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MATRIX GEL IN FOOT SURGERY:
A PROSPECTIVE RANDOMIZED CONTROLLED
STUDY COMPARING DEMINERALIZED BONE
MATRIX TO AUTOLOGOUS BONE GRAFT**

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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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ABSTRACT

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

A total of 28 patients were recruited to the study: 14 subtalar fusions and 14 tarsometatarsal (TMT) fusions. The patients were randomized into DBM 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 DBM group, six fused in eight to twelve weeks, while six of six healed in the autograft group in the same period of time. Six of the six DBM TMT fusions healed in eight to twelve 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 DBM versus autograft in two common foot procedures. Demineralized bone matrix proved to be safe, reliable and cost effective.

Introduction

Non-union of foot fusions continues 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 time period away from 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 to deal with this issue. These products include a series of DBM preparations and 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 healing 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. Each group had seven DBM fusions and seven autograft fusions. The patients were randomized into the DBM and autograft groups.

Inclusion criteria for the study included the following: between 20 and 65 years of age, midfoot 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 midfoot or hindfoot requiring a significant corrective osteotomy or bone block fusion at the same time.

Weight bearing x-rays were completed 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 Scale (VAS) 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 tomography (CT) at 12 weeks.

The same surgical approach and fusion technique were used for both groups. With the midfoot fusions, one dorsal incision was used if only the medial two rays were fused (three in the DBM group and four in the autograft group). Therefore, four of the DBM and three of the autograft group received a fusion 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 DBM group, the remnants of articular cartilage were removed and the apposing surfaces fish-scaled to improve healing. Between 1cc and 2cc of DBM 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.

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

A standard 3cm Ollier sinus tarsi incision was used for the subtalar fusions. 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.

The DBM group had 5cc gel 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. The average hospital stay was 0.6 days (range 0 to 3 days). Ten of the subtalar fusions and five of the midfoot fusions were outpatients. Patients were instructed to be heel touch weight bearing only, maximum 25 pounds. The first cast and 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 fusion, the patient could ambulate without support and started physical therapy. Therapy focused on gait training, proprioception, strengthening and mobility.

Results

A total of 13 DBM 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 from the autograft group confessed to be a pack a day smoker and was removed. The remainder of the report will only discuss these 25 patients.

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



Figure 1. Successful subtalar fusion in a DBM patient.

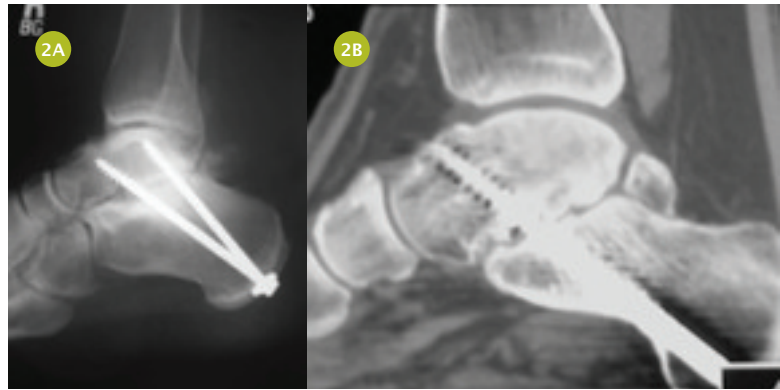


Figure 2A & 2B. An x-ray and CT of a non-union of a subtalar fusion in the DBM group.

Six of six of the autograft fusions healed in eight to twelve weeks (*Figure 3*), compared to five of six of the autograft group. One in each group was imaged with CT, but only the patient in the autograft group had a non-union (*Figure 4*). The non-union included the 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 TMT fusion in a DBM 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 a DBM patient that quickly resolved. There was also a 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 DBM group as a whole was 48 (range 10-65), and in the autograft group was 46 (range 13-66). The mean pre-op score for the midfoot fusions were as follows: DBM 44 (range 10-58), autograft 43 (range 14-56).
- The mean AOFAS scores for the subtalar fusions were as follows: DBM 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 groups' scores were within two points of each other at every interval.
- The DBM 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 worthwhile 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, DBM proved to be equally as effective as 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 DBM appears to be equally as beneficial as autograft.

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

References

- Diezi C, Favre P, Vienne P. Primary isolated subtalar arthrodesis: outcome after 2 to 5 years follow-up. *Foot Ankle Int.* 29(12):1195-1202, 2008.
- Drosos GI, Kazakos KI, Kouzoumpasis P, Verettas DA. Safety and efficacy of commercially available demineralized bone matrix preparations: a critical review of clinical studies. *Injury.* 38 Suppl 4:S13-21, 2007.
- Kang J, An H, Hilibrand A, et al. Grafton® & Local Bone Has Comparable Outcomes to Iliac Crest Bone in Instrumented Single Level Lumbar Fusions. *Spine (Phila Pa 1976).* 2011 Nov 8.
- Kolk A, Handschel J, Drescher W, et al. Current trends and future perspectives of bone substitute materials – From space holders to innovative biomaterials. *J Craniomaxillofac Surg.* 2012 Jan 30. [Epub ahead of print].
- Markel DC, Guthrie ST, Wu B, Song Z, Wooley PH. Characterization of the inflammatory response to four commercial bone graft substitutes using a murine biocompatibility model. *J Inflamm Res.* 5:13-18, 2012. Epub 2012 Jan 18.
- Nandi SK, Roy S, Mukherjee P, et al. Orthopaedic applications of bone graft & graft substitutes: a review. *Indian J Med Res.* 132:15-30, 2010.
- Schwartz Z, Hyzy SL, Moore MA, et al. Osteoinductivity of demineralized bone matrix is independent of donor bisphosphonate use. *J Bone Joint Surg Am.* 21;93(24):2278-2286, 2011.
- Trnka H-J, Myerson MS, Easley ME: Preliminary results of isolated subtalar arthrodesis: factors leading to failure. *Foot and Ankle Int.* 20:678-678, 1999.
- Zimmermann G, Moghaddam A. Allograft bone matrix versus synthetic bone graft substitutes. *Injury.* 42 Suppl 2:S16-21, 2011.



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