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A. JASIK*,#, M. MROCZEK**

THE INFLUENCE OF MECHANICAL, AND MATERIAL FACTORS ON THE BIOLOGICAL ADAPTATION PROCESSES OF THE FEMORAL BONE IMPLANTS

Abstract. The study covers some aspects of the issue of determination of mutual connections between the mechanical and material factors, as well the biological implant adaptation processes. The main objective of the operation was adopted to develop models of cementless hip prosthesis company Fitmore Zimmer, taking into account the heterogeneity of material properties of bone tissue. These models were loaded in particular stages of the human gate and then they were used for the analysis of stress changes. The identification of the relations between the mechanical properties of osseous tissue required the conducting of computer simulations by means of the Finite Element Method (FEM).

Keywords: orthopedic implants, stress, Finite Element Method (FEM)

1. Introduction

While making an attempt to define the requirements that should be fulfilled by the modern bone implant, two main groups may be distinguished among them. The first one determines the success conditions compliant with the criteria that guarantee obtaining a durable connection between the graft and the bone, paying particular attention to the influence of geometrical features of the implant on the load apportionment in the bone. The second group comprises imitation of the characteristics of natural arrangement susceptibility. This group should include the issues of suppression of dynamic loads and mitigation of static overloads. These features must be examined in connection with biocompatibility of the materials used for the implants and with consideration of reaction of the organism in the system of conjunction between the features of a mechanical and physiological nature. The specified features have been considered to various extents in particular solutions of grafts used nowadays.

The characteristic element of the specified requirements is the significant role of the mechanical factor in anchoring the implants. Therefore, the methods of assessment of anchoring quality should be to a great extent based on the laws from the field of mechanics. The study covers some aspects of the issue of determination of mutual connections between the mechanical and material factors, as well the biological implant adaptation processes. Despite the large number of studies relating to this issue, a lot of phenomena occurring in the human organism after the implantation procedure remain unexplained. There is still a need to develop a new model approach of the specified phenomena that imitate the complex geometrical and material structure of bio-mechanical systems occurring after the surgery in a more exact way. This relates both to the specificity of performance of the new implant solutions and to the possibility of a more exact understanding of the mechanisms that are responsible for adaptation processes. The study focuses on selected types of hip joint implants, simultaneously comparing the results of model tests of the motor organ equipped with implants with examinations of natural organs.

A lot of studies have been devoted to the issue of determination of stress distributions in the femur equipped with various types of implants, and there are some papers in which loads affecting the hip joint in the conditions of movement were determined [1-13]. These loads were determined according to analytical and experimental methods. However, there is still a need to determine the stress distributions around the implants, in various types and phases of movement, and changeable over time. This issue seems to be important for assessment of the quality of implant anchoring in terms of mechanical criteria. There are a lot of aspects of this issue, including the durability aspect connected with assessment of the durability of the grafts themselves and the surrounding bone tissue. The issue of mutual relationships between the state of stress and deformation, and the state of bone tissue surrounding implants, which is presented for hip joint endoprosthesis in a particularly extensive way and described in a lot of studies, is equally important [1-5]. The biological adaptation processes of the femoral bone implants showed Philips et al. [14] and Miller et al. [15].

At a lot of studies the macroscale bone have been considered as a continuum without voids, with material properties assigned across elements based on empirical relationships between computed tomography attenuation values, density and Young's modulus [16-18].

Finite element modeling is a method which allows the analysis of the spatial distribution of stress and strain fields generated by an applied force on an object [19]. Zhi-Qiang Lian et al. [7] showed how to obtain a better understanding

* SILESIAN UNIVERSITY OF TECHNOLOGY, FACULTY OF MATERIALS ENGINEERING AND METALLURGY, 8 KRASIŃSKIEGO STR., 40-019 KATOWICE, POLAND

** SILESIAN UNIVERSITY OF TECHNOLOGY, FACULTY OF MATERIALS ENGINEERING AND METALLURGY GRADUATE, 8 KRASIŃSKIEGO STR., 40-019 KATOWICE, POLAND

Corresponding author: Anna.Jasik@polsl.pl

of the procedure of bone grafting surgery by finite element analysis, with more focus on the comparison of mechanical environment before and after surgical operation in femoral head. The finite element method is one of the most frequently used methods in stress analysis in both industry and science [5].

Three-dimensional finite element analysis has been widely used for the quantitative evaluation of stresses on the implant and its surrounding bone. FEA was selected for use in this study to examine the effect of the structure and elastic modulus of dental implant on the stress distribution at implant–bone interface [20,21]. Eskitascioglu et al. [22] demonstrated that vertical loading at different locations resulted in high stress values within the bone and implant.

2. The purpose and scope of work

Taking into account the available studies relating to the issue of the durability of orthopedic implants, and assessment of the necessity for further research on the phenomena of engraft adaptation in the human organism, development of natural hip joint models and models of hip joints with Fitmore cement-free prosthesis produced by Zimmer, which take into consideration the heterogeneity of material features of the bone tissue, were adopted. This approach should ensure the possibility to determine the relationships between local values of mechanical parameters constituting the potential factors stimulating the processes of bone tissue reconstruction. The developed models took into account the heterogeneity of material features' distribution in bone capacity through introduction of the structure with diversified mechanical features.

3. Methodology for analysis of stress distribution in the femur

In physiology and in pathological processes of the hip joint, an important role is played by mechanical influence. During walking, the femur head is systematically loaded; this phenomenon will decide on proper metabolism of the articular cartilage and bone tissue [4,9]. The passive human motor system may carry very big loads. The value of these loads depends on the speed and method of moving. Lower limb joints have proper structure to minimize the negative effects of the loads [23].

Determination of the impact of mechanical and material factors of adaptation processes required the performance of computer simulations using the finite element method (FEM).

The Fitmore endoprosthesis, more and more commonly used in endoprosthesis, was selected.

Algor software was used for numerical calculations. Algor program computational procedures are closed, and procedures are not available to the user of the software.

In this model calculation assumes isotropic linear-elastic material, therefore it should be assumed, that are the applied classical equations involving stress tensor and a strain tensor, as:

$$T_\sigma = Q \cdot T_\varepsilon \tag{1}$$

where:

T_σ - stress tensor,

T_ε - strain tensor

Q - stiffness tensor.

In the whole capacity of the femur, the linear-elastic isotropic material model was adopted. Diversified component features were assumed in the femur models (Tab.1). In addition, different values of elasticity modulus and Poisson's ratio were assumed for particular components. For the natural femoral bone model, averaging thickness values of particular layers were assumed: cortex bone tissue, spongy bone tissue and cartilage bone tissue. In the model after alloplasty of the Fitmore stem, the area of the material constituting the stem of the endoprosthesis were taken into consideration.

TABLE 1

The properties of the components of the bone model femur – prosthesis

Components	Modulus of elasticity E [MPa]	Poisson ratio υ
Cortical bone	15 x 10^3	0,29
Spongy bone tissue	10 x 10^3	0,38
Fitmore endoprosthesis steam and head	11,4 x 10^4	0,33

Three types of Fitmore endoprosthesis with various neck inclination angles: 140,137,127, were modelled in Alibre Design software. Geometrical features of the models were selected on the basis of Zimmer's catalogue. These models were designed on the xz plane. Figures 1 and 2 present the modelled stems of the discussed endoprosthesis, as well as the head with a 36 mm diameter. Thanks to the function of Boole's algebra it was possible to assemble the stems with the head (Figure 3) and then to insert the ready endoprosthesis into the bone. The modelled prostheses' stems were assembled with the femur model.

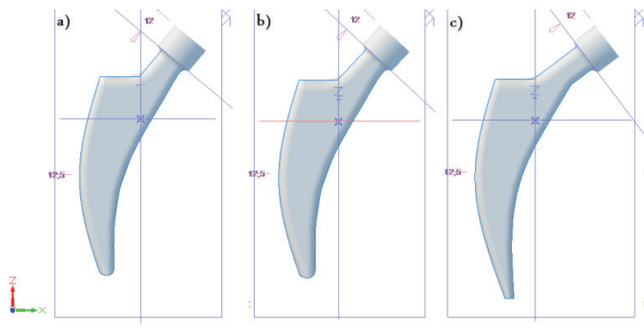

Fig. 1. Model of endoprosthesis stems: a) Fitmore A, b) Fitmore B, c) Fitmore C. View in front plane

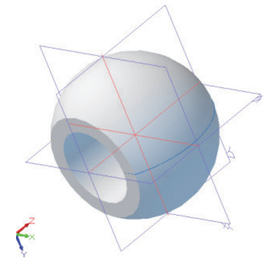

Fig. 2. Model of Fitmore endoprosthesis head

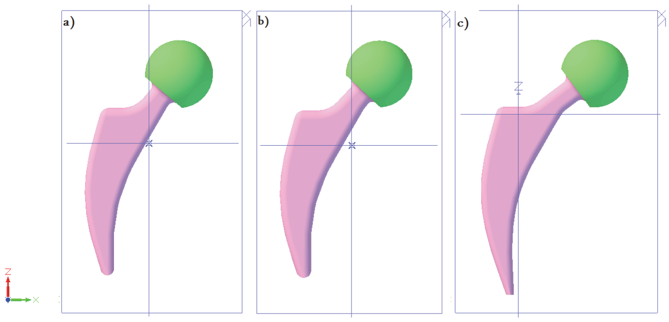

Fig. 3. Model of endoprosthesis: a) Fitmore A, b) Fitmore B, c) Fitmore C. View in front plane

After designing the endoprosthesis models in Alibre Design software, computer simulation was conducted in Algor software with the use of the finite element method (FEM).

The main assumption of FEM is division of the continuous geometric model into finite elements that are linked in so-called nodes, consequently creating a discrete geometric model. The result of the discretisation is a transformation of the system with an infinite number of degrees of freedom into a form of the system with a finite number of degrees of freedom. During calculations, all other physical values represented in the system by means of continuous functions (e.g. loads, fixing, stress) [9,23] underwent simultaneous discretization. A mesh was generated for the examined area, dividing the model into a finite number of geometric primitives (Figure 4). In the program ALGOR were generated mix of bricks, wedges, pyramids and tetrahedra finite element mesh type. Individual models of the femur after endoprosthesis implantation were divided into a mesh with the following number of elements: for Fitmore A -15309, for Fitmore B-15791, for Fitmore C -15832.

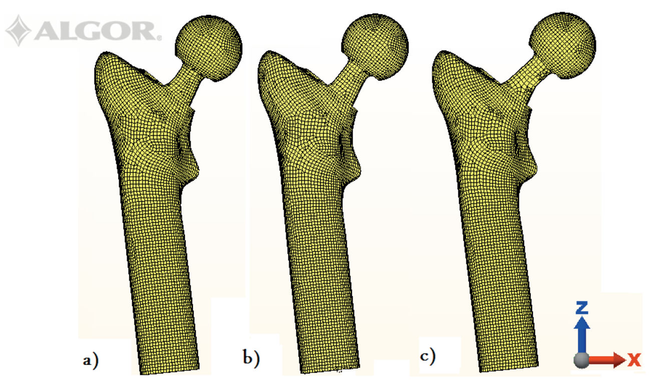

Fig. 4. A mesh for the model of the femur after endoprosthesis implantation: a) Fitmore A, b) Fitmore B, c) Fitmore C. View in front plane

To characterize the effects of the combined effect of stress at a particular point use the concept of tension σred replacement. Its value defines Strength theories, involving the possibility of finding a point for the different states of stress common measure stress intensity. The most commonly used hypothesis is a hypothesis Huber which is used for materials with different properties - both plastic materials and fragile [24]. According to the hypothesis Huber stress substitution is expressed as:

$$\sigma_{red} = \frac{1}{\sqrt{2}} \sqrt{(\sigma_X - \sigma_Y)^2 + (\sigma_Y - \sigma_Z)^2 + (\sigma_Z - \sigma_X)^2 + 6\left(\tau_y^2 + \tau_z^2 + \tau_x^2\right)} \quad (2)$$

The models were fixed and loaded. The surface of contact compliant with the anatomical one was adopted for the endoprosthesis head, and it was loaded with the pressure of the value corresponding to the natural load of the femur head. In the designed endoprosthesis, the influence of the forces of abductors Q_m and P_m, of various directions and values that affect the greater trochanter of the femur, was taken into consideration.

Table No. 2 and Figure 5 present the values of loads of the model of the natural femur with the implanted endoprosthesis for the 16th phase of the human walk. It is representative of the phase of human gait - load right lower limb. The two hemi pelvises are on the same frontal plane. The pelvis inclines toward the limb in stance increasing the cover of the superior quadrants of the femoral head [25].

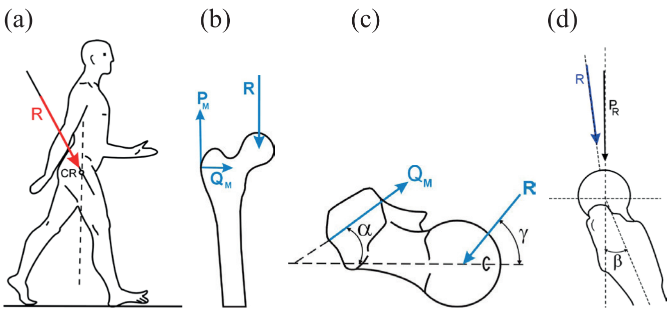

Fig. 5. Loading of the femoral bone during human motion: (a) – effect on the femoral bone head: the phase of lifting the leg off the ground, (b) – forces distribution in frontal plane, (c) – forces distribution in horizontal plane [25]

The zone corresponding to the area of the iliofemoral ligament was loaded with pressure operating in three directions: of x-, y and z-axis. The iliofemoral ligament stretches spirally from the hip bone to the femur, performing the function supporting the articulations and protecting the hip joint [26].

This work not included wear tribological processes hip. In many works were presented this problem [27-29].

TABLE 2

Values of loads of the model of the femur with the implanted endoprosthesis [25]

Gait phase	16
R [N]	1117,85
Q_m [N]	303,7
P_m [N]	791,3
α [°]	5,5
β [°]	2,2
γ [°]	9,8

R – resultant reaction of the influence into femur head,

Q_m – trochanter muscles action,

P_m – trochanter muscles action,

α - angle of inclination of force Q_m

β – femur inclination angle during human gait

γ - angle of inclination of force R

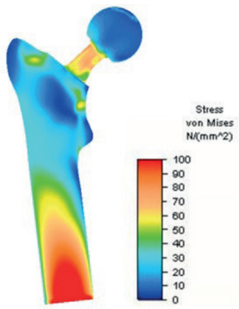

Fig. 6. Distribution of reduced stresses determined according to Huber hypothesis in a model of femur after implantation of endoprosthesis Fitmore C. Coronal plane view

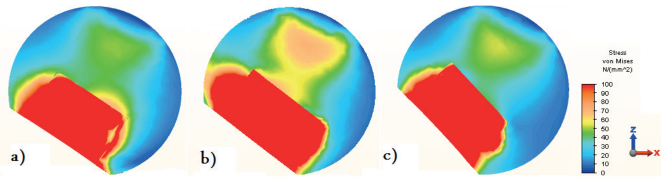

Fig. 7. Equivalent stress distribution determined in compliance with Huber's hypothesis for a section of the head of the endoprosthesis. View in the sagittal plane

4. Results

Research on the mechanical states comprised analysis of the state of stress and deformation in the hip joint after implantation of Fitmore stems with various neck inclination angles. The performed numerical calculations allowed for determination of stress distributions in the hip joint after implantation of various types of endoprosthesis. In order to characterize the effects of the combined influence of stress in a determined point, the concept of equivalent stress σz was used. Its values are defined by the equation hypotheses, assuming the possibility of finding a common measure of stress intensity for various stress states in a point. For the analysed models, the stress distributions were determined in compliance with Huber's hypothesis.

While analysing the distribution of the equivalent stress in the model of femur with the implanted endoprosthesis it was noted that below the greater trochanter it is similar to the one that is even along the bone axis (Fig. 6). Implantation of Fitmore endoprosthesis stem leads to de-loading of the area of the femur along the stem and redistribution of stress in all areas of the stem of the femur. The place of 'leaning' of the prosthesis stem is de-loaded in this case.

While analysing the stress distributions for sections of endoprosthesis' heads (Fig. 7) it may be stated that they were properly loaded, since stress obtained the characteristic shape of a sandglass. Stress distribution in the artificial head is similar to the anatomical arrangement of bone trabecules. This is a compression strip, extending from the upper quadrant of the femur's head to the Adams arch. The second overload area is a mirror reflection of the first one; it runs from the lower quadrant of the femur's head to the opposite place on the Adams arch. The most loaded place is the area of contact of the head with the stem of the endoprosthesis.

In order to determine the values of equivalent stress, characteristic areas of de-loading of the bone tissue were selected. Fig. 8 presents the selected area marked with No. 1 for the models of: stems of the prosthesis and natural bone after implantation. It characterises the influence of the prosthesis stem on the bone tissue in the area of the Adams arch. Charts of stress for the selected area were made in Algor software. Distance in the direction of the x-axis.

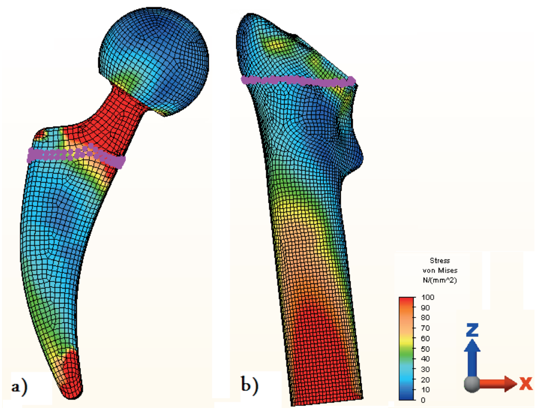

Fig. 8. Selection of area No. 1 for detailed stress analysis (marked with pink dots): a) in Fitmore C endoprosthesis, b) in the bone. Coronal plane view

This results from the chart of dependence of σz on the distance in the direction of the z-axis that equivalent stress in the bone is very little; its greater values stay within the range of 0-12 MPa. On the other hand, equivalent stress occurring in the prosthesis in area No. 1 is almost ten times bigger. Based on this, it may be concluded that de-loading of the femur with this type of implant may result in instability of the stem, or even fracture of the bone.

In the determined stress distributions for the Fitmore B prosthesis – as in the previous case - it may be observed that the prosthesis transfers the majority of loads. The greatest values of stress for the Fitmore B endoprosthesis amount to ~93 MPa, while in the bone they are almost three times lower ~ 32 MPa. On the other hand, the greatest values of stress for the Fitmore C endoprosthesis amount to ~80 MPa, and they are caused by the significant load on the neck. In the bone, this stress fluctuates within the limit of 50 MPa. It is probably caused by the geometry of the analysed case.

For a clearer illustration of the obtained results, a couple of characteristic points of equivalent stress were selected, which were then averaged. The values of average equivalent stress for the selected area of the prostheses and bones that were subjected to the analysis were compared on the charts (Fig. 9). It was assumed that the symbol of the prosthesis is the equivalent of bone marking. For example, the name ‘bone A’ was assigned to the Fitmore A prosthesis.

This results from the charts of average equivalent stress σz that in area No. 1 (Fig. 9a) the greatest values of this stress for the prostheses occur in the Fitmore A model, and they amount to ~102.33 MPa. This stress is 1.5 times greater than in the other two models, in which these values fluctuate within the limits of ~72-82 MPa.

In the case of equivalent stress occurring in the bone in area 1 (Fig. 9b), an opposite situation may be observed, e.g. the greatest equivalent stress occurs in bone C (~40 MPa) and B (~31 MPa). On the other hand, bone A transfers the least loads in this area, taking values that are close to ~26 MPa.

a) b)

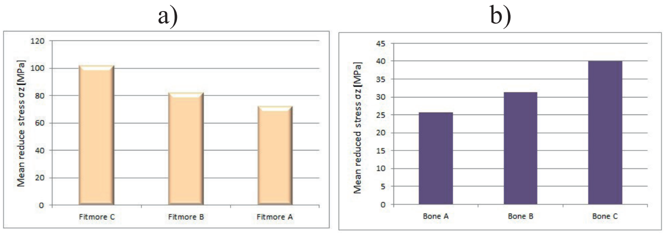

Fig. 9. Cumulative list of mean reduced stress σ_z in area 1 for: a) endoprosthesis b) bones

All the groups of Fitmore prostheses subjected to the analysis, varying by neck inclination angle, distance from the middle of the stem to the middle of the head, and the length of the stem in relation to its main contour. These differences allow for more exact reconstructions of the femur and for better adjustment of the endoprosthesis to the patient’s anatomy. This results from the research showing that the most frequently selected prosthesis comes from group B, as it has the biggest range of distances from the middle of the stem to the middle of the hand. On the other hand, hip varus may be treated by the prostheses from group C.

Fitmore system implants have a rounded shape that allows for protecting the bone. A short section of the stem with a hooked shape allows for maintenance of the natural construction of the greater trochanter of the patient’s bone. The endoprosthesis is fixed at the bottom of the femur in the intertrochanteric area. The streamlined shape of the prosthesis and a short stem allow for small interference in the bone. The analysed prosthetic arthroplasty system ensures stable reconstruction of individual parts of the bone and reinstatement of the biomechanical properties of the femur due to its innovative concept of adjustment in various curvatures. The construction of the stem and the closer part allow for safe implantation of the cement-free endoprosthesis according to the press-fit method.

5. Summary

The analysis of stress distributions in the hip joint has shown significant changes in the field of loading and de-loading of the hip joint. The functionality of implants is conditioned by stress distribution in the artificial hip joint. The closer the stress values in the prosthesis to stress in the bone, the better the functioning stem of the endoprosthesis. Fitmore B and C stems de-load the natural bone the least - they perform their function best in the artificial hip joint. The smaller the angle of endoprosthesis neck inclination, the better the functionality of the stem. It should be borne in mind that the results of FEM analyses present performance of the system in an approximate way, and they are always burdened with some error. The precise assessment of the approximation error is impossible due to lack of knowledge on the ‘true’ solution; yet, based on the form of the finite elements of the solved issue, it may be limited in order to determine the method’s quality [30,31].

The shape of the prosthesis that is maximally comparable with the form of the medullary cavity duct, which is presented in the study by means of Fitmore prostheses’ models, is the achievement of modern engineering and biomechanics. Construction solutions of the hip joint endoprostheses should move towards achievement of a shape which – with the application of a proper material – would ensure that stress and dislocation distributions in the bone with the endoprosthesis are as close to respective distributions in the natural bone as possible. In order to ensure good functionality of the artificial hip joint, development of an endoprosthesis with a flexible stem should be strived for, since the stem should be made for the bone, not the bone for the stem.

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