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REVIEW ARTICLE

Current benchtop protocols are not appropriate for the evaluation of distraction-based growing rods: a literature review to justify a new protocol and its development

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Abstract

Purpose Although distraction-based growing rods (GR) are the gold standard for the treatment of early onset scoliosis, they suffer from high failure rates. We have (1) performed a literature search to understand the deficiencies of the current protocols, (2) in vitro evaluation of GRs using our proposed protocol and performed a finite element (FE) model validation, and (3) identified key features which should be considered in mechanical testing setups.

Methods PubMed, Embase, and Web of Science databases were searched for articles published on (a) in vivo animal, in vitro cadaveric, and biomechanical studies analyzing the use of GRs as well as (b) failure mechanisms and risk factors for GRs. Both FE and benchtop models of a proposed TGR test construct were developed and evaluated for two cases, long tandem connectors (LT), and side-by-side connectors (SBS). The test construct consisted of five polymer blocks representing vertebral bodies, joined with springs to simulate spinal stiffness. The superior and inferior blocks accepted the pedicle screw anchors, while the three middle blocks were floating. After the pedicle screws, rods, and connectors were assembled onto this construct, distraction was performed, mimicking scoliosis surgery. The resulting distracted constructs were then subjected to static compression-bending loading. Yield load and stiffness were calculated and used to verify/validate the FE results.

Results From the literature search, key features identified as significant were axial and transverse connectors, contoured rods, and distraction, distraction being the most challenging feature to incorporate in testing. The in silico analyses, once they are validated, can be used as a complementing technique to investigate other anatomical features which are not possible in the mechanical setup (like growth/scoliosis curvature). Based on our experiment, the LT constructs showed higher stiffness and yield load compared to SBS (78.85 N/mm vs. 59.68 N/mm and 838.84 N vs. 623.3 N). The FE predictions were in agreement with the experimental outcomes (within 10% difference). The maximum von Mises stresses were predicted adjacent to the distraction site, consistent with the location of observed failures in vivo.

Conclusion The two-way approach presented in this study can lead to a robust prediction of the contributing factors to the in vivo failure.

Keywords ASTM-F1717 · Early onset scoliosis (EOS) · Benchtop test protocols · Traditional growing rods (TGR) · Magnetically controlled growing rods (MCGR)

Introduction

Early Onset Scoliosis (EOS) is a complex three-dimensional deformity associated with an excessive lateral curvature of the spine, usually observed in patients under the age of ten [1]. In the treatment of EOS, the goal is to reverse the scoliotic curve progression over time without arresting natural spinal growth.

Growing Rods (TGR/MCGR) are the surgical standard for EOS treatment around the globe. This distraction-based technique corrects the spinal deformity by applying

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a distractive force on the concave side while still allowing for natural growth until skeletal maturity has reached.

Each rod consists of two segments joined by axial connectors spanning multiple spinal segments in the thoracolumbar region. Instrumentation includes two foundations, one at the proximal and one at the distal site. Each foundation consists of at least four anchors across two to three vertebral bodies [2]. Various axial connector configurations are used, based on the patient's anatomy and surgeon preferences. These connectors allow for rod lengthening as the patient grows [2, 3].

Following initial implantation and distraction, patients undergo additional periodic distraction surgeries to provide more correction and to allow for growth [4].

Although the distraction-based growing rod surgeries have successful clinical outcomes in terms of correcting scoliotic deformity, they exhibit a high rate of complications (rod breakage, anchor failure, dislodgment) [5–11].

Thus, in this manuscript, we aim to:

1. Present a literature review on the distraction-based growing rod constructs and identify the key features which should be considered in the mechanical testing setups and in silico modeling to address the clinically observed complications associated with these implants.
2. Present a novel benchtop testing protocol for traditional growing rods, including FE model validation.

Methods

Literature review

A systematic search of PubMed, Embase and Web of Science databases was conducted to understand the use of distraction-based growing rod systems. By using the advanced search builder function in each database, the following search terms were used to search the relevant publications: growing (growth) rods, in vitro, biomechanical studies, and scoliosis.

Inclusion and exclusion criteria

For further consideration, the literature reviewed had to involve evaluation of either finite element models, or benchtop mechanical testing of distraction-based growing rods. Studies focused on non-distraction-based systems such as growth-guidance systems, flexible anterior/anterolateral vertebral tethers were excluded (Fig. 1).

Similar databases were searched using the following terms: growing (growth) rods, in vivo, failures, fractures and risk factors. The publication abstracts were reviewed, and literature regarding the risk factors and failure mechanisms of distraction-based systems in a clinical setting were selected.

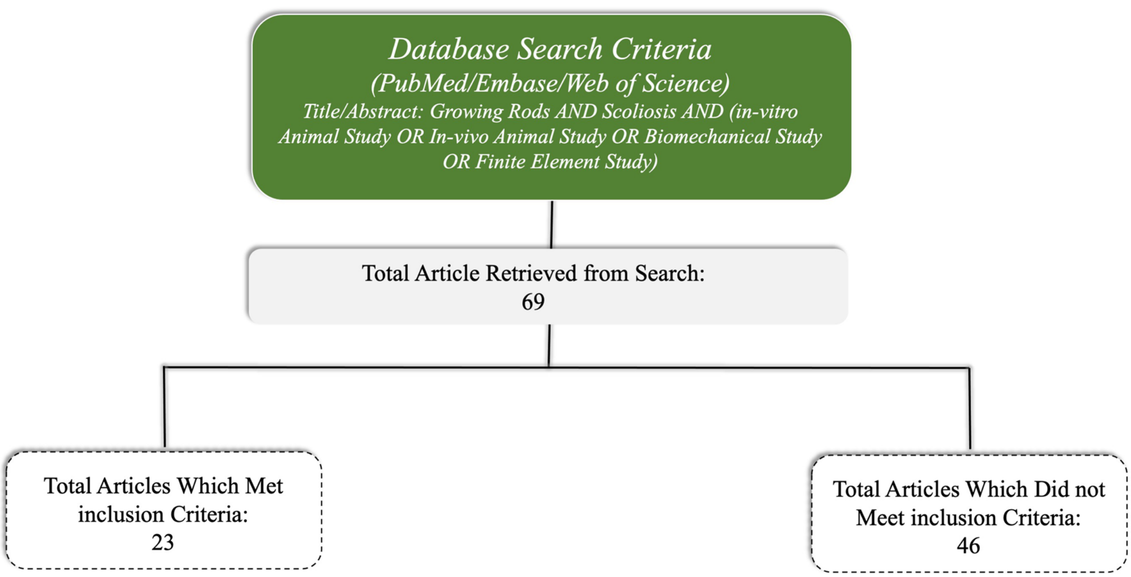

Fig. 1 Schematic of the article's selection process

Benchtop testing

Recently, the authors proposed a modification of the ASTM F1717 testing protocol, adding additional simulated vertebral bodies, and connecting all the body elements with springs. The initial proof-of-concept of this new testing protocol was provided by a finite element-based study presented earlier by the authors [12–14].

Two types of distraction-based growing rod constructs were assembled: (a) a 75-mm-long tandem connector construct (LT), and (c) a side-by-side/domino connector construct (SBS) (Fig. 2). A total of five test blocks supported by four sets of red die springs (stiffness of 129 N/mm) were used in each construct to replicate four functional spinal units (FSUs). Four Ti6Al4V alloy pedicle screws (Ø4.5 × 45 mm) were inserted into the top and the bottom blocks along with four lengths of Ø5.5 mm titanium rod. In the SBS model, the top and bottom rods on each side were interconnected using a stainless steel domino (Fig. 2). In the LT model, a 75-mm-long stainless steel tandem connector was used on each side. The springs were rigidly clamped to the test blocks by means of plates and bolts (Fig. 3). The block moment arm was maintained at 40 mm as per ASTM-F1717. The initial active length was set at 193 mm. The assembled constructs were mounted on an MTS Bionix biaxial material testing machine (MTS Corp, Eden Prairie MN, USA). A three-step loading protocol was used. A 6.2 mm was marked on the rods (outside the axial connectors), and distraction was applied to the superior most block until the marked position on the rods reached. Then, the connectors were fixed, 90 and the constructs allowed to relax. Finally, static compression bending was applied under displacement control at a rate of 0.2 mm/sec.

FE modeling

All the parts to be used in the assembly were modeled in SolidWorks V2018 (Dassault Systèmes, Waltham MA, USA) and imported into ABAQUS v6-14 (Dassault Systèmes, Waltham MA, USA). The optimal mesh seed size and type to be used for each model component was determined using a mesh convergence study which was explained in

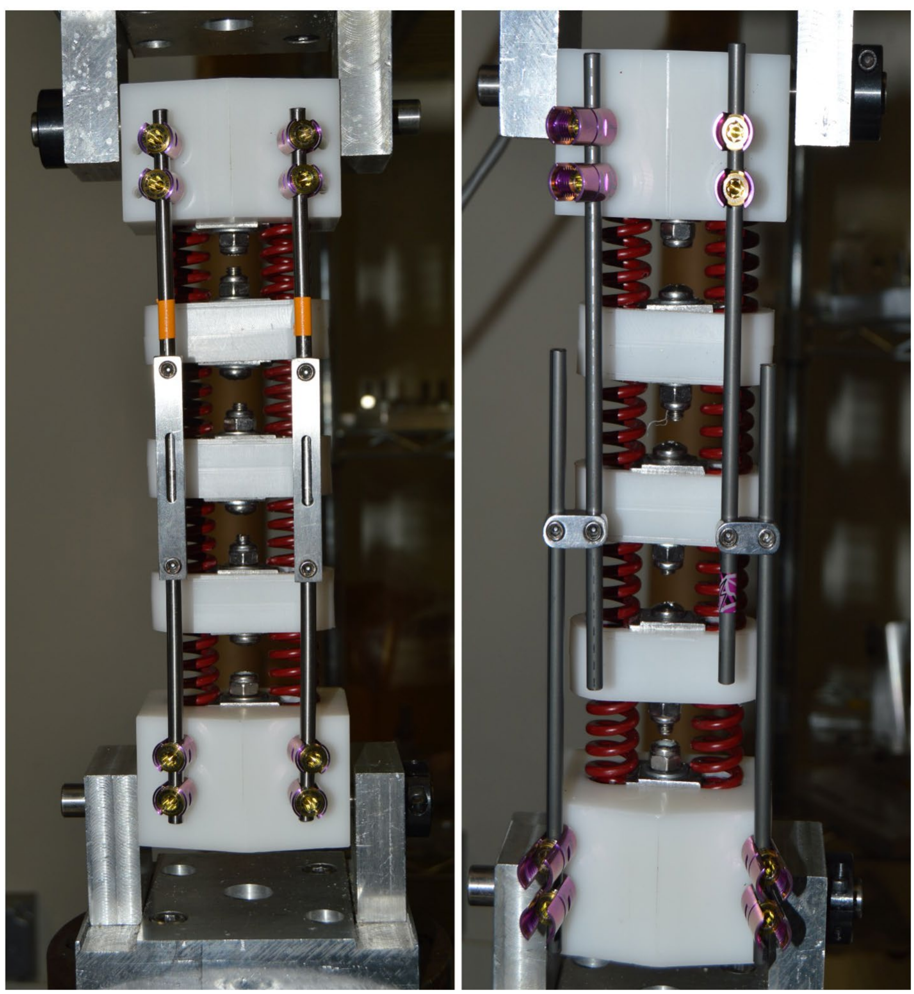

Fig. 2 Configurations developed and tested in the current study. From left to right models with long tandem connectors (LT), and side-by-side connectors (SBS)

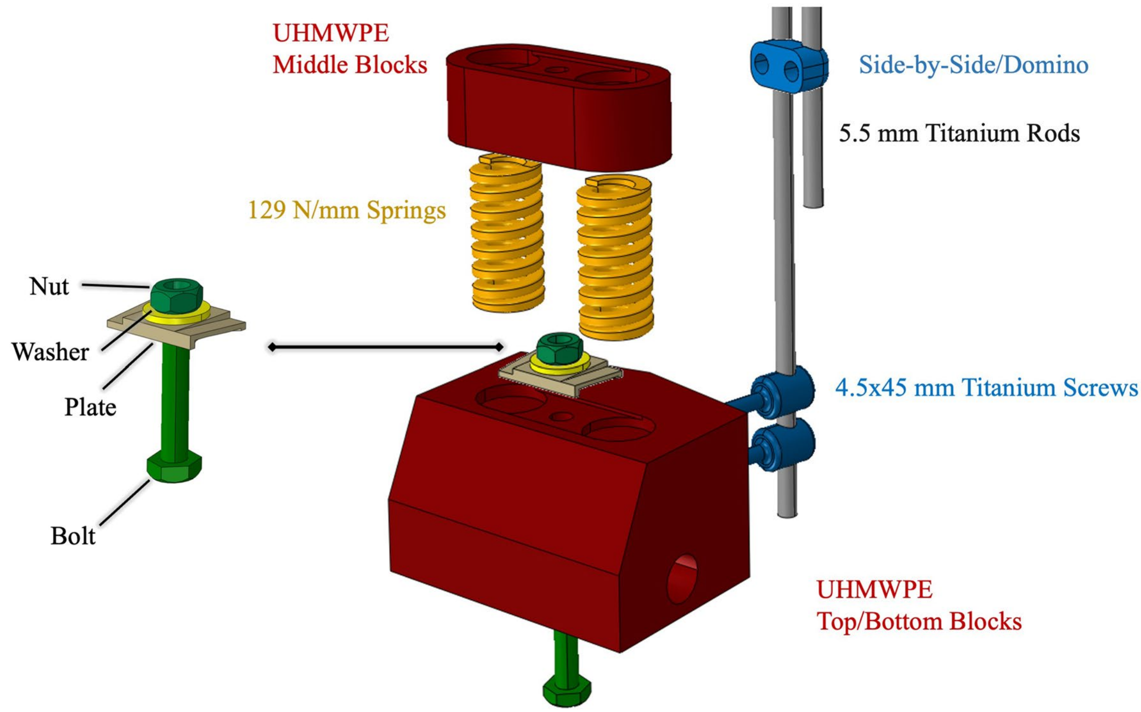

Fig. 3 A clamping mechanism was used to attach the die springs to the test blocks in the in vitro testing setup. At each side of the block's, springs were secured rigidly by means of a plate and bolt shown here. This mechanism was simplified in the FE model development by coupling the springs to plastic blocks

Table 1 Material properties used in FE model development for each components [12, 13]

Component	Material	Elastic		Plastic	
		Young's modulus (MPa)	Poisson's ratio	Yield stress	Plastic strain
Springs, axial connectors	Stainless Steel	207,000	0.29	–	–
Blocks	UHMWPE	690	0.46	21	0
Rods, Screws	Titanium	105,000	0.36	600	0
				750	0.00148571
				880	0.00338571
				935	0.00519048
				970	0.00828571
				1153.6	0.107614

detail in the author's previously published work [12, 13]. Appropriate material properties were adapted from the literature and assigned to each component (Table 1).

Interaction definitions between the model components were taken from the literature [12, 13]. An appropriate surface-on-surface interaction was defined between the cranial rods and axial connector in each step (Table 2). Loading and boundary conditions were matched to the physical experiment (Table 2).

The load versus displacement graph was captured from the "compression-bending" step at the superior most block (force along the longitudinal direction). The stiffness and 2% yield load were computed for each model

Table 2 Boundary conditions defined in each step for the FE model development. For each step, a specific surface-on-surface interactions was defined between the rod and axial connector (i.e., tandem/side-by-side connector)

Component	Step 1 Distraction	Step 2 Relaxation	Step 3 Compression-ben
Boundary conditions			
Top block	$U_2 = 7.9$ mm, $U_3 = 0, UR_2 = 0$	$U_1 = U_3 = UR_2 = 0$	$U_2 = -20$ m $U_1 = U_3 = UR_2$
Bottom block	Constrained along all directions	$U_1 = U_2 = U_3$ $= UR_2 = 0$	$U_1 = U_2 = U_3 =$
Surface-on-surface interaction			
Rod-connector interface	Simulating rod-connector sliding mechanism:	Simulating rod-connector locking mechanism	
	Tangential behavior:	Tangential behavior:	
	Penalty/friction = 0	Penalty/rough	
	Normal behavior	Normal behavior	
	Linear/Default	Hard/Penalty/stiffness = 600	
	Geometric Properties	Geometric Properties	

and the values were validated with the experimental data. The rod's maximum von Mises stresses were captured and reported.

Results

Literature review

Human cadaveric spine studies, in vitro and in vivo animal studies

The literature search strategy yielded no relevant result involving the use of human cadaveric scoliosis spines. Likewise, the current in vivo/in vitro animal studies [15–27] do not provide any information regarding the failure mechanism/location (Table 5).

Clinical studies: risk factors associated with distraction-based growing rods

Clinical studies have reported that distraction-based growing rods experience a high rate of complications [6, 7, 9, 28–34]. Upasani et al. [9] studied 263 complications associated with traditional growing rods used for EOS patients, of which 129 (49%) were implant-related complications (i.e., rod breakage, screw pullout, and anchor dislodgement). Similar results were observed in magnetically controlled growing rods; 46.7% [30] & 44.5% [31] of MCGR were associated with complications (including rod fracture, foundation failure, failure in the distraction procedure, and infection [30, 31]).

Due to these complications and implant failures, distraction-based techniques showed a high rate of unplanned revision surgeries [29]. In these revision surgeries, the fractured implant is replaced with a new device. However, Yang et al. found that in 80% of the devices with repeated fractures, failure occurred at the same or within one vertebra level [10]. They hypothesized that fracture was a construct-dependent phenomenon [10].

The most common risk factors associated with higher complications with TGRs were single rods [7, 10], smaller rod diameter [10, 35, 36], stainless steel rods [10, 35, 36], short tandem connector [10, 37], larger scoliosis major curve magnitude [9, 33, 34], number of levels instrumented [32], earlier TGR implantation [6, 9], number of lengthening procedures [6, 7, 9, 30, 33, 38, 39], lengthening intervals (or frequency of rod lengthening) [7, 30], and preoperative thoracic kyphosis [7, 9, 33–36, 40] (Table 3).

The most common risk factors associated with MCGRs were the number of rod-lengthening surgeries [30, 38, 39], the magnitude of rod lengthening [38], off-axis loading [38, 41], lengthening intervals [30], rod contouring [39, 42, 43], location of MCGR relative to apex of the spinal curvature [43], patient body weight [43], and preoperative kyphosis of the patient [40] (Table 3).

The fracture rates were approximately similar in constructs with tandem and side-by-side connectors (18% vs. 16% [10]). However, using short tandem connectors lead to a higher incidence of rod breakage compared to long tandem connectors [10, 28]. Hosseini et al. [35] found that in the fractured rod group, the average length of the tandem connectors was shorter compared to the non-fractured group (65.5 mm vs. 67.5 mm). Moreover, the rod slot's shape in

Table 3 Risk factors reported in literature for distraction-based growing rods

Study	Risk factors
Hosseini et al. [35]	Rod diameter
	Rod material
Hosseini et al. [36]	Rod diameter
	Preoperative kyphosis
	The ratio of number of construct levels/number of anchored levels
Yang et al. [10]	Prior rod fracture
	Using single rods
	Rod material (stainless steel rods)
	Rod diameter
	Proximity to tandem connectors
	Using short tandem connectors
	Preoperative ambulation
Du et al. [32]	Preoperative musculoskeletal deficits
	Shorter pre-op T1-S1 height
	Number of levels instrumented
	Number of implants used
	Combined anterior/posterior fusion
	Use of antibiotics (vancomycin) after final fusion
	Use of subcutaneous implants
Upasani et al. [9]	Age at implantation
	Major curve magnitude
	Thoracic height
	Maximum thoracic kyphosis
	Number of lengthening procedures
	Spine height
Schroerlucke et al. [34]	Thoracic kyphosis
Bess et al. [6]	The age at the initial instrumentation
	Distraction surgery
Liang et al. [7]	Number of surgical procedures
	Number of lengthening procedures
	Rod-lengthening interval
	Use of single versus dual growing rods
	Preoperative T5–T12 kyphosis angle
	Curve magnitude at last follow-up
Watanabe et al. [33]	Increases in the upper thoracic scoliotic curve
	Preoperative thoracic kyphosis
	Number of rod-lengthening procedures
	Number of surgical procedures increase
Wei et al. [38]	Number of rod-lengthening procedures
	Magnitude of rod-lengthening
	Off-axis loading of the rod
Cheung et al. [39]	Number of rod-lengthening procedures
	Contouring of proximal rods
Beaven et al. [43]	Contouring of proximal rods
	Location of rod actuator proximal to apex of the curve
	Patient body weight
Pasha et al. [42]	Contouring of proximal rods
Kwan et al. [30]	Number of rod-lengthening procedures
	Frequency of rod-lengthening procedures
Abdelaal et al. [40]	Preoperative thoracic kyphosis

side-by side connectors impacted the rod's slippage rate; Lee et al. observed that connectors with a circular rod slot showed a higher incidence of rod slippage than the connectors with a V-groove rod slot (41% vs. 4%) [44].

Although the effect of rod material has been investigated in the literature [10, 28, 35], we found only one study which investigated the use of different materials for connectors and rods. Using cobalt chromium rods decreased the odds of rod breakage, while it increased the odds of connector failure [45].

In a cohort of eighty-six fractured rods, Yang et al. identified that most fractures occurred "within 1 cm of a tandem connector" [10]; their study reported thirty-five rods failed near the thoracolumbar junction, thirty-four failed below and above the tandem connector, twelve fractured at the vicinity of anchors, and two failed adjacent to crosslinks [10]. However, Farooq et al. found that caudal rods had more incidences of rod breakage, and that fracture was observed more frequently adjacent to the distal anchors [46].

In another study, Hill, et al. presented a more detailed investigation regarding rod fracture [37] and showed that the fracture location could be a function of the position of axial connectors with respect to the apex of the major curve:

- Long rods + short tandem connector (connector was positioned toward one end): failure at mid construct (4 of 16) [37].
- Connectors positioned in the center of constructs: failure adjacent to the tandem connectors (7 of 16) [37].
- Long cranial rods and short caudal rods + long tandem connector (the connector positioned at the thoracolumbar junction): failure adjacent to the distal anchor foundation (5 of 16) [37].

There is a controversy in the literature with respect to the effect of crosslinks on rod breakage. Hosseini et al. [36] found no significant correlation between the presence of crosslinks and complication rate. In contrast, Hill et al. found that 94% of failed rods were associated with at least 2–4 crosslinks; however, in 19% of the intact group, there was either no or one crosslink [28].

Clinical studies have shown that one of the most important sources of complications in growing rod constructs is repeated lengthening and distraction surgeries. In a retrieval study by Hill et al., five rods failed after the second to fifth lengthening episodes, and two rods failed after the eighth lengthening surgery. They indicated that with the increase in a rod's overall length, a higher chance of rod breakage was expected [28]. This is why some authors believe applying less distraction with more frequent surgeries is favorable [6, 47–49]. However, additional surgeries would increase the chances of non-implant-related complications such as wound infection [6, 47–49]. Authors have shown that each additional surgery (either distraction or revision surgery) increases the risk of complications by 24% [2, 6].

Although the number of lengthening procedures is an important factor effecting rod breakage, some authors have shown that the time interval does not seem to have a specific impact on their fracture rate. In a study of 138 EOS patients with GRs, Hosseini et al. found that there was no significant correlation between rod failure and the lengthening intervals for distraction surgeries [35, 36]. Their results showed a mean of 36.3 months to fracture after index surgery [35, 36].

While the number and magnitude of distractions are an important 182 factor effecting rod breakage, there are other factors interrelated with distraction which need further investigation. These include the patient's age at index surgery [6, 9, 50], the time period of implant in situ, and $T1$-$S1$ growth rate [47–49, 51–55]. Bess et al. [6] reported that with an increase in each year in the patients' age at the initial implantation surgery, chances of complication decreased by 13%. They indicated that while early instrumentation might enhance pulmonary development [6, 9, 50], and might lead to a better curve correction, it will also increase the chances of implant-related complications due to the "less soft-tissue coverage, smaller bones, and less physiologic reserve" [6] in younger patients. Moreover, when patients undergo implantation at a younger age, they probably need more surgical procedures until the final fusion, which might increase the chances of construct failure or wound infection [6].

FE investigation: T1-S1 growth

Several in silico studies have attempted to investigate the effect of distraction force on $T1$-$S1$ growth [47–49, 51–55]. Abolaeha et al. developed an FE model of single growing rod instrumentation over a 2-year growth period with adjustments at 6-month intervals [54]. Agarwal et al. [47–49, 51–53, 55] observed that having frequent distraction surgeries (with lower rod lengthening at each episode) results in a lower stress on the rods compared to a lesser number of distractions with higher lengthening magnitude at each episode.

Benchtop mechanical studies: modifications of ASTM-F1717

The American Society for Testing and Materials (ASTM) F1717, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" [56] covers the benchtop testing of spinal fusion devices. The ASTM-F1717 standard has been modified to evaluate scoliosis correction devices; however, the literature on this practice is sparse [12, 57–59]. Foltz et al. [57] modified the ASTM-F1717 protocol to accommodate 205 long (376 mm) and short growing rods (76 mm) using side-by-side connectors. They showed that as the rod lengths increased, the constructs failed at lower loads [57].

Another modification of the ASTM-F1717 was presented by Hill et al. [58]. In their protocol, four sets of screws were inserted into the top and bottom blocks to represent a real-life condition. They also investigated the effect of crosslinks on the fatigue performance of growing rods [58]. Their study highlighted that in the presence of crosslinks, the critical stress location moved to the proximity of these transverse connectors and the number of cycles to failure decreased significantly [58].

In the aforementioned studies, the only modification was to lengthen the vertebrectomy setup to accommodate the longer constructs, and the use of two sets of screws in each block. No attempt was made to model distraction. However, recently, Shekouhi et al. proposed a new clinically relevant protocol to evaluate growing rod constructs. The presence of anterior support corresponding to the pediatric spine in their proposed protocol allowed for simulation of distraction [12, 14].

Benchtop and biomechanical testing + FE model validation

The results from our benchtop testing showed that at the end of distraction, a 385.9 N and 382 N force was measured for the SBS and LT constructs, respectively. The LT constructs demonstrated higher stiffness and yield load compared to the SBS (78.85 N/mm vs. 59.68 N/mm and 838.84 N vs. 623.3 N, Table 4, Fig. 4). Due to the presence of the anterior support, the construct stability increased, and fracture did not happen but yielding was observed in the static mechanical testing (Fig. 5). The static tests were stopped when posterior bulging of the intermediate blocks caused contact with the hardware (Fig. 5).

The FE predictions were in a good agreement with the 228 experimental data. A comparison between compressive load versus displacement graphs obtained from in vitro and FEA is given in Fig. 4. FE results indicated that rods experienced less von Mises stress in the SBS construct than LT at the end of relaxation (Fig. 5). However, at the end of compression bending, stresses were slightly higher in SBS construct (Fig. 5). The critical stress location was observed adjacent to the distraction site (Fig. 5).

Discussion

Clinical studies have shown that the complications associated with distraction-based growing rods are multifactorial [6, 7, 37]; they depend on anatomical characteristics as well as construct structure. Hence, research for GRs should be directed toward using in vivo clinical/retrieval studies to identify the risk factors which contribute to postoperative complications, and to refine benchtop testing protocols to include such factors.

The major mechanical issues observed in the literature include proximity to the axial connectors [10, 35–37, 60], repeated lengthening and distraction surgeries [6, 7, 10, 28, 30, 38, 39], and preoperative kyphosis [9, 33–36, 40, 42]. Thus, it is necessary to develop a benchtop testing protocol which can consider different combinations of key features affecting the performances of GRs.

Since the building blocks of GR systems were developed for spinal fusion surgeries, these components are traditionally tested using the standard for posterior spinal fusion constructs, ASTM F1717 [56], simulating the "worst-case" scenario, where anterior support is absent.

However, two questions have not been addressed yet; (1) Can we use the same rationale to define the worst-case scenario in fusion and non-fused implants, and (2) what are the key features that should be included in the mechanical testing to address the most important complications observed in vivo.

Based on our study, a unique rationale (specific for GRs) is needed 251 to define a well-designed benchtop testing protocol for these implants, allowing us to better understand the underlying reasons for the observed failure modes. Key features that should be included in the mechanical testing are as follows:

- *Axial/transverse connectors*

The configuration of axial connectors has been identified as an important contributing factor to rod breakage and slippage in TGR implants by biomechanical [12, 57, 58] and clinical [10, 28, 35, 36, 60] studies. Several retrieval investigations have shown that in most fractured rods, cracks initiate at the locations where they interconnect with other components such as screws, axial or transverse connectors, or even external surgical tools during repetitive surgeries [28, 61]. Hence, from a mechanical perspective and due to the connector's stress rising effect, these connectors should be present in mechanical testing. Although there is a controversy in the literature with respect to the effect of crosslinks on growing rod breakage, based on several clinical investigations, the presence of these transverse connectors reduces rod fatigue life. [10, 28, 36, 58] Although they do not necessarily change the location of failure [37, 58],they should be considered in the mechanical testing.

The two modifications of ASTM-F1717 by Hill et al. [58] and Foltz et al. [57] were able to consider the effect of axial/transverse connectors in GR evaluation. However, the presence of these connectors alone in the mechanical setup is not adequate to address the complications arising from these

Table 4 Comparison between construct with long tandem (LT), side-by-side connector (SBS)

	SBS			LT		
	FE	Experiment	Fe-exp/exp (%)	FE	Experiment	Fe-exp/exp (%)
Initial Displacement (mm)	2.72	2.48	10.01	2.76	2.85	3.26
Stiffness (N/mm)	61.67	59.68	3.33	77.22	78.85	2.07
Yield load (N)	595.95	623.30	4.39	761.13	838.84	9.26

Compared to SBS, the LT model showed higher stiffness and yield load. The FE predictions were 352 in 10% within the experimental range

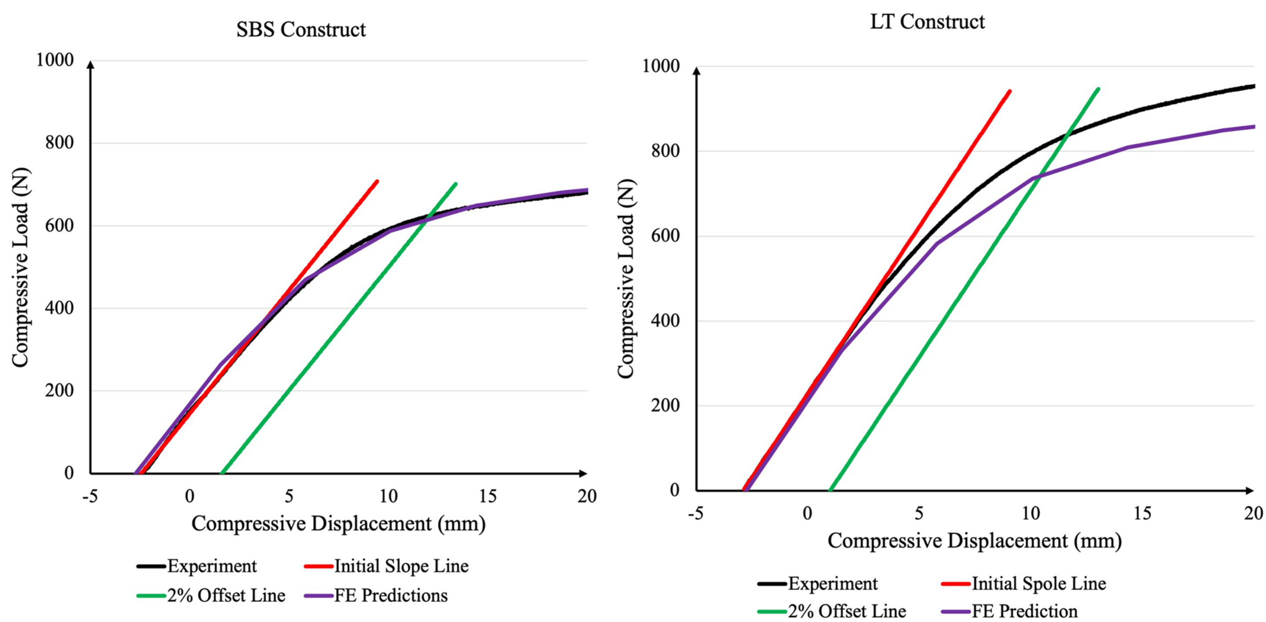

Fig. 4 Compressive load–displacement curves for construct with side-by-side (SBS) and long tandem (LT) connectors. The LT model demonstrated higher stiffness and yield load compared to the SBS. The FE predictions showed a good agreement with the experimental data

components. The diverse fracture locations in the literature show that the combined effect of axial connectors with other features such as distraction and growth seem to be responsible for complications observed in vivo.

- *Simulation of distraction*

Clinical studies have shown that one of the most important sources of complications in growing rod constructs is repeated lengthening and distraction surgeries [6, 37, 47–49]. With each lengthening procedure, the rod's length increases, and higher bending moment is induced on these implants which will increase loading on the construct. Thus, with a larger increase in the rod's length, higher chances of rod breakage are expected, and a suitable protocol, can help us optimize the force magnitude or frequency of rod lengthening.

In standardizing distraction force, it is important to consider the effect of corrections made during index surgery which might influence the risk of failure. During index surgery, with a relatively small distraction force, large displacement is achieved. However, as the patient grows, the increased stiffness of the spine due to skeletal maturity requires higher distraction forces for less lengthening [62]. Since the main lengthening is obtained in the first 3–4 years after index surgery, the amount of correction achieved in the index surgery affect the constructs' failure incidences [62]. Thus, by finding the stiffness corresponding to the pediatric spine in early stages of treatment, we can mimic the worst-case scenario experienced by growing rods.

In the most recently proposed protocol by the authors, a modification of ASTM-F1717 was introduced [12–14]. We hypothesized that distraction induces relatively high stresses on the growing rods (during repetitive scoliosis surgeries,) and contributes to a higher incidence of failures. To simulate distraction, we used anterior elements corresponding to the

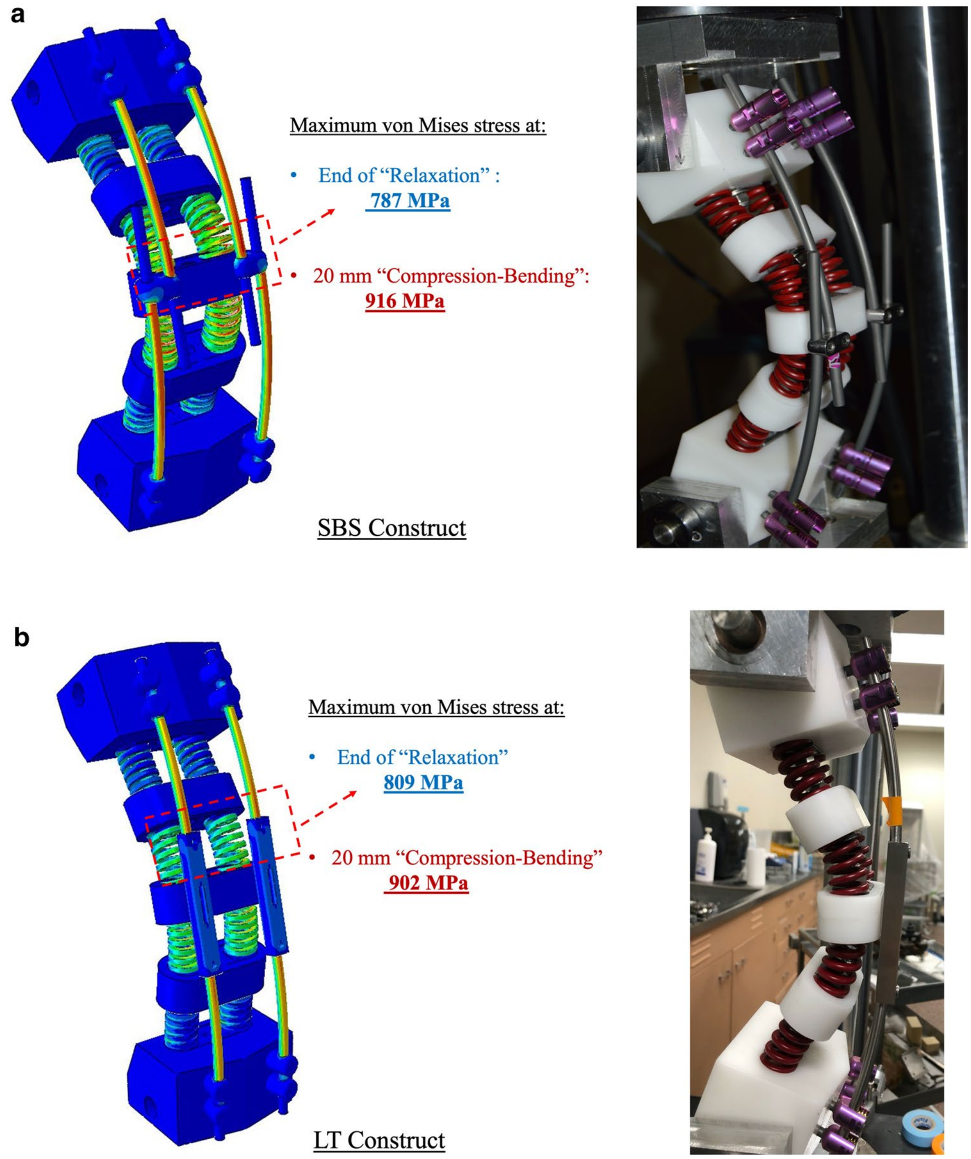

Fig. 5 von Mises stresses (MPa) obtained from FE analysis as well as the pictures for the corresponding construct obtained from in vitro analysis. For each construct, the maximum von Mises stresses were reported at the end of relaxation and at 20 mm compression bending. Due to the higher stiffness, the LT construct showed higher von Mises stresses at the end of relaxation however lesser von Mises stresses at 20 mm compression bending. Both critical stress locations were observed at the distraction site

pediatric spine [12–14]. In the proposed protocol, various physiological parameters could be investigated including number of levels (FSUs), spring constants, and different distraction forces [10, 37].

Results from our mechanical testing confirmed that distraction caused an additional compressive load and bending moment on the growing rods. Moreover, locking of the rods to the axial connectors produced stresses at the distraction site prior to compression bending, which increased the overall stresses adjacent to this location. These pre-existing stresses were higher in the model with long tandem connectors compared to the SBS construct (Fig. 5). Moreover, the FE predictions were fairly accurate in predicting the mechanical behavior of growing rod constructs and could be used as a viable and cost-effective alternative for evaluation of distraction-based growing rods.

Once this model is validated, one can investigate the effect of other anatomical features such as $T1$-$S1$ growth or scoliosis curvature which are not possible in the mechanical testing setup. The FE models can be used as a complementing technique to benchtop tests and together they can lead to a robust prediction of the contributing factors to the in vivo failure. Since only one episode of distraction was performed, both rods were unlocked simultaneously and from the unloaded position. Thus, the proposed protocol is unable to consider the resting load prior to distraction surgeries. However, in real life and as a result of the spine's soft tissues, the first rod is lengthened and locked in place. Hence, the second rod experience may much lower resting pressure [62].

- *Contoured rods*

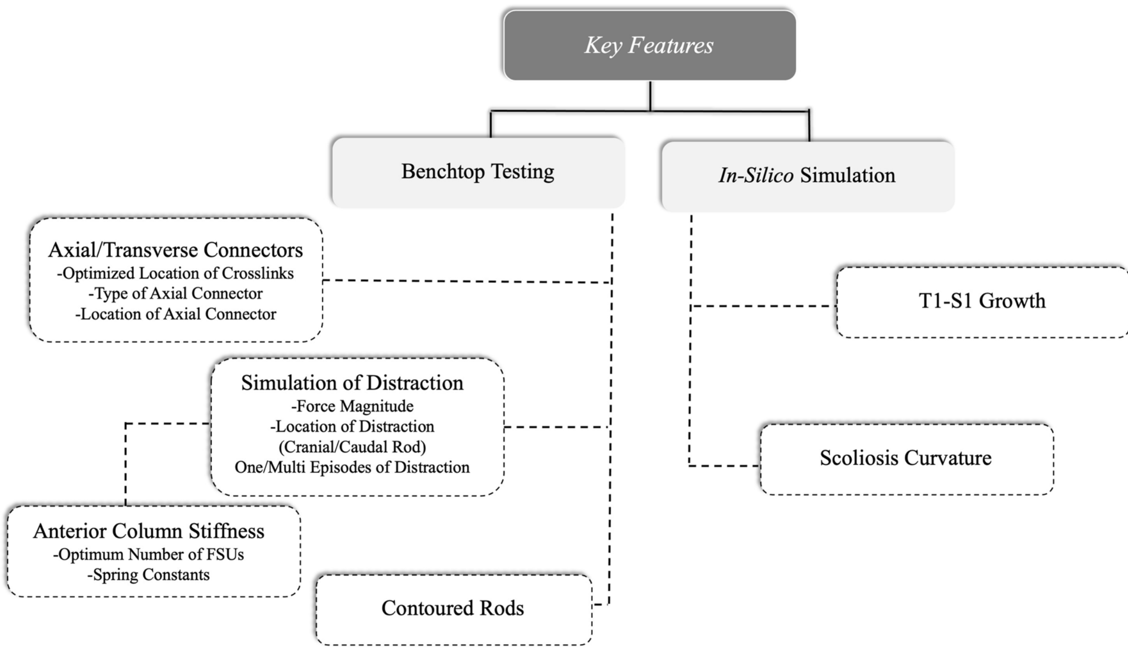

Fig. 6 Two-way joint approach presented in this study. Understanding the combined effect of these key features on distraction-based GRs is essential to improve their biomechanical performances

The last feature which should be included in experimental setups is to contour the rods prior to mechanical testing. During the initial implantation procedure, surgeons manually contour the growing rods to achieve a better sagittal alignment [63]. However, authors have shown that contouring the rods manually reduces their mechanical performance as a result of notch effects [63, 64] and increases the chances of rod fracture. Recently, Shaw et al. showed that compared to manually contoured rods, pre-contouring results in a greater plastic deformation and lower corrective forces [63].

In order to address all issues that are currently observed in growing rods, we propose a joint approach of using a suitable benchtop testing protocol and in silico finite element analysis (Fig. 6). The proposed testing protocol can evaluate the growing rods under a physiological loading scenario and by considering various parameters such as axial/transverse connectors, the number of levels and spring constant, contoured rods, and distraction force magnitude. The in silico analyses, on the other hand, will be validated and used to consider other anatomical features which are not possible in the mechanical testing (like growth and scoliosis curvature). This specific approach can increase our understanding of the implant-related contributing factors to the observed failures and could lead to improvements in current designs, benefiting both patients and clinicians. Moreover, future studies can extend the benchtop testing protocol presented herein to accommodate other surgical techniques used for EOS patients (such as the growth-guidance systems or flexible anterior/anterolateral vertebral tethers). However, it is undeniable that even this two-way approach is associated with limitations; for instance, it is unable to consider the effect of subcutaneous versus submuscular placement of growing rods.

Conclusion

Our literature search indicated that the current guidelines are not able to address the combined effect of anatomical/structural factors in evaluating GRs. By means of the two-way approach proposed herein, the underlying reasons for the observed failure modes would be better understood. The benchtop testing set up used in this study would serve as a good starting point for modifications to an ASTM test standard that is clinically relevant for the evaluation of growing rods.

Appendix

See Table 5.

Table 5 In vitro and in vivo animal studies on the distraction-based growing rods. TGR, MCGR, and SMA represent traditional growing rods, magnetically controlled growing rods, and shape memory alloy

In vitro and in vivo animal studies	Instrumentation technique	Number of levels	Loading condition	Specimen information		Spine's curvature	Main findings
Quick et al. [15]	TGR	7 (T10-L1)	Axial rotation: 4Nm Distraction: No	6	Skeletally immature English white large pigs (16–22 weeks old)	No	The use of semi-rigid rods showed similar vertebral stiffness in axial rotation compared to un-instrumented intact spine
Bylski-Austrow et al. [16, 17]	TGR	13 (T1–T13)	Lateral Bending: ± 5 NM Flexion Extension: ± 5 NM Distraction: No	6	Skeletally immature domestic swine (Yorkshire cross pigs) (10–14 weeks old)	No	The use of PEEK rods, increase the stiffness compared to metal rods while decrease the stiffness compared to the intact spine
Chen et al. [18]	A novel self-adaptive unidirectional ratchet growing rods, free movable growing rods, & standard rods	T2-T9	Lateral Bending: ±5Nm Flexion Extension: ±5Nm Distraction: No	6	Skeletally mature pigs	No	They validated the new ratchet growing rods
		–	Axial tensile force to extend the rods for 24 mm	3	New Zealand white rabbits	No	
Chen et al. [19]	Novel growing rod system and traditional growing rods	T6-7 to L2-3	Distraction: 4 weeks interval for a total period of 12 weeks Then animals were harvested, and the spine's stiffness was obtained manually	12	Immature swine (10 weeks old)	No	They validated a new growing rod device which was effective in preserving the spinal growth
Mahar et al. [20]	Traditional rods with varying foundation techniques (hook, screw, etc.) with and without crosslinks	Single motion segments (from T3–T4 to L5–L6)	Axial pullout applied to the constructs (Four screws/hooks + 2 rods)	8	Immature porcine spine (12 weeks old)	No	Four pedicle screws in two adjacent segments seemed to provide the strongest foundation
Yilmaz [23]	Growing rods	T12-L1 & L4–L5	Distraction: 1-month interval, 1 cm distraction For a three-total number of lengthening (one index and two distraction surgery)	12	Immature domestic pigs (10 weeks old)	No	Vertebral bodies continue growing under distraction force

Table 5 (continued)

In vitro and in vivo animal studies	Instrumentation technique	Number of levels	Loading condition	Specimen information		Spine's curvature	Main findings
Demirkiran et al [22]	TGR	T11-L4	Distraction: 1-month interval, 5 mm distraction for a three-total number of lengthening	13 TGR (7) Fusion (3) no surgery (3)	Piglets (10–14 weeks old)	No	They studied the effect of multiple distractions on the disk/facet joint degeneration/fusion No significant changes observed for the disk/facet joint degeneration/fusion in growing rod group Distraction forces were found to simulate epiphyseal growth of the spine
Yilgor et al. [21]	Growing rod in the fusion less group	T11-L4	Distraction: 1-month interval, 5 mm distraction for a three-total number of lengthening 5 kg loading was applied and side bending and flexion–extension were measured at the adjacent levels	13	Piglets (10–14 weeks old)	No	They studied the effect of fusionless instrumentation versus instrumented fusion on the motions of the adjacent segments Use of fusionless techniques reduce the degeneration at the adjacent segments compared to fusion They found that the fusionless technique has a closer biomechanical property to normal spine even after several lengthening procedures
Akbarnia et al. [24]	MCGR	T6–T8 to L4–L5	Distraction: One-week interval, 7 mm distraction, for a 7-total number of lengthening	8	Immature Yucatan mini pigs (7 months old)	No	They observed that MCGR could provide 80% of predicted spinal growth

Table 5 (continued)

In vitro and in vivo animal studies	Instrumentation technique	Number of levels	Loading condition	Specimen information		Spine's curvature	Main findings
Takaso et al. [26]	MCGR	N/A	Distraction: 1 cm distraction at 3, 6, 9, and 12 weeks after initial instrumentation	5	Beagle dogs	Scoliotic deformity (average 25°)	They used a specific technique to create scoliosis curvature: After spine was instrumented and initially lengthened, device was shortened to create a scoliotic curvature,
Eroglu et al. [25]	MCGR	T6-L2	MRI waves were applied for 45 min and temperature change as well as rod's length were measured	3	Merino breed sheep (mean age of 12 months)	No	The investigated the MRI compatibility of MCGR and observed no adverse effect on the rod's lengthening when they were exposed to MR wave
Hou et al. [27]	Electromagnetically controlled shape memory alloy (SMA)	L2–L6	Animals were implanted with SMA rods (from L2–L6) with help of sublaminar wires Induction heating was applied to the rods post-operatively (every 4 days for 1 month) SMA rods were removed after 1 month and animals were monitored for 4 months after rods removal for any adverse reaction	5	New Zealand white rabbits (2 months old)	Kyphotic deformity (45°)	Gradual contactless spinal deformation was achieved A proof-of-concept was obtained which provided evidence that SMA rods could be used to correct kyphotic/scoliotic deformity remotely

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Declarations

Conflict of interest The authors declared that they have no conflict of interest.

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