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A Comparative Study of Incorporation Rates between Non-xenograft and Bovine-based Structural Bone Graft in Foot and Ankle Surgery

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ABSTRACT

Several types of structural bone grafts are available, each with different characteristics. Our previous study showed poor performance with the bovine-based xenograft in foot and ankle applications. In the present study, we compared the incorporation rates of non-xenografts, including allografts and autografts, with the bovine-based xenograft to determine whether the poor result was unique to the graft type and not institutional. The proportion of incorporated grafts at 12, 24, 36, and 48 weeks was compared between the non-xenograft and xenograft groups. Furthermore, Cox regression analysis was used to evaluate the factors associated with nonunion. A total of 61 patients (23 women and 38 men) with a median age of 24.0 years were enrolled. The factors associated with slower incorporation included side of operation ($p = .033$), tobacco use ($p = .010$), and graft type ($p = .001$). At 48 weeks, 5% of the nonxenografts and 58% of the xenografts were not incorporated. The median incorporation time for the non-xenograft and xenograft group was 16 and 57 weeks, respectively. We have concluded that it is not advisable to use a bovine-based bone xenograft in foot and ankle surgery.

Structural bone grafts have been used in reconstructive foot and ankle surgery for many years (1–4). The fast incorporation of such bone grafts to achieve structural rigidity is essential in foot and ankle applications, because early range of motion and weightbearing are key elements in a successful rehabilitation process.

Different types of bone grafts are available, each with its own unique characteristics. These grafts include corticocancellous autografts, allografts, xenografts, and synthetic bone grafts. Bovine-based xenografts have been suggested to provide structural integrity and ease of use in reconstructive foot surgery. However, our previous study showed poor performance for a bovine-based xenograft in foot and ankle applications. Although we suspected that the poor result was solely due to the graft characteristics, we were unable to exclude the possibility of poor surgical performance at our institution. Therefore, we decided to conduct a comparative study to evaluate the xenograft incorporation rate versus that of other grafts used by the same surgeons at the same institution.

Patients and Methods

The present retrospective cohort study was conducted at the Scott and White Health Care System and was approved by the internal review board. We used the surgeons' personal surgery logs and the Scott and White Health Care System's surgery records from January 1, 2006 to July 1, 2012 to find the patients. Consecutive patients who had undergone reconstructive foot and ankle surgery with a Common Procedural Terminology code of 28300 (calcaneus osteotomy with or without internal fixation), 28302 (talus osteotomy), 28304 (tarsal osteotomy other than calcaneus/talus), or 28305 (osteotomy tarsal bones other than calcaneus/talus with autograft) using an autograft, an allograft, or a bovine-based xenograft were identified. These subjects were then evaluated according to our inclusion and exclusion criteria (Table 1). To be included in the present study, a patient had to be 7 to 80 years old. Those patients who had had a traumatic injury to the operated foot within 3 months of surgery and those who had undergone a procedure in the foot to treat a traumatic injury or for revision surgery of a previous poor outcome were excluded.

Gender, age, tobacco use, and procedure type were recorded for each patient. Age was defined as the patient's age at surgery. Tobacco use was defined as the regular use of tobacco products, regardless of the amount, frequency, or duration.

The patients' serial, postoperative radiographs were reviewed to evaluate incorporation of the bone graft by 1 rater (N.S.), who evaluated every radiograph available for each subject, regardless of the apparent early incorporation of the graft to ensure that no subsequent radiograph showed signs of incomplete incorporation. The rater

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was aware of the postoperative week from the date of surgery when evaluating the radiographs but was unaware of the clinical findings for the corresponding radiograph.

Incorporation of the bone graft was defined as bridging of the interface between the graft and native bone by bone callus or trabeculae at 3 of 4 cortices and obliteration of the graft interface. Corrales et al (5) reported that this was the definition most used in orthopedic research of fracture healing. We adopted this definition because many other studies investigating graft incorporation have used similar definitions.

Survival analysis, with "bone incorporation" as the event of interest, was used to show the rate of bone healing. A Kaplan-Meier curve was used to show the overall "time to event" trend. The starting point was the day of surgery. Incomplete or censored data included patients with nonunion at the end of data collection, patients lost to follow-up before bone incorporation, and patients who had undergone a revision procedure before bony union because of complications related to the index procedure. The proportion of patients who had radiographic bony union before 12, 24, 36, or 48 weeks postoperatively was also estimated using Kaplan-Meier curves for the autograft/allograft and xenograft groups. Clinical healing at the graft site was not evaluated; rather, incorporation of the graft was determined solely from the plain radiographs.

Cox regression analysis was used to evaluate the factors associated with nonunion. The statistical analysis was performed using the R statistical package (R Developmental Core Team, R: A Language and Environment for Statistical Computing 2013; available at: http://www.R-project.org).

Results

A total of 61 patients met our inclusion and exclusion criteria during the study period. Of the 61 patients, 23 were women (38%) and 38 were men (62%). Their median age was 24.0 years (range 9-80, mean ± standard deviation 30.3 ± 19.66). Of the 61 patients, 53 (87%) did not use any tobacco products and 8 (13%) did. Seventeen procedures were done by the primary author (N.S.), who also rated the radiographs in the present study.

Of the structural grafts, 13 (21%) were autografts, 17 (28%) were allografts, and 31 (51%) were bovine-based xenografts. All the xenografts were CANCELLO-PURE wedge™ grafts (Wright Medical Technology, Inc, Arlington, TN). The 31 patients with a xenograft were the same cohort from our previous study. However, more follow-up radiographs were available for several of these patients for the present study. The structural grafts included 2 for the first metatarsal phalangeal joint, 2 for opening wedge bunion surgery, 5 for both Evans and Cotton osteotomies, 9 for Cotton medial cuneiform osteotomy alone, and 43 for Evans calcaneal osteotomy. Overall, 21 patients (34%) had no incorporation and 40 (66%) had incorporation at a mean follow-up point of 27.6 ± 26.15 weeks (range 4 to 170, median 18). Of the 30 allografts/autografts and 31 xenografts, 21 and 17 were stabilized with internal fixation, respectively. Finally, 25 of the 30 allografts/autografts and 23 of the 31 xenografts were used for Evans calcaneal osteotomy.

The Kaplan-Meier and Cox regression analyses revealed that gender, age, and location of surgery were not significant factors associated with graft incorporation. The factors significant for the association were the side of operation ($p = .033$), tobacco use ($p = .010$), and graft type ($p = .001$). The hazard ratio for incorporation of the xenograft versus nonxenograft (autograft/allograft) was 0.19 (95% confidence interval 0.09 to 0.43). The Kaplan-Meier estimates of the proportion of the nonincorporated grafts (autografts/allografts versus xenografts) at 12, 24, 36, and 48 weeks are listed in Table 2 and shown in Fig. 1. At 48 weeks, an estimated 58% and 5% of the xenografts and nonxenografts had not incorporated, respectively.

The median incorporation period for the nonxenograft and xenograft group was 16 and 57 weeks, respectively. For a secondary analysis, we evaluated the difference between the autografts and allografts. The median incorporation period for the autografts and allografts was 16 and 22 weeks, respectively.

Table 1
Inclusion and exclusion criteria

Criteria
Inclusion
Reconstructive foot surgery with implantation of structural autograft, allograft, or bovine-based xenograft
Age 7–80 y
Exclusion
Obvious trauma to operated foot within 3 mo postoperatively
Nonelective procedure
Revision surgery

Table 2
Kaplan-Meier estimates of incorporation of xenografts versus nonxenografts (N = 61 patients)

Postoperative Week	Estimated Nonincorporation of Xenograft (%)	Estimated Nonincorporation of Autograft/Allograft (%)
12	96 (88.6–100.0)	66 (51.2–85.7)
24	65 (47.4–90.0)	30 (16.8–52.8)
36	60 (41.6–86.1)	19 (8.5–40.8)
48	53 (34.6–81.9)	4 (0.7–30.2)

Data in parentheses are 95% confidence intervals.

Discussion

An autograft will be advantageous in many situations, because the graft has been harvested from the patient. It is less likely to be rejected and more likely to be incorporated. It also has osteogenic and inductive properties that assist bone healing. However, harvesting an autograft adds an extra procedure to the reconstructive surgery, and donor site complication can be an issue (6–10). Also, in patients with many comorbidities, harvesting a compromised bone will not provide bone healing potential to the operative osteotomy/fusion site. Furthermore, an autograft must have intact cortices to ensure structural rigidity.

Other types of grafts, such as allografts, xenografts, and synthetic grafts, eliminate the need for secondary procedures and obviate donor site complications. However, rejection and slower

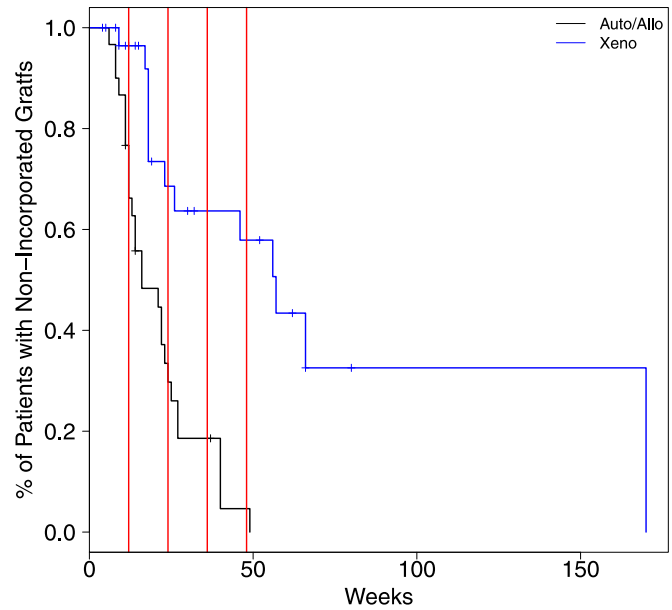

Fig. 1. Survival analysis, with "bone incorporation" as event of interest. Kaplan-Meier curve showing overall "time to event" trend (starting point, the day of surgery). Incomplete and censored data included those with nonunion at data collection, those lost to follow-up before bone incorporation, and those who underwent a revision procedure before union. Vertical lines represent examination points at 12, 24, 36, and 48 weeks postoperatively (N = 61 patients).