**In vitro Fatigue Evaluation of Polymer Dampeners Utilized in a Total Spine Arthroplasty Device**

*J. Gimbel¹, K. Lesk¹, E. Wagner¹*

¹Flexuspine, Pittsburgh, PA, United States

**Introduction:** Lumbar disc and facet degeneration is a common cause of pain and disability. Fusion treats both disc and facet pain but restricts motion and alters adjacent segment kinematics. Total disc replacements (TDR) allow motion but only treat disc degeneration. Total Spine Arthroplasty (TSA), however, treats both pain generators and allows motion. The Flexuspine FSU is a TSA device that replaces the three-joint complex with TDR and posterior dampener components. The posterior dampener consists of a metal rod and cylindrical silicone dampeners that act in compression to resist pedicle screw motion. The objective of this study was to characterize the fatigue behavior of the dampeners.

**Methods:** Compression fatigue testing was performed using an MTS test machine. Cylindrical silicone dampeners were placed between washers on dowel pins to simulate the FSU rod component and tested in 37°C deionized water or 30g/L serum. Compression up to 40% strain was cyclically applied for 10Mc and 20Mc (n=6 each) at 4 Hz in a sinusoidal manner with a rigid stop controlling the maximum displacement. Load soak specimens served as controls. Dampener length was measured with a digital caliper and weight was measured over time. Static testing to 40% strain was also performed on a subset of specimens (n=5 control, n=2 at 10Mc, n=3 at 20Mc) upon completion of fatigue testing using an Instron test machine. Stiffness was determined in the initial toe region and final linear region since the load-displacement curves were non-linear.

**Results:** The specimens remained intact through 20Mc. Circular indentations in the top/bottom surfaces and an indentation ring in the middle of the internal surface was observed over time. The length decreased by an average of 2.7±0.8% after 10Mc and 4.1±0.9% after 20Mc. The average wear rate was 0.8mm³/Mc for each dampener, which was consistent over time. Compressive stiffness slightly increased after 10Mc (+1% toe region; +25% linear region) and slightly decreased after 20 Mc (-13% toe region; -9% linear region).

**Conclusions:** Compression fatigue testing was performed on the silicone dampener component of the Flexuspine FSU device. This testing demonstrated that the dampeners could withstand 40% compression for up to 20Mc without failure while still maintaining their geometric and mechanical properties. This corresponds to more than 15° of flexion-extension and approximately 160 years of clinical use (assuming 125,000 significant bends/year), which is greater than the expected in vivo ROM and the lifetime of the device (Phillips, 2010).

Fatigue damage and wear of the dampeners was observed over time as expected. Compression into the washers resulted in circular indentations on the top and bottom surfaces. Deformation of the dampeners at higher strains resulted in an indentation ring in the center of the internal surface. Abrasion of the dampeners against the washers and dowel pins resulted in a wear rate of 0.8mm³/Mc.

The findings of this study support the use of a properly selected polymer for a posterior dampener of a TSA device.