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Biomechanical Flexibility Testing of an In Situ-Cured Silicone-Based Disc Nucleus Prosthesis

Britt Norton*, W. Loren Francis#, Tara Sherman*, John Sherman**

*Medavise LLC, Eden Prairie, MN, USA #Spinal Stabilization Technologies LLC, San Antonio, TX, USA **Twin Cities Orthopedics, Edina, MN, USA

PURPOSE

A new intervertebral disc nucleus replacement device having three major features has been designed, comprising: 1) a peripheral textile band, 2) a silicone membrane filled with silicone that cures in situ forming an elastomeric implant and 3) an internal chamber that allows for deformation of the cured component (Figure 1). Samples of this device were subjected to biomechanical flexibility testing to determine the impact of device implantation on functional spinal unit (FSU) range of motion (ROM).

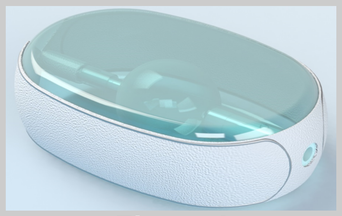

Figure 1

METHODS

Eight human fresh frozen cadaver lumbar FSU's with a mean donor age of 43 years were selected using x-ray evaluation and DEXA scans to eliminate specimens with excessive degeneration. Four each of L2-L3 and L4-L5 vertebral levels were used. Specimens were prepared by removing all non-connective tissue. Each FSU was tested under three conditions: intact, enucleated and implanted with the device. Each FSU was subjected to flexibility testing with bending moments of ± 7.5 Nm in flexion/extension, right/left lateral bending and axial rotation motions using a six degree of freedom hydraulically-actuated spinal loading gimbal attached to a servo-hydraulic load frame (Figure 2). Bending moments were applied at a rate of 0.5 Nm/sec, using two test cycles to condition the samples and a third cycle for data acquisition. An example hysteresis curve with data for each condition in flexion/extension testing is shown in Figure 3.

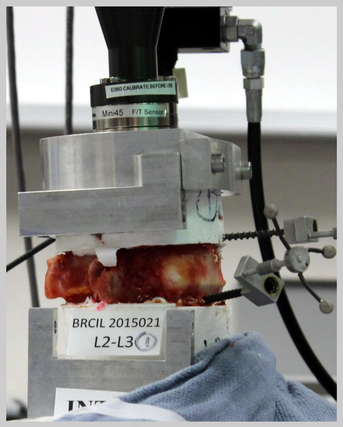

Figure 2

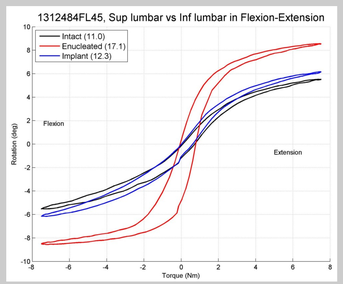

Figure 3

FINDINGS

Enucleation of the specimens significantly increased ROM to 133%, 129% and 165% of the intact condition for flexion/extension, lateral bending and axial rotation, respectively ($p < 0.01$ for all motions). Implantation of the device in the enucleated specimens reduced the ROM to 102%, 102% and 97% of the intact conditions for the same motions, representing a significant decrease over the enucleated condition ($p < 0.01$ for all motions). The differences in ROM between the intact and implanted conditions were not statistically significant (p-value range = 0.49 – 0.53). An example graph of ROM results for each condition is shown in Figure 4. A T-1 weighted magnetic resonance image of an implanted sample is shown in Figure 5.

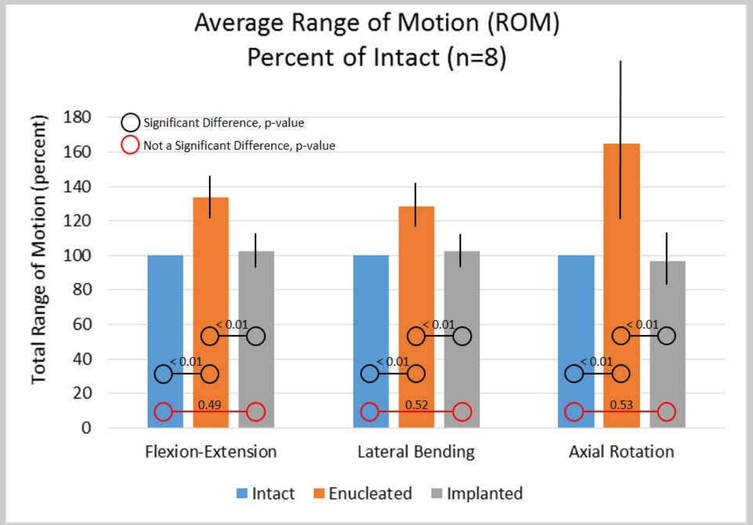

Figure 4

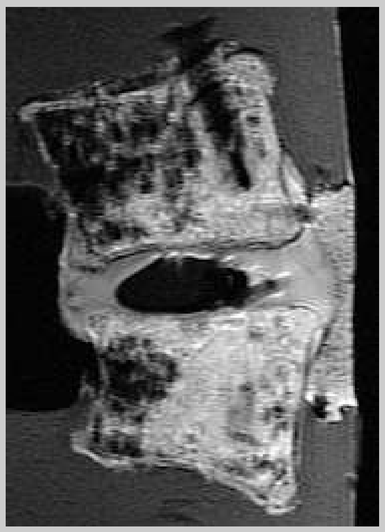

Figure 5

CONCLUSIONS

The range of motion of implanted FSU specimens in flexion/extension, lateral bending and axial rotation was indistinguishable from that of the intact specimens. These results suggest that this silicone rubber-based injectable device is able to produce a stiffness profile sufficient to restore stability and normal motion to the lumbar vertebrae under physiologic loads.

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