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Clinical Study

Does the interfacing angle between pedicle screws and support rods affect clinical outcomes after posterior thoracolumbar fusion? A retrospective clinical study

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Abstract

BACKGROUND CONTEXT: Proper alignment and tightening of the pedicle screw/rod assembly after instrumented posterior fusion of the lower spine is known to be crucial in order to achieve satisfactory clinical results. Such interfacing angle mismatches indicate stress overloading of the implant system.

PURPOSE: The objective of this study is to investigate the incidence of postoperative screw/rod interfacing angle mismatch and to analyze the impact of mismatches on clinical outcome in terms of (1) revision surgery, (2) adjacent segment degeneration (ASD), and (3) pain.

STUDY DESIGN: This is a monocentric retrospective observational study.

PATIENT SAMPLE: Patients underwent fusion surgery with pedicle screw/rod systems for predominantly degenerative pathologies.

OUTCOME MEASURES: Pedicle screw/rod interfacing angle mismatch (mismatch is the angular deviation from 90° formed by the rod axis and the pedicle screw head axis as an indicator for missing form-fit) revision rate, ASD at the immediately adjacent cranial segment and VAS pain.

METHODS: Revision refers to subsequent procedures in which all or part of the original implant configuration is changed or removed. Radiographic parameters are evaluated using a/p and lateral radiographs at final follow-up. The interfacing angle mismatch between pedicle screw and rod is measured as the angle between two parallel lines on either side of each pedicle screw head and a line laterally along the associated rod. Multiple comparisons are counteracted by Bonferroni correction, adjusted significance level is at *p<.01.

FDA device/drug status: Not applicable.

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RESULTS: Pedicle screw and rod interfacing angle mismatch was found in 171/406 (42.1%) of patients undergoing fusion surgery, affecting 613/3016 (20.3%) screws. The overall revision incidence was 11.8% (48/406), and a new ASD occurred in 12.1% of all patients (49/406) with an average follow-up of 5 years. Mean VAS pain score at final follow-up was 2.0. Comparison of the two groups with and without mismatches revealed statistically significantly higher (1) numbers of revision procedures performed (26.9% vs. 0.9%), (2) numbers of new ASD developed (27.5% vs. 3.8%), and (3) higher VAS pain scores (2.8/10 vs. 1.4/10) for cases with mismatch. When comparing patients who underwent intraoperative correction and/or reduction with those who did not, statistically significant more screw mismatches (63.4% vs. 39.7%) and revision surgeries (29.3% vs. 9.9%) were noted in patients who had these forceful maneuvers.

CONCLUSIONS: Pedicle screw/rod interfacing angle mismatch is a frequent occurrence after fusion surgery. Mismatches indicate that the construct was assembled under mechanical stress. All preventable mechanical stresses, for example, unintentional uncontrolled forces on the instrumentation, should be avoided as much as possible, as they can negatively influence the clinical outcome.

Key words: Adjacent segment degeneration; Force control; Revision surgery; Screw/rod mismatch; Spine biomechanics

Introduction

Instrumented posterior thoracolumbar fusion with pedicle screw systems is an established procedure for the surgical treatment of numerous degenerative spinal disorders, with increasing case numbers worldwide [1]. Although most patients benefit from the intervention, the cumulative revision rate after spinal fusion surgery is approximately 15% no later than 5 years after surgery [2−5] and increases to well over 20% after 10 years [5−9]. For scoliosis correction, revision rates as high as 18% to 56% are reported 4 to 6 years postoperatively [10−15]. More than 60% of all reoperations after primary fusion surgery are due to device failures such as screw pull-out, screw loosening, disassembly, and implant breakage, as well as pseudarthrosis, loss of correction, or secondary malalignment, rather than progression of the original disease or development of a new disease [7,16]. The causes of these construct failures are typically attributable to mechanical misloading and overloading during and immediately after surgery. Their consequences are not only evident in the operated segment itself, but also affect the adjacent structures due to spinal imbalances [17−20]. Although it is unclear to what extent degeneration of adjacent segments is the result of progressive preexisting pathology, natural aging, or altered biomechanics after fusion, incidences of 80% at 15 years [6] with an average reoperation rate of 2.5% per year [8,9] are alarming.

Proper alignment and tightening of the pedicle screw/rod assembly is known to be crucial in order to achieve satisfactory results [17,18,21−23]. Ardura et al. [18] have reported on one of their patients who developed a spinal deformity shortly after bisegmental posterior lumbo-sacral instrumented fusion surgery. A detailed analysis of the postoperative radiographs revealed a cranial screw/rod mismatch with asymmetric rod alignment. The authors concluded that this is caused by stress overloading of the implant system with misbalancing, which is released into the surrounding structures, where it manifests as a scoliotic deformity in the form of bending, rotation, and translation of the lumbar spine and readjustment of the rods [18]. To our knowledge, nothing has been reported to date on the incidence of such postoperative screw/rod interface mismatches and how they affect clinical outcomes after posterior instrumentation.

The objective of this study is to investigate the incidence of postoperative screw/rod interfacing angle mismatch after instrumented posterior fusion of the lower spine and to analyze the impact of mismatches on clinical outcome in terms of (1) revision surgery, (2) adjacent segment degeneration (ASD), and (3) pain.

Materials and methods

This retrospective observational clinical study includes all patients from the Spine-Unit of Valladolid University Hospital (Valladolid, Spain) who underwent fusion surgery with pedicle screw/rod systems for predominantly degenerative pathologies between January 2013 and December 2018 and for whom clinically and radiologically complete preoperative, postoperative, and follow-up data are available. Inclusion criteria are listed in Table 1.

Revision includes all subsequent procedures in which all or part of the original implant configuration is changed or

Table 1
Inclusion criteria

Inclusion criteria
• Fusion surgery with pedicle screw/rod system between January 2013 and December 2018
• Clinical data: preoperative, postoperative, and at follow-up; at a minimum, VAS pain measures for each time point and information on revision surgery, if applicable
• Radiographs: preoperative, postoperative, and at follow-up; at a minimum, a/p and lateral spine radiographs for each time point

removed. Radiographic parameters recorded are pedicle screw/rod interfacing angle mismatch (no/yes; mismatch is the angular deviation from 90° formed by the rod axis and the pedicle screw head axis as an indicator for missing form-fit), degree of pedicle screw/rod interfacing angle mismatch (angular deviation from a 90° alignment), and signs of ASD (osteophytes, narrowing of disc space, rotation, translation) at the immediately adjacent cranial segment. These parameters are analyzed for the entire study population and for the diagnostic subgroups of degeneration, deformity, and fracture. The mismatch between the pedicle screw and rod is measured as the angle between two parallel lines on either side of each pedicle screw head and a line laterally along the associated rod (see Figure). Based on validation of radiographs and CTs, angles other than 90°± 0.3° are considered mismatched. Inter- and intraobserver agreement with radiographs was examined by an orthopedic surgeon specializing in the spine and a radiologist specializing in the musculoskeletal system. The Kappa value for the inter-observer agreement was 0.74 (p<.001) and regarding the intraobserver analysis, the Kappa value was 0.83 (p<.001) (BiAS. 11.12, Epsilon Verlag, Hochheim Darmstadt, Germany).

Statistical analyses were performed using IBM SPSS Statistics, version 21. A two-tailed exact Pearson's chi-square test was used to compare proportions, and a *t* test for independent samples to compare means. Multiple comparisons are counteracted by Bonferroni correction. Adjusted significance level is at *p<.01 (0.05/5).

Results

Patient demographics and interventions

Of 1183 cases screened, 406 met the above inclusion criteria. For patients' demographics see Table 2.

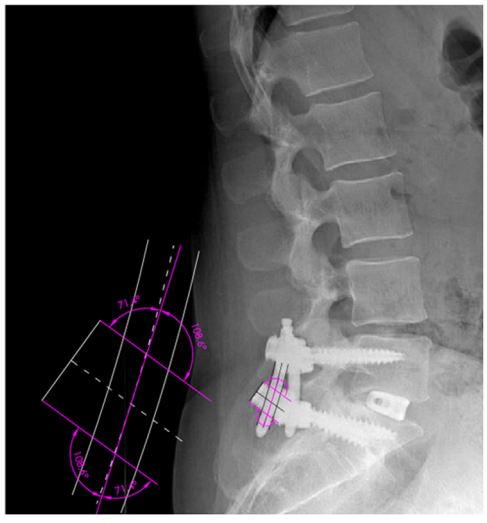

Figure. A/p radiograph showing measurement of pedicle screw head/rod mismatch. Interfacing angle between pedicle screw head and support rod other than 90°±0.3° are considered mismatched.

Table 2
Patient demographics

Total N = 406	Mean (SD) /N (%)*
Age in years	50.4 (10.7)
Preoperative VAS pain	7.2 (0.4)
Gender	
Male	151 (37.2%)
Female	255 (62.8%)
Primary diagnosis	
Degenerative, incl.	259 (63.8%)
– Degenerative disc disease	*119 (29.3%)*
– Stenosis	*102 (25.1%)*
– Degenerative spondylolisthesis	38 (9.4%)
Deformity	44 (10.8%)
Fracture	45 (11.1%)
Failed back surgery	44 (10.8%)
Inflammation	4 (1.0%)
Others	10 (2.5%)
Preoperative ASD	
No	357 (87.9%)
Yes	46 (11.3%)
Number of levels fused	
1	135 (33.3%)
2	120 (29.6%)
3	62 (15.3%)
4	25 (6.2%)
5	9 (2.2%)
6	10 (2.5%)
7	7 (1.7%)
8	13 (3.2%)
9	3 (0.7%)
10	8 (2.0%)
11	5 (1.2%)
12	3 (0.7%)
13	4 (1.0%)
14	2 (0.5%)

* based on total number of patients.

In these patients, a total of 3016 pedicle screws were implanted between T2 and S2. All patients underwent arthrodesis with standard pedicle screw/rod systems including MESA Spinal System (Stryker, Kalamazoo, MI, USA), VIPER (DePuy Synthes, Raynham, MA, USA), and CD Horizon Solera Spinal System (Medtronic, Dublin, Ireland). In addition, in 285/406 (70.2%) of the patients a decompression, in 41/406 (10.1%) a correction or reduction, in 17/406 (4.2%) a kyphoplasty, and in 13/406 (3.2%) another additional procedure such as debridement, cementing, discectomy, corpectomy, or tumor resection was performed. The mean follow-up time was 5 years and ranged from 1 to 7 years (SD 1.1).

Clinical and radiographic outcome

Pedicle screw and rod interfacing angle mismatch was found in 171/406 (42.1%) of patients undergoing fusion surgery, affecting 613/3016 (20.3%) screws. The mean degree of pedicle screw/rod interfacing angle mismatch was 8.7° and ranged from 0.5° to 44.1° (SD 5.0, n=613). The overall revision incidence was 11.8% (48/406), and a

new ASD occurred in 13.8% of all patients (56/406) during postoperative follow-up. Mean VAS pain score at final follow-up was 2.0 and ranged from 0 to 5.0 (SD 1.1), a significant improvement over preoperative mean score.

Comparison of the two groups with and without mismatches revealed statistically significant differences in (1) number of revision procedures performed, (2) signs of newly developed ASD, and (3) pain for the entire study population. Except for test (2) in the deformity group, this is also true for the degeneration, deformity, and fracture subgroups. Table 3 provides the respective distributions.

When comparing patients who underwent intraoperative correction and/or reduction with those who did not, there were statistically significant differences in the presence of pedicle screw/rod interfacing angle mismatch and revision incidence (Table 4).

Discussion

The overall results obtained in the present study for revision rate (11.8%), ASD rate (12.1%), and mean VAS pain score (2.0) are consistent with those reported in the literature [2–5,8,9,24,25]. With an incidence of 42.1%, pedicle screw/rod interfacing angle mismatch is a frequent occurrence after fusion surgery. Mismatch, which is the angular deviation from 90° formed by the rod axis and the pedicle screw head axis, indicates that it was impossible to obtain a secure form-fit between the pedicle screw head and the rod. The use of torque limiters is intended to ensure that the set screws are tightened securely and that the rod is brought into the desired mechanically ideal 90° form-fit position. Rod insertion and final tightening under constraint, however, can prevent this.

The mechanical tests performed by Ardura et al. [18] show that for conventional set screws, proper tightening of the set screw is impossible when the rod is inserted into the pedicle screw head at an angle of 5° and with a preload of 7.5 Nm. A mismatch between pedicle screw and rod occurred in 75% of the cases. Other authors [26] found that a deviation of 15° from the desired perpendicular alignment between the rod and the screw leads to a significantly reduced pull-out stiffness of the pedicle screw. In clinical practice, it is common to reduce residual mismatches between pedicle screws and rods with specific reduction devices, so-called rod persuaders. By forcing the rod into the pedicle screw head, the rod becomes constrained and inadvertently blocks the polyaxiality of the screw head, placing the entire construct under uncontrolled stress. The consequences of such forceful reductions were investigated in a cadaver model by Paik et al. [27] who analyzed the

Table 3
Clinical and radiographic outcome by pedicle screw and rod interfacing angle mismatch

Outcome	Population	Without mismatch N=235 Mean (SD)/N (Column %)†	With mismatch N=171 Mean (SD) /N (Column %)†	Statistical test p-value
Revision procedure	All diagnosis			<.001*
	No	233 (99.1%)	125 (73.1%)	
	Yes	2 (0.9%)	46 (26.9%)	
	Degeneration			<.001*
	No	164 (98.8%)	79 (84.9%)	
	Yes	2 (1.2%)	14 (15.1%)	
	Deformity			.008*
	No	15 (100%)	18 (62.1%)	
	Yes	0 (0%)	11 (37.9%)	
	Fracture			.002*
	No	25 (100%)	13 (65%)	
	Yes	0 (0%)	7 (35%)	
ASD, newly developed	All diagnosis			<.001*
	No	226 (96.2%)	124 (72.5%)	
	Yes	9 (3.8%)	47 (27.5%)	
	Degeneration			<.001*
	No	160 (96.4%)	63 (67.7%)	
	Yes	6 (3.6%)	30 (32.3%)	
	Deformity			.149
	No	15 (100%)	24 (82.8%)	
	Yes	0 (0%)	5 (17.2%)	
	Fracture			.001*
	No	25 (100%)	12 (60%)	
	Yes	0 (0%)	8 (40%)	
VAS at final FU	All diagnosis	1.4 (0.8)	2.8 (0.8)	<.001*
	Degeneration	1.4 (0.9)	2.7 (0.8)	<.001*
	Deformity	1.6 (0.6)	2.9 (0.8)	<.001*
	Fracture	1.2 (0.6)	3.0 (0.8)	<.001*

* Statistical significance (p<.01).
† based on total number of patients per group.

Table 4
Pedicle screw and rod interfacing angle mismatch and revision by intraoperative correction/ reduction procedure

Outcome	Without correction/reduction N=365 N (Column %)†	With correction/reduction N=41 N (Column %)†	Statistical test p-value
Mismatch			.004*
No	220 (60.3%)	15 (36.6%)	
Yes	145 (39.7%)	26 (63.4%)	
Revision procedure			.001*
No	329 (90.1%)	29 (70.7%)	
Yes	36 (9.9%)	12 (29.3%)	

* Statistical significance (p<.01).
† based on total number of patients.

effect of reducing a 5mm rod/screw gap. The results showed a weakening of the pedicle screw strength by 48% in normal and osteoporotic bone, resulting in 47% of screws showing visible pull-out movement. The work energy to failure decreased significantly as a result of the reduction performed [27]. Other authors [28] confirmed significantly reduced pullout forces due to the reduction of misalignment in the setting of Ponte osteotomies. Loenen et al. [17] used finite element analysis to investigate the loads and deformations of a 6mm coronal and sagittal mismatch reduction on the instrumentation and adjacent structures, as well as their biomechanical consequences during physiologic flexion motion after L4–S1 fusion. The authors found excessive reduction forces (0.7–1.0 kN) resulting in screw pullout, affecting the alignment of the entire lumbar spine by substantially rotated lumbar vertebrae, which in turn leads to increased asymmetric pressure in the facet joints and raises the risk of ASD [17].

Mechanical stress acting on the implant construct and the adjacent spine may be indicated to the extent necessary in cases requiring greater correction or reduction due to scoliotic deformity, trauma, or spondylolisthesis. In all other cases, however, instrumentation is needed only for stabilization and not for correction. The present results may indicate that both the interfacing angle mismatch rate and the revision rate are higher when intraoperative forced maneuvers such as corrections or reductions are performed (Table 4). Whenever possible, forced assembly of the construct should be avoided in principle as this is known to result in mechanical mis- and overloading of the instrumentation, possibly leading to pedicle screw pull-out with or without signs of loosening [17,22,27], screw or rod breakage, disassembly of the construct including set screw loosening [18,29], cold welding of the pedicle- and set screw [18], pseudarthrosis, loss of correction, misalignment [17], and any signs of degeneration at adjacent levels [17], summarized as ASD and pain [17,22]. Sawa et al. [30] have demonstrated in vitro significant prestrains on instrumentation induced when attaching apparently well-contoured rods to the pedicle screws. The study results show an association between the presence of pedicle screw/rod interfacing angle mismatch as an indicator of mechanical stress on the implant construct during fixation of the rod to the pedicle screw heads and poorer clinical outcomes in terms of revision surgery, ASD, or pain for all diagnostic subgroups investigated. This supports the universal meaning of the relationship, regardless of the diagnosis. However, the degree of the pedicle screw/rod interfacing angle mismatch is not directly related to the amount of stress in the system. In fact, the latter depends on the extend of the gap or angulation between the polyaxial screw head and the rod before tightening. The larger the gap or angulation, the higher the forces required for complete reduction and consequently the higher the induced stress. The degree of the remaining interfacing angle mismatch after final tightening, however, results from the ratio of the mismatch before tightening and the applied force during reduction.

Unique, adequate screw placement in terms of position, angle, and depth, as well as rod bending that considers individual sagittal, axial, and coronal balance, are essential to achieve the least stressful instrumentation possible. Unintentional uncontrolled forces on the instrumentation should be avoided as far as possible. In particular, distraction that attaches to the pedicle screws has a significant negative impact on the bone/screw interface [21,31,32]. When necessary, screw reinsertion appears to be biomechanically superior to rod reduction [27], cantilever bending is superior to in situ bending [33], and technologies providing a more precise rod bending are preferable over manual bending [23,34].

Numerous biomechanical studies have investigated associations between intraoperative mismatch of pedicle screws and rods and their connection under constraint [17,18,26–28]. The results indicate potential adverse effects in terms of implant failure and/or spinal imbalance, which may lead to revision surgery, ASD and pain. To our knowledge, the present study is the first to investigate these conclusions clinically. Nevertheless, the study also has its limitations. These include the retrospective design with varying follow-up periods and the heterogeneous study population, which includes thoracic, thoracolumbar, and lumbosacral stabilization and various indications requiring different surgical techniques. On the other hand, the surgical step of inserting the rod and then tightening the pedicle screw/rod interface does not differ by pathology

or treated level. An association between postoperative pedicle screw/rod interfacing angle mismatch and increased risk of revision could be demonstrated for all main diagnoses. Moreover, the relatively high number of cases and the patient population reflecting the reality of a university spine center are worth mentioning. The study design is not suitable to rule out that factors such as intraoperative bone resection, the extent of reduction performed, or sagittal imbalance also have an influence on the outcome. Prospective controlled clinical studies and radiographic in-depth analyses are needed to further investigate the clinical outcome of enforcing fixation and the biomechanical factors behind it.

Conclusion

Pedicle screw/rod interfacing angle mismatch, defined as any deviation from 90° formed by the axes between the rod and the pedicle screw head, is a frequent occurrence after fusion surgery. Mismatches indicate that the construct was assembled under mechanical stress, which can be associated with a higher risk of revision surgery, more frequent ASD, and more severe postoperative pain. Mechanical stress cannot always be completely prevented but attention should be paid to avoidable stress. This includes unintentional uncontrolled forces on the instrumentation. Unique, adequate screw placement as well as rod bending that considers the patient's individual balance, are essential to achieve the least stressful instrumentation possible.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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