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Impact of a Novel Patient-Specific, Patient-Matched Bezier Parametric Curve Rod Platform on Proximal Junction Biomechanics in an in Silico Thoracolumbar Fusion Model

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Table of Contents

Abstract

Background

Spinal rods play a critical role in guiding and stabilizing the spine to promote fusion, with varying materials and designs impacting postoperative outcomes. Excessive stiffness in rods can contribute to complications such as stress shielding, implant loosening, and Proximal Junctional Kyphosis (PJK) and subsequent failure. The optimal rod design that balances stiffness for spinal realignment while potentially mitigating PJK risk is not well established.

Objective

This study aims to evaluate the biomechanical performance of a novel technology: Bezier Surface-Smoothed transition rod, and to compare it to conventional and stepped rods, focusing on correction capability, spinal stabilization, instrumentation and spinal loading related to PJK risk.

Methods

A spine finite element model with patient-specific 3D spinal geometry was used. The model was used to simulate a 68-year-old female with a severe sagittal imbalance characterized by thoracolumbar kyphosis (Schwab type K classification). Surgical instrumentation with five rod configurations were simulated to compare spinal deformity correction capabilities: (1) constant 6.0mm diameter, (2) stepped 6.0mm to 5.0mm diameter, (3) Bezier 6.0mm-5.5mm-5.0mm diameter, (4) constant 5.5mm diameter, and (5) Bezier 5.5mm-5.0mm-4.75mm diameter. Gravitational forces and flexion movements were simulated to compare load transfer between the spine and instrumentation post-operatively.

Results

All rod configurations achieved equivalent sagittal correction, with thoracic kyphosis (TK) ranging from 36° to 37° and lumbar lordosis (LL) from 47° to 49°. Load distribution analysis showed that Bezier rods provided smoother load transitions and better offloading of proximal segments compared to constant diameter rods. The highest moment sustained by the segment adjacent to the instrumentation was observed with the constant 6mm rod (9N.m), while the Bezier 5.5-5-4.75mm rod showed the lowest moment (7.5Nm), indicating reduced stress of 16% on the upper adjacent vertebrae. Similarly, the Bezier rods were more effective in offloading pedicle screws up to 45% with respect to the stiffer rod construct, potentially reducing the risk of PJK.

Conclusion

The simulation analysis demonstrates Bezier rods offer promising biomechanical benefits particularly in load distribution and stress reduction at the adjacent levels to the instrumentation. Future efforts will focus on clinical validation and optimization of patient specific design.

Introduction

Spinal rods play a critical role in guiding and stabilizing the spine to promote spinal fusion. Currently, these rods are typically made from metal alloys such as Titanium, Cobalt-Chromium, and Stainless Steel, or Molybdenum-Rhenium, each with varying Young's modulus. The diameter of the rod is a key determinant of its bending rigidity, which increases significantly as the diameter increases **(Figure 1).** The choice of material and diameter together determine the flexural stiffness of the rod, as shown in the various configurations compared in **Table 1**.

Figure 1: The flexural stiffness of a rod is directly proportional to the fourth power of its diameter. Changes in diameter have a significant impact on the rod's stiffness, with even small variations resulting in substantial differences in stiffness

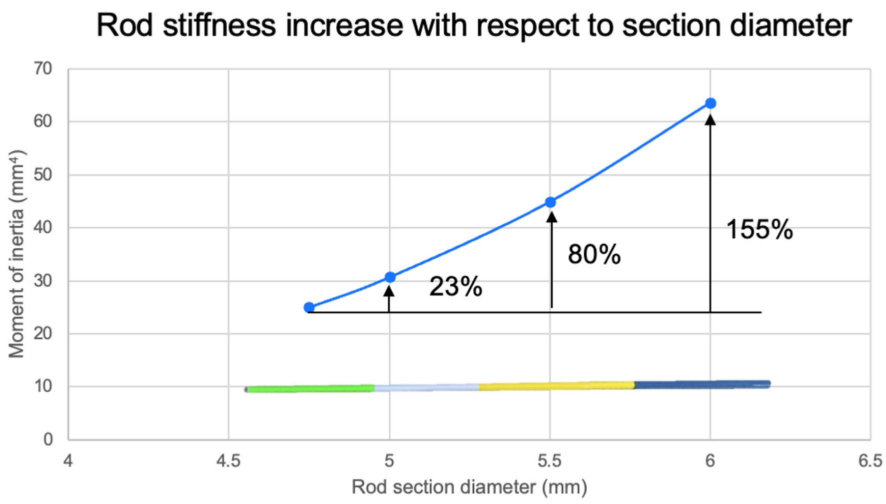


Table 1 : Rod flexural stiffness calculated for different rod diameters and materials modulus of elasticity

	Rods Flexural Stiffness (N.m²)			
Rod diameter (mm)	4.75	5	5.5	6
Ti6Al4v (E=113 Gpa)	2.8	3.5	5.1	7.2
SS316L (E=193 Gpa)	4.8	5.9	8.7	12.3
Cobalt Chromium (E=220 Gpa)	5.5	6.7	9.9	14.0
Molybdenum-Rhenium (E=365 Gpa)	9.1	11.2	16.4	23.2

While stiff rods can help correct spinal deformities more effectively, excessive stiffness may contribute to complications such as stress shielding, implant loosening, and Proximal Junctional Kyphosis (PJK) characterized by abnormal kyphosis at the upper adjacent segment of the instrumented spine.

PJK is a well-recognized complication in spinal deformity surgery, occurring in 6% to 62% of patients with potential added treatment costs of $55,547 - $193,277 (Alvarez Reyes et al. 2022; Cho, Shin, and Kim 2014; Han et al. 2017; Theologis et al. 2016; Safaee et al. 2018).

Several factors have been linked to Proximal Junctional Kyphosis (PJK), including bone density, preoperative sagittal malalignment, fusion level, BMI, smoking, and the stiffness of the construct.

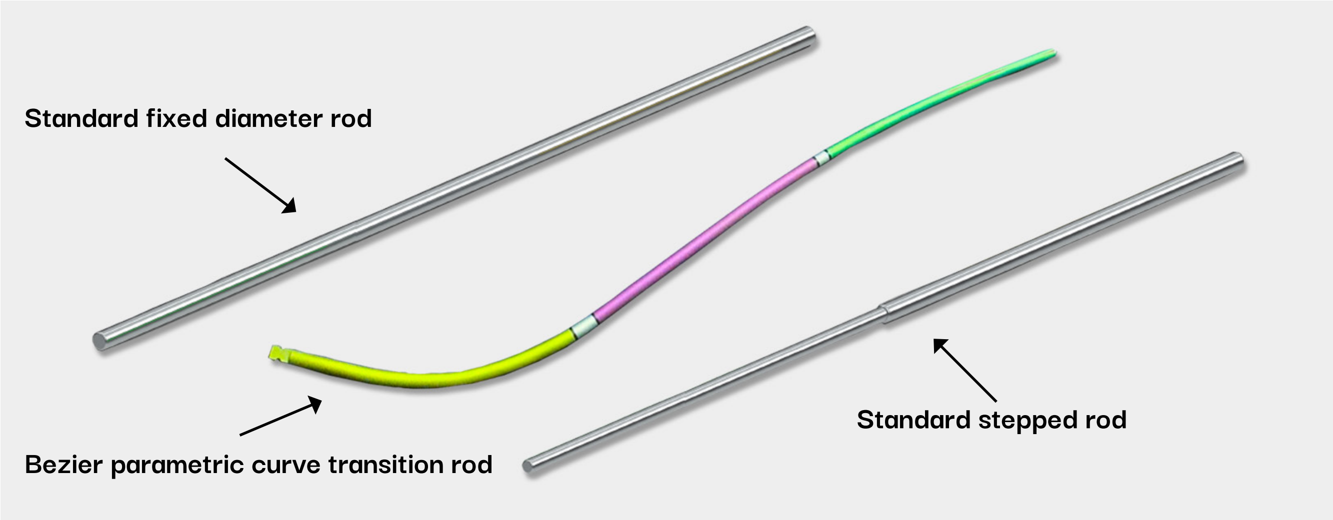
Among these, the stiffness of the construct, influenced by the choice of rods, is a risk factor that the surgeon can control (Sebaaly et al. 2018; Etebar and Cahill 1999; Cahill et al. 2012; Dubousset and Diebo 2023).

Several studies have investigated various rod materials and diameters, yet there remains no consensus on the optimal rod design that balances correction capabilities with mitigating PJK risk (Han et al. 2017; Ye et al. 2023; Facchinello et al. 2015; Cammarata et al. 2014).

Most studies have focused on rods with consistent diameters, offering uniform stiffness along the spine **(Figure 2)**. Stepped rods have been proposed to address these needs, but they pose challenges such as stress concentration at the transition, resulting in an increased risk of rod breakage and difficulties in screw placement **(Figure 2)** (Cahill et al. 2012; Cammarata et al. 2014).

The introduction of Bezier Surface-Smoothed transition rods, which vary in stiffness based on local rod section diameter, aims to tackle these challenges **(Figure 2)**.

Figure 2: Different rod profiles available for posterior spinal fixation: constant diameter (left), Bezier Surface-Smoothed transition rod (middle), and multi-diameter stepped rods (right)



Bezier rods are patient-specific and can be designed with greater stiffness where needed for different clinical application such as:

- 3-column osteotomy,
- multilevel posterior column osteotomies,
- lumbosacral junction

while maintaining flexibility near the upper instrumented vertebra to promote a biomechanical “soft landing” at the junction of instrumented and native spine.

The objective of this study is to evaluate the performance of the Bezier Surface-Smoothed transition rod compared to conventional and stepped rods in terms of:

- correction capability
- spinal stabilization and instrumentation
- spinal loading related to PJK risk.

We hypothesize that this innovative rod design alleviates biomechanical stress at the instrumented-non-instrumented transition, thereby lowering PJK incidence while maintaining robust correction capabilities.

This study leverages in-silico biomechanical analysis on patient-specific spinal finite element model, offering insights into load and stress distribution within the spine and instrumentation in a controlled and repeatable environment.

Materials and Methods

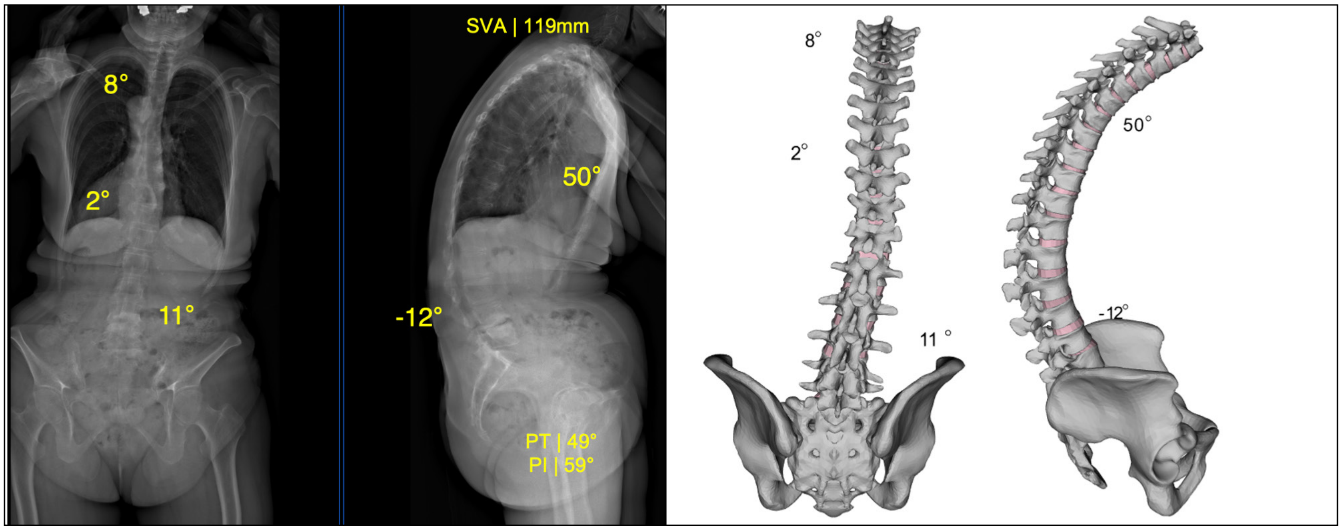
Materials

A spine Finite Element Model (FEM) that has undergone multiple validation activities related to posterior spinal instrumentation to support previous research hypotheses was utilized (Taleghani et al. 2021; Clin et al. 2019; Driscoll, Mac-Thiong, Labelle, and Parent 2013; Driscoll, Mac-Thiong, Labelle, Slivka, et al. 2013; Decker et al. 2024).

Based on preoperative standing posteroanterior and lateral calibrated radiographs, a patient-specific 3D spinal geometry of a 68-year-old female was reconstructed from T1 to the pelvis with a precision of 1.8mm followed by the constructions of an osteo-ligamentous finite element model.

The patient's morphology indicated a thoracolumbar kyphosis (type K Schwab ASD classification, Pre-operative Thoracic Kyphosis T4-T12 (TK): 50°, Lumbar Lordosis L5-L1 (LL): -12°, **(Figure 3)** (Humbert et al. 2009; Carreau et al. 2014).

Figure 3: The finite element model is tailored to precisely replicate the 3D spinal geometry of individual patients, as determined from bi-planar radiographs. The mechanical properties of the model are customized at each vertebral level to accurately reflect the specific disc space dimensions and the corresponding range of motion of each segment.



The pelvis and vertebrae were modeled as rigid bodies due to their minimal deformation during surgery.

The non-linear behavior of each functional spinal unit (FSU), comprising two adjacent vertebrae and associated soft tissues, was defined with a 6x6 non-linear joint calibrated using data from cadaveric experimental studies (Manohar M. Panjabi, Hausfeld, and White 1981; Oxland, Lin, and Panjabi 1992; Gardner-Morse and Stokes 2004; M M Panjabi, Oxland, and Yamamoto 1994; M M Panjabi, Brand, and White 1976a; 1976b).

Adjustment of the moment-rotation curves for each thoracic intervertebral unit incorporated a stiffening multiplier to reflect the biomechanical influence of the rib cage (Liebsch et al. 2017).

Methods

Spinal fusion surgery was simulated to assess the correction achieved by a posterior construct from T10 to S1 using bilateral pedicle screw constructs and Titanium rods with five different types of sections **(Figure 4)**.

Figure 4: Five surgical strategies simulated. All instrumentation strategy parameters remained consistent except for the rod section profile along the instrumented levels.

	Scenario 1 Constant Rod ø6mm	Scenario 2 Stepped Rod ø6mm	Scenario 3 Bezier Rod 1 Ø6-5.5-5mm	Scenario 4 Constant Rod Ø5.5mm	Scenario 5 Bezier Rod 2 Ø5.5-5-4.75mm
Instrumented levels	Upper Instrumented Vertebra : T10 Lower Instrumented Vertebra: S1				
Osteotomies	Ponte osteotomies at all levels + PSO at L3				
Screw types	Polyaxial screws at all levels				
Rod material	Titanium Ti 6Al4V				
Rod contouring	Same curvature				
Rod section / diameters	 Diameter: 6.0 mm	 Distal diameter: 6.0 mm Proximal diameter: 5.0 mm Step between T12/T11	 **Bezier rod: 6.0/5.5/5.0** • 6.0: S1 to L2/L1 • 5.5: L2/L1 to T12/T11 • 5.0 : T12/T11 to T10	 Diameter: 5.5 mm	 **Bezier rod: 5.5/5.0/4.75** • 5.5: S1 to L2/L1 • 5.0: L2/L1 to T12/T11 • 4.75 : T12/T11 to T10

Rod material was modeled with an elastoplastic multilinear stress-strain relationship to account for rod permanent deformation (E=113 Gpa, Yield stress= 950 Mpa, Ultimate strength= 1180 Mpa at 10% elongation).

- The first rod scenario used a constant diameter rod of 6.0mm.
- The second scenario involved a stepped rod with a distal diameter of 6.0mm and a proximal diameter of 5.0mm, with a step between T12 and T11.
- The third scenario featured a Bezier rod with a diameter of 6.0mm from S1 to L2/L1, 5.5mm from L2/L1 to T12/T11, and 5.0mm from T12/T11 to T10.
- The fourth scenario used a constant diameter rod of 5.5mm.
- The fifth scenario employed a Bezier rod with a diameter of 5.5mm from S1 to L2/L1, 5.0mm from L2/L1 to T12/T11, and 4.75mm from T12/T11 to T10.

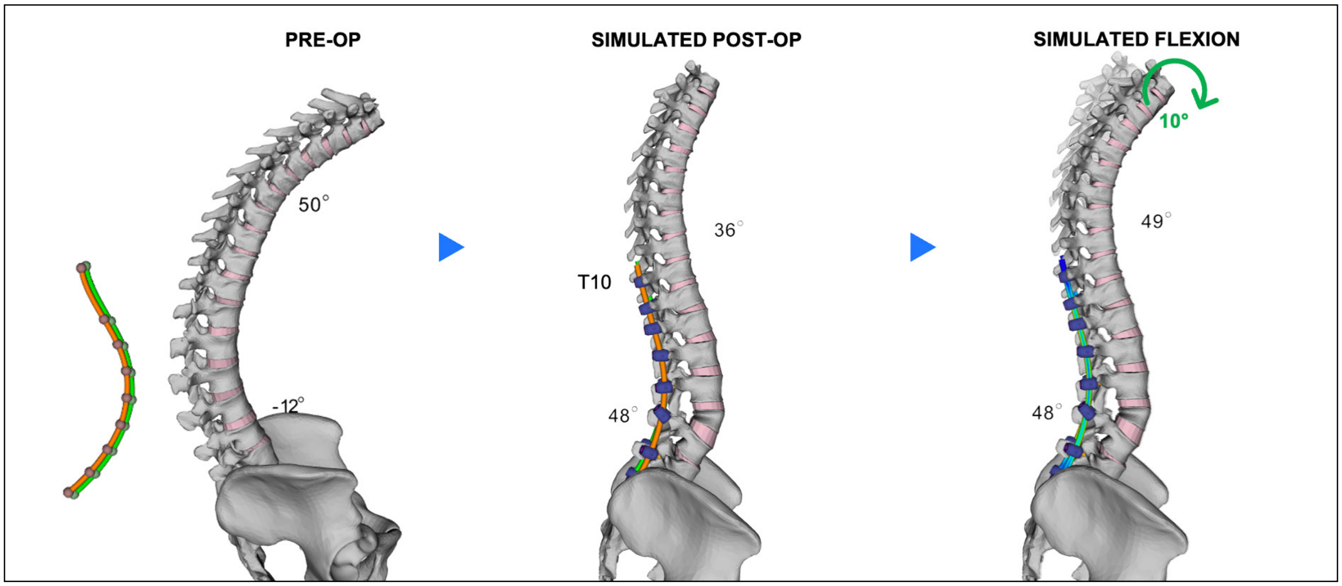
The patient's transition from a weight-bearing standing position to an intraoperative prone position was simulated (Patwardhan et al. 1999; Pearsall, Reid, and Ross 1994; Pearsall, Reid, and Livingston 1996).

Facetectomies were performed from T10 to S1, except at L3, where a pedicle subtraction osteotomy (PSO) was conducted to recreate a lumbar lordosis.

Polyaxial screws were then positioned posteriorly in the vertebrae at the selected levels, followed by rod insertion and compression of the PSO at L3.

Finally, the transition back to a standing and weight-bearing position was simulated **(Figure 5)**.

Figure 5: Simulation steps, from pre-operative spinal shape with rod contouring strategy similar for each simulated scenarios, simulated post-operative spinal shape in standing position, and simulated spinal shape under 10° flexion.



- Gravitational forces were applied in a follower-load manner to mimic physiological conditions (Patwardhan et al. 1999).
- Post-operative Pelvic Tilt (PT) was defined based on Pelvic incidence (PI) with respect to Lafage et al. and LeHuec equations for sagittal balance (Lafage et al.: PT < 20° & LeHuec et al.: PT = 0.44*PI – 11.4 = 15°).
- To further evaluate load distribution during functional movement, a similar flexion motion was simulated for each scenario by applying a forward rotation of 10 degrees at the T1 vertebral level **(Figure 5)**.

Metrics

The output metrics and related patient outcomes measured in this study focused on several key areas.

- Sagittal balance correction capability was assessed by comparing changes in lordosis and kyphosis between pre- and postoperative conditions.
- Spinal stabilization capability was evaluated by examining the range of motion (ROM) of the instrumented spine under flexion.
- PJK risk mitigation was analyzed by assessing the loading on spinal units and the ROM of the upper adjacent vertebrae. As such, their respective discontinuities under flexion and the loading on the upper instrumented vertebrae screws were compared.
- Instrumentation failure risks were evaluated by measuring rod stresses and the forces sustained by pedicle screws.

These metrics provide comprehensive insights into the biomechanical performance and potential clinical outcomes of different spinal rod configurations.

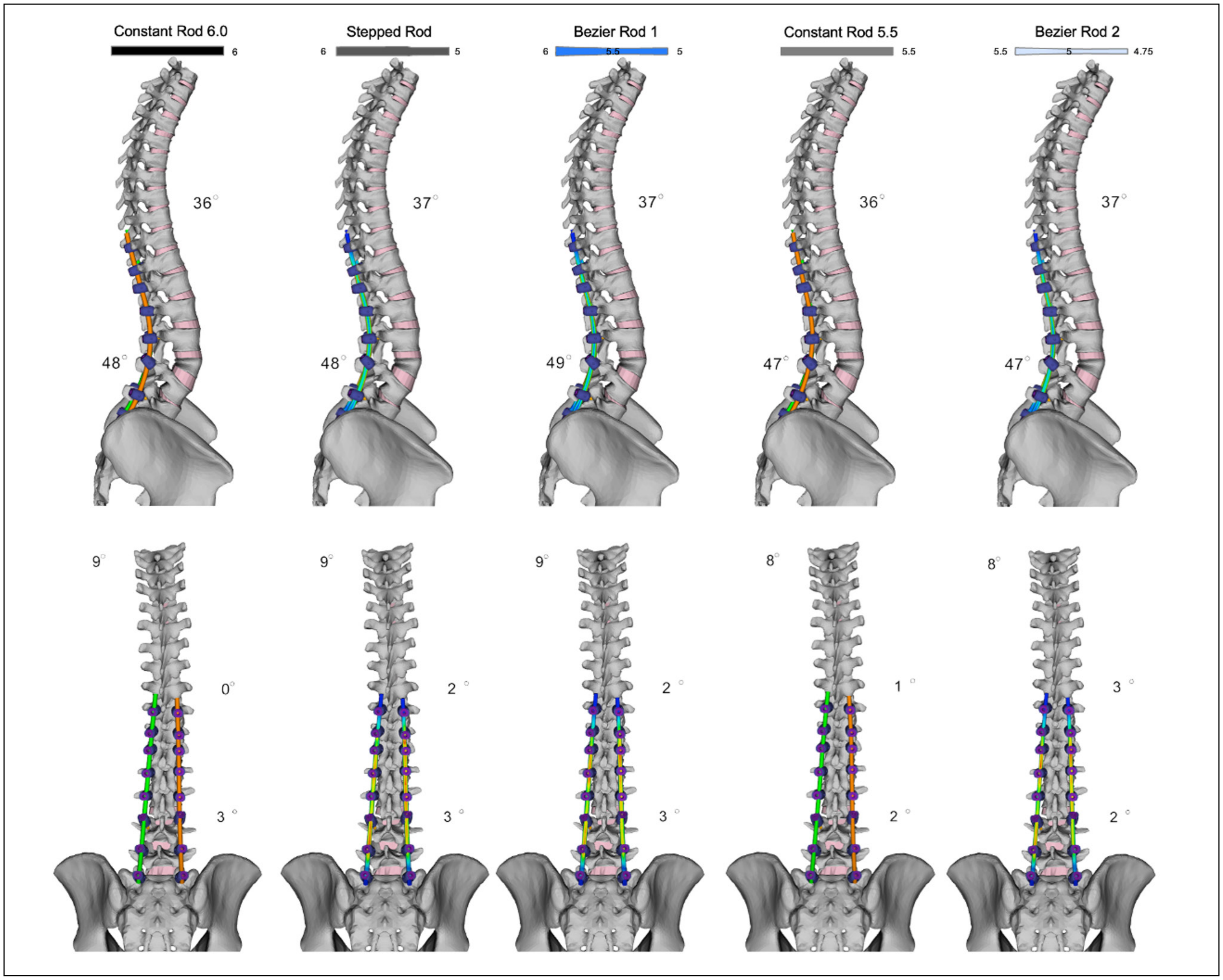
Results

The post-operative sagittal correction achieved with the five different strategies ranged from 36° to 37° for TK and from 47° to 49° for LL **(Figure 6)**.

The pre-operative PI-LL mismatch of 72° (where PI = 60° and LL = -12°) was reduced to an average of 12° across the different rod configurations.

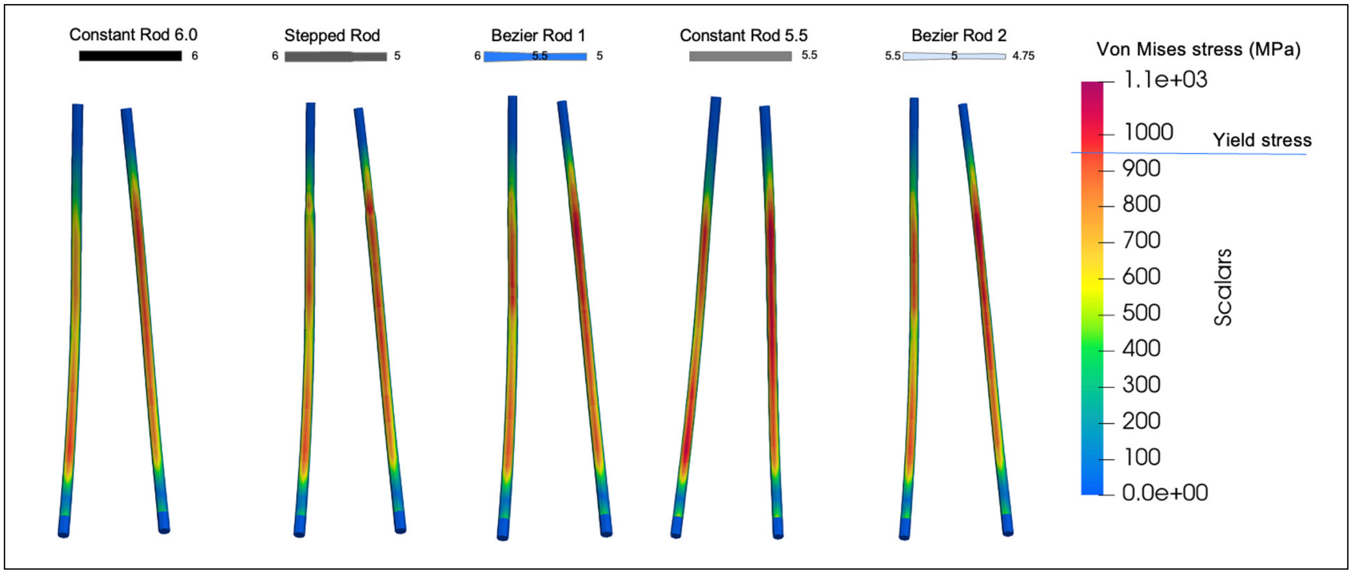
In the coronal plane, the lumbar Cobb angle ranged from 2° to 3°, with all strategies yielding similar outcomes in terms of correction.

Figure 6: Post-operative standing spine in the sagittal plane following instrumentation with the 5 instrumentation scenarios



Rod deformation and stress distribution were also comparable across the simulated instrumentation scenarios, with stresses exceeding the yield stress of the material, indicating permanent deformation of the rods **(Figure 7)**. The stepped rod exhibited higher stress levels at the transition zone.

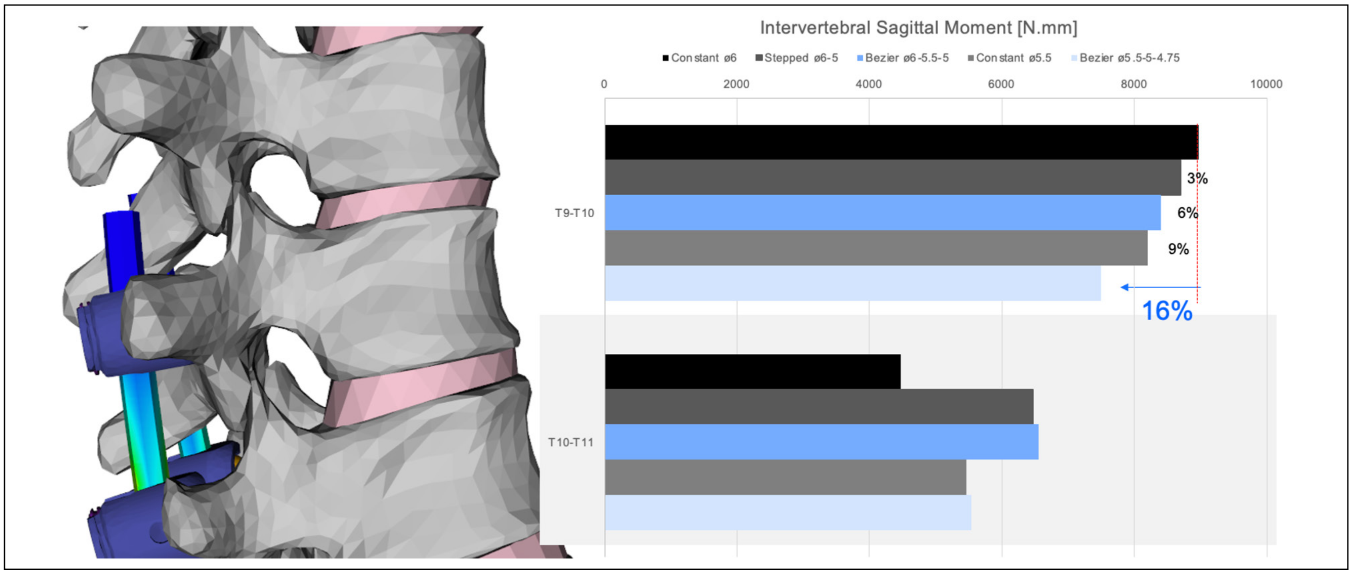
Figure 7 : Stress distribution within the rods under standing position for the 5 simulated instrumentation scenarios



Under flexion, the stabilization achieved by all constructs was equivalent. The highest range of motion in the instrumented segment was 0.36° at the upper instrumented segment, and a maximum of 0.10° at the levels below, demonstrating the ability of all constructs to stabilize the spine post-operatively.

In terms of loading, the analysis focused on the moment sustained by the segment above the instrumentation where PJK might develop under 10° flexion **(Figure 8)**.

Figure 8 : Intervertebral sagittal moment sustained by the upper instrumented segment and the one adjacent to the instrumentation under flexion for the 5 instrumentation scenarios

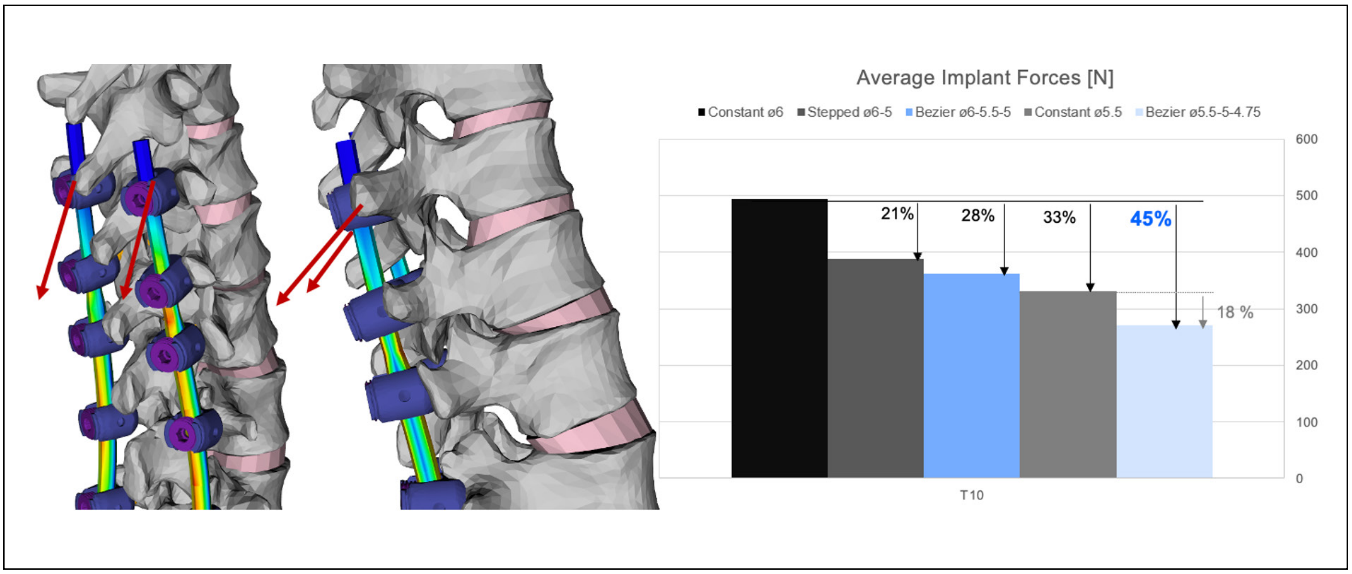


The highest moment sustained by the level adjacent to the vertebra was observed with

- the constant 6mm rod (9.0 N.m),
- followed by the stepped 6 to 5mm rod (8.7 N.m),
- the Bezier 6-5.5-5mm rod (8.4 N.m),
- the constant 5mm rod (8.2 N.m),
- and finally the Bezier 5.5-5-4.75mm rod (7.5 N.m).

Proximal spinal loading was reduced by up to 16% with the Bezier 5.5-5-4.75mm rod. Similar patterns were seen for the forces sustained by the screws at the upper instrumented vertebra **(Figure 9)**.

Figure 9 : Average force magnitude sustained by the two proximal pedicle screws under flexion for the 5 instrumentation scenarios



The highest loads were observed with

- the constant 6mm rod (493 N),
- followed by the stepped 6 to 5mm rod (388 N),
- the Bezier 6-5.5-5mm rod (362 N),
- the constant 5mm rod (331 N),
- and finally the Bezier 5.5-5-4.75mm rod (270 N).

Screw loading was reduced by up to 45% with the Bezier 5.5-5-4.75mm rod. While the primary focus was on the adjacent level to the instrumentation, a similar trend in loading patterns across different constructs was observed at the upper spinal levels for both spinal and instrumentation loading.

Discussion

The current study underscores the importance of rod design in achieving optimal biomechanical outcomes and minimizing complications in spinal surgery.

The ideal rod for spinal deformity surgery would have sufficient stiffness to allow the surgeon to achieve goals of spinal realignment, without placing excessive forces on junctional transitions.

In this study, we demonstrate in silico biomechanical results of a novel, patient-specific rod with continuous shaping which enables modulation of rod flexibility along the spinal segments.

This design targets the selection of specific rod sections for segments requiring greater stiffness to correct deformities, while aiming at providing flexibility to smooth load transitions to adjacent segments.

While rod design is crucial, the extent of correction depends on

- patient factors such as bone quality and spinal flexibility, and
- surgeon factors such as soft tissue releases and bony osteotomies.

The study results indicate that all rod configurations achieved similar correction in terms of lumbar lordosis and thoracic kyphosis. The PSO at L3 was the main strategy for achieving lordosis in the lumbar spine.

However, the load transfers between the instrumented segments and the adjacent segments varied substantially based on the rod design. The Bezier rods demonstrated a smoother load transition from the instrumented to the non-instrumented spine compared to constant diameter rods, leading to less stress on the proximal segments, which may result in lower PJK risk.

Moreover, PJK mitigating devices or approaches (e.g., tethers) aim to reduce excess spinal loading proximally and bring spinal loading closer to normal conditions, which was the tendency observed with the Bezier rods (Buell, Buchholz, et al. 2019; Buell, Bess, et al. 2019).

Additionally, the Bezier rods were more effective in offloading the pedicle screws, especially the Bezier 5.5 - 5 - 4.75 scenario, which had the lowest implant loads.

These variations in load distribution highlight the potential of Bezier rods to reduce stress levels and potentially mitigate the risk of PJK, warranting further investigation into critical load thresholds and the physiological factors involved.

Future research will focus on the additive effects of the Bezier rod constructs in combination with other PJK-prevention techniques (i.e. cement augmentation at the upper instrumented vertebra (UIV) and UIV+1) to demonstrate possible superiority.

Furthermore, further evaluation of tri- and quad-rod constructs are necessary to investigate differences between each of the rod constructs studied in this manuscript.

This is especially important in the setting of extreme PI-LL mismatch and stiff sagittal deformity requiring PSO and multi-level SPOs.

The design of the rod is a critical factor in the performance of the instrumented spinal construct.

While stepped rods were effective in offloading the proximal section compared to their constant section counterparts, they can, from a mechanical perspective, introduce stress concentrations at the transition points, increasing the risk of rod breakage under repeated loading conditions and complicating surgical maneuvers due to repeated screw engagement.

In contrast, the Bezier rods, with their smooth transitions, provided a more gradual load shift between instrumented and non-instrumented spinal sections. This may be a benefit both for adult spinal deformity surgery, where proximal failure is a non-trivial event, but also for pediatric spinal deformity surgery, where both proximal and distal transitions can be tailored to reduce adjacent segment stresses to reduce PJK and distal junctional kyphosis (DJK) failure modes.

Further, the Bezier rods may provide a powerful solution for multi-level fusion constructs in degenerative lumbar fusion scenarios (such as L2 to Pelvis fusion), to blunt adjacent segment stresses and avoid adjacent segment degeneration.

However, future research is required to validate these models and ascertain the magnitude of clinical benefit.

This study leveraged an in-silico patient-specific model, providing a relevant clinical scenario while allowing for high control over the model input variables, enabling rigorous comparative analysis.

This approach reduces the experimental variability often encountered in cadaveric studies. However, a notable limitation is that only a single case was studied.

To draw more definitive conclusions and understand the optimal balance between rod design and spinal stiffness, additional case simulations are necessary.

Conclusion

All rod configurations provided comparable correction capabilities for sagittal balance restoration, with the Bezier rods showing a smoother load transition and reduced stress on proximal segments.

This suggests that Bezier rods may offer superior performance in terms of reducing the risk of PJK compared to conventional rod designs.

Future research should focus on validating these findings across a broader patient population to confirm the benefits of Bezier rods and better understand how specific rod sections should be tailored with respect to the different vertebral levels for optimal clinical outcomes.

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