INTRODUCTION: A physical, surrogate annulus fibrosus (AF) model for multidirectional wear and fatigue testing of nucleus pulposus replacements (NPRs) has been designed and validated [1]. However, this model is comprised of the AF only. Within the intervertebral disc, the nucleus is bound by both the AF and endplates. The endplates facilitate uniform load distribution while regulating nutrition and fluid transport across the disc. In this study, the existing model was modified to include a representative material for endplate interfaces. A validation study was conducted to assess the performance of the modified model using lumbar motions and loads prescribed in an industry wear guidance standard for total disc replacements, ISO 18192-1.

METHODS: Twenty-six materials including rubbers, foams, and medical-grade biomaterials were evaluated to identify materials that may represent functional endplate properties. The equilibrium response of articular cartilage has been satisfactorily described by an isotropic elastic model [2]. To adequately compare candidate synthetic materials to cartilage, materials were tested per methods described in Korhonen et al. Specifically, materials were characterized under unconstrained compression. A stepwise stress-relaxation test was performed up to 20% strain, in increments of 5% strain at 0.001 strain/sec. The aggregate modulus (Hg) was determined as the ratio of equilibrium stress to equilibrium strain and interpreted to identify a representative surrogate endplate material. Properties used to represent cartilage in intervertebral disc finite element models were also considered when interpreting results from candidate endplate material characterization.

Eight surrogate intervertebral disc models were included in the validation study, where six were utilized for wear and fatigue characterization and two for load soak control. Each model included four injection molded parts: a surrogate NPR (VytasFlex10, Smooth-On); a surrogate AF (QM264, Quantum Silicones), and both superior and inferior surrogate endplates (RenCast6401, Huntsman).

The surrogate intervertebral disc model was validated on a 6DOF spine wear simulator (MTS, EdenPrairie, MN) in accordance with motion and loading profiles defined in ISO 18192-1 up to 2.5Mcycles of wear testing. Specifically, models were loaded sinusoidally between 600 and 2800 N while flexion/extension, lateral bending, and axial rotations were performed at ±0.0-3.0°, ±2.0°, and ±2.0°, respectively. Angular rotations and axial loading were applied at 3 Hz and 6 Hz, respectively.

Each model was subjected to axial compressive loading at 1.0mm/s to characterize stiffness under denucleated and nucleated states at 0.0 and 2.5Mcycles. Models were submersed in a 37±2°C PBS bath and imaged using fluoroscopy. Surrogate NPRs were characterized for geometric and dimensional changes at 0.5Mcycle intervals. Surrogate endplates were characterized for dimensional changes using micrometers and surface roughness changes using white light interferometry at 0.0 and 2.5Mcycles. Representative surrogate NPRs (n=2) and endplates (n=2) were imaged with optical microscopy and microCT for evidence of microcracking and wear.

RESULTS: The aggregate modulus (Hg) for a candidate urethane rubber (RenCast6401, Huntsman) was determined to be 4.95 ± 0.67 MPa. This value was comparable to moduli reported for cartilaginous endplates in validated finite element models of the intervertebral disc. Surrogate endplates performed superiorly, with respect to wear. Results show no significant changes in height (p>0.99) or surface roughness (p>0.05) after wear testing. Articulating surfaces did not appear worn, and no signs of internal cracking were observed on corresponding microCT images. These results suggest that wear along surrogate NPRs evaluated in this study were not an artifact of interfacing surrogate endplate wear. Additionally, similar wear patterns on both the superior and inferior surfaces of surrogate NPRs suggest that the surrogate intervertebral disc model imprints more uniform loading patterns.

A physical disc model has been validated for multidirectional wear and fatigue testing of NPRs, including a surrogate endplate material interface. In comparison to the prior model,[1] the present model, with surrogate endplates, facilitated a more uniform load distribution across the remaining structures of the disc. The optimized model has been designed to impart clinically relevant loading patterns and constraint to surrogate NPRs [6-7]. This pre-clinical test was used to characterize wear and fatigue of surrogate NPRs in terms of mass loss, height loss, contribution to SIVDM stiffness, and physical features of wear and fatigue.

DISCUSSION: The surrogate endplate material was selected based on comparison of aggregate modulus to range of moduli used to represent cartilaginous endplates in validated finite element models of the intervertebral disc. Surrogate endplates performed superiorly, with respect to wear. Results show no significant changes in height (p>0.99) or surface roughness (p>0.05) after wear testing. Articulating surfaces did not appear worn, and no signs of internal cracking were observed on corresponding microCT images. These results suggest that wear along surrogate NPRs evaluated in this study were not an artifact of interfacing surrogate endplate wear. Additionally, similar wear patterns on both the superior and inferior surfaces of surrogate NPRs suggest that the surrogate intervertebral disc model imprints more uniform loading patterns.

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