Modelling Total Knee Replacement Polyethylene Wear *in Silico*: Model Verification and Validation

Jack L. Yang[1], Markus A. Wimmer[2], Hannah J. Lundberg[2], Steven P. Mell[2]
[1]Carle Illinois College of Medicine, Urbana, IL, [2]Rush University Medical Center, Chicago, IL
jackly2@illinois.edu

Disclosures: Jack L. Yang (N), Markus A. Wimmer (5-Zimmer Biomet), Hannah J. Lundberg (6-Zimmer Biomet), Steven P. Mell (N)

INTRODUCTION: Total knee replacement (TKR) is widely used to treat end-stage osteoarthritis, in which even low per-patient failure rates translate into a substantial absolute burden of implant failure. With newer materials lowering clinically reported wear, registry classifications may nonetheless mask particulate-driven loosening and inflammation over the long term [1]. The American Joint Replacement Registry attributes only 3.9% of revisions to wear particle–induced osteolysis; however, nearly 50% are classified as aseptic loosening or noninfectious inflammation, suggesting underreporting of particulate-driven failures [2]. In addition, preclinical wear testing remains required for FDA clearance, though current ISO standards only test a single implant size under one loading profile, limiting real-world relevance. *In silico* wear modeling offers a way to supplement mechanical testing by rapidly evaluating implant designs, patient-specific loading, surgical variability, and edge cases not captured by standard testing of 'average' conditions. This study aimed to assess a computational wear model within the ASME V&V 40 framework [3], evaluating both regulatory-grade credibility and potential as a preclinical decision-support tool for industry.

METHODS: A finite element analysis (FEA) wear model for cruciate-retaining TKRs [4–8] was assessed using the ASME V&V 40 risk-informed credibility framework. Code verification compared FEA outputs (volumetric wear, spatial distribution of wear on the bearing surface, linear penetration depth, and contact area) against analytical [9] and Python-based numerical solutions for both TKR and pin-on-disk (POD) models. Solution verification included a mesh convergence study using simplified wheel-on-flat geometry (seed sizes: 0.7–2.0 mm) to replicate rolling, sliding, and cross-shear behavior with volumetric wear as the primary output. Sensitivity analyses evaluated several modeling choices: 1) cycle partitioning, comparing two 500k-cycle runs to a single 1M-cycle run, 2) material model choice (J2 Plasticity model [10] vs. linear-elastic), and 3) polyethylene fibril orientation, comparing uniform anterior-posterior alignment versus an initial pre-analysis of node-specific directions (Figure 1). Experimental validation was performed against multiple datasets, including gravimetric wear from pin-on-disk and wheel-on-flat tests, short-term simulator wear scar mapping with tibial rotation varied from 25° external to 25° internal in 5° increments (n=11), and long-term mechanical knee simulator tests under three kinematic conditions (ISO 14243-3:2004, ISO 14243-3:2014, and population-average stair ascent) to evaluate the model's ability to predict cumulative volumetric wear, spatial wear scar morphology, and medial-lateral wear distribution over 3 million cycles.

RESULTS: Code verification: There was strong agreement between FEA, analytical, and numerical results, all within one standard error of POD experimental wear rates (8.41 ± 0.12 mg/million cycles) (Figure 2A). Solution verification: Mesh convergence confirmed stable volumetric wear predictions across all seed sizes (0.7, 1.0, 1.5, and 2.0 mm); spatial wear distributions were consistent across mesh densities, with a 0.9 mm global seed chosen to balance accuracy and efficiency (Figure 2B). Sensitivity analyses showed minimal effect from cycle partitioning (0.67% wear difference between 2×500k vs. 1×1 million cycles), but higher wear when using an elastic-plastic model (+9.4%) and when incorporating initial fibril orientation (+34%). Experimental validation: Short-term simulator wear scars closely matched experiments, capturing key morphological features, and long-term simulator studies demonstrated strong correlation with gravimetric wear ($R^2 = 0.84$) (Figure 2C). Predicted medial-lateral wear distribution and progression patterns were consistent with experimental data.

DISCUSSION: Model risk was rated medium under ASME V&V 40, indicating moderate influence and consequence. The model reliably predicts wear but should complement, not replace, other preclinical evaluations. Accurate replication of experimental wear rates and scar morphology supports its credibility for preclinical testing and hypothesis-driven research. Key findings highlight the need to initialize fibril orientation and account for plastic deformation for improved accuracy. Cycle partitioning minimally impacted outcomes, most likely due to the modeling choice to ablate material during simulation progression. Future work will focus on uncertainty quantification and validation under extreme implant alignment scenarios to further enhance regulatory readiness and potential application in probabilistic modeling studies and virtual clinical trials [11].

SIGNIFICANCE: By reliably reproducing experimental and clinical wear patterns, this *in silico* framework provides manufacturers with a preclinical decision-support tool that can accelerate TKR design iteration, reduce reliance on simulator testing, and generate regulatory-grade digital evidence. With appropriate verification and validation, *in silico* models have the potential to shorten development timelines while improving implant safety and longevity.

REFERENCES: [1] Asher et al. Arthroplasty Today 2024. [2] AJRR Annual Report AAOS (2024). [3] V&V 40 ASME (2018). [4] Mell et al. J Eng Med 2018. [5] Mell et al. J Biomech 2019. [6] Mell et al. Lecture Notes Comput Vision Biomech 2020. [7] Mell et al. JOR 2020. [8] Mell et al. JMBBM 2022. [9] Schwenke et al. Wear 2013. [10] Bergström et al. Biomaterials 2002. [11] Mell, S. P. et al. JBJS 10.2106/JBJS.23.01236 (2024)

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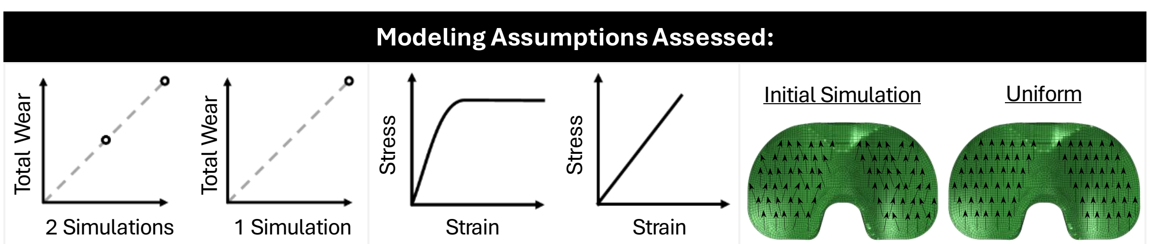

Figure 1. Assessments of the sensitivity of wear predictions to modeling assumptions, including (but not limited to) comparison of partitioning simulation cycles (i.e., number of simulations to reach 1,000,000 wear cycles), material constitutive models, and initial fibril orientation.

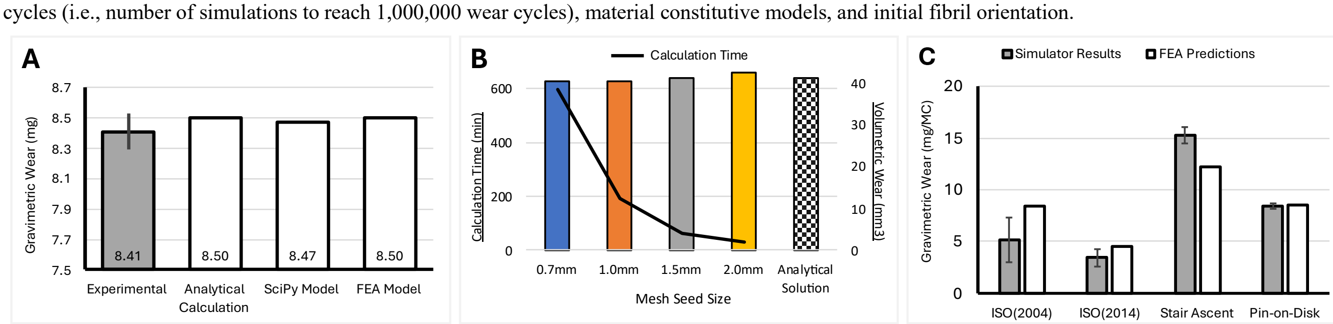

Figure 2. Verification and Validation of the Computational Wear Model: (**A**) code verification results, (**B**) mesh convergence study results, and (**C**) model validation against long-term simulator experiments.