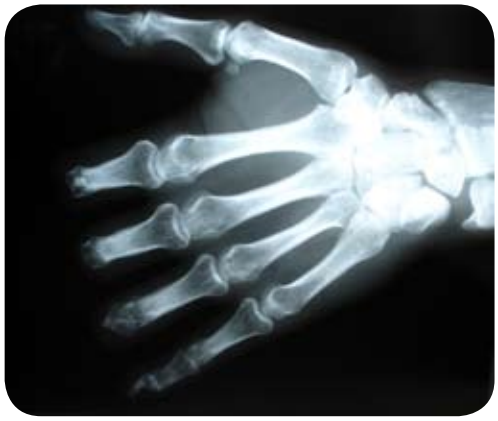
biologics

BioSET Starts Bone Graft Trials

BioSurface Engineering Technologies, Inc.[BioSET], a privately held company developing synthetic peptide growth factor mimetics for advanced tissue repair, is reporting that two pilot clinical trials, one in the U.S. and one in Canada, have been initiated with the company's AMPLEX osteo-promotive bone graft system. AMPLEX is a combination medical device that incorporates BioSET's B2A, a BMP-2 growth factor analog, with ultra high-grade ceramic bone scaffold for use in lumbar interbody spine fusion surgery.

BioSET has received the FDA nod of approval to initiate a pilot safety and preliminary efficacy study to evaluate its AMPLEX in approximately 22 patients. Additionally, the company received approval from Health Canada of a similar study design intended to enroll 24 patients in the land of the maple leaf. Both studies are randomized, prospective, multi-center, controlled studies comparing autograft from the hip to AMPLEX in lumbar interbody fusion procedures for patients with degenerative disc disease.

BioSET also reports the first patient surgery in its Canadian study was performed by Dr. Stephan du Plessis, Assistant Professor, Neurosurgery and Vice Chairman, University of Calgary Spine Program at the Foothills Medical Centre in Calgary, Canada. In the news release, Dr. du Plessis commented, "This patient presented with grade 1 spondy and foraminal stenosis at level L5/S1. We performed a decompression and standard TLIF in combination with posterior fixation for this patient using this new material as the bone graft. We found the material handled no differently than other ceramic graft alternatives when packing into the cage and the disc space. The patient is recovering well after surgery and I will be keenly interested in how this new growth factor material compares to other osteo-inductive synthetics."



"This first use of AMPLEX in our Canadian clinical series represents a significant achievement in our development of a safe and effective alternative to autologous graft harvested from a second surgical site as well as bone graft substitutes that are either very costly, have safety concerns or have not been proven to be osteo-inductive", noted Tom Roueche' in the news release. Roueche', BioSET's President and CEO, added, "We look forward to enrolling our first patient in the U.S. study later this month, and reviewing the top line data from all patients 6 month follow-up visits in the second half of 2009."

BioSET also reported that the company received a Notice of Allowance of BioSET's patent titled "Positive Modulator of Bone Morphogenic Protein 2" which covers the B2A peptide used in the AMPLEX graft construct. The patent, expected to publish early in 2009 and last through 2029, is the first in a series of worldwide patent filings covering AMPLEX, its materials and methods of use.

Additionally, BioSET reported publication of two preclinical studies relating to the safety and effectiveness of AMPLEX in spine fusion. The May 2008 issue of Spine described a study from researchers at the University of Iowa that AMPLEX enhanced spine fusion as compared to iliac crest autograft in a rabbit model. A 2008 presentation at the Orthopedic Research Society authored by researchers in Towson, Maryland, demonstrated that AMPLEX enhanced spine fusion in a sheep interbody fusion model.

Commenting to OTW, Roueche' noted, "BioSET remains committed to expanding patient access to a safe, highly efficacious and cost effective bone graft supported by rigorous clinical data. If our pilot study data confirms our positive pre-clinical work, we plan to seek funding to pursue pivotal clinical studies in spine fusion, with a goal of achieving PMA approval and commercialization of our product in the U.S. and Canada."

— *EH (December, 2008)*