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A biomechanical investigation of dual growing rods used for

fusionless scoliosis correction

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Abstract

Background: The use of dual growing rods is a fusionless surgical approach to the treatment of early onset scoliosis (EOS), which aims of harness potential growth in order to correct spinal deformity. The purpose of this study was to compare the *in-vitro* biomechanical response of two different dual rod designs under axial rotation loading.

Methods: Six porcine spines were dissected into seven level thoracolumbar multi-segmental units. Each specimen was mounted and tested in a biaxial Instron machine, undergoing nondestructive left/right axial rotation to peak moments of 4Nm at a constant rotation rate of 8deg.s⁻¹. A motion tracking system (Optotrak) measured 3D displacements of individual vertebrae. Each spine was tested in an un-instrumented state first and then with appropriately sized semi-constrained growing rods and 'rigid' rods in alternating sequence. Range of motion, neutral zone size and stiffness were calculated from the moment-rotation curves and intervertebral ranges of motion were calculated from Optotrak data.

Findings: Irrespective of test sequence, rigid rods showed significantly reduction of total rotation across all instrumented levels (with increased stiffness) whilst semi-constrained rods exhibited similar rotation behavior to the un-instrumented (P<0.05). An 11% and 8% increase in stiffness for left and right axial rotation respectively and 15% reduction in total range of motion was recorded with dual rigid rods compared with semi-constrained rods.

Interpretation: Based on these findings, the semi-constrained growing rods do not increase axial rotation stiffness compared with un-instrumented spines. This is thought to provide a more physiological environment for the growing spine compared to dual rigid rod constructs.

Keywords - Scoliosis, Fusionless correction, Growing rod, *In vitro*, Porcine, Biomechanical, Range of motion, Stiffness, Intervertebral.

1. Introduction

Current treatment options for managing scoliosis are limited to observation, bracing and surgery. Although there are some scoliotic curves in the very young that do not progress, others can deteriorate significantly despite non-operative management. It is these progressive curves that impose significant health risks for developing children and present dilemmas for the treating surgeon. Adolescents who fail bracing or conservative treatment options can obtain acceptable deformity correction through instrumented spinal fusions, however in the younger child or early onset scoliosis (EOS) group, fusing the spine for deformity correction can consequently limit chest wall and lung growth (Karol et al., 2008).

Normal growth rate slows significantly between the ages of 5 to 10 years, having peaked in the first five years of age during which the thoracolumbar spine has already achieved up to two thirds of its adult height (Dimeglio, 2001). Surgical treatment of EOS without arthrodesis, usually occurs in this period and has the potential to allow continued spinal growth until maturity, without the deleterious outcomes of spinal fusion (Akbarnia and Marks, 2000). Known as 'fusionless' growth modulation, Skaggs (Skaggs et al., 2010) divided these procedures into two categories consisting of either distraction (tension based) or growth guiding procedures. By harnessing the patient's potential growth, correction can be achieved through initial instrumentation and redirection, so as to achieve near maximal potential spinal length and maintain spinal motion.

Harrington originally reported the technique of growing rods in 1962 (Harrington, 1962), which was further developed by Moe et al. through the use of "subcutaneous rods", with rod lengthenings at set time intervals (Moe et al., 1984). These early constructs typically used only a single rod. Akbarnia et al. incorporated a dual / bilateral rod modification to the original design, with several studies reporting superior deformity correction and maintenance with dual rods (Akbarnia et al., 2008, Akbarnia et al., 2005, Thompson et al.,

2005). Subsequent improvements were made and rods redesigned. Luque (Pratt et al., 1999) introduced a growth guidance system utilizing sublaminar wires along several spinous processes, a technique which removed the need for repeated lengthenings. This construct has been reported to achieve 90% of expected spinal growth across the instrumented spine (Ouellet, 2011). However, design concerns still exist, even with the modernized Lugue trolley. These include the inability to control for rotational deformity and the occurrence of spontaneous fusion, possibly due to subperiosteal exposure during initial instrumentation and inferred from the loss of deformity correction in documented cases (Luque and Cardoso, 1977. Moe et al., 1984, Mardjetko et al., 1992, Ouellet, 2011). An alternative and more recent growing rod design is the semi-constrained growing rod (Medtronic, Memphis TN, USA). It improves on previous designs with the preservation of soft tissues through submuscular instrumentation and the ability to enable telescopic lengthening via interconnecting male and female components. Similar to the Shilla technique (McCarthy et al., 2010), semi-constrained growing rods enable growth, but do not eliminate the need for repeated lengthenings entirely. It is believed that this new design of growing rod is more physiological in function during corrective growth management of patients with EOS, when compared with conventional rigid rods. Unlike rigid rods which have been shown to constrain rotation (Fricka et al., 2002), the primary rationale for design of the semi-constrained growing rod was to reduce the degree of rotational constraint, allowing axial rotation similar to un-instrumented spines. Little is known, however, about the biomechanical effect of semi-constrained growing rods during axial rotation and in particular the effect on the commonly instrumented thoracolumbar region.

The aim of this study was to measure the response in axial rotation of the newer semi-constrained growing rods (Figure 1, next page) in comparison with rigid rods. We hypothesize that in axial rotation the overall multi segment unit (MSU) construct would be

significantly less stiff with the semi-constrained growing rods then with the rigid rods. We also hypothesized that with the semi-constrained growing rods, the intervertebral rotations at each level of instrumentation would be similar to those of the un-instrumented MSU's, while the rigid rods would significantly reduce these intervertebral rotations.



Figure 1. Semi-constrained growing rod and telescopic sleeve component.

2. Methods

2.1 Specimen preparation and surgical procedure

Six fresh frozen immature spines from English Large White pigs were used in this study. The specimens were obtained from a local abattoir and ranged in age from 16 to 22 weeks with a weight range of 40-60kg. Each specimen was harvested and frozen immediately following euthanasia and kept frozen at minus 20 °C until required for testing. To exclude any anatomical anomalies, each specimen underwent pre-test CT scanning. There was no radiological evidence of any spinal pathology in the spines tested. Each vertebral column was sectioned once thawed to room temperature (a process which entailed 12-15 h at 4 °C and a further 1-2 h at room temperature), to give a multi-segment unit (MSU), consisting of seven vertebrae and six intervertebral discs, from thoracic vertebrae ten through to fifteen and the first lumbar vertebrae (T10-15 and L1). All musculature was carefully removed leaving the ligaments intact, including preservation of the costotransverse and costovertebral articulations with approximately 3cm of ribs on either side (Oda et al., 1996). The zygapophysial joints were localised and exposed at the second and sixth vertebral level of the MSU. Two 4.5mm x 25mm multi-axial screws (Medtronic CD Horizon ® Legacy ™, Sofamor Danek Memphis, TN, USA) were inserted into the pedicles at levels 2 and 6 of the MSU, using standard instruments and surgical procedure. All instrumentation and testing were performed by one person. Note that, the terms 'instrumented' and 'un-instrumented' are used to refer to the presence or absence of growing rods secured by break-off set screws. Accurate positioning of the multi-axial screws was confirmed on post-test CT scanning. During instrumentation outlined below, levels 1 and 7 of the MSU were always left intact and embedded in stainless steel cups using polymethylmethacrylate (PMMA) with three screws driven into the upper and lower end vertebrae to optimize fixation of the cephalic and caudal vertebrae in the PMMA. All zygagpophysial joints were kept free from PMMA fixation. Specimens were then wrapped

in plastic bags and stored again at minus 20 °C. After a minimum of 48h the MUS specimens were re-thawed (using the same process as described above) to room temperature for a second time prior to testing. Rigid body markers containing three LEDs were attached to each spinous process of the MSU for detection by the optical tracking system and separate markers were kept aside and attached to the rod construct during testing. During MSU preparation and testing the spines were kept moist by being wrapped in saline soaked gauzes. All tests were performed at room temperature (21 °C).

2.2 Experimental test setup

A custom built dynamic spine testing apparatus mounted in an Instron MTS 8874 biaxial testing machine (Instron, Norwood, MA, USA) was used to test each specimen. Pilot studies showed that the response of the un-instrumented spine was not affected following repeated testing with rigid rods attached. There being less than 7% increase in the range of motion for the whole specimen. Each test as outlined in Table 1 consisted of five fully reversed cycles of non-destructive axial rotation to maximum moments of 4Nm at a constant rotation rate of 8deg.s⁻¹.

SPECIMEN	Test 1	Test 2	Test 3	Test 4	Test 5
1	UN - IN	GR	UN - IN	RIGID	UN - IN
2	UN - IN	RIGID	UN - IN	GR	UN - IN
3	UN - IN	GR	UN - IN	RIGID	UN - IN
4	UN - IN	RIGID	UN - IN	GR	UN - IN
5	UN - IN	GR	UN - IN	RIGID	UN - IN
6	UN - IN	RIGID	UN - IN	GR	UN - IN

(UN-IN; un-instrumented. RIGID; dual rigid rods. GR; dual semi-constrained growing rods)

Table 1. The order of testing for each specimen, comprised of 5 continuous cycles at a constant 8deg.s^{-1} to maximum moment of ± 4 Nm. There was a 5 minute rest between each test.

These limits were tested during pilot studies confirming that they provided nondestructive full ranges of motion of the MSU with repeatable results. Data from the fifth cycle of each test was analysed with the first four cycles used to precondition each specimen test. Between each test there was 5 min of rest to allow for any viscoelastic recovery. The most superior cup was secured to the Instron and constrained to move only in axial rotation whilst the inferior cup was allowed to translate freely in the horizontal plane by an x-y plate. No axial preload was applied and the vertical z-axis was fixed during testing so that no translation could occur in this direction.

Prior to testing, pedicle screws for securing the rods to the spines were inserted at levels two and six. These un-instrumented spines were then tested. Following this, pairs of each rod construct (5.5mm titanium alloy, Medtronic, Memphis TN, USA) were secured to the pedicle screws with four break-off 4.5mm set screws (Medtronic CD Horizon ® Legacy ™) using appropriate surgical equipment, schematically shown in Figure 2.



Figure 2. Schematic diagram of the two dual rod constructs tested. A) Dual rigid rods and B)Dual semiconstrained growing rods.

Set-screws were reused and re-inserted using a torque limiting screw driver and counter torque spanner. Each rod construct was appropriately sized for the MSU including adequate overlap of the telescopic sleeve of the semi-constrained growing rod (Supplementary 1). Note that when instrumented with either dual semi-constrained or dual rigid rods, the first and seventh level of the MSU construct were left as intact intervertebral joints to be secured by PMMA in the stainless steel cups. Tests were then conducted according to the sequence shown in Table 1.

A 3D optical system (Optotrak 3020, Northern Digital Inc. Waterloo ON, Canada) was used to measure the intervertebral motion for each test. Rigid body markers were attached to each spinous process and the rod components as shown in Figure 3. Prior to testing, a global co-ordinate system was created to align the axis of the Optotrak (accuracy 0.1°) (Grant, 2012) with the mounted spine specimen.



Figure 3. A rigid body Optotrak marker frame was attached onto each component of one semiconstrained growing rod (left–A arrows) where as a single rigid body marker frame was attached onto one of the rigid rods (right–B arrow).

A single vertebral anatomical landmark point was also digitized at the mid anterior position of each vertebral body to enable a local co-ordinate system for each vertebral level to be defined. Additional points in positive x and positive y orientation were generated from this digitized landmark. Using the local co-ordinate system with respect to the global one, Optotrak data was processed with a custom designed MATBLA program (2013a, MathWorks Inc., Natick MA, USA)

2.3 Data analysis

Moment-rotation curves were generated using the fifth loading cycle from each test. The neutral zone (NZ) was calculated using a similar method to previous studies (Clarke et al., 2007, Wilke et al., 1997), taking the range of movement where the loading curves during left and right axial rotation crossed the x-axis at 0Nm moment. This enabled a centralized point to be obtained and the maximum range of axial rotation (ROM) to be calculated for both left (positive) and right (negative) rotation, achieved between the set positive and negative 4Nm moment limits. Stiffness during maximum applied moment in each loading direction was calculated as the slope between +2 and +3Nm and -2 and -3Nm (or between 60 and 80% of the maximum applied moment in each direction) since this part of the curve showed approximately linear characteristics. After checking for normality of the test data, paired t-tests were used to compare the stiffness of the rod constructs. A significance level of *P* <0.05 was considered statistically significant.

The intervertebral rotations of each vertebral level with respect to the level beneath were calculated from Optotrak data using MATLAB. To compare the intervertebral ROM of the two dual rod implants, Optotrak results were normalized to the average of the un-instrumented tests. Statistical significance was assessed using two tailed t-tests with significance when P<0.05.

1 3. Results

2 3.1 Biomechanical growing rod comparison

3 A representative moment versus axial rotation graph is shown in Figure 4. All test 4 sequences for Specimen 2 are shown together on the same graph for comparison. The 5 maximal change in total ROM between test 5 and 1 (Table 1) from all un-instrumented 6 MSU spine testing was 6.7% (mean 4.7, range 1.7 to 6.7%), suggesting that there were 7 minimal changes in the stiffness of the un-instrumented spine itself throughout the testing 8 protocol. Normalizing the implant (dual semi-constrained and rigid rods) ROM and stiffness 9 test results against the mean of all un-instrumented ROM and stiffness values for each of 10 the six specimens, produced the graphs shown in Figures 5, and 6 respectively. Paired t-11 test analysis showed significant differences between the two types of rods tested, 12 irrespective of test order.



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Figure 4. Moment versus axial rotation curves from the 5th cycle of each test sequence from Specimen 2 tested to ±4Nm at 8deg.s⁻¹. UN–un-instrumented, GR–dual semi-constrained growing rods and RIGID–dual rigid rods. Also refer to Table 1 for test order. The three tests with the specimen un-instrumented are almost identical.

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The rigid rods significantly reduced the total ROM compared to semi-constrained growing rods (P<0.05) and resulted in a significantly stiffer spine for both left (11.1%) and right (8.1%) axial rotation (P<0.05). During testing z-axis loads reached maximum values

- 23 of 70N during un-instrumented spine and semi-constrained growing rods testing and 110N
- 24 when rigid rods were tested. There were no extreme outliers in recorded data.





Figure 5. The average normalized total ROM for the six specimens during rod testing. (The bars represent \pm SD). Each specimen was normalized with respect to its average un-instrumented ROM.

Figure 6. The average normalized stiffness for the six specimens with instrumented rods during left and right axial rotation (±SD). Each specimen was normalized with respect to its average un-instrumented stiffness.

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27 3.2 Intervertebral joint ROM

28 Each individual intervertebral ROM from Specimen 2, derived from Optotrak data is 29 shown in Figure 7. When rigid rods were attached, the instrumented levels (levels 2 to 6) 30 showed reduced intervertebral ROM, whereas with semi-constrained growing rods the 31 instrumented levels showed similar intervertebral ROM to un-instrumented tests. Post-test 32 CT scanning revealed changes in facet joint orientation below the second level with similar 33 endplate and intervertebral disc height throughout the seven level MSU construct. This 34 might account for the large intervertebral ROM seen in the most superior two levels. 35 However, this was not a study investigating the morphological difference across spinal 36 levels. The intervertebral ROM for each level of each spine when instrumented was 37 normalized to the value of its averaged un-instrumented value. Figure 8 shows combined 38 normalized intervertebral ROM for both the dual rigid rod and semi-constrained growing 39 rod constructs. A 30-50% difference was noted between the instrumented levels of 2-3 to 40 5-6, when comparing dual semi-constrained growing rods with dual rigid rods.



Figure 7. Intervertebral ROM from Optotrak data of Specimen 2 during un-instrumented testing A). Average of the three un-instrumented tests (±SD) as per Table 1 B). The dual rigid rod test with rods secured at levels 2 and 6 C). Dual semi-constrained rod testing with fixation at level 2 and 6 of the seven level construct.





4. Discussion

This study compared the biomechanics of two designs of growing rods currently used to manage early onset scoliosis (EOS). The new semi-constrained allows axial growth through the telescopic sleeve and is expected to provide less constraint on axial rotation than the rigid rod design. It is because of this aspect that the current study focused on axial rotation only to further understand the semi-constrained growing rod.

Constrained moment-controlled axial rotation testing was used in this study for two reasons; firstly to ensure that each vertebra within the multi-segment unit (MSU) experienced a consistent maximum moment about the primary axis. Secondly, a fixed rotation rate prevented the possibility of test speed changing during attainment of the set maximum moment. Constrained (constant rotation rate) testing is not well documented in the published literature, with few published articles clearly outlining the strain rate used during spinal testing (Lysack et al., 2000, Dickey and Kerr, 2003, Clarke et al., 2007, Hongo et al., 2008). The constant rotation rate of 8deg.s⁻¹ was chosen to give test durations of several seconds per load–unload cycle and also to respect upper limits on the data acquisition rate of the testing system.

Since the pilot studies showed reproducible moment versus axial rotation curves during repeated dual rod analysis (and also between the initial un-instrumented state and after rod removal) there was support for test-retest of specimens. Accordingly, the protocol used consisted of alternating instrumented rod construct tests between un-instrumented tests (as described in Table 1). The small changes (less than 7%) in ROM found between newly mounted and re-tested un-instrumented specimens could be attributed to repeated specimen cycling or tissue property changes, although these were not statistically significant changes.

The findings from this biomechanical investigation indicate that semi-constrained growing rods enable a similar degree of axial rotation to un-instrumented porcine spines

under a constant rate of rotation to a set maximum moment. When comparing all tested specimens it was found that, irrespective of test sequence order, dual rigid rods significantly decreased total ROM (14.9% decrease) and increased stiffness during both left (11.1%) and right (8.0%) axial rotation when compared with semi-constrained growing rods. The results for the rigid rods showed greater variation than the un-instrumented and semi-constrained rod tests. This suggests that these rods while producing a stiffer construct also had a more variable affect then the semi-constrained rods. Optotrak analysis of intervertebral motions showed that irrespective of test sequence order, dual rigid rods significantly reduced the intervertebral ROM across every instrumented level within the seven level MSU spine, compared with semi-constrained growing rods. By contrast, no significant difference was found when comparing semi-constrained growing rod tests with un-instrumented tests, across all specimens.

As with most *in-vitro* studies there is a scarcity of pediatric cadaveric tissue. For spinal research the pig is claimed to be the most representative of the human spine (McLain et al., 2002, Smit, 2002, Bozkus et al., 2005, Kouwenhoven et al., 2007, Busscher et al., 2010a). Immature porcine vertebrae have been assessed in several anatomical measurement (Bozkus et al., 2005, Busscher et al., 2010a, McLain et al., 2002) and biomechanical analysis papers (Busscher et al., 2010b, Dickey and Kerr, 2003, Hongo et al., 2008, Yazici et al., 2006, Kouwenhoven et al., 2007). Mature porcine spines assessed by Dath et al., in an anatomical paper, demonstrated larger differences when compared to human vertebrae. The paper by McLain et al. is the only paper that directly compared the immature and mature porcine spine with human vertebrae, stating that the immature porcine spine most closely models the human specimen across several anatomical parameters. This includes the shape of the end plates, spinal canal, pedicle size, facet orientation (in particular the lower thoracic porcine vertebrae with facet orientation similar to human lumbar vertebrae in the sagittal plane) and contour (McLain et al., 2002, Bozkus

et al., 2005, Dath et al., 2007, Busscher et al., 2010a, Busscher et al., 2010b). Hence, for this study mid and lower thoracic immature porcine spinal segments were used for biomechanical testing because they represented the most commonly instrumented levels and most prevalent apex location for EOS curves.

Intervertebral disc height was noted on CT scanning to be consistently similar throughout the seven-level mid to lower thoracic MSU construct tested in the current study. A finding reflected in several comparative anatomical porcine spine papers which also note similar ratio of disc height to vertebral body size when comparing mid to lower thoracic porcine spines with human spines (Bozkus et al., 2005, Busscher et al., 2010a). Because of these factors, disc height is unlikely to have had an effect on the findings of stiffness difference between the tested rod designs. Despite known differences in bone density between pig and human vertebrae the aim of the current study was not to examine construct failure nor screw pull-out.

Earlier research by Busscher et al. supports the use of multi-segment porcine spines as a valid in-vitro model to human spine in-vitro testing (Busscher et al., 2010b). The current study achieved similar physiological ranges of axial rotation to those found by Busscher et al. without damaging the porcine segment between mid to lower thoracic levels. Although double the maximum moment used by Busscher et al., moments below 4Nm were found to not reach the same physiological range of motion and in a pilot study 4Nm was shown to achieve comparable ranges of motion without any evidence of damage to spinal segments. Optotrak data from the current study show significantly larger values of axial rotation in the superior levels of the MSU construct (which included mid-thoracic vertebrae) compared with lower levels of the construct (which included lower thoracic and upper lumbar vertebrae). This finding is similar to the results published by Busscher et al., 2010b). Busscher et al. also concluded that because of facet joint morphology, the lower

thoracic porcine spine is similar to the human lumbar spine. The substantial difference in axial rotation stiffness and recorded intervertebral rotations between porcine intervertebral joints in this study can be potentially explained in terms of differences in zygapophysial joint orientation between the upper two (T10 and T11) and the lower remaining levels (T12 through to T15 and L1) in the MSUs. Although measurement of the anatomy of these joints was beyond the scope of this study, anatomical changes were noted when analyzing post-test CT scans of each MSU spine. This included zygapophysial joint alignment being in a more sagittal orientation in the lower porcine thoracic region, which is similar to joint orientation and anatomy of human lumbar vertebrae noted in previous research (Dath et al., 2007, Busscher et al., 2009, Busscher et al., 2010b).

The choice of specimen length and number of vertebral levels depends on the experimental question being asked and the type of implants being investigated. There is gathering consensus regarding the use of multi-segment spine units for testing of implants which include at least one free functional spinal unit on either side of the construct length so as to evaluate spinal devices (Goel et al., 1995, Wilke et al., 1996, Wilke et al., 1998, Lysack et al., 2000, Goel et al., 2006). The most appropriate size for investigating the modified semi-constrained growing rod in this study was found from pilot studies to be a seven level vertebrae model, allowing adequate telescopic sleeve overlap. The semi-constrained growing rods were modified by shortening the telescopic sleeve and solid rod inferiorly so as to appropriately fit the seven level MSU. Longer constructs were not tested and were beyond the scope of this study. If a MSU vertebral construct shorter than seven levels were used, there would not be adequate overlap at the telescopic sleeve component of the semi-constrained growing rod component, which might result in altered rod function.

A wide variety of compressive preloads applied prior and throughout biomechanical spine testing have been documented in the literature from 100 to over 4000N (Janervic et

al., 1991, Dickey and Kerr, 2003, Hongo et al., 2008, Busscher et al., 2009, Busscher et al., 2010b, Busscher et al., 2011). It is difficult to know what is the appropriate preload with such varied values in previous research. However because the z-axis was held during testing there were small tensile forces recorded acting throughout each test, which returned close to zero during the 5minute rest period between tests. Several experiments have shown that compressive preloads increase the stiffness of spinal segments attributed to both intervertebral discs and facet geometry (Janervic et al., 1991, Stokes et al., 2002, Dickey and Kerr, 2003, Tawackoli et al., 2004). The small z-axis tensile forces (<110N) recorded during testing are unlikely to have contributed to the differences in stiffness between the two tested rod constructs because similar and consistently small tensile forces were recorded during each test and between each rod constructs.

There are several limitations of this study. As mentioned earlier human cadaveric specimens are difficult to obtain and the results of this study should be interpreted with this in mind. Absolute pediatric biomechanical parameters are not established in this study but rather a representative model of the human spine (Bozkus et al., 2005, Busscher et al., 2010a, McLain et al., 2002) tested with two different growing rod designs. Of note is that identical test protocols were applied to both the intact and instrumented spines. Therefore relative changes in spinal motion under the applied primary moment have been measured under consistent conditions enabling comparison between the two difference (axial rotation) between the two tested rod constructs. We acknowledge that the performance of the semi-constrained growing rod under other loading conditions would also be of interest and anticipate future studies building upon the findings in this key first study.

5. Conclusion

This is the first study to our knowledge that evaluates the in-vitro biomechanics of the semi-constrained growing rod. Our data shows that semi-constrained growing rods do not increase axial rotation stiffness compared with un-instrumented porcine spines nor do they reduce the range of rotation compared with un-instrumented spines. With the potential to improve growth guidance through the telescopic sleeve component, semi-constrained growing rods provide a promising fusionless construct to manage EOS.

Supplementary 1. Schematic diagram of the two dual rod constructs A) Dual rigid rods and B) Dual semi constrained growing rods.



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