A Retrospective Radiographic and Clinical Study Evaluating an Allogeneic, Cancellous Bone Sponge in Patients Undergoing Foot and Ankle Arthrodesis

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My disclosure is in the Final AOFAS Program Book.

I have a potential conflict with this presentation due to:

*Paid Consultant: Wright Medical, Bacterin International*
Introduction

- The majority of ankle and foot arthrosis is due to prior acute traumatic injuries such as ankle and calcaneus fractures\(^1\).
- Arthrodesis is a procedure that can reduce pain and allow continuation of an active lifestyle.
- This study is limited to patients undergoing foot and ankle fusion with a demineralized cancellous sponge allograft.
- **Primary objective** - to demonstrate that subjects undergoing foot and ankle fusion with human demineralized sponge allograft have successful fusions while not experiencing adverse events related to the product.
- **Secondary objective** - to demonstrate that fusion is maintained in the long term.
Methods

- 25 consecutive subjects (45 joints) were reviewed
- Inclusion Criteria:
  - 18 years of age or older
  - records of 12 months post arthrodesis available
- Exclusion Criteria:
  - concomitant use of a second orthobiologic product
  - Postoperative bone stimulator use
- Serial Parameters Reviewed
  - Time to fusion utilizing radiographic analysis
    - evaluated at 6 weeks, 3 months, 6 months, and 12 months
  - Pain: Visual Analog Scale with a numeric rating system (VAS-NRS)
    - evaluated at 3 months, 6 months, and 12 months
  - Function: American Orthopedic Foot and Ankle Scale (AOFAS)
    - evaluated at 3 months, 6 months, and 12 months
Endpoints Reviewed

- Percent of patients with successful fusion from radiographs, compared to literature
- Mean time to achieve fusion, compared to literature
- Patient Reported Outcomes (PRO)
  - Percent of patients successfully treated at 12 months
  - VAS-NRS <4
  - AOFAS >75
- Percent of patients with a reported adverse event.
**Results**

- 25 Subjects (45 Joints), Average age: 57.2 years
  - 11 Midfoot
  - 34 Hindfoot/Ankle
- Average Time to Radiographic Fusion
  - Midfoot: 13 weeks
  - Hindfoot/Ankle: 21 weeks
- Non-Unions
  - Midfoot= 1 (1\textsuperscript{st} MC Joint)
  - Hindfoot/Ankle= 1 (calcaneocuboid joint)
Results

- A 95.5% (43 out of 45) union rate was observed at 12 months.
Results

- No major postoperative complications were recorded
- No adverse events were observed which were related to the graft
Conclusion

- A fusion rate (95.5%) significantly higher than average was observed across the subjects reviewed\textsuperscript{2-5}
- At six months post-operatively, almost a four-fold decrease in reported pain levels was observed.
- The patient reported function score (AOFAS) almost doubled in the six month post-operative period
- Since these joints underwent standard fusion techniques, it is reasonable to deduct that the cancellous bone sponge aided fusion rates in patients undergoing foot and ankle arthrodesis.
- This analysis demonstrates that allogenic cancellous bone sponge can be a safe viable tool to assist surgeons in challenging foot and ankle fusions.
References


