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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 instumented 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[17]. Pathologic progression of degenerative intervertebral disc changes leads to loss of disc height. The resultant instability by facet joint hypertrophy may worsen the spondylosis,[9] and hypertrophy of ligamentum flavum which compress thecal sac of cauda equina particularly during extension[19,20].

Posterior lumbar decompression and fusion has been the traditional treatment for lumbar stenosis with low back pain or lumbar instability[22]. 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[2,5]. Posterior lumbar fusion may developed adjacent segmental degeneration particular segmental instability[7,11]. 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"[16]. 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.[13,15,21] 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

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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[12,23]. However, long-term follow-up results are still remaining unclear.

We retrospectively analyzed the role of interspinous implan tation, 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.

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

Age (yr, mean±S.D.)	59.1±6.3
Sex	
Male (%)	6(31.3%)
Female (%)	13(68.4%)
Diagnosis	
Spinal stenosis (%)	15(68.4%)
Herniated lumbar disc disorder (%)	3(15.8%)
Degenerative spondylolisthesis (%)	3(15.8%)
Follow up months (mean±S.D.)	38±11.7

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, interpedicular 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 2. Clinical outcome by VAS score

	VAS score	
	Preop	Postop
Leg pain	4.9±2.4	2.6±1.2*
Back pain	7.5±1.6	3.0±1.8*

*p<0.01

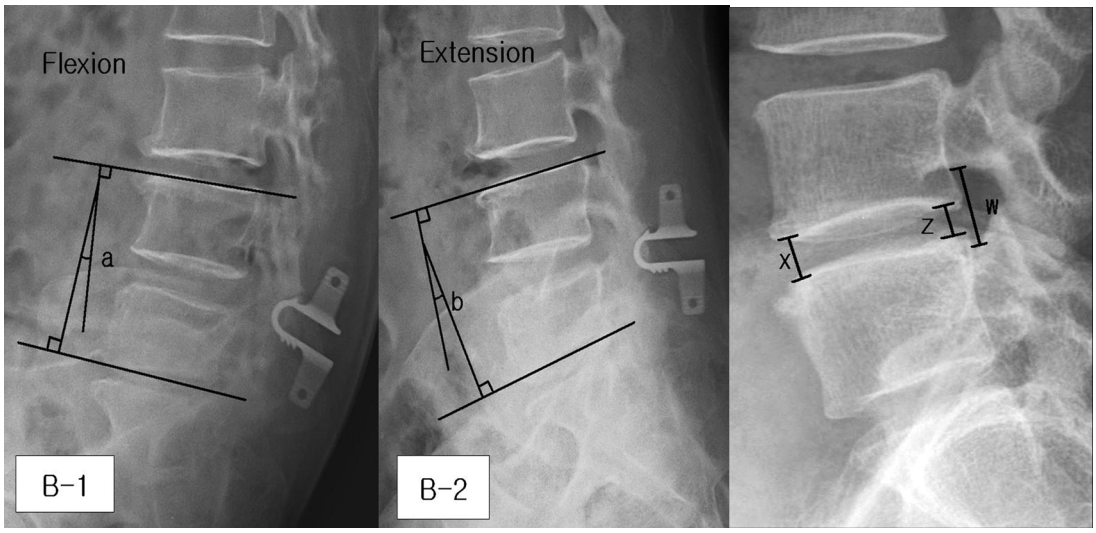

Fig. 1. Measurement of radiological parameters.
A) X, anterior disc height (mm); Z, posterior disc height (mm); W, distance between lower border of the pedicle of the superior spinal level and superior border of the pedicle of the inferior spinal level at pedicle-laminar junction (mm). **B**) U, range of motion (ROM, º), 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

	Odom' s criteria			
	Excellent	Good	Fair	Poor
Low back pain (%)	7(36.8%)	9(47.3%)	3(15.7%)	0(0%)
Leg pain (%)	7(36.8%)	11(57.9%)	1(5.2%)	0(0%)

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[3,4,16], 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[6,16]. Degeneration of annulus, disc herniation, and loss of disc height lead to instability and stenosis from hypertophy of ligamentum flavum and facet joint[1]. 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

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, °)
All Patients (19)§	Preop (Mean±SD)	16.8±2.8	9.6±1.7	21.8±2.1	-9.5±3.9
	Postop (Mean±SD)	15.1±4.1*	8.6±2.6*	21.1±2.3	-8.0±6.5
Table 4B.					
		Anterior disc height (X, mm)	Posterior disc height (Z, mm)	Interpedicular distance (W, mm)	ROM(U, °)
Discectomy group (12)	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.					
		Anterior disc height (X, mm)	Posterior disc height (Z, mm)	Interpedicular distance (W, mm)	ROM(U, °)
Non-discectomy group (7)	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 Knowles device[18]. 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[12,23]. Zuckerman et al.[23] 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[14]. 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.[8] 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 10).

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, postoperative anterior and 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.

Interspinous device is designed to preserve disc height and instrumented segmental motion. Our study also shows coflex device has good clinical outcome and preserves instrumented segmental motion but decreases disc height, because discectomy at instrumented level accelerated disc degenerative change. Although loss of disc height in the patient with coflex device surgery with discectomy was found in long-term follow-up, in the patient with coflex device surgery without discectomy, the anterior disc height was preserved; furthermore posterior disc height was increased statistically significant. This means that the coflex device preserves disc height, but in the patient undergone discectomy at instrumented level, degenerative change of disc may be occurred for long term follow-up.

Limitation in our study is small sample size to conclude

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

1. Amundsen T, Weber H, Lilleas F, Nordal HJ, Abdelnoor M, Magnaes B: Lumbar spinal stenosis. Clinical and radiologic features. **Spine 20**:1178-1186, 1995
2. Boos N, Webb JK: Pedicle screw fixation in spinal disorders: A european view. **Eur Spine J 6**:2-18, 1997
3. Fujiwara A, Lim TH, An HS, Tanaka N, Jeon CH, Andersson GB, et al: The effect of disc degeneration and facet joint osteoarthritis on the segmental flexibility of the lumbar spine. **Spine 25**:3036-3044, 2000
4. Fujiwara A, Tamai K, An HS, Kurihashi T, Lim TH, Yoshida H, et al: The relationship between disc degeneration, facet joint osteoarthritis, and stability of the degenerative lumbar spine. **J Spinal Disord 13**:444-450, 2000
5. Gibson JN, Grant IC, Waddell G: The cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis. **Spine 24**:1820-1832, 1999
6. Herno A, Saari T, Suomalainen O, Airaksinen O: The degree of decompressive relief and its relation to clinical outcome in patients undergoing surgery for lumbar spinal stenosis. **Spine 24**:1010-1014, 1999
7. Kanayama M, Hashimoto T, Shigenobu K, Harada M, Oha F, Ohkoshi Y, et al: Adjacent-segment morbidity after graf ligamentoplasty compared with posterolateral lumbar fusion. **J Neurosurg 95**:5-10, 2001
8. Kim KA, McDonald M, Pik JH, Khoueir P, Wang MY: Dynamic intraspinous spacer technology for posterior stabilization: Case-control study on the safety, sagittal angulation, and pain outcome at 1-year follow-up evaluation. **Neurosurg Focus 22**:E7, 2007
9. Kirkaldy-Willis WH, Wedge JH, Yong-Hing K, Reilly J: Pathology and pathogenesis of lumbar spondylosis and stenosis. **Spine 3**:319-328, 1978
10. Kong DS, Kim ES, Eoh W: One-year outcome evaluation after interspinous implantation for degenerative spinal stenosis with segmental instability. **J Korean Med Sci 22**:330-335, 2007
11. Lee CK: Accelerated degeneration of the segment adjacent to a lumbar fusion. **Spine 13**:375-377, 1988
12. Lee J, Hida K, Seki T, Iwasaki Y, Minoru A: An interspinous process distractor (x stop) for lumbar spinal stenosis in elderly patients: Preliminary experiences in 10 consecutive cases. **J Spinal Disord Tech 17**:72-77; discussion 78, 2004
13. Minns RJ, Walsh WK: Preliminary design and expe rimental studies of a novel soft implant for correcting sagittal plane instability in the lumbar spine. **Spine 22**: 1819-1825; discussion 1826-1817, 1997
14. Schiavone A, Pasquale G: The use of disc assistance prostheses (diam) in degenerative lumbar pathology: Indications, tchnique, and results. **Ital J Spinal Disord 3**:213-220, 2003
15. Senegas J: Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: The wallis system. **Eur Spine J 11 Suppl 2**:S164-169, 2002
16. Sengupta DK: Dynamic stabilization devices in the treatment of low back pain. **Orthop Clin North Am 35**: 43-56, 2004
17. Verbiest H: A radicular syndrome from developmental narrowing of the lumbar vertebral canal. **J Bone Joint Surg Br 36-B**:230-237, 1954
18. Whitesides TE, Jr.: The effect of an interspinous implant on intervertebral disc pressures. **Spine 28**:1906-1907; author reply 1907-1908, 2003
19. Wildermuth S, Zanetti M, Duewell S, Schmid MR, Romanowski B, Benini A, et al: Lumbar spine: Quantitative and qualitative assessment of positional (upright flexion and extension) mr imaging and myelography. **Radiology 207**:391-398, 1998
20. Willen J, Danielson B, Gaulitz A, Niklason T, Schonstrom N, Hansson T: Dynamic effects on the lumbar spinal canal: Axially loaded ct-myelography and mri in patients with sciatica and/or neurogenic claudication. **Spine 22**:2968-2976, 1997
21. Wiseman CM, Lindsey DP, Fredrick AD, Yerby SA:

The effect of an interspinous process implant on facet loading during extension. **Spine 30**:903-907, 2005

22. Zindrick MR, Wiltse LL, Widell EH, Thomas JC, Holland WR, Field BT, et al: A biomechanical study of intrapeduncular screw fixation in the lumbosacral spine. **Clin Orthop Relat Res**: pp99-112, 1986
23. Zucherman JF, Hsu KY, Hartjen CA, Mehalic TF, Implicito DA, Martin MJ, et al: A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the x stop interspinous implant: 1-year results. **Eur Spine J 13**:22-31, 2004