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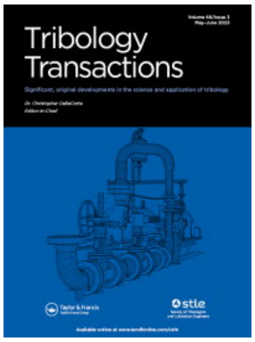

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Effect of Component Position and Inward–Outward Rotation on the Wear of Different Ultra-High Molecular Weight Polyethylenes in an Orbital Bearing Type Hip Joint Simulator

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ABSTRACT
The orbital bearing machine is the world's most widely used hip joint simulator design for wear testing of prosthetic hips. It has been used with inverted and anatomic component position and with and without inward–outward rotation. Still the effect of component position on the wear of the most widely used bearing material, ultrahigh molecular weight polyethylene (UHMWPE), has not been studied directly. With a modified orbital bearing machine, the effects of the component position, anatomic versus inverted, and of the inward–outward rotation, present versus absent, on polyethylene wear were studied for the first time. Acetabular liners made from different ultra-high molecular weight polyethylenes articulated against alumina femoral heads in alpha calf serum. The inverted position resulted in the most realistic, burnished appearance of the polyethylene bearing surfaces. In the inverted position, the wear rate decreased with increasing gamma dose that is known to improve wear resistance by cross-linking. In the anatomic position, the bearing surface was not always entirely burnished. The wear was similar with and without inward–outward rotation. The mean wear rate of vitamin E stabilized highly cross-linked ultra-high molecular weight polyethylene was close to clinical observations. Clinically relevant wear could be produced with the orbital bearing machine for both established and advanced bearing materials. The inverted position appeared preferable in the orbital bearing machine. Inward–outward rotation did not appear important.

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KEYWORDS
Orbital bearing machine; hip joint simulator; inverted position; inward–outward rotation; extensively cross-linked polyethylene

Introduction

Several different hip joint simulators have been designed for wear testing of prosthetic hips. *(1, 2)* The most widely used design is the orbital bearing machine (OBM). *(3)* The OBM is also called a biaxial rocking motion (BRM) simulator because the sinusoidal flexion-extension (FE, ±23°) and abduction-adduction (AA, ±23°) have a phase shift of $\pi/2$ (Fig. 1). The OBM was introduced in the early 1980s with an inverted component position, *(4, 5)* and commonly utilized as such. *(6–8)* Most importantly, the wear mechanisms produced, specifically the microscopic wear particles of ultrahigh molecular weight polyethylene (UHMWPE), and macroscopic burnishing, were shown to be similar to those observed clinically, *(9)* even with a static load. *(10)* Later, an anatomic component position was brought into use *(11)* (Fig. 2). Nearly four decades after its introduction, the long-lasting OBM design is still a subject of new development projects. *(12)*

The component position may affect wear because in the anatomic position, the contact stress field is stationary relative to the acetabular cup, whereas in the inverted position it translates along a circular track (diameter $= 2\pi \sin 23^\circ r$, where r is femoral head radius) within the cup. *(13, 14)* In both cases, the resultant horizontal friction vector rotates about the vertical loading axis at a constant angular velocity. The anatomic position could be assumed to represent a more intense test condition with respect to wear because of the stationary contact stress field. *(2)* However, studies explicitly comparing the two positions regarding the wear of polyethylene liners in the OBM have not been published before the present study.

It has been shown that in addition to the FE and AA, the OBM has a third motion component, inward–outward rotation (IOR) provided that the axis of the rotation control lever does not go through the center of the joint. *(2)* If it does, the IOR is absent. In other words, the lever is of an offset or zero-offset type. The range of the IOR depends on the dimensions of the machine. The IOR has the same phase as the AA (Fig. 1). The multidirectionality of the relative motion can be illustrated by so-called slide track patterns *(1,2)* (Fig. 3). They consist of tracks of selected surface points on the counterface due to the relative motion. With both component positions, the relative motion of the

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OBM is highly multidirectional. Although the IOR somewhat changes the slide track pattern, it does not increase the multidirectionality. Studies on the effect of the IOR on wear in the OBM have not been published either before the present study.

To elucidate these issues, an OBM was modified so that tests could be run with it using both the anatomic and the inverted position, and rotation control levers with and without offset. Tests were carried out with 3 UHMWPE materials that differed from each other with respect to the dose of gamma irradiation. According to clinical experience, UHMWPE cross-linked by large doses of gamma irradiation shows significantly lower wear than conventional, unirradiated or gamma-sterilized UHMWPE. *(15–17)* A valid hip joint simulator must reproduce this difference. The 3-part question to be answered by the present study was as follows. Does the UHMWPE wear rate produced by the OBM depend on component position, IOR, and gamma dose?

Materials and Methods

The experimental acetabular liners represented 3 different polyethylene materials:

1. Unirradiated GUR 1020 UHMWPE.
2. GUR 1020 UHMWPE liners inert packed and gamma sterilized by 30 kGy, hereafter "UHMWPE-γ."
3. Vitamin E stabilized, 100 kGy gamma-irradiated GUR 1020-E, hereafter "VEXLPE" (ASTM F648, ISO 5834-1,2, ASTM F2695, ASTM F2565, 0.1% blended alpha tocopherol, no stabilizers or processing aids, compression molded, post-consolidation irradiated, no post-irradiation thermal treatment).

All liners were manufactured according to the same drawing. The inner diameter of the hemispherical liners was 28.3 mm and thickness was 6.0 mm. The liners were metal-backed (stainless steel) such that the equatorial rim was fully supported. The liners articulated against 28.0 mm diameter alumina ceramic (Biolox Forte) femoral heads. The head/cup clearance, 0.3 mm, was considered to be sufficiently large to avoid excessive frictional heating, typical of joints with low clearance, *(18, 19)* that could have a negative effect on the lubrication behavior of proteins. *(7, 20, 21)* The lubricant was HyClone alpha calf serum SH30212 with a protein concentration of 40 g/L. The serum was not diluted in order to have sufficiently soluble protein for sustaining lubrication. *(7, 21–24)*

The 3-station OBM with an anatomic component position has been described in detail elsewhere. *(25)* In the present tests, one of the anatomic position test stations had a zero-offset lever, and so it did not produce any IOR (Fig. 2). The second anatomic position test station had an offset lever that produced an IOR of ±6°. The third test station was modified for an inverted position. This station also had an offset lever and an IOR of ±6°. Hence the 3 test stations represented 3 different OBM test conditions (Fig. 3, Table 1). These 3 different test configurations were used simultaneously. The load was static 1 kN and the test frequency was 1 Hz. The test

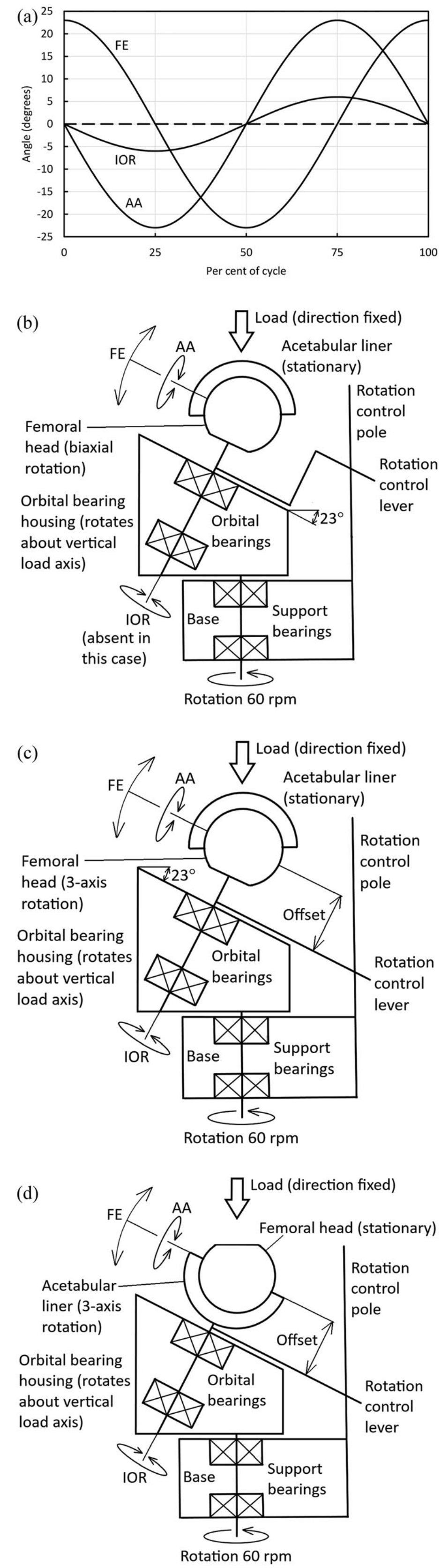

Figure 1. a) OBM motions with present offset lever. Dashed line indicates IOR with zero-offset lever. FE is flexion–extension, AA is abduction–adduction and IOR is inward–outward rotation. b) Schematic of OBM station 1, anatomic position and rotation control lever with its axis going through the center of joint (zero-offset lever). c) Schematic of OBM station 2, anatomic position and rotation control lever with offset. d) Schematic of OBM station 3, inverted position and rotation control lever with offset.

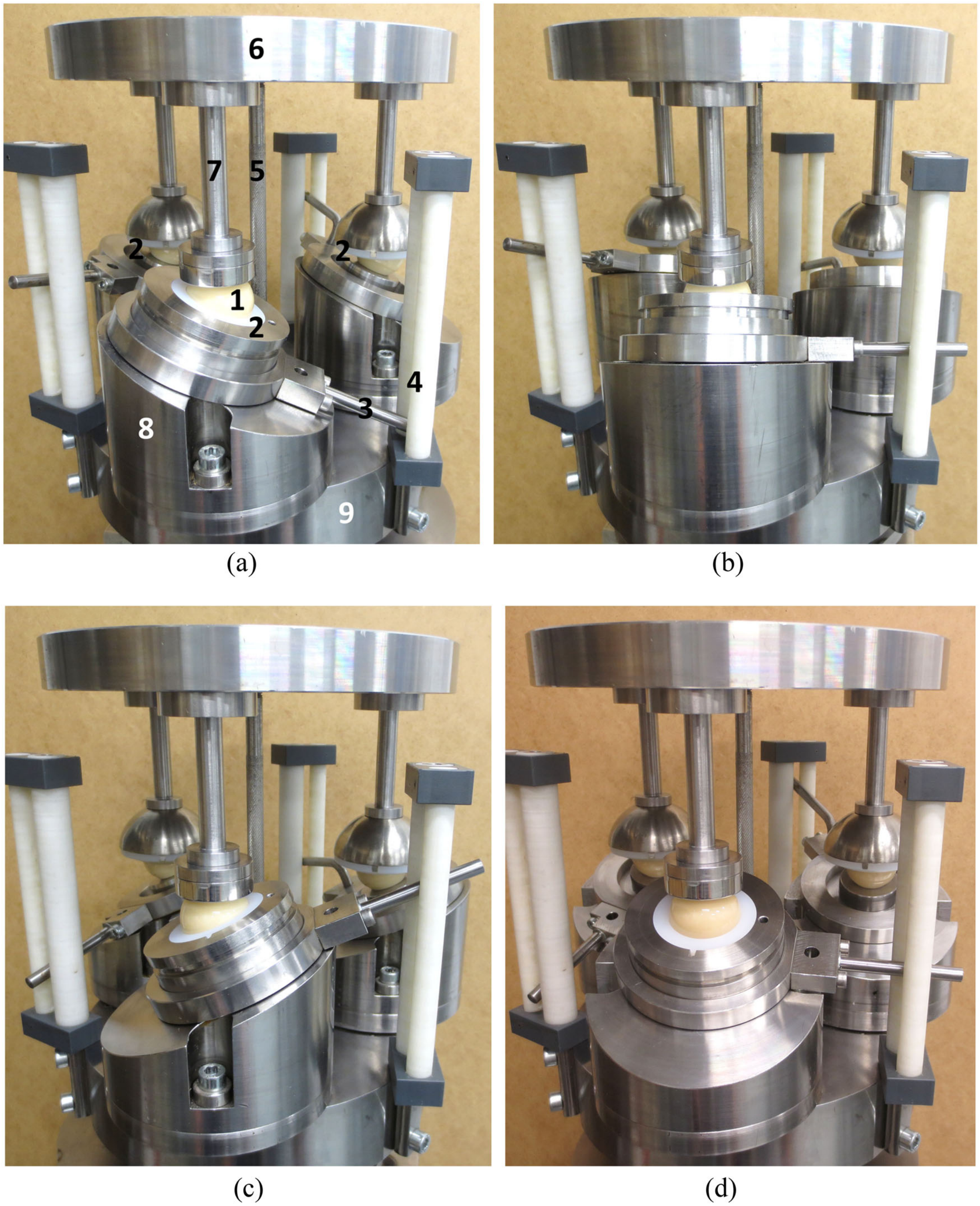

Figure 2. OBM shown without lubricant chambers in 4 positions of cycle, at intervals of 25% of cycle time (from a to d). Station 1 (back, right) and station 2 (back, left) have anatomic specimen position, station 3 (front) has inverted specimen position. Station 1 has lever with its axis going to the center of joint and stations 2 and 3 have offset levers. (see Fig. 1(b, c, d)). 1 Femoral head, 2 Acetabular liner, 3 Rotation control lever, 4 Rotation control pole, 5 Pull bar for generation of load via spring (below Base), 6 Loading plate, 7 Loading bar, 8 Orbital bearing housing, 9 Base.

length was 3 million cycles and the sample size was 3. Since there were 3 materials and 3 test stations, the total testing time was 54 weeks. The test was stopped every 0.6 million cycles (once a week) for a gravimetric wear measurement, *(25)* based on which the wear rate was determined by linear regression. In each test, there was a soak control liner for the correction of fluid absorption. The test was continued with fresh lubricant. Each lubricant chamber contained 130 mL of lubricant. Evaporation was compensated by deionized water. The tests were done at room temperature of 22 °C.

Results

The mean wear rate of UHMWPE was of the order of 20 mg/10^6 cycles and it was not sensitive to the position or IOR (Fig. 4). The mean wear rate of UHMWPE-γ in station 1 and 2 was 50% higher than that of UHMWPE, whereas the mean wear rate of UHMWPE-γ in station 3 was 25% lower. VEXLPE showed by far the lowest mean wear rate, 2.1 mg/10^6 cycles. VEXLPE wear rate was not sensitive to the position or IOR. All liners macroscopically showed burnishing (Fig. 5). Burnishing did not extend to the equator in any of the liners.

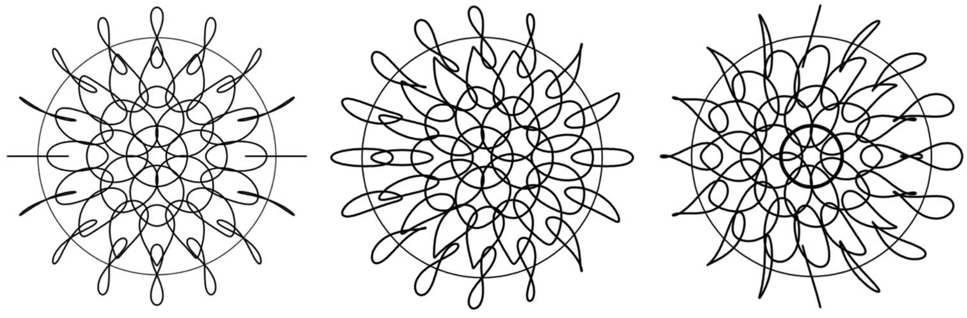

Figure 3. Flattened slide track patterns on acetabular liners produced by OBM hip joint simulator, (a) station 1, (b) station 2, and (c) station 3. Large circle represents equator. Half tracks outside equator are drawn for illustrative purpose only, as liner is hemispherical. Note "force track" on (c) drawn with thicker line. In stations 1 and 2, force track is on femoral head instead. Direction of rotation control lever is 3 o'clock in each case. Source: Reprinted from the *Journal of Biomechanics*, 35, V. Saikko and O. Calonius, Slide track analysis of the relative motion between femoral head and acetabular cup in walking and in hip simulators, 455–464, 2002, and from the *Journal of Biomechanics*, 35, O. Calonius and V. Saikko, Slide track analysis of eight contemporary hip simulator designs, 1439–1450, 2002, with permission from Elsevier.

In addition to burnishing, UHMWPE showed another macroscopic phenomenon, that is, forming of a material layer on or near the dome of all liners of stations 1 and 2 (Fig. 5a). UHMWPE-γ showed similar layer formation in 1 liner of station 1 and 2 liners of station 2 (Fig. 5b). Station 3 never showed a material layer, nor did any of the VEXLPE liners (Fig. 5c). However, with UHMWPE-γ there was no correlation between the wear rate and the presence or absence of the layer in stations 1 and 2. After the tests it was found that the layer could be removed by scratching with a fingernail. The thickness of the detached chips was c. 0.05 mm, measured with a micrometer. However, since the layer was not loose debris, it was not removed prior to the weighing for Fig. 4. In optical microscopy (Fig. 6), the observations were typical of multidirectional relative motion, i.e., subtle crisscross scratches and mild protrusions caused by plastic deformation. The layers were excluded from microscopy because they were too uneven for focused views. On the alumina heads, there was no damage, such as scratching, grain removal, or layers.

The serum bulk temperature in stations 1 and 2 was typically 8 °C higher than the environment temperature (22 °C), and in station 3, it was 5 °C higher.

Discussion

For the first time, the effects of component position and IOR on the wear of UHMWPE, gamma-sterilized UHMWPE, and VEXLPE in an OBM hip joint simulator were studied. Since the principal macroscopic finding in retrieved UHMWPE acetabular cups is burnishing, *(9)* it can be stated that the inverted position best reproduced this with all 3 materials studied. No anomalous layers were formed in the inverted position. Additionally, since cross-linking and, consequently, the improvement in the wear resistance is dependent on the gamma dose, *(8, 15–17, 26–28)* the mean wear rate should decrease in the following order, UHMWPE, UHMWPE-γ, VEXLPE. This was the case in station 3 only, and therefore the inverted position appeared preferable in this sense as well. The role of the IOR proved insignificant, which is not surprising considering that the IOR did not change the slide track patterns much (Fig. 3). The change of the tracks was the most apparent on the equator, where no wear occurred because there was no contact. This could be deduced from the fact that burnishing did not extend to the equator in any of the 27 liners.

Table 1. Test conditions, see Fig. 2.[a]

	OBM test station 1	2	3
Component position	Anatomic	Anatomic	Inverted
Inward-outward rotation	Absent	Present	Present

[a]In each test station and test condition, UHMWPE, UHMWPE-γ, and VEXLPE were tested (n = 3).

In an inverted position OBM study of 5 million-cycle duration with 32 mm CoCr heads, liners of 8.5 mm thickness made from UHMWPE, gamma-irradiated by doses of 33 and 95 kGy, showed wear rates of 16.3 ± 0.5 mg/10^6 cycles and 2.1 ± 0.2 mg/10^6 cycles, respectively. *(8)* In an anatomic position OBM study of 5 million-cycle duration with 40 mm CoCr heads, VEXLPE (0.1% blended, 100 kGy gamma-irradiated) liners showed a mean wear rate of 0.5 mg/10^6 cycles. *(29)* The corresponding value for conventional UHMWPE was 9.5 mg/10^6 cycles. In another anatomic position OBM study of 2.4 million cycle duration with 36 mm CoCr heads, liners of 5.9 mm thickness made from extensively cross-linked (sequentially gamma-irradiated to 30 kGy followed by annealing 3 times with a total gamma dose of 90 kGy, 'X3') UHMWPE showed a wear rate of 2.3 ± 1.0 mg/10^6 cycles. *(30)* With the "Endolab" hip joint simulator design that is compatible with Part 1 of the ISO 14242 standard, *(31)* a wear rate of 19.0 ± 0.6 mg/10^6 cycles was obtained for conventional 30 kGy gamma-irradiated UHMWPE liners against 36 mm diameter alumina heads in a 5 million-cycle test. *(32)* The corresponding value for VEXLPE (0.1% blended, 80 kGy electron-beam-irradiated) was 2.4 ± 1.0 mg/10^6 cycles. In an "AMTI" simulator test of 5 million cycles against 32 mm diameter CoCr heads, the wear rate of conventional 30 kGy gamma-irradiated UHMWPE liners was 35.6 ± 2.6 mg/10^6 cycles, whereas in the 100 million-cycle test against 40 mm diameter CoCr heads, the wear rate of vitamin E blended (>0.1%), electron-beam-irradiated (>100 kGy) VEXLPE ("Vivacit-E") liners was 1.8 ± 0.2 mg/10^6 cycles. *(33)* In general, the present wear rates were in line with those produced by other research groups. The wear rate of highly cross-linked UHMWPE

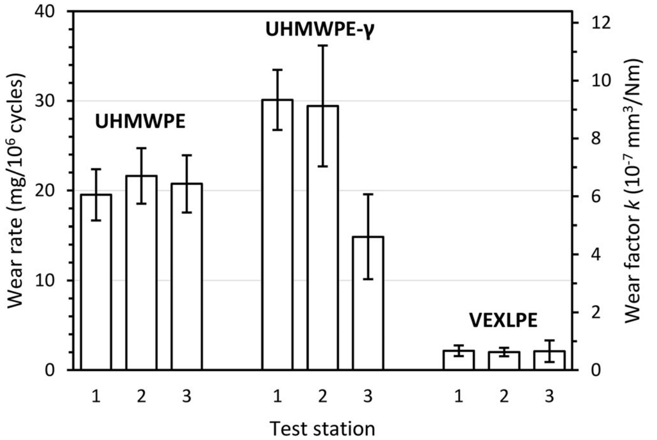

Figure 4. Wear rates and wear factors (mean and standard deviation) of 3 different polyethylene liners (n = 3) in 3 million cycle wear tests with 3 different OBM conditions, 1 anatomic, zero-offset lever, 2 anatomic, offset lever, 3 inverted, offset lever.

is roughly one order of magnitude lower than that of conventional, gamma-sterilized UHMWPE, that is, 2.0 mg/10^6 cycles versus 20 mg/10^6 cycles.

VEXLPE is a contemporary material, for which the UHMWPEs served as controls in the present study. Depending on the country, UHMWPE is being or has been replaced by VEXLPE. A volumetric clinical median wear rate of 3.5 mm^3/year has been obtained for VEXLPE against 32 mm CoCr heads. *(34)* Two million cycles in a hip joint simulator is usually taken to correspond to one year in vivo. *(35)* The present mean wear rate for VEXLPE, 2.1 mg/10^6 cycles, corresponds to 2.2 $mm^3/10^6$ cycles, that is, 4.4 mm^3 per 2 million cycles. Therefore, it can be stated the present VEXLPE wear rate was close to the above clinical wear rate. The is scarcity of published volumetric clinical wear rates for VEXLPE because it has not yet been in clinical use for a sufficient time to enable long-term clinical studies of wear.

Since stations 1 and 2 produced similar wear, it can be stated that the IOR was not important. The layer formation in the anatomic position with UHMWPE and UHMWPE-γ appeared as a test artefact as it is not observed in retrievals. *(9)* It may have been partly caused by a proposed "hot spot" *(7)* that thermally increased the creep deformation of the material. The higher lubricant bulk temperature in the anatomic position was indicative of a higher contact temperature. The dome looked as if material had been stretched as a dough to all directions tangentially by frictional shear, but since the contact stress field was stationary, the layered material could not be completely removed by the frictional shear stress that rotated about the load axis. The lower lubricant bulk temperature in the inverted position was probably attributable to the moving contact stress field that resulted in improved lubrication and lower friction, and was manifested as the absence of layer formation. Note still that in the assembly of the anatomic position specimens, care was taken that no air was trapped on the contact. The layers appeared to be also partly a material-specific phenomenon, since no layers formed in the anatomic position with VEXLPE or with another type of gamma-sterilized UHMWPE in an earlier OBM study. *(25)*

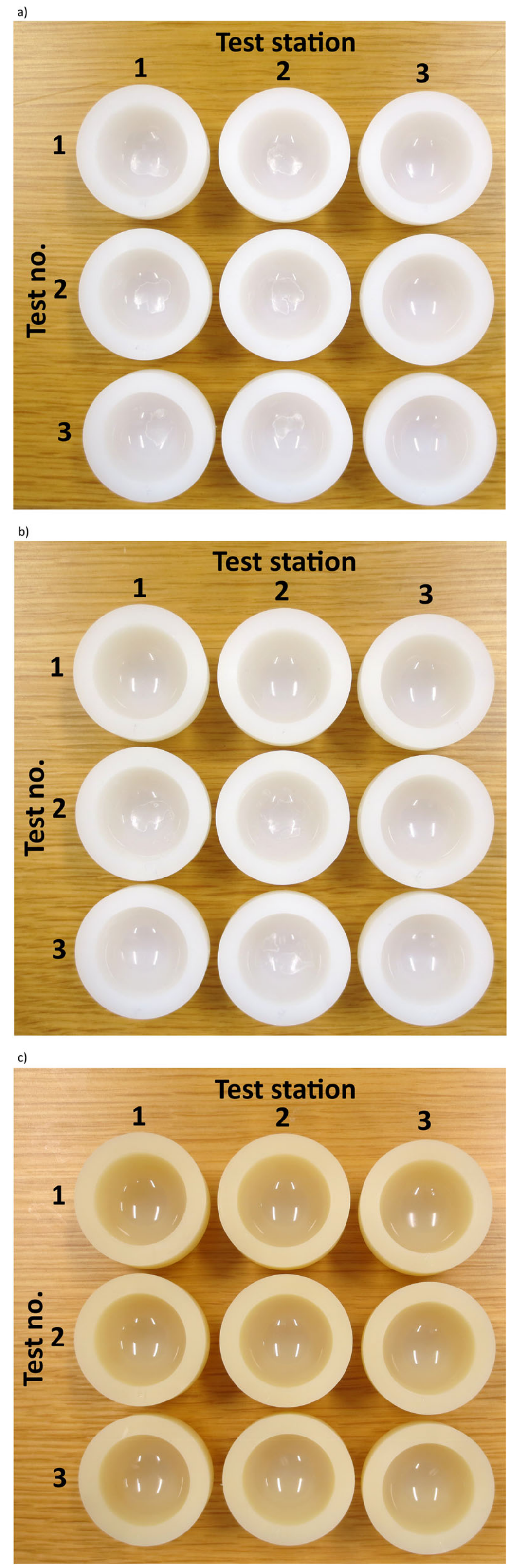

Figure 5. a) UHMWPE liners after test. b) UHMWPE-γ liners after test. c) VEXLPE liners after test.

A considerable advantage of the alumina femoral head is the reduced metal release. *(36–38)* A disquieting observation has been made recently that substantial metal release may occur clinically not only from the taper connection but also from the bearing surface of CoCr heads articulating against cross-linked polyethylene cups. *(39)* These two sources of

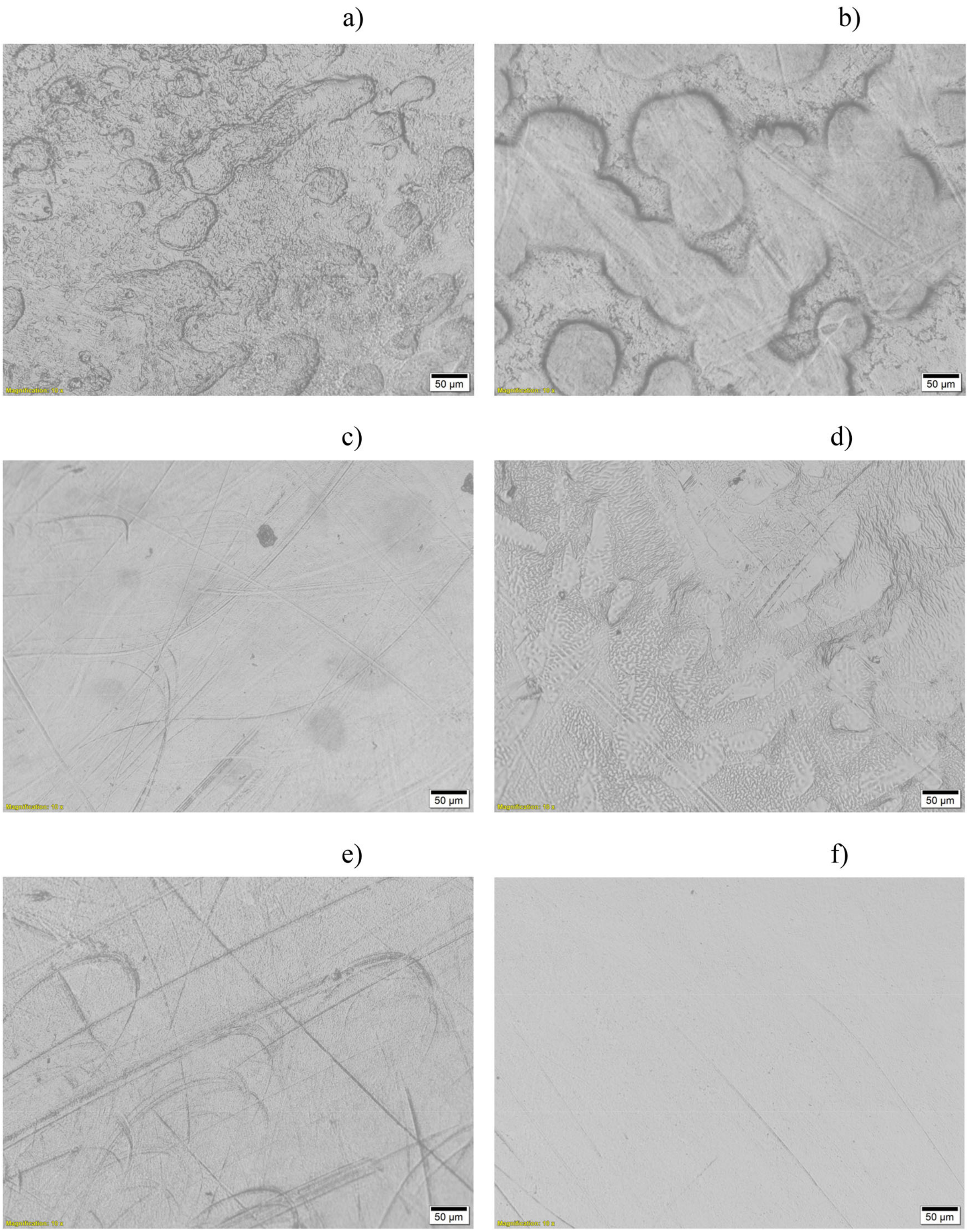

Figure 6. Optical micrographs from liner dome after wear tests: a) UHMWPE station 2; b) UHMWPE station 3; c) UHMWPE-γ station 2; d) UHMWPE-γ station 3; e) VEXLPE station 2; f) VEXLPE station 3.

metal release have been successfully distinguished with a hip joint simulator as well. *(40)* Alumina is more abrasion resistant than CoCr, but in the absence of abrasion, the wear of conventional UHMWPE against alumina has been found to be similar to that against CoCr. *(25)* Clinically, no significant difference in the wear of cross-linked polyethylene was found with CoCr versus alumina heads. *(41)* This indicates that the counterface material is unimportant for polyethylene wear as long as scratching or other types of roughening do not take place. The risk of roughening is lower with the harder alumina. In an OBM friction study, it was found that the frictional torque is of the order of 1 Nm in the anatomic position and test conditions similar to those of the present study, and that alumina and CoCr heads produced similar friction for UHMWPE. *(42)* This is in line with the similarity in UHMWPE wear against alumina and CoCr heads. *(25)*

A limitation of the present OBM test was static loading, but this did not prove to be problematic in the inverted position, the original test configuration. *(4, 5)* The relatively low load, 1 kN, could be considered another limitation. However, a wear rate as high as 48.3 mg/10^6 cycles was obtained with static 1 kN load for gamma-sterilized UHMWPE liners from a source different from the present source. *(25)* The test machine was the same and the test conditions were similar to those of the present study (28 mm alumina heads, alpha calf serum, no IOR). Burnishing and clinically relevant wear particle size distributions were produced in these conditions. *(25)* Overloading is likely to be a bigger risk. For example, a peak value of 3 kN in dynamic loading *(31)* leads to protuberance formation, *(43)* a phenomenon that is not observed clinically. The third limitation was the available head diameter, 28 mm. In contemporary orthopedic practice, the most popular diameter is 36 mm. However, it is unlikely that such a difference in the diameters causes major differences in wear mechanisms. *(44)* The larger head is used mainly to reduce the risk of dislocations. The fourth limitation was the sample size of 3 that hampers statistical testing. Three is nevertheless the most common sample size in hip simulator literature due to the limited testing capacity.

Conclusions

The inverted position resulted in a burnished appearance of the bearing surfaces of all liners of the 3 different polyethylenes. Burnishing is characteristic of clinically retrieved acetabular cups and it results from multidirectional relative motion and protein-based lubrication. In the inverted position, the wear rate decreased with increasing gamma dose that is known to improve wear resistance by cross-linking. For these two reasons, the inverted position appeared preferable in the present OBM with respect to contemporary UHMWPE materials. In the anatomic position, the wear was similar with and without IOR. Therefore, the significance of IOR appears small. Layer formation was observed in the anatomical position. Layers have not been observed in retrieved polyethylene acetabular components. Therefore, anatomic position appeared less recommendable for the OBM, based on the present tests. The mean wear rate of VEXLPE, of the order of 2 mg/10^6 cycles, was close to recent clinical observations and in agreement with wear rates produced in hip joint simulator studies by other research groups. The VEXLPE wear rate was an order of magnitude lower than that of conventional UHMWPE. This is also in agreement with clinical observations and other hip joint simulator studies.

Declaration of interest statement

There are no conflicts of interest.

Funding

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