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Original Article

Effect of conventionally fabricated and three-dimensional printed provisional restorations on hard and soft peri-implant tissues in the mandibular posterior region: A randomized controlled clinical trial

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ABSTRACT

Background: The purpose of this study was to conduct a randomized controlled clinical trial to compare and evaluate the effect of provisional restorations fabricated by two techniques, namely, conventional and three-dimensional (3D) printing processes on the peri-implant hard and soft tissues over early nonfunctional loaded implants in the mandibular posterior region.

Materials and Methods: A randomized controlled clinical trial was conducted across 24 subjects broadly divided into two groups with 12 dental implants each, i.e., GpIC with conventionally fabricated provisional restoration and GpIID with 3D printed fabricated provisional restoration. The prosthetic phase was carried out at 2 weeks, and subjects were evaluated at baseline (at the time of prosthesis placement), 2 months, and 4 months for peri-implant marginal bone level, mucosal suppuration, sulcular probing depth, and modified sulcular bleeding index. Patient satisfaction was assessed using 5-item questionnaires at 4 months. The intragroup comparison for all the data was done using Wilcoxon signed-rank test. The intergroup comparison for all the data was done using Mann–Whitney *U*-test. The comparison of frequency of responses between GpIC and GpIID was done using Chi-square test. $P < 0.05$ was considered to be statistically significant.

Results: Nonsignificant difference was observed in all the hard and soft tissue parameters between the groups at baseline, 2 months, and 4 months ($P > 0.05$). Improvement in bleeding on probing was found to be greater around dental implants restored with 3D printed provisional restoration than dental implants restored with conventionally fabricated provisional restoration from baseline to 4 months of follow-up, and the difference in finding was statistically significant ($P < 0.05$). There was a statistically nonsignificant difference seen for the frequencies between the groups ($P > 0.05$) for all questions related to patient satisfaction.

Conclusion: The effect of conventionally fabricated and 3D printed provisional restorations on peri-implant hard and soft tissues was comparable to each other on an early nonfunctionally loaded implant in the mandibular posterior region.

Key Words: Dental implants, dental prosthesis, three-dimensional printing

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INTRODUCTION

With continuing research in the field of digital dentistry, various novel technologies have emerged in recent years, one being the three-dimensional (3D) printing technology. Many researchers have explored various parameters of this technology so that its clinical implications can be widened. 3D printing has the potential to revolutionize conventional dentistry in clinical treatment, education, and research with the rapid development of new materials, printing techniques, and machines.[1]

In dentistry, 3D printing technology finds its use in the construction of surgical guides, stents, provisional restorations, resin patterns, dental models, and cast copings. Arguably, one of the procedures that can benefit the most from the recent developments in 3D printing technologies is the fabrication of provisional crowns and bridges. Placement of the provisional restoration is one of the very important steps in the treatment planning of dental implants. Although an important step in implant dentistry, this step is often overlooked and has been underutilized. Provisional restoration is used to evaluate the occlusal function, phonetics, soft tissue contours, and esthetics prior to delivery of the final restoration while maintaining and/or enhancing the condition of the peri-implant hard and soft tissues.[2]

Provisional restoration can be fabricated using the conventional chairside method, in the laboratory on working casts, and more recently by the use of digital technology by computer-aided designing/computer-aided milling (CAD/CAM) process or rapid prototyping (RP).

There are some studies which have evaluated and compared the marginal fit and accuracy of the 3D printed provisional restoration with conventionally fabricated restorations, but to the best of our knowledge, no previous study has compared the *in vivo* effect of provisional restorations fabricated using the 3D printing technique and conventional technique on peri-implant hard and soft tissue parameters.

Therefore, the purpose of this study was to evaluate the influence of full-coverage provisional restorations on hard and soft peri-implant tissues in two workflows, 3D printing versus conventional technique.

MATERIALS AND METHODS

Study design

The present study was designed as a randomized controlled trial with a two-group design. A prospective, clinical study was conducted in the department of prosthodontics and crown and bridge involving the subjects selected from November 2018 to June 2019. Ethical clearance was obtained from the institutional ethical committee vide letter number: PGIDS/IEC/2018/11, dated November 30, 2018. Systemically healthy individuals with maintainable oral hygiene were selected based on inclusion and exclusion criteria. After an explanation of proposed study criteria, including alternative treatment options, potential risks, and benefits, signed informed consent was obtained for all subjects prior to the dental implant placement.

Study population

A total of 58 subjects were screened from the outpatient department, based on the chief complaint requiring replacement of the mandibular single posterior tooth.

Inclusion and exclusion criteria

Subjects with age above 18 years and with partially edentulous mandible who were willing for tooth replacement with sufficient bone width and density for implant placement and who gave written consent for the participation in the study were included. Good periodontal health, no systemic disease, and adequate buccolingual, mesiodistal, and interocclusal space at the site of implant placement were also the criteria for inclusion in the study. Those subjects who had an infection around the proposed site of implant placement or had a condition that would interfere with the healing of the soft tissue and bone and in whom, for any reason, surgical procedure was contraindicated were excluded from the present study.

Grouping of the subjects

After examining the patients clinically and radiographically and based on the inclusion and exclusion criteria, 24 subjects (12 males and 12 females) were randomly allocated to the control and test groups each, by using the lottery method.

Group GpIC included subjects with single-stage implant placement and early nonfunctional loading with provisional restorations fabricated by the conventional method, whereas in Group GpIID,

fabrication was done by the digital light processing (DLP) 3D printing technique.

Presurgical assessment

A detailed history and clinical examination of patients were carried out. The implant site was assessed clinically. Preoperative records were obtained. Routine hematological (hemoglobin, bleeding time, clotting time, and blood sugar tests) and radiographic investigations were carried out to evaluate patient fitness for implant placement. Cone-beam computed tomography and standardized intraoral periapical (IOPA) X-ray were taken using a long-cone paralleling technique with a customized jig for the evaluation of bone quality and quantity.

Surgical phase

Local anesthesia was administered, and after confirming its effectiveness, incisions were given. A full-thickness mucoperiosteal flap was reflected followed by osteotomy preparation by sequential drilling. Thereafter, torque wrench was used to position the dental implant and the cervical collar of a dental implant was approximated with the margin of the crestal bone. Healing abutment was then positioned. The surgical site was then irrigated with a 0.9% saline solution and sutured. Postoperative instructions were given to the subject regarding diet and oral hygiene, and the medications were prescribed. Subjects were recalled after 24 h for review, and suture removal was done after 7 days.

Prosthetic phase

After a healing period of 10–14 days, the healing abutment was removed, the height of the gingival collar was assessed, and the selection of a suitable implant abutment was done. To transfer the orientation of the implant, a closed-tray transfer implant coping was used. Impression was made using polyvinyl siloxane impression material. After retrieval of the impression from the mouth, the implant analog was positioned over the close-tray transfer coping and secured on the impression. After retrieval of the cast, upper and lower models were articulated using the interocclusal record and a cement-retained provisional implant-supported restoration was fabricated.

Group I (GpIC)

In this group, provisional restoration was fabricated using the indirect method. After the application of die spacer, wax pattern of nonfunctional provisional restoration providing customized contours was fabricated on the abutment, i.e., the prostheses were kept out of occlusion in nonfunctional relationship with the opposing arch. A silicone putty index was made involving at least one tooth on either side of the abutment teeth. A cotton pellet was placed into the temporary abutment screw hole to prevent provisional restoration material from flowing into the screw access hole. As a separating medium, petroleum jelly was applied to the trimmed abutment and cold mold seal was applied on the adjacent teeth. Self-cure acrylic resin was injected into the tissue side of the putty index. After the provisional restoration material was set, the temporary restoration was removed carefully. The excess provisional restoration material was trimmed extraorally. The provisional restoration was relined if required. It was finished and polished and cemented on the implant abutment using a noneugenol temporary cement (Meta Biomed Co., Korea) [Figure 1].

Group II (GpIID)

A virtual working model of the cast was generated using a laboratory scanner (Medit Identica T500 scanner system). The nonfunctional provisional restoration was designed using the software program (Carestream, USA), and a Standard Tessellation Language file was generated and transferred to the DLP 3D printer (Anycubic Photon LCD, China). The planning for supporting pin placement was done. The provisional restoration was 3D printed using photo resin (NextDent C&B MFH, NextDent B.V., The Netherlands). The support pins were removed. The 3D printed provisional restoration was cleaned with 100% isopropyl alcohol and was

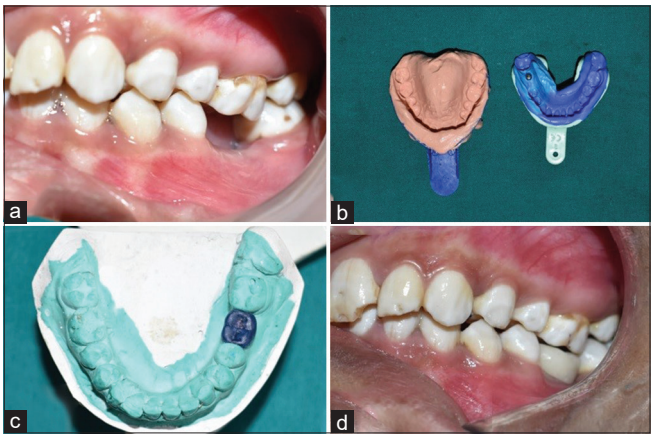


Figure 1: (a) Prerehabilitation intraoral view depicting missing 36, (b) Maxillary impression and mandibular impression with abutment and laboratory analog, (c) Wax pattern fabricated conventionally on mandibular cast, (d) Postrehabilitation intraoral view after cementation of conventional nonfunctional provisional restoration.

postcured in an ultraviolet curing unit according to the manufacturer's recommendations. The printed provisional restoration was then cemented onto the implant [Figure 2].

Follow-up phase

The evaluation of the clinical parameters was done at baseline, 2 months, and 4 months regarding marginal bone level (MBL), sulcular probing depth, modified sulcular bleeding index (mSBI), bleeding on probing (BOP), and mucosal suppuration.

The IOPA radiographs were digitalized using Digimizer Image Analysis, MedCalc Software, Version 4.3.5.0 (Medcalc software Ltd, Ostend, Belgium), for measuring the crestal bone level. To record the actual distance, the images were calibrated geometrically based on implant length. For analysis, the reference line was marked at the first thread of implant as it is static, permanently visible, and is easy to locate on all radiographs. The bone level was chosen at the point of bone-to-implant contact. From the reference line, perpendiculars were dropped to the bone level on the mesial and distal aspects of the implant and measurements were made.

A Hu-Friedy calibrated implant probe was used for measuring the sulcular probing depth and BOP at buccal, lingual, mesial, and distal sites. The presence or absence of BOP was assessed subjectively, and the mSBI criteria were used for its grading. Mucosal suppuration was also assessed using the same probe.

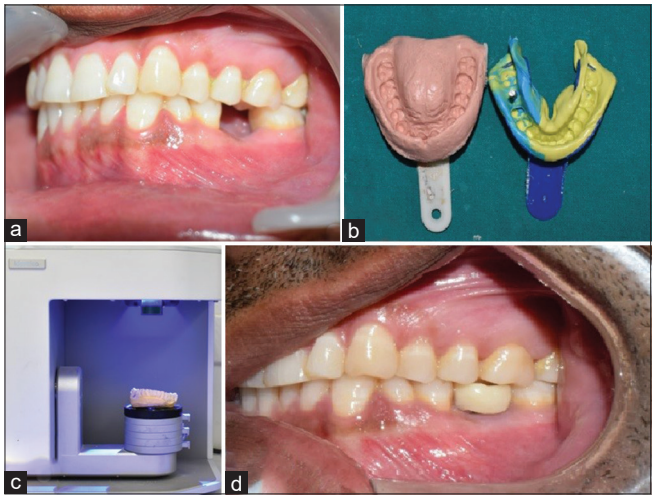


Figure 2: (a) Prerehabilitation intraoral view depicting missing 36, (b) Maxillary impression and mandibular impression with abutment and laboratory analog, (c) Scanning of the mandibular cast, (d) Postrehabilitation intraoral view after cementation of 3D printed nonfunctional provisional restoration. 3D: Three-dimensional

Patient-reported outcome measures

After 4 months, patient satisfaction regarding the provisional prosthesis was assessed using a 5-item questionnaire. Five-point Likert scale was used to record the responses. Scoring was done on a scale from 1 to 5. Score 1 was given to the strongly disagree response, whereas score 5 was given to strongly agree response.

All the observations were recorded in the case record form. Statistical analysis was done after tabulating all the data in the Microsoft Excel sheet. A flow diagram of the study is presented in Figure 3.

RESULTS

Table 1 shows the various parameters regarding the age, gender, location of dental implant, and dimensions of the dental implant. The subjects from Group GpIC1 to GpIC12 received conventionally fabricated provisional restorations. The subjects from Group GpIID1 to GpIID12 received 3D printed provisional restorations.

The intragroup comparison for all the data was done using Wilcoxon signed-rank test [Graphs 1 and 2].

Table 1: Basic details of the demographic data of patients with tooth replaced and size of dental implant used in the study

Serial number	Age/ gender	Tooth replaced	Dental implant dimensions (diameter × length in mm) (mm)
GpIC1	60/male	36	4.2 × 10.0
GpIC2	27/male	37	4.2 × 10.0
GpIC3	24/female	46	3.5 × 11.5
GpIC4	60/male	36	5.0 × 10.0
GpIC5	19/female	36	4.2 × 13.0
GpIC6	24/female	46	4.2 × 10.0
GpIC7	21/male	47	4.2 × 10.0
GpIC8	35/male	36	4.2 × 11.5
GpIC9	28/female	46	4.2 × 10.0
GpIC10	30/female	36	4.2 × 10.0
GpIC11	20/male	36	4.2 × 13.0
GpIC12	43/female	46	4.2 × 13.0
GpIID1	21/male	36	4.2 × 10.0
GpIID2	44/female	36	4.2 × 10.0
GpIID3	25/male	46	4.2 × 11.5
GpIID4	30/female	46	4.2 × 10.0
GpIID5	34/female	36	4.2 × 13
GpIID6	40/male	46	3.75 × 11.5
GpIID7	32/female	35	4.2 × 10.0
GpIID8	39/female	46	4.0 × 10.0
GpIID9	60/male	46	4.2 × 11.5
GpIID10	22/female	36	4.2 × 11.5
GpIID11	30/male	36	4.2 × 13.0
GpIID12	19/male	36	4.2 × 11.5

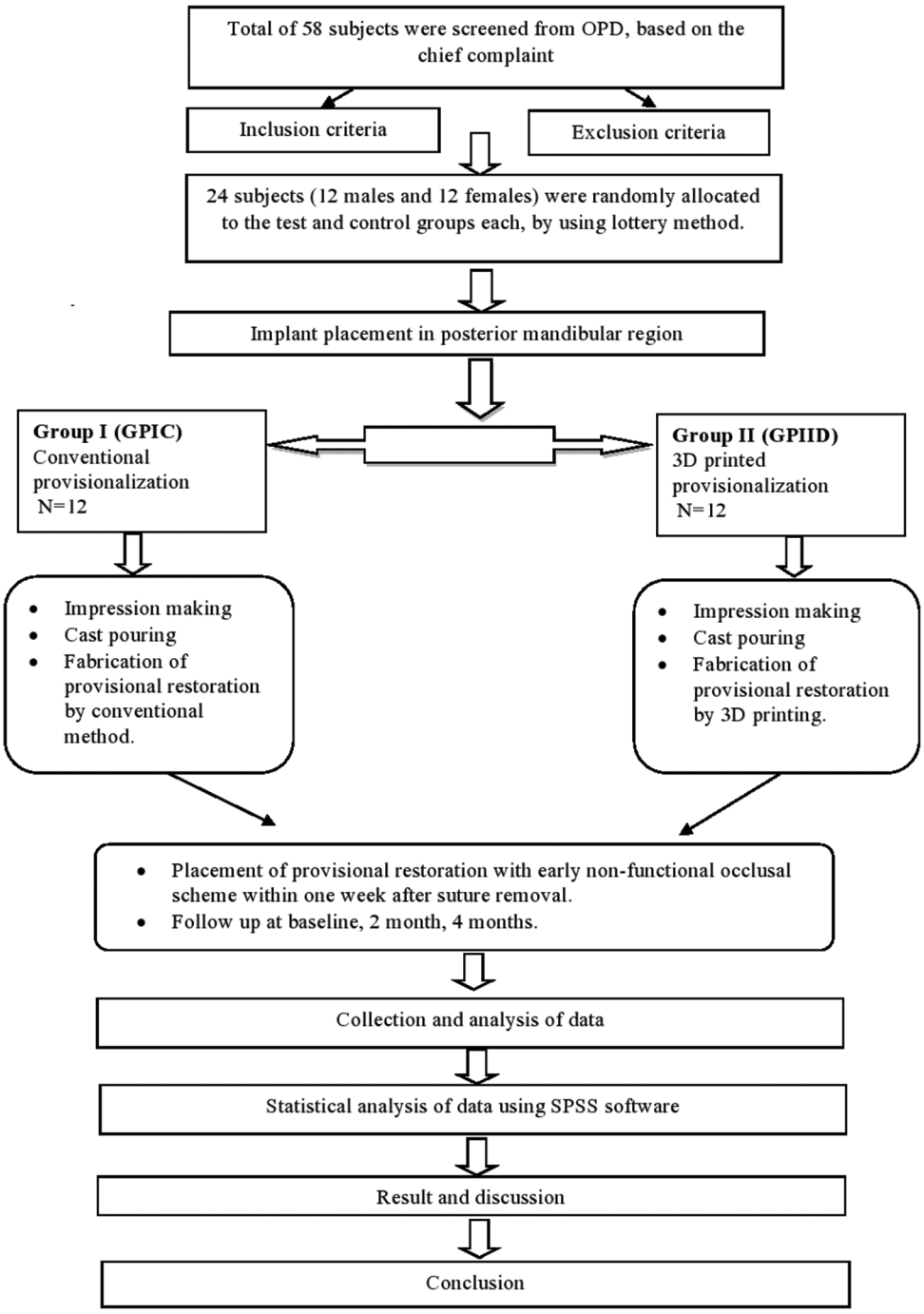


Figure 3: Flow diagram of the study.

Statistically significant ($P < 0.01$) intragroup variation in magnitude of MBL and probing pocket depth was noted throughout the study with the lowest values at baseline and highest values at 4 months of the follow-up period. The intragroup variation in mSBI and BOP was statistically significant ($P < 0.01$) in both the groups from baseline to 2 months of follow-up period without any further statistically significant variation in these clinical parameters from 2 months to 4 months of follow-up period.

The intergroup variation in the MBL [Table 2] around dental implants restored with conventionally fabricated provisional restoration was greater than around dental implants restored with 3D printed provisional restoration from baseline to 4 months of follow-up, but the difference in the finding was statistically as well as clinically nonsignificant ($P > 0.05$). The intergroup difference in sulcular probing pocket depth [Table 3] was found to be statistically as well as clinically nonsignificant ($P > 0.05$) over a period of 4 months.

Table 2: Comparison of peri-implant marginal bone level between GpIC receiving conventional provisional restoration and GpIID receiving three-dimensional printed provisional restoration at different time intervals at various sites

Time	Sites	Groups	*n*	Mean	SD	SEM	Mann-Whitney *U*-test	*Z*	*P* value of Mann-Whitney *U*-test
Baseline	Mesial	GpIC	12	0.2417	0.20936	0.06044	67.000	−0.289	0.773
		GpIID	12	0.2725	0.27270	0.07872			
	Distal	GpIC	12	0.2500	0.27818	0.08030	68.500	−0.897	0.840
		GpIID	12	0.2358	0.24938	0.07199			
2 months	Mesial	GpIC	12	0.2975	0.33049	0.09540	56.500	−0.347	0.370
		GpIID	12	0.2217	0.28718	0.08290			
	Distal	GpIC	12	0.3000	0.47892	0.13825	70.000	−0.202	0.908
		GpIID	12	0.2400	0.33909	0.09789			
4 months	Mesial	GpIC	12	0.5392	0.44836	0.12943	66.000	−0.116	0.729
		GpIID	12	0.4942	0.49704	0.14348			
	Distal	GpIC	12	0.5500	0.60551	0.17479	61.500	−0.607	0.544
		GpIID	12	0.4758	0.57527	0.16607			

SD: Standard deviation; SEM: Standard error of mean

Table 3: Comparison of peri-implant probing depth between GpIC receiving conventional provisional restoration and GpIID receiving three-dimensional printed provisional restoration in different time intervals at various sites

Time	Sites	Group	*n*	Mean	SD	SEM	Mann-Whitney *U*-test	*Z*	*P* value of Mann-Whitney *U*-test
Baseline-2 months	Mesial	GpIC	12	0.2500	0.26112	0.07538	48.000	−1.696	0.090
		GpIID	12	0.0833	0.19462	0.05618			
	Distal	GpIC	12	0.2083	0.33428	0.09650	69.500	−0.163	0.870
		GpIID	12	0.2083	0.25746	0.07432			
	Buccal	GpIC	12	0.1667	0.24618	0.07107	54.000	−1.476	0.140
		GpIID	12	0.0417	0.14434	0.04167			
	Lingual	GpIC	12	0.2083	0.33428	0.09650	60.500	−0.800	0.424
		GpIID	12	0.0833	0.28868	0.08333			
2-4 months	Mesial	GpIC	12	0.1250	0.22613	0.06528	46.500	−1.700	0.089
		GpIID	12	0.3333	0.32567	0.09401			
	Distal	GpIC	12	0.2500	0.33710	0.09731	58.000	−0.915	0.360
		GpIID	12	0.3333	0.24618	0.07107			
	Buccal	GpIC	12	0.0833	0.19462	0.05618	60.000	−0.923	0.356
		GpIID	12	0.1667	0.24618	0.07107			
	Lingual	GpIC	12	0.1250	0.22613	0.06528	60.500	−0.848	0.397
		GpIID	12	0.2083	0.25746	0.07432			
Baseline-4 months	Mesial	GpIC	12	0.3750	0.31079	0.08972	66.500	−0.371	0.710
		GpIID	12	0.4167	0.28868	0.08333			
	Distal	GpIC	12	0.4583	0.39648	0.11445	63.000	−0.565	0.572
		GpIID	12	0.5417	0.33428	0.09650			
	Buccal	GpIC	12	0.2500	0.26112	0.07538	66.000	−0.401	0.688
		GpIID	12	0.2083	0.25746	0.07432			
	Lingual	GpIC	12	0.3333	0.32567	0.09401	64.500	−0.478	0.633
		GpIID	12	0.2917	0.39648	0.11445			

SD: Standard deviation; SEM: Standard error of mean

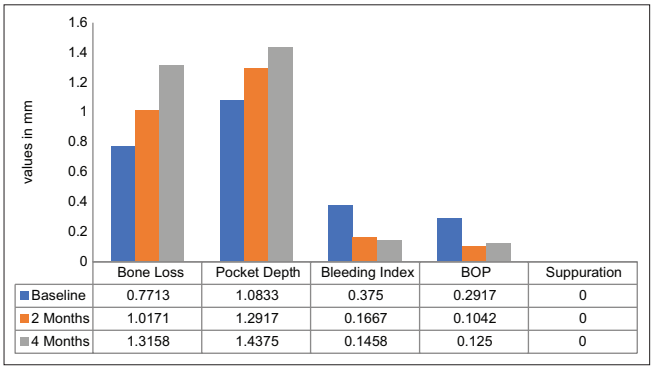
The intergroup comparison of mSBI score was found to be statistically nonsignificant ($P > 0.05$) over a period of 4 months [Table 4]. Improvement in BOP was found to be greater around dental implants restored with 3D printed provisional restoration than dental implants restored with conventionally fabricated provisional restoration from baseline to 4 months of follow-up [Table 5], and the difference in finding was statistically significant ($P < 0.05$). The mucosal suppuration around dental implants in both the groups was found to be negative and constant over a period of 4 months. There was a statistically nonsignificant difference seen for the responses between both

the groups ($P > 0.05$) for all questions related to patient satisfaction [Table 6].

DISCUSSION

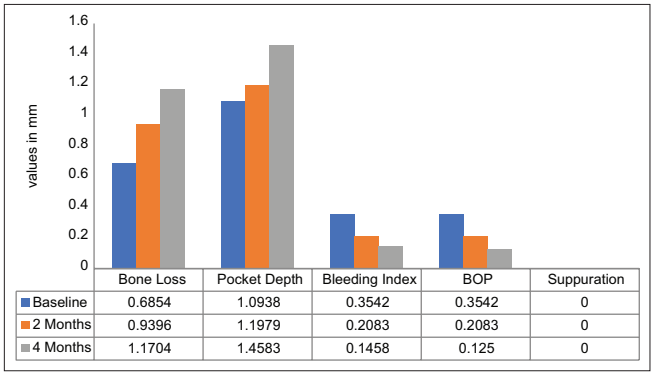
The conventional manual chairside fabrication of provisional restorations is very common and simple, but this method has its drawbacks such as low flexural strength,[3] incorporation of voids during the mixing procedures that could adversely affect the surface texture, low mechanical strength, and less precise fit of the restoration. Hence, other methods of provisional restoration have been explored, studied, and evaluated.

Recent technological advances such as the CAD/CAM method and the 3D printing method have enabled accurate and precise methods to fabricate provisional restorations. The principle on which CAD/CAM unit works is the subtraction of material. However,



	Bone Loss	Pocket Depth	Bleeding Index	BOP	Suppuration
Baseline	0.7713	1.0833	0.375	0.2917	0
2 Months	1.0171	1.2917	0.1667	0.1042	0
4 Months	1.3158	1.4375	0.1458	0.125	0

Graph 1: Intragroup changes in clinical parameters from baseline to 4 months in GpIC receiving conventional provisional restoration across time intervals.



	Bone Loss	Pocket Depth	Bleeding Index	BOP	Suppuration
Baseline	0.6854	1.0938	0.3542	0.3542	0
2 Months	0.9396	1.1979	0.2083	0.2083	0
4 Months	1.1704	1.4583	0.1458	0.125	0

Graph 2: Intragroup changes in clinical parameters from baseline to 4 months in GpIID receiving 3D printed provisional restoration across time intervals. 3D: Three-dimensional.

Table 4: Comparison of modified sulcular bleeding index score between GpIC receiving conventional provisional restoration and GpIID receiving three-dimensional printed provisional restoration at different time intervals at various sites

Time	Sites	Group	*n*	Mean	SD	SEM	Mann-Whitney *U*-test	*Z*	*P* value of Mann-Whitney *U*-test
Baseline-2 months	Mesial	GpIC	12	−0.3333	0.49237	0.14213	56.000	−1.164	0.244
		GpIID	12	−0.0833	0.51493	0.14865			
	Buccal	GpIC	12	−0.1667	0.38925	0.11237	72.000	0.000	1.000
		GpIID	12	−0.1667	0.38925	0.11237			
	Distal	GpIC	12	−0.3333	0.49237	0.14213	66.000	−0.440	0.660
		GpIID	12	−0.2500	0.45227	0.13056			
	Lingual	GpIC	12	−0.0833	0.28868	0.08333	72.000	0.000	1.000
		GpIID	12	−0.0833	0.28868	0.08333			
2-4 months	Mesial	GpIC	12	−0.0833	0.28868	0.08333	59.500	−0.956	0.339
		GpIID	12	−0.2500	0.62158	0.17944			
	Buccal	GpIC	12	0.0000	0.00000#	0.00000	72.000	0.000	1.000
		GpIID	12	0.0000	0.00000#	0.00000			
	Distal	GpIC	12	0.0833	0.51493	0.14865	66.000	−0.603	0.546
		GpIID	12	0.0000	0.00000	0.00000			
	Lingual	GpIC	12	0.0000	0.00000#	0.00000	72.000	0.000	1.000
		GpIID	12	0.0000	0.00000#	0.00000			
Baseline-4 months	Mesial	GpIC	12	−0.4167	0.51493	0.14865	68.500	−0.230	0.818
		GpIID	12	−0.3333	0.65134	0.18803			
	Buccal	GpIC	12	−0.1667	0.38925	0.11237	72.000	0.000	1.000
		GpIID	12	−0.1667	0.38925	0.11237			
	Distal	GpIC	12	−0.2500	0.45227	0.13056	72.000	0.000	1.000
		GpIID	12	−0.2500	0.45227	0.13056			
	Lingual	GpIC	12	−0.0833	0.28868	0.08333	72.000	0.000	1.000
		GpIID	12	−0.0833	0.28868	0.08333			

SD: Standard deviation; SEM: Standard error of mean. #Non Significant

Table 5: Comparison of bleeding on probing between GpIC receiving conventional provisional restoration and GpIID receiving three-dimensional printed provisional restoration at different time intervals at various sites

Time	Sites	Groups	*n*	Mean	SD	SEM	Mann-Whitney *U*-test	df	*P* value of Mann-Whitney *U*-test
Baseline-2 months	Mesial	GpIC	12	−0.0833	0.51493	0.14865	16.750#	2	0.000*
		GpIID	12	−0.0833	0.51493	0.14865			
	Buccal	GpIC	12	−0.0833	0.28868	0.08333	13.500#	1	0.000
		GpIID	12	−0.1667	0.38925	0.11237			
	Distal	GpIC	12	−0.2500	0.45227	0.13056	6.000	1	0.014
		GpIID	12	−0.2500	0.45227	0.13056			
	Lingual	GpIC	12	−0.0833	0.28868	0.08333	16.667#	1	0.000
		GpIID	12	−0.0833	0.28868	0.08333			
2-4 months	Mesial	GpIC	12	0.0000	0.00000	0.00000	10.667#	1	0.001
		GpIID	12	−0.3333	0.49237	0.14213			
	Buccal	GpIC	12	0.0000	0.00000[a]	0.00000	-	-	-
		GpIID	12	0.0000	0.00000[a]	0.00000			
	Distal	GpIC	12	0.0833	0.28868	0.08333	20.167#	1	0.000
		GpIID	12	0.0000	0.00000	0.00000			
	Lingual	GpIC	12	0.0000	0.00000[a]	0.00000	-	-	-
		GpIID	12	0.0000	0.00000[a]	0.00000			
Baseline-4 months	Mesial	GpIC	12	−0.3333	0.49237	0.14213	1.500#	1	0.201
		GpIID	12	−0.4167	0.51493	0.14865			
	Buccal	GpIC	12	−0.0833	0.28868	0.08333	13.500#	1	0.000
		GpIID	12	−0.1667	0.38925	0.11237			
	Distal	GpIC	12	−0.1667	0.38925	0.11237	8.167#	1	0.004
		GpIID	12	−0.2500	0.45227	0.13056			
	Lingual	GpIC	12	−0.0833	0.28868	0.08333	16.667#	1	0.000
		GpIID	12	−0.0833	0.28868	0.08333			

SD: Standard deviation; SEM: Standard error of mean. *$P \leq 0.05$ indicates significance. #Non significant

Table 6: Comparison of frequency of responses between GpIC receiving conventional provisional restoration and GpIID receiving three-dimensional printed provisional restoration

Question	Responses	GpIC	GpIID	χ^2	*P*
Question 1 I have not felt uncomfortable because of food packing during chewing	Agree	9	9	0.000	1.000#
	Neither agree nor disagree	1	1		
	Strongly agree	2	2		
Question 2 I feel secure that my implant prosthesis will stay in place while eating and speaking	Agree	9	10	1.053	0.591#
	Neither agree nor disagree	1	0		
	Strongly AGREE	2	2		
Question 3 I am satisfied with the convenience of oral hygiene and self-care of prosthesis	Agree	10	9	0.386	0.824#
	Neither agree nor disagree	1	2		
	Strongly agree	1	1		
Question 4 I am pleased with the shape and smoothness of the implant prostheses	Agree	10	9	0.386	0.824#
	Neither agree nor disagree	1	1		
	Strongly agree	1	2		
Question 5 I am satisfied with my implant prosthesis	Agree	11	11	0.000	1.000#
	Strongly agree	1	1		

#*P*>0.05 indicates nonsignificance

this method causes unnecessary loss and wastage of materials which is as high as 90%.[4] Furthermore, the construction of complex geometrical structures cannot be successfully reproduced.[5] 3D printing technology, on the other hand, offers various advantages such as it is time-saving, has high accuracy, and gives precise fitting of the constructions.[6] There is no risk of distortions and laboratory mistakes, the production of complex shapes can be done without the use of special tools, and there is almost no wastage of material.[6] 3D printed provisional restorations have sufficient mechanical properties to be used

intraorally.[7] 3D printed resins are unfilled composed of at least 90% methacrylic oligomers which are photo cross-linked, and in the monomer blend, up to3% phosphine oxides are present as photoinitiators.[8]

There have been many *in vitro* studies which compared the mechanical properties of conventional provisional restorative material and the 3D printed provisional restoration material and found contrasting results. Park *et al*.[9] concluded in their study that the wear resistance of the 3D printed resin material was in a comparable range to the conventionally fabricated or the milled resin materials. The 3D printing process was found to be suitable for manufacturing dental restorations. On the other hand, Munoz *et al*.[10] used the DLP technique to fabricate wax patterns for indirect manufacturing of cast gold crowns and found that the marginal gap was significantly larger for DLP fabricated patterns compared to the milled or manually fabricated wax patterns. Digholkar *et al*.[11] conducted an *in vitro* study on provisional crowns fabricated by conventional heat-activated resin, CAD/CAM, and RP. They concluded that the flexural strength values of all the groups were higher than minimal acceptable flexural strength of provisional FDP materials which is 50 MPa. According to Tahayeri *et al*.,[7] the modulus of elasticity of 3D printed samples was comparable to jet (the conventional methyl methacrylate resin). The peak stress of 3D printed samples was significantly higher than Jet, and the degree of conversion appeared to be higher than Jet.[7]

The present study compared the effect of conventional and DLP 3D printed provisional restoration on peri-implant hard and soft tissues. Change in MBL of 0.54 ± 0.52 mm and 0.48 ± 0.52 mm was seen in Group GpIC and Group GpIID, respectively, from baseline to 4 months of follow-up period. The mean crestal/MBL noted in both the groups was within the success criteria of an implant (mean crestal bone loss <1.5 mm within the 1st year of implant loading).[12] Both the groups showed a similar change in mean MBL at mesial and distal sites ranging from 0.51 mm to 0.55 mm from baseline to 4 months of follow-up.

The change in crestal bone level in the present study is comparable to that noted by Roccuzzo and Wilson[13] around early loaded implants. Resorption was about 0.65 mm for the implants loaded after 6 weeks and 0.77 mm for loading within 12 weeks. In addition, Salvi *et al*.[14] found resorption of 0.57 mm in implants loaded after 1 week and 0.72 mm in implants loaded after 6 weeks.

Apart from the evaluated hard tissue parameter as mentioned above, soft tissue parameters also play an essential role in the overall success of implant treatment and are usually a significant indicator of implant health. An increase in pocket depth was statistically significant and similar in both the groups from baseline to 4 months of follow-up period (GpIC 0.35 ± 0.32 mm ~ GpIID 0.36 ± 0.33 mm). Gradual increase of 0.21–0.55 mm in probing pocket depth was observed in both the groups from baseline to 4 months of follow-up with the highest increase at distal sites (0.46 mm, 0.55 mm) followed by mesial (0.38 mm, 0.41 mm), lingual (0.34 mm, 0.29 mm), and buccal sites (0.25 mm, 0.21 mm).

According to the study done by Adell *et al*.[15] and Buser *et al*.,[16] peri-implant probing depth (PPD) up to 3 mm is considered "healthy." Only a slight increase in PPD (<3 mm) and improvement in mSBI in the present study revealed the absence of progressive destruction of connective tissue around implants. The implant mucosa remained in a healthy condition as the patient's maintained good oral hygiene from the beginning of the study.

mSBI and BOP were higher at mesial and distal sites in both the groups followed by lingual and buccal sites. This intersite variation noted in values of mSBI and BOP may be attributed to differences in accessibility of these sites to oral hygiene measures. More bleeding sites resolved in the 3D printed group than the conventional group, but improvement noted in the mSBI was greater in the conventional group. Despite BOP being a diagnosis of peri-implant disease, bleeding, unusual in healthy periodontium, is found in most healthy peri-implant tissues. Therefore, according to Ferreira *et al*.,[17] it is not clearly defined whether peri-implant BOP could represent a reliable parameter for identifying the presence of peri-implant disease. Some studies suggest that peri-implant mucosa may be more sensitive to probing forces, causing more BOP when compared with teeth.[18,19]

Lesser marginal bone loss and better improvement in BOP observed in the GpIID group than the GpIC group may be attributed to better marginal fit and finish of 3D printed provisional restorations than conventionally fabricated provisional restorations, but the difference in marginal bone loss (0.54 ± 0.52 >0.48 ± 0.52) between the two

groups from baseline to 4 months of follow-up was statistically as well as clinically insignificant.

When assessing the various outcomes of dental implantology, it is essential to consider both patient and clinician appraisals. For the oral implant prosthesis longevity, frequency of complications and implant survival are the significant parameters; on the contrary, cost-effectiveness, the social and psychological impact of the treatment, its utility, and benefit are the important factors from a patient's point of view.[20] Nearly, all questionnaires regarding the level of patient satisfaction with implant treatment were scored positive in the present study. There was a statistically nonsignificant difference seen for the frequencies between the groups ($P > 0.05$) for all questions.

The nonfunctional loading concept was used in the present study. The nonocclusal pattern reduces the masticatory force on implants, and studies have shown that nonocclusal loads for short-span prostheses and single-tooth replacements are important factors for a successful hard and soft tissue outcome.[21]

The soft tissue attachment onto the implant surface is more delicate than that seen at the natural tooth surface due to the lack of Sharpey's fiber insertion, decreased number of collagen fibers, and altered direction of these fibers. Hence, any residual cement can cause gingival inflammation or peri-implantitis leading to bone loss or implant failure.[22,23] Thus, precaution was taken during cementation to avoid any residual cement after cementation.

To the best of our knowledge, there is no earlier *in vivo* study in the literature where the influence of provisional restorations on the outcome of clinical parameters has been studied, hence the results of this study could not be compared, being the first study of its kind. In the present study, all the subjects participated until the end of the study, showed good compliance with the study protocol, and maintained good oral hygiene except one case in GpIID and two cases in GpIC. These three cases showed peri-implantitis and were given suitable treatment accordingly. However, healing, in general, was uneventful with minimal discomfort to all the subjects.

Limitations

The marginal bone loss value may have been influenced by the variation in implant dimension in subjects of both the groups. However, the effect of implant dimensions on marginal bone loss has been studied in the past with variable result. According to Monje *et al*., other variables such as surgical trauma, prosthetic considerations, implant neck design, or patient's habits have a more significant impact on MBL.[24]

The present study collected data from a limited pool of patients and as specific site (posterior mandible); therefore, further trials are needed to generalize these results to a broader population and different areas of the mouth.

CONCLUSION

Both 3D printed and conventionally fabricated provisional restorations have a comparable impact on the clinical parameters related to peri-implant hard and soft tissue health. Therefore, it may be speculated that both can be used during the initial healing period with early nonfunctional loading protocol.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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