Porcine-Derived Xenograft Combined with a Soft Cortical Membrane versus Extraction Alone for Implant Site Development: A Clinical Study in Humans

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ABSTRACT

Background: An adequate alveolar crest is essential for implant placement in terms of esthetics and function. The objective of this randomized clinical trial was to compare the preservation of the alveolar ridge dimensions following tooth extraction using porcine-derived xenograft combined with a membrane versus extraction-alone (EXT) sites.

Methods: Fifteen patients who required double extraction of contralateral premolars and delayed implant placement were randomly selected to receive both ridge-preservation procedure and EXT. The test sites (alveolar ridge preservation [ARP]) included 15 sockets treated using a corticocancellous porcine bone xenograft (OsteoBiol® Gen-Os; Tecnoss srl, Giaveno, Italy) associated with a soft cortical membrane (OsteoBiol® Lamina; Tecnoss srl), while the corresponding control sites (EXT) were left without grafting for EXT. Horizontal and vertical ridge dimensions were recorded at baseline and 6 months after extractions.

Results: After 6 months, the EXT sites showed a significantly greater reabsorption of the buccolingual/palatal dimension of the alveolar ridge (3.7 ± 1.2 mm) compared with the ARP sites (1.8 ± 1.3 mm). The mean vertical ridge height reduction in the control sockets was 3.1 ± 1.3 mm at the buccal sites and 2.4 ± 1.6 mm at the lingual sites compared with 0.6 ± 1.4 and 0.5 ± 1.3 mm, respectively, in the test sockets. The differences between test and control sockets were not significant for the mesial and distal measurements.

Conclusions: The placement of a porcine xenograft with a membrane in an extraction socket can be used to reduce the hard tissue reabsorption after tooth extraction compared with EXT.

KEY WORDS: alveolar ridge preservation, biomaterials, bone graft, bone reabsorption, dental implants, guided bone regeneration

Tooth extraction normally results in a significant reabsorption of the alveolar ridge with quantitative and qualitative changes of its profile.[1–3] The height and width reduction of the edentulous site is progressive and irreversible[4,5] and it can make difficult to obtain an excellent functional and esthetic restoration with implant placement. The healing process following tooth removal often resulted in a more pronounced reabsorption on the buccal aspect of the ridge than on its lingual/palatal counterpart, and it includes dimensional changes in size and shape.[6] This gradual remodeling generally leads to modifications in both horizontal and vertical ridge dimensions, about 40% height and 60% width loss.[4,5] The effect of this combined resorptive pattern is the relocation to a more palatal/lingual position of the reduced alveolar ridge, which is a condition that may preclude the ideal placement of implants in a favorable prosthetic and esthetic location. Because these

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The authors declare that they have no conflict of interest.

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DOI 10.1111/j.1708-8208.2011.00398.x

dimensions are so critical, it is important to recognize that the ARP after tooth extraction is essential to ensure the support of an adequate edentulous ridge profile. In order to preserve or improve the original ridge dimensions and to allow an optimum implant location following tooth extraction, several materials including autogenous, allogenous, xenogenic, and alloplastic bone substitutes and/or barrier membranes have been advocated for grafting of the postextraction socket and to ensure the formation of alveolar bone.[7–12] The general understanding is that an intrasocket graft should maintain the dimensions of the hard tissue walls preserving the ridge profile; therefore, different regenerative techniques have been used to prevent the alveolar bone reabsorption. The alveolar ridge-preservation (ARP) procedure has been tested in controlled studies with membrane alone[13,14] or in combination with an intrasocket graft,[15] showing positive results and reduced ridge alterations compared with extraction alone (EXT).[14–16] According to the guided bone regeneration (GBR) principle, the combination treatment was based on the hypothesis that while the membrane acts as a barrier against the migration of connective tissue into the coronal portion of the extraction site, the grafting material may be useful to prevent possible membrane collapse and to guide the osteogenic cell proliferation.[17]

Recently, new xenogenic grafting biomaterials have been widely used in the treatment of ridge defects, in maxillary sinus elevation procedures, and in extraction sockets.[15,18,19] Although these current clinical trends support the use of resorbable membranes, the specific combinations of various types of membranes and bone substitutes aimed to obtain optimal results in immediate socket preservation are still being defined.

The purpose of this randomized, controlled, clinical investigation was to compare through a split-mouth design the contemporary postextraction dimensional changes occurred in the same patient following EXT or extraction plus ridge-preservation procedure using an intrasocket porcine-derived xenograft (OsteoBiol® Gen-Os; Tecnoss srl, Giaveno, Italy) in combination with a soft cortical membrane (OsteoBiol® Lamina; Tecnoss srl).

MATERIALS AND METHODS

Study Population and Design

Fifteen patients were enrolled during the period between June 2008 and March 2010 and they participated in this randomized, controlled, clinical trial. The patients received detailed written information about the treatment and signed an informed consent form. The study was approved by the local ethical committee. All subjects included in this study were over 18 years of age requiring double extraction of contralateral premolars located in symmetrical quadrants of maxillary or mandibular arches and they requested an implant restoration. All extraction sites had adjacent teeth. In addition, patients were not admitted to the study or were excluded if any of the following exclusion criteria were present: (1) systemic diseases that affect the periodontium or that contraindicate surgical treatment; (2) long-term nonsteroidal anti-inflammatory drug therapy; (3) failure to sign an informed consent; (4) smoking; (5) pregnancy or lactating period; and (6) buccal or palatal/lingual bony wall fractured or completely lost during the extraction procedure.

In this split-mouth study, the test sites (ARP) included 15 sockets treated according to the GBR principle[17] for the ARP procedure with a corticocancellous porcine bone xenograft (OsteoBiol Gen-Os) associated with a soft cortical membrane (OsteoBiol Lamina), while the control sites (EXT) included 15 sockets left without grafting for EXT. The test and control sites were randomly selected using a coin toss.

The xenogenic bone substitute consisted of corticocancellous porcine bone (OsteoBiol Gen-Os) in the form of mixed granules with a diameter ranging from 250 to 1,000 μm; the product was always hydrated with sterile physiological solution before the application into the socket. The membrane was a soft cortical laminae (OsteoBiol Lamina; $35 \times 35 \times 1$ mm) with a cortical porcine bone origin and a plastic consistency. The membrane was shaped each time with sterile scissors to reach the desired size, hydrated in sterile physiological solution until the desired plasticity was acquired, and adapted to completely cover the grafting site.

Demographic information and medical and dental history were recorded at the enrolment visit. Each case was accurately evaluated by standardized periapical radiographs, clinical examination to evaluate the extraction sites, photographic documentation, and study models. A customized acrylic template was fabricated using the study model of the mouth of each patient to serve as a fixed reference guide for the vertical measurements during extraction and in the surgical reentry procedure (Figure 1). Before study initiation all subjects

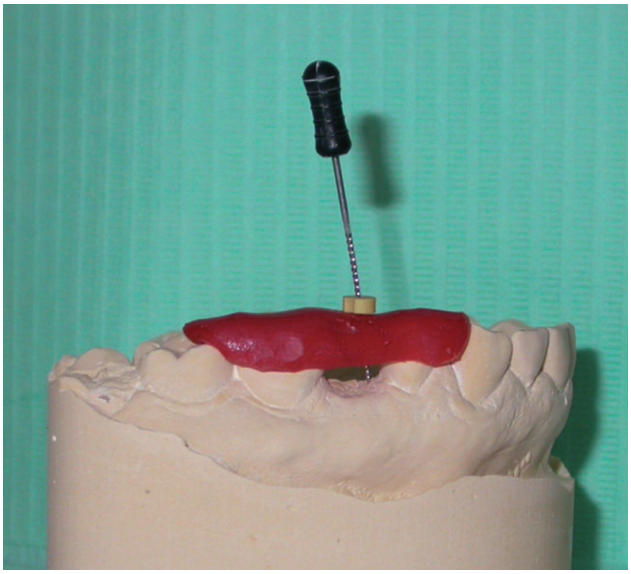

Figure 1 The customized acrylic template used as a fixed reference guide placed on a study model to show the intraoperative evaluation of vertical measurements.

underwent a rigorous oral hygiene regimen including any periodontal treatment when it was indicated.

The baseline data were collected before surgery and included probing pocket depth (PPD), gingival recession (REC), and bleeding on probing (BoP) measured at six sites (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual) adjacent to the extraction teeth by a single calibrated examiner using a standardized periodontal probe with a light probing force. The clinical indexes were recorded at the time of extractions and at the 6-month follow-up, immediately before the implant placement.

Surgical Treatment and Intrasurgical Measurements

Surgical procedures were performed under local anesthesia. By means of intracrevicular incisions minimally extended to the neighboring teeth, mucoperiosteal flaps were elevated to expose both the labial and palatal aspects of the involved teeth and the alveolar crest. No vertical releasing incisions were used in order to avoid any surgical trauma correlated to flap elevation and to decrease the reabsorption rate of the extraction socket.[20] An effort was made to preserve the interproximal papillae. The teeth were atraumatically extracted by means of forceps, attempting to preserve the surrounding bone. If necessary, the teeth were sectioned to preserve all socket walls. After the tooth removal, the granulation tissue was curetted and removed by means of bone curettes. Subsequently, the intraoperative measurements of ridge dimensions were taken in both test and control sockets using a standardized procedure. In each postextractive socket, a caliber was used to measure the postoperative buccolingual/palatal width of the alveolar ridge at the midpoint of the alveolar crest, while a total of four K-Files (Dentsply Maillefer K-Files) no. 40 in size and 31 mm in length, were used in order to register the vertical bone height at four sites (midbuccal, midlingual/palatal, mesial, and distal). To optimize the vertical measurements, a customized acrylic template was used as a fixed reference guide to introduce the K-Files and to reproduce their initial position at the reentry procedure. The stop ring of each K-File was blocked at the measurement length reached and the values obtained were evaluated by means of a caliber (Figure 2). Furthermore, these data were compared with the measurements registered with the same procedure after 6 months of healing. The application of this method allowed to express the difference data (delta) of horizontal and vertical measurements recorded between the extraction time and the reentry surgery after 6 months.

In the ARP sites, the porcine-derived xenograft (OsteoBiol Gen-Os) was placed into the extraction

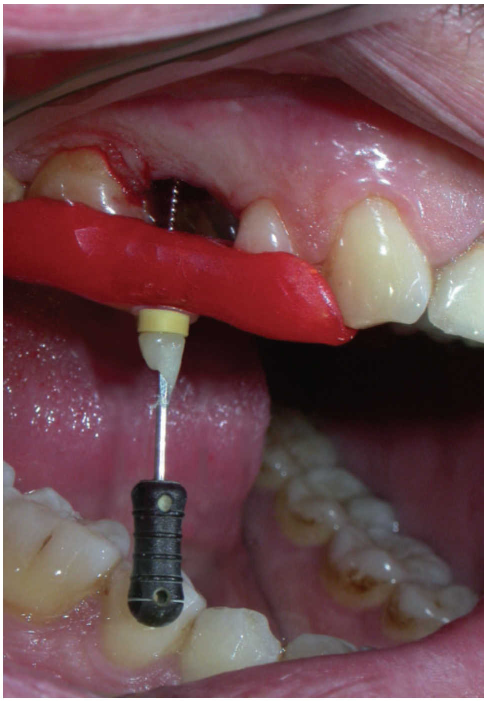

Figure 2 Clinical view of the acrylic template with a K-File in place immediately after tooth extraction. The stop ring was blocked and the data were compared with the measurements obtained at the reentry procedure.

socket in combination with a soft cortical membrane (OsteoBiol Lamina) hydrated in sterile saline and trimmed to completely cover the socket. The EXT sites were left without treatment. Mucoperiosteal flaps were always replaced and sutured with 4-0 silk to allow a free-tension primary closure. In case of anticipated membrane exposure the ARP sites healed by secondary intention. Every time patients were seen weekly until completion of soft tissue healing.

Postoperative Care

Medications prescribed to all subjects consisted of amoxicillin 500 mg every 8 hours for 6 days, nimesulide 100 mg every 12 hours for 3 days, and chlorhexidine, 0.12%, twice daily until soft tissue closure. Sutures were removed after 7 days, and the subjects were seen weekly during the healing phase. Any removable temporary prostheses were not worn for the first 2 to 3 weeks and subsequently were adjusted to relieve any pressure elicited to the wound area.

Reentry Procedure

At 6 months after the first surgical procedure, a reentry procedure was performed in order to repeat the initial clinical parameters, to collect dimensional ridge data, and to place implants. Mucoperiosteal flaps were elevated to allow access to the alveolar ridges of both involved sockets; the horizontal and vertical measurements were reevaluated. The buccolingual/palatal width of the alveolar ridge was reevaluated at the midpoint of the alveolar crest and the acrylic template was used to reintroduce four new K-Files at the same initial vertical positions. The stop rings were blocked at the new bone level to define the vertical bone height, the lengths obtained were measured with a caliber, and finally the difference data were evaluated. An osteotomy site was prepared with a surgical handpiece and the implants were inserted in both control and test sockets. Flaps were always replaced and sutured with 4-0 silk. Every time patients were seen weekly until completion of soft tissue healing and they received the same postoperative care as the initial surgery. All patients tolerated the surgical reentry procedure well, with no postoperative complications.

Statistical Analysis

A two-way analysis of variance was used to evaluate the statistical significance of the differences between test and control sites and changes from baseline to final examination. A value of p less than .05 was considered statistically significant.

RESULTS

Each of the 15 patients enrolled in this study (six males and nine females, aged 28–58 years) contributed two extraction sites to permit both ARP procedure and EXT. All surgeries were successfully carried out without any complications; the most frequent postsurgical signs and symptoms were pain and swelling.

Clinical Indexes

The results of the clinical indexes on adjacent teeth are given in Table 1. The baseline clinical parameters showed similar initial periodontal conditions in both test and control sites, without significant differences. All sites did not show at neighboring teeth a statistically significant reduction in PPD, BoP, and REC from the baseline to the final reevaluation. The statistical comparison of clinical indexes revealed no significant differences between ARP and EXT sites and all parameters remained relatively stable. Both treatments equally preserved the baseline level of the free gingival margin at the neighboring teeth after the extractions.

Horizontal Alveolar Ridge Width Changes

Mean and range values for horizontal ridge width in ARP and EXT sites are given in Table 2. At baseline, the ARP sites had a mean initial buccolingual/palatal width of 9.8 ± 1.2 mm that decreased to 8.0 ± 1.1 mm ($p < .05$) after 6 months of healing, whereas the EXT

TABLE 1 Clinical Indexes for EXT and ARP Sites (mm, mean ± SD)

Index/Sites	*N*	Initial	Final	Change
PPD				
EXT	15	2.3 ± 0.2	2.2 ± 0.3	0.1 ± 0.2
ARP	15	2.2 ± 0.2	2.1 ± 0.2	0.1 ± 0.2
BoP				
EXT	15	0.4 ± 0.2	0.3 ± 0.2	0.1 ± 0.2
ARP	15	0.3 ± 0.2	0.2 ± 0.1	0.1 ± 0.1
REC				
EXT	15	0.4 ± 0.3	0.3 ± 0.2	0.1 ± 0.2
ARP	15	0.4 ± 0.2	0.4 ± 0.2	0.1 ± 0.2

ARP, alveolar ridge preservation; BoP, bleeding on probing; EXT, extraction alone; PPD, probing pocket depth; REC, recession.

TABLE 2 Horizontal Ridge Width (mm; mean ± SD) for ARP and EXT Sites

Sites	Initial	Implant Placement	Change
ARP	9.8 ± 1.2	8.0 ± 1.1	−1.8 ± 1.3*
EXT	9.9 ± 1.0	6.2 ± 1.3	−3.7 ± 1.2*

*$p < .05$ between test and control sites.
ARP, alveolar ridge preservation; EXT, extraction alone.

sites ranged from an initial alveolar width of 9.9 ± 1.0 mm to 6.2 ± 1.3 mm ($p < .05$). Test and control sites showed a significant horizontal width reduction from baseline to final examination; however, a significantly greater horizontal reabsorption was observed at EXT sites (3.7 ± 1.2 mm) compared with ARP sites (1.8 ± 1.3 mm) ($p < .05$).

Vertical Ridge Height Changes

Mean and range values for vertical changes in ridge height related to the initial midbuccal, midpalatal/lingual, mesial, and distal socket walls are shown in Table 3.

In the test sites, the change in vertical dimension for midbuccal measurements was 0.6 ± 1.4 mm and in the control sites it was 3.1 ± 1.3 mm, whereas for midpalatal/lingual measurements the differences were 0.5 ± 1.3 and 2.4 ± 1.6 mm for test and control sites, respectively. A significantly greater vertical reabsorption for the midbuccal and midpalatal/lingual socket walls was observed at EXT sites compared with ARP sites ($p < .05$) (see Table 3). The midbuccal and midpalatal/lingual measurements remained relatively unchanged only in the ARP sites. The differences between ARP and EXT sites were not significant for the mesial and distal measurements.

TABLE 3 Vertical Ridge Height Changes (mm; mean ± SD) for ARP and EXT Sites

Location	ARP	EXT
Midbuccal	−0.6 ± 1.4	−3.1 ± 1.3*
Midlingual	−0.5 ± 1.3	−2.4 ± 1.6*
Mesial	−0.3 ± 0.8	−0.4 ± 1.2
Distal	−0.4 ± 0.8	−0.5 ± 1.0

*$p < .05$ between test and control sites.
ARP, alveolar ridge preservation; EXT, extraction alone.

DISCUSSION

The presence of tooth presents a crucial role in maintaining the dimensions of the alveolar process. During the alveolar wound healing, most changes occur in the first months and a reduction in the vertical ridge height with a horizontal reabsorption in the buccolingual direction must be expected.[6,15] Following tooth extraction alveolar dimensional changes can cause esthetic and functional problems; therefore, the preservation of the ridge is necessary to avoid the alveolar bone reduction and soft tissue collapse. The present randomized clinical study compared the ARP procedure (ARP sites) performed using corticocancellous porcine-derived bone (OsteoBiol Gen-Os) combined with a soft cortical membrane (OsteoBiol Lamina) to EXT treatment (EXT sites).

After 6 months of healing the implants were placed in all sockets, although some EXT sites had a slight buccal dehiscence that required bone regeneration procedures after implant insertion. The clinical evaluations showed significant differences between the two treatments.

The horizontal ridge width was similar for test and control sites at baseline: 9.9 ± 1.0 mm for EXT sites and 9.8 ± 1.2 mm for ARP sites. After 6 months, the mean width for the ARP sites was 8.0 ± 1.1 mm (a reduction of 18.3%) versus 6.2 ± 1.3 mm (a reduction of 37.3%) for the EXT sites, a difference of about 2 mm between treatments ($p < .05$) (see Table 2). Therefore, the use of porcine-derived xenograft as intrasocket graft combined with a membrane reduced significantly the bone loss; however, an alveolar ridge width of 8.0 mm is usually preferable for implant therapy, while the 6.2-mm width could lead more easily to a dehiscence. A buccolingual/palatal width reduction of the alveolar ridge was observed in all sites, confirming previous reports that describe a postextraction healing always characterized by osseous reabsorption especially in the horizontal plane of the residual alveolar ridge.[2,6] These changes may be limited but not avoided when grafting of the socket is used.[15,21]

After 6 months of healing, a significant vertical reduction was demonstrated in the EXT sites for midbuccal (−3.1 ± 1.3 mm) and midpalatal/lingual measurements (−2.4 ± 1.6 mm), whereas in the ARP sites the ridge height remained relatively unchanged (see Table 3). Moreover, the loss of vertical bone height was more pronounced at the buccal wall than at the palatal/lingual counterpart of the EXT sockets.

Furthermore, in the vertical ridge evaluation the statistical analysis did not show any significant difference for mesial and distal measurements between test and control sites and the values remained stable any time (see Table 3). This feature is not in agreement with other studies[14,15,22] probably due to the presence of teeth adjacent to the extraction sites.

In the 6-month interval following tooth extraction, significant horizontal and vertical reductions of the residual alveolar ridge were observed in this comparative study. However, evaluations of both horizontal and vertical measurements confirm previous studies[6,14,22,23] that demonstrated the greatest loss in the horizontal ridge width, which occurs along with a vertical reabsorption that takes place primarily at the expense of the buccal aspect of the socket. The ARP procedure compensates the loss of vertical ridge height, but it is only partially able to reduce the loss of horizontal ridge width. Likewise, it must be considered that the use of a xenograft in combination with a membrane reduces buccal reabsorption in a ridge crest, which naturally tends to a more palatal/lingual position following tooth extraction, thus decreasing possibility of dehiscence and favoring an ideal implant placement. This has the greatest significance in the esthetic zone, where the loss of hard tissue in addition to the loss of buccal soft tissue certainly has a significant visual impact.

The ARP procedure with an intrasocket graft may be adequate for posterior sites, while both an intra- and an additional extrasocket buccal overlay osseous graft may be preferred in the maxillary anterior region to preserve the original esthetic ridge contours.[24]

Some studies demonstrated less bone reabsorption in extraction sockets treated with ridge-preservation procedure when compared with the control sites,[14,15,22] while other investigators[16] showed that the loss of alveolar height and width occurred despite the use of an intra- and extrasocket graft for ridge preservation. It should be taken into consideration that other factors may be involved in bone reabsorption that take place during healing such as the adaptation to the lack of function at the extraction site and the tissue adjustments in the absence of teeth. Obviously, different soft tissue quantities and qualities, and gingival tissue biotypes, as well as different anatomical and dimensional characteristics of the hard tissue compartment together with other factors (e.g., smoking, reason for extraction, tooth location, etc.), may influence the final outcome of the postextractive socket.

In conclusion, the ARP approach using porcine bone in combination with a soft cortical membrane significantly limited the bone dimensional changes after tooth extraction when compared with EXT. Therefore, even if some EXT sites allowed an implant placement, the most predictable maintenance of the horizontal and vertical ridge dimensions was achieved only with the ARP procedure.

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