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Spinal Alignment/Deformity

Patient-specific implants and spinal alignment outcomes

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ABSTRACT

Background: Patient specific (PS) technology has become popular in the field of spine surgery, as it gives surgeons control over the manufacturing of implants based on a patient's anatomy. Patient specific surgical guides, preoperative planning software, and patient specific implants – such as rods and cages, have demonstrated promising results in the literature for helping surgeons achieve spinal alignment goals.

Methods: A review of the literature regarding PS technology in spine surgery for the correction of spinal deformity was performed and is compiled here.

Results: A description of the PS tools currently used for deformity correction and treatment of degenerative spine pathology with example cases are included in this manuscript.

Conclusions: The use of PS technology in spine surgery is an important development in the field that should continue to be studied.

Introduction

The use of patient specific (PS) implants has gained popularity in spine surgery. Advances in technology have allowed for the manufacturing of custom implants using patient imaging such as biplanar slot scanning radiography, computed tomography (CT) or magnetic resonance imaging (MRI). The use of PS implants has been seen in all forms of spine surgery, including degenerative [1,2], traumatic [3], neoplastic [4,5], and infectious spinal conditions [6,7]. Additionally, the use of custom-made implants in spinal deformity surgery has been hypothesized to improve the ability to achieve surgical goals, and is particularly promising. The integration of this technology in designing interbody fusion cages [1,3], spinal rods [8], and planning pedicle screw trajectory [9,10] has revolutionized the approach to surgery in contemporary deformity correction cases.

Three-dimensional (3D) printing technology

The invention of "stereolithography", more commonly referred to as 3-dimensional (3D) printing, was introduced by Charles Hull in 1986 [11]. Hull's system was described as generation of 3D objects by successive layering of cross-sectional shapes from mediums that could respond to appropriate stimulation until a desired structure was obtained. This process has revolutionized medical device manufacturing, allowing PS implants to be manufactured by 3D printing with various materials. These include plastic, metal, ceramics, powders, liquid or living cells [12–14]. Also referred to as additive manufacturing (AM), rapid prototyping (RP), or solid free-form technology (SFF), these technologies can be used to build almost any 3D object defined by a computer-aided design (CAD). Specifically, 2-dimensional (2D) radiographic images such as plain radiographs, magnetic resonance imaging (MRI) and computerized tomography (CT) scans can be converted into 3D print files that serve as the design to build customized structures with the desired anatomic or biomechanical properties.

In 2014, the 3D printing industry was a 700 million dollar industry with only 1.6% of the investments being applied to the medical field; however, in the next 10 years, 3D printing is expected to grow into an 8.9 billion dollar industry with almost 2 billion dollars invested into field of medicine [13]. Tack et al. [15] performed a systematic literature review in 2016 on the application of 3D printing in the medical setting and found 60% of the published results were for surgical guides while 38% were models for surgical planning. The use of 3D printing for the use of custom-made implants, molds for prosthetics and models for implant shaping were much less common in the published literature. Orthopedics had the largest proportion of publications of the multiple surgical domains included in the review, with papers involving implants

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for the knee (30.7%), hip (8.7%), and spine (7.46%) representing 3 of the top 5 most frequently published topics.

Techniques in spine surgery have been developed with the aim of adequately decompressing neural structures, obtaining appropriate spinal alignment, and providing stability when necessary. The selection of implants to achieve these goals often pertains to patient factors such as body habitus, degree of deformity, or the presence of challenging anatomy. Patient specific implants are the most recent and interesting addition to the repertoire of a spine surgeon to achieve these goals. These tools allow the surgeon to incorporate a patient's anatomy into the design of a device in anticipation of the surgical steps required to obtain the desired outcome.

Preoperative planning and patient specific surgical guides

The use of patient specific technology in surgical planning has been theorized to improve outcomes by shifting complicated, time-consuming decision making to a preoperative setting. This is highlighted in the use of pedicle screw guides and planned trajectories through computer software linked to robotic-assisted procedures. Using CT scans or MRI images, 3D models can replicate a patient's anatomy, and pedicle screw guides can be created that fit the patient based on the model (Fig. 1). Computer software can be utilized to plan pedicle screw trajectory for each level to be included in the desired construct (Fig. 2). This can be especially useful in patients with small or dysmorphic anatomy, where placement of pedicle screws can be more challenging. Studies of patient-specific surgical guides (PSSG) have demonstrated over 90% accuracy of inserted screws with a variety of different guiding tools including a drill, k-wires, probes, and multistep systems. This is compared to 50%–87% accuracy using free-hand technology in the literature [16]. Hu et al.[17] described the use of rapid prototyping drill template (RPDT), which involves the creation of a posterior guide that fits on the lamina in a "lock and key" fashion based on the patient's anatomy, to aid in accurate placement of thoracic pedicle screws. Their group accurately placed 96.1% of the screws in the thoracic pedicles using this system (N=582 screws). A randomized clinical trial in 2019 [18] demonstrated more accurate placement of pedicle screws using patient specific 3D printed guides (N=297 screws) compared to pedicle screws placed using the traditional free-hand technique (N=243 screws). Additionally, the use of robotic-assisted pedicle screw fixation with a patient specific trajectory based on preoperative CT scan, compared to traditional open free-hand technique has demonstrated biomechanical superiority. This was achieved by decreasing intra-discal pressure at the adjacent level of a fusion construct [19], and the authors of this study attributed the results of this finite element (FE) analysis on their ability to achieve a more lateral entry point for the pedicle screws with a large convergent angle using a plan based on the individual patient's anatomy. This study highlights the advantage of PS planning software in the surgical process and is a common thread throughout all the implants discussed in this review.

Patient specific rods

Even with the advancement of surgical planning technologies, alignment goals can be difficult to obtain with surgery. A tool that can be employed to aid in achieving adequate correction in spinal deformity surgery is the use of patient specific rods (PSRs). The manual bending of a rod during surgery has been considered the gold standard in spine

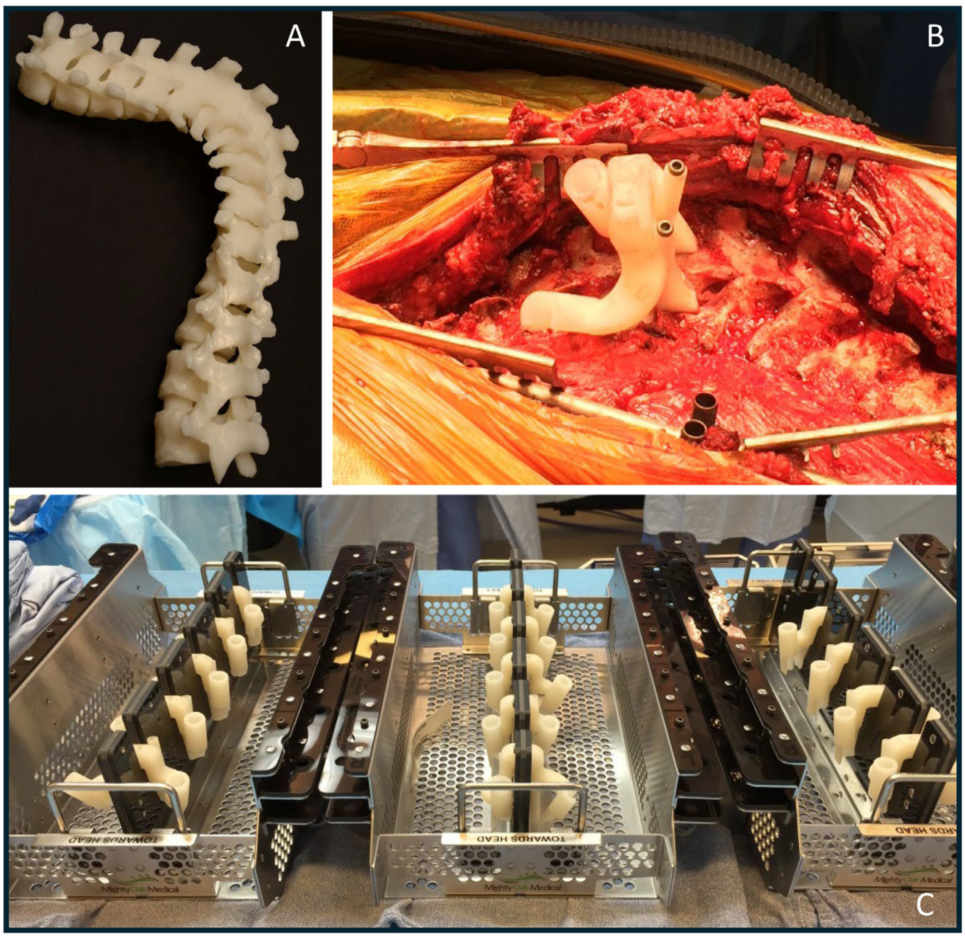


Fig. 1. (A) A 3D model of the patient is created from a CT scan. (B) Pedicle screw guides are made to fit the model based on anatomy and can be positioned onto the spine during surgery. (C) Multiple guides are made for positioning of pedicle screws at each level based on the desired fusion construct.

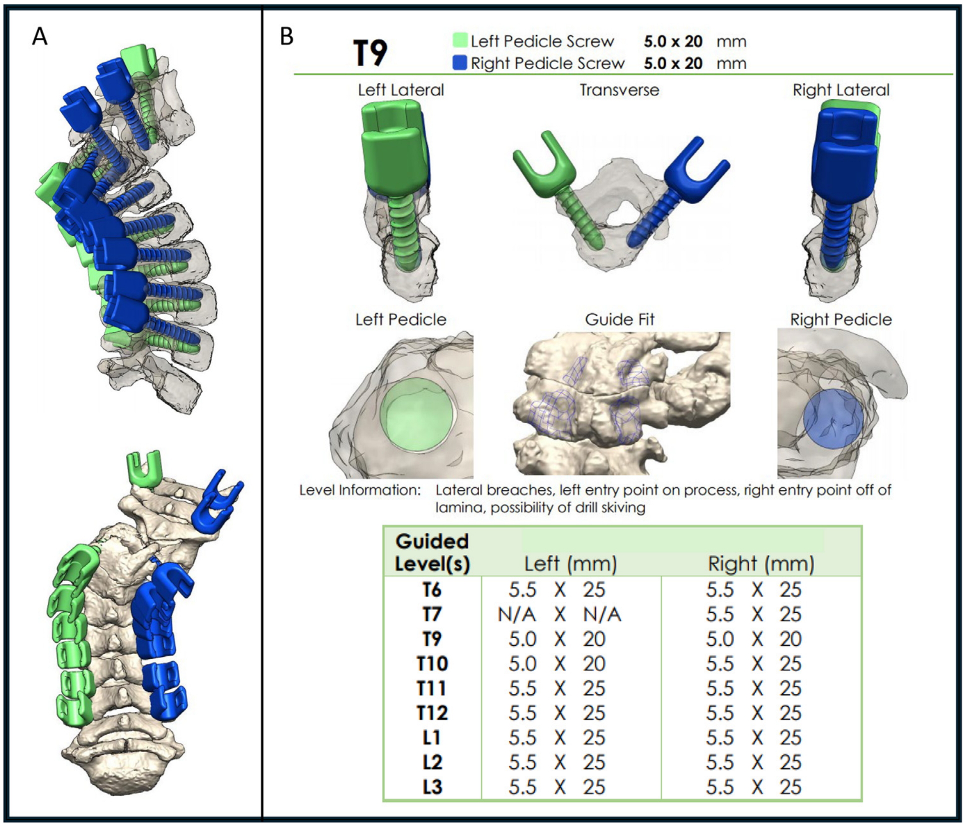


Fig. 2. (A) Computer software is used to plan pedicle screw trajectory based on the patient's anatomy. (B) For each spinal level, the length, trajectory, and size of each screw can be templated before the day of surgery.

surgery and is a process that occurs intra-operatively after corrective soft tissue releases and osteotomies have been performed. This step can influence the final alignment of the spine if the rod is not contoured to adequately restore sagittal and coronal parameters intended. Because it is operator dependent, manual bending of rods is not standardized and it may be difficult to confirm the accuracy of curvature in the rods after bending. Examples of these rods are presented in the "Case Examples" section of the manuscript. Studies have shown that surgeons have a tendency to "overbend" rods [20,21], and this is also affected by screw position and the use of polyaxial screws [22]. Further, metal shape memory, notching, and cold-working metallic rods are all variables that can lead to failure to achieve correction and failure of the rods over time. The use of a template to achieve proper manual bending of the rods can help mitigate this mismatch [23]; however, the use of precontoured rods manufactured with the desired curvature based on the desired spinal alignment completely removes this factor from consideration.

The literature on alignment outcomes using PSRs has varied results. Sadrameli et al. compared sagittal vertical axis (SVA) in patients who had spine surgery using in-situ bent rods (N=17) compared to a group who using PSRs (N=17) and found no difference between the planned and postoperative values in the 2 groups [24]. On the contrary, Kleck et al. demonstrated improvement in SVA from 66.8 mm to 9.8 mm (N=34) from preoperatively to 2 years after surgery [25]. The final SVA obtained in the cohort was almost identical to the planned average goal of 9.9 mm, and there was also improvement in pelvic incidence (PI) and lumbar lordosis (LL) mismatch (PI-LL) after surgery. In fact, several studies have demonstrated improvement in PI-LL with the use of PSRs [8,25–28]. Though the outcome of spinal parameters seems to improve with the use of PSRs, there is still variability in the projected and obtained outcome, highlighting the importance of other factors in sagittal alignment outcomes such as preoperative SVA, age, and the use of pedicle subtracting osteotomies (PSO) [8,26,28].

Combining preoperative planning strategies and PSRs seem to improve outcomes in spinal deformity surgery. Tachi et al. [29] describe a planning simulation system with finite element (FE) analysis to predict the outcomes of deformity correction in adolescent idiopathic scoliosis (AIS) patients using PSRs. They were able to demonstrate a significant correlation between the actual postoperative alignment and the simulated measurements used to create the prebent rods. Other studies using these types of models, such as the UNiD (Unique Identity) predictive model using patient specific rods, have allowed surgeons to create plans that more accurately anticipate postoperative alignment and successfully achieve alignment goals [30]. This study shows an improvement in the mean error for achieving the desired thoracic kyphosis (TK) and pelvic tilt (PT) with using both the model and PSRs. The results of these studies indicate that being able to predict the alignment after a deformity correction surgery and creating an implant that matches these outcomes is a powerful tool for surgeons. As is the case for most of the literature using PS implants, the applicability of these results is limited by the number of patients included in the studies, and further evaluation must be performed to validate the potential benefit of these technologies.

Patient specific cages

Difficult anatomy can complicate the type of implants used in spine surgery. For example, this is especially true in malignancies in the spine. The presence of tumors can alter surrounding anatomy and often requires radical resection of bony and soft tissue structures. Because of the variability of disease and required surgical intervention, patient specific implants can be useful in the treatment of these conditions. The advantage is in the manufacturing of cages designed to fit the anatomy after surgical resection. Several studies describe patient specific implants used in the setting of Ewing sarcoma, metastatic carcinoma, and chondrosarcoma [4,31–33]. The use of patient specific implants can also aid

Table 1
Preoperative spino-pelvic parameters for patients A-C and the planned parameters after surgical correction

	A		B		C	
	Pre-op	Plan	Pre-op	Plan	Pre-op	Plan
Pelvic Tilt (PT, °)	19.8	13.8	28.1	23.1	28.2	19.2
Pelvic Incidence (PI, °)	40	40	58.5	58.5	51.7	51.7
Sacral Slope (SS, °)	20.2	26.2	30.5	35.5	23.5	32.5
Lumbar Lordosis (LL, °)	−33.2	−46.6	−37.3	−56.8	−7.4	−51
PI – LL (°)	6.8	−6.6	21.2	1.7	44.3	0.7
L1-L4 (°)	7.6	−6.2	−24.5	−40.4	11.5	−26
L4-S1 (°)	−40.7	−40.4	−12.8	−16.4	−19	−25
T1 Pelvic Angle (TPA, °)	9.5	5.1	32.6	21	40.6	15.1
Sagittal Vertical Axis (SVA, mm)	−43.9	−38.2	110.9	38.1	182.5	17
Thoracic Kyphosis (TK, °)	22.4	45.7	45.6	51.1	27.9	39.3

in challenging cases relating to infection in the spine. Several case reports can be found in the literature describing the use of custom made vertebral body resection cages in the setting of tuberculosis and infectious spondylitis [7,34]. In these cases, destruction of the spine caused by infection can be more easily managed by cages manufactured to fit the patient's anatomy compared to the off-the-shelf options. Because congenital anomalies and degenerative conditions can also lead to significant changes in the anatomy of the spine, the use of patient specific interbody cages [35], custom made posterior plates [36], and reconstructive prostheses[5] are not limited to the treatment of rare tumors or infection.

The geometry of cages has been demonstrated to play a role in sagittal alignment restoration [37]. Thus, the ability to manufacture patient specific (PS) interbody cages to a shape based on the patient's alignment needs is an exciting development in spine surgery. Biomechanical studies have shown an increase in contact area between PS cages and adjacent endplates compared to commercially available lumbar interbody fusion (LIF) cages by up to 74% [38]. By increasing contact area between the implant the endplate, PS cages result in lower contact stresses in the surrounding spine and thus provide a theoretical advantage against subsidence, especially in weaker bone. A cadaveric study confirmed this concept, demonstrating that PS cages required higher compression forces to produce failure and produced a stiffer construct compared to commercial cages [39]. Studies comparing PS cages and off-the-shelf cages should be replicated in the clinical setting to elucidate these results in an *in-vivo* setting. A further purported advantage is the infinite values of height and angular values of the cages, greater than any off-the-shelf system, allowing patient specific reconstruction of the sagittal and coronal parameters. At the time of this review, there were no high-powered studies of this nature regarding spinal alignment outcomes.

Case examples

The following cases demonstrate patients who have undergone deformity correction surgery using patient specific implants. Patients A-C presented to care with debilitating symptoms relating to their deformity (Fig. 3). Patient A presented with degenerative scoliosis and sagittal imbalance and underwent anterior lumbar interbody (ALIF) fusions from L3-S1, and transforaminal lumbar interbody fusions (TLIF) from L1-L3. Patient B presented with sagittal imbalance, loss of lumbar lordosis, and hyper-kyphotic upper thoracic levels, and underwent posterior spinal fusion from T10-pelvis with TLIFs at L3-S1. Patient C presented with sagittal imbalance, degenerative kyphosis, and loss of lumbar lordosis, and underwent posterior spinal fusion from T10-pelvis with TLIFs at L3-S1 and an L3 pedicle subtracting osteotomy (PSO). In all cases, a patient specific plan was formulated, and a patient specific rod was templated based on the planned surgery. Table 1 includes the preoperative and planned spinopelvic parameters for each patient. It should be noted that for each of these cases, the rods manufactured to fit the surgical plan vary significantly (Fig. 4), but exactly match the desired morphology of the spine after the correction performed. Patient D represent another example of a case with severe coronal and sagittal deformity that was treated with a long construct for posterior spinal fusion. Preoperative radiographs, surgical plan for correction of deformity, as well as spinopelvic parameters can be seen in Fig. 5. Postoperatively, correction of thoracic kyphosis, coronal vertical axis (CVA) and sagittal vertical axis (SVA) was achieved with the use of patient specific implants (Fig. 6).

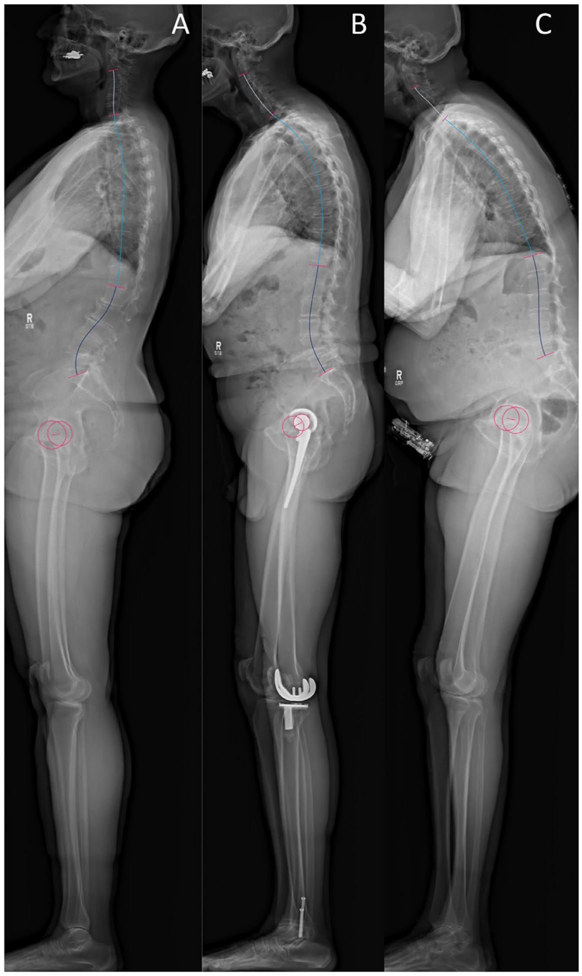


Fig. 3. Patients A-C were indicated for deformity correction surgery due to either sagittal plane imbalance, degenerative kyphosis, loss of lumbar lordosis, or a combination of these 3 conditions.

The use of patient specific cages can also be used to correct deformity in many cases. Patient E represents a case of degenerative scoliosis of the lumbar spine with loss of disc height, spondylolisthesis of L4 on L5 and foraminal narrowing at L5-S1 (Fig. 7). A 3D reconstruction of the patient's anatomy was created using a CT scan of the lumbar spine

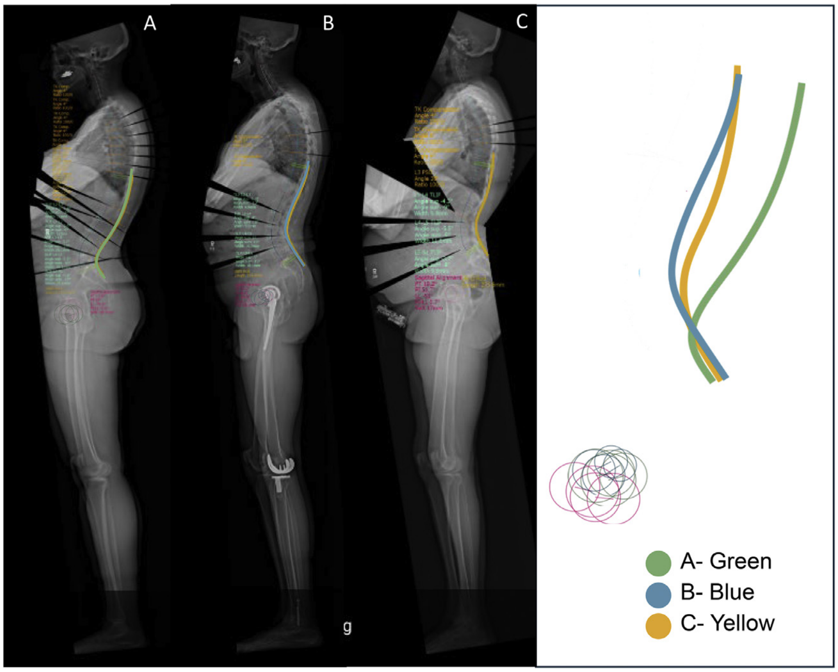
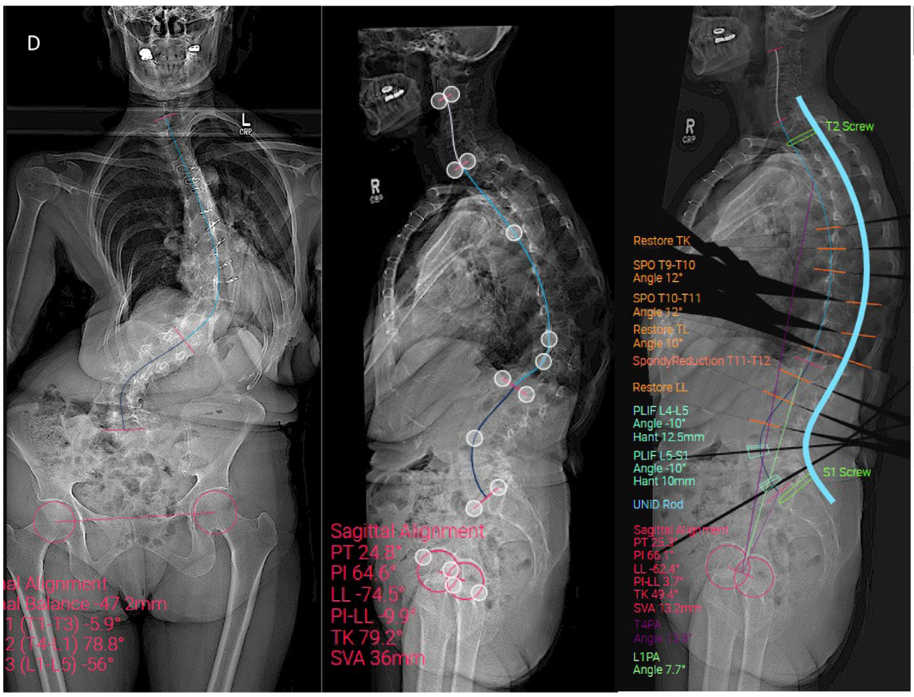


Fig. 4. A patient-specific plan was created for correction of deformity in the sagittal and coronal planes for each patient. A custom rod was templated to fit the specific surgical plan. Notably, the rods vary widely between patients based on the morphology of each patient's spine and differences in the surgical plan.



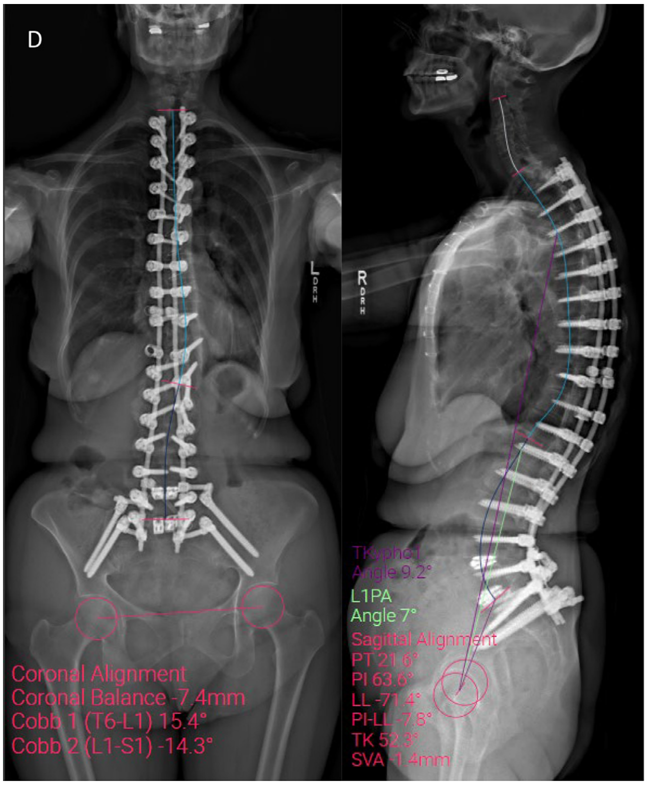
Parameter	Pre-Op	Plan
PT	25	25
L1PA	5	8
T4PA	15	14
LL	-74	-62
TPA	23	20
TK	79.2	49
PI-LL	-9.9	4
SVA	36	13

Fig. 5. Patient D—Case example of a patient with severe degenerative scoliosis with coronal deformity. A surgical plan was created for correction of deformities, and an implant was templated to fit the correction.

and a plan was created for correction of deformity using the patient's anatomy and desired segmental lordosis goals via posterior spinal fusion and TLIF from L3-S1. Postoperative measurements demonstrate the ability to achieve the desired lordosis at the operative levels selected with the patient specific interbody cages (Fig. 8).

Discussion

Perhaps the biggest drawback to the use of patient-specific implants in spine is the paucity of currently available high-quality studies/trials relating to this new technology. Even the larger studies available only demonstrate provisional results with small patient populations, making the generalizability of the conclusions difficult to determine. It is true that as our understanding of spinal deformity grows, the more questions arise about the implants we use to achieve our surgical goals. Numerous studies have demonstrated that health related quality of life scores and patient reported outcomes are correlated with certain global and regional spinopelvic parameters [40–45]. However, the correlation between spinopelvic alignment parameters and patient reported outcomes have been called into question in the recent literature [46–48],



Parameter	Pre-Op	Plan	Post-Op
PT	25	25	22
L1PA	5	8	7
T4PA	15	14	9.2
LL	-74	-62	-71
TPA	23	20	15
TK	70	49	52
PI-LL	-8	4	-8
SVA	38	13	-1.4

Fig. 6. Patient D—Postoperative spino-pelvic alignment parameters demonstrating correction of thoracic kyphosis and coronal imbalance.

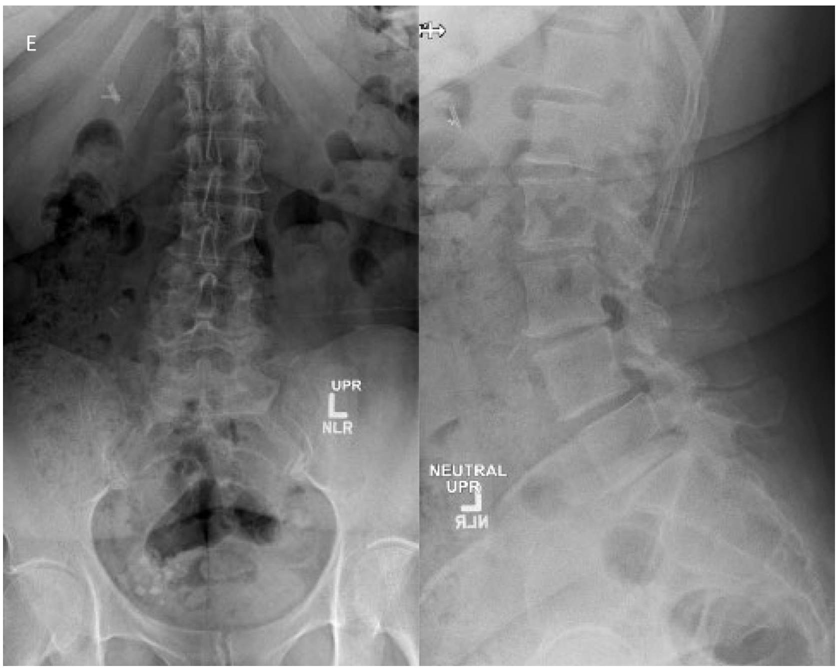
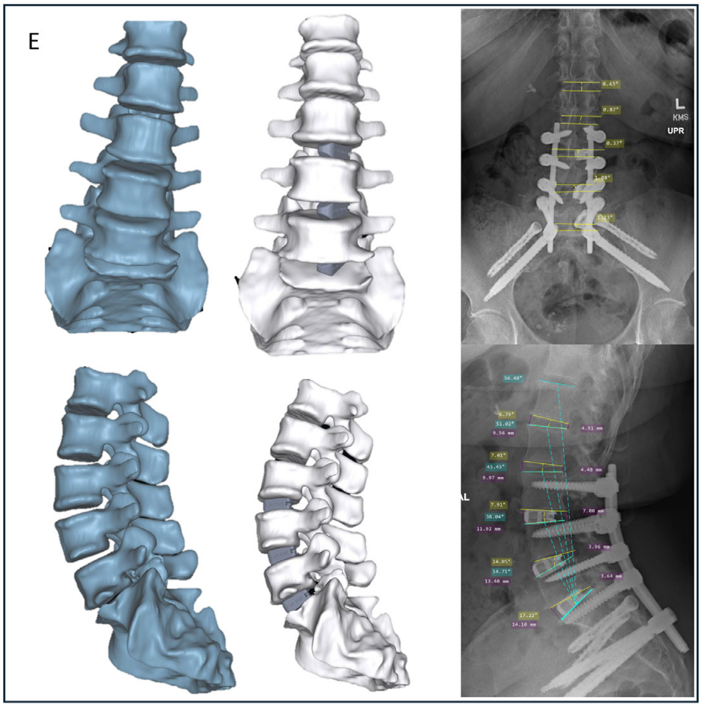


Fig. 7. Patient E—Case example of a patient with degenerative scoliosis of the lumbar spine with loss of disc height, spondylolisthesis of L4 on L5, and foraminal narrowing at L5-S1.

which has led to surgeons claiming that more refined systems should be developed to predict outcomes in spine surgery. Indeed, the solution to achieving excellent clinical outcomes does not lie in alignment goals alone, but is multifactorial, and includes preoperative optimization [49], multidisciplinary safety assessment [50], and patient expectations [51], to name a few. Surgeon-related factors even play a role. Daniels et al. demonstrated that efficiency in the OR is related to less complications, blood loss, fewer ICU admissions, and shorter hospital stays. The next wave of innovation in spine surgery will involve technology that incorporates thoughtful surgical planning, patient and surgeon specific factors, and validated predictive models for each case. Time will reveal if the evolution of 3D-printed additive manufacturing of patient specific implants is the catalyst that allows the field of spine surgery to arrive at the next chapter of excellent patient care.



Degrees (°)		Preop	Plan	Postop
L34 (TLIF)	Lordosis	10	10	8
	Coronal	-2	0	0
L45 (TLIF)	Lordosis	8	13	14
	Coronal	-1	0	1
L51 (TLIF)	Lordosis	7	13	17
	Coronal	-1	0	1

Fig. 8. Patient E (continued) - A 3-D reconstruction of the patient's anatomy was created, and 3 custom cages were manufactured based on the surgical correction goals. Postoperative alignment parameters closely match the planned values.

Conclusion

There has been a notable increase in the popularity of patient specific implants in spine surgery over the last decade. With the expected influx of health care spending in the field of 3D-printing, the use of these implants can be expected to grow on par. Patient specific surgical guides, preoperative planning software, and patient specific implants – such as rods and cages have demonstrated promising results in the literature for helping surgeons achieve spinal alignment goals. In the search for improved outcomes in spine surgery, patient specific technology must be considered as a promising solution in the next era of spine surgery.

Informed patient consent

Complete written informed consent was obtained from the patient for the publication of this study and accompanying images.

Declaration of competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.xnsj.2024.100559.

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