Research Article

Patient-Specific Growth-Rod Distraction Frequency may Reduce Chances of Rod Fracture in Juvenile Idiopathic Scoliosis

Aakash Agarwal[1]*, Arvind Jayaswal[2], Anand K. Agarwal[1], and Vijay K. Goel[1]

[1]*Department of Bioengineering and Orthoapedic Surgery Engineering Center for Orthopaedic Research Excellence (E-CORE), University of Toledo, USA*
[2]*Department of Orthopaedics, Primus Super Speciality Hospital, India*

Abstract

Study design: A finite element study to establish the relationship between a patient's curve flexibility (curve correction under gravity) in juvenile idiopathic scoliosis and the required distraction frequency to avoid rod fracture as a function of time.

Objective: To perform a parametric analysis using a juvenile scoliotic spine model (single mid-thoracic curve with the apex at the eighth thoracic vertebra) and establish the relationship between curve flexibility (curve correction under gravity) and the distraction interval that allows a higher factor of safety for the rods.

Method: The parametric study was performed by varying the material properties of the disc and hence altering the axial stiffness of a scoliotic spine model. The stresses on the rod were found to increase with increased axial stiffness of the spine, and consequently also increased the required optimal frequency to achieve a factor of safety of two for growth rods.

Results and conclusions: The current study demonstrates the possibility of translating fundamental information from finite element modeling to the clinical arena for mitigating the occurrence of growth rod fracture, i.e., establishing a relationship between optimal distraction interval and curve flexibility (curve correction under gravity).

INTRODUCTION

About 2.5% of children across all age groups have scoliosis [1]. The Scoliosis Research Society defines scoliosis as a lateral deviation of the normal vertical line of the spine which, when measured by X-ray, is greater than 10°. Idiopathic scoliosis is the most common deformity, and it represents 80–85% of all scoliosis cases [2]. Progression of scoliosis in children poses a substantial challenge for spinal surgeons. These young patients are undergoing active growth, and early fusion of any kind would stunt their growth and adversely affect their quality of life. However, if left untreated, a major curve progression becomes imminent, with chances of respiratory insufficiency. This has led to the advent of growth-friendly surgical management of early scoliosis, which aims to avoid, delay, or limit spinal fusion.

Distraction-based dual growth rods are the most commonly used growth-friendly surgical instruments [3,4]. In a typical growth-rod implant surgery, two rods (proximal and distal) are attached along the two lateral sides of the spine using bone anchors. Bone anchors commonly used in posterior spinal surgery can be classified into three categories: (1) hooks (infra- or supralaminar hooks, transverse process hooks,andhook-end plate-screw combinations), (2)wires or bands (sublaminar wires, spinous process wires,and transverse process wires), and (3) pedicle screws. Among these, pedicle screws are the strongest and most widely used anchors for the foundation [5].

Initial surgery corrects the curve by about 50% [6-8]. A regular construct lengthening (at six months to a year) is continued for a period of five to ten years after implantation, until the spine's longitudinal growth stops. During such lengthening surgeries, the proximal and distal rods at each side are distracted apart. The position of the rods after distraction is maintained using a tandem connector [9]. In contrast, magnetically controlled growth rods have a single rod on either side and can be distracted (lengthened) noninvasively.

Despite its advantages, the major failure seen with this instrumentation is growth rod fracture. Growth rod fractures occur in 15% of patients treated with growing rods [4,10,11]. Thompson et al., reported a 29% (two out of seven patients)

complication rate of growth rod breakage[12]. Klemme et al., reported 12 rod breakages in 67 patients [13]. In 2005, Akbarnia et al., reported two rod breakages among 23 patients [14]. Yang et al. found that the risk of rod fracture increases with single rods, stainless steel rods, and smaller diameter rods. They also found that rod fracture was more prevalent among patients with preoperative ambulation ability [4]. Nevertheless, rod fracture also occurred in non ambulatory patients. Some researchers also believe that the distraction forces applied are so high that it stimulates growth rather than sustaining it [15]. Sakai et al., presented a case study in which they observe an 8.3-mm gap between T11-T12 immediately after distraction. This space was remarkably wider than the adjacent disc spaces, raising the suspicion of a distraction phenomenon (a severed union between soft and hard tissue), which was confirmed with computed tomography (CT) [16]. Following this, Agarwal et al. [17-19], reported results from a series of studies that shed light on the relationship between distraction (magnitude and frequency) and the residual stresses it generates on the rods. They found that higher distraction forces lead to higher residual stresses and increases the propensity of rod fracture. Additionally, they reported that frequent distraction (utilizing noninvasive procedure) with a lower distraction magnitude could reduce such occurrences. The objective of the current study is to perform a parametric analysis using a juvenile scoliotic spine model (a single mid-thoracic curve with the apex at the eighth thoracic vertebra) to establish the relationship between curve flexibility (curve correction under gravity) and the distraction interval that allows a higher factor of safety for the rods.

METHODOLOGY

This study uses a finite element model of a representative juvenile scoliotic spine (single mid-thoracic curve with the apex at the eighth thoracic vertebra) to run a parametric analysis. As described in previous publications, a normal juvenile spine was used as the foundation to produce multiple representative juvenile scoliotic spines. In this process, a CT was taken of a typical nine-year-old juvenile patient, and the vertebral body and intervertebral height were recorded [17]. Next, a validated T1-S1 normal adult spine model was scaled down to 71% of its original size to represent a juvenile spine, based on the literature data. However, the ratio of vertebral body to intervertebral height in an adult spine differs from that of a juvenile. For this reason, the mesh of this scaled-down finite element model of a normal spine was altered using ABAQUS (Dassault Systèmes, Simulia Inc., Providence, RI) to personalize the vertebral body and intervertebral body height to that of the heights recorded in the juvenile CT data. Thereafter, the desired scoliotic spine was generated with a custom script (MATLAB, Natick, MA UNITED STATES), utilizing polynomial transformations of finite element nodes.

Growth rods were simulated in the FE spine model with eight 4.5-mm titanium alloy (Ti6Al4V) pedicle screws and four 4.5-mm titanium alloy (Ti6Al4V) rods (two distal and two proximal) (Figure 1). Four out of eight pedicle screws were anchored bilaterally at the pedicles of the upper two vertebral foundations; the rest were placed bilaterally at the pedicles of the lower two vertebral foundations. The pedicle screws were kinematically
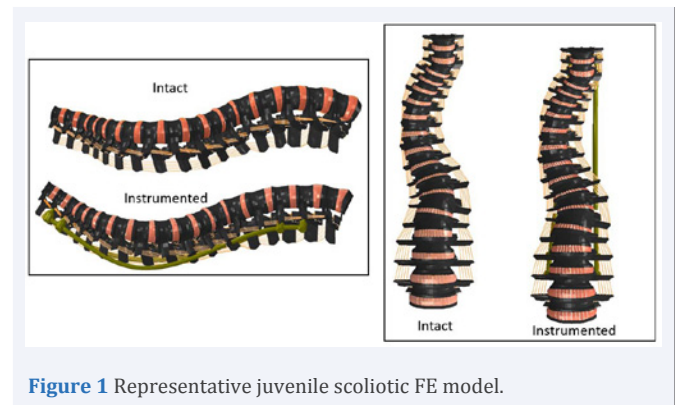

Figure 1 Representative juvenile scoliotic FE model.

coupled to the pedicles in all three degrees of freedom. The proximal rods were tied bilaterally to their respective ipsilateral proximal pedicle screws, and the distal rods to their ipsilateral distal pedicle screws. The tandem connection was simulated by kinematically coupling the ipsilateral free ends of the rods in all three degrees of freedom. As the model was simulating the postimplantation serial distractions, the initial curve was given a Cobb angle of 35°, kyphosis of 38°, and lordosis of 39°.

After the representative scoliotic juvenile finite element model was developed, all meshed regions were assigned juvenile spine material properties [18,19] (Figure 1). The follower load technique was chosen and simulated to account for the load at different vertebral levels due to upper body mass and muscle contraction [20]. The spine was loaded with 14% body weight at T1, following a 2.6% body weight increase between succeeding vertebrae. The given proportions were used to calculate the follower load for the current nine-year-old patient's spine with a mean weight of 22 kg. The boundary condition consisted of restraining the inferior surface of the S1 vertebra in all degrees of freedom based on previously approved methodology for growth simulation in finite element modeling [20]. Unlike an adult spine, a juvenile spine has a certain rate of longitudinal growth, which is affected per the Hueter-Volkmann principle. This altered growth rate is captured in the following empirical equation:

$$G = G''[1 + \beta(\sigma - \sigma'')]$$

where G is the actual growth strain, G'' is the mean baseline growth strain (at a given age), σ is the actual compressive stress on the growth plate (in MPa), σ is the mean baseline stress on the growth plate for the intact spine (in MPa), and β is equal to $1.5MPa^{-1}$ for vertebrae. For the intact model, G is equal to G'', and G'' is equal to 0.035 per six months for a nine-year-old child's spine, according to the published literature [19].

In addition to growth, another clinically observed phenomenon, autofusion, was also incorporated into the model. As previously shown, the forces required to achieve distraction increase with subsequent distraction [21]. This is attributed to autofusion at the spinal segments and is an important aspect included in the current models. In brief, the phenomenon was incorporated into the models by increasing the stiffness of the spine as a function of time, using the available data on diminished lengthening on subsequent distractions [17].

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Parametric analysis

The simulation was performed by varying the stiffness of the spine and applying distraction up to a maximum stress of 255 MPa. Thereafter, optimal distraction force was applied to each model with different stiffness values: 8.2 N/mm, 12.5 N/mm, 13.8 N/mm, 14.7 N/mm, 16.2 N/mm, 18.2 N/mm, 20.2 N/mm, 21.9 N/mm, 23.1 N/mm, and 25.5 N/mm. A stress of 255 MPa was chosen to keep the factor of safety equal to two and to account for possible stress concentrations and notching in implanted titanium rods due to surgical steps, as the fatigue strength of titanium alloy (Ti6Al4V) is 510 MPa. The stiffness was varied by increasing the modulus of elasticity of nucleus pulposus and annulus fibrosus. As described in previous publications [17,18], the slopes of increase in the spine's longitudinal stiffness (in tension) with respect to Young's modulus (N/mm^2) of nucleus pulposus and shear modulus (N/mm^2) of annulus fibrosus were 0.55 mm^{-1} and 7.2 mm^{-1}, respectively. Data recorded during the simulation included the percentage of Cobb's angle correction by gravity (representing unconstrained traction), axial stiffness, and the distraction interval required to achieve stresses limited to 255 MPa.

RESULTS AND DISCUSSION

Figure (2) shows the relationship between the axial stiffness and the percentage correction in Cobb's angle due to gravity alone. As expected, it shows that the unconstrained correction under gravity is higher for a flexible curve and lower for a rigid curve. Figure (3) shows the relationship between the percentage correction in Cobb's angle due to gravity alone and the required distraction interval for limiting the maximum von Mises stress to 255 MPa on the growth rods. The distraction interval required to limit the stresses to the selected nominal value reduces with increased stiffness of the spine. Please note that these values are for only the first distraction interval following the initial surgery.

Figure (4) shows how the distraction interval requirement changes with autofusion to keep the factor of safety at two; that is, the maximum von Mises stresses are still equal to 255 MPa. It can be seen that the distraction interval reduces for each model as the spine becomes stiffer with time (autofusion). Hence, an optimal distraction frequency is a time-dependent variable. Figure (5) shows the frequency of distraction that must be achieved to keep the maximum von Mises stress under the specified factor of safety. This represents the correlation that exists between the initial Cobb's angle correction and the dynamic frequency that is required to keep the stresses on the rods under limit. In both figure (4) and figure (5), the model simulated with 0.2% Cobb's angle correction always resulted in stresses higher than 255 MPa. A patient with such high stiffness would require a technology that can sense the stress and lengthen automatically.

Rod fracture is a common complication of growing-rod treatments and has been highlighted in several studies [4,12-14]. Therefore, lowering the stresses on the rods will help to reduce the occurrence of failure. Spinal stiffness varies among patients and changes after surgery (autofusion). Based on the extent of the patient's spinal stiffness, even the lowest stresses (the optimal distraction force) generated may result in growth rod fracture. A proposed hypothesis for this situation would be to change the
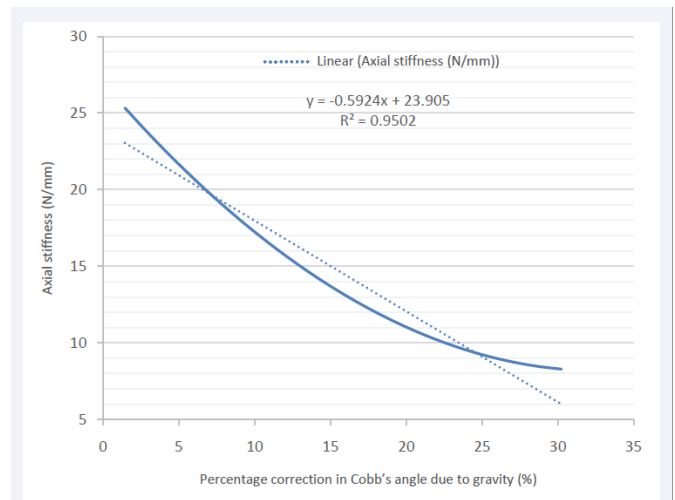

Figure 2 The graph shows the relation between the axial stiffness and percentage correction obtained at that given stiffness with gravitational loads.
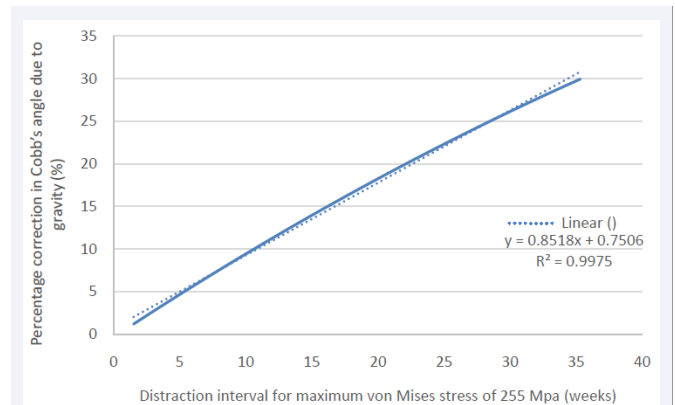

Figure 3 The graph established relationship between maximum allowed distraction intervals (for maximum von Mises stress up to 255 MPa) on the rod for a given percentage of Cobb's angle correction under gravitational loads. For 0.2% correction, the distraction always resulted in stresses higher than 255 MPa.
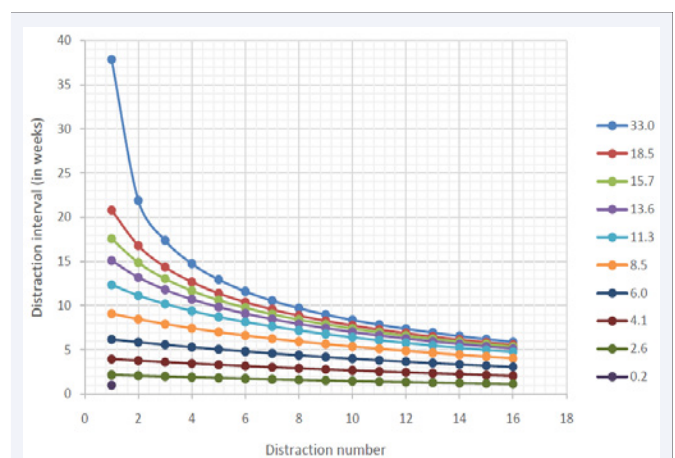

Figure 4 Change in distraction intervals (for maximum von Mises stress up to 255 MPa) with consecutive distraction.

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distraction frequency, therefore lowering the magnitude of the required optimal distraction force, according to the patient's spinal stiffness.

Optimal distraction force refers to distraction force required to produce height gain equal to normal height as observed in the non instrumented spine [17-19]. The distraction frequency and distraction forces are integrated; i.e., for every distraction frequency there is an optimal distraction force. This optimal value is equivalent to the force required to distract the spine for the specific distraction interval. It is because of this reduction in optimal distraction force that the stresses on the rod reduce. Therefore, the distraction force of approximately zero magnitude would ideally mean a growth rod technology that can sense the change in compressive stresses and lengthen automatically as a negative feedback mechanism.

At present, the growth rod technique is not a single-surgery technique: several invasive distractions must follow the main surgery, and the child suffers extreme morbidity and discomfort as a result. For example, a five-year-old child implanted with growth rods would undergo 10 to 14 consecutive distraction surgeries. Moreover, there have been many instances of failure. With traditional growth rods, changing the frequency of distraction wasn't an option because of its invasive nature. A higher frequency of distraction (<6months) will give the patient high risk of complications. A lower frequency of distraction (>1 year) lowers the growth potential. However, new growth rod technology in the spine industry now means that serial distractions could be achieved noninvasively. The results from the sensitivity study help translate this information into clinical practice. We developed and simulated a representative scoliotic model varying in material properties (to account for stiffness variation among scoliotic patients) to establish a relationship between axial stiffness of the spine, percentage correction in Cobb's angle due to gravity, and required distraction interval, for a factor of safety equal to two. The study results show that by measuring the percentage correction before the surgery, a specific distraction interval could be chosen based on the

required factor of safety for the growth rods. The idea behind using a graphical representation instead of a single number for the ideal distraction frequency is based on the existence of variance in spinal stiffness among the patients.

As with all surgical procedures, patient selection is an important factor that affects the efficacy of any technique. The ideal frequency for one patient may not be suitable for the other. Therefore, this study refrains from selecting a particular distraction frequency as a cautionary measure. Furthermore, ideal distraction forces change for a given patient with time (function of autofusion).We do recommend higher frequencies of distraction whenever possible with the optimal distraction force as an ideal choice to reduce von Mises stresses on the rods, but properly understanding assumptions is a prerequisite before using these numbers for the patients. These specific values and recommendations are limited to the nine-year-old age group based on typical anatomical considerations (intervertebral disc height). Additionally, the growth rods used in this study were 4.5 mm in diameter and used Ti6Al4V as their material type [17].

There area few limitations to the current study. First, the surgical procedure of initial rod attachment was not simulated; and the scoliotic curves are considerably larger before the surgery (more than 45–50°). However, given their nonstructural nature, they exert only 5–8% of total von Mises stress for about 40–50% of correction [9]. Second, due to lack of awareness about how suboptimal distraction forces and distraction frequencies itself results in rod fracture, there isn't a clinically available direct method to apply the findings of this study (i.e., the ability to measure loads vs. distraction during surgery). Some indirect methods include presurgical planning using finite element modeling with the patient's standing and side-bending radiographs. Nevertheless, new technologies are being developed that could either provide or calculate the optimal distraction based on sensors incorporated in the device [22,23].

CONCLUSION

The current study describes a method to translate fundamental information from finite element modeling to the clinical arena for mitigating the occurrence of growth rod fracture, and it establishes a relationship between optimal distraction interval and curve rigidity. The study results show that to reduce the stresses on the rods, the distraction interval can be shortened as a function of time-consecutive ones per the patient's requirements (measured from initial flexibility measurement).This is not feasible with traditional growth rods, but other noninvasive distraction methods, such as magnetically controlled growth rods, present great potential.

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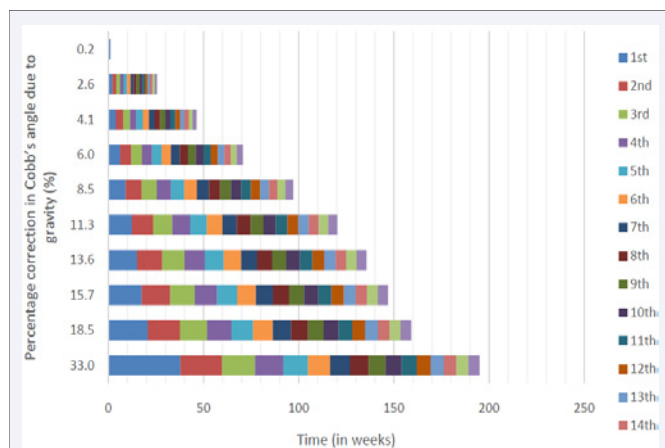
Figure 5 Dynamic distraction intervals for models simulating scoliotic spine with different axial stiffness (recognized clinically by Cobb's angle correction). For 0.2% correction, the distraction always resulted in stresses higher than 255 MPa.

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Email: aakash.agarwal@rockets.utoledo.edu

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