

USE OF MECHANICAL SIMULATOR OF THE HUMAN WALKING TO TEST PROsthESIS HIP-JOINT

USO DE SIMULADOR MECÂNICO DA CAMINHADA HUMANA PARA TESTE DE PRÓTESES TOTAL DE QUADRIL

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Abstract

In this work it was used one mechanical simulator, developed with Brazilian technology and low cost, for superficial damage evaluation of hip-joint implants. This machine reproduces the kinematics of human body articulations and load specifications based on ISO14242-1:2002 standard requirements. One test, adapted to standard mentioned, was carried out on one prosthetic pair hip-joint composed by femoral head (steel) and acetabular component (polymer). It was used 500,000 cycles, at 1 Hz, representing around six months of clinical use, and a 0,9 % NaCl isotonic solution at 37 °C as fluid test medium. The prosthetic pair specimen tested presented superficial damage and material transference between components which appearance is similar to those found in implants removed from real patients. The results suggest the equipment could contribute for analysis of wear in prosthetic of hip joint.

Key words: Total hip-joint, Mechanic simulator, Wear test, Tribology

Resumo

Neste trabalho foi utilizado um simulador da caminhada humana, desenvolvido com tecnologia brasileira e de baixo custo, destinado a avaliar o dano superficial de próteses totais de quadril. Esta máquina reproduz a cinemática das articulações do corpo humano e as especificações de carga baseados nos requisitos estabelecidos na norma ISO 14242-1:2002. Foi realizado um ensaio, adaptado a norma mencionada, num conjunto articular formado por uma cabeça femoral (aço), e um componente acetabular (polímero). Foram realizados 500.000 ciclos, a 1 Hz, que representam aproximadamente seis meses de uso clínico, empregando como meio uma solução isotônica de 0,9% NaCl a 37 °C. Os componentes protéticos ensaiados apresentaram evidências de dano superficial e transferência de material entre si, com aparência semelhante a aquelas encontradas em implantes removidas de pacientes vivos. Os resultados sugerem que este equipamento poderia contribuir para análises de desgaste de próteses de quadril.

Palavras-chave: Prótese total de quadril, Simulador mecânico, Ensaio de desgaste, Tribologia

Introduction

The natural hip-joint is formed by the femoral head and acetabular pelvic bone cavity. It is a sensible region and it subjects to mechanical efforts. Superficial damages in this joint require, normally, the use of a surgical procedure named hip arthroplasty (total substitution of the hip-joint). Such surgical modality aims at the substitution of damaged bone parts, for prosthesis or artificial

components implanted in the human body with the purpose to reestablish the natural functions and physiological conditions.

Diverse factors justify the surgical interventions in this region, for example, the increase of the life expectancy of the people, osteoporoses and number of automobile accidents (ALVES 2004, CGEE 2005).

The great incidence of this surgical modality stimulated industry and the world-wide commerce of products and accessories of hip-joint orthopedic implants, putting into motion in the year of 2002 about 2.5 billion dollar (CGEE 2005).

The useful life of the hip-joint implants is limited, and then manufacturers of these elements guarantee a good performance, clinically proven, for fifteen to twenty years use only (FONSECA 2005). However, premature fails can occur for diverse reasons, mainly for (AZEVEDO 2002, CALLISTER 2000, DUMBLETON 1975, POHLER 1986, RAVAGLIOLI 1992):

- mechanical damage (wear at the interfaces due to the contact and the fatigue);
- pitting corrosion caused by immersion fluid;
- errors in product design, materials selection and manufacture process;
- inadequate surgical technique for putting or choice of the implants;
- bones quality, biological age, clinical conditions of the patient

Some standards aim to characterize the materials used in implants in function of its structure, chemical composition, hardness, surface roughness, creep, porosity, and others (WANG 1995, WANG 1999, WANG 2001). Another type of standards intends to regularize tests in implants using mechanic simulators (SAIKKO 2001, SAIKKO 2002, BROWN 1996).

Cyclical tests with simulators allow, in a reduced period, to get records about the wear performance of the prosthetic components, beyond comparing them with others clinically observed. In case that the performance “in vitro” does not correspond clinically to the observed one, questions relatives to material quality, component design, manufacture process, etc., can be considered before regular production (GRAY 1985, CLARKE 2008).

Currently, metallic alloys, ceramic and polymeric are materials used to manufacture hip-joint implants for human beings. The more used and studied materials for hip-joint prosthetic pairs are: polymer UHMWPE, for acetabular component, and stainless steel, for the femoral head (WANG 1995, LANDY 2008, JASTY 1990).

Recent research shows that the better way to investigate the physical phenomena that limit the wear performance of hip-joint prosthetic implants is to use mechanical simulators assisted by the continuous evolution of analytical methods of materials characterization (ESSNER 2005, HUA 2008).

This work presents the use a mechanical simulator developed to study the superficial damage of prosthetic hip-joints in function of cyclical loading and displacement parameters, according ISO 14242-1:2002 requirements. The test was adapted using a 0,9 % NaCl isotonic solution like fluid medium test and only 500,000 cycles to time test. Wherever, this equipment is able to carry out standardized tests as experimental tests that are not often available in commercial simulators.

Materials and Methodology

The simulator allows carrying out tests according to cinematic conditions established on ISO 14242-1: 2002. This standard specifies the angular displacements, loads to be applied, the speed and duration of cycle, temperature and environment for testing.

The prosthetic hip-joint was fixed to simulator according to specifications of clinical use and in agreement with standard ISO 14242-1 recommendations.

According to standard ISO 14242-1, the use of a fluid test medium of non-biological origin may be considered when performance requirements relating to this test method are being decided. In this study, because the objective is to study superficial damage, was used a isotonic solution of 0,9% NaCl at 37°C as environment test. A system, thermocouple and electric resistance connected to a controller, was used to keep constant the temperature of the fluid, according figure 1.

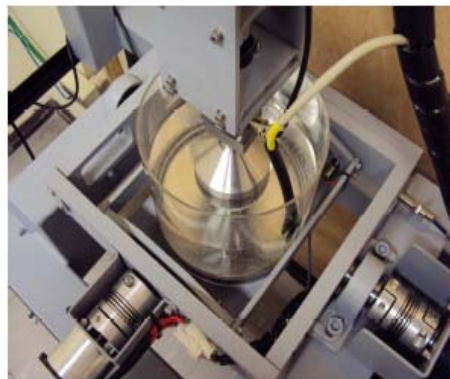


Figure 1. System of fluid temperature control into the test device

The prosthetic set was characterized, before and after the tests, by means of analyzes metallographic, measurement of superficial hardness Vickers to steel; and hardness Shore D and density to polymer (ASTM D792 standard); and observations using optical and scan electronic microscopy.

Fixed the prosthetic components, the test was carried out to 1,0 Hz speed, during 500,000 cycles. The angular displacements and loads were followed according to standard ISO 14242-1.

In figure 2 are show the trajectories of curves of relative displacement between both components in contact (femoral – acetabular component). It is noted the smoothness and homogeneity of the curves behavior, that it satisfies the standard ISO completely.

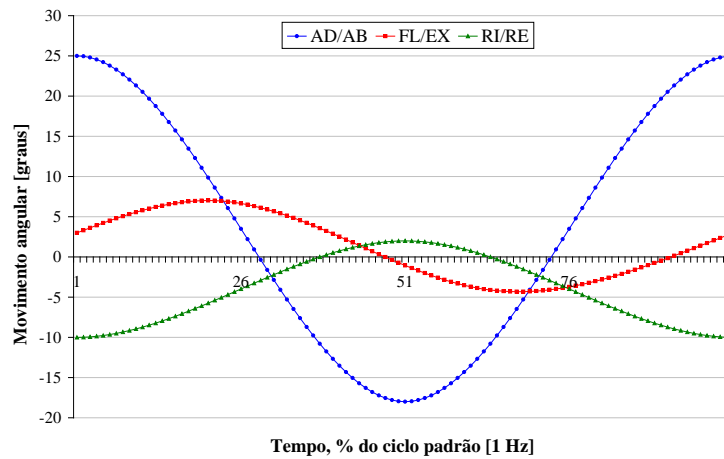


Figure 2. Trajectory curves relative displacement between components: blue (extension/flexion), red (abduction/adduction) and green (rotations inward/outward).

In table 1 are shown the loads applied for the simulator, in function of test time, which admits variations to ± 90 N.

Table 1. Cycles of loads performed by the simulator.

Time, % of cycle	Loads (N)
	ISO 14242-1
0	0,3
12	3,0
32	1,5
50	3,0
62	0,3
100	0,3

Results and Discussion

Metallographic analysis carried through on the steel of the femoral component, showed a microstructure formed, basically, by austenite. EDS analysis also revealed high fractions of Cr, Ni, Mo in its chemical composition; typical of stainless steels, as shown in figure 3. Its hardness was of (194 ± 11) HV.

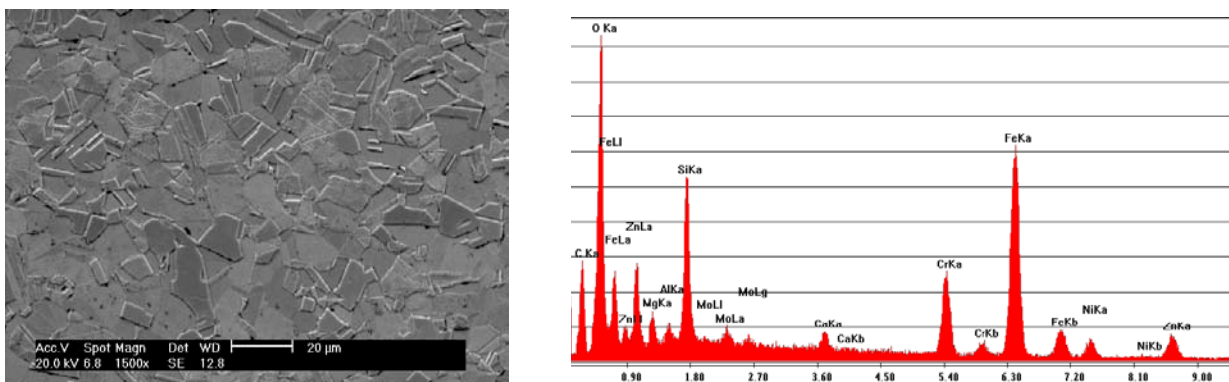


Figure 3. Microstructure and EDS spectrum of the steel used as femoral component - austenitic matrix.

For the polymer, the hardness measured in Shore D scale was (59 ± 1) and $0,931\text{g/cm}^3$ of density. These values suggest polymer could be a UHMWPE category.

The temperature, measured during the period of test, presented a variation of $\pm 0,1\text{ }^\circ\text{C}$ on the value of reference of $37\text{ }^\circ\text{C}$. Considering the standard ISO admits error near to $\pm 2,0\text{ }^\circ\text{C}$, the control of temperature system projected was totally satisfactory.

By scan electronic microscopy (SEM) it was possible to observe the initial state of the prosthetic components surfaces tested, as shown in figure 4. Femoral component surface was initially polished but in figure are observed some defects like pits and grooving marks. Unfortunately did not find any information or parameters to establish if these defects were created by manipulation error or manufacturing fail of component. Neither, if they are accepted or not in new prosthetic components. In any case, thinking about superficial damage, the defects found could have influence on wear behavior. The holes of pits could provide sites to storage wear debris, indeed, modify the surface and friction conditions along the test. In the same way, the grooves observed could change the lubricants conditions between components, promoting highest grooving or removing material from acetabular component.

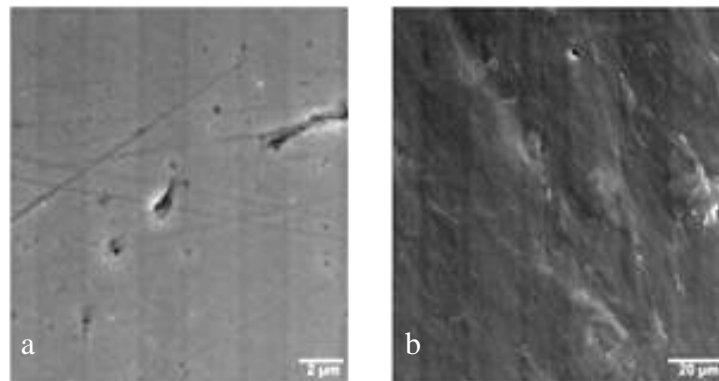


Figure 4. Initial surfaces of prosthetic components: a) as polishing for femoral component, b) as mechanical turning for polymer.

After the test, similar materials characterizations were conducted on both prosthetic components. These analyses showed that the femoral component had suffered severe surface damage. In figure 5 are observed grooved surfaces originated by severe contact between prosthetic components. The wear marks follow well defined trajectories revealing the traveled path by asperity during its dislocation. The form of these trajectories also shows the simulator capacity of reproducing the relative movement between parts, as specified by standard ISO.

In figure 5 are also observed dark areas on worn surface. Initially, it seems an oxide layer or polymer transferred from acetabular component to steel. EDS analyses identified the chemical composition of this areas and proved that it was polymer, ending the possibility to be an oxide.

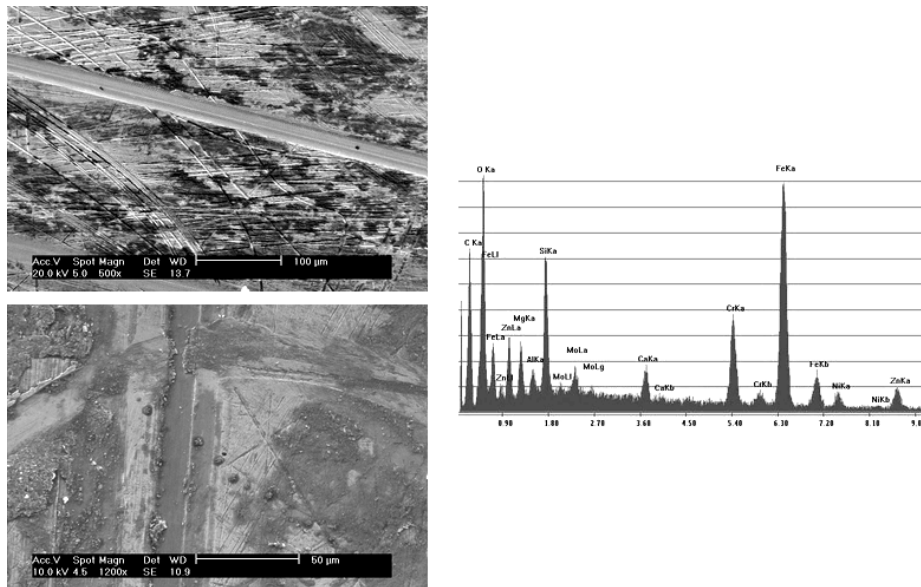


Figure 5. Superficial damage on femoral component. EDS spectrum of material adhered to spherical surface of femoral component, during the test.

In figure 6 is shown the acetabular component after the test. It was also observed that the superficial damage is similar to those saw in femoral prosthetic, showing movement trajectories between components during the test. The dark areas are debris of polymer that were removed by friction, in some cases stayed adhered at surface and in others were dislocated to path wear frontiers.



Figure 6. Surface of acetabular component after the test.

Ideally, this prosthetic hip-joint pair should stand over 10 million cycles during the wear-testing (which is equivalent to a life of 10 year) but the current results indicated that to the conditions used in this test (not totally according to standard ISO) the life of the prosthetic pair presented severe superficial damage even just below 500 thousand cycles.

Conclusions

The mechanical simulator developed to test prosthetic hip-joint implants is able to reproduce the specifications of loads and angular displacements, according to Standard ISO 14242-1:2002.

The superficial damage observed in prosthetic components surfaces tested was similar to those found in implants removed from real patients.

Material is transferred from acetabular component to steel sphere during contact. Dark areas were formed because of this polymer transference.

The versatility of mechanical simulator performance allows saying that it could be used in security and precision to test another kinds of prosthetic implants, materials biomedical, environments, temperatures and standards test.

This equipment should contribute to development and, in the future, certificate new prosthetic products, and hip-joint implants, specifically.

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