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Full Length Research Paper

Treatment of bisegmental lumbar spinal stenosis: Coflex interspinous implant versus bisegmental posterior lumbar interbody fusion

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To evaluate the clinical efficacy of coflex interspinous implant for bisegmental lumbar spinal stenosis, 23 cases of bisegmental lumbar spinal stenosis were treated with coflex interspinous implant for lumbar fusion (Coflex plus fusion, n=12), or bisegmental posterior lumbar interbody fusion (bisegmental fusion, n=11). The operation time, bleeding volume, and the visual analog scale (VAS) for lumbar pain, the VAS for leg pain, the Oswestry Disability Index (ODI), and the range of motion (ROM) for the upper and lower surgical segments and upper adjacent segment prior to operation and at the last follow up within or between two groups were compared. The bleeding volume was less in the coflex plus fusion group than in the bisegmental fusion (P=0.03). The ROM for the upper surgical segments was smaller at the last follow up than prior to operation in two groups (P=0.04; P<0.01). No statistically significant difference was noted in the ROM for the upper surgical segments between two groups prior to operation (P=0.79), while it was statistically significantly higher in the coflex plus fusion group than the bisegemental fusion group (P<0.01). There was no statistically significant difference in the ROM for the upper adjacent segments between two groups prior to operation (P=0.02), while it was significantly higher in the bisegmental fusion group than in the coflex plus fusion group at the last follow up (P<0.01). The Coflex interspinous implant for lumbar fusion achieves similar efficacy with bisegmental posterior lumbar interbody fusion in clinical practice. But it causes less bleeding, retains intervertebral activity for surgical segments, and effectively reduces the intervertebral space activity for the upper adjacent segments.

Key words: Bisegment, lumbar spinal stenosis, coflex, posterior lumbar interbody fusion

INTRODUCTION

Lumbar spinal stenosis is a common disease of the spine. It is characterized by signs of lower lumbar pain, intermittent lameness, and radiating pain of lower limbs. Posterior interspinal compression, excision of interspinal disk and interspinal implant for fixation and fusion relieve nerve compression, improve nerve function, and reconstruct spinal stability, achieving favorable short-term outcomes (Zdeblick, 1993). The motion of the fusion segments following lumbar fusion is lost, accompanied by rapid degeneration of adjacent intervertebral space. Thus non-fusion techniques are increasingly welcomed by clinicians (Park et al., 2004). This study compared the coflex interspinous implant for lumbar fusion with the bisegmental posterior lumbar interbody fusion for treatment of bisegmental lumbar spinal stenosis, aiming to evaluate the clinical efficacy of the coflex interspinous implant for the disease.

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PATIENTS

General information

Twelve patients with lumbar spinal stenosis including seven males and five females received coflex interspinous implant for lumbar

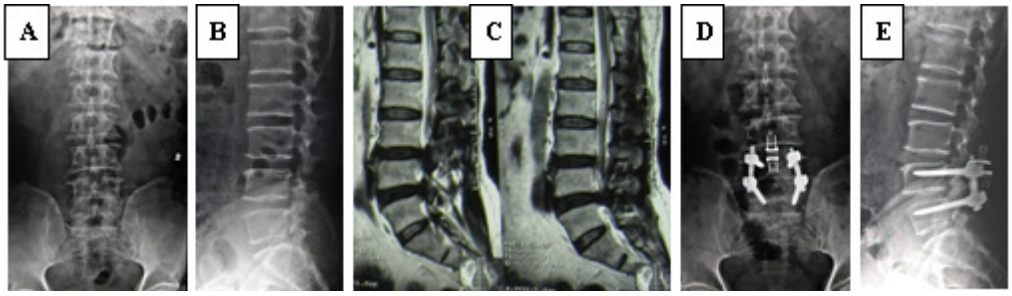

Figure 1. AP (A) and Lateral 1(B) radiographic view of a patient with bisegmental lumbar spinal stenosis showing degenerative changes at multiple levels. Sagital view MRI (C) showing multiple degenerative disc disease and spinal stenosis postoperative AP (D) and lateral (E) radiographic view showing coflex interspinous implant for lumbar fusion.

fusion. When a patient presents with the typical symptoms of lumbar spinal stenosis (leg pain, with or without back pain, which is aggravated by walking), a conclusive diagnosis is made using imaging studies from an MRI scan or a CT scan with myelogram (using an x-ray dye in the spinal sack fluid). They ranged in age from 40 to 76 years old with an average of 61 years old. The surgical segments involved L3 to L5 in five patients and L4 to S1 in seven patients. Eleven patients including seven males and four females received the bisegmental osterior lumbar interbody fusion. They ranged in age from 40 to 83 years old with an average of 59 years old. The surgical segments involved L3 to L5 in five patients and L4 to S1 in six patients. Informed consent was obtained from each patient and the whole study was approved by the Ethics Committee of The First Affiliated Hospital of Ji'nan University.

Surgical techniques

Inclusion criteria and exclusion criteria for surgery

Inclusion criteria included; at least moderate lumbar stenosis from L1 to L5, at one or two contiguous levels, confirmed by MRI or CT, with up to Grade 1 spondylolisthesis; Radiographic confirmation of no angular or translatory instability of the spine at index or adjacent levels; VAS back pain score of at least 50 mm on a 100 mm scale; Neurogenic claudication as defined by leg/buttocks or groin pain that can be relieved by flexion; At least one epidural injection at any prior time point, and at least 6 months of prior conservative care without adequate and sustained symptom relief; were the appropriate candidate for treatment using posterior surgical approach. Patients with severe unstable abdominal vertebra; severe osteoporosis; two small processus spinosus; abdominal vertebra tumor or infections were excluded.

Coflex interspinous implant

Following general anesthesia, the patient was placed at the prone position. For the surgical procedure involving L3 to L5, the surgical area was identified using the C-arm machine. The midline of the back was incised, separated layer by layer. L3 to L5 supraspinous ligament was exposed, and incised beside the spinous process to expose the vertebral lamina. The lower one fourth of the L3 lamina was excised to clear hyperplasic and thickening yellow ligament. Bilateral nerve roots were investigated and nerve compression was alleviated appropriately. Nerve roots and dural sack were drawn to the midline, and nucleus pulposus was removed. The lower L3 spinous process and upper L4 spinous process were trimmed. After model testing, a coflex with an appropriate size was selected and its upper and lower arms were expanded. The Coflex was then implanted between the spinous processes to ensure a distance of 3 to 5 mm between the U top and the dural sack. The arms of coflex were clamped closely. At the lateral hole of the upper and lower arms, the spinous process was bored and the arms were fixed using sutures. Screws were implanted at bilateral vertebral pedicles of L4 and L5. The lower one fourth of L4 lamina and upper one fifth of L5 lamina were excised until the inner edge of the articular process. The hyperplastic and thickening yellow ligament and hyperostenogeny were removed, and bilateral nerve roots were decompressed. Nerve roots and dural sack at one side were drawn to the midline to expose L4/L5 intervertebral space. Nucleus pulposus was removed and the cartilages of upper and lower end-plates were scraped. The connecting rod was installed to appropriately expand the intervertebral space and implant a bone graft with an appropriate size. The bone graft and the upper and lower end-plates were closely connected though vertical force. The screws were fastened then. The positions of the Coflex and the screw-rod system were investigated. Bilateral nerve roots were not compressed, and no active bleeding existed. The wound was flushed and a drainage tube was placed. The supraspinous ligament was sutured and fixed to the spinous process, and the wound was sutured layer by layer (Figure 1).

Bisegmental posterior lumbar interbody fusion

Following general anesthesia, the patient was placed at the prone position. The paravertebral muscle was separated to expose the vertebral lamina, the spinous process and the articular process. A screw was implanted at the bilateral vertebral pedicle of L3, L4 and L5. L3/L4 and L4/L5 interspinal ligaments were cut and L3 and L4 vertebral laminas, yellow ligaments and hyperplastic inner edge of articular processes to expand the lateral recess. Nerve roots were decompressed and nucleus pulposus were removed. The cartilages of upper and lower end-plates were scraped. The connecting rod was installed to appropriately expand the intervertebral space and implant a bone graft with an appropriate size at L3/L4 and L4/L5. The screws were fastened then. The positions of screws and the physiological radian were investigated before the rod was placed. The wound was flushed and a drainage tube was placed. The wound was then sutured (Figure 2).

Postoperative treatment

Routine antibiotics were given to prevent infection for three days. The drainage tube was removed at 24 to 48 h post operation. Patients were recommended to walk with waistline protection. The

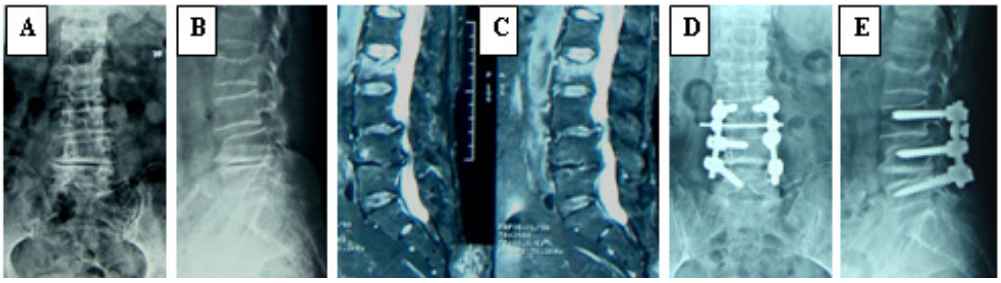

Figure 2. AP (A) and Lateral 1(B) radiographic view of a patient with bisegmental lumbar spinal stenosis showing degenerative changes at multiple levels. Sagital view MRI (C) showing multiple degenerative disc disease and spinal stenosis postoperative AP (D) and lateral (E) radiographic view showing bisegmental interbody fusion.

Table 1. General information in the coflex plus fusion group and the Bisegmental fusion groups.

	Coflex plus fusion	Bisegmental fusion
Number of patients	12	11
Male	7	7
Female	5	4
Mean age (years)	61.2	58.8
Operative site		
L3-L5	5	5
L4-S1	7	6

protection remained for three months.

Evaluation

Clinical efficacy indexes

Surgical time and bleeding volume were evaluated. The lumbar pain and leg pain were evaluated using the visual analogue scale (VAS). The Oswestry disability index questionnaire (ODI) was used to assess the functional recovery.

Imaging indexes

Lumbar dynamic x-ray was performed prior to operation and at the last follow up for all patients. The range of motion (ROM) was defined as the difference between the maximum extension angle (E) and the maximum flexition (F) for the surgical segments and the upper adjacent segment (ROM=E-F). ROM<<3°indicated bone fusion (Lee et al., 1995).

Statistical analysis

All statistical analyses were done using SPSS 13.0. The operation time and the bleeding volume were compared between the coflex plus fusion group and the bisegmental fusion group using the independent samples t test. The VAS for lumbar and leg pain, the ODI, and activity of the surgical segments and the upper adjacent segment prior to operation and at the last follow up were compared using the paired samples t test for each group and using the independent samples test between two groups. A statistically significant difference was considered if P was <0.01.

RESULTS

There was no statistically significant difference in the sex ratio, age, and the surgical site between the coflex plus fusion group and the bisegmental fusion group (Table 1).

There was one case of dural sack leakage in each group, but was healed through elevation of the bed end and change of medications. The follow up was 11.5 ± 3.9 months for the coflex plus fusion group and 12.2 ± 4.3 months for the bisegmental fusion group. Spinous process fracture, relaxation of internal fixation, or screw or rod break was not found during follow up.

There was no statistically significant difference in the operation time (140.36 ± 28.63 min VS 155.74 ± 29.69 min) between the coflex plus fusion group and the bisegmental fusion group (F = 1.73, t = 1.26, and P = 0.24). The bleeding volume was statistically significantly lower in the coflex plus fusion group than in the bisegmental group (512.86 ± 86.75 ml VS 606.33 ± 96.55 ml, F = 1.03, t = 2.43, and P = 0.03) (Table 2).

Clinical scores

The VAS for lumbar pain was 6.54 ± 1.76 prior operation

Table 2. Operation time and bleeding volume in the coflex plus fusion group and the bisegmental group ($\overline{X}$ ±S).

Group	Operation time(min)	bleeding volume(ml)
Coflex plus fusion	140.36 ± 28.63	512.86 ± 86.75
Bisegmental fusion	155.74 ± 29.69	606.33 ± 96.55
	t=1.26, P=0.24	t=2.44, P=0.03

Table 3. VAS for lumbar pain and leg pain in the Coflex plus fusion group and the bisegmental group ($\overline{X}$ ±S).

Group	Preoperative		Last follow up	
	lumbar pain	leg pain	lumbar pain	leg pain
Coflex plus fusion	6.54±1.76	6.71±1.74	2.68±1.49	2.74±1.26
Bisegmental fusion	6.84±1.65	6.11±2.01	2.93±1.41	2.69±1.48
	t = 0.42, P = 0.76	t = 0.76, P = 0.45	t = 0.41, P = 0.77	t = 0.08, P = 0.87

Table 4. ODI in the coflex plus fusion group and the bisegmental fusion group ($\overline{X}$ ±S).

Group	Preoperative	Last follow up
Coflex plus fusion	70.45±15.91	34.94± 16.85
Bisegmental fusion	67.74±18.74	37.16±17.55
	t = 0.37, P = 0.79	t = 0.31, P = 0.80

and 2.6± 1.49 at the last follow up in the coflex plus fusion group. A statistically significant difference was observed between the two time points (t = 5.65, P<0.01). The VAS for lumbar pain was 6.84 ± 1.65 prior operation and 2.93 ± 1.41 at the last follow up in the bisegmental fusion group. A statistically significant difference was observed between the two time points (t = 6.09, P<0.01). There was no statistically significant difference in the VAS for lumbar pain between two groups prior to operation and at the last follow up (F = 1.13, t = 0.42, P = 0.76 prior to operation; F = 1.12,t = 0.41,P = 0.77 at the last follow up) (Table 3).

The VAS for leg pain was 6.71 ± 1.74 prior operation and 2.74 ± 1.26 at the last follow up in the coflex plus fusion group. A statistically significant difference was observed between the two time points (t=6.21, P<0.01). The VAS for leg pain was 6.11 ± 2.01 prior operation and 2.69 ± 1.48 at the last follow up in the bisegmental fusion group. A statistically significant difference was observed between the two time points (t = 4.61, P<0.01). There was no statistically significant difference in the VAS for leg pain between two groups prior to operation and at the last follow up (F = 1.33, t = 0.76, P = 0.45 prior to operation; F = 1.37, t = 0.08, P = 0.87 at the last follow up) (Table 3).

The ODI was 70.45 ± 15.91% prior to operation and 34.94 ± 16.85% at the last follow up in the coflex plus fusion group. A statistically significant difference was observed between the two time points (t = 5.20, P<0.01). The ODI was 67.74 ± 18.74% prior operation and 37.16 ± 17.55% at the last follow up in the bisegmental fusion group. A statistically significant difference was observed between the two time points (t = 4.13, P<0.01). There was no statistically significant difference in the ODI between two groups prior to operation and at the last follow up (F = 1.39, t = 0.37, P = 0.79 prior to operation; F = 1.08, t = 0.31,P = 0.80 at the last follow up) (Table 4).

Lumbar ROM

The ROM for fusion segments was 9.46±2.72° prior to operation and 1.32±0.67° at the last follow up in the Coflex plus fusion group, signaling bone fusion. A statistically significant difference was observed between the two time points (t = 10.07, P<0.01). The ROM for grafting segments was 7.90±2.88° prior operation and 5.59±2.43° at the last follow up in the in the Coflex plus fusion group, indicating bone fusion. A statistically significant difference was observed between the two time points (t = 2.12, P<0.04). The ROM for lower diseased segments was 9.19±2.27° prior to operation and 1.02±0.85° at the last follow up in the bisegmental fusion group, signaling bone fusion. A statistically significant difference was observed between the two time points (t = 11.68, P<0.01). The ROM for upper diseased segments was 7.46±3.02° prior to operation and 1.26±0.96° at the

Table 5. Activity of surgical segments and upper adjacent segments in the coflex plus fusion group and the bisegmental group prior to operation and at the last follow up ($\overline{X}$ ±S).

Group	Preoperative			Last follow up		
	Lower diseased segments	Upper diseased segments	Upper adjacent segments	Lower diseased segments	Upper diseased segments	Upper adjacent segments
Coflex plus fusion	9.46±2.72°	7.90±2.88°	6.68±3.00°	1.32±0.67°	5.59±2.43°	8.15±3.29°
Bisegmental fusion	9.19±2.27°	7.46±3.02°	8.07±2.86°	1.02±0.85°	1.26±0.96°	12.79±3.58°
	t=0.26,P=0.81	t=0.36, P=0.79	t=1.13, P=0.20	t=0.94, P=0.38	t = 5.52,P<0.01	t=3.24, P<0.01

last follow up in the bisegmental fusion group, signaling bone fusion. A statistically significant difference was observed between the two time points (t = 6.78, P<0.01). There was no statistically significant difference in the ROM for lower diseased segments between two groups prior to operation and at the last follow up (F = 1.65, t = 0.26, and P = 0.81 prior to operation; F = 2.31, t = 0.94, and P = 0.38 at the last follow up). There was no statistically significant difference in the ROM for upper diseased segments between two groups prior to operation (F = 1.21, t = 0.36, and P = 0.79). A statistically significant difference was noted in the ROM for upper diseased segments between two groups at the last follow up (F = 4.39, t = 5.52, P = 0.01) (Table 4).

The ROM for upper adjacent segments was 6.68 ± 3.00° prior to operation and 8.15 ± 3.29° at the last follow up in the coflex plus fusion group. There was no statistically significant difference between the two time points (t = 1.12, P<0.20). The ROM for upper adjacent segments was 8.07 ± 2.86° prior to operation and 12.79 ± 3.58° at the last follow up in the bisegmental fusion group. There was a statistically significant difference between the two time points (t = 3.56, P<0.01). No statistically significant difference was noted in ROM for upper adjacent segments between the two groups prior to operation (F = 1.10, t = 1.13, and P = 0.20), but it was statistically significantly lower in the coflex plus fusion group compared to the bisegmental fusion group at the last follow up F = 1.19, t = 3.24, and P<0.01) (Table 5).

DISCUSSION

The therapy for lumbar spinal stenosis often aims to completely and effectively relieve compression of nerve roots and reconstruct spinal stability. The posterior lumbar interbody fusion has achieved favorable outcomes in nerve decompression, nerve function recovery and spinal stability. However, loss of motion function of fusion segments and rapid degeneration of adjacent segments are left to be potential long-term complications for lumbar fusion techniques.

The compression of adjacent segments and the compression and compromised activity of intervertebral disks result in rapid degeneration of adjacent segments (Eck et al., 1999). One major factor leading to degeneration of adjacent segments is that the adjacent intervertebral space bears many abnormal activities beyond its limits. Krag (1991) thought that the impact of firm fusion on the activity of adjacent segments was a major factor affecting rapid degeneration of adjacent segments. They also found motion change for patients with posterior lumbar interbody fusion through imagining that inevitably leads to adjacent segment degeneration (ASD) or deteriorates existing degeneration. Mummaneni and Haid (2004) established the finite element model for L1 to L5 lumbar vertebrae to compare results between the normal group and the L4/L5 posterior lumbar interbody fusion group, and found the von Mises stress of end-plates of adjacent segments increased apparently after the interbody fusion and even by 117% under the condition of flexion loading, while the stress for the adjacent fibrous ring also increased, and even by 209% under the condition of flexion loading, thus indicating increase of stress of end-plates and fibrous ring are a cause of ASD. Weinhoffer et al. (1995) and Lee (1988) through biomechanical research on corps found that adjacent non-infusion segments bore increased stress, displacement and motion especially in small bone joints due to stiffness of fusion segments and backward transfer of local rotational centers of adjacent segments after infusion technique or especially internal fixation, leading to instability, degeneration, and even emerging symptoms.

The aim of this study was to objectively exhibit the clinical efficacy of coflex interspinous implant, but not emphasize the advantages of this device. The bleeding volume was less in the coflex plus

fusion group than in the bisegmental fusion (P = 0.03). The ROM for the upper surgical segments was smaller at the last follow up than prior to operation in two groups (P = 0.04; P<0.01). Implantation of coflex between spinous processes achieves dynamic stability with controlled activity, avoiding rapid degeneration of adjacent segments following interspinal fusion (Tsai et al., 2006). Coflex is made up of titanium alloy that does not affect imaging examination after implantation. It is able to provide effective stability. Relaxation of interspinal ligaments and spinal stability compromise following lumbar decompression can be rectified to rebuild spinal completeness and stability through coflex implantation (Deyo et al., 1992; Katz et al., 1997).

Results in the current research indicate no difference in clinical efficacy regarding lumbar and leg pain between the bisegmental posterior lumbar interbody fusion and the Coflex implant for lumbar fusion. However, because of procedure in the intervertebral space for the posterior lumbar interbody fusion technique, scraping upper and lower end-plates adds to bleeding. Thus the bleeding volume was relatively lower in the Coflex implant technique. Compared to the bisegmental posterior lumbar interbody fusion, the Coflex implant procedure retained motion activity of grafting bones, and effectively reduced activity of the upper adjacent lumbar vertebra, thus preventing adjacent segment degeneration. No complications were observed following Coflex implantation.

Conclusion

There is no statistically significant difference in short-term efficacy between the coflex interspinous implant for lumbar fusion and the bisegmental posterior lumbar interbody fusion. The former technique can maintain lumbar activity and prevent ASD. As it is brought into clinical use for a short time, the long-term efficacy and middle-term and late complications should be followed up.

Complications for coflex interspinous implant include implant relaxation or break, and fracture of spinous processes and vertebral pedicles. These were, however, not discovered in this study. We controlled indications for the procedure through lumbar anterior-posterior, lateral, and dynamic X-ray to locate disease segments. Severe instability, small spinous process, lumbar cancer and infection should be excluded for this technique. The upper/lower spinous processes less than 25 mm at the diseased segments do not reach the width of the upper arm of coflex between spinous processes, and thus tend to fall out. For patients with osteoporosis, coflex should not be used owing to poor fixation for coflex.

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