Introduction: Total spinal arthroplasty is a promising alternative to fusion because it treats the main pain generators yet also allows motion. Flexuspine’s FSU device is comprised of a metal-on-metal Core component (two paired cobalt chrome halves that allow flexion/extension, lateral bending, and axial rotation) and a posterior Dampener component (cobalt chrome rod construct with silicone dampeners, referred to as inner and outer dampeners), which provides physiological resistance to motion. Previous full range of motion (ROM) wear testing has been performed for the FSU device (Gimbel, 2010). The objective of this study was to verify the long-term durability of the device under simulated daily-use conditions and compare the wear to that observed during full ROM testing.

Methods: Wear testing of five FSU devices and a load soak control was performed for 40 million cycles (Mc) using an MTS Bionix Spine Wear Simulator. The motion profile (applied at 4 Hz) consisted of flexion between 0.5 and 2.5° and compression between 700 and 1600N. These values were calculated based on loads and motion determined during walking (Pare, 2008; Cappozzo, 1984). Testing was carried out in 30 g/L bovine calf serum at body temperature and the disc component was declined by 10° to generate shear loading. A similar testing setup was used for full ROM testing, which was performed for 10 Mc with -3/+6° of F/E and 600-2000N axial loading (Gimbel, 2010).

Results: The Core components averaged 0.01±0.01mm³/Mc during the long-term F/E testing compared with 0.66±0.10mm³/Mc during the full ROM F/E testing. The outer dampener weights increased initially for the long-term test due to fluid uptake and then averaged a wear rate of 0.02±0.02mm³/Mc per dampener compared with 0.20±0.25mm³/Mc during the full ROM testing.

Conclusions: Comparisons were made during long-term testing, which represents walking, and full ROM testing, which represents worst case F/E motion based on previous cadaver testing (Phillips, 2010). The wear rates observed in this test were greatly reduced from those observed in the full ROM testing; Core component and outer dampener wear rates during the long-term test were approximately 2% and 10%, respectively, of those observed in the full ROM testing. The wear rates during the full ROM testing were consistent with those observed for artificial disc replacements tested under similar conditions (9.78mm³/Mc for a metal/polymer disc and 4.91mm³/Mc for a metal/metal disc as found by Bushelow, 2007).

All specimens completed the long-term testing without failure demonstrating durability under these conditions. Assuming 1 million gait cycles and 125,000 significant bends occur each year (Hedman, 1990), 40Mc of the long-term testing and 5Mc of the full-ROM testing would represent approximately 40 years of clinical use. So although the wear rates were much less for the long-term testing, they become more significant when compared over a 40 year time frame due to the larger number of cycles per year (12% cobalt chrome and 80% silicone wear relative to the full ROM wear). This suggests that long-term testing and full ROM testing are both important in evaluating the overall wear of a device.