

Alveolar Cleft Repair in Adults Using Guided Bone Regeneration with Mineralized Allograft for Dental Implant Site Development: A Report of 2 Cases

Bach T. Le, DDS, MD, FICD^a, Ian Woo, MS, DDS, MD^b

^aClinical Associate Professor, Department of Oral & Maxillofacial Surgery, Los Angeles County/University of Southern California Medical Center, Los Angeles, California.

^bChief Resident, Department of Oral & Maxillofacial Surgery, Los Angeles County/University of Southern California Medical Center, Los Angeles, California.

Introduction

Patients with cleft lip and palate deformity require multiple surgical procedures over long periods by multiple specialists in various fields. Prosthetic rehabilitation of those patients with missing teeth is the goal in the final stages of treatment. Dental endosseous implants are quickly becoming the standard in patient with missing teeth. However, the success of dental implants is predicated on the presence of adequate alveolar bone volume in the precise anatomical position so that a prosthetically harmonious restoration can be supported. Currently, the standard treatment for alveolar cleft repair is grafting with autogenous bone from various sites, most commonly from the iliac crest.¹ Numerous other materials such as tibia², mandibular symphysis³, rib⁹ and cranium¹⁰ have been reported for use in grafting cleft defects but with less than ideal results also owing to significant resorption. Schultze-Mosgau et al reported an overall success rate of 88% in ICBG to alveolar cleft grafting with respect to bone resorption.⁶ A CT volumetric analysis by Tai et al showed a total average volume loss of 43.1% at approximately 1 year after the secondary alveolar cleft repair with ICBG.⁷ Feichtinger reported a mean bone loss in the first year after surgery (prior to eruption of the permanent canine) to

be as much as 49.5%.⁸ This resorption may prevent successful placement of endosseous implant without further grafting.

This article reports on the success of using mineralized human allograft to treat two adult patients with severe alveolar cleft defects. The repairs were accomplished using a guided bone regeneration technique, with subsequent successful placement of an endosseous implant. This is significant in that this was accomplished without the use of any autogenous bone. This opens up the possibility of avoiding harvesting iliac crest bone graft and its associated morbidities and expense with using only mineralized allograft and a GBR technique in an out-patient office setting.

Case 1

A 43 year old female Caucasian with congenital unilateral cleft palate presents for consultation regarding implant treatment for replacement of missing tooth # 10. The patient had previously been treated for cleft palate and lip closure. She had never had alveolar cleft repair. Tooth # 10 was recently extracted 3 months previously by her general dentist due to bone attachment loss and mobility. Her past medical history is not significant for any medical conditions that would preclude

bone grafting or implant treatment. She is not a tobacco user. Clinical exam revealed a large fistula on the buccal vestibule of # 10 areas extending into her right nostril. She does not complain of any fluid communication. Panorax and CT scan revealed a large alveolar cleft defect between tooth # 9 and 11 (Fig.1 & 2). Aside from her desire to have dental implant treatment to replace missing tooth #10, the patient had no other complaints or reasons for repair of the alveolar cleft.

Treatment and Follow-up

The decision was made to use mineralized human allograft (Puros, Zimmer, San Diego, California) for grafting this particular site because the patient did not want to undergo iliac crest bone harvest. The surgery was performed under IV sedation in an office-based setting. The patient was prepped and draped in the usual fashion for intraoral dentoalveolar surgery. She was given a preoperative rinse with 1% Chlorhexidine. The cleft defect was exposed completely with the creation of a nasal layer (Fig.3). This nasal layer was closed primarily using 3-0 chromic gut. A resorbable collagen membrane (Biomend, Zimmer, San Diego, California) was next placed to re-enforce the recreated nasal lining. Mineralized human allograft mixed with the

patient's blood was then placed into the cleft defect (Fig.4). The oral mucosal layer was closed with 3-0 chromic gut in a tension-free manner. Perioperative broad-spectrum antibiotics was used and continued for 1 week. The patient's post-operative course was uneventful without any evidence of oral-nasal fistula or infection.

Re-entry in 5 months revealed dense bone where the graft was placed (Fig.5). There was no evidence of clinically significant resorption. A 3 mm core specimen was taken of the predetermined implant site and sent for histologic evaluation. The specimen showed large sections of vital bone surrounding remaining particles of non-vital bone (Fig. 6). An endosteal implant (3I, Biomet, Florida) was placed with an insertional torque of 35 N in a two-stage protocol using a surgical guide (Fig.7). The implant was uncovered after 3 months and noted to have good osseointegration with an ISQ measurement of 78. The patient was referred back to her general dentist for final prosthetic restoration. At 12 months after final crown cementation, periodontal health was good with healthy gingival and normal probing depth and a peri-apical x-ray of the implant revealed stable crestal bone position (Fig.8 & 9). The alveolar bone height and width remained stable.

Case 2

22 year old healthy Hispanic female with congenital cleft lip and palate presents at the oral and maxillofacial surgery clinic at USC Medical Center seeking implant treatment for missing tooth # 10 (Fig. 10). She has had multiple previous surgeries including palatoplasty and lip repair and subsequent alveolar cleft repair with iliac crest bone grafting. She reports that alveolar cleft graft was performed at the age of 11. Panorex radiograph and computed tomography of her maxilla revealed a large alveolar defect at site the #10 which was unsuitable for implant placement (Fig. 11). A small bridge of bone measuring approximately 1 mm existed between the major and minor alveolar segments (Fig. 12). No fistula was noted.

Treatment and Follow-up

Mineralized human allograft (Puros, Zimmer, San Diego, California) mixed with Infuse Bone Graft material (Medtronic) was used for grafting this particular site (Fig. 13). The surgery was performed under IV sedation in an office-based setting. The patient was prepped and draped in the usual fashion for intraoral dentoalveolar surgery. She was given a preoperative rinse with 1% Chlorhexidine. The cleft defect was exposed completely. Mineralized human allograft mixed

with multiple small 2 x 2 mm strips of BMP-2 soaked gelfoam (Infuse Bone Graft) and the patient's blood was then placed into the cleft defect (Fig. 14). A resorbable collagen membrane (Biomend, Zimmer, San Diego, California) was placed over the graft material and the oral mucosal was closed with 3-0 chromic gut in a tension-free manner. Peri-operative broad-spectrum antibiotics was used and continued for 1 week. The patient's post-operative course was uneventful without any evidence of oral-nasal fistula or infection.

Re-entry in 5 months revealed dense bone where the graft was placed (Figure 15). There was a small amount of resorption at the alveolar ridge noted, but this did not affect the placement of a 3.25 mm x 10 mm size implant (Tapered Screw Vent, Zimmer Dental, San Diego, California) with an insertional torque of 45 N (Fig. 16). A 3 mm core specimen was taken of the predetermined implant site and sent for histologic evaluation. The implant was placed in a one-stage protocol using a surgical guide. The implant was stable and integrated at 3 months and the patient was referred back to her general dentist for prosthetic restoration. At 4 months after final crown cementation, periodontal health was good with healthy gingival and normal probing depth and a peri-apical x-ray of the implant site revealed stable crestal bone position. The alveolar bone height and width remained stable.

Discussion

Currently, the standard treatment for alveolar cleft at most institutions is grafting with autogenous bone from the iliac crest. The goals of surgery are to provide a stable foundation for which the partially formed canine can erupt, provide a stable bridge between the major and minor segments, repair any existing oral-nasal fistulous tract, and to improve the projection of the nasal base. A major objective of treatment is to provide an adequate foundation for which a dental implant can be placed so that the patient can be dentally rehabilitated. Although no literature exists on the number of alveolar cleft repairs which result in inadequate bone volume for implant placement, it is suspected that this number may be very high. The second patient had previous grafting using iliac crest bone graft at a younger age and there appeared to be almost complete resorption of the graft at the time of our treatment. Based on the first author's experience, most alveolar cleft repairs using iliac crest bone graft require secondary grafting prior to implant placement. Resorption rates of iliac crest bone graft of up to 50% in the first year have been reported.^{7,8} Although the bone graft may have been successful in bridging the defect between the major and minor segments, the bone volume is

often inadequate for implant placement and requires additional grafting before an implant can be placed.

In our first patient, the primary objective was for dental rehabilitation. The patient's primary chief complaint was to be able to have a tooth at site # 10. Although a fistula was present upon probing, she did not have any negative subjective complaints. The rationale for using mineralized allograft was based on avoiding the morbidity and costs associated with iliac crest bone harvesting. Due to a lack of financial resources, this patient had opted not to have iliac crest bone graft for repair of her cleft defect. The use of mineralized allograft has never been reported for use in alveolar cleft repair but has been reported for use in dental implant reconstruction.^{12,13,14} Le and Burstein reported the successful use of using mineralized allograft for the reconstruction of 10 consecutive patients with severely atrophic maxilla for implant placement.¹² Recently, Le and Burstein reported on using mineralized allograft as a particulate onlay graft to augment atrophic alveolar ridge for single implant site development.¹⁵ Froum et al in a split mouth study comparing Xenograft (Biooss) with mineralized allograft for maxillary sinus lifts reported an average viable cell count of 29% for allograft and 13% for xenograft.¹⁴

Minocetti reported on the successful use of mineralized allograft for grafting of extraction socket defects prior to implant placement.¹³

The patient was not interested in a hospital-based operation and a prolonged period of recovery potentially affecting her ambulatory status. With our recent success of using mineralized allograft in the reconstruction of atrophic maxilla for implant placement and single implant site reconstruction, we postulated that mineralized allograft could achieve similar results as autogenous bone graft without the associated disadvantages. In these two adult patients, using mineralized allograft in an office-base setting eliminated many of the obvious disadvantages of using iliac crest bone. No additional grafting was required prior to implant placement and both patients were able to have successful prosthetic rehabilitation of the implants with a healthy periodontium.

In the second patient, BMP-2 was added to mineralized allograft. Bone morphogenetic protein (BMP) is a generic name for certain proteins extracted from bone matrix that may have osteoinductive properties. Fiorellini et al showed that BMP-2 impregnated in a collagen sponge had a striking effect on de novo osseous formation in extraction defects prior to the placement of dental implants.¹⁶ Herford et al has showed that alveolar cleft repair can be successfully achieved using

only Gelfoam impregnated with BMP.¹¹ The perceived disadvantage of using this technique is that a collagen sponge may not provide enough structural support for bone formation in large three dimensional defects. It is not clear how many of these alveolar cleft patients required additional grafting. Also not clear is whether implants were successfully placed in all these patients. Infuse Bone Graft (BMB-2) was added to the allograft in the second patient to theoretically act as an osteoinductive agent, while the allograft provided structural support for bone formation in the cleft defect.

This report of two cases demonstrates that grafting alveolar cleft defects using only mineralized allograft or mineralized allograft mixed with BMP can be successful. Of interest is that in our first patient, grafting was achieved with allograft material alone without BMP. It provided a solid bone foundation of good quality for dental implant placement. The amount of bone resorption was also found to be minimal and there was no need for secondary grafting. The histological analysis of the core specimen showed osseous components comparable to that of native bone. Further research and clinical trials will be needed to elucidate the long-term stability of this procedure in adults as well as children, clarify the effects of using mineralized allograft as an osseo-conductive agent to hold the space for the osseo-

inductive properties of BMP, and whether mineralized allograft alone is sufficient to predictably graft these defects. These two cases suggest that using mineralized allograft for repair of adult alveolar cleft defects provides a feasible, more economical and less surgically-invasive option for patients seeking dental implant treatment and provides bone of adequate quality for osseointegration.

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Figure 1. CT scan of the cleft defect between tooth # 9 and 11.

Figure 2. 3D reconstruction view of the alveolar cleft defect.

Figure 3. The cleft defect exposed.

Figure 4. Mineralized human allograft mixed with the patient's blood was placed into the cleft defect.

Figure 5. Dense bone revealed at grafted site during re-entry at 5-month in patient 1.

Figure 6. Histological evaluation of bone core taken at time of implant placement (5 months after bone graft). It shows large sections of vital bone surrounding remaining particles of non-vital bone.

Figure 7. Endosteal implant placed with Puros overlay on buccal ridge.

Figure 8. Peri-apical x-ray of the implant revealed stable crestal bone position.

Figure 9. Clinical photographs of the implant at 12-month followup.

Figure 10. Clinical photographs of the alveolar cleft defect in patient 2.

Figure 11. CT scan of the cleft defect.

Figure 12. Small bridge of bone between the major and minor alveolar segments.

Figure 13. Mineralized human allograft (Puros) mixed with rhBMP-2 (Infuse).

Figure 14. Puros mixed with multiple small 2 x 2 mm strips of BMP-2 soaked gelfoam placed into the cleft defect

Figure 15. Dense bone revealed at grafted site during re-entry at 5-month in patient 2.

Figure 16. Placement of the implant at 5-month re-entry.