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Stability of pedicle screw in patients with osteoporosis: Follow-up visit☆

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Abstract

BACKGROUND: Screw loosening and loss of correction are main complications in patients with osteoporosis receiving pedicle screw implantation. Therefore, osteoporosis is considered as a relative contraindication for pedicle screws.

OBJECTIVE: To study the clinical results of methods for improving stability of pedicle screw in patients with osteoporosis.

METHODS: Thirty-four patients with osteoporosis were treated with pedicle screw internal fixation, and the methods of improving stability of pedicle screw were applied during the operation. There were 14 cases of fractures (fracture group) and 20 cases of osteopathy. Spinal posterolateral or intervertebral body graft fusion was performed in the 20 cases of osteopathy and five cases of fractures (fusion group). According to Jikei grading scale for osteoporosis, eight cases were in early stage, 11 cases Ⅰ stage, eight cases Ⅱ stage and seven cases Ⅲ stage. For 19 cases inearly stage and Ⅰ stage osteoporosis, longer and large size of pedicle screws were used, combined with rod system with ankylosing connection between screws and connecting rods using two cross-link devices, placement of pedicle screw with large angles in the horizontal and the sagittal planes were applied to improve the relative stability of screw. For 15 cases of Ⅱ stage and Ⅲ stage osteoporosis, bone cement was used to fill the screw path to improve the absolute stability of screw.

RESULTS AND CONCLUSION: There was no breakage of screw during the follow-up with the mean period of 14 months (ranged 9–26 months), only two cases in fracture group with Jikei Ⅰ stage osteoporosis had screw loosening at 5 to 6 months after fixation, as well as partial loss of correction of reduction, but no other adverse effects. The loss of correction of reduction in the fracture group was 5% in average, and the fusion rate was 100% in the fusion group. Different methods of improving the stability of pedicle screw applied in patients with osteoporosis according to different situations may reduce the occurrence of complications, such as screw loosening and loss of correction.

Key Words: bone and joint implants; spinal implants; bone nails; osteoporosis; pedicle screw; stability; bone cement; cross-link device; toe-nail effect; fusion; photographs-containing paper of bone and joint implants

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INTRODUCTION

The application of pedicle screws in patients with osteoporosis often meets with high incidence of screw loosening and loss of correction, and thus osteoporosis is considered as the relative contraindication for pedicle screws. With the increasing of posterior spinal fixation surgery performed in degenerative spine and elderly patients, which accompanied by some degree of osteoporosis, how to improve the stability of pedicle screw and make the relative contraindication to become the relative adaptation has become a clinical research subject. There are more experimental studies of improving stability of pedicle screw, but fewer reports

of clinical applications, especially the method of screws augmented with bone cement to fill the screw path presents some complications or risk, so it is carried out later and less in clinic[1-3]. Application of methods of improving absolute or relative stability of pedicle screw for different degree of osteoporosis, and get good results.

SUBJECTS AND METHODS

Design

Application research.

Time and setting

The experiment was completed in the Department of Orthopedics, the Second Affiliated Hospital of Soochow University, Wuxi Traditional Chinese Medicine Hospital and Wuxi No. 9 People's Hospital from January 1999 to December 2007.

Subjects

There were 34 cases, 20 males and 14 females; aged 40−71 years, averaged 57 years old. Primary osteoporosis found in four cases and secondary osteoporosis found in 30 cases. According to Jikei classification[1, 4], early stage osteoporosis occurred in eight cases, Ⅰ stage osteoporosis in 11 cases, Ⅱ stage osteoporosis in eight cases, Ⅲ stage osteoporosis in seven cases. There were 14 cases of thoracolumbar fracture (fracture group) and 20 cases of osteopathy, the latter included lumbar spondylolisthesis in nine cases, lumbar spinal canal stenosis in eight cases, degenerative lumbar instability in three cases. Transpedicular vertebral body bone graft performed in eight cases and spinal posterolateral graft performed in five cases in the fracture group. Spinal posterolateral or intervertebral body graft fusion performed in the 20 cases of osteopathy and five cases of fracture (fusion group). There were three cases of nerve injury in the fracture group (Frankel C grade in one case, D grade in two cases).

Diagnostic criteria

According to Jikei[1, 4] osteoporosis grading scale, the osteoporosis could be divided into early stage: the number of bone trabeculae was normal, bone density was decreased and bone trabeculae became thinning; Ⅰ stage: transverse trabeculae was decreased, vertical trabeculae and endplate prominent; Ⅱ stage: transverse trabeculae was further decreased, vertical trabeculae also decreased; Ⅲ stage: transverse trabeculae was nearly disappeared, vertical trabecular bone was not clear and its shape like a meadow.

Products of thoracic and lumbar spine in titanium alloy AF, screw rod system and the lifting screw system from Jiangsu Jinlu Group Medical Instrument Limited Company and Jiangsu Zhangjiagang Jinfeng Ideal Medical Instrument Limited Company.

Methods

Methods for application

For 19 cases of osteoporosis in early stage and Ⅰ stage osteoporosis, longer and large size of pedicle screws were used (6.0 mm−7.0 mm screw diameter, closed to or perforated the front cortex of vertebral body by 2 mm or less) to improve the stability of screw. At the same time, combined with rod system with ankylosing collection between screw and rod with two cross-link devices, placement of pedicle screws with large angles in the horizontal and the sagittal planes were applied to improve the relative stability of screw. For 15 cases of osteoporosis in Ⅱ stage and Ⅲ stage osteoporosis, bone cement was used to fill the screw path to improve the absolute stability of screw, which including polymethyl methacrylate in 12 cases and hydroxyapatite cement in three cases. After drilling the hole and verifying that the screw path not perforating the pedicle, then while it was in paste state injected 2−3 mL of bone cement into the vertebral body and screw path in each side, at last placed screw into pedicle.

Evaluation criteria

Loss of correction: loss of correction of reduction for fracture was evaluated using percentage of anterior vertebral body height, and loss of correction for spondylolisthesis using percentage of vertebral body length on lateral X-ray. Bone fusion with Suk standard to judge: fused in the bone graft area judged as there was a clear continuity of trabeculae, the changes of intervertebral angle in hyperextension and hyperflexion lateral X-ray should be less than 4°; non fused

judged as there was no continuity of trabeculae in the fusion zone, gap was visible and the changes of intervertebral angle in hyperextension and hyperflexion lateral X-ray should be more than 4°. If X-ray was difficult to judge, CT examination was performed.

RESULTS

Quantitative analysis of participants

Thirty-four cases were followed-up with no peeling off, the follow-up time ranged from 9 to 26 months, mean 14 months, all were involved in the result analysis.

Baseline data of two groups (Table 1)

Table 1 Comparison of baseline data of the patients in two groups

Item	Fracture group (*n*=14)	Fusion group (*n*=25)
Gender (male/female)	8/6	15/10
Age (yr)	40–69	42–71
Osteoporosis (primary/secondary)	3/11	3/22
Jikei grade (early/Ⅰ/Ⅱ/Ⅲ)	5/4/3/2	4/8/7/6
Nerve injury (*n*)	3	

Fixation effect

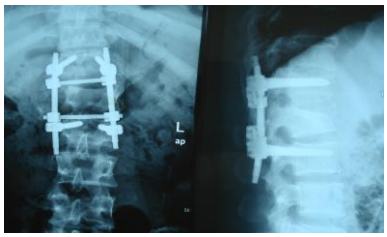
No breakage of screw could be seen, only two cases with Jikei Ⅰ stage osteoporosis in the fracture group in whom non-cement method was used noted with screw loosening and partial loss of correction of reduction at 5–6 months after operation, but no other adverse effects were found. The loss of correction of reduction in the fracture group was 5%, the fusion rate was 100% in the fusion group. In the three cases of nerve injury, one case recovered from Frankel C preoperatively to Frankel D level postoperatively, the other two cases recovered from Frankel D preoperatively to Frankel E level postoperatively.

Typical case analysis

Typical case 1

Male, 61 years old, L_1 fracture-dislocation with Jikei Ⅰ stage osteoporosis. He was treated with pedicle screws 12 days after trauma, and underwent decompression of laminectomy and intertransverse process graft fusion. The diameter of screw was 6.5 mm, placement of screw closed to the front cortex of vertebral body, combined with rigid connection between screw and rod, two cross-link devices, placement of pedicle screws with large angles in the horizontal and the sagittal planes were applied. The patient was followed-up for 12 months without screw loosening, the loss of reduction was 5% (Figure 1).

A: Preoperative X-ray film



B: Postoperative 6 mon X-ray film

Figure 1 L_1 fracture dislocation with Jikei Ⅰ stage osteoporosis. Longer pedicle screws were used and placed close to the front cortex of vertebral body to improve the stability of screw, combined with rigid collection between screw and rod, two cross-link devices, placement of pedicle screws with large angles in the horizontal and the sagittal planes were applied to improve the stability of screw

Typical case 2

Male, 67 years old, L_5 spondylolisthesis with Jikei Ⅰ stage osteoporosis. The patient underwent pedicle screws and intervertebral body graft fusion. The diameter of screw was 6.5 mm, which was placed perforating the front cortex of vertebral body by less than 2 mm. The patient was followed-up for 15 months, and got fused fine without screw loosening (Figure 2).

A: Preoperative X-ray film

B: Postoperative 9 mon X-ray film

Figure 2 L_5 spondylolisthesis with Jikei Ⅰ stage osteoporosis. Longer pedicle screws were used to perforate the front cortex of vertebral body in order to improve the stability of screw

Typical case 3

Female, 70 years old, $L_{4,5}$ degenerative lumbar instability with Jikei Ⅲ stage osteoporosis, who

underwent pedicle screws and posterolateral fusion, polymethyl methacrylate was used to fill the screw path to improve the stability of screw. The patient was followed-up for 24 months, and exhibited well fusion without screw loosening (Figure 3).

Figure 3 Postoperative 12 mon X-ray film of $L_{4,5}$ degenerative lumbar instability with Jikei Ⅲ stage osteoporosis, screws augmented with bone cement polymethyl methacrylate to fill the screw path

DISCUSSION

Factors closely related with the stability of pedicle screw are the quality of screw placement and the connection between screw-bone interface and screw. Among these factors, the key is screw-bone interface. It is generally believed that bone mineral density is positively correlated with the stability of screw. With the increasing of screw length and diameter, the contact area in the screw-bone interface increases, the screw stability increases correspondingly. Weinstein *et al* [5] study showed that 60% of fixation strength of pedicle screw lies in the pedicle, and the cancellous bone of vertebral body increased by 15%−20%, close to but not perforate the front cortex and increased by 16%, perforate the front cortex increased by 20%−25%. Sacrum is the weakest part for pedicle screw in thoracolumbar spine, as in which the channel length is short, only about 30−35 mm; if perforating the front cortex, the fixation strength will increased by 60%. Therefore, perforating the front cortex (especially in sacrum) is an effective way to improve stability of screw, but do not forget to control the perforation of cortical less than 2 mm, so as not to damage the blood vessels and other important tissues. Studies also showed that screw diameter and length synergy with each other. When increase 2 mm in diameter and 10 mm in length, compared with that increase 1 mm in diameter and 5mm in length, there is very significant difference in the increasing of the stability of screw in the former[6-7]. As cortical and cancellous bones are non-homogeneity, stability of screw close to cortex of pedicle is better than that of screw completely located within cancellous bone[8-9]. Yin *et al* [9-10] showed that when the pedicle screw placed close to the cortex even if very small part of perforation of pedicle cortex, the pullout strength and torque of screw have not been reduced especially in osteoporosis, but more than those of screw completely located within cancellous bone. Using a large size of screw causes pedicle expansion, as long as the insertion direction is accurate, nerve damage caused by pedicle perforation could be avoided. Therefore, application of thicker and longer screws is clinically safe and convenient way to improve stability of screw[5-6].

For severe osteoporosis spine, the most reliable method to improve the stability of screw is to use strengthening agent in the screw path, of which polymethyl methacrylate has the best effect. Experimental studies have shown that polymethyl methacrylate can immediately increase the pullout strength of screw by 95%, adding pressure to raise 196%[10-12]. Soshi *et al* [4] reported that the pullout strength doubled in the osteoporosis spine using bone cement to fill the screw path. However, the application of polymethyl methacrylate has some disadvantages such as: aggregation produces high heat, wrong injection or overflow that will injury the nerve tissue, long-term retention may have some toxic and carcinogenic risks, difficult for further removing, without bone conduction, a layer of connective organization grows between bone and metal screw, which under long-term load can produce relaxation and lead to bone resorption and pedicle fracture[10]. Human artificial chromosome, calcium phosphate cement, composite bio-ceramic bone cement and other new enhancers are blessed with good biocompatibility and bone conductivity, slow degradation *in vivo*, non-toxication, does not produce high heat. In these areas, they are better than polymethyl methacrylate, but their effect in improving the stability of screw is poor than polymethyl methacrylate. The main complication of new strengthening agent is leakage out of screw path and might cause nerve tissue damage[7, 10, 12]. There was no neurovascular injury or nerve damage in this paper. We understood that probe must be used to verify that there is not rupture of pedicle wall before application of strengthening agent, furthermore, while it is in paste state inject bone cement into vertebral body and screw path, as well as the pressure injected is not too high. In this way to use strengthening agent was yet relatively safe.

Enhancement of bone cement or replacement with thicker and longer screws can increase stability of screw that is the change of absolute value of stability of screw. On the other hand, the role of pedicle screw fixation does not rely solely on a single screw to work, but through connection between screw and rod or plate, that means

the whole set of instruments plays a regular role as a whole. Therefore, the upper and the lower screws, the left and the right screws with different connectors, placement of screws in different directions will affect the stability of screws in the device, which named as the change of relative value of stability of screw by Yin *et al* [13]. Biomechanical tests show that the application of screws with rigid collection between screw and rod with two cross-link devices, screw placement with large angles for the upper and the lower screws in the sagittal plane and the left and the right screws in the horizontal plane, respectively, as well as more fixing segments, will help to improve the relative value of stability of screw in osteoporosis spine [13-14]. As the rod system with rigid connection between screw and rod, and two cross-link devices put the apparatus together into one solid whole, just like screws in a locking plate, which have a good anchor force and pullout strength, meanwhile also have an increase in torque and fatigue resistance stability of apparatus. Screws placed in large angles in the sagittal plane and horizontal plane increase the shear strength of screw, which gives a triangular stability. Krag and Yin *et al* [13] named them as “toe-nailing effect” in the horizontal and the sagittal planes, respectively. Zhang *et al* [15] reported that application of thicker and longer screws and a larger horizontal angle of screws placement can improve the stability of screws in less osteoporosis spine and achieve good clinical results.

Polly and other studies[6,8] have shown that the same screw inserted at the first time has the greatest stability, but spin out and then spin in again, the screw torque will drop 34% than the initial. Therefore, in patients with osteoporosis, the screw must be placed in a one-time, do not spin out and replace. Drilling a small hole and placement with a needle to ensure accurate location under C-arm X-ray machine, then placement with screw in the surgery, that is the right way.

Soshi and other studies[1, 4] showed that for Jikei early and Ⅰ stage osteoporosis spine, an increase of 20% in diameter of screw can double the screw pullout resistance, whereas for Ⅱ and Ⅲ stage osteoporosis spine, the effect of simply increasing the diameter of screw on the increasing of screw pullout resistance is not very obvious, thus other methods must be used in this situation. Instability such as screw loosening and partial loss of correction of reduction in two cases with Jikei Ⅰ stage osteoporosis, in whom non-cement augmented screw was used after 5 to 6 months in this group, that showed the effect of this method was limited and there were still defects, the same method should not be used in patients with Jikei Ⅱ and Ⅲ stage osteoporosis. In general, the authors agreed with views that for Jikei early and Ⅰ stage osteoporosis spine using thicker and longer screws to increase the absolute stability of screw is safe and convenient, combined with rigid collection between screw and rod with two cross-link devices, and placement of pedicle screw with large angles in the horizontal and sagital planes were applied to improve the relative stability of screw. However, for Jikei Ⅱ and Ⅲ stage osteoporosis spine, more reliable method of bone cement must be used to improve the absolute stability of screw[6,16]. According to these principles, we used different methods to improve the stability of screw in 34 cases with osteoporosis, the overall results showed that the methods were safe and effective. Resently, expandable and cannulate fenestrated pedicle screws in osteoporotic patients have achieved good fixation effect, it is a promising research subject[2-3, 16].

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骨质疏松患者椎弓根螺钉稳定性的随访☆

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文章亮点：对于轻度骨质疏松患者，采用较粗和较长螺钉，同时结合采用螺钉与连接棒强直性连接，且有两根横向连接装置，左右、上下椎弓根螺钉分别在水平面和矢状面以较大成角置入螺钉等方法提高螺钉固定相对稳定性;对于较严重骨质疏松患者，采用钉道注入骨水泥方法提高螺钉固定绝对稳定性。

关键词：骨关节植入物；脊柱植入物；骨钉；骨质疏松；椎弓根螺钉；稳定性；骨水泥；横杆；斜钉效应；融合；骨关节植入物图片文章

摘要

背景：骨质疏松患者置入椎弓根螺钉后，易发生螺钉松动和复位矫正丢失等固定不稳现象，因此，骨质疏松被认为是椎弓根螺钉的相对禁忌证。

目的：观察骨质疏松患者提高椎弓根螺钉稳定性方法的临床应用效果。

方法：34 例骨质疏松患者行椎弓根螺钉内固定，术中采用了提高椎弓根螺钉稳定性方法。骨折患者 14 例(骨折组)，骨病患者 20 例。20 例骨病患者和 5 例骨折患者行脊柱后外侧或椎间植骨融合(融合组)。骨质疏松按 Jikei 分级，初级 8 例，Ⅰ级 11 例，Ⅱ级 8 例，Ⅲ级 7 例。对 19 例初级和Ⅰ级骨质疏松患者，采用较粗和较长螺钉，同时结合采用螺钉与连接棒强直性连接，且有两根横向连接装置，左右、上下椎弓根螺钉分别在水平面和矢状面以较大成角置入螺钉等方法提高螺钉固定相对稳定性；对 15 例Ⅱ级和Ⅲ级骨质疏松患者，钉道注入骨水泥以提高螺钉固定绝对稳定性。

结果与结论：随访 9−26 个月，平均 14 个月，无螺钉断裂，骨折组仅 2 例 Jikei Ⅰ级患者固定后五六个月时发生螺钉松动、部分复位矫正丢失等固定不稳，但无明显其他不良影响。骨折组复位矫正丢失平均 5%，融合组植骨融合率 100%。对于骨质疏松患者，根据骨质梳松程度采用不同的提高螺钉固定稳定性方法，可以减少螺钉松动和复位矫正丢失等固定不稳并发症。

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