Preliminary Clinical and Radiographic Results from a Multicenter, Prospective Lumbar Spinal Fusion Study of Trinity ELITE™ Allograft

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Disclosures

• Orthofix - consultant, research support
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Background context and purpose

• 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 75 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 ELITE Allograft).
• At 12 months, radiographic fusion was assessed
  ▪ Angular and translational motion (<3° and <3mm, respectively) from flexion/extension X-rays (by Medical Metrics, Inc.)
  ▪ Combined with presence of bridging bone across the adjacent endplates on thin-cut CT scans.
Methods – Cont.

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 presented as mean ± standard error
Results - Demographics

- Mean age: 59.6 ± 1.4 years
- Mean BMI: 29.7 ± 0.7
  - 40.0% were obese or extremely obese
- Risk factors:
  - Age 65+ (40.0%); BMI > 30 (40.0%); Smokers: 9.3%
  - Diabetics: 21.3%; Osteoporosis (5.3%); 2-level fusion (28.0%)
- Females: 69.3%
- Graft Type:
  - CBA alone: 50.7%
  - CBA plus locally-derived autograft: 49.3%
- Fusion Type:
  - Interbody: 68.0%
  - Posterolateral: 32.0%
Results – Fusion Rate

Overall fusion rate assessment at 12 months

• Both motion and bridging bone: 92.0%
• Only bridging bone: 97.3%
• 2-level arthrodesis (n=21): 95.2%
• Subjects with PLF procedures (n=24): 95.8%
• Stratified fusion rate based on risk factors:
  ▪ Age 65+, BMI > 30, Smoker, Diabetes, Osteoporosis, 2-level fusion

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>n</th>
<th>Fusion rate (%)</th>
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</thead>
<tbody>
<tr>
<td>1 risk factor</td>
<td>31</td>
<td>96.8%</td>
</tr>
<tr>
<td>2+ risk factors</td>
<td>32</td>
<td>93.8%</td>
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Results – Adverse Events

• No serious allograft-related adverse events occurred and all non-unions were asymptomatic.
• None of the following occurred as a result of the allograft for the 75 patients:
  ▪ Infections
  ▪ Neuro complications
  ▪ Wound complications
  ▪ Increased swelling
Results – Patient Reported Outcomes

Results presented as mean ± std.err.
* P<0.001 relative to baseline
Conclusions

Patients undergoing one- or two-level lumbar posterolateral or interbody arthrodesis, with CBA alone or with CBA plus locally derived autograft, achieved:

- High rate of fusion
- Pain reduction
- Improved function
- Increased quality of life

The results were achieved without observing serious allograft-related adverse events in this preliminary evaluation of the first 75 patients that have reached 12 month follow-up.
Thank You!

Trinity ELITE Instructions For Use (IFU):