Effect of Flapless Surgery on Single-Tooth Implants in the Esthetic Zone: A Randomized Clinical Trial

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Background: Implant therapy is a highly predictable treatment option; however, insufficient data exist to show whether flapless implant surgery provides better esthetic outcomes and less bone loss than implant surgery with a flap approach.

Methods: In this randomized, controlled study comparing the flapless and traditional flap protocol for implant placement, 24 patients received a single implant in the anterior maxillary region. A cone beam computed tomography–aided surgical guide was used for implant placement surgery for both groups. Implants were restored using a one-piece, screw-retained ceramic crown at 3 months. Radiographic and clinical measurements were assessed at baseline (implant placement) and at 3 (crown placement), 6, 9, and 15 months. Clinical parameters evaluated were plaque index, gingival index, papillary index (PPI) (0 = no papilla, 1 = less than half, 2 = more than half but not complete, 3 = complete fill, and 4 = overfill), marginal tissue levels, biotype, width of keratinized tissue, and soft tissue thickness.

Results: Implant success rate was 92% in both groups. Mean PPI values for the flap control group and flapless test group were 2.38 ± 0.51 versus 2.31 ± 0.48 at crown placement ($P = 0.68$) and 2.52 ± 0.52 versus 2.64 ± 0.54 at 15 months ($P = 0.42$), respectively. PPI increased over time in both groups, although the flapless group had a significantly larger change in PPI from crown placement to 6 and 9 months ($P < 0.01$). Crestal bone levels in the flap group were more apical in relation to the implant platform than those in the flapless group for the duration of the study. No differences among groups were noted for all other measurements.

Conclusions: Both flapless and flap implant placement protocols resulted in high success rates. A flapless protocol may provide a better short-term esthetic result, although there appears to be no long-term advantage. *J Periodontol 2013;84:1747-1754.*

KEY WORDS

Dental implants; dental implants, single-tooth; oral surgical procedures; surgical procedures, minimally invasive; trials, randomized clinical; wound closure techniques.

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Replacing missing teeth with dental implants is highly predictable. However, achieving implant esthetics remains a challenge with respect to re-creating a natural-appearing gingival margin and papilla. One technique to overcome this concern is flapless implant placement.[1] This technique involves removing a small amount of tissue over the crest of the edentulous ridge, just sufficient to expose the underlying bone to facilitate implant placement. As a consequence, no sutures are required, and no soft tissue flap is reflected, potentially reducing postoperative discomfort and swelling.[2] This is in contrast to the traditional flap approach, in which an incision is made through the gingiva along the crest of the ridge, and the gingival tissue is reflected away from the underlying bone to allow access for implant placement. This technique requires suturing; potentially involves more postoperative bleeding, discomfort, and swelling; and may result in a compromised esthetic result due to the potential bone loss and recession associated with raising a flap.[3] A study in beagle dogs compared buccal bone plate resorption between flapless and flap approaches to implant placement.[4] At 3 months, the flapless approach resulted in 0.67 mm less buccal bone resorption than the flap approach. Promising results have been reported in a number of animal and human clinical

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trials and reports regarding the flapless approach.[4-9] Those studies provide evidence that a flapless approach may provide some additional advantages over traditional flap implant placement protocols and could have a use in regular clinical practice.

Although some studies have compared outcomes between the flapless and traditional flap approach, esthetic outcomes have not been a major focus.[9,10] One study directly comparing the two surgical approaches evaluated bone density surrounding the implants over a period of 18 months and found no difference among groups.[10] Another study evaluating the flap versus flapless approach found no difference in either survival rates or bone density (as measured using computed tomography) among groups.[9] Fewer studies are available to provide information on esthetic outcomes and other measures of implant success versus merely survival. Because the flapless approach is a relatively new treatment approach, data regarding healing patterns of periimplant tissues, implant survival/success rates, and esthetic outcomes are not sufficient in the literature. In 2006, one group used a flapless surgical approach to compare early versus delayed loading of implants.[7] The results of that study indicated that a flapless approach results in an esthetic soft tissue profile that is stable for up to 6 months, although a control group using a flap approach was unavailable for comparison. Similarly, Becker et al.[5] evaluated 79 implants placed using the flapless approach over a 2-year period. Again, no control (flap) group was available for comparison, but the authors reported only minimal changes in crestal bone levels, probing depth (PD), and inflammation throughout the study. Hence, the primary objective of this randomized controlled study is to compare clinical outcomes of flapless implant surgery with those of traditional flap implant placement.

MATERIALS AND METHODS

This single-center, randomized, controlled study of implant placement using either a flapless or traditional flap protocol was conducted after institutional review board approval was obtained at the University of Michigan. A signed written informed consent was obtained after the patients were given verbal and written information describing the nature and duration of the study. Patient information was protected according to the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996.

Twenty-four adult patients (10 males and 14 females) missing a single tooth in the esthetic zone (maxillary anterior or premolar region)[11] were randomized using a computer-generated randomization schedule into two groups: 12 (aged 27 to 78 years, mean age: 52.8 ± 15.6 years) in the control group (implant placement using a traditional flap protocol) and 12 (aged 22 to 76 years, mean age: 52.8 ± 16.2 years) in the treatment group (flapless implant placement protocol). Both groups had the final crown restoration placed 3 months after implant insertion. All patients were recruited from the patient pool at the University of Michigan School of Dentistry. Inclusion criteria included: 1) missing maxillary anterior or premolar tooth; 2) ≥18 years old; 3) no medical contraindication to dental surgery; 4) adequate (>2 mm) keratinized gingiva (KG); and 5) adequate space for implant placement. In addition, sufficient bone thickness (>6.5 mm) and height (>10 mm) were required, assessed by cone beam computed tomography (CBCT). Exclusion criteria included: 1) unstable systemic diseases or conditions that would compromise healing potential; 2) osseous metabolic disorders; and 3) pregnancy. Patients were enrolled beginning in March 2009, and the study was completed in August 2011.

Surgical and Prosthodontic Procedures

Preliminary alginate impressions and study casts were fabricated before surgery. A diagnostic wax-up of the study tooth was created, and a radiographic stent was made on the study cast that was worn during a CBCT scan before implant placement. An acrylic surgical stent was fabricated based on the wax-up and CBCT to facilitate implant placement. For the traditional flap protocol group (control), a crestal incision over the edentulous area was made, following intrasulcular incisions around the adjacent teeth. For the flapless group (test), a soft tissue punch (4 mm) was used to remove the gingival tissue to facilitate implant placement. In both groups, microthreaded, platform-switching implants with a fluoride-modified nanostructure surface‡ were placed according to the manufacturer's protocol. The implants were placed using a one-stage surgical procedure. All surgical procedures were performed by two trained periodontists (T-JO and JB). At 3 months, the healing abutment was removed, and a zirconium abutment with an all-porcelain crown was placed. Per manufacturer's recommendations, the abutment was torqued to 20 Ncm (3.5- or 4.0-mm implant) or 25 Ncm (4.5- or 5.0-mm implant). The prosthodontist (IR) ensured that proper occlusion, crown contours, and crown margins were present in the final restoration.

Clinical and Radiographic Evaluation

A CBCT scan was taken at screening (before implant placement) and at the final study visit (15 months after baseline) to verify adequate bone thickness and ensure implant stability, respectively. CBCT scans

‡ OsseoSpeed, Astra Tech, Waltham, MA.

were done by a board-certified oral radiologist at the University of Michigan School of Dentistry (Erika Benavides). Standardized radiographs (periapical) were taken for each study site at baseline (implant placement) and at 3, 6, 9, and 15 months. Custom-made stents were fabricated from plastic film holders and bite registration material[§] to ensure reproducibility. An aluminum stepwedge was included in the films to standardize film density. Radiographs were evaluated using digital subtraction radiography to assess linear bone levels and change in bone levels over time using digital software.[‖] Linear bone levels were measured from the most crestal aspect of the implant to the most apical extent of bone adjacent to the implant. All assessments were made by one experienced and masked periodontist (JB) at the end of the study. Implant success was assessed using Albrektsson criteria.[12] Clinical measurements included plaque index (PI),[13] gingival index (GI),[14] bleeding on probing, mobility, papillary index (PPI) (0 = no papilla, 1 = less than half, 2 = more than half but not complete, 3 = complete fill, and 4 = overfill),[15] width of KG, marginal tissue level, and thickness of keratinized tissue. The marginal soft tissue level was measured from a reference line drawn from the highest free gingival margins of the adjacent teeth, with a negative value recorded when the tissue was coronal to the reference line and a positive value recorded when the tissue was apical to the reference.[7] Patients were considered to have a thin biotype if the KG thickness was ≤1.5 mm.[16] These parameters were assessed at baseline (implant placement) and at 3, 6, 9, and 15 months.

One calibrated and masked examiner performed all measurements (Mary Gilson Layher, RDH, BSDH, University of Michigan School of Dentistry, Ann Arbor, MI). A manual probe[¶] and soft tissue calipers were used to take the measurements. Clinical photographs were taken at each appointment.

Statistical Analyses

Differences among groups were evaluated using the Student *t* test at each study time point, and analysis of variance was used for comparison among different time points in each group. Clinical, radiographic, and survey data were averaged for each patient at every time point, with average values per group calculated along with the respective standard deviations. Categorical survey data were compared among groups at each study visit using χ^2 tests. For all other data, independent sample *t* tests were conducted with a significance level of 0.05.

RESULTS

Table 1 provides baseline demographic information regarding the study participants. There were no significant differences in baseline characteristics among groups. The overall survival rate was 92% for both groups, with one implant failing in each group. The remaining implants were successful according to Albrektsson criteria and did not have any PDs >5 mm at any time point. Figures 1 and 2 show cases treated using the traditional flap approach and flapless approach, respectively.

Table 1.

Demographics and Baseline Clinical Characteristics

Characteristic	Flap	Flapless	Total
n	12	12	24
Sex (n)			
Male	5	5	10
Female	7	7	14
Tooth type (n)			
Incisors	2	3	5
Premolars	10	9	19
Biotype (n)			
Thick	9	6	15
Thin	3	6	9
Soft tissue thickness (mm) (mean ± SD)			
Mesial	2.8 ± 0.5	2.7 ± 0.6	2.7 ± 0.5
Mid-facial	2.5 ± 0.6	2.3 ± 0.6	2.4 ± 0.6
Distal	3.1 ± 0.6	2.9 ± 0.6	3.0 ± 0.6

The PI and GI were not significantly different between groups at baseline (Table 2). However, patients in the flapless group had significantly higher PI scores at 6 and 9 months, although this difference was no longer statistically significant at 15 months. Significant differences in GI were found at 3 and 9 months. The average GI and PI were <1 for all time points and all groups, indicating that this population had minimal inflammation and good plaque control throughout the study.

There were differences in the width of KG between the flap (4.7 ± 1.9 mm) and flapless (3.8 ± 1.3 mm) groups at baseline, with the flap group having an average of 0.86 mm wider KG than the flapless group. This difference was statistically significant at baseline and 3 months. Both groups had a decrease in the amount of KG from baseline, although the flap group experienced a greater loss of KG over time, resulting in KG levels that were not significantly different between the flap and flapless groups after the 3-month time point.

§ Blu-Mousse, Parkell, Edgewood, NY.
‖ Emago, Oral Diagnostic Systems, Amstelveen, The Netherlands.
¶ UNC probe, Hu-Friedy, Chicago, IL.

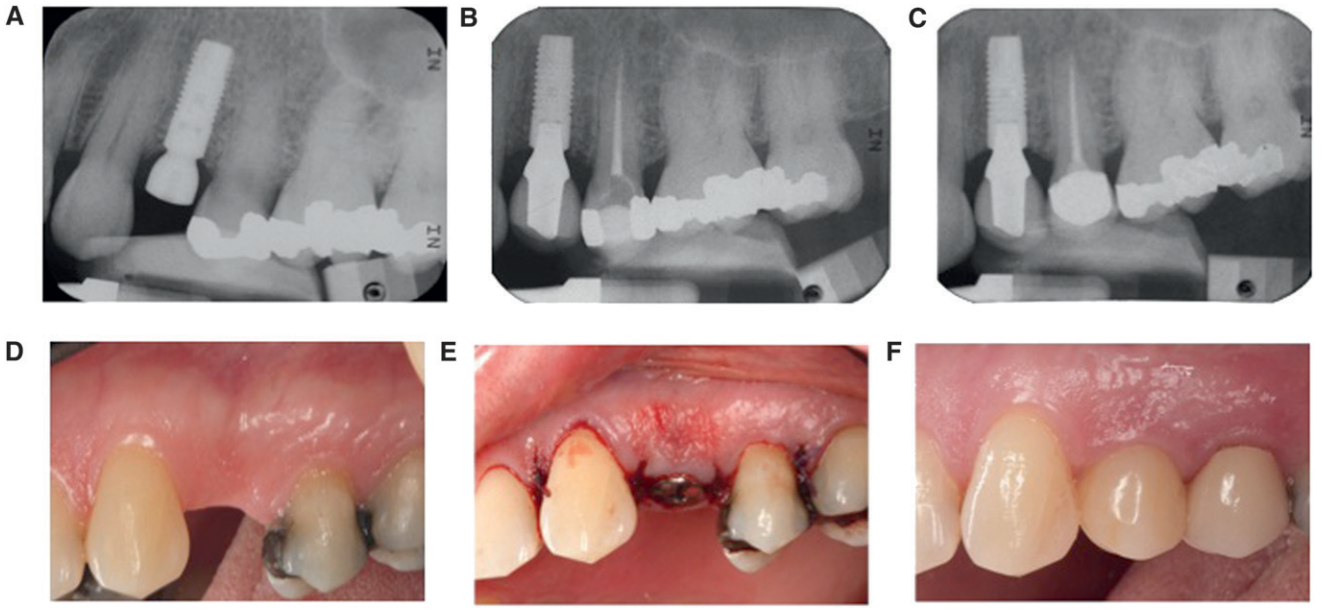

Figure 1.
Traditional flap placement. ***A through C)*** *Standardized radiographs taken at baseline implant placement (A), 3-month crown placement (B), and 15-month follow-up (C).* ***D through F)*** *Photographs of initial (D), postoperative (E), and 15-month follow-up (F) clinical situation.*

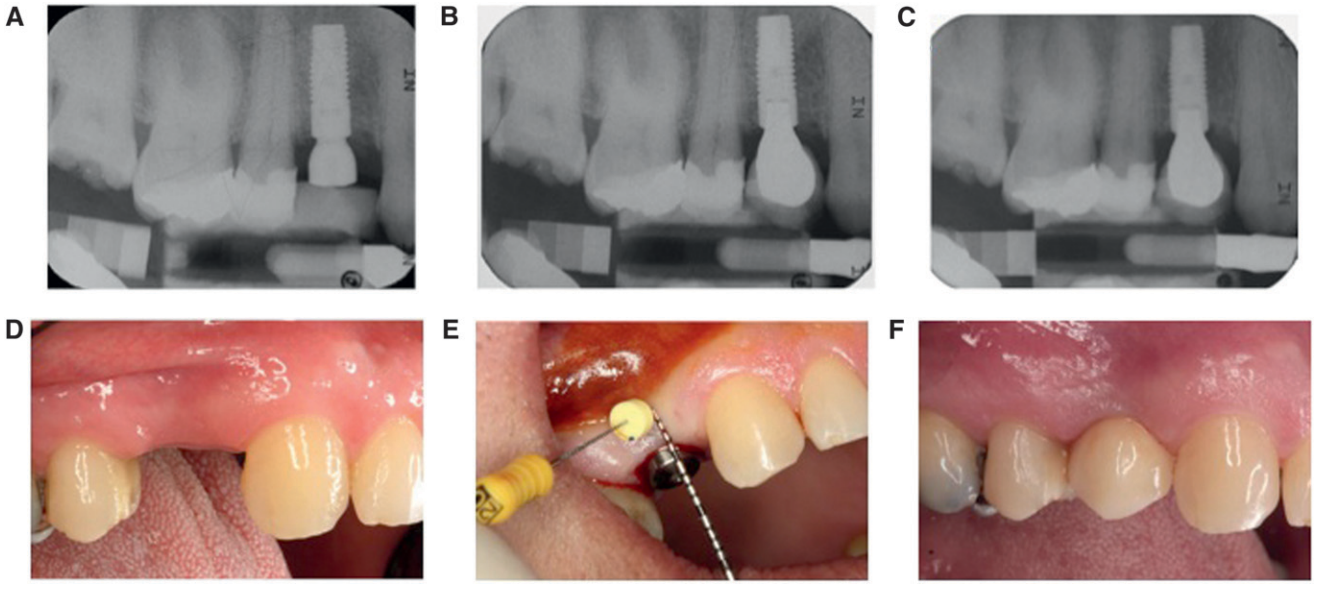

Figure 2.
Flapless implant placement. ***A through C)*** *Standardized radiographs taken at baseline implant placement (A), 3-month crown placement (B), and 15-month follow-up (C).* ***D through F)*** *Photographs of initial (D), postoperative (showing iodine staining for KG measurements and soft tissue thickness measurements) (E), and 15-month follow-up (F) clinical situation.*

The marginal soft tissue level was used to measure the gingival margin location at the implant site. Immediately after implant placement, the flap group had a mean marginal soft tissue level of 2.17 ± 1.01 mm; that of the flapless group was 1.17 ± 0.83 mm (Fig. 3A). This was significantly different at baseline immediately after implant placement (P = 0.01), although there were no differences immediately before surgery or after 3 months. There were no significant differences between groups at any time point for this measurement.

Patients who received implant placement using a flap approach had an initial decrease in PPI, whereas patients assigned to the flapless group

Table 2.

Comparison of Clinical Parameters Among and Within Groups Over Time

Parameter	Flap	Flapless
n	12	12
Survival rate (%)	92	92
Implant diameter (n)		
4.0 mm	11	8
3.5 mm	1	4
PI (mean ± SD)		
Baseline (implant placement)	0.40 ± 0.49	0.50 ± 0.10
3 months (crown placement)	0.48 ± 0.50	0.64 ± 0.48
6 months	0.39 ± 0.57*	0.76 ± 1.03*
9 months	0.58 ± 0.50*	0.90 ± 0.98*
15 months	0.54 ± 0.61	0.64 ± 1.02
GI (mean ± SD)		
Baseline (implant placement)	0.38 ± 0.49	0.51 ± 0.50
3 months (crown placement)	0.29 ± 0.46*	0.64 ± 0.48*
6 months	0.36 ± 0.48	0.40 ± 0.49
9 months	0.45 ± 0.50*	0.77 ± 0.59*
15 months	0.56 ± 0.59	0.71 ± 0.60
KG width (mm) (mean ± SD)		
Baseline (implant placement)	4.71 ± 1.94*	3.85 ± 1.26*
3 months (crown placement)	3.97 ± 1.59*	3.33 ± 0.74*†
6 months	4.05 ± 1.40	3.57 ± 0.79
9 months	3.95 ± 1.33	3.51 ± 0.92
15 months	4.02 ± 1.35	3.58 ± 0.96
PPI		
3 months (crown placement)	2.38 ± 0.51	2.31 ± 0.48
6 months	2.28 ± 0.46	2.57 ± 0.46
9 months	2.38 ± 0.51	2.62 ± 0.47
15 months	2.52 ± 0.52	2.64 ± 0.54
Overall patient satisfaction	1.00 ± 0.00	1.09 ± 0.30

* Significantly different between groups (Student *t* test; $P < 0.05$).
† Significantly different from baseline within the group (Wilcoxon signed-rank test; $P < 0.05$).

had a significant increase in PPI during the first 6 months (Fig. 3B). PPI increased over time in both groups, although the flapless group had a significantly larger increase at 6 and 9 months. This difference was no longer significant at the 15-month time point.

Linear radiographic measurements were taken from the most coronal portion of the implant to the most apical extent of the crestal bone level, with a negative measurement indicating subcrestal placement of the implant. At baseline, implants placed using a flap technique were placed at the level of the crest with an average linear radiographic measurement of –0.02 mm. In contrast, implants placed using the flapless technique were an average of 0.85 mm subcrestal at the time of placement. This difference was statistically significant at baseline through 15 months (Fig. 3C).

Thirty-eight percent of patients had a thin biotype. No differences in PPI were noted between flap and flapless groups in patients with thin biotypes ($P > 0.05$, data not shown). In contrast, 62% of patients presented with a thick biotype. In this population, patients with a thick biotype who received flapless implant placement had a trend toward greater papilla fill than the flap group at 9 months after placement (2.86 ± 0.29 versus 2.40 ± 0.52; $P = 0.10$), although this difference was no longer significant at 15 months (2.86 ± 0.29 versus 2.46 ± 0.53; $P = 0.18$).

In general, patients were satisfied with their treatment results, with an overall average patient satisfaction level of 1.00 ± 0.00 in the flap group and 1.09 ± 0.30 in the flapless group, with 1 being the best possible score and 4 being the worst. There were no significant differences between groups for subcategories of satisfaction (Fig. 3D).

DISCUSSION

One implant in each group failed, for an average success rate of 92%. Average implant success rates using the flapless protocol range from 74.1% to 98.7% with up to a 10-year follow-up.[17-19] High success rates are noted in both the flap and flapless groups in the present study, suggesting that both protocols are acceptable techniques for implant placement. While both groups reported satisfaction with the treatment outcome, several other studies have reported that the flapless approach may confer advantages such as reduced treatment time, less bleeding, and minimal discomfort.[2,20]

Studies on flapless implant placement have reported mean radiographic alveolar bone loss ranging from 0.7 to 2.6 mm at 1 year.[21-23] In this study, the mean radiographic bone level is 0.4 mm above the implant's coronal aspect in the flapless group at 15 months. The minimum bone loss observed in the current study may be attributed to the specific implant design used (micro-threaded, platform-switching with a nanostructured surface).[24] However, it is important to note that the implants in the flapless group were placed an average of 0.85 mm subcrestally at baseline, which may account for this result. Still, it is notable that this protocol allowed the bone levels to remain above the implant platform in some cases. In contrast, implants placed using the flap protocol lost an average of 0.6 mm of crestal bone at 1 year. At the time of placement, these implants were at the level of the crestal bone (0.02 mm). It is unknown what the long-term consequences of subcrestal implant placement of the flapless group are on bone levels

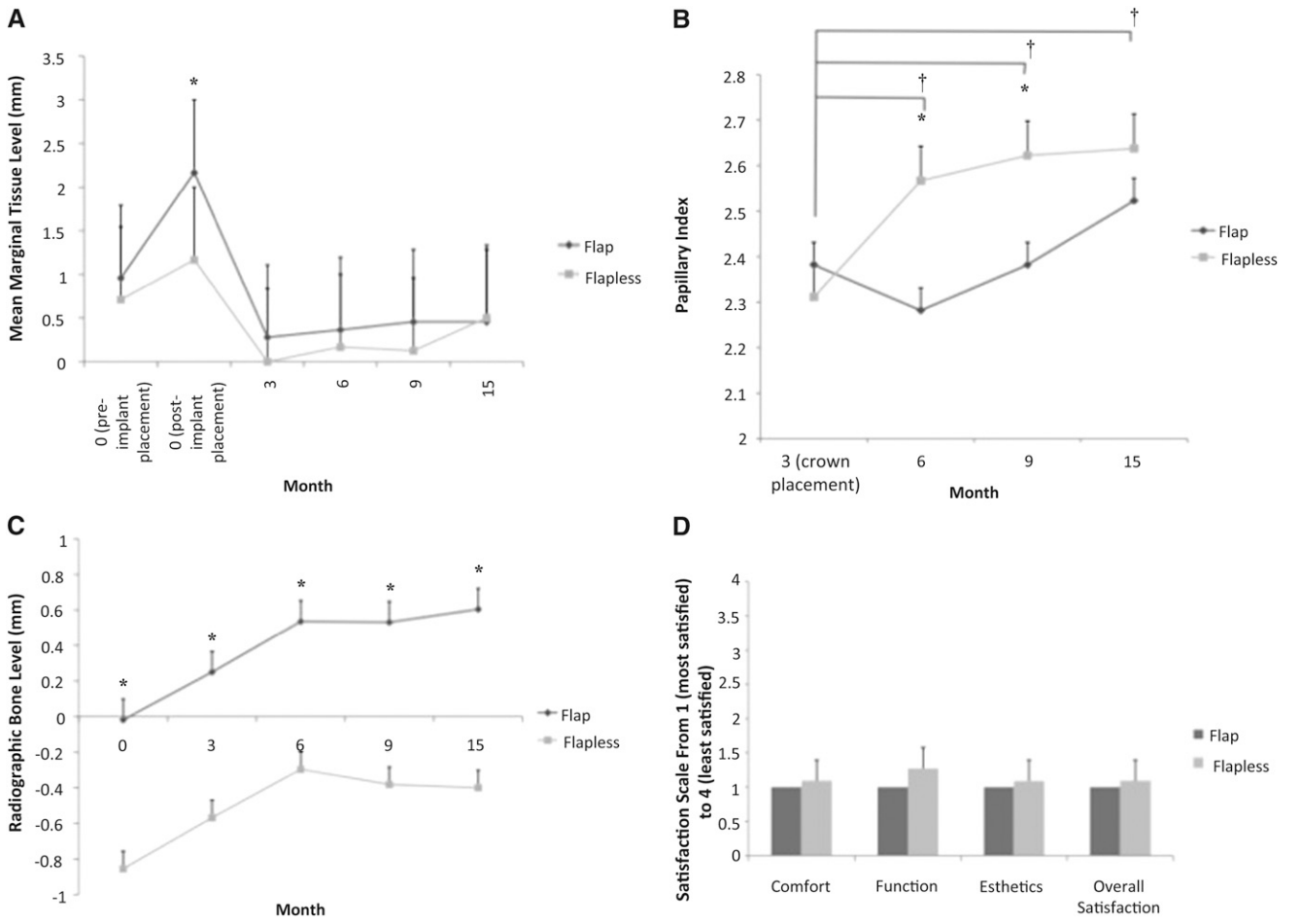

Figure 3.
Summary of results. ***A)*** *Marginal tissue level changes over time in both groups.* ***B)*** *PPI over time among and within groups.* ***C)*** *Linear radiographic bone level over time.* ***D)*** *Patient satisfaction among groups at the 15-month time point.* ***** *P <0.05; significant difference between groups.* † *P <0.01; significant difference within groups.*

and esthetics, although this study suggests that in the short term, subcrestal placement of the implant keeps bone levels and esthetic parameters stable.

Several recent reviews are divided as to whether KG is essential for periodontal health, but most agree that it may contribute to enhanced esthetic outcomes.[25-28] Using a tissue punch in the flapless protocol significantly reduced the amount of KG in this group, although a wide band of KG was still present, and the procedure did not influence marginal tissue levels in this study. However, it may be important to select sites for flapless implant placement only where sufficient KG is present. Interestingly, the amount of KG was reduced more significantly in the flap group compared with the flapless group. This may be due to the apical repositioning of the flap around the healing abutment combined with the mucogingival junction maintaining its original position. While not clinically or statistically significant over the long term, this may be important to consider in areas with minimal KG.

The flapless approach may confer esthetic benefits in the early stages of healing, although after 15 months there appears to be no esthetic advantage to using the flapless technique. In the flapless group, papilla fill occurred faster during the 6- to 9-month period compared with the group receiving a flap approach. Additionally, the marginal soft tissue level of the implant was greater in the flap group at baseline, indicating that raising a flap temporarily results in greater recession compared with the flapless approach. Alternatively, this transient change in marginal tissue level may be a result of suturing. This may be an important point to consider in the esthetic zone. However, the marginal tissue levels were equal at later time points, and so there is no difference in this esthetic parameter in the long term between flap and flapless approaches.

In this study, the presence of a thin biotype does not influence treatment outcomes among groups, nor do patients with thin biotypes have worse esthetic outcomes than those with thick biotypes. In the early stages of healing, patients with a thick biotype appeared to have a better esthetic result when a flapless approach was used, which resulted in earlier and greater papilla fill. However, there was no long-term esthetic advantage to using a flapless approach in patients with a thick biotype. This may be because all patients had minimal interproximal bone loss and adequate bone thickness as assessed by CBCT before placement. Several studies have highlighted the importance of adequate bone thickness and small contact-to-interproximal distance in optimizing papilla fill and minimizing gingival recession.[29-31] It was also reported that patients with a thick biotype had better early esthetic results when the flapless technique was used.[32] Recent studies showed that thin biotypes were at an increased risk for incomplete papilla fill and marginal recession.[32,33]

CONCLUSIONS

Limitations of this study include a small sample size and subcrestal placement of the implants in the flapless group. Within the confines of the study, it can be concluded that both flapless and flap implant placement protocols result in high success rates, although a flapless protocol may provide a better short-term esthetic result. Nonetheless, larger studies are needed to confirm these results.

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