Effect of incision design on interproximal bone loss of teeth adjacent to single implants. A randomized controlled clinical trial comparing intrasulcular vs paramarginal incision

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Abstract

Purpose: To evaluate the effect of incision design in implant surgery on interproximal bone loss of posterior teeth adjacent to interdental single implants, comparing intrasulcular and paramarginal incision. A further aim was to assess the influence of the incision technique on peri-implant bone remodeling.

Materials and methods: A controlled randomized clinical trial was carried out in a University Clinic. All the patients received an interdental posterior single implant. The incision type was randomly divided into two groups: (a) intrasulcular or (b) paramarginal. Standardized periapical digital radiographs were made with the parallel technique and a silicone index individualized in each patient. Radiographs were made immediately after implant placement, at abutment connection, 6 and 12 months post-loading. Two radiographic reference points were detected at the interproximal aspect of the adjacent teeth: (A) the cemento-enamel junction and (B) the most coronal aspect of the bone crest. The interproximal bone loss of the adjacent teeth was calculated as the difference from A to B between the different follow-up periods and baseline. Two different examiners evaluated the radiographic measurements twice.

Results: Sixty patients, each with one implant, were included, 30 in each group. A mean interproximal bone loss in teeth of 0.09 mm in the intrasulcular and 0.10 mm in the paramarginal group was found at 12 months post-loading. Mean peri-implant bone remodeling was 0.17 mm in the intrasulcular group and 0.15 mm in the paramarginal group. Differences between incision types were not statistically significant ($p > .05$).

Conclusions: Both incision designs used to place interdental single implants resulted in minimum bone loss at the interproximal aspect of adjacent teeth. The incision design did not significantly influence the radiographically assessed interproximal bone loss nor peri-implant bone remodeling.

Keywords
bone implant interactions, periodontology, radiology imaging, soft tissue–implant interactions, wound healing
INTRODUCTION

Mucoperiosteal flaps are used to access the bone and root surface in periodontal, endodontic and oral surgical procedures. During the dissection procedure, the soft tissues are incised and the periosteum is separated from the alveolar bone (Fickl et al., 2011). Crestal incisions may continue to the interproximal aspect of the adjacent teeth, sometimes including the interproximal tissue. During implant placement, with a paramarginal incision, the soft tissues of the interproximal and the mid-facial marginal gingiva are maintained, unlike the intrasulcular incision where this tissue is dissected and elevated from the underlying bone. Experimental studies in animals and humans (Brägger, Pasquali, & Kornman, 1988; Fickl et al., 2011) have demonstrated that the exposure of alveolar bone by full-thickness flap elevation induces osteoclastic activity and results in bone resorption.

In a previous publication (Girbés-Ballester, Viña-Almunia, Peñarrocha-Oltra, & Peñarrocha-Diago, 2016), the effect of the incision design in the clinical parameters of the neighboring teeth to single implants was studied. The incision design did not affect the clinical parameters; there was an increase in recession and an improvement in papilla formation over time irrespectively of the incision type. Gomez-Roman (Gomez-Roman, 2001) performed a prospective study to evaluate peri-implant bone loss following interdental implant placement, using a paramarginal or an intrasulcular incision design. Significantly less peri-implant bone loss and better papilla fill following the paramarginal incision technique were recorded. In an experimental study in rats (Binderman et al., 2001), bone remodeling was analyzed comparing intrasulcular and paramarginal incision, the former presenting worse results. Fischer et al. (2014) in a study in dogs evaluated the reduction of the interproximal soft tissue by comparing a paramarginal incision technique with a vertical release incision (3 mm from the adjacent tooth) and the intrasulcular incision, obtaining less gingival contraction with the first one. In other fields of oral surgery, there are studies that analyze the incision design on the healing characteristics. In periapical surgery, intrasulcular incision has shown less papilla fill (Velvart, Ebner-Zimmermann, & Ebner, 2004) and more gingival recession (von Arx, Salvi, Janner, & Jensen, 2009) than other incision techniques. In periodontal plastic surgery, a study of coronal advancement flaps to cover recessions with or without release incisions showed no difference in the reduction of recessions, although there was a greater probability of complete root coverage without release incisions (Zucchelli et al., 2009).

Peri-implant bone loss was analyzed in relation to the flap technique, especially using the flapless approach (Bashutski et al., 2013; Lin, Chan, Bashutski, Oh, & Wang, 2014), but it is unclear whether interproximal bone loss of adjacent teeth can be affected by the incision technique used during implant placement. The aim of this controlled randomized clinical trial was to evaluate the effect of incision design in implant surgery on interproximal bone loss of posterior teeth adjacent to interdental single implants, comparing intrasulcular and paramarginal incision. A further aim was to assess the influence of the incision technique on peri-implant bone remodeling. This article was written following the CONSORT statement for improving the quality of RCTs (Schulz, Altman, & Moher, 2010).

MATERIAL AND METHODS

Study design and patient selection

A double-blind randomized controlled parallel clinical trial was carried out in the Oral Surgery Unit of the University of Valencia, between February 2013 and March 2016. The allocation ratio was 1:1. The study design was approved by the local ethics committee (Ref. number: H1359714956078) and performed following the principles of the Declaration of Helsinki. All patients were required to sign an informed consent form to participate in the study.

The following inclusion criteria were used: (i) single posterior edentulous area with at least 8 mm of mesiodistal space; (ii) healthy adjacent teeth (not supporting fixed prostheses and without periodontal alterations); (iii) keratinized mucosa width of at least 3 mm; (iv) indication of implant not requiring simultaneous bone regeneration techniques; (v) full-mouth plaque and full-mouth bleeding scores <25%; (vi) non-smoking or smoking ≤10 cigarettes/day (all pipe or cigar smokers were excluded); and (vii) follow-up of 1 year after implant loading. The exclusion criteria were as follows: (i) implants placed closer than 2 mm to adjacent teeth; (ii) systemic diseases contraindicating surgery; and (iii) sites with acute infection.

The primary outcome of the study was to evaluate the effect of incision design in implant surgery on interproximal bone loss of posterior teeth adjacent, comparing two incisions. A value of 0.7 mm was used for the sample size calculation and a SD of 0.7. These values were chosen due to the lack of evidence published in the literature about this topic, to the best of our knowledge. The 0.7 mm value was a conservative choice based in the 1 mm clinically relevant threshold of difference in marginal bone loss and the presence of papilla reported by Tarnow et al. (Tarnow et al., 2003). However, Tarnow et al. did not report SD, so a commonly reported SD value of 0.7 for bone loss in adjacent teeth (Galindo-Moreno et al., 2017) was used. For a statistical power of 95%, an effect of 0.7 mm and α-value of 0.05, the necessary sample size was determined to be 27 patients per group with a final sample of 60 patients (10% more patients were included to avoid attrition bias).

Randomization

Random assignment of the patients to the groups was performed according to computer-generated randomization tables. A 6 permuted blocks of 4 elements randomization approach was used to prepare the randomization tables in order to avoid imbalance between the two incisions. Assignment was performed using sealed envelopes. The investigation team was composed by a principal investigator who designs the study and made the permutation, two calibrated examiners who performed the radiographic analysis, the surgeon that made the treatment and completed the follow-up and the statistician. Participants
were informed about the different incisions, but blinded to their assignment. Radiological periodontal parameters were assessed by a two blinded investigators different from the surgeon. The procedure was also blinded for the principal investigator and statistician.

2.3 | Surgical and restorative treatment

All patients in the study underwent a supragingival scaling 3 weeks before the implant surgery. Delayed implant placement was performed. All implants (Frontier®, Ilerimplant, Lleida-GMI, Spain) were placed using the same surgical protocol under local anesthesia with 4% articaine with epinephrine 100'000. At this point, an assistant was asked to open a randomization envelope and the assigned incision technique was revealed and performed accordingly:

Group (A) Intrasulcular incision: A crestal incision was performed in the attached mucosa of the edentulous area including the sulcus of the adjacent teeth, without release incisions (Figure 1a).

Group (B) Paramarginal incision: A crestal incision was performed in the attached mucosa of the edentulous area without reaching the interproximal soft tissue surrounding the adjacent teeth and making two release incisions. The distance from the mid-crestal incision to the interproximal aspect of the adjacent teeth was approximately 1.5–2 mm (Figure 1b).

After the incision, a full-thickness mucoperiosteal flap was raised. Implant platform was placed 1–1.5 mm subcrestally. A non-submerged approach was used and the flap was repositioned and sutured around the healing abutments. To avoid flap advancements, only cases that did not require bone augmentations were selected. Perioperative antibiotic prophylaxis was initiated 2 hr prior to surgery and maintained for 3 days post-surgery (Amoxicillin 1 g, twice a day, orally) (Buser et al., 2009). Post-surgical medication also included ibuprofen 600 mg tablets, when patients perceived pain, and rinsing with 0.12% chlorhexidine digluconate for 1 min, twice a day for 2 weeks. No provisionalization was performed as cases belonged to the posterior region, where the esthetic demand is lower than the anterior region. Sutures were removed 1 week after surgery. After a healing period of 12 weeks, screw-retained porcelain restorations were inserted and loaded.

2.4 | Follow-up examinations and radiographic evaluation

The study patients were monitored for 1 year after implant loading. Radiographic examination was carried out using the intraoral XMind system (Groupe Satelec-Pierre Rolland, Bordeaux, France) and the RVG intraoral digital sensor (Kodak Dental System, Atlanta, GA, USA). To reproduce the X-ray angulation in consecutive follow-ups, positioners were used (Dentsply, Des Plaines, IL, USA), placing the guide bar parallel to the direction of the X-ray beam, perpendicular to the digital sensor. A silicone bite block was individualized in each patient. This bite block was modified once the implant-supported crown was placed in order to obtain an accurately standardized radiograph. Radiographic follow-up was performed as follows: baseline (immediately after implant placement), at abutment connection (3 months post-surgery), 6 and 12 months post-loading.

Intra- and interindividual radiographic assessment was made. In this context, two different blinded clinicians, other than the surgeon, evaluated the radiographs twice. The measurement used for the analysis of bone loss was the mean of the 4 measurements. Measurements were calibrated using the known implant platform diameter with the ImageJ program (Schneider, Rasband, & Eliceiri, 2012) (Figure 2).

2.5 | Distance from the CEJ to the most interproximal coronal aspect of the bone crest

In order to assess interproximal bone loss of the teeth adjacent to the implant, we proceeded as follows: Two reference points were detected at the interproximal aspect of the adjacent teeth in the post-surgical radiograph (baseline): (A) the cementoenamel junction (CEJ) and (B) the most coronal aspect of the bone crest. A straight line along the root was traced from point A to B. This distance was considered the baseline. The distance between these reference points was measured at the different radiographic follow-up examinations. The difference between the time points examination and baseline distance was considered as interproximal bone loss. Mesial and distal aspects of the teeth were measured in each examination period; bone loss value was calculated as the average of the measurements at the either mesial or distal surfaces of the neighboring teeth (Figure 3a).

2.6 | Distance from the implant shoulder to the first bone-to-implant contact

The distance from the implant shoulder to the first bone-to-implant contact (DIB) was measured as follows (Buser et al., 2011): The DIB
on the mesial and distal aspect of the implant was measured at each examination, and one DIB value was calculated as the average of the mesial and distal values. At baseline, the mean DIB was 0.00 mm for the 60 implants. The peri-implant crestal bone remodeling was calculated as the difference between baseline and each time-point examination. As the implants were inserted subcrestally, in the periapical radiographs in which the bone crest was above the platform, the DIB was considered 0.00 mm (Figure 3b).

### 2.7 Statistical analysis

Continuous variables were described by the number of observations (n), minimum (min), median, maximum (max), mean, and standard deviation (SD) values and discrete variables by frequencies and percentages. Within-group and between-group comparisons were calculated using general linear models (ANOVA), with multiple comparisons based on Bonferroni’s test. A two-sided p-value < .05 was considered as being statistically significant. In the preliminary study of the error, two intraobserver (one for each examiner) and one interobserver tests were performed. The systematic error was analyzed with the paired t test. The Dahlberg d was used to measure both, systematic and random error, and the intraclass correlation coefficient (ICC) was used to assess the random error.

### 3 RESULTS

During the study period, 62 patients were screened for inclusion, and 60 patients participated in the study. Two patients were excluded for not meeting the inclusion criteria: Two patients smoked >10 cigarettes/day. No dropouts occurred during the observation period (Figure 4).

A total of 60 patients (24 men and 36 women, mean age of 49.1 years with a range of 19–80 years) were treated with 60 implants: 30 patients underwent the intrasulcular incision and 30 patients the paramarginal incision. All implants were successfully integrated and
in function at 1 year (100% survival rate). Of the total 60 implants, 44 were in the molar region and 16 in the premolar region. Thirty-six implants were placed in the mandible and 24 in the maxilla. Implants were 10–11.5 mm long and 3.75 mm to 4.75 mm in diameter. Fifty patients were nonsmokers, and 10 were smokers of ≤10 cigarettes per day.

**FIGURE 4** Flowchart of the study

**TABLE 1** Bone loss in adjacent teeth by treatment group (intrasulcular vs. paramarginal incision) and by global changes

<table>
<thead>
<tr>
<th></th>
<th>Surgery</th>
<th>Loading</th>
<th>6 months post-loading</th>
<th>12 months post-loading</th>
<th>Change from surgery to loading</th>
<th>Change from surgery to 6 months</th>
<th>Change from surgery to 12 months</th>
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</thead>
<tbody>
<tr>
<td><strong>Intrasulcular</strong></td>
<td>No.</td>
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<td>No.</td>
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<tr>
<td>Mean ± SD (range)</td>
<td>2.34 ± 1.10 (0.54–6.15)</td>
<td>2.51 ± 1.03 (0.26–5.50)</td>
<td>2.44 ± 0.99 (0.81–5.18)</td>
<td>2.43 ± 0.97 (0.90–5.30)</td>
<td>-0.17 ± 0.60 (-1.25–1.00)</td>
<td>-0.10 ± 0.68 (-1.80–1.33)</td>
<td>-0.09 ± 0.64 (-1.75–1.39)</td>
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<tr>
<td>Median</td>
<td>2.16</td>
<td>2.35</td>
<td>2.14</td>
<td>2.15</td>
<td>-0.12</td>
<td>0.01</td>
<td>-0.03</td>
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<td>p-value</td>
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<td><strong>Paramarginal</strong></td>
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<tr>
<td>Mean ± SD (range)</td>
<td>2.66 ± 0.87 (1.23–4.33)</td>
<td>2.74 ± 1.11 (0.94–4.68)</td>
<td>2.68 ± 1.02 (0.94–4.50)</td>
<td>2.76 ± 1.03 (1.37–4.65)</td>
<td>-0.09 ± 0.55 (-1.47–1.17)</td>
<td>-0.03 ± 0.53 (-1.38–1.10)</td>
<td>-0.10 ± 0.53 (-1.39–1.10)</td>
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<tr>
<td>Median</td>
<td>2.62</td>
<td>2.54</td>
<td>2.60</td>
<td>2.62</td>
<td>-0.08</td>
<td>-0.02</td>
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<td>p-value</td>
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<td>60</td>
</tr>
<tr>
<td>Mean ± SD (range)</td>
<td>2.50 ± 0.99 (0.54–6.15)</td>
<td>2.63 ± 1.07 (0.26–5.50)</td>
<td>2.56 ± 1.00 (0.81–5.18)</td>
<td>2.59 ± 1.01 (0.90–5.30)</td>
<td>-0.13 ± 0.57 (-1.47–1.17)</td>
<td>-0.06 ± 0.60 (-1.80–1.33)</td>
<td>-0.09 ± 0.58 (-1.75–1.39)</td>
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<tr>
<td>Median</td>
<td>2.36</td>
<td>2.43</td>
<td>2.29</td>
<td>2.34</td>
<td>-0.09</td>
<td>-0.01</td>
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</tbody>
</table>

\( p = 0.538 \quad p = 1.000 \quad p = 1.000 \)

\( p = 0.583 \quad p = 1.000 \quad p = 1.000 \)

\( p = 0.213 \quad p = 0.346 \quad p = 0.340 \)
The systematic and randomized error was below 0.2 mm in the Dahlberg d values. In the adjacent tooth, the degree of reproducibility was high in both intra- and interexaminations (ICC = 0.97 and 0.94, respectively). For the implant, the degree of reproducibility was high in both intra- and interexaminations (ICC = 0.93 and 0.92, respectively).

3.1 Distance from the CEJ to the most interproximal coronal aspect of the bone crest

Table 1 shows the interproximal bone measurements for the teeth adjacent to the implant in both groups. Following implant placement, the mean bone position with respect to the CEJ was 2.34 ± 1.10 [95% CI: 1.93; 2.75] mm in the intrasulcular group and 2.66 ± 1.03 [95% CI: 2.33; 2.98] mm in the paramarginal group. After a 12-month follow-up, the mean bone position was 2.43 ± 1.10 [95% CI: 1.93; 2.75] mm in the intrasulcular group and 2.66 ± 1.03 [95% CI: 2.33; 2.98] mm in the paramarginal group. The mean bone reduction from baseline to 1-year follow-up was 0.09 [95% CI: −0.14; 0.32] mm in the intrasulcular group and 0.10 [95% CI: −0.10; 0.29] mm in the paramarginal group. These differences were not statistically significant (p = .213). Considering the whole sample, a mean bone reduction of 0.09 [95% CI: −0.05; 0.24] mm was recorded at the end of the follow-up. The degree of reproducibility was high in both intra- and interexaminations (intraclass correlation coefficient (ICC) = 0.97 and 0.94, respectively).

3.2 Distance from the implant shoulder to the first bone-to-implant contact

After a 12-month follow-up, mean peri-implant bone remodeling was 0.17 ± 0.34 [95% CI: −0.04; 0.32] mm in the intrasulcular group and 0.15 ± 0.32 [95% CI: −0.03; 0.28] mm in the paramarginal group. No significant differences were found in DIB changes between groups (p = .756). The frequency analysis showed 21 and 19 implants in the intrasulcular and in the paramarginal incision, respectively, with no rough implant surface exposed. This means that at the 12-month follow-up, the implant was in a crestal or subcrestal position. In the intrasulcular group, nine implants showed marginal bone loss between 0.01 and 1 mm, and no implant showed more than 1.01 mm. In the paramarginal group, ten implants showed between 0.01 and 1 mm, and one implant showed more than 1.01 mm. Considering the whole sample, minimal DIB changes were found between implant placement and the twelve-month follow-up (0.16 mm). Table 2 shows bone remodeling in implants by treatment group and by global changes of the whole sample. The degree of reproducibility was high both in intra- and interexamination (intraclass correlation coefficient (ICC) = 0.93 and 0.92 respectively).

4 DISCUSSION

The purpose of this prospective study was to compare the effect of the incision technique applied for interdental implant placement on

<table>
<thead>
<tr>
<th>TABLE 2 Bone remodeling in implants by treatment group (intrasulcular vs. paramarginal incision) and by global changes</th>
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<tbody>
<tr>
<td>Surgery</td>
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<tr>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Intrasulcular</td>
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<tr>
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<td>Mean ± SD (range)</td>
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<td>Median</td>
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<td>Mean ± SD (range)</td>
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<td>Total</td>
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<td>No.</td>
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<td>Mean ± SD (range)</td>
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<td>Median</td>
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<td>p-value</td>
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*p < .05; **p < .01; ***p < .001.
the interproximal bone loss of adjacent teeth. Two different incision types were used: intrasulcular and paramarginal. The main difference between the two techniques is that with the intrasulcular incision, the interproximal soft tissue that pertains to the adjacent teeth is elevated, while with the paramarginal incision, it is maintained. The results of the present investigation demonstrated that after raising a flap, a minimal amount of bone remodeling, measured by radiographs, occurs, but the incision type does not influence this resorption.

In a previous report (Girbés-Ballester et al., 2016), we analyzed the influence of incision type on soft tissue changes and clinical parameters of adjacent teeth. Although not statistically significant, a better papilla formation was found in the paramarginal incision group. Gomez-Roman (2001) concluded that the use of a paramarginal incision for single-tooth implants is indicated to avoid possible loss of the papilla and minimize interproximal crestal bone loss. These findings must be critically valued as paramarginal incisions require a buccal releasing incision, which, in turn, may cause esthetically impairing scar formations.

In different fields of oral surgery, a variety of flap designs have been compared by controlled clinical trials (von Arx et al., 2009; Binderman et al., 2001; Fickl et al., 2014; Gomez-Roman, 2001; Velvart et al., 2004; Zucchelli et al., 2009). It is obvious that, depending on the treatment goals, different flap designs may be indicated. In periapical surgery, when access is only required from the buccal aspect, the sulcular incisions can be continued at the base of the papilla, thus, completely preserving both, the buccal and oral papilla without elevation of the interdental gingiva (Velvart 2002, von Arx et al. 2007). On the other hand, when the interdental area has to be surgically accessed, either one of the two papillae may be incised at its base in order to preserve the entire anatomical structure of the papilla. In such cases, the modality of the problem will dictate the extension of the tissue elevation. Thus, an intrasulcular incision ending in the col area might preserve the papilla as well, as it remains pedicled at the opposite end. It has to be mentioned that the original term “papilla preservation” has been introduced in the context of the surgical access of interdental sites affected by periodontitis. Such situations with two papillae and the interdental col differ anatomically from the situations in the present study, where no col tissue was present due to the fact that a neighboring tooth was missing. In the present study, the intrasulcular incision defined two flaps (buccal and lingual/palatal), in which the interproximal bone adjacent to the neighboring teeth was denuded. In contrast, in the paramarginal incision, the interproximal bone was not exposed.

The results of the present investigation showed no differences in bone loss between the 2 groups. All implants were placed in posterior areas where the crest is wider than in the anterior areas. In addition, only periodontally healthy patients, with no probing depths greater than 4 mm in the interproximal aspect, good oral hygiene and edentulous areas with no fixed restorations at neighboring teeth, were included. It is also important to mention that the presence of fixed restorations at neighboring teeth could have an impact in hard and soft tissue alterations due to the fact that a restoration margin is present. In those cases, soft tissue alterations would have a higher esthetic impact because a submarginal or juxtagingival margin of the preparation could result in a supragingival position. It remains to be studied whether the absence of differences observed in the present study will apply also in non so ideal situations after the execution of different incision techniques. The contour of the implant-supported crown could also influence the soft tissue characteristics between implant and neighboring teeth. In the present study, direct screw retained rehabilitations with flat or concave profile were performed.

Another important factor that must be underlined is the distance between the vertical releasing incision and the interproximal aspect of the adjacent teeth in the paramarginal incision. In a study in dogs, Fickl et al. (2014) concluded that the papilla preservation technique induces significantly less tissue contraction following flap surgery compared to intrasulcular incisions. However, this was an animal study with longer edentulous areas, where it was possible to leave 3 mm of distance between the vertical releasing incision and the interproximal aspect of the teeth. Since mesiodistal space in premolars and molars is 7 and 11 mm in humans, in the present clinical study the allowed distance was 1.5–2 mm in molars and 1–1.5 mm in premolars. This space limitation might explain the different outcomes between the mentioned animal study and the present clinical investigation.

The present study shows that minimal bone remodeling is going to occur in the neighboring teeth, irrespective of the incision design. A previous study (Girbés-Ballester et al., 2016) performed by our group demonstrated that paramarginal incision showed slightly better papilla index and less recession in the adjacent teeth than intrasulcular incision, although differences were not significant. Both investigations were conducted using selected cases with healthy, unrestored teeth adjacent to the edentulous area.

The appropriate flap design depends on the treatment goals of the individual surgical intervention and is based on patient, site and even surgeon-specific criteria. Specific surgical requirements such as flap advancement after bone augmentation may dictate the incision lines and help the surgeon to choose the most suitable approach. In particular, in the zone of esthetic priority, flaps design and incision lines should be carefully selected as already minor changes in soft tissue contour, texture and color may negatively affect the esthetic outcome. The two treatment modalities compared in the present study did not differ regarding bone loss at neighboring teeth. Nevertheless, an approach without releasing incisions may be preferred when scar formations have to be avoided. Future investigation should focus on the influence of incision design in the esthetic area, where changes in hard and soft tissues have higher impact on final treatment outcomes.

5 | Conclusion

Within the limits of the present investigation, it can be concluded that both incision designs resulted in a minimum amount of bone loss at the interproximal aspects of adjacent teeth. The incision design did not significantly influence the radiographically assessed bone loss. Peri-implant bone remodeling was similar in both incision groups.
CONFLICT OF INTEREST

None of the authors have conflict of interest in the present study.

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REFERENCES


SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.