ABSTRACT

INTRODUCTION: Autologous cancellous bone is generally considered the gold standard for promoting spinal fusion. However, harvesting the autograft is associated with increased length of surgery and blood loss, as well as significant morbidity at the donor site and other complications. In addition, the availability of quality autologous graft may be limited.

Synthetic calcium-based bone void fillers have been used successfully in combination with autologous bone marrow aspirate for spinal fusion. Compared to cancellous bone, these materials reduce operative time, offer increased patient safety with no donor site morbidity, and are available in unlimited quantity.

PURPOSE: This study measured one level ALIF spinal fusion rates and the radiological appearance of fusion in patients treated with an ultraporous synthetic bone graft made of b-tricalcium phosphate (VITOSS®, Orthovita, Inc., Malvern, PA) mixed with autogenous bone marrow aspirate (BMA) packed in and around cylindrical titanium cages. Low back and/or leg pain and function were also compared before and after surgery.

STUDY DESIGN/SETTING: This is a prospective, open-label study conducted at a single, private practice site. Patients were enrolled between April 2003 and April 2004.

PATIENT SAMPLE: Twenty-five consecutive patients were entered into the study. Patients were 18 years of age or older and diagnosed with degenerative disc disease. Each patient received a stand-alone, L5-S1 anterior lumbar interbody fusion (ALIF).

OUTCOME MEASURES: Fusion and graft incorporation were measured using standard anterior-posterior and lateral radiographs, lateral flexion/extension radiographs, and a lumbar computed tomography (CT) scan. Physical examination of patients included motor and sensory testing. Pain and functional status were assessed using the Visual Analogue Pain Scale (VAS), the Oswestry Low Back Pain Disability Index (ODI), and the SF-12 health survey.

METHODS: Prior to implantation of interbody cages, bone marrow was aspirated from the iliac crest and mixed with VITOSS in approximately a 1:1 ratio. The VITOSS/BMA mixture was placed inside the cages prior to implantation. Additional VITOSS/BMA was then packed into the interbody space and around the cylindrical titanium cages.

RESULTS: All patients had a diagnosis of degenerative disc disease without herniation. At 12 months, radiographic fusion occurred in 91% of the patients. There was an overall improvement in back pain, leg pain, function, work status and a significant reduction in pain medication usage. Five patients experienced at least one complication within the 12-month postoperative period.

CONCLUSIONS: VITOSS, an optimized synthetic bone graft, resulted in a 91% fusion rate at 12 months when used with BMA in stand-alone ALIF. Continued follow-up is needed to evaluate the long-term results in this patient population.