7:00 – 8:55 am

SESSION 1: Bone

Moderator:
Sheldon S. Lin, MD
Newark, New Jersey

7:00 – 7:40 am

Basic Science / Issues behind Bone Fusion

7:00 – 7:05 am

Comparison of CT/X-ray to Clinical Outcome Based on Phase III Clinical Trial
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Establishing the Relationship between Clinical outcome and Extent of Osseous Bridging by CAT scan assessment in Isolated Hind Foot and Ankle Fusions
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Introduction:
Determination of fracture healing and joint fusion following arthodesis is often a diagnostic dilemma with both clinical and diagnostic imaging factors playing important roles. Standard radiographs may not be ideal for quantitative evaluation of fusion and healing, and the ability to determine union on radiographs has been questioned. The emerging role and significance of computed tomography (CT) scans to assess fusion and healing is promising given its superior osseous detail. Recent studies consider Ct to be the best currently available imaging method for assessment of osseous fusion status in both fracture healing and arthodesis models [1-3]. This study will use data from the largest randomised control trial assessing bone graft substitutes efficacy in hind foot and ankle fusion operations to determine the relationship between clinical outcome and extent of CT osseous bridging.

Materials and Methods:
Between April 2007 and January 2010 a blinded, multi centered, prospective, randomized, controlled pivotal trial was performed at 37 different clinical sites across the U.S. and Canada to asses the clinical efficacy of ankle and hind foot fusion using standard rigid internal fixation with autologous bone graft, or 2 rhPDGF-BB and β-TCP (Augment Bone Graft, BioMimetic Therapeutics, Inc).

Patients (n=275) were enrolled in the current study if they had an isolated ankle or hindfoot fusion. The clinical and radiographic outcomes were asses at 24 weeks. The health related quality-of-life was assessed using the Short Form (SF-12)[4]. The joint specific clinical outcomes were assessed using American Orthopaedic Foot and Ankle Society (AOFAS) outcomes score [5] and Foot Function Index (FFI)[6]. Pain with weight-bearing was assessed using a Visual analogue scale (VAS).

The radiologist assessed the extent of osseous bridging across the joint in question using semi-quantitative methodology (SQM). The SQM scoring was determined by a global categorization of estimated osseous bridging to one of the following CT osseous bridging groups: Absent (0-24% osseous bridging); Minimal (25-49% osseous bridging); Moderate (50-74% osseous bridging); Complete (75-100% osseous bridging).
Patients were categorized as a “Clinical Success” if they did not have a revision surgery and had reduced pain on weight bearing compared to their pre operative status. Those patients that had revision surgery or did not have improved pain relief with weight bearing were considered a “Clinical Failure”.

The relationship between CT osseous bridging and Clinical outcome success was determined using the clinical outcome scores (SF-12, FFI, and AOFAS) that were compared between the patients that were deemed to have a “Clinical Success” (improved pain with weight bearing and no revision surgery) and to those patients that were deemed to have a “Clinical Failure”.

**Results:**
Using the criteria of improved pain with weight bearing and no revision surgery there were 216 patients that were deemed a clinical success and 59 patients deemed a clinical failure.

All mean clinical outcome scores (SF-12, FFI, and AOFAS) were improved in those patients that were deemed a clinical success compared to those that were deemed a clinical failure. There was a clinically significant improvement of 11 points for FFI, 6 points for AOFAS and 2 points for SF-12.

All mean clinical outcome scores were improved as the extent of osseous bridging increased (Figure 4.). Further, all mean clinical outcomes scores were improved by a clinically significant amount (as determined above) in patients with minimal osseous bridging (25-49%) compared to those with absent osseous bridging (0-24%) and the clinical outcome scores were not improved by a clinically significant amount in patients with minimal osseous bridging (25-49%) compared to those with moderate (50-74%) and complete osseous bridging (75-100%).

**Conclusion:**
This study suggests that clinical outcome scores (AOFAS, FFI and SF-12) improve as the extent of osseous bridging increases on CT scans. Further, it may be suggested that a minimal osseous bridging (25-49%) is required for patients to have a clinical success as defined by improvement in pain with weight bearing and no required revision surgery.

**References:**