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Uncertainty determination for X-ray computed tomography wear assessment of polyethylene hip joint prostheses

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ABSTRACT

Hip joint replacements have been successfully used in the field of orthopaedic medicine for over fifty years. Whilst clinical studies have shown encouraging long-term clinical performance, failure of these devices due to wear still occurs. The laboratory determination of wear rate is an important part of the pre-clinical validation of prostheses. The most commonly applied method for wear evaluation of prosthetic joint components is the gravimetric method. It is generally accurate and reliable but has certain limitations. In particular, gravimetric measurements cannot provide information about localization of wear damage and deformation over the component's surface. As an alternative, tactile coordinate measuring machines are used to evaluate both volumetric wear and wear damage distribution over the worn surface. However, considering polymeric prosthetic components, these machines could induce unwanted damages and/or deformations due to clamping and probing forces leading to a large measurement uncertainty. X-ray computed tomography recently emerged as an advanced non-contact technique capable of performing dimensional measurements with high accuracy. Moreover, X-ray computed tomography can be used for volumetric wear measurement as well as for determination of local distribution of wear and deformations without any risk of further damaging or deforming polymeric components. Nevertheless, the uncertainty of such measurements has yet to be investigated. The purpose of the work was to determine the uncertainty in both volumetric wear measurements and assessment of local distribution of wear and deformations using X-ray computed tomography. More in depth, in this work, tomographic measurements were conducted on nine hip joint components made from three different types of ultrahigh molecular weight polyethylene. This investigation identified and quantified the main individual uncertainty contributions.

1. Introduction

Ultrahigh molecular weight polyethylene (UHMWPE) is the most commonly used bearing material in total joint replacement. Wear of UHMWPE is a serious clinical problem that can limit the longevity of orthopaedic implants. A systematic study of wear is required in order to improve the understanding of the tribological performance of a hip prosthesis and obtain its pre-clinical validation [1–3]. At the state of the art, wear of hip joints prosthetic components can be evaluated by using gravimetric and/or volumetric methods as recommended by the ISO 14242-2 [4]. The former method is the standard measurement practice adopted by orthopaedic industry: using a high-resolution microbalance, the component weight is measured before and after wear tests by following the procedure described in [4]. The weight loss is measured as the difference of the two measurements. On one side, this method has proven to be sufficiently accurate to quantify globally the worn material [5]; on the other side, it cannot provide information about the local distribution of wear over the worn surface and damages not involving material loss – such as possible plastic deformations – cannot be assessed [6,7]. The volumetric method based on tactile coordinate measuring machines (CMMs) is an alternative to the gravimetric method, allowed by ISO 14242-2 [4]. This method has the advantage of enabling also accurate location and assessments of wear scars, besides quantification of wear volume [8]. Carmignato et al. [9] established an approach for uncertainty determination and validation of their CMM measurement method in comparison with the gravimetric method for ceramic femoral heads. Moreover, Bills et al. [10] studied the impact of three-dimensional uncertainty of volumetric wear assessment of retrieved metal-on-metal hip prostheses. However, tactile CMMs can cause possible damages and unwanted deformations when measuring polymeric (deformable) prosthetic components due to clamping and probing forces, hence increasing the measurement uncertainty [11].

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More recently, X-ray computed tomography (CT) has been used for wear evaluation of prosthetic components thanks to the capability of obtaining a three-dimensional (3D) model of the entire scanned object geometry with the possibility of conducting measurements in a non-destructive and non-contact way [12,13]. Not only CT allows evaluating both global wear volume and local wear distribution and deformations but, differently from contact CMMs, it can also be considered particularly suited for analysing polymeric components since it does not induce any damage to the component [14]. However, although CT is now currently used as a metrological technique allowing accurate dimensional measurements [15], as long as the measurement uncertainty for the specific measurement task is not determined the actual reliability of the achievable results cannot be stated.

The most common approach for task-specific uncertainty determination in coordinate metrology is based on the standard ISO 15530-3 [16] dedicated to CMMs, which has been already adapted for CT in literature [17,18]. This method can be successfully applied when a calibrated object similar to the actual components is available or producible with sufficiently low calibration uncertainty [19], while it is limited when similar calibrated objects with sufficiently low calibration uncertainty are not available. This is the case of polymeric samples with complex geometry (as the acetabular cups that will be investigated in this paper), for which a CMM calibration would produce a too large uncertainty because of clamping and probing forces that could generate unwanted deformations of the components.

In this work, experimental investigations were performed on three different configurations of polyethylene's acetabular cups: vitamin E-stabilized cross-linked PE (XLPE_VE), cross-linked PE (XLPE), and standard UHMWPE (ST_PE). The main objective was to identify and quantify the individual uncertainty contributions and to determine the uncertainty of wear measurements conducted by CT (including volumetric wear and local distribution of wear and deformations) on such type of components. In particular, an alternative approach with respect to the above-mentioned most common but non-applicable approach based on ISO 15530-3 was applied. The CT-based method was finally validated through comparison with the gravimetric method, here chosen as reference method. The presented methodology can be generally adopted when measuring the uncertainty of CT evaluations of polymeric parts subjected to *in vitro* wear tests.

2. Components and instrumentation

Components used in this work were 9 acetabular cups made by three different types of UHMWPE [14]: XLPE_VE, XLPE, and ST_PE (three components for each batch). Each cup was measured before and after the wear test by two methods: X-ray computed tomography and gravimetric method. The gravimetric method consisted of measuring the weight loss using a microbalance Cubis MSE 225 s-000-du (Sartorius, Goettingën, Germany) with resolution of 0.01 mg, by averaging the results of three repetitions conducted for each component.

For the tomographic measurements, a metrological micro-CT system Nikon X-Tek MCT225 (Nikon Metrology, Tring, UK) was used, characterized by a 225 kV micro-focus X-ray tube, 2000 × 2000 pixels flat-panel detector (16 bit), temperature-controlled cabinet (20 ± 0.5 °C) and maximum permissible error for spheres distance measurements equal to $(9 + L/50)$ µm (where L is the length in mm). The CT scanning parameters used in this work are reported in Table 1. The X-ray 2D projections obtained from the acquisition step were used in the reconstruction step for obtaining a 3D volume of the investigated components by means of a filtered back-projection algorithm [20]. Local adaptive methods [12] were applied to determine the surface location of the reconstructed model with high accuracy. The software VGStudio MAX 3.0 (Volume Graphics GmbH, Heidelberg, Germany) was used to: (i) compute the volumetric wear calculated as the difference in volume between the 3D models obtained before and after the wear test and (ii) generate deviation maps showing local wear and deformations as distributed over the worn surfaces (see example in Fig. 1). The alignment between unworn and worn scanned components (necessary for (ii), see Section 3) was performed using VGStudio MAX 3.0 as well.

Table 1
CT scanning parameters optimized for UHMWPE acetabular cups.

Parameter	Value
Voltage	194 kV
Current	46 µA
Exposure time	1415 ms
Nr. of projections	1500
Voxel size	31 µm
Filtering	None

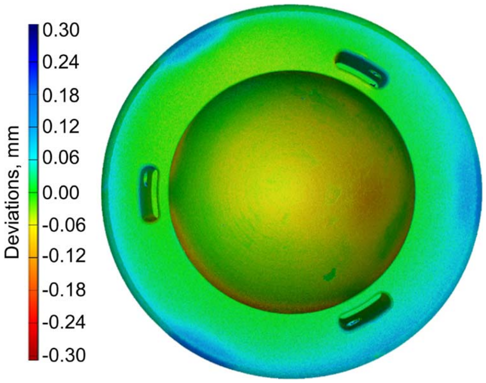

Fig. 1. Wear/deformation map of one of the nine acetabular components investigated in this work. Wear can be appreciated over the internal calotte surface (yellow-red coloured), while deformations due to the wear test set-up are localized over the external circular crown (light blue–blue coloured).

3. Determination of individual uncertainty contributions

For establishing the metrological traceability of CT wear measurements, a task specific uncertainty assessment is required, as stated in the "Guide to the expression of uncertainty in measurement (GUM)" [21]. The uncertainty determination is needed also for a consistent comparison with the gravimetric measurements (see Section 5, which is focused on the identification and quantification of individual uncertainty components that are connected to the most influencing measurement error sources). The accurate determination of each single uncertainty contribution is a complex task due to multiple error sources, which characterize the entire CT measurement procedure [22].

Since CT can be employed for measuring volumetric wear as well as local distribution of wear and deformations over the worn surface, specific individual uncertainty contributions were identified for both these types of evaluation and are summarized in Table 2. Procedures applied to quantify such contributions are described in Sections 3.1 and 3.2. As it can be observed in Table 2, the uncertainty contributions related to alignment and surface determination were neglected in the case of volumetric wear evaluation. Infact, since the wear volume was evaluated as difference between CT volume measured before the wear test and CT volume measured after the wear test, it can be considered independent from the alignment between the two volumes, as well as from the surface determination errors (which are compensated when comparing the two surfaces measured before and after the wear test).

Concerning the contribution of surface topography, the surface roughness was measured by confocal microscopy, using a Plu Neox optical profiler (Sensofar, Barcelona, Spain) with 20 × objective. For unworn surfaces, which have higher roughness than worn surfaces, the following values of roughness parameters were measured: $Rz = 0.007$ mm and $Rp = 0.003$ mm (average values obtained from