Development of Surrogate Annulus for Nucleus Replacement Devices- A Load Sharing Study

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INTRODUCTION: Nucleus replacement device (NRD) concepts, especially the injectables, are well suited for patients with early onset of degenerative disc disease and intact annulus fibrosus. It is imperative to consider the load sharing between the device and the surrogate annulus (SA) while mechanically evaluating these devices. The proposed ASTM standard (WK4863) for the mechanical evaluation of NRDs suggests a silicone based one-piece SA model. However the model has several limitations, one of which is the SA must be sacrificed to monitor the NRD during testing. In this study we evaluated the alternative SA models performance and how these models share load between the device and the SA for each.

METHODS: Three SA models were mechanically evaluated where each model consisted of a kidney shaped base and a small core fabricated using QM264 or QM280 silicone (Quantum Silicones, Richmond, VA) with Shore-A hardnesses of 60 and 80 respectively. The surrogate nucleus (SN) was made by injecting and curing Vytaflex® 10 silicone (Smooth-On, Inc., Easton, PA) in the silicone core of the SA (Fig 1). The three models varied either in the SA hardness or in the size - Model-I Shore 60, 50x34x10mm; Model-II Shore 80, 50x34x10mm; and Model-III Shore 80, 50x34x18mm. All models were tested on a spine wear simulator (MTS, Eden Prairie, MN) using a sinusoidal compressive load of 300-1000N with combined motion of (+6°, -3°) flexion - extension (FE); (±2°) lateral bending (LB); (±2°) axial rotation (AR) in 0.9% NaCl solution maintained at 37°C.

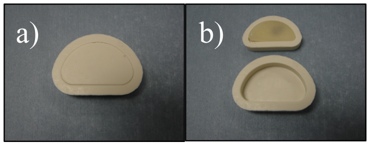

Figure 1: a) Two-piece SA b) Silicone base and core

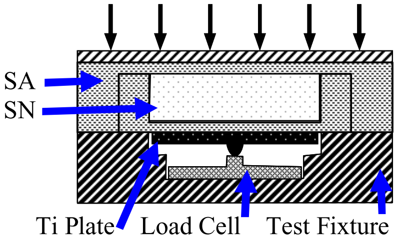

Figure 2: Load sharing setup in neutral position

Following the mechanical test, three SA models and the ASTM one-piece model (Model-IV) were evaluated for the load sharing between the nucleus and the SA. Load sharing test set up consisted of a uniformly applied load across the SA with a Titanium (Ti) plate located under the nucleus core rested on the load cell (Cooper Instruments, VA) as shown in Fig 2. The Ti plate had a pivot to accommodate the changing load vector from test motions. The SA models were applied with the combined loading conditions described above and was followed by a static FE test under a constant load of 1000 N.

RESULTS: Mechanical test on Model-I completed about 2 million cycles (MC) before the SA was damaged due to the impingement between superior and inferior fixtures. Model-II & III successfully completed over 5 MC without any apparent failure. In the load sharing test, Model-I transmitted the highest load on to the SN while Model-IV had the most load shielding effect on the SN. Fig 3 presents an example of the combined test motions and load sharing measurements at the highlighted points of interest while Fig 4 presents percentage of the applied load transmitted to the SN for each model at these points. Additional static FE test showed that percentages of the applied load carried by the SN in flexion was 28, 24, 26, and 26% and in extension was 24, 21, 23, 20% for Models-I to IV, respectively.

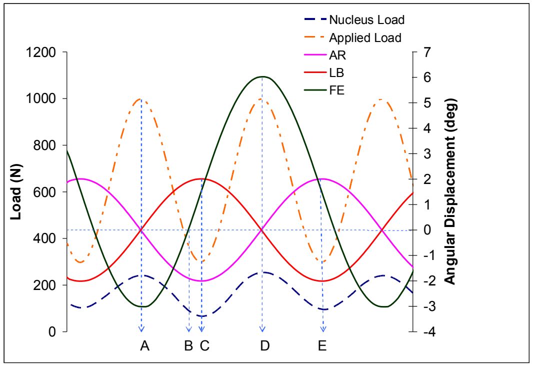

Figure 3: Test motion and load sharing for combined test

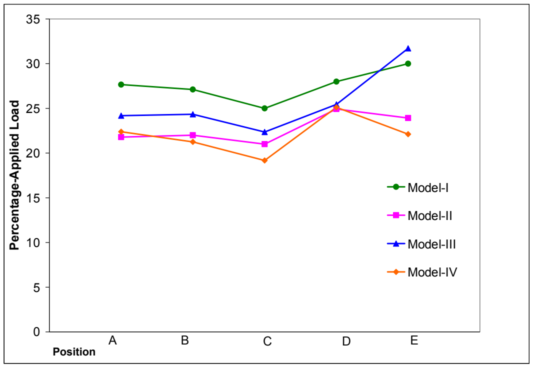

Figure 4: Percentage of applied load for combined loading

DISCUSSION: Load sharing was shown to be dependent on the amount of applied load, test motion, SA hardness and size. Agreement between the combined loading and static FE tests suggests load shielding was more prevalent in extension than flexion. The hardness, size and design of SA have an effect on the load sharing based on the findings in this study. Important considerations for testing NRD lie within the stiffness of the device, characterizing the load sharing, periodic monitoring of NRD, and the testing parameters.

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