DOI: 10.5137/1019-5149.JTN.16097-15.1
Received: 18.09.2015 / Accepted: 13.11.2015
Published Online: 25.05.2016

Original Investigation

Can the Interspinous Device, SPIRE™, be an Alternative Fixation Modality in Posterior Lumbar Fusion Instead of Pedicle Screw?

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ABSTRACT

AIM: Although conventional posterior lumbar interbody fusion (PLIF) using pedicle screws provides successful outcomes, pedicle screw related complications are sometimes noted. SPIRE™ was invented as an interspinous fixation device (ISD) to replace pedicle screw. The aim of this study is to evaluate the clinical and radiological outcomes in patients who underwent unilateral PLIF using SPIRE™ compared with a pedicle screw.

MATERIAL and METHODS: All consecutive patients who show medically intractable lumbar degenerative disease with unilateral radiculopathy and mild instability were enrolled. Thirteen patients who underwent the PLIF using SPIRE™ (ISD group), and age, gender, and index level matched patients who underwent the PLIF using pedicle screw (PS group) were recruited in a 1:1 ratio. Pain, Oswestry Disability Index (ODI), disc height, and slippage were evaluated.

RESULTS: Both PS and ISD groups revealed significant improvement and there was no significant difference between them (back pain, p=0.18; leg pain, p=0.51; ODI, p=0.82). Although the ISD group showed spondylolisthesis for the first 3 months after the surgery, there was no significant difference compared with the PS group (p=0.65). Disc height decreased in both the ISD group (10.8 mm→7.7 mm) and the PS group (12.8 mm→10.8 mm), and this difference had statistical significance (p<0.01). In aspect of perioperative outcomes, the ISD group displayed better outcomes than the PS group (blood loss, p<0.001; surgery time, p=0.017).

CONCLUSION: SPIRE™ fixation for PLIF demonstrates comparable clinical outcomes with pedicle screw. It may provide weak fixation but it is acceptable. This technique may be an alternative for the patients with unilateral radiculopathy and mild instability.

KEYWORDS: Interspinous, SPIRE™, Fixation, Pedicle screw, Outcome, Lumbar

INTRODUCTION

Pedicle screw fixation during posterior lumbar interbody fusion (PLIF) has become an established method for creating rigid fixation of the lumbar spine. However, pedicle screw related disadvantage and complications were reported such as muscle traction injury, nerve injury, deep wound infection, and cerebrospinal fluid (CSF) leakage (1,3, 10). To avoid the complications of pedicle screw installation, novel fixation systems have been introduced (9,11). Among them, interspinous fixation device (ISD) composed of rigid spinous process plates and connecting rod was introduced such as CD HORIZON SPIRE™ (Medtronic, Memphis, TN, USA), Aspen (Lanx, Inc., Broomfield, CO, USA), Prima LOK (OsteoMed, Addison, TX, USA), and Axle (X-Spine, Miamisburg, OH, USA) (8,12,13). In biomechanical studies comparing ISDs and pedicle screw fixation, prior investigators demonstrated that SPIRE™ limited the flexion–extension range of motion to the same degree of bilateral pedicle screws

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and rod constructs (11,13). However, these studies addressed oppose results in the restriction of lateral bending and axial rotation. In clinical studies, the SPIRE™ fixation during PLIF accomplished favorable outcomes compared with pedicle screw fixation (6,12).

Unfortunately, our initial early experiences of the SPIRE™ following bilateral partial hemilaminectomy and interbody fusion were not as good as the prior clinical papers (6,12). Common complications were spinous process fracture along the bilateral laminectomy site and spondylolisthesis. Therefore, we used the SPIRE™ only after unilateral PLIF in limited patients to prevent spinous process fracture. The purpose of this study was to evaluate the comparative efficacy of the SPIRE™ plate and pedicle screw fixation during PLIF.

MATERIAL and METHODS

This study was approved by the Institutional Research Board of our institute (B-1207/162-113). We retrospectively reviewed the records of all patients receiving unilateral PLIF using the SPIRE™ the lumbar spine at a single referral hospital from August 2011 through March 2013. This intervention comparison study was approved by the Institutional Review Board. The index surgery was performed by one neurosurgeon. Patient demographics, clinical presentation, indications for hardware placement, radiological studies, operative variables, and length of follow-up were reviewed for each case.

The unilateral PLIF using an SPIRE™ as an ISD fixation (ISD group) instead of pedicle screw was performed when the patients met following criteria. The inclusion criteria were (1) unilateral symptomatic degenerative lumbar spinal disease, (2) failure of conservative therapy, (3) moderate to severe foraminal stenosis (moderate, perineural fat obliteration in both the transverse and vertical directions; severe, collapse of the nerve root), and (4) mild instability (spondylolisthesis, less than grade II) (7). Exclusion criteria included (1) bilateral neurological symptoms and signs, (2) previous surgery at the intended treatment level, (3) osteoporosis (the lowest bone mineral density (BMD) T-score ≥ - 2.5, (4) L5-S1 fusion because the spinous process of S1 is too short to fix with the SPIRE™ plate, and (5) disabling back or leg pain from causes other than degenerative lumbar disease (e.g., acute compression fracture, metabolic neuropathy, vascular claudication). The patients who underwent conventional PLIF using pedicle screw-rod fixation group (PS group) were matched with the ISD group for age (±4 years), sex, and fusion level.

Surgical Procedure

Patients were placed in the prone position on the Jackson frame (Orthopedic Systems, Inc., CA, USA), with the legs in a sling to slightly flex the lower back. After a skin incision of 4 cm at the midline, unilateral partial hemilaminectomy and intervertebral discectomy were performed. After confirming decompression of spinal root and thecal sac, a poly-ether-ether-ketone (PEEK) cage filled with autograft was placed in the intervertebral space. We used the SPIRE™ plate (35 mm) to the interspinous space in all cases as shown in Figure 1. Contralateral laminas were decorticated and covered with auto- and allograft in order to induce posterior fusion.

Outcome Measure and Follow-up

All patients followed up minimum 24 months. Clinical outcomes were evaluated by self-reported questionnaire such as the Oswestry Disability Index (ODI) and visual analog pain scale (VAS, 1-10) of back and leg at the time of baseline

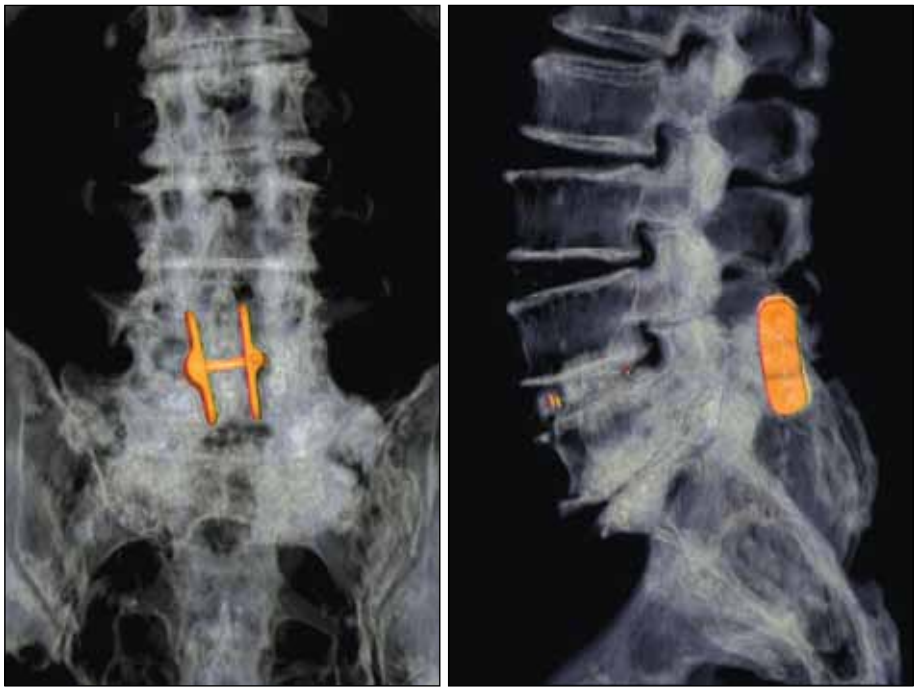

Figure 1: Postoperative reconstructed image of computed tomography. There is one interbody cage and interspinous device (SPIRE™) at the L4/5 level. A SPIRE™, interspinous fixation device, was composed of 2 plates and a connecting rod. Some spikes are located on the inner plane and are embedded in the spinous process.

(before surgery), 1 week, 1 month, 3 months, 6 months, 12 months, and 24 months after the surgery. Radiological outcomes evaluated were disc height at the middle of the intervertebral disc and vertebral body slippage on the index level (spondylolisthesis). All patients were assessed with standing anteroposterior and dynamic lateral view (neutral, flexion, and extension) radiographs at each time. We compared postoperative plain radiographs till 24 months to the preoperative imaging. Perioperative data such as estimated blood loss and operation time were collected.

Statistical Analysis

Statistical analyses were performed with the SPSS 18.0 statistics software (SPSS Inc., IL, USA). The categorical variables were compared by use of the Chi-square test. A linear mixed repeated measures model was used to test the differences between each time point and patient baseline score (VAS, ODI, TIH, and spondylolisthesis). Clinical and radiological outcomes were evaluated as changeover pretreatment values. Variability in sampling associated with the estimated odds ratios was assessed by two-sided 95 percent confidence intervals (CI). Statistical significance was defined as a p value of less than 0.05.

RESULTS

A total of 13 patients were enrolled in the ISD group and matched patients (1:1 ratio) were enrolled in the PS group. The patient characteristics are summarized in Table I. There were 4 men and 9 women included in each group. The mean age was 71.3 years in the ISD group and 70.7 years in the PS group (p=0.814). There was no significant difference in baseline back pain (p=0.544), leg pain (p= 0.393), ODI (p =0.100), disc height (p=0.415), spondylolisthesis (p=0.350), and BMD (p=0.654).

Up to 7 measurements were made in each patient, resulting in a total of 182 measurements, of 152 to 178 measurements were used for modeling back, leg pain, ODI, disc height, spondylolisthesis because of missing values. Both the PS and ISD groups had significant improvement from baseline clinical outcomes as times go on (back, leg pain, and ODI; p≤0.001) as shown in Figure 2 A-C. Mean back pain decreased from 6.7 to 2.2 for the ISD group for 24 months, and from 6.1 to 3.9

Table I: Patient Demographics in the ISD and PS Groups

Variables	Interspinous device (SPIRE™)	Pedicle screw	p
Gender (male/female)	4/9	4/9	
Age (years)	71.3 ± 7.0	70.7 ± 6.1	0.814
BMD	-1.36 ± 0.76	-1.06 ± 2.17	0.654
Baseline back pain VAS	6.69 ± 1.93	6.08 ± 3.04	0.544
Baseline leg pain VAS	7.15 ± 1.86	7.77 ± 1.74	0.393
Baseline ODI	20.46 ± 5.61	25.64 ± 9.04	0.100
Baseline disc height	9.17 ± 3.21	10.10 ± 2.47	0.415
Baseline spondylolisthesis	2.34 ± 2.97	3.71 ± 4.25	0.350

BMD: *Bone marrow density,* ***VAS:*** *Visual analog scale,* ***ODI:*** *Oswestry disability index.*

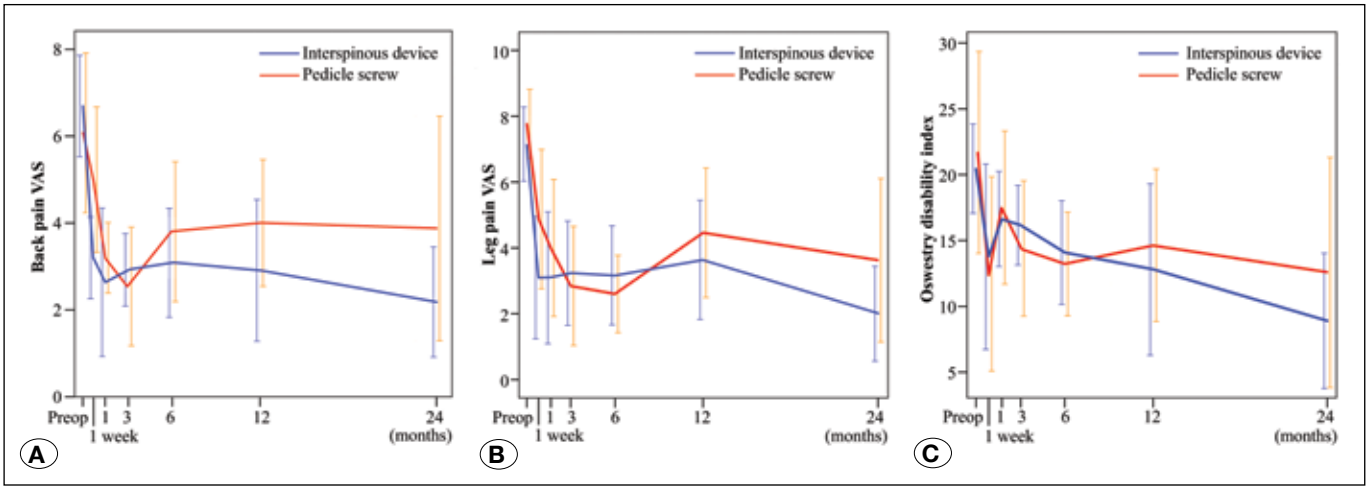

Figure 2: Changes from baseline back pain **(A)**, leg pain **(B)**, and ODI **(C)** over time of the patients who underwent PLIF using SPIRE™ and conventional PLIF using pedicle screw. Back, leg pain, and ODI of both groups decrease over time. There is no substantial difference between the ISD and PS group. Error bars indicate the 95% confidence interval.

for the PS group. Mean leg pain decreased from 7.2 to 2.0 for the ISD group, and from 7.8 to 3.6 for the PS group. Mean ODI improved from 20.5 to 8.9 for the ISD group, and from 21.7 to 12.6 for the PS group. There were no significant differences between the ISD and PS groups (back pain VAS, p=0.18; leg pain VAS, p = 0.51; ODI, p=0.82).

Mean spondylolisthesis at the index level increased from 1.75 mm to 2.48 mm for the ISD group for 24 months after the surgery. Spondylolisthesis of the ISD group was usually aggravated for the first 3 months after the surgery, and then maintained the plateau. In turn, mean slippage of the PS group was near 1.8 mm during the study period in Figure 3 A,B. There was no significant difference in the spondylolisthesis between 2 groups because of high standard error (p=0.65). Disc height decreased from 10.8 mm to 7.7 mm for the ISD group 24 months after the surgery, and from 12.8 mm to 10.8 mm for the PS group in Figure 3 A,B. Substantial subsidence occurred in the ISD group compared to the PS group (p<0.01), with a statistically significant difference in the trend in the 2 groups with time (p<0.01).

Perioperative outcomes showed substantial difference between the ISD and PS group. The average surgery time was 177.1 minutes in the ISD group and 236.9 minutes in the PS group (p<0.001) in Table II. The mean estimated blood loss during PLIF using pedicle screw and SPIRE™ was 429.2 ml and 252.5 ml, respectively (p=0.017). There was no significant difference between the 2 groups in terms of complications. One patient of the PS group underwent revision surgery because of misplacement of screw. One patient of the ISD group underwent pedicle screw installation due to progressive spondylolisthesis and radiculopathy. There was no spinous process fracture in any patient.

DISCUSSION

SPIRE™ has been introduced to fix the index level easily and less invasively. Some clinical and biomechanical studies have reported that SPIRE™ provided lumbar stability comparable with pedicle screw instrumentation and had several advantages over the pedicle screw fixation (6,11-13). This study displayed that the fixation force of SPIRE™ seemed to be weak compared with that of pedicle screw, but acceptable to some patients.

A biomechanical study reported that the SPIRE™ plate restricted flexion and extension equivalent to bilateral pedicle screw fixation, whereas lateral bending and axial rotation with the SPIRE™ were similar to that associated with unilateral pedicle screw constructs (13). Other biomechanical studies dealing with other ISDs also reported that the ISD significantly restricted range of motion, particularly during flexion and extension, and to a lesser degree during lateral bending and axial rotation (2,4,5).

A few clinical studies have reported that the SPIRE™ plate may have a fixation role as well as the pedicle screw and can accomplish good outcomes corresponding to those of pedicle screws (6,12,13). However, we experienced that SPIRE™ had weak fixation force compared with the pedicle screw and a risk of spinous process fracture. Therefore, we used the SPIRE™ only in the patients with unilateral radiculopathy and mild instability, and the ISD may be a suitable construct in those patients. The ISD group showed comparable clinical outcomes (back, leg pain, and ODI) with the PS group till 24 months after the surgery. They accomplished better perioperative outcome (short surgical time and less blood loss) and early improvement of pain than the PS group.

Table II: Perioperative Outcomes of the ISD and PS Group

Variables	Interspinous device (SPIRE™)	Pedicle screw	p
Surgery time (minutes)	177.1 ± 26.2	236.9 ± 45.2	**< 0.001**
EBL (ml)	252.5 ± 81.4	429.2 ± 221.8	**0.017**

EBL: *Estimated blood loss.*

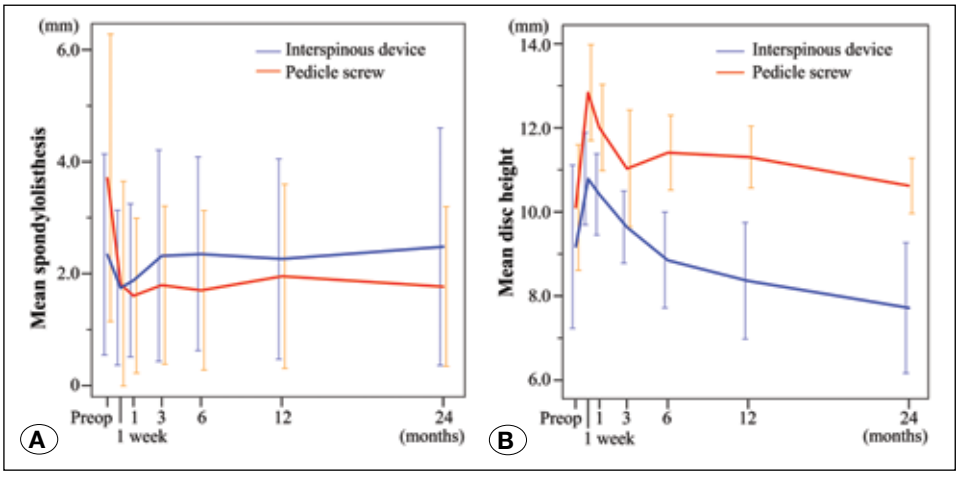

Figure 3: Changes from baseline spondylolisthesis **(A)** and disc height **(B)** over time of the patients who underwent PLIF using SPIRE™ and conventional PLIF using pedicle screw. Spondylolisthesis increased at early postoperative period in the ISD group, and was stationary 3 months after the surgery. This does not show a significant difference between the ISD and PS group. Mean disc height decrease in both groups. The values of the ISD group decreased substantially compared with that of the PS group (p < 0.01). Error bars indicate the 95% confidence interval.

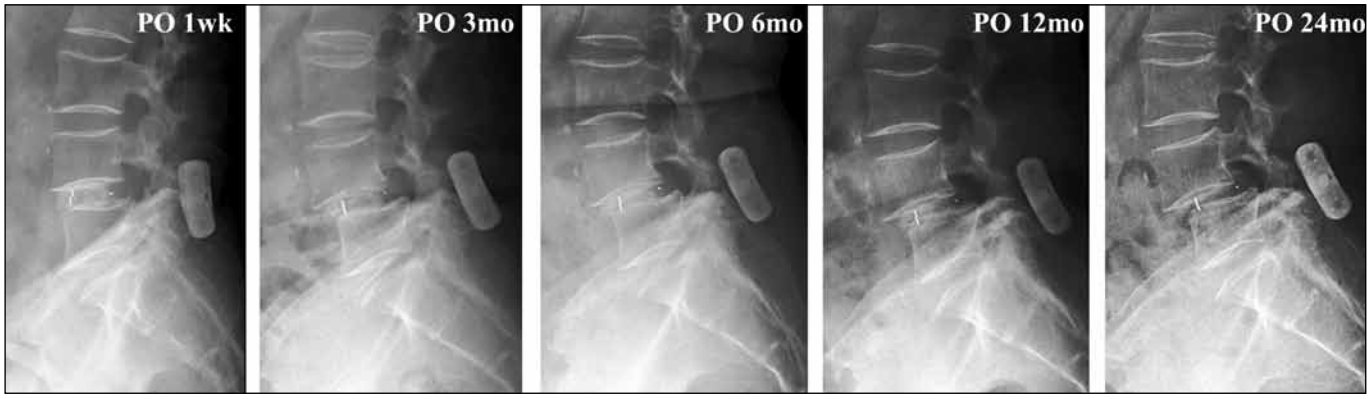

Figure 4: An illustrative case. A 75-year-old woman underwent unilateral PLIF using SPIRE™. Spondylolisthesis and back pain were aggravated 3 months after the surgery. Afterwards, the spondylolisthesis was stationary till 24 months and the back pain decreased.

There was a tendency of the ISD group to display better pain score than the PS group at 1 week after the surgeries and they equalized about 3 months after the surgeries. Moreover, surgical time and blood loss of the ISD group were much better than those of the PS group. It means that the ISD group promptly improved back and leg pain early compared with the PS group because the ISD group underwent minimally invasive surgery. Prior investigators also addressed the merits of ISD regarding perioperative results (6). Both groups accomplished favorable clinical outcomes at 24 months, and a substantial difference was not observed between 2 groups.

The ISD group revealed higher subsidence than the PS group, which showed substantial difference ($p < 0.01$). The reason may be related to incomplete discectomy and single short cage insertion. We could only remove the intervertebral disc incompletely because of the unilateral window. Moreover we did not place a long and big cage such as crescent cage due to incomplete discectomy, and installed a usual PEEK cage for PLIF. Although this radiological finding did not affect clinical outcomes for 24 months, further technical advances are needed.

Spondylolisthesis frequently occurred in the ISD group and progressed till 3 months after the surgery. After then, spondylolisthesis of the ISD group seemed to be stationary as shown in Figures 3 A,B and 4. Prior biomechanical study was not evaluated fully in this aspect and further evaluation is needed (13).This study revealed that the fixation force of SPIRE™ seemed to be weaker than that of pedicle screw in the aspect of anterior sliding. However, SPIRE™ may be regarded an acceptable fixation tool because spondylolisthesis was stopped and did not have a bad effect on clinical outcomes.

There are two limitations that need to be acknowledged and addressed regarding the present study. The first limitation concerns a retrospective study of this research project. However, we established a strict indication and performed the index surgery on all eligible patients, and followed them up to 24 months. Moreover, we made comparisons with the matched patients who underwent conventional surgery. Therefore, this study can be regarded to a well-controlled cohort study. The second limitation has to do with the extent to which the findings can be generalized beyond the cases studied. The number of cases is too limited for broad generalizations. The small population size may not make differences between the study groups potentially detectable due to an underpowered sample size. However, all the patients were followed up continuously to the end of the study.

CONCLUSION

SPIRE™, as an ISD, fixation for PLIF demonstrates a comparable clinical outcomes with conventional PLIF using pedicle screw for 24 months and better perioperative outcome because of less invasiveness. The fixation force of SPIRE™ may be weak compared to that of pedicle screw, but is acceptable for the limited group of patients. This technique may be regarded as an alternative technique to the patients with unilateral radiculopathy and mild instability.

DISCLOSURE

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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