Functional Outcomes Following the Total Facet Arthroplasty System (TFAS) in the Treatment of Degenerative Lumbar Spinal Stenosis

B. Hierlmeier¹, S. Webb², A.E. Castellvi³
¹Florida Orthopaedic Institute, Tampa, FL, United States, ²Florida Spine Institute, Tampa, FL, United States, ³Florida Orthopaedic Institute, Center for Spinal Disorders, Tampa, FL, United States

Study design: Prospective clinical trial.
Aim: To compare patients self reported preoperative pain, health related quality of life, satisfaction, function and symptom severity, to postoperative evaluations at selected intervals.

Summary of background data: Total Facet Arthroplasty System (TFAS) is a non-fusion investigational device that can be used in the treatment of spinal stenosis and degenerative disease of the facets of L3-4 and L4-5. There have been no studies to date on the clinical outcomes of (TFAS) in terms of Zurich Claudication Questionnaire (ZCQ), Visual Analog Scales (VAS), Medical Outcomes Study short form (SF-36) and satisfaction with surgical results.

Methods: 24 patients (16 female, 8 male) were implanted with the TFAS with wide decompressive laminectomy and bilateral facetectomy at the stenotic level and followed in a prospective clinical trial. Patients were screened preoperatively and followed at 1, 3, 6, 12, 24 and 36 months postoperatively. Data collection included the Zurich Claudication Questionnaire (ZCQ), Visual Analog Scales (VAS) for back and leg pain, Medical Outcomes Study short form (SF-36) and a Patient Satisfaction Questionnaire.

Results: The mean age of the patients was 71 years (range 85-54). There were 16 (66.7%) female: 8 (33.3%) male. The mean BMI was 30.06 kg/m². Data collected at most recent follow up was compared to preoperative scores. 79.2% (19/24) had clinically significant improvement in both function and symptoms. 95.8% (23/24) of these patients with TFAS had significant improvement in their Leg Pain. 81% (17/21) of these patients with TFAS had clinically significant improved in their back pain. Three patients not included due to having back pain scores of less than 2 on a scale of 1-10 which were to low to be considered clinically significant. Of these patients none had an increase in back pain after surgery. Significant improvement in the quality of life was seen in patients following TFAS surgery.

Conclusions: Total Facet Arthroplasty System device has shown to be effective in relieving clinical symptoms of lumbar spinal stenosis and this improvement in back and leg symptoms translates to an improvement in the patients’ quality of life. Although this IDE study has been terminated, patient outcomes and satisfaction continue to be excellent. Hopefully this data will resuscitate the advancement and continue the development of the Total Facet Arthroplasty System.