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USE OF DEMINERALIZED BONE MATRIX GEL IN FOOT SURGERY:

A PROSPECTIVE RANDOMIZED CONTROLLED STUDY COMPARING DEMINERALIZED BONE MATRIX TO AUTOLOGOUS BONE GRAFT

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A Prospective Randomized Controlled Study Comparing Demineralized Bone Matrix to Autologous Bone Graft

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ABSTRACT

There continues to be an appreciable number of non-unions with both mid and hindfoot fusions and the quest persists to reduce this number in a cost-effective and reproducible way. The purpose of the study was to test the ability of demineralized bone matrix (DBM), (AlloFuse®, AlloSource®, Centennial, CO) to affect fusions after midfoot and subtalar fusions.

A total of 28 patients were recruited to the study; 14 were subtalar fusions and 14 tarsometatarsal (TMT) fusions. The patients were randomized into AlloFuse and autograft groups. Both groups were followed for 12 months. The same surgical approach and fusion technique was used for both groups.

Of the seven subtalar fusions in the AlloFuse group, six fused in eight to 12 weeks, while six of six healed in the autograft group in the same period of time. Six of the six AlloFuse TMT fusions healed in eight to 12 weeks, compared to five of six in the autograft group.

Although the numbers in this study were small, there was no statistical difference between the fusion rates of AlloFuse versus autograft in two common foot procedures. AlloFuse proved to be safe, reliable and cost effective.

Introduction

Non-union of foot fusions continue to be one of the most common and most bothersome of the complications of foot surgery. Often requiring a revision surgery, with the associated significant financial and psychological cost to the patient. These surgeries require an extended period of work, activity modification and difficulties with weight bearing restrictions during the convalescence.

Therefore the quest continues to find a cost-effective and reproducible way to lower the non-union rate. There is ongoing research and multiple new products on the market dealing with this issue. These products include a series of DBM preparations and also a variety of specific bone morphogenic proteins.

The purpose of the study was to test the ability of DBM, (AlloFuse, AlloSource, Centennial, CO) to affect fusions after midfoot and subtalar fusions.

Methods

From January to July of 2004, 28 patients were recruited to the study. Of these, 14 were subtalar fusions and 14 TMT fusions. Therefore each group had not had seven subtalar fusions and seven TMT fusions. The patients were randomized into AlloFuse and autograft groups.

Inclusion criteria for the study included the following: between 20 and 65 years of age, mid-foot or subtalar indication for a fusion (post-traumatic degeneration or rheumatoid arthritis) and no other ipsilateral foot or ankle fusions.

Exclusion criteria included: smoking, peripheral neuropathy or peripheral vascular insufficiency, severely deformed hind or midfoot requiring a significant corrective osteotomy or bone block fusion at the same time.

Weight bearing x-rays were done pre-op and post-op at six weeks, three months, six months, and one year. The AOFAS Ankle-Hindfoot Scale and Midfoot Scale, Visual Analog Pain (VAS) Scale, and a clinical questionnaire were used. These were completed at the same intervals as the x-rays. Patients with a questionable fusion or ongoing pain were further evaluated using computed tomograph (CT) at 12 weeks.

The same surgical approach and fusion technique was used for both groups. With midfoot fusions, one dorsal incision was used if only the medial two rays were fused (three in the AlloFuse group and four in the autograft group) therefore four of the AlloFuse and three of the autograft group had a fusion done of the medial three rays. This was done through two incisions, the first between the first and second TMTs, and the second overlying the third metatarsal.

In the AlloFuse group the remnants of articular cartilage were removed and the apposing surfaces fish-scaled to improve healing. Between 1cc and 2cc of AlloFuse Gel was injected in the spaces between the joints prior to multiple screw fixation. The medial ray was immobilized with two screws, while the second and third with either one screw or a staple each.

In the autograft group, cancellous bone was harvested from the calcaneus through a small lateral incision packed in the joint spaces. Fixation was performed in an identical fashion as the AlloFuse group.

With the subtalar fusions, a standard 3cm ollier sinus tarsi incision was used. The posterior and middle facets were exposed and denuded of cartilage. The apposing surfaces were also feathered with a small osteotome to improve healing. Two screws were inserted from the posterior aspect of the calcaneus into the talus for compression.

In the AlloFuse group 5cc gel was injected into the posterior facet and sinus tarsi. In the autograft group the space was filled with cancellous graft taken from the ipsilateral proximal tibia.

The post-operative course was exactly the same for the two groups. Average hospital stay was 0.6 days (0 to 3 days). Ten of the subtalar fusions were done as outpatients, while five of the midfoot fusions were outpatients. Patients were instructed to be heel touch weight bearing only, maximum 25 pounds. The first cast and the sutures were removed at two weeks. A second cast was applied and the same restrictions were followed until the six week visit. The forms were then completed and x-rays taken. If there were adequate signs of fusion, a walking boot was applied with the instructions to increase weight bearing to full weight bearing over two to four weeks. The boot was removed for sleeping and showering.

A follow-up X-ray was performed between 10 and 12 weeks. If this again showed adequate, the patient could ambulate without support and started physical therapy. Therapy focused on gait training, proprioception, strengthening and mobility.

Results

A total of 13 AlloFuse patients and 12 autograft patients were followed for the entire duration of the study. One in each group was lost to follow-up between three and six months and it was decided not to include their data. One patient of the autograft group confessed to be a pack a day smoker and was removed. The remainder of the study will only discuss these 25 patients.

Of the seven subtalar fusions in the AlloFuse group, six fused in eight to 12 weeks *(Figure 1),* while six of six healed in the autograft group in the same period of time. Two in each group had ongoing pain and questionable fusions at three months. CT scans were done on all four. Only one in the AlloFuse group proved to be a delayed/non-union as seen in *Figure 2A* and *2B*. A revision fusion was done at four months using autograft from the iliac crest. In three of the AlloFuse and two of the autograft patients, hardware from previous open reduction internal fixation of calcaneal fractures was removed at the same time.

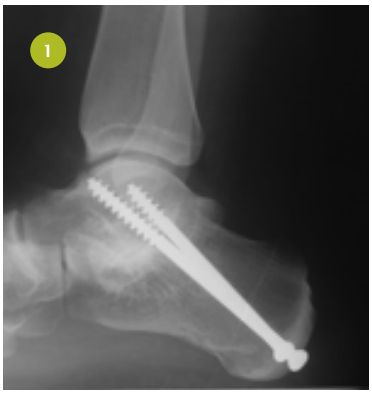

Figure 1. Successful subtalar fusion in a AlloFuse patient.

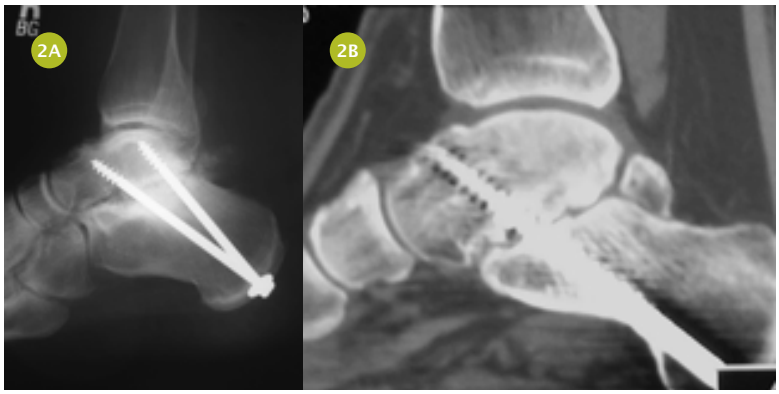

Figure 2A & 2B. An x-ray and CT of a non-union of a subtalar fusion in the allograft group.

Six of six of the AlloFuse TMT fusions healed in eight to 12 weeks *(Figure 3)*, compared to five of six of the autograft group. One in each group had a CT scan done but only the patient in the autograft group had a non-union *(Figure 4)*. This was of both first, second and third TMT joints and was revised using autograft from the tibia mixed with platelet rich concentrate (Symphony®, DePuy, Warsaw, IN).

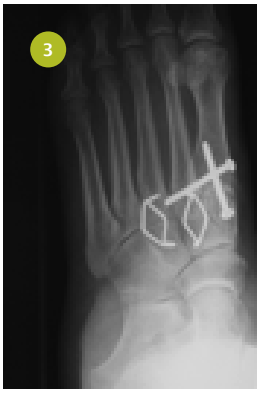

Figure 3. Successful fusion in a AlloFuse patient.

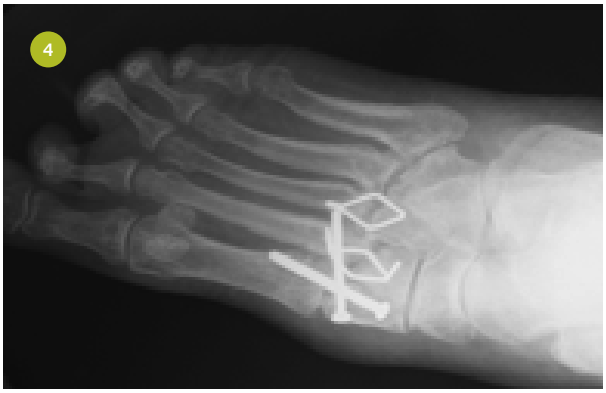

Figure 4. Non-union of the tarso-metatarsal joint in a patient with autograft.

There were no major complications in either group. There was one superficial wound infection in a TMT fusion in an AlloFuse patient, that quickly resolved. There was also one transient superficial peroneal nerve numbness over the dorsum of the foot in one each of the two midfoot fusion groups.

Other details include:

- The mean pre-op AOFAS score for the AlloFuse group as a whole was 48 (range 10–65), while the autograft group was 46 (range 13–66). The mean pre-op score for the midfoot fusions were as follows: AlloFuse 44 (range 10–58), autograft 43 (range 14–56).
- The mean AOFAS score for the subtalar fusions was as follows: AlloFuse 52 (range 17–61), autograft 50 (range 14–59).
- At one-year follow-up, the AOFAS score was 83 (range 63–100) for the combined groups. The individual group's scores were within two points of each other at every interval.
- The AlloFuse group had scores of 85 (range 62–100) for the TMT fusions, and 79 (range 64–89) for the subtalar fusions.
- The autograft group was very similar at one year. The TMT fusion group showed a mean score of 81 (range 61–100), and the subtalar fusion group was 84 (range 65–89).
- Even though the numbers were too small to draw conclusions, there was no statistical difference of any parameter at any interval.
- The VAS pain scale showed scores that were very similar for both groups.

Discussion

There are multiple options available for grafting of fusions in orthopedic surgery. Some have osteoinductive, some osteoconductive and others a combination of characteristics. Autologous bone graft remains the gold standard against which everything else is measured. It is, however not without sacrifice. There are multiple reports in the literature discussing the complications and problems, including cost of recovering autograft.

For this reason, it is worth while to explore materials that can perform equal or better than autograft as far as cost, ease of use and success rate in obtaining a fusion.

In this study, AlloFuse proved to be equally effective to autograft. With the gel, the delivery system is easy to use because it comes in different packaged volumes. It is especially useful in the small joint spaces of the foot. Further, larger studies are necessary, but the use of AlloFuse appears to be equally beneficial to autograft.

Although the numbers in this study were small, there was no statistical difference between the fusion rates of AlloFuse versus autograft in two common foot procedures. AlloFuse proved to be safe, reliable and cost effective.

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