

A new interspinous process distraction device BacFuse in the treatment of lumbar spinal stenosis with 5 years follow-up study

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Abstract

To explore a suitable indication of interspinous process distraction device for lumbar spinal stenosis with BacFuse.

Patients of lumbar spinal stenosis (LSS) who experienced interspinous process distraction device surgery with BacFuse from June 2014 to January 2015 in our institute were included. We classified LSS into central and lateral types, and then divided these into severe and moderate according to the degree of stenosis. Each type was divided into 2 groups. Patients in group A underwent distraction without bone decompression (stand-alone), while patients in group B underwent bone decompression combined with distraction. Follow-up was performed at 1 month, 3 months, 6 months, 2 years, and 5 years after surgery. Zurich Claudication Questionnaire (ZCQ) was recorded to assess the patient's postoperative condition at each follow-up.

A total of 142 patients were available for follow up at each time interval. There was a significant difference between the preoperative and final follow-up ZCQ scores for every LSS type. In addition, there was no difference between group A and group B in the postoperative ZCQ scores with the exception of the lateral severe type. In the study, 22 of the 23 patients (95.65%) in the lateral moderate type were considered to have a satisfactory result in group B, with a similar result of 93.33% (14/15) in group A (P=.75). In the lateral severe type, the patient satisfaction rate was 65.22% (15/23) and 90.63% (29/32) in group A and group B (P=.02), respectively. In the central moderate type, the patient satisfaction rate was 81.82% (15/23) and 76.92% (10/13) in group A and group B (P=.77), respectively. Satisfaction rate for the follow-up results in the central severe type reached 57.14% (4/7) in group A, and 54.55% (6/11) in group B (P=.91). Moreover, no relationship was found between satisfaction and neurogenic intermittent claudication.

The most suitable indication for BacFuse treatment was the lateral moderate type. For lateral severe patients, distraction combined with decompression is suggested for a higher satisfaction rate. Severe central spinal stenosis was shown to be a relative contraindication for BacFuse.

Abbreviations: IPD = interspinous process distraction device, LSS = lumbar spinal stenosis, NIC = neurogenic intermittent claudication, ZCQ = Zurich Claudication Questionnaire.

Keywords: decompression, interspinous process distraction device, lumbar spinal stenosis

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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1. Introduction

Lumbar spinal stenosis (LSS) is caused by degenerative changes in the spine, which include the process of herniated discs, cohesion of the zygapophyseal joints and hypertrophy of the ligamentum flavum.^[1] Neurogenic intermittent claudication (NIC) is a typical sign of LSS, which is worsened by extension and relieved by flexion.^[2] Conservative treatment is the first choice to treat LSS, which includes drugs, physical therapy, traction, steroid injections and other methods. Surgical intervention will be considered if conservative treatment fails after 6 months.^[3] The application of interspinous process distraction device (IPD) for LSS has been documented in previous studies for nearly 20 years, and emphasized a minimally invasive idea.^[4-7] Many studies have reported the effectiveness and safety of IPD for the treatment of patients with LSS. However, a higher recurrent or unsatisfied rate exists compared with the traditional bone resection decompression and fusion procedure in long term follow-up.^[4-7] Therefore, there is currently no consensus on the clinical effect of the IPD. We insist that the IPD should be a better instrument in the treatment of LSS, but it is important that we pay attention to patient selection and

surgical technique. Therefore, in addition to bone resection we have used a new type of IPD device called BacFuse. The objective of our study was to explore a suitable indication through a 5-year follow-up retrospective study.

2. Materials and methods

A retrospective controlled study was performed at our institute after obtaining approval from the Bioethics Committee. All patients and their families were informed about the possible benefits and risks of the surgery, and then signed informed consent.

2.1. Patient selection

We reviewed 142 cases of LSS who experienced BacFuse surgery from June 2014 to January 2015 in our institute. The patients consisted of 83 women and 59 men, with an average age of 62.5 \pm 3.24 years (range from 50 to 78 years). Patients were divided into 2 groups according to the different surgical methods. Patients in group A underwent distraction without bone decompression (stand-alone), while group B underwent bone decompression in conjunction with distraction.

2.2. Inclusion criteria

- 1. Patients who were at least 50 years old that complained of pain in the buttock, groin, and leg, with or without back pain.
- 2. Radiological stenosis was confirmed by MRI or CT at 1 or 2 levels (absolute stenosis was a cross-sectional area less than 75 mm^2 and the relative stenosis was less than $100 mm^2$)^[8].
- 3. The patients' symptom was not relieved after strict conservative treatment for at least 6 months.

2.3. Exclusion criteria

- 1. Patients with basic diseases who cannot tolerate surgery;
- 2. Spondylolisthesis greater than grade I;
- 3. Severe symptomatic lumbar stenosis with more than 3 levels;
- 4. Scoliosis (Cobb >25°);
- 5. Severe osteoporosis;
- 6. More than 2 lesion segments.

2.4. BacFuse device

BacFuse is a novel device that is different from previous IPD. BacFuse cannot only distract the spinous process, but also can achieve fusion of the posterior column. There are 5 types of distraction ranges, from 8 to 16 mm. There are multiple spikes on the medium side of the flanks, to fix the device between the spinous processes. In addition, bone graft can be placed in the middle isthmus cavity to promote interspinous process fusion.^[9]

2.5. Operative technique

All operations were performed by Dr Tang, an experienced spinal surgeon. The patients were placed in the prone position after subarachnoid anesthesia. A posterior midline approach was used to strip the soft tissue away until the spinous processes were clearly exposed. If decompression was performed, the vertebral laminae and articular process joints were exposed. The interspinous ligament was pierced due to the placement of different dilators between the spinous processes, while the superior spinal ligament was left intact. The correct size of the device was determined according to the tension of the supraspinous ligament. Whether to perform laminotomy depended on the surgeon experience. Nerve roots needed to be explored after laminectomy. If there was disc compression, partial discectomy was performed. We defined simple distraction as stand-alone (group A) and laminotomy as combined with decompression (group B). The Cem-Ostetic bone graft was mixed with autologous bone and implanted into the cavity of the device. The device was implanted between the spinous processes through a sleeve and tightened with a screwdriver. Radiological examination was performed to confirm correct device positioning.

2.6. Follow-up care

Follow-up was performed at 1 month, 3 months, 6 months, 2 years, and 5 years after surgery. The average final follow-up time for all patients included in the study was 5.2 years (range from 5.0 to 5.4 years). Zurich Claudication Questionnaire (ZCQ) was utilized to assess the patients' postoperative condition at each follow-up.

2.7. Evaluation

Preoperative lumbar MR or CT was used to evaluate the type and degree of the disease. The degree of stenosis was determined based on the closest normal above and below intervertebral level. Central stenosis was classified as moderate when the midsagittal and/or transverse dimensions were decreased up to 40% and severe when the decrease was greater than or equal to 41%. Lateral stenosis was classified as moderate when the most medial part of the lateral canal was decreased up to 40% and severe when the decrease was greater than or equal to 41%. Radiological assessment was performed by a radiologist and a spinal surgeon together. Different opinions were ultimately decided by Dr Tang.

The ZCQ score was defined as a primary outcome in the study. The satisfaction score in ZCQ was performed as an indicator of satisfaction rate. A patient satisfaction score of less than or equal to 12 points was considered satisfactory.

2.8. Statistical analysis

Data analysis was performed using available software (SPSS version 20.0, SPSS, Inc., Chicago, IL). ZCQ data were continuous variables and conformed to a normal distribution. Therefore, the comparison between groups used the independent sample t test, and the comparison within groups used the paired sample t test. The satisfaction rate was a discontinuous variable that was analyzed through Chi-squared test. P < .05 was considered to be statistically significant.

3. Result

Patient demographics were shown in Table 1. The patients were classified into 4 types (lateral moderate; lateral severe; central moderate; central severe) according to the location and severity of stenosis. Each type of LSS was divided into group A and group B. No significant differences were observed in the age, gender,

 Table 1

 Clinical data of patients treated with 2 surgical methods.

	Group A	Group B
Basic information		
Age (yr)	65.35	67.73
Sex ratio (male/female)	28/35	31/48
Pain duration (rr)	3.52	3.47
Physiotherapy (%)	72.38	67.36
Clinical presentation		
Intermittent claudication	39	42
Pain at rest and on walking	24	37
Type of stenosis		
Central	25	24
Lateral	38	55
Severity of stenosis		
Moderate	26	36
Severe	37	43
Operative complications	2	2

duration, or physical procedure between the 2 groups. All patients experienced posterior lumbar surgery and no serious complications occurred. ZCQ scores were recorded at each follow-up.

3.1. Effectiveness

The ZCQ scores at each follow-up were presented in Figure 1. There was a significant difference between group A and group B in the lateral moderate type (P < .05). In addition, we compared the ZCQ scores between pre-surgery and the final follow up in each group of patientsand found that there was a significant difference between before surgery and the final follow-up (Fig. 2). Typical cases were presented in Figures 3 and 4.

The patient satisfaction rate was shown in Table 2. From this table, we could conclude that 22 of the 23 patients (95.65%) in the lateral moderate type were considered to have a satisfactory result in group B, with a similar result of 93.33% (14/15) in group A (P=.75). In the lateral severe type, the patient satisfaction rate was 65.22% (15/23) in group A and 90.63% (29/32) in group B (P=.02), respectively. In the central moderate type, the patient satisfaction rate was 81.82% (15/23) in group A and 76.92% (10/13) in group B (P=.77), respectively. Satisfaction rate for the follow-up results in the central severe type reached 57.14% (4/7) in group A and 54.55% (6/11) in group B (P=.91).

We also examined the relationship between satisfaction rate and intermittent claudication in Table 3. No relationship was found between satisfaction and intermittent claudication.



Figure 1. Pre-surgery and postoperative assessments of Zurich Claudication Questionnaire scores. (A) Lateral moderate, (B) lateral severe, (C) central moderate, (D) central severe. For the comparison of Group A and Group B, * indicates P < .05, # indicates P > .05.



Figure 2. Pre-surgery and postoperative assessments of Zurich Claudication Questionnaire scores. (A) Lateral moderate, (B) lateral severe, (C) central moderate, (D) central severe. For the comparison of the pre-surgery and 5-years follow-up values within group A, * indicates P < .05. For the comparison of the pre-surgery and 5 years-follow-up values within Group B, * indicates P < .05.

3.2. Safety

In group A, 2 patients experienced spinous process fracture during the procedure. In subsequent follow-up, these patients did not achieve a satisfactory result. The internal fixation was not removed, and the fracture finally healed after conservative treatment. In group B, 2 patients experienced a dural tear during the decompression procedure without serious consequences after meticulous treatment. None of the remaining patients had serious complications.

4. Discussion

Patients with LSS had typical feature of neurogenic intermittent claudication, which presented as pain that increased when straightening the waist and decreased when bending down. NIC was mainly caused by a loose and hypertrophic ligamentum flavum, which led to segmental epidural venous stasis in extension. Therefore, it is believed that bending down can alleviate symptoms by increasing the cross-sectional area of the spinal canal, which has been shown biomechanically.^[10] Based on this theory, implantable IPD has been utilized for distracting the spinal posterior column and reducing compression. PierVittorio Nardi reported that the Aperius device provided better clinical results through a stand-alone technique to acquire nerve decompression by expanding the spinal canal area.^[11] Although the clinical application of IPD had persisted for many years and

showed promising results in the short-term, its effectiveness still remains controversial, especially for postoperative recurrence and satisfaction rate.^[12–14] Studies reported that IPD can significantly decreased ZCQ and Oswestry Disability Index, but there was a possibility of a "bound back" in 1 to 2 years after surgery.^[15–18] Zucherman reported that the satisfaction rate with X-STOP for LSS was nearly 70% in 1-year follow-up.^[19] The main cause of patients' dissatisfaction was recurrent or persistent symptoms after surgery. As for any new device, proper patient selection was critical to achieving successful outcomes. We speculated that the success rate of surgery greatly varied due to many factors, such as patient selection, surgical technique and measure method of outcomes.

In our study, we classified lumbar spinal stenosis into central and lateral types and then divided these into severe and moderate according to the degree of stenosis. Compared with the preoperative and the final follow-up in the ZCQ score, all types of patients had symptom relief to some degree. By using the Oswestry questionnaire and other clinical assessments as the measure method of outcomes, subjective disability or functional status could not been accurately presented.^[19] The ZCQ was applied in our study because of recording data in 3 different domains: symptom severity, physical function, and treatment patient satisfaction, which can express slight improvement in patients.^[20,21]

A comparison of stand-alone and combined with decompression, we found no significant differences except for the lateral



Figure 3. A 69 years old female patient who complained of pain in the left lower limb with NIC. She was defined as lateral moderate type. Her pre-surgery and postsurgery Zurich Claudication Questionnaire were respectively 42 and 18 and symptoms decreased after surgery. (A, B) Preoperative MRI of the mid-sagittal image and axial image(L3/4). (C, D) The post-operative anteroposterior and lateral X-ray image (L3/4). (E, F) Post-operative MRI of the mid-sagittal image (L3/4). (G) Postoperative CT of axial image(L3/4). From the comparison before and after the surgery, the prominent disc has been absorbed or retracted.

severe type. It is essential to decompress for patients with lateral severe stenosis, the effect of which could not be achieved simply by distraction. In our 5-year follow-up study, the satisfaction rate of patients with severe lateral recess stenosis combined with decompression reached 90.63% and patients with stand alone reached 65.22%. Severe degeneration, a hyperplastic and cohesive zygapophyseal joint, and a bulging disc could result in a situation with an inflamed nerve root that cannot be released sufficiently by distracting. According to previous reports in the literature, effective results could be achieved by decompression alone without internal fixation.^[22] However, decompression alone could cause spinal instability, especially for patients with spondylolisthesis. One study had reported that patients decompressed alone had a recurrence of 41.45%, with symptoms equal to or worse than they were at initial presentation after 6.75 years.^[23] In our previous study, the BacFuse device could be used for fusion of the posterior vertebral column and decompression without compromising the stability of the lumbar spine.^[9] Therefore, mostly lateral severe patients experienced surgery with distraction and decompression yielded satisfactory long-term results.

In our study, the optimum indication for BacFuse for the treatment of LSS was the lateral moderate type. At 5-year follow-

up, satisfaction rates reached 93.33% and 95.65%. There was no significant difference between the stand alone group and the combined with decompression group. The results compared well with a meta-analysis which reported the rate of excellent/good clinical outcome just reached 64%.^[24] For lateral moderate LSS, the distraction of the posterior column tightens the ligamentum flavum and reduces the stress of the posterior column.^[25,26] The cross-sectional area of the spinal canal can be increased by 25% to 35% by distraction of the IPD.^[27] In patients whose effect was not affirmed after distraction, further decompression was suggested to probe the nerve root canal to ensure the relaxation of the nerve roots.

For central moderate patients, both stand alone and combined with decompression had better satisfaction rates. Moreover, there was no obvious difference between the 2 methods. The main reason for this type was disc protrusion and ligamentum flavum hypertrophy. Distraction can significantly increase the crosssectional area of the spinal canal and the height of the foramina, which can achieve nerve decompression in the short term.^[23] Moreover, biomechanical experiments had showed that the spine was subjected to continuous axial pressure, which resulted in the degeneration of the disc as a result of significant decreases in the number and quality of nucleus pulposus cells.^[28] The fixation and



Figure 4. An 80 years old male patient who complained of pain in the left lower limb persistently. He was defined as lateral severe type. His pre-surgery and postsurgery Zurich Claudication Questionnaire were respectively 43 and 20 and symptom decreased after surgery. (A) Preoperative MRI of the mid-sagittal image. (B, D) Preoperative MRI.

fusion of the posterior spinal column could stabilize the pressure on the intervertebral disc and prevent or reverse the process of disc degeneration in the long term.^[29] Therefore, the effect of distraction was confirmed on the basis of our research. However, the effect of bone decompression is not clear for the central LSS adopting IPD, because it was not possible to perform fenestration to directly reduce ventral compress for central stenosis.

For LSS patients with central severe type, we did not consider BacFuse to be the preferred treatment option. We treated some patients who did refuse traditional fusion surgery or could not stand general anesthesia surgery in the method of BacFuse. Our

Table	2			
Satistad	Lateral		Central	
	Moderate	Severe	Moderate	Severe
Group A Group B	14/15 (93.33%) 22/23 (95.65%)	15/23 (65.22%) 29/32 (90.63%)	9/11 (81.82%) 10/13 (76.92%)	4/7 (57.14%) 6/11 (54.55%)

Table 3

The relationship between satisfaction and neurogenic intermittent claudication.

	Group A			Group B		
	Satisfied	Unsatisfied	Р	Satisfied	Unsatisfied	Р
NIC	31	8	.68	36	6	.81
UNIC	18	6		31	6	

NIC = neurogenic intermittent claudication, UNIC = non-neurogenic intermittent claudication.

study found that some patients did improve in their symptoms to some extent. Symptom improvement can be concluded using the ZCQ score in the data, and the satisfaction rates was 57.14% in stand-alone group and 54.55% in the other group. However, this satisfaction rate might not be clinically acceptable. We concluded that severe central spinal stenosis was a relative contraindication for BacFuse.

It could be thought that BacFuse was absolute indication for patients with NIC whose spinal column were placed in the flexion condition by posterior column traction. However, no relationship was found between satisfaction and NIC in our study. We speculated that there were 2 reasons: first, NIC, as a sign of LSS, was not very specific and sensitive; secondly, our sample size was too small to grouping to further study.

5. Limitations

This was a single-center study with a small sample size, especially for some types of LSS. In addition, we only took a scoring scale, which may be partially biased.

6. Conclusion

BacFuse, as a new type of IPD, avoided the disadvantages of previous IPD and increased the fusion characteristic. It was an effective alternative treatment options for LSS. The best indication for BacFuse treatment was the lateral moderate type. For lateral severe patients, distraction combined with decompression was suggested for higher satisfaction rate. Severe central spinal stenosis was a relative contraindication for BacFuse.

Author contributions

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