

MiDAS I

(*mild*[®] Decompression Alternative to Open Surgery)
**Six Month Follow-up of a Prospective,
Multi-Center Clinical Study**

17th Annual NAPA Pain Conference

David L. Caraway, M.D., Ph.D.

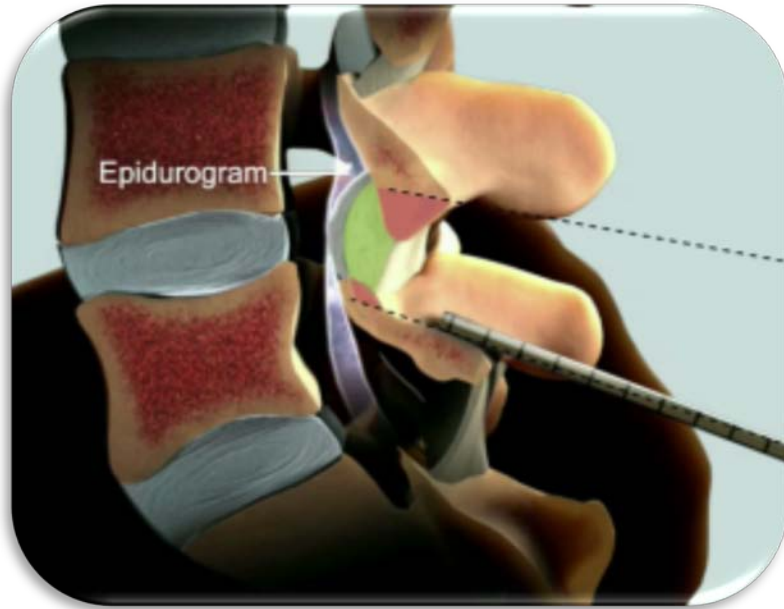
St. Mary's Pain Relief Center

Huntington, WV

mild[®] Procedure

- Minimally invasive – 6 G *mild* Portal access
- Fluoroscopic image guidance
- Local anesthesia with light sedation
- Total procedure less than 1 hour
- Minimal muscle and bone disruption
- Decompression of lumbar spine
- Spine structural integrity maintained

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

mild[®] Procedure Candidates

- Primary Enrollment Criteria
 - Symptomatic LSS
 - Co-morbidities such as osteophytes, facet hypertrophy and disc protrusion were typical.
 - Radiologic evidence of hypertrophic ligamentum flavum as a contributing factor.
 - Dural sac cross sectional area reduced, requiring intervention to restore space.
 - Unilateral or bilateral symptomatology.
 - One or more levels of stenosis.

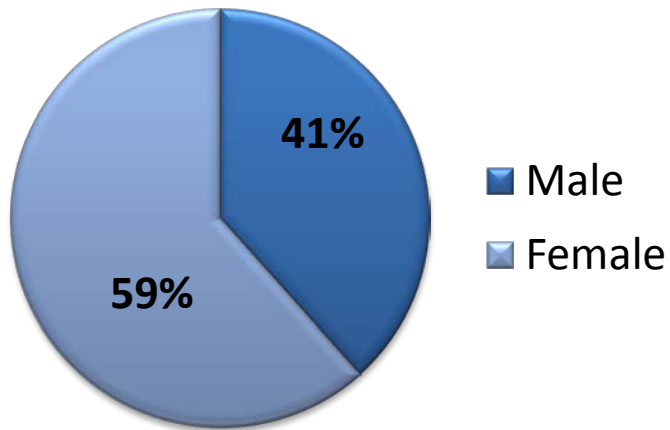
Success Goals

- *mild*[®] procedure completed as planned
- Mobility improves 15 points on ODI (An FDA panel has suggested a minimum 15-point change from baseline in ODI score is clinically significant)
- VAS pain score improves minimum of 2 points
- Improvement in Zurich Claudication & SF-12v2[®] patient reported outcomes
- No *mild*[®] device/procedure Significant Adverse Events (SAEs)

Demographics & Length of Stay

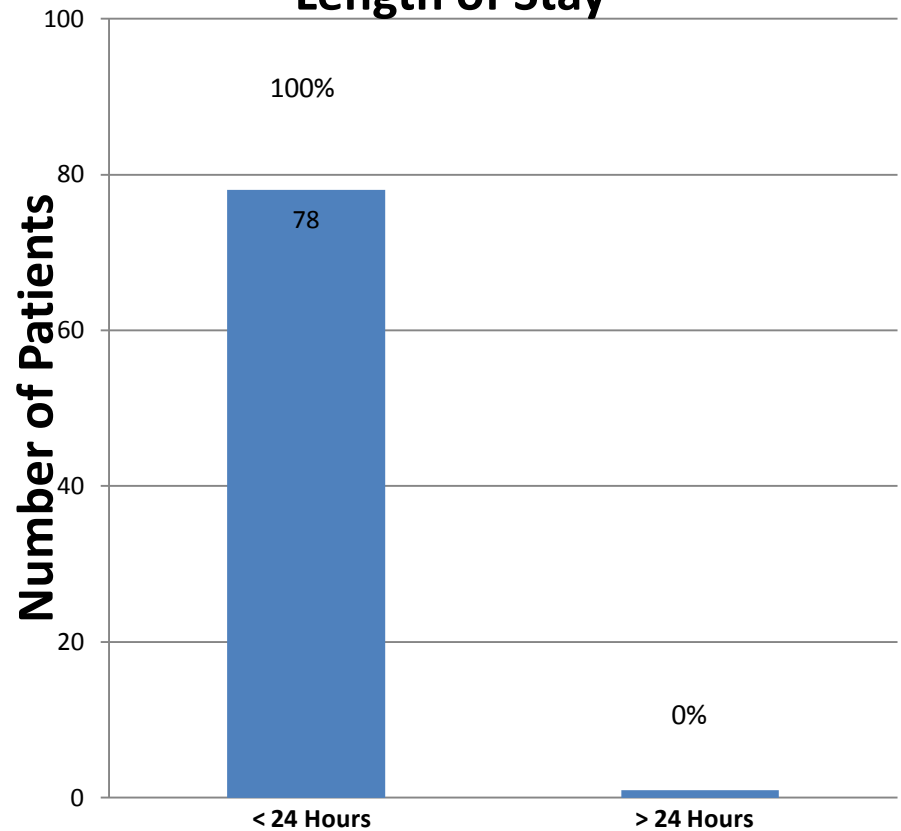
(N=78)

Demographics



Average Age: 70 Years

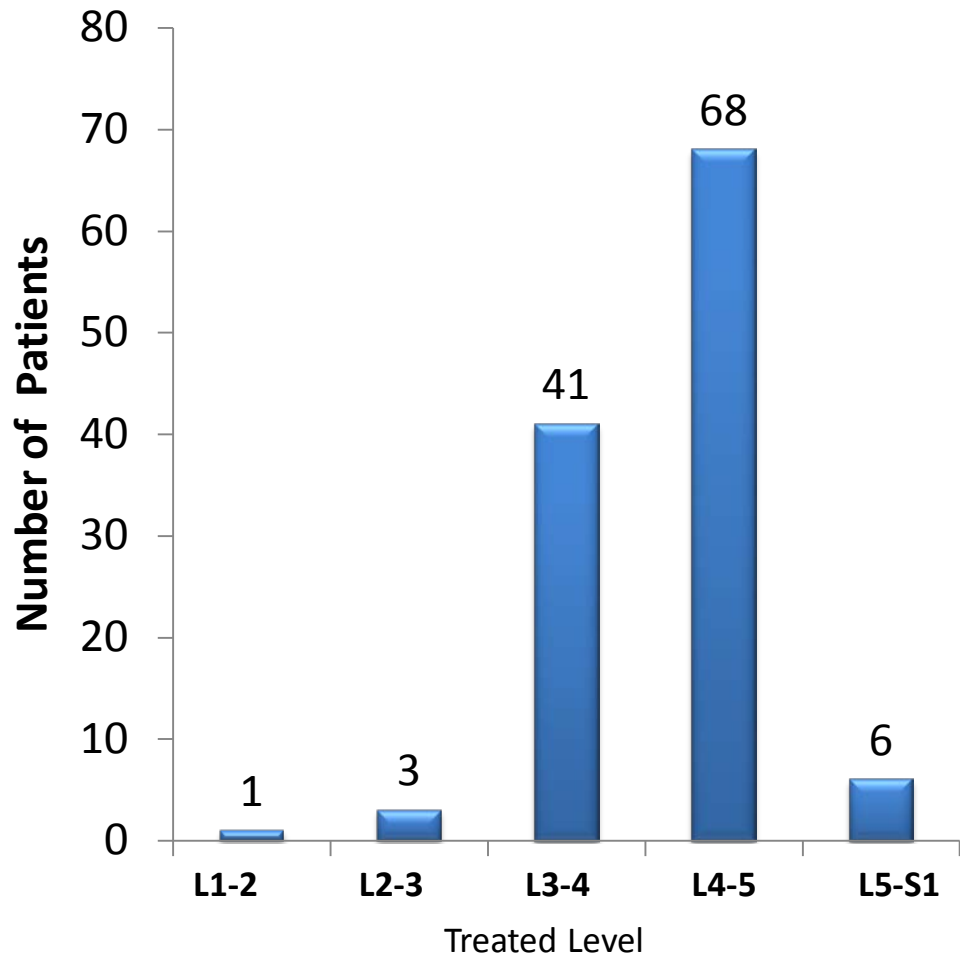
Length of Stay



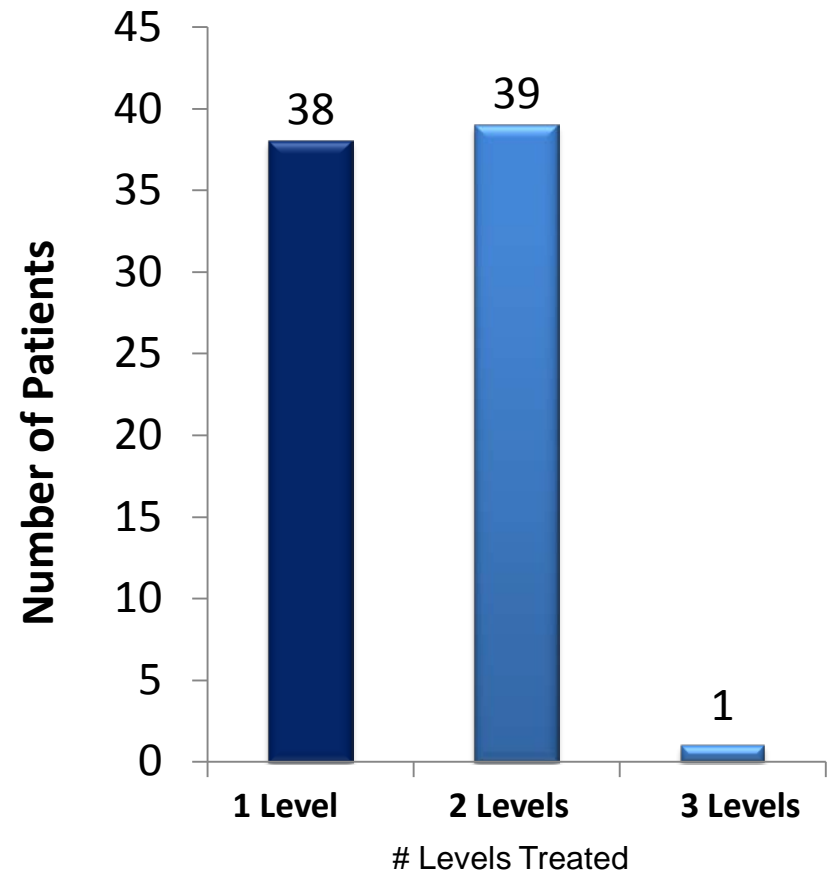
Levels Treated

(N=78)

Total Levels Treated = 119



Number of Levels Treated Per Patient



Safety

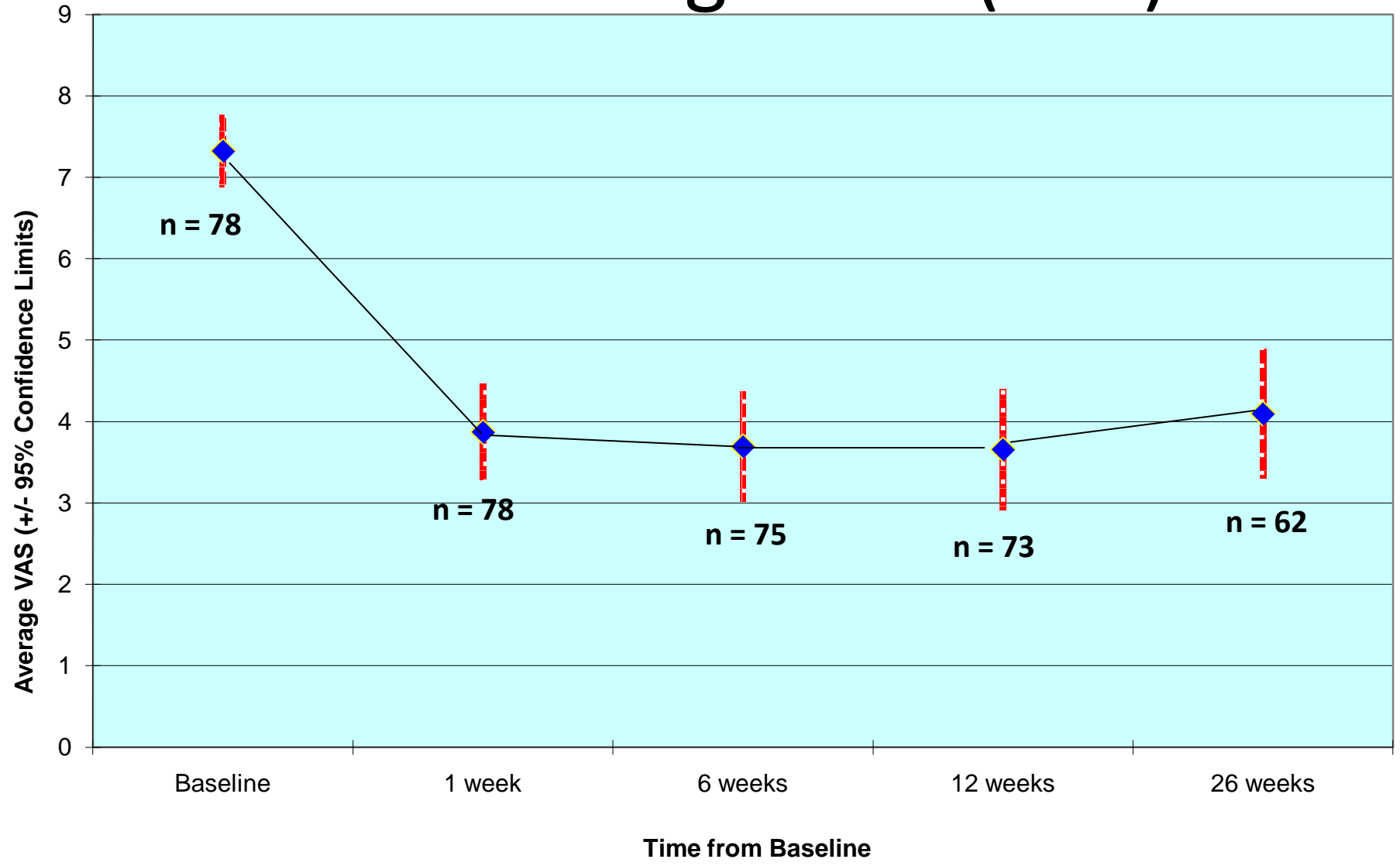
	MIDAS I Study Patients¹	Deer / Kapural Publication on <i>mild</i> Patients²	SPORT³
Number of Patients	78	90	394
Dural Tears	0%	0%	9.2%
Blood Transfusions	0%	0%	14.3%
Overall Adverse Events*			
Intraoperative	0%	0%	9.9%
Postoperative	0%	0%	12.3%

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.

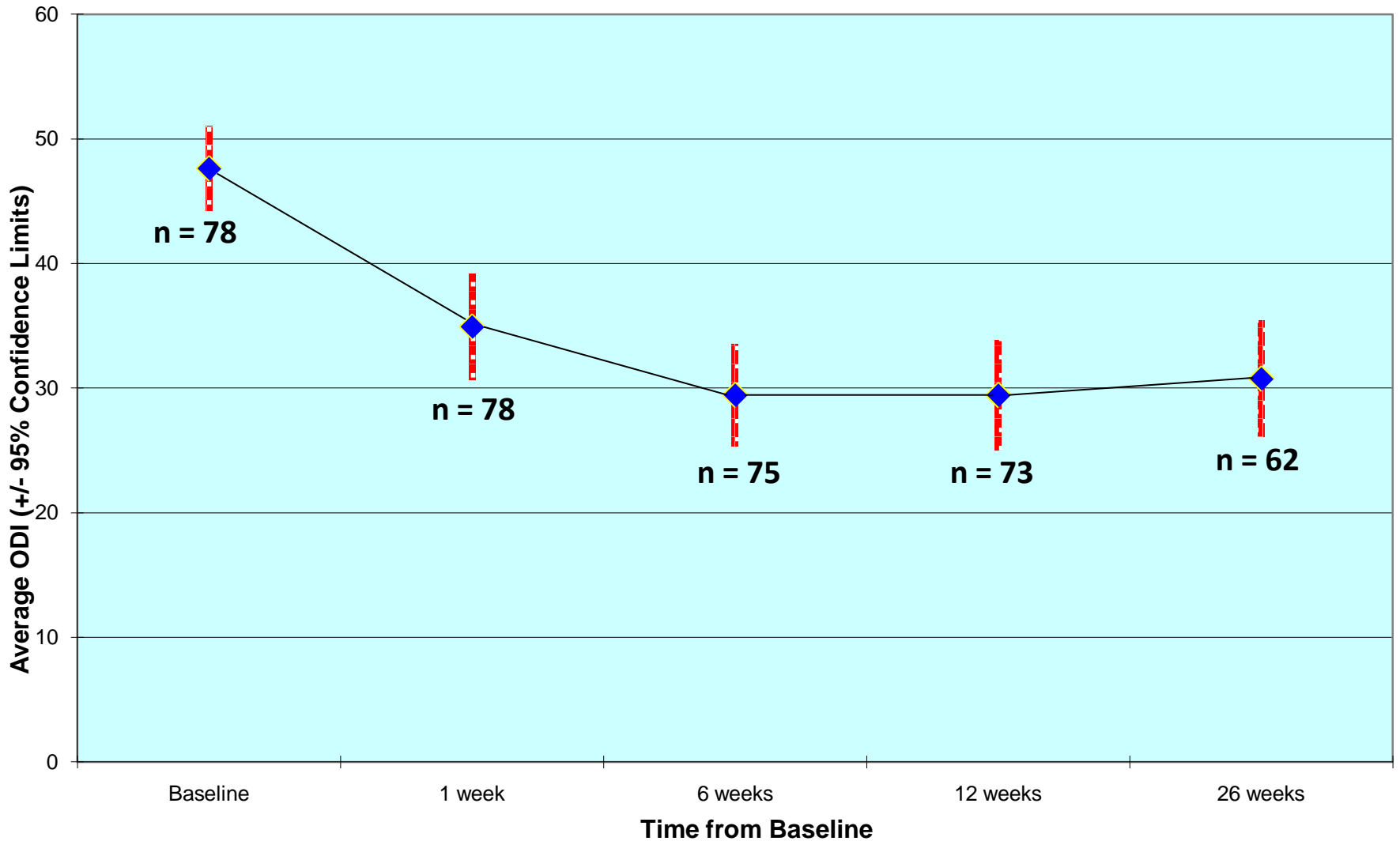
²Pain Physician (Deer & Kapural) – no major adverse events in 90 *mild* procedures.

³Weinstein, et al, for the SPORT Investigators. Surgical vs. Nonsurgical Therapy for LSS. New Engl J Med. 2008;358:794-810.

Visual Analog Score (VAS)



Oswestry Disability Index (ODI)



Zurich Claudication Questionnaire

Domains & Sub-Domains	# Patients Responding	Week 26 Mean Improvement
Overall Symptom Severity		
Pain Sub-Domain	54	1.39
Neuro-Ischemic Sub-Domain	56	0.95
Physical Function Domain	56	0.77
Patient Satisfaction	58	1.97*

- Improvements in all ZCQ domains were statistically significant (t-test, $p < 0.0001$) and clinically relevant (improved > 0.5) at 26 weeks.
Note: The authors of the ZCQ estimated after validity analysis that a 0.3-0.5 point change is significant.
- Mean Patient Satisfaction of 2 on a scale of 1 (very satisfied) to 4 (very dissatisfied) indicated that the patients were satisfied with their overall outcomes.

*Week 26 Patient Satisfaction is a 'response' rather than an 'improvement from baseline'.

SF-12v2[®] QOL Survey Outcomes

Domain	Mean Improvement	Effect Size (Cohen 1998)	Important / Unimportant (Norman 2003)	Minimally Important Difference (MID) (Quality Metric)
Physical Component Summary (PCS)	7.11*	Moderate	Important	> 2x threshold
Mental Component Summary (MCS)	6.12	Moderate	Important	> 2x threshold

- The primary focus of SF-12v2[®] in the MiDAS I Study protocol was the Physical Component Summary(PCS).
- *Mean PCS was statistically significantly improved at 26 weeks.
- Mean Mental Component Summary (MCS) and all other SF-12v2[®] domains were also improved at Week 26.

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

\geq 8 points = Large clinical effect

Norman: Published in Medical Careconcluded 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

QualityMetric*: MID 2-3 for PCS;MID 3 for MCS

*Ref: MID study of SF-36 (2007); results correlated with concurrent PRO instruments.

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)
 - 100% < 24 hours in *mild*[®] study cases
- Favorable compared to open and minimally invasive procedures^{2,3}
 - 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.⁴

¹ *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.

² Deyo, 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.*

³ Weinstein, et al, for the SPORT Investigators. Surgical versus Nonsurgical Therapy for LSS. *New Engl J Med.* 2008;358:794-810.

⁴ List of references on file at Vertos Medical Inc.

VAS/ODI

Discussion of Week 26 Results

- Patient pain and mobility outcomes
 - **Pain reduced:** Mean VAS improvement of 3.21 points from baseline was statistically significant. $p < .0001$
 - **Mobility increased:** Mean ODI improvement of 17.58 points from baseline was statistically significant ($p < .0001$) and clinically relevant (15 points).
 - 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/SF-12v2[®]

- Patient claudication and QOL outcomes
 - Statistically significant ZCQ Symptom Severity and Physical Function improvement; overall, patients were satisfied with outcomes (mean 1.97).
 - 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[®])