

## Original Article

# Intermediate-term clinical effects of Dynesys dynamic stabilization system on double-segmental lumbar disc herniation

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**Abstract:** Objective: To investigate the intermediate-term clinical effects of Dynesys dynamic stabilization system on double-segmental lumbar degenerative disease. Methods: Sixty patients with double-segmental lumbar disc herniation who underwent Dynesys dynamic stabilization system from January 2013 to December 2016 were prospectively analyzed and followed up for two years. Visual analogue scale (VAS) and Oswestry disability index (ODI) of patients were recorded before and after treatment; the intervertebral height and nucleus pulposus signal intensity of adjacent segments were measured by imaging examination; logistics regression analysis was used to analyze the related risk factors of adjacent segment degeneration (ASD). Results: Sixty patients were successfully treated with Dynesys dynamic stabilization system and all of them were followed up. At the last follow-up, the ODI score of lumbocrural pain was  $20.9 \pm 2.7$  and VAS score was  $2.1 \pm 0.2$ , which were significantly lower than those before operation, reaching statistical difference ( $P < 0.05$ ). There was no statistical significance in the scores of the adjacent intervertebral space height and the nucleus pulposus signal intensity before and after operation ( $P > 0.05$ ). The rate of adjacent intervertebral disc degeneration was 18.3%, which was associated with body mass index (BMI) and age by logistics regression analysis results. Conclusion: Dynesys dynamic stabilization system for double-segmental lumbar disc herniation achieves satisfactory intermediate-term effects, significantly relieves lumbocrural pain, and has little effect on adjacent segments. This research provides an experimental basis for the clinical application of Dynesys dynamic stabilization system.

**Keywords:** Lumbar disc herniation, degenerative disease, Dynesys dynamic stabilization system, lumbar interbody fusion

## Introduction

Lumbar interbody fusion can result in a significant decrease in the motor activity of the segments, and increased stress adds the risk of adjacent segment degeneration (ASD); besides, its limitations have increasingly drawn universal attention from clinicians [1]. In recent years, concept of dynamic internal fixation that aims to maintain the normal physiological activity of fixed segments, which effectively preserves spinal stability and prevents ASD. Dynesys dynamic stabilization system is the most widely used posterior lumbar non-fusion technology at present [2, 3]. Studies have shown that Dynesys dynamic stabilization system is more effective

than rigid internal fixation in maintaining spinal stability, reducing the influence on adjacent segments, decreasing interior pressure in the intervertebral disc, retaining the activity of partial intervertebral activities and maintaining the flexibility of spinal lateral flexion and extension [4, 5].

Previous studies have focused on the application of Dynesys dynamic stabilization system for single-segmental lumbar disc herniation, lumbar spinal stenosis, lumbar instability, lumbar spondylolisthesis, etc. [6-8]; however, there are few reports on its application in double-segmental lumbar disc herniation, and reports on its long-term clinical follow-up are absent. Thus

**Table 1.** General information of patients before surgery

| Basic characteristic   | Value (N / mean $\pm$ standard deviation) |
|--|---|
| Age (years )   | 45.2 $\pm$ 3.5                            |
| Gender   |   |
| Male (cases)   | 38  |
| Female (cases)   | 22  |
| Body Mass Index (kg/m <sup>2</sup> )                             | 27.8 $\pm$ 4.84                           |
| ODI  | 65.8 $\pm$ 9.7                            |
| VAS  | 6.3 $\pm$ 0.4                             |
| Intervertebral space height of adjacent segmental (mm)           | 11.25 $\pm$ 1.55                          |
| Signal intensity score of nucleus pulposus of adjacent segmental | 1.94 $\pm$ 1.18                           |

Note: ODI: Oswestry dysfunction index; VAS: visual analogue scale.

### *Surgical methods*

The operation was performed by the same group of spine surgeons. Under intravenous-inhalation combined anesthesia, the patients were in prone position. Surgeons made posterior median incision on the patient, separated muscles along the spinous process,

the purpose of this study is to provide experimental basis for the clinical application of Dynesys dynamic stabilization system through investigating the clinical efficacy of Dynesys dynamic stabilization system for double-segmental lumbar disc herniation two years after operation.

### **Materials and methods**

#### *General information*

From January 2013 to December 2016, 60 patients with double-segment lumbar disc herniation were treated with Dynesys dynamic stabilization system, including 38 males and 22 females aged 35-65 years with an average age of 45.2 $\pm$ 3.5 years. Among them, there were 24 cases of damage segment in L3-L5, 15 cases of L2-L4, 21 cases of L4-S1, and all of patients appeared no degenerative change in the adjacent segment before surgery. Inclusion criteria: Patients were diagnosed as double-segment lumbar disc herniation by magnetic resonance imaging (MRI) clearly, and suffered from low back pain with unilateral or bilateral lower limb pain; no history of trauma, scoliosis, infection and surgery; complete preoperative imaging data (X-ray film of lumbar spine anteroposterior & lateral and MRI of the lumbar spine); poor effects of more than six months' strict non-surgical treatment. Exclusion criteria: Patients suffered from serious cardio-cerebrovascular diseases, severe osteoporosis, grievous lumbar malformation, critical lumbar instability and progressive degeneration of intervertebral disc. The enrolled patients' general information is shown in **Table 1**. This study was approved by the Hospital Ethics Committee; all the patients and their families signed informed consent.

exposed vertebral plate, articular process and part of the transverse process, implanted a register needle at the upper one-third position where the lateral superior articular process and transverse process met, and placed titanium screws (length of 40-50 mm, diameter of 6.0 mm, produced by Zimmer Holdings, Inc.) after confirming location by the PA and lateral view of C-arm X-ray. Then, surgeons measured the distance between the left and right sides of the screws by the PA and lateral view of C-arm X-ray again, after confirming the proper location, intercepted the needed intervertebral length of polycarbonate-carbamate elastic tube, then inserted polyethylene-phthalate rope between the flexible liner and the upper and lower vertebra screws, tightened the rope gradually with certain tension, fastened the rope by small screws, and at last, cut it within about 1 cm free-end. Resection of nucleus pulposus of the corresponding segment was performed to remove the nerve root compression after stable fixation. In the end, bleeding was stopped, wound washed, drainage tube placed, and layer by layer sutured.

#### *Postoperative treatment*

Routine use of antibiotics for 3 days was to prevent infection. Drainage tube was removed 48 hours after surgery. Surgeons should encourage patients to move both lower limbs and turn over frequently. And patients began to get out of bed and take part in activities with soft elastic waistband 1 week after operation for 6 weeks.

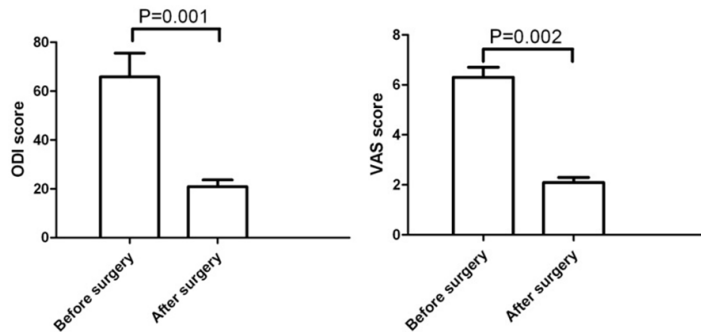
#### *Evaluation index*

The follow-up was carried out by telephone reservation and outpatient reexamination for 2

**Table 2.** Comparison of preoperative and postoperative scores of ODI and VAS (n=60, means  $\pm$  SD)

| Project | Preoperative result | Postoperative result | T      | P     |
|---------|---------------------|----------------------|--------|-------|
| ODI     | 65.8 $\pm$ 9.7      | 20.9 $\pm$ 2.7*      | 17.237 | 0.001 |
| VAS     | 6.3 $\pm$ 0.4       | 2.1 $\pm$ 0.2*       | 16.395 | 0.002 |

Note: Compared with preoperation, \*P<0.05.

**Figure 1.** Comparison of preoperative and postoperative scores of ODI and VAS in the Dynesys dynamic stabilization system for double-segmental lumbar disc herniation.

years. Oswestry dysfunction index (ODI) and visual analogue scale (VAS) were recorded before and after surgery. ODI can evaluate the improvement of the patient's quality of life and functional recovery, including pain, life independence, lifting goods, walking, sitting, standing, sleep, sex life, social activities and travel, with a total of 50 points. The scoring method: actual score/50 (the highest possible score) \*100%; if there was one question missed, the scoring method was actual score/45 (the highest possible score) \*100%. The higher the score was, the more serious the dysfunction was. The total score of VAS was 10 points, and the scoring method was as follows. 0 score was considered as painless; under 3 scores meant slight pain and the patient could endure; 4-6 scores stood for pain and the patient's sleep was affected but still bearable; 7-10 scores indicated the patient had a strong pain, which was unbearable, and affected his appetite and sleep.

Preoperative and the last follow-up routine lumbar spine anteroposterior & lateral view radiograph and MRI were performed. The intervertebral height of the adjacent segments (the average value of height between vertebral anterior and posterior of vertebral body) and the nucleus pulposus signal intensity were measured; adjacent segment degeneration

was defined as clinically symptomatic and radiographically confirmed adjacent segment degeneration.

#### Statistical analysis

SPSS13.0 was used to Import and analyze the data; measurement data was expressed as mean  $\pm$  standard deviation; ODI, VAS pain score, intervertebral space height and nucleus pulposus signal intensity score of adjacent segmental before and after surgery were compared by paired t test, and risk factors for ASD were analyzed by binary logistic regression analysis. P<0.05 was set as statistical significance.

#### Results

##### *Evaluation of clinical curative effect of Dynesys dynamic stabilization system on double-segmental lumbar disc herniation two years after operation*

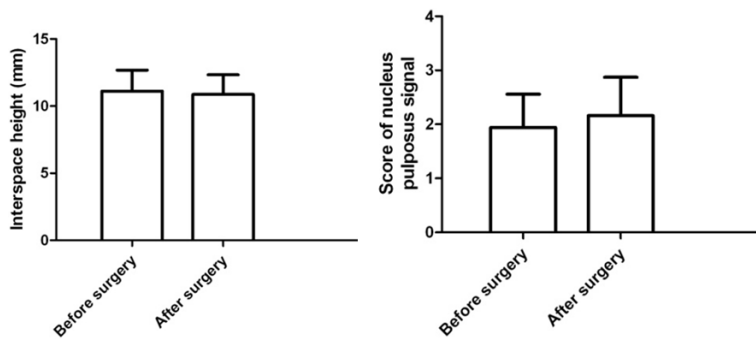
The average value of ODI before operation and two years after operation was (65.8 $\pm$ 9.7) and (20.9 $\pm$ 2.7), with statistically significant difference (P=0.001). The average VAS pain score in lumbocrural pain before operation and two years after operation was (6.3 $\pm$ 0.4) and (2.1 $\pm$ 0.2), with statistically significant difference (P=0.002), as shown in **Table 2** and **Figure 1**. After operation, there was one patient suffered from wound infection, who recovered and discharged after debridement and suture again. Two years after operation, there was no loosening, prolapse or breakage of internal fixation and other severe complications.

##### *Occurrence of ASD two years after the operation of Dynesys dynamic stabilization system for double-segmental lumbar disc herniation*

The intervertebral space height of adjacent segment reduced slightly after operation; the score of nucleus pulposus of adjacent segment improved after operation; while both had no statistically significant difference (P>0.05), as shown in **Table 3** and **Figure 2**. According to the assessment criteria of ASD, there were 4 cases (16.67%) of damage segment in L3-L5 lesion, 3 cases (20%) of L4-L2 lesion and 4 cases

**Table 3.** Comparison of preoperative and postoperative intervertebral space height and the nucleus pulposus signal intensity score of adjacent segment in the Dynesys dynamic stabilization system (n=60, means  $\pm$  SD)

| Index                                   | Preoperative result | Postoperative result | T     | P     |
|---|---------------------|----------------------|-------|-------|
| Intervertebral space height (mm)        | 11.25 $\pm$ 1.55    | 10.89 $\pm$ 1.46     | 5.455 | >0.05 |
| Nucleus pulposus signal intensity score | 1.94 $\pm$ 1.18     | 2.16 $\pm$ 0.71      | 4.147 | >0.05 |

**Figure 2.** Comparison of preoperative and postoperative intervertebral space height & signal intensity score of nucleus pulposus of adjacent segment in the Dynesys dynamic stabilization system for double-segmental lumbar disc herniation.

(19.05%) of L4-S1 lesion, and there was no statistically significant difference ( $P>0.05$ ). Among all patients, there were 11 cases suffering from ASD with the total incidence of 18.3% (11/60). Taking the ASD as the dependent variable, the age, gender, BMI, preoperative intervertebral height and preoperative signal intensity score of nucleus pulposus as risk factors, binary logistics regression analysis demonstrated BMI and age were the risk factors of ASD, see **Table 4**.

### Discussion

The lumbar disc herniation is the commonest one in the degenerative lesions of lumbar spinal in spine surgery, and the surgical treatment is the conventional method for symptomatic lumbar disc herniation. As the widely used posterior lumbar non-fusion technology at present and an effective lumbar internal fixation system, Dynesys dynamic stabilization system consists of pedicle screws, polyethylene terephthalate cords and polycarbonate urethane elastic tubes [9]. Dynesys dynamic stabilization system can properly restrict lumbar activities by the dynamic stabilization of polyester fiber rope tension belt and elastic spacer. It was reported that Dynesys dynamic stabilization system can diminish the flexion-extension, lat-

eral bending and axial rotation of lumbar vertebra [10]. However, there are still some controversies on the indications of Dynesys dynamic stabilization system. Given that Dynesys dynamic stabilization system for lumbar disease was just approved by the Food and Drug Administration (FDA) in 2009 [11], the clinical application time, and follow-up time of Dynesys dynamic stabilization system are relatively short and mid-long term clinical trials are still lack, the

results of this current research are of great significance in the expansion of indications and clinical value of Dynesys dynamic stabilization system.

A previous study indicated that Dynesys dynamic stabilization system could significantly relieve the clinical symptoms of lumbocrural pain for the patients suffering from degenerative lumbar disease [12]. Compared with the posterior lumbar fusion technology, patients who are treated with Dynesys dynamic stabilization system not only has better VAS and ODI, but also preserves more operation sections and range of motion of the whole lumbar spine [13]. A study on lumbar spondylolisthesis describes that the VAS score on lumbocrural pain and walking distance shows notable improvements, fixed segments are stabilized, and there is no aggravation of spondylolisthesis after the Dynesys dynamic stabilization system [14]. Additionally, the VAS score on lumbocrural pain and ODI score improve significantly for patients with lumbar spinal stenosis after Dynesys dynamic stabilization system [15]. Nevertheless, there are few reports on the cases of Dynesys dynamic stabilization system for double-segmental degenerative lumbar diseases. In this study, VAS scores and ODI scores on lumbocrural pain before and after Dynesys

**Table 4.** Binary Logistics regression analysis of ASD

| Variable  | Regression coefficient | Standard error | Wald value | P     | 95% Confidence interval (CI) |               |
|---|------------------------|----------------|------------|-------|------------------------------|---------------|
|   |                        |                |            |       | Minimum value                | Maximum value |
| Age   | 1.645                  | 0.707          | 6.535      | 0.006 | 2.137                        | 11.428        |
| Gender  | -1.341                 | 0.789          | 2.751      | 0.100 | 0.075                        | 1.248         |
| BMI   | -1.012                 | 0.357          | 7.685      | 0.009 | 0.254                        | 0.647         |
| Preoperative intervertebral space height of adjacent segment                | -0.767                 | 0.344          | 3.848      | 0.072 | 0.129                        | 1.128         |
| Preoperative signal intensity score of nucleus pulposus of adjacent segment | 0.873                  | 0.454          | 3.772      | 0.082 | 0.883                        | 3.872         |

Note: ASD: adjacent segment degeneration; BMI: body mass index.

dynamic stabilization system respectively were compared, the patients with double-segmental degenerative lumbar diseases have improved significantly after two-year follow up ( $P < 0.05$ ), and there is no loosening, prolapse or breakage of internal fixation or other severe complications, demonstrating that Dynesys dynamic stabilization system has affirmative clinical efficacy for double-segmental degenerative lumbar disease.

Whether Dynesys dynamic stabilization system can prevent ASD or not is always a hot spot recently in clinic. It has been reported that Dynesys dynamic stabilization system can preserve more intervertebral range of motion in fixed segment whereas less range of motion and less proportion in ASD; thus, we can say that it can prevent ASD effectively [16]. However, the current studies cannot rule out the possibility that adjacent segment degeneration results from the natural development of lumbar degenerative disease. Furthermore, it also shows that Dynesys dynamic stabilization system can increase the load of adjacent segment, causing the early ASD [17]. Therefore, that Dynesys dynamic stabilization system can prevent adjacent segment degeneration remains controversial. In the 60 cases of this research, neither intervertebral space height nor ASD changes significantly indicating that Dynesys dynamic stabilization system has little effect on ASD. In this study, there were 11 patients suffering from ASD after treated with Dynesys dynamic stabilization system, with the incidence of 18.3%. Logistics regression analysis showed that BMI and age were related high risk factors of ASD. What's more, numerous studies have proven that weight loss contributes to prevent the ASD [18-20]. The limited mobility, late ambulation, low immunity, low repair capacity, combined with osteoporosis and paraspinal muscle degeneration of ad-

vanced age patients may be the reason why age is one of the high risk factors [21, 22].

In conclusion, Dynesys dynamic stabilization system for double-segmental lumbar disc herniation can relieve lumbocrural pain significantly with few complications, achieving good intermediate-term clinical effects but there exists a certain degree of ASD. In consideration of few cases in this study, further follow-up study is needed to carry out to confirm the long-term effects of Dynesys dynamic stabilization system for ASD.

#### Disclosure of conflict of interest

None.

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