

Twenty-four month radiographic and clinical outcomes in subjects that underwent single level or multi-level anterior, posterior, or lateral interbody fusion with a cellular bone allograft.

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Source: NCT02969616



# Introduction

- There are a number of bone grafting options available, each providing one or more of the essential bone forming properties of autograft
- Cellular Bone Allografts (CBA) are the only available option that provides the osteogenic, osteoinductive and osteoconductive elements necessary for bone repair
- Trinity ELITE is an allogeneic cancellous bone matrix with native osteogenic cells and a demineralized cortical bone, with BMP-2 tested on every lot, providing the required environment necessary for successful bone grafting in patients at high-risk for nonunion
- There is a lack of prospective lumbar fusion studies with comprehensive and objective outcome assessments that utilize bone graft substitutes, particularly for patients with risk factors for non-union

# Methods

## Notable Inclusion Criteria

- ✓ 18 Years of Age, Candidate for Lumbar Arthrodesis
- ✓ Requires 1-4 Levels of Contiguous Fusion (L1-S1)
- ✓ Non-responsive to Conservative Care for At Least 6 Months
- ✓ Minimum of 50% Trinity ELITE (by volume) Per Level Fused

## Notable Exclusion Criteria

- ✓ Prior Lumbar Spine Fusion Surgery at Target Level
- ✓ Currently Undergoing Treatment for Malignancy or Treatment in Past 5 Years
- ✓ Is/Planning to Become Pregnant
- ✓ Allergy to DMSO

# Study Design

- **Prospective**, multi-center to assess the safety and effectiveness of Trinity ELITE in lumbar arthrodesis

- 184 patients at 24 month follow up
- Interbody fusion: Single & Two-Level
  - Posterior (TLIF/PLIF)
  - Lateral (OLIF/XLIF/LLIF/DLIF/MIDLIF)
  - Anterior (ALIF)

- Fusion Criteria for Success

Patient must have:

- Bridging bone (CT scans)
- Angular and translational motion ( $<3^\circ$  and  $<3\text{mm}$ , respectively) from flex/ext X-rays



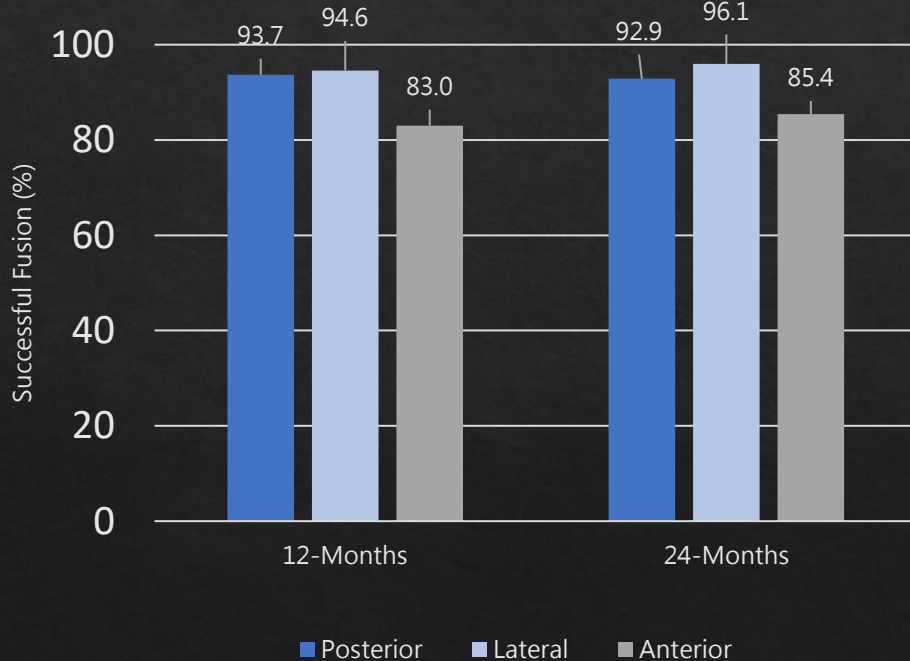


# Results

Study Completion: December 2021

- 252 subjects enrolled that underwent an interbody fusion
- 184 subjects assessed at 24-months
  - Mean age 59.6 years, 61% (n=121) female
  - Anterior Surgical Approach: n = 48
  - Lateral Surgical Approach: n = 51
  - Posterior Surgical Approach: n = 85
- Overall fusion success rates were 91.2% (187/205) at 12 months, and 91.8% (169/184) at 24 months

# Fusion Rate by Surgical Approach



Surgical Approach	Treatment	12-Months Fusion Rate	24-Months Fusion Rate
Posterior (n=85)	Single-Level	92.4 (73/79)	91.3 (63/69)
	Two-Level	100 (17/17)	100 (16/16)
Lateral (n=51)	Single-Level	97.5 (39/40)	97.2 (35/36)
	Two-Level	87.5 (14/16)	93.3 (14/15)
Anterior (n=48)	Single-Level	80.6 (25/31)	83.8 (26/31)
	Two-Level	85.7 (18/21)	86.6 (13/15)
	Three-Level	100 (1/1)	100 (2/2)

# Pain and Disability

Mean ODI significantly ( $p = <0.0001$ ) improved at 24-months for subjects treated via anterior (21.0 points), posterior (25.0 points), or latera (18.2 points).

Similarly, back and leg pain scores improved significantly ( $p = <0.0001$ ) in subjects treated with an anterior (44.1 and 22.3 points), posterior (39.7 and 31.85 points), or lateral (54.2 and 40.67 points) approach at 24-months.

Mean EQ-5D improved significantly ( $p = <0.001$ ) at 24-months for subjects treated with anterior (0.17 points), posterior 0.2 points), and lateral (0.15 points) approach.

