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CLINICAL ARTICLE

Clinical Outcomes and Quality of Life in Elderly Patients Treated with a Newly Designed Double Tube Endoscopy for Degenerative Lumbar Spinal Stenosis

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Abstract

Objective: To evaluate the clinical outcome and quality of life in elderly patients in poor conditions with unilateral symptomatic degenerative lumbar spinal stenosis (DLSS) who were treated with percutaneous endoscopic lumbar discectomy (PELD) assisted by double tubes.

Methods: This study was designed retrospectively. From June 2017 to June 2018, 31 consecutive elderly patients who were presented with unilateral symptomatic DLSS, underwent PELD assisted by double tubes under local anesthesia. American Society of Anesthesiology score (ASA) was used to evaluate the patients' conditions. The operative time, intraoperative blood loss, hospital stay, and complications were evaluated. Clinical outcomes were assessed by the visual analog scale (VAS), Oswestry disability index (ODI), and modified Macnab criteria. Short Form 36 (SF-36) was used to evaluate the life quality. The CT or MRI was used to evaluate the spinal area.

Results: Thirty-one patients were enrolled and 25 cases achieved at least a 24-month follow-up. Three patients were lost to follow-up and three patients died from other diseases. A total of 76% (19/25) of the patients presented an ASA score of more than 3. The mean operative time was 67.80 min, the mean blood loss was 18.2 ml, and the hospital stay was 6.92 days. The postoperative 12-month follow-up VAS score significantly decreased compared with that before the operation $(1.12 \pm 0.73 \text{ vs.} 5.12 \pm 1.81, p < 0.01)$. Although the VAS score decreased at the final follow-up, there was no significant difference compared with that at the 12-month follow-up ($0.92 \pm 0.64 \text{ vs.} 1.12 \pm 0.73, p = 0.549$). So did the ODI. Also, there was no difference in the ODI scores between the 12-month follow-up and the final follow-up ($12.52 \pm 5.58 \text{ vs.} 9.44 \pm 6.32, p = 0.172$). The overall excellent rate was 92% (23/25) at the final follow-up. The scores of the physical function, mental function, and social function of SF-36 after the operation improved significantly compared with those before operation (p < 0.05). But there was no difference in the physical function score ($84.00 \pm 6.29 \text{ vs} 84.40 \pm 6.18$, p = 0.871), mental function score ($81.76 \pm 8.01 \text{ vs} 81.68 \pm 6.67, p = 0.974$), or social function score ($115.50 \pm 13.64 \text{ vs} 118.50 \pm 12.03, p = 0.437$) between the 12-month follow-up and the final follow-up. There were no differences in the VAS, ODI, and SF-36 between the $1_{4/5}$ and L_5S_1 groups before operation or at the final follow-up. There were no differences in the VAS, ODI, and SF-36 between the $1_{4/5}$ and L_5S_1 groups before operation or at the final follow-up (p > 0.05). The postoperative radiology indicated the lateral recess is opened and the area of the dural sac is expanded. Two cases (8.0%, 2/25) experienced recurrence and a secondary PELD was performed.

Conclusions: PELD assisted by double tubes is effective for unilateral symptomatic DLSS in elderly patients with comorbidities and could improve life quality.

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DOUBLE TUBES FOR DLSS

Key words: clinical outcomes; degenerative lumbar spinal stenosis; double tubes; elderly patient; life quality; percutaneous endoscopic lumbar discectomy

Introduction

D egenerative lumbar spinal stenosis (DLSS) is usually associated with degenerative changes in intervertebral discs, zygapophyseal joints, and ligamentum flava and osteophyte formation.¹ DLSS usually occurs in the elderly population and causes a poor quality of life, especially in individuals older than 60 years of the age.² The number of people over 60 years of the age is projected to increase to 2 billion before 2050 because of the decreasing fertility rate and increasing life expectancy.^{3,4} Thus, much attention should be given to treating elderly patients with DLSS.

Traditionally, open discectomy decompression with or without spinal fusion under general anesthesia is considered the gold standard treatment and is associated with good clinical outcomes.⁵ However, not all elderly patients are candidates for the standard operative plan under general anesthesia because of the high rates of postoperative delirium, pneumonia, and stroke.^{6,7} Moreover, most elderly patients suffer from coronary heart disease, diabetes, hypertension, and chronic obstructive pulmonary disease, which could increase the risk of all-cause mortality during the perioperative period.⁸ In addition, spinal fusion surgeries are associated with a higher risk for major complications and postoperative mortality than decompression only.9 Therefore, the balance between surgical effects and safety is especially important for elderly patients, especially for those with comorbidities such as coronary heart disease, diabetes, hypertension, and chronic obstructive pulmonary disease.

Minimally invasive techniques, which result in lower complication rates and lower hospital resource utilization, are the best choice. Percutaneous endoscopic lumbar discectomy (PELD) is believed to be a relatively safe and suitable technique for the treatment of degenerative disc disease in elderly patients.¹⁰ Because the decompression range of the dorsal canal using the traditional PELD technique was insufficient, PELD was not a recommended therapy for patients with DLSS.¹¹ With the development of new instruments, PELD is advancing. ZESSYS, which is a modified version of the traditional transforaminal endoscopic surgical system (TESSYS) technique, is originally designed for overcoming the anatomical limitations at the L₅S₁ level, such as high iliac crest, sacral ala, large facet joint, large L5 transverse process, and narrowed foramen.¹² ZESSYS is a targeted and quantificational foraminoplasty device and was proved to be efficient and safe in treating lumbar disc herniation at the L₅S₁ level. It is reported that ZESSYS is much easier for acupuncture, foraminoplasty, and it is easily to reach the decompression target and widen the foramen and lateral recess compared with conventional TESSYS.¹³ Due to its remarkable advantages of foraminoplasty and decompression large enough for

lateral recess, we hypothesize it is possible to use ZESSYS to treat DLSS.

In this study, we aimed to evaluate the clinical outcomes and life quality of elderly patients with comorbidities suffering from DLSS who underwent PELD assisted by ZESSYS and completed a minimum 2-year follow-up.

Materials and Methods

Patients

The study was performed based on the data of patients who underwent PELD assisted by ZESSYS for unilateral sympathetic DLSS from June 2017 to June 2018. Inclusion criteria: (i) patients with mild or moderate symptomatic DLSS presenting with intermittent claudication and unilateral radicular lower extremity pain or numbness; (ii) patients older than 70 years of the age, suffering from comorbidities such as coronary heart disease, diabetes, hypertension, or chronic obstructive pulmonary disease; (iii) failure of conservative treatment for more than 3 months. Exclusion criteria: (i) patients with grade II to IV spondylolisthesis, severe lumbar spinal stenosis, severe calcification of the ligamentum flavum and/or posterior longitudinal ligament; (ii) more than two-segment lumbar disc herniation (LDH); (iii) combined with previous lumbar surgery, fracture, infection, or tumor; (iv) patients who were loss to follow-up. The same senior physicians performed the surgical procedures.

The severity of DLSS was graded according to the method reported by Bartynski in 2003, which used magnetic resonance imaging (MRI)¹⁴: Grade 0, no stenosis in the lateral recess and no root compression; Grade 1, small stenosis in the lateral recess but no root compression; Grade 2, small stenosis in the lateral recess combined with root compression; and Grade 3, severe root compression. In this study, we classified Grade 1 as mild, Grade 2 as moderate, and Grade 3 as severe.

Surgical Tools

An instrument (ZESSYS) specifically designed for PELD is a double tube with two different diameters. The instrument includes a fixed tube and a working tube (Figure 1A). The fixed tube diameter is approximately 3 mm, and the working tube diameter matches the trephine (Joimax, Germany) (Figure 1B). The working tube can theoretically rotate 360° around the fixed Kirschner wire. This can enlarge the foramen from 360°. If rotated 360°, the soft tissue pathway needs to be further expanded, which may be the disadvantage of this device. The trephine works inside the working tube, preventing any damage to exiting and traversing nerve roots. A percutaneous endoscope spine surgical system (Joimax,

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Fig. 1 The structure of ZESSYS. (A) ZESSYS including two tubes: a narrow tube is for fixing, and the wide tube is for working. (B) The working tube is matched with the trephine

Germany) and tip-flexible electrode bipolar radiofrequency system (Joimax, Germany) were used in a PELD procedure. The radiolucent equipment used in the operation was the Garm (Whale, USA).

Surgical Operation

Positioning of Body Surface

For all patients, the procedure was performed under local anesthesia in the prone position on a radiolucent table using G-arm fluoroscopy. The needle entry point was determined at the intersection of the skin and in horizontal line from the posterior aspect of the spinal process.

Establishing a Working Approach

After the intended needle entry tract was infiltrated with 10 ml of 1.0% lidocaine, a Kirschner wire (2.5 mm) was inserted to the position where the Kirschner wire tip was fixed in the posterior upper rim of the distal vertebra in the lateral view and the tip of the Kirschner wire was between the medial pedicle line and the spinous process line in the anteroposterior view (Figure 2A,B). Serial dilations that would pass over the Kirschner wire were introduced to extract the soft tissues.

Foraminoplasty

After the dilations were removed, the ZESSYS was inserted into the trajectory with the fixed tube guided by the Kirschner wire. According to the planned decompression range, a suitable ZESSYS was selected, and the working tube could also change direction around the Kirschner wire (Figure 2C,D). The matched trephine was used to perform foraminoplasty through the working tube (Figure 3A,B). The ventral portion of the superior articular process could be removed along with the trephine (Figure 3C). Then, the guidewire was inserted through the working tube before the ZESSYS and Kirschner wires were removed.

Decompression

An 8-mm working tube (Joimax, Germany) was inserted through the guidewire. The hypertrophied flavum ligament lateral and posterior to the traversing nerve root was endoscopically resected to achieve lateral recess and posterior decompression. Then, ventral hypertrophied posterior longitudinal ligaments, herniated discs, and lateral recess stenosis were resected under endoscopic visualization. The decompression of the traversing root and dural sac could be confirmed (Figure 4).

Perioperative Observational Index

The American Society of Anesthesiologists (ASA) score was used to evaluate the physical health of patients.¹⁵ All patients' outcomes were scored based on the operative time, intraoperative blood loss, hospital stay, and complications.

Clinical Evaluation

The clinical outcomes were evaluated using the visual analog scale (VAS) for lower extremity pain, and Oswestry disability index (ODI). VAS and ODI scores were recorded before and 1, 12, and 24 months after surgery. The modified Macnab criteria were used to evaluate clinical efficacy.

Visual Analog Scale (VAS)

The VAS is used to evaluate the degree of pain using a ruler, and the score is determined by measuring the distance (cm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0 to 10. A score of 0 means no pain and 10 means unbearable pain. A higher score indicates greater pain intensity.

Oswestry Disability Index (ODI)

The ODI is a measurement used to evaluate spinal disorders and to assess patient progress in clinical practice. The ODI score system includes 10 sections: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. Each section includes six statements, and the total score is 5. Intervening statements are scored according to rank. The highest score was recorded if more than one box was marked in each section. If all 10 sections are completed, the score is calculated: total score out of total possible score \times 100. If one section is not applicable, the score is calculated as follows: (total score/(5 \times number of questions answered)) \times 100%. 0%–20% is considered mild dysfunction, 21%–40% is moderate dysfunction, 41%–60% is severe dysfunction, and 61%–80% is considered disability.

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Fig. 2 The position of the Kirschner wire and ZESSYS. The position of Kirschner wire and ZESSYS in anteroposterior (A, C) and lateral view (B, D)



Fig. 3 The trephine in the working tube. (A) In anteroposterior view. (B) In lateral view. (C) The portion of the superior articular process

Patients with a score of 81%–100% are either long-term bedridden or exaggerating the impact of pain on their life.

Evaluation of Life Quality

The physical function, mental function, and social function scales in the Short Form 36 (SF-36) questionnaire were used

for neurologic assessments before and after the operation (1, 12, and 24 months) for each patient.¹⁶

Image Assessments

Computed tomography (CT) or MRI scans were performed before and after the operation for each patient to evaluate decompression. CT was performed using an Aquilion Orthopaedic Surgery Volume 14 • Number 7 • July, 2022 DOUBLE TUBES FOR DLSS



Fig. 4 Decompression using PELD assisted by ZESSYS endoscopically. (A) The TNR is compressed by HFL. (B) HFL is resected. (C) Ventro HLD is resected. (D) The TNR after decompression. Abbreviations: HFL, hypertrophied flavum ligament; HLD, herniated lumbar disc; IVS, intervertebral space; SAP, superior articular process; TNR, transversing nerve root

64-slice scanner. Images were obtained with patients using 5-mm thick slices. The abrasion of the superior articular process was assessed on CT images. The MRI images were obtained with a 1.5-Tesla unit. The slide thickness was 4 mm on all studied images. The disc Flava ligament space was described on axial T2-weighted MRI.

Statistical Analyses

Statistical analysis of the data was performed using IBM SPSS 20.0 software (International Business Machines Corporation, Armonk, New York). Values are presented as the means \pm standard deviations. The paired-sample *t*-test was used to compare data before and after the operation. Multiple comparisons between samples were analyzed by analysis of variance (ANOVA). Differences with two-tailed *p* values <0.05 were considered statistically significant.

Results

Patients

According to the inclusion and exclusion criteria, 31 patients were enrolled, and 25 patients achieved at least a 24-month follow-up (Table 1). Reasons for loss to follow-up included loss of contact with three patients and three patients died from other diseases. The studied population included 12 males and 13 females, with a mean age of 76.8 years (range, 70–87 years). The mean follow-up time was 26.64 months (range, 24–36 months). There were four patients with one comorbidity, 11 patients with two comorbidities, eight patients with three comorbidities, and two patients with four comorbidities. A total of 76% (19/25) of the patients presented an ASA score of more than 3. There were 14 cases at $L_{4/5}$ and 11 cases at L_5S_1 .

Intraoperative Findings

All patients successfully underwent surgery under local anesthesia. The hypertrophied flavum ligament was seen after the ventral portion of the superior articular process was removed with the trephine (Figure 3C, Figure 4A). The dorsal and ventral portions of the traversing root and dural sac could be seen after the flavum ligament and the herniated disc were resected (Figure 4).

Perioperative Observational Index

The average operative time was 67.80 min (18.20 \pm 5.93 min, range, 50–90 min). The average blood loss was 18.2 ml (67.80 \pm 10.84 ml, range, 10–30 ml). The length of hospital stay was 6.92 days (6.92 \pm 2.41 days, range, 4–15 days).

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TABLE 1 The clinical data of the patients								
Cases	Age (year)	Gender	ASA	Segment	Follow-up (months)	Hospital stay (days)	Time (min)	Blood loss (ml)
1	77	F	Ш	L _{4/5}	24	7	60	10
2	71	F	III	L _{4/5}	26	8	55	15
3	75	М	III	L_5S_1	25	9	67	15
4	78	F	Ш	L _{4/5}	24	5	76	10
5	79	М	IV	L _{4/5}	25	7	80	20
6	70	М	Ш	L_5S_1	30	8	90	15
7	71	М	III	L _{4/5}	28	4	65	10
8	87	F	IV	L _{4/5}	24	5	55	25
9	79	F	Ш	L_5S_1	27	4	70	15
10	73	F	III	L _{4/5}	30	7	75	30
11	75	М	III	L _{4/5}	26	5	50	20
12	77	F	Ш	L_5S_1	25	6	65	15
13	79	F	IV	L_5S_1	24	15	60	10
14	80	М	IV	L _{4/5}	24	8	75	15
15	86	М	IV	L _{4/5}	24	6	60	20
16	71	F	Ш	L_5S_1	36	10	90	25
17	76	М	III	L _{4/5}	30	5	55	20
18	77	F	III	L_5S_1	25	6	60	30
19	74	F	III	L_5S_1	26	6	65	25
20	81	М	IV	L _{4/5}	27	5	70	15
21	78	М	III	L_5S_1	26	10	70	20
22	70	М	111	L _{4/5}	34	7	80	15
23	78	F	IV	L_5S_1	25	9	57	20
24	77	F	III	L_5S_1	27	6	80	25
25	81	М	IV	L _{4/5}	24	5	65	15

TABLE 2 Results of the VAS and ODI preoperatively and at follow-ups					
	VAS scores	ODI			
Pre-OP	$\textbf{5.12} \pm \textbf{1.81}$	$\textbf{31.12} \pm \textbf{10.07}$			
Post-OP 1 month	$\textbf{2.08} \pm \textbf{1.15}$	$\textbf{19.24} \pm \textbf{8.83}$			
Post-OP 12 month	$\textbf{1.12}\pm\textbf{0.73}$	12.52 ± 5.58			
Final follow-up	$\textbf{0.92} \pm \textbf{0.64}$	9.44 ± 6.32			
F	67.974	36.855			
p	0.000	0.000			

Abbreviations: Pre-OP, pre-operation; Post-OP, post-operation.

Clinical Outcomes

The postoperative 1-month VAS score significantly decreased compared with that before the operation $(2.08 \pm 1.15 \ vs \ 5.12 \pm 1.81, \ p < 0.01, \ Table \ 2)$. The VAS score continued to decrease at the postoperative 12-month follow-up compared with that at the postoperative 1-month follow-up ($1.12 \pm 0.73 \ vs \ 2.08 \pm 1.15, \ p < 0.01, \ Table \ 2$). Although the VAS score decreased at the final follow-up, there was no significant difference compared with that at the 12-month follow-up ($0.92 \pm 0.64 \ vs \ 1.12 \pm 0.73, \ p = 0.549$). The ODI scores were significantly decreased after the operation compared with that before operation (p < 0.01, Table 2). Also, there was no difference of the ODI scores between the 12-month follow-up and the final follow-up ($12.52 \pm 5.58 \ vs \ 9.44 \pm 6.32, \ p = 0.172$). This indicated that symptoms

reduced steadily after the postoperative 12-month follow-up. At the final follow-up, the overall excellent rate was 92% (23/25). Subgroup analysis based on the different segments performed. No significant differences were found in the preoperative and final follow-up VAS and ODI scores between the $L_{4/5}$ and L_5S_1 groups (p > 0.05, Table 3).

Outcomes of Life Quality

The results on the physical, mental, and social function scores of the SF-36 questionnaire indicated that the scores improved and peaked at the 12-month follow-up and maintained a steady state until final follow-up compared with those before the operation and at the 1-month follow-up (Table. 4). This indicated that the overall quality of life was significantly improved. We also found that there was no difference between the 12-month and final follow-ups in the physical score ($84.00 \pm 6.29 \ vs \ 84.40 \pm 6.18, \ p = 0.871$), mental score ($81.76 \pm 8.01 \ vs \ 81.68 \pm 6.67, \ p = 0.974$), or social score ($115.50 \pm 13.64 \ vs \ 118.50 \pm 12.03, \ p = 0.437$). The results indicated that life quality reached a steady state after 12 months. No significant differences were found in the preoperative and the final follow-up SF-36 scores between the L_{4/5} and L₅S₁ groups (Table 3, p > 0.05).

Radiographic Outcomes

Postoperative sagittal (Figure 5E) and axial (Figure 5F) CT scans showed resection of the superior articular process. Postoperative sagittal (Figure 5G) and axial (Figure 5H) MRI scans showed expansion of the dural sac. The disc flava ligament space was significantly increased. Compared with the

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TABLE 3 Comparison between subgroups $L_{4/5}$ ($n = 14$) and L_5S_1 ($n = 11$) before operation and the final follow-up						
	L _{4/5}	L_5S_1	t	р		
Pre-OP VAS	5.50 ± 1.83	5.73 ± 1.68	-0.320	0.752		
Final follow-up VAS	$\textbf{1.00} \pm \textbf{0.68}$	$\textbf{0.82}\pm\textbf{0.60}$	0.697	0.493		
Pre-OP ODI	$\textbf{32.86} \pm \textbf{10.32}$	$\textbf{28.91} \pm \textbf{9.76}$	0.972	0.341		
Final follow-up ODI	$\textbf{11.36} \pm \textbf{6.89}$	7.00 ± 4.73	1.788	0.087		
Pre-OP PF scores	$\textbf{62.14} \pm \textbf{11.22}$	65.45 ± 14.91	-0.635	0.532		
Final follow-up PF scores	84.64 ± 4.99	84.09 ± 7.69	0.217	0.830		
Pre-OP MF scores	57.14 ± 11.47	63.64 ± 8.85	-1.548	0.135		
Final follow-up MF scores	81.43 ± 7.98	82.00 ± 7.64	-0.181	0.858		
Pre-OP SF scores	77.68 ± 14.85	$\textbf{79.55} \pm \textbf{14.00}$	-0.320	0.752		
Final follow-up SF scores	117.86 ± 11.72	119.32 ± 12.95	-0.296	0.770		

Abbreviations: MF, mental function; PF, physical function; Post-OP, post-operation; Pre-OP, pre-operation; SF, social function.

TABLE 4 Results of the SF-36 questionnaire preoperatively and at follow-ups						
	PF	MF	SF			
Pre-OP	63.60 ± 12.79	60.00 ± 10.71	$\textbf{78.50} \pm \textbf{14.22}$			
Post-OP 1 month	77.40 ± 7.65	$\textbf{73.60} \pm \textbf{8.41}$	104.50 ± 14.38			
Post-OP 12 month	84.00 ± 6.29	$\textbf{81.76} \pm \textbf{8.01}$	115.50 ± 13.64			
Final follow-up	84.40 ± 6.18	$\textbf{81.68} \pm \textbf{7.67}$	118.50 ± 12.03			
F	31.452	34.064	44.744			
p	0.000	0.000	0.000			

Abbreviations: MF, mental function; PF, physical function; Post-OP, post-operation; Pre-OP, pre-operation; SF, social function.



Fig. 5 A representative case of a patient with $L_{4/5}$ stenosis. Preoperative sagittal (A) and axial (B) CT demonstrating the stenosis of the left spinal canal at the $L_{4/5}$ level. Preoperative sagittal (C) and axial (D) MRI showing dural sac and left L_5 never root compression at the $L_{4/5}$ level. Postoperative sagittal (E) and axial (F) CT showing resection of the superior articular process. Postoperative sagittal (G) and axial (H) MRI shows the expansion of the dural sac. Brown arrow indicated the position of the stenosis, yellow arrow indicated the decompression range of the $L_{4/5}$

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Fig. 6 Female, 75 years old. (A) The trephine in the working tube in anteroposterior view. (B) In lateral view. (C) HFL is resected endoscopically. Orange arrow indicated the never root; Blue arrow indicated the flavum ligament. (D) Preoperative axial CT showing dural sac and left L_5 never root compression at the $L_{4/5}$ level. (E) Postoperative axial CT showing resection of the superior articular process. Green arrow indicated resection of the superior articular process

preoperative state (Figure 5A-D), the lateral recess opened and the area of the dural sac was expanded. A typical case is also shown in Figure 6.

Complications

Only two patients (8.0%, 2/25) experienced recurrence after 3 and 5 months postoperatively, and a secondary PELD using TESSYS was performed. After the secondary PELD and neurotrophic drug treatment, the symptoms of both patients were significantly relieved and did not recur in the follow-up periods. There were no complications including cerebral spinal fluid leakage, vascular injury, surgical infection, or postoperative nerve root injury.

Discussion

The results of our study are the first to report that treatment for DLSS using PELD assisted by ZESSYS in elderly patients with comorbidities was effective and resulted in excellent life quality.

The Feature of ZESSYS

DLSS is highly prevalent in elderly patients.¹⁷ These individuals have similar features, such as severe comorbidities and a short life expectancy.¹⁸ Considering the above problems, minimally invasive approaches have been proposed as a first-line treat-ment for patients with DLSS.¹⁹ Compared with traditional PELD, our instrument is much easier to use for foraminoplasty. Henmi measured foraminal distance (distance between the posterior edge of the disc and ventral aspect of the facet joint) and found that the distance, in most cases, was less than 8 mm, which is the diameter of the cannula of PELD.²⁰ If a cannula is inserted through a narrow foramen, the cannula may compress the exiting nerve root, and cause postoperative nerve root dysesthesia.²¹ Among elderly patients, the distance is much less than 8 mm because of hypertrophied superior articular processes or osteophytes. ZESSYS is an eccentric axial design and is convenient for performing dorsal foraminoplasty by enlarging the ventral superior articular process. At the same time, the working tube can theoretically rotate 360° around the fixed Orthopaedic Surgery Volume 14 • Number 7 • July, 2022 DOUBLE TUBES FOR DLSS

Kirschner wire, and a target puncture can be easily achieved by modulating the direction of the working tube. Compared with the two portal techniques reported by Torudom,²² no potential space needs to be created, and no partial resection of the bilateral lamina needs to be burred in our technique. Thus, spinal stability was retained. The new instrument designed by Li^{23} is similar to the traditional instrument, and the working tube was not rotated 360°. This made the dorsal foraminoplasty limited.

Life Quality Compared with Other Studies

In a recent report, the physical, psychological, and social function scores of the SF-36 were significantly increased 3 months after PELD and continued to increase in subsequent follow-ups.²⁴ Kapetanakis reported that the SF-36 parameters exhibited maximal improvement at 6 months in obese patients and 6 weeks in patients with a normal body mass index (BMI).²⁵ This finding indicated that the recovery time after PELD is associated with BMI. In our study, the SF-36 score increased and peaked at the 12-month follow-up and reached a steady state. The difference may be related to the inclusion criteria: patients who were solely diagnosed with lumbar disc herniation syndrome were included in their study. Additionally, sex, BMI, and age would be other reasons.^{24,25}

Complications in our Study

In the present study, satisfactory outcomes were achieved after 12 months postoperatively and the satisfactory rate reached 92% (23/25), which is superior to 88.7% (47 in 53).²⁶ Rare surgery-related complications occurred, even in patients with severe comorbidities (ASA grade higher than III). Numerous studies reported that the percentage of post-operative complications, such as pneumonia and stroke, was as high as 20% when patients aged 60 years or older received

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posterior lumbar interbody fusion for DLSS.^{7,27,28} Compared with open surgery, the rate of postoperative complications in our study was much lower. Only two patients (8%) who had a herniated disc needed to undergo reoperation after the first PELD assisted by ZESSYS. The reported reoperation rate ranges from 3.5% to 16.3% for minimally invasive surgery in patients with DLSS with/without herniated discs after different follow-ups.^{29–31} Many factors were responsible for the reoperation, such as age (\geq 50 years old), obesity (BMI \geq 25), and the learning curve of the surgeon (<200 cases).³²

Limitations of this Study

There are some limitations associated with the current study. First, the number of subjects included in our study was relatively small. A large sample study needs to be performed in the future. Second, according to the US Preventive Services Task Force grading system, our study was observational. A randomized controlled study is needed in the future. Finally, a longer follow-up period is needed to show long-term outcomes. Our results showed that the best benefits appeared at 12 months after surgical decompression. Therefore, additional long-term clinical outcomes, as well as postoperative instability and restenosis, need to be thoroughly assessed.

Conclusion

The clinical outcomes and life quality results in our study have confirmed that PELD assisted by ZESSYS is effective. ZESSYS could be considered as a treatment device for different segmental DLSS in elderly patients with comorbidities.

Conflicts of Interest

Il the authors declare no conflicts of interest.



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