# Effectiveness of dynamic fixation Coflex treatment for degenerative lumbar spinal stenosis

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**Abstract.** The aim of the present study was to examine the curative effect of dynamic fixation Coflex treatment for patients with degenerative lumbar spinal stenosis. In the present study, 78 patients with degenerative lumbar spinal stenosis were recruited and divided equally into the control and observation groups. The control group was treated with traditional decompression fusion and the observation group received dynamic fixation Coflex system. Surgery and hospitalization were shorter in the observation group than in the control group. Intraoperative blood loss and drainage volume after surgery were significantly lower in the observation group compared to the control group. The treatment effective rate for the observation group was significantly higher. Visual analogue scale, Oswestry disability index and Japanese Orthopaedic Association pain and functional scores as well as postoperative vertebral canal area and adjacent segment quantitative scores improved after surgery in the two groups, but the observation group showed greater improvement. The curative effect of dynamic fixation Coflex treatment for degenerative lumbar spinal stenosis demonstrates advantages over traditional surgery, including less trauma and bleeding, pain reduction, improved postoperative rehabilitation, and lower incidence of adjacent segment degeneration.

## Introduction

Degenerative lumbar spinal stenosis is a common lumbar disease and one of the main reasons for the high incidence of intermittent claudication (1). The clinical manifestation of degenerative lumbar spinal stenosis is chronic pain in the waist and lower limbs, which limits activity and alters normal work and daily life activities (2). The traditional therapeutic method to treat degenerative lumbar spinal stenosis are laminectomy, decompression, and bone graft fusion. However, these therapies have significant disadvantages, resulting in movement disturbances of the fused segments, which impacts the adjacent segments and promotes degeneration (3).

The Coflex system, which has been applied in the clinic since the 1990s, can effectively resolve intermittent claudication, relieve lumbar spinal stenosis, and is especially suitable for elderly patients (4).

The aim of the present study was to demonstrate a satisfactory curative effect by conducting dynamic fixation Coflex treatment for patients with degenerative lumbar spinal stenosis.

## Patients and methods

*Clinical data*. We recruited 78 patients with degenerative lumbar spinal stenosis who were admitted to our hospital from July 2014 to June 2015. Inclusion criteria for the study were: degenerative lumbar spinal stenosis identified by imagological examination such as MRI and X-ray. Patients had obvious intermittent claudication combined with backache or lower limb radiating pain. Patients signed informed consent. Exclusion criteria for the study were: olisthy or instability of adjacent segments; and history of lumbar surgery, serious osteoporosis, or lumbar vertebral wound. Patients were divided equally into the control and observation groups (n=39). The control group received traditional decompression fusion, whereas the observation group was treated with dynamic fixation Coflex system. The general biometric data for the patients in the two groups showed no statistical differences (Table I).

*Preoperative preparation*. Before surgery, the clinical history of patients was evaluated and surgical contraindications were excluded to decrease the surgical risk. Functional scores were collected, including the Japanese Orthopaedic Association (JOA) score, Visual analogue scale (VAS) pain score, and the Oswestry disability index (ODI) score. Appropriate surgical timing was selected and methylprednisolone was provided 30 min before surgery followed by general anesthesia.

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Table I. Baseline patient information.

| Items | Control (n=39) | Observation (n=39) | t/$\chi^2$ | P-value |
|---|---|---|---|---|
| Sex (male/female) | 20/19 | 22/17 | 0.051 | 0.820 |
| Age (years) | 45-75 | 45-80 | | |
| Average age (years) | 58.56±6.47 | 58.85±6.38 | 0.199 | 0.842 |
| Intermittent claudication type (n, %) | | | | |
|   Gesture claudication | 21 (53.84) | 19 (48.72) | 0.051 | 0.820 |
|   Ischemic claudication | 18 (46.16) | 20 (51.28) | | |
| Pain type (n, %) | | | | |
|   Backache combined with leg pain | 26 (66.67) | 29 (74.35) | 0.247 | 0.619 |
|   Backache or leg pain | 13 (33.33) | 10 (35.65) | | |

*Traditional fusion for the control group.* After general anesthesia, the patients were placed in the prone position and X-ray machine perspective was used to locate the surgical segments. An 8-10 cm incision was carried out along the waist posterior median. The deep fascia and the paravertebral muscle were peeled to expose the spinous process of the vertebral plate. A guide needle was used to puncture the bilateral locating point of L4 and L5, and a pedicle screw was implanted according to the depth. X-ray perspective was used to check the position, then fixed with preloaded nut. Rongeur was applied for L4 and L5 spinous process to eliminate incrassated (ossified) ligamentum flavum and small zygopophysis as well as the vertebral plate that induced bony stenosis, with a full decompression. Bilateral rod was shaped to assemble the segments, nuts were screwed down, and washed with normal saline. The cut spinous process and vertebral plate were trimmed to proper size, which were implanted between the intervertebral spaces. A drainage tube was indwelled and the incision was sutured layer by layer to conclude the surgery.

*Dynamic fixation Coflex for the observation group.* After general anesthesia, the patients were placed in prone position and C-arm X-ray perspective was used to locate the surgical spot and the median incision (approximately 5 cm long) was selected. The supraspinous ligament was separated till the upper edge of the L4 spinous process and the lower edge of the L5 spinous process appeared. Lumbodorsal fascia was stripped and the paravertebral muscle was bluntly stripped to completely expose the spinous process and bilateral vertebral plate. Bilateral facet joints were protected. Incrassated ligamentum flavum and proliferous zygopophysis were cut, paying attention to lateral recess decompression. If an obvious protrusion of intervertebral disc was identified, the nucleus pulposus of protrusion was picked out. Proper Coflex fixator was selected and placed on L4-L5 that pressed close to the spinous process root and vertebral plate (approximately 2 mm away from the dural sac), and X-ray perspective was used to check the position. After the appropriate position was confirmed and tight, the two ends of the fixator were clamped moderately clinging to spinous process. The prosthesis bye hole and supraspinous ligament were sutured together, placing drainage tube, and suturing the incision.

*Postoperative care.* The patients were sent back to the ward and kept under electrocardiograph monitoring. Patients were required to remain prostrate on the bed for rest. After surgery, conventional rehydration, antibiotics, and neurotrophy drugs were administered as well as pain management. The drainage tube was removed 48 h after surgery, and the patients were provided with a waist belt for more than 3 months to avoid excessive contortion and extension. Day three after surgery, bed exercise of waist function was initiated. Day four after surgery, patients could start early off-bed activity and anteroposterior movement. Lateral X-ray of the lumbar vertebra was taken for observation of the implantated materials. The patients were evaluated again 12 months later.

*Evaluation methods.* Clinical data were: age of patients ≤60 years marking 1 score, and BMI ≤25 marking 1 score. MRI iconography was used to determine the average area of the spinal canal of patients. We compared the surgery time, intraoperative blood loss, volume of drainage after surgery, and hospitalization days to determine the effects of the surgeries. During follow-up 12 months later, the evaluation was conducted according to the MacNab standard as follows: Excellent, straight leg raise >70°, normal muscle force of lower limbs and movement, no pain in the waist and lower extremities. Good, straight leg raise <70°, but >30°, Grade 4 for muscle force, normal work and daily life with slight pain in waist and lower extremities sometimes. Medium, straight leg raise <30°, but >15°, Grade 3 for muscle force, alleviated pain in waist and lower extremities, with some use of drugs. Poor, no change, even aggravated, which required drugs to relieve pain. The total effective rate was calculated as: (excellent + good + medium) x 100.

VAS was used to evaluate pain level, with 0 indicating no pain and 10 indicating unbearable and acute pain. The JOA score was applied to evaluate low back pain level before and after surgery (5), with total score of 29. The evaluation standards were: poor, <10 score; medium, 10-15; good, 16-24; excellent, ≥25.

ODI was applied to score for dysfunction, with 0 indicating no dysfunction and 5 indicating obvious dysfunction. ODI was applied in three dimensions, including single capacity, pain, and personal comprehensive abilities and 9 total items (sexual

Table II. Surgical and post-surgical data.

| Groups | Cases | Surgery time (min) | Intraoperative blood loss (ml) | Volume of drainage after surgery (ml) | Hospitalization (days) |
|---|---|---|---|---|---|
| Observation | 39 | 56.83±3.62 | 75.47±6.63 | 77.86±7.45 | 5.23±1.53 |
| Control | 39 | 98.14±3.57 | 162.57±9.38 | 131.97±8.37 | 8.56±1.47 |
| t-test | | 50.740 | 47.354 | 30.157 | 9.801 |
| P-value | | <0.0001 | <0.0001 | <0.0001 | <0.0001 |

Table III. Macnab curative effect (n, %).

| Groups | Cases | Excellent | Good | Medium | Poor |
|---|---|---|---|---|---|
| Observation | 39 | 18 (46.15) | 16 (41.02) | 4 (10.26) | 1 (2.56) |
| Control | 39 | 14 (35.89) | 11 (28.21) | 5 (12.82) | 9 (23.07) |

MacNab method was used to compare between two groups, Z=0.423 and P=0.022 by rank.

Table IV. JOA scores before and after surgery.

| Groups | Cases | Pre-surgery | 1 month after surgery | 6 months after surgery | 12 months after surgery |
|---|---|---|---|---|---|
| Observation | 39 | 12.81±2.24 | 17.62±2.63 | 20.78±2.24 | 23.13±2.23 |
| Control | 39 | 12.29±2.34 | 15.53±2.37 | 17.93±2.36 | 20.76±2.37 |
| t-test | | 1.002 | 3.678 | 5.470 | 4.548 |
| P-value | | 0.319 | 0.0004 | <0.0001 | <0.0001 |

JOA, Japanese Orthopaedic Association.

life was excluded due to age), with a total maximum score of 45. ODI was calculated as accumulating scores/100x100.

The Pfirrmann grading method (6) was used and combined with the clinical data to produce a quantitative score from 0-10: Grade I, 4 points; Grade II, 3 points; Grade III, 2 points; Grade IV, 1 point; and Grade V, 0 points.

Imagological examination: sagittal plane angle of adjacent segment ≥10˚, 1 point; lateral displacement ≤3 mm, 1 point; intercalated disc wedging ≤5˚, 1 point; sagittal plane shifting ≤4 mm, 1 point.

*Statistical analysis.* SPSS 19.0 software (IBM SPSS, Armonk, NY, USA) was used to conduct statistical analysis. Measurement data are shown as mean ± standard deviation and tested by t-test. Enumeration data was expressed by rate (%) and tested by $\chi^2$. Ranked data were analyzed by rank sum test. P<0.05 was considered to indicate a statistically significant difference.

**Results**

*Surgery and postoperative condition of patients.* Surgery time and hospitalization days of the patients in the observation group were significantly shorter than in the control group (Table II).

Intraoperative blood loss and volume of drainage after surgery were significantly smaller in the observation group than in the control group (Table II).

*MacNab curative effect.* The effective rate for the observation and control groups were 97.44 and 76.93%, respectively, and the difference was statistically significant (Table III).

*Pain VAS scores before and after surgery.* Before surgery, the pain VAS scores for the observation and control groups were 6.83±1.14 and 7.06±1.23, respectively, the difference had no statistical significance (Fig. 1). One month after surgery, the pain VAS scores for the observation and control groups were 3.16±1.13 and 4.36±1.25, respectively. A total of six months after surgery, the VAS scores for the observation and control groups were 2.35±1.14 and 3.08±1.26, respectively. A total of 12 months after surgery, the VAS scores for the observation and control groups were 2.03±1.12 and 2.76±1.17, respectively. The VAS scores decreased in the two groups compared with before operation, but the observation group showed lower values at each time point compared to the respective control group (Fig. 1).

The JOA scores prior to surgery were similar between the two groups (Table IV). The scores increased in the two groups

Table V. Vertebral canal area before and after surgery (mm$^3$).

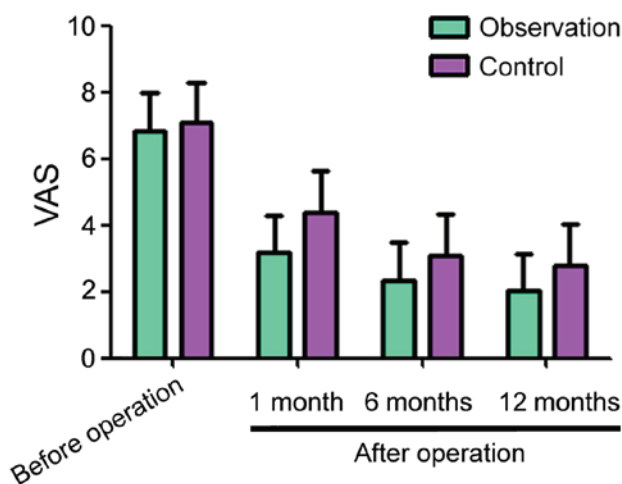| Groups | Cases | Pre-surgery | 6 months after surgery | 12 months after surgery | F | P-value |
|---|---|---|---|---|---|---|
| Observation | 39 | 225.81±12.24 | 263.78±19.24 | 262.13±12.23 | 80.458 | <0.0001 |
| Control | 39 | 227.29±12.34 | 246.93±15.36 | 231.76±12.37 | 22.909 | <0.0001 |
| t-test | | 0.532 | 4.271 | 10.903 | | |
| P-value | | 0.596 | 0.0001 | <0.0001 | | |



Figure 1. Pain VAS scores before and after surgery. VAS, visual analogue scale.
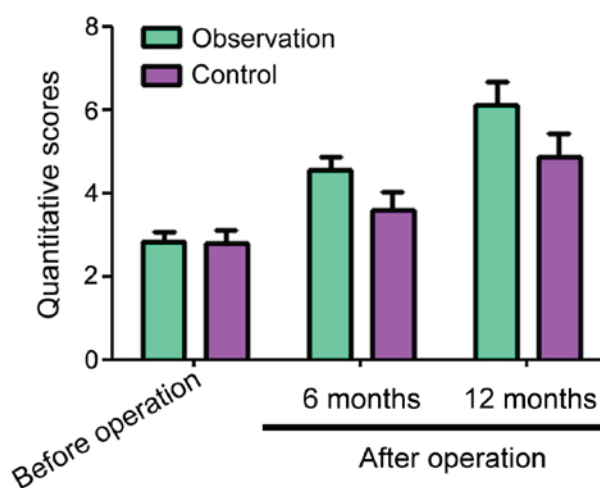


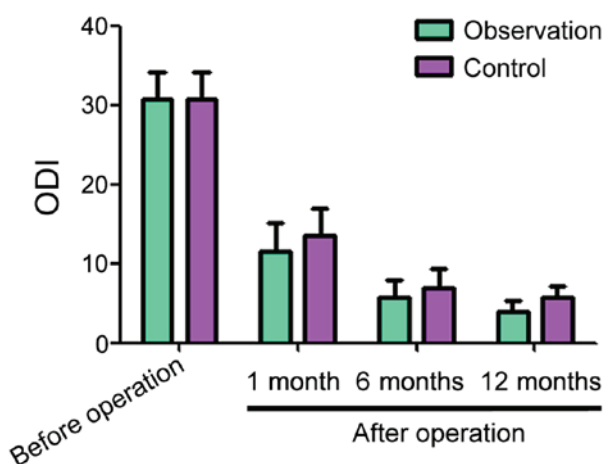Figure 3. Adjacent segment quantitative scores before and after surgery.



Figure 2. ODI scores before and after surgery. ODI, Oswestry disability index.

after surgery, but the values were consistently higher in the observation group at 1, 6 and 12 months follow-up (Table IV).

*ODI scores before and after surgery*. The ODI scores before surgery for the observation and control groups were 30.83±3.24 and 30.77±3.34, respectively (Fig. 2). One, 6 and 12 months after surgery, the ODI scores for the observation and control groups decreased compared with before the surgery. However, the scores for the observation group were lower than for the control group at each time point (Fig. 2).

*Vertebral canal before and after surgery*. In terms of vertebral canal area, the preoperative average vertebral canal area for both groups was comparable. The postoperative average vertebral canal area for the observation group was significantly larger than that for the control group 6 and 12 months later (Table V).

*Adjacent segment quantitative scores*. Before surgery, the adjacent segment quantitative scores for the observation and control groups were 2.83±0.24 and 2.77±0.34, respectively (Fig. 3). Six and 12 months after surgery, the adjacent segment quantitative scores for the observation and control groups decreased compared with before surgery, but the observation group had significantly higher scores than the control group at both time points (Fig. 3).

**Discussion**

Degenerative lumbar spinal stenosis can be caused by relaxation and hypertrophy of the ligamentum flavum, proliferation of the superior articular process, protrusion of the intervertebral disc, hyperostosis of the vertebral posterior border, and other reasons. Stenosis is divided into bony, which is caused by bony channel stenosis, such as lateral recess, nerve root canal, or central spinal canal, and non-bony, which is caused by spinal canal volume lessening due to hypertrophy of the ligamentum flavum, protrusion of the intervertebral disc, and calcification (7,8). The development of this condition causes continuous oppression of the spinal cord and spinal nerve root, leading to dysneuria and long-term low back pain

and leg pain (9). The course of degenerative lumbar spinal stenosis is insidious and develops slowly. The initial pain is not serious and is often combined with muscular soreness, which can be improved by changing position or rest (10). The nucleus pulposus of the normal intervertebral disc is even and the architectural features in each direction of the intervertebral disc are uniform. When degeneration occurs, the colloid in the nucleus pulposus becomes splintery and heterogeneous. Occasionally, end plate fragments or fiber rings enter into the intervertebral disc, leading to stress concentration and maldistribution of end plate load. Normal load sharing and conduction change, resulting in low back pain that gradually moves down to the legs. It is often combined with regional low muscle contraction and local numbness, which may oppress the cauda equina and result in intermittent claudication, leading to serious inconvenience to normal work and life activities (11-13).

The treatment of degenerative lumbar spinal stenosis can be divided into conservative and surgical approaches. The conservative treatments include general treatment (physiotherapy, waist protection, exercise of lumbodorsal muscles, and bed rest), drug therapy (dehydration drugs, analgesia drugs, and neurotrophy drugs), acupuncture, and block therapy (14). When the conservative treatment fails, it is necessary to resort to the surgical treatment, which includes decompression (wide laminectomy and ablation of the facet joint), bone graft fusion internal fixation, and non-fusion (15). The short-term efficacy of traditional fusion is excellent in relieving pain. However, the original biomechanics environment is damaged after surgery, resulting in accelerated degeneration of adjacent segments, with poor long-term curative effect (16). Dynamic fixation Coflex treatment belongs to the non-fusion category. This method is combined with intraoperative decompression, which can control the range of activity among vertebral bodies, and selectively and effectively increases the cross sectional area of the spinal canal (17). The results of the present study showed that VAS, ODI, and JOA scores improved after surgery in the observation group compared to the control group. The vertebral canal area of the observation group was larger than that in the control group. Compared with traditional fusion, the holding time of the vertebral canal area improvement was longer, because the Coflex system can reduce the burden on the intervertebral disc and zygapophyseal joint, relieving low back pain. It also improves stability and keeps the disc in place when the spine takes activities such as anteflexion, rear protraction, and rotation (18). Our results showed that several intra and postoperative parameters improved in the observation group. This is due to the advantages of the Coflex system, like simple surgery and small wound compared with traditional fusion. Therefore, surgery is shorter, reduce blood loss, and accelerate recovery.

When the conservative treatment fails, the patients receive traditional spinal fusion treatment, which often changes the spine biomechanics and leads to segment movement dysfunction. Under these circumstances, the compensatory mobility and displacement of the adjacent segments increase and the stress in the adjacent segments also become bigger, resulting in degeneration (19). Coflex system implantation has no remarkable influence on activity in different directions for adjacent segments, and it also can change the burden distribution of operative segments and make their mobility similar to the normal spinal activity. This provides stability and changes the way adjacent segments bear the burden to reduce the pressure, as well as the influence on adjacent segments, therefore it can relieve the degeneration of adjacent segments after fusion (20). The results of the present study showed that postoperative quantitative scores for adjacent segments in the observation group were superior to the control group, suggesting that dynamic fixation Coflex can be regarded as the connector between spine fusion segment and non-fusion segment, as a transition area with less influence on adjacent segments compared with traditional fusion.

In conclusion, dynamic fixation Coflex treatment for patients with degenerative lumbar spinal stenosis features remarkable effects. It can reduce the influence on adjacent segments and delay degeneration, which improves spine stability. The sample size of this study is small and the follow-up time is short, which requires a further study of large sample size and long-term follow-up.

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