Comparison of flapped versus flapless dental implant insertion subjected to immediate functional loading protocol: A parallel group randomised control trial for radiographic bone density changes

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Abstract

Purpose: To evaluate and compare the hard tissue (Bone density) outcomes of flapped and flapless surgically placed dental implants in mandibular posterior region subjected to immediate functional loading protocol.

Materials and Methods: Forty patients, meeting predetermined inclusion and exclusion criteria for dental implant placement in mandibular posterior region were recruited for a single center, parallel group, double blinded randomized control trial. Patients were randomly allocated in two groups on the basis of surgical method used for implant placement: flapped & flapless. Implants were loaded functionally with provisional auto-polymerizing composite resin within 48 hours of surgery and after 4 month replaced by metal- ceramic permanent restorations.

Outcome Measures: Bone density was measured through cone beam computed tomography (CBCT) in patients of both groups at baseline, 4months, 8months and 12 months.

Results: No drop out occurred after 12 months of implant placement. Five implants failed 3 in flapped group and 2 in flapless group. Intergroup comparison (flapped & flapless) of mean bone density in gray scale at different time intervals (baseline, 4 months, 8 months and 12 months) in falpped was lesser than flapless at 4 months [flapped 1081.1±156.66, flapless 1174.6±192.79], at 8 months [flapped 1212.2±121.67, flapless 1317.8±158.21], at 12 months [flapped 1307.9±126.27, flapless 1418.3±162.19] and difference was statistically significant (P values were .008*, <0.001*, <0.001* at 4, 8 and 12 months respectively).

Intra group comparison of mean bone density from baseline to different time intervals was higher in flapped group from baseline values and difference was statistically insignificant. (p values were .002, 0.000,.000 at 4 months, 8 months and 12 months respectively) and the mean bone density was, at 4 months [-45.27], at 8 months [-176.32], at 12 months [-272.09]. For flapless group the mean bone density was at 4 months [-42.71], at 8 months [-185.93], at 12 months [-286.47] and difference was statistically insignificant. (p values were 0.004, 0.000, 0.000 at 4 months, 8 months and 12 months).

Conclusion: Within limitations of study it was concluded that flapless surgical technique could be considered for implant placement for more bone density which was increased around implant in both the groups. Mean bone density was higher in flapless group at all recall intervals and the difference was statistically significant.

Keywords: Bone Density, Micro-motion, Osseointegration, Immediate functional loading.

Introduction

The purpose of tooth replacement with a dental implant is to restore adequate function and esthetics without affecting adjacent hard and soft tissue structures. Osseointegrated dental implantation is traditionally implemented by a flap method that includes soft tissue flap reflection and necessitates the introduction of sutures after implant placement. This procedure can be performed in 1 stage or 2 stages, where by the mucosal flap acts to prevent bacterial infection and minimize micro motion.[1-4]

Alternative to conventional technique, a flapless surgical approach was introduced by Lederman (1977) in which, mucosa is directly punched or a mini- incision technique is used.[4] Additional method of flapless implant surgery is penetrating through a round bur directly through the mucosa into the alveolar bone. Flapless procedure has several advantages over conventional flap surgery involving reduced surgical time, less traumatic surgery, no suture required, accelerated post-surgical healing and better maintenance of the soft tissue profiles.[5,6]

After surgical placement, dental implant is loaded prosthetically either delayed or immediate (functional or non-functional). Delayed loading refers to the prosthetic loading of an implant after a non-loaded healing period of 3 to 6 months. The drawbacks of the delayed loading protocol are the lengthy treatment period usually of 6 to 14 months and the resultant patient inconvenience. Besides, the bone density around the implant after the 6 month period was found to be a reduced due to lack of functional stimulation.[7] In consequences number of investigators have turned their concentration to whether osseointegration might also be obtained in the form of immediate loading.

Immediate loading refers to loading the implant with a provisional restoration within 48 hours of implant placement.[8] The advantages include elimination of second stage surgery, development of peri-implant soft tissues before fabrication of the final prosthesis, shortened treatment time, an advanced bony foundation for the definitive prosthesis,[8,9] better function and greater patient satisfication.[11] Implants subjected to immediate loading may have provisional restoration with direct occlusal contact

(functional) or not (non-functional). Certain studies comparing immediate functionally loaded and non-functionally loaded implants have found a significant difference in crestal bone loss and implant survival rates.[12,13]

Various research works have been noticed in present literature dealing with a flapped and flapless surgical approach for dental implant insertion subjected to delayed as well as immediate loading protocols.[14,15] However, there is scarcity of studies that had evaluated and compared radiographic bone density of full thickness flapped and flapless surgically placed dental implants under immediate functional loading in mandibular posterior region. Therefore, this study was designed to determine and compare radiographic bone density of flapped versus flapless surgically placed dental implants under immediate functional loading through CBCT.

Materials and Methods

This study was a single-center, non-stratified with balanced randomization, double blind, parallel group study conducted at the Department of Prosthodontics, King George Medical University, Lucknow, India from Sep 2016 to Sep 2018.

All the patient requiring dental implant treatment for missing mandibular posterior region (single tooth gap),were screened for predetermined inclusion and exclusion criteria for the study. Inclusion criteria for the study were: healed extraction sites, age group of 18-65years, good oral hygiene and periodontally sound teeth, sufficient amount of bone (more than 10 mm in height and 5mm in width, as determined by pre-operative dental CT scan), Co-operative patients, ready to give written consent.

Patients were not considered for the study if any of the following criteria were present: poor oral hygiene, periodontally weakened teeth, medically compromised patient, any parafunctional habit, history of pan chewing, smoking, alcohol, drug dependency, signs of infection at surgical site and uncooperative patients. Patients were enlisted and treated in an Indian government hospital, settled with capacious experts in oral implantology. Study procedure was explained thoroughly and signed written consent forms taken from all the patients before enlisted in the RCT. All surgical procedures were executed by an expert surgeon, while all the prosthetic procedures were executed by another prosthodontist. Primary screening was achieved by using intraoral periapical and panoramic radiographs. Finally edentulous spaces to be restored were assessed for sufficient bone height and width on preoperative dental Cone Beam Computed Tomography (CBCT) (CS9300 carestream, Atlanta, GA).

Partially edentulous patients requiring dental implant treatment for missing mandibular posterior region (single tooth gap) were randomised for dental implant insertion after flap elevation or with a flapless procedure. Thus patients were divided into two identical groups (allocation ratio 1:1) based on surgical technique used for dental implant placement: flapped (20 patients) and flapless (20 patients). Subjects were assigned in both groups by a computer aided simple randomization procedure. After the delivery of local anaesthesia, patients were treated according to the allocated procedure (either flapped or flapless). Surgical stent clearly determined the location of the final restoration was fabricated on the diagnostic cast with acrylic resin denture tooth and auto-polymerizing acrylic resin (Pyrax Polymers, Roorkee, India) to guide the placement of dental implants. Prophylactic antibiotic coverage (2gm Amoxicillin) 1 hour prior to surgery was prescribed to the patients. Surgeon, who was not aware regarding randomisation procedure, was informed whether to raise the flap or not. A crestal incision was made on the center of edentulous ridge; full thickness mucoperiosteal flap was raised to expose the bone in flapped group. Circular tissue punch with a diameter smaller than the implant diameter was used in flapless surgical procedure. For both groups, pilot drill of 2 mm was used to create initial osteotomy of predetermined implant length followed by removal of surgical stent then osteotomy site was prepared with bone drills with sequentially increased the diameter as mentioned by the manufacturer. Paralleling pin of 2mm diameter was used to assess the angulations and position of osteotomy site. Implant was inserted with the motor driven implant driver at 30 rpm by a low speed high torque hand piece (Kavo, Warthausen, Germany) and finally tightened with torque wrench up to the insertion torque 40N/cm. Myriad Plus implant system (Equinox medical Technologies B.V, Amersfoort, Netherland) was selected according to the available bone. After implant placement, healing cap was screwed to the implant, immediately to close the opened implant site. In the flapped group, flap was approximated with interrupted suture technique using non-resorbable 3-0 silk suture (Ethicon, Johnson & Johnson Ltd, Chennai, India). Post-operative instructions were given to the patients in both group regarding diet, oral hygiene maintenance, warm saline gargle after 24 hour of surgery for 3-4 days. Antibiotic amoxicillin (625mg, twice a day), analgesic Zerodol SP (100mg, twice a day) were prescribed for three days. Follow up examinations were made after 48 hours, 4 months, 8 months and 12 months for bone density evaluation.

Indirect provisional crowns for subjects of both groups were fabricated into the laboratory with Protemp^{tm} 4 autopolymerising composite resin temporization material (3M ESPE Minnesota, USA) and were adjusted to have occlusal contact only in centric occlusion to fulfill the principal of implant protective occlusion. Provisional restoration was splinted to the adjacent teeth by autopolymerizing composite resin. After 4 months provisional restoration was replaced by definitive Porcelain to Fused Metal restoration. Closed tray impression were made with elastomeric impression material (Zhermack zetaplus, Italy). Final prosthesis was fabricated with standard protocol and tried in patient's mouth. The definitive Porcelain to Fused Metal restoration was luted by GIC type 1(GC Gold label, Tokyo, Japan) under the principal of implant protective occlusion. Patients of both groups were recalled every month throughout the study for check-up.

The outcome measure of the study was: Radiographic bone density for which DICOM files (Digital Imaging and Communications in Medicine) format were opened on computer multiplanner screen with the help of software (CS 3D imaging). Navigation was done on the multiplaner screen until accurate views of dental implants were observed on the reformatted sagittal and coronal planes. On CBCT, (CS9300 carestream, Atlanta, GA) experienced examiner, performed the evaluation of radiographs. Software automatically illustrates the changes in the grey values in numbers by moving the pointer from region to another on the monitor. The grey values of the bone around each implant were measured in three regions of interest and at four points: Apical region, middle region and cervical region, of the radiological implant length, each mesially, distally, buccally and lingually. Coronal views along the middle of the implants were used to measure the grey values in the three regions mesially and distally), while sagittal views along the middle of the implants were used to measure the grey values buccally and lingually.

All outcome measures were assessed by blinded clinician, who was not aware of patient's allocation. Sample size was calculated on the basis of the patients coming to the department for Prosthodontic rehabilitation of missing teeth by implants in a given time period of 1 year were screened for inclusion. Sample size was calculated using the formula: $n=17\sigma2/\Delta2+1$

Where: n= Sample size per group, Δ= Difference in the means, σ=half of the confidence interval which is 0.5. Assuming 80% power, 5% significance level with 95% confidence interval as well as assuming standard 0.4, the required sample size per group is 18. Assuming 10% loss to follow-up, the final sample size was 20 per group.

Results

Fifty four patients were assessed for inclusion in the study, but 14 patients could not be involved in the study due to the following reasons: 4 patients decline to participate, four patients had unhealed extraction sites, three patients were medically compromised and three patients did not have sufficient bone for implantation. Forty patients fulfilling the inclusion criteria were involved in the study and were treated according to the allocation (Flapped vs Flapless). No drop outs occurred during follow up period. Elective patients were selected from Sep 2016 to Feb 2017.All implants were placed between March 2017 and Oct 2017. Data for crestal bone loss and bone density were recorded until March 2018. Total 40 patients were included in the study, out of which 3 in flapped and 2 in flapless underwent failure, so total 35 implants, 17 in flapped and 18 in Flapless group were subjected to statistical analysis.

Mean bone density in flap group was lesser than flapped group at 4 months [flapped 1081.1±156.66, flapless 1174.6±192.79], at 8 months [flapped 1212.2±121.67, flapless 1317.8±158.21], at 12 months [flapped 1307.9±126.27, flapless 1418.3±162.19] and difference was statistically significant (*P* values were 0 .008*, <0.001*, <0.001* at 4, 8 and 12 months respectively)-see Table 1. Table 2 showed that intra group comparison of bone density from baseline to different time intervals. For flap Group, the mean bone density, at 4 months [-45.27], at 8 months [-176.32], at 12 months [-272.09] was higher from baseline values and difference was statistically insignificant. (P values were 0.002, 0.000, 0.000 at 4 months, 8 months and 12 months respectively), for flapless Group, the mean bone density, at 4 months [-42.71], at 8 months [-185.93], at 12 months [-286.47] and difference was statistically insignificant. (P values were 0.004, 0.000, and 0.000 at 4 months, 8 months and 12 months).

Table 1: Inter group (Groups I vs Group II) comparison of bone density (gray scale) at different time interval

Time Interval	Groups	Mean±SD	Std. Error Mean	Mean Difference	95% Confidence intervals		t value	p-value
					lower	upper		
At base line	Group I	1074.4 ± 68.55	9.61	-57.43	-76.09	1.24	-1.920	0.058
	GroupII	1131.8 ± 122.25	16.636		-75.62	.77		
At 4 months	Group I	1081.1 ± 156.66	21.936	-93.46	-161.68	-25.23	-2.717	0.008*
	GroupII	1174.6 ± 192.79	26.236		-161.29	-25.62		
At 8 months	Group I	1212.2 ± 121.67	17.037	-105.62	-160.47	-50.76	-3.818	<0.001*
	Group II	1317.8 ± 158.21	21.529		-160.09	-51.14		
At 12 months	Group I	1307.9 ± 126.27	17.681	-110.39	-166.87	-53.90	-3.876	<0.001*
	Group II	1418.3 ± 162.19	22.071		-166.49	-54.28		

Table 2: Intra group comparison of bone density (gray scale) from base line to different time interval

	Paired Differences					t	df	p-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
Group I				Lower	Upper			
At 4 months	-45.27	98.698	13.82054	-73.02	-17.51	-3.275	50	0.002
At 8 months	-176.32	56.587	7.92382	-192.23	-160.40	-22.252	50	0.000
At 12 months	-272.09	68.203	9.55036	-291.28	-252.91	-28.490	50	0.000
Group II								
At 4 months	-42.71	102.836	13.994	-70.78	-14.64	-3.052	53	0.004
At 8 months	-185.93	62.187	8.463	-202.89	-168.95	-21.970	53	0.000
At 12 months	-286.47	71.529	9.734	-305.10	-266.95	-29.431	53	0.000

Discussion

Previously numerous studies illustrated, resorption of bone, following elevation of mucoperiosteal flap as well as flapless surgical protocol for dental implant insertion subjected to immediate as well as delayed loading.[16-18] Although there is paucity of studies comparing the bone density using flapped and flapless surgical procedure for dental implant insertion subjected to immediate functional loading in mandibular posterior region. As the extent and condition of bone are important for osseointegration, it was relevant to study the variation in bone density with these procedures. Thus this study was designed to evaluate if implants placed with flapless procedure subjected to immediate functional loading in mandibular posterior region manifest similar clinical outcomes, when compared with the implants placed by conventional flapped procedure subjected to immediate functional loading or whether postoperative morbidity could be reduced without flap elevation. This study was a single-center, non-stratified with balanced randomisation, double blind, and parallel group study. Randomization was done to eliminate "selection bias" and allowed for comparability. Cone Beam Computed Tomography (CBCT) (CS9300 carestream, Atlanta, GA) was obtained to evaluate detailed visualization and measurements of vital structures, from the surgical sites. The conventional preimplant imaging modalities such as Intra Oral Periapical Radiograph (IOPA), Panoramic Radiograph (OPG), Radiovisiography (RVG), Cephalometric and tomographic images are 2-Dimensional images, where measurements of the bone density, is not possible. These also possess disadvantages such as superimpositions, projection geometry and completely lack the third dimension of bone depth. Therefore we used Cone beam computed tomography (CBCT) because it provides a 3-Dimensional imaging modality which helps in better visualization of implant recipient sites and associated anatomical structure, which enhance the surgical and prosthetic decision making and also improve the accuracy of the overall implant treatment and reduces postoperative morbidity.[19]

Despite of these advantages, CBCT produces significantly more ionising radiation than conventional radiographs. Effective radiation dose of Intra Oral Periapical Radiograph, Panoramic Radiograph and CBCT are ≤8.3 µSv, 9-26 µSv and 5-38.3 µSv.[20] This factor should be taken into account when considering a CBCT as an alternative to a conventional radiographs.

The present study showed that, the mean bone density in gray scale values around immediate functional loaded implants in flapless group was higher at different time intervals. These results were in accordance with other studies which found that immediately loaded implants, micromovements can improve osseointegration and can dramatically increase the bone density[9,21] The reason of more mean bone density in flapless group was due to the intact blood supply from soft tissue which facilitates maintenance of nutrition, which is a critical factor in preventing initial bone loss around the implant.[5] This helps in soft tissue contour, better osseointegration, decreased bone loss, increased bone density as increased in our study in both groups.

Along with alteration in vascularization, incision design also contributes to bone resorption and decreased bone density. Various flap designs have been published in the past. Two type of incisions, crestal and remote and three designs like papilla regeneration, resecting contouring and lateral flap advancement to maintain adequate keratinized tissue around implants were described by Cranin AN et al.[22] in their respective articles. However crestal incisions create the most foreseeable levels of primary soft tissue healing. Novel incision (paracrestal, visor, serpentine) may delay primary healing and may cause the loss of alveolar bone found beneath them.[22]

The present study was a single stage surgery followed by immediate functional loading. The implant placement followed by single stage in present study demonstrated that success rates were higher when proper techniques are utilized and patients with good bone quality, adequate keratinized tissue and adequate bone height and width are selected.[21] Immediate loading was followed after single stage implant placement by conventional flap and flapless surgery. Immediate loading has been widely used in implant therapies, particularly in mandibles with good bone quality. Some author conducted a study on immediate versus early loading of flapless placed dental implants and suggested that these protocols provide good esthetics, enhanced function and almost immediate comfort and have a favorable implant survival rate due to continuous improvements in implant materials, designs and surface treatment techniques.[23]

In this study, immediate loading protocol was used with the rationale of improving the alveolar bone foundation around the implant before it could finally be loaded with a definitive prosthesis. The present study was in accordance with the studies conducted by Xu et al.[23] Cochran DL et al.[24] and Nordin T et al.[25] which indicates that both immediately loaded and delayed loaded implants were successful in selected patients, with no statistically significant differences in the outcomes. However, the results suggested that immediate loaded implants might fail more often than conventionally loaded implants. This study suggested that immediate loading of implants is equally good yielding the same results as delayed loading with shorter period of time which is beneficial for the patients as well as the clinician.[26]

Conclusion

This study suggested that immediate loading of implants is equally good yielding the same results as delayed loading with shorter period of time which is beneficial for the patients as well as the clinician. Bone density was increased around implant in both the groups flapped and flapless. Mean bone density was higher in flapless group at all recall intervals and the difference was statistically significant. The sample size in our study was limited. Future research with larger sample size may substantiate the results obtained in our study. The follow up time in our study was limited to 12

months. Future studies with longer follow up time up to 15-18 months could add to the findings of our study.

Source of funding
None.

Conflict of interest
None.

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How to cite this article: Singh N, Agrawal KK, Chand P, Mishra N, Singh K, Agarwal B, Anwar M. Comparison of flapped versus flapless dental implant insertion subjected to immediate functional loading protocol: A parallel group randomised control trial for radiographic bone density changes. *Int J Oral Health Dent* 2019;5(4):198-202.