Outcomes of Hindfoot and Ankle Fusions Treated with Augment Injectable Bone Graft: Results of a Prospective Randomized Controlled Trial

**Foot & Ankle Category:** Hindfoot

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**Introduction**
This study is a multi-center, randomized, controlled trial that examines the safety and efficacy of Augment Injectable Bone Graft substitute (Recombinant human platelet-derived growth factor with a tricalcium phosphate carrier (rhPDGF-BB/β-TCP) as a bone graft substitute compared to autograft for ankle and hindfoot fusions.

**Methods**
Standardized surgical and post operative protocols were utilized, and patients were followed prospectively for one year. Patients were followed up at post-operative weeks 1-3, 6, 9, 12, 16, 24, 36, and 52. CT scans were performed at 9, 16, 24, and 36 weeks. Patients underwent standard internal fixation augmented with either autogenous bone graft or 0.3 mg/ml rhPDGF-BB in a collagen matrix. All treated patients were analyzed. The primary endpoint was percentage of subjects fused by CT scan at 24 weeks (defined as ≥50% osseous bridging), determined by an independent blinded radiologist. Secondary endpoints included plain radiographs and clinical interpretations including clinical success rate (no revision surgery and improved pain on weightbearing), VAS pain assessment, and functional outcome assessment scores (AOFAS Ankle-Hindfoot Scale, Foot Function Index, and SF-12). Autograft data from a previous RCT using an identical surgical protocol was used to improve the number of patients in this group.

**Results**
Assessment of the primary endpoint revealed that 53/63 (84.13%) of the Augment Injectable-treated patients and 100/154 (64.94%) of the autograft-treated patients, were fused as determined by six month CT assessment (p<0.001). Clinically, 57/63 (90.48%) of the Augment Injectable patients and 120/154 (77.92%) of autograft patients achieved clinical success (p<0.001). No safety concerns were identified upon preliminary analysis of adverse events. All Augment Injectable-treated patients were spared the additional risk of bone graft harvest.
Conclusion
As with any fusion surgery, key mechanical and biological principles apply, including thorough debridement, bone-to-bone apposition, and rigid internal fixation. Full contact of prepared bone surfaces will ensure mechanical stability of the fusion site. Application of rhPDGF in a collagen matrix appears to be a safe and effective alternative to autogenous bone graft for foot and ankle fusions.