Comparison of Patients Undergoing 1- and 2-level Lumbar Fusions Using Demineralized Bone Matrix (Optecure, Exactech Inc.) as a Bone Graft Extender when Compared with Autograft

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Purpose: This study was designed to evaluate the effectiveness of DBM graft (Optecure, Exactech Inc.) as a bone graft extender when compared to autograft in patients undergoing one or two level fusions.

Study design/setting: Single Blind, Multi-Center, Randomized, Prospective Clinical Study implemented at six US sites.

Methods: Patients suffering from lumbar stenosis and instability, who had failed conservative treatments, were enrolled into the study. All participating centers obtained IRB approval prior to initiation of study procedures. Oswestry Disability Index (ODI), SF-12 patient health surveys, and perceived pain noted on visual analog scales (VAS) were collected preoperatively and at 6-week, 3, 6, 12 and 24-month postoperative time points. Surgical approaches included: posterolateral fusion (PLF), combined posterolateral and interbody fusion (PLF/ILF), and interbody fusion (ILF). Operated levels ranged from L2-S1 and in each case instrumentation was utilized. Anteroposterior, lateral, flexion, and extension radiographs were obtained at each time point. The amount of motion and the quality of the boney fusion was evaluated by an independent radiologist. CT also aided in evaluation of fusion mass at 12-months. Fusion was based on presence of continuous bridging trabecular bone in the interbody or posterolateral fusion, < 5 degree angular motion, and ≤ 3mm translational motion on the flexion/extension radiographs.

Results: Ninety-four patients were enrolled and 82 were randomized. Seventy-six of the patients completed at least 6 months of follow up and were evaluated. Thirty PLF, 18 ALIF, 24 PLF/ILF, and four ILF cases were enrolled into the study. There were 49 1- level (27 DBM, 22 ABG) and 27 two level (17 DBM, 10 autograft) procedures. Intraoperative complications were noted in 7 patients; dural tear (4), pedicle fracture (1), coagulopathy (1), and unspecified (1). Fifty-one percent (20/39) of post-operative complications related to back pain /radiculopathy. Clinically significant improvements in VAS, ODI, and SF-12 measures were noted in both groups when compared to the pre-operative time point; however, there were no statistically significant differences. Distribution of harvested autograft was statistically significant (p=0.003) between the 2 groups; A larger volume of local bone was utilized in the DBM group; 30cc versus11cc in the autograft only group. There were no statistically significant differences in fusion between the DBM and autograft only group at 24 months (p=0.311, respectively). At 24 months the 1- and 2-level rates of fusion were 91% in the Optecure group, versus 87.5% and 81.8%, respectively in the autograft only group.

Conclusions: Near equivalent fusion rates were seen in the autograft and the DBM group and 24 month time points. Near equivalent clinical outcome scores were also recorded between the two groups across all time points. The results support the use of Optecure as a DBM extender in 1- and 2-level lumbar fusions. The use of Optecure as a local autograft extender can potentially decrease the morbidity associated with iliac crest bone graft harvest site.