



TWELVE-WEEK MiDAS I CLINICAL STUDY DATA CONFIRM
SAFETY, EFFICACY OF VERTOS MEDICAL'S *mild*[®]

ALISO VIEJO, Calif. – July 19, 2010 – Medical device company [Vertos Medical Inc.](#) has announced the unveiling of 12-week clinical data from its prospective, 75-patient MiDAS I (***mild*** Decompression **A**lternative to open **S**urgery) study that further validate the safety and efficacy of *mild* for the treatment of lumbar spinal stenosis (LSS). Consistent with the positive six-week study results released in March and May, the new MiDAS I data demonstrate that *mild* patients continued to experience statistically significant improvement in pain, physical function and mobility 12 weeks following treatment. The study's medical monitors also concluded that *mild* is safe, with no reports of major adverse events related to the procedure or devices.

The new MiDAS I results were presented by study Co-Medical Monitor David Caraway, M.D., Ph.D. (St. Mary's Pain Relief Center, Huntington, W. Va.) at the International Spine Intervention Society meeting in Maui, Hawaii on July 17.

"This new data is quite encouraging, as it shows us that *mild* is able to provide LSS patients with lasting, statistically significant improvement across all key outcomes measures," said Dr. Caraway. "With *mild*, physicians and patients now have an earlier, safer alternative for lumbar spine decompression that achieves sustained relief without the traditional risk profile."

Key outcome measures at twelve weeks included changes in Visual Analog Score (VAS), which measures pain; changes in Oswestry Disability Index (ODI), which assesses functional ability; as well as patient-reported responses to the SF-12v2[®] Quality of Life Survey and Zurich Claudication Questionnaire (ZCQ). The latter are widely accepted tools for measuring relative change in patient symptom severity, physical function as well as overall satisfaction with the results of the intervention.

The data showed that MiDAS I participants achieved:

- *Sustained pain improvement (VAS)*. Study protocol defined success as a minimum two-point VAS improvement from baseline. The 12-week data showed an average improvement of 3.68 points from baseline across all patients. This compares to 3.6 points found at six weeks post-treatment.
- *Even greater improvement in functional ability (ODI)*. Study participants achieved an average ODI improvement from baseline of 18.6 points at 12 weeks, as compared with the 17.9 points found at six weeks. Both scores are noteworthy, as a U.S. Food and Drug Administration panel on orthopedic and rehabilitation devices has given guidance that a minimum 15-point change in ODI score from baseline is clinically significant.¹
- *Sustained improvement in quality of life (Physical Component Score, SF-12v2)*. At 12 weeks, participants reported not only a statistically significant improvement from baseline, but

also a clinically relevant improvement of greater than two times the minimally important clinical difference (MID). These results mirror outcomes observed six weeks post-treatment.^{2,3}

- *Sustained improvement in patient satisfaction, overall symptom severity and physical function (ZCQ).* At 12 weeks, participants reported an average satisfaction rating of 2.02 on a scale from 1 (highest) to 4 (lowest). This rating was unchanged from six weeks. In addition, improvement in overall symptom severity and physical function (as with SF-12v2) was statistically significant at both six and 12 weeks post-treatment.

“The 12-week MiDAS I data represent a meaningful validation of *mild*’s role in the early treatment of LSS, where traditionally physicians have had to balance the risks of open, more invasive procedures for lasting effectiveness,” said James M. Corbett, president and chief executive officer of Vertos. “We believe these new findings will further increase physician confidence in and adoption of *mild* in clinical practice.”

Peer-reviewed publication of comprehensive MiDAS I study data is anticipated later this year. Based on an extensive scientific literature review, MiDAS I has been shown to employ the most comprehensive array of validated patient reported outcomes tools in LSS studies submitted for publication in recent years.⁴

About *mild*

mild is an image-guided procedure used to treat patients with LSS, a condition diagnosed in 1.2 million patients annually in the United States.⁵ A less invasive alternative to open or endoscopic surgery, *mild* safely and therapeutically reduces pain and increases mobility while maintaining structural stability.

About Vertos Medical, Inc.

Vertos Medical was founded to advance the treatment of patients suffering with lumbar spinal stenosis (LSS), a degenerative, age-related narrowing of the lower spinal canal. Its proprietary platform technologies include *mild*, which offers a therapeutic intervention to treat LSS and achieve lumbar spine decompression. For more information, visit www.vertosmed.com.

* Vertos *mild* is FDA cleared for treating lumbar spinal stenosis.

¹ FDA, Center for Devices and Radiological Health, Orthopedic and Rehabilitation Devices Panel Meeting, Friday, September 9, 2005.

² The concept of the minimally important clinical difference (MID) refers to the smallest difference in a score that is considered to be worthwhile or important.

³ Ware JE, Snow KK, Kosinski MK, Gandek B. SF-36 Health Survey: Manual and Interpretation Guide. Boston: The Health Institute, New England Medical Center; 1993

⁴ Spinal Stenosis and Decompression: Recent Research and Advances. Florida Society of Interventional Pain Physicians Annual Meeting, May 23, 2010.

⁵ Derived from the Longitudinal Medicare Database.

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