



Novel i-FACTOR™ Biologic Bone Graft Shown to Improve Clinical Outcomes in ALIF Procedures

Results from the first prospective clinical study of i-FACTOR™ bone graft in anterior lumbar interbody fusion surgery published in the Journal of Neurosurgery: Spine.

WESTMINSTER, Colo. - October 20, 2014 – Cerapedics, a privately-held orthobiologics company, today announced that results from the first prospective clinical study evaluating the safety and efficacy of i-FACTOR bone graft in anterior lumbar interbody fusion (ALIF) have been published in the peer-reviewed *Journal of Neurosurgery: Spine*. Findings from the study, entitled, “Clinical Outcomes and Fusion Rates Following Anterior Lumbar Interbody Fusion with Bone Graft Substitute ‘i-FACTOR’ – an ABM/P-15 Composite,” were presented by the research team led by Ralph J. Mobbs, MD, Prince of Wales Hospital in Australia.

In the non-blinded study, a total of 110 patients were treated with i-FACTOR™ biologic bone graft and evaluated for fusion rates and clinical outcomes with a mean follow-up of two years. Treatment was shown to provide favorable clinical outcomes in patients who undergo ALIF surgery for degenerative spine conditions by facilitating successful fusion of two or more vertebrae, also known as arthrodesis. Fusion rate was assessed using fine cut coronal CT scans. In total, 94 percent of patients achieved arthrodesis. The one-level fusion rate was 98 percent (78/80), the two-level fusion rate was 82 percent (22/27), and the three-level fusion rate was 100 percent (3/3). While the mean follow-up time for collection of radiological data was 24 months, evidence of fusion was demonstrated as early as 3-6 months post-surgery in some patients (43% of one-level, 44% of 2-level).

Results also showed a statistically significant improvement between preoperative and postoperative scores when assessing patients using the Oswestry Low Back Pain Disability Questionnaire (ODI), Short Form-12, Odom’s criteria score, and a visual analogue scale for pain (VAS).

“Grafting supports bone regeneration in a variety of cases in orthopedic surgery, but harvesting autologous bone graft has been associated with a number of complications including chronic pain, infection, and fracture,” said Dr. Mobbs. “The use of orthobiologic materials that can deliver high fusion rates without the need to harvest autologous bone graft will represent a significant advance in patient care, and so these results involving treatment with i-FACTOR™ biologic bone graft are especially encouraging.”

The current standard of care to achieve arthrodesis in ALIF procedures is autologous bone graft typically obtained from the iliac crest along the largest bone in the pelvis. The procedure requires patients to undergo a second surgery to harvest bone for use in the grafting procedure. i-FACTOR biologic bone graft is composed of anorganic bone matrix (ABM) enhanced with synthetic small peptide (P-15), based on a proprietary technology developed by Cerapedics.

“The results represent a major advance in our commitment to developing and commercializing novel orthobiologic products,” said Glen Kashuba, CEO at Cerapedics. “We look forward to advancing the clinical research program for i-FACTOR biologic bone graft as we continue to investigate potential new applications for our proprietary small peptide technology.”

About Cerapedics

Cerapedics is an orthobiologics company focused on developing and commercializing its proprietary synthetic small peptide (P-15) technology platform. i-FACTOR Peptide Enhanced Bone Graft is the only biologic bone graft that incorporates a small peptide as an attachment factor to stimulate the natural bone healing process. This novel mechanism of action is designed to support safer and more predictable bone formation at a lower cost compared to commercially available bone growth factors. More information can be found at www.cerapedics.com.

CAUTION: i-FACTOR biologic bone graft is currently not approved for commercial use in any indication in the United States and is limited by U.S. Federal Law to investigational use only.

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