Spinal Stenosis Decompression and coflex™ Interspinous Stabilization: I.
Clinical Results from An International Multicenter Retrospective Study

Kornelis A. Poelstra, MD, PhD¹, Dieter Adelt, MD², Jacques Samani, MD³, Woo-Kyung Kim, MD, PhD⁴, Marcus Eif, MD⁵, Gary L. Lowery, MD, PhD⁶ and Robert Chomiak, MS⁷,

1. University of Maryland – Shock Trauma
   Department of Orthopaedic Surgery
   Baltimore, MD 21201

2. Ostseeklinik Damp GmbH
   Damp, Germany

3. Orthopaedic Surgeon
   Lyon, France

4. Department of Neurosurgery
   Gachon Medical School, Gil Medical Center
   Gu-Weol Dong, Nam-Dong Gu, Incheon, Korea

5. Department Head of Neurosurgery
   Städtisches Klinikum Görlitz GmbH
   Görlitz, Germany

6. Executive Vice President, Research and Technology
   Orthopaedic and Spinal Surgeon
   Paradigm Spine, LLC
   New York, NY 10022
7. Corporate Associate, Research and Technology
Paradigm Spine, LLC
New York, NY 10022

Correspondence to:
Gary L. Lowery, MD, PhD
Paradigm Spine, LLC
505 Park Avenue, 14th floor
New York, NY 10022
Gary.Lowery@paradigmspine.com

Acknowledgement to Nick Wharton and John Hipp from Medical Metrics Inc. for aid in the quantitative and qualitative analysis of the radiographic data.
Objective:

The purpose of this study was to determine the safety and efficacy of coflex™ for the primary diagnosis of one or two level spinal stenosis in patients with neurogenic claudication between the ages of 40 and 80 years old.

Introduction:

Degenerative spinal stenosis is a severely disabling disease common in the elderly with patient symptoms usually including bilateral radicular pain that radiates to the buttocks and posterior thighs, intermittent neurogenic claudication, sensation disturbance and loss of strength in the lower extremities. The coflex™ interspinous stabilization device (Paradigm Spine) is a functionally dynamic implant (compressible in extension) used to stabilize the motion segment after direct surgical decompression of moderate to severe stenosis without concomitant fusion. The coflex is implanted after a direct surgical decompression of the stenotic canal and theoretically provides slight facet distraction therefore off-loading the forces on the posterior degenerated disc and facet joints at the affected level, while maintaining patency of the neural foraminae.

Methods:

Retrospective data were gathered on 589 patients from four European sites and one Asian site where surgeons had contemporaneous clinical and radiographic follow-up review of all patients. Follow-up was available at 6 to 121 months for all patients. An analysis was performed using VAS, objective examination measures, radiographic data and Odom’s criteria to determine safety and efficacy of the coflex in relieving neurogenic claudication, radiculopathy and back discomfort.

Results:

Of the 589 patients identified as recipients of a coflex implant, a total of 429 were located and agreed to participate in the study and contained a complete data set. The mean follow-up time was 33 months and the median follow-up time was 20 months. Stenosis was the primary indication for 275 patients. Sixty-six patients did not match our IDE inclusion criteria, which left 209 patients for analysis. Stenosis alone was the single diagnosis in 128 patients (61%), 57 patients (27%) had stenosis and a grade I spondylolisthesis and 24 patients (12%) suffered from scoliosis (<25 degrees).

Moderate to severe low back pain improved in 75% of patients while leg pain and claudication improved in up to 88% of patients. Claudication improved in 91% of patients as well as 79 % improvement in walking distance. Using Odom’s criteria, 88% of the patients scored good-excellent and 92% said they would have surgery again. These results were achieved at 1 year and did not deteriorate over the long-term. No permanently deformed or fractured coflex implants were seen. Two spinous process fractures and 1 implant migration (>5 mm) were observed. Four patients underwent fusion after incomplete relief and explantation of the coflex.

Conclusions:
coflex interspinous stabilization after microsurgical decompression for spinal stenosis demonstrates excellent short term and long term results for back pain, neurogenic claudication and patient satisfaction.