Simulation of Polyethylene Wear in Ankle Joint Prostheses

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Abstract: The performance of total ankle replacements (TARs) have not been comparable to those of the other major joints of the lower extremity. The aim of this work was to develop a new simulator test to compare the wear of a new mobile bearing TAR (Mobility) with one with a good clinical history, the Buechel Pappas, using kinematic inputs derived from the literature. The wear rate for the Mobility components was lower than that for the Buechel-Pappas ankle joints at all time points. The wear rate for both sets of components increased with the inclusion of an anterior/posterior displacement in the kinematic inputs. This was expected as the components are subjected to higher kinematic demands and reproduces similar effects found in knee prostheses. This study has demonstrated that it is possible to study wear of TARs in a modified simulator originally designed for total knee replacements. It was also shown that the new Mobility ankle compares favorably with the Buechel Pappas ankle, which has a successful clinical history, under the simulator test conditions described. J Biomed Mater Res Part B: Appl Biomater 81B: 162–167, 2007

Keywords: ankle; joint replacement; simulation; wear

INTRODUCTION

Historically, fusion of the joint has been the primary mode of treatment for most disabling conditions of the ankle joint. This however has many disadvantages, including a long immobilization time for the patient, severe loss of joint function, and fusion has had a variable rate of success, with infection a common complication.[1] The short comings of ankle fusion have lead to the development of numerous ankle joint replacements.

Two main types of prosthesis have been developed since the 1970s. The first type are two component prostheses, which can be further subclassified into constrained, such as a simple hinge joint; semi-constrained, with limited axial rotation and gliding; and nonconstrained, which give a generous range of motion. The second kind of prosthesis is the three component prostheses, which have a free gliding core and give multi-axial motion. In the three component designs the upper articulation allows for gliding and rotation and the lower articulation allows for flexion/extension.

Although encouraging short-term results were achieved in the 1970s and early 1980s with total ankle replacements (TARs), disappointing long-term results has however lead to the disuse of most designs. The main problem encountered in constrained designs has been high rates of loosening, due to high forces at the bone prosthesis interface. In a study by Demottaz et al.,[2] 21 implants of various fixed bearing types showed only 2 of the 21 having good results with the majority showing signs of loosening and pain. Unger et al.[3] reported the results of 22 fixed bearing implants and showed an 83% satisfactory result after 2 years; however, deterioration of the results with time was noted. The failure rate for constrained designs has been reported to be as high as 50% after 5 years, increasing to 90% after 10 years.[4] Kitaoka and Patzer,[5] in a study of over 200 primary fixed bearing ankle arthroplasties over a 14-year period, concluded that they would not recommend a constrained ankle arthroplasty for rheumatoid arthritis or osteoarthrosis of the ankle. In unconstrained designs problems have occurred because of the high ranges of motion that can occur and have lead to instability and impingement resulting in failure of the device.[6] Studies have also shown a higher failure rate for cemented ankle prostheses at 76% failure[7] compared with uncemented prostheses at 23% failure.[8]

The overall *in vivo* performance of ankle replacements is widely regarded as unacceptable, although clinical reports generally have small numbers and different follow-up times. However there are two ankle prostheses with good clinical histories. These are the LCS design, which in a clinical study of 40 components at 10 years reported an 85% good or excellent outcome.[9] The second is the Buechel Pappas (BP) design.[10] A recent clinical study of 14

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components of this design at 3 years showed a 93% good or excellent outcome.[11] An older clinical study of 237 of the original BP design showed a 90.7% survivorship at 18–72 months of follow-up.[12] It should be noted that both these designs are uncemented, unconstrained, meniscal bearing, congruent TARs.

Overall results of total ankle arthroplasty have not been comparable to those of the other major joints of the lower extremity. Difficulties with other forms of operative treatment for disabilitating diseases of the ankle have lead to a continued search for a viable ankle replacement. Some mobile bearing prostheses have been successful. This is due to their ability to allow complex ankle motion while maintaining low contact stress with a congruent contact, throughout the gait cycle. There has been little *in vitro* or *in vivo* assessment of the wear of ankle joint prostheses.

The purpose of this study was to develop and perform wear simulations on a new mobile bearing ankle design (Mobility), developed and manufactured by DePuy (a Johnson & Johnson Company) and compare it with a TAR with a good clinical history, the BP.

MATERIALS AND METHODS

The wear of three BP, size 3 titanium alloy (Ti-6Al-4V) total ankle components [Figure 1(a)] was investigated along with three of a new mobile bearing ankle design (Mobility, DePuy International) [Figure 1(b)]. The talar and tibial BP components were titanium nitride (TiN) coated. Titanium nitride coating is necessary when titanium alloy is selected as the substrate material, as the titanium alloy has unsatisfactory tribological properties when sliding against polyethylene. The BP polyethylene insert was manufactured from 1150 UHMWPE powder, machined from extruded bar and sterilized using gas plasma. The Mobility components were cobalt chrome (CoCr) alloy. The Mobility polyethylene insert was manufactured from 1050 UHMWPE powder, machined from extruded bar and sterilized using gamma irradiation under vacuum (GVF).

For both the Mobility and BP components the tibiotalar joint is resurfaced with near natural articulating surfaces, giving it similar internal/external (IE) and medial/lateral (ML) stability as the normal ankle. A single talar radius is used to allow full congruity throughout the range of motion. anterior/posterior (AP) stability is primarily extrinsic as it is in the natural ankle.[10]

Although standard wear simulator methodologies have been widely developed and adapted for both hip and knee prostheses, there has been no simultaneous development of simulation methodologies for ankle joint prostheses. Hence a new simulator wear methodology was required for this study.

Testing was performed in a six station simulator (ProSim Simulation Solutions, Manchester, UK), which has previously been used to test total knee replacements.[13] All inputs were displacement controlled to ensure excessive motions did not occur, that could result in dislocation of the ankle joint. Samples were tested in two banks of three, and each design was rotated round the stations in each bank, every million cycles, to minimize the effect of interstation variability. Components were tested in an inverted position. The BP tibial plate was implanted with a 7° tilt and the Mobility tibial plate with a 5° tilt, as is recommended clinically. A posterior tilt on the tibial platform provides posterior shear resistance. The mounting of the components in the simulator is shown in Figure 1.

KINEMATIC INPUT RATIONALE

All components were tested using kinematic inputs derived from the literature (Figure 2).

The force profile was taken from work by Stauffer et al.[14] The basic force profile was used, with a scaling factor to achieve a maximum of 5 times body weight (3.5 kN). Five times body weight was initially chosen, as a review of the literature showed this to be the highest force found during walking. Stance phase was assumed to be 60% of the gait cycle and a minimum load was applied during swing phase (100 N). Once testing was started it was found that the simulator could not consistently apply a maximum load of 3.5 kN and achieve the other kinematic inputs. Consequently the peak load was reduced to 3.1 kN to ensure consistent loading conditions throughout this study.

The inputs for plantar/dorsi flexion were taken from work published by Calderale et al.[15] This paper included a review of the literature and reproduced the graph from data by Lamoreux.[16] The shape of the curve was comparable to many other studies in the literature, but the range of motion was slightly higher, so this was used to produce slightly harsher test conditions. The input cycle for the simulator was taken from the mean value of plantar/dorsi flexion. This curve has peak motions of 10° plantarflexion at ~10% of the gait cycle, 15° dorsiflexion at just before 50% of the gait cycle, and 15° plantarflexion at 65% of the gait cycle (just into swing phase).

The profile decided upon for IE rotation was also taken from the paper by Calderale et al.,[15] who reproduced the results of Lamoreux.[16] This was the only graphical representation of the range of IE rotation found in the literature. The basic shape of the profile was followed with a range of motion from 2° internal rotation to 8° external rotation. This range is similar to that stated by Raikin et al.,[17] who expressed the normal physiologic range for internal–external rotation to be –3° to +5°.

The first 5 million cycles (MC) of the test were run without any AP displacement, as no precise information on AP translation in the ankle could be found in the literature. From 5 to 6 MC a limited AP displacement was included. The general literature consensus is that there is some anterior motion during dorsiflexion and posterior motion during plantarflexion; however the magnitude is unknown.[18,19] A

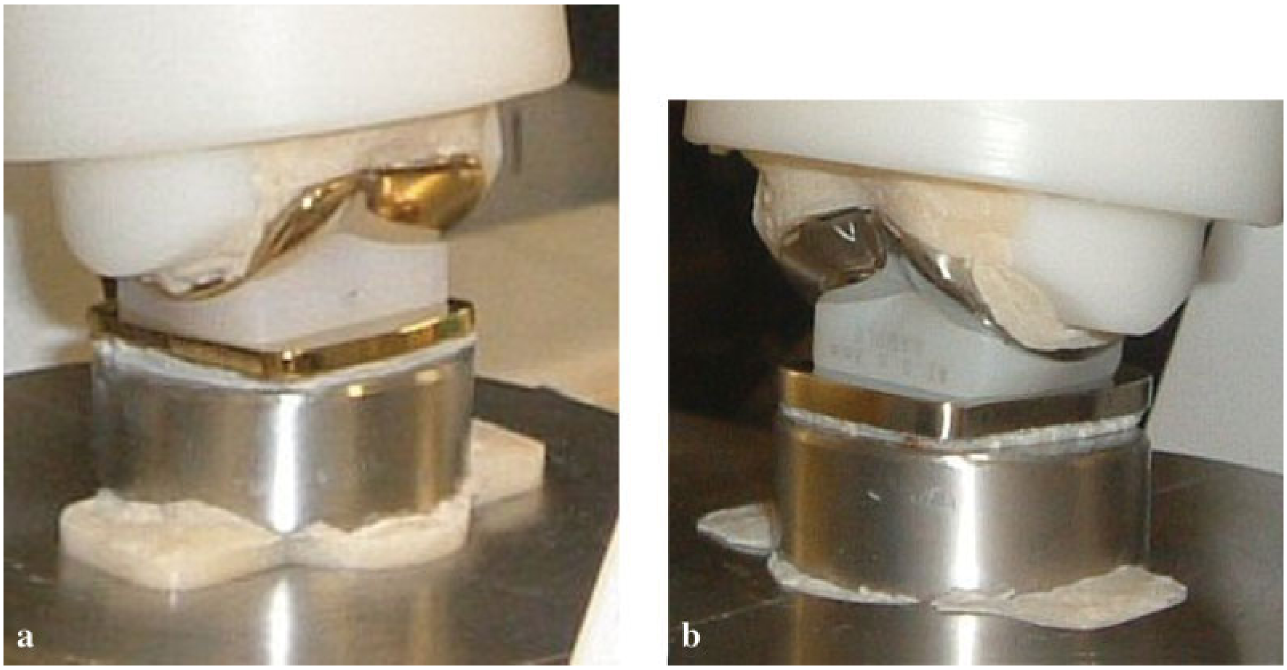

Figure 1. (a) BP TAR. (b) Mobility TAR.

maximum AP displacement of 3 mm was chosen, to prevent dislocation of the plastic insert. The AP input cycle had the same profile as the flexion curve, but reduced in magnitude, thus following the consensus of direction of motion during gait.

Testing was performed at 1 Hz using a 25% (v/v) newborn calf serum (Harlan Serlab, Loughborough, UK) with 0.1% (m/v) sodium azide solution in de-ionized water.

Wear measurements were taken every 0.5–3 MC, then for every million cycles subsequently until 6 MC were

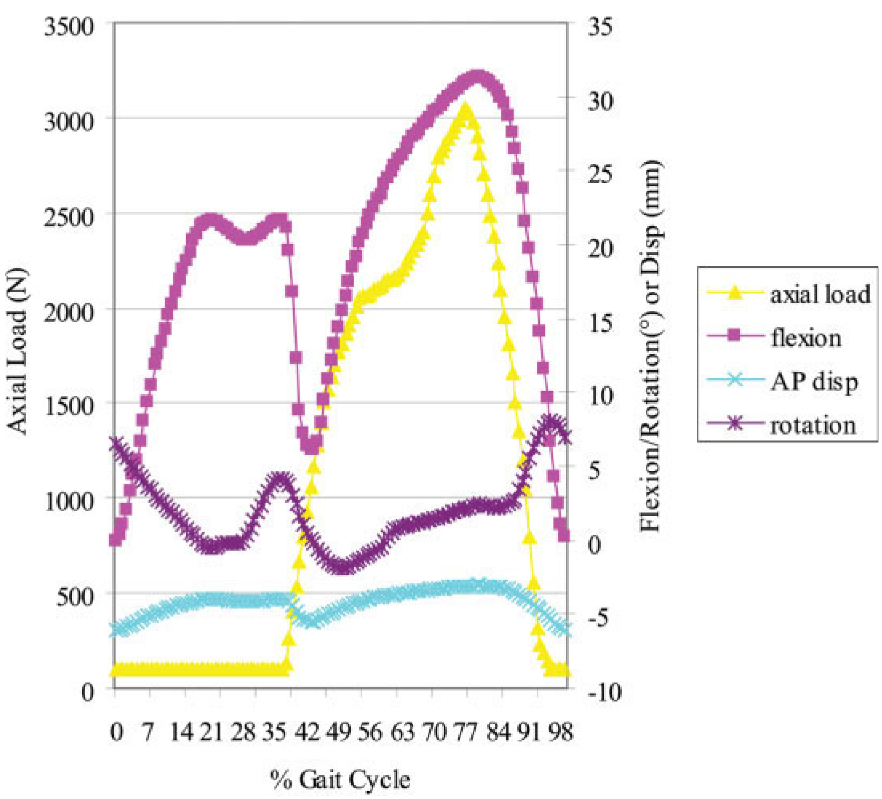

Figure 2. Simulator kinematic input profiles (derived from the literature).

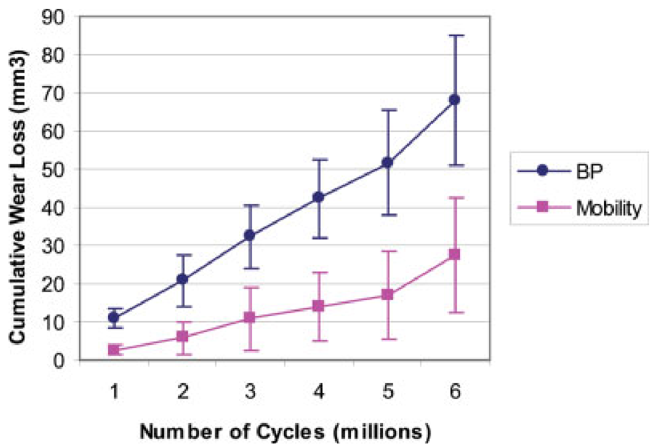

Figure 3. Mean wear rates ± standard error of the mean for BP and Mobility TAR components.

reached. Gravimetric analysis was performed using a Mettler AT201 microbalance (Leicester, UK) with unloaded soak controls to adjust for moisture uptake. Volumetric wear was calculated from the weight loss of the insert using a density of 0.934 mg/mm^3. Digital images of the wear scars on the upper bearing surface of the UHMWPE inserts were also obtained using Image-Pro Plus software (Media Cybernetics, MD). Talar and tibial tray surface damage was analyzed using a Form Talysurf (Taylor Hobson, Leicester, UK) stylus profilometer at the start of the test, after 1.5 and 3 MC and at the end of the test.

Volumetric wear rates were plotted as mean ± standard error bars. Results were analyzed for statistical significance using one-way ANOVA, with individual differences determined using the T-method.

RESULTS

The kinematic inputs and outputs were monitored daily during the test. Adjustments to the servo control system were regularly made to ensure close correlation between input and output cycles and to ensure all stations were behaving in a similar manner.

After 5 MC the mean wear rate with 95% confidence limits for the BP ankle was 10.36 ± 11.8 mm^3/MC. In contrast, the wear of the Mobility was 3.38 ± 10.0 mm^3/MC. The Mobility had lower wear than the BP at all time points but this was not statistically significantly ($p = 0.05$). The mean wear rate from 5 to 6 MC (when AP motion was introduced) for the BP ankle was 16.4 ± 17.4 mm^3/MC and for the Mobility components was 10.4 ± 14.7 mm^3/MC. Both sets of components showed an increase in wear with the increase in kinematics (Figure 3); however these increases were not statistically significant ($p = 0.05$).

The mean wear scar areas for the BP and Mobility were analyzed at every data point. Both components had a high degree of contact and large wear scars. The mean wear scars

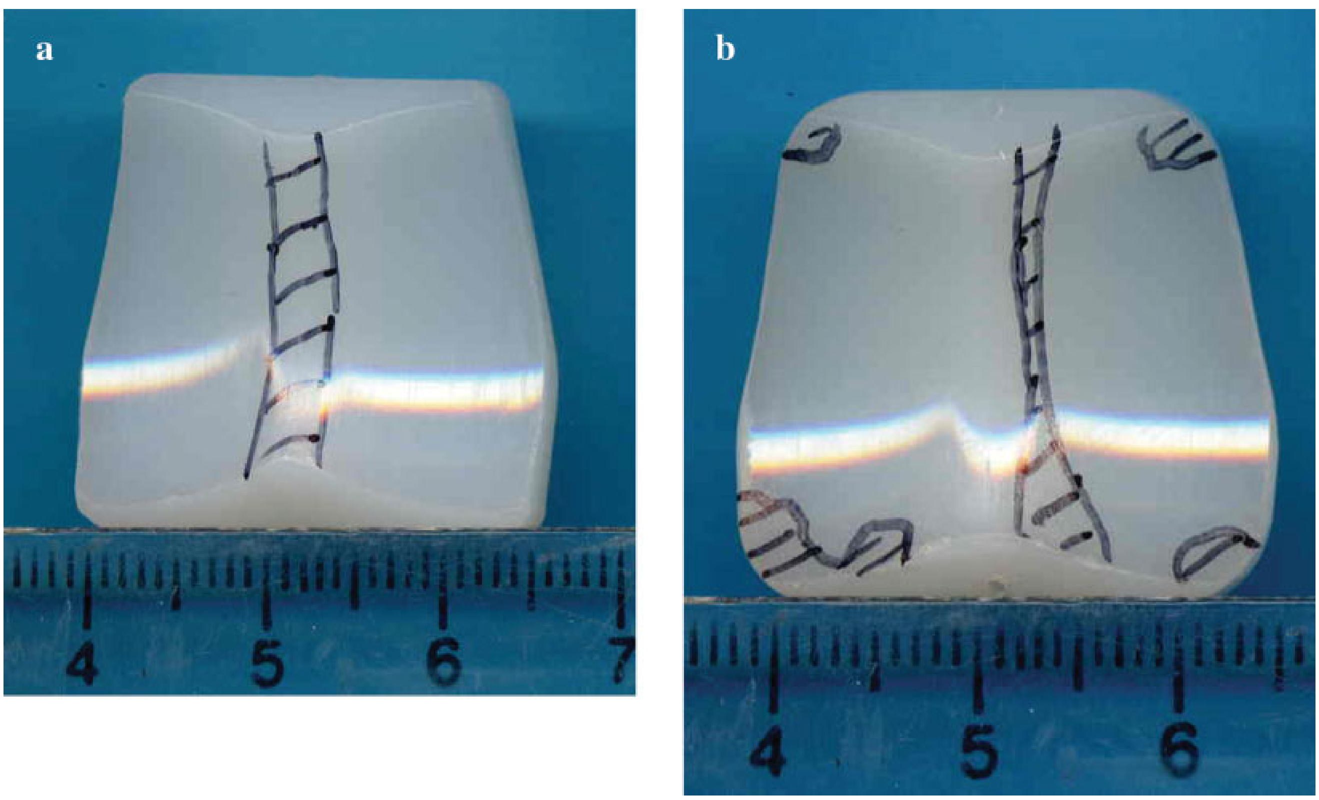

Figure 4. (a) BP UHMWPE insert after 5 MC. (b) Mobility UHMWPE insert after 5 MC.

TABLE I. Talysurf Mean ± 95% Confidence Intervals Surface Roughness Measurements

	Pretest	3 MC	6 MC
Mobility tibial	0.021 ± 0.009	0.021 ± 0.013	0.023 ± 0.012
BP tibial	0.012 ± 0.005	0.014 ± 0.002	0.015 ± 0.003
Mobility talar	0.013 ± 0.001	0.022 ± 0.025	0.030 ± 0.039
BP talar	0.065 ± 0.005	0.062 ± 0.010	0.058 ± 0.021

MC, million cycles; BP, Buechel Pappas.

on the DePuy Mobility components ranged from 78% at half a million cycles to 86% at 6 MC. For the BP components it was very difficult to discern areas that were not worn, so effectively had a wear scar area of 100%. Figure 4(a,b) shows representative digital images of a BP insert and a Mobility insert respectively. These scans were taken after 5 MC and the shaded areas indicate areas that have not worn. The wear areas did not increase between 5 and 6 MC.

The surface roughnesses of the metallic components were measured during the test and are given in Table I. The average surface roughness of the TiN coated BP components showed no significant change in average roughness with time and no scratching was seen on any of the components. Some circular scratching was seen on the Mobility tibial components and scratching parallel to the flexion extension axis was seen on the Mobility talar components, which progressed with time, as is indicated in the increase in average roughness of these components (Table I).

DISCUSSION

The wear rate for the Mobility components was lower than that for the Buechel-Pappas ankles under the same kinematic conditions at all time points. However, the results were not statistically significant, probably due to the small sample size ($n = 3$). Ideally a larger sample size ($n = 6$) should be tested so as to achieve statistical significance.

These mobile bearing style TARs, like mobile bearing total knee replacements, will allow translation of complex input motions into more unidirectional motions.[20] Decoupling of linear sliding in the flexion extension axis to the talar bearing surface of the insert and rotation to the tibial bearing surfaces of the insert can occur. These two unidirectional motions then result in lower wear than would be seen in a fixed bearing ankle design, as there is decreased cross shear of the molecularly orientated polyethylene. Similar effects have been found in rotating platform mobile bearing knee designs.[20]

Both types of ankle joints studied benefited from the mobile design. The BP ankle design had TiN coating. TiN provides scratch and damage resistance.[21] In previous pin on plate studies, TiN produced similar wear rates of polyethylene to cobalt chrome counterfaces when it had similar surface roughness values. However, when both counterfaces were deliberately damaged, the increased damage resistance of the TiN led to reduced polyethylene wear. The TiN coating did not lead to reduced wear in the ankle simulator. The mobile bearing design produces primarily linear motion on the two articulating interfaces. This resulted in any scratches to the metallic counterfaces being primarily aligned in the direction of motion. These parallel scratches if they occurred had little effect on polyethylene wear, and did not result in increased wear in the cobalt chrome Mobility components. Table I shows that the TiN coating on the BP prostheses had a low value for surface roughness on the tibial component. However, the TiN-coated talar components had higher surface roughness values than those previously reported for TiN.[21] A number of studies have reported an increase in polyethylene wear with increase in the counterface roughness, and this effect is more marked under unidirectional kinematics condition when the wear rates on the smooth counterface are much lower.

Other factors that are known to affect wear rates of UHMWPE components are grade of UHMWPE, backside wear and conformity of the design. Although no wear rates for UHMWPE inserts in the ankle have been published, comparison can be drawn from pin on plate studies and knee simulator testing of mobile bearing type components. Studies[22] have shown that calcium stearate containing UHMWPE, such as the 1150 BP polyethylene, has a slightly higher wear rate than nonstearate containing UHMWPE (i.e. the 1050 Mobility polyethylene). However, the different sterilization methods for these two materials will also affect their wear rate with the GVF process, imparting a degree of crosslinking of the polyethylene, which in a mobile-type component could result in a lower wear rate than a noncrosslinked polyethylene (such as the gas plasma sterilized 1150 BP component).

No measurement of the extent of backside wear was made in this study. Qualitative visual inspection showed more wear on the tibial bearing surface of Mobility polyethylene inserts, than on the BP inserts.

The BP had greater conformity at the talar interface than the Mobility as evidenced by their larger wear scar areas. The literature is complex on the effect of contact area and contact stress on wear. Historically high contact stress has been shown to accelerate fatigue-type wear in knees and in some ball on plate studies. More recent studies have shown that as you move to more conforming contacts and lower contact stresses, wear can actually increase with the measured contact area.[23–25] Analysis of real contact areas by Wang et al.[25] offers a potential explanation for this. The situation is more complex when lubrication is included. Although the lubrication regimes improve with lower contact stresses and larger contact areas, if the contact area reaches the edge of the polymer component as is the case in the BP ankle, or if the half width of the contact exceeds the sliding distance, this may lead to lubricant starvation, and acceleration of wear.

The wear rate for both sets of components increased with the addition of an AP displacement. The BP components showed nearly a 60% increase in volumetric wear. However, the Mobility components showed a greater than threefold increase in wear. A higher wear rate was expected as the components are subjected to higher kinematic demands after the introduction of AP sliding. If the AP sliding occurred at the unconstrained tibial interface, as expected, the unidirectional circular motion found without AP motion would have changed to more complex multidirectional motion, hence increasing wear. Further work is needed to investigate a wider range of kinematics as input conditions.[26]

There has been little published literature on the wear of ankle joints and no previous published simulator studies. This study has shown that it is possible to study wear of TARs in a simulator originally designed for total knee replacements. It was also shown that the new Mobility ankle compares favorably with the BP ankle, which has a successful clinical history, under the simulator test conditions described. The clinical significance of the wear rates and the resulting wear debris needs to be studied further. The wear rates found with the Mobility ankle joint are comparable with the levels found in the rotating platform mobile bearing knee,[20] which has over 20 years of successful clinical history. Clinical studies currently underway on the Mobility ankle joint prosthesis will help determine the clinical significance of these low wear rates.

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