

# Reported clinical outcomes of coflex dynamic stabilization device vs instrumented decompression and fusion in degenerative lumbar stenosis

## Abstract

**Introduction:** The concept of dynamic stabilization” or “soft stabilization” was introduced with aim to provide a solution to problems related with spinal fusion. In theory, dynamic stabilization system should provide sufficient support at the inserted level allowing for load transmission of a spinal motion segment, without major restriction to motion at the affected segment allowing to relieve pain and avoiding adjacent level disease encountered with spinal fusion.

**Methods:** Assessment of outcomes of Coflex dynamic stabilizers versus decompression and Mild to moderate degree lumbar degenerative foraminal stenosis was assessed in a prospective study between February 2008 and December 2011 at the Queen Elizabeth the Queen Mother Hospital, East Kent NHS Trust, Margate, Kent. Validated pain rating scale, Oswestry disability questionnaire, and operative data were used to compare outcomes.

**Results:** 208 patients were included in this study. 121 patients were treated with decompression and Coflex dynamic stabilization (Group I) and 87 patients were treated decompression and lumbar fusion (Group II). All patient included were followed for a minimum period of 2 years (2 - 3.9 Years). The Majority of patients were satisfied with the results in the immediate postoperative period with 82% of patients happy with surgical outcome. Visual analogue score results improved in both groups with a mean preoperative VAS score 8.4, 4 at one year 3.2 for the decompression and coflex group ( $p < 0.001$ )

**Conclusion:** The Coflex@ inter-spinous implant is a simple surgical treatment strategy with a low risk. Early results show a good improvement of both clinical and radiological parameters.

**Keywords:** Dynamic stabilizer, Coflex, Lumbar fusion, Degenerative lumbar stenosis

Volume 5 Issue 6 - 2016

Tamer T Kamal,<sup>1,2</sup> Sherif El Nikety,<sup>3</sup> Oscar J MacCormac,<sup>4</sup> Nitin Shah,<sup>3</sup> James N Casha<sup>3</sup>

<sup>1</sup>Orthopaedic department, Robert Jones and Agnus Hunt Hospital, UK

<sup>2</sup>Orthopaedic department, Cairo University, Cairo, Egypt

<sup>3</sup>Orthopaedic department, East Kent NHS Trust, UK

<sup>4</sup>Orthopaedic department, Royal Hampshire county Hospital, UK

**Correspondence:** Tamer T Kamal, Orthopaedic department, Robert Jones and Agnus Hunt Hospital, Oswestry, UK, Email tamerkamal@yahoo.com

**Received:** July 29, 2016 | **Published:** September 27, 2016

## Introduction

Degenerative lumbar spinal stenosis is common spinal problem among the elderly population, many affected individuals complain of pain and intermittent neurogenic claudication. Decompression surgery is still recommended as the best treatment option. Two options currently available for patients interested in having non-fusion for the lumbar spine, the first is lumbar artificial disc replacement and the second is dynamic stabilization developed to provide stability to a lumbar spine that is exhibiting instability causing severe low back pain. The source of back pain is most commonly associated with degenerative disc disease but can be also due to lumbar facet disease. Since the 1950s, various interspinous devices were created to help with lumbar degenerative disease time. Fred Knowles was a pioneer in dynamic stabilization when he inserted a metal plug to act as a spacer between two spinous process, a large number of posterior dynamic stabilization devices (PDS) were introduced since 1980s. The mechanism of action of Interspinous devices is by acting as a mechanical blocker to extension when inserted between the two spinous process. By distracting the spinous process, the spacers are able to increase foraminal height, space and offload the facet joint at the affected level.

The Coflex interspinous device was developed by French company Padagrim spine, the device is designed from titanium alloy into a single compressible U shaped device, the two long arms of the “U” are inserted paralleling the long axis of the spinous processes while the bone-facing surfaces are ridged to provide stability and prevent displacement (figure1). It is functionally dynamic compressible in

extension, allowing flexion with increased rotational stability while keeping the center of rotation close to the spinal canal. It provides a large contact area which helps stress distribution, reduce stress on facet joints and help maintain foraminal height. The device is can be easily inserted in a less invasive tissue sparing procedure without major disruption to posterior elements.

The use of coflex dynamic stabilizer is not recommended in the following conditions:

- A. In case of previous fusion or decompressive laminectomy at any level of lumbar spine.
- B. Vertebral bodies compromise due to either trauma or malignancy.
- C. Severe facet hypertrophy.
- D. Grade II or greater spondylolisthesis.
- E. Isthmic spondylolisthesis or spondylolysis (pars fracture)
- F. Degenerative lumbar scoliosis with a Cobb angle of or greater than 25 degrees.
- G. Osteoporosis.
- H. Back or leg pain of unknown etiology.
- I. Morbid obesity defined as a body mass index greater than 40
- J. Active or chronic infection
- K. Known allergy to titanium or titanium alloy
- L. Cauda Equina Syndrome

## Aim of this study

Aim of this study it to assess clinical outcome of coflex dynamic stabilization for foraminal stenosis compared with decompression and instrumented spinal fusion for spinal stenosis.

## Materials and methods

208 patients with symptomatic, moderate degree degenerative lumbar spine foraminal stenosis were included in this prospective multicenter study. Departmental ethical approval was obtained. 121 patients were treated with decompression and Coflex dynamic stabilization (Group I) and 87 patients were treated decompression and lumbar fusion (Group II).

Clinical outcome measures were assessed using Oswestry Disability Index (ODI) and visual analogue scale (VAS) for back pain and leg pain prior to surgery and at three, 6, 12, 18 and 24 month intervals. Clinical questionnaire were collected in follow-up clinics and by phone interview. Radiological assessment was carried pre-operatively, immediate post-operative period, 6 month, and one and two years follow-up visits. Data was also collected in relation to operative time and blood loss.

## Statistical analysis

Statistical analysis was performed using R package stats for data analysis.<sup>1</sup>The results obtained were analyzed using the student's t-test and verified with Fisher's exact test. Significance was accepted at  $P < 0.05$  to analyze data.<sup>1</sup>

## Results

A total of 208 patients with symptomatic, moderate degree degenerative lumbar spine foraminal stenosis were included in this prospective study. 121 patients were treated with decompression and Coflex dynamic stabilization (Group I) and 87 patients were treated decompression and lumbar fusion (Group II). Group I consisted of 67 males and 54 females, the mean patient age was 61 years (44 - 80). We had 65 single level decompression, 43 double level decompressions, and seven three level decompressions and coflex stabilization. Group II Consisted of 46 males and 31 females, the mean patient age was 64 years (48 - 77). We had 43 single level decompression, 34 double level decompression, and four three level decompressions and fusion. All patient included were followed for a minimum period of 2 years (2 - 3.9 Years)

### Operative time

Coflex Group I experienced significant shorter operative times ( $P < 0.001$ ) with an average 32% reduction in operative time (Figure 1).

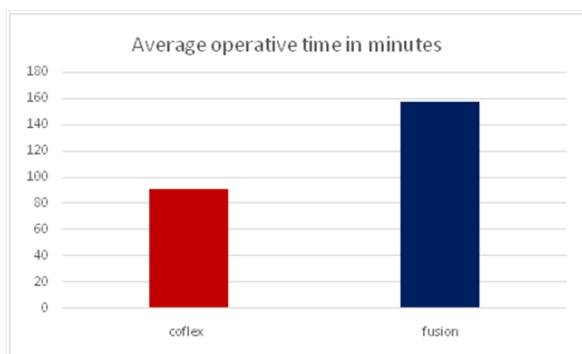


Figure 1 Average Operative time in minutes.

### Blood loss

A major reduction in blood loss was noted in the coflex group I ( $P < 0.001$ ) with an average 54% reduction in blood loss (Figure 2).

### Patient Satisfaction

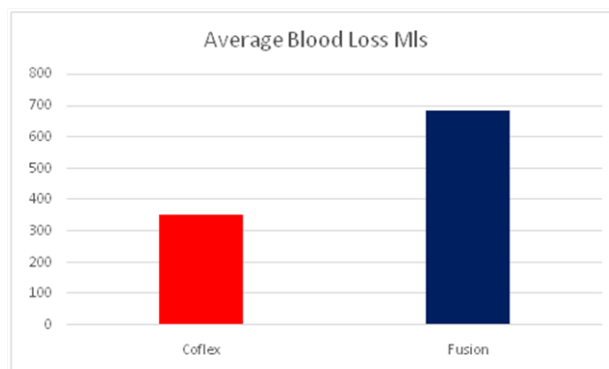


Figure 2 Average blood loss in Mls.

### Patient Satisfaction

Majority of patients were satisfied with the results in the immediate postoperative period with 82% of patients happy with surgical outcome in group I in comparison to 79% satisfaction for group II at 2 years' period (No statistical Significance between both groups  $P = 0.9$ ) (Figure 3).

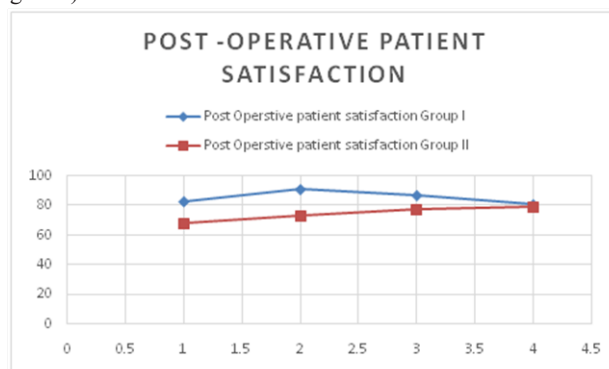


Figure 3 Post Operative patient satisfaction.

### Visual analogue score

Visual analogue score results improved in both groups with a mean preoperative VAS score 8.4, 4.8 at 3 month, 4 at one year 3.2 for the decompression and coflex group ( $p < 0.05$ ), and a mean preoperative score VAS score of 6.8, 6.2 at 3 month, 4.5 at one year and 3.1 at two years. The decompression and coflex stabilization had better VAS score during the immediate post-operative in period in comparison to fusion group ( $P = 0.05$ ) with both group having near similar results at one year and two follow-ups. ( $P = 0.4$ ) (Figure 4).

### Oswestry disability score

Both groups demonstrated significant improvement from pre-operative values. The decompression and coflex group showed a more significant improvement in the early post-operative period ( $P < 0.04$ ), with no significant differences between both groups at the 2 years mark ( $P = 0.8$ ) (Figure 5).

## Discussion

Adjacent level degeneration after spinal fusion is a well-documented condition which may lead to further surgical interventions. Recent

surgical treatments for spinal stenosis are geared towards preserving spinal segment movement aiming at prevention of adjacent level disease.

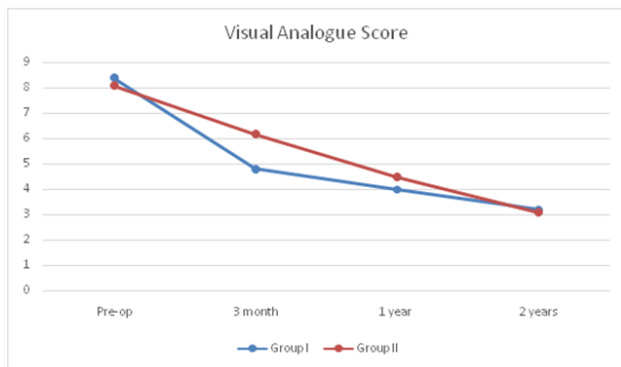


Figure 4 Visual Analogue score.

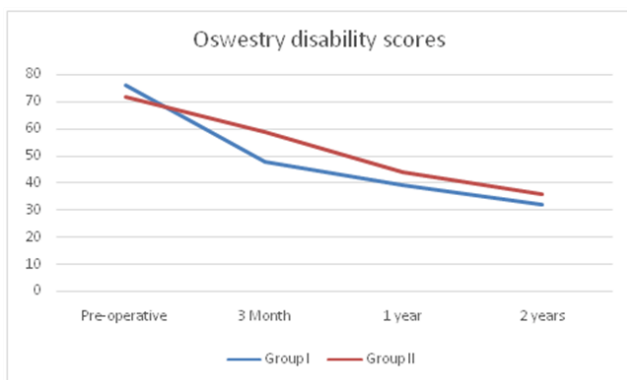


Figure 5 Oswestry Disability Score.

Biomechanical cadaveric studies showed a significant reduction in flexion-extension range of motion at instrumented level using coflex while providing adequate stabilization of partially unstable cadaveric specimens in terms of flexion/extension and axial rotation;<sup>2</sup> with no significant increase in range of motion at adjacent level when compared to PLIF (posterior lumbar interbody fusion).<sup>3</sup> Trautwein et al.<sup>4</sup> conducted an in vivo posterior loading environment of the Coflex assessing the average loads exerted by the Coflex implant on the spinous process and lamina and found that forces exerted represent only 11.3% and 7.0% of their respective static failure load and concluded that Coflex fatigue failure is extremely rare.

In 2013 the results of an FDA (Food and Drug Administration) funded prospective, randomized, multicenter trial evaluating both safety and efficacy of Coflex stabilization in comparison to posterior spinal fusion in the treatment of single and double level spinal stenosis and degenerative spondylolisthesis were published. Results showed a significant improvement in visual analogue scale, in Short-Form 12 physical health outcomes ( $P = 0.050$ ) and equivalent mental health outcomes in both groups. Coflex subjects experienced significant improvement in all Zurich Claudication Questionnaire outcomes measures compared with fusion ( $P = 0.023$ ); physical function ( $P = 0.008$ ); patient satisfaction ( $P = 0.006$ ). With a greater improvement in mean Oswestry Disability Index scores in the Coflex group ( $P = 0.075$ ). This study demonstrated a similar overall success results based on the Food and Drug Administration composite for overall success criteria, with a success rate of 66.2% for Coflex and 57.7% for fusion. ( $P = 0.999$ ).<sup>5</sup>

One recent study evaluated interlaminar stabilization following decompression for lumbar spinal stenosis in patients' low back

pain. Data were collected from two European registries, patients were closely matched into two cohorts, those receiving coflex after decompression and those receiving decompression alone. The group receiving the dynamic stabilizing device had significantly better results based on several outcome assessments, with similar high rate of satisfaction achieved in both treatment groups.<sup>6</sup>

Richter et al.<sup>7</sup> evaluated the outcome of decompressive surgery versus decompressive surgery and Coflex interspinous device supplementation in patients with symptomatic lumbar spinal stenosis. 60 patients were divided into two groups with half (30 patients) treated with decompression surgery alone and the remaining patients had an additional implantation of a coflex dynamic device. Results at the one year follow-up mark showed no statistical differences between both groups in all assessed outcome measures.<sup>7</sup>

In a clinical study, 18 patients undergoing Coflex placement and concomitant lumbar decompression were compared with 24 patients undergoing PLIF procedure. All patients in the study had mild segmental instability. Clinical evaluation was done using VAS and ODI which improved significantly in both the patient groups with no major clinical significant differences.<sup>8</sup> One study compared the cost-effectiveness study of coflex to instrumented posterior fusion over the course of five years. The authors found that the interlaminar device was significantly less costly.<sup>9</sup>

This study proved similar outcomes in both leg and back pain scores in both cohorts. With coflex supplementation proving to provide better earlier outcomes with less operative time, blood loss. One of the main limitations of this study was the limited duration of follow-up limited to a minimum of 2 years. Further investigation through longer period of follow-up and investigation will be highly beneficial.

## Conclusion

Coflex interlaminar stabilization is a safe and efficacious alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis. The Coflex@ dynamic stabilizer implant is able to provide a simple surgical treatment modality with minimal surgical risk. During the early post-operative period the decompression and coflex group (group I) had better outcome in both VAS and ODS scores in comparison with the fusion group. No statistical difference was present between the two groups results in both VAS and ODS scores at both one and two year follow-up. Although patients may obtain some benefits from interspinous spacers implanted through a minimally invasive technique long term results should be analyzed further for complications and cost effectiveness.

## Acknowledgments

None.

## Conflicts of interest

None.

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