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Prospective Study

# MiDAS I (*mild*® Decompression Alternative to Open Surgery): A Preliminary Report of a Prospective, Multi-Center Clinical Study

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**Background:** Neurogenic claudication due to lumbar spinal stenosis is a common problem that can be caused by many factors including hypertrophic ligamentum flavum, facet hypertrophy, and disc protrusion. When standard medical therapies such as pain medication, epidural steroid injections, and physical therapy fail, or when the patient is unwilling, unable, or not severe enough to advance to more invasive surgical procedures, both physicians and patients are often left with a treatment dilemma. Patients in this study were treated with *mild*®, an ultra-minimally invasive lumbar decompression procedure using a dorsal approach. The *mild* procedure is performed under fluoroscopic imaging to resect bone adjacent to, and achieve partial resection of, the hypertrophic ligamentum flavum with minimal disruption of surrounding muscular and skeletal structure.

**Objective:** To assess the clinical application and patient safety and functional outcomes of the *mild* lumbar decompression procedure in the treatment of symptomatic central canal spinal stenosis.

**Study Design:** Multi-center, non-blinded, 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, 6-week follow-up was available for 75 patients.

**Outcome Assessment:** Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2® Health Survey. Outcomes were assessed at baseline and 6 weeks post-treatment.

**Results:** There were no major device or procedure-related complications reported in this patient cohort. At 6 weeks, the MiDAS I Study showed statistically and clinically 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 and clinically significant in this study.

**Limitations:** This is a preliminary report encompassing 6-week follow-up. There was no control group.

**Conclusions:** In this 75-patient series, and in keeping with a previously published 90-patient safety cohort, the *mild* procedure proved to be safe. Further, based on near-term follow-up, the *mild* procedure demonstrated efficacy in improving mobility and reducing pain associated with lumbar spinal canal stenosis.

**Key words:** Spine, lumbar, decompression, fluoroscopy, mild, stenosis, ligamentum flavum, minimally invasive

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Neurogenic claudication due to lumbar spinal stenosis (LSS) is a common problem that can be due to many factors including, but not limited to, hypertrophic ligamentum flavum (LF), facet hypertrophy, disc protrusion, or a combination of these factors (1,2). When standard medical therapies such as pain medication, epidural steroid injections, and physical therapy fail, or when the patient is unwilling, unable, or not severe enough to advance to more invasive surgical procedures, both physicians and patients are often left with a treatment dilemma.

This study utilizes a novel, commercially available, minimally invasive lumbar decompression single-use devices kit (*mild*®, Vertos Medical, Aliso Viejo, CA) to perform lumbar spinal canal decompression using a dorsal approach. *mild* treats LSS by removing portions of the lamina and debulking the LF to restore space in the spinal canal. The restoration of space in the canal can be confirmed during the procedure by visualization using the epidurogram. The *mild* procedure is performed via a 6 gauge (5.1 mm diameter) port under fluoroscopic imaging, to resect bone adjacent to, and achieve partial resection of, the hypertrophic LF. This is accomplished with minimal disruption of surrounding paraspinal muscular and skeletal tissues.

In this report, the authors present comprehensive safety data and patient reported outcomes at week 6 following the *mild* procedure. Acute safety of 90 patients treated with the *mild* procedure has been previously described (3).

## Methods

The study was conducted by 14 US spine specialists from July 2008 through January 2010. The study protocol was approved by an Institutional Review Board (IRB) for each participating site, and was registered on the U.S. Clinical Trial Registry (NCT00956631). All investigators were trained in the appropriate use of the *mild* devices and associated image guidance procedures, using a cadaver in a standard program. The length of time in medical practice ranged from 6 to 24 years for these interventionalists.

## Participants

Seventy-eight patients were treated in this study, and of these, 6-week follow-up was available for 75 patients. Adult patients with symptomatic LSS who met the study enrollment criteria were offered the *mild* procedure as an alternative to surgery or continued standard non-surgical medical management. The *mild* devices were used to treat study participants and these patients continued on the medical management considered appropriate by their physician investigator. All patients were provided with the IRB-approved informed consent document which described in detail all aspects of the study and withdrawal process.

## Inclusion Criteria

Inclusion criteria were symptomatic LSS primarily caused by dorsal element hypertrophy, prior failure of conservative therapy, radiologic evidence of LSS, hypertrophic LF > 2.5mm, central canal sectional area ≤ 100 square mm, anterior listhesis ≤ 5.0mm, ability to walk at least 10 feet unaided before being limited by pain. Further inclusion criteria included patients who were available to complete follow-up and provided written informed consent. Use of the *mild* devices also had to be consistent with the product labeling instructions for use.

## Exclusion Criteria

Exclusion criteria were prior surgery at the 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 or current use of anticoagulants, and use of ASA or NSAID within 5 days of treatment, and epidural steroids within prior 3 weeks. Also excluded were patients with any potential wound healing pathologies that may have compromised outcomes, patients with dementia or the inability to give informed consent, pregnant women, and patients on worker's compensation or considering litigation associated with back pain.

Although patients who also had foraminal stenosis and lateral recess stenosis were not excluded, the target patient population was those with lumbar central canal stenosis with hypertrophic LF as a contributing factor.

## Outcomes Assessments

At the time of initial treatment (baseline) and at six-week follow-up, patients were asked to complete the questionnaires for Visual Analog Scale (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2® Health Survey.

VAS is a scale that measures the amount of pain that a patient feels across a continuum. In this study, this continuum was represented by a 10-point scale, with one being no pain and 10 being the worst pain

imaginable. ODI is used to measure permanent functional disability through a series of questions which characterize the disturbance of activities of daily living resulting from chronic back pain. A higher ODI score indicates greater disability.

The ZCQ is a validated outcomes measurement tool specific to lumbar spinal stenosis. ZCQ consists of symptom severity and physical function domains that are completed before and after surgery, and the patient satisfaction domain that is completed after surgery. For each domain, lower scores indicate better baseline conditions or outcomes.

The symptom severity domain consists of 7 questions, and this domain has been subdivided into 2 subsets. The pain domain subset consists of questions 1–4 and the neuro-ischemic domain subset includes questions 5–7. Each of these questions receive a score from 1 (no symptoms) to 5 (very severe symptoms). The physical function domain contains 5 questions relating to performance of physical activity, each of which receives a score from 1 (comfortably) to 4 (none). The scores from each domain are then averaged. After surgery, patient satisfaction is measured by averaging the scores of 6 questions, each of which receives a score from 1 (very satisfied) to 4 (very dissatisfied) (4,5).

The SF-12v2 Health Survey is a multipurpose short-form with 12 questions. It is a generic measure of health status and outcomes in both general and specific populations. The SF-12v2 consists of 8 survey scales and 2 summary scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). The 8 survey scales include the following health concepts: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH).

## *MILD* Procedure

As previously described (3), the *mild* procedure is performed via a 6 gauge port (*mild* Portal), with a separate port placement at each hemi-laminar level. The procedure is typically conducted using local anesthetic and mild sedation. The patient is placed prone on a radiolucent table using a ventral bolster, as needed, to facilitate opening of the interlaminar space.

Fluoroscopy is used to visualize performance of the procedure. The contralateral oblique fluoroscopic view is the primary working view for the procedure, but verification of medial/lateral positioning under the lamina is assessed by an anterior/posterior view. Lateral fluoroscopic views are also utilized to confirm depth, particularly when performing the epidurogram.

An epidurogram utilizing a myelographically compatible contrast media is performed ipsilateral to the intended treatment level, providing a fluoroscopic visual landmark. When utilizing fluoroscopy in a contralateral oblique view, the contrast media highlights the epidural space, allowing for identification of the LF. This fluoroscopic view also provides the thickest visualization of the lamina, creating a posterior working zone. Instruments should not be placed beyond this visual landmark, thereby preventing inadvertent penetration into the thecal sac. Additional contrast media can be added as needed throughout the procedure to assist in maintaining visualization of the working zone and to assess the amount of decompression achieved.

Following epidurography, the *mild* Trocar and Portal are inserted percutaneously from an inferiorly placed ipsilateral stab incision, passing through fascia and muscle at an angle such that the tip of the Portal is ultimately docked at the superior lamina at the inferior aspect of the interlaminar region of interest (e.g., for a left L4-L5 target level, the cannula is placed at the superior left L5 lamina). The Trocar is then removed leaving the hollow *mild* Portal in the interlaminar space. The Portal angle is maintained at the skin surface using the Portal Stabilizer, and the Depth Guide is placed over the Portal limiting forward motion of the working instruments. This Portal allows minimally invasive working instrument access to the lamina and the LF.

First, the *mild* Bone Sculpter Rongeur is advanced through the Portal to the free edge of the superior and inferior laminar regions where the laminotomy is performed. Removal of laminar bony edges creates improved access to the interlaminar space, and partially releases the hypertrophic LF. The *mild* Tissue Sculpter is then advanced through the Portal and under the lamina into the dorsal aspect of the LF. The unique design of the Tissue Sculpter tip allows for debulking and remodeling of the LF by removing the collagen-laden posterior portion of the ligament, while leaving the ventral fibers intact. These ventral ligamentum fibers remain as a protective zone to the epidural space. When the trigger of the Tissue Sculpter is engaged, the outer cannulated cutting surface closes over the 2 cutting jaws, capturing and resecting a piece of the ligament. The device is then retracted from the Portal and the specimen is ejected from the device with the thumb trigger. This process is repeated as often as necessary to debulk the hypertrophic LF, decompressing the spinal canal. Decompression is confirmed through visual

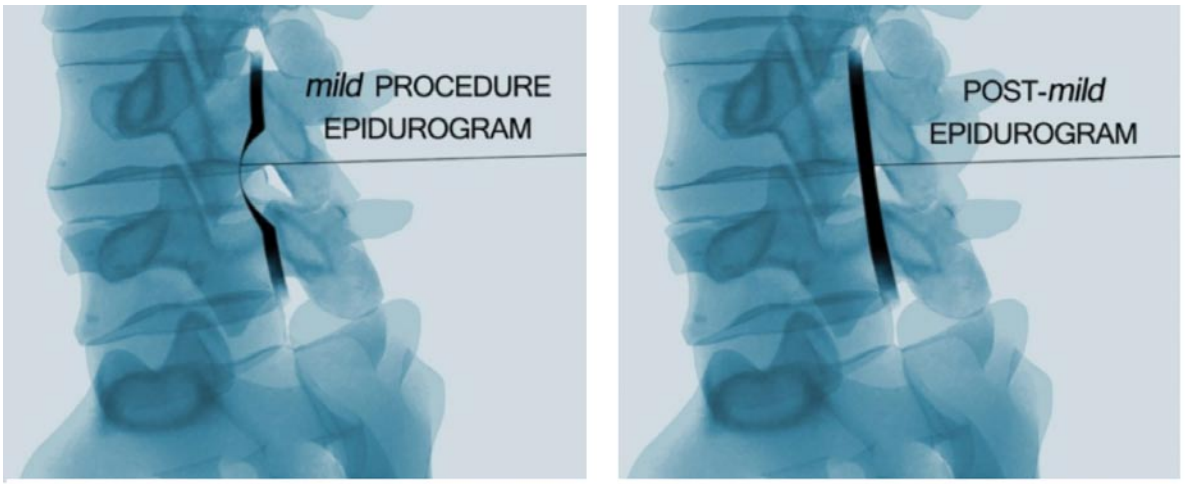



Fig. 1. *Illustration of pre and post-*mild *epidurograms*

Table 1. *Patient demographics*

| | |
|---|---|
| Average Age | 70.0 |
| Age Range | 37–88 |
| Male (%) | 29 (38.7%) |
| Female (%) | 46 (61.3%) |

Table 2. *Number of levels treated and treated level.*

| **No. of Levels:** | **Patients (%):** |
|---|---|
| 1 | 36 (48%) |
| 2 | 38 (51%) |
| 3 | 1 (1%) |
| **Treated Level:** | **Number of Levels Treated:** |
| L1-L2 | 1 |
| L2-L3 | 3 |
| L3-L4 | 40 |
| L4-L5 | 65 |
| L5-S1 | 6 |
| **Total Levels Treated*** | 115 |

* Total levels treated: (1x36)+(2x38)+(3x1) = 115.

changes in the epidurogram and contrast flow. Once decompressed, the injected contrast media flows more easily into the epidural space. The epidurogram contour typically changes from a bowed to a straightened morphology after successful decompression (Fig. 1).

After confirmation of adequate decompression, the Depth Guide, Portal Stabilizer, and Portal are removed, leaving no implants behind. The Portal site is closed with a sterile adhesive strip, with no need for sutures. The entire process may be repeated on the contralateral side of the interlaminar region to provide bilateral decompression of the central canal.

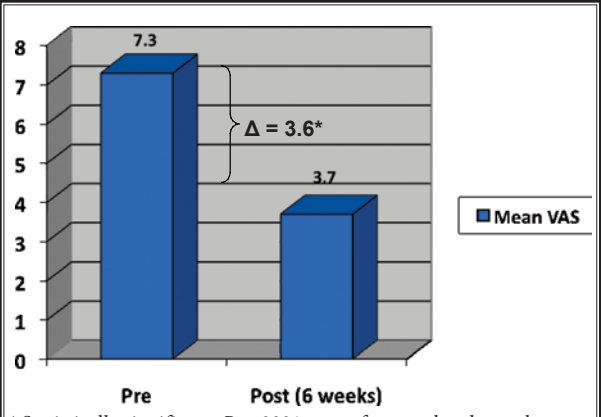
## Results

### Demographics

Of 78 patients treated in this study, 6-week follow-up was available for 75 patients. Patient demographics are presented in Table 1. Fifty-one percent of patients were treated at 2 levels, and the majority of treatments were at L4-L5 (Table 2). Of the 115 total treated levels, 11 were treated unilaterally.

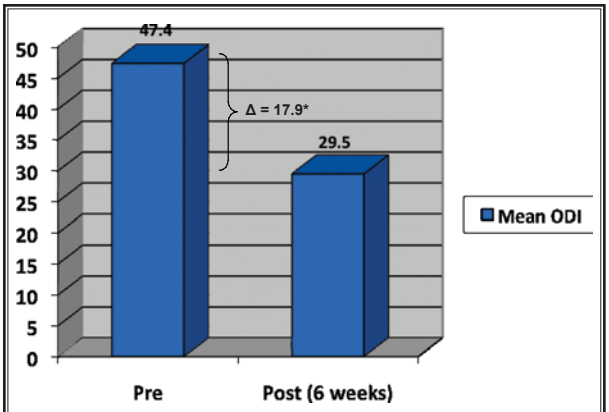
### Safety

There were no major *mild* device or procedure-related complications reported in this patient cohort, with major complications defined as dural tears, nerve root injury, post-op infection, hemodynamic instability,




* Statistically significant, $P < .0001$, t-test for correlated samples

Fig. 2. *Mean VAS improvement from baseline to 6-week follow-up.*




* Statistically significant, $p < .0001$, t-test for correlated samples

Fig. 3. *Mean ODI improvement from baseline to 6-week follow-up.*

and post-op spinal structural instability. Minor complications such as soreness at the incision site were not tracked in this study.

### Length of Stay (LOS)

Of the 75 patients in this cohort, 39 patients (52%) were discharged from the hospital on the same day as the procedure, and 36 patients (48%) stayed for one night only.

## Outcomes

### Visual Analog Scale (VAS)

Patients experienced a statistically significant ($P < 0.0001$, t-test for correlated samples) pain score improvement from baseline to 6 weeks post-*mild* procedure. The average baseline VAS was 7.3 (range 3 to 10). Average VAS at 6-week follow-up improved to 3.7 (range 0 to 10), an improvement of 3.6 points from baseline to 6-week follow-up (Fig. 2).

### Oswestry Disability Index

Patients experienced a statistically significant ($P < 0.0001$, t-test for correlated samples) mobility improvement from baseline to 6 weeks post-*mild* procedure. Average baseline ODI was 47.4 (range 16 to 84). Average ODI at 6-week follow-up improved to 29.5 (range 0 to 72), an improvement of 17.9 points from baseline to 6 weeks post-mild treatment (Fig. 3).

### Zurich Claudication Questionnaire (ZCQ)

Six weeks after mild treatment, patient physical function and symptom severity (in both pain domain and neuro-ischemic domain) were statistically significantly improved ($P < 0.001$, paired t-test) from baseline and patients were satisfied with their overall outcomes after the mild procedure (mean = 2.02).

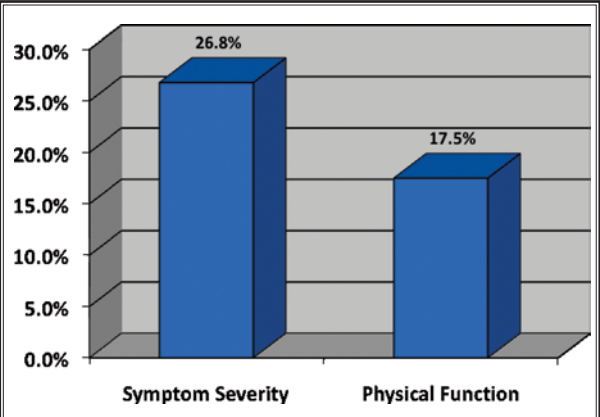
Pre-and post-treatment scores in the symptom severity and physical function domains are shown in table 3. The pain domain subset of symptom severity had a pre-treatment mean of 4.05 (post-treatment 2.60). The

Table 3. *Pre and post-treatment ZCQ scores*

| | Patients | Pre-Treatment Means (Ranges) | Post-Treatment Means (Ranges) |
|---|---|---|---|
| Overall Symptom Severity | 62 | 3.69 (1.57 to 5) | 2.35 (1 to 4.57) |
| Pain Sub-Domain | 63 | 4.05 (2 to 5) | 2.60 (1 to 4.75) |
| Neuro-Ischemic Sub-Domain | 67 | 3.07 (1 to 5) | 1.99 (1 to 4.66) |
| Physical Function Domain | 61 | 2.67 (1 to 4) | 1.96 (1 to 3.20) |

neuro-ischemic domain subset of symptom severity had a pre-treatment mean of 3.07 (post-treatment 1.99). The physical function domain mean baseline was 2.67 (post-treatment 1.96).

From baseline to 6-week follow-up, Study patients improved a mean of 1.34, or 26.8% of the maximum possible score in The Overall Symptom Severity Domain; and improved a mean of 0.71, or 17.5% of the maximum possible score in Physical Function ($P$ <0.001, paired t-test.) (Fig. 4).




* Statistically significant, $P$ < .0001, t-test for correlated samples

*Fig. 4. ZCQ domain improvement rates from baseline to 6-week follow-up.*

Of the 75 patients in this cohort, 61 responded to their level of satisfaction with the procedure. The true mean was 2.02 (2 = satisfied). With a 95% Confidence Interval of 2.02 ± .23, lower and upper limits are 1.79 and 2.25, respectively.

## SF-12v2® Health Survey

The health of the patients 6-weeks after *mild* treatment as measured by SF-12v2 was significantly improved at 95% CI. The patients' health status was improved for the 2 summary surveys (PCS and MCS) and all 8 survey scales as compared to baseline (Fig. 5). This improvement is statistically significant (95% CI) for all but the General Health (GH) survey scale.

Only subjects with complete data at baseline and 6-weeks were used for this interim 6-week report (n = 67). The data for the 2 summary scales and 8 survey scales have been normalized so each scale has the same mean (50 points) and the same standard deviation (10 points) in the general 1998 U.S. population. By using this method, anytime a scale is below 50, health status is below average, and each point is one-tenth of

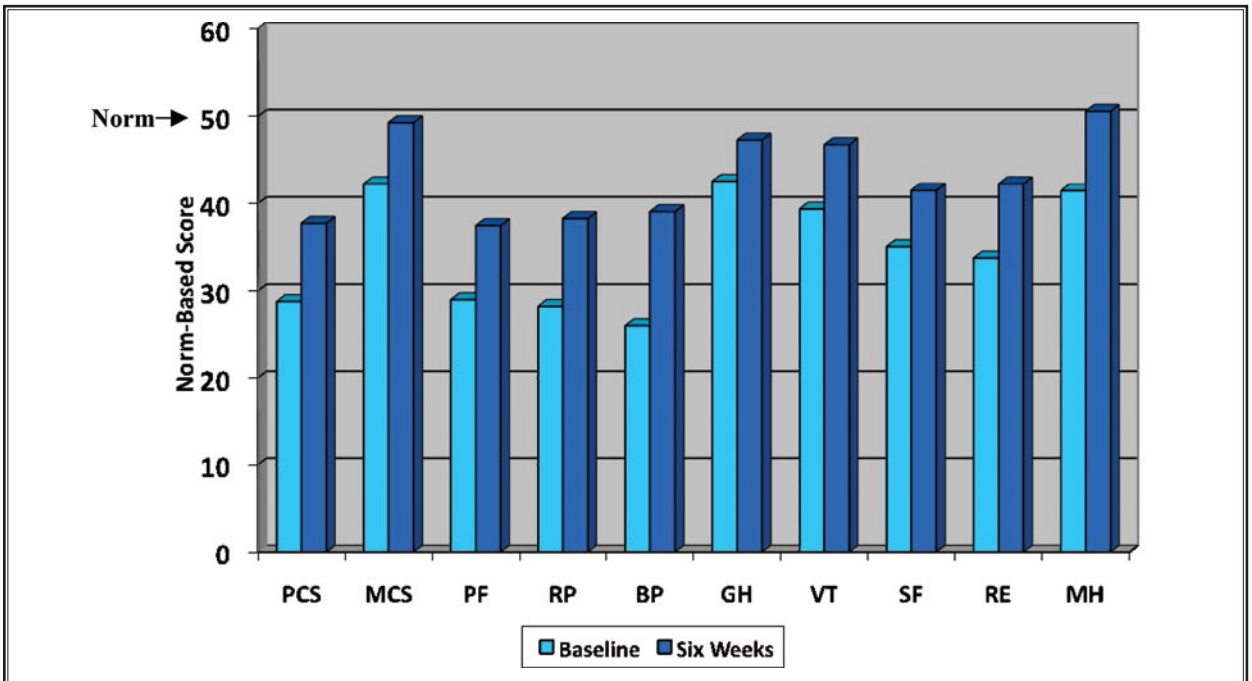



Fig. 5. *SF-12v2 norm-based PCS and MCS summary measures and 8 health survey scales.*

a standard deviation. The summary measures take into account the correlations among the 8 SF-12v2 Health Survey scales, and show the broad impact on physical (PCS) and mental (MCS) health.

## Discussion

### Safety

Table 4 presents a summary comparison of reported major complication rates in the surgical treatment of LSS for both open surgical and minimally invasive surgical series. "Open" surgery is defined as a procedure requiring the surgeon to create a larger incision and operate utilizing "traditional" medical instruments. In addition, it is an inpatient procedure, where the stay will be days longer than with minimally invasive surgery due to the chance of complication and the size of the wound (increased chance for infection). Recovery time is generally longer in comparison to minimally invasive procedures, with patients needing to heal for longer periods of time prior to returning to work and physical activities. We note, however, that in some cases the open method is necessary due to some patient-specific risks. The most common complication in both open-surgical and minimally invasive series is dural tear or spinal fluid leak, ranging from 2.0% to 20.0% in open surgery, and 1.1% to 12.5% in minimally invasive surgery. Blood transfusions occurred in a disparate 1.1% to 76.9% of open surgical cases, and 0% of minimally invasive surgeries. Overall, with no major device or procedure-related complications, the *mild* procedure compares favorably with reports of both open surgical and minimally invasive series. It should be noted that minor complications such as incision site soreness were not collected in MiDAS I.

### Length of Stay (LOS)

None of the patients in this study stayed in the hospital for more than one night, and the majority (52%) were discharged on the same day. This can be compared to reported mean hospital stays for LSS open surgical series that range from 3 to 7.2 days, and for minimally invasive series that range from 1.2 to 4.0 days (7-10,13,18,19,21,23,24).

### Outcome Assessments

#### *Visual Analog Scale (VAS)*

VAS protocol success was defined as the patient experiencing a 2-point improvement in VAS from baseline at week 26. In this report of 6-week follow-up, the mean VAS improvement of 3.6 points from baseline was statistically significant. Further, 66.7% of patients reported VAS improvement of at least 2 points at 6-week follow-up.

#### *Oswestry Disability Index*

The 17.9 point improvement in mean ODI from baseline to 6-weeks post-*mild* treatment was statistically significant. The FDA has suggested that a minimum 15 point change from baseline in the ODI score is clinically significant (25). In addition, published opinions regarding ODI clinical significance thresholds range from a change of 4 to 18.4 points (26,27). These reports indicate that the mobility improvement for patients in this study was clinically significant at 6 weeks.

#### *Zurich Claudication Questionnaire (ZCQ)*

Improvements of 26.8% in symptom severity and 17.5% in physical function in the Zurich Claudication Questionnaire were statistically significant at 6 weeks. Further, the absolute values at 6 week follow-up indicated a low level of symptom severity (2.35 on a scale

Table 4. *Complication rates reported for lumbar spinal stenosis surgical series*

| | Surgical Series | |
|---|---|---|
| | Open Surgery | Minimally-Invasive Surgery |
| Blood Transfusion (6–9) | 1.1%–76.9% | 0.0% |
| Dural Tear or Spinal Fluid Leak (6–22) | 2.0%–20.0% | 1.1%–12.5% |
| Hematoma (6,8,9,11,13,14,16,18,20,21) | 0.0%–5.0% | 0.0%–5.0% |
| Post-Op Infection (8–12,16–18,21,23) | 0.0%–5.7% | 0.0%–4.0% |
| No Intraoperative Complications (7,9,11,13,16,17,20–22) | 77.5%–95.0% | 79.2%–94.6% |
| No Postoperative Complications (7,9,13,20,21) | 65.9%–92.0% | 88.6%–96.0% |

of 1 to 5), and a comfortable level of physical function (1.97 on a scale of 1 to 4). At 6 weeks, the mean patient satisfaction response of 2.02, on a scale of 1 to 4, indicated that the patients were satisfied with their overall outcomes after the *mild* procedure.

### *SF-12v2® Health Survey*

SF-12v2 is a validated tool that uses norm-based scoring to determine treatment outcomes. Like the SF-36 Health Survey, the SF-12v2 is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. It was developed to be a much shorter, yet valid, alternative to the SF-36 Health Survey. The SF-12v2 consists of 2 summary measures and 8 health domain scale scores (Table 5).

Table 5. *SF-12v2® measurement scales*

| **Summary Measures:** |
|---|
| Physical Component Summary (PCS) |
| Mental Component Summary (MCS) |
| **Health Domain Scales:** |
| Physical Functioning (PF) |
| Role-Physical (RP) |
| Bodily Pain (BP) |
| General Health (GH) |
| Vitality (VT) |
| Social Functioning (SF) |
| Role-Emotional (RE) |
| Mental Health (MH) |

It is clear that, on average, these patients are functioning well below the average range prior to surgery, scoring one to 2 standard deviations below the US general population norm on all health domain scales except Mental Component Summary (MCS), General Health (GH) and Mental Health (MH). The burden of the condition seems more physical than mental, as demonstrated by higher scores on both MCS and MH. Six weeks after the mild procedure, patient scores noticeably improved in all domains (Fig. 5 and Table 6).

With norm-based scoring, the standard deviation (SD) is standardized to 10 in the general US population. Cohen's standardized effect size approach uses the mean change divided by the standard deviation to serve as an "effect size index." According to Cohen's recommendation, standardized effect sizes of 0.2 to <0.5 should be regarded as "small," 0.5 to <0.8 as "moderate" and those above 0.8 as "large" (28). Table 6 presents the Cohen effect sizes for the summary measures as well as the eight health domain scales. Six of 10 measures indicated a large effect, while 3 were moderate, and one was small.

A 2003 report by Norman addressed the issue of interpreting changes in health related quality of life scores. The study was a meta analysis of studies presenting change scores on some of the more widely used disease-specific and generic health related quality of life instruments. The conclusion of this study was that "in most circumstances, the threshold for discrimination for changes in health-related quality of life for

Table 6. *SF-12v2® Health Survey Outcomes*

| Domain | Mean Improvement | Effect Size (Cohen 1998) (28) | Important / Unimportant (Norman 2003) (29) | Minimally Important Difference (MID) (Ware 2007) (30) |
|---|---|---|---|---|
| Physical Component Summary (PCS) | 9.02* | Large | Important | > 3x threshold |
| Mental Component Summary (MCS) | 7.05* | Moderate | Important | > 2x threshold |
| Physical Functioning (PF) | 8.54* | Large | Important | N/A |
| Role-Physical (RP) | 10.11* | Large | Important | N/A |
| Bodily Pain (BP) | 13.08* | Large | Important | N/A |
| General Health (GH) | 4.73 | Small | Unimportant | N/A |
| Vitality (VT) | 7.36* | Moderate | Important | N/A |
| Social Functioning (SF) | 6.48* | Moderate | Important | N/A |
| Role-Emotional (RE) | 8.52* | Large | Important | N/A |
| Mental Health (MH) | 9.14* | Large | Important | N/A |



* Statistically significant improvement from baseline to six-weeks post-mild, 95% CI.

chronic disease appears to be one-half of a standard deviation" (29). This is roughly equivalent to 5 points on the norm-based scoring of the SF-12v2 and is equal to a "moderate" effect size according to Cohen. Table 6 presents "important" and "unimportant" changes for each of the SF-12v2 summaries and scales. All but one of the measures showed an "important" change from baseline to 6 week follow-up based on the Norman threshold.

Minimally Important Difference (MID) is a measure of true clinical relevance of a difference. The MID for group level comparisons for PCS is 2 to 3 points, and for MCS is 3 points (30). The mean improvement in this study for PCS was 9.02, or over 3 times the MID of 2 to 3. In addition, the mean improvement for MCS was 7.05, or over 2 times the MID of 3. Both of these summary measures showed significant clinically relevant differences based on this measure (Table 6.)

## Conclusion

In this 75-patient MiDAS I trial, and in keeping with a previously published 90-patient safety cohort, the *mild* procedure proved to be safe. Further, based on near-term follow-up, the *mild* procedure demonstrated efficacy in improving mobility and reduced pain associated with lumbar spinal canal stenosis. When applied to a general patient population suffering from LSS where hypertrophic LF is one of the contributing factors, the reduction of pain as measured by VAS, ZCQ, and SF-12v2 at week 6 was statistically and clinically significant. In addition, this population achieved a statistically and clinically significant improvement in physical function and mobility as measured by ODI, ZCQ, and SF-12v2 (Table 7).

Given the treatment dilemma created with failed therapies, patients unwilling, unable, or not severe enough to advance to more invasive surgical procedures, the *mild* procedure may represent a preferred treatment option for physicians and their patients suffering from LSS.

This procedure is minimally invasive, does not involve implants, is performed with minimal anesthesia, has minimal to no major device or procedure-related adverse events to date, and allows the patient to return home sooner, enjoying a more rapid recovery than major open LSS surgery. Therefore, *mild* represents potentially improved cost-effectiveness as compared to standard open surgical treatment of lumbar spinal stenosis.

The authors are monitoring progress of longer term data from this MiDAS I series as well as data from several additional ongoing randomized, double-blind *mild* procedure trials.

Table 7. *Overall MiDAS I outcomes metrics.*

| Measure | Baseline | Week 6 | Mean Improvement | Statistical Sig.* | Clinical Sig. |
|---|---|---|---|---|---|
| VAS | 7.3 | 3.7 | 3.6 (51%) | Yes | Yes |
| ODI | 47.4 | 29.5 | 17.9 | Yes | Yes |
| SF-12v2 (PCS) | 28.71 | 37.73 | 9.02 (3x MID)† | Yes | Yes |
| SF-12v2 (MCS) | 42.23 | 49.28 | 7.05 (2x MID) † | Yes | Yes |
| Zurich Symptom Severity (Overall) | 3.68 | 2.34 | 1.34 | Yes | Yes |
| Zurich Physical Function | 2.67 | 1.97 | .70 | Yes | Yes |
| Zurich Satisfaction | NA | 2.02 | Satisfied | NA | Yes |

† Ref: Ware (30); *$P$-values presented in corresponding sections of this paper

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