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Some aspects of custom-made 3d-printed hip joint implant structural simulation

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Abstract. Current article is devoted to the application of computer-aided engineering technologies to the virtual testing of customized endoprostheses of large joints. The research is performed for a representative case, where the personalized prosthesis of the hip joint is used as a part of the process of treatment of osteosarcoma, as conventional systems are not applicable. The study is highly relevant due to the intensive development of personalized medicine allowing for the patients' successful recovery and mobilization. However, since each of the customized implants is a unique part, a rapid, accurate and financially efficient methodology of performing the structural analysis of such components is required to avoid the real testing of each implant. The article describes the all steps of the structural simulation of the series of loading scenarios for the biomechanical system consisting of the pelvis and endoprosthesis. The process of preparing the finite element models of pelvic bones and components of the implant is also explained in detail. The stress-strain state of the pelvis and implant is investigated for a number of values of the pretension force of the screws. Based on the comparative analysis, a set of practical recommendations is formulated to reduce the stress in the bone tissue. The discussed steps are the elements of the methodology of the rapid finite element virtual testing of the customized implants that is currently developed by the research group.

1. Introduction

Every year, several million [1] of total hip arthroplasty surgeries are carried out in the world, and this number grows every year. In recent decades, such type of arthroplasty has become a standard procedure. The main reasons for the hip replacement are arthrosis and other types of degenerative diseases caused by the destruction of the cartilage of the hip joint.

Currently, due to the significant development of additive manufacturing technologies based on the metal powder compositions, the 3D printing of customized endoprostheses has become very common and popular. The key advantage of this approach is that such type of implant precisely fits the shape of the pelvis including the areas with defects.

The development of the market of customized orthopedic structures can be considered as the result of the recent improvements of the engineering software technologies. These technologies allow using the computer tomography data to generate the geometrical model of the bones, perform the surgery planning and design the customized implant.

The engineering simulation technologies such as finite element modeling make it possible to perform virtual tests of the designed implants. These tests are very important as the real testing of each implant will significantly increase the cost of such solution. However, the virtual testing or structural analysis itself leads to a number of specific technical issues.

The article presents the intermediate results of the development of the methodology of rapid virtual testing of customized implants. The process of preparing the finite element model, running the simulation and carrying out the analysis of the results is explained, and recommendations regarding the possible changes in the implant design are formulated.

2. Review of current studies

Numerical simulations based on the patient's computer tomography and the corresponding digital models of implants are widely used in modern orthopedics to analyze the stress-strain state of the prostheses of large joints [2]. This approach allows getting the stress and strain distribution in the implant and bone tissue and to assess their strength. Study [3] presents the results of the structural analysis of the hip reconstruction using rod-screw systems. The same method is used for simulation of the pelvic ring reconstruction with the double-barreled vascularized fibular free flap [4, 5] and for investigating the efficiency of the internal fixation of implants [6, 7].

In the considered articles, the finite element models are prepared on the basis of the geometry of the patient's skeleton elements obtained as a result of computer tomography. The implants are simulated as deformable three-dimensional solids. A vertical load is applied to the lumbar vertebrae, and the biomechanical system is analyzed in the standing position. Based on the prepared models, the strength of the system is assessed and the conclusions regarding the possible changes to the shape of the implant are made.

The paper [8] describes the results for a modular endoprosthesis that is used for the reconstruction of a half of the pelvis. A comparative analysis of the stress distribution is done between the normal pelvis and the pelvis with the implant considering three static positions: sitting, standing on two legs and standing on a leg of the injured side. The loads, areas of their application and boundary conditions are similar to those described in [3].

In clinical medicine, various reconstruction methods are used to treat osteosarcoma. The typical methods are arthrodesis, alloplasty, autoplasty and various types of prosthetics. The introduction of computer-aided design and engineering technologies, as well as additive manufacturing, opens up new opportunities in the reconstruction of the pelvic bones. Digital technologies make it easier to create geometrically accurate customized implants that can be used as an alternative to massive bone allografts, and can also be used in cases, where modular prostheses cannot be used [9]. The use of selective laser melting (SLM) and electron beam melting (EBM) technologies allows creating porous structures for better osseointegration [10, 11].

The practical results of implementation of the 3D printed implants in conventional and oncological orthopedy confirm that the patients with the individually designed implant show successful recovery and mobilization, which are the sequences of high anatomical accuracy of the structures, availability of various fixation methods and high manufacturing speed [9, 12, 13].

3. Object of the research

The article presents the process of preparing the finite element models and performing the structural analysis of the system containing the pelvis of a 14-year-old patient with the diagnosis of osteosarcoma of the left ilium.

The patient was admitted to the clinic of the Research Institute of Pediatric Oncology and Hematology of the National Medical Research Center of Oncology named after N.N. Blokhin with complaints of

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pain in the left hip joint and limitation of mobility (Fig. 1). After the neoadjuvant chemotherapy, it was decided to perform the surgery with pelvic resection and reconstruction with a personalized implant.

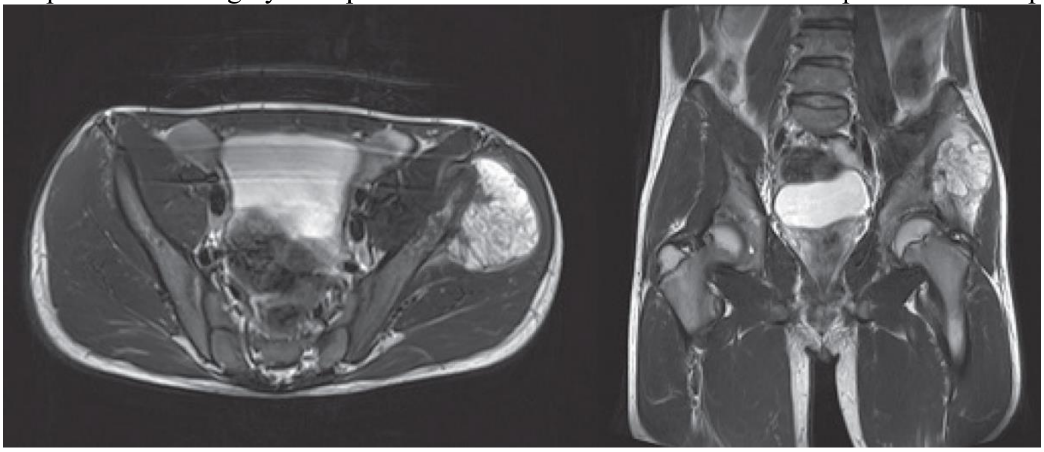

Figure 1. Magnetic resonance tomography image of the patient [14].

At the first stage of the design process of the endoprosthesis, the three-dimensional geometric models of the pelvic bones in STL format were prepared using the data obtained from the computer tomography study. On their basis, the specialists of the Research Center and their manufacturing partners determined the boundaries of the resection and developed the virtual model of the operation of osteosynthesis with the customized implant.

Using the anatomical data of the patient and the information about the surgery, the implant design was developed in such a way that it reconstructs the damaged regions of the bone tissue (Fig. 2). The implant includes the hemispherical acetabular cup and supporting flanges connecting the part with the ilium, ischium and pubic bone. The regions, where the implant contacts the bone tissue, were covered with a porous lattice layer to improve the osseointegration [11].

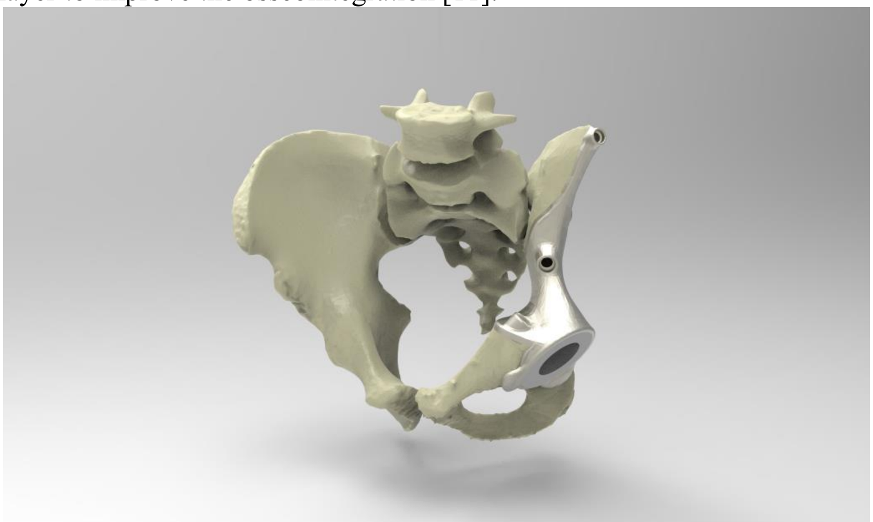

Figure 2. Location of the analyzed implant.

The part was printed with Ti6Al4V alloy powder with extra low interstitials (Fig. 3). After the printing, the implant was post-processed and examined for hidden defects.

Figure 3. Additively manufactured customized implant [14].

4. Preparing the finite element model

The final goal of current project is to develop the methodology of rapid virtual testing of customized implants based on the detailed finite element analysis of the stress-strain state of the endoprosthesis and bone tissue. The first step of carrying out such simulation is the preparation of the finite element model of the object, which begins with preparing the geometric model.

Three-dimensional models of the pelvic bones generated on the basis of computer tomography data in STL-format consist of a large number of triangular surfaces and have a rather complex shape. At the first stage of the work with the model, the triangulated geometry of the pelvis is checked for intersections, missing elements and other defects. The mesh quality is fixed and homogenized (Fig. 4). While preparing the analysis model, it is taken into account that the bone has a double-layer structure and consists of the cortical and spongy layers with different properties. The outer cortical layer is formed by a stiffer and stronger material, while the inner spongy bone is much more flexible and weaker. The mesh near the screw holes is refined to increase the accuracy of the results. Based on the prepared surface mesh, a tetrahedral volume mesh is generated. The STL-mesh processing and the finite element mesh generation is performed with the special software tools.

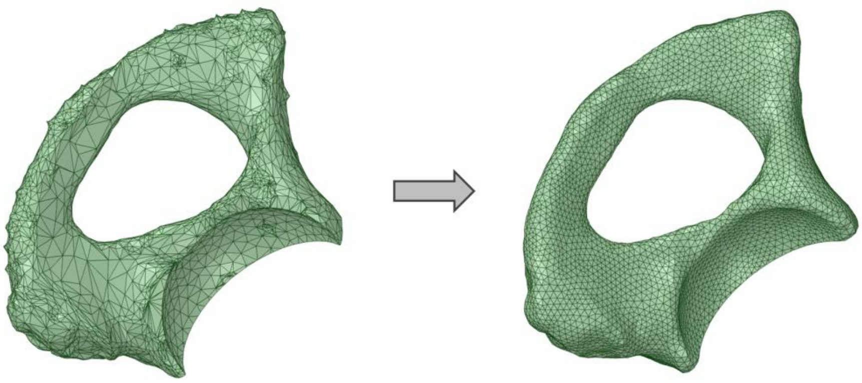

Figure 4. Results of the mesh processing from the geometrical triangular mesh to the finite element mesh.

The current study considers the presented biomechanical system in the standing position with the support from two legs. As the load case is symmetric, a half of the pelvis might be excluded from consideration if the geometry is also symmetric. Surely, the model of the pelvis after performing the resection and reconstruction is not symmetric, and the stress-strain state of the side with the prosthesis is not equal to the stress-strain state of the opposite side. However, since this research is devoted to the study of the stress-strain state of the damaged part of the pelvis, and the prosthesis allows reconstructing the shape of this part and the biomechanics of the hip joint quite well, it is assumed in the research that the opposite side of the pelvis can be replaced by the symmetry boundary conditions.

The developed finite element models were imported into SIMULIA Abaqus (Fig. 5). Such components as the polyethylene cup, femur implant and the simplified representation of the leg were added using the tools of Abaqus/CAE preprocessing system. The femoral component of the joint is modeled in the simplified way, because this part of the system is out of scope of the research.

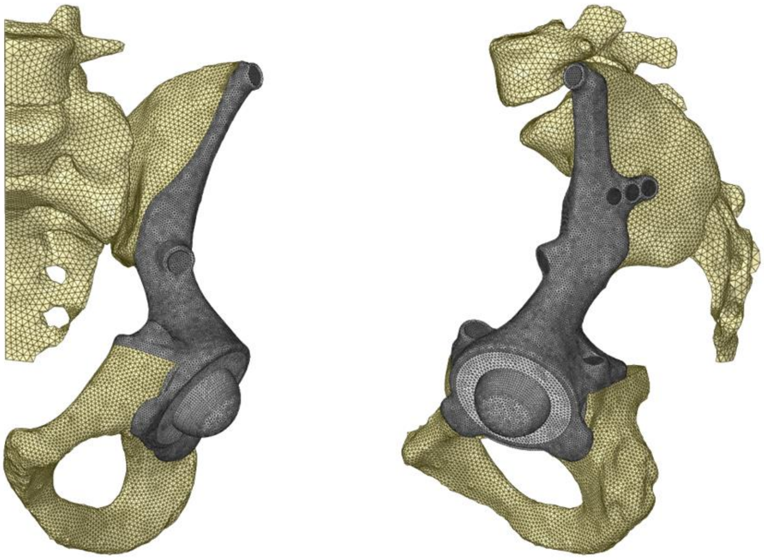

Figure 5. Finite element mesh of the pelvic, implant, acetabular cup and femur head.

The characteristics of the finite element model are:

- number of elements – 612 260;
- number of nodes – 172 997;
- number of degrees of freedom – 519 thousand.

The following element types are used:

- C3D10 – quadratic tetrahedral solid element (screws and polyethylene cup);
- C3D4 – linear tetrahedral solid element (implant, pelvic bones);
- S3 – triangular linear shell element (femur head);
- B31 – linear beam element (representation of the leg).

During the process of preparing the finite element model, additional kinematic constraints and contact interactions are created. The constraints are added to the model in order to simulate the real connections between the components of the biomechanical system. The contact interactions are specified to show the analysis system, in which regions in should control the relative positions of the parts in order to avoid their intersection.

5. Materials

The mechanical properties of spongy and cortical bone tissues were obtained experimentally in various studies and vary due to many factors. As a result of the analysis of the studies, the average values of the necessary parameters were chosen from [15]. The screws, implant and the femoral component of the implant are made of titanium alloy Ti6Al4V. The mechanical characteristics of this alloy are given according to [16]. The polyethylene cup is made of ultrahigh molecular weight polyethylene that is characterized by high mechanical performance, low friction coefficient and biocompatibility [17].

Since the calculation takes into account the contact interaction with the nonlinear behavior, the effect of friction shall be taken into account. The friction forces are based on the coefficients from [18].

The mechanical properties of the materials are listed in Table 1, friction coefficients are listed in Table 2.

Table 1. Mechanical properties of the materials.

Material name	Density, kg/m3	Elastic modulus, MPa	Poisson ratio	Critical stress, MPa
Spongy bone	1 188	500	0.2	10
Cortical bone	1 470	10 000	0.3	160
Titanium alloy	4 410	110 000	0.3	1065
Polyethylene	930	27 000	0.35	27

Table 2. Friction coefficients for the pairs of materials.

First material	Second material	Coefficient of friction
Titanium alloy	Spongy bone	0.3
Titanium alloy	Cortical bone	0.2
Titanium alloy	Polyethylene	0.15

6. Loads and model setup

The problem described is solved in two steps. The first step is dedicated to the screw pretension, and the second one is used for applying the main loading.

At the first step the current research considers several values of the screw pretension force within the range between 100 N and 400 N. Such approach is implemented in order to estimate the optimal value of the force, which leads to the reliable connection between the bone and the implant in combination with the stress level within the allowed limits.

The second step is devoted to the modeling of the standing condition. In the basic statement of the task, the gravity force equal to 245 N (half of the patient's weight) should be applied to the center of gravity of the body located in the plane of symmetry of the human. But from the computational point of view, it is more convenient to fix the region of the sacrum, considering the pelvis to be immobilized, and apply the load at the end of the simplified model of the leg.

The following kinematic boundary conditions are applied:

- the top surface of the sacrum is fixed in two directions (uy = uz = 0);
- the mid-surface of the sacrum is fixed in normal direction (ux = 0).

The task is solved with Abaqus/Standard implicit solver. The solution is done with the assumption that the displacements are small. However, the task is solved in the nonlinear mode to make it possible to describe the contact behavior correctly.

7. Results

An important issue during the hip arthroplasty is the estimation of the proper screw pretension force between the implant and the bone. As it was mentioned earlier, this paper considers several values of the force. Particular attention is paid to the stresses in the bone tissue of the pelvis, since high pretension force can cause the bone destruction.

The stress distribution in the cortical and spongy layers of the pelvic bones for the cases of pretension forces of 100 N, 200 N, 300 N and 400 N are presented in Fig. 6 and Fig. 7. In each of the illustrations, the upper limit of the legend is set equal to the value of the permissible stress in each of the materials. In the areas colored grey, the stresses exceed the allowable limits.

Neglecting the local hot-spots caused by the singularity of the stress fields, it is possible to conclude that the optimal value of the screw pretension force is in the range between 200 N and 300 N. The lower force of 100 N leads to the relatively low contact pressure between the components, and the higher force of 400 N causes the extreme stress level in the bone tissue.

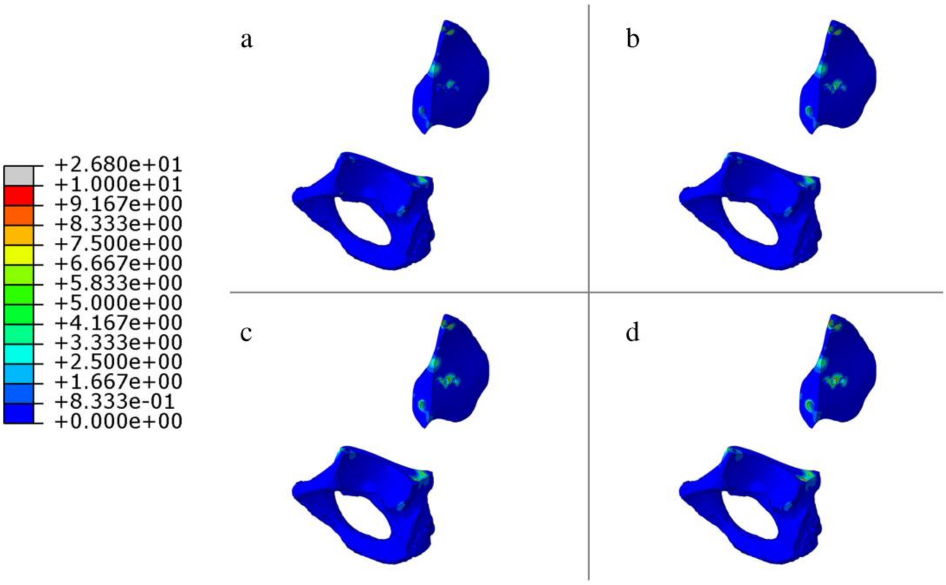

Figure 6. Stress field in the spongy bone for the screw pretension force of 100 N (a), 200 N (b), 300 N (c) and 400 N (d). Von Mises equivalent stress, MPa.

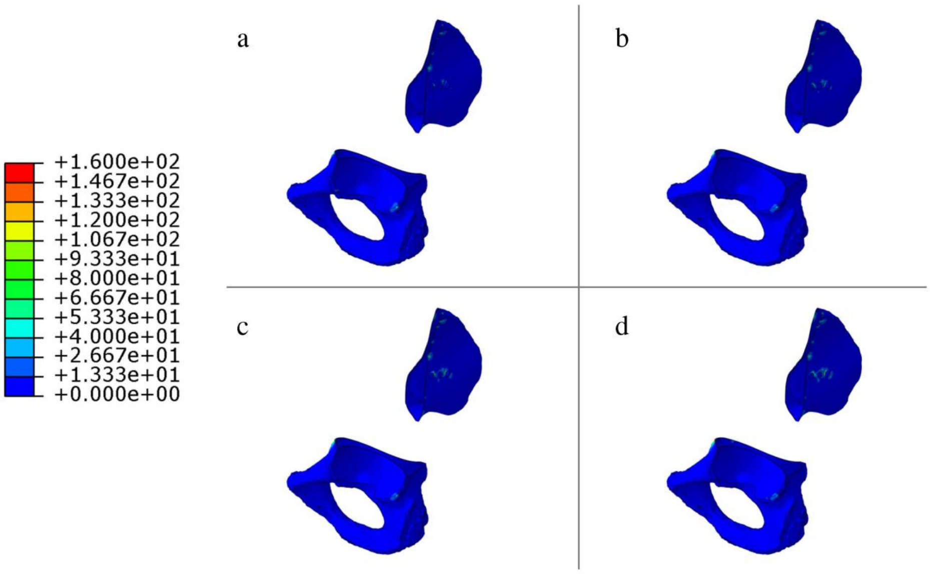

Figure 7. Stress field in the cortical bone for the screw pretension force of 100 N (a), 200 N (b), 300 N (c) and 400 N (d). Von Mises equivalent stress, MPa.

The following step representing the standing condition is based on the results of the first step for the values of pretension force equal to 200 N and 300 N.

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The stress fields in the pelvis, implant, screws and polyethylene cup obtained from the static structural analysis and caused by the both screw pretensions and body weight are shown in Fig. 8 – Fig. 12.

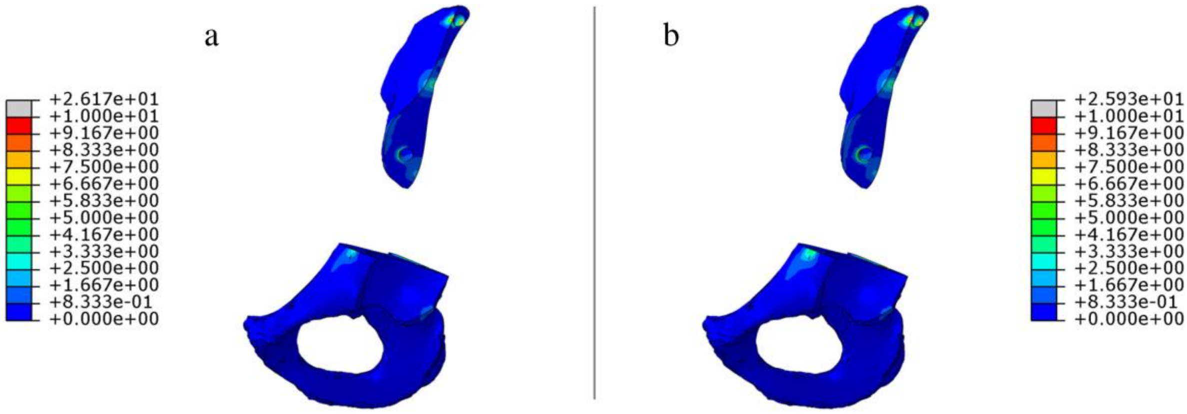

Figure 8. Stress field in the spongy bone for the screw pretension force of 200 N (a) and 300 N (b). Von Mises equivalent stress, MPa.

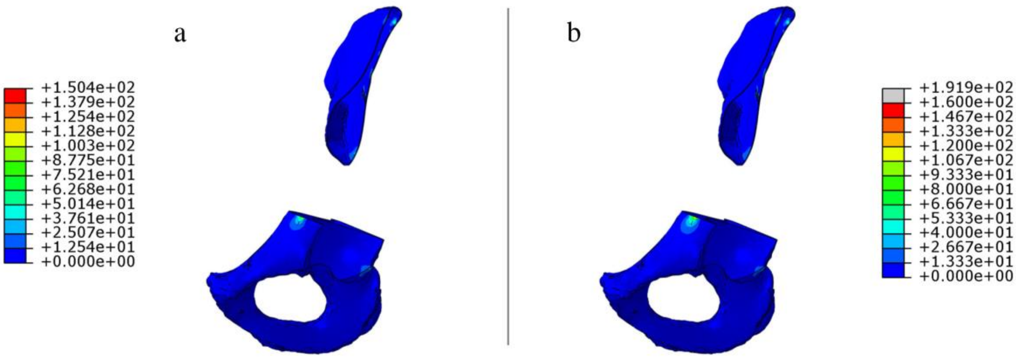

Figure 9. Stress field in the cortical bone for the screw pretension force of 200 N (a) and 300 N (b). Von Mises equivalent stress, MPa.

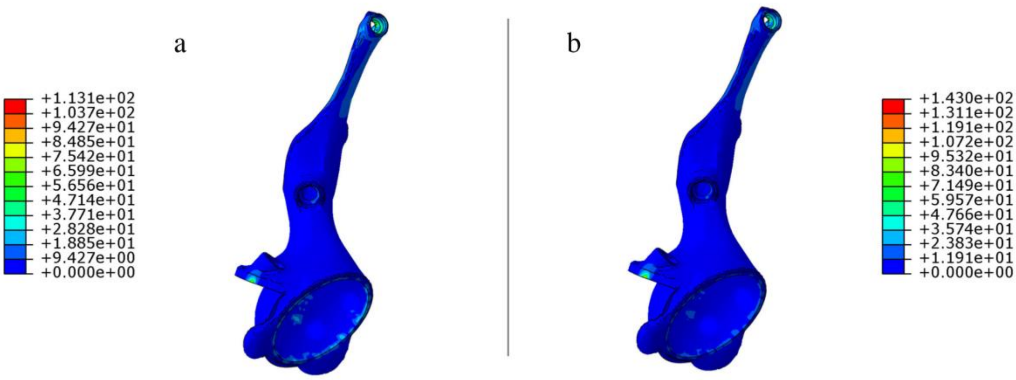

Figure 10. Stress field in the customized implant for the screw pretension force of 200 N (a) and 300 N (b). Von Mises equivalent stress, MPa.

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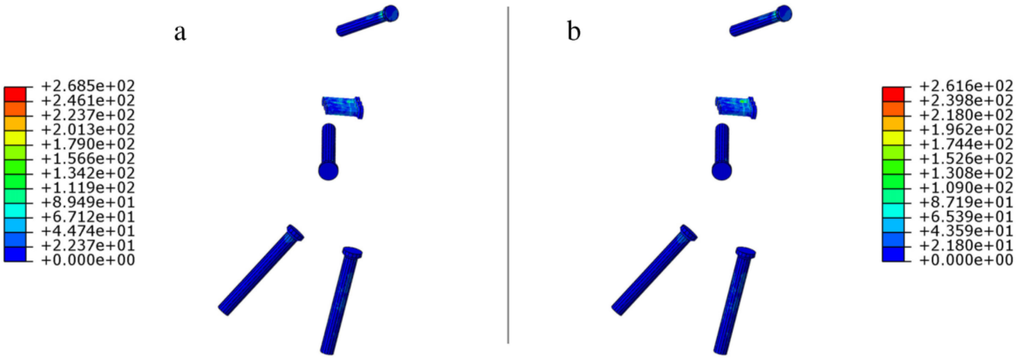

Figure 11. Stress field in the screws for the screw pretension force of 200 N (a) and 300 N (b). Von Mises equivalent stress, MPa.

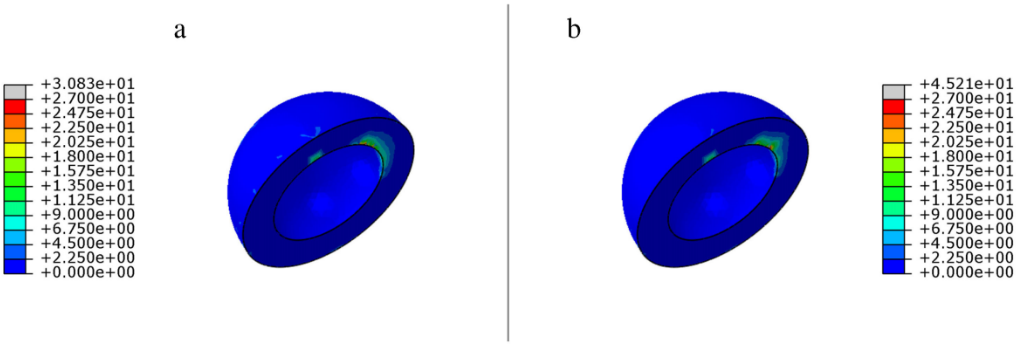

Figure 12. Stress field in the acetabular cup for the screw pretension force of 200 N (a) and 300 N (b). Von Mises equivalent stress, MPa.

The stress fields shown in Fig. 8 – Fig. 12 demonstrate that the critical value of the pretension force could be chosen equal to 300 N. For this value of the pretension, the stress levels in the implant and in the screws are well within the specified limits. The maximum stress values in the cortical and spongy bone formally exceed the allowable stress, but a more detailed analysis shows that the peak values take place mostly in the local hot-spots and should not cause any significant damage. But it is important to mention that the issue can be resolved by adjusting the positions of the screws in such a way that the screw holes do not form any thin bridges between them and do not approach the surface of the bone.

8. Conclusion

The article presents the basic information about the main steps of the development of the personalized hip joint prosthesis. The process of performing the finite element analysis of the pelvic implant is considered in detail as an important stage of the currently developed methodology for rapid virtual testing of individual endoprostheses of large joints.

The stress values, which were obtained from the analysis, show that the critical value of the pretension force equals 300 N. If this value is exceeded, then a high risk of destruction of the spongy layer occurs. The most dangerous are the areas, which are close to the screw holes, and regions with several screws placed close to each other or close to the surface of the bone.

Based on the simulation results, the following key conclusions and recommendations can be formulated to reduce the stress level in the pelvic bones with the endoprosthesis installed.

1. Some measures should be taken to reduce the stress level in the areas, where the screws intersect the surface of the bone. One of the possible solutions is to install additional flexible rings or gaskets

reducing the contact pressure. Such elements could be made of special biocompatible medical polymers [19].

2. The design of the implant could be improved to avoid such positioning of the screws, which leads to formation of thin bridges between the screw holes and intensive stress concentration due to the superposition of several stress concentrators.

The treatment of the patient was completed in April 2018 (Fig. 13). The observation period at the time of preparation of the article was 23 months with no indication of any local recurrence or progression of the underlying disease [14]. The functional assessment of the hip joint confirms the excellent result. There was no clinical or radiological indication of any instability at the time of the latest visit to the clinic. These results are in good agreement with the results of the structural assessment of the system performed with finite element analysis.

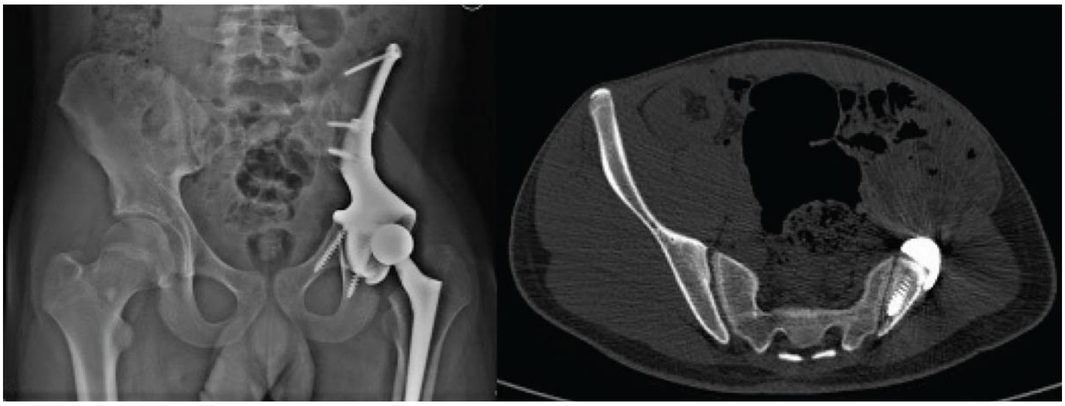

Figure 13. X-ray image and computer tomography study of the pation after the treatment completion [14].

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