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Original scientific paper

Development and Experimental Verification of a Generative CAD/FEM Model of an External Fixation Device

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Abstract: This paper presents the development and experimental verification of a generative CAD/FEM model of an external bone fixation device. The generative CAD model is based on the development of a parameterized skeleton algorithm and sub-algorithms for parametric modeling and positioning of components within a fixator assembly using the CATIA CAD/CAM/CAE system. After a structural analysis performed in the same system, the FEM model was used to follow interfragmentary fracture displacements, axial displacements at the loading site, as well as principal and Von Mises stresses at the fixator connecting rod. The experimental analysis verified the results of the CAD/FEM model from an aspect of axial displacement at the load site using a material testing machine (deviation of 3.9 %) and the principal stresses in the middle of the fixator connecting rod using tensometric measurements (deviation of 3.5 %).The developed model allows a reduction of the scope of preclinical experimental investigations, prediction of the behavior of the fixator during the postoperative fracture treatment period and creation of preconditions for subsequent structural optimization of the external fixator.

Keywords: external fixation device; generative CAD model; interfragmentary displacements; principal stresses

1 INTRODUCTION

With regard to the organization of models and the application of modern technologies, the design process should be based on the widespread use of computer support in all its stages, i.e. it should be based on the principle of simultaneous design. All this leads to the fact that it is necessary to develop a computer model of products that will meet the requirements defined by a systematic approach to design. In this sense, the basis of a generative CAD model should be a parameterized model with characteristics meeting the requirements of simultaneous design.

Parametric modeling has an advantage over classical modeling enabling a quick and easy acquisition of various design variants, memorization of structural changes and reuse of previously formed models [1]. In engineering analysis, it is often necessary to represent some physical form using unambiguous expressions. These relationships should mathematically describe the geometric shape of an associated 2D or 3D continuous physical shape using scalar parameters. The geometric shape is described by parametric equations and a set of scalar parameters, enabling its visualization, simulation of the interaction of the shape with the environment and geometric transformations. There are many published studies on generative design and parametric modelling [2-7].

The parameterization technique is one of the key points in the process of the automation of an analysis and optimization of design. It should be flexible to allow the description of various complex shapes with a minimum number of geometric constraints. Parameterization adds intelligence to the model, defining the interdependencies between the elements, dimensions and parameters of the model. This allows changes to be made to all model elements connected with the parameters, thereby updating the model transferring it to the new desired configuration. In this way, it is possible to express all dimensions of the fixator as a function of several sizes or parameters and to couple them with the processes of calculation and later optimization.

The parameterization method used and the algorithms developed should allow for an automatic link between the CAD and FEM models. The developed parameterized model of the external fixator should meet the following requirements: the geometry of the model should as closely as possible map the geometry of the real fixator to enable the FEM analysis and then structural optimization; rapid change of geometry parameters in order to form different fixator configurations; parametric modeling approach based on technical elements with as few design parameters as possible; regularity check of fixator design; analysis of elements loading and stress-strain states using appropriate solver and associativity.

Prior to the fixator parameterization process, the following activities were performed: the fixator configuration complexity check, development of the fixator model design plan, definition of basic independent and dependent parameters, as well as establishment of the most efficient method of the fixator parameterization.

2 DEVELOPMENT OF A GENERATIVE CAD MODEL

With the aim to develop a generative model and to achieve the flexibility of the created fixator model, the so-called Top-Down design method was used. This method involves a working mode with a view from the top over the basic model design, as well as applying associativity and parameterized relations [6]. This approach is actually reflected in the formation of a so-called parameterized skeleton representing the infrastructure of the fixator through which appropriate interactions between design parameters are established (Fig. 1). In this way, the knowledge about design is integrated into the CAD model through the skeleton, which represents the basis of a so-called *generative modeling*. Therefore, the generative model is not only an extension of the parametric model, but forms a certain knowledge base of the design forms represented by the CAD model forms. The knowledge base can also be composed of information obtained "externally" based on experimental and/or structural analysis. The use of a parameterized skeleton of the fixator enables:

- Design based on detailed specifications. All relevant information are stored in the skeleton model. The spatial constraints are completely defined within the skeleton in order to position the components within the fixator assembly.
- Updating the model. The skeleton allows changes to be made to the models of individual components as well as the complete fixator, so that the modifications in the skeleton are reflected to all individual components and subsets of the fixator.
- Model flexibility. The key information stored in the skeleton can be associated with the corresponding fixator components. However, the components can be modified independently of each other and independently of the skeleton, because of not being interconnected. Also, it is possible to remove specific components of the fixator without affecting the others.

The skeleton is formed at the very beginning of the development of a parameterized model based on the analysis of the geometrical characteristics of the components and assembly, as well as their interrelations.

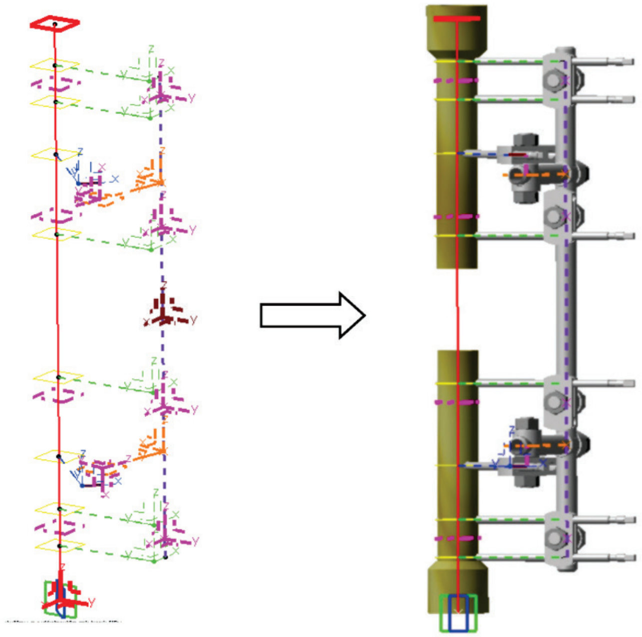

Figure 1 Parametrized skeleton and fixator model

Also, functional requirements and model elements considered necessary to fulfill its function are included in the analysis. Skeleton basically contains knowledge stored in the form of parameters, relations and basic geometry of design. It is important to define the referent design parameters in the skeleton, i.e. parameters that, through appropriate relations, connect the geometry of the complete structure. After defining the parameters in the skeleton, they are published and used as external parameters when defining the shape and position of individual components within the fixator assembly. In this way, the parameterized skeleton gives the necessary flexibility to the fixator design in terms of rapid adaptation to the new parameter values [7].

The relations within the skeleton give flexibility of the fixator design in terms of defining the way of changing the shape, position, and orientation of the components in the assembly. Relation arguments contain referent design parameters and geometric elements that position the fixator components with respect to the main coordinate system of the skeleton (Figure 1). Relationships represent the most important part of the generative model and reflect knowledge of the structural, functional and technological properties of the fixator.

The complete fixator design is parameterized with 28 design parameters in order to define the shape of the components, 9 of which are independent parameters. The three referent design parameters of the fixator model are: the outer diameter of the connecting rod d_s, the wall thickness of the rod δ and the basic thickness of the plate δ_{po}. Appropriate relations have been established between these three referent parameters and certain parameters of fixator model components comprised by the updating process. In this way, the complete fixator model is updated based on the values of the referent parameters. The referent parameters were selected on the basis of the following ascertainments: their change produces a significant effect on the mass and stability of the fixator; the relations are simply connected with other parameters and allow easy modification of both components and complete fixator; by changing their values, the existing simplicity of the design is retained [10].

In addition to parameters and relations, the skeleton contains the basic geometry of the fixator with all the referent elements for positioning components in space such as points, axes and planes. The position of all the above elements is precisely defined with respect to the main coordinate system of the skeleton using referent parameters for positioning (coordinates of points, distances, lengths, etc.). Subsequently, the local coordinate systems, axes and characteristic points of the fixator components are aligned with the skeleton reference elements (Figure 1). In this way, the complete flexibility of the fixator model is achieved and simultaneous modifications of its components are supported.

After the formation of the fixator skeleton, it is necessary to form parameterized models of its components via the sub-algorithms formed. Fixator components that will change their shape, dimensions or position in the structure during the optimization process need to be parameterized. In this way, parameterization of the model connecting rod of the fixator, clip, clamping ring, clips carrier and clamping plates was performed. In order to design component models, their parameters are first defined in the skeleton and then linked to the fixator components via external parameters.

Developed sub-algorithms are in charge of controlling modifications of parameterized models of the fixator components. These sub-algorithms include: external parameters, relations and commands for shaping models and modifying formed shapes. Sub-algorithms within components retrieve external parameter values from the skeleton. The next step considers relating the design parameters of the components to the external parameters via relations. Finally, modeling of the components is performed using sub-algorithms via shaping commands.

During the formation of the fixator model, it is very important, when associating the relations between components, that all constraints are defined due to proper parameterization. Also, when changing the dimensions of individual components, it is important that complete fixator is properly updated. Testing of the flexibility and correctness of the fixator CAD model also considers its analysis in order to determine possible interference of two or more components of the fixator. When updating a model, overlapping or uncontrolled backlash may occur due to parameter changes. The geometric and meritorious connections of the forms of individual elements allow for an instant adaptation to the changes of the model. Development of generative CAD model is performed in CATIA CAD/CAM/CAE system.

3 STRUCTURAL ANALYSIS

Fixator components are modeled by finite elements of linear (TE4) and parabolic (TE10) tetrahedron type. Both elements belong to the group of 3D isoparametric elements, i.e. solids with six edges, using the same interpolation functions and the same nodes to approximate the geometry and fields of the basic unknowns in the element [8]. There are three degrees of freedom in each node of these finite elements. These are the displacements u, v and w in directions of x, y and z axes of the rectangular coordinate system.

The external fixator is made of special stainless steel for the manufacture of medical devices. For isotropic materials, the constitutive relations or stress-strain relations for a linear elastic material contain only two independent constants: the modulus of elasticity E and the Poisson's coefficient ν. A special form of anisotropic material is an orthotropic material with three planes of symmetry. It is common for orthotropic material to define material parameters such as modulus of elasticity, Poisson's coefficient and shear modulus [8]. Bone segment models are made of beech wood with known properties.

The basic loading form of the external fixator is axial pressure. FEM model has been developed to simulate experimental investigation under axial loading, taking into account complete geometry of the fixator and bone model, the connections between the components, the applied load and the constraints applied [9]. During axial loading, bone models relied on spherical joints, while the intensity of axial compression of the proximal bone segment ranged in the interval $F = 0 - 600$ N with an increase in loading rate of 5 N/s. The FEM model layout of the fixator model before and after maximum axial compression with a representation of the interfacial displacements is given in Fig. 2.

In order to define maximum interfragmental displacement at the fracture site R, displacements of a pair of adjacent points at the end planes of the proximal and distal segments at the fracture site in x, y and z directions were determined [10]. The relative craniocaudal and lateromedial displacements (x and y directions) and axial displacements (z direction) of the observed points are determined by the following relations:

$$\begin{aligned} r_{D(x)} &= D_{p(x)} - D_{d(x)} \\ r_{D(y)} &= D_{p(y)} - D_{d(y)}, \\ r_{D(z)} &= D_{p(z)} - D_{d(z)} \end{aligned} \tag{1}$$

where $r_{D(x)}$, $r_{D(y)}$ and $r_{D(z)}$ are relative displacements of bone model segments at the fracture site in x, y and z directions, $D_{p(x)}$, $D_{p(y)}$ and $D_{p(z)}$ are absolute displacements of bone endpoints of the bone model proximal segment in x, y and z directions, $D_{d(x)}$, $D_{d(y)}$ and $D_{d(z)}$ are absolute displacements of bone endpoints of the bone model distal segment in x, y and z directions.

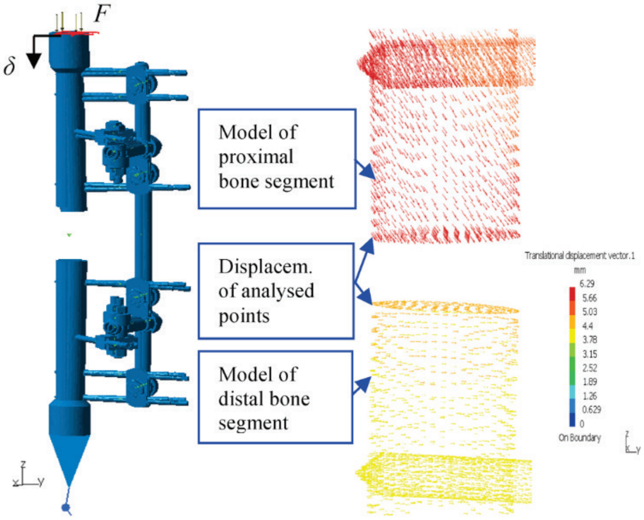

Figure 2 Non-deformed and deformed structure of the system under a maximum axial load and interfragmentary movement at the fracture site

The intensity of maximum interfragmental displacement vector at the fracture site R is defined by

$$R = \sqrt{\left(r_{D(x)}\right)^2 + \left(r_{D(y)}\right)^2 + \left(r_{D(z)}\right)^2}, \tag{2}$$

Complete mechanical investigations of the fixator stability, in addition to the analysis of displacements at the fracture site, include the analysis of principal stresses at the characteristic locations of the fixator structure [8, 9]. Here, appropriate stress analysis will only be presented for the case of axial compression as the dominant loading.

During structural FEM and experimental analysis, intensities and directions of principal stresses at two control points in the middle of the fixator connecting rod were monitored and analyzed. The measurement point closer to the bone model segment is labeled as MP-, while the location on the opposite side of the fixator connecting rod is labeled as MP+ (Fig. 3).

The direction of the maximum principal stress σ_1 at MP+ measuring point and the direction of the smallest principal stress σ_3 at MP- measuring point coincide with z axis and the axis of symmetry of the connecting rod, respectively. Fig. 3 shows the directions and intensities of the principal stresses at the measuring points (view B). It is observed that at MP+ measuring point the highest principal stress is actually the tensile stress, while at MP- measuring point the lowest principal stress is actually the compression stress. The tensile stresses have a lower intensity than the compression stresses, which is a direct consequence of the eccentric pressure the fixator connecting rod is exposed to. Also, it is noticeable that the dominant principal stresses (σ_1 and σ_3) are in a bending plane of the fixator, which does not coincide with the plane of the half-pins [11].

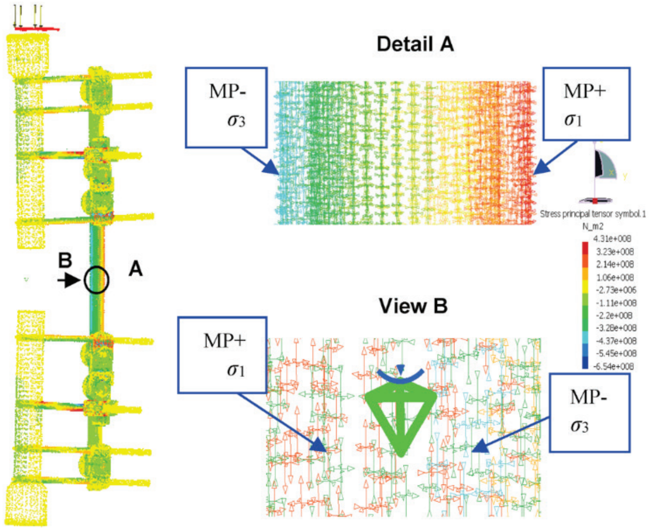

Figure 3 Principal stresses

4 EXPERIMENTAL ANALYSIS

Experimental tests of the fixator were performed at a Material Testing Laboratory at Faculty of Mechanical Engineering of the University of Sarajevo using a tensometric analysis equipment. In real conditions, the fixator is exposed to loading through bone segments. This fact was taken into account so that, during the experimental tests, the fixator loading was performed by means of bone model segments made of beech wood (mechanical properties similar to those of bone) [12].

During the tests, the displacement of the proximal bone segment at the loading site δ was monitored by a displacement transducer, whereas the loading F was controlled by a force transducer (U2A from HBM - Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany) on a material testing machine (Zwick GmbH & Co., Ulm, Germany, model 143501). Stress analysis by tensometric measurements was performed using a DMC 9012A digital measuring amplifier system with built-in DMV 55 modules to receive signals from type 3/120LY11 electrical resistance strain gauges manufactured by HBM (Fig. 4).

Two Wheatstone quarter bridge circuits with compensatory strain gauges were formed as the connecting rod was exposed to eccentric pressure due to the axial compression at the site of the proximal segment of the bone model [11]. This form of loading is manifested by the unequal distribution of tension and compression stresses along the longitudinal section of the connecting rod, meaning the neutral line does not coincide with the axis of symmetry of the rod (Fig. 5). Wheatstone quarter bridge circuits consist of an active SG strain gauge and a compensation or inactive SG2 strain gauge of the same type (Fig. 4 and 5). Compensation strain gauges are placed on unloaded plate tied to the fixator connecting rod in immediate vicinity of the active strain gauges. The plate is made of the same material as rod (fixator).

Figure 4 Fixator experimental setup

Applying general Wheatstone bridge equation [13]:

$$\frac{V_o}{V_s} = \frac{K_t}{4}\left(\varepsilon_{1'} - \varepsilon_{2'} + \varepsilon_{3'} - \varepsilon_{4'}\right), \tag{3}$$

to used quarter bridge circuit with compensating strain gauge, measured deformation is obtained based on the following relation:

$$\varepsilon_{1'} = \frac{4}{K_t}\frac{V_o}{V_s}, \tag{4}$$

where V_o and V_s are output voltage and supply voltage of Wheatstone bridge, K_t is a strain gauge coefficient, $\varepsilon_{1'}, \ldots \varepsilon_{4'}$, are strains measured by the strain gauges.

The active strain gauges were placed on diametrically opposite sides of the connecting rod at the closest and farthest point from the bone model (Fig. 3 and 5). Therefore, their longitudinal axis coincides with the directions of dominant principal strains (ε_1 and ε_3) at the measuring points. In this way, it is possible to determine the intensity of the dominant principal stresses at the measurement points [13, 14]. On the other hand, previously derived FEM analysis determined the direction and intensity of the principal stresses and observed that intensities of the other two principal stresses are negligible in relation to the highest principal stress σ_1 on MP+ and the lowest principal stress σ_3 on MP- (Tab. 2). In this case, the flexural strains are much larger than the compression strains ($|\varepsilon_s| \gg \varepsilon_p$) [15]. The strain distribution in the longitudinal section of the fixator connecting rod is shown schematically in Fig. 5. The principal stresses at the points MP+ and MP− are determined by the following relations:

$$\sigma_1 = \varepsilon_1 E\,; \;\; \sigma_3 = \varepsilon_3 E, \tag{5}$$

where E is the modulus of elasticity of the connecting rod material.

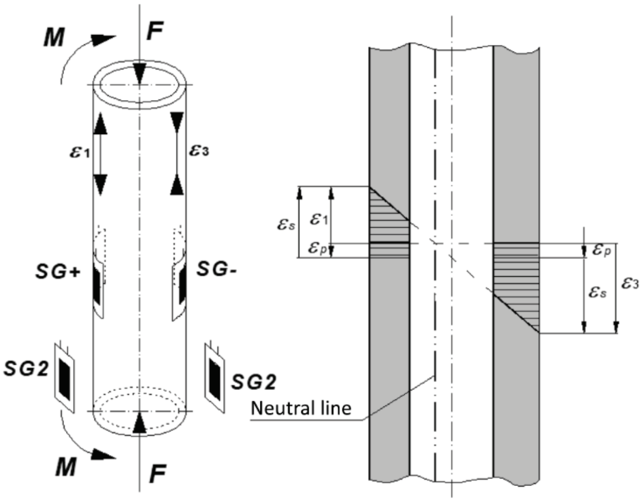

Figure 5 Strain gauges arrangement with distribution of strains at fixator connecting rod

Using the Catman software (HBM) for acquisition, processing, monitoring and analysis of measurement results from a measuring system, by scaling option, the original output strain unit mV/V is transformed to μm/m taking into account strain gauge and bridge factor values.

5 RESULTS AND CONCLUSION

Comparative diagrams of changes in the principal stresses σ_1 and σ_3, as well as a comparative diagram of axial load as a function of displacement at the loading point obtained by experimental testing and FEM method are shown in Fig. 6. A good agreement of the results is observed with maximum deviations of 3.9 % for displacements and 3.5 % for principal stresses.

Tab. 1 shows the values of interfragmentary displacements and displacements at the loading points. It can be observed that the relative axial displacements $r_{D(z)} = 4.14$ mm are dominant at the fracture points, and that the relative transverse displacements $r_{D(y)} = 0.15$ mm and $r_{D(x)} = 0$ mm leading to fracture unhealing or poor healing are significantly smaller (Eq. (1)).

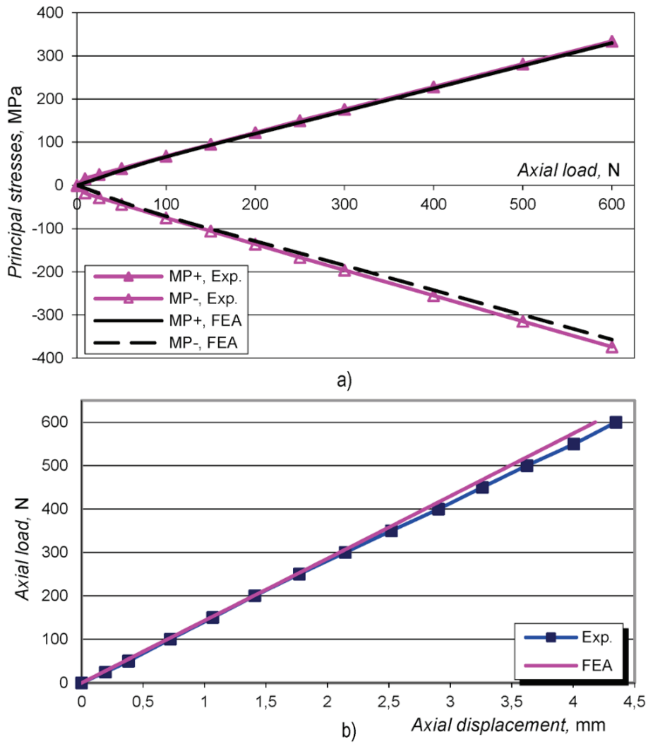

Figure 6 Comparative diagram of the principal stresses σ1 on MP+ and σ3 on MP- (a) and comparative diagram of the axial displacement at the point of load (b)

Table 1 Values of displacements under maximum intensity of load

Methods	Displacement of proximal segment at the fracture gap, mm			Displacement of distal segment at the fracture gap, mm			Max. relative displ. at the gap, mm	Displ. at the point of load, mm
	$D_{p(x)}$	$D_{p(y)}$	$D_{p(z)}$	$D_{d(x)}$	$D_{d(y)}$	$D_{d(z)}$	R	δ
FEA	0.53	4.14	−4.36	0.53	4.29	0.22	4.58	4.18
Exp.	-	-	-	-	-	-	-	4.35

Tab. 2 shows the intensities of the principal and Von Mises stresses generated at the measurement points.

Table 2 Values of displacements under maximum intensity of load

Methods	Principal stresses, MPa						Von Mises stress, MPa	
	MP+, SG+			MP−, SG−			MP+	MP−
	σ_1	σ_2	σ_3	σ_1	σ_2	σ_3	σ_{vm}	σ_{vm}
FEA	330	0.2	0.001	−0.003	−0.4	−355	330	355
Exp.	334	-	-	-	-	−368	-	-

The intensity of the principal stress σ_1 at MP+ measuring point is significantly higher than the other two principal stresses (σ_2 and σ_3). Also, the intensity of the principal stress σ_3 at MP- measuring point is significantly higher than the other two principal stresses (σ_1 and σ_2).

The performed research has shown a linear relationship between the load and displacement of bone segments. This is a consequence of the absence of major rotations, displacements and plastic deformations of the fixator components as well as shear within its joints. This also satisfies the basic requirement of fixator stability in terms of preserving the anatomical reduction of bone fragments.

Using the developed CAD/FEM fixator model, it is possible to control the displacements and stresses generated at any point in the fixator-bone system. The created model can also be used by surgeons in predicting fixator behavior during the postoperative period of bone fracture treatment. Due to extreme flexibility of created CAD model, rapid changes not only of the geometry and position of components and fixator, but also to biomaterials finding their application in external fixation now became possible. In this way, conditions have been created to optimize the fixator design, significantly shortening the time and reducing the costs of the development of medical devices for external bone fixation. Also, the use of such models significantly reduces the volume of preclinical experimental tests on fixators.

Acknowledgements

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