Clinical: Posterior dynamic pedicular stabilization
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2 Year Results from a US IDE Trial Evaluating a Lumbar Posterior Dynamic Stabilization (PDS) System
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Introduction: Pedicle screw based Posterior Dynamic Systems (PDS) are intended to offer stability and are used in conjunction with decompression to treat patients with degenerative lumbar stenosis as an alternative to traditional decompression and fusion when indicated. This study compares clinical outcomes at 2 years with preop findings of patients treated with the Stabilimax® system at 1 or 2 levels from 2 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. Decompression and stabilization with the PDS system was performed at index level(s). Patients were evaluated preop and at 6 weeks, 3, 6, 12, 18 and 24 months postop. Outcomes included: 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: 28 consecutive patients (17 females, 11 males) with mean age of 55 years were enrolled in 2 sites. There were 17 one-level patients and 11 two-level patients. Patient data was available for 24 patients completing 12 month follow-up, with 17 of those patients completing 18 month follow-up and 14 patients completing 24 month follow-up. Preoperatively, patients had significant disability (Figure 1). There was significant improvement in all outcome measures in comparison to preop (p< 0.11) at all time intervals (Figure 1).

![Functional Outcomes](image)

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 were replaced with 2nd generation shot-peened screws later in the trial. 4 patients have had shot-peened screws with no untoward effect.

Conclusion: The data shows that the combination of decompression coupled with a PDS device designed to allow near normal Range of Motion (ROM) and Inter-Pedicular Travel (IPT) results in a significant improvement in patient based pain and functional outcomes at 2 year follow-up in this case series.

Significance: PDS may be a viable alternative to fusion in patients with lumbar stenosis requiring decompression and stabilization.