Int J Clin Exp Med 2017;10(12):16395-16401
www.ijcem.com /ISSN:1940-5901/IJCEM0066017

Original Article

Efficacy of lumbar fusion in treating lumbar degenerative disease

Yang Cong[1,2], Haoyi Lian[2], Liangliang Hu[2], Bohua Zhang[2], Jianmin Lu[2]

[1]Zunyi Medical University, Zunyi City, Guizhou Province, P. R. China; [2]Third Department of Orthopedics, Zhongshan Hospital Affiliated to Dalian University, Dalian City, Liaoning Province, P. R. China

Received September 21, 2017; Accepted November 5, 2017; Epub December 15, 2017; Published December 30, 2017

Abstract: Objective: To evaluate the efficacy of the lumbar fusion surgery in the treatment of lumbar degenerative diseases. Methods: A total of 150 patients with single-segment lumbar degenerative diseases were randomly assigned to undergo the lumbar fusion surgery (lumbar fusion group) or the lumbar non-fusion surgery (Coflex system; lumbar non-fusion group). The outcome measures included the pain score on the visual analogue scale (VAS), the Oswestry disability index (ODI) score, the MOS 36-item short-form health survey (SF-36) score, the range of motion (ROM) on radiographs and the Stauffer-Coventry scale score. The differences in the clinical outcomes were compared between the two groups. Results: The VAS score, the ODI score and the SF-36 score after surgery were improved markedly as compared with those before surgery among the patients in the same group (All $P<0.001$). However, the differences in the VAS score, the ODI score and the SF-36 score after surgery were insignificant between the two groups (All $P>0.05$). The ROM of the L3-L4 lumbar segments increased substantially in the lumbar fusion group versus in the lumbar non-fusion group ($P<0.001$). On the Stauffer-Coventry scale, the rate of good and excellent clinical results was 81.3% among the patients with the lumbar fusion surgery, and 84% among those with the lumbar non-fusion surgery, and the difference was insignificant ($P>0.05$). Conclusion: Both the lumbar fusion and the lumbar non-fusion achieved satisfactory outcomes in treating single-lumbar degenerative disease, but the lumbar fusion has a greater influence on the ROM of the lumbar segments.

Keywords: Lumbar degenerative disease, lumbar vertebra, lumbar fusion, lumbar non-fusion

Introduction

Lumbar degenerative disease, a common disease seen in the Department of Orthopedics, manifests the symptoms of lumbar disc-related lower back and leg pain as a result of compression of the sciatic nerves by lumbar disc herniation [1]. Currently, nucleotomy is extensively used in the management of lumbar disc herniation. Despite its proven effect of relieving symptoms, the narrowing intervertebral space after surgery leads to lower stabilization of the interbody, and even recurrence of lumbar disc herniation [2, 3]. Spinal fusion maintains or restores the height of the intervertebral space and spinal curvature by increasing stability between the lumbar segments, and has exerted certain beneficial effect in clinical practice [4, 5]. With the advance of fusion technique, however, a follow-up trial has revealed spinal stabilization and fusion might cause the problems like increased exacerbation degenerated articular processes, lumbar instability or spondyolysis, adjacent segment degeneration and graft nonunion [6, 7]. Over recent years, various techniques of internal stabilization and non-fusion have been applied clinically. Theoretically, the non-fusion stabilization system provides considerable stability, effective pain relief, maintains proper intervertebral motion and has better flexibility. However, few reports have been involved in the comparison between the effectiveness of the lumbar fusion and lumbar non-fusion.

As a non-fusion stabilization technique, the Coflex system has been extensively utilized in the management of lumbar degenerative diseases including lumbar spinal stenosis, lumbar disc herniation and lumbar instability [8]. After Coflex internal stabilization, the clinical outcomes have shown to be improved significantly;

Table 1. General data of the patients

Variable	Case	Age (year)	Male/Female (n)	Course disease (year)
Lumbar fusion group	75	46.7±5.4	45/30	2.4±0.7
Lumbar non-fusion group	75	47.9±5.8	48/27	2.7±0.6
t/X^2 value		2.157	1.125	1.637
P value		0.573	0.702	0.635

thus, the Coflex internal stabilization plays a role of enhancement of spinal stability [9]. Therefore, in this study, we assigned 150 patients with single-segment lumbar degenerative disease to undergo internal stabilization with lumbar fusion or lumbar non-fusion (Coflex) and then compared their efficacy, so as to aid in providing strategies for guiding the clinical treatment of lumbar degenerative diseases.

Materials and methods

Participants

This study obtained approval from the Hospital Ethics Committee and each patient provided written informed consent. Between January 2014 and December 2016, 150 patients with degenerative lumbar diseases admitted to the Department of Orthopedics in the author's institution were enrolled in this study. All the patients had single-segment lumbar degenerative disease. Patients who were 18-65 years old were eligible for this study if they met the diagnostic criteria for lumbar degenerative diseases, with L4-L5 single-segment lesion, and required surgery after invalid regular non-surgical treatment for more than half a year or progressive disease. Patients were excluded if they had severe underlying disease, which was a contradiction to surgery, or they were intolerant of surgical treatment, other comorbidities of non-lumbar degenerative diseases including lumbar deformity and spondylolysis, lesions in more than two segments, or were unwilling to cooperate in follow-ups. All the eligible patients were randomly assigned to the lumbar fusion group or the lumbar non-fusion group in terms of operation methods.

Surgical procedures

Under general anesthesia, the patients had routine disinfection and draping done and then an incision was made at the middle of the lumbar region. The subcutaneous tissue was isolated layer by layer, and the dorsal fascia was incised along both sides of the spinous process. The nerve roots were conventionally loosened, followed by decompressive laminotomy and nucleotomy. Among the patients in the lumbar fusion group, pedicle screw stabilization and interbody fusion were performed at the intersection of the lateral vertical line of articular process and the horizontal line of transverse process. For the patients in the lumbar non-fusion group, the supraspinous ligaments were preserved, and then sharp dissection was made on the supraspinous ligaments in L4-L5 segments which was pulled laterally, followed by removal of the inter-spinous ligaments, opening of the interspace (moderate anteflexion) of L4-L5 segments. The Coflex device was installed if the model was appropriate. After operation, a drainage tube with negative pressure was placed and finally the incision was sutured layer by layer.

Postoperative treatment

All the patients in the two groups were required to have postoperative bed rest for 3-6 days and routine use of antibiotics. Within 48 h after removal of negative pressure drainage tube, they were instructed to do lumbar back muscle exercise and straight leg-raising training, and ambulate with waist-belt protection, trying not to twist or bend the waist. At approximately one month postoperatively, the patient was allowed to gradually resume normal activity without belt protection.

Follow up

All patients were followed by telephone appointments and clinic visits for 1 year, and every six months, the anteroposterior and lateral radiographs were made. The main activities in follow-up included recording the visual analogue scale (VAS) score, Oswestry disability index (ODI) score, the MOS 36-item short-form health survey (SF-36) score, postoperative complications, range of motion (ROM) of adjacent segments and the curative effects.

Table 2. Comparisons of the VAS and ODI scores before and after surgery among the patients in the two groups

Variable	VAS score			ODI score		
	Before surgery	6 months after surgery	1 year after surgery	Before surgery	6 months after surgery	1 year after surgery
Lumbar fusion group	7.4±0.5	2.8±0.4*	2.1±0.3*	63.5±4.5	19.3±4.4#	16.5±3.7#
Lumbar non-fusion group	7.7±0.6	2.7±0.5*	2.2±0.4*	65.4±5.6	21.2±4.7#	17.8±3.4#
t value	0.243	0.189	1.153	1.398	0.528	0.814
P value	0.626	0.872	0.325	0.276	0.487	0.394

Note: *P<0.001 for comparison of preoperative VAS score within the same group; #P<0.001 for comparison of preoperative ODI score within the same group.

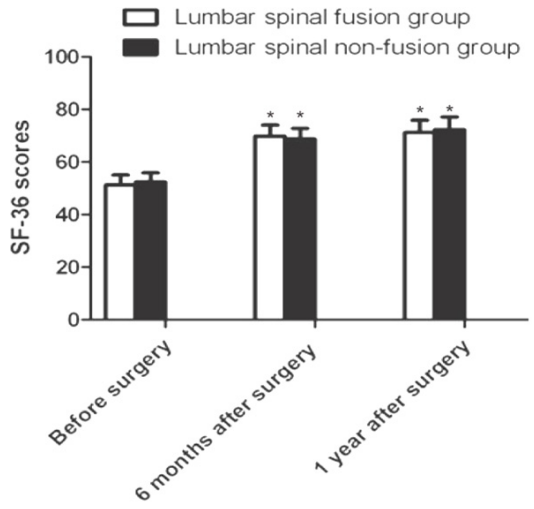

Figure 1. Comparison of the SF-36 scores before surgery and at different time points after surgery between the two groups; comparison within the same group after surgery, *P<0.001.

Outcome measures

Pain in lower back and leg on the VAS, ODI, SF-36, postoperative complications, adjacent segmental ROM and the clinical outcomes before surgery, at 6 months and 1 year after surgery were compared between the two groups. The VAS was a scale of 0 to 10 points, with 0-3 indicating painlessness or mild pain, 4-6 pain affecting sleep, and 7-10 severe pain. The ODI is a scale ranging from 0-100%, with higher ODI indicating more serious dysfunction (0 normal ODI). At each visit, an examination of L-Spine anteroposterior and lateral radiographs was performed to measure the ROM of adjacent segments in patients. The Stauffer-Coventry scale was utilized to assess the outcomes and the good and excellent results at the final follow-up [10]. The curative effects were rated as follows: excellent, indicating the patient's complete disappearance of clinical symptoms and return to normal life and work; good, disappearance of clinical symptoms, with moderately-restricted ambulation, without significant effect on life; fair, alleviated symptoms, with restricted ambulation, affecting the normal work and life of the patient; poor, the symptoms without alleviation, and even worse.

Statistical analysis

All the statistical analyses were made using the SPSS statistical software, version 19.0. Measurement data were expressed as $\bar{x}\pm s$; the independent sample t-test was applied to compare the data at individual time points between the two groups, whereas the repeated-measures-analysis of variance was utilized to compare the data at different time points. Count data were expressed as rates, and the chi square test was used for between-group comparison. P<0.05 was deemed as statistically significant.

Results

General data of the patients

There were 75 patients in the lumbar fusion group, including 45 males and 30 females, with an age of 30-65 years (mean, 46.7±5.4 years), and the course of disease ranging from 7 months to 6 years (mean, 2.4±0.7 years). There were 75 patients in the lumbar non-fusion group, including 48 males and 27 females, with an age of 37-66 years (mean, 47.9±5.8 years), and the course of disease ranging from 8 months to 7 years (mean, 2.7±0.6 years). The general data were not statistically different

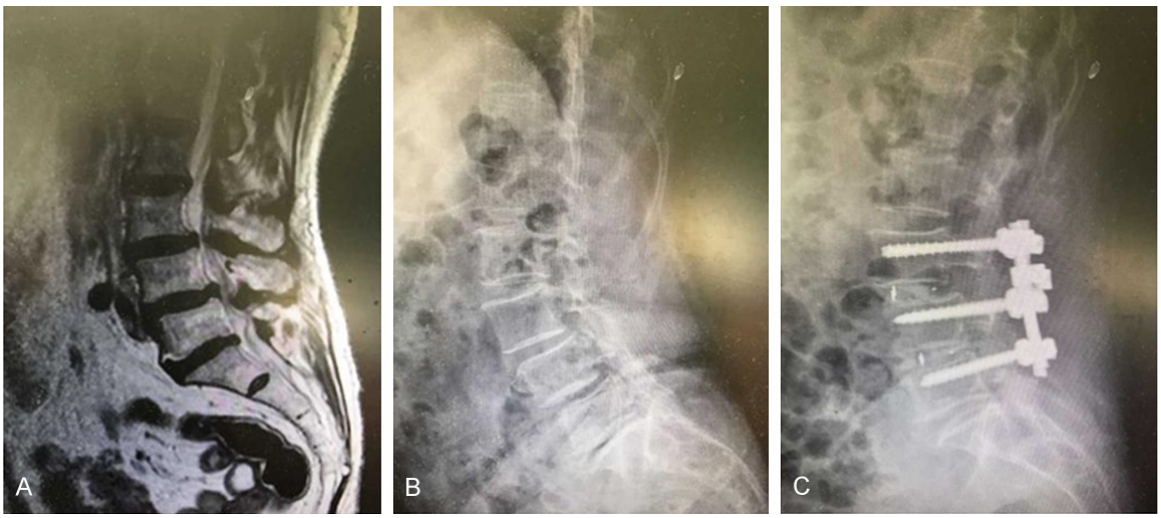

Figure 2. Results of radiographic examination of the lumbar fusion group. A: Preoperative sagittal MRI; B: Preoperative lateral radiographs; C: Postoperative lateral radiographs at the final follow-up.

among the patients in the two groups, so they were comparable (P>0.05, **Table 1**).

VAS and ODI scores before surgery and at different time points after surgery

Preoperative VAS and ODI scores showed no significant differences between the lumbar fusion group and the lumbar non-fusion group (Both P>0.05). Nevertheless, is the post-operative VAS and ODI scores of the patients were improved substantially when compared with those preoperatively (Both P<0.001). The VAS scores at different time points after surgery were not statistically significant different within the same group, neither were the ODI scores (All P>0.05); at any time point after surgery, the VAS scores differed insignificantly between the two groups, so did the ODI scores (P>0.05, **Table 2**).

SF-36 scores

Insignificant difference was noted in the SF-36 scores before surgery between the two groups (P>0.05). The SF-36 scores at different time points after surgery became substantially higher than those before surgery in both the lumbar fusion group and the lumbar non-fusion group (Both P<0.001); but no significant differences were seen in the SF-36 scores at diverse time points after surgery within the same group (Both P>0.05). At each time point after surgery, the difference between the two groups in the SF-36 score was statistically insignificant (Both P>0.05, **Figure 1**).

Postoperative complications

All the patients were followed up and had radiographic examinations before and after surgery reviewed (**Figure 2**). In the lumbar fusion group, 2 patients had poor wound healing and the wounds were healed by active dressing changes and symptomatic treatment. In the lumbar spinal-non fusion group, cerebrospinal fluid leakage occurred in 1 patient who was cured after symptomatic treatment. During the follow-up period, no complications including rupture or loosening of internal stabilization were present among the patients in both groups. The incidences of postoperative complications were similar in the two groups (P=0.145).

ROM in adjacent segments of lumbar vertebra

The preoperative ROM differed insignificantly between the two groups (P>0.05). In both groups, the ROM of L3-L4 lumbar segments at the final follow-up increased considerably as compared with that before surgery (6.2±0.5 vs 11.2±0.8; 6.3±0.6 vs 8.5±0.7, both P<0.001). Compared with the lumbar non-fusion group, the ROM of L3-L4 segments at the final follow-up increased markedly in the lumbar fusion group (P<0.001). In addition, the ROM of L5-S1 lumbar segments at the final follow-up

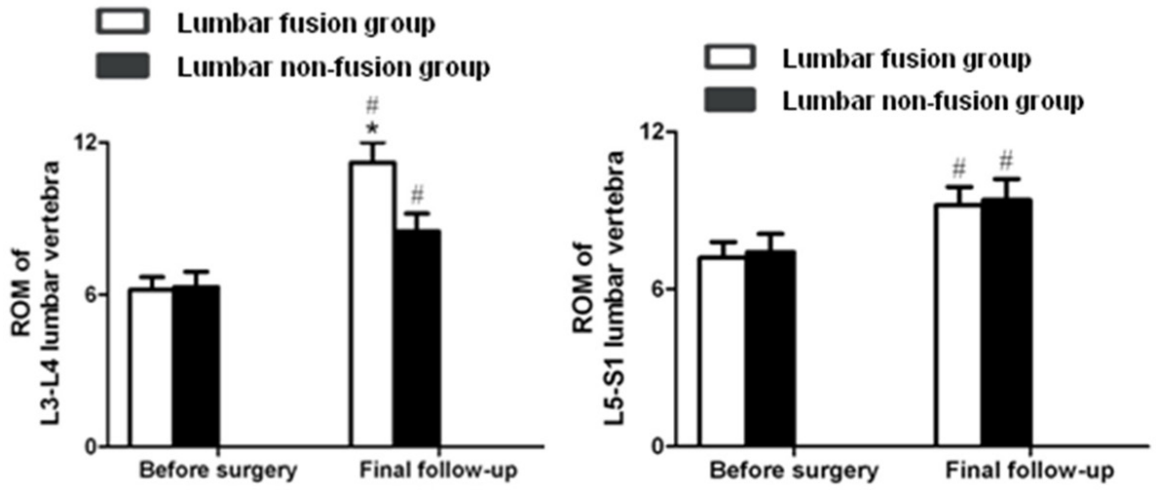

Figure 3. Comparison of the ROM of adjacent segments between the two groups; for comparison with the lumbar non-fusion group, *P<0.001; for comparison within the same group before surgery, #P<0.001.

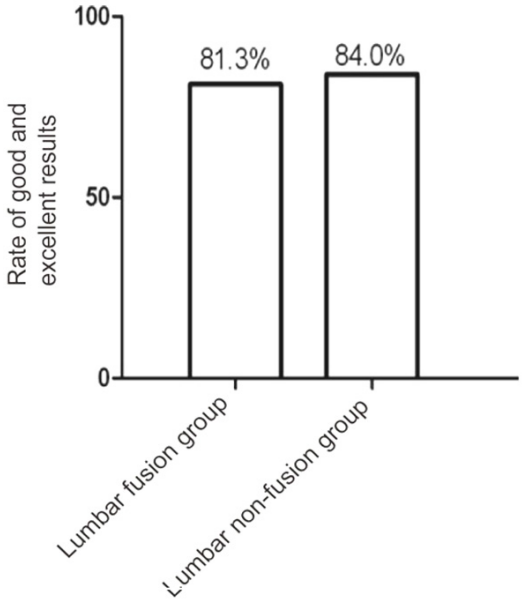

Figure 4. Comparison of the rate of good and excellent results between the two groups.

increased significantly in both groups (7.2±0.6 vs 9.2±0.7; 7.4±0.7 vs 9.4±0.8, both P<0.001) but differed insignificantly between the two groups (P>0.05, **Figure 3**).

Rate of good and excellent results

The efficacy evaluation at the final follow-up on the Stauffer-Coventry scale showed that, the rate of good and excellent results was 81.3% (61/75) in the lumbar fusion group and 84% (63/75) in the lumbar non-fusion group, and the differences between the two groups was statistically insignificant (P=0.158, **Figure 4**).

Discussion

Lumbar degenerative disease is one of the most common spinal diseases. A patient is prone to develop disease under stress or excessive fatigue because the range of motion and loading of lumbar vertebra are greater than those of other parts of the spine [11]. The main symptoms of lumbar degenerative disease are low back pain accompanied by lower limb pain in diverse severity, which is detrimental to the quality of life of the patients. Surgery is required for the patients who remain ineffective after conservative treatment. However, the choice of surgical procedures is often influenced by the patient's age, general condition and range of motion.

The technique of the lumbar fusion is widely used in spinal surgery. However, according to a study, degeneration occurs in approximately 3.9%-41% of adjacent segments of the spine after the spinal fusion due to the discrepancy in follow-up time and fixed segments [12]. The major reasons for adjacent segment degeneration include the redistribution of ROM of the spinal segments; increased compensatory motion in the adjacent segments, and increased instability and segregation in the segments tend to exacerbate degeneration. The main imaging findings include narrowing of the intervertebral space, lumbar disc herniation, inter-

vertebral instability or spondylolysis or even spinal stenosis [13]. Re-surgery is required if serious adjacent segment degeneration gives rise to recurrent symptoms [14]. In one study, the results of follow-up of 1732 patients with interbody fusion showed that 34% of the patients had adjacent segment degeneration, whereas only 14% had obvious symptoms [15]. Of note, the lumbar fusion relieved pain in the patients, but the problem of adjacent segment degeneration arose.

In recent years, the use of the non-fusion stabilization system is on the increase for the purpose of reducing the stress of the intervertebral disc and joint and partly restricting the ROM of the spine. The Coflex dynamic stabilization system of interspinous space, owing to its small trauma and convenient operation, is increasingly used in clinic practice and has achieved satisfactory outcomes [16]. However, whether the dynamic stabilization system can reduce adjacent segment degeneration is controversial. In case of degenerative lumbar disease, the dynamic stabilization system of interspinous space has effectively maintained the stability of the spine and has little effect on degeneration of the adjacent segments and intervertebral discs [17]. Another follow-up study revealed that the adjacent intervertebral disc continued to degenerate after Coflex dynamic stabilization of interspinous space, possibly due to the development and progression of the patient's underlying disease instead of the surgery [18].

The effect of the lumbar fusion technique on the clinical outcomes remains controversial. In one study, the incidence of adjacent segment degeneration was higher in patients after lumbar fusion [19]. Approximately 29% of patients have proven to have upper adjacent segment degeneration on radiography at 43 months of follow-up after L4-L5 lumbar fusion, but they were insignificantly different from those without regeneration in recovery of clinical functions [20]. Another study also revealed the magnitude of improvements in both the Japanese Orthopaedic Association (JOA) and ODI scores at the final follow-up differed insignificantly between the patients with degeneration and those without degeneration [21]. In the current study, the lumbar fusion had a greater effect on ROM of the upper adjacent segments than the lumbar non-fusion did, but no significant differences were observed in the scores of ODI, VAS and SF-36, and efficacy between the patients with lumbar fusion and those with lumbar non-fusion, which was basically in agreement with the findings in the previous studies [22]. One study showed that adjacent segment degeneration after lumbar stabilization mostly occurred at the upper stabilized segments [23]. Aota et al. suggested that at the rate of adjacent segment degeneration was 2.6% in the lower stabilized segments and 25.5% in the adjacent segments of upper lumbar spine [24]. In the present study, the lumbar fusion had a significantly greater effect on the ROM of the upper adjacent segments than the lumbar non-fusion, but both the lumbar fusion and the lumbar non-fusion had similar effects on the ROM of the lower adjacent segments, indicating that the lumbar fusion had little effect on lower adjacent segment degeneration, which was consistent with the reports in previous literature [22].

In conclusion, compared with the lumbar non-fusion, the lumbar fusion relatively increases the ROM of adjacent segments, but the efficacy of both techniques were insignificantly different between the degenerative lumbar patients with lumbar non-fusion and those with lumbar fusion. There are some limitations in the current study, including a small sample size, single center, short-term follow-up, and no blank control group (conservative treatment group). In the current study, additional studies are required to investigate whether degeneration in the L3-L4 upper adjacent segments is due to natural degeneration or the result of stabilization. In addition, the follow-up in this study lasted only for 1 year, which was a short-term follow-up. Therefore, the conclusions in this study are necessary to be further validated by long-term follow-up in a large sample, multicenter, randomized controlled study.

Disclosure of conflict of interest

None.

Address correspondence to: Jianmin Lu, Third Department of Orthopedics, Zhongshan Hospital Affiliated to Dalian University, No. 6 Jiefang Street, Zhongshan District, Dalian City 116001, Liaoning Province, P. R. China. Tel: +86-0411-62893141; E-mail: jianminlu5@126.com

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