INTRODUCTION: The need to critically evaluate the efficacy of current total knee replacement (TKR) wear testing methodologies is great. Proposed international standards for TKR wear simulation have been drafted, yet their validity continues to be debated. The “gold standard” to which all wear testing methodologies should be compared is the measured in vivo TKR performance of the patient population. With the exception of retrieval analyses, few detailed comparisons of in-vitro vs. in-vivo TKR performance have been performed to date. The current study compares simulator TKR wear testing kinematics to measured in vivo TKR kinematics to evaluate the validity of the proposed ISO force-controlled wear testing methodology.

MATERIALS AND METHODS: All patients who were scheduled for their one year post-op clinical visit (n=28) were solicited, and seven subjects with 8 PCL retaining TKRs of the same design (Natural Knee II, Standard Congruent, Sulzer Orthopaedics, Austin, TX) gave informed consent to participate. All patients had good to excellent HSS scores. The subjects were on average, 75 years old (64-88 years), weighed 72 kg (51-84 kg), were 167 cm tall (152-185 cm), and were 13 months post-op (11-15 months). Lateral video fluoroscopy recorded TKR level treadmill walking motions at 30 frames/s. Four gait cycles were recorded and processed for each knee. Knee kinematics were determined using model based shape matching techniques to an accuracy of ±1 deg. and ±0.5 mm. The anterior/posterior (AP) locations of tibio-femoral contact were estimated from the femoral condyle points closest to the tibial baseplate.

At a different institution, 4 NKII size 3 femoral/tibial implants were installed and worn tested to 5 million gait cycles at 1 Hz on the Instron/Stanmore knee simulator using the proposed 1999 ISO force-control testing standard, #14243. In vivo capsular strains were simulated with 20N/mm AP and 0.27Nm/deg. axial rotational (IE) springs, and a 50% (+0.2%N,N) bovine serum lubricant used during testing. All simulator TKR components were aligned in zero (neutral) AP displacement and IE rotation with respect to the tibial mid-line at zero degrees femoral flexion. After every 10⁶ cycles of testing, the lubricant was replaced and TKR kinematics were recorded. At 2 million cycles, the kinematics from 10 complete gait cycles were isolated and averaged for comparison with the in vivo data.

Both the simulator and fluoroscopic kinematic data were fit to a stance phase of gait between 0-68%, and a swing phase between 69-99% of a walking cycle. For interstudy tribological comparisons, measures of femoral flexion, tibial IE rotation, global tibial AP displacement, medial and lateral condylar contact (MCC and LCC) displacements, and total angular rotational travel and/or linear distance travel per cycle were calculated. Statistical comparisons were assessed using Students-T tests (p<0.05).

RESULTS: Four “active” TKR patients, with statistically higher treadmill speeds (0.76 vs. 0.39 m/s, p<0.04) and a slower cadences (89 vs. 102 steps/min, p<0.02), were isolated for statistical comparison with the simulator data. This increased activity level better reflected that of the experimental subjects from whom the ISO simulation standards are primarily based; namely young, surgically intact patients[2], and decreased the variability of the in vivo data. The in vivo and simulator data showed statistically similar kinematic patterns, ranges of motion, and total travel distance/cycle during walking. Both sets of data showed that the TKR design pivots around its lateral condyle, with statistically similar average centers of rotation located 1.5±17mm and 10.5±15mm lateral to the tibial center (in vivo and simulator respectively). The kinematic patterns of the in vivo knees exhibited 6-8° of surgically induced femoral external rotation with respect to the M/L midline. This constrained the in vivo kinematics causing in vivo MCC to occur on the anterior half of the tibial insert, and LCC to occur on the posterior half (figure 1). The simulator TKRs were aligned in neutral rotation, and MCC and LCC remained centered around the tibial M/L midline during motion. This allowed the simulator TKRs a greater IE rotational span (7.5 vs. 5.6 deg., p<0.03) during stance than in vivo. Even with this rotational alignment difference, the kinematic trends of the two groups are very similar, with 87%, 53%, 73%, 31%, and 87% of the gait cycle kinematic magnitudes being statistically similar for flexion angle, IE rotation, global tibial AP translation, MCC and LCC respectively. By shifting the in vivo data 6 degrees about the center of rotation to correct for surgical alignment, these values jump to 87%, 100%, 84%, 89%, and 100% respectively. The computed measures of angular and linear travel/cycle (table 1) show that tribologically the in vivo and simulator kinematics subject the implant material to statistically similar wear travel distances per cycle, and that the kinematic spans of this travel are statistically similar as well (except for LCC in both measures, p<0.05).

DISCUSSION: The “active” patient group was hypothesized to be more likely to produce wear in vivo and was therefore isolated for comparison with the simulator data. Statistically however, the two patient groups had similar kinematic spans and travel distances for all reported measures (p<0.05). The surgical rotational alignment was shown to be a primary variable affecting the in vivo and simulator comparison. Extreme care should be undertaken during simulation to align TKR designs in a manner reflecting the in vivo case. Imposed or unintentional TKR alignments can alter implant kinematics and could ultimately lead to shortened implant longevity. To complete this data set, future work will compare the in vivo wear retrieval results to the simulator wear data from this study. This study's statistical findings offer support for the validity of the simulation of in vivo walking cycle wear kinematics can currently be achieved with a force controlled testing methodology.


Table 1: Kinematic Travel/cycle and Span of the data sets. (* = statistically different from in vivo data, p<0.05)

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