Evaluation of Lumbar Inter-Spinous Spacer (CoflexTM) in Treatment of Degenerative Lumbar Spinal Stenosis

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Abstract

Objective: To evaluate the surgical outcomes of using dynamic inter-spinous spacer CoflexTM in treatment of degenerative lumbar spinal stenosis.

Methods: 30 patients who were all treated in Suez Canal University Hospital for a one or two level symptomatic LSS with decompressive surgery were included. Pre-and postoperatively disability and pain scores were measured using the Oswestry disability index (ODI), the visual analogue scale (VAS) and the pain-free walking distance (WD). Patients underwent postoperative assessments 3, 6 and 12 month including the above-mentioned scores as well as patient satisfaction.

Results: Statistically significant improvement in the clinical outcomes assessed in the ODI for evaluation of back pain, in the VAS and in the pain-free WD at all times of reinvestigation compared to base line.

Conclusion: Dynamic inter-spinous spacer CoflexTM offers a less invasive and least destructive relief of patient’s complaint.

Key Words: Interspinous process device – CoflexTM device – Lumbar dynamic stabilization – Lumbar spinal stenosis – Decompression surgery.

Introduction

LUMBAR spinal stenosis (LSS) due to degenerative changes is a disabling disease common in the elderly [1]. Surgery is an accepted, commonly performed treatment of symptomatic lumbar spinal stenosis and the fastest growing reason for spinal surgery in adults over 65 years of age [2,3].

Decompressive surgery was shown to be a successful treatment in relieving symptoms of lumbar spinal stenosis and being superior to conservative treatment in long-term examinations also. But, there is no clear evidence about the most effective technique of decompression or the extent of that decompression [4-7].

Interspinous-based dynamic stabilization after decompressive surgery is currently being investigated as a good additional procedure which might improve the clinical outcome. Therefore a growing number of interspinous process devices have been introduced recently. There clinical goals range from treatment of degenerative spinal stenosis, discogenic low back pain, facet syndrome, disc herniation and instability. Those spacers can be divided into static and dynamic implants [8].

One of the dynamic interspinous implants is the CoflexTM device (Paradigm Spine, LCC, New York, NY), formerly Interspinous ‘U’. It is a compressible U-shaped titanium device that is interposed between the spinous process after decompressive surgery. It was first invented in 1994 by the French orthopaedic surgeon Jacques Samani as an alternative to arthrodesis, in order to protect adjacent levels after spinal surgery and for the protection of degenerative segments following decompressive surgery [9]. The aim of this interspinous device is to unload the facet joints, restore foraminal height and provide stability after decompressive surgery in order to improve the clinical outcome. Published information is limited, and there are no data of comparison between this implant and traditional surgical approaches such as laminotomy.

Material and Methods

During October 2008 to June 2011 we prospectively followed a cohort of 30 patients where decompressive surgery due to spinal stenosis was
carried out. Patients presenting to Suez Canal University hospital with symptoms, signs, and MRI findings of a lumbar spinal stenosis and a period of minimum 3 months of frustrating conservative treatment were eligible for microsurgical decompressive surgery. For this study inclusion and exclusion criteria were defined as shown in Table (1).

Only patients at the age of 40-80 with one or two level stenosis were included and no previous surgery at the lumbar spine took place. Patients with a stable degenerative spondylolisthesis grade one were included. We defined segmental instability on the standing lateral radiographs with a degenerative spondylolisthesis greater than grade one or a slip greater 3mm in inclination.

The operation was performed under general anesthesia and the patients were placed in a prone position. All of the subjects underwent posterior decompression surgery through a midline approach and microsurgical bilateral decompression. Decompression involved a partial laminotomy, removal of ligamentum flavum and undercutting facetectomy. Up to the surgeon the midline structures were preserved or resected and the CoflexTM interspinous device was implanted in one or two levels. The implanting technique of the CoflexTM device is simple. After resection of the interspinous ligaments the device size is chosen using templates and the device is inserted with tightened clips around the spinous process. We controlled the effect of the chosen template by radiographs to see the effect of distraction and segmental kyphosis.

The outcome was measured pre- and postoperatively with disability and pain scores using the Oswestry disability index (ODI), the visual analogue scale (VAS) and the pain-free walking distance (WD). The WD was estimated by the patient, an unlimited WD was defined with the value of 5,000m. The patients underwent postoperative assessments 3,6 and 12 months including the above-mentioned scores as well as the survey of the patient satisfaction and operative decision.

Dynamic and static radiographs were obtained presurgery and postsurgery at first follow-up. The mean total sagittal ROM (from full extension to full flexion) for the segmental intervertebral angles at the operated levels were measured and compared on flexion-extension radiographs in the study group using Cobb’s method.

**Results**

From October 2008 until June 2011 we treated and followed 30 patients in our hospital with this procedure. In the study group there were 17 male and 13 female patients who ranged in age from 52 to 74 years (mean 66 years). 20 patients (67%) presented with stenosis only, 10 (33%) presented with a combination of stenosis and spondylolisthesis and in 4 patients (13%) a stenosis and an additional scoliosis was found. There were 5 cases of double level decompression and Coflex insertion.

Median follow-up was 12.5 months. Our results showed marked improvement in low back pain. Postoperatively, we found, 74% of patients did improve and 44% even showed no low back pain anymore. Mean preoperative walking distance was <1000m in 89% of patients, postoperatively 87% of patients could walk >1000m. According to the patients opinion, 92% of patients were satisfied or very satisfied, only 8% were not satisfied. Long-term follow-up did not show a decrease of patients' satisfaction. 95% stated that they would undergo this surgery again. Immediate postoperative complications occurred in 7%, as 1 patient with seroma in wound, and 1 worsening of existing sensory deficit possibly from manipulation. No patients had the coflexTM removed and we saw only 1 migrated coflexTM (5mm, no clinical signs). We found no broken or deformed coflexTM.

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<th>Table (1): Inclusion and exclusion criteria.</th>
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<td><strong>Inclusion criteria</strong></td>
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<td>Clinical and radiographic criteria of a symptomatic lumbar spinal stenosis</td>
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<td>Failed conservative treatment (3 month)</td>
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<td>One or two level stenosis</td>
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<td>No signs of segmental instability</td>
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<td>Age between 40 and 80</td>
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<td><strong>Exclusion criteria</strong></td>
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<tr>
<td>Isthmic spondylolisthesis</td>
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<td>De novo scoliosis &gt;15º</td>
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<td>Previous lumbar spine surgery</td>
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<td>Signs of instability &gt;Meyerding 1</td>
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Fig. (1): 55 years old male patients with neurogenic claudication for 6 months. Preoperative axial T2 MRI showing central canal stenosis. Postoperative Axial & Sagittal MRI show the effective neural decompression plus Coflex device proper position. X-ray Lumbosacral spine showing the stability of the Coflex device in flexion and extension.

Discussion

Lumbar spinal stenosis is an increasingly common diagnosis in ageing individuals and the rates of surgery have risen all over the world. Decompressive surgery was shown to be a successful treatment in relieving symptoms of lumbar spinal stenosis [6,7]. But there is still controversy of the long-term benefit of surgical versus non-surgical treatment. In long-term outcomes surgically treated patients reported greater improvement in leg symptoms and back-related functional status than nonsurgically treated patients [8]. Next to the expected improvement of leg pain it is well known that there is also a significantly improvement in back pain in the short and mid term results [4].

Surgery typically means the microsurgical decompression of the neural structures by resection of the ligamentum flavum, partially laminotomy and undercutting facetectomy. Furthermore, spinal stenosis is often accompanied with spondylolisthesis or instability in the affected segment. That is one of the reasons why there is a need for less invasive strategies that provide a balance between safety and effectiveness [10]. A number of interspinous process devices have recently been introduced [8]. One of those “dynamic” devices is the CoflexTM device (formerly Interspinous ‘U’), which was originally invented by the orthopedic surgeon Jacques Samani in 1994 as an alternative to arthrosis, as a so-called “topping off” in order to protect adjacent levels after rigid spinal instrumentations or as a protection of degenerative motion segments following decompressive surgery [11]. The aim of implanting this interspinous device is to unload the facet joints, restore foraminal height.
and provide stability in order to improve the clinical outcome of surgery. The main indication for this device is a symptomatic moderate to severe stenosis in the region of L1 to L5 with or without concomitant low back pain including conditions such as stable grade I spondylolisthesis.

In an unpublished report by Samani, he saw in his 80 patients where the device was implanted with “no arthrodesis” good results and followed that the major indication for this device is to treat instability, lumbar spinal stenosis and recurrent disc herniation in the level L4/5. Kaech [11] used the implant in 18 patients with a variety of indications for surgery and followed that it appears to be a minimal invasive restabilization device for patients undergoing microsurgical decompressive procedures and who have signs of minor instability or the risk of a potentially increasing postoperative instability.

The biomechanical effect of this interspinous device is now well investigated. Wilke et al. [12] and Kettler et al. [13] could show that the implant stabilized and overcompensate the instability caused by a decompression defect up to 50% of the range of motion of the intact state, but only for extension. There is almost no stabilization effect in flexion, lateral bending and axial rotation.

Kong et al. [14] made a comparison analysis between decompression with concomitant surgical placement of a CoflexTM Device and PLIF- instrumentation and found at 1-year follow-up a comparable clinical outcome in the VAS and Oswestry score. The authors followed that the additional implantation of the CoflexTM device is safe, simple and gives good and excellent results in decompressive surgery of LSS.

Our current study reviewed the outcome of a group of patients in whom decompressive surgery was carried out with an interspinous CoflexTM device was additionally implanted. In our group we could see a significant improvement in the clinical outcome assessed in the ODI, in the VAS and in the pain-free WD at all times of reinvestigation compared to base line. At 1-year follow-up, there were also improvement in all ascertained parameters including the patient satisfaction and subjective operation decision. This study has a limitation in the short-term follow-up period of 12 month, the missing of control group and the number of patient being included.

Conclusions:

After decompressive surgery for lumbar spinal stenosis, all measured parameters improved significantly compared to base line. The placement of a CoflexTM interspinous device seems to be a safe procedure.

References