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Stratification by Indication Analysis of the *Dynesys*® Dynamic Stabilization System IDE Study 24-month Results

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Objectives: The results of a prospective, randomized IDE study examining dynamic stabilization with the *Dynesys*® Dynamic Stabilization System were analyzed based on the primary indications of central stenosis, instability (spondylolisthesis and retrolisthesis), and lateral stenosis. This stratification analysis includes the 24-month outcomes of 217 patients following dynamic stabilization (DS) and 89 patients treated with 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.

Results: Central stenosis: The mean reduction in VAS leg pain scores in patients treated with DS was 52.1mm, mean ODI scores were reduced 23.8 from baseline, the composite neurological status success score was 90%, 9% of patients required an additional surgical procedure, and 100% of patients reported radiographic success. Patients in the control cohort reported a mean reduction in VAS leg pain scores of 51.4mm, ODI reduction of 30.7, neurological success was 84%, 3% of patients required an additional surgical procedure, and 89% of patients presenting with central stenosis reported radiographic success.

Instability: Patients treated with DS reported a reduction in mean VAS leg pain scores of 62.0mm, mean ODI scores were reduced by 32.4, neurological success was 94%, and the rate of additional surgical procedures was 9%. The PLF cohort reported mean VAS leg pain scores were reduced by 47.4mm, 24.2 reduction of mean ODI scores, neurological success was 82%, and an 8% rate of additional surgical procedures. The radiographic success for patients treated with DS was 98% compared to 61% for the control cohort. The reported differences between cohorts presenting with instability were statistically significant for VAS leg pain and ODI scores, neurological success, and radiographic success (p< 0.05).

Lateral stenosis: The reduction in mean VAS leg pain scores for patients in the DS cohort was 51.3mm, mean ODI scores were reduced 29.0 from baseline, 92% of patients reported neurological success, 8% of patients reported an additional surgical procedure, and 98% of cohort reported radiographic success. Patients treated with PLF reported a reduction in mean VAS leg pain scores of 40.3mm, mean ODI scores were reduced by 17.7, neurological success rate was 88%, rate of additional surgical procedures was 17%, and an 88% radiographic success rate.

Conclusions: The 24M data stratified by indication show clinical improvement in patients treated with the *Dynesys* Dynamic Stabilization System and presenting with central stenosis, instability, and lateral stenosis. This improvement was reported in VAS leg pain scores, ODI scores, neurological success rate, and radiographic success rate. The rate of additional surgical procedures was not significantly different between cohorts for the three indications analyzed. The use of the *Dynesys* System in patients suffering from instability showed significantly greater improvement in VAS leg pain scores, ODI scores, neurological success and radiographic success compared to PLF.