

ORIGINAL ARTICLE

MATHEMATICAL MODELING OF THE STRESS-STRAIN STATE OF THE "BONE-IMPLANT" SYSTEM DURING THE OSTEOSYNTHESIS WITH A PHILOS WITH POLYLACTIC ACID IMPLANTS

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ABSTRACT
The aim: To study was to use mathematical modeling in assessing the stress-strain state of the bone-implant system during plate osteosynthesis with a PHILOS plate of a proximal humerus fracture with polylactic acid implants.

Materials and methods: Two bone-implant systems with a three-fragment humerus fracture according to the Neer classification (type 11-C1 according to the AO / ASIF classification) were selected for the study, one of which was with additional reinforcement of the head fragment with two polylactic acid implants (PLA – polylactide Ingeo™ Biopolymer 4032D). Sawbones (Europe AB, Malmö, Sweden) built the humeral model on 3D scanning of the composite model № 3404 of the left humerus.

Results: A comparative analysis of the obtained results of mathematical modeling of the stress-strain state of the bone-implant systems showed that with given constraints (hand abduction to 90°), the use of two polylactic acid implants can reduce the stress in the plate and screws, respectively, by 11% and 6% .

Conclusions: The use of polylactic acid implants during osteosynthesis of three- and four-fragment fractures of the proximal humerus, especially in the case of osteoporosis, allows providing for the reinforcement of metal structures and supporting of the articular surface without deterioration of fixation rigidity.

KEY WORDS: implant, polylactide, mathematical modeling, osteosynthesis, 3D printing, proximal humerus fractures

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INTRODUCTION
According to the literature [1–3], up to 80 % of the proximal humerus fractures (PHF) are two-fragment fractures according to the Neer classification [3] or A2 / A3 type according to the AO / ASIF classification [4]. 20 % of patients have three- and four-fragment PHF (type A and C by AO / ASIF), which are difficult to treat, especially in patients older 60 with osteoporosis [5]. Conservative treatment methods for PHF are used in case of a minimum fragments displacement, which is up to 2–3 mm [5–7], and in chronic somatic diseases with a high risk to life during surgical treatment. In other cases, open reposition and internal fixation of the PHF are prescribed, which may be ineffective due to osteoporosis. Despite the widespread clinical practice of new designs for osteosynthesis (plates with angular stability, blocked intramedullary rods, cannulated screws) and a number of publications, demonstrating the effectiveness of their application [7–11]. There is a high risk of avascular necrosis development in the head of humerus, nonunion of fragments, redislocation of fragments and metal migration which according to different authors can comprise up to 30 % [7–12].

Minimally traumatic "percutaneous" methods of osteosynthesis using 3–4 mm needles or cannulated screws were developed for three- and four-fragments PHF to avoid additional damage to soft tissues and to preserve blood supply to the head of humerus as much as possible. However, there is no convincing evidence of their effectiveness [13]. A number of works [14–16] deal with studying the mechanical stability of various fixation methods, at the same time, the obtained results are difficult to compare, since each study used its own methodology. Some authors believe that one of the possible ways to solve the problem of fragments fixation instability of the head of humerus in osteoporosis is the use of various auto- or allo-implants, as well as bone cement [16]. Based on the experimental results [17], we proposed to use Ingeo ™ Biopolymer 4032D polylactide as a supporting and reinforcing implant. Experimental studies [17] proved the Ingeo ™ Biopolymer 4032D (PLA) material to have a high biocompatibility and osteointegrative qualities ensuring the formation of mature bone tissue around the biomaterial and gradual bone ingrowth. Thus, the study of the fixing rigidity of PHF during osteoporosis with a PHILOS plate with PLA implants as a supporting and reinforcing element is relevant and deserves further study.

THE AIM
To study was to use mathematical modeling in assessing the stress-strain state of the bone-implant system during

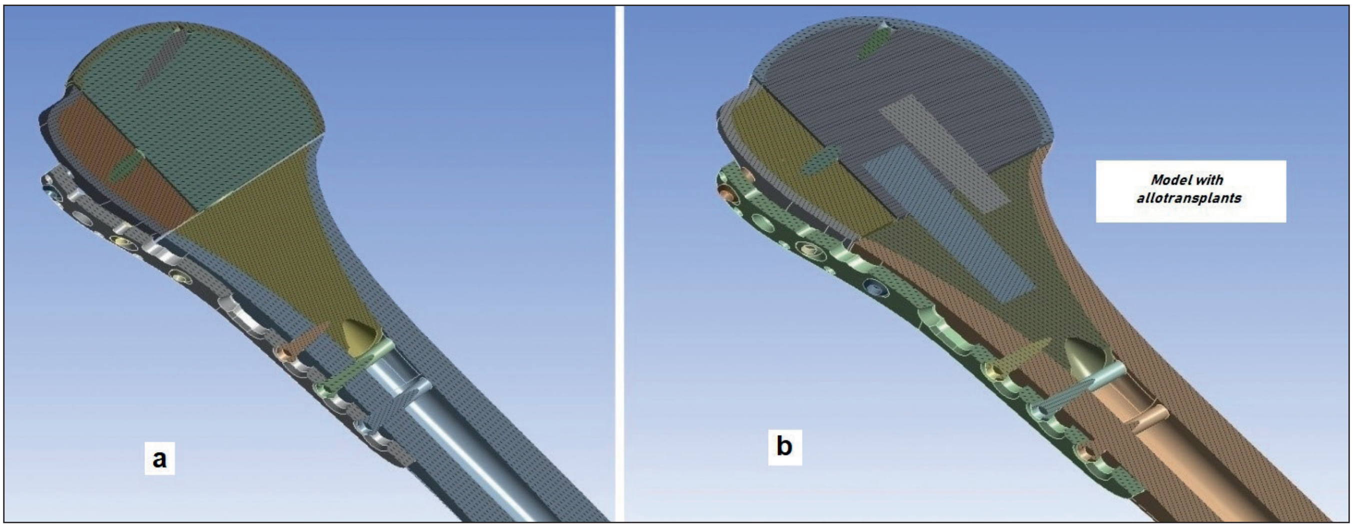

Figure 1. Models of bone-implant systems: a) three-fragment PHF and the PHILOS; b) three-fragment PHF and the PHILOS with PLA implants.

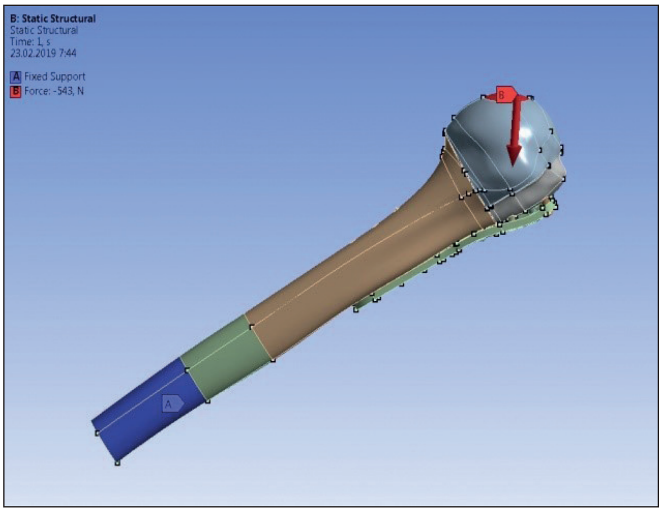

Figure 2. The considered case and calculation of loads

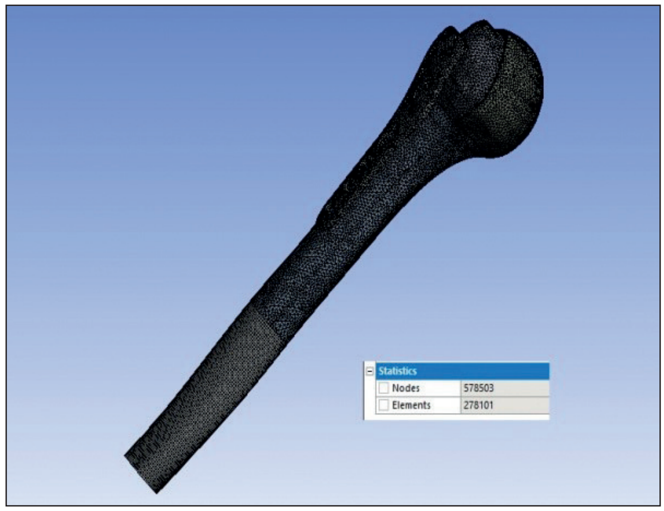

Figure 3. The meshing model

plate osteosynthesis with a PHILOS plate of a proximal humerus fracture with polylactic acid implants.

MATERIAL AND METHODS

The studies were conducted on the basis of the State Institution "Specialized Multi-Profile Hospital No. 1 of the Ministry of Health of Ukraine", Dnipro, Ukraine. For mathematical modeling and study of PHF osteosynthesis, two "bone-implant" systems were selected with a three-fragment fracture of the humerus according to the Neer classification (type 11-C1 according to AO / ASIF classification): 1) PHILOS and 3.5 mm locking cortical and cancellous screws made of stainless steel without implants; 2) a bone osteosynthesis plate with angular stability PHILOS and 3.5 mm locking cortical and cancellous screws of stainless steel with additional reinforcement of the head fragment with two implants made of polylactic acid (PLA – Ingeo™ Biopolymer 4032D polylactide); reinforcement of the head of humerus with this material ensures the filling of voids and support of the articular surface by counteracting its collapse. The humeral model was built using 3D scanning of the composite model № 3404 of the left humerus by Sawbones (Europe AB, Malmö, Sweden), and the three-fragment fracture model is similar to the model in. As in an isotropic linear model with the following physical and mechanical characteristics was used for modeling with all materials: for cortical bone – Young's modulus $E = 12.65$ *GPa*, Poisson's ratio $\nu = 0.3$, density $\rho = 1640$ kg / m^3, allowable stress $[\sigma] = 157$ *MPa*; for cancellous bone – $E = 47$ *MPa*, $\nu = 0.48$, $\rho = 200$ kg / m^3, $[\sigma] = 3.9$ *MPa*; for a PLA implant – $E = 1.28$ *GPa*, $\nu = 0.36$, $\rho = 1252$ kg / m^3, $[\sigma] = 70$ *MPa*; for steel EN14301 – $E = 200$ *GPa*, $\nu = 0.28$, $\rho = 7800$ kg / m^3, $[\sigma] = 220.0$ *MPa*.

For three-dimensional modeling of the bone-implant system, the SolidWorks 2019 SP 1.0 program was used with subsequent mathematical modeling with the finite element method and stress-strain state analysis in Ansys, 2017 (ANSYS, Inc., Canonsburg, PA, USA). The models of the bone-implant systems under study are shown in Fig. 1.

The following simulation case was used for the analysis: both models were inclined by 52.5° to the vertical, simi-

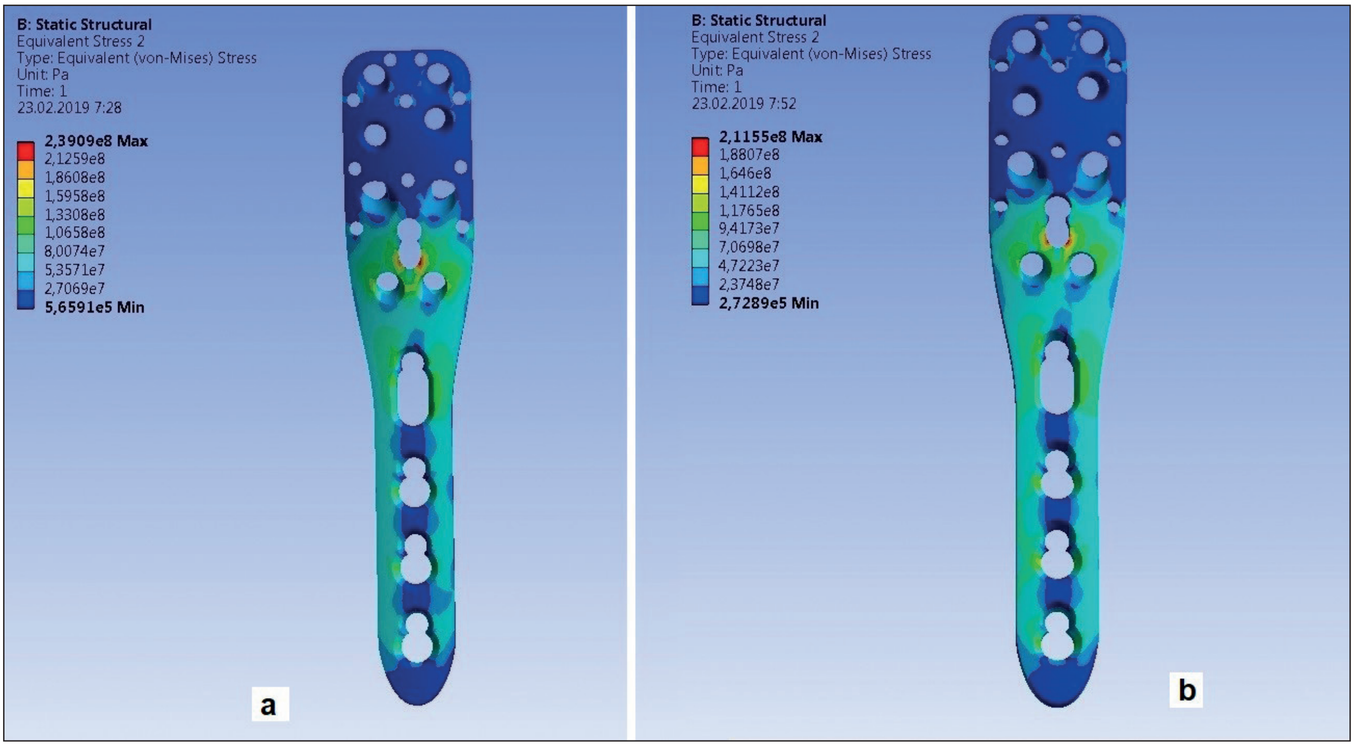

Figure 4. The distribution of the von Mises yield criterion in the plate: a) without PLA implants; b) with PLA implants.

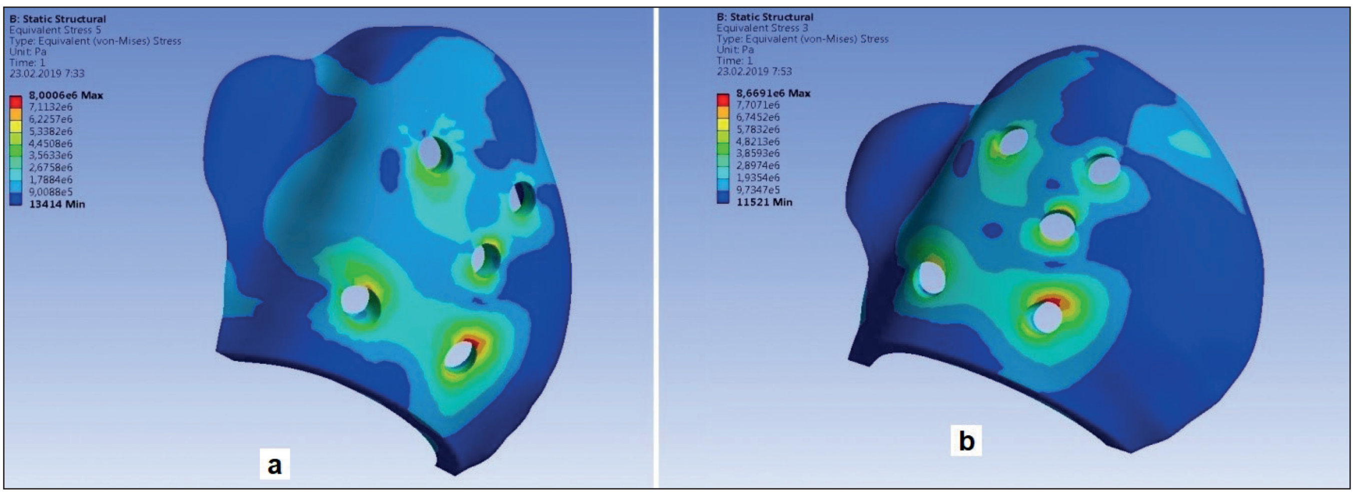

Figure 5. The distribution of the von Mises yield criterion in the large tubercle of the head of humerus: a) without PLA implants; b) with PLA implants.

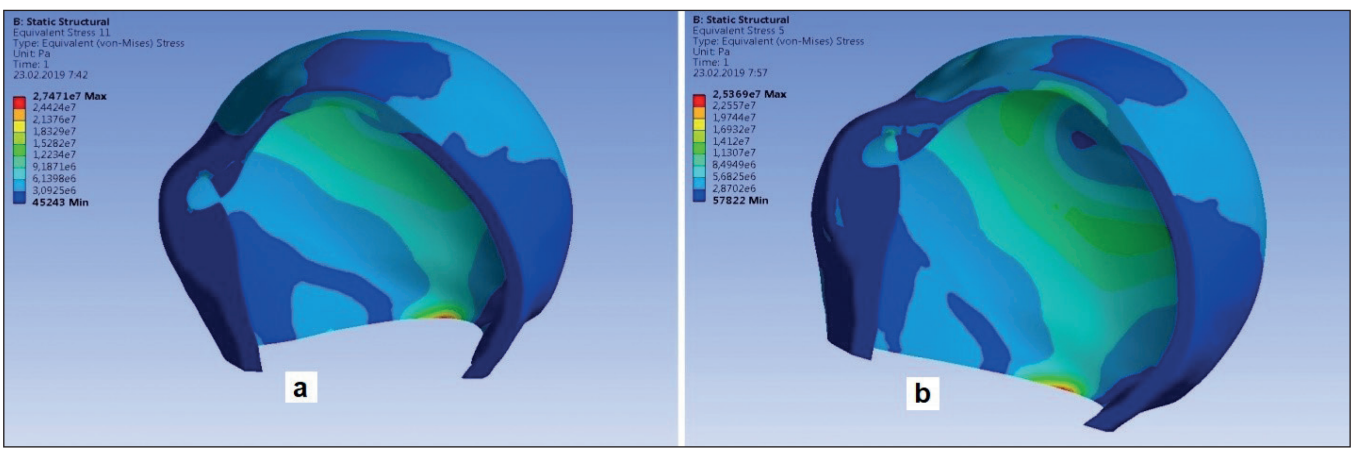

Figure 6. The distribution of the von Mises yield criterion in the head of humerus: a) without PLA implants; b) with PLA implants.

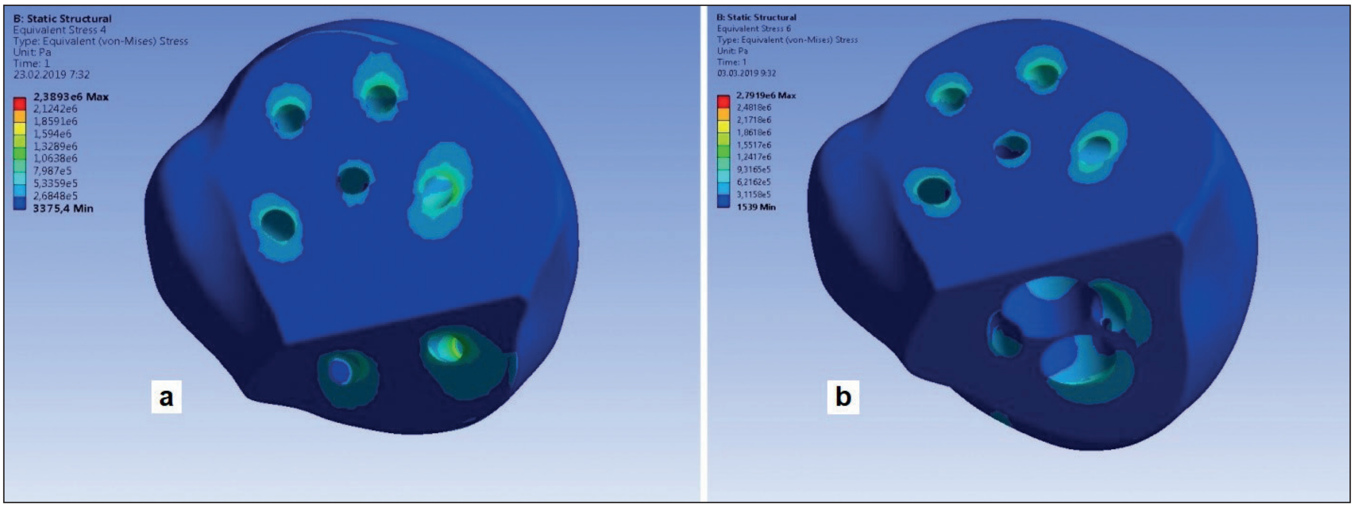

Figure 7. The distribution of the von Mises yield criterion in the head of humerus along the fracture line at the level of the surgical cervix: a) without PLA implants; b) with PLA implants.

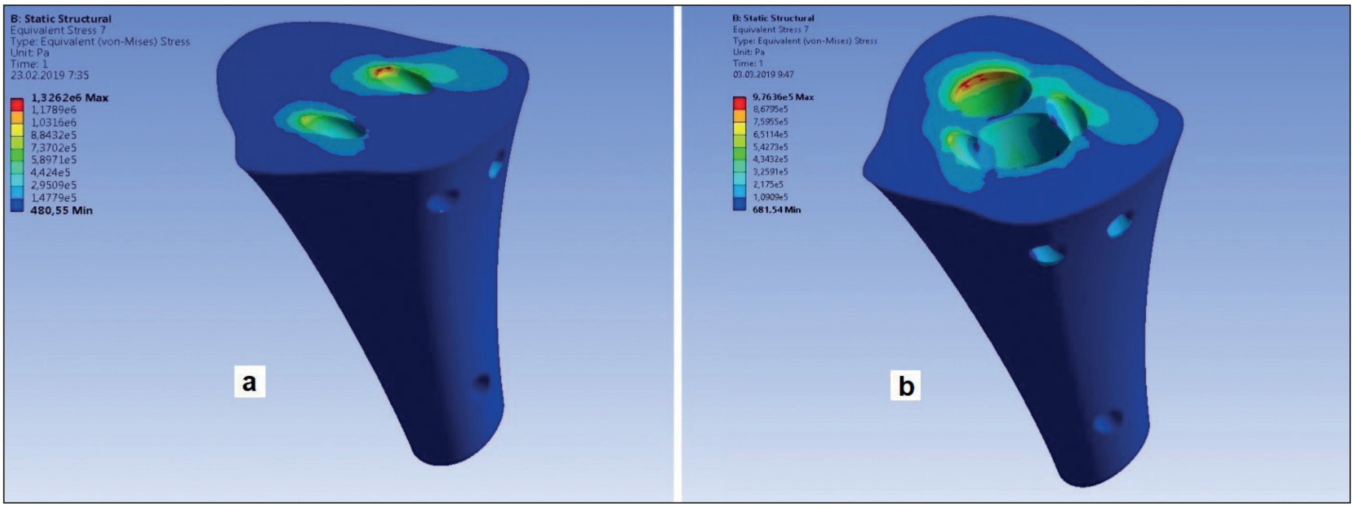

Figure 8. The distribution of the von Mises yield criterion in the distal fragment of the humerus along the fracture line at the level of the surgical cervix: a) without PLA implants; b) with PLA implants.

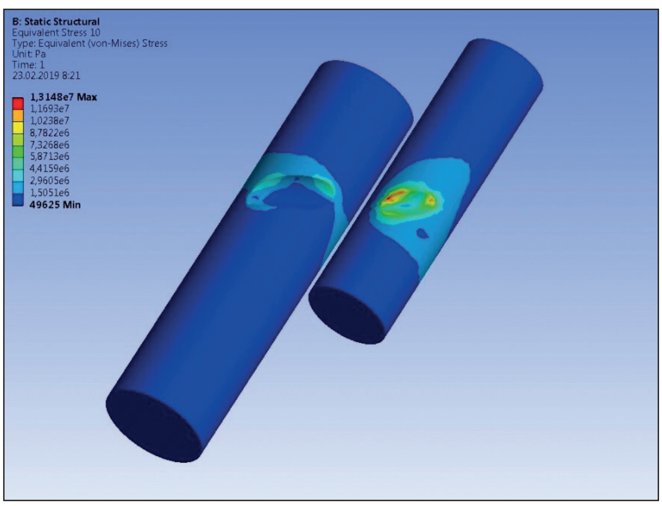

Figure 9. The distribution of the von Mises yield criterion in PLA implants.

larly to, and a distributed load was applied to the articular surface with the resulting force of 543N (Fig. 2). The end of the humerus is fixed in space. The considered case approximately repeats the physiological loads on the proximal part of the humerus according to the data of.

To solve the problem, the construction of a meshing model with a tetrahedron side of 1 mm was performed. Fig. 3 shows the meshing model of a bone osteosynthesis plate with a PHILOS angular stability plate and a 3.5 mm locking cortical and cancellous stainless steel screws without PLA implants.

RESULTS AND DISCUSSION

The evaluation of the stress-strain state of the bone-implant models was performed by comparing the von Mises yield criterion for various joints and parts of the bone. The distribution of the von Mises yield criterion in the plate in the two studied bone-implant systems is shown in Fig. 4. The distribution of the von Mises yield criterion in the PHF fragment, represented by a large tubercle of the head of humerus, is shown in Fig. 5. The distribution of the von Mises yield criterion in the head of humerus is shown in Fig. 6.

The distribution of the von Mises yield criterion in the head of humerus along the fracture line at the level of the surgical cervix is shown in Fig. 7. The distribution of the von Mises yield criterion in the distal fragment of the humerus along the fracture line at the level of the surgical cervix is shown in Fig. 8. The distribution of the von Mises yield criterion in PLA implants is shown in Fig. 9.

A comparative analysis of the obtained results of mathematical modeling of the stress-strain state of the "bone-implant" systems showed that with the given constraints (abduction of the hand up to 90°), the use of two implants made of polylactic acid allows reducing stresses in the plate and screws. The decrease in the maximum the von Mises yield criterion in the plate was 11 % and in screws it was 6 %. It was proved that the two lower cortical screws are subject to minimal stress. A comparative analysis of the considered loading range showed that the stiffness and the strain value of the system do not change in both cases. Polylactic acid implants perform an additional (reinforcing) function of fixing screws in the head of humerus. Cortical screws due to the connection with PLA implants have a large contact surface fixation, which leads to a decrease in the possible number of degrees in the screw freedom when fixing a fracture of the humerus, weakened by osteoporosis. It should be also noted that the function of cortical screws fixation leads to an increase in the local effect of the plate on the cortical bone for the considered simulation case. The loading of the cortical bone in the cases under consideration leads to the same increase in maximum stress by 12 %. However, this increase in stresses does not affect the bond strength. The contact of the cancellous screws with the PLA implants does not cause significant changes in the stress-strain state in the cortical bone, nor the cancellous bone of the fragments of the head of humerus. The cancellous bone stress value in the area of PLA implant location increased by 0.4 *MPa*, while in the other analyzed areas the deviation did not exceed 0.01 *MPa*. In the lower part of the head of humerus, at the level of a fracture in the area of the surgical cervix, there was a redistribution of stress fields with a decrease in the maximum stress value in case of using PLA implants. The value of stress arising in PLA implants does not affect the strength of the connection, and they are 5 times lower than those allowed for PLA.

Clinical observations showed that, despite the use of locking plates, osteosynthesis failures with three- and four-fragment PHF take place in 15.6–35.4 % of cases according to different authors. In order to prevent the collapse of the head fragment and the varus displacement of the head due to the muscle tone of the rotation cuff, the perforation of the fragments of the head of humerus with screws, and the migration of metal structures, some of the authors use cancellous cannulated screws followed by the introduction of bone cement. A number of researchers proposed to use the fibula allograft, and some metal mesh sliding structures. A number of studies showed that the introduction of support screws allows achieving satisfactory stability of fragments with three and four-fragment PHF. Our experimental studies showed that using two polylactic acid implants can increase the stiffness of the "bone-implant" system. A comparative study of the stress-strain state confirmed experimental data, which let us recommend the use of this relatively inexpensive and easy-to-process material as a reinforcing and supporting implant during osteosynthesis of three- and four-fragment PHF, especially in case of osteoporosis.

CONCLUSIONS

A comparative analysis of the stress-strain state of the bone-implant system during osteosynthesis with PHILOS angular stability plate with and without polylactic acid implants showed that polylactic acid implants allowed reducing the plate and screws stresses by 11 % and 6 %, respectively. A comparative study of the stress-strain state of these two "bone-implant" systems showed that the rigidity and deformation value of the systems did not change in any case. Using polylactic acid implants during osteosynthesis of three- and four-fragment PHF, especially in case of osteoporosis, allowed providing reinforcement of metal structures and support for the articular surface.

Prospects for further research: The prospect of further research is the experimental substantiation of non-toxic implants.

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Conflicts of interest:
Authors declare no conflict of interest.

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