# coflex® Interspinous Stabilization: Clinical and Radiographic Results from an International Multicenter Retrospective Study

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## Abstract

The purpose of this study was to determine the safety and efficacy of the coflex® interspinous implant in patients between the ages of 40 and 80 years old with the primary diagnosis of spinal stenosis (1 or 2 levels), neurogenic claudication and low back pain.

Retrospective data were gathered on 589 patients from 4 sites with 429 patients having contemporaneous clinical and radiographic follow-up. Clinical analysis was performed on a homogenous population of 209 patients. VAS and objective examination measures were used to evaluate improvement in neurogenic claudication, radiculopathy and back pain. The median follow-up was 20 months (range 6 to 121 months). Radiographic data was collected to evaluate spinal segment motion (index and adjacent levels), implant position and migration and bony remodeling at the bone-implant interface.

Moderate to severe low back pain improved in 75% of patients, while leg pain improved in 87% of patients. Claudication improved in 87% of patients. These results were achieved by 1 year and did not deteriorate over the long-term. In addition, improvement in walking distance occurred in 74% of the patients and patient satisfaction was 89%. Range of motion and translation measurements were essentially the same for all diagnoses, follow-up time points and levels of implantation. No expulsions and only 1 migration (>5 mm) was observed. Mild or moderate bone-implant interface remodeling was noted in 15.4% of the patients and there were no broken or permanently deformed implants.

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

## Introduction

The coflex interspinous implant was invented by Dr. Jacques Samani in 1994 and has been in continuous use since 1995 outside the United States. Initially, the product was known as the Interspinous "U" and was marketed by Fixano SAS (Peronnas, France). Transfer of ownership to Paradigm Spine was finalized in early 2005, and the product was renamed "coflex interspinous implant". The design and materials were not changed, but two new sizes were added. The only differences between the Interspinous "U" and the coflex interspinous implant are the manufacturing technique (from a wire EDM manufactured device to a milled device) and the tightening of tolerances.

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The coflex interspinous implant is intended for use in the treatment of lumbar spinal stenosis. The device is specifically designed to provide stabilization without fusion in cases of stenosis with or without facet joint hypertrophy and subarticular recess stenosis, foraminal stenosis, and/or stable grade I spondylolisthesis or equivalent retrolisthesis. It is limited to use in one or two level lumbar stenosis from L1-L5 in patients with at least moderate impairment in function.

Spinal stenosis is any type of narrowing of the central spinal canal, subarticular recess or intervertebral foramina[1]. Symptoms most often occur in patients 50-70 years of age, with a large impact on the elderly population. Data from the Framingham Heart Study indicates that 1% of men and 1.5% of women already had evidence of stenosis at baseline (mean age of 54), increasing to 11% of men and 25% of women over the 25-year follow-up period[2].

In addition to published reports[3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13], the company has gathered retrospective data on the clinical outcomes of 429 patients treated with the coflex interspinous implant, as well as contemporaneous clinical and radiographic data on the same cohort of patients.

## Methods

Surgeons with a significant history and patient volume were contacted to participate in a retrospective review of their patient experience with the Fixano Interspinous "U", the predecessor device to the coflex interspinous implant. Four sites participated in this data collection effort. The surgeons attempted to contact all patients who had received the device. All patients who were greater than six months postoperative were given the option to participate in this data collection, which the company believes helped to minimize selection bias. Of the 589 patients identified by the surgeons, 429 (73%) responded and agreed to participate. All patients were asked to return for contemporaneous history and clinical examination and dynamic x-rays. These results were compared to available patient records pertaining to their quality of life and neurological function and pre-existing x-rays to ascertain implant survivorship. Patient data for the retrospective study was gathered via a questionnaire that captured the following information: 1) Date of Birth, 2) Gender, 3) Preoperative diagnosis, 4) Preoperative clinical evaluation, 5) Previous conservative therapy, 6) Previous spinal therapies, 7) Concomitant medical conditions, 8) Operative data, 9) Radiographic and diagnostic tests, 10) Postoperative clinical examination, 11) Qualitative postoperative x-ray analysis. Of these patients, 209 were treated for spinal stenosis at a single level or two adjacent levels. This population is substantially similar to the population for the protocol that is the subject of a current USA FDA IDE.

## Results

### Clinical Data

Patient case report forms and x-rays were reviewed by an independent orthopaedic spine surgeon who identified 209 patients with spinal stenosis (from the 429) which closely matched the inclusion criteria for the IDE. The remaining patients were treated for various indications such as "topping-off" of spinal fusions, use of the de-

Table 1: Composite Pertinent Patient Outcomes vs. Time Intervals

| Postoperative Outcomes N = 209 | Overall | Follow-up Time Intervals | | |
|---|---|---|---|---|
| | | 6 to 12 mo Median= 9 mo | >12 to 24 mo Median= 19 mo | >24 mo[t] Median= 33 mo |
| Improvement in moderate or severe preop low back pain | 75% | 73% | 82% | 72% |
| Improvement in preoperative leg pain | 87% | 84% | 87% | 85% |
| Improvement in preoperative claudication | 87% | 90% | 85% | 87% |
| Improvement in preoperative walking distance | 74% | 83% | 75% | 66% |
| "Patient satisfaction" | 89% | 90% | 91% | 88% |
| "Would have surgery again" | 92% | 96% | 90% | 91% |
| Adverse Events (n = 17) | 8.1% | 8.1% | 0% | 0% |
| "Device Related" issues (n = 7) | 3.4% | 1.9% | 0.5% | 1% |

[t]range = > 24 to 121 months

vice with other spinal implants, disc herniation, and others diagnoses, many of which are contraindicated in the USA IDE trial. The median follow-up was 20 months (range 6 to 121 months).

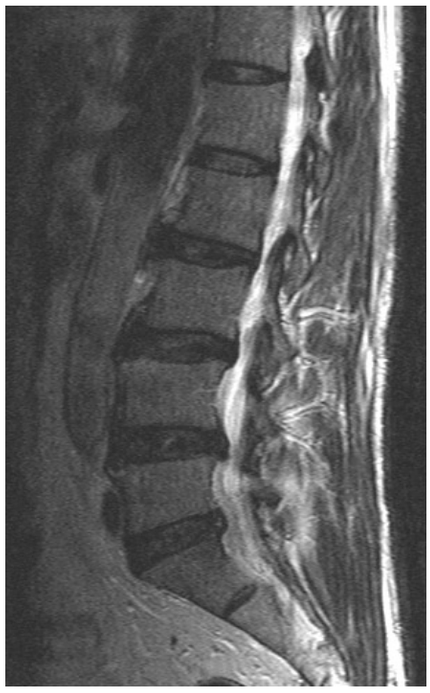
Table 1 demonstrates that the patients achieved their maximum clinical effect by 6-12 months. This clinical effect, which consists of clinical outcomes for back pain and claudication, shows a stable and consistent effect at 6-12 months and at long term follow-up. Overall, 75% of the patients had improvement in their moderate or severe preoperative low back pain and this remained constant over time. Claudicatory symptoms improved overall in 87% of the patients, again, reasonably constant over time. Postoperative walking distance improved overall in 74% of the patients with a slight tapering effect at the longer-term follow-up period (66%). This tapering effect is a result of natural aging of patients. Patient satisfaction was positive in 89% of the patients overall and 92% of the patients overall stated they "Would have surgery again". There were no differences whether 1 or 2 levels of stenosis, or whether the patients had mild instability (≤ 25º coronal deformity or ≤ stable Grade I spondylolisthesis).

**Radiographic Data**

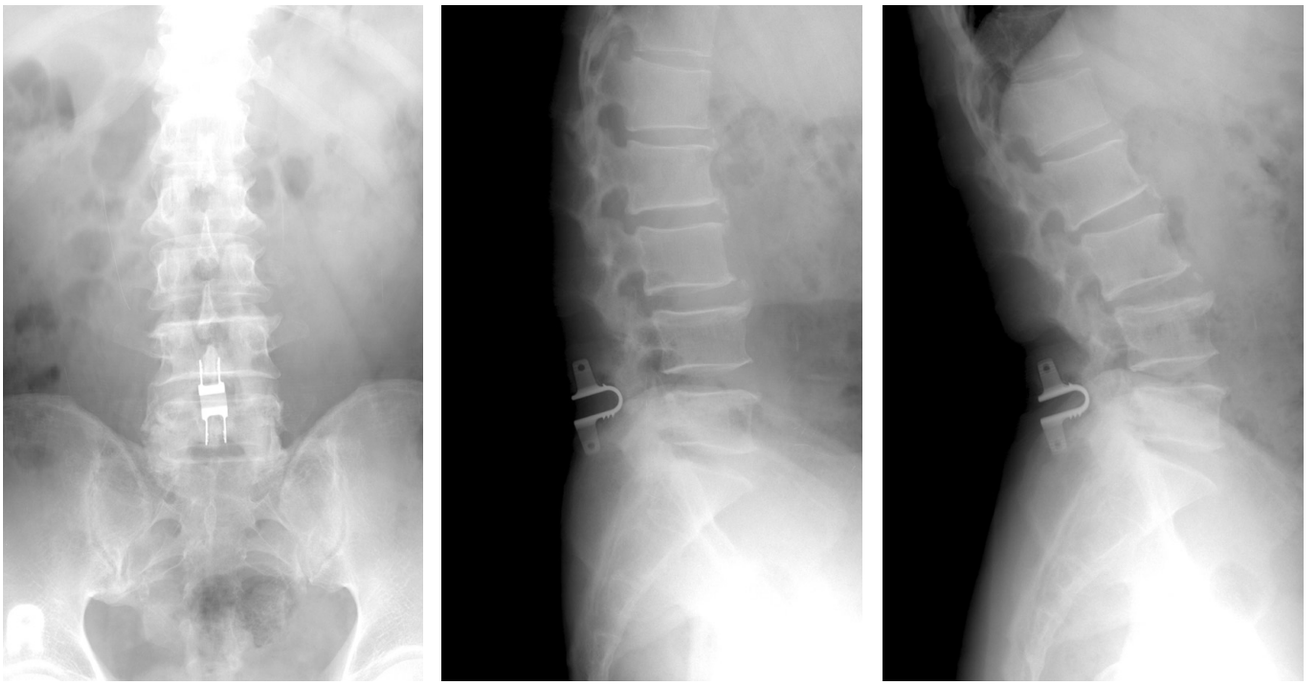
An independent radiographic core laboratory, Medical Metrics, Inc. (Houston, Texas) conducted an analysis of the range of motion. Range of motion (flexion/extension) of the coflex interspinous implant and adjacent levels was analyzed on 180 patients who had a complete good quality set of x-rays (preop and postop). The analysis determined that the range of motion for one level coflex implantations at pre-operative timepoint was 4.3 degrees, 2.1 degrees for one year, 2.3 degrees for the two year timepoint, and 2.1 degrees for the greater than 2 year timepoint. The range of motion for the two level patients was 4.0 degrees at the preoperative timepoint, 2.1 degrees for one year, 1.6 degrees for the two year timepoint, and 3.4 degrees for the greater than two year timepoint.

When evaluating the additional risks of implanting the coflex interspinous implant at two levels, several additional factors must be considered including the effects on kinematics and the increase in the risk of migration or expulsion. In flexion/extension, the retrospective data demonstrated no change in range of motion from one level to two level devices. The medium range of motion was determined to be 2.3 degrees for one level implantations and 2.1 degrees for two level implantations at the one year timepoint.

Non-device-related adverse events (8.1%) occurred uniquely in only the short-term follow-up group (6-12 months). "Device-related issues" were low (3.4% overall) and the majority were noted less than 24 months postoperatively (2.4%). When evaluating the occurrence of expulsion, the data demonstrated that there were no expulsions from between the spinous processes. There was 1 (0.5%) migration (> 5 mm) which was attributed to settling of the device and resulted in



Preoperative MRI



18 Months postoperative - AP, Flexion and Extension Images

no clinical sequelae. There were no device fractures at the "U" portion and no permanent deformations. Two unrecognized unilateral wing fractures were noted immediately postoperatively. The device caused no fractures of the spinous processes in the 209 patients. Four patients (1.9%) had the device removed. One patient had immediate removal when the spinous process fractured during evacuation of a seroma, one patient needed additional decompression for HNP at the same level in the early postoperative period and one patient needed a fusion for excessive disc settling after discectomy (with stenosis decompression) at 13 months. Therefore, three of four coflex interspinous implant removals occurred in the very short time frame (≤13 months). The additional patient was doing well until three years postoperatively when they fell and developed a slippage at the L4/L5 level. Although four explants occurred, none of these were secondary to device failures.

## Discussion

Patients diagnosed with significant spinal stenosis with progressive and sustained neurogenic claudication often cannot be treated with conservative therapy. Surgery typically consists of decompression of those structural changes directly compressing the neural elements. Inadequate initial decompression is the most common cause of failure of spinal stenosis surgery [14]. However, radical decompression without stabilization may also result in a poor outcome, particularly in the presence of a preexisting dynamic spondylolisthesis (angular or translatory) [15]. To prevent this, spinal stabilization following decompression has been advocated [16]. While other surgical procedures are available, autologous posterolateral fusion with or without pedicle screw fixation is often the procedure of choice, especially in the face of intraoperative structural destabilization or anticipated short and/or long-term instability. Successful posterolateral fusion adds rigidity that may prevent the complications associated with instability, and serves to maintain both disc space height and the patency of the neuroforamen. Apart from the issue of adjacent segment degeneration, rigid spinal instrumentation, especially pedicular fixation and posterolateral fusion, carries its own set of complications. These include, but are not limited to, screw fracture and pull-out, neural injury, increased operative time and blood loss [17]. Given these considerations, a simpler surgical approach, such as decompression via interspinous process implantation may have distinct advantages. The coflex interspinous implant was designed to address the clinical needs of spinal stenosis patients by providing stabilization of the affected level without fusion.

On page 3 is a case example of a 61 year old male patient diagnosed with severe stenosis at L4-L5. The patient experienced severe low back pain for 6 months and claudication for 10 months prior to treatment. The patient failed conservative treatment. Eighteen months after implantation of the coflex interspinous implant the patient showed improvement to mild back pain and had no claudication.

## Conclusion

Based on the retrospective data it was concluded that the coflex interspinous implant demonstrates a clear record of safety as well as preliminary evidence of efficacy for lumbar spinal stenosis. Optimized results were achieved by 6-12 months and were maintained out to 10 years follow-up. There were no major device issues in the short or long-term follow-up. Neurological issues were improved by a direct surgical decompression and outcomes for moderate/severe low back pain were good to excellent through mechanical stabilization and "controlled restricted motion" with this functionally dynamic implant.

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