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 developed 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 in selected conditions posing less stress on the superior adjacent level than PLIF.

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
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 (≥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 CoflexTM 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 CoflexTM 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 CoflexTM 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 lamina 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 vertebrae) 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.
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\textsuperscript{TM} 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\textsuperscript{TM} 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\textsuperscript{TM} 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\textsuperscript{TM} group (11.1\%) \((p>0.05)\).
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 postsurgery.

**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 (±3.7)       | 5.8 (±3.8)      | 7.2 (±4.1)      | 10.5* (±5.2)   | NS                                         |
| L4-5         | 10.0 (±4.1)      | 5.1* (±4.8)     | 12.7 (±3.7)     | 0.7* (±1.5)    | NS                                         |
| L5S1         | 6.6 (±4.8)       | 5.1 (±4.8)      | 11.2 (±5.8)     | 10.2 (±7.6)    | NS                                         |
| PDH (mm)     | 7.8 (±1.8)       | 9.1* (±2.2)     | 6.9 (±2.9)      | 11.2* (±1.3)   | NS                                         |

Mean value ± 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).
with an interspinous implant. This result was much better than that of 12% in the control patients who were 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 invasive 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 conclusion, 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 lumbosacral stenosis with instability in selected conditions.

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