Abstract: 155

Clinical Outcomes for Worldwide Cohort of 106 Lumbar Spinal Stenosis Patients Treated with ACADIA™


1Spine Colorado, Durango, CO, USA, 2Spine Group Beverly Hills, Beverly Hills, CA, USA, 3Central Texas Spine Institute, Austin, TX, USA, 4Greater Baltimore Medical Center, Baltimore, MD, USA, 5Albany Medical Center, Albany, NY, USA, 6Spine Midwest Research, Jefferson City, MO, USA, 7Hospital Servidor Publico Estadol, Sao Paulo, Brazil, 8HSK, Dr. Horst Schmidt Klinik, Wiesbaden, Germany, 9National Centre of Spine Surgery, Budapest, Hungary, 10The Spine Institute, Loveland, CO, USA, 11OrthoCarolina, Charlotte, NC, USA, 12Neuro-Spine Solutions, Bristol, TN, USA, 13Charleston Brain & Spine, Charleston, SC, USA, 14Fort Wayne Orthopaedics, Fort Wayne, IN, USA, 15Desert Orthopedic Center, Rancho Mirage, CA, USA, 16Springfield Neurological & Spine Institute, Springfield, MO, USA, 17Cedar Sinai Spine Center, Santa Monica, CA, USA, 18The Center for Sports Medicine & Orthopedics, Chattanooga, TN, USA

Introduction: Patients with lumbar radiculopathy or neurogenic claudication secondary to lumbar stenosis and/or spondylolysis are often treated with laminectomy and concomitant segmental stabilization. Lumbar arthrodesis is the current standard of care for achieving segmental stability however changes in lumbar biomechanics due to the elimination of motion at the index level have the potential to accelerate degenerative changes at adjacent levels. ACADIA™, a posterior non-fusion device, may provide the required stability while also preserving the natural balance of forces in the lumbar spine, thus reducing the risk of accelerated degenerative changes at adjacent levels. This paper reports the clinical outcomes from a worldwide cohort of stenosis patients treated with ACADIA™.

Methods: Eighteen centers participating in multiple OUS and US clinical trials enrolled 106 patients diagnosed with symptomatic lumbar stenosis at L3/4, L4/5 and/or L5/S1. Decompression of the neural elements was achieved by performing complete bilateral facetectomies along with the resection of the pars intra-articularis. Pedicle screws were placed and implant bone beds were prepared with specialized instrumentation on the dorsal aspect of each pedicle. Articulating facet implants were attached to pedicle based screws and a cross connector was applied. Outcome measures including Oswestry Disability Index (ODI), Visual Analog Scale (VAS) pain scores for the back and legs and the Zurich Claudication Questionaire (ZCQ) were recorded. Patient follow-ups were conducted at 6 weeks, 3, 6, 12 and 24 months.

Results: Patients ranged in age from 34 to 82 years (mean age of 60 years). The mean BMI was 29 kg/m². Mean operative time, blood loss and hospital stay were 213 minutes, 481 mL, and 3.5 days, respectively. The L4/5 level was treated in 87.5% of the patients while the L3/4 and L5/S1 levels comprised 8.7 and 3.8% of the procedures, respectively. The most frequent complications were dural tears (15.1%), worsening pain due to stenosis (4.7%) and wound infection or dishiscence (3.8%). The mean improvement in ODI was 33 points at 3 months, 36 points at 6 months and 44 points at 12 months. The mean VAS back pain fell from 63 mm at pre-op to 16 mm at 12 months. The VAS right and left leg pain scores also showed improvement falling from 57mm to 12mm and 59 mm to 18 mm at 12 months, respectively. The mean ZCQ symptom severity score fell from 3.54 pre-operatively to 1.57 at 6 months. The mean physical function score fell from 2.78 to 1.39 at 6 months and the patient satisfaction score was 1.37 at 6 months. No device related adverse events or re-operations have been observed in any of the US or OUS cohorts.

Discussion: Perioperative measures and complication rates for ACADIA™ are similar to those published for decompression with posterior fusion. This worldwide cohort demonstrated significant improvements in functional and pain outcome measures at all post-operative time points across a large and varied group of investigators. While none of the patients in this cohort have required additional surgery, long-term follow-up will reveal whether or not ACADIA™ reduces the incidence of adjacent segment disease when compared with fusion.