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Experience with the Second-Generation Wallis Interspinous Dynamic Stabilization Device Implanted in Degenerative Lumbar Disease: A Case Series of 50 Patients

Dejeneratif Lomber Hastalıkta İmplante Edilen İkinci Nesil Wallis İnterspinöz Dinamik Stabilizasyon Cihazı Deneyimi: 50 Hastalık Bir Olgu Serisi

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ABSTRACT

AIM: This study aimed to evaluate the short- to medium-term outcomes of the second-generation Wallis interspinous dynamic stabilization device for treatment of lumbar degenerative disease.

MATERIAL and METHODS: Fifty patients with lumbar degenerative disease treated from August 2007 to September 2009 were included in this retrospective study. The Japanese Orthopedic Association (JOA) score and the Oswestry Disability Index (ODI) were used for therapeutic efficacy evaluation. Odom's criteria were used to evaluate postoperative outcome with regard to symptoms. Anteroposterior X-rays were obtained after surgery. All patients were followed up for 2 years.

RESULTS: Based on Odom's criteria, 22, 24 and 4 patients had excellent, good, and fair results respectively. The JOA score at 3, 12, and 24 months after surgery was significantly higher than before surgery (all $p < 0.001$), and the ODI score at 3, 12, and 24 months after surgery was significantly lower than before surgery (all $p < 0.001$). The posterior intervertebral disc height and the neural foramina height at 12 and 24 months after surgery was significantly higher than before surgery (both $p < 0.001$).

CONCLUSION: Implantation of the second-generation Wallis interspinous dynamic stabilization device produced satisfactory clinical outcome at short- and medium-term follow-up in patients with lumbar degenerative disease.

KEYWORDS: Lumbar degenerative disease, Wallis interspinous implant, Postoperative outcome, Dynamic instrumentation, Lumbar interspinous spacer, Non-rigid fixation

ÖZ

AMAÇ: Çalışma, lomber dejeneratif hastalığın tedavisi için ikinci nesil Wallis interspinöz dinamik stabilizasyon cihazının kısa ve orta vadeli sonuçlarını değerlendirmeyi amaçlamıştır.

YÖNTEM ve GEREÇLER: Ağustos 2007 ile Eylül 2009 tarihleri arasında tedavi edilen 50 lomber dejeneratif hastalık olgusu bu retrospektif çalışmaya dahil edildi. Terapötik etkinlik değerlendirme için Japon Ortopedi Derneği (JOA) skoru ve Oswestry Engellilik İndeksi (ODI) kullanıldı. Semptomlar ile ilgili postoperatif sonuçları değerlendirmek için Odom kriterleri kullanıldı. Ameliyat sonrası anteroposterior röntgenler çekildi. Tüm hastalar 2 yıl boyunca takip edildi.

BULGULAR: Sonuçlar Odom kriterlerine göre sırasıyla 22, 24 ve 4 hastada mükemmel, iyi ve makul oldu. Ameliyattan sonra 3., 12. ve 24. aylarda JOA skoru ameliyat öncesine göre anlamlı derecede yüksek (tümü $p < 0,001$) ve ameliyattan sonra 3., 12. ve 24. aylarda ODI skoru ameliyat öncesine göre anlamlı derecede düşük (tümü $p < 0,001$) bulundu. Ameliyattan sonra 12. ve 24. ay posterior intervertebral disk ve nöral foramen yüksekliği ameliyat öncesine göre anlamlı derecede yüksek bulundu (her ikisi $p < 0,001$).

SONUÇ: İkinci nesil Wallis interspinöz dinamik stabilizasyon cihazının implantasyonu lomber dejeneratif hastalığı olan hastalarda kısa ve orta vadeli takipte tatmin edici klinik sonuçlar verdi.

ANAHTAR SÖZCÜKLER: Lomber dejeneratif hastalık, Wallis interspinöz implantı, Postoperatif sonuç, Dinamik enstrümantasyon, Lomber interspinöz boşluk, Non-rijid fiksasyon

INTRODUCTION

Lower back pain is the main symptom of lumbar degenerative disc disease. Presently, most researchers still consider that lower back pain in lumbar degenerative disc disease is caused by the instability of motion segments, and that this instability can be eliminated by stabilizing the affected segment. Based on the aforementioned theory, degenerative lower back pain has been treated mainly by lumbar fusion surgery using rigid fixation. Though the fusion rate of lumbar internal fixation is as high as 90%, but the clinical satisfaction rate has been reported to be considerably lower (4). Meanwhile, adjacent segment degeneration (ASD) due to stress concentration after lumbar fusion surgery (6) may induce new lower back pain, and fusion surgery inevitably results in loss of partial function of the lumbar spine.

In recent years, some investigators have proposed that the abnormal distribution of intradiscal stress loading due to abnormal motion is the direct reason for degenerative lower back pain, and since the pain is not related to the segmental instability caused by abnormal activity, they suggested the concept of dynamic stabilization (8). Dynamic stabilization is also known as soft fixation or flexible fixation. The so-called dynamic fixation system is an internal fixation system which can preserve the activity of the motion segment and change the load transmission simultaneously without spinal fusion using bone grafts being performed. The intention is to alter the load bearing pattern of the motion segment, as well as to control any abnormal motion at the segment. The hypothesis behind dynamic stabilization is that control of abnormal motions and more physiological load transmission would relieve pain, and prevent adjacent segment degeneration because it permits a certain degree of motion in the fixed segment (7).

Several dynamic stabilization devices have been developed. These devices include the Colfex, Wallis, DIAM, and X-STOP (3, 5, 19). The Wallis dynamic stabilization system was one of the earliest interspinous dynamic stabilization devices used in clinical practice. The first-generation Wallis system was developed in 1986. The material used for interspinous distraction was titanium. The interspinous spacer was fixed between the upper and lower spinous processes by two artificial polyester bands. Sénégas et al. (12) developed the second-generation Wallis system based on the first-generation device, which that group also developed. It is mainly different from the first-generation system in that polyether ether ketone (PEEK) is used for the spacer instead of the titanium alloy. The elastic modulus of PEEK matches that of the structure posterior to the vertebral body more accurately, which decreases the load-bearing of the lumbar spine in the standing position and absorbs the vibration energy during exercise. The whole system forms a "floating" device between two spinous processes. It is not a permanent fixation of the lumbar spine. It may reduce the load on the posterior portion of the annulus fibrosus and increase the stability of the unstable segment. Therefore, we hypothesized that implantation of the second-generation Wallis device would lead to a good clinical outcome in patients with degenerative lumbar disease.

Only a few studies have evaluated the outcomes of implanting the second-generation Wallis device (11). Therefore, the aim of the current study was to evaluate the short- to medium-term clinical results of implanting the second-generation Willis interspinous dynamic stabilization device in patients with degenerative lumbar disease.

MATERIAL and METHODS

This retrospective study was conducted from August 2007 to September 2009 at our hospital. A total of fifty patients were included in the current study. This is a purely clinical observational study without any form of support or involvement from the manufacturer of the Wallis device.

Patients

Demographic characteristics of the patients are presented in Table I. There were 30 male patients and 20 female patients. The mean age of the patients was 51.6±9.6 years. The mean disease duration was 4.2±2.7 years (range, 1 to 11). Forty-six patients had a single-segment lesion and 4 patients had a two-segment lesion. L3,4 was involved in 4 patients, L4,5 in 42 patients, and both L3,4 and L4,5 in 4 patients. Ten patients had discogenic lower back pain; 18 had recurrent lumbar disc herniation after surgery; 8 had degenerative lumbar instability, defined as recurrent low back and leg pain with restricted movement of lumbar spine flexion/extension, and X-ray showing anterior-posterior vertebral displacement of ≥3 mm or endplate angle ≥15 degrees without intervertebral spondylolysis; 6 had lumbar spinal stenosis, and 8 had voluminous herniated disc. Forty-six patients underwent single-segment application of the Wallis device and 4 underwent two-segment application of the device, which is composed of a pad and two polyester bands. Lumbar anteroposterior, bilateral oblique and dynamic X-rays, discography, CT or MRI were carried out before surgery to confirm the diagnosis

Inclusion and Exclusion Criteria

Patients were included if they had (1) Discogenic lower back pain: intractable lower back pain without typical nerve root symptoms and signs; physical examination and imaging examinations excluded lumbar disc herniation, tuberculosis, tumor and other diseases; lumbar MRI showed degeneration in one or several discs; and lumbar discography induced typical concurrent pain. (2) Recurrent lumbar disc herniation after surgery: the symptom was relieved at least more than 6 months after lumbar discectomy, and recurrent lumbar disc herniation occurred after that in the ipsilateral or contralateral lumbar segment or adjacent segments. (3) Degenerative lumbar instability: repeated lower back pain and leg pain, and lower back extension and flexion were restricted; dynamic X-ray showed equal to or more than 3 mm anteroposterior displacement or equal to or more than 15^0 of endplate angles,

Table I: Baseline Characteristics of the Study Populations

	Lumbar Degenerative Disease (n=50)
Age, yr	51.6 ±9.6
Disease course, yr	4.2 ±2.7
Gender	
Male	30 (60.0)
Female	20 (40.0)
Pathologies	
Single-level	46 (92.0)
Double-level	4 (8.0)
Location	
L3,4	4 (8.0)
L4,5	42 (84.0)
L3,4 + L4,5	4 (8.0)
Symptoms	
Discogenic low back pain	10 (20.0)
Recurrent lumbar disc herniation (post-op)	18 (36.0)
Degenerative lumbar instability	8 (16.0)
Lumbar spinal stenosis	6 (12.0)
Voluminous herniated disc	8 (16.0)
Pain Location	
Low back pain	24 (48.0)
Low back and leg pain	26 (52.0)
Surgical method	
Wallis implantation	24 (48.0)
Wallis implantation + decompression	26 (52.0)
Operative time, min	35.4 ±5.5
Operative blood loss, ml	70.4 ±22.5

The continuous variables were presented as mean and standard deviation; The categorical variables were presented as count and percent.

and the imaging examination showed no spondylolysis. (4) Huge lumbar disc herniation: diagnosis in accordance with lumbar disc herniation and the protruded part exceeded 50% of the spinal canal in the imaging picture. (5) Lumbar spinal stenosis: imaging examination showed decreased sagittal diameter or axial diameter of the spinal canal; there were moderate to severe nerve compression symptoms with or without mild lower back pain; and there were intermittent claudication and serious or progressive neurologic dysfunction. All patients received regular conservative treatment for at least 6 months, but outcomes were poor.

Conversely, patients were excluded if they had (1) osteoporosis, (2) scoliosis or lumbar spondylolisthesis due to spondylolysis, or (3) mild lumbar disc herniation.

Treatment

The patient was placed in the prone position after receiving general anesthesia. The patient's waist was maintained in the natural position. A posterior midline incision was made in the lower back. Bilateral paraspinal muscles were routinely exposed and dissected. The supraspinous ligament was completely dissected and pulled aside. The integrity of the supraspinous ligament was maintained maximally. The interspinous ligament of the affected segment was removed. The inferior margin of the upper spinous process and the superior margin of the lower spinous process were trimmed to make the interspinous space match the shape of the interspinous pad of the second-generation Wallis device. The implant size was decided on according to the template size. The interspinous pad was installed between the spinous processes, and the polyester bands in the upper and lower ends of the pad were used to pass through the adjacent interspinous spaces respectively and pulled tightly. Two ends of the polyester bands were passed through an anchoring device and the latter was locked at the root of the polyester bands. The supraspinous ligament was fixed to the spinous process. Discectomy or spinal decompression was performed in advance for 24 patients with typical nerve root symptoms and signs, and then the second-generation Wallis device was implanted to proactively prevent iatrogenic instability or reduce recurrent disc disease post-operatively.

The drainage tube, which was inserted to prevent post-operative wound hematoma, was removed 24-48 h after surgery. The patient started walking after wearing a back brace. Activities like running, jumping and waist weight-bearing were started 10-12 weeks after surgery. The back brace, which was placed in the polyester strip to prevent loosening of the strip, was discarded 1 month after surgery.

Outcome Evaluation

The operative time and intraoperative blood loss were recorded. Outcome evaluation was carried out 3, 12 and 24 months after surgery. The degree of postoperative symptom improvement was evaluated using Odom's criteria (9). Excellent: All preoperative symptoms relieved; able to carry out daily activities without impairment. Good: Minimal persistence of preoperative symptoms; able to carry out daily activities without significant interference. Fair: Definite relief of some preoperative symptoms, but physical activities were significantly limited. Poor: Symptoms and signs unchanged or exacerbated. We conducted a questionnaire survey of patients by having them fill out the Japanese Orthopedic Association (JOA) scoring system, and Chinese version of the Oswestry Disability Index (ODI). The postoperative scores were compared with the preoperative scores.

Anteroposterior X-ray examination of the lumbar spine was carried out after surgery to evaluate the presence of displacement and loosening of the Wallis device, and fractures of the spinous processes and lamina. The preoperative and postoperative height of the intervertebral disc space and the

Table II: Comparison of Preoperative and Postoperative Efficacy in 50 Patients

	Pre-operation	After 3 months	After 12 months	After 24 months	p-value
JOA	12.0 (10.0, 14.0)	25.0 (21.0, 27.0) †	26.0 (21.0, 28.0) †	25.0 (21.0, 26.0) †	<0.001*
Oswestry	13.0 (11.0, 15.0)	5.0 (4.0, 7.0) †	5.0 (4.0, 6.0) †	5.0 (4.0, 6.0) †	<0.001*

The continuous variables were presented as median and inter-quartile range (IQR), and compared with the repeated measurements by the Friedman test.
** indicates a significant difference among the repeated measurements; † indicates a significant difference compared with the pre-operation.*

Table III: Comparison of Preoperative and Postoperative Imaging Measurements in 50 Patients

	Pre-operation	After 12 months	After 24 months	p-value
Posterior intervertebral disc height, cm	0.71 (0.58, 0.88)	1.02 (0.87, 1.12) †	0.99 (0.88, 1.14) †	<0.001*
Neural foramina height, cm	1.11 (0.99, 1.19)	1.72 (1.62, 1.89) †	1.72 (1.65, 1.80) †	<0.001*

The continuous variables were presented as median and inter-quartile range (IQR), and compared with the repeated measurements by the Friedman test.
** indicates a significant difference among the repeated measurements; † indicates a significant difference compared with the pre-operation.*

height of the spinal root canal were measured according to Wang's method using the image measurement software (18). The height of the intervertebral disc space was defined as the distance between the inferior margin of the upper endplate and the superior margin of the lower endplate on the X-ray film. The height of the neural foramina was defined as the distance between the apex of the superior articular process and the margin of the inferomedial angle of the superior vertebral pedicle.

Statistical Analysis

Continuous variables were presented as median and inter-quartile range (IQR), and compared with the repeated measurements by the Freidman test. When a significant difference between the repeated tests was apparent, multiple comparisons were performed using the Bonferroni procedure with type-I error adjustment. SAS software package version 9.2 (SAS Institute Inc., Cary, NC, USA) was used for the statistical analysis. All statistical assessments were evaluated at a two-sided P value of 0.05.

RESULTS

Comparison of Preoperative and Postoperative Efficacy

Table II summarizes the operative efficacy from pre-operation to 24 months after surgery. The JOA score after surgery was significantly higher than before surgery (all p<0.001). But, there was no significant difference in the score among the three post-operative evaluations. The ODI score after surgery was significantly lower than before surgery (all p<0.001). However, there was no significant difference in score among the three follow-up evaluations. In addition Odom's criteria were used to assess outcomes 24 months after surgery, and outcome was excellent in 22 patients, good in 24 patients and fair in 4 patients. No patients had processus spinosus fracture during 2 years of follow-up.

Comparison of Preoperative and Postoperative Imaging Measurements

Table III summarizes the imaging measurements from before surgery to 24 months after surgery. The posterior intervertebral disc height after surgery was significantly higher than before surgery (all P<0.001). But, there was no significant difference between measurements at 12 and 24 months after surgery. The neural foramina height after surgery was significantly higher than before surgery (all p<0.001). However, there was no significant difference between measurements at 12 and 24 months after surgery.

Results of Imaging

No fracture of a spinous process or lamina occurred during the postoperative follow-up period. Typical cases are shown in Figures 1(A-F), 2(A-D), 3(A-B).

DISCUSSION

In this study, we found that implantation of the second-generation Wallis interspinous dynamic stabilization device in 50 patients with degenerative lumbar disease resulted in excellent or good outcomes in 46 (92%) patients at 2-year follow-up based on Odom's criteria. There was also significant improvement in the JOA score and ODI score. Radiographic imaging showed that there was a significant increase in posterior intervertebral disc height and neural foramina height. Also, there were no occurrences of spinous process or lamina fracture during follow-up.

The long-term safety and efficacy of the first-generation Wallis dynamic stabilization device have been proven in clinical practice (13). The reoperation rate within 10 years after surgery due to recurrent disease in the affected segment and ASD was 17.2% (14). Even after 13 years, 80% of patients with satisfactory outcomes could avoid revision or spinal fusion surgery (13). The second-generation Wallis device has been gradually applied in clinical practice and preliminarily has achieved excellent outcomes. A study of 129 patients with lumbar spinal stenosis who underwent implantation of the second-generation Wallis device showed that the device can reliably control the clinical symptoms over a long time (15). In a multicenter, large-sample prospective clinical study of the Wallis device there was improvement in the visual analogue scale score and JOA score after surgery (2). The results of the current study showed that lower back pain improved

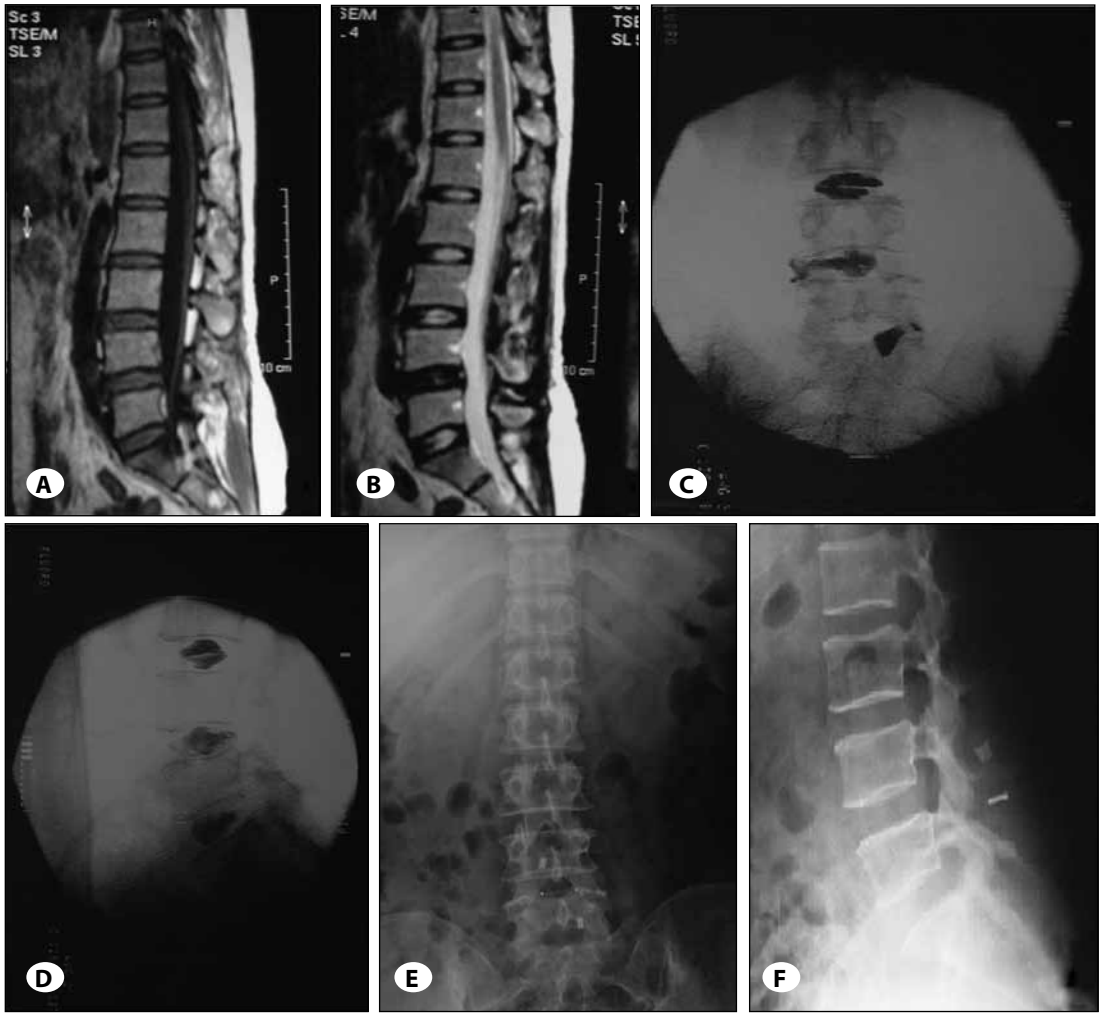

Figure 1: A 48-year-old female patient with discogenic low back pain. **A, B)** Preoperative MRI showed intervertebral disk degeneration and high intensity zone on T2-weighted MRI in L4,5. **C, D)** The results of lumbar discography showed the internal annular disruption and pain reproduction response in L4,5. **E, F)** The lumbar X-ray image after surgery.

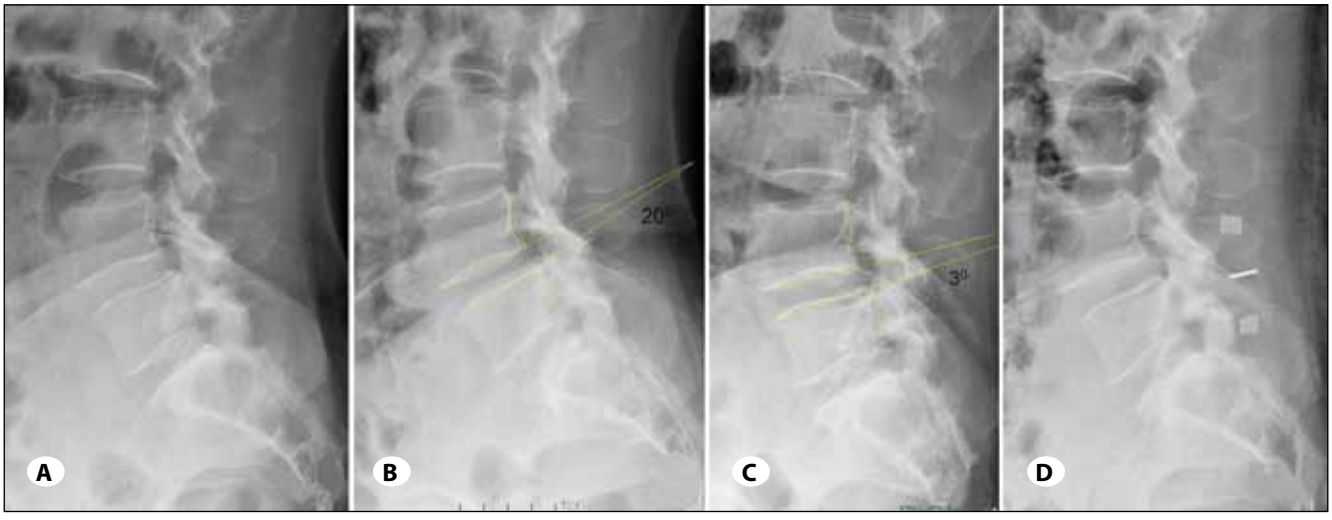

Figure 2: A 44-year-old female patient with lumbar instability. **A)** Lateral position film. **B)** Extension position film. **C)** Flexion position film. **D)** Neutral position film. Preoperative flexion-extension position X-ray showed lumbar spine instability. Postoperative X-ray at 1 year showed no loss of intervertebral height.

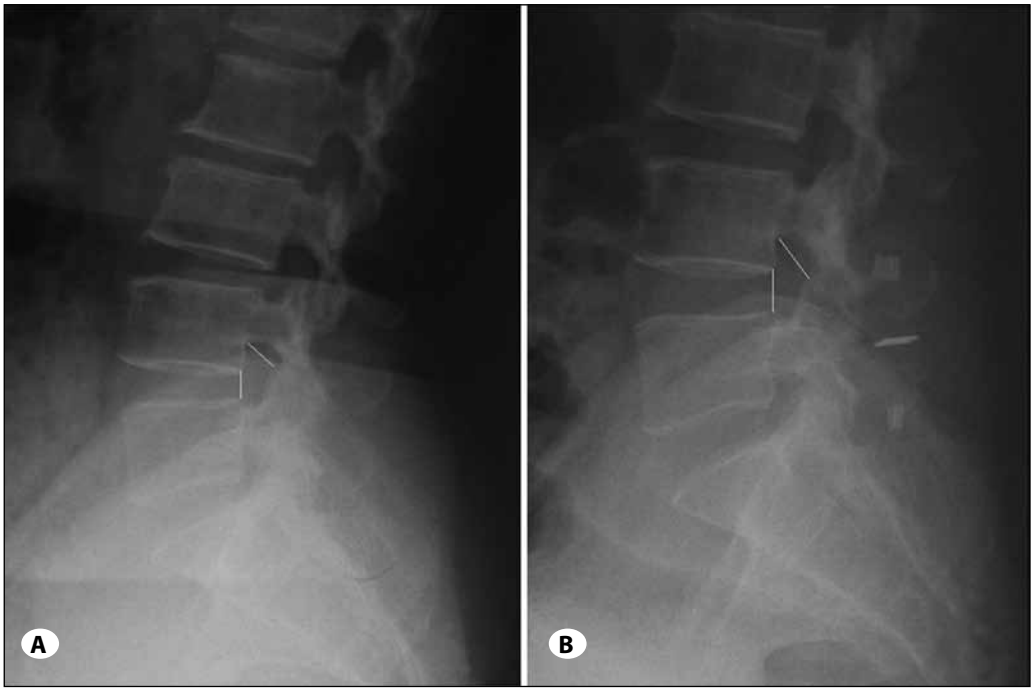

Figure 3: A 52-year-old female patient with lumbar spinal stenosis. **A)** Preoperative lateral lumbar image; the edge height of the L4,5 intervertebral disc space was 0.70 cm, the neural foramina height was 0.95 cm. **B)** Postoperative lateral lumbar image; the edge height of the L4,5 intervertebral disc space was 0.97 cm, the neural foramina height was 1.60 cm.

significantly after surgery in all 50 patients. Ninety-two percent of patients had good to excellent outcomes based on Odom's criteria. And there was significant improvement during follow-up in the JOA score and ODI score. Our results suggest that the second-generation Wallis device has a positive effect on patients' short- and medium-term clinical outcomes.

There is a significant correlation between nerve root entrapment and disc space height together with neural foramina height, that is, an increase in disc space height may enlarge the neural foramina height and subsequently improve nerve root compression (18). In our study, disc space height and neural foramina height were obtained as imaging parameters before and after surgery. The results showed that after applying the Wallis device, the disc space height increased from 0.71 (IQR: 0.58, 0.88) cm before surgery to 1.02 (IQR: 0.87, 1.12) cm at 12 months after surgery, and was maintained at 0.99 (IQR: 0.88, 1.14) cm 24 months after surgery, and the neural foramina height increased from 1.11 (IQR: 0.99, 1.19) cm to 1.72 (IQR: 1.62, 1.89) cm 12 months after surgery and was maintained at 1.72 (IQR: 1.65, 1.80) cm 24 months after surgery. There was no significant collapse in disc space height and neural foramina height over time. The Wallis device maintains disc height by the effect of interspinous distraction, which stretches the creased ligamentum flavum, improving spinal canal volume and neural foramina volume, thereby theoretically relieving the stenosis in the spinal canal and neural foramina, and consequently decompression of the spinal canal and nerve root occurs. This suggests that the Wallis device can be used for mild spinal stenosis or neural foramina stenosis. In addition, it also can be used for the loss of disc space height after removing huge disc fragments.

The Wallis device is mainly indicated for: (1) loss of a large amount of disc tissue after discectomy for a huge disc herniation; (2) recurrent disc herniation after discectomy; (3) disc herniation associated with sacralization of L5 requiring discectomy; (4) degenerative disc disease in the adjacent segment after spinal fusion; and (5) lower back pain caused by the Modic type I lesion (13). Besides the indications mentioned above, we included the lumbar degenerative diseases discogenic lower back pain and degenerative spinal instability in the current study. Theoretically, mild spinal stenosis and neural foramina height stenosis are indications for the Wallis device. Although our study proved that satisfactory clinical outcomes could be achieved with inclusion of lumbar degenerative diseases, further studies should be carried out to confirm the safety and efficacy of the Wallis device in the treatment of lumbar degenerative diseases and lumbar spinal stenosis.

It has been reported that mechanical or chemical stimulation of pain-sensitive nerve endings by degenerative tissue during disc degeneration is the pathophysiological basis of discogenic pain (17). Many researchers have reported treating discogenic lower back pain using spinal fusion (1, 16). However, it has rarely been reported that discogenic lower back pain has been treated with a non-fusion technique. In this study, 10 patients with discogenic lower back pain underwent implantation of the Wallis device and achieved excellent clinical outcomes. We speculate that this may be related to the fact that the Wallis device changes the mechanical load transmission pattern in the disc of the fixed segment, and restricts "abnormal motion" of the affected segment. In a previous study, we found that the flexion/extension range of the stabilized segments decreased, but

the corresponding lateral bending and axial rotation did not decrease significantly (10). Moreover, it has advantages compared to traditional spinal fusion surgery because it does not need bone grafting, so there are no donor site complications; there is little intraoperative bleeding; surgical trauma is mild; operative time is short; patients recover quickly; and it can be carried out under local anesthesia, and hence, it is very suitable for older patients with serious heart and lung diseases. In addition, compared with lumbar spine fusion it reduces the incidence of ASD (7).

Our study had several limitations. The study was retrospective in design. The sample size of 50 patients was small. The follow-up period was 2 years which is relatively short for evaluating the outcome of surgery for degenerative lumbar disease as degenerative changes in adjacent segments more than 2 years after surgery. Finally, there was no control group for comparison with the treatment group.

In conclusion, we found that implantation of the second-generation Wallis interspinous dynamic stabilization device for treatment of degenerative lumbar disease produced mostly good to excellent short- to medium-term outcomes. It is particularly noteworthy that excellent outcomes were achieved in patients with discogenic lower back pain. Long-term outcomes of implantation of the Wallis device in patients with degenerative lumbar diseases should be evaluated in future studies.

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