Neurosurgical Review (2019) 42:691–698
https://doi.org/10.1007/s10143-018-1030-5

ORIGINAL ARTICLE

Pedicle screw shift without loosening following instrumented posterior fusion: limitations of pedicle screw fixation

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Received: 1 March 2018 / Revised: 10 July 2018 / Accepted: 28 August 2018 / Published online: 5 September 2018

Abstract

The disc angle at the fused segment is extended in operative prone position, but eventually returns to preoperative neutral position within 6 months to 1 year. This study aimed to assess pedicle screw (PS) shift without loosening to identify the mechanism of the change in disc angle after posterior fusion for degenerative lumbar spondylolisthesis (DLS). Sixty-three consecutive patients who underwent facet fusion for L4 single-level DLS were retrospectively reviewed using computed tomography (CT) immediately after surgery and 6 months postoperatively. Twenty-two patients (88 PSs) in whom the disc angle had decreased by more than 4° at 6-month postoperative radiographic follow-up were selected to more readily identify and quantify PS shift. Six patients with PS loosening and/or nonunion were excluded. We reconstructed a CT plane, vertical to the cranial endplate of the vertebrae and passing through the cannula used for percutaneous PSs. Angle α, which is formed by the cranial endplate and the cannula on this plane, was measured. A change in angle α of more than 2° between the immediate postoperative period and the 6-month follow-up was defined as a PS shift. Angle α did not change by more than 2° in any of the 44 PSs in the upper vertebrae of the fused segment. In the lower vertebrae, angle α changed by more than 2° in 22 of 44 PSs. The change in angle α in the lower vertebrae (average, 2.3°) was significantly greater than that in the upper vertebrae (average, 0.2°) ($P < 0.0001$). The change in the disc angle was not relevant to clinical outcomes assessed by the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire, the Roland-Morris Disability Questionnaire, and the visual analogue scale. The disc angle at the fused segment returned to preoperative neutral position due to PS shift without loosening, mainly in the lower vertebrae. PS shift is caused by bone remodeling in response to biomechanical load, similar to that in orthodontic tooth movement. As PS has limited ability to maintain a lordotic disc angle, even with the insertion of a cage, lumbar alignment will return to preoperative neutral position owing to cage subsidence or adjacent segment disease. These findings might indicate that it is not necessary to correct the spinal alignment for DLS.

Keywords Facet fusion · Bone remodeling · Loosening · Orthodontic treatment · Degenerative lumbar spondylolisthesis · Preoperative neutral position

Introduction

The pedicle screw (PS) system is used as a rigid fixator for spinal fusion. Based on long-term follow-up of posterolateral fusion (PLF) using a PS system for degenerative lumbar spondylolisthesis (DLS), Tanno et al. reported good clinical outcomes with a lower incidence of adjacent segment disease (ASD) than after posterior lumbar interbody fusion (PLIF) [15]. The disc angle at the fused segment was extended due to operative prone position, but eventually returned to preoperative neutral position within a year, without any loosening of the PS, irrespective of the degree of preoperative lumbar instability (Fig. 1). This angle was maintained thereafter. Miyashita et al. reported that facet fusion (FF) with a percutaneous PS system achieved good clinical outcomes that were superior to those of PLF, with a comparable fusion rate, and is therefore a minimally invasive evolution of PLF and a suitable method for managing DLS [12]. After FF, the disc angle at the fused level, which was extended due to operative prone position, returned to preoperative neutral position

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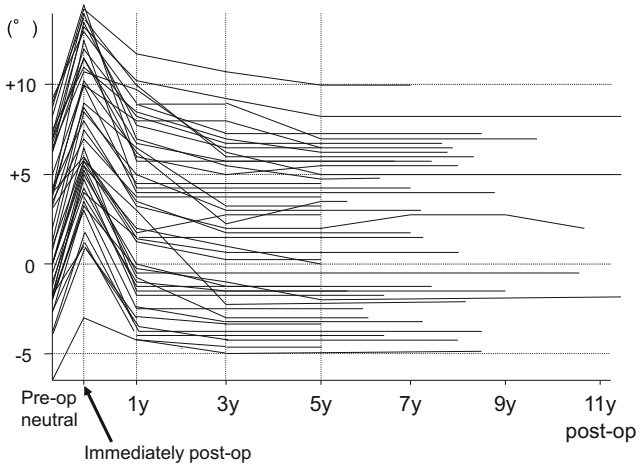

Fig. 1 Change in the disc angle at the fused segment following posterolateral fusion for degenerative lumbar spondylolisthesis. Although the disc angle at the fused segment is extended due to operative prone position, the angle eventually returns to preoperative neutral position within 1 year and is maintained thereafter (reproduced, with permission, from Tanno et al. [15])

within 6 months, without any loosening of the PS, achieving a result similar to that of the PLF study mentioned above (Fig. 2). During changes in the disc angle, the PSs appear to shift in the vertebrae without loosening. We assessed PS shift in detail to identify the mechanism of change in the disc angle after posterior fusion for DLS.

Methods

Patient population

This retrospective study used radiography and computed tomography (CT) performed immediately after surgery and 6 months later to assess 63 consecutive patients (36 women, 27 men; average age, 66.9 years; range, 41–84 years) who underwent FF for L4 single-level DLS between March 2010 and August 2015. All patients presented with intractable radiculopathy and intermittent claudication, even after several months of conservative treatment. Patients complaining of low back pain (LBP) alone preoperatively were excluded. The indications for lumbar fusion were (1) sagittal translation 8% or more on a flexion-extension lateral radiograph, or (2) anterior wedging of 5° or more on a flexion radiograph and a disc range of motion (ROM) of 10° or more. When lumbar fusion was indicated, we did not use other approaches, such as interbody fusion or reduction of slippage, and all DLS patients were treated with FF regardless of the grade of spondylolisthesis.

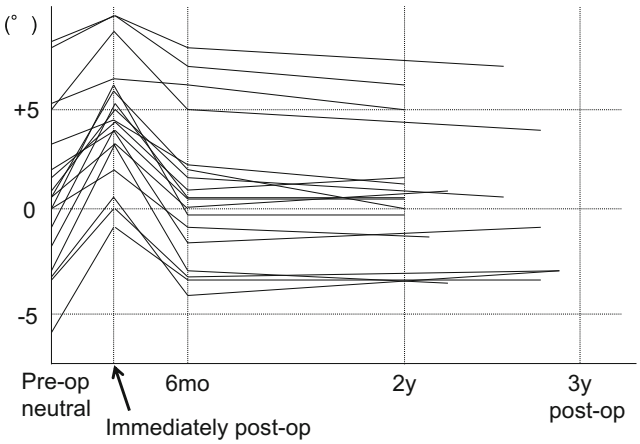

Fig. 2 Change in the disc angle at the fused segment following facet fusion for degenerative lumbar spondylolisthesis. Following posterolateral fusion as in Fig. 1, the angle eventually returns to preoperative neutral position within 6 months, even though the disc angle at the fused segment is extended due to operative prone position. The angle is maintained thereafter

Operative procedure

The FF procedure was performed according to Miyashita's method [12]. Thus, the central canal and lateral recess were decompressed using laminar fenestration. Bone chips harvested from the spinous process and laminae were pushed into the thoroughly decorticated facet joint spaces. Percutaneous PSs with a maximum diameter of the pedicle were then inserted through the fascia. Of 252 screws, 217 were of 7.5-mm diameter and were the widest available in the PS systems used (Sextant until March 2012 and Solera-Sextant after April 2012: Medtronic Sofamor Danek, Inc., Memphis, TN, USA; Viper: Depuy Spine, Inc., Raynham, MA, USA; and Ballista: Biomet, Inc., Warsaw, IN, USA).

Postoperative protocol

The patients were allowed to sit up in bed with a soft brace on the first postoperative day and were mobilized with physiotherapy after the removal of the drain and urinary catheter on the second postoperative day. The soft brace was worn for 3 months postoperatively. In nine patients who were judged to have severe osteoporosis based on X-ray appearance rather than with bone mineral density testing, a hard brace was used for 3 months, followed by a soft brace for another 3 months.

Fusion assessment

CT was performed at 3 months and every 6 months postoperatively until adequate fusion was confirmed (up to 36 months). Loosening was indicated by a lucent zone around the PS on CT. Fusion was assessed according to Miyashita's grading system for FF [12], and nonunion was identified when continuity in the bone could not be confirmed at any portion of a facet joint (grade III) or with obvious FF nonunion (grade IV). Of 63 patients, 57 with adequate fusion, in whom CT showed complete (grade I) or partial (grade II) bony continuity on a facet joint, had no motion at the fused level on flexion-

extension lateral radiography. Six patients with PS loosening and/or nonunion on CT were excluded.

Of these 57 patients, we selected a subset of 22 (88 PSs), in whom the disc angle at the fused level on the lateral radiograph had decreased by 4° or more from the extended angle due to the operative prone position in the period between 1 week and 6 months postoperatively (changed group). We set the range of measurement error as 4° because Cakir et al. reported a 95% confidence interval for measurement error of ± 4.0° using the superimposition method and ± 4.2° using the Cobb method, when experienced observers measured sagittal plane segmental ROM in the lumbar spine [2]. We based our analyses on these patients to more readily identify and quantify PS shift. The other 35 patients, in whom the disc angle at the fused level had decreased by less than 4°, were defined as a control group for comparison of clinical outcomes (unchanged group).

Radiological measurement

CT was performed with a 16-slice Aquilion TSX-101A (Toshiba Medical Systems Corporation, Ohtawara, Tochigi, Japan). The window level was 3000 Hounsfield units (HU) and the window width was 10,000 HU. We reconstructed a CT plane, vertical to the cranial endplate of the vertebra in which the PS was inserted and passing through the cannula used for percutaneous PS (Fig. 3). Five experienced spine surgeons measured angle α, formed by the cranial endplate and the cannula of the screw in the reconstructed plane. The planes were blindly evaluated on two separate occasions (a total of ten measurements of each angle α) under standard viewing conditions using the same operative systems and same electronic tools. Jiang et al. reported a mean difference of 1.9° in the Cobb angle between readings, using midsagittal CT images of thoracolumbar burst fractures, with intra- and inter-observer reliability using intra-class correlation coefficients (ICCs) of 0.969–0.986 and 0.941–0.953, respectively [7]. Accordingly, a change in angle α of more than 2° between the immediate postoperative period and the 6-month follow-up was defined as a PS shift.

Clinical outcome measures

The therapeutic effectiveness of FF was assessed using the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ) preoperatively and 1 year postoperatively as a clinical outcome [3]. The Roland-Morris Disability Questionnaire (RMDQ) and the visual analogue scales for LBP (LBP-VAS), buttock and lower limb pain (BLP-VAS), and buttock and lower limb numbness (BLN-VAS) were also recorded at the same time as the JOABPEQ. Clinical outcomes were compared between the changed and unchanged groups.

Statistical analysis

ICC was calculated to determine both intra- and inter-observer reliability (SPSS 17.0, SPSS Inc., Chicago, IL, USA) for measurements of angle α. The Wilcoxon signed-rank test (Statcel2, OMS publishing Inc., Tokorozawa, Saitama, Japan) was used to determine significant differences in angle α between the upper and lower vertebrae of the fused segment and between preoperative and 1-year postoperative RMDQ and VAS scores. The nonparametric Mann-Whitney *U* test was used to determine differences in age, body mass index (BMI), and RMDQ and VAS scores between the changed and unchanged groups. Fisher's exact probability test was used to assess differences in sex and therapeutic effectiveness, expressed as JOABPEQ categories, between the changed and unchanged groups. The level of significance was set at $P < 0.05$.

Institutional ethics committee approval

This study was approved by the Medical Ethics Committee of our hospital (#25-13).

Results

The average postoperative follow-up period was 45.1 (13–86) months. Excluding six patients with PS loosening and/or nonunion, adequate fusion was confirmed at 8.7 (3–24) months

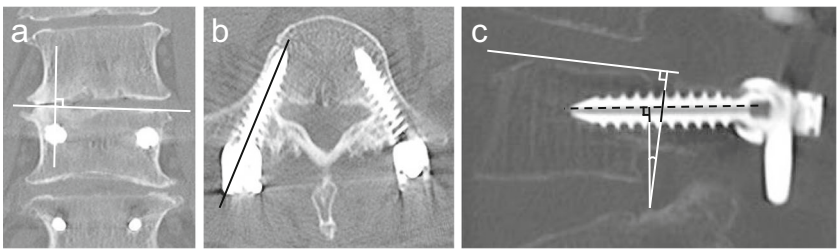

Fig. 3 Steps in measurement with computed tomography. **a** Reconstruction of a vertical plane to the cranial endplate of the vertebra. **b** Adjustment of the plane through a cannula used for the percutaneous pedicle screw. **c** Measurement of the angle between the cranial endplate and the cannula of the screw in the reconstructed plane (angle α)

Table 1 Group characteristics classified by pedicle screw shift (averages ± standard errors)

	Group		*P* value
	Changed	Unchanged	
Sex (F:M)	15:7	20:15	0.29
Age	68.3 ± 1.9	64.8 ± 1.6	0.18
BMI (kg/m^2)	23.5 ± 0.7	23.7 ± 0.5	0.77

F female, *M* male, *BMI* body mass index

postoperatively on average. There was no significant difference between the changed and unchanged groups in sex, age, and BMI (Table 1).

Pedicle screw shift

Reproducibility of measurements of angle α for each observer was quite high and ICC for intra-observer reliability was 0.87 for observer 1, 0.994 for observer 2, 0.927 for observer 3, 0.907 for observer 4, and 0.818 for observer 5. ICC for inter-observer reliability was 0.819, which was above the statistically acceptable threshold of > 0.8. The average angle α in ten measurements did not change by more than 2° in any of the 44 PSs in the upper vertebrae of the fused segment (Fig. 4a). However, in the lower vertebrae, 22 of 44 PSs showed a change in angle α of more than 2°, and the tips of all 22 PSs shifted caudally (Fig. 4b, c). All 44 PSs in the upper vertebrae and the other 22 in the lower vertebrae showed a change in angle α of less than 2°. The change in angle α in the lower vertebrae (average, 2.3°; range, − 0.3 to 9.4°) was significantly greater than that in the upper vertebrae (average, 0.2°; range, − 1.1 to 1.9°) ($P < 0.0001$).

Clinical outcomes

In the changed group, the JOABPEQ category scores demonstrated therapeutic effectiveness for walking ability in 88.2% of patients, for social life function in 76.5%, for low back pain in 64.3%, for mental health in 58.8%, and for lumbar function in 53.3%. In the unchanged group, the scores showed therapeutic effectiveness for walking ability in 93.8%, for social life function in 68.8%, for low back pain in 82.1%, for mental health in 40.6%, and for lumbar function in 57.1%. There was no significant difference in therapeutic effectiveness between the changed and unchanged groups in any category.

The average RMDQ score significantly decreased from 12.1 preoperatively to 4.2 postoperatively in the changed group ($P < 0.001$), and from 11.3 to 3.7 in the unchanged group ($P < 0.001$). There was no significant difference in the postoperative score between the changed and unchanged groups.

The average preoperative LBP-VAS, BLP-VAS, and BLN-VAS scores in the changed group were 55.1, 58.8, and 64.3, respectively. At 1 year postoperatively, these scores significantly decreased to 17.7, 13.2, and 26.3, respectively ($P < 0.01$). The average preoperative VAS scores in the unchanged group were 49.5, 73.6, and 69.7, respectively. The postoperative scores significantly decreased to 15.9, 23.9, and 22.0, respectively ($P < 0.001$). There were no significant differences in postoperative scores between the changed and unchanged groups in any category.

Among the 63 patients, including those with PS loosening and/or nonunion, none had a bad clinical outcome and no revision surgery was required.

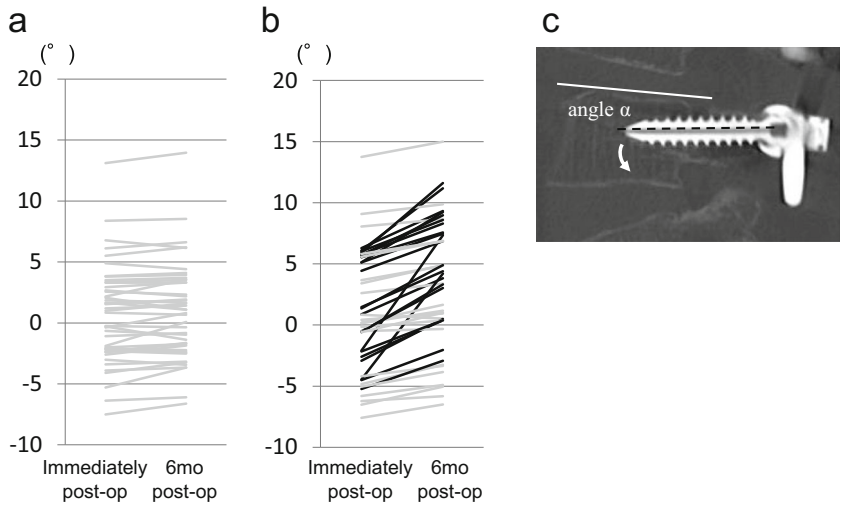

Fig. 4 **a** The change in angle α in the upper vertebra of the fused segment between the immediate postoperative period and the 6-month follow-up. None of the 44 pedicle screws show a change in angle α of more than 2°. **b** The change in angle α in the lower vertebra. Angle α shows a change of more than 2° in 22 of 44 pedicle screws. **c** A schematic diagram of pedicle screw shift in a lower vertebra. The tips of all 22 pedicle screws shift caudally. The black bars in Fig. 4a, b indicate a case in which angle α changed by more than 2°, and the gray bar indicates a case in which angle α changed by equal to or less than 2°

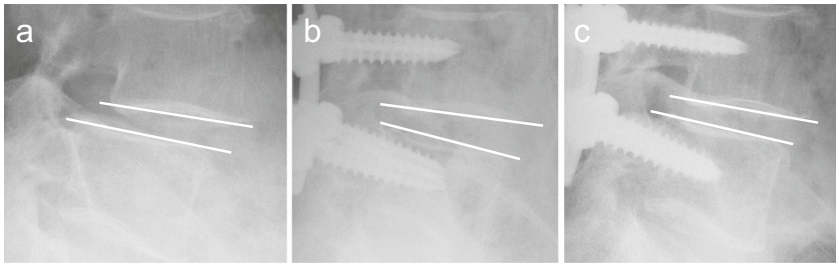

Fig. 5 Lateral radiographs of a 74-year-old woman with L4 degenerative lumbar spondylolisthesis. **a** Preoperative radiograph in neutral position showing a focal L4–L5 angle of 1°. **b** Radiograph obtained immediately after surgery showing a focal L4–L5 angle of 6°. **c** Radiograph obtained 6 months after surgery showing a focal L4–L5 angle of 1°, the same as that in the preoperative neutral position

Case presentation

A 74-year-old woman with L4 DLS underwent L4–L5 FF (Fig. 5a, b). Lateral radiography immediately after surgery showed a focal L4–L5 angle of 6°, which was extended due to the operative prone position (Fig. 5b). The disc angle at the fused segment decreased gradually within 6 months until it returned to preoperative neutral position. The focal L4–L5 angle 6 months after surgery was 1°, which was the same as the preoperative value in neutral position (Fig. 5a, c). During postoperative follow-up, CT did not detect any PS loosening (Fig. 6). Bilateral angles α in the L5 vertebra changed between the immediate postoperative period and the 6-month follow-up, although bilateral angles α in the L4 vertebra showed almost no change.

Discussion

The present study demonstrated that changes in the disc angle after FF were caused by PS shift in the vertebrae without loosening. PSs in the lower vertebrae of the fused segment mainly shifted caudally, while PSs in the upper vertebrae shifted very little. PS shift and changes in the disc angle were not relevant to clinical outcomes.

Pedicle screw shift and bone remodeling

Few reports have discussed PS shift without loosening. Jain et al. reported that despite use of segmental pedicle instrumented correction and fusion, pedicle migration or shift with longitudinal growth of the spine, due to biological remodeling of the plastic posterior fusion mass and pedicles, may explain at least a few cases of recurrent deformity after posterior fusion in scoliosis surgery [5]. They reported no evidence of pedicle fracture or breach, and no implant loosening, infection, or breakage. Their findings appear to reflect the PS shift that we also report, and they suggest that the pedicles seemed to have remodeled well at their new positions, with the implication that PS shift without loosening is a result of bone remodeling.

Tsubota et al. investigated the effect of PSs on three-dimensional trabecular structural changes in the vertebral body, using voxel-based finite element models of trabecular surface remodeling [16]. They found that trabecular structural changes depended on the direction of load applied to the screw in the case of the bone-screw interface. They also indicated

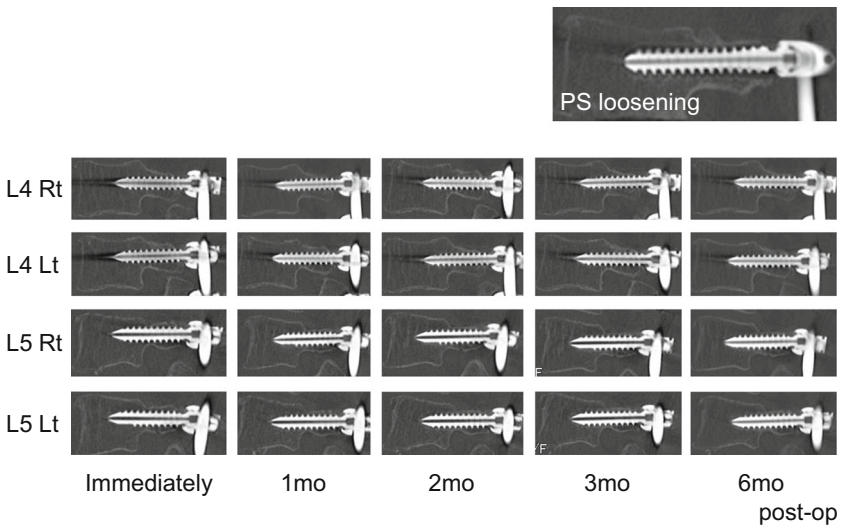

Fig. 6 Computed tomography images of each pedicle screw (PS) obtained immediately, and 1, 2, 3, and 6 months after surgery in the same patient shown in Fig. 5. Screw loosening is not detected at any point. An image of PS loosening in another patient is shown in the upper right for comparison. Bilateral angles α in the L5 vertebra change between the immediate postoperative period and the 6-month follow-up, although bilateral angles α in the L4 vertebra change very little

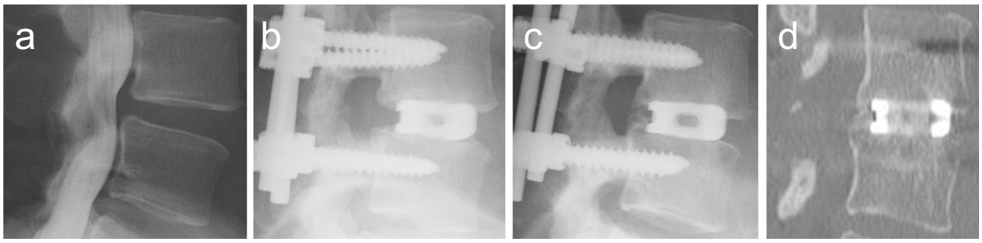

Fig. 7 Lateral radiographs of a 48-year-old woman with L3–L4 left foraminal herniation. **a** A preoperative myelogram in the neutral position. **b** A radiograph obtained immediately after L3–L4 transforaminal lumbar interbody fusion showing distraction of intervertebral space. **c** A radiograph obtained 3 years after surgery showing a return to same alignment as the preoperative neutral position due to cage subsidence. **d** Computed tomography image obtained 3 years after surgery showing complete bone union. Pedicle screw loosening was not detected

that the direction is one of the critical factors in determining bone resorption at the bone-screw interface.

Pedicle screw shift and orthodontic tooth movement

Histological evaluation to determine the contribution of bone remodeling to PS shift is impractical in humans, who walk upright. However, the mechanism of PS shift seems to be similar to that in orthodontic tooth movement. Extensive basic orthodontic research has demonstrated that tooth movement in response to mechanical force depends on remodeling changes in dental and periodontal tissues [4, 13, 17]. The periodontal tissues primarily affected by orthodontic forces can be divided histologically into a compression region and a tension region. Alveolar bone resorption occurs in the compression region during tooth movement. Bone resorption occurs when osteoclastic activity creates cavities, known as lacunae, which will later be filled by osteoblasts. In the tension region, new bone is formed by osteoblasts. During orthodontic treatment, the tooth moves in the direction of force without loosening.

Loosening of a tooth can occur with orthodontic treatment and is caused by alveolar bone loss [1, 6, 14]. Janson et al. reported that alveolar bone response to orthodontic tooth movement depends on force levels and the type and extent of movement [6]. The mechanism of PS loosening might be the same as that in tooth loosening after orthodontic treatment, occurring in response to greater force and extent of PS shifting.

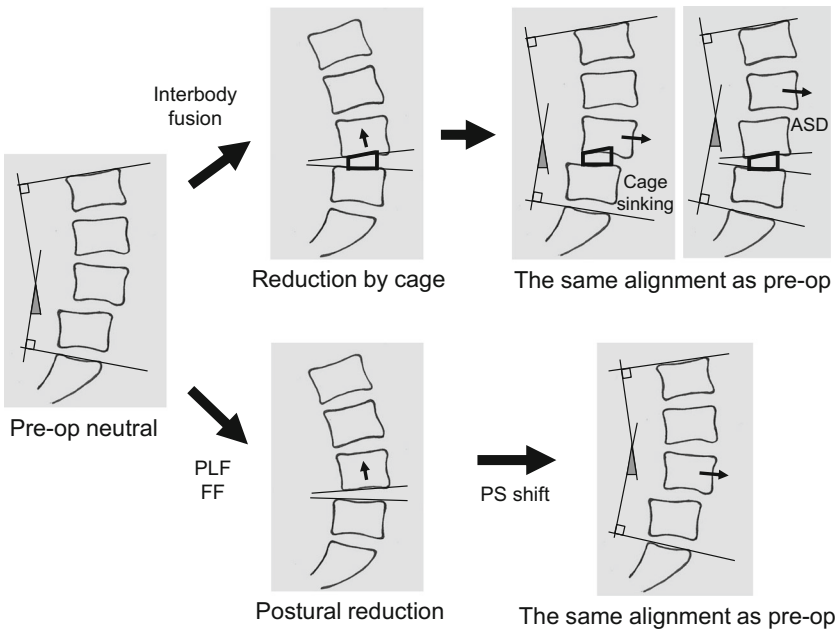

Fig. 8 A schematic diagram of differences in lumbar alignment after interbody fusion, and after PLF and FF for degenerative lumbar spondylolisthesis. After correction to lordotic disc angle with the insertion of a cage, the alignment will return to the preoperative neutral position due to cage subsidence. If spinal fusion develops before cage subsidence, the alignment will return to the preoperative neutral position with ASD. In the case of PLF and FF, the disc angle at the fused segment was extended due to operative prone position, but eventually returned to preoperative neutral position with PS shift. ASD indicates adjacent segment disease; PLF, posterolateral fusion; FF, facet fusion; PS, pedicle screw (reproduced, with permission, from Tanno et al. [15])

Clinical significance of pedicle screw shift

Our study suggests that PSs are limited in their ability to maintain a lordotic disc angle after correction; even with the insertion of a cage, lumbar alignment will return to the preoperative neutral position, i.e., "settle to the comfortable position," due to cage subsidence in some cases (Fig. 7). It is difficult to explain cage subsidence without PS loosening, which is often seen, without taking PS shift into consideration. Recently, a relatively wider footprint cage has been used for lateral lumbar interbody fusion. This is thought to be advantageous because of a wider vertical stress distribution, which reduces the incidence of cage subsidence. However, some authors have even reported subsidence with such a cage and supplemental PS fixation [9–11]. After distraction of the intervertebral space and insertion of a cage, subsidence may be inevitable due to bone remodeling, regardless of the width of the cage. If spinal fusion develops before cage subsidence, we speculate that alignment will return to the preoperative neutral position with ASD and/or proximal junctional kyphosis, as Tanno et al. theorized (Fig. 8) [15]. Kaito et al. reported that excessive distraction of the disc space during PLIF was a significant risk factor for ASD [8]. They interpreted this finding by suggesting that distraction of the disc space by cage insertion exerts significant mechanical stress on the adjacent segment. Our speculation is, therefore, in line with their view. These findings and the observation that changes in the disc angle were not relevant to clinical outcomes might indicate that it is not necessary to correct spinal alignment for DLS.

Mechanical load on the pedicle screw

The reason for PS shift mainly in the lower vertebrae of the fused segment is unclear. The difference in mechanical load on PSs in the upper and lower vertebrae may account for this finding. The load can even be different between left and right PSs in the same vertebra, and can change with spinal alignment, fused level, muscle volume, and/or bone density. Although we defined a change in angle α of more than 2° as a PS shift, some of the 44 PSs in the upper vertebrae and 22 in the lower vertebrae actually shifted less than 2°, according to the individual load.

Study period

The current study compared radiographs taken 1 week after surgery and at the 6-month follow-up because preliminary data indicated that the disc angle at the fused segment after FF decreased within 6 months, until return to preoperative neutral position (Fig. 2). The study only included patients with confirmed adequate fusion and excluded those in whom CT showed PS loosening and/or nonunion at more than 6 months of follow-up. Tsubota et al. suggested that trabecular structural changes around implants occur within a few months to a few years following surgery, and that trabecular remodeling must be considered in order to evaluate a vertebral body with PSs as a load-bearing structure [16]. Although our study period of 6 months was thought appropriate, a longer period might identify a later PS shift in other patients, thereby improving the accuracy of the results.

Description of the phenomenon

Throughout this paper, we have described the phenomenon under study as PS shift in the vertebrae for ease of communication. However, the phenomenon may be more precisely described as movement of the vertebra in spite of PS fixation, leading to a change in the disc angle.

Limitations

This study has some limitations. First, it had a retrospective design. Second, levels other than L4–L5 and multi-level fixation were not evaluated. Third, it is not clear whether the mechanism of PS shift in the vertebrae is the same as that in orthodontics; further study is required to clarify the mechanism.

Conclusions

The disc angle at the fused segment after posterior fusion for single-level DLS returned to the same angle as the preoperative neutral position because the PS shifted without loosening, mainly in the lower vertebrae. PS shift was the result of bone remodeling in response to biomechanical load. The mechanism seemed similar to that in orthodontic tooth movement. PS shift and changes in the disc angle were not relevant to clinical outcomes. PS has limited ability to maintain a lordotic disc angle after correction.

Acknowledgements The authors wish to thank Dr. Daisuke Ishigami for information about orthodontic treatment.

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.

Informed consent For this type of study, formal consent is not required.

Institutional ethics committee approval This study was approved by the Medical Ethics Committee of Matsudo City General Hospital (#25-13).

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