

Clinical Outcomes and Fusion Rates Following Anterior Lumbar Interbody Fusion with Bone Graft Substitute i-FACTOR, an Anorganic Bone Matrix/P-15 Composite

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Objective: To determine the safety and efficacy of i-FACTOR™ Peptide Enhanced Bone Graft composite used in patients who underwent ALIF by evaluating fusion rates and clinical outcomes.

Methods: 110 patients with degenerative spinal disease underwent single- or multi-level ALIF using i-FACTOR Bone Graft composite with a mean 24-month (minimum 15-month) follow-up were enrolled into the study.

- Radiological assessment of fusion at 6, 12, and 24 months
- Clinical outcomes assessed via SF-12, ODI, and VAS scoring

Results:

Time	% Fusion	% Improvement in Score		
		SF-12	ODI	VAS Pain
6-months	43%			
12-months	78%			
24-months	94%	35%	53%	64%

Fusion Rate Sub-analyses: Smokers (84%), Diabetes (70%), Worker's Compensation (82%)

Conclusions: The use of i-FACTOR Bone Graft demonstrates promising results for facilitating successful fusion and improving clinical outcomes in patients who undergo ALIF surgery for degenerative spinal pathologies

Key Points:

- This is the first study to investigate i-FACTOR Bone Graft as a bone graft in human ALIF procedures.
- This study results showed a statistically significant improvement in clinical outcomes ($p < 0.05$)
- This study demonstrates high fusion rates and clinical improvements in line with published results for autograft or BMP in an ALIF without the associated complications specific to those materials.