

24. The Use of Silicate Substituted Calcium-Phosphate Bone Graft Substitute Without ICBG for the Surgical Treatment of Degenerative Lumbar Spine Disease: One Year Results

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BACKGROUND CONTEXT: Development of bridging bone across the affected level largely determines the clinical outcome of spinal fusion surgery. The posterolateral fusion mass can be derived from a variety of sources including autograft, allograft, and synthetic bone graft substitutes (BGS). ICBG is the historical gold standard, though it presents issues with donor site morbidity, bone quality, limited supply, and increased anesthesia time. Silicate-substituted calcium phosphate synthetic BGS is similar in structure to bone mineral, but has site-specific substitution of phosphate with silicate ions. Silicon significantly increases the speed and extent of bone formation through up-regulation of osteoblast proliferation and differentiation, osteoinductive gene expression, and Type I collagen synthesis.

PURPOSE: Our purpose is to examine the 1 year clinical and radiographic outcomes of 69 patients with degenerative lumbar disease who underwent posterolateral fusion using silicate-substituted calcium phosphate BGS and compare to the historical standards of ICBG. **STUDY DESIGN/SETTING:** This is an IRB-approved retrospective review of prospectively collected data. All subjects were evaluated by a single surgeon at a multi-disciplinary Spine Center, and underwent surgery at an academic, tertiary care medical center.

PATIENT SAMPLES: Included in this review are 102 adults with degenerative lumbar disease who underwent decompressive surgery with posterolateral fusion using silicate-substituted calcium phosphate BGS by a single surgeon (PLC) between 2005 and 2008. Fifty-five percent had DDD, and 33% had spondylolisthesis. The mean age was 57.2 years and 59% were female. Fifteen percent had a single level fused, 45% had two levels, and 41% were fused at three or more levels. A posterior-only approach was used for 66%; the remainder also had anterior fusion.

OUTCOME MEASURES: Subjective outcomes include pain status, satisfaction, SF-36, and Oswestry scores. Objective outcomes include functional, work, and neurologic status assessments. Postoperative radiographs were obtained.

METHODS: In addition to a standard posterolateral fusion, a mix of silicate substituted calcium-phosphate granules and local autograft was placed in the posterolateral gutters of all subjects. Medical records were reviewed for demographic and clinical information.

RESULTS: Among 69 patients with 1 year follow-up data, 57% report relief of back pain and 67% report relief of leg pain. The mean VAS is 1.75. Surgery was worthwhile for 81%, and 95% had no sensory or motor deficits at one year (Fig.1).

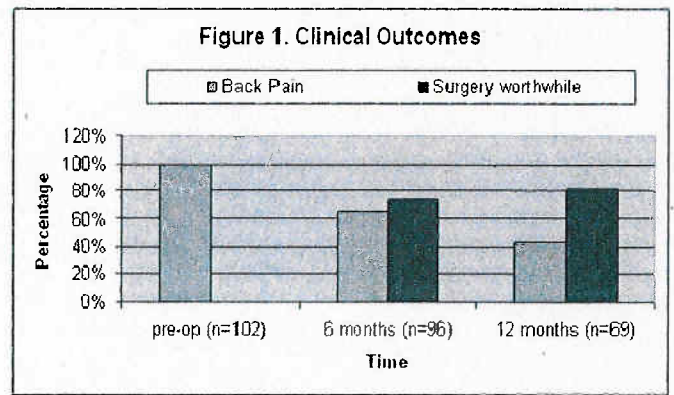


Figure 1.

Mean SF-36 PCS improved from 27.2 prior to surgery, to 37.7 at 6 months, and 35.4 at one year. Mean Oswestry scores improved from 54.6 prior to surgery to 38.7 at 6 months, and 42.0 at one year (Fig. 2). At 1 year, 81% (82% at 6 months) of all patients had radiographic evidence of bilateral bridging bone. There was one case of implant loosening.

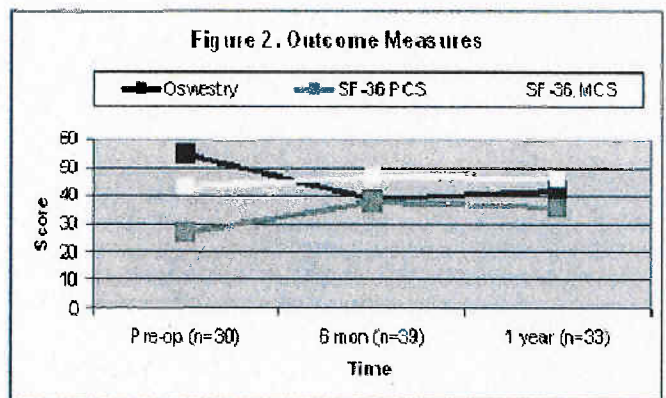


Figure 2.

CONCLUSIONS: These results suggest that silicate substituted calcium-phosphate synthetic BGS mixed with local autograft is an excellent alternative to ICBG for posterolateral spinal fusion in patients requiring surgical treatment for degenerative disease of the lumbar spine. At 1 year, this cohort demonstrates good return of neurological function, substantial pain relief, and considerable functional improvement. Imaging results support the clinical picture of solid fusion.

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