

7:42-7:47 a.m.

23. Prospective Evaluation of Lumbar Fusions Using Silicated Calcium Phosphate Bone Graft

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BACKGROUND CONTEXT: Iliac crest autograft is currently the gold standard for lumbar fusions. However, morbidity including infection, bleeding, pain, fractures, neuromas, etc., has been well documented. This has prompted investigation into alternative bone graft materials.

PURPOSE: This study evaluates silicated calcium phosphate (Si-CaP, Actifuse™ Synthetic Bone Graft) in posterolateral lumbar fusions (PLF) with instrumentation, with or without a posterior interbody arthrodesis.

STUDY DESIGN/SETTING: A prospective evaluation of 46 patients.

PATIENT SAMPLES: Thirty-eight patients have completed two-year follow-up. All have a diagnosis of lumbar stenosis, with spondylolisthesis in 22, spondylosis in 8, degenerative scoliosis in 6, and discogenic pain in 2. Twenty-four had a Transforaminal Lumbar Interbody Fusion (TLIF) in addition to the PLF fusion. The average age was 62 (range 37-78), with 23 females and 15 males. Twelve (31.5%) were smokers, and only 2 were a workers compensation case. There were 14 (36.8%) one-level, 16 (42.1%) two-level and 8 (21.1%) three-level procedures.

OUTCOME MEASURES: Clinical evaluation consisted of Visual Analogue Scales (VAS) as well as patient satisfaction at 6 weeks, 3 months, 6 months, 1 year and 2 year follow-up. Radiographic evaluation includes plain films at each visit and flexion/extension films at one and two years. TLIF patients also underwent a thin cut lumbar CT scan with sagittal and coronal reconstructions at one and two years. The fusion rate was determined by two independent neuro-radiologists using the Lenke classification for PLF and a classification system developed by Brantigan and Steffee for the TLIF.

METHODS: A bone graft composite was formed by combining local autograft with 10 cc's of Si-CaP and 8-10cc's of Bone Marrow Aspirate (BMA) taken from the iliac crest, per level. Multi-axial pedicle screws were then placed per standard technique. A unilateral TLIF was performed by removing as much disk as possible, including removal of endplates, and packing the interbody space with the bone graft composite. A PEEK cage was then packed with the bone graft composite and placed at a 45 degree angle towards the midline. For the PLF procedures a high-speed burr was utilized to decorticate the transverse processes, pars interarticularis, and facet joints at the appropriate levels and rods were inserted.

RESULTS: The VAS pain level decreased from 8.0 pre-operatively to 2.6 (68% decrease) at two-years with 36 (95%) patients reporting good or excellent satisfaction results. There was one revision of the operated levels secondary to a pseudarthrosis. There were no incidences of infection, bone graft complications or instrumentation failures. PLF fusion rate was graded as 84% (32/38) by the first radiologist and 87% (33/38) by the second radiologist at two years. TLIF fusion rate was graded as 83% (20/24) by both radiologists. Ninety percent (34/38) of the patients achieved a fusion in either the posterolateral gutter or interbody space.

CONCLUSIONS: The 2-year follow-up data show that Si-CaP is a new bone graft alternative with encouraging clinical results and a fusion rate comparable to ICBG. There were no adverse side effects with Si-CaP. Further study and longer-term follow-up evaluations are required.

FDA DEVICE/DRUG STATUS: Actifuse Synthetic Bone Graft: Approved for this indication.