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Complications in degenerative lumbar disease treated with a dynamic interspinous spacer (Coflex)

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Abstract

Purpose The purpose of this study was to quantify the intraand postoperative complications of an interspinous process device (Coflex) in managing degenerative lumbar diseases and to investigate corresponding therapeutic strategies.

Methods Between January 2008 and December 2012, we retrospectively analysed a total of 131 patients who underwent decompressive surgery along with the Coflex system for the treatment of degenerative lumbar diseases. The related complications were reported, and appropriate measures were taken. Clinical outcomes and radiological data were collected and analysed, and clinical outcomes were evaluated with paired-samples T test.

Results Related complications occurred in 11 patients. Among them, six cases were found with surgical technique-related complications, including device-related complications in three cases: spinal process fracture (n=1), Coflex loosening (n=1), fixedwing breakage (n=1), dura mater tear in two cases and superficial wound infection in one case. All of them received corresponding conservative treatment and obtained a good result. The other five cases had non-device-related complications and required additional spinal surgery. The conservative therapy group had apparent improvement of VAS score and ODI, and remained well to final follow-up (P<0.05). The second operation group also improved postoperatively (each P<0.05).

Conclusion The Coflex dynamic interspinous process device shows a low complication and re-operation rate. Standard operation and strict follow-up observation can effectively avoid surgical technique-related complications. The key points to ensure surgical effect and to reduce non-device-related complications are mastering surgical indications and thorough intra-operative decompression.

Keywords Coflex · Spinal decompression · Spinous process fracture · Spinal stenosis · Recurrent disc herniation · Complications of coflex · Interspinous distraction · Interspinous device · Dynamic stabilisation

Introduction

Degenerative lumbar disease is one of the most common diseases in spine surgery. Traditionally, decompression and fusion with internal fixation has been the mainstay of surgical approaches to the management of low back pain or lumbar instability. Furthermore, there is some evidence that fusion may increase the biomechanical stresses imposed on the adjacent segments leading to transitional diseases [1-3], and may be related to other problems such as serious trauma, transfusion requirement, higher morbidity and mortality for elderly patients as well as pseudarthrosis and fusion mass fracture [4, 5]. In order to overcome these deficiencies associated with fusion surgery, the interspinous process device-Coflex system (Paradigm Spine Inc.®, Germany) was developed as a possible alternative to spinal decompression with a posterolateral fusion and instrumentation for the treatment of symptomatic degenerative lumbar disease including mild segmental instability, degenerative disc disease, and lumbar spinal stenosis [6, 7]. Recently, the encouraging results of Coflex have been widely reported. However, the complications were rarely reported [8, 9]. Although some case reports have shown a few complications such as prosthesis loosening, prosthesis breakage and spinous process fracture [7, 10], none of them has systematically analysed its incidence and therapeutic measures.

In this retrospective study, we compare statistics about complication rates and types, and investigate corresponding therapeutic strategies.

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Materials and methods

Patients' data

Between January 2008 and December 2012, a consecutive series of 131 patients (81 males and 50 females with a mean age of 56.2 years, ranging from 37 to 78 years) who underwent decompression and Coflex dynamic stabilization surgery for a primary diagnosis of lumbar spinal stenosis or lumbar disc herniation affecting one or two levels between L3 and S1 were included for study and were followed-up for at least six months. Of these patients, single segment lumbar disc herniation and/or lumbar spinal stenosis were shown in 105 cases; double segments were displayed in 26 cases. The affected segments were all located in L3/L4, L4/L5 and L5/S1. Operating time, blood loss, and related complications were collected and assessed.

Surgical technique

Surgery was performed under general anaesthesia with the patient flexed on the Wilson frame. Surgical exposure involved a midline longitudinal skin incision and careful preservation of the supraspinous ligament spanning the surgical levels. Symptomatic side paraspinal muscles were dissected and adequate decompression was achieved by laminotomy, removal of ligamentum flavum and resection of herniated disc when necessary, followed by confirming lateral margins of the thecal sac and freely movable exiting roots after foraminotomy under an operative microscope. Then, the interspinous ligament was excised and the optimal size of the Coflex was measured with trial molds. Subsequently, the supraspinous ligament was sewn back after the Coflex was inserted between two spinous processes and tightened wings with clamp. Early low back muscles and straight leg raising

Table 1 List of patients with complications

functional training on postoperative rehabilitation should be encouraged. The patients were allowed to ambulate freely two weeks after operation and kept in a lumbar orthosis for three months.

Clinical outcomes and radiological data

Oswestry disability index (ODI) and visual analogue scale (VAS) of low back and leg pain were collected and evaluated pre-operatively and in the sixth month initial postoperatively, sixth month second postoperatively and final follow-up. Plain radiographs (anteroposterior and lateral view) and CT scan were obtained during the same follow-up period, while MRI was taken pre-operatively and at final follow-up.

Statistical methods

Paired-samples *T* test was performed comparing the ODI and VAS in patients at different visiting time points. Statistical significance was defined as P<0.05. The analysis was carried out using the statistical package SPSS 19 (SPSS Inc., Chicago, IL, USA).

Results

The mean duration of operation was 86 min (range 55–160), and estimated blood loss volume was 96.5 ml (range 45–360). All patients were regularly monitored. The mean follow-up time was 30.3 months (range six to 59). A total of 11 out of 131 (8.40 %) patients had complications (Table 1). There were six patients who had been found with surgical technique-related complications, three of which were device-related ones. Imaging data of typical cases are shown in Figs. 1 and 2.

Case no.	Age (years)	Gender	Preop diagnosis	Affected levels	Initial surgery	Complications	Additional treatments
1	40	Female	LDH	L4/5	L4/5, D&C	Fixed-wing breakage (left inferior)	None
2	50	Female	LDH	L4/5,L5/S1	L4-S1, D&C	Prosthesis loosening (upper)	None
3	66	Male	LSS	L4/5,L5/S1	L4-S1, D&L4/5,C	Spinous process fracture (L5)	None
4	60	Male	LSS	L4/5	L4/5, D&C	Dura mater tear	Intraoperative repair
5	47	Male	LSS	L4/5	L4/5, D&C	Dura mater tear	Intraoperative repair
6	67	Female	LDH	L4/5	L4/5, D&C	Superficial wound infection	Anti-infection and dressing chang
7	69	Female	LDH	L4/5	L4/5, D&C	Lumbar disc reherniation	Resection of nucleus pulposus
8	50	Female	LDH	L5/S1	L5/S1, D&C	Lumbar disc reherniation	Resection of nucleus pulposus
9	64	Female	LSS	L3/4,L4/5	L3-5, D&L4/5,C	Residual lumbar spinal stenosis	Extensive decompression
10	70	Male	LDH	L4/5	L4/5, D&C	Late-onset lumbar spinal canal hematoma	Second exploratory operation
11	51	Male	LDH	L4/5,L5/S1	L4-S1, D&L4/5,C	Residual radiating pain	Revision with internal fixation of pedicle screws

LDH lumbar disc herniation, LSS lumbar spinal stenosis, D&C decompression and coflex fixation

Fig. 1 A 40-year-old female patient. The X-ray image in anterior–posterior one day postoperatively showing left inferior fixed-wing broken (a). Two-year postoperative dynamic radiographs in lateral (b, c) views and MRI (d) showing stable implant



In case 1, a 40-year-old female was diagnosed as lumbar disc herniation (L4/5) and treated with fenestration and decompression associated with Coflex fixation. The Xrays one day after operation showed the left inferior fixed-wing had been broken. The patient was in good condition and successfully completed two-year follow-up. The implant did not shift (Fig. 1). In case 2, a 50-year-old female, whose pre-operative MRI showed degenerative lumbar disc herniation at L4/5 and L5/S1 with compression of the dural sac, underwent fenestration discectomy and Coflex fixation at two levels. Dynamic X-rays threemonths postoperatively showed the upper prosthesis loosening, but the position of the device was still maintained. The patient felt good and managed with conservative treatment during the two-year follow-up period, and further displacement of prosthesis was not observed. In case 3, a 66-year-old male underwent fenestration of two levels and Coflex fixation at L4/5 for the diagnosis of lumbar spinal stenosis (L4/5 and L5/S1). L4 spinous process fracture was found in CT scan one week postoperatively, which was considered to be associated with excessive tightness of the fixed-wing. The patient was wearing lumbar orthosis for three months postoperatively and was functionally excellent over three-month follow-up. Bone healing could be seen in CT one year after operation.

Two cases (cases 4 and 5) had dura mater tear and cerebrospinal fluid leaks, which were both repaired intra-operatively under a high-power microscope with Prolene sutures and with no further postoperative intervention required. Superficial wound infection occurred in one patient (case 6), which was delayed healing by anti-infection and dressing change.

Ultimately, five cases (3.82 %) were found to have nondevice-related complications (Table 1) and required additional spine surgery. Two patients (cases 7 and 8) were recommended to undergo resection of nucleus pulposus because of lumbar disc reherniation. One patient (case 9) was diagnosed with residual lumbar spinal stenosis due to incomplete decompression at target segments and was treated with extensive decompression. One patient (case 10) developed increasing pain in the low back and legs because of long-term use of anticoagulant drugs, and was diagnosed with lumbar spinal canal hematoma determined with MRI, and was taken back to surgery for second-look exploration at 31 months postoperatively. Another patient (case 11), who underwent resection of nucleus pulposus at L4/5 and L5/S1 levels, with residual low back pain and radiating pain down the legs postoperatively and with MRI suggesting incomplete decompression in initial surgery, received revision with internal fixation of pedicle screws. These additional surgeries occurred anywhere from six to 31 months after the initial Coflex placement.

The second operation group consists of cases 7-11, and the conservative therapy group includes case 1-6. The clinical outcomes from pre-operation to final follow-up were presented in Table 2. In the second operation group, the VAS scores of low back and leg pain and ODI decreased from 5.62±1.33/7.80±1.25/72.5±8.77 pre-operatively to $4.88 \pm 1.64/6.79 \pm 1.15/69.4 \pm 7.10$ in the sixth month initial postoperatively (P>0.05), and further dropped to $1.74 \pm 0.87/1.52 \pm 0.43/18.1 \pm 2.02$ in the sixth month second postoperatively (P < 0.05). There is insignificant difference between the data of the sixth month second postoperatively and final follow-up (P > 0.05). In the conservative therapy group, the data significantly decreased from $4.37 \pm 1.01/7.57 \pm 0.91/71.6 \pm 7.65$ pre-operatively to $2.23\pm0.60/2.14\pm1.15/20.4\pm4.93$ in the sixth month initial postoperatively (P < 0.05). There was no significant difference between the data of the sixth month initial postoperatively and final follow-up (P > 0.05).

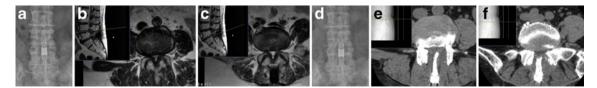


Fig. 2 A 64-year-old female patient (sacralization of fifth lumber vertebra) underwent decompression of two levels (L3-5) and Coflex fixation at L4/5 (a). Postoperative MR images demonstrating L3/4 (b)

and L4/5 spinal canals (c) residual stenosis, and six months later the patient received a second extensive decompression (d). Second postoperative CT illustrating wide spinal canals (e, f)

Group	VAS (low back pain)	ck pain)			VAS (leg pain)	(1			IQO			
	Preoperative	Preoperative Sixth month initial postoperatively	Sixth month Sixth month initial second postoperatively postoperatively	Final follow-up	Preoperative	Preoperative Sixth month initial postoperatively	Sixth month second postoperatively	đ.	Preoperative	Preoperative Sixth month Sixth month Final initial second follow postoperatively postoperatively	Sixth month Sixth month initial second postoperatively postoperatively	Final follow-up
Second operation	5.62 ± 1.33 4.88 ± 1.64^{a}		$1.74\pm0.87^{ m b}$	$1.75 \pm 0.85^{\circ}$	7.80±1.25	$1.75\pm0.85^{\circ}$ 7.80±1.25 6.79±1.15 ^a	1.52 ± 0.43^{b}	$1.50{\pm}0.47^{c}$	72.5±8.77	$1.50\pm0.47^c 72.5\pm8.77 69.4\pm7.10^a 18.1\pm2.02^b$	18.1 ± 2.02^{b}	$17.8 \pm 1.80^{\circ}$
group($n=3$) Conservative therapy 4.37±1.01 2.23±0.60 ^b group($n=6$)	4.37±1.01	2.23 ± 0.60^{b}	I	1.91±0.42°	$1.91\pm0.42^{\circ}$ 7.57±0.91 2.14±1.15 ^b	2.14±1.15 ^b	I	1.92±1.27°	1.92 ± 1.27^{c} 71.6±7.65 20.4±4.93 ^b	20.4 ± 4.93^{b}	I	18.6±2.86°
VAS visual analogue scale, ODI oswestry disability index, SD standard deviation	scale, ODI os	westry disability	index, SD stanc	lard deviatio.	n							
^a Versus preoperative, $P>0.05$	/e, <i>P</i> >0.05											
^b Versus preoperative, P<0.05	/e, <i>P</i> <0.05											

Versus ^b, P>0.05

Table 2 VAS pain scores and ODI scores (mean \pm SD) from 11 patients with complications

Discussion

According to the literature, the complication rates of posterior vertebral canal decompression surgery and decompression and fusion with pedicle screws were 17.27-20% [4, 11] and 34.9-49% [12, 13], respectively. Transforaminal lumbar interbody fusion surgery has been associated with a high intra- and postoperative complication rate and a long recovery process in patients undergoing surgery for painful degenerative disc disease [13–15]. Minimally invasive surgery techniques can reduce soft tissue trauma, intra-operative blood loss, and recovery time, which led us to believe that use of a Coflex dynamic interspinous spacer could reduce complication rate. As it turned out, the complication rate of Coflex in our study was 8.40\%, which was lower than traditional posterior fusion with internal fixation surgery.

Coflex non-device-related complications

Five patients (3.82 %) were found to have non-device-related complications during our follow-up period and needed reoperations. All of them were not directly related to Coflex devices.

Among the patients undergoing re-operation, two patients (cases 7 and 8) underwent resection of nucleus pulposus because of lumbar disc reherniation. Currently, the Coflex system for the treatment of lumbar disc herniation is rarely reported in the literature, and whether it can prevent and reduce the recurrence of disc herniation remains a question. One reported clinical trial [16] provides evidence that the interspinous nonrigid stabilization-Coflex was useful against leg pain due to degenerative lumbar disc herniation without recrudescence in the two-year follow up period and the intervertebral space height was preserved. However, this trial didn't draw an objective conclusion, because of the small case number and short follow-up time. We learned from these two cases (cases 7 and 8) that although the Coflex interspinous implant maintained favourable disc height, it can not completely prevent the recurrence of disc herniation. Some scholars revealed that patients' age, sex, weight, smoking habit, vocation, the form of herniated nucleus pulposus, the amount of residual nucleus pulposus after initial surgery (or inadequate decompression) and day-to-day activity level of low back were associated with recurrent disc herniation [17-19]. In other words, the combined effects of multiple factors result in recurrent lumbar disc herniation, and the preventive role of Coflex is limited.

The reason for cases 9 and 11 undergoing second surgery is that the initial surgical decompression was incomplete and led to partial remission in signs and symptoms. Radiological and biomechanical evidence showed that a dynamic lumbar interspinous spacer obtained beneficial effects like significant increasing neural foramen and spinal canal dimension, lowering intradiscal pressure at target level, and decreasing pressure at the facets [20, 21]. However, our experience indicated that thoroughly decompressing the dural sac and nerve root is an important principle to ensure the efficacy of the surgery for the patients with obvious lumbar disc herniation, hyperosteogeny and/or ossification of the ligamentum flavum, which cause stenosis of the spinal canal and spinal cord compression. Some scholars [22] think that the patients with severe spinal canal stenosis at multiple levels may not be candidates for the interspinous implant as a stand-alone device, because they need extensive decompression, removal of the lamina around the spinous process and possibly even more, including part of the articular process, and thus lead to too difficult-to-place Coflex.

Postoperative late-onset lumbar spinal canal hematoma formation in case 10 had no direct correlation with operation and Coflex device. The patient's own underlying disease and postoperative inappropriate anticoagulation therapy might be possible explanations for that.

Coflex device-related complications

The data in our study show a low incidence of Coflex devicerelated complications (2.29 %, 3/131), including spinal process fracture, Coflex loosening, and fixed-wing breakage. There were no late neurological complications related to the device and no cases of Coflex penetration inside the canal or infection. Richter et al. reported 3.3 % hardware related complications (spinal process fracture and prosthesis loosening) in 2010 [7]. An international multicenter retrospective study [23] that included 209 patients who underwent Coflex fixation surgery reported a 3.4 % device-related complication rate, most of which were fixed-wing breakage and prosthesis loosening.

Coflex device-related complications are classified as surgical technique-related ones by us, because we think that may be relevant to non-standard surgical techniques.

The main reason for fixed-wing breakage in our study is the binding clasp jaw did not fully enter into the chute so that the fixed wing fractured due to abnormal stress. The patient in our study with spinous process fracture had successful clinical outcomes during the follow-up period. The reasons for the spinous process fracture were unknown, although possible factors include the patient's degree of osteoporosis, putting excessive load on spinous process and possible overdistraction of the interspinous space with a large Coflex device [24]. Hence, the bone mineral density of each patient and the size of the implant should be carefully evaluated pre-operatively. A moderate size device and modest distraction may be needed to avoid spinous process fracture, especially in patients with osteopenia and osteoporosis. Coflex is a non-fusion fixation method, so the longterm dynamic stability without looseness is required. Coflex loosening occurred in patients with double-level fixation in our group and was considered to be related to two prostheses sharing in a smaller L5 spinous process. For this reason,

careful pre-operative assessment of spinous process volume will avoid the aforementioned complication.

Besides that, some scholars [9, 25–27] recommend application of Coflex to elderly patients for its shorter operation time and minimally invasive merits. However, bone erosion around the Coflex, especially around spikes, was found in 57 % of all patients treated with the interspinous process device [9]; therefore, its use in the elderly, especially in severe osteoporotic patients, should be carefully considered.

In some literature reports [28], heterotopic bone formation around a dynamic interspinous device is a potential mid- and long-term complication, which may hamper motion preservation. However, in our opinion, heterotopic ossification around the Coflex device is not necessarily a bad thing. Theoretically, it could enhance the dynamic stabilization of the instrumented segment. Therefore, we might use the device to treat low-grade degenerative spondylolisthesis or instability caused by decompressive surgery, rather than applying lumbar fusion [6, 29].

It may be difficult to make generalized conclusions from our results as we had a small number of patients, and surgeries were performed at only one surgical centre. The lack of sufficient number of cases and long-term follow-up studies are the limitations.

Conclusions

In summary, the Coflex dynamic interspinous process device is feasible and effective in treating degenerative lumbar disease, which is associated with a low rate of intra- and postoperative complications. Standard operation and strict follow-up observation can effectively avoid surgical technique-related complications. The key points to ensure surgical effect and to reduce non-device-related complications are mastering surgical indications and thorough intra-operative decompression.

Conflict of interest The authors declare that they have no conflicts of interest.

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