Lumbar Interbody Fusion with Osteosponge® Demineralized Allograft in a Peek Cage as Compared to Fusion with RhBMP-2: Long-term Post Operative Assessment

K. Huntsman¹, S. Scott², M. Berdugo³, G. Juda³, S. Roper³

¹Salt Lake Orthopaedic Clinic, Spine Surgery, Salt Lake City, UT, United States, ²Intermountain Healthcare, Orthopaedics, Salt Lake City, UT, United States, ³Bacterin International, Belgrade, MT, United States

Background context: Several grafting materials can be used in lumbar spinal fusion (i.e. allograft, autograft and BMP-2). To date no studies have compared the use of OsteoSponge® with BMP as an effective and comparable long-term option.

Purpose: OsteoSponge® as a graft material in a lumbar fusion model in conjunction with postero-lateral fusion in single and two-level procedures will be compared to Infuse in a blinded manner to demonstrate equivalency.

Study design: Prospective, blinded two to three year cohort.

Outcome measures: A two sample t-test was utilized to measure long-term Oswestry Disability Index (ODI), SF-36, Visual Analog Scale (VAS), and radiologic findings such as: Disc fusion, screw loosening, breakage or motion; as defined by AP, Lateral, Flexion, and Extension X-Ray films. CT scan imaging of spine including Hounsfield scale units.

Methods: 28 patient sample: 16 patients were randomized to Osteosponge™ and 12 patients to the Infuse group. During the PLIF procedure, OsteoSponge® or Infuse were placed in PEEK cages for anterior fusion. Anterior fusions were accomplished via PLIF procedure and Posterolateral fusions were completed with Actifuse. Clinical and radiologic data were analyzed.

Results: Long-term data shows radiographic and CT scanning of Osteosponge® to be equivalent to BMP-2 in achieving an anterior fusion when used with BMA (bone marrow aspirate) and placed in a PEEK cage. The average X-Ray fusion rating for the OsteoSponge® (OS) group was 3.85 and 3.72 (p=0.17) for the BMP-2 group. Leg pain in the OS group was reported as 2.46 compared to 2.83 for BMP-2 (p=0.21). SF-36 score for OS group was 65.4 and for BMP-2 62.8. ODI scores were 15.9 for OS and in the BMP-2 group 22.1, however the difference was not significant (p=0.45). Housefield unit measurements for fusion density were 194 for OS and 241 for BMP-2 (p=0.12); adjacent level density for OS was 178 and 163 for BMP-2. Back pain for the two groups was not statistically different.

Conclusion: These results suggest that a comparable fusion can be generated with OsteoSponge® with an improved quality of life and without the risk of complications as reported to be associated with the use of BMP-2.