Clinical Outcomes from a Prospective Study on Archus Total Facet Arthroplasty System for Treatment of Lumbar Stenosis with Degenerative Spondylolisthesis

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Purpose: To report clinical outcome on a subgroup of patients with lumbar stenosis and degenerative spondylolisthesis who participated in a randomized prospective trial on the Archus Total Facet Arthroplasty System (TFAS).

Method: Data was obtained from a subgroup of patients who were a part of a multi-center prospective randomized controlled trial on TFAS. Ten patients with lumbar stenosis and grade 1 degenerative spondylolisthesis underwent total facet arthroplasty at one institution between April 2007 to January 2009. Outcomes were measured based on clinical examination, questionnaires (including the Zurich Claudication Questionnaire, Visual Analog Scale for Pain, Oswestry Disability Index), and radiographs. Data were collected at pre-operative, 1, 3, 6, 12, and 24 month post-operative visits. Adverse events occurred during this period were also reported.

Results: Ten patients ranging from 50 to 74 years of age (mean age 62.6 years), who underwent total facet arthroplasty at L4-5 after decompression, were followed for 2 years. The Zurich Claudication Questionnaire (ZCQ) Symptom score showed statistically significant improvement (p< 0.05) from baseline at 1, 3, 6, and 12 months. The mean Visual Analog Scale (VAS) for back pain also showed significant improvement (p< 0.05) at 1, 3, 6, and 12 months, while the VAS for leg pain had improvement (p< 0.05) at all post-operative visits. The mean Oswestry Disability Index (ODI) did not demonstrate any statistically significant improvement (p>0.05). Neurologically, 2 patients developed dysesthesia post-operatively at L2 distribution. The post-operative segmental angular motion (SAM) measured on lateral flexion and extension radiographs taken at each visit demonstrated no significant change (p< 0.05) from preoperative measurement.

Four catastrophic adverse events were recorded which included 2 stem breakages, 1 hardware loosening and migration, and 1 cement extrusion into the canal. Three of the 4 patients had BMI (mean 38.2) at the upper end of the spectrum (group mean 33.0), and all 4 patients required subsequent conversion to fusion.

Conclusion: The Archus TFAS has demonstrated reasonable pain relief and functional improvement during the 2 year followup period. However, given the high incidence of catastrophic adverse events (40%), its safety is a serious concern. The risks of this innovative device outweigh its benefits and short-term success, and is not currently recommended for the treatment of lumbar stenosis with degenerative spondylolisthesis.