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Wear and deformation of metal-on-polyethylene hip bearings under edge loading conditions due to variations in component positioning

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ABSTRACT

Despite the clinical success of hip joint replacement, the risk of revision, particularly in younger and more active patients, still remains a concern. To identify conditions of high wear, fatigue and potential failure modes, there is need to be able to replicate a range of *in vivo* conditions with pre-clinical testing methods in order to predict the range of clinical wear. In particular, edge loading of metal-on-polyethylene hip replacements has the potential to have impact on both surface wear and fatigue failure. The mode of edge loading explored in this study involves separation of the centres of the femoral head and acetabular cup during a portion of the gait cycle. Such edge loading can occur due to variations in translational and/or rotational positioning of the hip replacement. In this study, the influence of translational positioning along the medial-lateral axis (medial-lateral translational mismatch) combined with rotational positioning of the acetabular cup about the anterior-posterior axis (cup inclination angle) on the occurrence and severity of edge loading, and wear and plastic deformation, was investigated for size 36 mm metal-on-polyethylene total hip replacements on a ProSim EM13 electromechanical hip joint simulator. A two phase approach was used; a short term study where the mechanics of the hip bearing were assessed under a wide range of input conditions (45° and 65° cup inclination angle and 1, 2, 3, 4 mm medial-lateral translational mismatch); followed by wear simulation for a lower number of conditions.

Larger medial-lateral translational mismatch conditions led to increased levels of dynamic separation between the femoral head and acetabular cup with the largest dynamic separation (2.4 ± 0.2 mm, mean ± 95% confidence limits) measured under 4 mm translational mismatch with the 65° cup inclination angle conditions. The load at the rim at 0.5 mm of separation was also highest at this condition, as was the mean wear rate (23.0 ± 2.4 mm^3 / million cycles).

Dynamic separation, load at the rim and wear was consistently greater with the steeper cup inclination angle of 65° compared to 45° for all translational mismatch conditions. Translational mismatch conditions of 3 mm and 4 mm resulted in dynamic separation displacements >0.5 mm. At a 45° cup inclination angle under standard concentric conditions (zero translational mismatch) minimal wear and plastic deformation occurred at the rim of the cup, however at a 65° cup inclination edge contact at the rim was identified.

Variations in rotational (cup inclination angle) and translational (medial-lateral) positioning influenced the magnitude of dynamic separation, severity of edge loading, and wear of metal – on - moderately cross-linked polyethylene hip replacements, demonstrating the importance of surgical component positioning.

1. Introduction

Hip replacements are one of the most successful types of total joint replacements, with metal-on-polyethylene being the most widely used bearing. These hard-on-soft bearings are showing long term success beyond 20 years following implantation, however the demands of younger and more active patients increase the need for higher performing and more reliable hip replacements with longer lifetimes [1,2]. Despite the clinical success of hip joint replacement, the risk of aseptic loosening, osteolysis due to wear debris, subluxation, dislocation, impingement, material fracture and fatigue, still remain a concern and need to be reduced further to extend longevity in young and active patients. Loading of hip replacements and sliding contact between the femoral head and acetabular cup lead to wear of the implant and

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subsequently wear debris released into the surrounding tissue may lead to osteolysis induced aseptic loosening of the implant [3,4].

The wear rates of conventional polyethylene were found to be 30–50 mm^3/million cycles *in vivo* and 35 mm^3/million cycles *in vitro* using hip joint simulators [5,6]. Wear has been significantly reduced with the introduction of cross-linked polyethylene [7], with wear rates of highly cross linked polyethylene reported to be <10 mm^3/million cycles [8], and moderately cross linked polyethylene 8–15 mm^3/million cycles (ProSim pneumatic and EM13) [9]. Further, clinical studies up to 15 years show low levels of osteolysis for cross-linked polyethylene in the hip [10,11].

To ensure the long term success of hip replacements and identify conditions of high wear, fatigue and potential failure modes, there is need to be able to replicate a range of *in vivo* conditions with pre-clinical testing methods in order to predict the range of clinical wear. Therefore hip joint simulators and simulator methods have been developed and used to carry out preclinical experimental simulation on hip replacements under a wider range of conditions [2,9,12–16]. Traditionally, experimental simulation has been based on standard gait (walking cycle) conditions, assuming well positioned and concentric implants. However, separation of the femoral head from the acetabular cup has been observed clinically using fluoroscopy during different patient activities, including the walking gait cycle [17]. This separation can result in edge loading, where the contact area between the head and the cup is located on the rim chamfer of the acetabular cup. Such adverse mechanics during activities that are frequently undertaken such as walking, have the potential to have impact on both surface wear and fatigue failure. For hard-on-soft bearings for example, edge loading may lead to an increase in plastic deformation, damage, cracking and wear, at the rim of the cup [18–20]. Indeed, edge loading in crosslinked polyethylene bearings may lead to increased surface wear as well as increased risk of fatigue or fracture in the longer term.

Edge loading can be a result of many different factors, including component positioning, soft tissue reconstruction, implant design and patient factors. However, two different modes can be considered; one that involves mechanical impingement of the stem neck on the cup and lever out of the head from the cup, and a second that does not involve impingement, but involves separation of the centres of the femoral head and acetabular cup during a proportion of the gait cycle, which could in the extreme lead to subluxation. It is the latter, separation and edge loading without impingement that is considered in this study. The simulation methodology to replicate edge loading was pioneered in the early 2000's by Nevelos et al. [21] who observed stripe wear on ceramic-on-ceramic retrievals [22]. In this methodology, a pre-defined fixed level of 0.5 mm separation between the head and the cup, known as micro-separation, was used to create the edge loading. This *in vitro* method replicated the wear rates, stripe wear pattern and bi-modal wear debris distribution observed clinically for ceramic-on-ceramic hip replacements [23].

More recently, rather than pre-defining the level of separation, a force control system has been developed, based on a (medial–lateral) translational mismatch between the centres of the femoral head and acetabular cup, and then the level of dynamic separation (usually between 0.5 and 5 mm) has been used as a measure of the severity of edge loading as well as wear rates [24,25].

Edge loading can occur due to variations in translational and/or rotational positioning of the hip replacement. Specifically, translational positioning of the femoral head and the acetabular cup can be defined as the position of the centres of the rotations of the acetabular cup and femoral head relative to each other along the medial-lateral, anterior-posterior and/or superior-inferior axes. Rotational positioning of the acetabular cup can be described as cup inclination (rotation about the anterior-posterior axis), version (rotation about the superior-inferior axis) and tilt (rotation about the medial-lateral axis). In this study, translational positioning along the medial-lateral axis (medial-lateral translational mismatch) and rotational positioning of the acetabular cup about the anterior-posterior axis will be investigated (cup inclination angle). These are also the positional variables that have been incorporated into an ISO pre-clinical hip simulator testing standard (International Organization for Standardization, ISO14242-4 (2018)) [26].

This international ISO standard describes a two part approach that has been developed to assess a number of component positioning variables to investigate the mechanics and then wear of hip replacements [24]. The rationale of this approach is to consider a wide range of variables and factors to understand effects of these variables on the occurrence and severity of edge loading before proceeding to wear simulation studies, that will predict the wear under certain edge loading conditions chosen from the many configurations.

This approach was used in this study to:

- o Investigate the occurrence and severity of edge loading of metal-on-polyethylene bearings under different levels of medial-lateral translational mismatch conditions at 45° and 65° cup inclination angles. These cup inclination angles were chosen as 45° is currently considered a target inclination angle during surgery, being within the 'safe zone' as defined by Lewinnek *et al* (1978) [27], whereas a 65° cup inclination angle is considered a steep cup inclination angle and has been used in previous investigations [24,25].
- o Determine the wear and plastic deformation of metal-on-polyethylene bearings under edge loading conditions resulting from translational mismatch at 45° and 65° cup inclination angles.

2. Materials and methods

Size 36 mm metal-on-polyethylene hip replacements (Moderately Cross linked UHMWPE (Ultra-High-Molecular-Weight-Polyethylene) Marathon™, DePuy Synthes Joint Reconstruction, Leeds, UK) were studied on a ProSim EM13 electromechanical hip joint simulator (Simulation Solutions, Stockport, UK). The polyethylene cups were backed by a metallic shell (PINNACLE®, DePuy Synthes Joint Reconstruction, Leeds, UK) and the cobalt-chrome heads (Articuleze®, DePuy Synthes Joint Reconstruction, Leeds, UK) were placed onto vertical spigots with a 12/14 taper.

The ProSim EM13 electromechanical hip joint simulator is a multi-axis multi-station machine capable of simulating a gait cycle as defined by ISO14242-1 [28]. Flexion/extension (+25°/−18°), abduction/adduction (−4°/+7°) and internal/external (+2°/−10°) rotations were applied to the femoral head. The acetabular cup was positioned superiorly to the femoral head and the axial load applied vertically through the centre of the acetabular cup. The simulator allows the acetabular cup to self-align with the femoral head in all three axes of translation. However, a spring system in the medial-lateral axis allowed the introduction of medial-lateral translational mismatch between the femoral head and the acetabular cup centres [25].

This study was split into two parts:

- Part 1: A short term study where the mechanics of the hip bearing were investigated under a wide range of input conditions. The dynamic separation between the head and cup during gait and the maximum load at the rim during separation were assessed.
- Part 2: Studies of wear and deformation, where wear simulation was carried out at a smaller range of different cup inclination angles and medial-lateral translational mismatch conditions.

For the mechanical studies (part one), six metal-on-polyethylene bearings were used. The cups were inclined at *in vivo* equivalent angles of 45° ($n = 3$) and 65° (n = 3) with 1, 2, 3, 4 mm medial-lateral translational mismatch. The rotational positioning of the cup was set by using cup holders which were inclined at the required cup inclination angle. The translational mismatch was set by displacing the cup and therefore it's bearing centre away from the head bearing centre along the medial-lateral axis by the required level of mismatch. As translational mismatch was investigated in the ML plane only, the version angle was fixed for all cases.

For all studies three-axes of rotation conditions were applied in accordance with ISO14242-1 [28], with all rotations being applied to the femoral head. A twin peak 3kN vertical load was applied with a 70 N swing phase load through the acetabular cup to represent standard gait loading conditions. The test frequency was 1 Hz, and 128 data points were collected during the gait cycle.

The dynamic separation along the medial-lateral axis was measured during the gait cycle using a linear variable displacement transducer (LVDT). The axial and medial loads were measured using a bespoke six axis load cell positioned above the acetabular cup during the gait cycle (Simulation Solutions, Stockport, UK) [25]. The load outputs were analysed to determine the rim load at 0.5 mm of dynamic separation. The load at the rim was not determined for dynamic separation displacements lower than 0.5 mm due to the uncertainty of measurements at low level of displacements.

For the mechanical study (part one), each condition ran for 500 cycles. For the wear simulation (part two), two million cycles or three million cycles were run for the different conditions considered in this study (Table 1).

The lubricant used for all testing was 25% new-born calf serum supplemented with 0.03% (*v*/v) sodium azide to minimise bacterial growth. For the wear simulation, the simulator was stopped at approximately every 330,000 cycles for a clean and change of lubricant. Components were removed from the simulator approximately every one million cycle and cleaned in accordance with a standard operating procedure for gravimetric and geometric measurements to be carried out. Gravimetric wear was determined using a microbalance (Mettler Toledo XP205 analytical balance, Greifensee, Switzerland) which had a readability of 0.01 mg. The change in mass was converted to volumetric wear using a density of 0.934×10^{-3} g/mm^3 for UHMWPE. Unlike hard bearings such as metals and ceramics, polyethylene deforms under loading. Creep is permanent plastic deformation of the polyethylene component as a result of loading. Coordinate measurement machines have been used to show that the majority of the polyethylene creep deformation occurs within the first two million cycles of *in vitro* hip simulation [7,8]. A coordinate measurement machine (Legex 322, Mitutoyo, Japan) was used to produce three-dimensional surface maps of the polyethylene cups. The coordinate measurement machine output data were imported into Redlux software (Southampton, UK) to produce surface plots of the cups and to measure the penetration depths (as a result of wear and creep) on the cups.

Mean values and 95% confidence limits were calculated, trends and descriptive statistics were used to describe the majority of the data. Statistical analysis of the wear rates was carried out using a two-way ANOVA (two independent variables of medial-lateral translational mismatch and cup inclination angle) with significance levels taken at $p < 0.05$.

The data associated with this article are openly available through the University of Leeds data repository [29].

3. Results

Larger medial-lateral translational mismatch conditions led to increased levels of dynamic separation between the femoral head and acetabular cup with the largest dynamic separation (2.4 ± 0.2 mm, mean ± 95% confidence limits) measured under 4 mm translational mismatch with the 65° cup inclination angle conditions (Fig. 1). Minimal separation (<0.5 mm) was observed at the 1 mm translational mismatch conditions. Translational mismatches of 3 mm and 4 mm resulted in dynamic separation displacements >0.5 mm. Dynamic separation was consistently greater with the steeper cup inclination angle of 65° compared to 45° for all translational mismatch conditions.

Higher loads at the rim were recorded under conditions with higher inputs of translational mismatch. The load at the rim at 0.5 mm of separation was higher for the 65° cup inclination angle compared with a 45° cup inclination angle conditions with the highest load recorded under 4 mm translational mismatch with the steep cup inclination angle condition (Fig. 2). The load at the rim was not determined for dynamic separation displacements lower than 0.5 mm due to the uncertainty of measurements at low level of displacements, and hence were not determined for the 1 mm and 2 mm translational mismatch conditions.

The mean wear rates of polyethylene significantly increased as the level of medial-lateral translational mismatch increased ($p < 0.01$, two way ANOVA) (Fig. 3). Increasing the cup inclination angle from 45° to 65° caused a significant increase in wear ($p < 0.04$, two way ANOVA). The lowest mean wear rates measured were at 0 mm translational mismatch at 45° cup inclination angle (12.9 ± 3.8 mm^3 / million cycles) and the highest mean wear rates occurred at 4 mm translational mismatch with the steep cup inclination angle conditions (23.0 ± 2.4 mm^3 / million cycles). There was no interaction between cup inclination angle and translational mismatch ($p > 0.81$).

Under standard concentric conditions (0 mm translational mismatch) with inclination angle of 45°, the wear area was confined within the spherical part of the acetabular cup (Fig. 4). As the cup inclination angle increased to 65°, the wear area intersected with the rim (chamfer) of the acetabular cup, however, the maximum penetration was still within the spherical bearing surface. However, when a translational mismatch was introduced between the head and the cup under steep cup inclination angle, the maximum penetration occurred at the rim (chamfer) of the acetabular cup (Fig. 4). The largest maximum penetration depth occurred at 4 mm translational mismatch for cups inclined at 65° (Fig. 5). At three million cycles, the penetration (wear and deformation) was greater at the edge of the cup at 65° compared to 45° cup inclination angles. There was larger penetration at the edge of the cup when 4 mm translational mismatch was applied compared with 2 mm translational mismatch for the same cup inclination angle.

4. Discussion

A two stage preclinical testing approach has been applied to study the effect of variations in rotational (cup inclination) and translational (medial-lateral) positioning on metal-on-polyethylene bearings on the occurrence and severity of edge loading and the resulting wear and plastic deformation. This is the first study to investigate the relative effects of combinations of cup inclination angle and medial-lateral translational mismatch on the biomechanics and wear of metal-on-polyethylene hip replacements.

Higher levels of translational mismatch and steeper cup inclination angles led to increased dynamic separation and load at the rim (Figs. 1 and 2); such high levels increase the risk of cup damage (that is; wear, plastic deformation, fatigue and cracking). The higher wear rates at 4 mm translational mismatch corresponded with the increased loading at the rim and higher severity of edge loading observed at this translational mismatch condition. At a 45° cup inclination angle under standard concentric conditions (zero translational mismatch) minimal wear and deformation occurred at the rim of the cup, however at a 65° cup inclination edge contact at the rim was identified (Fig. 4). Wear (Fig. 3) increased significantly with increasing cup inclination angle ($p < 0.04$) and with increasing medial-lateral translational mismatch ($p < 0.01$).

Table 1
Wear study conditions (part two).

Translational mismatch (mm)	Inclination angle (*in vivo* equivalence)	Number of cycles	Number of repeats
0	45°	2 million	3
	65°	2 million	3
2	45°	3 million	6
	65°	3 million	6
4	45°	3 million	6
	65°	3 million	6

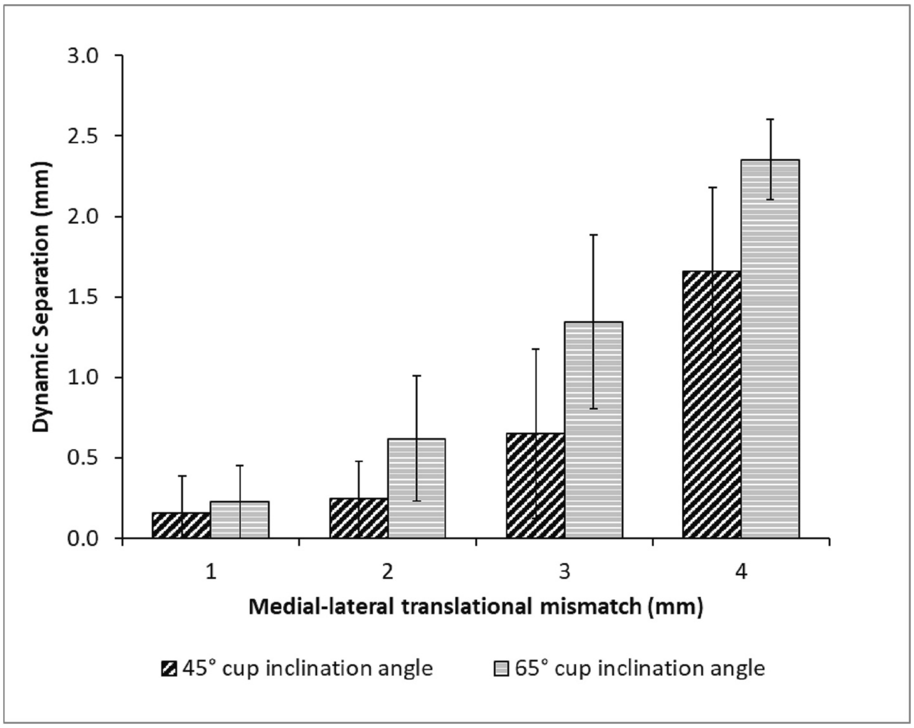

Fig. 1. Dynamic separation (mean ± 95% confidence limits, $n = 3$) of 36 mm diameter metal-on-moderately crosslinked UHMWPE bearings at 45° and 65° cup inclination angles with 1, 2, 3 and 4 mm of medial-lateral translational mismatch.

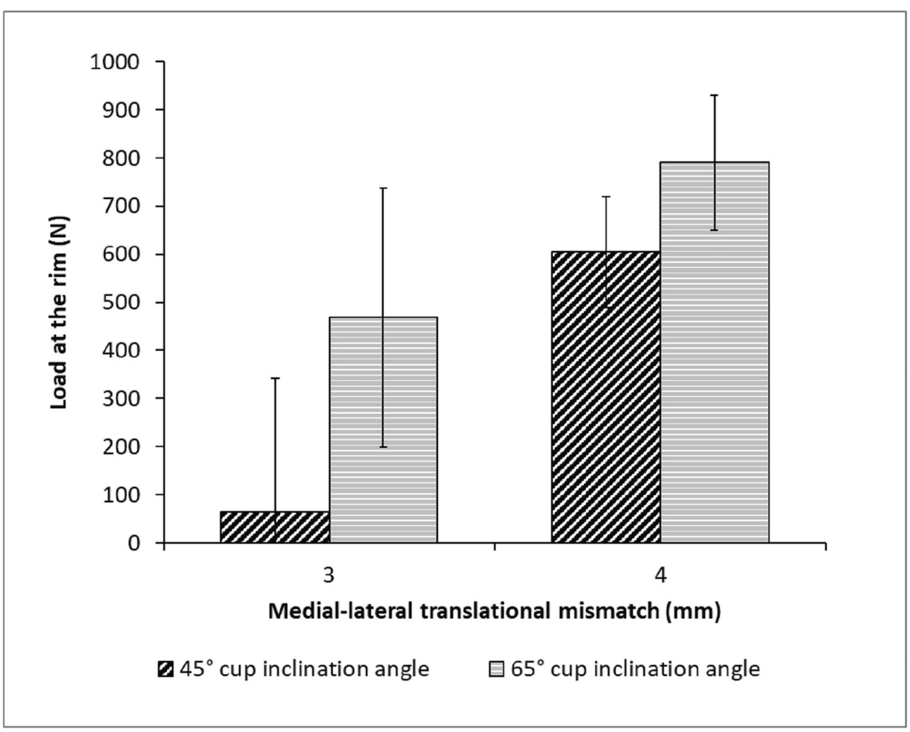

Fig. 2. Load at the rim at 0.5 mm of dynamic separation (mean ± 95% confidence limits, $n = 3$) of 36 mm diameter metal-on-moderately crosslinked UHMWPE bearings at 45° and 65° cup inclination angles with 3 and 4 mm of medial-lateral translational mismatch (The load at the rim was not determined for dynamic separation displacements lower than 0.5 mm due to the uncertainty of measurements at low level of displacements, and hence were not determined for the 1 mm and 2 mm translational mismatch conditions).

The increased loads, contact and severity of edge loading at the rim explains the increase in wear and deformation at the rim at these steeper and higher mismatch conditions. Increased penetration (wear and deformation) under edge loading near the rim of the cup (Fig. 5) may lead to cracking and fatigue failure in longer term studies with oxidative degradation of the polyethylene, and should therefore be avoided.

This study did not simulate or represent oxidative degradation and ageing of the UHMWPE which can occur in the body over long periods of time. This needs to be incorporated into future work in conditions that more closely represent those found in the body. Such degradation can adversely affect both surface wear, and fatigue wear and fatigue failure.

Further developments in polyethylene materials such as antioxidant UHMWPE have been shown to improve the mechanical properties of polyethylene in comparison to cross linked polyethylene whilst not

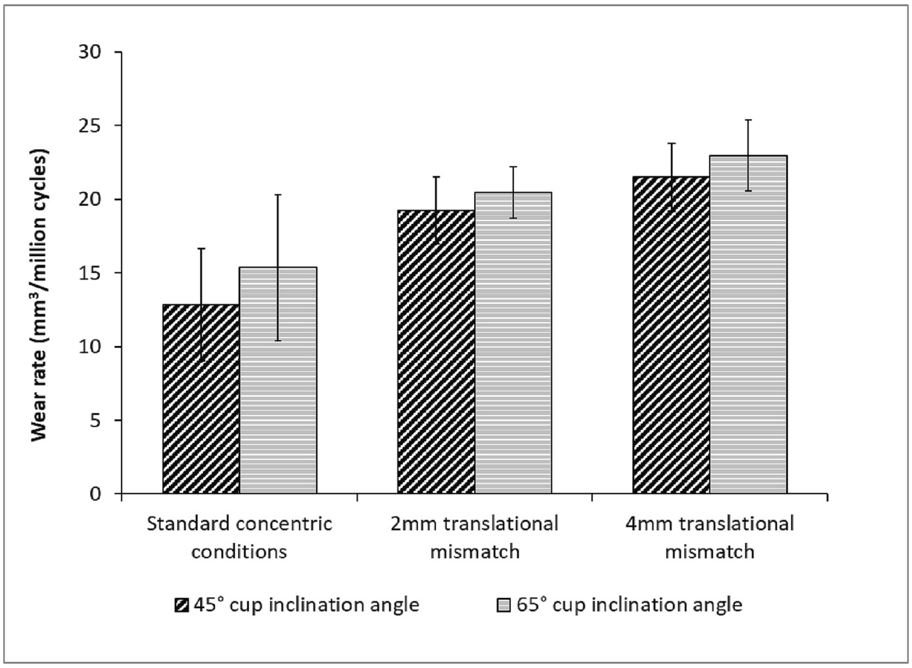

Fig. 3. Wear rates (mean ± 95% confidence limits) of 36 mm diameter metal-on-moderately crosslinked UHMWPE bearings at 45° and 65° cup inclination angles with 0 mm ($n = 3$), 2 mm ($n = 6$) and 4 mm (n = 6) of medial-lateral translational mismatch.

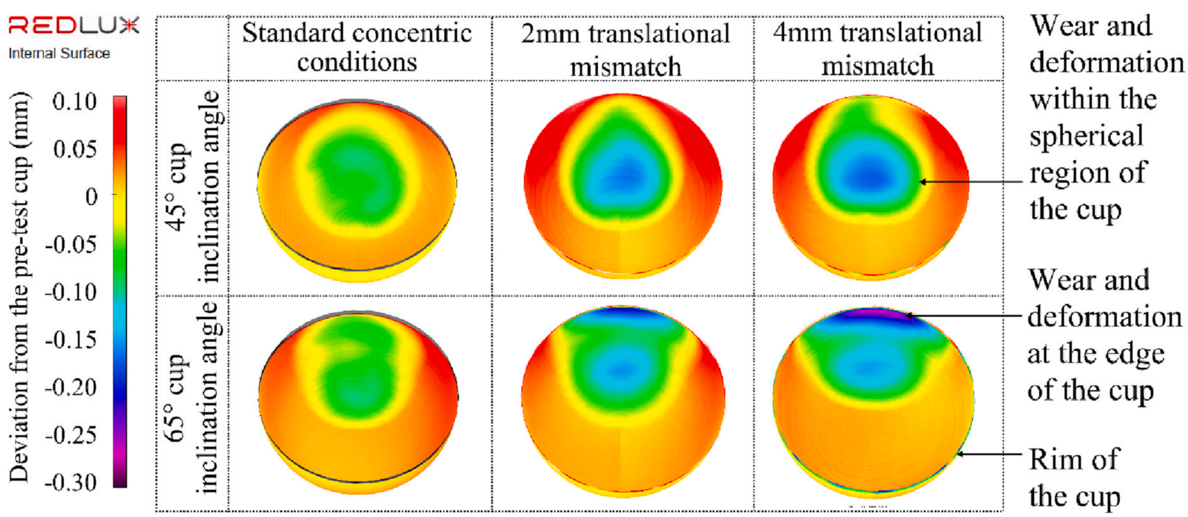

Fig. 4. Combined wear and deformation of 36 mm diameter metal-on-moderately crosslinked UHMWPE bearings at 45° and 65° cup inclination angles with 0 (*i.e.* standard concentric condition), 2 and 4 (mm) of medial-lateral translational mismatch at three million cycles. Negative values indicate penetration on the cup.

comprising wear resistance [30]. Understanding their performance under conditions explored in this study would be of interest. Edge loading is a condition that is relevant to all bearing types and material combinations. The consequence of edge loading, however, is different for different material combinations. In this study of unaged metal-on-polyethylene these consequences appear to have been limited to a two-fold increase in wear rates and plastic deformation on the rim of the acetabular cup. Whereas, the consequences for other bearing materials, such as ceramic-on-ceramic, were a many fold increase in wear rates and stripe wear mechanisms that have been linked to audible squeaking [24,25]. Furthermore, the consequences in metal-on-metal bearings have been the most severe with many fold increase in wear rate, wear debris and metal ion release that have been linked with severe implant failure clinically [16,31–33].

This study has specifically studied the effects of cup inclination angle and medial-lateral translational positioning. In reality, translational positioning variation may occur in all three axes, making this experimental model a simplified model of the clinical scenario. The other rotational and translational positioning factors (for example, version angle and anterior-posterior translation) may affect the tribological performance of hip replacement, and will be studied in future.

5. Conclusion

Variations in rotational (cup inclination angle) and translational (medial-lateral) positioning influenced the magnitude of dynamic separation, severity of edge loading, and wear of metal – on - moderately cross-linked polyethylene hip replacements, demonstrating the importance of surgical component positioning.

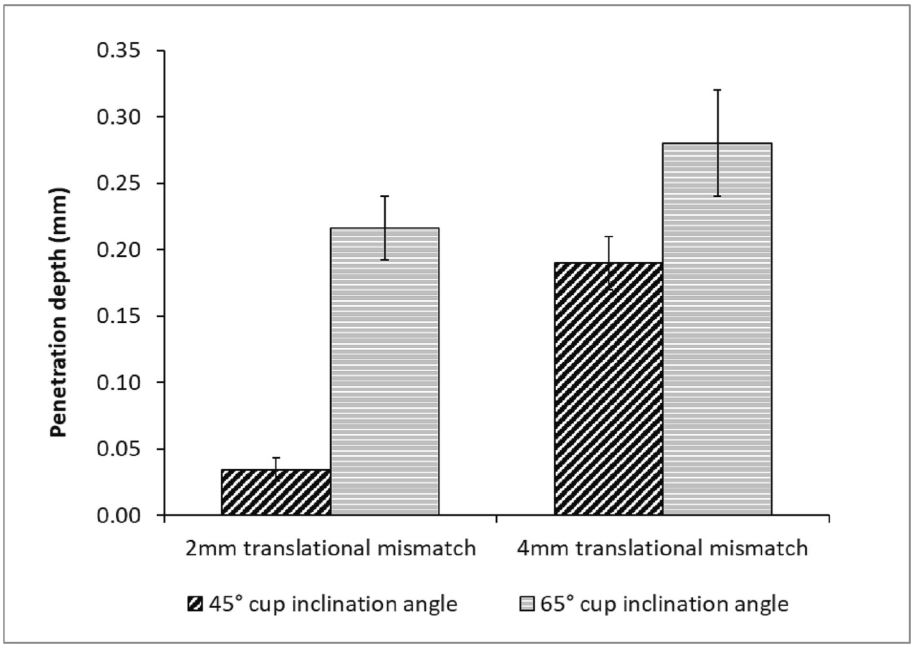

Fig. 5. Maximum penetration depth at the edge of cup at 45° and 65° cup inclination angles with 2 and 4 (mm) of medial-lateral translational mismatch at three million cycles.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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Data availability

The data associated with this article will be openly available through the University of Leeds data repository [29].

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