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Patient-Specific Rods in Adolescent and Adult Spinal Deformity Surgery: A Narrative Review

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ABSTRACT

Spinal deformity surgery often requires complex surgical interventions that can have a drastic effect on both patient quality of life and functional capacity. Modern-day corrective solutions for these deformities include spinal osteotomies, pedicle screw instrumentation, and dual/multirod constructs. These solutions are efficacious and are currently considered standard practice for spinal surgeons, but they lack individualization. Patient-specific rods (PSRs) are a novel technology that attempts to offer a personalized approach to spinal deformity correction based on preoperative computerized tomography scans. Moreover, PSRs may offer several advantages to conventional rods, which include achievement of desired rod contour angles according to surgical planning alignment goals, reduced operative time, and reduced blood loss. In adolescent idiopathic scoliosis, those instrumented with PSR have observed coronal Cobb reductions up to 74%. In adult spinal deformity, PSRs have offered superior correction in radiographic parameters such as sagittal vertical axis and pelvic incidence minus lumbar lordosis. However, there still remains a paucity of research in this area, mainly in health care expenditure, cost-effectiveness, and longitudinal clinical outcomes. The purpose of this article is to survey the current body of knowledge of PSR instrumentation in both adolescent and adult spinal deformity populations. The current strength, limitations, and future directions of PSRs are highlighted throughout this article.

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Keywords: patient-specific rods, adult spinal deformity, adolescent idiopathic scoliosis, adolescent spinal deformity, novel technology, Spine surgery

INTRODUCTION

Spinal deformities, including adult spinal deformity (ASD) and adolescent idiopathic scoliosis (AIS), represent complex musculoskeletal conditions that can significantly impact patients' quality of life and functional outcomes. ASD encompasses a spectrum of spinal disorders characterized by a combination of abnormal curvature of the spine, sagittal malalignment, and associated symptoms such as back pain, neurological deficits, and impaired mobility. The burden of ASD is expected to increase as the elderly population continues to grow.^{1,2} In contrast, AIS, which is the most common form of scoliosis in adolescents, is characterized by a curvature of the spine in the coronal plane as well as the sagittal and axial planes leading to a 3-dimensional deformity.^{3,4} In these young patients, coronal and sagittal malalignment can significantly impact long-term quality of life.^{5,6}

Spinal deformity surgery has undergone significant advancement in recent years, including advances in

technology, imaging modalities, and surgical techniques. Traditionally, surgery uses a combination of osteotomies and manually contoured instrumentation to obtain regional and global spinal alignment goals. Traditionally, rods are contoured by the surgeon to achieve the desired correction; however, this can result in rods that are over or under-contoured.⁷⁻⁹ Patient-specific rods (PSRs) have emerged as a solution to address these challenges by offering customized implants tailored to each patient's unique spinal anatomy and patient-specific radiographic alignment goals.^{7,10,11}

Despite early promising results, several challenges and considerations need to be addressed to optimize the utilization of PSRs in the management of ASD and AIS. These include cost-effectiveness, regulatory approval, surgical technique refinement, and long-term clinical outcomes assessment. Moreover, further research is needed to evaluate the comparative effectiveness of PSRs vs conventional implants, identifying patient selection criteria, and refine surgical indications.

In this article, we provide a comprehensive overview of the use of PSRs in the surgical management of ASD and AIS. We discuss the underlying principles and technological advancements of PSR technology, review the current evidence supporting its clinical efficacy and safety, examine the challenges and limitations associated with its adoption, and explore future directions.

RATIONALE, DEVELOPMENT, AND FABRICATION

PSRs are spinal implants designed to achieve the preoperatively planned regional and global alignment goals specific to each patient. By leveraging advanced imaging techniques, computer-aided design software, and additive manufacturing technology, PSRs offer tailored solutions for patients with complex spinal deformity.¹² Computer-aided design software provides tools for virtual surgical planning, allowing surgeons to design PSRs based on the patient's anatomy and surgical objectives.

One avenue in which PSRs can be obtained is selecting a "best match" rod from a set of prebent rods based on preoperative planning. Additional rod contouring and cutting can be performed to match the individual patient's anatomy.^{13–15} Other options include using a sterile 1:1 dimension paper template of a digitally created PSR that can be printed. This method can be used intraoperatively, and the surgeon can contour the rod to the template geometry.^{16,17} Similarly, rods can be intraoperatively contoured with a calibrated bender that is linked to a program using computer-aided design software.¹⁸ PSRs can also be obtained via industrial fabrication of bent rods based on preoperative computed tomography or magnetic resonance imaging.¹⁹

The concept of PSR stems from the recognition that spinal anatomy and alignment vary widely among individuals, making conventional spinal implants suboptimal in some cases.^{7,20} Conventional rods are typically manufactured in standard sizes and shapes, requiring intraoperative bending and contouring to fit the patient's anatomy. This manual adjustment process can be time-consuming and imprecise and may compromise the biomechanical integrity of the implant by creating multiple notches in the implant.^{21,22} In contrast, PSRs are precisely customized based on preoperative advanced imaging and machine-learning applications, allowing for optimal fit, alignment, and performance. With each case, new data are iteratively added into the machine-learning algorithms, allowing for more accurate plans to be produced over time.^{10,23}

SAGITTAL VERTICAL AXIS IN ASD

Although PSRs are an emerging technology in spinal deformity surgery, several articles have examined the relationship between PSRs and sagittal alignment, notably the effect of PSRs on achieving a goal sagittal vertical axis (SVA). In a retrospective case series, Barton et al found an SVA improvement (96.8 ± 56.8 mm to 21.8 ± 37.1 mm, $P < 0.001$) after corrective surgery in ASD patients.¹⁰ However, there was a significant difference in what the proprietary software's projected outcome was compared with the true postoperative outcome (14.3 ± 22.4 vs 21.8 ± 37.1 , $P = 0.002$).¹⁰ Sadrameli et al analyzed preoperative, planned, and postoperative spinopelvic parameters in a cohort of 17 patients who underwent ASD surgery with prefabricated rods compared with 27 patients who underwent ASD surgery with in situ bent rods. They found no significant difference between the planned SVA and achieved postoperative SVA (14.8 ± 17.2 mm vs 21.6 ± 44.5 mm, $P = 0.49$).¹² However, the authors concluded that PSRs allowed for improved spinopelvic alignment and postoperative spinopelvic alignment within the preoperatively planned goal.¹² Faulks et al prospectively reviewed 20 patients who underwent ASD surgery using PSRs. They found that their planned SVA correction correlated with their postoperative results.²⁴ However, in cases with longer-term follow-up, some of the achieved correction was lost with proximal junction kyphosis (PJK).²⁴

In another study examining planned and actual outcomes for the use of PSRs, Kleck et al reported a preoperative SVA improvement from 66.8 ± 48.2 mm to 9.8 ± 33.9 mm at 2-year follow-up.²⁵ This study included 34 patients with a mean age of 63.4 years, and their 2-year follow-up SVA was almost identical to the planned average (9.8 ± 33.9 mm vs 9.9 ± 39.5 mm). However, the authors concluded that planning accuracy could use further improvement as SVA was corrected more frequently than the original surgical plan predicted ($R^2 = 0.05–0.36$).²⁵ Prost et al prospectively evaluated 86 patients who received PSRs with a minimum 1-year follow-up.¹¹ Preoperatively, 47 of the patients had an age-related SVA above a predetermined threshold. Postoperatively, they found significant sagittal correction (53 vs 30 mm, $P = 0.007$).¹¹ In a follow-up study, Prost et al had similar results at 3-month follow-up with a mean correction of SVA of 27.1 mm ($P < 0.0001$).⁷ Additionally, consistent with previous literature, the authors found that in patients with Parkinson's disease, the mean SVA correction was larger at 53 mm ($P = 0.0005$).^{7,26} Ou-Yang et al directly compared 16 patients who underwent PSR implantation for complex spinal deformity to matched controls.²⁷ Preoperatively, the PSR cases had an average SVA of 82.7 mm compared with 72.4

mm for the control group. The PSR cohort experienced superior SVA correction with 81% of the PSR cohort achieving an SVA of <40 mm compared with 63% of the controls, but this was not statistically significant.²⁷

SAGITTAL PELVIC PARAMETERS IN ASD

There have been several publications reporting on the utility of PSRs in addressing pelvic incidence minus lumbar lordosis (PI-LL) mismatch. Solla et al examined 60 patients and found no significant correlation between the planned PI-LL and achieved postoperative PI-LL ($R^2 = 0.1$, $P = 0.5$).²⁸ However, they concluded that postoperative PI-LL improved significantly with PSR implantation.²⁸ In contrast, Barton et al found that their cohort of patients' PI-LL changed significantly with the use of PSRs ($29.2^\circ \pm 16.7^\circ$ to $-4.1^\circ \pm 7.5^\circ$, $P < 0.001$).¹⁰ There was a significant correlation between planned and postoperative PI-LL ($R^2 = 0.4$, $P < 0.011$).¹⁰ Kleck and colleagues reported their PSR cohort PI-LL ranged from -16° to 51° preoperatively. Postoperatively, PI-LL improved substantially with 67% of patients having a PI-LL mismatch of less than 10° ($P < 0.001$).²⁵ However, the authors concluded that the correspondence between the plan and the postoperative outcomes ranged from moderate to weak ($0.20 \geq R^2 \leq 0.47$, $P \leq 0.01$).²⁵ In their prospective study, Prost et al found that 66 of their patients had an average preoperative PI-LL = 15° and at 1 year were corrected to an average of 8° ($P = 0.006$).¹¹ In a follow-up study, Prost found that preoperative PI-LL improved from an average of 20.8° to 8.3° with the use of PSRs ($P < 0.001$).⁷ Ouyang et al compared the preoperative PI-LL mismatch of a PSR cohort to a control group (21.9° vs 18.8°). The authors defined PI-LL $< \pm 10$ as an adequate correction.²⁷ They found that 100% of patients in the PSR cohort were corrected vs 75% in the matched control cohort, but this difference was not statistically significant.²⁷

For pelvic tilt (PT), Solla et al found no significant correlation between planned and postoperative PT ($R^2 = 0.2$, $P = 0.175$).²⁸ Similarly, Prost et al were unable to find a correlation between preoperative PT and postoperative PT in patients who underwent PSR implantation.^{7,11} However, Kleck et al found a moderate correlation between planned PT and true postoperative PT ($R^2 = 0.4$, $P < 0.02$).²⁵ Barton et al found that PT improved from a mean of $32^\circ \pm 10.9^\circ$ to $17.7^\circ \pm 8.0^\circ$ ($P < 0.0001$). Additionally, they found that the planned PT and actual postoperative PT did not differ significantly ($20.5^\circ \pm 9.6^\circ$ vs $17.7^\circ \pm 8.0^\circ$, $P = 0.144$).¹⁰

Sadrameli found that PT improved from $24.82^\circ \pm 9.6^\circ$ to $18.00^\circ \pm 8.6^\circ$ ($P < 0.01$). Moreover, the software predicted PT was similar to the achieved postoperative PT ($16.9^\circ \pm 3.8^\circ$ vs $18.00^\circ \pm 8.6^\circ$, $P = 0.51$). There

was no significant difference between PSRs and in situ bending in terms of PT.¹²

CORONAL CORRECTION IN AIS

Several studies have examined the effect of PSRs on coronal correction in patients with AIS. Ferrero et al retrospectively reviewed 47 Lenke Type 1 and Lenke Type 2 AIS patients treated with PSRs.^{16,29} Preoperatively, these patients had a mean Cobb angle of $59^\circ \pm 13^\circ$ which was corrected to $18^\circ \pm 11^\circ$ ($P = 0.01$) for a resultant 70% curve correction.¹⁶ Marya et al studied a cohort of 61 patients with Lenke 1 to 4 curve and found that patients were optimally corrected through the thoracic spine.¹⁷ Proximal thoracic curves decreased from $30.5^\circ \pm 10.2^\circ$ to $15.6^\circ \pm 7.1^\circ$ for a $48\% \pm 22.5\%$ change ($P < 0.001$). Main thoracic curves improved preoperatively from a mean $68.5^\circ \pm 13.4^\circ$ to $17.4^\circ \pm 9.0^\circ$ for a $75.4\% \pm 11.3\%$ change ($P < 0.001$). Thoracolumbar curves improved from a mean $43.4^\circ \pm 14.2^\circ$ to $15.5^\circ \pm 9.1^\circ$ for a $67.4\% \pm 28.0\%$ change ($P < 0.001$). In terms of shoulder alignment, they found a mean change in clavicle angle of 5.5° and a T1 tilt of 7.9° ($P < 0.001$).¹⁷ For main thoracic curves, conventional rods have been reported to achieve $81.45\% \pm 7.51\%$ coronal Cobb correction (preoperative coronal Cobb: 49.18 ± 13.29 vs postoperative coronal Cobb: 9.25 ± 4.75).³⁰

Thomas et al studied 48 AIS patients with Lenke 1 to 4 curves with a minimum 2-year follow-up. Preoperative, 6-month, and 2-year radiographs were collected. The authors found a statistically significant coronal thoracic scoliotic curve correction from 62.7° to 22.4° at a 2-year follow-up.¹⁹ Similarly, Grobost et al reported on 49 patients treated with PSRs and found a 62% correction between preoperative and final imaging ($54^\circ \pm 10^\circ$ to $21^\circ \pm 8^\circ$).³¹ Solla et al analyzed 37 patients treated with PSRs with a minimum of 1-year follow-up and reported that the coronal Cobb angle improved from 53° to 13° for a 74% correction.³²

SAGITTAL CORRECTION IN AIS

Thoracic kyphosis (TK) is of primary concern following posterior AIS fusion surgery. Specifically, there is a concern regarding insufficient restoration of TK, which may increase the risk of PJK.³³⁻³⁸ While there is some variation, many authors try to obtain "normal" postoperative TK, which can be defined as 10° to 40° , according to Lenke's classification, or between 20° and 50° .^{29,39}

Ferrero et al found that their cohort of patients had a preoperative mean TK of $34^\circ \pm 14^\circ$. Five patients were hypokyphotic with less than 20° . Postoperative TK significantly

increased to $45^\circ \pm 12^\circ$ ($P < 0.001$). Moreover, the authors found no significant difference in 3D planned vs actual postoperative kyphosis ($38^\circ \pm 6^\circ$ vs $37^\circ \pm 12^\circ$, $P = 0.98$). They found no difference in SVA postoperatively (preoperative SVA: 2 ± 25 mm vs postoperative SVA: 4 ± 16 mm, $P = 0.58$).¹⁶ Marya et al stratified their patients based on whether they were hypokyphotic, normo-kyphotic, or hyperkyphotic, with “normal” being 20° to 40° . In the hypokyphotic cohort, TK improved from $8.4^\circ \pm 9.5^\circ$ to $22^\circ \pm 3.7^\circ$ ($P = 0.0096$). The normo-kyphotic cohort did not significantly change with a mean difference of 1.62° . The hyperkyphotic cohort improved from $49.2^\circ \pm 7.7^\circ$ to $38.2^\circ \pm 9.5^\circ$ ($P = 0.001$). Seventy-seven percent of patients had normal TK postoperatively. The authors found no significant difference in planned vs postoperative TK (33.5° vs 33.07° , $P = 0.40$), while analysis of variance showed a significant correlation between the 2 values ($P < 0.0001$). In terms of SVA, the authors found no difference with the use of PSRs with a mean difference of 6.7 mm ($P = 0.31$). However, T1 pelvic angle significantly increased with a mean difference of 2.8° ($P = 0.0061$).¹⁷

Thomas et al found that PSRs resulted in increased TK with an increase from 26.5° to 33.0° with their entire cohort. Subgroup analysis demonstrated that the hypokyphotic cohort's mean TK increased from 10.6° to 29.7° at 2-year follow-up ($P < 0.001$). Moreover, TK increased from -5.7° to 49.1° in the hypokyphotic cohort ($P < 0.001$). 3D apical rotation decreased from 16.1° to 7.7° at 2-year follow-up ($P < 0.001$). The authors found no significant difference in sagittal alignment across the thoracolumbar junction. There was no significant difference between planned sagittal parameters and actual 2-year follow-up parameters with the exception of SVA.¹⁹ Grobost et al reported an increase in TK from $19.9^\circ \pm 13^\circ$ to $29.6^\circ \pm 8.3^\circ$ which was almost identical to their planned TK of $30.7^\circ \pm 10.1^\circ$ ($P < 0.001$). They found that their mean thoracolumbar angle became more neutral as well ($0.9^\circ \pm 13.3^\circ$ to $0.06^\circ \pm 8.9^\circ$).³¹

Similarly, Solla et al reported a significant change in TK across the entire cohort and the hypokyphotic subgroup. Overall TK increased from 20° to 35° , while the hypokyphotic group increased from 11° to 32° ($P < 0.0001$).³² In a prospective follow-up study, Solla et al found increases in TK in both normo-kyphotic and hypokyphotic subgroups ($P < 0.0001$ and $P < 0.0001$). These postoperative corrections were not significantly different than the planned values ($P = 0.593$). Ninety-one percent of patients had TK within 20° to 40° at final follow-up.⁴⁰

When examining lumbopelvic parameters, Marya et al found that PI-LL changed from -10.7° to -6.5° ($P = 0.007$) and PT changed from 7.8° to 10.8° ($P = 0.001$).¹⁷

Thomas et al found that their use of PSRs did not accurately predict the postoperative outcome for PI-LL with significant differences found between the values ($P < 0.001$).¹⁹

PATIENT-REPORTED OUTCOMES AND MECHANICAL COMPLICATIONS

Regional and global spinal parameters have their utility, though their correlation with patient-reported outcomes (PROs) has been demonstrated to be weak.⁴¹ This highlights the importance of obtaining PROs as opposed to relying solely on radiographic imaging for clinical outcomes. Faulks et al reported statistically significant improvements in visual analog scale, Oswestry Disability Index (ODI), and 12-item Short Form Survey compared with baseline mean at 6 weeks, 6 months, 12 months, and 24 months in their PSR cohort.²⁴ In AIS patients, overall Scoliosis Research Society-22 (SRS-22) scores were found to improve, and each subdomain also improved significantly after PSR instrumentation.^{19,32,40}

Compared with PSRs, conventional rod constructs have been reported to show comparable results. In ASD patients, 1 study noted that both conventional dual rod and multirod construct groups resulted in improvements in SRS-22, ODI, and numerical rating scale back scores with 76%, 56%, and 76% (SRS-22, ODI, and numerical rating scale back) of patients achieving the minimally clinically important difference after surgery, respectively.⁴² A study by Bourghli et al observed similar results with improvements in the SRS-22 total and subtotal scores at 2-year follow-up after deformity correction with multirod constructs.⁴³ Future studies are needed to investigate whether PSRs result in superior results in PROs when compared with conventional rod constructs.

To date, a paucity exists on PSR's ability to reduce mechanical complications. Faulks and colleagues examined junctional complications in PSR-instrumented patients.²⁴ They found that PSR instrumentation did not reduce radiographic PJK and distal junctional complications from occurring. However, PSR's resulted in a proximal junctional failure rate of 5% (1 of 20), compared with reported proximal junctional failure rates of up to 35%.

Prost et al observed that 18% of patients experienced mechanical complications such as PJK, pseudarthrosis, and rod fracture at 1-year postoperative status.¹¹ Eight patients had a rod fracture, attributed to undercorrection, which ultimately led to revision surgery. Three patients

rod curvature, length, and diameter based on individual patient anatomy allows for precise alignment correction and optimization of spinal biomechanics, leading to better functional outcomes and quality of life. PSRs represent a paradigm shift, offering personalized surgery tailored to each patient's unique anatomical and biomechanical characteristics. With continued research, innovation, and collaboration between clinicians and industry partners, this technology has the potential to revolutionize spinal surgery and improve the lives of patients with complex spinal deformities. However, further research is needed to gain a better understanding of this technology from a clinical, radiological, and cost-effectiveness perspective.

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