INTRODUCTION:
Fusionless scoliosis growth rod systems pose many challenges to bench top biomechanical testing, because the systems do not easily fall into any of the standard implant categories. The vertebrectomy standards that are currently used for evaluation of constructs do not sufficiently evaluate the uniqueness of these systems. The ISO vertebrectomy model uses six 375 N/mm springs for anterior support in a two-level construct. The ASTM vertebrectomy model is a single-level construct, but provides no anterior support. Because of the drawbacks of the published vertebrectomy models, an analogue thoracolumbar (TL) spine model and a hybrid vertebrectomy model were evaluated for the dynamic testing of a growth rod scoliosis system.

The Shilla system, which included bilateral 4.5 mm stainless steel rods, pedicle screws, and set screws. This system was used to evaluate the two potential test methods. The objective of this study was to develop a fatigue test model that could do the following: 1) withstand millions of cycles of fatigue without degradation, 2) evaluate the unique properties of a growth rod system, and 3) have enough modularity to permit different implantation scenarios.

METHODS:
Two different models were developed for the assessment of the Shilla system. The first method entailed the development of a custom bending fixture, which included a frictionless sliding rod system that used the motion of a servo-hydraulic actuator to create pure bending moments on the spine. (Figure 1) An analogue polymeric TL spine was constructed with high durometer intervertebral discs and high tension posterior and anterior longitudinal ligaments. No posterior element, lateral ligaments or facet capsules were represented in this model.

The analogue spine and two cadaveric spines (Mean age 44 ± 0.9 years) were instrumented by an experienced spine surgeon with the Shilla system, which included bilateral 4.5 mm stainless steel rods, pedicle screws, and set screws. From each spine, the most cephalad (T3) and caudal (S1) vertebral bodies were rigidly embedded in a urethane potting compound. Flexion and lateral bending (LB) were evaluated using the custom bending fixture. Load and sliding rod displacement were collected at 5 mm increments of actuator travel. The bending moment on the spine was then calculated and used to determine construct stiffness.

A second model was developed to evaluate the bimodal nature of the Shilla Growth Rod system. Components of ISO 12189 and ASTM F1717-04 were combined to create a dynamic construct. The hybrid model was a single-level construct that possessed three anterior springs (123 N/mm). (Figure 2) The spinal rods were then pre-bent in the sagittal and frontal planes and then forced into the heads of the pedicle screws. This allowed the corrective shear forces of a scoliosis procedure to be represented in this hybrid model.

RESULTS:
The bending model showed that the cadaveric spines were able to reach relatively high moments (10+ Nm), whereas the analogue model attained much lower bending moments (~3 Nm). (Figure 3) The stiffness ratios (intact/instrumented) between the analogue and cadaveric models were equivalent, indicating consistent construct construction; however, the stiffness magnitudes differed by a factor of four.

The initial hybrid construct dynamic compression results demonstrated that the model was able to successfully evaluate the Shilla system by attaining fatigue loads that fall within the range of regular deformity systems.

DISCUSSION:
The plastic analogue model is the most clinically relevant test setup, because the entire Shilla construct can be evaluated in one test. However, there are many inherent problems, the largest being the stiffness differences, as compared to a cadaveric spine model. Without the inclusion of the posterior elements and lateral ligaments, as well as facet capsules, all of the bending force is carried by the disc, creating non-physiologic motion and the inability to attain the required bending moments. Also, the disc supradjacent to the instrumentation began to come unglued during LB, so the analogue model was not able to withstand even a few cycles of bending without degrading.

The hybrid vertebrectomy construct test model was able to accommodate the uniqueness of the Shilla system by providing anterior support and allowing for shear load (corrective forces) to be represented. Preliminary fatigue results are promising for the construct to withstand the millions of cycles required for fatigue testing.

The advantages of an analogue model lie in its anatomic similarities to an actual human spine. However, until the biomechanical properties can be accurately mimicked and the durability of the model improved, the analogue model is not recommended for dynamic evaluations. Conversely, the hybrid construct is a durable model that provided a consistent method for evaluation of these unique systems and, thus, is the suggested method for the dynamic evaluation of growth rod scoliosis systems.

REFERENCES:
1. ISO/FDIS 12189:2008(E) 2. ASTM F1717-04