

**Pedicle screw loosening after posterior spinal fusion for
adolescent idiopathic scoliosis in upper and lower instrumented
vertebrae having major perforation**

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ABSTRACT

Background: Pedicle screws are widely used in posterior spinal fusion for adolescent idiopathic scoliosis (AIS), although postoperative loosening can occur. However, few reports exist on screw loosening after pedicle screw fixation in young scoliosis patients and the etiology of loosening is not well known. This study investigated the incidence and characteristics of screw loosening in surgically treated AIS patients.

Methods: 120 AIS patients (9 males, 111 females; mean age: 15.0 years) who had received pedicle screw fixation were retrospectively reviewed. All patients underwent routine CT reconstruction scans at six months post-operatively to assess screw position, bony fusion, and the presence of screw loosening. The perforation status of each pedicle screw was assigned a grade of 0 to 3 using Rao's classification.

Results: Forty-three of 1624 (2.6%) screws showed evidence of loosening on CT. Screw loosening rates according to vertebral insertion level were upper instrumented vertebra (UIV): 9.6%; lower instrumented vertebra (LIV): 5.4%; one vertebra below the UIV: 1.8%; one vertebra above the LIV: 0.5%; two vertebrae below the UIV: 1.2%; and three vertebrae below the UIV: 0.9%. Screw loosening rates based on screw perforation grade were Grade 0: 1.4%; Grade 1: 3.1%; Grade 2: 15.5%; and Grade 3: 15.2%. Multivariate analysis revealed a distance from the UIV or LIV of one vertebra as well as the presence of major perforation to be independent factors affecting screw loosening. The ORs of UIV/LIV insertion and major perforation were 73.4 and 17.2, respectively. When major perforations occurred in the UIV or LIV, the OR for loosening approached 1262.

Conclusions: Pedicle screw loosening after posterior spinal fusion in AIS patients tend to occur in the UIV or LIV. Major screw perforation is also significantly associated with screw loosening. The risk of loosening becomes compounded when major perforations are present in the UIV or LIV.

Level of evidence: III.

Key Words: adolescent idiopathic scoliosis, posterior spinal fusion, screw loosening, perforation rate, complication, upper instrumented vertebra, lower instrumented vertebra

Mini abstract

The present study examined to assess screw position, bony fusion, and the presence of screw loosening. Pedicle screw loosening after posterior spinal fusion in adolescent idiopathic scoliosis patients tends to occur in the upper instrumented vertebra or lower instrumented vertebra. Major screw perforation is also significantly associated with screw loosening.

Key Points

- There are few reports exist on screw loosening after posterior spinal fusion in adolescent idiopathic scoliosis patients and the etiology of loosening is not well known.
- Pedicle screw loosening after posterior spinal fusion in adolescent idiopathic scoliosis patients tends to occur in the upper instrumented vertebra or lower instrumented vertebra.
- Major screw perforation is also significantly associated with screw loosening.

Introduction

The most important considerations in scoliosis surgery are cosmesis and respiratory dysfunction and back pain that may occur during adulthood. To achieve these goals, pedicle screws are widely used in corrective spinal fusion for scoliosis patients [1]. The posterior approach for scoliosis surgery has become the preferred surgical method since it offers greater placement strength owing to fixation from the posterior column to the anterior vertebral body. Although pedicle screw constructs have been shown to achieve better correction than older techniques [2, 3], they carry a risk of postoperative screw loosening.

The phenomenon of screw loosening has been studied in patients receiving pedicle screw fixation for lumbar degenerative diseases [4, 5]. Loosening is also a well-known complication of fixation in the elderly and patients with osteoporosis. Young scoliosis patients tend to have better bone quality than do elderly patients. However, the long spinal fixation needed for correction may exert greater mechanical forces and cause screw loosening. Few reports exist on screw loosening after pedicle screw fixation in adolescent idiopathic scoliosis (AIS) patients and the etiology of screw loosening remains elusive. The present study therefore analyzed the clinical and radiological features and outcomes of 120 consecutive AIS patients who underwent posterior spinal fusion with pedicle screws to better characterize the incidence and features of screw loosening in this age group.

Materials and Methods

Following approval by the investigational review board of our hospital (approval number: 3574), the medical records of 120 consecutive AIS patients (9 males, 111 females; mean \pm standard deviation [SD] age: 15.0 ± 2.4 years; range: 11-24 years) who had undergone posterior spinal fusion using pedicle screws between March 2006 and July 2016 were retrospectively reviewed. Early onset scoliosis and degenerative scoliosis were excluded in this series. Neuromonitoring and CT-based navigation were used in all cases. We inserted thick screw as much as possible by using a CT-based navigation system.

All patients underwent routine CT reconstruction scans of instrumented vertebrae six months after surgery to assess screw position, bone union, and the presence of screw loosening. Screw loosening was judged as the appearance of radiolucency around pedicle screws [4, 6] (Fig. 1). Pedicle screw perforation was evaluated in both axial and sagittal planes. Each screw was assigned a grade of 0 to 3 according to Rao's classification, as follows: Grade 0 signified no perforation of the pedicle; Grade 1 indicated less than 2 mm of perforation of the pedicle and one screw thread outside of the pedicle; Grade 2 represented pedicle perforation of 2-4 mm; and Grade 3 reflected pedicle perforation of greater than 4 mm [7]. Grade 2 and 3 perforations were considered major perforations. The distance from the upper instrumented vertebra (UIV) or lower instrumented vertebra (LIV) was also investigated as depicted in Figure 2.

All operations were performed by one author (JT). Image measurement was conducted by a spinal surgeon (MU) who was not involved in the surgeries. For statistical analysis, we used a mixed logistic regression model with pedicle screw looseness as a response variable, loosening-related factor candidates as a fixed effect, and individuality as a random effect. Statistically significant items identified in univariate analysis were included in subsequent multivariate analysis using the statistical package R, version 3.2.0 (<http://www.r-project.org>). The level of significance was set at $p < 0.05$.

Results

A total of 1624 pedicle screws was inserted into T1-L4 using a CT-based navigation system (Stealth Station TREON™ and Stealth Station 7; Medtronic, Sofamor Danek, Memphis, TN, USA). The mean \pm SD number of fused vertebrae was 9.2 ± 2.8 (range: 4-15), mean \pm SD surgical time was 219 ± 76 minutes (range: 94-420 minutes), and mean \pm SD blood loss volume

was 834 ± 680 ml (range: 50-3100 ml).

Signs of loosening of one or more screws were identified in 32 of 120 (27%) patients (2 males, 30 females; mean age: 15.4 ± 2.8 years). The distribution (7 males, 81 females) and mean age (14.8 ± 2.3 years) of patients without apparent screw loosening were comparable. Total score of SRS-22 in 6 months after operation was 4.3 ± 0.6 in patients who observed screw loosening and 4.2 ± 0.5 in patients without screw loosening, not showing significant difference between two groups ($p=0.12$). Forty-three of 1624 (2.6%) screws exhibited signs of loosening on CT, of which 36 (83.7%) screws had been inserted into the UIV or LIV. Fourteen of loosed 43 (32.6%) screws with loosening exhibited signs of loosening on the other side. According to univariate analysis, the preoperative factors of age, sex, and preoperative major curve Cobb angle did not remarkably affect screw loosening (Table 1).

Pedicle screw loosening rates based on screw diameter were 4.0 mm: 2.3% (2/87); 4.2 mm: 0% (0/8); 4.35 mm: 3.2% (9/281); 4.5 mm: 4.7% (13/278); 4.75 mm: 0% (0/5); 5.0 mm: 2.2% (7/320); 5.2 mm: 0% (0/3); 5.5 mm: 1.7% (4/239); 6.0 mm: 1.1% (3/271); 6.5 mm: 3.2% (4/124); 7.0 mm: 16.7% (1/6); and 7.5 mm: 0% (0/2). Screw loosening tended to occur most frequently for screws with a diameter of 4.5 mm or less (Fig. 3).

The numbers of loose screws according to vertebral insertion level were UIV (n=240): 23 (9.6%); LIV (n=240): 13 (5.4%); one vertebra below the UIV (UIV+1) (n=170): 3 (1.8%); one vertebra above the LIV (LIV+1) (n=210): 1 (0.5%); two vertebrae below the UIV (UIV+2) (n=172): 2 (1.2%); and three vertebrae below the UIV (UIV+3) (n=106): 1 (0.9%) (Table 2). Proximity to the UIV or LIV tended to increase screw loosening rate (Fig. 4).

Two patients who experienced loss of correction demonstrated screw loosening in the LIV, one of which received revision surgery one year after surgery. For three patients in whom we detected loosening in a medially perforated screw, the hardware was removed after achievement

of bone union (mean: 29 months [range: 18-42 months] after surgery). There were no cases of neurological deficit or spinal fluid leakage.

The major (Grade 2 or 3) screw perforation rate in any direction was 7.2% and that of Grade 3 perforations was 2.8%. No associated complications, such as injury to the spinal cord, nerve root, lung, or aorta, were noted in this series. Screw loosening rates according to screw perforation grade were Grade 0: 1.4%; Grade 1: 3.1%; Grade 2: 15.5%; and Grade 3: 15.2%. Major perforations tended to exhibit a higher rate of loosening (Fig. 5).

Next, the effects of surgery-related factors on screw loosening were analyzed statistically. Narrower screw diameter, a distance from the UIV or LIV of one vertebra, and major perforation all had significant influences on loosening. According to multivariate analysis, a distance from the UIV or LIV of one vertebra and major perforation were independent factors associated with loosening. Narrower screw diameter influenced screw loosening depending on the distance from the UIV or LIV. The ORs of UIV/LIV insertion and major perforation were 73.4 and 17.2, respectively (Table 3).

The rate of screw loosening was 7.5% in pedicle screws inserted into either the UIV or LIV. In examinations of skipped (skip group) and unskipped adjacent vertebrae (non-skip group), the loosening rate of the skip group had no significant difference (5.6% vs. 6.7%; $p=0.73$).

Furthermore, we added a sub-analysis as follows. The numbers of loose screws according to screw insertion side were concave side ($n=859$): 18 (2.1%) and convex side ($n=765$): 25 (3.3%), not showing significant difference between two groups ($p=0.14$). Loosening rates of the screws in the vertebrae which inserted two screws and the vertebrae which inserted only one screw were 2.7% (32/1172) and 1.8% (7/380), respectively. There was no significant difference between two groups ($p=0.34$).

Discussion

The present study investigated the incidence and features of screw loosening in 120 AIS patients who underwent posterior spinal fusion using pedicle screws. Univariate analysis revealed that the preoperative factors of age, sex, disease, and major curve preoperative Cobb angle did not exert a remarkable effect on loosening. In contrast, multivariate analysis revealed that a distance from the UIV or LIV of one vertebra and major perforation were independent factors affecting screw loosening. Narrower screw diameter influenced loosening depending on the proximity to the UIV or LIV.

Following its introduction in 1995 [8], segmental pedicle screw fixation has become widely used in posterior fixation for correction of the scoliotic deformity. However, pedicle screw loosening is one of the most frequently reported complications of this procedure. Ohtori et al. [4] witnessed 15 (14.7%) loosened pedicle screws in 102 insertions in patients with osteoporosis. Screw loosening is usually a consequence of pseudoarthrosis and may occasionally be associated with screw breakage and progressive kyphosis [9, 10]. Loosening is also known to occur in patients receiving multilevel fusion [11]. In one of the largest series analyzing pedicle screw insertion accuracy in spinal deformities, 4604 thoracic pedicle screws were assessed in 462 surgical cases. The rate of screw malpositioning was 1.5%, with 7.6% (35) of misplaced screws displaying loosening. However, only 20 CT scans were available for review in the study [12]. Kasim et al. reported CT to be more sensitive in detecting screw loosening than plain radiography. Forty-seven of 1666 (2.8%) screws among 26 of 81 (32%) patients showed evidence of loosening [6]. In the present series, loosening of one or more screws was witnessed in 32 of 120 (27%) patients with 43 of 1624 (2.6%) screws appearing loose, both of which were similar to Kasim's report. There was no significant difference in the total score of SRS-22 between the patients with screw loosening and without screw loosening ($p=0.12$) in this study.

Our study also revealed that the rate of screw loosening in the UIV or LIV was higher than that in other levels. Multivariate analysis uncovered a distance from the UIV or LIV of one vertebra as an independent loosening influence factor. The OR for the UIV or LIV was as high as 73.4. It was noteworthy that loosening rate had no significant difference whether the adjacent vertebra was instrumented or not. There was no apparent screw loosening at UIV+4, LIV+2, or

LIV+3. Thus, even if screws contact the spinal cord or aorta at these levels, removal may not be necessary since the risk of loosening is very low. Screw diameter was 4.5 mm or less in 56% of loose screws in our study. In one patient who experienced correction loss by screw loosening, the screw diameters in the LIV were 4.35 mm. Multivariate analysis demonstrated that narrow screw diameter influenced loosening depending on the distance from the UIV or LIV. Accordingly, surgeons may elect to extend fixation level when screws of at least 5.0 mm cannot be inserted into the LIV.

A systematic review of pedicle screw insertion into the thoracic and lumbar human spine demonstrated that the rate of Grade 2 or 3 perforations was 3-20% for the free hand technique, 0-7% for CT navigation, and 0-29% for fluoroscopy-based navigation [13]. The major perforation rate of 7.2% in this series was in agreement with published findings of 10% or more. Our study identified that major screw perforation (OR 17.2, 95% CI 6.9-49.6; $p < 0.01$) was significantly associated with screw loosening. When a perforation of greater than 2 mm occurred, the risk of screw loosening increased by roughly 17-fold. Since the OR of screw loosening rose sharply to approximately 1262 when such a perforation was found in the UIV or LIV, close attention is advised in cases of major perforation in these critical vertebrae.

The limitations of the current investigation include no evaluation of the relationships between screw loosening and clinical results, such as correction loss, bony union rate, and back pain. Another limitation was the study's retrospective design. We examined for evidence of screw loosening by CT at six months after surgery in this study. Although the precise timing of screw loosening is uncertain, most loose screws appeared in the early postoperative period (i.e., < 6 months) in a series reported by Stoll, and none appeared later than one year [14].

Taken together, our findings indicate that the screws inserted into the vertebrae adjacent to the UIV or LIV should be as thick and long as possible. If a screw of at least 5.0 mm in diameter cannot be placed into the LIV, an additional screw should be inserted into an adjacent vertebra.

Conclusion

Pedicle screw loosening after posterior spinal fusion for AIS patients primarily occurs in the

UIV or LIV in young patients. The UIV+4, LIV+2, and LIV+3 vertebral levels all seem to be safe from pedicle screw loosening. Major screw perforations are also significantly associated with screw loosening. Especially when the UIV or LIV are involved, the likelihood of screw loosening was increased at these levels in this study and requires careful attention.

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Figure Legends

Figure 1. Evidence of screw loosening. CT shows radiolucent areas around screws.

Figure 2. Distances from the UIV or LIV. Pedicle screw fixation was performed from T4 to T12. Figure numbers indicate the vertebral distance from the UIV or LIV.

Figure 3. Screw loosening rates according to inserted screw diameter. Loosening was most frequent for screws of 4.5 mm or less in diameter.

Figure 4. Screw loosening rates according to vertebral insertion level. Loosening was most frequent in the UIV or LIV.

Figure 5. Screw loosening rates according to perforation grade. Loosening was most frequent for major (Grade 2 or 3) perforations.

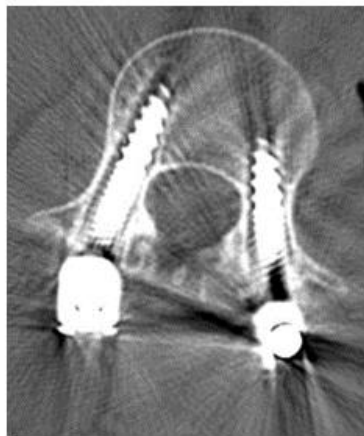


Figure 1

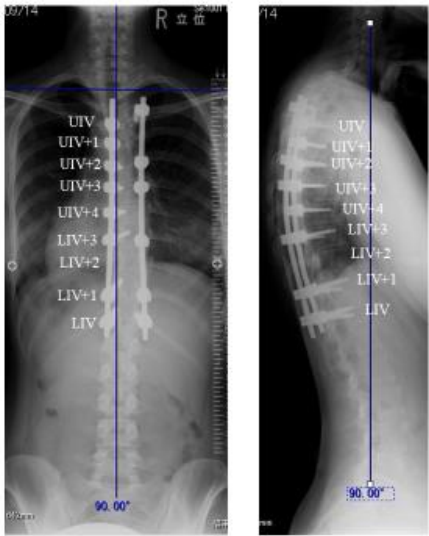


Figure 2

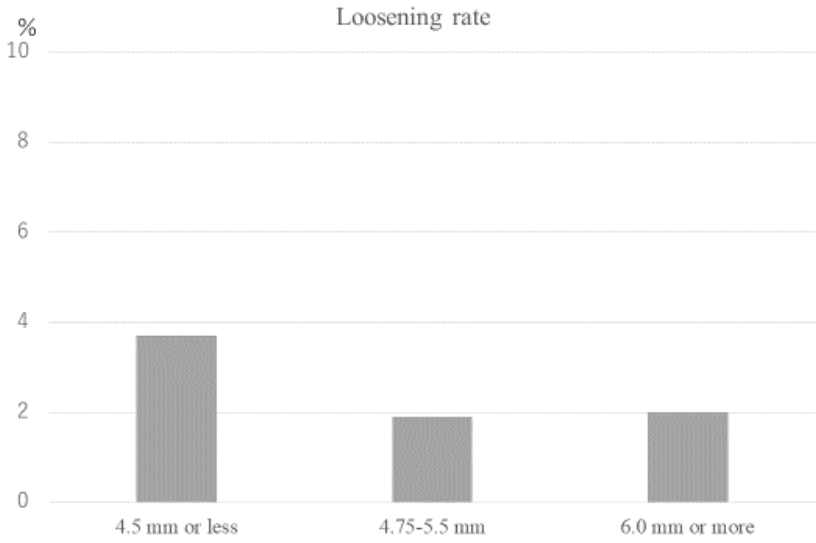


Figure 3

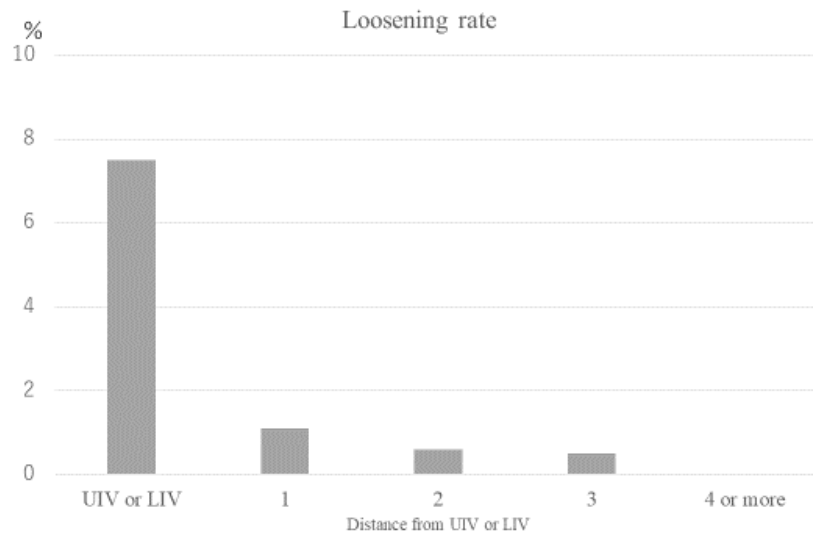


Figure 4

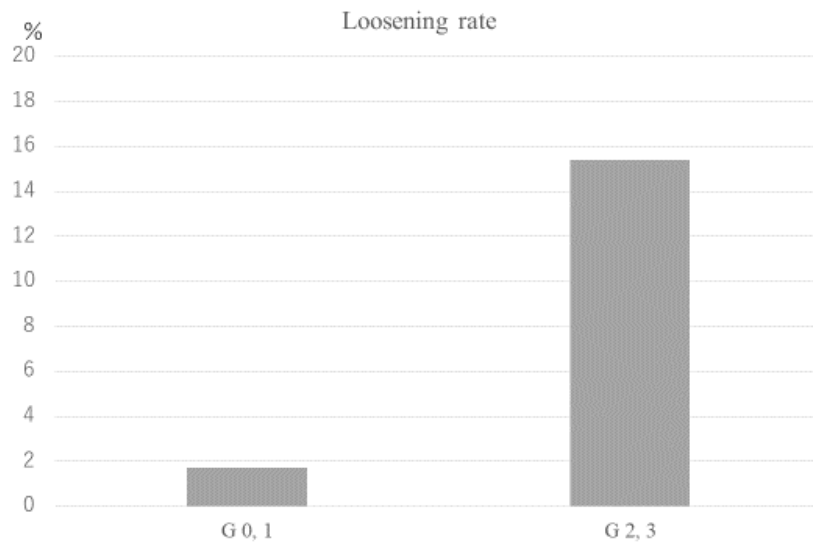


Figure 5

Table 1. Influence of preoperative factors on screw loosening (univariate analysis)

Factor	Odds ratio (95% CI)	<i>p</i> value
Age (+1 year)	1.1 (0.9 – 1.2)	0.39
Sex (Male)	1.2 (0.3 – 4.1)	0.81
Pre-op Cobb angle (main curve) (+10 degrees)	0.9 (0.7 – 1.3)	0.62

Table 2. Screw loosening rate by vertebral insertion level

Vertebral insertion level	Screw loosening rate
UIV	9.6% (23/240)
LIV	5.4% (13/240)
1 vertebra below the UIV (UIV+1)	1.8% (3/170)
1 vertebra above the LIV (LIV+1)	0.5% (1/210)
2 vertebrae below the UIV (UIV+2)	1.2% (2/172)
3 vertebrae below the UIV (UIV+3)	0.9% (1/106)
Total	2.6% (43/1624)

UIV: upper instrumented vertebra, LIV: lower instrumented vertebra

Table 3. Influence of surgery-related factors on screw loosening (univariate and multivariate analyses)

Factor	Univariate		Multivariate	
	Odds ratio (95% CI)	<i>p</i> value	Odds ratio (95% CI)	<i>p</i> value
Correction rate (main curve) (+10%)	1.0 (0.8 – 1.3)	0.99		
Screw diameter (4.5 mm or less)	1.9 (1.1 – 3.6)	0.04	1.6 (0.8 – 3.5)	0.19
Distance from UIV or LIV (vs. 3 vertebrae or more)				
2	3.4 (0.3 – 74.6)	0.31	5.8 (0.5 – 135.4)	0.17
1	5.6 (0.8 – 812.2)	0.12	10.1 (1.3 – 214.9)	0.05
0 (fixed end)	45.2 (9.4 – 812.2)	< 0.01	73.4 (13.3 – 1437.6)	< 0.01
Screw perforation (Grade 2 or 3)	15.1 (7.1 – 34.0)	< 0.01	17.2 (6.9 – 49.6)	< 0.01

UIV: upper instrumented vertebra, LIV: lower instrumented vertebra