

MiDAS I (*mild* Decompression Alternative to Open Surgery): 12-week follow-up of a prospective, open label, multi-center clinical study

by: david I. caraway, md, ph.d.

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.

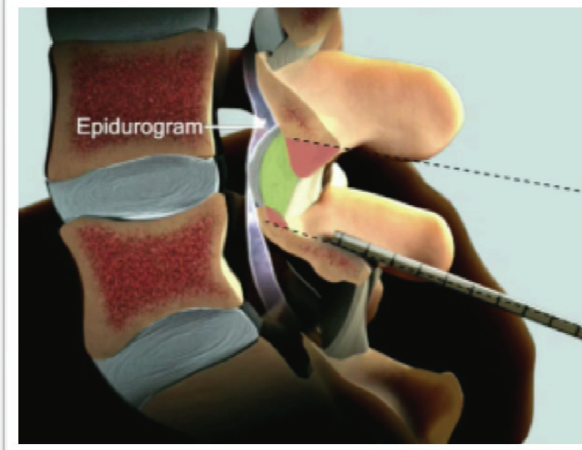
results

At twelve weeks, the MiDAS I Study patients achieved a statistically 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 statistically 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 canal stenosis.

mild Maintains Structural Stability



Decompression

- Removes only a small portion of the lamina
- Debulks the ligamentum flavum
- Leaves anterior ventral fibers of the ligament intact
- 5.1 mm *mild* Portal minimizes tissue and muscle disruption

Supporting Structures Left Intact

- Spinous process
- Facets
- Majority of the lamina

Primary Considerations

Patient Inclusion Criteria	Patient Exclusion Criteria
<ul style="list-style-type: none"> Symptomatic LSS with dorsal element hypertrophy Prior failure of conservative therapy Radiologic evidence of LSS/ligamentum flavum thickness > 2.5 mm Dural sac cross sectional area reduced (typically < 100 mm²) Anterior listhesis < 5.0 mm Able to walk at least 10 feet unaided before being limited by pain Available to complete required follow-up visits Able to understand and give informed consent 	<ul style="list-style-type: none"> Prior surgery at intended treatment level History of recent spinal fractures with concurrent pain symptoms Disabling back or leg pain from causes other than LSS Significant/symptomatic disc protrusion or osteophyte formation Excessive/symptomatic facet hypertrophy Bleeding disorders; use of anti-coagulants within 3 days of procedure Use of ASA and/or NSAID within 5 days prior to treatment Epidural steroids within prior 3 weeks of procedure Inability of the patient to lie prone with anesthesia support Potential wound healing pathologies Pregnancy

Outcome Measures

- mild* procedure completed/no technical/patient complications
- Acceptable safety - consistent with other similar procedures
- Patient success - supported by validated questionnaires
 - Leg/Back pain measured by a 10-point visual analog scale (VAS)
 - Function measured using Oswestry Disability Index (ODI) and Zurich Claudication Questionnaire (ZCQ)
 - Quality of Life Physical Component Score (PCS) as measured by the SF-12v2®
- Changes in neurological status determined by physical examination

Success Goals

- mild* procedure completed as planned
- Mobility improvement of at least one category on ODI
- Mobility improves 15 points on ODI (The FDA has suggested a minimum 15-point change from baseline in ODI score is clinically significant)
- VAS pain score improves minimum of 2 points
- No *mild* device/procedure Significant Adverse Events (SAEs)
- No re-operations or additional LSS-directed treatments required

Demographics & Length of Stay (n=73)

Demographics

61.6% Male, 38.4% Female

Length of Stay

51% Same Day Discharge, 49% One Night Stay

Levels Treated[†] (n=73)

Treated Levels

L1-L2, L2-L3, L3-L4, L4-L5, L5-S1

Number of Levels Treated

49% 1 Level, 49% 2 Levels, 1% 3 Levels

[†]Total levels treated= 111

Safety

	<i>mild</i> Study Patients ¹	Deer / Kapural Publication on <i>mild</i> Patients ²	SPORT ³
Number of Patients	73	90	394
Dural Tears	0%	0%	9.2%
Blood Transfusions	0%	0%	14.3%
Overall Adverse Events*			
Intraoperative	0%	0%	9.9%
Postoperative	0%	0%	12.3%

VAS & ODI (n=73)

Mean VAS

Pre: 7.34, Post (12 Weeks): 3.66 (Δ = 3.68* (50.1%))

Mean ODI

Pre: 48.1, Post (12 Weeks): 29.4 (Δ = 18.7*)

*Statistically significant improvement demonstrated by 15-point ODI improvement (FDA Panel Guidance)

Zurich Claudication Questionnaire

	Patients	Baseline Mean	Week 12 Mean	Improvement
Overall Symptom Severity	61	3.6	2.4	1.2
Pain Sub-Domain	62	4.0	2.6	1.4
Neuro-ischemic Sub-Domain	66	3.0	2.1	0.9
Physical Function Domain	64	2.7	2.0	0.7
Patient Satisfaction	65	N/A	2.01	N/A

- Improvements in all ZCQ domains were statistically significant at 12 weeks (t-test, p < 0.001)
- At 12 weeks, the mean Patient Satisfaction response of 2.01 on a scale of 1 to 4 indicated that the patients were satisfied with their overall outcomes.

SF-12v2® Statistical & Clinical Relevance of Improvement

Statistical: 95% CI established for each domain

Cohen: 2-4 points = Small clinical effect
5-7 points = Moderate clinical effect
≥ 8 points = Large clinical effect

Norman: Published in Medical Care ...concluded change equivalent to 5 points (equal to moderate effect size in norm-based reporting, which is what we used) is the threshold for true change in health QOL for chronic disease

Quality Metrics²: MID 2-3 for PCS; MID 3 for MCS

SF-12v2® QOL Survey Outcomes

Domain	Mean Improvement	Effect Size (Cohen 1998)	Important / Unimportant (Norman 2003)	Minimally Important Difference (MID) (Ware 2007)
Physical Component Summary (PCS)	6.08*	Moderate	Important	> 2x threshold
Mental Component Summary (MCS)	5.91	Moderate	Important	> 1x threshold

- The primary focus of SF-12v2® in the MiDAS I Study protocol was the Physical Component Score (PCS).
- Mean PCS was statistically significantly improved at 12 weeks.
- Mean Mental Component Summary (MCS) and all other SF-12v2 domains were improved at 12 weeks.
- This improvement was significant for the Role Physical (RP), Bodily Pain (BP), and Mental Health (MH) domains.

Discussion of Results - Safety

- Safety**
 - No dural tears
 - No blood transfusions
 - No nerve root damage
 - No hematomas
- Overall, with no major device or procedure-related complications, the *mild* procedure compares favorably with reports of both open surgical and minimally-invasive series.

Discussion of Results- LOS

- Length of Stay (LOS)¹
 - Average < 24 hours in all *mild* study cases
 - Majority (52%) discharged same day
- Favorable compared to open and minimally invasive procedures^{3,7}
 - Mean hospital stay for LSS open surgical series is 3.4 days.¹
 - Mean for minimally invasive series ranges from 1.2 to 4.0 days.⁸

Discussion of Results – VAS/ODI

- Patient pain and mobility outcomes
 - Pain reduced:** Mean VAS improvement of 3.68 points from baseline was statistically significant.
 - Mobility increased:** Mean ODI improvement of 18.7 points from baseline was statistically significant and clinically relevant.
- * Note: Clinical significance demonstrated by 15-point ODI improvement (FDA Panel Guidance). Published opinions regarding ODI clinical significance thresholds range from a change of 4 to 18.4 points.

Discussion of Results- ZCQ/SF12v2®

- Patient claudication and QOL outcomes
 - Statistically significant ZCQ Symptom Severity and Physical Function improvement; Overall, patients were satisfied with outcomes. (Mean 2.02)
 - Statistically significant SF-12v2® Physical Component Summary (PCS) improvement; All 8 domains and both physical and mental summaries were improved.

Conclusions

- Safety: the *mild* procedure is safe**
 - No serious device or procedure-related complications
- Efficacy: the *mild* procedure is efficacious**
 - Statistically significant reduction in pain (VAS, ZCQ and SF-12v2®)
 - Statistically significantly improved physical function and mobility (ODI, ZCQ and SF-12v2®)

¹No major intraoperative or postoperative *mild* Device or procedure-related adverse events (blood transfusions, dural tears, hematomas, nerve root damage) reported in any studies, publications, or presentations.
²*mild* Decompression Alternative to Open Surgery I Study (MiDAS I) presented on March 8, 2010 at the 12th Annual Cleveland Clinic Foundation Pain Symposium –multicenter, prospective trial with 75 patients.
³Pain Physician (Deer & Kapural) – no major adverse events in 90 *mild* procedures.
⁴Weinstein, et al. for the SPORT Investigators. Surgical vs. Nonsurgical Therapy for LSS. New Engl J Med. 2008;358:794-810.
⁵Statistically significant, p < 0.0001 (t-test for correlated samples).
⁶Ref. MID study of SF-36 (2007); results correlated with concurrent PRO instruments.
⁷Statistically significant improvement from baseline to 12-week follow-up, 95% CI.
⁸Deys, Richard, et al. Trends, Major Medical Complications, and Charges Associated With Surgery for Lumbar Spinal Stenosis in Older Adults. The Journal of the American Medical Association (JAMA) 2010;303(13):1259-1265.
⁹List of references on file at Vertos Medical, Inc.