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Increased Conformity Offers Diminishing Returns for Reducing Total Knee Replacement Wear

Wear remains a significant problem limiting the lifespan of total knee replacements (TKRs). Though increased conformity between TKR components has the potential to decrease wear, the optimal amount and planes of conformity have not been investigated. Furthermore, differing conformities in the medial and lateral compartments may provide designers the opportunity to address both wear and kinematic design goals simultaneously. This study used a computational model of a Stanmore knee simulator machine and a previously validated wear model to investigate this issue for simulated gait. TKR geometries with different amounts and planes of conformity on the medial and lateral sides were created and tested in two phases. The first phase utilized a wide range of sagittal and coronal conformity combinations to blanket a physically realistic design space. The second phase performed a focused investigation of the conformity conditions from the first phase to which predicted wear volume was sensitive. For the first phase, sagittal but not coronal conformity was found to have a significant effect on predicted wear volume. For the second phase, increased sagittal conformity was found to decrease predicted wear volume in a nonlinear fashion, with reductions gradually diminishing as conformity increased. These results suggest that TKR geometric design efforts aimed at minimizing wear should focus on sagittal rather than coronal conformity and that at least moderate sagittal conformity is desirable in both compartments.
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Keywords: *total knee arthroplasty, biomechanics, wear simulation*

1 Introduction

Polyethylene wear remains an important factor limiting the longevity of total knee replacements (TKRs) [1–3]. Wear particles liberated from the polyethylene tibial insert can induce osteolysis (i.e., bone resorption caused by upregulation of osteoclast activity [4,5]) which in turn can lead to component loosening [6]. Though TKR survivorship has been reported to be 78% at 15 years [7], improved wear performance is becoming increasingly important as younger, more active patients are implanted [8]. Ideally, the implant should outlive the patient while not limiting function. TKR damage and survivorship have been reported to be worse in younger than in older patients [9], causing many younger patients to limit the physical activities in which they participate.

Increased conformity between the femoral component and tibial insert has been proposed as a means for reducing wear [1,10–13]. Increased conformity in well-aligned implants reduces contact stresses on the polyethylene tibial insert [14–16]. These contact stress reductions are believed to result in reduced polyethylene wear [13], since adhesive and abrasive wear is due to the combined effect of contact stress and sliding conditions. As a side benefit, increased conformity has also been reported to improve the stability of the implant [17]. However, other studies have reported that increased conformity may have little effect on polyethylene wear volume [18,19], possibly because the decrease in contact stress is counteracted by an increase in contact area subjected to sliding. Furthermore, increased conformity has potential disadvantages such as increased contact stress if the components are malaligned [20–22], increased wear due to easier entrapment of wear particles between the articular surfaces [16], and increased component interface stresses [12,13,23]. Thus, one of the challenges of TKR design is to determine the conformity conditions that strike a balance between these potential advantages and disadvantages.

Testing of TKR designs with different amounts of conformity has historically been performed using knee simulator machines, such as the Stanmore and AMTI machines as well as custom designed machines [24–27]. Such tests are useful for screening new TKR designs and comparing the wear performance of different designs. However, testing of a single design typically costs tens of thousands of dollars and requires several months to complete. Furthermore, for any particular design, variability of motion and load inputs as well as positioning of the components in the machine can have a significant influence on the resulting wear volume [28]. These factors make it difficult to compare wear performance for different TKR designs, and no studies can be found

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in the literature where head-to-head wear evaluation of a large number of design variations has been performed experimentally.

For these reasons, recent studies have sought to develop computational models of knee simulator machines to speed up and improve the implant design process [29–33]. Such models are able to generate wear predictions in a matter of minutes or hours for new TKR designs, rather than months as with physical wear testing. Recent studies have investigated whether the wear depths, areas, and volumes predicted by such models are accurate when compared with experimental wear results obtained from the same implant design subjected to the same motion and load inputs. These studies have revealed that a sequence of wear simulations, where the tibial insert geometry is worn progressively from one simulation to the next, is required to predict wear depths and areas accurately, whereas a single simulation performed with "virgin" insert geometry is capable of predicting wear volume accurately [29,31]. Computational models can therefore provide a cost effective, time efficient, and well controlled complement to physical wear testing for evaluating how TKR geometry alternations (e.g., changes in conformity) affect resulting wear performance. In particular, computational models can make it possible to evaluate systematically a wide range of geometric designs to identify the geometric parameters to which wear volume is most sensitive.

This study used a validated computational model to assess the effect of varying TKR conformity on polyethylene wear volume [29,34]. The three-dimensional computational model, which mimicked a Stanmore knee simulator machine performing a simulated gait motion, was used to perform wear simulations in two phases. The first phase blanketed a wide range of TKR conformity conditions, while the second phase performed a more focused investigation of the conditions to which wear volume was sensitive. Use of a computational rather than experimental approach facilitated rapid evaluation of this large range of geometric designs. The hypothesis tested was that wear volume would decrease nonlinearly with increased sagittal but not coronal conformity due to a corresponding nonlinear reduction in sliding motion. The results provide general design guidelines for when increased sagittal and coronal conformity may, and may not, be valuable for reducing wear volume in total knee replacements.

2 Methods

2.1 Stanmore Simulator Machine Model. A computational model of a Stanmore knee simulator machine was constructed in the Pro/MECHANICA MOTION (Parametric Technology Corporation, Waltham, MA) multibody dynamics simulation environment (Fig. 1). The tibial component in the model was allowed to translate freely in the medial-lateral (ML) and anterior-posterior (AP) direction and was allowed to rotate freely around a superior-inferior (SI) axis. The femoral component was allowed to translate freely in the SI direction and rotate freely around an AP axis. These degrees of freedom were the same as in the real simulator machine except for two minor modifications. In the actual machine, SI translation is accommodated on the tibial rather than the femoral side, and tibial translations are achieved via sagittal and coronal plane rotations about a point far below the tibial component rather than via transverse plane translations. Other studies have used the same modeling idealizations used here to develop computational simulations of the Stanmore machine [17,35].

One-cycle dynamic gait simulations were performed with the computational model using International Standards Organization (ISO) standard motion and load inputs for the Stanmore machine (ISO 14243-1, 2000). An AP control force and internal-external (IE) control torque (i.e., directed about an SI axis) were applied to the tibial component, while an SI control force was applied to the femoral component. Flexion of the femoral component was prescribed about the femoral flexion axis. Soft tissue restraints were simulated by attaching two spring bumpers to the anterior and posterior sides of the tibial component. The springs were attached

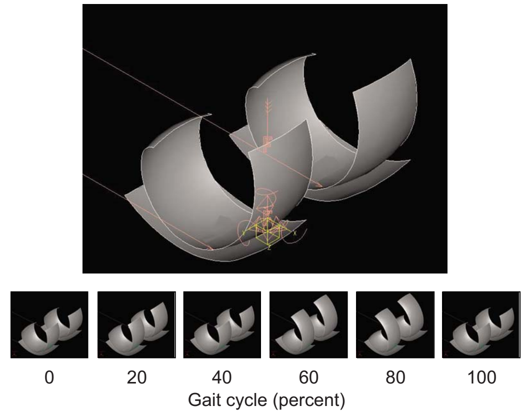

Fig. 1 Computational model of a Stanmore knee simulator machine constructed in Pro/MECHANICA MOTION showing idealized femoral and tibial articular geometry from one of the tests. Multiple time frames over the gait cycle are displayed to illustrate the predicted motion of the components during a dynamic simulation.

at the same locations as in the actual simulator machine, and the stiffness of each bidirectional spring was set to 14.48 N/mm for an effective stiffness of 28.96 N/mm [24].

Contact pressures between the femoral component and tibial insert were calculated using a custom elastic foundation model incorporated into the Pro/MECHANICA MOTION simulator machine model [36,37]. Geometry evaluations required by the model were performed using the ACIS 3D Toolkit (Spatial Corporation, Westminster, CO). To prevent excessive interpenetration, the contact model utilized springs distributed uniformly over the articulating surfaces of the tibial insert, where each spring was treated as independent from its neighbors and was associated with a single tibial surface element of known area. The contact pressure p for each element was calculated from [38,39]

$$p = \frac{(1-\nu)E}{(1+\nu)(1-2\nu)}\frac{d}{h} \tag{1}$$

where E is Young's modulus of the elastic layer (463 MPa [14]), ν is the Poisson's ratio of the elastic layer (0.45 [40]), h is the layer thickness at the element location (average value of 10 mm across the insert), and d is the element's spring deflection, defined as the interpenetration of the undeformed surfaces in the direction of the local surface normal. The distance d for each element was computed at each time instant from the relative position and orientation of the femoral component with respect to the tibial insert. Individual element pressures were converted into element forces using the known area of each element, and these forces were treated as equal and opposite loads applied to the articulating surfaces during a dynamic simulation.

Wear volume for each dynamic gait simulation was calculated using the predicted time histories of contact pressures and sliding conditions for each tibial insert surface element (Fig. 2). Over the course of a one-cycle simulation, the total depth of material removed from an element δ_{Wear} was predicted using Archard's classic law for mild wear [41]

$$\delta_{\text{Wear}} = k\sum_{i=1}^{n} p_i |v_i| \Delta t_i \tag{2}$$

where k is the material wear rate (representative value of 1×10^{-7} mm^3/N m [42–45]), i is a discrete time frame within the one-cycle simulation, n is the total number of time frames, p_i is the element contact pressure at instant i, $|v_i|$ is the magnitude of the element's relative sliding velocity at instant i, and Δt_i is the time increment used in the analysis [34]. Wear volume for each

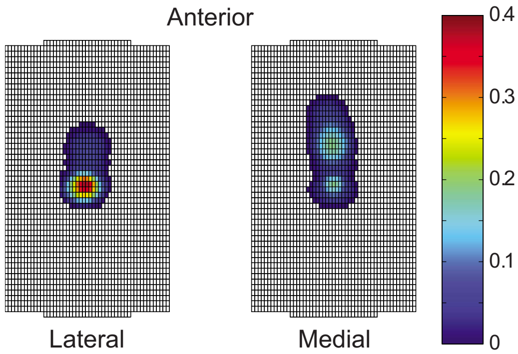

Fig. 2 Wear scars and depths (in mm) predicted by the computational model for the implant geometry and simulation shown in Fig. 1

surface element was calculated by multiplying element wear depth by element area, and total wear volume was calculated by summing element wear volumes over all surface elements. One-cycle wear volume was extrapolated out to 5×10^6 cycles, representative of the total number of cycles commonly used for testing in a simulator machine.

2.2 Computational Wear Tests. Computational wear testing was performed in two phases using tibial and femoral geometries representing a wide range of sagittal and coronal conformities. All geometries were created using SolidWorks computer-aided design software (SolidWorks Corporation, Concord, MA). Idealized femoral component geometry was constructed using a sagittal profile with three distinct radii and a coronal profile with a single radius. The sagittal geometry was kept constant for all tests, with contact occurring only on the 21.55 mm radius during simulated gait. Idealized tibial insert geometry was constructed using a sagittal and coronal profile each with a different single radius. Conformity in each plane was defined as the femoral radius divided by the tibial radius [15], with all conformity changes created by changing the tibial geometry.

Phase one tests utilized a matrix of sagittal and coronal conformities to blanket a broad design space representative of contemporary knee replacement geometries. The matrix consisted of three femoral coronal radii (20, 40, and 80 mm), six combinations of coronal and sagittal conformity varied separately on the medial side, and two combinations of coronal and sagittal conformity varied together on the lateral side (Table 1). A wider range of conditions was modeled on the medial side than on the lateral side to keep the phase one test matrix to a reasonable size.

Phase two tests involved detailed analysis of the conformity conditions in phase one to which predicted wear volume was sensitive. All phase two sensitivity tests were variations away from a nominal case utilizing sagittal and coronal conformity of 0.5 in both compartments and the intermediate femoral component coronal radius of 40 mm. Starting from this nominal case, sagittal conformity was increased and decreased incrementally in the medial and lateral compartments separately and together (Table 2), with no changes made to coronal conformity. In addition, coronal conformity was increased and decreased in both compartments together without varying sagittal conformity to confirm the lack of sensitivity to geometry variations in this plane (Table 3).

3 Results

For the phase one tests, sagittal but not coronal conformity significantly affected predicted wear volume (Figs. 3 and 4). When lateral compartment coronal and sagittal conformity were 0, wear volume exhibited little change as medial compartment sagittal conformity increased from 0 to 0.91 (Fig. 3). In contrast, when lateral compartment coronal and sagittal conformity were 0.5, wear volume decreased as medial compartment sagittal conformity increased from 0 (i.e., flat) to 0.91 (i.e., high conformity). However, the decrease from 0 to 0.5 (i.e., moderate conformity) was much larger than that from 0.5 to 0.91 (Fig. 4). Regardless of the values of medial and lateral sagittal conformity, changing medial coronal conformity from 0 to 0.5 had little impact on predicted wear volume. Changing the femoral component coronal radius from 20 mm to 80 mm also had little impact.

Table 1 Matrix of 36 different combinations of medial and lateral coronal and sagittal conformities used for the phase one tests. Femoral component sagittal profile was constant for all tests. In either direction, conformity of 0 corresponds to a flat tibial insert (nonconformal), 0.50 to a ratio of radii of 2:1 (moderately conformal), and 0.91 to a ratio of radii of 1.1:1 (highly conformal).

Femoral coronal radius (mm)	Medial coronal conformity	Medial sagittal conformity		Lateral conformity
20	0.0	0.00		
20	0.0	0.50		
20	0.0	0.91		
20	0.5	0.00		
20	0.5	0.50		
20	0.5	0.91		
40	0.0	0.00		
40	0.0	0.50		
40	0.0	0.91		
40	0.5	0.00	+	Coronal and sagittal conformity of 0.0 or coronal and sagittal conformity of 0.5
40	0.5	0.50		
40	0.5	0.91		
80	0.0	0.00		
80	0.0	0.50		
80	0.0	0.91		
80	0.5	0.00		
80	0.5	0.50		
80	0.5	0.91		

For the phase two tests, changes in sagittal conformity in one or both compartments resulted in nonlinear changes in wear volume (Figs. 5–7). When sagittal conformity was changed in either compartment from its nominal value of 0.5, large increases in wear volume occurred as sagittal conformity decreased toward 0 (i.e., less conformal), while only small decreases occurred when it increased toward 0.75 (i.e., more conformal). When only medial sagittal conformity was changed, little change in lateral compartment wear volume occurred (Fig. 5). A similar situation occurred when only lateral sagittal conformity was changed and medial sagittal conformity was held constant (Fig. 6). The largest wear volume changes occurred when sagittal conformity was varied in both compartments together (Fig. 7). Changes in coronal conformity in both compartments together resulted in little change in wear volume.

4 Discussion

This study used a validated computational wear model to investigate the influence of sagittal and coronal conformity on wear volume in an idealized total knee replacement design. The design was representative of the features present in contemporary knee designs and was tested in a computational model of a Stanmore knee simulator machine. The tests were performed in two phases, where the first phase blanketed a wide variety of TKR sagittal and coronal geometry combinations, while the second phase focused on conformity conditions from the first phase to which wear volume was found to be sensitive. Overall, wear volume was much more sensitive to sagittal than coronal conformity changes and decreased nonlinearly with corresponding reductions in sliding motion, consistent with our original hypothesis. This sensitivity was evident only when the medial and lateral compartments had different sagittal conformities. Furthermore, at least moderate sag-

Table 2 Sagittal conformity combinations used for the phase two tests. Sagittal conformity of the nominal design was varied three ways: in the medial compartment only, in the lateral compartment only, and in both compartments together.

Femoral sagittal radius (mm)	21.55	21.55	21.55	21.55	21.55	21.55	21.55	21.55
Tibial sagittal radius (mm)	Infinite	172.40	114.88	86.20	68.96	57.47	43.00	28.73
Conformity	0.0	0.125	0.188	0.250	0.313	0.375	0.500	0.750

ittal conformity was needed in both compartments to minimize wear volume. Though not completely unexpected, these findings may be useful for improving the wear resistance of future TKR geometric designs.

The nonlinear relationship between sagittal conformity and wear volume reflects an underlying linear relationship between AP translation range, IE rotation range, and wear volume. When sagittal conformity is changed, the relative kinematics between the femoral component and tibial insert change as well. The most obvious changes are in the range of AP translation and IE rotation. To investigate the relationship between wear volume and these kinematic ranges, we performed a two-variable linear regression analysis in MATLAB (The Mathworks, Natick, MA). We found that for each of the three phase two tests, the R^2 value was 0.95 or higher, indicating that these two kinematic ranges are excellent predictors of wear volume. This finding helps explain why at least some sagittal conformity is needed in both compartments to reach the "diminishing returns" portion of the phase two wear volume versus sagittal conformity curves (Figs. 5–7).

Our computational results are in contrast to a previous in vitro simulator study that investigated the influence of sagittal conformity on wear volume [19]. In that study, wear volume was measured for two TKR designs—an existing design and a modified version in which the posterior sagittal radius of the tibial insert was increased (i.e., the design became less conformal). The authors found that experimentally measured wear volumes from the

Table 3 Coronal conformity combinations used for the phase two tests. Coronal conformity of the nominal design was varied in both compartments together.

Femoral coronal radius (mm)	40.00	40.00	40.00	40.00
Tibial coronal radius (mm)	Infinite	160.00	80.00	53.33
Conformity	0.0	0.25	0.50	0.75

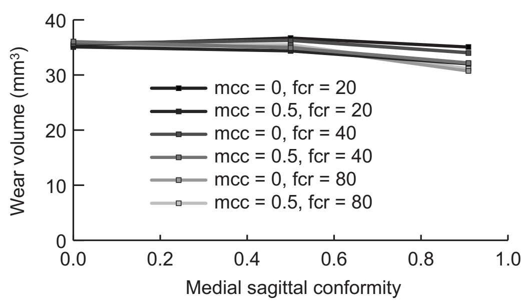

Fig. 3 Phase one tests: wear volume as a function of changes in medial sagittal conformity when coronal and sagittal conformity on the lateral side are 0. In the legend, "mcc" indicates the medial coronal conformity, while "fcr" indicates the femoral coronal radius in mm.

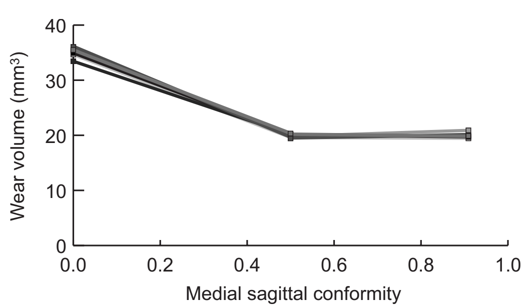

Fig. 4 Phase one tests: wear volume as a function of changes in medial sagittal conformity when coronal and sagittal conformity on the lateral side are 0.5. Lines are the same as in Fig. 3.

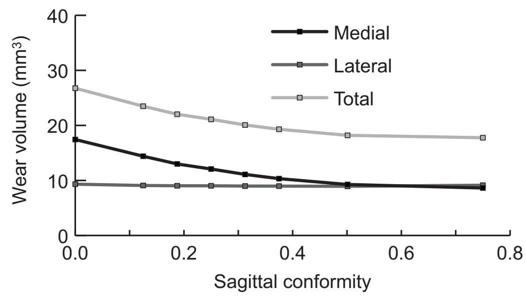

Fig. 5 Phase two tests: wear volume as a function of changes in sagittal conformity of the nominal design when medial sagittal conformity was varied and lateral sagittal conformity was held constant.

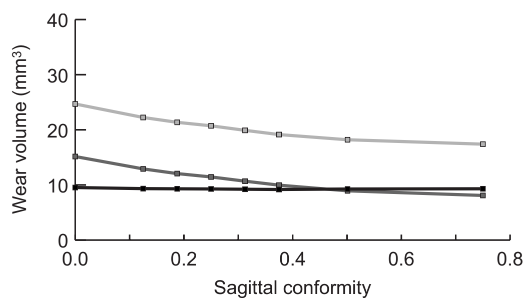

Fig. 6 Phase two tests: wear volume as a function of changes in sagittal conformity of the nominal design when lateral sagittal conformity was varied and medial sagittal conformity was held constant. Lines are the same as in Fig. 5.

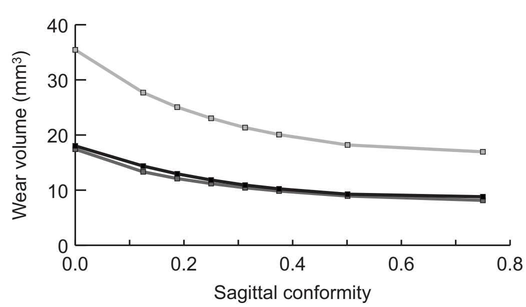

Fig. 7 Phase two tests: wear volume as a function of changes in sagittal conformity of the nominal design when medial and lateral sagittal conformity were varied together. Lines are the same as in Fig. 5.

two designs were not statistically different. There are two possible explanations why these results differ from those of our study. First, the in vitro study used a displacement-controlled simulator machine with prescribed AP translation and IE rotation. For this situation, the linear regression relationship developed from our computational simulations (see above) would predict no change in wear volume for the two insert designs. Second, the in vitro study did not specify the tibiofemoral sagittal conformity for the two designs, and it is possible that both designs were in the diminishing returns portion of the sagittal conformity range.

Our predicted AP displacement ranges as a function of sagittal conformity compare favorably with experimental measurements made on an actual Stanmore simulator machine [24]. That study investigated how TKR geometric design influences the resulting kinematics. To evaluate whether our computational predictions were reasonable, we calculated AP displacement range and sagittal conformity for the designs used in that study and plotted them against predictions from our study. For sagittal conformities greater than 0.2, the agreement between our predicted AP displacement range and that measured in Ref. [24] was excellent. For sagittal conformities below 0.2, our predicted AP displacement ranges were higher than those measured in Ref. [25], possibly due to "bottoming out" of the spring bumpers in the physical simulator machine.

The computational approach used in our study to predict wear volume changes as a function of conformity changes could be implemented as part of the design process utilized by orthopedic implant companies. Implant designers could generate a wide range of geometry variations for initial investigation, similar to our phase one study, to screen design variations under consideration. They could then use those results to determine the most promising design parameters on which to focus for a more detailed investigation, similar to our phase two study. By following this process, implant designers could minimize the creation and testing of physical prototypes for designs that would likely exhibit poor wear performance. Once an optimal design was identified, a physical prototype of this design could be tested in a knee simulator machine and the resulting wear volume compared with that of a nominal design, thereby providing a means for experimental validation of the final proposed design.

If such a design approach was followed, it would be critical to perform the physical validation tests on the same type of simulator machine as used in the computational study. In particular, when studying the effects of conformity on wear volume, a simulator machine should be chosen for which AP translation and IE rotation are load controlled rather than motion controlled. It would also be critical to ensure that the motion and load outputs produced by the simulator machine closely matched those of the computational study. The effect of errors in motion and load outputs on the measured wear volume could be estimated by performing a Monte Carlo analysis using recently reported "ultrafast" contact modeling techniques that are capable of performing wear simulations in a matter of seconds rather than minutes [28,46]. In this way, whether or not the measured wear volume was consistent with the computational prediction could be assessed objectively.

Even though idealized geometries were used in this study, they still provide valuable insight into the effect of sagittal and coronal conformity changes on wear volume. Retrieval studies have attempted to analyze the effect of conformity on wear in retrieved tibial inserts, but few studies have looked at explicit quantitative changes in sagittal and coronal conformity [1,11,47]. The results from the present study suggest that increased conformity can reduce wear, something that has been suggested by previous studies [1,10–13,15]. Several retrieval studies have shown that more conformal inserts tend to reduce wear [1,11]. However, quantitative conclusions on exactly what type of conformity, and how much, are needed to decrease wear volume significantly are hard to draw from retrieval studies. The main reason is confounding factors such as unknown patient activity levels, differing UHMWPE manufacturing techniques, and a lack of detailed information about the conformity of the retrieved implants. Finite element (FE) studies have shown that increased conformity can lead to decreased stresses if the components are properly aligned [14–16]. Though decreased contact stress has been linked to a decrease in wear rate [48], the corresponding increase in contact area subjected to sliding may result in little net change in wear volume [18]. The present study supports that hypothesis for sagittal conformities greater than about 0.5.

Minimizing wear is not the only goal when developing TKR geometric designs. Other factors such as interface stresses and laxity are important as well. On the one hand, increased conformity appears to decrease mild wear in a nonlinear diminishing fashion, which is beneficial, while on the other hand, it increases interface stresses and decreases laxity, which may be detrimental [23]. A recent in vivo study using instrumented knee implants demonstrated that golf in particular requires high rotational laxity, making high conformity undesirable for this task [49]. Thus, the geometric design recommendations arising from this study must be interpreted within the larger scope of potentially competing design goals, and the various trade-offs must be weighed carefully by the orthopedic implant design engineer.

The results of our study should not be surprising given knowledge available from previous studies. A change in conformity results in altered contact pressure, contact area, and kinematics [15,50,51]. Increased conformity has been reported to decrease contact pressure [15,51]. Thus, one might expect wear volume to decrease with increased conformity in a similar manner. However, for fixed kinematics, a previous simulation study reported that decreasing the contact pressure by increasing the insert thickness produced no change in wear volume calculated using Archard's wear law [18]. The potential reduction in wear volume resulting from decreased contact pressure was cancelled by a corresponding increase in contact area subjected to pressure and sliding. In the present study, contact pressure was decreased and contact area increased by increasing conformity rather than insert thickness. Consequently, conformity affected wear volume by changing AP translation and IE rotation rather than by changing contact pressure. Since one would expect these two kinematic quantities to decrease nonlinearly as conformity is increased, it was reasonable to hypothesize that wear volume would follow a similar trend. Further investigation is required to understand more fully the relationship between the radii of the contacting geometries and the amount of translational and rotational constraint.

Our computational study possesses several limitations. One limitation was that wear volume predictions for 5×10^6 cycles of simulated gait were generated by extrapolating one-cycle wear results for virgin geometry. Thus, the surface geometry of the insert was not worn gradually by the model as in real life, since simulation of progressive surface wear is much more demanding computationally. However, two previous computational studies of knee simulator machines have shown that wear volume predictions, but not wear depth and area predictions, are insensitive to whether or not the surface geometry is changed progressively over a sequence of simulations [29,31]. Predicted wear volume has also been shown to be insensitive to whether the tibial insert is treated as a linear or nonlinear elastic material and whether or not a creep model is included in the wear prediction process [29]. Thus, extrapolation of one-cycle wear volume results out to 5×10^6 cycles appears to be appropriate for design purposes, since osteolysis is a function of wear volume rather than wear depth or area. In contrast, progressive wear simulation is needed when attempting to validate proposed damage models using experimental measurements of damage volume, area, and depth.

Another limitation of our wear prediction methodology was the use of a constant wear factor. The selected value of 1×10^{-7} mm^3/N m was chosen as representative of the range of values reported in the literature (approximately 1×10^{-6} to

1×10^{-8} mm^3/N m [42–45]). Since wear volume in our model is a linear function of the selected wear factor, increasing or decreasing the wear factor would scale all of our wear volume results up or down proportionally. Though wear factors can increase with cross shear [52], we used a constant wear factor since cross shear is generally minimal in TKR designs [53] and since a previous computational study produced excellent agreement with experimental wear volume measurements using a constant wear factor [29]. In our computational simulations, the designs that rotated the most (i.e., the less conformal designs) had the worst wear volumes. Causing the wear factor to increase as a function of cross shear would only increase wear volume further for these designs and would not change our general conclusions.

A limitation of the contact model used in our wear simulations was the omission of friction. Though friction and wear are related to surface roughness, modeling of friction is not required to produce accurate wear volume predictions [29]. Archard's wear law is not dependent on the presence or omission of a friction model, as the wear factor accounts for the influence of surface roughness on wear volume. Inclusion of a friction model in the contact model would, however, reduce the predicted anterior-posterior translation range slightly, thereby reducing predicted wear volume slightly as well. Nonetheless, wear simulations performed without friction have been shown to match experimental wear volume measurements closely [29,31], suggesting that inclusion of friction in the contact model is not critical for predicting wear volume accurately.

A final limitation was that wear simulations in this study were performed exclusively for gait. Though surface damage is altered when other tasks such as stair climbing are simulated as well [34], use of gait simulations alone still provides a basis for evaluating overall wear trends.

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