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TESTING THE COBALT ION EMISSION ON THE STAND FOR DIFFERENT ANGLES OF POSITIONING THE COMPONENTS OF THE METAL–METAL HIP JOINT ENDOPROSTHESIS

STANOWISKOWE BADANIA EMISJI JONÓW KOBALTU DLA RÓŻNYCH KĄTÓW OSADZENIA KOMPONENTÓW ENDOPROTEZY STAWU BIODROWEGO TYPU METAL–METAL

Key words: endoprostheses, wear, ion emission.

Abstract: The paper deals with the subject related to the assessment of the influence of the axis angle of the metal components of the hip joint on the emission of cobalt ions. The tribological tests were carried out with the use of a simulator for the examination of hip joint endoprostheses, the structure of which enables the fixation of endoprosthesis components in accordance with the anatomical structure of the human hip joint. During the tests, the simulator performs flexion and extension movements as well as loads occurring in the human hip joint while walking. Loss-wear tests were carried out for nine variants of the “head–cup” system settings. These settings were determined on the basis of CT images obtained from patients after arthroplasty. After the tribological tests were completed, samples of the lubricating fluid with the wear products suspended in it were collected in order to determine the concentration of cobalt ions, which was carried out using the atomic absorption spectrometry method. As a result, the influence of the head antetorsion angle (α) and the acetabular anteversion angle (β) on the concentration of cobalt ions was analysed.

Słowa kluczowe: endoprotezy, zużycie, emisja jonów.

Streszczenie: W pracy poruszono problematykę związaną z oceną wpływu kątów elementów endoprotezy stawu biodrowego na emisję jonów kobaltu. Badania tribologiczne przeprowadzono przy użyciu symulatora do badania endoprotez stawu biodrowego, którego konstrukcja umożliwia mocowanie elementów endoprotezy zgodnie z budową anatomiczną stawu biodrowego człowieka. Podczas testów symulator wykonuje ruchy zgięcia i wyprostu oraz obciążenia występujące w stawie biodrowym człowieka podczas chodzenia. Testy zużycia przeprowadzono dla dziewięciu wariantów ustawień układu „głowa–panewka”. Ustawienia te zostały określone na podstawie obrazów CT uzyskanych od pacjentów po endoprotezoplastyce. Po zakończeniu badań tribologicznych pobrano próbki cieczy smarującej z pozostałymi w niej produktami zużycia w celu oznaczenia stężenia jonów kobaltu, co przeprowadzono metodą atomowej spektrometrii absorpcyjnej. W rezultacie przeanalizowano wpływ kąta antetorsji głowy (α) i kąta antewersji panewki (β) na stężenie jonów kobaltu.

INTRODUCTION

Hip joint diseases, such as osteoarthritis, destructive changes due to rheumatic diseases, sterile femoral head necrosis, and injuries, cause the destruction of the articular surfaces. The advanced process of hip joint destruction reduces the patients' quality of life, limiting their ability to move **[L. 1]**. In most cases, the only effective method of treatment is the use of hip arthroplasty **[L. 2]**. These treatments restore mobility of the joint, eliminate pain and enable the patient to return to active professional and social life.

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In recent years, hip arthroplasty has been the most frequently performed orthopaedic procedure, and it consists in replacing damaged joint elements (articular cartilage and subcartilage bone) with an artificial endoprosthesis. Due to the anatomical structure of the joint, the surface of which has a shape similar to a sphere, the implants are in most cases characterized by a similar structure that imitates the operation of the spherical acetabular joint. The hip joint implant consists of a cup mounted in the pelvis, a pin placed in the medullary canal of the femur, and a head mounted on a pin working in the socket (**Fig. 1**).

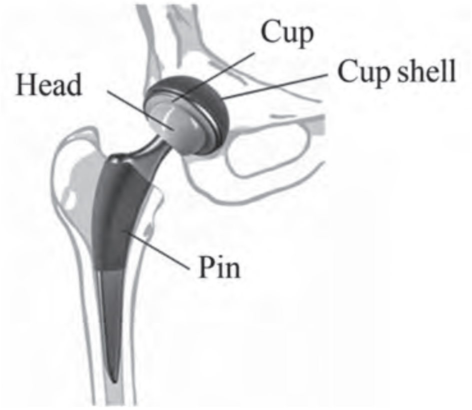

Fig. 1. Hip endoprosthesis [L. 3]
Rys. 1. Endoproteza stawu biodrowego **[L. 3]**

In the human natural hip joint while walking, there are loads related to body weight. In individual phases of movement, the value of the load on the hip joint changes, reaching four times the human body weight **[L. 4]**. The tribological system, which is the hip joint, experiences approximately one million impact loads each year. The coefficient of friction μ for the "metal-polyethylene" friction part ranges from 0.1 to 0.05 and is 2–3 times greater than the coefficient of friction occurring in a healthy joint. The friction coefficient for the metal–metal pair is much higher and amounts to approx. 0.8 **[L. 5]**.

Regardless of the choice of the implant material combination, the most important factor limiting the durability of endoprostheses is the susceptibility to tribological wear **[L. 6]**. There are many publications in which the authors pay attention to the influence of the axis of seating of endoprosthesis components on the frictional resistance and wear mechanisms and, as a result, on the endoprosthesis durability **[L. 7, 8, 9, 10, 11, 12]**. The alignment of the implant components affects its stability (dislocation probability), the range of motion, and the number of wear products produced.

The results of wear tests are often limited only to the determination of the value of linear wear and weight loss, however, it is worth paying attention to the phenomenon of metal ion release. CoCrMo alloys owe their biocompatibility to the ability to produce a thin oxide passivation coating on the surface with a thickness of up to 3 nm, which is a mixture of chromium and molybdenum oxides (with a distinct predominance of Cr_2O_3) **[L. 13]**. In the friction node, the phenomenon of cyclic stripping of the passivation coating from the friction surfaces occurs. The wear products remaining in the friction node are also subjected to cyclical mechanical impact of the friction surfaces. The presence of physiological fluids in the immediate vicinity of the prosthesis promotes the release of metal ions from the rubbing surfaces and from the surfaces of wear products. With the decreasing size of the wear products, the total surface area of the wear products increases, and this translates into the amount of released ions. Metallic wear products, as well as ions emitted from their surfaces, may have a negative effect on the patient's immune system **[L. 14]**.

The aim of the presented research was to determine the emission of cobalt ions for various positions of the prosthesis elements on the test stand. The scope of research includes:

- analysis of the results of computed tomography examinations of patients in order to determine the clinical range of angles of endoprosthesis insertion;
- bench tribological tests of endoprostheses elements for different angles of their seating;
- determination of the concentration of cobalt ions in the lubricating fluid after tribological tests.

Additionally, before the tribological tests, the microhardness and roughness of endoprosthesis elements were measured, and after the tests, photos of the endoprosthesis surfaces and wear products were taken.

METHODS

Research object

The subject of the friction and wear tests were nine sets of metal-metal hip endoprostheses with a head diameter of Ø44 mm (manufactured by Zimmer

Inc., USA). Endoprostheses were made of high-carbon Co28Cr6Mo alloy after plastic processing (Metasul, ISO 5832-12) **[L. 15]**.

The individual components of the tested hip prostheses are shown in **Figure 2**, and they were, respectively the following:

– The conical attachment ("adapter"): size ´M'/0, "Metasul alloy";
– The head: size Ø44 mm, "Metasul alloy"; and,
– cup: size Ø50/44 mm, "Metasul alloy," outer surface of the cup has been covered with a layer of porous titanium.

Fig. 2. Components of the hip joint endoprosthesis by ZIMMER Inc., from the left: cup, head, conical attachment

Rys. 2. Komponenty endoprotezy stawu biodrowego firmy ZIMMER Inc. od lewej: panewka, głowa, mocowanie stożkowe

The chemical composition of the "Metasul alloy" (Protasul-21WFzg. ISO 5832-12 **[L. 16]**) is presented in **Table 1**.

Table 1. The chemical composition of the Metasul® alloy

Tabela 1. Skład chemiczny stopu Metasul®

[x% wag.]	Co	Cr	Mo	Ni	Fe	Mn	C	Si	N
Minimum	rest	26.0	5.0	–	–	–	–	–	–
Maximum	rest	30.0	7.0	1.0	0.75	1.0	0.35	1.0	0.25

The working surfaces of the head and cup were characterized by a microhardness in the range from 521 to 551 HV0.1 and a roughness of Ra below 0.05 µm, which is recommended as the maximum roughness of working surfaces for endoprostheses of the osteoarticular system **[L. 17]**. 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 mm).

Test stand

The friction and wear tests were carried out with the use of a simulator to test the tribological properties of hip endoprostheses SBT-01.1 (**Fig. 3**). The design of the simulator reflects the anatomical structure of the human hip joint during one cycle, i.e. a variable load is applied that is characteristic of loads occurring during walking **[L. 18]**.

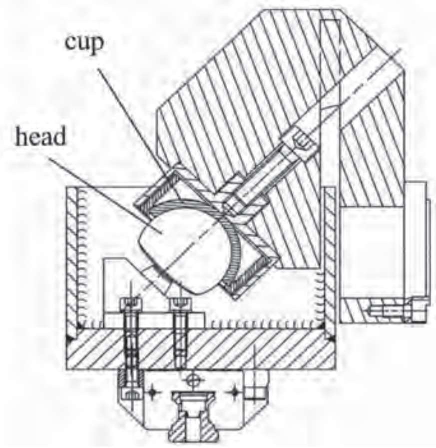

Fig. 3. The SBT-01.1 simulator (mounting socket of "head–cup" system)

Rys. 3. Symulator SBT-01.1 (gniazdo montażowe systemu „głowa–panewka")

The endoprosthesis cup is mounted in the socket of the head, while the head of is mounted on a pedestal placed at the bottom of the vessel filled with a lubricating fluid. Three heads and three pedestals, differing in the geometry of the endoprosthesis components mounting, made it possible to carry out tribological tests with nine variants of settings. **Figure 2** shows a diagram of the socket for fixing prosthesis components.

The simulator operating parameters are presented in **Table 2**.

In friction and wear tests, demineralized water was used as the lubricating fluid, and the use of a fluid with the lowest possible concertation of foreign ions was to eliminate the influence of other factors on the test result. Before starting the friction and wear tests, the content of Co^{2+} ions was tested in the lubricating fluid, and the ion content was 0.0226 ng/ml.

Table 2. Testing parameters of the SBT-01.1 simulator
Tabela 2. Parametry pracy symulatora SBT-01.1

Parameter	Value
Number of research cycles	1 000 000
Frequency	1 Hz
Angular range of motion	-10° – 30°
Maximum load	1 300 N
Lubrication	distilled water

The selection of the angular values of positioning components of endoprostheses on the simulator of the hip joint

In order to determine the range of motion in the hip joint, it is necessary to define the directions of movements. For this purpose, it is helpful to introduce the concept of body planes (planes of motion) and body axes.

The planes of the body in the places where they intersect form three basic axes of the body (**Fig. 4**) **[L. 19]**:

- Sagittal axis – directed horizontally from front to back, being the place of intersection of the transverse and sagittal planes,
- Vertical axis – running from the top of the head to the feet, being the intersection of the frontal and sagittal planes, and
- Transverse axis – passing horizontally from left to right, being the point of intersection of the transverse and frontal planes.

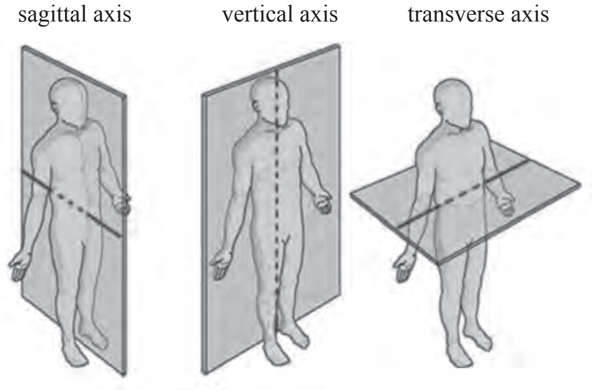

Fig. 4. Body axes [L. 19]
Rys. 4. Osie ciała **[L. 19]**

These planes are used to determine the angles of the head and cup of the prosthesis, as shown in **Figure 5**: the head antetorsion angle (α), the cup anteversion angle (β), the implant molar angle of the head (Δ), and the cup inclination angle (γ).

The selection of the angular values of the position of the endoprosthesis elements was made on the basis of the computed tomography results of 36 patients. The obtained images were assessed using the Syngo CT.3D diagnostic platform (Siemens, Germany), obtaining a three-dimensional image of the pelvis with hip joints and knee joints for the correction of the limb rotation setting. The research was carried out in the Department of General Orthopaedics, Oncology and Traumatology in Poznań on patients who underwent unilateral hip arthroplasty (Zimmetr Metasul, Ø44 mm). All patients achieved a very good clinical result of surgical treatment, and their follow-up period ranged from 13 months to 3 years.

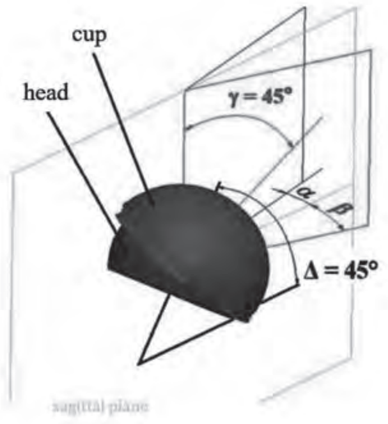

Fig. 5. "Head–cup" system: angle α – antetorsion, angle β – anteversion, angle γ – inclination, angle Δ – implant-molar
Rys. 5. Schemat układu „głowa–panewka": kąt α – antetorsji, kąt β – antewersji, kąt γ – inklinacji, kąt Δ – implantowo-trzonowy

Table 3. The angular values of mutual alignment setting of components of the ''head–cup" system
Tabela 3. Wartości kątowe dla poszczególnych ustawień wzajemnych układu „głowa–panewka"

Test number	Angular settings	
	Head	Cup
	α	β
1	-5°	-10°
2	-5°	20°
3	-5°	30°
4	10°	-10°
5*	10°	20°
6	10°	30°
7	25°	-10°
8	25°	20°
9	25°	30°

On this basis were planned nine options of the "head–cup" system settings listed in **Table 3**. The implant molar angle of the head (45° + 90°) and the cup inclination angle (45°) were assumed as permanent (**Fig. 5**). The positioning of the endoprosthesis elements as recommended for implantation was also taken into account (in **Table 3** marked as trial 5*).

Testing the concentration of cobalt ions in the lubricating fluid

As a result of the friction of the metal-metal hip prosthesis components, wear products are formed, which are characterized by a spheroidal shape with a diameter of 50 to 90 nm. Wear products and friction surfaces of implants cause an increased emission of metal ions. As part of tribological tests, using the method of atomic absorption spectrometry, the concentration of Co ions in the lubricating fluid was determined. The friction and wear tests were conducted for 480 hours (1 million cycles), and the prosthesis components were immersed in a vessel with a 1.5 litre lubricating fluid. 50 ml distilled water samples were taken for analysis after the end of the test.

Lubricating fluid samples were taken directly after the friction wear test from the container in which the friction steam was immersed. The determination of the concentration of cobalt ions in the lubricating fluid was carried out by atomic absorption spectroscopy (AAS) in a graphite cuvette using a Varian Spectra AA 200 HT apparatus.

Using the R300S Digital Scale (Sartorius, Germany) analytical balance, samples weighing 0.5 g were weighed with an accuracy of 0.0001 g. Then, they were mineralized in nitric acid V (HNO_3) in a Marsxpress CEM International closed system, equipped with a rotor, with the participation of microwaves. The purpose of mineralization was to transform complex compounds into simple inorganic compounds for which the analysis of the content of elements is more accurate.

The electrothermal graphite cuvette used for atomization made it possible to carry out a multi-stage sample preparation, while ensuring full control of the temperature and time of the process. The measurement cycle begins with the introduction of a specific sample volume into the atomiser and starting the temperature program, consisting of several stages, in which the temperatures and temperature maintenance times are defined (**Table 4**). The measurement of atomic absorption was carried out only during the atomization stage, i.e. after the formation of a cloud of free atoms of the element being determined.

The test was carried out with the use of Varian hollow-cathode lamps (4.0 mA) with the appropriate wavelength, characteristic for a given element (240.7 nm for Co). The measurement was repeated three times for each sample. The accuracy of the Varian Spectra AA 200 HT was ±0.0001 µg/L.

Table 4. Temperature program
Tabela 4. Program temperaturowy

Stage	Sequence	T [°C]	t [s]
Evaporation of the solvent	1	85	5
	2	95	40
	3	120	10
Pyrolysis	1	750	5
	2	750	1
	3	750	2
Atomization	1	2300	0.8
	2	2300	2
	3	2300	2

RESULTS

Figure 6 shows the results of the observation of the topography of the friction surfaces of the components of hip endoprostheses (made with the FEI Inspect S microscope). The observations were made immediately after the completion of the friction and wear tests before washing. There are visible remains of the lubricating film with particles of wear products trapped in it.

In order to determine the shape and size of the wear products, the observations were carried out using aHR-SEM high resolution scanning electron microscope (FEI Fegsem Quanta 3D microscope). The HR-SEM observation (**Fig. 7**) revealed that individual wear products were characterized by nanometric dimensions and a regular spheroidal shape. It is known from the experience of hip arthroplasty that the size, shape and chemical composition of wear products have a significant impact on the patient's body response.

The results of the determination of the ion concentration by atomic absorption spectroscopy (AAS) in the lubricating fluid after the end of the friction and wear tests of endoprostheses are presented in **Table 5** and **Fig. 8**.

To better visualize the differences in the concentration of cobalt ions for different angles of

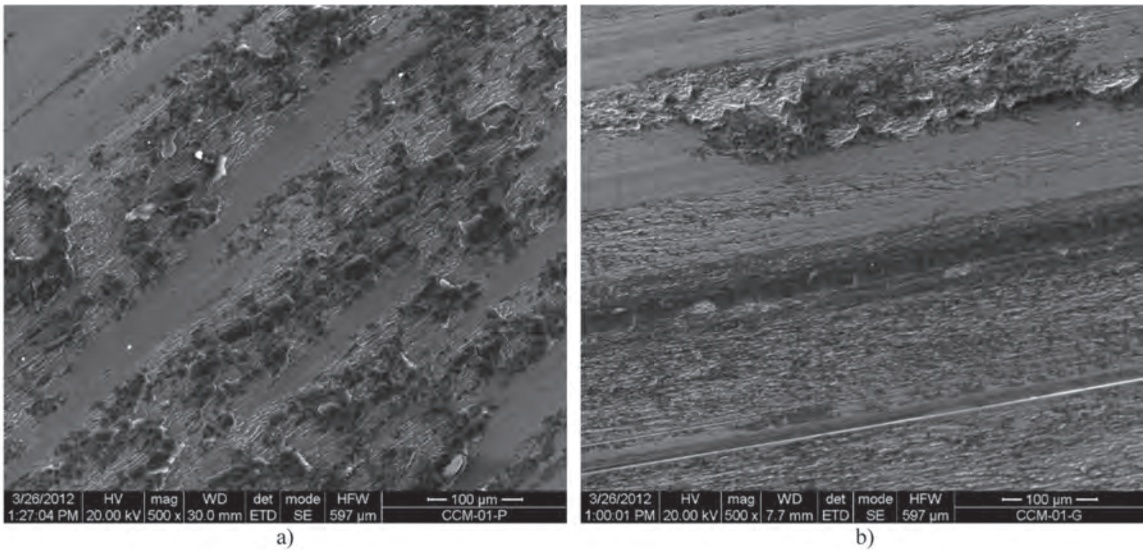

Fig. 6. Topography of friction surfaces, components of hip joint prostheses after M-M material-related friction wear tests: a) cup surface (magnification 500x), b) head surface (magnification 500x)

Rys. 6. Topografia powierzchni trących, komponentów endoprotez stawu biodrowego po testach tarciowo-zużyciowych o skojarzeniu materiałowym M-M: a) powierzchnia panewki (pow. 500x), b) powierzchnia głowy (pow. 500x)

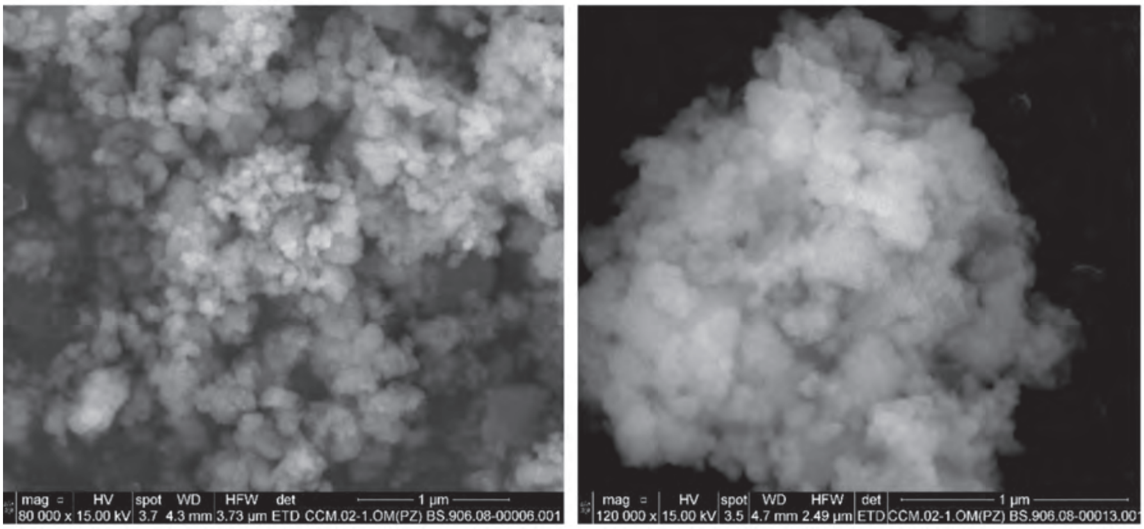

Fig. 7. HR-SEM observation of wear products: a) 80,000x, b) 120,000x

Rys. 7. Obserwacja HR-SEM produktów zużycia: a) pow. 80 000x, b) 120 000x

the prosthesis components, the results are presented in graphs, grouping the data according to angles α and β (**Fig. 8**).

The data presented above show that changing the position of the components of the hip joint prosthesis in relation to each other has an impact on the amount of Co^{2+} ions released into the lubricating fluid.

The lowest concentration of ions of the analyzed elements was found for the setting of the head anteversion angle of α = -5°, regardless of the setting of the acetabular anteversion angle β (settings no. 1, 2 and 3) and for the setting no. 7 (α = 25°, β = -10°). For these variants, the concentration differs slightly and ranges from 16.55 to 18.02.

On average, the highest concentration of Co^{2+} ions in the lubricating fluid was found for the head anthrust angle of α = 10°.

For the head anteversion angle to be set at α = 25°, the ion emission depended on the acetabular anteversion angle setting and increased with increasing the anteversion angle β.

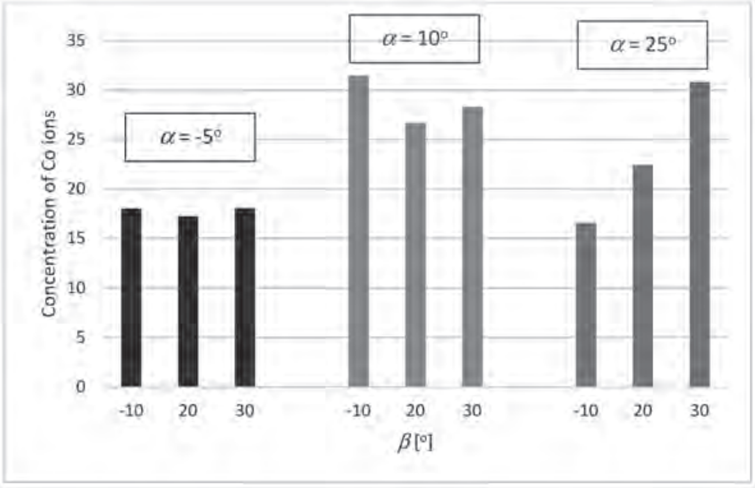

Fig. 8. The concentration of cobalt ions for different angles of the prosthesis components
Rys. 8. Stężenie jonów kobaltu w zależności od wzajemnego ustawienia kątów komponentów endoprotezy

Table 5. Concentration of Co^{2+} ions in the lubricating fluid after the end of friction and wear tests
Tabela 5. Stężenie jonów Co^{2+} w cieczy smarującej po zakończeniu testów tarciowo-zużyciowych

Test number	Angle		Ion concentration
	α [°]	β [°]	Co^{2+} [mg/dm^3]
1	-5	-10	18.003
2		20	17.199
3		30	18.020
4	10	-10	31.482
5		20	26.680
6		30	28.286
7	25	-10	16.548
8		20	22.420
9		30	30.820

CONCLUSIONS

The tested endoprostheses were made of CoCrMo alloy, which produces a passive coating on its surface that is resistant to reaction with the environment in which it is located. The contact surface on which cyclical destruction of the passive coating occurs is a source of metal ion emission. The second source of ion emission is the wear products generated in the friction node. Wear products are torn off the friction surfaces and remain in the friction node. The friction surfaces of the prosthesis have a mechanical effect on the wear products, causing them to fragment and change their shape (after reaching the size from 106 to 164 nm, they are washed out of the friction zone).

A different intensity of wear of the tested endoprostheses – and hence a different emission of metal ions – should be seen in the variability of the contact surface area between the head and the cup, which changes depending on the mounting angles of the endoprosthesis components relative to each other.

The conducted tests and analyses do not allow for the creation of a dependence describing the influence of the positioning of the endoprosthesis elements on the emission of cobalt ions, because a number of other important factors should be taken into account, such as the concentration of chromium ions, mass wear, and change in the roughness of rubbing surfaces.

Nevertheless, on the basis of the conducted research, it can be concluded that there are significant differences in the concentration of cobalt ions in endoprostheses working with the head antetorsion angle (α) and the cup anteversion angle (β), which may be helpful in finding the optimal settings of the prosthesis components.

The importance of the problem may be proved by the letter of the National Consultant in the field of Orthopaedics and traumatology of the locomotor system to provincial consultants from 2012, in which it is recommended to provide special care to patients after implantation of a metal-metal hip joint endoprosthesis. The recommendation was to check orthopaedic patients every 3 months to measure serum cobalt and chromium levels. Magnetic resonance imaging of the operated hip joint when the serum cobalt and chromium ions levels exceed 7 ppb.

Friction and wear tests of endoprostheses conducted in laboratory centres may significantly contribute to reducing the occurrence of postoperative complications. It is possible to simulate in laboratory tests (in vitro) problems related to the alignment of hip endoprosthesis components within the ranges defined in clinical trials (in vivo).

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