mean±SD
		0	1	2	3	4	
1	Positioning	7	15	28	24	26	2.47±1.13
2	Reclining	8	11	27	24	30	2.57±1.25
3	Repositioning	0	1	27	28	44	3.15±0.86
4	Fear of fall	2	5	29	33	31	2.86±0.99
5	Enjoyment	0	1	25	37	37	3.10±0.81
6	Discomfort	0	0	34	29	37	3.03±0.85
7	Dentist's discomfort	0	0	44	28	28	2.84±0.84
8	Use in future	0	0	15	30	55	3.40±0.74
Overall mean score±SD (range) [median score]							23.42±3.11 (15–29) [24]

SD: Standard deviation

Table 3: Overall subjective experience

Overall subjective experience	*n* (%)
Poor	2
Fair	18
Good	37
Very good	40
Excellent	3

Table 4: Association of overall experience with age, sex, and type of disability

Variable	Overall experience				
	Poor	Fair	Good	Very good	Excellent
Age (years)					
21–40 (*n*=33)	0	6 (18.2)	11 (33.3)	14 (42.4)	2 (6.1)
41–60 (*n*=32)	1 (3.1)	4 (12.5)	13 (40.6)	14 (43.8)	0
61–80 (*n*=26)	0	6 (23.1)	9 (34.6)	11 (42.3)	0
>80 (*n*=9)	1 (11.1)	2 (22.2)	4 (44.4)	1 (11.1)	1 (11.1)
χ^2, *P*	13.344, 0.345				
Sex					
Male (*n*=58)	1 (1.7)	8 (13.8)	20 (34.5)	28 (48.3)	1 (1.7)
Female (*n*=42)	1 (2.4)	10 (23.8)	17 (40.5)	12 (28.6)	2 (4.8)
χ^2, *P*	4.761, 0.313				
Type of disability					
Temporary (*n*=60)	2 (3.3)	11 (18.3)	21 (35.0)	25 (41.7)	1 (1.7)
Permanent (*n*=40)	0	7 (17.5)	16 (40.0)	15 (37.5)	2 (5.0)
χ^2, *P*	2.498, 0.645				

to provide dental care to wheelchair-bound patients have also been done in the past;[4,8,9] however, most of these devices could not become part of routine dental practice as they merely remained some technological innovations for academic purposes that failed to achieve clinical applicability owing to lack of dentist/patient acceptability. In fact, the roles of patients in diffusing innovations are highly under-recognized.[10] Unfortunately, previous developments in the related area did not include the patient perspective on their innovations.[4,8,9] In the present study, patient feedback and experience were gathered for our innovative development as the essential part of the overall innovation program. As such, new product development is a continuous process that requires a constant match between the user expectations and the capability of the product to deliver the same.[11-13]

In the present study, overall positive feedback was received from the patients on the issues such as positioning, reclining, repositioning, fear of fall, enjoyment, discomfort, perception of dentist's discomfort, and intent to use in the future, obtaining scores of higher order. Overall, the median feedback score was 24 out of a maximum of 32, thus showing that the extent of positive feedback was up to 75% in our study population. Overall, the subjective experience of the patient was also good to very good in 77% of cases. These findings are encouraging.

However, the acceptability of technological innovation is also dependent on the profile and type of patient needs. Patient characteristics hold the key to the overall patient experience toward an innovation.[11] If differences in patient characteristics have an influence on their overall experience, then the innovation in question might have a variable acceptance among patients with different characteristics, and hence universal acceptability and application of this innovation may be jeopardized. In the present study, the impact of age, sex, and type of disability was analyzed on the overall patient experience and found it to be statistically not different across patient groups differentiated by different characteristics in question, thus showing that the recliner developed by us had a universal homogeneous acceptability.

The feedback achieved from the patients, however, highlighted some gaps – such as feedback areas such as positioning, reclining, fear of fall, and perception of dentist's discomfort that were identified with low mean scores. The findings of the study thus reflected that not only the physical recliner product developed by us affect the patient feedback, but it somehow lagged behind some psychological issues. It must be understood that the patient feedback recorded by us was on first-time use of this device and recurring use of this recliner during subsequent dental visits of the patients may help improve their feedback on these issues too. The significance of patient feedback on existing and newly developed services and products is

essential and has been highlighted in earlier studies too.[14,15] Such exercises help improve the quality of patient care.

The findings of the present study showed that the innovative reclining device developed by us was in general acceptable to the patients. This feedback will help improve the device further and to make it a popular, clinically acceptable product that could help make dental care access for wheelchair-bound patients easier.

CONCLUSION

The patient feedback and overall experience to the innovative reclining device to provide dental care to wheelchair-bound patients was satisfactory and highlighted some gaps. Taking care of these gaps would help increase the overall acceptability of the product, which would help make dental care access easier for wheelchair-bound patients.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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Original Article

Effect of different concentrations of titanium and silver nanoparticles on maxillofacial silicone MDX4-4210 on cell viability, tear bond strength, and shore strength: An *in vitro* study

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Abstract

Aim: The aim was to evaluate and compare the cell viability, tear bond strength, and shore hardness of MDX4-4210 silicone reinforced with titanium dioxide and silver nanoparticles in 1%, 2%, and 3%.

Settings and Design: The study design involves *in vitro* comparative study.

Materials and Methods: MDX4-4210 silicone incorporated with 1%, 2%, and 3% by weight of silver and titanium dioxide nanoparticles. A total of 112 specimens were prepared and grouped into 7, with 16 specimens in each group. Group 1 - control, Groups 2, 3, and 4 were 1%, 2%, and 3% silver, respectively. Groups 5, 6, and 7 were 1%, 2%, and 3% titanium dioxide nanoparticles, respectively. Cell viability was tested by MTT ASSAY on MG63 cell lines, tear bond strength was tested by peeling force in universal testing machine, and Shore A hardness was tested in durometer.

Statistical Analysis Used: The cell viability values were statistically analysed using one-way analysis of variance, and Tukey honestly significant difference test, tear bond strength and shore hardness values were analysed using Mann–Whitney test.

Results: Based on the MTT ASSAY test, 1% silver nanoparticles incorporated MDX4-4210 silicone showed maximum cell viability of 42.10%, whereas minimum cell viability was 18.06% for 3% of titanium dioxide-reinforced silicone. The mean value of tear bond strength of 1% silver and 1% titanium dioxide nanoparticles reinforced room temperature vulcanized maxillofacial silicone were 62.81 ± 3.637 N/m and 59.69 ± 5.313 N/m and the mean value of shore hardness of room temperature vulcanized of 1% silver and 1% titanium dioxide nanoparticles reinforced room temperature vulcanized maxillofacial silicone were 38.06 ± 1.237 and 36.75 ± 1.291.

Conclusion: Cell viability of 1% silver nanoparticles reinforced MDX4-4210 silicone was higher in comparison to the other groups, and tear bond strength and shore hardness were significantly higher in

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1% silver nanoparticles reinforced silicone compared to 1% titanium nanoparticles reinforced MDX4-4210 silicone.

Keywords: Cell viability, maxillofacial silicone, shore hardness, tear bond strength

INTRODUCTION

Maxillofacial defects occur due to stomatognathic disturbances, trauma, surgical resections, and burns. Surgical intervention is done to correct and prevent the disease, but a maxillofacial prosthesis is made to restore the patient's esthetics and oral function.[1] An intraoral prosthesis is to restore oral function, whereas extraoral prosthesis restores esthetics.[2]

Silicones are classified into heat-temperature-vulcanizing and room-temperature-vulcanizing (RTV) silicones. The various room-temperature-vulcanizing (RTV) silicones available are Silastic 382, 399, Silastic A-2186, Silastic 891, MDX 4-4210, Cosmesil, etc.[3] Silicone elastomers are now being reinforced with several nanosized particles to improve their mechanical, biological, and optical properties. Titanium dioxide nanoparticles incorporated with silicone materials showed increased physical, mechanical, and biological properties. This is due to the suspension of nanoparticles in the continuous phase of the silicone, which results in more force and cross-sectional area that leads to the formation of more cross-linked structure composite material. It has been proved that the incorporation of titanium dioxide is nontoxic.[4]

Silver nanoparticles are biocompatible with wide antimicrobial effect with specific physicochemical and optical properties. They have antifungal properties, but its biomedical properties have not been investigated yet. Cytotoxicity is the noxious effect of chemical agents on surviving cells. Cytotoxicity tests are very important in nanoparticles for biomedical applications. Usually, dyes are used for the evaluation of cytotoxicity of therapeutic agents. Hensten *et al*.[5] assessed the cytotoxicity of silicones through a cell culture technique. They used human epithelial cells and mouse fibroblasts in four RTV silicones (Silastic 399, R and S 330, MDX 4-4210, and SK 43) and concluded that test I comprising human and mouse cells, human epithelial cells were more sensitive than the mouse fibroblasts. In test II, trypsinization of the cells showed that MDX 4-4210 was less cytotoxic than the other materials.

Akay *et al*.[6] stated that the incorporation of nanoparticles of silica and titanium dioxide to A-2000, A-2006, and MDX4-4210 maxillofacial silicone did not exhibit any cytotoxicity in his research. To date, there are no studies done on the cytotoxicity of silver nanoparticles incorporated MDX4-4210.

The commonly used method of testing the bond strength between two elastic materials is tear bond strength/peel strength. The success of adhesive-retained facial prostheses depends on the retention of the artificial part to the skin. Facial prostheses are attached with the help of adhesives, mechanical means, and/or implants. Adhesive materials with skin present several problems, such as the longevity of the bond, (sensitivity) and to completely remove adhesive residue. Maintenance of the skin and prosthesis needs daily effort by the patient.[7]

Cevik *et al*.[8] experimented with the addition of titanium dioxide and silica nanoparticles with two RTV silicone (A-2000 and A-2006) in their mechanical properties and found that the properties of the materials were improved with TiO_2 nanoparticles. However, none of the previous studies evaluated the tear bond strength or peel strength and Shore A hardness of titanium dioxide nanoparticles reinforced MDX4-4210 and silver nanoparticles reinforced MDX4-4210. Hence, the study was done with the purpose of evaluating the cell viability, tear bond strength, and Shore A hardness of silicon elastomer (MDX4-4210) incorporated with titanium dioxide nanoparticles and silver nanoparticles in 1%, 2%, and 3% concentrations. A hypothesis was formulated that the cell viability, tear bond strength, and shore A hardness of titanium dioxide nanoparticles incorporated MDX4 4210 and silver nanoparticles reinforced MDX4 4210 at 1%, 2%, and 3% by weight would be similar.

MATERIALS AND METHODS

The study was approved by the Institutional Review Board of SRM Dental College, Ramapuram, Chennai, Tamil Nadu. (SRMDC/IRB/2020/MDS/No. 208). According to the ASTM D2240 standard, ISO/IEC 17025: 1999 stainless steel mold of 30 mm radius and 10 mm height and another mold of diameter 60 mm × 10 mm were prepared[9] [Figure 1]. The specimens were selected using a simple random sampling method. Power analysis was carried out to calculate the number of specimens to be

made for the study using G-power 3.1. 9.7 for Windows XP. (Heinrich Heine Universitat Dusseldorf, Dusseldorf, Germany) A total of 112 specimens were fabricated, which were divided into seven groups, each containing 16 specimens for testing cell viability wherein 1% silver nanoparticles reinforced silicone and 1% titanium dioxide reinforced silicone, which was the most viable cells (16 specimens each) were further used for testing tear bond strength and shore A hardness.

The RTV silicone (MDX 4-4210, Dow Corning, RBS Enterprises, Haryana, India) base and catalyst silicones were mixed in 10:1 ratio on a glass plate with a stainless-steel spatula to obtain a uniform mix. It was then placed in the vacuum chamber for 20 min to remove the air bubbles. The mix was poured into the stainless-steel molds and was compressed using a glass slab to apply constant pressure such that the material was equally spread around the die space by a single operator, and 32 specimens were made using the same method. The mold was coated with a layer of petroleum jelly for easy retrieval of the specimen. The silicone material was permitted to cure at room temperature for 24 h, then the specimens were retrieved carefully, and the excess material was removed with the help of a scalpel.

Titanium dioxide nanoparticles (Ultrananotech, Bangalore, Karnataka, India) and Silver nanoparticles (Ultrananotech, Bangalore, Karnataka, India) were weighed using a digital analytical balance (Citizen CY204 Analytical Balance, Gujarat, India), and 1%, 2%, and 3% and titanium dioxide nanoparticles and silver nanoparticles by weight size (0.02 μm) were added to the RTV Silicone MDX4 4210. (Dow Corning, RBS Enterprises, Haryana, India) Titanium dioxide nanoparticles and silver nanoparticles were added to the catalyst separately, so that they can be easily dissolved in the catalyst and then added to the pre-weighed base and mixed for 30 min to obtain a homogeneous mix. It was then placed in the vacuum chamber for another 20 min to eliminate any air bubbles. Then, the specimens were polymerized at room temperature for 24 h, and then MTT ASSAY testing was carried out for cell viability.

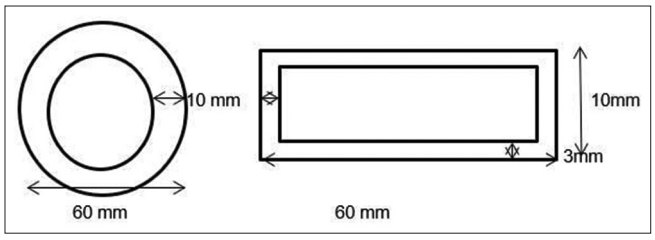

Figure 1: Schematic diagram of master die for shore hardness and tear bond strength respectively

MG-63 cell lines (King Institute, Chennai, Tamil Nadu, India) were kept in minimal essential medium (MEM) added with 10% fetal bovine serum (FBS), penicillin (100 U/mL), and streptomycin (100 μg/mL) in a humidified atmosphere of 50 μg/mL CO_2 at 37°C. For MTT assay testing [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide] (Hi Media Laboratories, Chennai, Tamil Nadu, India) and other chemical reagents (Sigma Aldrich, St. Luis, USA). Cells (1×10^5/well) were poured into 24 well plates and incubated at 37°C with a 5% CO_2 atmosphere for 24 h. Then, the specimens were taken off from the well and cleaned with phosphate-buffered saline (pH 7.4) and again incubated for 4 h. One milliliter of DMSO was poured into wells after incubation [Figure 2]. Ultraviolet spectrophotometer (YS6060 Benchtop, 3nh global) was used to assess the absorbance capacity at 570 nm with DMSO. The computation was done to determine the 50% inhibition concentration and the half-maximum inhibitory concentration (IC50) by graphical method. Percent cell viability = A570 (absorbance at 570 nm) of treated cells/A570 of control cells × 100.[8]

Curing of silicone rubber strips was done in 60 mm × 20 mm steel molds for 24 h. The dorsal surface of subject's anyone hand was chosen and cleaned with acetate stencils and permitted to dry for a few minutes. Medical adhesive (Prebond adhesive, Technovent, Bridgend, UK) was applied to the silicone rubber strips, and then, the strips were fixed to the skin. The subjects were asked to rest their hand on the crosshead of the machine, which was lowered at a rate of 10 cm/min. After 5 min, the strip was peeled from the subject's skin in a Universal Testing Machine (Instron-6800 series, Bengaluru, India) by gently elevating one edge of the strip, which was attached to a pneumatic grip. The peeling was done in 90° from the surface of the skin. The maximal peel force was calculated in grams force.[9]

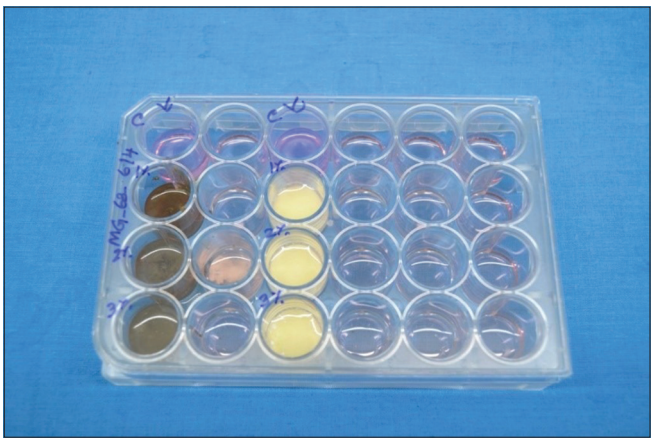

Figure 2: [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide] (MTT) assay test

The hardness of 6 mm thickness maxillofacial silicone was done using Durometer (Shore D Durometer, Samruddhi Industries, Gujarat, India). The durometer of the indenter hand held in a standing setting, and the indenter tip penetrates the surface of the material under a 10N load. For accurate measurements, three measurements were performed on each specimen, and the mean value was reported in shore units. The position of the specimen was changed from top to bottom, and the test was done again.[9] The experimental specimens were examined under a scanning electron microscope (Supra 55; Zeiss) [Figures 3 and 4].

Statistical analysis

The obtained values were analysed using the statistical software IBM SPSS Statistics version 22 for Windows IBM Corp; Armonk NY; USA). Comparison of cell viability of 1%, 2%, and 3% silver nanoparticles and 1%, 2%, and 3% titanium dioxide nanoparticles incorporated MDX4-4210 within the group was done using one-way analysis of variance and multiple group comparison was made using Tukey honestly significant difference test. Shapiro Wilk test was used to check the normality of the data for tear bond strength and shore hardness of 1% silver and 1% titanium dioxide nanoparticles incorporated MDX4-4210. The test showed that the data did not follow normal distribution, hence, non-parametric test Mann Whitney's U test was used to compare the tear bond strength and shore hardness between the two groups. The values were considered statistically significant when the $P < 0.05$.

RESULTS

1% silver nanoparticles incorporated MDX4-4210 with base showed a mean value of 41.3425%, whereas 1% titanium dioxide nanoparticles incorporated MDX4-4210 with a base mean value of 40.8513% [Table 1]. Mean square value between groups was 10970.807 and within groups was 0.163. F value between groups was 67195.503 [Table 2]. Silver and titanium dioxide nanoparticles incorporated MDX4-4210 in 1%, 2%, and 3% concentration showed a significant value of *P* 0.000, which was <0.05. Hence, it was considered as statistically significant between all seven groups [Table 3].

The mean and standard deviation of tear bond strength for silver nanoparticles incorporated MDX4-4210 was 62.81 ± 3.637 N/m and for titanium dioxide nanoparticles incorporated MDX4-4210 was 59.69 ± 5.313 N/m. The Man-Whitney U value for tear bond strength was 77.500. The significant value *P* was 0.038, which was <0.05. Hence there was a statistical significant difference observed in1% Silver and titanium dioxide nanoparticles incorporated MDX4-4210 [Table 4].

The mean and standard deviation of shore hardness value for 1% silver nanoparticles was 38.06 ± 1.237 and 1% titanium dioxide nanoparticles were 36.75 ± 1.291. For shore hardness the Man-Whitney U value was 52.500 and the significant value *P* 0.003, which was <0.05. Hence, it was considered as statistically significant between groups [Table 5].

1% silver nanoparticles and 1% titanium dioxide nanoparticles incorporated MDX4-4210 showed maximum cell viability; hence, only that specific concentration was taken for evaluation of hardness test and tear bond strength test. 1% silver nanoparticles incorporated MDX4-4210 showed more tear bond strength and shore hardness compared to 1% titanium dioxide nanoparticles incorporated MDX4-4210.

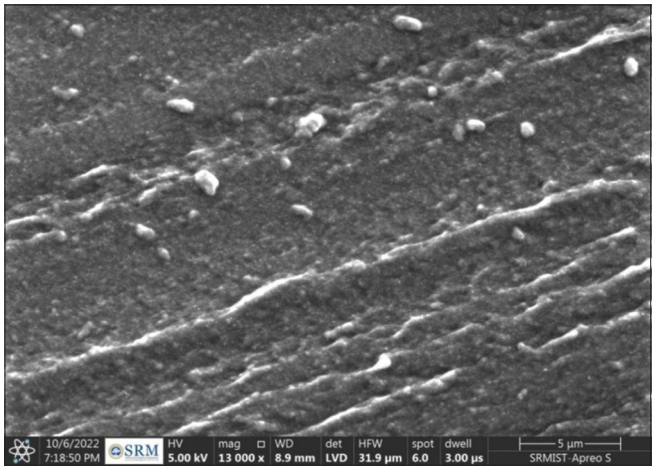

Figure 3: Scanning electron microscope image of MDX 4-4210 silicone with 1% silver nanoparticle (magnification ×13000)

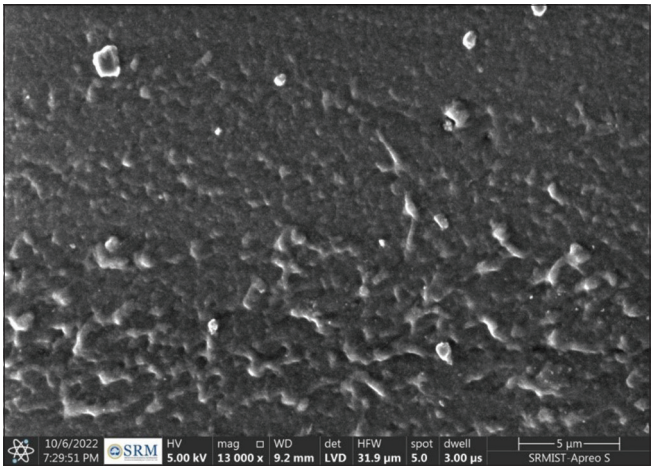

Figure 4: Scanning electron microscope image of MDX 4-4210 silicone with 1% titanium dioxide nanoparticles (magnification ×13000)

Table 1: Mean and standard deviation of cell viability

Group	*n*	Mean	SD	SE	95% CI for mean		Minimum	Maximum
					Lower bound	Upper bound		
Base	16	62.4500	0.01366	0.00342	62.4427	62.4573	62.42	62.48
Base + Ag1%	16	41.3425	1.07770	0.26943	40.7682	41.9168	39.07	42.10
Base + Ag 2%	16	33.6075	0.37878	0.09469	33.4057	33.8093	32.90	33.85
Base + Ag3%	16	25.5919	0.01834	0.00458	25.5821	25.6016	25.55	25.61
Base + TiO_2 1%	16	40.8513	0.01746	0.00437	40.8419	40.8606	40.82	40.87
Base + TiO_2 2%	16	30.3419	0.00981	0.00245	30.3366	30.3471	30.32	30.35
Base + TiO_2 3%	16	18.0588	0.01708	0.00427	18.0496	18.0679	18.00	18.07
Control	16	100.000	0.00000	0.00000	100.0000	100.0000	100.00	100.00
Total	128	44.0305	24.5938	2.17379	39.7289	48.3320	18.00	100.00

SD: Standard deviation, SE: Standard error, CI: Confidence interval

Table 2: One-way ANOVA for cell viability

(I) Group	Sum of squares	df	Mean square	*F*	Significant
Between groups	76,795.647	7	10,970.807	67,195.503	0.000
Within groups	19.592	120	0.163		
Total	76,815.239	127			

DISCUSSION

Silver nanoparticles and titanium dioxide nanoparticles reinforced maxillofacial silicone elastomer MDX4-4210 showed lesser cell viability and more cytotoxicity as the concentrations of nanoparticles increased. Silver nanoparticles incorporated silicone are more biocompatible at 1% and exhibit greater tear bond strength, and Shore A hardness values than titanium dioxide nanoparticles incorporated in silicone. The previous studies[10,11] reported that the incorporation of silver nanoparticle at 0.5% concentration showed the least cytotoxicity 16% ± 0.21% when compared to 1%.Hence the present study results confirmed the results of the previous study.

Akay *et al*.[6] stated that when titanium dioxide, fumed silica, and silaned silica were added to A-2000 and A-2006 maxillofacial silicones, neither of the nanoparticles proved to be cytotoxic at an interval of 24, 48, and 72 h. In another research, the authors evaluated the cytotoxicity of 20 ppm concentrated silver nanoparticles incorporated maxillo-facial silicone A-2000 and A-2006 and found that the addition of silver nanoparticles at 20 ppm concentration decreased the hardness of silicone elastomer 15 ± 0.52 KN, and the color stability and tear strength were unaffected.[12]

A previous study reported the assessment of *in vitro* cytotoxicity of silicones through a cell culture method in mouse fibroblasts and human epithelial cells for four RTV silicones (Silastic 399, R and S 330, MDX 4-4210, and SK 43) and concluded that test I comprising of human and mouse cells, human epithelial cells were more sensitive than the mouse fibroblasts. In test II, trypsinization of the cells showed that MDX 4-4210 was less cytotoxic than the other materials.[13]

A previous study stated that 2% titanium dioxide nanoparticles incorporated silicones showed good mechanical and aging resistant properties and showed more biocompatibility in *in vitro* cellular studies compared with 4%–6% titanium dioxide nanoparticles incorporated silicones. Hence, these previous studies stated that as the concentration of nanoparticle increases, biocompatibility decreases.[14]

Literature reported the effect of the addition of titanium dioxide, fumed silica, and silaned silica nanoparticles to RTV silicones (A-2000 and A-2006) on the mechanical properties. Most of the silica specimens showed a high tensile strength of 4.30 ± 1.11 MPa compared with control and TiO_2 groups 2.23 ± 0.21 MPa for A-2000 and A-2006 silicones.[15] The TiO_2 group showed more hardness value for A-2000 of 38 ± 5 KN and a less hardness value for A-2006 of 22 ± 37 KN. The fumed silica and TiO_2 groups showed significantly more tear strength of 17.17 ± 1.18 N/m than the control.

As the percentage of nanoparticles increased, cell viability decreased; hence, 1% of both the nanoparticle-reinforced silicones showed the highest biocompatibility compared to 2%–3% incorporated silicones. Hence, the study results rejected the null. Furthermore, 1% silver nanoparticles incorporated silicones showed higher biocompatibility, tear bond strength, and shore A hardness than 1% titanium dioxide nanoparticles incorporated silicones in the previous studies.[16,17]

Limitations of this study were that as the concentration of nanoparticles increased, biocompatibility decreased; hence, the incorporation of silver or titanium dioxide nanoparticles of more than 1% concentration did not show a favourable outcome. The incorporation of silver nanoparticles caused a colour change in the maxillofacial silicone MDX4-4210. Moreover, there was the randomness of the mechanical properties on changing the concentrations of the nanoparticles.

Table 3: Tukey honestly significant difference *post hoc* test for cell viability

Group (I)	Group (J)	Mean difference (I–J)	SE	Significant	95% CI	
					Lower bound	Upper bound
Base	Base + Silver Nano 1%	21.10750*	0.14286	0.000	20.6668	21.5482
	Base + Silver Nano 2%	28.84250*	0.14286	0.000	28.4018	29.2832
	Base + Silver Nano 3%	36.85813*	0.14286	0.000	36.4174	37.2989
	Base + titanium 1%	21.59875*	0.14286	0.000	21.1580	22.0395
	Base + titanium 2%	32.10813*	0.14286	0.000	31.6674	32.5489
	Base + titanium 3%	44.39125*	0.14286	0.000	43.9505	44.8320
	Control	−37.55000*	0.14286	0.000	−37.9907	−37.1093
Base + Silver Nano 1%	Base	−21.10750*	0.14286	0.000	−21.5482	−20.6668
	Base + Silver Nano 2%	7.73500*	0.14286	0.000	7.2943	8.1757
	Base + Silver Nano 3%	15.75063*	0.14286	0.000	15.3099	16.1914
	Base + titanium 1%	0.49125*	0.14286	0.018	0.0505	0.9320
	Base + titanium 2%	11.00063*	0.14286	0.000	10.5599	11.4414
	Base + titanium 3%	23.28375*	0.14286	0.000	22.8430	23.7245
	Control	−58.65750*	0.14286	0.000	−59.0982	−58.2168
Base + Silver Nano 2%	Base	−28.84250*	0.14286	0.000	−29.2832	−28.4018
	Base + Silver Nano 1%	−7.73500*	0.14286	0.000	−8.1757	−7.2943
	Base + Silver Nano 3%	8.01563*	0.14286	0.000	7.5749	8.4564
	Base + titanium 1%	−7.24375*	0.14286	0.000	−7.6845	−6.8030
	Base + titanium 2%	3.26563*	0.14286	0.000	2.8249	3.7064
	Base + titanium 3%	15.54875*	0.14286	0.000	15.1080	15.9895
	Control	−66.39250*	0.14286	0.000	−66.8332	−65.9518
Base + Silver Nano 3%	Base	−36.85813*	0.14286	0.000	−37.2989	−36.4174
	Base + Silver Nano 1%	−15.75063*	0.14286	0.000	−16.1914	−15.3099
	Base + Silver Nano 2%	−8.01563*	0.14286	0.000	−8.4564	−7.5749
	Base + titanium 1%	−15.25937*	0.14286	0.000	−15.7001	−14.8186
	Base + titanium 2%	−4.75000*	0.14286	0.000	−5.1907	−4.3093
	Base + titanium 3%	7.53313*	0.14286	0.000	7.0924	7.9739
	Control	−74.40813*	0.14286	0.000	−74.8489	−73.9674
Base + titanium 1%	Base	−21.59875*	0.14286	0.000	−22.0395	−21.1580
	Base + Silver Nano 1%	−0.49125*	0.14286	0.018	−0.9320	−0.0505
	Base + Silver Nano 2%	7.24375*	0.14286	0.000	6.8030	7.6845
	Base + silver Nano 3%	15.25937*	0.14286	0.000	14.8186	15.7001
	Base + titanium 2%	10.50937*	0.14286	0.000	10.0686	10.9501
	Base + titanium 3%	22.79250*	0.14286	0.000	22.3518	23.2332
	Control	−59.14875*	0.14286	0.000	−59.5895	−58.7080
Base + titanium 2%	Base	−32.10813*	0.14286	0.000	−32.5489	−31.6674
	Base + Silver Nano 1%	−11.00063*	0.14286	0.000	−11.4414	−10.5599
	Base + Silver Nano 2%	−3.26563*	0.14286	0.000	−3.7064	−2.8249
	Base + Silver Nano 3%	4.75000*	0.14286	0.000	4.3093	5.1907
	Base + titanium 1%	−10.50937*	0.14286	0.000	−10.9501	−10.0686
	Base + titanium 3%	12.28313*	0.14286	0.000	11.8424	12.7239
	Control	−69.65813*	0.14286	0.000	−70.0989	−69.2174
Base + titanium 3%	Base	−44.39125*	0.14286	0.000	−44.8320	−43.9505
	Base + Silver Nano 1%	−23.28375*	0.14286	0.000	−23.7245	−22.8430
	Base + Silver Nano 2%	−15.54875*	0.14286	0.000	−15.9895	−15.1080
	Base + Silver Nano 3%	−7.53313*	0.14286	0.000	−7.9739	−7.0924
	Base + titanium 1%	−22.79250*	0.14286	0.000	−23.2332	−22.3518
	Base + titanium 2%	−12.28313*	0.14286	0.000	−12.7239	−11.8424
	Control	−81.94125*	0.14286	0.000	−82.3820	−81.5005
Control	Base	37.55000*	0.14286	0.000	37.1093	37.9907
	Base + Silver Nano 1%	58.65750*	0.14286	0.000	58.2168	59.0982
	Base + Silver Nano 2%	66.39250*	0.14286	0.000	65.9518	66.8332
	Base + Silver Nano 3%	74.40813*	0.14286	0.000	73.9674	74.8489
	Base + titanium 1%	59.14875*	0.14286	0.000	58.7080	59.5895
	Base + titanium 2%	69.65813*	0.14286	0.000	69.2174	70.0989
	Base + titanium 3%	81.94125*	0.14286	0.000	81.5005	82.3820

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

Clinical implications

Cell viability test MTT assay depicts that 1% silver nanoparticles showed the least cytotoxicity and increased tear bond strength and hardness, suggesting greater flexibility, long shelf life, and higher bio-compatibility.

CONCLUSION

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

1. The mean cell viability of room temperature vulcanized 1% silver and 1% titanium dioxide nanoparticles

Table 4: Mann Whitney U test to compare the tear bond strength

Group	Minimum	Maximum	Mean	Std. Deviation	Mean Rank	Sum of Ranks	Man Whitney *U*	*P*
Titanium	50	70	59.69	5.313	13.34	213.50	77.500	0.038
Silver	60	70	62.81	3.637	19.66	314.50		

The mean difference is significant at the 0.05 level

Table 5: Mann Whitney U test to compare the shore hardness

Group	Minimum	Maximum	Mean	Std. Deviation	Mean Rank	Sum of Ranks	Man Whitney *U*	*P*
Titanium	34	38	36.75	1.291	11.78	188.50	52.500	0.003
Silver	35	39	38.06	1.237	21.22	339.50		

The mean difference is significant at the 0.05 level

reinforced maxillofacial silicone were 41.34 ± 1.07770 and 21.1075 ± 0.14286. Therefore, the cell viability of 1% silver nanoparticles reinforced maxillofacial silicone was greater in comparison to the other groups

2. The mean value of tear bond strength of 1% silver and 1% titanium dioxide nanoparticles reinforced room temperature vulcanized maxillofacial silicone were 62.81 ± 3.637 N/m and 59.69 ± 5.313 N/m. The tear bond strength of 1% silver nanoparticles reinforced maxillofacial silicone was >1% titanium dioxide nanoparticles reinforced maxillofacial silicone and the mean difference between the groups was statistically significant.
3. The mean values of shore hardness of room temperature vulcanized 1% silver and 1% titanium dioxide nanoparticles reinforced room temperature vulcanized maxillofacial silicone were 38.06 ± 1.237 and 36.75 ± 1.291. Therefore, the shore hardness value of 1% silver nanoparticles reinforced maxillofacial silicone was >1% titanium dioxide nanoparticles reinforced maxillofacial silicone and the mean difference between the groups was statistically significant.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Original Research

An *in vitro* comparison of the marginal fit of provisional crowns using the virtual tooth preparation workflow against the traditional technique

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Abstract

Aim: This study investigates the effectiveness of an innovative virtual tooth preparation workflow for the fabrication of dental crowns using cone-beam computed tomography (CBCT) and intraoral scanners (IOSs) with conventional workflow using extraoral/laboratory scanners.

Settings and Design: This *in vitro* experimental study was conducted in the laboratory of a university in Chennai, India. The dental laboratory and research facilities at the institution were utilized for the fabrication of the temporary crowns and the data acquisition process.

Materials and Methods: Institutional approval was obtained from the university. It was basically a comparison between the virtual prep technique using CBCT and IOS and the conventional digital technique using extra oral scanners (EOS) for temporary crown fabrication. The sample size was estimated using an effect size of 1.5004, assuming a normal distribution, a significance level of 0.05, and a power of 0.95 in G power software. Based on this calculation, an extracted second lower molar was used to fabricate 10 samples in each group. The samples were divided into three groups: the CBCT (Group 1), the IOS (Group 2), and laboratory scanner (Group 3 as control) groups. The vertical marginal gap of all the surfaces of the crown was evaluated using a scanning electron microscope.

Statistical Analysis Used: Data were analyzed using one-way ANOVA using the SPSS software version 26.0, IBM, Armonk, NY, USA.

Results: Acceptable marginal discrepancy values were obtained in all three groups. There was no significant difference in the marginal discrepancy recorded ($P = 0.113$).

Conclusion: Virtual tooth preparation using CBCT and IOSs can be used as an alternative to the conventional workflow for provisional crown and bridge fabrication.

Keywords: Cone-beam computed tomography, digital dentistry, intraoral scan, marginal fit, virtual tooth preparation

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INTRODUCTION

With the advent of digital dentistry, various methods of provisional crown fabrication have been employed lately.[1] Currently, the use of computer-aided design (CAD)/computer-aided manufacturing (CAM) technology is the most preferred method of fabrication following tooth preparation over manual methods.[2] This includes scanning of the prepared tooth surface and then designing the crowns. This is both time-consuming and usually requires an additional clinical appointment.

Virtual tooth preparation workflow revolutionizes the fabrication of temporary crowns by utilizing computer-generated tooth preparation technology.[3,4] This innovative approach eliminates the conventional need for in-mouth tooth preparation followed by prefabricated dental wax-ups, as the prosthesis is readily available even before commencing the tooth preparation process.[5,6] This allows for efficient relining and cementation of the prosthesis in accordance with the patient's specific preparation requirements. This method has several advantages, such as improved accuracy, reduced time required for crown fabrication, increased efficiency, enhanced understanding of the treatment procedure and outcomes, and greater patient involvement in the treatment process.[7]

Newer methods of data acquisition have been advocated for obtaining three-dimensional (3D) models to fabricate dental prostheses, including conventional extra oral scanners (EOS) and other methods such as intraoral scanners (IOS) and cone-beam computed tomography (CBCT).[8-10] This scan data can be converted into standard tessellation language (STL) file format, which can later be imported into digital dental designing software for fabrication of crowns using virtual tooth preparation workflow.[11-13] Achieving proper adaptation of dental prostheses is crucial for the long-term success of prosthetic treatments.[14,15] Previous studies[16-20] have proposed a clinically acceptable range of 80–200 microns as the permissible difference between the tooth surface and the prosthesis.

This research aims to compare the marginal fit of crowns created using a virtual tooth preparation workflow from CBCT data and intraoral scan with the commonly used digital workflow to fabricate dental crowns and bridges using extraoral scan. The null hypothesis was that there would be no difference in the marginal fit of crowns fabricated using either workflow.

MATERIALS AND METHODS

Study setting and estimation of sample size

In this *in vitro* study, an extracted lower second molar tooth was used to create 10 crowns for each group from 10 CAM outputs to assess the marginal discrepancy for the four surfaces of each crown (n = 40 for each group). To determine the sample size, the effect size was estimated (dz = 1.5004) assuming a normal distribution, with a = 0.05 and a power of 0.95 (1-b error probability). The sample size calculation was performed using G*Power 3.1.9.3 for Mac OS X®,[21] based on data from a previously published study.[5] Ethical approval for this study was obtained from the university (approval number: IHEC/SDC/PROSTHO-2002/23/124).

Scanning and manufacturing protocol

This study was a comparison between the virtual prep technique using CBCT and IOS and the conventional digital technique using EOS for temporary crown fabrication.

The samples were divided into three groups: test Group 1 (CBCT group), test Group 2 (IOS group), and control Group 3 (EOS) [Figure 1]. The samples in the test groups were fabricated similarly in each step except for their method of data acquisition. The scans obtained from each of these methods were exported in STL file format into CAD software (3Shape, Niels Juels Gade 13, 1059 Copenhagen K Denmark), where a virtual tooth preparation workflow was followed. This involved digitally removing the necessary tooth structure to accommodate the temporary crown restoration while ensuring proper retention and esthetics by fine-tuning the preparation parameters, such as the path of insertion, depth, taper, and margin design, to achieve the desired dimensions and characteristics. This step allowed for customization based on the specific requirements of the design and was standardized for all three groups. The margin line was kept at the cementoenamel junction to follow the crown contour. The crown fabrication process incorporated specific set cement space dimensions, with margins allowing 20 μm, whereas the rest of the internal spaces allowed for 60 μm space. Once satisfied with the virtual tooth preparation, the pertinent information was transferred to CAM software (CORiTEC iCAM V5; imes-icore GmbH) and milling (CNC; CORiTEC 550i; imes-icore GmbH). Utilizing a cutting-edge CNC machine (CORiTEC, imes-icore GmbH), the crowns were milled meticulously from polymethyl methacrylate (PMMA) blocks. It is noteworthy that the PMMA crowns underwent no further treatment or adjustments subsequent

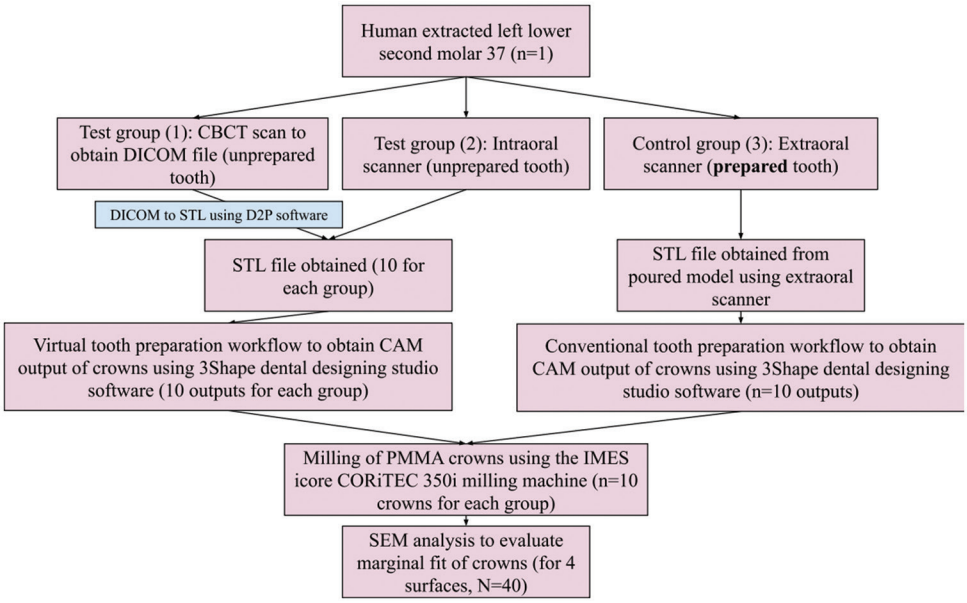

Figure 1: Flowchart describing the methodology for fabricating the temporary PMMA crowns using three different scanning protocols. CBCT: Cone-beam computed tomography, DICOM: Digital Imaging and Communications in Medicine, STL: Standard tessellation language, D2P: DICOM to print, CAM: Computer-aided manufacturing, IMES: Integrated mechanics electronics software, SEM: Scanning electron microscope

to the milling process.

Cone-beam computed tomography group (experimental Group 1)

The tooth was scanned using CBCT (Carestream CS9600, Carestream Dental India, Mumbai, Maharashtra, India) at the recommended setting parameters (voxel resolution: 0.125 mm at the resolution settings of 0.200 mm, 80 kV, 2 mA, 11.4 s, 582 mGy·cm^2, and field of view 5 × 5) in Digital Imaging and Communications in Medicine (DICOM) format. This was later converted using DICOM to Print (D2P) software (3D systems, Rock Hill, South Carolina) into a STL format. This 3D model of the tooth was later imported into 3Shape dental designing software to fabricate crowns using a virtual tooth preparation workflow [Figure 2].

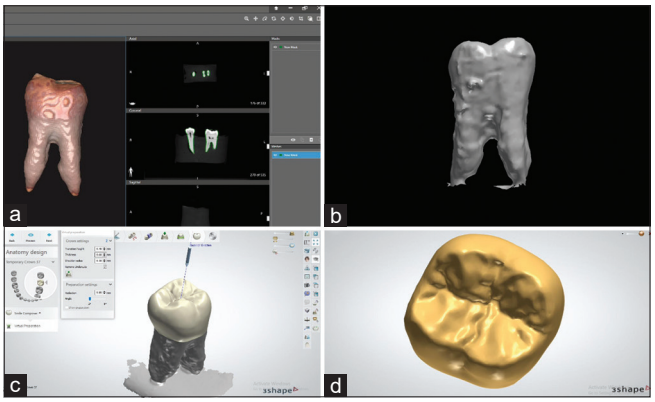

Figure 2: Cone-beam computed tomography (CBCT) scanning protocol of crown fabrication (a: CBCT recorded in DICOM format, b: file converted to standard tessellation language [STL] file format, c: Crown designed on 3Shape dental manager using the virtual tooth preparation workflow, d: Final crown prosthesis STL file)

Intraoral scanners group (experimental Group 2)

An intraoral scan of the tooth specimen was recorded using the 3Shape Trios IOS (3Shape, Niels Juels Gade 13, 1059 Copenhagen K Denmark) using a standardized methodology. The scanning sequence followed a systematic approach, beginning with the occlusal surface and progressing to other surfaces of the tooth in a sweeping motion to capture the entire tooth area. Proper illumination was maintained throughout the procedure to ensure clear visualization, and a dry field using cotton rolls was used to optimize the scanning accuracy and reduce potential interferences from saliva or moisture. The scan was then processed and imported as a STL file format to obtain a 3D model of the scan, which was later imported into the 3Shape dental designing studio for designing the temporary crowns using the virtual tooth preparation workflow (3Shape, Niels Juels Gade 13, 1059 Copenhagen K Denmark) [Figure 3].

Specimen preparation

Tooth preparation was done on the extracted tooth sample by an experienced prosthodontist (V.K) to receive an anatomically contoured PMMA temporary crown. A meticulous tooth preparation technique involved using a diamond rotary instrument (TF 12; MANI, INC., Tochigi 321-3231, Japan) and a high-speed handpiece (Nsk Pana Air FX SB02; NSK, Kanuma, Tochigi 322-8666, Japan) with coolant to a create precise 1.0 mm shoulder margin encircling the tooth.

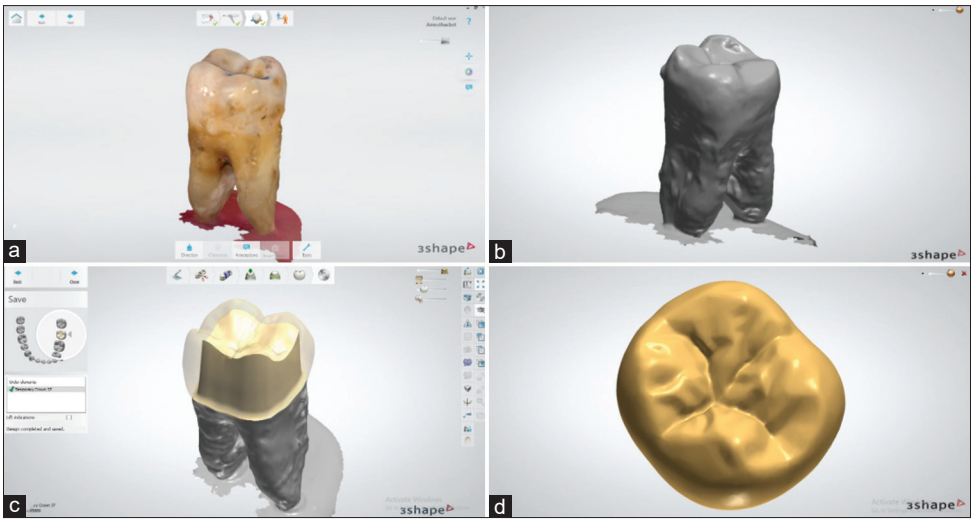

Figure 3: Intraoral scanning protocol of crown fabrication (a: Intraoral scanning using 3Shape Trios intraoral scanner, b: Standard tessellation language [STL] file format obtained, c: Crown designed on 3Shape dental manager using the virtual tooth preparation workflow, d: Final crown prosthesis STL file)

EOS group (Group 3 control)

The prepared tooth was used to record a two-stage putty impression, and a dental stone model was poured to obtain a positive replica of the tooth preparation. This model was then scanned using an extraoral laboratory scanner (3Shape E4 laboratory scanner, 3Shape, Niels Juels Gade 13, 1059 Copenhagen K, Denmark) using a standardized methodology. The scan obtained was later used for designing the PMMA temporary crown using the conventional crown fabrication workflow [Figure 4]. The CAM output obtained was then used to mill 10 samples of this design.

Marginal fit evaluation

The vertical marginal gap of all samples was evaluated using a scanning electron microscope (SEM) (JSM-IT800, JEOL Tokyo, Japan). Before analysis, the specimens were coated with 24-carat gold using a metallizer (Q15RS, Quorum Technologies, Sussex, UK) to prevent any electron distortion. The SEM captured an image of the specimen at a magnification of ×250 using an energy dispersal detector (Link Pentafet, Oxford Instruments, Abingdon, UK). The image was then transferred to a computer with INCA Suite 4.04 software (Oxford Instruments; Abingdon, UK) to digitize and capture the image. To ensure consistency, a marker pen (Sakura marker, Sakura Color Product Corporation, Japan) was used to mark three points on the middle of each surface of each crown. This ensured that the measuring area was standardized and the positions were repeatable for all crowns. The marginal fit was determined by measuring the average of 360 measurements (3 markings for each of the 4 surfaces per tooth for 30 crowns) to calculate the marginal gap of each crown [Figure 5].

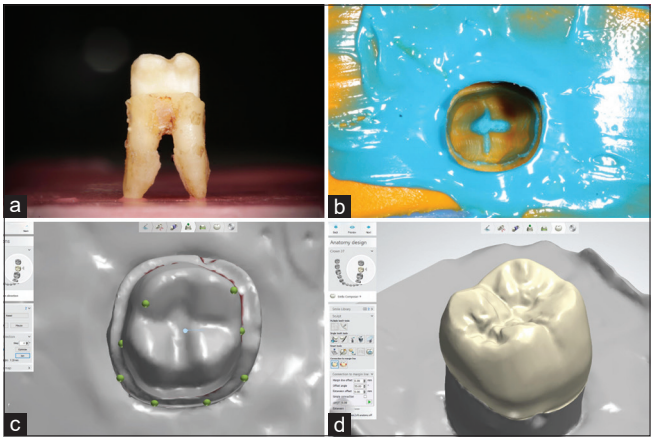

Figure 4: Conventional tooth preparation workflow (a: Tooth preparation done on the sample to accept polymethyl methacrylate (PMMA) crowns followed by. b: recording two stage putty impression. c: Tooth preparation scan to accept. d: PMMA crown fabrication)

Statistical analysis

The information was gathered and organized using Google Sheets, then transferred to statistical software, SPSS version 26.0, IBM, Armonk, NY, USA, to get statistical significance at $\alpha = 0.05$. The data showed a normal distribution based on the Shapiro–Wilk test. The overall marginal discrepancy of each surface was determined using a one-way ANOVA.

RESULTS

The average marginal gap for all three groups was found to be 113.37 ± 45.758 μm (Group 1 = CBCT), 127.82 ± 43.655 μm (Group 2 = IOS), and 107.30 ± 44.893 μm (Group 3 = EOS) [Table 1]. The mean difference among groups was not significant ($P > 0.05$),

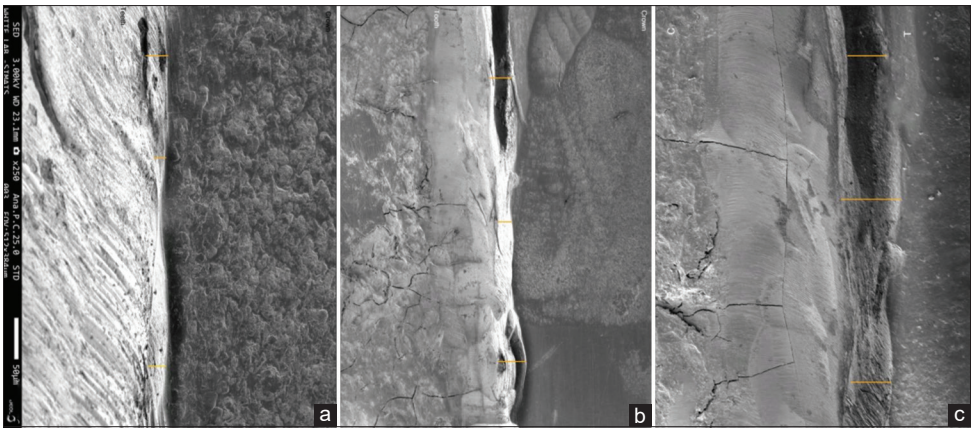

Figure 5: Scanning electron microscope analysis (×250) of the marginal discrepancy of the (a) control and (b) cone-beam computed tomography and (c) intraoral scanner groups

indicating the acceptance of the virtual preparation technique using CBCT and IOS**.** Although the difference was recorded, they were all in the range of clinically acceptable limits for temporary crowns (<200 μm). When comparing discrepancy on each surface, more discrepancies were observed on the buccal surface, followed by the lingual, mesial, and distal surfaces, respectively [Figure 6]. However, no statistically significant differences were seen among surfaces while evaluating for marginal discrepancy ($P > 0.05$) [Table 2].

DISCUSSION

The findings of this investigation indicate that the null hypothesis was accepted, as there were no statistically significant disparities observed in the marginal discrepancy of all three groups, indicating similar outcomes between the experimental groups (virtual preparation using CBCT and IOS) and the control group (conventional preparation and scanning using EOS). Analyzing the results of the present study, it was found that crowns fabricated using the conventional workflow exhibited the lowest marginal gap measurement (107.30 ± 44.893 μm), and although the crowns fabricated using the virtual tooth preparation workflow displayed higher values of vertical marginal discrepancies (CBCT: 113.37 ± 45.758 μm, IOS: 127.82 ± 43.655 μm), the mean gaps for all three groups fell within the clinically acceptable range.

The significance of achieving precise marginal fit has been extensively discussed in various publications.[22-25] While horizontal discrepancies may allow for clinical adjustments, vertical marginal discrepancies pose a greater challenge and are less amenable to compensation or correction, potentially leading to complications and failures, as reported by Holmes *et al*.[26] Therefore, this study specifically focused on evaluating the vertical marginal gap. Recent investigations

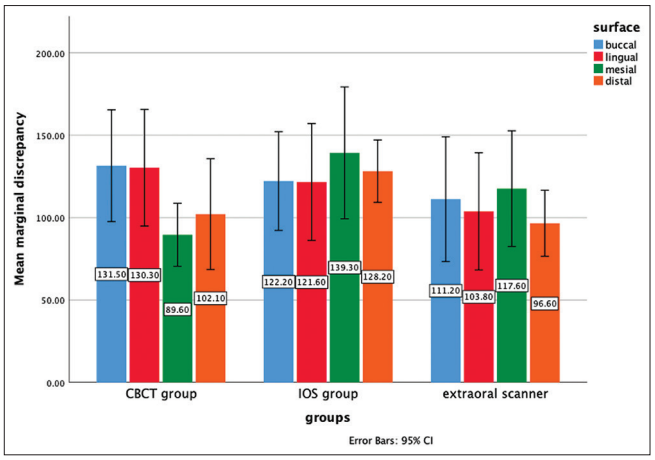

Figure 6: Bar graph depicting the mean marginal discrepancy of all three groups recorded for each surface of the tooth was derived using a one-way ANOVA test ($F = 2.218$). CBCT: Cone-beam computed tomography, IOS: Intraoral scanners

have established that marginal gaps ranging from 80 to 200 microns are clinically acceptable for ensuring the longevity of cemented crowns.[27] It is worth noting that no adjustments were made to the crowns before measuring the marginal fit. However, had the prosthodontist done adjustments on the intaglio surface of the crowns as one would normally do in a clinical or laboratory setting, the marginal gap would have been even lesser.

Traditional methods of fabricating temporary crowns include tooth preparation, which is followed by recording impressions and then using a putty index on a wax mockup or a time-consuming digital design of crowns on the prepared tooth surface. The final temporaries obtained after polishing may also injure the soft tissues around the prepared teeth. This process can be time-consuming and dependent on the expertise and precision of the technician or operator.[28,29] By digitally fabricating crowns before tooth preparation in a clinical setting, several advantages can be achieved. First,

Table 1: Mean marginal discrepancy recorded for all three groups derived using a one-way ANOVA test accepting the null hypothesis (*P*>0.05)

Group	*n*	Mean±SD (μm)	*F*	*P*	Null hypothesis
CBCT	40	113.37±45.758	2.218	0.113#	Accepted
IOS	40	127.82±43.655			
EOS (control)	40	107.30±44.893			

#No statistical significant at *P*>0.050. SD: Standard deviation, CBCT: Cone-beam computed tomography, IOS: Intraoral scanners, EOS: Extra oral scanners

Table 2: Marginal discrepancy of all three groups recorded for each surface of the tooth was derived using a one-way ANOVA test

Group	Surface	*n*	Mean±SD	*F*	*P*
CBCT	Buccal	10	131.5±47.394	2.287	0.095#
	Lingual	10	130.3±49.481		
	Mesial	10	89.6±26.738		
	Distal	10	102.1±47.021		
IOS	Buccal	10	122.2±41.912	0.336	0.800#
	Lingual	10	121.6±49.567		
	Mesial	10	139.3±55.886		
	Distal	10	128.2±26.402		
EOS (control)	Buccal	10	111.2±52.855	0.391	0.760#
	Lingual	10	103.8±49.714		
	Mesial	10	117.6±49.055		
	Distal	10	96.6±28.040		

#No statistical significant at *P*>0.050. SD: Standard deviation, CBCT: Cone-beam computed tomography, IOS: Intraoral scanners, EOS: Extra oral scanners

it allows patients to visualize the temporary prosthesis beforehand, enhancing their understanding of the treatment plan and instilling confidence in the dentist's capabilities. In addition, digital fabrication using CBCT data enables accurate registration of teeth, arch, and bone anatomy, utilizing the patient's preexisting diagnostic radiographic records (CBCTs) where implants could not be placed due to insufficient bone quality and quantity. This, along with intraoral scans eliminate the need for diagnostic cast pouring and mounting, streamlining the process.[30] This workflow also acts as a template to achieve a desirable amount of tooth preparation, thereby allowing better insertion direction. It is also important to acknowledge certain limitations of this study, including the potential requirement for relining the temporary crowns in a clinical setting due to the virtual tooth preparation workflow. Furthermore, artifacts in CBCT images may be a consideration, particularly in cases with metal restorations. Nonetheless, within the scope of this study, the use of preexisting diagnostic CBCT data and intraoral scans holds promise for fabricating crowns in proper occlusion before tooth preparation, with minimal adjustments needed. Moving forward, future research in this field should evaluate the clinical outcomes of the prosthesis fabricated using the same workflow. Such investigations will shed light on the practical implications and efficacy of the digital approach.

CONCLUSION

As per the findings reported in this study, the following conclusions can be drawn:

1. The virtual tooth preparation workflow yields a similar marginal fit when compared to the commonly used digital workflow
2. Diagnostic CBCTs and IOS can be used as an alternative to conventional methods of provisional crown fabrication (EOS) as they provide better accuracy, reduced time required for crown fabrication, increased efficiency, enhanced understanding of the treatment procedure and outcomes, and greater patient involvement in the treatment process.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Case Report

A clinical tip for conservative retrieval of fractured abutment screw

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Abstract

Fractures of the abutment screw are an extremely dreadful and taxing experience even for experienced clinicians. Retrieval of fractured screw segments due to excessive torque and improperly placed implants pose a great challenge to the clinician. The authors present a case wherein the fractured abutment screw was retrieved successfully with the help of an intraoral plastic mixing tip of light body putty material. The intraoral plastic mixing tips are a more readily available, cost-effective, and feasible alternative to other means of screw retrieval like ultrasonic scalers, endodontic files, and screw retrieval kits.

Keywords: Abutment screw fracture, dental implants, screw loosening

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INTRODUCTION

Complications associated with hardware failure are commonly seen in cases of single-tooth implants due to various mechanical or biological factors.[1] Loosening of the screw and excessive torque are the two main causes that can lead to fracture of the abutment screw.[2]

Fractures of the abutment screw are rare; however, the challenging issue encountered is the retrieval of the fractured segment. Retrieval of fractured screw segments due to excessive torque poses a great challenge to the clinician. With advancements in implant dentistry, various techniques for the removal of fractured abutment screws are mentioned in the literature.[3-5]

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These include techniques such as:

a. Use of ultrasonic scalers
b. Dental probes
c. Endodontic files.

Retrieval using kits specially made for this purpose is also commonly done by clinicians;[6] however, these kits are expensive and not readily available. Using rotary instruments can permanently damage the internal architecture of the implant. Hence, devising a technique for retrieval, which results in minimal or no impairment to the internal structure of the implant, is very important for the enduring success of the dental implant.

We present a case where the abutment screw had fractured due to loosening after 5 years of loading the implant due to suspected excess torque during placement.

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CASE REPORT

A 45-year-old male patient reported to the department of oral and maxillofacial surgery at our institute with the loosening of an implant-supported prosthesis in the mandibular left first premolar region. The implant prosthesis was done 5 years back. After careful clinical examination, it was ascertained that the abutment screw had fractured just below the implant collar which resulted in the loosening of the prosthesis. Various conservative techniques mentioned in the literature, such as ultrasonic scalers, dental probes, and endodontic files, were tried for retrieval of the fractured segment without success. The authors then decided to use the intraoral plastic mixing tips (available with GC Flexceed light body) that had a hollow end to engage the fractured end of the abutment screw [Figure 1]. Modification of the intraoral mixing tip was done by cutting it so that a snug fit was achieved at the visible end of the fractured segment. It was then rotated in an anticlockwise direction to retrieve the fractured portion of the screw taking care that the internal structure of the implant was not damaged [Figure 2].

DISCUSSION

The literature mentions various techniques which have been used for the retrieval of fractured abutment screws. Any approach used for the retrieval of the fractured screw should aim at its removal without impairing the internal structure of the implant. This would enable the clinician to reuse the same implant without causing surgical trauma and financial burden to the patient. If the abutment screw fractures above the implant collar, retrieval becomes easier using a hemostat, or a sharp explorer. However, if the fracture occurs within the body of the implant, its removal is a challenging task due to the lack of adequate space for manipulation by any instrument.

Different techniques such as ultrasonic scalers, dental probes, endodontic files, screw retrieval kits, and rotary instruments have been mentioned in the literature for the retrieval of fractured abutment screws.[3-6] Certain authors have made a slot in the remaining fragment of the screw and then used ultrasonic scalers to loosen the screw.[7] Such techniques although effective have a higher risk of damaging the internal implant collar, thus making the implant no longer functional. The authors in this case used a more feasible alternative like the intraoral plastic mixing tips used for light body impression material.

The tip was modified by cutting the end to get a better fit around the fractured screw fragment due to its curved shape and plasticity; it firmly held onto the fractured segment of the screw. This technique can be used only if the screw fractures are at the level of the implant collar or just below it, making it easier to grasp the portion of the fractured screw.

A few advantages of this technique:

1. Cost-effective
2. Readily available in every clinic
3. Plasticity of the tip allows it to be modified to fit the fractured part of the screw.

However, the authors feel that the plastic mixing tip may not be useful for retrieval if the fractured fragment is broken below the implant collar and is completely tightened.

Although every effort must be made to prevent the fracture of the abutment screw, we would advocate the use of intraoral plastic mixing tips for the successful removal of the fractured segment of the abutment screw without impairing the internal structure of the implant [Figure 3].

CONCLUSION

Within the limits of this technique, it was successfully used to retrieve a fractured fragment of the abutment screw. Even

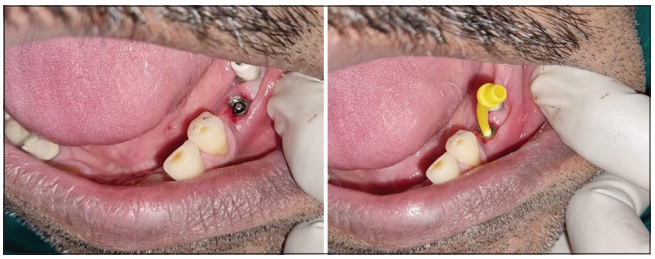

Figure 1: Picture showing fractured abutment screw and engaging of the intraoral putty light body plastic mixing tip to the fractured segment

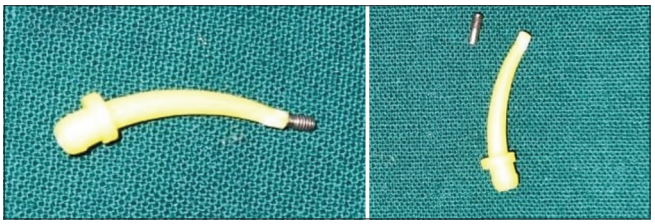

Figure 2: Retrieval of the fractured segment of the abutment screw

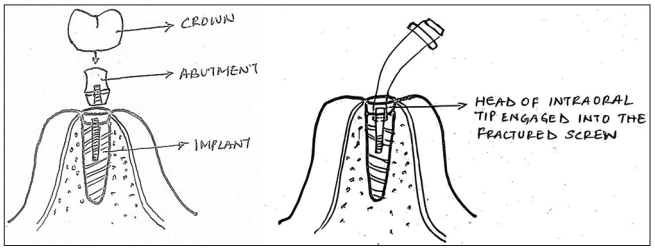

Figure 3: Diagrammatic representation showing retrieval of fractured segment of the abutment screw by the intraoral putty light body plastic mixing tip

after proper care is taken during the implant procedure, if the abutment screw fractures at the level of the implant collar, this technique may be useful for conservative retrieval without impairing the internal structure of the implant.

Declaration of patient consent

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

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Case Report

Maxillofacial rehabilitation of an acid attack survivor – The journey from scar to smile

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Abstract

Acid attack is a form of violent assault involving the act of throwing acid or any corrosive substance such as sulfuric acid, nitric acid, and hydrochloric acid with the intention to disfigure, maim, torture, or kill. A combination of surgical intervention along with prosthetic management using maxillofacial prosthesis serves a good treatment modality for rehabilitation in such cases. The advent of technological advancements has made the rehabilitation procedure easier, faster, and comfortable both for the patient and prosthodontist.

Keywords: Acid burn, fused deposition modeling, maxillofacial prosthesis, silicone, stereolithography

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INTRODUCTION

According to the National Crime Records Bureau, 1326 acid attacks were reported in India in the past 5 years and more than 80% of them were females.[1] Acid burn injuries in the maxillofacial region may cause defects in the region posing the risk of hypertrophic scarring, keloid formation, and contractures postplastic surgery, which for rehabilitation requires prosthetic intervention.[2] Reconstruction of these large defects by surgical as well as prosthetic intervention often presents a challenge. Facial prosthesis in such cases serves the purpose of restoring form and near-normal orofacial appearance, thereby enhancing the overall quality of life.[3]

Fabrication materials for maxillofacial prosthesis have evolved from acrylic resins to silicone elastomers. Various ways to enhance retention of these prostheses exist that include spectacles, utilizing anatomical undercuts in the defect, medical-grade skin adhesives, magnets, and at times acquires combination of more than one.[4,5]

The present article describes the prosthetic management of an acid burn survivor using a silicone facial prosthesis, thereby enhancing patients' esthetics, confidence, and overall mental well-being.

CASE REPORT

A 21-year-old female victim of acid burn operated 33 times in the past 3 years reported to our department with a chief complaint of deformed face. General examination showed deformed and scarred face, missing right ear, missing right eye, absence of eyebrows, and deformed nose and upper lip along with facial asymmetry [Figure 1].

A comprehensive case history was taken, meticulous clinical examination was performed, and investigation data in

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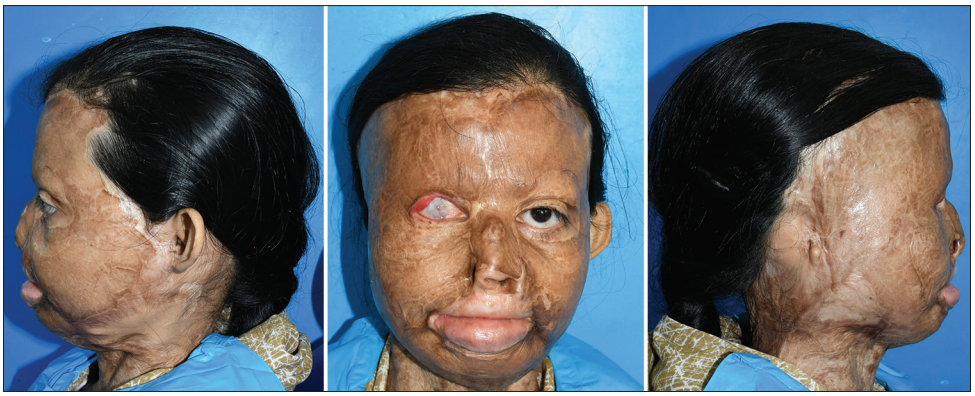

Figure 1: Preoperative photographs (left lateral, frontal, and right lateral)

the form of previous follow-up noncontrast computed tomography (CT) was collected. A comprehensive treatment plan was formulated that included fabrication of a facial, ocular, and auricular prosthesis which would be retained with spectacles. The treatment plan was informed to the patient in her preferred language, and her written informed consent was obtained [Figure 2].

Digital design file in the form of stereolithography (STL) image was created from the CT scan using the software (Materialise Mimics software (Version 24.0), Materialise NV, Leuven, Belgium) to replicate the overlying skin outline by both designing and mirroring [Video 1]. This was used to fabricate the fused deposition modeling (FDM) models from the Fusing deposition modeling machine (Flashforge 2S FDM three-dimensional [3D] printer, Zhejiang Flashforge 3D Technology Co., LTD, China): one for the facial prosthesis and the other with mirror image of unaffected ear, thereby eliminating the need of a donor ear [Video 2]. Wax pattern of facial, auricular, and ocular prosthesis was made with modeling wax (DPI Modelling wax, India) over the FDM model [Figure 3]. The wax up of the eyebrows, right eyelid, nose, upper lip, and right ear was also made. The ocular prosthesis was made using corneal button derived from stock eye (Monoplex System, American Optical Corp., Southbridge, USA). This corneal button was embedded in the scleral shell using NAES ruler for iris centering followed by flasking, deflasking, and packing. The ocular prosthesis was customized by characterization of scleral shell, and the eyelid was contoured over the ocular prosthesis by molding warm wax strips.

The superior surface of wax was carved to form contractures to resemble the patients existing skin to mimic esthetics. During the patient's next visit, try in of the wax pattern was performed [Figure 4] along with acrylic substructures at the glabella and over the helix of

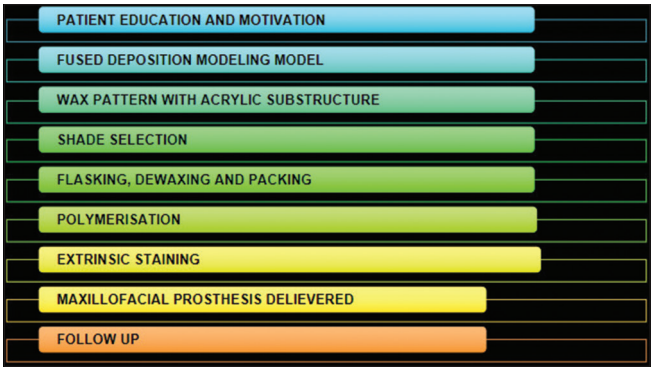

Figure 2: Treatment plan for the patient

Figure 3: Wax pattern adapted over fused deposition modeling model

the ear. The margins were redefined to merge and improve adaptability to the tissues.

The wax pattern was flasked, dewaxed, and cooled to room temperature. Silicone M511 (Technovent, Bridgend, UK) was packed and cured for 2 h at 90°C. After curing, the prosthesis was disinvested and cleaned followed by trimming and cleaning. Try in was made, and prosthesis was extrinsically colored (Technovent, Bridgend, UK) for creating pigmentation [Figure 5].

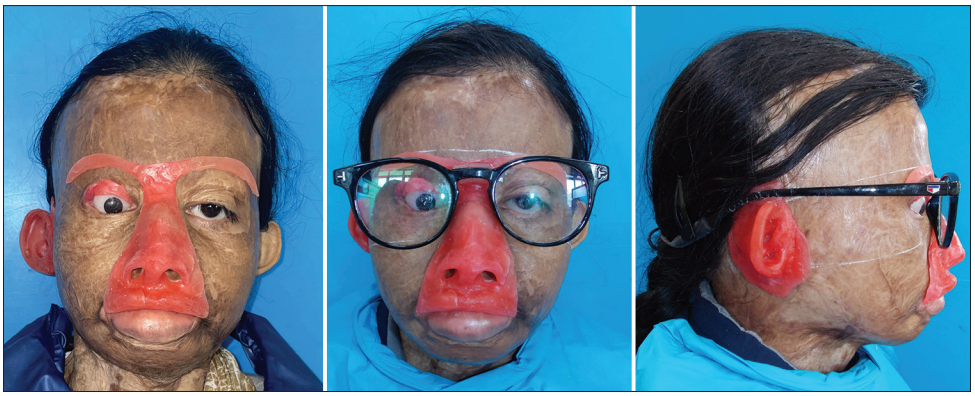

Figure 4: Wax pattern try in retained by spectacle

Figure 5: Maxillofacial prosthesis postextrinsic staining

Adequate retention was gained for maxillofacial prosthesis by virtue of spectacles as mechanical aid. It also provided protection and easy camouflage of margins of silicone prosthesis. For better edge, merging with the skin patient was advised the use of medical-grade skin adhesive (Daro Adhesive, Technovent, Bridgend, UK).

Hygiene instructions and maintenance instructions of the prosthesis were explained to the patient, and she was recalled for follow-up quarterly [Figure 6].

DISCUSSION

Prosthetic rehabilitation of acid burn patients is better accomplished with combination of surgery and maxillofacial prosthesis ensuring optimum esthetics in shorter duration of time. Various factors that govern the treatment of choice are location of burn, its size, any local or systemic disease affecting the patient, and age of patient.[6] From the earliest records of skin grafting by Sushrutha in 600 BC to the establishment of first skin bank Safdarjung Hospital, Delhi, our country has come a long way in the rehabilitation of such cases. Despite this, challenges still persist in rehabilitation of such defects starting from the first step of impression making to insertion and maintenance of prosthesis. This has been attributed to the hypertrophic scarring and contracture of the tissues which are the part of postburn sequelae.

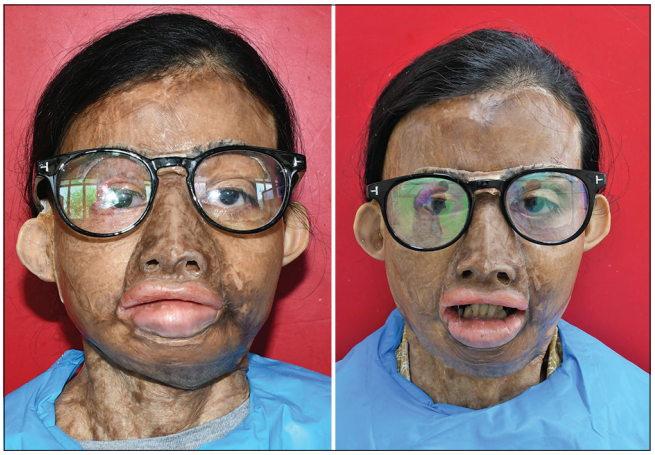

Figure 6: Postoperative photograph and 1-year follow-up of the patient

In this case, digital method of recording impression and model fabrication was followed. Of all the materials used for fabricating maxillofacial prosthesis, silicone is the most commonly used material due to ease of availability and low cost.[3]

To enhance retention, of the prosthesis, aids such as mechanical (spectacles, magnets, implants), chemical (tissue adhesives), anatomical (tissue undercuts), and combinations of the above are used.[5]

3D facial scanners are the new advent which record facial topography by recording landmarks on the face

with acceptable accuracy.[7] The advantage of digital impression in the form of STL image over conventional is the ease, accuracy, and ability to replicate the affected part, repeatability, data storage, and integration with other digital technologies. The main disadvantages are difficult availability and cost factor.[8]

The STL file is converted into the model by 3D printing process using FDM technology. This is an additive manufacturing process comprising of extrusion of thermoplastic filament (in this case, PLA-polylactic acid) and its deposition in layers. It is simple and easy to use, ensuring comfort and reduced appointments for the patient. PLA is biocompatible, environment friendly, and stable with high mechanical strength.[9] Other materials such as acrylonitrile butadiene styrene, polycarbonate, and polyetherimide resin are also used. Although the application of this technology to create working models for wax pattern adaptation is an efficient method, limitations such as high cost, acquiring digital design files, and lack of well-trained operators are the drawbacks of this methodology.[10]

Extraoral titanium implants were not contemplated in this patient because of acute pathological bone loss due to stimulation of osteoclastic activity and compromised homeostasis in the grafted regions. The burnt skin is extremely susceptible to infection due to lack of protective intact skin layers.[11]

Limitations of silicone prosthesis include delamination, degradation of the silicone, reduced marginal integrity, and compromised edge strength. These shortcomings were subdued with meticulous treatment planning of the prostheses and patient education. The patient was instructed to take out the prosthesis at night and clean it daily with soft-bristled brush and neutral soap along with maintenance of hygiene of adjacent skin. Furthermore, the contact of the silicone prosthesis with the outer environment was minimized due to the use of spectacles. Postinsertion instructions provided to the patient were helpful in achieving favorable outcome that was evident at follow-up visits.

Declaration of patient consent

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

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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