Preliminary Clinical and Radiographic Results from a Multicenter, Prospective Lumbar Spinal Fusion Study of a Cellular Bone Allograft

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Disclosures

• Consultant
  • Stryker Spine, Depuy Spine, Solco Spine, Hans Biomedical, Arthrex

• Royalties
  • HD Lifesciences

• Committee Membership
  • AAOS
Introduction

• Cellular Bone Allograft (CBA) possesses the osteogenic, osteoinductive and osteoconductive elements essential for bone healing.

• There is a lack of prospective lumbar fusion studies with comprehensive and objective outcome assessments that utilize CBA.

• This prospective, multicenter clinical study was performed to assess the safety and effectiveness of a CBA in patients undergoing lumbar arthrodesis
  • Independent evaluation of fusion, prospective safety data collection and several patient-reported outcome measures.
Methods

• This analysis represents the outcome measures from the first 49 of a minimum of 120 patients from eight centers that have completed the 12-month follow-up (NCT 02969616).

• Patients underwent either interbody or posterolateral fusion at one or two levels with CBA (Trinity Cellular Allograft).

• At 12 months, radiographic fusion was assessed
  • Angular and translational motion (<3° and <3mm, respectively) from flexion/extension X-rays (by independent core lab)
  • Combined with presence of bridging bone across the adjacent endplates on thin-cut CT scans.
Methods

12 month Patient Reported Outcome (PRO) measures

• Clinical pain
  • VAS back and leg pain (left and right)

• Function
  • Oswestry Disability Index (ODI)

• Quality of life
  • EQ-5D (VAS and index-based score)
Results - Demographics

• Mean age: 57.9 ± 12.7 years
• Mean BMI: 30.1 ± 6.4
• 42.9% were obese or extremely obese
• Smokers: 12.2%
• Diabetics: 20.4%
• Females: 73.5%
• Graft Type:
  • CBA alone: 49.0%
  • CBA plus locally-derived autograft: 51.0%
• Fusion Type:
  • Interbody: 69.4%
  • Posterolateral: 30.6%
Results – Fusion Rate and Adverse Events

Overall fusion rate assessment at 12 months
• Both motion and bridging bone: 91.8%
• Only bridging bone: 97.9%
• 2-level arthrodesis (n=13): 100%

Adverse events
• No serious allograft related adverse events occurred and all non-unions were asymptomatic.
Results – Patient Reported Outcomes (PROs)

- **VAS back pain**
  - Baseline
  - 12 Months

- **VAS leg pain**
  - Baseline
  - 12 Months
  - Right Leg
  - Left Leg

- **ODI**
  - Baseline
  - 12 Months

- **EQ-5D VAS**
  - Perceived Health (%)
  - Baseline
  - 12 Months

- **EQ-5D Index Score**
  - Index Score
  - Baseline
  - 12 Months

* P<0.001 relative to baseline
Discussion

Patients undergoing one- or two-level lumbar posterolateral or interbody arthrodesis with CBA alone or with CBA plus locally derived autograft had a high rate of fusion, pain reduction, function and quality of life success without serious allograft-related adverse events in this preliminary evaluation of the first 49 patients that have reached 12 month follow-up.
Summary Points

• Prospective, multicenter clinical study was performed to assess the safety and effectiveness of a Cellular Bone Allograft (CBA) in patients undergoing lumbar arthrodesis (1 and 2 level)

• 49 patients reported on at 12 months

• High rate of fusion
  • 91.8% (criteria: motion (<3 deg rotation + <3mm translation) + presence of bridging bone)
  • 97.9% (criteria: bridging bone)

• Significant pain reduction
  (VAS decrease: Back = 34.7mm; R-leg = 14.1mm; L-leg = 22.0mm)

• Significant increase in function (ODI decrease: 25.0 % points)

• Significant increase in quality of life
  (EG-5D increase: VAS=16.6 % points; Index score = 0.206)

• Success without serious allograft-related adverse events