Vertical Ridge Augmentation Using a Flexible Heterologous Cortical Bone Sheet: Three-Year Follow-up

Maurizio Ludovichetti *
Danilo Alessio Di Stefano **
Stefano Pagnutti B.Sc. *
Enrico Vaccari B.Sc. PhD *
Francesco Saverio Ludovichetti *
Renato Celletti MD, DDS ***

*MD, DDS, Private Practice, Padova, Italy
**DDS, Private Practice, Milano, Italy
*Private Practice, Padova, Italy
*DDS, Private Practice, Padova, Italy
*Private Practice, Padova, Italy
***MD, DDS Professor and Director of Postgraduate Implantology and Aesthetics, Dental School, University G. d’Annunzio, Chieti, Italy. Private Practice, Rome, Italy

Corresponding author:
Prof. Renato Celletti
Via Cola di Rienzo 217, 00192 Rome, Italy
Email address: celletti@unich.it
Abstract

Rehabilitation of the atrophic alveolar ridge is often problematic. Bone-augmentation surgery may be hindered by the lack of surfaces from which blood vessels can spread during the initial stages of bone regeneration. If heterologous biomaterials are used as an alternative to autologous bone grafts, the standard delivery formats – blocks or granules – both have significant limitations. The present study was designed to evaluate the effectiveness of an alternative material -- flexible equine bone sheet -- for vertical ridge augmentation. Forty-nine implants were placed in 18 patients whose vertically atrophic maxillary or mandibular ridges were simultaneously augmented with flexible cortical bone sheets derived from equine femurs. After 4 months, the ridge volume for all patients was completely restored, all implants had successfully osseointegrated, and definitive prostheses were placed. These parameters remained unchanged throughout 3 years of follow-up.
Introduction

When the maxilla and/or mandible are highly atrophic, rehabilitation presents a difficult challenge. In such cases, performing bone regeneration is nearly always mandatory, even when minimal primary implant stability is achievable. However, the anatomy of the atrophic alveolar ridge often limits the extent to which regeneration is possible. This is particularly true if the atrophy has primarily occurred in the vertical dimension. The reduction in bone height limits the area of vital bone that can be in contact with the graft material. That area is the only one from which blood vessels can spread and invade the grafted volume, transporting in cells, growth factors, nutrients, and oxygen. 1

As a standard procedure, autologous bone blocks collected from the iliac crest, cranial bone, or other surgical sites are positioned as onlays.2,3 However, the use of such grafts increases the surgical and post-surgical risks and has a low rate of patient acceptance. Although autologous bone continues to be regarded as the gold standard for bone regeneration, the unpredictable supply and high morbidity associated with it has led surgeons to seek alternative bone substitutes, such as synthetic or natural biomaterials.4-6

Recently, flexible bone sheets derived from equine cancellous bone and treated with enzymatic deantigenation and partial demineralization have been successfully used for horizontal mandibular ridge augmentation. Horizontal bone width was completely recovered, and newly formed bone quantity and VEGF expression were comparable to control sites, while microvessel density was significantly increased.7 The enzymatic process used to treat these bone substitutes seems to preserve the osteoclastic remodeling properties of the donor bone and also preserve Type I bone collagen, whose presence maintains the mechanical properties of the donor bone.8-16
The present authors sought to assess whether similar flexible bone sheets derived from cortical, rather than cancellous, equine bone, could be helpful in increasing and maintaining over time the vertical volume of atrophic maxillary and mandibular ridges. Because the total remodeling time was unknown, a decision was made to use the cortical bone sheets for grafting only when the residual bone was sufficient to enable achievement of primary stability for the implants.

**Method and materials**

Eighteen patients, 10 women and 9 men, ages 45-75, were enrolled in the study. The bone at all implant-placement sites also had to consist of dense to thick porous cortical bone on the crest over porous trabecular bone (D2 on the Misch bone-density classification\(^{19}\)) or thinner porous cortical crest over fine trabecular bone (D3). Bone quantity at all sites needed to be sufficient for primary implant stability.

Excluded from participation were patients who were:
Smokers (more than 10 cigarettes/day), Pregnant, Alcohol or drug addicts, Diabetics (glycemia > 180), Collagen diseases or treated with cortisone, Under bisphosphonates treatment, Kidney disorders, Radiotherapy, Chemotherapy, Liver cirrhosis or chronic hepatitis, Malignant neoplasm, Neurological disorders, Incapable of maintaining good oral hygiene.

After all patients had provided informed consent, panoramic radiographs and computed tomography (CT) scans were taken preoperatively. Impressions were also made, models were mounted upon articulators, diagnostic waxing was performed, and implant positions were decided accordingly.

On the evening before surgery, all patients were treated with 1200 mg bacampicillin. This was continued every 12 hours for 5 days, and 550 mg sodium naproxen was prescribed twice a day for 3-4 days (first tablet 1 hour before surgery). Patients were sedated with 2
mg/ml diazepam (15-30 drops, according to the physical structure and weight of the patient) 30 minutes before surgery. Chlorhexidine gluconate mouth washings just before surgery and then 2 or 3 times a day for 7 days were prescribed. All anesthesia was performed with 4% articain and 1:100,000 epinephrine.

Regenerative surgery

After opening a full-thickness flap, bone tissue was cleaned and prepared with a 0.3 mm spherical bur. Implant osteotomies were created according to the manufacturer’s protocol for placing externally hexed Osseotite implants (3i/Implant Innovations).\textsuperscript{20,21}

A sterile template was placed on the ridge and shaped with sterile scissors. The template was then punched with a specillum over the osteotomies, and these holes were enlarged with sterile surgical scissors.

Each template was placed on a cortical bone sheet (Osteoplant Osteoxenon Cortical Sheets, Bioteck, Italy), and the sheets were shaped with sterile scissors, following the contours of the templates. Depending on the size of the grafting site, one of two sizes of the sheets was used (25x30x2.5 mm or 40x30x2.5 mm). A 1:1 mixture of cortical and cancellous bone granules (Osteoplant Osteoxenon Mix Granules, Bioteck, Italy - 0.5/1 mm) was also used. Both the sheets and granules are derived from equine femur sections.

The points of implant insertion were reproduced on each sheet by creating 1 mm holes with a pilot drill. The holes were then enlarged up to the diameter of the implants (4 or 5 mm) with a 4 mm bur, by rotating the bur laterally around the vertical axis of the osteotomy in order to make it slightly conic.

Both shaping and drilling were performed without hydrating the bone sheets, in order to avoid weakening them and increasing the risk of breakage. The sheets are never hydrated before being placed at the graft site; after placement they slowly hydrate with blood. For each grafting site, the first implant was positioned on the bone sheet and the implant was screwed.
into the bone sheet to a depth of 4-5 mm. If three implants were being placed, the first one was always put in the central position.

The bone sheet was tried in, and if any gaps existed between it and the recipient bone, bone granules were hydrated with sterile saline for 2-3 minutes at room temperature and used to fill the gaps.

The sheet was positioned over the grafting site, and the remaining hole/holes in the sheet were aligned with the other implant osteotomies. After screwing in the first implant completely, the remaining implants were inserted. Each implant hexagon was left protruding. Implant stability was then assessed by means of reverse torque testing (10NCm) and a standard percussion test.

The bone sheet was secured with implant cover screws. Cover screws 1 mm larger than the implants were purposely used to enhance the sheet's stability. No guided bone regeneration (GBR) membrane was necessary. Flaps were widely released and approximated using horizontal mattress sutures and single sutures.

Panoramic radiographs were taken every 15 days after implant placement, up to implant uncovering (at 4 months Implant uncovering and prosthetic rehabilitation)

Four months after the initial surgery, a wide mucoperiosteal flap was created to allow for adequate inspection of the site. Implant stability was again assessed by means of reverse torque testing (10 NCm), and a standard percussion test. Ten days after uncovering and suture removal, impressions were made.

Prosthetic rehabilitation was then carried out, using either total dentures supported by Ackermann bars or individual porcelain-fused-to-gold crowns. Patients were recalled for follow-up 1 week after placement of the definitive prosthesis, and then subsequently at 1 month, 6 months, and yearly for at least 3 years. At each follow-up visit, panoramic radiographs were taken, the restorations were visually inspected, and probing depths around
the implants were recorded. Implant success was assessed according to the criteria of Albrektsson and Zarb.\(^2^2\)

Figures 1-8 illustrate the treatment of one of the study patients.

Results

Forty-nine externally hexed Osseotite implants were placed in the 18 enrolled patients. Table 1 presents the diameters and lengths of the implants placed.

Table 1

<table>
<thead>
<tr>
<th>Implant length</th>
<th># Placed</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5x 4 mm</td>
<td>11</td>
</tr>
<tr>
<td>10.0x 4mm</td>
<td>30</td>
</tr>
<tr>
<td>11.5x 4 mm</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>49</td>
</tr>
</tbody>
</table>

Lengths and diameters of implants placed

All 49 implants successfully passed the reverse torque and percussion tests, both at the time of initial placement and at the second-stage surgery. Throughout the study period, all were judged to be successful, according to the Albrektsson and Zarb criteria. At all follow-up visits, the probing depths around each implant remained stable (at 2-3 mm).

At the time of second-stage surgery, no reduction of the graft volume was evident at any site throughout the study period. Radiographic examination confirmed these findings throughout the three years of follow-up.

Table 2 presents the details of the prosthetic rehabilitations delivered to the patients. After the 3-year follow-up, all prostheses were continuing to function successfully.
Table 2

<table>
<thead>
<tr>
<th>Type of prosthesis</th>
<th># of patients</th>
<th># of implants/patient</th>
<th>Implants/prosthetic type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary bar</td>
<td>5</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Mandibular bar</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Maxillary single crowns</td>
<td>4</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Mandibular single crowns (&gt;1 per patient)</td>
<td>4</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Mandibular single crowns</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>18</strong></td>
<td></td>
<td><strong>49</strong></td>
</tr>
</tbody>
</table>

Types of prostheses

Discussion

The standard approach to regenerating atrophic maxillae and mandibles involves the use of autologous bone, often collected from extra-oral sites. The balance between risks and advantages of this technique must be always carefully assessed and compared to the choice of using alternative biomaterials.

Up to now, the use of bone substitutes to regenerate atrophic ridges has been limited by the available formats: granules or rigid blocks. Both have technical disadvantages. Granules are difficult to stabilize, while blocks must be shaped, a time-consuming process that still often fails to guarantee full contact between the block and the recipient bone.

In this paper, a technique has been described for augmenting vertically atrophic ridges with flexible sheets derived from equine cortical bone. This technique has already been successfully applied to horizontal ridge augmentation, using similar, but cancellous, flexible bone sheets and titanium-reinforced ePTFE membranes. Use of the flexible sheeting in this onlay technique enables maximum contact between the donor and recipient bone. Moreover,
the cortical sheets protect any granules placed at the site, and no membranes are necessary, since the sheet itself is a barrier. This reduces both the duration and cost of surgery.

Antigens are eliminated from the cortical bone sheets by means of digestive enzymes that leave the bone-mineral component unaltered and preserve its osteoclastic remodeling properties. The sheets are made flexible by means of an electrolytic process (HCl 0.1 M, ΔV = 1.5V) to partially demineralize the femur sections. This process is possible since Type I bone collagen is left unaltered by the selective enzymatic process.

As the present study demonstrates, this approach allows for vertical augmentation and implant placement to be achieved in a one-step procedure that reconstructs the correct ridge profile and ensures successful implant outcomes.

No resorption of the graft material was observed throughout the 3-year follow-up period, a result that seldom can be achieved when grafting with autologous bone.

**Conclusion**

The use of flexible heterologous cortical bone sheets to augment atrophic maxillae and mandibles appears to effectively guarantee the success of prosthetic rehabilitation of such ridges over the short to medium term. Use of this material reduces patient costs and eliminates the need to harvest autologous material, with the attendant risks of morbidity. Additional clinically controlled studies including a larger number of patients are needed to confirm these results.

**Acknowledgments**

The authors would like to thank Biomet 3i (Palm Beach Gardens, FL USA) and Biomax SRL (Vicenza, Italy) for their help and contributions.

We would like to thank Jeannette De Wyze for help with editing of the manuscript.
References


**Figure Legends**

Figure 1 Pre-surgical panoramic radiograph of the 72-year-old female. Note severe mandibular atrophy, she had a bone graft from the iliac crest 5 years previously, and 2 implants had subsequently failed.

Figure 2 Granulated bone is placed to eliminate any gaps between the graft-recipient site and the bone sheet.

Figure 3 The first implant is screwed partway through the cortical sheet.

Figure 4 After placement of the remaining implants, oversized cover screws are used to secure the cortical sheet.

Figure 5 The second-stage surgery

Figure 6 Ackermann bar secured to the implants

Figure 7 Radiograph of the bar after placement.

Figure 8 The definitive prosthesis secured to the Ackerman bar