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12-24 Month Results from a US IDE Trial Evaluating a Lumbar Posterior Dynamic Stabilization (PDS) System
N. Anand1, M. Lorio2, R. Rosemann1
1Cedars-Sinai Medical Center, Los Angeles, CA, USA, 2Neuro-Spine Solutions, Bristol, TN, USA

Introduction: Pedicle screw based PDS systems are intended to offer stability and are used in conjunction with decompression to treat patients with degenerative lumbar stenosis. These devices offer patients an alternative to traditional decompression and fusion when indicated. This study compares clinical outcomes at 12-24 months with preoperative findings for patients treated with Stabilimax® system at one or two levels from two sites of the US IDE trial.

Methods: Patients with leg/back pain due to degenerative spinal stenosis were enrolled in a prospective, randomized clinical trial, and results from 2 of the 20 sites were evaluated. Decompressive surgery was performed at index level(s). Each level(s) was then stabilized with the PDS system. Patients were evaluated preoperatively and at six weeks, 3, 6, 12, 18 and 24 months postoperatively. Outcomes included the following scores: ZCQ-SS (Zurich Claudication Questionnaire-Symptom Severity), ZCQ-PF (Physical Function), ODI (Oswestry Disability Index), VAS-R (Visual Analogue Scale - Right Leg Pain), VAS-L (Left Leg Pain) and VAS-B (Back Pain).

Results: 23 consecutive cases (14 females, 9 males) with mean age of 55 years were enrolled in 2 sites. There were 12 one-level patients & 11 two-level patients. Patient data was available for 21 patients completing 12 month follow-up, with 13 of those patients completing 18 month follow-up and 5 patients completing 24 month follow-up. Preoperatively, patients had significant disability (Figures 1, 2 and 3). There was significant improvement in all outcome measures in comparison to pre-op (p< 0.11) at all time intervals (Figures 1, 2 and 3). There was one device related reoperation for a second look at the instrumentation which was found to be intact. There were four instances of fractured grit-blasted screws, three of which were two level cases; all patients are asymptomatic and are being observed. Grit-blasted screws have been replaced with 2nd generation shot-peened screws.

Discussion: The data shows that the combination of decompression coupled with a PDS device designed to allow near normal Range of Motion (ROM) and InterPedicular Travel (IPT) results in a significant improvement in patient based pain and functional outcomes at 12-24 month follow-up in this group being evaluated.