Abstract: 255

3-year Results from a Prospective, Randomized IDE Study of the Dynesys® Dynamic Stabilization System

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Objectives: Patients with radicular pathology due to spondylolisthesis or stenosing lesions are typically treated with decompression and spinal fusion. A posterior stabilization system has been developed to stabilize the segment without the need for fusion. Preliminary long-term outcomes from a cohort of patients in an IDE clinical trial examining dynamic stabilization with the Dynesys Dynamic Stabilization System are being reported. The purpose of this study is to evaluate and compare long-term clinical outcomes following posterior dynamic stabilization (DS) or instrumented, posterolateral fusion (PLF).

Methods: Patients enrolled in this study exhibited lateral or central spinal stenosis, degenerative spondylolisthesis or retrolisthesis (up to Grade I), and were appropriate for instrumented fusion at 1-2 contiguous spinal levels (L₁-S₁). Participants randomly received treatment with DS or instrumented PLF (2:1 ratio) and were evaluated pre-operatively and post-operatively at 3-weeks, 3-, 6-, 12-, and 24-months, and annually thereafter. 36-month follow-up was collected for a cohort of patients enrolled in the IDE clinical trial and is being reported.

Results: At 36M, the DS cohort reported 55.6mm improvement in leg pain scores, a reduction in ODI scores of 31.8, 28.6mm improvement in back pain, and 92% of subjects either improved or maintained their level of neurological success compared to pre-op assessment. In the PLF cohort, leg pain scores improved by 51.5mm, ODI scores were reduced by 27.3, back pain scores improved by 21.7mm, and 96% of subjects reported improved or maintained neurological success compared to pre-op evaluation. VAS back pain, patient satisfaction, and likelihood to recommend scores reported at 36-months were statistically significant between groups (p< 0.05). Additionally, 36M data shows a 14.5 point and 7.3 point improvement in SF-12 Physical Component and Mental Component scores, respectively, for the DS cohort. Similar results were reported in the PLF group. The revision rate for the DS group was 9.9% and 10.5% for the PLF cohort.

Conclusions: Preliminary long-term clinical outcomes from an IDE clinical trial are reported. At 36M, the subjects implanted with the Dynesys Dynamic Stabilization System show an improvement in ODI, Neurological Success, leg pain and SF-12 scores and a significant improvement in VAS back pain, VAS patient satisfaction, and VAS likelihood to recommend scores compared to the control group.