Reoperation rates and impact on outcome in a large, prospective, multicenter, adult spinal deformity database

Clinical article

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Object. Complications and reoperation for surgery to correct adult spinal deformity are not infrequent, and many studies have analyzed the rates and factors that influence the likelihood of reoperation. However, there is a need for more comprehensive analyses of reoperation in adult spinal deformity surgery from a global standpoint, particularly focusing on the 1st year following operation and considering radiographic parameters and the effects of reoperation on health-related quality of life (HRQOL). This study attempts to determine the prevalence of reoperation following surgery for adult spinal deformity, assess the indications for these reoperations, evaluate for a relation between specific radiographic parameters and the need for reoperation, and determine the potential impact of reoperation on HRQOL measures.

Methods. A retrospective review was conducted of a prospective, multicenter, adult spinal deformity database collected through the International Spine Study Group. Data collected included age, body mass index, sex, date of surgery, information regarding complications, reoperation dates, length of stay, and operation time. The radiographic parameters assessed were total number of levels instrumented, total number of interbody fusions, C-7 sagittal vertical axis, uppermost instrumented vertebra (UIV) location, and presence of 3-column osteotomies. The HRQOL assessment included Oswestry Disability Index (ODI), 36-Item Short Form Health Survey physical component and mental component summary, and SRS-22 scores. Smoking history, Charlson Comorbidity Index scores, and American Society of Anesthesiologists Physical Status classification grades were also collected and assessed for correlation with risk of early reoperation. Various statistical tests were performed for evaluation of specific factors listed above, and the level of significance was set at p < 0.05.

Results. Fifty-nine (17%) of a total of 352 patients required reoperation. Forty-four (12.5%) of the reoperations occurred within 1 year after the initial surgery, including 17 reoperations (5%) within 30 days. Two hundred sixty-eight patients had a minimum of 1 year of follow-up. Fifty-three (20%) of these patients had a 3-column osteotomy, and 10 (19%) of these 53 required reoperation within 1 year of the initial procedure. However, 3-column osteotomy was not predictive of reoperation within 1 year, p = 0.5476. There were no significant differences between groups with regard to the distribution of UIV, and ODI did not have a significant effect on reoperation rates. Patients needing reoperation within 1 year had worse ODI and SRS-22 scores measured at 1-year follow-up than patients not requiring operation.

Conclusions. Analysis of data from a large multicenter adult spinal deformity database shows an overall 17% reoperation rate, with a 19% reoperation rate for patients treated with a 3-column osteotomy, and a 16% reoperation rate for patients not treated with 3-column osteotomy. The most common indications for reoperation included instrumentation complications and radiographic failure. Reoperation significantly affected HRQOL outcomes at 1-year follow-up. The need for reoperation may be minimalized by carefully considering spinal alignment, termination of fixation, and type of surgical procedure (presence of osteotomy). Precautions should be taken to avoid malposition or instrumentation (rod) failure. (http://thejns.org/doi/abs/10.3171/2013.7.SPINE12901)

**KEY WORDS** • spinal deformity • reoperation • HRQOL • quality of life

**Abbreviations used in this paper:** ASA = American Society of Anesthesiologists performance status; BMI = body mass index; HRQOL = health-related quality of life; ISSG = International Spine Study Group; ODI = Oswestry Disability Index; SF-36 = 36-Item Short Form Health Survey; SRS-22 = Scoliosis Research Society 22-item patient questionnaire; SVA = sagittal vertical axis; UIV = uppermost instrumented vertebra.

**MANAGEMENT** of adult spinal deformity poses great challenges to the surgeon and historically been associated with relatively high rates
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of complications and the need for reoperation. Studies have documented the complications that arise, assessing the rates of reoperation, analyzing factors that increase the likelihood of reoperation, and suggesting methods to prevent the need for reoperation. These studies not only reported complications following primary spine surgery but also compared complication rates between different types of spine surgeries and between primary and revision procedures. Rates of reoperation are frequently cited, ranging from 10% to 25%, and among the many reasons behind reoperation—including infection, curve progression, proximal junction kyphosis, implant failure, and removal of painful implants—pseudarthrosis emerges as one of the most commonly documented indications. There are also studies that have investigated the effects of demographic factors, suggesting older age as a risk factor for developing pseudarthrosis, with the consequent need for revision surgery. However, few studies have focused on the effects of reoperation and pseudarthrosis on patients’ scores on outcome measures, including the SRS-22 and the ODI. While most of these studies address in detail the challenges of spine surgery that frequently result in reoperation, each examines a collection of individual issues, such as specific complications, risk factors, techniques to prevent reoperation, or outcome measures. However, there has yet to be a comprehensive analysis combining all aspects related to reoperation in adult spinal deformity surgery from a global perspective, with a focus on the relatively short-term setting of the 1st year following surgery.

Furthermore, there is a need to investigate the factors that influence rates of complications and reoperations across key time frames that are currently used as quality measures by governmental agencies and third-party payers. Reoperation within 30 days and reoperation within 1 year may be important quality metrics that will require baseline rates at centers of excellence to set acceptable occurrence standards for these events. HRQOL measures can also be used to compare the rate of the recovery and clinical change timeline of reoperation versus primary surgery to determine the extent to which a reoperation may slow or potentially permanently limit clinical improvement following deformity surgery.

This study attempts to address in detail the following 4 primary aims: 1) determine prevalence of reoperation following surgery for adult spinal deformity, 2) assess indications for these reoperations, 3) evaluate for a relation between specific radiographic parameters and the need for reoperation, and 4) determine the potential impact of reoperation on HRQOL measures.

Methods

This study is a retrospective review of a prospective, multicenter adult thoracolumbar spinal deformity database of the International Spine Study Group (ISSG), which is composed of 11 sites across the United States. Data from consecutive cases involving patients treated between 2010 and 2012 were obtained, and all patients were enrolled into an institutional review board–approved protocol by the respective sites. Inclusion criteria for the ISSG database are: age of at least 18 years and presence of spinal deformity, as defined by a Cobb angle of at least 20°; an SVA measurement (distance between the C-7 plumb line and posterior superior margin of the sacrum) of at least 5 cm; a pelvic tilt of at least 25°; and/or thoracic kyphosis of at least 60°. Exclusion criteria included spinal deformity of a neuromuscular etiology and the presence of active infection or malignancy.

Data collected included age, sex, date of surgery, complications, reoperation dates, and HRQOL outcomes. Reoperation was defined as any unplanned return to the operating room as a result of the original surgery. The reoperation indications were divided into the following categories: instrumentation malposition/rod fracture, radiographic (proximal junction failure, distal junction failure, pseudarthrosis, coronal malalignment) neurological compromise, infection, medical (cardiopulmonary, vascular gastrointestinal, renal), operative, and wound. The instrumentation malposition/fracture category described situations in which there was implant failure or migration, malpositioning, painful implants, or bony fracture due to implants not related to proximal junction failure.

Other variables that were assessed included BMI, the total number of anterior and posterior levels instrumented, the total number of interbody fusions, preoperative SVA measurement, total operative time (minutes), length of hospital stay (days), the uppermost instrumented vertebra (UIV) location (characterized as upper thoracic for fixation with superior termination between T-2 and T-8 and inferior fixation between L-5 and the ilium, thoracolumbar for fixation with superior termination between T-8 and L-3 and inferior fixation between L-4 and the ilium, middle for fixation with superior termination between T-1 and T-8 to and inferior fixation between T-12 and L-5, and lumbar for fixation with superior fixation between L-1 and L-5 and inferior fixation between L-4 and the ilium), and the presence of 3-column osteotomies (including pedicle subtraction osteotomy and vertebral column resection). Smoking history, Charlson Comorbidity Index scores, and American Society of Anesthesiologists performance status grades (ASA grades) were also collected and assessed for correlation with risk of early reoperation.

The HRQOL measures were collected preoperatively and at 1 and 2 years after the index surgery and included ODI, SF-36 mental and physical component summary, back and leg pain numerical rating scale (range 0 [no pain] to 10 [maximal pain]), and SRS-22. Analyses of HRQOL in the present study were confined to patients who had a minimum of 1 year of follow-up of at least one standardized measure. A subset analysis was performed using data from only patients with a minimum of 2 years of follow-up.

Patients were divided between 2 groups based on whether a reoperation was performed. Patients who underwent repeat surgery were further grouped into the following 4 categories based on the time from the date of index surgery: less than 30 days (the Reop Within 30 Days Group), between 30 days and 1 year (the Reop 30 Days–1 Year Group), less than 1 year (the Reop Within 1 Year Group), which includes patients in the “within 30
days” category), and more than 1 year (the Reop After 1 Year Group).

Statistical analysis was performed using the Student t-test for normally distributed data and the Wilcoxon rank-sum or Kruskal-Wallis tests when appropriate for non-normal data distributions. All statistical analyses were conducted using commercially available software (JMP v 5.0, SAS Institute, Inc.), and the level of significance was set at \( p < 0.05 \).

**Results**

**Incidence of Reoperation**

The prospective multicenter database included a total of 352 patients enrolled between October 2010 and October 2012. The overall mean follow-up was 1.6 years (range 6 weeks to 2 years), and during this follow-up interval, a total of 59 (17%) of 352 patients required reoperation. In 44 cases (75% of the reoperation group and 12.5% of all cases in the database), these reoperations occurred within 1 year following initial surgery, including 17 (5%) within 30 days of initial surgery. Seven patients required a minimum of 2 reoperations, and of those 7 patients, 4 required 3 reoperations. Of the total 352 patients in the database, 268 patients (76%) had a minimum of 1 year of follow-up, and 169 (48%) had 2 years of follow-up. Of the patients with at least 1 year of follow-up (n = 268), 46 (17%) required reoperation at some point, with 31 (12%) of these procedures being within 1 year of the index surgery and 12 (4%) being within 30 days of the index surgery.

**Indications for Reoperation**

Reoperation indications for all patients requiring reoperation (n = 59) included the following: instrumentation malposition/fracture (n = 19), radiographic (n = 19), infection (n = 7), neurological compromise (n = 6), operative (n = 2), wound (n = 2), medical (n = 1), both neurological and radiographic (n = 2), and neurological, operative, and wound combined (n = 1). For those patients who underwent reoperation within 30 days of the index surgery (n = 17; subset of the total of 59 who required reoperation), the most prominent reason was neurological compromise (n = 4). Other indications were described as instrumentation malposition/fracture (n = 3), infection (n = 3), radiographic (n = 2), wound (n = 2), medical (n = 1), both neurological and operative (n = 1), and neurological, operative, and wound combined (n = 1).

**Demographic and Surgical Results**

All results represent only the cohort of patients with a minimum of 1 year of follow-up (n = 268), and the averages with standard deviations are presented in Table 1. There were no significant differences in age between patients requiring reoperation within 1 year of the index surgery (mean age 56 ± 15 years, n = 31 [including the 12 patients who required reoperation within 30 days]), within 30 days of the index surgery (47 ± 19 years, n = 12), more than 1 year after the index surgery (53 ± 16 years, n = 15), and not requiring any reoperation (55 ± 15 years, n = 222, p > 0.05 for all comparisons). However, patients who underwent reoperation within 30 days of index surgery were significantly younger (mean age 47 ± 19 years) than patients who underwent reoperation between 30 days and 1 year after the index procedures (60 ± 13 years, p = 0.02808).

There were no significant differences between the groups of patients who did not undergo reoperation or underwent reoperation within 30 days, between 30 days and 1 year, within 1 year, or more than 1 year of index surgery for the rest of the variables including preoperative BMI, Charlson comorbidity index, ASA grade, or smoking history (p > 0.05). Patients who underwent reoperation within 30 days of the index procedure had a significantly smaller preoperative SVA (2.0 ± 5.7) than patients who underwent reoperation between 30 days and 1 year after the index procedure (7.0 ± 6.3, p = 0.0219), but there were no other significant differences between the groups with respect to preoperative SVA measurement, number of anterior or posterior instrumented levels, total number of interbody fusions, total operative time, and length of hospital stay (p > 0.05).

Of the total patient group (n = 268), 53 patients (20%) had a 3-column osteotomy and 10 (19%) of the 53 required reoperation. Six of these reoperations occurred within 1 year of the index procedure, and 4 occurred more than 1 year after the index procedure. However, 3-column osteotomy was not predictive of reoperation at any time point (p = 0.5476). Three patients required a second reoperation during the study period, and 2 of these patients had been treated with a 3-column osteotomy as part of the initial procedure. The indications for reoperation for patients who had been treated with 3-column osteotomies were implant failure (n = 4), neurological compromise (n = 3), radiographic (n = 2), and operative (n = 1).

In the 46 patients who underwent reoperation (out of 268 patients), the UIV was classified as follows: upper thoracic in 15 cases (33%), thoracolumbar in 25 cases (54%), middle in 5 cases (11%), and lumbar in 1 case (2%). For those patients who underwent reoperation within 1 year (n = 31), the UIV was classified as upper thoracic in 10 cases (5%), thoracolumbar in 16 cases (10%), middle in 4 cases (2%), and lumbar in 1 case (1%). For the 222 patients who did not undergo reoperation, the UIV was classified as upper thoracic in 70 cases (32%), as thoracolumbar in 95 cases (43%), as middle in 42 cases (19%), as lumbar in 6 cases (3%), and as unknown in 9 cases (4%). There were no significant differences between groups with regard to the distribution of UIV, and UIV did not have a significant effect on reoperation rates.

**Reoperation Impact on Clinical Outcome**

**Reoperation Within 1 Year Versus No Reoperation.** There were no significant preoperative differences for HRQOL measures (p > 0.05). At 1-year follow-up, the Reop Within 1 Year Group had a significantly higher mean leg pain score (3.8 ± 3.2) than the patients who had not undergone reoperation (the No Reop Group, 3.3 ± 2.9, p = 0.0026). There was no significant difference in back pain scores between the 2 groups (p > 0.05). (Note: All follow-up times in this paper refer to the time since
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### TABLE 1: Demographic and surgical data for patients with at least 1 year of follow-up*

<table>
<thead>
<tr>
<th>Parameter at Index Surgery</th>
<th>All Pts (n = 288)</th>
<th>No Reop (n = 222)</th>
<th>All Reop (n = 46)</th>
<th>Reop After 1 Yr (n = 15)</th>
<th>Reop w/in 1 Yr (n = 31)</th>
<th>Reop w/in 30 Days (n = 12)</th>
<th>Reop 30 Days–1 Yr (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>age (yrs)</td>
<td>55 ± 15</td>
<td>55 ± 15</td>
<td>55 ± 15</td>
<td>53 ± 16</td>
<td>56 ± 15</td>
<td>47 ± 19</td>
<td>62 ± 9</td>
</tr>
<tr>
<td>male/female</td>
<td>38:231</td>
<td>30:192</td>
<td>8:38</td>
<td>2:13</td>
<td>6:25</td>
<td>2:10</td>
<td>4:15</td>
</tr>
<tr>
<td>BMI</td>
<td>27.2 ± 6.5</td>
<td>27.3 ± 6.7</td>
<td>26.7 ± 5.6</td>
<td>26.8 ± 6.9</td>
<td>26.7 ± 5.0</td>
<td>27.6 ± 5.7</td>
<td>26.2 ± 4.6</td>
</tr>
<tr>
<td>smoking</td>
<td>23</td>
<td>18</td>
<td>5</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>ASA</td>
<td>2.3 ± 0.7</td>
<td>2.2 ± 0.7</td>
<td>2.3 ± 0.7</td>
<td>2.3 ± 0.6</td>
<td>2.3 ± 0.7</td>
<td>2.1 ± 0.7</td>
<td>2.4 ± 0.8</td>
</tr>
<tr>
<td>CCI</td>
<td>1.4 ± 1.6</td>
<td>1.4 ± 1.6</td>
<td>1.6 ± 1.7</td>
<td>2.1 ± 2.1</td>
<td>1.3 ± 1.4</td>
<td>1.1 ± 1.1</td>
<td>1.4 ± 1.5</td>
</tr>
<tr>
<td>preop SVA (cm)</td>
<td>5.3 ± 7.6</td>
<td>5.1 ± 7.4</td>
<td>5.7 ± 8.3</td>
<td>6.9 ± 11.8</td>
<td>5.2 ± 6.6</td>
<td>2.0 ± 5.7</td>
<td>7.3 ± 6.3</td>
</tr>
<tr>
<td>anterior instrumented levels</td>
<td>4.3 ± 3.9</td>
<td>3.9 ± 3.2</td>
<td>5.6 ± 6.2</td>
<td>3.7 ± 0.6</td>
<td>6.4 ± 7.4</td>
<td>4.3 ± 0.5</td>
<td>9.3 ± 11.8</td>
</tr>
<tr>
<td>posterior instrumented levels</td>
<td>11.5 ± 4.8</td>
<td>11.6 ± 4.8</td>
<td>11.6 ± 4.5</td>
<td>11.3 ± 4.3</td>
<td>11.7 ± 4.7</td>
<td>12.6 ± 3.9</td>
<td>11.1 ± 5.2</td>
</tr>
<tr>
<td>interbody fusions</td>
<td>2.6 ± 1.9</td>
<td>2.5 ± 1.8</td>
<td>3.0 ± 2.0</td>
<td>3.3 ± 2.3</td>
<td>2.9 ± 1.9</td>
<td>3.2 ± 2.7</td>
<td>2.8 ± 1.4</td>
</tr>
<tr>
<td>presence of 3CO (% of group)</td>
<td>53 (20.0%)</td>
<td>43 (19.4%)</td>
<td>10 (21.7%)</td>
<td>4 (26.7%)</td>
<td>6 (19.4%)</td>
<td>3 (25.0%)</td>
<td>3 (15.8%)</td>
</tr>
<tr>
<td>operative time (minutes)</td>
<td>391 ± 131</td>
<td>387 ± 127</td>
<td>410 ± 149</td>
<td>403 ± 146</td>
<td>413 ± 153</td>
<td>422 ± 147</td>
<td>407 ± 158</td>
</tr>
<tr>
<td>length of stay (days)</td>
<td>8.7 ± 10.5</td>
<td>8.1 ± 4.9</td>
<td>11.3 ± 22.5</td>
<td>7.6 ± 4.1</td>
<td>13.0 ± 27.0</td>
<td>7.2 ± 1.8</td>
<td>8.9 ± 4.6</td>
</tr>
</tbody>
</table>

* Stratification of subgroups by time is based on time from the index surgery to reoperation. Values are shown as means with SDs or numbers of patients (% of group). CCI = Charlson Comorbidity Index; pts = patients; reop = reoperation; 3CO = 3-column osteotomy.

The only significant difference between the groups at 1-year after the index surgery was found to be in SRS pain scores, with the Reop Within 30 Days Group having a higher score (3.6 ± 1.0 vs 2.8 ± 1.0, p = 0.0472). At 2 years after the index surgery, patients in the Reop Within 30 Days Group had significantly better SRS-22 activity (4.3 ± 0.6), pain (4.2 ± 0.7), and total (4.2 ± 0.4) scores than those in the Reop 30 Days–1 Year Group (3.2 ± 1.2, p = 0.0477; 3.0 ± 1.2, p = 0.0483; and 3.1 ± 1.0, p = 0.0278, respectively).

**Reoperation Impact on Clinical Outcomes: Patients With at Least 2 Years of Follow-Up**

**Reoperation Within 1 Year Versus No Reoperation.** There were no significant differences between the Reop Within 1 Year and No Reop groups for any of the HRQOL outcomes at 1- or 2-year time points (p > 0.05).

**Reoperation After 1 Year Versus No Reoperation.** There were no significant differences between the Reop After 1 Year and No Reop groups for any 1-year HRQOL outcomes (p > 0.05). Patients who underwent reoperation more than 1 year after the index surgery had significantly lower 2-year SF-36 physical component summary scores (35.6 ± 10.4) and SRS-22 pain scores (3.0 ± 1.0) than those who did not have reoperation (42.5 ± 11.6, p = 0.0311; 3.5 ± 1.1, p = 0.0429, respectively). In addition, patients who did not undergo reoperation had a significantly larger increase in the 2-year PCS (compared with preoperative scores) than the Reop After 1 Year Group (8.7 ± 10.9 vs. 1.8 ± 8.9, p = 0.0242).

**Reoperation Within 30 Days Versus Reoperation 30 Days–1 Year After the Index Surgery.** There were no significant differences between the Reop Within 30 Days and the Reop 30 Days–1 Year groups for any 1-year HRQOL outcomes (p > 0.05). At the 2-year follow-up, those who underwent reoperation less than 30 days after the index procedure had significantly better SRS activity.
(4.3 ± 0.6), pain (4.2 ± 0.7), and total (4.2 ± 0.4) scores than those who had reoperation more than 30 days and less than 1 year after the index procedure (3.2 ± 1.2, p = 0.0477, 3.0 ± 1.2, p = 0.0483, and 3.1 ± 1.0, p = 0.0278, respectively).

Discussion

Analysis of a large multicenter adult spinal deformity database shows an overall reoperation rate of 17% at a mean follow-up of 1.6 years following the initial procedure. This is comparable to previous studies that have reported rates ranging from 10% to 25%.

This study has shown that age may not have a significant effect on the reoperation rate, with the exception of patients undergoing reoperation within 1 year of index surgery. Patients who underwent reoperation within 30 days of index surgery were significantly younger than those who underwent reoperation within 1 year but more than 30 days after the index procedure.

Of the indications requiring reoperation, the most common included instrumentation complications and radiographic failure. This reinforces the importance of preoperative planning, intraoperative imaging, and surgical technique. Lastly, the results show that reoperation within 1 year does have an effect on HRQOL at 1 year for the minimum 1-year follow-up cohort. The patients who had reoperation had significantly worse outcomes in many areas of HRQOL. This result suggests that a second surgery within 1 year of the index surgery can have an adverse effect on the patient, including a significant impact on pain, disability and SRS-22 subscores. The poorer HRQOL also further emphasizes the importance of critical preoperative planning and careful surgical technique to attempt to minimize the potential need for short-term reoperation. Despite the difference in 1-year HRQOL scores, at 2 years the scores normalized and there was no significant difference in any of them between the 2 groups. The minimum 2-year follow-up cohort did not show any significant difference in HRQOL between patients who underwent reoperation within 1 year of the index procedure and those who did not undergo reoperation. This may be a result of patients being lost to follow-up, as there were 31 patients who had reoperation within 1 year in the 1-year minimum follow-up cohort and only 16 in the 2-year minimum follow-up cohort. This could alter the results away from any effect on 1-year outcomes as about half of those patients were not seen at 2 years.
The 2-year minimum follow-up cohort results should not discount the results from the 1-year minimum follow-up cohort because those patient who had reoperations within 1 year in the 1-year minimum follow-up cohort were followed up for at least a year and did have an effect on 1-year outcomes. Similarly the patients who had reoperation more than 1 year after the index surgery in the 2-year minimum follow-up cohort had a significant negative effect on HRQOL results at 2 years.

Of 53 patients treated with 3-column osteotomy, 19% required one or more reoperations. Six of these patients underwent reoperation within 1 year of the index surgery, 4 underwent reoperation more than 1 year after the index surgery, and 2 of the 3 patients in this study requiring a second reoperation had undergone 3-column osteotomies. Given the complex nature of 3-column osteotomies, it is not surprising that the most common indications for reoperation were implant failure and neurological compromise, both of which are likely to occur early after surgery.

Even though pseudarthrosis has been reported as one of the most commonly documented reasons for reoperation, it is generally evaluated later than 1 year after the index surgery. This study has focused on reoperation within 1 year and its effect on HRQOL. The need for reoperation may possibly be minimized by careful planning and execution of a number of factors, including spinal alignment, termination of fixation, and most importantly, precautions that could be taken to avoid malposition or instrumentation (rod) failure, such as usage of additional satellite rods across the 3-column osteotomy.

Conclusions

Adult deformity spine surgery remains technically challenging, with high rates of complications that may lead to reoperations. An analysis of data from a large multicenter adult spinal deformity database showed an overall 17% reoperation rate, with a 16% reoperation rate for patients treated with 3-column osteotomy and a 16% reoperation rate for patients not treated with 3-column osteotomy. The most common indications for reoperation included instrumentation complications and radiographic failure. Undergoing a reoperation within 1 year of index surgery significantly adversely affected HRQOL measures at 1-year follow-up. The need for reoperation may be minimized by carefully considering spinal alignment, termination of fixation, and type of surgical procedure (presence of osteotomy). Precautions should be taken to avoid malposition or instrumentation (rod) failure.

Disclosure

Dr. Shaffrey reports a patent holder relationship with Medtronic and Biomet; a consultant relationship with Medtronic, Biomet, NuVasive, and Globus; and receiving clinical or research support for this study from DePuy. Dr. Ames reports a consultant relationship with DePuy, Medtronic, and Stryker; a patent holder relationship with Fish & Richardson, P.C.; direct stock ownership in Trans1, Visualase, and Doctors Research Group; and receiving royalties from Lanz and Aesculap. Dr. Smith reports a consultant relationship with Biomet and Medtronic and receiving clinical or research sup-

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Author contributions to the study and manuscript preparation include the following. Conception and design: Ames. Acquisition of data: Scheer. Analysis and interpretation of data: Scheer, Tang, Smith, Drafting the article: Scheer, Tang, Smith, Shaffrey. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Scheer. Statistical analysis: Scheer. Administrative/technical/material support: Ames. Study supervision: Ames.

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