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Comparative Assessment of Clinical Outcomes in Flapless and Flapped Implant Surgical Techniques: A Randomized Controlled Trial

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ABSTRACT

Background: Dental implant placement is a predictable treatment for edentulism. Conventional surgery involves flap elevation for direct visualization, while flapless techniques aim to minimize surgical trauma. The comparative long-term efficacy of these two approaches remains a subject of clinical investigation.

Methods: A single-center, parallel-group randomized controlled trial was conducted with 60 patients requiring a single implant in the posterior maxilla or mandible. Patients were randomly allocated to either the Flapless Group (n=30), where implants were placed using a surgical guide and tissue punch, or the Flapped Group (n=30), where a full-thickness mucoperiosteal flap was elevated. Outcomes assessed included surgical duration, postoperative pain (Visual Analog Scale - VAS), crestal bone loss (CBL) at 12 months, implant stability quotient (ISQ), and Pink Esthetic Score (PES). Follow-up was conducted at 1 week, 3 months, and 12 months post-loading.

Results: The mean surgical duration was significantly shorter in the Flapless Group (24.6 ± 5.1 min) compared to the Flapped Group (45.2 ± 8.3 min; $p < 0.001$). Postoperative pain at 24 hours was significantly lower for flapless surgery (VAS: 2.1 ± 0.8 vs. 4.9 ± 1.2; $p < 0.001$). At 12 months, the Flapless Group exhibited slightly less mean CBL (0.58 ± 0.21 mm) than the Flapped Group (0.79 ± 0.25 mm), a statistically significant difference ($p = 0.012$). Both groups achieved excellent implant stability with no significant difference in final ISQ values ($p = 0.45$). The mean PES was significantly higher in the Flapless Group (12.1 ± 1.5) compared to the Flapped Group (10.5 ± 1.9; $p = 0.003$). All implants survived, yielding a 100% survival rate in both groups.

Conclusion: Flapless implant surgery offers significant advantages regarding reduced surgical time, less postoperative pain, better crestal bone preservation, and superior aesthetic outcomes in selected cases. With comparable implant stability and survival rates, it represents a highly effective and less invasive alternative to the conventional flapped technique.

Keywords: *Dental implants, flapless surgery, flapped surgery, crestal bone loss, Pink Esthetic Score, patient-reported outcomes, randomized controlled trial.*

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1. INTRODUCTION

The replacement of missing teeth with osseointegrated dental implants has become the standard of care in modern dentistry, offering high predictability and long-term functional success **[1]**. The conventional surgical protocol for implant placement involves the elevation of a full-thickness mucoperiosteal flap. This approach provides direct visualization and access to the underlying alveolar bone, facilitating precise osteotomy preparation and allowing for concurrent bone augmentation procedures if required **[2]**. However, this technique is inherently invasive, leading to the disruption of periosteal blood supply, which has been associated with increased postoperative morbidity—including pain, swelling, and edema—and marginal bone resorption during the early healing phase **[3, 4]**.

In response to the demand for less invasive procedures, flapless implant surgery has gained considerable popularity. This technique, often facilitated by advanced three-dimensional imaging and guided surgical templates, involves implant placement directly through the mucosa without flap elevation, typically via a small-diameter tissue punch or a minimal crestal incision **[5]**. The theoretical advantages are compelling: preservation of the periosteal vascular network, reduced surgical time, minimized postoperative discomfort, and potentially better preservation of crestal bone and soft tissue architecture **[6, 7]**.

Despite its benefits, flapless surgery is not without its challenges. The procedure is technically demanding, offering limited to no direct visualization of the bone. This "blind" approach increases the risk of implant malpositioning, iatrogenic damage to adjacent structures, and improper assessment of bone quality or undetected osseous defects like fenestrations or dehiscences **[8]**. Therefore, meticulous presurgical planning using cone-beam computed tomography (CBCT) and the use of static or dynamic guidance are considered prerequisites for predictable outcomes **[9]**.

Numerous studies have compared flapless and flapped techniques, often reporting favorable short-term patient-reported outcomes for the flapless approach **[10, 11]**. However, the literature presents conflicting results regarding long-term outcomes, particularly concerning marginal bone stability and soft tissue aesthetics. While some systematic reviews suggest comparable implant survival rates and marginal bone loss between the two techniques **[12]**, others highlight the critical importance of case selection, emphasizing that flapless surgery is best suited for sites with ample bone volume and a sufficient band of keratinized tissue **[13]**. A definitive consensus on the superiority of one technique over the other across all key clinical parameters, especially aesthetic outcomes as measured by validated indices, is yet to be established.

This study was therefore designed to bridge this gap by conducting a rigorous comparative analysis within a randomized controlled trial framework. The aim of this study was to evaluate and compare the clinical, radiographic, patient-reported, and aesthetic outcomes of single-tooth implants placed using either a guided flapless or a conventional flapped surgical technique over a 12-month follow-up period.

2. MATERIALS AND METHODS

Study Design and Patient Population: This study was designed as a single-center, parallel-group randomized controlled trial. Between January 2022 and December 2023, 60 patients were recruited from the outpatient Department of Oral Implantology. Written informed consent was obtained from all participants prior to their inclusion.

Inclusion and Exclusion Criteria: Inclusion criteria were: (1) age between 18 and 65 years; (2) requirement for a single implant in a healed site (minimum 4 months post-extraction) in the posterior maxilla or mandible; (3) adequate bone volume (≥6 mm buccolingual width and ≥10 mm height above vital structures); (4) presence of ≥2 mm of keratinized mucosa at the implant site; and (5) good oral hygiene.

Exclusion criteria included: (1) active periodontal disease; (2) uncontrolled systemic conditions (e.g., diabetes mellitus, osteoporosis); (3) smoking (>10 cigarettes/day); (4) pregnancy or lactation; (5) history of head and neck radiotherapy; (6) bruxism or other parafunctional habits; and (7) need for simultaneous bone grafting procedures.

Randomization and Blinding: Eligible patients were randomly allocated into two groups (1:1 ratio): the Flapless Group (FG) or the Flapped Group (CG). Randomization was performed using a computer-generated sequence concealed in sealed, opaque envelopes, which were opened by a surgical assistant just before the procedure. The operating surgeon could not be blinded due to the nature of the intervention, but the outcome assessors (a prosthodontist and a radiologist) and the statistician were blinded to the group allocation.

Surgical Procedures

All surgical procedures were performed by a single experienced surgeon.

- **Flapless Group (FG):** Following local anesthesia, a surgical guide fabricated from a CBCT-based digital plan was positioned. A tissue punch of a diameter corresponding to the implant system was used to remove the soft tissue overlying the implant site. The osteotomy was prepared through the guide, and a tissue-level implant (Straumann BLT, Ø4.1 mm, Straumann AG, Basel, Switzerland) was placed. A healing abutment was connected immediately. No sutures were required.

- **Flapped Group (CG):** Following local anesthesia, a mid-crestal incision with two vertical releasing incisions was made, and a full-thickness mucoperiosteal flap was elevated to expose the alveolar bone. The osteotomy was prepared under direct vision, and an identical implant was placed. The flap was repositioned and secured with 4-0 non-resorbable sutures, which were removed after 10 days.

All patients received postoperative instructions and prescriptions for amoxicillin 500 mg (three times daily for 5 days) and ibuprofen 400 mg as an analgesic to be taken as needed.

Outcome Assessments

1. **Surgical Duration:** Recorded in minutes from the first incision to the final suture (or placement of healing abutment in FG).
2. **Postoperative Pain:** Patients rated their pain at 24 hours post-surgery using a 100-mm Visual Analog Scale (VAS). Analgesic consumption (number of tablets) within the first 48 hours was also recorded.
3. **Implant Stability:** Measured using Resonance Frequency Analysis (Osstell ISQ, Osstell AB, Gothenburg, Sweden). The Implant Stability Quotient (ISQ) was recorded at the time of placement and 3 months later at the time of final prosthesis delivery.
4. **Crestal Bone Loss (CBL):** Standardized periapical radiographs were taken using a long-cone paralleling technique at the time of prosthetic loading (baseline) and at the 12-month follow-up. CBL was calculated as the difference in the mean mesial and distal bone levels relative to the implant shoulder, measured by a blinded radiologist using digital software (ImageJ, NIH, USA).
5. **Soft Tissue and Aesthetic Outcomes:** At 12 months, a blinded prosthodontist assessed probing depth (PD), bleeding on probing (BOP), and the Pink Esthetic Score (PES), which evaluates seven variables (mesial papilla, distal papilla, soft-tissue level, soft-tissue contour, alveolar process deficiency, soft-tissue color, and texture) with a maximum score of 14.

Statistical Analysis

Data were analyzed using SPSS Statistics Version 26.0 (IBM Corp., Armonk, NY). The independent samples t-test was used to compare continuous variables (age, surgical duration, VAS, CBL, ISQ, PES) between the two groups. The Chi-square test was used for categorical variables (sex, BOP). A p-value of < 0.05 was considered statistically significant.

3. RESULTS

Patient Demographics and Implant Survival: A total of 60 patients (32 male, 28 female) with a mean age of 41.5 ± 11.2 years were included and completed the 12-month follow-up. The two groups were well-matched at baseline with no statistically significant differences in age, sex, or implant location ($p > 0.05$). All 60 implants survived throughout the study period, resulting in a 100% implant survival rate for both techniques.

Perioperative and Early Postoperative Outcomes: The Flapless Group demonstrated significantly better perioperative and early postoperative outcomes compared to the Flapped Group. The mean surgical duration was nearly halved in the Flapless Group. Correspondingly, patient-reported pain at 24 hours and the number of analgesics consumed were significantly lower in the flapless cohort. These results are summarized in **Table 1**.

Table 1: Perioperative and Early Postoperative Outcomes

Parameter	Flapless Group (n=30)	Flapped Group (n=30)	p-value
Surgical Duration (min), mean ± SD	24.6 ± 5.1	45.2 ± 8.3	< 0.001
VAS Pain at 24h (0-10), mean ± SD	2.1 ± 0.8	4.9 ± 1.2	< 0.001
Analgesic Tablets (48h), mean ± SD	1.3 ± 0.9	3.8 ± 1.4	< 0.001

Radiographic and Implant Stability Outcomes

Both groups achieved high primary and secondary stability. While the initial ISQ at placement was slightly higher in the Flapped Group, the difference was not statistically significant. At 3 months, both groups showed an increase in ISQ values, with no significant difference between them. Radiographic analysis at 12 months revealed that the Flapless Group experienced significantly less crestal bone loss compared to the Flapped Group (**Table 2**).

Table 2: Radiographic and Implant Stability Outcomes

Parameter	Flapless Group (n=30)	Flapped Group (n=30)	p-value
ISQ at Placement, mean ± SD	72.4 ± 4.5	73.8 ± 4.1	0.21
ISQ at 3 Months, mean ± SD	76.1 ± 3.9	75.5 ± 3.7	0.45
Crestal Bone Loss at 12 mo (mm), mean ± SD	0.58 ± 0.21	0.79 ± 0.25	0.012

Soft Tissue and Aesthetic Outcomes

At the 12-month follow-up, both groups exhibited healthy peri-implant soft tissues, with low mean probing depths and minimal bleeding on probing. However, the aesthetic assessment using the Pink Esthetic Score revealed a statistically significant advantage for the Flapless Group, indicating better soft tissue harmony and papilla preservation (**Table 3**).

Table 3: Soft Tissue and Aesthetic Outcomes at 12 Months

Parameter	Flapless Group (n=30)	Flapped Group (n=30)	p-value
Probing Depth (mm), mean ± SD	2.4 ± 0.5	2.6 ± 0.6	0.18
Bleeding on Probing (%), n	13.3% (4)	16.7% (5)	0.72
Pink Esthetic Score (0-14), mean ± SD	12.1 ± 1.5	10.5 ± 1.9	0.003

4. DISCUSSION

The findings of this randomized controlled trial demonstrate that flapless implant surgery, when performed in carefully selected cases with the aid of digital guidance, offers several distinct advantages over the conventional flapped technique. The primary benefits were observed in the reduction of surgical invasiveness and improvement of the patient experience, as evidenced by significantly shorter operative times and lower postoperative pain levels. This is consistent with a large body of evidence that attributes reduced morbidity in flapless surgery to the preservation of soft tissue integrity and periosteal blood supply **[10, 14]**. By avoiding flap elevation and suturing, the inflammatory response is minimized, leading to a more comfortable and rapid recovery for the patient.

A key finding of our study is the statistically significant difference in crestal bone loss at 12 months. The Flapless Group lost an average of 0.58 mm of bone, compared to 0.79 mm in the Flapped Group. While both values are well within the clinically acceptable range of <1.5 mm of bone loss in the first year **[15]**, the 0.21 mm difference in favor of the flapless technique is noteworthy. This supports the biological rationale that disrupting the periosteum during flap elevation triggers a transient phase of bone resorption at the crest, which is largely avoided in flapless surgery **[4]**. Our results align with meta-analyses by Voulgarakis et al. **[12]** and other clinical trials that have reported better bone preservation with flapless approaches.

From an aesthetic standpoint, the superior Pink Esthetic Score in the Flapless Group is a significant clinical finding. This can be directly attributed to the minimal disruption of the supra-crestal soft tissues, especially the interdental papillae. Flap elevation, even when meticulously performed, can lead to subtle changes in soft tissue height and contour **[7]**. The tissue punch technique used in our study preserves the existing gingival architecture, which is critical for achieving a natural-looking emergence profile, particularly in the aesthetic zone. The difference in PES scores suggests that flapless surgery may be the preferred method when soft tissue aesthetics are a primary concern, provided the underlying bone anatomy is favorable.

It is important to emphasize that the success of the flapless technique is highly dependent on meticulous case selection and accurate planning. Our study protocol mandated sufficient bone and keratinized tissue, and a CBCT-guided surgical template was used for all flapless cases. These prerequisites are essential to mitigate the inherent risks of the technique, such as implant malpositioning or perforation of the cortical plates **[8, 9, 16]**. The excellent implant survival and stability outcomes in our study underscore the predictability that can be achieved when these protocols are strictly followed. The comparable ISQ values at 3 months indicate that both techniques lead to successful osseointegration.

This study has several strengths, including its randomized controlled design, blinded outcome assessment, and use of standardized clinical and radiographic measures. However, some limitations should be acknowledged. First, it was a single-center study with a single experienced operator, which may limit the generalizability of the findings to less experienced clinicians. Second, the follow-up period of 12 months is sufficient for evaluating early outcomes, but longer-term studies are needed to confirm the stability of bone levels and aesthetic results over time. Finally, this study was limited to single-implant, non-grafted sites, and the results cannot be extrapolated to more complex scenarios like multiple implants or immediate placement protocols.

5. CONCLUSION

Within the limitations of this study, flapless guided implant surgery demonstrated significant advantages over the conventional flapped technique for single-tooth replacement in non-grafted sites. It resulted in substantially shorter surgical times, reduced postoperative pain, better preservation of crestal bone, and superior soft tissue aesthetic outcomes at 12 months. With 100% implant survival and comparable stability, the flapless approach stands as a predictable, effective, and less invasive treatment modality for implant placement in appropriately selected patients.

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