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RESEARCH ON FRICTION WEAR OF HIP JOINT ENDOPROSTHESES OF POLYETHYLENE-METAL MATERIAL COMBINATION ON HIP JOINT SIMULATOR

BADANIA TRIBOLOGICZNE ENDOPROTEZ STAWU BIODROWEGO O SKOJARZENIU POLIETYLEN–METAL NA SYMULATORZE STAWU BIODROWEGO

Key words: endoprosthesis, wear, polyethylene-on-metal articulation.

Abstract The article presents the results of friction wear tests of hip joint endoprostheses. The study comprised tests of endoprostheses, commercially available on the European market, used in total hip arthroplasty. The friction pair was formed by an actual cupacetabular cup made of ultra-high molecular weight polyethylene (PE-UHMW) along with a head having a diameter of 28 mm made of stainless steel FeCrNiMnMoNbN.
The friction and wear tests were performed using an SBT 01.2 hip joint simulator of the authors' own design, which was constructed taking into account the ISO 14242-1 standard. Bovine serum was used as the lubricant. The tests of each friction pair were made up to 5·106cycles of motion. During the tests, simulator operation was interrupted every 5·105 cycles to replace the lubricating liquid, and mass control was performed every 1·106 cycles.
Prior to testing, the polyethylene cup was soaked in the lubricant to minimize liquid absorption during the test. Proper preparation of the cup and testing by taking into account a control group weight measurement allowed an accurate determination of the mass loss of the polyethylene cup.

Słowa kluczowe: endoproteza, zużycie, skojarzenie materiałowe polietylen–metal.

Streszczenie Przedstawiono wyniki badań tarciowo-zużyciowych endoprotez stawu biodrowego. Materiał badany stanowiły endoprotezy komercyjne dostępne na rynku europejskim, stosowane w alloplastyce całkowitej stawu biodrowego. Parę trącą tworzyła panewka wykonana z polietylenu o ultrawysokiej masie cząsteczkowej PE-UHMW wraz z głową o średnicy 28 mm wykonaną ze stali o symbolu producenta SS (FeCrNiMnMoNbN). Badania tarciowo-zużyciowe przeprowadzono przy użyciu symulatora ruchu stawu biodrowego SBT 01.2 własnej konstrukcji, który skonstruowany został w oparciu o normę ISO 14242-1. Jako medium smarujące zastosowano surowicę bydlęcą, która przygotowywana była do testów zgodnie z wytycznymi opisanymi w normie ISO 14242-1. Dla każdej pary trącej zadana liczba cykli ruchu wynosiła 5·106. W trakcie trwania testów, co 5·105 cykli praca symulatora była przerywana celem wymiany cieczy smarującej, a co 1·106 przeprowadzano kontrolę masy próbek.
Przed przystąpieniem do testów tarciowo-zużyciowych polietylenowa panewka namaczana była w cieczy smarującej celem zminimalizowania absorpcji cieczy w trakcie trwania testu. Odpowiednie przygotowanie panewek oraz przeprowadzenie testu z uwzględnieniem grupy kontrolnej pozwoliło na określenie zużycia masowego panewek polietylenowych.

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INTRODUCTION

Degenerative changes occurring in the hip in the majority of cases are of an idiopathic nature but are also due to joint deformities following inflammation, injury, or as a result of developmental dysplasia of the joint [**L. 1**]. In the treatment of degenerative changes and in the treatment of injuries, arthroplasty (endoprosthetic surgery) is the surgical replacement of a natural hip joint with an artificial joint – an endoprosthesis [**L. 2**]. Hip joint arthroplasty is a commonly performed procedure that allows the patient to return to full functionality by restoring normal joint mobility and freeing the patient from chronic pain. Early treatment results in much better outcomes than those performed at advanced stages of the disease and provide an opportunity for significant improvements in patient performance. The conditions for an optimum outcome of the treatment is correct implant selection and a proper surgical technique [**L. 3**].

Since 2005, a steady increase has been seen in the annual number of joint arthroplasty services rendered by healthcare providers under contracts concluded with the Polish National Health Fund. In 2015, about 119% more joint arthroplasty services were performed than in 2005. According to the data of the Polish Social Insurance Institution, in 2015, 42 485 primary hip joint arthroplasty and 4 200 revision arthroplasty (including 661 revision surgeries without replacement) were performed. The age range of the patients was 6 to 106 years, and the average age of operated women was 71, men 65 years old. Among the patients who underwent hip joint arthroplasty, the highest proportion in the total number of people was aged 60–69. The next largest in terms of age was the age range of 70 to 79 years. Over 58% of all hip joint arthroplasty was performed in the people of these age groups. Among the endoprostheses implanted in 2015, cement-free endoprostheses accounted for almost 75%. In people over 80 years of age, cemented endoprostheses were used much more often, while in younger patients, it was mainly cement-free endoprostheses [**L. 4**].

One of the major challenges of biomedical engineering today is to prolong the endurance of hip joint endoprosthesis, which is currently 10–15 years. Currently, the most commonly used biomaterials for the friction elements of hip endoprostheses are cobalt alloys (CoCrMo), ceramics (Al_2O_3, ZrO_2), and ultra-high molecular weight polyethylene (PE-UHMW). An important feature of biomaterials used for friction pairs is their resistance to tribological wear. Also important is the amount and type of wear products arising from the use of the implant, which, in the form of microparticles of polyethylene, metal, or ceramics accumulate in the periprosthetic space of the implant or in the form of nanoparticles, can migrate into the body causing toxic, allergic reactions and often cause the formation of cancerous cells [**L. 5**].

MATERIALS AND TEST METHODS

The subject of the simulator study was three sets of metal-polyethylene total modular hip joint endoprostheses. The endoprostheses consisted of the following components: a 28 mm stainless steel FeCrNiMnMoNb head, a PE-UHMW cup (ISO 5834-1 and 2 [**L. 6, 7**]), and an acetabular cup made from Ti6Al7Nb alloy (ISO 5832-11 [**L. 8**]) with an outer diameter of 42 mm coated with TiCP (ISO 5832-2 [**L. 9**]). All the components were supplied by the leading endoprosthesis manufacturer in Europe – the Swiss company Mathys Ltd Bettlach.

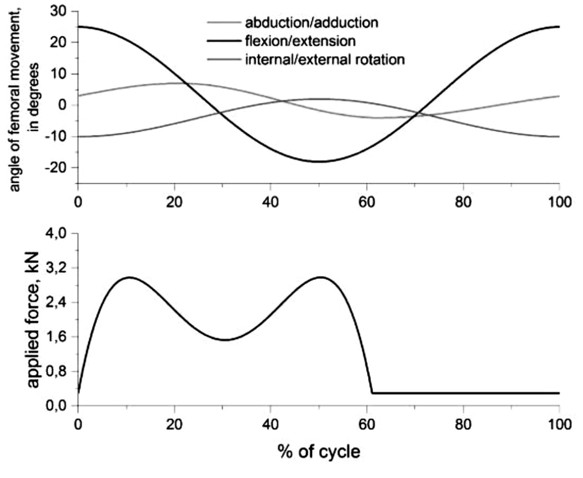

Fig. 1. Graphs of variability over time: a) angular movements of femoral component, b) loading force values

Rys. 1. Wykresy zmienności w czasie: a) ruchów kątowych komponentu udowego, b) wartości siły obciążającej

The cups for the friction wear tests were made of ultra-high molecular weight polyethylene (PE-UHMW) and were pre-soaked in the lubricating medium. This was to minimize the effect of fluid sorption during the test and the effect of this phenomenon on determining the actual material wear. The cup, in accordance with ISO 14242, was soaked in filtered bovine serum, monitoring its mass for 48 ±2 h until its incremental weight change was less than 10% of the previous weight change. In the conducted studies, the lubricant was a solution of bovine serum prepared according to the guidelines described in ISO 14242-1 [**L. 10**]. The bovine serum designated for testing was diluted with deionized water to a protein mass concentration of 30 g/l ±2 g/l. In order to mask the calcium ions and minimize calcium phosphate precipitation on the carrier surfaces, which could significantly affect the coefficient of friction, ethylenediaminetetraacetic acid (EDTA) of a 20mM concentration (7.45 g/l) was added to the carrier surfaces and 0.3% concentration sodium azide was added as an antibacterial reagent. Prior to testing, the serum solution was filtered through a sterile filter with a pore diameter of 2 μm to remove impurities that could affect the abrasive properties of the tested samples. During testing, the volume, concentration, and temperature of the medium were controlled to maintain constant lubrication conditions prevailing in the friction zone. The tests were performed at 37 ±2°C. A B5-B4 laboratory thermostat (Sondermaschinenbau GmbH, Germany) was used to heat the lubricant medium, from which the liquid was fed to the endoprosthesis fixation socket BT100-2J (Longer Pump Ltd, China) equipped with a YZ1515X head (Longer Pump Ltd, China).

Friction-wear tests were performed using an SBT 01.2 simulator, designed to test the tribological properties of hip joint endoprostheses, meeting the requirements of ISO 14242-1 [**L. 10**]. The design of the simulator loading and kinematic units is based on the anatomical structure of the hip joint, taking into account the variable load characteristics of the human gait described in ISO 14242-1. Key performance parameters of the simulator during the test are the cycle number for one test was 5 million, angle range in accordance with ISO 14242-1, and variable load in accordance with ISO 14242-1. The maximum instantaneous nominal load amounted to 3 kN, and motion frequency was equal to 1 Hz. After operating for a successive$5 \cdot 10^5$ cycles, the test was stopped to replace the lubricating medium. Sample weight monitoring was performed after 0.5, 1, 2, 3, 4, and $5 \cdot 10^6$ cycles. Each time before mass inspection, the polyethylene cups were washed and dried according to the procedure described in ISO 14242-2 [**L. 12**]. After washing the sample, the cup was dried under nitrogen and then soaked in alcohol (isopropanol) for 5 min. ±15 s. The cup was dried again under nitrogen and then in a vacuum at a pressure of at least 13.33 Pa for at least 30 min. The first weighing of the cup can be conducted 90 minutes after removing it from the vacuum. The cup was then re-placed in the vacuum for 30 minutes and then re-weighed after another 90 minutes. If successive indications differed by at least 100 μg, the vacuum drying procedure was repeated. Mass measurements were made using an EX 2225DM laboratory scale (Ohaus Corp, USA) with a resolution of 0.00001 g, taking into account the weight gain due to absorption of the lubricating medium by polyethylene. For this purpose, a control group consisting of a pre-soaked polyethylene cup, such as the tribological test cups, was then subjected to pressures in accordance with ISO 14242-2 [**L. 12**] for a period corresponding to the operation of $5 \cdot 10^6$ cycles at the frequency of 1 Hz. The cup (control group) was subjected to the same procedures for lubricant exchange and mass control as the tribological cups. Taking into account the weight gain of the control group caused by the absorption of the lubricant by polyethylene allows accurate the determination of the exact wear value of the cups subjected to tribological tests.

Based on the recorded values of friction torque (the reading was taken every 1800 cycles), the frictional characteristics of the friction pairs (friction coefficients as a function of the number of cycles) were determined, and their mass loss was determined. The friction coefficient values were calculated as the mean of one operation cycle (0–60% of the cycle).

Analysis of the wear mechanism of the materials under investigation was based on SEM observation of the surface morphology using a scanning electron microscope Inspect S (FEI). Ra measurements were made using a Hommel Etamic T8000RC (Jenoptik AG) profilometer.

TEST RESULTS

Figure 2 shows the course of changes in the coefficient of friction defined for the flection/extension movement. By analysing the presented graphs, it can be stated that the course of changes in the friction coefficient as a function of the number of conducted cycles was repeatable for both tests and exhibited stable values throughout the test at 0.020 (±0.002). The values obtained correspond to the coefficient of friction values given in the open literature [**L. 15**], where the authors have obtained an average value of the coefficient in the range of 0.02 to 0.07.

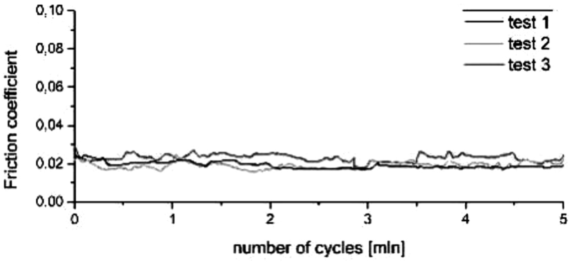

Fig. 2. Friction coefficient curve for SBT simulator tests 01.2

Rys. 2. Wykres przebiegu współczynnika tarcia dla testów przeprowadzonych na symulatorze SBT 01.2

Based on the tribological studies, the mass loss of the polyethylene cup was calculated as a function of the number of cycles carried out (**Fig. 3**).

The mass loss increases with an increasing number of cycles. The linear increase of wear of the polymeric cup during the test is typical for non-crosslinked PE-UHMW [**L. 16**]. This means that the wear process is a stable mechanism during the entire operation time, and it seems to be the result of the development of plastic strains. The phenomenon of a reduction in roughness on the polyethylene cup surface is explained by the increase in the proportion of permanent strains. On the protrusions of the micro-inequalities of the friction elements, particularly favourable flow conditions are created, which facilitates quick smoothing of the friction surface of the polyethylene material and thus reduces the roughness. Surface smoothing reduces the actual unit pressure. Fast stabilization of the friction coefficient and

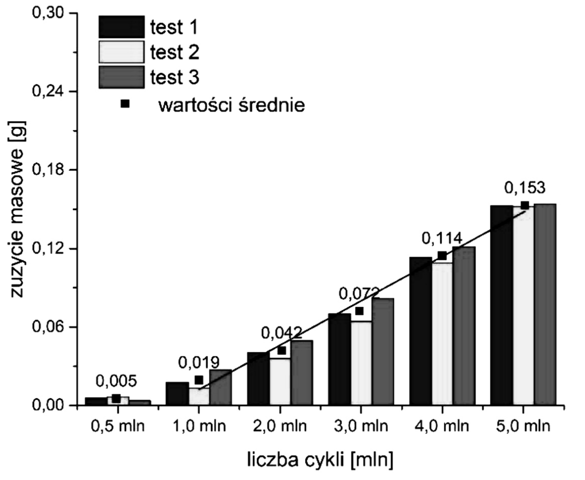

Fig. 3. Mass loss of polyethylene cup taking into account control group
Rys. 3. Zużycie masowe panewki poletylenowej z uwzględnieniem grupy kontrolnej

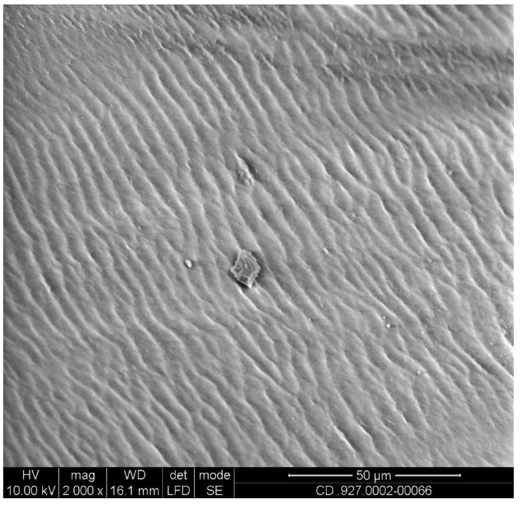

Fig. 4. The surface of PE-UHMW cup after the test
Rys. 4. Powierzchnia panewki polietylenowej PE-UHMW po teście

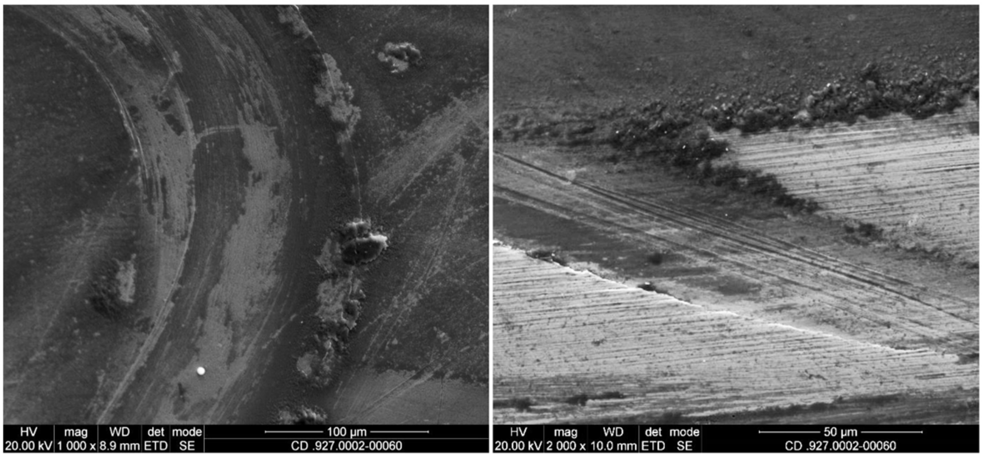

Fig. 5. Morphology of head friction surface
Rys. 5. Morfologia powierzchni wytarcia głowy

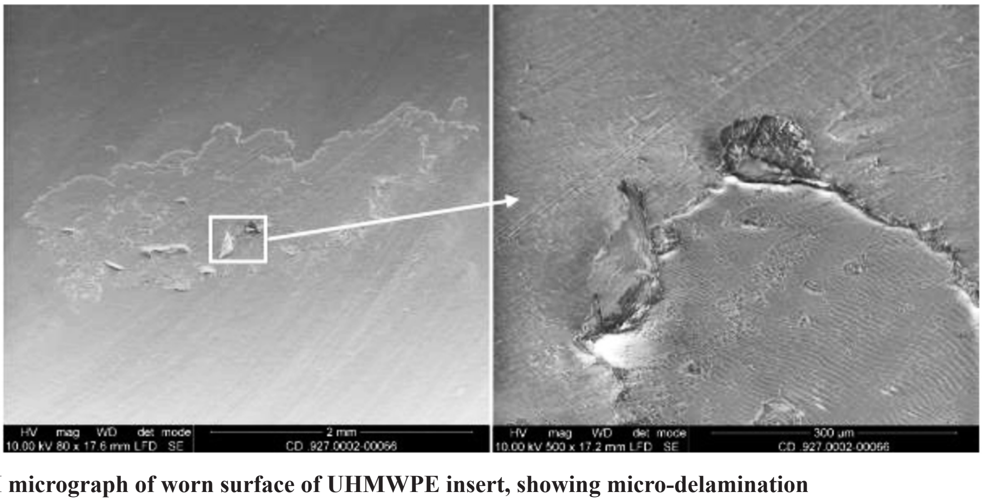

Fig. 6. SEM micrograph of worn surface of UHMWPE insert, showing micro-delamination
Rys. 6. Mikrografia SEM zużytej powierzchni wykazująca mikrorozwarstwienie

surface roughness as well as harmonious operation of the friction node occurs. During the operation of such a friction pair, uneven micro-slips occur at the contact points of the friction surfaces, and this, in turn, has an effect on the appearance of waving of the friction surface. This phenomenon is visible in **Fig. 7**. The intensity of the occurrence surface waving is decisive in the surface deformation process and increases, among others, along with the increase in roughness of the surface of the metal head.

Based on morphology observations of the friction surfaces, it was found that the main wear mechanism was abrasive-adhesive wear, characterized by material mass loss caused by scratching and grooving. On the metal surface of the head (**Figure 5**), oxides are visible which, as a result of friction, separate from the surface of the metal and move on the contact surface, resulting in scratches of a characteristic shape corresponding to the angular behaviour of the simulator (**Figure 1a**). For the PE-UHMW cup (**Figure 6**), due to the high resistance to contact with the hard surface (head), delamination of the top layer of the polymer was observed and micro-delamination occurred.

Table 1. Mean Ra roughness values of tested endoprosthetic components (mean value of 5 measurements)

Tabela 1. Średnie wartości chropowatości Ra testowanych elementów endoprotez (wartość średnia z 5 pomiarów)

Component	Mean value from 5 measurements			
	Rt	Ra	RzISO	Rmax
	µm			
New SS head	0.22	0.08	0.17	0.22
SS head test 1	2.48	0.23	1.69	2.37
SS head test 2	1.05	0.14	0.67	0.98
SS head test 3	1.07	0.17	0.72	1.24
New PE-UHMW cup	2.23	0.34	1.73	2.12
PE-UHMW cup test 1	2.46	0.27	1.33	2.46
PE-UHMW cup test 2	0.66	0.10	0.47	0.62
PE-UHMW cup test 3	0.94	0.21	0.57	0.84

The surface of the endoprosthesis head was evaluated by analysing the Ra roughness parameter (**Tab. 1**). The mean value of Ra for the new head was 0.08 µm, while for the insert it was 0.34 µm. After the test, the head roughness increased significantly (0.14–0.23 µm), the increase of roughness is a result of abrasive (scratches) and adhesive wear. Moreover, the polyethylene was transferred from the PE-UHMW cup to the head. The polyethylene insert roughness decreased to between 0.10–0.27 µm, and a lover value of friction coefficient was caused by the effect of smoothing of the surface.

CONCLUSIONS

The simulation research on hip joint endoprostheses performed on the simulator of the authors' own design (patent protection [**L. 17**]) carried out in the Metal Forming Institute allowed the following conclusions to be drawn:

1. The coefficients of friction during the entire test were stable, and, for both tests, they remained at the level of 0.020 (±0.002).
2. The mass loss of the cup increased linearly throughout the entire test, which is typical behaviour for the PE-UHMW wear processes.
3. Based on the conducted research and SEM observations, it was found that the main mechanism of metal head wear was abrasive-adhesive wear; whereas, on the polyethylene surface, the formation of delamination of the surface layer was observed.

In the next phase of the work, simulation studies on hip joint endoprostheses made from new materials are planned. The presented results will be used to carry out comparative analysis of new materials with reference materials.

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REFERENCES

1. http://www.nazdrowie.pl/artykul/alloplastyka-ratunek-dla-stawu.
2. http://anatomiazycia.pl/.
3. Gierzyńska-Dolna M., Wiśniewska-Weinert H., Adamus J.: Tribologoczne i materiałowe uwarunkowania stosowania endoprotez stawów, Tribologia vol. nr 1 (2009), s. 47–62.
4. http://psz.zus.pl/.
5. Skalski K.: Endoproteza krążka międzykręgowego kręgosłupa – konstrukcja, technologia wytworzenia i przygotowania do zastosowań klinicznych: Monografia, Instytut Obróbki Plastycznej, Poznań 2013.

6. (ISO 5834-1:2005) Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 1: Powder form.
7. (ISO 5834-2:2011) Implants for surgery – Ultra-high-molecular-weight polyethylene – Part 2: Moulded forms.
8. (ISO 5832-11) Implants for surgery – Metallic materials – Part 11: Wrought titanium 6-aluminium 7-niobium alloy.
9. (ISO 5832-2:1999) Implants for surgery – Metallic materials – Part 2: Unalloyed titanium.
10. (ISO 14242-1:2012) Implants for surgery – Wear of total hip-joint endoprostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test.
11. Wiśniewski T., et al.: Stand for tribological testing of hip endoprostheses., Tribologia vol. 6 (2016), s. 167–177.
12. (ISO 14242-2:2012) Implants for surgery – Wear of total hip-joint endoprostheses – Part 2: Methods of measurement.
13. Banchet V., et al.: Wear and friction characterization of materials for hip prosthesis, Wear vol. 263 (2007), s. 1066–1071.
14. Yan Y., Dowson D., Neville A.: In-situ electrochemical study of interaction of tribology and corrosion in artificial hip prosthesis simulators, Journal of the Mechanical Behavior of Biomedical Materials vol. 18 (2013), s. 191–199.
15. Saikko V.: A simulator study of friction in total replacement hip joints, Proc. Inst. Mech. Engrs. vol. 206 (1992), s. 201–211.
16. Okazaki Y.: Effect of head size on wear properties of metal-on-metal bearings of hip prostheses, and comparison with wear properties of metal-on-polyethylene bearings using hip simulator, Journal of the Mechanical Behavior of Biomedical Materials vol. 31 (2014), s. 152–163.
17. Zgłoszenie patentowe „Tester tribologiczny”: z dn. 16.09.2016.