Investigation of wear of knee prostheses in a new displacement/force-controlled simulator

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Abstract: The performance of two knee simulators designed by ProSim (Manchester, UK) was evaluated by comparison of the wear seen in the press-fit condylar (PFC) Sigma (DePuy) knee prosthesis. Twelve specimens of the same design and manufacturing specification, were subjected to a wear test of 2×10^6 cycles duration using bovine serum as a lubricant. The anterior/posterior displacement and internal/external rotation inputs were based on the kinematics of the natural knee. International Standards Organization (ISO) standards were used for the flexion and axial load. The wear rates and wear scar areas were compared across all stations. The mean wear rates found were 17.6 ± 5 mm^3/10^6 cycles for stations 1 to 6 and 19.6 ± 4 mm^3/10^6 cycles for stations 7 to 12, resulting in an overall mean wear rate of 18.1 ± 3 mm^3/10^6 cycles. The differences between the two simulators were not significant. The average wear scar area seen on inserts from stations 1 to 6 was calculated at 32.4 ± 1 per cent of the intended articulating surface. Similarly on stations 7 to 12 the average wear scar area was 30.7 ± 3 per cent. The wear scars seen were a good physiological representation of those found from clinical explant data. This study has shown good repeatability from the simulator, both within and between the simulators.

Keywords: total knee replacement, wear simulator, wear, kinematics

NOTATION

A/P	anterior/posterior
HS–HS	heel strike to heel strike
I/E	internal/external
M/L	medial/lateral
p (ANOVA)	p value calculated using analysis of variance
PFC	press-fit condylar
R	Pearson's correlation coefficient
R_a	arithmetic mean deviation of profile from centre-line average
R_p	maximum peak height of profile above centre-line average
R_v	maximum valley depth of profile below centre-line average
TKR	total knee replacement
UHMWPE	ultra-high molecular weight polyethylene

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1 INTRODUCTION

For several decades total joint replacements have been used to alleviate the pain and reduced mobility associated with osteo- and rheumatoid arthritis in a joint, in particular the hip and the knee. In comparison with the prosthetic hip joint with a life span of approximately 15 years, the earlier designs of the prosthetic knee joint were considered to be relatively unsuccessful because of their shorter life expectancy. However in recent years, with the development of better fixation techniques and designs, 90–95 per cent of patients receiving condylar fixed-bearing knee replacements achieve excellent or good results, with a total knee replacement (TKR) life of 10 years or sometimes more [1]. However, the longer-term perspective, particularly in younger patients, remains a major concern.

There are currently many different bearings and approaches available for TKR designs and with an increasing number of different polyethylenes (with various levels of cross-linking) becoming available, there is a need for more extensive and vigorous simulator studies to compare both the designs and the materials.

Tribological testing using simple configuration tests can provide a base from which to define wear properties under a cyclic loading and motion pattern [2] and can help in the understanding of relationships between individual tribological variables. However, these findings may not always correlate to the behaviour of the same materials *in vivo* [3, 4]. There are many variables that affect the wear of a polyethylene bearing *in vivo*, including the load to which it is subjected, the lubrication mechanism, the sliding distance and motion patterns. Preclinical, physiological wear simulation methods should therefore simulate the interactions between these factors. In the case of the TKR, it is the geometric variations in designs that define its stability, the reason being that it is the geometry of the condylar bearing surfaces that dictates its resistance to anterior/posterior (A/P), medial/lateral (M/L) and rotational displacements. Once a TKR is implanted it becomes difficult to isolate its design as a sole variable affecting any experimentally measured result [5]. Therefore in order to assess the effect of both geometric design and the nature of the contacting materials on wear and contact stresses, any new design should be tested in a mechanical wear simulator prior to clinical use.

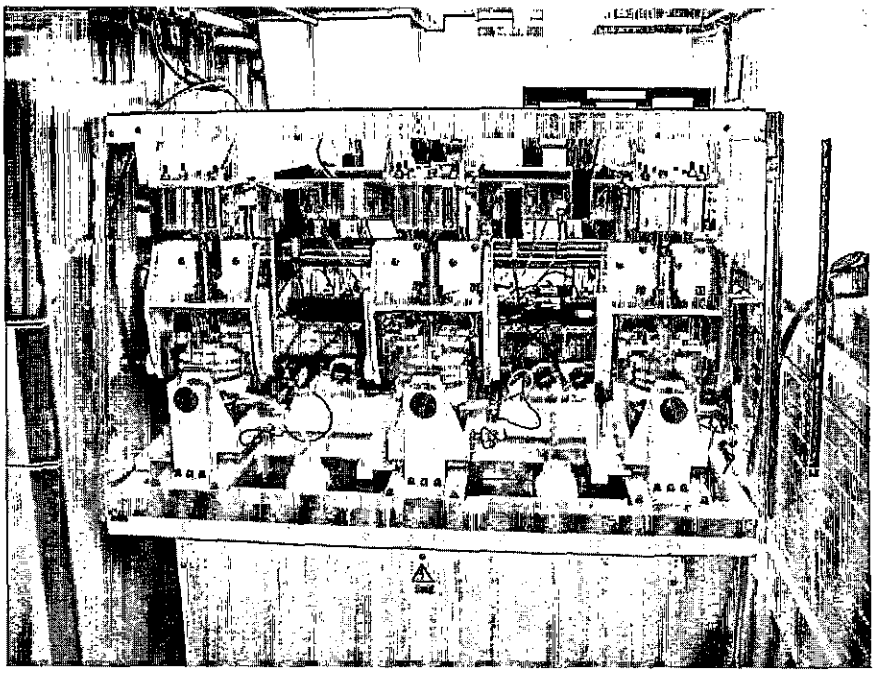
The *in vitro* testing of materials in hip joint simulators has been well documented [6, 7]; however, the complexity of the kinematic and physiological issues that need to be replicated during *in vitro* testing of the TKR has led to slower development of knee wear simulators. As a result, knee simulator wear testing is still in development, both in terms of kinematic control and testing standards. In the recent literature, two philosophies of control have been reported: force control and displacement control. Previous studies have shown relatively low wear with current generation polyethylenes in force-controlled motion simulators [8], that use springs to represent the restraining forces of the natural ligaments and also in some displacement-control machines [9, 10]. More recent studies [11] have shown that the wear rate is sensitive to the kinematic inputs with increased wear occurring with increased A/P displacement and tibial rotation. There is, however, a concern that running under current testing standards, displacement-controlled simulators may introduce abnormal contact mechanics and kinematics for any particular design of TKR. A new simulator has been developed that allows both force and displacement control. Under displacement control the machine is force limited to prevent the TKR from experiencing excess kinematics. In this study the implants were of the posterior cruciate retaining type and therefore the simulator was run in displacement control. The aim of the study was to assess the reproducibility of the wear of one particular knee design in two separate six-station simulators of the same design.

2 MATERIALS AND METHODS

Two pneumatically controlled simulators designed by ProSim (Manchester, UK) were used in this study. Each simulator consisted of six stations, aligned in two banks of three (see Fig. 1a). The knees were mounted in the anatomical position (see Fig. 1b). Each station had six degrees of freedom, with four controlled axes of motion. The axial load was force controlled and both the anterior/posterior (A/P) displacement and the internal/external (I/E) tibial rotation could be controlled using either force or displacement inputs. Each station had an individual pneumatic actuator for axial load, A/P displacement and I/E rotation. The femoral flexion/extension was motor controlled and common to the three stations per group. The input and output kinematics of the four controlled motions were monitored on a computer. Abduction/adduction was allowed but not controlled and an M/L offset was predefined.

To assess fully the capability of the machine, and produce measurable wear with which to validate across the stations, the input kinematics were defined according to the walking conditions described for the natural knee; this is an approach similar to that which has been extensively used in hip joint wear testing procedures. The A/P displacement and I/E rotation input profiles were therefore based on the kinematics of the natural knee during the gait cycle [12]. This resulted in a maximum I/E rotation of $\pm 4°$ and a maximum anterior displacement of $+10$ mm (see Figs 2a and b). To conform to current testing standards, the International Standards Organization (ISO) standards (ISO/CD 14243-1) for axial load and flexion/extension were used (see Figs 2c and d).

Testing and validation of the simulator were carried out in two phases: an initial assessment of the ability of the simulator to deliver the kinematic inputs in an unconstrained situation and a second test using 12 TKRs, of the same design and manufacturing specification, to validate wear rates and wear scars between individual stations. Both tests were carried out at a frequency of 1 Hz and displacement control was implemented for both I/E rotation and A/P displacement. The initial assessment of the kinematic response of the simulator was conducted by running them with geometrically unconstrained components, a stainless steel cylinder replacing the femoral component and a polyethylene flat representing the tibial component. The computer interface allowed instantaneous comparison of the desired input kinematics and the resulting output kinematics for each station. In order to compare across the stations, every 100 000 cycles the outputs of the displacement and rotation transducers throughout one gait cycle were saved. The data were then compared across the stations and also with duration of the test. The simulator was found to reproduce the desired input kinematics to within repeatable 95 per cent confidence limits of



(a)

(b)

Fig. 1 (a) The ProSim (Manchester, UK) knee simulator; (b) anatomical mounting of the TKR

± 1 mm in the displacement axis and $\pm 0.7°$ in the rotation axis.

For the second test, the wear of 12 individual knees was assessed using the PFC Sigma (DePuy) cruciate-retaining total knee design. The sterilization method used for the ultra-high molecular weight polyethylene (UHMWPE) was gamma irradiation in a vacuum. The components were size 3 with 10 mm inserts. The duration of the second test was also 2×10^6 cycles.

Prior to testing, the UHMWPE tibial inserts were placed in containers of deionized water for 3 weeks, after which they were cleaned, left in a controlled environment for 48 h and then weighed. This procedure allowed the samples to establish an equilibrated fluid absorption level prior to the test in order to reduce variability due to fluid weight gain during the first part of the wear test. Both the tibial tray and the femoral component were cemented into their respective fixtures and silicon sealant was used to cover any exposed cement to prevent cement debris from entering the test chamber. All axial loads were offset medially from the centre of the joint by 7 per cent of its width, as designated by ISO/CD 14243-1. The tibial components were aligned in the machine with their respective femoral components by bringing into line the

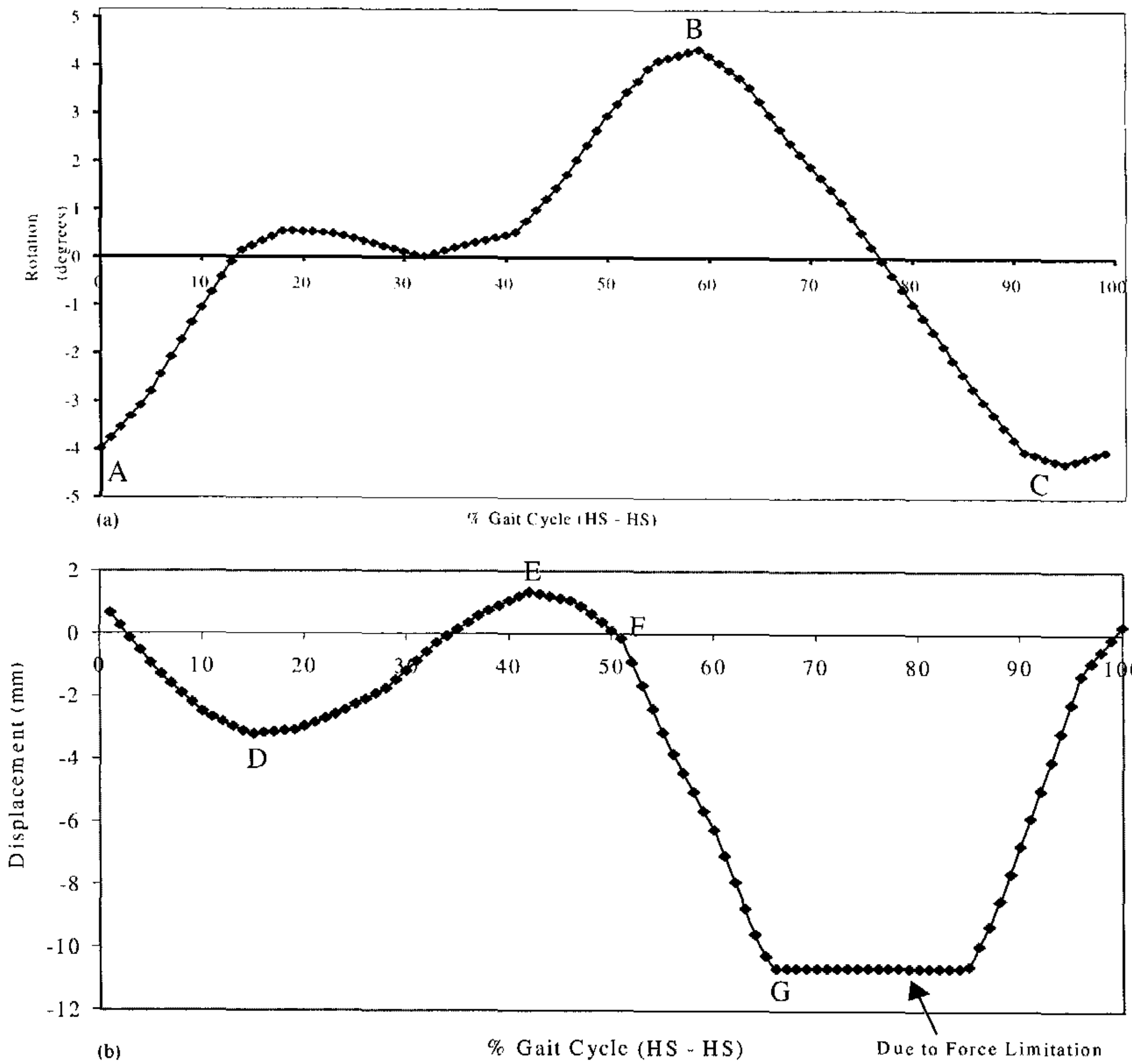


Fig. 2 Continued over.

lowest articulating points of both components. This was defined as the 'zero' position for all kinematic measurements. As occurs *in vivo*, the UHMWPE inserts were held into the tibial trays using a snap fit. The knee components were fully enclosed in a flexible silicon bag, designed to hold the test lubricant, limit fluid evaporation and prevent foreign materials from entering the test cell. The lubricant used was bovine serum diluted with 0.1% w/v sodium azide to a 25% v/v concentration. The simulator was stopped after every 500 000 cycles and using a surgical tool, the inserts were removed from the trays. The inserts were then weighed and wear determined gravimetrically. Volumetric wear was then calculated using a density of 0.934 mg/mm^3 as specified for GUR 1020. An unloaded bovine serum soak control was used to adjust for moisture uptake and differences in weighing conditions. New lubricant was added prior to restarting the test. All 12 stations were subjected to the same volume of lubricant, lubricant concentration, frequency of lubricant change and load.

The simulator was run under displacement control for both the tibial A/P displacement axis and rotation axis with a simulator-imposed force limit of 300 N in the displacement axis and a torque limit of 8 N/m in the rotational axis. The kinematics of all the stations were again monitored every 100 000 cycles, throughout the duration of the test. At the end of the 2×10^6 cycles, the boundary of the wear area was manually outlined. All modes of wear seen were included in the selected wear area; i.e. creep, burnishing and scratching. A digital image of the insert (resolution 400 dots/in) was obtained using an EPSON GT-700 digital scanner. Image-Pro Plus (Media Cybernetics), was then used to quantify the outlined damaged wear area. The percentage wear area

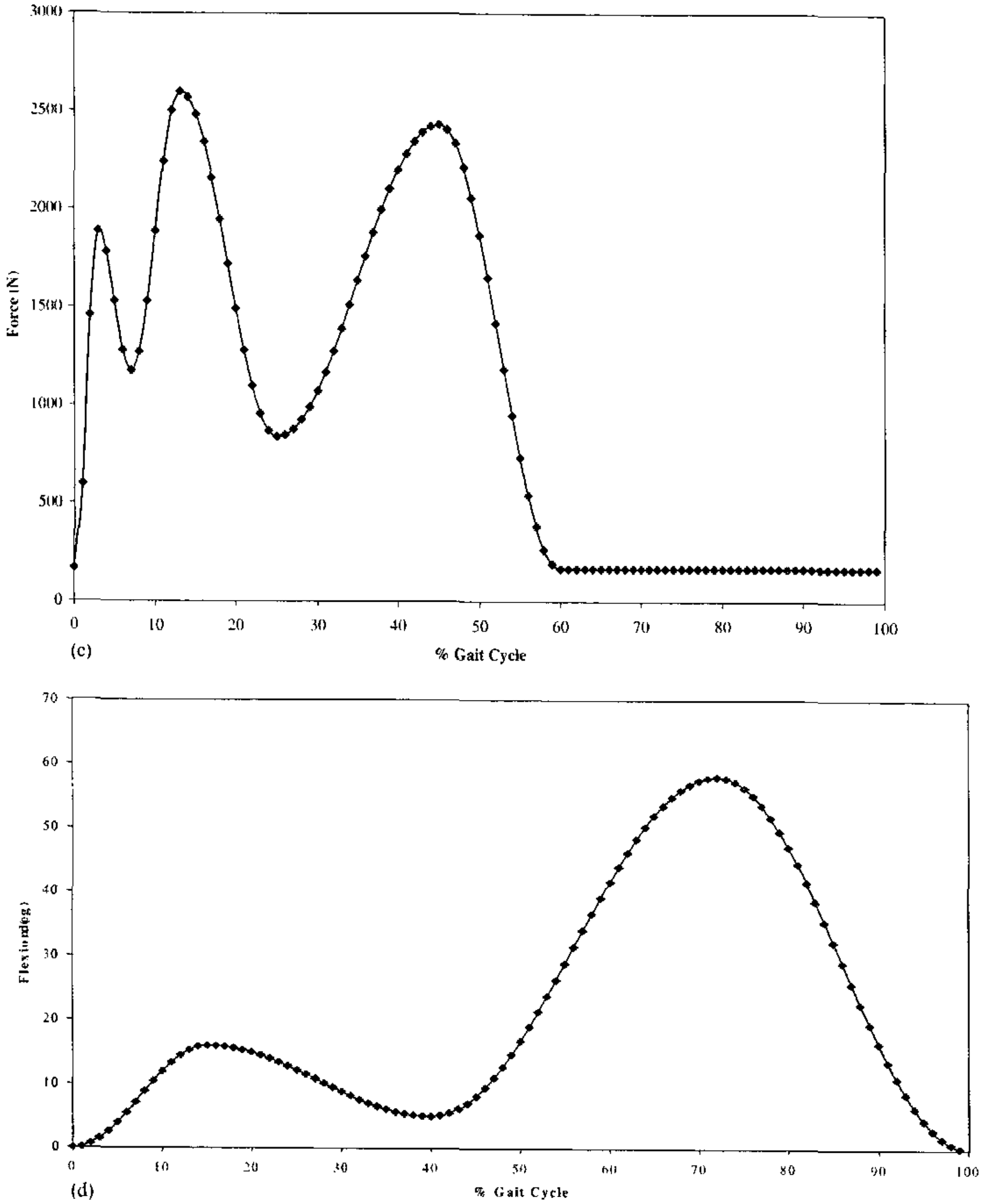


Fig. 2 (a) Rotation input as defined by Lafortune *et al.* [12], internal tibial rotation has been defined as positive. (b) Displacement input as defined by Lafortune *et al.* [12], anterior displacement of the tibia has been defined as negative. A to G refer to motion magnitudes in Table 2. (c) ISO/CD 14213-1 standard for axial load. (d) ISO/CD 14213-1 standard for femoral flexion/extension

was obtained for each component by dividing the damaged area by the intended articulating surface (excluding the central region of the insert). The wear area was calculated on a grid system with each grid element equal to 0.0036 mm^2. The accuracy was such that the wear area calculated could be overestimated by 0.05 mm^2/(mm wear scar perimeter), which when calculated came to an average of 13 ± 10 mm^2/condyle or a maximum overestimation of approximately 6 per cent when looking at percentage wear area for the entire insert. Repeated measurements showed the wear area measurements to be repeatable to within ± 10 mm^2 for each condyle (cf. a worn area of 310 mm^2), therefore indicating the percentage wear areas calculated to be repeatable to within ± 3 per cent.

At the end of the 2×10^6 cycles the tibial tray and femoral component surface parameters were measured using a contacting profilometer, the Taylor Hobson Form Talysurf 120L device (Taylor Hobson, Leicester, UK).

3 RESULTS

The kinematic inputs were characterized by dividing the input gait cycle into two phases, stance and swing. The initial study showed that the machine, with the imposed force limits, was capable of reproducing the defined kinematic inputs to within repeatable 95 per cent confidence limits of ± 1 mm in the A/P displacement axis during the stance phase and to within $\pm 0.7°$ in the rotational axis during both the stance and swing phase. During the swing phase the maximum anterior displacement of 10 mm was reached by all 12 stations. When running the simulator with the PFC Sigma it was found that the kinematic outputs were reduced in comparison with those measured when running with geometrically unconstrained components. The maximum motion achieved was then measured. The maximum simulator input kinematics, based on the kinematics of the natural knee [12], in comparison with those achieved by the machine when running with unconstrained and constrained geometries are shown in Table 1.

Table 1 Comparison of kinematics when running under non-constraining and constraining geometry

Kinematic condition	Maximum input demand from natural knee	Maximum kinematics delivered with non-constraining geometry	Maximum kinematics delivered with PFC Sigma
I/E tibial rotation (stance phase) (deg)	−4	−3.5	−1.5
I/E tibial rotation (swing phase) (deg)	+4	+3.5	+3
A/P displacement (stance phase) (mm)	+3.5	+3	+1.7
A/P displacement (swing phase) (mm)	+10	+10	+9.2

The performance of the axial load actuator was such that the initial peak on heel strike was not achieved (Fig. 3), however the maximum load of 2300 N was commensurate with the input load as defined by the ISO standard. This load is approximately equal to four times average body weight. Previous studies [13] have shown that this leads to contact pressures that approach 24 MPa, although the localized stresses and plastic strains associated with the surface asperities and third-body particles, during the wear process, can be much larger [14]. These contact pressures exceed the elastic limit of polyethylene and can lead to creep deformation, as was seen in the early part of this test. In the case of oxidized and degraded gamma-in-air-sterilized polyethylene, this can also result in delamination fatigue. In this study, stabilized, gamma-in-vacuum-sterilized UHMWPE was used and delamination was not seen. During swing phase the axial load was reduced to a constant value of 100 N. Flouroscopy studies of *in vivo* TKR kinematics [15], have shown that lateral lift off can occur during mid-flexion such that axial load reduces to zero. During these tests however, lift off was not simulated.

The variation in kinematics between the stations was also assessed by, again dividing the cycle into two phases, stance and swing, and then comparing the total magnitude of the kinematic motion seen by the TKR during each phase. The points between which the magnitudes were calculated are denoted by letters and are shown in Fig. 2. The magnitudes and 95 per cent confidence limits of the kinematic motions, calculated per simulator, when testing the PFC Sigma are presented in Table 2.

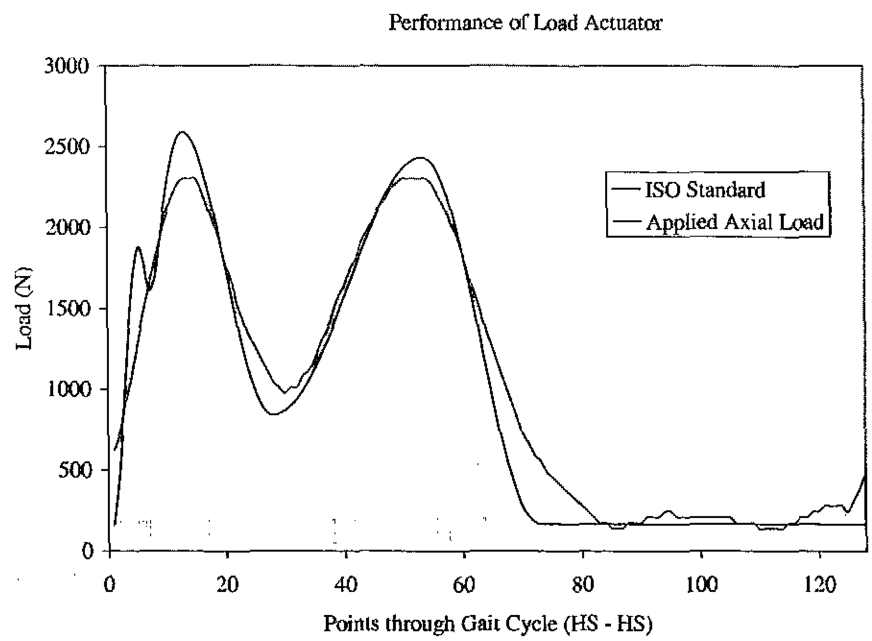


Fig. 3 Performance of the axial load actuator

Table 2 Mean kinematic inputs ±95 per cent confidence limits. Letters are as shown on Figs 2a (A–C) and b (D–E)

Kinematic motion	Range of motion magnitudes	
	Stations 1 to 6	Stations 7 to 12
I/E tibial rotation (stance phase; A–B)	5.9 ± 0.7	6.30 ± 0.4
I/E tibial rotation (swing phase; B–C)	6.4 ± 1.3	7.35 ± 0.7
A/P displacement (stance phase; D–E)	0.54 ± 0.1 mm	0.98 ± 0.5 mm
A/P displacement (swing phase; F–G)	8.8 ± 0.3 mm	9.00 ± 0.8 mm

At the end of the test the average wear area seen on each PFC Sigma from stations 1 to 6 was calculated at 32.4 ± 1 per cent of the intended articulating surface. Similarly the average wear area seen from stations 7 to 12 was 30.7 ± 3 per cent. The small variation observed in the contact areas could be explained by the kinematic variability between the stations. The position of the wear scars on the tibio-femoral articulating surface is shown in Fig. 4. The wear scars were located centrally with the predominant damage mode of burnishing extending to the posterior lip of the inserts. Some unidirectional scratching was seen in the A/P direction and on some of the polyethylene components the onset of pitting was observed in the central region of the condyles, although no delamination was seen. Some polishing was seen on the backside of the UHMWPE tibial surface, although this was not quantified.

The mean cumulative wear at 500 000-cycle intervals was calculated for each simulator ($n = 6$) and the mean wear and 95 per cent confidence limits were then calculated for all 12 stations ($n = 12$) (see Fig. 5). The data followed a normal distribution but showed a slight positive skew (skewness factor 0.6). The mean wear rates, averaged over the 2×10^6-cycle interval and including statistical 95 per cent confidence limits, are shown in Table 3. The differences between the two simulators were not found to be significant ($p > 0.05$, ANOVA), similarly there was no significant difference in the wear between the first and second 10^6 cycles ($p > 0.05$, ANOVA).

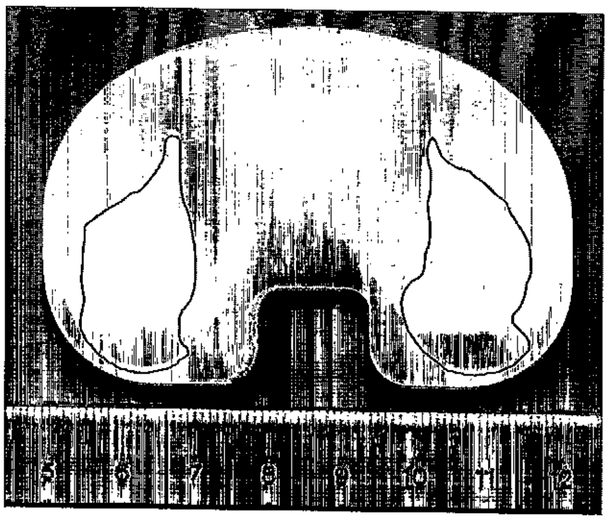


Fig. 4 Image of UHMWPE insert after 2×10^6 cycles showing position of wear scars

Some deep femoral counterface scratching was observed. The scratching was characterized by low R_p values (< 1 μm), i.e. no existing scratch lips, and by R_v in the range 5–25 μm. The scratch widths ranged between 150 and 350 μm. The scratching on both the medial and the lateral condyles was of similar severity.

Inspection of the tibial trays revealed signs of fretting wear on the top surface. The fretting appeared to coincide with the direction of rotation, with the areas of greatest damage being at the outer edges of both the lateral and medial sides of the tray. Analysis of the surface parameters of the tibial trays showed a tendency towards decrease in surface roughness, R_a, with test duration. The surface roughness of six unworn tibial trays were measured at 1.1 ± 0.2 μm. The surface roughness of the tibial trays after 2×10^6 cycles ranged from 0.3 to 1.3 μm, with a mean value of 0.7 μm.

The variations in wear rate and wear scar area and any association with station kinematics (displacement, rotation) or component damage (femoral scratch parameters and tibial tray roughness) were investigated using scatter plots. No clear associations were evident although a weak inverse correlation (Pearson coefficient $R^2 = 0.5769$) between wear area and the R_a of the tibial tray was found. The scatter plot for wear area and R_a of the tibial tray is shown in Fig. 6a. A reduction in R_a of the tibial tray is an indication of fretting wear as the reciprocal, small amplitude motion between the tray and the insert results in a smoothing effect by wearing down any peaks of material, thereby creating a smaller mean deviation of the surface profile from a centre-line average. This fretting wear was associated with an increase in the wear area on the femoral surface. Little association between wear volume and tibial tray roughness or femoral damage, R_p, was found, as shown in Figs 6b and c.

4 DISCUSSION

A debate remains about the relative merits of using a displacement-controlled knee simulator [**9, 10**] versus a force-controlled simulator [**8, 16**]. To the authors' knowledge this is the first knee simulator that can be used in either control mode. It has the added advantage that when one control mode is selected (for example, displacement, as in this case) the tibial force can be limited in the A/P displacement and I/E rotation axes. The outputs demonstrated this, for although the simulator was demanding a particular displacement waveform, the

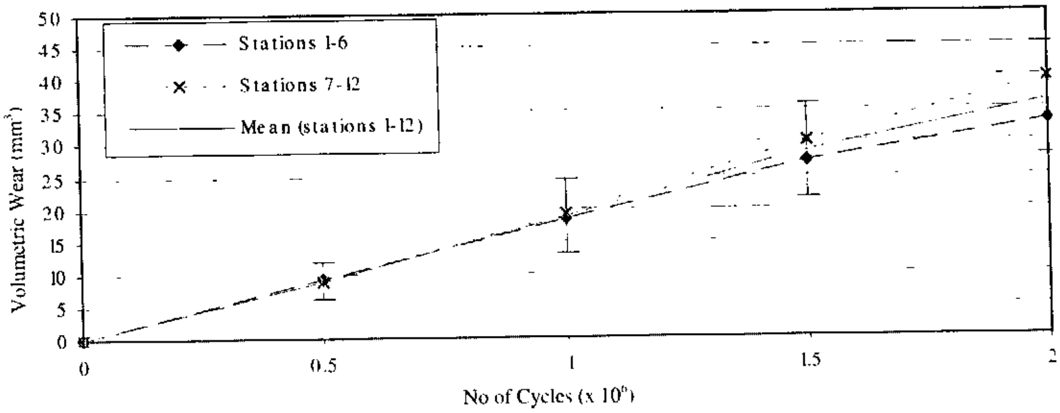


Fig. 5 Wear rates for each of the simulators per 500 000 cycles and mean wear ±95 per cent confidence limits over 2×10^6 cycles

Table 3 Mean wear rates (calculated over the 2×10^6 cycles) ±95 per cent confidence limits for each simulator

Stations	Mean wear rate ($mm^3/10^6$ cycles)
1 to 6	17.6 ± 5
7 to 12	19.6 ± 4
Overall average	18.1 ± 3

simulator would only deliver a maximum force to achieve the waveform. Hence the total A/P displacement and I/E rotation were limited such that the TKR components were not driven outside their geometric design constraints.

A consistent constrained range of motion was found on each station and this low variability in the kinematic output ensured good repeatability between stations and between simulators. There was no significant difference between the wear rate of the two machines. The error found between the stations, as a percentage of the wear, decreased as the test progressed for both simulators. This was due to a component of the error being concerned with the accuracy of weighing and moisture uptake which, as a percentage of the total wear, decreases as the total wear increases. When averaging over the 2×10^6 cycles (Table 3), the 95 per cent confidence limits on all 12 stations were ±16 per cent of the total wear rate, and these increased to ±20 and ±28 per cent on the individual six-station simulators. This level of station to station variability is not dissimilar to that found on multistation hip simulators [7].

The total wear rate of $18.1 \pm 3\ mm^3/10^6$ cycles was higher than previously reported for the PFC Sigma knee in a study conducted by Young *et al.* [10]; however, the kinematic inputs in this study were of increased magnitude compared with Young's study. The studies were also carried out on different simulators so other factors, such as lubricant concentration, may have contributed to the differences seen. Other studies have shown that increased kinematics will increase wear [**11**] and this may be one possible explanation for the increase in wear found in this study compared with that of Young *et al.* [**10**]. The wear rates found in this study also agreed well with those found from load-control simulators [**16**] using inputs of only slightly lower magnitude than in this study.

All inserts exhibited similar wear scar patterns and when compared as percentage area of intended articulating surface, the wear areas across all 12 stations was similar. Some variation was found between the stations when comparing the position of wear scars on the lateral condyle. All stations were set up and aligned in the same manner, however, due to the conformity of the contact a small anterior shift in initial contact area may have resulted in a greater contact area during maximum posterior displacement of the tibia. If this occurred the wear scar tended to span the length of the lateral condyle with a reduced and more posteriorly placed wear scar on the medial condyle. The worn areas of the bearing surface were shiny, indicative of burnishing. Slight unidirectional scratching was seen in the A/P direction. The burnishing indicated a predominance of adhesive wear with some abrasive wear causing the scratching. A large range of damage areas between 13 and 62 per cent for retrieved inserts has been reported [**17**], and in comparison to this the variability in wear area found across the 12 stations of the simulators was small. This study has therefore shown an average representation of physiological wear scars but with reduced variation.

The scratches seen on the femoral components were characterized by the fact that they had virtually no peaks above the average surface level. It is not known whether third-body particles caused scratches without any initial lips or whether the peaks were worn away with the duration of the test. The depth and width of the scratches indicated that particles with diameters of 150–350 μm

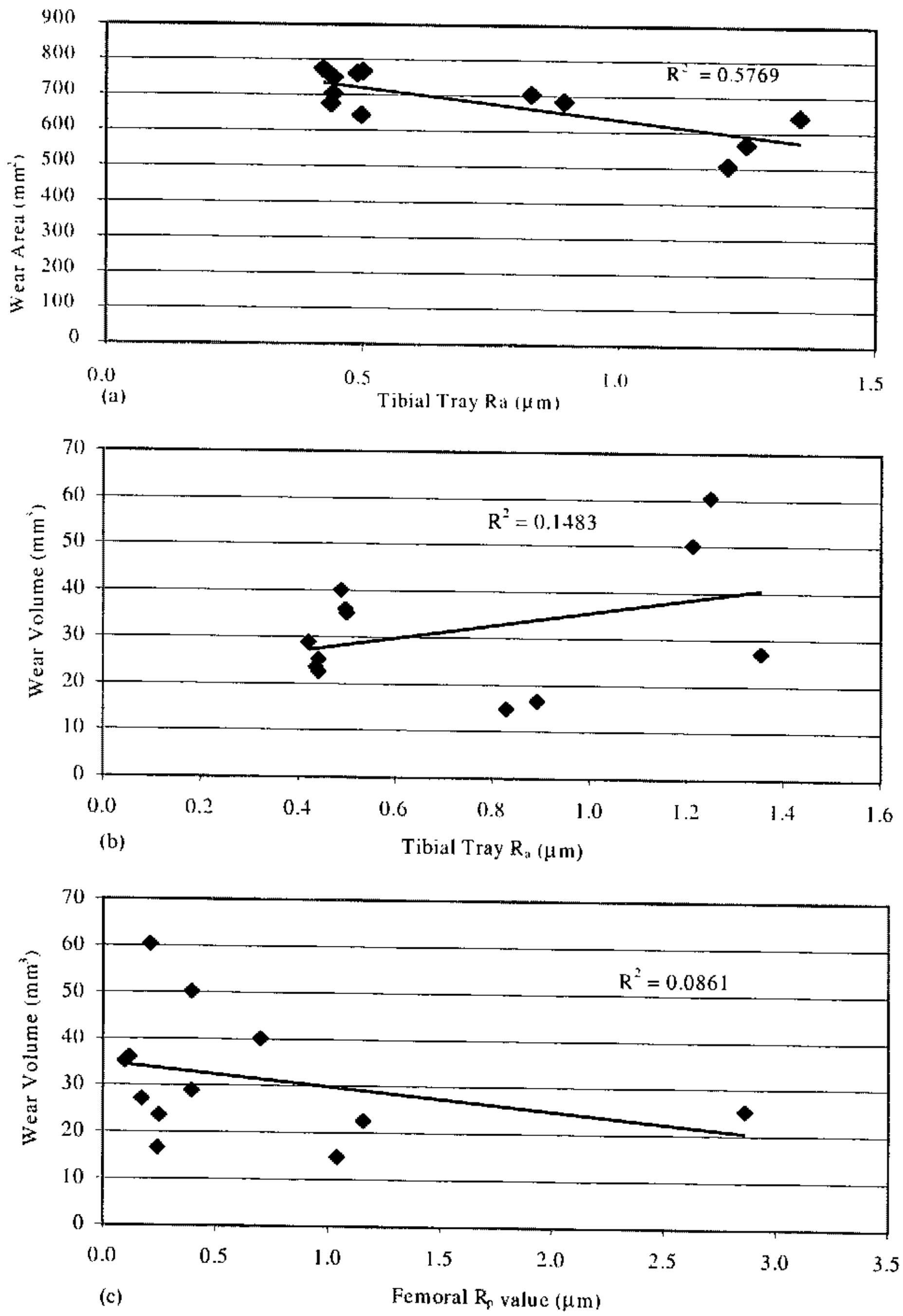


Fig. 6 (a) Scatter plot showing weak correlation between total tibial wear area and tibial tray roughness, R_a. (b) Scatter plot showing low correlation between total volume loss and tibial tray roughness. (c) Scatter plot showing no correlation between total wear volume and femoral surface roughness parameter of R_p

were probably the primary cause of the femoral damage. One potential cause of these scratches was titanium debris from fretting the tibial tray.

The flecking and pitting seen on the tibial tray was taken as evidence of backside wear, with the average surface roughness being used as an indicator of the amount of backside wear occurring, with a high level of smoothing (large decrease in R_a) indicating increased backside wear. This evidence of backside wear was consistent with studies conducted on explanted fixed-bearing designs [18] which have reported flecks and lines. On closer examination it appeared that particles of titanium (up to an approximate length of 400 μm) were plucked from the tray surface rather than scratching occurring. It is hypothesized that these particles were then removed from the non-articulating surface by the entraining motion of the lubricant, thereby entering the primary articulation interface and causing the deep scratches seen on the femoral surfaces. This may in turn have contributed to measured wear, although no correlation was found between the tibial tray surface characteristics and wear rate. Backside wear requires further investigation and the extent of the backside wear seen in this study may have been primarily due to interaction between the simulator kinematics and the prosthesis design.

No clear associations were found between kinematics and wear or femoral counterface damage and wear. However, wear is a multifactorial process and the variation in the wear seen is a result of the combination and interaction between the different processes. Future studies should investigate the roles of backside wear, counterface damage and system kinematics with respect to wear, by deliberately introducing systematic changes to these conditions.

5 CONCLUSION

This study has shown good repeatability from the new simulator, both within and between simulators, and although there was some variability between the stations, simple relationships between any kinematic differences and wear could not be defined. Some variation in wear rate was found between stations and this indicated the need for conducting tests with six replicates, in order to generate acceptably low confidence levels on the mean value. This simulator has given a physiological representation of wear scars in that the mean wear area found was similar to that found from explanted TKRs [17].

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