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50-Patient European Study of a Viscoelastic Total Disc Replacement
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Purpose: To evaluate the clinical and radiographic outcomes of a viscoelastic one-piece total disc replacement.

Introduction: Surgical management of symptomatic lumbar degenerative disc disease (DDD) currently consists of fusion or implantation of a first generation total disc replacement (TDR). First generation lumbar TDRs have either a metallic or UHMWPE core with a ball and socket design. This study is the first to evaluate an elastomeric one-piece TDR in a 50-patient European study.

The viscoelastic TDR (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. This device is designed to match the morphology of the vertebral body endplates, with features for short and long term fixation. The one-piece design allows restoration of disc height and sagittal angle. The surgical technique and design allow for a large, subsidence resisting footprint while preserving the outer annulus for additional segmental stability.

Methods: 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. Regulatory approvals and patient consents were obtained prior to patient enrollment. Preoperatively, all patients were unresponsive to at least 6-months of non-operative therapy. Patients were assessed clinically and radiographically at 6 weeks, 12 weeks, 6 months, 1 year and 2 years, and have planned annual follow-up assessments. Oswestry Disability Index (ODI), Visual Analogue Scale (VAS) and SF-36 questionnaires were used to assess clinical outcomes.

Results: Twenty-eight males and twenty-two females were enrolled in the study. The average age of patients was 39.7 (23 to 61). The operative level was L4/L5 in 13 patients and L5/S1 in 37 patients. There were no intra-operative complications. Quantitative radiographic assessment indicates that the VTDR restores and maintains a physiologically appropriate disc height and angle (lordosis), while providing flexion/extension range of motion and translation similar to those provided by the natural disc. Mean preoperative ODI scores decreased from 48% pre-operatively to 23% at two years follow up. Mean VAS low back pain scores decreased from 7.1 cm pre-op to 2.7 cm at two years. Median scores (Figure 1) indicate that half of the patient population have ODI scores below 13% and VAS back pain scores below 0.5 cm.

[Figure 1: Median VAS and ODI Scores]

Conclusions: The results of this 50-patient study demonstrate that the VTDR performs clinically and radiographically as intended for the treatment of symptomatic lumbar DDD.

CAUTION - Investigational device. Limited by USA Federal law to investigational use.