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# STAND FOR TRIBOLOGICAL TESTING OF HIP ENDOPROSTHESES

## STANOWISKO DO BADAŃ TRIBOLOGICZNYCH ENDOPROTEZ STAWU BIODROWEGO

**Key words:**

hip joint simulator, endoprosthesis, friction torque, wear, metal-on-polyethylene articulation

**Słowa kluczowe:**

symulator ruchu stawu biodrowego, endoproteza, moment siły tarcia, zużycie, skojarzenie materiałowe metal-polietylen

**Abstract**

The paper presents a new construction of hip-joint simulator. The SBT-01.2 simulator is designed for conducting tribological testing of hip endoprostheses based on ISO 14242-1, which specifies the requirements for the range of motion and load characteristics of the friction pair (femoral head vs. acetabular cup) during one test cycle. The construction of the simulator is based on the anatomical structure of the human hip joint. The prosthesis acetabulum is

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mounted in the upper part of the mounting head while maintaining the inclination angle relative to the axis of the socket to the direction of the loading force. The head of the prosthesis is mounted on a pin embedded in the bottom, movable base. After placing a special sleeve on the lower base, liquid lubricant is applied on the head-cup tribological system. The employed software enables continuous control, online visualization, and data recording. During testing, parameters such as lubricant temperature, instantaneous loading force, friction torque, and the number of cycles are recorded.

## INTRODUCTION

Total hip replacement became one of the most common orthopaedic procedures at the beginning of the twenty-first century **[L. 1]**. The surgical procedure involves removing the degenerated joint elements and their replacement by an endoprosthesis **[L. 2]**. It is estimated that worldwide each year, over one million such operations are performed **[L. 3]**. It is anticipated that this number will increase each year. According to data from the National Health Fund in Poland, 5532 total hip replacements were performed in 1999, 26 089 in 2005, and 41 984 in 2014 **[L. 4]**.

Statistical data indicate that the most common causes of failures leading to revision surgery are the loosening of the prosthesis components and osteolysis. Osteolysis is the result of tribological and corrosive wear of endoprostheses, generating microscopic wear products. They cause irritation of the periprosthetic tissues and contribute to a reduction in bone mineral density **[L. 5]**. Hence, it is important to conduct tribological testing under controlled conditions, whose purpose is not only to evaluate the wear resistance of the applied material to produce the endoprostheses, but also to investigate the wear mechanisms.

Technical devices used to test the wear resistance of endoprostheses under the kinematics of the motion and loads similar to those that occur in a natural joint are called simulators. In the literature, many different constructions of joint motion simulators are described **[L. 6]**. Some of the simulators reported in the literature limit motion to two instead of three anatomical planes **[L. 7]**. The angular range of motion and the value of the applied load may vary, not only because of the nature of the simulated activity, but may also result from constructional constraints **[L. 8]**. Solutions in which the design of the test system is reversed compared to the anatomical (acetabulum is below the head) are also common **[L. 9]**. This solution results in the confinement of the generated wear products in the bearing and intensifies the phenomenon of secondary wear of the friction surfaces **[L. 7, 9]**. There are also solutions in which the acetabular motion simulates flexion of the limb and not the femoral component **[L. 9, 10]**. As can be seen from the above description, not all simulators enable the realization of testing in accordance with applicable standards. In the case of hip joint simulators, ISO 14242-1: 2012 **[L. 11]** or ASTM F3057M-15 **[L. 12]** are specified. Although there are studies criticizing the guidelines contained in these standards **[L. 13]**, it is only compliance to them that enables meaningful comparison of the test results obtained in different laboratories throughout the world.

The purpose of this article is to present the construction of the SBT.01.2 hip joint simulator. According to the authors' knowledge, the construction of simulator is the first in Poland that enables the realization of hip endoprosthesis tribological testing based on international standards **[L. 11]**. The distinguishing feature of the SBT-01.2 simulator is the ability to analyse the friction resistance occurring in the endoprosthesis tribological system based on measurements of instantaneous friction torque. The article presents example test results of a metal-polyethylene endoprosthesis, whose purpose was to verify the proper operation of all the simulator systems.

## MATERIALS AND TEST METHODS

### Standard guidelines for kinematic motion and loads

Conducting friction and wear testing of endoprostheses using motion simulators is a complex task with the purpose of determining the wear rates of the articulating materials. It is obvious that the wear resistance of endoprosthesis bearing surfaces is determined by many factors, starting from the value and nature of the bearing load, frequency, extent and type of motion, the type of lubricant, and ending with the temperature at which the tests are carried out. The only guarantee for obtaining realistic test results is to perform them under conditions as similar as possible to those found in a natural joint. By taking into account the above factors, it was decided that a simulator would be designed and constructed that enabled the realization of friction and wear tests based on the guidelines contained in the international ISO standard **[L. 11]**. In addition, it will enable the measurement of selected friction parameters.

The above-mentioned standard clearly specifies the relative angular movement between endoprosthesis components **(Fig. 1a)**, setting them relative to one another, the loading point and the formula for the value of instantaneous force loading the friction node **(Fig. 1b)**, the relative speed of motion, and environmental requirements (type of lubricant, protein content, temperature, method of filtering and storage).

a) b)

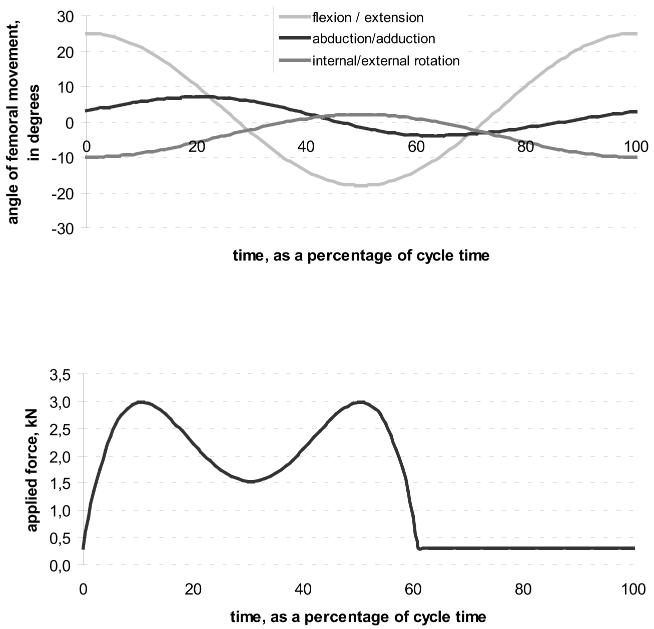


**Fig. 1. Variation in time of (a) angular movements of femoral test specimen and (b) applied loading force along the loading axis**

Rys. 1. Zmienność w czasie: a) ruchów kątowych próbki komponentu udowego oraz b) wartości siły obciążającej przyłożonej wzdłuż osi pionowej

## Trial test

The subject of research in the course of tests, whose aim was to verify the proper operation of all the simulator systems, was a metal-polyethylene total hip endoprosthesis. It consisted of the following components: 1) a stainless steel FeCrNiMnMoNb 28 mm diameter head, 2) a UHMWPE inlay (ISO 5834-1 + 2), and 3) a Ti6Al7Nb alloy acetabulum (ISO 5832-11) having an outer diameter of 42 mm, coated with a TiCP layer (ISO 5832-2). All of the components were provided by Mathys Ltd Bettlach (Switzerland).

To begin testing, the polymer inlay was placed in a vessel with lubricating fluid having a temperature of 37 ± 2°C for a period of five days in order to stabilize the UHMWPE. Bovine serum diluted with deionized water to a protein concentration of 30 ± 2 g/l was used as the lubricating medium. The concentration was monitored by a GenesysTM 20 spectrophotometer (Spectronic Instruments, USA). Sodium azide (0.3 wt%) and EDTA were added to the solution at 20 mM for the purpose of inhibiting bacterial growth and binding calcium ions, and the mixture was filtered through a sterile filter (pore size 22 um). The test was conducted at the temperature of 37 ± 2°C. To heat the lubricant, a Laboratory B4 B5 thermostat (Sondermaschinenbau GmbH, Germany) was applied from which the liquid was applied into the endoprosthesis mounting socket via a peristaltic pump BT100-2J (Longer Pump Ltd, China) equipped with a YZ1515X head (Longer Pump Ltd, China).

The set number of motion cycles that the endoprosthesis was to perform was 5 $10^6$. The simulator operation was interrupted every 5 $10^5$ cycles. During this time, the endoprosthesis mounting socket and all the endoprosthesis components were thoroughly washed and dried, and the lubricating medium was replaced. The of the endoprosthesis components were washed in deionized water and isopropanol using an ultrasonic bath, then dried in a vacuum (13.3 ± 0.13 Pa) for 30 min. The procedure is described in detail in the standard **[L. 14]**.

## TEST RESULTS

### Simulator construction

**Figure 2** presents a general schematic of the simulator.

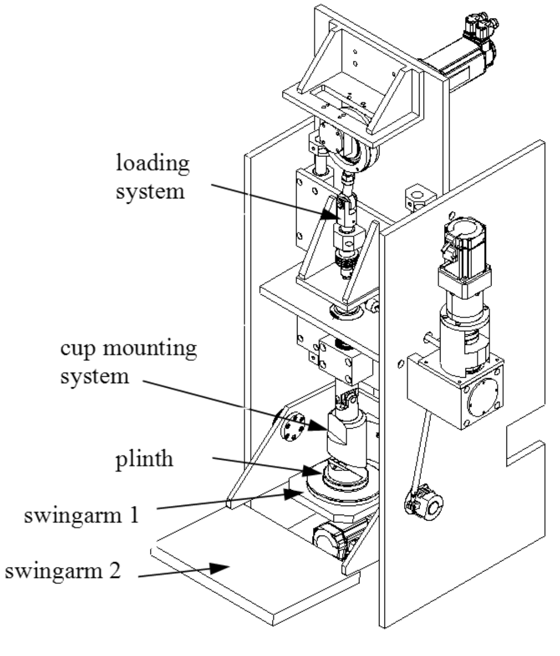


**Fig. 2. General schematic of the SBT-01.2 hip-joint simulator**
Rys. 2. Symulator ruchu stawu biodrowego SBT-01.2, schemat ogólny

In the course of the test, the components of the endoprosthesis are placed in a container filled with a lubricating medium and are subjected to cyclic loading, during natural movement simulating the motion occurring in the hip joint. The endoprosthesis acetabulum performs a swinging rotation motion around a vertical axis, and it is pressed against the head carrying out a swinging movement about two horizontal, mutually perpendicular axes. In addition, the acetabulum is rotated and pressed against the spherical ends of the endoprosthesis by a hinge element, which eliminates the occurrence of transverse forces in the tested connection. The clamps enable the correct setting of the rotation angles relative to the cycle time, while the motion carried out by three servomotors provides appropriate timing among all the drive axes. On the bottom of the container with the liquid lubricant, a plinth is embedded in which a pin is secured and thereon the endoprosthesis head is mounted. The bottom of the plinth is bolted to the swinging arm, bearing on the driveshaft, in the forked integument body, mounted in the body of the simulator to allow rotation. On the shaft, a pulley wheel is fastened, driven by a toothed belt and the pulley wheel of the servomotor is attached to the forked integument body. The mechanisms driving the swinging motions are selected in such a way as to implement tilt in accordance with the guidelines contained in the standard, and their greatest tilts were offset from each other so that the maximum tilted acetabulum rotation accounted for half of the cycle time, whereas the maximum tilt of the forked integument body is at the beginning of the cycle. Strain gauges are mounted to the swinging arm driveshaft, measuring the strain in the driveshaft and the torque. A dynamometer to measure the force occurring during endoprosthesis loading is located under the tappet. A thermocouple measuring the temperature of the lubricant is located in the container. The acetabulum placed above the head is tilted from the direction of the loading force at an angle of 30° and is swinging rotated relative to the load axis at an angle from -10° to + 2°. The head swings around the horizontal axis in the range of 7° to -4° with a phase shift of 21% of the cycle time relative to the second horizontal axis, perpendicular to the previous one in the range of 25° to 18°, with simultaneous measuring of the forces, torques, and temperatures of the process.

The innovative hip joint endoprosthesis tester is characterized by the fact that the drive is carried out by three mutually synchronized servomotors, fulfilling all the kinematic and dynamic requirements of **[L. 11]**, and at the same time, enabling the fulfilment of other technical requirements.

## Trial test

During the test, the following parameters were recorded: lubricant temperature, instantaneous loading force, friction torque, the current number of cycles, and the head tilt angle. **Figure 3** shows an example of the measured results of friction torque and friction coefficient during the course of one measurement cycle. The friction coefficient values were calculated by dividing the friction torque by the loading force value.

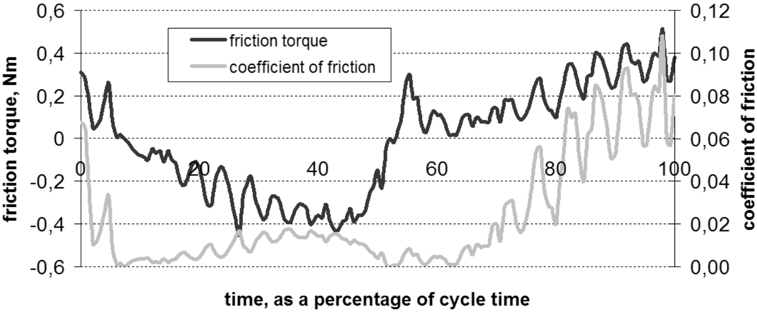


**Fig. 3. Friction torque and friction coefficient in relation to time, as a percentage of cycle time**

Rys. 3. Moment tarcia i siła tarcia w funkcji czasu jako procent czasu trwania pojedynczego cyklu

The instantaneous friction and friction coefficient values presented in **Fig. 1** are synchronized in time with those presented in **Fig. 3**. The friction coefficient value during a single test cycle varies in the range from about 0.01 to 0.10. By comparing the instantaneous values of this parameter with the load values, it can be seen that the friction reached minimum values when the system was loaded to the maximum value (respectively 10 and 50% of the cycle). Reducing the system load to about 300 N resulted in achieving the maximum frictional resistance. The authors of **[L. 15]** draw attention to a similar phenomenon. They explain that reducing the load of the hip joint endoprosthesis results in deterioration of the effectiveness of lubricant entrainment at the friction node. As a result of reducing the thickness of the lubricating film, the coefficient of friction is increased and the wear of the friction surfaces becomes more intense. Tipper and colleagues **[L. 16]** emphasized in their work that the wear of the endoprosthesis bearing surfaces depends on the kinematic conditions and load cycle. According to Hooke's theory **[L. 17]**, the thickness of the lubricating film increases with increasing speed of surfaces moving relative to each other, increasing the viscosity of the lubricant, increasing the radius of the ball joint and decreasing the modulus of elasticity, and decreasing the bearing load.

**Figure 4** illustrates the course of change in the friction coefficient as a function of the number of cycles. A single point on the graph corresponds to the mean value for a single cycle (n = 150).

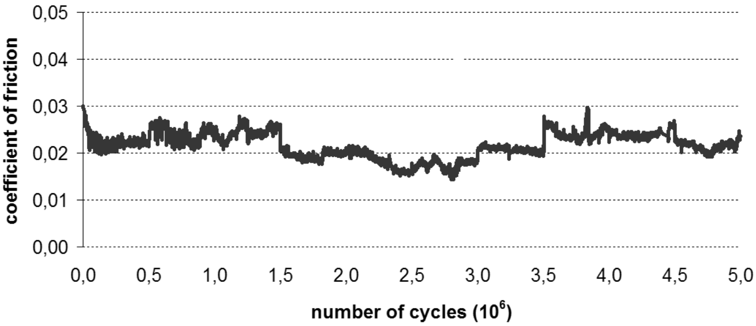


**Fig. 4. Mean values of the friction coefficient in relation to number of cycles**
Rys. 4. Średnia wartość współczynnika tarcia w funkcji liczby cykli

Based on these results, it can be concluded that the mean coefficient of friction varied in the range of approximately 0.02 to 0.03. Reducing the ratios after approximately $1.5 \cdot 10^6$ cycles can attest to the mutual run-in of the friction surfaces. Over the next 1.5 million cycles, this value fluctuated around 0.02. After working $3.0 \cdot 10^6$ cycles, the friction resistance increased to about 0.025.

By analysing the obtained results, it can be concluded that the simulator measuring systems work correctly. The coefficient of friction values corresponds to the values reported in the available literature. The use of aqueous serum as the lubricant enables obtaining relatively low frictional resistance **[L. 18]**. For the stainless steel-UHMWPE friction pair, the estimated friction coefficient value should be in the range from 0.06 to 0.10, depending on the type of applied standard tribological tester **[L. 19, 20]**. When testing real endoprostheses using joint simulators, the observed frictional resistances are smaller **[L. 21]**. The mean coefficient value should be in the range of 0.02 to 0.07 **[L. 22]**. For the tested friction pair, the mean friction coefficient during the performance of the entire test was 0.021 (± 0.002).

## CONCLUSIONS

The SBT-01.2 simulator is designed to simulate the motion and loads occurring in the human hip joint based on ISO 14242-1 **[L. 11]**. It is used at the design stage of the endoprosthesis, as well as conducting comparative tribological testing. The construction of the simulator is the subject of patent protection **[L. 23]**.

Based on comparison of the obtained results with the literature data, it can be concluded that the simulator measurement systems work correctly. In the case of the tested endoprosthesis, the friction coefficient value as a function of the number of cycles was stable, and it ranged from 0.02 to 0.03. Analysis of the changes in the value of this parameter during a single cycle showed that they are dependent on the instantaneous value of the loading force. This phenomenon is consistent with the theory of elastohydrodynamic lubrication (EHL) **[L. 17]**, which demonstrates the change in friction conditions over the duration of one cycle, and it will be the subject of further analysis.

In this article, the authors have not presented the wear volume values of the components of the tested endoprosthesis. According to the standard **[L. 14]**, tribological wear can be determined from the average of three tests, using control groups.

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**Streszczenie**

**W artykule przedstawiono nową konstrukcję symulatora ruchu stawu biodrowego. Symulator SBT-01.2 przeznaczony jest do realizacji badań tribologicznych endoprotez stawu biodrowego w oparciu o normę ISO 14242-1, która określa wymogi dotyczące zakresu ruchów i charakterystyki obciążenia pary trącej (głowa-panewka) w czasie jednego cyklu badawczego. Konstrukcja symulatora oparta została na anatomicznej budowie stawu biodrowego człowieka. Panewka endoprotezy zamontowana jest w górnej części w głowicy mocującej z zachowaniem kąta inklinacji osi panewki względem kierunku przyłożenia siły obciążającej. Głowa endoprotezy mocowana jest na trzpieniu osadzonym w dolnej, ruchomej podstawie. Po założeniu specjalnego rękawa na dolnej podstawie układ tribologiczny głowa-panewka zalewany jest cieczą smarującą. Zastosowane oprogramowanie umożliwia stałą kontrolę, wizualizację online i zapis danych. Podczas testu rejestrowane są takie parametry jak: temperatura cieczy smarującej, chwilowa wartość siły obciążającej, moment siły tarcia i aktualna liczba cykli.**