TriboBR
First International Brazilian Conference on Tribology – TriboBr-2010 and
ITS - IFToMM 2010 - 2nd International Tribology Symposium of IFToMM
24th to 26th november, 2010
Copacabana, Rio de Janeiro/RJ, Brazil
ISSN 2179-3956

WEAR SIMULATION OF HIP JOINT PROSTHESES: PRELIMINARY RESULTS[1]

Marcia Marie Maru [2]
Lídia Ágata de Sena [2]
Leandro Reis Lidízio [2]
Willian Lima de Oliveira Filho Junior [3]
Wellington Santos Barros [3]
Jailton Carreteiro Damasceno [2]
Carlos Alberto Achete [4]

Abstract
This paper presents the preliminary results of a wear simulation test of hip joint prosthesis. The test was performed in a multi-station wear simulator machine with acetabular cups of UHMWPE against stainless steel femoral heads, under conditions similar to those described in ISO 14242-1 standard, up to 398,714 cycles. The results obtained from gravimetry, profilometry and debris microscopy are discussed.
Keywords: Hip joint; Wear simulation; UHMWPE.

SIMULAÇÃO DE DESGASTE DE PRÓTESES ORTOPÉDICAS: RESULTADOS PRELIMINARES

Resumo
Esse trabalho apresenta resultados preliminares de um ensaio de simulação de desgaste de prótese de quadril. O ensaio foi realizado em uma máquina de simulação de desgaste multi-estações com copos acetabulares de UHMWPE contra cabeças femorais de açco inoxidável, sob condições de carga e movimento similares às descritas na norma ISO 14242-1, até um total de 398.714 ciclos. Os resultados obtidos por gravimetria, perfilometria e microscopia do resíduo de desgaste são discutidos.
Palavras-chave: Prótese de quadril; Simulação de desgaste; UHMWPE.

[1] *Technical contribution to the First International Brazilian Conference on Tribology – TriboBr-2010, November, 24th-26th, 2010, Rio de Janeiro, RJ, Brazil.*
[2] *Divisão de Metrologia de Materiais – Inmetro, Duque de Caxias, RJ, Brazil*
[3] *Divisão de Metrologia Mecânica – Inmetro, Duque de Caxias, RJ, Brazil*
[4] *Divisão de Metrologia de Materiais – Inmetro, Duque de Caxias, RJ, Brazil. Programa de Engenharia Metalúrgica e de Materiais – UFRJ, Rio de Janeiro, RJ, Brazil*

ISSN 2179-3956

1 INTRODUCTION

A technological application of great importance are the orthopedic prostheses because their directly impact on the human lives that make use of such devices. Around 500 thousand surgeries of a total of 1,5 million surgeries in orthopedics are on hip and knee replacement,[1,2] predominantly because of fracture and bone diseases. Current durability should be around 10 to 15 years.[1] In national context there is lack of information concerning the durability of prostheses. However, there are indications that quality control of these products must be improved.[3]

The bearing components of hip and knee joint prostheses are made of different materials. Hip joint prostheses are composed of acetabular cup liners made of polymer (UHMWPE), metal (CoCr, CoCrMo) or ceramic (alumina), running against ceramic (alumina, zirconia) or metal (stainless steel, CoCr or CoCrMo) femoral heads.[4] In Brazil, the polymeric acetabulum with a metallic femoral head is one of the most used pair of materials.[5] The durability of the prosthesis implanted into the body depends on several factors, going from the surgical technique ability to the activity and health of the patient, in addition to the mechanical strength and tribological and chemical behavior of the materials used in each component of the implant (cement and the components of the prosthesis itself).[5,6] In the case of polymeric implants, the main damage mechanism is reported as aseptic loosening and osteolysis caused by debris detachment mainly from polymer components.[7,8] Indeed, wear of polymer is an imperative issue regarding polymeric prosthesis durability.[9,10]

One way to study the wear of prosthesis components is through in-vitro simulation making use of wear simulators. The prostheses perform a relatively complex tribossystem of three-dimensional contact geometry subjected to non uniform cyclic loading immersed in biological fluid. Discrepancies exist between wear patterns of simulated versus actual retrieval specimens.[10] While hip simulator experimentation has been valuable in providing information on polyethylene wear, in vivo wear has proven to be a complex and multi-factorial process,[10] with variations in the level of polyethylene oxidation, the rigidity of component fixation, the strength of peri-acetabular support, and hip kinematics of test versus retrieval specimens.[10] It is evident that a more accurate way to assess the wear of prostheses is by analyzing the components after use in service, or in-vivo explants.[11] However, it can take several years and the performance will depend on patient behavior.

In order to simulate wear on hip replacement devices, gait simulators have been developed with wear testing commonly performed to ISO 14242-1 standard.[12] These simulate up to 10 million cycles of gait activity, and the wear is measured gravimetrically.[13] Each million of cycles can represent one year of clinical use.[14] However, in these simulators, everyday activities other than gait (such as sitting on or rising from a chair or going up and downstairs), and any other, less frequent activities (such as sports) are mostly ignored. The under-estimation of wear by simulators is all the more relevant o younger patients where 10 millions cycles of load may only represent a few years of life.[15] Anyhow, the use of standards is thought as the best method approach in order to obtain comparable reference wear values.

On the other hand, in the currently existent simulators, the load profile may differ, what makes wear comparison difficult.[16] One of these examples is that reported by Affatato and coworkers[17] for commercial 28mm size Zimmer Inc. hip prostheses. After 3 million of 1Hz cycles of wear simulation with a sinusoidal load having a peak magnitude of about 2kN lubricated with calf serum in room

ISSN 2179-3956

temperature conditions, the cup, of conventional UHMWPE, had a total of 109±31mg mass loss running against CoCr alloy femoral head. However, depending on the polymer characteristics, such as crystallinity degree, the wear loss can vary orders of magnitude, going from 9 to 189 mg after 5 million cycles as reported by Affatato and coworkers.[18] Wear resistance can also be altered by the type of sterilization.[19] Another variable for wear resistance of polyethylene is the presence of third body particles.[19] After 2.5 million cycles in the presence of polymethylmetacrilate (PMMA) particles (170μm size in 1mg/ml concentration) the polymer had a wear of around 120mg, compared to near 20mg without PMMA particles.[19]

Concerning the mounting of the hip joint prosthesis in the simulator, the three-dimensional contact geometry of the joint is better accomplished as better as the alignment among the bearing surfaces. The alignment of the center of both samples is important so as to have smooth sliding and thus minimize problems of localized wear during wear simulation.

Inmetro has recently acquired a hip joint wear simulator intended to assess the wear performance of total hip joint prostheses manufactured in Brazil. This paper presents preliminary results obtained from the 398,714 cycle’s test of a commercial polymer-metal prosthesis with UHMWPE acetabular cups and stainless steel femoral heads under motion and loading conditions as described in ISO 14242-1 standard.[12] Some misalignment of cup-head contact was applied just to check the effect of this variable on the wear result. In order to have accelerated wear the lubricant fluid was Type II pure water instead of calf serum diluted in distilled water required in the ISO 14242-1 standard. It is emphasized that these conditions are not exactly as those prescribed in the ISO 14242-1 standard but were adopted just to accomplish accelerated wear and, in this way, check for the influence of misalignment in the cup-wear contact on wear. Classical tribological analyses, such as gravimetry, microscopy of surfaces, profilometry and analysis of debris, were performed as a protocol for wear analysis.

2 MATERIALS AND METHODS

The machine for wear tests was an AMTI-Boston 6 station hip wear simulator. The same axial force and motions are applied to all work stations by a unique servo-hydraulic system monitored and controlled by load and position sensors. The acetabular cup and femoral head samples were commercial, of 26mm nominal diameter. The cup material was of ABNT NBR ISO 5834-2 UHMWPE, ethylene oxide (EtO) sterilized. Femoral heads samples were of ASTM F138 Cr-Ni-Mo stainless steel.

Figure 1 shows the cup (Figure 1a) and head (Figure 1b) samples mounted in the respective holders. The cup sample is manually cemented into the holder with surgical cement (compound material based on PMMA). Three pairs of samples were wear tested (ST1, ST2 and ST3) and two load soak controls (SK upper and SK bottom) were tested under the same applied load with no motion (Figure 1c). The manual cementation of the cup has leaded to some misalignment in XY plane (see Figure 4).

ISSN 2179-3956

Figure 1. (a) Polymeric acetabular cup and (b) metallic femoral head mounted in the respective holders; (c) schematics of test configuration.

The test was performed by applying the conditions of loading and motions as established in the ISO 14242-1 standard,(12) up to a total of 110h45min corresponding to 398,714 test cycles of 1Hz frequency. The test was stopped before the first stop at 500,000 cycles stated in the ISO standard since visible flaky particles probably resulting from delamination were noticed in the fluid. Figure 2a shows the three applied angular motions (E/F: extension/flexion; IR/OR: inward/outward rotation, AB/AD: abduction-adduction), Figure 2b shows the applied axial load (Fz) and Figure 2c shows the work station configuration with the samples inside a plastic bag. The samples were lubricated with Type II water warmed to 37°C, continuously re-circulated by peristaltic pumping. Although the lubricant fluid described in the ISO 14242-1 standard is calf serum diluted in distilled water, pure water was used in the test in order to achieve accelerated wear. Some misalignment of cup-head contact in XY plane was applied just to check the effect of this variable on the wear result.

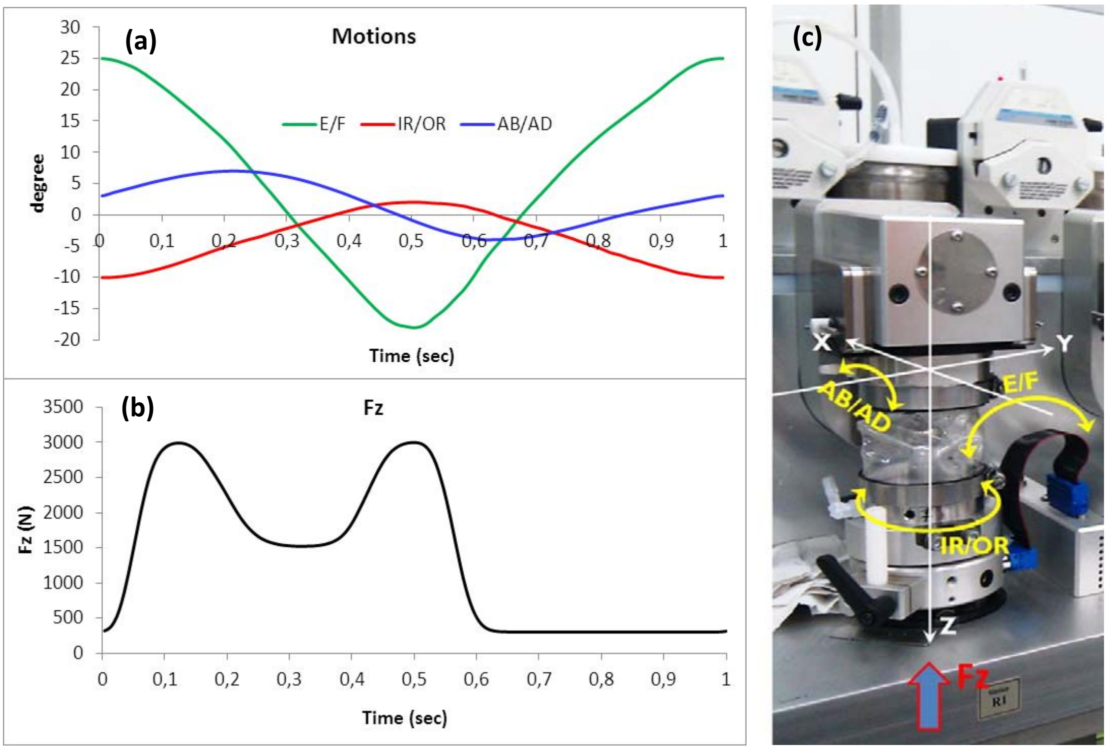


Figure 2. (a) E/F, IR/OR and AB/AD motions and (b) axial load Fz through one cycle of test; (c) work station configuration with test samples embedded into fluid bag.

The mass loss of the tested cup samples was obtained with a scale of 0.01mg resolution, after cleaning the samples according to the conditions specified in the ISO 14242-2 standard.(20) Surface roughness was measured in terms of Ra (mean height of asperities in the roughness profile) with a surface profiler, according to the conditions described in ABNT NBR ISO 7206-2 standard(21) using a cut-off of 0.08

ISSN 2179-3956

mm and a total length of 15 mm. Waviness Pt parameter (maximum peak-to-valley in the waviness profile) was also measured in order to take error form information. An average Ra and Pt of each cup specimen was obtained from the measurements performed in 4 quadrants. For the head specimens, the measurements were performed in two perpendicular lines passing through the pole. Besides that, measurements of diameter were performed by using a coordinate measuring machine following the conditions established in ABNT NBR ISO 7602-2 standard.(21) The parameter of sphericity deviation is the highest difference of the radius measured in three circles, one taken at the equator plane, other at 60^o plane and the other one at 30^o plane, see Figure 10) and at the pole from the radius of the sample.(21) The radius of the sample is obtained from the adjustment of all diameter data by least square method. Surface analyses of the worn areas and debris were conducted in microstereoscope and scanning electron microscope, respectively.

3 RESULTS AND DISCUSSION

Figure 3 shows the mass loss results for the five tested acetabular cup samples. Three observations can be made: 1) high scatter level among work stations ST1, ST2 and ST3; 2) high level of mass loss; 3) negative mass loss for both load soak control stations SK upper and SK bottom. The last observation is clearly explained because no motion was applied to these stations but some absorption of fluid may occur by the polyethylene material. Evidently, fluid absorption occurred to all stations.

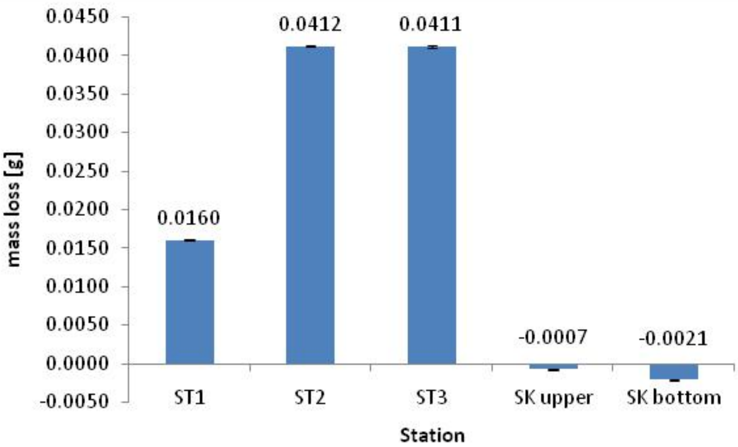


Figure 3. Mass loss of tested UHMWPE cup samples.

Taking into account that all stations worked under the same conditions of motions and Fz, the high scatter level of cup wear among work stations can have been caused by differences in several variables: 1) samples alignment; 2) forces undergoing in each work station; 3) topography; 4) wear resistance of polyethylene material. The high wear level of the cups can have resulted from several sources: 1) abrasion by oxidized surface of the femoral head; 2) abrasion by PMMA cement particles falling into the fluid; 3) polyethylene material with low wear resistance, 4) use of pure Type II water without bovine serum. These are discussed below.

The main source of error due to sample misalignment is attributed to the embedment of cup sample into its holder. Figure 4 shows the top view of the tested samples. It is evident some misalignment in the embedment of the cups of ST1 and

ISSN 2179-3956

ST3 work stations. However, it is clear that the observed misalignment was not significant to affect the mass loss trend.

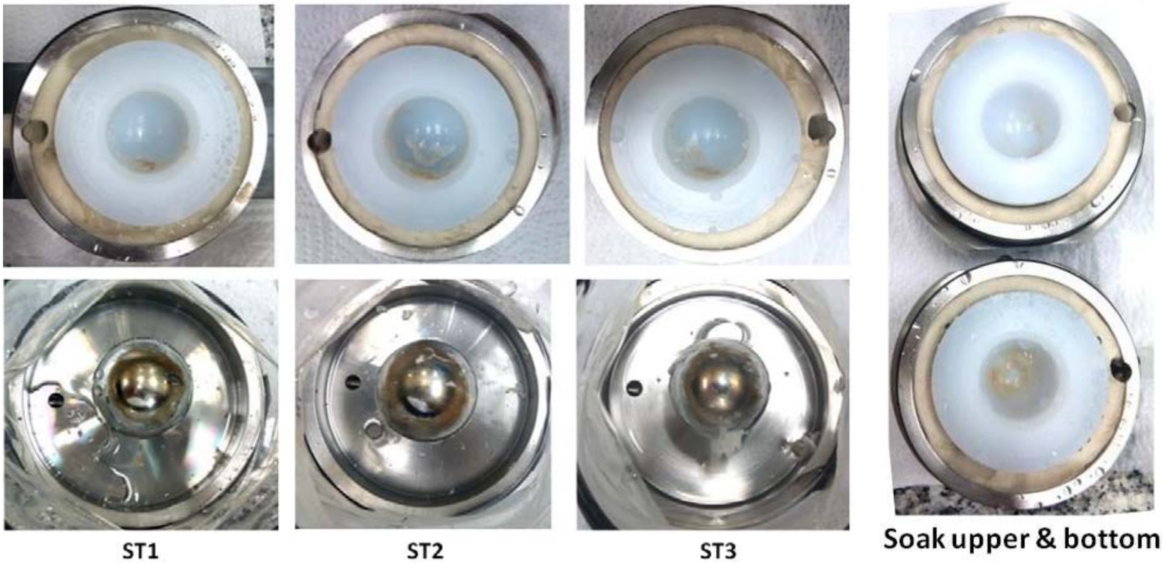


Figure 4. Macroscopic aspect of the tested acetabulum cup and femoral head samples. Femoral heads of load soak stations not shown. Reference for topography measurements: ↑0 degree; →90 degrees.

It is also clear from Figure 4 that the steel femoral heads present a marked oxidized surface. Presence of oxide in the fluid can have enhanced abrasion phenomenon to the cup sample and then contributed to increase the delamination wear (see laminar wear particles in Figure 7 and Figure 8) of the polyethylene material. Presence of oxide particles in the test is also noticed even in the bottom load soak control cup sample, evidenced by the deposit of brown colored particles inside it (Figure 4, right, confirmed in Figure 5). This suggests the possibility of some contamination of the test fluid. Type II pure water used in the test had the measured pH value of 6.43, which should not be significant to cause corrosion. However, the measured electrical conductivity was 1.512 μS/cm, which is higher than the limit of 1.0 μS/cm established in the ASTM D 1193-6 standard[22] and thus points out to a slightly ionic nature. The oxidation seen on the femoral head material is still under investigation.

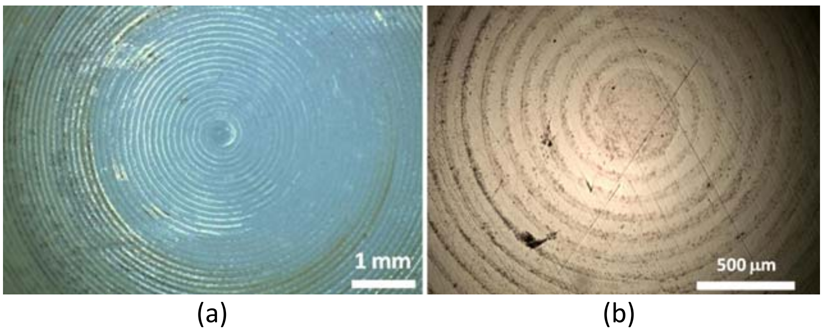


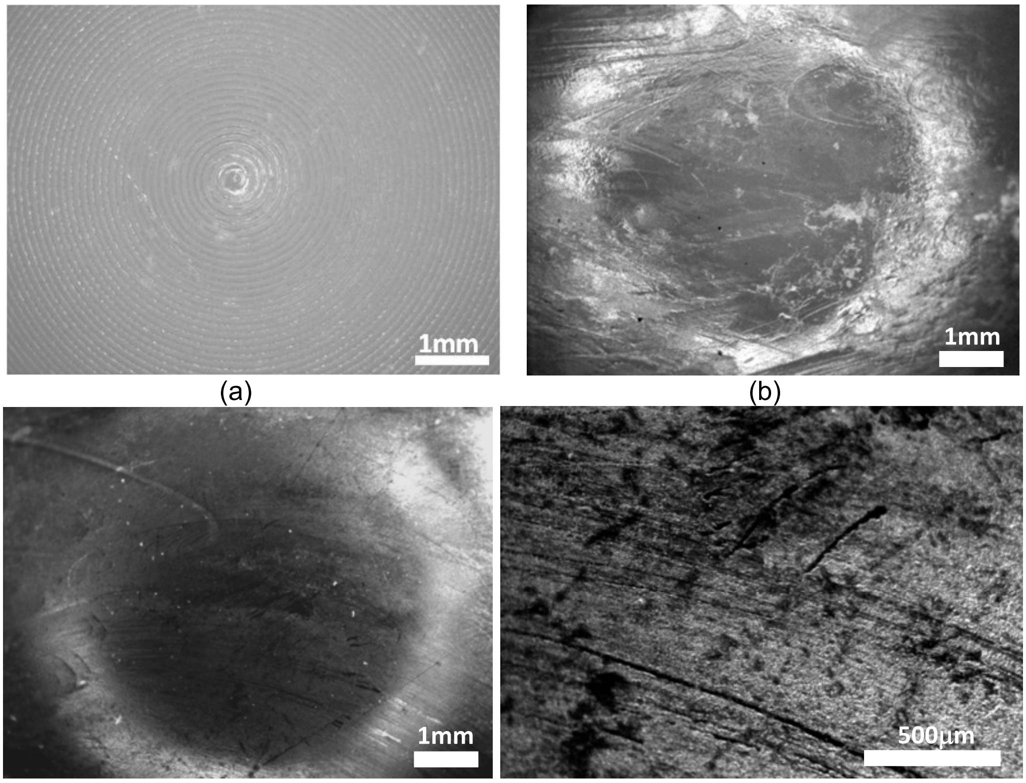
Figure 5. Images of load soak control bottom samples. a) microestereoscope image of the cup; b) optical microscope image of the femoral head.

Figure 6 shows the surfaces observed by microstereoscope. Figure 6a shows the surface of a polymer cup before the wear test. After the test, severe deformation of cup material is seen (Figure 6b). Several scratches on both the cup surface

ISSN 2179-3956

(Figure 6b) and femoral head (Figure 6c, 6d) can also be seen after the test, which indicates abrasion occurrence on both samples.

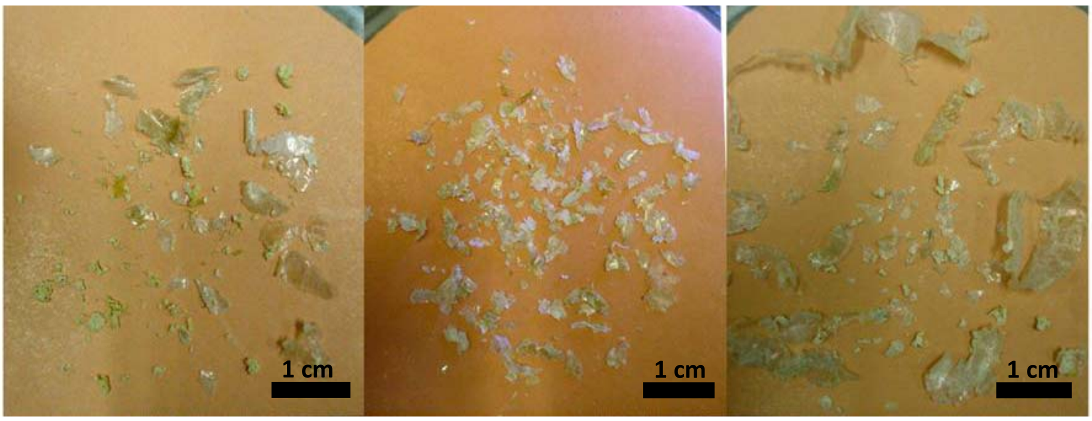
Figure 7 shows the particles found in the fluid after the test; the color, morphology and size clearly confirm very severe delamination wear of the polymer material. Figure 8 shows the microscopic aspect of the particles observed in a scanning electron microscope. Morphology of cup surface finishing is clearly observed in the particles denoting a probable extrusion mechanism of particles during friction contact. A probable mechanism of particles agglomeration and detachment after reaching a critical size is suggested according to findings in the literature.[23] Such a mechanism was probably caused by the use of pure water instead of diluted bovine serum and evidently resulted in accelerated wear.



(a) (b)

(c) (d)

Figure 6. Images by microstereoscope of (a) acetabulum cup before the wear test; (b) acetabulum after the wear test, (c) femoral head after the wear test and (d) detail of the femoral head in (c).



(a) (b) (c)

Figure 7. Macroscopic aspect of debris found in the tested fluid. a) ST1; b) ST2; c) ST3.

ISSN 2179-3956

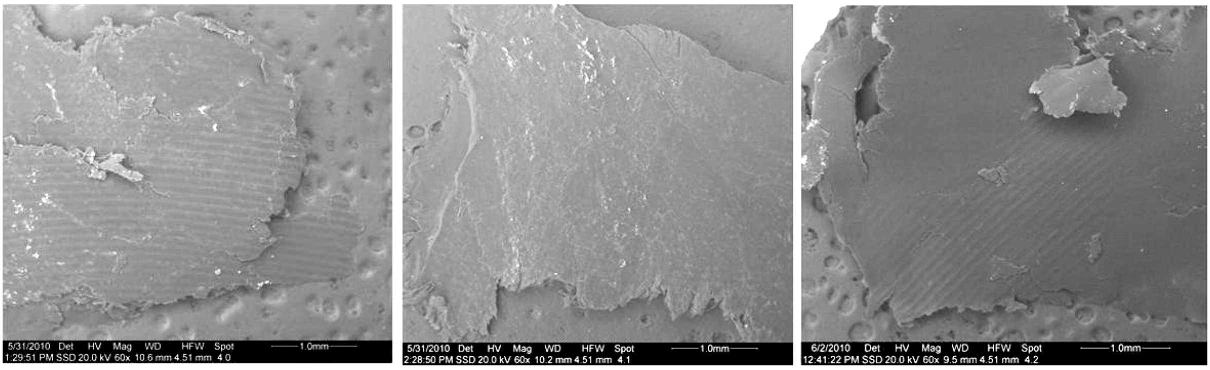


Figure 8. Secondary electron images through scanning electron microscope of particles found in the fluid after the test.

Besides the abrasion occurrence by the presence of oxide in the re-circulating fluid, another possible source of increased polymer delamination wear could be related to abrasion caused by cement detached from the holder. According to the cement manufacturer there is zirconium oxide besides PMMA in its final composition. Zirconium presence in the cement material was confirmed by energy dispersive X-ray analysis. In literature it is reported that PMMA effect on UHMWPE wear is dependent on the PMMA concentration. For instance, the wear of UHMWPE running against CoCr head under 2450N load increased from around 70 to 140mg in 1 million cycles test with PMMA at 10g/l concentration in 50% diluted bovine calf serum.(14) Two techniques, Energy Dispersive Spectroscopy (EDS) and Raman Spectroscopy, were used to check for the existence of PMMA particles in the fluid. Some particles were collected from the fluid containers but no PMMA was found in the analyzed particles. A microfiltering system should be implemented in order to collect all particles present in the fluid.

On the other hand, the wear resistance of UHMWPE may be associated to crystallinity degree of the material.(18) Non-destructive analysis by X-ray diffraction was performed on the polymer material and revealed occurrence of some degree of crystallinity in all three cups of ST1, ST2 and ST3 prior to the wear test. However, more detailed investigation is needed specifically in the surface after the wear due to the probability of material damage caused by friction. Development of a protocol to determine the crystallinity level of the tested polymer surfaces is in course.

The measured topography (Ra and Pt parameters) of the surfaces before and after the wear test is presented in Figure 9. There is no any significant difference among samples. It is interesting to note that the Ra values of all three tested cups were strongly reduced (Figure 9a); conversely, high severe wear can be readily identified when looking at the markedly increased Pt values (Figure 9b). Oxidation was evidently responsible for increased Ra values of all tested femoral heads (Figure 9c), keeping Pt values almost unchanged (Figure 9d).

ISSN 2179-3956

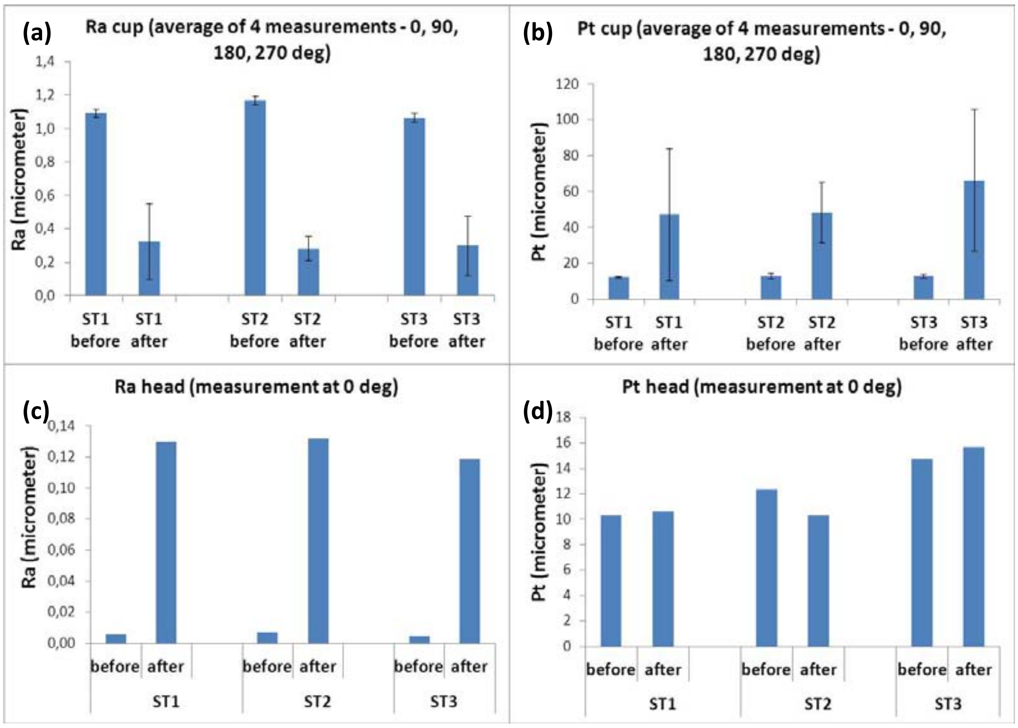


Figure 9. Ra and Pt values of tested surfaces. a) Ra of cup samples; b) Pt of cup samples; c) Ra of head samples; d) Pt of head samples. Samples of control stations: nearly unchanged.

The strong deformation of cups after the wear test revealed by high Pt values (Figure 9b) is even more evident when analyzing changes in radius measured by the coordinate measuring machine. Figure 10 shows the radius measurements of the tested cups. The results for the SK upper cup, not shown, were very close to those of the SK bottom cup. Eight radius values were taken in three circles, at the equator, at 60^o and at 30^o planes, before and after the wear test.

ISSN 2179-3956

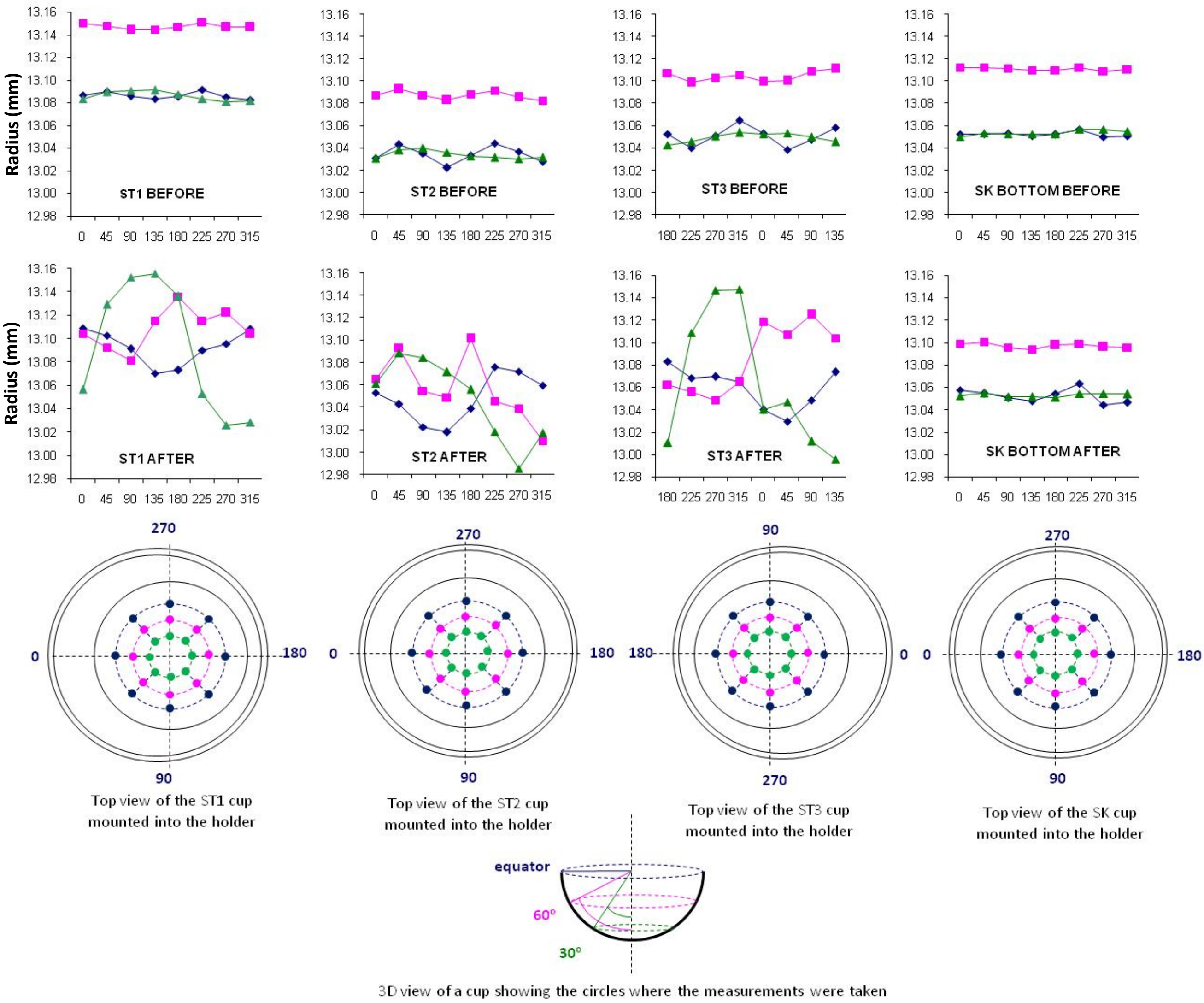


Figure 10. Diameters of the cups before and after the wear test measured by a coordinate measuring machine and schematics of the measured points.

The parameter of sphericity deviation is taken from the highest difference of the radius measured in the three circles (equator, 60^o and 30^o planes) and at the pole, from the radius of the sample.[21] The radius of the sample is obtained from the adjustment of all diameter data by least square method. It is important to report that the highest radius difference happened at the pole of all samples. Measured radius at the pole was always smaller than the average radius. Thus, the sphericity deviation was related to radius deviation at the pole. From Figures 11a and 11b it is clear that the worn cup samples had the spherical feature slightly reduced (increase in sphericity deviation) after test while the load soak cup samples underwent the opposite behavior. On the other hand, from Figures 11c and 11d the worn head samples had the sphericity deviation almost unchanged. It is surprisingly noticed that the trend of the sphericity deviation graph of head samples (Figures 11c and 11d) was very similar to the trend of the wear graph (Figure 3). Apparently, less spherical head samples caused more wear in the cup sample. Less spherical head can have caused decrease in the contact area with the cup; however, detailed analysis of the

ISSN 2179-3956

contact area is needed to confirm the relationship between head sphericity and cup wear.

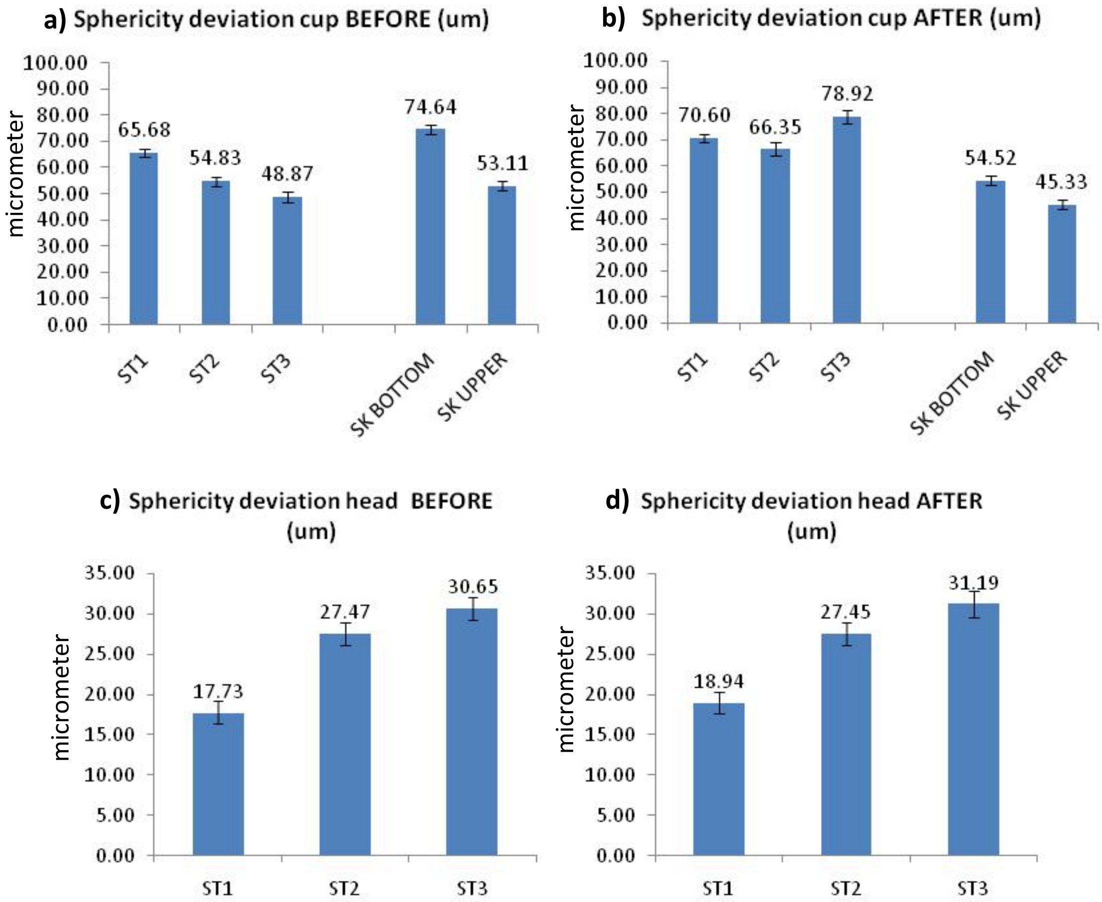


Figure 11. Sphericity deviation of tested cup and head samples.

The last analysis performed was in the forces and moments resulting from the three work station ST1, ST2 and ST3. Forces and moments in the three cartesian axes can be monitored by the multi-axis load sensors present in each work station. The load sensor senses the applied Fz force and the Fx and Fy forces and Mx, My and Mz moments resulting from the friction between the cup and the femoral head surfaces. One example of the measured forces and moments is shown in Figure 12. The data sampling corresponded to 100 data encompassing two complete cycles and was triggered by the first instant of the cycle (see the first instant in Figure 2). It can be noticed that there are no differences in the monitored dynamics of each work station that could be correlated to the wear loss trend among work stations. The misalignment of the contacting samples could also have caused some unbalancing to the contact forces but no visible effect was detected. The use of bovine serum can alter the force levels because of protein presence at the contact and consequently can change the wear level. A new series of test is in course to check this hypothesis.

ISSN 2179-3956

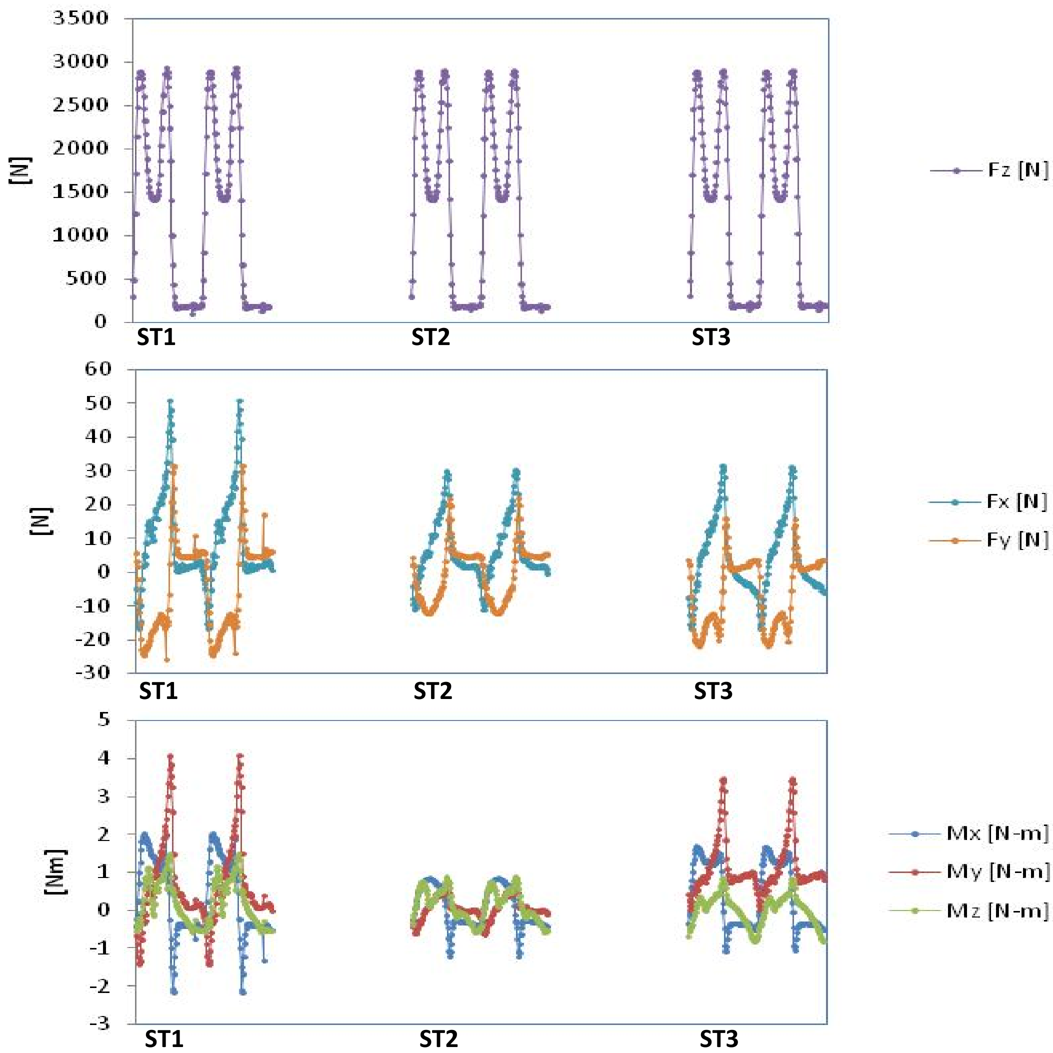


Figure 12. Applied Fz axial force and monitored Fx and Fy forces and Mx, My and Mz moments. Data acquisition of 2 cycles of 1 Hz.

4 CONCLUDING REMARKS

This work summarizes the results obtained from a wear simulation test of polymer-metal hip joint prostheses using a protocol analysis developed with classical tribological techniques – gravimetry, microscopy, profilometry and debris analysis. Some observations could be pointed out: high amount and scatter in mass loss of UHMWPE cups, probably affected by the random presence of cement particles in the fluid and by sphericity deviation of femoral head counterpart, severe delamination wear mechanism of UHMWPE, probably caused by the use of pure water instead of bovine serum, indication of oxidation on stainless steel femoral heads. Some causes of uncertainties to the wear amount were discussed, as machine dynamics, mechanical alignment, material, surface topography, type of fluid and the presence of external particles, in this case, particles coming from PMMA cement used to fix the cup samples in the holders. A new series of test is needed in order to confirm the observed trends.

Acknowledgements

The authors are grateful to CNPq, Faperj and Finep/Deprot 01.06.0847.00.

ISSN 2179-3956

REFERENCES

1 L. Blunt, P. Bills, X. Jiang, C. Hardaker, G. Chakrabarty, The role of tribology and metrology in the latest development of bio-materials, Wear, 266(3-4), (2009) 424-431
2 http://www.clinicalage.com.br/artigos/art_osteoartrose.html (available Aug.2010)
3 http://www.anvisa.gov.br/DIVULGA/NOTICIAS/2007/031007.htm (available Aug.2010)
4 L.Mattei, F.Di Puccio, B.Piccigallo, E.Ciulli, Lubrication and wear modeling of artificial hip joints: A review, Tribology International (in Press)
5 Alves, H.A. Desenvolvimento de um sistema de blindagem com lubrificação em próteses de quadril modular, Dissertação de Mestrado, Universidade do vale do Paraíba, 2008.
6 Azevedo, C.R., Hippert Jr., E. Análise de falhas de implantes cirúrgicos no Brasil: a necessidade de uma regulamentação adequada, Cad. Saúde Pública, Rio de Janeiro, 18(5):1347-1358, set-out, 2002.
7 H. M. J. Mcewen, P. I. Barnett, C. J. Bell, R. Farrar, D. D. Auger, M. H. Stone, J. Fisher, The influence of design, materials and kinematics on the in vitro wear of total knee replacements, Journal of Biomechanics 38-2 (2005) 357-365
8 Sargeant, A., Goswami, T., Hip implants: Paper V. Physiological effects, Materials & Design 27-4 (2006) 287-307
9 Kurtz, S. M., Hozack, W., Marcolongo, M., Turner, J., Rimnac, C., Edidin, A., Degradation of mechanical properties of UHMWPE acetabular liners following long-term implantation, The Journal of Arthroplasty 18 (2003) 68-78
10 Douglas A. Dennis, Richard D. Komisteka, Jorge A. Ochoac, Allan Ritchie ‘‘In vivo’’ determination of hip joint separation and the forces generated due to impact loading conditions, Journal of Biomechanics 34 (2001) 623–629
11 P.Bills, P., Blunt, L., Jiang, X. Development of a technique for accurately determining clinical wear in explanted total hip replacements, Short communication, Wear 263 (2007) 1133–1137
12 ISO 14242-1 Implants for surgery – wear of total hip-joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test (2002)
13 M. Tuke, A. Taylor, A. Roques, C. Maul, 3D linear and volumetric wear measurement on artificial hip joints — Validation of a new methodology, Precision Engineering 34 (2010) 777–783
14 Wang, A. Essner, Short communication Three-body wear of UHMWPE acetabular cups by PMMA particles against CoCr, alumina and zirconia heads in ahip joint simulator, Wear 250 (2001) 212–216
15 S. Affatato, G. Bersaglia, D. Emiliani, I. Foltrana, A. Toni, Sodium-azide versus ProClin300: Influence on the morphology of UHMWPE particles generated in laboratory tests, Biomaterials 25 (2004) 835–842
16 S. Affatato, M. Spinelli, M. Zavalloni, C. Mazzega-Fabbro, M. Viceconti, Tribology and total hip joint replacement: Current concepts in mechanical simulation, Medical Engineering & Physics 30 (2008) 1305–1317
17 S. Affatato, G. Bersaglia, M. Rocchi, P. Taddei, C. Fagnano, A. Toni, Wear behavior of cross-linked polyethylene assessed In vitro under severe conditions, Biomaterials 26 (2005) 3259–3267
18 S.Affatato, M.Zavalloni, P.Taddei, M.DiFoggia, C.Fagnano, M.Viceconti Comparative study on the wear behavior of different conventional and cross-linked polyethylenes for total hip replacement Tribology International 41 (2008) 813–822
19 S.Affatato, G.Bersaglia, I.Foltran, P.Taddei, G.Fini, A.Toni The performance of gamma- and EtO-sterilised UHWMP acetabular cups tested under severe simulator conditions Part 1: role of the third-body wear process Biomaterials 23 (2002) 4839–4846
20 ISO 14242-2 Implants for surgery – wear of total hip-joint prostheses – Part 2: methods of measurement (2002)

ISSN 2179-3956

21 ABNT NBR ISO 7602-2 Implantes para cirurgia – Próteses parcial e total de articulação de quadril Parte 2: Superfícies de articulação feitas de materiais metálico, cerâmico e plástico (1999)
22 ASTM D 1193-6 Standard specification for reagent water (2006)
23 Wang, A. Essner, C. Stark and J.H. Dumbleton, Comparison of the size and morphology of UHMWPE wear debris produced by a hip joint simulator under serum and water lubricated conditions, Biomaterials 17 (1996) 856-871