Development and evaluation of a low cost minimally invasive growth rod for juvenile scoliotic patients

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INTRODUCTION: Growth rods have been used for the treatment of severe scoliosis in young children. Traditional growth rod (TGR) systems require large incisions for distraction, and may lead to severe complications and morbidities [1]. To account for this a magnetic controlled growth rod (MCGR) system has been developed for non-invasive rod distraction. While these rods address the complications associated with consecutive surgeries in the TGR, they are very expensive for emerging economies and unsuitable for infants [2]. Other issues pertain to distraction difficulties caused by limited distraction forces generated by MCGR [2]. The purpose of this study was to design, and evaluate a low cost growth rod construct (LCC) that will allow surgeons to perform serial distractions with incisions of less than 2 cm.

METHODS: A coaxial mechanical construct (growth rod) with an integrated gear and locking mechanism (equivalent to tandem connector) was designed and evaluated in two steps. Step 1. Mechanical comparison of the construct: a TGR was modeled based on existing growth rod designs currently available on the market. In order to compare the mechanical characteristics of our design versus the predicate design, ASTM F1717 torsion and compression bending tests were simulated using the finite element (FE) methods. Per ASTM F1717 standard, devices were attached to two ultra-high molecular weight polyethylene (UHMWPE) test blocks and assigned titanium alloy material properties (Figure 1). Plastic deformation was considered for all materials. The rod diameter was 5.5 mm. Step 2. Clinical simulation of growth modulation using LCC: An FE model of a scoliotic T1-S1 spine (9 years and weighing 22 kg) integrated with growth modulation was used in this study for further biomechanical analysis of the LCC (Figure 2) [3]. Simulation steps consisted of initial quarter-turn in both gears (for distraction) followed by body weight (BW) application and 6 months of growth. Growth simulation was done as previously published by our group [3].

RESULTS: Step 1: ASTM F1717 compression bending test data showed that compressive bending yield load of the LCC design was 50% higher than the TGR. Compressive bending stiffness was 2.4 times greater in the LCC design (Figure 3). The torsion testing showed 24% higher torsional stiffness in the LCC design compared to the TGR design. Additionally, yield torque for the LCC design was 1.75 times greater than the TGR design (Figure 4). Step 2: The FE scoliotic spine analysis showed that the maximum stress generated on the gears during distraction accompanied with BW application was 144 MPa. The T1-S1 height gain was 7mm in 6 months with no progression of deformity, i.e. Cobb's angle changed very little from 43 degrees pre-op to 41 degrees after 6 months of growth simulation.

DISCUSSION: Based on higher yield load/torque and bending/torsion stiffness for LCC than TGR, this construct performed better in static compression bending and torsion scenarios prescribed by ASTM F1717. Scoliotic spine FE analysis indicated much lower stresses for gears during distraction and growth simulations than compressive yield strength of titanium alloy (1080 MPa). It can be concluded that the LCC design performed equivalent and better than the TGR construct. Therefore, owing to its low cost of production over MCGR and equivalent and better mechanical performance to TGR, it would address the needs of emerging economies for minimally invasive distractions. A provisional patent has been filed for this design [4].

SIGNIFICANCE: This study proposes a low cost growth rod system for the minimally invasive distraction of juvenile (growing) scoliotic patient. The proposed design can be manufactured in less than $500, allowing affordability and state of art care to emerging economies, which TGR and MCGR fails to provide due to its technology and cost, respectively.

REFERENCES: **1)** Bess S, J Bone Joint Surg Am, 2010 **2)** Cheung, JPY et al, J Orthop Surg, 2015 **3)** Agarwal A, Spine J., 2015 **4)** Agarwal A. K, WO2014145470 A2

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IMAGES AND TABLES:

Figure 1. ASTM F1717 constructs
(Low cost construct(left)-Traditional Growth Rod(right))

Figure 2. Low cost construct implanted on a juvenile scoliotic spine FE model

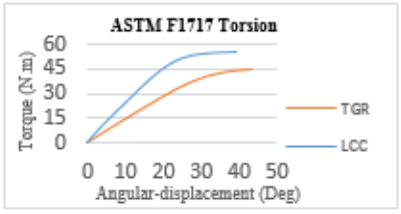

Figure 3. ASTM F1717 Compression test

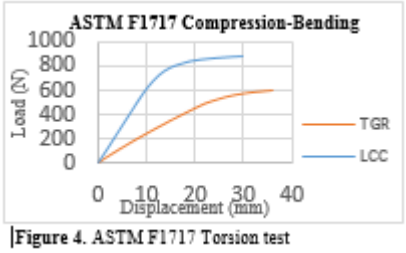

Figure 4. ASTM F1717 Torsion test