Cadaveric Evaluation and Mechanical Testing of the Foot with an Evans Calcaneal Osteotomy Comparing a Bi-phasic Ceramic Bone Substitute to Tricortical Cancellous Allograft

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Abstract

The Evans calcaneal osteotomy is an effective and popular surgical procedure for the correction of adult acquired flatfoot and flexible adolescent flatfoot. During the surgery the foot is lengthened and a tri-cortical cancellous bone allograft is placed to maintain the correction. However, accurate sizing of the graft is often by trial and error resulting in insertion and removal until the dimensions of the graft are satisfactory. An injectable alternative which stays where it is placed would provide an attractive solution which would allow the screw(s) to be inserted once only to the appropriate correction.

To establish the feasibility of an injectable bone void filler, a bi-phasic flowable bio-ceramic material was chosen and cadaveric procedures were conducted. Ten corrections were performed and in all cases the flowable bio-ceramic stayed where it was placed. Thereafter comparative mechanical testing was conducted to establish the integrity of the bio-ceramic construct. Six fresh-frozen cadaveric limbs were tested; three received a tricortical cancellous allograft and three the flowable bio-ceramic.

The flowable bio-ceramic performed at least as well as a tricortical cancellous bone allograft in static and cyclic testing when used as a filler material for the Evans calcaneal osteotomy. There was no fragmentation or deterioration of the filler, as determined by radiographic analysis.

Based on the testing it appears that the bio-ceramic material may be used as an effective filler material alternative to tricortical cancellous bone allograft for the Evans calcaneal osteotomy procedure with the potential to reduce surgery time.

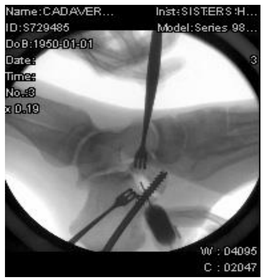


Figure 1. Fluoroscopic views of osteotomy and bone substitute filler injection.

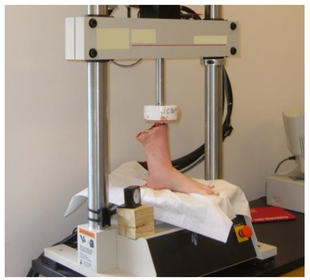


Figure 2. Image of foot specimen loaded Into biomechanical test system.

Introduction

Adult acquired flatfoot deformity and flexible adolescent flatfoot can be debilitating and painful compromises that may lead to the need for surgical intervention. Lateral column lengthening is invariably incorporated as a solution, and calcaneal osteotomy rather than distraction arthrodesis of the calcaneocuboid joint is recommended (1). The key is to protect the "essential joints" to preserve necessary articulation (2). The Evans procedure is popular because it allows for extra-articular correction of the flatfoot deformity which is especially desirable in the adolescent patient (3).

The lead author has been using a flowable bio-ceramic that is a synthetic, injectable osteoconductive bone void filler. It comprises of hydroxyapatite dispersed within calcium sulfate. The calcium sulfate resorbs in tune with normal bone remodeling to facilitate new bone encapsulating the hydroxyapatite particles (which are constituents of bone).
The injectable bio-ceramic material has the potential to eliminate the need for graft size and shape assessment during surgery and any required trial, removal and re-shaping thus reducing the "fiddle factor" and surgery time. It is readily available, has demonstrated clinical safety and efficacy in other orthopedic applications and offers potential as a credible alternative to allografts and autografts for the Evans Calcaneal Osteotomy.

Table 1
Limb Donor and Assignment Details

Donor	Age	Sex	Left Foot	Right Foot
#1	55	F	1CBVF[1]	1BG[2]
#2	60	F	2CBVF	2BG
#3	57	M	3BG	3CBVF

[1]bio-ceramic bone void filler specimens
[2]tri-cortical bone graft specimens

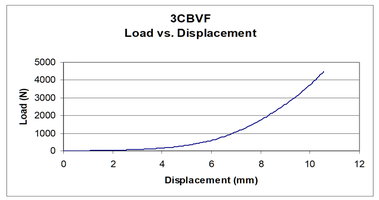


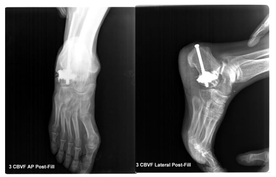
Figure 3. Load versus displacement curve for specimen 3CBVF. There is no evidence of a significant decrease in the slope of the curve or a sudden drop in load.

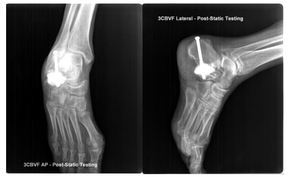
Methods and Materials

The bi-phasic bio-ceramic bone substitute is composed of a mixture of synthetic calcium sulfate (60% by weight) and hydroxyapatite (40% by weight) that is produced into a flowable injectable paste. The material sets within 15 minutes and fully hardens within 45 minutes. This material has an immediate compressive strength similar to that of cancellous bone (4). An allograft iliac strip, approximately 5 cm in length, 2.5 cm in height and 1.25 cm in depth, was donated by the Musculoskeletal Transplant Foundation (MTF, Edison, NJ, USA).

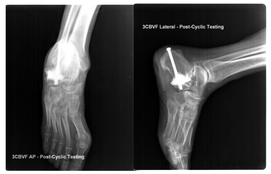
To compare the performance of the bio-ceramic material to that of a tricortical cancellous allograft in an Evans calcaneal osteotomy procedure, a total of six fresh-frozen cadaveric limbs were tested; three which received a tricortical cancellous allograft (BG) and three that received the bio-ceramic (CBVF) instead of a graft (Table 1). The standard Evans procedure was performed, and a screw was inserted to leave the appropriate correction gap, and the flowable bio-ceramic injected into the gap (Figure 1).

A computer-controlled biomechanical test system (Figure 2) was used to simulate static and cyclic vertical ground reactive forces. For static testing, the foot was loaded in compression at rate of 1.27 cm/minute to 4500 N (1012 lbf). Immediately after loading, lateral and AP radiographs were taken of the limb to evaluate the graft/filler and screw for evidence of failure. If failure was not observed, the limbs the limbs were then tested under cyclic loads. The foot was cyclically loaded between approximately 667 N and 2669 N (150 lbf and 600 lbf) at 5 Hz for ten hours, or 180,000 cycles.





A) Prior to testing **B) After static testing**



C) After cyclic testing

Figure 4. Post "surgery" radiographs for specimen 3CBVF before and after testing.

Results

Both treatments endured approximately 4,500 N of compressive load without failing or sign of damage, a load which is in excess of reported maximum clinical levels for walking (5). The pre-testing, post-static and post-cyclic AP and lateral radiographs for one limb containing the bio-ceramic is shown in Figure 4. There was no evidence of fracture, degradation or any other form of failure of the filler after either static testing or cyclic testing in any of the limbs. There was also no radiographic evidence in any of the limbs that the fixation screws were deformed or otherwise damaged during testing.

The pre-testing, post-static and post-cyclic AP and lateral radiographs for all limbs containing the bone graft showed no evidence of fracture, degradation or any other form of failure of the graft after either static testing or cyclic testing in any of the limbs. There was also no radiographic evidence in any of the limbs that the fixation screws were deformed or otherwise damaged during testing.

Discussion

Flowable bio-ceramic injectable is designed to increase cancellous bone mass. The calcium sulfate resorbs with time producing porosity which allows for new bone ingrowth through occupation of osteoprogenitor cells and osteoblasts, while the hydroxyapatite acts as a long-term osteoconductive matrix. The calcaneus is rich in blood supply (6) and is highly supportive to the remodeling process. Via a process of creeping substitution the bio-ceramic supports the bone biology repair process to facilitate bone remodeling and healing, as demonstrated by Hatten and Voor (7) both pre-clinically using micro-CT scans and histology and clinically using CT scans. Delivery of the flowable material via a needle allows accurate targeted positioning in the bone, making it attractive for placement in to the wedge osteotomy site in an Evans calcaneal procedure.

There were three limitations to the testing. First, screws with only two different lengths were available for testing. As a result, in several specimens the tip of the screw passed through the calcaneocuboid joint and into the cuboid bone itself. Secondly, the radiographs were taken by holding the limb in position by hand. As a result, there were slight variations in the positioning of limb each time that the radiographs were taken. However, the radiographs do provide AP and lateral views of the limbs. Finally, the MTS testing system had insufficient load capacity to perform the static tests to failure. However, the tests did exceed appropriate maximum clinical load levels (5) without damage to either treatment.

Conclusions

In the current pre-clinical investigation the bio-ceramic material performed at least as well as a tricortical cancellous bone allograft in static and cyclic testing when used as a filler material for the Evans calcaneal osteotomy. There was no fragmentation or deterioration of the filler, as determined by the radiographs. In conclusion, based on the testing conducted, it appears that flowable bio-ceramic can be used as a safe, effective and more versatile filler material for the Evans calcaneal osteotomy procedure.

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