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DEVELOPMENT OF THE ENDOPROSTHESIS OF THE FEMUR ACCORDING TO THE CHARACTERISTICS OF A SPECIFIC PATIENT WITH USING MODERN METHODS FOR PRODUCT DESIGN AND RAPID PROTOTYPING

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ABSTRACT

Arthroplasty of the hip joint is one of the most widely implemented endoprothetical aids in humans. Each year, around 800,000 operations such this are done in the world. The main factors influencing the success of the surgery are the operative procedure, the degree of adaptation elements of prosthesis to the patients, and its mechanical properties. Due to the large number of influencing factors, the best results are achieved by the development of prostheses tailored to the patient. The custom-made development of the endoprosthesis body includes four group activities as follows: data acquisition from diagnostic images and the reconstruction of the morphology of the affected elements of the skeletal system, definition of a computer model for a hip endoprosthesis, verification using the appropriate computer analysis and production of physical prototypes by applying of rapid prototyping methods.
This paper describes the specific activities in the development of hip endoprosthesis specifying their advantages and limitations. The presented results are the part of the research on development of the custom made endoprostheses at the Faculty of technical sciences.
Keywords: *custom-made endoprsthesis, hip joint, CAD, CAE, Rapid Prototyping.*

1. INTRODUCTION

Medical imagining is an area of medicine that deals with the generation of images of the human body for diagnosis by computerized imaging method. These methods show the cross-section of the body in layers of specified thickness.

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The intensity of life activities and illnesses occurring as a consequence have a significant impact on the elements of the locomotion system. In everyday physical activities, every person makes approximately 10,000 steps per day[1], and as the consequence, the elements of the hip and knee joints suffer the most, since they are exposed to the most intensive workloads. Due to the problems in these elements of the locomotion system, there are about 800,000 total hip replacement surgeries performed yearly worldwide [2].
According to the form and manner in functioning, the hip is a spherical joint establishing the connection between the pelvis and the femur. This joint consists of several elements, as presented in Fig. 1.

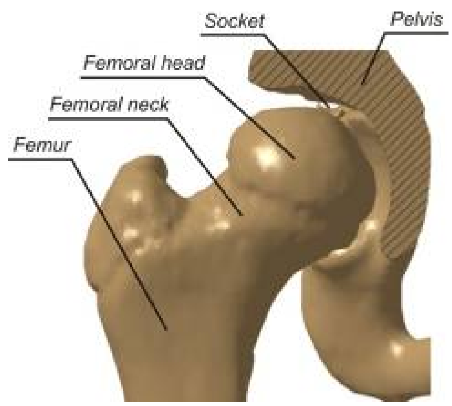

Fig. 1. - Elements of the hip

Operative treatment of replacing the natural with the artificial hip joint is generally composed of several phases: separation of the natural femoral head and the neck from the femur bone (Fig. 2a); installation of the acetabular component presenting the artificial seat of the hip joint (Fig. 2b); installation of the endoprosthesis body into the medullary channel of the femur bone with the elements replacing the natural neck (Fig. 2c); setting of the artificial head to the neck of the prosthesis body (Fig. 2d); and, connection of elements of the artificial hip joint into a unity (Fig. 2e) [2].

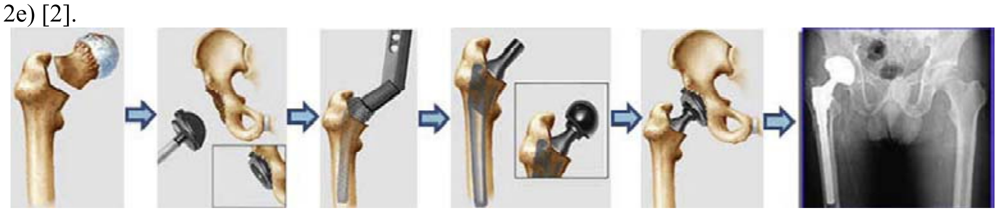

Fig. 2 - Phases of the operative treatment of replacing the natural with artificial hip join

The success of the operative treatment of replacing the natural hip joint with the artificial one is measured by the time period necessary for the recovery of the patient and the exploitation life of the prosthesis. The main factors influencing the success of the surgery are the operative procedure, the degree of adaptation of prosthesis elements to the patient, and its mechanical properties.
From the aspect of the development of the endoprosthesis, the most significant element of the artificial hip joint is the femoral stem. It provides the connection between the hip joint and the

femur, and it overtakes the largest workload during the physical activities. In developing the endoprosthesis body, it is important to bear in mind that the femur is the mechanically most loaded bone in the human locomotion system.
The success of the installation of the hip joint endoprosthesis, as well as the exploitation life in the organism, depend on many factors, from which the most important one is the proper selection of the shape and the size of the endoprosthesis body. The most common method for the development of the endoprosthesis is the "methodology of the typization". Beginning with the stated methodology, the most common method is the systematization of endoprosthesis according to the type (primary, revision…), the dimensions (usually up to 10 per type), and the mode of fixing into the femur (cement, cementless). The selection of prosthesis for a particular patient, from the offered set of prosthesis, is based on the following: the complexity of the disease, patient's age and femur dimensions.
In the recent year, the research in the area of biomedical engineering has been directed towards the development and manufacture of prosthesis according to the morphological characteristics of a patient (so-called custom-made endoprosthesis). This type of endoprosthesis, apart from femur dimensions and shape, maximally considers the type and the extent of the disease [4], as well as some other parameters. The objectives in the development of the hip joint endoprosthesis tailored for a specific patient are the maximum design speed providing minimal invasiveness in the operative treatment, short recovery period and long exploitation life of the implant. This can be achieved by using the computer technologies that enable the design, analysis and simulation of the product behaviour in all developmental stages. The custom-made development of the endoprosthesis body includes four group activities [5] as follows:

- Data acquisition from diagnostic images and the reconstruction of the morphology of the affected elements of the skeletal system;
- Definition of a computer model for a hip endoprosthesis;
- Verification using the appropriate computer analysis of virtual prototype; and
- Production of physical prototypes with using rapid prototyping methods and analyses his compatibility with femur.

The paper describes the activities in the development of the hip joint endoprosthesis tailored for a specific patient, as well as the tendency to develop each of these based on the contemporary research in the area.

2. DATA ACQUISITION AND FEMUR MORPHOLOGY RECONSTRUCTION

Determining the properties of the diseases in the elements of the human locomotion system largely depends on the sharpness and the quality of images used in diagnostics. Furthermore, for the development of endoprosthetic implant the significant role is attributed to the recording method, recording angle and device calibration. Hence, in the past years, there has been an intensive development of the methods based on the spatial images of the diseased limb (mainly by applying tomographic recording methods) [6], which generate digital copies of the desired cross-section of the subject. In medicine, and hence in the orthopaedics as well, the most commonly used are the computerized tomography (CT) and magnetic resonance imaging (MRI). Both methods allow the generation of a series of images showing the cross section of the diseased tissue (Fig. 3).

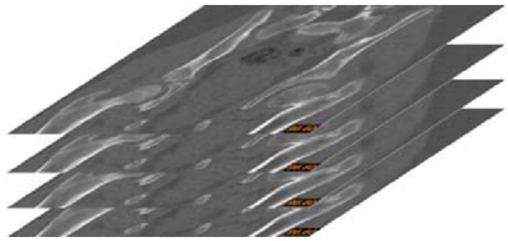

Fig.3 - CT image of the pelvis region

The application of the tomographic imaging in diagnostics enables the determination of the type and the extent of the disease, as well as the measuring of characteristic sizes of the diseased limbs [6]. This enables the possibility to define the geometric parameters of the femur [3]. In addition, the application of tomographic methods provides prerequisites for the formation of spatial computer models of the diseased limb in order to design the endoprosthesis, and in later phases, to simulate its behaviour in the exploitation conditions, as well as to simulate the surgical procedure. Modelling of the diseased femur, among others, is performed by applying specialized software systems for the reconstruction of tomographic images. This procedure consists of three following activities:

- Preparation activities;
- Manual or automated segmentation of the bone and tissue mass;
- Definition of output data in the form of a database containing the coordinates of the cloud of points or the creation of a volumetric model by introducing volume elements (voxels) between segmented image planes.

First, the preparation activity, includes the processing of diagnostic images most commonly in the form of a series of image planes with the cross section of the recording object. It implies the correction of contrasts in order to segment the bone mass more easily, as well as the input into the software system for the reconstruction of the bone system morphology.

Tissue segmentation includes the identification of the image area belonging to relevant organs. This is one of the most significant steps in the reconstruction process based on the series of images, and the accuracy of the generated model highly depends on it [2]. Fig. 4 presents the diagnostic image and the segmentation of the femur bone tissue.

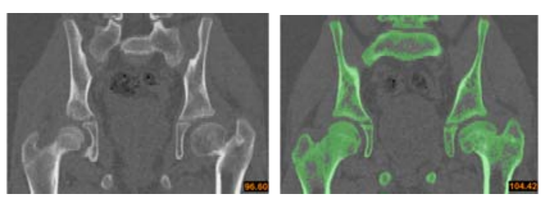

Fig. 4 - Example of the hip segmentation on a diagnostic image

Further process in the organ reconstruction (in this case, femur and its medullary channel) includes the generation of the characteristic points which describe the formation of a spatial femur model. A simpler form in the femur description is the cloud of characteristic points (Fig. 5) which is suitable for further processing [7] and the reconstruction of the areas in the CAD software systems (CATIA, PTC Creo, and the like).

Fig. 5 - Cloud of points describing the femur

The model of the affected skeleton segment can also be obtained by replacing the elementary unit (pixel) images with spatial elements (voxels), realized in the specialized software system for the reconstruction of the tomographic images (ScanIP, Mimics, etc.). As a result, the volumetric model of the reconstructed femur is obtained (Fig. 6).

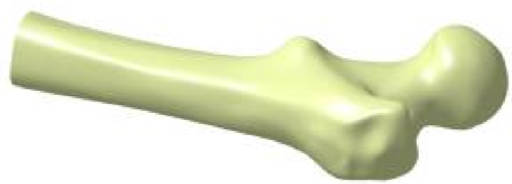

Fig. 6 - Computer model of the femur

Both described procedures allow the generation of a computer model suitable both for defining the necessary parameters and for computer verification of the designed endoprosthesis body.
The reconstruction of the femur geometry implies the reconstruction of the outer and the internal geometry of the femur, i.e. medullary channel. Spatial model of the internal geometry of the femur, obtained by the reconstruction of the points of clouds, is presented in Fig. 7.

Fig. 7 - Computer model of the medullary channel

3. DESIGN OF THE ENDOPROSTHESIS

Design of the endoprosthesis body tailored for a specific patient, from the application of tomographic image methods of the patient, is based on defining the following: characteristic cross sections of the endoprosthesis based on the adequate cross sections of the femur (Fig. 8a) and the properties of the medullary channel in it. The subsequent design phases for the endoprosthesis imply the formation of the geometric surface around the defined cross sections and hence the formation of the endoprosthesis body (Fig. 8b).

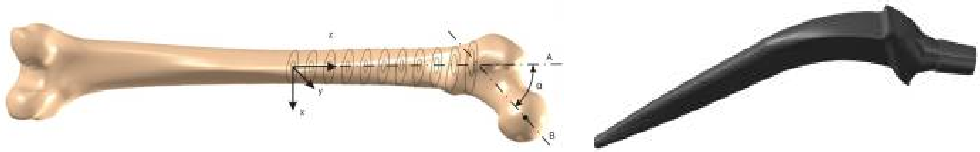

Fig. 8 - Computer model of the femur (left) and the endoprosthesis body (right)

In order to minimize the period for designing the endoprosthesis body, there are two methods utilized for implementing the influential parameters (geometric, exploitation and operative) into the geometric form creating the computer model of the endoprosthesis body. Both methods, apart from including the existing ones, also allow for the introduction of new influential factors. These two methods are as follows:

- Method of parameter modelling, and
- Method for model definition by applying general mathematical laws (general mathematical models).

Parameter modelling is the most suitable method for creating computer models for a group of products with the similar geometry. In the case of the endoprosthesis body, it implies the typization of elements of its geometry, separate individual definitions of each element, and the definition of constraints. Geometry of the endoprosthesis body consists of a series of surface or volumetric shapes that determine the lower (distal), middle (medial) and upper (proximal) segment of the endoprosthesis. The method of parameter modelling, most common, apart from the generalized geometry defined by general sizes, also includes the application of a database containing the values of these sizes (Fig. 9).

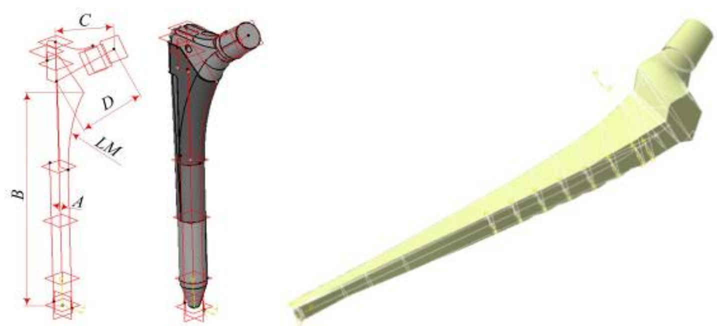

Fig. 9 - Appearance of the parameter model [8,9]

The parameter modelling method is suitable for application in designing the body of the hip endoprosthesis when the Rtg method is used for diagnosing the disease. The application of the Rtg method can be used to define the limited number of geometric parameters of the femur. The advantage of this method is in the relatively simple automation of the geometric parameter input, since it is a plane imaging. Drawbacks of this method include complexity and “rigid” structure of the model. That structure disables the introduction of new geometric parameters into the design process.

Second method, in which the geometry of the endoprosthesis body is described by applying spatial generated models, is based on the application of mathematical laws made from polynom expressions. This method is suitable to describe parts of complex geometric forms [10]. This general mathematical method for describing the endoprosthesis body, due to its generalized form, has several advantages in relation to parameter modelling. They primarily include the significantly more flexible procedure for describing the geometry that can be utilized for more types of endoprosthesis, and the final model form which contains the decreased number of geometric elements. The most commonly used are polynom and rational Bezier curves[1] and similar functions. Fig. 10 shows a segment of the general model of an endoprosthesis body for a hip joint developed by applying the rational Bezier function.

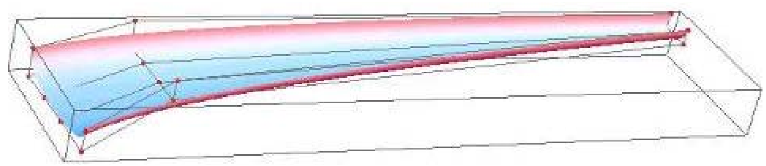

Fig. 10 - Segment of a general model of an endoprosthesis body

4. VERIFICATION OF THE SOLUTION

The final phase in the development of obtained solution of the endoprosthesis according to the characteristics of a specific patient is verification. It is carried on: a computer model (virtual prototype) trough verification of behavior in exploitation conditions and on the physical prototype trough geometrical analysis of the shape and dimensions.

For the verification of the design methodology is created computer model of endoprosthesis body by the femoral sample that are scan with MRI device. Then are conducted analysis of the stress and life on virtual model of the endoprosthesis and the analysis of the geometry of the physical prototype, obtained by rapid prototyping

4.1 Computer verification

Verification of the solution includes the evaluation of the endoprosthesis behaviour using the computer simulation in exploitation conditions by applying software systems for the computer model analysis with the finite element method [Heller, Weinans]. Considering the properties of tension and the conditions to which the endoprosthesis can be exposed under the transfer of the force from the leg to the pelvis and vice versa, it can be observed that the endoprosthesis and the artificial joint are exposed to constant workloads (static ones in standing and dynamic ones in motion). Behaviour analyses in static and dynamic conditions are used to evaluate the developed solutions, as well as to optimize geometric parameters of the endoprosthesis from the aspect of static, kinematic and dynamic properties. Regardless the software system that performs the verification of the endoprosthesis body and the type of analysis, the procedure itself includes the following: discretization of the developed model (Fig. 11), definitions of workload, environmental conditions and constraints, and the calculations of forces and deviations in individual model nods.

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[1] *Bezier curves were developed by Pierre Bezier for the demands of the automobile factory Renaults at the beginning of 1960s [10].*

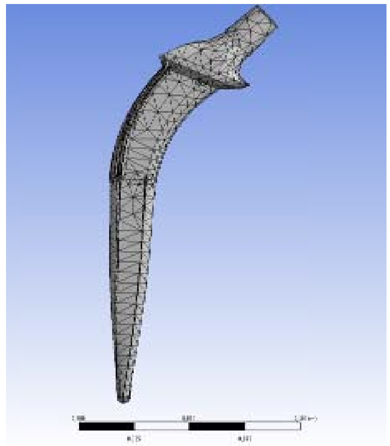


Fig. 11 - Discretized model of the endoprosthesis body of the hip joint

The success in the simulation of the endoprosthesis behaviour depends on defining the forces and constraints which can be obtained by biomechanical analyses of the human locomotion system [11]. In doing so, the distal part of the prosthesis provides the positioning in medullary channel of the femur. In orthopaedic practice, the prosthesis body is placed in the femur so that the resultant force is acting at an angle of α=20° to the vertical plane (Fig. 12a). However, the structure of the pelvis and the operative procedure as such (Fig. 12b) can, as a consequence, also have another angle of the action of the resultant force. In order to determine the relation between the angle of the force and the behaviour and the exploitation of the endoprosthesis body in the exploitation conditions, the analyses have been performed for diverse values of this angle. Fig. 12c shows the force angle on the discretized model of the endoprosthesis.

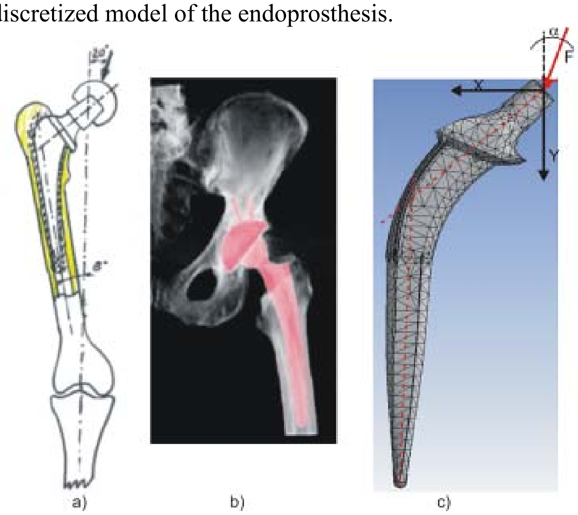
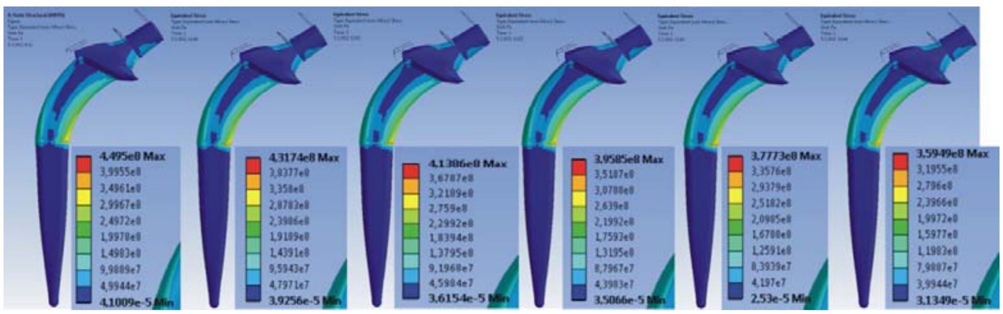


Fig. 12 - Load on the endoprosthesis body of the femur: a) load angle; b) X-ray image of the implanted endoprosthesis; c) force angle on the discretized model in static analysis

4.2 Static analysis

For the analysis on the behaviour of the endoprosthesis body, in static conditions, apart from the load angle and the force intensity (4,000N), incarcerations should also be defined. Most commonly, they are defined as the fixation of a third of the height of the distal part. Fig. 13 shows graphic results, and Table 1 shows maximal values of the Van-Misses stresses depending on the load angle.



α=15° α=16° α=17° α=18° α=19° α=20°

Fig. 13 - Graphic presentation of the equivalent Van-Misses stresses

Table 1 - Maximal equivalent Van-Misses stresses

Load angle [α°]	Maximal equivalent Von-Misses stress σ_{ekv} [MPa]
15	449.5
16	431.7
17	413.8
18	395.8
19	377.7
20	359.4

4.3 Analyses on the exploitation life of the endoprosthesis body

On the other hand, the main objective of implementing the endoprosthesis is the return of the function of the diseased organ for a longer period of time. Therefore, the development of the endoprosthesis for a specific patient must also include the analysis on the exploitation life in the organism. Based on the biomechanical researches, it has been concluded that the twenty-year-long life span of the endoprosthesis implies $N=2*10^8$ cycles [12]. Table 2 presents the life span of the endoprosthesis and the minimal safety factor obtained for the model of total endoprosthesis for the hip joint tailored for a specific patient (in Fig. 14 it is presented within the reconstructed model of the femur).

Table 2 - Minimal safety factor and life of failure shown in cycles for different load angles

[α°]	Min. safety factor	Life of failure x 10^8 cycles
15	1.08	0.9
16	1.18	1.3
17	1.34	1.5
18	1.67	1.7
19	1.98	1.9
20	2.01	2.3

Fig. 14 - Connection of endoprosthesis and femur

4.4 Verification of physical prototype produced by Rapid Prototyping

In order to analyze of the geometry of the body of hip endoprosthesis is made physical prototype designed prosthesis. The method is based on the 3D printing with powder on the ZPrinter 310 Plus device installed at the Faculty of Technical Sciences in Novi Sad. In Fig. 15 are presents ZPrinter 310 Plus device and a physical model of the body prosthesis.

Fig. 15 - ZPrinter 310 Plus device and a physical model of the body prosthesis

The obtained model was subjected to analysis in terms of checking the clearance between the modularly canal of the femur and the physical model by positioning in the appropriate position in the femur (Fig. 16).

Fig. 16 - Physical model of the endoprothesis

The analysis shows that the model of endoprosthesis body satisfies all geometric criteria that are set to the endoprosthesis (size, shape), as well as additional criteria formed due the type of prosthesis (the gap between the body of the prosthesis and the walls of the femoral channel) and operational techniques that are applied during operation.

5. FINAL CONSIDERATIONS

Based on the analyses of papers in the field of designing endoprosthetic implants, acquisition of diagnostic images and biomechanics of the locomotion system, it can be concluded that the future of the endoprosthetics, among others, implies the development of endoprosthetic implants tailored for a specific patient. The reasons include a significantly longer exploitation life of the endoprosthesis designed for a specific patient, shorter post-operative recovery, less invasiveness of the operative procedure, etc.

Further research in the field of medical prosthetics follows the direction of lowering the costs of implants by shortening and partially automating the development of an endoprosthesis. Furthermore, new research is being performed in the direction of including a greater number of geometric and exploitation parameters used for defining the shape and the dimensions of an implant.

The procedure for developing an endoprosthesis body described in this paper contains a combination of three group activities (bone reconstruction based on tomographic images, endoprosthesis design and verification using the FEM methods) which are being developed independently. Hence, the directions of future researches can be observed through their individual development.

Geometric reconstruction of the femur (and other elements of the skeletal system), as well as the definitions of their geometric properties, present a series of standardized activities which can almost entirely be automated by applying adequate software technologies (as well as additional libraries of classes, such as VTK library) [13].

Defining the computer based model of the endoprosthesis based on the general mathematical models and the integration of methods for defining the characteristic parameters (position of individual anatomic surfaces on the femur) can also be automated to a larger degree. Hence, the designer is left with only the key decisions related to the character of the disease and the implementation procedure of the endoprosthesis.

Software systems for computer verification enable the automation of the shape and mass optimization for the endoprosthesis by correcting the adequate parameters on a geometric model of the endoprosthesis prior to its production.

The second part of the verification of the prosthesis obtained by the methods of rapid prototyping provides additional analysis of the obtained solutions that cannot be implemented on computer model. In addition, this allows for the preparation of medical personnel for the implementation of the endoprosthesis.

Further improvement and automation of individual designing phases can greatly shorten the time for the development and the production of an endoprosthesis tailored for a specific patient, which would be a justification for the high price for this type of implant.

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RAZVOJ ENDOPROTEZA ZGLOBA KUKA PO MERI PACIJENTA PRIMENOM SAVREMENIH METODA PROJEKTOVANJA PROIZVODA I BRZE IZRADE PROTOTIPOVA

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REZIME

Artoplastika zgloba kuka predstavlja jednu od najčešće korišćenih ortopedskih pomagala kod čoveka. Godišnje se u svetu se godišnje ugrađuje kod oko 800.000 pacijenata. Osnovni faktori koji utiču na uspeh operacije su operativni postupak, stepen prilagođenosti elemenata proteza za određenog pacijenta, i njene mehaničke osobine. Zbog velikog broja uticajnih faktora, najbolji rezultati se postižu razvojem proteza prema merama pacijenta. Razvoj takvog tipa tela endoproteze obuhvata četiri grupe aktivnosti: prikupljanje podataka iz dijagnostičkih snimaka i rekonstrukcija morfologije pogođenih elemenata skeletnog sistema, definisanje kompjuterskog modela endoproteze zgloba kuka, verifikacija pomoću odgovarajuće kompjuterska analiza i izrada fizičkih prototipova primenom brze izrade prototipova.

U radu se opisuju konkretne aktivnosti u razvoju endoproteza kuka navodeći svoje prednosti i ograničenja.

U radu su opisane karakteristične aktivnosti prisutne u razvoju endoproteza zgloba kuka uz navođenje njihovih prednosti i ograničenja. Prikazani rezultati predstavljaju deo istraživanja dobijenih razvojem endoproteza na Fakultetu tehničkih nauka.

Ključne reči: *endoproteze, zglob kuka, CAD, CAE, Rapid prototajping*