An Association between the Center of Rotation and Clinical Outcome in Patients Implanted with a Viscoelastic Lumbar Total Disc Replacement

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Purpose: To determine if correlations exist between center of rotation and clinical outcomes in patients implanted with a viscoelastic total disc replacement (VTDR).

Introduction: Fifty patients with single-level, symptomatic lumbar DDD at L4-S1 were enrolled in a clinical trial of the Freedom® Lumbar Disc at three European sites. Patients were assessed clinically and radiographically at baseline and at 6 weeks, 12 weeks, 6 months, 1 year and 2 years. Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) pain questionnaires were used to assess clinical outcomes.

The VTDR studied is an elastomeric one-piece design with a core that closely replicates the normal biomechanical characteristics of a human lumbar disc. The polymer’s biomechanical properties allow motion in all directions while providing load transfer and shock absorption. The one-piece design allows restoration of disc height and sagittal angle.

Methods: A comprehensive, independent review of the radiographic and clinical outcomes of the VTDR study was conducted and analyzed for correlations. Data from preoperative through 2 years were available. ODI scores were classified as evidence of achieving a minimal clinically significant difference (MCID) if the ODI score was at least 15 points lower than at preoperative. The center of rotation (COR) was calculated for the index levels. The coordinate system for COR has an x-axis that is colinear with the superior endplate of the inferior vertebra. The origin is at the center of the endplate, and the y-axis is oriented so that a positive y-coordinate is inferior to the endplate. The COR for the index level was also compared to COR data for an asymptomatic population. Each COR coordinate was classified as abnormal if outside of the 95% confidence interval for an asymptomatic population.

Results: Based on the latest available follow-up for each patient, 69% of the patients had achieved at least a 15 point ODI improvement, and 76% of the patients achieved at least a 10 point ODI improvement. At the latest available follow-up, 78% of cases had a normal COR-X and 92% had a normal COR-Y. Based on latest available timepoint for each patient, the improvement in ODI score was significantly better for patients with a normal anterior-posterior (AP) coordinate of the COR (P=0.03). Anterior COR corresponded with anterior placement of the device in the disc space, and patients were almost 7 times less likely to get at least a 15 point improvement in the ODI score if the COR was positioned too anteriorly. This effect can also be seen in the average AP coordinate of the COR for patients who achieved the MCID in ODI. No correlation existed for the cranial-caudal coordinate of the COR.

Conclusions: A viscoelastic TDR can restore a normal COR. This is the first study to show that a normal COR correlates to a clinically relevant decrease in patient disability.

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.