


## SCIENTIFIC ARTICLE

# Safety and Efficacy of Minimally Invasive Transforaminal Lumbar Interbody Fusion Combined with Gelatin Sponge Impregnated with Dexamethasone and No Drainage Tube after Surgery in the Treatment of Lumbar Degenerative Disease

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**Objective:** The aim of the present study was to use a gelatin sponge impregnated with dexamethasone, combined with minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) and no drainage tube after the operation for early postoperative recurrence of root pain caused by edema.

**Methods:** A prospective case series study was designed. From September 2015 to January 2018, eligible patients diagnosed with lumbar degenerative disease underwent MIS-TLIF combined with a gelatin sponge impregnated with dexamethasone and no drainage tube after surgery. The short-term clinical data were collected, such as visual analog scale (VAS) scores for low back pain and leg pain preoperatively and on postoperative days (POD) 1–10, time bedridden postoperatively, and length of hospital stay postoperatively. Long-term indicators include the Japanese Orthopaedic Association (JOA) score, the Oswestry Disability Index (ODI) score, and the 36-Item Short-Form Health Survey (SF-36) score, evaluated preoperatively and 1 week, 3 months, and more than 1 year postoperatively.

**Results:** Complete clinical data was obtained for 139 patients. All patients were followed up for more than 12 months ( $13.7 \pm 3.3$  months). The average bedridden period was  $1.5 \pm 0.4$  days and hospital stays were  $2.7 \pm 0.9$  days. The VAS score of leg and back pain on POD 1–10 were all decreased compared with preoperation (all  $P < 0.0001$ ). At the last follow up, the VAS scores for back pain and leg pain ( $0.69 \pm 0.47$ ;  $1.02 \pm 0.55$ ) and the ODI score ( $11.1 \pm 3.5$ ) decreased (all  $P < 0.0001$ ), and the JOA score ( $27.1 \pm 3.2$ ) and the SF-36 (physical component summary,  $50.5 \pm 7.3$ ; mental component summary,  $49.4 \pm 8.9$ ) increased (all  $P < 0.0001$ ) compared with preoperative values. Patients' early and long-term levels of satisfaction postoperatively were 92.8% and 97.8%, respectively. At POD 7 and the last follow-up, the improvement rate of the JOA score, respectively, was  $41.8\% \pm 10.6\%$  and  $87.7\% \pm 8.2\%$ , and clinical effects assessed as significantly effective according to the improvement rate of the JOA score was 16.5% and 66.9%, respectively. There were 2 (1.4%) cases with complications, including 1 (0.7%) case of wound infection and 1 (0.7%) case of deep vein thrombosis. There were no device-related complications or neurological injuries.

**Conclusion:** Use of a gelatin sponge impregnated with dexamethasone combined with MIS-TLIF and no drainage tube after the operation, compared with previous studies, appears to be safe and feasible to reduce recurrent back pain and leg pain after decompression in the treatment of lumbar degenerative disease.

**Key words:** Dexamethasone; Drainage; Gelatin sponge; Lumbar; MIS-TLIF

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## Introduction

With the changes in modern lifestyles and the environment, the degeneration of lumbar intervertebral discs has been significantly accelerated compared with the past. Degeneration of the lumbar intervertebral disc can be identified with a diagnosis of lumbar disc herniation, lumbar spinal stenosis, and lumbar spondylolisthesis. The most common symptom is low back pain, which is reported to be experienced by 15%–20% of the population in the USA<sup>1</sup>. According to Lv *et al.*, the overall prevalence of lumbar degenerative diseases is 9.17% in Beijing and 12.6% in those who perform manual labor<sup>2</sup>.

Patients with surgical indications (e.g. with neurological symptoms) can achieve pain relief after decompression surgery. However, in some patients, severe leg pain or back pain re-occurred on the 2nd to 5th day after surgery (it could also occur on the non-decompression side)<sup>3</sup>. Imaging examination did not show compression of the nerve root. The pain was due to either edema caused by the traction of the nerve root during the decompression<sup>4</sup> or a local inflammatory reaction around the nerve root and the increase of nerve sensitivity caused by the anesthesia<sup>5</sup>. Cen *et al.* found that in patients with lumbar disc herniation who underwent simple nucleus pulposus removal, the proportion with recurrence of sciatica was as high as 57.3%<sup>6</sup>. The recurrence of root symptoms caused by edema will not only lead to discomfort of patients but will also affect patients' ability to participate in early postoperative rehabilitation exercise and reduce patients' postoperative satisfaction. Dehydration, non-steroidal painkillers, and intravenous glucocorticoids are used conventionally for symptomatic treatment, as well as opioid analgesics for short-term pain relief<sup>7</sup>.

Liu *et al.* found that sodium aescin is an effective and safe drug for the treatment of postoperative nerve root edema after decompression of lumbar disc herniation, which benefits from the preventive and therapeutic anti-inflammatory and anti-exudation effects of sodium aescin in the nervous system<sup>8</sup>. Cai *et al.* found that early neurodynamic mobilization intervention in patients after minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) is a safe and reliable method to reduce the incidence of recurrence of early postoperative root pain<sup>9</sup>. However, as a postoperative rehabilitation measure, neurodynamic mobilization needs to be carried out by professional rehabilitation therapists, and the limited rehabilitation resources limit the possibility of the universal use of this technique. Moreover, when sodium aescin is administered intravenously, its anti-inflammatory effect is not as good as that of local application of hormones to the nerve root.

Therefore, we tried using a gelatin sponge impregnated with dexamethasone combined with MIS-TLIF and no leaving drainage after the operation for early recurrence of root pain caused by edema. The main purposes of this study include: (i) to observe the safety of this innovative method (e.g. whether it will be accompanied by obvious complications); (ii) to determine its short-term clinical effects, including postoperative low back pain, leg pain, time bedridden postoperatively, duration of hospital stay, and other aspects

of the intervention effect; and (iii) to identify its long-term effects based on postoperative functional recovery and the satisfaction of patients as measured during follow-up. To our knowledge, this is the first report of this new combined method being used to treat lumbar degenerative disease.

## Materials and Methods

### Patient Selection

From September 2015 to January 2018, patients diagnosed with a lumbar degenerative disease (symptomatic recurrent lumbar disc herniation, symptomatic lumbar stenosis, or symptomatic lumbar spondylolisthesis) underwent MIS-TLIF combined with a gelatin sponge impregnated with dexamethasone and no drainage tube after surgery. The inclusion criteria were: (i) patients with a previous diagnosis and with typical neurological symptoms, in whom conservative treatment was ineffective; (ii) middle-aged patients (age, 45–60 years); (iii) patients with MIS-TLIF surgical indications and who underwent surgery; (iv) single-level decompression and fusion; (v) patients had been evaluated for all clinical indicators; and (vi) the inclusion of patients is based on the design of the case series.

Exclusion criteria were: (i) patients with other diseases that may cause leg pain or back pain; (ii) postoperative usage of painkillers or patient-controlled analgesia pump; (iii) pregnant patients; (iv) patients with screw-related neurological complications; and (v) loss to follow-up or incomplete data.

### Surgical Procedure

#### Probes Insertion and Exposure

After routine surgical preparation, all pedicle screw channels were prefabricated using a percutaneous method and guide probes were fixed. The skin on the side of the guide probe was then cut, and the channel was built to expose the decompression zone. The inner side of the MIS-TLIF opening area is generally close to the spinous process. The lateral residual part of the facet joint was not completely destroyed, to ensure communication with the intervertebral foramen<sup>10</sup>. After decompression, the cage was inserted and fixed.

#### Intervention Details

After repeated douching, an artificial dura mater (1.5 cm × 1.5 cm × 0.3 cm) (Tianxinfu Medical Devices, Beijing, China) was placed on the surface of the dura mater at the axillary side of the nerve root. A piece of gelatin sponge (2 cm × 2 cm × 0.5 cm) (Jinling Pharmaceutical, Nanjing, Jiangsu, China) impregnated with 2.5-mL dexamethasone injection (1 mL: 5 mg) (Hubei Tianyao Pharmaceutical, Xiangfan, Hubei, China) was placed around the nerve root before closing the wound (Fig. 1). No drainage tube was used after the surgery. After the cosmetic suture, the wound was tightly wrapped with a sterile dressing.

#### Postoperative Management

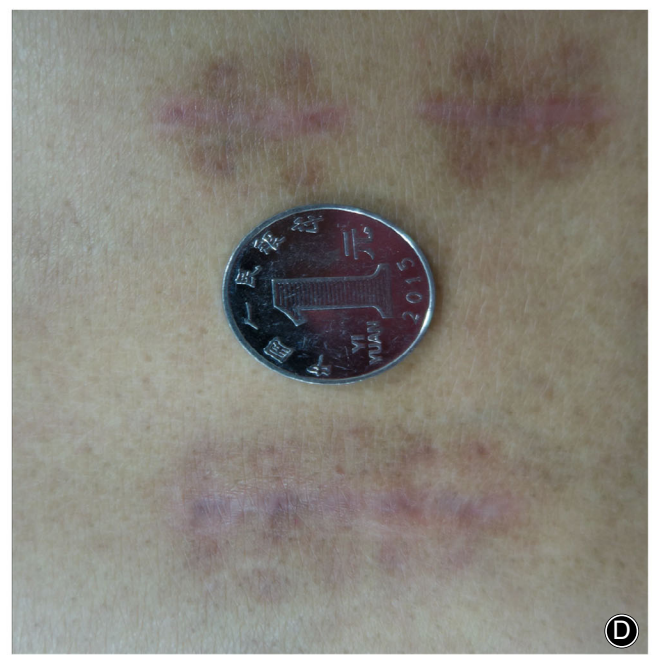
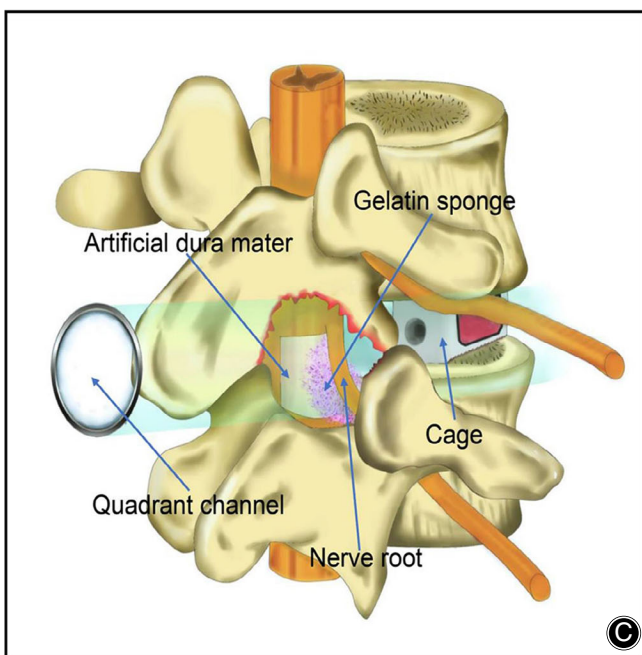
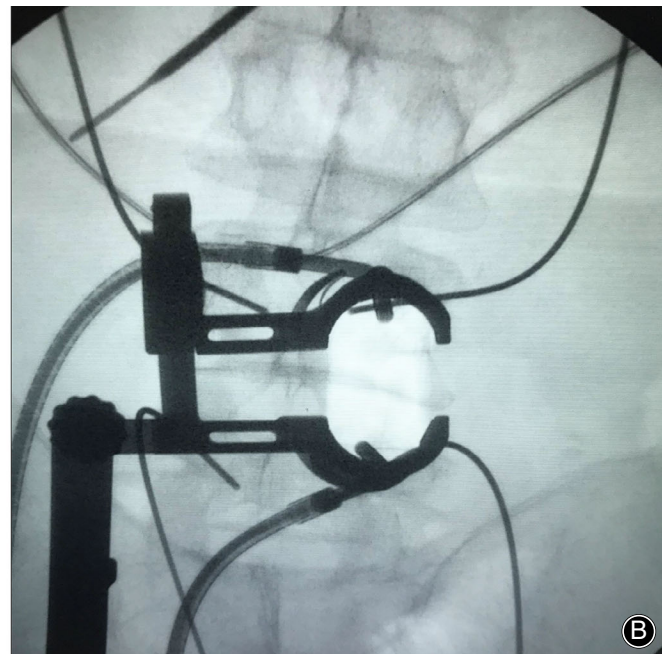
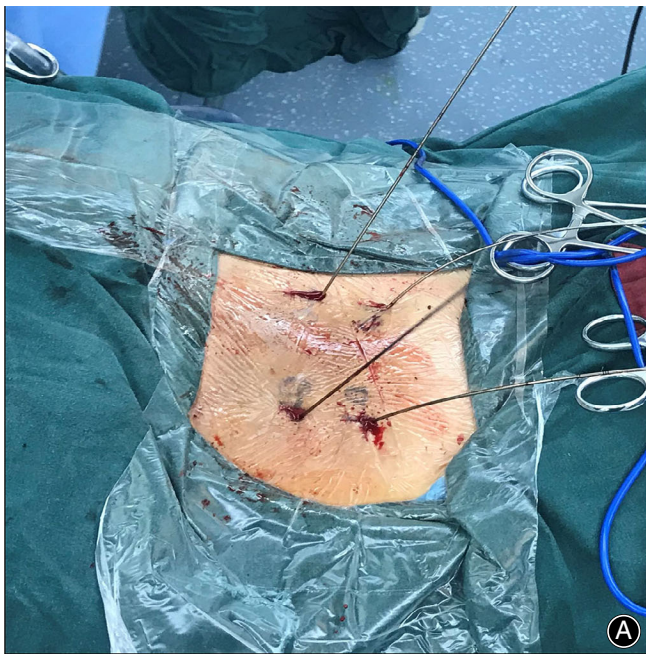
Wounds were redressed regularly, and antibiotics were given routinely after surgery. Dehydration, glucocorticoids, and non-

steroidal anti-inflammatory painkillers were not routinely used after the operation. Postoperatively, all patients wore hard lumbar braces (Kangbo Medical Equipment, Cixi, Zhejiang, China) and commenced out-of-bed activity and rehabilitative exercise when low back pain and leg pain could be managed and infection was not present.

### Assessment Criteria

#### Baseline Data Assessment

Basic indicators included symptom duration, fusion level, surgical time, intraoperative blood loss, length of hospital stay postoperatively, and time bedridden.



**Fig. 1** (A) Guide probes were used to prefabricate pedicle screw channels. (B) Decompression after positioning in the correct area. (C) Location of the intraoperative gelatin sponge. (D) The healing wound.

### *Pain Assessment and Clinical Outcomes*

Changes in postoperative low back pain and leg pain was evaluated using the visual analog scale (VAS) through follow-up interviews preoperatively and at postoperative days (POD) 1–10. Changes in quality of life and outcome scores were evaluated using the Japanese Orthopaedic Association (JOA) scoring system, the Oswestry disability index (ODI), the 36-Item Short-Form Health Survey (SF-36), and a satisfaction questionnaire (preoperatively, at 1 week and 3 months postoperatively, and at the last follow-up [LF]).

### *Visual Analog Scale*

The VAS allows a person to describe the intensity of his/her pain, it is a continuous scale anchored by a score of zero, indicating no pain, and a score of 10, representing the worst pain.

### *Japanese Orthopaedic Association Scoring System*

The Japan Orthopaedic Association (JOA) scoring system is used to assess the severity of clinical symptoms. It comprises six domain scores (motor dysfunction in the upper extremities, motor dysfunction in the lower extremities, sensory function in the upper extremities, sensory function in the trunk, sensory function in the lower extremities, and bladder function) scaled from 0 to 4, 4, 2, 2, 2, and 3, respectively. The minimum total score is 0 and the maximum total score is 17. Improvement index = post-treatment score – pre-treatment score. Post-treatment score improvement rate = (post-treatment score – pre-treatment score)/(29 – pre-treatment score) × 100%. By improving the index, it can reflect the improvement of lumbar function before and after treatment. The improvement rate can be used to understand the clinical treatment effect. When the improvement rate is 100%, it is cured, when the improvement rate is more than 60%, it is significant effective, 25–60% is effective, and less than 25% is invalid.

### *Oswestry Disability Index*

The ODI is a principal outcome measure designed to evaluate patient progress in routine clinical practice. It is a self-administered questionnaire divided into 10 sections: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. Each section is scored on a scale of zero to five, with five representing the greatest disability. The index is calculated by dividing the total score by the total possible score, and then multiplying the results by 100. The intervals of 0%–20%, 21%–40%, 41%–60%, 61%–80%, and 81%–100% were considered mild dysfunction, moderate dysfunction, severe dysfunction, disability, and long-term bedridden, respectively.

### *36-Item Short-Form Health Survey*

The SF-36 questionnaire<sup>11</sup> is a validated international questionnaire widely used in the current literature to evaluate the physical and mental health of patient. This questionnaire measures general health-related quality of life and includes

36 questions. All questions are summarized in two different final measures: the physical health status, represented by the Physical Component Summary (PCS), and the mental dimension, represented by the Mental Component Summary (MCS).

The SF-36 measures eight scales, which contribute in different proportions to the scoring of both PCS and MCS measures. Each scale is scored separately, from 0 to 100 points, where lower scores indicate poorer function. The scales are physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health<sup>12</sup>.

### *Satisfaction Questionnaire*

Patient satisfaction is an important component of healthcare and treatment quality, reflecting the healthcare or treatment provider's ability to meet patients' needs and expectations. Our patient satisfaction evaluation was related to patient assessment of the treatment effects of the surgery. Patient satisfaction included four grades: very satisfied, satisfied, neutral (fairly satisfied), and dissatisfied. The questions were measured on a four-point scale from "very satisfied" to "dissatisfied." The patient chose a relative point according to their own evaluation of treatment at POD 7 and LF.

We recorded any possible complications and adverse events to observe the safety of this method. Patient follow up was conducted by a research assistant for at least 1 year. The research assistant independently collected basic data for patients and clinical data. The study was approved by the institutional research ethics committee of Xi'an Honghui Hospital and written informed consent was obtained from each subject.

### *Statistical Analysis*

Quantitative data were expressed as mean ± standard deviation ( $\bar{x} \pm s$ ). Comparison of preoperative and postoperative data among previous endpoints was performed using single factor analysis of variance, then using the least significant difference *t*-test. Significance was defined as a *P*-value of less than 0.05. All statistical analyses were performed using Statistical Product and Service Solution Version 18.0 (SPSS, Chicago, IL, USA).

## **Results**

### *Preoperative Characteristics*

A total of 139 patients were included in the study. There were 60 men and 79 women, with an average age of  $52.8 \pm 4.6$  years (range, 46–60 years). Symptom duration was 0.2 to 13 months, with an average of  $4.2 \pm 8.8$  months, and the mean body mass index was  $24.7 \pm 3.3$  kg/m<sup>2</sup> (range, 20.4–27.1 kg/m<sup>2</sup>). There were 83 cases of symptomatic recurrent lumbar disc herniation, 26 cases of symptomatic lumbar stenosis, and 30 cases of symptomatic lumbar spondylolisthesis. All patients underwent MIS-TLIF combined with use of a gelatin sponge impregnated with

**TABLE 1** Baseline characteristics

Variables	Value (%)
Number of patients	139
Females, n (%)	79 (56.8)
Age ( $\bar{x} \pm s$ , years)	52.8 $\pm$ 4.6
Mean BMI ( $\bar{x} \pm s$ , kg/m <sup>2</sup> )	24.7 $\pm$ 3.3
Symptom duration ( $\bar{x} \pm s$ , month)	4.2 $\pm$ 8.8
<b>Diagnosis, n (%)</b>	
Symptomatic lumbar disc herniation	83 (59.7)
Symptomatic lumbar stenosis	26 (18.7)
Symptomatic lumbar spondylolisthesis	30 (21.6)
<b>Fusion level, n (%)</b>	
L <sub>3</sub> -L <sub>4</sub>	8 (5.8)
L <sub>4</sub> -L <sub>5</sub>	72 (51.8)
L <sub>5</sub> -S <sub>1</sub>	59 (42.4)
Surgical time ( $\bar{x} \pm s$ , min)	187.6 $\pm$ 29.7
Blood loss ( $\bar{x} \pm s$ , mL)	112.9 $\pm$ 21.4
Length of hospital stay postoperatively ( $\bar{x} \pm s$ , day)	2.7 $\pm$ 0.9
Time bedridden ( $\bar{x} \pm s$ , day)	1.5 $\pm$ 0.4

BMI, body mass index.

dexamethasone and no drainage tube after surgery. The average surgical time was 187.6  $\pm$  29.7 min (range, 140.8--211.3 min), and the average blood loss was 112.9  $\pm$  21.4 mL (range, 94.5--330.0 mL). The fusion level was mainly L<sub>4</sub>-L<sub>5</sub> and L<sub>5</sub>-S<sub>1</sub>, as shown in Table 1.

### Pain Assessment and Clinical Outcomes

#### Visual Analog Scale

The average preoperative (POD 1-10) VAS score for leg pain and low back pain was 1.8 (range, 0-4) and 2.6 (range, 1-5), respectively. The VAS score for postoperative leg pain and back pain were all decreased compared with the preoperative score (all  $P < 0.0001$ ), as shown in Table 2. At the LF, the VAS scores for back pain and leg pain (0.69  $\pm$  0.47 and 1.02  $\pm$  0.55, respectively) decreased (all  $P < 0.0001$ ) compared with preoperative values.

#### Length of Hospital Stay Postoperatively and Time Bedridden

The average length of hospital stay postoperatively was 2.7  $\pm$  0.9 days (range, 1.3-4.5 days) and the average time bedridden was 1.5  $\pm$  0.4 days (range, 0.8-2.7 days), as shown in Table 1.

#### Oswestry Disability Index

All patients were followed up for more than 12 months (13.7  $\pm$  3.3 months). The preoperative ODI was 55.1  $\pm$  10.4. The ODI values at POD 7, POM 3, and LF were 36.8  $\pm$  9.1, 17.6  $\pm$  7.7, and 11.1  $\pm$  3.5, respectively. These values decreased gradually with each follow-up and were all decreased (all  $P < 0.0001$ ) compared with preoperative values, as shown in Table 3 and Fig. 2.

**TABLE 2** Short-term VAS score from preoperation to postoperative day 10

VAS score	Low back pain	Leg pain
PRE	5.74 $\pm$ 1.61	7.47 $\pm$ 2.02
POD1	2.44 $\pm$ 0.74	1.64 $\pm$ 0.40
POD2	2.22 $\pm$ 0.91	1.71 $\pm$ 0.44
POD3	3.16 $\pm$ 0.86	2.05 $\pm$ 0.89
POD4	3.67 $\pm$ 0.95	2.37 $\pm$ 0.91
POD5	3.38 $\pm$ 1.11	2.26 $\pm$ 0.84
POD6	2.75 $\pm$ 0.64	1.88 $\pm$ 0.77
POD7	2.24 $\pm$ 0.69	1.81 $\pm$ 0.72
POD8	2.01 $\pm$ 0.59	1.67 $\pm$ 0.68
POD9	1.98 $\pm$ 0.67	1.59 $\pm$ 0.66
POD10	1.90 $\pm$ 0.59	1.51 $\pm$ 0.64
<i>P</i> -value (PRE vs POD 1-10)	<0.0001*	<0.0001*

POD, postoperative day; PRE, preoperatively; VAS, visual analog scale.  
\* Significant *P*-value ( $P < 0.05$ ). VAS, visual analog scale.

#### 36-Item Short-Form Health Survey

At the LF, SF-36 values (PCS: 50.5  $\pm$  7.3; MCS: 49.4  $\pm$  8.9) increased (all  $P < 0.0001$ ) compared with preoperative values (PCS: 29.6  $\pm$  8.8; MCS: 27.3  $\pm$  9.1), as shown in Table 3.

#### Satisfaction Questionnaire

The satisfaction rate for surgery shows that patients' early postoperative satisfaction reached 92.8%, with a very satisfied rate of 38.8%; the long-term satisfaction rate was 97.8%, with a very satisfied rate of 41.7% (Table 4).

#### Japanese Orthopaedic Association Scoring System

At the LF, the JOA score (27.1  $\pm$  3.2) increased ( $P < 0.0001$ ) compared with preoperative values (8.7  $\pm$  5.2). At POD 7 and the LF, the improvement rate of JOA, respectively, was 41.8%  $\pm$  10.6% and 87.7%  $\pm$  8.2%, and the proportion of clinical effects assessed as significantly effective according to the improvement rate of the JOA score, respectively, was 16.5% and 66.9% (Table 5). A typical case is shown in Fig. 3.

#### Complications

There were 2 (1.4%) cases with complications, including 1 case (0.7%) of wound infection, resolved with antibiotics and local wound treatment, and 1 case (0.7%) of deep vein thrombosis, resolved with 6 months of therapy. There were no device-related complications (e.g. hardware loosening and cage migration) or neurological injuries.

### Discussion

#### Aims of the Study

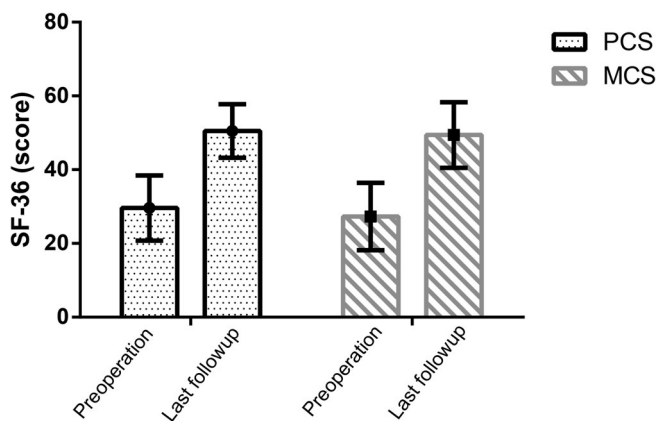
In an evidence-based clinical guideline<sup>13</sup> for the diagnosis and treatment of lumbar disc herniation with radiculopathy developed by the North American Spine Society, transforaminal epidural steroid injections (ESI) are recommended (grade of recommendation: A) to provide short-term

**TABLE 3 Comparison and paired comparison of clinical and radiological indexes before and after operation (Mean±SD)**

Variables	N	VAS (back pain)		VAS (leg pain)		JOA (score)		ODI (score)		SF-36 (score)			
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	PCS		MCS	
PRE (1)	139	5.74 ± 1.61		7.47 ± 2.02		8.7 ± 5.2		55.1 ± 10.4		29.6 ± 8.8		27.3 ± 9.1	
POD 7 (2)	139	2.24 ± 0.69		1.81 ± 0.72		16.4 ± 4.9		36.8 ± 9.1		—		—	
POM 3 (3)	139	1.73 ± 0.70		1.35 ± 0.60		21.6 ± 4.0		17.6 ± 7.7		—		—	
LF (4)	139	0.69 ± 0.47		1.02 ± 0.55		27.1 ± 3.2		11.1 ± 3.5		50.5 ± 7.3		49.4 ± 8.9	
F value		258.35		426.22		123.95		317.84		166.26		200.57	
P-value		<0.0001*		<0.0001*		<0.0001*		<0.0001*		<0.0001*		<0.0001*	
Paired comparison		T-value	P-value	t-value	P-value	t-value	P-value	t-value	P-value	t-value	P-value	t-value	P-value
(1): (2)		15.59	<0.0001*	27.66	<0.0001*	23.44	<0.0001*	9.93	<0.0001*	—	—	—	—
(1): (3)		26.75	<0.0001*	22.58	<0.0001*	39.68	<0.0001*	28.31	<0.0001*	—	—	—	—
(1): (4)		37.10	<0.0001*	34.43	<0.0001*	45.56	<0.0001*	33.46	<0.0001*	12.21	<0.0001*	10.66	<0.0001*

\* Significant P-value ( $P < 0.05$ ). —, no value.; JOA score, Japanese Orthopaedic Association score; LF, last follow-up; MCS, mental component summary; ODI, Oswestry disability index; PCS, physical component summary; POD, postoperative day; POM, postoperative month; PRE, preoperatively; SF-36, 36-Item Short-Form Health Survey; VAS, visual analog scale.

(2–4 weeks) pain relief for patients with lumbar disc herniations with radiculopathy. ESI is used for the treatment of lumbar spondylolisthesis and lumbar spinal stenosis with low back pain and leg pain and achieves great clinical results<sup>14–16</sup>. However, almost all spine surgeons regard ESI as an important conservative treatment<sup>17,18</sup>. For the recurrence of leg pain and low back pain several days after decompression, oral non-steroidal anti-inflammatory drugs and intravenous corticosteroids are preferred. So why not consider applying the concept of ESI to decompression surgery? We used a gelatin sponge to infuse hormones for open posterior lumbar interbody fusion and transforaminal lumbar interbody fusion (TLIF) surgery previously, but the necessary continuous drainage after open surgery makes the hormone



**Fig. 2** Bar chart of 36-Item Short-Form Health Survey (SF-36) scores preoperation and at last follow-up. The Physical Component Summary (PCS) and Mental Component Summary (MCS) at the last follow-up were significantly higher than those before the operation, which proved that the quality of life of the patients was significantly improved after treatment with this method.

**TABLE 4 Short-term and long-term satisfaction**

Follow-up	Satisfaction, n (%)			
	Very satisfied	Satisfied	Neutral	Dissatisfied
POD 7	54 (38.8)	75 (54.0)	9 (6.5)	1 (0.7)
LF	58 (41.7)	78 (56.1)	3 (2.2)	0 (0)

LF, last follow-up; POD, postoperative day.

concentration in the gelatin sponge decrease rapidly, so that the expected results cannot be achieved. With the skilled application of MIS-TLIF technology, less trauma and less intraoperative blood loss, it is possible to not leave a drainage tube after MIS-TLIF, which provides a great opportunity for the combination of ESI and decompression surgery.

#### Theoretical Basis

Many spine surgeons appreciate the benefits of using MIS-TLIF technology, such as the minimal trauma, the small amount of bleeding, the quick recovery, and the great

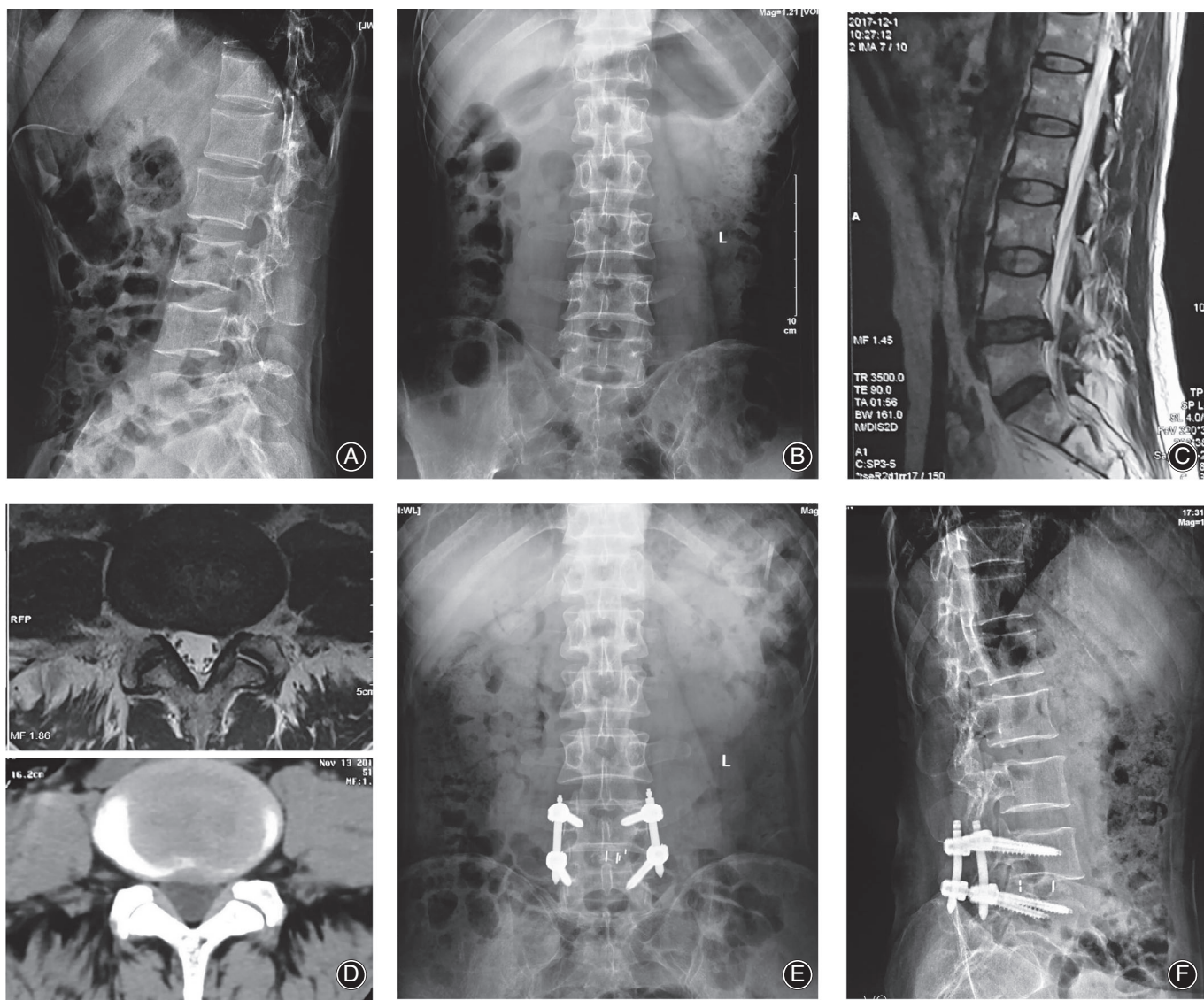
**TABLE 5 Short-term and long-term clinical effects according to improvement rate of JOA score**

Follow-up	Improvement rate ( $\bar{x} \pm s$ , %)	Clinical effects, n (%)		
		Significantly effective	Effective	Invalid
POD 7	41.8 ± 10.6	23 (16.5)	115 (82.7)	2 (1.4)
LF	87.7 ± 8.2	93 (66.9)	46 (33.1)	0 (0)

JOA score, Japanese Orthopedic Association score; LF, last follow-up; POD, postoperative day.

treatment effect<sup>10</sup>. In addition, the paramedian small incision avoids denervation and atrophy caused by the separation of paravertebral muscles. Recently, some studies have focused on the necessity of placing a drainage tube after MIS-TLIF. Liang *et al.*<sup>19</sup> reported that the average drainage volume after single-segment MIS-TLIF was  $58.7 \pm 21.4$  mL, while ideally the draining volume should be  $<50$  mL. Huang *et al.*<sup>20</sup> and Xu *et al.*<sup>21</sup> examined the necessity of placing a drainage tube after MIS-TLIF. They found that postoperative incision

infection, hematoma compression, and other complications did not increase due to the absence of a drainage tube. The time bedridden postoperatively and the length of hospital stay postoperatively were significantly reduced, and postoperative low back pain was significantly improved. Proving that the drainage tube does not need to be used would reduce risk and provide clinical benefits. We used a gelatin sponge impregnated with dexamethasone and no drainage tube to help reduce inflammation of the nerve root postoperatively.

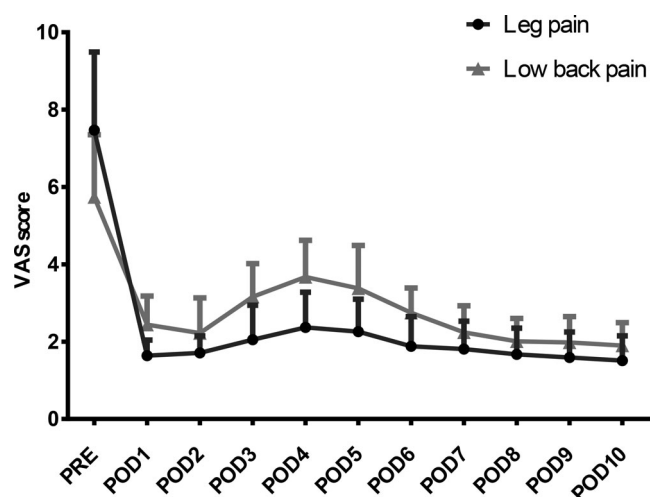


**Fig. 3** A 56-year-old man complained of low back pain with radiation pain of the left lower limb for 6 months and aggravated for 10 days. Six months previously, after the diagnosis of lumbar disc herniation was confirmed at a local hospital, radiofrequency ablation was performed, and the symptoms of low back pain and leg pain were partially relieved. Conservative treatment followed, with oral drugs taken at home. The sudden symptoms were aggravated after working 10 days previously and it could not be improved with rest. The muscle strength of both legs was normal and the straight leg raising test of the left lower limb was  $40^\circ$  positive. After being admitted to our hospital, he was diagnosed with recurrent lumbar disc herniation (L<sub>4-5</sub>) and underwent MIS-TLIF. (A–B) Preoperative lumbar X-ray film; (C) sagittal lumbar MRI film; (D) transverse MRI and CT film, level L<sub>4-5</sub>; and (E–F) postoperative lumbar X-ray film.

The concentration and action time of dexamethasone is not reduced due to drainage. It can reduce the risk of bias and improve the accuracy of the research. Gelatin sponges are often used for hemostasis and have strong water absorption. It is used as a carrier by many surgeons to infuse tranexamic acid to reduce postoperative hemorrhage through its slow-release effect<sup>22, 23</sup>. The purpose of using artificial dura mater is to prevent delayed cerebrospinal fluid leakage. Previous cases of arachnoiditis caused by epidural block anesthesia have been reported<sup>24</sup>. The possible reason was that the needle penetrated the dura mater and glucocorticoid and local anesthetic drugs mistakenly entered the subdural space. Weng *et al.*<sup>25</sup> pointed out that subarachnoid injection of corticosteroids may have potential side effects. Dexamethasone can inhibit the excitability of nerve endings, improve local blood circulation, make local metabolites easy to remove from the blood circulation, alleviate local acidosis, and help reduce inflammation<sup>26</sup>. Dexamethasone can also reduce pain related to the irritation of the dorsal root ganglion typical to MIS-TLIF. Current systematic reviews and meta-analyses of epidural and non-granular steroids show that granular steroids provide no significant improvement in pain relief compared with non-granular steroids. Considering the concern about the safety of granular steroids, it is recommended that non-granular steroids (dexamethasone) are used<sup>18</sup>.

### Summary of the Clinical Outcomes

Zhao *et al.*<sup>27</sup> designed a retrospective cohort study to compare MIS-TLIF and open TLIF for lumbar disc herniation. The POD 7 VAS scores for leg pain and back pain were  $2.06 \pm 0.66$  and  $2.88 \pm 0.33$ , respectively, in the MIS-TLIF group. Our outcomes showed that the POD 7 VAS score of leg pain and back pain were all lower than that of them (Fig. 4). Kim *et al.*<sup>28</sup> reported clinical outcomes of MIS-TLIF, with a minimum 5 years of follow-up, and indicated that the average postoperative VAS scores for leg pain and back pain were 3.7 and 3.5, respectively. In our study, the VAS scores for leg pain and back pain were  $1.02 \pm 0.55$  and  $0.69 \pm 0.47$  at the LF, which are lower than the values reported by Kim *et al.* but similar to those reported by Chen *et al.*<sup>29</sup>. Zhao *et al.*<sup>27</sup> also reported on patients in an MIS group, including bedridden period ( $2.35 \pm 0.49$  days) and hospital stay ( $3.82 \pm 0.73$  days) after surgery. However, the results in our study were lower (time bedridden:  $1.5 \pm 0.4$  days and hospital stay:  $2.7 \pm 0.9$  days). Short-term and long-term patient satisfaction rates were 92.8% and 97.8% in our study but only 80% (short term) described in Kim *et al.*<sup>28</sup>. This indicates that although the VAS score for leg pain and back pain inevitably rebounded from POD 2 to POD 6, in comparison with previous general MIS-TLIF<sup>27-29</sup>, the application of a gelatin sponge impregnated with dexamethasone and no drainage tube after surgery can prevent the recurrence of early postoperative root pain and increase patient satisfaction. Compared with the previous literature<sup>30, 31</sup>, the current research results show a 1.4% complication rate



**Fig. 4** Short-term visual analog scale (VAS) score of leg and back pain from preoperatively (PRE) to postoperative day (POD) 10. The low back and leg pain of patients decreased significantly on POD 1 but gradually increased from POD 2 and reached a small peak on POD 4, and then decreased gradually until POD 10.

and there are no new or serious complications, demonstrating the safety of this method. Other outcomes of our research were consistent with those of previous articles<sup>32-34</sup>.

In this study, we found that VAS scores for low back pain and leg pain began to increase on POD 2 (Fig. 4), indicating that edema of the nerve root began to appear on POD 1, and the VAS score reached a peak on POD 4. Although anti-inflammatories continue to work, early rehabilitation exercises will stimulate the aggravation of reactive edema of the nerve root. There is also a clear advantage of using a gelatin sponge impregnated with dexamethasone. Compared with the postoperative routine of intravenous or oral administration of various hormones and non-steroidal painkillers, the present study illustrates a low-cost method, which can greatly reduce the economic burden of patients. In addition, we found that most patients are very careful after their operation, and their compliance with the early exercises recommended by doctors is not high, so we are used to requiring patients to wear a hard lumbar brace to get out of bed early after surgery. On the one hand, it plays a role in assisting stability and reducing low back pain; on the other hand, its main purpose is to increase patients' confidence and to promote early rehabilitation exercise.

### Limitations

At present, the main limitation of this case series is the lack of a control group; therefore, the persuasive power of the findings has been reduced. However, this is our preliminary exploration report, which focused on the safety and effectiveness of this new method compared with previously reported research. In the next step, a single-center prospective



randomized controlled trial will be designed to further increase the reliability of the findings.

### Conclusion

Use of a gelatin sponge impregnated with dexamethasone combined with MIS-TLIF and no drainage tube after surgery is safe. Compared with previous studies, it appears to be a feasible technique to reduce recurrent back pain and leg pain after decompression in the treatment of lumbar degenerative

disease. However, further large sample randomized controlled trials are necessary.

### Disclosure

There was no commercial party involved this study. The authors declare that there is no competing interest. This research was supported by the National Natural Science Foundation of China (81772357).

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