Surface evaluation of orthopedic hip implants marketed in Brazil


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Abstract: One of the factors that contribute to the quality of total hip prostheses is the degree of accuracy in the manufacturing of the joint surfaces. The dimensional control of joint components is important because of its direct influence on the durability and, consequently, in the patients’ life quality. This work presents studies on the form and roughness of orthopedic hip prostheses marketed in Brazil. The results provide data for quality control of the surfaces of the femoral heads and acetabular components of hip prostheses and indicate the need of improvement in the procedures used to this control.

Keywords: roughness, sphericity, hip implants.

1. INTRODUCTION

The technology of orthopedic implants allowed significant improvement in the life of patients suffering from muscle-skeletal disorders. However, the failure of implants in clinical use is not rare, and the poor quality of products, this concerning several requirements, is regarded as one of the major causes of adverse events. In order to ensure the safety and efficacy of implants, manufacturers of medical devices have to meet biomechanical requirements related to the biological, physical, chemical and tribological properties. In parallel, suitable geometric design, selection of materials and manufacturing are important factors to obtain a final product which fulfills such requirements [1].

Regarding the geometrical features of surface metrology, the past half century has been extremely rich in events related to equipment design, data treatment and development of standards. Consequently, the manufacturing and metrology of orthopedic hip implants have been also improved.

There are two essential areas of metrology that guide the evaluation of orthopedic implant design: geometry measurement and surface finish assessment. Both techniques are used as quality monitoring methods of the manufacturing process, and are useful tools in the assessment of the performance of orthopedic implants. Geometrical metrology encompasses techniques such as the assessment of form by sphericity measurement in submicron resolution. In contrast, surface texture assessment is focused on nanometer measurement [2].

Particularly in Brazil, the Brazilian Health Surveillance Agency (Anvisa) is the official agency responsible for regulating the orthopedic implants trading. Additionally, the Brazilian government has been investing in several projects aiming to control the quality of orthopedic hip prostheses produced by national and international manufacturers. Another important point to be considered is the fact that the Brazilian population is currently 195 million, of whom 10% are over 60 years old (i.e., around 20 million). It is estimated that in 2050 the

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Brazilian population will be approximately 215 million, with 30% over 60 years old; that is, over 64 million people [3]. The increase of elderly population will cause an increase in chronic and degenerative diseases, surgical requirements, and thus, increase in orthopedic hip prosthesis surgeries is therefore predicted.

One of the main clinical problems limiting the functional life of a total hip implant is the aseptic loosening, which is related to the osteolysis resulting from the reaction of the host tissue with the particles (debris) produced by wear during the sliding contact between the femoral head and the polyethylene liner [4, 5]. Decreasing the generation of debris is a challenging objective in the design and selection of materials of a hip implant. To reach this goal, sphericity and roughness of both femoral head and acetabular liner are key factors, since these parameters can potentially affect the wear behavior. In the case of polymer bearing surfaces running against smooth counterfaces, the resulting polymer wear will involve adhesion wear mechanism [6, 7]. On the other hand, with high roughness counterfaces, the asperities will provoke deeper deformations in the polymer, and the wear will result from polymer abrasion and plastic deformation, as well as severe damages by fatigue mechanism. Thus, the counterface roughness characteristics play an important role regarding the transition from smooth to severe wear mechanisms and the associated wear rate.

Currently in Brazil, the measurement of the dimensional parameters of a hip implant is usually performed by the manufacturer, based on the procedure recommended in ABNT NBR ISO 7206-2 [8]. This work reports the findings of measurements carried out on national and imported acetabular liners and femoral heads with respect to their surface roughness and sphericity.

2. MATERIAL AND METHODS

2.1. Hip implant specimens

The specimens studied in this work were: 03 national femoral heads (NFH) and 02 imported metallic femoral heads (IFH), both made of stainless steel in accordance to ASTM F138 standard [9], 03 national acetabular liners (NAL) and 03 imported acetabular liners (IAL), all made of ultra-high molecular weight polyethylene (UHMWPE) following the ASTM F648 standard [10]. In the field of orthopedics, the UHMWPE material is still considered as the gold standard for articulating surface for total joints [11].

2.2. CMM and Roughness equipment

Sphericity measurements were carried out on a calibrated Coordinate Measurement Machine (CMM), based on the ABNT NBR ISO 7206-2 [8] standard recommendations. A total of 25 data points were taken for all hip components, being 8 points equally spaced along a circumference in 3 planes (one in the equatorial plane and the others, dislocated in 30° and 60° from the polar axis) and a point on the pole.

The sphericity was calculated using the 25 points measured, according to equation 1:

\[ \text{De} = \text{distance OP} - 0.5D \] (1)

Where “De” is the sphericity deviation, “D” the mean diameter, “O” the femoral head center and “P” the measured points.

Roughness measurements were performed through a calibrated surface profilometer with 0.8 nm height resolution and 8mm height measurement range. Three measurements were taken for each femoral head, in two orthogonal directions. The Ra roughness parameter was obtained with cut-off value of 0.08 mm, Gaussian filter and least square arc fitting over 15 mm length. For the UHMWPE liners, the same measurement procedure was applied, but at 4 quadrants, 0°, 90°, 180° and 270°.

The expanded uncertainty values (U) of the measurements were determined according to the equation 2 [12].

\[ u^2(z_g) = u^2(P_t) + u^2(b) + u^2(z_0) \] (2)

Where \( u^2(z_g) \) is the overall profile uncertainty, \( u^2(P_t) \) the uncertainty of reference standard and \( u^2(z_0) \) the uncertainty due to
background noise of the measurement device.

3. RESULTS

The results of sphericity deviation for the national femoral heads and UHMWPE liners are shown in Table 1.

Table 1 – Sphericity deviation values for the NFH and NAL components.

<table>
<thead>
<tr>
<th></th>
<th>NFH</th>
<th>NAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (µm)</td>
<td>30.65</td>
<td>91.61</td>
</tr>
<tr>
<td>2 (µm)</td>
<td>27.47</td>
<td>81.02</td>
</tr>
<tr>
<td>3 (µm)</td>
<td>17.73</td>
<td>86.13</td>
</tr>
<tr>
<td>U (µm)</td>
<td>1.40</td>
<td>1.50</td>
</tr>
</tbody>
</table>

According to the requirements described in the ABNT NBR ISO 7206-2 standard [8], the maximum value for the sphericity deviation of the femoral head is 10 µm. It can be noted from the data in table 1 that all of the national femoral heads (NFH) do not meet the requirements of the standard. This was associated to the existence of a deep valley in the pole of the femoral heads, detected in the measurements done.

Concerning the UHMWPE liners (NAL), the ABNT NBR ISO 7206-2 standard [8] describes that the sphericity deviation shall not be greater than 100µm. By observing the data presented in table 1, it is concluded that all measured specimens fulfill this requirement.

The roughness results of the NFH and IFH are shown in table 2.

Table 2 – Roughness values of the NFH and IFH specimens.

<table>
<thead>
<tr>
<th></th>
<th>NFH</th>
<th>IFH</th>
</tr>
</thead>
<tbody>
<tr>
<td>cut-off (mm)</td>
<td>0.08</td>
<td>0.08</td>
</tr>
<tr>
<td>1 (µm)</td>
<td>0.006</td>
<td>0.005</td>
</tr>
<tr>
<td>2 (µm)</td>
<td>0.007</td>
<td>0.005</td>
</tr>
<tr>
<td>3 (µm)</td>
<td>0.006</td>
<td>-</td>
</tr>
<tr>
<td>U (µm)</td>
<td>0.005</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Based on the requirements established in the ABNT NBR ISO 7206-2 [8] standard, which specifies that the Ra roughness value of femoral heads shall not exceed 0.05 µm, it is seen that all the NFH and IFH specimens were in agreement with the criteria according to the ABNT NBR ISO 7206-2 [8].

A discussion should be made concerning the procedure taken for obtaining the roughness parameters for the acetabular liner specimens (NAL and IAL). The ABNT NBR ISO 7206-2 standard [8] recommends 0.08 mm cut-off value, since most of the measurement equipment applies this cut-off. In opposite, ISO 4288 standard [12] describes that 0.8 mm cut-off shall be used if the Ra values are between 0.1 and 2 µm.

The results obtained for the roughness of the acetabular liners, using 0.08 mm and 0.8 mm cut-off, are shown in table 3.

Table 3 – Roughness values of the IAL and NAL specimens.

<table>
<thead>
<tr>
<th></th>
<th>IAL</th>
<th>NAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>cut-off (mm)</td>
<td>0.08</td>
<td>0.08</td>
</tr>
<tr>
<td>1 (µm)</td>
<td>0.362</td>
<td>0.968</td>
</tr>
<tr>
<td>2 (µm)</td>
<td>0.320</td>
<td>0.652</td>
</tr>
<tr>
<td>3 (µm)</td>
<td>-</td>
<td>0.646</td>
</tr>
<tr>
<td>U (µm)</td>
<td>0.018</td>
<td>0.030</td>
</tr>
</tbody>
</table>

According to the ABNT NBR ISO 7206-2 standard [8], the Ra value for UHMWPE acetabular liners shall be equal or lower than 2 µm. Applying 0.08 mm cut-off, it can be seen that all of the IAL and NAL specimens were approved in terms of roughness measurements.

However, carrying out the analysis based on the ISO 4288 [13] with 0.8 mm cut-off, the NAL do not comply the ABNT NBR ISO 7206-2 requirements [8], because the Ra values exceed the maximum accepted criterion of 2 µm. In opposite, the Ra values for the IAL specimens...
did not exceed 1.00 µm with the same 0.8 mm cut-off, being them even so approved.

The above discussion suggested that the cut-off value recommended in the ABNT NBR ISO 7206-2 standard [8] is not suitable for adequate control of the surface roughness quality of the acetabular liners. Therefore, it is important that manufacturers in Brazil carefully adopt the method with the larger cut-off value of 0.8 µm for the Ra roughness evaluation; as it is more conservative. Also, it must be observed that it do reveal the existing high roughness in the liner surface that can lead to early failures, especially with respect to wear, because the roughness values can be 25 to 50% higher than those considered suitable [14].

4. CONCLUSIONS

The results of the measurements of the national femoral head indicate that all of them did not fulfill the criteria for sphericity according to the ABNT NBR ISO 7206-2 standard.

Based on the roughness measurements using 0.08 mm cut-off, all the femoral heads and acetabular liners were approved.

Nevertheless, using 0.8 mm cut-off for the roughness analyses, all the national acetabular liners would be rejected due to the values be higher than the limit established in ABNT NBR ISO 7206-2 standard. On the other hand, all of the imported acetabular liners were still approved despite the use of a larger cut-off value.

5. REFERENCES
