Flexible Growing Rods: Polymer Rod Constructs Provide Stability to Skeletally Immature Spines

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Introduction: Early onset scoliosis (EOS), a spine deformity in children under 5 years of age, has much greater morbidity and mortality rates than adolescent or adult scoliosis due to concomitant chest wall deformities that restrict pulmonary development. Current treatment methods for EOS include casting, bracing, rib expansion instrumentation, and spine distraction instrumentation. Conservative treatments such as bracing or casting are not always effective. Surgical treatments such as rib expansion and growing rod instrumentation typically require multiple surgeries and involve many complications. Most growing rods are lengthened at 6 month intervals. Complications include infection, rod breakage, screw pull-out, joint fusion, and junctional kyphosis. Constructs that lengthen magnetically are under investigation. Although these would reduce repeated surgeries, they are relatively stiff and bulky, and the elongating section cannot be contoured. Physicians have suggested that a more flexible growing rod construct might result in a more flexible spine with fewer surgical complications.

Polymer rods have been previously investigated for use in adult, short segment, lumbar spine surgery.²,³ The material, polyetheretherketone (PEEK), is flexible in bending, and so would presumably allow for greater range of motion (ROM) than the current metal rods of cobalt-chrome alloy (CoCr) or titanium (Ti). However, it is not known whether PEEK rods of the length and diameter required for growing rods have sufficient stability to withstand physiological loading ranges and allow for distraction and curve correction,⁴ even in very young children with low physiological loads. Therefore, the purpose of this study was to determine changes to the biomechanical properties of skeletally immature spines after implantation of simulated growing rod constructs with a range of clinically relevant structural properties. The hypothesis was that ROM of spines instrumented with PEEK rods would be both much greater than metal rods and significantly lower than uninstrumented controls. It was further expected, however, that ROM with PEEK rods would remain closer to controls than to metal rod constructs, and so be unlikely to provide sufficient stability.

Methods: In vitro biomechanical tests were conducted on six skeletally immature porcine thoracic spines (domestic pigs, 2-4 months of age, body mass 35-40 kg). Spines were sectioned to include vertebrae T1-T13, with posterior ligaments carefully preserved. Specimens were tested before and after instrumentation. Paired pedicle screws were inserted into T3 and T4 at the proximal end, and T10 and T11 at the distal end. An open intervertebral joint remained above and below the surgical construct. Specimens were tested 1) before dual rod insertion, followed by 2) PEEK rods (6.25 mm dia, n=6), 3) Ti rods (4 mm dia, n=6), or 4) CoCr rods (5 mm dia, n=4). Tests were conducted in lateral bending (LB) and flexion-extension (FE) by applying moments with a minimum magnitude of ±5 Nm using a materials test system with cable-pulley attachments. Five cycles were applied, the fourth was analyzed. Vertebral positions at each level were measured from arrays of markers (LEDs) using high definition video, and rotations were calculated using a custom program (MATLAB). Range of motion was defined as the maximum side-to-side rotation for each level. ROM for the treated region was determined by adding all ROMs at each instrumented level (T3-T11). Differences in ROM by treatment were determined by two-tailed paired t-tests and Bonferroni correction based on four primary comparisons: PEEK vs control and PEEK vs CoCr, in LB and FE.

Results: In lateral bending, ROM after each treatment was lower than uninstrumented control, including treatment with PEEK rods, at each of the instrumented levels. PEEK rods allowed greater ROM than both Ti or CoCr rods at every instrumented level. ROM was greater at the proximal and distal uninstrumented segments of instrumented specimens compared to control. Mean ROM at proximal and distal uninstrumented levels was lower for PEEK than for Ti and CoCr.

In flexion-extension, ROM after each treatment was lower than uninstrumented control, including treatment with PEEK rods, at each of the instrumented levels. PEEK rods usually allowed greater ROM than Ti or CoCr rods at individual levels, but variability was greater in FE than in LB. Mean ROM at proximal and distal uninstrumented levels was lower for PEEK than for Ti and CoCr. Combining treated levels, in LB, ROM for PEEK rods was 35% of uninstrumented control (p<0.0001) and 270% of ROM of CoCr rods (p<0.05). In FE, ROM for PEEK rods was 27% of uninstrumented control (p<0.005) and 180% of ROM of CoCr rods (p<0.05).

Discussion: The large reduction in ROM after instrumentation with PEEK rods indicated significantly increased spine stability due to the construct. Flexible polymeric growing rod constructs significantly decreased range of motion compared to
uninstrumented controls. ROM with PEEK rods remained significantly greater than ROM with cobalt-chrome alloy rods. The hypothesis that PEEK rod constructs provide insufficient stability for growing rod constructs was not supported, whereas the hypothesis that PEEK rods provide increased flexibility compared with metal rods was supported. Further, smaller increases in ROM at proximal and distal adjacent discs occurred with PEEK compared to the metal rods, which may decrease propensity for junctional kyphosis.

To the investigators’ knowledge, this is the first feasibility study of flexible growing rods in early onset scoliosis. Limitations include in vitro tests on physiologically normal spines from a large quadruped, and intact rods without distraction capability. Further biomechanical tests are needed in buckling and torsion, and biomechanical properties of PEEK in fatigue have not yet been considered. Physiological loads of body weight, activity, and curve correction are not yet well defined. However, results warrant continued investigation into the concept and application of flexible growing rods for early onset scoliosis.

**Significance:** Flexible growing rods may form the basis of an improved treatment option for very young patients with severe spinal deformity. Retaining more spine flexibility may allow for fewer complications, and higher satisfaction for patients, parents, and caregivers.

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Range of Motion for Treated Region

- Control
- PEEK
- Titanium
- CoCr

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Data from the image suggests a comparison of different treatments on range of motion, with CoCr showing the highest increase.

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**Note:** The diagram indicates statistical significance with ***for CoCr and **for Titanium, compared to Control.