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MECHANICAL STABILITY ANALYSIS OF THE EXTERNAL FIXATION SYSTEM SARAFIX

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1. Introduction

After J. F. Malgaigne invented the external fixator in 1840, their selection and application was generally carried out on empirical grounds and accumulated experience in clinical orthopedics and traumatology. In order to promote and carry out necessary research to improve fixation, a development of a theoretical analysis of problems fixation based on the principles of structural mechanics is pursued.

The external fixator is a medical device for the immobilization of fractures or serious damage to the structure of extremities. External fixation is a method of fracture immobilization achieved by the application of pins or wires into or through a bone and their binding to the outer frame. The above basic concept of the method has not changed since its origin, but progress is reflected through the development of new design solutions and materials used. In the last two decades, a closer link between medical science and other disciplines of science (Technics, Medical Engineering, Biomechanics etc.) has been created, with the aim of multidisciplinary solving contemporary medical problems. One example of association of scientists of different profiles for the purpose of designing and improving medical equipment is the application of methods of external fixation and the development of systems for external fixation.

The idea for the development of the external fixator Sarafix was developed by a group of orthopaedists of "prim.dr. Abdulah Nakas" General Hospital in Sarajevo under siege, in May 1992. The idea was triggered by the insufficient number of existing fixators, as the result of the expansion of the war activities. Shortly after, the first fixator called *Sara*jevo war *fix*ator - *Sarafix* (Figure 1) was produced.

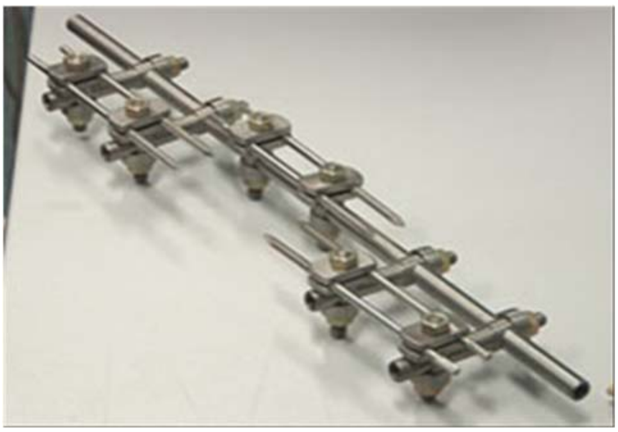

Figure 1. Sarafix external fixator

During the war, the Sarafix found its highest application in the treatment of extensive gunshot-explosive fractures of long bones of the extremities. Today, in peacetime traumatology, it is used in accidental injury in traffic accidents and industrial trauma.
Sarafix external fixation system represents a unilateral, biplanar external fixator which belongs to a group of modular fixators with one-half pins. Owing to the high flexibility and mobility, its application is possible to the complete human skeleton. Sarafix is the holder of numerous awards and prizes at international exhibitions of innovations, and gold medals at the exhibitions of innovations Brussels Eureka 95 and Geneva 1996, and Sarajevo's Sixth of April Award for 2001 should be emphasized.

2. Objective and methods

All commercial fixators, now in use, passed a biomechanical study before their first application. Mechanical testing of Sarafix fixator was not performed before its clinical application, because of the war-time circumstances in which it originated. Complete mechanical research of the fixator, besides the examination of its stiffness to the loads to which it was exposed after the application, includes the analysis of stresses (von Mises and principal stresses) on the characteristic location of fixator design. Extensive studies of the mechanical research of the Sarafix fixator were carried out within the thesis [Mesic 2008]. Due to the limited scope of this paper, only the results of the axial compression tests will be presented.
With the aim of determining stability of external fixators, various sensors and transducers are set up on their designs [Jasinska-Choromanska et al. 2001]. During the past few years, except of performing the experimental testing, there has been an increased use of geometrical modeling and finite element analysis (FEA), in order to more fully describe the behaviour of the fixator and its components during the loading [Radke et al. 2006].
This paper presents results of mechanical stability analysis of the most used configuration of the Sarafix external fixator in the case of an unstable tibial fracture. An open fracture at the middle of tibia with fracture gap of 50 mm (severe extensive injury with a considerable defect of bone structure) was examined. The most complicated aspect of bone fractures, both in terms of complexity of treatment and structural stresses of external fixator, is an open fracture. In the case of open fractures, in the initial phase of treatment, the full load is transferred through the fixator. The analyzed configuration of the Sarafix fixator contains four one-half pins in proximal and distal bone segment (Figure 2). The mechanical stability analysis of the Sarafix fixator was carried out using FEA and experimental analysis under axial compression.
Understanding the physical behaviour of the model is a basic prerequisite for successful process of modeling real systems. Before that, it is necessary to make numerous assumptions related to modeling: structure, joints between the components, boundary conditions, loads, materials, etc.
Geometrical modeling of the Sarafix fixator and FEA were carried out at the Laboratory for Computer Aided Design - CADlab of the Faculty of Mechanical Engineering Sarajevo. The first step consisted of forming a 3D geometrical model of the analyzed Sarafix fixator configuration, whereupon the FEA was performed on the model using CAD/CAM/CAE (Computer Aided Design/Computer Aided Manufacturing/Computer Aided Engineering) system CATIA. During the structural FEA, values of von Mises stresses were observed at two control points in the middle of the fixator connecting rod. The intensity and direction of principal stresses were monitored and analyzed at the same points.
Figure 2 shows the CAD and finite element method (FEM) model of the analyzed Sarafix fixator configuration after pre-processing. During the processes of the linear FEA, the material of wooden bone models was defined as orthotropic, while materials of the fixator design were modeled as isotropic. The FEM model consisted of solid finite elements of a linear (TE4) and parabolic tetrahedron (TE10) type. Join elements of the spider type were used for modeling the joints between the components of the Sarafix fixator. The following joints were used: Fastened connection, Contact connection and Bolt tightening connection. The modeling of the influence of supports was performed using a Smooth virtual part.
At the end of the proximal bone segment, the axial load in the form of surface force (Force density) was applied in the direction of the z axis of the Cartesian coordinate system. A displacement constraint

of the Sarafix FEM model was derived by using the Ball join restraint on the model of distal bone segment. Likewise, a displacement constraint at the model of proximal bone segment was performed by using the User-defined restraint, which prevented the two translations in direction of x and y axis of the Cartesian coordinate system.

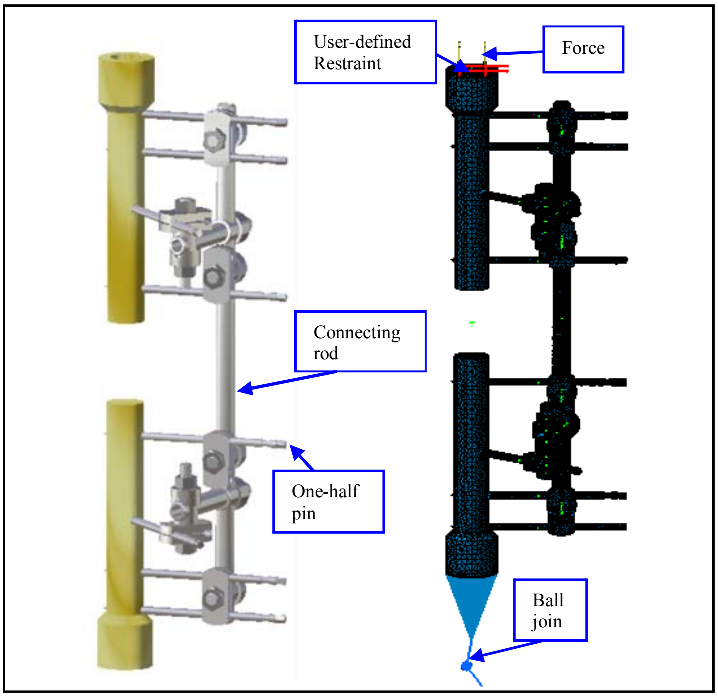

Figure 2. 3D CAD and FEM model of the analyzed *Sarafix* fixator configuration

Experimental testing was conducted at the *Laboratory for materials testing* and *Laboratory for machine elements* of the Faculty of Mechanical Engineering Sarajevo (Figure 3). At the Laboratory for materials testing, the examination of the analyzed configuration of the Sarafix fixator on the axial compression was performed, using a universal material testing machine (Zwick GmbH & Co., Ulm, Germany, model 143501). The analyzed configuration of the Sarafix fixator was attached to proximal and distal tibia bone segments modeled with cylindrical wooden bars with known physical properties. During the testing, the intensity of the load (0 to 600 N at the rate of 5 N/s) on the model of proximal segment of the tibia was controlled, using the force transducer (U2A, HBM-Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany). A wooden model of the proximal and distal bone segments are supported on the ball joint supports.

Tensometric measurement equipment (*Laboratory for machine elements*) was used to control and monitor the value of the dominant principal stress on the two measurement points at the middle of the fixator connecting rod. The following equipment from the HBM manufacturer was used:

- digital measuring amplifier system (DMC) 9012A,
- computer with software for acquisition, monitoring and processing of measurement results – Catman, and
- four strain gauges (type 3/120LY11) connected in two Wheatstone half-bridges.

The strain gauges were placed on the opposite sides of the Sarafix fixator connecting rod at the same locations where intensities of maximum and minimum principal stresses were monitored during the FEA. Thereafter, the strain gauges were connected with the DMC system and computer through two separate channels. In this way, the maximum and minimum principal strains on the measuring points were measured independently. This measurement method was applied because the connecting rod was subjected to a compound strain, which consisted of bending strain and axial compressive strain. The connecting rod, due to the axial compression at the proximal segment of the bone model, is exposed to the combined loading (eccentric pressure), which consists of a combination of bending and axial compression. This form of the strain is manifested by the unequal distribution of tensile and compression stresses along the longitudinal section of a connecting rod, i.e. neutral line does not coincide with the axis of symmetry of the fixator connecting rod. Therefore, the two separate Wheatstone half-bridges were formed and connected with the DMC system via two measurement channels.

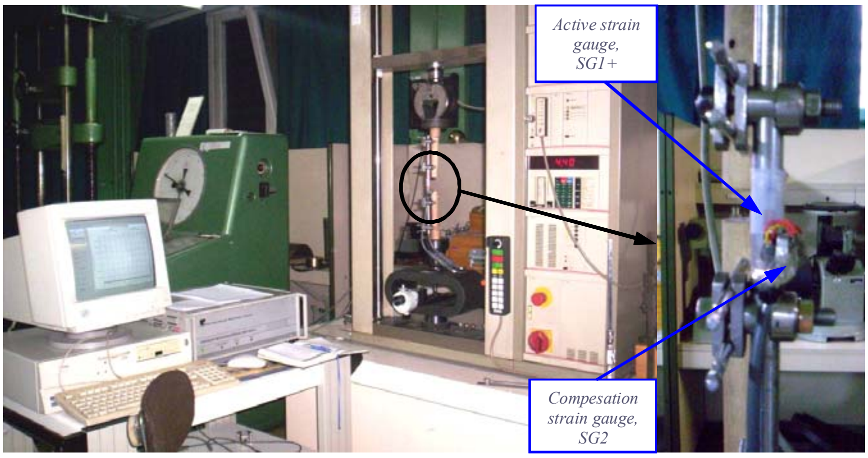

Figure 3. Set-up for experimental testing on axial compression

Wheatstone half-bridges consist of active strain gauge SG1 and compensation (inactive) strain gauge SG2 (Figure 3). The compensating strain gauges were placed near the active strain gauges on a plate tied to a connecting rod. Compensating strain gauges are used to compensate the effect of temperature on the measurement and they are of the same type as the active ones. The plate and connecting rod are made of the same material.

3. Stiffness analysis

Most biomechanical studies of the external fixation analyze only total characteristics of stiffness of diverse types of fixators and configurations. This paper, except the value of the *Sarafix* fixator observed configuration's stiffness, analyzes also gap stiffness.
One of the reasons for determining construct stiffness of the external fixators is its impact on the stress generated in the contact of one-half pin-bone. Increasing the stiffness of the fixation device significantly reduces the axial load to the one-half pins, and thus stresses generated at the one-half pin-bone contact. This helps reduce the risk of weakening (relaxation) of the one-half pins and infection in the area around the one-half pin, which is usually related to complications of external fixation of bone. On the other hand, after the initial phase of treatment, for the purpose of dynamization process and in order to stimulate consolidation of the bone, it is desirable to control fixator stiffness and coordinate to the trend of fracture healing [Yang et al. 2000].
One of the possibilities of structural analysis using FEM is to determine the direction and intensity of displacement of any point of the bone models and fixator. The construct stiffness of the fixator is defined as the ratio of load and displacement (Figure 4). Axial construct stiffness of the fixator was calculated using the following equation:

$$C = \frac{F}{\delta} \tag{1}$$

where:
F – is the applied axial loading force (N),
δ – is the axial displacement of proximal segment at the point of load (mm).
Figure 4 shows the 3D FEM model of the analyzed configuration *Sarafix* fixator before and after the action of maximum axial load. The directions and intensities of deformation of each point of the structure of the system and bone models are observed in the Figure 4.
Fixator construct stiffness is an important characteristic, but it cannot provide direct information about displacement of a fracture gap. The precise information can be provided by analyzing relative

displacements of end bone segments under simulated conditions of loads. However, in addition to numerous research, it remains unclear which forms of movement are helpful and harmful to the healing of fractures, therefore the information about the values of relative movement of the bone parts is of limited value. But on the basis of literature the following two hypotheses [Koo et al. 2005] could be suggested:

- Cyclic axial micro motion is beneficial for healing of fractures.
- Shearing motions of bone segments at the fracture site are detrimental to its healing.

Absolute displacements of analyzing points at the proximal and distal fracture endplate in the x, y and z direction were determined. Analyzing points were selected in such a manner for the resulting vector of relative displacements (R) has maximal value (Figure 4).

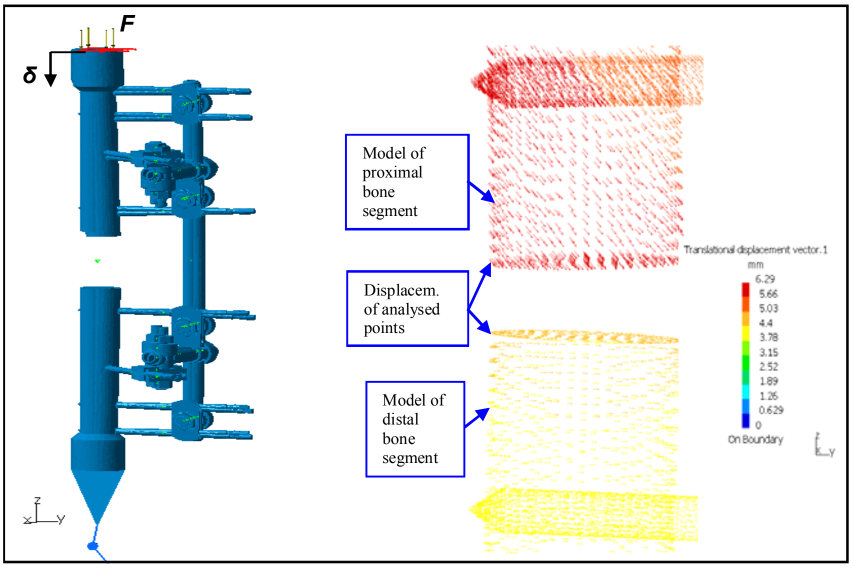

Figure 4. Non-deformed and deformed structure of the system under maximum axial load and translation displacement vectors of points at the fracture gap

Relative craniocaudal and lateromedial displacements (x and y direction) and axial displacements (z direction) for analyzed points were calculated as:

$$r_{D(x)} = D_{p(x)} - D_{d(x)}; \quad r_{D(y)} = D_{p(y)} - D_{d(y)}; \quad r_{D(z)} = D_{p(z)} - D_{d(z)} \tag{2}$$

where:

$r_{(D)x}$, $r_{(D)y}$ and $r_{(D)z}$ - are the relative displacements at the fracture gap in the x, y and z directions (mm),

$D_{p(x)}$, $D_{p(y)}$ and $D_{p(z)}$ - are the absolute displacements of points at the proximal fracture endplate in the x, y and z direction (mm),

$D_{d(x)}$, $D_{d(y)}$ and $D_{d(z)}$ - are the absolute displacements of points at the distal fracture endplate in the x, y and z direction (mm),

The gap stiffness was calculated as the applied force divided by total displacement at the analyzing points in the case of the axial compression:

$$C_p = \frac{F}{R} = \frac{F}{\sqrt{(r_{D(x)})^2 + (r_{D(y)})^2 + (r_{D(z)})^2}} \tag{3}$$

4. Stress analysis

The principal stresses of the stress tensor are the distinctive values of the stress tensor, while their direction vectors are the principal directions or eigenvectors [Zienkiewicz et al. 2005]. When the coordinate system is chosen to coincide with the eigenvectors of the stress tensor, the stress tensor is represented by a diagonal matrix:

$$\boldsymbol{\sigma} = \begin{bmatrix} \sigma_1 & 0 & 0 \\ 0 & \sigma_2 & 0 \\ 0 & 0 & \sigma_3 \end{bmatrix} \tag{4}$$

where: σ_1, σ_2 and σ_3 are the principal stresses.

The values of the principal and von Mises stress were controlled on two locations at the middle of the fixator connecting rod during the FEA. The measuring point closer to the model of the bone segment was marked with MP- and the point on the opposite side of the connecting rod was marked with MP+ (Figure 5).

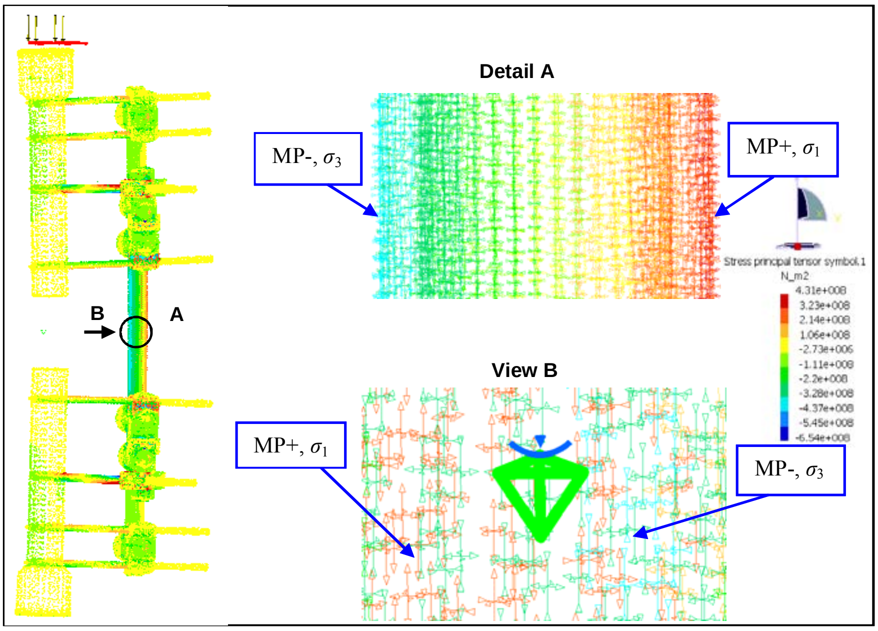

Figure 5. Plot of the principal stresses

Compressive stresses, which were recorded at the measuring point MP- have a higher intensity compared to the tensile stress at the MP+. This is a direct consequence of the appearance of an eccentric compression that exposed fixator connecting rod. The direction of the maximum principal stress (σ_1) on the measuring point MP+ coincides with the direction of z axis, i.e. the axis of symmetry of the connecting rod. Likewise, the direction of the minimum principal stress (σ_3) on the MP- coincides with the axis of symmetry of the connecting rod. The minimum principal stress compared to the other two principal stresses at the MP- is dominant. Within the Figure 5 a view B is given where directions and intensities of the principal stresses on the measuring points are presented. Note that at the MP+ the maximum principal stress is in fact the tensile stress, while at the MP- the minimum principal stress is actually the compressive stress. Also, it can be seen that the dominant principal stresses (σ_1 and σ_3) are in the bending plane of the fixator which is not parallel with AP (anterior-posterior) plane. For this reason, the vectors of the dominant principal stresses do not match either (Figure 5, View B).

A quantity called the equivalent stress or von Mises stress is commonly used in solid mechanics to predict yielding of materials under multiaxial loading conditions using the results from simple uniaxial tensile tests. The equivalent stress is defined as:

$$\sigma_e = \sigma_{vm} = \sqrt{3J_2} = \sqrt{\frac{1}{2}\left[(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2\right]} \tag{5}$$

where J_2 is the second deviatoric stress invariant.

The von Mises stress is equivalent to the maximum distortion strain energy and it is a good indicator of the yielding of materials. By analyzing the distribution of von Mises stress fields shown in Figure 6, it can be concluded that the highest stresses on the fixator design did not occur at the measuring points. Generally, the maximal von Mises stress on the Sarafix fixator design occurred in the contacts between the one-half pins (1) and the clamping plates (σ_{vm} = 550 MPa). The maximum value of von Mises stress at the measuring points was σ_{vm} = 355 MPa. Also, it can be seen that the maximal von Mises stresses at the measuring points occurred in the bending plane of the fixator which is not parallel with the AP plane (Figure 6).

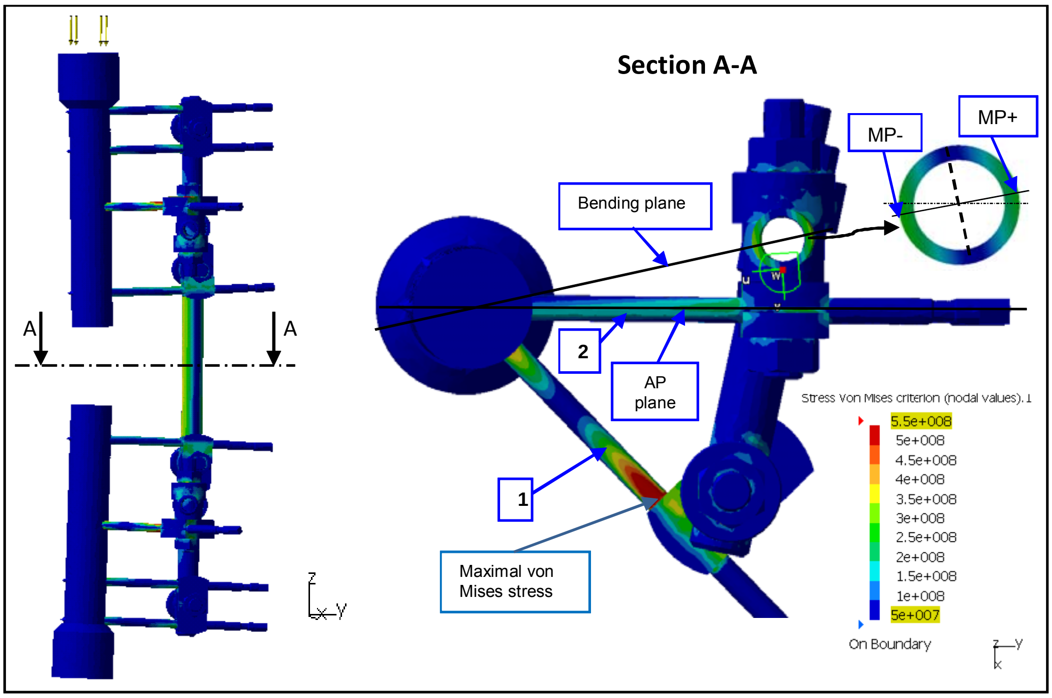

Figure 6. Von Mises stress contour plot on the model of the Sarafix fixator

Previously performed FEA determined the direction and intensity of the principal stresses. Also, it was noted that the intensities of the other two principal stresses at the measuring points were negligible compared to the maximum (σ_1 on MP+) and minimum (σ_3 on MP-) principal stress (Table 2). Active strain gauges are placed on the opposite sides of the connecting rod at the nearest and farthest point from the model of the bone, so that their longitudinal axis coincides with the directions of dominant principal strains (ε_1 and ε_3) at the measuring points.
The strain, registered by Wheatstone half-bridge with one active and one compensation strain gauge, is given by the relation [Khan et al. 2001]:

$$\varepsilon = \frac{4}{k} \cdot \frac{U_A}{U_E} \tag{6}$$

where: k - is gauge factor,
U_A - bridge output voltage,
U_E - excitation voltage (bridge input).
The dominant principal stresses at the measuring points (MP+ and MP-) are determined through the relations:

$$\begin{aligned} \sigma_1 &= \varepsilon_1 E \\ \sigma_3 &= \varepsilon_3 E \end{aligned} \tag{7}$$

Simultaneous measuring of the largest positive and negative principal strains on the opposite sides of the fixator connecting rod was carried out independently at two measurement points (Figure 7). In the following analysis, the strain gauge placed on the side of the connecting rod closer to the bone model will be referred to as SG-, while a strain gauge placed on the opposite side will have a label SG+.

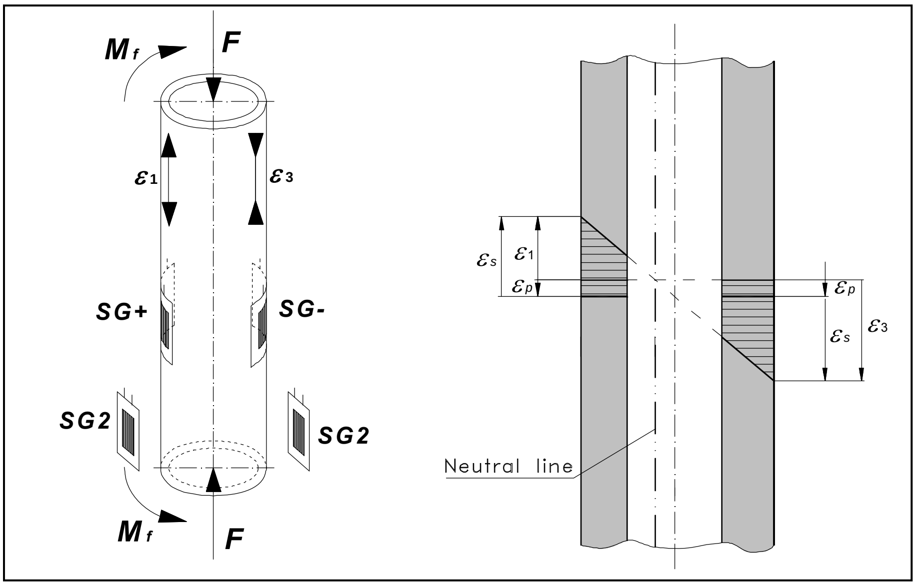

Figure 7. Arrangement of strain gauges and distribution of loads and strains in the longitudinal section of the connecting rod

This way of setting up strain gauges enables the measurement of the greatest positive principal strain (ε_1) at the measuring point MP+, on the basis of which the intensity of the maximum principal stress (σ_1) is determined. Analogously, on the measuring point MP-, the greatest negative principal strain (ε_3) was measured, on the basis of which the intensity of the minimum principal stress (σ_3) is determined. The minimum principal stress compared to the other two principal stresses at the point MP- is dominant. Independently measured total strains at the measuring point consisted of the compressive and bending strain. The total (principal) strains are defined by the principle of superposition, as follows:

$$\begin{aligned} \varepsilon_1 &= -\varepsilon_p + \varepsilon_s = -\frac{F}{AE} + \frac{M}{EZ} \\ \varepsilon_3 &= -\varepsilon_p - \varepsilon_s = -\frac{F}{AE} - \frac{M}{EZ} \end{aligned} \tag{8}$$

where: ε_p – is the strain component caused by the axial compressive force,
ε_s – the strain component caused by the bending moment,
A – the area cross-section of the fixator connecting rod,
E – modulus of elasticity,
M – bending moment,
Z – section modulus of the fixator connecting rod.

In this case of load, the bending strain was significantly higher than the compression strain ($|\varepsilon_s| \gg \varepsilon_p$). Distribution of the strains in the longitudinal section of the fixator connecting rod is shown schematically in the Figure 8. Acquisition, display and processing of measurement results are performed using the HBM Catman software.

5. Results

In order to achieve a direct comparison of results of the FEA and experimental analysis, all parameters of geometry, materials, loads, restrains on the FEM model are set according to experimental settings.

Displacements were analyzed at the point of load and fracture gap using FEM and experimental testing. Diagram of axial displacement proximal segment model of bone at the point of load was obtained by the structural analysis using FEM and experimental testing. It shows the intensity of deformation of the analyzed Sarafix fixator configuration during testing under axial compression.

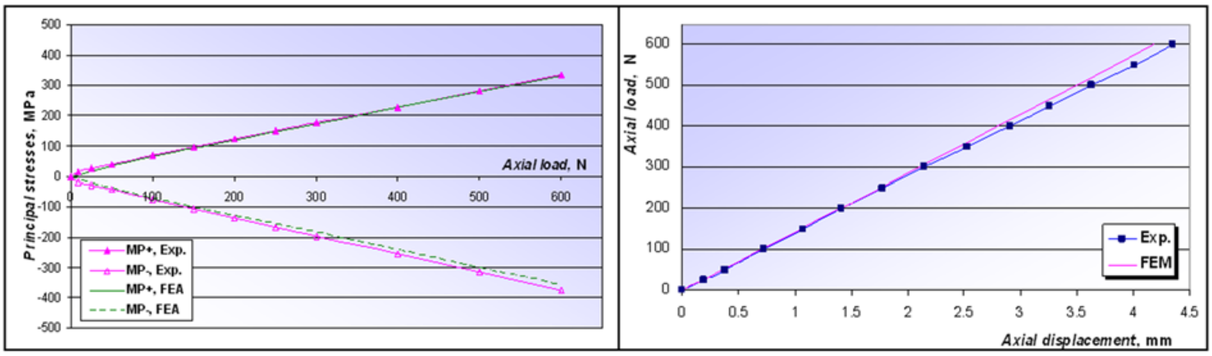

Figure 8. Comparative diagram of the principal stresses (σ_1 on MP+) and (σ_3 on MP-) and comparative diagram of the axial displacement at the point of load

Based on the displacement at the point of load (δ i θ), the values of the construct stiffness (C) are determined, based on the relative displacements at the fracture gap (R), the values of gap stiffness (C_p) are determined as shown in the Table 1.

Table 2 shows the intensities of principal and von Mises stresses generated at the measuring points in the case of maximum axial compression force. The value of the maximum principal stress (σ_1) at the MP+ was significantly higher than the other two principal stresses (σ_2 and σ_3). On this basis, and bearing in mind the relationship by which the value of von Mises stress are calculated (relation 5), it follows that at the MP+ the von Mises stress (σ_{vm}) has the same value as the maximum principal stress (σ_1). Likewise, the value of the minimum principal stress (σ_3) at the MP- was significantly higher than the other two principal stresses (σ_1 and σ_2). Analogously as in the previous case, it follows that the von Mises stress (σ_{vm}) is equal to the minimum principal stress (σ_3) at the MP-.

Table 1. Values of stiffness and displacements under maximum intensity of load

Methods	*Displ. of the prox. segment at the fracture gap,* mm			*Displ. of the distal. segment at the fracture gap,* mm			*Max. relat. displ. at the gap,* mm	*Displ. at the point of load,* mm	*Gap stiff.,* N/mm	*Cons. stiff.,* N/mm
	$D_{p(x)}$	$D_{p(y)}$	$D_{p(z)}$	$D_{d(x)}$	$D_{d(y)}$	$D_{d(z)}$	R	δ	C_p	C
FEA	0,53	4,14	-4,36	0,53	4,29	0,22	4,58	4,18	130,93	143,54
Exp.	-	-	-	-	-	-	-	4,35	-	137,93

Table 2. Maximum values of principal and von Mises stresses at the measuring points

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 maximum deviations of the results obtained by FEA in relation to the results obtained by experimental testing are range: the principal stress σ_1 to 1,2%, and the principal stress σ_3 to 3,6% (Figure 8). Principal stresses with the negative sign represent compressive stress. It is noted that at the MP+ all principal stresses are positive, while at the MP- all principal stresses are negative (Table 2). The maximum values of von Mises and maximum principal stress at the control points is respectively

σ_{vm} = 355 MPa and σ_3 = 368 MPa and they are lower than the yield strength of the material of the fixator connecting rod (σ_V = 650 MPa).

6. Conclusions and further work

The conducted research has shown that there is a linear dependence between the loads and stresses generated on the fixator connecting rod, as a result of the absence of large displacement and plastic deformation of the fixator components. The above fact is also a basic requirement for the fixator's stability in terms of preserving anatomical reduction of bone fragments in the postoperative load conditions. Detailed data of the stability of external fixation systems are needed by the orthopedic surgeon to predict successful healing of a fracture. The stability provided by the Sarafix fixator has been proven by mechanical research, confirming good clinical results in the treatment of bone fractures.

Comparing the results of FEA and experimental analysis of the displacements and principal stresses at the measuring points reveals their good agreement. We can conclude that the developed FEM model of the Sarafix fixator was verified.

The CAD/CAM/CAE system CATIA can be successfully used in the development of CAD models, FEA and computer simulations of the process from different areas of technics and medical engineering. Using the developed CAD/FEM model of the Sarafix fixator, it is possible to control displacements and stresses generated at any point of the bone-fixator system. It is anticipated that this model will provide useful information to surgeons who use Sarafix external fixator for fracture fixation.

Due to extreme flexibility of the formed 3D geometrical model, rapid changes were enabled not only to the geometry and position of components and fixator, but also to the materials applied in the external fixation (from stainless steels to radio-transparent composite materials). In this way, conditions for design optimization of the external fixator are created, which would significantly shorten time and reduce development costs of medical devices for external fixation of bones. In addition, the application of such models greatly reduces the volume of conventional preclinical experimental testing of fixators.

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