

**ASRA 2010 Annual Pain Medicine  
Meeting and Workshops**

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**Abstract Title:**

MiDAS I (*mild*<sup>®</sup> Decompression Alternative to Open Surgery): Comprehensive Follow-up of a 78 Patient Prospective, Open Label, Multi-Center Clinical Study

**Background:**

Lumbar spinal stenosis (LSS) with resultant pain and reduced mobility is a common problem often caused by many factors. Prominent factors include hypertrophic ligamentum flavum, facet hypertrophy, and disc protrusion. MiDAS I patients were treated with *mild*, a new commercially-available lumbar decompression procedure. Using a dorsal approach, the minimally invasive *mild* procedure focuses on partial hypertrophic ligamentum flavum resection with adjacent bone resection. The procedure is performed under fluoroscopic imaging with only slight muscular and skeletal structure disruption.

**Objective:**

To assess device and procedure safety and Patient Reported Outcomes (PRO) following *mild* treatment and to describe the four validated outcomes instruments utilized in the study.

**Methods:**

Between July 2008 and January 2010, 78 patients were treated for LSS in the MiDAS I Study. Validated outcomes instruments including Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2<sup>®</sup> 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, twelve and twenty-six post-treatment and will be presented for Week 26.

**Results:**

At six months post-treatment, the MiDAS I Study patients achieved statistically and clinically significant reduction in 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 statistically significant and clinically relevant. These data are remarkable in that a significant positive

response was achieved in all four validated outcomes instruments. No *mild* device or procedure-related serious adverse events were reported in this patient cohort.

**Conclusions:**

Based on six-month data, the *mild* procedure is a safe, effective method for improving mobility and achieving reduction in pain due to lumbar spinal stenosis.

**Key Words:**

Spine, decompression, fluoroscopy, *mild*, stenosis, ligamentum flavum