Comparative Biomechanical Study of Crosslinked Polyethylene Wear with 36-mm Ceramic Femoral Heads and with 32-mm Metal Femoral Heads

Estudo biomecânico comparativo do desgaste do polietileno reticulado com cabeças femorais cerâmicas de 36 mm e com cabeças metálicas de 32 mm

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Abstract

Objective This study aims to compare the in vitro wear rate of crosslinked, high molecular weight polyethylene coupled to 36-mm diameter ceramic heads and 32-mm diameter metal heads.

Methods Ceramic-on-polyethylene (36 mm) and metal-on-polyethylene (32 mm) tribological pairs were submitted to biomechanical tests in a simulator to determine the wear rate after 15 x 10^6 cycles.

Results A statistically significant difference (p = 0.0005) was detected when comparing the wear rate of assemblies with metallic heads (average wear: 14.12 mg/MC) and ceramic heads (average wear: 7.46 mg/MC).

Conclusion The present study demonstrated the lower wear rate in prosthetic assemblies using 36-mm crosslinked ceramic-on-polyethylene tribological pairs compared to 32-mm crosslinked metal-on-polyethylene assemblies. This finding demonstrates the effectiveness of ceramic-on-polyethylene tribological pairs, even with large diameter heads.

Resumo

Objetivo O objetivo do presente estudo foi comparar, in vitro, a taxa de desgaste do polietileno de alto peso molecular reticulado acoplado a cabeças cerâmicas de 36 mm de diâmetro e acoplado a cabeças metálicas de 32 mm de diâmetro.

Métodos Foram realizados ensaios biomecânicos em simulador de desgaste para os pares tribológicos cerâmica-poli (36 mm) e metal-poli (32 mm) a fim de verificar a taxa de desgaste após em 15 x 10^6 ciclos.

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Introduction

The last two decades witnessed an evident evolution of biomaterials and hip prosthetic implants design. However, the long-term survival of total hip arthroplasty (THA) still represents an enormous challenge for orthopedics and bioengineering. Several strategies have been adopted to improve THA outcomes. The use of hard on hard surfaces, that is, metal-on-metal and ceramic-on-ceramic, was widespread in the early 21st century. However, complications related to the metal-on-metal surfaces (pseudotumor, extensive osteolysis, and increased serum chromium-cobalt levels) and ceramic-on-ceramic surfaces (noise, fractures, trunnionosis), in addition to the high cost of the latter tribological pair, reduce their use all over the world.

As such, more traditional tribological pairs (ceramic-on-polyethylene and metal-on-polyethylene) are still widely used, and the development of polyethylene materials with greater wear resistance saw major advances. In this sphere, crosslinked high molecular weight polyethylene (UHMWPE) represented a great evolution since it is associated with lower production of wear particles (debris) and greater arthroplasty durability compared to conventional polyethylene.

The combination of UHMWPE with ceramic femoral heads implies in a lower wear rate compared to metal heads. However, it is unclear if this advantage remains even when using large diameter heads. The increased use of larger femoral heads results from the greater freedom of movement without causing impingement, such as acetalular component and femoral stem collision. Therefore, the greater the range of movement, the lower the risk of dislocation; in addition, larger diameters are closer to natural measurements in humans, with an average of 48 mm for women and 55 mm for men.

Studies compared polyethylene wear on metallic and ceramic femoral heads of the same diameter, showing an obvious advantage for ceramics. The current study aims to verify whether such an advantage is maintained even when using large diameter ceramic femoral heads (36 mm).

As such, the present study compares the in vitro wear rate of UHMWPE coupled to 36-mm ceramic heads and to 32-mm metallic heads.

Material and Methods

Total hip joint prostheses were submitted to wear tests performed according to the International Organization for Standardization (ISO) 14242-1 and 14242-3 at the Biomechanical Engineering Laboratory from Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil (Laboratory Accredited by the Brazilian Network of Testing Laboratories [Rede Brasileira de Laboratórios de Ensaios, RBLE/J Brazilian National Institute of Metrology Standardization and Industrial Quality [Instituto Nacional de Metrologia, Qualidade e Tecnologia, INMETRO]). Six tribological pairs of hip prostheses (three metal-on-polyethylene pairs and three ceramic-on-polyethylene pairs) from the company Víncula (Rio Claro, SP, Brazil) were analyzed. To quantify liquid absorption by the polymeric component during the wear test, a tribological pair from each group was maintained as a control specimen (CS) and subjected only to loading cycles, with no movement (kinematics). Common elements in each sample were the following: an uncemented acetabular component, an acetabular insert, and two acetabular screws. The difference at each assembly was the interchangeable femoral head: the first group used a metal head with a 32-mm diameter, whereas the second group had a ceramic head with a 36-mm diameter.

Acetabula and acetabular screws were made of titanium alloy, according to the American Society of Testing and Materials (ASTM) F136, whereas acetalular inserts consisted of UHMWPE, according to the ASTM F648. The metal femoral heads were produced with stainless steel (ASTM F138), and the ceramic femoral heads were composed by Biolox Delta ceramic (Al203/Zr02). Samples are presented in Table 1 and identified at Figures 1 and 2.

Procedures

Three prosthetic assemblies from each sample were subjected to both angular displacement (kinematics) and loading; these samples were referred to as test specimens (TSs) for wear. The other two assemblies from each sample were subjected to loading only to assess changes in mass resulting from fluid absorption and referred to as CSs. A hydraulic hip joint simulator with six stations for TSs and two stations for CS was used, as shown in Figure 3. The simulator and other equipment and instruments used at testing are listed in Tables 1 and 2.
The test was carried out in a laboratory environment at a room temperature of 23 °C ± 4 °C. Test parameters were configured according to the Brazilian National Standards Organization (Associação Brasileira de Normas Técnicas, ABNT), Brazilian Standards (Normas Brasileiras, NBR) ISO 14242-1: 2016 Technical Standard (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).

The TS acetabulum was fixed to the upper simulator support with bone cement and two acetabular screws to ensure no mobility between the acetabular component and support. The assembly was carried out with a template, assuring a 30° ± 3° inclination of its polar axis in relation to the compressive load line. Subsequently, the acetabular insert was attached to the acetabulum. The TS femoral head was mounted on a conical coupon manufactured with the same design conditions as defined for the finished product. The coupon was designed to ensure component orientation in their intermediate positions, that is, at midpoint of angular movements in relation to the load line after mounted on the lower simulator support (Fig. 4). The CSs were assembled with the polar axes of the femoral head and the acetabular insert coinciding with the compressive load line.

After assembly, the TSs and CSs were enclosed and immersed in a biological test fluid (fetal bovine serum with 30 g/L of protein). To avoid microbial proliferation, 2 g/L of sodium azide was added, along with 8 g/L of ethylenediaminetetraacetic acid (EDTA) as a chelating agent. The fluid was kept at 37 ± 2°C and circulated through the test chamber using an active, closed system. The fluid was replaced every 500,000 cycles until the end of the test.

The femoral and acetabular components of the TS were subjected to compressive loading varying in time, simultaneously to angular movements simulating the physiological

### Table 1 Identification of assemblies with ceramic femoral head

| Identification | Product Identification | Code / Register | Lot number |
|----------------|------------------------|----------------|------------|
| Vincula        | PHENOM Poly acetabular insert post. roof 36 × 58/60 mm crosslinked | LP.13.24.36060 | 120975 CP47.2018ED-01 |
| Vincula        | PHENOM Poly PS acetabulum 60 mm diameter | 04.01.34.00060 | 04859R |
| Vincula        | Interchangeable femoral head 36 mm standard neck delta ceramics | 04.04.10.36002 | 3150387 |
| Vincula        | Low-profile acetabular screw Ti Ø 6.5 × 15 mm | 04.43.19.65015 | 11808S |
| Vincula        | PHENOM Poly acetabular insert post. roof 36 × 58/60 mm crosslinked | LP.13.24.36060 | 120975 CP47.2018ED-02 |
| Vincula        | PHENOM Poly PS acetabulum 60 mm diameter | 04.01.34.00060 | 04859R |
| Vincula        | Interchangeable femoral head 36 mm standard neck delta ceramics | 04.04.10.36002 | 3150389 |
| Vincula        | Low-profile acetabular screw Ti Ø 6.5 × 15 mm | 04.43.19.65015 | 11808S |
| Vincula        | PHENOM Poly acetabular insert post. roof 36 × 58/60 mm crosslinked | LP.13.24.36060 | 120975 CP47.2018ED-03 |
| Vincula        | PHENOM Poly PS acetabulum 60 mm diameter | 04.01.34.00060 | 04859R |
| Vincula        | Interchangeable femoral head 36 mm standard neck delta ceramics | 04.04.10.36002 | 3150390 |
| Vincula        | Low-profile acetabular screw Ti Ø 6.5 × 15 mm | 04.43.19.65015 | 11808S |
| Vincula        | PHENOM Poly acetabular insert post. roof 36 × 58/60 mm crosslinked | LP.13.24.36060 | 120975 EC47.2018ED-01 |
| Vincula        | PHENOM Poly PS acetabulum 60 mm diameter | 04.01.34.00060 | 04859R |
| Vincula        | Interchangeable femoral head 36 mm standard neck delta ceramics | 04.04.10.36002 | 3150391 |
conditions of the hip joint. The test was carried out at a frequency of 1 Hz, and it was completed when reaching the programmed threshold of 5 million cycles. The wear rate of the acetabular component was evaluated using the gravimetric method, according to the Technical Standard ABNT NBR ISO 14242-2: 2006 (Implants for surgery—Wear of total hip-joint prostheses—Part 2: Methods of measurement). At first, the acetabular inserts were immersed in the test fluid for 48 hours, dried, cleaned, and weighed until a stable fluid absorption rate was established. Subsequently, the TS acetabular inserts were subjected to 500 thousand cycles at the simulator and, then, wear was evaluated through mass loss analysis. The CSs were subjected only to variable loading, without angular movements, and underwent the same drying, cleaning, and weighing procedures to establish a reference parameter for mass variation resulting from fluid absorption. This procedure was repeated every 1 million cycles during the test.

The following regimen was used to clean the TS acetabular inserts and CSs:

- Rinse in deionized water;
- Vibration for 10 minutes in deionized water;
- Rinse in deionized water;
- Vibration for 10 minutes in a solution with 10% (volume) of neutral detergent in deionized water;
- Rinse in deionized water;
- Vibration for three (3) minutes in deionized water;
- Rinse in deionized water;
- Drying in filtered nitrogen jet at 2-bar pressure;
- Immersion in isopropyl alcohol for 5 minutes;
- Drying in filtered nitrogen jet at 2-bar pressure;
- Final drying in a vacuum chamber with silica at 13.3 Pa ± 0.13 Pa for 12 hours.

### Table 2
Identification of assemblies with metallic femoral head

| Manufacturer | Product Identification | Code / Register | Lot number | Assay code |
|--------------|------------------------|----------------|------------|------------|
| Víncula      | PHENOM Poly acetabular insert post, roof 32 x 50/52 mm crosslinked | LP.13.24.32052 | 11868S | CP46.2018ED-01 |
|              | PHENOM Poly PS acetabulum 52 mm diameter | 04.01.34.00052 | 04450R |
|              | Interchangeable femoral head 32-mm standard neck | 04.04.07.32002 | 05151R |
|              | Low-profile acetabular screw Ti Ø 6.5 x 15 mm | 04.43.19.065015 | 11808S |
| Víncula      | PHENOM Poly acetabular insert post, roof 32 x 50/52 mm crosslinked | LP.13.24.32052 | 11868S | CP46.2018ED-02 |
|              | PHENOM Poly PS acetabulum 52-mm diameter | 04.01.34.00052 | 04450R |
|              | Interchangeable femoral head 32 mm standard neck | 04.04.07.32002 | 05151R |
|              | Low-profile acetabular screw Ti Ø 6.5 x 15 mm | 04.43.19.065015 | 11808S |
| Víncula      | PHENOM Poly acetabular insert post, roof 32 x 50/52 mm crosslinked | LP.13.24.32052 | 11868S | CP46.2018ED-03 |
|              | PHENOM Poly PS acetabulum 52 mm diameter | 04.01.34.00052 | 04450R |
|              | Interchangeable femoral head 32 mm standard neck | 04.04.07.32002 | 05151R |
|              | Low-profile acetabular screw Ti Ø 6.5 x 15 mm | 04.43.19.065015 | 11808S |
| Víncula      | PHENOM Poly acetabular insert post, roof 32 x 50/52 mm crosslinked | LP.13.24.32052 | 12276S | EC46.2018ED-01 |
|              | PHENOM Poly PS acetabulum 52-mm diameter | 04.01.34.00052 | 00544P |
|              | Interchangeable femoral head 32-mm standard neck | 04.04.07.32002 | 05151R |

### Table 3
Average mass loss in specimens 1, 2, and 3 with 32-mm metal femoral heads

| NUMBER OF CYCLES (x 10^6) [mg] | 0.5 | 1 | 2 | 3 | 4 | 5 |
|-------------------------------|-----|---|---|---|---|---|
| CP.462018ED-01                | -2.87| -2.05| -20.51| -31.67| -40.74| -56.45|
| CP.462018ED-02                | -2.89| -4.06| -20.70| -30.42| -40.11| -57.47|
| CP.462018ED-03                | -1.25| -3.07| -21.03| -31.93| -44.14| -65.11|
| MEAN                          | -2.34| -3.06| -20.75| -31.34| -41.66| -59.68|
| STANDARD DEVIATION            | 0.94| 1.01| 0.26| 0.81| 2.17| 4.73|
After cleaning, each acetabular insert was weighed twice alternately until the difference between measurements was less than 100 \( \mu \text{g} \). These weighing and cleaning procedures were repeated at 24-hour intervals until the incremental mass change for each acetabular insert was less than 10% of the previous accumulated mass change.

Statistical Analysis
Statistical analysis was performed in Excel Office 2010 (Microsoft Corp., Redmond, WA, USA) and SPSS V20 (IBM, ARMONK, NY, EUA). Descriptive data were expressed as mean values and standard deviation. Variables were compared using the Student \( t \) and paired \( t \)-tests after checking data homogeneity, normality, and variance. The \( p \)-value for significance was 0.05, with a 95% confidence interval.

Results
Tests were completed after reaching the programmed threshold of 5 million cycles. Gravimetric wear was calculated using the following expression:

\[
W_n = W_{an} + S_n,
\]

in which \( W_n \) represents the average net mass loss in TSs after \( n \) test cycles, \( W_{an} \) is average mass loss resulting from TS wear after \( n \) test cycles, and \( S_n \) is the average mass of test fluid absorbed by CSs during the same \( n \) cycles.

- **Tables 3 and 4** present the average mass loss in TSs (\( W_{an} \)) with 32-mm metallic and 36-mm ceramic femoral heads, respectively.
- **Table 4** presents the average mass loss in specimens 1, 2, and 3 with 36-mm ceramic femoral heads.

| NUMBER OF CYCLES (x 10^6) [mg] | 0.5 | 1 | 2 | 3 | 4 | 5 |
|-------------------------------|-----|---|---|---|---|---|
| CP47.2018ED-01                | 2.19 | 4.70 | -4.35 | -10.57 | -13.72 | -19.05 |
| CP47.2018ED-02                | -0.32 | 2.99 | -3.19 | -11.80 | -13.54 | -21.44 |
| CP47.2018ED-03                | -0.50 | 1.51 | -6.46 | -11.40 | -16.75 | -26.70 |
| MEAN                          | 0.45 | 3.07 | -4.66 | -11.26 | -14.67 | -22.40 |
| STANDARD DEVIATION            | 1.51 | 1.60 | 1.66 | 0.63 | 1.80 | 3.91 |

The mass loss in the TS was significant after 2 million cycles (\( p = 0.0013 \) for the 32-mm metallic head assembly, and \( p = 0.046 \) for the 36-mm ceramic head assembly). A significant difference (\( p = 0.018 \)) was observed when comparing the average mass losses from metal versus ceramic head assemblies.

- **Tables 5 and 6** present the average mass of test fluid absorbed by CSs (\( S_n \)) with 32-mm metallic heads and 36-mm ceramic heads, respectively.
- **Table 7** and **8** present the average net mass loss (\( W_n \)) for TSs with 32-mm metallic and 36-mm ceramic heads, respectively. There was a statistically significant difference (\( p = 0.014 \)) in \( S_n \) measures between metallic and ceramic heads.

The average wear rate was calculated from the linear regression of the wear curve \( W_n = a_n (n) + b \), in which...
average wear rate in micrograms per million cycles \( (\text{mg/mc}) \), \( n \) = number of cycles, and \( b \) is a constant value.

The initial mass, measured before loading cycles and angular displacements, was not considered in this calculation.

Tables 9 and 10 present the average wear rate \( (a_g) \) and the determination coefficient \( (R^2) \) for TSs with metallic and ceramic femoral heads, respectively.

A statistically significant difference \((p = 0.0005)\) was detected when comparing wear rate measurements from assemblies with metallic (14.12) and ceramic heads (7.46).

### Discussion

The main finding of our study was the significant reduction in the wear rate of the ceramic-on-crosslinked polyethylene tribological pair in comparison with the metal-on-crosslinked polyethylene tribological pair, even with a large diameter ceramic head.

The investigation of factors involved in prosthetic wear is of great interest for hip arthroplasty because aseptic loosening is the main cause for revision in hip prosthesis records.\(^2,12\) The main wear mechanisms of high molecular weight polyethylene are polishing, abrasion, corrosion and scratching.\(^13,14\) To reduce debris production and ensure greater prosthetic survival, hip arthroplasties with crosslinked polyethylene have been widely performed all over the world.\(^7,13\) Currently, large diameter femoral heads, especially ceramic heads, have been used in hip arthroplasties, particularly in young and active patients, to achieve greater range of joint movement and prosthetic stability.\(^15\) Analyzing data from the National Arthroplasty Records, Tsikandylakis et al.\(^16\) identified that large, over 32 mm, femoral heads have a lower risk of dislocation. As such, the literature raised doubts about the wear behavior of crosslinked polyethylene in large diameter ceramic femoral heads. Our study demonstrated that, in vitro, the benefit of the reduced wear rate in ceramic-on-crosslinked polyethylene tribological pair was sustained, despite the use of a larger diameter ceramic head, even in comparison with a smaller metallic head (32 mm).
Another important finding was a significant increase in mass loss resulting from wear in each prosthetic assembly after 2 million test cycles, which was significantly greater in assemblies with metallic heads. This phenomenon may explain the greater prosthetic wear observed in more physically active individuals, especially with metallic heads. However, it is known that, in vivo, arthroplasty survival is contingent on the tribological pair, positioning of the prosthetic components, activity level, gender, age and immunological characteristics of the patient.17

The movement cycle of a patient with total hip arthroplasty represents a complex sequence of different activities interspersed with resting periods. In addition to walking, which is generally used as a reference activity, daily living activities contributing to wear and tear are not included in laboratory standard wear tests. Thus, several studies reveal the different size of debris generated in simulator tests and in vivo samples.18,19

The younger age of patients is related to the greater wear and tear of total hip arthroplasties. Studies evaluating wear in different age groups showed that it is higher in patients younger than 60 years old.20,21 In a radiographic study with 1,024 hips, linear wear was 33% higher in patients under 6022 Perez et al.,21 in a study evaluating a group of young patients (mean age, 49; range, 18–66 years-old), reported that their wear rates were 40% higher compared to the average wear rate from the other group. Griffith et al.23 reported that in patients with very high linear wear rates (> 0.18 mm/year), 12% were under 50 years old, and only 1.5% were over 60 years old. The greater wear and tear in younger patients result, at least in part, from the higher average activity level. In a pedometric study,24 age was significantly associated with activity (p = 0.048), but with a high variability degree (standard deviation, 3,040 steps per day). On average, patients younger than 60 years-old walked 30% more than patients aged 60 and over.

Compared to women, men were associated with higher rates of polyethylene wear. Dividing their patients into high and low wear rates, Griffith et al.23 and Nashed et al.20 showed that, in the high wear group, 70% of the patients were male, compared to only 23 to 34% in the low-wear group. Callaghan et al.25 found a statistically significant correlation between the male gender and polyethylene wear in a group of 210 hips. In a radiographic evaluation of 1,024 hips, the femoral head linear penetration was 37% higher in male patients.22 In a detailed study of 37 hips of patients with functional level, activity was quantified using a step monitor. This cohort showed no difference in average walking activity between male and female patients. However, the average femoral head polyethylene penetration rate in males was approximately twice the rate seen in females. There were significant differences in average height and weight between male and female patients, and a multivariate logistic regression analysis was performed. After correction for known covariates (such as height and weight), the correlation between male gender and wear continued to be high.22 Further studies regarding other differences related to hip prosthesis wear in men and women, including specific anatomical changes, weight distribution, gait pattern, body composition and physical chemical properties of synovial fluid, are required.

Wear is a function of use, as in a set of car tires.26 The fundamental wear equation includes variables as the inherent wear resistance of the tribological pair, lubrication and friction coefficient, load magnitude and direction, movement pattern and sliding distance. The most common clinical assessment of wear is the radiographic analysis of femoral head linear penetration into the polyethylene component. However, limitations of this methodology to quantify specific factors contributing to wear and tear must be valued. In vivo polyethylene wear is a multifactorial event, including several factors related to the patient. Since the clinical evaluation of some of these factors is limited, retrospective variables are used. For instance, the age and condition of the patient often replace his/her activity. The factors that are most variable and difficult to quantify are the frequency and intensity of prosthesis use during the lifetime of arthroplasty. A standardized evaluation of the frequency and intensity of the patient’s activity related to the use of the prosthesis would reinforce the clinical evaluation of THA patients.17

As such, in vitro studies are a parameter for clinical practice guidance in choosing the tribological pair for hip arthroplasty, which must consider all patient characteristics. In vivo wear still presents issues that have not been fully clarified.

Conclusion

The present study demonstrated a lower wear rate in -36-mm ceramic-on-crosslinked polyethylene tribological pairs compared to 32-mm metal-on-crosslinked polyethylene assemblies. This finding demonstrates the effectiveness of ceramics, even when large diameter heads are used. Its clinical effectiveness, however, must be proven by long-term follow-up studies (20 to 25 years).

Conflict of Interests

The authors have no conflict of interests to declare.

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