Do temperature variations at the bearing surface during gait affect polyethylene wear in Charnley low-friction arthroplasty of the hip? Simulator study comparing UHMWPE and highly cross-linked polyethylene

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A B S T R A C T

Introduction: There are significant individual variations in the polyethylene (PE) wear of Charnley total hip arthroplasty (THA) in published studies. This could be in part related to variations in hip joint kinematics with abnormal heating at the metal/PE interface. The objectives of our hip simulator experiment were: (1) to measure PE wear as a function of hip kinematics and temperature variations at the interface; (2) to compare ultra-high molecular weight polyethylene (UHMWPE) to latest generation highly cross-linked PE (XLPE).

Hypothesis: Our hypothesis was that PE wear is correlated with temperature increases at the interface and thereby hip joint kinematics.

Material and methods: A simulator study was performed with four UHMWPE cups (Initiale™, Amplitude, Valence, France) and two XLPE cups (X3, Stryker, Kalamazoo, Michigan, USA) subjected to 5 million cycles each. The temperature at the femoral head/cup interface was measured every 500 cycles and implant dimensions were measured every 1 million cycles.

Results: The average temperature was 42°C for 1 Hz and 50°C for 1.5 Hz, no matter the type of PE tested. There was a large difference between UHMWPE and XLPE in their roughness, but no temperature variations or wear effects. Femoral head penetration after the first 1 million cycles was 0.18 mm for the XLPE and 0.075 mm UHMWPE on average. Between 1 and 5 million cycles, the penetration was less than 0.1 mm per million cycles, with XLPE being similar to UHMPE.

Discussion: Our study found a significant temperature increase at the bearing interface as a function of frequency. But there was no correlation between temperature variations and PE degradation. However, shear stresses were underestimated because our simulator could not reproduce abduction and adduction movements. Our hypothesis was not confirmed because PE deformation was not correlated to temperature variations. XLPE was not better than UHMWPE in the particular conditions of this study. Simulator studies are limited because of the lack of standards on cycling and the simulator bath.

Level of evidence: III–prospective case-control study in vitro.

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analysis with a Vicon™ optoelectronic motion capture system found a correlation between wear and maximum angular speed in flexion-extension during stance and swing phases. We hypothesized that temperature variations at the metal head/PE interface could result in heating of the PE and reduction in its wear resistance.

The objectives of our study were:

- to reproduce the gait cycle of patients who have abnormal PE wear on a hip simulator by varying the frequency between 1.0 and 1.5 Hz and measure PE deformation and temperature variations at the implant interface over 5 million cycles;
- to compare an early generation UHMWPE component with a latest generation highly cross-linked PE (XLPE) component at a 1.5 Hz walking frequency.

Our hypothesis was that PE wear is correlated with temperature increases at the interface and thereby hip joint kinematics.

2. Material and Methods

2.1. Material

This experimental study was carried out in an ISO 9001 certified laboratory for design controls. A hip simulator was used. Six bearings were testing: four UHMWPE cups (Iinitiale™, Amplitude, Valence, France) made of GUR 1050 gamma sterilized at 25 KGY and two XLPE cups (X3, Stryker, Kalamazoo, Michigan, USA) made of GUR 1020 that was cross-linked using three 3 Mrad cycles, annealed at 130° and gas plasma sterilized. The same femoral head was used in all bearings: a 22.2-mm diameter stainless steel. The cups had a 44-mm outer diameter and were taken from sterile implantable stock.

2.2. Experimental methods

The stimulator (Fig. 1) allowed flexion/extension and rotation movements to be made. The 400 mL simulator bath was filled with 25% (+2%) foetal bovine serum in demineralized water. The protein concentration was 37 g/L in accordance with the ISO 14242-1:2002 standard (protein concentration > 17 g/L). The bath temperature was 37 ± 2°C. The bath level was checked daily and adjustments made for evaporation. A thermocouple was used to measure temperature variations at the bearing interface and placed at the bottom of a tunnel with the end located 0.65 mm from the femoral head's surface.

Each cup was cemented into a cup holder; centring was verified (Fig. 2) using a coordinate measuring machine (CMM) (Renishaw, Champ-sur-Marne, France) (accuracy ± 0.5 μm). The cup holder was then positioned on a vertical rotating shaft with H7f6 adjustment (maximum play of 79 μm). The prosthetic femoral head was placed on the head support and its height checked with the CMM.

After positioning the femoral head and its support on the simulator, femoral head centring was checked again to verify the femoral head alignment on the rotating shaft of the cradle (cup support) to avoid any cam effects. We used a comparator (Fig. 3) secured to the vertical rotating axis that could be turned around the head to verify its centring. A maximum offset of 50 μm was tolerated.

All the cups were tested using the same cyclic loading protocol on the simulator; the only difference was a frequency of 1.0 or 1.5 Hz. An 800 N preload was applied. A cyclic load of 3500 N (Fig. 4) was applied in combination with 20° rotation (15° external rotation; 5° internal rotation) and 18° flexion/extension (18° flexion, 18° extension). This amplitude corresponds to the range of motion used by patients in the pilot gait study who had abnormal PE wear; as a consequence, this protocol did not conform to ISO 14242.

2.3. Measurement method

The following measurements were carried out:

- temperature every 500 cycles (average calculated every 1 million cycles);
- dimensions of each cup at the start of the study and then every 1 million cycles (change of femoral head shape, roughness at pole and equator of cup, subsidence of sphere relative to cup construct).
3. Results

Table 1 shows the average temperature for each of the six bearings tested. Bearings 1 and 2 (XLPE; 1.5 Hz) had an average temperature of 49.7 °C, which was close to the 49.15 °C temperature of bearings 3 and 6 (UHMWPE; 1.5 Hz). Bearing 4 (UHMWPE; 1Hz) had an average temperature of 41.97 °C. Bearing 5 (UHMWPE 1Hz) had a greater than 5 degree change in temperature between 3 and 4 million cycles, going from an average of 42 to 47.5 °C.

Femoral head shape was not altered in any of the bearings after 5 million cycles. The roughness of the femoral heads was 0 µm Ra at the start of the study and after 5 million cycles. The temperature in the bath varied less than 0.5 °C.

The roughness at the pole of bearings 1 and 2 (XLPE) was 0.165 µm Ra on average before the simulator was started. The roughness decreased after 1 million cycles and then stabilized at about 0.1 µm Ra. The roughness at the pole of bearings 3 to 6 (UHMWPE) was 0.95 µm Ra on average before the simulator was started. The roughness decreased after 1 million cycles, with average values ranging from 0.053 and 0.25 µm Ra. The roughness after 5 million cycles (average of 0.12 µm Ra) was similar to that of the XLPE bearings. The UHMWPE bearings' roughness was not affected by temperature or cycling frequency.

Penetration of the sphere relative to the jig was measured as the distance between the bottom of the cup's sphere and the upper portion of the cup support. This is evidence of femoral head penetration in the PE and corresponds to deformity due to wear and creep (Table 2).

Femoral heads from bearings 1 and 2 (XLPE, 1.5 Hz) had the greatest PE penetration during the first 1 million cycles. The penetration was 0.15 and 0.22 mm for bearings 1 and 2, respectively, versus an average of 0.1 mm for UHMWPE bearings, no matter the frequency.

Penetration, no matter the type of PE, was especially noticeable as the simulator was starting up, between 0 and 1 million cycles. It was 0.18 mm for XLPE and 0.075 mm for UHMWPE on average. Beyond the first 1 million cycles, all femoral heads (except bearing 5) had less than 0.1 mm penetration per million cycles. Head penetration into the XLPE and UHMWPE cups at 1.0 Hz and 1.5 Hz was not correlated to simulator frequency or interface temperature.

Bearing 5 (UHMWPE, 1 Hz) had a large increase in femoral head penetration (0.16 mm) between 3 and 4 million cycles. Penetration was 0.25 mm between 4 and 5 million cycles. This increase...
in femoral head penetration was correlated to a 6°C temperature increase starting at 4 million cycles.

4. Discussion

PE wear is one the main causes of THA failure. These failures can either be biological (loosening) because of macrophage activation due to the presence of PE particles or mechanical (dislocation) because of loss of joint congruency. Thus it is essential to look into intrinsic and extrinsic factors that can accelerate PE wear. The results of our study confirm that the bearing interface heats significantly and is related to simulator frequency; however our primary hypothesis of PE deformation being correlated to temperature was not confirmed.

Our study has several limitations:

- only 5 million cycles were done. This test duration corresponds to the average of published studies. The changes in wear and temperature had stabilized after 3 million cycles in our study;
- the simulator does not reproduce hip abduction and adduction movements. Our simulator protocol did not comply with the ISO 14242-1 standard. It is possible that shear stresses at the PE surface were underestimated;
- the small number of samples did not allow for statistical testing; however this was a pilot study and more samples will be added in the future;
- no quantitative or qualitative measures of wear debris from the two types of PE were made. Although this would have allowed us to specify the origin of the cup deformation (wear or creep), we wanted to focus this study on heating at the interface.

We found no temperature variations related to the type of PE. During testing, bearing 5 had a temperature spike and augmented PE deformation after 4 million cycles. This was likely due to incorrect positioning of the cup holder after surface measurements (offset relative to femoral head). Measuring the temperature at the interface of THA simulators could be a good method to indirectly control correct implant positioning. But very few simulator studies include this measurement. The temperatures measured at the simulator interface confirm the results of a clinical THA study [12]. A heat sensor on the femoral stem found temperatures ranging from 42.5 to 43.1°C in a patient walking at 4 km/h (frequency 1 Hz).

The temperature dropped by an average of 2.4°C between 1 and 5 million cycles. This temperature decrease may be related more to creep than to wear [13–16]. Different studies [17–19] have shown that after 6–12 months, the measured femoral head penetration is nearly exclusively due to PE wear and creep is negligible. Since PE wear particles in the simulator bath were not measured, we cannot differentiate between the contribution of wear and creep.

Our study found an initial difference in surface roughness of the two types of PE cups, but this had no effect on temperature variations at the interface. The mechanism through which roughness is altered is not known: do the PE particles get impacted into the surface (creep) or are they released by adhesion? Massive release of PE particles during the first 1 million cycles could explain certain cases of early periprosthetic osteolysis.

In our study, femoral head penetration rate was not reduced by PE cross-linking. The multitude of different XLPE manufacturing processes can explain the different properties in vivo [20–23] and certain cases of early failure with surface microrocks and early oxidation [24,25]. Campbell et al. [26] published early clinical results (2 years’ follow-up in 21 patients) after implantation of the X3 cup—the same cup used in our study—in combination with a 32-mm diameter femoral head. The median penetration measured by RSA of the femoral head was 0.009 mm during the first year and 0.024 mm during the second year. This penetration is similar to the
average femoral head penetration of 0.014 mm/year reported by Dumbleton et al. [27]. At the end, Dumbleton et al. [27] found an annual average penetration of 0.015 mm in a clinical study with the X3 cup; this was less than the value reported for the Crossfire cupTM (1st generation XLPE) of 0.036 mm/year [28] and 0.023 mm/year [29]. The discrepancy between these published findings and our study results can be explained by use of a 22.2-mm inner diameter cup, which is never used in published studies because XLPE is combined with large diameter femoral heads.

5. Conclusions

Our study validates the relationship between hip kinematics and temperature variations at the prosthetic interface. These temperature variations are not related to the type of PE. Femoral head penetration into the PE due to wear or creep is not correlated to gait frequency or temperature variations. This simulator study revealed limitations in how PE degradation is measured in vitro due to lack of consensus on the gait pattern being reproduced on the simulator, and lack of standardization on the type of fluid used in the simulator bath, beyond the minimum protein content.

Disclosure of interest

The authors declare that they have no competing interest.

References