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Evaluation of Polyethylene Wear in a Brazilian Ultracongruent Knee Prosthesis with a Rotating Platform*

Avaliação do desgaste do polietileno de uma prótese de joelho nacional ultracongruente de base rotatória

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Abstract

Objective To evaluate the wear of polyethylene in a Brazilian ultracongruent knee prosthesis with a rotating platform (Rotaflex, Víncula, Rio Claro, SP, Brasil).

Methods We used the test method with the loading and preparation parameters mentioned in the standards regulation *ISO 14243-1:2009*, and the measurement methods mentioned in the standards regulation *ISO 14243-2:2009*, for the evaluation of the wear behavior of a Brazilian prosthesis with a rotating platform. The equipment used for the wear test was the ISO 14243–1 gait simulator (EndoLab, Riedering, Germany).

Results After 10 million cycles, the evaluation of the polyethylene wear showed a regular appearance of surface wear at a mean rate of 2.56 mg per million cycles.

Conclusion The wear of the polyethylene of the evaluated prosthesis was minimal after the tests performed and with safety limits higher than those recommended by biomechanical engineering.

Keywords
- arthroplasty, replacement, knee
- knee prosthesis
- prosthesis design
- prosthesis failure

Resumo

Objetivo Avaliar o desgaste do polietileno de uma prótese de joelho brasileira ultracongruente de base rotatória (Rotaflex, Víncula, Rio Claro, SP, Brazil).

Métodos Utilizou-se o método de ensaio com os parâmetros de carregamento e preparação citados na norma *ISO 14243-1:2009*, e os métodos de medição citados na norma *ISO 14243-2:2009*, para a avaliação do comportamento de desgaste de uma prótese nacional com base rotatória. O equipamento utilizado para o teste de desgaste foi o simulador de marcha ISO 14243–1 (EndoLab, Riedering, Alemanha).

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Palavras-chave
- artroplastia do joelho
- prótese do joelho
- desenho de prótese

Resultados Após 10 milhões de ciclos, a avaliação do desgaste do polietileno mostrou uma aparência regular do desgaste da superfície com taxa média de 2,56 mg por milhão de ciclos.

Conclusão O desgaste do polietileno da prótese avaliada foi mínimo após os ensaios realizados e com os limites de segurança superiores aos preconizados pela engenharia biomecânica.

Introduction

The aging of the population and the higher prevalence of patients with osteoarthritis has increased the frequency of indications for total knee arthroplasty (TKA).[1,2] Total knee arthroplasty can be defined as a highly-complex surgical procedure for the treatment of arthrosis that is capable of demonstrating satisfactory and long-lasting data on the improvement in pain, quality of life and patient functional outcomes, as well as in the correction of deformities and instabilities with origins related to degenerative processes that compromise the knee joint.[3] This procedure has excellent postoperative results in relation to implant survival, with rates higher than 95% in at least 10 years of follow-up.[4]

Polyethylene wear can produce debris that influences the release of prosthetic components. Total knee arthroplasty with a rotating platform has theoretical biomechanical advantages over a fixed-platform design.[5] These advantages include an improvement in kinematics by increasing the range of motion, facilitating axial rotation, better distribution of stress between the femoral and tibial components, and reduction in release forces at the implant interface with the bone.[6–8] Many variables can influence the frictional wear behavior of polyethylene, like the design of the prosthesis, the raw material used, and the surgical technique applied and the patient's morbidities, such as the activity level and body mass. The objective of the present study was to evaluate the wear of polyethylene of a Brazilian ultracongruent knee prosthesis with a rotating platform (Rotaflex, Víncula, São Paulo, SP, Brasil).

Materials and Methods

We used the test method with the standard parameters for loading and preparation listed in the norm *ISO 14243-1:2009– Implants for Surgery – Wear of Total Knee Joint Prostheses – Part 1: Loading and Displacement Parameters for Wear Testing Machines with Load Control and Corresponding Environmental Conditions for Tests (Accredited)*, and the measurement methods mentioned in the norm *ISO 14243–2:2009 Implants for Surgery – Wear of Total Knee Joint Prostheses – Part 2: Methods of Measurement (Accredited)*. For the evaluation of the wear behavior, the Rotaflex prosthesis was used.[9,10]

In total, 3 simultaneous tests were performed in the ISO 14243–1 knee joint gait simulator (EndoLab, Riedering, Germany) in 5 systems, totaling 15 components (►**Figures 1** and **2**).

In the simulations, the implant was attached to the extension device. A cyclical flexion-extension variation from 0° to 58° was applied (►**Table 1**). An axial force ranging from 168 N to 2,600 N was also applied, depending on the degree of flexion, simulating a normal human walk (►**Table 1**). The tibial base was free to accommodate to the femoral component under the influence of applied contact forces, with this movement having all degrees of freedom, except the flexion-extension angle, which followed the specified cyclic variation. With this simulation, the applied contact force actions were: axial force, anteroposterior (AP) force, and tibial rotation torque. The femoral and tibial metal components, as well as the polyethylene, were immersed in a fluid medium simulating human synovial fluid throughout the test, which was carried out in a controlled environment, simulating the physiological conditions.

The wear assessment followed the *ISO 14243–2:2009* norms, with 10 million cycles and measurements taken at every millionth cycle. In accordance with the aforementioned norms, the wear was assessed by analyzing the loss of mass.

Results

After 10 million cycles, the qualitative analysis of the polyethylene surface showed an appearance of regular wear, with polished and matte areas (►**Figure 2**). This regular wear pattern indicates an intrinsic stability of the prosthetic components (►**Figure 3**).

The quantitative result of mass wear for every millionth cycle is found in ►**Table 1**. ►**Figure 3** expresses the results mentioned in ►**Table 2**.

The mean wear rate was 2.56 mg per millionth cycle, which was determined after 10 million cycles (►**Figure 1**).

Discussion

Total knee arthroplasty aims to promote pain relief and improve function in a lasting way. However, surgery can fail for a number of reasons, such as loosening of the components, infection, instability, and persistent pain, for example.[11] In order to reduce the wear of the polyethylene and consequently the production of debris, a tibial component with a rotating platform was created, in which the polyethylene can move rotationally over the tibial component, hypothetically reducing its friction and wear.[6,7,12]

In a study,[11] the authors state that prostheses with ultracongruent rotational support have the advantage of

Fig. 1 Representation of the individual test chamber.

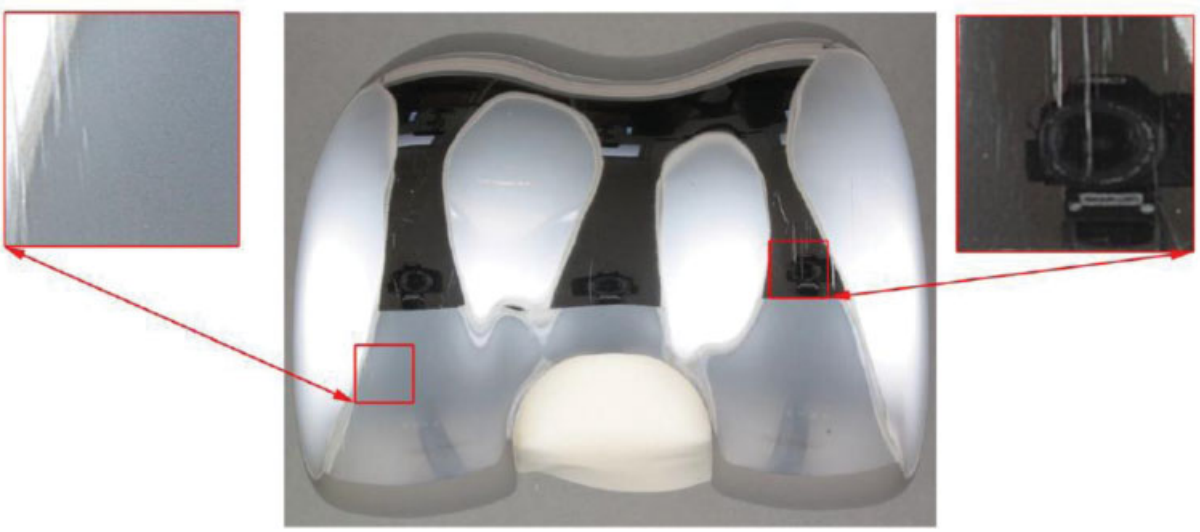

Fig. 2 Qualitative virtual analysis of the wear.

standardizing the contact pressures between components, thus reducing the formation of polyethylene particles and, consequently, osteolysis, in addition to the better adaptation of the extensor mechanism to possible imperfections in the rotational positioning of the tibial component.[11] An in-vivo video-fluoroscopic study, followed by three-dimensional reconstruction of the images obtained, comparing prostheses with fixed and mobile bases, with the same origin and design, showed that the femorotibial contact surface is twice as large in prostheses with rotational support when compared to those with fixed support.[13] In this study, the authors noted that the good results were similar in both models, but, both objectively and subjectively, the mobile platform was judged to be the closest to the normal knee.[13]

The high durability of prostheses with a rotating polyethylene component is well elucidated in the literature, and the prostheses can last for more than 20 years in 97.7% of cases.[14]

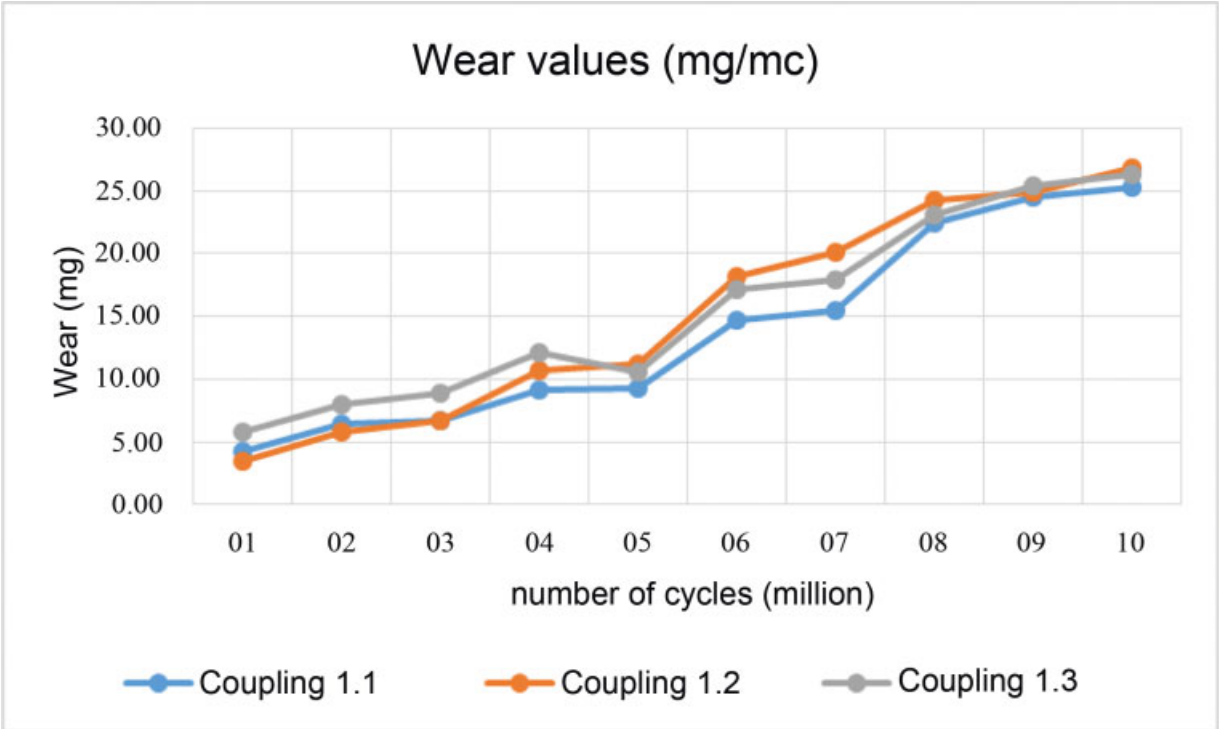

Fig. 3 X-UHMWPE insert wear versus number of cycles.

Table 1 Loading parameters

Parameter	Values according to ISO 14243–1
Flexion/Extension	0° to 58°
Axial force	168 N to 2,600 N
Anteroposterior force	-265 N to 110 N
Torque	−1 Nm to 6 Nm
Frequency	1 Hz
Test fluid	Calf serum
Movement restriction - anteroposterior* (contrary to the positive anteroposterior movement)	9.3 N/mm
Movement restriction - anteroposterior* (contrary to the negative anteroposterior movement)	44 N/mm
Restriction of tibial rotation**	0.36 Nm/°

Notes: *The system's anteroposterior movement restriction is 0 when the total knee joint is equal to or close to 2.5 mm in any direction from the reference position. **The tibial rotation restriction of the system is 0 when the total knee joint is equal to or close to +/- 6° in any direction from the reference point.

Schmidt et al[15] studied the wear rate of polyethylene in different models of prostheses already commercialized and established in the market, and they found values of volumetric wear that ranged from 1.9 mg/mc to 14.6 mg/mc. In the present study, the result obtained of 2.67 mg/mc of volumetric wear after 10 million test cycles, compared to the values found by Schmidt et al,[15] demonstrated that the Rotaflex system approaches the lowest rate found (1.9 mg/mc). In addition, the 2.67 mg/mc of wear of the polyethylene component measured in this Brazilian prosthesis obtained a wear resistance performance 5.47 times higher than the maximum published values.

Conclusion

The wear of the polyethylene of the evaluated prosthesis was minimal after the tests performed with safety limits higher than those recommended by biomechanical engineering.

Table 2 Wear data of the X-UHMWPE tested (polyethylene) inserts

Coupling	1.1		1.2		1.3	
	Mass		Mass		Mass	
Cycles (million)	X-UHMWPE 1.1 insert (g)	X-UHMWPE 1.1 insert (mg)	X-UHMWPE 1.2 insert (g)	X-UHMWPE 1.2 insert (mg)	X-UHMWPE 1.3 insert (g)	X-UHMWPE 1.3 insert (mg)
0.0	44.71242	0.00	44.48231	0.00	44.66329	0.00
0.5	44.70981	3.91	44.48121	2.41	44.65973	4.86
1.0	44.71073	4.24	44.48138	3.48	44.66000	5.84
2.0	44.71047	6.47	44.48102	5.81	44.65979	8.01
3.0	44.71210	6.71	44.48202	6.69	44.66085	8.83
4.0	44.71149	9.18	44.47986	10.70	44.65949	12.06
5.0	44.71378	9.30	44.48183	11.14	44.66343	10.52
6.0	44.71097	14.74	44.47747	18.13	44.65948	17.09
7.0	44.71004	15.47	44.47531	20.08	44.65842	17.95
7.5	44.71357	17.77	44.47810	23.13	44.66167	20.54
8.0	44.70607	22.38	44.47417	24.17	44.65625	23.06
9.0	44.70556	24.50	44.47504	24.90	44.65551	25.40
10.0	44.70660	25.23	44.47497	26.75	44.65645	26.24

Conflict of Interests
The authors declare that there are no conflict of interests.

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