Rod Fracture in Adult Spinal Deformity Surgery: Incidence, Risk Factors and Impact on Health Related Quality of Life in 526 Patients

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IMAST2017 Paper WC# 5

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Background: Limited data analysis exist on rod fracture (RF) following posterior spinal fusion to the sacrum to treat adult spinal deformity (ASD). Our study evaluated the incidence of and risk factors for RF and determined outcomes changes associated with RF after ASD surgery.

Methods: We performed a retrospective single-center analysis of ASD patients (age > 18 years) undergoing ≥ 5 vertebrae posterior fusion to the sacrum from 2004 to 2014. Patients were included if they demonstrated RF occurrence or did not develop RF with a minimum 2-year follow-up. We analyzed baseline demographic, radiographic, clinical outcomes, and operative data. We identified risk factors for RF using separate Cox proportional hazard models depends on rod material and diameter.

Results: RF occurred in ninety-seven patients (18.4%) out of 526 patients that were included in the study. Risk factors for RF from multivariable model with cobalt chromium (CoCr) 5.5 mm rod diameter (CoCr5.5 model) included preoperative sagittal vertical axis (hazard ratio (HR), 1.07 (95% confidence interval [95%CI], 1.02 to 1.14) per 1-cm increase), preoperative thoracolumbar kyphosis (HR, 1.02 [95%CI, 1.01 to 1.04] per 1-degree increase) and number of levels fused for patients received rhBMP-2 < 12 mg per level fused (HR, 1.48 [95%CI, 1.20 to 1.82] per 1-level increase). CoCr 5.5 mm rod diameter and stainless steel 6.35 mm rod diameter model also showed the same risk factors as shown in CoCr5.5 model with additionally included CoCr 5.5 mm rod (HR, 8.49 [95%CI, 4.26 to 16.89] compared to stainless steel 6.35 mm rod). The RF group had less overall improvement in Scoliosis Research Society (SRS) satisfaction (p = 0.007) and SRS self-image domain (p = 0.01).

Conclusions: The incidence of RF after index procedure was 18.4 %. Greater preoperative sagittal vertical axis, greater preoperative thoracolumbar kyphosis, increased number of vertebrae fused for patients received rhBMP-2 < 12 mg per level fused, and CoCr 5.5 mm rod were associated with RF risk. Less improvement in patient-satisfaction and self-image was noted in the RF group.

Introduction

Adult spinal deformity (ASD) affects 9% of adult population and has negative impacts on quality of life of the patients (1-3). Surgical treatment, has been proved to provide significant benefit to patients suffering from adult spinal deformity (4, 5). Since the improvement of spinal instruments and surgical techniques over the past years, surgeons are able to treat more complex deformity and improve the surgical outcomes of adult spinal deformity (6, 7). In recent decades, the complex surgical procedures to treat adult spinal deformity gain more popularity with increasing rate of fifteen fold from 2002-2007 (8).

Despite the benefits obtained with surgical treatment for adult spinal deformity, it is not without risk. The surgical treatment of adult spinal deformity is challenging and technically high demand with postoperative complication rate is relatively high, with some reports as high as 72% (5, 9-12). Cho et al. reported a major complication rate of 34.3% in patients undergoing revision long fusion surgery for spinal deformity (13). Soroceanu et al. reported radiographical and implant-related complication rate of 31.7% in adult spinal deformity surgery (14). Among the major complications, rod fracture (RF) is one of the most common implant-related complications (12, 14). Furthermore, development of RF is the leading cause of revision surgery in ASD which has substantial impact on the patient (15). There have been few studies that have identified consistent risk factors for RF in ASD surgery (16-18). These studies were based on short follow-up. In addition, prior studies have not examined the impact of RF on health-related quality of life (HRQOL) compared with patients who did not develop RF.

The purpose of our study was to better define the incidence of RF and determine demographic, radiographic and surgical risk factors for RF in ASD patients undergoing long construct posterior spinal fusion to the sacrum at a minimum two-year follow-up and evaluate the impact of RF on HRQOL compared with patients with no RF occurred. We hypothesized that severity of spinal deformity and

surgical parameters would be risk factors for RF and that HRQOL would be more favorable among patients who did not develop RF.

Materials and Methods

This is a retrospective cohort study of ASD patients undergoing long construct posterior spinal fusion to the sacrum performed by one of two senior spine surgeons from 2004 to 2014 at a single institution.

Study Design and Inclusion Criteria

This study was conducted after institutional review board approval was obtained. Inclusion criteria were: (1) patient age > 18 years, (2) scoliosis of ≥ 20°, sagittal vertical axis (SVA; horizontal distance between C7 plumbline and posterosuperior margin of the sacrum) of ≥ 5 cm, pelvic tilt ≥ 25°, and/or thoracic kyphosis > 60° and (3) undergoing ≥ 5 vertebrae posterior instrumented spinal fusion to the sacrum. Included subjects had complete baseline, early postoperative and latest follow-up full-length standing radiographs and had development and evidence of RF or a minimum 2-year follow-up in patients without RF. Patients with spinal deformity resulting from neuromuscular disease, active infections, trauma or tumors were excluded. Patients were assigned to one of two groups: (1) patients with no RF occurred after index surgery to latest follow-up (with a minimum of 2-year follow-up), or (2) patients with RF occurred at any time points after index surgery.

Data Collection and Analysis

Patient demographic and clinical characteristics, including age, sex, weight, body mass index (BMI), smoking status, diabetes, osteoporosis, American Society of Anesthesiologists (ASA) performance status grade, diagnosis, history of prior spine surgery and duration of follow-up, were collected. Surgical information including the number of vertebral levels fused, upper instrumented vertebra, presence of posterior column osteotomies or three-column osteotomies (including pedicle subtraction osteotomy

and vertebral column resection), rod material, rod diameter, number of rods in the construct, interbody fusion use, approach (transforaminal lumbar interbody fusion, anterior lumbar interbody fusion), presence of pelvic fixation, transverse connector use and grafting material use (autogenous local or iliac bone graft, allograft or rhBMP-2) were assessed.

Full-length free-standing postero-anterior and lateral spine radiographs (36-inch cassette) obtained at baseline, early postoperative (between 6 and 8 weeks) and latest follow-up were analyzed using validated software (Surgimap; Nemaris Inc. New York, NY, USA) (19) . Two of the authors, independent of the operative team, performed all radiographic measurements based on standard techniques (20). Radiographic parameters included preoperative and early postoperative values and the changes in these values (early postoperative subtracted by preoperative values) for the following: sagittal vertical axis, pelvic incidence, pelvic tilt, sacral slope, lumbar lordosis (L1-S1), pelvic incidence minus lumbar lordosis mismatch, thoracic kyphosis (T5-T12), thoracolumbar kyphosis (T10-L2) and coronal Cobb angle of the major curves.

Rod fracture was defined as unanticipated rod breakage at least one site in the rod constructs following index surgery. Rod fracture events were evaluated through review of follow-up full-length radiographs for each patient at follow-up intervals of 6-8 weeks, 6 months, 1 year, 2 years, 3 years, 5 years, and in 5-year intervals and were confirmed with office-visit note by the surgeon managing each patient. If the evidence of rod fracture events from the radiographs was discordant with office-visit note, the senior author (M.C.G.), who was independent of the operative team, would make the decision whether there was RF event or not. RF events were collected including those that were symptomatic and those found incidentally. The details of RF event were collected including date of RF, unilateral or bilateral, level of fracture, symptoms of patients relating with RF and management of RF based on reviews of outpatient chart and operative records.

HRQOL outcomes including the Scoliosis Research Society (SRS) and Oswestry Disability index (ODI) questionnaires were evaluated at baseline, 1-year postoperatively and latest follow-up. Patients undergoing revision for other reasons than RF were excluded from HRQOL analyses so as to eliminate these confounders on HRQOL outcomes analyses.

Statistical Analysis

To account for different durations of follow-up from the index surgery, univariable Cox proportional hazards regression was used to determine if patient risk factors are associated with the probability that RF will develop during the study period. Non-rod fracture revision status was included as a time-dependent covariate to account for the ten patients who underwent a non-rod fracture revision during the study period. Patients who did not develop RF were statistically censored at the time of the final x-ray.

Multivariable Cox models were used to determine a subset of risk factors that are independently associated with RF. Due to sample size limitation, we were not able to assess the combined effects of rod material and rod diameter. Thus, a separate multivariable model was conducted for cobalt chromium material with 5.5 mm rod diameter (177 patients) and for cobalt chromium material with 5.5 mm rod diameter and stainless steel material with 6.35 mm rod diameter (327 patients). Variables that were significant at the $p < 0.05$ level in the univariable analyses were candidates for inclusion in each multivariable regression model. The final subset of variables was selected *a priori* to reduce intercorrelations among variables and to maximize clinical relevance. For stainless steel material, hazard rates were not consistent across the thirteen years of follow-up and were truncated at six years (which parallels the cobalt chromium multivariable model with maximum follow-up of 5.7 years). Model fit was increased by the inclusion of the interaction between the number of levels fused and categorized high

dose of BMP-2 per level fused, meaning that the effect of the number of levels fused on RF depends on whether the patient received a low or high dose of BMP per level fused.

HRQOL outcomes were analyzed using mixed model repeated measures analysis of variance (RM-ANOVA) with a compound symmetry covariance structure. Patients that contributed HRQOL data at more than one visit were included in the analyses. Hypotheses regarding change within each group were tested with a separate RM-ANOVA for patients with and without RF where visit was the independent variable. Hypotheses regarding the equality of changes over time in the two-rod fracture groups were tested with RM-ANOVAs with a focus on the interaction between visit and group.

An ancillary analysis (data not reported) was performed to determine if the rate of RF differs depending on the calendar year in which the surgery was performed (p=0.09 by chi-square). Histograms revealed no pattern of association. Thus, surgical year was not included as a potential covariate in the reported analyses. The data analysis was performed with SAS software, version 9.4 of the SAS System for Linux (SAS Institute Inc., Cary, NC, USA).

Results

Base on the inclusion criteria, 657 patients were eligible; however, 131 patients were excluded (two died and 129 patients were followed for less than two years). Five hundred and twenty-six patients with an average age of 56.8 years (range, 18 to 80 years; median, 58 years) at the time of surgery were enrolled in the study. There were 70 men (13.3%) and 456 women (86.7%). The average duration of follow-up was 55 months (range, 13 to 152 months; median, 57 months). Patients follow-up rates based on the postoperative time interval were as follow: 100% at one year, 99.6% at two years, 72.2% at three years, and 46% at five years. All data were completed except osteoporotic data that was available in 430 patients (81.7%). The baseline demographic characteristics and surgical data of the patients are summarized in Table 1.

RF was identified in ninety-seven (18.4%) of the 526 patients at an average of 39.6 months (range, six to 121 months). The survivorship curve is shown in Figure 1. RF occurred within three years in 51 patients (52.6%), between three to five years in 23 patients (23.7%), between five to ten years in 22 patients (22.7%), and more than ten years in one patient (1%) after index surgery (Fig. 2).

There were 143 RF sites among 97 patients that developed RF. Sixty-one patients with unilateral RF developed 64 RF sites: three patients had ipsilateral rod fractures (two rod fracture sites in the same rod) and 58 patients had one fracture site in the constructs. Thirty-six patients with bilateral RF developed 79 RF sites: one patients had four RF sites in the construct (Fig.3), five patients had three RF sites in the construct and thirty patients had two RF sites in the construct. RF occurred most commonly at L5-S1, which was the site of 28% (forty) of the 143 RF sites and at L3-L4, which was the site of 23.8% (thirty-four RF sites) (Fig.4). Among 97 patients with RF three had only the breaking sound of a crack with no other symptoms, twelve had the breaking sound of a crack preceding development of persistent back pain, twenty had persistent back pain, seven had progression of deformity, and one had prominent implant. As of last follow-up, there were no apparent clinical symptoms for fifty-four patients and the fracture was found in a radiograph at a follow-up visit.

Only forty (41.2%) of the 97 patients with RF required revision surgery due to their symptoms including back pain, progressive deformity and prominent implant (thirteen patients with unilateral RF and twenty-seven patients with bilateral RF). The average time to revision after RF detection was three months (range, two days to twenty months). Pseudarthrosis was confirmed intraoperatively for all patients who underwent revision surgery except one patient with unilateral RF and had persistent back pain. Our strategy for revision surgery was using an increased number or size of rods, appropriate preparation of fusion base and ample graft material as previously described (21).

Risk factors for Rod Fracture

From univariate analysis, baseline patient characteristics considered as potential risk factors for RF included age (hazard ratio [HR] = 1.37; p = 0.003), weight (HR = 1.10; p = 0.003), BMI (HR = 1.32; p = 0.004) and ASA grade (HR = 1.67; p = 0.01) (Table II). Surgical factors considered included rod material (HR = 4.07 for cobalt chromium compared to stainless steel; p < 0.0001), rod diameter (HR = 1.71 for rod diameter 5.5 mm compared to rod diameter 6.35 mm; p =0.03 and HR = 7.85 for rod diameter 6 mm compared to rod diameter 6.35 mm; p = 0.006) and number of levels fused (HR = 1.12; p < 0.0001). Categorized high dose of rhBMP-2 per level fused (HR = 0.53; p = 0.002) was associated with a lower risk of RF (Table II). Baseline radiographic parameters considered as potential risk factors for RF included pelvic tilt (HR = 1.90 for pelvic tilt > 30° compared to pelvic tilt ≤ 30°; p = 0.002), thoracic kyphosis (HR = 1.02; p = 0.001), thoracolumbar kyphosis (HR = 1.02; p < 0.0001) and major coronal Cobb angle (HR = 1.01; p = 0.02). Early postoperative radiographic parameters considered as potential risk factors included pelvic tilt (HR = 1.71 for pelvic tilt > 30° compared to pelvic tilt ≤ 30°; p = 0.03), thoracic kyphosis (HR = 1.02; p = 0.005) and thoracolumbar kyphosis (HR = 1.03; p = 0.0008). The change of thoracolumbar kyphosis (HR = 0.98; p = 0.0002) and the change of major coronal Cobb angle (HR = 0.98; p = 0.001) were associated with a lower risk of rod fracture. (Table III).

The multivariate Cox proportional hazard model for cobalt chromium model with 5.5 mm rod diameter revealed that increased preoperative sagittal malalignment measured by C7-S1 sagittal vertical axis (HR, 1.07 [95% CI, 1.02 to 1.14] per 1-cm increase in sagittal vertical axis), increased thoracolumbar kyphosis (T10 – L2 angle) (HR, 1.02 [95% CI, 1.01 to 1.04] per 1-degree increase in thoracolumbar kyphosis angle) and increased number of levels fused for patients that received a low dose of rhBMP-2 (< 12 mg) compared to a high dose per level fused, (HR, 1.48 [95% CI, 1.20 to 1.82] per 1-level increase in the number of levels fused) were positive risk factors for RF. For model with cobalt chromium 5.5 mm rod diameter and stainless steel 6.35 mm rod diameter, positive risk factor associated with RF included increased preoperative sagittal malalignment measured by C7-S1 SVA (HR, 1.06 [95% CI, 1.02 to 1.10]

per 1-cm increase in sagittal vertical axis), increased thoracolumbar kyphosis (HR, 1.02 [95% CI, 1.005 to 1.03] per 1-degree increase in thoracolumbar kyphosis angle), increased number of levels fused for patients that received a low dose of rhBMP-2 (< 12 mg) compared to a high dose per level fused, (HR, 1.24 [95% CI, 1.09 to 1.41] per 1-level increase in the number of levels fused) and cobalt chromium 5.5 mm rod diameter compared to stainless steel 6.35 mm rod diameter (HR, 8.49 [95% CI, 4.26 to 16.89) (Table IV).

Health-related quality-of-life outcomes

There were 446 patients (84.8%) included in HRQOL outcomes analyses (84 patients (86.6%) with RF and 362 patients (84.4%) with no RF). Both groups had significant improvements in HRQOL, as measured by ODI ($p < 0.0001$) and all SRS scales ($p < 0.0001$). The overall longitudinal change of ODI ($p = 0.13$), SRS average ($p = 0.11$), SRS pain ($p = 0.70$), SRS function ($p = 0.06$) and SRS mental health domain scores ($p = 0.46$) were similar in both groups. However, patients with RF had significantly lower overall improvement in SRS satisfaction (0.93 versus 1.32; $p = 0.007$) and SRS self-image domain scores (0.72 versus 1.02; $p = 0.01$) (Fig.5).

Discussion

To our knowledge, this is the largest study to date to determine the incidence of and risk factors for rod fracture and evaluated the impact of rod fracture on health-related quality-of-life outcomes in adult spinal deformity patients undergoing long fusion to the sacrum. Our results demonstrated an overall rod fracture rate of 18.4%, which is consistent with prior study by Kim et al. (22). Of the patients who developed RF, greater than half (53%) had RF occurred within the first three years and RF still occurred up to ten years or more after index surgery (Fig.2). Akazawa et al. reported RF rate after long construct fusion for spinal deformity of 5.2%. Their study was limited by small number of subjects and heterogeneous population (18). Smith et al. analyzed RF rate following surgery for ASD and found RF

rate lower to our investigation (9% versus our rate of 18.4%). However, their study was limited by short follow-up period. In their study, patients without RF had a mean follow-up of 19 months (range 12 to 24 months) (16). Additional follow-up time could demonstrate additional rod fractures as found in our study.

Greater preoperative SVA was associated with a higher risk of RF which is consistent with prior reports. Smith et al. reported that patients who developed RF had significantly greater baseline SVA compared with those who did not developed RF (11.8 cm compared with 5.0 cm; p = 0.001) (16). Soroceanu et al. evaluated 246 adult patients who underwent surgical procedure to treat spinal deformity. The authors found that greater baseline SVA was independent risk factor for radiographical and implant-related complications (OR, 3.43 [95% CI, 1.75 to 6.73]) (14). As a consequence, patient with SVA translate anteriorly may have increased mechanical stress on the posterior implant. The anterior translation of the body mass causes an increase in the moment arm of the trunk which results in increasing the cyclic bending stress on the rods and increase tensile force posteriorly. In addition, tensile force through the posterior spinal graft leads to bone resorption and may contribute to the development of nonunion. As found in our study, RF occurred most commonly at lumbosacral junction, at the rate of 28% (Fig. 4). Difficulties achieving solid arthrodesis at the lumbosacral area seem to be associated with biomechanical demands at that level together with greater sagittal malalignment.

Patients with greater preoperative thoracolumbar kyphosis had a higher risk for RF. Prior reports have shown a significant relationship between a higher severity of thoracolumbar kyphosis and pseudarthrosis (22, 23). Biomechanical factors may contribute to increase likelihood of pseudarthrosis at thoracolumbar junction. These factors may include the transition from stiff thoracic kyphosis to a mobile lumbar lordosis along with the smaller bony surface of the posterior elements at T12-L1 (22). Our finding suggests that particular attention should be given to regional thoracolumbar alignment including

preoperative planning of correction, implant application and meticulous arthrodesis procedure might be appropriate.

Use of cobalt chromium 5.5 mm rod diameter compared to stainless steel 6.35 mm rod diameter was associated with a higher risk of RF. Akazawa et al. evaluated risk factor for RF in patients with spinal deformity and underwent correction and fusion surgery using titanium alloy or commercially pure titanium rod. They found that use of smaller-diameter rods (< 6 mm) increased risk of RF (OR, 16.3 [95% CI, 1.7 to 152.6])(18). An in vitro biomechanical study revealed that rod diameter influences rod stiffness to resist axial load to spinal instrumentation devices. The percentage of load transferred to the disc varies according to load and instrumentation stiffness (24). There is discordance within the literature regarding type of rod material on risk factor for RF. Smith et al. found that the rate of RF was significantly higher with cobalt chromium rods (14.2%) than with titanium alloy (2.4%) or stainless steel (3.8%) rods ($p = 0.025$) (16). While the previous report from the same authors group demonstrated the trend toward a lower RF rate with cobalt chromium rod (2.7%) compared with stainless steel rod (7.4%) and titanium alloy (8.6%). However, this study did not analyze the data in the patients who did not develop RF. Moreover, this study focused only symptomatic patient who developed RF which does not reflect any rod fractures that may have occurred without symptoms (17). Biomechanical properties determining rod stability include yield strength, stiffness, and fatigue life (25). However, the ideal biomechanical properties of the rods for spinal deformity surgery remain unknown. Future biomechanical and clinical studies are warranted to explore the potential protection benefits of rod material for spinal deformity surgery.

The effect of the number of levels fused on RF heavily depends on whether the patient received a low dose (< 12 mg) or high dose (≥ 12 mg) of rhBMP-2 per level fused. If the patient received a high dose of BMP/level fused, the total number of levels fused does not matter much (i.e., model with cobalt chromium 5.5 mm rod diameter: HR increase is only 1.13 per increase additional level fused, and the

confidence interval overlaps one). But if the patient received a low dose of rhBMP-2 per level fused, the total number of levels fused matters much more (i.e., model with cobalt chromium 5.5 mm rod diameter: HR increase is 1.48 per additional level fused). The effect of the total number of levels fused appears to be more severe for patients that received a low dose of rhBMP-2 per level fused. The finding that longer arthrodeses, especially when performed with use of relatively low dose of rhBMP-2, are associated with higher risk of RF may be due to increased risk of pseudarthrosis and/or increased biomechanical demands on the implants of the constructs. Arthrodesis of more than twelve vertebrae (p = 0.037) were identified as risk factor for pseudarthrosis in the literature prior to use of rhBMP-2, in which consisted of 232 patients with adult spinal deformity who underwent surgery with autogenous iliac bone graft alone (23).

Previous studies reported that three column osteotomies are associated with increased rate of RF (16, 17). While in our study, there were higher percentage of three column osteotomy patients in the RF group but the differences in RF rates were not statistically significant (Table 2). The senior authors strive to adopt methods of mitigating complications relating with three column osteotomies. At the site of the osteotomy, they may use multiple-rod constructs, perform interbody fusion for all large discs adjacent to osteotomy site, and/or use higher doses of rhBMP-2 and ample bone graft. These strategies seem to decrease the RF rate associated with three column osteotomies in our cohort (7, 26, 27) .

Regarding the context of our cohort, utilization of the median dose of rhBMP-2 per level fused at 12 mg, we also found that the patients who did not undergo interbody fusion procedure did not have higher risk factor for RF compared to the patients who underwent circumferential fusion procedure (transforaminal interbody fusion or anterior lumbar interbody fusion). Our findings were supported by previous studies (26, 28). Rahman et al. compared the nonunion rates at L5-S1 area between the patients who underwent posterolateral-only fusion utilization of 20 mg of rhBMP-2 posterolaterally at L5-S1 compared with the patients who underwent transforaminal interbody fusion cage placed with 6

mg of rhBMP-2 in the cage and 6 mg of rhBMP-2 used posterolaterally at L5-S1. They found no apparent nonunion in both groups (28).

Surprisingly, the occurrence of RF was not found to affect the improvement in ODI or SRS average domain. This may be due to 56% of the patients who developed RF showed no apparent clinical symptom as seen in our study. However, we found that patients who developed RF had less overall improvements in SRS-satisfaction and SRS self-image domain. To our knowledge, this study was the first to document the impact of RF on patient satisfaction. Compared with other SRS subscore domains and ODI scores, the improvement of self-image domain has been shown to be correlated most with patient satisfaction after adult deformity surgery to the sacrum at 5-year follow-up (correlation coefficient = 0.59; $P < 0.0001$) (29). The findings in the present study may reflect a long-term impact from specific types of complication after index operation. Other studies have demonstrated similar findings with worse patient satisfaction scores reported for patients who had major complications following index operation (14, 22, 30). With the increased emphasis on patient centered care, a better understanding of risk factors for this specific complication will improve long-term patient outcomes.

The strengths of our study include overall large number of patients evaluated and treated by the same two surgeons at a single institution, longer period of follow-up and the extensive amount of data recorded and analyzed. However, there are also various limitations of our study. One limitation is the retrospective study design. Despite the retrospective nature of this study, the data was extensively collected. Only osteoporotic data that was not available for all of the patients in the cohort. As with any long term study, the drop-out rate may confound the findings of the study; 46% of the patients were available for follow-up five-year after index surgery. We did not evaluate the fusion status and it is likely that RF occurrence reflect a combination of pseudarthrosis and mechanical instrumentation failure. However, we do not routinely obtain computed tomography scans postoperatively unless the patient is symptomatic or we suspect for pseudarthrosis. Finally, we used only cobalt chromium and stainless steel

rods in the majority of patients in our cohort. There were only two patients that underwent spinal fusion with use of titanium alloy rods. The absence of titanium alloy material rods did limit the generalizability of our results toward patients that use this material rod.

In conclusion, this study highlights the relatively high rod fracture rate (18.4%) after the primary surgical procedure. Greater sagittal vertical axis, greater thoracolumbar kyphosis, increased in number of levels fused for patient received < 12 mg of rhBMP-2 per level fused and cobalt chromium 5.5 mm rod were associated with rod fracture risk. Health-related quality of life for patients who developed rod fracture improved, although patient satisfaction and self-image improvement were less than patients who did not develop rod fracture. Patients need longer follow-up time up to ten years to detect rod fracture following surgical procedure to treat adult spinal deformity. Rod fracture occurrence may be minimized by carefully evaluation of spinal alignment, fusion termination and meticulous implant selection.

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Table I Characteristics of the Index Cohort

Parameter	Findings
Age* (yrs)	56.8 ± 10.5
Female sex†	456 (86.7%)
Weight* (kg)	70.7 ± 15.1
BMI* (kg/m^2)	27.1 ± 4.9
Ever smoked†	173 (32.9%)
Diabetes†	27 (5.1%)
Osteoporosis†‡	96 (22.3%)
Prior spine surgery†	270 (51.3%)
ASA†	
ASA 1	27 (5.1%)
ASA 2	405 (77.0%)
ASA 3	94 (17.9%)
Rod material†	
Cobalt chromium	196 (37.2%)
Stainless steel	325 (61.8%)
Titanium alloy	2 (0.4%)
Cobalt chromium and stainless steel	3 (0.6%)
Rod diameter†¶ (mm)	
5.5	348 (66.4%)
6.0	7 (1.3%)
6.35	149 (28.4%)
Combination rod diameters	20 (3.8%)
Number of Rods in construct†	
2-rod	416 (79.1%)
3-rod	72 (13.7%)
4-rod	38 (7.2%)
Number of Levels fused§	9 (8)
Pedicle subtraction osteotomy†	96 (18.3%)
Three-column osteotomy†	111 (21.1%)
Interbody fusion†	307 (58.4%)
Transverse connector use†	356 (67.7%)
Pelvic Fixation†	495 (94.1%)
BMP-2 posterior†	517 (98.3%)
BMP-2 interbody†	284 (54.0%)
Total dose of BMP-2*	121 ± 73.9

*The values are given as the mean and the standard deviation.

†The values are given as the number of patients, with the percentage of cohort in parentheses.

§ The values are given as the median, with the interquartile range (defined as the 75th minus 25th percentile) in parentheses.

‡ Data unavailable for ninety-six patients.

¶ Data excluded for two patients with rod fracture at additional rods.

Table II Univariable Analysis of Baseline Demographic Characteristics and Surgical Parameters as Risk Factors for the Occurrence of Rod Fracture within the Study Period

Parameter	Non Rod Fracture (N = 429)	Rod Fracture (N = 97)	P Value#	HR (95% CI for HR)
Baseline Demographic				
Age* (yrs)	56.3 ± 10.7	59.0 ± 9.2	0.003	1.37 (1.11 - 1.70)
Female Sex†	377 (87.9%)	79 (81.4%)	0.06	0.61 (0.37 - 1.02)
Weight* (kg)	69.7 ± 14.5	75.2 ± 16.5	0.003	1.10 (1.03 - 1.17)
BMI* (kg/m^2)	26.8 ± 4.9	28.5 ± 5.0	0.004	1.32 (1.09 - 1.59)
Ever smoked†	141 (32.9%)	32 (33.0%)	0.82	1.05 (0.69 - 1.60)
Diabetes†	21 (4.9%)	6 (6.2%)	0.72	1.16 (0.51 - 2.67)
Osteoporosis†§	77 (22.1%)	19 (23.5%)	0.21	1.39 (0.83 - 2.32)
Prior spine surgery†	219 (51.0%)	51 (52.6%)	0.64	1.10 (0.74 - 1.64)
ASA†:			0.01	1.67 (1.12 - 2.50)
ASA 1	27 (6.3%)	0 (0%)		
ASA 2	328 (76.5%)	77 (79.4%)		
ASA 3	74 (17.2%)	20 (20.6%)		
Surgical Factor				
Rod material†:				
Cobalt chromium††	149 (35.1%)	47 (49.0%)	<0.0001	4.07 (2.59 - 6.40)
Stainless steel††	276 (64.9%)	49 (51.0%)	*reference*	*reference*
Rod diameter† (mm):				
5.5‡‡	277 (67.6%)	71 (75.5%)	0.03	1.71 (1.04 - 2.79)
6.0‡‡	5 (1.2%)	2 (2.1%)	0.006	7.85 (1.79 - 34.4)
6.35‡‡	128 (31.2%)	21 (22.3%)	*reference*	*reference*
Number of Rods in construct†:				
2-rod	342 (79.7%)	74 (76.3%)	0.92##	1.04 (0.44 - 2.46)
3-rod	56 (13.0%)	16 (16.5%)	0.64##	0.79 (0.29 - 2.13)
4-rod	31 (7.2%)	7 (7.2%)	*reference*	*reference*
Number of Levels fused‡	8 (8)	14 (7)	<0.0001	1.12 (1.07 - 1.18)
Pedicle subtraction osteotomy†	77 (18.0%)	19 (19.6%)	0.86	1.04 (0.63 - 1.73)
Three-column osteotomy†	89 (20.8%)	22 (22.7%)	0.69	1.10 (0.68 - 1.78)
Interbody fusion†	244 (56.9%)	63 (65.0%)	0.42	1.19 (0.78 - 1.81)
Interbody fusion approach†:				
ALIF	60 (14.0%)	14 (14.4%)	0.23	0.67 (0.35 - 1.28)
TLIF	184 (42.9%)	49 (50.5%)	0.09	1.47 (0.95 - 2.28)
no interbody fusion	185 (43.1%)	34 (35.1%)	*reference*	*reference*
Transverse connector use†	282 (65.7%)	74 (76.3%)	0.40	1.22 (0.76 - 1.97)
Pelvic Fixation†	401 (93.5%)	94 (96.9%)	0.14	2.37 (0.75 - 7.48)
BMP-2 posterior†	422 (98.4%)	95 (97.9%)	0.90	0.91 (0.22 - 3.73)
BMP-2 interbody†	223 (52.0%)	61 (62.9%)	0.35	1.22 (0.80 - 1.85)
Categorized high dose of BMP-2 per level fused (≥ 12 mg)†§§	243 (56.6%)	38 (39.2%)	0.002	0.53 (0.35 - 0.79)

*The values are given as the mean and the standard deviation.

†The values are given as the number of patients, with the percentage of rod fracture group in parentheses.

‡The values are given as the median, with the interquartile range (defined as the 75^{th} minus 25^{th} percentile) in parentheses.

§In the non-rod fracture group, data unavailable for eighty patients. In the rod fracture group, data unavailable for sixteen patients.

#Except where noted, p-values compare patients without and with a rod fracture detected by Cox proportional hazards regression. Hazard ratios (HR) express the risk of rod fracture detection during the study period. For dichotomous factors, the reference level for the HR is absence of the factor. For all other factors, HR are expressed for the following change in the factor: decade increase in age, 5 kg increase in weight, 5 kg/m^2 increase in BMI, one-category increase in ASA, cobalt chromium compared to stainless steel rod material as reference, 5.5 and 6.0 rod diameter compared to 6.35 as reference, 1-level increase in the number of levels fused and interbody fusion approach compared to no interbody fusion as reference.

##P-value compares patients without and with a rod fracture by logistic regression (since the proportional hazards assumption could not be satisfied). Odds ratios (ORs) with 95% CI for the ORs express the odds of rod fracture detection during the study period where 4-rod is the reference level. Logistic regression does not consider when the rod fracture or censoring occurred and does not assume that the influence of covariates is constant over the study period.

†† If the patient underwent rod fracture, data are specific to the fractured rod (bilateral fractures have the same rod material for both fractures). If the patient did not undergo rod fracture, data include the material used across all rods (right, left and additional rods). Data excluded for 3 patients with both CC and SS material, and 2 patients with titanium alloy material.

‡‡ If the patient underwent rod fracture, data are specific to the fractured rod (s). If the patient did not undergo rod fracture, data include the diameter(s) used across the main rods (right and left). Data excluded for 2 patients with rod fracture that occurred at additional rods and 20 patients with combination rod diameters.

§§ Dose of BMP-2 per level fused was analyzed as a categorized variable (high dose versus low dose using a median split of 12 mg).

Table III Univariable Analysis of Baseline, Two-month Postoperative and Two-month Postoperative Correction of Radiographic Parameters as Risk Factors for the Occurrence of Rod Fracture within the Study Period

Radiographic Parameter	Non Rod Fracture (N = 429)	Rod Fracture (N = 97)	P Value§	HR (95% CI for HR)
C7-S1 Sagittal vertical axis* (cm)				
Baseline	6.5 ± 7.1	7.0 ± 6.9	0.55	1.01 (0.98 - 1.04)
At 2 month postoperatively†	2.0 ± 4.2	2.3 ± 4.2	0.39	1.02 (0.98 - 1.07)
Correction†	-4.2 ± 5.6	-4.7 ± 6.7	0.88	0.99 (0.96 - 1.03)
Pelvic tilt categorized‡				
Baseline: ≤ 30°	294 (68.5%)	51 (52.6%)	*reference*	*reference*
> 30°	135 (31.5%)	46 (47.4%)	0.002	1.90 (1.27 - 2.83)
At 2 month postoperatively†:≤ 30°	360 (85.9%)	74 (77.9%)	*reference*	*reference*
> 30°	59 (14.1%)	21 (22.1%)	0.03	1.71 (1.05 - 2.77)
PI minus LL mismatch* (°)				
Baseline	21.4 ± 21.6	21.7 ± 24.5	0.94	1.00 (0.99 - 1.01)
At 2 month postoperatively †	6.7 ± 15.3	7.0 ± 15.9	0.51	1.01 (0.99 - 1.02)
Correction†	-14.6 ± 15.1	-14.7 ± 19.1	0.67	1.003 (0.99 - 1.02)
Thoracic Kyphosis* (T5-T12) (°)				
Baseline	29.1 ± 18.6	35.9 ± 20.5	0.001	1.02 (1.01 - 1.03)
At 2 month postoperatively†	32.8 ± 13.9	36.7 ± 13.2	0.005	1.02 (1.01 - 1.04)
Correction†	4.0 ± 12.6	1.0 ± 17.3	0.10	0.99 (0.97 - 1.002)
Thoracolumbar Kyphosis* (°)				
Baseline	13.1 ± 18.4	24.1 ± 23.3	<0.0001	1.02 (1.02 - 1.04)
At 2 month postoperatively†	6.3 ± 12.4	10.3 ± 14.8	0.0008	1.03 (1.01 - 1.04)
Correction†	-6.6 ± 15.4	-14.0 ± 19.3	0.0002	0.98 (0.97 - 0.99)
Major coronal Cobb angle* (°)				
Baseline	47.6 ± 23.8	53.6 ± 27.1	0.02	1.01 (1.001 - 1.02)
At 2 month postoperatively†	24.2 ± 16.5	24.5 ± 18.8	0.76	1.00 (0.99 - 1.01)
Correction†	-23.7 ± 17.3	-29.1 ± 17.7	0.001	0.98 (0.97 - 0.99)

*The values are given as the mean and the standard deviation. PI = pelvic incidence, LL = lumbar lordosis.

† Postoperative and correction data exclude measurements collected after a non-rod fracture revision (10 and 2 measurements excluded from the non-rod fracture and the rod fracture groups, respectively). Correction is calculated by subtracting the baseline value from the postoperative value.

‡The values are given as the number of patients, with the percentage of rod fracture group in parentheses. To satisfy the proportional hazards assumption, pelvic tilt was categorized (30° or less versus greater than 30° based on the functional form of martingale residuals).

§P-values compare patients without and with a rod fracture detected by Cox proportional hazards regression. With the exception of pelvic tilt, hazard ratios (HR) express the risk of rod fracture detection during the study period for a 1-unit increase in the parameter. For pelvic tilt categorized, ≤ 30° is the reference level for the HR.

Table IV Results of Multivariable Analysis of Independent Risk Factors for the Occurrence of Rod Fracture within Six Years of Surgery		
Model with Cobalt Chromium Model with 5.5 mm Rod Diameter (N=177: 135 non-rod fracture, 42 rod fracture)*		
Risk Factor	**Rod Fracture Risk†**	**P value†**
Age (per decade increase)	1.10 (0.77 - 1.58)	0.59
BMI (per 5 kg/m^2 increase)	1.33 (0.95 - 1.87)	0.10
Interbody fusion approach: Transforaminal lumbar interbody fusion no interbody fusion	 1.08 (0.41 - 2.83) *reference*	 0.88 *reference*
Sagittal vertical axis (per 1-cm increase)	1.07 (1.02 - 1.14)	0.01
Thoracolumbar kyphosis (per 1-degree increase)	1.02 (1.01 - 1.04)	0.004
Number of levels fused	n/a	0.0003
Categorized high dose of BMP-2 per level fused	n/a	0.05
Effect of 1-level change in number of levels fused by categorized high dose of BMP-2/level fused: low dose (< 12 mg) high dose (≥ 12 mg)	 1.48 (1.20 - 1.82) 1.13 (0.98 - 1.31)	 0.0003 0.09
Model with Cobalt Chromium 5.5 mm Rod Diameter and Stainless Steel 6.35 mm Rod Diameter (N=327: 268 non-rod fracture, 59 rod fracture)		
Risk Factor	**Rod Fracture Risk†**	**P value†**
Age (per decade increase)	1.12 (0.86 - 1.45)	0.40
BMI (per 5 kg/m^2 increase)	1.15 (0.89 - 1.50)	0.28
Interbody fusion approach: Anterior lumbar interbody fusion Transforaminal lumbar interbody fusion no interbody fusion	 0.56 (0.06 - 5.03) 1.08 (0.52 - 2.26) *reference*	 0.61 0.84 *reference*
Sagittal vertical axis (per 1-cm increase)	1.06 (1.02 - 1.10)	0.008
Thoracolumbar kyphosis (per 1-degree increase)	1.02 (1.005 - 1.03)	0.008
Rod material-diameter: cobalt chromium 5.5 mm stainless steel 6.35 mm	 8.49 (4.26 - 16.89) *reference*	 <0.0001 *reference*
Number of levels fused	n/a	0.0008
Categorized high dose of BMP-2 per level fused	n/a	0.24
Effect of 1-level change in number of levels fused by categorized high dose of BMP-2/level fused: low dose (< 12 mg) high dose (≥ 12 mg)	 1.24 (1.09 - 1.41) 1.09 (0.96 - 1.24)	 0.0008 0.19
*Model excludes one non-rod fracture patient with anterior lumbar interbody fusion approach. †The values are given as the hazard ratios, with the 95% CI in parentheses. P-values and hazard ratios are adjusted for all other risk factors in the model. Hazard ratios (HRs) are not reported for main effects that are included in the interaction (i.e., number of levels fused and categorized high dose of BMP-2 per level fused). For the interaction, p-values and HRs separately for patients that did and did not receive a high dose of BMP-2 per level fused are from statistical contrasts that express the risk of rod fracture for each level increase in the number of levels fused.		

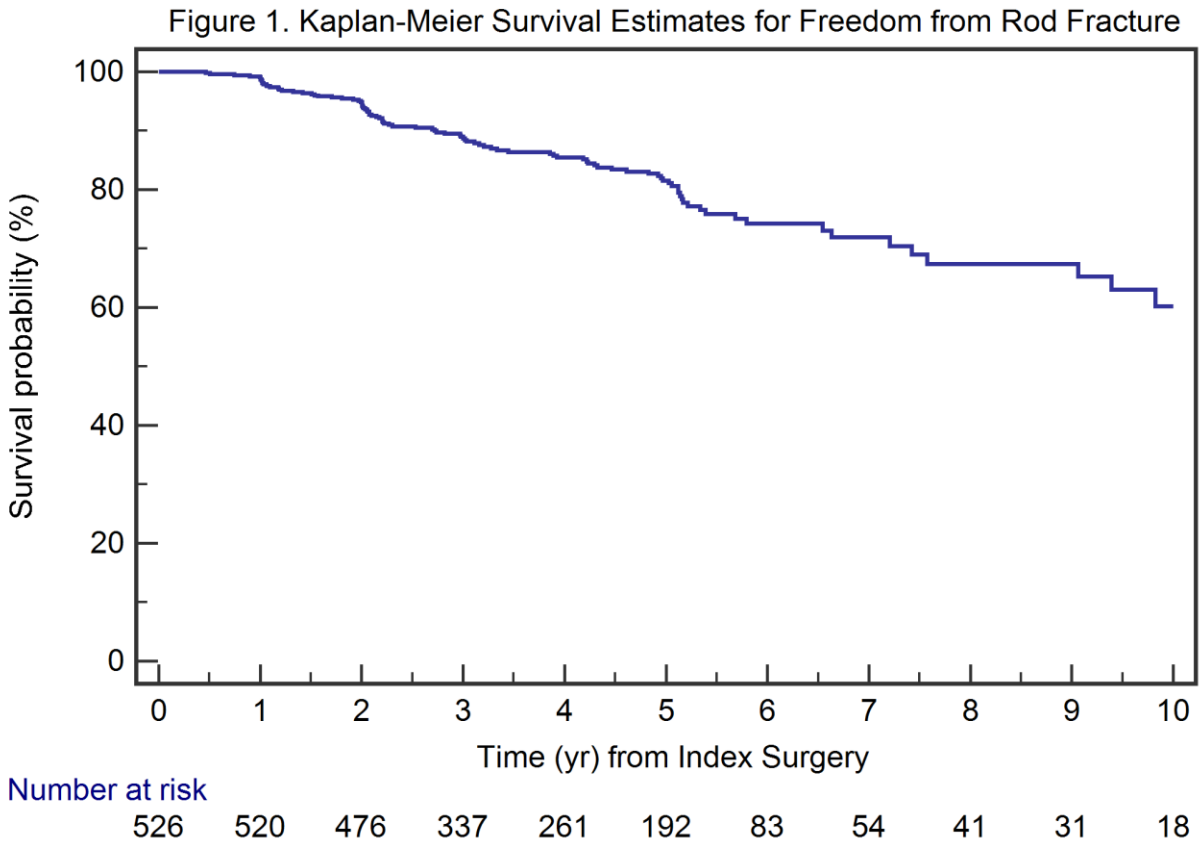

Fig. 1 The Kaplan-Meier plot shows the probability of survival to a first rod fracture event.

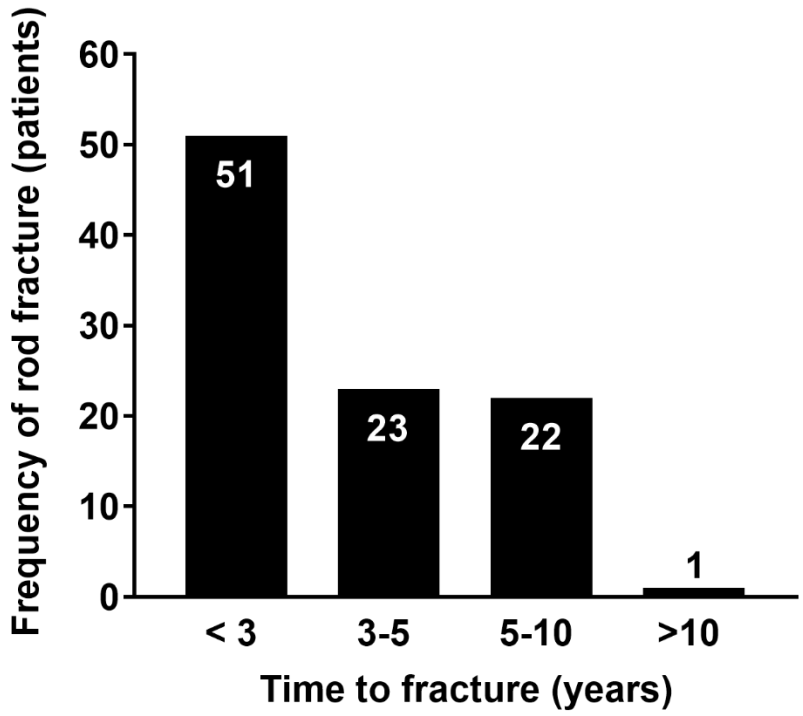

Fig. 2 Graph depicting the frequency of rod fractures corresponding to time interval from index surgery.

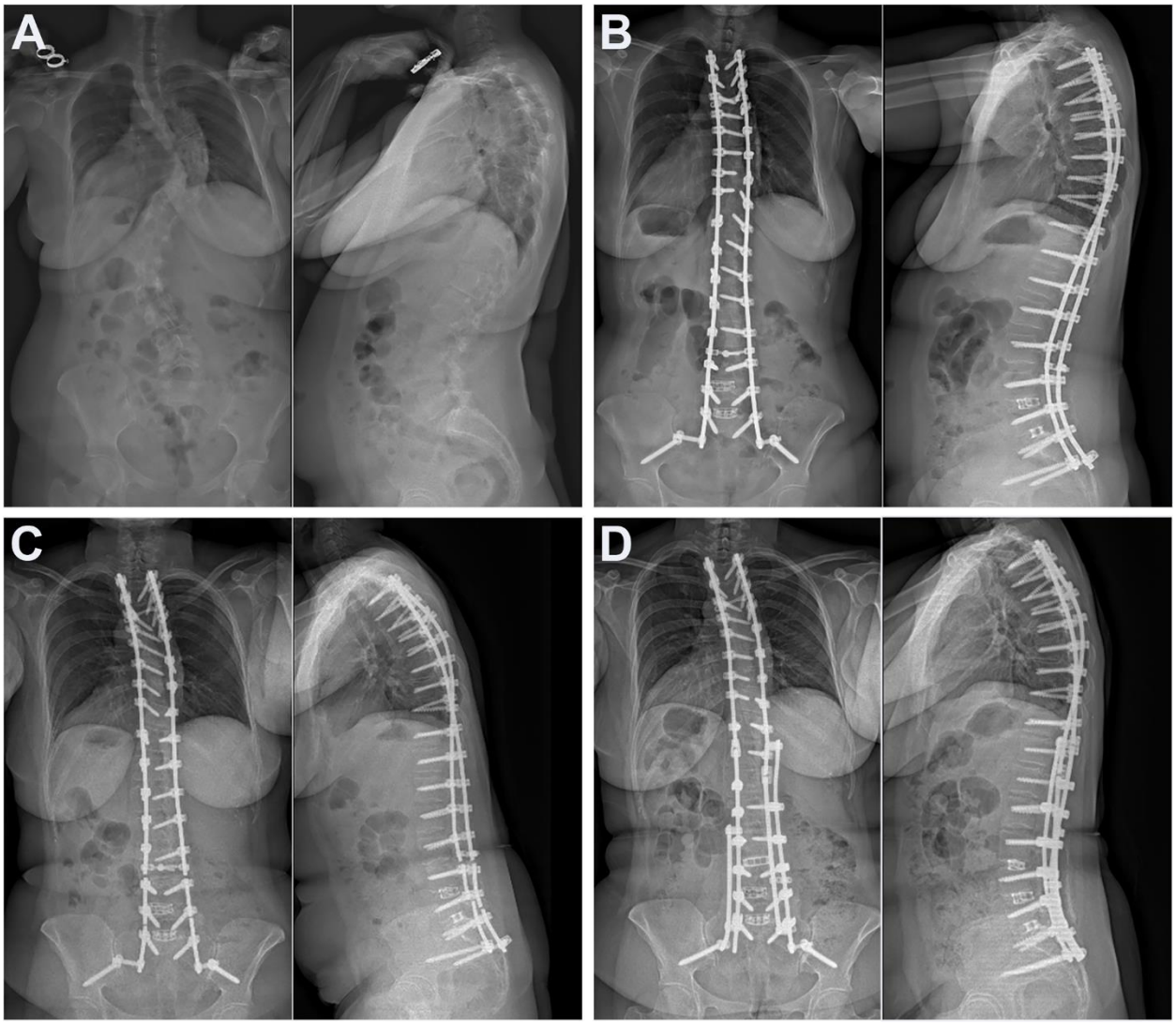

Fig. 3 A 39-year old woman underwent posterior segmental spinal instrumented fusion from T3 to sacrum and posterior interbody fusion from L4 to sacrum for adult idiopathic scoliosis (Fig. 3-A). Two months postoperative standing radiographs demonstrate well reduced and balance spine (Fig.3-B). Four years postoperative standing radiographs revealed bilateral rod fracture occurrence at L3-L4 and lumbosacral area with progressive global sagittal imbalance (Fig. 3-C). Revision posterior spinal instrumentation and posterior interbody fusion at L3 to L4 was performed to repair rod fracture and pseudarthrosis at L3-L4 and lumbosacral area (Fig. 3-D).

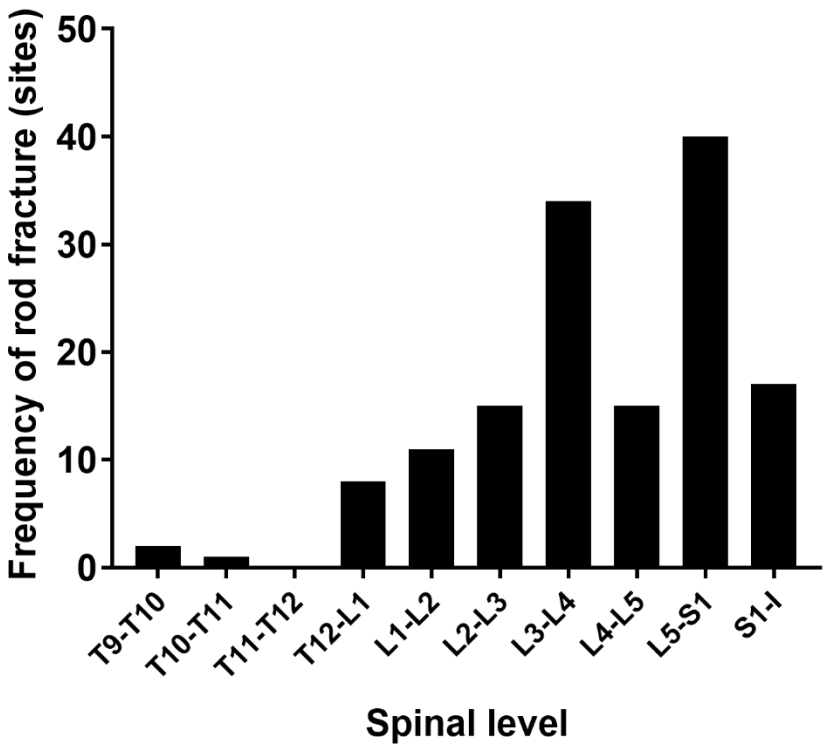

Fig. 4 Graph shows the frequency of rod fractures versus vertebral level. There were 143 fracture sites among 97 patients. S1-I indicates sacro-iliac level.

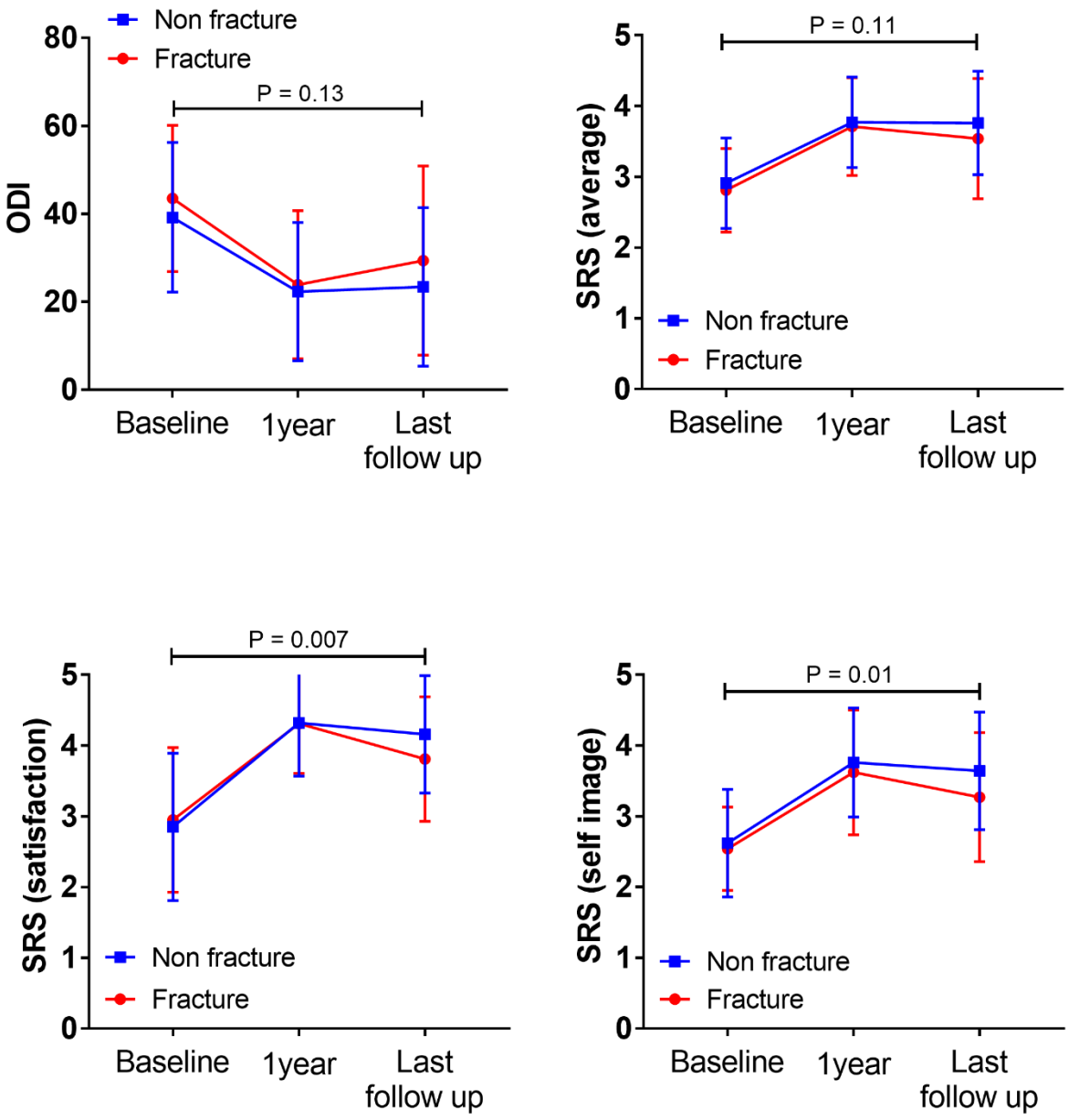

Fig. 5 Patient-report outcomes (ODI, SRS-average, SRS-satisfaction and SRS self-image) over time in the group that developed rod fracture and the group that did not develop rod fracture. The error bars indicate standard deviation. P-value detect the statistical difference between the two groups for the longitudinal change over time. $P < 0.05$ was considered to be statistical significance.