Nucleus replacement load sharing, deformation and the relationship to subsidence
Andrew L. Freeman¹, Brian P. Beaubien¹, Adam L. Gullickson², Seme J. Steven²
¹Gustilo Medical Education Center and Midwest Orthopaedic Research Foundation, Minneapolis, MN; ²Raymedica, LLC, Bloomington, MN
afreeman@gustilocenter.com

Introduction: As with all interbody devices, nucleus replacement devices are subject to subsidence in the adjacent vertebral bodies. Subsidence is related to numerous factors including bone quality, device stiffness, implant-endplate contact area and load sharing with surrounding tissues. Devices with a large contact area that can also mimic the load sharing characteristics of the intact spine may be advantageous in reducing the incidence of subsidence. Hydrogel nucleus replacements may possess these characteristics, but little research has been performed to characterize how changes in device stiffness may affect the stiffness, load sharing and subsidence properties in the lumbar spine. We hypothesized that two different hydrogel nucleus replacements would provide more physiologic load sharing than a “rigid” PEEK spacer and that both subsidence and load sharing would be related to changes in the hydrogel device endplate contact area under load.

Materials and Methods: Hydrated HydraFlex (n=14), the more rigid PDN-SOLO (n=4) hydrogel nucleus replacements and rigid PEEK spacers (n=6) underwent in vitro cadaveric testing to quantify device subsidence and load sharing between the implant, annulus and posterior elements. Twenty four human lumbar motion segments were potted in neutral alignment and tested under axial compression in load and displacement control. Loads were applied to 1600 N in the intact, denucleated, and implanted states to quantify the segmental stiffness. Stiffness was calculated in the primary (0–500N) and secondary (1000–1600N) regions. Load sharing tests were conducted in displacement control to the peak displacement recorded at 1600 N with the device implanted. The peak load was recorded in the implanted state, after annulus removal and after posterior element removal. Load sharing for a given structure was calculated by recording the decrease in load after removal of the structure.

Subsidence tests were performed after removal of the annulus and posterior elements. Tests were conducted at 800 N and repeated to increasing loads (200 N increments) until subsidence >3 mm was observed. Fluoroscopic images acquired after unloading were used to identify the initiation of subsidence. Contact area and pressure data for the nucleus replacements was acquired by the manufacturer using pressure sensitive film (Tekscan Model 5051) placed between the devices and concave steel platens. Compressive loads of 200 N, 800 N and 1600 N were applied and contact areas and pressures were recorded. The PEEK spacer was not expected to experience substantial changes in contact area with loading.

Results: The two nuclear replacements had similar primary stiffness but that of the PEEK spacer was higher and near the intact value (Fig.1). The secondary stiffness values for all devices were within 33% of the mean intact segment stiffness (Fig.1). In the load sharing tests, annulus removal resulted in mean±SD load decreases of 730±332 N for HydraFlex, 832±127 N for PDN and 305±250 N for PEEK spacers (Fig.1). Load reduction with removal of the posterior elements did not differ across groups (182±102 N overall). Subsidence loads were greatest for HydraFlex, followed by the PEEK spacer, and were lowest with PDN (Fig.2). Subsidence of the PEEK spacer occurred simultaneously with endplate fracture whereas initiation of subsidence occurred 600-800 N prior to gross device subsidence in the nucleus replacements. With loading the HydraFlex footprint area increased more than PDN and resulted in lower contact pressures (Table 1).

Discussion: Devices with a lower primary stiffness resulted in lower motion segment stiffness, greater load sharing, a greater increase in footprint area with loading, decreased contact pressures and increased subsidence loads compared to their stiffer counterparts. The load-sharing results suggest that greater differences in the subsidence loads would be observed with an intact annulus. In the absence of a complete-fill, nucleus replacement device stiffness must be optimized to maintain sufficient disc height while maximizing load sharing and minimizing endplate stresses.

Acknowledgements: The authors thank Raymedica, LLC for donation of implants and funding.