Wear Testing Simulation Performance and Outcomes for 3DKnee™ Total Knee Prosthesis

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Introduction
The wear of ultra-high molecular weight polyethylene (UHMWPE) is a critical concern in total knee replacement (TKR) systems today. Wear is a limiting factor in the functional longevity of the bearing material, and it is also a primary contributor to the production of UHMWPE wear particles, which has been linked with premature bone resorption and implant loosening associated with osteolysis. Recent computational results of the 3DKnee™ system (figure 1) indicate low contact stresses throughout dynamic activity, which complement the design’s unique geometric balance of articular conformity and guided stability. These low contact stresses are theorized to decrease UHMWPE wear during functional activity, which would be of great benefit to the functional longevity of the design. The current report summarizes the results of a long-term wear test of the 3DKnee™ system utilizing a force-controlled TKR wear testing simulator to investigate this hypothesis in the laboratory.

Materials and Methods
Four sets of 3DKnee™ systems were prepared for wear testing on an Instron/Stanmore Total Knee Replacement Wear Testing Simulator (figure 2). Following initial laboratory assessment of implant surface roughness and weight, the four TKR systems were aligned in neutral rotation and tilt within the simulator, and the soft tissue systems of the simulator were set to provide 20N/mm of AP and 0.27Nm/deg of rotational resistance to motion, similar to the ligaments of a normal knee joint. A 25% (+0.2%NaN₃) solution of 0.5 liter bovine serum was utilized as a biological lubricant and changed every 0.5 million cycles for each station. An ISO force-controlled walking cycle (#14243-1) was programmed on the simulator at 1 cycle per second, with the study lasting approximately 3 months. Interim measurements at 0.5 million cycle intervals included femoral and UHMWPE non-contact surface profilometry for roughness, and UHMWPE weight loss (±0.1 mg) which was normalized for fluid absorption using a static loaded soaked control. Statistical significance was assigned at p<0.05.

Results

Simulator Performance: The simulator performed very well, with all stations producing statistically similar loading waveforms and motions throughout testing, in agreement with assigned ISO loading standards.

TKR Kinematics: The 3DKnee™ kinematics were in good agreement with recently published data from normal healthy knees, with tibial motions being dominated by “lateral pivoting” during mid-to-late stance. Dynamic walking cycle tibial motions ranged from 0.8±0.2 mm anteriorly to 2.5±0.2 mm posterior, and tibial rotations ranged from 8.3±0.3 deg. internally to 0.7±0.4 deg. externally, and these ranges were maintained throughout the 5 million cycle wear test.

UHMWPE Wear: The UHMWPE inserts exhibited a very low wear rate, averaging 4.4 (+/−3.0) mg per million cycles between 0 to 5 million cycles. Figure 3 shows that this wear rate compares very favorably with other TKR wear testing data in the published literature.

Discussion
The low wear rates seen in the 3DKnee™ complement the earlier findings of low contact stresses at the bearing surface during functional activity. The polished wear areas on the UHMWPE surfaces became polished and showed clear evidence of a “lateral pivot” motion pathway, while the femoral component showed only minor scratching, and no pitting or delamination. The femoral surfaces roughened slightly during testing, as expected. Wear patterns on the conforming lateral condyle were laterally crescent shaped, while on the wider medial condyle they were centered in the A/P direction (fig. 4).

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