



Comparison between free-hand and O-arm-based navigated posterior lumbar interbody fusion in elderly cohorts with three-level lumbar degenerative disease

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Abstract

Purpose This retrospective cohort study aims to evaluate the effects of introducing the O-arm-based navigation technique into the traditional posterior lumbar interbody fusion (PLIF) procedure treating elderly patients with three-level lumbar degenerative diseases.

Methods Forty-one consecutive elderly patients were enrolled according to the criteria. There were 21 patients in the free-hand group and 20 patients in the O-arm group. Both two groups underwent the PLIF with or without the O-arm-based navigation technique. The demographic features, clinical data and outcomes, and radiological information were collected for further analysis.

Results The average follow-up time was 18.3 (range, 12–28) months in the free-hand group and 16.7 (range, 12–24) months in the O-arm group. Comparison between two groups revealed no significant difference regarding demographic features. The operation time took in the navigation group was significantly less than that in the free-hand group (222.55 ± 38.00 mins versus 255.19 ± 40.26 mins, $P < 0.05$). Both VAS and ODI were improved post-operatively in two groups while comparison between groups showed no difference. The accuracy rate of pedicle screw positioning was 88.7% in the free-hand group to 96.9% in the O-arm group ($P < 0.05$).

Conclusion The O-arm-based navigation is an efficacious auxiliary technique which could significantly improve the accuracy of pedicle screw insertion, especially in cases of patients with complex anatomic degenerative diseases, without sacrificing the feasibility and reliable outcome of traditional PLIF.

Keywords Posterior lumbar interbody fusion · O-arm-based navigation · Three-level · Elderly patients · Lumbar degenerative disease

Introduction

Lumbar degenerative disease mainly consists of lumbar disc herniation, lumbar stenosis, and spondylolisthesis and has a high prevalence in the working years. Since Cloward et al. first introduced the posterior lumbar interbody fusion (PLIF)

in 1953 [1], it has become one of the most recommended methods once such patients reach the indications to perform the surgery. Transpedicular screw fixation has been proved to have an advantage over other forms of spinal instrumentation and effective fusion between vertebrae ensures the maintenance of lumbar stability [2, 3]. As a well-accepted and classic surgical procedure, PLIF still has a broad indication compared to modified approach or minimally invasive surgeries, especially for treating multilevel lumbar degenerative disease.

However, PLIF continues to have a high complication rate (dural tear, 5.4 to 10%; neurologic injury, 9 to 16%) [4] and malposition of the pedicle screws could significantly contribute to severe complications. Penetration on the sagittal plane may cause neural root stimulation and injury while severe medial penetration could cause a dural tear or spine injury. Also,

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overlong screws may breach the vertebral anterior edge and bleeding could occur once screws pierce the presacral vessels. Further, the surgery performed on elderly patients was proved to be challenging, for the anatomic bony structures were usually imprecise. As a result, the surgical technique for PLIF continues to be modified and refined. Besides the use of supplemental posterolateral bone grafting and engineered interbody devices to add spine stability, the employment of equipment that improving pedicle screw instrumentation accuracy extremely promotes the outcome of patients undergoing the surgery. There have been various techniques fulfilling the demands of screw positioning navigation. Among these clinically used image-assisted systems, the O-arm-based navigation has high precision robotics for real-time and preset positioning and could obtain both 2D or 3D images intra-operatively, which shows great advantages over other devices. This retrospective study aims to research on the effects of the O-arm-based navigation applied in the conventional PLIF procedure treating elderly patients with three-level lumbar degenerative diseases.

Materials and methods

Patients

From January 2014 to June 2016, the database of patients who admitted to the spinal department of our hospital for surgical treatment were screened with criteria as follows. The including criteria were (1) all patients were operated upon by the same surgical team; (2) patients presented low back pain with or not radiation pain to the lower extremities, intermittent claudication, and neurological symptoms; (3) radiological examination revealed lumbar disc herniation, spinal stenosis, degenerative spondylolisthesis or instability, and other degenerative changes in three consecutive segments; (4) patients underwent at least three months of regular conservative therapy with an unsatisfactory outcome; (5) patients were at least 65 years old; and (6) at least one segment was performed fusion. The exclusive criteria were (1) patients had previous history of lumbar surgery; (2) adjacent tumours, active tuberculosis or other infections, fractures, or other traumas were found; (3) patients had arthritis deformans; (4) isthmic spondylolisthesis; and (5) patients with severe osteoporosis and/or internal medical diseases were unsuitable for surgery.

Forty-one patients were eligible in this cohort study ultimately. Of all the patients enrolled in this study, 21 patients underwent conventional open PLIF while the remaining 20 patients underwent open PLIF under the O-arm-based navigation. All the patients were free to choose the surgical procedure when surgeon explicated the pre-operative informed consent.

Surgical techniques

PLIF under the O-arm-based navigation

Under general anesthesia, the patient was placed in a prone position on the Jackson carbon-fibre operating table. The segments were verified before operation by palpating the spinal process, iliac crest, and other superficial bony landmarks. The dynamic reference frame was fixed on the adjacent spine process. A median incision was made according to the prepared markers and paravertebral muscles were subsequently retracted to expose the relevant bony structures. Before the screw implantation, 3D reconstructed images were obtained from intra-operative scans which was performed by the O-arm device and the data was then transferred to the StealthStation navigation system. Passive Planar Probe was utilized to preset the entry point and canal direction based on the virtual elongated navigation trajectory. Afterwards, a cannula and a high-speed drill were used to avoid deviating while creating the screw path. The pedicle hole was explored using a guided tap to eliminate any possibility of severe penetration. Appropriate screws with best length and width were inserted through the pedicle. Following the serial placement of pedicle screws, spinal process along with lamina was removed and then cut into stripes as autogenous bone graft. Also, the ligamentum flavum was detached carefully to acquire the complete decompression. A discectomy was performed and the vertebral endplates were carefully prepared. Filled with previously processed bone chips, the cage was inserted deeply into the intervertebral space. After two rods were attached connecting the adjacent pedicle screws respectively, a final scan was performed using the O-arm technique to recheck the appropriate position of implantations. These intra-operative data were all saved and transmitted to the StarPACS computerized imaging software system. The fascia, subcutaneous tissue, and skin were closed carefully.

Conventional PLIF

The conventional PLIF was performed as other literature reviewed [5]. A C-arm fluoroscopy was used for intra-operative assessment and the pedicle screw was positioned by free-hand on the basis of the Roy-Camille technique [6].

Clinical and radiological evaluation

Clinical data including operating time, intra-operative blood loss, post-operative drain, amounts of transfusion, length of stay, post-operative complications, and surgical outcomes were collected for analysis. CT scan for patients of the free-hand group was acquired before they

discharged from the hospital. All the patients received favorable follow-up for at least 12 months. They were asked for making both clinical and radiological assessment at six and 12 months post-operatively and annually afterwards. The fusion status was evaluated referring to the Bridwell's posterior fusion grades, by means of plain radiographs [7]. Intra-operative O-arm scans and post-operative CT scans were used to evaluate the position of pedicle screws, according to the classification used by the vast majority of eligible studies [8, 9]. In terms of clinical outcomes, visual analog scale (VAS) was used to quantify the back and leg pain while the daily life condition was assessed by the Oswestry Disability Index (ODI). To reduce bias, independent researchers made individual analysis in their respective works.

Statistical analysis

Statistical analyses were performed with the SPSS 19.0 software (SPSS Inc., Chicago, IL). The continuous variables were checked by Shapiro-Wilk (*W* test) to determine whether they are normal distribution. The Student's *t* test was used to operate comparison when the data obey normal distribution, and the nonparametric rank sum test was adopted when the data was non-normal distribution. Paired *t* test was used to operate intra-group comparisons that the data were at different time points in the same group. The chi-square test or Fisher's exact test were used to compare categorical variables between two groups. $P < 0.05$ indicated that the difference was statistically significant.

Results

Detailed characteristics of the patients were displayed in Table 1. Comparison between two groups revealed no significant difference regarding demographic features. Also, in terms of clinical assessments including intra-operative blood loss and post-operative drainage, as well as total blood transfusion, no significant difference was observed between two groups. The average operation time was 255.19 ± 40.26 min in the free-hand group and 222.55 ± 38.00 min in the O-arm group ($P = 0.011$, Table 2). There were four patients in the free-hand group compared to two patients in navigation group developed post-operative complications. One patient was found to have a dural tear during the surgery while another one patient developed temporary nerve root symptoms when he woke up from anesthesia in the free-hand group, and their symptoms improved before leaving the hospital. Also, there occurred two superficial infections in both two groups respectively.

In all, 168 screws were implanted in the free-hand group and 160 screws were implanted in the O-arm group. Every segment involved received a screw insertion and no fixation

Table 1 Characteristics of enrolled patients with three-level lumbar degenerative disease

Variables	Group		<i>P</i> value
	Free-hand group (<i>n</i> = 21)	Navigation group (<i>n</i> = 20)	
Mean age (years)	72.57 ± 6.41	72.15 ± 5.58	0.824
Gender			
Male	12	9	0.437
Female	9	11	
Diagnosis			
Lumbar disc herniation	7	6	0.777
Lumbar spinal canal stenosis	9	11	
Lumbar spondylolisthesis	5	3	
Lesion segments			
L1-L4	0	1	0.582
L2-L5	13	12	
L3-S1	8	7	
Fusion			
Single segment	7	7	0.408
Two segments	10	6	
Three segments	4	7	

* $P < 0.05$

failure occurred intra-operatively while, among them, two screws were revised in the free-hand group shortly after the fluoroscopy. One hundred forty-nine screws were satisfactorily remained inside the pedicle in the free-hand group in comparison to 155 screws in the O-arm group. Twelve screws versus three screws, five screws versus two screws, and two screws versus zero screws were observed penetration in two groups respectively in an ascending grade of minor (0–2 mm), moderate (2–4 mm), and severe (4–8 mm) penetration (Table 3). To add together, 19 of 168 screws were considered as malposition in the O-arm group compared to five of 160 screws in the free-hand group (Table 3). The accuracy rate of screw positioning was 88.7 to 96.9% accordingly ($P < 0.05$). One representative challenging case treated under the O-arm base navigation was attached as Figs. 1 and 2.

The average follow-up time was 18.3 (range, 12–28) months in the free-hand group and 16.7 (range, 12–24) months in the O-arm group. The intra-group comparison revealed that VAS scores for back/leg pain and ODI were significantly improved at six and 12 months after operation. However, no significant differences were observed between two groups either pre-operatively or during the follow-up. The fusion rate was 89.7% (35/39) in the free-hand group and 92.5% (37/40) in the O-arm group (Table 3) by checking the plain radiographs at end of the follow-up ($P > 0.05$). No cage was found displaced throughout the follow-up (Fig. 2).

Table 2 Clinical outcomes of patients with three-level lumbar degenerative disease in the two groups

Parameters	Group		P value
	Free-hand group (n = 21)	Navigation group (n = 20)	
Operation time (min)	255.19 ± 40.26	222.55 ± 38.00	0.011*
Blood loss (ml)	838.1 ± 261.68	822.5 ± 300.65	0.704
Transfusion (ml)	845.24 ± 403.08	812.5 ± 328.82	0.958
Drainage (ml)	589.52 ± 285.03	559.25 ± 247.46	0.917
Hospital stay	15.43 ± 2.2	14.9 ± 2.63	0.415
VAS of back pain			
Preoperative	5.1 ± 0.83	5.2 ± 0.89	0.757
6 months postoperative	2.48 ± 0.75*	2.4 ± 0.68*	0.616
12 months postoperative	1.9 ± 0.62*	1.8 ± 0.62*	0.739
VAS of leg pain			
Preoperative	5.95 ± 1.54	6.2 ± 1.54	0.755
6 months postoperative	2.38 ± 0.80*	2.5 ± 0.61*	0.439
12 months postoperative	1.86 ± 0.85*	1.7 ± 0.73*	0.602
ODI			
Preoperative	43.44 ± 8.19	44.21 ± 9.49	0.917
6 months postoperative	20.85 ± 2.62*	21.12 ± 2.98*	0.757
12 months postoperative	18.85 ± 3.82*	18.2 ± 3.99*	0.652

**P* < 0.05

Discussion

Multilevel degenerative lumbar spine disease is the common cause of lumbar and leg pain in elderly patients which severely affect the quality of life of patients. It is characterized by severe degeneration, and often combined with degenerative scoliosis, spinal stenosis, and spondylolisthesis, and accordingly, the treatment is challenging. PLIF has been a classical surgical procedure for decades and still been used worldwide in the treatment for elder patients with multilevel lumbar degenerative diseases. In order to overcome the difficulty of pedicle screw implantation, plenty methods have been introduced in clinical, such as repeated fluoroscopy during operation, pre-operative 3-

D printing technique, navigation-assisted surgery, and robot-guided surgery [10, 11]; however, the optimal method remains controversial. As a result, in this article, we integrate the navigation technique with the conventional PLIF. It is notable that the latest studies have already acquired an exhaustive comprehension on the great importance of the different guidance methods on lumbar surgery, and the superiority of navigation via O-arm device has already reached broad consensus [12, 13]. To the best of our knowledge, few clinical studies have been published regarding the difference between the clinical outcomes and radiological assessments between conventional PLIF and PLIF under navigation in elder patients suffered from multi-segment lumbar degenerative diseases.

In this study, the O-arm group was found take visibly less surgical time in comparison to the free-hand group. Operation time is one of the pivotal causes which have been proved to have strong relations with the prognosis of patients [14]. Elderly people are considered to have less compensatory capacity for the post-operative recovery so that reduction in operative time may save a critical situation to a great extent. For all the surgery was performed by the same surgical team and there was no obvious difference between groups until the screws insertion, we supposed that the radiology-associated activities play the major role in the operation time. We have estimated the frequency and time for intra-operative assessment usage and found that the O-arm scan took less time in total compared to the C-arm radiography, as the scan based on O-arm device needs only one shot for succeeding activities while the C-arm has to repeatedly change its location and arm

Table 3 Comparison between two groups regarding the radiological assessment

Parameters	Group		P value
	Free-hand group (n = 21)	Navigation group (n = 20)	
Fusion rate (%)	89.70% (35/39)	92.50% (37/40)	0.666
Screw position			
Inside pedicle	149	155	
Minor penetration	12	3	
Moderate penetration	5	2	
Severe penetration	2	0	
Accuracy rate	88.7% (149/168)	96.9% (155/160)	0.004*

**P* < 0.05

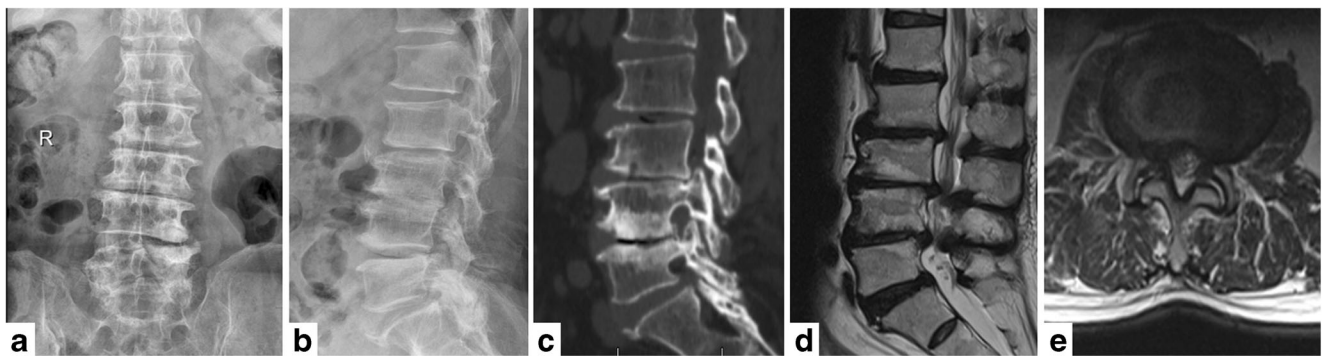


Fig. 1 Preoperative images of an 80-year-old male patient who suffered from multilevel disc herniation accompanied with spine canal stenosis. Anteroposterior and lateral radiographs (**a, b**) showed slight scoliosis and narrowing of the L3–4 segment. Sagittal scan (**c**) demonstrated the severe

sclerosis, and MR (**d, e**) revealed the severe spine canal stenosis generated from disc herniation and hypertrophy of ligamentum flavum of L2–5 segments

position to cater for the proper angle of filming. This advantage may not be noticed in just single-level operation but to be amplified when performing multilevel screw placement. It is worth mentioning that, though as a better technique than the 3D fluoroscope-based navigation, the O-arm-based navigation still needs time for peri-operative preparation including interface between O-arm and navigation system, data transmission, data reconstruction, and processing. Nonetheless, more valuable time could be saved once we master this technology.

Accuracy of the pedicle screw placement was evaluated by post-operative CT scans in the free-hand group and O-arm films in navigation group. The accuracy rate was 88.7 to 96.9% respectively, indicating that application of the O-arm-based navigation device could further evolve the craft of screw insertion. The accuracy rates that antedate this study range from 69 to 94% in the free-hand group while the O-arm-based navigation group reported an accuracy rate

from 91.9 to 99% [15–18], which is in conformity with our results. Unfortunately, despite great caution, two patients in the free-hand group still developed relatively severe complications. Both of them had trouble with screw positioning. By rechecking the pre-operative CT of them referring to the classification regarding the grading of facet joint degeneration [19] and degenerative scoliosis [20], we discovered that both the two patients had severe degeneration that one's facet joint reached grade 4 by criteria of Pathria on CT while the other had scoliosis along with a grade 3 facet joint degeneration. It is worth mentioning that either advanced age or long-level degeneration could significantly contribute to the secondary local anatomic changes, for instance, excessive thickness of the facet joint, osteophyte generation, and degeneration combined with slight acquired deformity. Such cumbersome alterations may partly conceal the necessary landmarks while surgeons perform PLIF referring to the

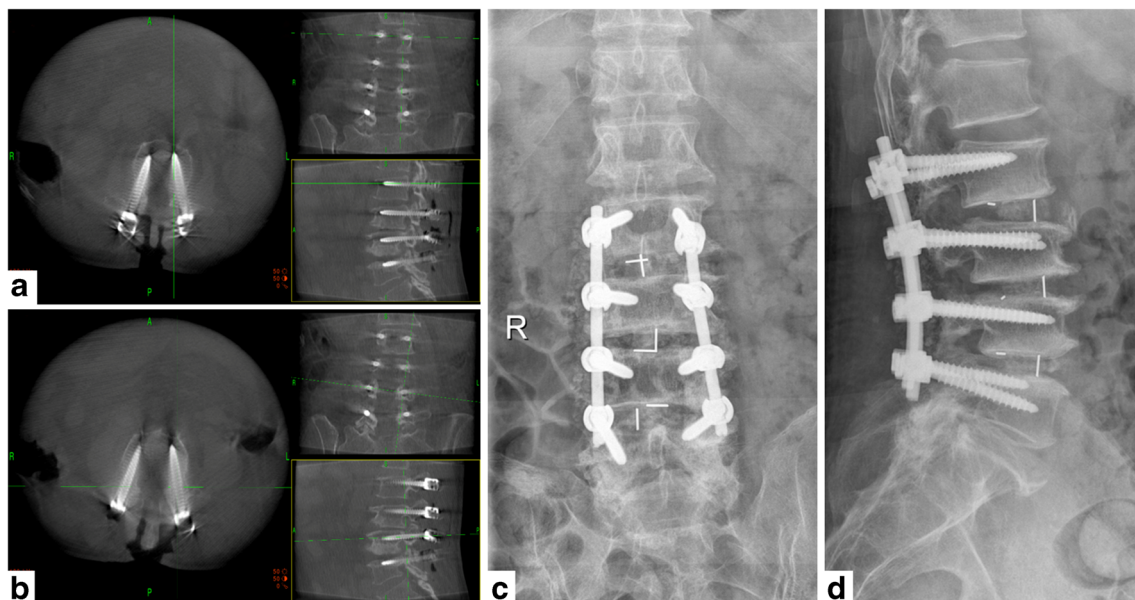


Fig. 2 Intra-operative images (**a, b**) showed that navigation based on O-arm device could provide real-time and precise virtual trajectory. Post-operative radiographs (**c, d**) showed all screws remained a satisfactory position and the degenerative changes were treated efficaciously

classical principles. Comparatively, by resorting to the navigation technique, working canal through the pedicle may become directly visible so that subsequent adjustment could be maneuvered in advance to ameliorate the screw positioning despite the superficial osseous hyperplasia.

The intra-operative blood loss, transfusion volume, postoperative drainage volume, and duration of hospital stay in the O-arm group were all slightly less than those in the free-hand group. However, the difference between two groups was not statistically significant. This seems to be a weak point compared to minimally invasive surgeries in treating single segment lesions due to the open procedure [21]. Yet, in multi-segmental degenerative diseases with complex anatomies, an open incision is still recommended to guarantee the absolute safety of the surgery. As for clinical outcomes and postoperative complications, though two relatively troublesome morbidities occurred as mentioned above, combined analysis revealed no significant difference between two groups, which means both two procedures ensure the remarkable effect of surgery.

The radiation exposure to medical staff is always an inevitable issue while orthopaedic surgeons perform internal implant placement. Mroz et al. reported that radiation exposure was associated with potential morbidity like cataract formation, skin erythema, or malignancies [22]. As all the staff would leave operation room in advance, the hazard could be deemed as nearly zero level.

Although navigation brings great benefits, it may significantly prolong the operation time when surgeons initiate this novel technique despite its merit of reducing the learning curve of junior doctors. Consequently, essential practices are recommended before carrying out this technology, especially in the extreme case of advanced age. It is also a pity that surgery via open incisions could reduce neither the blood loss, nor the duration of hospital stay, which deviates the principle of fast recovery. As to the study design, this article failed to gather more cases and almost all the patients were indigenous residents.

Conclusions

Open PLIF under navigation based on the O-arm device is an efficacious, safe modification of the traditional PLIF. The accuracy of pedicle screw positioning assisted by the O-arm-based navigation is superior to the free-hand group. Besides, the operation time is significantly shortened and still has great potential to make progress. Meanwhile, it maintains a guaranteed clinical outcome but does not sacrifice the merits of primary surgery. To sum up, we deem that surgery under navigation based on the O-arm device deserves to be promoted as a routine surgical procedure treating elderly patients with three-level degeneration diseases.

Compliance with ethical standards

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

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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