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A Split Mouth Study on Crestal Bone Architectural Changes by Flapped and Flapless Implant Surgical Procedures

Preet Jain[1*], C. M. Ravi Kumar[2], Meetu Jain[3], Punit Fulzele[4], Amit Porwal[5] and Rahul N. Gaikwad[6]

[1]Department of Prosthodontics R. R. Dental College and Hospital Udaipur, India.
[2]Department of Prosthodontics PDCRC Udaipur, India.
[3]Department of Periodontics R. R. Dental College and Hospital Udaipur, India.
[4]Department of Pedodontics, Sharad Pawar Dental college, Datta Meghe Institute of Medical Sciences, Sawangi(M), Wardha. , India.
[5]Faculty of Dentistry, Jazan University, India.
[6]Department Community Dentistry and Oral Epidemiology, College of Dentistry, Qassim University, Buraydah, India.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Rehabilitations by dental implants have often been utilized as an efficient procedure for restoring missing teeth. For implant placement two types of surgical methods are well documented. Conventional surgical approach involves raising a mucoperiosteal flap to gain access and see the underlying alveolar bone, instead there is this procedure which does not involve the reflection of the flap. Both the techniques are known to have their individual benefits and shortcomings. The present study was aimed to evaluate the longitudinal comparison and evaluation of hard tissue changes around endosseous implants placed using flapped as well as flapless surgical procedures in mandibular first molar region.

Materials and Methods: A total of 10 healthy patients with bilateral mandibular first molar were involved in the study and 20 endosseous implants were inserted (10 in each group). Radiographic assessment was done for deviations in the marginal bone levels on both mesial and distal side and their average value was calculated at 1 month, and 3 months. All these parameters were statistically analyzed using the paired Student t test, and two-way ANOVA test and were considered to be significant if the p value was ≤ 0.05.
Results: During the 3 months observation period, the change in crestal bone height around the implants placed by flapless and flap surgery were statistically significant. The flapless group showed less reduction in the crestal bone height compared to the flap group.
Conclusion: Both flap and the flapless techniques of endosseous implant placement had statistically significant effect on peri-implant bone loss over the 3 month period.

Keywords: Endosseous implants; peri-implant bone; dental implants; alveolar bone.

1. INTRODUCTION

Dental implants have been a successful and effective way of rehabilitating the missing teeth over the last few decades [1]. Implant therapy aims to restore tissue contour, function, comfort, aesthetics, and phonetics. In clinical scenarios, before the implant insertion process, the surgeon has an option to choose between the flapped and flapless approaches. Over the past three decades there have been quite a lot of modifications to the flap design [2,3]. A flap is normally raised for better visualization of the region when inserting dental implants. Flap elevation allows for simple identification and protection of anatomical landmarks. Flap elevation will facilitate implant placement by optimizing implant positioning and minimizing the risk of bone fenestration when the amount of bone available is limited. Flaps, however, are related to some degree of morbidity and pain, and involve suturing. There are cases where raise of the flap may not be required as the amount of bone is adequate and complication risk is minimal. Under these conditions, there could be signs of flapless implant placement. The surgeon operates blindly when inserting implants with a flapless procedure and perforations of the bones are more likely to occur. Guided surgery using customized operating templates made from computerized tomography (CT) scans can help clinicians minimize the risk of perforation and incorrect alignment of the implants [4,5].

Retrospective [6,7] and prospective studies [4,8] have shown that dental implants can be successfully placed without raising a flap, even when the implants are immediately loaded [9,10]. A Cochrane systematic review [11] concluded, based on two randomized controlled trials (RCTs) [12,13], that placement of flapless implants is feasible and patient pain and discomfort in appropriately selected patients has been shown to reduce. In patients treated bilaterally with and without flap elevation, a more recent RCT, examining computer-guided surgery in the posterior maxilla, did not find any disparity or pattern in postoperative pain / discomfort [14]. In the few accessible RCTs, there are additional constraints such as the small sample sizes, lack of data on the implant outcome [13], the presence of confounding factors such as immediate loading only in the flapless group, and inconsistent postoperative pain outcomes [12,14] which make it quite challenging to analyze the findings correctly. A properly designed RCT is still needed to better assess the potential benefits and risks associated with the placement of flapless implants.

From a patient perspective, if the risks of implant failure don't seem to be increasing, it will be optimal to receive a functional fixed prosthesis after minimal surgical intervention based implant placement, minimizing pain, recovery time and costs. There is evidence that immediate loading is a feasible procedure if adequate torque of injection is obtained at installation of the implants [15,16]. The aim of this study was to observe the effect of flap and flapless procedure on soft tissue as well as hard tissues.

2. MATERIALS AND METHODS

2.1 Patient Selection and Preoperative Procedures

The present study was a randomized control trial designed as a multicentric longitudinal research in which two separate implant surgical centers in India were selected. Parametric observations of the variation in bone morphology, in two major variants of implant surgical techniques, mainly

flap elevated implant placement procedure and flapless implant surgical method were done.

2.2 Sampling

A random sampling for the selection of patients was done. The study was conducted from baseline to three months. This study was conducted among the 10 participants and split mouth design was used among them. Total of 10 implants were placed in Group 1 (Flapless) and Group 2 (Flap) respectively. The sample size was calculated using G*Power Version 3.1 [17] taking into account of the power of previously published literature.

2.3 Inclusion and Exclusion Criteria

Their patients [18] included in the study had bilateral absence of mandibular first molar. Both adjacent molar and premolars were present. The residual bone had a minimum width of 5mm and a vertical height from mandibular canal was at least >10 mm. The ridge was adequately healed, remodeled and showed no signs of periodontal disease. There was no signs of any form of pathological migration from the opposing arch. The patient agreed to be part of this trial and anyone who was unwilling to sign informed consent was omitted from the study. Patients who had type 4 bone[(59)] and required any bone augmentation procedures were also omitted from the study. Pregnant patients, medically compromised, patients suffering from any inflammatory and autoimmune diseases were also excluded. Patients with poor oral hygiene and had a habit of smoking were also prohibited to be part of the study.

2.4 Surgical Procedure

All patients were advised to a chlorhexidine 0.2% mouth rinse immediately prior to surgery. The patient's face was disinfected with 7.5%povidone Iodine. The oral cavity was prepared with 5% povidone-iodine and patient draped as per standard principles of surgery. to block regional nerve supply and help in hemostasis, local anesthetic xylocaine 1:100,000 epinephrine, Astra, Zanacea Rutherford, NJ was administered.

A conventional flap was raised for the site chosen for flap, was elevated with a No.9 Molts periosteal elevator, both buccally and to the lingual to expose the mandibular bone. Care was taken to prevent the flap from tearing. After adequate exposure of crestal bone, the surgical stent was placed [19,20]. For the flapless a crestal mini-incision, approximately 5mm horizontally with alveolar crest, was made at the center of the implant site [21,22]. Local gingiva was undermined not exceeding 5mm, and within the range of a large diameter implant.

2.5 Implant Placement Procedure

A pilot hole is made with No.6 round bur. The center of implant site prepared with the pilot drill for initial depth of bone preparation for implant length. The osteotomy preparation was proceeded according to drill sequence. After drilling, crestal heights in facial and lingual plates were reassessed by measuring osteotomy depth and the mucosal thickness around the crest. The probe was then inserted gently into the osteotomy walls, analyzing for any perforation of the cortical plate and to assess if any soft tissue debris was left in the prepared site. The implants were then inserted 2mm below the crest of the bone. The incised wounds were sutured with a single Silk 4-0 suture after placement of the cover screws. In both groups, dental implants were manually placed with a wrench and post-operative radiographs were taken.

2.6 Postoperative Care

An antibiotic regimen of amoxicillin 500 mg and an analgesic 400 mg was generally prescribed for the patient. In addition, the patient was advised to rinse with 0.2% chlorhexidine twice a day for 2 weeks and to begin regular brushing after 1 week post-surgery. The patient was advised to maintain proper oral hygiene throughout the healing period. Patients were seen 3 days after the implantation procedure for a checkup to assess the postsurgical pain and swelling and to evaluate the consumption of analgesics. Then, 7 days after implantation, patients were seen for a second checkup, where suture removal and oral hygiene instruction were given. A follow-up of was done for a time period of one month and three month period.

2.7 Parametric Evaluation

2.7.1 Crestal bone loss -radiographic evaluation

Radiographs were taken with long cone paralleling technique after implant placement, one and three months' post-operative period to assess changes in the crestal bone levels. The

distance between the fixture shoulder and the apical level of the marginal bone was measured. Implant height was used for calibration purposes. Images [23], an open platform for scientific image processing programs designed for scientific multidimensional images.

Before the start of the study two examiners were selected and both were kept blind for the study group. Both examiners were calibrated regarding procedure by subject experts. Their agreement was calculated and when it has been reached more than 80 percent then both examiners were considered for the final evaluation at 1, and 3 months follow up.

3. RESULTS

This study aimed at evaluation and comparison of flap and flapless implant placement on the crestal bone loss.

3.1 Intra Group Comparisons

We can see from Table 1 the crestal bone loss in the flapless group mean varied between 0.35 with a standard deviation of 0.053 at 1 month. When the bone loss was seen for 3 months, a mean of 0.49 with a std. deviation of 0.13 was observed. When comparisons were done within the flapless group for the crestal bone loss from 1 months to 3 months for flapless group, highly significant changes p-value < 0.021 were observed.

We can see from Table 1 the crestal bone loss in the flap group mean varied between 0.47 with a standard deviation of 0.082 at 1 month. When the bone loss was seen for 3 months, a mean of 0.60 with a std. deviation of 0.14 was observed. When comparisons were done within the flapless group for the crestal bone loss from 1 months to 3 months for flapless group, highly significant changes p-value < 0.028 were observed.

3.2 Intergroup Comparisons

Table 2 compares the values of crestal bone loss between flapless and flapped groups, indicating there was significant difference in the crestal bone loss observed with p-value **<** .001 in the first month of implant placement. Contrary to one month follow up, when evaluations for the same parameter was done in 3 months, no significant difference p> .05 was found between the groups.

4. DISCUSSION

The aim of the present multicentric pilot project was to examine the effect of flapless implant surgery on hard tissue compared with flap implant surgery. The comparison showed that there were significant results for the flap as well as flapless group over a period of time from 1 month to 3 months. It was decided to use a split-mouth design in order to minimize biological variables and to be able to evaluate patient preference.

Long-term success and failure of different procedures rely on a traumatic surgical operation, osseointegration of implant and eventually the quantity and quality of the bone covering the implant. Flap configuration is one of the vital factors that may influence the prognosis of implant treatment [3,24,25] Flap elevation allows easy operator visibility of the alveolar

Table 1. Crestal bone loss in the flapless group

Parameter	Follow-up	Mean SD	t-value	P-value
Crestal Bone	1 month	0.35±0.053	-2.806	0.021*
Height- Flapless	3 Months	0.49±0.13		
Crestal Bone	1 month	0.47±0.082	-2.623	0.028*
Height-Flap	3 Months	0.60±0.14		

**p<0.05 Significant*

Table 2. comparative values of crestal bone loss between flapless and flapped groups

Surgical Technique	Crestal Bone Height	
	1 month	3 Months
Flapless	0.35±0.053	0.49±0.13
Flap	0.47±0.082	0.60±0.14
t-value	3.882	-1.819
p-value	0.001*	0.086

**p<0.05 Significant*

bone and assess bone morphology of the ridge [26]. Further, modification and augmentation of crestal ridge morphology could be achieved using this approach. This procedure, however, is considerably invasive and induces increased catabolic activity which leads to elevated osteoclastic activity and thereby resulting in marginal bone loss.

With “flapped” technique, crestal bone loss in 1 months and 3 months period was found to be significant. Van der Zee et al. [27] investigated guided bone regeneration and its impact of flap reflection on gingiva and bone, and found that gingival recession and bone resorption were statistically significant 12 months after surgery. The results of the study indicated a significant reduction in crestal bone height at all time intervals on both the proximal aspects when using "with flap" technique. Wood et al. [2] registered bone losses of 0.23 to 1.60 mm in 4–6 months post elevation of the flaps. Campelo and Camara noticed that the thickness of the flap at the surgical site and bone resorption is related, using "with flap" technique [6]. In the first year of implant functional use, the average marginal bone loss should be < 1.5 mm, according to the success criteria of Albrektsson et al. [24] Findings from this research have shown that after the first year of loading, none of the implants with both techniques had a bone loss of more than 1.5 mm.

The results of the present study showed “flapless” and flap technique, change in average crestal bone loss was clinically significant during the initial 3 months. The overall change in crestal bone loss was mean 0.49±0.13 and 0.60±0.14 respectively. [Table 1]

Sunitha and Sapthagiri found that flapless surgery resulted in the non-significant loss of crestal bone (0.03–0.09 mm) [28] and Jeong et al. with flapless technique over a 1-year period observed mean marginal bone loss ranging from 0.0 to 1.1 mm [29]. Becker et al also noted nonsignificant bone loss around implants put up to 2 years using a flapless technique. Becker et al also noted nonsignificant bone loss around implants inserted and followed for 2 years using a flapless technique [8] A MEDLINE analysis on studies conducted between 1966 and 2008 documented a mean radiographic bone loss ranging from 0.7 to 2.6 mm after flapless technique [3].

Comparison of both techniques in this study revealed substantially less bone loss with "flapless" than "with flap" technique. Job et al. reported similar results as they observed the 0.06 mm crestal bone loss with a "flapless" technique and 0.4 mm "with flap" technique over a 3 month period [30]. Nickenig et al. found that during the healing phase, marginal bone levels adjacent to implants showed similar results with flapless (0.7–2.4 mm) and flap (2–3 mm) [31]. Al-Juboori et al reported similar findings, too [32].

Jeong et al. performed their analysis in canines and, after an 8-week healing cycle, observed more peri-implant bone height (10.1 mm) with flapless technique compared to open flap site (9.0 mm) [33]. In a retrospective study by Campelo and Camara [6], the success rate for implants inserted with a flapless one-stage surgical technique was found to be between 74.1 percent to 100 percent over a 10-year period. More flapless technique of crestal bone resorption is due to preservation of bone vascularisation [25,33,34].

As described in the preceding literature, the intact blood supply from soft tissue in the "flapless" procedure promotes nutrition maintenance, which would be a crucial step in minimizing initial bone loss around the implant. This also helps to preserve the site's soft tissue architecture and hard tissue volume [35,36]. Tissue healing is accelerated, allowing the patient to instantly resume standard hygiene protocols as opposed to the sites where sutures are given. Early plaque maintenance plays a significant role in promoting the periimplant mucosal health and in minimizing periimplant bone loss, according to previous studies [6,8,37,38].

Variations between the initial and later stages of study may be due to the intact periosteum which preserved a better blood supply, thereby reducing the probability of early bone resorption while normal physiological bone resorption was observed in later stages [39,40].

When comparisons were drawn between flapless and flapped groups significant changes were significant between the two for a period of 1 month. The three months duration demonstrated no significant difference of crestal bone losses between the two procedures. [Table 2].

The greater bone loss occurrences at "with flap" sites is attributable to the fact that the periosteum gets denuded from the interproximal bone in the vicinity of the adjacent tooth. This can affect

bone and papillae nutrition resulting in a degree of resorption of the inter-proximal crestal bone [41]. Sunitha et al also studied the impact of two different flap designs on CBH and reported that flap elevation during the healing period leads to increased bone loss [42-46]. Literature, however, also indicates that the flapless technique generated increased crestal bone loss around the implants [47-51].

5. CONCLUSION

This research, with its limitations, parametric evaluation of peri-implant bone crestal bone resorption has no statistical significance between flapped and flapless implant placement procedures. Furthermore, the scientific data from this present study should not be interpreted as substantial evidence for clinical outcomes as further research is required. It is difficult to estimate the impact of various variables and confounding factors. Therefore,for more validity and reliability of the results. a larger sample size, long time duration, and inclusion of various confounding factors should be considered.

6. LIMITATIONS OF THE STUDY

Time duration to evaluate the effect of surgery was less. Number of subjects used for the study is less confounding factors may have affected the long-term outcomes

CONSENT AND ETHICAL APPROVAL

The study adhered to the principles outlined in the Helsinki Declaration on clinical research, after the ethical committee clearance of the institution; patients were screened and given detailed descriptions of surgical and prosthetic procedures with a follow-up of the same. A signed informed written consent form was then taken before their enrollment in the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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