Article

Patient-Specific Rods vs Traditional Rods in Surgical Correction of Adult Spinal Deformities: A Case-Matched Study

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AIM: Patient specific pre-contoured rods (PSRs) represent a relatively new technological development aimed at improving surgical outcomes and reducing complications in adult spinal deformity surgery. To date, only a limited number of studies have been published comparing PSRs with traditional spinal rods. In this paper, we compare the surgical, imaging, and clinical outcomes of PSRs and traditional spinal rods in a single-center case-matched study.
METHODS: Thirty cases of adult spinal deformities (ASD) were retrospectively analysed. These included 10 patients who were operated on using UNiD™ (Adaptive Spine Intelligence, MedTronic, Minneapolis, MN, USA) PSRs and 20 operated on using traditional rods from January 2023 to August 2023. Minimum post-surgical follow-up was 6 months. General demographics and standard radiographic parameters, as well as Scoliosis Research Society (SRS)-22, Oswestry Disability Index (ODI) and Short Form Health Survey (SF-12) Scores, were measured at pre-operative examination and at 6-month follow-up. Follow-up imaging data were compared with software-planned correction goals. Intra-operative data and complications were also recorded.
RESULTS: Patients in the two groups were matched in terms of age, body mass index (BMI), sex, type and severity of spinal deformity. The magnitude of the coronal deformity ($p = 0.812$) and preoperative sagittal imbalance ($p = 0.845$) were similar between the two groups. The number of fused levels ($p = 0.439$), osteotomies ($p = 0.188$), implant density ($p = 0.880$), and surgery duration ($p = 0.299$) were similar between the two groups. Sagittal correction goals set during preoperative planning were achieved in the PSRs group, with the exception of pelvic tilt (PT) ($p = 0.042$). In contrast, PT ($p = 0.040$), L1-S1 lordosis ($p = 0.032$) and global tilt (GT) ($p = 0.001$) remained significantly undercorrected in the control group at 6-month follow-up. Clinical outcomes (ODI and SF-12 Scores) and complication rates were similar between the two groups.
CONCLUSIONS: The use of PSRs improves the achievement of better post-operative spinopelvic alignment in adult spinal deformity surgery. Moreover, no significant differences were noted in terms of complications, operative times, and clinical outcomes compared to traditional spinal rods at 6-month follow-up.

Keywords: adult scoliosis; patient-specific rods; artificial intelligence; sagittal alignment; spinal deformity surgery

Introduction

Adult spinal deformities (ASD) is a major source of disability and is responsible for a significant reduction in health-related quality of life [1]. When conservative measures fail, surgery becomes the only viable option for treating ASD. The number of surgical procedures performed annually for ASD has constantly increased over the last decade, and it is expected to rise further as the population continues to age [2].

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Although several surgical options exist for ASD treatment, the current gold standard is posterior spinal instrumented fusion (PSIF) surgery. The goal of this procedure is to restore normal sagittal and coronal alignment of the spine. Historically, greater attention has been paid to coronal plane correction. However, study has shown that best clinical outcomes are achieved with optimal sagittal plane correction [3]. Correction of the deformity in the sagittal plane is challenging and it is commonly achieved by combining posterior spinal osteotomies and correction manoeuvres using hand-contoured spinal rods. Traditionally these rods are cut and contoured by hand according to the surgeon's experience and preferences.

Patient specific pre-contoured rods (PSRs) and instrumentation are emerging as an alternative to traditional implants; providing the surgeon with pre-contoured rods which will help achieve the defined correction goals in the sagittal and coronal plane [4]. The patients' demographics (i.e., height, weight, and date of birth) and pre-operative whole spine anteroposterior and lateral-view X-rays are uploaded into dedicated software. Pre-operative imaging parameters are measured, and a surgical plan is devised using an artificial intelligence algorithm supervised by an engineering team. The artificial intelligence algorithm collects pre-operative and post-operative outcomes from the same surgeon and from other surgeons and can make suggestions based on previously operated cases. Lastly, the operating surgeon is asked to check the plan and make necessary changes based on their experience and judgement. The two rods are then manufactured and shipped to the hospital facility in time for surgery [5].

While this type of technology is already available on the market and some centres use it, there is a lack of comparative data assessing the real benefits and outcomes of this technology. The aim of this study is to compare surgical and clinical outcomes of adult deformity patients treated with patient-specific rods vs traditional rods.

Materials and Methods

After receiving Institutional Review Board (IRB) approval, we retrospectively reviewed all consecutive cases of patients with adult spinal deformity who underwent posterior spinal instrumented fusion (PSIF) at our institution between January 2023 and August 2023. Inclusion criteria for the study were age $\geq$25 years, major Cobb angle $\geq$35°, $\geq$6 levels fused, standard titanium 6.0 mm rods, and $\geq$6-month follow-up after surgery. Patients with a history of previous spinal surgery were excluded from the study. All patients underwent surgical treatment with PSIF with the addition of posterior osteotomies in the thoracic and/or lumbar area; pelvic fixation and/or interbody cages were used as per the surgical plan. The study was approved by our local ethical committee (Comitato Etico Aziendale) with approval number 20230021569i. The study was performed in accordance with ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients gave their written informed consent at the enrollment for surgery and were included into an observational database. During the enrollment period of the study, a total of 10 patients underwent PSIF with PSRs and 35 patients with traditional rods. To eliminate any bias in the selection of the surgical strategy, the decision was made to use PSRs for patients listed for surgery every other week of the month. The patients included were divided into two groups (i.e., traditional spinal rods and PSRs) and were matched for age, body mass index (BMI), sex, type of curve (Scoliosis Research Society (SRS)-Schwab classification [6]), and magnitude of the deformity. Fifteen patients operated on with traditional rods were excluded from the study because they did not meet inclusion criteria for the study. Surgical records and clinical charts were probed for data extraction by an independent investigator who was not involved in the surgical management of the patients.

General demographics (i.e., age at surgery, sex, and body mass index) and clinical and radiographic variables were recorded before surgery. Radiological parameters including major coronal Cobb angle, T5-T12 kyphosis angle, L1-S1 lordosis angle, C7 sagittal vertical axis deviation (negative values for posterior deviation, positive values for anterior deviation) and sagittal balance parameters (i.e., pelvic incidence, sacral slope, pelvic tilt, global tilt) were measured using our institutional Picture archiving and communication system (PACS) as already described [6] and collected before surgery and at the latest available follow-up (minimum 6 months). In addition, intraoperative data were collected, including total surgical time and blood loss, fusion area (upper to lower instrumented vertebra), number of osteotomies and interbody cages inserted. Intraoperative and postoperative complications were also recorded.

All surgeries were performed by the same fellowship-trained spinal surgeon. The pre-operative plan for patients treated with PSRs (UNiD^{TM} Adaptive Spine Intelligence, MedTronic, Minneapolis, MN, USA) was developed by the operating surgeon and a dedicated engineering team using a dedicated online platform [4]. In brief, two weeks before surgery pre-operative standing two views whole spine X-rays were obtained. The DICOM files of the X-rays were uploaded online through a proprietary online platform. The X-rays were measured by an engineering team and a surgical plan was devised. The proposed plan was sent back to the operating surgeon for final approval. Finally, the rods were manufactured according to the plan and sent to the hospital facility at least two days before surgery (Fig. 1). In all cases, standard 6.0 mm titanium rods were used. During surgery no attempts were made to modify the shape of the PSRs with the only exception of *in situ* coronal contouring performed at the end of the surgery after the rods were engaged and setscrews tightened. Sagittal balance and targets for correction (i.e., ideal pelvic tilt, lumbar lordosis, and global tilt) were confirmed using the global alignment and proportion (GAP) Score algorithm [6]. Patients were followed-up regularly after surgery in our outpatient clinic. The standard schedule for post-operative appointments was 6 weeks, 3 months, 6 months, and 1 year after surgery. At each post-operative appointment patients were clinically assessed, whole spine 2 views X-rays were taken and patients were asked to fill in post-operative questionnaires (i.e., Oswestry Disability Index (ODI), SRS-22 and Short Form Health Survey (SF-12)) [7–9].

Statistical Analysis

Shapiro-Wilks test was used to verify normal distribution of the variables included in the study. Data were expressed as average ± standard deviation if normally distributed, or as median [P25, P75] if not normally distributed. Mann-Whitney U and Wilcoxon signed-rank tests were used to test differences in demographics, deformity, and surgical parameters between the two study groups for not normally

Fig. 1. An example of pre-contoured spinal rods. Rods are 6.0 mm titanium. They are shipped to the operating room at least 2 days before surgery. The two rods are pre-contoured and ready for implantation.

distributed variables, while Student's t test was used for normally distributed variables. The Fisher's exact tests was used to compare the categorical data between the two groups, with the data presented as percentages. A p value $\leq$ 0.05 was considered significant. Data were analyzed using the SPSS Statistics software, version 23 (SPSS, Chicago, IL, USA) and Microsoft Office Excel 365 Professional (Microsoft, Redmond, WA, USA).

Results

A total of 30 patients were enrolled in this study (10 patients in the PSRs group and 20 patients in the traditional rods group). Average age was not statistically different between the two groups, although patients in the PSRs group were slightly older (p = 0.169). BMI and sex distribution were similar between the two groups (Table 1). In the PSRs group, 2 patients had a thoracic-only deformity, 1 patient had a thoracolumbar curve, and 7 patients presented with a double curve; in the control group, there were 6 thoracic, 2 thoracolumbar and 12 double curves. The analysis of pre-operative deformity values showed similar magnitudes of coronal deformity between the two groups (major Cobb angle, p = 0.812). Patients in both groups had sagittal imbalance with anteriorly displaced sagittal vertical axis (SVA) and reduced lumbar lordosis. GAP Score analysis revealed an imbalanced spine in patients in both groups (p = 0.845) (Table 1).

All patients underwent PSIF procedure with multiple-level Ponte osteotomies (p = 0.188) and interbody fusion (using the Transforaminal Lumbar Interbody Fusion (TLIF) technique) was performed when needed (Figs. 2,3). The average number of levels fused was 14.3 $\pm$ 3.8 in the PSRs group and 15.0 $\pm$ 1.0 in the control group (p = 0.439). The pelvis was included in the fusion area in 40% and 30% of patients in the PSRs and control group respectively. Surgery duration was not significantly different between the two groups (p = 0.299); similarly intra-operative blood loss was also not significantly different between the two groups (p = 0.356) (Table 2).

Analysis of post-operative correction revealed some interesting differences between the two groups: not only was the coronal correction not significantly different between the two groups (p = 0.472), but also C7 sagittal vertical axis (SVA) alignment remained similar after surgery in both groups (p = 0.328). While all correction targets were achieved in the PSRs group (i.e., pelvic incidence (PI)-lumbar lordosis (LL), L1-S1 lordosis and global tilt (GT)) except for PT, a significant under correction was noted in the control group PT (p = 0.040), L1-S1 lumbar lordosis (p = 0.032), and GT (p = 0.001). Final GAP Score after surgery showed slightly better values in the PSRs group compared to the control group, although this did not reach statistical significance (p = 0.823) (Table 3).

A total of 7 complications were recorded in the study group: one case of deep infection and one case of wound seroma in the PSRs group, and 4 cases of intra-operative dural tear (1 case in the PSRs group and 3 cases in the control group). The patient with infection required surgical site debridement and washout 35 days after index surgery. All cases of dural tear were repaired intra-operatively without any further complications. One case of rod breakage was observed in the control group at the 6-month follow-up (Table 4).

Table 1. Pre-operative demographic and radiographical comparison of the two study groups.

	PSRs group	Control group	*t/U/Fisher*	*p*
Number of patients	10	20		
Age (yrs)	57.0 [23.3, 62.7]	42.8 [25.7, 57.0]	*U* = 68	0.169
Sex (M/F)	3 M/7 F	2 M/18 F	*Fisher* = 1.92	0.300
BMI (Kg/m^2)	24.6 ± 4.8	24.5 ± 3.0	*t* = 0.070	0.944
Deformity type			*Fisher* = 0.35	0.848
Thoracic (n)	2	6		
Thoracolumbar (n)	1	2		
Double (n)	7	12		
Major Cobb (°)	49.0 [39.0, 60.0]	53.5 [45.0, 58.0]	*U* = 94	0.812
C7 SVA (mm)	23.0 [–20.5, 90.2]	17.0 [–22.0, 65.0]	*U* = 96	0.880
PI (°)	56.0 [49.5, 60.0]	54.0 [48.0, 65.0]	*U* = 96	0.880
PT (°)	22.0 [11.2, 28.0]	18.5 [15.0, 36.0]	*U* = 92	0.746
L1-S1 lordosis (°)	54.0 [28.2, 73.7]	42.0 [24.0, 63.0]	*U* = 81	0.422
T4-T12 kyphosis (°)	46.5 [32.2, 57.2]	27.0 [12.0, 36.0]	*U* = 54	**0.044**
PI-LL (°)	2.5 [–9.7, 25.7]	5.0 [–9.0, 31.0]	*U* = 99	0.983
GT (°)	19.0 [9.0, 33.7]	16.0 [10.0, 40.0]	*U* = 97	0.914
GAP Score	8.3 ± 3.6	8.0 ± 4.1	*t* = 0.196	0.845
SRS-22 Total Score	2.8 ± 0.6	2.6 ± 0.7	*t* = 0.771	0.447
ODI Score	50.0 [42.0, 63.5]	24.0 [17.5, 36.5]	*U* = 5	0.112
SF-12 Mental Score	46.7 ± 10.0	43.4 ± 16.8	*t* = 0.569	0.573
SF-12 Physical Score	34.6 ± 4.7	28.4 ± 3.5	*t* = 4.077	**0.001**

Data are expressed as average ± standard deviation if normally distributed or median [P25, P75] if not normally distributed. Bolded data is for significant comparisons (*p* values less than 0.05). PSRs, Patient specific pre-contoured rods; BMI, body mass index; SVA, sagittal vertical axis; PT, pelvic tilt; LL, lumbar lordosis; PI, pelvic incidence; GT, global tilt; GAP, global alignment and proportion; SRS, Scoliosis Research Society; ODI, Oswestry Disability Index; SF-12, Short Form Health Survey.

Discussion

Restoring a normal sagittal alignment is of pivotal importance in adult spinal deformity surgery [10]. The achievement of a balanced spine in the sagittal plane is associated with better clinical outcomes and reduced incidence of mechanical complications (e.g., rod breakage, proximal junctional kyphosis, and failure) [3]. Intraoperative contouring of the rods is a fundamental step to achieve a proper postoperative sagittal alignment. Until now, rod contouring has been left to the surgeon's experience and preferences. PSRs have been developed specifically to overcome these limitations and improve postoperative sagittal balance correction. While computer-assisted planning tools have been available for quite some time now, translating detailed pre-operative plans into surgery remains a significant challenge for the operating surgeon. PSRs represent a step forward in the direction of a more precise surgery and adherence to the pre-operative plan [4].

Our study compared surgical and imaging outcomes of patients with ASD treated with PSRs and traditional rods. The two study groups were similar in general demographics and magnitude of the deformity. The number of levels fused was similar between the two groups, as well as the number of osteotomies performed, and the percentage of patients fused to the pelvis. Although the PSRs group had slightly shorter surgical times in our study, the difference was not statistically significant. The reduction of surgical time was also reported by Solla *et al.* [11] in a retrospective analysis of 60 adult patients operated on with PSRs. However, a similar retrospective review by Sadrameli *et al.* [12] did not report any significant difference in terms of surgical timing. Although the reduction in surgical timing seems reasonable due to the intraoperative measurement and contouring of the rods not being needed, it also depends on many other variables, including the surgeon's routine and workflow and as such is not easily comparable between studies and centres.

Our study also shows that PSRs can help achieve better post-operative sagittal alignment. Coronal correction was not significantly different between the two groups. However, when comparing the ideal vs achieved correction of the sagittal parameters, no statistical differences were found in the PSRs group with the only exception of post-operative PT (Table 3); however in the control group (traditional rods group) the achieved PT was significantly worse than the ideal software-calculated PT; similarly, the L1-S1 lumbar lordosis achieved was significantly smaller than the ideal software-calculated lordosis; also, the achieved GT was larger than ideal software-calculated GT. Our data suggest

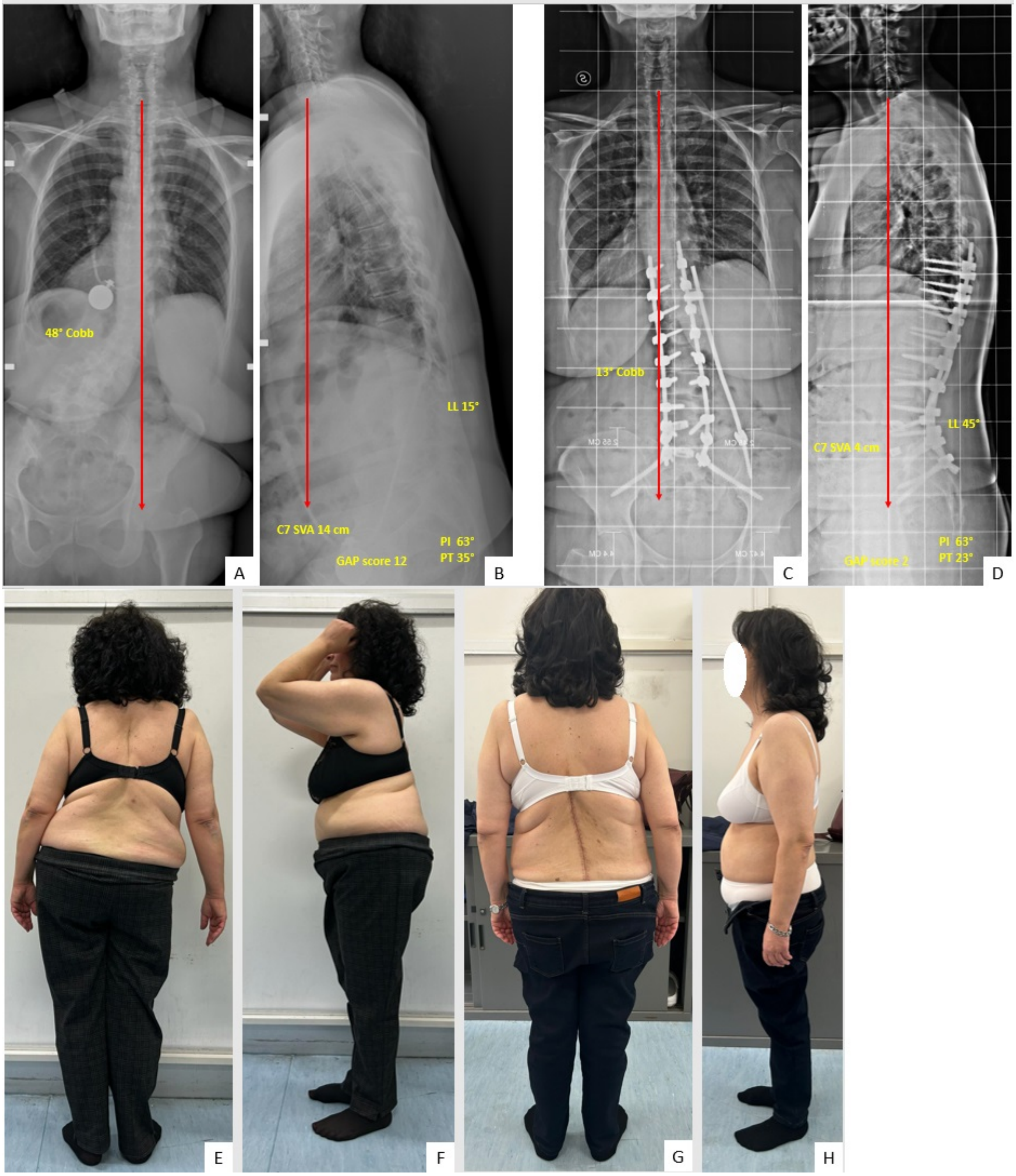

Fig. 2. 58 y/o female patient with severe coronal and sagittal pre-operative imbalance. The red arrows in the figure represent the C7 plumb line in the coronal and sagittal plane. (A,B) Pre-operative Antero-posterior (AP) and LL view of the spine showing a severe coronal and sagittal imbalance. Lumbar spine is in severe kyphosis and anterior displacement of C7 SVA is demonstrated (14 cm). GAP Score is 12, severely unbalanced spine. (C,D) 6-months post-operative AP and LL view of the spine showing good restoration of coronal and sagittal balance after surgery. Lumbar lordosis has been recovered and final GAP Score is 2, namely a proportioned spine. PSRs have been used for this case (the round X-ray mark observed in the pre-operative X-rays is needed for calibration and rod manufacturing). (E–H) Pre- and 6-months post-operative clinical appearance. The figure was drawn using Microsoft Office PowerPoint Professional (v 2408, Microsoft, Redmond, WA, USA).

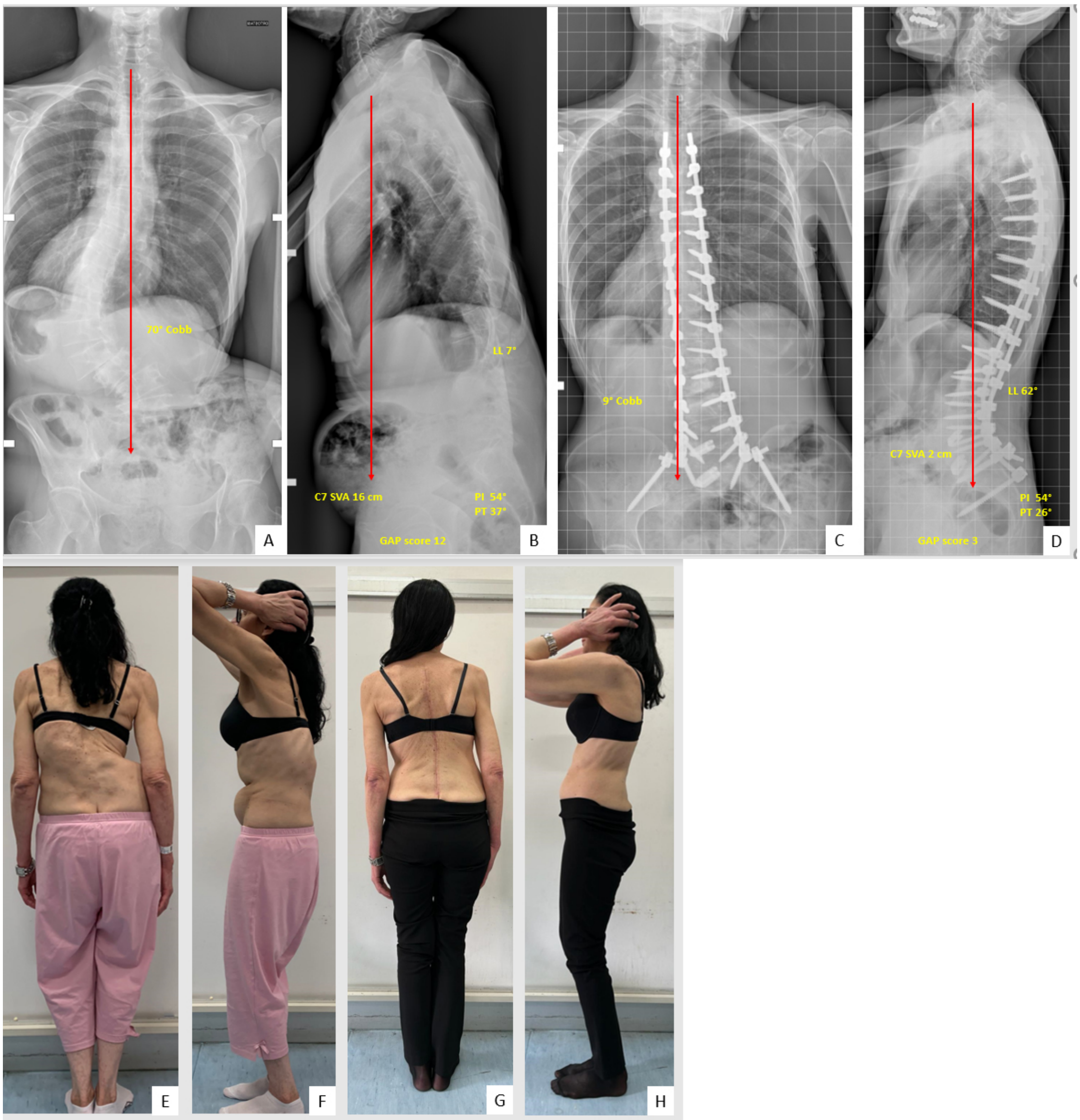

Fig. 3. 54 y/o female patient with severe coronal and sagittal pre-operative imbalance. The red arrows in the figure represent the C7 plumb line in the coronal and sagittal plane. (A,B) Pre-operative AP and LL view of the spine showing a severe sagittal imbalance. C7 SVA line is anteriorly displaced by 16 cm and lumbar lordosis is reduced to 7°. GAP Score is 12, severely unbalanced spine. (C,D) 6-months post-operative AP and LL view of the spine showing good restoration of coronal and sagittal balance after surgery. Lumbar lordosis has been recovered and final GAP Score is 2. The patients were operated on with standard non pre-contoured titanium rods. (E–H) Pre- and 6-months post-operative clinical appearance. The figure was drawn using Microsoft Office PowerPoint Professional (v 2408, Microsoft, Redmond, WA, USA).

that PSRs may offer a measurable advantage over traditional rods in achieving surgical correction goals. Even if the evidence in literature is still sparse, our results find confirmation in the works of Sadrameli *et al*. [12], and Solla *et al*. [11]. In fact, Solla *et al*. [11] retrospectively analysed imaging outcomes of 60 adult patients treated with PSRs showing that patients treated with PSRs were 2.6 times more likely to be optimally corrected. As highlighted by other authors, one advantage of PSRs is that they provide the surgeon with a visual aid for achieving the final correction. In our experience having the pre-contoured rods available at the start of surgery is useful to gauge the extent of posterior element release needed before correction is attempted.

The main advantages of achieving a good post-operative sagittal balance are to improve patient reported outcomes and reduce mechanical post-operative complications [3]. While there is limited evidence in literature, PSRs have been reported to reduce mechanical complications [4]. In a prospective case series of 20 patients who underwent $\geq$4 levels ASD surgery by Faulks *et al*. [13] the authors noted a reduction of the Proximal Junctional Kyphosis (PJK) rate

Table 2. Operative data comparison of the two study groups.

	PSRs group (n = 10)	Control group (n = 20)	*t/U/Fisher*	*p*
No. of fused levels	14.3 ± 3.8	15.0 ± 1.0	*t* = 0.783	0.439
Implant density (%)	100 [98.2, 100.0]	100 [100, 100]	*U* = 96	0.880
Pelvic fixation (%)	4 (40%)	6 (30%)	*Fisher* = 0.33	0.690
Interbody cages (%)	3 (30%)	4 (20%)	*Fisher* = 0.37	0.657
No. of osteotomies	9.1 ± 3.2	7.6 ± 2.7	*t* = 1.349	0.188
Surgery duration (min)	395.0 ± 93.1	430.0 ± 81.7	*t* = 1.056	0.299
Blood loss (mL)	860.3 ± 329.1	992.9 ± 381.2	*t* = 0.937	0.356
Intra-op. transfusion (mL)	0 [0, 500]	125 [0, 250]	*U* = 99	0.983

Data are expressed as average ± standard deviation, unless stated otherwise; Intra-op., intra-operative.

Table 3. Comparison of planned vs achieved correction in the two study groups (6-month follow-up).

	PSRs group (n = 10)				Control group (n = 20)			
	Ideal	Achieved	*Z*	*p*	Ideal	Achieved	*U/Z*	*p*
Major Cobb (°)	-	10.0 [6.0, 19.5]		-	-	9.0 [5.0, 13.0]	*U* = 77	*p* = 0.562
Coronal correction (%)	-	78.0 [64.5, 87.5]		-	-	83.5 [76.0, 91.0]	*U* = 74	*p* = 0.472
C7 SVA (mm)	-	–27.5 [–43.2, 30.7]		-	-	4.0 [–25.0, 20.0]	*U* = 60	*p* = 0.328
PT (°)	18 [5.2, 21.0]	24.5 [14.7, 27.5]	***Z* = –2.03**	***p* = 0.042**	13.0 [11.0, 18.0]	24.5 [17.0, 26.0]	***Z* = –2.0**	***p* = 0.040**
L1-S1 lordosis (°)	63.5 [68.5, 57.2]	59.5 [70, 46.2]	*Z* = –1.43	*p* = 0.150	62.0 [69.0, 59.0]	59.0 [63.0, 54.0]	***Z* = –2.2**	***p* = 0.032**
T5-T12 kyphosis (°)	-	48.5 [44.2, 56.0]	-		-	38.5 [37.0, 50.0]	*U* = 46	*p* = 0.089
PI-LL (°)	–6 [–22.2, –0.7]	–8 [–13, 11.2]	*Z* = –1.4	*p* = 0.150	–8.0 [–11.0, –4.0]	–6.0 [–6.0, 11.0]	***Z* = –2.0**	***p* = 0.040**
GT (°)	11.5 [8.5, 13.5]	14.5 [6.2, 26.2]	*Z* = –0.7	*p* = 0.481	11.0 [8, 16]	25.0 [22, 30]	***Z* = –3.7**	***p* = 0.001**
GAP Score	-	3.0 [1.2, 7.2]		-	-	3.5 [2.0, 5.0]	*U* = 75	*p* = 0.823

Data are expressed as average ± standard deviation, unless stated otherwise; Values in the *U/Z* column represent values from Mann-Whitney U and Wilcoxon signed-rank tests, respectively. The bold form highlights statistically significant values/comparisons.

Table 4. Post-operative outcomes at 6-month follow-up.

	PSRs group (n = 10)	Control group (n = 20)	*t/U*	*p*
Total no. of complications	3	4		0.657
Infections (no.)	1	0		
Wound seroma (no.)	1	0		
Dural tear (no.)	1	3		
Rod breakage (no.)	0	1		
Fixation failure (no.)	0	0		
Hospitalization (days)	7.0 [5, 11]	7.0 [5, 11]	*U* = 8	0.518
SRS-22 Total Score	3.4 ± 0.7	3.8 ± 0.3	*t* = 2.209	**0.035**
ODI Score	28.8 [12.3, 46.1]	18.0 [4.0, 42.0]	*U* = 8	0.476
SF-12 Mental Score	47.6 ± 11.8	54.0 ± 7.0	*t* = 1.871	0.071
SF-12 Physical Score	35.9 ± 5.4	37.5 ± 9.1	*t* = 0.510	0.613

Data are expressed as average ± standard deviation if normally distributed, or as median [P25, P75] if not normally distributed, unless stated otherwise. The bold font highlights significant differences in the table.

compared to the literature (35%). Furthermore, another advantage of PSRs is to avoid notching due to manual contouring. Whether this can reduce long-term rod breakage rates is still controversial [5]. We did not observe any mechanical complication in our cohort of PSRs; however, our follow-up is still too short to draw significant conclusions about this aspect. Evidence from literature is still sparse with regard to a reduction in mechanical complications with PSRs [5]. Similarly, PSRs have been marketed on the premise of reducing post-operative infections due to prolonged operative times, a well-known complication in spinal surgery [14].

We acknowledge the limitations of our study. The retrospective design of our study limits the generalizability of our findings. It must be noted though that PSRs are a new development in technology, used only in a minority of specialized centres. As far as we know, no randomized controlled trial has been designed or published yet on this topic.

All the available evidence is based on retrospective or limited prospective study [4]. The study population is too small to draw definitive conclusions about the real benefits of PSRs technology. Furthermore, the impact of the learning curve on this technology over the early results should be taken into consideration. Finally, the follow-up is still too short to fully assess the impact of PSRs on reducing mechanical complication rates. Some limitations are mitigated by the fact that this was a consecutive series of patients operated on by the same surgeon at the same centre (i.e., same surgical technique) included in a robust and longitudinal database.

Conclusions

Our study shows that PSRs can improve post-operative sagittal correction in ASD surgery compared to traditional rods. The use of PSRs can help surgeons achieve L1-S1 lumbar lordosis, and GT correction goals more effectively than traditional rods. Complication rates were no different between the two groups. However, longer follow-up is needed to evaluate the impact of PSRs on mechanical complications (e.g., rod breakage). The number of patients included in the study is still too small, our findings will need to be confirmed in larger series with longer follow-ups. Longer follow-ups with a larger cohort of patients will also help to assess the cost-effectiveness of this technology.

Availability of Data and Materials

The datasets generated during the current study are available from the corresponding author upon request.

Author Contributions

The conception and design of the study: LAN, EP; data collection: CP, AS, PU, AC; data analysis and interpretation CP, PU, LAN; article drafting and revision LAN, AS, AC, EP; study supervision LAN, EP, AS. All authors contributed to important editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

The study was approved by our local ethical committee (Comitato Etico Aziendale) with approval number 20230021569i. The study was performed in accordance with ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The study obtained the patients' informed consent.

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Conflict of Interest

The authors declare no conflict of interest.

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