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ORIGINAL ARTICLE **OPEN ACCESS**

A Study To Compare The Hard Tissue And Soft Tissue Changes In Flap and Flapless Technique of Implant Placement in Mandibular Posterior Edentulous Area-An *In Vivo* Study

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ABSTRACT
Flapless surgical therapy aims to reduce the surgical trauma in implant placement. Crestal bone levels and osseointegration have improved by comparing surgical flap elevation technique to flapless implant surgery. The crestal bone levels and soft tissue profile after implant insertion using the flap and flapless techniques in mandibular posterior edentulous areas were compared in our study After agreeing to participate, patients were randomly allocated and were followed for 6 months for outcome of interest. Study was done over a span of 2 years. Twenty mandibular edentulous sites in ten patients eligible for Dental Implant placement were selected for the present study. Dental Implant placement were done in bilateral mandibular posterior edentulous area following the conventional surgical flap elevation technique on one side and on other side using flapless technique. Crestal Bone Level were recorded using RVG by paralleling technique using a customized occlusal bite jig and soft tissue thickness was recorded using customized acrylic stent at intervals of 1 month, 3 month and 6 month respectively.: The mean difference in crestal bone level on mesial side between test and control group at baseline to 6 month was 0.3 mm . The mean difference in crestal bone level on distal side between test and control group at baseline to 6 month was 0.37 mm which is statistically significant (p-value=0.011). The mean difference in tissue thickness at baseline to 6 month was 0.05mm which is statistically significant (p-value=0.018).Less crestal bone loss was seen on both the mesial and distal side of flapless group as compared to conventional flap group and there was lesser thickness loss of soft tissue in flapless group as compared to conventional flap group.
Keywords: *Crestal bone loss, Dental Implant, Flaps, Flapless Implant surgery, Tissue*

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INTRODUCTION

Dental implant therapy has been a very effective treatment option, and it is regarded as a trustworthy method of restoring missing teeth. Since dental implants first came into use, the surgical process for implant implantation has undergone significant alterations [1]. The initial Branemark technique called for a flap and a two-stage procedure. Dental implants that are inserted after reflecting flaps have been observed to have some bone resorption. This happens unexpectedly as a result of the flap reflection's modification to the vascularization of the bone periosteum [2]. Dental radiography imaging has undergone significant technological advancement in recent years, which has improved implantology predictability. Flapless approach in implantology is a form of minimally invasive surgery, which has attracted a lot of attention in recent years. Without causing any surgical trauma, flapless surgery also includes implant implantation. Consequently, the wound heals more quickly and without incident. In flapless surgery, the lack of a flap and sutures makes the procedure much simpler and, in most cases, faster. The majority of the time, lack of suture results in the surgery area having a more straightforward postoperative appearance[3]. Recent years have seen significant technology advancements in dental radiography imaging, such as newly created dental implant treatment planning software that enables 3D evaluation of possible Implant Sites. The acceptance of flapless is more due to latest advancement [4]. Numerous experimental studies have shown that avoiding flap reflection when placing dental implants improves the behaviour of the mucosa, periosteum, and peri implant bone by preventing changes to the local vascularization. Less crestal bone resorption is produced by atraumatic techniques, which may also

affect ultimate aesthetic outcomes [5]. A previous study has Jeong et al reported that in comparison to the surgical flap elevation procedure, flapless surgery have favourable results [6]. sing a spherical tissue punch, the soft tissue on the crestal bone at the implant site is removed during the flapless surgical procedure. As a result, less time is spent during surgery, soft and hard tissue are maintained, and there may be less pain and swelling after surgery because no sutures are needed or soft tissue flaps are reflected. It also preserves the periosteal vascular supply to bone, facilitates maintenance of nutrition and minimizes the possibility of future crestal bone loss [7-8]. This characteristic of minimally invasive surgery makes it particularly recommended for senior patients along with some illnesses (diabetes, immunodeficiency), when it is crucial to cause the least amount of patient harm and complete the procedure as quickly as feasible. The flapless approach significantly reduces the risk of moderate or protracted bleeding that occurs with conventional treatments, making it safer for the treatment of these patients. [9] However, in flapless surgery, there is limited visibility during drilling, an increased risk of damaging nearby structures or heating the bone due to lack of external irrigation during the preparation of the implant site with guided surgery, and difficulty to visualize the Implant placement (too shallow/too deep) optimally [10,11]. There is minimal epithelial tissue at osteotomy place using the flapless approach. Such a circumstance is extremely unfavourable as it may prevent full osseointegration onto the implant surface, leading to implant failure. Increasing the amount of soft tissues or papillae is challenging using the flapless approach [12,13]. In a different investigation, Becker and Cols [14] evaluated the flapless placement of implants and discovered that it shortens both the surgical process and the recovery period. In order to compare the bone and soft tissue following implant placements with the Flap and guided techniques in the Mandibular Posterior Edentulous area, the study's advantages and disadvantages were taken into account

MATERIAL AND METHODS

Study Design: Split Mouth Randomized Controlled Trial

After agreeing to participate, patients were randomly allocated and were followed for 6 months for outcome of interest. Study was done over a span of 2 years from 15/11/2018 to 15/12/2020. The present Study was conducted in Department of Prosthodontics, SGT University, and Gurugram over a span of 2 years from 15/11/2018 to 15/12/2020. Patients were explained about the complete procedure and treatment plan. Further procedures were performed after the patient's consent.

Sample size: Using G power 3.1.2, was used to calculate sample size for the present study with an effect size of 0.67, 80 power with 5% marginal error and 95 % confidence interval. The minimum sample size for the study was 20.

Inclusion Criteria: The study included 10 patients with total of 20 Mandibular posterior edentulous sites eligible for Dental implant placement. Patients were in the age group of 18-60 years. Patients with recent history of myocardial infarction, uncontrolled diabetes, chronic renal failure, and radiation therapy in orofacial region where Implant surgery is contraindicated were excluded from study. Incomplete facial growth, teeth eruption and insufficient bone quantity were well evaluated with the help of cone beam computed tomography.

Crestal bone level and soft tissue thickness was noted for all the patients. Crestal bone level was calculated as the separation between the point where the bone made contact with the implant shoulder on the mesial and distal sides, and the crest of the bone. Stent was placed on the ridge and soft tissue thickness was measured on buccal side, 2mm apical to the gingival margin on the mid buccal aspect. In this study inclusion criteria consisted of subjects having well healed ridges with post extraction period of more than 6 months. The bone volume and bone quality were found sufficient for implant placement as per cone beam computed tomography.

Exclusion Criteria:

Patients with recent history of myocardial infarction, uncontrolled diabetes, chronic renal failure and radiation therapy in orofacial region where Implant surgery is contraindicated were excluded from study. Incomplete facial growth, teeth eruption and insufficient bone quantity were well evaluated with the help of cone beam computed tomography.

Pre-Operative Assessment

Routine blood investigation was done. Using perforated stock trays, diagnostic impressions were created in irreversible hydrocolloid (Figure1).

Figure 1 Pre operative picture showing edentulous site on 34,36,46,47

Dental stone was used to cast the impressions. Digital periapical radiographs, panoramic radiographs, and cone beam computed tomography (Figure 2,3) were the radiographs that were used to evaluate the implant site.

Figure 2 Preoperative OPG

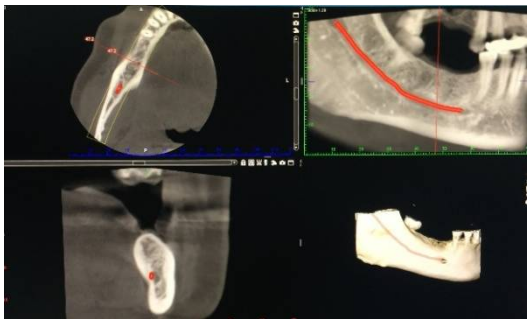

Figure 3 Cone beam computed tomography implant site

For the implantation of flapless implants, a cone beam computed tomography-fabricated tooth-supported guided surgical stent was used.

Implant Selection: The Adin Touareg™-S Implants were selected in width and length according to the available bone at the restorative site as determined by radiographic evaluation.

Two groups were made:-

Figure 4 Conventional flap site 34 region Figure 5 Post operative Implant

Group 1 (flap Group) A total of 10 edentulous site were included in this group. Dental Implant placement was done in Mandibular Posterior Edentulous area following the Conventional Surgical Flap elevation technique (Figure 4,5)

Figure 6 Post operative Radiographic view of Implant placed with flapless technique

Figure 7 Tooth supported surgical guide placed on edentulous site 46,47 region for flapless implant placement

Group 2 (flapless Group) A total of 10 edentulous site were included in this group. Dental Implant placement was done in Mandibular Posterior Edentulous area following flapless technique using soft tissue punch (Figure 6 and 7).

Standardization Of Radiographs (Iopa) And Soft Tissue Thickness

Radiographs

A customized occlusal bite jig was made using putty index on Rinn xcp film holder (dentsply) and IOPA was taken with customized occlusal bite jig using parallel cone beam technique.

Customized acrylic stent

On diagnostic model customized acrylic stent was made to measure change in soft tissue thickness. Stent was placed on the ridge and soft tissue thickness was measured on buccal side, 2mm apical to the gingival margin on the midbuccal aspect. Soft tissue thickness was measured with the help of 20 number H endodontic file with stopper (Figure 8).

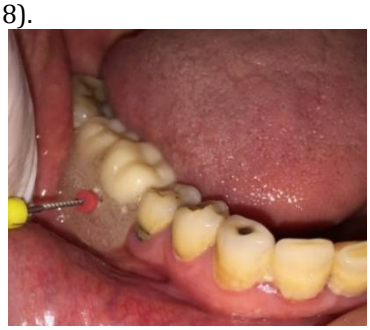

Figure 5 : Soft tissue measurements at flapless Implant site

Dental Implant placement were done in bilateral mandibular posterior edentulous area following the conventional surgical flap elevation technique on control side and on other side using flapless technique. Flapless Implant placement was done using tooth supported surgical guide based on cone beam computed tomography (Figure 9). In the study, the implant's shoulder served as the reference point. On the mesial and distal sides of the implant shoulder, the distance between the point and the crest of the bone where it made contact with the implant was measured (Figure: 10).

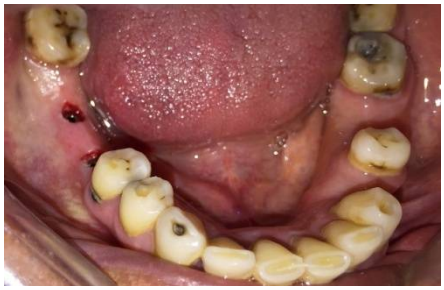

Figure 6 Post operative picture site

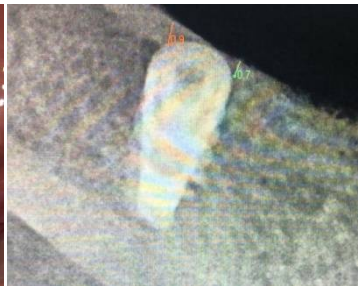

Figure 10 measurement of crestal bone

Radiographic representations of the distance between the spots were used. The distance measured and variations in the levels of the crestal bone were examined on each recall visit. The thickness of soft tissue around dental implants was measured by gently inserting an endodontic file with a rubber stopper until the underlying hard tissue is contacted. Then file was removed and measurements were recorded using digital vernier caliper. Clinical and radio graphical success of implant was assessed by evaluating and comparing the RVG and soft tissue profile at different time intervals i.e. 1month, 3 month and 6 month of Implant placement (Figure11,12).

Figure 11 flapless implant site after 6 months

Figure 12 conventional flap site after 6 months

After three months for the control site, second stage surgery was performed under local anesthesia after three months of Implant placement, followed by placement of healing cap. For the test site, healing cap was already been placed at the time of Implant placement. After 2 weeks of second stage, healing caps of both the sites were removed, impression coping were attached and impression was made. Laboratory analogue were attached with gingival mask and impression was poured in die stone. Final restorations were made on master cast. Abutment were screwed on the Implants and the prosthesis were cemented on both the sites after the verification of occlusion with luting GIC cement followed by closing of access hole with composite resin (Figure13).

Figure 13 Post operative implant prosthesis in flapless and conventional flap implant site

Statistical Analysis: Tables and graphs were used to present the summarized data. Data did not follow a normal distribution as determined by the Shaperio-Wilk W test (p-value was more than 0.05). For comparison of (two or more dependent data readings), repeated measures of Anova were utilised. Pair wise t tests were performed for two paired readings. Between groups Statistical significance was defined as p 0.05.

RESULTS AND DISCUSSION

Friedmann test was used for comparison of (two or more dependent data readings): Intra group and Wilcoxon sign test for used for two paired readings: Inter group. Crestal bone level on Intra group evaluation The Mean difference observed in crestal bone level in control group on mesial side at baseline to 1 month was o.28mm, baseline to 3 month was 0.44mm and at baseline to 6 month was 0.65mm. The Mean difference observed in crestal bone level in control group on distal side at baseline to 1 month was 0.28mm, baseline to 3 month was 0.60mm and baseline to 6 month was 0.69mm. The Mean difference observed in crestal bone level in test group on mesial side at baseline to 1 month was 0.16mm, baseline to 3 month was0.27mm and baseline to 6 month was 0.35mm. The Mean difference observed in crestal bone level in test group on distal side at baseline to 1 month was 0.13mm, baseline to 3 month was0.25mm and baseline to 6 month was 0.32mm. There was statically significant difference in the mean crestal bone

level from baseline to 6 months for mesial and distal side for control group. The mean crestal bone level in the test group's distal side varied significantly statistically from baseline to six months (Table 1).
On inter group evaluation The mean difference observed in crestal bone level on mesial side between test and control group at baseline to 1 month was 0.12 mm, at baseline to 3 month was 0.17 mm and at baseline to 6 month was 0.3 mm which is statistically significant. The mean difference in crestal bone level on distal side between test and control group at baseline to 1 month was 0.15 mm, at baseline to 1 month was 0.35 mm and at baseline to 6 month was 0.37 mm which is statistically significant.

Soft tissue thickness

table 2 shows the mean difference in tissue thickness at baseline to 1 month was 0.1mm which is statistically significant (p-value=0.031). The mean difference in tissue thickness at baseline to 3 month was 0.13mm which is statistically significant (p-value=0.016). The mean difference in tissue thickness at baseline to 6 month was 0.05mm which is statistically significant (p-value=0.018).

Table 1: Inter group comparison of difference in crestal bone level

Side	Time interval	Control group		Test group		Mean Difference	t-test value	p-value
		Mean	Std. Deviation	Mean	Std. Deviation			
Mesial	Baseline-1 Month	0.28	0.24	0.16	0.05	0.12	2.152	0.036*
	Baseline-3 Months	0.44	0.3	0.27	0.13	0.17	2.175	0.032*
	Baseline-6 Months	0.65	0.5	0.35	0.26	0.3	2.259	0.038*
Distal	Baseline-1 Month	0.28	0.1	0.13	0.07	0.15	3.845	0.001**
	Baseline-3 Months	0.6	0.47	0.25	0.14	0.35	2.246	0.037*
	Baseline-6 Months	0.69	0.36	0.32	0.21	0.37	2.824	0.011*

Table 2 Inter group comparison of difference soft tissue thickness at test and control group

	Test site		**Control site**				
Time interval	Mean	Std. Deviation	Mean	Std. Deviation	Mean Difference	t-test value	p-value
Baseline-1 Month	0.21	0.06	0.31	0.03	-0.1	-3.049	0.031*
Baseline-3 Months	0.21	0.04	0.33	0.03	-0.13	-3.263	0.016*
Baseline-6 Months	0.24	0.06	0.35	0.05	-0.12	-2.841	0.018*

When choosing the position and angulation of the Implants, firsthand observation of the crestal bone is always useful. Reflection of the flap enhances operator accessibility and view of the surgical site. Flapless Implant surgery preserves soft tissue and do provide better esthetic results when indicated for immediate or delayed single-tooth Implants, as it is quicker and less traumatic [15-16].The supporting tissues provides a protective seal and anchorage to the Implant as well as maintains its health and vitality too. The implant's long-term prognosis is highly dependent on the creation of this initial soft tissue seal. This biologic seal also prevents bacterial invasion. In total, Twenty Mandibular edentulous sites eligible among 10 patients for Dental Implant placement were selected. In our study the sites were arbitrarily alienated in two groups: In group 1: test group (flapless techniques) and in group 2: control group (conventional flap technique). For the present study, Guided Surgical stent was made. These computed CT images were used to incorporate the proposed prosthesis, taking into account the planned superstructure as well as the jawbone anatomy to improve the biomechanics and aesthetics. the use of surgical guides for the placement of Implant in the optimal position, during the presurgical planning phase. The guided surgical stent was fabricated under the supervision of skilled and experienced Prosthodontist to minimize the above stated errors. CBCT were undertaken from the patient's jawbone to have clear vision of the anatomy [17].

Crestal Bone Level

According to the results of the current study, the test group experienced less crestal bone loss than the control group did on both the mesial and distal sides.
The mean change from 0-1 month, 1-3 month, 3-6 month, and 0-6 month for flapless technique was significantly lower (0.127 to 0.527 mm for flapless technique and 0.186 to 0.707mm for with flap technique) than with flap technique, according to research by Nidhin R et al. (2014).It highlights the discovery that the mean crestal bone alterations for the flapless procedure from baseline to six months duration were considerably lower than for the flap method [18].In settlement to the outcomes of the present study, Anumal D et al. mentioned, Crestal bone loss decreased from baseline to 6 months mesially

for the flap technique [19]. Similarly Wadhwa B et al. also found that bone loss was less in patients where Implant placement was done using flapless technique [20]. Seung *et al*. also found out that the bone loss was more in the Implants placed, with the flap procedure [21]. Oliver R reported that a flapless technique increases the survival rate of dental Implants .The vessels of the alveolar bone, the plexus of the periodontal ligament, and the supra-periosteum vessels control the blood flow to the underlying bone. Periodontal ligament plexus get lost on tooth extraction. Under this environment, the reflection of flap causes loss of supra periosteum vessels, then blood supply of bone is done only by its own vessels. After surgical procedures i.e. dental Implants, which involve incision flap elevation, resorption of crestal bone occurs at the site. This resorption occurs due to change in the blood supply of the bone periosteum [22-23].Whereas, the avoidance of soft tissues reflection with flapless surgery reduces the surgical trauma. Faster healing of soft tissue is evident, as the wound is minimal, with almost negligible complications. The blood supply is also hardly affected. Henceforth in the present study, bone loss for flapless procedure was significantly lower for the observational period of six months.

Soft tissue thickness

In the present study it was reported that there is less retraction of soft tissue in test group as compared to control group. Oliver R found that that a flapless surgical procedure is advantageous for preserving mucosal health. Becker and Cols determined that, flapless procedure leads to lessened surgical time, inflammation, lessened postoperative discomfort and perceived minimized bleeding.

The findings of the current study concur with those of Sunitha and Sapthagiri's investigation [24]. Shibu et al. discovered that FL surgery has superior osseointegration and bone levels as compared. When COMPARED to the flap approach, Abdul-Saheb et al. found that FL Implant implantation provides reduced bone level reduction [25-26.].Raising a full-thickness periosteal flap, for a second stage surgery increases the chances of bone loss

LIMITATIONS

Although this study provided insight into the benefits of doing flapless Implants. It has its own limitations. Firstly, smaller sample size. There was difficulty in standardizing selection of patients for the study. Secondly the present research spanned over a period of 6 months, a greater observational period of one year, two year and five year probably would have been helpful in understanding of the crestal bone loss around Implants. Thirdly, Soft tissue thickness was recorded using a customised acrylic resin stent. This stent was used for a period of 6 months. Although the stent was stored in water but there could have been dimensional changes in acrylic stent, thereby affecting the reading, measured by the digital caliper

CONCLUSION

Flapless Implant placement procedure have positive effect on crestal bone level and lesser thickness loss of soft tissue. However there is need for prospective trials with longer duration.

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