Interspinous Implantation for Degenerative Lumbar Spine: Clinical and Radiological Outcome at 3-yr Follow Up

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Objective: Interspinous devices for dynamic stabilization of lumbar spine are undergoing development and clinical trials. A few short-term outcomes of interspinous devices have been reported but little has been mentioned about long-term outcomes. We reviewed 19 cases of interspinous implantation (Coflex Paradigm spine, Germany) to evaluate clinical long-term outcome and radiologic features.

Methods: From January 2003 to March 2004, 19 patients (13 female and 6 male) who underwent interspinous implantation were included and follow-up data on clinical and radiologic outcomes were obtained at last clinic visit (mean follow-up: 38 months). Clinical outcomes were assessed by Visual analogue scale (VAS) score and Odom’s criteria.

Results: Preoperative VAS score for low back pain and leg pain was improved from 4.9±2.4 and 7.5±2.4 to 2.6±1.2 and 3.0±1.8 respectively at postoperative last clinic visit (p<0.01). Using Odom’s criteria, 7 and 9 patients showed excellent (36.8%) and good (47.3%) results for low back pain and 7 and 11 showed excellent (36.8%) and good (57.9%) results for leg pain. Anterior and posterior disc height were decreased significantly on postoperative follow-up radiologic data due to discectomy at the level of instrumentation (p<0.01). There were no complications such as infection or device failure.

Conclusions: In this long-term follow-up study, clinical outcome was good but disc degeneration after discectomy at instrumented level resulting in decrease of disc height was observed.

Key Words: Interspinous implantation • Dynamic stabilization • Lumbar stenosis

INTRODUCTION

It has been described that neurogenic claudication secondary to lumbar stenosis is manifested by radicular pain, often bilateral, exacerbated by standing, walking and other positions, especially in extension. Pathologic progression of degenerative intervertebral disc changes leads to loss of disc height. The resultant instability by facet joint hypertrophy may worsen the spondylosis, and hypertrophy of ligamentum flavum which compress thecal sac of cauda equina particularly during extension.

Posterior lumbar decompression and fusion has been the traditional treatment for lumbar stenosis with low back pain or lumbar instability. The improvement in radiologic fusion rate between 90 to 100% has been achieved by advanced bone fusion technology. However, some studies have reported that clinical outcome of lumbar fusion is less satisfactory comparing radiologic fusion rate. Posterior lumbar fusion may developed adjacent segmental degeneration particular segmental instability. Thus, dynamic stabilization, or soft stabilization, was introduced. Dynamic stabilization has been defined as "a system that would alter favorably the movement and load transmission of a spinal motion segment, without the intention of fusion". Interspinous devices reduced the degree of thecal sac impingement following the buckling of the ligamentum flavum. Furthermore, it is thought that these devices act to off-load the facet joints by acting like a shock-absorber. The coflex device (Paradigm spine, Germany) and interspinous stress-breaker device (DIAM®, Medtronic Inc, Minneapolis, MN) are undergoing development and clinical trials; therefore, published information is limited.
and follow-up duration is short. In some short-term follow-up studies, coflex device appears to improve clinical symptoms that are exacerbated in extension, reduce adjacent segmental instability, and preserve disc height and segmental motion\textsuperscript{12,23}. However, long-term follow-up results are still remaining unclear.

We retrospectively analyzed the role of interspinous implantation, particularly coflex device, in long-term clinical and radiological outcome.

**MATERIALS AND METHODS**

1. **Patient population**

All 19 patients (13 female and 6 male) who underwent coflex device implantation were enrolled. Surgery was performed at between January 2003 and March 2004. Mean age was 59.15±6.3 year (range: 46-70). Follow-up duration was 38±11.78 months (range: 12-49) (Table 1).

2. **Operative Technique**

Under endotracheal general anesthesia, surgery was performed in prone position and full flexed Wilson frame. We removed interspinous ligaments and bony attachments with rongeur. Subtotal laminectomy and foraminotomy were performed. If disc protrusion observed, discectomy at instrumented level was performed and then the size of the coflex implant was measured using a trial inserter. Finally, the coflex implant was inserted tightly into the interspinous space and wing clamps were tightened.

3. **Assessment of clinical outcome**

Symptomatic improvement after operation was assessed by Visual analogue scale (VAS) score at clinic visit prior to surgery and at last clinic visit for low back pain and leg pain and Odom's criteria at postoperative last clinic visit. All patients were followed up at 1, 3, 6, and 12 month and last clinic visit postoperatively.

4. **Assessment of radiologic outcome**

All patients were examined with plain radiographs and magnetic resonance imaging. Standing lateral and dynamic radiography before operation and at last follow-up visit were obtained. To compare preoperative and postoperative images, Four parameters were measured: \(X\), anterior disc height; \(Z\), posterior disc height; \(W\), distance between lower border of the pedicle of the superior spinal level and superior border of the pedicle of the inferior spinal level at pedicle-laminar junction; \(U\), difference of Cobb's angle between flexion and extension (Range of Motion: ROM) (Fig. 1).

5. **Statistical analysis**

Standard statistical analysis was applied to this study. We used the non-parametric Paired-Sample Wilcoxon Signed Rank Test to evaluate the differences between preoperative and postoperative VAS score, disc height, interpedicu lar height, and ROM using SPSS for Windows software (SPSS Inc., Chicago, IL). The confidence level for significance was \(p<0.05\).

**RESULTS**

1. **Clinical outcome by VAS score and Odom's criteria**

The VAS score for low back pain and leg pain showed significant improvement. The results are as follows: preoperative VAS score for low back pain and leg pain was improved from 4.9±2.4 and 7.5±1.6 to 2.6±1.2 and 3.0±1.8 at postoperative last clinic visit (\(p<0.01\)) (Table 2).

According to postoperative long-term follow-up by Odom's criteria, 7 and 9 patients showed excellent (36.8%) and good (47.3%) results and only 3 showed fair (15.7%) results for

**Table 1. Demographic data obtained in patients who underwent interspinous implantation**

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr, mean±S.D.)</td>
<td>59.1±6.3</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>6 (31.3%)</td>
</tr>
<tr>
<td>Female (%)</td>
<td>13 (68.4%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Spinal stenosis (%)</td>
<td>15 (68.4%)</td>
</tr>
<tr>
<td>Herniated lumbar disc disorder (%)</td>
<td>3 (15.8%)</td>
</tr>
<tr>
<td>Degenerative spondylolisthesis (%)</td>
<td>3 (15.8%)</td>
</tr>
<tr>
<td>Follow up months (mean±S.D.)</td>
<td>38±11.7</td>
</tr>
</tbody>
</table>

**Table 2. Clinical outcome by VAS score**

<table>
<thead>
<tr>
<th>VAS score</th>
<th>Preop</th>
<th>Postop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg pain</td>
<td>4.9±2.4</td>
<td>2.6±1.2*</td>
</tr>
<tr>
<td>Back pain</td>
<td>7.5±1.6</td>
<td>3.0±1.8*</td>
</tr>
</tbody>
</table>

*\(p<0.01\)
Measurement of radiological parameters. A: X, anterior disc height (mm); Z, posterior disc height (mm); W, distance between lower border of the pedicle of the superior spinal level and superior border of the pedicle of the inferior spinal level at pedicle-laminar junction (mm). B: U, range of motion (ROM, °), the difference in degrees between Cobb’s angle of flexion and extension (U=a-b), a lordosis angle was negative value and a kyphosis angle was positive value.

Table 3. Clinical outcome by Odom’s criteria

<table>
<thead>
<tr>
<th>Odom’s criteria</th>
<th>Excellent</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low back pain (%)</td>
<td>7 (36.8%)</td>
<td>9 (47.3%)</td>
<td>3 (15.7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Leg pain (%)</td>
<td>7 (36.8%)</td>
<td>11 (57.9%)</td>
<td>1 (5.2%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

low back pain. 7 and 11 patients showed excellent (36.8%) and good (57.9%) results and only 1 showed fair (5.2%) results for leg pain (Table 3.).

2. Radiologic outcome

Table 4. shows preoperative and postoperative radiologic data. All patients who underwent coflex device surgery showed that radiologic data of interpedicular height, and ROM were not changed significantly between preoperative and postoperative lateral lumbar image. Anterior and posterior disc heights were decreased significantly in postoperative follow-up radiologic data. In the patients (19 patients) with coflex device surgery, anterior disc height decreased from 16.8 ± 2.8 to 15.1 ± 4.1 (p < 0.05) and posterior disc height decreased from 9.6 ± 1.7 to 8.6 ± 2.6 (p < 0.05) (Table 4A). We divided the patients underwent coflex device surgery into discectomy and non-discectomy patients. In patients (12 patients) with coflex device surgery with discectomy, anterior disc height decreased from 16.5 ± 3.3 to 14.2 ± 4.9 (p < 0.05) and posterior disc height decreased from 9.4 ± 1.8 to 7.5 ± 2.1 (p < 0.05) (Table 4B) but in patients (7 patients) with coflex device surgery without discectomy, anterior disc height was not decreased significantly further more posterior disc height was increased from 10.0 ± 1.6 to 10.8 ± 1.9 (p < 0.05) (Table 4C).

DISCUSSION

The progressive degeneration of a lumbar disc leads to a reduction in motion, rather than an increase in mobility as would be expected if the process led to instability. It altered transmission of forces with a resultant increase in the stress by annulus. The increased stress that causes mechanical back pain depends on posture. Degeneration of annulus, disc herniation, and loss of disc height lead to instability and stenosis from hypertrophy of ligamentum flavum and facet joint. Degenerative spinal stenosis, discogenic low back pain, facet syndrome, and disc herniation and instability were traditionally treated with posterior spinal fusion or decompressive laminectomy. Posterior spinal fusion accelerated degenerative change of adjacent segments that were forced to flex and extend more to compensate for lack of mobility at fusion level. Alternatives for degenerative spinal stenosis were investigated. The concept of an interspinous implant to induce flexion in the lumbar spine was introduced as early as the 1950s with...
the Knowles device. The coflex device allows it to compress against the superior and inferior edges of the spinous processes in both flexion and extension, maximizing its ability to maintain position. Indications for the coflex device are broad, such as herniated lumbar disc, spinal stenosis, and degenerative disc disease with lumbar instability. Interspinous implantation, comparing spinal fusion, is less invasive and the clinical results are satisfactory. Zuckerman et al. showed a success rate of 59% at 1-yr postoperative follow-up. It has been reported that 22 patients with segmental degenerative disease who underwent DIAM implantation (mean follow up of 10 months) showed, 16 had excellent outcome and 4 had good outcome. Our 38-mo follow-up study showed 84% improvement (excellent or good) for low back pain and 94% improvement (excellent or good) for leg pain.

Interspinous implantation caused posterior shifting and kyphosis, increasing posterior disc height and maintaining ROM. A 1-yr follow-up study reported that there was no statistically significant difference between preoperative and postoperative disc height. However, ROM was increased postoperatively. Kong et al., in a 1-yr follow-up study, showed that posterior disc height significantly increased postoperatively from 7.8±1.8 to 9.1±2.2 mm.

Our study showed that there was significant decrease of disc height postoperatively. Interpedicular distance and ROM were not changed significantly between preoperative and postoperative radiographic data. In the patients with coflex device surgery with discectomy, posterior disc height were decreased significantly but in the patients with coflex device surgery without discectomy, the results showed that the anterior and posterior disc height were preserved.

Table 4. Preoperative and postoperative (at mean 38 months follow up) value of radiological measurement

| Table 4A. | | | | |
| --- | --- | --- | --- |
| | Anterior disc height (X, mm) | Posterior disc height (Z, mm) | Interpedicular distance (W, mm) | ROM (U, °) |
| Preop (Mean±SD) | 16.8±2.8 | 9.6±1.7 | 21.8±2.1 | -9.5±3.9 |
| All Patients (19) | 15.1±4.1* | 8.6±2.6* | 21.1±2.3 | -8.0±6.5 |

Table 4B. Discectomy group (12)

| | | | | |
| | Anterior disc height (X, mm) | Posterior disc height (Z, mm) | Interpedicular distance (W, mm) | ROM(U, °) |
| Preop (Mean±SD) | 16.5±3.3 | 9.4±1.8 | 21.6±2.5 | -9.6±4.4 |
| Postop (Mean±SD) | 14.2±4.9* | 7.5±2.1* | 20.1±1.9* | -9.5±6.2 |

Table 4C. Non-discectomy group (7)

| | | | | |
| | Anterior disc height (X, mm) | Posterior disc height (Z, mm) | Interpedicular distance (W, mm) | ROM(U, °) |
| Preop (Mean±SD) | 17.1±1.6 | 10.0±1.6 | 22.1±1.5 | -9.3±3.2 |
| Postop (Mean±SD) | 16.7±1.3 | 10.8±1.9* | 22.9±1.9 | -5.7±6.9 |

*Statistically significant between preop and postop (p<0.05).
§All patients include patients who underwent coflex device surgery.

Discectomy group include the patients who underwent coflex device surgery with discectomy at instrumented level. Non-discectomy group include the patients who underwent coflex device surgery without discectomy at instrumented level.
the long-term outcomes of this device. Although the use of interspinous implantation is not conventional treatment, early studies have shown promising clinical and radiologic outcome comparable to fusion. However, there are few long-term follow-up studies to compare the therapeutic effect of interspinous implantation. To conclude the benefit of interspinous device, well-designed prospective randomized study should be required.

CONCLUSIONS

In this long-term follow-up study, clinical outcome was good as in other short-term follow-up studies but disc degeneration after discectomy at instrumented level resulting in decrease of disc height might not be prevented.

REFERENCES

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