

# Clinical outcomes of MED and iLESSYS® Delta for the treatment of lumbar central spinal stenosis and lateral recess stenosis: A comparison study

BOYU WU<sup>1\*</sup>, CHENGJIE XIONG<sup>2\*</sup>, LINYING TAN<sup>1</sup>, DONGDONG ZHAO<sup>3</sup>, FENG XU<sup>2</sup> and HUI KANG<sup>2</sup>

<sup>1</sup>The First Clinical College, Hubei University of Chinese Medicine, Wuhan, Hubei 430065;

<sup>2</sup>Department of Orthopaedics, General Hospital of Central Theater Command of PLA, Wuhan, Hubei 430070;

<sup>3</sup>The First School of Clinical Medicine, Southern Medical University, Guangzhou, Guangdong 510515, P.R. China

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**Abstract.** Microendoscopic discectomy (MED) is an established procedure used to treat lumbar central spinal stenosis (LCSS) and lateral recess stenosis (LRS). The Interlaminar Endoscopic Surgical System iLESSYS® Delta approach has been developed from the traditional interlaminar endoscopic technique for the treatment of LCSS and LRS. In the present study, MED was used as a reference to evaluate this newly developed approach. A total of 82 and 52 patients with radicular leg pain and/or neurogenic claudication symptoms were treated by spinal canal decompression using the MED or iLESSYS® Delta approach, respectively. The clinical outcomes of the patients were analyzed using the Modified MacNab's criteria, visual analogue scale (VAS) leg pain score, VAS back pain score and the Oswestry Disability Index (ODI) score. Finally, the effectiveness of the decompression was evaluated on a cross-sectional area of the dural sac (CSAD) at the disc level. The incision length in the iLESSYS® Delta group was significantly decreased compared with the MED group ( $P < 0.05$ ); however, the duration of the operation in the iLESSYS® Delta group was significantly longer compared with the MED group ( $P < 0.05$ ). The VAS score of the back and ODI score in the iLESSYS® Delta group were significantly decreased compared with the MED group at the 1-week follow-up ( $P < 0.0125$ ). The postoperative CSAD was also significantly increased in both groups compared with before the operation ( $P < 0.05$ ); however,

there were no significant differences in the postoperative CSAD between the two groups. The good-to-excellent rates of the MED and iLESSYS® Delta approach were 89.0 and 90.4%, respectively, whereas the complication rates of the MED and iLESSYS® Delta system were 3.66 and 3.85% in the two groups, respectively. In conclusion, the iLESSYS® Delta approach was identified to be comparable with the MED approach for treating LCSS and LRS, demonstrating both precise and limited decompression. In addition, the iLESSYS® Delta approach may reduce the short-term back pain and promote faster recovery compared with the MED.

## Introduction

Lumbar spinal stenosis (LSS) is a common degenerative disease that is prevalent among the elderly population. LSS can be divided into lumbar central spinal stenosis (LCSS), lateral recess stenosis (LRS) and foraminal stenosis; LCSS is commonly combined with LRS (1). The pathogenesis behind LCSS and LRS was discovered to be responsible for compression of the dural sac and nerve roots, which are directly caused by disc herniation (DH), hypertrophic ligamentum flavum (LF) and hypertrophic facet joint (2,3). The main aim of surgical treatment in LCSS and LRS is to decompress the nerve roots and relieve the symptoms (4). As a consequence, the majority of patients who suffer from LCSS and LRS will undergo surgery if traditional treatment regimens fail to relieve the neurological symptoms (5).

Traditional open surgery encompasses fenestration, semi-laminectomy and total laminectomy; however, although these traditional surgical methods can improve the neurological symptoms, surgery is often associated with postoperative complications, especially in elderly populations with comorbidities (6,7). Compared with traditional surgical procedures, minimally invasive spinal surgery (MISS) has been observed to minimize iatrogenic traumatization, promote recovery and preserve the segmental stability (8,9). Notably, following the development of medical instruments, complicated degenerative neurological disorders such as LSS have also been successfully treated using MISS (6). Microendoscopic discectomy (MED) is one of the MISS procedures that is used to treat LSS (10-12).

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*Correspondence to:* Dr Feng Xu or Dr Hui Kang, Department of Orthopaedics, General Hospital of Central Theater Command of PLA, 627 Wuluo Road, Hongsha, Wuhan, Hubei 430070, P.R. China  
E-mail: fengxu1969@163.com  
E-mail: kanghuicss@163.com

\*Contributed equally

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At first, MED was only used to treat LCSS with unilateral recess stenosis; however, following the development of the MED system, bilateral over-the-top decompression under microendoscopy has also been successfully performed using a unilateral approach, which is now known as the unilateral laminectomy for bilateral decompression (ULBD) technique (13). Microendoscopic ULBD is the standard procedure for the treatment of LCSS and LRS in the General Hospital of Central Theater Command of PLA (Wuhan, China).

Following the advancement of the full endoscopic system, another MISS procedure, known as percutaneous endoscopic lumbar discectomy (PELD), has also demonstrated favorable clinical results for the treatment of lumbar degenerative disease (8,14-16). PELD is primarily used to treat intervertebral DH; however, certain limitations, such as the lack of effective surgical instruments, narrow endoscopic vision and a steep learning curve, restrict its application for the treatment of more complicated degenerative neurological disorders, such as LSS. Therefore, the Interlaminar Endoscopic Surgical System (iLESSYS<sup>®</sup>) Delta system (Joimax<sup>®</sup> GmbH) has been subsequently developed from the traditional PELD system for the treatment of LSS. The iLESSYS<sup>®</sup> Delta system is equipped with a larger size working cannula and endoscopic instruments, which permits big osteophytes or soft tissues to be removed without extra maneuvers under good endoscopic visualization (8,16,17). This design has made the treatment of LCSS and LRS more efficient through using the interlaminar approach (8,16,17). Therefore, the present study aimed to retrospectively compare the radiographic and clinical outcomes of LCSS and LRS treated with both the MED and iLESSYS<sup>®</sup> Delta approaches.

## Materials and methods

**Patient studies.** Between November 2015 and November 2017, 134 patients (85 males and 49 females; range 53-82 years) underwent MED or the iLESSYS<sup>®</sup> Delta approach in the General Hospital of Central Theater Command of PLA (Wuhan, China). The patients were categorized into two groups: i) The iLESSYS<sup>®</sup> Delta group (52 patients; 34 males and 18 females; range 54-79 years) and the MED group (82 patients; 51 males and 31 females; range 53-82 years). These surgical procedures were performed by one experienced surgeon. All the procedures in the present study were approved by the Ethics Committee of the General Hospital of Central Theater Command of PLA (Wuhan, China), and were in accordance with the Helsinki Declaration. Written informed consent was obtained from each patient. The following inclusion criteria were used to select the patients: i) Patients with symptoms of neurogenic claudication and/or radicular leg pain; ii) single-level degenerative LCSS and LRS, which were diagnosed using CT scanning and MRI with the Schizas Grading System applied (18); iii) neurological symptoms which were consistent with the CT scans and MRI findings; iv) no dynamic spinal instability observed; and v) patients who had received traditional therapeutic regimens for a period of at least 6 weeks. The following exclusion criteria were applied: i) Dynamic spinal instability; ii) degenerative spondylolisthesis of a Meyerding grade >I (15,19); iii) combined foraminal stenosis at the same or a lower level; iv) patients

with severe cardiopulmonary diseases who were unable to tolerate surgery; and v) prior surgery at the same segment. In the present study, all patients were informed objectively about the surgical procedure, benefits and potential risks, and each patient was able to freely elect for the surgical option.

**Clinical assessment.** The medical data from all included patients were collected and assessed for basic demographic, perioperative and postoperative data. Each patient was evaluated using the visual analogue scale (VAS) for back pain and leg pain; and the Oswestry disability index (ODI) questionnaires (20). Both questionnaires were asked preoperatively and at each follow-up time point (1-week, 6-months and the latest follow-up). The VAS and ODI scores were recorded in the questionnaires at each follow-up in the outpatient department. Postoperative Modified Macnab criteria was also used for the clinical global outcome assessment (21). Occasionally, follow-ups were obtained by telephone communication.

MRI was also performed to determine the extent of the spinal canal decompression. The cross-sectional area of the dural sac (CSAD) was analyzed using ImageJ software (1.50; National Institutes of Health) and the preoperative and postoperative MRIs were compared to evaluate the efficiency and safety of the decompression between the two groups.

## Surgical approaches

**MED.** All patients underwent surgery in the prone position under general anesthesia. The intervertebral disc space at the stenosis level was located using C-arm fluoroscopy. Briefly, a 1.5-2 cm vertical incision was made beside the spinous process on the dominant symptomatic side. The fascia and subcutaneous tissue were dissected, and hemostasis was achieved by bipolar coagulation. Subsequently, the sequential dilators were inserted to expose the desired upper lamina. A tubular retractor was passed over the dilator, which was then removed and the flexible arm was attached to the tubular retractor firmly. The endoscope was subsequently inserted into the tubular retractor and connected to it. Following the identification of the inferior border of the upper lamina, ipsilateral semi-laminectomy was performed. The base of the spinous process was undercut using a high-speed drill, known as the 'over-the-top' technique (22). The LF located at the dorsal side of the dural sac was resected using a Kerison punch (Medtronic Sofamor Danek, Memphis, TN) to initiate the decompression of the central stenosis. The tubular retractor was then tilted to expose the contralateral recess. Finally, the contralateral recess decompression was performed until the contralateral nerve roots were decompressed.

**iLESSYS<sup>®</sup> Delta approach.** All procedures were performed using the iLESSYS<sup>®</sup> Delta system (Joimax<sup>®</sup> GmbH). Each patient underwent surgery in the prone position under general anesthesia. Briefly, under the guidance of C-arm fluoroscopy, the interlaminar space at the desired level was identified by inserting a guide needle near the spinous process on the dominant symptomatic side. A skin incision (1-1.5 cm) was made at the entry site of the needle and the guide wire was introduced through the needle, which was subsequently withdrawn. Subsequently, sequential dilators were introduced through the surface of the inferior margin of the upper lamina over the

Table I. Comparison of demographic characteristics in the two groups.

Characteristics	iLESSYS Delta (n=52)	MED (n=82)	t/ $\chi^2$ -value	P-value
Age, years	67.35±7.20	65.72±6.36	1.37 <sup>a</sup>	0.17
Gender, male (%)	34 (65.38)	51 (62.20)	0.14 <sup>b</sup>	0.71
Diabetes (%)	6 (11.54)	9 (10.98)	0.01 <sup>b</sup>	0.92
Lower extremity atherosclerosis disease (%)	5 (9.62)	10 (12.20)	0.21 <sup>b</sup>	0.64
Duration of symptoms, months	10.92±2.96	11.89±4.08	1.48 <sup>a</sup>	0.14
Operative level, L4/5/(L4/5+L5/S1) (%)	35 (67.31)	61 (74.39)	0.79 <sup>b</sup>	0.38
Schizas grade, Schizas grade C/(Schizas grade C + Schizas grade D) (%)	17 (32.69)	23 (28.05)	0.33 <sup>b</sup>	0.57
Follow-up, months	20.54±5.49	21.22±5.09	0.73 <sup>a</sup>	0.47

The age, duration of symptoms and follow-up data were compared using Student t-tests. <sup>a</sup>the data were analyzed using  $\chi^2$  Student t-tests. The gender, diabetes, lower extremity atherosclerosis, operative level and Schizas grade data were compared using  $\chi^2$  tests. <sup>b</sup>the data were analyzed using  $\chi^2$  tests. Schizas grades were awarded according to Schizas Grading System based on the morphology of the dural sac on MRI images. P<0.05 represented statistical significance. iLESSYS, Interlaminar Endoscopic Surgical System; MED, microendoscopic discectomy.

Table II. Comparison of clinical operation effects between the two groups.

Items	iLESSYS Delta (n=52)	MED (n=82)	t-value	P-value
Incision length, cm	1.41±0.17	1.89±0.26	11.97	<0.05
Duration of surgery, min	83.81±11.07	58.32±12.30	12.15	<0.05
Time to return to work, days	10.71±2.17	11.44±2.69	1.64	0.10

The incision length, duration of surgery and time to return to work data were compared using Student t-tests. P<0.05 represented statistical significance. iLESSYS, Interlaminar Endoscopic Surgical System; MED, microendoscopic discectomy.

guide wire and the tubular retractors for the endoscope were placed over the dilators. The guide wire and the dilators were then removed. An endoscope system was assembled using two irrigation channels and an eccentrically placed 6-mm working cannula (Fig. 1A). The upper and lower lamina were located, and the soft tissue was removed using bipolar radiofrequency and grasper forceps. In addition, the cranial and caudal lamina, as well as the partial facet joint were removed using a high-speed drill (Fig. 1B). The LF located at the dorsal side of the dural sac was resected using a Kerrison punch (Joimax® GmbH) to decompress the central stenosis. The contralateral decompression was performed by tilting the working cannula and endoscope, and the base of spinous process was undercut. Subsequently, the ventral portion of the upper articular process and the LF were removed to promote the decompression of the contralateral LRS (Fig. 1C). The working cannula and endoscope were then moved away for the ipsilateral lateral recess decompression (Fig. 1D). Finally, the decompression was determined by assessing the retained mobility of the dural sac and nerve roots.

**Statistical analysis.** Statistical analysis was performed using SPSS version 17.0 software (SPSS, Inc.). Significant differences between the mean age, duration of symptoms, follow-up, incision length, duration of surgery and time to return to work were determined using unpaired Student's t-tests. Significant

differences between sex, diabetes status, lower extremity atherosclerosis, operative level, Schizas grade and MacNab evaluation were analyzed using  $\chi^2$  tests. The CSAD was verified using Student's t-tests before and after the operation between the two treatments. VAS and ODI were compared using Mann Whitney U tests and post-hoc Bonferroni adjustments. Measurement data are expressed as mean ± standard deviation, and enumeration data was shown by rate (%). P<0.05 (or P<0.0125 with Bonferroni adjustments) was considered to indicate a statistically significant difference.

## Results

**Comparison of basic demographic characteristics.** A total of 134 participants (iLESSYS® Delta, 52 cases; MED, 82 cases) who met the inclusion criteria were enrolled in the present study. The basic demographic characteristics (age, sex, comorbidities, duration of symptoms, operative level, Schizas grade and follow-up) were compared and presented in Table I. There were no significant differences observed regarding the basic demographic characteristics between the two groups.

**Comparison of surgery-related indicators between the two groups.** The incision length (1.41±0.17 cm) in the iLESSYS® Delta group was significantly shorter compared with the MED group (1.89±0.26 cm). However, the duration of the surgery in

Table III. Comparison of VAS and ODI scores in the two groups.

Items	iLESSYS Delta (n=52)	MED (n=82)	P-value
VAS of Leg			
Pre-operation	7.71±0.91	7.95±0.99	0.15
1-week after operation	2.10±0.10	2.17±0.68	0.48
6-month after operation	1.81±0.84	1.85±0.83	0.77
The latest follow-up	1.62±0.74	1.71±0.74	0.37
VAS of Back			
Pre-operation	5.13±1.03	4.93±1.04	0.34
1-week after operation	2.12±0.55	2.45±0.52	<0.0125
6-month after operation	1.83±0.71	1.90±0.73	0.46
The latest follow-up	1.58±0.70	1.52±0.76	0.51
ODI			
Pre-operation	74.62±9.12	76.90±9.43	0.09
1-week after operation	32.15±8.38	35.46±9.26	<0.0125
6-month after operation	27.08±7.15	27.95±6.47	0.16
The latest follow-up	26.71±6.45	28.15±6.59	0.98

The VAS and ODI scores were compared using Mann Whitney U tests. P<0.0125 represented statistical significance (0.05/4 comparisons) after Bonferroni correction. iLESSYS, Interlaminar Endoscopic Surgical System; MED, microendoscopic discectomy; ODI, Oswestry dysfunction indexes; VAS, visual analogue scale.

Table IV. Comparison of MacNab evaluation in the two groups.

Groups	n	Excellent	Good	Fair	Poor
iLESSYS Delta	52	29 (55.77)	18 (34.62)	3 (5.77)	2 (3.85)
MED	82	37 (45.12)	36 (43.90)	6 (7.32)	3 (3.66)
$\chi^2$	1.53				
P-value	0.68				

$\chi^2$  test was used to compare between the two groups. Data are shown as n (%). P<0.05 represented significance. iLESSYS, Interlaminar Endoscopic Surgical System; MED, microendoscopic discectomy.

Table V. Results of clinical images study.

Outcome (mm <sup>2</sup> )	iLESSYS Delta (n=52)	MED (n=82)	t-value	P-value
Pre-operation area	55.14±5.27	53.98±5.58	1.19	0.23
Post-operation area	168.96±7.60	170.13±7.23	0.89	0.37
Reduced area	113.82±7.37	116.15±8.31	1.65	0.10

The cross-sectional area of the dural sac was compared using Student's t-tests before and after the operation. P<0.05 represented statistical significance. iLESSYS, Interlaminar Endoscopic Surgical System; MED, microendoscopic discectomy.

the iLESSYS<sup>®</sup> Delta group (83.81±11.07 min) was significantly longer compared with the MED group (58.32±12.30 min). There was no significant difference reported in the time to return to work between the iLESSYS<sup>®</sup> Delta group (10.71±2.17 days) and the MED group (11.44±2.69 days) (Table II).

*Comparison of clinical and functional outcomes.* The average VAS score of back/leg pain following the operation improved in both the MED group and the iLESSYS<sup>®</sup> Delta group was analyzed. The average VAS score of the leg pain was reduced from 7.95±0.99 to 1.71±0.74 in the MED group

and from  $7.71 \pm 0.91$  to  $1.62 \pm 0.74$  in the iLESSYS® Delta group. The average VAS score of the back pain was reduced from  $4.93 \pm 1.04$  to  $1.52 \pm 0.76$  in the MED group and from  $5.13 \pm 1.03$  to  $1.58 \pm 0.70$  in the iLESSYS® Delta group. In addition, the average ODI scores following the operations were also improved; the average ODI score were reduced from  $76.90 \pm 9.43$  to  $28.15 \pm 6.59$  in the MED group and from  $74.62 \pm 9.12$  to  $26.71 \pm 6.45$  in the iLESSYS® Delta group (Table III).

There was also no significant difference found between the two groups for the average VAS score of the leg pain at any time point (Fig. 2A). Notably, the average VAS score of the back pain in the iLESSYS® Delta group was significantly lower compared with the MED group at the 1-week follow-up; however, there was no significant difference between the two groups at both the 6-month and the latest follow-up (Fig. 2B). Similarly, the ODI score in the iLESSYS® Delta group was significantly lower compared with the MED group at the 1-week follow-up; however, there was no significant difference between the two groups at the 6-month and the latest follow-up (Fig. 2C).

Following the application of the modified MacNab criteria, a good-to-excellent evaluation was found in 89.0% of the patients in the MED group, whereas a good-to-excellent rate of 90.4% was found in the iLESSYS® Delta group. There was no significant difference observed between the good-to-excellent rates between the two groups (Table IV).

**Comparison of the CSAD.** There were no significant differences reported in the preoperative CSAD between the two groups. In addition, there were no significant differences observed in the postoperative area and reduced CSAD between the two groups (Table V).

**Comparison of complications and recurrence.** Complications occurred in three patients (3.66%) in the MED group and two patients (3.85%) in the iLESSYS® Delta group. One patient in the MED group experienced transient urinary retention following the operation, which resolved itself with bed rest within 2 days postoperatively. In addition, two patients in the MED group had the procedure converted to open surgery due to a dural tear. One patient in the iLESSYS® Delta group experienced a small sized dural tear (<5 mm) and complained of a headache following the operation, which improved following bed rest and Etoricoxib tablets (60 mg, 1/day; orally). One patient in the iLESSYS® Delta group also complained of postoperative dysesthesia, with these symptoms being reversed following a combination of physical treatment and Mecobalamin Tablets (500 ug, 3/day; orally). No patient in either group presented with complications such as neurological injury, spondylodiscitis, surgical wound infection or cauda equina syndrome. Altogether, there was no significant difference discovered in the complication rates between the two groups.

One patient in the iLESSYS® Delta group and two patients in the MED group who suffered with neurogenic claudication and/or radicular leg pain prior to the surgery, suffered from the same symptoms following the operation. The patients with recurrent neurogenic claudication and/or radicular leg pain were subjected to transforaminal posterior lumbar interbody fusion upon the failure of traditional management regimens.

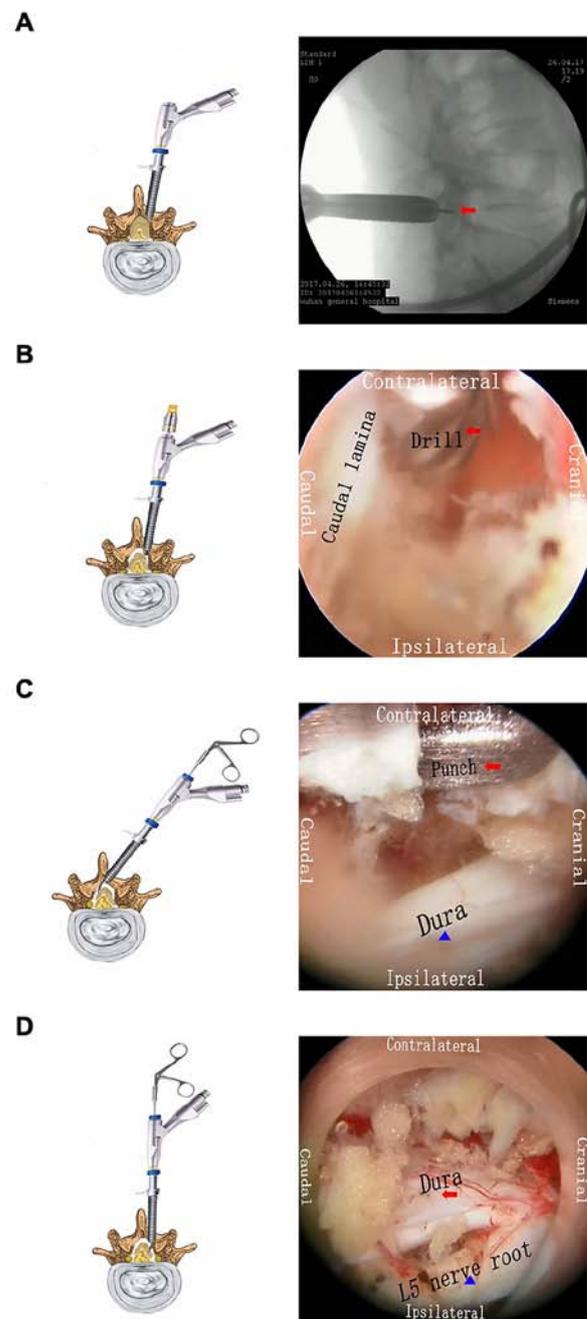


Figure 1. Operative steps of the iLESSYS Delta approach. (A) A working cannula was passed over the dilators and it was positioned into the interlaminar space. The arrow indicates the interlaminar space determined by the C-arm fluoroscopy. (B) A high-speed drill was used for laminotomy. The arrow indicates the high-speed drill. (C) Dorsal decompression of the contralateral dural sac and nerve roots. The red arrow indicates the Kerrison punch (Joimax® GmbH) and the blue arrow indicates the dural sac. (D) Dorsal decompression of the ipsilateral dural sac and nerve roots. The red arrow represents the dural sac and the blue arrow, the nerve roots.

Notably, the symptoms of these patients were successfully alleviated up to the final follow-up. There were no significant differences found in the recurrence rates between the two groups.

**Representative cases.** Representative cases who underwent an operation using the iLESSYS® Delta system are presented.

Table VI. Comparison between the iLESSYS Delta and MED approaches.

Items	iLESSYS Delta	MED
Approach	Interlaminar	Interlaminar
Medium	Water	Air
Incision	Smaller	Small
Puncture site	Paraspinal muscle 1-1.5 cm lateral to the midline	Paraspinal muscle 1.5-2 cm lateral to the midline
Diameter of working tube	13.7 mm	18 mm
Size of Kerrison punch	1.5 and 3 mm	2 and 3 mm
Diameter of burr	4.5 mm	3 mm
Hemostasis instruments	Bipolar radiofrequency, water pressure	Bipolar coagulation, aspirator
Manipulation	One hand	Two hands

iLESSYS, Interlaminar Endoscopic Surgical System; MED, microendoscopic discectomy.

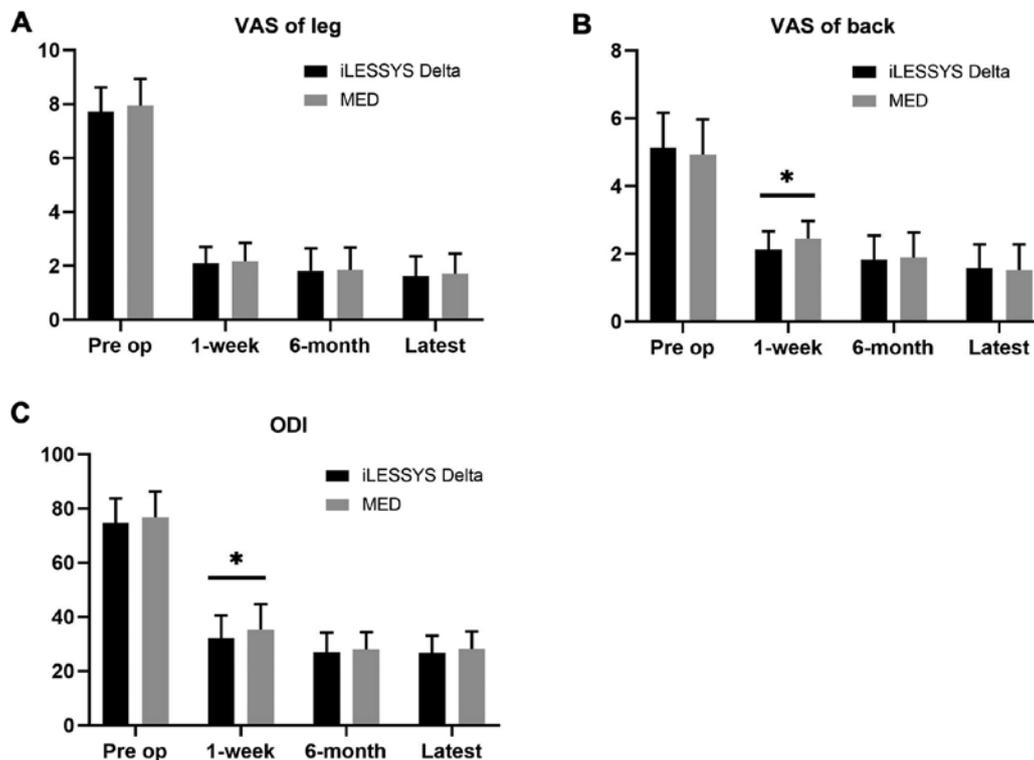


Figure 2. Comparison of the (A) VAS score of the leg, (B) VAS score of the back and (C) ODI at different time points. \* $P < 0.125$ , iLESSYS Delta group vs. MED group. VAS, visual analogue scale; ODI, Oswestry disability index.

Pre- and Post-operative CT and MRI scans (LCSS and LRS at L4/5) were presented in Fig. 3.

## Discussion

The present study aimed to retrospectively compare MED and the iLESSYS<sup>®</sup> Delta system for the treatment of LCSS and LRS. In the General Hospital of Central Theater Command of PLA (Wuhan, China), MED is regarded as a standard minimally invasive treatment option and routinely applied to treat LCSS and LRS. The iLESSYS<sup>®</sup> Delta system is a newly developed endoscopic technique used to treat LCSS and LRS; however, to

the best of our knowledge, no previous studies have compared this technique with MED. Therefore, MED was used as a reference to evaluate the efficiency and safety of the iLESSYS<sup>®</sup> Delta system. The present study aimed to determine the demographic characteristics, operation-related indicators, functional recovery, radiographic changes, the complications, recurrence, efficiency and safety of both MED and the iLESSYS<sup>®</sup> Delta system. The preliminary results demonstrated that the iLESSYS<sup>®</sup> Delta approach may have the potential to treat LCSS and LRS with favorable clinical outcomes compared with MED.

The PELD technique was originally designed to perform disc discectomy (23,24). Compared with traditional open

surgery, favorable clinical results were achieved using this technique to treat DH (25,26). Following the improvement of the PELD technique, the technique has since been expanded from solely treating DH to being used to treat LSS (27). The decompression of the LSS can be performed using either a transforaminal or interlaminar approach. The transforaminal approach is mainly used for the decompression of the LRS and foraminal stenosis, whereas the interlaminar approach is suitable for the decompression of the LCSS and LRS. However, several limitations, such as ineffective surgical instruments and narrow endoscopic vision, have prevented the application of PELD for the treatment of LCSS and LRS. As aforementioned, the iLESSYS® Delta system was subsequently developed from the traditional PELD procedure. The iLESSYS® Delta set contains specially designed instruments to enable a comprehensive decompression of the spinal canal and the size of the working cannula and endoscopic instruments are larger compared with those used in the traditional endoscope system (8,16,17). The 10-mm outer diameter endoscope and 6-mm working cannula used in the iLESSYS® Delta system have been found to provide a broader endoscopic field of view, permitting the use of a larger burr for the resection of osteophytes and more powerful grasper forceps to remove the residual fragments (17). By taking advantage of these advantages, ULBD can be performed under endoscopy using the iLESSYS® Delta system to treat LCSS and LRS.

The surgical principle of the iLESSYS® Delta system is similar to the MED; however, there are still several differences between the two approaches, which have been summarized in Table VI. Firstly, unlike MED, the iLESSYS® Delta approach is performed under continuous saline irrigation, which offers certain advantages (16,28); for example, it has been suggested that the release of inflammatory cytokines may be attenuated by the saline irrigation and that the pressure of the saline solution may reduce the bleeding, ensuring that the surgical field remains clean. In addition, it is easier to resect the LF under endoscopy compared with using MED. It was hypothesized that the infusion pressure of the saline solution may establish a space between the dural sac and the LF (28); however, to the best of our knowledge, no relevant study has been conducted to support this hypothesis. Secondly, the endoscopic instruments are easier to handle using the iLESSYS® Delta system compared with the MED system. In the MED system, the endoscope is fixed firmly in one location with a fixed angle, making the visualization of a desired surgical field difficult. Furthermore, the patient is required to be positioned to the contralateral side to expose the contralateral recess. Meanwhile, in the iLESSYS® Delta system, improved surgical visualization is solely acquired by adjusting the angle of the endoscope (8,16,17). Conversely, an advantage of the MED system is that it is more convenient for surgeons to perform complicated maneuvers, since more surgical devices can be manipulated by two hands concurrently through using the tubular retractor (28).

In the present study, enrolled patients were diagnosed with either LCSS and/or LRS, and a strict inclusion and exclusion criteria were applied to avoid potential selection bias. In total, there were 134 patients (range 53-82 years) with >20-month follow-ups reported. No significant differences regarding the demographic characteristics were found between the two

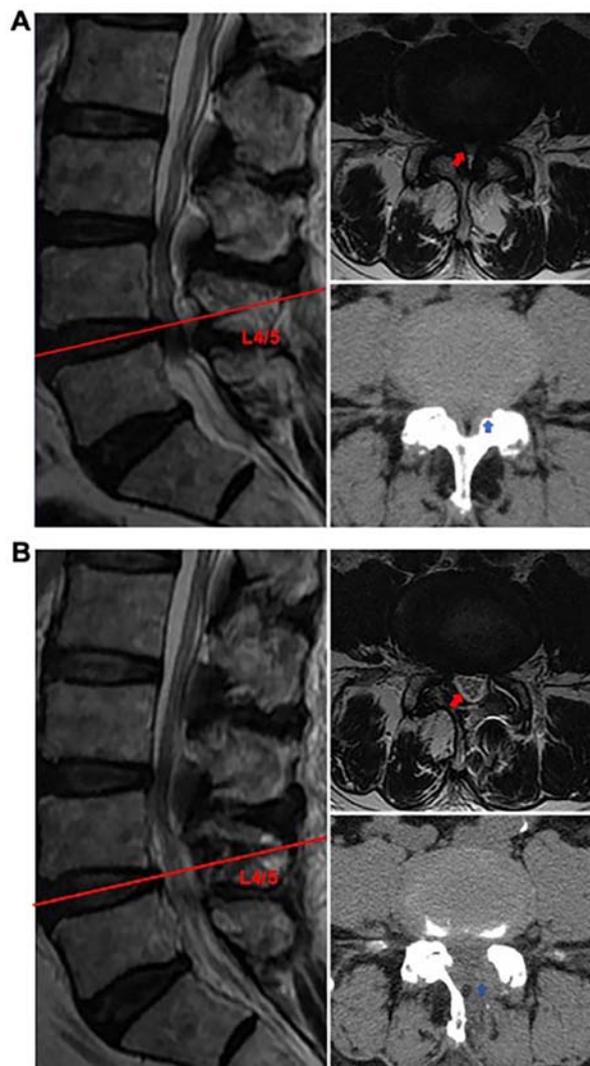


Figure 3. MRI and CT scans of a patient with LCSS and LRS treated with the iLESSYS® Delta approach. (A) Pre-operative CT and MRI scans demonstrated severe LCSS and LRS at L4/5. Red line indicates the L4/5 level. The red arrow indicates the severe dural sac compression and the blue arrow indicates the central stenosis caused by the hypertrophic ligamentum flavum and facet joint. (B) Postoperative MRI and CT scans demonstrated the decompressed dural sac and nerve roots. Red line indicates the L4/5 level. The red arrow represents the decompression of dural sac and the blue arrow represents a portion of the lamina and ligamentum flavum resected by the iLESSYS® Delta approach. iLESSYS, Interlaminar Endoscopic Surgical System; LCSS, lumbar central spinal stenosis; LRS, lateral recess stenosis.

groups. Although comorbidities were common in the present study, they were well controlled for at the study entry and the surgical choices for these patients were not affected. The MISS operation provides an opportunity for older populations with pre-existing comorbidities to undergo the procedure. Compared with the MED group, the incision length in the iLESSYS® Delta group was significantly shorter; however, there was no significant differences found in the time to return to work between the two groups. These findings suggested that operation-related trauma was minimized in both of the two techniques with both techniques having little influence on the postoperative mobility. However, most patients were at retirement age, which may have added bias towards this result. Nonetheless, the duration of the surgery in the iLESSYS®

Delta group was significantly longer compared with the MED duration. It was suggested that this may be due to the more complex procedural steps and the relatively subtle endoscopic manipulation in the iLESSYS<sup>®</sup> Delta group.

Both the VAS and ODI scores of the two groups were improved compared with those at the pre-operative stage. The improvements in the postoperative VAS score for lower back pain and ODI score in the iLESSYS<sup>®</sup> Delta group were significantly decreased compared with the MED group at the 1-week follow-up. This may be explained by the fact that the prolonged tubular retraction in the MED group may result in denervation and ischemia of the paraspinal muscle, causing muscle atrophy and pain following the operation in the MED group (29). Compared with the MED, the damage to the paraspinal muscle caused by the iLESSYS<sup>®</sup> Delta endoscope and working cannula were markedly smaller. In addition, participants experienced greater VAS leg pain relief compared with VAS back pain relief. Although the MISS operation has been discovered to effectively decompress the dural sac and/or nerve roots, it may exaggerate the tendency for spinal instability (30), which is a prominent cause of lower back pain (31). However, in the present study, it was assumed that the patients tolerated the postoperative back pain well, since the patients in both of the two treatment groups returned to work within 2 weeks. The ODI is widely used to evaluate the quality of life of patients following the operation, with a >15% improvement in the ODI representing favorable surgical outcomes (32). A similar change in ODI was observed following both protocols. In addition, it has been reported that the ODI score is strongly associated with the VAS and SF-36 (the MOS 36-item short form health survey) (33), thus the changes in the ODI score may be explained by the corresponding changes in the VAS scores observed in the present study.

The present study also investigated the extent of the spinal canal decompression through evaluating the CSAD using MRI. It has been confirmed that a CSAD of <100 mm<sup>2</sup> is a reliable diagnostic parameter for LSS (34). The average CSAS in both groups were significantly increased after the operation, however, no significant differences in postoperative CSAD were observed between the two groups. Similar results for the postoperative CSAD (145 mm<sup>2</sup>) following MED have also been reported in a previous study (12). Although the diameter of the iLESSYS<sup>®</sup> Delta tubular retractor is smaller than the tubular retractor used in the MED system and markedly less bone resection was performed in the iLESSYS<sup>®</sup> Delta group, an equal post-operative decompression efficiency was still obtained in the current study. Thus, it was suggested that the iLESSYS<sup>®</sup> Delta technique may not only achieve decompression of the spinal canal effectively, but it may also preserve the integrity of the posterior stabilizing structures of the spine. However, a longer-term follow-up study is required to investigate the following biomechanical changes of the spine.

Postoperative dysesthesia is a one of the most frequent complaints in patients treated with spinal endoscopic surgery (6,15,16). It has been suggested that postoperative dysesthesia is due to the temporary compression of the nerve roots and dural sac, which is caused by the frequent mobility of the working cannula during the procedure (35,36). The exposure, stripping or displacement of the nerve roots may promote localized ischemia, followed by mild nerve demyelination. Therefore, it has been suggested that the working cannula should be mobilized

gently during the operation to reduce postoperative dysesthesia. The occurrence of a dural tear (2.24%) in the present study was similar to that reported in previous studies (9,15,37). A total of 2 patients experienced a dural tear in the MED group and in this circumstance, endoscopic surgery was changed to open surgery. In addition, one participant experienced a small-sized dural tear in the iLESSYS<sup>®</sup> Delta group; however, the patient recovered following bed rest without any specific symptoms. As aforementioned, it was hypothesized that the infusion pressure of the saline solution in the iLESSYS<sup>®</sup> Delta system may prevent the occurrence of a dural tear. However, the occurrence of dural tears between the two groups was not significant. In addition, there were three patients (2.24%) who suffered from reoccurrence, one in the iLESSYS<sup>®</sup> Delta group and two in the MED group, which may have been due to the following reasons: Recurrent stenosis and a progressive slip after laminectomy (38,39) or the incomplete decompression of the spinal canal during the operation (30,40).

Several limitations exist in the present study. Firstly, this was a retrospective study without random assignment and a small cohort of patients. A randomized, prospective study with a larger sample size will therefore be required to confirm these findings. Secondly, the follow-up period was insufficient to evaluate the potential spinal instability following the MISS operation. Thirdly, all the procedures were performed by the same experienced surgeon; therefore, a multi-center study with surgeons at various levels should be conducted in the future to determine the clinical outcomes between the two techniques.

In conclusion, the iLESSYS<sup>®</sup> Delta approach was found to be comparable to the MED approach for the treatment of LCSS and LRS, exhibiting precise and limited decompression. Moreover, the iLESSYS<sup>®</sup> Delta technique was revealed to have several advantages, including minimal short-term post-operative back pain and a faster recovery rate compared with MED. As the iLESSYS<sup>®</sup> Delta approach was found to be safe and exhibited effective results for the treatment of LCSS and LRSS, it may be regarded as an effective treatment alternative for the treatment of LCSS and LRS.

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### Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

### Authors' contributions

BW, CX and FX have made substantial contributions to the conception and design. HK, CX and BW was involved in

drafting the manuscript or revising it critically for important intellectual content. FX and HK performed the operation. LT and DZ collected and analyzed the data. All authors read and approved the final version of the manuscript.

### Ethics approval and consent to participate

All the procedures in the present study were approved by the Ethics Committee of the General Hospital of Central Theater Command and were in accordance with the Helsinki Declaration. Written informed consent was obtained from each patient.

### Patient consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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