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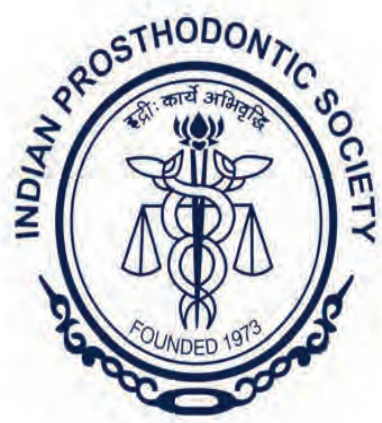

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The Journal of Indian Prosthodontic Society is the official publication of The Indian Prosthodontic Society. Published quarterly, this journal serves as a platform for the exchange of interesting case reports, scientific studies, literature reviews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

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

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CONTENTS

CASE REPORTS

DENTAL TECHNIQUE

Images in scientific writing

Images provide a pictorial insight into the research when appropriately used. Images alter the initial perception of professional editors and reviewers while assessing the manuscript.[1,2] It is essential to display images that are more relevant and explanatory to the text with a precise legend that could make the readers understand better.

Scientific images, unlike conventional photography, are data that should be of high informational value. The authors should design the figures for a wider audience that focuses on vital data with a single type of visual contrast of either color, shape, or size.[2,3] This editorial message highlights the salient features for improving the quality of images that need to be considered before submitting the manuscript to a journal.

IMAGE RESOLUTION

Image resolution is the number of pixels displayed per inch (dpi) of the image, and higher pixels provide better resolution.[4] A minimal resolution of 300 dpi is essential for submission in a scientific journal [Figure 1]. Alteration of the low-pixel images as per the journal's requirements leads to lured, soft images reducing the resolution and quality. Increasing the resolution of an image decreases the image size to compensate for the number of pixels. For example, if an image is 10" × 5" at 300 dpi, it would modify to 8" × 3" at 600 dpi. At 300 dpi, the image would fill the entire page with a good, sharp image, whereas at 600 dpi, the image size would be small, but the quality of images will be very high.[4] Photo editors potentially decrease the quality of the image: hence, it is better to capture an image at high resolution.

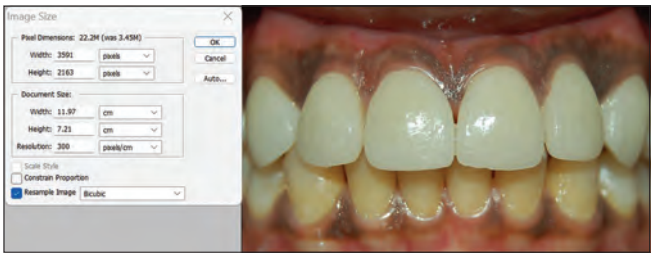

Figure 1: An image modified to 300 dpi resolution with Photo Editor software

TYPES OF IMAGE FORMATS

The quality of images depends on the type of format it is stored. The Joint Photographic Experts Group[5,6] (.jpg., jpeg) has the advantage of storing the file in small size; however, the compression distorts the image details during transfer, leading to a pixelated image. These files are easy to upload due to their small storage size. Tagged Image File Format[5,6] (.tif, tiff) is an uncompressed image file type that helps in retaining detailed and high-resolution image data even after multiple transfers of the file. The "tiff" images are versatile in the color scheme that would suit the requirement of a publication. However, the file size is larger and requires more space to upload. Portable Network Graphics[5,6] (.png) can be compressed without distortion of data. It is often used for editing image over image or text over an image. However, it does not support all color schemes. It can be used for saving line diagrams, and the file size can be small which eases the upload. The device-independent bitmap[5,6] and bitmap (.bmp) files are raster graphics that store two-dimensional images such as charts that exactly match the original source. However, the file size would be large and can be compressed using programs such as zip. Encapsulated PostScript[5,6] (.eps) is a graphic file in vector format. It is especially a master image file that can be edited and scaled to infinity without loss of resolution. It has been replaced by adobe illustrator and Portable Document Format (.pdf). The RAW image files[7] (.raw., cr2., nef., orf., srz) are raw digital negative, comprising uncompressed and unprocessed image data. The image format is usually captured by the camera sensor, and later requires software to obtain the desired output. Although the image is of high resolution, it needs specific software to read the format and requires high storage space.

TYPE OF IMAGES

The types of images that are commonly included in a dental

journal are photographs, charts, microscopic images, and radiographs.

A photographic image used in dental journals should accurately represent the color perceived by the eyes during dental/facial examination.[8] A digital single-lens reflex camera equipped with a macro lens (85–105 mm) and an external ring flash mounted in front of the lens is required for high-quality intraoral macrophotography.[9,10] The image should be captured close to the region of interest, avoiding the undesirable anatomical structures with the anti-fog mirrors. The camera is set in the manual mode for an intraoral photograph, with an aperture of f/20-22 to f/32, a shutter speed of 1/125–200, ISO 100–200, and magnification of 1:2.[9] White balance is accurately adjusted based on the neutral color of the environment so that the color is represented in its natural form depending on the light source. The white balance can be preset as sunlight, incandescent, fluorescent, etc., and can also be set based on the color temperature in kelvin. The color temperature that varies between 5500 and 6500 K gives an accurate representation of natural color to help in differentiating between healthy and diseased sites.[11] However, if the camera stores the image in RAW format, the white balance can be adjusted in postprocessing software.[12] An extraoral picture should be taken with a black background or contrast background.[13] Although most cameras prefer to store the image in jpeg format, it is preferable to store the images in the uncompressed and editable RAW format in a separate folder that can be used later to modify according to journal requirements. It is also preferable to use tiff format compared to jpeg after the final modification.

Grafts, charts, or line diagrams are vector images that are preferable to be stored in the png/tiff/pdf formats and if required to convert to jpeg format as per journal requirement.[14,15] This would ensure high resolution of the primary image during storage that can be modified when required without loss in image quality.[15] The vector images do not lose their resolution on scaling or resizing the image, however, an appropriate graphic file format such as png/tiff should be chosen. ".png" files improve the quality of graphics and are especially used while uploading to a website. Screenshots should be avoided as they may reduce the resolution of the images. The image shows saving the chart in a template (.crtx extensions) [Figure 2]. The chart can also be saved as an Excel file to enable editing of data later. The charts during submission for publication should be saved as an image file in the png/tiff/pdf formats.

Microscopic images used in publications are magnified images of an object and hence an appropriate scale of magnification

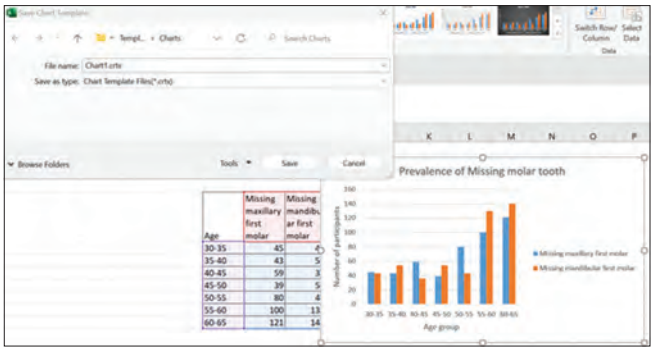

Figure 2: Chart template in .crtx extension format

is essential to satisfy the output of the research.[16,17] The scale bar is necessary for every image and should be visible in the corner of an image.[16,17] The author should make sure that the bar is maintained in the same position on all the images or follows the journal guidelines. The use of appropriate colorblind safe colors to represent the microscopical data is essential.[18] Although the image could be saved in gray or color scales, the author should perform a grayscale visibility test to ensure that the black-and-white print of color images also represents the same color variation that is visible in the color micrograph. When representing a single color, a grayscale image would be appropriate for publication. Figure 3a shows a blurred scale bar and the image due to storage of the microscopic image in jpeg format and resaving it multiple times leading to loss of data, whereas Figure 3b shows the clarity of image stored as tiff.

Radiographs are an integral part of dental treatment and should be saved in the tiff, adobe Photoshop, or Electronic Software Download to retain the highest resolution that does not lose any details.[19,20] Appropriate contrast, wide dynamic range, spatial resolution, noise reduction, and avoidance of artifact are important components of the image quality of radiographs.[20]

LEGENDS FOR FIGURES

Legends are an accurate representation of either the methodology or the results. The figure legends should be a comprehensive but detailed representation of the image. The title of the figure should be in an inactive voice which can either be a clear description of the methodology or declarative of the result from the image in a comprehensive way.[21,22] For example, a preoperative radiograph of a maxillary tooth could be better written as a preoperative intraoral periapical radiograph of the right maxillary first molar. Similar to the content of the main text, the figure should also be in the past tense. The use of symbols, colors, and scale bars should be explained in the legend. The sublegends should also be labeled as 1a and 1b to

Table 1: Preferred image format in scientific writing

Type of image	Preferred image format in storage and editing	Preferred image format during upload
Photographic image	.raw, .cr2, .nef, .orf, .srz, .tif, .tiff	.tif, .tiff, .png, .jpg, jpeg
Grafts, charts, or line diagrams	.eps, .crtx, .bmp, .png	.png, .tif, .tiff, .pdf
Microscopic or radiographic image	. tif, .tiff, .png	.tif, tiff, .png, .jpg, .jpeg

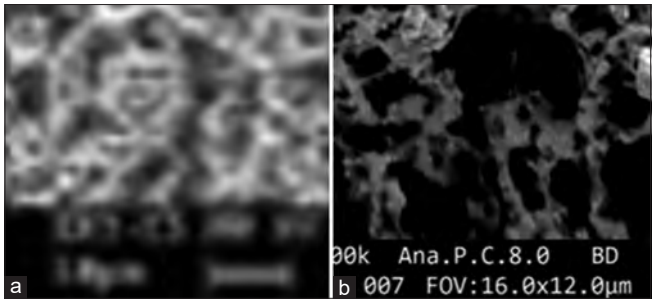

Figure 3: Scanning electron microscope image: (a) blurred image in .jpeg format after multiple formats, (b) clarity of image in .tiff format

specify the difference between the images, for example, Figure 1: scanning electron microscopy of implant surface shows (a) adherence of microbes in the coronal portion at ×100 and (b) microbial colonization in the middle third at ×500.

COPYRIGHT/RIGHT TO USE FIGURE

If any part of the figure is reproduced from published data, prior permission from the authors and the concerned journal/publisher is mandatory and should be referenced. Citing the source without prior permission will lead to outright rejection of the manuscript.

An author should follow the journal guidelines for images that are more specific and vary between journals [Table 1]. The format of images given in the author guidelines in a journal should be used for uploading images.

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Review

A comparison of marginal bone loss, survival rate, and prosthetic complications in implant-supported splinted and nonsplinted restorations: A systematic review and meta-analysis

Aesha Harsh Shah, Pankaj Patel, Aumkar Trivedi, Adit Shah, Nikki Desai, Mitangi Talati

Department of Prosthodontics and Crown and Bridge, Gandhinagar, Gujarat, India

Abstract

Aim: To compare marginal bone loss (MBL), implant survival rate and prosthetic complications of implant-supported splinted and non-splinted restorations (NSR).

Settings and Design: This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines (PRISMA). The PROSPERO registry, which keeps track of prospective systematic reviews, also received this paper (CRD42021229477).

Material and Methods: An electronic search was done in PubMed, the Cochrane Central Trials Register, Scopus, Science Direct, and Google Scholar searches were carried out. The search was limited to articles published in English and covered the period from January 2010 to August 2020.

Statistical Analysis Used: To conduct the meta analysis, researchers employed methodologies such as continuous measurement and odds ratios.

Results: For both qualitative and quantitative analysis, 19 scientific studies were chosen. 3682 implants were placed in 2099 patients with a mean age of 59 years (splinted, 2529; non-splinted, 1153); the mean age was not provided in 5 trials. For splinted restorations, there were statistically significant differences in MBL, indicating the former has less MBL than for NSR. Splinted restorations had much greater survival rates than NSR, according to a qualitative study. Rest prosthesis complications with or without splinting were essentially the same.

Conclusions: Splinted implant restorations lost less bone than non-splinted implant restorations, according to this meta analysis. This was particularly true for posterior restorations. Lower implant failure was associated with splinted restorations. Restorations with and without splinting had the same level of prosthetic problems.

Keywords: Alveolar bone loss, dental implant, implant supported fixed prosthesis

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INTRODUCTION

Completely and partially edentulous individuals can benefit from dental implants, which are a proven, well-documented treatment option.[1] Implant-supported restorations help patients restore their chewing ability and their dental health.[2,3]

The longevity of these dental implants is highly dependent on the host, implant insertion site, procedure, implant fixture, and kind of prosthesis used to restore them. All of these implant fixture-associated parameters are related to an implant's surface roughness, diameter, and length, as well as macro-and microstructures. Occlusal scheme, retention method, and prosthesis type are all implant prosthesis-related factors.[4] And apart from these primary factors, the maintenance of crestal bone height, improved oral hygiene, abutment connection design, the stress distribution of occlusal forces over time, prevention of soft tissue inflammation, and difficulty in achieving a passively fitting framework all play an important role in an implant's success.[5,6]

According to Albrektson *et al*., success factors for dental implants include mean bone loss of 1.5 mm in the first functional year and <0.20 mm/year after that, as well as the formation of biologic width without clinical features of implant infection linked to surgical trauma, peri-implantitis, occlusal overload, implant macroscopic characteristics at the neck region in contact with the bone, implant-abutment interface, and micro gap position.[6-9]

Abnormal functional stress on implant restorations causes screw loosening and ceramic chipping, as well as prosthesis decementation or fracture and osseointegration failure of an implant.[6] Splinting restorations can be utilized to prevent screw loosening or to compensate when less than optimum implant length and occlusal stress distribution.[5] For limiting the number of forces given to the teeth, splinting has long been regarded an important part of occlusal treatment. The philosophy of tooth or implant abutment splinting with varying degrees of bone loss improves the stability of implant restorations.[1]

Splinting implants (also known as splinted restorations, or SR) have been shown by certain researchers to aid minimize marginal bone loss (MBL) when compared to nonsplinted restorations (NSR) by distributing functional stresses.[9] Conversely, NSR provides better oral hygiene and framework passivity while allowing better emergence profiles and cervical contour, although they may be subjected to more stress on the prosthodontic components (NSR).[2,10]

The study's purpose was to compare implant restorations with and without a splinting in regards to MBL, implant survival rate, and prosthetic complications.

Null hypothesis

When splinted implant restorations were compared to nonsplinted implant restorations, the null hypothesis was that MBL, implant survival rates, and prosthesis complications wouldn't change.

MATERIALS AND METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses criteria were met by this systematic review.[11,12] PROSPERO, the Prospective Register of Systematic Reviews, has accepted this paper (CRD42021229477). The search technique was designed using a population, intervention, control, and outcomes Structure by the researchers [Figure 1].

Strategy for search

In PubMed, the Cochrane Central Trials Register, Scopus, Science Direct, and Google Scholar searches were carried out. The search was limited to articles published in English and covered the period from January 2010 to August 2020. All databases were searched using the Mesh terms, search phrases, and combinations listed below:(1) Dental implants, (2) implant-supported fixed prosthesis, (3) crestal bone loss, and (4) prosthetic complications, survival analysis, splinted implant restorations, and nonsplinted implant restorations. They included relevant research after carefully scanning the chosen publications' reference lists. Only studies that satisfied particular inclusion criteria were taken into consideration for this systematic review:

1. Human cohort studies, prospective and retrospective research, and randomized clinical trials
2. Patients who will receive at least two implants, since the splinted implant group requires at least two implants
3. Up to 12 years of follow up

DOMAIN	DESCRIPTION
Population	Patients undergoing implant treatment
Intervention	Minimum two implants placed in either arch
Comparison	Splinted and Non-splinted implant restorations
Outcomes	A) Primary outcome: Crestal/marginal bone loss B) Secondary outcomes: Implant survival rate and prosthetic complications
Study design	Clinical studies performed in humans involving randomized and non-randomized clinical trials, prospective and retrospective studies with follow up to 12 years

Figure 1: Population, intervention, control, and outcomes of the study

4. Systematically healthy patients who have had splinted and/or NSR placed on adjacent implants
5. Articles published in English, with access to the full text.

Human clinical trials, preclinical studies, and retrospective analyses were all considered in this complete review. The study's participants might be of any age.

A total of nine trials were included in this analysis, which looked at factors such as MBL, implant survival, and prosthesis complications. The following criteria were used to assess all the three factors in the studies that were included:

1. Clinical stability and pain-free function
2. No suppuration, infection, or discomfort at the implant site, or any other persistent pathology
3. Radiolucency all around the implant.

Selection screening

The titles and abstracts of papers to be included in the analysis were reviewed by two different investigators. The researchers then received the whole text of any previously unpublished research that could have been relevant to their findings to conduct their review. In the event of a quarrel about inclusion, a fresh researcher was called in to resolve the situation.

Extraction of data

A data extraction form was filled out by two investigators who worked independently to collect data. Trial data consisted of (1) the author and publication date; (2) research design; (3) kind of implant restoration; (4) the number of patients; (5) the number of restorations that were splinted and nonsplinted; and (6) the follow-up period.

Risk of bias in individual studies

For both randomized and nonrandomized intervention trials, the Cochrane Collaboration Tool for Assessing Risk of Bias in Randomized Trials was used to assess trial bias risk in the included randomized clinical trials.[13] A domain-based approach to the evaluation criteria was used, with important assessments made separately for each domain. These assessments would include: Generation of random sequences, concealment of allocation, blinding of participants and personnel, blinding of outcomes, incomplete outcome data, selective reporting, and others. The Cochrane Handbook for Systemic Reviews of Interventions outlines the following criteria: (version 5.1.0.) For each domain, the risk of bias was graded as high, low, or unknown. A risk bias assessment of the chosen non randomized controlled trials (RCT) studies was carried out using the Newcastle-Ottawa scale[14] (prospective, retrospective, and clinical human studies). Selection, comparability, and outcome make up the three main components of the Newcastle-Ottawa scale for cohort studies. On the quality scale, the highest quality study gets a maximum of 9 stars. With fewer than five stars, there's a higher chance of bias; with six or more, the risk is lower. Sample size biases can be detected using an asymmetrical funnel plot.[15]

Statistical analysis

Splinted versus nonsplinted dental implant restorations have been the subject of a meta-analysis to see if there are variations in crestal bone loss, implant survival rates, and prosthetic complications. The odds ratios (OR) for implant survival, prosthetic complication rates were calculated and MBL was calculated using a continuous mean difference (MD) and a 95% confidence interval. There is a better survival probability for splinted implant restorations than nonsplinted implants if the OR values are considerably higher than 0.05. Similarly, nonsplinted implant restorations would show higher MBL than splinted implant restorations if the MD values were larger than 0. The MedCalc software application (version 19.5.2) was utilized for the meta-analysis and funnel diagrams. It was decided how much heterogeneity was there by looking at the value of I^2. There were two types of outcomes: Positive and negative. Significant heterogeneity was defined as I^2 values over 75, whereas heterogeneity was not deemed to be present if I^2 values were <75.

RESULTS

Selection of study

An electronic database search and a manual inquiry involving 1000 research projects were conducted. A total of 500 full-text papers were examined once the duplicates had been removed, with a total of 500 studies being rejected by both researchers. For different reasons, 460 more full-text papers were ruled out from consideration once eligibility was determined for the final 46. When the remaining 46 full-text studies were evaluated for eligibility, 27 more research were eliminated for various reasons. Finally, 19 studies were included in the current systematic review and meta-analysis [Figure 2].

Study characteristic

The review examined numerous studies published between January 2010 and August 2020. A total of nigh teen investigations, including four prospective ones[5,18,19,29] and a total of two randomised controlled trials,[3,9] as well as thirteen retrospective ones[6,9,10,18-26,28] were completed. 3682 implants (2529 splinted implants and

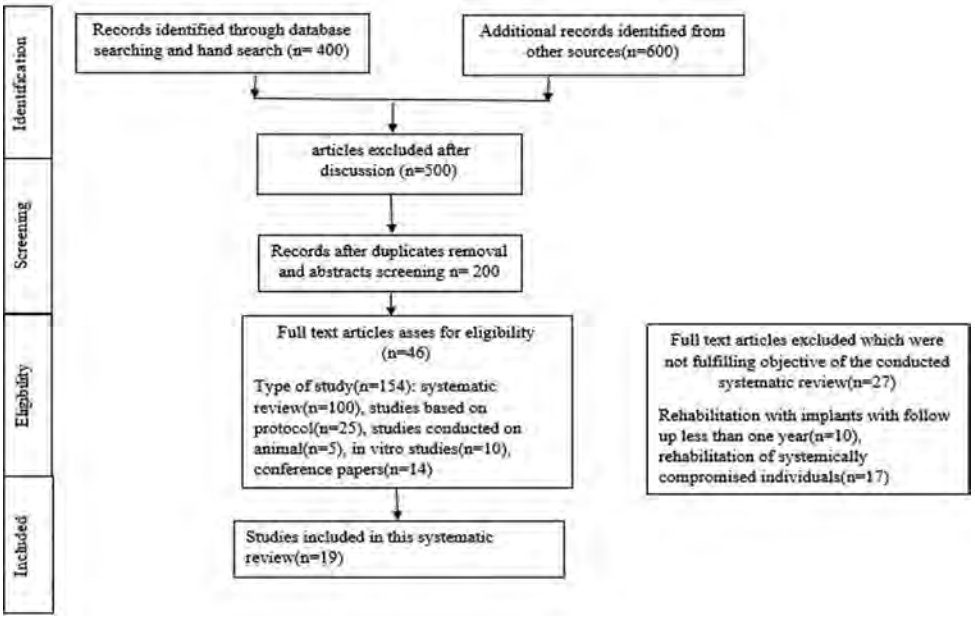

Figure 2: Article selection flowchart for the systematic review according to PRISMA guidelines

1153 nonsplinted implants) were put in 2099 individuals with a mean age of 59 years, the mean age was not reported in 5 studies.[19,20,21,25,27] The mean follow-up period was 87.8 months. Tables 1 and 2 summarise the findings of these investigations. Implants with external connections were utilized in three studies,[9,18,25] whereas implants with internal connections were used in seven studies,[5,16,19,20,21,23,28] one study used a cone log screw-line implant,[3] and implants with Platform switching abutments were used in a study[8] There was no mention of an implant-abutment relationship in any of the seven research articles.[17,22,24,26,27,29,30] Also there were some differences in the number of implants placed, prosthetic materials, prosthesis design, different retention systems in the methods followed in individual studies.

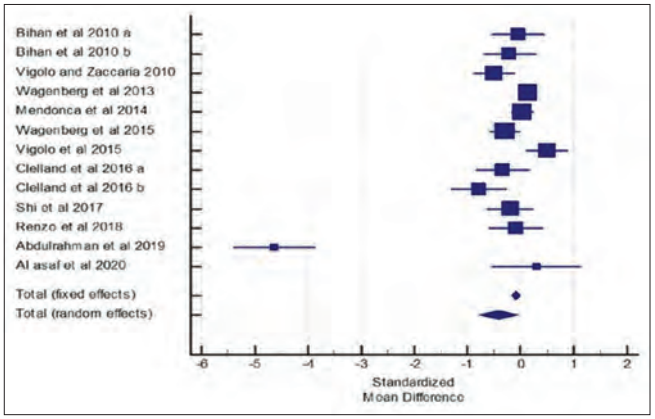

Figure 3: Forest plot of comparison of marginal bone loss between splined and nonsplinted implant restorations

First meta-analysis: MBL around implants

Eleven studies focused on MBL.[3,5,8,9,16,18,24,25,27-29] Quantitative study determined the standardized mean MBL comparing implant restorations with and without splinting the implants [Figure 3]. Both random and fixed model effects were statistically significant at the 95% level of confidence, and the random effect model is used if heterogeneity is statistically significant. In this case, the restorations with splinted restorations have less MBL than NSR, and their I^2 values are higher at >90%. It suggests a wide range of heterogeneity was considered (P = <.001, I^2 = 93.52%).

Second meta-analysis: The implant survival rate.

The qualitative analysis revealed an OR for implant survival. 60 implants failed (3.4%), with 26 splinted (99.1% survival rate) and 34 nonsplinted according to the research (96.5% of survival rate)[3,17,18,20,21,23,25,26,30] Forest plot survival rates did not differ significantly at a 95% confidence level (OR = 1). Because there was no heterogeneity across the studies with I^2 = 0% and a P value larger than 0.05, a multivariable fixed effect model was utilized, which is more one-sided and shows that nonimplant restorations are more likely to fail than restorations with splinted implants [Figure 4].

Third meta-analysis: The complications of prosthetic restorations, both splinted and nonsplinted

Ten studies[3,5,8,19,20,21,22,23,28,30] were carried out to assess whether or not prosthesis difficulties such as ceramic chipping and soft tissue irritation may arise following implantation of the prosthesis. NSR were plagued by decemenation and screw loosening, while splinted implants suffered from ceramic chipping as the most common problem.[3,5,22,28,30] There was

Table 1: The studies selected

Study and publication year	Patients (*n*)	Mean age (years)	Implants (*n*)	Number of S and NS implants	Length of follow up (months)	The average marginal bone loss was observed (mm)	Lost implant (*n*)	Lost prosthesis (*n*)	Prosthetic complication (*n*)	Survival rate (%)
Bilhan *et al*., 2010[16]	36	54.97	126	S - 106 NS - 20	36	S - 0.99, NS - 0.96 proximal S - 0.97, NS - 0.94 on the mesial scale	NR	NR	S - 0 NS - 0	NR
Sohn *et al*., 2010[17]	43	55.8	122	S - 103 NS - 19	108	NR	S - 2 NS - 1	NR	NR	S - 98 NS - 94.7
Vigolo and Zaccaria 2010[18]	44	51	123	S - 63 NS - 60	60	S - 0.7 NS - 0.8	NR	NR	NR	S - 0 NS - 0
Perelli *et al*., 2011[19]	40	NR	50	S - 29 NS - 21	60	NR	S - 3 NS - 4	S - 0 NS - 4	NR	NR
Perelli *et al*., 2012[20]	87	NR	110	S - 47 NS - 63	60	NR	S - 3 NS - 6	S - 0 NS - 6	3	S - 93 NS - 90
Rodrigo *et al*., 2013[21]	159	NR	223	S - 209 NS - 14	72	NR	S - 1 NS - 1	NR	NR	S - 99.5 NS - 92.9
Sivolella *et al*., 2013[22]	109	53	50	S - 20 NS - 30	192	NC	NC	NC	S - 15 NS - 6	NC
Vanlıoğlu *et al*., 2013[23]	95	41.2	231	S - 106 NS - 125	120	NR	NR	S - 2 NS - 2	S - 4 NS - 3	S - 94.4 ISB - 96 NS - 98.4
Wagenberg *et al*., 2013[24]	541	58.75	1187	S - 970 NS - 217	264	S - 0.44 NS - 0.55	NR	NR	NR	NC
Mendonça *et al*., 2014[25]	198	60.45	453	S - 219 NS - 234	264	S - 0.44 NS - 0.55	NR	NR	NR	S - 97.7 NS - 93.2
Sohn *et al*., 2014[26]	42	NR	84	S - 69 NS - 15	108	NR	S - 6 NS - 2	NR	NR	S - 92 NS - 82.2
Wagenberg and Froum 2015[27]	312	NR	312	S - 240 NS - 72	144	S - 0.5 NS - 0.3	NR	NR	NR	NC
Vigolo *et al*., 2015[9]	38	51	114	S - 60 NS - 54	120	S - 1.2 NS - 1.3	S - 0 NS - 0	NR	NR	NC
Clelland *et al*., 2016[5]	15	56	64	S - 32 NS - 32	36	Machined surface S - 0.68 NS - 0.33 Machined beveled surface S - 0.52 NS - 0.14	S - 0 NS - 1	S - 0 NS - 0	S - 1 NS - 5	NC
Shi *et al*., 2018[28]	67	38.29	98	S - 65 NS - 33	96	S - 1.22 NS - 1.10	NR	NR	S - 10 NS - 13	NC
Renzo Guarnieri *et al*., 2019[29]	30	28	64	S - 32 NS - 32	36	Mesial S - 0.47 NS - 0.31	NR	NR	NR	NC
Ravidà *et al*., 2019[30]	145	60.33	145	S - 52 NS - 40 ISB - 53	76.2	NR	NR	ISB - 0 NSC - 9 SC - 7	NSC - 28 SC - 13 ISB - 8	ISB - 100 SC - 88.5 NSC - 92.5
Al Aali KA *et al*., 2019[8]	78	25	102	S - 43 NS - 59	36	S - 1.2 NS - 1.3	NR	NR	NC	NR
Al-Sawaf *et al*., 2020[3]	20	59	24	S - 11 NS - 13	36	S - 0.1 NS - 0.3	S - 0 NS - 0	S - 0 NS - 0	S - 2 NS - 1	S - 100 NS - 100

*NC: Not clear, NS: Nonsplinted, NSC: NS crowns, S: Splinted, SC: Splinted crowns, NR: Not reported, ISB: Implant-supported bridge[6]

statistically considerable heterogeneity (I^2 = 74.62%) found between trials, thus a random effect model was adopted that is more one-sided and suggests that splinted implant restorations had 0.722 higher odds for prosthetic problems than nonsplinted implant restorations. There is a *P* value larger than 0.05 in the forest plot for prosthetic problems, showing that cumulative data are significant at a 95% confidence level [Figure 5] Restorations with and without splinting of implants showed no difference in appearance.

Figure 6a shows an asymmetric funnel plot concerning MDs across studies[3,5,8,9,16,18,24,25,27-29] looking at a MBL; however, asymmetrical plot was found in the funnel plot with implant failure analysis.[3,17,18,20,21,23,25,26,30] [Figure 6b]. The funnel plot demonstrated an imbalance in the occurrence of prosthetic problems.[3,5,8,19,20,21-23,28,30] [Figure 6c].

Consequently, the revised Cochrane risk of bias instrument (RoB2) was used to assess the risk of bias in randomized trials in the two investigations.[3,9] They both are having a low risk of bias [Supplemental Table 1]. Nonrandomized Newcastle-Ottawa scale coding manuals were used in 17 non-RCT studies,[5,8,16-30] with only 1 study receiving 5 stars, 3 studies receiving 6 stars, both

Table 2: Characteristics of the studies selected

Study	Year	Design of the study	Implant system/ connection type	Diameter/ length (mm)	Implants in the arch (*n*)	Localization	Prosthesis/ type of retention	Prosthetic complications
Bilhan *et al*.[16]	2010	Retrospective	Astra Tech-Bio Lok-BioHorizons/ Straumann-Zimmer Dental/internal connection	NR	NC	NC	NR/ cement-retained	NR
Sohn *et al*.[17]	2010	Retrospective	Endopore (Innova Life Science)/NR	4.1, and 5.0/5, 7, 9, and 12	Mandible: 122	Posterior: 122	NR/NR	NR
Vigolo and Zaccaria[18]	2010	Prospective	Biomet 3i/external connection	4.0/10, 11.5, 13	Maxilla: 123	Posterior: 123	Metal-ceramic/ cement-retained	NR
Perelli *et al*.[19]	2011	Prospective	Endopore (Innova Life Sciences)/ internal connection	4.1 and 5.0/5 and 7	Mandible: 50	Posterior: 50	Metal-ceramic/ cement and screw retained	Four single crown prostheses failed, but the others may be used without replacing them because of the failure of the prostheses
Perelli *et al*.[20]	2012	Prospective	Endopore (Innova Life Sciences)/ internal connection	4.1 and 5.0/5 and 7	Maxilla: 110	Posterior: 110	Metal-ceramic/ cement and screw retained	After 3 and 4 years of usage, two abutments came loose, and a ceramic chip was found in a metal-ceramic dental prosthesis that was secured in place with sutures. Nine of the ten implants were found to be defective and had to be removed As a result, six of the prostheses had a single crown and failed, whereas the other three had splints between the implants, preventing failure
Rodrigo *et al*.[21]	2013	Retrospective multicenter	SLA-surfaced implants (Straumann)/ internal connection	4.1 and 4.8/6	Maxilla: 16 Mandible: 207	Anterior: 2 Posterior: 221	Metal-ceramic/ cement and screw-retained	One implant in a free-end setting failed 3 weeks after loading In the other implant, peri-implantitis in a smoker who missed maintenance appointments caused it to fail after 32 months of service and was splinted to a longer implant
Sivolella *et al*.[22]	2013	Retrospective	Biomet 3i and Osseotite (Biomet 3i)/NC	3.75 and 4.0/7 and 8.5	Mandible: 50	NC	NR/cement retained	The veneer has been damaged in 15 places. 2 veneer chips, 2 abutment screw loosening, and 2 abutment screw break on S NS
Vanlıoğlu *et al*.[23]	2013	Retrospective	Straumann/ internal connection	NR	Maxilla: 72 Mandible: 105	NC	Metal-ceramic/ cement-retained	S - 4 porcelain fractures NS - 3 porcelain fractures
Wagenberg *et al*.[24]	2013	Retrospective	NR	3.75, 4.0, 5.0, and 6.0/NR	NC	Anterior: 471 Posterior: 716	NR/NC	NR
Mendonça *et al*.[25]	2014	Retrospective	NR/internal and external connection	4.1 and 5.0/7, 8.5, and 10	Maxilla: 60 Mandible: 393	Posterior: 453	Metal-ceramic/ NR	NR
Sohn *et al*.[26]	2014	Retrospective	Endopore (Innova Life Sciences)/NR	4.1 and 5.0/7, 9, and 12	Maxilla: 84	Posterior: 84	NR/NR	NR
Wagenberg and Froum[27]	2015	Retrospective	NR	3.75, 4.0, 5.0, and 6.0/NR	NC	NC	NC/NC	NR

Contd...

Table 2: Contd...

Study	Year	Design of the study	Implant system/ connection type	Diameter/ length (mm)	Implants in the arch (*n*)	Localization	Prosthesis/ type of retention	Prosthetic complications
Vigolo *et al*.[9]	2015	RCT	Biomet-3i/ external connection	3.0, 3.4, and 4.0/10, 11.5, and 13	Maxilla: 114	Posterior: 114	Metal-ceramic/ cement-retained	No complications
Clelland *et al*.[5]	2016	Prospective	Osseo speed (Dentsply Sirona)/internal connection	3.5, 4, and 5/6, 8, 9, and 11	NC	Posterior: 82	Metal (gold) and metal-ceramic/ cement and screw-retained	S - 1 case of porcelain chipping NS - 5 screw loosening cases
Shi *et al*.[28]	2018	Retrospective	An internal connector for Straumann standard SLA implants	3.3/10 and 12	Maxilla: 42 Mandible: 56	Posterior: 98	Metal-ceramic/ cemented retained	S - 10 ceramic chipping NS - 5 losses of retention, 8 ceramic chipping
Renzo Guarnieri *et al*.[29]	2019	Prospective	Tapered/internal connection	4.6/6, 7.5, 9, 12/ internalconnection	Maxilla: 36 Mandible: 28	Posterior: 64	NC	NC
Ravidà *et al*.[30]	2019	Retrospective	Bone level implants	NC	Maxilla: 64 Mandible: 81	NC	Metal ceramic/ screw and cement-retained	NS - 13 Decementation, chipping, fracture, screw loosening S - 15 Decemenation, chipping, fracture
Al Aali KA *et al*.[8]	2019	Retrospective	ITI platform switch	3.3/10,12	NC	Posterior: 102	Screw and cement-retained	NS - 15 loss of retention and chipping of crowns S - 8
Al-Sawaf *et al*.[3]	2020	RCT	Conelog screw-line implants	3.8–4.3/7/ platform switch	NR	Posterior: 48	Ceramic/ cement retained	S - 1 minor chipping of crown

NC: Not clear, NS: Nonsplinted, S: Splinted, NR: Not reported; RCT: Randomized controlled trial, SLA: Sandblasted large grit acid-etched, ITI: International team for implantology

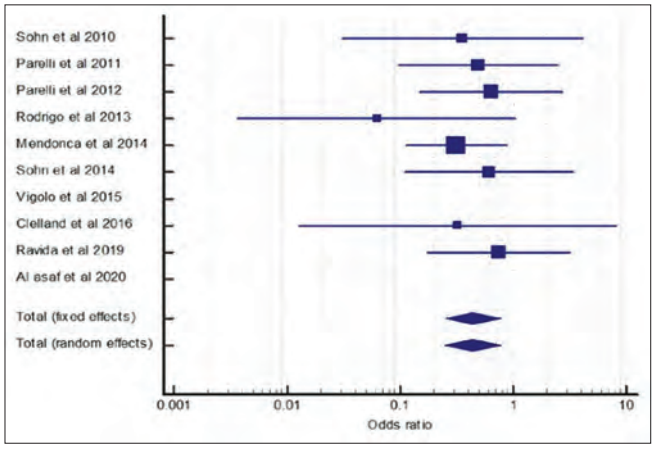

Figure 4: Forest plot of comparison of implant survival rate between splinted and nonsplinted restorations

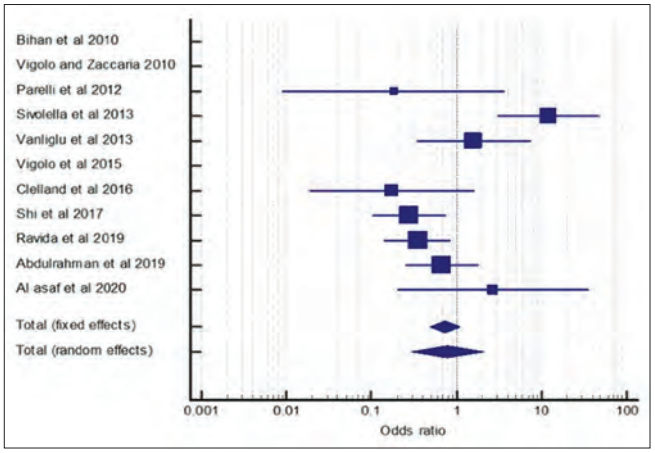

Figure 5: Forest plot of comparison of prosthetic complications between splinted and nonsplinted implant restorations

representing a high risk of bias, 11 studies receiving 7 stars, and 2 studies receiving 8 stars, both representing a low risk of bias and high quality. "A big portion of the absence of stars was due to the "result of interest not having been present at the outset" [Supplemental Table 2].

DISCUSSION

Replacing missing teeth with Osseointegrated implants has proven to be the best option for both totally and partially edentulous individuals.[20] After assessing the benefits and drawbacks of each clinical setting, the choice to splint or not splint restorations should be made during the implant planning stage.[6]

Several parameters were studied to determine the success of splinted or nonsplinted implant restoration including MBL, implant survival, and prosthetic

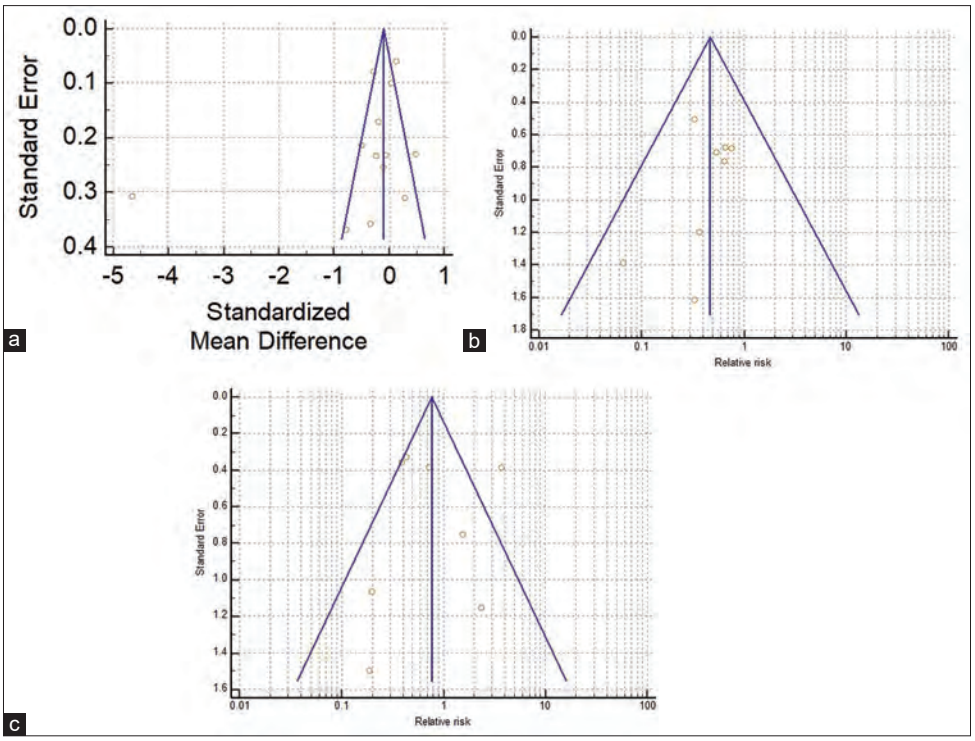

Figure 6: Funnel plots for assessment of publication bias: outcome, (a) Marginal bone loss. (b) Implant survival rate. (c) prosthetic complication

complications. There were nineteen papers identified that met the criteria for inclusion in the literature review. There were two RCTs (11%); five prospective clinical studies (26%); and the remaining twelve were retrospective, nonrandomized comparative studies (63%).

MBL surrounding the implant, which is assessed with radiographs and closely connected to implant therapies' long-term effectiveness, is critical to implant success.[29,31,33] A study conducted by Wagenberg and Froum,[27] who examined the bone stability around 302 anodic oxidized implants, found a statistically significant difference between nonsplinted and splinted implants (P = 0.023). These variations, on the other hand, were not clinically significant because they did not exceed 0.3 mm.

Using functionally loaded cemented restorations, Vigolo *et al*.[9] performed a randomized controlled experiment in the posterior maxilla in 2015 to compare the changes in marginal bone level surrounding neighboring splinted and nonsplinted implants after 5 and 10 years. 60 of the 114 remaining implants (external hexagon implants, Diameter = 410-13 mm) received splinted cemented restorations, whereas the other 54 had nonsplinted cemented restorations, with an average follow-up of 10 years. Splinted individuals lost 0.7 mm at 5 years and 1.2 mm at 10 years (interquartile range: 0.2 mm); those who were not nonsplinted lost 0.8 mm at 5 years and 1.3 mm at 10 years (interquartile range: 0.2 mm). (interquartile range: 0.2 mm). As a consequence, the MBL differed significantly between the two groups (P = 0.004). But the difference of 0.1 mm wasn't thought to be clinically important.

Al Amri and Kellesarian[2] examined the amount of bone loss in the area of neighboring implants with and without splinting restorations. They included six studies and concluded that Implants treated with splinted fixed restorations and implants not treated with splinted fixed restorations showed no difference in crestal bone loss.[37-41]

There was no statistically significant difference between a splinted and NSR for internal connection implants longer than 6 mm according to Clelland *et al*.[5] Further investigation revealed a statistically significant difference between splinted and nonsplinted 6 mm length implants at 24 (P = 0.0061) and 36 months (P = 0.0144).

According to the findings of this research, implants with splinted restorations have less bone loss at the crest than NSR. Consequently, it was determined that the initial null hypothesis was incorrect.

The survival rates of implants supporting splinted restorations and those that were not were significantly different. Prior studies have shown that implants with

splinted restorations had a good survival rate. These new findings corroborate prior studies. In a study by Mendonça *et al*.,[25] the survival rates of short dental implants (10 mm) placed in partially edentulous posterior jaws that were either splinted or not splinted were examined. The splinted group had 219 implants in their study, while the nonsplinted group had 234 implants. Those who used splinted restorations had higher success rates (97.7%) than nonsplinted (93.2%). When all implants were taken into account, no significant difference could be identified between the splinted and nonsplinted groups ($P = 0.086$). Implants longer than 8 mm exhibited reduced success rates sustaining nonsplinted prostheses, indicating that individuals with single posterior implants would experience greater masticatory stresses than those with many implants. Single posterior restorations have been shown to have larger masticatory forces than splinted ones, according to this theory as well. Consequently, the splinted implant may be necessary to avoid tissue and bone damage.[17]

A retrospective study by Ravidà *et al*.[30] examined three nonsplinted crowns (NSC), three SC, or a three-unit implant-supported bridge over two implants (ISB), with a survival rate of 92.5% for the NSC, a 100% rate for the ISB, and an 88.5% rate for the SC in the NSC. Twelve implants failed after 12 months, according to Golab *et al*.,[30] with no splinted implants failing during the follow-ups (98% survival rate). There were five failures in nonsplinted partial instances.

Vanlioglu *et al*.[23] did a retrospective investigation on 95 partly edentulous patients to determine the prevalence of prosthetic problems with single crowns, SC, and implant-supported three-unit fixed partial dentures (FPDs). As a result, they determined that single-unit restoration or short span FPD supported by implants had a low incidence of prosthetic difficulty, with veneer porcelain fracture being the most prevalent (3.95%). Single implant crowns, as opposed to FPDs and single-implant cantilever FPDs, had the lowest risk of prosthetic complications, according to Wang *et al*.[42,43]

Splinted restorations supported by narrow-diameter implants had reduced complication rates than single crowns, according to research done by Shi *et al*.(15.4% and 39.4%, respectively).

Clelland *et al*.[5] discovered screw loosening after a nonsplinted rehabilitation period. In contrast to previous research, the current systematic analysis of prosthetic complications found no significant difference between splinted and NSR.

NSR lost retention more frequently, according to the qualitative study. One reason for this is because splinted implants tend to distribute the load more evenly across the screw components than nonsplinted implants[6,32,34-36] In clinical situations, splinting of posterior implants may help to reduce retention loss.[6]

Only studies comparing splinted versus NSR were selected to avoid an unintentional comparison. Bruxism patients and implant abutment attachment to the maxilla or mandible could not be studied in detail, as could implant splinting effects on different implant sizes and lengths. Structural splinting of the implants typically reduces lateral pressure bending moment.[37]

Limitations of the study

Participants agreed to adhere to a strict maintenance plan and maintain good oral hygiene as part of the study's requirements. People who have nonsplinted dental implant restorations, however, are exempt from following these guidelines because oral hygiene is much easier for those with NSR. Neither the retention mechanism (screw or cement) nor the influence on MBL, survival rate, and prosthetic problems of engaging or nonengaging abutment type was discussed in this study. Furthermore, the study's ability to choose relevant publications was constrained by the inclusion criteria, and the length of the implant was not considered because sufficient studies were not found that fit into my inclusion criteria also, we haven't considered compromised individual who has undergone severe ridge resorption to place an ultra-short implant. As a result, broadening the inclusion criteria is proposed for further studies.

CONCLUSIONS

The following are the findings reached:

1. Bone loss around implant-supported splinted restorations is especially in the posterior region. This difference is statistically significant but has no clinical relevance
2. Implant restorations with splinted restorations have a higher rate of survival than implant-supported NSR
3. Between splinted and nonsplinted implant restorations, there was no statistically significant difference in the occurrence of prosthetic complications.

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Conflicts of interest

There are no conflicts of interest.

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Supplemental Table 1:

Study	Random sequence generation	Allocation concealment	Blinding of		Incomplete outcome data	Selective reporting	Other bias
			Participants and personnel	Outcome assessment			
Vigolo *et al*. 2015[9]	Low	Low	Low	low	Low	Low	Unclear
Al-sawaf *et al*. 2020[3]	Low	Low	Low	Low	Low	Low	Unclear

Supplemental Table 2:

Studies	Selection	Comparability	Outcome	Total stars
Bihan *et al* (2010) [16]	**	-	***	*****
Sohn *et al* (2010) [17]	***	*	***	*******
Vigolo and zaccaria (2010)[18]	****	*	***	********
Parelli *et al* (2011) [19]	***	*	***	*******
Parelli *et al* (2012) [20]	***	*	***	*******
Rodrigo *et al* (2013) [21]	***	*	***	*******
Sivolella *et al* (2013) [22]	***	*	***	*******
Vanliglu *et al* (2013) [23]	***	*	***	*******
Wagenberg *et al* (2013)[24]	***	-	***	******
Mendonca *et al* (2014)[25]	***	*	***	*******
Sohn *et al* (2014) [26]	***	*	***	*******
Wagenberg *et al* (2015)[27]	***	-	***	******
Clelland *et al* (2016)[5]	****	*	***	********
Shi *et al* (2017) [28]	**	*	***	******
Renzo *et al* (2018) [29]	****	-	***	*******
Ravida *et al* (2019) [30]	***	*	***	*******
Abdulrahmn *et al* (2019)[8]	***	*	***	*******

Review

Influence of presence or absence of posts on the failure rates of post endodontic restorations: A systematic review and meta-analysis

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Abstract

Aim: The study was designed to evaluate the existing evidence on the failure rates of post-endodontic restorations retained with and without post in endodontically treated teeth (ETT).

Settings and Design: Preferred Reporting Items for Systematic Reviews and Meta-Analyses- Protocol (PRISMA-P) guidelines were used to formulate the review.

Materials and Methods: Randomized controlled trials (RCT's) and prospective clinical studies comparing post endodontic restorations retained with and without post were included. PubMed/Medline, Embase, Cochrane Library and Scopus databases were searched to recognize relevant full-text articles in English language. The quality of the RCT's were evaluated using the Cochrane collaboration tool to assess the risk of bias and reported as having high, low or unclear risk. Random-effects model at a 95% confidence interval was used for the meta-analysis.

Statistical Analysis Used: Meta-analyses was performed using the Mantel -Haenszel method31 and risk ratio, with a 95% confidence interval (CI), was estimated for dichotomous data. Random effects model32 was used as the pooling method and 95% confident interval (α = .05 for RR values) in Review Manager (RevMan) [Computer program]. Version 5.4. The Cochrane Collaboration, 2020).

Results: Four studies comparing post retained and post free restorations in ETT with a total of 916 restorations were included in the analysis. The total risk ratio was 2.16, (95% CI:1.25 to 3.72).

Conclusion: ETT with post retained restorations exhibited significantly lower failure rates compared to restorations without post. Well-designed RCT's are warranted to develop a clinical protocol with respect to post-retained restorations.

Keywords: Coronal wall, ferrule, post endodontic restorations, post

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INTRODUCTION

Endodontically treated teeth (ETT) are generally associated with significant loss of tooth structure owing to access cavity, existing restorations, and trauma. This in turn reduces the capacity of the tooth to withstand the functional loads.[1,2] Further, loss of clinical crown height reduces the retentive quality of the crown. Post retained restorations are widely used as a predictable treatment modality in ETT.[3] However, *in vitro* studies have demonstrated that preparation of post space involves additional removal of the tooth structure and may cause significant damage leading to failure of the restoration and tooth.[4-7]

The extent of tooth structure loss and a circumferential ferrule of 2 mm has been considered as a key factor for the prognosis of post endodontic restorations.[8-12] The presence of ferrule has been shown to have a favorable impact on the resistance of the abutment tooth to fracture, crown retention, and function.[13-16]

It has been reported in some studies that post placement may not always be necessary for all the ETT,[17-19] especially in teeth with minimal tooth loss.[20-22] Recent advancements in adhesive dentistry also may be considered to improve retention of the post endodontic restorations. Therefore, whether the post is required or not in a particular situation depends on the volume of residual coronal structure present, functional requirements, and type of teeth. Frequently, post is indicated when coronal tooth structure is insufficient and a ferrule preparation is not possible which may further compromise the tooth structure.

Biomechanical failures associated with postcore restorations still represent a critical issue and are a challenging task for clinicians.[23] A recent survey report involving general practitioners suggested the use of various post endodontic restorative options including no post placement.[24]

Considering the various factors affecting the success of post endodontic restorations and inconsistent results of laboratory and clinical studies, literature search does not yield unequivocal guidelines and developing a clinical protocol is thus hampered.[25-28]

The aim of the present review was to investigate the influence of post on the failure rate of post endodontic restorations in ETT. Further, effect of ferrule and remaining coronal wall on the failure rate of tooth/restoration has been studied to explore whether post effect is superior to the ferrule effect. The null hypothesis was that post endodontic restorations retained with or without post would demonstrate the same risk of failure. The alternate hypothesis was that post endodontic restorations retained with or without post would demonstrate different risks of failure.

MATERIALS AND METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines (PRISMA-P) were used to perform the meta-analysis.[29] A nonregistered protocol was prepared to precede the literature search, complying with the PICOTS strategy as follows: the population (P) was ETT in need of core restorations, the intervention (I) was post free restorations on ETT, the comparison© was post retained restorations on ETT, outcomes (O) were failure reporting with regard to post debonding, post fracture, root fracture, crown dislodgement, coronal tooth fracture, core fracture, endodontic failure, recurrent decay, tooth loss, (T) time frame of minimum 6-month follow-up, and study type (S) was randomized controlled trials (RCT's) and prospective clinical studies.

Eligibility criteria

RCTs and prospective clinical studies comparing the failure rates of post retained and post restorations were included in the review. Studies that provided information on each group and subgroup were considered. Studies with a minimum 10 participants, minimum of 6-month follow-up duration, published in English were included. Only studies that compared post and post free restorations with information on ferrule/nonferrule, remaining coronal dentine, and whether a crown was placed after the post placement were included. Retrospective studies, *in vitro* studies, cohort studies, observational studies, finite element analysis, literature reviews, abstracts, *in vivo* studies, and clinical reports were excluded. Studies were excluded when a fixed partial denture was fabricated, no crown placement was done, and a endo crown was placed.

Search strategy

Two review authors (VKS, MKB) independently performed an extensive search using PubMed/Medline, Embase, Cochrane Library, and Scopus databases to recognize relevant full-text articles in English language published until December 2020, with no limitations to the commencement year. Based on the PICOTS questionnaire, keywords were employed for search in all selected databases, split by the Boolean operator OR, later combined by the Boolean operator AND. A typical search was performed in PubMed using PICOTS strategy as follows: ("Ferrule "[MeSH Terms] OR ("ferrule"[All Fields] AND "effect"[All Fields]) OR "post and core technique"[All Fields] OR "post and core"[All Fields]) OR ("post and core technique"[MeSH

Terms] OR ("post "[All Fields] AND "dowel"[All Fields]) OR "coronal dentin"[All Fields] OR "coronal wall "[All Fields]) OR "ferrule"[All Fields].

Data management, screening, and selection

Titles and abstracts were separately scrutinized by two review authors (AR, GAM) for possible inclusion. Duplicates and irrelevant articles were excluded and full-length articles were analyzed. The consent of all the authors was required to inclusion of an article in the final review. Any conflict regarding article selection was resolved by consulting a third review author (RSK). The important data obtained from the included articles were extracted and tabulated using an electronic format (Office Excel-Home and student 2016 software, Microsoft Corporation, One Microsoft Way, Redmond, WA 98052-6399, USA). The extracted information from the studies included study design, participants, intervention, extent of tooth structure loss, type of post and core, type of teeth restored, type of final restoration, reported failures, and follow-up time. The effect of presence and absence of post on failure risk of restorations and teeth was given consideration. Any additional information was considered only for descriptive review.

Assessment of risk of bias

The quality of the RCTs was evaluated by two review authors (VKS, MKB) using the Cochrane collaboration tool to assess the risk of bias and reported as having high, low, or unclear risk. The methodological quality for nonRCTs was assessed in accordance with the ROBINS-I tool.[30] The third review author (RSK) resolved any ambiguity between them after a mutual discussion.

Data analysis

Meta-analyses were performed using the Mantel-Haenszel method[31] and risk ratio, with a 95% confidence interval (CI), was estimated for dichotomous data. Random effects model[32] was used as the pooling method and 95% CI ($\alpha = 0.05$ for relative risk values) in Review Manager (RevMan) [Computer program]. Version 5.4. The Cochrane Collaboration, 2020).

Q test (χ^2) was used for the analysis of heterogeneity and was significant at $P < 0.1$. I^2 values above 50% represented substantial heterogeneity.[33] Forest plot was employed to graphically represent the pooled estimates and 95% CI (Z-test).

RESULTS

Data selection

The initial database screening resulted in 378 citations. After the elimination of duplicates and titles and abstract screening, 22 full texts were evaluated for eligibility. After full text reviewing, only four studies were selected for the analysis [Figure 1] which included two RCT's[34,35] and two prospective clinical studies.[9,36] The information gathered from the included studies are presented in Table 1.

A total of 579 post retained restorations and 337 post free restorations were considered. The follow-up period ranged from 24 months to 72 months. The teeth included were mainly premolars and two studies[34,36] considered anterior and posterior teeth for evaluation. The type of final restorations mainly included metal-ceramic crowns, complete/partial coverage metal-ceramic restorations, and metal-free prosthesis.

Risk of bias

The quality control and risk of bias assessments indicated that 2 RCTs[34,35] had a low risk of bias [Figure 2]. Assessor blinding was not possible for the radiographic and clinical analysis. Further, the lack of blinding may not influence the study outcome. Regarding prospective clinical studies [Figure 3], one article[9] presented low risk of bias whereas the other article[36] presented moderate risk of bias mainly because of bias during preintervention, at intervention and post intervention stage. Except in one study,[35] the outcome assessment was done by one or two calibrated examiners who were not involved in the restorative procedures presenting a low risk of bias for outcome assessment.

Meta-analyses

Four studies met the criteria for quantitative analysis. The primary outcome analysis was done for the post versus post free restorations. Meta-analyses were performed from the data on number of restoration/tooth failures by generating forest plots.

A total of 916 restorations were included in the analysis of failure risk. The included studies did not show statistical heterogeneity ($Tau^2 = 0.14$. $Chi^2 = 5.98$, degree of freedom = 3, $P = 0.11$, $I^2 = 50\%$). The total risk ratio was 2.16 (95% CI: 1.25–3.72). Figure 4 shows that failure rate of post retained restorations was significantly lower than the post free restorations ($P = 0.005$).

Two studies comparing effects of ferrule and no ferrule on the risk of restoration failures with a total of 187 restorations were included. The included studies did not show statistical heterogeneity ($I^2 = 0\%$). The total risk ratio was 1.17 (95% CI: 0.93–1.46). Figure 5 shows no significant difference between the risk of restoration failure in ferruled and nonferruled teeth ($P = 0.18$).

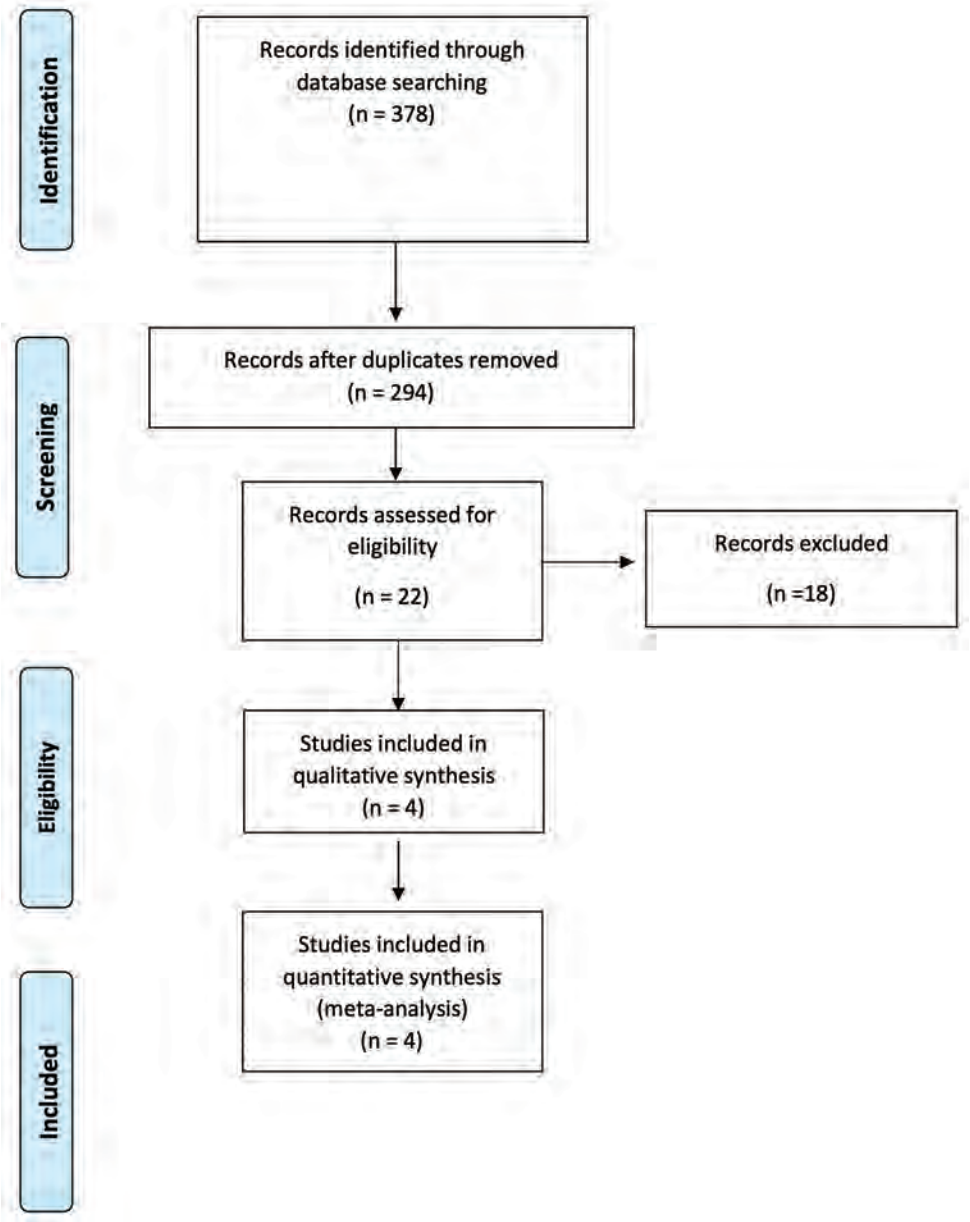

Figure 1: Search strategy according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement

Three studies comparing effects of coronal wall and no coronal wall on the risk of restoration failures with a total of 674 restorations were included. The included studies were not heterogenous (I^2 = 0%). The total risk ratio was 3.14 (95% CI: 2.48–3.98). Figure 6 shows that risk of restoration failure for teeth with remaining coronal wall was significantly lower than teeth without coronal wall ($P < 0.00001$).

DISCUSSION

Clinical performance of ETT is affected by several factors which need careful consideration while making a predictable choice of restoration.[37,38] Conservation of sound tooth structure has been shown to improve the survival rate of ETT in many studies.[9,23,34,35] The use of post is often emphasized to retain core restorations in ETT. However, additional dentin removal from the root canal to create post space may further weaken the tooth structure. Similar outcomes in terms of failure rate have been observed with post free and post retained restorations in ETT primarily on teeth with minimal loss of tooth structure.[17-19] Most of the available clinical evidence has focussed on performance of different types of post and the information on which situations benefit from the presence or absence of post in terms of reducing the risk of failure is sparse. Hence, the restorative dentist is often confronted with the challenge of decision making on how to rehabilitate ETT in a predictable

Table 1: Summary of included articles

Authors	Year	Study design	Sample size (number of patients/ number of teeth	Total number of teeth with post	Total number of teeth without post	Amount of tooth structure present	Total number of teeth with ferrule	Total number of teeth without ferrule	Type of teeth restored	Type of post	Type of core	Restoration type	Follow-up time	Type of failure
Ferrai M	2007	Prospective clinical study	210/240	120	120	4, 3, 2, 1 coronal wall/ ferrule/no ferrule	40	40	Premolars	Composite fibre post	Composite core for post- and postfree groups	Single unit porcelain fused to metal crown	24 months	Post: 9 post debonding No post: 27 crown dislodgement, 9 RF
Creugers	2008	Prospective clinical study	201	159	42	Substantial dentin height present	Not considered	Not considered	Anterior teeth, premolars, molars	Prefabricated cast post/ fiber post	Palladium alloy core/ composite core	Single crowns	5 years	Post: 5 RF No post: 1 tooth loss, 1 RF
Bitter	2009	Randomized controlled trial	90/120	60	60	2 or more walls and 1 wall exceeding 2 mm above the gingival wall with ferrule/no wall exceeding 2 mm above the gingival wall with ferrule	Not considered	Not considered	Anterior teeth, premolars, molars	Quartz fiber post	Composite core	Single unit restorations	32 months	Post: 1 post dislodgement 1 vertical RF, 1 post fracture No post: 1 core dislodgement, 2 core dislodgements with vertical RF, 1 core dislodgement with secondary caries, 1 core dislodgement with substance loss
Ferrai M	2012	Randomized controlled trial	345/360	240	120	4, 3, 2, 1 coronal wall/ ferrule/no ferrule	60	60	Premolars	Composite fiber post, custom fiber post	Composite core	Single unit porcelain fused to metal crown	6 years	Post: 12 post debonding, 2 post fracture, 17 endodontic failures, 4 RF, 14 postcore factures, 14 crown dislodgements No post: 15 endodontic failures, 32 crown dislodgment, 15 RF

RF: Root fracture

manner. Therefore, the present systematic review and meta-analysis were undertaken to find clinical evidence on influence of post retained and post free restorations on the risk of failure of post endodontic restorations/tooth.

The failure analysis included all four selected studies, irrespective of the remaining coronal structure. The effect of ferrule and remaining coronal wall was considered as secondary outcome analysis.

The analysis suggests that failure rates in ETT with post retained restorations are significantly less than the restorations retained without post. Therefore, the null hypothesis that post and post free restorations exhibits the same risk of failure was rejected and alternate hypothesis was accepted. Ferrari *et al*.[35] investigated the influence of post placement and contribution of remaining coronal wall on survival of ETT compared to post free restorations over a 6-year observation period. The presence of at least one coronal wall with post significantly contributed to the survival of the ETT. Similar results were reported by Ferrari *et al*.[9] over a 2-year observation period. Bitter *et al*.[34] observed no significant difference between the failure rates in post retained and post free restorations in teeth with different amount of coronal substance loss. However, post free restorations exhibited higher number of failures. In no wall group with a 2 mm ferrule, post free restorations exhibited a significantly higher failure rate compared to post retained restorations. No failure was reported in teeth with more than two coronal walls. Post placement did not show any difference in failure rates of teeth with one or more coronal walls compared to post free group. The study by Creugers *et al*.[36] reported no significant differences between failure rates in teeth with limited loss of coronal tooth structure restored using post compared to post free restorations. A possible explanation could be the selection of teeth with adequate coronal tooth structure and shorter follow-up time. It was also observed that no root fracture was seen with placement of post and fiber post appeared to contribute to a protective role against root fracture. Debonding of the post was the most frequently reported failure with post retained restorations. In post free restorations, mostly crown dislodgments and root fractures were reported.

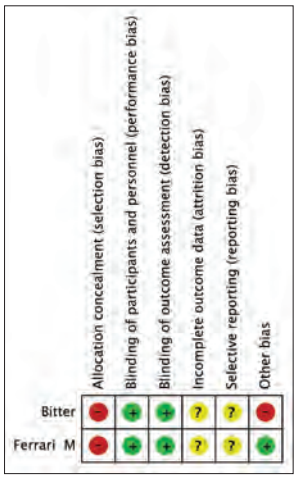

Figure 2: Summary of risk of bias assessment for randomized controlled trials

Several studies have emphasized residual coronal wall as a key determinant in the success and survival of post endodontic restoration.[16,13,39] Moreover, ferrule exerts a positive effect by improving the fracture resistance and favorable stress distribution in the tooth.[13-16] Therefore, these two factors were further explored in the analysis.

Several laboratory studies have focussed on the influence of ferrule on post core restorations and the conflicting conclusions were drawn.[27,40-44] Contrary to the bulk of evidence supporting ferrule as a key factor in improving fracture resistance of the tooth, present meta-analysis on effect of ferrule and no ferrule on the risk of failure did not yield a significant difference. Ferrari *et al*.[9,35] reported

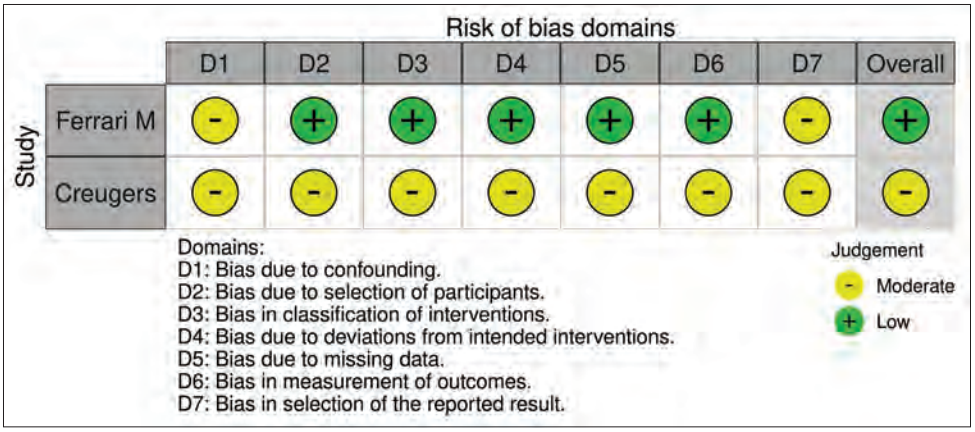

Figure 3: Summary of risk of bias assessment for nonrandomized controlled trials

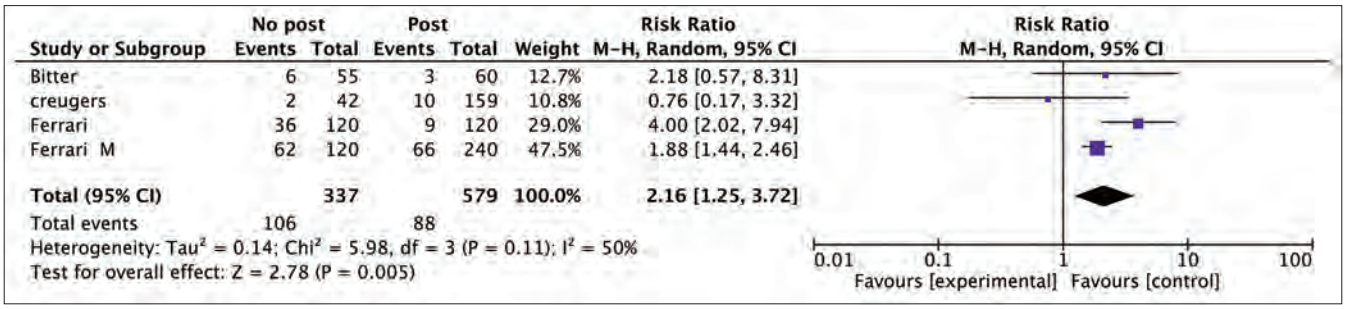

Figure 4: Forest plot for comparison of teeth with and without post

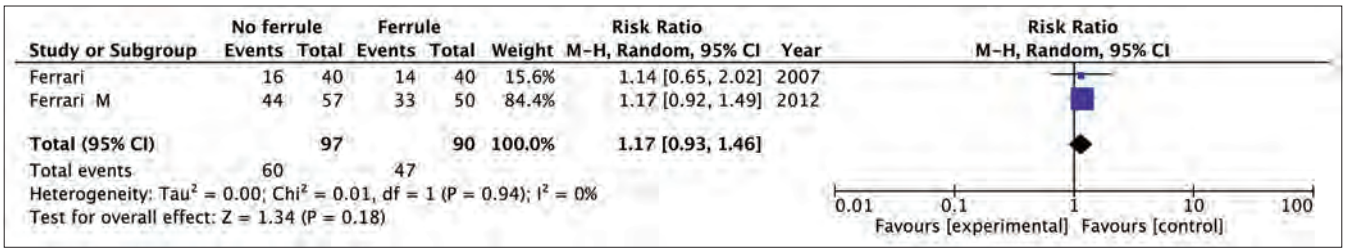

Figure 5: Forest plot for comparison of teeth with and without ferrule

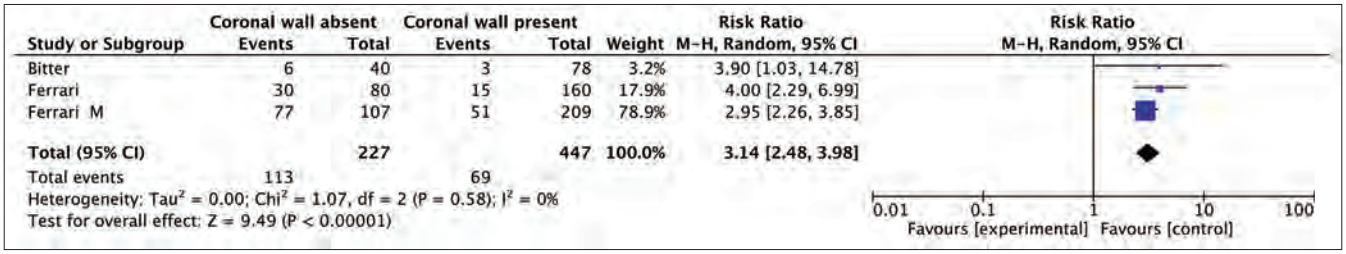

Figure 6: Forest plot for comparison of teeth with and without coronal wall

significant risk of failure associated with ferrule as well as no ferrule irrespective of presence or absence of post. However, the number of failures were more in teeth with no post compared to presence of post. This suggests placement of post to favor tooth survival when limited residual dentin is present.

Yet, no definite implication for practice could be made from the analysis as only two clinical studies were included. A possible explanation for the conflicting results is that the two included studies[9,35] grouped the samples into teeth with ferrule and without ferrule before the abutment preparation. Abutment preparation may have further reduced the available dentin leading to overestimation of amount of ferrule in both the studies. Assessing the remaining tooth structure after the tooth preparation probably could have yielded more accurate results and should be considered in future clinical trials. The dimensions of the ferrule in terms of height and circumferential extension should also be considered in precise to arrive at definite conclusion. Although ferrule is a highly debated topic in the literature, clinical studies are sparse and in the future more clinical trials should consider evaluating protective role of ferrule in ETT.

The results of this meta-analysis provided evidence that the risk of failure of restoration/tooth in ETT without coronal wall was significantly more compared to teeth with the presence of coronal walls. The failure rate was more if the teeth had been restored without post compared to post free restorations. Survival probability of the restoration increased significantly with preservation of one coronal wall compared to teeth without coronal wall irrespective of whether a post was present or absent. Furthermore, more the number of coronal walls, there was insignificant difference in the failure rates between post and post free restorations. This suggests that decision of placing the post should be considered with caution, especially in teeth with limited loss of tooth substance to avoid overtreatment. Since only three studies[9,34,35] were considered in the meta-analysis, inference should be made with caution. In future, well-designed studies are warranted as to substantiate and clarify the present findings and to arrive at a definite conclusion on predicting the risk of failure based on the exact number of coronal walls.

Further, definition of coronal wall inferred a wall extending 2 mm above the gingival wall[34] and in others complete coronal wall was considered.[9,35] Substantial dentin height based on percentage of available circumferential dentin and height in terms of marginal gingiva was considered in a study.[36] There was variation in the description of ferrule and type of teeth used across all the included studies. The possibility of group allocation bias and selection bias by the investigators by excluding teeth with high risk in an attempt to produce good results for the study cannot be ruled out. Inadequate handling of teeth in preparing the roots and inserting the posts may also be a confounding factor in this study.

Some of the limitations of this meta-analysis are heterogenous coronal restorations, number and type of teeth are not the same across all the groups. Furthermore, fixed partial denture abutments are not considered and sample size is small in few included studies. Nonetheless, it is difficult to ascertain if studies were adequately performed or if there was an error in reporting. It would be worthwhile to perform well-designed RCTs with longer follow-up duration to enhance the quality of available studies in the future and to avoid ambiguity between different studies addressing similar outcomes.

CONCLUSIONS

Substantial research has been done to expound on the effect of post and post free restoration on risk of restoration failure in ETT; however, well-designed clinical trials are still lacking. The following conclusions were drawn from the available clinical evidence analyzed in this study.

1. The risk of restoration failure associated with the post retained restoration was significantly lower than that of the postfree restorations in ETT
2. Absence of coronal wall increases the risk of failure of post endodontic restorations and more the number of coronal walls remaining, less is the failure rate. Hence, the primary focus should be on preserving remaining tooth structure
3. Difference in the risk of failure associated with presence or absence of ferrule was not significant. Number of failures associated with ferrule was less compared to no ferrule. Therefore, the role of ferrule cannot be ignored
4. In teeth with minimal loss of tooth structure post placement should be considered with caution after evaluating all other factors affecting the success of restorations to prevent overtreatment.

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Conflicts of interest

There are no conflicts of interest.

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Review

Aging resistance of infiltrated monolithic zirconia compared to noninfiltrated monolithic zirconia: A systematic review of *in vitro* studies

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Abstract

Aim: The aim of the study is to systematically assess the impact of low-temperature degradation (LTD) simulation in an autoclave on mechanical and microstructural properties of infiltrated monolithic zirconia compared to the noninfiltrated zirconia.

Settings and Design: Systematic review following Preferred Reporting Items for Systematic Reviews and Meta-Analysis 2020 guidelines.

Materials and Methods: An electronic search was done within these databases: PubMed, Scopus, and Web of Science, Science Direct, Embase, Wiley, Google Scholar for articles published between 2000 and March 2021. Search results that met eligibility criteria were categorized into two groups based on properties assessed of infiltrated monolithic zirconia exposed to LTD (also called aging simulation) – (a) mechanical (flexural strength and fracture toughness) and (b) microstructural properties (phase transformation rate and m content).

Statistical Analysis Used: Qualitative analysis.

Results: The search identified 272 preliminary results. After discarding duplicates, and screening of titles, abstracts, and full texts, 10 articles finally met inclusion criteria. Data were collected on author's details and their countries, journal and year of publication, type and percentage of infiltration, aging protocol (duration and temperature), mechanical, and microstructural properties. All the included studies invariably revealed better aging resistance without a change in mechanical properties for infiltrated monolithic zirconia as compared to noninfiltrated species.

Conclusion: Infiltration within monolithic zirconia can reduce degradation and simultaneously maintain their mechanical properties by preventing water entry into grain contours. The final m content was less for infiltrated Zirconium, indicating a lesser phase transformation and better aging resistance.

Other Information: Systematic review protocol registered at PROSPERO CRD42021248153.

Keywords: 3-mol % Yttria-stabilized tetragonal zirconia polycrystal, aging resistance, aging, biaxial flexural strength, infiltration, low-temperature degradation, monolithic zirconia, phase transformation, three-point bending

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INTRODUCTION

In the mid-1980s, Yttria-stabilized tetragonal zirconia drew the attention of biomedical applications, for the manufacture of hip implants.[1,2] Lately, the use of monolithic zirconia for dental crowns and fixed partial dentures has increased with the development of computer-aided design and computer-aided machining.[3]

Initially, porcelain veneered zirconia restorations were fabricated with zirconia as the core material, but chipping of porcelain over time led to higher failure rates than conventional metal-ceramic restorations.[4] Hence, monolithic zirconia restorations with reduced restoration thickness were fabricated which preserved the tooth structure.[5] Its production was also quicker because the additional step of veneering was not necessary.

Three temperature-dependent crystallographic forms exist for zirconium oxide-monoclinic (m), tetragonal (t), cubic (c). The monoclinic form is stable at room temperature up to 1170°C. It changes to tetragonal at 1170°C–2370°C and then to cubic above 2370°C until it melts.[6,7] When local forces are activated, tetragonal grains transform into monoclinic, increasing the crystal volume by approximately 4% at the crack tip. This exerts pressure around the crack making it difficult to propagate and is called the transformation toughening.[8]

In veneered restorations, the porcelain protects zirconia against moisture, pH and temperature variations, and impact from chewing forces.[9] Although monolithic zirconium has a thin protective glaze layer, this can wear off within a short period of the function, creating occlusal defects on restorations.[10] Aging (also called low-temperature degradation [LTD]), the focused problem of monolithic zirconia, is characterized by spontaneous monoclinic phase formation caused by masticatory forces and humid oral atmosphere.[3,11-13] When water fills the superficial oxygen vacancies, surface roughness increases first.[14,15] Progression into the bulk of the material affects mechanical properties when it involves the zirconia grains.[16,17] In transformation toughened zirconia, the mechanical properties are temperature dependent. Fractures due to aging occur when the internal stress exceeds the tensile strength of the material at that temperature.[18-21]

Glass/silica infiltration,[22,23] a method of functionally grading zirconium prevents water entry into the grain contours and reduces degradation. The resulting graded zirconium has a better stress distribution and good flexural strength, in addition to its best match with the tooth shade and improved adhesion to resin cement.

Campos *et al*.[24] illustrated that silica infiltration promotes bonding between zirconia and resin cement without affecting its mechanical properties due to structural homogeneity and wettability of the material.[22,24,25] A glass/zirconia multilayer formed in the sol-gel method of grading imparts load-bearing capacity.

Previous systematic reviews on infiltrated zirconium evaluated its influence on bonding ability with resin cement,[26-28] the effect of different surface treatments on their mechanical behavior,[29] and the effect of aging on its properties. However, reviews comparing the aging resistance of infiltrated and noninfiltrated zirconium are lacking. Therefore, we aimed to assess the aging resistance by comparing the t to m^6 transformation rate of infiltrated and noninfiltrated monolithic zirconia. In addition the prepost aging values of flexural strength and fracture toughness were also compared.

Our objectives were to:

1. To assess the microstructural and mechanical properties of infiltrated zirconia before and after aging
2. To assess the microstructural and mechanical properties of noninfiltrated zirconia before and after aging
3. To compare the aging resistance of infiltrated and noninfiltrated zirconia.

As the actual effect of infiltrated monolithic zirconia on the aging resistance is not yet clear, this systematic review would update the existing literature.

Thus, our systematic review addresses the research question: "Does infiltrated monolithic zirconium as a dental material have a better aging resistance than noninfiltrated zirconium?"

MATERIALS AND METHODS

Protocol and registration

This review was performed according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis 2020 guidelines.[30]

Eligibility criteria

Studies were selected based on P-population, I -intervention, C-comparison, o- outcome, S- study design (PICOS) elements:

Population

Monolithic Yttrium-stabilized Tetragonal Zirconia Polycrystal (Y-TZP) specimen with any geometry.

Intervention

Infiltrated zirconia subjected to aging simulation.

Control

Noninfiltrated zirconia subjected to aging simulation.

Outcomes

(a) Microstructural properties-phase transformation rate and monoclinic phase content, (b) Mechanical properties-flexural strength and fracture toughness.

Study design

In vitro studies.

Inclusion criteria

Studies:

i. That followed the *in vitro* design
ii. Reported in the English language
iii. That compared infiltrated zirconia against noninfiltrated zirconia subjected to aging
iv. That assessed mechanical properties and structural stability (phase transformation) as outcomes
v. With autoclave-simulated aging.

Exclusion criteria

Studies with:

i. *In-vivo* design
ii. Veneered zirconia
iii. Infiltrated zirconia evaluated for interfacial bonding between zirconia and silica
iv. Surface grading or simulation of aging not done
v. That evaluated outcomes other than mechanical properties or structural stability
vi. That evaluated the behavior of Y-TZP implants and femoral heads
vii. Thermal cycling in solutions other than water, aging under ultraviolet light, or coloring liquids (coffee, wine, tea, cola, etc.,).

Information sources and search strategy

The literature search was carried out in PubMed, Scopus, and Web of Science, Science Direct, Embase, Willey, Google Scholar databases to identify relevant articles from January 2000 to March 2021. A combination of Medical subject headings (MeSH) and entry terms was used with a sensitive search strategy as shown in Table 1. These keywords were used with Boolean operators AND, OR, and NOT. The retrieved results were cross-checked to eliminate duplicates.

Table 1: Search strategy

Search tool		Search terms
Population	#1	3Y-TZP OR "monolithic zirconia" OR "zirconia crown" OR zirconium (MeSH) OR "zirconium oxide" OR "yttria stabilized polycrystalline tetragonal zirconia" OR "yttria stabilized tetragonal zirconia" OR "all ceramic (MeSH)"
Intervention	#2	"Infiltrated zirconia" OR "graded zirconia" OR "functional grading" and "aging simulation" OR "autoclave aging" OR "hydrothermal degradation" OR "low temperature degradation"
Comparisons	#3	"Noninfiltrated zirconium" OR "nongraded zirconia" and "aging simulation" OR "autoclave aging" OR "hydrothermal aging" OR "low temperature degradation"
Outcomes	#4	"Mechanical property" OR "mechanical behavior" OR "flexural strength" OR "fracture toughness" OR "phase transformation" OR "monoclinic content" OR "monoclinic fraction" OR "rate of t-m transformation" OR "aging resistance"
Search combination		#1 AND #2 AND #3 AND #4

MeSH: Medical subject headings

Selection of articles

Stage 1

Titles and abstracts were screened by two independent review authors (AAK and SVP) following the inclusion criteria. Articles with disagreement between the two reviewers were set aside for full-text evaluation.

Stage 2

Full-text evaluation of all included and doubtful articles selected from 1st stage was done by 2 independent review authors (AAK and SVP) and disagreements were resolved through a third author (ASK).

Stage 3

Two review authors (AAK and SVP) together evaluated the reference lists of all articles selected in the second stage, and full texts of potentially fitting studies were examined.

Data extraction process

A Standardized data extraction table was created on Microsoft excel to collect data on:

1. Publication details: Authors and year of publication
2. Sample size and specimen geometry
3. Control and experimental groups
4. Aging protocol-pressure, temperature, and duration
5. Method of strength assessment
6. Microstructural and mechanical properties for the two groups.

Risk of bias assessment

The evaluation of the risk of bias was adapted from a previous systematic review.[31] Each study was assessed for a set of domains and given any one of the three codings – 0, 1, 2 if the specific approach was mentioned, inadequately mentioned, or if undisclosed, respectively. A total score of 0 or 1 was considered as low risk of bias,

1–3 moderate, and ≥4 as high risk.[32] The assessment was done independently by the two authors, and any uncertainty was resolved by discussion.

RESULTS

Search and selection

From the 272 studies retrieved through the electronic and manual searches, 72 duplicates and 175 ineligible studies were excluded leaving twenty reports for full-text analysis. After a complete evaluation, 10 reports were finally retained in the systematic review [Figure 1]. The characteristics of the included studies are presented in Table 2 and excluded studies in Table 3.

Risk of bias within the studies

Risk of bias

Of the 10[32-42] studies, 8 studies[33,34,36-41] had a low risk of bias, one[35] had a medium risk of bias, and one study[42] possessed a high risk of bias. Out of the 9 domains, as mentioned in Table 4, the risk of bias for the sample size domain was high for most of the studies.[35,42] A clear description of the sample size and criteria for calculation was lacking, and even if explicitly mentioned was <30 for the remaining studies.

The methods mentioned were compared with that under results section to assess reporting bias for each study.

Risk of bias across the studies

This was assessed by comparing the methodology and results of each included study. None of them had reporting or publication bias.

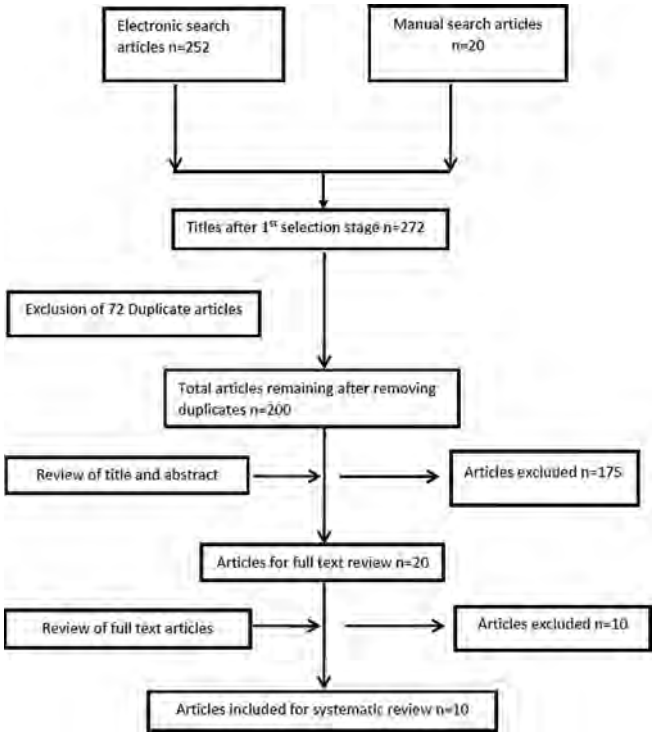

Figure 1: Flow chart

Qualitative summary

A summary of different infiltrated materials used in all studies is presented below [Table 5].

Microstructural property assessment

As shown in Table 6 all ten studies assessed aging resistance concerning microstructural properties. The percentage of m content was assessed in 3 studies[33,40,41] and the rate of t-m phase transformation was compared for the study and control groups in the remaining 7 studies. X-ray diffractometry (XRD) was used to assess the monoclinic content in all the studies except in the one by Nogiwa-Valdez *et al*. 2013[38] that used Raman spectroscopy for evaluating t-m transformation.

Rate of t-m phase transformation

To study the rate of t to m phase transformation was the only objective of Campos *et al*. 2020,[33] Samodurova *et al*. 2014,[36] Hallmann *et al*. 2012,[39] and Gremillard *et al*. 2002.[42] Zhang *et al*. 2017[34] aimed to evaluate the balance between aging and slow crack growth resistance; Zhang *et al*. 2014,[37] Zhang *et al*. 2015,[35] and Nogiwa *et al*. 2013[38] analyzed the phase transformation rate of change in mechanical properties. The exact percentages or fraction of m content before and after aging were checked and compared for both the groups in three studies.

Silica, Alumina, and Lanthanum were used for infiltration of monolithic Zirconium, either independently or in combination [Table 4]. Irrespective of the material used, all studies revealed a slow t to m phase transformation for the infiltrated monolithic zirconia compared to noninfiltrated zirconia.

The influence of different concentrations of Alumina on aging resistance was also studied by Zhang *et al*. 2014[37] and Hallmann *et al*. 2012.[39] A 0.25% concentration of alumina had a greater retarding effect than the higher concentrations of 2% and 5%[37] and aging was stabilized up to 0.05 weight % of alumina.[39] Furthermore, Samodurova *et al*.[36] found that the phase transformation rates were different for Alumina and silica infiltration.

Percentage of monoclinic phase

All the 3 studies that assessed the percentage of m phase in the infiltrated and noninfiltrated Zirconia found lesser values for the graded species. The aging duration, however, varied widely from 5 h in Nakamura *et al*. 2012[40]-140 h in Campos *et al*. 2020.[33]

Table 2: Details of included studies

Author publication year	Sample size	Sample geometry	Control group 3Y-TZP	Experimental group - 3Y-TZP + infiltration	Method of infiltration in monolithic zirconia	Sintering temperature	Low temperature aging protocol	Method of strength assessment	Mechanical property assessed	Microstructural property
Campos *et al.*, 2020[33]	180	Disc (39 mm × 19 mm × 15.5 mm)	Vita InCeram YZ Germany	Sílica gel (Si (OH) 4): 3% water (H2O): 97%	Silica sol method for infiltration Sílica gel (Si (OH) 4): 3% water (H2O): 97%	1530°C, 2 h	134°C and 2 bars of pressure, times 35 h or 140 h	Universal testing machine	Biaxial flexural test	XRD - m phase identification
Zhang *et al.*, 2017[34]	54	Not reported	3Y-TZP powders (Tosoh, Japan)	0.2 mol % La2O3 0.1 mol % Al2O3	Mixing La2O3 and Al2O3 in ethanol for 24 h	1500°C for 2 h	134°C and 0.2 MPa upto 100 h	Vickers hardness test	Fracture toughness	XRD - m phase identification
Zhang *et al.*, 2015[35]	-	Disc	3Y-TZP powders (Tosoh, Japan)	0.25, 2 and 5 weight % alumina	Nitrate coating technique	1550°C	134°C and 0.2 MPa up to 40 h	Vickers hardness test	Fracture toughness	XRD - m phase identification
Samodurova *et al.*, 2014[36]	150	Disc	3Y-TZP powders (Tosoh, Japan)	0.25%, 0.5% silica and alumina	Silica sol method and addition of aqueous ammonia (25 weight.%) at room temperature	1450°C for 4 h	134◦C for 6, 8, 24, 48	Universal testing machine	Biaxial flexural test	XRD - rate of t-m transformation
Zhang *et al.*, 2014[37]	120	Disc	3Y-TZP powders Tosoh, Japan	0.25 weight % Al2O3	Nitrate coating technique	1350°C-1550°C for 2 h	134°C and 0.2 MPa 40 h	Vickers hardness test	Fracture toughness	XRD m phase identification
Nogiwa-Valdez *et al.*, 2013[38]	24	Disc	3Y-TZP powders Tosoh, Japan	0.1 weight % Al2O3 (0.1 AZ) 0.5 weight % Al2O3 (0.5 AZ) and 0.1 weight % La2O3+0.1 weight % Al2O3 (LAZ)	Mixing La2O3 and Al2O3 in methanol	1450°C for 3 h	0.5, 1, 3, 6, 12, 24, 48 and 72 h	Indentation method on Vickers microhardness machine	Fracture toughness	SCM Raman spectroscopy AFM
Hallmann *et al.*, 2012[39]	252	Disc	3Y-TZP, Japan 3Y-TZP, Germany	Al2O3 0.25 weight %	Not specified	1350°C–1600°C for 2 h	134°C C 2.3 bar up to 2 h	-	-	XRD - m phase identification SEM
Nakamura *et al.*, 2012[40]	20	Mandibular molar crown	3Y-TZP, Japan	0.2 mol % silica-doped Y-TZP block	Hot isostatic pressing and mixing silica in block	1450°C for 3 h	Accelerated aging test for 5 h at 200°C and 2 bar	Universal testing machine	Biaxial flexural test	XRD - rate of t-m transformation decreases with silica
Nakamura *et al.*, 2011[41]	28	Disc (20×4 × 12) mm	3Y-TZP, Japan	0.2 mol % silica-doped Y-TZP block	Hot isostatic pressing and mixing silica in block	1400-1500°C	Accelerated aging test for 5, 10, 20, 40 h at 200°C and 2 atm	Universal testing machine	Biaxial flexural test	XRD - m phase identification SEM
Gremillard *et al.*, 2002[42]	Not known	Disc	3Y-TZP, Japan	Silica content of 0.5 weight %, colloidal silica	Slip-casting method	1450°C for 5 h	134°C 2 bar (0.2 Mpa) up to 16 hour	Subcritical crack growth	Double-torsion tests	XRD m phase identification TEM

XRD: X-ray diffractometry, SEM: Scanning electron microscopy, AFM: Atomic force microscopy, TEM: Transmission electron microscopy, OH: Hydroxide, LAZ: Lanthanum Alumina Zirconia, AZ: Alumina reinforced zirconia, Y-TZ: Yttria stabilized tetragonal zirconia

Table 3: List of excluded studies

Excluded studies	Reasons for exclusion
1. Ramos *et al*., 2020[43]	Evaluated bond strength with zirconium
2. Toyama *et al*., 2019[27]	Used porcelain veneered zirconia
3. Ramos *et al*., 2019[26]	Evaluated bond strength with zirconium
4. Reis *et al*., 2019[44]	Used veneered feldspathic porcelain
5. Sun *et al*., 2018[45]	Evaluated biocompatibility
6. Mao *et al*., 2018[46]	Comparison group was 5Y-TZP
7. Madani *et al*., 2016[47]	Evaluated bond strength of resins
8. Chai *et al*., 2015[48]	Evaluated bond strength with zirconium
9. Inokoshi *et al*., 2015[49]	Evaluated sandblasting techniques
10. Vanderlei *et al*., 2014[50]	Evaluated bond strength of resins

Mechanical property assessment

As shown in Table 7. Four out of ten included studies had data on autoclave aging-induced change in mechanical properties (flexural strength and fracture toughness) of infiltrated versus noninfiltrated monolithic 3-mol % Y-TZP (3Y-TZP). The values before and after aging for the two groups were compared. All 4 studies evaluated flexural strength using a universal testing machine. The units for flexural strength were Megapascal (MPa) except for fracture toughness in Nakamura *et al*. study[40] that was in Newton. Since the units of flexural strength are recorded differently in different article, as there is no uniformity among the different studies, thus we could not go ahead with meta-analysis. The toughness was calculated[33,36] by measuring the crack lengths produced by the Vickers indentation (noted in MPa m1/2) directly.

While the infiltration material used in 3 studies was silica that reported exact before and after aging values for flexural strength/fracture load,[33,40,41] the fourth study[36] focused on the effect of both aluminum and silica infiltrations on monolithic zirconia. Only the direction of result for the independent and combined effect of the addition of these two materials was mentioned by the authors.

All four studies demonstrated a significant reduction in mechanical properties due to aging, for the noninfiltrated zirconia, whereas infiltration prevented such a noticeable reduction for the experimental group. The results did not vary with the type of material infiltration.

DISCUSSION

The monolithic zirconia ceramics used for full-contour restorations not only solved the problem of porcelain-chipping from the zirconium core but also needed a very conservative tooth preparation. Zirconium oxide possesses other superior properties such as strength, fracture toughness, biocompatibility, aesthetics, and transformation toughness. The transformation toughening mechanism[51] provides resistance against crack initiation.

Table 4: Risk of bias assessment

	Campos *et al*., 2020[33]	Zhang *et al*., 2017[34]	Zhang *et al*., 2015[35]	Samodurova *et al*., 2014[36]	Zhang *et al*., 2014[37]	Nogiwa-Valdez *et al*., 2013[38]	Hallmann *et al*., 2012[39]	Nakamura *et al*., 2012[40]	Nakamura *et al*., 2011[41]	Gremillard *et al*., 2002[42]
Clearly stated aim	0	0	0	0	0	0	0	0	0	0
Cleary mentioned Study design	0	0	0	0	0	1	1	1	0	1
Sample size mentioned	0	1	2	0	1	1	0	0	0	2
Standardization of specimen preparation	0	0	1	1	1	0	0	0	1	1
Experimental group - method of infiltration mentioned	0	0	0	0	0	0	0	1	1	1
Sintering cycle protocol	0	0	0	0	0	0	0	0	0	1
Specified aging protocol	0	0	0	0	0	0	0	0	0	1
Execution of mechanical parameter mentioned clearly	0	-	0	0	0	0	-	0	0	-
Method of phase transformation	0	0	0	0	0	0	0	0	0	0
	Low risk	Low risk	Medium risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	High risk

For each parameter scores were assigned from 0 to 2, 0 - If information about the domain clearly mentioned, 1 - Information mentioned, but not clear, 2 - Information not presented, If total sum - 0-1 = low risk, 1-3 = medium risk, > than 4 = high risk

Table 5: Summary of different infiltrated materials used

Infiltration	Studies
Only silica infiltration	Campos *et al*., 2020[33]
	Nakamura *et al*., 2011[41]
	Nakamura *et al*., 2012[40]
	Gremillard *et al*., 2002[42]
Only alumina infiltration	Zhang *et al*., 2015[35]
	Zhang *et al*., 2014[37]
	Hallmann *et al*., 2012[39]
Combination of alumina and lanthanum	Zhang *et al*., 2017[34]
	Nogiwa-Valdez *et al*., 2013[38]
Combination of silica and alumina	Samodurova *et al*., 2014[36]

However, the excessive transformation in moisture weakens the material as the tensile forces cause bulk propagation of the transformation. This process called aging/LTD is believed to occur due to a multitude of direct (repeated masticatory forces, water, and temperature changes)[52] and indirect factors (pH changes and oral microflora) within the oral cavity, triggering the t-m phase transformation.[15,53] The clinical adjustments that sometimes may be necessary for a perfect occlusion also play a role in crack propagation, which gets accelerated by subsurface defects. Deprivation of the toughening mechanism reduces the crack tip shielding effect of the transformation zone.[54]

To evaluate the performance of monolithic zirconia in the presence of aging, autoclave or steam chambers are used to simulate oral conditions. The autoclave parameters such as the pressure of water vapor, temperature, and time are all under manual control.[17] One hour of autoclave treatment in steam at 134°C is equal to 3–4 years *in vivo* at 37°C, and aging of about 60 h in an autoclave might correspond to about 20 years in clinical service. The outermost area of 10 μm gets affected within this duration.[55]

Chevalier *et al*.[56] suggested that dense zirconium with smaller grain sizes resists the passage of water molecules into the internal pores and crack surfaces, thereby preventing aging. Grinding[57] and functional grading of zirconia,[58] pretreatment during sintering,[59] and surface modifications with air abrasion treatment[56] also protect against aging. The rate of t to m transformation is, however, dependent on surface roughness[60] and also varies with the duration of the autoclave.

The aging kinetics can hence be evaluated either by quantifying the monoclinic ZrO2 fraction in-depth or by measuring the rate of phase transformation.[61] We evaluated the percentage of m content and rate of phase transformation.

Of the many materials used for infiltration-Al3+, Fe3+, Pr3+, Cu2+, Ce4+, Bi3+, La3+, Si4+, some of them were found to have a good aging resistance without losing mechanical properties-fracture toughness and strength.[36,38,42,56] The studies included in our review had alumina, silica, and lanthanum as the grading material, either singly or in combination with each other.

Infiltration and microstructural properties

As aging involve a crystallographic change from t to m phases, techniques sensitive to such changes like the XRD, or methods that quantify the number of m phases like the Garvie and Nicholson method, Rietveld method, and the Raman spectroscopy[56] can also be used to study them. XRD was used in nine out of ten studies in our review, but this method has certain limitations like analyzing just the superficial surface and being unsuitable for those materials with monoclinic content of <5%. Raman spectroscopy was used by Nogiwa-Valdez *et al*.[38] due to its increased sensitivity and precise identification of minor amounts of m phase. The Rietveld method[33,34,37] and the Garvie and Nicholson[36,40,41] methods were used in three studies each.

Silica was used as the material for infiltration in four studies.[33,40-42] In all of them, irrespective of the percentage composition of silica, a lesser rate of phase transformation with a corresponding lesser m-content was noticed in the graded species. Two protocols of different duration, namely 35-h and 140-h were used by Campos *et al*.[33] and the m content was slightly greater at 140 h in both groups. Whereas, Nakamura *et al*.[41] studied the effect of different sintering temperatures (1400, 1450, and 15,000c) and found a comparatively lesser m content for graded species at all temperatures.

Infiltration of monolithic zirconium with silica results in the formation of zirconium silicate (ZrSiO4) on the surface and grain boundaries, which blocks the entry of water.[44] It also leads to the formation of cubic zirconium that is better resistant to aging without affecting its mechanical properties.[26]

Out of the three studies in which only alumina was used, Zhang *et al*.[35] concluded that independent of the yttria content and sintering temperature, 0.25% alumina infiltration reduced aging susceptibility better than 2% and 5% alumina.

The greater retarding effect of the smaller amount was explained by the segregated aluminum ions at the grain boundary of zirconia, which were better in producing oxygen vacancies than the higher valence Zr4+ ions.[30,31] The vacancies thus produced not only serve as the initiation point for the t–m transformation but also allow its easy

Table 6: Results for microstructural properties

Study ID	Property studied	Sample size	Method of study	Comparison groups	Method for measuring monoclinic content	Comparison criteria	Findings	Authors' conclusion
Zhang *et al.*, 2014[37]	t to m phase transition	20	XRD	Noninfiltrated Zr 0.25 weight % alumina doped Zr	Rietveld analysis	Rate of t to m phase transition in relation to hardness and fracture resistance	Alumina doped Zr showed slower phase transition in comparison to noninfiltrated Zr	Alumina infiltration to zirconium reduced aging susceptibility without affecting hardness and fracture resistance
Zhang *et al.*, 2015[35]	t to m phase transition	10	XRD	Noninfiltrated Zr versus 0.25%, 2% and 5% alumina infiltrated Zr	Mehl-Avrami–Johnson	Rate of t to m phase transition in relation to hardness and toughness	Not only alumina addition but also amount of alumina added also did not result in a significant change in toughness/hardness Due to solubility limit of alumina in Zr during sintering, 0.25% Al had greater degradation retarding effect than 2 and 5% Al	Zr infiltrated with Al had better resistance to aging than noninfiltrated ones, without impacting the toughness and hardness
Zhang *et al.*, 2017[34]	t to m phase transition	28	XRD	Undoped 3Y-TZP versus 0.25% Al-3Y-TZP versus La-Al co doped 3Y-TZP	Rietveld analysis	Balance between aging and slow crack growth resistance	Phase transformation rate of noninfiltrated 3Y-TZP was>0.25% Al-3Y-TZP and La-Al co doped 3Y-TZP	Both alumina doping and alumina-lanthanum co doping presented better balance between aging and slow crack growth resistance than undoped Zr
Nogiwa-Valdez *et al.*, 2013[38]	t to m phase transition	20	XRD	Noninfiltrated 3Y-TZP (Z) versus 0.1% Al-3Y-TZP (0.1 AZ) versus 0.5% Al-3Y-TZP (0.5 AZ) versus (0.1% La+0.1% Al (LAZ))	Mehl-Avrami–Johnson	Rate of t to m phase transition in relation to fracture toughness, density, and grain size	Al and La additions had partial phase transition compared to undoped Zr that had complete transition	Significant deceleration of aging kinetics in 3Y-TZP was observed by co-doping trace quantities of alumina and lanthenum without modifying density, grain size and fracture toughness
Samodurova *et al.*, 2014[36]	t to m phase transition	40	XRD	Noninfiltrated versus 0.25%versus 0.5% silica infl zirconium	Garvie and Nicholson method	Rate of t to m phase transition in relation to mechanical properties, density and grain size	Alumina and silica additions influenced phase transformations to different extents without affecting any of these properties	Rate of t to m phase transition was reduced by individual additions of Al and Si. In addition, their combination increased aging resistance without reducing fracture toughness
Hallmann *et al.*, 2012[39]	t to m phase transition	12	XRD	Noninfiltrated versus 0.01% versus 0.05% Al infl zirconium		Rate of t to m phase transition in relation to sintering temp (1350°C – 1580°C), grain size and dopant addition	Alumina addition up to a concentration of 0.05 weight % stabilized Y-TZP against aging	Nature and concentration of dopants significantly influence aging rate
Gremillard *et al.*, 2002[42]	t to m phase transition	-	XRD	Noninfiltrated versus 0.5% silica infiltrate zirconium		Rate of t to m phase transition in relation to crack propagation resistance	Both noninfiltrated and infiltrated Zr present nucleation of m phase, but only noninfiltrated Zr undergoes growth in monoclinic nuclei, due to surrounding stresses and micro cracking	Resistance to aging is highly improved by addition of silica, without affecting crack propagation resistance
Campos *et al.*, 2020[33]	Percentage m after t to m phase transition	30	XRD	Noninfiltrated versus silica infiltrate zirconium	Rietveld method	Percentage m content in both the groups before, 35 h and 140 h after aging	Noninfl Zr 0=0 35 h=65±3 140 h=66±3 Infl Zr 0=0 35 h=26±1 140 h=31±2	Silica infiltration inhibits transformation of t to m Zr

Contd...

Table 6: Contd...

Study ID	Property studied	Sample size	Method of study	Comparison groups	Method for measuring monoclinic content	Comparison criteria	Findings	Authors' conclusion
Nakamura *et al.*, 2011[41]	Percentage m after t to m phase transition	14	XRD	Noninfiltrated (Z) versus 0.2% silica infiltrate zirconium (S)	Garvie-Nicholson equation	Percentage m content in both the groups at different sintering temperatures (1400, 1450, 1500°C) and durations	1. 1400°C (before and after aging) Z=8.53-82.30 S=5.33-81.46 2. 1450°C (before and after aging) Z=8.66-78.47 S=7.45-47.88 3. 1500°C (before and after aging) Z=8.71-70.31 S=9.42-55.92 Values at different durations not clear (represented only in graph)	For both types, m content increased with aging and as well as aging duration and temperature, but silica doped Zr revealed lesser m content and good resistance to aging
Nakamura *et al.*, 2012[40]	Percentage m before and after milling and after aging	20	XRD	Noninfiltrated (Z) versus 0.2% silica infiltrate zirconium (S)	Garvie-Nicholson equation	Percentage m values before milling - after milling - after aging	Change in m content Premilling to postmilling to postaging Z=0-25-65% S=0-23-30%	M content increased after milling and aging for both types, but postmilling aging (and postaging m content) was far lower in silica doped Zr

XRD: X-ray diffractometry, LAZ: Lanthanum alumina zirconia, AZ: Alumina reinforced zirconia

Table 7: Results for mechanical properties

Study ID	Sample size	Material infiltrated	Duration of aging	Time of measurement	Flexural strength (MPa)		*P*	Inference	Conclusion
Campos *et al.*, 2020	30	Silica	35 h, 140 h		**Graded**	**Nongraded**	Not mentioned	No significant change in FS found from baseline for graded, but reduction was significant for nongraded	Silica infiltration can prevent reduction of mechanical property due to LTD on partially stabilized Zr
				Baseline	920.3 (890-951)	974 (901-1052)			
				35 h	935.9 (913-958)	1161.5 (1127-1196)			
				140 h	1033.6 (997-1071)	698.5 (680-716)			
Nakamura *et al.*, 2011	28	Silica and alumina	50 h	Baseline	1160–1200	1010–1050	<0.01 for baseline comparison between graded and nongraded	FS of graded Zr dropped by only 20%, but by 50-60% for nongraded Zr, after 50 h of aging	Zr doped with silica underwent lesser reduction in FS than undoped Zr
				50 h	≥950	380–520			
Samodurova 2014	30	Silica	24 h		**Plain Zr**	**Silica doped**		Baseline FS of aluminum infiltrate Zr was >noninfiltrated Zr When both aluminum and silicon were added to Zr, aging resistance increasing without reducing fracture toughness	FS of graded Zr subjected to accelerated LTD for 24 h had nearly identical values to those before aging
				Plain Zr	1051±13	1076±114	Not mentioned		
				0.05 alumina	1072±48	1207±98			
				0.25 alumina	1226±183	1244±56			
Nakamura *et al.*, 2012	20	Silica	5 h	Baseline	1728 N	1723 N	*P*<0.001 for before-after comparison of nongraded Zr and not significant for	FS reduced significantly from baseline to 5 h of aging for nongraded, but not for graded	Grading with silica prevented a significant reduction of fracture load after aging
				5 h	1622 N	1370 N			

FS: Flexural strength, LTD: Low-temperature degradation

propagation into the material.[34] On the other hand, the limited segregation of Al3+ due to the limited solubility of the alumina in zirconia was responsible for lesser resistance in high alumina concentrations. They further explained that an adequate amount of alumina should be added, for it to be aging-resistant and avoid affecting the translucency of 3Y-TZP ceramics.[35]

Silica and alumina co-doping by Samodurova *et al*.[36] showed a deceleration in aging by two different dominant mechanisms, i.e., by strong grain boundaries that limit microcracking of the transformed layer in alumina, and by rounded glassy grains at multiple grain junctions that reduce the internal stresses in silica.

Alumina and lanthanum co-doping were used in two studies.[34,38] Better aging resistance due to this combination was attributed to a changed relationship between nucleation and growth. Not only was the rate of nucleation of fresh monoclinic nuclei after 3 h prevented but also the growth rate of the transformation was also reduced.

La, Al-doped 3Y-TZP have strongly bonded oxygen vacancies of La3+ and Al3+ cations, which slow down the diffusion of the water molecules at the grain boundary and increase the activation energy for the aging process. Both the above mechanisms render zirconium resistant to aging.[34]

The direction of the result was the same in all included studies, but the lack of a significant difference between the graded and nongraded species could be due to the different duration and temperatures used. Pereira *et al*.[31] suggested a temperature-dependent nucleation-growth curve. A lesser duration is needed for transformation to occur at higher temperatures, and vice-e-versa, thus concluding that both temperature and time determine the aging resistance.

Infiltration and mechanical properties

Monolithic zirconia needs to be aging resistant, without its mechanical properties-flexural strength and fracture toughness-being affected. Uni and bi-axial flexions are two standardized and internationally approved techniques of testing the flexural strength of ceramics.[62]

In all the four studies that evaluated the mechanical properties, the reduction in flexural strength was either significant only for nongraded species[33,40] or relatively lesser in graded zirconia41. Silica was the material of choice in the three of them. Samodurova *et al*.[36] found similar results for fracture toughness of silica-alumina co-doped zirconia. The flexural strength of cubic/tetragonal mixed structure for ZrO2 normally ranges between 490 and 577 MPa. But in those containing greater tetragonal phase, flexural strength is as high as 1000 − 1200 MPa.[63-65] This is due to stabilization with 3Y-TZP which maintains the superior mechanical properties, while the greater t phase in them is due to controlled aging.[66]

Aging is characterized by a crystallographic change from orthorhombic to monoclinic phases, accompanied by a 4% increase in volume. Hence, the greater fracture resistance for graded species is due to the lesser shedding of the monoclinic portion on the surface.[40]

Limitations

Our review has a few limitations – (1) the risk of bias concerning the sample size domain was high in all the included studies, (2) although the temperature and pressure within the autoclave were consistent across different studies, variation existed in the duration, which could have affected the final percentage of m phase within each species, (3) the interaction between different determinants like sintering temperature, and grain size of graded material, etc., could have a confounding effect on the outcome, which was not considered in every included study and is out of scope of this review, (4) the sample size for the studies was less, and hence, the review results should be cautiously interpreted. (5) The *in vitro* study design does not completely simulate the oral conditions but contributes to an initial understanding before conducting *in vivo* studies on patients.

In addition, the very few studies and the incomplete reporting of the flexural strength and m content values prevented us from conducting a meta-analysis.

However, on the other hand, our review has its distinct features-this is the first to compare the infiltrated and noninfiltrated zirconia for phase transformation rate and aging resistance. Second, the risk of bias in all the studies was low, except for the sample size domain. Third, irrespective of the nature and percentage of the infiltrated material, the direction of effect was the same in all studies, i.e., infiltrated zirconia showed better aging resistance than noninfiltrated monolithic zirconia.

Other information

The protocol for this systematic review was registered on Prospero (international prospective register of systematic reviews) CRD42021248153.

CONCLUSION

Within our study limitations, infiltrated zirconium

was found to have a better aging resistance than the noninfiltrated zirconia. The phase transformation rate and the subsequent m content were less for graded zirconia. Infiltration increases the structural homogeneity and hardness of monolithic zirconia, whereas it reduces the fracture toughness.

As very few studies on the comparison of aging resistance between infiltrated and noninfiltrated zirconia were found, we recommend additional studies with larger sample sizes on this topic that would help in a better understanding of the differential effect of the type and concentrations of grading material.

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Conflicts of interest
There are no conflicts of interest.

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Research

Effect of silver diamine fluoride, potassium nitrate, and glutaraldehyde in reducing the post vital tooth preparation hypersensitivity: A randomized controlled trial

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Abstract

Aim: Hypersensitivity is the most common clinical problem which is encountered by most of dental patients undergoing a vital tooth preparation for a fixed crown prosthesis. The aim of this study is to evaluate the effect of silver diamine fluoride, potassium nitrate, and glutaraldehyde in reducing dentinal hypersensitivity following vital tooth preparation.

Settings and Design: This study is a randomized control trial performed on 119 teeth of 68 patients who are in need of fixed prosthesis treatment.

Materials and Methods: After a thorough clinical examination, patients were allocated into any of the randomly assigned four groups (Control, silver diamine fluoride, potassium nitrate, and glutaraldehyde) and the level of hypersensitivity was measured by blasting air on the surface of tooth at five different intervals (before preparation, after preparation, after application of desensitizers, before cementation and after a follow up period of about 30 days) and is graded using Schiff 's cumulative hypersensitivity index.

Statistical Analysis Used: Kruskal wallis test is used to compare the rate of sensitivity between the 4 groups. Friedman and Wilcoxon test is used to compare the rate of sensitivity at 5 different intervals.

Results: All the desensitizers used in this study reduced the level of hypersensitivity. Among which, silver diamine fluoride was found to be more effective after application, before cementation, and after a follow up period of about 30 days followed by GLUMA and potassium nitrate.

Conclusion: The results of this study suggest that silver diamine fluoride was found to be more effective after application, before cementation of the definitive prosthesis and after a follow up period of 30 days.

Keywords: Dentinal hypersensitivity, desensitizers, vital tooth preparation

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INTRODUCTION

Dentinal hypersensitivity is one of the most common clinical conditions encountered by most of the general practitioners characterized by "short, sharp pain arising

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from the exposed dentin in response to any stimuli which can be thermal, evaporative, tactile, osmotic or chemical that cannot be ascribed to any other dental defect or pathology."[1-4] Different terms have been used to describe dentinal hypersensitivity like cervical/root/cemental/dentine hypersensitivity/dentine sensitivity.[3,4] Dentinal hypersensitivity is a prevalent disorder and is one of the most unbearable conditions among the patients which can lead to both physical and psychological discomfort for the patient having a negative effect on the quality of a person's life, especially with regard to the selection of diet and hygiene maintenance. It has been found to be more prevalent among the population with the incident rate of about 4%–74% with it being more common among the females than in males with the peak of 30–40 years of age in canines followed by premolars being the most commonly affected teeth.[4-6]

Several attempts have been made to treat hypersensitivity either by desensitizing the nerve, forming precipitates of protein within the tubules, sealing/plugging the dentinal tubules or by laser therapy.[7] Commonly used desensitizing agents are Potassium Nitrate, Glutaraldehyde, Silver Nitrate, Sodium fluoride, Strontium Chloride, Zinc Chloride, Methyl methacrylate, and Silver diamine fluoride.[8] Potassium nitrate acts by preventing the nerve from getting depolarized and the entrance of sodium ions into the nerve thereby reduces the level of sensitivity[9] Gluma is a combination of glutaraldehyde and hydroxyethyl methacrylate which acts by coagulating the proteins within the dentinal tubules and thereby decreasing the level of sensitivity.[10] Silver diamine fluoride solution is been used as therapeutic agent at a concentration of about 38% for the management of dental caries which has a ph of 8–9.[11] However, its prevalence as a desensitizer following vital tooth preparation is less among the general practitioners as they are not aware of the pros and cons of the material. Application of the solution topically on the exposed dentinal surface resulted in the formation of squamous layer plugging the dentinal tubules, thereby reducing the dentinal hypersensitivity.[12] And so, the primary objective of this study is to evaluate the effect of silver diamine fluoride, potassium nitrate, and glutaraldehyde in reducing dentinal hypersensitivity following vital tooth preparation. The secondary objectives of this study are to observe for any incidences of debonding and hypersensitivity following cementation of the definitive prosthesis and after a follow-up period. The null hypothesis is that there is no measurable difference in the reduction of Hypersensitivity following vital tooth preparation on using silver diamine fluoride than potassium nitrate and glutaraldehyde.

MATERIALS AND METHODS

This study was conducted among the patients who were referred to the Department of Prosthodontics, IGIDS for crown and bridge prosthesis in vital tooth during the period of May 2019 to Dec 2020. Ethical approval was obtained from the Institutional Review Board (IRB No: IGIDSIRB2018NRP40PGSAPRI) and Institutional Ethical Committee (IEC No: IGIDSIEC2018NRP40PGSAPRI). Trial was registered in clinical Trials Registry-India (CTRI-REF/2020/01/031226). 119 teeth of 68 patients who met the inclusion criteria participated in the study [Table 1]. Informed consent were obtained from all the participants before the recruitment in the study. The sample size for the study was estimated by a statistician and block randomization was generated using computer software. Patients were allocated and assigned into any of the 4 groups (Control, Silver diamine fluoride, potassium nitrate, and glutaraldehyde). The details of the Materials and equipment used are shown in Table 2.

METHODOLOY

Patient and site preparation

Rubber dam isolation is done before the preparation and tooth sensitivity to the specific site is checked using Schiff's cumulative index.[17] The level of Sensitivity was determined using air-water syringe of a dental unit. The degree of hypersensitivity on the buccal and occlusal surface of the

Table 1: Inclusion and exclusion criteria for recruitment into the study

Inclusion criteria	Exclusion criteria
1. Vital teeth in need of fixed prosthetic restorations	1. Age <25 years
2. Age above 25 years[13]	2. Allergic to desensitizers[14]
3. Absence of restorations/fracture of tooth[16]	3. Pregnant/breast feeding
4. Teeth should be free of decay, pulpal and periodontal pathologies	4. Noncooperative patients
5. Co-operative patients	5. Patients who require antibiotic or steroid therapy[15]
	6. Nonvital tooth
	7. Amelogenesis imperfecta
	8. Dentinogenesis imperfecta
	9. Periodontal diseases
	10. Carious tooth
	11. Pain related to the orofacial region

Table 2: Materials used

Materials used	Manufacturer
Silver-diamine fluoride	RIVASTAR, dental avenue India private limited (Haryana)
Gluma	Heraeus kulzer, (South bend)
Potassium nitrate	Himalayan Drug Company, India
Rubber dam	GDC fine crafted Dental Pvt Ltd, Punjab
Oro micro applicator tips	Reach global India Pvt Limited, Maharastra
Luxatemp provisional material	Dental avenue India Pvt Ltd, Haryana
Non eugenol zinc oxide eugenol	3M ESPE, Karnataka

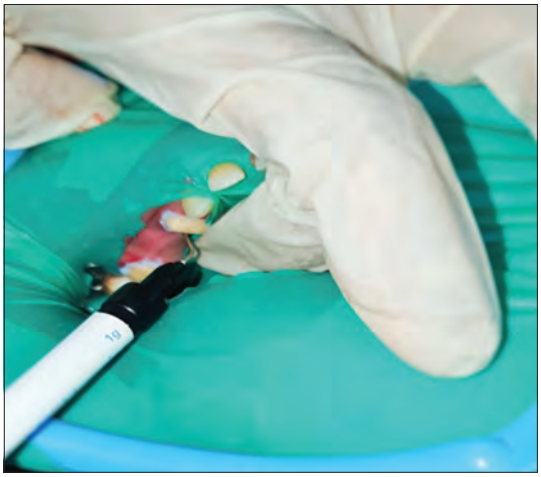


Figure 1: Rubber dam isolation done and gingival barrier placed in relation to 13 and 15

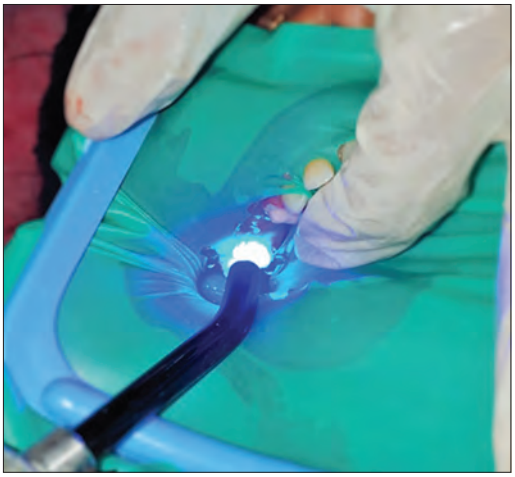


Figure 2: Gingival barrier cured with the light cure unit in relation to 13 and 15

tooth site is checked by blasting air at a distance of 1 cm for minute and it was graded using Schiff's cumulative index.[18-21] Schiff's cumulative hypersensitivity index is used to measure the severity of sensitivity and based on the nature of pain, participants grade the degree of hypersensitivity from 0 to 3.(0-no response to stimulus, 1-Responds to air stimulus but does not require removal of the stimulus, 2-Responds to air stimulus and requires removal of the stimulus, 3-Responds to stimulus and found the stimulus to be painful and requires removal of stimulus).

Tooth preparation

Selected teeth were prepared for a definitive prosthesis with a shoulder bevel finish line on the buccal surface and chamfer line on the lingual surface under local anesthesia (Lidocaine 2% and epinephrine 1:100000). Following the loss of anesthetic effect on the pulp (60 min), degree of hypersensitivity is measured for each sample. Based on the random allocation concealment the desensitizing substances (Water-Control, Silver diamine fluoride, 5% potassium nitrate, Glutaraldehyde) were applied onto the randomly assigned prepared teeth [Figure 1-7, Application of the desensitizer - Silver diamine fluoride]. Following preparation and after application of the specific desensitizing agents onto the surface, air is blasted onto the prepared surface using air-water syringe and the degree of hypersensitivity is recorded. Patients were blinded throughout the procedure and is unaware of the type of material used for each abutment tooth.[22]

Temporarization

Following vital tooth preparation and impression making, the prepared teeth were protected with temporary crown fabricated with Bis Acryl Methacrylate Composite (Luxa temp/Trantemp provisional restoration material) and is luted with eugenol free Zinc oxide cement (3M ESPE Relyx Temp NE) for a period of about 15 days until the definitive prosthesis is fabricated. During this period, any incidence of hypersensitivity is recorded.[23-26]

FPD cementation

Porcelain fused metal restorations were fabricated in the laboratory by an experienced technician. Before the cementation of definitive prosthesis, degree of hypersensitivity is again checked by blasting air onto the prepared surface and is graded according to Schiff's cumulative hypersensitivity index and the scores were recorded. The final prosthesis is checked for esthetics, marginal fit, and occlusion and is luted with glass ionomer cement.

Follow-up

Patients were recalled after 30 days to check for any symptoms of hypersensitivity and the values were recorded. There were no incidences of debonding of the definitive

Figure 3: RIVASTAR- Silver diamine fluoride and potassium iodide capsules

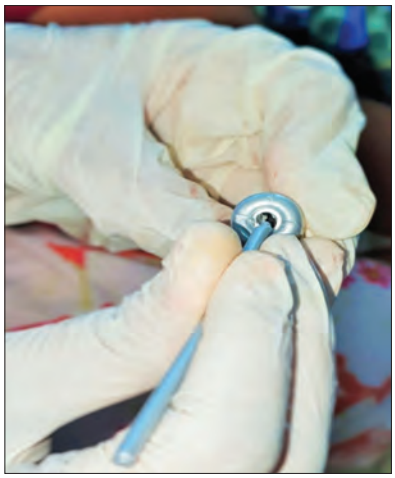


Figure 4: Pierce the silver foil-silver diamine fluoride

Figure 5: Apply it onto the prepared surface of the tooth and rub it

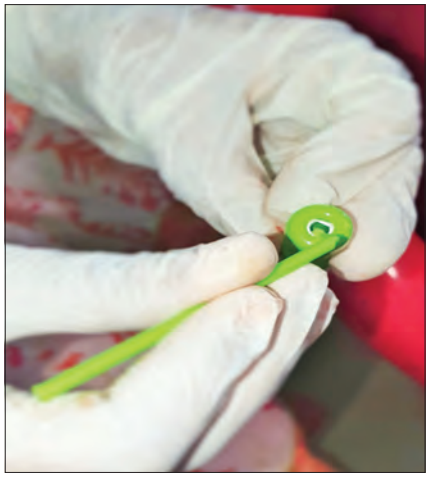


Figure 6: Pierce the green foil –Potassium iodide

prosthesis in any of the samples during the period of the study.

Sensitivity test

Adjacent teeth is isolated with gauze and a blinded examiner evaluated sensitivity and the values were recorded. Hypersensitivity was evaluated by blowing compressed air onto the buccal and the occlusal surface of the tooth at a distance of about 1 cm for 1 min. The degree of hypersensitivity is graded using Schiff's Cumulative index with the values ranging from 0 to 3. Following dentinal stimulation, the sensitivity level is graded by the patients from 0 to 3. The level of sensitivity on the abutment tooth is measured at 5 different intervals (Before preparation, 2 h after preparation as local anesthesia loses its effect, after application of desensitizing agents, prior to cementation of definitive prosthesis and after a follow-up period of about 30 days).

Statistical methods

To compare the rate of sensitivity between the four groups: Silver diamine fluoride, potassium nitrate, GLUMA, and control group, Kruskal–Wallis test was used.

For comparing sensitivity at different times, Friedman statistical test followed by Wilcoxon is used.

RESULTS

The present study is carried out with an aim to evaluate the effect of silver diamine fluoride, potassium nitrate, glutaraldehyde in reducing the post vital tooth preparation dentinal hypersensitivity. For this purpose, a total of 119 vital abutment teeth of 68 patients who are in need of fixed prosthesis in the anterior and posterior regions. Of the 68 patients involved in the study, there were 42 Males and 26 females with 63 anterior teeth and 56 posterior teeth in need of definitive restorations. All the patients participated till the end of the study and there were no dropouts noticed. The mean and standard deviation were calculated from the collected data. The results were statistically analyzed and

calculated using the Friedman test between the 5 intervals and overall comparison was statistically analyzed using Kruskal-Wallis test.

Preoperative sensitivity

As per the inclusion criteria, hypersensitivity in all the samples of 4 groups (water, silver diamine fluoride, potassium nitrate, GLUMA) before the preparation was found to be zero.

Postoperative sensitivity

Kruskal–Wallis test is used to compare the rate of sensitivity between the four groups (water, silver diamine fluoride, potassium nitrate, GLUMA). $P = 0.000$ indicated a highly significant difference between the four groups.

The same statistical method is used to compare the degree of hypersensitivity after the application of desensitizing agents between the four groups (water, silver diamine fluoride, potassium nitrate, and GLUMA) and it is found that $P = 0.000$ indicated a highly significant difference between the four groups.

Desensitizing agents at 5 different intervals

Friedmann test is used to compare the difference in the group at 5 different intervals (before preparation, after preparation, after application of desensitizing agents, before cementation and after a follow-up period of about 30 days). All the desensitizing agents used showed a highly significant difference ($P = 0.000$) in the group at 5 different intervals [Table 3].

Silver diamine fluoride

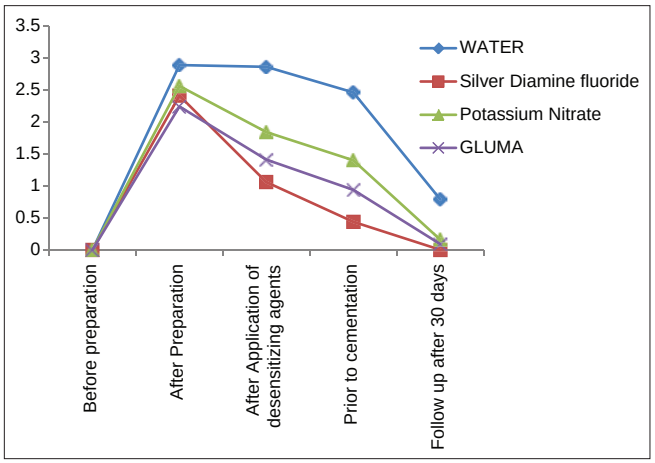
The degree of sensitivity is found to be least before the cementation and after a follow-up period and was most after tooth preparation [Table 3 and Graph 1].

Potassium nitrate

The degree of sensitivity is found to be least after the application of the desensitizer and was most after the preparation [Table 3 and Graph 1].

Gluma

Degree of sensitivity is found to be least after a follow-up period and was most after the preparation [Table 3 and Graph 1].



Graph 1: Comparison of the groups at 5 different intervals

Table 3: Comparison of the control group, desensitizers at 5 different intervals

Intervals	Sample size	Mean	SD	Minimum	Maximum	*P*
Water						
Before preparation	28	0.00	0.000	0	0	0.000
After preparation	28	2.89	0.315	2	3	
After application of desensitizers	28	2.86	0.356	2	3	
Prior to cementation	28	2.46	0.576	1	3	
Follow up after 30 days	28	0.79	0.738	0	3	
Silver diamine fluoride						
Before preparation	32	0.00	0.000	0	0	0.000
After preparation	32	2.41	0.560	1	3	
After application of desensitizers	32	1.06	0.619	0	2	
Prior to cementation	32	0.44	0.564	0	2	
Follow up after 30 days	32	0.00	0.000	0	0	
Potassium nitrate						
Before preparation	25	0.00	0.000	0	0	0.000
After preparation	25	2.56	0.507	2	3	
After application of desensitizers	25	1.84	0.374	1	2	
Prior to cementation	25	1.40	0.645	0	2	
Follow up after 30 days	25	0.16	0.473	0	0	
Gluma						
Before preparation	34	0.00	0.000	0	0	0.000
After preparation	34	2.24	0.606	1	3	
After application of desensitizers	34	1.41	0.557	0	2	
Prior to cementation	34	0.94	0.694	0	3	
Follow-up after 30 days	34	0.09	0.288	0	1	

SD: Standard deviation

Control

Degree of sensitivity is found to be more after preparation, after the application of the agent and before cementation of the definitive prosthesis and was least after the follow-up period [Table 3 and Graph 1].

Comparison of the desensitizing agents

Kruskal-Wallis test is used to compare the difference between the 4 groups (control, silver diamine fluoride, potassium nitrate, and glutaraldehyde). It was found that the least amount of sensitivity is observed in the silver diamine fluoride group followed by GLUMA and potassium nitrate and was most in the Control group (WATER). A finding of $P = 0.000$ indicated a highly statistical difference in all the groups [Table 3 and Graph 1].

Comparison of the control versus desensitizing agents

Comparison of the control and the other desensitizing agent groups at 5 different intervals (before preparation, after preparation, After application of the desensitizing agents, before cementation of the definitive prosthesis and after a follow-up period) indicated a highly statistical difference with silver diamine fluoride found to be more effective in reducing the post vital tooth preparation hypersensitivity followed by GLUMA and potassium nitrate [Tables 4-6].

DISCUSSION

Addy *et al.* defined Hypersensitivity as a transient short and sharp pain which occurred as a result of the exposure of dentinal tubules in response to any stimuli.

In situations, where the vital tooth is prepared to receive a definitive prosthesis, the dentin is exposed and left uncovered for a sufficient period till the provisional crown is fabricated.[27] After the definitive prosthesis is fabricated, the provisional crown and the residual cement remaining on the tooth structure are removed.[28] Definitive prosthesis made of either metal or ceramic material will be tried to check the accuracy of fit, marginal adaptation, proximal contours, and occlusion.[29] All the above-mentioned instances happen in regular clinical practice and the patient is comforted stating that the sensitivity is a transient phenomenon. During cementation of the prosthesis, acidic luting agents may sometimes increase the sensitivity and cause intolerable discomfort to the patient.[30] The entire procedure becomes an uncomfortable experience for the patient. Using desensitizing agents for dentin exposure due to caries and noncarious lesions as already mentioned is very well recorded in literature. Following tooth preparation, many desensitizing agents have been recommended for use.[31] Though hypersensitivity and desensitizing agents are not novel to the dental profession, its use following tooth preparation to handle postpreparation sensitivity does not have enough literature to support. We find many articles in the literature on the use of desensitizing agents to reduce hypersensitivity for conditions like carious and noncarious lesions.[32-38] Very few evidences exist on the use of various desensitizing agents following vital tooth preparation. In 2009, Jatalian *et al.* conducted a study to find out the effectiveness of the desensitizers in reducing the post vital tooth preparation dentinal hypersensitivity and found that Potassium nitrate used before cementation reduced postoperative vital tooth preparation sensitivity than GLUMA. The knowledge and practice of such desensitizing agents following vital tooth preparation is less among the general practitioners as there are no much literature evidence. Hence, the aim of this study is to evaluate the effect of silver diamine fluoride, potassium nitrate, and glutaraldehyde in the reduction of post vital tooth preparation hypersensitivity.

Comparison of the dentinal hypersensitivity among the four groups (water, silver diamine fluoride, potassium

Table 4: Comparison of the control group versus silver diamine fluoride

Groups	Sample size	After preparation	After applying desensitizing agents	Prior to cementation	Follow up
Water (control)	28	2.893	2.857	2.464	0.786
Silver diamine fluoride	32	2.406	1.063	0.438	0.000

Table 5: Comparison of the control group versus potassium nitrate

Groups	Sample size	After preparation	After applying desensitizing agents	Before cementation	Follow-up
Water (control)	28	2.893	2.857	2.464	0.786
Potassium nitrate	25	2.406	1.84	1.4	0.16

Table 6: Comparison of the control group versus Gluma

Groups	Sample size	After preparation	After applying desensitizing agents	Before cementation	Follow up
Water (control)	28	2.893	2.857	2.464	0.786
Gluma	34	2.235	1.412	0.941	0.88

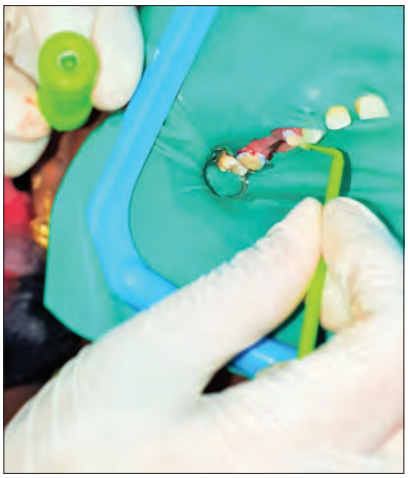


Figure 7: Apply potassium iodide solution over the previously applied solution until the creamy white precipitate turns clear

nitrate, glutaraldehyde) showed the same value before preparation indicating that there is no meaningful statistical difference ($P = 1.000$) between the groups which determined the equality of the characteristics of the groups at the start of the procedure. Furthermore, as per the inclusion criteria, the rate of sensitivity in all the samples of the four groups is found to be before the preparation.

When silver diamine fluoride is used as desensitizer, comparison of the rate of hypersensitivity at five different intervals (before preparation, after preparation, after application of desensitizing agents, before cementation of the definitive prosthesis and after a follow-up period of about 30 days) revealed a highly significant difference ($P = 0.000$). The least amount of sensitivity is observed before cementation of the definitive prosthesis and marked difference is noted after preparation. No report of sensitivity is observed after the follow-up period (mean = 0.00). Thus, Silver diamine fluoride when used as desensitizer reduced the level of hypersensitivity immediately after application and over time with no sensitivity reported after follow-up period indicating that it has a long-term effect. When using Potassium nitrate as a desensitizer, comparison of the degree of hypersensitivity at 5 different intervals (Before preparation, After preparation, after application of desensitizing agents, before cementation of the definitive prosthesis, and after a follow-up period of about 30 days) showed a highly significant difference ($P = 0.000$). Least amount of hypersensitivity is observed after a follow-up period of 30 days and most is noted after preparation. Thus, Potassium Nitrate when used as a desensitizer reduced the degree of hypersensitivity immediately after application of the agent and over time indicating that it has a long term effect. When using GLUMA as a desensitizer, comparison of the degree of hypersensitivity at 5 different intervals (Before preparation After preparation, After application of desensitizing agents, before cementation of the definitive prosthesis and after a follow-up period of about 30 days) revelead a highly significant difference ($P = 0.000$). Least amount of sensitivity was observed after a follow-up period of about 30 days and most was after preparation. Thus, GLUMA as a desensitizer reduced the rate of hypersensitivity immediately after application and over time indicating that it has a long-term effect. Comparing the degree of sensitivity in the control group at 5 different intervals (Before preparation, After preparation, After application of desensitizing agents, prior to cementation of the definitive prosthesis and after a follow up period of about 30 days) showed a significant difference ($P = 0.000$). Water is applied as a control instead of desensitizing agent and sensitivity on the abutment teeth is measured at different intervals. It was found that least amount of sensitivity is observed after a follow-up period and is most after preparation and application. The reduction in hypersensitivity occurred slowly over time which may be due to the sclerotic dentin formation as a result of constant stimulation. Thus, it can be concluded that there is little reduction in the level of hypersensitivity over time even without the use of desensitizers. When compared to the instantaneous effect of the desensitizers in other groups, the effect seems to be very little and occurs gradually over time. It was found that there is a highly statistically significant difference between the four groups ($P = 0.000$) after the application of desensitizing agents (silver diamine fluoride, potassium nitrate, GLUMA) and the control group. Comparison of the desensitizing agents and the control group showed that there is the significant reduction in the rate of hypersensitivity after application of desensitizing agents. Least amount of sensitivity after application of the agents is observed in the Silver diamine fluoride group followed by GLUMA and potassium nitrate and higher degree of sensitivity was observed in the control group. Comparison of the degree of sensitivity before cementation of the prosthesis among the four groups (Control, silver diamine fluoride, potassium nitrate and GLUMA) showed a highly significant difference ($P = 0.000$) between the four groups. The least amount of sensitivity prior to the cementation of the prosthesis was observed in silver diamine fluoride group followed by potassium nitrate and GLUMA and most was observed in Control group. Null hypothesis was rejected as there were significant difference in the reduction of hypersensitvity using silver diamine fluoride than potassium nitrate and glutaraldehyde. To the extent of our knowledge, this was the first report which compared the efficacy of silver diamine fluoride in the reduction of

post vital tooth preparation hypersensitivity. In this study, the results showed that silver diamine fluoride was superior to the other desensitizing agents in reducing the pain and discomfort among the patients at four different intervals. The null hypothesis which was stated at the start of the study is rejected as there is highly significant difference on using silver diamine fluoride in reducing the post vital tooth preparation hypersensitivity than the potassium nitrate and GLUMA. However, of the 34 treated with gluma desensitizer 12 of them showed mild pulsating pain which can be considered as one of the side effects of the material. One of the limitations of the current randomized controlled trial is the sample size and a longer follow-up period is needed to evaluate the significant difference between the materials. Further Randomized control studies with longer follow-up period are needed to evaluate the effect of silver diamine fluoride as a desensitizer in reducing the post vital tooth preparation hypersensitivity.

CONCLUSION

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

1. Desensitizers used in this study are effective in desensitizing the prepared vital tooth
2. Among the desensitizers used, silver diamine fluoride seems to be more effective after application, before cementation of the definitive prosthesis, and after a follow-up period of 30 days
3. There was no debonding of any definitive prosthesis noted during the period of the study.

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Conflicts of interest

There are no conflicts of interest.

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Research

Effect of local application of platelet-rich fibrin scaffold loaded with simvastatin on peri-implant bone changes

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Abstract

Aim: The purpose of this study was to compare the effects of autologous platelet-rich fibrin (PRF) alone and PRF loaded with SIM on peri-implant bone changes and implant stability in patients undergoing implant rehabilitation.

Settings and Design: This was a nonrandomized controlled split-mouth study

Materials and Methods: The study included 8 males between the ages of 45 and 60 years. Each patient received two implants, one on each side of the arch. One side was treated with PRF alone and the other side with PRF loaded with SIM at the time of osteotomy. A cone-beam computed tomography was used to evaluate bone changes around the insertion of implant sites at 3, 6, and 12 months postoperatively. The secondary outcome included measuring implant stability using Osstell device at baseline and 3 months postinsertion. To compare groups at different time periods, data were examined using a two-way analysis of variance.

Statistical Analysis Used: The results were compared between the groups using a two-way analysis of variance, followed by a post hoc Bonferroni test. To examine total bone changes and stability comparisons between the two groups at the end of the trial, an unpaired t-test was utilized

Results: The mean crestal bone-level changes in the SIM/PRF group were significantly lower than the PRF group, with a mean shift of 0.9788 ± 0.04853 versus 1.356 ± 0.0434, respectively ($P < 0.0001$). There was no significant difference between the two groups in implant stability.

Conclusion: Peri-implant application of SIM/PRF resulted in less bone changes than PRF alone, which may prove to be beneficial for the long-term success of implants. SIM showed promising results in limiting peri-implant bone resorption providing new clinical application for SIM in dental implant rehabilitation.

Keywords: Bone loss, peri-implant bone changes, platelet-rich fibrin, simvastatin

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INTRODUCTION

It is inevitable for bone resorption to occur in the edentulous sites of the jaw after natural teeth extraction.[1] Restoring function and esthetics after bone resorption requires additional surgeries, which makes prosthetic

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management more challenging. Currently, implant dentistry is a well-studied and documented treatment option for the treatment of edentulous jaws.[2]

Bone changes surrounding an osseointegrated implant are considered an important factor to predict the survival of the implant, the long-term prognosis, as well as implant success. Thus, the ultimate target for implantologists is to achieve minimal bone loss around a dental implant.[3]

Approaches to accelerate bone regeneration or reduce bone resorption include specific surgical grafting techniques which use autogenous bone, membranes, substitutes, growth factors, stem cell treatments, and, more recently, osteopromotive pharmaceutical substances. Pharmacological techniques have gotten a lot of interest because of how easy they are to use and how cost-effective they are when combined with other grafting materials. Simvastatin (SIM), of other pharmaceutical substances, has been studied extensively for its osteopromotive effects since the 1990s.[4]

SIM, a hypercholesterolemic drug, works by reversibly inhibiting the HMG-CoA reductase enzyme in the mevalonate pathway, resulting in a decrease in blood cholesterol and other metabolites. SIM's pleiotropic effects on bone metabolism are mainly attributed to the increased BMP-2 and vascular endothelial growth factor gene expression, which stimulates osteoblastic cell differentiation.[5] SIM has also been proven to reduce bone resorption by preventing the fusion of osteoclast precursors and causing a decline in the number of active osteoclasts by decreasing the expression of TRAP and cathepsin K.[6] As a result, SIM is currently being investigated for its alternative mechanism of action on bone (in the field of dentistry) for the purpose of treating alveolar bone defects and preventing peri-implant bone loss.

SIM acts as an osteoclastogenesis inhibitor.[7] This mechanism was described as the suppression of the pathways that signal reactive oxygen species. Previous studies demonstrated the effect of SIM for the prevention of bone loss in experimental animals.[5,8] These studies concluded that SIM is an effective inhibitor of bone loss in periodontal procedures performed on rats' alveolar bone regions.

A platelet concentrate obtained through centrifuge separation contains platelet-rich fibrin (PRF), a biological scaffold produced from human blood. It is widely used in medical and dentistry for postsurgery rehabilitation and healing, as well as tissue regeneration. Platelet-rich plasma is a byproduct that contains many growth agents within the fibrin meshwork.[9]

Local PRF application has been shown to increase bone regeneration in experimental animals and improve tissue regeneration of critical-sized bone defects.[10] Previous clinical studies have also shown that PRF has an effect on soft- and hard-tissue regeneration. The findings of these articles and studies support the use of PRF as a biological scaffold alone or in combination with other materials.[11-13] Till now, there is only one experimental study on animals that investigated the effect of PRF in combination with SIM on bone regeneration,[14] however, there are no records of human clinical trials investigating the dual effect of PRF with SIM on treating bone defects.

The aim of this study was to compare the effects of PRF alone as a biological scaffold and in combination with SIM on long-term peri-implant bone changes and the stability of implants in implant rehabilitation cases.

MATERIALS AND METHODS

Approval of the Research Ethics Committee of the Faculty of Dentistry, The British University in Egypt, for all aspects of this study was obtained (approval no. 20-001). The study was carried out between August 2019 and September 2020. Clinical trial registration has been done on ClinicalTrials.gov website and has been accepted, with ID number: NCT05008068.

Patient recruitment

All the patients enrolled in this controlled, split-mouth study were randomly recruited from The British University Hospital in Egypt. Informed written consent was signed by all participating patients.

The sample size was calculated using G*Power 3.1.9.2 Software. The sample size calculation was based on a previous study.[15] The power of the *t*-test was calculated to be 95%, using a two-tailed significance level of 5%. The calculated sample size will be six implants in each group, with a total of 12 implants. The sample size will be increased by 30% to eight implants per group (16 implants in total). Every patient will receive two implants, one of each group, for a total of eight patients to compensate for dropouts.[16] All patients were male between the ages of 45 and 60 years.

Inclusion and exclusion criteria

To minimize the possible risks of this study, which may include swelling, postoperative pain, and ulcers after prosthesis insertion, patient selection was based on the following inclusion and exclusion criteria.

Inclusion criteria

Patients with a Kennedy class I partially edentulous mandible indicated for rehabilitation with implant prostheses, any extractions, or surgeries performed at least 6 months earlier were included in the study. Bone density was evaluated using cone-beam computed tomography (CBCT), and only D3 bone patients were recruited for the study for standardization purposes.

Exclusion criteria

Patients suffering from systemic diseases affecting bone quality or resorption, dysfunction in the temporomandibular joint, extreme attrition, or parafunctional uncontrolled habits, patients undergoing chemotherapy or radiotherapy, heavy smokers, and vulnerable groups such as psychologically disturbed patients were excluded from the study.[17,18]

Patients' privacy was adequately protected, and interviews took place in private spaces. In addition, patients who decided to withdraw from the study were still able to receive the standard treatment at the University Hospital.

All the selected patients had a Kennedy class I configuration [Figure 1] and have been partially edentulous for 1 to 3 years. All patients received an implant-retained removable partial denture, which was made using the same techniques of construction.

Patient grouping

All patients received two mandibular implants, one on each side. Grouping was done as follows: following a split-mouth study technique. Group I (PRF) consisted of all implants on the right sides of the patients, and these received PRF alone at the site of the osteotomy. Group II (SIM/PRF) consisted of all implants on the left sides of the patients, and these received PRF loaded with SIM at the site of the osteotomy. Bone changes were measured using CBCT.

Prosthetic procedures

Partial dentures of Kennedy class I configuration were constructed for all patients. Maxillary and mandibular preliminary impressions were recorded using alginate (Alginmax, Major Prodotti Dentari SPA., Moncalieri, Italy) in stock trays and were followed by final impressions recorded using medium consistency rubber base (Swiss TEC, Coltene, Whaledent, Altstatten, Switzerland) in custom trays. Bite blocks were constructed on the master casts and used to register jaw relation. Master casts were then mounted on a semi-adjustable articulator, and the artificial teeth were set. Elimination of occlusal contacts during lateral excursions was established to protect the implants. Try-in of the waxed-up denture was carried out in the patients' mouths, then flasking and processing into heat-cured acrylic resin (Lucitone 199, Dentsply, York, PA, USA). Laboratory remounting was performed prior to finishing the denture, and necessary occlusal adjustments were made.

Surgical procedures

Strict infection control measures were taken during all procedures to minimize the risk of infection.

One-stage implant surgery with immediate loading of the partial denture on the day of insertion was performed for each patient, where two implants were inserted for every patient (Vitronex, Elite, Italy), one on each side of the arch [Figure 2].

On the right side, PRF was placed into the osteotomy during implant insertion. On the left side, PRF loaded with SIM (Sigma, ST. Louis, MO, USA) was added [Figure 3].

Five milliliters of blood was withdrawn from the patient and subjected to centrifuge at a speed of 3000 rotations per minute (rpm) for 12 min.[15] It then settled into three layers: a cream-colored cellular plasma, a red bottom part

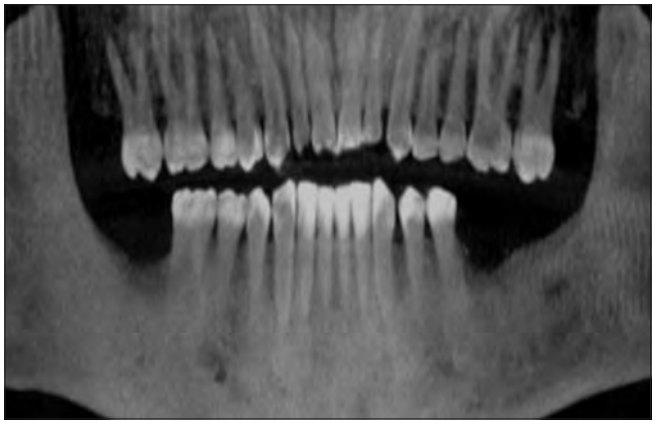

Figure 1: Kennedy class I

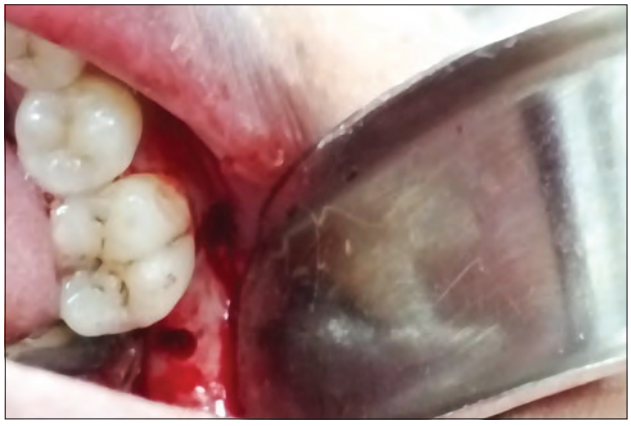

Figure 2: Two-stage implant surgery; site of osteotomy

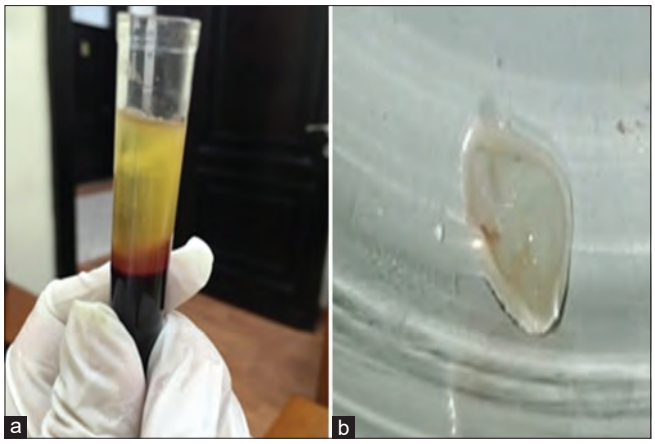

Figure 3: Platelet-rich fibrin separation, (a) the three layers after centrifuge; upper straw-colored cellular plasma, red bottom layer containing red blood cells, and the intermediate layer containing the fibrin clot, (b) PRF clot after separation

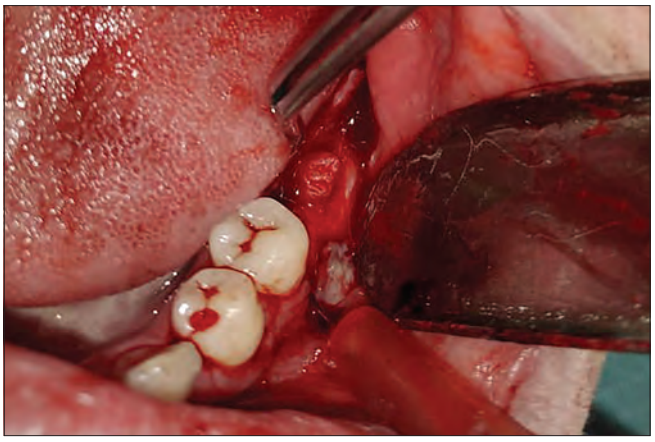

Figure 4: Platelet-rich fibrin loaded with simvastatin added into the osteotomy

containing red blood cells, and the intermediate layer which contained the fibrin clot [Figure 3a]. After removing the upper straw-colored layer, the intermediate fraction was collected with sterile forceps and placed in a sterile Petri dish [Figure 3b].

On the left side, PRF + 1.2-mg SIM powder was mixed manually and added into the osteotomy during implant insertion [Figures 3 and 4].[14]

All implants on the right side of all patients were classified as the PRF group, and all implants on the left side of all patients were classified as the SIM/PRF group.

A ball attachment (Vitronex, Elite, Italy) was then screwed onto each implant, with the housing of the attachment embedded into the denture's fitting surface through a chairside direct pickup technique. All undercuts on the ball attachment were blocked using temporary filling material before direct pickup. Partial denture delivery was carried out on the day of implant insertion following an immediate loading technique.

The principal investigator and other researchers were responsible for all treatment procedures and follow-up throughout this study. Any adverse events were reported and reviewed by the principal investigator through continuous contact with the patients and setting monthly follow-up visits.

Evaluation of bone changes

Evaluation of bone changes around implant sites for both the groups was carried out using a CBCT. CBCT was carried out at 0, 3, 6, and 12 months after the implant insertion. Measurements were taken at the regions buccal, lingual, mesial, and distal to each implant, and a mean was calculated from these measurements. A vertical line was drawn from the apex of the implant bisecting its center into two halves. Another line was drawn parallel to the centerline, from the labial crest of bone to the apex of the implant, and its distance was measured. Another line was drawn parallel to the centerline from the lingual bone crest to the apex of the implant and its distance was measured. The same procedure was carried out mesial and distal to the implant, and an average of all four readings was taken for each implant, and a mean was calculated from these measurements. This was done to standardize the measurement procedures.

Evaluation of implant stability

Implant stability was evaluated using Osstell device on the day of insertion and 3 months after the surgery.

Statistical analysis

The data are presented as mean ± standard deviation. The results were compared between the groups at different time periods using a two-way analysis of variance, followed by a *post hoc* Bonferroni test. To examine total bone changes and stability comparisons between the two groups at the end of the trial, an unpaired *t*-test was utilized. All tests and figures were done using GraphPad Prism version 7.00 (GraphPad Software, San Diego, CA). Statistical significance was defined as $P < 0.05$.

RESULTS

Bone changes

Crestal bone-level changes were statistically analyzed in both the PRF and SIM/PRF groups at 0, 3 months, 6 months, and 12 months after surgery. For each group, the mean crestal bone-level change was calculated. After 3 months, the crestal bone-level changes observed in the SIM/PRF group were significantly lower

than those observed in the PRF group, with a mean difference of 0.42 (±0.021) versus 0.63 (±0.044), respectively ($P < 0.0001$) [Table 1 and Figure 5].

The crestal bone-level changes from 3 to 6 months were calculated at 6 months postoperatively, and the results showed that the SIM/PRF group had significantly lower bone changes than the PRF group, with a mean shift of 0.31 ± 0.028 versus 0.45 ± 0.046 ($P < 0.0001$) [Table 1 and Figure 5].

Crestal bone-level changes from 6 to 12 months were calculated for both the groups at 12 months postoperatively. Statistical analysis showed that the SIM/PRF group had significantly less bone-level changes than the PRF group, with a mean shift of 0.26 ± 0.034 versus 0.32 ± 0.033, respectively ($P = 0.0065$) [Table 1 and Figure 5].

The total crestal bone-level changes were calculated from insertion day to the end of the study (0–12 months). The mean crystal bone-level changes in the SIM/PRF group was significantly lower than that of the PRF group with a mean shift in 0.975 ± 0.0438 versus 1.356 ± 0.0384, respectively ($P < 0.0001$) [Table 2 and Figure 6], as shown in [Figures 7-10].

Implant stability

Statistical analysis for implant stability was done for the SIM/PRF group versus PRF group at baseline and 3 months postoperatively. The mean of stability measurements at baseline for the PRF group 58.3 (±1.57) was significantly lower than that at 3 months 72.7 (±1.49) and also the mean of the SIM/PRF group at baseline 59 (±2.1) was significantly lower than that at 3 months 72.6 (±2.01). Results showed that there was no significant difference in implant stability between both the groups at baseline and after 3 months of the study [Table 3 and Figure 11].

DISCUSSION

The results of the study were evaluated in the form of changes in the level of crestal bone. These bone changes determine the extent to which bone loss has occurred in the area surrounding the implant. The shift in the level of

Table 1: Comparison of the mean crestal bone-level changes of the simvastatin/platelet-rich fibrin group versus the platelet-rich fibrin group at different time intervals

Group time (months)	Mean (mm±SD)		MD	SED	*t*	*P*
	PRF (*n*=8)	PRF/SIM (*n*=8)				
0-3	0.63±0.044	0.42±0.021	0.213	0.0158	13.46	<0.0001*
3-6	0.45±0.046	0.31±0.028	0.1400	0.0158	8.846	<0.0001*
6-12	0.32±0.033	0.26±0.034	0.0580	0.0158	3.665	0.0017*

*Significant at $P<0.05$. MD: Mean difference, SED: Standard error of difference, PRF: Platelet-rich fibrin, SIM: Simvastatin, SD: Standard deviation

Table 2: Comparison of the total crestal bone-level changes of the simvastatin/platelet-rich fibrin group versus platelet-rich fibrin group at the end of the study

Group time	Mean (mm±SD)		*P*
	PRF (*n*=8)	PRF/SIM (*n*=8)	
Total bone changes (mm)	1.36±0.0384	0.9750±0.0438	<0.0001*

*Significant at $P<0.05$. PRF: Platelet-rich fibrin, SIM: Simvastatin, SD: Standard deviation

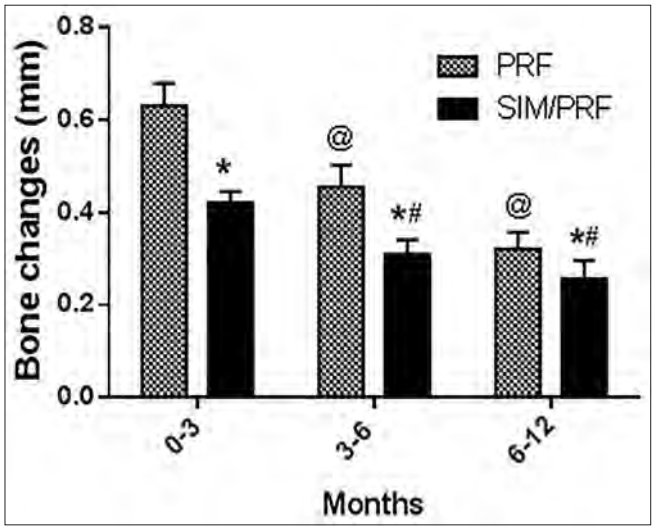

Figure 5: Crestal bone changes (mm) in the platelet-rich fibrin and simvastatin/platelet-rich fibrin groups at 0–3, 3–6, and 6–12 months postoperatively. *$P < 0.05$ versus platelet-rich fibrin group (same interval). #$P < 0.05$ versus respective group (different intervals). $P < 0.05$ versus respective group (different intervals) using two-way ANOVA and Bonferroni test *post hoc* analysis. Results are shown as mean ± standard deviation ($n = 10$ implants per group)

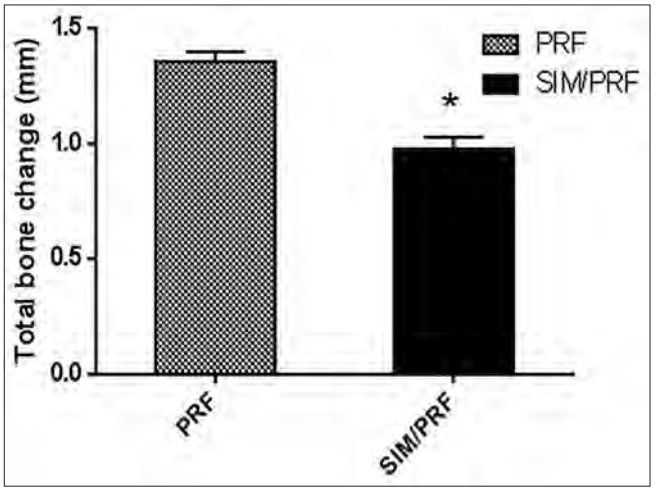

Figure 6: Total crestal bone changes (mm) in the platelet-rich fibrin and simvastatin/platelet-rich fibrin groups at 0–12 months postoperatively. $P < 0.05$ versus platelet-rich fibrin group at the same time interval using unpaired *t*-test. The results are presented as mean ± standard deviation ($n = 10$ implants per group)

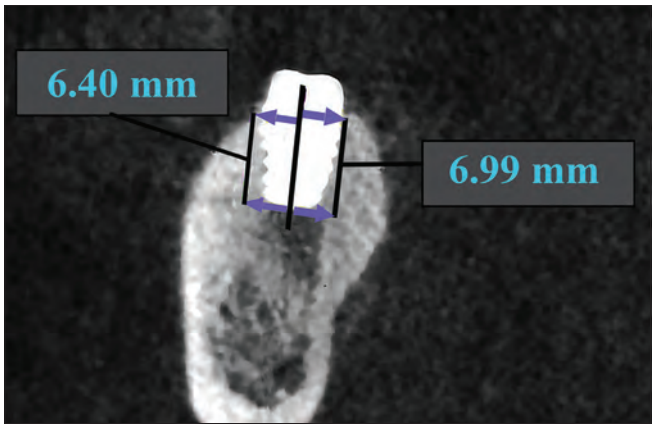

Figure 7: Representative cross-sectional radiographs of Group I showing bone changes at baseline for platelet-rich fibrin group

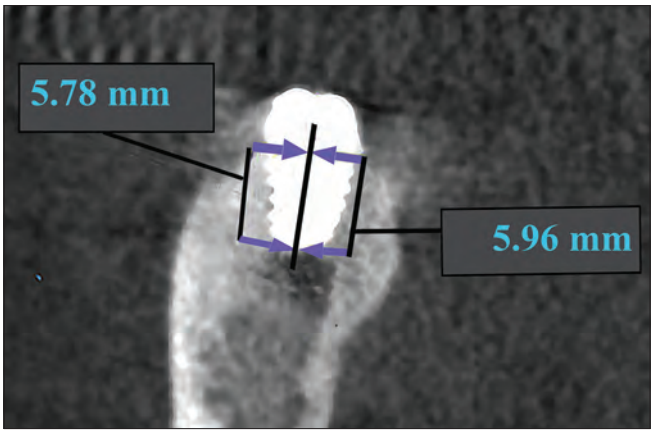

Figure 8: Representative cross-sectional radiographs of Group I showing bone changes at 12 months for platelet-rich fibrin group

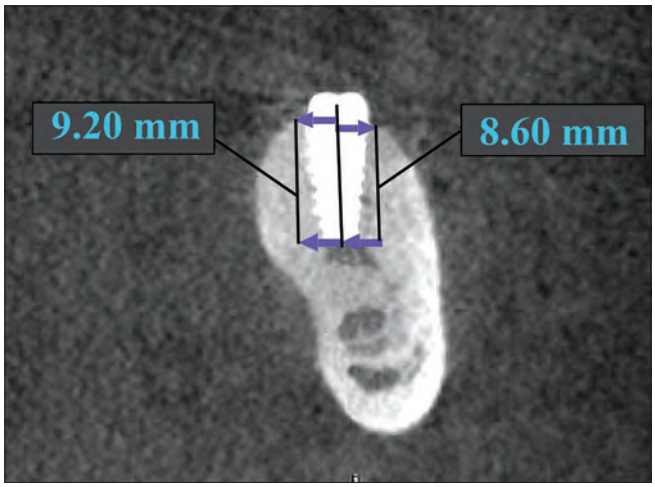

Figure 9: Representative cross-sectional radiographs of Group II showing bone changes at baseline for platelet-rich fibrin + simvastatin group

Table 3: Mean values of implant stability of the simvastatin/platelet-rich fibrin group versus platelet-rich fibrin group at baseline and 3 months postoperatively

Group time	Mean (mm±SD)		*P*
	PRF (*n*=8)	PRF/SIM (*n*=8)	
Base line	58.3±1.57	59±2.1	0.4105
3 months	72.7±1.49	72.6±2.01	0.9010

*Significant at $P<0.05$. PRF: Platelet-rich fibrin, SIM: Simvastatin, SD: Standard deviation

bone was noted and examined using a CBCT scan. Since the study contributes toward the prolonged prognosis of the implant sites, the examination was performed at intervals of 3 months, 6 months, and then 12 months.

In the present study, the results of both the groups of implants were compared. The first group of implants (Group PRF) was treated only with PRF, which was previously incorporated as a bioscaffold in previous clinical trials.[11-13] The second group of implants (Group SIM/PRF) was treated with PRF loaded with SIM. SIM is a

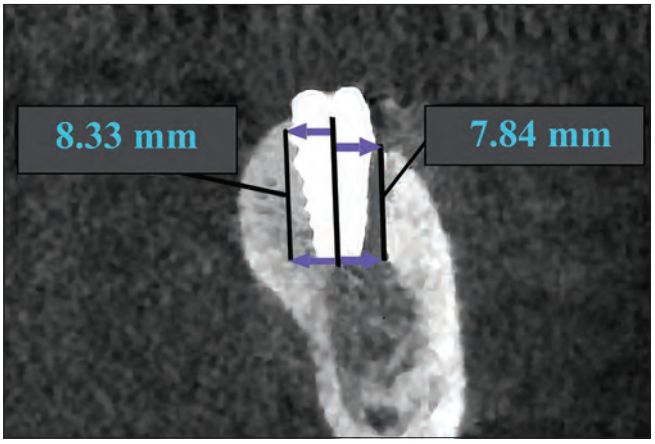

Figure 10: Representative cross-sectional radiographs of Group II showing bone changes at 12 months for platelet-rich fibrin + simvastatin group

pharmacological drug that acts to decrease cholesterol blood levels and discovered to possess an osteopromotive effect via increasing osteoblastic activity, inhibition of osteoclast activity, and promoting neovascularization, hence speeding up tissue regeneration.

The 1.2-mg SIM dose was chosen according to results from earlier *in vivo* animal research,[14,19] and a clinical trial,[20] which revealed that SIM had a dose-related effect on the regeneration of bone upon local application, and 1.2-mg SIM had a beneficial effect on the repair of bone defects.

PRF was used in this study, alone and in combination with SIM, as a biological scaffold which is completely biodegradable within 2 weeks and can gradually release SIM and the incorporated growth factors locally around the dental implants.[21] PRF previously has been proven to have an osteopromotive activity, along with the advantage of its simple preparation procedures and low cost compared to alternative methods.[22]

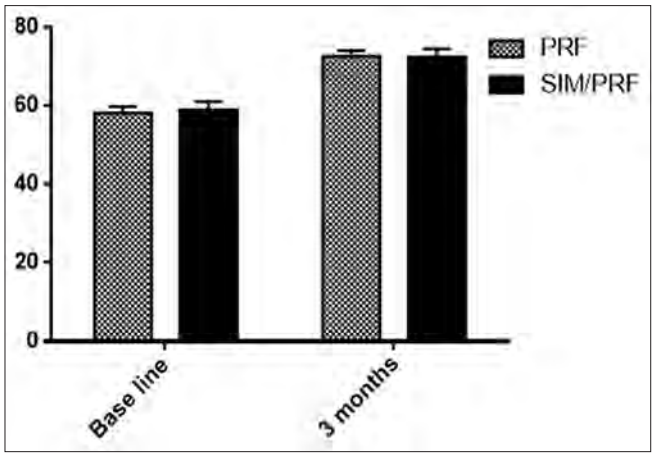

Figure 11: Bar chart showing stability values in the platelet-rich fibrin and simvastatin/platelet-rich fibrin groups at baseline and 3 months postoperatively. Comparison between groups was done at the same time interval using unpaired *t*-test. Results are shown as mean ± standard deviation, *n* = 10 implants per group

Previous studies reported that the local application of SIM in mandibular defects has proven to be more efficient than the systemic use of the drug. Rutledge *et al*. in 2011 reported a 240% improvement in bone density after applying SIM locally in mandibular defects.[23] In contrast, Kiliç *et al*. 2008 studied the effect of SIM on closed defects like distraction osteogenesis and reported that the surface area of the studied bone was higher in the local administration group of statins.[24] In the current study, local administration of SIM was used as it has the advantage of avoiding the systemic side effects of the drug and bypassing its hepatic degradation.[25]

In the current study, radiographic investigations carried out after 3 months revealed that the crestal bone-level changes were significantly lower in the SIM/PRF group compared to results obtained from the PRF group ($P < 0.0001$). These results support that bone loss was lower in the SIM/PRF group and can be interpreted as a positive outcome observed in the use of SIM with PRF rather than PRF alone.

Radiographic results in the 6th and 12th months postoperatively showed similar results. The crestal bone-level changes were lower for the SIM/PRF group indicating less bone loss. Hence, it can be interpreted that SIM/PRF treatment is likely to decrease peri-implant bone resorption with better long-term prognosis after dental implant surgery.

Within our scope of research, no other studies have researched the effect of SIM on bone remodeling around dental implants clinically in patients, although several *in vitro* and *in vivo* animal studies have formerly concluded that it promotes osteoblast differentiation and controls osteoclastogenesis through the OPG/RANKL/RANK signaling pathway, thereby causing decrease in bone resorption.[6]

The osteopromotive effect of SIM was studied by previous *in vitro* studies. Chen *et al*. 2010 explained the details of osteoblast differentiation initiated by SIM and reported that SIM promoted osteoblast viability and differentiation via membrane-bound Ras/Smad/Erk/BMP-2 pathway.[26] Pullisaar *et al*. 2014 reported an increasing release of osteoprotegerin, a strong anti-osteoclastogenic protein, from MSCs seeded on TiO2 scaffolds after SIM release from the scaffolds' alginate coating.[27] Furthermore, Zhang *et al*. (2018) investigated the effects of SIM on the differentiation of rat MSCs into osteogenic cells and suggested that SIM can promote MSC differentiation into osteoblast-like cells, with the mechanism being relevant to the Wnt/β-catenin pathway and increasing Runt-related transcription factor 2, which is important for osteoblastic differentiation.[28]

Previous studies on experimental animals reported the effect of SIM in limiting bone resorption. Xu *et al*. 2014 investigated the systemic and local effect of SIM on preventing bone loss in rats suffering from periodontitis and osteoporosis.[29] The results of their study proved that the use of SIM caused an increase in alveolar crest height and inhibited alveolar bone resorption using histomorphometric and radiographic analysis. Moreover, Vaziri *et al*. 2007 also provided results for lower periodontal bone loss after SIM administration subperiosteally in the mandible of the ovariectomized (OVX) rats using histological analysis.[30]

A recent study by Gao *et al*. 2021 examined the therapeutic efficiency and possible mechanisms of action of systemic SIM administration in alveolar bone loss caused by hypercholesterolemia. The study results showed that SIM intervention significantly downregulated NF-κB expression, decreased RANKL mRNA transcription, and significantly mitigated the hypercholesterolemia-induced alveolar bone loss.[5]

In line with the findings of our study, the effect of SIM on bone around dental implants was previously investigated by some studies using experimental animals. Du *et al*. 2009 studied the systemic effect of SIM around titanium implants in OVX rats' tibiae and reported that SIM significantly improved the osseointegration of pure titanium implants in rats with osteoporosis.[31] Mansour *et al*. 2014 studied the regenerative potential of SIM when used as a graft material around immediate dental implants in dogs using histomorphometric analysis and reported

that SIM enhanced peri-implant osteogenesis resulting in their osseointegration.[32] Xu *et al*. 2018 used a rat model of oral implant osseointegration and concluded that the *in situ* application of SIM showed greater novel bone formation at the implant–bone interface in comparison to that of its systemic use using histomorphometrical analysis and micro-CT.[33]

Several clinical studies supported the effect of SIM when used in different oral bone defects. A clinical trial conducted by Gouda *et al*. 2017 showed that SIM enhanced bone formation when used locally with beta-tricalcium phosphate for sinus lifts after 9 months of the surgical procedures.[34] Furthermore, Ranjan *et al*. 2017 assessed the effect of SIM on periodontal intrabony defects using clinical and radiographic evaluation. Ranjan *et al*. 2017 noted that SIM increased the amount and percentage of bone formation compared to the patients in the control group.[20]

Other clinical trials demonstrated the effect of SIM on bone regeneration using SIM with other materials; Kinra *et al*. 2010 reported a significant increase in bone fill when SIM was used in combination with demineralized freeze-dried bone allograft.[35] In addition, Chauhan *et al*. 2015 stated that SIM significantly increased bone density in third molar extraction sockets when used in combination with gel foam.[36]

Randomized controlled studies investigating the impact of PRF around dental implants were performed. Boora *et al*. 2015 investigated the effect of PRF on peri-implant bone response after single-stage implant insertion. Radiographic investigations done by this study showed lesser changes observed in the PRF group in the mean marginal bone changes.[15] Öncü *et al*. 2015 compared the stability of single-stage dental implants placed with or without PRF, and claimed that PRF application improved implant stability in the primary healing stages.[37]

A split-mouth randomized clinical trial by Tabrizi *et al*. 2017 evaluated the effects of PRF placed with maxillary posterior implants. Their results showed that PRF improved the postinsertion stability of dental implants during healing.[38]

The results of the current study showed that PRF alone and PRF loaded with SIM significantly increased the implant stability after 3 months compared to the same respective group at baseline, however, there was no significant difference between both the groups after 3 months. Several clinical trials investigated the effect of PRF on implant stability. Torkzaban *et al*. 2018 evaluated the effect of PRF on implant stability which was measured at baseline, 1st week, and at 1 month after implantation.[39] The study showed a significant increase in implant stability in the PRF compared to the control group. Another clinical trial by Brouwers *et al*. 2019 analyzed implant stability using autologous PRF and reported increased implant stability 10 days after implantation.[40] In the current study, despite that SIM/PRF decreased peri-implant bone resorption compared to PRF alone, it showed no significant difference between the groups in implant stability. This may be attributed to the measurement of implant stability after 3 months and that early differences were not detected in both the groups. Earlier measurement of implant stability is recommended in future studies using SIM to detect early changes of implant stability between the groups.

In the light of the results of the present study, PRF loaded with SIM, a pharmacological drug, has proven to decrease bone resorption by decreasing peri-implant crestal bone changes through the whole study period. Using PRF alone or in combination with SIM improved implant stability, however, no significant improvement in the implant stability with the combination was observed.

CONCLUSION

The results of the study revealed that the combination of SIM and PRF showed promising results in limiting peri-implant bone resorption, indicating a promising clinical local application of this combination to enhance bone healing, particularly in patients with a guarded prognosis and compromised bone quantity/quality.

Limitations

Some uncertainties do still exist in our study; first, the study has a relatively short-term follow-up (12 months). Further studies should be conducted using long-term follow-up up to 24–36 months. Second, a digital intraoral periapical radiograph should be used instead of CBCT as it could be more precise in detecting minor bone changes. Finally, early measurement of implant stability, within the 1st month of implant insertion, is recommended to detect early differences between the groups, not just primary stability.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Research

Effects of wearing removable dentures and aging on palatal mucosa blood flow by laser doppler

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Abstract

Aim: The purpose of this work is to analyze the effects of removable dental prostheses and aging on blood microcirculation in the palatal mucosa.

Settings and Design: Blood flow was measured in two groups using the Laser Doppler Flowmeter at three specific anatomical sites: Retro incisive papilla, medial raphe, and Schroeder area.

Materials and Methods: Group 1 included young, healthy dentulous individuals (mean age: 23 ± 3 years), and Group 2 contained elderly edentulous individuals (mean age: 62 ± 11.69 years). For Group 1, measurements were taken in a single session; for Group 2, the measurements were taken in two sessions: The first just before the prosthetic load (E1) and again 1 week after new dentures were provider (E2).

Statistical Analysis Used: Statistical analyses were performed using SAS software, Version 9.4 of the SAS System for Windows, Copyright © 2017 SAS Institute Inc. (Cary, NC, USA). A $P < 0.05$ was classified as statistically significant.

Results: Measurements of blood flow of the palatal mucosa showed that the healthy young dentulous participants had significantly lower perfusion unit values than the elderly edentulous participants at all three anatomical sites ($P < 0.05$). For Group 2, the comparisons between the measurements taken before (E1) and after (E2) new dentures were provided showed no significant differences.

Conclusion: Our results indicate that the process of aging significantly modifies the blood flow of the palatal mucosa while wearing removable dental prostheses does not modify the blood flow of the palatal mucosa in a 1week period. These results are not influenced by systemic pathology (e.g., diabetes, cardiovascular diseases) or smoking.

Keywords: Aging, laser Doppler flowmeter, microcirculation, palatal mucosa, removable denture

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INTRODUCTION

The introduction of removable dental prostheses alters the ecosystem of the mouth and can disrupt the various essential functions of the oral cavity. The biomechanics

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of mucosal responses to mechanical loading is partially dependent on mucosal anatomy and three characteristic physiological aspects: Static, dynamic, and volumetric.[1] Covering the palatal mucosa with a denture leads to changes at different levels, including in the epithelium, the connective tissue (lamina propria), the submucosa, and the underlying bone.[2-6] As a highly vascularized tissue, the mucosa contains a considerable amount of interstitial fluid and blood, and its protective function arises from the mechanical cushioning effect.[7]

The behavior of the palatal mucosa when it is subjected to the pressure of a removable prosthesis depends on tissue heterogeneity. A deformed epithelium and deeper connective tissue require clinical supervision. Prolonged exposure to occlusal loading throughout the day can affect these two tissues. Consequently, it is necessary to understand the biomechanics when managing traumatized tissues to effectively manage any problems with the tissues. The pressure induced by dentures provides a pumping effect that pushes the interstitial fluid to unsolicited neighboring tissues.[8,9] The first manifestations of oral mucosa inflammation are vascular changes that essentially consist of capillary dilation and increased blood flow.[10] Specifically, stomatitis is clinically a pathology of tissular modifications under removable dentures. This pathology for among 67% of denture wearers, is characterized by the combination of pressures during different activities (chewing, phonation, swallowing) applied by the denture on the oral mucosa, and the inflammation induced by a mycobacterial biofilm.[11,12] Recently, an *in vivo* model was developed to analyze the biomechanical behavior of the keratinized oral mucosa and to obtain information about its mechanical properties in relation to the recovery of palatal mucosa after partially or completely removable dental prostheses had been introduced.[13]

To date, little research has examined the effects of both aging and a removable dental prosthesis on the microcirculation of the vascular palatal mucosa. Despite progress in oral rehabilitation, the prosthetic denture remains one of the most important and common challenges facing prosthodontists today. The edentulous population has expanded as life expectancy has increased, resulting in a significantly increased need for prosthodontic treatment.[14,15] Indeed, the use of removable dental prostheses is estimated to affect 230 million people worldwide by 2030.[16,17] The therapeutic denture is primarily used (among other groups) in the elderly with general or mild systemic pathologies, as well as people with addictions.[18-20]

Our objective is to measure the influence of aging and the wearing of dental prostheses on the variations in the vascular flow of the lamina propria of the palatal mucosa. The ultimate objective is to characterize the physiological changes in microcirculation, prevent the development of stomatitis, and develop a better understanding of the pathophysiology of oral tissues diseases. To achieve this goal, we measured the blood flow of the palatal mucosa covered by a denture in a sample of both current and new participants in this study with removable prostheses, as well as in a sample of young tooth participants. Measurements were taken using a Laser Doppler Flowmeter (LDF) because as a method for investigating microcirculation it is simple to implement, noninvasive, reliable, and reproducible.[21,22]

MATERIAL AND METHODS

Subjects

The study was performed with two groups. 54 young adults (between 20–26-year-old; 32 men, 22 women) at the University of Nantes, without any clinical inflammation of the palatal mucosa (baseline) [Table 1]. This research complies with the respect of the convention established in 2002 in Helsinki. Group 2 included 51 edentulous subjects (33 men, 18 women; mean age 62 years) who visited the department of prosthetics dentistry at the dental college of Nantes. The participants were selected from among the dental patients who came to obtain removable

Table 1: Healthy young, toothed patient (group 1)[23] and subject' (group 2) demographic data including age, gender, edentulous area, pathology, denture status and lifestyle habits

Parameters	Group 1	Group 2
Age		
n	54	51
Minimum–maximum	20.00-26.00	33.00-91.00
Mean±SD	23±1.34	61.86±11.69
Median	24	60.00
Q1–Q3	22.00-24.00	55.00-68.00
Edentulism, *n* (%)		
Partial	No	33 (64.71)
Total	No	18 (35.29)
Pathology, *n* (%)		
No	54 (100)	37 (72.55)
Diabete	No	7 (13.73)
Artery hypertension	No	7 (13.73)
Prosthesis, *n* (%)		
Had old dentures	No	26 (50.98)
Did not wear dentures	No	25 (49.02)
Gender, *n* (%)		
Women	22 (40.74)	18 (35.29)
Men	32 (59.25)	33 (64.71)
Tobacco, *n* (%)		
Yes	12 (22.22)	22 (43.14)
No	40 (77.77)	29 (56.86)

SD: Standard deviation

prosthetic rehabilitations (partial or complete maxillary denture) without regard to gender, ethnicity, and social class after obtaining consent and applying the selection criteria. The study was approved by the Ethical Committee (Ref: RC15_0344) issued by Groupe Nantais d'Ethique dans le Domaine de la Santé (GNEDS) of Nantes hospital.

The recorded clinical features of the palate included angle classification, shape, colour, adhesion, and surface texture of the palate. Additional criteria included the absence of trauma or injury to the oral cavity and the absence of clinical inflammation in the palatal mucosa. The general condition of the participants is assessed following a systematic and detailed check.

Participants were selected with consideration for certain parameters, and they were divided into different subgroups according to the following criteria: Denture history (presence or absence of previous sets of dentures), specific comorbidities human disease diabetes, and hypertension (if well-controlled), and lifestyle habits (tobacco smoking) [Table 1].

Measurements of blood flow

Blood flow was measured with an LDF Perfusion Monitor (PeriFlux System 5000; Perimed, Stockholm, Sweden) using the same criteria as in the previous work for the participants in Group 1.[23] In Group 2, recordings were obtained for each participant on the palatal mucosa at three different anatomical sites: The retro-incisive papilla (RPI), the medial raphe (MR), and the Schroeder area (SA). Two sessions were performed on each participant: The first before renewing a denture or making a new one (E1), and the second after delivering the new denture (after 1 week, E2) [Table 2]. The use of LDF to evaluate oral soft tissue blood flow must meet many obligations,[22] including gutter fixity at the three sites (SA, RPI, MR) to maintain more precise contact between the probe and the mucosa without any movement.[23]

Statistical analysis

Descriptive statistical analysis was used to determine the central tendency parameters (mean, median, standard deviation [SD], etc.) of the quantitative variables. Wilcoxon tests were used to compare the measurements of Group 2 in E1 and the measurements of Group 1. The same measurements from Group 1 participants were also compared to Group 2 participants at E2 using Wilcoxon, Chi-square, and Fisher tests.

The differences between E1 and E2 measures were compared with Wilcoxon Signed Rank tests in all Group 2 participants and in each of the different subgroups (old or new denture wearers, complete denture cases). Statistical analyses were performed using SAS software, Version 9.4 of the SAS System for Windows, Copyright © 2017 SAS Institute Inc. (Cary, NC, USA). A $P < 0.05$ was classified as statistically significant.

RESULTS

Among the 51 participants in Group 2, 39 participants (76.47%) experienced both planned measures (E1 and E2), and 12 (23.53%) participants experienced only one measure. This incomplete assessment was due to participants failing to come to appointments. The first analysis compared blood flow measurements (E1) between the 51 edentulous participants (26 currently with dentures and 25 currently without dentures) (mean age: 61.86 years) (SD: 11.69) and 54 young dentulous participants (mean age: 20–26 years) (SD: 1.34) We followed the same protocol and team measurements of this group as those published in a pilot study in 2016.[23]

The results show a significant difference between the two groups at the three measured areas. Young dentulous participants had PU values showing much less blood flow compared to edentulous participants ($P < 0.05$) [Figure 1]. This finding remains significant when the analysis includes the effects of gender and smoking [Table 3]. When participants with medical comorbidities in the edentulous Group 2 were removed, Group 1 participants still had much less blood flow than those Group 2 participants without medical comorbidities (37) ($P < 0.05$) [Figure 2].

To eliminate the bias of participants already wearing a denture, a second comparison retained only edentulous participants (aging 62 years old) who had never worn removable dental prostheses. For this second investigation,

Table 2: Distribution of participants in group 2 according to their previous denture history and the number of measurements taken

	Denture history	Different measures: Before (E1) and after treatment (E2)		Missing participants (12)
		E1 (51)	E2 (39)	
Group 2 (51 participants)	Participants with old removable dental prosthesis	25 participants	20 participants	5 participants
	Participants did not wear removable dental prostheses	26 participants	19 participants	7 participants

Table 3: Comparisons of blood flow in E1, considering the gender (Men/Women) and smoking (Yes/No) parameters between 51 young participants (23 years old on average) and 54 elderly participants group (62 years on average)

N (105)	Variable	Mean	Standard deviation	IC 95%	*P*-value
RPI	Control group Group carrying prosthesis	-133.95	22.98	[-179.53; -88.37]	<0.05
MR	Control group Group carrying prosthesis	-197.04	28.84	[-254.25; -139.82]	<0.05
SA	Control group Group carrying prosthesis	-119.32	29.47	[-177.79; -60.86]	0.05

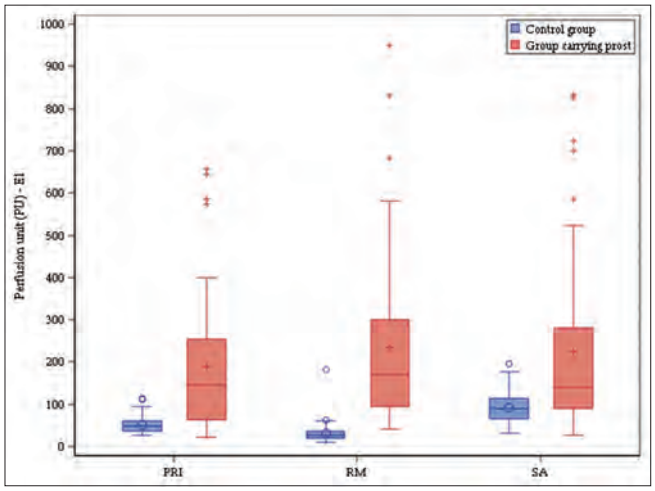

Figure 1: Comparisons of E1 measurements between healthy young tooth participants (control group)[23] and participants requiring a removable prosthesis (group carrying prosthesis) Measured values in the three zones. *Statistically significant difference between the different anatomical areas ($P < 0.05$). Retro-incisive papilla, Medial raphe and Schroeder area

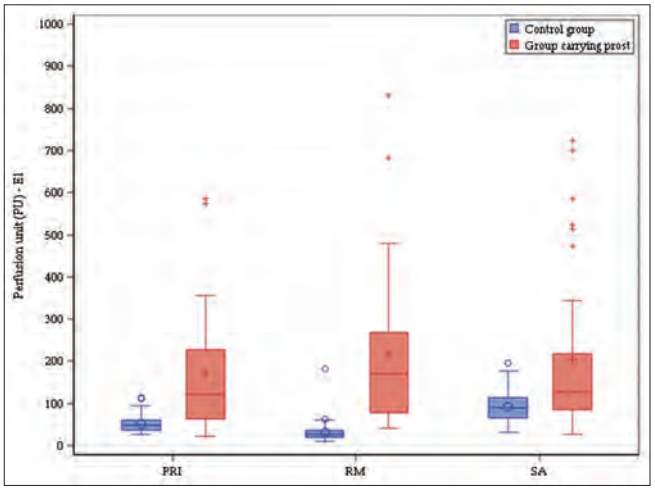

Figure 2: Comparisons of E1 measurements between healthy young tooth participants (control group)[23] and participants requiring a removable prosthesis patient without general pathologies (group carrying prosthesis) Measured values in the three zones. *statistically significant difference between the different anatomical areas ($P < 0.05$). Retro-incisive papilla, Medial raphe and Schroeder area

the E1 blood flow measurements of 25 edentulous participants were compared with Group 1 participants (51 young participants, mean 23 year old). The results of this comparison show a significant difference, with a clear increase in blood flow in the three palatal areas in the edentulous participants ($P < 0.05$) [Figure 3].

We then studied the effect of wearing a removable prosthesis on the group of participants with an average age of 61 years. For this purpose, in another appraisal, the blood flow at E1 of the 25 participants (62-years old) who had never worn removable dental prostheses was compared with the blood flow at E1 of the 26 participants (62 years old) who had worn removable dental prostheses for more than 2 years. This comparison showed no significant difference at the three sites measured [Figure 4]. This result persists when the analysis includes the effect of partial and total edentulism; that is, when the partial and total edentulism participants are separated, the result remains unchanged [Table 4a and b].

After removing the measurements of the 12 participants in Group 2 who were not able to complete both exams [Table 2], the E1 and E2 measurements of the remaining 39 participants who completed both measurements were compared at the three zones (SA, RPI, and MR) of the palatal mucosa. In this analysis, no significant difference was found between the two sets of measurements at the three sites [Table 5].

DISCUSSION

The need for prosthodontic treatment continues to increase as the population ages[24-26] despite the associated clinical complications of the treatment. Within the highly vascular, denture-supporting tissue interface, functional pressure, namely the interstitial fluid pressure, has been identified as one of the most important etiological factors causing these complications.[27-31]

No Among these complications, inflammation of the mucous membrane under the prosthesis is an essential parameter conditioning the development of vascular pathologies in denture prosthesis wearers. This very widespread pathology affects up to three quarters of users of removable prostheses.[11,32] The study of

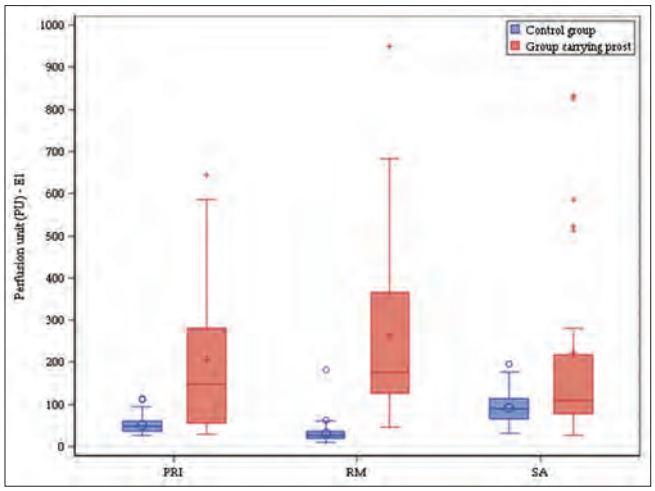

Figure 3: Comparisons of E1 measurements between healthy young tooth participants (control group)[23] and who have never benefited from wearing a removable prosthesis (group carrying prosthesis) Measured values in the three zones. *Statistically significant difference between the different anatomical areas ($P < 0.05$). Retro-incisive papilla, Medial raphe and Schroeder area

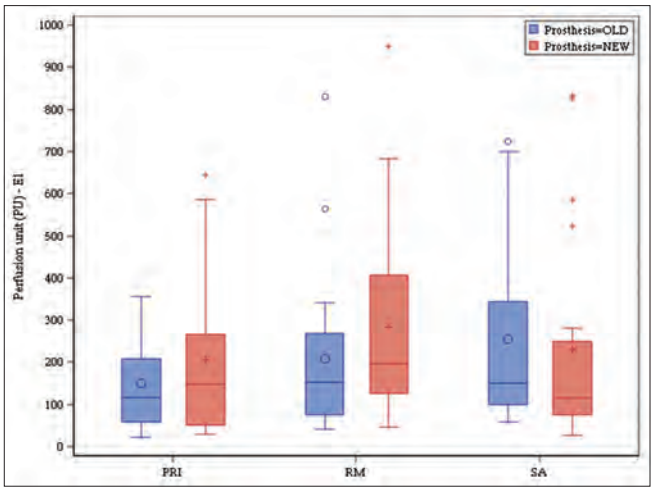

Figure 4: Comparisons of E1 measurements between participants who have never benefited from wearing a removable prosthesis (Prosthesis NEW) and participants with old removable prosthesis (Prosthesis OLD) Measured values in the three zones. No statistically significant difference between the different anatomical areas. Retro-incisive papilla, Medial raphe and Schroeder area

Table 4a: Comparisons of E1 measurements between partial and total edentulous in participants requiring removable dental prostheses

	Partial edentulous (*n*=15)	Total edentulous (*n*=10)	*P*
E1_RPI			
Mean±SD	201.77±196.62	214.44±166.16	>0.05
Median	147.80	155.04	
E1_MR			
Mean±SD	286.79±245.56	235.49±195.64	>0.05
Median	207.74	141.38	
E1_SA			
Mean±SD	245.87±265.36	185.72±198.79	>0.05
Median	125.43	83.37	

Measured values in the three zones, No significant difference.
RPI: retroincisive papilla, MR: median raphe, SA: Schroeder area

Table 4b: Comparisons of E1 measurements between partial and total edentulous in participants carrying removable dental prostheses

	Partial edentulous (*n*=18)	Total edentulous (*n*=8)	*P*
E1_RPI			
Mean±SD	163.22±154.95	190.40±115.70	>0.05
Median	113.13	179.73	
E1_MR			
Mean±SD	156.72±114.63	307.02±258.49	>0.05
Median	125.35	214.41	
E1_SA			
Mean±SD	190.91±166.91	314.80±195.88	>0.05
Median	128.92	293.69	

Values measured in the three areas (RPI: Retro incisive papilla, MR: Median raphe, SA: Schroeder area), no statistically significant difference

Table 5: Comparisons of E2-E1 measurements between 39 participants were based on the two predicted measures (E1 and E2), of which 20 had never had a removable dental prosthesis and 19 had a removable dental prosthesis

Parameters	Old removable dental prostheses wearers (renewal) (*n*=19)	New removable dental prostheses wearers (*n*=20)	*P*
RPI: E2 - E1			
n	19	20	>0.05
Mean±SD	7.90±145.96	−10.11±224.90	
Median	6.18	6.50	
MR: E2 - E1			
n	19	20	>0.05
Mean±SD	86.42±348.64	−64.24±256.12	
Median	14.53	17.16	
SA: E2 - E1			
n	19	20	>0.05
Mean±SD	−12.95±255.24	−78.21±261.37	
Median	−3.54	2.26	

Values measured in the three areas (RPI: Retro incisive papilla, MR: Median raphe, SA: Schroeder area), no statistically significant difference

changes in vascularization is a means of understanding the first changes in the microcirculation of the tissues under the prosthetic base. This research evaluated the changes in blood flow before, during, and after making a removable resin dental prosthesis for 51 participants aged 62 ± 11 years, representative of the mean age of denture wearers in Europe.[24]

This original research intentionally targeted participants without any palatal mucosa inflammation, which was clinically detectable as the participants are former or future denture wearers.

The 51 denture wearers in the study had clinically healthy oral mucosa, characterized by a smooth palatal surface, without signs of inflammation.[10] In contrast, inflamed tissues under a removable prosthesis are clinically described by more or less extensive redness and edema.

These signs are specific to DRS and may be accompanied by taste disturbances and/or a sensation of intraoral warming.[11]

This research measured the blood flow at three sites (SA, RPI, RM) of the palatal mucosa in elderly participants (never fitted (25 participants) to date or needing to renew their removable dentures (26 participants) before renewing or providing a new denture; these participants all presented with high levels of blood flow, both those with removable dental prostheses and those without them.

First, results were compared with measurements taken under the same conditions (team research, operators, site [SA, RPI, MR), LDF] with a group of healthy young tooth participants).[23] These results show a significantly higher blood flow for the entire group of elderly participants ($P < 0,05$) [Figure 1]. This information is consistent with previous research by Kocabalkan and Turgut,[33] who also found high blood flow values when they performed the same measurements under the same conditions on the mandibular mucosa, with a sample of participants of average age 62 years.[33] Heckmann *et al.* and Svalestad *et al.* also reported high blood flow in the palatal mucosa under the same conditions.[34,35]

Although it is generally accepted that blood pressure increases with age[36] and human blood microcirculation increases naturally as individuals age (beyond 60 years).,[37] the question remains: Can a removable dental prosthesis constitute a mechanical stress that accelerates the increase or decrease of blood flow in elderly participants? Our results show that differences in blood flow are not significant in participants who had worn their dentures for more than 2 years compared to those who had never before worn dentures, regardless of which palatal areas were tested.

From a clinical point of view, it can be deduced that in the absence of clinically detectable DRS symptoms, wearing a removable dental prosthesis has little influence on the blood microcirculation of the palatal mucosa in elderly participants. From a histological point of view, the thickness of the entire mucosa varies from 0.30 mm to more than 3 mm across the three sites tested (SA, RPI, and MR).[38,39] Still, between the three sites, we found no significant difference in the level of blood flow. One probable explanation is that the mucosa contains highly vascularized tissue, forming a considerable amount of interstitial fluid, which in turn provides a mechanical cushioning effect that serves a protective function.[1] When the masticatory load increases, the interstitial fluid builds up,[26-28] but more than the vascular pressure, the blood flow will be reduced and may temporarily cease, potentially leading to localized ischemia[33,40-42]

Finally, concerning the observed differences in blood flow that was observed between different age groups, another explanation is possible. In young subjects, blood flow can be almost fully restored following a short stress, and the recovery may even exceed the initial blood flow by as much as 10%.[40] In contrast, in aging denture wearers, a more permanent decrease in blood flow may result from wearing dentures for over 6 months.[33] Our results show no significant difference concerning blood flow between the group of 19 formerly-fitted participants (>2 years) and the group of 20 newly-fitted participants when both groups present with clinically-healthy palatal mucosa.

It is at this level that the numbers of complete unimaxillary and partial maxillary prostheses in the formerly fitted participants (>2 years) should be noted. The absence of significant differences between these two groups should be emphasized. This lack of differences suggests that the presence of natural teeth in the maxilla of the partially fitted participants did not alter the results.

Similarly, the participants with a complete unimaxillary prosthesis did not show any modification of their blood microcirculation despite a complete covering of the palatal mucosa and the absence of natural teeth likely to relieve the occlusal pressures on the removable prosthesis. Finally, it is important to note that these patients were in general good health, which is important because tooth loss can influence the general condition of the patients.[43]

It can thus be deduced from this study that wearing a removable dental prosthesis has little influence on the blood microcirculation of the palatal mucosa in healthy, elderly participants; instead, aging seems to have a greater effect.

CONCLUSION

Our study shows that in elderly participants with healthy mucosa under their dentures, mucosal blood flow (MBF) is increased, a finding commonly associated with aging. Despite the prevalence of diabetes, cardiovascular disease, and smoking among the participants, the MBF did not differ significantly across lifestyle subgroups. We hypothesize that aging is the most important factor affecting blood circulation, not the recovery of palatal mucosa with removable dentures. The accumulated evidence suggests a physiological relationship between age and increased blood flow of the palatal mucosa. If we take into consideration the advanced nature of LDF

measures, they may be sufficient for understanding the link between increased blow flow and initial inflammation under dentures. The use of LDF may prove an interesting method for monitoring the mucosa under the removable dental prosthesis. In these clinical conditions, LDF can become a tool to supervise the health of the oral mucosa and prevent inflammation under dentures.

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Conflicts of interest

There are no conflicts of interest.

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Research

Effect of advanced platelet-rich fibrin and concentrated growth factor on tissues around implants in maxillary anterior region

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Abstract

Aim: To assess the effect of advanced platelet-rich fibrin (APRF) and concentrated growth factor (CGF) on tissues around implants in the maxillary anterior region.

Settings and Design: This was a prospective clinical study.

Materials and Methods: Thirty subjects were divided into three groups with 10 dental implants in each group, i.e., Group 1: Control group, Group 2: Endosseous implant placement with APRF, and Group 3: Endosseous implant placement with CGF. The subjects were assessed at baseline (at the time of prosthesis placement), 2 weeks, 2 months, 6 months, and 1 year for modified sulcular bleeding index, periimplant probing depth, mucosal suppuration, bleeding on probing, crestal bone level as well as implant stability.

Statistical Analysis Used: Oneway Analysis of variance and Post hoc Bonferroni were the statistical tests used.

Results: The difference in implant stability at 2 months was significantly ($P < 0.05$) more among the control and CGF groups compared to APRF group. However; the crestal bone levels, periimplant probing depth, modified sulcular bleeding index, mucosal suppuration, and bleeding on probing were statistically non-significant ($P > 0.05$).

Conclusion: CGF and APRF accelerated osseointegration. Furthermore, they had a positive effect on stabilization values. However, CGF showed better results and with further clinical trials may show a positive effect on implant healing period.

Keywords: Advanced platelet-rich fibrin, concentrated growth factor, dental implants

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INTRODUCTION

The success as well as stability of dental implants is significantly dependent on osseointegration. However, the timing concerning osseointegration and prosthetic loading has no standardization. This activity ranges between 0

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and 6 months.[1] Osseointegration can be accelerated by enhancing healing after the placement of an implant.[2] Recently developed platelet concentrates (PC) when come in association with exposed endothelium (due to damaged tissue), get triggered and release several bioactive mediators that play a significant role in bone healing.[3]

PCs were first introduced in 1954. Titanium platelet-rich fibrin (PRF), advanced PRF (A-PRF) and injectable PRF have been introduced recently.[4] In 2006, "Concentrated Growth Factors (CGF)" were introduced by Sacco.[4] CGF is obtained from blood by an altered centrifugation speed and time, permitting the separation of a fibrin matrix that is much larger, concentrated and richer in growth factors.[5,6] The agglutination of various factors including fibrinogen, factor XIII, and thrombin results in greater cohesion of the fibrin clot, thus, shielding from degradation by plasmin that further results in greater tensile strength and stability of fibrin.[7] Moreover, the amalgamation of fibrins and cytokines within CGF acts as a potent platform with a reservoir of growth factors for tissue regeneration.[8]

A-PRF is, however, obtained by centrifuging at a slow speed (1500 rpm for 14 min).[9] Modification to the centrifugation protocol improves the number of platelet cell as well as the behavior of monocytes/macrophages, resulting in an interdependent correlation that favors regeneration of tissues.[10] In addition, osteoblastic activity of alveolar bone is also magnified by A-PRF.[11]

Although the progress made in reference to PCs has shown to improve tissue regeneration,[10] scarce scientific evidence is available until today regarding the comparison of the effect of A-PRF and CGF on hard and soft tissues around implants. Thus, the aim of the present study was to evaluate the effect of A-PRF and CGF on tissues around implants in maxillary anterior region. Various parameters such as crestal bone level, implant stability, peri-implant probing depth, modified sulcular bleeding index, mucosal suppuration, and bleeding on probing were evaluated at baseline, 2 weeks, 2 months, 6 months, and 1 year after implant restoration placement.

MATERIALS AND METHODS

A prospective, clinical study involving subjects selected from the Department of Prosthodontics and Crown and Bridge was done. Ethical approval was obtained from Institutional Ethical Committee (PGIDS/IEC/17/36). The sample size was calculated using the mean and standard deviation values from literature using the formula:-

$$\frac{(Z_{\alpha/2} + Z_{\beta})^2 \times 2 \times \quad ^2}{(\mu_1 \quad \mu_2)}$$

Where $Z_{\alpha/2}$ is the level of significance, Z_{β} is the power of the study, σ is the pooled standard deviation, μ_1 is the standard deviation of Group 1 and μ_2 is the standard deviation of Group 2. Considering the level of significance or confidence interval of 95% and the power of the study to be 80%, a sample size of 10 in each group was decided.

A total of 62 subjects were evaluated based on chief complaints requiring replacement of missing maxillary anterior teeth. After meticulous clinical and radiographic examination, 30 subjects (24 males and 6 females) were included in the study based on inclusion and exclusion criteria. The proposed study criteria, alternative treatment possibilities including potential risks and advantages were explained and signed informed consent was obtained for all subjects before surgery. The study included young systemically healthy individuals with maintainable oral hygiene and sufficient bone density, height, and width. They were randomly assigned [Table 1] into three groups (10 implants per group): Control group (Group I), A-PRF group (Group II), and CGF group (Group III). Although the split-mouth design would have been an ideal study design for a comparative study like this to avoid the patient variability, we grouped it into separate groups considering the feasibility of our institutional setup.

Subjects with infection around implant region, history of a bleeding disorder or on anticoagulant drugs, with immunocompromised condition and debilitating disease, with parafunctional habits, with any other systemic diseases such as diabetes or a recent history of myocardial infarction, were excluded from the study. The surgical sites were evaluated presurgically with an intraoral periapical radiograph (IOPA) and cone-beam computed tomography images.

Advanced platelet-rich fibrin preparation

Blood was drawn in a sterile test tube without an anticoagulant solution. The tube was then immediately kept in the centrifuge (Laboratory centrifuge, model R-303, Remi, India, with in-built fixed-angle rotors) at 1500 rpm for 14 min, following the previously published protocol.[10] After centrifugation, the fibrin clot was carefully removed from the tube and separated from the red blood cell (RBC) fraction using sterile tweezers and scissors. It was then pressed to form a membrane.

Concentrated growth factors preparation

Using the same approach as that of A-PRF, blood was drawn in the test tube and centrifuged with the following

characteristics: 30 s acceleration, 2700 rpm for 2 min, 2400 rpm for 4 min, 2700 rpm for 4 min, 3000 rpm for 3 min, and 36 s deceleration and stop; prepared according to the previously published protocol.[5] At the termination of the procedure, three blood fractions were created. The topmost layer with platelet-poor plasma was separated using a sterile syringe. The central fibrin clot was detached from the RBC section using a scissor and then pressed to form a membrane.

Surgical procedure

Surgery was performed under local anesthesia. After the reflection of flap, the osteotomy site was prepared according to the guidelines of the Myriad Plus implant system (Myriad Plus, Equinox Implants, Straumann Group, Basel, Switzerland), using the pilot drill. After completion of the final osteotomy, the implants representing the control group were placed in the prepared site with no further procedure [Figure 1]. On the other hand, in the A-PRF/CGF group, the A-PRF/CGF membrane was placed along the implant cavity wall followed by implant placement [Figures 2 and 3], following the previously published A-PRF/CGF placement protocol.[5] The implants were torque wrenched using torque ratchet with an optimal insertion torque of 35 Ncm. A single-stage implant surgery was performed in all three groups. Gingival formers were placed and suturing was done with 3-0 silk suture material.

Table 1: Basic details of the various parameters

Group	Age/ gender	Tooth number	Dental implant dimensions (diameter×length) (mm)
Group I			
1	22/male	21	3.8×11
2	42/male	11	3.3×13
3	27/male	11	3.8×11
4	32/male	11	3.8×13
5	32/male	21	3.8×11
6	18/male	21	3.8×13
7	35/female	23	3.8×13
8	62/male	12	3.3×13
9	25/male	21	4.5×13
10	59/female	23	3.8×13
Group II			
1	22/female	11	3.3×13
2	30/male	11	3.8×13
3	18/male	21	3.3×13
4	18/male	21	3.3×11
5	25/male	11	3.8×13
6	27/male	21	3.3×13
7	20/male	21	3.8×13
8	20/male	21	3.3×9.5
9	18/male	21	3.8×13
10	24/male	21	3.3×11
Group III			
1	22/female	11	3.3×13
2	18/male	21	3.8×13
3	20/male	12	3.3×11
4	29/male	21	3.3×9.5
5	21/female	11	3.3×11
6	40/male	21	3.3×13
7	19/female	21	3.3×11
8	27/male	21	3.8×13
9	38/male	11	3.3×11
10	28/male	13	3.8×13

The patients were instructed to apply cold compresses after surgery. Medication was prescribed and they were recalled after 24 h for review and after 7–10 days for suture removal. The crown placement was done in the following 2 weeks [Figures 4-6]. The clinical parameters such as modified sulcular bleeding index, peri-implant probing depth, mucosal suppuration, bleeding on probing, crestal bone level, implant stability were evaluated clinically at baseline, 2 weeks, 2 months, 6 months, and 1 year.

Implant stability quotient measurements

Implant stability was assessed using periotest. The periotest value ranges from −8 to +50 with −8-0 indicating good osseointegration, +1 – +9 indicating clinical examination required and +10 – +50 indicating osseointegration is insufficient. At measurement time, the metal tip of the periotest was positioned on the incisal area of the prosthetic part of the implant. For each implant, Implant Stability Quotient (ISQ) values were obtained at different time intervals. The ISQ values of the implants were measured at baseline, 2 weeks, 2 months, 6 months, and 1 year.

Statistical analysis

A one-way analysis of variance test was applied for intra-group comparison between the three groups. *Post hoc* Bonferroni test was used for inter-group comparison between three groups at different time intervals. Chi-square test was used for nominal data such as mucosal suppuration

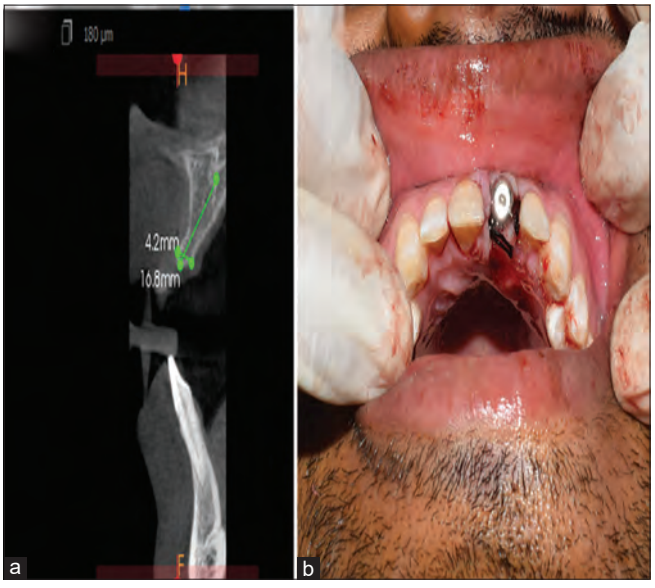


Figure 1: Control group: (a) Preoperative cone beam computed tomography, (b) Dental Implant *in situ*, healing cap placed and sutured

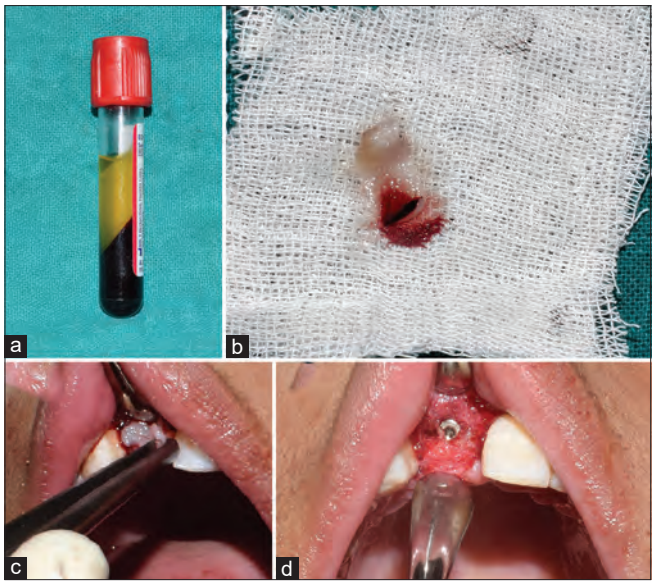


Figure 2: Advanced platelet-rich fibrin group: (a) advanced platelet-rich fibrin prepared, (b) advanced platelet-rich fibrin membrane, (c) advanced platelet-rich fibrin membrane in osteotomy site, (d) Dental implant placed

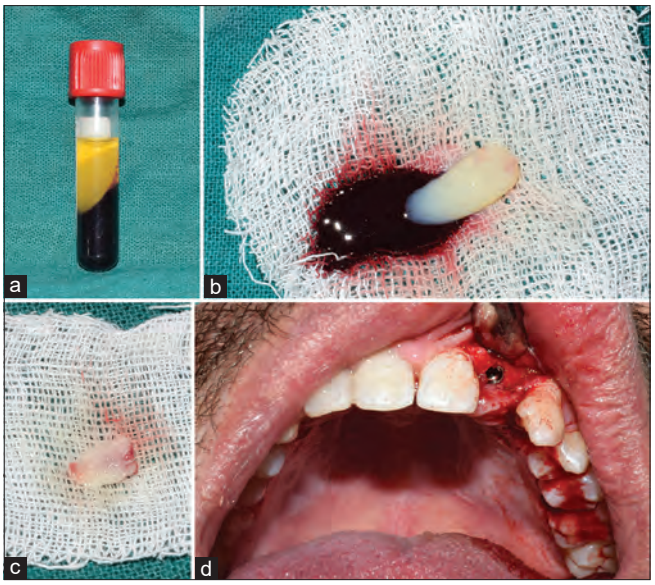


Figure 3: Concentrated growth factor group: (a) concentrated growth factor prepared, (b) concentrated growth factor fibrin clot, (c) concentrated growth factor membrane, (d) concentrated growth factor and dental implant placed

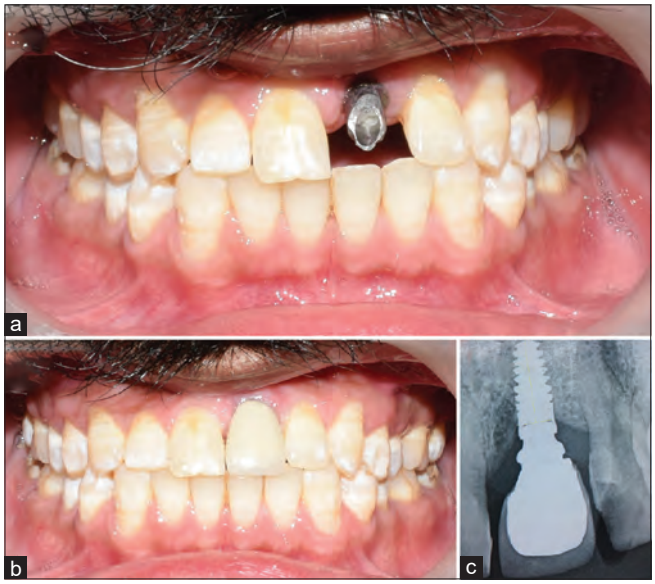


Figure 4: Control group: (a) Prosthetic abutment placed (b) Postoperative tooth in occlusion (c) Postoperative IOPA

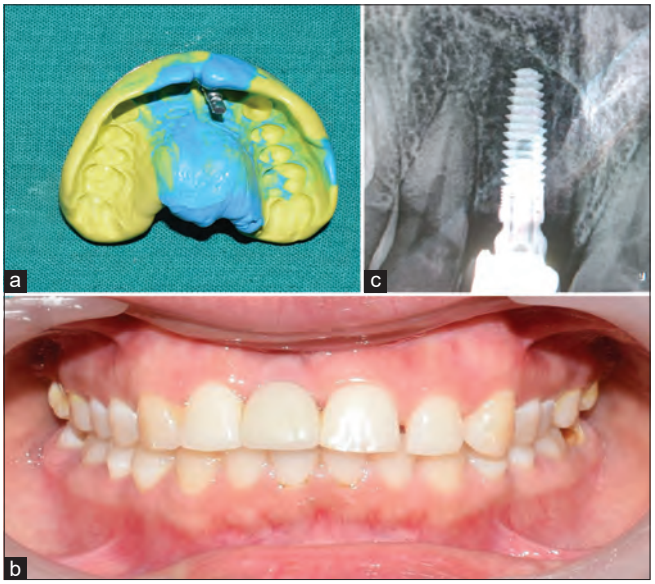


Figure 5: Advanced platelet-rich fibrin group: (a) Postoperative closed tray impression taken (b) Postoperative tooth in occlusion, (c) Postoperative IOPA

and bleeding on probing. Statistically, significant value was considered for $P < 0.05$. Data were analyzed using SPSS Statistics for Windows, version 17.0 (SPSS Inc., Chicago, Ill., USA) software.

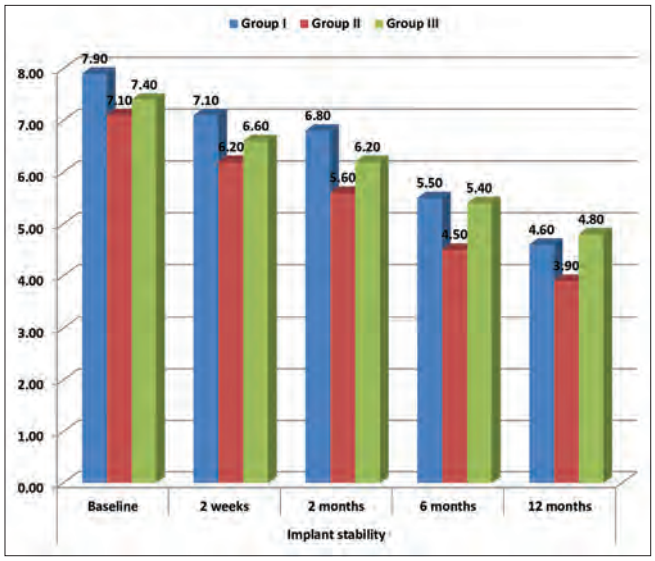
RESULTS

Statistically nonsignificant difference ($P > 0.05$) was observed in the mean crestal bone levels (mesial and distal) between Groups 1, 2, and 3 over a period of 1 year [Table 2]. The difference in mean implant stability between Groups 1, 2, and 3 at 2 months was significantly more among Groups 1 and 3 compared to Group 2 [Table 3 and Graph 1]. Statistically nonsignificant difference ($P > 0.05$) was observed in the mean peri-implant probing depth (mesial, buccal, distal and palatal) between Groups 1, 2, and 3 over a period of 1 year [Table 4]. There was no statistically significant difference ($P > 0.05$) in modified sulcular bleeding index (mesial, buccal, distal and palatal) between Groups 1, 2, and 3 over a period of 1 year [Table 5]. The mucosal suppuration (mesial, buccal,

Table 2: Inter-group comparison of mean crestal bone levels at different time intervals using *post hoc* Bonferroni test

Crestal bone loss	Group I		Group II		Group III		*P*	Post-hoc comparisons
	Mean	SD	Mean	SD	Mean	SD		
Mesial								
At baseline	0.86	0.84	1.15	0.82	0.86	0.49	0.600	N/A
At 2 weeks	0.94	0.77	1.26	0.75	0.94	0.49	0.494	N/A
At 2 months	1.04	0.83	1.34	0.79	1.04	0.47	0.564	N/A
At 6 months	1.23	0.75	1.57	0.76	1.26	0.46	0.464	N/A
At 1 year	1.48	0.75	1.75	0.75	1.31	0.44	0.341	N/A
Distal								
At baseline	1.26	0.96	1.34	0.86	1.04	0.51	0.688	N/A
At 2 weeks	1.36	0.91	1.45	0.84	1.17	0.52	0.712	N/A
At 2 months	1.45	0.91	1.54	0.80	1.27	0.50	0.723	N/A
At 6 months	1.68	0.85	1.72	0.73	1.48	0.48	0.719	N/A
At 1 year	1.90	0.89	1.94	0.73	1.63	0.51	0.591	N/A

SD: Standard deviation, N/A: Not applicable



Graph 1: Inter-group comparison of mean implant stability at baseline, 2 weeks, 2 months, 6 months, and 1 year

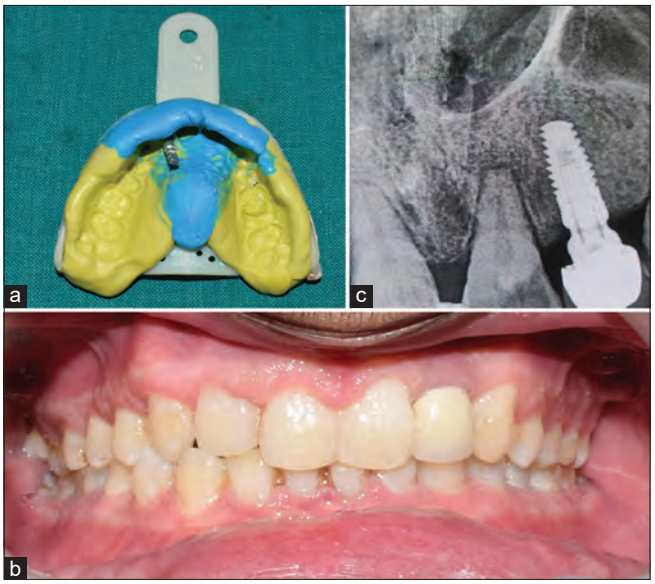


Figure 6: Concentrated growth factor group: (a) Postoperative closed tray impression taken, (b) Postoperative teeth in occlusion, (c) Postoperative IOPA

distal and palatal) between Groups 1, 2 and 3 was found to be negative and constant over a period of 1 year [Table 6]. Statistically nonsignificant difference ($P > 0.05$) was found in bleeding on probing (mesial, buccal, distal, and palatal) between Groups 1, 2, and 3 over a period of 1 year [Table 7].

DISCUSSION

The favorable outcome of implant therapy in the aesthetic maxillary anterior zone depends on tissue healing around implants. To overcome aesthetic demands and accelerate healing, grafting platelets obtained from the patient's blood was introduced.[12]

Various platelet aggregates such as platelet-rich plasma (PRP), leukocyte and PRP, pure PRF, leukocyte and PRF have been used earlier to accelerate new bone formation.[13,14] PRF alone or in association with grafting materials have been applied clinically in orthopedic, periodontal, and implant surgeries.[15-20] Ghanaati *et al.* formulated a new low-speed centrifugation protocol called A-PRF which further improved tissue regeneration. This modification increased the platelet cell numbers and the behavior of monocytes/macrophages.[10] Several authors have described yet another PC named CGF which seemed to accelerate bone healing.[7,21-23]

CGF is a new generation fibrin matrix with a significant amount of growth factors such as platelet-derived growth factor (PDGF), transforming growth factor β (TGF-β), fibroblast growth factor (FGF), insulin-like growth factor (IGF), epidermal growth factor (EGF) and bone morphogenetic protein.[24] PDGF invigorates angiogenesis, proliferation of osteoblast, division of the mesenchymal cell and synthesis of collagen by fibroblast.[25] TGF-β

Table 3: Inter-group comparison of mean implant stability at different time intervals using *post hoc* Bonferroni test

Implant stability	Group I		Group II		Group III		*P*	*Post-hoc* comparisons
	Mean	SD	Mean	SD	Mean	SD		
Baseline	7.90	0.88	7.10	1.10	7.40	0.84	0.181	N/A
2 weeks	7.10	0.88	6.20	1.03	6.60	0.84	0.110	N/A
2 months	6.80	0.92	5.60	1.07	6.20	0.63	0.021*	1, 3>2
6 months	5.50	1.65	4.50	1.84	5.40	1.43	0.342	N/A
1 year	4.60	2.01	3.90	1.79	4.80	0.92	0.448	N/A

*Significant difference. SD: Standard deviation, N/A: Not applicable

Table 4: Inter-group comparison of mean peri-implant probing depth at different time intervals using *post hoc* Bonferroni test

Peri-implant probing depth	Group I		Group II		Group III		*P*	*Post-hoc* comparisons
	Mean	SD	Mean	SD	Mean	SD		
Mesial								
At baseline	1.95	0.60	1.30	0.48	1.30	0.48	0.013*	1>2, 3
At 2 weeks	1.90	0.61	1.70	0.48	1.85	0.47	0.682	N/A
At 2 months	2.05	0.60	2.05	0.55	2.25	0.59	0.676	N/A
At 6 months	2.05	0.98	2.10	0.84	2.25	0.75	0.866	N/A
At 1 year	2.40	0.91	2.45	0.72	2.45	0.76	0.987	N/A
Buccal								
At baseline	2.10	0.32	1.60	0.52	1.60	0.52	0.031*	1>2, 3
At 2 weeks	2.20	0.35	2.00	0.47	2.15	0.34	0.501	N/A
At 2 months	2.25	0.42	2.20	0.42	2.35	0.47	0.743	N/A
At 6 months	2.55	0.50	2.50	0.47	2.70	0.42	0.611	N/A
At 1 year	2.85	0.47	2.80	0.42	2.70	0.42	0.742	N/A
Distal								
At baseline	1.90	0.39	1.65	0.47	1.65	0.47	0.370	N/A
At 2 weeks	2.00	0.58	2.05	0.44	2.05	0.16	0.956	N/A
At 2 months	2.35	0.82	2.25	0.79	2.40	0.70	0.907	N/A
At 6 months	2.50	0.85	2.25	0.79	2.65	0.67	0.514	N/A
At 1 year	2.85	0.85	2.45	0.80	2.75	0.59	0.477	N/A
Lingual								
At baseline	1.50	0.53	1.30	0.48	1.20	0.42	0.375	N/A
At 2 weeks	1.10	0.32	1.30	0.48	1.20	0.42	0.563	N/A
At 2 months	1.45	0.60	1.45	0.60	1.35	0.58	0.910	N/A
At 6 months	1.85	0.82	1.95	0.76	1.55	0.76	0.501	N/A
At 1 year	1.95	0.86	2.10	0.91	1.55	0.76	0.338	N/A

*Significant difference. SD: Standard deviation, N/A: Not applicable

affects osteoblast in an early stage of development and stimulates collagen synthesis by fibroblasts, which facilitates the regeneration of bone and cartilage.[26] IGF helps in osteogenesis.[27] PDGF and TGF-β ameliorates tensile strength and callus formation of soft tissue and bone.[28-31]

The parameters used during the follow-up phase of dental implants should be sensitive enough to allow discrimination of early changes. According to Albrektsson *et al*., the established criteria for implant success is that the change in marginal bone level in the 1st year should be <1.5 mm.[32] In our study, the intragroup comparison of mean crestal bone level was observed to be statistically nonsignificant ($P > 0.05$). The crestal bone level in all three groups at different time intervals was within the success criteria of an implant. Our result was in accordance with the study done by Boora *et al*. who evaluated mean marginal bone changes in both control and PRF groups from baseline to 3 months, with smaller changes seen in PRF group.[33] Clark *et al*. in their study evaluated the efficacy of A-PRF alone and with freeze-dried bone allograft (FDBA) and found an improved formation of vital bone and dimensional stability of alveolar bone during ridge preservation.[34] They concluded that A-PRF alone or in combination with FDBA can be used for ridge preservation as an acceptable biomaterial.

A significant finding of this study was that comparatively among all three groups, the CGF group showed the least amount of crestal bone loss, however, the difference with other groups was statistically nonsignificant. Javi *et al*. illustrated the use of CGF alone for sinus graft which showed greater bone volume 3 months' postoperative surgery.[35] Kim *et al*. used CGF, without any additional graft material, in flapless transcrestal sinus augmentation and observed good results.[23] In the study done by Sohn *et al*., CGF was used in sinus augmentation and positive results were obtained after radiographical, clinical. and histological examination. They concluded that CGF rapidly induces formation of new bone during sinus augmentation procedures.[22]

Table 5: Inter-group comparison of modified sulcular bleeding index at different time interval using *post hoc* Bonferroni test

Modified SBI	Group I		Group II		Group III		*P*	*Post-hoc* comparisons
	Mean	SD	Mean	SD	Mean	SD		
Mesial								
At baseline	0.40	0.52	0.40	0.52	0.40	0.52	1.000	N/A
At 2 weeks	0.20	0.42	0.30	0.48	0.30	0.48	0.857	N/A
At 2 months	0.10	0.32	0.20	0.42	0.20	0.42	0.804	N/A
At 6 months	0.20	0.42	0.10	0.32	0.20	0.42	0.804	N/A
At 1 year	0.10	0.32	0.10	0.32	0.10	0.32	1.000	N/A
Buccal								
At baseline	0.40	0.52	0.30	0.48	0.30	0.48	0.873	N/A
At 2 weeks	0.40	0.52	0.40	0.52	0.60	0.52	0.612	N/A
At 2 months	0.50	0.53	0.40	0.52	0.60	0.52	0.694	N/A
At 6 months	0.30	0.48	0.30	0.48	0.40	0.52	0.873	N/A
At 1 year	0.30	0.48	0.30	0.48	0.40	0.52	0.873	N/A
Distal								
At baseline	0.30	0.48	0.30	0.48	0.30	0.48	1.000	N/A
At 2 weeks	0.30	0.48	0.30	0.48	0.50	0.53	0.590	N/A
At 2 months	0.40	0.52	0.40	0.52	0.70	0.48	0.324	N/A
At 6 months	0.30	0.48	0.30	0.48	0.40	0.52	0.873	N/A
At 1 year	0.10	0.32	0.20	0.42	0.40	0.52	0.293	N/A
Lingual								
At baseline	0.10	0.32	0.10	0.32	0.10	0.32	1.000	N/A
At 2 weeks	0.20	0.42	0.20	0.42	0.20	0.42	1.000	N/A
At 2 months	0.10	0.32	0.20	0.42	0.10	0.32	0.769	N/A
At 6 months	0.20	0.42	0.30	0.48	0.50	0.53	0.375	N/A
At 1 year	0.20	0.42	0.10	0.32	0.30	0.48	0.563	N/A

SD: Standard deviation, N/A: Not applicable

Implant stability is another parameter known to verify implant success.[36] In the present case, a significant difference ($P < 0.05$) was observed during intra-group comparison of mean implant stability at 2 months between Groups I, II, and III. The inter-group comparison of mean implant stability at 2 months was significantly more among the control and CGF group compared to the A-PRF group [Table 3]. Rodella *et al.* observed that CGF administration enhances FGF-β or VEGF release that plays significant role in angiogenesis and enhance migration of the neutrophils by releasing integrin.[6] CD34-positive cells in the CGF network also result in angiogenesis, neovascularization and vascular continuity.[4] A study done by Pirpir *et al.* showed that the administration of CGF affects the primary stability with a positive effect on osseointegration.[5]

Nevertheless, Kalash *et al.* showed improved implant stability in support of the A-PRF group.[37] El Kenawy *et al.* also found better periotest scores in A-PRF cases during the follow-up periods with a statistically significant difference at 3 months.[38] Kalash *et al.* attributed the positive effect of A-PRF on implant stability to the biological properties of A-PRF that regenerates bone and promote osseointegration.[37] However, further clinical studies are required to justify the effect of A-PRF in implant osseointegration.

The platelets contain abundant growth factors which serve as early modulators of the healing process. CGF contains activated platelets that help in providing improved implant stability and accelerate osseointegration.[39] Park *et al.* reported that CGF consists of thicker fibrinogen fibers per unit area as compared to PRF.[40] The fibrin membrane of CGF reinforces the peri-implant tissues, forms a barrier, and protects the implant from the oral conditions.[24] Also, by providing growth factors, permeable fibrin matrix leukocytes, and endothelial as well as epithelial cell growth, CGF stimulates neoangiogenesis and enhances gingival healing.

The soft tissue parameters also are significant indicators of implant health. However, the present study findings showed a nonsignificant difference in peri-implant probing depth, modified sulcular bleeding index and bleeding on probing at the implant site. There was no mucosal suppuration present in any of the three groups. Kalash *et al.* proved that A-PRF placed in the peri-implant gaps helped maintain natural and healthy peri-implant gingiva.[34] Boora *et al.* used PRF around immediate implants and observed a comparatively more reduction in probing depth than the non-PRF group.

In our study, the dropout rate of the subjects was zero. All subjects maintained good oral hygiene. No complication was recorded in any of the cases except for one case where implant placement could not be done due to periapical infection of the adjacent tooth. Throughout the study, a single implant system (Myriad Plus, passive, threaded implants) was used. The A-PRF and CGF were freshly

Table 6: Inter-group comparison of mucosal suppuration at different time intervals using *post hoc* Bonferroni test

Mucosal suppuration	Groups (%)			χ^2	*P*
	Group I	Group II	Group III		
Mesial					
At baseline					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 weeks					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 6 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 1 year					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
Distal					
At baseline					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 weeks					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 6 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 1 year					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
Buccal					
At baseline					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 weeks					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 6 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 1 year					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
Lingual					
At baseline					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 weeks					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 2 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 6 months					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000
At 1 year					
No	10 (100.0)	10 (100.0)	10 (100.0)	0.000	1.000

prepared and used immediately to achieve the maximal favorable effect. The same centrifuge machine was used throughout the study for the preparation of A-PRF and CGF using their standard centrifugation protocol. Digital intraoperative periapical (IOPA) X-rays used for the measurement of changes in bone level were standardized by using occlusal putty zig. This putty zig was used for taking further IOPA at later time intervals.

This study has the potential to consider the use of CGF and A-PRF for its application in implantology. However, a small sample size and short follow-up time were the limitations of the present study.

Table 7: Inter-group comparison of bleeding on probing at different time intervals using *post hoc* Bonferroni test

Bleeding on probing	Groups (%)			χ^2	*P*
	Group I	Group II	Group III		
Mesial					
At baseline					
No	6 (60.0)	6 (60.0)	6 (60.0)	0.000	1.000
Yes	4 (40.0)	4 (40.0)	4 (40.0)		
At 2 weeks					
No	8 (80.0)	7 (70.0)	9 (90.0)	1.250	0.535
Yes	2 (20.0)	3 (30.0)	1 (10.0)		
At 2 months					
No	9 (90.0)	8 (80.0)	8 (80.0)	0.480	0.787
Yes	1 (10.0)	2 (20.0)	2 (20.0)		
At 6 months					
No	8 (80.0)	9 (90.0)	8 (80.0)	0.480	0.787
Yes	2 (20.0)	1 (10.0)	2 (20.0)		
At 1 year					
No	6 (60.0)	9 (90.0)	8 (80.0)	2.609	0.271
Yes	4 (40.0)	1 (10.0)	2 (20.0)		
Distal					
At baseline					
No	7 (70.0)	7 (70.0)	7 (70.0)	0.000	1.000
Yes	3 (30.0)	3 (30.0)	3 (30.0)		
At 2 weeks					
No	6 (60.0)	7 (70.0)	5 (50.0)	0.833	0.659
Yes	4 (40.0)	3 (30.0)	5 (50.0)		
At 2 months					
No	6 (60.0)	6 (60.0)	3 (30.0)	2.400	0.301
Yes	4 (40.0)	4 (40.0)	7 (70.0)		
At 6 months					
No	7 (70.0)	7 (70.0)	6 (60.0)	0.300	0.861
Yes	3 (30.0)	3 (30.0)	4 (40.0)		
At 1 year					
No	7 (70.0)	7 (70.0)	6 (60.0)	0.300	0.861
Yes	3 (30.0)	3 (30.0)	4 (40.0)		
At baseline					
No	6 (60.0)	7 (70.0)	7 (70.0)	0.300	0.861
Yes	4 (40.0)	3 (30.0)	3 (30.0)		
Buccal					
At 2 weeks					
No	6 (60.0)	6 (60.0)	4 (40.0)	1.071	0.585
Yes	4 (40.0)	4 (40.0)	6 (60.0)		
At 2 months					
No	6 (60.0)	6 (60.0)	4 (40.0)	1.071	0.585
Yes	4 (40.0)	4 (40.0)	6 (60.0)		
At 6 months					
No	7 (70.0)	7 (70.0)	6 (60.0)	0.300	0.861
Yes	3 (30.0)	3 (30.0)	4 (40.0)		
At 1 year					
No	4 (40.0)	8 (80.0)	6 (60.0)	3.333	0.189
Yes	6 (60.0)	2 (20.0)	4 (40.0)		
Lingual					
At baseline					
No	9 (90.0)	9 (90.0)	9 (90.0)	0.000	1.000
Yes	1 (10.0)	1 (10.0)	1 (10.0)		
At 2 weeks					
No	8 (80.0)	8 (80.0)	8 (80.0)	0.000	1.000
Yes	2 (20.0)	2 (20.0)	2 (20.0)		
At 2 months					
No	9 (90.0)	8 (80.0)	9 (90.0)	0.577	0.749
Yes	1 (10.0)	2 (20.0)	1 (10.0)		
At 6 months					
No	8 (80.0)	7 (70.0)	5 (50.0)	2.100	0.350
Yes	2 (20.0)	3 (30.0)	5 (50.0)		
At 1 year					
No	8 (80.0)	8 (80.0)	8 (80.0)	0.000	1.000
Yes	2 (20.0)	2 (20.0)	2 (20.0)		

CONCLUSION

Within the limitations of the study, it can be concluded that on assessing the effect of A-PRF and CGF, when placed in the maxillary anterior region, on the peri-implant hard and soft tissues through most parameters was found to be statistically nonsignificant ($P > 0.05$) over a period of 1 year. However, implant stability was found to be statistically significant ($P < 0.05$) in the 2nd month in all three groups. Moreover, implant stability was significantly more in the control and CGF groups in comparison to the A-PRF group in the 2nd month.

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Conflicts of interest
There are no conflicts of interest.

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Research

Effects of surface modification techniques on zirconia substrates and their effect on bonding to dual cure resin cement - An *in- vitro* study

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Abstract

Aim: This study aims to evaluate the effect of different surface treatments of monolithic zirconia on the bond strength of resin to zirconia and, to explore alternative methods to improve this bonding.

Settings and Design: *In-Vitro* study.

Materials and Methods: Fifty rectangular sintered blocks of Yttria-stabilized Tetragonal Zirconia Polycrystal ceramics of dimensions were milled and sintered. These specimens were further divided into five groups (control, air abrasion, etching with primer application, air abrasion with primer application and novel glass infiltrated zirconia surface group), containing 10 samples each. The specimens were analyzed for surface roughness, tensile bond strength to resin cements, and adhesive and cohesive mode of failures.

Statistical Analysis Used: ANOVA and Post-Hoc Tukey test was perform to evaluate the significant differences in the mean values of the groups.

Results: Air-abraded samples showed the highest surface roughness (4.95 ± 0.65) ($P < 0.05$). The group with air abrasion followed by primer application showed the highest tensile bond strength (7.12 ± 0.69) ($P < 0.05$). The lowest surface roughness (0.638 ± 0.8093) and tensile bond strength (2.03 ± 0.58) was seen in samples that were subjected to etchant treatment followed by application of methacryloyloxydecyl di-hydrogen phosphate (MDP) primer. The changes in comparison to the control group were statistically insignificant ($P > 0.05$). Except Groups A (control) and C (etchant followed by primer), all other groups showed a cohesive failure.

Conclusion: Air abrasion of the zirconia surface with 50 μm alumina particles increases the surface roughness without damaging the surface. Air abrasion followed by MDP primer application is the recommended method of surface treatment to achieve superior bonding. Glass infiltration also showed promising results in terms of tensile bond strength.

Keywords: Air abrasion, methacryloyloxydecyl di-hydrogen phosphate molecules, Y-TZP

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INTRODUCTION

Porcelain-fused-to-metal restorations are known for their longevity, albeit their aesthetic limitations and the occasional delamination of the veneering ceramic are some of their known drawbacks,[1] which led to the shift towards metal-free restorations.

Over the years, zirconia ceramics have gained popularity in dentistry because of their versatility.[2,3]

However, it has poor bonding to adhesive resin cement as it cannot be etched with hydrofluoric acid and silanated using silica-based primers, unlike the silica-based ceramics.[4,5] To overcome this problem, various surface modification techniques have been suggested. Durability of the resin-ceramic bond depends upon the prototype of this bonding whether it is purely mechanical, chemical, or a combination of both.[6,7]

Mechanical techniques such as air abrasion increase the surface area by surface roughening and provide mechanical interlocking of zirconia with resin cement.[6,8] The effect varies according to the type, size, and injection pressure of the abrasive particles.[9] Although air abrasion using alumina particles is commonly used and has shown promising results.[10] authors have stated that the surface of Y-TZP ceramics gets damaged, which adversely affects its mechanical properties.[10-13] Silica coating has also been reported to be a simple and effective method for bonding since it increases hydroxyl groups for silane coupling and also mechanically roughens the surface.[3]

Apart from the mechanical techniques, studies have also shown promising results with chemical agents to aid in bonding zirconia to the resin cement.[12,14] 10-methacryloyloxydecyl di-hydrogen phosphate (MDP) coating, a dentin primer/silane agent, containing a phosphate ester is a popular technique to achieve chemical bonding between zirconia and resin cement. The presence of divalent phosphoric group within the MDP monomer chemically bonds with the zirconia surface, and improves the bond strength.[13,15-18]

Studies have concluded that the modification of zirconia surface by glass-infiltration improved the aesthetic outcomes by reducing the opacity, improving the flexural strength of the prosthesis, and providing resistance to fracture and edge chipping.[19-24] Studies also show that it is the glass phase, and not just the surface treatment that is responsible for the enhanced bond strength to resin cement.[17,19-27] This approach can potentially extend the clinical indications of zirconia in conservative and adhesive dental treatments.

Strong, durable bonds with every interface (resin to tooth, tooth to restoration) are critical for long-term success of any restoration.[27-30] The purpose of this study was to evaluate the effect of different treatments of the zirconia surface on its bond strength to luting resin and to explore alternative methods to improve the bonding between resin cement and zirconia, since existing literature is inconclusive. The null hypothesis of the present study was that there is no statistically significant difference between zirconia–resin bond following air abrasion, application of ceramic primer, air abrasion followed by ceramic primer application, and glass infiltration of zirconia surface.

MATERIALS AND METHODS

Sample size estimation

The sample size was determined by using the effect sizes from the previously published study[31] and with the help of the following formula:

$$n\,(\text{Per Group}) = 2\left[\frac{\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)\sigma}{\Delta}\right]^2$$

Where, n = Sample size (per group)

$Z_{\alpha/2}$= (1.96) for 95% confidence (i.e., $\alpha = 0.05$). =1.96

Z_{β} = Cut-off value for power ($1 - \beta$). = 0.8416 (80.0% power)

Δ = Mean difference to be detected (minimum difference) = 2.0 units of delta E

Δ/σ = Effect size in SD units = 0.600

Thus sample size according to this formula is 8 (minimum per group), i.e., total 40 (minimum). The sample size was kept as 10 per group, total 50 samples to improve the power of the study.

Specimen preparation

Fifty presintered blocks of Y-TZP (Lava 3M™ ESPE™ St. Paul, Minnesota, United States), 97% zirconium dioxide stabilized with 3% Yttria were milled from a disc using a Standard Tessellation Language file of dimension 15 mm × 3 mm x 3 mm (dimensions specified by ASTM) and sintered at 1450°C according to the manufacturer's recommendations.

Specimens were randomly divided into five groups, 10 specimens per group.

Surface treatment

Group A: No surface modification was done for this group.

Group B: The specimens were air abraded with 50 μm alumina particles at 2.5 bar pressure for 15 s at a distance of 10 mm in a sandblasting unit[32] followed by ultrasonic bath to remove residual alumina particles from the zirconia surface.

Group C: The specimens' bonding surfaces were coated with MDP containing primer (Clearfil Kuraray, Osaka Japan) after etching with 9% HF (Ultradent, USA).

Group D: The specimens were air abraded followed by primer (Clearfil Kuraray, Osaka Japan) application. Air abrasion was done with alumina particles of 50 μm at 2.5 bar pressure for 15 s from a distance of 10 mm in a sandblasting unit followed by an ultrasonic bath to remove residual alumina particles from the zirconia surface. After air-drying the specimens, MDP containing primer (Clearfil Kuraray, Osaka Japan) was applied to the specimens.

Group E: Glass containing SiO_2 55%, Na_2O 3%, ZnO 8%, B_2O_3 3%, TiO 2%, BaO 5.5%, K_2O 23.5% was manufactured in house at Centre of materials electronics and technology.[3] It was then powdered into fine particles and were sieved to get uniform particle size of <350 μm. This powder was coated in thin layer on the bonding surface of zirconia using a thin paint brush. Specimens were then kept in a furnace at a temperature of 800°C–900°C for 10–15 min.

Determination of surface roughness

The surface roughness of the specimens from each group was measured using surface profilometer (Kawasaki, Mitutoyo, Japan). The tip of profilometer was kept perpendicular to the specimens while testing as described by Sandhu *et al*.[33]

Specimen preparation for testing tensile bond strength

The methodology followed for this aspect of the study was similar to the protocol described by Kern and Thompson.[6]

An acrylic block was prepared using a custom metal mold of dimension 1.5 cm × 1.5 cm × 1.5 cm. The specimens were then embedded in the center of the acrylic block, to stabilize the specimens whilst testing.

Composite (Ivoclar Vivadent Liechtenstein) bars of dimensions similar to that of the zirconia samples, were fabricated to test the bonding using a custom mold. Acrylic block was made to embed the composite bars in a similar manner.

Bonding of resin luting agent to zirconia samples

Equal amounts of paste A and paste B of the resin cement (Panavia F 2.0, Kuraray, Osaka, Japan) were used. The paste was applied to the composite surface, which was then seated onto the zirconia specimen.

This was carried out using a custom-made alignment apparatus[12] under a load of 1000 g in order to maintain a uniformity in the layer of cement as per protocol described by Brental *et al.*

The embedded composite bars were exactly parallel to the embedded zirconia surface during the bonding process.

Determination of tensile bond strength

The mounted specimen of each group was stabilized in a universal testing machine (Instron®, Massachusetts, USA). With the help of a metal holder. The two blocks were then pulled apart using a crosshead speed of 2 mm/min. The values of the tensile bond strength were measured, according to the protocol used by Kern and Thompson for all five groups.[6]

Analysis of the mode of bond failure

The de-bonded samples of all five groups were examined under the stereomicroscope (Stemi 2000-C, Carl Zeiss, Gottingen, Germany) with the magnitude of ×40. This examination was done to determine whether the type of fracture was:

- Cohesive failure – At composite-resin cement
- Adhesive failure - At zirconia-resin cement.

Statistical analysis

Data were collected, tabulated, formulated, and analyzed by subjecting to appropriate statistical test. Test was carried out by using SPSS 22.0 (IBM Analytics, New York, USA.)

RESULTS

Evaluation of surface roughness

Surface roughness was measured using a profilometer.

On inter-group comparison, Group A (control group) had the surface roughness of 0.565 ± 0.1086, Groups B (4.95 ± 0.65), D (4.611 ± 0.1604), E (4.583 ± 0.6792) showed a statistically significant higher surface roughness in comparison ($P < 0.05$) whereas,

group C (0.638 ± 0.8093) showed a statistically insignificant higher surface roughness ($P > 0.05$) [Figure 1].

On the intra-group comparison, Group B (4.95 ± 0.65) and C (0.638 ± 0.8093) were compared, a statistically significant higher roughness was observed for group B compared to Group C. However, the difference between Group B and D (4.611 ± 0.1604) and E (4.583 ± 0.6792) was statistically insignificant [Table 1].

Scanning electron microscopy analysis for evaluating surface roughness

Group A (Control) showed a smooth substrate surface [Figure 2].

Group B (Air abrasion with 50 µm alumina) showed micro-cracks and irregularities on zirconia substrate [Figure 3].

Group C (MDP primer and 9% HF) showed the presence of smooth surface on the zirconia substrate [Figure 4].

Group D (Air abrasion followed by primer application) showed irregular craters on the substrate [Figure 5].

Group E (Glass infiltrated zirconia) demonstrated irregular spheres of diameter 30–70 µm. No micro-cracks were seen on the substrate [Figure 6].

Evaluation of tensile bond strength

On inter-group comparison, Group A showed tensile bond strength of 2.069 ± 0.6562, Group B (4.75 ± 0.53), D (7.12 ± 0.69), and E (3.59 ± 1.16) showed a statistically significant higher tensile bond strength whereas Group C (2.03 ± 0.58) showed a statistically insignificant higher tensile bond strength [Figure 7].

On intragroup comparison, a statistically significant higher tensile bond strength was observed for Group D (7.12 ± 0.69) compared to Group B (4.75 ± 0.53), C (2.03 ± 0.58), and E (3.59 ± 1.16). However, the difference in tensile strength between Group E and C was statistically insignificant ($P > 0.005$) [Table 2].

Evaluation of modes of failure

The results obtained were as follows:

Group A and Group C exhibited predominantly adhesive failure.

Whereas, Groups B, Group D, and Group E exhibited predominantly cohesive failure mode.

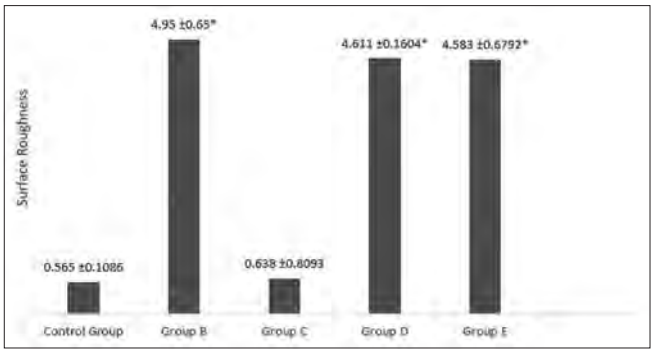

Figure 1: Surface roughness measured in µm

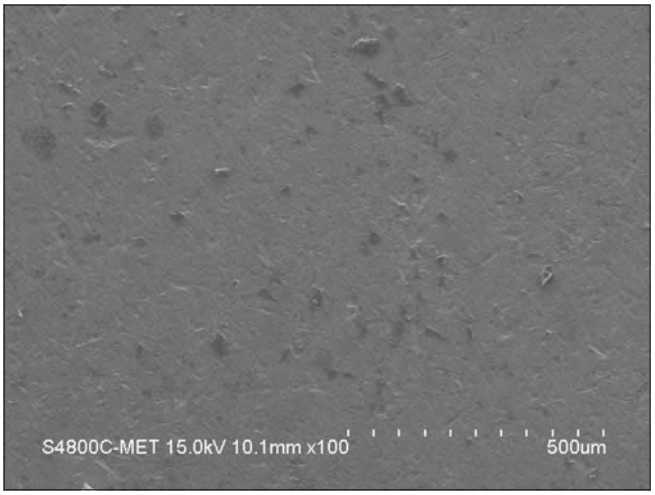

Figure 2: Control samples exhibiting a smooth substrate surface

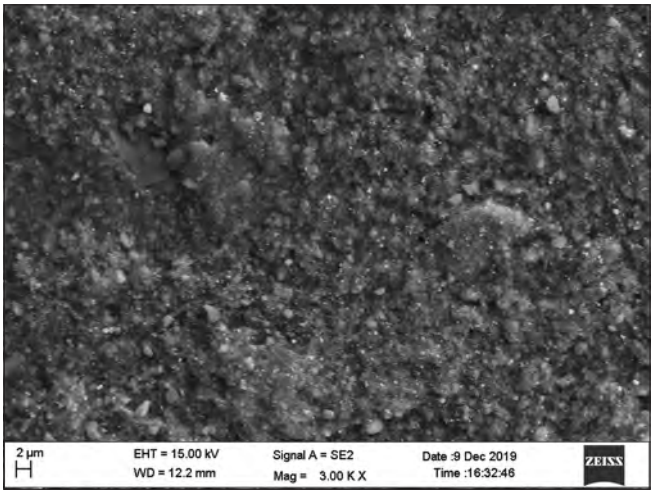

Figure 3: Air abrasion with 50 µm alumina showing micro-cracks and irregularities on zirconia substrate

DISCUSSION

The results of this study showed statistically significant difference in zirconia–resin bond between air abrasion, application of ceramic primer, air abrasion followed by ceramic primer application, and glass infiltration of zirconia surface. Hence, the null hypothesis was rejected.

Table 1: Tuckey Honestly Significant Difference *post hoc* comparison of all the 5 different techniques with respect to surface roughness

Group	Difference	95% CI limit	P
Control versus air abrasion	4.39	3.6791-5.1061	0.0000*
Control versus air abrasion with primer	4.046	3.3325-4.7595	0.0000*
Control versus etching with primer	0.073	−0.6405-0.7865	0.9984
Control versus glass infiltration	4.018	3.3045-4.7315	0.0000*
Air abrasion versus air abrasion with primer	0.3466	−1.0601-0.3669	0.6431
Air abrasion versus etching with primer	4.319	−5.0331-−3.6061	0.0000*
Air abrasion versus glass infiltration	0.374	−1.0881-0.3389	0.5730
Air abrasion with primer versus etching with primer	3.973	−4.6865-−3.2595	0.0000*
Air abrasion with primer versus glass infiltration	-0.028	0.7415-0.6855	1.000
Etching with primer versus glass infiltration	3.645	3.2315-4.6585	0.000*

*Statistically significant. CI: Confidence interval, HSD: Honestly Significant Difference

Table 2: Tukey Honestly Significant Difference *post hoc* comparison of all the 5 different groups with respect to tensile bond strength

Group	Difference	95% CI limit	*P*
Control versus air abrasion	2.6830	1.7166-3.6494	0.0000*
Control versus air abrasion with primer	5.0600	4.0936-6.0264	0.0000*
Control versus etching with primer	−0.0250	−0.9914-0.9414	1.0000
Control versus glass infiltration	1.5210	0.5546-2.4874	0.0005*
Air abrasion versus air abrasion with primer	2.3770	1.4106-3.3434	0.0000*
Air abrasion versus etching with primer	−2.7080	−3.6744-−1.7416	0.0000*
Air abrasion versus glass infiltration	−1.1620	−2.1284-−0.1956	0.0113
Air abrasion with primer versus etching with primer	5.0850	−6.0514-−4.1186	0.0000*
Air abrasion with primer versus glass infiltration	−3.5390	−4.5054-−2.5726	0.0000*
Etching with primer versus glass infiltration	1.5460	0.5796-2.5124	0.0004

*Statistically significant. CI: Confidence interval, HSD: Honestly Significant Difference

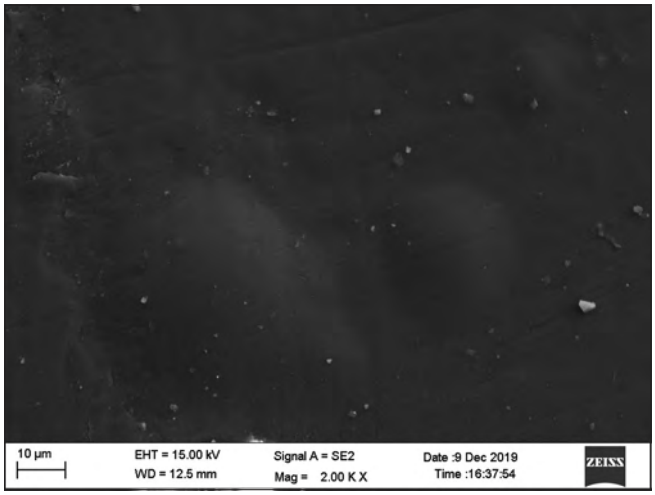

Figure 4: Acid etching followed by primer application showing a smooth zirconia substrate

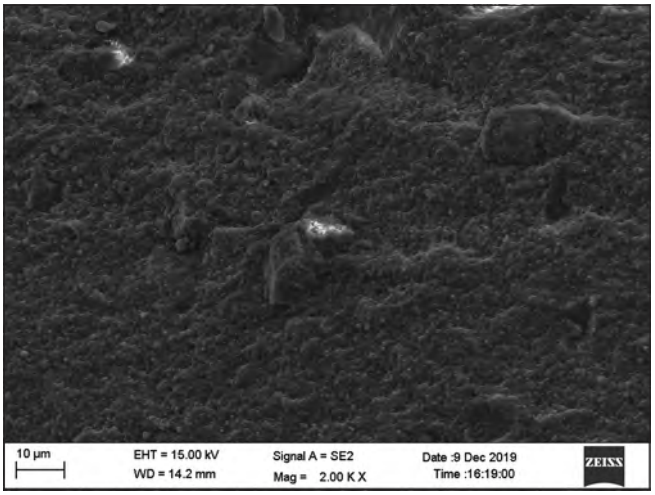

Figure 5: Air abrasion followed by primer application showing irregular craters on the substrate

Surface treatment of zirconia is important to enhance its bond with luting resin.

The present study predominantly revealed the following: (i) Air abrasion is an effective method for increasing surface roughness of zirconia as compared to other methods. (ii) Air abrasion followed by primer application led to statistically significantly higher tensile bond strength. (iii) Glass infiltration of zirconia demonstrated statistically significantly higher surface roughness and increase in bond strength when compared to the control group. (iv) Both adhesive and cohesive failures were noted in zirconia samples.

Air abrasion with alumina particles is the most commonly used method to condition zirconia as it is cost-effective, easy to perform, and effective in creating desired surface roughness. A mean roughness of 4.95 Ra ($P < 0.000$) was achieved, which was statistically significantly higher amongst all the other groups. The results of the present study are in agreement with the study performed by Subaşı and Inan Subasi,[34] Piascik *et al*.[35] and Hallmann *et al*.[10]

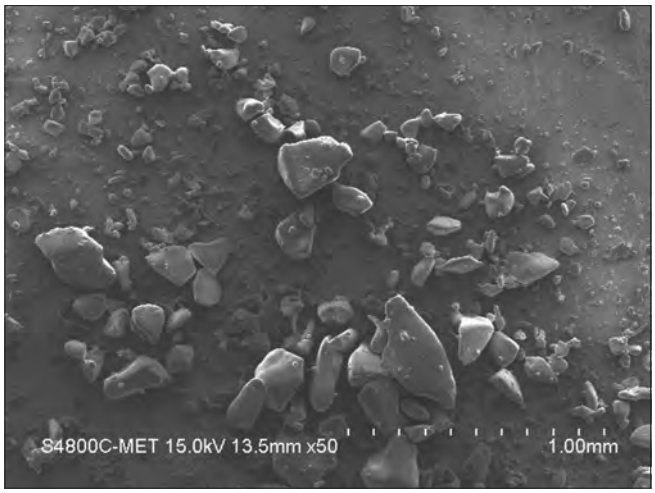

Figure 6: Glass infiltrated zirconia demonstrating irregular spheres

where it was found that alumina particles create a significant increase in the surface area and surface roughness by creating desired micro-retentions onto to the surface.[3]

Hallmann *et al.* evaluated the changes in surface topography after using 150 μm of alumina particles and noted decrease in flexural strength of the zirconia substrate.[10] However studies have noted that surface treatment with 50 μm Al_2O_3 increases the surface roughness and activates the zirconia surface without causing damage.[13,15,21,35] Therefore in this study 50 μm of Al_2O_3 was used for surface treatment.

Alternative techniques such as hot chemical etching, use of lasers, ferric chloride solutions to dissolve zirconia grain structures have been investigated. Hot chemical etching is a corrosion controlled process, which leads to the dissolution of the grain structure present in the zirconia substrate and could prove to be an effective method to improve bonding.[36,37] Another method to improve adhesion is use of tribochemical coating. In this technique, the zirconia substrates are blasted with silica-coated alumina particles under compressed air. These methods lead to deposition of silica particles that helps in improving the adhesion to the zirconia substrate. Several studies have demonstrated higher bond strengths when tribochemical[18] coating combined with silanization compared to air borne particle abrasion alone.[24,38-40] Apart from these techniques, various surface coatings such as nanostructured alumina coating, selective infiltration technique have been researched upon in order to modify zirconia surfaces.[12,41]

Another effective technique is acid etching. Acid etching is known to yield superior results with feldspathic and lithium disilicate reinforced ceramics.[42,43] In aluminum oxide and zirconia-based ceramics, it is seldom used as etching is not the best possible method due to the compact nature

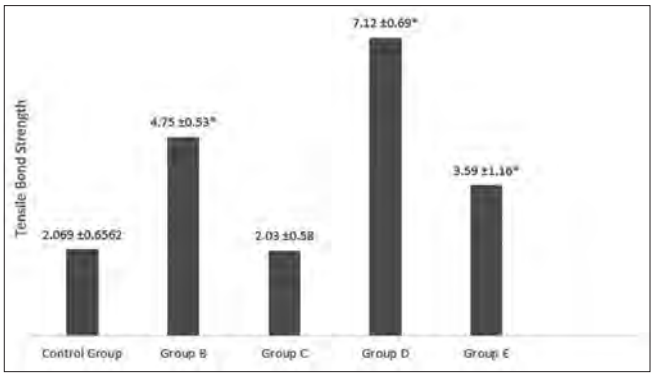

Figure 7: Tensile Bond Strength measured in Mpa

and hardness of zirconia. In addition, lack of silica in the composition of zirconia makes etching difficult in this material.[31,38,43]

Studies have reported that the application of a 9.5% or 5% HF to a zirconia surface does not cause any morphologic changes in its structure, but cleans the surface from organic contaminants.[42] In the present study, 9% HF was used to clean the zirconia surface, in order to remove contaminants. The change in surface roughness was statistically insignificant. Similarly, Goyatá *et al.* investigated the efficacy of acid etching to evaluate the surface roughness of zirconia. They observed that, Y-TZP treated with aluminum oxide particle abrasion leads to enhanced surface roughness as compared to 5 or 9% of hydrofluoric acid.[44]

A promising method for enhancing the bonding of zirconia and improving its mechanical properties is infiltration of silica-based glass in the Y-TZP.[17,45] Vu *et al.* evaluated the effect of glass infiltration on zirconia, they observed that infiltration of silica-containing glass increased the surface roughness as compared to control samples.[46]

In the present study, in-house glass containing (composition aforementioned) was fabricated and coated in thin layer onto the zirconia substrate. The surface roughness showed statistically significant increase in surface roughness as compared to control samples.

In order to evaluate the surface topography of the zirconia samples, scanning electron microscopy analysis was performed for all the groups. No change in surface topography was observed when only primer application was performed on the zirconia substrate. Similarly, 9% HF did not reveal any change in the surface topography. In contrast, irregular glass particles were observed in the substrate. These particles adhered to the surface without causing any irregularities on the substrate.Achieving optimal bonds between the restoration and luting resin is essential

for increasing the longevity of restorations. Differences in conditions of the zirconia surface, chemical and physical properties of luting agents significantly influence the nature of the bonds, the mechanism of bonding, and durability of bonds.[12,33] Y-TZP cannot be bonded using traditional methods due its inertness and resistance to multiple chemical agents. The chemomechanical interlocking between resin cement and ceramics forms the basis for successful bonding.

Primers containing adhesive functional monomers such as MDP, phosphoric acid acrylate monomer and composite resin containing adhesive phosphoric acid group have the potential to improve the bonding to zirconia via surface treatment since zirconia comprises of metal oxides.[12,20] These adhesive monomers are responsible for forming chemical bonds with metal oxides. Interfacial forces like the van-der Waals forces or hydrogen bonds improve the zirconia-resin bonding.[22,33,47] The 10-MDP acidic functional monomer is known to show stable hydrolysis because of its long carbonyl chain. Literature has documented that stable bond between resin cement and Y-TZP zirconia are achieved when MDP-based treatments are used.[33,47-49]

In this study, tensile bond strength to resin luting agent was evaluated following each type of zirconia surface treatment. A statistically significantly higher bond strength ($P < 0.000$) was noted when zirconia samples were abraded with alumina particles followed by the application of primer. This is in agreement with the previous studies performed by Wolfart *et al*.,[27,30] Yang *et al*.[16] and Kern and Thompson.[6]

Studies have reported that the application of MDP containing primer alone without mechanical surface modifications, does not yield superior results.[3,50,51] Similarly, Yang *et al*. noted a higher bond strength when air abrasion was followed by application of MDP primer. This could be as a result of mechanical surface conditioning with air-abrasion, which plays an important role in the bonding by increasing the surface roughness.[34] Moreover, air abrasion removes organic contaminants from ceramic surface, improving the wettability. Thus, allowing a chemical bond between phosphoric acid group of MDP primers and oxide layer of zirconia. Similar results were noted by Kern *et al*.[26]

Several methods have been studied to explore alternative techniques to air abrasion which establish a micromechanical or chemical bond that is durable and stable; some techniques involve adoption of selective infiltration, low-fusing porcelain glaze, deposition of silica nano-structured coatings and use of various types of lasers.[52,53]

Among these, infiltration of silica-containing glass into the zirconia substrate has shown promising results. Powdered glass (composition aforementioned) was used to coat the bonding surface of zirconia. This enabled etching with hydrofluoric acid and silane application to obtain micro-mechanical retention. This method showed statistically significant higher bond strength (3.4 MPa) as compared to the control group and primer application alone. The results of the present study are in agreement with the study performed by Zhang *et al*. and Chai *et al*.[17,45] Zhang *et al*. concluded that, by infiltrating glass, heterogeneous structure can be created that showcases superior properties such as improved aesthetics, higher resistance to flexural damage and supposed improved cementation and veneering properties over homogenous Y-TZP.

In the present study, a statistically significantly higher tensile bond strength was noted in group D as compared to other groups. Similar findings were observed by Wolfart *et al*. and Yang *et al*.[16,30] Adhesive monomers exhibit properties of forging chemical bonds with metal oxides at the resin-zirconia interface.

The failure mode analysis predominantly revealed adhesive type of failure for the untreated specimens and the specimens which were etched without abrasion. Whereas, for air abrasion and glass infiltration treated surfaces, a cohesive failure was observed. The results of the present study are in agreement with previous studies.[10,48,54] Ebeid *et al*. and Hallmann *et al*. noted that surface treatment using air abrasion and glass infiltration leads to a stable bond between the zirconia and the resin cement as compared to untreated surface.

This study was an *in vitro* simulation of the clinically used zirconia restorations. Although standardized protocols for fabrication of the samples and testing of the sample were followed, the actual clinical use of the restorations in daily life can be different and variable. The current study also assessed only a few modification techniques on zirconia substrate.

This being an *in vitro* study, the glass fabricated for infiltration was not checked for biocompatibility.

CONCLUSION

Air abrasion of the zirconia surface with 50 μm alumina particles increases the surface roughness without damaging the surface. Air abrasion followed by MDP primer application is the recommended method of surface

treatment to achieve superior bonding. Glass infiltration also showed promising results in terms of tensile bond strength.

Glass infiltrations with different compositions, physical properties, and thicknesses are the exciting areas of future research, which can be carried out to determine the efficiency and future potential applications of this method without any ill-effects on zirconia substrate.

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Conflicts of interest
There are no conflicts of interest.

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Research

Comparative evaluation of effect of microcurrent electrical stimulation on acupoints to control gag reflex in patients receiving prosthodontic treatment: An *in vivo* study

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Abstract

Aims: The aim of this study is to see if microcurrent electrical stimulation on two acupoints, auricular and Hegus, can help patients prevent their gag reflex.

Settings and Design: This was an *in vivo* cross-sectional study.

Materials and Methods: Thirty patients were randomly assigned to three groups: A, B, or C, of ten patients present in each group. Group A and Group B undergone electroacupuncture (microcurrent electrical stimulation) using electroacupuncture device on auricular point and Hegus point (Li 4), respectively, for 1 min and Group C formed the placebo group, point Shou San Li (Li 10). The gag severity index and the gag prevention index were used to measure the gag reflex, which was done in two steps.

Statistical Analysis Used: SPSS (SPSS Inc., Chicago IL, USA) version 24 software was used for statistical analysis. Paired *t*-test, one-way analysis of variance test, *post hoc* Bonferroni test was used to analyse and compare the data.

Results: It was found that Point A and Point B were significantly effective in reducing the severity of gag reflex. Point C demonstrated insignificant results. In addition, Point B (Hegus [Li4]) is more effective than Point A (auricular) in controlling the gag reflex in patients within the set age group of 20–70 years of age.

Conclusions: Microcurrent electrical stimulation is a useful adjuvant in the treatment of unfavorable gag reflexes during routine dental procedures. Point Hegus and point auricular acupuncture are both useful in decreasing the severity of gag reflex, with point Hegus being more effective than point auricular.

Keywords: Alginate impression, electroacupuncture device, gag reflex, gagging prevention index, gagging severity index, microcurrent electrical stimulation

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INTRODUCTION

The gag reflex is a defensive and physiological system that protects the pharynx, larynx, and trachea from invading noxious stimuli or foreign objects. It is most commonly seen in the practice of dentistry during various dental procedures which can be debilitating, leading to an

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avoidance behavior and eventually compromising the quality of the treatment.[1]

Gagging may be caused by either somatic or psychological factors. Somatic gagging can occur due to the stimulation of the trigger zones around the oropharynx and psychogenic gagging can occur due to any thought, smell, sound, or sight.[2]

Different methods to prevent gag reflex involve relaxation, desensitization, distraction, pharmacological, and psychological techniques as well as other complementary medicine therapies including acupuncture as well as acupressure.[3]

Mild gagging can be easily managed with simple chairside techniques (applying topical anesthetics drugs, table salt, nitrous oxide, and distracting the patient during treatment), but severe gagging can be triggered by any contact with an instrument or previous dental experience, resulting in a compromise in treatment quality and ultimately affecting the treatment outcome.

Gagging is an area of dental study that has yet to be investigated. A hyperactive gag reflex can make dental treatments difficult, such as a simple examination, or even complex procedures such as impressions for crowns and bridges, leaving the patient unwilling to accept complex clinical procedures.

Acupuncture is a modality well explained in the literature for the prevention of gag reflex. It involves the application of needle, vacuum, pressure, electrical, or laser stimulus to specific parts/points on the human body for the prevention of disease, as a therapy or for the maintenance of health.[4,5]

According to traditional Chinese medicine, energy flows along 14 meridians present in the human body, on which certain energy points lies, which when stimulated produces specific effects on the human body.[6]

Electroacupuncture has a definitive role in dentistry, but it is not a substitute for conventional treatments. Controlling this hyperactive reflex will make it easier to provide care.

The overall benefits of an acupuncture-based approach include reduced emetic response, increased patient comfort during dental treatment, and decreased patient/doctor stress, all of which improve treatment success.

The external acoustic meatus's skin and the region adjacent to the auricle correspond to the anti-gagging point present on the ear, i.e., auricular point.[7] The second metacarpal's radial palmar side has a point termed Hegus (LI4), which runs between the adductor pollicis and the first dorsal interosseus muscle.[8] It is possible that stimulating this anti-gagging acupuncture point will prevent the musculature from contracting, thus inhibiting the gag reflex.[2]

There are several researches which suggest that acupuncture on auricular point is helpful in preventing severe gag reflex, while some suggest similar results in regard to Hegus point.[2,7,8]

Therefore, the impact of microcurrent electrical stimulation, a variant of electroacupuncture, which induces low-frequency electrical stimulation of skin sensory receptors, using a meridian acupuncture pen on two acupoints to regulate gag reflex in patients was investigated in this research.

Aim of the study

This study aimed to evaluate the effect of microcurrent electrical stimulation on two acupoints, auricular and Hegus to control the gag reflex among the patients receiving prosthodontic treatment.

Objectives of the study are

1. To evaluate the effect of microcurrent electrical stimulation on auricular point to control gag reflex in patients
2. To evaluate the effect of microcurrent electrical stimulation on Hegus point to control gag reflex in patients
3. To evaluate whether there is an effect of microcurrent electrical stimulation on placebo acupoint (Shou San Li) that is not documented to control gag reflex
4. To compare if there exists any difference in control of gag reflex among patient who receive microcurrent electrical stimulation at documented acupoints and placebo group.

MATERIALS AND METHODS

The research was a 6-month cross-sectional study that began in October 2019–March 2020 after receiving approval from the institutional review board. Ethical committee number- DMIMS(DU)/IEC/Sept-2019/8434.

A total of 30 patients of age 20–70 years were included in the study.

Inclusion criteria

I. A maxillary alginate impression is needed for current dental care (edentulous/partially dentulous/dentulous)
II. According to the gagging severity index (GSI), patients with moderate (Grade III) to very severe gagging (Grade V)
III. Patients who have had a history of gag reflex during the dental impressions procedure
IV. The individual who is capable of giving informed consent.

Exclusion criteria

I. Subjects with systemic disorders and comorbidities affecting psychomotor function
II. Patients who were aware of electroacupuncture as a modality to control gag reflex were also excluded
III. Antiemetic drugs or medications were taken by the patients
IV. Various precautions undertaken to reduce gagging involved consistency (not too thin), position of chair (upright), as well as patients were instructed not to eat for the duration of 2 h before the appointment.

Equipments used in the study

Equipment used in the study was electroacupuncture device (meridian acupuncture pen [Figure 1]).

About the meridian acupuncture pen

Depending on the various areas of application, the electric acupuncture instrument comes with two distinct heads. Sensitivity, intensity, and frequency controls are all customizable as well as it helps in the auto-detection of meridian energy points. It features nine different intensity settings that can be changed according to your needs, and it automatically switches off to prevent overheating and save energy. There is no skin piercing. It is easy to use and transport. There are no adverse effects, and it is completely safe. Both traditional Chinese medicine and western science support the efficacy of the therapy.

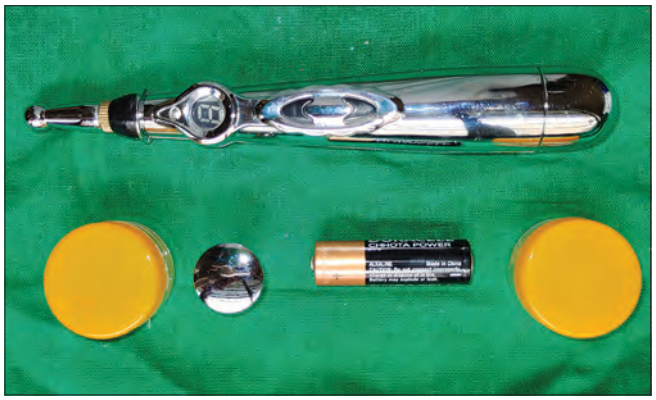

Figure 1: Electroacupuncture device (meridian acupuncture pen)

Device details-

Size of the device: 15 cm × 10 cm × 8 cm

Use with: Massage Gel (shock absorber)

Battery: 1 × AA battery

Output: 3.7V 300 Ma ±/50 mA

Pulse frequency: 0.01–300 Hz

Pulse width: 100 us–320 us.

Two massage gels – ultrasound gel and biofreeze gel were applied before use to lubricate the skin and increase comfort.

Data collection tools

I. GSI[9] [Table 1]
II. Gagging prevention index (GPI)[9] [Table 2].

Location of acupoints

Point A: The auricular point on the ear refers to the external acoustic meatus's skin and the region adjacent to the auricle [Figures 2 and 3].

Point B: The second metacarpal's radial palmar side has a LI4, which runs between the adductor pollicis and the first dorsal interosseus muscles [Figures 4 and 5].

Table 1: Gagging severity index

The GSI[9]	
The gagging reflex is:	
I	Very mild, occasional and controlled by the patient
II	Mild, and control is required by the patient with reassurance from the dental team
III	Moderate, consistent and limits treatment options
IV	Severe and treatment is limited
V	Very severe, affecting patient behaviour & dental attendance and making treatment impossible

GSI: Gagging severity index

Table 2: Gagging preventive index

The GPI[9]	
Treatment management method employed	
I	Obtunded gag reflex; treatment successful
II	Partially controlled gag reflex; all treatment possible
III	Partially controlled gag reflex but frequent gagging; simple treatment possible
IV	Inadequately controlled gag reflex; simple treatment unable to be completed
V	Gag reflex severe; no treatment possible

GPI: Gagging preventive index

Point C: The placebo group, Shou San Li (Li 10), location of acupoint is on the outer surface of the forearm, three-finger space distal to elbow crease when the elbow is bent 90° [Figures 6 and 7].

Methodology

A thorough case history, examination, diagnosis was carried out for the patients reporting to the outpatient department. Before being included in the study, all participants received information about it and signed a written informed consent document.

Patients were randomly assigned to one of three groups: A, B, or C. There were a total of ten patients present in each group within a range of 20–70 years of age. Group A and Group B underwent microcurrent electrical stimulation using meridian acupuncture pen on auricular point and L4, respectively, for 1 min and

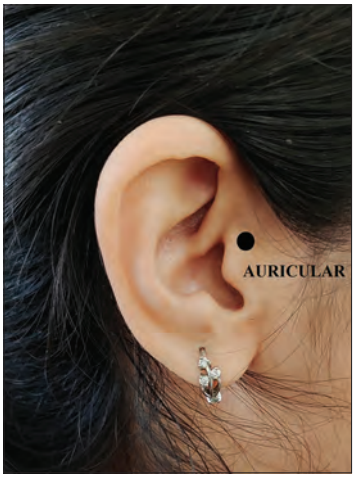

Figure 2: Auricular point

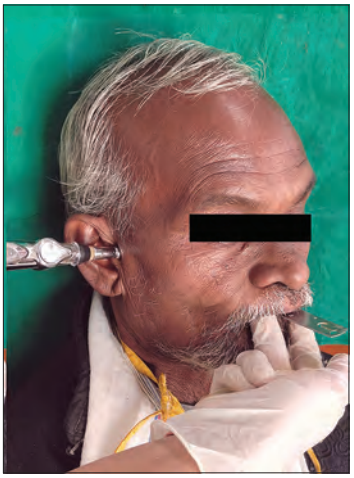

Figure 3: Auricular point (clinical depiction)

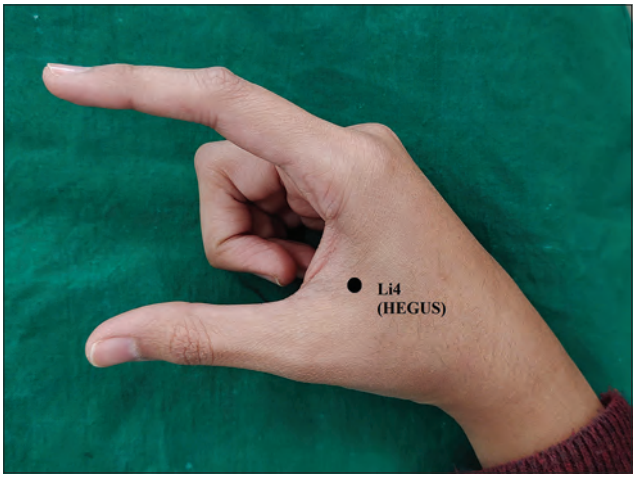

Figure 4: Hegus point

Figure 5: Hegus point (clinical depiction)

Figure 6: Shou San Li point (placebo)

Group C formed the placebo group with Li 10 point to eliminate the bias. The placebo point served the purpose of blinding the subject and also the observant. The observer was independent of the study group without having any knowledge about the study acupoints and single observers recorded the observations to eliminate the observer bias.

The GSI and the GPI were used to measure the gag reflex, which was done in two steps. Before the application of microcurrent electrical stimulation, the gag reflex severity was determined using the GSI for each treatment group. The GPI was used to evaluate the microcurrent electrical stimulation efficacy after the procedure. In Stage I, the patient's tolerance for an empty tray[4] being placed intraorally was assessed, in which GSI was taken, while in Stage II, the patient's tolerance for a loaded tray being placed intraorally was assessed, in which GPI was taken. Impressions were made during the microcurrent electrical stimulation. The empty tray was used to assess the severity of gag index in place of any other instrument such as mouth mirror or finger with the purpose that if the severity of gag is more while placing an empty tray, it will definitely be much more when it will be loaded. Hence, the necessary prevention will be required after loading the tray.

Participants

Three groups (10 patients in each group divided randomly):

1. Participants receiving microcurrent electrical stimulation on Hegus point
2. Participants receiving microcurrent electrical stimulation on auricular point
3. Participants receiving microcurrent electrical stimulation on Shou San Li point which is not documented to reduce gag reflex (placebo).

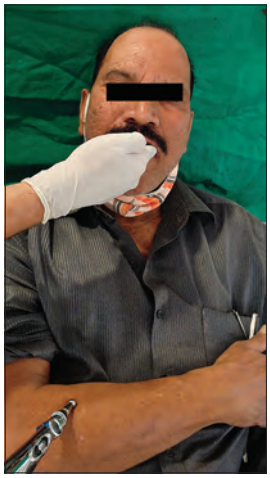

Figure 7: Shou San Li point (placebo) (clinical depiction)

Statistical analysis of observations

Statistical analysis was done using the SPSS (SPSS Inc., Chicago IL, USA) version 24 software. To determine the scores of GSI and GPI, Paired *t*-test was used. Intergroup comparison was done by one-way analysis of variance test. Intragroup comparisons were assessed by *post hoc* Bonferroni test and $P < 0.05$ was taken as a standard level of significance.

RESULTS

From the above statistical analysis, it was observed that $P < 0.05$ is the level of significance. Out of the 30 subjects, the results were tabulated for preapplication and postapplication of acupuncture at the respective points [Tables 3-10]. It was found that Point A and Point B were significantly effective in reducing the severity of GR. Point C demonstrated insignificant results. In addition, Point B – Hegus (Li4) – is more effective than Point A – auricular in controlling the GR in patients within the set age group of 20–70 years of age.

Table 3: Results-gagging severity index and gagging preventive index (Hegus)

	Mean	*n*	SD	SEM	*t*
GSI	3.60	10	0.69	0.22	14.69
GPI	1.20	10	0.42	0.13	*P*=0.0001 (S)

GPI: Gagging preventive index, GSI: Gagging severity index, SEM: Standard error mean, SD: Standard deviation, S: Significant

Table 4: Results-gagging severity index and gagging preventive index (auricular)

	Mean	*n*	SD	SEM	*t*
GSI	3.70	10	0.67	0.21	10.58
GPI	1.80	10	0.42	0.13	*P*=0.0001 (S)

GPI: Gagging preventive index, GSI: Gagging severity index, SEM: Standard error mean, SD: Standard deviation, S: Significant

Table 5: Results-gagging severity index and gagging preventive index (placebo)

	Mean	*n*	SD	SEM	*t*
GSI	3.40	10	0.51	0.16	1.50
GPI	3.20	10	0.63	0.20	*P*=0.16 (NS)

GPI: Gagging preventive index, GSI: Gagging severity index, SEM: Standard error mean, SD: Standard deviation, NS: Not significant

Table 6: Comparison of gagging severity index score in three groups

Group	*n*	Mean	SD	SE	95% CI for mean		*F*
					Lower value	Upper value	
Hegus	10	3.60	0.69	0.22	3.09	4.10	0.57
Auricular	10	3.70	0.67	0.21	3.21	4.18	*P*=0.56 (NS)
Placebo	10	3.40	0.51	0.16	3.03	3.76	

SD: Standard deviation, NS: Not significant, SE: Standard error, CI: Confidence interval

Table 7: Gagging severity index-bonferroni multiple comparison test

Group	Mean difference (I-J)	SE	*P*	95% CI	
				Lower value	Upper value
Hegus					
Auricular	−0.10	0.28	1.000(NS)	−0.82	0.62
Placebo	0.20	0.28	1.000 (NS)	−0.52	0.92
Auricular					
Placebo	0.30	0.28	0.901 (NS)	−0.42	1.02

NS: Not significant, SE: Standard error, CI: Confidence interval

Table 8: Comparison of GPI score in three groups

Group	*n*	Mean	SD	SE	95% CI for mean		*F*
					Lower value	Upper value	
Hegus	10	1.20	0.42	0.13	0.89	1.50	41.82
Auricular	10	1.80	0.42	0.13	1.49	2.10	*P*=0.0001
Placebo	10	3.20	0.63	0.20	2.74	3.65	(S)

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

Table 9: Gagging preventive index-bonferroni multiple comparison test

Group	Mean difference(I-J)	SE	*P*	95% CI	
				Lower value	Upper value
Hegus					
Auricular	−0.60	0.22	0.038 (S)	−1.17	−0.02
Placebo	−2.00	0.22	0.0001 (S)	−2.57	−1.42
Auricular					
Placebo	−1.40	0.22	0.0001 (S)	−1.97	−0.82

S: Significant, SE: Standard error, CI: Confidence interval

Table 10: Percentage of improvement amongst all the three groups

Group	Percentage of improvement
Hegus	66.66
Auricular	51.35
Placebo	5.88

DISCUSSION

Acupuncture can be used as an adjunct therapy or as an appropriate substitute for a variety of medical conditions, and it can be incorporated into a comprehensive management program (National Institutes of Health, 1997). The gag reflex is triggered when trigger zones in the posterior region of the oral cavity, which are innervated by the glossopharyngeal nerve, are activated. Acupuncture activates muscular myelinated nerve fibers, which deliver impulses to the spinal cord and then activate the midbrain and pituitary–hypothalamus.[10] Enkephalin, beta-endorphin, serotonin, dynorphin, and noradrenalin have all been found to be involved in the process.[11] The activation of acupoints such as Hegus and auricular causes impulses to flow to the nucleus of the raphe magnus in the midbrain, which is the brain's primary source of serotonin (5-HT). This is converted to beta-endorphin, which has anti-emetic properties. As a result, when acupoints are activated, the serotonin pathway is triggered, releasing 5-HT, which helps to suppress the gag reflex.[12]

Several studies were conducted in the literature for the prevention of gag reflex among patients.[2,8,13] In a study of 48 patients, Sivinagini V used acupuncture and acupressure to avoid gag reflexes and discovered that the Hegus point (LI4) is successful in regulating the gag reflex.[8] Another research, conducted on ten patients by Hashim *et al*., found that ear acupuncture on the auricular point is effective in the management of the gag reflex.[13] Fiske G in his study conducted on 10 subjects for the prevention of gag reflex using acupuncture in the auricular point concluded the ear acupuncture to be effective in its management.[2]

Microcurrent electrical stimulation, a form of electroacupuncture, induces low-frequency electrical stimulation of skin sensory receptors, which causes the hypothalamus to release endorphins. Compelling literature exists to support the use of microcurrent electrical stimulation in various other human applications.[14-16] In a meta-analysis comparing microcurrent electrical stimulation, laser acupuncture, acupressure, and acupuncture, it was found that microcurrent electrical stimulation has a greater effect in prevention of the gag reflex.[17] Furthermore, according to a research conducted by Ulett GA *et al*., in 1998, electroacupuncture was found to be more efficient than manual acupuncture.[18]

The impact of microcurrent electrical stimulation on two acupoints to regulate gag reflex in patients was investigated in this research. The two acupoints which were chosen are auricular and Hegus points. A third point was also included Shou San Li (Li 10) (placebo), to eliminate the bias. This placebo point served the purpose of blinding the subject and also the observant. The chosen placebo point is used to treat anxiety in traditional Chinese medicine. To test the efficacy of microcurrent electrical stimulation on a point that does not have any anti-gag reflex action, the placebo point was chosen differently from the acupuncture points Hegus and auricular.

In this research, a meridian acupuncture pen was used for the application of microcurrent electrical stimulation. It is a dual-purpose handheld device which is battery operated, provided with a gel which act as a shock absorber. It provides painless stimulation without any piercing of skin.

The results of this study showed that there was a statistically significant reduction in the gag reflex among patients after

the microcurrent electrical stimulation was applied on the points Hegus and auricular. There was no significant reduction in the gag reflex in the placebo group of patients after receiving the microcurrent electrical stimulation. In addition, point Hegus was proved to be more effective than point auricular in the reduction of gag reflex.

Other studies concerning other methods for the prevention of gag reflex such as laser acupuncture or needle acupuncture has its own disadvantages such as pain at the respective sites, vertigo, or drop of blood pressure if the vessel is close to the site.[19] But in this study, none of the above disadvantages were observed.

This research aids to the knowledge that an easily available device like a meridian acupuncture pen can be easily used in daily clinical practice for the application of microcurrent electrical stimulation on two easily identifiable points over the body aiding in the reduction of troublesome gag reflex.

Limitations

Several other anti-gag points have been documented in the literature that were not taken into consideration in this study, and their effectiveness remains unknown.

Gender predilection was not taken into account in this study.

Microcurrent electrical stimulation has not been compared to other management techniques for reducing gag reflexes.

Long-term investigations will provide more substantial results.

CONCLUSION

As per the results of this study, it is recommended that microcurrent electrical stimulation is a useful adjuvant in managing unfavorable gag reflexes during conventional dental procedures. The effectiveness of microcurrent electrical stimulation at point Hegus and point auricular in decreasing the severity of gag reflex has been demonstrated in this study, with point Hegus being more effective than point auricular. The procedure is safe, rapid, low cost, and noninvasive. As a result, it appears as a novel method of controlling gag reflex in patients receiving the prosthodontic treatment.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initial s will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Case Report

Novel prosthodontic technique in fabrication of customized nasal stent in an infant

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Abstract

Burn injuries have a major impact on the physical and functional aspects of patients, thereby affecting their quality of life. Nasal stenosis which occurs as a result of wound contraction may lead to serious complications if not intervened at the earliest. In the prosthodontic front, nasal stents may be utilized in conjunction with reconstructive surgery procedures to minimize scar contraction and prevent nasal stenosis. This clinical report focuses on a customized technique in the fabrication of nasal stent to maintain the nasal airway patency in an infant who had suffered burn injuries. An intraoral tip was employed as a receptacle for accurate impression making, followed by the insertion of an intermediate stent fashioned from a scalp vein set catheter. The definitive stent fabricated using methyl methacrylate resin served to maintain the patency of the nasal passageway.

Keywords: Burns, intraoral tip, nasal stenosis, nasal stent

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INTRODUCTION

The nose is one of the most prominent features of the face. Due to its critical location and projected anatomy, it is often prone to damage from various congenital and acquired deformities.[1]

Sequelae of burn injuries have a major impact on the individual's psychological and social status. In addition, nasal stenosis which occurs as a result of burn injuries can lead to various consequences such as reduction in nasal diameter, reduced efficiency in nasal breathing, asymmetrical nostrils, oral breathing, dry mouth, susceptibility of oral mucosa to inflammation, and disturbance in cranial growth and development.[2] The treatment of an individual who has sustained extensive burns poses a challenge to the skills of professionals in various health care disciplines. In the prosthodontic front, nasal stents may be utilized in conjunction with reconstructive surgery to minimize scar contraction following skin grafting procedures or to counteract previously formed scar tissue and widen the nostrils prior to the grafting procedures.[3]

Nasal stents should be inserted early in the primary stage of healing. In case of narrowing, a serial nasal stenting protocol can be followed to gradually increase the nasal passageway.[4] The common feature in the construction of nasal stents is the use of burs to hollow out the stents for respiration. This is difficult and time consuming, especially when the impression takes a tortuous path.[5]

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This case report highlights a technique in the fabrication of an individualized and custom-fashioned nasal stent for an infant who had suffered burn injuries. The prosthetic treatment goal was to maintain a patent nasal airway during the healing process with minimal discomfort to the patient.[6] A noninvasive, cost-effective, noncollapsible, and tissue-tolerant intraoral tip was employed as a receptacle for accurate impression making which was a prerequisite in the fabrication of the hollow nasal stent. Following the impression procedure, a novel, customized bilateral nasal stent fashioned out of a scalp vein set catheter was inserted.[7] Prior to the delivery of the definitive stent made of heat-cure methyl methacrylate resin, this immediate stent served to guard the patency of the nasal passageway.

CASE REPORT

A 10-month-old female child was referred to the Department of Prosthodontics from the Department of Plastic Surgery seeking prosthetic aid for the maintenance of patency of the nostrils. The patient suffered burn injuries all over the body due to accidental spill of boiling water 4 days prior and was admitted to the casualty ward with 51% burns on the face, trunk, and extremities. The patient was treated with split skin graft and dressing only at the chest and abdominal region. She was referred by the plastic surgeon for the fabrication of a nasal stent to prevent nasal stenosis resulting from wound contraction, facilitate proper breathing, and ensure internal airway patency.

On examination, the patient was alert, well-oriented, and in no acute distress. Close, visual inspection under direct lighting showed epidermal burn on the external surface of the nose and blanched areas. The nostrils were asymmetrical with constriction in relation to the right side. The skin was firm, free from discharge and eruptions [Figure 1]. No surgical intervention was performed on the nose as such. Intranasal stent was fabricated taking into consideration the age, nasal esthetic subunits, and the comfort of the patient ensuring nontraumatic maintenance of the internal airway patency during wound healing.

The patient was seated upright on the parent's lap with the head supported on the parent's bosom and stabilized to prevent any untoward movement of the patient during the clinical procedures. This also helped in limiting the posterior-superior flow of impression material and avoiding distortion of the soft tissues during impression making of the nasal vestibule.

Intraoral tips (yellow mixing tips; Shreem Inc. India) [Figure 2] were inserted to an approximate length of the nasal vestibule and the dimensions were marked. Tray adhesive (Tray adhesive; Medicept UK Ltd, Middlesex, United Kingdom) was applied up to the demarcated portion of the tips and allowed to dry. The nasal cavity was smeared gently with petroleum jelly to facilitate the ease of insertion and removal of the impression. An impression of the nasal cavity was made with addition silicone heavy body (Reprosil, Dentsply Caulk, Milford, USA) using the demarcated intraoral tips as receptacles [Figure 3a and b]. The taper and contour of the tips served to conform to the anatomy of the nasal cavity. Care was taken not to force the impression material beyond the nasal cartilage. The impression of the right and left nasal cavities were made separately to avoid breathing difficulty [Figure 3c]. In addition, silicone putty (Elite P and P putty soft-normal set; Zhermack, Rovigo, Italy) was used to record the external anatomy of the nose including the columella, tip and the alae, and pick up the intranasal impressions [Figure 3d]. The putty impression, along with the intranasal impression, was retrieved and inspected for accuracy [Figure 4].

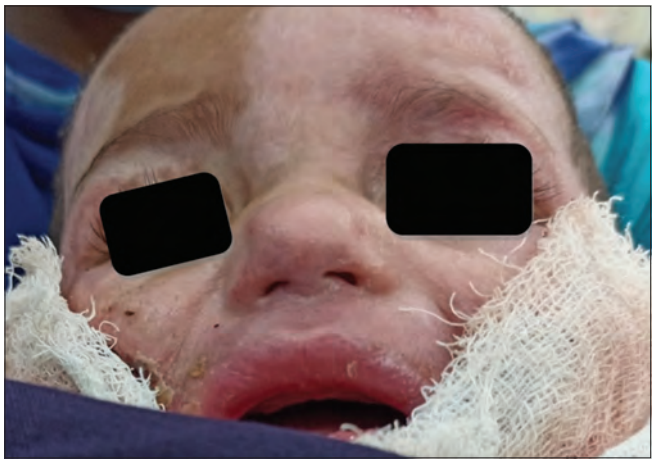

Figure 1: Preoperative photograph of the patient

Figure 2: Intraoral tips

A silicone scalp vein set catheter (Angle Scalp vein set; Devparv Surgico, Ahmedabad, India) [Figure 5a] conforming to the size of the nostril was bent into U-shape and cut according to the length and width of the columella to be inserted through the two nostrils [Figure 5b]. This served as an intermediate nasal stent until the definitive stent was fabricated for insertion [Figure 6].

The impressions of the external form of the nose and nasal passages were beaded, boxed, and poured with Type IV dental stone (Kalrock, Kalabhai Karson Pvt Ltd, Maharashtra, India) using the split cast technique. The intraoral tips were retained and secured in position to maintain the lumen of the nasal stent [Figure 7].

The assembly was flasked and cured in heat-cure methacrylate resin (DPI Heat cure; Dental Products of India, Maharashtra, India) using split mold technique [Figure 8a] with different compartments to acrylize the stent [Figure 8b]. The definitive cast (split cast) was invested in the lower half of the flask, over which the index with intraoral tips was placed. The intraoral tips served to maintain the patency of the lumen throughout the acrylization procedure. After retrieval of the nasal stent, the intraoral tips were discarded. The stent was finished, polished [Figure 9a and b], and inserted with utmost care to avoid any insult to the delicate nasal mucosa ensuring the closest adaptation. The stent was self-retentive due to the projected intranasal portion and the winged extensions over the external surface of the nose.

The parents were educated on home care maintenance and usage of the prosthesis postinsertion. Proper cleansing and flushing of nasal secretions from the surface of the stent were demonstrated. Regular follow-up appointments were scheduled at regular intervals for 2 months and the postoperative results were satisfactory with adequate healing and least complications. Noticeable improvement of the nares was seen during the subsequent follow-up visits [Figure 10].

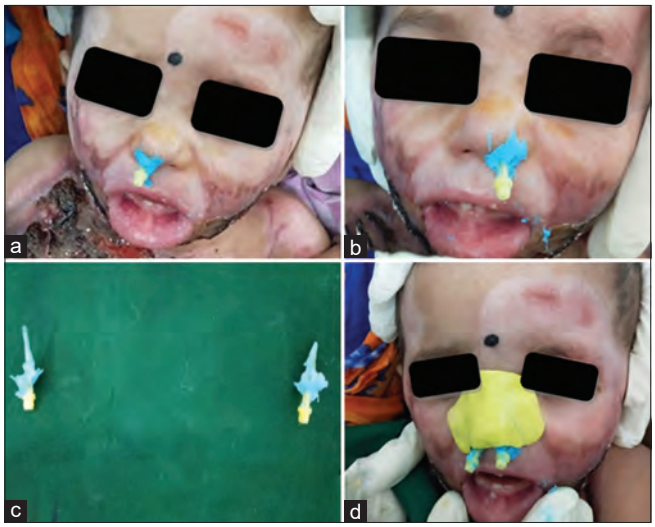

Figure 3: (a) Intranasal impression (right), (b) intranasal impression (left), (c) separate impressions of the right and left nasal vestibule, and (d) impression of the nose made using putty elastomeric impression material

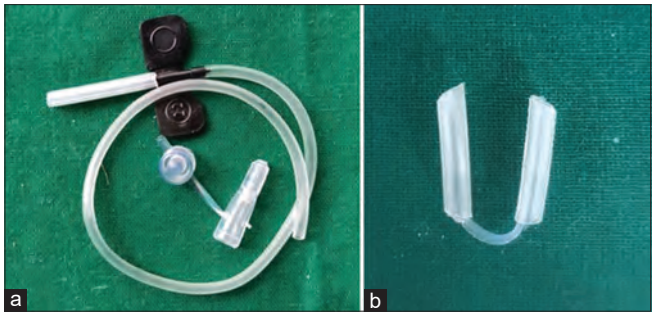

Figure 5: (a) Scalp vein set catheter, (b) customized immediate nasal stent

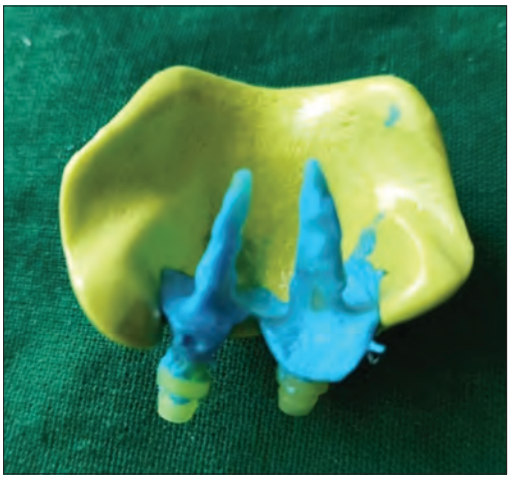

Figure 4: Complete impression of the external nose and nasal vestibule

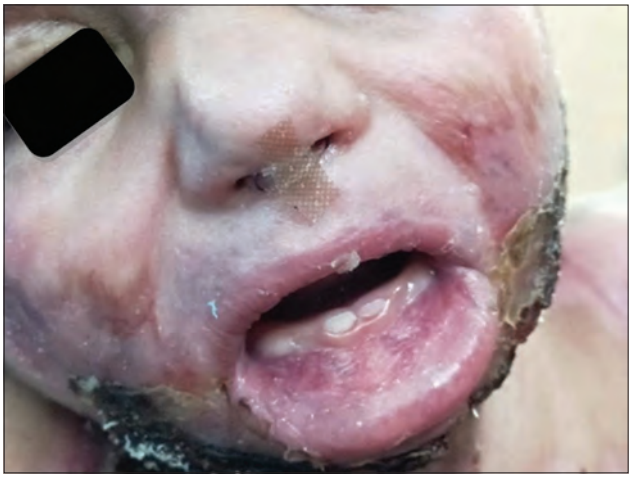

Figure 6: Post insertion of the immediate nasal stent

DISCUSSION

Nasal stenosis which occurs as a result of burn injuries can lead to various consequences if not treated promptly. Symmetry, contour, and function are the three goals of nasal reconstruction. Dorsum, lateral surface, alae, and the tip-columella complex which form the nasal esthetic subunits define the anatomy of the nose and must be given due priority in case of burn injuries.[8] A comprehensive reconstructive treatment plan must begin with a proper diagnosis and an understanding of prosthodontic treatment. The nasal stent must be stable and designed in such a way so as to maintain the patency of nasal cavity as well as negate the inevitable effects of gravity and distortion phenomena related to scarring.[2]

In the case presented here, owing to the minimal dimension of the nostrils, a customized receptacle was a challenge for impression making. The use of an intraoral tip with a tapering lumen and curved architecture helped serve the purpose to an effective extent. A customized impression technique using an intraoral tip helped us in omitting the tedious task of hollowing the stents using burs which would have caused deterioration of the stent. The laboratory technique was further simplified by using the elastomeric impression material as a model for stent fabrication, thereby eliminating dewaxing procedures. The functional and anatomical dimensions of the nose were given due importance throughout the treatment.

A vented custom made heat processed acrylic stent or silicone stent is commonly indicated in case of bilateral anterior obstruction in younger patients.[9] Hard acrylic stents are advantageous in that they are rigid, prevent collapse of the nasal wall, and can be precisely shaped, trimmed and polished to a smooth finish. They can accommodate slight undercuts and reportedly provide a scaffold for mucosal regeneration and minimize scar formation.[10] Although a few demerits such as long-term usage, low patient tolerance, and probability of mucosal irritation due to improper insertion exist, the merits outweigh them. Risk for dislocation and aspiration of the stent is also minimal in hard acrylic stents compared to surgical packs and silicone stents. Moreover, they are economical but their usage is limited to small defects in the anterior nasal cavity with nonstretchable nostrils.[2]

Although silicone stents are effective alternatives for nasal stenting in children, they are porous, friable, and lead to sorption of nasal secretions resulting in irritation of

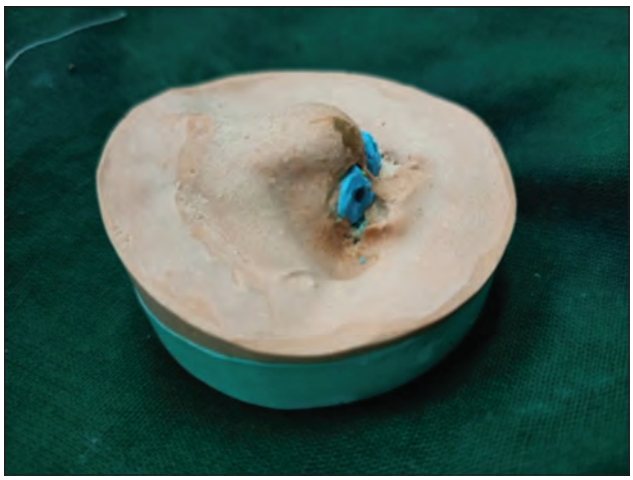

Figure 7: Definitive cast poured with Type IV dental stone using split cast technique

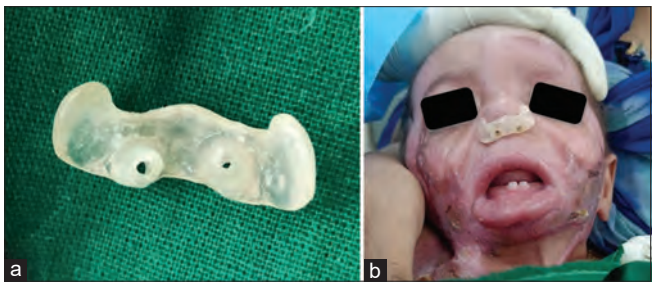

Figure 9: (a and b) The definitive nasal stent finished, polished and inserted

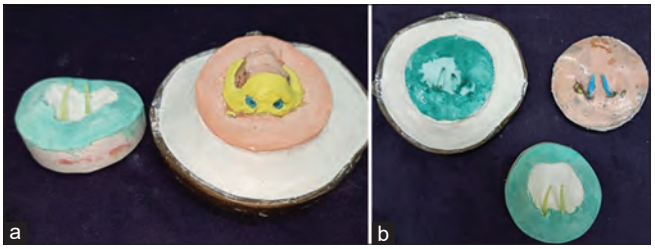

Figure 8: (a) Flasking of the assembly using split mold technique, (b) different compartments of the split mold

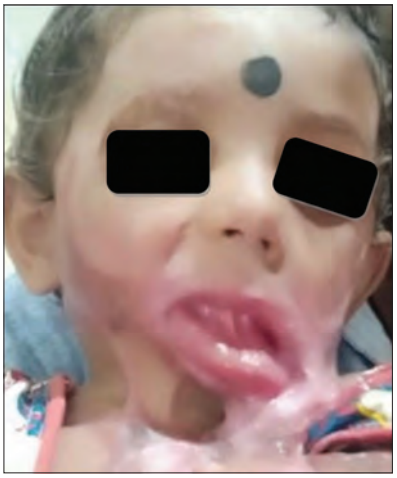

Figure 10: Postoperative follow-up after 6 months

tissues from adhesion of mucus crust and tearing of the material. In addition, they can be prone to fungal growth and failure to achieve the goal of reconstruction. They may also require additional reinforcement within the lumen to prevent collapse of the nares during inhalation.

CONCLUSION

The prosthodontic treatment of burn injuries balances the seemingly disparate goals of establishing structure, improving contour, and esthetics as well as restoring the patency and function of the nasal airway. The treatment modality presented here helped serve the dual purpose of minimizing scar contraction due to burn injuries and also fend off surgical intervention as a consequence. The custom-fabricated nasal stent discussed here was self-retentive, atraumatic, and conformed well to the internal nasal passageway. This technique is not only conservative but also serves to prevent further complications like restenosis of the nasal passageway due to extensive wound contraction in the long run.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initial s will not be published and due efforts will be made to conceal their 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

Palatopharyngeal obturator prosthesis – A substitute for a dynamic separator: A technique

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Abstract

The dynamic of velopharyngeal sphincter mechanism is a complex motor skill involving coordination of soft palate and posterior and lateral pharyngeal walls. At rest, the soft palate drapes downward so that the oropharynx and the nasopharynx open allowing for normal breathing. However, during deglutition and certain speech, sounds such as plosives require complete or nearly complete velopharyngeal closure, whereas during utterance of vowels, the port needs to be open at varying degrees. Defects in velopharyngeal mechanism lead to hypernasality and decreased intelligibility of speech. The aim of this article is to understand the technique used to rehabilitate a patient with velopharyngeal insufficiency using a palatopharyngeal obturator prosthesis connected via a metal velar connector to a maxillary complete denture, with nasal endoscopic and lateral cephalometric examinations done to evaluate the outcome.

Keywords: Lateral cephalometry, metal velar connector, nasal endoscopy, palatopharyngeal obturator prosthesis, speech assessment

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INTRODUCTION

Velopharyngeal sphincter mechanism is a complex motor skill involving the middle one-third of the soft palate arcing upward and backward to contact the posterior pharyngeal wall. The lateral pharyngeal walls move medially while the posterior pharyngeal wall moves anteriorly to facilitate contact with the elevated soft palate.[1,2] This mechanism regulates speech utterance and resonation and also partakes in nonspeech oral activities, such as deglutition, whistling, blowing, and sucking. Velopharyngeal deficiencies are classified based on physiology and structural integrity as palatal insufficiency, which is inadequate length of hard and/soft palate, and palatal incompetency, which states that the velopharyngeal structures are normal; however, the mechanism is affected due to some neurological deficits.[1,2] The following case was diagnosed as palatal insufficiency. Hence, a palatopharyngeal obturator prosthesis was planned which was connected to the upper denture through a thin cast metal velar connector instead of using the conventional acrylic resin connectors incorporated with wire, which has been shown to exhibit fracture due to extensive cantilever action, weight, and has a greater tendency for tongue interference.[3,4] An acrylic obturator was fabricated instead of a silicon obturator as it is prone to fungal infections and gets deformed during mastication.[5,6]

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CASE REPORT

A male patient aged 60 years reported to the Department of Prosthodontics, Tamil Nadu Government Dental College and Hospital, with a chief complaint of hypernasality with speech, nasal regurgitation, and complete edentulism. The patient had a history of squamous cell carcinoma of the oropharynx, involving the left side of the soft palate. Surgical excision was done 4 years back, followed by concurrent chemoradiotherapy. The size of the defect was 2 cm × 3 cm with slight deviation of uvula to the left side [Figure 1].

Preliminary impressions were made [Figure 2], and a diagnostic cast was obtained wherein a special tray was fabricated with autopolymerizing resin (DPI autopolymerizing resin) such that it had a velopharyngeal extension with serrations for retaining the border molding material; this extension was connected via a "U-"shaped loop using a 21-gauge stainless steel wire (KONARK.) [Figure 3]. Low fusing impression compound (DPI pinnacle tracing stick) was used for peripheral tracing of upper arch followed by the tracing of defect area which should begin in the anterior margin and proceeded posterolaterally.[1,2]

Series of movements were performed to record the defect area[1,2] by asking the patient to move his head in a circular manner and head extended forward and downward and patient was then instructed to speak. Excess material was trimmed off, and the movements were repeated until there was a uniform contact obtained. Finally, a wash impression was obtained using light body-condensation silicone impression material (Zhermack, Italy) [Figure 4]. An altered master cast made of type IV dental stone material(ultrareal die stone) was obtained [Figure 5]. Tentative jaw relation was recorded. Facebow record was obtained and transferred to a semi-adjustable articulator (Hanau wide view 183).

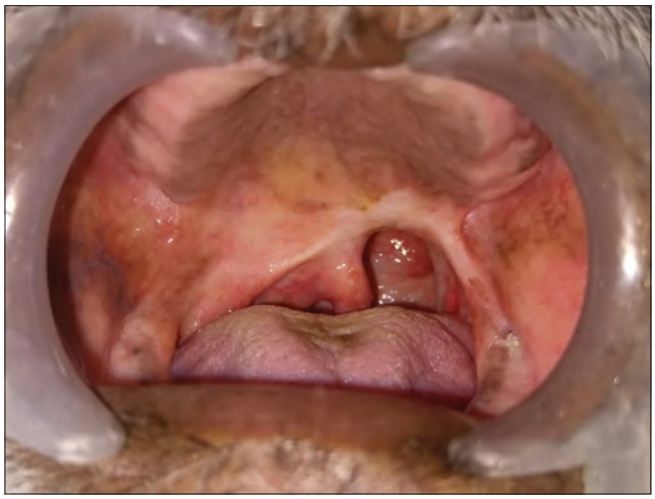

Figure 1: Intraoral view of defect involving left side of soft palate with deviation of the uvula to the respective side

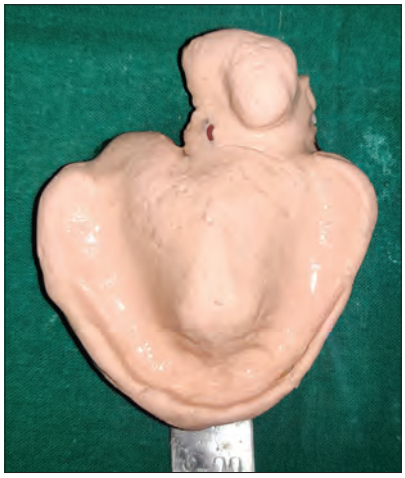

Figure 2: Preliminary impression

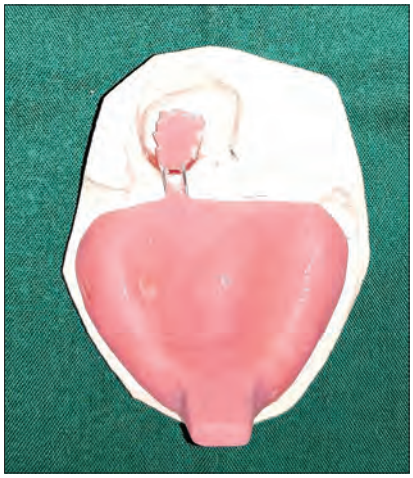

Figure 3: Customized tray with serrations in extension area

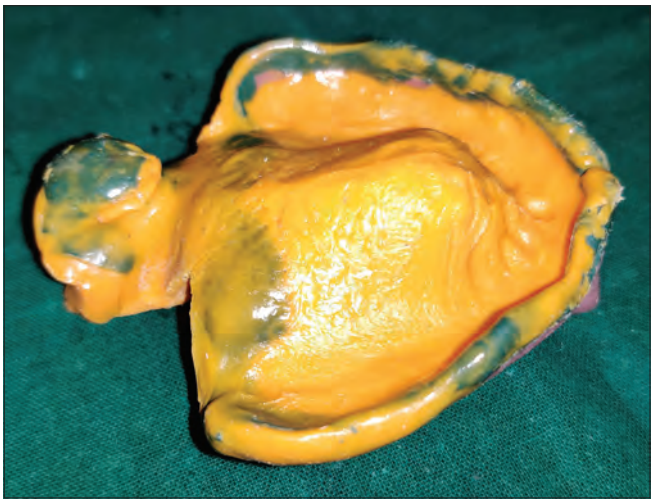

Figure 4: Wash impression made with light body condensation silicone

Tooth setting in balanced occlusion was done. Try-in was verified. Wax pattern for the metal velar connector was made such that it had an external finish line which lies along the posterior vibrating line and an internal finish line along the anterior border of the defect and had loop extensions for attachment into acrylic resin over the palate and into the defect.[3] Wax pattern was cast to get a thin metal velar connector made of Co-Cr[3,4,7] [Figure 6]. Denture was processed using heat-cured acrylic resin while the obturator with clear heat-cured acrylic resin (DPI Clear heat cure acrylic resin). At the time of insertion, retention and stability of denture were evaluated and tissue conditioner (GC soft liner, Tokyo, Japan) was applied. Bulb extension was checked by asking the patient to do the functional movements. No tongue interference, gagging, and difficulty in breathing was experienced by the patient during evaluation. Postdenture insertion, lateral cephalometric radiographic evaluation was done with soft palate at rest without prosthesis [Figure 7] and with prosthesis wherein tempered gutta percha (2–3 mm thick) was adapted over the pharyngeal bulb for radiopacity; here, a gap of 3–4 mm can be seen between the posterior border of the bulb and the posterior pharyngeal wall when soft palate is at rest which facilitates nasal breathing [Figure 8]. Nasal endoscopic examination was carried out with and without the prosthesis at rest and during function [Figures 9 and 10]. Nasal endoscopy gives the visualization of velopharyngeal sphincter mechanism from above. It detects the hypoplasia of musculus uvulae, closure of adenoids, and gaps or leakage surrounding obturator prosthesis.[1] Temple street scale rating [Table 1] introduced by Temple street was used to rate hypernasality, hyponasality, and nasal airflow errors for speech assessment.[8] The patient was asked to

Table 1: Temple street scale for hypernasality

Temple street scale rating	Scale vales and inference
0	Absent
1	Mild - evident but acceptable
2	Mild/moderate - unacceptable distortion, evident on high vowels
3	Moderate - evident on high and low vowels
4	Moderate/severe - evident on all vowels and some consonants
5	Severe - evident on all vowels and most voiced consonants

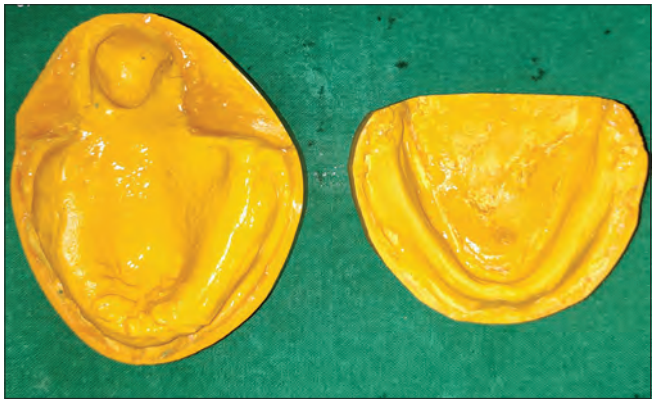

Figure 5: Altered master cast

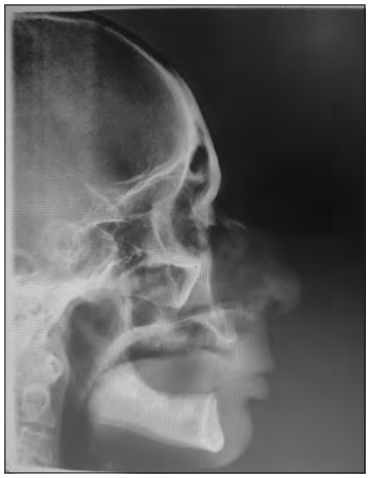

Figure 7: Left lateral cephalogram of patient without prosthesis at rest

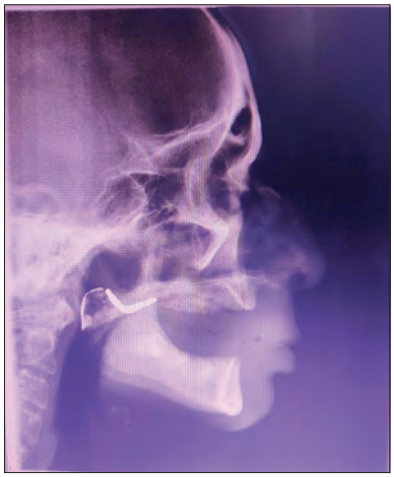

Figure 6: Cast metal velar connector made of Co-Cr

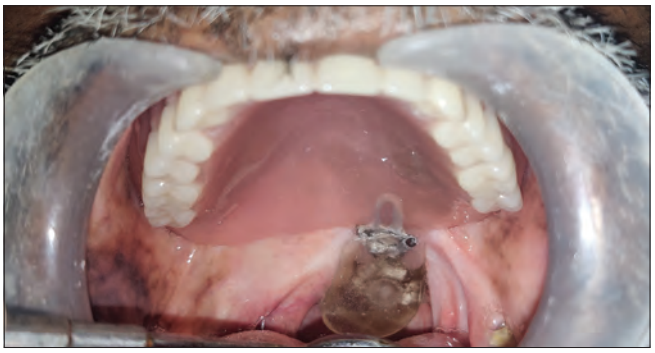

Figure 8: Left lateral cephalogram of patient with prosthesis at rest coated with gutta percha showing 2–3 mm gap between obturator and posterior pharyngeal wall

count from 1 to 20 and to repeat 20 words which included all phonemes of local language. Then, the inference was perceived based on perceptual assessment and audio records on two occasions with 2 weeks gap. Speech scale of the patient without the prosthesis was 4 and with prosthesis was 1. A speech pathologist hence confirmed that hypernasality was reduced, and the patient was advised for further speech training classes. The patient was reviewed after 1 week and was not associated with any discomfort and speech hindrance [Figure 11].

DISCUSSION

An adequate velopharyngeal closure prevents the passage of air from the oropharynx into nasopharynx, i.e., maintaining a balanced oral and nasal resonance.[9] A gap of around 5 mm should be present between posterior border of obturator and the pharyngeal walls at rest and adequate valving should be provided for speech.[1] Walter and Karnell *et al.* cautioned that swallowing should not be used to develop an obturator bulb physiologically, as the velopharyngeal musculature contracts more during deglutition compared to speech, resulting in an under extended bulb prosthesis.[10,11] In normal patients, closure of soft palate against the posterior pharyngeal wall extends approximately 5–7 mm in vertical height.[12,13] According to Beumer *et al.*, the guidelines for location of obturator segment of prosthesis are as follows.[1,2] It should be located in the nasopharynx at the level of normal velopharyngeal closure. Superior margins should not extend above the level of muscular activity, while the inferior margin should not extend below the level of residual velopharyngeal muscular activity, and its inferior extension should be an extension of palatal plane to posterior pharyngeal wall.

A customized palatopharyngeal bulb was fabricated with the following features: its superior surface was made convex and polished to facilitate deflection of nasal secretions,[1] its inferior surface was made slightly concave to prevent tongue interference,[1] its lateral margins were polished to improve hygiene and deflection of secretions and the bulb had a superior extension of around 8 mm, and its lateral dimension was determined by lateral and posterior pharyngeal wall movements during border molding.[1] Moreover, 3–4 mm space was provided between posterior border of the bulb and posterior pharyngeal wall at rest. Evaluation of the patient after rehabilitating the defect with this customized palatopharyngeal bulb showed speech improvement and reduced hypernasality. The patient was asked to swallow water and checked for nasal regurgitation which was negative. Periodic recall was followed to get a proper position and satisfactory contour of the obturator.

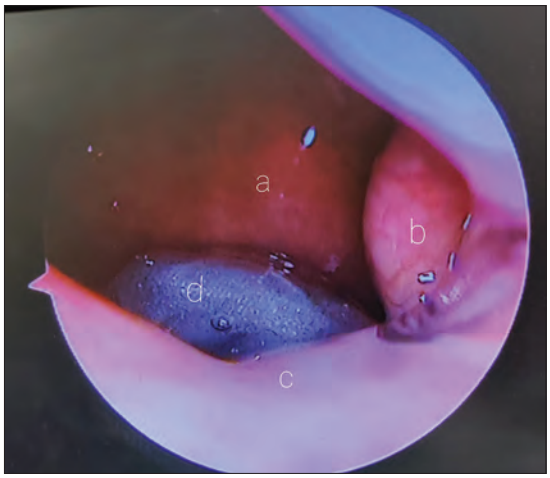

Figure 9: Nasal endoscopic view with prosthesis at rest presenting slight gap between obturator and the pharyngeal walls – (a) posterior pharyngeal wall, (b) lateral pharyngeal wall, (c) soft palate, (d) obturator

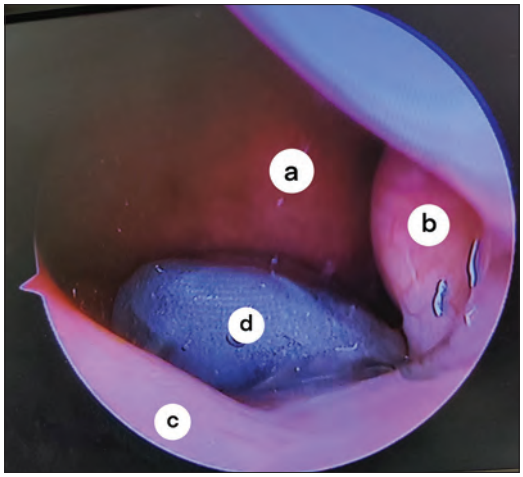

Figure 10: Nasal endoscopy at rest image view with prosthesis during speech utterance presenting with uniform contact between obturator and pharyngeal walls – (a) posterior pharyngeal wall, (b) lateral pharyngeal wall, (c) soft palate, (d) obturator

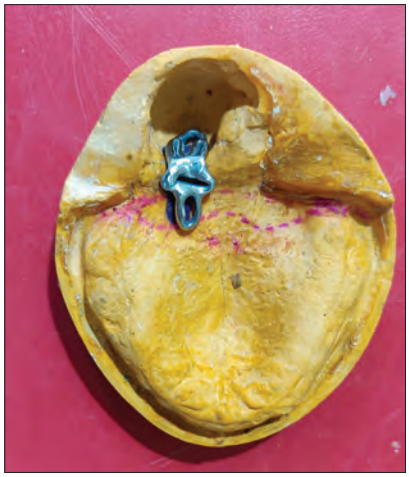

Figure 11: Intraoral view of adjusted prosthesis

CONCLUSION

Here, in this technique, we utilized a thin cast metal velar connector made of Co-Cr instead of using the conventional acrylic resin connectors incorporated with stainless steel wire which has been shown to exhibit fracture and tongue interference. An acrylic obturator was fabricated instead of a silicon obturator as it is prone to fungal infections and gets deformed during mastication. The ultimate goal of providing palatopharyngeal obturator prosthesis is to restore the defect, improve esthetics and function, and thereby enhance the overall quality of life.

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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Dental Technique

Fully digital workflow for reinforced mandibular implant overdenture – A novel method

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Abstract

Mandibular overdenture is suspected to fracture, especially in the midline and anterior region due to low surface area of coverage and minimum acrylic thickness in addition to attachments pickup holes that weakens the denture. Dentures used to be conventionally reinforced with metal meshwork which cannot be done in a digital workflow. This *in vitro* report introduces a novel approach of digital overdenture reinforcement using computer-aided design, computer-aided manufacturing, and rapid prototyping technologies. This novel approach provided digital reinforced, stable, and well-adapted overdenture with accurate and easy attachment pickup. Digital reinforced denture has fewer clinical steps with fewer laboratory complications. The newly developed overdenture fabrication techniques have the ability to change the conventional clinical and laboratory workflow from analog to digital. Which grantee standardization of the outcome on both research and clinical work.

Keywords: Attachments, digital reinforced denture, implants, overdenture

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INTRODUCTION

The overgrowing in the use of digital technologies to construct a removable denture added many values over conventional ones such as increased accuracy, especially when it is incorporated with attachments.[1]

Dentures fabricated using computer-aided design (CAD)/computer-aided manufacturing have better mechanical properties fit well to tissue offering more retention and patient satisfaction which in turn enhances chewing ability and speech in addition to a smaller number of visits compared to conventional ones. Full denture digitalization leads to standardization of both clinical results and research work, denture base thickness can be adjusted and kept minimal and consistent along the whole denture.[1-4]

Overdenture fractures occur most frequently in areas near to the implants or abutment teeth. This is due to the encroachment of the prosthetic space inside the denture base by the attachments which in turn reduces acrylic resin thickness. Attachment housing may act as a fulcrum leading to stress concentration, denture rotation, deformation, and fracture.[5]

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Overdenture fracture ranges from 9.3% to 21.4% for implant-supported overdentures complications. Overdenture fracture is an inconvenient complication, as the patient is generally unable to use the prosthesis until it is repaired. Repaired dentures are not as strong to function properly as intact ones; several techniques have been suggested to strengthen the denture base.[6] Embedded metal framework at the acrylic denture base better distributes stress preventing fractures and ensuring a permanent overdenture treatment. It is reported that denture reinforcement with rigid metal distributes masticatory forces more on the residual alveolar ridge, thus decreasing the rate of bone resorption.[7] Conventional metal framework reinforcement is associated with additional laboratory procedures and costs.[8]

Deng *et al.* stated that one of the disadvantages of digital denture is the inapplicability of denture reinforcement with metal.[9] The aim of our present dental technique is to report the possibility of the construction of digitally reinforced overdenture.

Technique

1. Design an implant placement surgical guide according to prosthetically driven implant placement in an implant planning software (Real guide 5.0 software 3DIEMME; Italy) to place two parallel implants between lateral and canine bilaterally (Internal tapered BioHorizons dental implant). Moreover, ensure any undercuts that may prevent the guide from complete seating were blocked out by setting a path of insertion from the occlusal direction as seen in Figure 1
2. Import the blocked-out undercut model and the implants extrusion models created in the surgical guide design to a free designing software (MESHMIXER 3.5 software, Autodesk)
3. Draw the metal framework design on the model using the select tool (Software tool) with appropriate size by outlining the lingual, buccal extents, then draw a meshwork between the outlined borders as seen in Figure 2
4. Optimize and smooth the meshwork boundaries. Then select an offset of 1 mm which means how far off the ridge you want this meshwork to set
5. Give three-dimensional (3D) shape and thickness to the meshwork by extrude tool (Software tool) to have a thickness of 1 mm
6. Create tissue stops using attract brushes (Software tool) to keep the meshwork 1 mm away from tissues which will create space for processing acrylic so the meshwork will be fully impeded in the denture as seen in Figure 3
7. Join the designed metal meshwork to the original epoxy model to be one STL file on which the denture designing will be done to accommodate the metal meshwork in its fitting surface as seen in Figure 4
8. Import the joined model and meshwork as jaw scan to computer-aided design software (exocad GMBH Dental CAD software; Germany) and choose denture module for complete denture designing
9. Block out the unfavorable undercut to create virtual wax-up bottom according to the desired path of insertion
10. Draw the denture borders according to the limiting anatomy of the lower jaw and adapt it on the joined model with meshwork then characterize, finish, and smooth the denture polished surface using the gingival design wizard
11. Merge the final restoration teeth and gingiva and save them in the form of an STL file. The result is to have a digitally designed metal-reinforced denture with space for the meshwork in its fitting surface as seen in Figure 5
12. Import the denture to free design software (blender software V 2.83); then perform Boolean difference operation (Software tool) between the denture and the implant extrusion to create holes for attachment pickup over the implants as seen in Figure 6

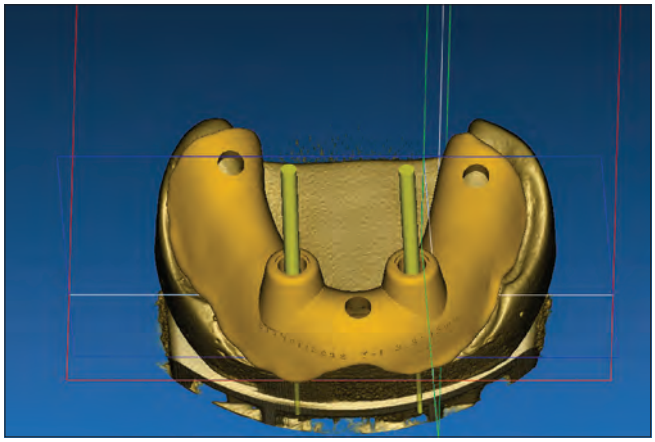

Figure 1: Designed surgical guide for implant placement

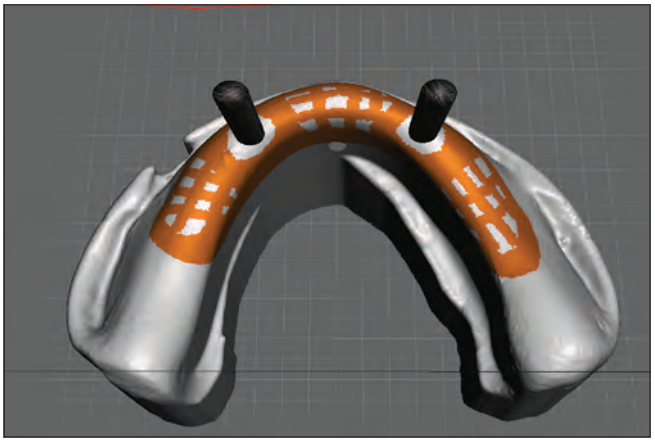

Figure 2: Designing of the metal meshwork by outlining its boundaries

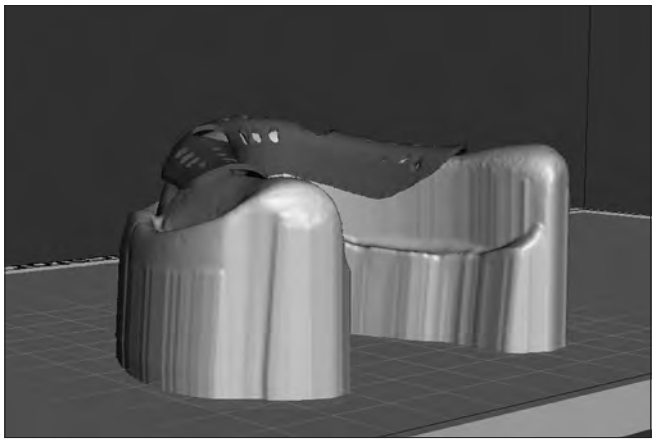

Figure 3: Designed metal meshwork with tissue stops creating 1 mm space for acrylic resin processing

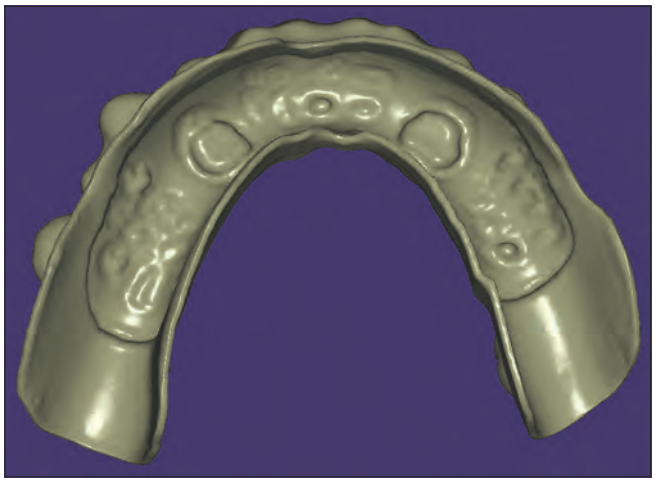

Figure 5: Denture fitting surface prepared for metal meshwork incorporation

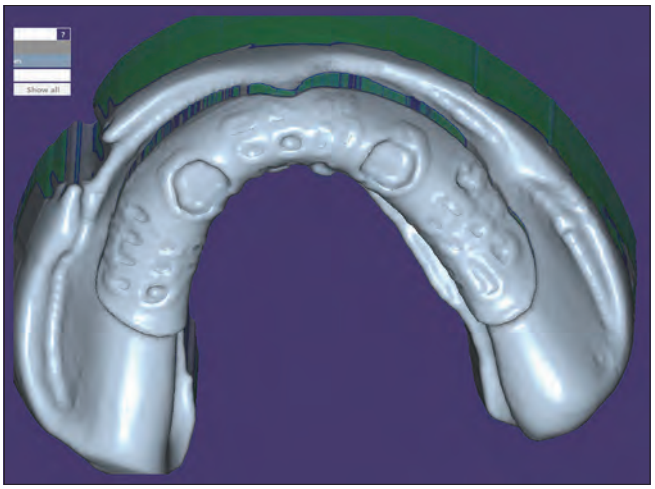

Figure 4: Joined mandibular model and metal meshwork as one STL file

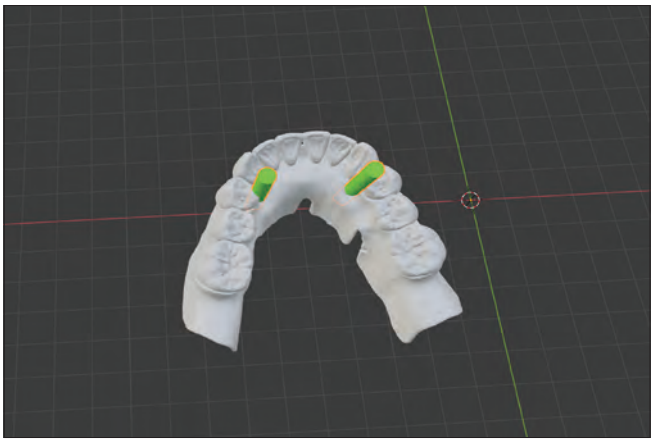

Figure 6: Boolean difference operation preparing the denture for attachments pickup

13. Mill the designed meshwork in metal or 3D print it in either metal or castable resin, then cast it in cobalt–chromium by lost wax technique as seen in Figure 7
14. 3D prints the denture using white porcelain-like as seen in Figure 8. Then apply different shades of red-white resin (Crea. lign, Bredent; Germany) in layers over the denture. As seen in Figure 9.
15. Sandblast metal meshwork and bond it to the denture fitting surface by (DTK-adhesive material, bredent; England). Then reline the denture with the metal meshwork over the model with self-cured acrylic or in the patient mouth with relining material which will offer mechanical retention with the framework.

DISCUSSION

Any prosthetic rehabilitation aims to provide a long-lasting dental prosthesis that maintains the biomechanics of the oral cavity and integrity of the supporting dental structures.

The proposed digital technique in fabricating a meshwork reinforced over denture reduces the number of clinical and laboratory steps as was reported by Neumeier and Neumeier that Digital dentures eliminate laboratory steps as pouring impressions with stone as well as acrylic resin tooth grinding.[10]

The digital meshwork eliminated many laboratory steps and reduced the treatment cost as conventional reinforcement of dentures with metal meshwork requires complicated laboratory work including modified master cast and refractory cast which in turn increase the cost of fabrication.

Blocking out the unfavorable undercut was done on the CAD step to simulate the denture's path of insertion, especially with a well-developed ridge and severe undercut.[2]

Tissue stops were designed in the metal meshwork to create 1 mm space beneath the denture to be processed by acrylic

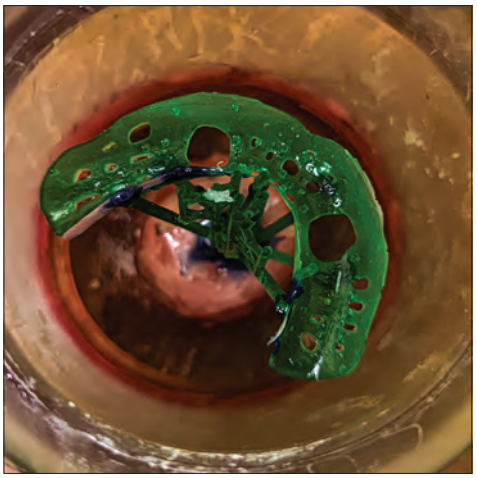

Figure 7: 3D-printed meshwork in green castable resin

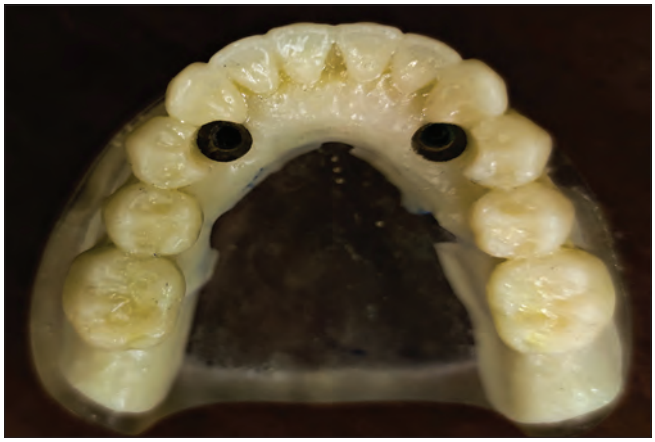

Figure 8: 3D-printed denture in white resin

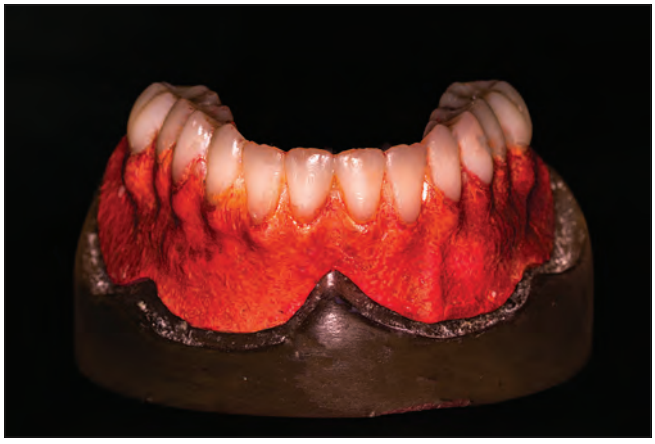

Figure 9: Characterized 3D-printed reinforced denture

resin then denture relining was done to incorporate the metal meshwork into the denture fitting surface.

In the step of meshwork designing, the borders of the meshwork must be drawn around the implant above the center of the ridge as stated by Berger *et al.* that best stress distribution in overdenture cases is obtained when reinforcements are placed in the middle region directly above the implants and over the inflection point of the residual ridge as fracture occurs at the area of attachment pickup after relieving the denture base for housing insertion.[5,7,11]

The Boolean difference operation was done by subtracting the implant extrusions from the denture base which in turn opens the holes for the attachment pickup decreasing the time and effort in the pickup procedures. This technique of denture reinforcement facilitated attachment pickup and reduced chairside time as was reported by Kamar Affendi NH.[12]

The proposed technique has solved the problem of digital denture reinforcement as reported by Deng *et al.* that one of the limitations of the digital denture is the inability of denture reinforcement with metal.[9]

SUMMARY

This article describes a novel approach for a digital reinforced denture that provides fewer clinical and laboratory steps for overdenture fabrication. Digital reinforced denture grantee accuracy during the attachment pickup procedure and standardization of clinical and research results.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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