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“Patient-specific” rods in the management of adult spinal deformity. One-year radiographic results of a prospective study about 86 patients



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ABSTRACT

Introduction. – Based on global knowledge regarding sagittal alignment, preoperative planning is a crucial point in the management of adult spinal deformity (ASD). Patient-specific rods (PSR) have been recently developed in order to change preoperative planning into a postoperative reality. The aim of this study was therefore to analyze the 1-year radiographic results of prospective ASD cohorts managed using PSR.

Methods. – In this prospective study, all patients managed for an ASD using PSR since 2014 and with a minimal follow-up of 1-year were included. Radiographic parameters were evaluated pre and post-operatively and patients were stratified according to their final sagittal alignment status (A: aligned vs. MA: malaligned) according to the age-related Schwab classification. Statistical analyses were performed using the Student's-*t*-test in order to compare groups.

Results. – Eighty-six patients were included in the study, with a mean age of 57.2 years. At one-year follow-up, mean sagittal vertical axis and pelvic incidence-lumbar lordosis mismatch were significantly improved. Twenty-two patients were aligned on both sagittal and coronal planes, 52 patients were still considered as malaligned in the sagittal plane, 3 were still malaligned in the coronal plane and 9 patients were malaligned in both planes (vs. 42 patients preoperatively). At final follow-up, the rate of mechanical complications was 18%.

Conclusion. – Based on our results, patient-specific rods can represent a useful supplementary tool in the management of ASD and transform preoperative planning into a postoperative reality. Corrections rates are comparable to other series in the literature with conventional rods, and fewer complications have been reported. However, further studies will be required in order to confirm these results.

1. Introduction

Accurate prevalence of ASD is difficult to determine depending on the variability of symptoms, however it may represent up to 60% of the population over 65. Global aging of the population associated with high functional demand is progressively leading to an increase in adult spinal deformity (ASD) surgical procedures. However, these strategies remain major surgeries with frequently sub-optimal radiographic results. Various studies have revealed statistical correlations between sagittal radiographic parameters and clinical outcomes in ASD patients [1–3]. Among these parameters, pelvic tilt (PT), pelvic incidence-lumbar lordosis (PI-LL) mismatch and sagittal vertical axis (SVA) have been well described and used in the ASD classification of the Scoliosis Research Society [4]. Fur-

thermore, a description of age-related changes and pathologic thresholds according to age [5] has been used in order to establish surgical correction objectives for ASD procedures.

Currently, approximately 30% of patients surgically managed for ASD remain above correction objectives and pathological thresholds postoperatively [6] despite substantial surgical morbidity and mortality. It seems therefore important to identify, during the preoperative period, the most relevant clinical and radiographic parameters that can influence postoperative correction and to develop new tools in order to reach these objectives. Recently, the medical industry developed patient-specific rods (PSR) that are specifically bent and adjusted according to the “ideal” sagittal alignment of the patient based of preoperative planning. The aim is to perform precise surgical planning and to obtain specific rods that will act as a support for the surgical correction needed for each patient.

The aim of this study was to evaluate the efficacy of PSR in the management of ASD in terms of the correction of radiographic

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sagittal parameters (SVA, PI-LL, PT and Cobb angle) based on the hypothesis that PSR may reduce the rate of under corrected patients postoperatively. At the same time, an analysis of clinical and surgical parameters with a significant influence on postoperative correction and complications was also conducted.

2. Methods

2.1. Study design

This was a single center prospective study of consecutive patients surgically managed for an ASD using PSR (IRB approval 00009118). For each patient, preoperative planning was done using Surgimap® (Nemaris, New York, NY.) at the beginning of our experience and then later Medicea UnidHub® (Medicea International, Rilleux-la-Pape, France).

Inclusion criteria were as follows: at least one pathologic parameter of the SRS-Schwab classification adjusted by age [7], performing preoperative planning of PSR and effective use of the PSR during the surgical procedure. Patients with neurological deformity, Parkinson disease or those patients who refused to participate in the study were excluded.

Main demographic data (age, sex, BMI), previous spine surgery and comorbidities were routinely recorded.

Radiographic evaluation included in all the cases preoperative and 1-year postoperative full-spine anteroposterior and lateral X-rays. Measurements included: coronal Cobb angle, SVA, PI-LL mismatch, posteroanterior and thoracic kyphosis.

During the follow-up period, all complications (clinical and radiologic) were routinely collected.

2.2. Surgical data

For each patient, surgical data were collected and included: the type of PSR (titanium 6 mm or Cr-Co 6 mm), upper and lower instrumented vertebrae, number of levels fused, circumferential fusion and the type of posterior osteotomy.

2.3. Radiographic evaluation and statistical analysis

At 1-year follow-up, the correction of each parameter was evaluated and stratified in 4 groups “Normal without modification”, “incomplete improvement”, “postoperative deterioration” and “postoperative correction” according to the age-related pathological thresholds [5]. A Student’s *t*-test was used in order to determine if a significant change between pre and postoperative measurements was achieved.

The global correction at 1-year was also evaluated and patients were divided in 4 groups according to radiographic parameters: “Aligned”, “Coronal deformity”, “Sagittal deformity” and “Combined deformity”.

A statistical analysis using a Student’s *t*-test was performed between “Aligned” and “Malaligned” groups at one-year follow-up in order to determine which parameters were associated with achievement of postoperative thresholds. For each statistical analysis, the level of significance was set at 5%.

3. Results

3.1. Demographic results

During the inclusion period, 111 ASD patients were managed using PSR at our institution between April 2014 and January 2018 (Table 1). Eighty-six patients met the inclusion criteria and were included in this study. The sex ratio was 5 women/1 man and the

Table 1
Demographic data.

Demographic data	n (%)
Sex ratio	
Male	17 (19.8)
Female	69 (80.2)
Total	86 (100)
Mean age	57.2 ± 19.2
Comorbidities	
Smokers	18 (20.9)
Diabetes	9 (10.5)
Osteoporosis	5 (5.8)
Overweight	22 (25.6)
Obesity	12 (13.9)
ASA Score	
1	15 (17.4)
2	47 (54.6)
3	24 (27.9)
Etiology	
Degenerative ASD degenerative	55 (63.9)
Adult idiopathic scoliosis	16 (18.6)
Postoperative flat back	11 (12.8)
Malunion	4 (4.6)
Previous spine surgery	
Yes	31 (36.0)
No	55 (63.9)

mean age was 57.2 years SD = 19.2. Among the 86 patients, degenerative scoliosis was the most common diagnosis (54% in the series) and 39% of the patients had previous spine surgery.

3.2. Operative data

In the entire series, the upper instrumented vertebra was T2 or T4 for more than 50% of cases and the lower instrumented vertebra was the pelvis in 75% of cases (Table 2). A pedicle subtraction osteotomy was performed in 24 cases, in L3 for most of the cases (17 patients). In the entire series, poly axial pedicular screws were used in the thoracolumbar area. In a few cases, a claw using sub-laminar hooks was placed at the upper instrumented level if insertion of pedicle screws was not possible.

A circumferential arthrodesis was performed during the same operative time (PLIF) or during a second surgical stage (ALIF or OLIF) for 36 patients including 13 patients for whom a pedicle subtraction osteotomy (PSO) was performed.

3.3. Radiologic results

3.3.1. Preoperative radiographic parameters and type of curves

In our series, 55 patients had a preoperative coronal Cobb angle > 30° related to a Thoracolumbar/Lumbar (L) deformity in the SRS-Schwab classification and 34 patients had an isolated sagittal malalignment.

Eight patients of our cohort were aligned in the sagittal plane (SVA, PI-LL, and PT below the age-related thresholds) but with preoperative coronal malalignment.

Patients diagnosed with an isolated sagittal malalignment were significantly older than patients with a coronal deformity (64.4YO ± 8 vs. 53.1YO ± 22.2 *P* < 0.001) and patients with a sagittal malalignment without coronal deformity had more a previous history of spine surgery (18% vs. 67.7% *P* < 0001).

3.3.2. Preoperative sagittal deformity

During the preoperative evaluation, 38.4% of the patients had the 3 radiographic parameters above the pathologic thresholds and only 17 patients had one pathologic parameter (Table 3).

Table 2
Surgical data of the series.

Surgical data	n (%)
Pedicle subtraction osteotomy	
Total	25 (29)
Number	
1	21 (24.4)
2	4 (4.6)
Level	
L4	7 (8.1)
L3	17 (19.7)
L2	2 (2.3)
L1	2 (2.3)
Other	1 (1.2)
Circumferential fusion	
Total	36 (41.9)
Number of level/patient	
1	18 (20.1)
2	10 (11.6)
3	8 (9.3)
Level	
L5S1	17 (19.8)
L4L5	19 (22.1)
L3L4	15 (17.4)
Others	11 (12.8)
Instrumentation	
Upper level	
T1	4 (4.7)
T2	15 (17.4)
T3	6 (6.9)
T4	21 (24.4)
T5	8 (9.3)
Lower level	
L2	2 (2.3)
L3	4 (4.6)
L4	6 (6.9)
L5	8 (9.3)
S1	13 (15.1)
S2	22 (25.6)
Ileum	31 (36.0)
Average number of level fused	12.6 ± 3.5
Rods	
Chrome Cobalt	39 (45.3)
Titanium	47 (54.7)

3.4. Parameter corrections

At one-year of follow-up, all parameters were re-evaluated (Fig. 1). The Cobb angle was the parameter the most corrected (> 30° in 65% of the case preoperatively vs. 12.8% at 1-year) without aggravation.

On the sagittal plane, 47 patients had a preoperative age-related SVA above the threshold and a significant correction was obtained (53 mm SD = 63 vs. 30 mm SD = 41, $P = 0.007$). At one year of follow-up, 11 patients had an increase of SVA related in 8 cases to a proximal junctional kyphosis.

Sixty-six patients had a preoperative PI-LL mismatch (average 15°, SD = 20) with a significant ($P = 0.006$) correction at one-year (average 8°, SD = 14).

PT was the parameter the less corrected on the whole series (average 25° SD = 12 vs. 25° SD = 9, $P > 0.05$ from preoperative to 1-year respectively). In 9 cases, preoperative PT was below the pathological threshold in the preoperative course and above the threshold at one-year follow-up.

Table 3
Preoperative distribution of sagittal malalignment.

	Distribution of sagittal parameter n (%)							Total
	SVA	PI-LL	PT	SVA + PI-LL	SVA + PT	PI-LL + PT	SVA + PI-LL + PT	
Non-pathological	7	6	4	7	1	20	33	86

Table 4
Postoperative complications.

Immediate postoperative course n (%)			
Minors n = 11 (12.8)		Majors n = 7 (8.1)	
Urinary tract infection	6 (6.9)	Deep wound infection	3 (3.5)
Minor pulmonary infection	1 (1.2)	Severe pulmonary infection	1 (1.2)
Ileus	2 (2.3)	Pulmonary embolism	2 (2.3)
Deep vein thrombosis	1 (1.2)	Acute pulmonary edema	1 (1.2)
Gastric ulceration	1 (1.2)		
1 year postoperatively			
Minors n = 6 (6.9)		Majors n = 26 (30.2)	
Recurrent radicular pain	1 (1.2)	Deep wound infection	8 (9.3)
Recurrent pain	3 (3.5)	Postoperative neurologic deficit	2 (2.3)
Disc herniation	2 (2.3)	Rods breakage	9 (10.4)
		Symptomatic PJK	6 (6.9)
		Pseudarthrosis	1 (1.2)

Global analysis of the series at one year follow-up revealed that 22 patients were corrected on both the sagittal and coronal planes, 52 patients had a persistent sagittal deformity (mainly related to PT), 3 patients had a persistent isolated coronal deformity and 9 patients had a persistent combined deformity (vs. 42 patients during the preoperative evaluation).

3.5. Complications

Postoperative wound infection was the most frequent clinical complication (11 patients, 12.8%) and required debridement associated with antibiotics, without instrumentation removal (Table 4). A mechanical complication rate of 18% was reported at 1-year (pseudarthrosis, rod breakage, proximal junctional deformity [PJK]).

A rod breakage was observed in 8 patients (one patient had a rod breakage 2 times) and all patients required a revision surgery for rods replacement. All of these 8 patients were under corrected in the sagittal plane and 3 of them had a postoperative infection. Three patients underwent a revision surgery for a PJK that required an extension of fusion.

3.6. Risk factors of postoperative malalignment

Patients were stratified into 2 groups: A "Aligned" for patients that achieved sagittal and coronal thresholds at one-year follow-up and MA "Malaligned" for the others (Table 5).

Mean age, BMI and the number of level fused were not statistically different A and MA groups.

In terms of complications, the rate of rod breakage at 1-year was significantly higher in the NA group when compared to the A group (17 vs. 0% respectively, $P = 0.0017$).

PJK rate that required revision surgery was 4.5% in the A group vs. 7.8% in the NA group ($P = 0.57$).

4. Discussion

Correlations between clinical scores and sagittal alignment have been widely reported in the literature [1,2,8], and specific alignment objectives have been described in the management of ASD. Recently, these objectives have been adapted to each patient including normal aging of the spine [5,9].

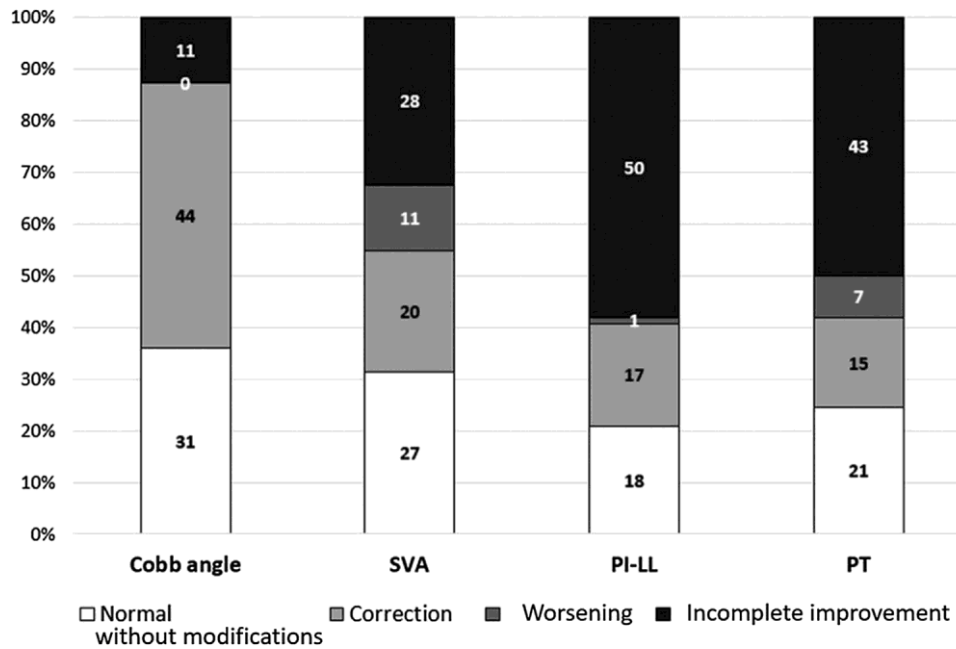


Fig. 1. Modification of the radiographic parameters at one-year follow-up.

Table 5

Comparison between pre and postoperative radiographic parameters for patients stratified according to correction thresholds.

Radiographic parameters	Preoperative			Postoperative			Surgical Correction		
	Aligned	Non Aligned	<i>P</i>	Aligned	Non Aligned	<i>P</i>	Aligned	Non Aligned	<i>P</i>
SVA (mm)	30.788	59.020	0.046	0.721	41.216	0.000	30.067	17.803	0.289
PT (°)	19.873	26.552	0.012	18.314	26.968	0.000	1.559	-0.417	0.204
LL (°)	-34.067	-35.448	0.863	-51.295	-47.971	0.331	16.445	9.329	0.367
PI-LL (°)	4.127	19.172	0.005	-3.773	11.582	0.000	7.265	7.817	0.870

Bold values indicate statistical significance

In this study, these age-related parameters were used, and age-related pathological thresholds were selected as correction objectives. This choice led to more drastic cut-offs for younger patients and more compliant cut-offs for older patients.

4.1. Coronal correction

While the coronal plane has been less correlated to clinical outcomes when compared with the sagittal plane [10], the correction of the coronal deformity remains a critical surgical objective, as it is a visible outcome for the patient. In our series, 55 patients had a pathological preoperative Cobb angle and this parameter was the most corrected during the postoperative evaluation with only 13% of the patients that remained pathologic at one-year follow-up. This result is at least comparable to literature data of ASD patients managed with conventional rods as Moal et al. [7] reported almost 25% of patients under corrected in the coronal plane.

4.2. Sagittal correction

Preoperatively, 90.7% of our patients had a sagittal malalignment and 39% of the patients have the 3 radiographic parameters above the pathologic thresholds. Restoring an optimal sagittal alignment has been demonstrated as a beneficial factor at short, medium and long term for the patients, but also in order to prevent mechanical complications. Literature data have reported that an incomplete sagittal correction was associated with an increased rate of PJK and rods breakage [11].

Each radiographic parameter is related to a component of the deformity and its associated compensatory mechanism. SVA is a global sagittal parameter that reflect the alignment of the trunk, its increasing value reflects the anterior shift of the body related to a loss of lumbar lordosis. This loss of lumbar lordosis is mainly located in the upper lumbar spine and is compensated initially by a loss of thoracic kyphosis that requires a continuous muscular effort [12]. At the same time the loss of distal lordosis is compensated by a pelvic retroversion (increased PT) and all these compensatory mechanisms are trying to maintain a horizontal gaze.

In our series, SVA was normalized for 55% of the patients at one year of follow-up (47 patients) and the average postoperative SVA was significantly improved when compared to preoperative values. 11 patients have a postoperative aggravation of SVA at 1-year related in 8 cases to a PJK without neurological deficit and that did not require revision surgery.

In this cohort, like reported in literature, PT is the most difficult parameter to correct [6,13]. Only 15 patients (17.4%) have a corrected PT at one-year follow-up. This result underline the crucial need for considering PT in the preoperative planning that will require a higher amount of lumbar lordosis, especially in its distal part. Among the proposed solutions, we can consider the opportunity to perform pedicle subtraction osteotomy on lower lumbar vertebra (L4 or L5). Another solution that may improve postoperative distal lordosis could be found in performing multi-level ALIF prior to the posterior approach.

With regards to PI-LL, the actual value used in order to determine the ideal lumbar lordosis for each patient is imperfect as we are not able to evaluate the distribution between upper and lower lordosis.

It may seem therefore more logical, as suggested by Yilgor et al., to define a distribution index of the lumbar lordosis in order to set the amount and distribution of the lordosis required by each patient [14]. This point is especially crucial for patients with a high pelvic incidence ($> 60^\circ$), which was the case for 36% of the patients in our series.

A better distinction between degenerative changes and adaptive mechanisms will normally allow surgeons to obtain a better surgical planning and a better radiographic correction of ASD patients.

4.3. Global correction

The use of PSR manufactured according to the theoretical ideal sagittal alignment of each patient led to a satisfactory transformation from the preoperative planning to postoperative results. The use of these rods required a complete release of the operated spine in order to place the rods without excessive constraints and bring back the spine towards the rods that were acting as a support for correction. However, in our results, only 26% of the patients had a complete correction at 1-year of follow-up. This mitigated result can probably explain by several factors. The initial factor can be found in the planning by itself as for 37 patients the planning was above the age-related pathological threshold for one of the three parameters. Secondly, at the beginning of our experience, there were no marks on the rods in order to place them perfectly (this point has been corrected since) that led to probable loss of distal lordosis. Lastly, the in-vivo behavior of the rods is still unclear and PSR might have as other rods a flattening effect that require further explorations.

Despite these results on correction, it is interesting to underline the fact that in our series the rate of rod breakage was significantly lower in the aligned group. This is consistent with literature data and confirm the presence of biomechanical overload on rods in under corrected patients [15].

4.4. Statistical analysis

The comparison between patients aligned and under corrected is important in order to identify factors on which we can have an influence to improve our results. In our series, aligned patients at one-year of follow-up did not have significant demographic or surgical differences with malaligned patients. The only significant differences between groups were radiographic: patients with the most severe deformities were significantly less corrected. This result is important for surgeons as these patients will require a more aggressive correction and a precise planning will be necessary for best results.

4.5. Strength and limitations of the study

The large number of patients managed with PSR and the prospective aspect of the study are positive factors and, to the best of our knowledge, this is the first study on PSR using age-related correction thresholds.

The major limit of this study is related to the follow-up period and the absence of clinical evaluation. However, we can also consider that one-year can be sufficient for radiographic results in absence of complications. This has been advocated by McDowell et al. that reported that sagittal alignment was not significantly different between one year and 2 years of follow-up, except for patients with PJK [16]. On the other hand, in order to evaluate clinical results, one-year results are not long sufficient as most clinical improvements are reported by patients after 1-year of follow-up [8] and further studies including health related quality of life scores (including pain and disability) and return to work data will be needed.

5. Conclusion

PSR represent a promising tool in order to transform the surgical planning into a postoperative reality in the management of ASD patients. Corrections rates with PSR are comparable with results of patients managed with conventional rods in the literature, with fewer mechanical complications such as rod breakage. These results confirm the interest of preoperative sagittal parameters and the crucial impact of surgical planning integrating age-related corrections thresholds. Further studies will therefore be needed in order to confirm these results especially for clinical evaluation.

Human and animal rights

The authors declare that the work described has been carried out in accordance with the Declaration of Helsinki of the World Medical Association revised in 2013 for experiments involving humans as well as in accordance with the EU Directive 2010/63/EU for animal experiments.

Informed consent and patient details

The authors declare that this report does not contain any personal information that could lead to the identification of the patient(s) and/or volunteers.

Disclosure of interest

The authors declare the following financial or personal relationships that could be viewed as influencing the work reported in this paper: S. Fuentes and B. Blondel are consultant for Medicea International (personnal fees).

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Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

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