# Performance Testing of an Injectable Silicone Rubber Based Nucleus Replacement Device

J Sherman,MD*, L Francis#, B Norton+

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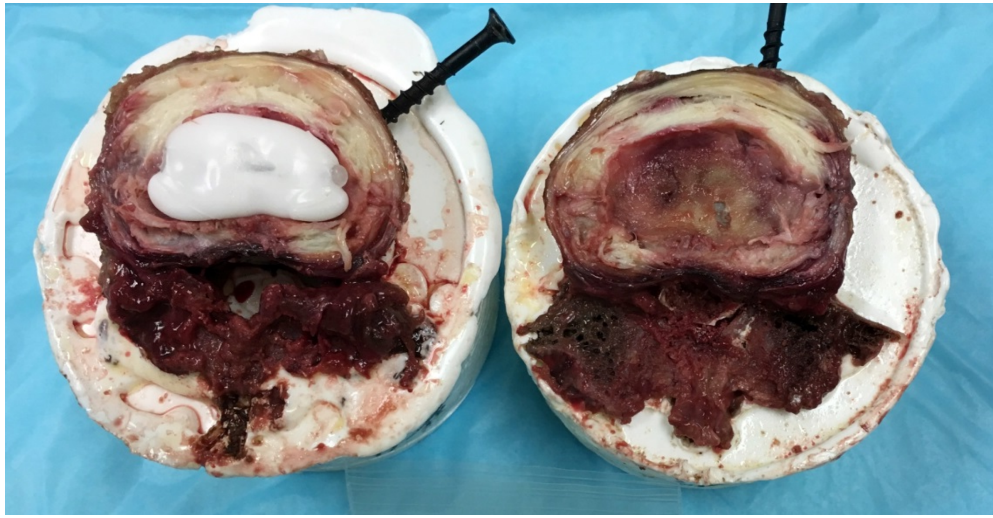
*Twin Cities Orthopedics, Minneapolis, MN
#SST San Antonio, TX,
+Medivise, Minneapolis, MN

# Purpose

A novel intervertebral disc nucleus replacement device is comprised of an elastic silicone membrane filled with liquid in situ curable silicone to form an elastomeric implant surrounding a central gas chamber that allows inward deformation of the cured component under load. Samples of this device were subjected to finite element analysis (FEA), digital pressure mapping and biomechanical flexibility testing to determine the impact of the device on disc structure and biomechanical function.

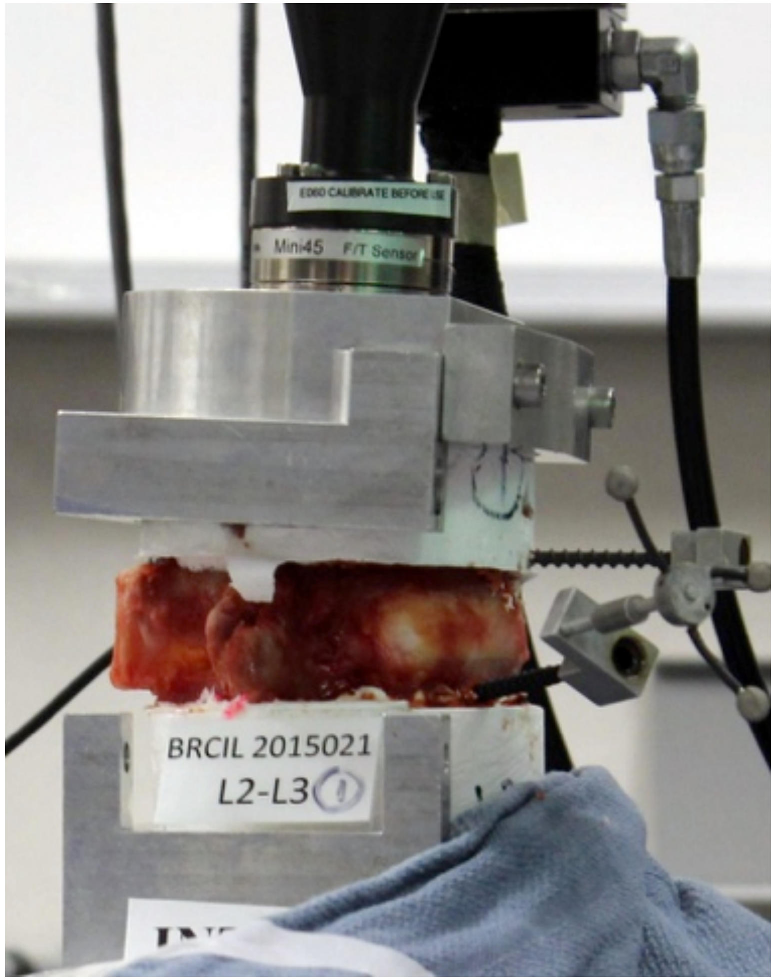
# PerQdisc Nucleus Replacement Device

- The PerQdisc device is a balloon enclosure, which is implanted into the enucleated space then filled with fast curing silicone that forms the final shape.
- For implantation a nuclectomy is performed on a lumbar disc.
- The device is introduced through a 6.5 mm access through the annulus.
- The balloon is filled with a fast curing silicone to 35 psi.



# Biomechanics Testing

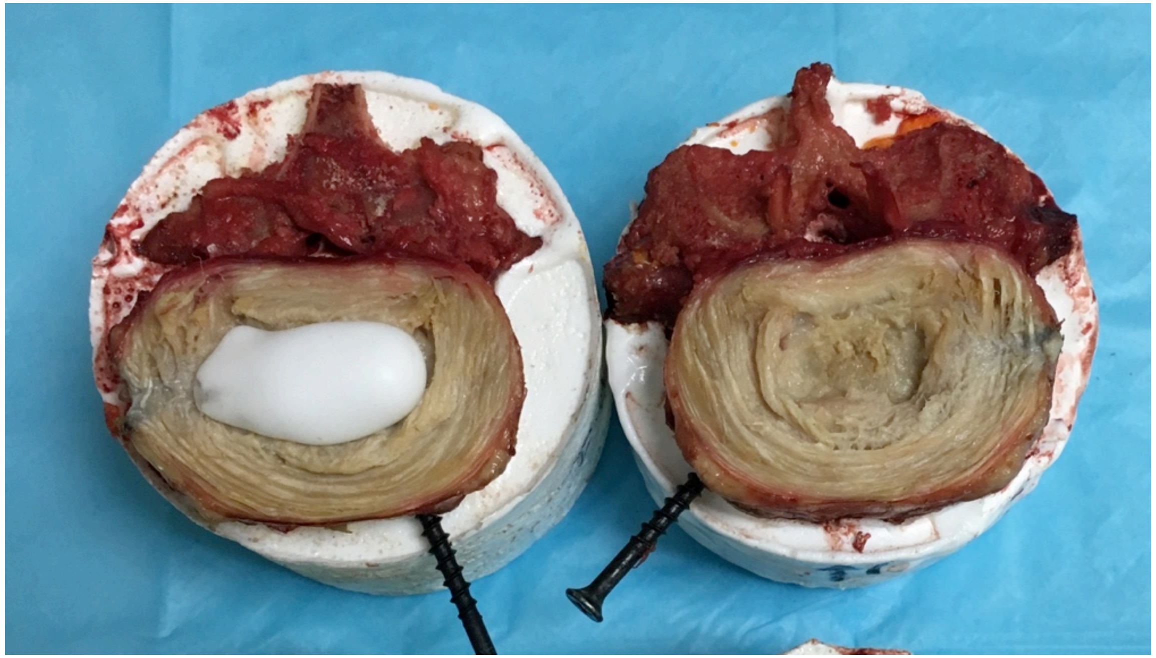
- Eight human cadaver lumbar FSU (4 x L2-L3 and 4 x L4-L5) with a mean donor age of 43 years were selected for biomechanical flexibility testing.
- Following removal of all non-connective tissue, each FSU was tested under three conditions: intact, enucleated and implanted with the device.
- Each FSU was subjected to bending moments of ± 7.5 Nm applied at 0.5 Nm/sec in flexion/extension, right/left lateral bending and axial rotation motions using a hydraulically-actuated loading gimbal attached to a servo-hydraulic load frame, with results reported as range of motion (ROM)



# Biomechanics Results

## Implanted Devices

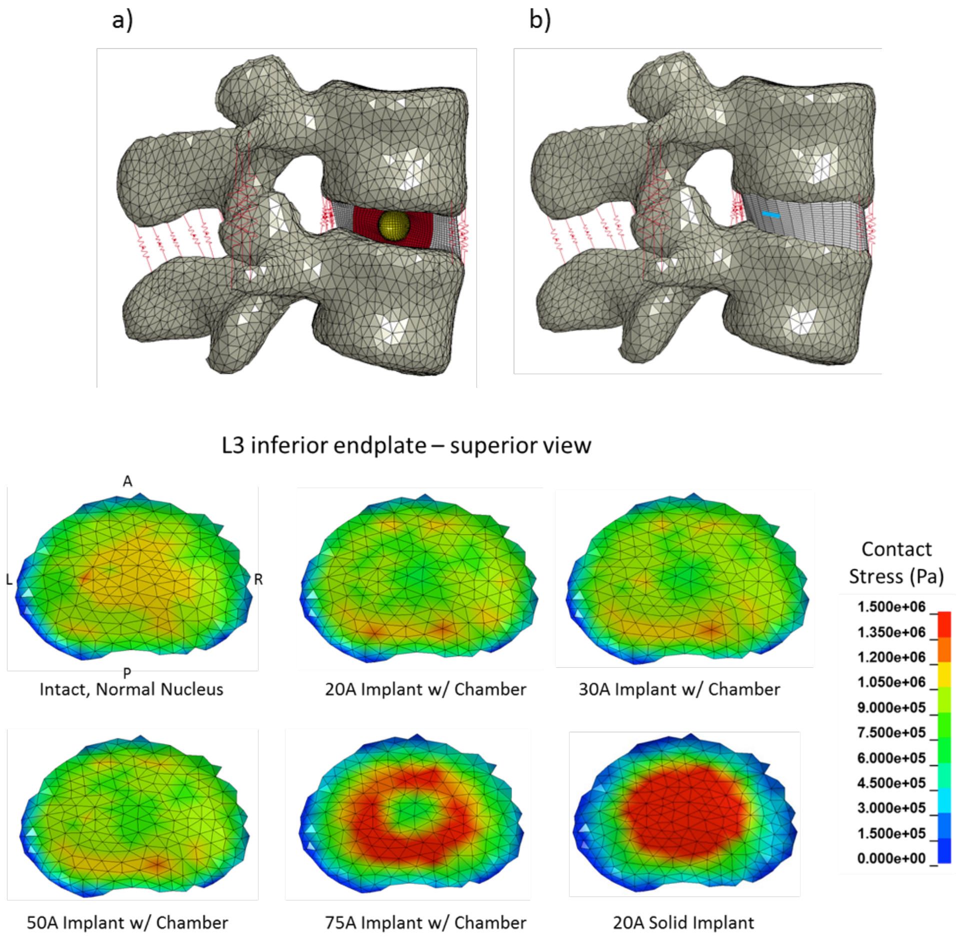
L2L3



L4L5

# Finite Element Analysis

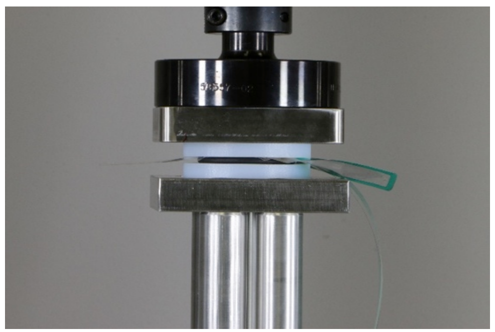
- A finite element model was constructed and used to verify that the durometer of the silicone resulted in a physiological response that was equivalent to healthy nucleus
- The finite element model of the L3-L4 motion segment was able to determine the biomechanics associated with the implantation of the PerQdisc. The device replicates similar biomechanics to the motion segment compared with an intact normal nucleus.

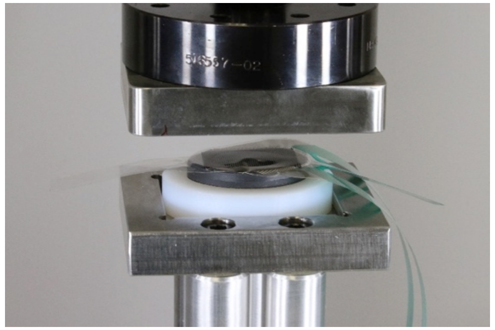


# Pressure Distribution

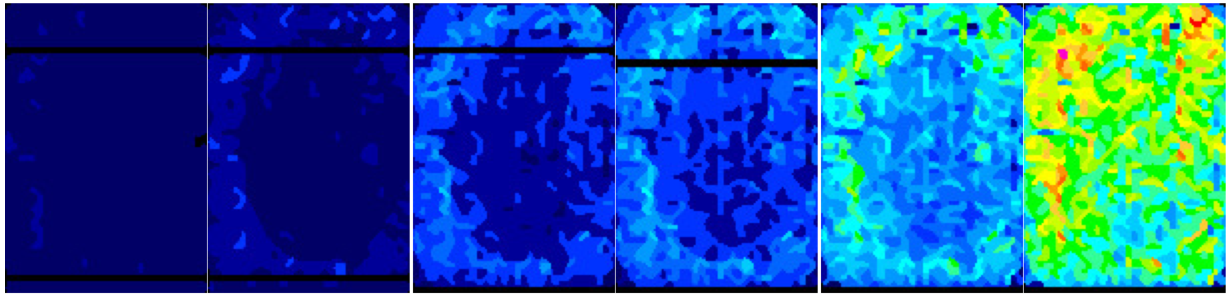
A PerQdisc implant and surrogate annulus assembly were loaded in static compression to 2500N. Pressure mapping was acquired using a Tekscan K-Scan Joint Analysis System and Pressure Mapping Sensor

The pressure distribution maps of the PerQdisc and surrogate annulus assembly show that the device evenly distributes the pressure across the endplates. When the surrogate disc and device system was loaded to 2,500N, the average endplate pressure measured by the pressure sensor was in the range of 1.5 to 3.0 MPa for the various groups. These pressures were considerably less than the conservative 80 MPa stress value often referenced for failure of cortical bone under tension (Adam, et al. (2003)).

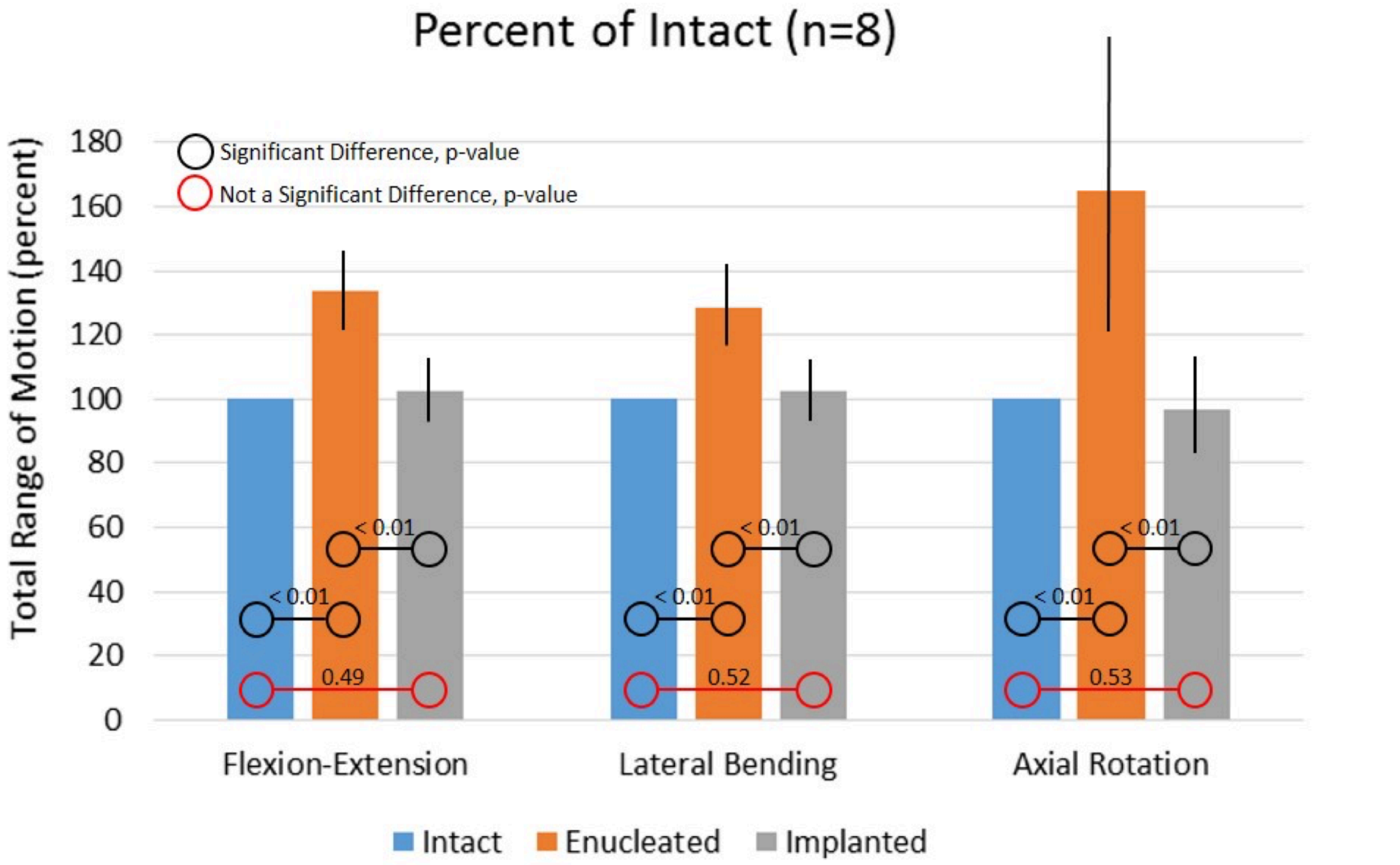




Pressure Distribution as Load Increases to 2500N



# Total Range of Motion



# Flexion & Extension ROM

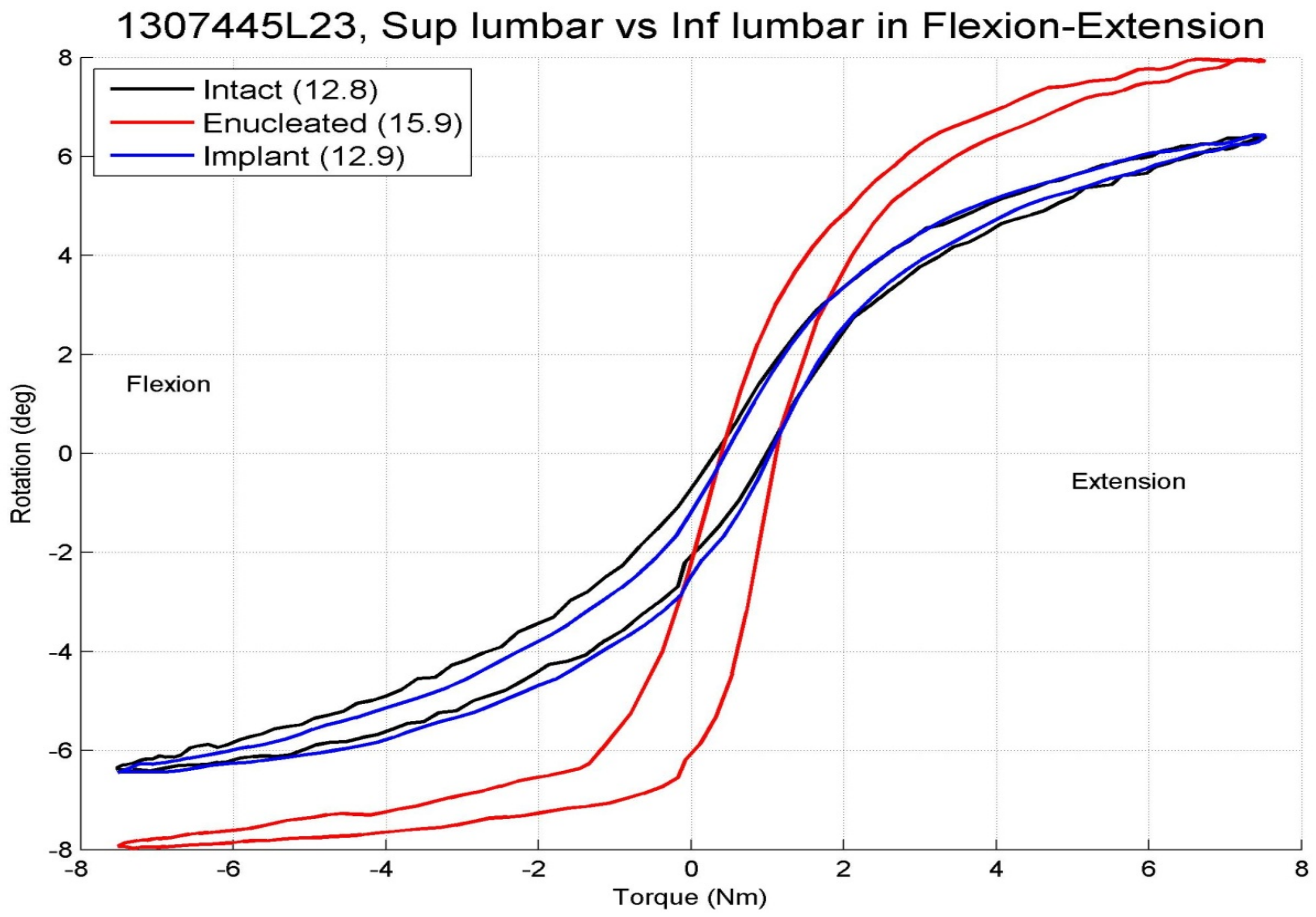
Comparison of ROM in:

- Intact (black)
- Enucleated (red)
- Implanted (blue)

in a L2L3 motion segment

<u>Note:</u>

Increase in Neutral Zone (red) - with enucleation and normalization of curve with implant (blue)



# Conclusion

The endplate stresses and pressures at 2,500N were considerably less than the conservative 80 MPa stress value often referenced for failure of cortical bone under tension. The suitability of the device for use as a nucleus replacement was confirmed by biomechanical testing, wherein the range of motion of implanted specimens was indistinguishable from that of intact specimens.

# Disclosures

John E Sherman
Consultant for Spinal Stabilization Technologies

W Loren Francis
Employee for Spinal Stabilization Technologies

Britt Norton
Consultant for Spinal Stabilization Technologies