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SURFACE RANDOM PARAMETERS FOR ENDOPROSTHESIS LUBRICATION

PARAMETRY LOSOWE POWIERZCHNI DLA SMAROWANIA ENDOPROTEZ

Key words:

endoprosthesis, surfaces, geometrical random parameters, measurements, gap height, hydrodynamic pressure, random lubrication prognosis.

Słowa kluczowe:

endoprotezy, powierzchnie, losowe parametry geometryczne, chropowatość, pomiary, wysokość szczeliny, ciśnienie hydrodynamiczne, losowe prognozy smarowania

Abstract

Within the last ten years in the European Union the number of bone fractures caused by the osteoarthritis increased twofold. More than 100000 hip or knee joints in total have been implanted in Germany during one year. Within ten years, 5% of them have failed by aseptic loosening. The non-invasive determination of friction forces and the control of their values during lubrication of cartilage cells on the superficial layer of human joint surfaces before implanta-

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tion have a significant but not sufficient influence on the observation of the early abrasive wear of cartilage joint and the development of osteoporosis. From this fact was drawn the inspiration for the performed investigations referring the endoprosthesis surface parameters, because knowledge of the roughness of prosthesis surfaces and friction forces and their control methods makes it possible to provide the necessary random standard deviation of gap height and finally information about implantation possibility. This paper has been prepared based on the objective knowledge gained from the author's experimental and theoretical experiences to represent the methodology and goal of the idea described in the study and to make possible a wider discussion on this subject for further developments during the realization of various bioengineering projects in the field of hydrodynamic artificial human and humanoid robots joints.

INTRODUCTION

In 2015 in the EU, 450,000 joint fractures were recorded. The increase in number of joint fractures in the EU, anticipated based on demographic development in the next 50 years, would reach about one million. Therefore, endoprostheses replacements will be made even in the young. Taking into account the increase in artificial hip-joint replacements, it is necessary to know the condition of the surface of the endoprosthesis. In this occasion, we cannot ignore aseptic loosening of endoprostheses. Therefore, this paper presents detailed results of measurements of the geometrical structure parameters of cooperating head, pivot surfaces, and cement in an endoprosthesis at the micro level. Obtained results are dependent on the features of the prosthesis material. The prosthesis surfaces on the head and acetabulum (sleeve) are made very soft and made of materials such as Vitalium, Endocast, Zircon, Polyethylene, or Aluminium ceramic. The obtained results for prosthesis surface measurements, namely irregularities and unevenness, have been based on actual implants and applied to the real gap height, pressure, load carrying capacity, and wear prognosis in artificial human hip joints. The goal of this paper is to examine the possibility of the application of Geometrical Structure Surface parameters to evaluate the load carrying capacity and wear of endoprostheses. Therefore, this paper defines and describes the random parameters connected with the surfaces of an endoprosthesis.

The problem of endoprosthesis surface lubrication for unsteady periodic stochastic motion has been considered by K. Oczoś and V. Lubimov, J. Cwanek, V.C. Mow et al. **[L. 1– 4]**. Up to now the random considerations and solution methods have been based only on the probability symmetric density functions of gap height changes. For example, classical Gauss and Pseudo-Gauss probability density functions of gap height changes are considered. Such assumed conditions denote that in each arbitrary time period, the occurring probabilities of gap height decreases have the same rank as the probability values of gap height increases. The random changes of the gap height of the natural normal and pathological human hip joint or gap height between the head and acetabulum of endoprosthesis are caused mainly by vibrations and the roughness of the joint surfaces. After many experimental observations, it follows that, during the arbitrary chosen time period of unsteady periodic motion of a hip joint, the probabilities of joint gap height decreases are not equal to the probabilities of gap increases. Therefore, in this paper, the asymmetric density function for probability gap height changes is taken into account **[L. 2, 3]**.

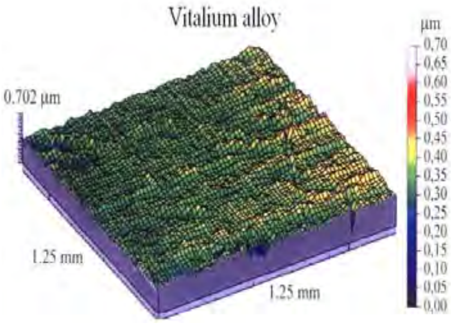
INVESTIGATION METHOD PERFORMANCES

The operation and in the particular case of the hydrodynamic lubrication of artificial Vitalium, Endocast, Zircon, Polyethylene, Aluminium ceramic endoprosthesis, is associated with the precise analysis of irregularities and unevenness of endoprosthesis cooperating surfaces, with an exactness of less than one micrometre. The measurements of the head of the endoprosthesis's surfaces were performed by using micro sensor laser installed in the Rank Taylor Hobson-Talyscan 150 Apparatus and then elaborated by means of the TALYMAP Expert and Microsoft Excel Computer Program. From many measured samples, the following statistical parameters have been calculated: **St**, **Sz,** and **Sa** of surface roughness smaller than one micrometre. We calculated, for example, the following: **St** – differences between values of rises and deeps of head surfaces in endoprosthesis, **Sz –** arithmetic mean between values of 5 rises and 5 troughs of head's surface, **Sa –** standard deviation of the probability density function of the roughness distribution of artificial joint surface.

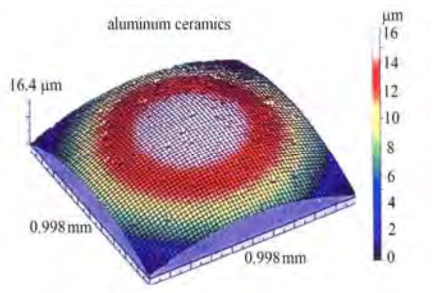
RESULTS OF MEASUREMENTS

The measurements of samples of artificial hip joint surfaces of endoprosthesis are performed by means of mechanical and laser sensors. The measured samples have been made of Endocast alloy, zircon, and ceramic aluminium (see **Fig. 1a**, **Fig. 1b**). The samples used during the measurements made of Vitalium or Endocast and zircon material were either 1.25 mm long and 1.25 mm wide or 2.50 mm long and 2.50 mm wide. The samples made of ceramic aluminium were 0.988 mm long and 0.988 mm wide. In the case of Weller's artificial endoprosthesis, the metal surface of the head is coated with randomly shaped chaos scratches obtained due to abrasive grain treatment **[L. 5]**.

The measured values of **St** for metal heads of Weller's endoprosthesis barely reached the value of 0.702 micrometres. The three dimensional (3D) structure of surface geometry of the unused head seated onto the corundum ceramic pin is shown in **Fig. 1b**.



a)



b)

Fig. 1. a) Isometric view of unused surface of head of Vitalium alloy of Weller's endoprosthesis, b) 3D view of the surface of unused head of endoprosthesis made of corundum ceramic

Rys. 1. a) Widok izometryczny nieużywanej powierzchni głowy endoprotezy Wellera wykonanej ze stopu Vitalium, b) widok 3D nieużywanej głowy endoprotezy z ceramiki korundowej

Based on the performed measurements, it is easy to see that the asperities of the artificial joint surfaces are smaller than those occurring in natural bone surfaces of human hip joints **[L. 4, 5]**.

Over the entire polished surface of aluminium ceramics, micro-cavities (micro-hollows) chaotically spread over the measuring area can be observed. The distribution density of such micro-cavities is within the range of 10 to 120 (and even more) elements per one mm^2, depending on a kind of ceramics and its firing process. The depth of micro-cavities reaches the values from 4 to 8 micrometres, measured on the area from 1 to 4 square micrometres. The occurrence of the micro-cavities on the polished ceramic surface is due to the manufacturing process of ceramic elements, which belongs to the powder metallurgy field.

During the process of compacting the powder and firing the ceramic elements, natural micro-pores are produced. The pores open and convert into micro-cavities during machining, when successive layers of excess material are removed, as well as in the course of the final polishing process. The influence of the micro-cavities on operational merits of ceramic heads of an endoprosthesis may be considered as a positive phenomenon, since, on the smooth surface, they form a specific network of micro-ponds playing the role of the containers for lubricating media.

The roughness of the surface areas between micro-cavities is low, and it maintains within the range of St – values from 0.4 to 0.8 μm **[L. 4, 5]**. Within the unevenness with a height of 16.4 μm shown in **Fig. 1b**, apart from surface roughness, a shape deviation from the ideal spherical surface is accounted for.

An example of hip joint half-endoprosthesis with the head seated onto the pin is the Francobal endoprosthesis. Its head consists of an outer metal element having spherical form and an inner element made of polyethylene.

Figures 2 and **3** present the geometrical structure of the surface and the vertical 2D cross-section of an unused head of Francobal`s artificial hip joint.

In the presented geometrical structure in **Fig. 2**, we have the following amplitude parameters: Sa = 0.0604 μm, St = 0.632 μm, and Sz = 0.538 μm.

In the presented geometrical structure in Fig. 3, we have the following amplitude parameters: Sa = 0.0582 μm, St = 0.602 μm, and Sz = 0.425 μm.

The prevailing number of the acetabulum of hip joint endoprostheses is made of polyethylene by using the high-pressure compacting method in metal moulds. A typical image of the surface of a new, unused polyethylene acetabulum of a hip joint is shown in **Fig. 4**.

From the presented figures, it can be observed that some concentrically orientated unevenness resulting from its manufacturing process are superimposed on the basic hollow surface of the acetabulum. This phenomenon is also found in other manufacturing processes, and it is generally called *technological heritage*. In the case in question, the phenomenon is characteristic of the unevenness of the mould that has been imprinted on the acetabulum surface **[L. 4, 5]**.

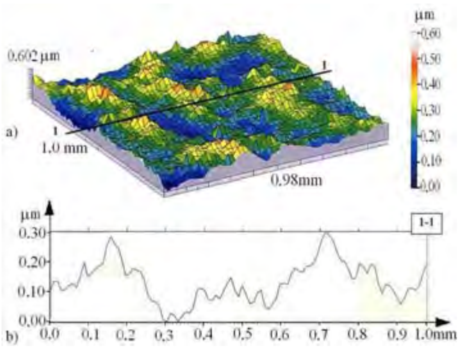


Fig. 2. Sample of a new head of endoprosthesis FRANKOBAL GL46MM: a) measured roughness of cartilage surface, b) vertical section of cartilage surface

Rys. 2. Próbki nowej głowy endoprotezy FRANKOBAL GL 46MM: a) mierzone chropowatości powierzchni chrząstki, b) przekrój pionowy powierzchni chrząstki

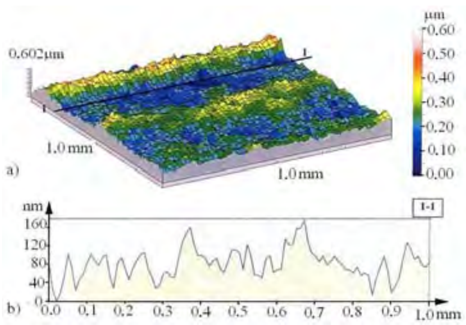
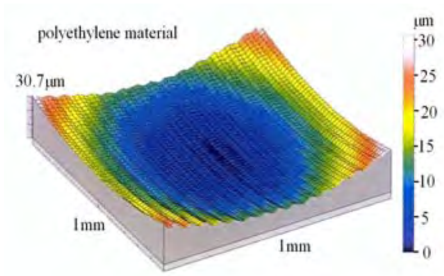
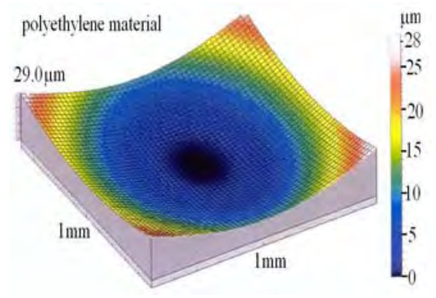


Fig. 3. Sample of a new head of endoprosthesis FRANKOBAL GL54MM: a) measured roughness of surface, b) vertical section

Rys. 3. Próbka nowej głowy endoprotezy FRANKOBAL GL54 MM: a) mierzona chropowatość powierzchni, b) przekrój pionowy powierzchni chrząstki



a)



b)

Fig. 4. Unused acetabulum of hip joint endoprosthesis: a) general view, b) separated initial spherical surface of the radius R = 14.012 mm

Rys. 4. Nie używane powierzchnie panewki endoprotez: a) widok ogólny, b) początkowo odłączona powierzchnia sferyczna o promieniu R = 14,012 mm

APPLICATION OF STOCHASTIC PARAMETERS

The experimental measurements **[L. 5]** enable one to show (**Fig. 5a, b**) two dimensionless, asymmetrical probability density functions (f_A, f_a) for endoprosthesis gap height, versus dimensionless stochastic gap height corrections δ_1. The probability density function for gap height indicate probability values of gap height, corresponding to the dimensionless gap height corrections during the operation time. Negative (positive) gap height corrections denote decrements (increments) of relative value of gap height. **Fig. 5a** presents the case where the probability values of gap height density functions are smaller for negative gap height stochastic corrections δ_1 in comparison to the probability values of the density function with positive stochastic correction values δ_1. **Fig. 5b** presents the case where probability values of gap height density functions are significantly larger for negative gap height stochastic corrections δ_1 in comparison with the probability values of the density function with positive stochastic correction values δ_1.

Stochastic changes of joint gap height are determined by virtue of the main random parameters such as the expectancy value and standard deviation. Mentioned parameters are now defined. The indefinite integral of the product of the real gap height (*) and probability density function f denotes average probability values, i.e. the expectancy stochastic value of gap height defined by **[L. 6, 7]**:

$$E(*) = \int_{-\infty}^{+\infty} (*) \times f(\delta_1) d\delta_1 \tag{1}$$

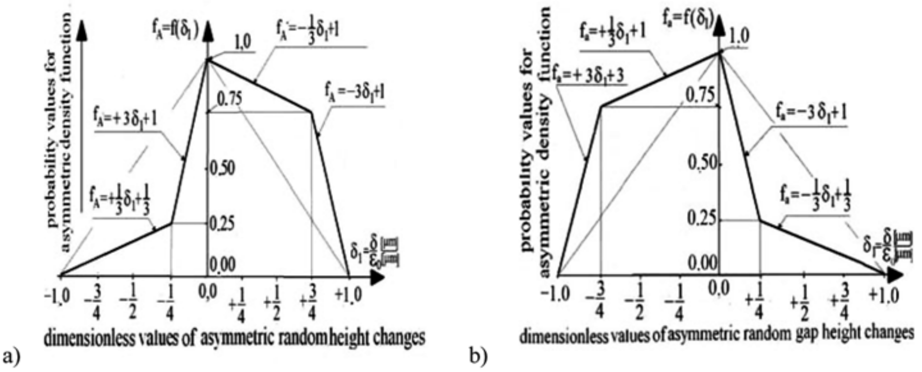


Fig. 5. Asymmetric gap height probability density functions f versus gap height stochastic dimensionless correction values δ_1: a) probability values f_A for negative correction values δ_1 are smaller than values f_A for positive correction values δ_1; b) probability values f_a for negative correction values δ_1 are significant larger than values f_a for positive correction values δ_1

Rys. 5. Niesymetryczne funkcje f określające gęstości prawdopodobieństw dla wysokości szczeliny endoprotezy w zależności od wartości δ_1 stochastycznych korekt wysokości szczeliny; a) wartości funkcji gęstości f_A dla ujemnych δ_1 są mniejsze niż f_A dla dodatnich δ_1; b) wartości funkcji gęstości f_a dla ujemnych δ_1 są znacząco większe niż wartości f_a dla dodatnich δ_1

Standard deviation, σ, has the following form **[L. 6, 7]**:

$$\sigma \equiv \sqrt{E\left(*\right)^2 - E^2\left(*\right)} \tag{2}$$

The standard deviation describes the scope of the deviation of the measured gap height correction values δ_1 from the correction corresponding with the expectancy probability for gap height value.

STOCHASTIC LUBRICATION OF MEASURED SURFACES

The spherical dimensionless gap height ε_{T1} between two co-operating endoprosthesis surfaces depends on the dimensionless variable φ in circumferential and ϑ_1 in meridian direction and time t_1, and it consists of two parts:

$$\varepsilon_{T1} = \varepsilon_{T1s}(\varphi,\vartheta_1,t_1) + \delta_1(t_1) \quad \text{for} \quad 0 < \varphi < 2\pi;\ \pi/8 < \vartheta_1 < \pi/2 \tag{3}$$

Symbol ε_{T1s} denotes the total dimensionless time-dependent part of the height of a thin fluid layer, without random changes, δ_1-denotes the dimensionless stochastic corrections of gap height caused by the geometry of the endoprosthesis head and acetabulum surface random changes. The modified stochastic Reynolds equations in spherical dimensionless coordinates (φ,ϑ_1) has the following form **[L. 4, 5]**:

$$\frac{1}{\sin\vartheta_1}\frac{\partial}{\partial\phi}\left[\frac{E\left(\varepsilon_{T1}^3\right)}{\eta_1}E\left(c\right)\frac{\partial p_1}{\partial\phi}\right]+\frac{\partial}{\partial\vartheta_1}\left[\frac{E\left(\varepsilon_{T1}^3\right)}{\eta_1}\frac{\partial p_1}{\partial\vartheta_1}\sin\vartheta_1\right]= \\ =\left(6\frac{\partial}{\partial\phi}+12\mathrm{Str}\frac{\partial}{\partial t_1}\right)E\left(\varepsilon_{T1}\right)\sin\vartheta_1=6\frac{\partial}{\partial\phi}E\left(\varepsilon_{T1}\right)\sin\vartheta_1 \tag{4}$$

We denote the following: $p_1 = p/p_0$ – dimensionless pressure, $p_0 = \omega\eta R^2/(\varepsilon_0)^2$, ω – angular velocity of the head, η_1 – dimensionless fluid viscosity, $\eta = \eta_0\eta_1$, ε_0 – dimensional characteristic value of gap height, R – dimensional radius of the head, Str – Strouhal number, t_1 – dimensionless time, φ –circumference, ϑ_1 – dimensionless meridian coordinate. After calculations, the expectancy dimensionless random values m of gap height, i.e. $E = E_A$, $E = E_a$, for asymmetric density functions f_A, f_a by virtue of equations Eq. 1, Eq. 2, and Eq. 3 and after results showed in **Figs. 5a, b**, are as follows **[L. 6, 7]**:

$$m_{A1}\equiv E_A(\varepsilon_{T1})=\int_{-\infty}^{+\infty}(\varepsilon_{T1s}+\delta_1)\times f_A(\delta_1)d\delta_1=\varepsilon_{T1s}+0.25 \\ m_{a1}\equiv E_a(\varepsilon_{T1})=\int_{-\infty}^{+\infty}(\varepsilon_{T1s}+\delta_1)\times f_a(\delta_1)d\delta_1=\varepsilon_{T1s}-0.25 \tag{5}$$

Additionally after calculations we obtain

$$E_{A1}(*)^3\equiv E_A\left(\varepsilon_{T1}^3\right)=\int_{-\infty}^{+\infty}\left(\varepsilon_{T1s}+\delta_1\right)^3\times f_A(\delta_1)d\delta_1=(\varepsilon_{T1s}+0.25)^3+3\sigma_{A1}^2(\varepsilon_{T1s}+0.25) \\ E_{a1}(*)^3\equiv E_a\left(\varepsilon_{T1}^3\right)=\int_{-\infty}^{+\infty}\left(\varepsilon_{T1s}+\delta_1\right)^3\times f_a(\delta_1)d\delta_1=+(\varepsilon_{T1s}-0.25)^3+3\sigma_{a1}^2(\varepsilon_{T1s}-0,25) \tag{6}$$

where the standard deviation by virtue of Eq. (2) has the value

$$\sigma_{A1}\approx\sigma_{a1}=0.38188 \tag{7}$$

To obtain dimensional value of the standard deviation $\sigma_A,\sigma_{a,}$ we must multiply σ_{A1}, σ_{a1} by the characteristic dimensional value of gap height $\varepsilon_0 = 10\cdot 10^{-6}\,m$. In this case, the dimensional standard deviation equals 3.81837 micrometres. From the measurements, it follows that the standard deviation value attains about 4.0 micrometres for the considered endoprosthesis.

EXAMPLE OF RANDOM PARAMETERS ESTIMATION

The dimensional gap height ε_T between endoprosthesis surfaces has an average value 70 μm. At first, we neglect the random changes, i.e. $\delta = 0$. For $\varepsilon_0 = 10$ μm, the dimensionless gap height defined by Eq. 3 has value: $\varepsilon_{T1} = \varepsilon_T / \varepsilon_0 = 5$. Taking into account random changes of endoprosthesis surfaces, i.e. $\delta \neq 0$, with Eq. 5, we calculate dimensionless m_{A1}, m_{a1} and corresponding dimensional m_A, m_a expectancy values of gap height for two cases of asymmetric density functions f_A, f_a (see **Fig. 5a, b**), respectively:

$$m_{A1} = 5.00 + 0.25 = 5.25,\ \ m_A = m_{A1}\cdot\varepsilon_0 = 52.50\ \mu m$$
$$m_{a1} = 5.00 - 0.25 = 4.75,\ \ m_a = m_{a1}\cdot\varepsilon_0 = 47.50\ \mu m \tag{8}$$

For results presented in **Figs. 5a, b**, the expectancy values of a cubed gap height according to Eqs. 6 and 7 are as follows:

$$E_{A1}(*)^3 = (5.25)^3 + 3 \times (0.3818)^2 \times 5.25 = 146.9990$$
$$E_A(*)^3 = E_{A1} \times (\varepsilon_0)^3 = 146\,999.0\ \mu m^3$$
$$E_{a1}(*)^3 = (4.75)^3 + 3 \times (0.3818)^2 \times 4.75 = 109.2491 \tag{9}$$
$$E_a(*)^3 = E_{a1} \times (\varepsilon_0)^3 = 109\,249.1\ \mu m^3$$

To obtain pressure p, we put the obtained values from Eq. 5 and Eq. 6 into a modified Reynolds equation (Eq. 4). The solutions are performed in a numerical way based on the results obtained in papers **[L. 8–10]**.

Expectancy value m of gap height for density functions f_A and f_a by virtue of Eq. (8) are estimated in the following interval:

$$47.50\ \mu m = m_a \leq\ m \leq\ m_A = 52.50\ \mu m \tag{10}$$

Using standard deviations (7), the dimensional standard deviation of the gap height has the following value:

$$\sigma_A \approx \sigma_a = \sigma_A \cdot \varepsilon_0 \approx\ \sigma_a \cdot \varepsilon_0 = 3.81837\ \mu m \tag{11}$$

The dimensional expectancy values $m_{A,}$ m_a of the gap height by virtue of Eqs. (8), (10), and (11) are estimated in following intervals:

$$48.68\ \mu m = m_A - \sigma_A\ \leq\ m_A\ \leq m_A + \sigma_A = 56.32\ \mu m$$
$$43.68\ \mu m = m_a - \sigma_a\ \ \leq\ m_a \leq m_a + \sigma_a = 51.31\ \mu m \tag{12}$$

The abovementioned analysis of surface random parameters for end prosthesis can be applied in other implants too **[L. 11, 12]**, based on the author's experience.

FINAL CONCLUSIONS AND RESULTS

1. After calculations from Eq. 4 to Eq. 12, it follows that the gap height increments and decrements caused by abrasive wear of endoprosthesis surfaces attain about 10%.
2. By virtue of intervals of expectancy gap height values Eq. 5 to Eq. 12, we have shown that the differences between the load carrying capacity for hydrodynamic pressure with random effects for pressure calculated from Eq. 4 for $\sigma \neq 0$, $\delta \neq 0$ and load carrying capacity without stochastic effects (i.e. for $\sigma = 0$, $\delta = 0$), attain about 20%.
3. The lubrication and load carrying capacity determination for a human hip endoprosthesis, considered without random analysis of gap height between two unworn cooperating surfaces is incorrect and gives large inaccuracies.

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Streszczenie

Na podstawie danych statystycznych WHO przeprowadzonych w Unii Europejskiej stwierdzono, że system tribologiczny, jaki tworzy endoproteza, doznaje ponad milion obciążeń o charakterze udarowym. Obciążenia dynamiczne mogą w wielu przypadkach przekraczać czterokrotną wartość ciała pacjenta. Znaczna część takich niepożądanych impulsów kończy się koniecznością ponownej wymiany endoprotezy biodra.

Badania doświadczalne wielu badaczy potwierdzają, że po wszczepieniu endoprotezy stawu biodrowego mamy często do czynienia z obszarami przeciążenia i niedociążenia. Zarówno jedne, jak i drugie są niekorzystne w trakcie eksploatacji endoprotezy. Po wszczepieniu trzpienia do kanału kości udowej pod wpływem siły mogą pojawić się pewne mikrometrowe przemieszczenia trzpienia względem cementu kostnego. Zarówno opisane przemieszczenia, jak też obszary przeciążenia i niedociążenia są na ogół powodowane niestosowną geometrią powierzchni zewnętrznych i wewnętrznych endoprotezy uzależnioną od chropowatości powierzchni, która ma bezpośredni wpływ na wysokość szczeliny. Klasyczne generowanie procesu produkcji i wytwarzania endoprotez o optymalnej strukturze geometrycznej powierzchni jest bardzo trudne, a w wielu przypadkach wręcz niemożliwe. Dlatego niezbędne jest uprzednie stochastyczne kształtowanie struktury geometrycznej projektowanych endoprotez polegające na oszacowaniu losowych wartości oczekiwanych, czyli średnich wartości probabilistycznych oraz odchyleń standardowych optymalnych wysokości mikrochropowatości powierzchni, które mają bezpośredni wpływ na pożądaną wysokość szczeliny, siły nośne, siły tarcia, wartości zużycia, a w końcu na optymalną możliwość implantacji endoprotezy stawu biodrowego człowieka.

Wyniki niniejszej pracy uzyskano na podstawie przeprowadzonych badań eksperymentalnych dotyczących pomiarów struktur geometrycznych powierzchni endoprotez oraz z wykorzystaniem wiedzy teoretyczno-numerycznej. Ukazane w niej rezultaty prezentują metodologię i cele opisanej idei badawczej, umożliwiając szeroką dyskusję potrzebną do dalszych badań w zakresie projektów bioinżynierii.

Przedstawiony został również parametryczny opis parametrów powierzchni endoprotez. Mogą one również znaleźć zastosowania przy probabilistycznej ocenie parametrów struktur geometrycznych powierzchni rozmaitych implantów.