

ASIPP 12th Annual Meeting

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Abstract Title:

MiDAS I (*mild*® Decompression Alternative to Open Surgery): 12-week Follow-up of a Prospective, Open Label, Multi-Center Clinical Study

Background:

Lumbar spinal stenosis with resultant pain and reduced mobility is a common problem that can be caused by many factors. Prominent factors include hypertrophic ligamentum flavum, facet hypertrophy, and disc protrusion. Patients in this Study were treated with *mild*®, a new commercially available minimally invasive lumbar decompression procedure. Using a dorsal approach, the *mild* procedure focuses on partial resection of the hypertrophic ligamentum flavum with bone resection adjacent to the ligamentum flavum. The procedure is performed under fluoroscopic imaging with minimal disruption of surrounding muscular and skeletal structure.

Objective:

To assess the patient safety and Patient Reported Outcomes (PRO) of the *mild* lumbar decompression procedure when used to treat symptomatic lumbar spinal stenosis.

Study Design: Multi-center, open label, prospective clinical study.

Setting: Fourteen US spine specialist practices.

Methods: Between July 2008 and January 2010, 78 patients were enrolled in the MiDAS I Study and treated with the *mild* procedure for lumbar decompression. Of these patients, twelve-week follow-up was available for 73 patients.

Outcome Assessment: Validated outcomes instruments including Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2® Health Survey were used. Safety has been assessed by records of device or procedure-related

adverse events. Outcomes were assessed at baseline, and weeks one, six and twelve post-treatment. The focus here is the week twelve data.

Results: At twelve weeks, the MiDAS I Study patients achieved significant reduction of pain as measured by VAS, ZCQ and SF-12v2. In addition, improvement in physical function and mobility as measured by ODI, ZCQ and SF-12v2 was significant in this Study. No *mild* device or procedure-related serious adverse events were reported in this patient cohort.

Conclusions: Based on three-month data from this 73 patient cohort, the *mild* procedure is a safe and effective method for improving mobility and achieving reduction in pain due to lumbar spinal stenosis.