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RESEARCH ARTICLE

Novel use of telescoping growth rods in treatment of early onset scoliosis: An *in vivo* and *in vitro* study in a porcine model

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Introduction: Treatment of early-onset scoliosis (EOS) can be difficult. Various forms of growing rods exist to correct deformity while delaying definitive spinal fusion. The disadvantage of traditional growing rods is need for repeated surgical lengthening procedures. Telescoping growth rods (TelGR) are a prototype new, guided growth technology with a rod mechanism that allows spontaneous longitudinal growth over time without manual lengthening. We hypothesized that the TelGR system will permit unrestricted growth with limited complications through 12 weeks *in vivo*, and that the range of motion (RoM) in each of three directions and stiffness of the TelGR system would not be significantly different than the rigid rod system *in vitro*.

Materials and Methods: *In vivo*: Six immature pigs were surgically implanted with TelGR with cephalad fixation at T6-7 and caudal fixation at T14-L1. Radiographs of the involved vertebral segments were measured postoperatively and after 12 weeks.

In vitro: A robotic testing system was utilized for flexibility tests in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) of eight immature porcine specimens (T3-T15). Testing was performed on both dual rigid rods and bilateral TelGR with instrumentation at T4-5 and T13-14.

Results: *In vivo*: Over the 12-week period, the rod length of the TelGR increased an average of 65 mm.

In vitro: TelGR demonstrated significantly increased motion in LB and AR RoM compared with rigid rods. No difference was noted in FE RoM.

Discussion: The *in vivo* results in this study showed expected skeletal growth with spines instrumented with TelGR. *In vitro* findings of increased RoM in AR and LB suggest that the TelGR system may be less rigid than traditional growing rods. Treatment with TelGR might, if proven efficacious in the clinical setting, decrease the need for repeated surgical intervention compared with traditional growing rods. This study adds to the limited body of biomechanical evidence examining guided growth technology.

KEYWORDS
biomechanics, early onset scoliosis, growing rods, guided growth techniques

1 | INTRODUCTION

Early-onset spinal deformities present multiple challenges to the surgeon. Treatment of early-onset scoliosis (EOS) is associated with a wide spectrum of complications secondary to the large potential for growth. The clinician must balance stabilizing or correcting the curve with allowing continued longitudinal growth. Typically, the goal in management of EOS is to stabilize the curve in an effort to prevent progression until the patient reaches skeletal maturity. Spinal bracing has been advocated for treatment of scoliosis in some cases[1,2]. However, bracing has been shown to be less effective in young children, especially in those with congenital or neuromuscular scoliosis[3]. Similarly, casting techniques have been advocated for treatment of EOS[4]. While this modality is noninvasive, it still requires anesthesia for

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Nicholas Vaudreuil and Jingbo Xue are designated as co-first authors manipulation during cast molding. Additionally, casts need to be changed every three to six months.

Rapidly progressing curves, severe curves, or failure of nonoperative treatment modalities are indications for surgical intervention for EOS. Rigid spinal fusion is not ideal for young children since they have adverse effects on the growth of thorax, lungs, and spine. Traditional rigid spinal fusions performed before the age of eight years can lead to growth abnormalities and pulmonary issues including a decrease in lung volume, which is a common limiting factor in the life expectancy of children with EOS[5]. Subsequently, instrumentation without fusion was developed for patients with significant potential for growth in order to cease curve progression and delay the definitive fusion procedure until spinal growth is sufficient[6–8].

Techniques for guided growth or instrumentation without fusion were developed to avoid the complications associated with rigid spinal fusion by allowing more physiological growth. Constructs such as vertical expandable prosthetic titanium ribs (VEPTR)[9,10] or traditional growing rod systems with single growing rods[11] or dual growing rods,[12,13] are treatment options. The disadvantage to these treatments is the requirement for repeat invasive surgical intervention as the spine grows, as well as association with high complication rates[14]. Infection, unintended autofusion, and implant failure are the most common complications and are influenced by the number of lengthening procedures performed[15–17]. Repetitive interventions are also associated with various socioeconomic disadvantages[18]. Constructs, such as the Shilla growth guidance system and magnetically controlled growing rods, allow lengthening in a noninvasive manner[19,20]. However, to our knowledge there are no *in vitro* biomechanical studies examining these guided growth techniques.

The concept of noninvasive spine lengthening after scoliosis correction without the need for iterative surgeries has long been appealing. The current study evaluated the use of a novel hybrid guided growth system with "Telescoping Growth Rods" (TelGR). This system theoretically provides an improved technique by allowing skeletal growth while maintaining alignment and preventing curve progression all without necessitating multiple trips to the operating room or clinic visits for magnetic lengthenings. We hypothesized that the TelGR system will permit unrestricted growth with limited complications through 12 weeks *in vivo*, and that the range of motion (RoM) in each of three directions and stiffness of the TelGR system would not be significantly different than the rigid rod system *in vitro*.

2 | MATERIALS AND METHODS

2.1 | TelGR design

The purpose of the TelGR's design is to utilize an internal mechanism that allows for one-way translation. This keeps the rod from shortening relative to the longest position it has achieved at any postoperative time point. The TelGR system includes five parts: a caudal rod, a locking bolt, a tapered sleeve, a cephalad rod, and conventional pedicle screws (Figure 1A). The locking bolt and sleeve slide onto the proximal caudal rod. The rods were made from titanium. The sleeve was designed to permit lengthening and prevent shortening with a tapered cone shape, which is oriented with the wider portion facing proximally (Figure 1B). Both components can move freely on the cephalad rod prior to connecting to the caudal rod fixture. After locking the screw in place, the locking nut pinches down on the tapered sleeve. In doing so, the connected rods allow axial lengthening but not shortening of the TelGR. The telescoping mechanism of the TelGR is positioned centrally at the presumed apex of the curve and was appropriately sized, including adequate overlap, to accommodate growth in the *in vivo* study. The most proximal and distal portions of the TelGR rods are captured by conventional pedicle screws and are locked in place using set screws.

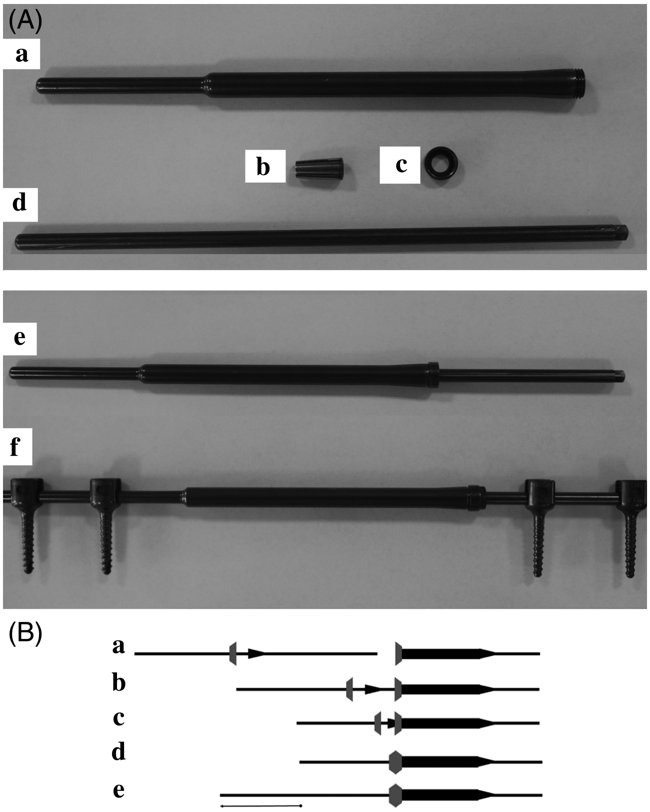

FIGURE 1 (A) Telescoping growth rod (TelGR) image showing: (a) caudal rod, (b) tapered sleeve, (c) locking bolt, (d) cephalad rod, (e) fully assembled TelGR, (f) fully assembled TelGR locked in place with pedicle screws. (B) Schematic of sliding mechanism of telescoping growth rod (TelGR): (a) assembled cephalad rod with tapered sleeve in place (left) and caudal rod with hollow core facing cephalad rod, (b) cephalad rod sliding into place within hollow core of caudal rod, (c) further sliding of cephalad rod into hollow core until sliding sleeve engages, (d) locking mechanism of cephalad rod over the sliding sleeve and onto the caudal rod, (e) postoperative time after device elongation

2.2 | *In vivo* study

This study involved animal subjects. Prior to study initiation, institutional approval was obtained. All procedures on animals followed the guidelines for humane treatment set by the Association of Laboratory Animal Sciences and the Center for Laboratory Animal Sciences at our institution. Six skeletally immature 3-month-old English Large White pigs underwent posterior spinal surgery. Induction of the anesthesia was achieved via 0.1 mg/kg intramuscular xylazine and 13 mg/kg ketamine via a bolus injection. Anesthesia was maintained with 1% to 3% volatilized isoflurane until the end of the procedure.

All animals were positioned in the prone position on the operating table. Two separate 5 cm skin incisions were made at the cephalad and caudal thoracic spine along the midline posteriorly. After the fascial incision, subperiosteal exposure was obtained along both sides of the spinous processes. The rods were contoured to attempt to match the native thoracic kyphosis of the animals. The TelGR were inserted and passed under the fascia through the two short posterior incisions. The cephalad end of the rods were connected to bilateral pedicle screws at the T6 and T7 vertebral levels (four total screws). The caudal ends of the TelGR were connected to bilateral pedicle screws at the T14, T15, and L1 vertebral levels (six total screws).

Postoperatively, all the animals were housed in individual cages with no additional restraint. The experimental protocol was to evaluate the animals over a 12-week study period after surgical implantation. This duration was chosen based upon the typical onset of puberty in immature pigs, five to six months of age on average, and previous biomechanics literature involving *in vivo* animal spines[21,22]. Radiographs of the involved vertebral segments were obtained postoperatively and again after 12 weeks. At the end of the 12-week study period, all animals were sacrificed through accepted techniques (intravenous pentobarbital 200 mg/kg). Spinal growth was calculated by measuring longitudinal change in rod length using the radiographic distance between the T7 screws and the T14 screws and comparing the change over the 12-week period. The measured bilateral rod growing lengths were averaged.

2.3 | *In vitro* study

Eight fresh frozen immature thoracic spines from English Large White pigs were used in this study. The specimens were obtained from a local distributor and ranged in age from 18 to 26 weeks with a weight range of 110 to 120 kg. Each specimen was harvested and frozen immediately postmortem and kept frozen at −20°C until required for testing. Prior to preparation, specimens were placed in 4°C cold room for 24 hours to adequately thaw. Dissection and instrumentation were performed at room temperature. Paraspinal musculature was debrided while preserving posterior 5 cm of ribs, transverse processes, all joint articulations, and ligaments[23]. Specimens were dissected to isolate the levels between the cephalad (T3) and caudal most (T15) levels. Instrumentation was performed bilaterally with pedicle screws (5.0 mm width and 30-45 mm length, polyaxial, titanium; DePuy Spine, Raynham, Massachusetts) at levels T4-5 and T13-14. Pedicle screw instrumentation was performed by a single spine surgeon via the standard technique. After preparation, specimens were returned to 4°C cold room for 12 hours prior to testing to maintain thawed status while not causing desiccation.

On the day of testing, spines were attached to a robotic testing system (Staubli RX90; Staubli, Duncan, South Carolina). Fixation of the specimen was achieved by placing three screws into the vertebral body, two in standard intrapedicle placement, and one into the anterior vertebral body. These screws were then attached to custom fixtures proximally and distally. The caudal vertebral body at T15 was attached to the rigid base of the table and the cephalad vertebral body at T3 was attached to the end-effector of the robot manipulator with an onboard six-axis load cell (JR3 Inc., Woodland, California) (Figure 2). The six-axis load cell had a 0-90 N/0-11 Nm detection range with 0.27 N/0.0023 Nm resolution. Custom software (MATLAB, Mathworks Inc., Natick, Massachusetts) was used to control the robot using adaptive displacement control, as described previously[24]. A pure moment target of 4.0 Nm was used for flexion-extension (FE), lateral bending (LB), and axial rotation (AR); this moment target was chosen based on previously validated parameters for porcine thoracic spines[25,26]. Three-dimensional segmental spinal kinematic measurements were tracked using an optical tracking system (VICON 460; VICON, Oxford, UK) with five cameras as previously described[27]. Reflective markers were attached to vertebral bodies of T4, T9, and T14 for detection by the tracking system. Euler angles and displacements were calculated for each step in the motion path by taking the root-mean square error over 10 cycles.

Dual rigid rods (cobalt chrome, 5.5 mm diameter, DePuy Spine) were contoured and placed in the pedicle screws bilaterally and were secured with set screws. After testing, the rigid rods were removed. TelGR rods were constructed as described above, then were manually contoured at the rod locations between the mechanism and anchor points to straighten the coronal plane and AR curves, while trying to fit the normal sagittal profile (Figure 2). Three consecutive cycles were performed for each loading condition. The first two cycles served as preconditioning cycles and the third cycle was used for analysis. Three-dimensional segmental spinal kinematics were analyzed from the optical tracking. The primary outcome was RoM. RoM was defined as the total arc of motion (in degrees) between full positive and negative directions at achieved moment targets. RoM was recorded in the desired plane of interest for each test. The system permitted coupled motions in other planes as the off-axis force and moment minimization allows primary moment to build up about while updating the center-of-rotation.

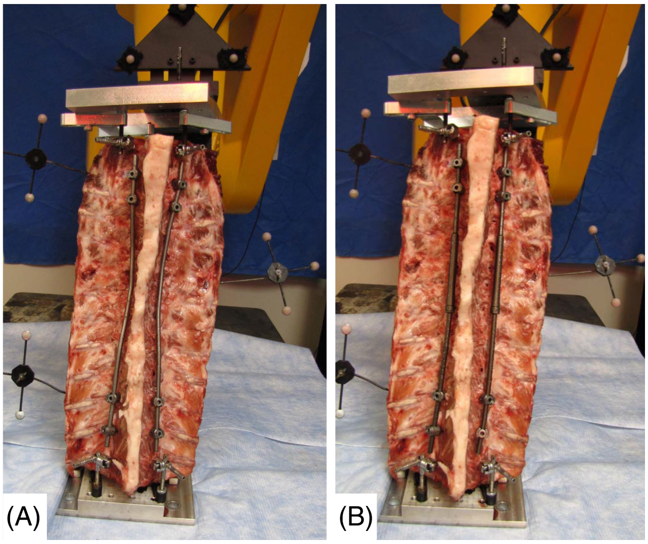

FIGURE 2 Porcine spine specimens mounted onto robot: (A) fixed rod and (B) telescoping growth rod (TelGR)

Neutral zone (NZ) and elastic zone (EZ) parameters were determined by fitting a double sigmoidal function to moment-rotation data to define the NZ as the high compliance region demarcated by extrema of the second derivative, as described by Smit et al[28]. NZ and EZ stiffness were defined as the inverse of the slope of a linear fit of the function in the NZ and EZ, respectively.

Computations were performed using Excel (Microsoft, Redmond, Washington) and statistical analyses were performed using SPSS (v 21.0, IBM, Armonk, New York). After confirming normality, comparisons between groups in the *in vitro* study were performed using Student's *t* tests with Bonferroni correction, with significance set at $P < 0.05$. Data were reported as mean ± 95% confidence interval.

3 | RESULTS

3.1 | *In vivo* study

All animals survived the initial surgery. One animal suffered an intraoperative spinal cord injury and was rendered paraplegic. The animal was subsequently sacrificed three days postoperatively. No other postoperative complications with the animals were noted. The remainder of the animals survived the 12-week study period.

At study conclusion no instrumentation complications were noted with TelGR rods. Instrumentation was not removed after sacrifice. No gross side-to-side differences between rods were noted. Over the 12-week period, all animals had radiographic evidence of growth with lengthening of the TelGR at an average of 65 mm (range 56-87 mm) (Figure 3). No shortening of the rods was noted.

3.2 | *In vitro* study

As shown in the representative moment rotation curves (Figure 4), the specimen when instrumented with the TelGR rods and the fixed rods both exhibited classic S-shaped curves with defined NZs, EZs, and hysteresis. Considering the RoM values calculated from these curves, the TelGR demonstrated significantly increased motion in two of the three motions tested, LB and AR (Figure 5). No differences in TelGR rod length were noted between pre- and post-testing. The FE RoM of the specimen when instrumented with the TelGR rods was 5.1 ± 1.8°, and 5.4 ± 1.3° when instrumented with the fixed rods. The difference in FE RoM between the TelGR and fixed rods was not significantly different ($P = 0.690$). LB RoM of the specimen instrumented with TelGR rods was 4.7 ± 1.8°, compared to 2.8 ± 1.5° with the fixed rods, which is a significant increase ($P = 0.005$). AR RoM of the specimen instrumented with TelGR rods was 24.8 ± 13.5°, compared to 9.5 ± 6.0° with the fixed rods, which is a significant increase ($P = 0.015$).

The EZ stiffness of the specimen instrumented with the TelGR rods was lower than when instrumented with the fixed rods (Figure 6A). The FE fixed rods EZ stiffness was 0.53 ± 0.07 Nm/degree and FE TelGR EZ stiffness was 0.52 ± 0.07 Nm/degree and this difference was not significantly different ($P = 0.384$). The LB-fixed rods EZ stiffness was 0.53 ± 0.03 Nm/degree and FE TelGR EZ stiffness was 0.45 ± 0.04 Nm/degree and this difference was significantly different ($P = 0.000$). The AR-fixed rods EZ stiffness was 0.28 ± 0.02 Nm/degree and FE TelGR EZ stiffness was 0.18 ± 0.01 Nm/degree and this difference was significantly different ($P = 0.002$).

Similarly, the NZ stiffness of the specimen instrumented with the TelGR rods was lower than when instrumented with the fixed rods for FE and AR (Figure 6B). The FE-fixed rods EZ stiffness was 0.16 ± 0.08 Nm/degree and FE TelGR EZ stiffness was 0.16 ± 0.04 Nm/degree and this difference was not significantly different ($P = 0.914$). The LB-fixed rods EZ stiffness was 0.06 ± 0.02 Nm/degree and FE TelGR EZ stiffness was 0.10 ± 0.06 Nm/degree and this difference was not significantly

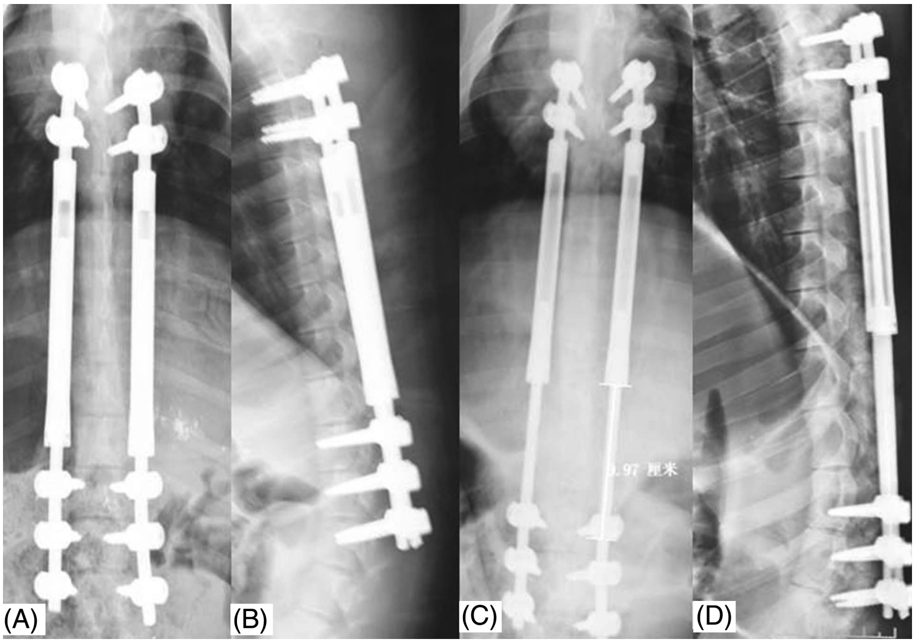

FIGURE 3 Posterior-anterior and lateral spine radiographs of *in vivo* porcine specimens instrumented with telescoping growth rod (TelGR) system at immediate postoperative time point (A and B) and at 12 weeks postoperatively (C and D)

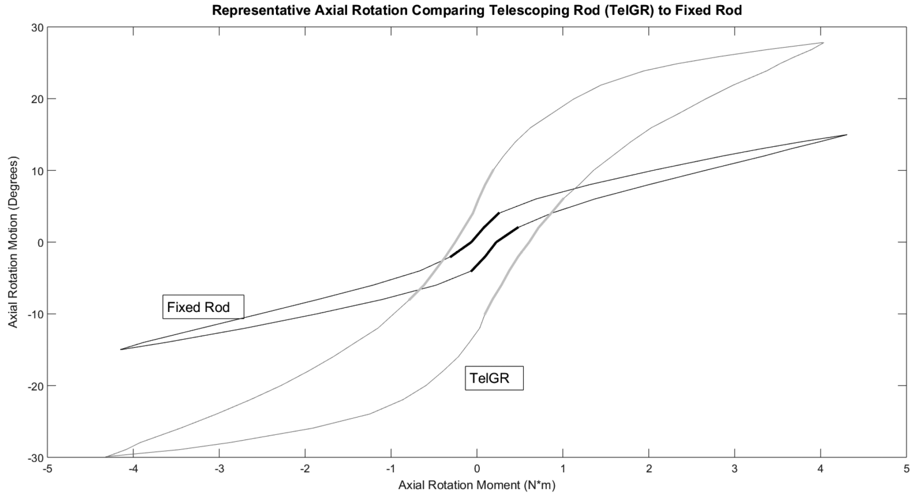

FIGURE 4 Representative moment rotation s-shaped curves from n = 1 specimen depicting the raw data utilized to extract the range of motion (RoM), elastic zone (EZ) stiffness, and neutral zone (NZ) stiffness parameters. The NZ region is highlighted in bold and the hysteresis present is also visible

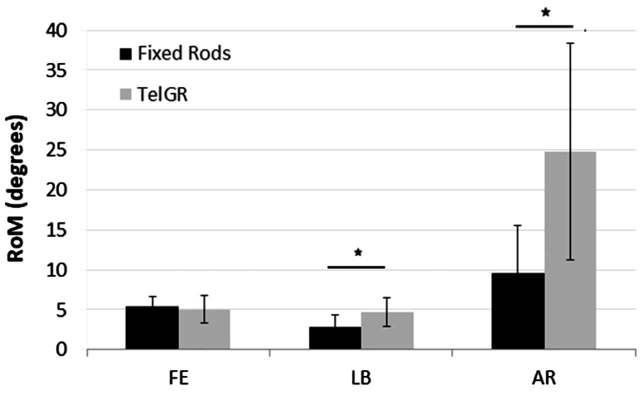

FIGURE 5 Range of motion (RoM) in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) motions for the telescoping growth rod (TelGR) and fixed rod constructs. Significant differences between groups ($P < 0.05$) designated with asterisk (*)

different ($P = 0.207$). The AR-fixed rods EZ stiffness was 0.08 ± 0.01 Nm/degree and FE TelGR EZ stiffness was 0.05 ± 0.01 Nm/degree and this difference was significantly different ($P = 0.003$).

Testing was nondestructive in all specimens over all test parameters. Complications such as instrumentation failure, fractures, or soft tissue injuries were not present at completion of testing. No gross screw loosening was noted at time of instrumentation removal at completion of study.

4 | DISCUSSION

The current study tested the biomechanics of a TelGR system with the potential to treat EOS. The TelGR system allows axial growth through a telescopic sleeve and is expected that the magnitude of the constraint is lower in AR than the fixed rod design. The *in vivo* results showed expected skeletal growth with spines instrumented with TelGR over the study period. *In vitro* findings of increased RoM and decreased EZ stiffness in AR and LB suggest that the TelGR system is less rigid, decreasing the theoretical risk of unintended autofusion. However, the decreased rigidity in the instrumentation, due to the added degrees of freedom of the motion device, may alternatively predispose it to complications such as breaking or bending of the rods

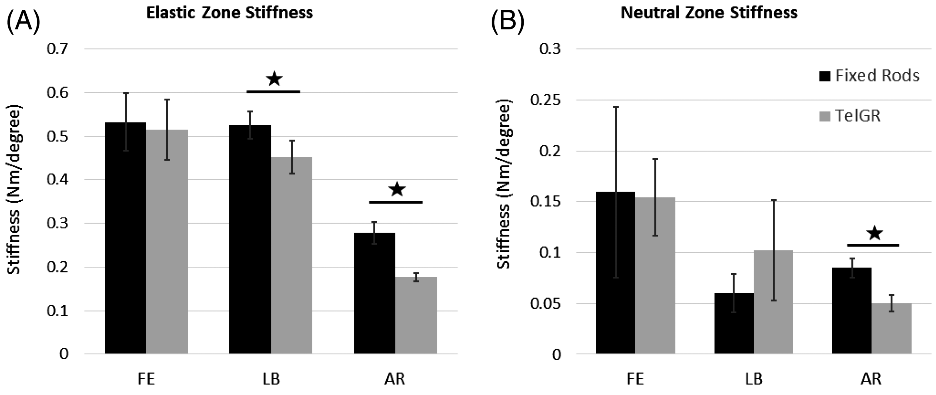

FIGURE 6 (A) Elastic zone stiffness in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) motions for the telescoping growth rod (TelGR) and fixed rod constructs, (B) neutral zone stiffness in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) motions for the TelGR and fixed rod constructs

or screw loosening. While motion preservation is highly advocated in many modern devices, this increased AR may represent a potential for difficulty with controlling rotation at the apex of the deformity. An additional consideration is that the dual rigid rods in the comparison group, which were made of the standard colbalt-chromium (Co-Cr), may represent a substantially more rigid construct with different biomechanical properties then a traditional growing rod system where a number of connectors and multiple smaller rods may be utilized. Utilizing a traditional growing rod system instead of rigid rods would perhaps have given us a more clinically relevant comparison; the decision was made to use rigid rods to minimize variability and maximize reproducibility, and provide a baseline comparison of likely greatest possible differences.

Using a hybrid guided growth system with self-lengthening rods such as TelGR theoretically avoids many of the issues seen with traditional growing rods by stabilizing the curve with instrumentation while allowing skeletal growth without iterative trips to the operating room. The TelGR system evaluated in this study shares many similarities with both the Shilla system and magnetically controlled growing rods, however, key differences should be discussed. The Shilla system utilizes proximal and distal fixation with pedicle screws that allow sliding of the rods; additionally they utilize apical fixation with locked pedicle screws. The key difference between TelGR and Shilla is that TelGR does not require instrumentation of the curve apex. The Shilla system has been shown to have positive clinical outcomes[19,29] and succeeds in decreasing the rate of repeat surgical interventions as compared to the traditional dual growing rod system[30]. At long-term follow-up of 5 years, however, a high rate of complications was noted with the Shilla system including infection, alignment issues, and implant-related issues[31]. No *in vitro* biomechanical testing of the Shilla system is currently available in the literature.

Magnetically controlled rods are implanted in a similar manner as the TelGR, utilizing locked pedicles screws as anchors proximally and distally without any intercalary anchors. Both systems utilize the rod itself for continual lengthening without iterative surgeries. The key difference between TelGR and magnetically controlled rods is that TelGR allows continued natural guided growth without the need for periodic activation of the lengthening mechanism via magnetism. Magnetic growing rods have shown positive clinical outcomes in the short term[20]. They have been shown to have equivocal curve correction and growth as compared to traditional dual growing rods, but with a dramatic decrease in total surgeries required over time[32]. They are also associated with a potential for great cost savings over the long-term treatment of EOS[33]. However, magnetic growing rods do not completely avoid the need for repeat invasive surgical procedures, due to an increased risk of instrumentation-related complications[34]. No biomechanical studies exist examining magnetically controlled rods.

Similar to the guided growth systems mentioned above, the TelGR system would also provide the benefit of avoiding repetitive lengthening procedures under general anesthesia while allowing longitudinal growth and curve correction over time. The TelGR device would also similarly be susceptible to inherent risks of guided growth systems such as implant-related complications and surgical site infection. The new features of the TelGR system compared to currently available technology are the potential for limited invasiveness in implantation, circumventing the need for apical fixation, providing a system of axial lengthening without shortening, and avoiding the need for magnetic activation of rod lengthening.

This study contains several key limitations. The first limitation is our modest sample size, though an n = 8 is fairly common for this type of biomechanical study[35]. A second limitation was the use of a porcine model to simulate a human scoliotic spine. Previous studies have shown pigs and humans have similar growth rate and vertebral anatomy in height, width, and pedicle diameter, especially in the mid to lower thoracic spine[36,37]. However, the porcine spines utilized were nondeformed and thus may represent substantially different biomechanical properties from spines with scoliotic curves[38]. Additionally, the upright posture of humans, and especially those with large progressive spine curvatures, can have markedly different biomechanical properties due to axial compression from standing. This makes extrapolation to clinical application more difficult. Without the ability to test TelGR instrumentation in a scoliotic curve, conclusive statements about their biomechanical profile *in vivo* cannot be made.

Additionally, the use of a 4 Nm moment target for testing may represent another potential limitation as this may vary from the physiologic forces seen in EOS. However, this value has been used previously in porcine biomechanical testing[25,26]. Our *in vitro* testing algorithm was to test the rigid rod construct before the TelGR construct; this process was chosen for ease of reproducibility but the failure to randomize may be a confounder to our results.

This study did not fully assess the mechanical properties of the TelGR rods, including strength to failure, expandability, and binding possibilities. Similar systems such as Shilla frequently encounter these issues,[31] including rod breakage. Future studies would take into consideration testing to rod failure. Increasing the number of cycles performed during cyclic loading would allow observations to be made on whether a similar phenomena occurs in TelGR as in Shilla in regards to rod breakage. Additional mechanical studies on the TelGR rods, including their changes in mechanical strength with rod lengthening and bending or contouring, and their potential for any inadvertent rod shortening despite the design, are necessary for future preclinical evaluation. The potential difference in wear between the titanium TelGR and Co-Cr fixed rod systems is also the subject of future studies.

The length of this study was likely inadequate to assess the risk of periprosthetic infection; this risk may be clinically higher given the possibility for metallosis due to tissue and serosanguineous fluid ingression into the relatively large hollow core of the caudal component along with motion of the components. Additionally, in the current TelGR design description, it is recommended that the telescoping mechanism be placed at the apex of the curve. This was chosen to maximize the strength of the construct at the apex of the curve, which is where the majority of the corrective forces will be seen in the coronal plane. This theoretically provides more mechanical strength to an area that is at highest risk of hardware failure. However, this may also lead to difficulty with placing the device, due to large or rigid curves, and additionally may cause issues with sagittal plane adjacent segment kyphosis due to the rigidity of the construct. The hope would be that contouring of the cranial and caudal aspects, on either side of the actual telescoping mechanism, of the TelGR construct would allow for placement of the device and minimizing the rigidity of the proximal thoracic connection of the device. This study was an early biomechanical evaluation of a new concept for treatment of EOS. To our knowledge, this is the first study to evaluate both *in vivo* and *in vitro* biomechanical profile of a construct for instrumentation without fusion for EOS.

The *in vivo* portion of the study demonstrated that the TelGR system allowed longitudinal growth of the immature porcine spine over time. The *in vitro* results found that the TelGR had a unique biomechanical profile compared with fixed rigid rods. Findings of increased RoM in AR and LB suggest that the TelGR may be less rigid and thus may be less prone to the development of autofusion but more susceptible to instrumentation failure. While the TelGR system may be a viable system for treatment of EOS, questions remain. Clinical studies are necessary to corroborate our biomechanical findings. Additionally, future studies are needed to compare the TelGR system with other commercially available systems for instrumentation without fusion such as the Shilla or the magnetically controlled growing rods.

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

Author contributions

Descriptions of individual author contributions are listed below. Each author has read and approved the final submitted manuscript. N.V. done data acquisition, data interpretation, manuscript drafting, manuscript editing, statistical analysis. J.X. done conception and design, data acquisition, data interpretation, manuscript drafting. R.R. done data acquisition, data interpretation, manuscript editing, statistical analysis. R.T. done data acquisition, data interpretation, manuscript editing, statistical analysis. M.D. done data interpretation, manuscript drafting, manuscript editing, statistical analysis. W.W. done conception and design, obtaining funding, supervision, manuscript editing. K.B. done data interpretation, conception and design, obtaining funding, manuscript editing, supervision, critical revisions.

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