## Wear test and morphological analysis of UHMWPE particles in a preclinical test in a hip prosthesis wear simulator

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INTRODUCTION: Aseptic loosening is the main limiting factor for Total Hip Arthroplasty (THA) in the medium and long term and is due to tissue response to particles arising from the wear of the Ultra High Molecular Weight Polyethylene (UHMWPE) acetabular insert. The particles generated during this process tend to be distributed in the tissue adjacent to the prosthesis, inciting the migration of macrophages, which in turn release cytokines and interleukins associated with the release of other mediators of the inflammatory cascade. Studies reveal that these factors stimulate the synthesis and maturation of osteoclasts, cells responsible for the reabsorption of the bone matrix. Without adequate bone support, the prosthesis loses its fixation and becomes loose, generating a critical disabling condition for the patient and determining the revision surgery. Since wear particles result in progressive bone destruction and loosening of components, leading to functional failure of hip arthroplasty, knowledge of the phenomenon of wear on the artificial joint surface is a great challenge for the longevity of prosthetic reconstruction. Therefore, to improve the performance of hip prostheses, it is important to estimate, in preclinical testing, the wear rate associated with each prosthesis model, as weel as the size and morphology of the particles referring to each inserted in vitro test. Although the UHMWPE particles sizes and morphology seems to be critical to the inflammatory cascade, the literature is this subject is sparse.

METHODS: The wear test of the tribological pairs was carried out in a hip joint simulator AMTI ADL-H06-1, designed to replicate the physiological environment of the joint and its movements, following the recommendations of the technical standard ABNT NBR ISO 14242-1. The preclinical test in the hip simulator was performed on prostheses from three different manufacturers named (A, B and C). Three tribological pairs from each manufacturer were tested, with each tribological pair tested to complete 5 million cycles. The tribological pair tested consisted of a metallic femoral head (stainless steel) and an acetabular insert in UHMWPE, both measuring 28 mm. After the test, the particles were digested (acid medium) and filtered through 2.0 and 0.4 µm polycarbonate membranes. After filtering, the membranes were analyzed by scanning electron microscopy with magnifications from 500X to 5000X. All the steps above were carried out following the recommendations of the technical standard ABNT NBR ISO 17853. To carry out the analysis of the size and shape of the particles, the criteria of the technical standard ASTM F1877-16 were used. The technical standard describes Equivalent Circle Diameter (ECD) as a measure of size defined as the diameter of a circle with an area equivalent to the area of the particle and has a unit of length. The technical standard also presents the nomenclature of the particles and classifies them into 6 groups: spherical, granular, globular, flakes, fibrils, and shrapnel particles. Particle analysis was performed only at the end of the test in 5 million cycles and a total of 200 particles were analyzed for each tribological pair.

RESULTS: The gravimetric wear results obtained in the hip joint simulator for the three tested tribological pairs from each of the three manufacturers are presented in Table 1. The average wear rate per million cycles was calculated through a linear regression using the method of least squares. The results of the morphological analysis are also described in Table 1, of the six groups of particles in the standard, four were identified in the work. The results of the particle size analysis from the ECD are described in the graphs of Image 1, three different graphical forms were presented to make the explanation more complete.

DISCUSSION: The variation in wear rates is certainly related to the physical, chemical, mechanical, and dimensional properties of the UHMWPE acetabular inserts from each manufacturer, which was not discussed in the work. Manufacturer C had the lowest wear rate but also had the smallest particles as shown in different ways in Image 1. Several studies in the literature indicate that UHMWPE particles with a size between 0.2 and 0.8  $\mu$ m are more biologically reactive, so the particles from the manufacturer that had the least wear, produced the smallest particles, which according to the literature are the most biologically active. The morphology of the particles that prevailed in the three manufacturers forms the fibrillar, followed by the spherical. These particles were certainly generated during the test by abrasion or adhesion wear mechanism. Many particles were deformed, compressed, grouped and may even be broken into smaller particles due to movements and mechanical loads between the tribological pair, which supposedly could have originated the sub micrometer particles. The two graphic methods used to treat the ECD data could be used to describe the same parameter as a function of the morphology of each particle, or even in different wear test parameters, which would make an even more complete analysis. Knowing the importance of particle characterization for the study of longevity of hip prostheses, since wear particles result in progressive bone destruction and loosening of components, knowledge of wear characteristics is a major challenge for the longevity of prosthetic durability.

SIGNIFICANCE/CLINICAL RELEVANCE: In order to improve the performance of hip prostheses, it is important to estimate, in the pre-clinical screening, the wear rate associated with each prosthesis model, in addition to the size and morphology of the particles referring to each insert in in vitro tests.

TABLE 1. Results of wear rate and morphological analysis

Manufacturer	Sample 1	Sample 2	Sample 3	Average	Morphological analysis			
A	$70.54 \pm 11.55$	$70.34 \pm 5.18$	$61.34 \pm 16.13$	$67.41 \pm 6.91$	25% Spherical	6% Granular	17% Flakes	52% Fibrilar
В	$70.67 \pm 8.78$	$82.49 \pm 9.27$	$61.98 \pm 14.20$	$71.71 \pm 10.61$	23% Spherical	4% Granular	16% Flakes	56% Fibrilar
C	$46.82 \pm 11.36$	$50.32 \pm 12.24$	$42.63 \pm 5.17$	$46.59 \pm 5.60$	30% Spherical	15% Granular	18% Flakes	38% Fibrilar

IMAGES. Particle size (ECD) of each manufacturer over the 5 million test cycles.

