

Effect of Severity of Rod Contour on Posterior Rod Failure in the Setting of Lumbar Pedicle Subtraction Osteotomy (PSO): A Biomechanical Study

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BACKGROUND: Rod failure has been reported clinically in pedicle subtraction osteotomy (PSO) to correct flat back deformity.

OBJECTIVE: To characterize the fatigue life of posterior screw-rod constructs in the setting of PSO as a function of the severity of rod contour angle.

METHODS: A modified ASTM F1717 to 04 was used. Rods were contoured to the appropriate angle for the equivalent 20-, 40-, or 60-degree PSO angles. Testing was performed on a mechanical test frame at 400/40 N and 250/25 N, and specimens were cycled at 4 Hz to failure or run-out at 2 000 000 cycles. The effect of the screw-rod system on fatigue strength of curved rods was compared using Cox proportional hazards regression.

RESULTS: At 400 N/40 N, Cox proportional hazards regression indicated that contouring rods from a 20-degree PSO angle to either 40 or 60 degrees significantly decreased fatigue life (hazard ratio = 7863.6, $P = .0144$). However, contouring rods from a 40-degree PSO angle to 60 degrees had no significant effect on the fatigue life ($P > .05$). At 250 N/25 N, Cox proportional hazards regression indicated that contouring rods from a 20-degree PSO angle to either 40 or 60 degrees significantly decreased fatigue life (hazard ratio = 7863.6, $P = .0144$). Furthermore, contouring rods from a 40-degree PSO angle to 60 degrees had a significant effect on the fatigue life (hazard ratio = 7863.6, $P = .0144$).

CONCLUSION: Results suggest that in the setting of PSO, the fatigue life of posterior spinal fixation rods depends largely on the severity of the rod angle used to maintain the vertebral angle created by the PSO and is significantly lowered by rod contouring.

KEY WORDS: Fatigue life, Pedicle subtraction osteotomy, Rod contour, Rod failure, Spine biomechanics

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Pedicle subtraction osteotomy (PSO) is a powerful technique to restore lordosis in the thoracic, lumbar, and, more recently, cervical spine. The procedure involves removal of the posterior elements and performing a posterior-based, wedge-shaped closing osteotomy in the anterior and middle columns.¹⁻³ The osteotomy surfaces are then compressed via a posterior screw-rod construct, thereby increasing the lordosis. The PSO works by shortening the posterior and middle columns, hinging on the anterior column. Because corrections as great as 30 to 40 degrees can be achieved with this

technique,^{1,4-7} contouring of the fusion rods can be quite extreme in PSO constructs. Rod failure during both the early and late postoperative period has been reported clinically and is thought to be associated with fatigue loading at the hyperacute bend in the early period and possibly pseudarthrosis in those patients who present at more than 1-year follow-up,^{1,7-9} although this study attempts to make no claim on the specific etiology. The mobility of the lumbar spine and its increased weight-bearing capabilities (compared with the thoracic spine, which is supported by the rib cage) have been suggested as potential factors that contribute to the likelihood of rod fractures in this region.^{1,7} In fact, instrumentation failure after PSO occurs

ABBREVIATIONS: CoCr, cobalt-chromium; PSO, pedicle subtraction osteotomy; Ti, titanium

frequently enough that several studies have reported and investigated revision strategies.¹⁰⁻¹²

A recent report from Smith et al¹³ provided assessment of symptomatic rod fracture rates after posterior instrumented fusion for adult spinal deformity. Of 442 patients, the overall rate of symptomatic rod fracture was 6.8%. Among patients with corrective surgery that included a PSO, the rate of symptomatic rod fracture was 15.8%. The majority of rod fractures that occurred in patients with a PSO occurred early (mean of 10 months), and the vast majority (89%) occurred at or adjacent to the level of the PSO. These findings suggest that stress at the PSO site may result in biomechanical vulnerability of the rods, resulting in increased fracture rates that typically require substantial revision surgery. Improved understanding of factors related to rod fracture could be valuable for improved implant design, surgical planning, and patient care.

Previous works have considered the effects of rod contouring on construct stiffness, but these studies focused largely on rod bending in kyphotic^{14,15} or scoliotic¹⁶ models. Nevertheless, all of these models exhibited a decrease in construct stiffness because of rod contouring. Orchowksi et al¹⁵ noted a one-third decrease in construct stiffness progressing from straight rod alignment to 27 degrees in kyphosis, and a 59% decrease for rods bent to 53 degrees in kyphosis. In a study done by Johnston et al,¹⁶ even a minimal 16-degree coronal bend of the rod proved vulnerable to mechanical stresses induced by body weight. Aside from stiffness, strain has also been observed to increase significantly in rods bent to kyphosis under physiological loading.¹⁴

Although the mechanical properties of sagittal rod contouring have not been examined in detail, this general concept of the instability introduced by a bend in the rod can be highlighted by Euler's equation for curved column loading.¹⁷ Contoured rods behave like bent columns that cannot resist loads and stresses to the same degree as straight columns. Because the PSO procedure can introduce vertebral wedge angles to as great as 40 degrees, the severity of the rod angle is undoubtedly a factor to consider that may contribute to the rate of rod fracture subsequently observed in the clinical scenario. To date, there have been no controlled studies to investigate the effect of the severity of sagittal rod contouring on the fatigue life of the PSO construct.

The purpose of this study was to characterize the fatigue life of posterior screw-rod constructs in the setting of PSO as a function of the severity of the rod contour angle via a biomechanical approach. A model of rod fatigue failure in the setting of a PSO is first developed and validated, and the fatigue life of high-, average-, and low-contour angle constructs is then biomechanically tested. The results of this study will have important implications in clinical practice because they may be useful in determining a threshold contour angle beyond which alternative fusion strategies (eg, double rod constructs, selection of larger diameter, different alloys) may be used to mitigate the risk of fatigue failure.

MATERIALS AND METHODS

Posterior Rod Angles

In the absence of data from the literature, a preliminary study was conducted to determine the range of possible rod angles for lumbar PSO. Nine patients from the Principal Investigator's practice were selected at random, and their radiographic records were pulled and blinded. All patients underwent PSO at L2 or L3 and eventually experienced uni- or bilateral rod failure near the site of the PSO (Figure 1). Rod angles



FIGURE 1. Bilateral fusion rod failure in the setting of a pedicle subtraction osteotomy. Images taken from the Principal Investigator's clinical practice.

were measured with standard commercial software (OsiriX v3.3) on standing lateral radiographs immediately after the initial surgery. Repeated measurements (3 measurements) were taken on each film by a single reviewer to ensure accuracy. Postfracture x-rays were also examined, and the location of failure was noted for future use in biomechanical test validation. Data from this preliminary analysis are presented in Table 1.

Rod angles selected for biomechanical testing corresponded to PSO angles of 20, 40, and 60 degrees. These angles represent a minimal extreme, average, and maximal extreme of the distribution observed in preliminary testing.

Biomechanical Testing

A modified version of ASTM F1717-04 was used for fatigue testing of the specimens. Because failures were observed in the clinical setting ± 1 level from the PSO, this model incorporates ± 2 levels. French benders were used to contour rods (5.5-mm cobalt-chromium [CoCr] rods) as would be done in the operating room, and special care was taken not to bend the rods too acutely in any one spot. Rods were contoured to the appropriate angle for the equivalent PSO angles, namely, 20, 40, or 60 degrees, and pedicle screws (6.5 x 45 mm, titanium [Ti] 6Al-4V) were inserted into polyethylene test blocks. The rod angle was measured as the angle between the most distal aspects of the rod following contour that would correspond to the posterior vertebral body wall in the clinical setting. Rods were secured to the screw heads at the manufacturer-recommended torque ratings. A linear spring element was inserted between the polyethylene blocks at the level of the PSO to simulate

compliance of unfused bone and adjacent discs. Axial loading was applied collinearly with the spring element, creating a compression-bending loading state on the posterior fusion construct. A schematic of the test setup is shown in Figure 2.

Testing was performed on a mechanical test frame with an in-line load cell (Instron 8521). The specimens were cycled at a load ratio (R = max/min) equal to 10 at a frequency of 4 Hz to failure or until run-out at 2 000 000 cycles. Testing was conducted at 2 load levels,^{18,19} beginning at 400 N/40 N and a second load level to be determined

TABLE 1. Results From Preliminary Testing to Determine Appropriate Rod Angles for Biomechanical Study^a

PSO Level	PSO Angle, Degrees	Observed Failure
1 L3	55 \pm 7	Unilateral rod failure at the level of the PSO, adjacent to the screw
2 L2	30 \pm 4	Bilateral rod failure at the level of the PSO, adjacent to crosslink
3 L2	36 \pm 2	Bilateral rod failure 2 levels inferior to the PSO, adjacent to the screw heads
4 L3	43 \pm 3	Unilateral rod failure at the level of the PSO, adjacent to the screw head
5 L3	43 \pm 5	Unilateral rod failure at the level of the PSO, within the rod span
6 L3	36 \pm 3	Unilateral rod failure at the level of the PSO, within the rod span
7 L3	26 \pm 4	Unilateral rod failure at the level of the PSO, within the rod span; rod was curved in the frontal plane to accommodate lumbar scoliosis
8 L2	32 \pm 2	Bilateral rod failure at the level of the PSO; 1 rod mid-span (longer span), 1 adjacent to the screw head
9 L3	39 \pm 2	Unilateral rod failure at the level of the PSO, adjacent to the screw head

^aPSO, pedicle subtraction osteotomy.

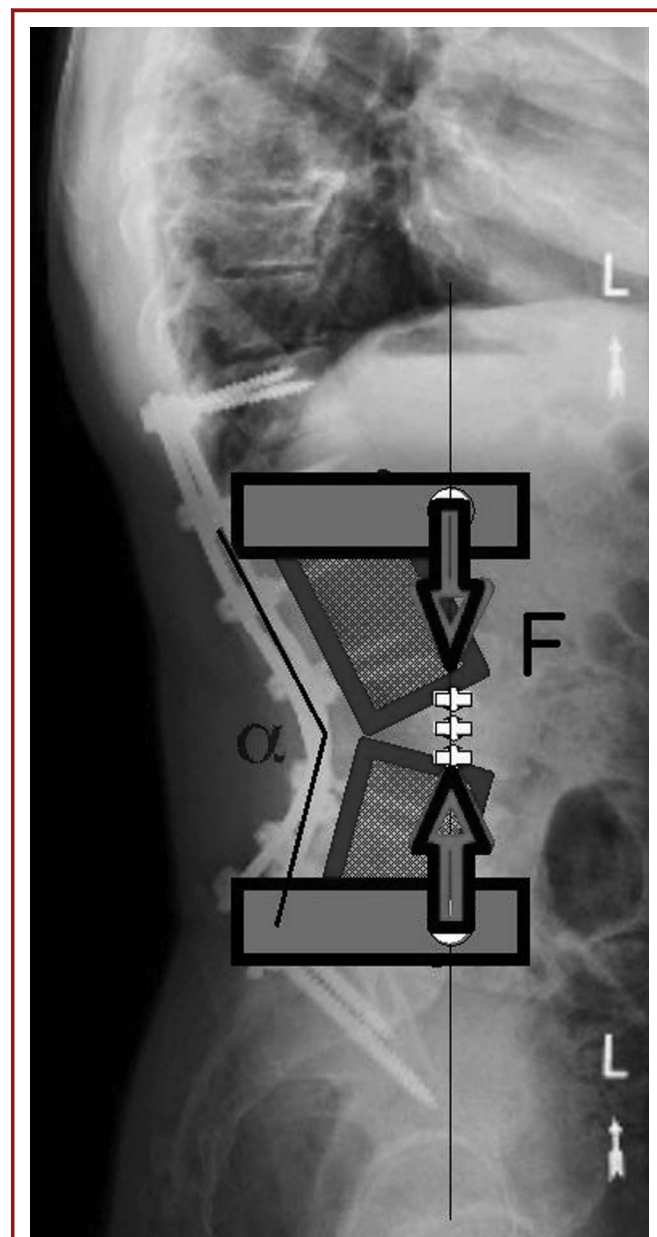


FIGURE 2. Schematic of the biomechanical test setup overlaid on a pedicle subtraction osteotomy patient's x-ray.

by the outcome of the 400 N/40 N test. If failures were observed before run out—the desired outcome—testing will be conducted at 250 N/25 N. However, if specimens reached run-out, loading was increased to 700 N/70 N. Three specimens were tested for each construct type at every load level, for a total of 18 test specimens (3 repeats \times 2 load levels \times 3 rod angles).

Outcome Measures

Outcome measures from testing included cycles to failure and location of failure. The effect of the screw-rod system on fatigue strength of curved rods was compared using Cox proportional hazards regression, and the level of significance was set at $P < .05$.

Biomechanical Test Validation

This study represents the first attempt to simulate fusion rod failure in the setting of a PSO, and, as such, the model was fully validated before running the final study. The objective of the test validation phase of the study was to recreate the clinical failure patterns observed from preliminary analysis of the Principal Investigator's patient population (Table 1), namely, unilateral or bilateral rod failure at the level of the PSO. The proposed biomechanical model (Figure 3) was created,

and 2 preliminary tests were conducted at 400 N/40 N load level until failure. The validation process was iterative until 2 sequential preliminary test specimens demonstrated rod failure at the level of the PSO.

RESULTS

Table 2 summarizes the results for the biomechanical fatigue testing.

20-Degree PSO Angle Specimens

All 3 specimens failed at the first load level of 400 N/40 N and were subsequently tested at the lower load level of 250 N/25 N. For the first 400 N/40 N load level, specimens with the least extreme PSO angle of 20 degrees failed at approximately 100.0 K, 93.0 K, and 89.3 K cycles. For all 3 specimens, rod fracture occurred unilaterally at the level of the PSO with the contralateral rod displaying cracks midway through the rod diameter (Figure 4).

At the second 250 N/25 N load level, all 3 specimens reached run-out at 2 000 000 cycles with no evidence of failure.

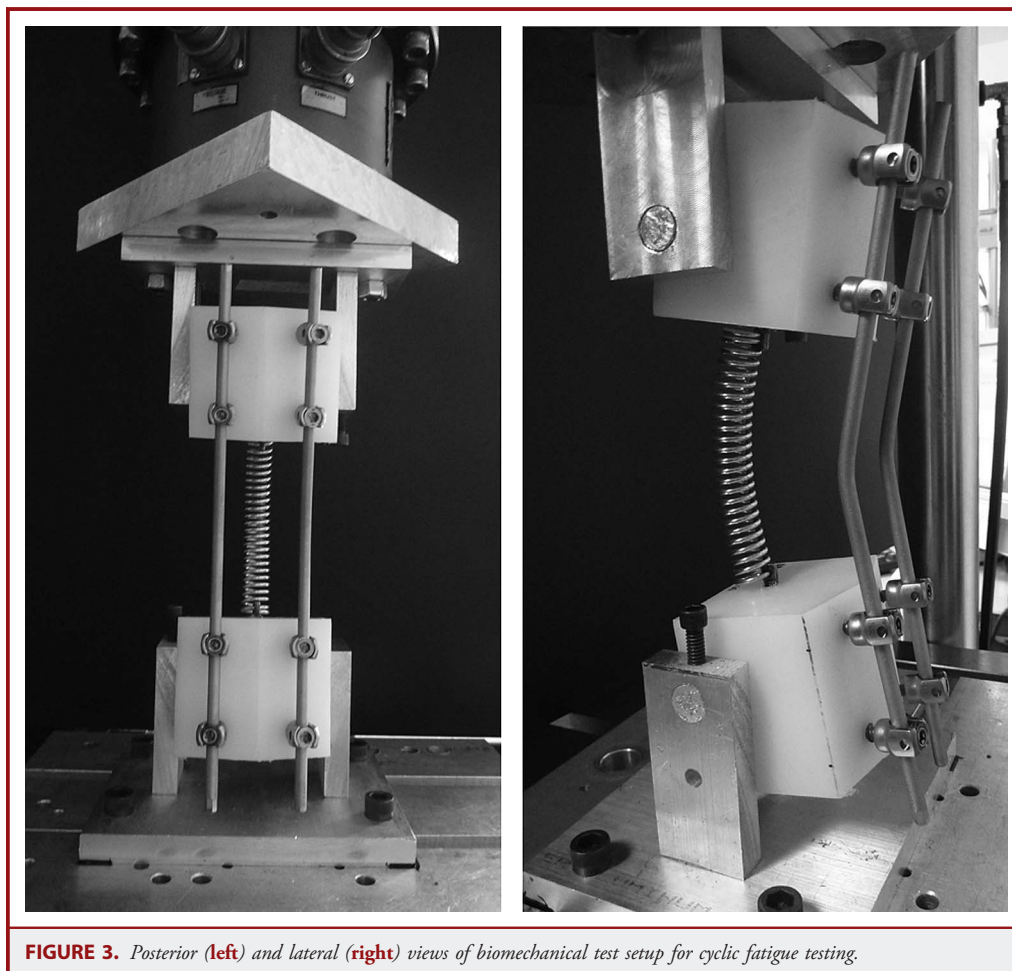


FIGURE 3. Posterior (left) and lateral (right) views of biomechanical test setup for cyclic fatigue testing.

TABLE 2. Summary of Results for Fatigue Testing^a

Specimen	PSO Angle, Degrees	Load Ratio, N	Cycles to Failure
1	20	400/40	100 010
2	20	400/40	89 310
3	20	400/40	93 009
4	40	400/40	62 163
5	40	400/40	48 257
6	40	400/40	43 957
7	60	400/40	59 067
8	60	400/40	62 538
9	60	400/40	59 112
10	20	250/25	2 000 000 ^b
11	20	250/25	2 000 000 ^b
12	20	250/25	2 000 000 ^b
13	40	250/25	874 374
14	40	250/25	580 391
15	40	250/25	671 264
16	60	250/25	225 368
17	60	250/25	294 108
18	60	250/25	398 270

^aPSO, pedicle subtraction osteotomy.

^bDenotes end of cycles with no failure observed.

40-Degree PSO Angle Specimens

All 3 specimens failed at the first load level of 400 N/40 N and were subsequently tested at the lower load level of 250 N/25 N. For the first 400 N/40 N load level, specimens with the average PSO angle of 40 degrees failed at approximately 62.2 K, 48.3 K, and 44.0 K cycles. For all 3 specimens, rod fracture occurred unilaterally at the level of the PSO with the contralateral rod displaying cracks midway through the rod diameter.

At the second 250 N/25 N load level, these specimens failed at approximately 580.4 K, 671.2 K, and 874.4 K cycles.

60-Degree PSO Angle Specimens

All 3 specimens failed at the first load level of 400 N/40 N and were subsequently tested at the lower load level 250 N/25 N. For the first 400 N/40 N load level, specimens with the most extreme PSO angles of 60 degrees failed at approximately 59 K, 59.1 K, and 62.5 K cycles. For all 3 specimens, rod fracture occurred unilaterally at the level of the PSO with the contralateral rod displaying cracks midway through the rod diameter. These cracks were noted as propagating fracture lines that did not extend completely across the rod diameter.

At the second 250 N/25 N load level, these specimens failed at approximately 225.4 K, 294.1 K, and 398.3 K cycles.

Cox Proportional Hazards Regression

Results of the statistical tests are presented graphically in Figure 5.

At the 400 N/40 N load level, the Cox proportional hazards regression indicated that contouring rods from a PSO angle of 20 degrees to either 40 or 60 degrees significantly decreased the fatigue life of the screw-rod construct (hazard ratio [HR] = 7863.6, $P = .0144$). However, contouring rods from a PSO angle of 40 to 60 degrees had no significant effect on the fatigue life of the screw-rod construct ($P > .05$).

At the 250 N/25 N load level, the Cox proportional hazards regression indicated that contouring rods from a PSO angle of 20 degrees to either 40 or 60 degrees significantly decreased fatigue life of the screw-rod construct (HR = 7863.6, $P = .0144$). Furthermore, contouring rods from a PSO angle of 40 to

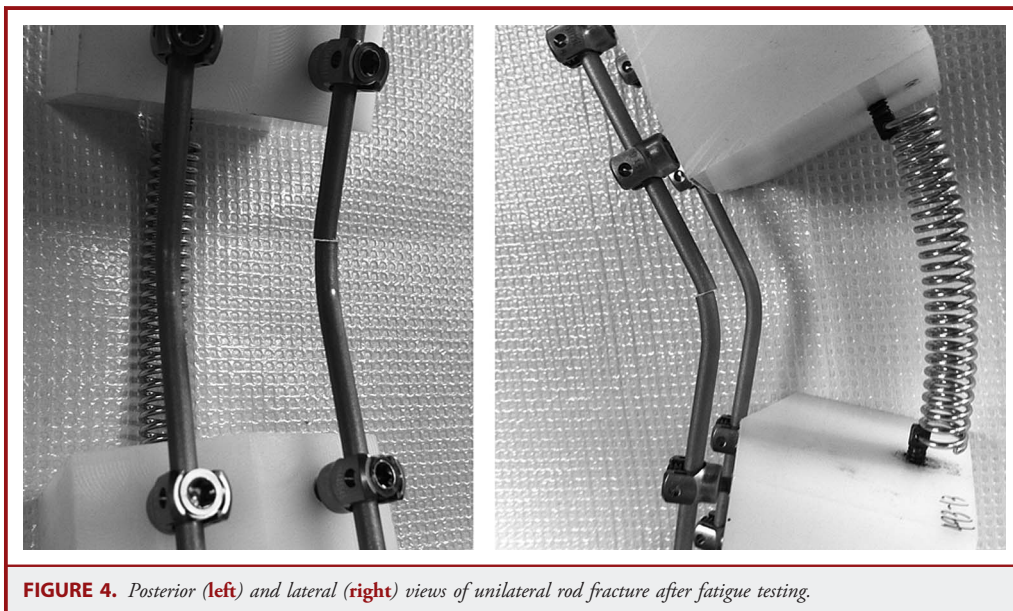
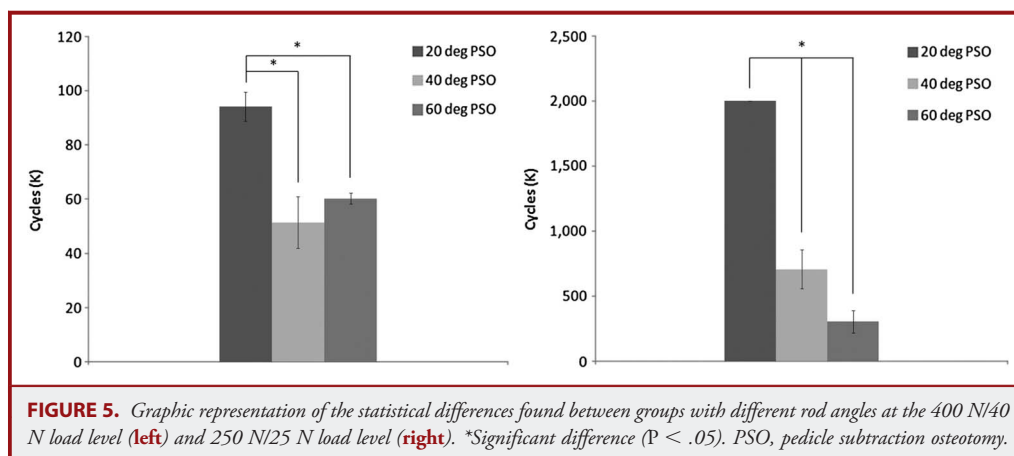


FIGURE 4. Posterior (left) and lateral (right) views of unilateral rod fracture after fatigue testing.



60 degrees had a significant effect on the fatigue life of the screw-rod construct (HR = 7863.6, $P = .0144$).

DISCUSSION

The results of this study support the intuitive concept that rods contoured to more severe angles have a greater probability of failure. In more technical terms, the fatigue life of posterior spinal fixation rods in the setting of PSO depends largely on the severity of the rod angle used to maintain the vertebral angle created by the PSO. Specifically, an increase in severity of the rod angle to correct PSO angles from 20 to 60 degrees significantly decreased fatigue performance. This difference was more distinct at the lower load level of 250 N/25 N.

There is plentiful evidence in the literature^{14-16,18-21} to support the results of this study that suggest that contouring rods for posterior spinal fixation constructs significantly lowers the fatigue life of the rods and weakens the entire construct. Studies that have examined the fatigue life of posterior spinal rods have evaluated a myriad of factors that contribute to construct failure including rod material, notch sensitivity, and rod curvature. It has already been well established that CoCr and Ti have a greater fatigue life than stainless steel,^{19,21} that Ti is extremely notch sensitive,^{19,20} and that inducing bends in the rods of the same material lowers their performance.^{14-16,18} In addition, failure occurred at the site of the bend for contoured rods but at the screw head for straight rods.^{18,21} In terms of metallic properties of CoCr, Ti, and stainless steel, CoCr is the most dense, has the greatest elastic modulus, and displays the greatest ultimate stress of the 3 metals.^{18,19,22} This study is unique in that it uses CoCr, an already established non-notch-sensitive material with a relatively high fatigue life, and compares the fatigue life of these CoCr rods contoured to a range of angles. It would be interesting to conduct future studies comparing the fatigue life of 6.0- and 6.5-mm CoCr rods with the 5.5-mm rod used in the current study.

The strengths of this study lie in its ability to replicate the clinical scenario in which failure has been observed. Indeed, all failures

were rod fractures that occurred at the level of the PSO where the most extreme bend was induced. This is the first study to examine a PSO construct using a modified version of the ASTM F1717-01. Preliminary testing validated the modified model, which accommodated the variations in rod angles and preserved the moment arms at the fulcrum of the PSO across different PSO angles. Implant characteristics were controlled for in that all constructs used in each scenario used 5.5-mm CoCr rods with 6.5 × 45-mm Ti pedicle screws. Three repeat trials were also used for each loading condition to eliminate data variability possibly induced by subtle differences inherent in manual rod contouring.

Criticism of this study is unavoidable as with any in vitro biomechanical testing due to the inability to completely simulate physiological conditions without muscles and soft tissue that undeniably contribute to construct rigidity and the stability of the bone-implant interface. However, the standardization of implants and polyethylene block models across all configurations ensures that any differences would be relative, which this study aims to elucidate. Furthermore, only 2 load levels were monitored, which may not illuminate a full spectrum of the characteristic fatigue life and whether a linear or nonlinear relationship exists between rod contour angle and fatigue life. Nevertheless, the 2 load levels simulate walking at 400 N and lying prone at 250 N,^{23,24} both of which are relevant physiological loading expected during postoperative recovery.

Another limitation is that we did not explore the effect of the rod diameter on the rod breakage. Rods thicker than 5.5 mm are routinely used, including 6.0- and 6.35-mm rods. Also, some of the newer strategies to avoid rod breakage, such as tripling or quadrupling the rods across the osteotomy site, might mitigate the incidence of rod fracture.

PSO is an extremely powerful technique by which the upper part of the axial skeleton is disconnected from the lower part, and very significant deformity correction is feasible. The drawback of the technique is that extreme stresses are being placed on the hardware bridging the osteotomy site, and hardware failure is seen at very high rates, unlike anywhere else in the spine. Thus, detailed knowledge of the effect of contouring on rod breakage is of paramount importance.

CONCLUSION

Contouring rods for posterior spinal fixation constructs significantly lowers the fatigue life of the rods and weakens the entire construct. Therefore, the severity of the coronal bends placed on rods for PSO procedures should be taken into consideration to avoid rod failure and the need for subsequent revision. Because severe vertebral wedge angles are often necessary for correcting lumbar sagittal deformity and these angles result in significant rod failure rates beyond 20 degrees of bend in 3-column osteotomies, new techniques and strategies should be evaluated to address this problem. Currently, we use 4-rod strategies on our lumbar osteotomy patients. It is possible that improved alloys with improved fatigue failure properties may decrease the need for supplementary rods. Future studies may compare the prevalence of rod failures between rods that are manufactured at specific angles and rods that are manufactured straight and then bent with French benders. With the first option, annealing the rods at predetermined angles may relieve internal stresses that would otherwise be present in manually bent rods. Questions remain regarding the optimal number of rods to stabilize an osteotomy site, the most appropriate rod diameter for a certain amount of surgical correction, and whether including a connector would be beneficial in distributing the stress at the region of maximal rod contouring.

Disclosures

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COMMENT

The authors present a biomechanical study evaluating the fatigue life of a rod in the setting of the pedicle subtraction osteotomy as a function of the rod contour angle in the sagittal plane. Using increasing PSO angles (20, 40, and 60 degrees) and 2 different load ratios, the authors cycled the rods to failure or to 2 million cycles. The fatigue strength of the various rods was then studied, with the data revealing a significant decrease in fatigue life when contouring a rod beyond 20 degrees. The authors' data confirm the intuitive conclusion that the fatigue life of a rod correlates directly with the forces to which the rod is exposed and the vertebral body angle created by the PSO.

The authors are to be congratulated on developing an acceptable biomechanical study to evaluate this concept. The basis of their biomechanical study was to mimic the clinical observations made in their experience with

patients who have undergone PSOs. The validation of their proposed study is sound in its reasoning and methodology, the data satisfactory from which to draw meaningful conclusions. Although the results of this study are congruent with the instinctive conclusion that many of us would draw from our own clinical observations, this study provides the empirical evidence for this conclusion. These data further our understanding of the implication of forces and angulation on a rod in the setting of a PSO and provide a basis to take corrective measures. The authors mention in their conclusion that they

use a 4-rod construct in their lumbar PSO patients. It would be interesting to review the data of such a construct with their current biomechanical model. The second suggestion regarding rods manufactured at specific angle instead of bending straight rods appears yet another topic ripe for evaluation with the authors' biomechanical model.

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