INTRODUCTION
The majority of artificial disc prostheses currently in clinical trials for treatment of degenerative disc disease include articulating bearing surfaces. The Charité artificial disc, which consists of a biconvex floating polyethylene core and two concave cobalt-chrome alloy endplates, has 17 years of clinical history.

Although there is no clinical evidence of osteolysis for the Charité artificial disc, its wear performance had not been characterized following ASTM draft standards. Local reactions to wear debris generated by hip and knee replacement devices have been shown to lead to failure of some devices via osteolysis and component loosening. The purpose of the present study was to investigate the in vitro wear characteristics of the Charité device under motion and loading conditions representative of those in the lumbar spine.

MATERIALS AND METHODS
Six of the smallest Charité artificial disc assemblies (Size 1, 7.5 mm, parallel endplates (DePuySpine, Raynham, MA)) were mounted in an AMTI (Watertown, MA) Boston hip simulator for wear testing. The endplates were held securely in fixtures with polymethylmethacrylate.

Gamma sterilized UHMWPE cores (4 year shelf life) were soaked in serum for 30 days prior to testing to allow serum absorption. The wear testing was conducted in 25% (17 g protein/l) bovine serum maintained at 37 °C and replaced every 200,000 to 300,000 cycles. Changes in core mass and height were recorded. Mass was determined using a calibrated precision balance with repeatability of 0.00002 g.

Loads and ranges of motion representative of those in the lumbar spine were applied. Test parameters from the ASTM draft for artificial disc wear testing (02/1703) were incorporated. Three implants were cycled in flexion-extension (±7.5°) while being axially rotated (±1.5°). Another three implants were cycled in left/right lateral bending (±7.5°) while being axially rotated (±1.5°). Motions were applied at the rate of 1.35 Hz. The axial load was also cycled from 900 N to 1850 N at the rate of 2.7 Hz so that the maximum axial load was achieved during maximum flexion, maximum extension, and maximum L/R bending. A total of 10 million motion cycles (20 million axial cycles) were performed. Six other UHMWPE cores were kept in 37 °C serum (same replacement schedule), three as unloaded soak controls, and three as loaded soak controls.

RESULTS
The total wear of the Charité artificial disc cores averaged 1.25 mg (0.2 to 2.1 mg) after adjustment for loaded soak controls. The total height loss (PE core after) after testing was 0.14 mm ± 0.02 mm. The cores appeared to be unchanged otherwise, except for faint scratches.

Approximately 700 particles were analyzed from the sample baths. Particle morphologies tended to be flakelike in earlier cycles and globular/granular in later cycles. The median diameter of the particles was approximately 0.2 microns, with sizes from 0.08 to 16.3 microns.

DISCUSSION
There are few artificial disc wear studies that have been reported in detail. Matthews et al [IMAST 2002] reported disc wear of 14 mg/million cycles of cobalt-chrome debris for the Maverick artificial disc (Medtronic Sofamor Danek, Memphis, TN) in the flexion-extension direction only. Delamarter et al [AAOS 2004] have reported an in vitro wear rate of 4.2 mg PE per million cycles for the ProDisc device (Spine Solutions/Synthes, New York, NY). Comparisons with these results are difficult because wear test parameters were not fully reported.

The Charité artificial discs in the present investigation showed a wear rate of 0.13 mg per million cycles. Hedman et al [Spine 1991] have estimated that 125,000 significant bends are performed annually. This investigation of 10 million cycles thus represents approximately 80 years of wear. In comparison, hips have demonstrated wear as high as 15 mg per million cycles in vivo [Heisel JBJS-A, 2004].

The majority of the wear particles in this study were submicron in size, as expected with a ball-and-socket metal-on-PE device. It is not known how much polyethylene debris can be tolerated in the disc space, but the present study shows a relatively low rate of debris generation. The osteolytic sequelae resulting from shed PE particles are associated with synovial tissues clinically, but the disc space has no synovial tissues. The adjacent neural structures, however, may present other challenges. Cunningham et al [SRS, 2003] have shown that PE debris is well tolerated by the spinal cord. In addition, the long history of the Charité disc indicates that wear debris is clinically irrelevant.

The low wear rates exhibited by the Charité artificial discs in this study may be due to its design. The Charité artificial disc allows anterior-posterior translation and rotation by sliding of the core relative to both endplates, thus possibly reducing internal shear stresses.

The results from the present study demonstrate excellent wear performance of the Charité artificial disc under loads and motions representative of those seen in the lumbar spine. Further understanding of the wear performance could be gained by simulating a spectrum of activities of daily living.