Microsurgical decompression with Coflex interspinous dynamic stabilization for treating lumbar degenerative stenosis

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Abstract

Introduction: Degenerative lumbar canal stenosis is a disease affecting population between 40-80 years of age and is treated by many surgical modalities. Patients suffering from a single level degenerative lumbar spinal stenosis are included in this prospective cohort study. The purpose of this study is to determine efficacy and safety and to analyze the clinical and radiological results of using Coflex device after microsurgical decompression of a single level degenerative lumbar spinal stenosis.

Patients and Methods: Twelve patients with lumbar spinal stenosis who treated by microsurgical decompression and Coflex stabilization were reported. Coflex stabilization was used after decompression of lumbar canal to treat degenerative segmental stenosis. 10-point Visual Analogue Scale (VAS) was used to evaluate leg pain and back pain post procedure. The neurogenic claudication distance was also calculated. The median follow-up period was 24 months. Radiographic data was collected and implant position and spinal segment motion was evaluated.

Results: Back pain was significantly improved in 83.3% of patients (P < 0.05), while radiculopathic pain was significantly improved in 91.6% of patients (P < 0.05). Also significant improvement in walking distance is achieved in 91.6% of the patients (P < 0.05). No expulsions or implant migration in postoperative follow-up occurred. Radiographic analysis revealed a significant decrease in spinal segment motion postoperatively during follow-up period.

Conclusions: Coflex implantation is safe and effective in treating degenerative lumbar spinal stenosis. It is rapid minimally invasive technique with no reported serious complications. It also, demonstrates excellent results along the whole time of follow-up for improvement of back pain, neurogenic claudication and patient’s postoperative satisfaction.

Key words: lumbar spinal stenosis, microscopic lumbar decompression, interspinous devices, Coflex.

Introduction

Lumbar spinal stenosis (LSS) due to degenerative changes is a disabling disease common in the elderly [1]. As the population ages, the prevalence of LSS is likely to increase, resulting in an increased need for management of this condition. Treatments for which there is evidence of effectiveness include intramuscular calcitonin, epidural steroid injections, and surgery [2]. Decompressive surgery was shown to be a successful treatment in relieving symptoms of LSS and being superior to conservative treatment such as bed rest, physical therapy, exercise, braces, traction, transcutaneous electrical nerve stimulation, spinal manipulation, narcotic analgesics, or epidural steroids when failed. [3, 4, 5, 6, 7, 8]. Newer surgical options such as interspinous implants have also demonstrated clinical effectiveness in such patients [8]. Those interspinous spacers can be divided into static and dynamic implants. One of the dynamic interspinous implants is the Coflex™ device (Paradigm Spine, LCC, New York, NY), formerly Interspinous ‘U’. It is a compressible U-shaped titan 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 purpose of this prospective cohort study is to determine efficacy and safety and to analyze the clinical and radiological results of using Coflex device after microsurgical decompression of a single level degenerative lumbar spinal stenosis.
Patients and Methods

Twelve patients with lumbar spinal stenosis were treated by microsurgical decompression and Coflex stabilization. All patients were suffering from symptoms of spinal stenosis such as pain, leg weakness tingling or numbness in the lower extremities experienced after walking or exercise. Patients commonly experience associated pain in the low back and buttocks. This pain can radiate down one or both legs. Often the pain shortens the stride, inhibiting walking or even immobilizing the patient. All patients find their symptoms are worst when standing or walking, and find some relief from sitting, lying down or bending forward. All patients met the following inclusion criteria: age over 40 years, Appropriate candidate for surgery, No more than 1 levels should require, No prior lumbar fusion, No lumbar disc herniation requiring concurrent surgery, and must have had at least 3 months prior care and failed non-operative treatment. We exclude any patient had any of the following exclusion criteria, presence of lumbar instability, previous surgery in lumbar spine, stenosis for more than one level. All patients underwent microsurgical decompression for the stenotic level the Coflex implant was inserted. All patients were followed up for at least 12 months. Patients are followed up at one month, 3 months, 6 months, one year. At time of follow up, all patients had clinical examination and X-ray taken. 10-point Visual Analogue Scale (VAS) was used to evaluate leg pain and back pain post procedure. The neurogenic claudication distance was also calculated. All patients were also evaluated by Oswestry Disability Index (ODI) [10]. Radiographic data was collected and implant position and spinal segment motion was evaluated. This study was approved by institutional review board of Menoufiya University. All patients provided written informed consent.

Operative technique

Under general anesthesia, the patient is placed in prone position with slightly lumbar flexion. After a midline skin incision of 3–5 cm, the paraspinous muscles are stripped off the laminae. The interspinous ligament is removed and the bony attachments are resected. The stenotic level is microscopically decompressed. To define the appropriate implant size, trials are utilized. Some bony resection of the spinous process may be needed. The interspinous implant (8, 10, 12, 14, or 16 mm) is introduced tightly with gentle hammering using a mallet. Thereafter, the wing clamps of the interspinous U are tightened against both edges of the upper and lower spinal process (fig. 1). Fixation at the spinous processes of Coflex is possible with crimping of the wings. The depth of insertion of the Coflex can be verified under lateral fluoroscopy. The proper depth is determined if a nerve hook can be passed freely leaving 3 to 4mm between the bottom of the Coflex and the thecal sac.

![Figure 1: A) microscopic photo showing decompression of the stenotic level, B) Template to determine Coflex size needed and C) Coflex device after being positioned properly in its place.](image)

Statistical analysis

Results were statistically analyzed by statistical package SPSS version 16 (SPSS Inc., Chicago Ill). Paired t test "parametric test" and Wilcoxon signed rank test "non-parametric test" were used for quantitative variable at different time sequences.

Results

Twelve patients suffering from single level spinal canal stenosis were included in this study. Seven patients were women. The patient's age ranged from 43 to 68 years with average age 59 years. Eight patients
were operated for L4-5 level and the remaining four cases for L3-4 level. The period of follow up ranged from 13 months to 37 months with median follow up period 24 months. All patients were followed up at one month, 3 months, 6 months, one year postoperatively and their clinical data are shown in table 1.

Table 1: show the clinical data of the examined 12 patients along one year follow up period.

<table>
<thead>
<tr>
<th>Postoperative Outcomes</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of improvement in moderate or severe</td>
<td>66.6%</td>
<td>75%</td>
<td>83.3%</td>
<td>83.3%</td>
</tr>
<tr>
<td>preop. LBP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of improvement in preop. Leg pain</td>
<td>83.3%</td>
<td>91.6%</td>
<td>91.6%</td>
<td>91.6%</td>
</tr>
<tr>
<td>% of improvement in preop. claudication</td>
<td>58.3%</td>
<td>75%</td>
<td>83.3%</td>
<td>83.3%</td>
</tr>
<tr>
<td>% of improvement in preop. walking</td>
<td>75%</td>
<td>91.6%</td>
<td>91.6%</td>
<td>91.6%</td>
</tr>
<tr>
<td>distance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of patients satisfaction</td>
<td>75%</td>
<td>91.6%</td>
<td>91.6%</td>
<td>91.6%</td>
</tr>
<tr>
<td>Would patient have surgery again</td>
<td>75%</td>
<td>91.6%</td>
<td>91.6%</td>
<td>91.6%</td>
</tr>
<tr>
<td>Postop. Complications</td>
<td>8.3%</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Device related complications</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Regarding clinical data of the examined 12 patients; there was a significant improvement in low back pain and leg pain compared to preoperative clinical data by the end of follow up period after one year (P< 0.05). Also, walking distance showed significant increment compared to preoperative data at one year follow up (P< 0.05). Finally, ODI scores showed highly significant change from preoperative severely disabled patients to persons with minimal disability from 1 month postoperatively and continue during the whole period of follow up (P< 0.001) (table. 2).

Table 2: shows relation between preoperative clinical data and postoperative data after one year follow up period.

<table>
<thead>
<tr>
<th></th>
<th>Preop. (N=12)</th>
<th>1 year Postop. (N=12)</th>
<th>Test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ±SD</td>
<td>Mean ±SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ODI %</td>
<td>85.50 ±5.31</td>
<td>8.66 ±1.77</td>
<td>45.53</td>
<td>&lt;0.001(HS)</td>
</tr>
<tr>
<td>VAS (leg)</td>
<td>9.91±0.28</td>
<td>1.50 ±1.31</td>
<td>3.09</td>
<td>0.002(S)</td>
</tr>
<tr>
<td>VAS (LBP)</td>
<td>9.08±0.66</td>
<td>1.41 ±2.02</td>
<td>3.11</td>
<td>0.002(S)</td>
</tr>
<tr>
<td>Walking distance</td>
<td>43.16±22.36</td>
<td>981.17 ±28992.92</td>
<td>3.06</td>
<td>0.002(S)</td>
</tr>
</tbody>
</table>

HS: highly significant
S: significant

Regarding radiological outcome, dynamic and static radiographs were obtained before surgery and postsurgery at first follow up. Segmental intervertebral angles (forced by lines drawn on the upper and lower
endplates of adjacent vertebrae) at the operated levels were measured and compared on standing lateral flexion-extension radiographs. All patients showed a decrease in the range of motion for flexion and extension in the functional spinal unit (fig. 2).

![Radiographs showing decreased motion segment](image)

*Figure 2: A) Flexion and B) extension lateral x-ray views showed decreased motion segment after inserting Coflex device.*

Endplate angle used to be acute preoperatively and becomes more or less parallel post Coflex insertion. This makes the foraminal height increased significantly post procedure (fig. 3).

![Radiographs showing foraminal height](image)

*Figure 3: Acute endplate lines become more or less parallel after Coflex device and the narrow foramina pre-Coflex becomes wide post-Coflex.*

Disc space was collapsed preoperatively, while post operatively it becomes more opened. Also, anterior and posterior disc heights showed significant increment postoperatively (fig. 4).
Discussion

Lumbar spinal stenosis (LSS), in which narrowing of the spinal canal results in pressure on nerves in the back and leg, affects as many as 38.8% of adults 60 years and older in the United States [1]. As the population ages, the prevalence of LSS is likely to increase, resulting in an increased need for management of this condition. In meta-analysis decompressive surgery was shown to be a successful treatment in relieving symptoms of lumbar spinal stenosis [5, 6]. Although decompressive surgery is an accepted commonly performed method, 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 non-surgically treated patients [4]. Next to the expected improvement of leg pain it is well known that there is also a significant improvement in back pain in the short and midterm results [3].

However, it is also known that there is a higher rate of complications in instrumented fusions in the elderly patients, such as pseudarthrosis, implant failure due to loosening and complications because of the comorbidity of the patients. That is one of the reasons why there is a need for less invasive strategies that provide a balance between safety and effectiveness [12]. Based on the company’s recommendation, the aim of implanting Coflex interspinous device is to unload the facet joints, restore foraminal height and provide stability in order to improve the clinical outcome of surgery.

Wilke et al. [13] and Kettler et al. [14] showed that the Coflex stabilized and over compensate 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. As the LSS manifestations are relieved by flexion and aggravated by extension, we used Coflex device in LSS cases only and all patients in the current study showed significant reduction in their leg pain and back pain (P<0.05) as the Coflex device slightly flex the stenotic level while restrict its extension. Also, they showed significant increment in walking distance post operative compared to preoperative data (P<0.05).

The clinical results of this study are concurrent with other studies from literature [15,16,17]. More than 90% of the treated patients were satisfied by the postoperative clinical results and 91.6% of them said that they will do the same surgery if they have the same problem again.

Zang et al [18] treated 133 patients with degenerative disease of the lumbar spine, sixty seven of them had LSS. They encountered intra and postoperative complications related to Coflex device in the form of spinous process fracture and device dislodgment in 13 patients (9.8%), seven of them in LSS cases. In our study, only one patient had wound infection postoperatively which soon treated by adding gram negative antibiotic to the usual antibiotic regimen. No implant related complications happened in this study population.

Radiologically, Coflex device is positioned interlaminarily very close to anatomical center of rotation, so; the range of motion of the facet joints is controlled, joint slightly distracted and unloaded. Foraminal height is
restored and the height is maintained by metallic stiffness of the Coflex itself. The results of our study showed that, a) endplate angles always become less acute, b) foraminal height always increases, c) disc height is definitely change in both anterior and posterior heights, and d) Coflex maintained functional dynamic movements because it is compressible in extension, while limiting flexion.

The known positive effect of distraction and decompression of neural structures on claudication and leg pain is evident with Coflex device. Distraction increased the dimensions of the spinal canal and neural foramina at the implanted level in extension, but it did not alter the dimensions of the adjacent intact levels in the extended, flexed, or neutral positions.

Conclusions

Coflex implantation is safe and effective in treating single level degenerative lumbar spinal stenosis. It is rapid minimally invasive technique with no reported serious complications. It also, demonstrates excellent results along the whole time of follow-up for improvement of back pain, neurogenic claudication and patient’s postoperative satisfaction. Although this series has limitation of a smaller sample size, it confirms satisfactory results. Longer follow up period is needed in the future.

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Disclosure

The authors certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers’ bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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