BIOGENNIX
SHAPING FUSION

osteoSPAN™
BONE GRAFT SUBSTITUTE

ADVANCED BONE GRAFT SUBSTITUTE

osteoSPAN Spine Fusion Study

osteoSPAN is an advanced bone graft substitute based on Biogennix' innovative TrelCor™ bone graft material. TrelCor consists of a calcium carbonate material with a nanocrystalline surface composed of hydroxycarbano-apatite (HCA). HCA is a mineral that is biomimetically similar to natural bone mineral. The combination of a nanocrystalline surface and an HCA composition results in graft that is actively involved in healing. The osteoSPAN advanced bone graft products consist of TrelCor in a 1-4mm granule or block form. When mixed with autograft, osteoSPAN is indicated for use as a bone graft extender in posterolateral spinal fusion.

Biogennix sponsored a multi-center, post-market clinical study of osteoSPAN using patient data that was consecutive, blindly selected, and retrospectively reviewed. 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. Radiographic fusion and osteoSPAN resorption were assessed.

The multi-site study consisted of a retrospective chart review of 60 patients enrolled at three hospitals by three different clinicians (20 patients per site). Physicians conducted radiographic assessments of 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). At 12 months, a fusion rate was determined with successful fusions being defined by Grade 3 and 4 scores. Similarly, osteoSPAN resorption was graded on a five point scale: Grade 1 (0-10%), Grade 2 (11-25%), Grade 3 (26-50%), Grade 4 (51-75%) and Grade 5 (76-100%).

The results showed increasing fusion scores over time. 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. At 12 months, the fusion rate was 98% (59/60 fusion scores of 3 or 4). In addition, the study data revealed a strong correlation between the resorption of osteoSPAN and bone fusion (Figure 2 & 3).

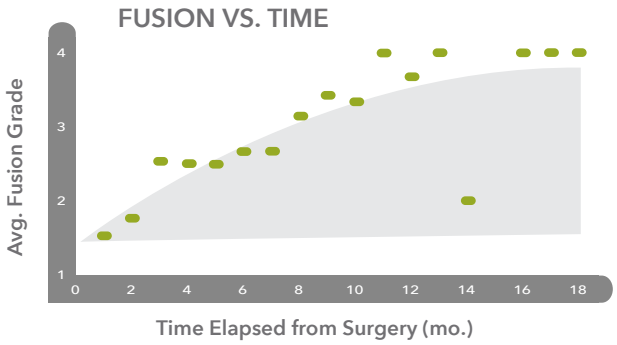

Figure 1

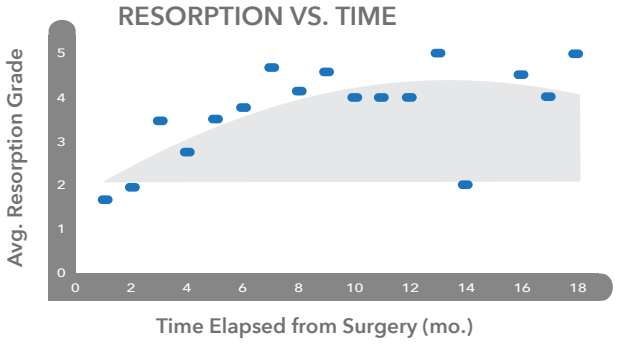

Figure 2

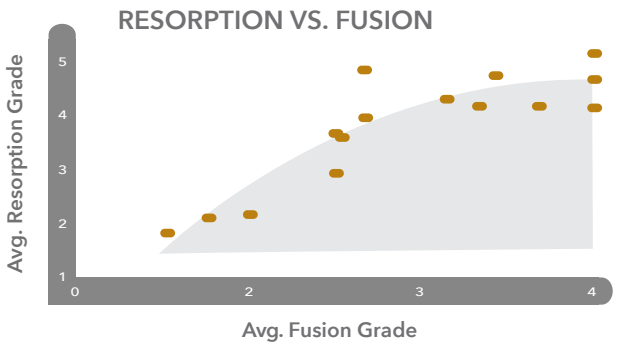

Figure 3

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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