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IS FLAPLESS IMPLANT PLACEMENT PROCEDURES BETTER THAN CONVENTIONAL FLAP IN PARTIALLY EDENTULOUS PATIENTS": RANDOMIZED CONTROL STUDY

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ABSTRACT

Background: Dental implants are a reliable rescue for edentulism. The dental implants had undergone various upgrades to improve the osseointegration. One of such is flapless implant placement.
Aim: To assess the efficacy of flap vs flapless implant placement.
Material and methods: A total sample of 20 implants were included which were randomly grouped into two based on the treatment they received; Group A (Control): 10 patients who are undergoing open flap implant placement surgery and Group B (Experimental group) included 10 patients who are undergoing flapless implant placement surgery. ISQ, Plaque index and soft tissue healing was assessed immediately and 2nd month follow up.
Results: Group B exhibited statistically significantly higher mean ISQ value compared to Group A at baseline and second post-op month. Group B exhibited a higher mean plaque Index and soft tissue healing index values compared to Group A at baseline and second post-op month but not statistically significant.
Conclusion: By avoiding the need for incision and flap reflection, maintaining the vascularity to the underlying bone, and reducing edema due to surgical intervention and its inflammatory mediators, flapless implant placement offers a promising role in implantology. This leads to a more stable soft tissue profile and higher implant stability following implant placement, as well as a more desirable aesthetic result.
***Keywords*:** Flapless implant placement; Atraumatic implant placement; Dental implant; ISQ; plaque Index

1. INTRODUCTION

Over the last decade, the increase in aesthetic demand and technical development has led to miraculous evolution in dental Implantology domain. Dental implants have emerged as a remarkable solution available in modern dentistry for both total and partial edentulism. [1] Although it has become the treatment of choice for most dentists, still, the implant failure, or implant stability and complications associated with implants are the biggest challenge.[2]

Various modifications have been investigated to improve Success of implant osseointegration. Nonetheless, to minimize the peri- and post-surgical discomfort, maximizing aesthetics, and improving the long-term success of the implants, minimally invasive flapless technique have been recently investigated.[3] This Atraumatic technique (with respect to the flap elevation and exhibition of the bone) provides less crestal bone resorption that could influence on final aesthetic results.[4] Also, as it minimizes surgical trauma, it subsequently reduces post-operative pain, swelling, faster healing, minimal interference on the blood, thereby by reduction of bleeding, surgical time, lower morbidity and an increase on patient comfort were the pros of this technique.[5,6] Jeong et al. [7] in 2011 conducted a prospective trial over 432 implants achieving 100% of success after a year, with an average bone loss of 0,3 mm. They come to the conclusion that the flapless technique is reliable and effectively maintains the health of the peri-implantary mucous and crestal bone.

Nonetheless, this particular approach is linked with certain setbacks too. The lack of flap reflection and the small diameter of mucous openness makes the vision very limited. [8] Subsequently, the limitations on the view have a possibility of damaging neighboring structures such as cortical bone, specially the buccal cortical plate, neighboring teeth roots, important nerves or the sinus.[5]

The biological stability of the flapless and flapped implant placement techniques has not been sufficiently studied. Thus the present study aims to compare the efficacy of stability using duration through resonance frequency analysis (RFA) in flap vs flapless implant placement. And also to evaluate the hypothesis "Does implant placement with a flap versus a flapless technique influence biological stability?"

MATERIAL AND METHODS

This randomized controlled study was conducted in the Department of Periodontology and Oral Implantology at Sree Balaji Dental College and Hospital in Chennai, India, between May 2023 and November 2024. The Sree Balaji Dental College and Hospital's Institutional Ethical Committee in Chennai, India, granted ethical approval prior to the study's commencement. (SBDCH-IEC-CT-/12-04/26).

Sample Size Calculation:

It was revealed that from a literature survey the mean ± S.D of the parameter of percentage change of means between two-time intervals of two groups; test group and control group were 09.90+0.32, 07.90+0.26. G* Power analysis revealed that the actual power and effect size was 90% and 3.342 respectively. So, for 95% confidence interval level of significance 5% the sample size was 10 in each group and the overall sample size was planned to be 20.

Study population:

Twenty patients (20 implants) were included. The study samples were randomly divided by flipping a coin into two groups based on the treatment they received. Group A (Control group): 10 patients who are undergoing open flap implant placement surgery. Group B (Experimental group) included 10 patients who are undergoing flapless implant placement surgery.

Selection Criteria:

Both male and female who are systematically healthy and aged 20-40 years with partially edentulous space in the posterior aspect of the maxilla or mandible were included. Minimum crestal width of 6mm, minimum Interocclusal distance of 5mm, minimum medio-distal width of 7-10 mm, crest to mandibular canal distance of at least 10 mm, and Minimum 10 mm of height were included.

Patients with cardiac history, Poorly or uncontrolled diabetic patients or on vasodilators, women who are Pregnant or those who are lactating were exempted. Patients with poor periodontal health or those requiring guided bone regeneration were excluded. Patients with a habit of smoking, Bruxism or parafunctional habits were excluded. Patients with previously implanted or bone grafts placed at the surgical site or traumatic extraction at the surgical site were excluded.

Study procedure:

- Following subject selection, informed consent after being briefed on study's methodology was obtained. A comprehensive medical and dental history was obtained prior to the examination. An IOPAR and CBCT imaging was performed in all cases. Prior to surgery, all patients received thorough supragingival scaling and root planning. Patients were evaluated after a period of 3 weeks and only those patients who were capable of maintaining adequate oral hygiene measures were included. Routine blood investigation was assessed.

- Group A (open flap implant surgery): A conventional open flap implant surgery was performed under an aseptic environment.

- Group B: As a sterile procedure, the flapless implant operation was performed. To prepare the pre-operative site, a 5% povidone-iodine solution was used. Local anaesthesia was given. At the implant insertion location, a rotary tissue punch set to a maximum speed of 35 rpm was used to cut the soft tissue at the crest of the alveolar bone in a circular motion. Following the instructions provided by the manufacturer, the implant placement operations were carried out after the circular soft tissue cut was removed using tissue forceps. An externally irrigated handpiece with a low speed and high torque was used in conjunction with an electric motor to prepare the implant site. External irrigation was done with sterile saline while the implant site was being prepared. The bone site preparation procedure was started with a 2

mm first drill to reach the desired length. To determine the depth of the osteotomy site, the depth gauge and direction indicator were utilized. Verify the implant's parallelism. Sequential drilling was completed up to the last drill. They employed Zimmer implants (Zimmer Dental, Carlsbad, CA, USA). Under light apical pressure, the implant was manually placed into its bed in a clockwise motion until it stopped. After inserting the implant to the ultimate insertion depth with a ratchet wrench, the healing abutment was put into the occlusal opening of the implant and tightened. The tenth postoperative day and the second postoperative month were used to evaluate each patient.

- Study outcomes: Implant stability quotient (ISQ), plaque Index (PI) and Soft Tissue Healing Index by Landry, Turnbull and Howley was assessed at baseline and at 2nd Postoperative month.

RESULTS

The average age of the participants in Group A and Group B in this study was 37.33 years and 34.87 years, respectively. Nine males and six females made up Group A, while seven males and eight females made up Group B.(Table 1)

Table 1. Study sample demographics for the current investigation

Variable	Category	Group A	Group B
Age (in years)	--	37.33 ± 6.11	34.87 ± 6.82
Gender	**Male**	9 (60%)	7 (46.7%)
	Female	6 (40%)	8 (53.3%)

Table 2 compares baseline and 2-month ISQ levels within each group. The ISQ values in group A were 68.47 at baseline and 76.13 after two months, respectively. The baseline and two-month ISQ values for group B were 70.73 and 80.00, respectively. The ISQ levels at two months were substantially higher than the baseline ISQ values in each group.

Table 2. Comparison of baseline and 2-month ISQ levels within each group

Group	Baseline		2 months		p-value
	Mean	SD	Mean	SD	
Group A	68.47	3.09	76.13	5.71	0.001*
Group B	70.73	1.71	80.00	4.14	0.001*
	0.037*				

A significant difference at p≤0.05 is indicated by the Wilcoxon signed rank test; *

Implant Stability Quotient (ISQ) levels in two groups (Group A and Group B) at baseline and two-month intervals are compared in Table 3. At the beginning of the study, Group B exhibited a statistically significantly higher mean ISQ value (70.73) compared to Group A (68.47). After 2 months, both groups showed an increase in mean ISQ values. Group B still had a higher mean ISQ (80.00) than Group A (76.13), but this difference was not statistically significant (p = 0.081). Since the baseline ISQ levels between the two groups differed significantly, an adjusted analysis was performed keeping baseline values as covariates. When adjusted means were compared using ANCOVA, the difference between the groups (Group A: 76.82, Group B: 79.31) was not statistically significant (p = 0.213).

Table 3. ISQ values compared between the two groups

Interval	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Baseline[¥]	68.47	3.09	70.73	1.71	0.037*
2 months[¥]	76.13	5.71	80.00	4.14	0.081
Adjusted mean[#]	76.82	1.32	79.31	1.32	0.213

¥Mann Whitney test; #ANCOVA test; * indicates a significant difference at p≤0.05

Table 4 compares the baseline and 2-month modified plaque index within each group. In each group, the 2-month modified plaque index score was significantly greater than the baseline modified plaque index score.

Table 4. Comparison of baseline and 2-month modified plaque index within each group

Group	Baseline		2 months		p-value
	Mean	SD	Mean	SD	
Group A	0.00	0.00	1.73	0.70	<0.001*
Group B	0.00	0.00	1.60	0.83	0.001*

Wilcoxon signed rank test; * indicates a significant difference at p≤0.05

The modified plaque index for Group A and Group B is compared in Table 5 at two separate time points: baseline and two months. Both at the start of the study and two months later, there was no statistically significant change in the modified plaque index between the groups.

Table 5. Comparison of the two groups' adjusted plaque index

Time interval	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Baseline	0.00	0.00	0.00	0.00	1.000
2 months	1.73	0.70	1.60	0.83	0.775

Mann Whitney test

Table 7 compares the baseline and 2-month soft tissue healing within each group. In each group, the 2-month soft tissue healing score was significantly lower than the baseline scores.

Table 7. Comparison of baseline and 2-month soft tissue healing within each group

Group	Baseline		2 months		p-value
	Mean	SD	Mean	SD	
Group A	2.20	0.41	1.60	0.63	0.007*
Group B	1.80	0.41	1.20	0.41	0.003* Denotes a significant difference at p≤0.05 in the Wilcoxon signed rank test.

* Denotes a significant difference at p≤0.05 in the Wilcoxon signed rank test.

Soft tissue healing at baseline and two-month intervals is compared between two groups (Group A and Group B) in Table 6. Both at the start of the study and two months later, there was no statistically significant difference in the soft tissue healing between the groups.

Table 6. Comparison of the two groups' soft tissue healing

Time interval	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Baseline	2.20	0.41	1.80	0.41	0.098
2 months	1.60	0.63	1.20	0.41	0.106

Mann Whitney test

DISCUSSION

Dental implants provide a robust and solid basis for dental restorations such as crowns, bridges, and dentures. A dental implant that has undergone osseointegration is a reflection of the biological and mechanical anchoring of the implant fixture into the jaw bone during normal clinical function.[11] The osseointegration can be measured as ISQ..

The ostell RFA configuration was chosen for the present study to test the stability of the implants over the healing phase since it was thought to be the most accurate, reliable, and least invasive technique. [12] This technique measures the stiffness of implant-bone connection. The experimental and control groups in this study had mean ISQ values of 80.00 and 76.13 at the second month follow-up, respectively. Compared to traditional flapped implants, flapless implants had higher ISQ values; however, this difference was not statistically significant (p = 0.081).

In line with the results of the present study, in Al-Juboori [13] et al study, the mean ISQ values at 12th month of 82.60 and 82.3 was yielded in experimental and control groups respectively and the difference was not statistically significant. However, Al-Juboori [13] et al noted no significant differences in implant stability between implants placed via the flapless and conventional flapped techniques during the healing period i.e in the first 6 postoperative months. This could be explained by the fact that low ISQ values are the result of ongoing bone remodeling and maturation in both groups during this healing phase. However, we found that there were notable differences both within and between groups in this study.

Similarly, the mean difference in RFA from 0–12 months between the flapless and flap implant placement techniques did not differ significantly in the Sonam Rana et al. [57] study. In contrast to the results of the present study, in the study performed by Cannizzaro et al [14], the ISQ values were similar between the two groups at baseline (2 months after loading/delivery of the definitive prosthesis) and 1 year after loading, and decreased significantly over time for both group.

In the present study, in each group, the 2-month modified plaque index score was significantly greater than the baseline modified plaque index score. The groups' differences in modified plaque index at two months after surgery were not statistically significant. Similar to the present study, Tsoukaki et al [15] noted that the flapped implants exhibited significantly higher mean mPLI values (P = 0.013) after 6 weeks compared with flapless implants. You et al. (2009)[16] in an experimental study showed that the flapped group had higher GI and bleeding on probing (BOP) compared with the flapless group (GI: 0.9 ± 0.5 and BOP: 0.7 ± 0.4 in the flapped group and zero values for both parameters in the flapless group), 3 months after implant placement. In Wang et al [17], after the 2nd week to 3rd month, there was a trend for a decreased mPI score in the flapped group, compared to 1-week post-surgery. In contrast, the MI group's mPI score dropped at the 4-week mark; however, no statistically significant differences were observed at the 1-, 2-, 4-, or subsequent appointments. Additionally, at one and two weeks following surgery, statistically significant differences between the two groups were discovered.

Additionally, the posterior maxilla's anatomical and structural characteristics, such as its close proximity to the maxillary sinus and consequently low bone quality and quantity, may jeopardize the clinical results of dental implants. Depending on the degree of resorption, the maxilla's shape changes when it becomes edentulous. In an elderly population, the maxillary cortical bone becomes thinner and more porous posteriorly.[18]

Although there was no appreciable difference between the flapped and flapless groups in terms of soft tissue healing and plaque index, the ISQ values of flapless implants were greater than those of the traditional flapped group in the current investigation. Fortin et al. [19] reported that in addition to these better results, flapless treatments resulted in a faster decrease in pain and a higher percentage of patients experiencing no discomfort. The flapless procedure, they say, aims

to reduce the invasiveness of surgery, hence reducing surgical consequences such as discomfort, edema, and hematoma. Due to its ability to reduce surgical edema and associated inflammatory mediators, protect the blood supply to the underlying bone, and eliminate the need for incision and flap reflection, seamless implant insertion has great promise in the field of implantology. As a result, there is less loss of crestal bone and a more stable soft tissue profile following implant placement, which produces a more appealing visual result. This is because patient comfort and satisfaction are important aspects of implant therapeutics.

The absence of a computer-guided template for patients is the study's limitation. Shorter follow-up period and small sample size are additional limitations. There needs to be more multicentric research done with a bigger sample size and a longer follow-up time.

CONCLUSION

Because it avoids the need for incision and flap reflection, maintains the vascular flow to the underlying bone, and lessens surgical edema and accompanying inflammatory mediators, we concluded that flapless implant placement offers a promising role in implantology. This results in an improved cosmetic outcome, a more stable soft tissue profile, and increased implant stability after implant placement. In light of the current study's modest sample size and brief follow-up period, more multicentric studies with a larger sample size and longer follow-up duration are needed to validate its findings.

DECLARATIONS

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Competing Interests:

The authors have no competing interests to declare.

Ethical Approval:

The study was approved by the appropriate ethics committee and conducted according to relevant guidelines and regulations.

Informed Consent:

Not applicable.

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