Spine Deformity
www.spine-deformity.org

Spine Deformity 4 (2016) 3–9

Biomechanics

Preventing Instrumentation Failure in Three-Column Spinal Osteotomy: Biomechanical Analysis of Rod Configuration

Zachary S. Jager, MD, Serkan İnceoğlu, PhD, Daniel Palmer, BS, Yusuf T. Akpolat, MD, Wayne K. Cheng, MD*

Department of Orthopaedic Surgery, Loma Linda University, School of Medicine, 11406 Loma Linda Dr, Suite 213, Loma Linda, CA 92354, USA

Received 7 January 2015; revised 27 May 2015; accepted 9 June 2015

Abstract

Study Design: Biomechanical analysis.
Objectives: To show the role of additional rods and long-term fatigue strength to prevent the instrumentation failure on three-column osteotomies.
Summary of Background Data: Three-column osteotomy such as pedicle subtraction osteotomy (PSO) and vertebral column resections are surgical correction options for fixed spinal deformity. Posterior fixation for the PSO involves pedicle screw—and rod-based instrumentation, with the rods being contoured to accommodate the accentuated lordosis. Pseudarthrosis and instrumentation failure are known complications of PSO.
Methods: Unilateral pedicle screw and rod constructs were mounted in ultra-high-molecular-weight polyethylene blocks using a vertebrectomy model with the rods contoured to simulate posterior fixation of a PSO. Each construct was cycled under a 200 N load at 5 Hz in simulated flexion and extension to rod failure. Three configurations ($n = 5$) of titanium alloy rods were tested: single rod (control), double rod, and bridging rod. Outcomes were total cycles to failure and location of rod failure.
Results: Double-rod and bridging-rod constructs had a significantly higher number of cycles to failure compared with the single-rod construct ($p < .05$). Single-rod constructs failed at or near the rod bend apex, whereas the majority of double-rod and bridging-rod constructs failed at the screw—rod or rod—connector junction.
Conclusions: Double-rod and bridging-rod constructs are more resistant to fatigue failure compared with single-rod constructs in PSO instrumentation and could be considered to mitigate the risk of instrumentation failure.

Keywords: Sagittal imbalance; Pedicle subtraction osteotomy; Spinal rod failure; Double rod; Bridging rod

Introduction

Fixed sagittal imbalance of the spine is a disabling condition resulting from lumbar degenerative kyphosis [1,2] or failure of prior lumbar surgeries [3-5]. Classically, it is described as "flatback syndrome." Patients typically exhibit painful loss of lumbar lordosis, forward inclination of the trunk, and inability to stand erect with the knees extended [5,6].

One of the surgical correction options for this deformity is pedicle subtraction osteotomy (PSO). PSO involves a posteriorly based three-column closing wedge osteotomy in the lumbar spine [2,7]. PSO can typically provide an approximately 30 to 35 degree increase in lumbar lordosis [3-5,8,9], which translates into correction of sagittal balance and more upright posture. Posterior fixation for PSO involves pedicle screw—and rod-based instrumentation [4,5,7], with the rods being contoured to accommodate the accentuated lordosis. Pseudarthrosis and instrumentation failure are known complications of PSO [2-4,10-16]. It has been reported that moderate [17] and excessive [18] lordotic contouring may predispose the rod to reduced stiffness and poor fatigue performance (Fig. 1).

Author disclosures: ZSJ (none); Sİ (none); DP (none); YTA (none); WKC (none).

*Corresponding author. Department of Orthopaedic Surgery, Loma Linda University, School of Medicine, 11406 Loma Linda Dr, Suite 213, Loma Linda, CA 92354, USA. Tel.: (909) 558-6444; fax: (909) 558-6118.
E-mail address: md4spine@yahoo.com (W.K. Cheng).

2212-134X/$ - see front matter © 2016 Scoliosis Research Society.
http://dx.doi.org/10.1016/j.jspd.2015.06.005

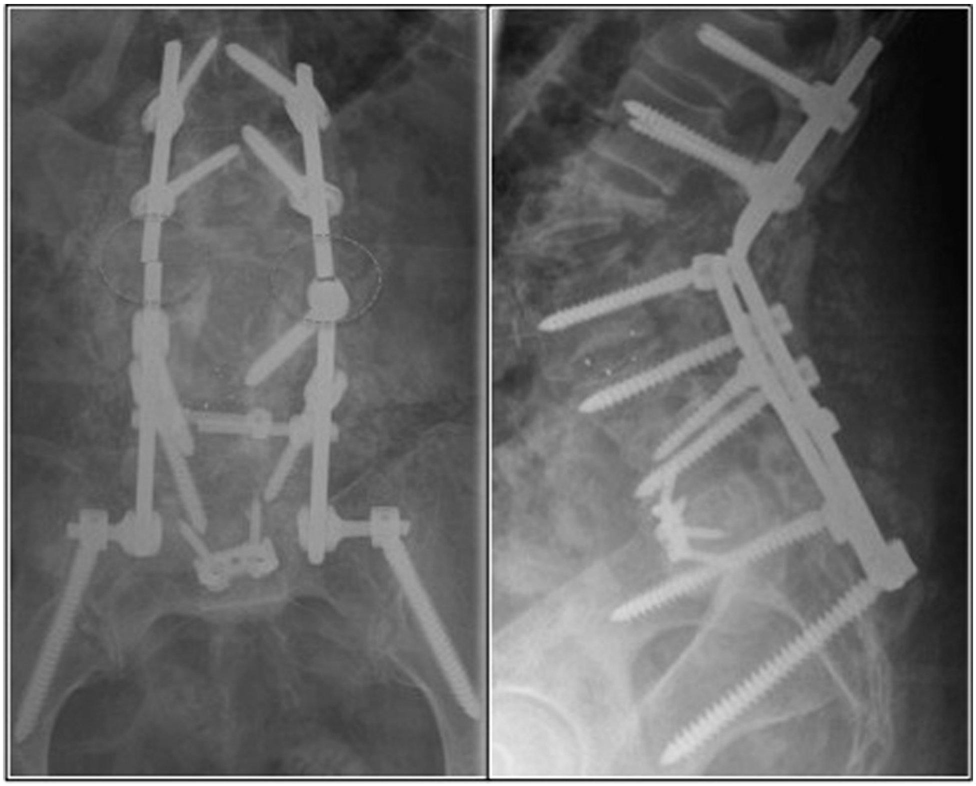

Fig. 1. X-ray image of a broken single-rod construct, AP (left) and lateral (right) view.

Clinical comparison of standard two-rod constructs to multiple-rod constructs for fixation across three-column spinal osteotomies has been recently reported by Hyun et al. [19]. In this study, the author strongly recommended using a multiple-rod construct during the initial osteotomy as a safe, simple, and effective method to prevent implant failure and symptomatic pseudarthrosis. Salvage constructs for fractured PSO instrumentation by additional rods to the

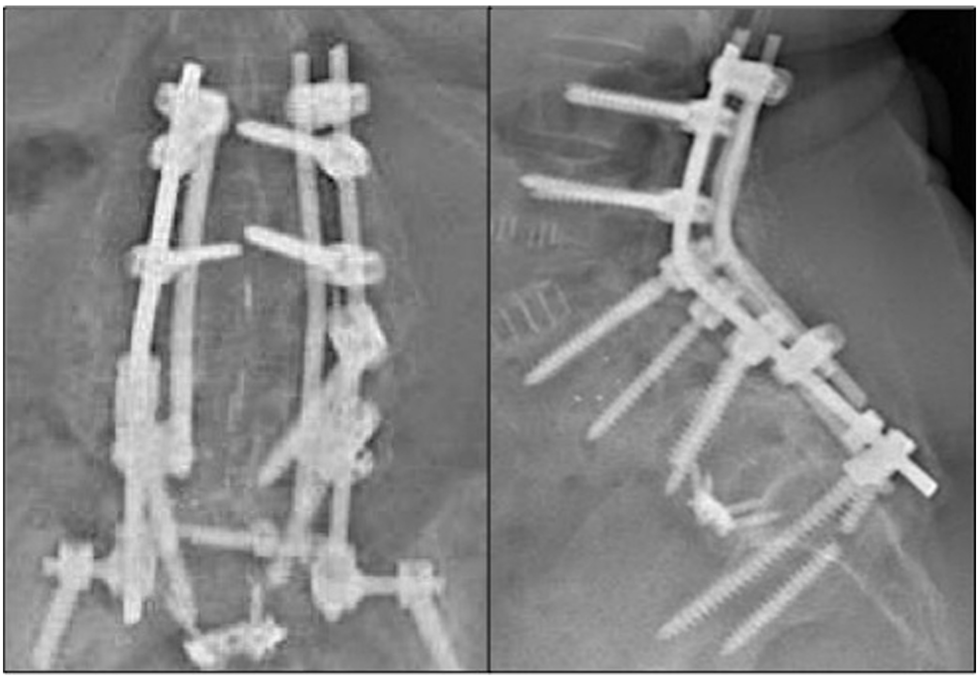

Fig. 2. X-Ray image of a double-rod construct, AP (left) and lateral (right) view.

construct (Fig. 2) also has been proposed, and initial biomechanical advantages have been demonstrated. However, the long-term fatigue strength and role of additional rods on fracture prevention are still not known. The purpose of the present study was to evaluate the fatigue strength of various rod configurations that may be used to supplement the area of lordosis to prevent instrumentation failure in PSO. The hypothesis of this study was that the addition of a secondary rod can significantly increase the long-term integrity of a PSO rod.

Materials and Methods

Single rod with pedicle screws (K2M, Leesburg, VA) constructs were mounted in ultra-high-molecular-weight polyethylene (UHMWPE) blocks using a vertebrectomy model similar to the ASTM F1717 standard [20]. The UHMWPE blocks are standard for wear testing of spinal rods because it does not allow fatigue loosening at the screw—block interface. Polyaxial titanium pedicle screws and contoured titanium alloy rods (Ti-6Al-4V) were used to simulate posterior instrumentation used as fixation for PSO. The rods were 5.5 mm, cut to a length of 165 mm and bent centrally to 50°, which was the average rod contour of posterior instrumentation in our series of patients with PSO. The polyethylene blocks were shaped to allow the placement of contoured rods without touching the blocks. Each construct was then mounted onto a biomaterials testing machine (MTS Systems, Eden Prairie, MN) and cycled under a 200 N axial load at 5 Hz simulating sagittal bending until rod failure (Fig. 3). This load and frequency were within the ranges previously described [17,18,21].

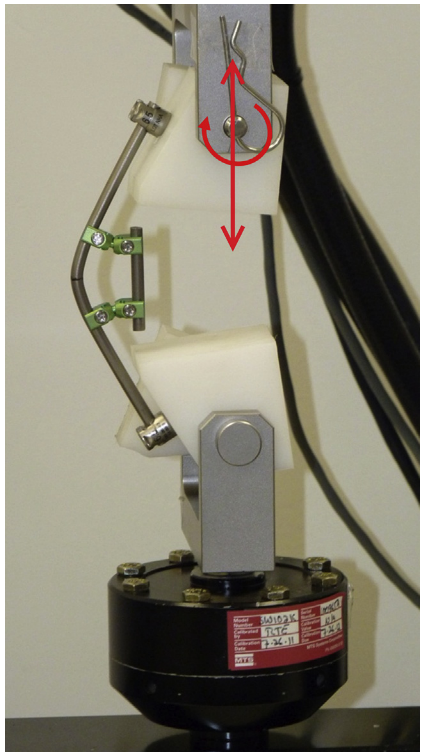

Fig. 3. Construct testing setup.

Single rod per side (control), double rod per side, and bridging-rod construct configurations were tested (n = 5, Fig. 4). The double rod per side configuration was constructed with two separate equally contoured rods held together with two side-to-side rod connectors positioned approximately 2.5 cm from the proximal and distal ends of the rods (Fig. 5). The bridging-rod configuration was constructed with a single contoured rod and a separate rod approximately 3 cm in length connected to the main rod using two small crosslinks. The smaller rod was positioned in the same plane as the primary rod and acted as a bridge across the apex of the angle. Polyethylene blocks, pedicle screws, set screws, rod connectors, and crosslinks were reused for construct assembly, as they were free of any apparent sign of fatigue, fracture, or deformation.

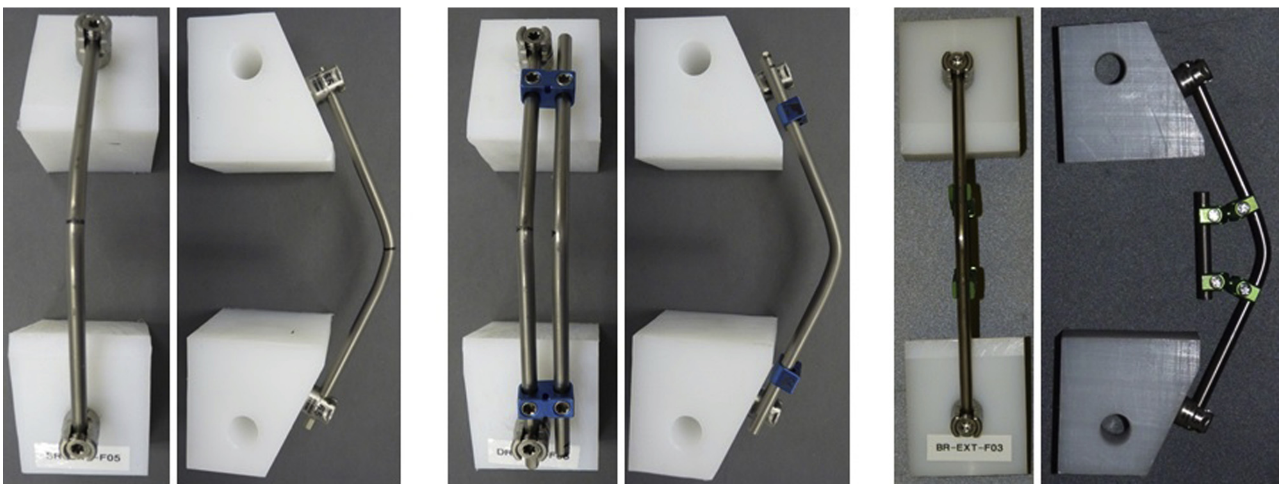

Fig. 4. Single-rod (left), double-rod (center), and bridging-rod constructs (right)

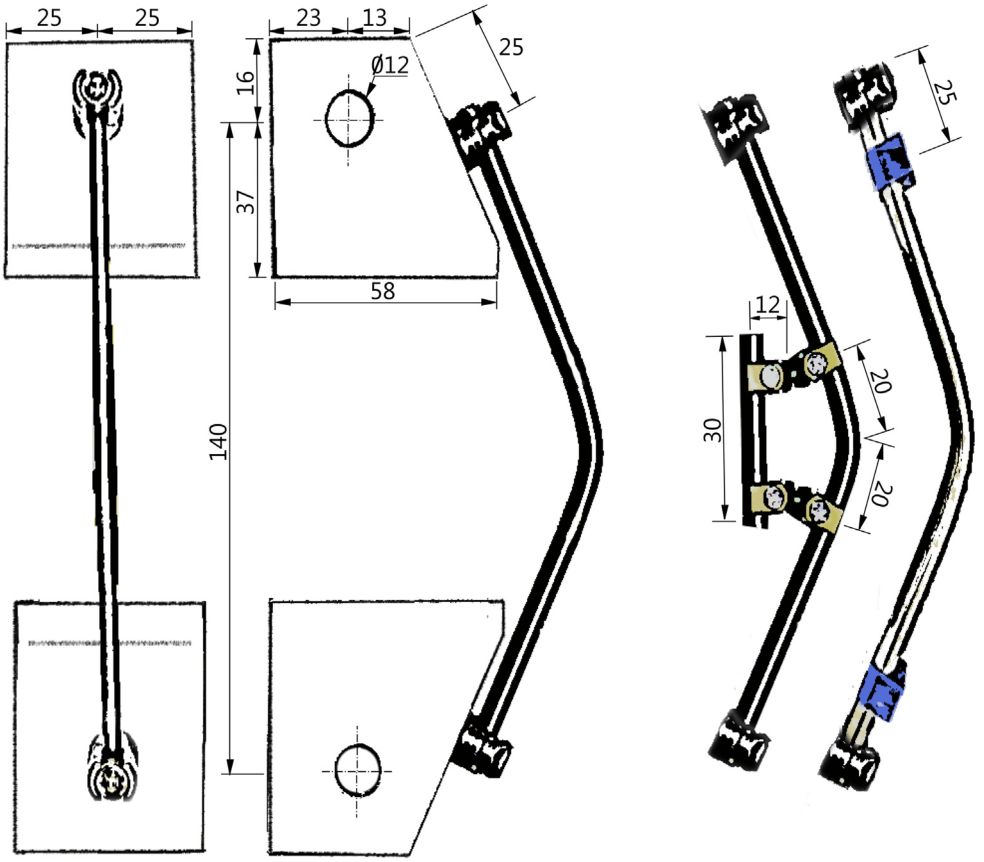

Fig. 5. Dimensional properties of single-rod, double-rod, and bridging-rod constructs.

The principal outcome measure was the total number of cycles to failure. The location of rod failure for each construct was also examined. Statistical analysis consisted of a Shapiro-Wilk normality test and equal variance test. The main comparison was performed using a Kruskal-Wallis test followed by post hoc Tukey pairwise comparisons.

Results

The medians and 25% to 75% quartiles of the number of cycles to failure for the single-rod, double-rod, and bridging-rod constructs were 59,294 (56,580 to 67,028), 561,214 (288,329 to 799,166), and 473,128 (345,160 to 506,192), respectively (Fig. 6). There was a statistically significant difference between the single-rod and double-rod constructs, as well as the single-rod and the bridging-rod constructs ($p < .05$). The difference between the double-rod and bridging-rod constructs was not statistically significant ($p > .05$).

All of the single-rod constructs failed at the apex of the rod bend (Fig. 7). In the double-rod configuration, the failure of the primary rod occurred either at the pedicle screw−rod junction (in three constructs) or at the junction with the rod-to-rod connector (in one construct), or just below the bend apex (in one construct) (Fig. 8). In the bridging-rod configuration, the construct failed at the junction of the pedicle screw and the rod in all five constructs (Fig. 9).

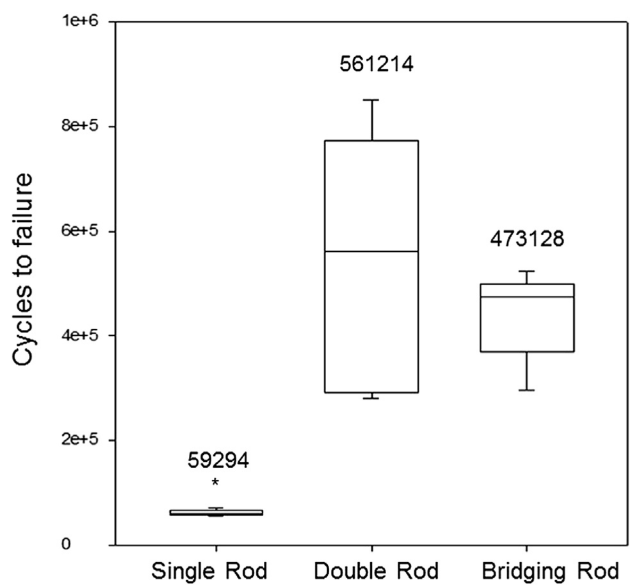

Fig. 6. Median and 25% and 75% quartiles for number of cycles to failure for single-rod, double-rod, and bridging-rod constructs. *$p < .05$.

Fig. 7. The mode of failure of the single-rod group. The rods broke at the apex.

Fig. 9. The mode of failure of the bridging-rod group. The rods broke at the rod−pedicle screw junction.

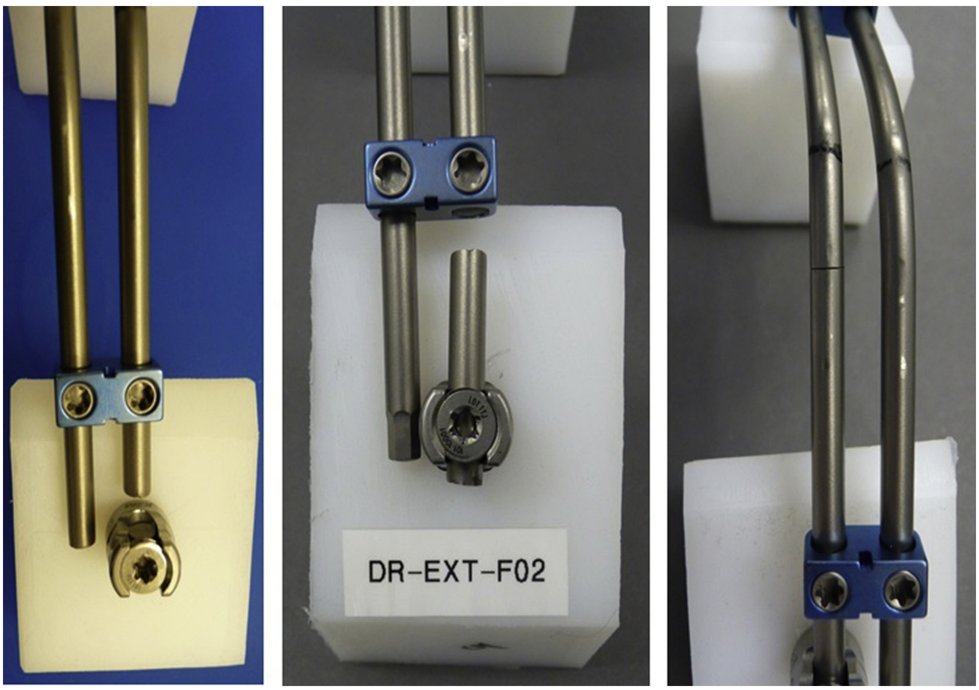

Fig. 8. The mode of failure of the double-rod group. The rods broke either at the rod−pedicle screw junction or at the rod−connector junction, or near the apex.

Discussion

Rod failure in PSO is a documented problem [3,10-15,22,23]. This study suggests that the implementation of supplemental rod configurations may strengthen the PSO construct and potentially avoid complications related to instrumentation failure.

It has been recently suggested in a study by Tang et al. that the degree of bend contoured into the rod can affect the fatigue resistance of the construct [18]. They showed that increasing the PSO angle from 20° to 40° or 60° significantly decreased fatigue life. In our series of patients with PSO, the average rod contour necessary to achieve the desired correction in sagittal balance was 50°. This would suggest that the instrumentation placed at the index surgery is subject to an inherent increased risk of failure due to the extent of rod bend. Supplemental strategies to further strengthen the PSO construct could help to mitigate this risk.

In a study by Scheer et al., revision strategies for instrumentation failure in PSO were examined [13]. Rod breakages in a cadaveric PSO model were repaired with in-line rod-to-rod connectors and supplemented with either crosslinks or satellite rods in various configurations. Their results showed that stiffness in flexion, extension, and lateral bending could be restored with these revision strategies and that stiffness in axial rotation could be restored with the use of crosslinks. The implementation of satellite rods had little effect on the stiffness of the constructs. They did suggest, however, that the satellite rods may confer a benefit in fatigue, which was not tested in their study.

Unlike salvage strategies in the previous investigations, we investigated whether it would be possible to extend the fatigue life of primary PSO construct to prevent fracture incidence. To our knowledge, this is the first study to evaluate instrumentation configurations that could be implemented during the index surgery to supplement PSO fixation constructs. The two supplemental constructs, double rod and bridging rod, were significantly more resistant to fatigue failure than the single rod control. There was not, however, a significant difference between the double-rod and bridging-rod constructs.

Each construct in the current study presents advantages and disadvantages. The double-rod construct is similar to the satellite-rod construct used by Scheer et al. [13], wherein the second rod lies adjacent to the primary rod following the same sagittal contour. As such, this construct requires that the supplemental rod be contoured to match the primary rod, subjecting it to decreased fatigue life equal to that of the primary rod as discussed earlier. The double rod also requires further lateral dissection to allow for construct assembly, which can be difficult in the standard posterior spinal approach. This construct can be reliably made with standard rod-to-rod connectors and does not add any additional bulk to the construct in the sagittal plane.

The bridging-rod construct is a novel design, with the primary rod bend angle being supplemented by a smaller rod in the sagittal plane. This construct was not necessarily proposed as an alternative to the standard technique, but it was a conceptual construct meant to emphasize a point that the addition of a stiffer element, specifically to the most angular portion of the single rod, could help extend the fatigue life of the primary rod. In this construct, the supplemental rod is not contoured but rather directly connected to the primary rod with two small crosslinks. This construct can be easily applied to the primary rod in a surgical setting and does not require additional dissection. The crosslinks used for this construct employ an articulating coupler at each end that accounts for the angular difference between the primary rod and the bridging rod. The bridging rod is located closely behind the bend of the rod, which is anterior to the most posterior and prominent portion of the primary rod. The bridging rod therefore does not add to the sagittal dimension of the construct which could result in prominence of the instrumentation, particularly if the bridging segment was placed across a long distance. The bridging-rod construct suggests a potential area for development of a specific implant that could bridge the rod bend angle while coupling directly to the primary rod. The crosslinks utilized in this construct are not labeled for this type of use by the FDA.

The single-rod constructs all failed at or near the rod bend apex, which is consistent with the findings of previous studies [17,18,21]. In the majority of double-rod and bridging-rod constructs, the point of failure was transferred to the rod−connector junction or the rod−pedicle screw junction. Lindsey et al. demonstrated that uncontoured rods failed at the rod−pedicle screw junction as opposed to contoured rods, which failed at the site of rod bend [17]. This would suggest that the supplemental double-rod and bridging-rod constructs effectively protect the rod bend and shift the site of failure closer to that seen in the absence of contouring.

There are some limitations to this study. We used a unilateral construct model unlike the bilateral design described in the relevant ASTM standard. This model eliminated the necessity for horizontal crosslinks, limited the variability between left and right sides that might have occurred during rod contouring, and reduced the number of cycles required for construct failure. It is important to note, however, that the construct used with a single rod is different from the clinical situation, and thus its clinical relevance is unclear. It is possible that the results can be extrapolated to bilateral cases because of the symmetry of the construct and, thus, the kinetics of the testing during sagittal bending. Please be aware that the PSO procedure is very unstable; therefore, bilateral instrumentation should always be used. In the future, it may be reasonable to conduct a study using bilateral rods to show more clinical relevance.

The constructs were tested only under axial loading conditions, simulating sagittal plane flexion and extension. In the in vivo spine, instrumentation constructs are subjected to axial, rotational, and bending stresses throughout the spectrum of human movement, which are not accounted for in this study. It should also be mentioned that the long-term success of any PSO construct is dependent on the eventual fusion of the affected vertebral segments [8,10,22,24,25]. The construct configurations discussed in this study have potential utility in increasing resistance to fatigue failure of PSO instrumentation; however, they are not intended to obviate the need for achieving a solid fusion.

Conclusion

In summary, double rod per side and bridging-rod constructs demonstrated significantly higher fatigue resistance than single rod per side constructs in uniplanar biomechanical testing. These supplemental construct configurations also had a protective effect across the rod bend by transferring the site of failure from the rod bend apex to the junction of the rod and pedicle screw or rod connector. Implementation of these constructs could be considered to reduce the risk of instrumentation failure.

References

[1] Kim WJ, Kang JW, Kang SI, et al. Factors affecting clinical results after corrective osteotomy for lumbar degenerative kyphosis. *Asian Spine J* 2010;4:7—14.

[2] Kim YJ, Bridwell KH, Lenke LG, et al. Results of lumbar pedicle subtraction osteotomies for fixed sagittal imbalance: a minimum 5-year follow-up study. *Spine* 2007;32:2189—97.

[3] Hyun SJ, Rhim SC. Clinical outcomes and complications after pedicle subtraction osteotomy for fixed sagittal imbalance patients: a long-term follow-up data. *J Korean Neurosurg Soc* 2010;47:95—101.

[4] Joseph Jr SA, Moreno AP, Brandoff J, et al. Sagittal plane deformity in the adult patient. *J Am Acad Orthop Surg* 2009;17:378—88.

[5] Potter BK, Lenke LG, Kuklo TR. Prevention and management of iatrogenic flatback deformity. *J Bone Joint Surg Am* 2004;86-A:1793—808.

[6] La Grone MO. Loss of lumbar lordosis. A complication of spinal fusion for scoliosis. *Orthop Clin North Am* 1988;19:383—93.

[7] Bridwell KH, Lewis SJ, Lenke LG, et al. Pedicle subtraction osteotomy for the treatment of fixed sagittal imbalance. *J Bone Joint Surg Am* 2003;85-A:454—63.

[8] Bridwell KH, Lewis SJ, Rinella A, et al. Pedicle subtraction osteotomy for the treatment of fixed sagittal imbalance. Surgical technique. *J Bone Joint Surg Am* 2004;86-A(suppl 1):44—50.

[9] Gill JB, Levin A, Burd T, Longley M. Corrective osteotomies in spine surgery. *J Bone Joint Surg Am* 2008;90:2509—20.

[10] Bridwell KH, Lewis SJ, Edwards C, et al. Complications and outcomes of pedicle subtraction osteotomies for fixed sagittal imbalance. *Spine* 2003;28:2093—101.

[11] Kim YJ, Bridwell KH, Lenke LG, et al. Pseudarthrosis in adult spinal deformity following multisegmental instrumentation and arthrodesis. *J Bone Joint Surg Am* 2006;88:721—8.

[12] Mok JM, Cloyd JM, Bradford DS, et al. Reoperation after primary fusion for adult spinal deformity: rate, reason, and timing. *Spine* 2009;34:832—9.

[13] Scheer JK, Tang JA, Deviren V, et al. Biomechanical analysis of revision strategies for rod fracture in pedicle subtraction osteotomy. *Neurosurgery* 2011;69:164—72; discussion 172.

[14] Smith JS, Sansur CA, Donaldson 3rd WF, et al. Short-term morbidity and mortality associated with correction of thoracolumbar fixed sagittal plane deformity: a report from the Scoliosis Research Society Morbidity and Mortality Committee. *Spine* 2011;36:958—64.

[15] Yang BP, Ondra SL, Chen LA, et al. Clinical and radiographic outcomes of thoracic and lumbar pedicle subtraction osteotomy for fixed sagittal imbalance. *J Neurosurg Spine* 2006;5:9—17.

[16] Cho KJ, Suk SI, Park SR, et al. Complications in posterior fusion and instrumentation for degenerative lumbar scoliosis. *Spine* 2007;32:2232—7.

[17] Lindsey C, Deviren V, Xu Z, et al. The effects of rod contouring on spinal construct fatigue strength. *Spine* 2006;31:1680—7.

[18] Tang JA, Leasure JM, Smith JS, et al. Effect of severity of rod contour on posterior rod failure in the setting of lumbar pedicle subtraction osteotomy (PSO): a biomechanical study. *Neurosurgery* 2013;72:276—82; discussion 283.

[19] Hyun SJ, Lenke LG, Kim YC, et al. Comparison of standard 2-rod constructs to multiple-rod constructs for fixation across 3-column spinal osteotomies. *Spine* 2014;39:1899—904.

[20] ASTM. Standard test methods for spinal implant constructs in a vertebrectomy model. Designation F1717-011-16.

[21] Nguyen TQ, Buckley JM, Ames C, Deviren V. The fatigue life of contoured cobalt chrome posterior spinal fusion rods. *Proc Inst Mech Eng H* 2011;225:194—8.

[22] Booth KC, Bridwell KH, Lenke LG, et al. Complications and predictive factors for the successful treatment of flatback deformity (fixed sagittal imbalance). *Spine* 1999;24:1712—20.

[23] Ikenaga M, Shikata J, Takemoto M, Tanaka C. Clinical outcomes and complications after pedicle subtraction osteotomy for correction of thoracolumbar kyphosis. *J Neurosurg Spine* 2007;6:330—6.

[24] Chang KW, Cheng CW, Chen HC, et al. Closing-opening wedge osteotomy for the treatment of sagittal imbalance. *Spine* 2008;33:1470—7.

[25] Cho KJ, Bridwell KH, Lenke LG, et al. Comparison of Smith-Petersen versus pedicle subtraction osteotomy for the correction of fixed sagittal imbalance. *Spine* 2005;30:2030—7; discussion 2038.