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STAND FOR TRIBOLOGICAL STUDIES OF HIP JOINT ENDOPROSTHESIS WITH THE POSSIBILITY OF CHANGING ACETABULUM ANTEVERSION ANGLE AND HEAD ANTI TORSION ANGLE

STANOWISKO DO BADAŃ TRIBOLOGICZNYCH ENDOPROTEZ STAWU BIODROWEGO Z MOŻLIWOŚCIĄ ZMIANY KĄTA ANTEWERSJI PANEWKI I KĄTA ANTEWERSJI GŁOWY

Key words: hip joint movement simulator, endoprosthesis, wear, metal-metal contact.

Abstract: The article presents the construction of a hip joint movement simulator intended for friction and wear studies of hip joint endoprostheses. The endoprosthesis head is mounted on a special base in the lower position with a neck-shaft angle of 135° , while the acetabular cup of the endoprosthesis is mounted in the upper part in the mounting head with an inclination angle of 45° . The production of three heads (responsible for the anteversion angle of the acetabulum) and three special bases (responsible for the antitorsion angle of the head) with different fixing angles of the components of the hip joint endoprosthesis, made it possible to carry out tribological tests with nine variants of alignment settings. The hip joint endoprosthesis tester is designed to simulate the following movements: flexion and extension as well as loads occurring in the human hip joint while walking. The subject of friction and wear studies were hip joint endoprostheses with a head diameter of 44 mm, made of high-carbon Co28Cr6Mo alloy. For each of the nine variants of endoprosthesis component alignment settings, average values of the coefficient of friction were calculated based on the recorded values of the friction. torque.

Słowa kluczowe: symulator ruchu stawu biodrowego, endoproteza, zużycie, skojarzenie materiałowe metal-metal.

Streszczenie: W artykule przedstawiono konstrukcję symulatora ruchu stawu biodrowego, przeznaczonego do badań tarciowo-zużyciowych endoprotez stawu biodrowego. Głowa endoprotezy mocowana jest na cokole w dolnym położeniu z kątem szyjkowo-trzonowym 135° , natomiast panewka endoprotezy zamontowana jest w górnej części w głowicy mocującej z zachowaniem kąta inklinacji 45° . Wykonanie trzech głowic (odpowiedzialnych za kąt antwersji panewki) oraz trzech cokołów (odpowiedzialnych za kąt antwersji głowy) różniących się kątami osadzenia komponentów endoprotezy stawu biodrowego umożliwiło przeprowadzenie testów tribologicznych z dziewięcioma wariantami ustawień. Tester endoprotezy stawu biodrowego przeznaczony jest do symulacji ruchów: zgięcia i wyprostowania oraz obciążeń występujących w stawie biodrowym człowieka podczas chodu. Przedmiotem badań tarciowo-zużyciowych były endoprotezy stawu biodrowego o średnicy głowy 44 mm, wykonane z wysokowęglowego stopu Co28Cr6Mo. Dla każdego z dziewięciu wariantów ustawień komponentów endoprotezy obliczone zostały średnie wartości współczynnika tarcia w oparciu o rejestrowane wartości momentu tarcia.

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INTRODUCTION

In the treatment of degenerative changes and injuries, arthroplasty is used. It is estimated that worldwide, 10% of men and 18% of women over the age of 60 have symptomatic osteoarthritis [L. 1]. In 2017, the average number of hip surgeries performed, according to the Organisation for Economic Cooperation and Development (OECD), was 182 per 100,000 inhabitants (Fig. 1). The countries with the highest rates of hip arthroplasty are Germany (309), Switzerland (307), and Austria

(286). In Poland, 160 hip operations per 100,000 inhabitants were performed [L. 1]. Since 2007, the number of hip replacements has increased rapidly in most OECD countries, with average hip replacement rates increasing by 30% between 2007 and 2017. This is in line with the increasing incidence of osteoarthritis caused by an ageing population and rising obesity rates in OECD countries.

In Poland, the Central Base of Arthroplasty (CBA) of the National Health Fund has been functioning since March 2005. Since this year,

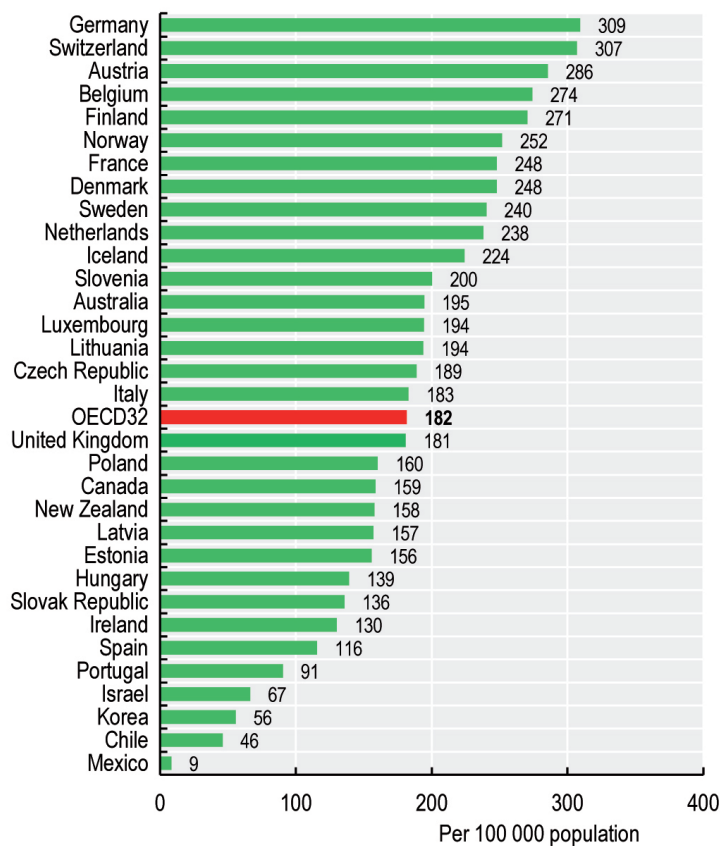


Fig. 1. Hip joint arthroplasty performed in 2017 according to OECD [L. 1]

Rys. 1. Przeprowadzone endoprotezoplastyki stawu biodrowego w 2017 roku wg OECD [L. 1]

a steady increase in the annual value of articular arthroplasty services carried out by service providers under contracts concluded with the National Health Fund has been observed. In 2019, over twofold more (about 227%) arthroplasty services were performed compared to 2005. According to the Social Insurance Institution data, 59,306 hip arthroplasty were performed in 2019 [L. 2].

Along with the increase in the number of arthroplasty procedures, the problem of the durability of implanted endoprostheses, which range from 10–15 years, has gained greater importance. The choice of materials for the head and an acetabular cup of the endoprosthesis has a fundamental influence on the lifetime of the implants. The choice of the friction pair affects

the wear rate of the friction surfaces, and thus the amount and the nature of the resulting wear products that cause inflammation in the periprosthetic tissues and may cause osteolysis. [L. 6].

The first endoprostheses (McKee, 1952) were made of stainless steel, the next ones were made of steel with an admixture of chromium and cobalt, and after 1962, they were made of vitallium [L. 3, 4, 5]. In October 1962, John Charnley implanted a modern endoprosthesis; the novelty was the introduction of an acetabular cup, initially made of Teflon and then of polyethylene. It was the first "low-friction" hip replacement [L. 3, 4, 5]. Ceramics were used to produce ceramic heads and inserts in the second half of the 1970s in hip joint endoprostheses [L. 5]. Currently, the most commonly applied biomaterials for the friction elements of hip endoprostheses are cobalt-based alloys (CoCrMo), ceramics (Al_2O_3 , ZrO_2) and ultra-high molecular weight polyethylene (UHMWPE).

Another important factor influencing the durability of the endoprosthesis is its alignment setting. As early as 1978, Lewinnek GE et al. described in detail the so-called "safe zone" recommended for the acetabulum setting [L. 7]. The authors proposed an inclination angle ranging from 30° to 50° and an anteversion angle of 5° to 25° . As a consequence of improper alignment settings of the acetabulum cup, there may be a collision between the edge of the acetabulum and the neck of the pin, edge load, a reduced range of motion, as well as differences in limb length, excessive wear and, in the case of polyethylene acetabular cups, leading to osteolysis and aseptic loosening [L. 8]. Excessive deviation of the acetabulum can lead to accelerated wear of the endoprosthesis components or dislocation, which is the most common cause of revision procedures [L. 9, 10].

In clinical trials, due to the specifics of the research, endoprosthesis wear can be studied only after endoprosthesis replacement surgery, hence the need for stand studies. Stand friction and wear studies of metal-metal endoprostheses carried out in various laboratory centres cover a wide spectrum of tests. The research is focused on determining the wear loss of the endoprosthesis components, taking into account the quality of the friction surface finish, the use of radial clearance or the use of a CoCrMo alloy with a different carbon content [L. 11]. Friction and wear studies were carried out to determine the effect of the head diameter on the wear of metal-metal implants [L. 12]. Another

direction is the comparative research of metal-to-metal endoprostheses with such material contacts as ceramics-ceramics or ceramics-polyethylene [L. 13]. Friction and wear studies were conducted by applying different maximum loads for individual friction pairs [L. 14]. In most laboratory studies, the wear of endoprostheses is presented as volumetric wear [L. 11–13]. The authors of article [L. 15], published in 2016 and the author of article [L. 16], published in 2018, present research employing hip simulators in which they show the research results in relation to the coefficient of friction. In a work from 2019 [L. 17], author V. Saikko conducted friction-wear studies on MoM implants with torque registration. It can be seen that there are few publications presenting data on measurements of the coefficient of friction.

In stand studies conducted by other authors, studies were conducted for various settings of the acetabular cup inclination angle of hip joint endoprosthesis [L. 14, 18, 19, 20]. The authors of article [L. 13] carried out research with anatomical alignment settings of the endoprosthesis components on the simulator, maintaining the same head and acetabulum angles. Article [L. 21] presents the results of research on endoprosthesis components for various settings of the acetabular cup inclination angle and anteversion. The abovementioned test stands do not allow friction and wear studies to be performed depending on mutual alignment settings of the head anti torsion angle and the acetabular cup anteversion angle.

This study aims to present a stand of the authors' own design for tribological studies of hip joint endoprostheses with the possibility of changing the acetabulum anteversion angle and the head anti torsion angle.

The scope of work includes:

- examination of the alignment of endoprosthesis components in clinical cases,
- description of the stand for tribological studies of hip joint endoprostheses,
- an example of the research results carried out on the stand.

METHODS

Investigation of alignment of prosthetic components in clinical cases

The aim of studying the alignment of endoprosthesis components in clinical cases was to assess the

Table 1. Extreme values of angular alignment of the acetabular cup and femoral components of hip joint endoprostheses for 36 examined cases

Tabela 1. Skrajne wartości ustawień kątowych komponentów panewkowych i udowych endoprotezy stawu biodrowego dla 36 przebadanych przypadków

Test No.	For 36 examined cases	Acetabular cup component		Femoral component	
		Inclination angle [°]	Anteversion angle [°]	Anti torsion angle [°]	Cervical-molar angle [°]
1	Min.	26.1	-14.6	-12.1	126
2	Max.	59.4	29.7	25.3	141.8
3	Average	44.52	6.35	5.42	134.5

actual angles: inclination, anteversion, anti-torsion and cervical shaft based on the analysis of tomographic projections. A group of 36 patients after unilateral arthroplasty was examined in Poznan's Department of General Orthopaedics, Oncology and Traumatology. The patients had very good clinical results, and the follow-up period ranged from 13 to 36 months. The obtained results of alignment measurements of the components of hip joint endoprostheses in clinical cases are presented in **Table 1**.

Formulation of requirements

Based on the results of clinical trials, it was assumed that friction and wear studies would be carried out for nine variants of the "head-acetabular cup" system alignment settings (**Table 2**), taking into account the alignment settings adopted as recommended for implantation (anti torsion angle $\alpha = 10^\circ$, anteversion angle $\beta = 20^\circ$). The 135° neck-shaft head angle and the 45° acetabular cup inclination angle were taken as constant. **Figure 2** presents the configuration of the head-acetabulum system in a graphic form.

Table 2. The angular values of the mutual alignment setting of components of the "head-cup" system

Tabela 2. Wartości kątowe dla poszczególnych ustawień wzajemnych układu „głowa-panewka”

Test number	Angular values			
	Head		Cup	
	α [Anti torsion angle]	Δ [Cervical-molar angle]	β [Anteversion angle]	γ [Inclination angle]
1	-5°	135°	-10°	45°
2	-5°	135°	20°	45°
3	-5°	135°	30°	45°
4	10°	135°	-10°	45°
5	10°	135°	20°	45°
6	10°	135°	30°	45°
7	25°	135°	-10°	45°
8	25°	135°	20°	45°
9	25°	135°	30°	45°

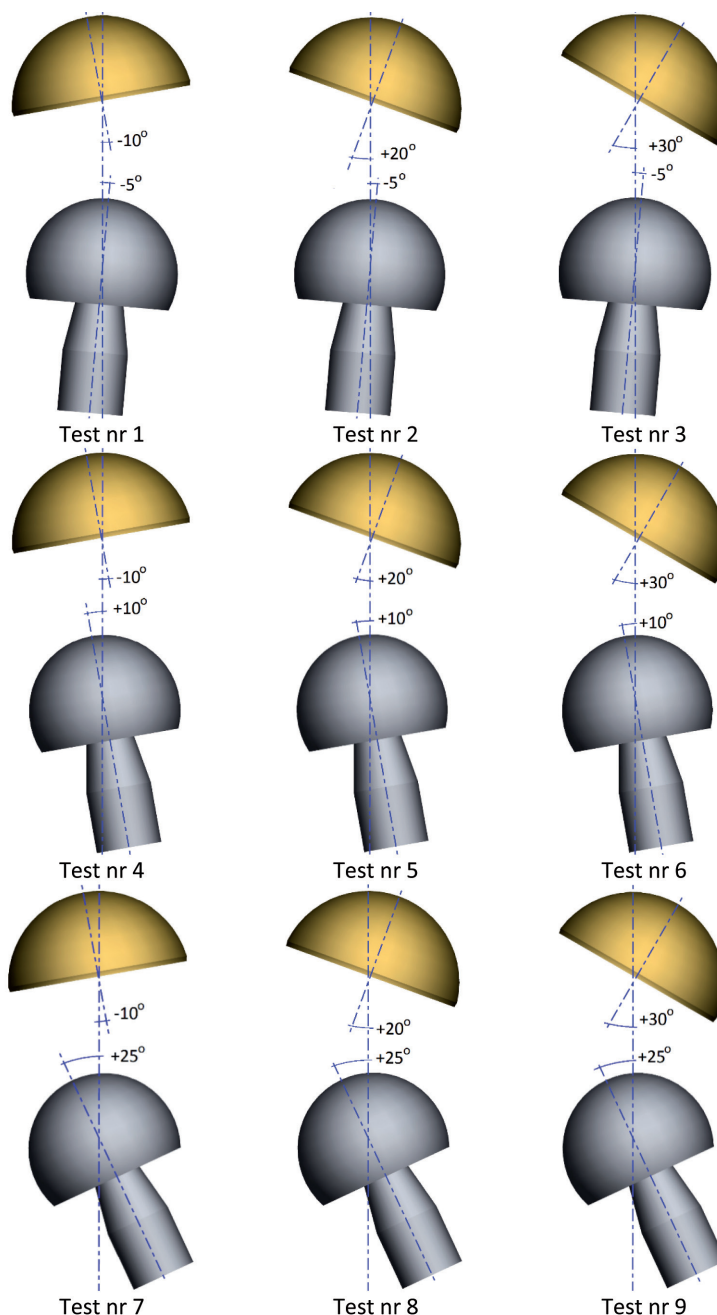


Fig. 2. Graphical representation of "head-acetabulum" system alignment settings
 Rys. 2. Graficzne przedstawienie ustawień układu „głowa–panewka”

SIMULATOR FOR TESTING HIP JOINT ENDOPROSTHESES

The simulator's design enables the fixing of hip endoprosthesis components in accordance with the anatomical structure of the human hip joint. The simulator has been designed so that the endoprosthesis head is in the lower position with a neck-shaft angle of 135° and the acetabular cup in the upper position with an inclination angle of

45°. The hip joint endoprosthesis tester is designed to simulate the following movements: flexion and extension, as well as loads occurring in the human hip joint while walking. It is equipped with two servo drives, providing a wide range of adjustments and settings of simulated movements and applied loads, with the possibility of synchronising the movement with the given loads (**Fig. 3**).

The upper motor (1), by means of the gear (2), the overload clutch (3), the torque meter (4) and the

bearing shaft (5), causes swinging movements of the rocker (6); these movements in the investigated endoprosthesis (7) simulate the movements: flexion and extension. The control ensures the setting of any angles in the range from -55° to $+55^\circ$. The endoprosthesis is placed in a container (8) filled with a lubricating liquid, mounted on a slide (9), supported by a dynamometer (10), a set of disc springs (11) and a cable (12) mounted on an eccentric mechanism (13). The lower motor (16), by means of the gear (15) and the overload clutch (14), drives the eccentric mechanism. This drive, by adjusting the angle of action of the eccentric mechanism, causes cyclic pressure of the endoprosthesis, synchronised with the pendulum movement of the rocker. The disc springs ensure a gradual build-up and diminution of force, as occurs when a joint is naturally loaded while walking.

Figure 4 shows a diagram of the acetabulum for fixing endoprosthesis components. The acetabular cup of the endoprosthesis (3) is placed in the head (2) of the rocker (1) in a manner ensuring its precise positioning in the acetabular cup. By changing the angle of the head seat (the

figure shows an example of 10°), it is possible to correct the spatial location of the acetabulum in accordance with the test requirements. The head of the prosthesis (4) is mounted on a special base (5) fixed in the container (6). The appropriate design of the special base ensures proper alignment of the head in relation to the acetabular cup in accordance with the test requirements. The sealed container enables testing in the lubricant and collection of the worn products for their subsequent analysis. Fixing the container on a trolley (7) bearing on a guide (8) fastened to the slider (9) allows the elimination of possible stiffening of the system.

Table 3. Testing parameters of the SBT-01.1 simulator

Tabela 3. Parametry pracy symulatora SBT-01.1

Parameter	Value
Number of research cycles	1 000 000
Frequency	1 Hz
Angular range of motion	$-10^\circ - 30^\circ$
Maximum load	1 300 N
Lubrication	distilled water

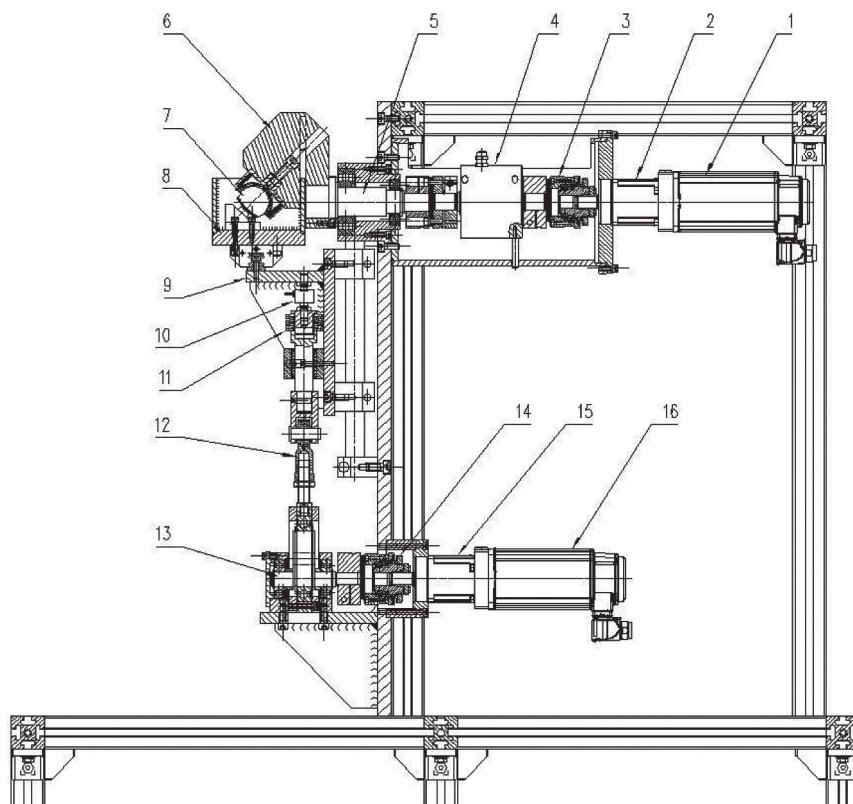


Fig. 3. Construction of SBT-01.1 simulator (side view)

Rys. 3. Konstrukcja symulatora SBT-01.1 (widok z boku)

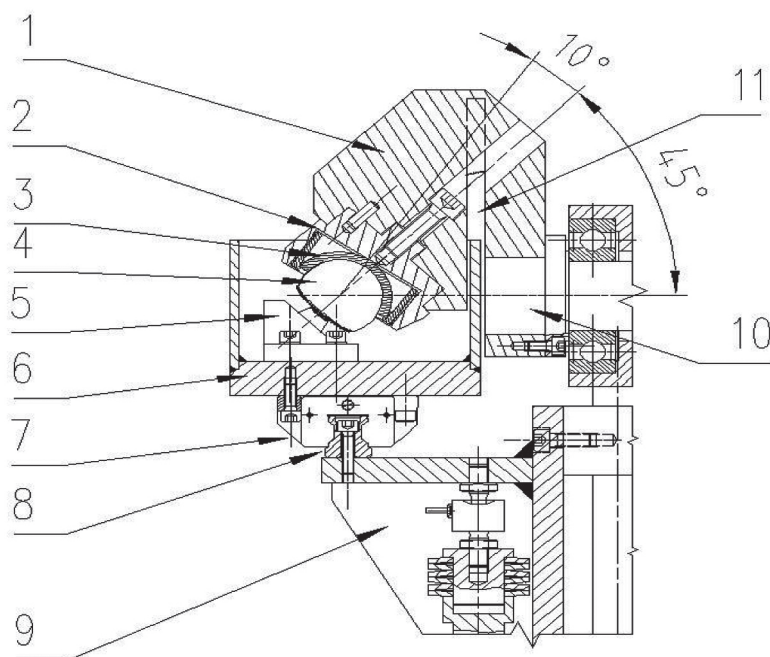


Fig. 4. Fixing of hip prosthesis on SBT.01 simulator

Rys. 4. Zamocowanie endoprotezy stawu biodrowego na symulatorze SBT.01

The production of three heads and three special bases with different fixing angles of the components of the hip joint endoprosthesis made it possible to carry out tribological studies with nine variants of alignment settings. Thanks to the use of control in the form of electronic cams, the simulator enables the reproduction of the variable value of the force loading the friction pair as a function of the human walking cycle (**Fig. 5**). The operating parameters of the simulator are presented in **Table 3**. The load parameter was selected in such a way that it varied in the range from 50 N to 1,300 N. [L. 22].

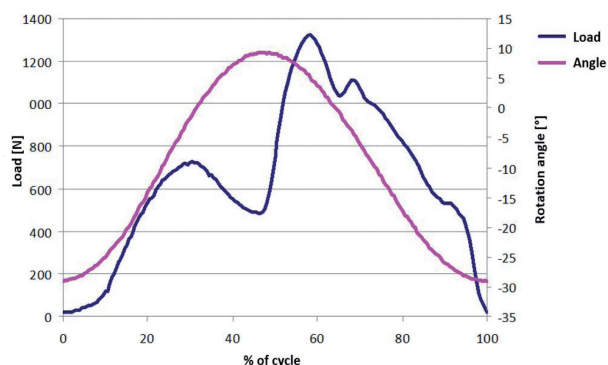


Fig. 5. Correlation of load value and angle of deflection of head fixing acetabulum as a function of the percentage of the work cycle

Rys. 5. Korelacja wartości obciążenia i kąta wychylenia głowy mocującej panewkę w funkcji procentu cyklu pracy

EXEMPLARY RESEARCH

Research object

The friction and wear studies subject comprised nine sets of metal-metal hip endoprostheses with a head diameter of $\varnothing 44$ mm (manufactured by Zimmer Inc., USA). The endoprostheses were made of high-carbon Co28Cr6Mo alloy after plastic processing (Metasul, ISO 5832-12) [L. 23].

The individual components of the investigated hip endoprostheses are shown in Figure 6, and they were, respectively, the following: the head: size $\varnothing 44$ mm, “Metasul alloy”, and acetabular cup: size $\varnothing 50/44$ mm, “Metasul alloy”.



Fig. 6. Components of the hip joint endoprosthesis by ZIMMER Inc., from the left: cup, head

Rys. 6. Komponenty endoprotezy stawu biodrowego firmy ZIMMER Inc. od lewej: panewka, głowa

A microhardness characterised the working surfaces of the head and cup in the range from 521 to 551 HV0.1 and roughness of Ra below $0.05 \mu\text{m}$, which is recommended as the maximum roughness of working surfaces for endoprostheses of the osteoarticular system [L. 24]. Microhardness measurements were carried out using the Vickers method (HV 0.1) using a MICROMET 2104 hardness tester (Wirtz-Buehler, Germany) in accordance with the PN-EN ISO 6507-01: 2007 standard. The roughness Ra measurements of the friction surfaces were made on a Hommel Etamic T8000RC profilometer (Jenoptik AG, Germany, the measuring section length was $L = 4.80 \text{ mm}$).

RESULTS

In the conducted studies, the measuring system employed in the simulator allows the calculation of the coefficient of friction based on the recorded values of the friction torque and the clamping force. Based on the intermediate results (recorded every 100,000 cycles), the mean values of this parameter for a given test were calculated. The list of average values of the coefficient of friction depending on the selection of the mutual angle alignment setting of the endoprosthesis components is presented in **Table 4** and **Figure 7**. The results of friction and wear studies employing the simulator confirm that the mutual angle alignment setting of the head and the acetabular cup has an impact on the value of frictional resistance occurring in the tribological pair.

Regardless of the angle of femoral component α , an increase in the mean value of the coefficient of friction was observed as a result of a decrease or increase in the value of angle β in relation to the initial setting ($\beta = 20^\circ$) (**Fig. 7**). Except for the alignment setting of the endoprosthesis components where angle $\alpha = -5^\circ$ and angle $\beta = -10^\circ$, such a setting was characterised by a similar mean value of the coefficient of friction to the initial setting ($\beta = 20^\circ$). Regardless of the value of angle β used, due to the frictional resistance, it is more advantageous to use angle $\alpha = -5^\circ$ compared to $\alpha = 10^\circ$ or $\alpha = 20^\circ$.

Table 4. Average values of coefficient of friction depending on mutual alignment setting of endoprosthesis components

Tabela 4. Średnie wartości współczynnika tarcia w zależności od wzajemnego ustawienia komponentów endoprotezy

Test number	Angle		Friction coefficient
	α [°]	β [°]	
1	-5	-10	0.144 ± 0.014
2	-5	20	0.139 ± 0.019
3	-5	30	0.191 ± 0.014
4	10	-10	0.231 ± 0.027
5	10	20	0.166 ± 0.012
6	10	30	0.217 ± 0.013
7	25	-10	0.169 ± 0.017
8	25	20	0.173 ± 0.015
9	25	30	0.198 ± 0.020

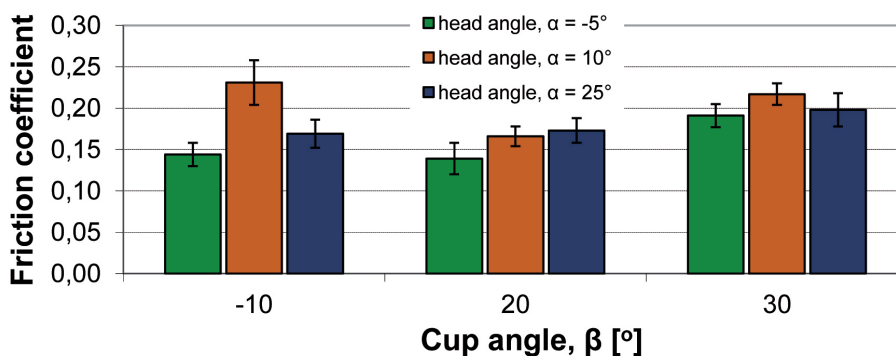


Fig. 7. Average values of coefficient of friction as a function of angle β depending on angle α used

Rys. 7. Średnie wartości współczynnika tarcia w funkcji kąta β w zależności od zastosowanego kąta α

CONCLUSIONS

The wear of hip joint endoprotheses depends on many factors, starting with the material used, which is CoCrMo alloy, which can be cast or forged. The implant design where the applied radial clearance, the quality of the friction surfaces, the type of lubricant used or the employed test parameters (range of motion, frequency, load characteristics and its maximum value) play an important role. It should be noted that most of the presented works concern research on the influence of the acetabular cup inclination angle on the wear of endoprotheses. In the presented studies, the acetabular inclination angle was assumed to be constant and amounted to 45°, while the angle of the acetabular anteversion and head anti torsion was changed. The inability to apply the same test standards makes comparing wear loss very difficult. Nevertheless, comparing the authors' own research results with the literature data gives some insight into the influence of the difficult operating conditions and extreme alignment- settings of the endoprosthesis components on the wear loss of hip joint endoprotheses. Studies carried out by means of the SBT-01.1 simulator confirm that the mutual angle alignment setting of the acetabular cup to the head affects the wear of the endoprosthesis. According to the authors of [L. 21], who conducted research for a variable inclination angle, the reasons for the different intensity of wear of the endoprosthesis components should be sought in the variability of the contact surface area depending on the mutual alignment settings of the head-acetabulum system.

The friction and wear studies were performed using the SBT-01.1 simulator, which, in addition to meeting the requirements for mapping the work of a natural hip joint in terms of loads and motion kinematics, enables the wear loss to be determined of individual components of endoprotheses.

An additional advantage of the simulator is the possibility of modelling the anti-torsion angle of the head as well as the anteversion angle and inclination of the acetabulum. This solution enables the performance of friction and wear studies taking into account the so-called implantation error and thus determination of the impact of this error on the wear of the endoprosthesis.

Based on the conducted experimental studies, the following conclusions can be drawn:

1. In analysing the results of calculations of the mean values of the coefficient of friction for each of the angular settings of the endoprosthesis components used, it was found that the implantation angle of the endoprosthesis components influenced the frictional resistance. The lowest friction coefficient values were observed for the acetabular cup anteversion angle of 20°, regardless of the head anti torsion angle setting.
2. The SBT-01.1 hip joint simulator meets the following conditions:
 - enables mapping of the load occurring in a natural hip joint,
 - enables the testing of a hip joint endoprosthesis in a natural position with the acetabulum at the top and the head at the bottom,
 - makes it possible to carry out tests at different angles of the endoprosthesis components, head and acetabular cup in relation to each other,
 - enables the collection of worn products and sampling the lubricating liquid for testing.

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