

## Original Article

# Direction-changeable cage reduces X-ray exposure in treating isthmic lumbar spondylolisthesis: a retrospective study

Haiping Zhang<sup>1</sup>, Qiang Miao<sup>2</sup>, Dingjun Hao<sup>1</sup>, Qinpeng Zhao<sup>1</sup>, Simin He<sup>1</sup>, Biao Wang<sup>1</sup>

<sup>1</sup>Department of Spine Surgery, Honghui Hospital, Xi'an Jiaotong University Health Science Center, Xi'an, Shanxi, China; <sup>2</sup>Department of Orthopedics, Yan'an People's Hospital, Yan'an, Shanxi, China

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**Abstract:** In spite of a variety of designs for the lumbar interbody fusion cage, there is no consensus on the optimal design so far. Different cage designs may cause different extent of X-ray exposure to visualize the cage position intraoperatively. In this study, we retrospectively evaluated the X-ray exposure and clinical outcomes of the direction-changeable cage in transforaminal lumbar interbody fusion (TLIF). The patients were divided into the direction-changeable cage group (group A, n=79) and non-direction-changeable cage group (group B, n=84). Intraoperative implantation duration, cage position adjustment times, implantation fluoroscopy times, fluoroscopy exposure time of cage implantation, Oswestry Disability Index (ODI) and visual analogue scale (VAS) scores were recorded before and after operation at the last follow-up. CT scanning was performed to evaluate lumbar fusion. All the patients underwent single-level TLIF and were followed up for 12 to 18 months. In the group A, intraoperative implantation duration, cage position adjustment times, implantation fluoroscopy times, and fluoroscopy exposure time of cage implantation were  $6.7 \pm 3.6$  min,  $1.2 \pm 0.4$  times,  $2.5 \pm 0.6$  times,  $7.84 \pm 1.83$  s, retrospectively. In the group B, these parameters were  $11.5 \pm 5.9$  min,  $2.6 \pm 1.3$  times,  $5.8 \pm 1.7$  times, and  $15.31 \pm 5.16$  s retrospectively, which were higher than those in the non-direction-changeable cage group with statistical significance ( $P < 0.05$ ). In terms of ODI and VAS scores, there was no statistical difference between the two groups before or after operation at the last follow-up ( $P > 0.05$ ). Regarding to the complications, there were 4 cases (4.49%) in the group A, with 3 cases of non-union and 1 case of dural laceration. Eight cases (10.53%) showed complications in the group B, with 7 cases of non-union and 1 case of infection. There was a significant difference between the groups in terms of the complication rate ( $P < 0.05$ ). In conclusion, the direction-changeable cage has merits like lower radiation exposure and fewer complications compared to the non-direction-changeable cage in treating isthmic lumbar spondylolisthesis. Both cages could yield equal clinical outcomes.

**Keywords:** Lumbar cage, spondylolisthesis, X-ray exposure, cage position

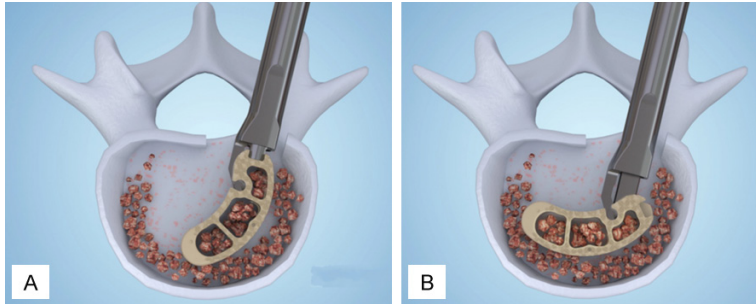
## Introduction

With the aging population, lumbar degenerative diseases have become prevalent, and lumbar pain could strongly affect the patients' quality of life. Lumbar fusion for treating progressive lumbar degeneration has proved to be effective [1], and transforaminal lumbar interbody fusion (TLIF) combined with posterior pedicle screw fusion has been a conventional surgical approach [2]. It mainly involves removal of the intervertebral disc of the lesion segment and implantation of a cage that is filled with bone-grafting materials. Implantation of the lumbar cage in the intervertebral space could stabilize

spinal levels, restore disc space height and neuroforaminal area and provide a good mechanical environment for grafting bone fusion [3].

Previous studies have shown that the incidence of cage migration ranges from 0.8% to 23%, [4-6] and the position for implantation could affect the postoperative fusion rate and cage migration [6-8]. Spine surgeons often choose the position for implantation from their own experience and the adjustment of implantation position is achieved with a pushrod. To achieve a satisfactory implantation, multiple intraoperative adjustments are common, which require

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**Figure 1.** Insertion of the direction-changeable cage: A. Initial implanting position; B. Implanting position after rotation.

repeated fluoroscopy and could cause undue radiation exposure for both patients and providers. Developing techniques that can reduce intraoperative radiation exposure while achieve an optimal position for cage implantation will benefit both patients and providers.

In this situation, we improved a polyetheretherketone (PEEK) non-direction-changeable cage and its pushrod to make it direction changeable, allowing it to be easily placed at the middle part of the intervertebral space. In this study, we retrospectively compared the X-ray exposure and clinical outcomes of the direction-changeable cage and non-direction-changeable cage in treating isthmic lumbar spondylolisthesis.

### Materials and methods

#### *Patient population*

The inclusion criteria included (1) patients diagnosed with lumbar isthmic spondylolisthesis involving a single segment at L4 or L5, (2) patients treated with a direction-changeable cage (national patent: ZL201420434595.7) (group A) or non-direction-changeable cage (group B) in our department. Patients in the group A were recruited from January 2013 to February 2014 and those in the group B were recruited from May 2014 to December 2015. The exclusion criteria included patients with a lumbar surgical history, tumor, and infection or without sufficient follow-up data. This retrospective study was approved by the Institutional Review Board of our Hospital, and all the patients provided signed informed consent.

#### *Surgical method*

All the surgical procedures were performed by 2 well-trained spine surgeons. A posterior mid-

line incision was made, and pedicle screws were placed at the spondylolisthetic vertebra and the lower vertebra, followed by decompression and removal of the intervertebral disc. Part of the bone graft was placed at the anterior part of the intervertebral space, and part of it was filled into the cage. For the group A, the cage was placed at the anterior and middle part of the intervertebral space, 5-7 mm

away from the posterior margin by rotating the pushrod (**Figure 1**). For the group B, after implantation, the cage was adjusted to the same position by knocking the pushrod under the fluoroscope.

#### *Assessment parameters*

Intraoperative cage implantation duration, cage position adjustment times, implantation fluoroscopy times, and X-ray exposure time during cage implantation were recorded. The visual analogue scale (VAS) and Oswestry disability index (ODI) scores were recorded before surgery, 1 month postoperatively, and at the last follow-up to assess the clinical outcomes. Complications were also recorded. Radiological data were collected to evaluate fusion rate, CT scanning was performed 12 months after the operation, and lumbar fusion was assessed according to Bridwell [9].

#### *Statistical analysis*

SPSS 19.0 (IBM, Armonk, NY, USA) was applied for statistical analysis. Quantitative data were expressed as mean  $\pm$  SD. One-way analysis of variance (ANOVA) was performed to compare the VAS score and ODI difference before surgery, 1 month postoperatively, and at the last follow-up within the group. A *t*-test was performed for comparisons of parameters like cage implantation duration, cage position adjustment times, implantation fluoroscopy times, etc. between the two groups. *P* values  $<0.05$  were considered statistically significant.

### Results

A total of 163 patients (87 male and 76 female) were included in the current study: 79 patients in the group A and 84 patients in the group B.

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**Table 1.** General data of two groups

	Direction-changeable cage group (n=79)	Non-direction-changeable cage group (n=84)	P value
Age (Year)	52.50 ± 10.34	54.12 ± 12.63	0.57
Gender (Male:Female)	44:39	43:37	0.18
Meyerding grading (I:II:III)	23:43:13	24:45:15	0.21
Involved segment (L4-5:L5-S1)	34:45	37:47	0.28
Follow-up	13.1 ± 5.58	14.6 ± 6.74	0.32

**Table 2.** X-ray exposure-related parameters between groups

	Direction-changeable cage group (n=79)	Non-direction-changeable cage group (n=84)	P value
Cage implantation duration (min)	6.7 ± 3.6	11.5 ± 5.9	0.003
Cage position adjustment times	1.2 ± 0.4	2.6 ± 1.3	0.005
Implantation fluoroscopy times	2.5 ± 0.6	5.8 ± 1.7	0.001
Fluoroscopy exposure time of cage implantation (sec)	7.84 ± 1.83	15.31 ± 5.16	0.000

**Table 3.** Clinical outcomes parameters between groups

	Direction-changeable cage group (n=79)	Non-direction-changeable cage group (n=84)	P value
VAS			
Preoperation	7.52 ± 1.67	6.84 ± 1.83	0.35
Last follow-up	1.89 ± 0.96	1.99 ± 0.99	0.49
ODI			
Preoperation	56.89 ± 8.54	51.53 ± 7.95	
Last follow-up	20.56 ± 8.54	19.15 ± 8.54	0.68
Complications	4 (4.49%)	8 (10.53%)	0.02
Non-union	3	7	
Dural laceration	1	0	
Incision infection	0	1	

and B, respectively (P<0.05). Fluoroscopy exposure time of cage implantation were 7.84 ± 1.83 and 15.31 ± 5.16 s (P<0.05) (**Table 2**).

### *Clinical outcomes parameters*

At the last follow-up, the VAS score in the group A was 1.89 ± 0.96 and that in the group B was 1.99 ± 0.99, and there was no statistical difference between the two groups (P>0.05). However, the VAS score was significantly lower than that before the operation in both groups: 7.52 ± 1.67 in the group A and 6.84 ± 1.83 in the group B (P>0.05). Similarly, the ODI at the last follow-up showed no difference between the two groups (P>0.05), but there was a statistical difference between them before the operation (P<0.05) (**Table 3**).

The average age in the group A and B was 52.5 ± 10.34 and 54.12 ± 12.63 years, respectively (P>0.05). According to Meyerding grading, the patients were all of grade I, type II, and type III. The mean follow-up duration was 14.3 ± 6.63 months, ranging from 12 to 24 months in both groups (P>0.05). There was no statistical difference between the two groups in terms of the general data (**Table 1**).

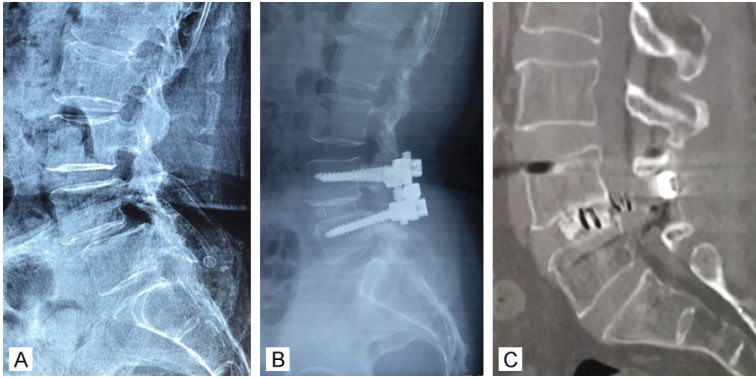
### *X-ray exposure-related parameters*

The average intraoperative cage implantation duration was 6.7 ± 3.6 and 11.5 ± 5.9 min in the group A and B, respectively (P<0.05). Cage position adjustment times were 1.2 ± 0.4 and 2.6 ± 1.3 times in groups A and B, respectively (P<0.05). Implantation fluoroscopy times were 2.5 ± 0.6 and 5.8 ± 1.7 times in the group A

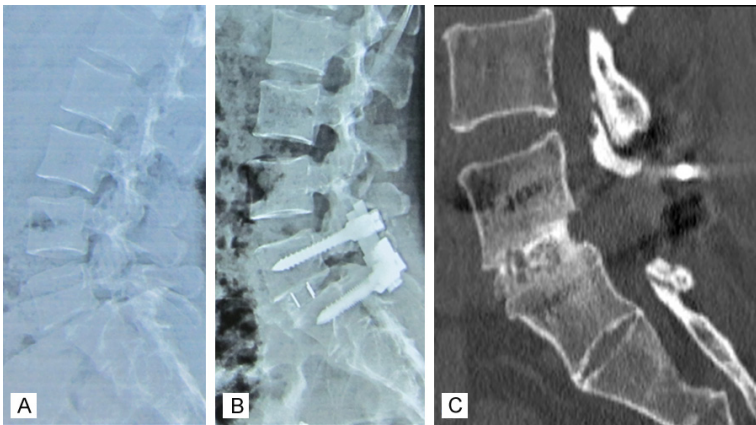
and B, respectively (P<0.05). Fluoroscopy exposure time of cage implantation were 7.84 ± 1.83 and 15.31 ± 5.16 s (P<0.05) (**Table 2**).

In the group A, there were 4 cases (4.71%) that presented complications: 3 cases of non-union according to the CT results at the follow-up 12 months after the operation, and 1 case of dural laceration, which was treated with surgical repair and reported no cerebrospinal fluid leakage. In the group B, 8 cases showed complications, with 7 cases of non-union (3 cases due to cage migration and 4 cases due to screw

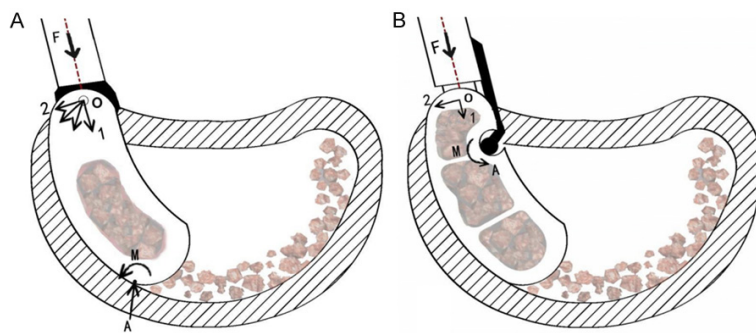
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**Figure 2.** A 45-year-old female with L4/5 isthmic spondylolisthesis was treated with a non-direction-changeable cage: A. Pre-operative lateral X-ray; B. Lateral X-ray 1 week after the operation; C. CT at the 3<sup>rd</sup> month after the operation, showing cage migration and bone non-fusion.



**Figure 3.** A 55-year-old female with L5/S1 isthmic spondylolisthesis was treated with a direction-changeable cage: A. Pre-operative lateral X-ray; B. Lateral X-ray 1 week after the operation; C. CT at the 3<sup>rd</sup> month after the operation, showing bone fusion.



**Figure 4.** The principle of cage placement: A. Non-direction-changeable cage; B. Direction-changeable cage.

breakage) and 1 case of superficial incision infection. The patient with infection was treated with dressing change and oral antibiotics

and recovered well. The patients with grafting bone non-union showed no symptoms and received no further treatment. Radiological information regarding the two cages was listed in **Figures 2** and **3**.

### Discussion

The lumbar cage has been widely used for spine fusion, but its complications have also raised concerns. Cage migration is one of the most common complications, and improper cage placement is an important cause of it [4, 6, 7]. An ideal position for cage placement is symmetrical to the midline of the spine, which can allow it to bear equal stress and maintain the stability of spine fusion [10]. But in reality, the position for cage placement is mainly decided by the surgeons' experience, and its adjustment is achieved with a pushrod under a fluoroscope. The non-direction-changeable kidney-shaped cage is common in clinical practice, and its placement with excessive force could lead to damage to the superior endplate, which may cause cage migration [11]. When the cage is pushed into the intervertebral space, it can be held back when its front edge touches the annulus or the implanted bone graft. When the cage is stuck at the point A, and if a force F is applied at the point O, the resultant force could be between the point 1 and 2 (**Figure 4A**), and the cage could rotate counterclockwise, taking the point A as the rotation axis (torque M). However, because the left side of the cage is stuck, the cage cannot be moved forward to the ideal position. The direction changeable cage we designed could well solve

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this problem. When the cage is pushed to the limit position, the clasper on the pushrod could hook the point A and the rotation axis could shift to the point A. When we apply the force F, the cage could rotate counterclockwise, taking the point A as the rotation axis, and cross the front barrier, and hence, it could be placed precisely at the midline of the spine (**Figure 4B**).

Current improvement in the lumbar cage is mainly limited to cage materials and shapes [12, 13], and kidney-shape and bullet-shape cages are mainstream cages in practice. An ideal lumbar cage should have enough mechanical strength and instant stability after implantation [14]. The approaches to cage implantation have also been well studied. An in vitro biomechanical study showed that anterolateral cage placement, compared to mediolateral or posteromedial placement, could provide significantly higher construct stability for all motions [15]. Some scholars changed the oblique placement approach into a transverse placement, which could increase the cage stability [3, 16, 17]. However, both approaches could add difficulty in measuring the angle of placement; in addition, the transverse manner requires higher surgical skills, and the adjustment of cage placement requires multiple fluoroscopies, which could increase the X-ray exposure for both providers and patients. The improvement of the direction-changeable cage in this study is based on the kidney-shape cage, which reserves the kidney shape and changes its rotation axis. By comparing the two groups, we found that the X-ray exposure parameters in the group A were significantly lower than those in the group B with statistical significance. Every adjustment of cage placement could double the X-ray exposure (anteroposterior and lateral) or even more. In addition, because the patients were covered by sterile drapes during the operation, it added the difficulty of positioning the C arm X-ray and hence increasing the exposure times. The accurate placement of direction-changeable cages could reduce the adjustment times and exposure times, which could not only shorten the surgical time but also effectively reduce X-ray exposure for providers and patients.

Our previous study compared the clinical outcomes between the direction-changeable cage we designed and the traditional bullet-shape cage, and we found that they showed similar

clinical outcomes, but the direction-changeable cage had advantages in terms of bone fusion rate and complications [18]. In the current study, we compared the clinical outcomes between the direction-changeable cage and the kidney-shape cage. We found the two cages had equal clinical outcomes: there was no statistical difference between the two groups in terms of ODI and VAS at the last follow-up, which could be explained by the same surgical approach being applied in both groups. It suggested that the grafting bone fusion rate in the group A was higher than that in the group B, which could be due to its larger bone-grafting area. We roughly estimated that the amount of bone graft loaded in the direction-changeable cage was nearly twice of that in the non-direction-changeable cage. Yoo et al. [19] also reported that a larger amount of bone graft loaded in the cage could lead to a significantly higher bone fusion rate: 92% (bone graft volume over 12 ml) vs. 81.5% (bone graft volume smaller than 12 ml); the authors therefore recommend at least a 12 ml of bone graft volume for successful fusion. Cages with a large contact area have advantages not only in bone fusion, but also in avoiding endplate subsidence. Le et al. [20] found that under the circumstance of equal length, cages with a width of 18 mm had a cage subsidence rate of 14.1%, and cages with a width of 22 mm had a cage subsidence rate of only 1.9%, suggesting that increasing the contact area could enhance the fusion rate and avoid cage subsidence.

There are some limitations in the current study. As a retrospective study, certain selection bias could exist. The direction-changeable cage requires a certain length of time to master the technique fully. We did not measure the radiation dose with radiation monitors [21, 22]. And as the radiation dose could be influenced by multiple factors, we only focused on whether the placement of the direction-changeable cage could reduce the radiation dose by reducing the adjustment times, exposure times and fluoroscopy exposure time.

In conclusion, the direction-changeable cage has merits like lower radiation exposure and fewer complications compared to the non-direction-changeable cage in treating isthmic lumbar spondylolisthesis. Both cages could yield satisfactory clinical outcomes.

## Disclosure of conflict of interest

None.

**Address correspondence to:** Dr. Dingjun Hao, Department of Spine Surgery, Honghui Hospital, Xi'an Jiaotong University Health Science Center, 555# Youyi East Road, Nanshao Gate, Xi'an, Shanxi, China. Tel: 086-13720732933; Fax: 029-8780-0002; E-mail: haodingjundr@163.com

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