



Comparison of clinical results between novel percutaneous pedicle screw and traditional open pedicle screw fixation for thoracolumbar fractures without neurological deficit

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Abstract

Objectives To compare the efficacy and safety of novel percutaneous minimally invasive pedicle screw fixation and traditional open surgery for thoracolumbar fractures without neurological deficit.

Methods Sixty adult patients with single thoracolumbar fracture between June 2014 and June 2016 were recruited in this study, randomly divided into open fixation group (group A) or minimally invasive percutaneous fixation group (group B). Clinical and surgical evaluation including surgery time, blood losses, radiation times, hospital stay, and complication were performed. The two groups of patients with pre-operative and last follow-up anterior height ratio of fracture vertebral, Cobb angle of fracture vertebral, and VAS score of back pain were compared.

Results All patients completed valid follow-ups, with an average time period of 15.4 months (12–26 months). Group B achieved much better results in time of operation, intra-operative blood loss, and length of stay than group A ($P < 0.05$). Group A was significantly better than group B in the times of radiation ($P < 0.05$). The VAS score was significantly lower in group B than in group A at three days after the operation ($P < 0.05$). There were no significant differences between the two groups in the anterior height ratio of fracture vertebral, Cobb angle, and VAS score in the last follow-up ($P > 0.05$). No injured nerve or other severe complications occurred in both groups; one of the patients from group A had back and loin pain lasting for about one month, which resolved after analgesia and functional training. There was no significant difference between the two groups in incidence of complications.

Conclusions Novel percutaneous pedicle screws with angle reset function can achieve the same effect as traditional open pedicle screw fixation in the treatment of thoracolumbar fractures without nerve injuries. Percutaneous minimally invasive pedicle screw fixation has the characteristics of shorter operative time, less bleeding, and less pain, but it needs more radiation times.

Keywords Percutaneous · Minimally invasive · Pedicle screw · Thoracolumbar fracture · Internal fixation

Thoracolumbar fractures are spinal injuries commonly seen in subjects involved in traffic accidents and other kinds of high-energy violence, which have been shown to make up more than 50% of all spinal fractures.[1] Although some of the patients with thoracolumbar fractures without neurological deficit can achieve favourable

clinical outcomes after conservative treatment,[2, 3] short-segment pedicle screw fixation has been proved to be a more effective in stabilizing fractures, correcting kyphosis and recovering the height of affected vertebra.[4] Pedicle screw internal fixation has been proved to be safe and effective in the treatment of thoracolumbar fractures,[5] but detachment of paravertebral muscle and long-time tissue traction are likely to injure the muscles and posterior branch of spinal nerves.[6] In 1984, Magerl [7] reported treatment of spinal fracture using minimally invasive percutaneous pedicle screw fixation for the first time, which was achieved satisfactory results. However, conventional percutaneous minimally invasive treatment of thoracolumbar fractures is faced with the disadvantages of small reduction force, loss of recovery height,

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and easy loosening of nuts.[8, 9] Therefore, it is very important to design a new type of percutaneous minimally invasive screw with strong reduction and prevent the nut from loosening. This study reviewed 60 cases of unstable thoracolumbar fractures respectively treated with conventional open fixation and minimally invasive percutaneous pedicle screw fixation, and compared the clinical outcomes of the two procedures.

Materials and methods

Basic information

A total of 102 patients with thoracolumbar fractures received surgical treatment in our hospital between June 2014 and June 2016, 82 of whom met the inclusion criteria (Table 1) and 22 among them refused to participate in randomization. The included patients were randomized to receive open fixation group (group A) or minimally invasive percutaneous fixation group (group B). Group A had 17 males and 13 females, with an average age of 41.45 ± 10.01 years old. Group B had 14 males and 16 females, with an average age of 39.90 ± 9.89 years old. All patients from both groups had fractures affecting a single vertebra, including T11 in 11 patients, T12 in 18 patients, L1 in 20 patients, and L2 in 11 patients. None of the patients experienced organ injury or neurological impairment. There were no significant differences between the two groups in age, sex ratio, ratio of the pre- to post-operative anterior heights of fractured vertebra, preoperative Cobb angle, and pain visual analog scale (VAS). Patients' general information is summarized in Table 2.

Operation procedure

Minimally invasive percutaneous reduction and fixation was performed using new percutaneous pedicle screws developed and modified independently by our hospital, and

Table 2 Comparison of general data between two groups

	Sex (<i>n</i>)		Age (year)	Fracture (<i>n</i>)			
	Male	Female		T11	T12	L1	L2
Group A	17	13	41.45 ± 10.01	5	10	9	6
Group B	14	16	39.90 ± 9.89	6	8	11	5
<i>T</i> value	$\chi^2 = 0.601$		$t = 0.493$	$\chi^2 = 0.604$			
<i>P</i> value	0.438		0.625	0.909			

open surgery was done with conventional thoracolumbar pedicle screw system. All procedures were performed by the same experienced surgeon. Patients of group A were placed in prone position after general anesthesia. Conventional incision was made to expose the fractured vertebra and the ones next to it. Pedicle screw fixation of these vertebrae was done, followed by proper distraction reduction. Spinal fusion with bone graft was not performed. Patients of group B were placed in prone position with abdomen off the operating table after anesthesia. Fractured vertebra was located with C-arm X-ray system, and body surface projections of the pedicle were located according to projected grid lines, making sure that the spinous process was in the middle and the projections of the pedicle symmetrical (Fig. 1). Following incision of the skin and fascia at 1 cm lateral to the projections of both pedicles, trocars were inserted with their tips positioned at 3 o'clock position to the right pedicle and 9 o'clock position to the right pedicle (Fig. 1a, b). The core needles were withdrawn and guide wires inserted. After dilation of the channels and tapping with a thread tap, new independently modified pedicle screws were screwed in, followed by insertion of titanium rods. The modified percutaneous pedicle screws have various bending angles, which helps to achieve automatic reduction of fractures during the distraction (Fig. 1c–f). Then, the fracture was gently distracted bilaterally, during which the surgeon tightened the screws while tightening the outer nuts at the end of the modified screws by rotating in the opposite direction

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Patients injured for ≤ 2 weeks	1. Fractures of more than 2 vertebrae
2. A type in AO classification of spinal fracture	2. Single-vertebra fracture with severe spine injury or dislocation
3. No locked facet joint	3. Fracture fragment invading $\geq 50\%$ of the spinal canal
4. No nerve injury symptom	4. Presence of nerve injury symptoms
5. Strong will to receive surgical treatment and avoid prolonged bed rest	5. Suspicion for osteoporosis or pathological fracture
6. Being followed up for more than 12 months	6. Being followed up for less than 12 months

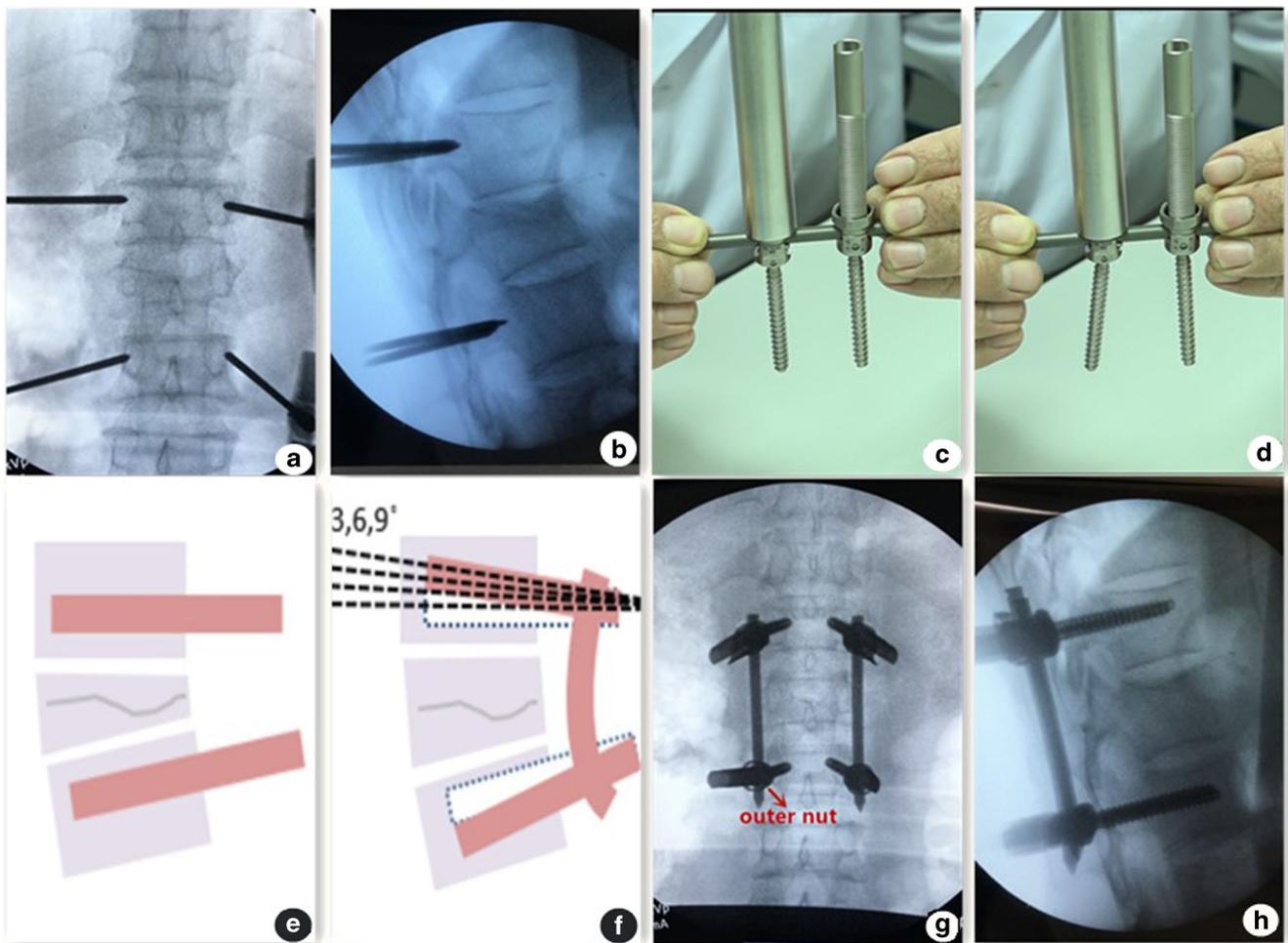


Fig. 1 Minimally invasive percutaneous fixation operating procedure

(Fig. 1g, h). Finally, the reduction was examined with C-arm X-ray system, the incisions were washed and closed, and drainage strip were placed.

Evaluation indicators

The operation time, radiation times, length of stay, and intra-operative blood loss of both groups were measured. The changes of pre- and post-operative anterior height ratio of fracture vertebral and Cobb angle of the fractured vertebra were measured through radiographic data. Pain visual analog scale was adopted to evaluate patients' condition before and after the surgery and during the last follow-up examination.

Statistical analysis

Comparative analysis of the collected data was analyzed with software SPSS 19.0. The measurement data was presented as mean \pm standard deviation. Intra-group comparisons between pre- and post-operational data were performed using paired Student's *t* test, and comparisons between groups using chi-

squared test and Student's *t* test. $P < 0.05$ indicated that the differences had statistical significance.

Results

All patients completed valid follow-ups, with an average time period of 15.4 months (12–26 months). Group B achieved much better results in time of operation, intra-operative blood loss, and length of stay than group A ($P < 0.05$, Table 3). Group A was significantly better than group B in the times of radiation ($P < 0.05$). The VAS score was significantly lower in group B than in group A at three days after the operation ($P < 0.05$). There were no significant differences between the two groups in the anterior height ratio of fracture vertebral, Cobb angle, and VAS score in the last follow-up ($P > 0.05$). No injured nerve or other severe complications occurred in both groups; one of the patients from group A had back and loin pain lasting for about one month, which resolved after analgesia and functional training. There was no significant difference between the two groups in incidence of complications. Two representative cases was attached as Fig. 2.

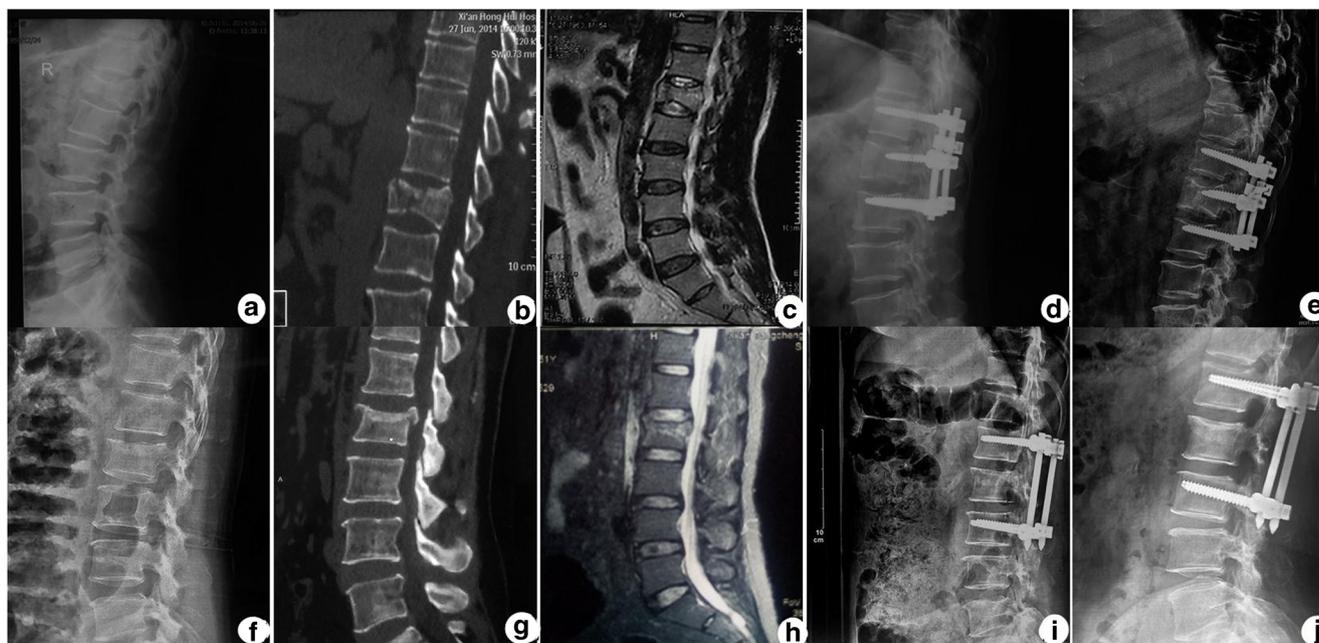


Fig. 2 Group A. A 42-year-old male patient from the open surgery group, who was admitted for lower back pain and limitation of motion after falling from height 1 day ago. Pre-operative X-ray, CT, and MRI demonstrated L1 burst fracture without apparent symptoms of spinal cord compression or neurological deficit (Fig. 2a–c). The anterior vertebral height recovered at 1 week after the surgery (Fig. 2d), and the follow-up examination at 20 months showed satisfied vertebral height without significant loss (Fig. 2e). Group B. A 49-year-old female patient from

minimally invasive percutaneous surgery group, who was admitted for lower back pain and limitation of motion for 8 h after a car accident. Pre-operative X-ray, CT, and MRI demonstrated L2 burst fracture without symptoms of neurological deficit (Fig. 2f–h). The anterior vertebral height recovered well at 2 days after the treatment (Fig. 2i), and the reexamination at 24 months showed no significant loss of vertebral height and the fracture was healed (Fig. 2j)

Discussion

The incidence of fractures is increasing year by year with the increasing of traffic accidents and aging of population. According to international statistics, about 5% of fractures are spinal fractures, among which 54.9% were thoracolumbar fractures.[1] It has been widely accepted that surgical treatment is required for fractures with neurological deficit and

unstable thoracolumbar fractures.[10–13] Early internal fixation of thoracolumbar spine fractures were done with extensive detachment of paraspinal muscles to expose vertebral plates, zygapophyses and even transverse processes, and prolonged traction of muscles and ligaments, which might result in denervation and scarring of the muscles, causing intractable pains, stiffness, and weakness in lower back.[6] For thoracolumbar fractures without neurological deficit,

Table 3 Comparison of results between two groups

	Group A (n = 30)	Group B (n = 30)	T value	P value
Operative time (min)	96.60 ± 8.844	51.55 ± 7.10	17.765	< 0.001
Blood loss (ml)	125.01 ± 19.87	63.75 ± 13.46	11.413	< 0.001
Radiation times	4.40 ± 1.50	11.93 ± 2.49	10.027	< 0.001
Hospital stay (days)	9.35 ± 1.49	5.15 ± 0.81	11.030	< 0.001
Anterior height ratio of fracture vertebral (%)				
Pre-operative	62.35 ± 8.28	67.20 ± 8.40	1.838	0.074
Final follow-up	88.50 ± 5.58	89.00 ± 4.91	0.301	0.765
Cobb angle (°)				
Pre-operative	23.95 ± 7.14	26.20 ± 6.19	1.065	0.294
Final follow-up	11.00 ± 2.99	12.80 ± 4.21	1.558	0.128
VAS of back pain				
Pre-operative	6.75 ± 0.79	6.90 ± 0.91	0.557	0.581
3D after operation	4.65 ± 0.81	2.85 ± 0.81	7.004	< 0.001
Final follow-up	1.25 ± 0.72	0.95 ± 0.69	1.352	0.184

decompression is not required, and the treatment focuses on recovering the height of fractured vertebra, restoring the stability of the spine and avoiding complications due to spinal cord injuries and prolonged bed rest. Therefore, a less invasive and more convenient and effective surgical procedure are desired for the treatment of thoracolumbar fractures in which decompression is not required.

In 1984, Magerl reported the treatment of patients with spinal fractures using percutaneous pedicle screws, pioneering the minimally invasive treatment of thoracolumbar fractures.[7] Percutaneous pedicle screw fixation has less effect on paraspinal muscles and faster post-operative recovery than open fixation.[6] Minimally invasive percutaneous screw insertion was done using paraspinal muscle fiber approach, without exposing vertebral plates and zygapophyses, causing little damage to the paraspinal muscles and ligamentous complex. What is more, traction of muscles, injuries of posterior rami of spinal nerves and post-operative denervation, and scarring of muscles are avoided, leading to minor wound, mild pains, and little blood loss.[14, 15] Ni et al. [16] reported 36 cases of thoracolumbar fractures without neurological deficit treated with minimally invasive percutaneous procedure, which all achieved satisfied outcomes. However, percutaneous pedicle screw is not without risks and complications. Wang et al. [17] found that Sextant's percutaneous internal fixation system for the treatment of thoracolumbar fractures is not as good as the open reduction internal fixation group in terms of fracture reduction ability. It is reported that percutaneous placed pedicle screws has a relatively high error rate, while the fracture height is easy to lose and the nuts is easy to fall off.[8, 9, 18, 19] Therefore, it is very important to design a new type of percutaneous minimally invasive screw with strong reduction and prevent the nut from loosening.

Treatment of thoracolumbar fractures using minimally invasive percutaneous procedures is associated with minor wounds and early recovery. However, it is concerned that this procedure cannot achieve a good outcome in fracture reduction. In conventional open surgery, the fracture is distracted with a clamp at the tail of the screws to ensure effective reduction. Whereas in minimally invasive percutaneous procedures, distraction is made at the long arm screws on body surface, and the distracting force transmits down the screws and disperses to a degree that it is not enough for effective reduction of the fractured vertebra. In addition, minimally invasive percutaneous procedures because of the difficulty in securing the rods, and more inclined to use multiaxial screws. Compared with the uniaxial screws used in open surgery, the multiaxial screws for percutaneous use are relatively weak in bone-screw loads.[20, 21] Therefore, in order to resolve the difficulties in the minimally invasive percutaneous reduction, we independently designed a new percutaneous pedicle screw characterized by its various bending angles, which helps to achieve automatic reduction of fractures

during the distraction. We designed the screws are based on the current internationally accepted titanium alloy material. They have good histocompatibility with the human body and meet the testing standards for spinal internal fixation developed by the American Society for Testing Materials (ASTM F1717). This new screw is available in three shapes (3°, 6°, and 9°), which can achieve individualized and precision treatment by choosing screws with appropriate angles based on the degree of vertebral compression. During distraction reduction, the new screw converts the nut tightening force to screw reduction force through a unique design of the bending angle, which is helpful for the recovery of the height of fractured vertebra and improvement of Cobb angle. Nut detachment and loosening of screw-rod connection are common complications of minimally invasive percutaneous procedures for thoracolumbar fractures.[22] To avoid nut detachment and increase the locking force of the nut, an outer nut is added in the percutaneous screw system, which is rotated in the opposite direction at the tail of the screw when the surgeon tightening the nut, producing a strong tightening force, allowing effective reduction of fracture and avoiding nut detachment. Group B was significantly better than group A in terms of early low back pain and length of hospital stay because of small wounds and less bleeding. Meanwhile, in the recovery of fracture height and kyphotic deformity, group B can achieve similar efficacy with group A. Long-term follow-up of patients received minimally invasive procedures showed significant improvement in anterior height of fractured vertebra and Cobb angle without significant loss in the last follow-up. All patients achieved satisfied outcomes in fracture reduction, without nut detachment or loosening of screw-rod connection, suggesting that the new percutaneous pedicle screw system is safe and effective in the treatment of thoracolumbar fractures without neurological deficit. Although the new type of percutaneous screws has advantages in restoring the height of the fracture, it also has some short plates, such as the operation requiring more radiation time, the operator needs a lot of routine surgery experience, and the learning process is a little longer.

In conclusion, novel percutaneous internal fixation with pedicle screws can obtain a similar outcome to the conventional open internal fixation and is associated with minor wounds, little bleeding and early recovery, but it needs more radiation times. It provides an option for the treatment of thoracolumbar fractures without neurological deficit, on the premise of having appropriate indications.

Compliance with ethical standards

The Ethics Committee in Xi'an Jiaotong University approved the study.

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

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