ISSN 2063-5346

CLINICAL EVALUATION OF FLAP AND FLAPLESS IMPLANT SURGICAL PROCEDURES ON GINGIVAL BIOTYPE: A PROSPECTIVE STUDY

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Article History: **Received:** 01.02.2023 **Revised:** 07.03.2023 **Accepted:** 10.04.2023

Abstract

Background and aim: Theoretical frameworks, treatment paradigms, and methodologies have all undergone substantial change in Implant dentistry. In this study, the clinical benefits of flapless implant surgery are compared to those of traditional flap implant placement.

Methodology: The present study is a prospective split mouth research where parametric observations of the variation in soft tissue and bone morphology, in two major variants of implant surgical techniques, mainly flap elevated implant placement procedure and flapless implant surgical method was done. The study was conducted among the ten participants and split mouth design was used among them. Total of twenty implants were placed in Group 1 [Flapless] and Group 2 [Flap] respectively.

Results: The present study shows almost similar results for both the groups. Statistically significant results were observed for soft tissue thickness, bucco-lingual width and modified bleeding index.

Conclusion: The embed dissatisfaction rates were significantly affected by the difference between the two methods (flapless versus flapped). However, when the study groups with a high and low risk of bias were pooled independently, a sensitivity analysis revealed variations, necessitating careful interpretation of the results. There were no statistically significant changes in the incidence of postoperative infection or minor bone loss between open flap surgery versus flapless surgery.

Keywords: Clinical Evaluation, Gingival Biotype, Gingival Biotype, Bleeding Index

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DOI: 10.31838/ecb/2023.12.s1.068

Introduction

Since the dawn of time, people have struggled with the issue of missing teeth. Although there are services available, the utilization of the services is reported in a meta-analysis to be 23.96% in Indian states with highest in the southern India (30.02%). (1) Better methods of tooth replacement emerged as a result of developments in the material sciences and more understanding of occlusion and the gnathostomatic system. The developments were all concerned with the three major goals of comfort, function and aesthetics, and any development which benefited in these goals was popularized. Throughout the past few decades, implant dentistry has seen significant developments. Principles, theories, and treatment techniques have undergone significant modification. The phases of implant therapy for the treatment of edentulism have experienced a variety of alterations recently. One of these is the adoption of a flapless (FL) surgical method in conjunction with single-stage implant implantation. Replacing missing teeth with dental implants is highly predictable. Yet, re-creating a natural-looking gingival margin and papilla for an implant still presents a problem in terms of implant esthetics. (2) Flapless implant procedure includes removing a minimal amount of tissue over the crest of the edentulous ridge, just sufficient to expose the underlying bone to permit implant implantation. As a result, no sutures are necessary, and no soft tissue flap is reflected, potentially minimizing pain and swelling after surgery.

A healing period of 3 to 6 months (submerged implants) with a load-free environment to support undisturbed healing was typically advised and practised throughout the decades when osseointegration was the primary issue.(3) Nevertheless, this notion has been contested by prolific outcomes demonstrated in several invitro and *in vivo* studies using a single-stage surgical protocol (non-submerged implants) and/or immediate loading (IL) of implants. The good outcomes from the aforementioned studies enabled clinicians to broaden the arena of implant dentistry, boosting aesthetic and functional outcomes in addition to osseointegration.

Further, the momentum of treatment time and minimal surgical intervention via IL protocol and one-stage surgical approach positively improves comfort, satisfaction, and acceptability of the patients. The flapless surgical method was created in the late 1970s by Ledermann (4) to combat the bone resorption process. There are few studies comparing the crestal bone height between flapless and flap surgical procedures. In this study, the clinical benefits of flapless implant surgery are compared to those of traditional flap implant placement.

Materials and Research Methodology

The present study is a bi-centric prospective split mouth research where parametric observations of the variation in soft tissue and bone morphology, in two major variants of implant surgical techniques, mainly flap elevated implant placement procedure and flapless implant surgical method was done. The measurements of peri-implant architecture i.e. hard and soft tissue architecture was clinically observed with a modified version of Castroviejo bone mapping caliper in which it was also possible to measure the thickness of soft tissue coverage over the buccal and lingual cortical plates of the edentulous surgical sites under study before and after the implant were placed.

A random stratified sampling of case selection was employed. The sample size was calculated based on the outcome of pilot study which was conducted for six months. The power of the study was fixed at 80%. The pilot study was conducted among the 5 participants and split mouth design was used among them. Total of five implants were placed in Group 1 [Flapless] and Group 2 [Flap] respectively. Mean crestal bone loss was calculated among both the groups and lowest value was taken for calculation of sample size. The anticipated crestal bone loss for Flapless techniques was .30±0.12 while in flap technique it was 0.40±0.14. The sample size was calculated using G*Power [Version 3.1]

Patient selection and Preoperative Procedures

Before treatment, patients underwent clinical and radiographical examinations. In addition to general health requirements for conventional implant treatments, patients had to be able to have mouth opening enabling enough space to accommodate the preparation of the implant sites. To be included in the study, sufficient

bone volume had to be present to allow for the insertion of two implants bilaterally in mandible edentulous region. The study adhered to the principles outlined in the Helsinki Declaration on clinical research involving human subjects. All patients were given detailed explanations of the procedures that were to be performed. An informed consent was taken prior to treatment performed. The ethical committee clearance was attained (SCHU/IEC/2020/04).

Radiographic Records:

A. Orthopantomograph
B. Intra oral periapical radiograph

Inclusion criteria:

Minimum crestal bone width of 5 mm with missing mandibular first molar missing from either side of the arch; Presence of both the adjacent molar and the premolar. The

1. Vertical bone height from bone crest to top of mandibular canal 10-12 mm or greater.
2. At least 1.5 mm in apico-coronal width, of attached non-mobile, preferably keratinized, soft tissue.
3. Agreed to follow-up visits for 1 year.
4. Signed surgical consent forms.
5. Adequately healed and remodeled ridge.
6. Absence of any periodontal problems in adjacent teeth.
7. Absence of supra-eruption of opposing teeth.

Exclusion criteria:

1. Insufficient bone volume, type 4 bone, requiring bone augmentation
2. Habit of smoking.
3. Medically compromised patients like patient suffering from Liver pathologies, blood dyscrasias, kidney, cardiac and endocrinal disorders.
4. Pregnancy or having Inflammatory and autoimmune diseases of the oral cavity
5. Poor oral hygiene

Surgical Procedure using Flap

Random sampling of a total of 10 patients into two groups (Flap and Flapless) were taken, who received 20 implants. The mandibular first molar region was chosen for the present study. A conventional flap was raised for the site chosen for flap. For the flapless procedure to be performed a mini incision technique was use. Since no soft tissue flaps were going to be raised during implant placement, the quantity and morphology of the bone that would host the implants required preoperative assessment. At least 7 mm of bone width was required for placement using a noninvasive technique with no undercuts, since the direction of the bur would not be visible. Bone anatomy and quantity were determined by means of a computed digital palpation, and specially designed caliper.

Conventional flap surgery

A crestal incision was then placed, was extended within the gingival crevices of adjacent teeth and a 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 flap from tearing. After adequate exposure of crestal bone, the surgical stent was placed.

The process of implant osteotomy begun with the punch cut of the pilot drill being made through the hole in the stent, to accurately reproduce the angulation. The osteotomy is then diametrically enlarged to desired width. All these steps are done under constant internal and external irrigation. The implant was then inserted 2mm below the crest of the bone with an insertion torque of minimum 35Ncm. A periapical radiograph was taken during the osteotomy to ensure appropriate angulation and length of the proposed implant site. Cover screws were placed and the mucoperiosteal flaps were sutured with Silk 4-0 sutures.

Implant Placement Procedure

An irreversible hydrocolloid impression was made and a diagnostic cast poured in dental stone. Using caliper/dividers, the available mesiodistal width available for the implant was measured. The diameter of the implant was decided based on Misch`s recommendation that an implant placed adjacent to a natural tooth should remain 1.5 to 2 mm away from the crown in the aesthetic regions. The length of the implant to be used was decided based on regional anatomical considerations as evident in the Orthopantomogram.

Flapless surgery

The soft tissue at the implant recipient site was prepared using a mini incision technique before the implant placement.

Surgical Preparation of the Implant Site

A crestal mini-incision, approximately 5mm horizontally with alveolar crest, is made at the center of the implant site. It is important that the incision be completed in one pass through the mucosa and periosteum, and the periosteum should be scored precisely. Local undermining of the gingiva was then performed. The amount of undermining of the implant site should not exceed 5mm, and it should fall within the range of a large diameter implant. During the undermining procedure, the soft tissue of both sides of the incision line was pushed aside to accommodate the drills and implant. A 5mm incision was appropriate for 4mm for diameter implants. More than >5mm mini-incision was used when the larger diameter implants were used.

A pilot hole is done 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 preceded according to drill sequence. The osteotomy site was irrigated frequently with cooled normal saline. The impact of external irrigation is limited because the procedure is performed below the soft tissue. Therefore, intermittently surgical osteotomies were paused and copious irrigation was done constantly.

After placement of the cover screws, the incised wounds were sutured with a single Silk 4-0 suture. In both groups, dental implants were manually placed with a wrench and an RVG was taken immediately after the procedure

Postoperative care

An antibiotic regimen of amoxicillin 500 mg and an analgesic 400 mg was generally prescribed for the patient. In addition, patient was instructed 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. Follow up was conducted at 3 days, and 7 days after implantation, for a second checkup, where suture removal and oral hygiene instruction were delivered

Parametric Evaluation

Buccolingual width of ridge:

Ridge mapping necessitates three measurements taken at each implant site: one at the level of the ridge crest, near where the center and the apex of implant would be positioned. This parameter was recorded at baseline, 3 months, and 1 year.

Modified sulcus bleeding index

All measurements were performed at four sites around each implant using periodontal plastic probe, Hu-Friedy® and the values obtained from these measurements were calculated for each implant. This parameter was recorded at 3, 6 month, and 1 year.

	Modified Sulcus Bleeding Index
0	No bleeding when a periodontal probe is passed along the mucosal margin adjacent to the implant
1	Isolated bleeding spots visible
2	Blood forms a confluent red line on Mucosal margin
3	Heavy or profuse bleeding

Soft tissue thickness

A modified caliper was used to record the soft tissue thickness. The examiners were calibrated so that the gingival tissue thickness was directly measured without any undue pressure to the gingiva at approximately 2 mm apical to the free gingival margin on the mid-facial aspect. During the measurement, the modified caliper was held by one of the two examiners and the gingival thickness was recorded to the nearest 0.1 mm. The measurements were made until two duplicate values were registered and recorded. The gingival biotype was considered thin if the measurement was $\leq$ 1.0 mm and thick if it measured > 1.0 mm. This parameter was recorded at baseline, 3 months, and 1 year.

Statistical Analysis

Data was analyzed using the IBM SPSS Statistical software package for Windows (Version 25). Descriptive Statistics were represented using Mean and SD; while the inferential statistics were computed using Mann Whitney U statistics for handling non-parametric data was conducted.

Results

The details of the soft tissue thickness, bucco-lingual width and modified bleeding index for individual groups at different follow up levels in the following tables. Group 1 have been compared the interval score for different parameters and a statistically significant difference was noted baseline scores and 1year follow up scores of STT, STT 6 months and 1 year; Bucco-lingual width scores comparisons from Baseline and 6 months, 1 year; 3 months to 6 months and 6month to 1 year. MBI comparison has shown a statistically significant difference from 3 to 6 months.

Table 1: Intragroup comparisons STT, BLW, MBI- Flapless Group 1

	Mean	N	Std. Deviation	Std. Error Mean	z score	P value
Baseline	1.80	10	.422	.133	-1.414[b]	.157
STT 3 months	2.00	10	.000	.000		
Baseline	1.80	10	.422	.133	-1.414[b]	.157
STT 6 months	2.00	10	.000	.000		
Baseline	1.80	10	.422	.133	-2.640[b]	.008*
STT 1-yr	2.80	10	.422	.133		
STT 3 months	2.00[a]	10	.000	.000	.000[c]	1.000
STT 6 months	2.00[a]	10	.000	.000		
STT 6 months	2.00	10	.000	.000	-2.828[b]	.005*
STT 1-yr	2.80	10	.422	.133		
Baseline	12.60[a]	10	.516	.163	.000[c]	1.000
BLW 3 months	12.60[a]	10	.516	.163		
Baseline	12.60	10	.516	.163	-2.449[d]	.014*
BLW 6 months	12.00	10	.667	.211		
Baseline	12.60	10	.516	.163	-2.889[d]	.004*
BLW 1-yr	10.20	10	.789	.249		
BLW 3 months	12.60	10	.516	.163	-2.449[d]	.014*
BLW 6 months	12.00	10	.667	.211		
BLW 6 months	12.00	10	.667	.211	-2.842[d]	.004*
BLW 1-yr	10.20	10	.789	.249		
MBI 3 months	1.00	10	.667	.211	-2.000[b]	.046*
MBI 6 months	.60	10	.516	.163		
MBI 3 months	1.00	10	.667	.211	-1.190[b]	.234
MBI 1-yr	.60	10	.516	.163		
MBI 6 months	.60	10	.516	.163	.000[c]	1.000
MBI 1-yr	.60	10	.516	.163		

*statistically significant

Table 2: Intragroup comparisons STT, BLW and MBI flap Group-2						
	Mean	**N**	**Std. Deviation**	**Std. Error Mean**	**z-score**	**p-value**
Baseline	1.80	10	.422	.133	-1.414[b]	.157
STT 3 months	2.00	10	.000	.000		
Baseline	1.80	10	.422	.133	-1.414[b]	.157
STT 6 months	2.00	10	.000	.000		
Baseline	1.80	10	.422	.133	-2.972[b]	.003*
STT 1-yr	3.60	10	.516	.163		
STT 3 months	2.00[a]	10	.000	.000	.000[c]	1.000
STT 6 months	2.00[a]	10	.000	.000		
STT 6 months	2.00	10	.000	.000	-2.889[b]	.004*
STT 1-yr	3.60	10	.516	.163		
Baseline	12.60	10	.516	.163	-1.857[d]	.063
BLW 3 months	12.00	10	.667	.211		
Baseline	12.60	10	.516	.163	-2.873[d]	.004*
BLW 6 months	10.60	10	.516	.163		
Baseline	12.60	10	.516	.163	-2.873[d]	.004*
BLW 1-yr	8.60	10	.516	.163		
BLW 3 months	12.00	10	.667	.211	-2.889[d]	.004*
BLW 6 months	10.60	10	.516	.163		
BLW 6 months	10.60	10	.516	.163	-2.842[d]	.004*
BLW 1-yr	8.60	10	.516	.163		
MBI 3 months	1.80	10	.422	.133	-2.271[b]	.023*
MBI 6 months	1.00	10	.667	.211		
MBI 3 months	1.80	10	.422	.133	-2.449[b]	.014*
MBI 1-yr	1.20	10	.422	.133		
MBI 6 months	1.00	10	.667	.211	-.743[c]	.458
MBI 1-yr	1.20	10	.422	.133		

*statistically significant

Group 2 have been compared the interval score for different parameters and a statistically significant difference was noted baseline scores and 1year follow up scores of STT baseline and 1 year; 6 months and 1 year; Bucco-lingual width scores comparisons from Baseline and 6 months, 1 year; 3 months to 6 months and 6month to 1 year. MBI comparison has shown a statistically significant difference from 3 month to 6 months and 3 months and 1 year.

Table 3: Inter Group Statistics for comparison of Soft tissue thickness, Bucco-lingual Width Modified bleeding index

	Groups	N	Mean	Std. Deviation	Std. Error Mean	z-score	p-value
Baseline	**Flapless**	10	1.80	.422	.133	.000	1.000
	Flapped	10	1.80	.422	.133		
STT 3 months	**Flapless**	10	2.00	.000[a]	.000	.000	1.000
	Flapped	10	2.00	.000[a]	.000		
STT 6 months	**Flapless**	10	2.00	.000[a]	.000	.000	1.000
	Flapped	10	2.00	.000[a]	.000		
STT 1-yr	**Flapless**	10	2.80	.422	.133	-2.952	.003*
	Flapped	10	3.60	.516	.163		
Baseline	**Flapless**	10	12.60	.516	.163	.000	1.000
	Flapped	10	12.60	.516	.163		
BLW 3 months	**Flapless**	10	12.60	.516	.163	-2.013	.044*
	Flapped	10	12.00	.667	.211		
BLW 6 months	**Flapless**	10	12.00	.667	.211	-3.502	.000*
	Flapped	10	10.60	.516	.163		
BLW 1-yr	**Flapless**	10	10.20	.789	.249	-3.479	.001*
	Flapped	10	8.60	.516	.163		
MBI 3 months	**Flapless**	10	1.00	.667	.211	-2.684	.007*
	Flapped	10	1.80	.422	.133		
MBI 6 months	**Flapless**	10	.60	.516	.163	-1.389	.165
	Flapped	10	1.00	.667	.211		
MBI 1-yr	**Flapless**	10	.60	.516	.163	-2.439	.015*
	Flapped	10	1.20	.422	.133		

*statistically significant

Statistically significant difference was noted for the inter group statistics at 1 year flap for Soft tissue thickness, at 3 months, 6 months and 1 year for Bucco-lingual width. For, MBI comparisons statistically significant difference was noted at 3 months and 1 year follow up.

Discussion

This study analyses and reports the clinical impacts of regular flapped and negligibly obtrusive flapless single embed methodology. Both careful modalities showed effective clinical results as long as a year, with insignificant bone misfortune also, appropriate patient fulfilment. There-front, the speculation that the flapless medical procedure for embed situation would yield better clinical outcomes to the flapped method was acknowledged. The decision for a careful strategy for implant placement methodology relies upon a number of several factors, including the extent of the appended gingiva region. The pertinence of assessing the viability of various careful methods and recuperating conventions in post-extraction inserts has been focused on in a few late re-sees and clinical examinations. Quick implants have turned into an everyday practice strategy as they have a comparative endurance rates when contrasted with inserts set in mended bone.(5) Prompt (type 1) convention is promptly acknowledged by clinicians and patients, as it

infers one single careful mediation, less injury, may give prompt aesthetics and solace and it abbreviates complete treatment time (Bianchi and Sanfilippo 2004; Norton 2004; Lang et al. 2007; Quirynen et al. 2007). Various clinical conventions have been recommended to control or limit the impacts of this mending system. The present study showed better representation of the soft tissue markers with flapless.(6)

While setting dental implants, a flapless is customarily raised to all the more likely picture the implants beneficiary site, it are obviously distinguished and safeguarded to give that a few physical milestones. At the point when a restricted measure of bone is accessible, a flapless height can assist with embedding position to decrease the gamble of bone fenestrations or holes (7) All the more as of late, the idea of flapless embed a medical procedure has been presented for the patients with adequate keratinized gingival tissue and bone volume in the implant beneficiary site. In a flapless system, a dental implant is introduced through the mucosal tissues without mirroring a flapless. The supposed motivations to pick the flapless procedure are to limit the chance of postoperative peri-implant tissue misfortune and to conquer the test of delicate tissue the board during or after medical procedure (8). Other asserted benefits of the flapless embed a medical procedure incorporate less horrible medical procedure, diminished usable time, fast postsurgical mending, less postoperative complexities and expanded patient solace (9), (10). An impediment of this method is that the genuine geology of the basic accessible bone can't be noticed on the grounds that the muco-gingival tissues are not raised, which might build the gamble for undesirable holes which in its turn could prompt esthetical issues or embed misfortunes (11). Besides, there is the potential for warm harm auxiliary to diminished admittance for outer water system during osteotomy arrangement (12).

Specialists have been attempting to assess whether the addition of inserts by the flapless method might impact the endurance of dental inserts. In any case, a few examinations might need factual power, given the modest number of patients per bunch in the clinical preliminaries looking at the procedures. In this manner, BR Chrcanovic et al led a meta-examination of recently distributed clinical investigations to explore whether there are any beneficial outcomes of flapless embed addition a medical procedure on implant failure rates, postoperative disease, and negligible bone loss in correlation with the more customary open flapless strategy. showing increased Bucco-lingual width, and reduced modified bleeding index scores for the flapless technique.

When placing implants, care must be taken due to the "blind" nature of flapless implant placement. It is essential to angle the implants that will be drilled in order to prevent perforation of the buccal and lingual cortical plates, particularly on the lingual in the mandibular molar area and the anterior maxilla (13). As a result, the surgeon must weigh the advantages of using a flapless technique against the rising risk of implant bone fenestrations or perforations, which are said to reduce implant success or raise the rate of implant failure (14). The dental implant may become infected and ultimately be lost if it is violated beyond the alveolar housing (15). If the patient has been selected appropriately and there is sufficient bone width for implant placement, there should not be any issues. A minimum of 7 millimeters of bone width and extensive training to use the appropriate technique were recommended by some authors (11). Due to the deposition of epithelial and connective cells from the oral mucosa in the bone during surgical preparation and implant surface contamination, the flapless procedure could potentially hinder osseointegration (15).

On the other hand, because the periosteum continues to cover the bone throughout the surgical procedure, a flapless procedure may benefit the initial process of bone remodeling. However, the highly compressed surgical template used to insert implants into completely edentulous jaws may make it difficult to access saline water and maintain proper cooling during the drilling process. This could have a negative impact on the implant surrounding the bone as well as the remodeling process that takes place during healing (16). Regarding marginal bone loss, one might anticipate that open flap surgery will result in greater marginal bone loss as a result of decreased supraperiosteal blood supply as a result of raising the tissue flap during the procedure. Studies have exhibited that fold reflection frequently brings about bone resorption around regular teeth (13).

Notwithstanding, it was displayed in five examinations that the flapless method created more peripheral bone misfortune around the inserts (15), (5). Some plausible explanations for this were provided by the authors of some of the articles reviewed here. De Bruyn and co. 5] suggested that the countersinking procedure was probably done too much in their study to cause this.(17)

Conclusion

The contrast between the systems (flapless versus flapped) measurably impacted the embed disappointment rates. A sensitivity analysis, however, revealed differences when the groups of studies with a high and low risk of bias were pooled separately, necessitating careful interpretation of the findings. There were no statistically significant differences between open flap surgery and flapless surgery in terms of the incidence of postoperative infection or marginal bone loss.

Conflict of interest

The authors report no financial or any other conflict of interest in this work.

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