Anterior Lumbar Interbody Fusion with Stand-Alone Interbody Cage in Treatment of Lumbar Intervertebral Foraminal Stenosis: Comparative Study of Two Different Types of Cages

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Objective: This retrospective study was performed to evaluate the clinical and radiological results of anterior lumbar interbody fusion (ALIF) using two different stand-alone cages in the treatment of lumbar intervertebral foraminal stenosis (IFS).

Methods: A total of 28 patients who underwent ALIF at L5-S1 using stand-alone cage were studied (Stabilis® [Stryker, Kalamazoo, MI, USA]; 13, Synfix-LR® [Synthes Bettlach, Switzerland]; 15). Mean follow-up period was 27.3 ± 4.9 months. Visual analogue pain scale (VAS) and Oswestry disability index (ODI) were assessed. Radiologically, the change of disc height, intervertebral foraminal (IVF) height and width at the operated segment were measured, and fusion status was defined.

Results: Final mean VAS (back and leg) and ODI scores were significantly decreased from preoperative values (5.6 ± 2.3 → 2.3 ± 2.2, 6.3 ± 3.2 → 1.6 ± 1.6, and 53.7 ± 18.6 → 28.3 ± 13.1, respectively), which were not different between the two devices groups. In Stabilis® group, postoperatively immediately increased disc and IVF heights (10.09 ± 4.15 mm → 14.99 ± 1.73 mm, 13.00 ± 2.44 mm → 16.26 ± 2.23 mm, respectively) were gradually decreased, and finally returned to preoperative value (11.29 ± 1.67 mm, 13.99 ± 2.01 mm, respectively). In Synfix-LR® group, immediately increased disc and IVF heights (9.80 ± 2.82 mm → 15.61 ± 0.62 mm, 14.01 ± 2.53 mm → 21.27 ± 1.93 mm, respectively) were maintained until the last follow up (13.72 ± 1.21 mm, 17.87 ± 2.02 mm, respectively). The changes of IVF width of each group was minimal pre- and postoperatively. Solid arthrodesis was observed in 11 patients in Stabilis group (11/13, 84.6%) and 13 in Synfix-LR® group (13/15, 86.7%).

Conclusion: ALIF using stand-alone cage could assure good clinical results in the treatment of symptomatic lumbar IFS in the mid-term follow up. A degree of subsidence at the operated segment was different depending on the device type, which was higher in Stabilis® group.

KEY WORDS: Anterior approach · Lumbar interbody fusion · Lumbar foraminal stenosis · Stand-alone cage.

INTRODUCTION

Anterior lumbar interbody fusion (ALIF) has been considered as one of the major surgical modalities of the degenerative lumbar disc diseases6,16,17. Particularly in the cases of lumbar intervertebral foraminal stenosis (IFS) causing by various pathologies, many reports have stated that ALIF could be effective to secure the intervertebral foraminal (IVF) height and decompress the exiting nerve root8,12,13,15,27,29. Conventional methods of ALIF surgery would include the insertion of the graft material insertion into the empty disc space after discectomy via anterior access and additional pedicle screws fixation via posterior approach.

Recently, ALIF using stand-alone interbody cage has been introduced and clinically used, which it can make the surgery to be performed only anterior access2,5,15,26,28. However, though there have been several biomechanical studies to assess stabilization property of stand-alone device, clinical studies to evaluate clinical and radiological results of stand-alone ALIF surgeries have been rarely reported. The present
study is retrospectively performed to evaluate the clinical and radiological results of ALIF utilizing two different stand-alone cages, and to determine its clinical usefulness in the surgical treatment of lumbar IFS.

MATERIALS AND METHODS

The authors selected the patients who underwent single level ALIF for the surgical treatment of symptomatic lumbar IFS of L5-S1. Between December 2004 and December 2007, 28 patients underwent ALIF using a Stabilis® (Stryker, Kalamazoo, MI, USA) (Fig. 1) or SynFix-LR® (Synthes Bettlach, Switzerland) (Fig. 2). Thirteen patients were operated using Stabilis®, and 15 were performed using SynFix-LR®. Stabilis® was used during the first half of the study period and SynFix-LR® during the second half. The demographic data of the patients by device type are listed in Table 1. Preoperative diagnosis was made on lumbar computed tomography and/or magnetic resonance images. When lumbar IFS was suspected on the radiological images, the exiting nerve root block was performed. If the concomitant pain was provoked during the procedure and presenting symptom was relieved after anesthetics injection, the authors confirmed IFS and carried out this surgery. If the patients showed osteoporosis (T-score < -2.5) on bone mineral density (BMD) study, the authors excluded the patients in this surgery. The surgeries were performed using standard anterior retroperitoneal approach. After radical discectomy, a device filled with autologous iliac bone was inserted into the empty disc space with a fluoroscopic guidance. The authors selected the size of devices according to the disc height of adjacent non-pathological segment. The size of devices used in the present study was listed on Table 2.

Mean follow-up period of all patients was 27.3 ± 4.9 months (range: 24 to 40 months). Because the follow-up data had been gathered in the order of operation date, the mean follow-up period of each device’s group was not significantly different (Stabilis®; 29 months, SynFix-LR®; 24 months). An assessment of clinical outcomes was performed by using visual analogue pain scale (VAS: 1-10) and Oswestry disability index (ODI). The authors measured disc height at the operated level according to the method described in Fig. 3. The height and width of IVF was also measured (Fig. 3). Fusion status at the operated segment

Table 1. Demographic characteristics and preoperative diagnosis

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>58 yr (32 - 68 yr)</td>
</tr>
<tr>
<td>Gender ratio</td>
<td>1:1</td>
</tr>
<tr>
<td>Mean follow up duration</td>
<td>27.3 months (24 - 40 months)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Foraminal stenosis</td>
<td>14</td>
</tr>
<tr>
<td>DDD + foraminal stenosis</td>
<td>9</td>
</tr>
<tr>
<td>Spondylolisthesis + foraminal stenosis</td>
<td>2</td>
</tr>
<tr>
<td>Recurred HNP + foraminal stenosis</td>
<td>3</td>
</tr>
</tbody>
</table>

DDD: degenerative disc disease, HNP: Hemiated nucleus pulposus

Table 2. Distribution of angle, height and footprint size of each device used in the present study

<table>
<thead>
<tr>
<th>Angle (°)</th>
<th>AH (mm)</th>
<th>PH (mm)</th>
<th>Depth (mm)</th>
<th>Width (mm)</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabilis®</td>
<td>8</td>
<td>13</td>
<td>7</td>
<td>25</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>15</td>
<td>8</td>
<td>25</td>
<td>32</td>
</tr>
<tr>
<td>SynFix-LR®</td>
<td>8</td>
<td>13.5</td>
<td>7</td>
<td>26</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>15</td>
<td>8.5</td>
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<td>32</td>
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<tr>
<td>Total</td>
<td></td>
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</tr>
</tbody>
</table>

AH: anterior height, PH: posterior height

Fig. 1. Stabilis® (Stryker, Kalamazoo, MI, USA). It is a titanium implant, which is made of an anatomically friendly frame with a bone graft delivery unit.

Fig. 2. SynFix-LR® (Synthes Bettlach, Switzerland). It is consisted with two distinct parts; Polyetheretherketone frame and titanium anterior plate. Diverging locking screws penetrate the vertebral body close to the anterior rim offering stability.
was classified from grade 1 to 3, according follow-up dynamic X-ray findings (Table 3). The authors divided the patients into two groups according to whether the subsidence more or less than 3 mm at the last follow-up, and performed statistical verification with respect to the outcome (VAS and ODI scores at the last follow-up) between the two groups.

Statistical analysis was performed using SPSS (SPSS, Version 10, SPSS, Chicago, IL, USA). A p-value < 0.05 was considered statistically significant.

RESULTS

At final follow-up, mean VAS (back and leg) and ODI scores were significantly decreased compared to their preoperative values [from 5.6 ± 2.3, 6.3 ± 3.2, and 53.7 ± 18.6 to 2.3 ± 2.2, 1.6 ± 1.6, and 28.3 ± 13.1, respectively (p = 0.000)]. Clinical outcomes obtained using the two devices types were similar (Fig. 4).

The radiological results according to the device type were indicated in Fig. 5. In Stabilis\textsuperscript{\textregistered} group, the mean preoperative disc height was increased postoperatively immediately (10.09 ± 4.15 mm → 14.99 ± 1.73 mm, p = 0.005). It was gradually decreased during follow up, and its value was not significantly different to preoperative value at the final follow up (11.29 ± 1.67 mm, p = 0.685). Postoperative immediate IVF height (16.28 ± 2.23 mm) was significantly higher than preoperative value (13.00 ± 2.44 mm) (p = 0.005). It was getting decreased postoperatively, and it was returned to almost preoperative value at the final follow up (13.59 ± 2.01 mm) (p = 0.789). The IVF width was not significantly
changed postoperative immediately and during further follow-up. In SynFix-LR® group, the mean preoperative disc height was increased postoperatively immediately (9.60 ± 2.82 mm to 5.61 ± 0.62 mm, p = 0.001). It showed a slight decrease during further follow-up, however, its value was still higher than preoperative value at the final follow-up (13.72 ± 1.21 mm, p = 0.001). The IVF height was significantly increased postoperatively immediately from preoperative value (14.01 ± 2.53 mm → 21.27 ± 1.93 mm, p = 0.001). Though it was also gradually decreased until last follow up, its final value was significantly higher than preoperative value (17.87 ± 2.02 mm) (p = 0.045). The changes of IVF width was minimal pre- and postoperatively. The statistical verification revealed that the changes of disc or IVF height did not significantly relate to the extent of improvement in VAS or ODI score at the last follow-up (Table 2). The correlation verification between the BMD score and the changes of disc or IVF height did not show statistical significant relation (p = 0.564, p = 0.753, respectively).

At the final follow up, fusion status was observed as 1 case of grade 1, 1 of grade 2, and 11 of grade 3 in Stabilis® group (grade 1: 7.7%, grade 2: 7.7%, and grade 3: 84.6%) and 1 case of grade 1, 1 of grade 2, and 13 of grade 3 in SynFix-LR® group (grade 1: 6.7%, grade 2: 6.7%, and grade 3: 86.7%). And, there was no significant difference of fusion state in each device. In both groups, surgery related complications were not observed during and after operation, except one case of transient retrograde ejaculation in Stabilis® group.

Overall, 9 cases (32.1%) showed more than 3 mm of subsidence at the last follow-up, and there was no statistical difference between the extent of improvement in VAS or ODI score at the last follow-up and a subsidence over or under 3 mm (Table 5).

### Discussion

Anterior access of lumbar spine allows easy removal of entire pathologic disc and restore collapsed disc. If enough stabilization is achieved by one single anterior approach, it could avoid the adverse effects related to additional posterior surgery. Postoperative pain would be minimal and short hospitalization and early return to social activity is possible. For these reasons, ALIF using stand-alone cage has been introduced and clinically attempted. In the present study, ALIF using two different kinds of stand-alone cage reduced pain and improved function in the patients of asymptomatic lumbar INS in mid-term follow up, regardless of device type.

However, radiological results of the present study were not uniform. Although both device groups showed a significant increase of disc and IVF height of the operated segment postoperatively immediately, each group presented a different degree of subsidence with time during follow up. In SynFix-LR® group, the restored disc or IVF height was maintained with statistical significance until last follow up. However, in Stabilis® group, higher degree of subsidence than that of SynFix-LR® group was noted. Those disc and IVF height in Stabilis® group restored postoperative immediately was returned to almost preoperative values at the last follow up.

Each device of the present study differs in fixation system. SynFix-LR® is composed of a polyetheretherketone body frame and an additional integrated metal plate. To obtain the immediate stabilization, four diverging locking metal screws penetrate the superior and inferior vertebral body close to anterior rim, and fix in integrated plate (Fig. 2). Cain et al. performed a human cadaveric biomechanical test of several fixation alternatives including SynFix-LR® device. According to their results, stand-alone SynFix-LR® did not show significant differences in the range of motion, neutral zone, elastic zone, and stiffness comparing to three other different fixation methods (SynFix-LR® with additional transarticular facet screws, simple cage with additional transarticular facet screws, and simple cage with additional pedicle screws. Schleicher et al. demonstrated the effective stabilization ability of stand-alone SynFix-LR® in all motion direction by performing human cadaveric three-dimensional stiffness test.

In the other hands, Stabilis® is made of trapezoid metal
body frame with an inner threaded cylinder. A metal frame is impacted in interbody space and threaded cylinder relies on endplate engagement to promote additional fixation effect and proper fusion (Fig. 1). To assess a stabilization property, Chen et al.10, did biomechanical comparison study of Stabilis® device with dual paralleled cages and a single large cage. In three dimensional finite element (FE) model study, they observed the superior stabilization properties of Stabilis® device in flexion, extension, lateral bending and torsion than those of other interbody cages compared. However, their study has a big limitation in device matching. Ordinary, dual paralleled cages or single large cage is required the additional posterior fixation in clinical use. Moreover, despite of comparison with the devices which were not designed for stand-alone manner, their results showed no differences of range of motion in extension and lateral bending between Stabilis® and other cages compared.

Although little is known about the factors relating to a subsidence, micro-motion of fused level has been considered. Kettler et al.14, performed in vitro study to evaluate effects of segment movement on subsidence in interbody fusion. They demonstrated that repeated movement of treated level induced the subsidence in direct proportion. According to their suggestion, if a device does not provide enough stabilization postoperatively, micro-motion would exist and higher grade of the subsidence would be presented with a time. The higher rate of subsidence in Stabilis® group in the present study might be caused by inferior stabilization property of that device compared with SynFix- LR® device. In addition, Stabilis® system has a possibility of large area end-plate damage while a metal body is inserted into the disc space. A screw-type, threaded round cylinder also could make additional damage to the bony end-plate arbitrarily. Oland et al.15, conducted a biomechanical cadaveric study to assess the effects of endplate removal on the structural properties of the vertebral bodies, and reported that the subsidence was markedly progressed after endplate removal. They suggested that removal of the vertebral endplate significantly reduced the local strength and stiffness in the vertebral bodies. Obviously, preparation of bony endplate of vertebral body is crucial factor determining the occurrence of the subsidence. Inevitable endplate damage during Stabilis® implantation would be the other cause of the higher grade of subsidence. Theoretically, the progression of subsidence of operated level which approaches the preoperative value of disc height has a potential of recurrent root symptoms. The final disc height of Stabilis® group was reached to preoperative value in this study. However, the statistical verification between the changes of disc or IVF height and the extent of clinical improvement did not show statistically significant relationship. Although the reason of this discordance is not clear, the authors conjecture that elimination of segmental motion by an arthrodesis could reduce mechanical irritation of exiting nerve root despite of re-stenosis of intervertebral foramen. Nevertheless, it is definite that a progression of the subsidence negatively affect on long-term clinical outcome. A consideration of proper designed device to minimize the subsidence would be required to increase success rate of ALIF surgery. Osteoporotic bone is also known as one of factors related to the progression of subsidence.4,11,12,27 In the present study, there was no meaningful difference of bone mineral density between two groups, and osteoporotic patients were basically excluded. Therefore, the present study did not reveal the relation of the subsidence to the degree of bone quality.

Without a doubt, one of major goals of fusion surgery is achievement of solid arthrodesis. Regrettably, early reports of laparoscopic single anterior surgery with stand-alone cage had noted unacceptable low fusion success rate.24,26 Therefore, single laparoscopic ALIF has been abandoned, or performed with an additional posterior instrumentation.17,18,20 Recently, the improved devices to enhance a stabilization effect for single anterior surgery have been introduced and promoted the fusion rate. Current reports of open ALIF surgery have stated 93-100% of fusion success rate, which would be comparable with other fusion procedures.16,17,20,25 However, the present study showed about 84-86% of fusion success rate, which was relatively inferior to other results previously reported. Moreover, defining fusion status in the present study was just carried out by observing X-ray findings. Computed tomographic observation has been known as better evaluation tool to assess fusion status, thus fusion rate would be more decreased if the authors could use computed tomographic images. To improve the fusion success rate of stand-alone ALIF, adjuvant use of fusion enhancing materials or additional posterior fixation should be considered.

The small number of cases and its retrospective non-randomized nature are flaws of the present study. The lack of a control group also would be a limitation. Nevertheless, the present study revealed that ALIF using stand-alone cage could be an effective surgical modality to obtain the reliable clinical results in the treatment of symptomatic lumbar IFS in mid-term follow up. However, relatively low fusion success rate could be a shortcoming. The occurrence of subsidence with a time was also observed, and it showed different degrees depending on the type of devices used. A subsidence following stand-alone device has a potential to affect on long term clinical results of stand-alone ALIF surgery.
CONCLUSION

The present study demonstrated that ALIF using stand-alone cage could assure good clinical results in the surgical treatment of symptomatic lumbar IFS in the mid-term follow up. However, relatively low fusion success rate and the occurrence of subsidence at the operated segment during the follow up are shortcomings. The degree of subsidence was different depending on the device type. To obtain successful long term clinical results, a well designed stand-alone device to improve stabilization property would be required.

References