Flap versus flapless procedure for ridge preservation in alveolar extraction sockets: a histological evaluation in a randomized clinical trial

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Abstract

Objective: The aim of this study was to evaluate and compare the histological and histomorphometric features of two different procedures carried out in extraction socket grafting; namely, the flapped and flapless technique.

Materials and methods: Patients considered eligible for the study were randomized to receive tooth extraction and ridge preservation with the porcine bone and collagen membrane, with a full thickness mucoperiosteal flap and primary soft tissue closure (control group), or, with a flapless procedure and a secondary soft tissue closure (test group). After 3 months of healing, the surgical re-entry procedure was performed and implants were inserted in the test as well as in the control sites. Bone core samples were harvested from both groups and processed to be observed under light microscopy. Outcome variables were percentages of newly formed bone, residual grafted particles and marrow spaces.

Results: Thirty-four patients were enrolled in the study. All of the scheduled implants were placed. Histological and histomorphometrical analyses did not report significant differences between the two groups (with \( P \)-values ranging from 0.690 to 0.917). The mean percentages of newly formed bone, soft tissues and residual grafted particles were 22.5 and 22.5%, 59.3 and 59.4%, and 18.6 and 18.2% respectively for flap and flapless approach.

Conclusion: No histological and histomorphometrical differences were observed when comparing the flap and the flapless technique for tooth extraction and socket grafting procedures.

The treatment of extraction sockets is a daily challenge for the clinical practice. Several bone dimensional changes occur after tooth extraction given that the alveolar process is a tooth-dependent tissue (Barone et al. 2008). The preservation of the alveolar ridge is recommended to maintain the existing soft and hard tissues, to preserve a stable ridge volume and to simplify the subsequent rehabilitation treatments, either for implant placement or for the traditional prosthetic restorations (Darby et al. 2009; Hämmerle et al. 2012; Novaes et al. 2012; Vignoletti et al. 2012). Morphological changes of the extraction sites resulted in a narrower and shorter ridge; moreover, the alveolar crest shifted lingually/palatally according to a specific pattern. Some clinical data indicated that the alveolar crest tends to move two-thirds lingually/palatally from the original buccal edge, thus the resorption at the mid-facial point represented the double of bone loss at the distal and the mesial points (Covani et al. 2011).

As, over the last years, aesthetic outcomes have received more emphasis in implant treatment planning, the resorption of the alveolar ridge has become a clinically relevant problem and may cause failing aesthetic
outcomes with an implant-supported crown and/or bridge. Indeed, adequate architecture of the alveolar bone and soft tissues are required to obtain a functional and aesthetic prosthetic rehabilitation [Buser et al. 1993, 2008; Darby et al. 2009; Barone et al. 2011; Kan et al. 2011].

The ridge preservation procedure is recommended in the following conditions: when the implant placement is not possible at the time of tooth extraction; when the patient is not available for an immediate implant placement; when primary stability of the implant cannot be obtained; and when adolescent patients should be treated [Hämmerle et al. 2012]. A recent consensus report [Hämmerle et al. 2012] assessed that it is important to distinguish between the various procedures used to preserve the alveolar ridge. The “ridge preservation” techniques include all the procedures that preserve the ridge volume within the envelope existing at the time of extraction [Hämmerle et al. 2012]. Several studies [Fiorellini & Nevins 2003; Barone et al. 2011] demonstrated that implants placed in grafted bone had a survival rate similar to implants placed in native bone. The ridge preservation technique allowed wider and longer implant placement when compared to non-augmented sockets, and, therefore, reduced the need for simultaneous augmentation procedures at the time of implant placement [Darby et al. 2009; Barone et al. 2011].

The use of various techniques and biomaterials has been proposed over the years; however, no significant differences have been shown between the different biomaterials, although collagen alone did not prove to be suitable to counteract tissue changes after tooth extraction [Farina et al. 2009; Oghli & Steveling 2010; Barone et al. 2011, 2012, 2013; Vignoletti et al. 2012].

A muco-periosteal flap reflection - with its interruption of vascular supply to underlying bone - during tooth extraction may have accounted for the slightly more pronounced bone remodelling of the alveolar ridge, when compared to a flapless extraction [Fickl et al. 2008b, Engler-Hamm et al. 2011; Novaes et al. 2011; Canullo et al. 2012]. However, no firm conclusions could be drawn on the advantages of flapless versus flap elevation during tooth extraction. Moreover, it should be taken into consideration that soft tissue primary closure was originally believed to be necessary for proper incorporation of the graft [Lekovic et al. 1997, 1998; Fickl et al. 2008a, Darby et al. 2009]. The early exposure of the membrane to the oral cavity was thought to be a complication which could jeopardise the effectiveness of tissue augmentation [Simion et al. 1997; Engler-Hamm et al. 2011]; these findings pointed out the importance of achieving full closure and primary healing when the socket is grafted and covered with a membrane [Darby et al. 2009].

In actual fact, the effect of flapless/flapped surgery on the healing process is still controversial, with results from experimental models reporting less pronounced bone remodelling of the alveolar ridge after socket preservation using a flapless approach [Fickl et al. 2008b]. However, other authors did not report any significant difference between the flapless and flapped approach [Araujo & Lindhe 2009].

The objective of this study was to investigate and to compare the effect of soft tissue primary closure on the bone healing of extraction sockets grafted with a xenograft and a collagen membrane. The histologic and histomorphometric examinations of grafted extraction sockets, where a mucoperiosteal flap was coronally moved to obtain a soft tissue primary closure, were compared to those of extraction sockets where no flap was raised and the collagen membrane was left intentionally exposed to the oral cavity. This study reported histological outcomes up to 3 months after grafting. The clinical outcome of this trial has been reported in a recent article [Barone et al. 2014]. Furthermore, to evaluate the success of the procedure over time, the patients were to receive a follow-up until the fifth year. This study was reported according to the CONSORT guidelines [Appendix S1] [Moher et al. 2010].

Material and methods

Study population and design

Patients requiring at least one single premolar or molar tooth extraction and subsequently an implant-supported restoration, and who were 18 years old or older and able to sign an informed consent form, were eligible for inclusion in this trial. The criteria for exclusion were as follows:

- History of systemic diseases that would contraindicate oral surgical treatment.
- Lack of opposite occluding dentition in the area intended for extraction and subsequent implant placement.
- Intravenous and oral bisphosphonate therapy.
- The absence of adjacent teeth.
- Sockets with a complete loss of a bone wall.
- Presence of severe untreated periodontal disease.
- Unwillingness to return for the follow-up examination.
- Use of more than 10 cigarettes per day. Subjects smoking <10 cigarettes per day were requested to stop smoking before and after surgery; however, their compliance could not be monitored.

Patients were recruited from the consultation clinic at the Dentistry Department of Versilia General Hospital, University of Pisa, from January 2010 to September 2011. The study was approved by the Ethics Committee of the Versilia General Hospital, Lido di Camaiore, Italy. The principles outlined in the declaration of Helsinki on clinical research involving human subjects were adhered to. All patients received thorough explanations and had to complete a written informed consent form prior to being enrolled in the trial. Patients who were included in the study were accurately evaluated by examining clinical aspects and periapical/panoramic radiographs; moreover, data were collected for each patient such as age, gender, smoking habits, and indications for tooth extraction based on both clinical and radiographic examination, tooth location and presence/absence of adjacent teeth. After the consent form had been signed, all patients underwent at least one session of oral hygiene prior to the extraction procedures to provide a more favourable oral environment for wound healing. All patients received tooth extraction and a ridge preservation procedure at baseline; 3 months after tooth extraction, all sites were re-entered, bone biopsies were taken and implants were inserted. Extraction sockets were randomly allocated to either a test [no flap with a secondary soft tissue healing] or control [flap elevation and primary soft tissue closure] group using a computerized random allocation process. The randomized codes were enclosed in sequentially sealed envelopes. Immediately after tooth extraction, the envelopes were opened and indicated to the surgeon to include the extraction socket as a test or a control site according to the randomization list. The treatment allocation was concealed to the clinician who was involved in enrolling and treating the patients included in this trial. The clinician [GI] involved in the histologic and histomorphometric examination was blinded to group allocation.
Surgical treatment

All patients received antibiotic therapy (2 g of amoxicillin or 600 mg clindamycin – if allergic to penicillins) 1 h before the extraction procedure and continued to take the antibiotic postoperatively (1 g amoxicillin or 300 mg clindamycin) twice a day for 4 days. All patients rinsed for 1 min with chlorhexidine mouthwash 0.2% prior to the surgery (and twice a day for the following 3 weeks), and were treated under local anaesthesia using lidocaine with adrenaline 1 : 50,000. All surgical procedures were undertaken by one surgeon (AB). All the patients were treated with the same surgical technique and periosteotomes were used around each single selected tooth. Moreover, ultrasound bone surgery (Piezosurgery, Mectron, Italy) was performed where necessary to avoid buccolingual movements, thus preventing damage or full fracture to the facial bone wall. The extraction socket was thoroughly curetted and irrigated with sterile saline solution.

Extraction sockets allocated in the test group were filled and slightly condensed with corticocancellous porcine bone (MP3, osteobiol, Coazze, Italy), and a trimmed collagen membrane (Evolution; osteobiol, Coazze, Italy) was used to completely cover the socket; the soft tissues were only undermined and no releasing incisions were performed. The collagen membrane was intentionally left exposed to the oral cavity and sutures were used to stabilize the membrane.

Extraction sockets allocated in the control group had a full thickness mucoperiosteal flap with two releasing incisions, and corticocancellous porcine bone and collagen membrane were applied; subsequently, the buccal flap was advanced coronally to allow a soft tissue primary closure. All patients were instructed to continue with prophylactic antibiotic therapy, and naproxen sodium 550 mg tablets were prescribed as an anti-inflammatory to be taken twice a day for as long as required. Removable prostheses, if present, were not permitted for use until they had been adjusted and refitted no sooner than 3 weeks after surgery.

After 3 months of healing, the surgical re-entry procedure was performed and implants (intralock®, boca-raton, Fl, USA) were inserted in test as well as in control sites. Surgical trephine burs were used to harvest bone core samples from the augmented socket sites.

After harvesting the bone samples, the osteotomy site was prepared according to the implant system manufacturer’s recommendations. Patients received the same drug prescription as that prescribed after the initial surgery. The bone cores were coded and sent for analysis to the Department of Medical, Oral and Biotechnological Sciences, University of Chieti-Pescara, Italy.

After 4 months, implants were manually tested for stability and impressions were taken using polyvinyl-siloxane impression material (flexitime, heraeus/kulzer, Hanu, Germany) and customized resin impression trays. Final prosthetic restorations were cemented and patients were enrolled in an oral hygiene programme, with a recall visit every 3 months.

Histological analysis

The bone cores were retrieved, immediately stored in 10% buffered formalin and then processed to obtain thin ground sections. The specimens were processed using the Precise 1 Automated System [Assing, Rome, Italy] (pit&attelli et al. 1997). The specimens were dehydrated in a graded series of ethanol rinses and embedded in a glycolmethacrylate resin (technovit 7200 VLC, kulzer, wehrheim, Germany). After polymerization the specimens were sectioned, along their longitudinal axis, with a high-precision diamond disc at about 150 μm and ground down to about 30 μm with a specially designed grinding machine. Three slides were obtained from each specimen. These slides were stained with acid fuchsin and toluidine blue and examined in transmitted and polarized light using a Leitz Laborlux® microscope (Leitz, wetzlar, Germany).

Histomorphometry of the percentages of newly formed bone, residual graft material and marrow spaces was carried out using a light microscope (laborlux S; Leitz) connected to a high resolution video camera (3CCD, JVC KY-F55B; JVC®, Yokohama, Japan) and interfaced to a monitor and PC (Intel Pentium III 1200 MMX; Intel®, Santa Clara, CA, USA).

This optical system was associated with a digitizing pad matrix (vision GmbH, Oppenweiler, Germany) and a histometric software package with image capturing capabilities [image-Pro plus 4.5; media cybernetics inc., immagini & computer sne Milano, Italy]. One single well-trained examiner (Gl), who was not involved in the surgical treatment, evaluated the histological results. The histomorphometric data were obtained from three sections for each specimen.

This study aimed to ascertain any significant differences in the histological outcomes between the two procedures. Outcome measures were as follows: percentages of newly formed bone, residual graft particles and marrow spaces.

Statistical analysis

To obtain an effective size of the samples, a power analysis was performed; mean and standard deviation reported by preliminary histomorphometric analysis for similar procedures (without xenograft employment) in animal models, and using a power of 0.9 and a significance of 0.05 (Statistics Toolbox, MatLab 7.0.1; The MathWorks, Natick, MA, USA).

The sample size calculation was performed using the data related to the percentage of mineralization of the tissue at 4 months in animal models subjected to flap and flapless procedures [Caneva et al. 2010]. The results of the power analysis suggested that a sample size of 68 might be necessary.

Normal distribution for each histomorphometric variable was carried out, but not confirmed by the shapiro–Wilk test with a significance of 0.05. The possible influence of gender was assessed by friedman’s nonparametric two-way analysis of variance (ANOVA) for each of the outcome variables. Pairwise comparisons were performed by the Wilcoxon rank sum test for unmatched data and P-values were obtained; the statistical significance was set at P = 0.05.

All measurements in the text and tables are described as median and interquartile ranges, m [IQR: the difference between the 75th and 25th percentiles]. The data distribution was plotted by a whiskers graph in Fig. 1.

Results

Forty-three patients were initially considered eligible, even though nine patients were not included in the trial for the following reasons: two patients were affected by uncontrolled diabetes, one patient was under treatment with oral bisphosphonates, three patients did not comply with the oral hygiene instructions, one patient refused to attend follow-up visits for the following 5 years and two patients had a complete loss of buccal bone wall after tooth extraction.

Thirty-four patients, who were 18 years old or older, underwent a tooth extraction with a ridge preservation procedure and a further implant treatment. All the 34 patients were enrolled in the trial and randomized as follows: 17 to the flapless group [test group] and 17 to the flap group [control group]. The test group received a ridge preservation procedure without a flap and a secondary soft tissue healing was left; while, the control group was treated with a primary soft tissue closure.
received a ridge preservation procedure with a mucoperiosteal flap to achieve a primary wound closure (Fig. 2). Corticocancellous porcine bone and a collagen membrane were used to completely cover the extraction socket as grafting material in both experimental groups. All the ridge preservation procedures had a successful outcome and implants were inserted in all the experimental sites. The clinical outcome of this trial can be found in a recent article (Barone et al. 2014).

The main baseline patient characteristics were reported in Table 1; the two groups did not show any imbalances.

**Histological findings**

In all biopsies, trabecular bone was formed over the entire grafted area; grafted material particles were present in all specimens.

**Control group**

In the control group specimens pre-existing bone was found, which was characterized by remodelling areas, showing cement lines and newly formed bone in close contact with the biomaterial particles (Fig. 3).

At higher magnification, most of the biomaterial particles were connected by newly formed bone characterized by large osteocytic lacunae. A few biomaterial granules had been partially reabsorbed and replaced by newly formed bone. The newly formed bone was observed inside some partially reabsorbed particles. The newly formed bone had a high affinity for dyes and was acid fuchsine positive, and, therefore, a highly stained line was observed at the grafting material and new bone interface. At an even higher magnification, large osteocytic lacunae were observed (Fig. 4). Collagen fibres with a parallel orientation, as occurs in lamellar bone, were seen in the marginal portion of the bone cores close to the pre-existing bone (Fig. 5).

No gaps were observed at the bone particle interface and the newly formed bone was always in strict contact with the grafting material. Marrow stromal cells and blood vessels were found inside the marrow spaces. A vascular growth was also observed next to the newly formed bone (Fig. 6). No inflammatory cell or foreign body reaction was noted around the grafted particles.

**Test group**

In the test group, trabecular bone and residual biomaterial particles were observed. At low power magnification, no pre-existing mature bone was found in contact with the grafted biomaterial particles (Fig. 7). At

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**Fig. 1.** Summary of the histomorphometric data with percentage of bone, soft tissue and residual graft material depicted for the two surgical techniques considered both as scatter data and box and whiskers plot, in which the box line represents the lower quartile, median and upper quartile values, while the whisker lines include the rest of the data. Outliers were data with values beyond the ends of the whiskers.

**Fig. 2.** Flow diagram of the progress through the phases of the two experimental groups.

**Table 1.** Patient and implant characteristics in the two experimental groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Flap group (control)</th>
<th>Flapless group (test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>9 (53%)</td>
<td>5 (29%)</td>
</tr>
<tr>
<td>Female</td>
<td>8 (47%)</td>
<td>12 (71%)</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>47 (35–71) years</td>
<td>43.5 (21–67) years</td>
</tr>
<tr>
<td>Number of maxillary pre-molars</td>
<td>3 (17.6%)</td>
<td>3 (17.6%)</td>
</tr>
<tr>
<td>Number of mandibular pre-molars</td>
<td>2 (11.7%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Number of maxillary molars</td>
<td>2 (11.7%)</td>
<td>4 (23.5%)</td>
</tr>
<tr>
<td>Number of mandibular molars</td>
<td>10 (58.8%)</td>
<td>9 (52.9%)</td>
</tr>
<tr>
<td>Reason for extraction: tooth fracture</td>
<td>7 (41%)</td>
<td>7 (41%)</td>
</tr>
<tr>
<td>Reason for extraction: tooth decay</td>
<td>8 (47%)</td>
<td>8 (47%)</td>
</tr>
<tr>
<td>Reason for extraction: endodontic failure</td>
<td>1 (5.9%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Reason for extraction: perio disease</td>
<td>1 (5.9%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Total number of inserted implants</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Number of 5 mm diameter implants</td>
<td>9 (53%)</td>
<td>11 (64.7%)</td>
</tr>
<tr>
<td>Number of 4 mm diameter implants</td>
<td>8 (47%)</td>
<td>6 (35.3%)</td>
</tr>
<tr>
<td>Mean implant length (SD) (mm)</td>
<td>12.1 ± 0.99 mm</td>
<td>12.1 ± 0.77 mm</td>
</tr>
</tbody>
</table>
higher magnification, biomaterial residual particles of different sizes could be detected. Small and large particles were partially surrounded by newly formed bone. Few particles presented irregularly shaped margins, probably due to a resorption process. There were no gaps at the bone-particle interface and the new bone was in strict contact with the granules. Newly formed bone was characterized by large osteocytic lacunae and bridged up most part of the biomaterial particles (Fig. 8). Collagen fibres with a parallel orientation, as occurs in lamellar bone, can be observed in the remodelling areas of pre-existing bone (Fig. 9). The marrow spaces of the newly formed bone contained a small number of marrow stromal cells and a vascular network. Some blood vessels were also seen close to the grafted particles (Fig. 10). No inflammatory cells or foreign body reaction cells were seen on the biomaterial surface.

Nonparametric two-way analysis of variance showed no statistically significant influence, of gender on the histomorphometric results. This data were verified by nonparametric pair-comparison tests, showing no significant differences between the control and the test group, in terms of newly formed bone, marrow spaces and residual graft particles (Table 2). In detail, the analysis showed that the median of the new bone percentage in the control group was 21(3), while in the test group it was 21(2); the marrow spaces percentage in the control group was 61(8) while in the test group it was 59(8); and the percentage of residual grafted particles in the control group was 18(5), while in the test group it was 19(5).

Discussion

Tooth extraction generally results in a loss of bone volume and remodelling of soft tissues (Schropp et al. 2003; Araujo & Lindhe 2005; Barone et al. 2008, 2011; Cardaropoli & Cardaropoli 2008). The socket bone walls will be markedly reduced in height and width, the dimensional changes have been seen to be more pronounced at the buccal than at the palatal/lingual bone plates. The ridge preservation procedure allows to counteract the bone...
loss after tooth extraction [Barone et al. 2008, 2012, 2013], even though the bone modelling and remodelling after a tooth extraction is not completely avoidable [Fickl et al. 2008a]. The dimensional bone changes occurring after flap and flapless procedures for tooth extraction were reported to be very similar [Araujo & Lindhe 2009], even though contradictory outcomes were observed by other authors [Fickl et al. 2008b] who reported differences in the remodelling of the alveolar process after flap or flapless approaches.

The present randomized clinical trial was performed to evaluate clinical and histological differences between flap versus flapless tooth extraction and ridge preservation procedures. While the clinical findings were reported in a previous publication [Barone et al. 2014] and showed that the flapless technique could preserve the horizontal hard tissues dimension and increase the keratinized gingiva more successfully than the flapped technique, this study analyzed the histological differences of the augmented bone.

The collagen membrane was covered with an advanced flap in the control sites, whereas no flap was raised and the collagen membrane was left exposed in the test sites. The main finding of this study was that – 3 months after ridge preservation – no significant differences could be found in the histological and histomorphometrical analysis when comparing a flap with a flapless approach for ridge preservation.

Some authors [Christgau et al. 1997; Piatelli et al. 1997; Engler-Hamm et al. 2011] have demonstrated that the membrane exposure to the oral cavity might cause bacterial penetration and also lower the quantity and quality of bone augmentation [Simion et al. 1997; Oh et al. 2003]. On the contrary, some more recent studies have shown that the secondary wound healing with membrane exposure did not seem to jeopardise bone regeneration [Cardaropoli & Cardaropoli 2008] in the ridge preservation procedures. Moreover, it should be taken into consideration that flap advancement, which is used to obtain a soft tissue primary closure, has been associated with marginal recession at adjacent teeth, defective interdental papilla, loss of keratinized mucosa and a shift of the muco-gingival junction in the coronal direction. The histomorphometric data from the present randomized controlled study failed to show differences in the amount of newly formed bone and residual graft particles between the test and the control sites.

Therefore, the similarity between the flap and flapless approach supports the hypothesis that the secondary soft tissue closure and membrane exposure did not affect the quality of bone regeneration. Based on this study, collagen membrane exposure to the oral cavity can be recommended, thus allowing a better preservation of the keratinized mucosa on the facial aspect. This might facilitate hygiene therapy and the aesthetic outcome of implant-supported restoration as well as reduce the risk for bleeding on probing, gingival recession and plaque-induced peri-implantitis. Tissue regeneration, during the ridge preservation procedures, had similarly developed in the control (flap approach) as well as in the test groups (flapless approach). The collagenated porcine bone supported new hard tissue formation in the extraction sockets and the graft particles seemed to become integrated with the newly formed bone. Porcine bone has been shown to be osteoconductive, with no adverse reactions and no inflammatory infiltrate [Barone et al. 2005, 2008, 2011; Orsini et al. 2006; Nannmark & Sennery 2008; Figueiredo et al. 2010; Iezzi et al. 2012]. This biomaterial has been reported to be reabsorbable, with clear active resorption signs of the porcine bone particle [Nannmark & Sennery 2008] and presence of scalloped lacunae [Pagliani et al. 2012].

The histomorphometrical analysis in the present study revealed that 22.5% of the total bone area was filled with new bone in the sites where a flap was raised and 22.5% in the flapless sites. Some other authors using a different experimental model (beagle dogs) and a different graft biomaterial (anorganic bovine bone) found out that the newly formed bone occupied between 15.6% and 18.1% of the total tissue volume [Suaid et al. 2013]. In the present randomized controlled study, the percentage of the residual graft material was 18.2% of the total bone area in the control as well as in the test group. On the contrary, the use of a different biomaterial with different healing time showed 32.8% of residual graft particles [Degidi et al. 2012].

The slow resorption rate of some biomaterials could be considered a clinical advantage in that it helps in stabilizing the contour, contrary to what has been reported with autogenous bone where a high resorption rate of the original volume was measured [Sbornone et al. 2011].

In conclusion, no differences in the histologic and histomorphometric analysis were found in this randomized clinical trial when comparing the flap with flapless approach for ridge preservation procedure. This study supported the hypothesis of the non-detrimental effect of collagen membrane exposure on bone regeneration during the ridge preservation procedures with a flapless approach.

This was a short-term follow-up study and the definitive outcomes will be published after 5 years of evaluation of implant restorations.

**Table 2. Mean ± standard deviation and median (interquartile range) percentages for the two surgical procedures employed, and related P-value obtained by Wilcoxon rank sum test for procedures’ comparison. No statistical differences were found**

<table>
<thead>
<tr>
<th>Measure of dispersion</th>
<th>Newly formed bone (%)</th>
<th>Marrow spaces (%)</th>
<th>Residual graft material (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flapless (test group)</td>
<td>Mean ± SD</td>
<td>22.5 ± 4.3</td>
<td>59.4 ± 6.8</td>
</tr>
<tr>
<td></td>
<td>Median (iqr)</td>
<td>21 (2)</td>
<td>59 (8)</td>
</tr>
<tr>
<td>Flapped (control group)</td>
<td>Mean ± SD</td>
<td>22.5 ± 3.9</td>
<td>59.3 ± 7.5</td>
</tr>
<tr>
<td></td>
<td>Median (iqr)</td>
<td>21 (3)</td>
<td>61 (8)</td>
</tr>
<tr>
<td>Nonparametric two-way ANOVA P-value</td>
<td>0.8808</td>
<td></td>
<td>0.3341</td>
</tr>
<tr>
<td>Wilcoxon test P-value (test vs. control)</td>
<td>0.917</td>
<td>0.850</td>
<td>0.690</td>
</tr>
</tbody>
</table>

SD: standard deviation; iqr: interquartile range.

References


**Supporting Information**

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** CONSORT 2010 checklist of information to include when reporting a randomized trial.