i-Factor™ Bone Graft versus Autograft in Anterior Cervical Discectomy and Fusion: Two-year Follow-up of the Randomized Single-blinded Food and Drug Administration Investigational Device Exemption Study

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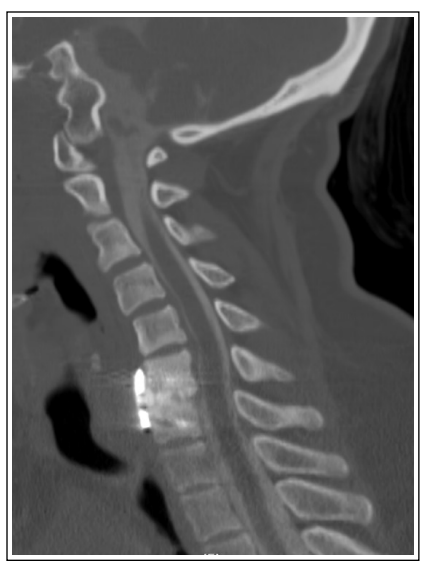
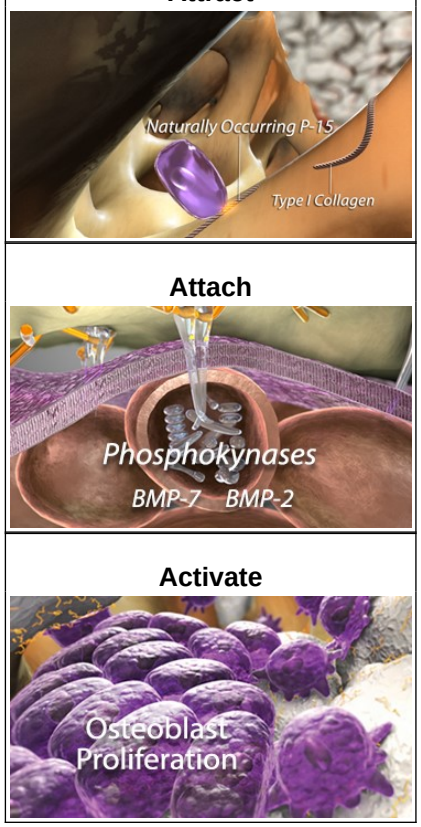
Introduction

P-15 is a novel synthetic 15-amino acid polypeptide that mimics Type I collagen. i-FactorTM Peptide Enhanced Bone Graft (Cerapedics, Westminster CO) is a bone substitute composed of P-15 adsorbed onto anorganic bone mineral and suspended in an inert biocompatible hydrogel carrier. We report 24-month outcomes of patients who received i-Factor or local autograft during single-level ACDF for symptomatic cervical disc disease.



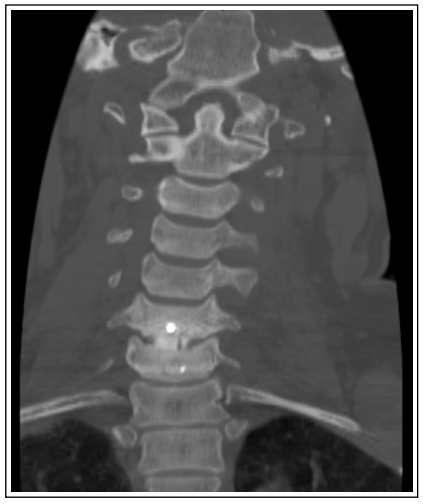
Methods

This pivotal prospective multi-center randomized FDA IDE single-blinded study from 2006-13 investigated safety and efficacy of i-Factor compared to autograft in 319 patients at 22 North American sites. Patients were evaluated preoperatively and postoperatively to 24 months. Outcome measures were: fusion; neurologic and NDI functional outcomes; VAS neck and arm/shoulder pain scores; SF-36v2 PCS and MCS; and Overall Success (fusion and neurologic success, NDI improvement >15, and absence of reoperations and device-related serious adverse events). Patients received either i-Factor (N=165) or local autograft (N=154) in a cortical ring allograft implanted into the target vertebral interspace prior to fixation device placement.



Results

The 12-month f/u rate was 136/159 (85.5%) and 139/151 (92.1%) in i-Factor and autograft patients, respectively. The 24-month f/u rate was 117/150 (78.0%) and 127/149 (85.2%), respectively. At 24 months, fusion was 97.3% and 94.4% in i-Factor and autograft patients, respectively; neurological success was 94.9% and 93.8%, respectively. NDI improved 28.30 and 26.95, respectively; VAS arm improved 5.43 and 4.97, respectively; VAS neck improved 4.78 and 4.41, respectively, SF36v2 PCS improved 10.23 and 10.18, respectively, and SF36v2 MCS improved 7.88 and 7.53, respectively. Overall Success was greater in i-Factor vs autograft patients (69.8% and 56.4%, respectively). 12 (7.5%) i-Factor patients and 16 (10.5%) autograft patients had reoperations.



Conclusions

Use of i-Factor in ACDF is effective and safe, and results in similar—and on some metrics superior—outcomes compared to local autograft at 24 months following surgery.