Coflex Interspinous Process Dynamic Stabilization for Lumbar Spinal Stenosis: Long-term Follow-up

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Abstract

[Objective]

To evaluate the long-term efficacy of Coflex interspinous process dynamic stabilization device in the treatment of lumbar spinal stenosis.

[Methods]

The clinical and imaging data of 73 patients undergoing Coflex interspinous process dynamic stabilization surgery from July 2008 to June 2012 were retrospectively analyzed. Clinical data include: visual analogue scale of pain (VAS), Oswestry disability index(ODI) and Japanese Orthopedic Association Scores(JOA) of preoperation, 6 months after surgery, and last follow-up; complications; reoperation rates and incidence of adjacent segment degeneration(ASD). Imaging data including: lumbar range of motion(ROM), intervertebral space height(ISH) and intervertebral foramen height (IFH) of operative and adjacent segment at preoperative, 6 months after operation and the last follow-up.

[Results]

56 patients were followed up. The follow-up time was 107.6 ± 13.3 months, the operation time was 10.0 ± 3.1 minutes, the intraoperative blood loss was 153.9 ± 80.6 ml, and the hospitalization time was 10.2 ± 3.2 days. The VAS, ODI and JOA scores improved significantly after surgery. At 6 months after surgery and the last follow-up, ROM was significantly lower than that before surgery with statistical significance ($P < 0.001$). ROM was slightly increased at the last follow-up compared with that 6 months after operation, but the difference was not statistically significant ($P > 0.05$). The ROM of adjacent segments increased at 6 months and at the last follow-up compared with that before surgery, but the difference was not statistically significant ($P > 0.05$). At 6 months after surgery, ISH and IFH of implanted segment was significantly higher than that before surgery, and the difference was statistically significant ($P < 0.05$). At the last follow-up, there was a decrease in ISH and IFH, with no statistical difference compared with that before the operation. During the follow-up period, a total of 11 patients (19.6%) experienced complications and 6 patients (10.7%) underwent secondary surgery.

[Conclusion]

Coflex interspinous process dynamic stabilization is effective in the treatment of lumbar spinal stenosis in the long term. The surgical segment retains a small range of motion. The incidence of complications and reoperation is low. However, the ISH and IFH of implanted segment can only be maintained for a short period of time.

Introduction

Lumbar spinal stenosis is the main cause of low back pain and intermittent claudication. For patients who have failed conservative treatment, surgery is an effective method. Intervertebral fusion , which

known as the "gold standard" of treating lumbar degenerative disease, has the effect of reducing pain and restoring stability by fixing responsible segments^[1]. However, fusion surgery eliminates the motion ability of the fixed segment, results in an increase in stress concentration and range of motion of adjacent segments in the fusion segment, causing such issues as pseudo-joint formation, ectopic ossification and adjacent segment degeneration(ASD) and other complications^[2,3]. For patients with degeneration in adjacent segments, if not protected, it is more likely to accelerate the degeneration process after fusion, and even needs reoperations. In recent years, the concept of dynamic stability and non-fusion has emerged, and Coflex has gradually gained the attention of spine surgeons. The Coflex system has been used in clinical applications since the 1990s. It can effectively solve intermittent claudication and relieve lumbar spinal stenosis. Coflex can avoid stress concentration in surgery and adjacent segments and prevent ASD^[4]. At present, good clinical effects have been obtained in domestic and foreign short-term studies^[5,6], but long-term clinical evidence is still lacking. From July 2008 to June 2012, 73 patients with single-segment lumbar spinal stenosis were treated with decompression combined with Coflex interspinous process dynamic stabilization in our hospital. The aim of this report was evaluating the long-term clinical efficacy and imaging changes of Coflex.

1. Patients And Methods

1.1 Inclusion and Exclusion Criteria

Inclusion criteria: (1) Those with a clear diagnosis of symptomatic lumbar spinal stenosis; (2) Those without lumbar spondylolisthesis or stable slippage within I degree; (3) Those who have failed conservative treatment for more than 6 months; (4) Those who underwent single lumbar decompression and Coflex implantation were followed up completely and regularly for more than 8 years.

Exclusion criteria: (1) People with previous history of lumbar spine surgery; (2) Those with isthmic spondylolisthesis or lumbar spondylolisthesis of degree II or above; (3) Patients with lumbar trauma, infection or tumor; (4) Patients with severe osteoporosis (5) Patients with severe heart, brain and lung dysfunction.

1.2 Patient Population

A total of 73 patients underwent decompression combined with Coflex dynamic stabilization surgery at TangDu Hospital between April 2009 to July 2011. 56 patients among them were followed up with complete clinical data and imaging data. There were 31 males and 25 females, aged 58.0 ± 18.2 years. All patients were single-segment lesions, including L_{2/3} 4 cases, L_{3/4} 8 cases, and L_{4/5} 30 cases. Preoperative lumbar lateral position and dynamic position X-ray, CT and MRI examination were performed. Clinical signs and imaging showed degenerative lumbar spinal stenosis. All patients had varying degrees of low back and leg pain before surgery, including 33 cases of intermittent claudication, 18 cases of L4 ~ 5 nerve root innervation area pain and hypoesthesia, and 12 cases of decreased hallux extensor muscle strength (Class IV ~ IV +), 5 cases with positive Lasegue sign, 3 cases had Achilles

tendon reflex weakened or disappeared. All patients underwent interlaminar decompression and Coflex implantation.

1.3 Surgical Procedure

After general anesthesia, patients were placed prone with appropriate positioning precautions. Using a standard midline incision, an open or mini-open surgical exposure was performed with typical technique, and confirmation of operative levels was finalized. And then incising the skin to the fascia, separating the supraspinous ligament longitudinally on both sides of the spinous process to expose the supraspinous ligament. dissociating and retracting the supraspinous ligament to preserve the integrity of the supraspinous ligament, and removing the interspinous ligament. Inserting a locating needle between the spines to determine the correct clearance, and then removing the yellow ligament. Removing part of the upper and lower lamina with lamina bite forceps and fully decompressing the dural sac and nerve root, so as to preserve spinous process roots and articular processes. Placing a proper Coflex fixator in a good position under fluoroscopy, tightening the wings. Rinsing and repairing the posterior structure, suturing the fascia and supraspinous ligament layer by layer, and then placing the drainage tube. After the surgery, drugs were used to prevent infection and intravenous drip of mannitol and dexamethasone 3d was performed. Observing and recording the drainage volume, and removing the drainage tube within 1~2 days. Observing and recording the drainage volume, and removing the drainage tube within 1~2 days. 3 days after the operation, the patients should carry out bed exercises, and then started to stand on the ground and walk for short distances with waist support, and gradually increased exercise intensity and walking distance until the recovery of daily life.

1.4 Evaluation methods.

Evaluation of clinical efficacy: During the perioperative period, operation time, intraoperative blood loss, hospitalization time and surgical complications were recorded. Visual Analogue Scale (VAS), Oswestry disability index (ODI) and Japanese Orthopedic Association (JOA) scores were used to evaluate the clinical efficacy before surgery, 6 months after surgery and at the last follow-up. At the same time, the reoperation rate and ASD incidence were recorded.

Imaging evaluation include: lumbar range of motion (ROM) - subtraction of the angle formed by the extension line of the target segment's upper and lower endplates on the spinal hyperextension and hyperflexion X-ray film. Intervertebral space height (ISH) - the vertical height at the midpoint of adjacent vertebrae on a lumbar lateral X-ray film. Intervertebral foramen height (IFH) - the distance between the lower edge of the upper vertebral pedicle and the upper edge of the lower vertebral pedicle. According to the imaging data before surgery, 6 months after surgery and at the last follow-up, the ROM, ISH and IFH of the operation and adjacent segments were measured.

1.5 Statistical analysis

All imaging data were measured by image analysis software IPP6.0; The data were statistically analyzed using SPSS 23.0 software (IBM SPSS, Armonk, NY, USA). Measurement data are shown as mean $\pm$ standard deviation and tested by t-test. Ranked data were used for rank sum test. $P < 0.05$ was considered statistically significant.

2. Result

2.1 Clinical outcomes

56 patients were followed up for 107.6 ± 13.3 months, the operating time was 103.7 ± 30.1 minutes, the intraoperative blood loss was 153.9 ± 80.6 ml, and the hospitalization time was 10.0 ± 3.1 days (Table 1). Incision bleeding occurred in 1 patient (1.8%) during the perioperative period, and exploratory incision was performed immediately to stop bleeding. During follow-up, ASD occurred in 6 cases (10.7%), restenosis of the Coflex implant segment occurred in 2 cases (3.6%), ectopic ossification occurred in 1 case (1.8%), and osteolysis occurred in 1 case (1.8%). A total of 11 (19.6%) complications occurred, of which 6 (10.7%) underwent reoperation. During the follow-up period, no complications such as loosening, displacement, shedding of the Coflex occurred. And no rupture of spinous processes were found. VAS scores at 6 months after surgery and at the last follow-up were significantly lower than that before surgery, and there was no statistical difference between the 6 months after surgery and the last follow-up. Compared with preoperative, the ODI score and JOA score improved significantly at 6 months after operation and at the last follow-up. There was a statistically significant difference between the 6 months after operation and the last follow-up ($P=0.001$) (Table 2).

2.2 Radiological outcomes

After Coflex implantation, the surgical segment kept a small ROM, which was significantly lower than that before surgery ($P < 0.001$). At the last follow-up, the ROM was slightly bigger than that 6 months after surgery, but there was no statistical significance ($P > 0.05$). ROM of upper adjacent segment and lower adjacent segment increased gradually after surgery, but there was no difference between 6 months after surgery and the last follow-up ($P > 0.05$) (table 3). ISH and IFH of adjacent segments had no significant change after surgery. At 6 months after surgery, ISH and IFH of operative segment was significantly higher than that before surgery, and the differences were statistically significant ($P < 0.05$). At the last follow-up, there was a significant decrease in ISH and IFH of operative segment compared with 6 months after surgery, with statistically significant differences ($P < 0.05$) (Table 3, Figure 1). There was no statistical significance of ISH and IFH at the last follow-up compared with that before surgery ($P > 0.05$). Typical case is shown in Figures 2.

Tab.1 Demographic data and perioperative data.

Agents	Value
Number of patients	56
Age (year)	58.0±18.2
Gender (male/female)	31/25
Follow-up period (months)	107.6±13.3
Operating time (minutes)	103.7±30.1
Intraoperative blood loss (ml)	153.9±80.6
Hospitalization (days)	10.0±3.1

Tab.2 Clinical outcomes ($\bar{x} \pm s$)

Agents	Pre-surgery	6 months after surgery	Final follow-up	P ₁	P ₂	P ₃
VAS score for leg pain	6.09±1.68	1.03±0.68	0.79±0.65	0.000	0.000	0.147
VAS score for back pain	4.91±1.63	1.06±0.83	0.91±0.81	0.000	0.000	0.406
ODI score	53.52±11.80	12.79±3.85	6.73±4.32	0.000	0.000	0.000
JOA score	13.30±3.12	22.24±2.88	24.52±3.03	0.000	0.000	0.004

P₁: P value comparing pre-surgery and 6 months after surgery; P₂: P value comparing pre-surgery and final follow-up; P₃: P value comparing 6 months after surgery and final follow-up.

Tab.3 Radiological outcomes

	Pre-surgery	6 months after surgery	Final follow-up	P ₁	P ₂	P ₃
ROM(°)						
Upper segment	7.64±2.01	7.72±1.84	7.79±1.87	0.629	0.543	0.827
Implanted segment	6.52±1.95	3.09±1.57	3.45±1.79	0.000	0.000	0.292
Lower segment	7.45±1.89	7.54±1.70	7.67±1.73	0.702	0.421	0.325
ISH(mm)						
Upper segment	10.13±1.64	10.27±1.69	9.91±1.84	0.699	0.625	0.415
Implanted segment	9.43±1.48	10.41±1.56	9.63±1.54	0.004	0.563	0.125
Lower segment	10.28±1.40	10.13±1.29	10.09±1.42	0.524	0.553	0.891
IFH(mm)						
Upper segment	20.73±2.65	20.48±2.61	20.15±2.50	0.559	0.375	0.571
Implanted segment	18.70±2.74	20.88±2.90	19.06±2.62	0.008	0.449	0.012
Lower segment	18.15±2.50	17.82±2.47	18.03±2.22	0.190	0.794	0.690

P₁: P value comparing pre-surgery and 6 months after surgery; P₂: P value comparing pre-surgery and final follow-up; P₃: P value comparing 6 months after surgery and final follow-up.

3. Discussion

In the 1990s, Professor Jacques Samani invented the U-shaped interspinous process fixation device, and achieved good results in clinical applications^[7]. The FDA approved indications for Coflex is one- or twolevel lumbar stenosis from L1 to L5 producing at least moderate impairment in skeletally mature patients^[8]. The FDA states that patients receiving this treatment should be those who experienced relief of symptoms with flexion of the lumbar spine and had undergone non-surgical treatment for more than 6 months. The presence of back pain does not exclude someone from receiving Coflex, but axial back pain only without leg, buttock, or groin pain is a contraindication. Other contraindicated factors of Coflex are: previous history of fusion or decompression surgery in symptomatic segments, compression fractures of the lumbar spine, instability induced by bone resection of severe facet joint hyperplasia, Lumbar spondylolisthesis of grade II or above, lumbar spondylolisthesis induced by lumbar isthmus, lumbar scoliosis with Cobb angle greater than 25°, osteoporosis and body mass index (BMI) are greater than 40. In addition, it is generally believed that Coflex is not suitable for the L5/S1 segment due to the narrow support surface. However, Xu^[9] and his team completed fourteen cases of Coflex implantation in L5/S1

segments by inverted prosthesis. The radiological outcomes and clinical outcomes of the patients improved significantly after 4 years. Therefore, it can be considered that on the premise that the sacrum has a good fixed support effect, narrow space is not an absolute contraindication to the application of the Coflex device, but further follow-up and multi-center research data are needed to prove it. Coflex has also been reported in three spinal segments and has achieved good clinical results^[10], indicating that its application may not be strictly limited by the number of degenerative segments.

The Coflex system is considered a safe and effective alternative to traditional fusion^[11-13]. It was designed to open the spinous process and limit the spine hyperextension^[14]. After Coflex implantation, the height of the interspinous process can be increased, thereby increasing the height of the posterior edge of the vertebral body, which means that the stress behind the disc is reduced and the space of the nerve root canal is enlarged. Coflex increases the height of the intervertebral space and unbends the tortuous ligamentum flavum. Partial removal of the ligamentum flavum and proliferative articular processes during surgery increases the volume of the spinal canal and relieves the clinical symptoms of the patient. But there is another view, that is restoration of the foraminal height may not be a responsible factor for clinical improvement. Celik^[15] et al found that the height of the intervertebral foramen could be increased in the short term after Coflex surgery. With the extension of follow-up time, the height of the intervertebral foramen gradually decreased and approached the preoperative level. They believed that postoperative clinical efficacy was not directly related to whether Coflex maintained the height of the intervertebral space, and the relief of postoperative clinical symptoms of patients should be attributed to the relief of nerve compression after decompression by laminectomy. This study also showed that Coflex could only maintain the height of intervertebral space and intervertebral foramen in a short period of time. At the 6-month after surgery, intervertebral space and foramen height of surgical segment was significantly greater than that at preoperative period, and decreased to the preoperative level at the last follow-up.

Compared with fusion, Coflex implantation has the advantages of less intraoperative blood loss and shorter operation time, which greatly shortens the patient's recovery period^[13,16]. Our study shows that the VAS, ODI, and JOA scores were significantly improved at 6 months after surgery and at the last follow-up, and the long-term efficacy was stable and the clinical effect was satisfactory. In this study, a small degree of activity was retained of the surgical segment after surgery, which was significantly lower than that before surgery. At the last follow-up, the activity increased slightly compared with 6 months after surgery, but there was no statistical difference. The ROM of the upper adjacent segment and the lower adjacent segment increased gradually 6 months after the operation and the last follow-up, but the difference was not statistically significant. Studies have shown that the Coflex system can partially retain the mobility of the inserted segments, weaken the compensatory effect of adjacent segments. while maintaining the mobility of the surgical segment, it also limits the excessive lumbar movement of the surgical segment, thus maintaining the stability of the spine, which may reduce the occurrence of postoperative lumbar instability and delay the degeneration of adjacent segments^[5,10,17].

The complications of the Coflex system include three aspects: surgery-related complications, direct implant complications, and indirect implant complications. Surgery-related complications are incision infections, local hematomas, and so on. This may be the U-shaped design of the Coflex implant device, which results in the formation of an inherent cavity after implantation between spinous processes, increasing the risk of infection and hematoma formation^[18]. In the study by Bae et al.^[5,12], the incidence of surgery-related complications in the Coflex group was 12.1%, and in the fusion group was 17.8%, with no statistical difference between the two groups. The direct complications of the Coflex device are loosening, displacement, detachment, fracture of the implant and fracture of the spinous process. Due to the long-term contact between spinous processes and Coflex devices, spinal process erosion and spinous process fractures often occurred^[6]. Bae et al^[5] found that the surgical failure rate due to loosening and rupture of the device was about 3.2%. The indirect complications of implants are mainly the degeneration of the original surgical segment and the occurrence of ASD. An FDA conformed study^[19] first reported the similar safety and adverse event rates of the Coflex system and fusion. The reoperation rate in the Coflex group was 10.7%, which was slightly higher than the fusion group of 7.5%, but the difference was not statistically significant. The rate of surgery-related complications in our study was 1.8%, the incidence of ASD was 10.7%, the incidence of total complications was 19.6%, and the reoperation rate was 10.7%. No complications such as loosening, displacement, shedding of the Coflex device, or rupture of the spinous process were found (Figure 4). Another long-term follow-up study^[20] showed that 30 patients had a 94.6 months follow-up, 3 cases (10%) had ASD, 1 case had Coflex segment restenosis, 1 case had non-adjacent segment degeneration, 4 cases (13.3%) had a second surgical treatment, 4 cases (13.3%) had osteolysis of spinous process around Coflex prosthesis, and 2 cases (6.7%) had ectopic ossification. The results are consistent with this study.

4. Conclusion

In summary, we found that lamina decompression combined with Coflex interspinous process dynamic stabilization relieved patients' symptoms, the long-term efficacy were satisfactory. The incidence of ASD was 10.7%, the incidence of complications was 19.6 %, and the reoperation rate is 10.7%, which has a good safety and effectiveness. Coflex can maintain the disc height of the surgical segment for a short period of time, retain a small range of motion, and reduce the risk of degeneration in adjacent segments. However, the number of cases in this study is small, and further multicenter randomized controlled trials with large samples are needed for further verification.

Abbreviations

VAS: visual analogue scale of pain

ODI: Oswestry disability index

JOA: Japanese Orthopedic Association Scores

ASD: adjacent segment degeneration

ROM: lumbar range of motion

ISH: intervertebral space height

IFH: intervertebral foramen height

Declarations

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Authors'contributions

MD, CZ and JQ contributed to study concept and design, FW and KZ provided supervision. CZ identified and acquired reports of trials, and extracted data. FW, MD and KZ contacted authors of trials for additional information. FW and KZ analyzed and interpreted the data. MD, CZ provided statistical advice and input. MD, CZ and FW contributed to the interpretation of the data. MD drafted the manuscript. CZ and JQ reviewed the manuscript. All authors approved the final version of the manuscript.

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Availability of data and materials

The patients' data were collected in the Tangdu Hospital of No4 Military Medical University. The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee (Tangdu Hospital of No4 Military Medical University), and an exemption from informed consent was obtained from our responsible Investigational Ethics Review Board.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no conflict of interest.

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Figures

Figure 1

A: Preoperative lateral X-ray film of lumbar spine ($a_1 = 9.51\text{mm}$, $b_1 = 18.22\text{ mm}$); B: lateral X-ray film of the lumbar spine at 6 months after operation ($a_2 = 10.62\text{mm}$, $b_2 = 21.02\text{ mm}$); C: lateral X-ray film of the lumbar spine at 9 years after operation ($a_3 = 9.97\text{mm}$, $b_3 = 18.86\text{ mm}$). a: ISH, b: IFH

Figure 2

A 73-year-old man diagnosed with "lumbar spinal stenosis (L4 / 5)". In February 2010, he was performed "single segment lumbar decompression Coflex interspinous process dynamic stabilization implantation". A, B. Preoperative frontal and lateral X-ray films; C. Preoperative lumbar MRI (sagittal); D. Preoperative lumbar MRI (axial, L4 / 5); E. Preoperative lumbar CT (axial, L4 / 5); F, G. Frontal and lateral X-rays at 6 months after operation; H, I. Frontal and lateral X-rays at 9 years after operation.

Figure 3

Nine years after operation, the interspinous process stabilization device and the spinous process were well anchored, with no significant loosening or osteolysis. A, B, C, D. Lumbar spine CT (sagittal position) at 9 years after operation; E, F. Lumbar spine CT (axial position, L4 / 5) at 9 years after operation.

Figure 4

A 60-year-old male patient was followed up for 8 years. The intervertebral space decreased, the vertebral body collapsed, and the device subsided, but the stability was good, and no signs of loosening and osteolysis were seen. A, B. Frontal and lateral X-rays at 8 years after surgery.