Clinical: Interspinous and ligamentoplasty

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Multi-center Clinical Experience with the FLEXUS™ Interspinous Spacer

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Purpose: A prospective, randomized IDE clinical trial is being conducted to assess the safety and effectiveness of the FLEXUS™ Interspinous Spacer for the treatment of lumbar spinal stenosis. This IDE study compares the clinical results of patients treated with the investigational FLEXUS™ device as compared to patients treated with the PMA-approved XSTOP device. Pooled data from the four top enrolling are presented.

Methods: The clinical trial is being conducted at up to 20 sites across the United States. Patients are randomized 1:1 to either the investigational FLEXUS™ device or the control XSTOP treatment. Patients suffering from lumbar spinal stenosis as defined by leg, buttock or groin pain, with or without back pain, that relieves during flexion, at one or two contiguous levels, were enrolled in the study. Zurich Claudication Questionnaire (ZCQ) scores, Visual Analog Scale (VAS) back and leg pain, SF-36 Health Status Survey, Owestry Disability Index (ODI) scores and patient satisfaction are collected pre-operatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. A total of 69 patients have reached the 12 month follow-up visit, 36 treated with FLEXUS™ and 33 with XSTOP. Outcome data from these patients are presented.

Results summary: Both treatment groups demonstrated an improvement in ZCQ scores at 12 months postoperative. Average ZCQ (symptom severity) for FLEXUS™ patients was 3.0 (±0.6) preoperatively, reduced to 1.9 (±0.9) at 12 months, compared to XSTOP patients with average scores of 3.2 (±0.6) at preop and 2.0 (±0.7) at 12 months. Average ZCQ (physical function) for FLEXUS™ was 2.5 (±0.4) preoperatively and 1.6 (±0.7) at 12 months, compared to 2.5 (±0.6) preoperatively and 1.5 (±0.5) at 12 months for XSTOP. Average ZCQ (satisfaction) was 1.7 for FLEXUS™ and 1.5 for XSTOP. VAS back and leg pain scores showed improvement in both cohorts. Average VAS back pain scores for FLEXUS™ were 54 (±31.7) preoperatively, reduced to 25.7 (±34.5) at 12 months, in comparison with XSTOP with 51 (±30.8) and 14.8 (±24.8), respectively. Average VAS right and left leg pain scores dropped significantly from preoperative values by the 12 month visit. Similarly, ODI and SF-36 MCS improved for both groups at 12 months compared to baseline. Five investigational FLEXUS™ patients underwent removals and laminectomies were then performed; four of these removals were due to ongoing or recurrent back and/or leg pain and one as a result of a spinous process fracture. Two XSTOP devices were removed due to ongoing or recurrent back and leg pain. Two FLEXUS™ patients received supplemental fixation at the treated level due to radiculopathy and continued back pain.

Conclusion: The FLEXUS™ and XSTOP treatment groups experienced improvement in both pain and function at 12 months as compared to the pre-operative baseline. Interspinous distraction appears to be a viable alternative for the treatment of spinal stenosis. Continued follow-up data is needed to determine long-term safety and efficacy of the FLEXUS™ Interspinous Spacer.