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**Orthobiologics: Foot and Ankle Surgeon’s Perspective**

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**REFERENCES**

**FOOT & ANKLE BONE MORPHOGENETIC PROTEIN**


**Background:** The purpose of this study was to evaluate the effect of rhBMP-2 on bone healing in patients who undergo high-risk ankle & hindfoot fusions.  
**Materials & Methods:** Patients who underwent high-risk, elective ankle and hindfoot fusions treated with rhBMP-2 augmentation were reviewed for
clinical outcomes and complications. The exclusion criteria were peripheral vascular disease, infection, and patients who were not available for usual follow-up protocol. Internal and/or external fixation was utilized for ankle and hindfoot fusions. Bone graft was used only for patients who had defects or malalignment. Postoperatively, non-weight bearing; radiographs were taken every 2 to 4 weeks (3 views per site). At plain radiographic union, a confirmatory CT scan was obtained. **Results:** A total of 112 fusion sites (69 patients) were reviewed for analysis. The mean age of the patients was 52 years (range 21 to 84 years). There were 37 males (53%) and 32 females (47%). Forty-four patients (64%) were smokers and 13 patients (19%) were diabetic. A history of high-energy trauma was present in 47 (68%) patients and avascular necrosis of the talus was present in 22 patients (32%). Forty-five patients (65%) had multiple risk-factors. Overall, 108 fusion sites went on to union (96% union rate) at a mean time of 11 weeks (as assessed by a CT scan) [ankle joint at 10 weeks; subtalar joint at 12.25 weeks; talonavicular joint at 12.7 weeks and calcaneocuboid joint at 10.9 weeks]. Different union times between ankle, subtalar, talonavicular, and calcaneocuboid joint were statistically not significant (P = 0.2571, Kruskal-Wallis Test Nonparametric ANOVA). All sites: [No graft] vs. [Autograft] vs. [Allograft]: P = 0.2421 (Kruskal-Wallis Test Nonparametric ANOVA), not statistically significant. Complications: Nonunion developed in 5 of 112 joints in 3 patients (4% joint nonunion rate; 4% patient nonunion rate) [subtalar joint, n = 2; talonavicular joint, n = 1; and calcaneocuboid joint, n = 1]. Two patients had wound complications and one other patient had a deep infection; all were successfully treated with local wound care, negative-pressure dressings and antibiotics.

**FOOT & ANKLE DEMINERALIZED BONE MATRIX**


**Methods:** Over a 29 month period, calcaneus fractures undergoing open reduction and internal fixation that possessed central cancellous bone defect were grafted with vancomycin/DBM-calcium sulfate bone graft substitute. Fractures without bone defect were treated with ORIF only. Patient demographics, medical history and CT fracture classification were recorded. Postoperatively, fractures were monitored every 2 weeks for healing and infectious/healing complications.

**Results:** Thirty-three displaced intraarticular calcaneal fractures were grafted with DBM-calcium sulfate impregnated with vancomycin powder. Eleven fractures were treated without grafting (control). Within the experimental group: mean age = 42.2 years; 23 males/10 females; 16 smokers (16/33 = 48.5%), 15 significant alcohol consumption (15/33 = 45.5%); fracture pattern distribution by Sanders’ CT classification: 11 type-II, 17 type-III, and five type-IV fractures; mean union time = 8.2 weeks, while the control group mean union time = 10.4 weeks (P = 0.0117). Wound problems occurred in five patients (5/33 = 15%), all in type III fractures with severe soft tissue swelling, and included two minor wound delays (2/33 = 6%), and three serious wound problems (3/33 = 9%). At a mean follow-up time of 22.4 months, no HDM-calcium sulfate grafted calcaneii demonstrated evidence of osteomyelitis.

**Conclusions:** This is the first study examining human DBM-calcium sulfate bone graft substitute to treat displaced intraarticular calcaneus fractures. Based on these initial data, human DBM-calcium sulfate acted as an acceptable and safe autograft alternative in displaced intraarticular calcaneus fractures with a moderate (5cc – 10cc) central cancellous bone defect.


**Prospective study, total N=55**
- ICBG vs. DBM
- Hindfoot fusions
- No statistically improved time to healing with DBM, but similar to ICBG
- Less blood loss than ICBG
Thordarson DB, Kuehn S. Use of demineralized bone matrix in ankle/hindfoot fusion. Foot Ankle Int. 2003 Jul;24(7):557-60

Comparative study of 2 DBM’s
- AJ & HF fusions, total study N=63
- 8% N-U rate DBM (Grafton®)
- 14% N-U rate [DBM + allo. bone] (Orthoblast®)
- N-U rate between the two DBM’s was not statistically significant
- DBM’s did Not offer better healing time than historical controls [ICBG]

FOOT & ANKLE PLATELET RICH PLASMA


Methods: High-risk patients undergoing elective foot & ankle surgery were prospectively enrolled to study the effect of APC on osseous fusion/healing. Bone grafting was performed only when required to span osseous defects or correct alignment. Patients were followed until radiographic union & monitored for healing and infectious complications.

Results: 123 procedures in 62 patients were performed. Mean patient age = 51 (R = 16-76); 36 females & 26 males; 24 smokers (39%); 65 fusion sites did not require bone grafting (53%); 65 fusion sites (53%) required bone grafting: 46 autograft sites (37%), 12 allograft sites (10%). Overall, 94% of patients (94% of fusion sites) achieved union at a mean time of 41 days. Subgroup Analysis: APC alone (no bone graft) mean union time = 40 days; mean union time (autograft + APC) = 45 days; mean union time (allograft + APC) = 31 days. Complications: Four patients developed a nonunion. Four patients developed a deep infection. There was no patient morbidity from blood collection. There was no wastage of APC materials & no Symphony™ machine malfunction. There were no incidents of hazardous exposure to blood products in the preparation of APC. The average time required for staff in-service was 30 minutes.

Conclusions: This is the first study examining the use of APC in elective high-risk foot and ankle surgery. These data demonstrate that use of APC resulted in an acceptable time to fusion in high-risk patients, and, the times to fusion with or without bone graft were similar. Nonunion rates and infection rates were lower than published data for implantable bone stimulators. Morbidity associated with APC preparation in minimal. When compared to implantable bone stimulators, cost savings are significant ($400/case vs. $1200/case institutional cost). Training time and safety for O.R. staff is acceptable. Based on these data, we conclude that APC results in an acceptable time to bone union in high-risk elective foot & ankle surgery, and may be a useful adjunct to promote osseous healing in high-risk patients undergoing elective foot and ankle surgery.


114 TAR w/ syndesmotic fusion; PRP stat. sig. improve 8 &12 wk. syndesmotic fusion rates & statistically significant reduction in syndesmosis delayed-unions & non-unions

FOOT & ANKLE MESENCHYMAL STEM CELL


A review was conducted of 23 patients who underwent implantation of mesenchymal stem cell allograft for revision foot or ankle surgery. Composed of viable mesenchymal stem cells derived from cadaveric donor tissue, the graft had osteogenic, osteoinductive, and osteoconductive properties, and was capable of direct new bone formation at the site of implantation. In all of the cases, radiographic new bone formation was observed at the area of implantation and a 91.3% union rate was observed, and no evidence of graft rejection or complications associated with implantation were recorded. Wilcoxon rank sum tests were used to determine whether gender, diabetes, chronic renal insufficiency, neuropathy,
number of previous surgeries, and smoking were associated with time to healing. Spearman’s rank correlation coefficient was calculated in an effort to identify the influence of continuous numeric variables on the time to bone healing. Based on the outcomes observed in this retrospective study, it appears that mesenchymal stem cell allograft is a beneficial biological adjunct to bone healing, and serves as a suitable bone autograft substitute in revision foot and ankle surgery. Level of Clinical Evidence: 4

**ADDITIONAL SUGGESTED READINGS**


Cho TJ, Gerstenfeld LC, Einhorn TA. Differential temporal expression of members of the transfor
