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Biomechanical Analysis of the System "External Fixation Device – Bone» Behavior at the Stages of Tibial Diaphyseal Fracture Healing

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Summary. *The use of external fixation devices for the treatment of diaphyseal fractures of the tibia has become the standard. However, most external fixation device (EFD) modifications have insufficient stiffness. Therefore, there is a need to develop an EFD design that could provide early limb loading with an optimal range of interfragmentary motion. A related challenge lies in determining the strength of bone regeneration during fracture healing, which cannot be objectively assessed in a clinical setting. However, these values can be calculated using the Finite Element Method (FEM).* ***Objective.*** *The objective of our work was to study the biomechanical behavior of the proposed «External Fixation Device – Tibia» system at the stages of bone regeneration under the condition of its loading by body weight using the FEM.* ***Material and Methods.*** *A computer simulation was carried out, at the initial stage of which a semi-full-scale prototype of the «External Fixation Device – Tibia» bone fragments fixation system was developed. Based on it, the next step was to create solid 3D models of the tibia and the EFD using the SolidWorks software package (Dassault, France). The EFD design used in the work consisted of 4 semi-rings (160 mm), 9 connecting beams (150 mm), two through pins (5 mm), 2 spongiosis screws (5 mm), 2 cortical screws (5 mm), and 6 clamps. All the components of the EFD were made of AISI320 stainless steel.* ***Results and Discussion.*** *Simulation computer modeling of the fixation capabilities of the proposed EFD showed that its stiffness is sufficient to provide a controlled load on the damaged limb within 20-24% of body weight from the first days of formation of granulation cartilage regenerate. It should be noted that the supporting function of the fibula is restored within 5-6 weeks after its fusion and is approximately 17-30% of the body weight. Therefore, in general, a controlled load on the limb can reach 50% of the body weight after 6 weeks of treatment. Subsequently, when mature bone tissue is formed around the fracture (most often within 8-17 weeks), the load on the limb can reach 130% of the body weight, which ensures the patient's movement without additional support.* ***Conclusions.*** *The performed computer simulation modeling makes it possible to determine the behavior of the biomechanical environment of the proposed «External Fixation Device – Bone» system and allows to establish the amouth of limb loading in the process of developing a scientifically based rehabilitation program to create optimal conditions for fracture healing. The proposed design of the EFD can be used for the final treatment of diaphyseal fractures of the tibia and provides for the possibility of early loading on the «External Fixation Device – Bone» system.*

Keywords: *tibial diaphyseal fracture; external fixation device; finite element method; limb loading.*

Introduction

The use of external fixation devices (EFDs) for the treatment of open diaphyseal fractures of the tibia has become the standard, since it enables extrafocal fixation of the fracture, is characterized by low tissue injury and comparative ease of use, and allows controlling the process of osteogenesis, implementing corrective, stabilizing, and dynamizing transformations of the fixation system during treatment. As a result, there are many modifications of EFDs, which can be divided into two main groups. The first group involves unilateral constructions of EFDs, which are quite simple to use but have

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limited fixation capabilities and are intended only for temporary stabilization of fragments with their subsequent replacement with another method of osteosynthesis [1]. At the same time, the second group of EFDs is characterized by significantly greater rigidity, since it there is a bilateral fixation of the device. This group mainly includes EFDs with annular and semi-annular external supports, for which through-hole drilling with two-sided fixation of spokes or rods is provided [2]. Such rigid devices can be used as the main final external method of osteosynthesis in cases where, for various reasons, contraindications to internal osteosynthesis arise [3].

Based on experimental and clinical studies, the effect of interfragmentary movement (IFM) of fragments on the process of bone healing, which is known to regulate mechanically induced tissue differentiation, has been revealed. At the same time, the range of IFM depends on both the magnitude of limb loading during treatment and the rigidity of the EFD – the mechanical behavior of the system «External Fixation Device – Bone». Excessive loading may lead to hypertrophic nonunion, whereas excessive rigidity of the EFD can cause bone tissue hypotrophy. Therefore, it is significant to develop such an EFD design that would provide optimal rigidity of the system «External Fixation Device – Bone», ensuring controlled limb loading with an appropriate range of IFM [4].

The intensity of bone regeneration during fracture healing and the safe amount of load cannot be objectively measured in clinical settings, as well as the type and extent of mechanical reaction that cause various tissue processes with intramembranous or endochondral ossification. However, the above quantities can be calculated using the Finite Element Method (FEM). Thus, the mechanical behaviour of the system «External Fixation Device – Bone» and its stability can be assessed quantitatively.

The objective of this work was to study the behaviour of the proposed «External Fixation Device – Bone» system at the stages of bone regeneration in the diaphyseal fracture of the tibia in the postoperative period after osteosynthesis.

Material and Methods

Simulation computer modeling was carried out, with development of the semi-full-scale prototype of the bone fragments fixation system «External Fixation Device – Tibia» (Fig. 1). 3D solid models of the tibia (Fig. 2) and the EFD (Fig. 3) were created using the SolidWorks software package (Dassault, France).

The EFD model with a rigid configuration for the final treatment of the diaphyseal fracture of the tibia with the possibility of a controlled load on the limb and dynamization of the system was used in the study.

The proposed EFD consisted of 4 semi-rings (160 mm), 9 connecting beams (150 mm), two through pins (5 mm), 2 spongiosus screws (5 mm), 2 cortical screws (5 mm), 6 clamps, 2 cantilever supports for fixing the rods, and 36 nuts (Fig. 1). All components of the EDF were made of AISI320 stainless steel. Four semi-rings were connected to each other by 9 beams passed through holes in the semi-rings and fixed with nuts. The beams were placed between the semi-rings by three units. In addition, two additional cantilever supports were used, connected to the proximal and distal semi-rings with bolts. All semi-rings were located in the axial plane [5].

Two through pins were passed through the epimetaphysis of the tibia in the coronal plane, at the distance of 2-3 cm from the articular surface. Two cortical screws were passed through the canals in the tibia at the distance of 3-4 cm from the fracture line. The remaining two unilateral spongiosis screws (2) were drawn in the sagittal plane through the canals in the epimetaphyseal area (Fig. 1).

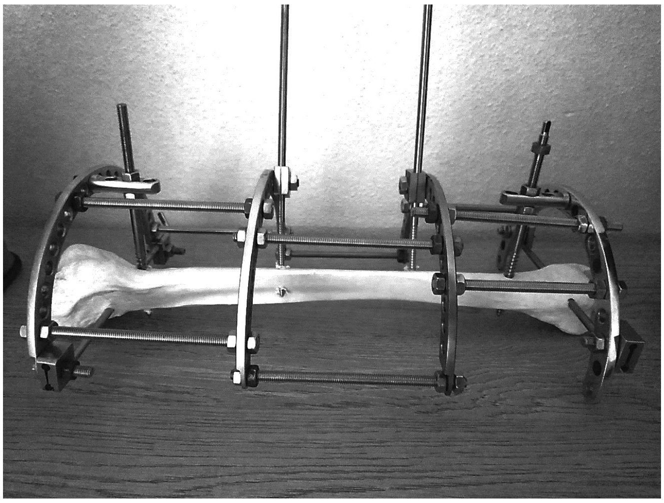

Fig. 1. Semi-full-scale prototype of the system «External Fixation Device – Tibia».

Anatomical and anthropometric data, closely approximating real conditions, were taken into account to develop the computer model. The cross-sectional model of the tibia included cortical bone, spongy bone, and bone marrow (Fig. 2).

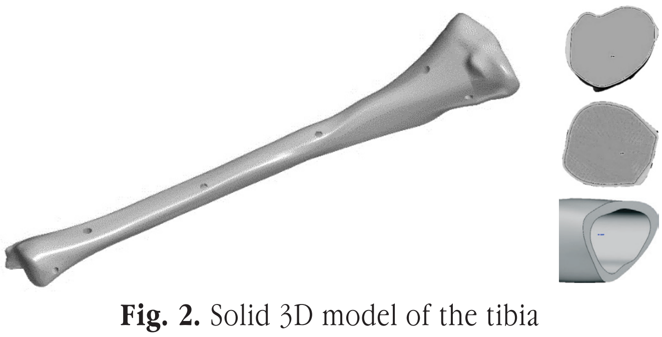

Fig. 2. Solid 3D model of the tibia and its cross-section

Solid models of the tibia and the EFD were assembled into a single system of bone fixation elements, where the tibial oblique fracture with an interfragmentary diastasis of 2 mm was created in the middle third of the diaphysis (Fig. 3). 3D model of the system «External Fixation Device – Tibia» was imported into the ANSYS Workbench Mechanical (R2020, ANSYS, Inc.) for further finite element analysis of its stress-strain state (SSS). Depending on the stage of bone regenerate formation in the postoperative period, the interfragmentary space was filled with the appropriate tissue using its mechanical properties (Table 1) obtained from the literature [6-8].

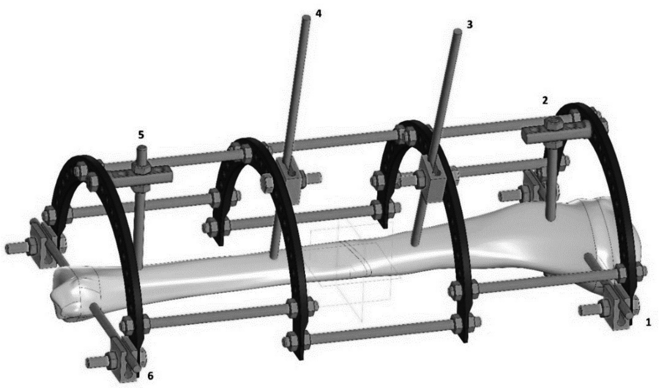

Fig. 3. Tibial diaphyseal oblique fracture fragments fixation in the EFD.

At the next stage, a finite element mesh of the tibial fracture fragments fixation system was generated. It consisted of 589,237 nodes and 332,270 elements, providing sufficient accuracy for calculations (Fig. 4). Linear tetrahedron finite elements with dimensions that did not exceed 1 mm predominated. In the most important transition areas of the model, with different mechanical properties, the finite element mesh was thickened to improve the accuracy of calculations. Discretization was performed with the elements which are sufficiently small, so reducing the size of the element to an acceptable level provides the necessary detail of the design model and ensures more reliable results.

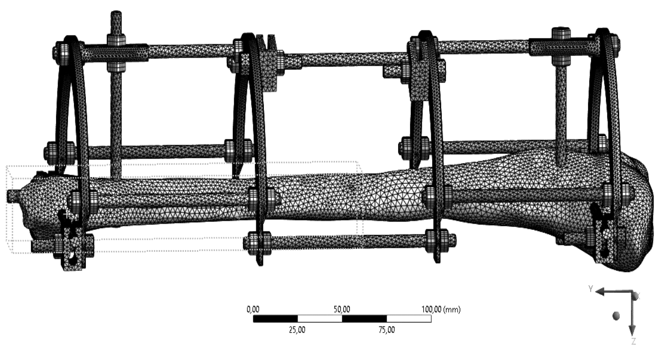

Fig. 4. Finite element mesh.

Table №1

Physical properties of materials

Material type	Young's modulus, MPa	Poisson's ratio	IFM,
Granulation tissue	1 [6]	0.17	%
Fibrous tissue	2 [6, 7]	0.17	10
Cartilaginous tissue	10 [6, 7]	0.17	10
Spongious bone tissue	500	0.28	5
Stiff callus	6,000 [7, 8]	0.3	-
Cortical bone tissue	20,000 [7, 8]	0.3	2
Medical steel	200,000	0.3	-

Boundary conditions and loading applications. The interface between the bone fragments and screws were modelled as a bonded contact condition, whereas the contact between the metal elements and bone fragments was specified as frictionless. Frictionless contacts were also specified between bone fragments. Screw threads were omitted from the models to simplify finite element analysis. A mesh convergence analysis was conducted to ensure solution convergence. Models were subjected to idealized loads representing a pseudo-static single-leg stance (100% body weight [BW] 800N), with force applied through the tibial plateau (B), directed distally along the mechanical axis of the tibia. The distal end of the tibia was fixed, while a force of 800N was applied to the proximal tibial surface in 1 sec with free motion. All finite element analyses were completed in the same boundary and loading conditions (Fig. 5).

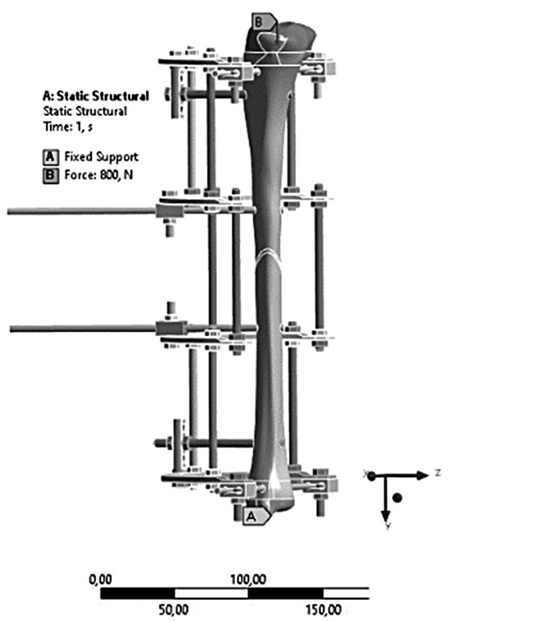

Fig. 5. Boundary conditions and loading applications.

Interfragmentary movement is taken as a criterion for the stability of fragment fixation [9]. The term «stability» is used in the study according to its use in clinical practice to define the displacement of fracture surfaces as a function of loading. With interfragmentary compression of fragments involved in the contact, their displacement is not observed, which indicates the absolute stability of fixation. The surfaces of fractures, which were fixed during osteosynthesis without the use of compression, are subject to interfragmentary displacement. It is proportional to the applied load and inversely proportional to the stiffness of the tissue in the interfragmentary area [10]. At the same time, according to the literature, stimulation of osteogenesis occurs with deformation of the soft tissue callus in the range of 5-10% of the size of the interfragmentary space and decreases to 1-2% in the later stages of bone remodelling at the fracture site. IFM at different stages of callus formation, depending on the type of tissue in the interfragmentary area, should not exceed 10% [11-13].

Quantitative assessment of interfragmentary movements under body weight load was carried out using the FEM with analysis of Directional Deformations in the interfragmentary space along the X-, Y-, and Z-axes (Fig. 5). Calculations of the possible ultimate loading on the bone regenerate for each stage of callus formation were performed based on the IFM under the influence of compression load that allowed up to 10% for granulation and fibrous tissue, 5% for cartilage tissue, and 2% for stiff callus [9, 10, 13, 14].

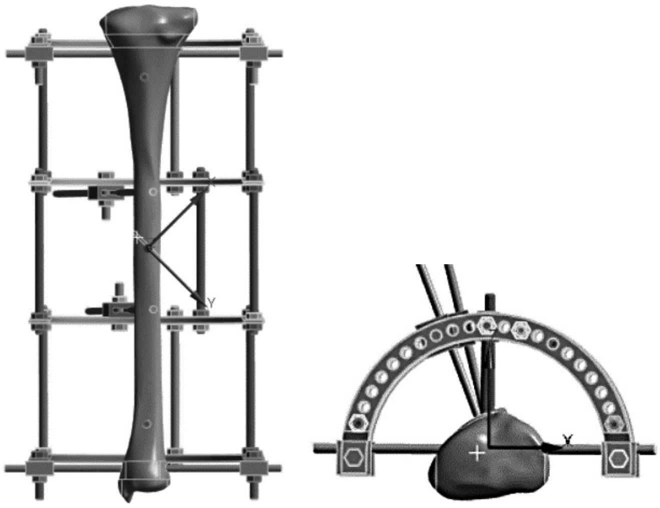

Fig. 6. Location of the X-, Y-, and Z-axes along the fracture plane for Directional Deformations calculations.

Validation of the FEM was carried out by mechanical loading of a semi-natural model of the «External Fixation Device – Bone» system in a universal testing machine Inspekt Solo 2.5 (Hegewald & Peschke, Germany), with registration of force and displacement data on a peripheral computer software. Instead of the tibia, a beech billet of the corresponding diameter was used, which in terms of mechanical properties is as close as possible to the properties of bone (Fig. 7). The beech billet was fixed using aluminium sockets mounted on its proximal and distal ends, with free moment under compression force of VT=1 mm/min.

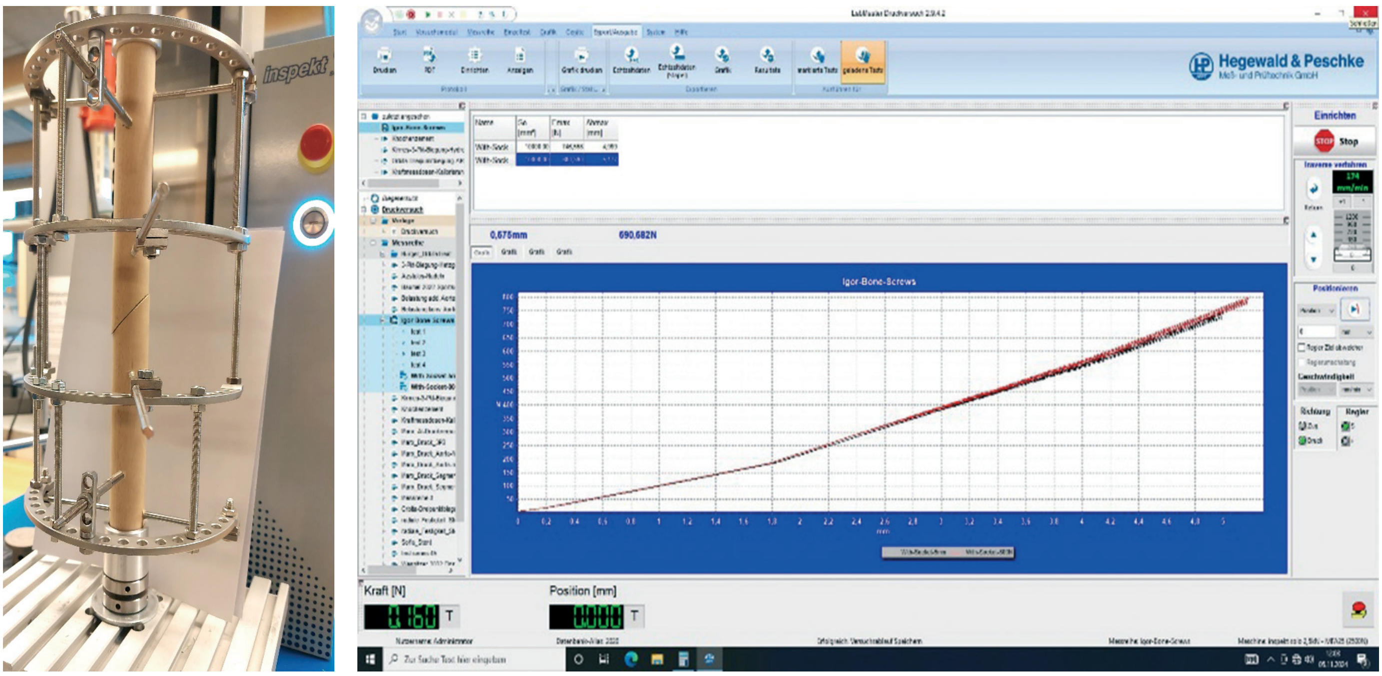

Fig. 7. Mechanical loading of a semi-natural model in a universal testing machine.

Results

The obtained values of Directional Deformations in X, Y and Z axes for each type of tissue in the interfragmentary space, depending on the stage of callus formation, are presented in Figure 8, and their correlation with the permissible values of IFM is presented in Table 2. The dimensions of the interfragmentary space are as follows: 2 mm in the direction of the X-axis, 28 mm in the direction of the Y-axis, and 22 mm in the direction of the Z-axis. Relative to these values, Directional Deformations in % were determined for each tissue type in the interfragmentary area in the direction of the X-, Y-, and Z-axes (Table 2).

Table №2

Directional Deformations (mm) for each tissue type in the interfragmentary area in the direction of the X-, Y-, and Z-axes

	X	Y	Z	X	Y	Z	IFM, %
	mm			%			
Granulation Tissue	0.98	1.58	1.15	49.0	5.6	5.2	10
Fibrous tissue	0.82	1.42	0.85	41.0	5.1	3.9	10
Cartilaginous tissue	0.41	0.75	0.34	20.5	2.7	1.5	5
Stiff callus	0.03	0.04	0.05	1.5	0.1	0.2	2
Interfragmentary space size	2	28	22				

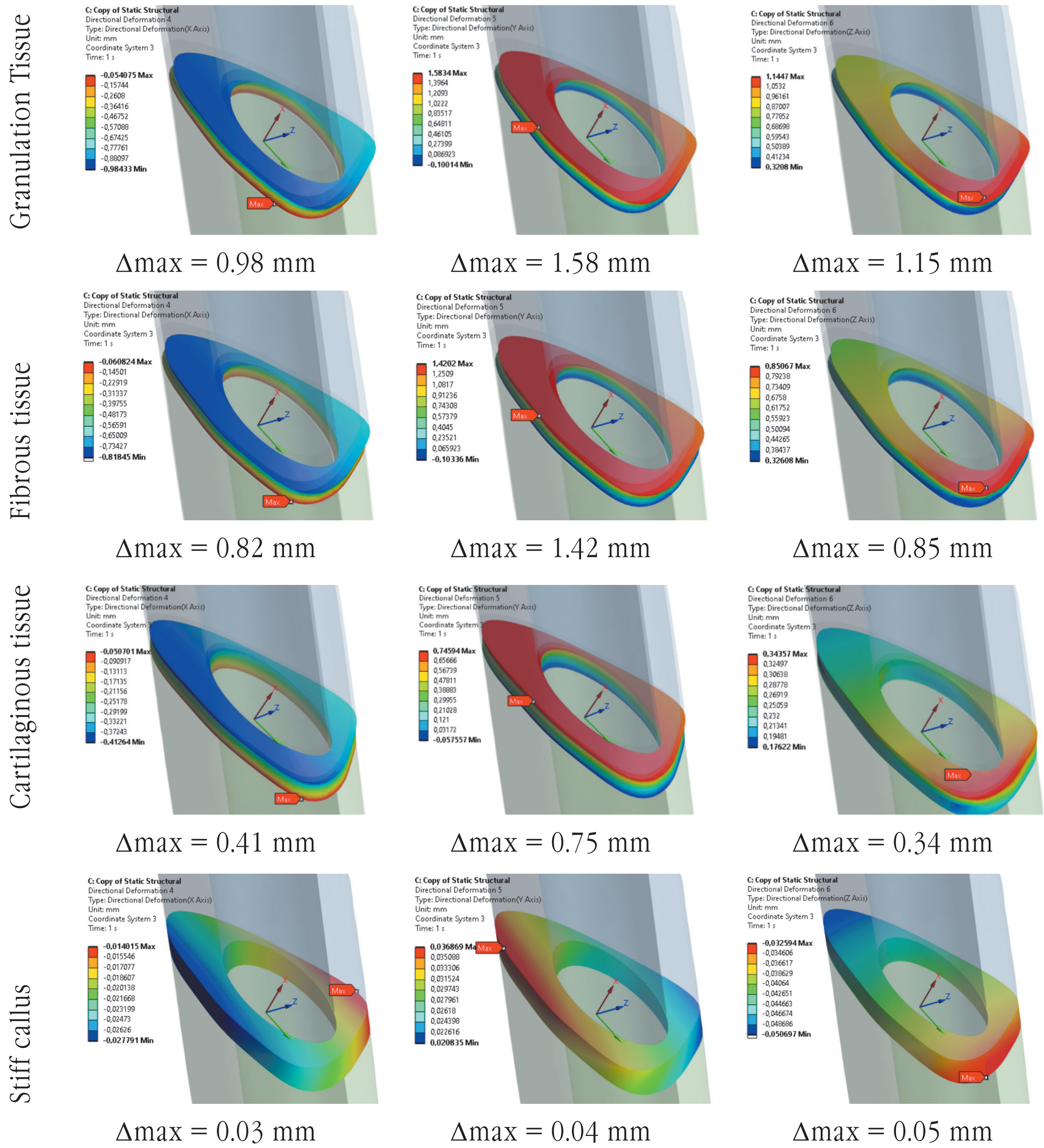

Fig. 8. Directional Deformations of the interfragmentary diastasis along the fracture plane in the direction of the X-, Y-, and Z-axes.

Based on the data obtained in simulation by the FEM, the values of possible ultimate limb loading, expressed as a percentage of body weight, were determined for different stages of callus formation (Table 3). The minimum value of Directional Deformations (X, Y, and Z) along the fracture plane in the interfragmentary area was selected as the basis for calculating the possible ultimate load for each type of callus tissue.

Table №3

Possible ultimate load calculation for each type of callus tissue

	Possible ultimate load calculation in the direction of axis, N			Minimum value, N	Possible ultimate load in % of body weight
	X	Y	Z		
Granulation tissue	163.3	1,417.7	1,530.4	163.3	20
Fibrous tissue	195.1	1,577.5	2,070.6	195.1	24
Cartilaginous tissue	195.1	1,493.3	2,588.2	195.1	24
Stiff callus	1,066.7	11,200.0	7,040.0	1,066.7	133

The obtained values of the Total Deformations of the semi-natural model of the «External Fixation Device – Bone» system in the universal testing machine under a compression load of 800N (body weight) were 5.17 mm, which fully corresponds to the Total Deformations of the FEM of the «External Fixation Device – Bone» under similar conditions – 5.21 mm (Fig. 9).

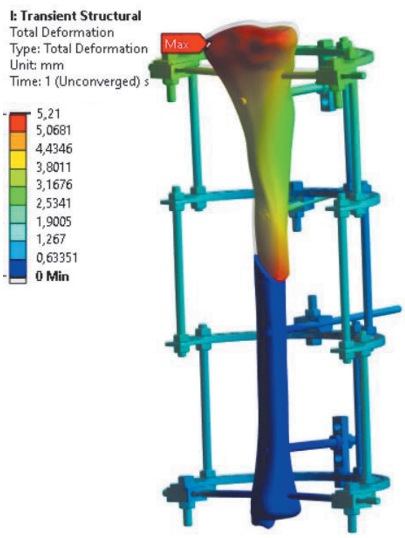

Fig. 9. Total Deformations of the FEM of the «External Fixation Device – Bone» under compression load of 800N.

Discussion

Based on the obtained data on the possible ultimate load on the limb for various stages of callus formation, recommendations for developing an appropriate rehabilitation program have been proposed. It is advisable to add a controlled load on the limb using floor scales to the rehabilitation program for the treatment of diaphyseal fractures in the EFD with the proposed composition. Fractures treated with early loading heal almost twice as fast as with other approaches [15, 16]. In the absence of complications, mechanical training of the callus can be started from the first week of the postoperative period. The decision to start the limb loading is made exclusively by the surgeon, taking into account the influence of the following factors: the complexity of the fracture, the outcome of the surgery in terms of the reliability of the reposition of bone fragments, the achieved stability of fixation, the composition of the EFD, the patient's body mass index, age, bone quality (osteoporosis), the presence of cognitive impairment, the level of mobility before the fracture, and the patient's compliance – the willingness to follow the doctor's recommendations for treatment. Any deviations from the normal course of reparative osteogenesis may be a factor in revising the tactics of rehabilitation treatment for this category of patients.

Computer simulation of the fixation capabilities of the proposed EFD demonstrated that its rigidity is sufficient to ensure early limb loading in the range of 20 – 24% of body weight from the first days of the granulation and cartilaginous tissues regenerate formation. Faster consolidation of the fibula (5-6 weeks) can shorten the duration of physical therapy measures with a controlled load on the operated limb in the EFD and provide the opportunity to increase its level at the stages of callus formation. As a result, the value of the limb loading can reach up to 50% of the body weight (double-leg stance) after 6 weeks of treatment. Later, when stiff callus is formed around the fracture (8-17 weeks), the load on the limb can reach 130% of the body weight, which will allow the patient to move without additional support [4]. Considering the obtained data, the EFD in the proposed composition allows it to be used as a final method of treatment and to carry out effective conversion, preventing the occurrence of complications. Recommendations are provided with a certain margin of safety.

All measures with loading on an operated limb are supervised by an orthopedic surgeon; the patient's condition, the state of bone fragments, the integrity of the EFD components, and the changes on the repeated radiograms undergo constant monitoring. The tactics and modes of rehabilitation protocol using controlled limb loading can be influenced by the size of the diastasis between the bone fragments, the type of fracture (oblique, transverse, or spiral), and the EFD composition.

Conclusions

The study suggests that in diaphyseal fractures of the tibia after osteosynthesis in the EFD, an early operated limb loading allows for «training» of callus formation. With fixation of an oblique diaphyseal fracture of the tibia with an interfragmentary diastasis of 2 mm in the proposed EFD, the limb loading should not exceed 20% of the body weight at the stage of granulation and fibrous tissue formation, 24% for the cartilaginous tissue stage, and 133% for the stiff callus stage. At the stage of callus transformation into the cortical bone, gradual dismantling of the EFD is possible. These mathematical calculations can help surgeons in providing more precise recommendations to patients regarding optimal limb loading regimens during rehabilitation treatment of tibial fractures in the EFD. Further studies of the maximum possible ultimate loading could form the basis for future prospective randomized studies, which in turn would guide the development of updated clinical recommendations.

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Біомеханічний аналіз поведінки конструкції «АЗФ-кістка» на етапах формування кісткового регенерату діафізарного перелому великогомілкової кістки

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Резюме. *Застосування апаратів зовнішньої фіксації (АЗФ) для лікування діафізарних переломів кісток гомілки стало стандартом. При цьому переважна більшість модифікацій АЗФ має недостатню ригідність. Отже постає необхідність в розробці такої конструкції АЗФ, яка б могла забезпечити раннє навантаження кінцівки при оптимальному обсязі міжфрагментарного руху. Дотичною проблемою є необхідність визначення механічної міцності кісткового регенерату під час загоєння перелому, яку неможливо об'єктивно виміряти в клінічних умовах. Проте вищезазначені величини можливо розрахувати за допомогою методу кінцевих елементів (FEM). Метою роботи стало визначення методом скінченних елементів (МСЕ) біомеханічної поведінки запропонованої конструкції «АЗФ-великогомілкова кістка» на етапах формування кісткового регенерату за умови його навантаження вагою тіла.* ***Матеріали та методи дослідження.*** *Проведено імітаційне компютерне моделювання, на початковому етапі якого створено напівнатурний прототип системи фіксації кісткових фрагментів «АЗФ–великогомілкова кістка». На його основі, наступним кроком, було створення засобами програмного пакету SolidWorks (Dassault, France) твердотільних 3D моделей великогомілкової кістки (ВГК) та АЗФ. У роботі використано конструкцію АЗФ яка складається із 4 напівкілець (160мм), 9 зєднуючих балок (150 мм), двох наскрізних стержнів (5мм), 2 спонгіозних стержнів (5мм), 2 кортикальних стержнів (5 мм), 6 замків. Всі компоненти АЗФ виконані з нержавіючої сталі AISI320.* ***Результати дослідження та їх обговорення.*** *Імітаційне компютерне моделювання фіксаційних можливостей запропонованого АЗФ показало, що його ригідність достатня для забезпечення дозованого навантаження ушкодженої кінцівки в межах 20 – 24 % ваги тіла ще з перших днів утворення грануляційно - хрящового регенерату. Необхідно врахувати що опорна функція малогомілкової кістки відновлюється вже через 5 – 6 тижнів після її зрощення і складає приблизно 17 – 30% ваги тіла. Отже загалом дозоване навантаження кінцівки може сягнути 50% ваги тіла вже після 6 тижнів лікування. У подальшому, коли утворюється зріла кісткова тканина навколо перелому, найчастіше протягом 8 - 17 тижнів, навантаження на кінцівку може складати 130% ваги тіла, що забезпечує рух пацієнта без додаткової опори.* ***Висновок.*** *Проведене імітаційне комп'ютерне моделювання дає можливість визначити поведінку біомеханічного середовища запропонованої системи АЗФ-кістка та дозволяє встановити обсяг навантаження кінцівки у процесі розробки науково обгрунтованої реабілітаційної програми для створення оптимальних умов зрощення перелому. Запропонована конструкція АЗФ може застосовуватись для остаточного лікування діафізарних переломів ВГК та передбачає можливість раннього навантаження системи АЗФ-кістка.*

Ключові слова: *перелом діафузу кісток гомілки, апарат зовнішньої фіксації, метод кінцевих елементів, навантаження кінцівки.*