A NOVEL METHOD FOR MEASURING IN SITU STRUCTURAL RIGIDITY OF TOTAL DISC REPLACEMENT SYSTEMS

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INTRODUCTION
A clinically relevant characteristic of any total disc replacement (TDR) system is its in situ structural rigidity, which culminates from device and surrounding tissue interactions. The nature of these interactions, which depend on TDR design, surgical technique, and tissue quality, can dominate clinical outcomes. Proper in vitro structural rigidity assessment requires multiaxial loading conditions that mimic those experienced in vivo. However, with the exception of non-physiologic pure moment loading, it is experimentally difficult to determine the internal mechanics of the TDR system during in vitro multi-axial tests. This is because internal forces and moments cannot be derived directly from the net loads applied to the spinal section. The objective of this study was to present a novel method for quantifying in situ TDR rigidity under physiologic, multi-axial loading conditions. We illustrated this technique by computing the effect of implant positioning on flexion-extension rigidity using a current TDR system (ProDisc®-L, Synthes Inc. West Chester, PA USA).

METHODS
One lumbrosacral spinal section (L5-S1, 56 y.o. male) was instrumented with a ProDisc®-L and loaded physiologically in both flexion and extension by applying combined axial compression (800 N) and anterior-posterior shear force (670 N). A multi-axial load cell was used to monitor net forces and moments during testing. Optical targets were mounted to the L5 and S1 spinal levels, and planar x-rays were taken to quantify marker position relative to the spinal anatomy. The load state experienced by the TDR was computed as:

\[ F_{TD} = F_{LC} \]
\[ M_{TD} = M_{LC} + r \times F_{LC} \]

where \( F_{TD} \) and \( M_{TD} \) are forces and moments experienced by the TDR; \( F_{LC} \) and \( M_{LC} \) are forces and moments recorded by the load cell; and \( r \) is the spatial vector from the centroid of the inferior endplate of the TDR to the load cell center. The effects of implant positioning on TDR rigidity were determined by repeating biomechanical testing with the device repositioned ±3 mm from the central position on the endplate.

RESULTS
TDR bending rigidity depended on device positioning, with the device being the most rigid when placed centrally on the vertebral endplate (2.1 Nm/deg for flexion, 4.0 Nm/deg for extension). When the device was repositioned 3 mm anteriorly, rigidity in
flexion and extension decreased by 78% and 18%, respectively. With posterior repositioning, decreases in rigidity were even greater (85% in flexion, 34% in extension). Changes in bending rigidity with positioning were not reflected in rigidity calculations based on the net moment experienced by the specimen (less than 0.1% change with ±3 mm repositioning).

**DISCUSSION**

We have illustrated a novel approach to determining *in situ* TDR rigidity that can be applied to physiologic testing protocols. This technique uses motion tracking and net multi-axial load cell measurements to non-invasively determine internal forces and moments. Our results indicate that this approach is necessary even for two-bone spinal sections because the internal forces experienced by the TDR are not equivalent to the net forces on the whole spinal section. This new technique should be viewed as an alternative to standard, pure moment testing protocols for biomechanical assessment of some TDR systems.