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ORIGINAL PAPER

Preliminary efficacy of inter-spinal distraction fusion which is a new technique for lumbar disc herniation

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Abstract

Introduction To investigate the short- and medium-term efficacy of inter-spinal distraction fusion (ISDF) for lumbar disc herniation with a spinal internal fixation device, the BacFuse Spinous Process Fusion Plate.

Methods Ninety-five patients who received ISDF between January 2014 and January 2015 were included for the current retrospective study. The symptoms and imaging results before surgery, immediately after surgery, at six months, and at the last follow-up were assessed using the leg visual analogue scale (VAS), Oswestry disability index (ODI), and 12-item short-form survey (SF-12). The intra-operative intervertebral angle (IA), anterior disk height (ADH), posterior disk height (PDH), foramina height (FH), foramina width (FW), and range of motion (ROM) were assessed using X-rays. The foramina and herniated disc area were assessed using computed tomography (CT).

Results The leg VAS, ODI, and SF-12 were significantly improved after surgery. All indices except ADH were also significantly improved after surgery. PDH and FH increased by 15.5% ($P < 0.001$) and 9.7% ($P < 0.001$) at the last follow-up. ROM was statistically different from before surgery. CT images indicated that the herniated disc area decreased by 3.1%, while the foramina areas increased by 5.7% at the last follow-up. 92.6% patients demonstrated successful outcome.

Conclusions ISDF significantly alleviated the clinical symptoms, improved spinal structure, and partially retracted the herniated disc. Our findings imply that ISDF is an effective minimally invasive procedure in the treatment of lumbar disc herniation.

Keywords Lumbar disc herniation · Inter-spinal distraction fusion · The spinous process fusion plate · Retraction of intervertebral disc

Background

Lumbar disc herniation (LDH) is a common condition that requires spinal surgery. It can be diagnosed using imaging examinations, such as computed tomography (CT) and magnetic resonance imaging (MRI), as well as special examinations such as electromyography and somatosensory-evoked potential [1]. Posterior lumbar interbody fusion is a traditional surgical procedure for LDH, which can alleviate symptoms and improve post-operative functions, but the surgical trauma is relatively large [2–4]. Transforamimal percutaneous endoscopic lumbar discectomy was also proved to be an effective surgical procedure for LDH [5, 6]. Interspinous process devices (ISP), such as X-STOP, Wallis, and Coflex, are a type of dynamic inter-spinal internal fixation system [7–10]. The technique developed because of the advent of inter-spinal distraction. The surgery expands the vertebral canal and foramina to reduce disc pressure by separating the spinous processes [11]. ISP is used to treat discogenic low back pain and lumbar stenosis, and LDH is also one of the indications [12]. However, the use of ISP is decreasing because of some disadvantages. According to previous research, the complication rate is 11.6~38% (including spinous process fracture and dura

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mater tear) and the re-operation rate is 4.6~85% (including device dislocation and poorer outcome) [13–17].

In order to overcome the weakness of the above two methods of operation, a new minimally invasive surgery, inter-spinal distraction, and fusion (ISDF) appeared. It can achieve the goal of fusion and fixation while still providing distraction. The BacFuse Spinous Process Fusion Plate (RTI Surgical, USA) was designed for ISDF and was approved by the U.S. Food and Drug Administration in 2011.

The principle of ISDF is completely different from previous surgical procedures, and the published literature is sparse on this technique. In this study, we retrospectively collected the clinical symptoms and imaging indices in patients who received ISDF. The data were then analyzed to study the efficacy of ISDF in the treatment of LDH.

Subjects and methods

Ethical approval

The study was conducted in accordance with the ethical standards of participating institutions and with the Helsinki Declaration of 1975, as revised in 2000.

Study design and subjects

The present study was an observational retrospective study and was conducted at the author's institute. Between January 2014 and January 2015, 95 patients (58 males and 37 females) were included in the study. The inclusion and exclusion criteria are listed in Table 1.

Implant and surgical instruments

For distraction and fusion between spinous process, the BacFuse Spinous Process Fusion Plate was chosen. This device is similar to an ISP device. However, there are some differences. The BacFuse device is composed of a hollow casing with bilateral flanks in which the hollow casing is used to support the middle part of upper and lower spinous processes. The hollow casing is filled with bone graft material for fusion (Fig. 1). The device has a size range of 8 to 16 mm for distraction. There are several spikes in the medial flanks, which can be screwed into the spinous processes to fix the device at the surgical level. Instrumentation includes a compressor, inserter, driver, sleeve, rasp, and dilator. Cem-Ostetic bone graft (Berkeley Advanced Biomaterials, Berkeley, CA, USA) was used to fill the hollow casing. It is a mixture of liquid (water) and solid (hydroxylapatite, β-tricalcium phosphate, and calcium sulfate) components.

Surgical procedure

Patients were placed in a prone position after having had a subarachnoid block or combined spinal-epidural analgesia. Soft tissues were dissected using the posterior median approach until the spinous process was exposed. The interspinal ligament was then dissected while the ligamentum supraspinale was retained. After the superior and inferior spinous processes were gradually expanded with dilation, the spacing was measured to determine which size to use. Sole neural decompression by fenestration through partial laminectomy was performed if patients had spinal stenosis. The Cem-Ostetic bone graft was mixed and implanted into the casing. The device was implanted from one side of the spinous process using a sleeve, followed by fixation of the titanium plate by a compressor. The surgery ended after satisfactory implantation was confirmed by fluoroscopy.

Assessment of clinical symptoms

Patients' symptoms before surgery, after surgery, at six months, and at the last follow-up were assessed. The assessment methods were leg visual analogue scale (VAS), Oswestry disability index (ODI), physical component summaries (PCS), and mental component summaries (MCS) in the 12-item short-form health survey (SF-12). Successful outcomes were defined as a reduction of at least 50% in leg VAS and ODI at the last follow-up.

X-ray analysis

Standard anteroposterior and lateral X-rays (DRVM 1.5, Philips, Germany) of the lumbar spine were taken in patients before surgery, after surgery, at six months, and at the last follow-up. The X-ray results were input into and measured using UniWeb Viewer 4.0 (EBM Technologies LLC, Honolulu, HI, USA). The following data were taken from the X-rays (Fig. 2) [19–22]:

1) Intervertebral angle (IA): angle between the inferior endplate of the upper vertebra and superior endplate of the lower vertebra (a);
2) Anterior disc height (ADH): distance from the anterior edge of the inferior endplate of the upper vertebra and superior edge of the lower vertebra (b);
3) Posterior disc height (PDH): distance from the posterior edge of the inferior endplate of the upper vertebra and superior edge of the lower vertebra (c);
4) Foramina height (FH): maximum distance between the inferior pedicle of the upper vertebra and superior pedicle of the lower vertebra (d);

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1) 40–65 years old 2) Confirmed LDH of single or double levels at L2–S1 by CT or MRI 3) Pain in unilateral radicular with or without mild to moderate lumbar spinal stenosis 4) Straight leg raising test ≤ 60° 5) Received ineffective conservative therapy for at least 3 months 6) Preoperative visual analogue scale (VAS) score > 5 (10 total points) 7) Preoperative Oswestry disability index (ODI) score > 20 (50 total points)	1) Extrusion, sequestration [18] or calcification of discs by CT or MRI 2) More than three herniated levels 3) Spondylolisthesis > 1 degree (Meyerding), instability of lumbar spine, or campylorrachis scoliosis (Cobb angle > 25°) 4) Posterior arch weakness or deficiency (laminectomy, isthmic injury) 5) Lumbar spinal stenosis caused by articular facet hypertrophy and hyperosteogeny 6) History of spinal surgery, trauma, or tumor 7) Body mass index > 40 8) Titanium or titanium alloy allergy 9) Severe cardiopulmonary anomaly, history of peripheral nervous system disease, peripheral vascular disease, rheumatoid immune systemic disease, or uncontrolled medical illness.

5) Foramina width (FW): the intersected level of extension of the inferior endplate of the upper vertebra with the foramina (e);
6) Range of motion (ROM): in the lumbar flexion and extension of the X-ray film. ROM = extended IA - flexional IA (f). ROM was measured at every time point expect post-operation. The ROM was only measured in patients with a single device for the reason that double implantation may have interaction with adjacent plate.

CT analysis

A CT scan of the lumbar spine was performed before surgery (Discovery CT 750 HD, General Electric Company, Milwaukee, WI, USA) for two-dimensional (2D) and three-dimensional (3D) reconstructions. A spectrum CT (Discovery CT 750 HD, General Electric Company, Milwaukee, WI, USA) of the lumbar spine was performed after surgery and at follow-up, from which the data at 120 keV were extracted for 2D and 3D reconstructions [18] to reduce the metal artifacts. The herniated disc area was measured at the reconstructed image in which the disc herniated most, and the foramina area at the affected side was measured as well. CT images were reconstructed and measured using VolumeShare 2 AW 4.4 (General Electric Company, Milwaukee, WI, USA).

Fig. 1 Illustration of BacFuse Plate

Statistical analyses

Statistical analyses were performed using SPSS 18.0 (IBM, USA). Clinical symptoms and X-ray indices were analyzed using repeated measures analysis of variance (ANOVA) and the non-normal data were analyzed using the chi-squared or rank sum test. $P < 0.05$ was considered statistically significant. Data were expressed as the mean ± standard deviation (±s), and the error bars in the figures refer to 95% confidence intervals.

Results

Baseline information

Ninety-five patients with a mean age of 58.3 ± 5.3 years (range, 42–65 years) were enrolled in the study, including 58 men and 37 women. The average duration of follow-up was 15.4 ± 3.4 months. A total of 110 surgical levels were performed on these patients, including 80 single levels and 15 double levels (Fig. 3). The device was implanted at L2–3 in four patients (3.6%), at L3–4 in 14 patients (12.7%), at L4–5 in 59 patients (53.6%), and at L5–S1 in 33 patients (30.1%).

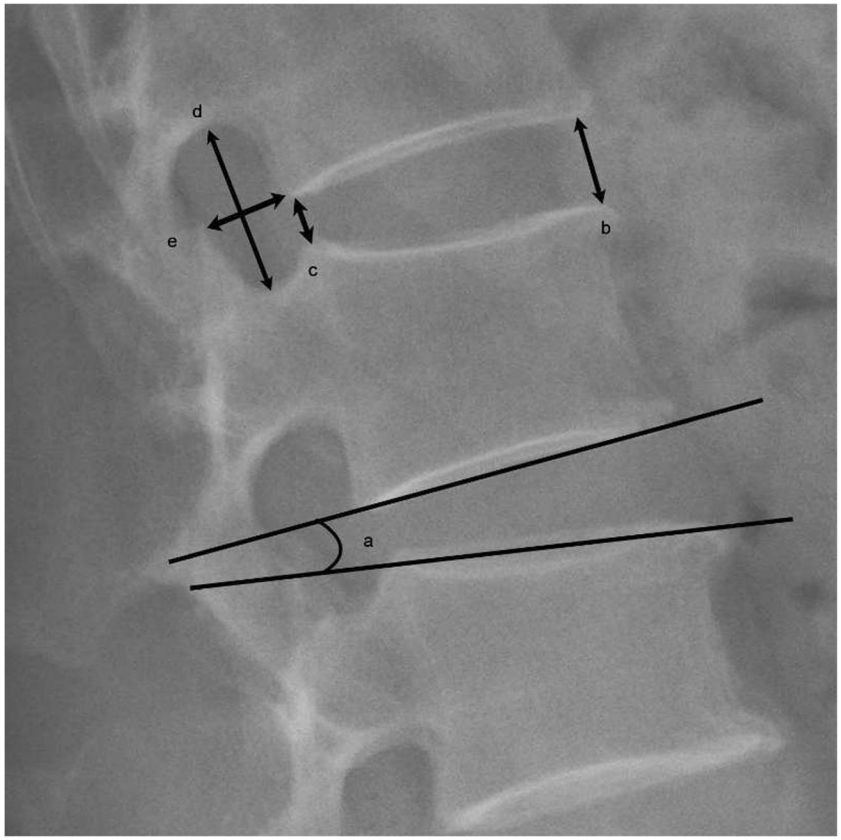

Fig. 2 Measurement of X-ray indices: (a) intervertebral angle, (b) anterior disc height, (c) posterior disc height, (d) foramina height, (e) foramina width

The average incision length was 11.2 ± 2.7 cm, the average blood loss was 32.3 ± 17.6 ml, and the average duration of operation was 57.2 ± 17.4 minutes (Table 2). The implantation size was 8 mm in four levels (3.6%), 10 mm in 11 levels (10.0%), 12 mm in 27 levels (24.5%), 14 mm in 41 levels (37.4%), and 16 mm in 27 levels (24.5%).

Clinical symptoms

Repeated measures ANOVA showed that there were statistical differences in leg VAS, ODI, and PCS and MCS of SF-12 over time. In addition, the above indices at the last follow-up were significantly different from those before surgery (Table 3). There were seven patients whose leg VAS and ODI were less than 50%. 92.6% of patients achieved a successful outcome.

Imaging results

X-rays showed that ADH at post-operation was not statistically different from that before surgery ($P = 0.502$); the other indices including IA, PDH, FH, and FW at post-

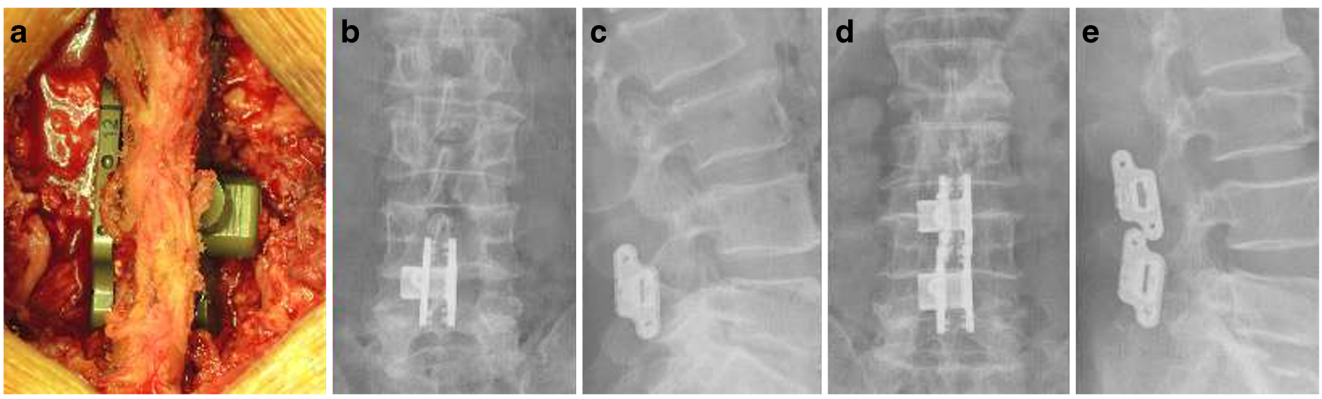

Fig. 3 **a** The image of a fixed spine at operation. **b**, **c** The post-operative anteroposterior and lateral X-ray of single-level implantation at L4–5. **d**, **e** The post-operative anteroposterior and lateral X-ray of implantation at L3–4 and L4–5

Table 2 Baseline of demographics and surgical information

Variables	Results
Demographics	95
Ages (years)	58.3 ± 5.3
Gender	
Male	58 (61.1%)
Female	37 (38.9%)
Follow-up duration (min)	15.4 ± 3.4
Surgical information	
Surgical level	110
Single	80 (72.7%)
Double	15 (27.3%)
Implantation level	
$L_{2–3}$	4 (3.6%)
$L_{3–4}$	14 (12.7%)
$L_{4–5}$	59 (53.6%)
L_5/S_1	33 (30.1%)
Incision length (cm)	11.2 ± 2.7
Bleeding (ml)	32.3 ± 17.6
Operative time (min)	57.2 ± 17.4

operation were statistically different from those before surgery ($P < 0.05$). At the last follow-up, X-ray images of IA, PDH, FH, and FW showed statistically significant changes over time ($P < 0.05$). At the last follow-up, IA, PDH, and FH were statistically different from those before surgery (Table 3, Fig. 4). Compared with pre-operative values, the PDH increased by 18.3% at post-operation and by 15.5% at the last follow-up. The FH increased by 9.7% at post-operation and by 4.1% at the last follow-up (Fig. 4). The ROM at six months was statistically different from those before surgery ($P < 0.05$). At the last follow-up, it was similar to six months ($P = 0.315$), and decreased by 63.4% at the last follow-up.

CT images (Fig. 5) indicated that the herniated disc area and foramina area (FA) after surgery were statistically different from those before surgery ($P < 0.05$). The repeated measures ANOVA implied that these indices showed significant changes over time ($P < 0.05$). At the last follow-up, these indices were statistically different from those before surgery (Table 3, Fig. 4). When compared to pre-operative values, the herniated disc area decreased by 6.7% after surgery and by 3.1% at the last follow-up, respectively, and the foramina area increased by 7.3% after surgery, and by 5.7% at the last follow-up (Table 3, Fig. 4).

Complications

Postoperative complications were found in one patient (0.9%). This patient had a spinous process fracture but did not suffer from significant post-operative back discomfort, and was asked to wear a back brace for three months.

Table 3 The changes in clinical symptoms and imaging

	Pre-operation	Post-operation	6 months	Last follow-up	*P* (last follow-up/ pre-operation)*
Clinical symptoms					
Leg VAS	6.7 ± 1.3	3.2 ± 1.3	2.4 ± 1.5	2.1 ± 1.4	< 0.001
ODI	33.3 ± 6.2	18.5 ± 6.9	13.3 ± 5.5	12.5 ± 5.7	< 0.001
PCS	32.9 ± 5.5	39.7 ± 5.6	42.4 ± 5.0	45.0 ± 5.4	< 0.001
MCS	35.7 ± 5.4	42.2 ± 5.8	45.2 ± 5.0	47.1 ± 4.9	< 0.001
X-ray					
IA (°)	10.2 ± 4.7	8.4 ± 4.2	8.7 ± 4.3	8.8 ± 4.3	< 0.001
ADH (cm)	1.54 ± 0.57	1.55 ± 0.56	1.54 ± 0.59	1.51 ± 0.54	0.300
PDH (cm)	0.71 ± 0.31	0.84 ± 0.32	0.81 ± 0.30	0.82 ± 0.29	< 0.001
FH (cm)	1.96 ± 0.33	2.15 ± 0.34	2.12 ± 0.35	2.04 ± 0.33	< 0.001
FW (cm)	0.98 ± 0.24	1.03 ± 0.26	1.01 ± 0.25	1.02 ± 0.23	0.075
ROM(°)	14.2 ± 3.4	–	5.3 ± 2.4	5.2 ± 2.2	< 0.001
CT					
Herniated disc area (mm^2)	84.0 ± 29.6	78.4 ± 29.4	80.5 ± 29.0	81.4 ± 30.1	0.008
Foramina area (mm^2)	91.0 ± 28.2	97.6 ± 28.5	96.3 ± 27.4	96.2 ± 27.1	< 0.001

VAS visual analogue scale, *ODI* Oswestry disability index, *PCS* physical component summaries, *MCS* mental component summaries, *IA* intervertebral angle, *ADH* anterior disc height, *PDH* posterior disc height, *FH* foramina height, *FW* foramina width

*The *P* value of comparison between pre-operation and last follow-up with repeated measures ANOVA

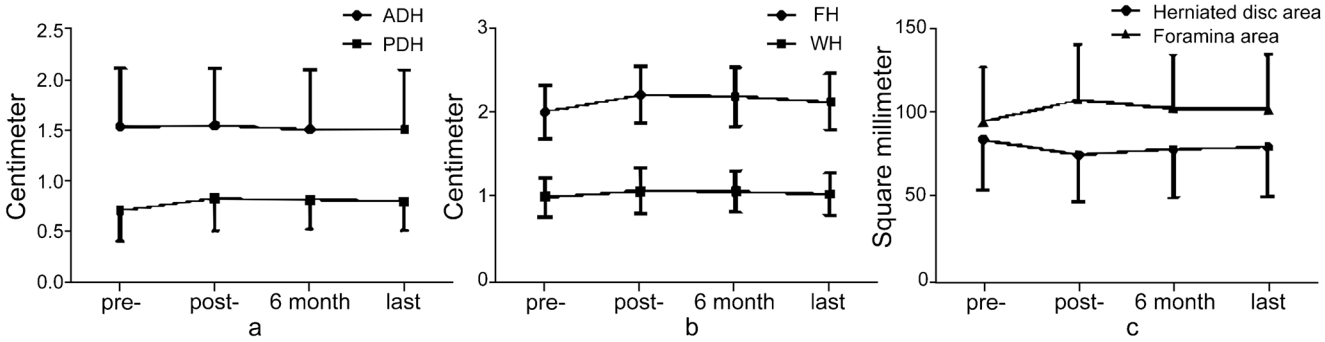

Fig. 4 The changes of anterior and posterior disc height (**a**), foramina height and width (**b**), and herniated disc area and foramina area (**c**) over time

Discussions

Feature of ISDF

Minimally invasive surgery has demonstrated efficacy in treating LDH. The goal of this surgery is to remove the herniated portion of the intervertebral disc, but this can present with a risk of nerve injury, deficient decompression, or other adverse events [23–25]. The ISPs distract the intervertebral space only with no fixation and fusion effect. Thus, the disc is still affected by flexion, rotation, and lateral stresses. Consequently, there is still a risk of continued degeneration and recurrent herniation of the intervertebral disc, even a possibility of failure of the ISP due to loosening. So, ISPs are mainly used for low back pain caused by LDH. While ISDF provides distraction, it also provides fixation and fusion.

The BacFuse Plate is indicated for disc degeneration, spinal spondylolisthesis, trauma (such as fracture or dislocation), and/or tumours from T1-S1 by the U.S. Food and Drug Administration. In the present study, the new surgical procedure ISDF with BacFuse Plate was similar to ISPs in intraoperative bleeding and surgery duration [26, 27] (Table 2), but follow-up and post-operative ROM were significantly reduced compared with those before surgery, indicating that ISDF with the BacFuse Plate provides significant fusion and fixation effects. The advantage is it includes spikes between

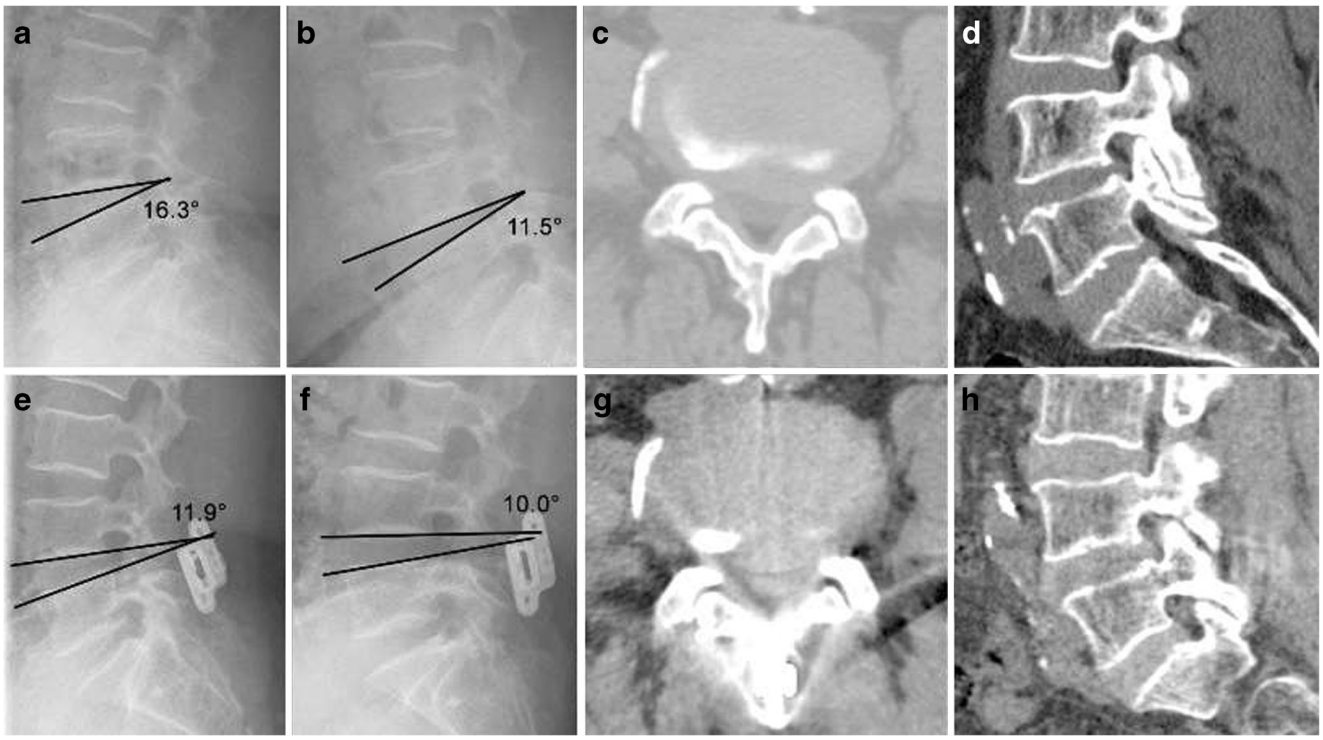

Fig. 5 The patient was a 64-year-old woman who complained pain in the left lower limb. Her pre-operation leg VAS and ODI were 6 and 36 and were 2 and 8 respectively at six months. **a**, **b** The pre-operative flexion and extension X-ray. The ROM was 4.8°. **c** The herniated disc in horizontal restructured image. **d** The foramen in sagittal restructured image. **e**, **f** Flexion and extension X-ray at six months. The ROM was 1.9°. **g** The herniated disc in horizontal restructured image at six months which have reduced the metal artifacts by spectrum CT. **h** The foramen in sagittal restructured image at six months by spectrum CT

the plates that can be compressed into the spinous process to fix the device, making it a more stable system. It may create the conditions for distraction and fusion between spinous process. The surgical segments will be fused, the degeneration and inflammation of the intervertebral disc will be reduced, and the intervertebral disc may gradually retract. Furthermore, the ISDF retains the supraspinal ligament and is applicable to two or more continuous vertebral levels which cannot be done with some ISP surgeries, like DIAM and Wallis, because of the their design features. Franco reported interspinous lumbar instrumented fusion for surgical treatment of degenerative spondylolisthesis. The interspinous ligament and supraspinal ligament was removed, a polyetheretherketone spacer was inserted, and bone graft was placed into the implant between the spinous processes. At two year follow-up, all patients were successfully fused. This procedure was similar to ours, showing that ISDF could provide a good fusion and fixation effect [28]. Especially, we had retained the interspinous ligament and supraspinal ligament.

Improvement of symptoms

The relationship between ISP and LDH has been rarely investigated. Fabrizi AP et al [29] studied the effect of two kinds of ISPs for degenerative spinal diseases. Two hundred eighty-three patients with LDH (1575 patients in total) received the DIAM or Aperius device. The VAS decreased from 7.54 to 2.41 and ZCQ increased from 42.31 to 63.09 at one year follow-up. The study from Xu et al. [30] has evaluated the short-term effectiveness of LDH by Coflex implantation as measured by JOA, VAS, and ODI scores. The results showed the average JOA score increased from (9.1 ± 1.1) to (26.4 ± 1.7), ODI decreased from (24.7 ± 4.8) to (4.5 ± 1.1), and VAS score decreased from (7.9 ± 0.8) to (3.0 ± 0.9) at six months post-operatively. The clinical symptoms after operation were significantly improved. In this study, the patient's leg VAS, ODI, and SF-12 had significant improvement after ISDF (Table 3). The physical pain, lower limb function, and quality of life were improved, with 92.6% of patients achieving a successful outcome. Therefore, the improvement of symptoms was similar to that of previous studies where dynamic stabilization was performed [29–31]. ISDF with the BacFuse Plate did not sacrifice the supraspinal ligament and may have a greater scope of application.

Changes in images

In this study, the post-operative PDH, FH and FA increased by 18.3, 9.7, and 7.3% as compared to pre-operative values (Table 3, Fig. 4). These are similar to the results from biomechanical studies [32–35]. However, PDH and FH incurred partial loss during follow-up. At the last follow-up, PDH had decreased by 2.4% and FH had decreased by 5.1% as compared with results after surgery (Table 3, Fig. 4), but the patients' clinical symptoms were still satisfactorily improved. A retrospective study by Sobottke [36] compared the efficacies of X-Stop, Wallis, and DIAM implantation, and the results showed that patients with X-STOP had the most significant improvements in FH, FW, and FA; however, PDH, FH, and FA during follow-up were decreased by 17.9%, 5.6%, and 11.4%, respectively, compared with those immediately after surgery. Another two studies found similar results [37, 38]. Although there was a loss in PDH and FH in this study, the values were still better than those in previous studies on ISP devices. We speculate that the design and different operating principles, which allow the BacFuse Plate to be firmly fixed between the spinous processes, lead to slight decreases in post-operation PDH and FH instead of a continuous decline.

The biomechanical studies from Hartmann [39] found that ISPs (Aperius, In-Spacr and X-Stop) could reduce extension at the surgical segment; however, the other directions of motion were not affected significantly. In a prospective observational study, 48 patients were treated with X-Stop and were evaluated with MRI. After two year follow-up, they did not find a significant change in ROM at the instrumented and adjacent levels [40]. In this study, the ROM of surgical segments with ISDF decreased 63.4% at the last follow-up. The spikes between the plates and the addition of bone graft fused the surgical segments together. The ROM results indirectly prove the stability of the spine; however, further research is needed to confirm directly.

Retraction of intervertebral disc and theory of in vivo tractor

Animal models showed that the intradiscal pressure might be reduced when the spinal column was subjected to continuous axial pressure, leading to degeneration of the intervertebral disc, while traction of the spine might stabilize the intradiscal pressure and partially reverse or prevent disc degeneration caused by compression of the spine [41]. Subsequently, conservative traction therapy has been used to alleviate the clinical symptoms of LDH [42, 43]. Some surgeons believe that traction therapy can achieve intervertebral disc retraction. Sari [44] performed static mechanical traction on 32 patients with acute LDH, in which the herniated disc area was reduced by 24.5% compared with that before traction. A prospective randomized controlled study by Ozturk [45] enrolled 46 patients with LDH, comprising 22 who had physical therapy and 24 who had physical and traction therapy. The CT results showed that the lumbar disc index improvement was 63.7 (23%) in the traction group, whereas it was 8 (2.7%) in the physical therapy group. BenEliyahu [46] performed spinal chiropractic therapy, including traction therapy, in 27 patients with cervical and LDH. A post-operative MRI found that 63% of patients had a reduced or even completely absorbed disc;

however, changes in intervertebral disc areas or volumes after ISP have not been reported.

CT images indicated that the herniated disc area decreased by 3.1%, while the foramina areas increased by 5.7% at the last follow-up (Table 3, Fig. 4). In ISDF, the plate was inserted between the spinous processes without removing the disc, so the decrease in area of herniated disc and increase in area of foramina could be the result of retraction of the disc and restoration of intervertebral space height. Considering the X-ray results of increasing in PDH, it can be inferred that the reason why the herniated disc area decreased was the pressure of the disc was decreased by distraction, traction, and fixation after BacFuse Plate implantation, which ultimately led to partial retraction of the intervertebral disc. The retraction of the disc and restoration of intervertebral space height relieved the pressure on the nerves, playing a positive role in alleviating the symptoms. The retraction effect of ISDF is similar to that of conservative traction therapy; however, the latter fails to maintain a sustained effect on the spine by the time the patients are standing. The spine is under compressive loads due to patient body weight, reducing the effect of traction therapy. On the contrary, the ISDF fixed the spinous processes and maintained the effect regardless of the position of the patient. Thus, ISDF converts conservative in vitro traction therapy into sustained in vivo traction.

Limitations

This retrospective and single-centre clinical study investigated the efficacy of ISDF with the BacFuse Plate in the treatment of LDH. This surgical procedure has been implemented at the authors' institution for a short time and has not been used countrywide. Thus, more cases must be gathered and longer follow-up must be conducted because conclusions with a large sample size and long-term follow-up are more persuasive. In addition, prospective and multicentre studies are desirable for obtaining more comprehensive data.

Conclusions

ISDF with BacFuse Plate is a minimally invasive treatment of LDH that can significantly alleviate the symptoms and improve patient quality of life. Imaging revealed that the procedure is prone to expand the foramina, increase the posterior disc height and spinal canal area, and achieve partial retraction of the herniated disc, playing the role of an in vivo tractor.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Kreiner DS, Hwang SW, Easa JE, Resnick DK, Baisden JL, Bess S et al (2014) An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy. Spine J 14:180–189
2. Buttermann GR et al (2004) Treatment of lumbar disc herniation: epidural steroid injection compared with discectomy. A prospective, randomized study. J Bone Joint Surg Am 86:670–679
3. Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Hanscom B, Skinner JS et al (2006) Surgical vs nonoperative treatment for lumbar disk herniation: the spine patient outcomes research trial (SPORT). A randomized trial. JAMA 2006(296):2441–2450
4. Weber H (1983) Lumbar disc herniation: a controlled, prospective study with ten years of observation. Spine 8:131–140
5. Fan G, Han R, Gu X et al (2016) Navigation improves the learning curve of transforamimal percutaneous endoscopic lumbar discectomy[J]. Int Orthop 41(2):1–10
6. Du J, Tang X, Xin J et al (2016) Outcomes of percutaneous endoscopic lumbar discectomy via a translaminar approach, especially for soft, highly down-migrated lumbar disc herniation[J]. Int Orthop 40(6):1247–1252
7. Christie SD, Song JK, Fessler RG (2005) Dynamic interspinous process technology. Spine 30(16 Suppl):S73–S78
8. Kabir SM, Gupta SR, Casey AT (2010) Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence. Spine 35:E1499–E1506
9. Bellini CM, Galbusera F, Raimondi MT, Mineo GV, Brayda-Bruno M (2007) Biomechanics of the lumbar spine after dynamic stabilization. J Spinal Disord Tech 20:423–429
10. Holinka J, Krepler P, Matzner M et al (2011) Stabilising effect of dynamic interspinous spacers in degenerative low-grade lumbar instability.[J]. Int Orthop 35(3):395–400
11. Gazzeri R, Galarza M, Alfieri A (2014) Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future. Biomed Res Int 2014: 975052
12. Jiang YQ, Che W, Wang HR, Li RY, Li XL, Dong J (2015) Minimum 5 year follow-up of multi-segmental lumbar degenerative disease treated with discectomy and the Wallis interspinous device. J Clin Neurosci 22:1144–1149
13. Barbagallo GM, Olindo G, Corvino L, Albanese V (2009) Analysis of complications in patients treated with the X-STOP interspinous process decompression system: proposal for a novel anatomic scoring system for patients selection and review of the literature. Neurosurgery 66:1111–1119
14. Bowers C, Amini A, Dailey AT, Schmidt MH (2010) Dynamic interspinous process stabilization: review of complications associated with the X-STOP device. Neurosurg Focus 28:E8
15. Kim DH, Tantorski M, Shaw J, Martha J, Li L, Shanti N et al (2011) Occult spinous process fractures associated with interspinous process spacers. Spine 36:E1080–E1085
16. Kutcha J, Sobottke R, Cysel P, Simons P (2009) Two-year results of interspinous spacer (X-STOP) implantation of 175 patients with neurologic intermittent claudication due to lumbar spinal stenosis. Eur Spine J 18:823–829
17. Xu C, Ni WF, Tian NF et al (2013) Complications in degenerative lumbar disease treated with a dynamic interspinous spacer (Coflex)[J]. Int Orthop 37(11):2199–2204
18. Fardon DF, Williams AL, Dohring EJ, Murtagh FR, Gabriel Rothman SL, Sze GK (2014) Lumbar disc nomenclature: version

2.0: Recommendations of the combined task forces of the North American Spine Society, the American Society of Spine Radiology and the American Society of Neuroradiology. Spine J 14:2525–2545
19. Wan Z, Wang S, Kozanek M, Xia Q, Mansfield FL, Lü G et al (2012) The effect of the X-stop implantation on intervertebral foramen, segmental spinal canal length and disc space in elderly patients with lumbar spinal stenosis. Eur Spine J 21:400–410
20. Kim HY, Choi BW (2013) Change of radiological parameters after interspinous implantation (X-stop®) in degenerative spinal stenosis. Eur J Orthop Surg Traumatol 23:281–285
21. Kumar N, Shah SM, Ng YH, Pannierselvam VK, Dasde S, Shen L (2014) Role of Coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. Asian Spine J 8:161–169
22. Wang Y, Qian B, Li B, Qin G, Zhou Z, Qiu Y et al (2013) Metal artifacts reduction using monochromatic images from spectral CT: evaluation of pedicle screws in patients with scoliosis. Eur J Radiol 82:e360–e366
23. Veresciagina K, Spakauskas B, Ambrozaitis KV (2010) Clinical outcomes of patients with lumbar disc herniation, selected for one-level open-discectomy and microdiscectomy. Eur Spine J 9: 1450–1458
24. Hoogland T, Schubert M, Miklitz B, Ramirez A (2006) Transforaminal posterolateral endoscopic discectomy with or without the combination of a low-dose chymopapain: a prospective randomized study in 280 consecutive cases. Spine 31:E890–E897
25. Righesso O, Falavigna A, Avanzi O (2007) Comparison of open discectomy with microendoscopic discectomy in lumbar disc herniations: results of a randomized controlled trial. Neurosurgery 61: 545–549
26. Heyrani N, Picinic Norheim E, Elaine Ku Y, Nick SA (2012) Interspinous process implantation for the treatment of neurogenic intermittent claudication. Anesth Pain Med 2:36–41
27. Siddiqui M, Smith FW, Wardlaw D (2007) One-year results of X-STOP interspinous implant for the treatment of lumbar spinal stenosis. Spine 32:1345–1348
28. Postacchini F, Postacchini R, Menchetti PP, Sessa P, Paolino M, Cinotti G (2016) Lumbar interspinous process fixation and fusion with stand-alone interlaminar lumbar instrumented fusion implant in patients with degenerative spondylolisthesis undergoing decompression for spinal stenosis. Asian Spine J 10:27–37
29. Fabrizi AP, Maina R, Schiabello L (2011) Interspinous spacers in the treatment of degenerative lumbar spinal disease our experience with DIAM and Aperius devices. Eur Spine J 20(Suppl 1):S20–S26
30. Xu D, Chen YH, Zeng HB, Chi YL, Xu HZ (2009) A short-term follow-up results of herniation, a clinical comparison study. Chin J Surg 47:1379–1382
31. Xu D, Xu HZ, Chen YH, Chi YL, Ni WF, Huang QS et al (2013) Discectomy and discectomy plus Coflex fixation for lumbar disc herniation, a clinical comparison study. Chin J Surg 51:147–151
32. Wilke HJ, Drumm J, Häussler K, Mack C, Steudel WI, Kettler A (2008) Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure. Eur Spine J 17:1049–1056
33. Richards JC, Majumdar S, Lindsey DP, Beaupré GS, Yerby SA (2005) The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. Spine 30: 744–749
34. Hirsch C, Breque C, Ragot S, Pascal-Mousselard H, Richer JP, Scepi M et al (2015) Biomechanical study of dynamic changes in L4-L5 foramen surface area in flexion and extension after implantation of four interspinous process devices. Orthop Traumatol Surg Res 101:215–219
35. Lee J, Hida K, Seki T et al (2004) An interspinous process distractor (X-STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases. J Spinal Disord Tech 17:72–77
36. Sobottke R, Schlüter-Brust K, Kaulhausen T, Iwasaki Y, Minoru A (2009) Interspinous implants (X Stop, Wallis, Diam) for the treatment of LSS is there a correlation between radiological parameters and clinical outcome. Eur Spine J 18:1494–1503
37. Park SC, Yoon SH, Hong YP, Kim KJ, Chung SK, Kim HJ (2009) Minimum 2-year follow-up result of degenerative spinal stenosis treated with interspinous u (coflex). J Korean Neurosurg Soc 46: 292–299
38. Guehring T, Unglaub F, Lorenz H, Omlor G, Wilke HJ, Kroeber MW (2006) Intradiscal pressure measurements in normal discs, compressed discs and compressed discs treated with axial posterior disc distraction: an experimental study on the rabbit lumbar spine model. Eur Spine J 15:597–604
39. Hartmann F, Dietz SO, Kuhn S, Hely H, Rommens PM, Gercek E (2011) Biomechanical comparison of an interspinous device and a rigid stabilization on lumbar adjacent segment range of motion. Acta Chir Orthop Traumatol Cechoslov 78:404–409
40. Nandakumar A, Clark NA, Peehal JP, Bilolikar N, Wardlaw D, Smith FW (2010) The increase in dural sac area is maintained at 2 years after X-stop implantation for the treatment of spinal stenosis with no significant alteration in lumbar spine range of movement. Spine J 10:762–768
41. Kroeber M, Unglaub F, Guehring T, Nerlich A, Hadi T, Lotz J et al (2005) Effects of controlled dynamic disc distraction on degenerated intervertebral discs: an in vivo study on the rabbit lumbar spine model. Spine 30:181–187
42. Kamanli A, Karaca-Acet G, Kaya A, Koc M, Yildirim H (2010) Conventional physical therapy with lumbar traction; clinical evaluation and magnetic resonance imaging for lumbar disc herniation. Bratisl Lek Listy 111:541–544
43. Choi J, Lee S, Hwangbo G (2015) Influences of spinal decompression therapy and general traction therapy on the pain, disability, and straight leg raising of patients with intervertebral disc herniation. J Phys Ther Sci 27:481–483
44. Sari H, Akarirmak U, Karacan I, Akman H (2005) Computed tomographic evaluation of lumbar spinal structures during traction. Physiother Theory Pract 21:3–11
45. Ozturk B, Gunduz OH, Ozoran K, Bostanoglu S (2006) Effect of continuous lumbar traction on the size of herniated disc material in lumbar disc herniation. Rheumatol Int 26:622–626
46. BenEliyahu DJ (1996) Magnetic resonance imaging and clinical follow-up: study of 27 patients receiving chiropractic care for cervical and lumbar disc herniations. J Manip Physiol Ther 19:597–606