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ORIGINAL ARTICLE

Early outcomes of 270-degree spinal canal decompression by using TESSYS-ISEE technique in patients with lumbar spinal stenosis combined with disk herniation

Chengjie Xiong[1] · Tao Li[2] · Hui Kang[1] · Hao Hu[1] · Jing Han[1] · Feng Xu[1]

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Abstract

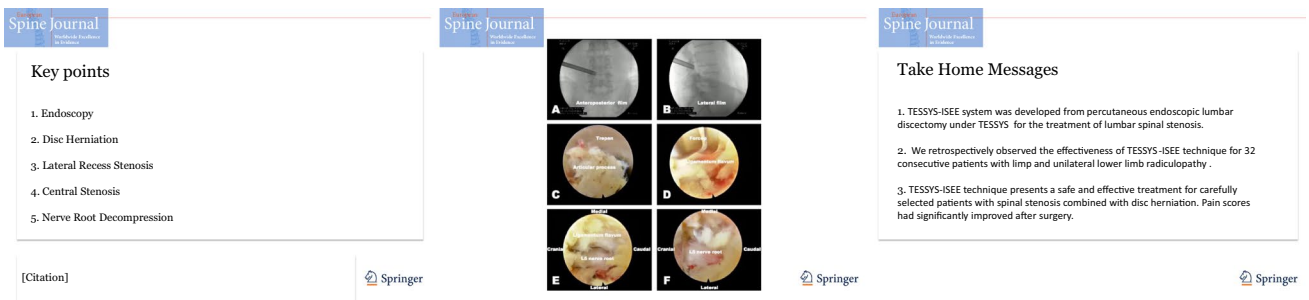
Purpose Traditional open approach is an efficient way to treat lumbar spinal stenosis (SS) combined with disk herniation (DH); however, risk factors such as advanced age, osteoporosis etc. are associated with the complications after the surgery. This study aims to analyze the early clinical and radiological outcomes of treatment on SS&DH by using newly developed minimal invasive TESSYS-ISEE technique.

Methods Patients with limp and unilateral lower limb radiculopathy underwent minimal invasive surgery by using TESSYS-ISEE technique. The visual analogue scale score (VAS) and Oswestry Disability Index (ODI) were evaluated before operation and 1, 3, 6 and 12 months after surgery. The clinical global outcomes were also evaluated using modified MacNab criteria after surgery.

Results A total of 32 cases underwent operation by using TESSYS-ISEE technique from December 2016 to December 2017. The mean age for the study group was 53.9 ± 11.14 years and the ratio between male and female was 1.29:1; Mean follow-up of the study was 7.78 ± 3.48 months and mean estimated blood loss was 11.41 ± 4.79 mL per-level. VAS leg score improved from 8.44 ± 0.98 to 2.18 ± 0.75 ($P < 0.001$), VAS back score improved from 4.44 ± 0.95 to 1.57 ± 0.54 ($P < 0.001$), and ODI improved from 73.88 ± 5.95 to 29.04 ± 7.48 ($P < 0.001$). The success rate was 90.7%. There were no serious complications during follow-up. Two patients experienced dysesthesia and one patient required revision surgery.

Conclusions It is safe and minimal-invasively to treat SS&DH by using TESSYS-ISEE technique. However, potential complications still require careful consideration and further evaluation.

Graphical abstract These slides can be retrieved under Electronic Supplementary material.



Dr. Chengjie Xiong and Dr. Tao Li contributed equally to this work

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Extended author information available on the last page of the article

Keywords Endoscopy · Disk herniation · Lateral recess stenosis · Central stenosis · Nerve root decompression

Introduction

The lumbar spinal stenosis (SS) is usually caused by the hypertrophy of ligament flava (LF) combined with intervertebral disk (IVD) herniation, which may lead to chronic low back pain (LBP) and sciatica. The purpose of treatment for SS is to allow the patient to walk normally without pain. When the non-surgical treatment is failed, the surgical treatment is considered [1, 2].

After the minimally invasive spinal surgery (MISS) was applied, the performance of microendoscopic discectomy (MED) was reported by Foley and Smith [3]. With the development of MED, the SS can be treated via a unilateral approach to achieve bilateral decompression and spinal canal enlargement [4]. Later, more less-invasive techniques, percutaneous endoscopic lumbar discectomy (PELD), were introduced by Yeung et al. and applied to treat disk herniation [5]. PELD is less invasive than MED for selected patients with lumbar disk herniation [6]. With the development of PELD, which can also be used to treat SS favorably, Kim et al. have gained good clinical outcomes in patients with SS by applying percutaneous full endoscopic technique [7, 8].

PELD under the transforaminal endoscopic spine system (TESSYS) was designed to remove herniated disk tissues by expanding foramen. Although TESSYS technique can effectively decompress anterior herniated disk, it failed to achieve adequate posterior decompression when disk herniation is combined with LF hypertrophy. Aiming to counter the disadvantage of TESSYS technique, TESSYS-ISEE system was developed to treat SS.

In this study, the ventral portion of articular joint was resected by a special designed trepan to obtain enough exposure. Nucleus forceps was applied to remove hypertrophied LF thoroughly and then to resect the anterior herniated disk by moving the tube under the endoscopic system. This paper reports on the preliminary results of the clinical application for TESSYS-ISEE system in patients with SS combined with disk herniation (DH).

Materials and methods

Between December 2016 and December 2017, 32 patients were treated with PELD under TESSYS-ISEE system. All the procedures were approved by the Wuhan general hospital of PLA Ethics Committee and were under Helsinki Declaration. Written informed consent was obtained from each subject. The indications were defined as follows: (1) patients who were diagnosed with degenerative lumbar SS (central with/without lateral recess stenosis); (2) patients who were diagnosed with disk herniation; (3) patients who complained about limp and sciatica; (4) patients who accepted non-operative treatments (medications or physical therapy) for more than 6 months. Specifically, the severity of SS based on morphology of the dural sac on the axial magnetic resonance imaging (MRI) was applied in our study [9]. The severity of SS was divided into 4 grades (Grades A, B, C and D). Cerebrospinal fluid was presented in Schizas Grades A and B, and was not presented in Schizas Grades C and D. Only patients with Schizas Grades C and D were included in our study. The contraindications were: (1) patients with segment instability (more than Grade II spondylolisthesis [10] or dynamic instability [11]); (2) patients combined with inoperable medical disease; (3) patients with peripheral nerve disease.

Surgical technique

All procedures were carried out via the transforaminal endoscopic spine system (Joinmax, Karlsruhe, Germany). Special instruments for the foraminoplasty were designed and constructed (Fig. 1). Neural foramen was expanded after the osteophyte was removed, and the schematic diagram of the foraminoplasty is shown in Fig. 2.

All patients underwent surgery in the prone position, the entry point was usually superior to the iliac crest and 10–14 cm lateral from the midline. After local anesthesia with 1% lidocaine, an 18-gauge spinal needle was then inserted into the superior articular process at an angle of 25°–30° to horizontal plane under the fluoroscopy guidance. The surgical procedure was performed as below: (1) a guide wire was passed through the needle, and the needle was removed; (2) a skin cut (1.5 cm) was made

Fig. 1 Instruments designed for the foraminoplasty. **a** A half-serrated working cannula was applied as an anchor on the articular process, **b** a special trepan was designed for the removal of osteophyte through the cannula under the endoscopic system and **c** a sharp, bevel-ended working cannula was applied for the nerve root decompression

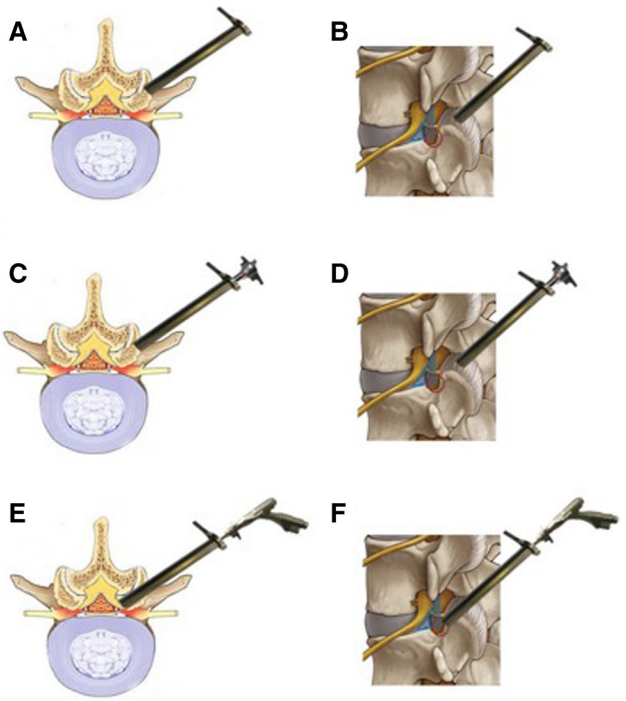

Fig. 2 The foraminoplasty of the superior articular process of L5. A half-serrated working cannula was placed and located on the superior articular process of L5 (**a**, **b**), a serrated trepan was introduced along the working cannula for the foraminoplasty (**c**, **d**), the trepan was then rotated clockwise a few turns with endoscopic system, and a column-like bone was removed by the trepan from the superior articular process of L5 (**e**, **f**). Cross-sectional image is shown in (**a**, **c** and **e**), and sagittal image is shown in (**b**, **d** and **f**)

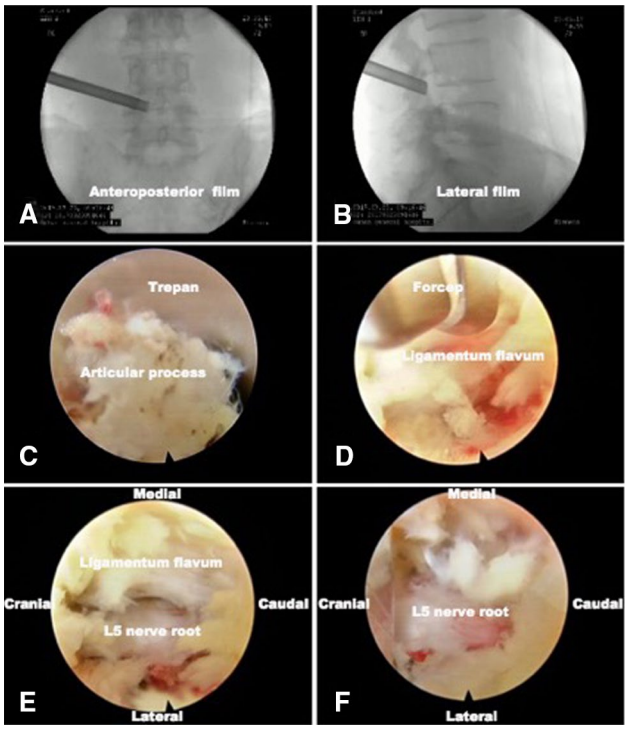

Fig. 3 The resection of LF. Illustration of the location of half-serrated working cannula using fluoroscopy is shown in (**a**, **b**). Anteroposterior image is shown in (**a**) and sagittal image is shown in **b** before endoscopic manipulation, **c** the column-like bone was removed by the trepan, and floated in it under the endoscopic system, **d** forceps were introduced by the bevel-ended working cannula into the space between bone and LF, **e** the LF was largely removed by forceps, and L5 nerve root was visualized and **f** the completion of the dorsal nerve root decompression. *LF* ligamentum flavum

at the entry point of the guide wire; (3) a cannulated obturator was inserted along the guide wire and directed toward the superior articular process; (4) a half-serrated working cannula was introduced over the obturator, which was then removed; (5) a trepan was introduced along the half-serrated working cannula; (6) an endoscope with an eccentrically placed 2.7-mm working channel and two irrigation channels was inserted; (6) ventral osteophyte on superior articular process were resected by the trepan and removed by forceps under endoscope (Fig. 2); (7) after the foraminoplasty, forceps were applied to remove the ipsilateral LF; (8) A sharp, bevel-ended working cannula was altered and directed toward annulus; (9) After the re-fluoroscopy for the location of the working cannula, the disk discectomy was performed; (10) annuloplasty was conducted by a bipolar radiofrequency (60°–65°); (11) the endoscope was withdrawn after the neural root was free from the compression (Figs. 3, 4). 270-degree Spinal Canal can be decompressed (Supplementary Fig. 1).

Outcome measures

The radiological outcomes were evaluated by X-ray, computed tomography (CT) and MRI. The clinical outcomes were evidenced by average visual analogue scale (VAS), Oswestry Disability Index (ODI) and Modified MacNab criteria [12] (Table 1). Walking distance and standing-time were measured (Supplementary Tables 1 and 2). All variables were collected at 1, 3, 6, 12 months after the surgery.

Statistical analysis

The Student's *t* test and Mann–Whitney U test were performed to analyze the variables by SPSS 17.0 software (SPSS Inc, Chicago, USA). *P* value of <0.05 was considered as significant.

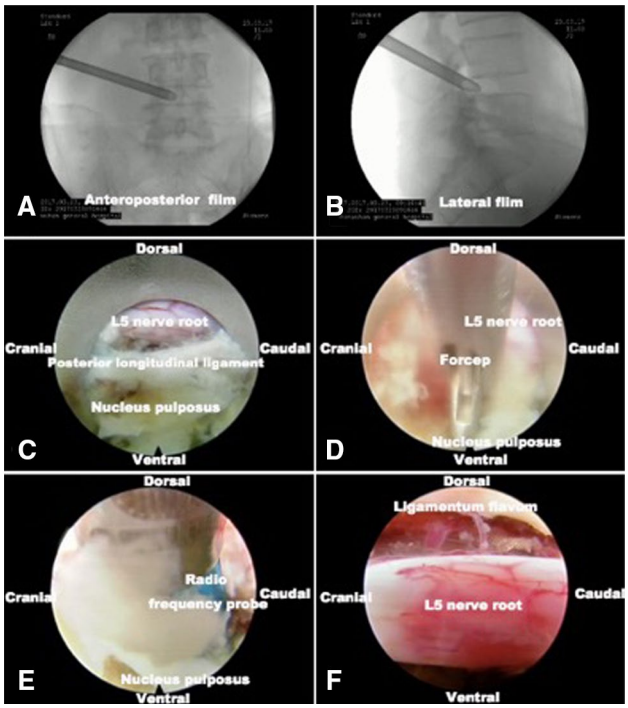

Fig. 4 The discectomy of L4/5 intervertebral disk. Illustration of the location of the working cannula using fluoroscopy is shown in (**a**, **b**). Anteroposterior image is shown in (**a**) and sagittal image is shown in (**b**) before endoscopic manipulation, **c** L5 nerve root, PLL and NP were visualized under the endoscopic system through the adjustment of the working cannula toward to the annulus, **d** forceps was introduced by the working cannula into the spinal column, and removed the herniated disk, **e** a radio frequency probe was introduced for the annuloplasty and **f** dorsal and ventral L5 nerve roots were fully decompressed. *PLL* posterior longitudinal ligament, *NP* nucleus pulposus

Table 1 Modified MacNab criteria

Outcome	Description	*n* (%)
Excellent	Complete relief of symptoms	14 (43.8)
Good	Marked improvement but occasional pain	15 (46.9)
Fair	Improved functional capacity and the need for pain medications	2 (6.2)
Poor	Unimproved symptoms or worsening	1 (3.1)

Results

Preoperative demographic characteristics and outcomes

The mean age of patients underwent the procedure was 53.9 years old (34–73), and the average duration of symptoms was 12.5 months (3–25). Nineteen males and 14 females were enrolled. There were five cases with grade I spondylolisthesis; however, no instability in the dynamic X-ray was observed. There were 19 cases with stenosis at L4/5 and 13 cases with stenosis at L5/S1. No SS at two levels was operated. There were 13 cases with central stenosis and 10 cases with lateral recess stenosis, and there were nine cases with stenosis of both. There were 19 cases with Schizas Grade C and 13 cases with Schizas Grade D. The average follow-up period was 7.8 months (3–12). The mean operation time was 89.7 min (60–120), and the blood loss was 11.4 mL (5–20). The mean hospital stay was 4.8 days (3–7) (Table 2).

Clinical results

Modified MacNab criteria were applied, and good-to-excellent rate in patients was 90.7%. Two patients had fair results, and one patient who underwent reversion surgery was rated poor. The details of the outcomes are shown in Table 1.

VAS of the leg decreased significantly after the operation from 8.44 ± 0.98 to 2.44 ± 0.98 and was 2.18 ± 0.75 at the latest follow-up (Fig. 5a). VAS of the back also decreased significantly after the operation from 4.44 ± 0.95 to 1.94 ± 0.67 and was 1.57 ± 0.54 at the latest follow-up (Fig. 5b). ODI also improved significantly, from 73.88 ± 5.95 to 28.62 ± 3.73 immediately after the operation and was

Table 2 Demographics of this study

	Median (range) or *n* (%)
Age (years)	53.9 (34–73)
Sex (male)	18 (56.3)
Duration of symptoms (months)	12.5 (3–25)
Levels involved	
L4–L5	19 (59.4)
L5–S1	13 (40.6)
Type of stenosis	
Central stenosis	13 (40.6)
Lateral recess stenosis	10 (31.3)
Central stenosis combined with lateral recess stenosis	9 (28.1)
Schizas grade C	19 (43.8)
Schizas grade D	13 (56.2)
Number of levels operated	
One level	32 (100)
Two levels	0(0)
Spondylolisthesis	
Grade 0	27 (84.4)
Grade 1	5 (15.6)
Follow-up (months)	7.8 (3–12)
Blood loss (mL)	11.4 (5–20)
Duration of surgery (min)	89.7 (60–120)
Hospital stay (days)	4.8 (3–7)

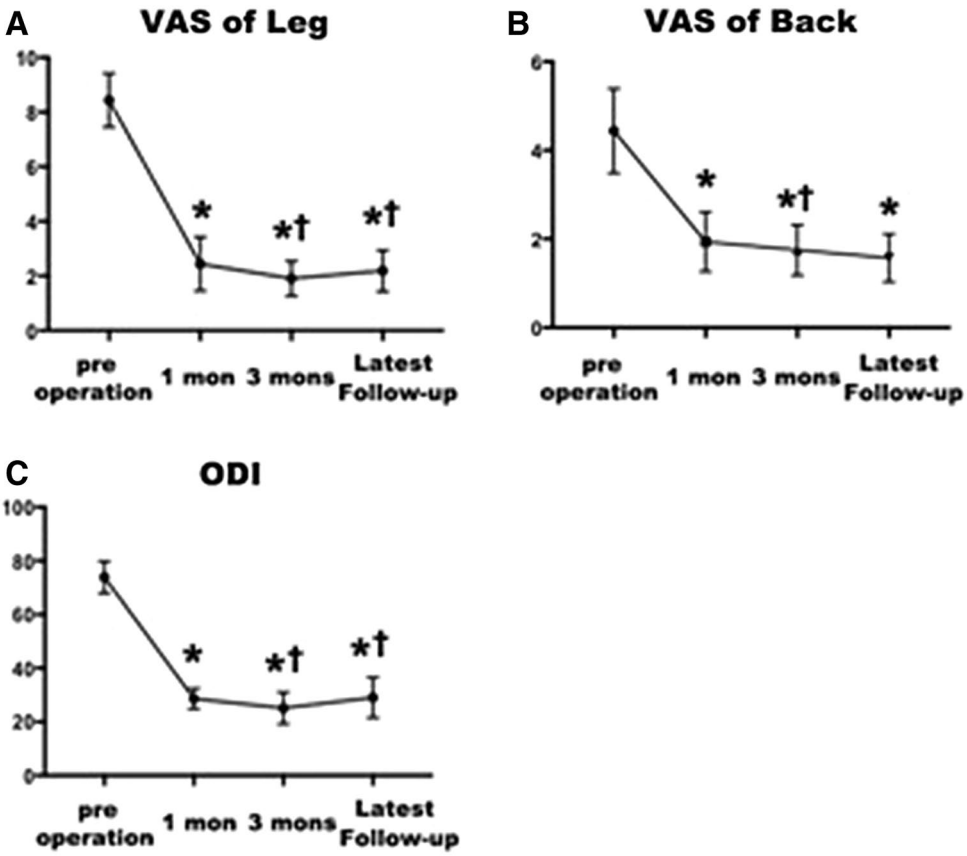

Fig. 5 Comparison of VAS score of leg (**a**), VAS score of back (**b**) and ODI (**c**) at different time points. *VAS* visual analogue scale, *ODI* Oswestry Disability Index, *Mon* month. *$P < 0.05$ versus Pre-operation group. †$P < 0.05$ versus the corresponding last follow-up group

Table 3 VAS and ODI improvements

Follow-up	Median (range)	*P* value
VAS of Leg (0–10)		
Pre-operation	8.44 (7–10)	
1 month after operation	2.44 (1–5)	< 0.01
3 months after operation	1.9 (1–3)	< 0.01
Latest follow-up	2.18(1–6)	< 0.01
VAS of back (0–10)		
Pre-operation	4.44 (2–7)	
1 month after operation	1.94 (1–4)	< 0.01
3 months after operation	1.75 (1–3)	< 0.01
Latest follow-up	1.57 (0–2)	< 0.01
ODI (0–100)		
Pre-operation	73.88 (63–84)	
1 month after operation	28.62 (19.8–36)	< 0.01
3 months after operation	25.12 (16.2–40)	< 0.01
Latest follow-up	29.04 (14.4–56)	< 0.01

ODI Oswestry Disability Index, *VAS* visual analogue scale

*$P < 0.01$, compared with pre-operation group

29.04 ± 7.48 at the latest follow-up (Fig. 5c). The details are shown in Table 3. Both walking distance and standing-time increased significantly after the operation (Supplementary Tables 1 and 2).

Complications and recurrence

Complications occurred in two patients (9.4%). Two patients experienced dysesthesia in the area distribution of the ipsilateral neighboring exiting nerve root. Their symptoms were recovered after physical treatment combined with nerve regenerative medicine. There were no major complications such as neuro-vascular injury, cauda equina injury and surgical wound infection.

Only one patient with sciatica suffered from the same symptom after 6 months. The patient with recurrent sciatica was subjected to transforaminal posterior lumbar interbody fusion (TLIF) when non-surgical management has failed. The sciatica of this patient had been relieved until the final follow-up.

Representative cases

Representative cases are illustrated in Fig. 6.

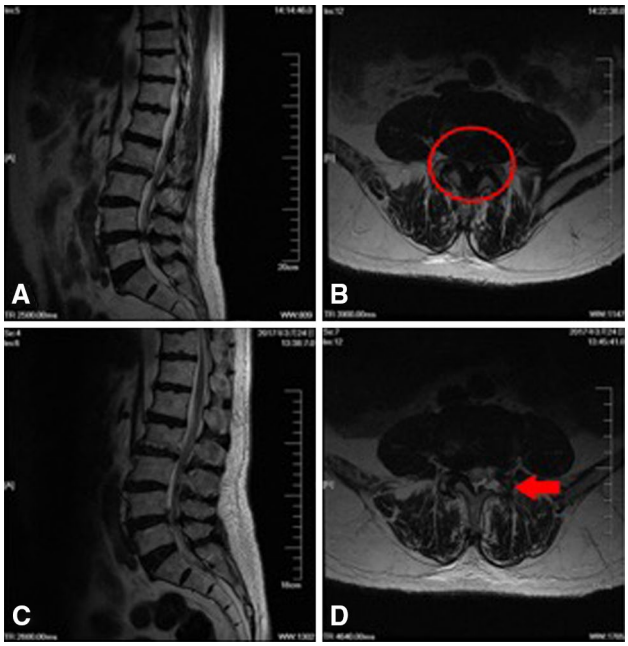

Fig. 6 CT scan and MRI of a case with lumbar stenosis treated with TESSYS-ISEE system. **a**, **b** Preoperative MRI. **c**, **d** Post-operative MRI showing dorsal and ventral decompression of L5 nerve roots. The stenosis combined with DH was indicated by red circle in (**b**), and the removal ventral osteophyte of articular process of L5 was indicated by red arrow in (**d**). *MRI* Magnetic Resonance Imaging, *DH* disk herniation

Discussion

The goal of this retrospective research was to introduce a new mini-invasive TESSYS-ISEE system for the SS&DH. Selective screening subjects were involved in our study. Although most of our patients experienced symptom relief following this new procedure, however, complications still occurred. However, the reasons for these complications might shed light on the future improvement for this new technique. The preliminary results demonstrated that TESSYS-ISEE system was a feasible and safe way to treat SS&DH.

Usually, non-operative therapy should be thoroughly tried before a surgical strategy is considered. The traditional procedure is consisted of the decompression of nerve roots and the correction of a fixed three-dimensional deformity [13]. However, open surgery for lumbar SS remains challenging. Disadvantage factors, such as advanced age, osteoporosis and loss of lordosis might lead to poor clinical outcomes [14, 15]. Moreover, some patients complained of residual axial LBP after instrument implantation [16].

It is widely accepted that the degree of spinal instability is dependent on the extent of resection of articular joint and ligamentous tissues [17]. Comparing the surgical treatment of SS with traditional open approach for instrumented posterior lumbar interbody fusion, the minimal invasive TESSYS-ISEE approach not only reduced the injury by surgery but also preserve the biomechanical structure of the affected segment. MED, as a standard MISS technique, can also be applied to treat SS with limited decompression. Studies have reported that bilateral decompression using MED instrumentation can be performed via a unilateral approach [4, 18]. By using this technique, the spinal canal enlargement was mainly dependent on the dorsal decompression, which was performed by laminotomy and undercutting. On the other hand, by using TESSYS-ISEE approach, the dorsal decompression was achieved by the partial resection of ventral superior articular process and LF; however, the structure of the facet joint capsule is still intact (Fig. 2). It seems like that more structure was preserved in our study, and MED approach provided more space for the affected spinal cord and nerve roots. M Castro-Menendez et al. have reported that the mean decrease of ODI was 34.3 points and the mean decrease of VAS for leg and back were 6.2 points and 1.6 points in patients with SS by using MED approach [19]. Yagi et al. have found that satisfactory neural decompression and symptomatic relief were obtained in 90% of patients with SS by MED [18]. However, similar functional improvement was achieved in our study. The good–excellent rate was 90.7%, the mean decrease of ODI was 44.8 points, and the mean decrease of VAS for leg and back was 6.3 points and 2.9 points in our study. It would be necessary to compare the long-time clinical outcomes and post-operative spinal stability of TESSYS-ISEE with that of MED in the future.

In this study, traditional TESSYS technique of PELD can be applied to treat disk herniation and decompress the lumbar nerve roots affected by herniated disks. However, dorsal structures such as LF are also involved in SS [20]. Both ventral and dorsal nerve decompression should be performed. TESSYS technique was not designed to resect LF and decompress dorsal nerve roots. TESSYS-ISEE technique was then developed to combine ventral and dorsal approach for the SS. However, TESSYS-ISEE technique was totally different from the TESSYS technique. The conception of TESSYS-ISEE technique was based on principle of traditional surgical approach. The surgical decompression of dural sac or nerve roots starts from the dorsal bony-plasty. The “bone window” was open under endoscopy to provide more space for the surgical manipulation. We then can resect targeted hypertrophied LF (Fig. 2). Besides, we should realize that there is usually not too much room between LF and underlying dural sac. Aggressive manipulation might cause dural tears or nerve roots injury. After that, we performed the ventral decompression. The transition from the dorsal side to the ventral side might pose potential risks of dural tears. Since natural protective obstacles, such as posterior bony structure and LF, were resected, the movement of working cannula in the spinal column can result in injury to

dural sac. We advised surgeons without too much experience to perform the ventral decompression step by step according to the principle of TESSYS technique. It would take more time, but it is safer. Certainly, with the accumulation of experience, surgeons can move the working cannula from the dorsal side to the ventral side under endoscopy directly (Supplementary video file). On the contrary, the surgical decompression starts from the disk discectomy by using TESSYS technique. However, there is not much room left for the dorsal decompression without the "bone window". So, MISS surgeons, especially those without training in open surgery, should be familiar with posterior anatomy of the spinal column, and cautious about potential risks or complications before carrying on this new technique. We have to admit that ipsilateral decompression of the bilateral lateral recess and foramen cannot be achieved by using TESSYS-ISEE technique. Therefore, indications were restricted to patients with SS&HD, who usually had a history of limp and unilateral lower limb radiculopathy. Specifically, the patients with central stenosis, lateral recess stenosis and combined stenosis were included in our study, and the ratio of patients with lateral recess stenosis was 31.3%. The lateral recess stenosis is commonly caused by disk herniation or hypertrophy of LF or joint capsule. Usually, the patients with lateral recess stenosis are younger than that with central stenosis reported in studies [21, 22]. Secondly, in order to comply with the indication to obtain optimized clinical results, only patients with limp and sciatica were included in our study, and some symptomatic elderly patients without sciatica might be excluded. Thirdly, this is a 1-year short-term study with only 32 patients included, and it might confound some of the observed results. We speculated that age factor in our study might affect the complication profile, since the occurrence of dural tears increased in the elderly population who received surgical intervention. In this perspective, it would be interesting to conduct a study to evaluate the clinical outcomes of patients over 70 years by using TESSYS-ISEE technique.

Transforaminal and interlaminar approaches provide two options of full endoscopic techniques for lumbar spine surgery. However, there is a clear differentiation between transforaminal and interlaminar approaches. With the transforaminal approach, the working channel can reach the spinal canal under continuous visualization, however, the osteophyte at the foramen and the exiting nerve roots can limit the mobility of the working channel. Moreover, the pelvis, especially at L5/S1 level, may block access of working channel [23, 24]. Therefore, the interlaminar approach was then developed to perform discectomy that cannot be achieved by transforaminal approach [25]. The interlaminar approach is effective in performing dorsal decompression. However, there are still limitations for this technique. Similar to laminotomy, extensive exposure of the dural sac is necessary for the decompression of the lateral recess, and it may increase the risk of dural sac injury [26]. Moreover, because the dural sac may be irritated during this operation, the local anesthesia is not sufficient and the general anesthesia is required. Usually, the interlaminar approach is suitable for the decompression of central with or without lateral recess stenosis; the transforaminal approach is applied to lateral recess stenosis and/or foraminal stenosis. However, with the development of instrumentation, these techniques are evolving rapidly. Previous indications might change into indications. Kim et al. have also conducted a study to treat later recess and foraminal stenosis by percutaneous endoscopic contralateral interlaminar lumbar foraminotomy [8]. Likewise, central stenosis can also be treated by transforaminal approach in our study. However, a steep learning curve needs to be overcome, and most surgeons are still unfamiliar with these new techniques. However, once these techniques are mastered, reliable clinical outcomes can be expected.

Patients with SS usually complained of limp and leg pain. The neuro-compressive phenomenon is associated with lumbar stenosis. Hamanishi et al. have demonstrated that 90% of patients with SS symptoms had a cross-sectional area of spinal canal less than 100 mm^2 at least two levels [27]. The limp can be relieved by augmenting the cross-sectional area of the spinal canal. Weiner et al. have demonstrated that patients with 50% reduction in cross-sectional area showed favorable outcome [28]. Although the cross-sectional area was not measured in our study, we removed the dorsal and ventral structures around the affected nerve root, and 270° of spinal canal area can be reduced. The cross-sectional area of spinal canal was obviously enlarged, even though contralateral decompression was not performed (Fig. 2). We attributed the relief of limp symptoms to the cross-sectional area enlargement of the spinal canal.

There are always risks and potential complications with the introduction of new technique. Firstly, post-operative dysesthesia often occurred in PELD via transforaminal approach. We had two patients of dysesthesia [29]. The common reason for dysesthesia is approach-related irritation of the exiting nerve root, which is usually caused by excessive intraoperative manipulation of instruments or laser. Fortunately, two patients' symptoms were relieved after physical and drug treatment. We speculated that nerve fiber swelling caused by the irritation of instruments disappeared. Reduced and precise intraoperative manipulation of instruments would be helpful in reducing symptoms of dysesthesia. Secondly, as we mentioned above, transforaminal approach is not appropriate for the central stenosis. Although this modified transforaminal approach provide the sufficient surgical filed for the dorsal decompression of the spinal canal, we still should recognize that the insufficient resection of dorsal structure, such as hypertrophied facet and LF, might lead to poor outcomes

after operation. However, extensive exposure and resection of dorsal structure might affect the spinal stability in long term, even though we can obtain relatively favorable functional recovery in short term. Last but not least, the switch of instrumentation from the dorsal structure to ventral structure posed potential risks of nerve roots injury. Since original anatomical structure was altered, the unexpected mobility of working channel might compress and even injure exposed dural sac or nerve roots. The surgeon should be familiar with transforaminal approach and reduced unnecessary intraoperative manipulation as much as possible. Only one patient (recurrent rate = 3.13%) complained of recurrent sciatica in the follow-up. After the operation, this patient remained symptom-free until 6 months later, when sciatica recurred. We attributed the reason for recurrence to the heavy work engagement without any lumbar brace protection. In our experience, postoperative extended bed rest and good lumbar protection support are important for the prevention of recurrence. PELD approach poses challenges to surgeons. Complications occurred during the learning curve. However, complications can be minimized by increased surgical experience and rigorous surgical techniques.

A 3-point improvement for the VAS and a 12-point improvement for the ODI were regarded as the minimum clinically important difference [30]. The results in Modified Macnab Criteria were good–excellent for 31 patients (90.7%). Kim et al. obtained improvement in 92.3% patients using percutaneous endoscopic contralateral interlaminar lumbar foraminotomy [8]. Komp et al. have reported that 93% patients got improvement by using full endoscopic uniportal bilateral decompression [31]. However, there was a significantly difference in VAS and ODI scores between the 3 months post-operation group and the latest follow-up group (Fig. 5). The reason might be due to that some patients with good clinical relief was lost to the latest follow-up, however, a longer and larger-scale follow-up was necessary for better evaluation of clinical outcomes. Although this is a preliminary study, the TESSYS-ISEE technique seems promising for the treatment of SS combined with DH in the SS patients with relatively younger age (average age: 53 years). However, for the better evaluation of the functional recovery, some important assessment questionnaire, such as Zurich claudication score, should be added in the future work.

In conclusion, it is safe and minimally invasive to achieve adequately decompression of SS&DH in the SS patients with relatively younger age by using TESSYS-ISEE technique. However, there are still risks and potential complications with the application of this technique. Long-term biomechanical changes and clinical outcomes following the operations should be paid attention to.

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Authors contribution CX and FX worked on conception and study design. HK and HH performed the operation. CX played a role in data analysis and interpretation. TL and JH drafted the manuscript. All authors played a role in critical review and revision of final manuscript for important intellectual content.

Conflict of interest No conflict of interest was declared.

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Affiliations

Chengjie Xiong[1] · Tao Li[2] · Hui Kang[1] · Hao Hu[1] · Jing Han[1] · Feng Xu[1]

✉ Chengjie Xiong
cjxiong1110@gmail.com

✉ Feng Xu
fengxu1969@163.com

[1] Orthopaedic Department, Wuhan General Hospital of PLA, #627 Wuluo Road, Hongshan District, Wuhan, Hubei, China

[2] Orthopaedic Department, Hubei Province Traditional Chinese Medicine College, Wuhan, China