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Evaluation of Surface Finish and Dimensional Control of Tribological Metal-Ultra High Molecular Weight Polyethylene Pair of Commercially Available Hip Implants

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ABSTRACT

Background: Dimensional control and surface finish of the femoral head and acetabular liner are critical factors in the manufacturing process due to the risk of increased polyethylene wear, which is the primary cause of aseptic failure of a metal/polymer hip prosthesis. The aim of this study is to perform a dimensional and surface finish analysis to evaluate the reproduction and accuracy of the manufacturing processes of metal femoral heads and ultra high molecular weight polyethylene acetabular liners.
Methods: Four femoral heads and acetabular liners from 5 manufacturers were evaluated. The methods of evaluation followed the standards ISO 7206-2:2011 and ISO 21535:2010.
Results: The diameter, sphericity, and roughness of the femoral heads from all the manufacturers were in accordance with the standard requirements. Only the sphericity showed a lack of repeatability among the manufacturers. The variability in sphericity was high among some manufacturers and low in others. The diameters of the acetabular liners of 2 manufacturers were not in accordance with the standard requirements. The repeatability of sphericity, thickness, and roughness of the acetabular liners were heterogeneous among the manufacturers, which means that some manufacturers need to improve quality control.
Conclusion: Our results showed a good dimensional and surface finish control of the manufacturing processes of the femoral heads. However, the same control was not shown during the manufacturing of the acetabular liners although all samples had a thickness and sphericity in accordance with the standard. A better quality control of the manufacturing process of ultra high molecular weight polyethylene acetabular liners should be made to improve the dimensional parameters of the acetabular liners and the tribological pair.

Despite the advances in tissue engineering techniques, total hip replacement remains the standard treatment in late-stage osteoarthritis. The expectancy is that the demand for this surgery will continue to increase. The increase in severe premature osteoarthritis cases has been responsible for anticipated surgery [1]. This fact associated to an increase in human life expectancy and the relative short average lifetime of the metal-ultra high molecular weight polyethylene (UHMWPE) implants (around 10-15 years) increases the probability of revision surgery in younger patients [2,3]. The main reason for implant failure is osteolysis induced by polyethylene particles resultant from wear, which is increased by inappropriate dimensional parameters and surface finish of the tribological pair [4].

A lack of diameter control may increase the clearance between the acetabular liner and femoral head. This clearance has been correlated with wear according to clinical [5], simulator [6], and finite element model [7] studies. Interestingly, the results are similar between the models and clinical studies [5,7], which have shown that wear resulting from hip motion is lower in clearances between 0.10 and 0.15 mm [7]. In this range, the clearance promotes a thicker film of fluid that distributes pressure over a larger contact area reducing the wear [8,9]. However, an extremely low clearance can cause a reduced thickness or depletion of the fluid film [9], and thus increase the wear rate. On the other hand, a larger

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clearance develops a higher contact stress in a small area [10] and also tends to increase the wear rate. The same mechanism has been observed with departure from sphericity (out-of-roundness) for both components (acetabular liner and femoral head). Heads that depart from sphericity by more than 9.0 μm and acetabular liners by more than 30 μm showed higher wear rates [11]. Also, high wear and inadequate acetabular thickness has been demonstrated in a primary arthroplasty review [12] and in a simulator study [13]. Moreover, according to numerical analyses, there is an increase in contract stress with a reduction in acetabular liner thickness [14].

Head roughness has been the focus of studies in the past attempting to control acetabular wear. Roughness affects the UHMWPE wear and has been widely evaluated both in explants [15,16] and in vitro experiments [17,18]. However, a recent study has indicated that there is an interactive effect between the head and acetabular roughness on wear. A pin-on-disk study showed that an UHMWPE component with a small roughness (0.022 μm) maintained a low wear with a smooth counter-face (about 0.01 μm) and with a rough one (about 0.04 μm). This behavior was not obtained with a UHMWPE component with a greater roughness (0.126 μm). The wear increased drastically with the increase in counter-face roughness [19].

Given the importance of dimensional control and quality of surface finish of both components to the success of the tribological pair, this study carried out an analysis of 5 of the most common manufacturers in Brazil. The aim is to assess the quality control of the manufacturing process, taking into account the parameters regulated by ISO: diameter, sphericity, roughness, and thickness.

Method

Samples

Four pairs of heads and acetabular liners from 5 manufacturers (20 pairs in total) were dimensionally evaluated according to ISO 7206-2:2011 and ISO 21535:2010. The femoral heads of groups A, B, and C implants were made of stainless steel in compliance with ASTM F138. The heads of groups D and E were made of Cr-Co-Mo alloy in compliance with ASTM 1537. All femoral heads (20) had a 28 mm diameter and 12-14 taper. The 20 acetabular liners were made of conventional UHMWPE with an inner diameter of 28 mm and an external diameter of 52 mm.

Dimensional Analysis

The dimensional analyses of the femoral heads and acetabular liners were performed in accordance with the international standards ISO 21535:2010 and ISO 7206-2:2011. The thickness was measured in the center of the acetabular liner, with a spherical feeler of 1 mm diameter from ITP (Völklingen, Germany). The diameter and sphericity of the head and acetabulum components were measured in 3 transversal planes (Fig. 1) with a coordinate measuring machine from Mitutoyo, model BEYOND A916 (Coventry, UK). For the femoral heads, the planes were perpendicular to the neck axis. The most inferior plane (A) was drawn 1 mm above the articular surface line. Away from plane A 2 other equidistant planes were drawn. Plane B was drawn at an angle of 60° from plane A, while plane C was drawn at an angle of 30° from plane A. Two measurements were made in each of the 4 quadrants of each plane, and 1 measurement at the pole of the spherical head. Five measurements were made to evaluate the diameter of each sample.

The sphericity of both components was defined as the highest separation value (RS) calculated according to Equation 1, where O is the coordinate of the center, P' is the point measured, and D is the average diameter. D was calculated using the least-squares technique. The components were divided in 4 quadrants. Twenty-five points were measured to cover the entire area of each quadrant. Five points were measured at the spherical pole.

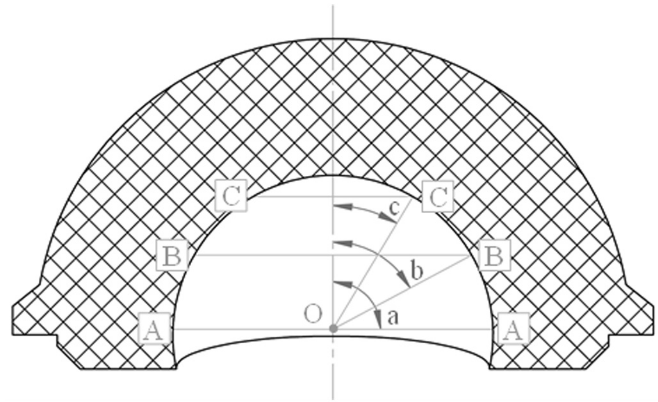

Fig. 1. Plans and position to dimensional measurement of femoral head and acetabular liner.

$$RS = \text{distance } OP' - 0.5D \quad (1)$$

Surface Finish Analysis

The roughness of the heads and acetabular liners were measured in accordance with ISO 7206-2:2011 and ISO 4288:2008. The measurements were made at 5 locations. For the heads, 1 measurement was made at the pole and 4 at 30° from that mark. For the acetabular liner, 1 measurement was made at the edge and 4 at 5 mm from the edge, evenly distributed around the equator of the acetabular liner. The direction was approximately perpendicular to any machining marks that were present. Three measurements were made for each quadrant, using a 2 μm feeler, velocity of 0.5 mm/s, and force of 1.5 mN. The Ra of the head was measured with a 0.08 mm cut-off, while for the acetabular liner a 0.8 mm cut-off was used. The Gaussian filter was used for the measurement of both components. The total assessment length was 0.48 mm for the 0.08 mm cut-off and the first and last 0.04 mm were not considered. The total assessment length was 4.8 mm for the 0.8 mm cut-off and the first and last 0.4 mm were not considered.

Statistical Analysis

The 2-tailed independent t-test was carried out to compare each manufacturer against the requirements of the international standard. The one-way analysis of variance was used to evaluate the difference in Ra_{max} among the manufacturers, and the pairwise 2-tailed independent t-test with Bonferroni correction was used for comparison between manufacturers. The β (type II) error (power, pwr) was calculated for 2-tailed one-sample t-test. The Bartlett test of variance was used to compare the homogeneity of the SD among the manufacturers. The significance level was set at 0.05.

Results

Dimensional Analysis

The international standard ISO 7206-2:2011 suggests a nominal diameter from 27.8 to 28.0 mm for the head, and from 28.1 to 28.3 mm for the acetabular liner. The results of the head and