INCREASED CONFORMITY OFFERS DIMINISHING RETURNS FOR TOTAL KNEE REPLACEMENT WEAR

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For Jasmine

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I would like to thank Dr. Fregly and Dr. Banks with providing me with excellent guidance through out my time here at the University of Florida. With your help, I have developed tremendously. I would like to thank all my lab mates who have helped me along my way. I would like to thank my friends here who have helped in various points of my life at the University. Finally, I would like to thank Jasmine for her tremendous contributions.

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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. 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 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 more 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 wear volume reductions gradually diminishing as conformity increased. These results suggest that TKR geometric design efforts should focus on sagittal rather than coronal conformity and that increased sagittal conformity offers diminishing returns in terms of decreased wear.

CHAPTER 1
INTRODUCTION

Osteoarthritis is the most common form of arthritis in the United States and affects approximately 21 million Americans [1] . Osteoarthritis occurs when the cartilage at the end of the bones in a joint gets worn away, leading to bone on bone contact. Osteoarthritis often affects the knee joint. Knee osteoarthritis can cause a limited range of motion, stiffness, and incredible pain. One treatment option for osteoarthritis in the knee joint is a TKR. According to the National Hospital Discharge Survey in 2003 over 475,000 patients received TKRs [2].

The long term survival of TKRs is a problem. A study of 11,606 TKRs found that ten years after implantation TKRs have a 91% survival rate. At fifteen years the survival rate drops to 84% and at twenty years the survival rate drops to 78% [3]. Polyethylene wear remains an important factor limiting the longevity of total knee replacements (TKRs) [4-6]. Wear particles liberated from the polyethylene tibial insert can induce osteolysis (i.e., bone cell death) which in turn can lead to component loosening [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. Practically, TKR damage and survivorship have been reported to be worse in younger than in older patients [9], causing many 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 [4, 10-13]. Increased conformity in well-aligned implants reduces contact stresses on the polyethylene tibial insert [14-16]. Since polyethylene wear is due to the combined effect of contact stress and sliding conditions, contact stress reductions have been hypothesized to reduce wear volume as well [13]. 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 malalgined [20-22], increased wear due to easier entrapment of wear particles between the articular surfaces [16], and increased component fixation forces [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.

This study used a validated computational model to assess the effect of varying TKR conformity on polyethylene wear volume [24, 25]. 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 allowed evaluation of this large range of geometric designs. The results provide general design guidelines for when increased sagittal and coronal conformity may, and may not, be valuable for reducing wear in total knee replacements

CHAPTER 2
METHODS

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. (Figure 2-1) 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 axial plane translations. Other studies have used the same modeling idealizations used here to develop computational simulations of the Stanmore machine [17, 26, 27].

One-cycle dynamic gait simulations were performed with the computational model using ISO standard motion and load inputs for the Stanmore machine (ISO 1423-2, 2000). An AP control force and internal-external (IE) control torque 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 at the same locations as in the actual simulator machine, and the stiffness of each spring was set to 14.28 N/mm based on personal communications with Dr. DesJardins at Clemson.

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 [28, 29]. 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 form its neighbors and was associated with a single tibial surface element of known area. The contact pressure p for each element was calculated from

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

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; [30]), h is the layer thickness at the element location, 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. 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[31]:

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

where k is the material wear rate (2.59x10-7 mm3/Nm; [24]), 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, $\left|v_i\right|$ is the magnitude of the element's relative sliding velocity at instant i, and Δt_i is the time increment used in the analysis[25]. Wear volume for each 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 million cycles, representative of the total number of cycles commonly used for testing in a simulator machine.

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. Phase one tests utilized a wide range of sagittal and coronal conformities to blanket a broad design space representative of contemporary knee replacement geometries. A sagittal profile was built using the expertise of Dr. Scott Banks, who has experience in building TKRs. The sagittal profile had three distinct radii, during normal gait contact would be on the radii of 21.55mm (Figure 2-2). The sagittal profile was kept constant through all the tests. Conformity in the sagittal or coronal dimension was defined as the femoral radius over the tibial radius. Changes in conformity were made by changing the tibial component's radii. The tibial component had a single radius in all cases. The first phase of testing mostly varied the conformity of the medial compartment, although the lateral compartment conformity was varied as well (Table 1). Results were analyzed and tests for the second phase of testing were selected in order to clarify questions raised by the first phase of testing.

Phase 2 tests performed a more focused investigation of the conformity conditions in phase one to which predicted wear volume was sensitive. The femoral sagittal profile used was the same one used in the first phase of testing. The femoral coronal radius used was 40mm. For this phase, sagittal conformity was varied in the lateral and medial compartments both separately and together (Table 2-1). In contrast to the first phase of testing, sagittal conformity was varied at more points, allowing a better understanding of how small increases in conformity affected wear volume. For sagittal conformity tests where only one compartment's conformity was varied, the opposite compartments sagittal conformity was 0.50. There was a common case for all three series of sagittal tests, where both the lateral and medial compartment had a sagittal conformity of 0.50. Coronal conformity tests were conducted to confirm first phase observations about the influence of conformal conformity (Table 2-3). The tests involved simultaneously varying the coronal conformity in both compartments.

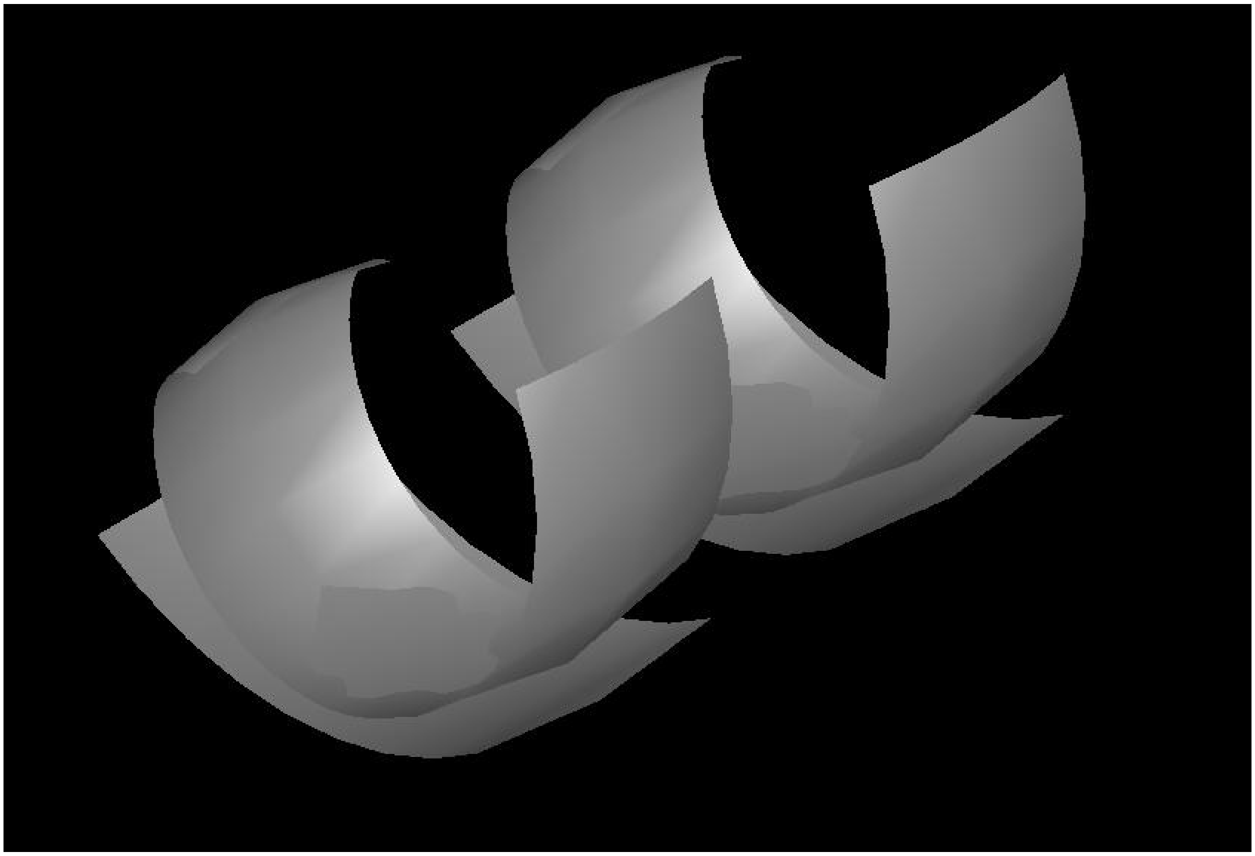

Figure 2-1. Sample femoral and tibial geometry in the computational Stanmore Simulator. The simulator was constructed in ProMECHANICA/MOTION.

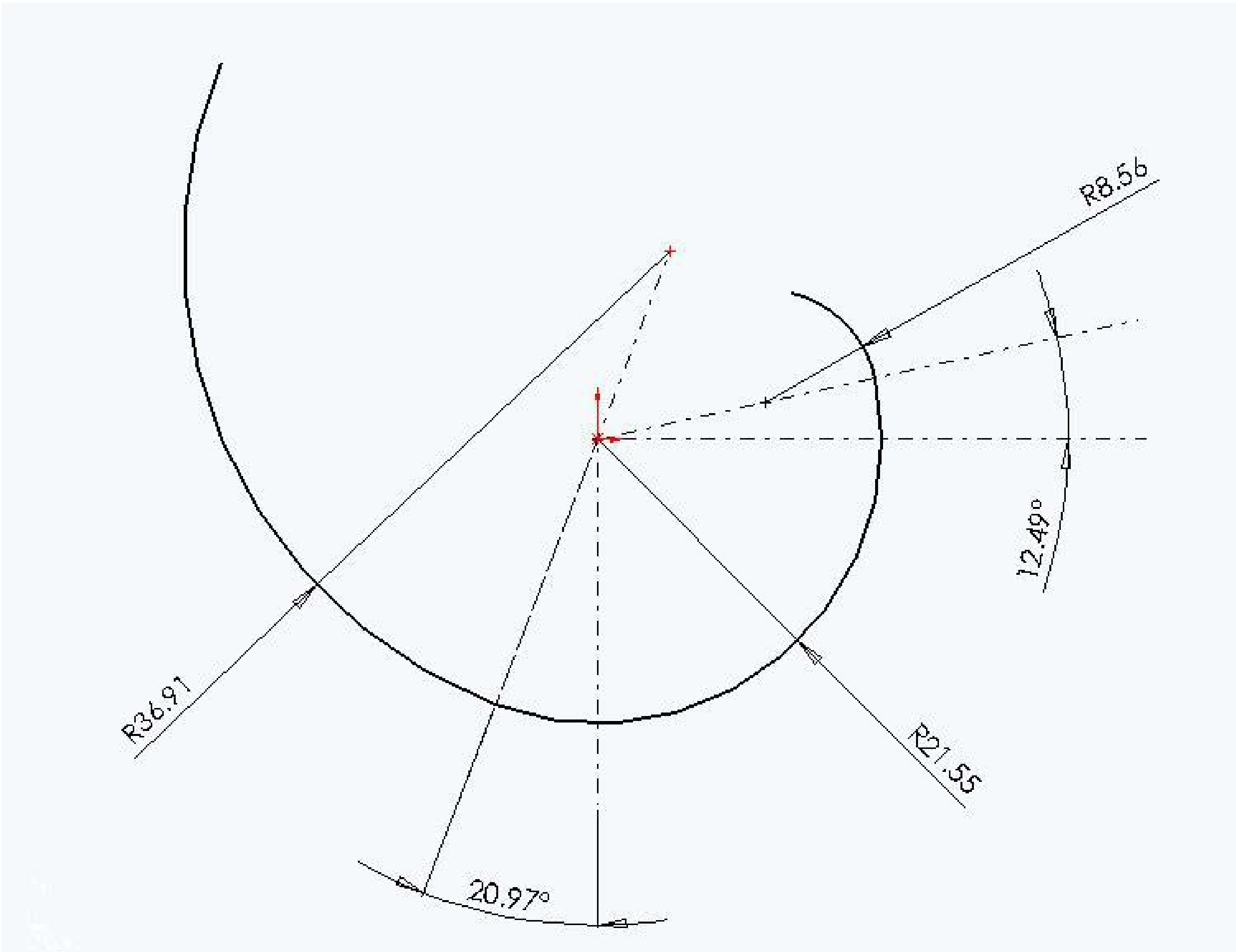

Figure 2-2. Sagittal profile of the TKR used in all tests There are three radii of 36.9mm, 21.55mm, and 8.56mm. During normal gait, contact occurs exclusively along the 21.55mm radius.

Table 2-1. The testing matrix for the first phase of testing. Conformity is defined as the radius of the femoral component over the radius of the tibial component. The femoral components sagittal profile was constant for all the tests. The coronal radius of the femoral component was either 20mm or 80mm. There were six different conformities in the medial compartment for both the 20mm and 80mm femoral components. The sagittal conformity of 0.91 was chosen as a data point because it corresponds to the ratio 1:1.1. For all the scenarios listed for the medial compartment, two tests were run. One test had a lateral compartment conformity of 0 in the sagittal and coronal dimensions. The other test had lateral compartment conformity of 0.5 in the sagittal and coronal dimensions. In total twenty four test cases were run.

Femoral Coronal Radius (mm)	Tibial Coronal Conformity	Tibial Sagittal Conformity		Lateral Compartment
20	0.0	0.00		
20	0.5	0.00		
20	0.0	0.50		Coronal And Sagittal Conformity are 0.0
20	0.5	0.50		
20	0.0	0.91		
20	0.5	0.91		
80	0.0	0.00	+	OR
80	0.5	0.00		
80	0.0	0.50		Coronal and Sagittal Conformity are 0.5
80	0.5	0.50		
80	0.0	0.91		
80	0.5	0.91		

Table 2-2. The sagittal testing matrix for the second phase of testing. There were three series of tests that varied the sagittal conformity of the tibial compartment. Medial compartment sagittal conformity was varied, lateral compartment sagittal conformity was varied, and both compartments sagittal conformity was varied simultaneously. Each series of tests had eight data points corresponding to the conformities listed above.

Sagittal Conformity Variations								
Femoral Sagittal Radii (mm)	21.55	21.55	21.55	21.550	21.550	21.55	21.55	21.55
Tibial Sagittal Radii (mm)	infinite	172.4	138	86.200	68.960	57.47	43	28.73
Conformity	0.0	0.125	0.156	0.250	0.313	0.375	0.501	0.750

Table 2-3. The coronal testing matrix for the second phase of testing. The coronal conformity was varied in both compartments simultaneously.

Coronal Conformity Variations				
Femoral Coronal Radii(mm)	40	40	40	40
Tibial Coronal Radii (mm)	infinite	160	80	53.33
Conformity	0	0.25	0.50	0.75

CHAPTER 3
RESULTS

The first phase tests revealed that sagittal but not coronal conformity significantly affects predicted wear volume. Medial sagittal conformity was found to decrease wear when going from no conformity to a moderate conformity of 0.50 if the lateral compartment was conformal in the medial and sagittal dimensions. Further increases in sagittal conformity from a moderate conformity of 0.50 to a high conformity of 0.91 lead to little change in wear (Figure 3-1). In contrast to the results obtained when the lateral compartment is conformal, when the lateral compartment was flat no changes in wear volume were seen when changing the medial sagittal conformity from either 0 to 0.50 or from 0.50 to 0.91 (Figure 3-2).

The second phase results indicated that increases in sagittal conformity decreased wear if the opposite lateral compartment had some sagittal conformity. Increases in sagittal conformity were found to decrease wear in the tibial compartment (medial or lateral) when conformity was increased (Figures 3-3, 3-4, 3-5). The largest effect from increases in sagittal conformity was observed when conformity was increased from a very low conformity to a higher conformity. Increases in conformity over 0.50 resulted in very small decreases in wear. The common case for all three sagittal tests had a maximum pressure of 48MPa, well above the yield pressure of 35MPa. The second phase coronal tests found that coronal conformity had little impact on wear, which confirmed the first phase findings.

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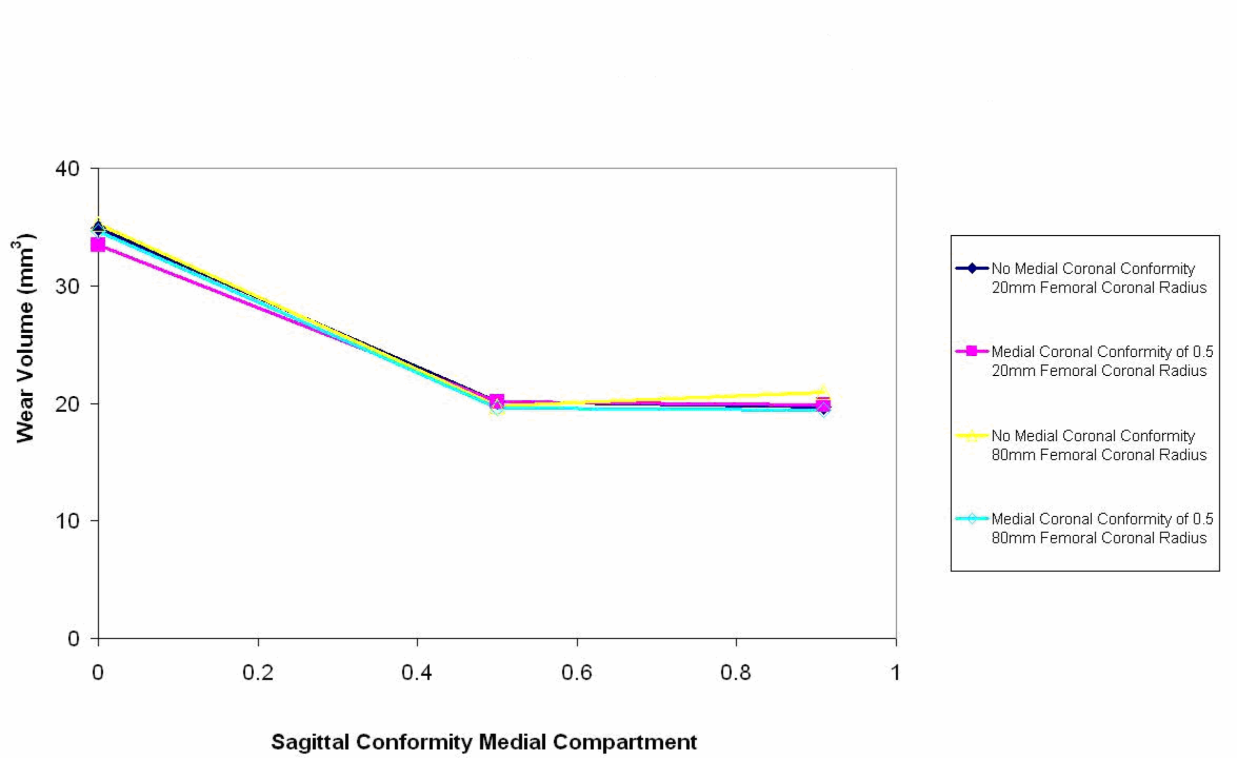

Figure 3-1. Results from the first phase of testing, moderately conformal lateral compartment. This graph shows all the tests where the lateral compartment has a sagittal and a coronal conformity of 0.5. Initially there is a sharp drop in wear volume produced with the increase in sagittal conformity from 0 to 0.5. The increase in sagittal conformity from 0.5 to 0.91 causes little change in wear volume

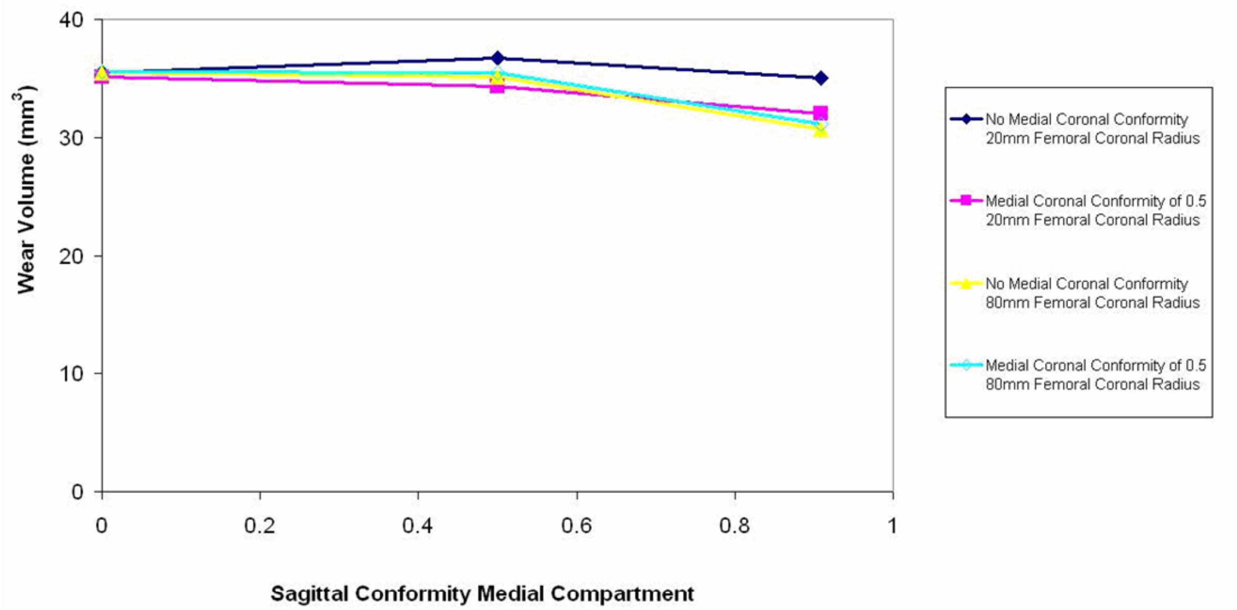

Figure 3-2. Results from the first phase of testing, flat lateral compartment. This graph shows all the tests where the lateral compartment has a sagittal and a coronal conformity of 0. In contrast to the tests where the lateral compartment had some conformity, the increase in sagittal conformity from 0 to 0.5 leads to very small increases or decreases in wear volume. The increase in sagittal conformity from 0.5 to 0.91 caused a slight drop in wear volume

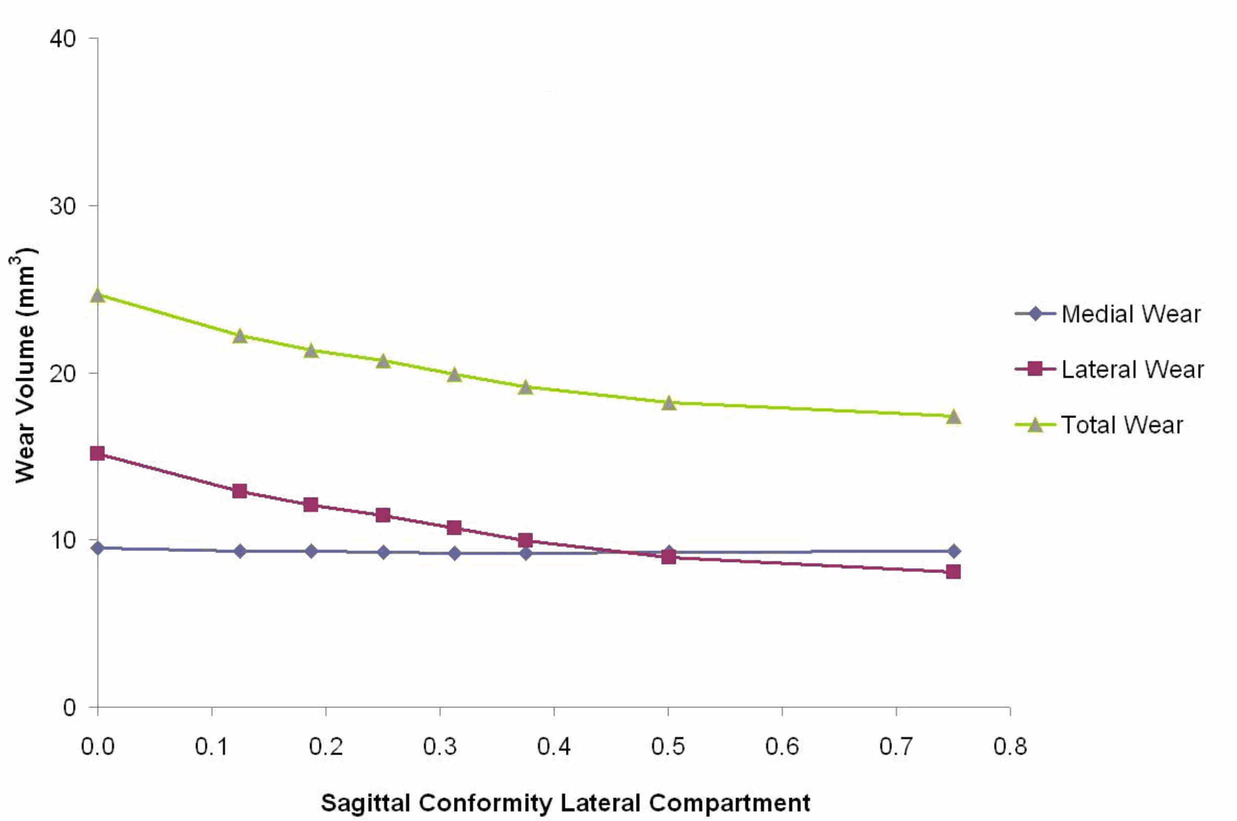

Figure 3-3. Results from tests varying the sagittal conformity in the lateral compartment. The sagittal conformity in the medial compartment was constant at 0.50. Wear in the lateral compartment decreases with increasing conformity while wear in the medial compartment holds relatively constant. The largest decrease in wear comes with the initial increase in conformity and after a certain point, increases in sagittal conformity provide diminishing returns.

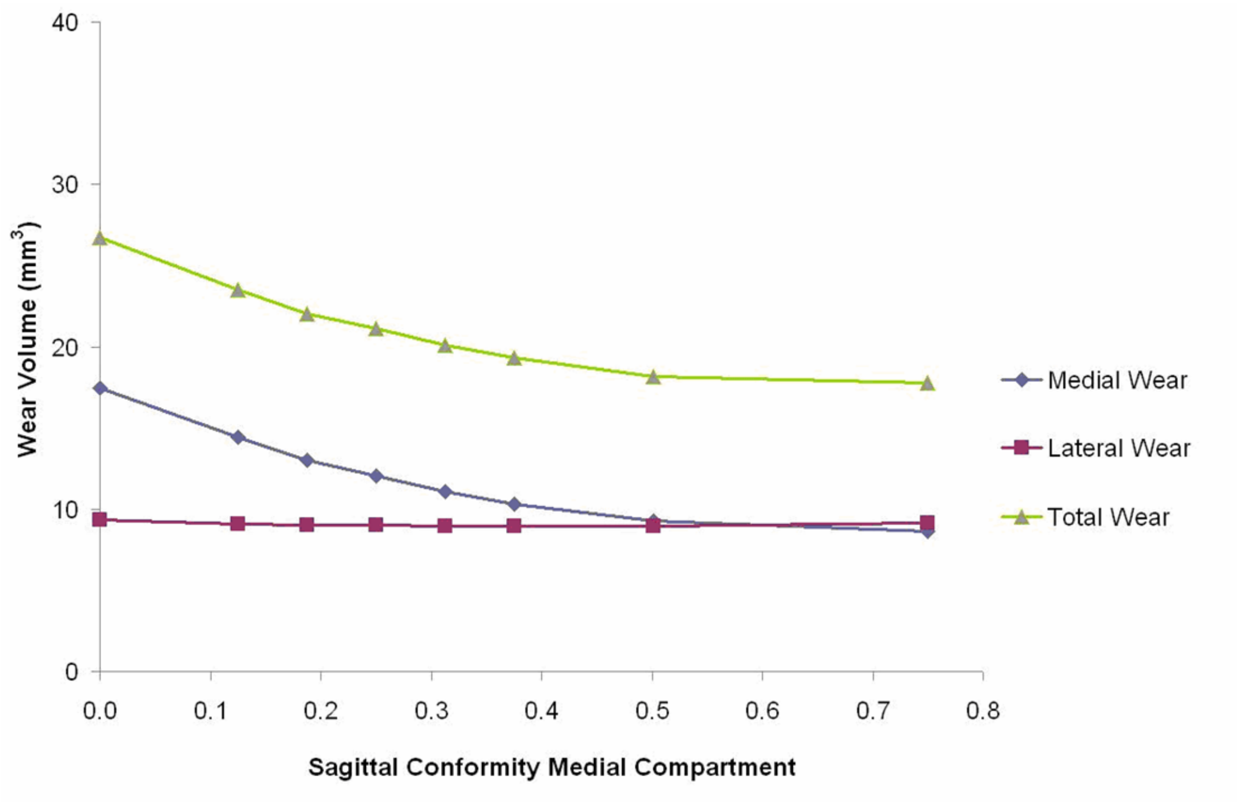

Figure 3-4. Results from tests varying sagittal conformity in the medial compartment. The sagittal conformity in the lateral compartment was constant at 0.50. Wear in the medial compartment decreases with increasing conformity while the wear in the lateral compartment stays relatively constant. The largest decrease in wear comes with the initial increase in conformity and after a certain point, increases in sagittal conformity provide diminishing returns. The results agree with the trends in Figure 1 that showed that increasing conformity in a compartment decreases wear in the compartment, while wear in the compartment that does not have the conformity being varied stays relatively constant. The initial wear in the medial compartment for the medial sagittal conformity tests is larger than the wear in the lateral compartment for the lateral sagittal conformity tests. This can be explained by the internal-external torque that is applied during the Stanmore simulations which causes the loads on the different compartments to be asymmetric.

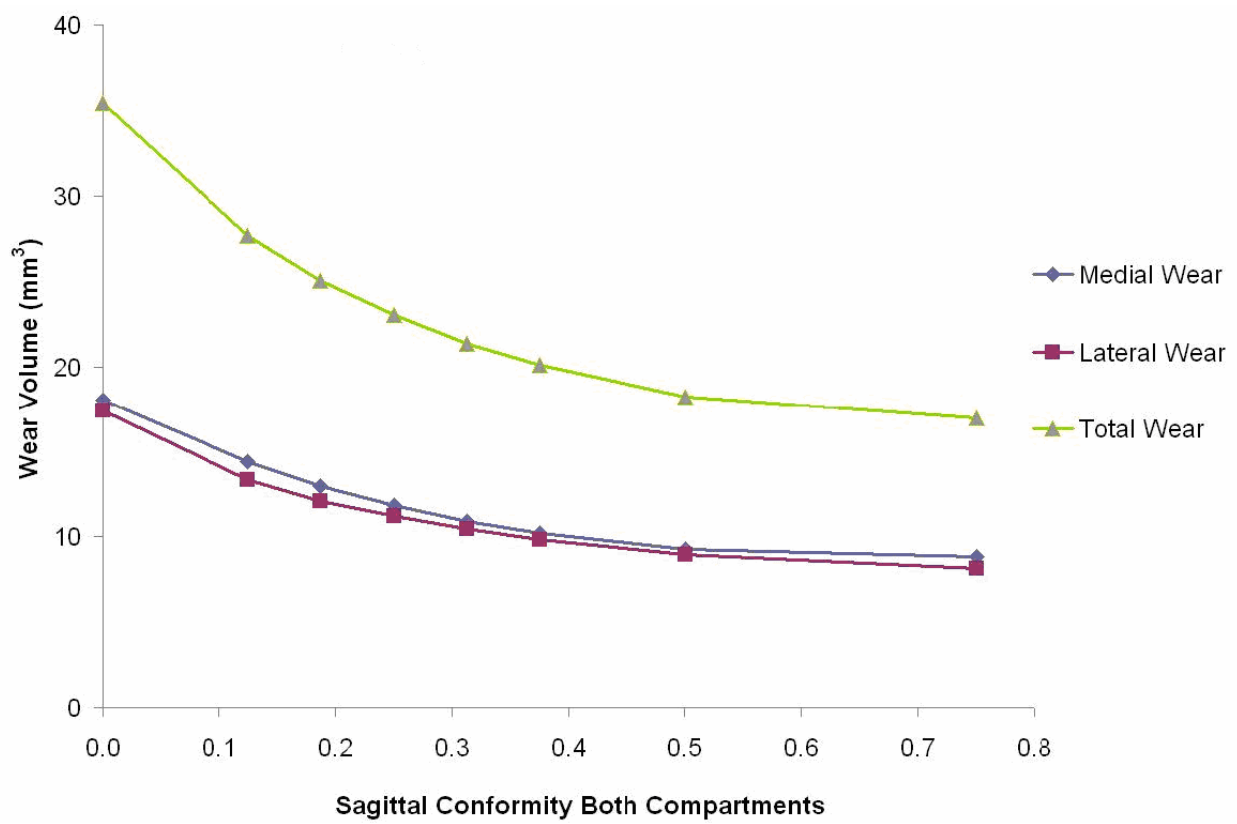

Figure 3-5. Results from tests varying the sagittal conformity in the lateral and medial compartments simultaneously. As in the tests where the medial and lateral compartment sagittal conformity were varied separately, the largest decrease in wear is seen with the initial increase in sagittal conformity. Also similar to the other tests there are diminishing returns on the decrease in wear with increasing sagittal conformity. The initial wear is greater than in the tests where the medial and lateral compartment sagittal conformity were varied separately, which is probably due to the fact that, in contrast to the other two series of tests, neither compartment has sagittal conformity initially.

CHAPTER 4
DISCUSSION

The computational tests conducted here offer a broad overview on the effects of increased conformity in the coronal and sagittal dimensions. The computational simulator, which is based on the Stanmore simulator, took TKR geometries of different conformities and predicted wear using a previously validated wear model. A wide range of TKR conformities were tested in two phases. The first phase of testing raised questions, which the second phase of testing attempted to answer. Results from the two phases of testing indicate that increased sagittal conformity decreases the wear volume if the opposite compartment has some sagittal conformity. The largest decreases in wear volume occur when increasing sagittal conformity in a compartment from a low conformity. Coronal conformity was found to be unimportant. The wear results for the tests where the medial compartment's sagittal conformity was varied and the wear results from the tests where the sagittal conformity was varied in the lateral compartment are not identical due to the non-symmetry of the applied loads (Figures 3-3 and 3-4). The IE torque applied to the tibia resulted in the femur pivoting on the lateral compartment.

The current studies results are in contrast to a previous *in vitro* simulator study [18]. The study looked at an existing TKR design and modified the design so the tibial insert had a larger sagittal radius. The wear results from the two designs were not statistically different. A lack of a drop in wear volume could possibly be explained by the difference in femoral sagittal profile and that the tibial insert had several radii compared to the current studies inserts which had one.

Even though idealized geometries were used in this study, they still yield 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 TKRs, but few have looked at conformity in the sagittal and coronal planes explicitly [4, 11, 32]. The results from the current study suggest that increased conformity can reduce wear, something which has been suggested by previous studies [4, 10-13, 15]. Several retrieval studies have shown that more conformal inserts tend to reduce wear [4, 11]. Quantitative conclusions on the influence of conformity are hard to draw from retrieval studies due to confounding factors such as unknown patients activity levels, differing UHMWPE manufacturing techniques, and a lack of detailed information given on the conformity of the TKRs retrieved. Finite Element (FE) studies have shown that increased conformity can lead to decreased stresses if the component is properly aligned [14-16]. Decreased contact stress has been linked to decreased wear factors [33].

The current study is based on certain limitations and assumptions. During a simulation, the surfaces of the TKR component are not updated, but during an *in vitro* simulation geometry can change considerably. A previous study using the wear model used in the current study to predict wear in a generated AMTI machine found that wear volume prediction was insensitive to surface updating, although other factors, such as wear depth, were sensitive to surface updating [24]. Similarly wear volume was found to be insensitive to creep or to modeling the UHMWPE as a non-linear material, things not accounted for in the current study [24]. The wear factor was taken as a constant, although wear factors can increase considerably with cross shear [34]. A study which used fluoroscopy to track the motion of a TKR patient found that there was little cross shear motion in the TKR during gait and stair climbing [35], so the assumption of a constant wear factor should not be a problem. The simulations run in this study were exclusively gait simulations. A previous study using the contact code found that more realistic damage areas were found if stair as well as gait loads were simulated, although gait was assumed to be the predominate factor [25]. The current study's focus on gait simulations should not be a problem since we are just looking at overall wear trends.

Overall the current study offers detailed information on the effect of conformity in the sagittal and coronal dimensions has on wear volume in TKRs. Sagittal conformity was found to reduce wear under certain conditions and a point of diminishing returns on wear reduction was identified. The information in this study can help future TKR designers identify where the advantages of TKR conformity start to be out weighed by the disadvantages of TKR conformity.

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BIOGRAPHICAL SKETCH

Carlos graduated from the University of Wisconsin–Madison with a BS in engineering mechanics. In order to pursue his interests in developing new medical technologies he came to the University of Florida to earn a ME in biomedical engineering. In the future, Carlos hopes to become involved in engineering projects that matter.