Fresh-Frozen Bone Allografts in Maxillary Alveolar Augmentation: Analysis of Complications, Adverse Outcomes, and Implant Survival

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Background: Success of any bone augmentation procedure is dependent on several factors. Because complications occur in some cases, the aims of this study are to analyze adverse events associated with placement of fresh-frozen bone allografts (FFBAs) during alveolar ridge augmentation and to assess 1-year survival of dental implants placed in reconstructed sites.

Methods: Fifty-eight consecutive patients (15 males and 43 females, aged 38 to 76 years; mean age: 58 ± 9.2 years) requiring maxillary bone reconstruction prior to implant placement were enrolled in this study. A total of 268 implants was subsequently placed in sites reconstructed with FFBAs. There were 22 posterior grafted sites, 19 anterior, and 17 full-arch sites. After a 4- to 6-month integration period, all patients received an implant-supported fixed prostheses. Complications occurring during treatment and the 12-month follow-up period were recorded and evaluated.

Results: Thirteen of 58 (22.41%) patients experienced some kind of complication in the receptor site. Infection occurred in six (10.34%) individuals, dehiscence in five (8.62%), and mucosal perforation in seven (12.07%). Adverse outcomes categorized as partial and total graft loss occurred in four (6.90%) and three (5.17%) patients, respectively. Implant failure rate was 16 (5.97%) of the 268 fixtures placed in 12 (20.70%) of 58 patients.

Conclusions: Infection and suture dehiscence are significantly correlated with graft loss in a maxillary FFBA augmentation. Patients with full-arch grafting reconstructions lost significantly more implants. Early diagnosis and prompt management of adverse events seem to be of great importance in prevention of total graft loss. *J Periodontol 2016;87:1261-1267.*

KEY WORDS

Allografts; alveolar ridge augmentation; bone transplantation; graft survival; postoperative complications; wound healing.

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Osseous allografts have been widely used as a bone substitute during dental implant surgery. Depending on processing methods used, grafting materials with distinct characteristics have been developed.[1-5] The most common are: 1) freeze-dried bone allograft (FDBA); 2) demineralized FDBA; and 3) fresh-frozen bone allograft (FFBA). Each form has a precise clinical application and all are well-documented in the literature.[2,6,7]

FFBA is a widely used substitute for autologous bone in large reconstructions when block grafts are indicated.[7-9] Numerous studies have shown both clinical evidence of alveolar ridge augmentation and histologic evidence of bone regeneration with use of this material.[7,9-15] While the osseous autograft has distinctive properties that make it the gold standard among grafting materials,[16] FFBA is available in unlimited supply and does not require a secondary harvesting site. Elimination of potential for secondary complications at a donor site represents a major benefit of its application.[17-19]

Success of any bone augmentation procedure depends on factors ranging from accurate preoperative planning to a complete patient health evaluation as well as a thorough preoperative clinical assessment and proper surgical technique.

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In the case of block reconstructions, special attention must be paid to proper shaping and fixation of grafts. Tension-free closure of flaps is imperative as is an appropriate post-surgical medication therapy and rigorous follow-up. A well-adapted provisional prosthesis (fixed or removable) with no excessive occlusal pressure is also of paramount importance for ideal graft maturation.[20-23]

Studies evaluating short-term receptor site outcomes of autografts and FDBA block ridge augmentation reported relatively low complication rates;[7,8,11,12,20,21,24-26] however, complications did occur. Most often, loss of soft tissue integrity at the receptor site led to loss of graft material, and contamination during the surgical procedure or inability of the patient to keep the surgical site clean led to local infection.[12,20,23,27-29] However, these complications did not necessarily lead to total failure of the grafting procedure.[20,27]

To the best of the authors' knowledge, no studies found in the literature assess prevalence of complications, defined as: 1) infection; 2) dehiscence or mucosal perforation; or 3) adverse outcomes, defined as partial or total graft loss or implant failure, after use of FFBA for maxillary augmentation. Aims of the present study are to analyze: 1) complications and subsequent adverse outcomes associated with use of FFBA in maxillary alveolar ridge onlay block graft augmentation and 2) 1-year survival of dental implants placed in these reconstructed sites.

MATERIALS AND METHODS

Fifty-eight consecutive patients (15 males and 43 females, aged 38 to 76 years; mean age: 58 ± 9.2 years) requiring maxillary bone block reconstruction prior to implant placement at the Department of Implantology at the Pontifical Catholic University in Rio de Janeiro, Rio de Janeiro, Brazil, were enrolled in this study from July 2010 to June 2014. Exclusion criteria were: 1) smoking; 2) systemic diseases; 3) patients currently or previously taking oral or intravenous bisphosphonates; and 4) patients irradiated in the past 5 years. A total of 268 implants was placed in reconstructed sites. Grafted sites were classified as posterior (n = 22), anterior (n = 19), and full-arch (n = 17). The study protocol was approved by the Ethics Committee of Pedro Ernesto University Hospital, Rio de Janeiro, Brazil (CEP-HUPE, 2762/2010). Eligible patients gave written informed consent prior to participation.

A diagnosis of severe alveolar ridge atrophy and indication for use of an FFBA block for bone reconstruction were determined by cone-beam computed tomography (CT).¶ The surgical plan and number and size of bone blocks were determined using linear measurements on CT scans. FFBAs were provided by the Musculoskeletal Tissue Bank of the National Institute of Traumatology and Orthopedics (INTO, Rio de Janeiro, Brazil). Grafts used were fragments of corticocancellous proximal tibia (n = 53), iliac crest (n = 3), and femur (n = 2).

Surgical Protocol

Prior to surgery, bone grafts were thawed in sterile saline for 30 minutes. Patients were asked to rinse with chlorhexidine (CHX) mouthwash 0.2% for 60 seconds. Antisepsis of the skin was accomplished using iodopovidone 10%. Local anesthetic and lidocaine 2% with epinephrine 1:100,000 were administered and a crestal incision placed over the length of the edentulous segment. Mesial and distal releasing incisions were also placed to improve surgical access, and a full-thickness mucoperiosteal flap was elevated to expose the recipient site. The alveolar ridge was perforated to increase vascularization of the grafts from recipient bone marrow. Allografts were sculpted to precisely fit defects and were secured with two titanium screws to ensure mechanical stability. No adjunctive particulate graft was used. The flap was undermined with a periosteal incision to release tension, and primary wound closure was achieved with 4-0 silk sutures. Patients were medicated with 500 mg azithromycin once daily for 3 days as an antibiotic therapy, and non-steroidal anti-inflammatory drugs (NSAIDs) were recommended every 6 hours as needed for postoperative pain control. CHX 0.12% mouthrinse was prescribed twice a day for 15 days as a topic antiseptic. Sutures were removed 7 to 14 days after surgery. Clinical appointments at 7, 14, 30, 60, 90, and 120 days post-surgery were scheduled to evaluate any possible complications.

After a healing period of 4 to 6 months, a new CT scan was taken to evaluate amount of bone augmentation and select the number and size of implants to be placed.

The implant placement procedures followed the same routine: locoregional anesthesia with lidocaine 2% and epinephrine 1:100,000 were used, and a full-thickness mucoperiosteal flap was elevated to expose grafted areas. Screws used to fix blocks were removed. Implants were placed using implant system drills according to specifications of the manufacturer. Flaps were repositioned and closed with 4-0 silk sutures. Patients were medicated with azithromycin, NSAIDs, and CHX 0.12% mouthrinse following the same protocol used for grafting surgeries. Sutures were removed 7 days after the procedure.

Implants were left submerged during healing. Second-stage surgery and initiation of prosthetic therapy occurred ≈4 months after fixture placement. All patients received implant-supported fixed prostheses.

¶ I-Cat Image Sciences International, Hatfield, PA.

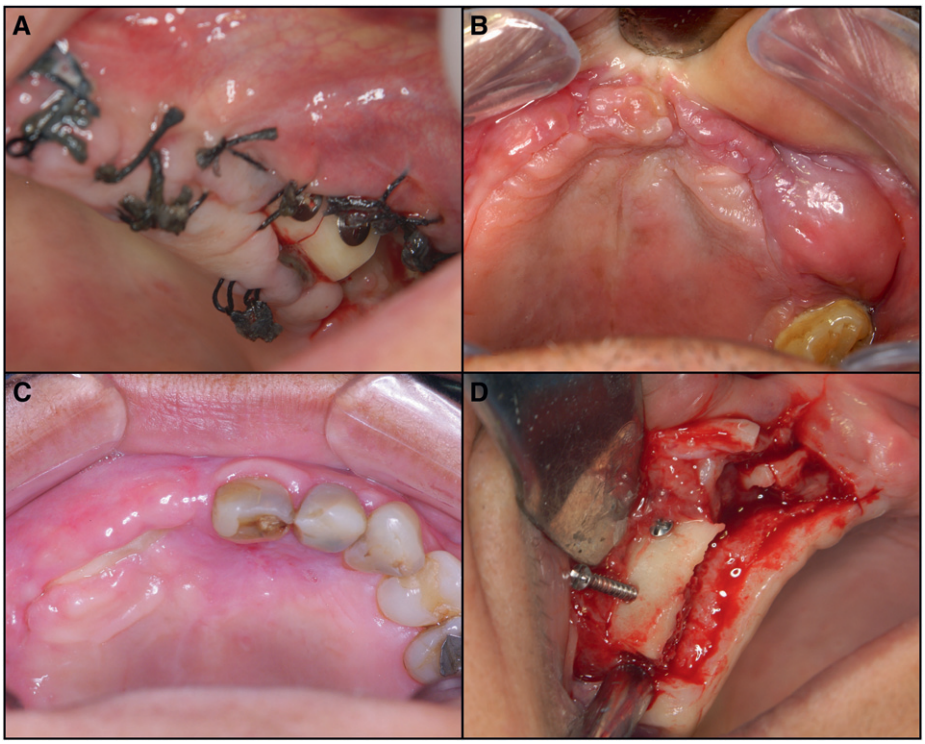

Figure 1.
A) *Suture dehiscence.* ***B)*** *Infection.* ***C)*** *Mucosal perforation.* ***D)*** *Total graft loss.*

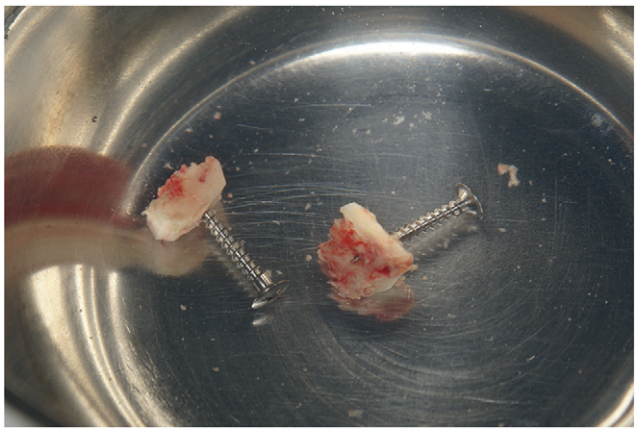

Figure 2.
Sample of removed material sent for histologic analysis.

The total follow-up period after loading implants was 12 months.

Complications and adverse outcomes were recorded and assessed. Complications observed were: 1) suture dehiscence; 2) clinical signs of infection; and 3) mucosal perforation (Figs. 1A through 1C). Mucosal perforation was characterized as a soft tissue loss of integrity exposing any part of the graft after incision line complete healing, differing from the dehiscence parameter. Adverse outcomes were partial or total graft loss (Fig. 1D) and implant failure. In cases where a partial or total graft loss occurred, a sample of removed material was sent for histologic analysis according to standard protocol (Fig. 2). Slides were examined and results were reported descriptively but were not used in any further assessments.

Evidence of a relationship between occurrence of a complication and an adverse outcome was sought. Statistical independent variables were infection, dehiscence, and mucosal perforation, while dependent variables were partial graft loss, total graft loss, and implant failure.

Likewise, an assessment was made as to whether there was a relationship between location of grafting site in the arch and occurrence of a complication or adverse outcome. Statistical independent variables in this instance were grafting sites, which were categorized as anterior, posterior, and full-arch, while dependent variables were complications and adverse outcomes that occurred. The Fisher exact test was used to explore these two relationships. Hypotheses were: 1) there was no association among variables (H_0) or 2) there was an association between variables (H_A). Consequently, if test results are significant, it could be said there is a statistical relationship among dependent and independent variables.

RESULTS

Fifty-eight patients with 92 atrophic alveolar ridges were treated in the study. Distribution of complications and adverse outcomes were analyzed using the individual as a unit. Complications recorded were: 1) infection in six (10.34%) patients; 2) dehiscence in five (8.62%); and 3) mucosal perforation in seven (12.07%). Adverse outcomes as partial and total graft loss occurred in four (6.90%) and three (5.17%) patients, respectively. Sixteen (5.97%) of 268 implants, placed in 12 of 58 (20.70%) patients, failed.

Infected sites showed significant statistical correlation with partial and total graft loss compared with sites without infection. Suture dehiscence also showed a statistically significant correlation with partial and total graft loss. Only one partial graft loss and one total graft loss were recorded in sites demonstrating mucosal

Table 1.

Prevalence of Adverse Outcomes According to Complications

			Partial Graft Loss			Total Graft Loss			Implant Failure (individual as unit)		
Complication	Occurrence	n (%)	Yes (%)	No (%)	*P* Value	Yes (%)	No (%)	*P* Value	Yes (%)	No (%)	*P* Value
Infection	Yes	6 (10.34)	2 (3.44)	4 (6.89)	0.04*	3 (5.17)	3 (5.17)	<0.001*	4 (6.89)	2 (3.44)	0.59
	No	52 (89.66)	2 (3.44)	50 (86.20)		0 (0)	52 (89.65)		42 (72.41)	10 (17.24)	
Dehiscence	Yes	5 (8.62)	2 (3.44)	3 (5.17)	0.03*	2 (3.44)	3 (5.17)	0.02*	3 (5.17)	2 (3.44)	0.27
	No	53 (91.38)	2 (3.44)	51 (87.93)		1 (1.72)	52 (89.65)		43 (74.13)	10 (17.24)	
Mucosal perforation	Yes	7 (12.07)	1 (1.72)	6 (10.34)	0.41	1 (1.72)	6 (10.34)	0.32	6 (10.34)	1 (1.72)	>0.99
	No	51 (87.93)	3 (5.17)	48 (82.75)		2 (3.44)	49 (84.48)		40 (68.96)	11 (18.96)	
Total		58 (100.00)	4 (6.90)	54 (93.10)		3 (5.17)	55 (94.82)		46 (79.31)	12 (20.68)	

* $P < 0.05$.

Table 2.

Prevalence of Adverse Outcomes (partial graft loss, total graft loss, and implant failure) According to Grafted Sites

		Partial Graft Loss		Total Graft Loss		Implant Failure (individual as unit)	
Site	n (%)	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
Anterior	19 (32.75)	2 (3.44)	17 (29.31)	0 (0)	19 (32.75)	4 (6.89)	15 (25.86)
Posterior	22 (37.93)	1 (1.72)	21 (36.20)	2 (3.44)	20 (34.48)	1 (1.72)	21 (36.20)
Full-arch	17 (29.31)	1 (1.72)	16 (27.58)	1 (1.72)	16 (27.58)	7 (12.06)	10 (17.24)
Total	58 (100.00)	4 (6.89)	54 (93.10)	3 (5.17)	55 (94.82)	46 (79.31)	12 (20.68)
Significance		0.82		0.62		0.02*	

* $P < 0.05$.

perforation. This was not statistically significant when compared with sites without mucosal perforation (Table 1).

Association between presence of a complication and implant failure was not statistically significant, suggesting it is not possible to determine a direct relationship among infection and implant failure, dehiscence, and implant failure, or mucosal perforation and implant failure (Table 1).

Results show (Table 2) implant failure was more prevalent in full-arch grafted patients than in anterior or posterior ridge reconstructions. Twelve of 58 (20.68%) patients lost at least one implant and seven (12.06%) of these had received full-arch bone grafting. It was not possible to find a correlation between prevalence of complications and the reconstructed sites (Table 3).

Histologic samples from fragments removed in partial and total graft loss were merely descriptive, showing severe inflammatory infiltrate as expected. In samples where bone loss occurred after initial graft incorporation, acute inflammatory cells were visible close to newly-formed bone (Fig. 3).

DISCUSSION

Currently, several different biomaterials and surgical techniques are available to augment extremely resorbed alveolar ridges.[25,30] Autologous onlay block grafting is one of the methods most often used to reconstruct large defects.[20,31] In contrast to particulate grafts, block grafts are self-contained and can provide space while maintaining stability, and when properly adapted, require no additional materials.[31] Onlay grafts have been evaluated in a large number of publications and are considered a reliable technique.[7,27,32]

This study used FFBA blocks for ridge augmentation. While there are reports in the literature of

Table 3.

Prevalence of Complication (infection, dehiscence, and mucosal perforation) According to Grafted Sites

		Infection		Dehiscence		Mucosal Perforation	
Site	n (%)	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
Anterior	19 (32.75)	1 (1.72)	18 (31.03)	0 (0)	19 (32.75)	1 (1.72)	18 (31.03)
Posterior	22 (37.93)	2 (3.44)	20 (34.48)	3 (5.17)	19 (32.75)	2 (3.44)	20 (34.48)
Full-arch	17 (29.31)	3 (5.17)	14 (24.13)	2 (3.44)	15 (25.86)	4 (6.89)	13 (22.41)
Total	58 (100.00)	6 (10.34)	52 (89.65)	5 (8.62)	53 (91.38)	7 (12.07)	51 (87.93)
Significance		0.56		0.25		0.26	

transmission of infectious diseases as a result of contaminated bone allograft transplantation,[33,34] modern processing techniques have proven to be extremely effective in preventing transmission of disease.[35-37] Because risk of a graft being infected with human immunodeficiency virus is less than 1 in 8 million,[35,36] FFBA grafts are currently considered safe from both an immunologic and virologic standpoint.[38,39]

In the current study, 13 of 58 (22.41%) patients experienced at least one complication assessed in the receptor site during follow-up. In five of the 13 cases, local infection was combined with another adverse event. Although, to the best of the authors' knowledge, reports specifically evaluating FFBA are not found in the dental literature, these data corroborate studies evaluating complications using all types of allogenic and autogenous block grafts.[27,40]

Proper care of a graft that has become exposed can prevent development of further complications. To avoid additional soft tissue damage and further wound margin retraction, debridement is performed without raising a flap. Using a bur under abundant irrigation, superficial layers of necrotic bone are removed until the vital bleeding part of the graft is exposed. The graft is concurrently recontoured to allow surrounding soft tissue to migrate over it. In the experience of the current authors, and as reported by Chaushu et al.,[27] if an exposed but decontaminated allograft is recessed within the confines of the wound edges, it will take 4 to 6 weeks for soft tissue to heal over it. An oral broad-spectrum antibiotic (amoxicillin or azithromycin) is prescribed for 5 to 7 days. The patient's oral hygiene is carefully monitored in an effort to preserve the graft, and cleaning of the wound is accomplished with topical CHX 2%.

Results suggested infection and dehiscence of the incision line could be directly related to both partial and total graft loss. As stated in other studies,[12,20,21,27,41] open flap surgery to correct these problems was avoided when possible and interceptive therapy consisted of: 1) debridement; 2) antibiotic therapy; 3) local CHX application; and 4) conscientious oral hygiene. It must be emphasized that early diagnosis and prompt treatment in cases of infection and suture dehiscence is of paramount importance to prevent total graft loss.

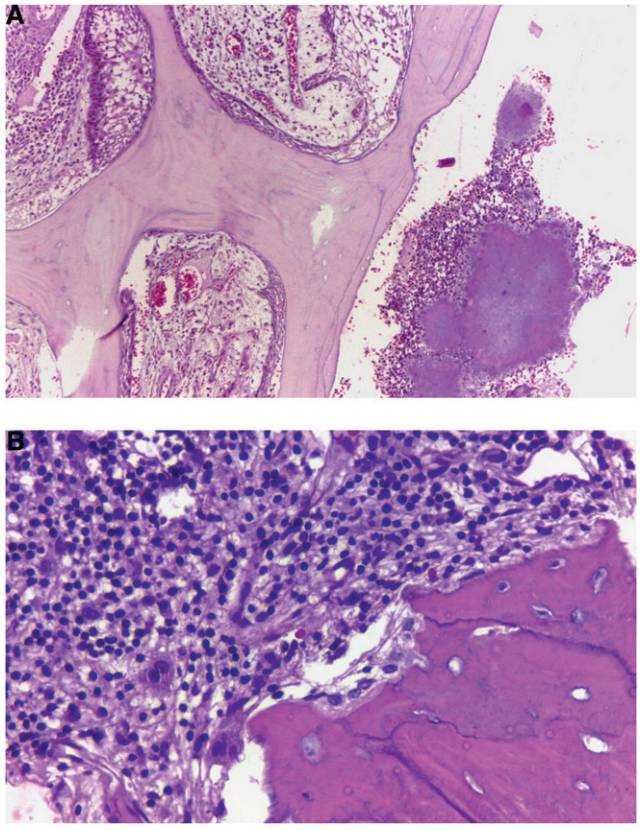

Figure 3.
Histologic samples removed after the initial graft incorporation showing acute inflammatory cells close to newly formed bone. (Hematoxylin and eosin stain; original magnification ×100 ***(A)*** *and ×400* ***(B)****.)*

Absence of a statistical correlation between occurrences of mucosal perforation and partial or total graft loss ($P = 0.41$ and $P = 0.32$, respectively) suggests progression of problems after graft exposure can be limited by use of a precise interceptive therapy and close follow-up of the grafted areas.

Within the limitations of this 1-year follow-up study which used FFBA for ridge augmentation in the maxilla, statistical correlation between implant failure and the complications evaluated was not found. This result is in accordance with results of previous studies evaluating use of block autografts and allografts.[20,27,41]

Additionally, no correlation was found between location of a grafted site in the arch and presence of a specific complication, although full-arch grafted cases were found to be more prone to implant failure. While most complications led to some degree of graft impairment, outcome of the final treatment was not jeopardized as all patients in this study received a final implant-supported fixed prosthesis after the healing period of the fixture.

Histologic samples of fragments of lost grafts showed a severe inflammatory infiltrate. In samples where the complication occurred after initial graft incorporation, particles of newly formed bone could be seen close to areas with acute inflammation.

CONCLUSIONS

Within limitations of sample size and the 1-year follow-up, infection and suture dehiscence demonstrated significant statistical correlation with graft loss in a maxillary alveolar ridge onlay block FFBA graft augmentation. Patients with full-arch grafting reconstructions lost significantly more implants. Early diagnosis and prompt management of adverse events seem to be of great importance in prevention of total graft loss. Future studies, including larger number of individuals and longer follow-up periods, are necessary to allow further conclusions.

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