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A numerical comparative analysis of ChM and Fixion nails for diaphyseal femur fractures

Dmitry Ivanov[1]*, Yuri Barabash[2], Anatoly Barabash[2]

[1] Saratov State University, Saratov, Russia
[2] Saratov Scientific Research Institute of Traumatology and Orthopedics, Saratov, Russia

*Corresponding Author:
Dmitry Ivanov, Saratov State University, 83 Astrakhansaya street, 410012 Saratov, Russia, Tel: +79173146807, e-mail: ivanovdv@gmail.com

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Abstract:

Purpose

Today intramedullary locked nails are widespread in treatment of diaphyseal long bone fractures of the lower limb. However, such nails have a number of drawbacks: complexity and duration of the installation, high axial stiffness, as well as the failure of locking screws and nail body.

Expandable nails such as Fixion have several advantages over lockable. They can be quickly installed without the need of reaming and provide sufficient stabilization of the fracture. However, many studies show their low stability under torsional loads.

Methods

In this paper, geometric characteristics of Fixion nail were investigated. Bone-nail systems (with Fixion and locked nail) under the influence of three types of loads were numerically studied. Two types of diaphyseal femoral fractures (type A and B in accordance with AO/ASIF classification) were examined.

Results

It was revealed that Fixion nail provides axial stiffness of 489 N/mm for the studied fractures. Expandable nail showed higher compression at fragments junction than locked nail. Torsional stability of Fixion nail was also high. Corrosion was found on inner surface of Fixion nail.

Conclusions

Fixion nail showed high stability under influence of the three studied loads. Corrosion on the internal wall of the nail may indicate its relatively low resistance to saline.

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Keywords: finite element analysis, intramedullary nail, femur, effective stress, stiffness, 3D model

1. Introduction

Intramedullary nails can be divided into two types. First – locked implants that are fixed in the bone canal with the help of locking screws. Such implants include ChM nails (ChM sp. z o. o., Poland). The second type is expandable nails such as Fixion (CarboFix Orthopedic Ltd, Israel), which are fixed in the medullary canal by changing their volume by 1.5-1.8 times while injecting saline into them under pressure up to 80 bar and don’t require distal screws. Both of these types are used in medical practice for a long bone fracture osteosynthesis.

Today locked intramedullary nail fixation is a common method of treatment of diaphyseal long bone fractures of the human lower limb [[22]]. This technique provides rapid stabilization of the fracture with a relatively minimally invasive procedure and returns the injured limb to full operation [[1]], [[10]]. Expandable nails are relatively new technological development and can be installed without the help of a guide wire and reaming. According to the authors [[15]], [[14]] Fixion nails provide the necessary stability of the fracture which allows not to fix the nail by locking screws.

A retrospective comparative study has shown advantages of an expandable Fixion nail in comparison with the “standard” locked nails in case of femur diaphyseal fractures osteosynthesis [[15]]. Expandable nail speeds up the surgery operation and reduces the harmful effects of radiation on the patient and surgeons which is especially important for patients with multiple injuries and fractures. However, the authors noted a significantly higher cost of expandable nail than locked nails [[15]].

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Despite the fact that expandable nails now are very promising, many studies on this subject show methodological flaws and require further investigation [[22]]. Moreover, such nails may not provide the necessary stability and stiffness of bone-implant system [[16]], [[20]], [[12]].

Many clinical [[17]], [[15]], [[18]], [[24]], [[2]] and biomechanical [[20]], [[16]], [[3]], [[12]] studies about Fixion nail were published. However, we couldn’t find studies where Fixion nail was investigated with the help of computer modeling techniques and in particular, the finite element method (FEM). At the same time locked nails were numerically studied in many researches [[9]], [[5]], [[7]].

FEM has been successfully used in biomechanics in the last few decades and has shown himself as a convenient, reliable and high-performance method. It allows taking into account not only a complicated structure of biological objects, but also their mechanical properties, as well as different loading and fixing conditions. Furthermore, computer modeling allows performing so-called “virtual” operations and making a prediction about the behavior of a particular implant after its installation. That is why we selected FEM as the main method of simulation.

The purpose of this study was to compare biomechanical performance of expandable Fixion nail versus “standard” locked nail ChM. Results are presented in order to compare the stability of these systems under the influence of external loads.

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2. Materials and methods

2.1. 3D model of Fixion nail

Three-dimensional (3D) geometric model of Fixion nail was constructed with the help of the original 340 mm length femoral nail d10-16. The nail was cut into three parts (Fig. 1). Since the cross sections of the nail throughout its length are similar, it was decided to cut the nail only in distal part. The remaining sections were modeled basing on their similarity to the distal sections.

Thickness of the wall, thickness of the longitudinal ribs and the characteristic diameter of the nail in proximal, medial and distal parts were measured. The measured geometric characteristics are listed in table 1.

On the basis of measured data 3D model of Fixion nail was constructed in SolidWorks (Dassault Systèmes, SolidWorks Corp.). 3D model of ChM nail was constructed based on a real model of the nail with diameter of 11 mm and a length of 340 mm. The geometry was obtained by reverse engineering. Both of the nails were modeled as solid bodies. Fig. 2 shows 3D models of ChM and Fixion nails.

Realistic 3D model of human femur (Fig. 3) was created basing of computer tomography (CT) images with the help of SolidWorks program. CT scans were collected in Saratov Scientific Research Institute of Traumatology and Orthopedics. Data from healthy patients was used. Cortical and trabecular bone layers were created. It was revealed that optimal periodicity of CT images should be between 0.5 and 5 mm [[7]] (Fig. 3).

Assemblage of the nails and bone models was also performed in SolidWorks. Then A1 and B2 diaphyseal fractures according to AO/ASIF (Association for Osteosynthesis/Association for the Study of Internal Fixation, Davos, Switzerland) classification were simulated.

Fig. 4 shows femur 3D model with A1 and B2 fractures and Fixion nail installed and applied loads.

It was assumed that ribs of Fixion nail had contact with trabecular layer following the shape of the femur medullar canal.

2.3. Femur and implant mechanical parameters

Material of the nails was assumed as homogeneous, isotropic and perfectly elastic with Young's Modulus of $1.93 \cdot 10^{11}$ Pa and Poisson's ratio of 0.33.

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Range of the bone tissue elastic moduli variation is large enough [[19]]. This is due to differences in research methods, methods of sample preparation etc. Most researchers conclude that the elastic modulus of trabecular bone is 20-30 % lower than the elastic modulus of cortical bone [[28]], [[26]]. Mechanical parameters of trabecular and cortical layers were taken from the literature [[8]] and are presented in table 2.

We assumed cortical and trabecular bones as isotropic and perfectly elastic. Such an assumption is justified and used by other authors when a comparative analysis of different implants from the mechanical point of view was performed [[7]]. Also we took into account large deformations of the bone fragments and nails. So the mathematical formulation of the problem included geometric nonlinearity

Finite element simulations were performed in Ansys Workbench (ANSYS, Inc) 15.0. Static problems were solved. We investigated bone-implant systems loaded with axial, lateral forces and torsional moment which were applied to the femur head. Distal end of the femur was fixed. Similar conditions were used by authors in [[9], [5]]. Types and values of investigated loads are listed in table 3 [[27]], [[5]] and illustrated in Fig. 4.

Nails were meshed with 20-noded quadratic hexahedral elements. Bone fragments were meshed with 10-noded quadratic tetrahedral elements. All elements had 3 degrees of freedom in each node. To determine optimal size of the mesh elements (to achieve mesh which has no effect on numerical results) mesh convergence problem was solved. It was found that size of the mesh elements should not be more than 0.5 mm. Thus, the number of nodes for each model (nail and 2 bone fragments) was about 1 500 000. Fragment of the hexahedral mesh created for Fixion nail is presented in Fig. 5.

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Special element HSFLD242 was used to model Fixion nail. This element was used to simulate inner 80 Bar pressure. This was done to simplify the formulation of the problem and not to solve FSI (fluid-structure interaction) problem.

The screw threads were not modeled. We assumed bonded contact between bone and screws. Between bone and nails, bone fragments we assumed frictionless contact [[23]], [[6]]. Contact types and their descriptions are listed in table 4.

Obviously, the static problems can not describe interaction between bone fragments and nail in the case of dynamic loads. However, such formulation may be used for stability and stiffness comparison of different implants.

3. Results

3.1. Equivalent stress distribution in nails

Numerical results for ChM nail showed that the highest equivalent stresses (ES) arised in locking screws and on nail holes for screws (Fig. 6). This was true for all three investigated types of loads. High (compared to other areas) stresses occured in the nail near fracture area. Stress concentrations in bone fragments were found in the areas of screw installation.

The highest ES values in case of axial loading were 340 MPa. In case of torsional load the highest ES values were more than 400 MPa. Such ES values for the ChM nail were higher than ES values for the Fixion nail. This assumption was right for axial and torsional loads.

If we analyze ES values in Fixion nail we can note that maximal ES value was 260 MPa. For the other load cases ES values were not higher than 205 MPa. The highest ES values were concentrated in fracture area. Fig. 7 shows a typical ES field for the three considered loads.

Maximal ES values for the two considered nails are listed in table 5.

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For the lateral load ES values in case of Fixion nail installation were higher than for ChM nail (260 and 250 MPa versus 220 and 200 MPa for A1 and B2 fractures).

3.2. Displacements of the bone head

Numerical results for the expandable nail showed its sufficient stability for all three investigated loads. Displacements of the bone head for Fixion nail were higher than for ChM nail (1.53 and 1.43 mm versus 1.10 and 1.05 mm for A1 and B2 fractures). Moreover, in the case of torsional moment expandable nail displacements were twice lower than for ChM nail (0.44 and 0.5 mm versus 1.10 and 0.99 mm for A1 and B2 fractures). This last fact indicates the high stability of the bone-expandable nail system in case of torsional loading. Table 6 shows the displacement values of the femoral head for both of the investigated nails.

Thus, axial stiffness of the bone-nail system with expandable Fixion nail was 1.4 times lower than in the case of ChM nail.

3.3. Contact pressure between bone fragments

Contact pressure distribution between bone fragments was analyzed. Numerical results showed that in case of the locked nail installation pressure field was significantly non-uniform. This was true for both fracture types and for all investigated external loads. In case of Fixion nail installation the situation was somewhat better. Pressure was distributed more uniformly. Moreover, pressure values have the same sign on the entire fracture surface. Fig. 8 and Fig. 9 show typical contact pressure fields for both fractures and nails.

The greatest values of contact pressure for both nails are listed in table 7. In most cases contact pressure for Fixion nail installation was higher than for ChM nail.

4. Discussion

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Intramedullary fixation of femur fragments is known in the world since the 40s of the last century and is constantly being improved. The aim of the fixation procedure is to combine bone fragments, achieve fracture stability and to transfer loads across the fracture site. With regard to osteosynthesis, the anatomy and function are restored during the surgery but physiological regeneration is impossible due to the destruction of the bone formation sources. Locked nail displaces bone marrow from the medullar canal and blocks the circulatory system. This type of fixation is always accompanied with micro thrombosis so the period of bone injuries healing increases.

Expandable Fixion nail doesn’t require reaming of the medullary canal during the installation procedure which is necessary for the locked nails. Fixion nail could be fixed in medullary canal by changing its shape, which allows not to use locking screws. Thus there is only partial damage of the vessels and the duration of surgery and radiation exposure to the patient are significantly reduced.

Despite the fact that clinical studies have shown advantages of expandable nail over locking [[22]], the question of the “bone-expandable nail” system stability requires additional investigation.

Biomechanics and computer modeling can be used to improve the treatment quality for patients with fractures and should be used at the preclinical stage of the designs study. It's not just the design of nails and other fixation devices, but the calculation of their biomechanical characteristics under the influence of various loads and constrains.

The present study was performed to investigate biomechanical properties of the bone-nail system behavior under influence of different loading conditions. Characteristics of the two nails (locked ChM and expandable Fixion) were evaluated. Bone tissue was expected to be inhomogeneous

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and isotropic [[5]], [[21]], [[4]]. Static problems were solved with the help of finite-element method [[9]].

Axial compressive stiffness was calculated for both of the nails. Fixion nail had axial stiffness of 489 N/mm which was practically 1.4 times smaller that the stiffness (up to 667 N/mm) of ChM nail. These results seem predictable to us.

In case of torsional loads Fixion nail proved to be stable and showed almost twice as much rigidity as compared with ChM nail. These data differ from results of other studies [[20]], [[12]], which showed that expandable nails worse resist torsional loads compared to locked nails.

Maximal equivalent stress values for ChM nail were detected in screws and holes, and in the nail body at fracture area. Similar conclusions were made by authors in [[9]], [[7]]. In case of torsional loading stresses reached their greatest values of 400 MPa. As the screw threads were not modeled, actual stress values at the thread/nail interface would be even greater [[7]]. For Fixion nail stresses were distributed more uniformly and the highest values were concentrated in nail body at the fracture area. Maximal ES values didn’t exceed 260 MPa.

It is necessary to pay special attention to the nails fatigue strength analysis. Stainless steel fatigue strength is up to half of its tensile strength and reaches values of 270 MPa. These values are higher than the maximal ES occurred in Fixion nail, and lower than the highest ES in ChM nail. This means that under cyclic loading Fixion nail will not fail during 10^7 loading cycles, and, consequently, will not fail during longer tests [[25]]. But there is a problem of fatigue failure of the ChM locking screws and its body [[27]].

Contact pressure distributions between the bone fragments for the two nails were significantly different. The most uneven pressure distribution (with multi-directional pressure areas), which can be seen in the left images of Fig. 8 and Fig. 9, was revealed for ChM nail. Multidirectional pressures indicate that on one part of the contact surface pressure is directed along the normal and

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on the other part of the surface – against the normal. Consequently, we can assume that in case of CnM nail installation the necessary compression between fragments is not achieved on the entire fracture surface [[27]]. This can be explained by the way of the nail attachment to the bone fragments which needs proximal and distal locking screws insertion.

Uniform and high contact pressure indicates that there is a good compression between bone fragments in case of Fixion nail installation. Moreover, Table 7 shows that the maximum value of the contact pressure in the case of Fixion nail installation is almost always higher than for ChM nail. From our view this is also a positive factor playing in favor of the expandable nail. This fact is consistent with the fact that axial stiffness for the expandable nail was 1.4 times less than for the locked nail. Other authors point out that normal stresses at fragment junction stimulate the process of fracture healing [[23]].

It should be noted that on the inner surfaces of the Fixion nail corrosion was founded. Apparently, this is evidence of its relatively low resistance to saline. But considering that this nail was used for 10 months perhaps it is a problem of a particular implant.

Regarding the simplifications that were made in this study, the following should be noted. First of all, only static load cases were considered in simulations. It is clear that muscle loads and loads encountered during walking [23] would lead to a different stress-strain states of the bone-implant systems but this question is now open and will be covered in future studies. Secondly, bone material was assumed to be isotropic. It is obvious that the bone material is anisotropic. However, several other studies showed that approximation of bone material with linear model gives acceptable results and can be used in biomechanical simulations [21].

Despite the simplifications this study is the result of a comparative analysis of the bone-implant system stress-strain states for the two considered intramedullary nails: expandable and locked. Conclusions about the stability of the studied systems under the influence of different loads were

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formulated. Conclusions about the expandable nail behavior compared to locked nail seem to be quite logical. In fact, today researchers while developing new intramedullary nails are trying to decrease their stiffness and to increase the compression at the junction of the bone fragments. This could be achieved by using composite materials [[23]] or by replacement of the distal locking screws with expandable end [[13]], [[11]], [[27]]. From the biomechanical point of view Fixion nail showed good results in comparison with the locked nail. Its design allows the proximal bone fragment to become in full contact with the distal one and to create a compression at fragments junction. The necessary stability and rigidity of the bone fragments fixation is achieved by expansion of the nail under influence of the internal pressure. Longitudinal ribs make the bone-implant system stable in case of torsional loads.

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Acknowledgment

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Figures:

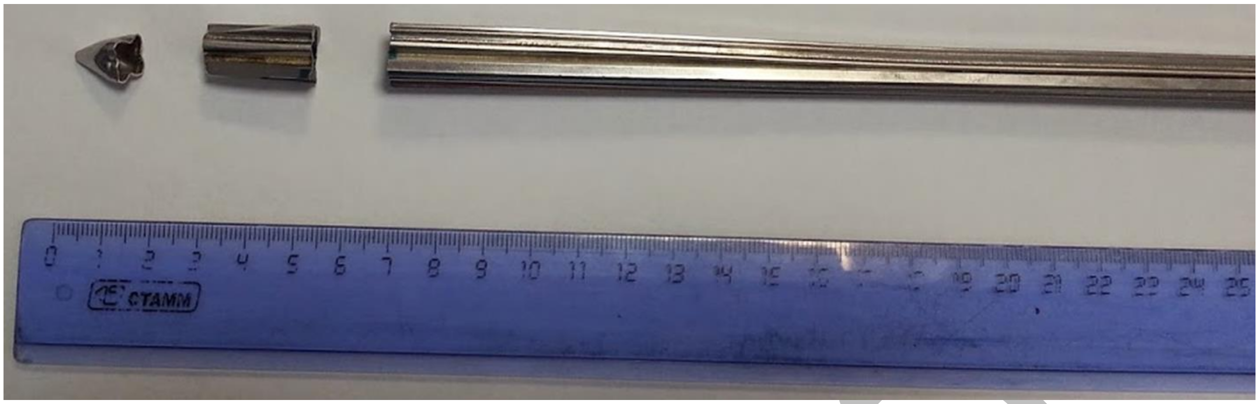

Figure 1. Fixion nail cut in distal part

Figure 2. 3D geometrical model of Fixion and ChM nails

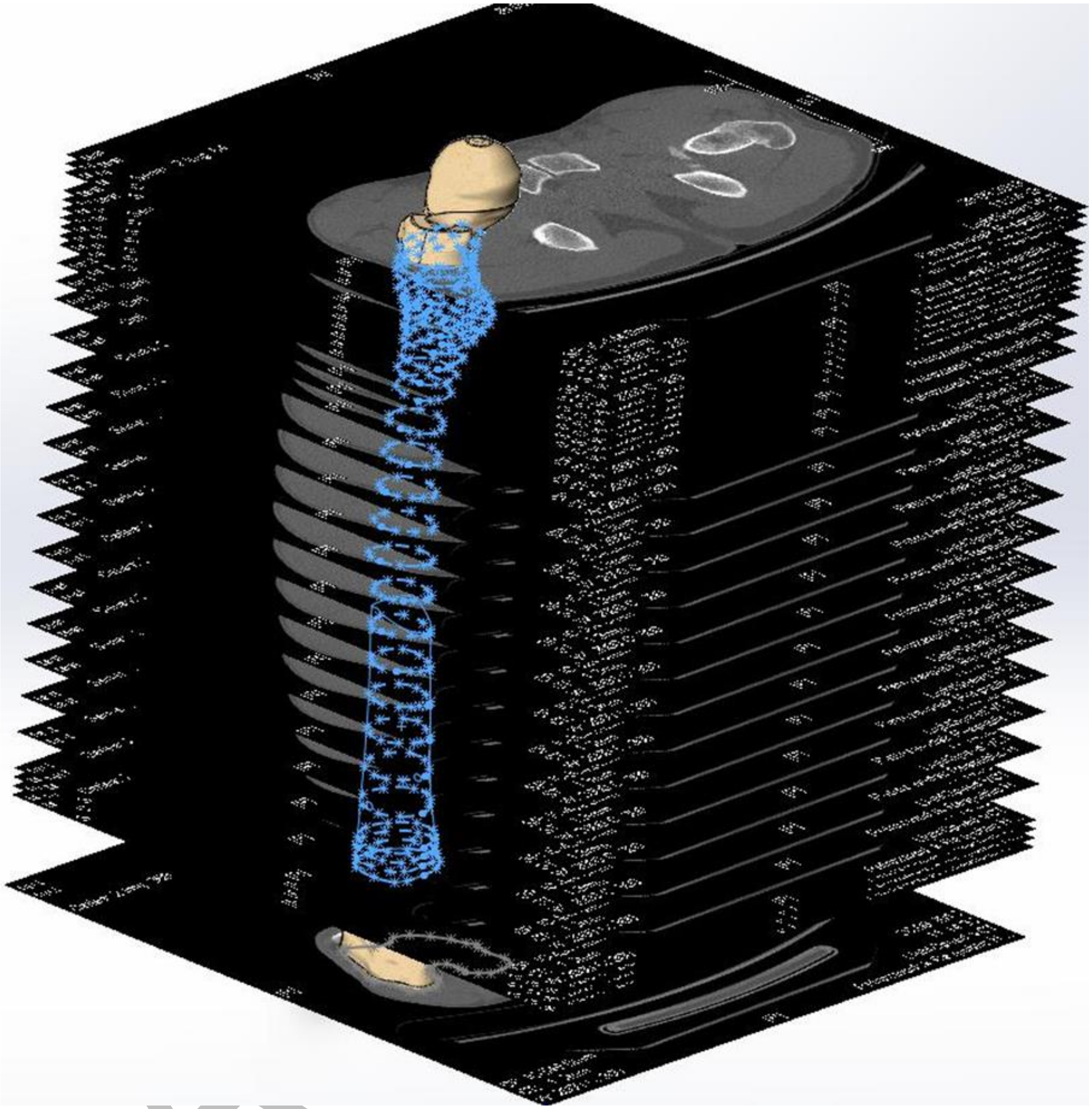

Figure 3. CT images and 3D model of human femur bone

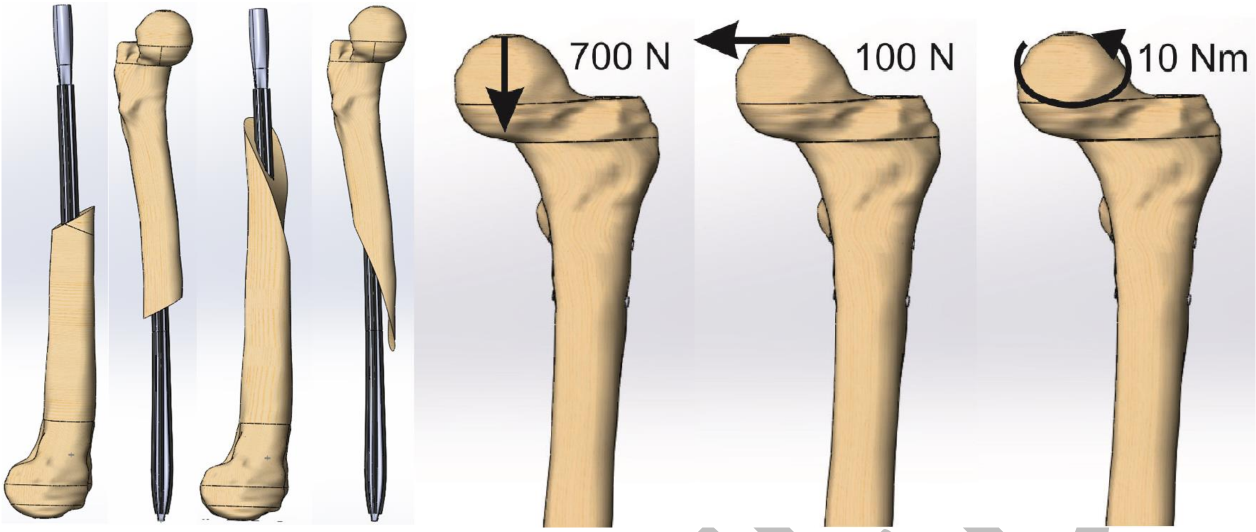

Figure 4. Types of the investigated fractures and loading conditions

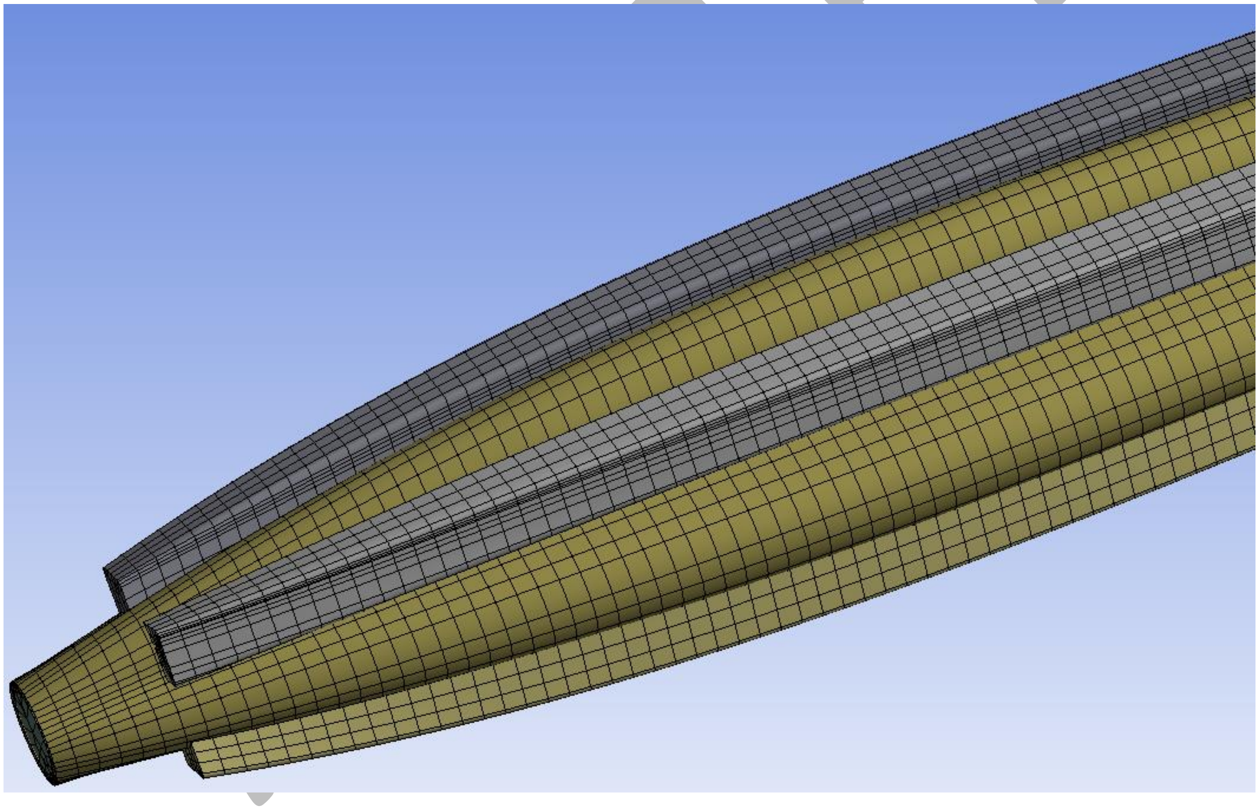

Figure 5. Fragment of the Fixion nail hexahedral mesh

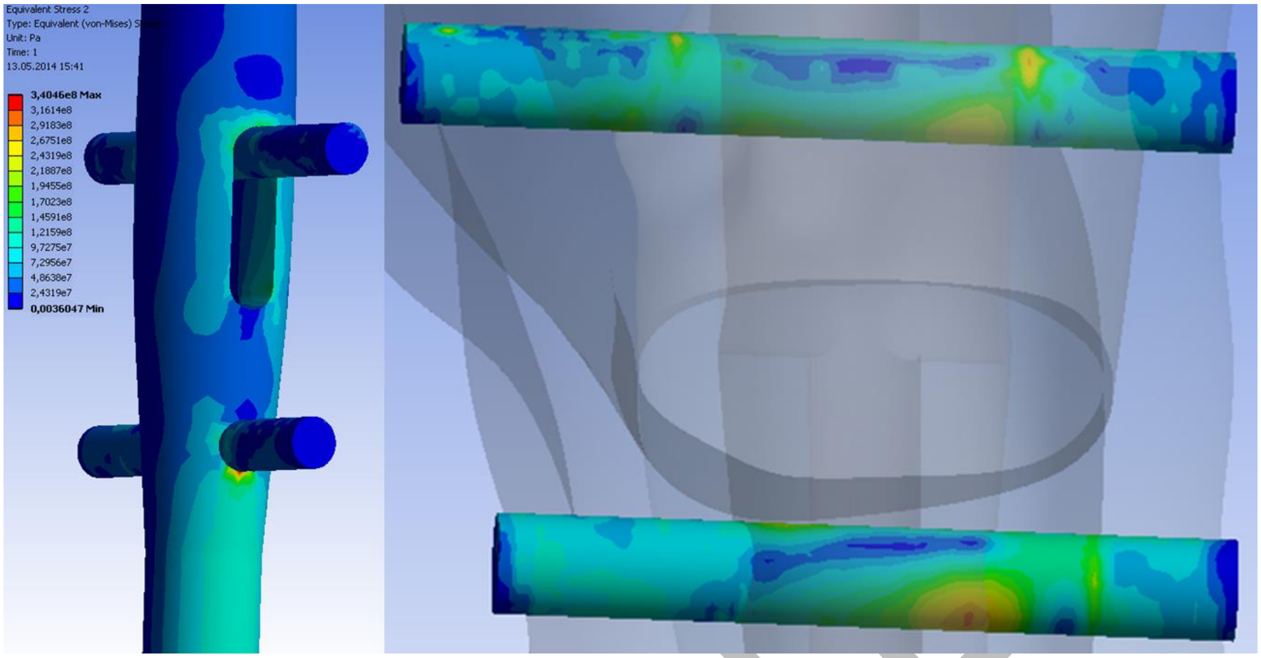

Figure 6. Stress concentrations on screws and at the contact area between screws and ChM nail

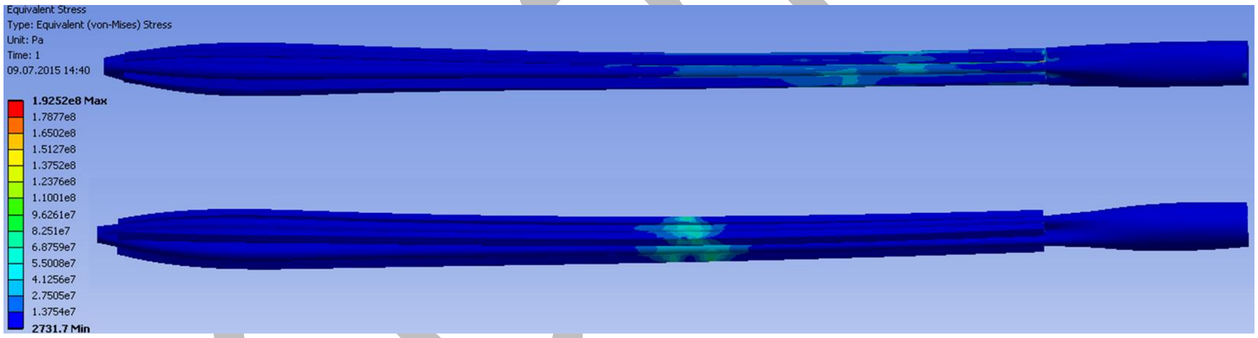

Figure 7. ES in Fixion nail in case of axial load for the A1 (upper picture) and B2 (lower picture) fractures

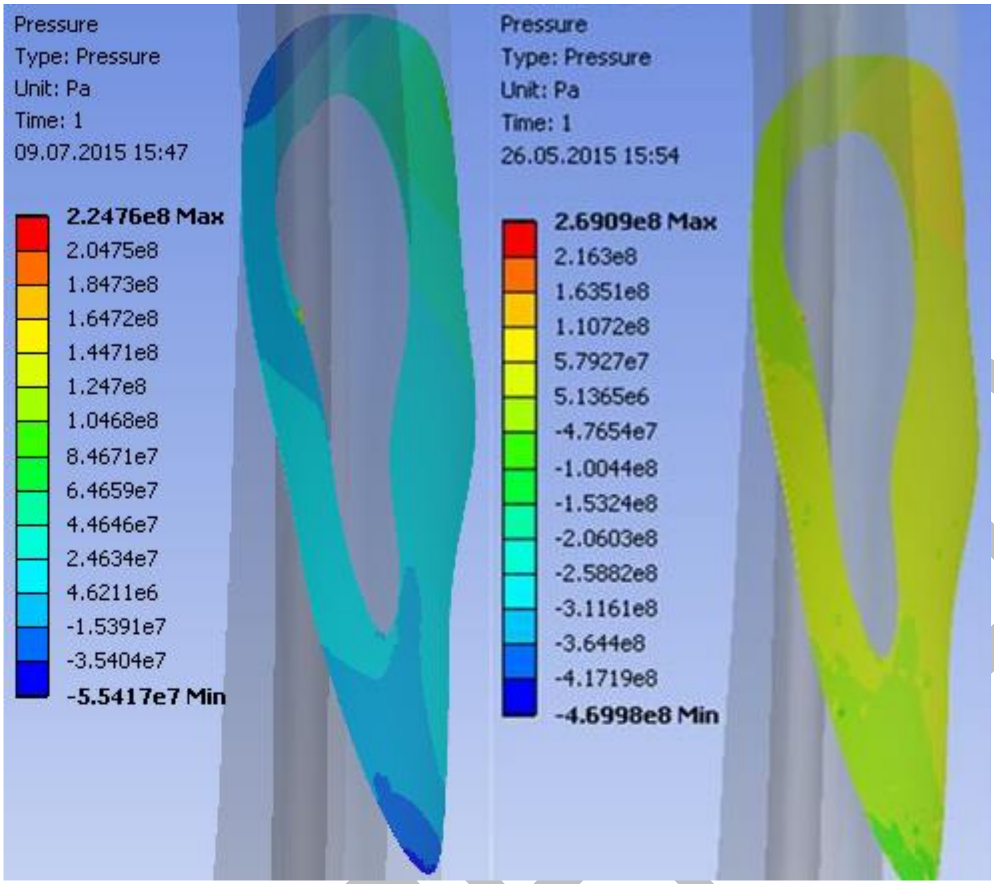

Figure 8. Contact pressure between bone fragments for A1 fracture and axial load: left picture is for ChM nail, right – for Fixion

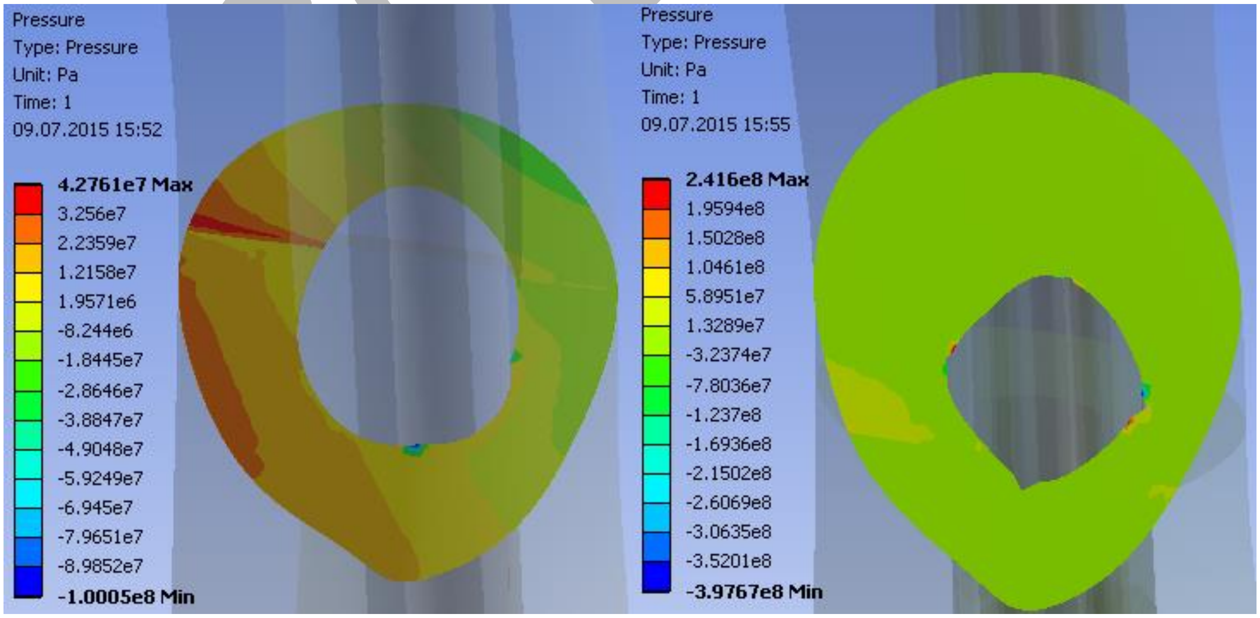

Figure 9. Contact pressure between bone fragments for B2 fracture and axial load: left picture is for ChM nail, right – for Fixion

Tables:

Table 1. Basic measured geometrical parameters of the Fixion nail which was removed 10 months after the operation from the femur

	Parameter	Value, mm
1	Nail length	340
2	Wall thickness	0.45
3	Longitudinal ribs thickness	3
4	Nail distal diameter	8
5	Nail proximal diameter	5
6	Nail medial diameter	7

Table 2. Bone mechanical properties

Parameter	Value
E cortical bone, Pa	$1.8 \cdot 10^{10}$
E trabecular bone, Pa	$1.2 \cdot 10^{10}$
ν cortical bone	0.3
ν trabecular bone	0.3

Table 3. Values of loads

	Load type	Value
1	Axial loada	700 N
2	Lateral load	100 N
3	Torsional moment	10 Nm

Table 4. Contact types

Contact	Type	Description
Bone-Nail Nail-Screw Bone-Bone	Frictionless	Contact surfaces are allowed to slide freely and contact can open and close depending on the loading.
Bone-Screw	Bonded	Both surfaces are bonded like glue. They are not allowed to separate. Not allowed to Slide.

Table 5. ES values in MPa

№	Type and load value	ChM	Fixion

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		Fracture type (according to AO\ASIF)			
		A1	B2	A1	B2
1	Axial 700 N	340	250	170	180
2	Lateral 100 N	220	200	260	250
3	Torsional 10 Nm	400	380	205	200

Table 6. Maximal displacements of the bone head in mm

№	Load type and value	ChM		Fixion	
		Facture type (according to AO\ASIF)			
		A1	B2	A1	B2
1	Axial 700 N	1.10	1.05	1.53	1.43
2	Lateral 100 N	3.30	2.89	2.48	2.40
3	Torsional 10Nm	1.10	0.99	0.44	0.5

Table 7. Contact pressure between bone fragments in MPa

№	Load type and value	(ChM)		Fixion	
		Fracture type (according to AO\ASIF)			
		A1	B2	A1	B2
1	Axial 700 N	250	43	270	130
2	Lateral 100 N	60	115	50	350
3	Torsional 10 Nm	20	45	12	90

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