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Chapter 8

A novel spinal implant for fusionless scoliosis correction: a biomechanical analysis of the motion preserving properties of a posterior periapical concave distraction device

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Abstract

Study Design: Biomechanical study.

Objective: Recently, a posterior concave periapical distraction device for fusionless scoliosis correction was introduced. The goal of this study was to quantify the effect of the periapical distraction device on spinal range of motion (ROM) in comparison with traditional rigid pedicle screw-rod instrumentation.

Methods: Using a spinal motion simulator, 6 human spines were loaded with 4 Nm and 6 porcine spines with 2 Nm to induce flexion-extension (FE), lateral bending (LB), and axial rotation (AR). ROM was measured in 3 conditions: untreated, periapical distraction device, and rigid pedicle screw-rod instrumentation.

Results: The periapical distraction device caused a significant ($P < .05$) decrease in ROM of FE (human, -40.0% and porcine, -55.9%) and LB (human, -18.2% and porcine, -17.9%) as compared to the untreated spine, while ROM of AR remained unaffected. In comparison, rigid instrumentation caused a significantly ($P < .05$) larger decrease in ROM of FE (human, -80.9% and porcine, -94.0%), LB (human, -75.0% and porcine, -92.2%), and AR (human, -71.3% and porcine, -86.9%).

Conclusions: Although no destructive forces were applied, no device failures were observed. Spinal ROM was significantly less constrained by the periapical distraction device compared to rigid pedicle screw-rod instrumentation. Therefore, provided that scoliosis correction is achieved, a more physiological spinal motion is expected after scoliosis correction with the posterior concave periapical distraction device.

Introduction

Adolescent idiopathic scoliosis (AIS) affects 1-3% of children between 10 and 16 years of age[1]. In progressive scoliosis, a good correction of the deformity can be achieved with current surgical techniques, but the postoperative spinal motion is significantly diminished due to the fusion of the spine[2]. Moreover, patients who underwent fusion surgery report a lower physical function as compared to nonscoliotic controls at long-term follow-up, which could be attributed to the invasive surgery and stiffening of the spine[3]. To overcome these negative consequences of extensive fusion procedures, recent research has been aimed at developing techniques that allow scoliosis correction without fusion[4,5].

A new less-invasive and potentially fusionless scoliosis correction system is a posterior concave periapical distraction device (the ApiFix system, ApiFix Ltd, Misgav, Israel), which spans 3 to 4 motion segments (Figure 1). The device is a unilateral construct that connects 2 periapical pedicle screws through polyaxial mobile ball-and-socket joints with a rod. The device is inserted on the concave side of the curve. The rod includes a ratchet that can elongate when the patient performs exercises after surgery, especially with side bending toward the convexity. By side bending, the ratchet allows elongation of the rod and thereby corrects the scoliotic curve (Figure 1). The ratchet does not allow for shortening when the patient stands upright again and thus it preserves the correction. The poly-axial joints allow the pedicle screws to have a range of motion (ROM) of 30° (15° per pedicle screw) in flexion, extension, and axial rotation (Figure 2). Floman et al⁶ recently demonstrated the effectiveness of the periapical distraction device by reducing the Cobb angle from 43°-53° to 22°-33° in a small case series. The authors stated that the new device is a less rigid construct than traditional rigid pedicle screw-rod instrumentation and as a result, preserves a more physiologic spinal ROM after treatment with this device[6].

Nevertheless, it is unknown whether spinal motion is indeed preserved after treatment with this new device. This is important, because rigid spinal instrumentation has been shown to fail in long term if fusion is not achieved and spinal loads are transferred to the instrumentation[7]. Also, when spinal flexibility remains intact after treatment with this new device, this could have beneficial effects on the postoperative physical function in comparison to traditional long fusion surgery. Before large clinical studies are started

with this fusionless scoliosis correction device, it should be analyzed whether spinal motion is indeed minimally constrained to prevent the transfer of loads to the implant. Therefore, the goal of this study was to analyze the effect of the posterior concave periapical nonfusion distraction device on the in vitro biomechanics of the spine.



Figure 1. Left: The posterior concave periapical nonfusion distraction device for scoliosis correction (the ApiFix system, ApiFix Ltd, Misgav, Israel). The device consists of a unilateral construct that connects 2 periapical pedicle screws through mobile polyaxial ball-and-socket joints with a rod with ratchet mechanism. Right: The device in detail. The device is inserted on the concave side of the curve. The rod includes a ratchet and can elongate as the patient is required to perform exercises after surgery. In theory, by side bending the ratchet allows elongation of the rod and thereby corrects the scoliotic curve.

Materials and Methods

Prior to the study, research agreements were signed by all parties to ensure the rights of academic freedom of the VU University Medical Center and consequently an independent publication of the research results.

Specimens and specimen preparation

Seventeen thoracic spines were harvested from fresh frozen (20°C) human cadavers. After radiographic evaluation and exclusion of specimens with bridging osteophytes or collapsed intervertebral disc spaces, 6 human thoracic spines (mean age years, range 65-86 years) were included. Additionally, we included 6 thoracic spines of immature domestic pigs (mean weight 72 kg, range 64-80 kg) obtained from a local abattoir. This allowed for a better comparison with the flexible spine of a young adolescent. In the human spine, the morphology of the facet joint alters below T12-L1. This change in facet orientation, and as a result a change in biomechanics, in porcine spines already occurs more proximally at T10-T11[8]. To allow for a comparison between the human and porcine specimens, we used the levels T5-T12 of the human specimens and T3-T10 of the porcine specimens.



Figure 2. The posterior concave periapical nonfusion distraction device with polyaxial pedicle screw-rod joints. The polyaxial joints allow the pedicle screws to have a range of motion (ROM) of 30° in flexion, extension, and axial rotation (15° per pedicle screw).

Testing conditions

The spines were tested in 3 phases: untreated (for baseline analysis), instrumented with the (unilateral) posterior concave periapical nonfusion distraction device and finally, after bilateral segmental rigid pedicle screw-rod rod instrumentation (Figure 3). The pedicle screws of the periapical distraction were implanted unilaterally at levels T7 and T10 in the human specimens and at levels T5 and T8 in the porcine specimens.

The internal ratchet of the periapical distraction device can be set in 3 positions: 1-way, locked and unlocked, with the latter 2 positions aiming to prevent and correct, respectively, any adverse overcorrection if needed. For this study, we set the ratchet in the locked position, thus fixing the rod length. We consider that the locked ratchet position represents the end situation after rod elongation and scoliosis correction, where the system effectively functions as a unilateral posterior rigid rod with a mobile connection to the polyaxial screws.

In half of the specimens the implant was placed on the right side and in the other half of the specimens on the left side, to exclude a possible effect of implant location. In the final third test the periapical distraction device was replaced by a bilateral segmental pedicle screw-rod system (Medtronic, CD Horizon Legacy Spinal System, Minneapolis, MN, USA) across the same motion segments as the periapical distraction device (T7, T8, T9, and T10 in the human specimens and at levels T5, T6, T7, and T8 in the porcine specimens) (Figure 3). Proximal and distal to the instrumented segments there were 2 untreated adjacent spinal motion segments (ie, 2 intervertebral discs). For the third phase of testing with the rigid instrumentation, the pedicle screw holes in the proximal and distal instrumented vertebra of the investigated periapical distraction device were reused by implanting pedicle screws with a 1 mm larger diameter and 2 to 5 mm greater length (depending on the size of the vertebral body) to ensure adequate bone purchase of the screws using the same pedicle screw holes. No screw loosening was observed during or after testing based on manual inspection of the instrumentation and analysis of the load displacement curves.

Biomechanical testing

The test setup and analysis has been described and validated previously[9-14]. Briefly, before testing, a compressive axial preload of 250 N was applied for 1 hour to obtain physiological conditions in the intervertebral disc[9]. Throughout testing, no compressive load was applied to prevent buckling of the spine[15].

The spinal segments were placed horizontally in a custom made spinal motion simulator (Figure 4) in which pure moments in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) can be applied to the spine using a hydraulic materials testing machine (Instron, model 8872; Instron and IST, Norwood, MA, USA). This spinal motion simulator allows for the biomechanical analysis of long, multisegment, spinal specimens.

The human spinal segments were tested at up to 4 and 4 N m and the porcine spinal segments at up to a moment of 2 and 2 N m to allow comparison with previous work[8]. Each movement direction was tested for 3 subsequent cycles. The third cycle was used for analysis. During loading, the displacement of 3 infrared-emitting LEDs, rigidly attached to each of the vertebral bodies, was recorded by an optoelectronic 3-dimensional movement registration system (Optotrak 3020, Northern Digital Inc, Waterloo, Ontario, Canada). A custom Matlab (Mathworks Inc, Natick, MA, USA) program was used to calculate the load-displacement curves and ROM of the loaded and coupled directions (rotation about an axis with additional motions about 1 or 2 other axes[16]) of the bridged and adjacent levels.



Figure 3. Biomechanical testing sequence with an untreated human cadaveric thoracic spine (left), after instrumentation with the posterior concave periapical nonfusion distraction device (middle), and after rigid pedicle screw-rod instrumentation (right).

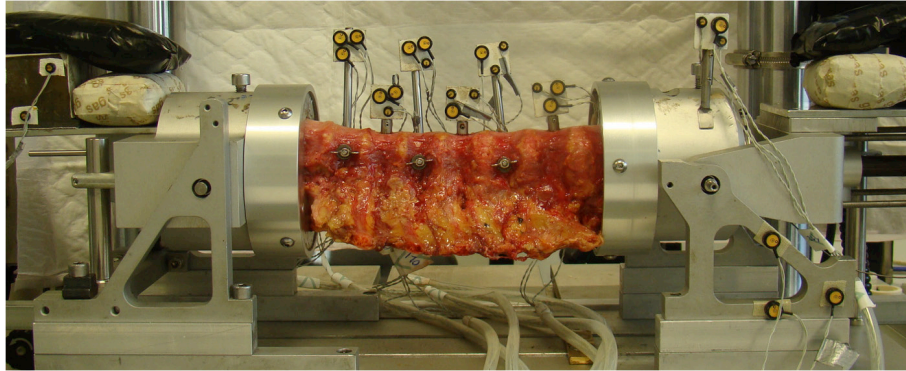


Figure 4. The experimental setup is shown with a human cadaveric thoracic spinal specimen positioned in the spinal motion simulator. The proximal and distal vertebrae were potted in a casting-mold and partially buried in a low melting point (48°C) bismuth alloy (Cerrolow-147; 48.0% bismuth, 25.6% lead, 12.0% tin, 9.6% cadmium, and 4.0% indium). The proximal and distal vertebrae were fixed securely into the alloy by adding screws into the vertebral body. All articulating parts were kept free. During the experiment, the spinal specimens were kept moist with 0.9% saline spray. A materials testing machine applied loads to the setup to induce flexion-extension, lateral bending and axial rotation. The markers with the LEDs were rigidly fixed to the vertebrae. An Optotrak camera registered the movement of the infrared-emitting LEDs.

Statistical analysis

Effects of type of instrumentation were tested separately for the untreated cranial motion segment, bridged motion segments (average of 3 bridged spinal motion segments), and for the untreated caudal motion segment, using a 1-way repeated measure analysis of variance with the surgical condition as the within-subject factor. Multiple comparisons based on Bonferroni-corrected paired *t* tests were applied for analysis among testing conditions. *P* values less than .05 were considered statistically significant. SPSS for Mac version 23.0 (IBM Corp, Armonk, NY, USA) was used for statistical analyses.

Results

No device failures were observed during testing.

Bridged segments

In the loaded direction, the (locked) periapical distraction device resulted in a significant decrease in ROM of FE (human, 40.0%, 1.10°, *P* .009; porcine, 55.9%, 4.10°, *P* < .001) and LB (human, 18.2%, 0.70°, *P* .020; porcine, 17.9%, 1.70°, *P* .007) of the bridged motion segments as compared with the untreated segments (Tables 1 and 2; Figure 5). No significant alteration in the ROM of AR of the bridged motion segments was observed.

Rigid pedicle screw-rod instrumentation caused a larger and significant decrease in ROM of FE (human, 80.9%, 2.20°, *P* .002; porcine, 94.0%, 6.90°, *P* .001), LB (human, 75.0%, 2.77°, *P* .001; porcine, 92.2%, 8.80°, *P* .001), and AR (human, 71.3%, 4.40°, *P* < .001; porcine, 86.9%, 9.30°, *PP* .001) of the bridged motion segments as compared with the untreated spine (Tables 1 and 2; Figure 5).

In the human specimens, coupled motions of the bridged motion segments were not significantly affected after instrumentation with the periapical distraction device (Table 3; Figure 6). In the porcine specimens, ROM of coupled LB during FE loading increased (122.7%, 1.90°, *P* .007), while ROM of coupled AR during LB decreased (20.5%, 1.00°, *P* .009) after instrumentation with the periapical distraction device (Table 4; Figure 6).

Rigid pedicle screw-rod instrumentation caused a significant decrease in ROM of coupled AR (39.7%, 0.390°, *P* .006) during FE loading, and conversely, in ROM of coupled FE (31.9%, 0.420°, *P* .031) during AR loading in the human spines of the bridged motion segments (Table 3; Figure 6). In the porcine spines, rigid pedicle screw-rod instrumentation caused a significant decrease in all coupled ROM except ROM of coupled FE during AR loading (Table 4; Figure 6).

Adjacent segments

Other than a decrease in ROM of AR (18.1%, 1.19°, *P* .011) of the proximal adjacent motion segment in the human specimens and an increase in ROM of AR (23.9%, 0.880°, *P* .038) of the distal adjacent segment in the porcine specimens after rigid pedicle screw-rod instrumentation, no significant adjacent segment effects were observed (Tables 1 and 2; Figure 5).

Table 1. Human Spines: Change in Range of Motion (ROM) in Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation(AR), With Mean and SD Expressed as Percentage (%).

ROM (% Change)	Posterior Concave Distraction Device vs Untreated			Rigid PS vs Untreated			Rigid PS vs Posterior Concave Distraction Device		
	Mean	SD	P	Mean	SD	P	Mean	SD	P
Human									
FE									
Proximal adjacent	-16.1	23.3	.454	-0.8	33.9	1.000	18.3	50.6	1.000
Bridged	-40.0	18.0	.009	-80.9	27.3	.002	-68.2	45.1	.042
Distal adjacent	-0.6	12.1	1.000	-6.3	21.8	1.000	-5.7	11.4	.816
LB									
Proximal adjacent	-8.2	10.1	.313	-17.1	22.4	.362	-9.7	30.0	1.000
Bridged	-18.2	10.0	.020	-75.0	19.1	.001	-69.4	20.5	.001
Distal adjacent	-6.0	6.3	.199	-3.2	11.9	1.000	3.0	14.1	1.000
AR									
Proximal adjacent	-12.2	12.9	.208	-18.1	8.7	.011	-6.8	22.0	1.000
Bridged	-0.1	2.6	1.000	-71.3	17.2	<.001	-71.3	18.0	.001
Distal adjacent	14.3	10.2	0.56	2.5	23.4	1.000	-10.3	22.9	.966

^aData of the 3 bridged motion segments is averaged. Boldfaced values indicate statistical significance ($P < .05$). Rigid PS: bilateral rigid pedicle screw-rod instrumentation.

Table 2. Porcine Spines: Change in Range of Motion (ROM) in Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation(AR), With Mean and SD Expressed as Percentage (%).

ROM (% Change)	Posterior Concave Distraction Device vs Untreated			Rigid PS vs Untreated			Rigid PS vs Posterior Concave Distraction Device		
	Mean	SD	P	Mean	SD	P	Mean	SD	P
Human									
FE									
Proximal adjacent	2.1	7.4	1.000	1.0	6.3	1.000	-1.0	2.8	1.000
Bridged	-55.9	7.1	<.001	-94.0	23.0	.001	-86.4	46.6	.018
Distal adjacent	-7.7	5.5	.056	-8.3	7.1	.105	-0.6	6.4	1.000
LB									
Proximal adjacent	-4.7	6.9	.455	-5.8	3.9	.045	-1.1	6.8	1.000
Bridged	-17.9	7.7	.007	-92.2	26.2	.001	-90.4	28.0	.002
Distal adjacent	-4.1	4.8	.268	-6.8	7.7	.244	-2.8	6.4	.970
AR									
Proximal adjacent	0.7	10.4	1.000	-9.4	22.1	1.000	-10.0	14.6	.459
Bridged	-3.9	3.3	.104	-86.9	23.2	.001	-86.3	21.8	.001
Distal adjacent	17.9	18.2	.183	23.9	15.4	.038	5.1	17.3	1.000

^aData of the 3 bridged motion segments is averaged. Boldfaced values indicate statistical significance ($P < .05$). Rigid PS: bilateral rigid pedicle screw-rod instrumentation.

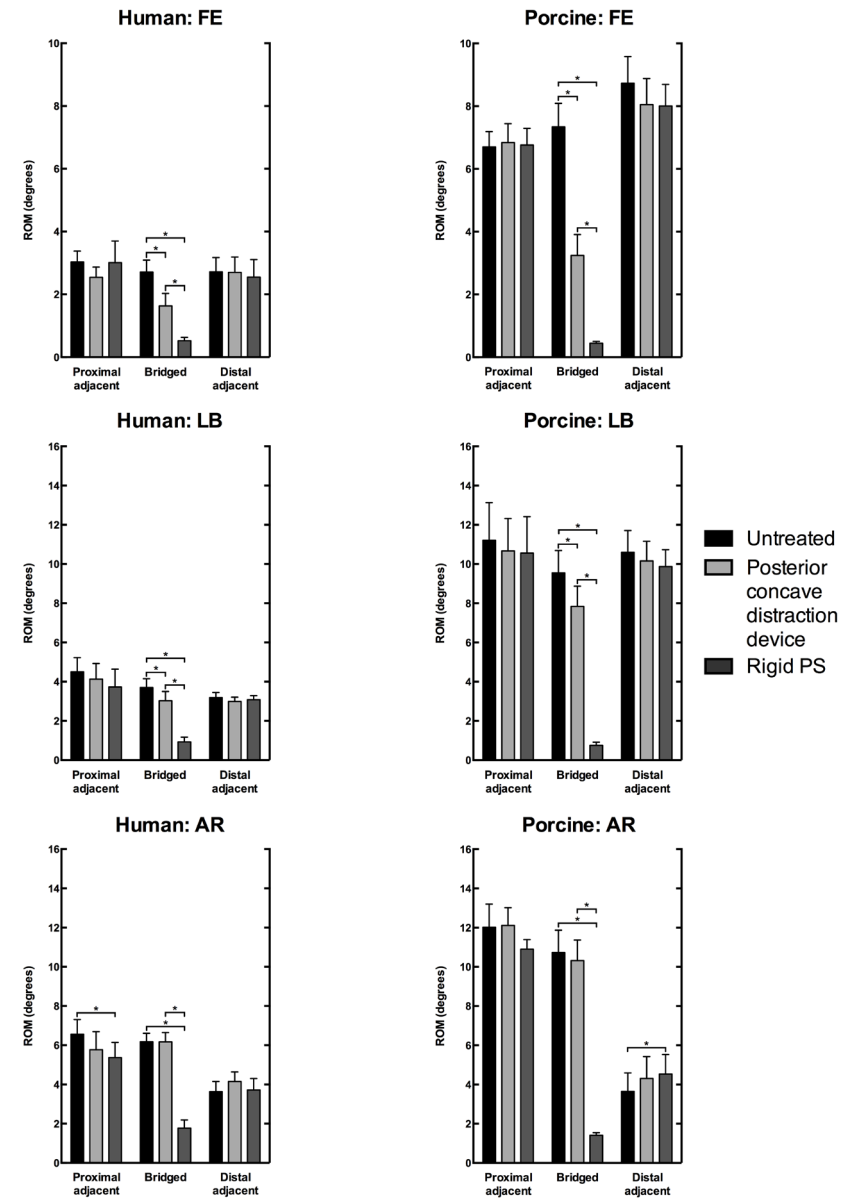


Figure 5. Range of motion (ROM) of the cranial adjacent, bridged, and caudal adjacent motion segments of the human spines under 4 N m loading and porcine spines under 2 N m loading in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) of the untreated spine, after posterior concave periapical nonfusion distraction device, and bilateral rigid pedicle screw-rod (rigid PS) instrumentation (mean + SD). Data of the 3 bridged motion segments is averaged. Asterisks (*) indicate statistical significance ($P < .05$).

Table 3. Human Spines: Change in Coupled Range of Motion (ROM) in Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation (AR), With Mean and SD Expressed as Percentage (%).

Coupled ROM (% Change) Porcine	Posterior Concave Distraction Device vs Untreated			Rigid PS vs Untreated			Rigid PS vs Posterior Concave Distraction Device		
	Mean	SD	P	Mean	SD	P	Mean	SD	P
	FE								
Coupled AR	-11.5	24.6	.908	-39.7	16.4	.006	-31.9	19.9	.033
Coupled LB	8.0	35.7	1.000	-28.1	31.1	.234	-33.4	27.7	.095
LB									
Coupled AR	1.1	17.5	1.000	-18.1	26.6	.467	-19.0	32.4	.628
Coupled FE	5.7	30.1	1.000	-27.6	27.3	.169	-31.5	31.2	.170
AR									
Coupled LB	4.6	11.4	1.000	-46.6	61.3	.366	-48.9	62.0	.334
Coupled FE	-13.3	12.1	.130	-31.1	19.6	.031	-21.5	31.8	.476

^aData of the 3 bridged motion segments is averaged. Boldface values indicate statistical significance ($P < .05$). Rigid PS: bilateral rigid pedicle screw-rod instrumentation.

Table 4. Porcine Spines: Change in Coupled Range of Motion (ROM) in Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation (AR), With Mean and SD Expressed as Percentage (%).

Coupled ROM (% Change) Porcine	Posterior Concave Distraction Device vs Untreated			Rigid PS vs Untreated			Rigid PS vs Posterior Concave Distraction Device		
	Mean	SD	P	Mean	SD	P	Mean	SD	P
	FE								
Coupled AR	-0.5	21.0	1.000	-42.5	23.1	.019	-42.2	33.6	.083
Coupled LB	122.7	53.4	.007	-37.0	25.0	.045	-71.7	28.5	.005
LB									
Coupled AR	-20.5	9.4	.009	-76.2	15.9	<.001	-70.0	12.6	<.001
Coupled FE	46.5	44.4	.151	-39.9	23.5	.026	-59.0	32.3	.020
AR									
Coupled LB	-9.0	12.4	.407	-85.6	23.1	.001	-84.2	17.2	<.001
Coupled FE	-2.8	22.7	1.000	-29.7	31.8	.212	-27.7	26.4	.151

^aData of the 3 bridged motion segments is averaged. Boldfaced values indicate statistical significance ($P < .05$). Rigid PS: bilateral rigid pedicle screw-rod instrumentation.

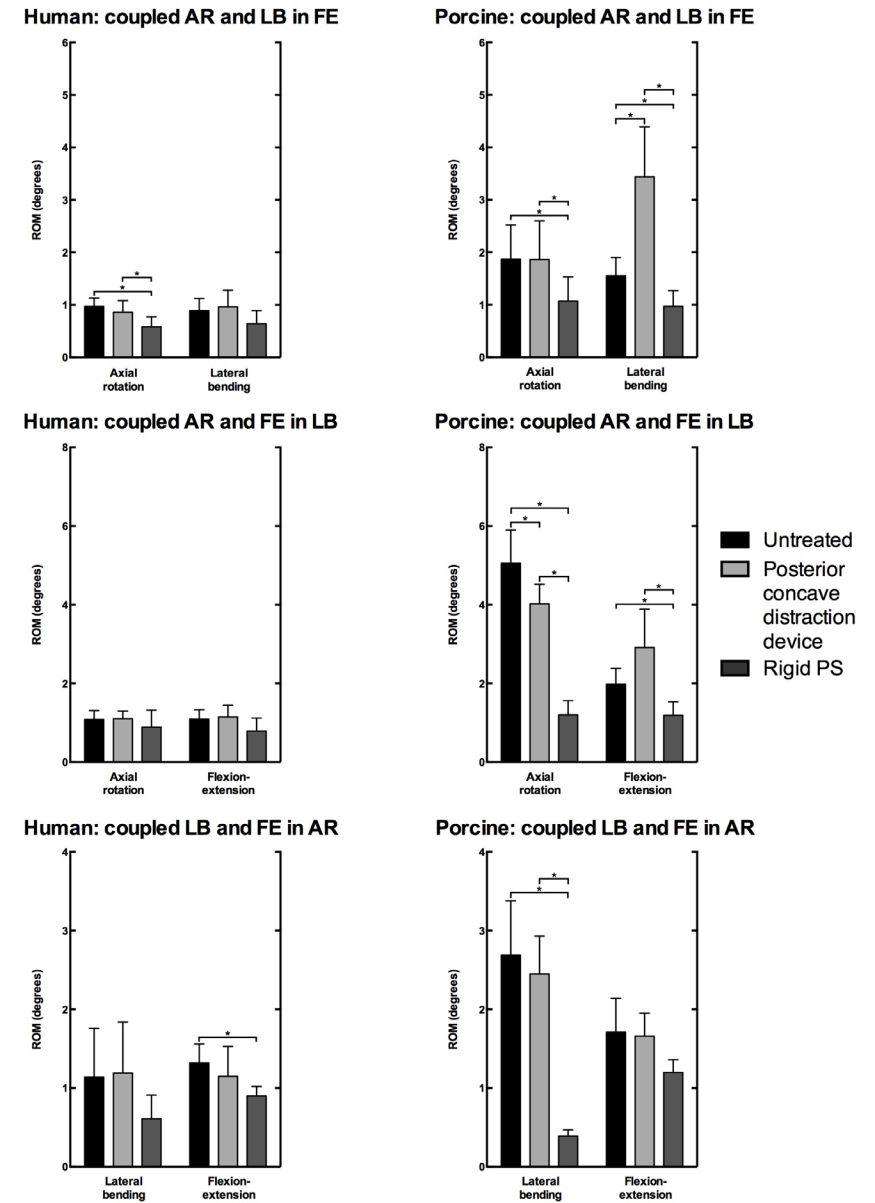


Figure 6. Coupled range of motion (ROM) of the cranial adjacent, bridged, and caudal adjacent motion segments of the human spines under 4 N m loading and porcine spines under 2 N m loading in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) of the untreated spine, and after posterior concave periapical nonfusion distraction device and bilateral rigid pedicle screw-rod (rigid PS) instrumentation (mean + SD). Data of the 3 bridged motion segments is averaged. Asterisks (*) indicate statistical significance ($P < .05$).

Discussion

Recently, a posterior concave periapical distraction device was presented for fusionless surgical correction of adolescent idiopathic scoliosis.⁶ This device is designed to maintain spinal motion by using mobile poly axial pedicle screw-rod joints. In fusion surgery, rigid spinal instrumentation has been shown to fail if fusion is not achieved and spinal loads are transferred to the instrumentation.⁷ A spinal implant designed for fusionless scoliosis correction should therefore minimally constrain spinal motion to prevent the transfer of loads to the implant, thereby reducing the risk of implant failure. The present in vitro biomechanical study was designed to determine the effect of the new periapical distraction device on spinal range of motion in comparison to traditional rigid pedicle screw-rod instrumentation.

This study shows that, across the bridged motion segments, the periapical distraction device roughly halved spinal ROM of FE (human -40.0% and porcine -55.9%), while LB was only slightly affected (human -18.2% and porcine -17.9%) and AR was unaffected. In comparison, the rigid pedicle screwrod instrumentation resulted in a far larger decrease in ROM of FE (human -80.9% and porcine -94.0%), LB (human -75.0% and porcine -92.2%), and AR (human -71.3% and porcine -86.9%).

The periapical distraction device was tested with the internal ratchet set in “locked” position. This ratchet position prevented rod elongation with each subsequent load cycle (each spine was loaded for 3 cycles) and thus prevented the creation of a scoliotic deformity while testing. In this mode, the periapical distraction device has a fixed length and functions as a unilateral posterior tether (ie, lengthening or shortening was not possible) attached to the pedicle screws with mobile ball and socket joints with large degrees of freedom. This is the situation that would occur after correction of the deformity. The fixed length of the device explains the decrease in ROM of FE after instrumentation of the spine. ‘The decrease in ROM of LB (human, -18.2%, 0.7°; porcine, -17.9%, 1.7°) due to the periapical distraction device was less than expected. With the ratchet of the device set in “locked” position, a larger decrease in LB was anticipated. The relatively mild reduction in ROM may be explained by the phenomenon of coupled motion. The thoracic spine has been shown to exhibit significant coupled motion under LB loading[17]. It appears that the mobile polyaxial rod-screw joint design of the periapical distraction device allows

coupled AR and FE during LB loading of the bridged segments in a magnitude comparable to the untreated spine with only minor changes (Figure 6). We speculate that, because of this, the instrumented spinal segments can find the path of motion with the least resistance (ie, a combination of LB, AR, and FE) to allow most of the LB without requiring a change in length of the periapical distraction device. Combined with the unilateral rod design, which is less rigid than a bilateral rod system, this may explain why there was only a relatively small and less than expected decrease of ROM of LB.

Although a causal relationship has yet to be established, adjacent segment degeneration after spinal fusion has been attributed to altered motion and disruption of the anatomy of the adjacent level[18]. In this study, the periapical distraction device did not significantly affect adjacent segment motion. In contrast, after rigid pedicle screw-rod instrumentation the ROM of AR decreased by 18.1% in the cranial adjacent segment of the human spines and increased by 23.9% in the caudal adjacent segment of the porcine spines. This could possibly be the result of an altered spinal alignment due to the instrumentation, although care was taken to customize the rod curvature to each individual specimen[19]. Also, proximal adjacent segment biomechanics can be affected by damage of spinal ligaments and joint capsules of the proximal facet joint due to pedicle screw placement[20,21].

Other options for fusionless surgery for adolescent idiopathic scoliosis such as vertebral body stapling or anterior spinal tethering have been investigated[4,5]. Current research on the use of vertebral body stapling shows a wide range of results of the effects on the ROM of FE (11% decrease to no decrease), LB (4% to 40% decrease) and AR (6% to 60% decrease) and therefore it is difficult to conclude if and how stapling alters postoperative spinal ROM[22-24].

We took great care to study the implant in vitro in a simulated end situation after rod elongation and scoliosis correction to evaluate possible safety concerns regarding its motion preserving properties. However, this and other preclinical studies examining new treatment options for AIS are limited due to the unavailability of cadaveric AIS specimens or an animal model that combines all characteristics of AIS (ie, a lateral deviation, rotation and alterations of the sagittal profile). Thus, the effectiveness of the periapical distraction device in correcting scoliosis could not be tested. The disadvantage of human cadaveric specimens is their high age and associated state of degeneration. Therefore,

we excluded specimens with bridging osteophytes or collapsed intervertebral disc spaces. Additionally, we also included thoracic spines from immature pigs, which have previously been shown to be good biomechanical models for the human spine and are more flexible to represent the adolescent spine[8,25].

In conclusion, although its effectiveness in scoliosis correction has still only been demonstrated in a small case series, this study demonstrates that the spinal ROM of the bridged segments after spinal instrumentation with the novel posterior concave periapical non-fusion distraction device is partially diminished and adjacent segment biomechanics were not significantly altered[6]. Consequently, a more physiological spinal ROM is expected after scoliosis correction with the periapical distraction device as compared with rigid spinal instrumentation. Thus, it is expected that the spinal flexibility of patients treated with this device is not significantly altered, which could have beneficial effects on the post-operative physical function in comparison with traditional long fusion surgery. Also, the risk of implant failure is deemed low as implant loads are expected to be minimal. Although no destructive forces were applied to the specimens in this study, no device failures were seen. We do not know how the implant will function over time in vivo with continued loading and motion. However, while clinically important, failure testing was beyond the scope of this study. Thus, patients treated with this new device should have regular and prolonged follow-up.

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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