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Digital modeling of critical conditions after metacarpophalangeal joint replacement

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Introduction The current status of small joint arthroplasty, the metacarpophalangeal joint replacement, in particular, dictates the need for development and research of new implant designs and materials for their manufacture. The vector of development of anatomically adapted implants has become established, and full preclinical study is required to obtain the best functional results from the use of new medical devices. **The objective** was to analyze digital models of critical conditions of metacarpophalangeal joint replacement using mechanical and clinical data. **Material and methods** A two-component all-ceramic, anatomically adapted endoprosthesis of the metacarpophalangeal joint was developed between 2017 and 2021. A digital model of the metacarpophalangeal joint endoprosthesis was constructed using 3D modeling technology. Critical conditions of the digital model imitating the main stereotypes of movements were explored with the finite element method; objective technical results obtained and interpreted in a clinical language. **Results** Loads over 20 kg should be avoided with movements up to 60° in the early postoperative period. The load must not exceed 10 kg for motion ranging between 60° and 90°. The endoprosthesis allowed for a functional range of motion of 30-60° after MCP joint replacement without significant risks of complications. **Discussion** The study has demonstrated the importance of objectifying clinical results to minimize the risk of complications in a clinical scenario. **Conclusion** The echnology based on a digital model of the metacarpophalangeal joint constructed to calculate critical conditions using the Ansys software facilitated prediction of most common complications of MCP arthroplasty and preceded further multicentric clinical trials.

Keywords: metacarpophalangeal joint replacement, finite element method, finger joint replacement, digital modeling

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INTRODUCTION

Orthopaedics and traumatology is one of the rapidly developing science with discoveries and outcomes in diagnosis and treatment that might be impossible some ten years ago. Joint surgery can offer benefits of surgical treatment for patients with osteoarthritis of various etiologies [1]. More than 80,000 joint replacement surgeries are performed annually in our country, and modern technologies allow for arthroplasty of almost any joint [2]. Excellent functional results can be achieved with arthroplastic procedures of large joints including the hip, shoulder with the annual prevalence of 90 % [2, 3]. However, a finger joint replacement is much less common than hip and knee replacements being less than 1 % of all arthroplasties [4]. Despite a wide range of organ-preserving operations on the metacarpophalangeal (MCP) joint, metacarpophalangeal joint replacement would be the best option for some clinical scenarios [4-7]. World statistics and our own clinical observations indicate a significant lag in this direction from surgery of large joints. Analysis of the foreign and Russian literature showed the need for the medical and scientific community to search for new design solutions and materials for the manufacture of hand and foot implants [8]. The human hand is a complex and multicomponent organ with the largest representation in the central nervous system that can perform extremely gentle and precise actions and means a huge challenge for the surgeon, rehabilitation therapist and medical devices used to restore the hand function [10-12]. Anatomically adapted implants is critical for hand arthroplasty [12].

MCP joint replacement has historically gone through a thorny path from the 60s of the last century to the current status. Many types of implants were created and tested using various materials for the manufacture. There is a trend towards the creation of anatomically adapted non-constrained endoprostheses and associated silicone implants for patients with rheumatoid arthritis and severe degenerative changes in the capsular-ligamentous apparatus and MCP bone tissue [13]. There is no ideal material for the manufacture of implants for small joints of the hand and foot. The materials have the advantages and disadvantages and functional results of MCP joint replacement are controversial. In recent years, zirconium ceramics has been used for for the manufacture of joint implants with the development of additive manufacturing technologies showing good wear resistance, bioinertness and biocompatibility, high corrosion resistance [14, 15]. Although hand surgeons report the experience with all-ceramic implants of the hand joints the problem of a universal product design is urgent and requires appropriate design, preclinical and approbation work [16, 17].

Modern medicine science is in powerful tandem with engineering, digital technologies and design. Specialists of various specialties work to help researchers accumulating high-precision results of preclinical studies, which is necessary for new technologies and medical products to be introduced into clinical practice [18]. Rehabilitation with hand therapy specialists at specialized rehabilitation departments and centers is an integral part of the treatment of hand diseases and injuries. The introduction of new technology into clinical practice today is accompanied by preclinical studies and tests. A medical device is to be technically tested in a certified laboratory, toxicologically examined using standard cell cultures, laboratory animals and cadaver experiments prior to the use at a medical institution [19]. Considering high demands placed on the hand surgeon, we developed and conducted the digital study to test the implant ex vivo, protecting the patient from additional physical and psychological injuries and closing the cycle of preclinical tests required for the certification of new technology.

The analysis of modern foreign and Russian literature demonstrated common complications of MCP joint arthroplasty with unconstrained implants:

1) dislocation of implant components;

2) fracture of the stem;

3) periprosthetic fracture of the phalanx or metacarpal bone.

Objective studies of the main stereotypes of movements in the MCP joint will help the hand therapist to achieve optimal functional results, and the patient to avoid complications [20]. The objective was to analyze digital models of critical conditions of metacarpophalangeal joint arthroplasty with mechanical and clinical aspects.

MATERIAL AND METHODS

Thirty four patients who sought help at the hospital of Samara State Medical University for osteoarthritis of the phalangeal joint were analyzed between 2017 and 2021 . The mean age of the patients was 47 ± 2.65 years, including 15 females (44.2 %) and 19 males (55.8 %). Patients presented with pain and limited movement in the MCP. Patient complaint data were collected, physical examination, radiographs of the hand in two projections and computed tomography (CT) produced. 3D CT scans were used to analyze the biomechanics of healthy and affected joints evaluating the congruence of the articular surfaces, the radius of curvature and deviation of the fingers in various nosological forms. A dissection of 36 cadaveric MCPs was performed to explore the anatomy of the capsular-ligamentous apparatus. Based on our own research, the experience of foreign and Rissuain colleagues researchers, considering the trends of personalized medicine we developed a construct for an all-ceramic two-component anatomically adapted endoprosthesis of the metacarpophalangeal joint [21] (Fig. 1).

The endoprosthesis is a non-constrained implant and is completely made of inert zirconium ceramics. The articular surface of the metacarpal component is made to ensure minimal resection of the native bone in two planes, and the articular surface of the distal component mimics the structure of the articular surface of the base of the proximal phalanx. The stems are tapered with rounded tips for ease of press-fit installation, and the longitudinal six on the proximal and four on the distal stems provide additional rotational stability and create conditions for osteontegration. The implant is designed in four sizes to be used with specially designed instrumentation [21].

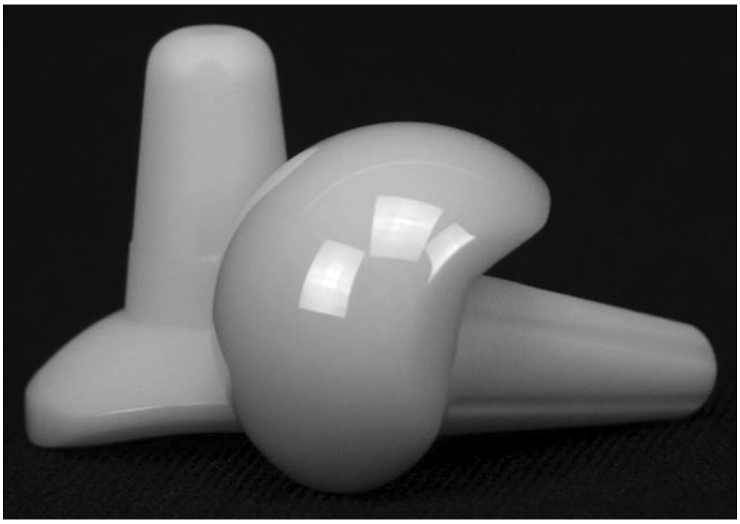

Fig. 1 All-ceramic two-component anatomically adapted endoprosthesis of the metacarpophalangeal joint

The new medical product has passed a full cycle of technical and toxicological tests. Technical tests were carried out at the ANCO "Center for Quality, Efficiency and Safety of Medical Use", Moscow (protocol No. 11/022.R-2021 dated November 10, 2021). The toxicological study was performed at the Delma physical and chemical laboratory, Pushchino (the program of toxicological studies of a medical device No. MI21-0208/02 dated August 2, 2021). The finite element method was applied to simulate critical situations in the use of the implant. The finite element method (FEM) is the main method for determining the stress-strain of the constructs. FEM is employed in medicine, in traumatology and orthopaedics for measuring loads on the implant (endoprosthesis, plate, screw, etc.) and on the musculoskeletal system. The method allows optimizing the shape of the implant, the parameters for the placement predicting the optimal service life under the loads. The Ansys software package, a reliable software for the implementation of the FEM in mechanical engineering, engineering, and medicine was used for the FEM [23]. The main stereotypes were selected from the variety of hand movements and processed as 3D models with the software.

A set of CT scans in the DICOM format was used to examine the anatomy and biomechanics of healthy and damaged MCP and 3D modeling performed using polygonal modeling, 3D sculpting, automated modeling systems developed at the Institute of Innovative Development of the Samara State Medical University. During this stage of the study, we used the ZBrush and Autodesk 3dsMax software packages were used to obtain three-dimensional models of the MCP joints for a new implant design [22]. The following properties of materials (ceramics) presented in Table 1 were used.

Mechanical properties of the cortical bone used in the development of the digital model:

– Young's modulus 1.8 × 1010 GPa;
– tensile strength 146 MPa;
– specific density 1800 kg/m^3.

Cortical bone measurements were used in a specially developed MCP digital model designed for the Ansys software, since modeling involves simplification and abstraction from the real clinical scenarios due to the complexity of recreating physiological and biomechanical processes in native bone, which was sufficient for the study. The three-dimensional model of the implant was integrated into the bone. Stress-strain of the implant components and stresses in the bone, which can be subject to destruction due to excess loads were measured.

Table 1

Mechanical properties of ceramics

Description	Measurement
Density, g/cm^3	6
Average particle size, microns	< 1
Bending strength, MPa	900
Young's modulus, GPa	210
Vickers hardness, HV 0.1	1200

The main stereotypes of movements were used for the digital model including spheric gripping with a bending angle of 0, 30, 60 and 90 degrees in the MCP with object compression. With the three-dimensional models constructed the stress-strain of the implant components and the bone was calculated to determine the maximum acceptable and working loads for each of the motion stereotypes. The analysis was carried out using the finite element method. The three-dimensional model of the implant was subdivided into finite elements, after which boundary conditions were applied: the phalangeal bone tissue was subjected to embedding – it was secured against movement along the end region of the model in all directions, and axial loads were applied to the metacarpal bone with a force in the equivalent of 0 to 50 kg. The finite element model of the implanted MCP endoprosthesis is shown in Figure 2. The model is shown with a load force of 50 kg. The angle of flexion in the MCP is 60º.

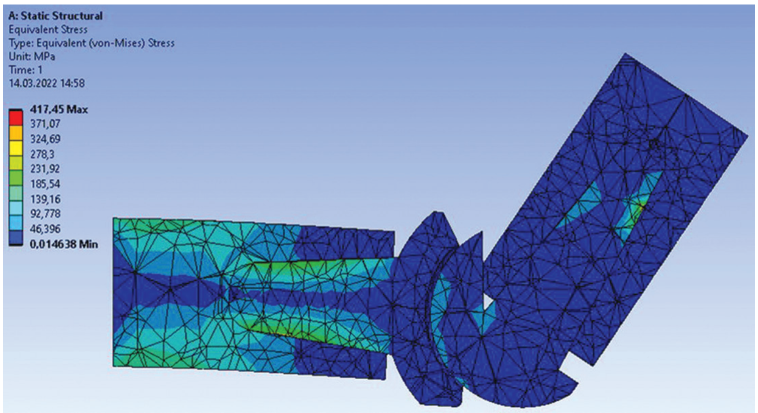

Fig. 2 Finite element model of implanted MCP. The model is shown with a load force of 50 kg. Flexion angle in MSR measuring 60º

A series of calculations was performed with the models constructed and divided into finite elements was used to evaluate working load limit and corresponding strength margins of the implant components and the bone. The calculations were performed with loading of the "spheric grip with a bending angle of 0, 30, 60, 90 degrees in the MCP, object under pressure". Loads were applied in the range of 1.0-50.0 kg. The stress-strain of the model component is shown in Figures 3 and 4.

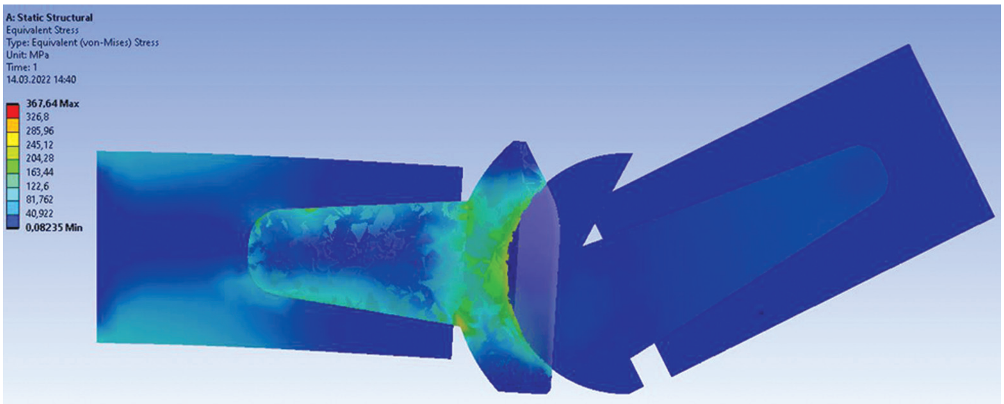

Fig. 3 Finite element model of implanted MCP endoprosthesis, flexion angle of 30º. The model is shown with a load force of 50 kg

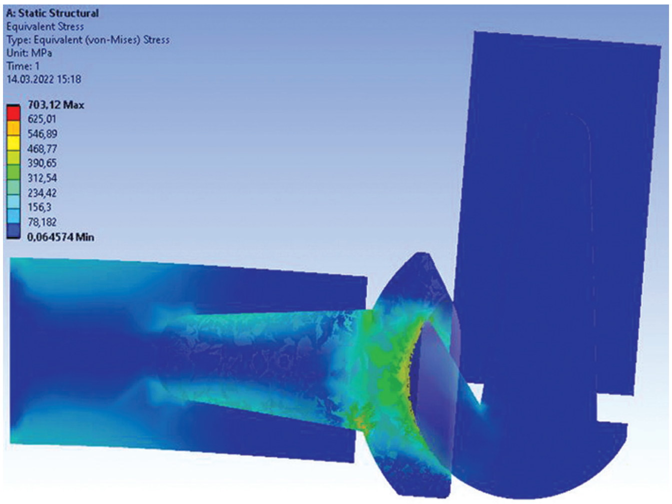

Fig. 4 Finite element model of implanted MCP endoprosthesis, flexion angle of 90º. The model is shown with a load force of 50 kg

RESULTS

The above figures show the stresses in the implant model integrated into the bone. The calculations demonstrate greater stresses in the model being experienced by the implant components including the articular phalangeal surface. The flexion angle in the MCP of 0º is an exception with the load being distributed evenly over the cavity of the phalangeal component of the implant with resultant stresses in the construct being significantly lower than those at other flexion angles in the MCP.

Taking into account the mechanical properties of the model components, the bone tissue appeared to be the most loaded and fracture-prone component in all calculations. The dependence of stresses in the bone tissue on the loads applied is shown in Figure 5.

The calculations showed the dependencies as follows:

1) with a load of more than 20 kilograms, loss of bone strength occurred at all flexion positions (30°, 60°, 90°), except for 0°. At 0°, the load was distributed on the bone in such a way that it was able to withstand a force of up to 50 kg or more. With a joint position of 90°, strength was lost after 10 kilograms of axial load;

2) the stability of the construct at angles of 30-60° had an extremely small spread in strength increasing sharply at angle positions close to 0°, and sharply decreasing when approaching a bending angle of 90°;

3) the strength of implant components significantly exceeded the strength of the bone tissue at the junction of the joint and the bone.

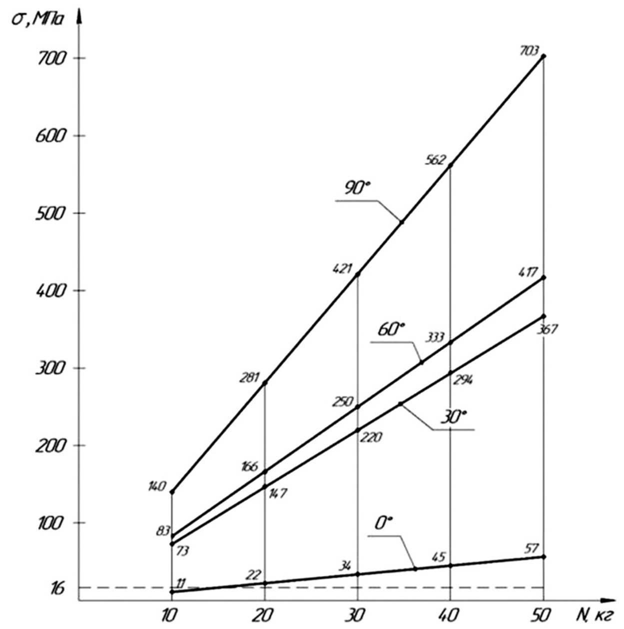

Fig. 5 Dependence of stresses in the bone on the loads applied

DISCUSSION

The requirements for scientific research and, consequently, for the products and devices being developed, are being annually upgraded and aimed at improvement of the quality of life and the medical care. Experimental laboratories and technologies from related specialties are available for the doctor and the researcher. New devices and implants are pre-clinically tested prior to clinical trials [24]. The present study shows the possibility of interdisciplinary research resulting from objective data based on mathematical modeling. The development of a mode of motor activity in patients undergoing total replacement of the metacarpophalangeal joint based on objective technical data will allow avoid the risk of formidable complications including dislocation of endoprosthetic components, stem fracture and periprosthetic fracture.

The digital model we offered is not ideal, it contains errors that are acceptable for experimental research and the modeling process [25]. The Ansys software package visualizes the implant as a simplified and allows mathematical calculations and abstracts the process from the real clinical situation. In general, this principle is possible in terms of complex pre-clinical studies, and, real clinical conditions have not been reconstituted at this stage. The study identified the boundary conditions for the mode of motor activity in the early postoperative period and outlined the optimal range of motion after MCP arthroplasty. The resulting concept can be supplemented and developed in further clinical trials of the implant developed, taking into account the findings reported to minimize physical and psycho-emotional trauma for the patient. In order to more clearly emphasize the need and relevance of bioengineering research, we applied a comprehensive assessment of the results from engineering and clinical aspects.

CONCLUSION

1. **Technical result**: implant components made of ceramics are able to withstand significantly greater loads than the bone at the site of integrated phalangeal component of the implant.

Clinical interpretation: The distal component of the metacarpophalangeal joint is susceptible to periprosthetic fracture.

2. **Technical result**: механические the mechanical properties of the bone at the site of integrated phalangeal component are decisive for optimal operating conditions of the metacarpophalangeal implant. Individual characteristics of the patient's bone (porosity, fragility and other factors) are essential for implant design and recommendations on motor activity and forces to be applied.

Clinical interpretation: the age of patients and comorbidities are to be considered with the phalangeal endoprosthetic component to be placed with the maximum precision in the formation of the canal due to the small volume of the peri-implant bone tissue of the phalanx.

3. **Technical result**: with a load of more than 20 kilograms, loss of bone tissue strength occurs at all bend positions (30°, 60°, 90°), except for 0°. At 0°, the load is distributed on the bone tissue in such a way that it is able to withstand a force of up to 50 kg or more. With a joint position of 90°, strength is lost after 10 kg of axial load.

Clinical interpretation: loads of more than 20 kg should be avoided with movements up to 60° in the early postoperative period. The load must not exceed 10 kg for movements from 60° to 90°.

4. **Technical result**: stability of the costruct at angles of 30-60° has an extremely small spread in strength, increasing sharply at angles close to 0°, and sharply decreasing when approaching a bending angle of 90°.

Clinical interpretation: the implant developed allows a functional range of motion in the MCP measuring 30-60° after total MCP replacement without significant risks of adverse events reported.

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Nikolaenko A.N. – conceptualization; validation; control; project management.
Ivanov V.V. – formal analysis; data processing.
Doroganov S.O. – research; writing the original version; editing; visualization.
Bukaty A.S. – research, data processing, writing the initial version.
Zgirsky D.O. – visualization, writing, editing.
Isaykin P.Yu. – visualization, writing, editing.

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