Introduction: Patients suffering from neurogenic claudication or lumbar radiculopathy secondary to lumbar spinal stenosis and/or instability are often treated with surgical decompression and segmental stabilization. Spinal arthrodesis is the current standard of care for restoring 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™, an anatomic facet replacement device, may provide the required stability while also preserving the natural balance of forces in the lumbar spine, thus mitigating the risk of accelerated degenerative changes at adjacent levels. The interim perioperative and clinical outcome data for the ACADIA™ prospective, randomized FDA IDE pivotal trial is reported herein.

Methods: Patients diagnosed with symptomatic lumbar spinal stenosis at L3/4, L4/5 and/or L5/S1 received the ACADIA™ device at a single level. Bilateral facetectomies and laminotomies were performed to achieve decompression of the neurovascular structures. Pedicle screws were placed and implant bone beds were prepared on the dorsal aspect of each pedicle with specialized instrumentation. Articulating facet implants were fixed to the pedicle screws and a cross connector was attached. Outcome measures including Oswestry Disability Index (ODI), Visual Analog Scale (VAS) pain scores for the back and legs and the Zurich Claudication Questionnaire (ZCQ) were recorded at baseline, 6 weeks, 3, 6, 12 and 24 months.

Results: Ninety-one patients at 16 centers have received the investigational device with 86 and 41 patients completing the 3 and 12 month follow-ups, respectively. Training cases accounted for 20 patients while 71 patients were randomized to ACADIA™. Patients ranged in age from 34 to 81 with a mean age of 60. The mean BMI was 30 kg/m². Mean operative time, blood loss and hospital stay were 172 minutes, 387 mL, and 2.7 days, respectively. The L4/5 level was treated in 84.6% of the patients while the L3/4 and L5/S1 levels comprised 8.8 and 6.6% of the cases, respectively. The mean ODI improvement was 29 points (63%) and 33 points (70%) at 3 and 12 months, respectively. The mean VAS back pain improvement was 52 points (74%) and 55 points (79%) at 3 and 12 months, respectively. The mean VAS leg pain improvement was 66 points (84%) and 72 points (89%) at 3 and 12 months, respectively. The mean ZCQ symptom severity improvement was 1.73 points (66%) and 1.72 points (66%) at 3 and 12 months, respectively. The mean ZCQ physical function improvement was 1.21 points (69%) and 1.22 points (71%) at 3 and 12 months, respectively. The ZCQ patient satisfaction scores were 1.36 and 1.37 at 3 and 12 months, respectively.

Discussion: The perioperative results for ACADIA™ are comparable to published data for decompression with instrumented posterolateral fusion. Large early improvements in functional and pain outcome measures were seen even at 3 months and maintained out to 12 months. While this interim data is strong, long-term follow-up is needed to determine whether or not ACADIA™ reduces the incidence of adjacent segment disease when compared with fusion.