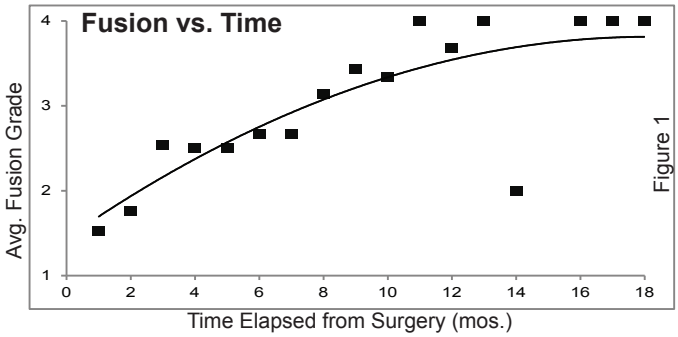
osteoSPAN
BONE GRAFT SUBSTITUTE

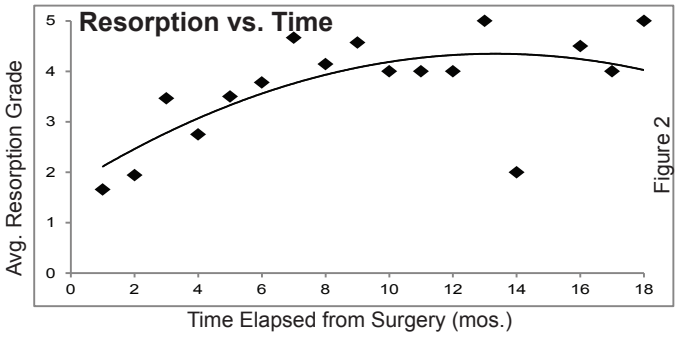
BIOGENNIX

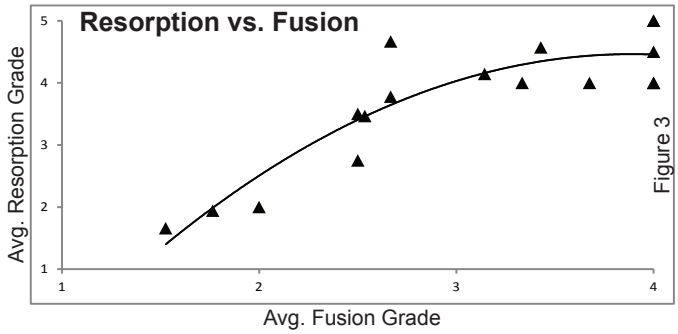
Study of osteoSPAN Bone Graft Substitute in Spine Fusion

OsteoSPAN is a bone graft substitute composed of calcium carbonate/calcium phosphate trellis with interconnected porosity, similar in morphology to cancellous bone. OsteoSPAN is indicated for use as a bone graft extender in posterior spinal fusion. Biogennix sponsored a multi-center, post-market clinical study of osteoSPAN using patient data that was consecutive, blindly selected and retrospectively reviewed by the operating surgeon. The purpose of the study was to evaluate the clinical performance of osteoSPAN bone graft substitute in combination with autogenous bone graft in patients who have undergone posterior lumbar spine fusion. The properties assessed were bone formation via osteoconduction and resorption of the composite ceramic.

The study consisted of 60 patients enrolled at three hospitals by three different spinal surgeons beginning in 2012. Patients averaged 62 years of age and ranged from 22 to 84 years old. There were 33 women and 27 men, 42 of which reported being non-smokers (have never smoked). While this study remains ongoing, the medical records of these patients were historically reviewed by their respective physician with radiographic assessments made of bone fusion and device resorption at postoperative periods extending out over a year. Fusion was graded on a four point scale: Grade 1 (No Fusion), Grade 2 (Incomplete), Grade 3 (Complete) and Grade 4 (Solid). Similarly, resorption of the ceramic was graded on a five point scale: Grade 1 (0-10%), Grade 2 (10-25%), Grade 3 (26-50%), Grade 4 (51-75%) and Grade 5 (76-100%).







At postoperative intervals of six months or less, fusion was typically assessed as being Grade 2 or “Incomplete” fusion (Figure 1). However, from 7 to 10 months following surgery, radiographic assessments generally showed “Complete” fusion with a mean fusion grade of 3.2. Patients evaluated 12 months after surgery were typically considered to have “Solid” fusion with a mean fusion grade of 3.7. In only one case was a patient’s fusion graded as incomplete at 12 months or more post-surgery. In addition to showing increased fusion over time, the study data reveals a strong correlation between the resorption of osteoSPAN and bone fusion (Figure 2 & 3). In half of the final postoperative visits, device resorption was graded as being in the range from 76-100%

This multi-center, retrospectively reviewed clinical study continues to demonstrate that:

- OsteoSPAN is effective when used as a bone graft extender in posterior lumbar spine fusion.
- OsteoSPAN functions as an osteoconductive trellis with radiographically visible bone formation within the fusion mass.
- OsteoSPAN undergoes a gradual resorption that is radiographically visible beginning as early as a few months.
- The resorption of osteoSPAN is correlated to the degree of bone fusion. That is, resorption increases as bone formation increases (Figure 3), presumably due to the interplay of osteoclasts and osteoblasts.

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