Long-Term Knee Wear Simulation Using Two Moderately Crosslinked Polyethylenes  
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INTRODUCTION
Expectations for the longevity of total knee arthroplasty (TKA) is increasing [1] and manufacturers continue to improve design and material choices to meet this demand. Wear is an important aspect of long term survival; however, most simulations evaluate 5 million cycles (Mcyc) [2,3], which may be insufficient to recreate some of the deleterious effects of long-term articulation. The objective of this study, therefore, was to evaluate two moderately crosslinked polyethylenes in a long-term TKA wear simulation. Specifically we quantified the gravimetric wear and the change in thickness of the inserts as well as monitored all of the TKA components for signs of long-term wear such as pitting, delamination, scratching, and stippling.

METHODS
Wear testing was conducted for 31.5 Mcyc using fixed bearing, cruciate retaining TKA components with identical partially conforming tibio-femoral articular geometries (Sigma™ knee system, DePuy, Warsaw IN). The femoral components and tibial trays were manufactured from CoCrMo (ASTM F1537). Tibial inserts (n=3 for each group) were composed of GUR 1020 and were either gamma irradiated at 40 kGy in a vacuum foil pouch (GVF) or gamma irradiated at 50 kGy, remelted, and then gas plasma sterilized (XLK). The inserts were presoaked in water at room temperature. Wear simulation was executed on six identical wear simulators (AMTI, Watertown, MA) at 1Hz using previously described inputs [3], which provide a larger range of motion than the ISO standard (Table 1). The devices were located according to ISO 14243-3 [2] using custom fixturing and secured with bone cement. Testing was performed in 25% bovine calf serum (Hyclone Laboratories, Logan UT) at 37±2°C with sodium azide (0.2%wt) and EDTA (20mM). At 0.5 Mcyc intervals, the components were cleaned for analysis and the serum was replaced. All components were visually inspected and photographed. Wear of the tibial inserts was determined gravimetrically at 0 Mcyc and then after each 0.5 Mcyc interval using a digital balance (XP250, Mettler-Toledo). A corrected wear value was computed by incorporating the apparent weight gain of non-articulating loaded soak controls. Finally, wear rates were calculated by linear regression and then compared between the two groups using a t-test (α=0.05). Laser scans (Metron Systems, Inc, Snoqualmie, WA) of the tibial inserts were acquired at the beginning and end of testing. The potential for wear-through was determined by quantifying the lowest point of the condylar surfaces with respect to the inferior surface using reconstructed images in GeoMagic Qualify 8 (GeoMagic, Inc., Research Triangle Park, NC).

RESULTS
Both groups maintained low wear rates through the extended wear testing (Figure 1), showing no evidence of delamination or wear-through. The wear rates (mean±sd) of the XLK group (6.1±0.5 mg/Mcyc) were significantly less than the GVF group (8.6±0.6 mg/Mcyc). Under visual inspection, the inserts primarily showed evidence ofburnishing and some scratching; the femoral components exhibited light scratching oriented in the AP direction; and the trays demonstrated no evidence of wear or stippling. Laser scans were in good qualitative agreement with contact scars and revealed more penetration in the medial condyle for both groups (Figure 2). Quantitatively, the minimum thickness of the polyethylene in the medial and lateral condyles decreased from an initial 8 mm down to 6.9 mm and 7.5 mm, respectively, for the GVF group and 7.4 mm and 7.7 mm, respectively, for the XLK group. Note, these values incorporate creep and wear.

DISCUSSION
The Sigma knee devices examined in this study functioned well in a long-term wear simulation. The wear rates generated by both groups are estimated to be below an osteolytic limit of 40 mg per year [4]. While this threshold was developed from hip penetration rates, it represents a helpful benchmark in the absence of knee-specific data. The moderately crosslinked and remelted XLK insert had superior wear performance after 31.5 million cycles of simulated gait. The penetration in the medial condyle was greater than the lateral condyle for both groups. Estimated linear penetration rates, which incorporate creep and wear, are 0.03 mm/Mcyc for GVF and 0.02 mm/Mcyc for XLK. At this rate, complete wear through would require an estimated 230 Mcyc. The two groups in this study produced very similar contact scars, but significantly different wear rates. This underscores the limitation of simply examining the 2D projections of contact scars without regard to their depth. Although we did not observe delamination or other indications of oxidation, it is important to note that the 1.5 years required to complete 31.5 Mcyc is insufficient to evaluate long-term oxidative stability. Future studies should examine the separate contributions of creep and wear as well as other factors for the long-term success of TKA including oxidative stability, fracture toughness, and fatigue strength.

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