Beam-Like rods do not Provide Additional Improvement to Thoracic Kyphosis Restoration when Compared to Sagittal Reinforced rods in Adolescents Undergoing Spinal Fusion with Pedicle Screw Instrumentation for Idiopathic Scoliosis

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■ OBJECTIVE: **Operative treatment of adolescent idiopathic scoliosis (AIS) with posterior spinal fusion aims for three-dimensional correction of coronal curve and thoracic kyphosis. Our aim was to compare two different designs of asymmetrical rods in adolescents who underwent a posterior spinal fusion with pedicle screw instrumentation for AIS with an emphasis on thoracic kyphosis restoration.**

■ METHODS: **This study was made with 76 consecutive adolescents (mean age 15.6 years, SD 2.0). Thirty-nine patients were operated with sagittal reinforced rods and 37 patients were operated with beam-like rods. The clinical and radiological results were assessed preoperatively, postoperatively, and during the follow-up visits at the outpatient clinic 6 months and 2 years after the surgery.**

■ RESULTS: **At the last follow-up, the mean (SD) major thoracic curves were 13° (6.2°) and 13° (6.0°) ($P = 0.717$). Correction percentages were 75% in the sagittal reinforced group and 73% in the beam-like rod group ($P = 0.517$). The mean (SD) thoracic kyphosis was 24° (11°) and 22° (7.8°) at the two year follow-up in the sagittal reinforced rod group and beamlike rod group ($P = 0.517$). There was a slight negative correlation between the major curve correction and thoracic kyphosis change in both groups, although this was not statistically significant (R = −0.19, $P = 0.094$ in the sagittal reinforced rod group, R = −0.16, $P = 0.180$ in the beam like rod group).**

■ CONCLUSIONS: **There are no significant differences in the coronal or sagittal deformity restoration in adolescent patients who underwent a posterior spinal fusion with sagittal reinforced rods and beam-like rods for adolescent idiopathic scoliosis.**

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) may lead to physical and psychosocial impairment depending on its severity.[1-3] Progressive deformities over 45° usually require operative treatment to prevent further progression of scoliosis.[4] Operative treatment with posterior spinal fusion aims for three-dimensional correction of both coronal curve and thoracic kyphosis (TK).[5] AIS is often associated with lowered thoracic kyphosis (i.e., hypokyphosis).[6] Thoracic hypokyphosis may cause pulmonary dysfunction and affect negatively the health-related quality of life.[7-10] Lenke classification for AIS categorizes TK as hyperkyphosis (>40°), normal kyphosis (10°−40°), and hypokyphosis (<10°).[11]

Previous techniques for deformity correction in AIS included Harrington instrumentation and hook-based instrumentation.[12,13] These techniques provide acceptable deformity correction for thoracic curves. However, loss of correction and loss of lumbar lordosis was typical in deformities with double major curves or significant lumbar curvatures. Modern spinal fusion is typically performed with posterior pedicle screw instrumentation and contoured bilateral rods, which provides effective coronal and

Key words
- Adolescent idiopathic scoliosis
- Beam-like rods
- Pedicle screw instrumentation
- Posterior spinal fusion
- Sagittal reinforced rods
- Thoracic kyphosis

Abbreviations and Acronyms
AIS: Adolescent idiopathic scoliosis
MT: Main thoracic
SD: Standard deviation
SRS-24: Scoliosis Society Score 24
TK: Thoracic kyphosis

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axial deformity correction.[14,15] Restoring the thoracic hypokyphosis remains a challenge with this technique. Pedicle screw instrumentation tends to further flatten the sagittal plane.[16] Improved TK restoration has been reported with stiffer rods.[6,17-20] Several operative techniques have been described to address the TK restoration, but no definitive solution has been found.

Asymmetric profile rods have been developed to increase the stiffness of the construct.[18,21] Optimal instrumentation providing the best coronal correction and sagittal alignment control has not yet been established. There is evidence that partially reinforced rods restore the TK more effectively than fully reinforced rods.[6] Since pedicle screws are fixed to the rod and these 2 ultimately work together as a single biomechanical construct, different pedicle screw options also require further exploration. Nevertheless, effects of the changes in the implant design on surgical outcomes should be investigated in detail in a postmarketing study before implementing these products worldwide. There are no previous comparisons between the tulipine and dual cup pedicle screw instrumentation using asymmetric rod profiles.

In this study, we aimed to compare sagittal reinforced rods to beam-like rods in adolescent patients who underwent a posterior spinal fusion with pedicle screws for idiopathic scoliosis. We hypothesize that dual cup pedicle screws with beam-like rods would provide improved correction of thoracic hypokyphosis with similar main curve correction to tulipine pedicle screws with sagittal reinforced rods.

PATIENTS AND METHODS

Two different types of instrumentation were used in our institution for AIS surgery between 2015 and 2020. The first group of consecutive patients treated between 2015 and 2017 were operated with sagittal reinforced rods, and the patients treated with beam-like rods were operated between 2018 and 2020. Thirty-nine patients with AIS treated with sagittal reinforced rods and 37 patients treated with beam-like rods were prospectively enrolled in a comparative cohort study. All operations were performed in a single tertiary university hospital.

The patients followed a standardized protocol, including preoperative and immediate postoperative assessment, and follow-up visits at the outpatient clinic at 6 months and 2 years. All patients had a minimum of 6 months follow-up (mean 5.8 years and 2.8 years in the sagittal reinforced and beam-like rod group, respectively). The ethical committee approved the study (ETMK 38/1800/2015) and all patients provided informed consent to participate in this follow-up study. Patients with curves classified as Lenke 5 or 6 (thoracolumbar/lumbar main curve) were excluded.

Surgical Technique

All procedures were performed by a senior orthopedic spine surgeon using a standardized approach. Segmental posterior spinal fusion was performed bilaterally along with en bloc direct vertebral derotation. Pedicle screws were inserted using the freehand technique according to Kim et al.[22] Smith-Petersen osteotomies were performed when necessary. Placement of the pedicle screws was verified using intraoperative three-dimensional imaging.[23] The selection of fusion levels was standardized according to the internationally accepted criteria and was based on the Lenke classification.[11] The lower end vertebra was selected according to the central sacral vertical line last substantially touched vertebra (Lenke 1 and 2 curves)[24] and L3 or L4 for Lenke 3 and 4 curves. Sagittal reinforced rods (6.0 CoCr Apex Rod, Solera 5.5/6.0 Instrumentation [Medtronic, Minneapolis, Minnesota, USA]) with tulipine pedicle screws or beam-like rods (Mesa 2 Spinal Deformity [Stryker, Portage, Michigan, USA]) with dual cup pedicle screws were used. The screw placement was standardized. Cranially, the construct ended with 2 or 3 pairs of polyaxial pedicle screws, the mid and lower thoracic levels were instrumented with fixed-head sagittal adjusting screws (Medtronic) or uniplanar screws (Stryker), and polyaxial screws were used in the lumbar levels. Motor evoked potentials, somatosensory potentials, and electromyography was used for intraoperative neurophysiological monitoring.

Health-Related Quality of Life Assessment

The Scoliosis Society Score 24 (SRS-24) questionnaire was used to assess the health-related quality of life of the patients.[25] The scores were collected preoperatively, at 6 months, and at 2-year follow-ups. SRS-24 is a 24-item questionnaire, in which each item is scored on a five-point Likert scale from 1 to 5 with a maximum score of 120 (corresponding a mean maximum of 5.0). A higher score indicates better patient outcomes. The questionnaire has 7 domains: pain, general self-image, general function, general activity level, postoperative self-image, postoperative function, and patient satisfaction.

Radiographic Parameters

Standing posteroanterior and lateral radiographs were collected preoperatively, postoperatively, at 6 months, and 2-year follow-up. Bending radiographs were taken preoperatively. Scoliosis curvatures were measured with Cobb angle from proximal thoracic, main thoracic (MT), and lumbar curves. TK (T5–T12) and lumbar lordosis (T12–S1) were measured from the lateral radiographs. The deformities were classified according to the Lenke classification.[11] TK $<10°$ was considered hypokyphosis.[26] Radiographic measurements were performed by an independent observer.

Statistical Analyses

The normal distribution assumption of the data was verified visually with Quantile-Quantile-plot and with the Shapiro–Wilk test. Descriptive analyses were reported as the means and standard deviations (SDs), or absolute numbers and percentages. Significant associations among categorical variables were investigated by the χ^2 test or Fisher exact test. The comparisons between the study groups were performed using a two-sample t test, one-way analysis of variance, or the Wilcoxon rank-sum test. The correlation between the main thoracic curve correction and TK restoration was calculated with the Kendall correlation coefficient. The statistical significance level was set at $P < 0.05$. Analyses were conducted in R (R 4.1.1, R Core Team, 2020).

RESULTS

The preoperative characteristics of the study groups are presented in Table 1. The mean age at surgery was 15.8 (SD, 2.1) and 15.4 (SD, 1.9) years in reinforced rod and beam-like rod groups, respectively (P = 0.193). The length of follow-up was significantly longer in the reinforced rod group (5.3 years; SD, 0.8) than in the beam-like rod group (2.8 years; SD, 1.3) (P < 0.005). The 2-year follow-up data were available in 39/39 (100%) of the patients in the sagittal reinforced rod group, and in 35/37 (95%) of the patients in the beam-like rod group. The mean intraoperative blood loss was 467 mL (range 100 mL–1570 mL) in the reinforced rod group and 525 mL (range 165 mL–1190 mL) in the beam-like rod group (P = 0.210). There were no significant differences in the distributions of gender or Lenke classification. The number of posterior column osteotomies and levels fused were similar in both groups (Table 1). The mean (SD) operative time was significantly shorter in the sagittal reinforced rod (2.7 hours; SD, 0.6 hours) than in the beam-like rod group (mean 2.9 hours; SD, 0.5 hours; P = 0.018). No neurological complications or deep surgical site infection occurred in any of the patients. One patient in the reinforced rod group underwent a reoperation with extension of the instrumentation for distal junctional kyphosis 1 year after the initial surgery without any further sequelae in the follow-up. There were no reoperations in the beam-like rod group. Additionally, there were no signs of mechanical complications (axial slip, screw breakage, rod fractures) in either group during the follow-up.

The mean (SD) MT curves were 54° (9.6) and 51° (5.3) preoperatively (P = 0.057), 13° (4.2) and 13° (5.1) after the surgery (P = 0.392), 11° (6.4) and 13° (6.1) at 6 months (P = 0.160), and 13° (5.9) and 13° (6.0) at the 2-year follow-up (P = 0.717) in the sagittal reinforced rod group and beam-like rod group, respectively (Table 2). The mean preoperative MT curves on bending radiographs were 36° (SD, 13°; range from 7° to 69°) in the sagittal reinforced rod group, and 34 (SD, 7.8°; range from 21° to 49°) in the beam-like rod group (P = 0.237). The mean MT curve correction was 75% in the sagittal reinforced group and 73% in the beam-like rod group at the 2-year follow-up (P = 0.467).

The mean (SD) TK was 21° (14.9) and 23° (13.9) (P = 0.302) preoperatively, 19° (6.5) and 19° (9.7) after the surgery (P = 0.397), 22° (6.8) and 20° (7.8) at 6 months (P = 0.165), and 24° (11.4) and 22° (7.8) at the 2-year follow-up (P = 0.517) in the sagittal reinforced rod group and beam-like rod group, respectively (Table 2, Figure 1). The mean change of TK was an increase of 3° in the sagittal reinforced rod group, and a decrease of 1° in the beam-like rod group (P = 0.855, Figure 1). The mean kyphosis correction was 42% in the sagittal reinforced rod group (range from −65% to +400%), and 32% in the beam-like rod group (range from −100% to +300%) (P = 0.744).

There was a slight negative correlation between the MT curve correction and TK change in both groups, although this was not statistically significant (R = −0.19, P = 0.094 in the sagittal reinforced rod group; R = −0.16, P = 0.180 in the beam-like rod group, Figure 2). Preoperative hypokyphosis (T5–T12 kyphosis <10°) was found in 7 patients in the sagittal reinforced rod group and 3 patients in the beam-like rod group (P = 0.205). At the last follow-up, 2 patients in the sagittal reinforced rod group and 1 patient in the beam-like rod group remained hypokyphotic (P = 0.587).

Table 1. Clinical Characteristics of the Groups

Characteristics	Sagittal Reinforced Rod Group (n = 39)	Beam-Like Rod Group (n = 37)	Significance
Age at surgery, years	15.8 (2.1)	15.4 (1.9)	0.193
Gender, M/F	10/29	10/27	0.89
Follow-up time, years	5.8 ± 0.8	2.8 ± 1.2	<0.001
Lenke classification, n (%)			
1	16 (42.1)	13 (37.1)	0.34
2	14 (36.8)	16 (45.7)	
3	3 (7.9)	5 (14.3)	
4	5 (13.2)	1 (2.9)	
Operative time, hours	2.7 (0.6)	2.9 (0.5)	0.018
Intraoperative blood loss, mL	467 (344)	525 (271)	0.210
Number of fused levels	11.3 (1.8)	11.6 (1.4)	0.200
Posterior column osteotomies, number	3.1 (0.2)	2.4 (0.3)	0.109
SRS-24 total score			
Preoperative	4.0 (0.7)	4.0 (0.5)	0.796
2-year follow-up	3.9 (0.6)	4.3 (0.3)	0.003

Values indicate mean and standard deviation (SD) unless otherwise specified.
M/F, male/female; SRS-24, Scoliosis Society Score 24.

Table 2. Radiographic Outcomes of the Study Groups

Radiographic Parameters	Sagittal Reinforced Rod Group (n = 39)	Beam-Like Rod Group (n = 37)	Significance
Main thoracic curve (°)			
Preoperative	54 ± 9.6	51 ± 5.3	0.057
Preoperative bending radiograph	36 ± 13	34 ± 7.8	0.237
Preoperative bending radiograph correction (%)	34 ± 17	33 ± 13	0.478
Postoperative	13 ± 4.2	13 ± 5.1	0.392
At 6 months	11 ± 6.4	13 ± 6.1	0.160
At 2 years	13 ± 5.9	13 ± 6.0	0.717
Curve correction (%)	75 ± 12	73 ± 12	0.467
Thoracic kyphosis (T5—T12, °)			
Preoperative	21 ± 15	23 ± 14	0.302
Postoperative	19 ± 6.5	19 ± 9.7	0.397
At 6 months	22 ± 6.8	20 ± 7.8	0.165
At 2 years	24 ± 11	22 ± 7.8	0.517
Lordosis (T12—S1, °)			
Preoperative	51 ± 12	57 ± 16	0.032
Postoperative	45 ± 9.8	46 ± 12	0.341
At 6 months	48 ± 13	49 ± 12	0.433
At 2 years	51 ± 11	50 ± 12	0.435

Values indicate mean ± standard deviation (SD) unless otherwise specified.

The total score of the SRS-24 questionnaire was significantly higher in the beam-like rod group than in the sagittal reinforced rod group at 2-year follow-up (mean, 3.9 vs. 4.3; P = 0.003) (Table 1). There were no other statistically significant changes between the study groups at this time point.

DISCUSSION

Surgical treatment of AIS aims for deformity correction on both coronal and sagittal planes. Restoration of TK has remained a challenge in posterior spinal fusion. In the current study, we found no significant differences in deformity correction between sagittal reinforced rods and beam-like rods in patients who underwent posterior spinal fusion for AIS.

Several factors have been shown to associate with postoperative TK: preoperative kyphosis,[8] rod diameter,[8,19] the density of the pedicle screws,[20] and surgical maneuvers all add up to the final three-dimensional deformity correction. The overall effect of underlying factors on the stability of the correction is not completely known. Increasing the diameter of circular rods does not seem to improve coronal deformity correction but may lead to better TK restoration.[19,20] Increased rod stiffness in asymmetrical axial profile rods has been reported to lead to better sagittal deformity correction.[6,17,18] However, the optimal asymmetrical rod profile remains unknown. According to our findings, there was no significant difference between the sagittal reinforced rods and beam-like rods concerning the TK change.

Corrective technique, rod diameter, and metal type may all play a role in kyphosis restoration.[20,27,28] The long-term effect of increased rod stiffness on spinal elements is unknown. It is hypothesized that increased rod stiffness might lead to decreased bone quality and increased risk of disk degeneration.[29,30] Increasing the rod stiffness may complicate the contouring of the rod and increase the risk of rod fractures. Posterior segmental distraction and overbending of the rods could serve as a solution method for improving the TK in patients with AIS. It is critical to give length to the posterior column by initially distracting the concave side to achieve adequate TK.[31] These maneuvers were used in both groups in the current study. Previous findings suggest that the overbending of the concave rod by 10° (or more) can help the restoration of patients with hypokyphosis but should be abstained in patients with normal TK.[32] In one study, instrumentation with high stiffness rods and high pedicle screw density on the concave side improved the sagittal deformity correction.[20] Partial beam-like rods have been reported to lead to better TK restoration with less flattening of the kyphosis as compared to full beam-like rods.[6]

Sagittal plane deformity is partially caused by coupling through rotational changes of the spine in adolescent idiopathic scoliosis. Sagittal reinforced rods provided similar coronal deformity correction but better TK restoration with less postoperative thoracic hypokyphosis when compared to circular rods in a previous study.[17] When compared to circular rods, beam-like rods

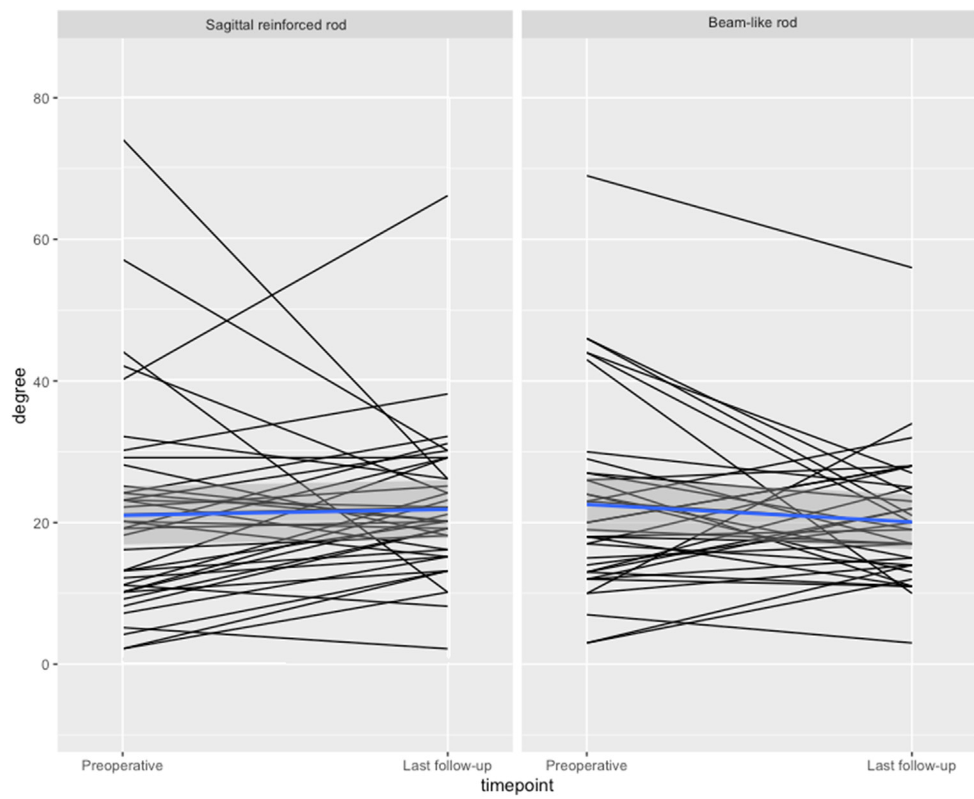

Figure 1. Change in the thoracic kyphosis (T5-T12) from preoperative to final follow-up.

were reported to lead to better coronal deformity correction with similar thoracic kyphosis decrease in both groups.[18]

The tulipine screw head and more specifically the 'sagittal adjusting screw' used in the apex of the deformity represents a fixed head screw containing a sliding saddle. We hypothesize that this type of screw provides a more biomechanically stable interface with the rods allowing an advanced three-dimensional correction of the apical area as compared with the dual cup locking screw head with less stability. This biomechanical superiority enhanced slightly both coronal and sagittal correction using the tulipine as compared with the dual cup locking instrumentation. In this context, the improved rod design of the beam-like rod versus sagittal reinforced rod could not overcome the limitations of the dual cup pedicle screws. Thus, increasing the biomechanical properties of the rods in terms of sagittal strength, did not lead to improved sagittal balance restoration. Even if filling the elastic pediatric pedicles with maximum-sized screws minor screw pullout occurs and this limit further the TK restoration.

In our study, there was a slight negative correlation between the loss of TK and coronal deformity correction although these findings were not statistically significant. This is in line with 2 previous studies which did not find a correlation between coronal deformity correction and change in TK in patients operated with beam-like rods.[6,18] Another study reported a negative correlation between the coronal deformity correction and the restoration of TK in patients with sagittal reinforced rods.[17]

TK was measured according to the recommendations of the Spinal Deformity Study Group Radiographic measurement manual between T5 and T12 to standardize the measurement of this parameter.[33] Measuring in this area may provide more accuracy because the visibility of the upper thoracic spine is limited due to the shoulder.[34] Measuring maximal TK would have been another option. However, midthoracic spine (T5–T12) is the area in which the apex of the main thoracic curve exists and also this area is most typically the lordotic one in contrast to the upper thoracic spine where kyphosis is more common even in AIS.[35]

The costs of the typical construct for a Lenke 1A curve (instrumentation between T4 and T12) would be approximately 7300€ for the sagittal reinforced group and 7550€ for the beam-like rod group, respectively. Thus, in terms of cost analysis, the difference is not a significant one.

Strengths and Limitations

The strengths of the current study include a standardized operative and follow-up protocol for all the patients. The data were collected prospectively and in a standardized manner. We used the SRS-24 questionnaire for the evaluation of patient-reported health-related outcomes. All patients in the sagittal reinforced group and 95% in

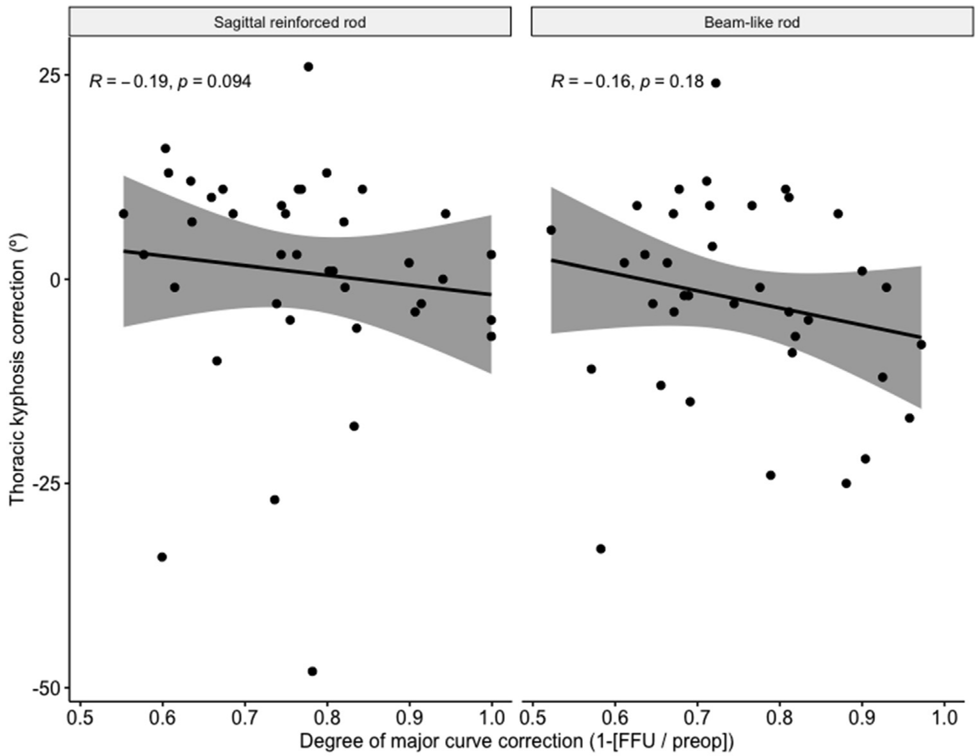

Figure 2. Correlation between the thoracic kyphosis correction (°) and degree of major curve correction (%) analyzed using the Kendall correlation coefficient.

the beam-like group reached minimum 2-year follow-up. The radiographic parameters (MT curve, TK, bending radiographs, Lenke classification) of the study groups were very similar preoperatively without any statistical tendencies for difference (mean values within two degrees, P values above 0.25 for all comparisons). The statistical power of this study with continuous variables and these standard deviations was more than 80% for the main outcome parameters: 90% for main thoracic curve, 80% for TK, and 94% for lumbar lordosis.

The current study represents a prospective cohort study with inherent bias since the first one was 'historical' and the second one current. In order to reduce the bias resulting from different overall follow-up times, the radiographic and health-related quality of life were followed at the 2-year follow-up time point in both study groups. Optimally 2 implant designs should be compared in a randomized clinical study. However, the first cohort presented at least similar radiographic outcomes than the second one, suggesting that the learning curve is not explaining the current findings. Additionally, preoperative radiographic parameters (main thoracic curve, TK, bending radiographs, Lenke classification) and surgical details (intraoperative blood loss, operative time, posterior column osteotomies) of the study groups were very similar without any statistical tendencies for any differences.

CONCLUSIONS

There were no significant differences in coronal deformity correction and TK restoration in adolescent patients who underwent a posterior spinal fusion with sagittal reinforced rods and beam-like rods for adolescent idiopathic scoliosis. In both rod design groups, the correction of coronal and sagittal deformity was sufficient. Further research on TK restoration is needed.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Eetu N. Suominen: Writing — original draft, Methodology. **Antti J. Saarinen:** Conceptualization, Methodology, Software. **Johanna Syvänen:** Methodology, Operation of the Patients, Writing — review & editing. **Matti Ahonen:** Operation of the Patients, Methodology, Writing — review & editing. **Linda Helenius:** Operation of the Patients, Writing — review & editing. **Ilkka J. Helenius:** Conceptualization, Operation of the Patients, Supervision, Writing — review & editing.

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