Flexible non-fusion scoliosis correction systems reduce intervertebral rotation less than rigid implants and allow growth of the spine: a finite element analysis of different features of orthobiomTM

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Abstract The orthobiomTM non-fusion scoliosis correction system consists of two longitudinal rods, polyaxial pedicle screws, mobile and fixed connectors and a cross-connector. The mobile connectors can move along and around the rod, thus allowing length adaptation during growth. The aim of this study was to determine the effects of different features of this novel implant on intervertebral rotations, to calculate the movement of the mobile connectors along the rods for different loading cases and to compare the results with those of a rigid implant construct. A finite element analysis was performed using six versions (M1–M6) of a three-dimensional, nonlinear model of a spine ranging from T3 to L2. The models were loaded with pure moments of 7.5 N m in the three main anatomical planes. First, the validated intact model (M1) was studied. Then, the orthobiomTM implant system was inserted, bridging the segments between T4 and L1 (M2). The effect of pedicle screws only in every second vertebrae was investigated (M3). For comparison, three connection variations of screws and rods were investigated: (1) an implant with rigid screws and mobile connectors (M4), (2) an implant with non-locking polyaxial screws and fixed connectors (M5) and (3) a completely rigid implant construct (M6). For flexion, extension and lateral bending, intervertebral rotation was reduced at all implant levels due to the implants. A rigid implant construct (M6) and an implant with non-locking polyaxial screws and fixed connectors (M5) led to the strongest reduction of intervertebral rotation. The orthobiomTM non-fusion implant system (M2,

M3) allowed much more intervertebral rotation than a rigid implant (M6). Differences in intervertebral rotations were small when polyaxial screws were placed at every second level only (M3) instead of at every level (M2). For axial rotation, intervertebral rotation was strongly reduced by a rigid implant construct (M6) and by an implant with rigid screws and mobile connectors (M4). For rotation, an implant with non-locking polyaxial screws (M2, M3, M5) led to nearly the same intervertebral rotations as in an intact spine without an implant (M1). The predicted maximum translation of the mobile connectors along the rod was 4.2 mm for extension, 3.1 mm for lateral bending, 1.6 mm for flexion and 0.8 mm for axial rotation. The movement of the connectors was highest for those closest to the ends of the rods. With rigid screws, the maximum translation was significantly reduced. This study, conducted under a load-controlled loading protocol, showed that intervertebral rotation was reduced much less by the non-fusion orthobiomTM system than by a rigid implant. The mobile connectors moved considerably along the rod when the spine was bent. It can be expected that the connectors also move along the rod as the adolescent grows, possibly leaving the discs intact until the patient is fully grown.

Keywords Scoliosis correction system · Non-fusion · Finite element method · Biomechanics

Introduction

Scoliosis in adolescents that will reach a Cobb angle of 50° or more by skeletal maturity is a principle indication for surgery [1]. Orthoses are typically prescribed for skeletally immature patients with curves ranging from 25° to 45° in

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an effort to prevent further curve progression [4]. Implants may be inserted either dorsally or ventrolaterally. The surgical treatment of growing children normally leads to many fused segments reducing growth in the fixed spinal region [1, 8]. A novel non-fusion scoliosis correction system (orthobiomTM system, Paradigm Spine GmbH, Germany) with movable connections between the different components has been designed to overcome this problem. This novel implant system for the treatment of adolescent idiopathic scoliosis is intended to have the function of an “internal brace”. The non-fusion implant is inserted dorsally using polyaxial pedicle screws which are connected to rods via mobile connectors. The mobile connectors may move along and around the rod axis. The polyaxial screws remain angularly mobile even after tightening the screw. At either one or two levels, fixed connectors prevent movement relative to the rod and thus serve as an anchor to the rods. These connectors are tightened after the scoliosis correction has been obtained. A mobile cross-connector (Fig. 1) connects the right and left rod next to a fixed connector. The human clinical implantation of the first orthobiomTM system is planned in the near future. A pre-clinical 2-year study in minipigs has been performed, demonstrating the functionality of this system [5]. Twenty pigs in growing period were subjected to posterior segmental fixation ranging from T10 to L5. Twelve were fixed with a rigid fixation system and eight with the flexible orthobiomTM system. Despite growth of the animals from

about 30 to more than 60 kg, the distance between the uppermost and lowermost screws remained unchanged in the group with the rigid fixation system while it increased from 25.3 to 30.0 cm in the group with the flexible system. Studying the mechanical effect of a scoliosis correction system is very difficult since there is great variety in the shape and stiffness of scoliotic spines, and it is very difficult to obtain cadaveric scoliotic spine specimens for experimental studies. Finite element analyses have been performed to study scoliosis correction by orthotic [11] and by surgical treatment [2, 3, 6, 7, 12]. Mostly the Cotrel–Dubousset instrumentation procedure was simulated with numerical analyses. Most finite element models of the scoliotic spine with implants are strongly simplified. Often the vertebrae are assumed to be rigid and either spring or volume elements were used to model the intervertebral discs.

The elasticity of the orthobiomTM system in contrast to a conventional rigid scoliosis implant is mainly caused by two components: (a) the non-locking polyaxial pedicle screws and (b) the mobile connectors. In this study we hypothesized that (1) intervertebral rotation is more increased by mobile connectors than by polyaxial screws and that (2) placing pedicle screws at every second vertebrae instead of every level additionally increases intervertebral rotations. Further aims of this study were to determine the effect of the non-fusion orthobiomTM implant system on intervertebral rotations, and to predict

Fig. 1 Drawings of implant components (*left*) and finite element model (version M2, see text) ranging from T3 to L2 with non-fusion orthobiomTM scoliosis correction system running from T4 to L1 and corresponding finite element mesh (*right*)

Table 1 Elastic moduli and element types used for the different components

Component	Element type	Number of elements	Elastic modulus (MPa)
Vertebrae	Rigid body	12	Infinite
Thoracic intervertebral discs (in plane/transverse)	8-Node hexahedral	1,130	96/5.9
Lumbar intervertebral annulus ground substance	8-Node hexahedral	1,440	Hyperelastic, neo-Hookean $C_{10} = 0.3448$, $D_1 = 0.3$
Lumbar intervertebral nucleus	Fluid	448	Incompressible
Ligaments	Spring	164	Nonlinear, adapted
Rods	Beam	24	200,000
Screws	Beam	140	200,000
Mobile connectors	Beam	32	200,000
Rigid connectors	Beam	4	200,000
Cross-connector	Beam	4	200,000
Connection: within screw	Connector element (Join + rotation)	20	–
Connection: rod–mobile connector	Connector element (Cartesian + rotation)	16	–
Connection: within cross-connector	Connector element (cylindrical)	1	–

the amount of translation of the mobile connectors as they glide along the rods. The results are compared to those for implants with rigid screws and/or fixed connectors.

Methods

A nonlinear three-dimensional finite element model of the spine ranging from T3 to L2 was used. Six versions of this model were investigated. The validated intact spine model (version M1) consists of 12 vertebral bodies, 11 intervertebral discs and ligaments bridging the discs (Fig. 1) [13, 17]. The geometry of the model was determined from CT scans. The vertebrae were simulated by rigid body elements (Table 1). To account for the facet joints, rigid beam constructions were attached to the vertebrae representing the facet joint interfaces. The beams' tips represent the centres of the articulating interfaces. The positions of these tips were chosen according to Masharawi et al. [10] with an initial distance of 0.5 mm. The joints were implemented as constraints that allow a maximum approach of two corresponding tips of 0.5 mm perpendicular to the facet orientation given by Masharawi et al. [9]. The facet joints could transfer only compressive forces. For the intervertebral discs of the thoracic spine, hexahedral elements with transversely isotropic elastic behaviour were used to account for the anisotropic fibre stiffness. The longitudinal direction is defined by an axis which is perpendicular to the

superior vertebral body endplate while the transverse plane is parallel to it. The Poisson's ratio for the disc was set at 0.45 which is common for lumbar annulus ground substance [12]. The major ligaments of the thoracic spine (anterior longitudinal ligament, interspinous ligaments and intertransverse ligaments) were also included in the model. According to their function, the ligaments were modelled as tension-only spring elements. In this model, the interspinous ligament represented a group of dorsal ligaments. The stiffnesses of the ligaments were adapted in a validation process using experimental data from the literature [13, 14].

In a convergence study, the number of elements for a vertebral disc was increased eightfold. For typical spinal loads, total strain energy and deformations differed less than 5.5% for the coarse and fine meshed models. Using thoracic spine specimens (T1–T12), Watkins et al. [14] applied moments of ± 2 N m to simulate flexion/extension and lateral bending and a moment of ± 5 N m to simulate axial rotation and measured the deformations. The stiffnesses of these specimens are given in Table 2. The corresponding stiffnesses of our finite element model [13] are also given and close to the experimentally determined values. In the present study, the model ranges from T3 to L2 and the applied loads are 7.5 N m. The stiffnesses for this model are also given in Table 2.

The lower endplate of the L2 vertebral body was fixed by constraining the corresponding nodes. A rigid beam

Table 2 Stiffnesses in different loading planes given in N m/deg

Model	Flexion/extension	Lateral bending	Axial rotation
Thoracic spine T1–T12, calculated stiffness from experimental data by Watkins et al. [14]	0.30 ^a	0.25 ^a	0.29 ^b
Thoracic spine T1–T12, finite element model by Zander et al. [16]	0.32 ^a	0.22 ^a	0.29 ^b
Spine region T3–L2, present finite element model	0.33 ^a /0.44 ^c	0.20 ^a /0.23 ^c	0.34 ^b /0.36 ^c

^a Secant stiffness for a moment of 2 N m

^b Secant stiffness for a moment of 5 N m

^c Secant stiffness for a moment of 7.5 N m

construction was connected to the T3 vertebra and pure moments of 7.5 N m were successively applied on the centre node of this beam construction in the three anatomical main planes to simulate flexion, extension, lateral bending and axial rotation.

The following versions were investigated:

- M1: Intact spine without implant
- M2: Spine with orthobiomTM system with mobile connectors and non-locking polyaxial screws at every level
- M3: Spine with orthobiomTM system with mobile connectors and non-locking polyaxial screws at every second level
- M4: Spine with an implant with mobile connectors and rigid screws at every level
- M5: Spine with an implant with fixed connectors and non-locking polyaxial screws at every level
- M6: Spine with an implant with fixed connectors and rigid screws at every level

All implant constructs were from T4 to L1 (Fig. 1). The screws, fixed connectors, mobile connectors, mobile cross-connector and longitudinal rods were modelled as beam elements with a diameter of 5 mm and an elastic modulus of 200,000 MPa. Two types of mobile connections were simulated in this finite element model. They were modelled as a kinematic representation. The first mobile connection (used in versions M2–M4) allows gliding along and rotation around the rod, while the second one (used in versions M2, M3, M5) simulates a non-locking polyaxial screw that remains angularly flexible but prevents movement of the rod in longitudinal direction of the screw. At the levels T8 and T9, fixed connectors were mounted to the longitudinal rods and a mobile cross-connector was used to connect the longitudinal rods between vertebrae T8 and T9. The mobile cross-connector allows rotation around and movement along its long axis and rotation in the frontal plane around an axis perpendicular to the rod.

The finite element model used in the present study consists of more than 3,300 elements. Intervertebral rotations, forces on the intervertebral discs and on the implant components, motions in the polyaxial screws and of the mobile connectors were calculated and evaluated. In this paper only intervertebral rotations and the translation of the mobile connectors along the longitudinal rod are presented. The finite element program ABAQUS, version 6.6-2 (Dassault Systèmes, Providence, RI, USA), was used together with the pre- and postprocessor MSC/PATRAN (MSC Software Corporation, Santa Ana, CA, USA).

Results

Intervertebral rotations

All implants (versions M2–M6) reduce intervertebral rotation at all implant levels (Figs. 2, 3, 4, 5). The reduction compared to the intact spine (M1) is smallest for the

Fig. 2 Comparison of effects of different implants on intervertebral rotation for the loading case flexion

Fig. 3 Comparison of effects of different implants on intervertebral rotation for the loading case extension

Fig. 4 Comparison of effects of different implants on intervertebral rotation for the loading case left lateral bending

orthobiomTM system (M2, M3). Rigid screws and mobile connectors (M4) as well as non-locking polyaxial screws and fixed connectors (M5) lead to further reduction of intervertebral rotation. Fixed connectors in combination with rigid screws (M6) lead to the strongest reduction of intervertebral rotations for all loading cases.

For the loading cases flexion (Fig. 2), extension (Fig. 3), and lateral bending (Fig. 4), intervertebral rotation is more reduced due to fixed connectors (M5) than due to rigid screws (M4). For these three loading cases, spinal motion is highest at the non-instrumented level L1/L2. For axial rotation (Fig. 5), rigid screws (M4, M6) strongly reduce intervertebral rotation at all implant levels while the effect of fixed connectors is relatively small. At the level of the cross-connector (T8/T9), intervertebral rotation is less than 0.5° for all types of implants except for axial rotation in combination with implants with polyaxial screws. Our

Fig. 5 Comparison of effects of different implants on intervertebral rotation for the loading case right axial rotation

Fig. 6 Displacement of the mobile connectors along the longitudinal rod for the loading case flexion. Results are compared for placing screws in every vertebra, in every second vertebrae and for rigid screws

hypothesis that intervertebral rotation is more increased by mobile connectors than by non-locking polyaxial screws could be corroborated for the loading cases where the spine is bent and could not be corroborated when it is rotated.

The results for the version with screws at every second level (M3) differ only in a minor degree from those with screws at every level (M2). This is true for all loading cases studied. Thus our hypothesis that placing pedicle screws at every second vertebrae instead of every level increases intervertebral rotation could not be corroborated.

Translation of a mobile connector

The relative translation of the mobile connector along the rod is highest for the connections close to the ends of the rod construct (Figs. 6, 7, 8). The highest values are predicted for

Fig. 7 Displacement of the mobile connectors along the longitudinal rod for the loading case extension. Results are compared for placing screws in every vertebra, in every second vertebrae and for rigid screws

extension (4.2 mm), followed by lateral bending (3.1 mm) and flexion (1.6 mm). Lower values at all levels (up to 0.8 mm) are predicted for axial rotation. For extension and flexion, the translations of the mobile connectors were very similar on the left and right side. For lateral bending to the left (Fig. 8), translation was less than 0.3 mm on the right side at all levels. For axial rotation, the translation on the left and right side differed strongly above the fixed connectors (levels T8 and T9) but were similar below this region. Mobile connectors in conjunction with rigid screws (M4) normally result in strongly reduced maximum translation.

Discussion

The effects of different features of the novel non-fusion orthobiomTM scoliosis correction system on intervertebral

Fig. 8 Displacement of the mobile connectors along the left longitudinal rod for the loading case lateral bending to the left. Results are compared for placing screws in every vertebra, in every second vertebrae and for rigid screws

rotations and amounts of translation of the mobile connectors along the longitudinal rod were studied using the finite element method.

The numerical study showed that the mobile connector moves considerably along the rod when the spine is bent. The mobile connectors of the non-fusion implant should also lead to increased distances between the connectors when an adolescent patient grows. Therefore, the implant allows nearly unrestricted growth of the vertebrae and intervertebral discs. This adaptation should prevent fusion in the regions of the mobile connectors. Only the segment between the fixed connectors (levels T8 and T9 in the present model) is likely to fuse due to significantly reduced motion. The orthobiomTM system acts like an “internal brace”.

This numerical study has several limitations. A healthy spine instead a scoliotic spine was studied. The shapes and curve patterns of scoliotic spines are very diverse. Validation of such a model is not possible since no experimental data exists for scoliotic spines. Consequently, the geometry of our model represents the situation after ideal scoliosis correction. However, as with all models of the spine, also the present one had to be simplified. The discs were assumed to be homogeneous and not all ligaments were included. As the loads are unknown, pure moments were applied in the three anatomical planes and the muscle forces and the upper body weight were not taken into account. No preload in the rods was assumed. Little information exists about the material properties of the ligaments. The position of the pedicle screws may vary to some degree resulting in a different curvature of the longitudinal rod. Due to these simplifications, the results presented represent trends rather than precise values. Our intact model was validated [16] by comparing the stiffnesses in the three anatomical planes with experimentally determined values [14]. Good agreement could be achieved in all cases. The maximum difference of the overall rotation between the measured median and the calculated value was less than 13% of the measured range. Therefore, we assume that the simplifications in our model do not affect the main conclusions drawn from this study.

For flexion and extension, calculated intervertebral rotations of the intact spine (M1) were higher in the lumbar and thoracolumbar segments than in the thoracic segments. This is in agreement with the experimentally determined ranges of motion (ROM) in these regions [15]. The calculated values were always below the measured ROM of the corresponding segment. Within a spine, the differences in intervertebral rotations between lumbar and thoracic segments are usually less than in our model. For this study, models of the lumbar and of the thoracic spine were merged. Each model was separately validated since no experimentally determined segmental stiffnesses for an

entire spine were available. In the experimental studies specimens of different ages were used. The average age was 35 years for the lumbar specimens and 72 years for the thoracic spines. This, however, does not affect the presented results since the segment L1/L2 is outside the implant region. It was included solely to reduce boundary effects. For axial rotation, the highest intervertebral rotations were predicted in the upper thoracic spine which agrees with the published ROMs [15].

Fixed connectors (M5) strongly reduce intervertebral rotation for flexion, extension and lateral bending but have only a minor effect for axial rotation. Polyaxial screws (M5) in contrast to rigid ones allow higher intervertebral rotations for the loading case of axial rotation but have only a minor effect for the other three loading scenarios. They also considerably increase the translation of a mobile connector along the rod. The strong reduction of intervertebral rotation for axial rotation in version M6 is mainly due to the rigid screws (compare to version M4).

Our finite element mesh of the thoracic spine is asymmetric. The insertion points of the screws and screw orientations differed between left and right side and thus the implant is asymmetrically inserted. In spite of this, motions of the mobile connectors were similar on the left and right side for loading in the sagittal plane.

The translation of the mobile connectors along the longitudinal rods increases with the distance from the fixed connectors (levels T8 and T9). Placing screws only in every second vertebrae (M3) has only a minor effect on displacement of the mobile connectors, since the stiffness of the spine/implant system is only slightly influenced by the number of screws and thus the screw distances. Additionally, using fewer screws has the advantage in reducing the operating time, the risk of screw misplacement and the cost of the implant. The total wear in the polyaxial screws is most probably also reduced since the number of screws is halved but the calculated maximum forces in the screws are not increased.

This study demonstrates that the non-fusion implant reduces intervertebral rotation if a load-controlled loading protocol is applied. A motion-controlled loading protocol would require higher loads to produce the same deformation as the intact spine. The reduction of intervertebral rotation is much stronger if a rigid implant or an implant with fixed connectors only is assumed. These finite element analyses predict the best results for an implant with mobile connectors and non-locking polyaxial screws at every second level, however, the ability to correct a scoliotic spine was not investigated and has to be proven clinically.

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