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Abstract Submission

Author:

David L. Caraway, M.D., Ph.D.
St. Mary's Pain Relief Center, Huntington, WV

Abstract Title:

MiDAS I (*mild*[®] Decompression Alternative to Open Surgery): 26-week Follow-up of a 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 minimally invasive interlaminar decompression procedure. Using a dorsal approach, the *mild* procedure focuses on partial hypertrophic ligamentum flavum resection with adjacent bone resection. The procedure is performed under fluoroscopic imaging with minimal muscular and skeletal structure disruption.

Objective:

To assess patient safety and Patient Reported Outcomes (PRO) following *mild* treatment.

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[®] 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. The focus here is Week 26 data.

Results:

At twenty-six weeks, the MiDAS I Study patients achieved statistically significant reduction in pain as measured by VAS, ZCQ (t-test, $p < .0001$) and SF-12v2[®] (95% CI). In addition, improvement in physical function and mobility as measured by ODI, ZCQ (t-test, $p < .0001$) and

SF-12v2 (95% CI) was statistically significant. Mean ZCQ patient satisfaction was 1.97 or 'satisfied' (1 = very satisfied, 4 = very dissatisfied). 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