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Clinical Assessment of Adjacent Level Effects (ALE) Induced by Stabilimax Lumbar Posterior Dynamic Stabilization (PDS) Implant through Measurement of Range of Motion (ROM) and InterPedicular Travel (IPT)
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Introduction: One goal of PDS systems is to preserve quality and quantity of motion at index level and thereby reduce ALE in the long run. The purpose of this study is to measure PreOp and PostOp quantity (ROM) as well as quality of motion (IPT and IPT/ROM) at adjacent levels in patients undergoing surgical treatment for lumbar spinal stenosis with application of Stabilimax PDS system as part of an IDE study.

Methods: Maximum voluntary flexion-extension (F-E) radiographs were obtained PreOp and PostOp (12 months) from 49 patients as part of an ongoing IDE study of a pedicle screw-based dynamic stabilization device. All patients were treated at a single level. The F-E radiographs were assessed using validated, computer assisted methods accurate to better than 1 degree and 1 millimeter. Interpedicular distance was measured between the mid-pedicular axes of adjacent vertebrae using points slightly posterior to the superior articular process of each vertebra, representing the typical location of the junction between the posterior rod and pedicle screw in dynamic systems. ROM was measured as the change in angle between adjacent endplates from flexion to extension. Interpedicular travel (IPT) was calculated as the change in interpedicular distance from flexion to extension. ROM and IPT were evaluated at the adjacent levels above and below the treated level.

Results: The average age of patients was 58 years (range: 35-82), including 22 males and 27 females. Out of 92 total adjacent levels, L3-L4 and L5-S1 each represented approximately 40% of the sample size. ROM and IPT at adjacent levels were non-normally distributed, so median and range values are reported. PreOp, the median ROM was 4° (range 14°) and median IPT was 2.7 mm (range 10 mm). The ratio of IPT to ROM PreOp was 0.68. At 12 months, the median PostOp ROM was 4.4° (range 19.4°) and median PostOp IPT was 2.8 mm (range 15.5 mm). The ratio of IPT to ROM was 0.64. Median changes in ROM and IPT were 0.2° and 0.2 mm respectively. PreOp and PostOp data sets were compared using Wilcoxon Signed-Rank Test (p< 0.05). For each patient, the “difference in PostOp and PreOp values” was plotted as a percentage frequency distribution graph (Figure 1).

Discussion: The results demonstrated that there was no change in ROM and IPT at the adjacent level following decompression and application of the Stabilimax. As one of the goals of PDS systems is protection of the adjacent level, these data support that Stabilimax had no significant impact on adjacent level kinematics at one year follow-up. Longer term data is necessary to confirm this positive outcome.