Utility of Patient-Specific Rod Instrumentation in Deformity Correction: Single Institution Experience

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Abstract:

Introduction: Patient-specific instrumentation is an emerging technology with the promise of a better fit to patient anatomy. With the advent of deformity correction planning software, prefabricated rods can mitigate the need to bend rods in the operating room. Prefabricated rods allow the surgeon to provide a deformity correction closely in line with the surgical plan.

Methods: A retrospective chart review was completed, and all patients with Medicrea UNiD rod were included. A minimum of 3 week follow up upright 36-inch lateral radiograph was necessary for analysis. Overall 21 patients had Medicrea UNiD rods placed; four were excluded (one for cervicothoracic fusion, three for incomplete follow up). Pelvic parameters were documented from the preoperative, surgical plan, and postoperative radiographs using Surgimap (Nemaris Inc, NY). The parameters for the rods were based on the surgical plan. Paired t-tests were used to compare the preoperative, surgical plan, and postoperative pelvic parameters.

Results: Average lumbar lordosis, pelvic tilt, sacral slope, and sagittal vertical axis in preoperative radiographs were 35.12°, 24.82°, 28.65°, and 65.65 mm, respectively. In postoperative imaging, lumbar lordosis, pelvic tilt, sacral slope, and sagittal vertical axis were 57.00°, 18.00°, 35.71°, and 21.59 mm, respectively. There was a statistically significant difference in pelvic tilt, sacral slope, lumbar lordosis, and sagittal vertical axis between the preoperative film and surgical plan ($p < 0.001$), whereas no statistically significant difference was found between the surgical plan and postoperative pelvic parameters ($p > 0.05$).

Conclusions: Cases in which prefabricated rods were utilized demonstrated improved spinopelvic alignment. Additionally, there was no statistical difference between the surgical plan and postoperative imaging in terms of pelvic parameters. Future studies are needed to investigate the possible benefits of prefabricated rods.

Keywords:

spinopelvic parameters, adult spinal deformity, patient-specific rods, software planning, prefabricated rods

Spine Surg Relat Res 2020; 4(3): 256-260

dx.doi.org/10.22603/ssrr.2019-0101

Introduction

Appropriate alignment of the spine is essential for the proper functioning of the musculoskeletal system. Adult spinal deformity (ASD) is a major source of disability due to alteration of spinopelvic parameters and alignment, leading to increased energy expenditure and decreased function. Historically, the focus was on correcting coronal plane deformity, but multiple studies have demonstrated the critical impact of sagittal plane deformity on quality of life measures. The current paradigm in degenerative adult scoliosis involves balancing the spine in the sagittal plane. This includes a sagittal vertical axis (SVA) less than 50 mm, pelvic incidence-lumbar lordosis (PI-LL) mismatch of less than 10°, and pelvic tilt (PT) less than 20°[1]. In the surgeon's armamentarium, there are a variety of tools that can be utilized to accomplish these parameters. Due to the large range of corrective maneuvers, preoperative planning becomes a key step in accomplishing a balanced spine. Deformity correction planning software assists with preoperative decision making and has been validated in the literature[2].

Patient-specific instrumentation is an emerging technology with the promise of a better fit to patient anatomy. With the advent of deformity correction planning software, prefabri-

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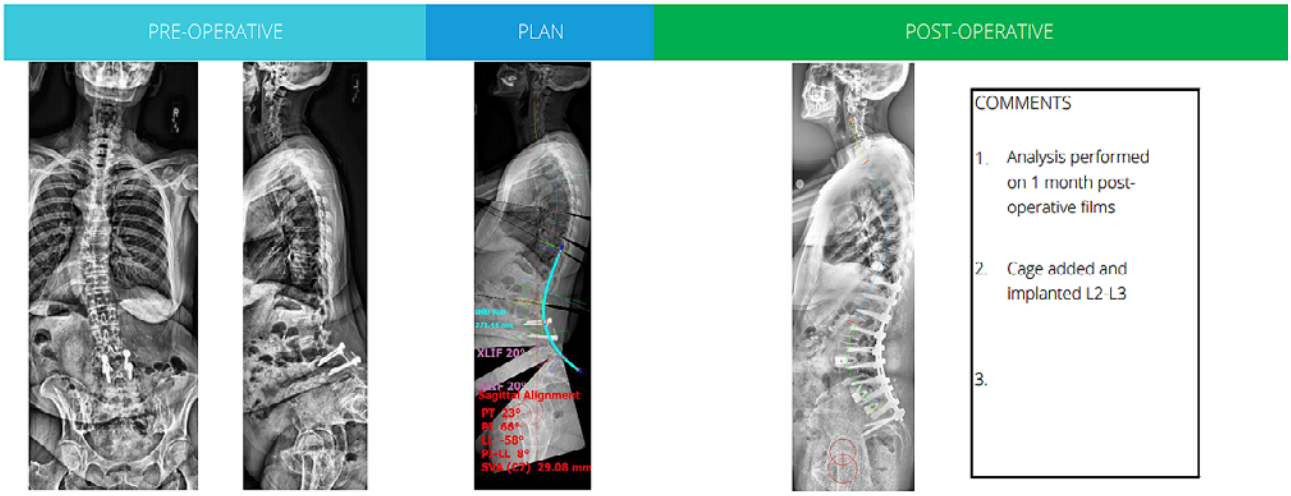
Received: November 1, 2019, Accepted: January 23, 2020, Advance Publication: March 19, 2020



SPINOPELVIC PARAMETERS	PREOP	PLAN	POSTOP
Pelvic Tilt (PT, °)	39	23	33
Pelvic Incidence (PI, °)	66	66	68
Sacral Slope (SS, °)	27	43	35
Lumbar Lordosis (LL, °)	17	58	55
PI-LL (°)	49	8	13
Thoracic Kyphosis (TK, °)	18	40	44
T1 Pelvic Angle (TPA, °)	46	20	28
Sagittal Vertical Axis (SVA, mm)	152	29	37

Gestures (Osteotomies, cages)	PLAN	POSTOP
Cage	N/A	L2-L3
XLIF (20°)	L4-L5	L4-L5
ALIF (20°)	L5-S1	L5-S1
TK Comp.		
Restore LL		

Figure 1. Top left: Preoperative 36-inch standing AP and lateral radiographs. Bottom Left: Table listing the preoperative, planned, and postoperative spinopelvic parameters. Middle: Preoperative plan utilizing Surgimap software to achieve ideal spinopelvic alignment. Top right: 1 month postoperative radiograph after implantation of patient-specific rods. Bottom right: Description of planned and actual cages implanted during the procedure.

cated rods can be created and mitigate the need to bend rods in the operating room. Prefabricated rods may allow the surgeon to provide and maintain a deformity correction which is closely in line with the surgical plan[3].

Materials and Methods

This research has been approved by the Institutional Review Board of the authors' affiliated institution. A retrospective chart review was completed, and all patients in whom a UNiD (MEDICREA Group, New York, USA) patient-specific rod was placed for a thoracolumbar fusion were included. To establish a cohort of controls, age-matched similar cases without the prefabricated rods were selected in the same time frame, and spinopelvic parameters as well as intraoperative clinical results were compared. Medical records and imaging were analyzed for patients who underwent instrumented posterior spinal fusion. All preoperative planning and surgeries were completed by the senior author. The following variables were the inclusion criteria: 1. older than 18 years of age, 2. diagnosis of ASD, 3. at least immediate postoperative follow up with upright 36-inch lateral radiograph, 4. underwent a posterolateral fusion that consisted of at least three levels. Exclusion criteria included lack of postoperative imaging, failure to implant patient-specific rods, or lack of preoperative planning data.

The process of creating patient-specific rods began at the first outpatient clinic appointment where 36-inch scoliosis series plain films were obtained. These films were analyzed with Surgimap (Nemaris Inc, New York, USA), a preoperative planning software (Fig. 1). These plans were then submitted to create the patient-specific rods. Parameters from Surgimap were utilized to contour the rods to exact specifications. Minor in-situ rod bending was completed at the time of surgery. Postoperative films were obtained at 3 weeks and were then repeated at 1 and 2 years following surgery.

Medical records of patients included in this study were evaluated. Demographic data such as age, sex, body mass index (BMI), number of levels fused, and type of osteotomy utilized were collected. Postoperative parameters including pelvic incidence, PT, sacral slope, lumbar lordosis, and SVA were also collected.

The data analysis involved comparing the preoperative to the planned pelvic parameters. Subsequently, planned pelvic parameters were compared with the postoperative parameters. Finally, a comparison of spinopelvic parameters, estimated blood loss, and operative time was performed between the traditional method with in-situ rod bending and the prefabricated rods. Paired t-tests and one-way ANOVA test were used to compare various parameters and define significance.

Results

Overall, 21 patients had patient-specific rods created, but

Table 1. Comparison of Intraoperative and Postoperative Spinopelvic Parameters between the Prefabricated and Traditional Rods. No Statistically Significant Differences in Blood Loss and Operative Time Were Noticed between the Two Cohorts.

	Prefabricated Rods	Traditional Rods	P-Value
Mean age in years ± SD	67 ± 6	66 ± 7	
Gender (%)			
Male	4 (24%)	10 (37%)	
Female	13 (76%)	17 (63%)	
BMI ± SD	27.5 ± 5.6	29.1 ± 4.6	
Number of levels fused	7.6 ± 2.7	8.3 ± 2.5	0.42
Estimated blood loss (cc)	861 ± 354	913 ± 308	0.35
Operative time (min)	411 ± 93	421 ± 111	0.76
Smith-Peterson Osteotomy (%)	100%	81%	0.06
Pedicle Subtraction Osteotomy (%)	6%	15%	0.38
Lumbar lordosis (deg)	57°	55.9°	
Pelvic tilt (deg)	18°	19.5°	
T1-pelvis angle (deg)	-	16.1°	
Sagittal vertical axis (mm)	21.6 mm	36.2 mm	
Length of follow-up in months ± SD	16 ± 8	14.5 ± 9	

Table 2. Comparison of Preoperative, Planned, and Postoperative Spinopelvic Parameters.

	Mean (SD)		
	Preoperative	Planned	*P*
Pelvic Tilt	24.82° (9.61°)	16.94° (3.8°)	0.0006
Pelvic Incidence	53.47° (10.11°)	53.47° (10.11°)	1
Sacral Slope	28.65° (9.84°)	36.53° (7.97°)	0.0006
Lumbar Lordosis	35.12° (25.34°)	54.88° (12.28°)	0.0001
Sagittal Vertical Axis (mm)	65.65 (72.87)	14.76 (17.18)	0.0045
	Mean (SD)		
	Planned	Postoperative	*P*
Pelvic Tilt	16.94° (3.8°)	18.00° (8.59°)	0.5171
Pelvic Incidence	53.47° (10.11°)	53.71° (10.44°)	0.9472
Sacral Slope	36.53° (7.97°)	35.71° (5.80°)	0.6217
Lumbar Lordosis	54.88° (12.28°)	57.00° (13.51°)	0.1758
Sagittal Vertical Axis (mm)	14.76 (17.18)	21.59 (44.54)	0.4878

four were excluded from this study. Three patients were excluded for lack of follow up imaging, and one was excluded since the rod was utilized for a cervicothoracic fusion. The average age of this cohort of patients was 67 years (SD 6), and the number of female and male patients was 13 and 4, respectively. The average BMI was 27.5 kg/m^2 (SD 5.6). Overall 11 patients had prior spinal surgery. All patients in this cohort had some form of a Schwab grade 2 osteotomy, whereas one patient (6%) had a Schwab grade 3 osteotomy[4]. The average number of levels fused was 7.6 (SD 2.7). The prefabricated rods used in these cases were all 5.5 mm in diameter and were made of cobalt-chromium. The average length of follow up was 16 months (SD 8).

In the traditional cohort, the average age was 66 years (SD 7) consisting of 10 males and 17 females. The average BMI in this cohort was 29.1 kg/m^2 (SD 6.4). In this group, 81% and 15% of the patients underwent Schwab grade 2 and grade 3 osteotomies, respectively[4]. All clinical parameters including average estimated blood loss (EBL) and operative time are shown in Table 1. As demonstrated, no significant differences were shown in EBL and operative time between the two groups.

Further imaging analysis of patients with prefabricated rods revealed that average lumbar lordosis, PT, sacral slope, and SVA in preoperative radiographs were 35.12°, 24.82°, 28.65°, and 65.65 mm, respectively. Analysis of postoperative films revealed lumbar lordosis, PT, sacral slope, and SVA of 57.00°, 18.00°, 35.71°, and 21.59 mm, respectively (Table 2). As desired, there were statistically significant differences in PT, sacral slope, lumbar lordosis, and SVA between the parameters in pre- and postoperative films ($p < 0.001$). On the contrary, there was no statistically significant

difference between the surgical plan and postoperative film for any pelvic parameter, as expected ($p > 0.05$). In the traditional cohort with in-situ rod bending, the average lumbar lordosis, PT, T1 pelvic angle, and SVA in preoperative radiographs were 30.1°, 26.8°, 29.7°, and 112 mm, respectively. In postoperative imaging, lumbar lordosis, PT, T1 pelvic angle, and SVA were 55.9°, 19.5°, 16.1°, and 36.2 mm, respectively, and all showed statistically significant differences between the pre- and postoperative measurements ($p < 0.02$). Results in the traditional cohort are in congruence with what was seen in the prefabricated rod group (Table 1).

Discussion

Consideration of sagittal balance is an essential step in the evaluation of all potential spine surgery patients. The literature has demonstrated that patients who undergo surgery with maintained or restored sagittal balance tend to have better postoperative outcomes. Health-related quality of life scores are closely related to the achievement of normal spinal alignment. Such measures include the Oswestry Disability Index (ODI), Short Form-12 (SF-12), and Scoliosis Research Society-29 (SRS-29)[5]. These studies support the concept of a cone of stability or cone of economy concept put forth by Jean Dubousset. The cone of economy concept states that there is a conical region of stability from the feet to the head. The ideal position is in the center of the cone where the head is centered over the feet. Positions that deviate from the center cause increased energy use which can lead to muscle fatigue and pain. Therefore, posture outside this cone leads to a loss of the erect position or obviates the need for external support[6].

If spinopelvic mismatch is the underlying cause of disability in ASD, achieving spinopelvic harmony must be the goal of any surgical intervention on the spine. Previous authors have set forth guidelines that assist in preoperative planning and intraoperative manipulation. In a retrospective review of radiographic parameters from 125 postoperative patients, Schwab et al. demonstrated a statistically significant difference in ODI when certain correction in spinopelvic alignment was accomplished. These parameters included SVA less than 50 mm, PT less than 20°, and PI-LL mismatch less than 9°[1]. To achieve these parameters, a variety of osteotomies can be utilized intraoperatively. These techniques have been well described and classified by Schwab and colleagues[4]. Ames and others have demonstrated that the location of the osteotomy is also critical since it determines the amount of correction. Osteotomies that are more caudal have a greater impact of LL and SVA than those which are more cranially located[7].

From the literature, it is evident that planning a deformity correction begins during the initial clinic visit, well before any surgery is undertaken. One advancement that has allowed surgeons to better plan spinal alignment corrections is preoperative planning software[8]. Programs such as Surgimap have been validated for measuring spinopelvic parameters with good to excellent inter- and intraobserver reliability. In addition to being consistent, these tools can be applied quickly to long cassette radiographs[9]. The process of planning a correction in Surgimap is relatively simple and involves four steps: 1. importing the patient's preoperative long cassette scoliosis radiograph, 2. rotating the image to achieve a PT of less than 20°, 3. quantification of pelvic parameters, and 4. simulation of planned osteotomies. Langella and colleagues executed this protocol and were able to demonstrate excellent correlation between values predicted by Surgimap and real-time postoperative imaging[2].

The next step in patient-specific deformity correction and maintenance would be instrumentation that is tailored to the individual patient's spinopelvic parameters. Ideally, this would be created before the operation and match the planned sagittal correction to ensure proper alignment. Our retrospective study attempted to prove the concept that sagittal plane correction could be initiated in the clinic by planning the correction preoperatively and designing patient-specific rods that fit these specifications. The patient population had a moderate level of spinopelvic mismatch with an average SVA of 65.65 mm. This population had a large standard deviation in respect to SVA, which suggests that there was a variety of kyphosis, some with more extreme sagittal plane deformity. This assertion can also be generalized to the lumbar lordosis. As demonstrated above there was statistically significant difference between the preoperative parameters and the planned parameters. The planned parameters fell well within the range of the recommendations put forth by Schwab and colleagues[1]. There was no statistically significant difference between the planned pelvic parameters and the achieved postoperative pelvic parameters which suggests that the authors were able to successfully implement the planned sagittal plane corrections.

Patient-specific rods coupled with preoperative planning software have been previously studied with moderate success in achieving planned corrections. Barton and colleagues utilized patient-specific rods from Medicrea and had similar level of success. Their preoperative and planned parameters were significantly different, whereas their postoperative and planned parameters did not exhibit any disparity. The authors of this study suggested that there may be four causes of variation: 1. deviation from the surgical plan, 2. discrepancy between the planned angle of osteotomy with the accomplished angle of osteotomy, 3. inability to account for postoperative kyphosis both from proximal junctional kyphosis and reciprocal kyphosis, and 4. difficulty with predicting pelvic relaxation[3].

Comparison of pre- and postoperative spinopelvic parameters in the traditional and prefabricated cohorts did not imply any differences in results. Interestingly, comparison of clinical intraoperative parameters, such as blood loss and operative time, did not prove usage of prefabricated patient-specific rods to be superior to the traditional method. This can partially be explained by the small number of subjects.

Moreover, more clinically relevant operative parameters, such as rod breakage incidence, operative time specific to rod placement, and rate of proximal junctional kyphosis, can be investigated to explore any possible differences between the two methods. In a recent study, Fiere et al. showed reduction in incidence of rod breakage (2.2%) by using prefabricated rods[10]. Future studies are needed to explore the possible advantages of patient-specific UNiD rods.

This study is an initial experience with patient-specific rods that are prefabricated based on preoperative planning software. There are limitations that are inherent in our study. This is a retrospective series and as such, the nature of this review will lend itself a certain degree of selection bias. Additionally, the number of cases with traditional in-situ rod placement far outnumbered the number of UNiD rod cases done at our institution; those included in the control group were selected at random from our surgical database to match the UNiD rod cohort patients' age and epoch of surgery. Nonetheless, this study is a small case series showing feasibility, and we are hopeful that it will pave the way for further examination of patient-specific spinal instrumentation in carefully selected patients. Future work is required to provide a more comprehensive prospective clinical analysis of patients undergoing spinal fusion with prefabricated rods, delineate possible contraindications, and present long-term clinical and radiographic outcomes.

Conclusions

The prefabricated rod can be a vital tool in the deformity surgeon armamentarium. Cases in which prefabricated rods were utilized demonstrated improved spinopelvic alignment. Additionally, there was no statistical difference between the surgical plan and postoperative imaging in terms of pelvic parameters. There may be additional benefits to prefabricated rods, which warrant further studies in the future.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

Acknowledgement: Special thanks to Brett Heldt for his help with data collection.

Author Contributions: The authors listed above all contributed to the design of the study, data collection, data analysis, manuscript preparation, and manuscript final edits.

Informed Consent: No informed consent was needed for this study per the Institutional Review Board approval.

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