INTRODUCTION: Using single rod anterior instrumentation for thoracolumbar/lumbar scoliosis, an unacceptable incidence of loss of correction, segmental kyphosis, and pseudarthrosis have been reported. Inadequate construct stiffness due to early postoperative bone-screw interface failure, especially at cephalad and caudal-end vertebrae, has been implicated as the cause of these complications. Dual-rod anterior systems provide improved stability at the bone-screw interface, with improved outcomes compared to single rod results, at the expense of increased technical complexity and instrumentation profile. A new rod-plate anterior implant was designed to provide plate fixation at the cephalad and caudal-end segments of a five-level anterior construct. Nondestructive biomechanical testing was performed on calf thoracolumbar spines instrumented with five level scoliosis anterior spine constructs. The objective of this study was to analyze the initial and post-fatigue stability of the new implant and compare results with a dual-rod anterior system.

METHOD: The Rod-Plate anterior implant is an L-shaped spinal plate with multiple screw holes designed for use with standard anterior instrumentation vertebral screws and a solid rod (Figure 1-A). Twenty calf spines (T12 to L5) were used in this investigation. Bone mineral density (BMD) was measured on each spine using P-DEXA (Norland Medical Systems Inc., Fort Atkinson, WI). The spines were first tested intact, and then a total discectomy and transection of the anterior and posterior longitudinal ligaments was performed at T13-L1, L1-2, L2-3, and L3-4. Anterior multisegmental instrumentation was then applied on the anatomic left side between T13 (cephalad-end vertebra) and L4 (caudal-end vertebra) using the titanium CD Horizon® Legacy™ dual-rod system (6.5-mm screws and 5.5-mm rods, Medtronic Sofamor Danek, Memphis, TN) or anterior TSRH® system (6.5-mm screws and 5.5-mm rod, Medtronic Sofamor Danek, Memphis, TN) with rod-plate implants (n = 10). Following instrumentation, nondestructive biomechanical testing was performed on a servohydraulic testing machine (Bionix 858 MTS, Eden Prairie, MN). The most inferior vertebra (L5) was fixed to the table via a 9-cm loading arm. The most superior vertebra (T12) was attached to the servohydraulic crosshead using a similar 9-cm loading arm (Figures 1-B & C). When ± 55.6 N loads were applied via crosshead, ± 5 N-m bending moments were applied to each spine in either flexion-extension or right-left lateral bending. The rate of loading was equivalent to 1 Nm/sec. Each instrumented vertebra was labeled with three infrared reflective markers rigidly attached to its spinous process in a triangle pattern from T13 to L4 (Figure 1-B & C). Angular motion at each vertebra was recorded using a three-dimensional motion analysis system and custom model (VICON and Body Builder, Oxford Metrics, Ltd., Oxford, England) and referenced with respect to its inferior vertebrae. After the initial stability analysis, cyclical testing in flexion-extension was performed for each spine in stroke control at a rate of 3 Hz with a peak/valley load of ±4 N-m maintained for total of 20,000 cycles. After fatigue simulation, each construct was again tested in flexion-extension and right-left bending. Then, the instrumented spine was separated into individual vertebrae for the screw pullout test. The cephalad-end vertebra (T13), the middle vertebra (L2), and the caudal-end vertebra (L4) were disarticulated from each specimen, and secured with a steel custom cable-plate (Figure 2). Screws were pulled out at a constant displacement rate of 1 mm/sec, and the maximum tensile pullout force (N) was recorded. The data of range of motion and screw pullout force were analyzed by performing a two-way analysis of variance (AOV) using PROC GLM in SAS® (Version 9.0).

RESULTS: The mean BMD of vertebrae were 1.393 ± 0.115 g/cm² in rod-plate group and 1.393 ± 0.141 g/cm² in dual-rod group. There were no significant differences of BMD between the two groups. In lateral bending, specimens instrumented with the rod-plate implant showed 55.7% (initial test) and 53.1% (post-fatigue) decrease at the cephalad and caudal-end segments range of motion compared to the dual-rod system (P < 0.05), however, there was no significantly different at the intermediate segments (P > 0.05). In flexion-extension, no significant difference in range of motion was found at the cephalad and caudal-end segments between the two systems, but the dual-rod intermediate segments had 82% (initial test) and 80.7% (post-fatigue) less range of motion than rod-plate intermediate segments (P < 0.001). Post-fatigue screw pullout strengths of the rod-plate system were significantly greater by 42.8% (cephalad-end screws) and 33% (caudal-end screws) compared to those of the dual-rod system (P < 0.05).

CONCLUSIONS: A new rod-plate implant to be used with a single-rod anterior instrumentation system is introduced and biomechanically compared with a dual-rod system. This new rod-plate implant has improved the single-rod system by plate fixation at the cephalad and caudal-end segments. In a calf thoracolumbar spine model, the rod-plate system provided better construct stability in lateral bending and achieved higher construct stiffness at the cephalad and caudal-end segments compared to a dual-rod system. The rod-plate system also has the potential to balance the construct stiffness between the end levels and the intermediate levels of the instrumented segments. This new anterior implant may afford improved fixation at the bone-screw interface in most cephalad and caudal-end segments and can be expected to better maintain coronal and sagittal correction in the postoperative period.