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System Analysis and Synthesis of Total Hip Joint Endoprosthesis

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Abstract

This paper presents new design of total hip endoprosthesis, elements of whose were developed from the standpoint of system analysis and synthesis of biomechanical objects and devices. The main objective of this work is to increase the functional reliability of the endoprosthesis. The system approach was used in all stages of its development, including formulation of the problem and designing of manufacturing techniques.

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Keywords: Hip joint; total endoprosthesis; reliability; system analysis; system synthesis

1. Introduction

"Over the last three centuries, treatment of hip arthritides has evolved from rudimentary surgery to modern total hip arthroplasty (THA), which is considered one of the most successful surgical interventions ever developed" [12]. THA is a complex high-tech surgical procedure in which the joint is replaced with endoprosthesis to restore its function. The main indications for the THA are fractures of femoral neck and their consequences, posttraumatic arthroses, coxarthroses, aseptic necroses of the femoral head, dysplasias, and rheumatoid arthritises [17].

Literature describes the first attempts of the THA, which date back to the XIX century [4], however, it is assumed that the first successful operation to install metal total endoprosthesis was performed only in 1940 by American surgeons Austin T. Moore and Harold R. Bohlman [20,36]. Currently in many clinical cases only THA is

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the radical method of treatment for patients with pathological changes in the hip joint which allows them to return to the active lifestyle and improve the quality of life [22,24,33].

Constructions of endoprostheses and technologies of their implantation seen steady improvement with different viewpoints [11,41,42,44]. Thus have been developed and improved elements of endoprostheses, methods of their fixation, were used different materials and processing technologies of complex surfaces. A brief history of the endoprostheses development is shown, for example, in [26,27].

Modern total hip joint endoprostheses are complex products (with the constructive and technological points of view) and have to meet very strict requirements which determined not only by their functional purpose, but also by accessibility for people needing the THA [7,39]. Currently, on the market widely represented commercially available endoprostheses of the leading world manufacturers: Zimmer, DePuy, Stryker, Smith & Nephew, Biomet, Aesculap and other companies.

The widespread adoption the THA in medical practice made it possible to obtain numerous statistical data about the functioning of endoprostheses in the human body, evaluate their service life and complications associated with THA [18,22,28]. Analysis of the literature indicates that main complications were and remain: osteolysis, instability of acetabular and femoral components, fracture of prostheses stems, increased wear of materials in a friction pair, the occurrence of debris, metallosis, dislocations of endoprostheses, complications associated with infections, with the use of bone cement and others [1-3,5,8-10,13-16,19,21,23,25,29-32,34,37,38,40,43].

Despite a number of serious complications indicated above, the THA is a very effective treatment for patients. But, at the same time, the endoprosthesis, nevertheless, foreign substance in human body as a holistic biomechanical subsystem, organically included in biosocial system which actively interacting with the environment. Thus, during the THA, it is necessary to provide conditions of the most natural implantation of the endoprosthesis into the human body and eliminate the most likely reasons for its rejection [7].

This is a very difficult task, and moreover, its optimal solution in many cases is a unique for each patient. However, at the modern level of engineering and technology in designing and manufacturing of endoprostheses can be taken into consideration many features of person as a specific biomechanical system, allowing to improve the reliability of the THA and the quality of patients life in the postoperative period.

In this paper on the basis of a comprehensive analysis of many modern endoprostheses and results of their implantation, main causes of complications, related with flaws of designs were elucidated. On the basis of the systematic approach, the total hip endoprosthesis, having an improved reliability in comparison with many known analogues, was developed.

2. The main concept of the total endoprosthesis designing

The main elements of total hip endoprosthesis are: femoral component (stem), acetabular component (cup) and head.

Cement and cementless femoral components are distinguished. In turn, they can be classified by shape: a) cement stems: classic, modified, wedge-shaped, elongated auditing, self-centering; b) cementless stems: wedge-shaped with a circular cross section, wedge-shaped with a rectangular cross section, straight anatomical with a collar and without it, anatomical curved, auditing of different length and shape.

According to the level of fixation in the femoral bone canal endoprostheses are subdivided into metaphyseal, distal and distal-metaphyseal. To improve fixation, femoral components covered titanium coating, titanium balls, fibers, hydroxyapatite, etc.

Acetabular components of the total endoprostheses are cups of cement and cementless fixation. Cementless cups are usually made of a metal base (CoCrMo, titanium, stainless steel) and insertions, which are made of ultra-high molecular weight polyethylene (hirulen), ceramics or metal. There are constructions of cementless cups in which for a better osteointegration the outer surface is coated with fine mesh.

The cement cups (full profile and low profile) do not usually have a metal substrate. Their external surface has usually ribbed structure to provide better contact with the bone cement.

The heads of total endoprostheses are made of stainless steel, CoCrMo, zirconium or aluminium ceramics, titanium alloy and single crystal sapphire. A common size range of heads: 22, 26, 28 and 32 mm diameter. Less commonly are used heads of 24 and 25 mm diameter. The head is mounted on a cone of femoral component which is made on the basis of the Morse cone. In the world practice are common neck cones 9/10 mm, 12/14 mm and 14/16 mm (other dimensions are used much less frequently).

The existing diversity of total endoprostheses allows carrying out selection of the rational design the most appropriate for a particular patient at the planning stage of the operation. But, nevertheless, it should be noted that

until now the ideal endoprosthesis has not been created yet, and, therefore, the process of improvement of the known variants and searching for the new design variants is permanent.

Designing the improved construction of the total hip joint endoprosthesis, we adopted the concept of the unity of all its elements, allowing achieving the greatest reliability of the product as a whole, providing comfortable conditions for the surgeon during implantation and reimplantation during reprosthetics necessary for medical reasons.

3. System analysis and synthesis of the total hip joint endoprosthesis

3.1. Femoral component of the endoprosthesis

The femoral component of endoprosthesis during implantation is inserted in a specially prepared femoral canal similar in form to the stem form. No additional fixing means in most cases are used. As a consequence, in the postoperative period due to different factors the stem of the endoprosthesis can lose contact with bone tissue and become unstable. In order to reduce the risk of instability, a series of endoprostheses with additional fixing elements was proposed.

For example, in one of constructions (USSR 1572604 A1 MKI5 A 61 F 2/32, 1990, BI № 23) it is suggested attaching the stem to the thigh bone by a screw. For this purpose during operation is previously required to resect the greater trochanter at the site of the femoral neck. It is clear that such procedure leads to the increased traumatism of the operation and duration of the rehabilitation period. In addition, there is a high probability of screw destruction in the postoperative period due to the shear deformations arising at translational and rotational movements of the endoprosthesis stem in service.

A special stylus is formed in the proximal part of the femoral Aesculap endoprosthesis stem (Hip Endoprosthesis System - AESCULAP - Prospect Nr. C-126 1292) to increase it fixing and anti-rotation abilities. When implanting this construction, an increase of the stylus width results in the need to increase the size of the canal. The technology of it implantation requires a bone graft and additional actions by the surgeon, increasing the time of operation. However, this in no way guarantees the provision of sufficient anti-rotation properties in the proximal area of the endoprosthesis stem of the indicated construction.

The original idea focused on the prevention of rotational motions of endoprosthesis stem relative to the femoral bone is used in the construction of the stem with a longitudinal groove, in which the anti-rotation plate with thickness of 2 mm is placed in the process of implantation (USSR 1602496 A1 MKI5 A 61 17/56, 1990, BI № 40). Simultaneously plate is inserted into the groove formed in the greater trochanter of the femoral bone. To exclude rotary piston movements of the endoprosthesis the two titanium screws through the greater trochanter and the locking plate installed in it, are injected. But, herewith, the groove made at the entire width of the greater trochanter leads to a decreased strength of the cortical layer of the bone tissue and to increasing traumatism of the operation due to possible dissection of the muscles attachment to the greater trochanter. When implanting of such endoprosthesis, the complexity of the operation and, thus, the time of it implementation is increased. In addition, at the revision arthroplasty due to ingrowth of the screws into the bone tissue, additional access expansion in scars to bare the greater trochanter is required, that complicates the process of implant removing.

The system analysis of results of the development process of existing endoprostheses testifies the desire of developers to increase their fixing properties by changing the shape of the stem or using a variety of additional items. However, all known attempts in this context lead to the increased traumatism of the surgical operations and to the occurrence of other types of problems.

In this case a problem of contradiction of criteria occurs. On one side it is necessary to create construction allowing providing reliable fixation that possible in principle from a technical and technological points of view. On other hand, its implantation should not be more difficult than in traditional cases, provide the lowest traumatism and the possibility of prosthetics without additional fracture of the femoral bone. The known to date designs with increased reliability of fixing do not solve this contradiction. In this connection, in most cases, endoprostheses are implanted with traditional designs of femoral components. Nevertheless, the problem of creation of endoprosthesis with high reliability of fixing without significant increase of the operation traumatism is topical and its solution will enhance the overall reliability of endoprosthesis.

When implanting of our proposed design, there is no need to change the procedure of preparing the canal for installation the femoral component, elements used in it that increase the reliability of fixing, do not assume the increasing of trauma and do not hinder the extraction of the endoprosthesis if the reprosthetics is necessary.

Proposed stem consist of rod 1 with a supporting flange and the neck. In the proximal area of the endoprosthesis perpendicular to the longitudinal axis below the support flange, the groove of rectangular shape that opened toward the outer wall of the stem is made (Fig. 1).

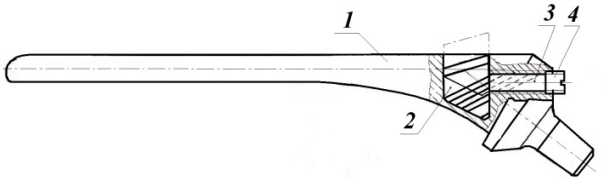

Fig. 1. Sketch of the prosthesis stem.

Into the groove with the possibility of translational movement perpendicular to the longitudinal axis of the rod, the flat slide 2 with the crossbar grooves on the side surface is mounted. The supporting flange at the upper part communicates on the outer side with a rectangular groove through the threaded hole. In the hole with the possibility of translational movement the cylindrical key 3 with the crossbar grooves made on it is mounted, and the key is connected with the same crossbar grooves made on the slide. Cylindrical key at its upper end contains the threaded cavity, and in the upper part of the threaded hole of the supporting flange the screw 4 is placed.

Such construction does not imply increasing of the operation trauma and destruction of the cortical layer on the greater trochanter, because the flat slide, having edge beveled to the distal area of the stem and at the same time sharpened, takes the form of a knife that, moving out of a rectangular groove, made in the stem rod, passes through only the cancellous bone tissue in the greater trochanter. The complexity of the operation also does not increase, since the rotation of just one screw located in the upper part of the threaded hole of the supporting flange by the cylindrical key, the slide is put forward from the stem rod.

The proposed construction of endoprosthesis provides an opportunity of its removal if the reprosthetics is necessary by the presence of a threaded cavity on the upper end of the cylindrical key, allowing moving the key up and returning the slide into the groove in the stem rod.

3.2. Acetabular component of the endoprosthesis

Ensuring the stability of the acetabular component of total hip joint endoprosthesis in the postoperative period also is an urgent task. Therefore many constructions aimed at solving this problem were suggested. For example, in one embodiment it is suggested producing the endoprosthesis of the acetabulum as a cup made from the discs with holes fixed on the releasable liner (USSR 1093339, MKI3 A 61 F 1/00, 1984, Bull. 19). A priori, it can be argued that the constructive complexity of such endoprosthesis directly affects its reliability. In addition, this design does not contribute to reducing of the probability of dislocation from the hip bone; it does not have any specific elements that contribute to the low-traumatic extraction if the reprosthetics is necessary.

In many acetabular endoprostheses as the fixing elements are used the movable knives with sharpened edges that have different form and location, and their external surface is provided with thread (USSR 925336, MKI3 A 61 F 1/03, 1982, Bull. 17; USSR 1123682, MKI3 A 61 F 1/00, 1984, Bull. 42; USSR 1123682, MKI3 A 61 F 1/00, 1984, Bull. 42). As a rule, knives are pivotally connected with the cup base, and using special keys, can rotate with bumping by sharp edges into the hipbone. It should be noted that most of the known constructions do not provide a reliable fixation of the cup. They are characterized by a high probability of dislocation and a high degree of trauma during the extraction from the hipbone. However, the modification of the thread, constructions and location of the knives on the cup surface and enabling them to rotate in the forward and backward directions eliminate many disadvantages.

In order to increase the reliability of the endoprosthesis fixation in the hip bone, to reduce the trauma of operation and simplify the process of possible dismantling, the improved design of the acetabular component is suggested (Fig. 2).

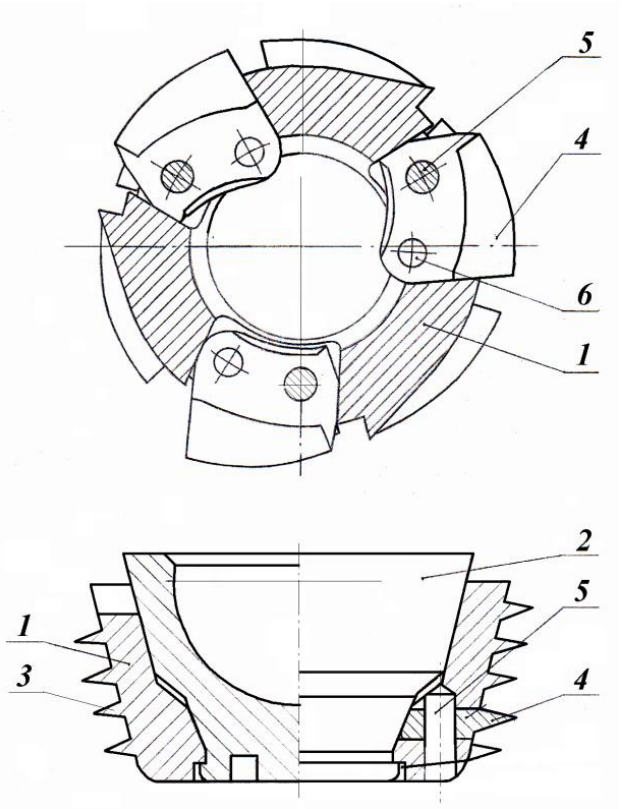

Fig. 2. Sketch of the endoprosthesis cup.

On the outer surface of the cup 1 with a fixed liner 2, the thread 3 is performed with slits to the profile height which divide the threaded surface on the sectors. In the lower half of the cup on the same distance from its bottom uniformly circumferentially are mounted movable knives 4, having the shape of a circular ring whose width does not exceed the width of the threaded sector. Knife rotation axis 5 is parallel to the longitudinal axis of the cup and is located on the side of the sector opposite to the direction of screwing. On the other side the through hole 6 is performed. The outer surface of each knife is performed as an element of the thread turn and is a continuation of the thread on the surface of the cup.

Hirulen liner, being one of structural elements of the cup, differs from analogues by an annular bulbous groove providing the required flexibility of the bottom part in the radial direction (Fig. 3). This structural element allows increasing girth surface of the femoral head by liner and thereby reducing the probability of its dislocation.

The objective of the modification of the cup design parameters was the desire to improve the reliability of its fixation into the bone and, thereby, reducing of postoperative rehabilitation period

Laboratory experiments confirmed the assumption of increasing of the restraining force when knives are plunged into the bone due to the growth of reactive torque, typical for this construction, and increasing of the contact area of the knives with the bone.

Constructive systematic approach allowed providing the best contact of the cup with the surface of the acetabulum due to the fact that the construction of the knives allows simultaneously with their pulling out the rotating of cup toward screwing direction.

Implantation of the proposed construction of the acetabular component is characterized by the less trauma compared to analogs. It provides the possibility of dismantling, if reprosthetics is necessary, by simply unscrewing the cup due to the special arrangement of the axes of rotation of the knives.

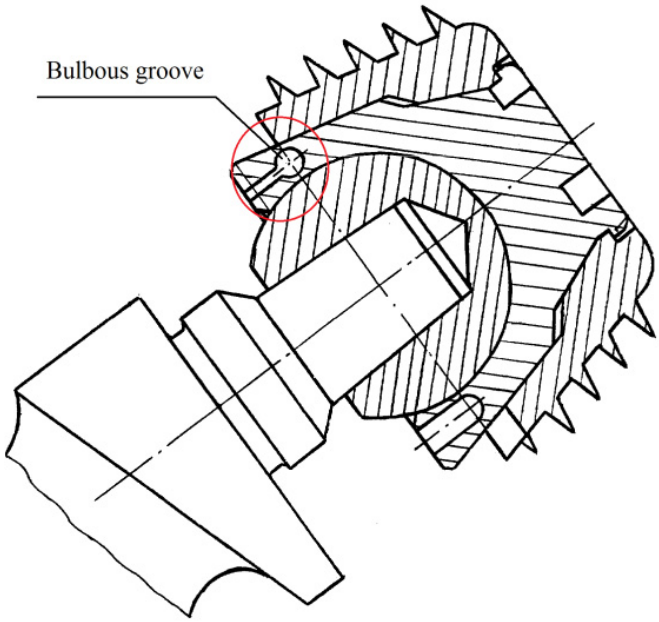

Fig. 3. Head and cup of the endoprosthesis assembled.

4. Discussion

Obviously, that from technical point of view it is possible to create many endoprostheses with reliable fixation of its elements. However, providing of compatibility of their elements with human bone structures and minimal trauma during implantations is complex biomechanical problem. Currently, considering the current level of technology, practically no ability to create hip joint endoprostheses fundamentally different from the classical ones. In this regard the systemic search for variants that improve the existing constructions is the most acceptable in this case.

The major design drawbacks of classic constructions are the low level of fixation reliability of the stem at the femoral bone and the possibility of dislocation of the cup from the acetabular of the hip bone. The continuous process of searching for new materials for the manufacturing of heads and cup liners is caused by the wear of intensively loaded surfaces of friction pairs typical for classical endoprostheses that is also a significant disadvantage.

The total hip endoprosthesis introduced in this paper relates to constructions of the classical type. In the process of its synthesis a systematic analysis of many commercially available analogues was carried out, their main advantages and disadvantages were identified.

After conceptual development of all structural components in the environment PowerSHAPE (DELCAM) 3D-model of endoprosthesis was created (Fig. 4), on the basis of which in the ANSYS Workbench the analysis of the stress-strain state of the construction was performed, taking into account its interaction with bone structures, (Fig. 5).

3000 N load applied to the femoral head and through it transmitted to the neck of the stem was specified as Remote Force. It was assumed that the stem body is limited by elastic base (Elastic Support) and its lower part is rigidly fixed to the absolute coordinate system (Fixed Support).

Analysis of the stress-strain state showed that under the assumed loading conditions, maximal stresses in the original version of the construction does not exceed 218 MPa (with ultimate strength of the material BT-1-0 1070 MPa), which allowed to optimize shape and size of stems, providing the ISO 14242 requirements.

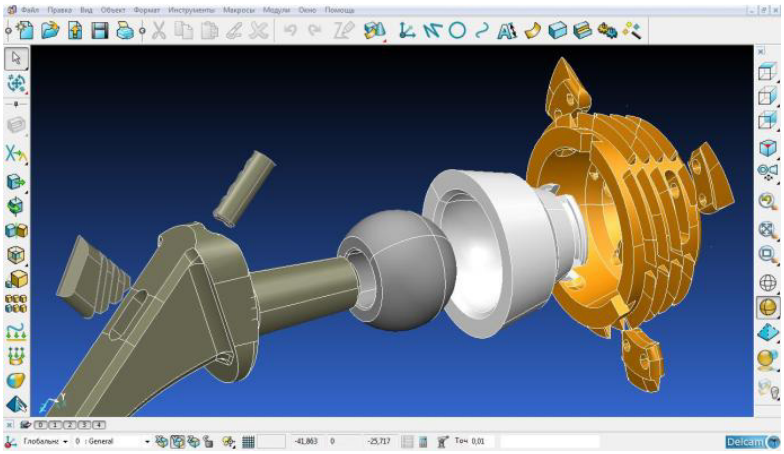

Fig. 4. 3d-model of endoprosthesis elements assembly.

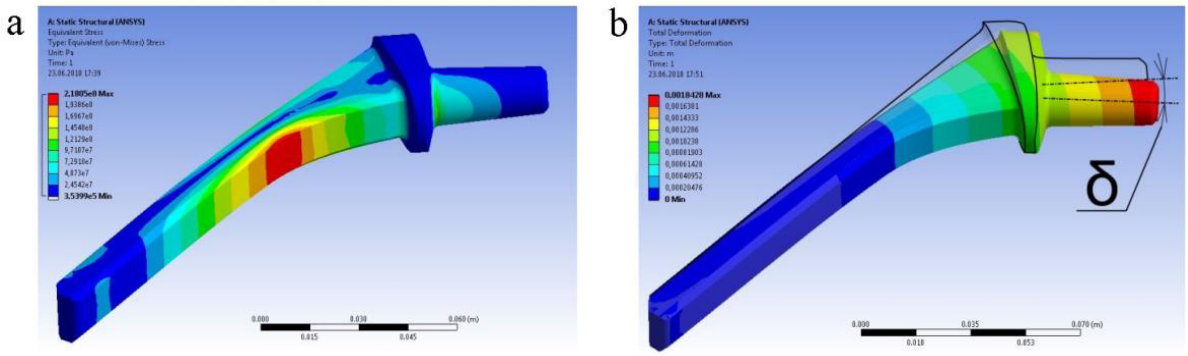

Fig. 5. (a) Stresses in the von Mises form on the surface of the endoprosthesis stem, (b) pattern of the endoprosthesis elements movements under load (scaled-up).

Conclusion

The main objective of this work was to create total hip endoprosthesis, having increased reliability compared with known analogues. Such prosthesis and its technology are developed based on methods of system analysis and synthesis. At the same time was taken into account biological properties of bone, biomechanical characteristics of the hip joint, mechanical characteristics of bioinert materials and technological methods of the prosthesis implantation. The study of 3D-models of the endoprosthesis at the stage of synthesis allowed us to estimate its stress-strain state in conjunction with the femur under the action of the maximum possible load. As a result, the final version of the design was changed that allowed to redistribute stresses and to reduce stress intensity in the most dangerous areas.

A general view of the proposed construction of the endoprosthesis is shown in Fig. 6.

Laboratory experimental researches have shown that the suggested constructive solutions in the endoprosthesis can significantly improve the fixation reliability of the stem in the proximal part of the hip bone. Moreover, this effect is achieved without increasing trauma during implantation.

Positive results were also obtained in the laboratory tests of the cup. At the same time, the assumptions about the relative simplicity of implantation of the proposed construction and the quality of its contact with the surface of acetabulum were confirmed.

All endoprosthesis elements can be made on the universal technological equipment with control system based on PC. At this the processing program is created in the environment PowerMILL (DELCAM) considering specific features of the patients. Thus, the construction, presented above, is the budget version of total hip joint endoprosthesis which will be available for many patients requiring THA.

Fig. 6. General view of the new endoprosthesis design.

In the near future, on the simulator will be carried out tests on wear different pairs of friction of the endoprosthesis. In particular, planned to study various defective variants of its implantations.

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