

## One year results from a US IDE trial evaluating the Stabilimax NZ™ dynamic stabilization system

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**BACKGROUND CONTEXT:** Pedicle screw based dynamic stabilization systems are designed to offer stability while permitting motion. Panjabi described the Neutral Zone (NZ) as a region of high spinal flexibility around neutral posture. He also postulated that spinal degeneration or injury caused by decompression increases the NZ, and may cause pain. The Stabilimax NZ™ was designed to restore the normal NZ by way of concentric springs and ball-and-socket joints. It is the subject of an ongoing US IDE trial.

**PURPOSE:** This study compares clinical outcomes at 6 (6MO) and 12 (12MO) months with preoperative findings for patients treated with the Stabilimax NZ™ in two IDE sites.

**STUDY DESIGN/ SETTING:** A prospective, randomized multi-center clinical trial. The study treats patients with leg/back pain due to degenerative spinal stenosis arising from one or two adjacent levels.

**PATIENT SAMPLE:** 23 consecutive patients were enrolled in the study at 2 out of the 20 IDE sites.

**OUTCOME MEASURES:** Zurich Claudication Questionnaire (ZCQ) - Symptom Severity (SS) – Range - 0-5, ZCQ - Physical Function (PF) – Range - 0-4, Visual Analogue Scale (VAS) - Right Leg (R) – Range - 0-100, VAS - Left Leg (L) – Range - 0-100, VAS - Back (B) – Range - 0-100, Oswestry Disability Index (ODI) – Range 0-100.

**METHODS:** Decompressive surgery was performed at index level(s). Each level(s) was then stabilized with Stabilimax NZ™. Patients were evaluated preoperatively, and at 6 weeks, and 3, 6 and 12 months postoperatively. Patients will continue to be evaluated up to 24 months.

**RESULTS:** 14 females & 9 males were treated, with mean age of 55 years ( $\pm$  13 years). There were 12 single-level patients & 11 multi-level patients. 23 patients had completed 6MO follow-up, with 16 of those patients completing 12MO follow-up. Preoperatively, patients had significant disability (ZCQ-SS: 3.5 (sd 0.6), ZCQ-PF: 2.6 (0.4), ODI: 41(14), VAS-R:45.1 (31.1), VAS-L: 57.0 (28.7), VAS-B: 46.7 (28.1)). At both six and twelve months, there was a significant improvement in all outcome measures in comparison to pre-op at  $p < 0.05$ . By twelve months, the average ZCQ-SS score had improved 37% relative to pre-op. Likewise, ZCQ-PF had improved by 26%, ODI had improved by 47%, the VAS-R had improved by 63%, the VAS-L had improved by 79% and VAS-B had improved by 55%. There was one device related reoperation for a second look at the instrumentation which was found to be intact. There were two instances of fractured screws; the patients were asymptomatic and are being observed.

**CONCLUSIONS:** Initial clinical outcomes of a cohort from a US IDE trial are presented. The data shows that the combination of decompression coupled with the Stabilimax NZ™ dynamic stabilization system results in a significant improvement in patient based on pain and function outcomes at the one year timeframe. The device related complication rate was less than ten percent.