One-year Outcome Evaluation after Interspinous Implantation for Degenerative Spinal Stenosis with Segmental Instability

The authors hypothesized that the placement of the interspinous implant would show a similar clinical outcome to the posterior lumbar interbody fusion (PLIF) in patients having spinal stenosis with mild segmental instability and that this method would be superior to PLIF without significantly affecting degeneration at the adjacent segments. Forty two adult patients having degenerative spinal stenosis with mild segmental instabilit who underwent implantation of Coflex™ (Spine motion, Germany) or PLIF at L4-5 between January 2000 and December 2003 were consecutively selected and studied for one-year clinical outcome. At 12 months after surgery, both groups showed a significant improvement in the visual analogue scale score and Oswestry disability index score for both lower extremity pain and low back pain. However, the range of motion at the upper adjacent segments (L3-4) increased significantly after surgery in the PLIF group, which was not manifested in the Coflex™ group during the follow-up. The authors assumed that interspinous implantation can be an alternative treatment for the spinal stenosis with segmental instability in selected conditions posing less stress on the superior adjacent level than PLIF.

Key Words : *Spinal Stenosis; Outcome*

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INTRODUCTION

Many patients suffer from disabling pain from lumbar spinal stenosis. Since neurogenic claudication secondary to spinal stenosis was first described by Verbiest (1), decompressive surgery has been required in patients who fail to respond to conservative therapy. Additional posterior fusion has been indicated in cases where the motion segment is believed to be unstable. In case that secondary instability is expected to develop after decompression of the posterior column, even a preventive fusion may be indicated although there is no preoperative instability. Therefore, in severe spinal stenosis with or without segmental instability, many surgeons tend to perform decompression with fusion.

However, posterior fusion is not an ideal treatment modality for spinal stenosis with segmental instability. Many studies have reported that this procedure can develop, so called, the adjacent segmental syndrome (2-4). If surgeons perform fusion surgery due to a concern about potential instability, too many fusions may be done unnecessarily. Therefore, there should be strict indications when one considers fusion in lumbar spinal stenosis.

The interspinous implants such as Coflex™ (Spine motion, Germany) and X-Stop (St Francis Medical Technologies, Concord, CA) have been designed to treat lumbar neurogenic claudication secondary to spinal stenosis. These newly devel-oped devices are composed of spacer made of titanium placed between two adjacent lumbar spinous processes (Fig. 1). Of these devices, Coflex™ should be implanted after the removal of the interspinous ligaments and resection of their bony attachment. This implant is placed in the interspinous space with the patient in a slightly flexed position. By preventing extension, it relieves the symptoms of lumbar spinal stenosis (5, 6). However, it cannot be used as a substitute for a rigid fusion in cases of marked instability (7).

The authors hypothesized that interspinous implantation would result in a similar clinical outcome to the posterior lumbar interbody fusion (PLIF) when it is used in patients suffering from spinal stenosis with mild segmental instability and that this surgical method would be superior to PLIF without significantly affecting the degeneration at the adjacent motion segments.

MATERIALS AND METHODS

This study included a total of 42 adult patients with spinal stenosis accompanying mild segmental instability, who consecutively underwent placement of L4-5 interspinous distractor (Coflex™ group) or PLIF (PLIF group) between January 2000 and December 2003. The demographic data of two groups are summarized in Table 1. In all cases, degenerative
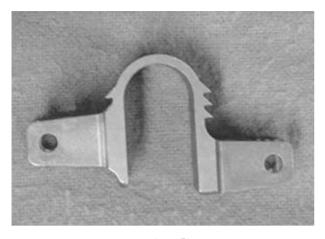
Fig. 1. The sagittal view of the Coflex™ implant. This device is designed to be placed between adjacent spinous processes. Implant migration is prevented by clamping of the lateral wings.

Table 1. Demographic data obtained in patients who underwent insertion of Coflex or PLIF. There was no statistically significcant difference between the two groups (Mann-Whitney U test)

	Coflex group	PLIF group
No of patients	18	24
Mean age (yr)	61.7	56
	(range: 41-71)	(range: 38-78)
Sex		
Male	3	15
Female	8	16
Diagnosis		
Spinal stenosis	7	7
with angular instability	7	11
with translational slip <4 mm	4	6

spinal stenosis with a mild segmental instability was present at L4-5 level. We defined the mild segmental instability on the standing radiography lateral film as 1) degenerative spondylolisthesis, grade I (<4 mm in the sagittal plane); or 2) angular instability (intervertebral range of motion [ROM] >10 degrees). Patients with marked degenerative spondylolisthesis ($\geq$5 mm), lesions involving more than two levels, and isthmic spondylolisthesis were excluded. The PLIF group included 24 patients. There were 8 males and 16 female patients who ranged in age from 38 to 78 yr (mean 56.0 yr) at the time of surgery. The Coflex™ group included 18 patients, 3 males and 15 females, who ranged in age from 40 to 71 yr (mean 61.7 yr). No significant difference was shown in the demographic data between the two groups. The pathological lesions in the two groups were confirmed by MRI scans. All patients had lateral standing and lateral flexion-extension roentgenograms of the lumbar spine before surgery as well as after surgery.

Operative techniques

In all patients, standard general anesthesia was administered and surgery was performed in the prone position, flexed on the Wilson frame (OSI, Union, CA). In the Coflex™ group, we removed interspinous ligaments and their bony attachments with rongeur after midline skin incision of approximately 4 cm. Foraminal decompression with partial laminotomy was performed. At this time, the measurement of the required size of the Coflex™ implant was made using a trial inserter. Thereafter, interspinous distractor was inserted tightly into the interspinous space. Finally, we tightened the wing-clamps of the implant. Meanwhile, in the PLIF group, we performed surgery using conventional posterior lumbar interbody fusion interbody cages such as Poly-ether-ether-ketone implants (Stryker Implants; ZI Marticot, Cestas, France) or CH cage (Spine-Tech, Minneapolis, MN, U.S.A.), followed by pedicle screw fixation. Autogenous iliac bone and/or lam-

ina bone was used as a bone graft material in all patients in the PLIF group. All operations were performed by two surgeons (Eoh W & Kim ES).

Radiographic analysis

Dynamic and static radiographs were obtained before surgery and postsurgery at 1, 3, 6, and 12 months. Segmental intervertebral angles (formed by lines drawn on the upper and lower endplates of adjacent vertebraes) at the instrumented level and the adjacent levels were measured and compared on flexion-extension radiographs in two groups (Fig. 2, 3). Positive values reflected lordosis and negative values reflected kyphosis. Posterior disc height (PDH) in standing and extension position was also measured.

In order to prevent interobserver variability, the same person who did not participate surgery performed the measurement blindly three times. The total sum of intervertebral angle between flexion and extension per level meant the ROM at the level.

Clinical analyses

The clinical outcome was quantified using the Visual Analogue Scale (VAS) score for low back pain and leg pain and the Oswestry disability index (ODI) score. There was no significant difference in these scores preoperatively between two groups. All patients were followed up at the outpatient clinic at regular intervals (at 1, 3, 6, and 12 months postsurgery).

Statistical analyses

The data were analyzed on a personal computer by using the commercially available SPSS software (SPSS Inc, Chicago, IL, U.S.A.). For the non-numerical variables for the clinical assessment in the two groups, Mann-Whitney U test was used. To compare variables for the radiological assessment between before and after surgery *Wilcoxon signed ranks test* was used for analysis. The confidence level for significance was $p<0.05$.
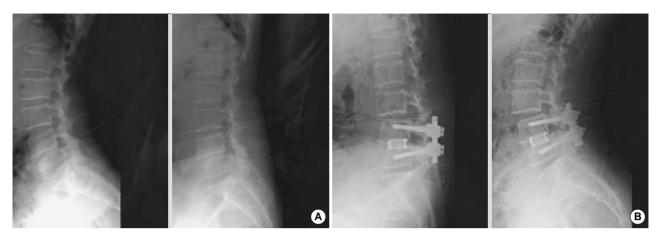
Fig. 2. Radiographs showing the change of range of motion (ROM) after surgery in a patient who had undergone PLIF at L4-5. Preoperative (A) and postoperative (B) flexion and extension images demonstrate that there is an increase of ROM at the upper adjacent segment (L3-4) postoperatively.

Fig. 3. Radiographs showing the changes of range of motion (ROM) after surgery in the Coflex™ inserted patient. Preoperative lateral X-ray films (A) show the spondylolisthetic instability at L4-5 level. Postoperative flexion and extension images (B) after implantation of Coflex™ do not reveal improvement of spondylolisthesis at L4-5 despite the clinical improvement of low back pain and radiating pain. However, they showed no significant difference of ROM at L3-4, as compared with preoperative images (A). Arrow indicates the degree of spondylolisthesis on flexion.

RESULTS

Clinical outcome assessment

The VAS and ODI scores were used as the primary measures of the 1-yr clinical outcome. There was a significant improvement in the VAS and ODI scores for lower leg pain and low back pain in both groups ($p<0.05$) (Fig. 4). However, no difference in outcome was noticed between two groups. There was no surgical complication in either groups.

Radiological outcome assessment

Preoperative radiological data and changes after surgery are shown in Table 2. There was no significant difference in the preoperative ROM at each level between two groups. The postoperative radiographs in the PLIF group indicated that the ROM at the instrumented level was almost zero as expected. In the Coflex™ group, the postoperative ROM at the instrumented level decreased significantly compared with the preoperative ROM, although the amount of decrease was not as much as that in the PLIF group. In the Coflex™ group, the PDH on standing radiographs increased significantly from preoperative 7.8 mm to postoperative 9.1 mm ($p<0.05$), whereas in the PLIF group, the PDH was determined according to the inserted cage size (9-14 mm).

The ROM at the upper adjacent segment (L3-4) in the PLIF group increased significantly after surgery ($p<0.05$), whereas the ROM in the Coflex™ group did not increase at this level (Table 2). The number of patients with an increase of ROM more than 5 degrees at the upper segment between preoperative and postoperative films was 8 among 24 patients in the PLIF group (33.3%) and 2 among 18 patients in the Coflex™ group (11.1%) ($p>0.05$, Fig. 5).

Table 2. Preoperative and postoperative (at one year follow up) range of motion (ROM) and posterior disc height at the instrumented and adjacent segments (Wilcoxon signed ranks test)

ROM (degree)	Coflex group (18)		PLIF group (24)		Difference between two groups
	Preop. ROM	Postop. ROM	Preop. ROM	Postop. ROM	
L3-4	6.1 ($\pm$3.7)	5.8 ($\pm$3.8)	7.2 ($\pm$4.1)	10.5* ($\pm$5.2)	NS
L4-5	10.0 ($\pm$4.1)	5.1* ($\pm$4.8)	12.7 ($\pm$3.7)	0. 7* ($\pm$1.5)	NS
L5S1	6.6 ($\pm$4.8)	5.1 ($\pm$4.8)	11.2 ($\pm$5.8)	10.2 ($\pm$7.6)	NS
PDH[†] (mm)	7.8 ($\pm$1.8)	9.1* ($\pm$2.2)	6.9 ($\pm$2.9)	11.2* ($\pm$1.3)	NS

Mean value$\pm$standard deviation.
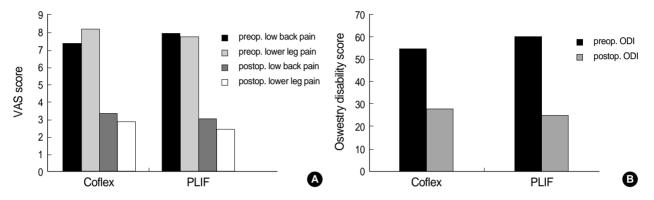*, significant statistically between preop. and postop. ROM; [†], posterior disc height at L4-5.

Fig. 4. Bar graphs showing the improvement of symptoms in the Coflex™ group and the PLIF group after surgery ($p<0.05$). (A) VAS score, (B) Oswestry disability index.
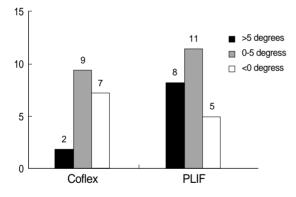

Fig. 5. Bar graph showing changes of ROM of the upper adjacent segment (L3-4). Note that the number of cases showing an increase of ROM more than 5 degrees was higher in the PLIF group (8 patients) than in the Coflex™ group (2 patients) ($p>0.05$).

DISCUSSION

The pathogenesis of degenerative spinal stenosis begins with the degeneration of the posterolateral annulus, progressing to disc herniation and resorption, then to instability with loss of disc height, and finally to stenosis from hypertrophy of the facet joints (8). Many cases of spinal stenosis are accompanied with degenerative spondylolisthesis, angular instability, and retrolisthesis. If the spinal stenosis is accompanied with these conditions, surgeons should consider spinal fusion as well as decompression. Posterolateral or posterior interbody fusion is currently the gold standard for surgical management of lumbar spinal instability (9, 10). However, restabilization of spine does not necessarily mean to bring only benefits. Cunningham et al. (11) reported a significant increase in intervertebral disc pressures after destabilization of the lumbar spine followed by stabilization with instrumentation. In case of spinal fusion, the motion segment is entirely immobilized, and the adjacent levels are forced to flex and extend appreciably more to compensate for the lack of mobility at the instrumented level. In addition, the pedicle fixation with screws often involves the posterior facet joint and may lead to damage in the motion of the upper segment. Several authors have observed that the interval to adjacent segment failure has been considerably shortened in patients who have undergone segmental fusion procedures in which instrumentation is used (4, 12, 13). Of note, there has been a report that a total of 18 out of 125 patients developed symptomatic adjacent segment degeneration at a previously asymptomatic level (2). The risk appeared to be especially high in postmenopausal women. Concerning the potential damage to adjacent segments, some authors reported that non-fusion techniques such as Graf ligamentoplasty or dynamic instrumentation showed similar clinical and radiological outcomes to the PLIF (3, 14).

The interspinous implantation is less invasive, and the preliminary clinical results appeared very satisfactory in patients whose symptoms deteriorated by extension (6, 7, 15). In a prospective and randomized multi-center study, Zuckerman et al. (6) showed a success rate of 59% at 1 yr postosurgery

with an interspinous implant. This result was much better than that of 12% in the control patients who were was treated only conservatively.

In the present study, ROM at the instrumented level was significantly decreased in both PLIF and Coflex™ groups. This means that the interspinous distractor has some restabilizing effect at an unstable segment. The Coflex™ group showed no change of ROM at the upper adjacent segment postoperatively. Meanwhile, the PLIF group showed a significant increase of ROM at this area. The number of patients with an increase more than 5 degree of ROM at this segment was 8 out of 24 (33.3%) in this group. Since there was no significant difference between the two groups, one can postulate that the observation that the mobility at the adjacent segment increased in some patients after surgery might be due to a physiologic compensation without any clinical hazard. However, we assume that interbody fusion rendered a stressful effect to the adjacent segment, which consequently resulted in hypermobility and accelerated degeneration. From this viewpoint, interspinous implant tends to affect the adjacent segment less than PLIF. Another biomechanical studies showed an unloading of the disc at the instrumented level without an effect at the adjacent levels with the interspinous distractor device (16). Considering these advantages, interspinous implantation could be more appropriate than PLIF to treat spinal stenosis with mild segmental instability. Although postoperative radiographs in the Coflex™ group showed less improvement of instability at the instrumented level compared with in the PLIF group, patients showed a similar improvement clinically. If longer-term studies confirm this clinical outcome, such techniques that can preserve much of normal anatomy and biomechanical function of the lumbar spine as interspinous implant, will be highly indicated in the surgical treatment of spinal stenosis with various instability. This minimally invasine surgery would be particularly beneficial to the elderly or to patients with osteoporosis or other poor general conditions.

In this study, interspinous implant prevented hyperflexion as well as hyperextension at the instrumented level. We assume that this result might be due to the fact that the implant is placed in a slightly flexed position, presumably preventing additional flexion at the instrumented segment.

A limitation of this study is that it is a retrospective unrandomized case-control study. In addition, the 1-yr follow-up duration in this study was too short to evaluate the efficacy of a new device completely in spinal stenosis with mild segmental instability. Prospective randomized studies are needed to overcome these limitations and to confirm the efficacy of this new device.

In conclusim, on results obtained at 1 yr posttreatment show that the Coflex™ -inserted group had a comparable clinical outcome to the PLIF group. Although this study had a limitation in terms of the of follow-up period, interspinous implant reduced ROM at the instrumented level and may not affect the ROM as much as in PLIF at the upper adjacent motion segment. Implantation of this device can be an alternative or superior treatment for degenerative lumbar stenosis with instability in selected conditions.

REFERENCES

1. Verbiest H. *A radicular syndrome from developmental narrowing of the lumbae vertebral canal. J Bone Joint Surg 1954; 36: 230-7.*

2. Etebar S, Cahill DW. *Risk factors for adjacent-segment failure following lumbar fixation with rigid instrumentation for degenerative instability. J Neurosurg 1999; 90: 163-9.*

3. Kanayama M, Hashimoto T, Shigenobu K, Harada M, Oha F, Ohkoshi Y, Tada H, Yamamoto K, Yamane S. *Adjacent-segment morbidity after Graf ligamentoplasty compared with posterolateral lumbar fusion. J Neurosurg 2001; 95 (Suppl 1): 5-10.*

4. Lee CK. *Accelerated degeneration of the segment adjacent to a lumbar fusion. Spine 1988; 13: 375-7.*

5. Swanson KE, Lindsey DP, Hsu KY, Zucherman JF, Yerby SA. *The effects of an interspinous implant on intervertebral disc pressures. Spine 2003; 28: 26-32.*

6. Zucherman JF, Hsu KY, Hartjen CA, Mehalic TF, Implicito DA, Martin MJ, Johnson DR 2nd, Skidmore GA, Vessa PP, Dwyer JW, Puccio S, Cauthen JC, Ozuna RM. *A prospective randomized multicenter study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. Eur Spine J 2004; 13: 22-31.*

7. Kaech DL, Jinkins JR. *The interspinous 'U': a new restabilization device for the lumbar spine Spinal Restabilization Procedures. Elsevier Science B.V.; 2002: 355-62.*

8. Amundsen T, Weber H, Lilleas F, Nordal HJ, Abdelnoor M, Magnaes B. *Lumbar spinal stenosis. Clinical and radiologic features. Spine 1995; 20: 1178-86.*

9. Bridwell KH, Sedgewick TA, O'Brien MF, Lenke LG, Baldus C. *The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis. J Spinal Disord 1993; 6: 461-72.*

10. West JL 3rd, Bradford DS, Ogilvie JW. *Results of spinal arthrodesis with pedicle screw-plate fixation. J Bone Joint Surg Am 1991; 73: 1179-84.*

11. Cunningham BW, Kotani Y, McNulty PS, Cappuccino A, McAfee PC. *The effect of spinal destabilization and instrumentation on lumbar intradiscal pressure: an in vitro biomechanical analysis. Spine 1997; 22: 2655-63.*

12. Schlegel JD, Smith JA, Schleusener RL. *Lumbar motion segment pathology adjacent to thoracolumbar, lumbar, and lumbosacral fusions. Spine 1996; 21: 970-81.*

13. Penta M, Sandhu A, Fraser RD. *Magnetic resonance imaging assessment of disc degeneration 10 years after anterior lumbar interbody fusion. Spine 1995; 20: 743-7.*

14. Korovessis P, Papazisis Z, Koureas G, Lambiris E. *Rigid, semirigid versus dynamic instrumentation for degenerative lumbar spinal stenosis: a correlative radiological and clinical analysis of short-term*

results. Spine 2004; 29: 735-42.

15. 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 2004; 17: 72-7; discussion 78.*

16. Lindsey DP, Swanson KE, Fuchs P, Hsu KY, Zacherman JF, Yerby SA. *The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. Spine 2003; 28: 2192-7.*