Introduction: A key design parameter for a constrained ball and socket TDR device is its fixed center of rotation (CoR). Malalignment between the implant CoR and the inherent rotational axis of the MSU may lead to an overloaded, over-constrained condition. Different paradigms exist for the surgical placement of TDR devices however conventional in-vitro testing methodologies lack the sensitivity to discern the effects of changes in implant placement.

Objective: The objective was to evaluate in-vitro changes in MSU mechanics and ROM due to variations in surgical placement of a simulated ball and socket TDR device, like the ProDisc-L, within a human cadaveric lumbar model.

Methods: A custom designed Spine Robot was programmed to prescribe pure rotation of an MSU about any desired CoR location. Six fresh human cadaveric lumbar spines, L4-L5, were implanted with the ProDisc-L (Synthes Spine). Lateral radiographs and Image-J software (NIH) were used to determine the surgical placement of the implant's CoR. Each specimen was mounted in the Spine Robot and rotated in flexion and extension about the implanted CoR. Subsequently, with the MSU held rigid in the robot, the implant was removed and rotation about the implant's CoR was repeated. Thereafter, simulated CoRs were tested as defined by a customized grid pattern of 8 CoRs simulating different possible placements of a medium and large size ProDisc-L implant with a 10mm inlay height and 6° lordosis (Figure 1). The pattern was based on surgeon preference for posterior placement of the implant with the largest size footprint and the smallest inlay height (i.e. point LP Figure 1). All subsequent points were offset from this point (mean distance 2.5mm). Specimens were rotated to an end limit of 8Nm or 15° rotation. Resultant shear forces, axial forces and global rotation were compared at each CoR using a RM ANOVA with SNK tests (p=0.05).

Results: During flexion, an increased net anterior shear force and net tensile axial force occurred as the simulated implant was positioned more posterior with significant differences occurring within and between the medium (6mm) and large (8mm) CoR planes. In extension net axial loads were compressive and significantly increased at midline-anterior placements in both planes. In extension ROM was significantly increased with posterior CoR placements in both planes. Simulated medium and large size implants performed in a similar manner.

Discussion: This study demonstrates the net posterior tissue response to varying simulated placements of the ProDisc-L which was sensitive in terms of loading mechanics and ROM. For both implant footprints,
posterior positioning of the simulated implant during flexion created a stiffer MSU construct with higher loading, while in extension posterior positioning promoted reduced loading and greater rotation. These data suggest that flexion and extension may have different initial CoRs. A study limitation is that a fully constrained ball and socket TDR may not always function as intended in-vivo.