ABSTRACT

Mechanical behavior of cranial implant is an important factor, which influences its function. It is influenced by external load from environment and by intracranial pressure. These loads can cause movement of implant and harm of living tissue.

This thesis summarizes knowledges and analyses of cranial defect reconstruction. It provides comparison of different implant materials and fixators based on stress-strain analysis of the implant loaded by force and intracranial pressure.

Key words

Cranial implant, fixators, stress-strain analysis, finite element analysis, deformation

ABSTRAKT

To, jak se bude implantát chovat v lebce, je velmi důležitým faktorem, který ovlivňuje jeho funkci. K ovlivnění dochází především vnějšími silami a nitrolebečním tlakem. Tato zatížení mohou způsobit pohyb implantátu a poškození živých tkání.

Tato práce shrnuje poznatky a analýzy, týkající se rekonstrukce poranění lebky. Srovnání implantátů z různých materiálů a fixátorů je založené na napěťově-deformační analýze implantátu, zatíženého vnějšími silami a nitrolebečním tlakem.

Klíčová slova

Lebeční implantát, fixátory, deformačně-napěťová analýza, metoda konečných prvků, deformace

BIBLIOGRAPHIC CITATION

CHAMRAD, J. *Deformační a napěťová analýza lebečního fixátoru.* Brno: Vysoké učení technické v Brně, Fakulta strojního inženýrství, 2016. 85 s. Vedoucí diplomové práce Ing. Petr Marcián, Ph.D..

DECLARATION

I declare that I have written this bachelor thesis Stress-strain analysis of cranial implant on my own according to the instructions of my Diploma thesis supervisor Ing. Petr Marcián, Ph.D., and using the sources listed in references.

27th of May 2016

Datum Bc. Jakub CHAMRAD

ACKNOWLEDGEMENTS

I would like to express my huge thanks to my Master Thesis supervisor Ing. Petr Marcián, Ph.D., from Institute of Solid Mechanics, Mechatronics and Biomechanics, Brno University of Technology, for guidance and essential advices and other help during whole process of writing this thesis and making analysis.

Special thanks are addressed also to my classmates, who helped me with exams after my Erasmus+ in Tampere in Finland and with help during writing this master thesis.

Last acknowledgment is to my family, which supported me not only during 4 and half years in Brno University of Technology and half year in Tampere University of Technology, but during whole 24 and half years of my life.

CONTENT

ABSTRACT ... **3**
Key words ... 3
BIBLIOGRAPHIC CITATION ... **4**
DECLARATION ... **5**
ACKNOWLEDGEMENTS ... **6**
CONTENT ... **7**
INTRODUCTION ... **9**
1 DESCRIPTION OF THE PROBLEM ... **11**
2 PROBLEM FORMULATION ... **12**
3 RESEARCH ... **13**
4 ELEMENTARY ANATHOMY OF CRANIO-MAXILLOFACIAL SYSTEM **14**
4.1. Neurocranial bones ... 14
4.2. Cranial scalp ... 15
4.3. Cranial bone tissue ... 15
5 INTRACRANIAL PRESSURE ... **18**
6 TYPES OF IMPLANTS ... **20**
6.1. Conventional approach ... 21
6.2. Patient specific approach ... 21
7 MATERIAL OF IMPLANTS ... **22**
7.1. Basic outline of biomaterials ... 23
7.1.1. Metals ... 23
7.1.2. Polymers ... 23
7.1.3. Ceramics ... 23
7.1.4. Composites ... 23
7.2. Specific materials for implants ... 24
7.2.1. Polymethyl methacrylate (PMMA) ... 24
7.2.2. Polyetheretherketone (PEEK) ... 24
7.2.3. Titanium alloys ... 25
7.2.4. Hydroxyapatite (HA) ... 27
8 TYPES OF FIXATORS ... **28**
9 MATERIAL OF FIXATORS ... **30**
10 SOLUTION METHOD ... **31**

11 COMPUTATIONAL MODEL 32
11.1. Model of geometry 32
11.2. Model of materials 38
11.3. Model of boundary conditions 39
11.4. FEM mesh creating 40
12 PRESENTATION OF RESULTS 41
12.1. Implant 42
12.1.1. Stress in implant 42
12.1.2. Directional deformation in implant 47
12.2. Fixator 52
12.3. Strain in Skull 57
12.4. Overall effects of implant thickness and quantity of fixators 63
12.4.1. Thickness influence 63
12.4.2. Fixation influence 65
12.5. Submodeing 69
CONCLUSION 73
LIST OF ABBREVIORS 73
LIST OF UNITS 75
LIST OF TABLES 76
LIST OF FIGURES 77
REFERENCES 80

INTRODUCTION

Biomechanics is one of the representatives of bioengineering field. Biomechanics is helping to nature using technology knowledge. It is theoretical – application field, which is involved in solving problems of living subjects using knowledge of engineering mechanics. One of those problems may be for example cranial bone substitution by system of implant and fixators [1].

Nowadays society is usually in the rush. People are using bicycles, motorbikes, scooters, in-line skates or doing adrenalin sports. This is contemporary lifestyle. Lots of those activities are performed, for some reason, without helmet or some other protection of head. This is the reason head injury may occur.

Head is one of the most complicated and multiform parts of human body. It consists of 28 bones, which form skull (cranium). Skull works as a protective shell or helmet for our brain (as shown in figure 1). Brain is the center of the nervous system. It controls most of the activities of our body (such as memory, ability to communicate, thinking, feeling emotions, being creative and so on), *conscious* (walking, running, etc.) and *unconscious* (breathing, heart beating, etc.) actions [2].

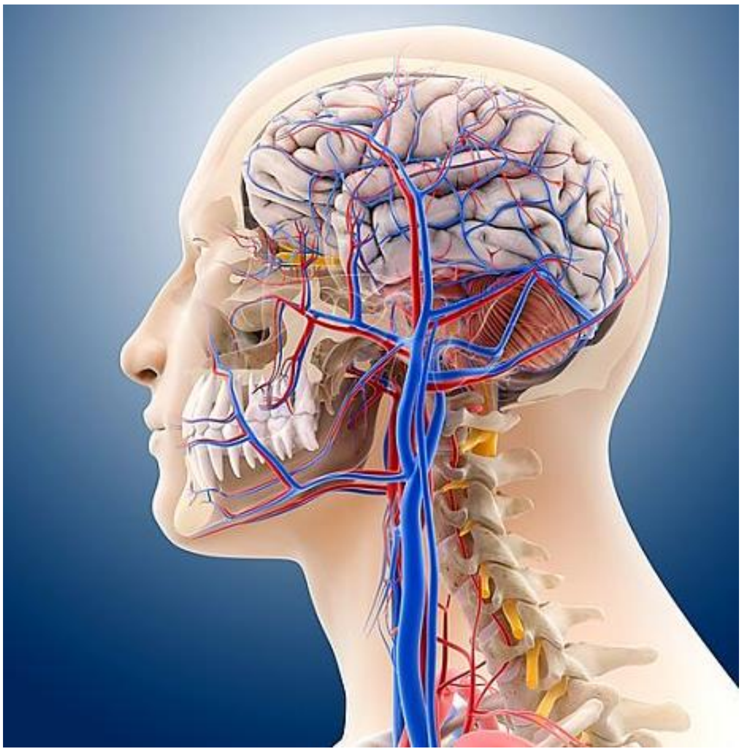

Fig. 1: Human head [3].

Head injuries are serious and it is important immediate hospitalization to prevent possible brain damage. Surgeons usually use implants to protect the brain and to provide mechanical support damaged tissue. Implant is connected to cranial bone by fixators and screws.

Using implants is not anything new. Finds of first primitive implants are from the Neolithic period (5000 years BC) [4]. Development is moving forward and today, surgeons are able to use patience specific implants designed using CAD or CAM methods and manufactured by rapid prototyping [49]. Although there is a big progress in implantology, it must be remembered that for successful recovery, patients have to follow all instructions of doctors. Successful implementation depends on experiences of surgeon.

He decides, how much is implant supposed to be machined or how many fixator will he use and their locations.

During recovery, there are several risks for implant during daily activities. Mass of a head is around 5 kg, which means, that force almost 50 N may push the implant inwards [5]. Intracranial pressure (ICP) pushes implant outwards. It is time variable value (as shown in figure 2), which depends on several factors (like position of the body and so on) [5], [6].

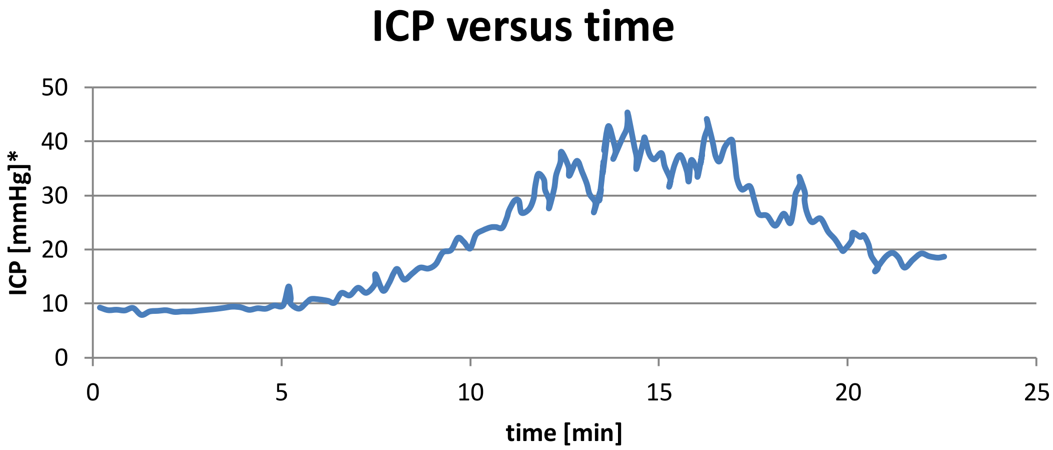

Fig. 2: ICP dependence on time [6].

** = Recalculation between mmHg and kPa is 1 kPa= 7,501 mmHg.*

1 DESCRIPTION OF THE PROBLEM

In case of head injury and skull defects, intracranial pressure rises, but in the same time, brain has to be protected. In this thesis, cranial implants are the main point of focus. They are used as a substitution for missing cranial bones. Each implant consists of implant body and fixators. Implant body covers the bone defect and fixators hold implant body in required position and fix it to surrounding bone tissue. Position and shape of usually 3 fixators is based on surgeon practice and experience. Important is to keep implant in motionless state. Displacements directly threaten the patient's life. The goal of implant is to protect brain tissue from external stresses and resist to ICP, which operates from internal side. Problem is to design implant, which resists stresses and loads from external and internal side and which does not influence patient in a way of its weight or thickness. Holes for screws (depth and diameter) have to be considered to the solution. Different biomaterials, which are used for Rapid prototyping method, are analyzed. Even the implant, which is manufactured as a patient specific will change the mechanical conditions in the region. In this Diploma thesis, the stress – strain analysis of human skull with skull implant and fixators will be analyzed.

Side target is cosmetic effect. It could help people also from psychological aspect. That is the reason, why implants are designed individually to each patient and manufactured using Rapid prototyping method. Scans of intact part of skull are used and then it is inverted by mirroring tool. Human body is not completely symmetrical, but insignificant irregularity can be eliminated by machining [5].

There are surgeries, related to skull:

- craniotomy;
- craniectomy.

During a craniotomy, pieces of skull bones are removed to provide access to brain. The bones are placed back after surgery and they are hold by metallic plates during healing process.

The difference between craniotomy and craniectomy is that bones are not returned back to their previous position after surgery. It may be caused by swollen brain, surgeon experience or other complications. They could be placed to the previous position later, in that case, they are put inside human body usually to abdomen under the fatty tissue. It is well protected and preserved inside own body [7].

Solving problem in the field of Biomechanics is most often done in two ways: Experimental and computational modeling. The experiment is very time consuming and requires appropriate experimental tissue samples, implants and fixators. It is preferable to apply computational modeling using Finite element method (FEM).

The computational model consists of sub-models:

- model of geometry;
- model of material;
- constraints (boundary conditions);
- model of load.

The data from devices such as computer tomography, magnetic resonance imaging etc. may be used to create model as real as it is possible [1].

Stress-strain analysis may be computed by FEM. This analysis determines stresses and strains in materials and structures subjected to loads (forces, pressure, etc.). Problem with the analysis of stress and strain is validation of results.

2 PROBLEM FORMULATION

Based on the chapter *Description of the problem*, it is possible to formulate problem this way:

Accomplish biomedical studies of cranial implants from material PMMA, PEEK and Titanium alloy using self-made model designed due to Computer Tomography (CT) pictures. Stress – strain analysis of skull including spongy part, implant body and fixators *(as shown in figure 3)* **will be done in this thesis.**

Goals of this thesis:

1) The state of art research
2) Creation of skull geometry model based on CT images
3) Creation of a computational model of the skull with fixed implant
4) Stress – strain analysis

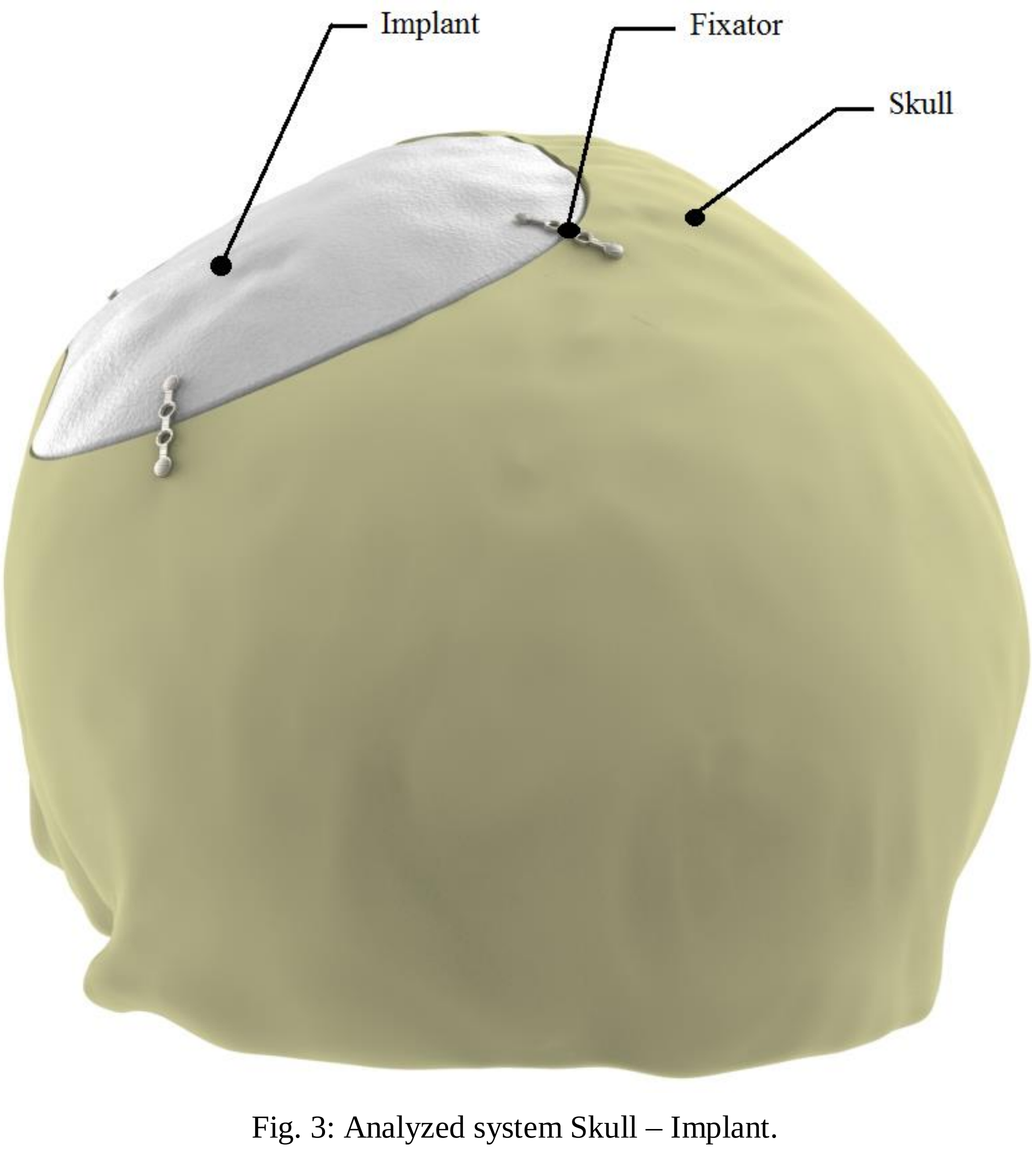

Fig. 3: Analyzed system Skull – Implant.

3 RESEARCH

The topic, this thesis is focused on, is not much explored. There are many articles about implants, biomaterials, stories of people with implemented implant and so on, but stress – strain analysis of cranial implant is not usual. One of the articles is from authors Ridwan-Pramana, Marcián, and others. The name of the article, which was published in Journal of Cranio-Maxillofacial Surgery, is *Structural and mechanical implications of PMMA implant shape and interface geometry in cranioplasty – a finite element study*. In this article, authors investigated an effect of defect contour curvature and osteotomy angle in bone – implant interface on the stress distribution. 15 different configurations were analyzed using finite element method [49].

Cranial implants and fixators were analyzed in Bachelor theses of Michal Hříčiště and David Klíštinec. David Klíštinec did stress – strain analysis of various titanium fixation plates, which were applied on PMMA implant. Michal Hříčiště did comparison of different shapes and materials of implant, based on stress – strain analysis. Both were analyzing model of skull, which the leader of the theses (Ing. Petr Marcián Ph. D.) provided them.

This Master thesis is unique, because model of the skull includes spongy part (as shown in figure 4), which has different material properties. It was not included in articles, which were mentioned before. It would significantly influence results of stress – strain analysis.

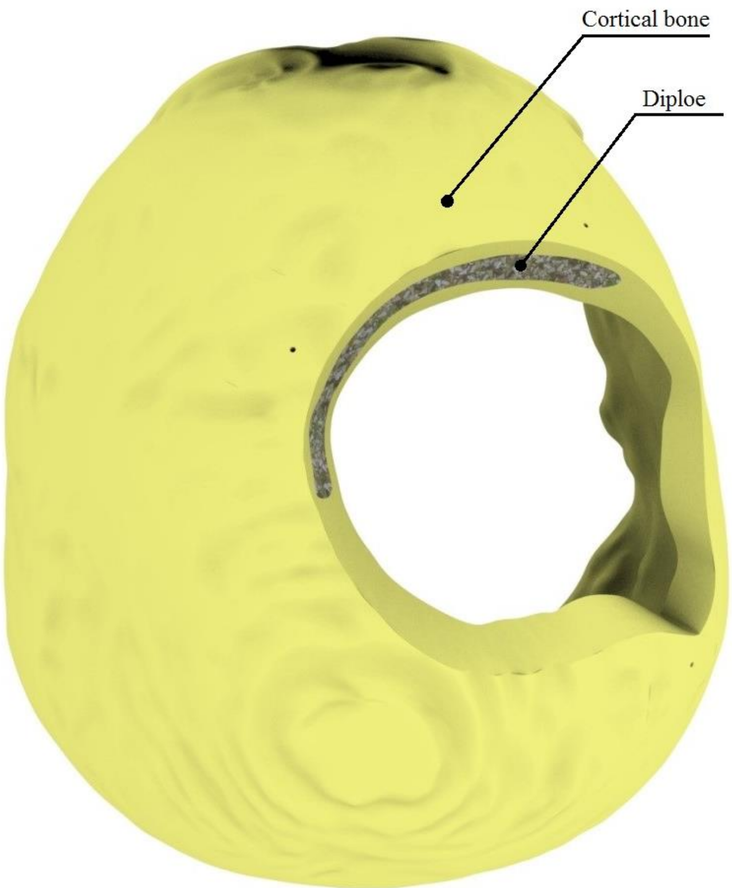

Fig. 4: Skull including spongy part.

4 ELEMENTARY ANATHOMY OF CRANIO - MAXILLOFACIAL SYSTEM

Human skull consists of 28 bones. Each one is unique as regards internal and external geometry. Skull is important to protect all 3 parts of brain (hindbrain, midbrain and forebrain). Skull is formed by 2 different types of bones:

- neurocranium (holding and protecting the brain);
- splanchnocranium (facial bones) [8].

For this thesis, neurocranium part is the point of focus.

4.1. Neurocranial bones

Neurocranial bones include paired bones (Parietal and Temporal bones) and unpaired bones (Occipital, Sphenoid and Frontal bone) as shown in figure 5. Neurocranium consists of 2 parts:

- calvaria (skullcap);
- basis crania (skull base).

Boundary between them was set by a line beginning with superciliary arches and going to inion (external occipital protuberance), which is located in the middle of occipital bone. Accordingly, skullcap is formed by parts of a frontal bone as well as part of Occipital bone and both Parietal bones [9].

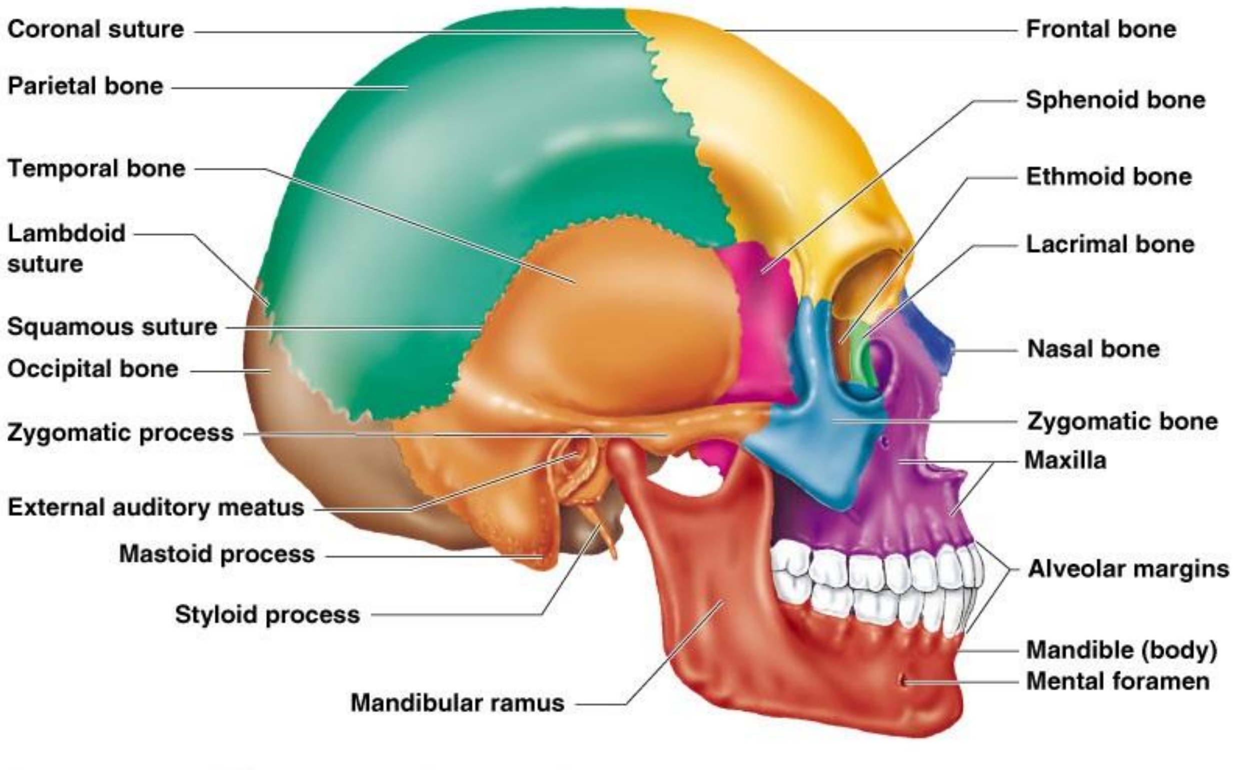

Fig. 5: A lateral view of a skull [10].

4.2. Cranial scalp

Scalp (figure 6) is a cover of the skull. Scalp is a protection of a head from hairline to the eyebrows. It consists of 5 layers, of which 3 are rigidly connected together. *Skin* of the scalp is the strongest in the human body. It is overgrown with hair. *Dense fibrous tissue* is under the skin and it contains a large number of arteries and veins. Under this layer, there is a *muscular layer*. These 3 layers are rigidly connected and dense fibrous tissue connects skin and muscular layer. Last two layers of scalp are *loose connective tissue* and *pericranium*. Loose connective tissue allow for previous 3 layers movement on pericranium, which covers skull bones [2].

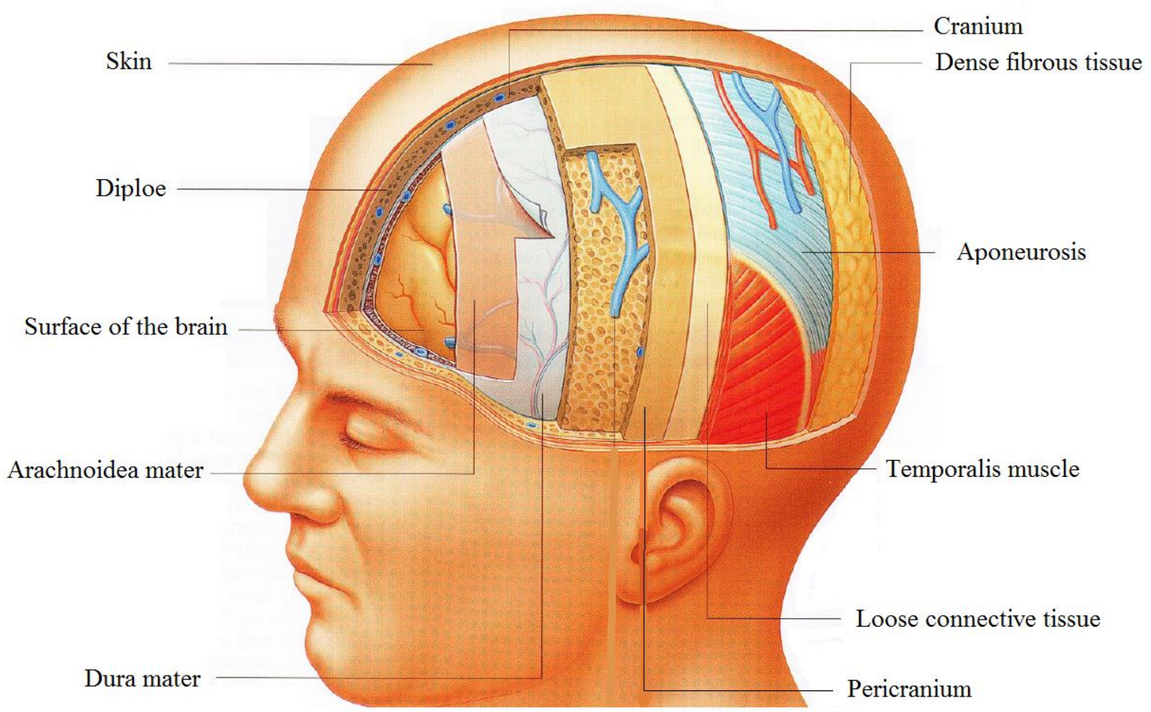

Fig. 6: Scalp [2].

4.3. Cranial bone tissue

The knowledge about behavior of cranial bones is important in treatment of head injuries [11]. Neurocranial bone is a flat bone. It consists of 2 layers:

- compact bone tissue;
- spongy bone tissue (diploe).

The ratio between these two parts is various. Cross-section of skullcap is divided into 3 parts (Fig. 7). Top and bottom is made from compact (cortical) bone tissue. These parts have high density. Central part is trabecular layer, the diploe. It is the low - density part of bone tissue, because of many randomly distributed pores [9].

The overall strength of skull is the most affected by thickness of the diploe. Diploe thickness in different places is different [5], [11]. Average porosity is around 10%, but there is no significant correlation between porosity and mechanical properties of cranial bones. On the other hand, when percent of bone volume increase, elastic modulus and maximum bending stress increase. Spongy bone is energy absorber and also it makes whole skull less heavy. Outer compact bone layers are stiff.

Unfortunately, studies, focused on tested mechanical properties of cranial bones, have shown large differences in results. It is because of different condition of samples (fresh, embalmed) [11].

Tab. 1: Several mechanical properties of cranial bone.

Density	*	[59]
Microhardness Vickers	$22 – 42^{1,2}$**	[60]
Young's (Tensile) modulus	15 000 MPa^{1} 2792 MPa^{2}	[47]
Poisson ratio	$0,3^{1,2}$	[47]
Ultimate Tensile Strength	90 – 130 $MPa^{1,2}$***	[20], [49]

** = depends on the thickness of diploe, which is influenced by many factors, such as age and so on.*
*** = in literature, there is a deviation to each value and there is a difference between tests of inner and outer surfaces.*
****= large differences in literature*
Index 1 means cortical bone and index 2 means spongy bone.

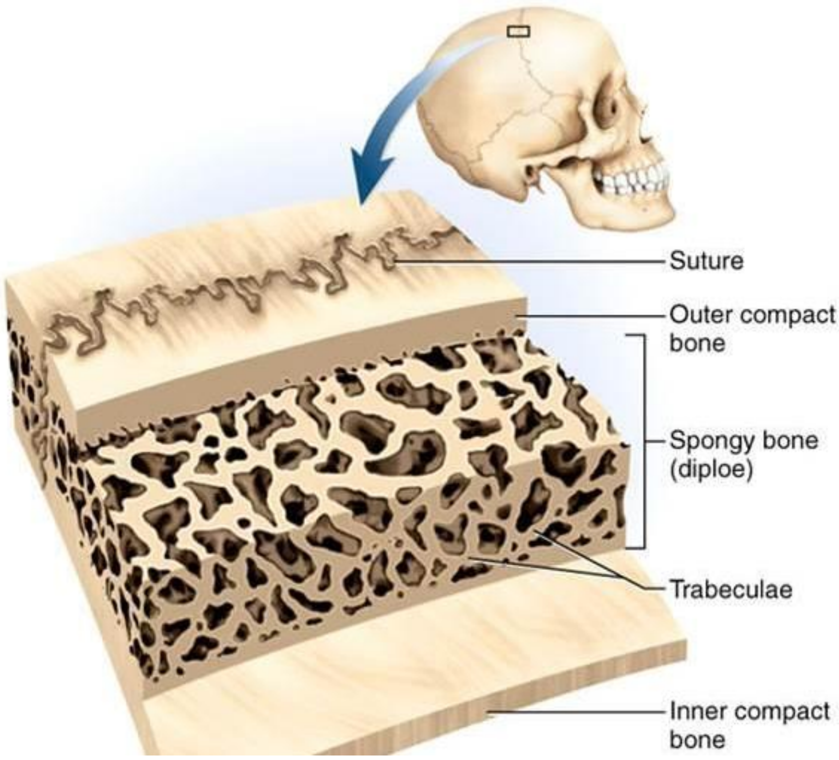

Fig. 7: Cross-section of skullcap bone [13].

Assumption is that cranial bone is composed as homogenous isotropic material with a uniform cross – section along its length. This assumption is not entirely accurate, however information available from microCT scans were evaluated consistent manner with a respect to location and orientation [61].

Most of mechanical properties of cranial bone are strongly influenced by the structural arrangement of the diploe [60]. The results showed, that impact speed plays an important role in fracture of adult scull. Other the most notable variables are porosity, overall bone thickness and thickness of each layer [61].

Frontal bone tends to be thicker, less porous and have higher percent of bone volume than parietal one. It means, that fracture of frontal bone requires higher forces [61].

In case, that material properties are unknown, special software is used to determine them. This software shows tissue in Hounsfield's units (HU). HU are counted from CT numbers (values shown in table 2). Equation (2) is used for the transformation. Linear relation between CT numbers and density of tissue was proved. The transformation from CT to HU is kind of calibration. The references of the calibration are CT number of water (CT_w = 1000) and CT number of air (CT_a= 0). Corresponding HU values are in table 5 [46].

$$HU = 1000 \cdot \frac{CT - CT_w}{CT_w - CT_a} [-] \tag{2}$$

Tab. 2: Values of Hounsfield's units for selected tissue and references for CT – HU transformation [46].

Tissue	HU
Enamel	2500 – 3000
Compact bone	900 – 1800
Diploe	150 – 900
Cartilage	80 – 130
Ligament	60 – 90
Muscle	35 – 70
(Water)	0
(Air)	- 1000

Each tissue of human body has characteristic value of HU. Values of HU represent specific shade of grey color. HU are recounted to density, which is, using relations for the transfer, converted to Young's modulus E [MPa] [46].

As it was mentioned before, materials were defined using Young's modulus and Poisson ratio from literature.

5 INTRACRANIAL PRESSURE

Intracranial pressure is determined by pressure of three components on the cranial cavity wall:

- brain tissue (80 % volume of cranial cavity);
- cerebrospinal fluid (10 %);
- blood (10 %) [14], [15], [16].

Intracranial pressure depends on reciprocal interaction between all three components and cavity volume. Change of volume of one of the component cause change of volume of the others components and also change of pressure inside cranial cavity, intracranial pressure. Volumes of all three components are variable and unstable [16]. It makes from intracranial pressure time variable value (as shown in figure 2). This value depends on actual volume values of components, age, body position and clinical conditions [17]. Difference among lying down and standing is doubled [18].

In case, ICP is rising, it may impede blood flow and cause ischemia*. ICP is derived from circulation of 2 different body fluids:

- cerebral blood (CF);
- cerebrospinal blood (CSF).

The simplified equation for ICP:

$$ICP = ICP_{CF} + ICP_{CSF} \text{ [mmHg]} \tag{1}$$

However, it is not certain whether the CSF operator in the equation is represented well by simple addition [6].

The normal range of ICP for healthy adult in horizontal position was reported as 7 – 15 mmHg (0,93 – 2 kPa**) as shown in figure 8. In vertical position, ICP is negative. The mean is around -10 mmHg (-1,33kPa), but not exceeding -15 mmHg (-2 kPa). Whether head injury occurs, average ICP is above 25 mmHg (3,33kPa). It increases risk of death twice. In that case, surgery (such as Decompression craniectomy) is necessary [6].

**Ischemia = restriction in blood supply to tissues. In case of cranial implants, it may be caused by dysfunction of tissue or as a result of damage.*

***Recalculation between mmHg and kPa is 1 kPa= 7,501 mmHg.*

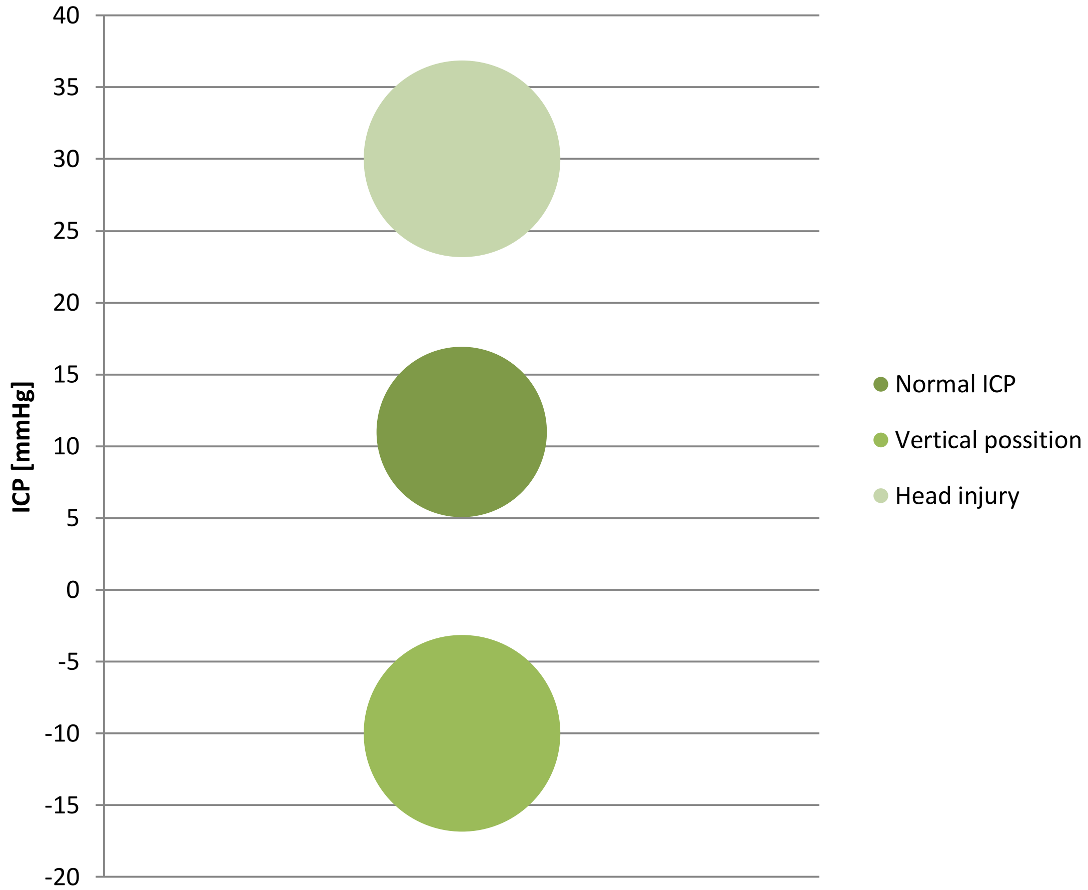

Fig. 8: Values of ICP during head injury, standing – vertical position and normal value of ICP [6].

6 TYPES OF IMPLANTS

Implant is a *medical device*, which means any instrument, apparatus, appliance, material or other article, which could be used in combination or alone to diagnose, monitor, control, treat, alleviate, replace, do modification or compensation.

Particularly *implants* are devices that are at least partially placed inside the body to perform a function. It can be made of one or several materials and it may perform one or several functions. [20]

In Europe, there are 4 different classes of medical devices. Classification depends on duration of body contact, invasive character, use of energy source, diagnostic impact and other criteria. Implants are included in classes IIb and III. Skull implant, this thesis is focused on, is in class IIb. Class IIb includes life-saving, invasive and long-term implantable devices [21].

List of implants types:

- orthopedic implants;
- dental implants;
- CMF (Cranial and Maxillofacial) implants;
- cosmetic reconstructing implants;
- body contouring implants;
- implants used to controlled drug delivery [20].

Main problem is to choose right material and production methods based on actual indication.

The biggest market is orthopedic implants (around 44% of selling all medical equipment). Orthopedic implants are used to repair, fix or replace bone tissue, repair or replace articulate cartilage (in joint). Most difficult to replace is shoulder joint.

Cosmetics and body contouring implants have two or more combined functions:

- space filler;
- mechanical support;
- fluid carrier;
- storage device;
- psychological function [21].

Most common are breast implants made from polysiloxanes [21].

6.1. Conventional approach

Conventional approach is older than *patient specific approach*. It takes longer (approximately 3 hours) and it is designed at the operating theater. There is a risk of complications such as local tissue damage (pure heat treatment) and intoxication. Quality of these implants depends on surgeon experiences and skills (as shown in figure 13).

Symmetry is important from the cosmetic point of view, but more important is sufficient fit of implant into defect. Any movement, extrusion or dislocation of the implant may cause injury of living tissue and premature removal of the implant [24].

6.2. Patient specific approach

Significant evolution of designing implants has been in previous years. Cooperation of additive manufacturing and digital imagining techniques such as computer tomography (CT) and magnetic resonance results to manufacturing precise anatomical structure [24], [25].

Computer tomography is mostly used in skull surgeries. It is preferred due to hard tissue contrast and spatial resolution of the 3D data [48]. Data from CT can be converted into Standard Tessellation Language (STL) files and then exported to CAD or CAM software, where the patient specific implant is designed. Reconstruction of damaged skull by designing an implant can be done these ways:

- CT dataset of the patient's (untouched) skull taken before injury can be used as a source of data to design the implant.
- Using mathematical algorithms based software to reconstruct cranial defects.
- Unaffected side of a skull can be mirrored into damaged part, however the skull (as well as whole human body) is not 100 % symmetrical (as shown in figure 9) [5].

Designing patient specific implant has a lot of advantages, but there are some limiting factors such as inaccuracies, which may occur during each step of designing implant, and overall costs, which is still high [5].

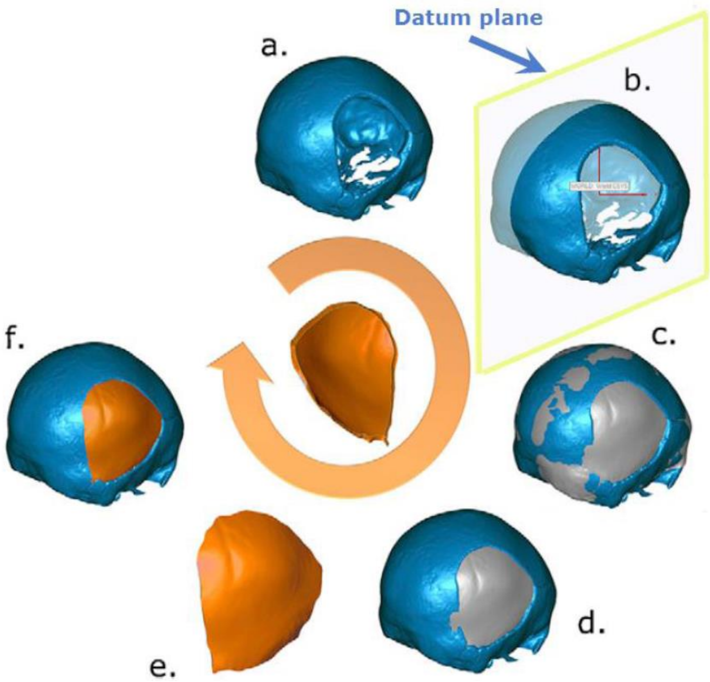

Fig. 9: Patient specific approach [26].

7 MATERIAL OF IMPLANTS

Solid materials could be classified (based on chemical and atomic structure) into four groups:

- metals;
- polymers;
- ceramics;
- composites (mixture of previous groups) [20].

Materials of these groups can be used in biomedical applications, but not all of them are suitable for implants.

Biomaterial is a material intended to interface with biological systems to treat, augment, replace or evaluate any tissue, organ or function of the body. [Williams 1999]

Biomaterials are multidisciplinary research field, which includes among others medicine, biology, chemistry, material science, mechanical engineering and more [1].

No material is perfectly inert, every time, there is some response.Tissue response to implanted material could be:

- toxic;
- nearly inert;
- bioactive;
- dissolution of implant [20].

Toxic response means that tissue is harmed or dies. Tissue reacts always in case of contact with foreign material. *Nearly inert* response means, that there is almost no response. The most common nearly inert response is formation of non-adherent fibrous capsule. *Bioactive* material is material intended to promote required biological response at the biological and material interface. Tissue forms covalent bonds with the implant. *Dissolution of implant* means, that tissue gradually replaces the implant.

Implant is a device that is at least partially placed inside the body to perform a function. It could be made of one or several materials and it may perform one or several functions. It is important, that implant is made from biocompatible material. Biocompatibility means ability of a material to perform with an appropriate host response in specific applications [Williams 1987]. Schematic description of biocompatibility is shown in figure 10 [20].

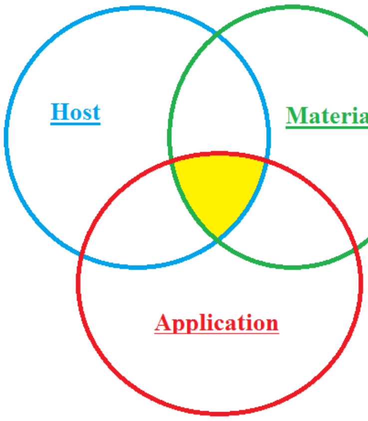

Fig. 10: Biocompatibility of material for given function (yellow color in the picture) [20].

7.1. Basic outline of biomaterials

7.1.1. Metals

- steel (easy to sterilize and cheaper then titanium);
- titanium oxide (capable of osteointegration*, Young's modulus closer to cortical bones);
- cobalt alloys (form corrosion resistant Cr_2O_3 layer);
- noble metals (chemically inert, good conductors) [20].

7.1.2. Polymers

- synthetic biostable** polymers;
- synthetic bioabsorbable*** polymers;
- natural bioabsobrable polymers;
- modified bioabsorbable polymers [20].

7.1.3. Ceramics

The microstructure of ceramics can be:

- completely glassy (only glasses);
- completely crystalline;
- combination of crystalline and glassy [20].

7.1.4. Composites

In composites, there are 2 main phases:

- matrix phase (continuous phase);
- reinforcing phase (dispersed phase, filler) [20].

** osteointegration = Direct structural and functional connection between bone tissue and the surface of implant [22].*

*** biostable = Material is intended to remain unchanged in long term contact with living tissue [20].*

**** bioabsorbable = Material that is capable of being absorbed by the body. The material is intended to disappear from the body commonly via metabolic routes. It is not biodegradable, which means Material that is capable of being degraded. The biggest advantage of bioabsorbable polymers is no need for second surgery [20].*

7.2.Specific materials for implants

Materials, which are used the most often for cranial implants are:

- Polymethyl methacrylate (PMMA);
- Polyetheretherketone (PEEK);
- Titanium alloys;
- Hydroxyapatite (HA).

7.2.1. Polymethyl methacrylate (PMMA)

PMMA is a linear polymer material, which started to be used more often after World War II. as an implantable material. Aircraft windows were made from PMMA and accidentally doctors realized, that PMMA is biocompatible [23]. PMMA can be used in 2 different ways. It can be prepared as *a malleable substance* and be laid on support (similar as shown in figure 13), which is usually Titanium mesh. This way may cause thermal damage of a tissue, because of the temperature of the melted substance. In some cases, host can respond to PMMA implant by allergic reaction. Later, with Rapid prototyping development it started to be 3D printed as a *patient specific implant* and fixed to the bone by fixators [27].

It is one of the hardest thermoplastic [28]. PMMA is light and cheap. The level of radiolucency is high. It is not a thermal conductor [23]. PMMA has high Young's modulus and mechanical strength. It has low elongation at break. It does not shatter on rupture. PMMA is scratch resistant [28]. On the other hand disadvantage is low level of osteointegration, which is crucial factor for some kind of implant (orthopedic). It can be improved by coating [29], [30], [31]. PMMA has lower Young's modulus than cortical bones [32].

Table 3: Properties of PMMA [28], [32]

Density	1.15 – 1.19 g/cm^3
Hardness, Rockwell	63 - 97 HRB
Young's (Tensile) modulus	3 GPa
Poisson ratio	0.35 – 0.4
Ultimate Tensile Strength	47 - 79 MPa
Elongation at break	1 - 30 %
Melting point	130 °C

7.2.2. Polyetheretherketone (PEEK)

PEEK is a semi-crystalline thermoplastic polymer, which is more strength and elastic comparable to PMMA (as shown in figure12). It can be printed by rapid prototyping. PEEK is chemically stable, resistant to X-rays. PEEK implants can be sterilized by steam or gamma radiation. PEEK does not conduct heat and it has low density. It is able to be stable up to 240 °C, it melts at 343 °C. On the other hand, price of this polymer is high and PEEK lacks osteointegration, which is the ability of the spontaneous healing after implant fracture. PEEK has to be coated by collagenous fibrous tissues to allow osteointegration [29], [33], [34].

Table 4: Properties of PEEK [36].

Density	1.30 – 1.32 g/cm^3
Hardness, Rockwell	261 - 285 HRB
Young's (Tensile) modulus	3.76 – 3.95 GPa
Poisson ratio	0.38 – 0.39
Ultimate Tensile Strength	70.3 – 103 MPa
Elongation at break	20 %*
Melting point	334 °C
***= unfilled PEEK (no glass or carbon fibers in the structure)**	

7.2.3. Titanium alloys

Titanium is used in its alloys. It is the most common metallic biomaterial, which is used for cranial implants. Titanium is non-magnetic, biocompatible material within risk of allergic reaction and with a low risk of infection [23], [24]. Mechanical and corrosion resistance properties are good enough for cranial implants. On the surface, layer of titanium oxide (TiO_2) is formed and it protects implant to corrosion.

The most common Titanium alloys for cranial implants are Ti6Al4V and Ti6Al4V ELI, which is a short form for extra-low interstitial version with very low impurities [24]. Ti6Al4V ELI has Poisson ratio 0.30 and a Young's modulus 110 GPa [37].

Titanium can be used in combination (for example with HA) as a mesh for cranial defect treatment (as shown in figure 13), but most of the time, it is made using rapid prototyping for patient specific implants (as shown in figure 11) [23].

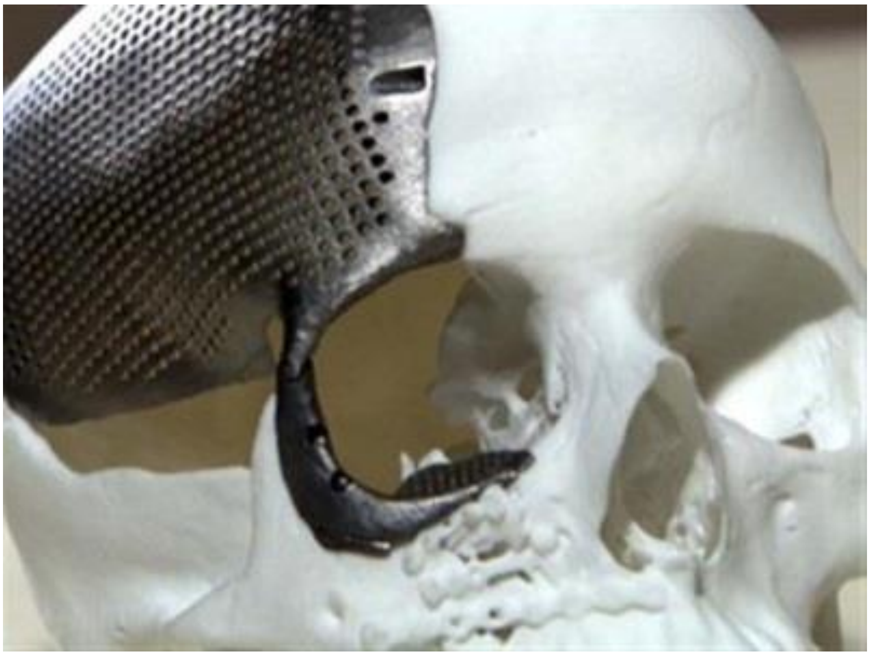

Fig. 11: Titanium alloys cranial implant [50].

Table 5: Properties of Ti6Al4V [37], [51], [52].

Density	4.43 g/cm^3
Hardness, Rockwell	334 HRC
Young's (Tensile) modulus	110 GPa
Poisson ratio	0.3
Ultimate Tensile Strength	950 MPa
Elongation at break	14 %
Melting point	1632 °C

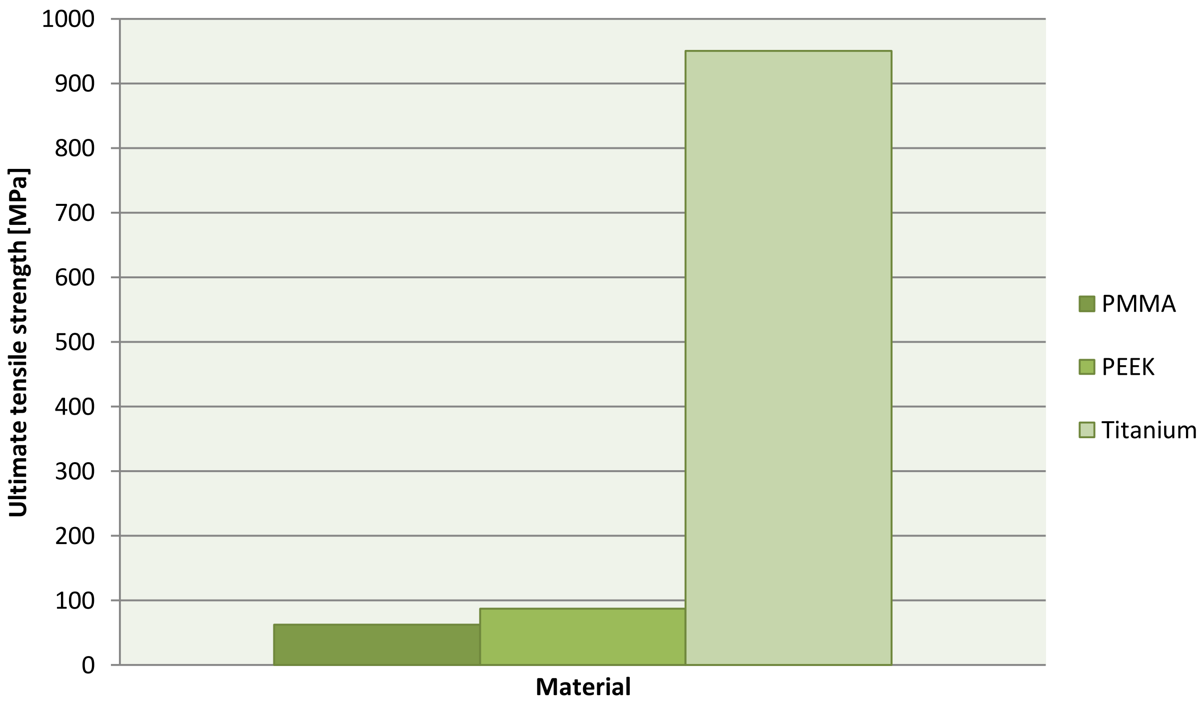

Fig. 12: Comparison of Ultimate Tensile Strength [28], [35], [36].

7.2.4. Hydroxyapatite (HA)

HA is a ceramic material that in mixture with water changes its properties from brittle and hard to mold to easy moldable and self-hardening [23]. HA is applied to mesh (usually made from Titanium) as shown in figure 13. HA has good biocompatibility and it is biomimetic, which means that implant from HA acts like a bone and it is accepted by the bone in the same way. Because of this, there are no immunological complications. HA allow osteointegration with a host bone. Limits of using HA are its poor plasticity and high costs [38].There is a wide variation of mechanical properties. It is due to variations in the structure influenced by manufacturing process. HA has high elastic modulus (40 – 117 GPa). Natural composites (such as for example Dentin) contain HA. Poisson ratio of HA is about 0.27 [53].

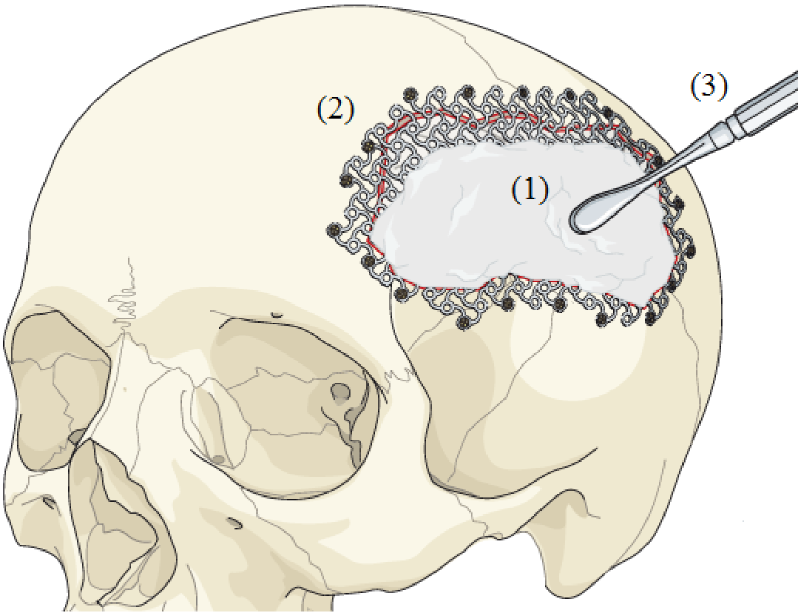

Fig. 13: Moldable HA cement (1) placed on Titanium mesh (2) using special tool (3) [39].

8 TYPES OF FIXATORS

Stability of implant is very important, because any displacement may cause damage of bone tissue, brain tissue or skin. It is still question for doctors, where to place fixators, how many screws and fixators to use. Usually, same type of fixators is used during surgery.

In case of using supporting mesh (as shown in chapter 6.2.4. *Hydroxyapatite*), there are already holes for screws in the mesh.

Fixators must hold the implant in its position, despite the fact that ICP and environmental impacts (as shown in chapter 4 *Loads*).

On the market, there are three sizes of fixators:

- large;
- medium;
- micro.

Companies, which manufacture fixators, make different screw heads (as shown in figures 14 to 17). Surgeons need also equipment from the specific company, which they use as contractor.

Size, shape and number of fixators are determined empirical. Also the number of screws is selected by experience of surgeon. Usually, it is enough to use 3 fixators, but sometimes, it is necessary to use more of them (extensive injuries). There is one unwritten rule, it should be the same amount of screws on implant and bone tissue side. Position of fixators is selected by two points of view:

- preclusion of implant movement;
- areas as planar as possible.

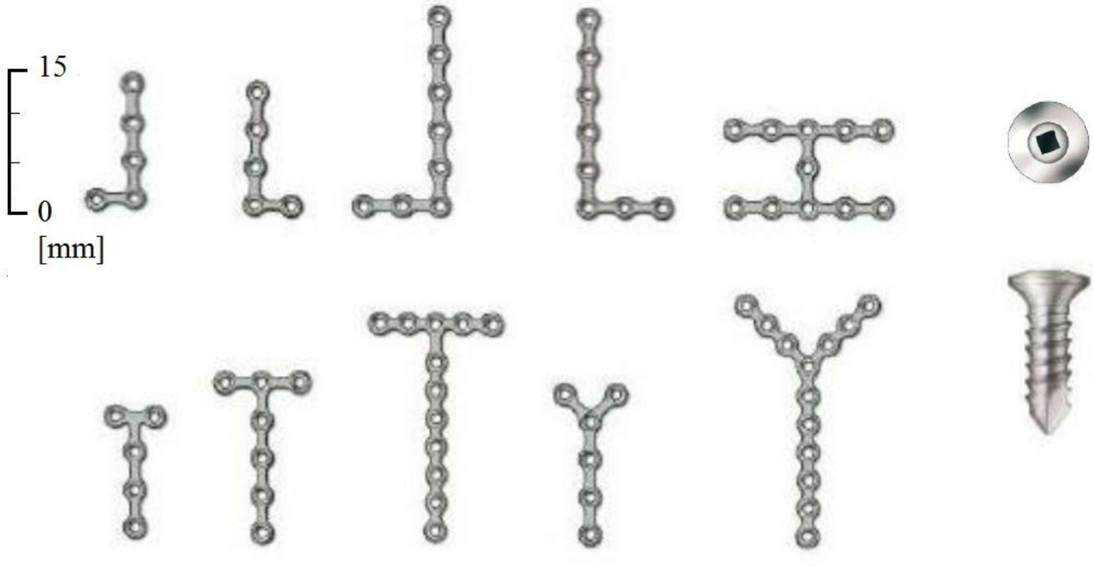

Fig. 14: Fixators and screw from company KLS Martin (screw is 3 mm long) [40].

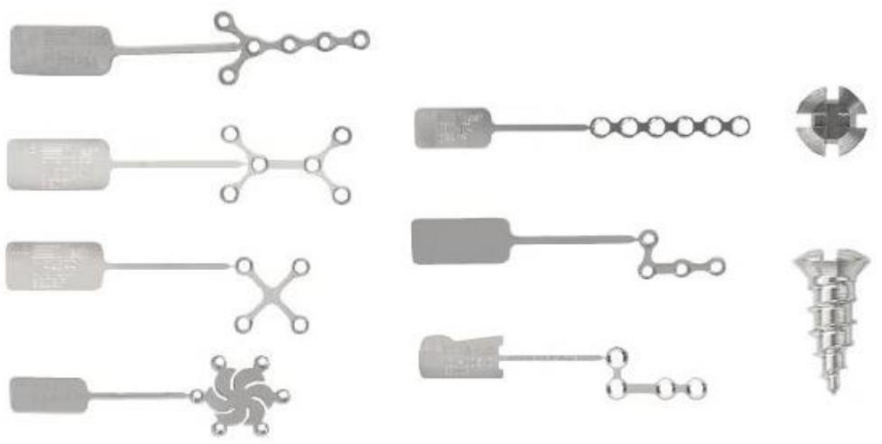

Fig. 15: Fixators and screw from company Medtronic [41].

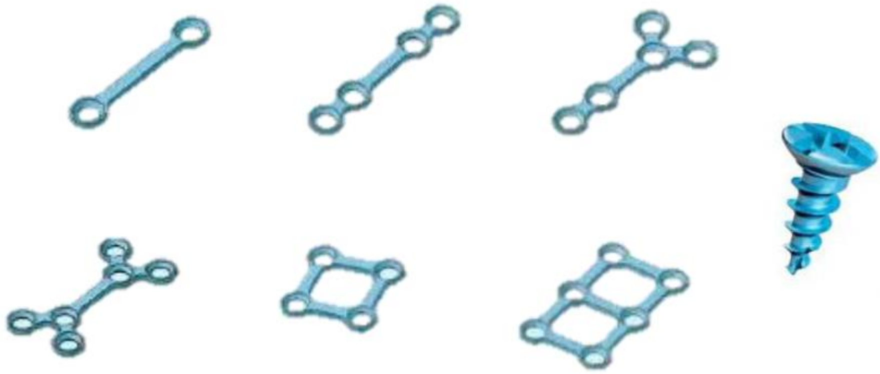

Fig. 16: Fixators and screw from company Aesculap [42].

Fig. 17: Unusual types of fixators [43]

9 MATERIAL OF FIXATORS

Fixators together with implant body form implant. Here is a list of requirements, that suitable fixator fulfills:

- reasonable costs;
- great stability inside human body;
- desired mechanical properties (to sustain internal and external loads);
- inconspicuous from esthetic point of view;
- biocompatibility and hemocompatibility;
- osteointegration;
- easy to use and to substitute;
- no distortion of CT and MRI;
- low profile [44].

The most widely used materials are Titanium alloys. It is the one well-known material, which comply with most requirements. Tissues form with Titanium alloys strong vascular and lymphatic bonds [44], [45].

Vitallium was used in past. It is an alloy of 65 % cobalt, 30 % chromium, 5 % molybdenum and other substances. This alloy corrodes and it may be damaged by fatigue. These processes are accompanied by biocompatibility and mechanical properties loss. Harmful substances may occur in human body, which could slow down healing, cause inflammation or the risk of cancer [45].

Stainless steel or cobalt alloys are surrounded by non-adherent fibrous capsule. It means, that tissue tries to isolate any foreign object from the host. No chemical or biological bonds can occur, which can cause relative movement [20], [44].

Titanium properties (such as tensile strength, resistance to fatigue, biocompatibility, and so on) outweigh mechanical properties of other materials and its alloys [44].

On the market, there are few kinds of fixators (KLS Martin, Medtronic, Aesculap, etc.). With fixators, there are also tools and equipment to bend the fixators to better copying contour of skull. Screws are self-tapping, it means, that surgeons do not have to drill, they just prepare small holes [44].

10 SOLUTION METHOD

Mechanical behavior of system skull – implant body – fixators (as shown in figure 18) can be evaluated by stress – strain states. These states may be determined either by experimental or computational modeling approach [1]. Method, used for solving tasks of this thesis, is computational modeling. Computational modeling calculates using Finite Element Method (FEM). A computational approach is more effective in Biomechanics than experimental modeling. It provides us more opportunities to analyze more thicknesses of implants and ways of fixing. Although FEM calculations have to be validated by experiment, but it is not included in this thesis. A computational model consists of partial models of geometry, materials and boundary conditions.

There are several software on the market, which are capable of doing FEM. ANSYS Workbench 16.2 was used in this thesis.

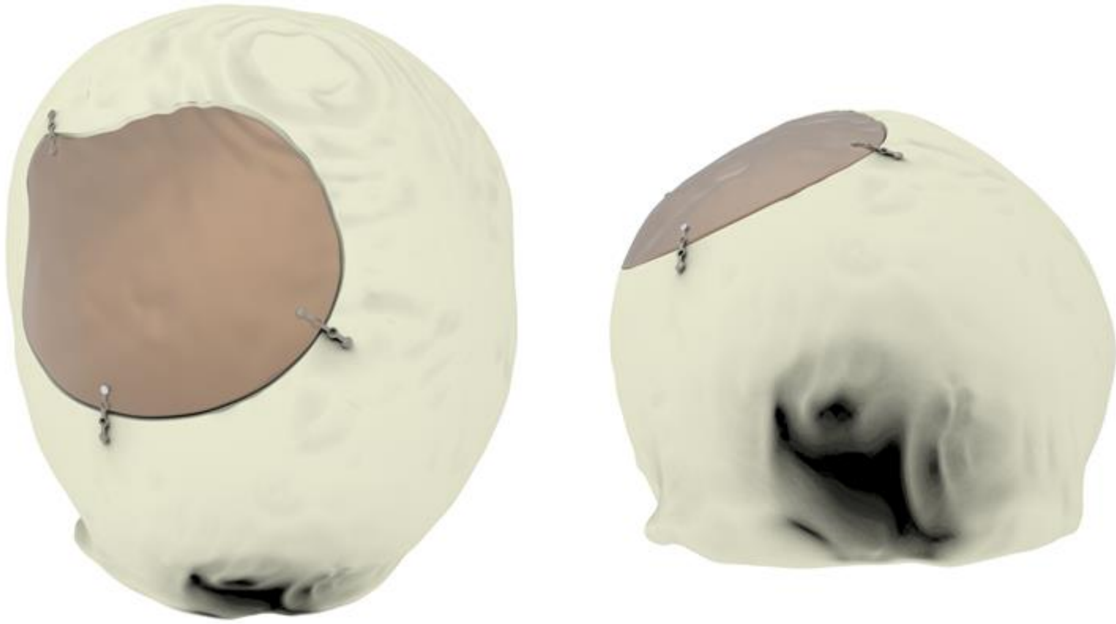

Fig.18: System skull – implant body – fixators.

11 COMPUTATIONAL MODEL

Computational model of the system skull – implant body – fixators can be divided into several steps:

- model of geometry;
- model of materials;
- model of boundaries and loads [46].

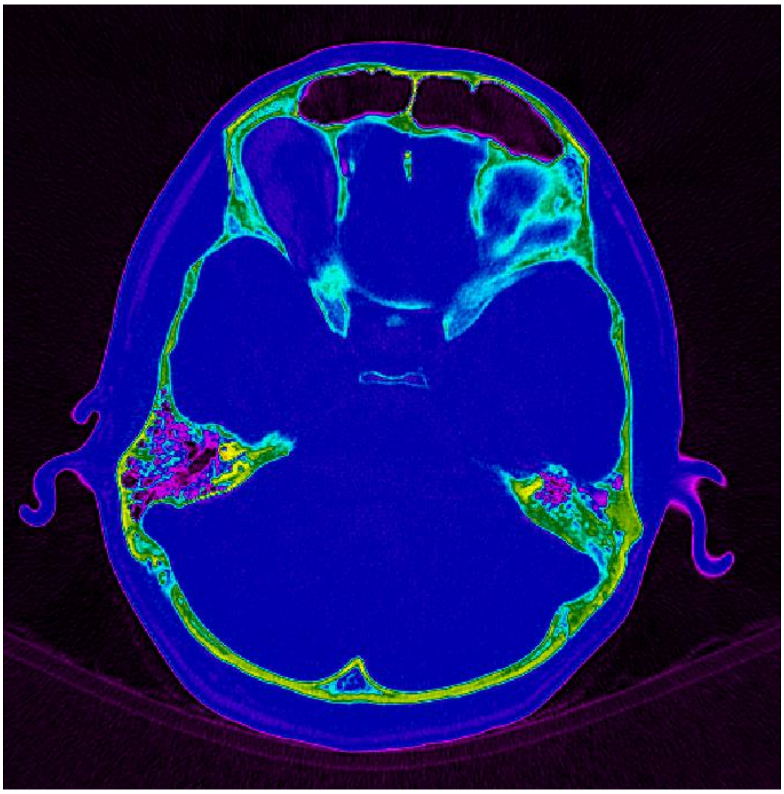

Fig. 19: Computed tomography picture of skull using Hot/cold color map.

11.1. Model of geometry

Designing model of geometry requires several steps. First step is collecting data from Computed tomography. Then using *STL Model Creator* is prepared STL*. STL Model Creator was designed in *Institute of solid mechanics, mechatronics and biomechanics Brno, University of Technology* in software Matlab. CT picture of skull in STL Model creator using Hot/cold color map is shown in figure 19.

Skull bone is demarcated from soft tissue using:

- automatic segmentation from scalp;
- manual segmentation from brain.

After segmentation, STL model creator creates STL of selected CT pictures [46]. Size of voxel, used in this thesis was 0.40234 mm *x* and *y* direction and 0.7 mm *z* direction.

**STL = STereoLithography– file format, which is widely used in rapid prototyping or CAM.*

STL provide information only about the shape of object. It is necessary to make volume model from output from STL Model Creator using software CATIA and SolidWorks. Some STL data can be unsuitable, it is possible to “clear” them (using special tool *mesh cleaner*) and prepare them for volume making process. Before that, it is also important to analyze STL model using tool *analyse*. There can be a lot of free points, it is important to remove them. For that operation, *isolated triangles* are used. It is also possible, that there are holes in the structure. It is necessary to fill the holes using tool *fill holes*. After that, mesh cleaner reiterate. The most important operation in CATIA is surface making. In this thesis, *automatic surface* was used. Output from software CATIA is shown in figure 24. After this process, model was saved as **.iges* format and imported to software SolidWorks [46].

For the volume making SolidWorks is used. There is a tool for automatic volume making, which is fast way, how to make the volume model. Disadvantage is, that the volume model consists of many surfaces. It can be influenced by choosing level of details. Minimum value means, that larger surfaces are created. The shape is not accurate. Maximum value of level of details means, that small surfaces are generated. They can have sharp shape, which can cause troubles during other processes. In case some surfaces were not able to be created, it is necessary to use tool *patch*. Then volume model is generated [46].

In this thesis, the process was done twice – for skull and for spongy part (as shown in figures 20 – 24).

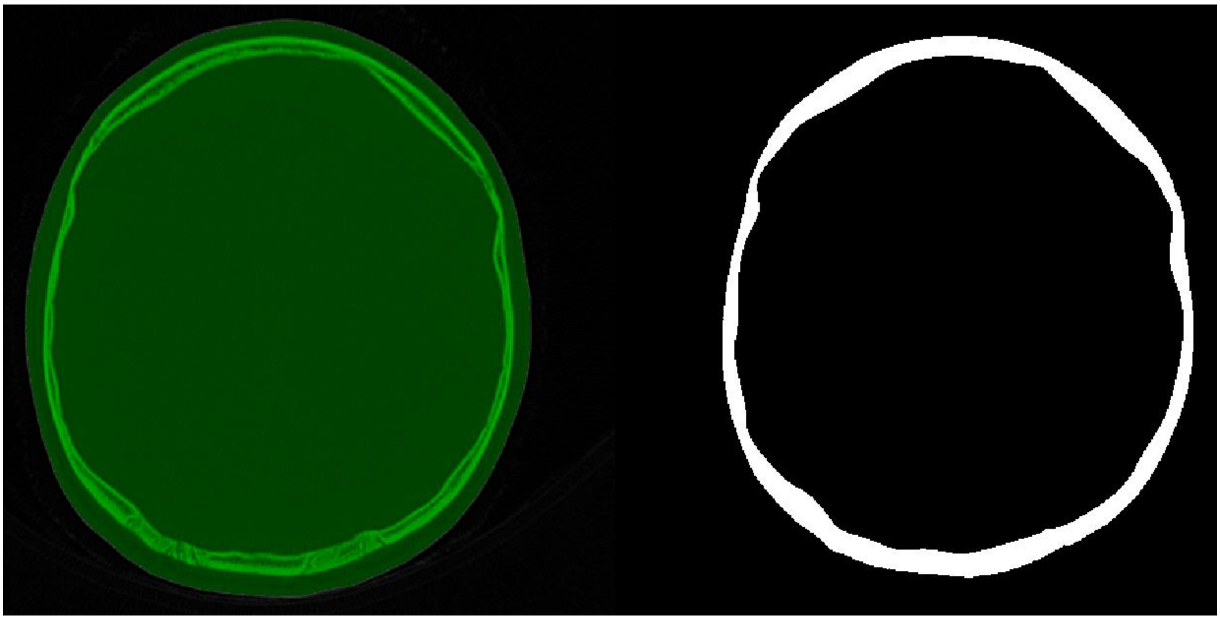

Fig.20: CT picture of skull (on the left) and binarised crop of cranial bone without diploe.

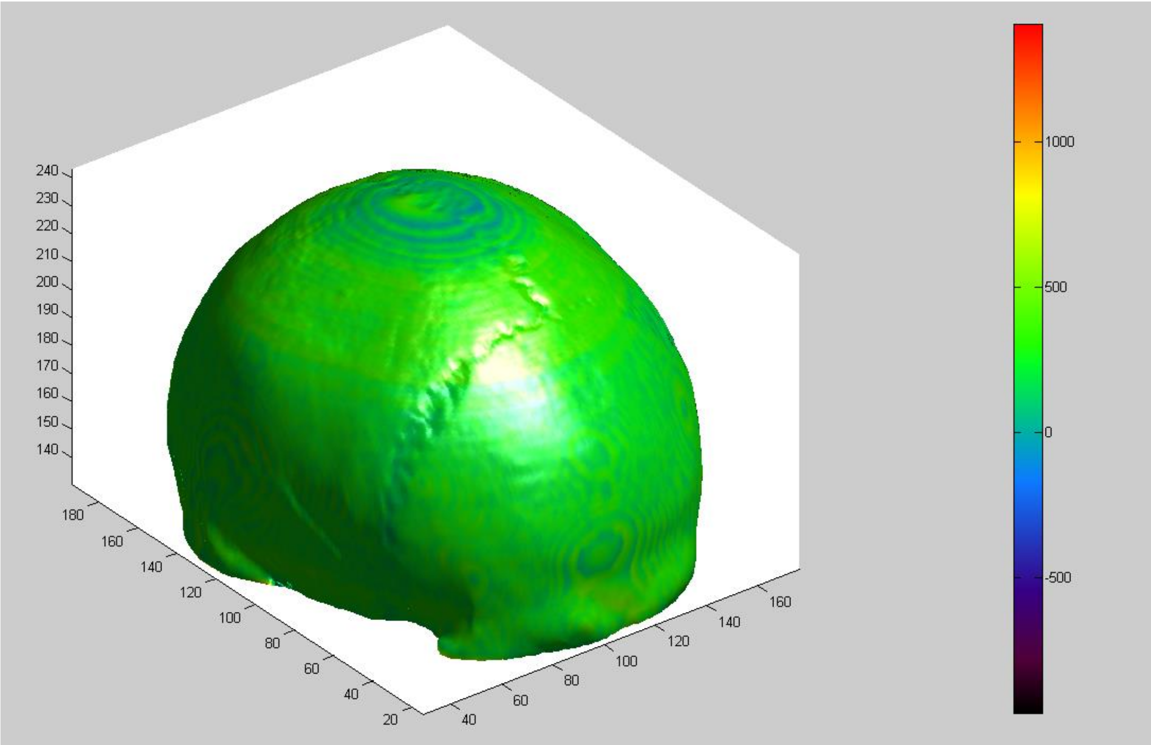

Fig. 21: Plot of part of the skull without diploe part.

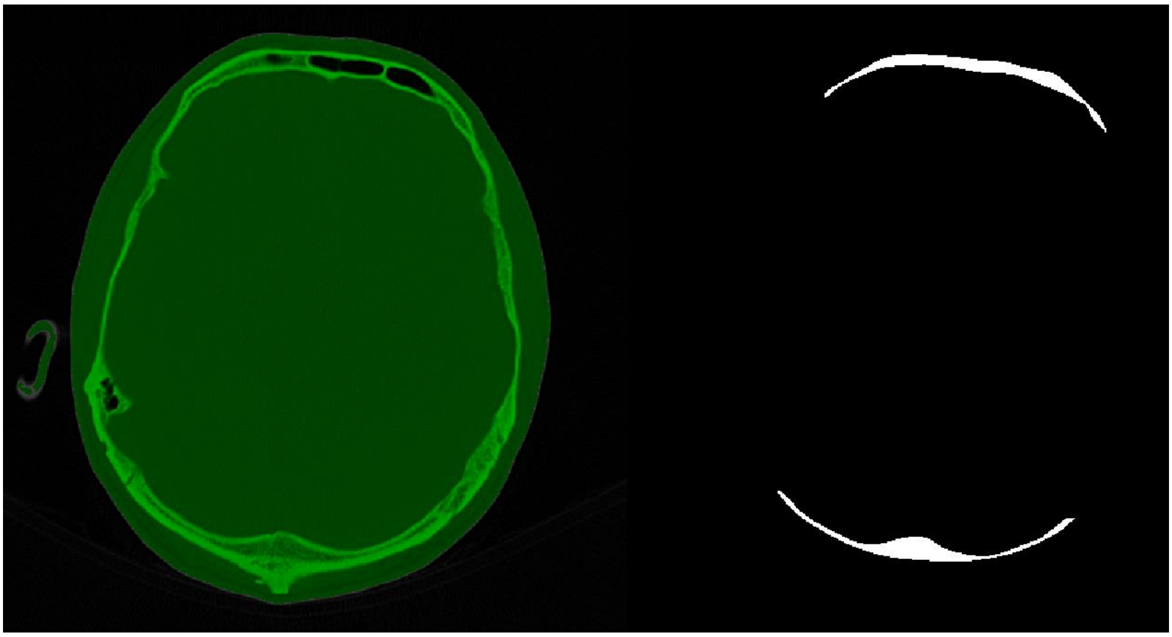

Fig. 22: CT picture of skull (on the left) and binarised crop of diploe part of cranial bone.

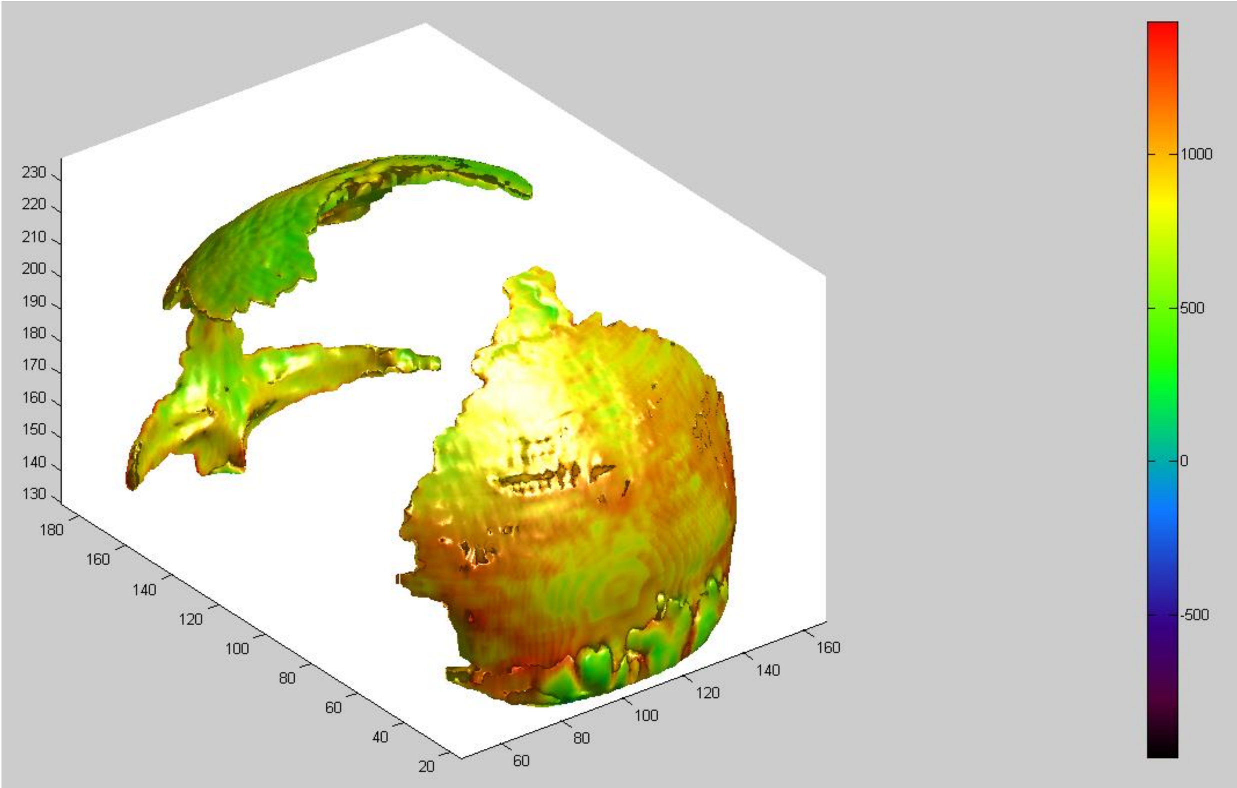

Fig. 23: Plot of diploe part of a skull, shown in figure 21.

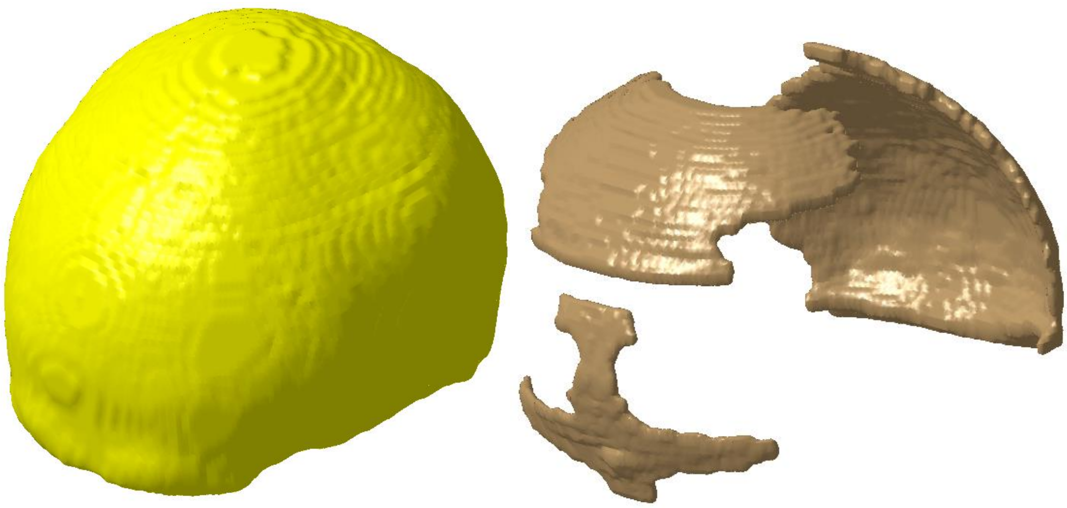

Fig. 24: Volumes of skull and spongy made in software CATIA.

First, volume model of skull (cortical bone) were created. Then volume model of diploe, which was subtract from cortical bone. Afterwards, the diploe was placed to the holes, which appear after subtraction (as shown in figure 25). This process is important, because it is possible to define different properties for cortical and spongy bone tissue.

When the skull includes spongy part, defect is created. Because the defect used in this thesis is general shape. It was designed in a plane with offset from skull surface. Using tool *extrude* defect was done to the skull. Implant was created subtracting skull with defect from skull without defect. Different thicknesses were made using tool *split* and *delete body*. In this thesis, 3 different thicknesses were made (as shown in figure 26).

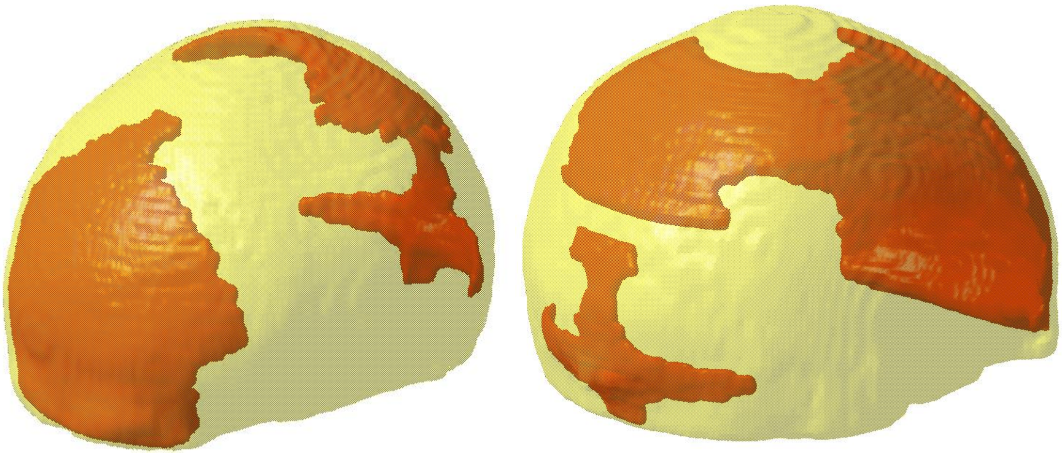

Fig. 25: Spongy part, placed inside the skull in software CATIA.

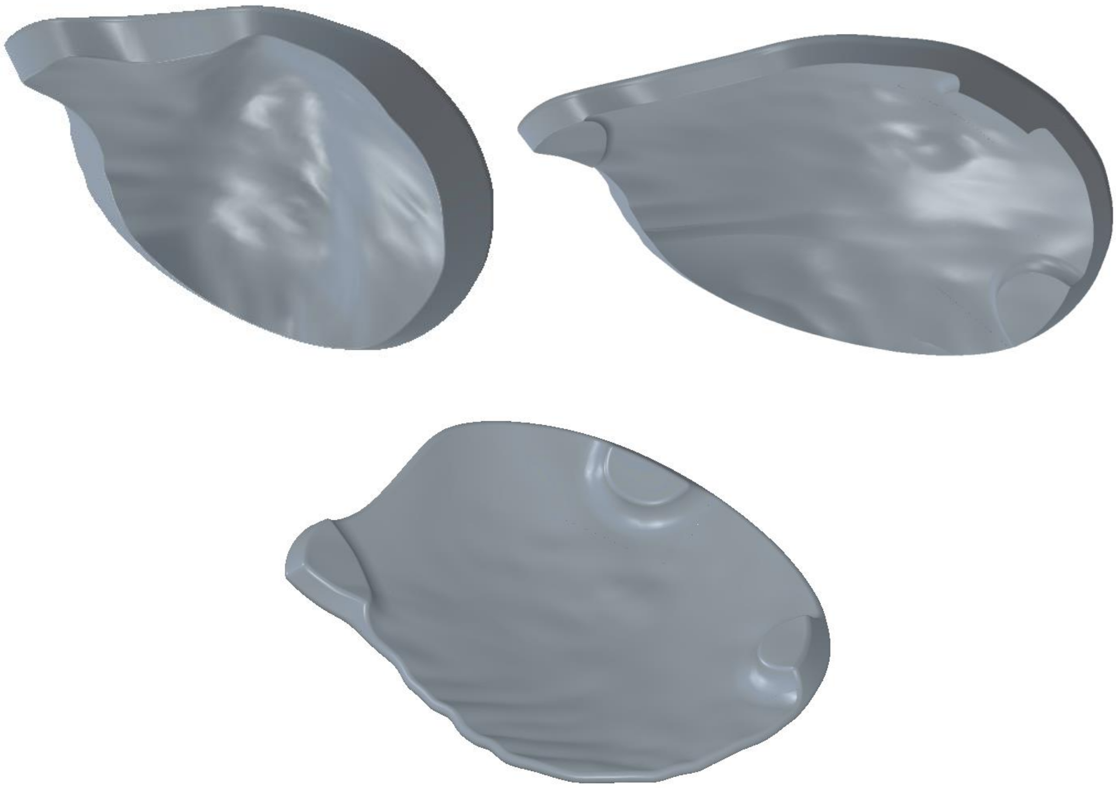

Fig. 26: *Wide* (top left), *medium* (top right) and *thin* (bottom middle) implants designed in software SolidWorks.

Threadless screws and fixators (shown in figure 27 and 28) were designed based on KLS Martin proucts. Diameter of cylinder, which substitue thread is mean diamater of KLS Martin screw. Fixator was also based on real fixator. Both components were made using standard tools *exrude* and *rotate*.

Fig. 27: Screw, designed in software SolidWorks.

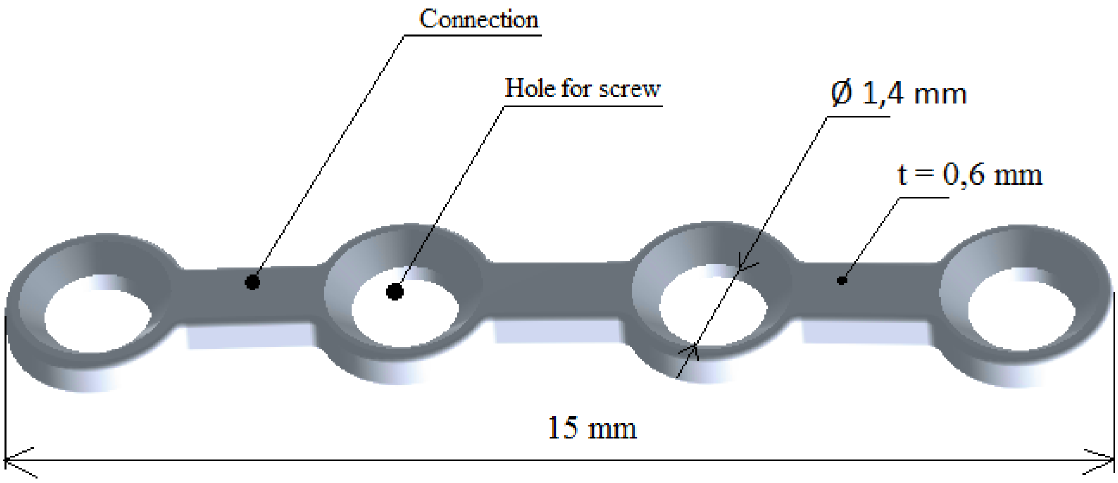

Fig. 28: Fixator, designed in software SolidWorks.

11.2. Model of materials

Models of materials are defined as homogeneous isotropic linear elastic materials (Hook's material). This kind of material is defined by two parameters:

- Young's modulus E [MPa];
- Poisson ratio μ [-].

Values of these two parameters are available in literature. Spongy part and compact part has different values of the parameters. These values are sensitive to several factors such as:

- age of bone tissue;
- density;
- obtain in state "in vivo" or "ex vivo".

Values of both important parameters of linear isotropic homogenous elastic materials for materials used in this thesis are shown in table 6.

Tab. 6: Materials used for implant and fixators and their defining parameters.

	E [MPa]	μ [-]	
Compact bone	15 000	0.3	[47]
Diploe	2 792	0.3	[46]
PMMA	3 000	0.375	[28]
PEEK	3 850	0.386	[36]
Titanium	110 000	0.3	[37]

11.3. Model of boundary conditions

In order to solve the system, it is necessary to specify to the computational model loads and using boundary condition to clearly define position in space.

Loads, which interact on skull (not defected one) in normal condition, don't cause any effect to skull. In case of head injury and replacing part of a skull with an implant, some problems (such as displacement of the implant) may occur. In this thesis, points of focus are:

- intracranial pressure (ICP);
- self – weight of a head.

The system was loaded by a force 50 N, which corresponds approximately to weight of a head, which relies on a hand or other object. Furthermore, it is loaded with the ICP. The value of ICP is 4 kPa (as shown in figure 29) [5].

Boundary conditions in space were defined as a *fix* on the bottom edge designed part of the skull.

It is also necessary to create a firm connection between the implant and skull bone tissue. Suitable variant is to use type of connection *frictionless* for implant and fixators with skull and *bonded* for spongy and cortical bone. Also screws, which were designed as a cylinder shape for coarse model - threadless and with a thread for submodeling, were set as *bonded* (cylinder shape) and *frictionless* (with a thread) [49].

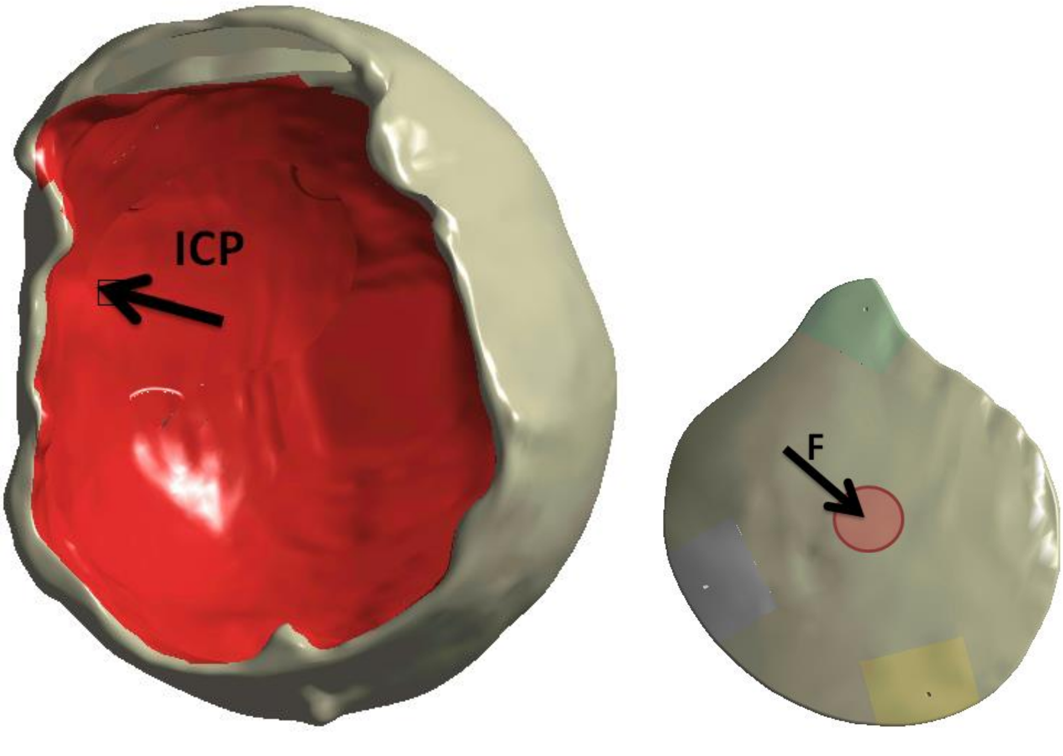

Fig. 29: Loads (force F = 50 N and ICP = 4 kPa).

11.4. FEM mesh creating

Volume model of skull with a defect, implant, fixators and screws is imported to ANSYS Workbench 16.2 in *.x_t format (parasolid). Then it is generated. Materials and boundary conditions are defined as written in chapter 11.2. and 11.3.

Before analyze, finite element mesh has to be defined. In this thesis, mesh was generated using tool sizing. Different size were used in different places (as shown in figure 30). 0.75 mm for rectangles around contacts, 2 mm around previous sizing and contacts without fixators and screws. Fixators and screws have mash size 0.2 mm. This values are for normal model. For submodel, it is much lower.

All parts were discretized using quadratic element types *SOLID186* and *SOLID187*. All contacting parts were connected using contact elements *TARGE160* and *CONTA174*. Number of elements, used in models is 75 000, number of nodes is 135 000.

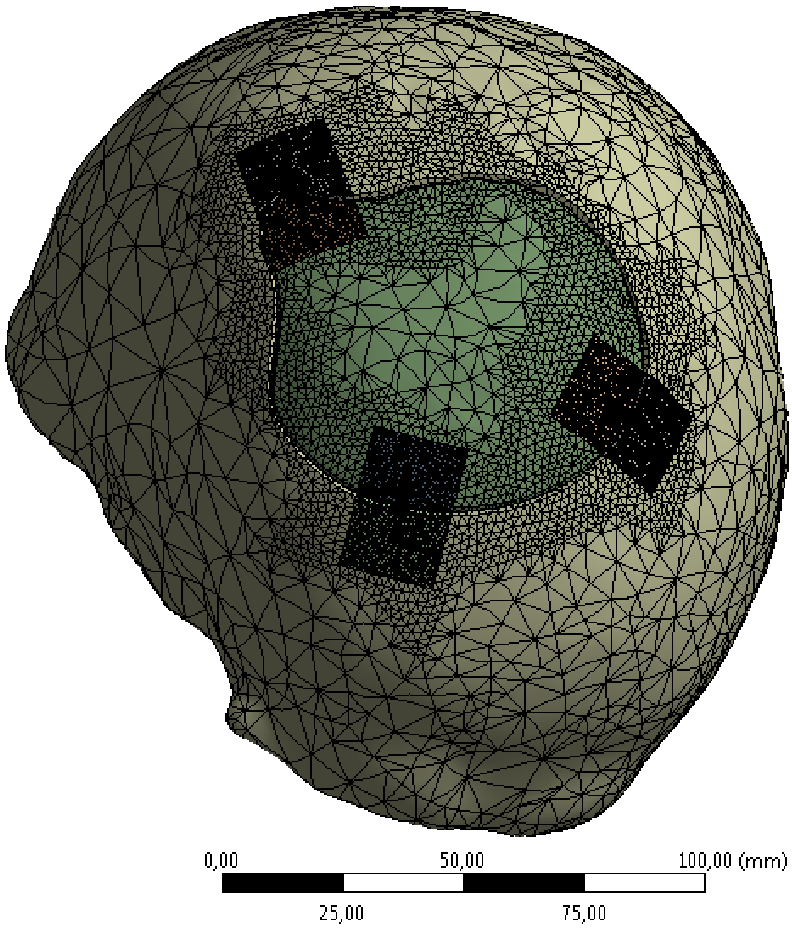

Fig. 30: Mesh.

12 PRESENTATION OF RESULTS

Comparison of different implants thicknesses or determining material type influence is a reason, why to calculate stress and strain and do whole analysis. As shown in figure 31, there are many possible combinations of skull, implant and fixators modifications. In this thesis, 45 different models are analyzed (3 different thicknesses, 3 different materials and 2 different loads and loads combination, 3, 4 and 5 fixators on wide implant).

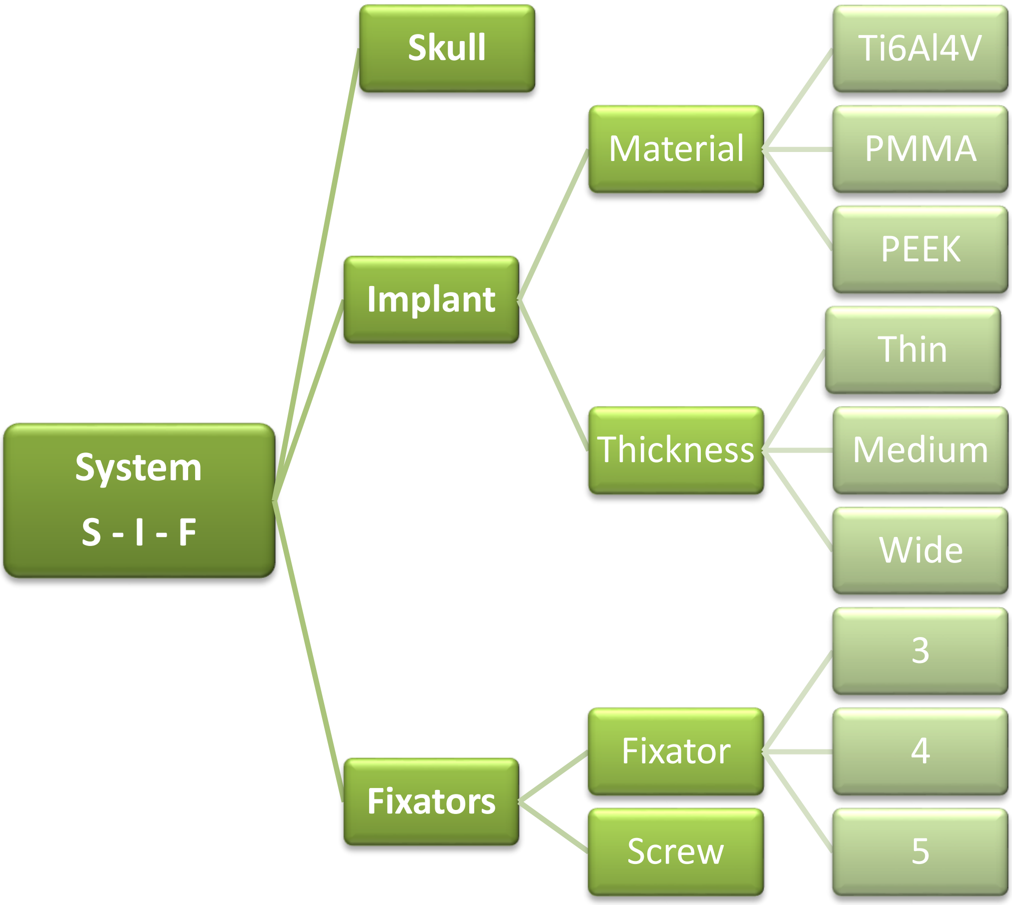

Fig. 31: Modifications of system Skull bone tissue – Implant body – Fixators, which are calculated in this thesis.

12.1. Implant

12.1.1. Stress in implant

In implants, there are 3 holes, which are supposed to be stress concentrators. As shown in figure 32, the highest stress in implant is mostly in hole 1, but in some cases for thin implant, it is in hole 2 (PMMA and PEEK loaded by force and force with ICP at the same time). All results are shown in figures 33 to 41 and table 7.

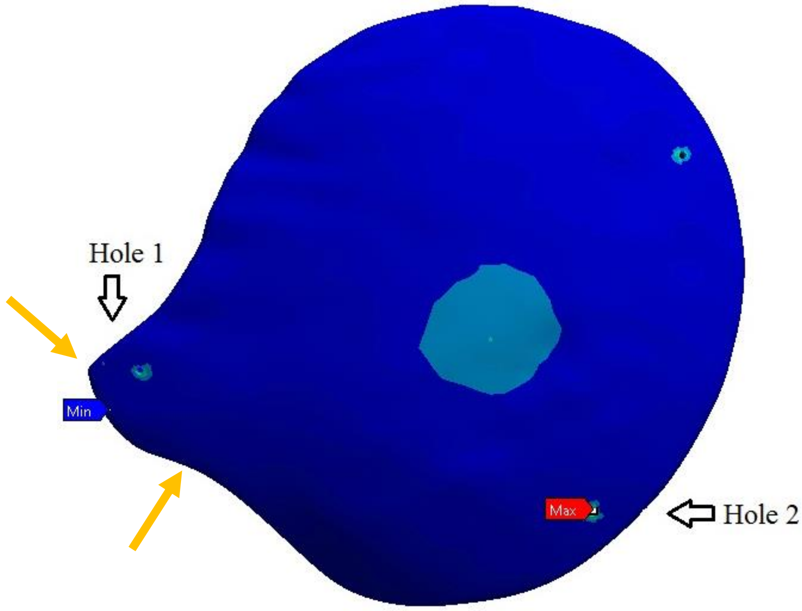

Fig. 32: Equivalent (Von Mises) stress in implant. Orange arrows shows other critical places (sharp parts), where the stress is concentrated.

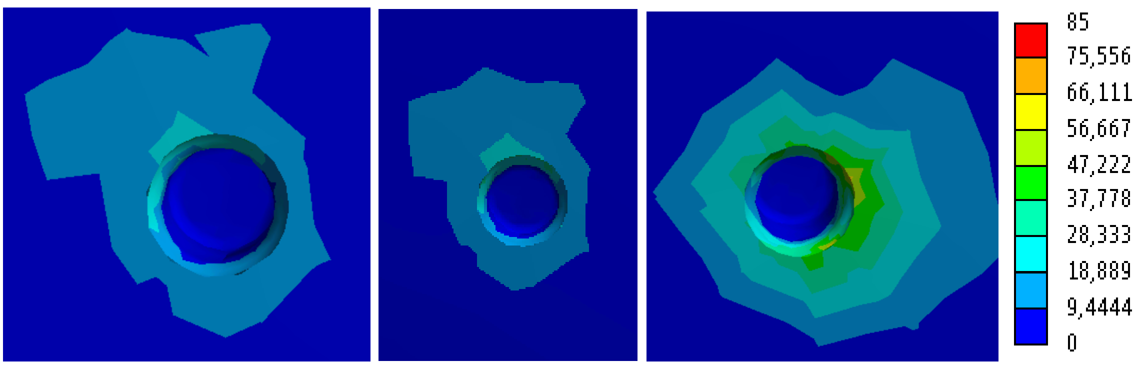

Fig. 33: Equivalent (Von Mises) stress [MPa] for PMMA *thin implant* holes load by force (left), force and ICP (middle) and just ICP (right).

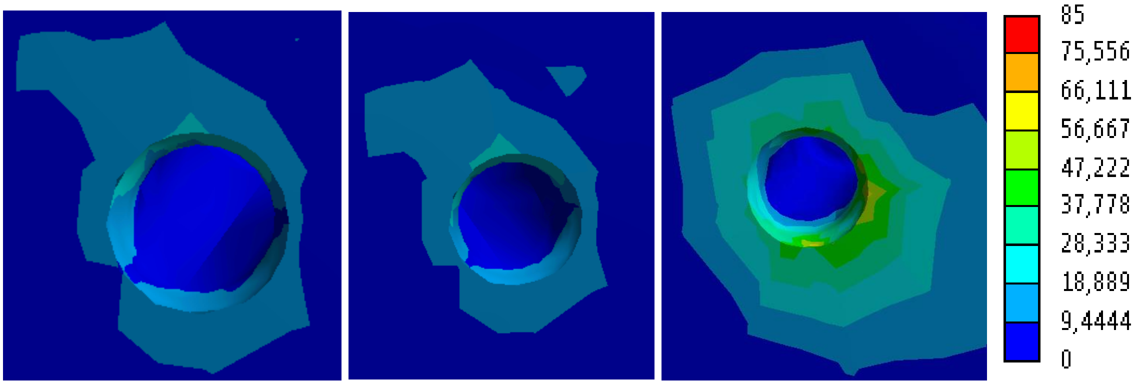

Fig. 34: Equivalent (Von Mises) stress [MPa] for PEEK *thin implant* holes load by force (left), force and ICP (middle) and just ICP (right).

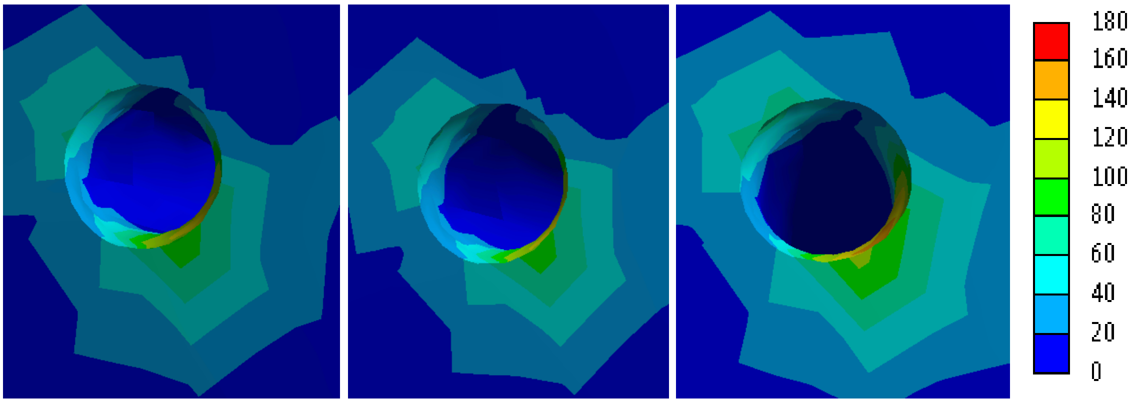

Fig. 35: Equivalent (Von Mises) stress [MPa] for Titanium *thin implant* holes load by force (left), force and ICP (middle) and just ICP (right).

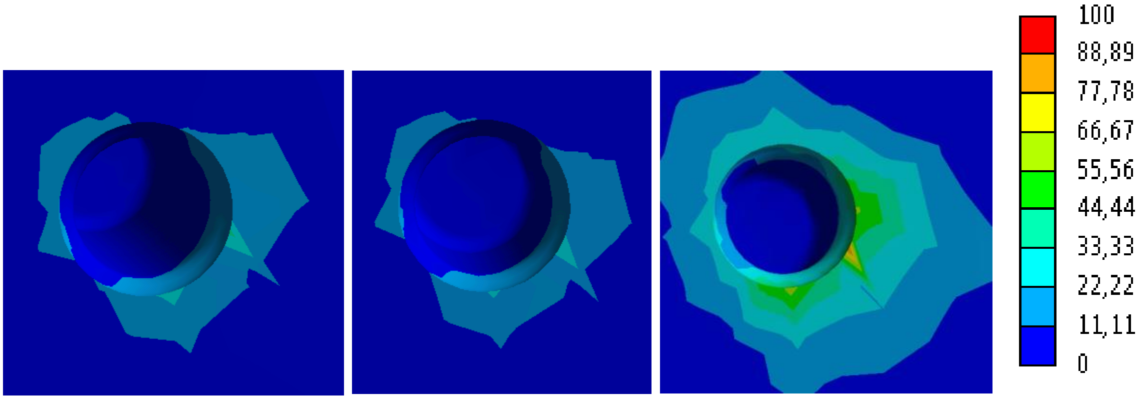

Fig. 36: Equivalent (Von Mises) stress [MPa] for PMMA *medium implant* holes load by force (left), force and ICP (middle) and just ICP (right).

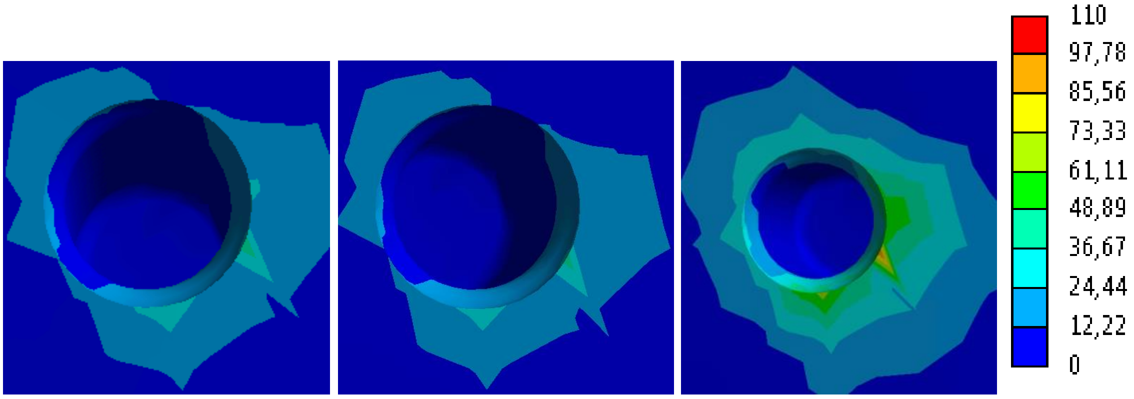

Fig. 37: Equivalent (Von Mises) stress [MPa] for PEEK *medium implant* holes load by force (left), force and ICP (middle) and just ICP (right).

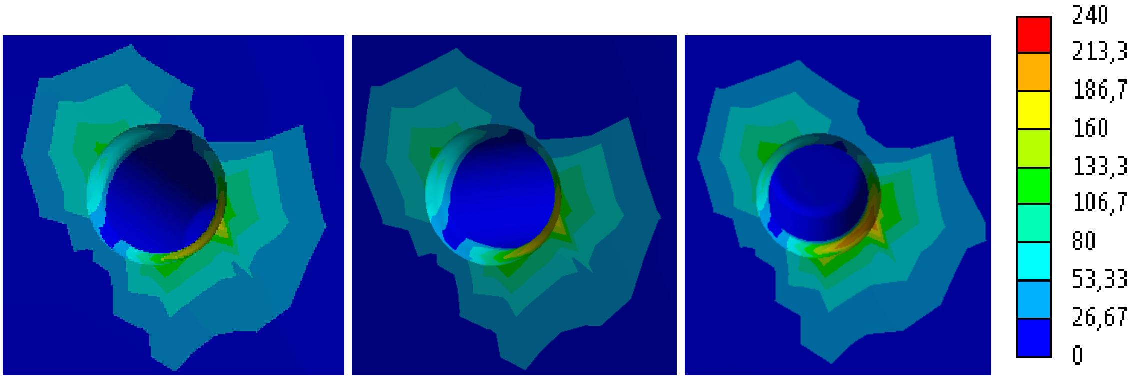

Fig. 38: Equivalent (Von Mises) stress [MPa] for Titanium *medium implant* holes load by force (left), force and ICP (middle) and just ICP (right).

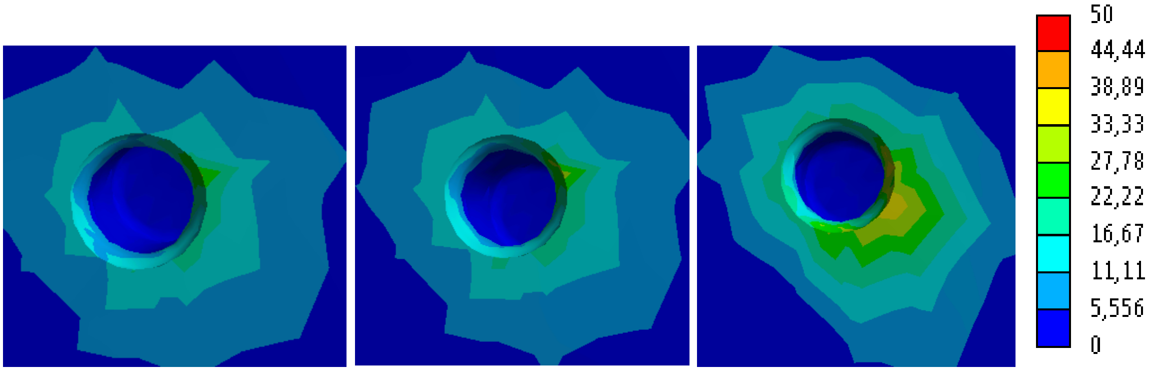

Fig. 39: Equivalent (Von Mises) stress [MPa] for PMMA *wideimplant* holes load by force (left), force and ICP (middle) and just ICP (right).

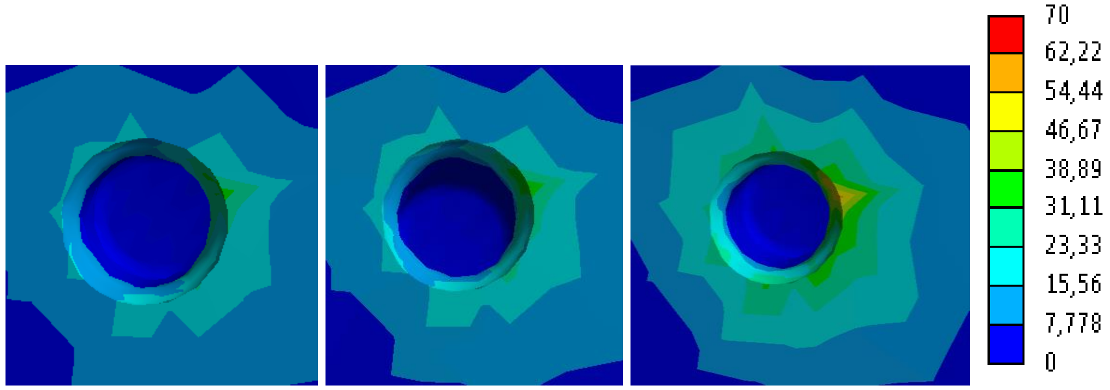

Fig. 40: Equivalent (Von Mises) stress [MPa] for PEEK *wideimplant* holes load by force (left), force and ICP (middle) and just ICP (right).

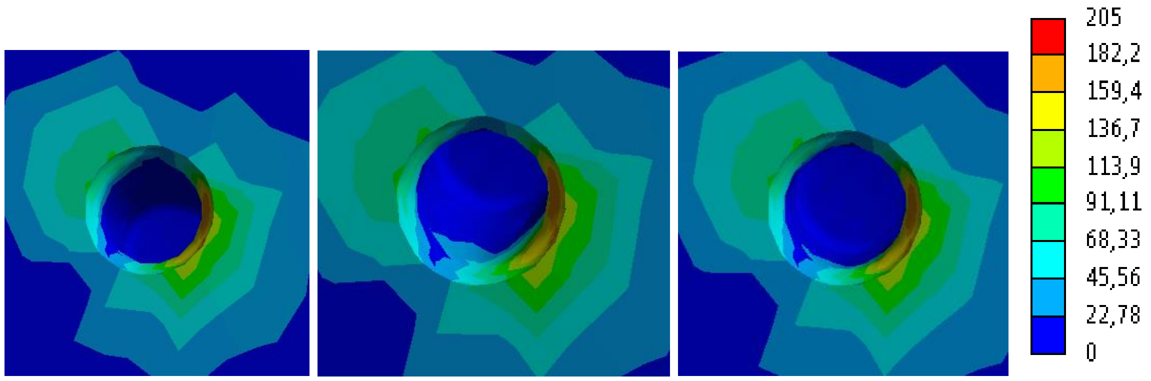

Fig. 41: Equivalent (Von Mises) stress [MPa] for Titanium *wideimplant* holes load by force (left), force and ICP (middle) and just ICP (right).

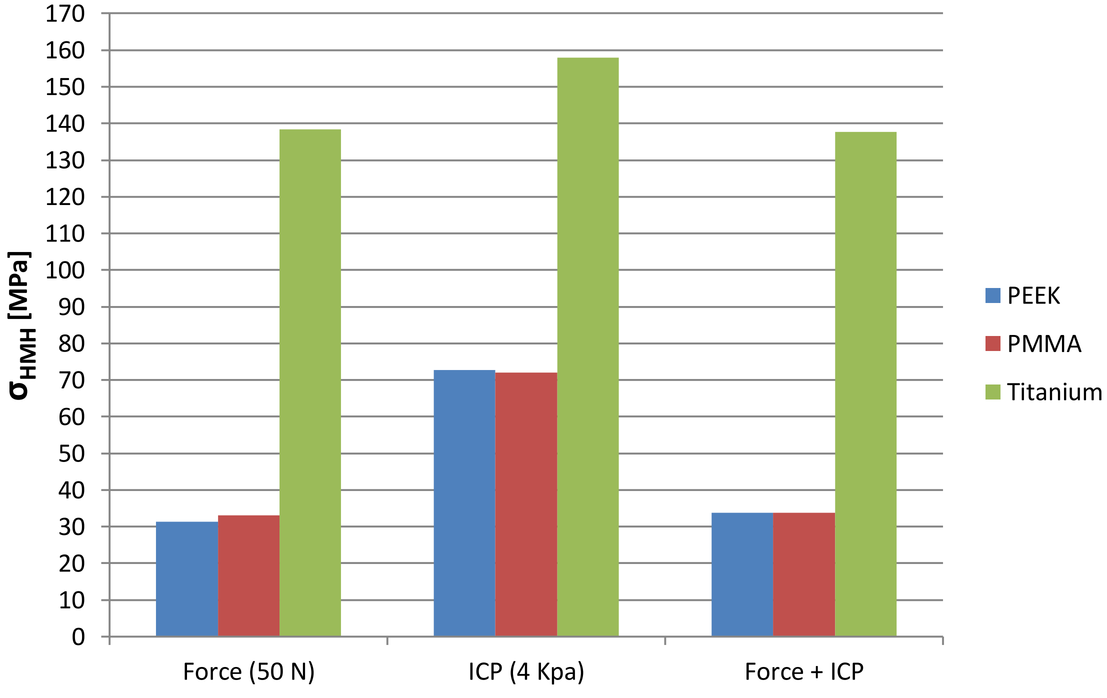

Fig. 42: Equivalent (Von Mises) stress for *thin implant.*

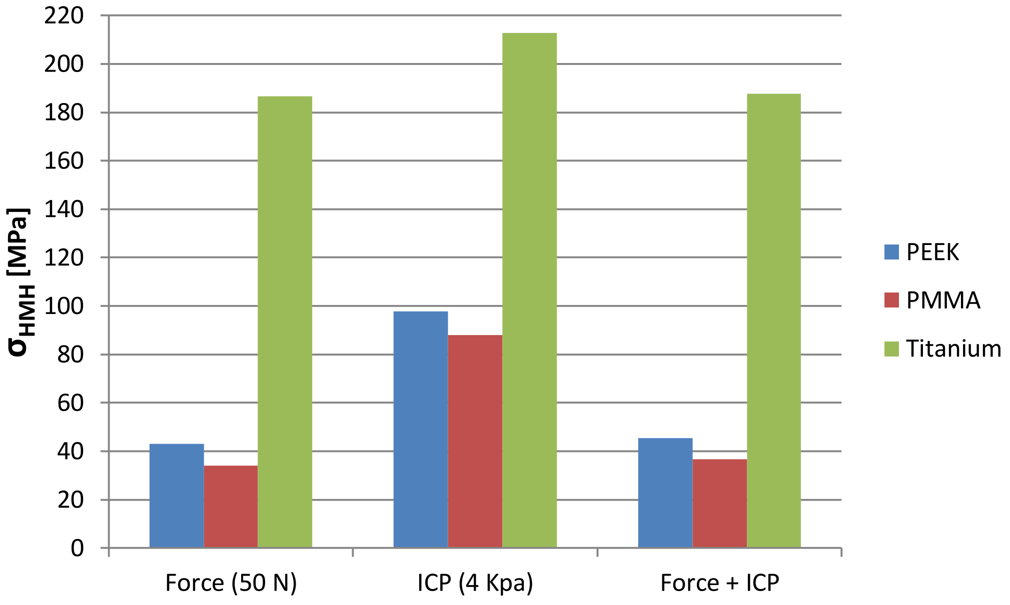

Fig. 43: Equivalent (Von Mises) stress for *medium implant*.

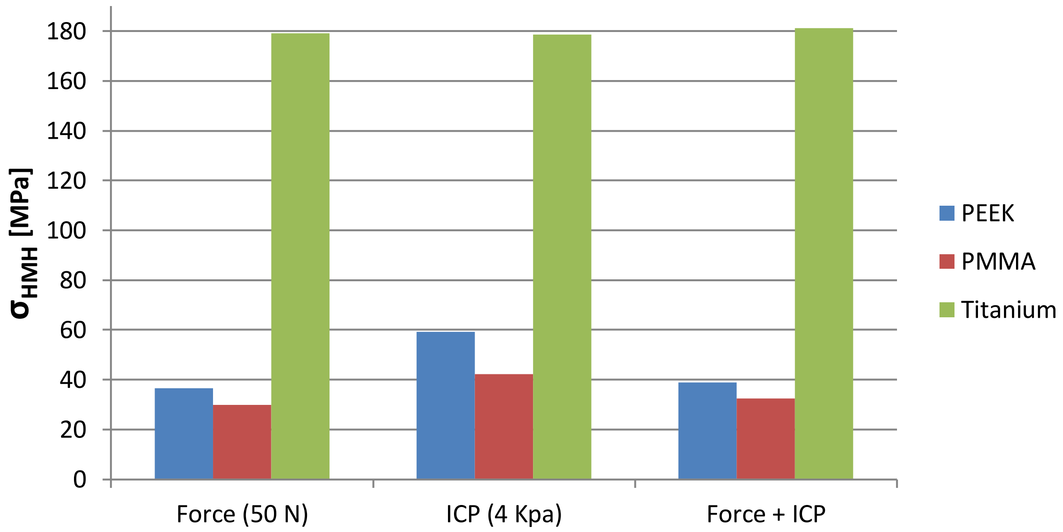

Fig. 44: Equivalent (Von Mises) stress for *wide implant*.

Tab. 7: Results of maximum value of HMH stress in implant.

Material	Load	Maximum HMH stress in implant [MPa]		
		Thin implant	Medium implant	Wide implant
PMMA	Force (50 N)	33	34	30
	ICP (4 kPa)	72	88	42
	Force + ICP	34	37	33
PEEK	Force (50 N)	31	43	36
	ICP (4 kPa)	73	98	59
	Force + ICP	34	45	39
Titanium	Force (50 N)	138	187	179
	ICP (4 kPa)	158	213	179
	Force + ICP	138	188	181

12.1.2. Directional deformation in implant

During calculations with 3, 4 and 5 fixators were deformation in force direction in a place of force effect lower for 3 fixators than for 4 and 5 of theme (as shown in figure 48). 4 and 5 fixators allow less deformation of implant at bone – implant contact, so implant is more deformed in the middle, where it was loaded by force (as shown in figures 45 – 47). In case of fixing using 3 fixators, the implant is moved as a unit (one piece). More fixators don't enable implant to move as a unit. That is the reason, why deformation is higher in location of force activity for fixing by 4 and 5 fixators. The highest values of deformation are for implant fixed with 3 fixators on the bone – implant contact. These values are positive for deformation in force direction and negative for deformation in direction opposite to the force one. Comparison for each material of implant using different fixation is shown in figures 49 – 51. Results are shown in table 8.

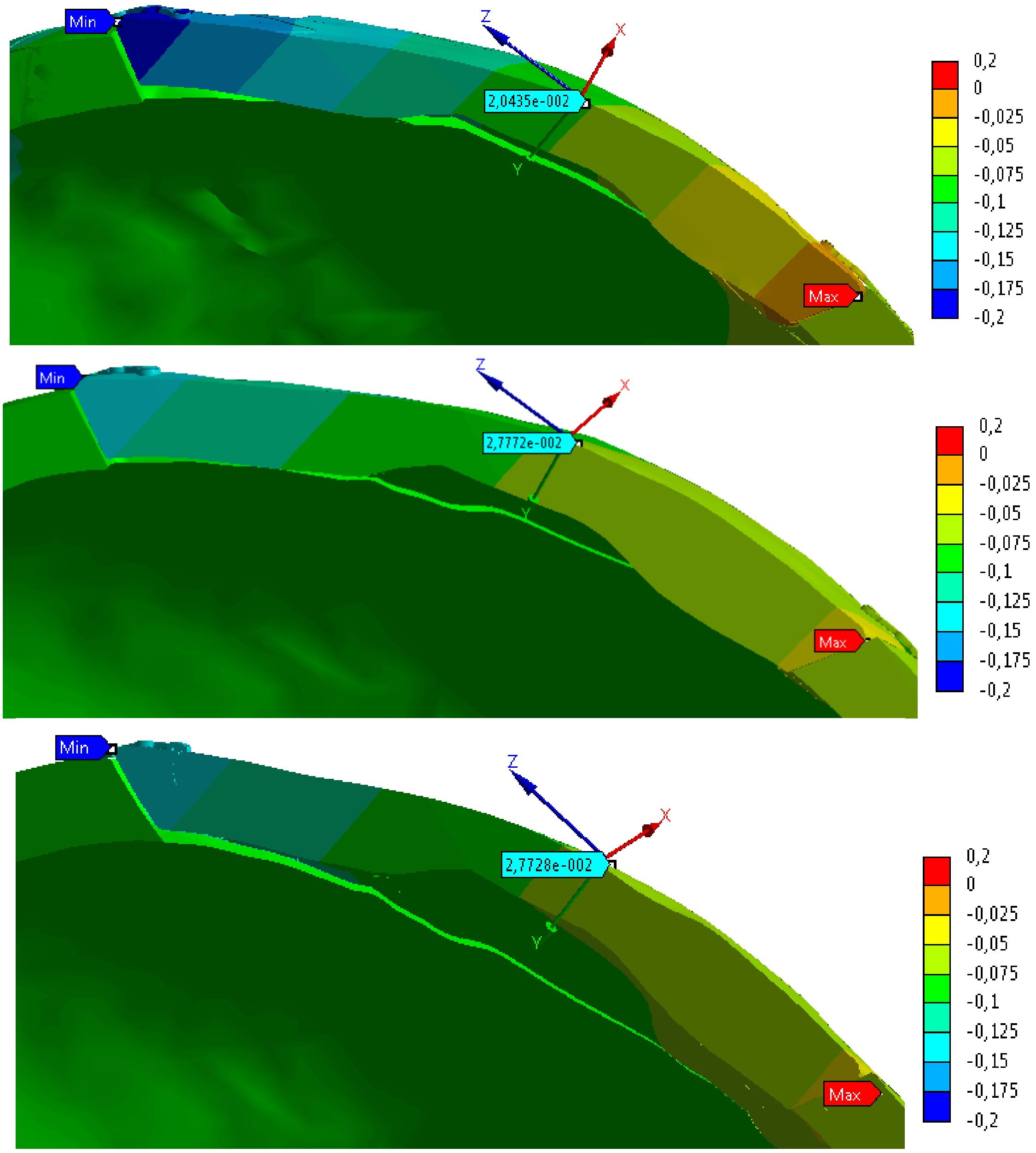

Fig. 45: Differences (in directional deformation [mm]) between using 3 (top), 4 (middle) or 5 (bottom) fixators on *wide PMMA implant* (scale of displacement is 10).

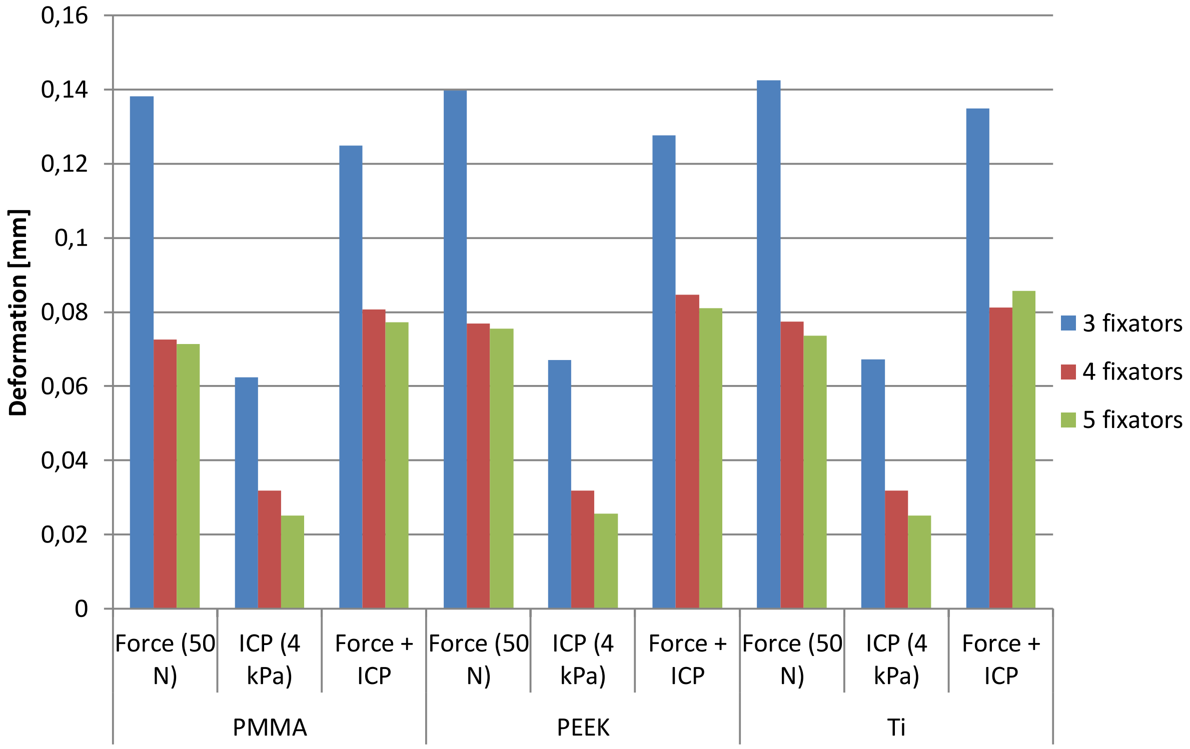

Fig 46: Maximum values of directional deformation for wide implant fixed using 3, 4 and 5 fixators.

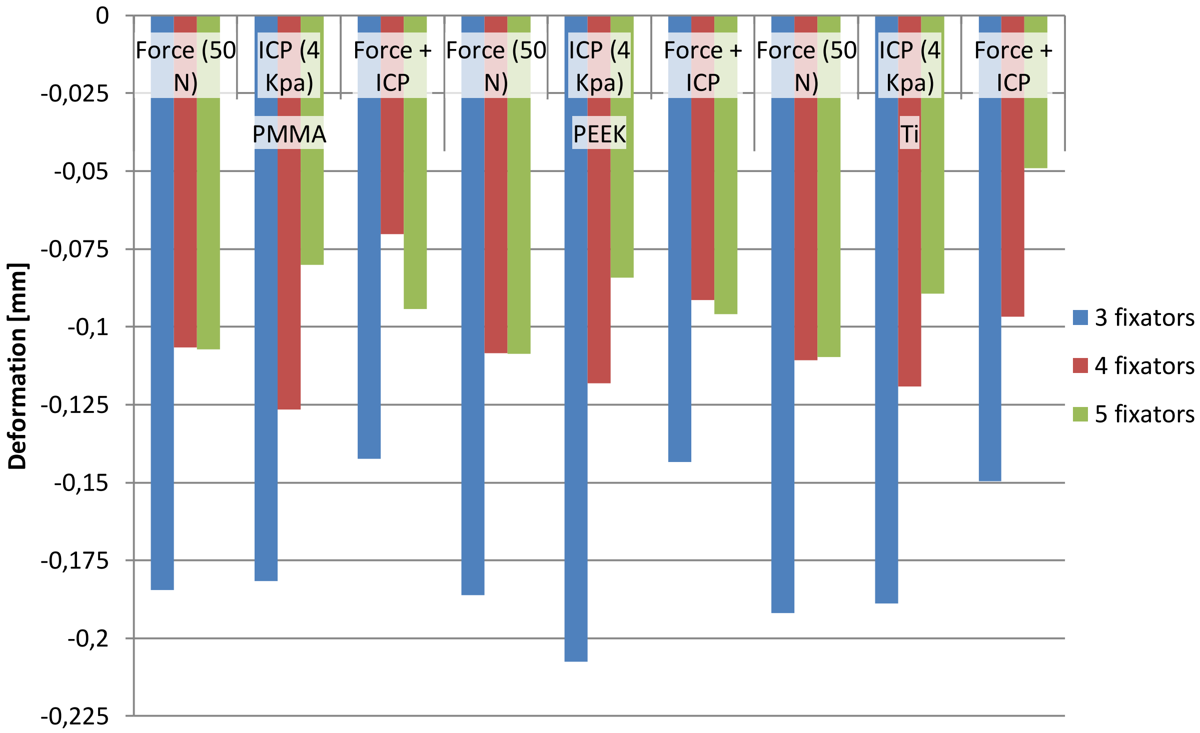

Fig 47: Minimum values of directional deformation for wide implant fixed using 3, 4 and 5 fixators.

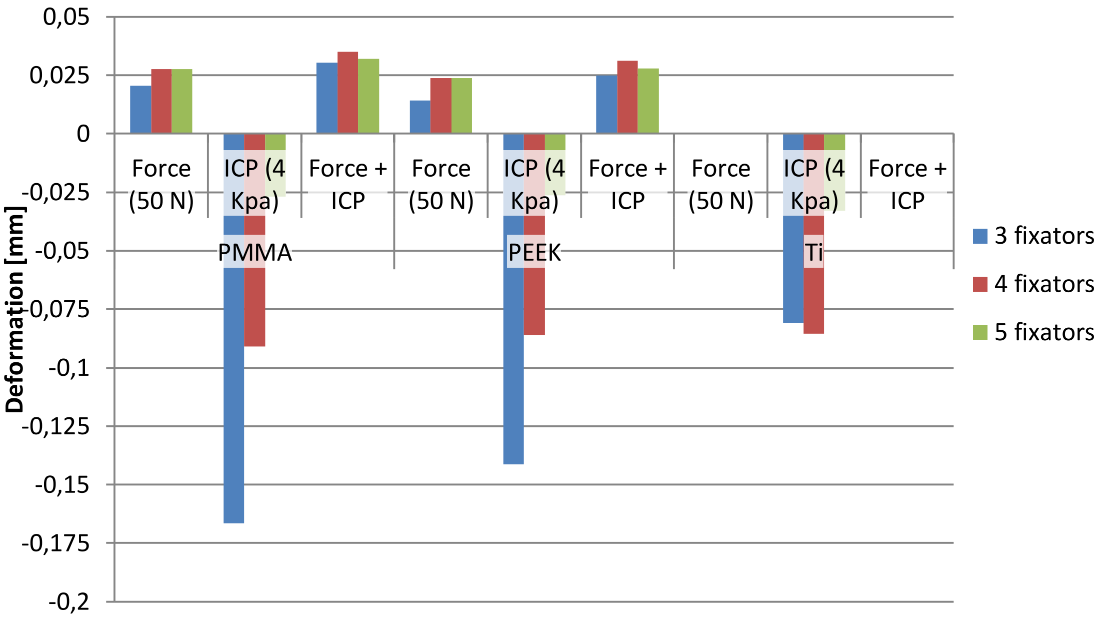

Fig 48: Values of directional deformation in a place of force sphere activity for wide implant fixed using 3, 4 and 5 fixators.

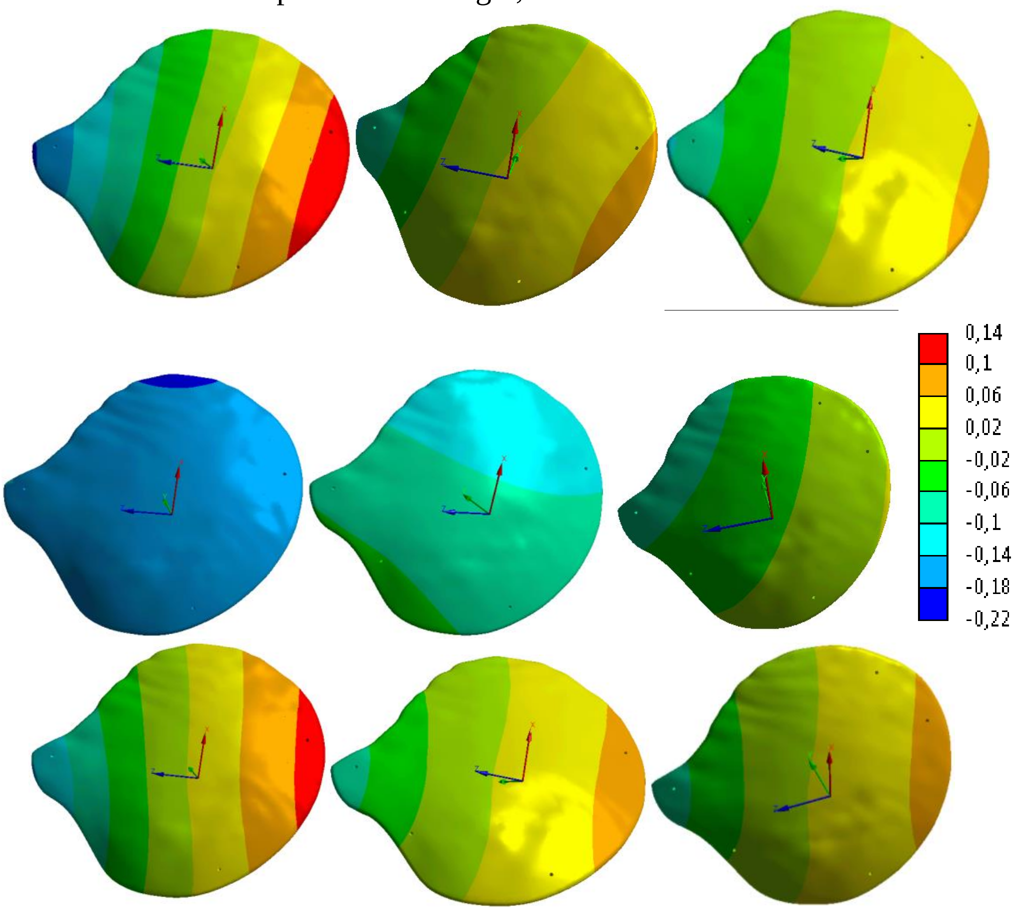

Fig. 49: Directional deformation [mm] using wide PMMA implant fixed using 3 (left column), 4 (center column) and 5 (right column) fixators loaded by force (top row), ICP (center row) and combination of force and ICP (bottom row).

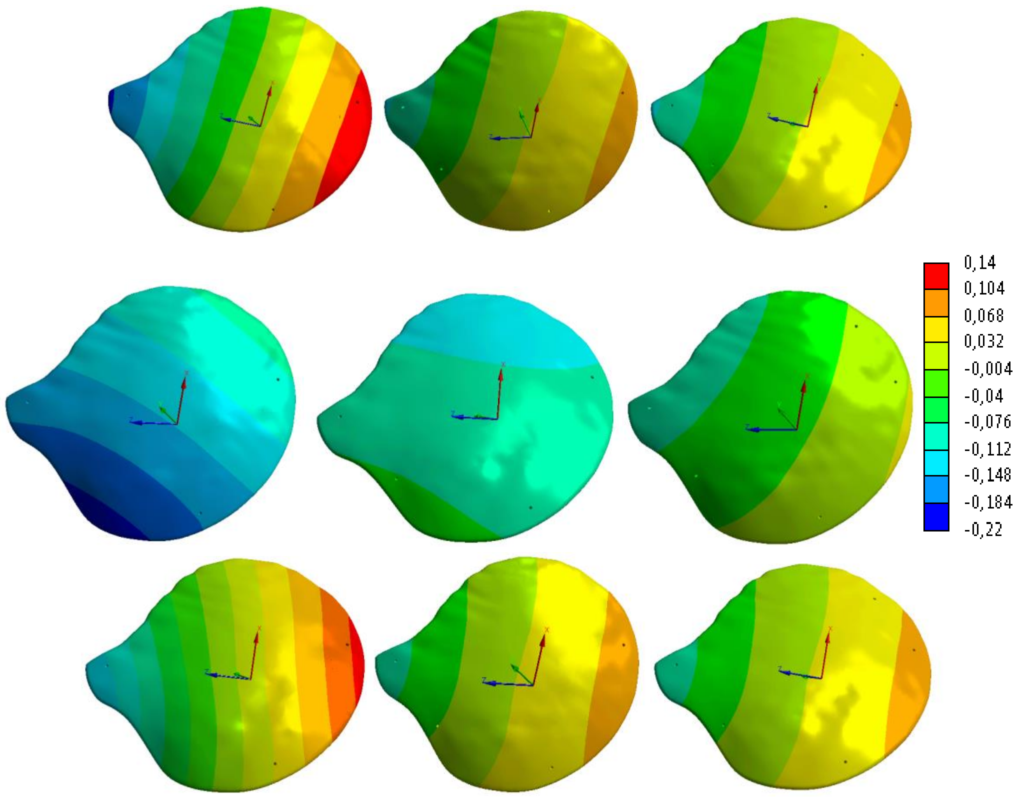

Fig. 50: Directional deformation [mm] using wide PEEK implant fixed using 3 (left column), 4 (center column) and 5 (right column) fixators loaded by force (top row), ICP (center row) and combination of force and ICP (bottom row).

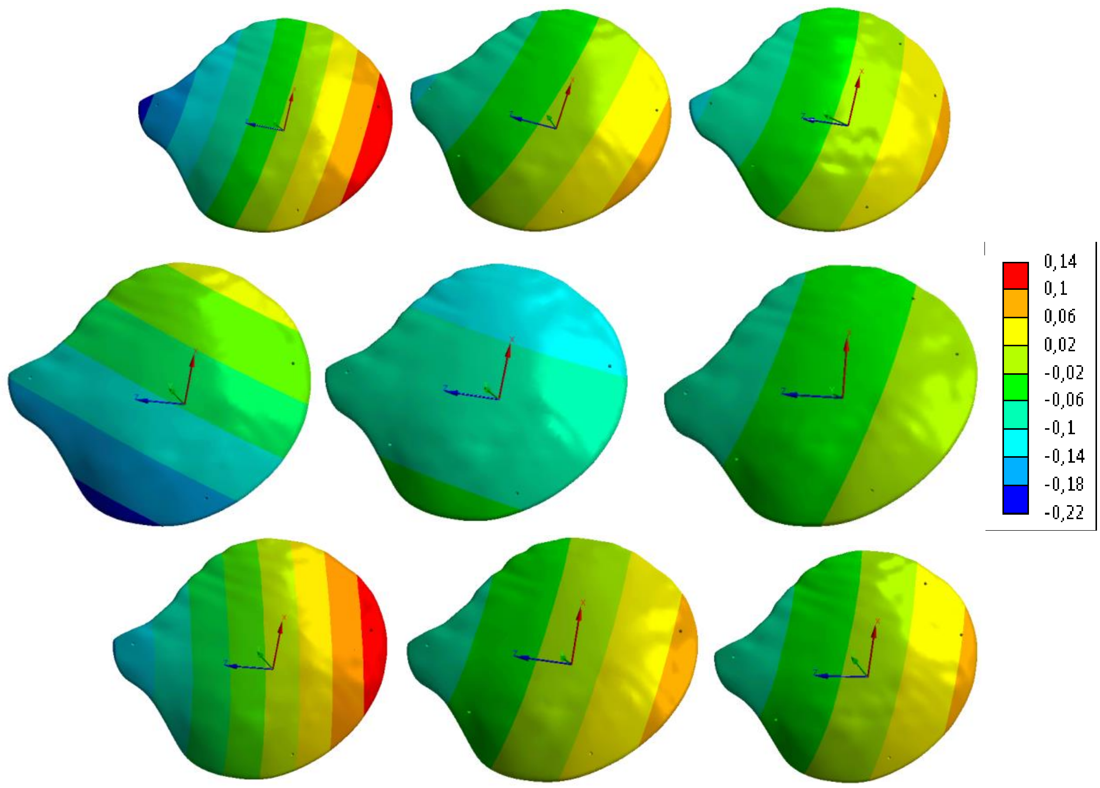

Fig. 51: Directional deformation [mm] using wide Titanium implant fixed using 3 (left column), 4 (center column) and 5 (right column) fixators loaded by force (top row), ICP (center row) and combination of force and ICP (bottom row).

Tab. 8: Results of maximum and minimum values of directional deformation and value in force sphere of activity, labeled as 0 in the table.

	Material	Load	Max [mm]	0 [mm]	Min [mm]
3 fixators	PMMA	Force (50 N)	0.14	0.02	-0.18
		ICP (4 kPa)	0.06	-0.17	-0.18
		Force + ICP	0.12	0.03	-0.14
	PEEK	Force (50 N)	0.14	0.01	-0.19
		ICP (4 kPa)	0.07	-0.14	-0.21
		Force + ICP	0.13	0.02	-0.14
	Titanium	Force (50 N)	0.14	0	-0.19
		ICP (4 kPa)	0.07	-0.08	-0.19
		Force + ICP	0.13	0	-0.15
4 fixators	PMMA	Force (50 N)	0.07	0.03	-0.11
		ICP (4 kPa)	0.03	-0.09	-0.13
		Force + ICP	0.08	0.04	-0.07
	PEEK	Force (50 N)	0.08	0.02	-0.11
		ICP (4 kPa)	0.03	-0.09	-0.12
		Force + ICP	0.08	0.03	-0.09
	Titanium	Force (50 N)	0.08	0	-0.11
		ICP (4 kPa)	0.03	-0.09	-0.12
		Force + ICP	0.08	0	-0.1
5 fixators	PMMA	Force (50 N)	0.07	0.03	-0.11
		ICP (4 kPa)	0.03	-0.03	-0.08
		Force + ICP	0.08	0.03	-0.09
	PEEK	Force (50 N)	0.08	0.02	-0.11
		ICP (4 kPa)	0.03	-0.03	-0.08
		Force + ICP	0.08	0.03	-0.1
	Titanium	Force (50 N)	0.08	0	-0.11
		ICP (4 kPa)	0.03	-0.03	-0.09
		Force + ICP	0.09	0	-0.05

12.2. Fixator

On the fixators, there is no significant place, where the stress concentrator is. In 70 % cases, the stress concentrator is on implant side and in all cases it is situated on the border between hole for screw and connections (described in figure 28). It is shown in figures 52 to 54. Places with the highest equivalent stress are pointed with small red pentagon. All results are written in table 9. Comparison of results is in figures 55 to 57. Unfortunately, the implant is too large for just 3 fixators, so results of equivalent (Von Mises) stress are very high.

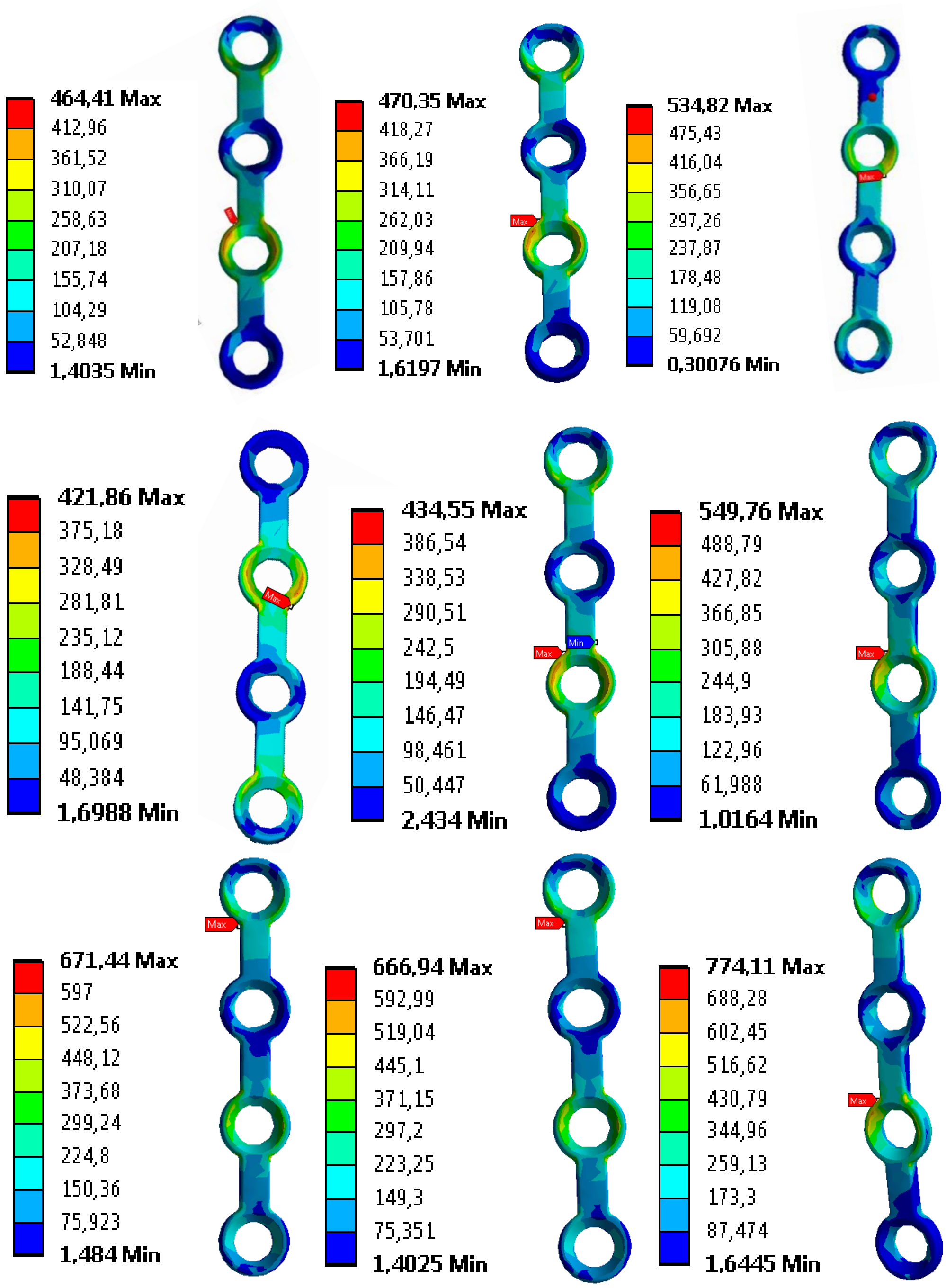

Fig. 52: Equivalent (Von Mises) stress for *thin implant* fixators from PMMA (left column), PEEK (middle column) and Titanium (right column) loaded by force (top row), force and ICP (middle row) and just ICP (botom row).

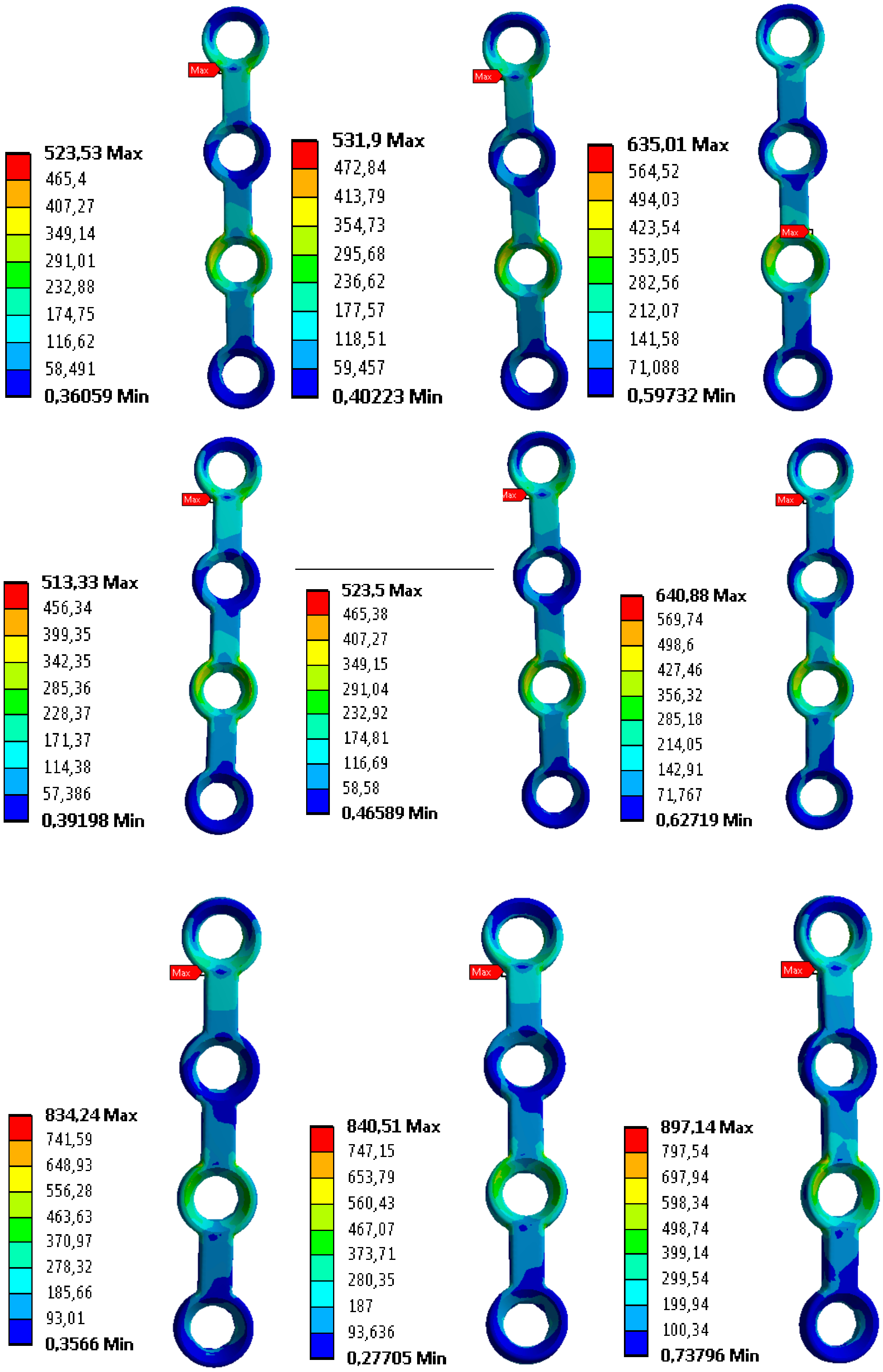

Fig. 53: Equivalent (Von Mises) stress for *medium implant* fixators from PMMA (left column), PEEK (middle column) and Titanium (right column) loaded by force (top row), force and ICP (middle row) and just ICP (botom row).

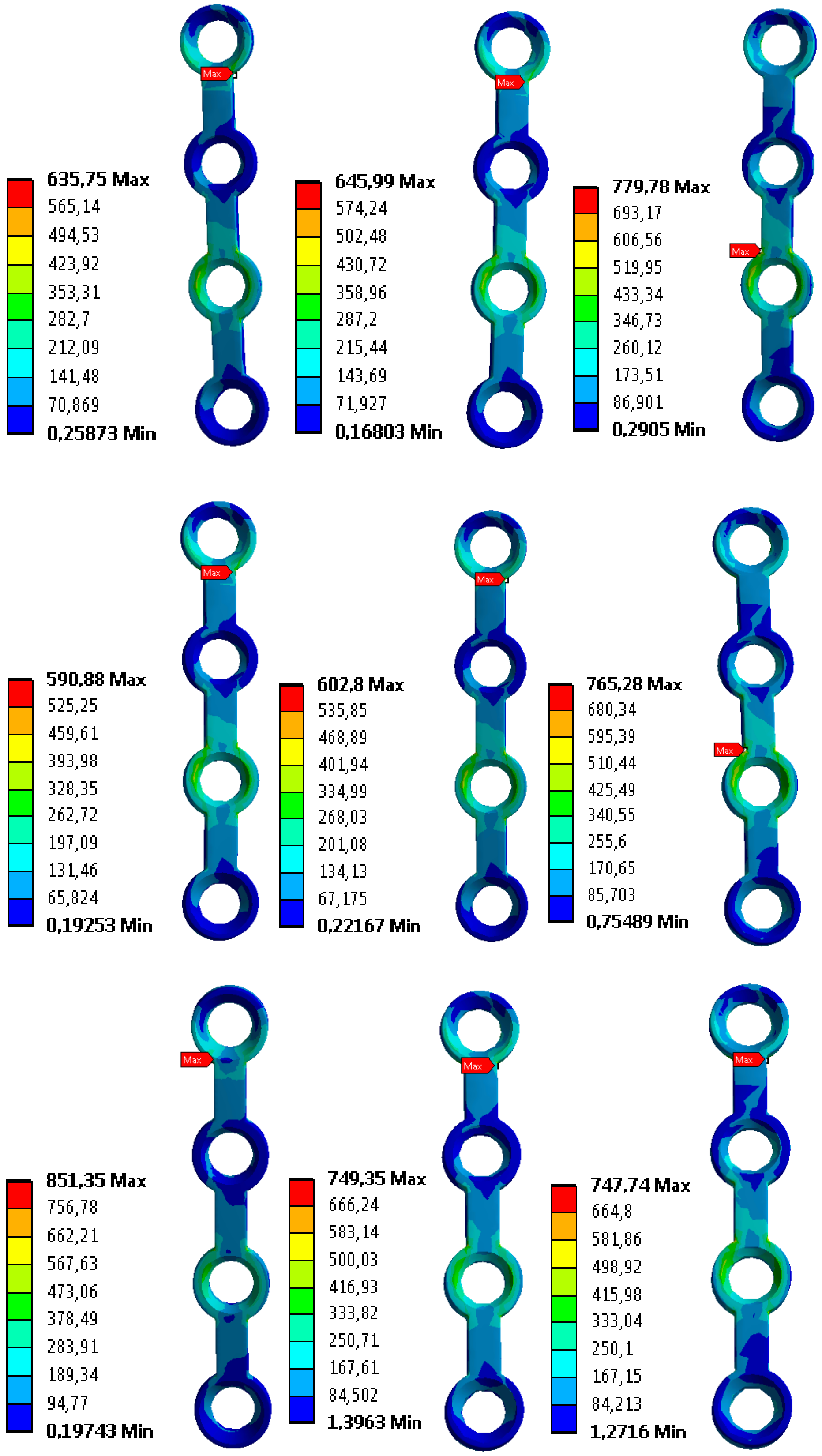

Fig. 54: Equivalent (Von Mises) stress for *wide implant* fixators from PMMA (left column), PEEK (middle column) and Titanium (right column) loaded by force (top row), force and ICP (middle row) and just ICP (botom row).

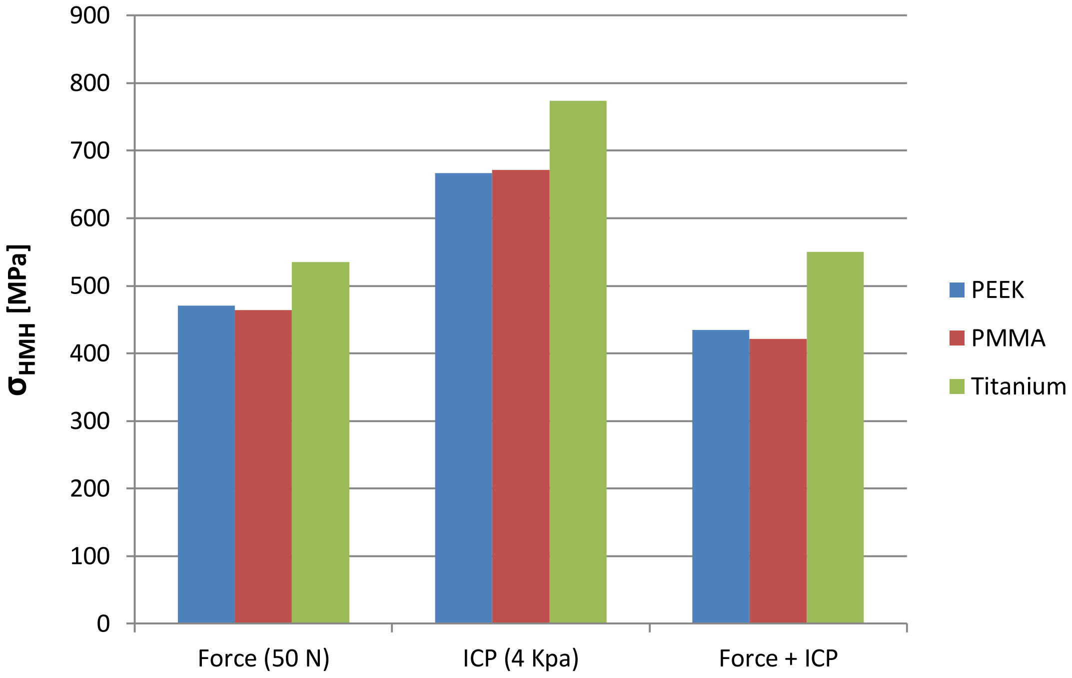

Fig. 55: Equivalent (Von Mises) stress for fixator using *thin implant.*

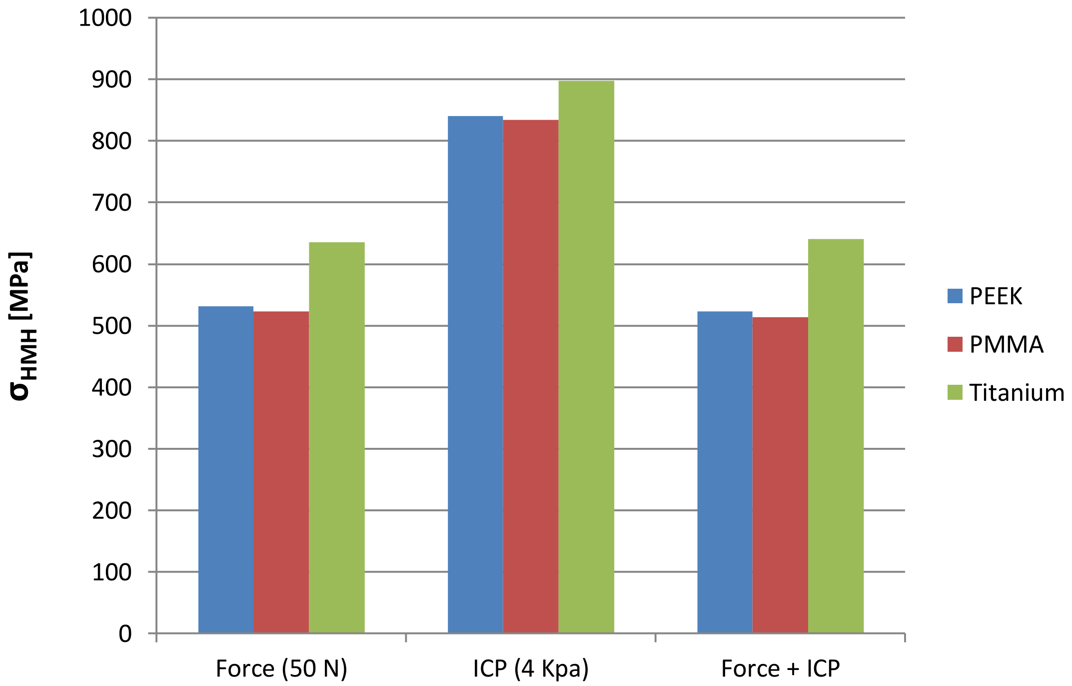

Fig. 56: Equivalent (Von Mises) stress for fixator using *medium implant.*

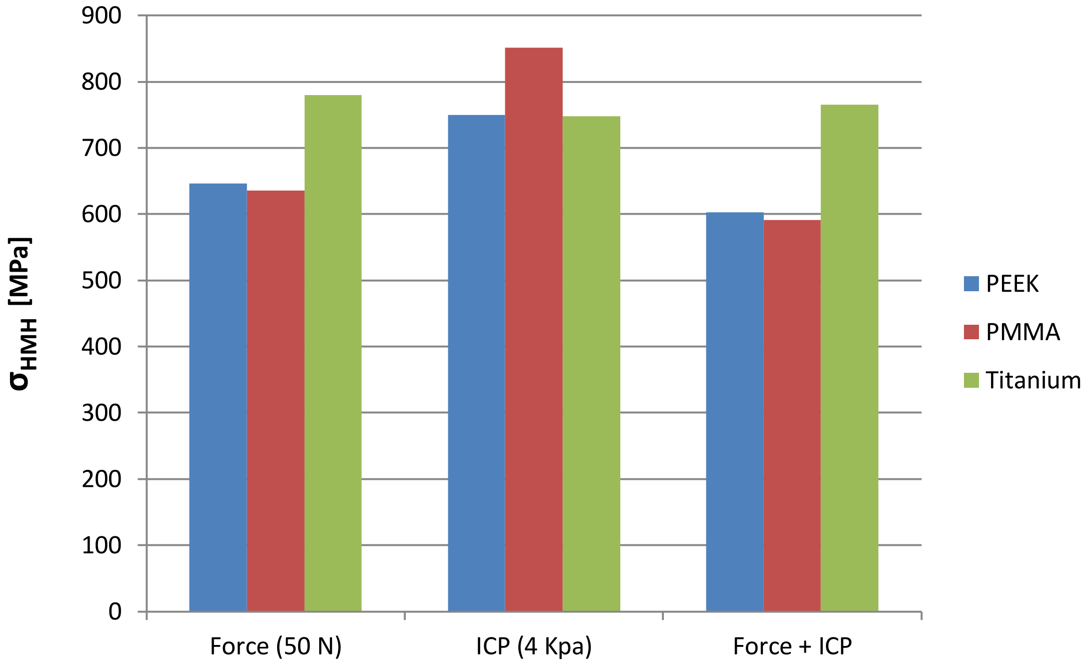

Fig. 57: Equivalent (Von Mises) stress for fixator using *wide implant.*

Tab. 9: Results of maximum value of HMH stress in fixator.

Material	Load	Maximum HMH stress in fixator [MPa]					
PMMA	Force (50 N)	Thin implant	464	Medium implant	524	wide implant	636
	ICP (4 kPa)		671		834		851
	Force + ICP		422		513		591
PEEK	Force (50 N)		470		532		646
	ICP (4 kPa)		667		841		749
	Force + ICP		435		524		603
Titanium	Force (50 N)		535		635		780
	ICP (4 kPa)		774		897		748
	Force + ICP		550		641		765

12.3. Strain in Skull

In this thesis, equivalent (von Mises) strain was used to analyze strain intensity of skull bone structure. In skull, there are 3 holes, which are supposed to be strain concentrators. As shown in figure 58 (hole 1, 2 and 3), the highest strain in implant is mostly in hole 1, but in some cases for thin implant, it is in hole 2 (PMMA and PEEK loaded by force and force with ICP at the same time). All results are shown in figures 59 to 70 and in table 9. Comparison of influence of implant type is shown in figures 59 to 61. Maximum values of equivalent strain are shown in table 10.

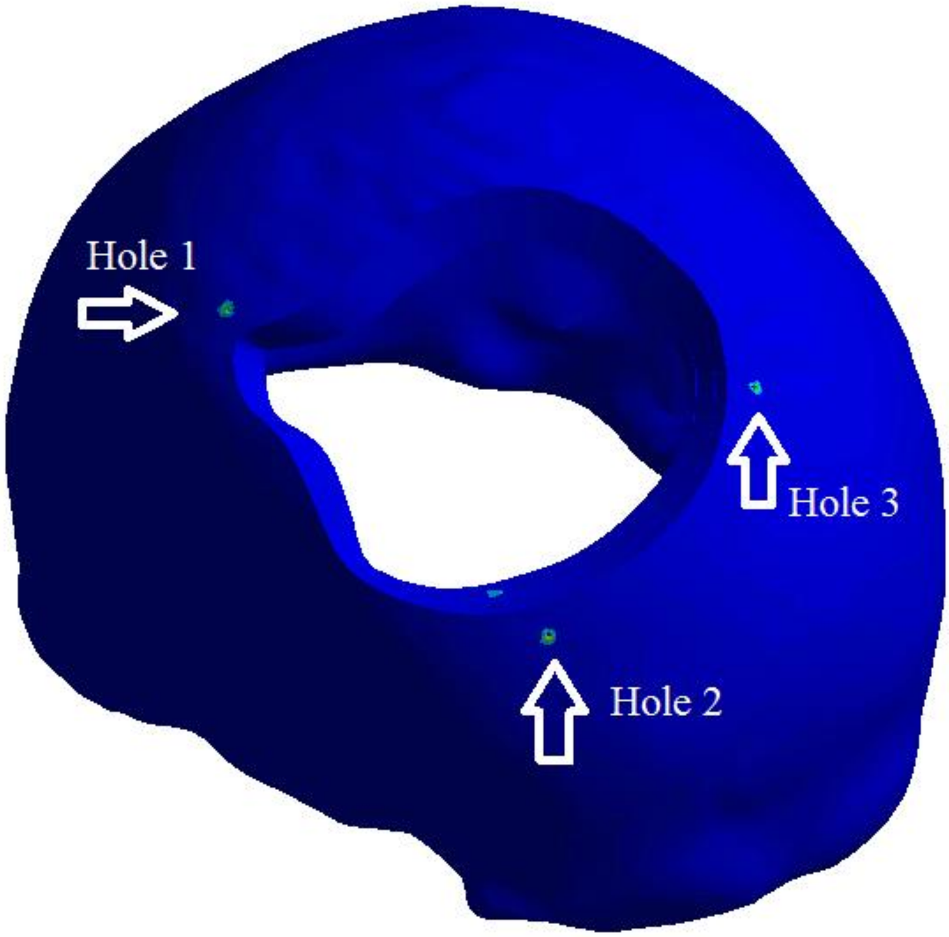

Fig. 58: Equivalent (Von Mises) strain in skull.

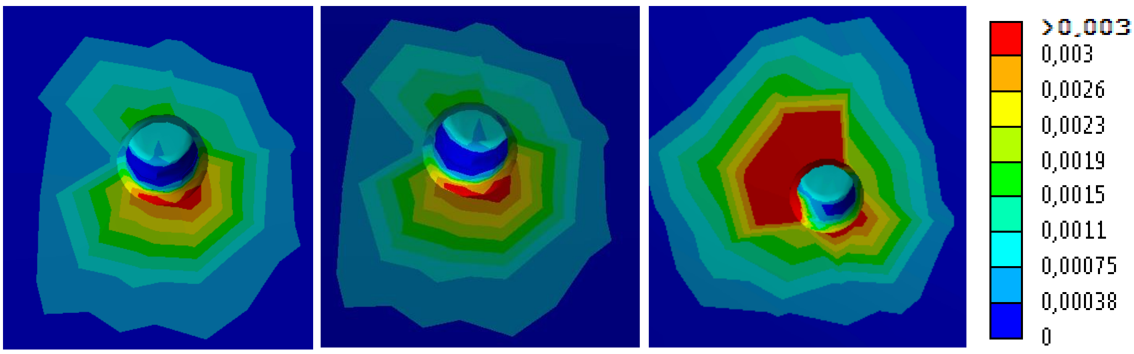

Fig. 59: Equivalent (Von Mises) strain for PMMA *thin implant* holes load by force (left), force and ICP (middle) and just ICP (right).

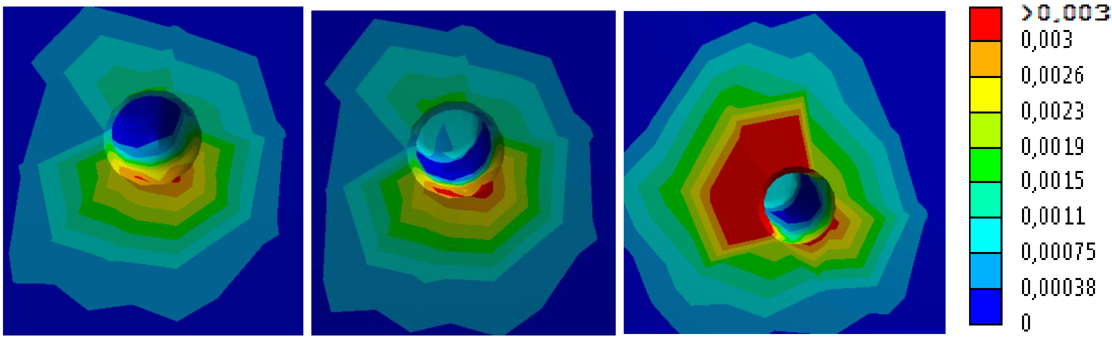

Fig. 60: Equivalent (Von Mises) strain for PEEK *thin implant* holes load by force (left), force and ICP (middle) and just ICP (right).

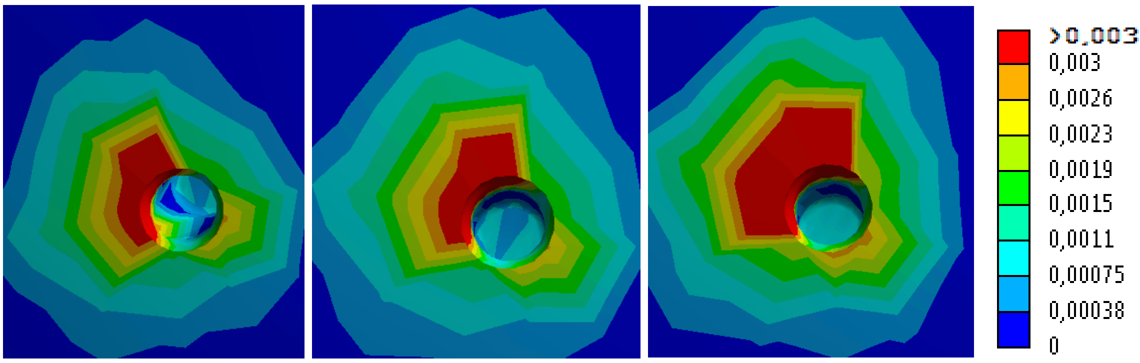

Fig. 61: Equivalent (Von Mises) strain for Titanium *thin implant* holes load by force (left), force and ICP (middle) and just ICP (right).

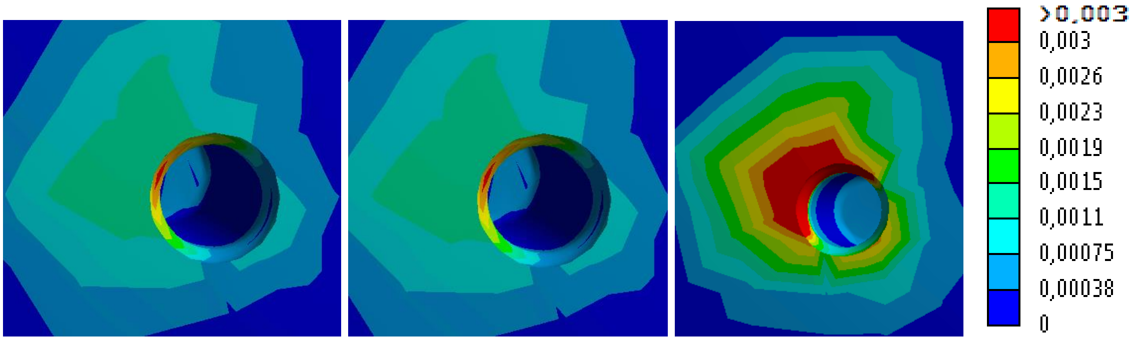

Fig. 62: Equivalent (Von Mises) strain for PMMA *medium implant* holes load by force (left), force and ICP (middle) and just ICP (right).

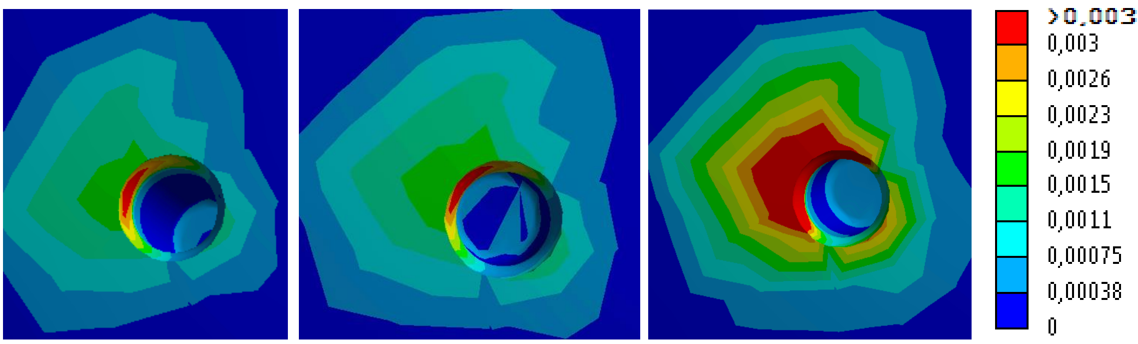

Fig. 63: Equivalent (Von Mises) strain for PEEK *medium implant* holes load by force (left), force and ICP (middle) and just ICP (right).

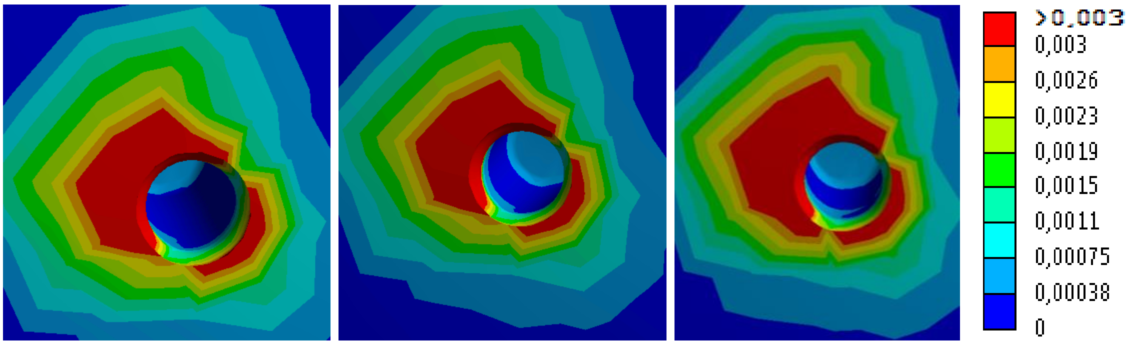

Fig. 64: Equivalent (Von Mises) strain for Titanium *medium implant* holes load by force (left), force and ICP (middle) and just ICP (right).

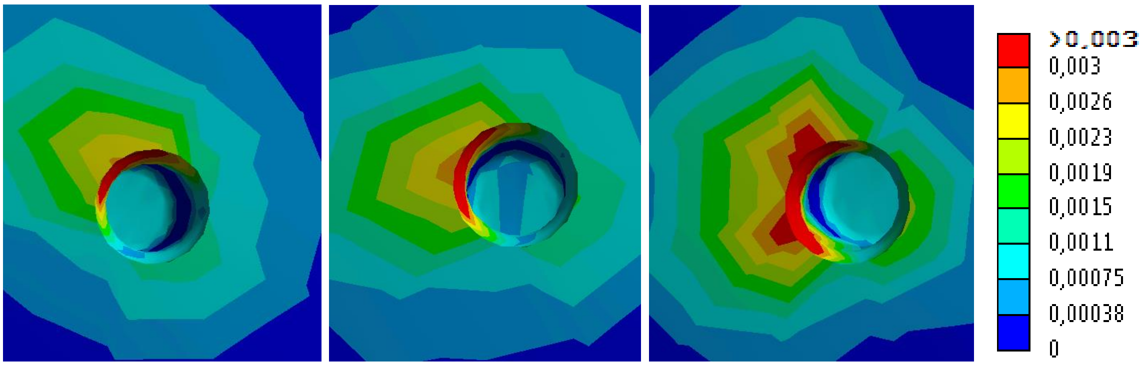

Fig. 65: Equivalent (Von Mises) strain for PMMA *wide implant* holes load by force (left), force and ICP (middle) and just ICP (right).

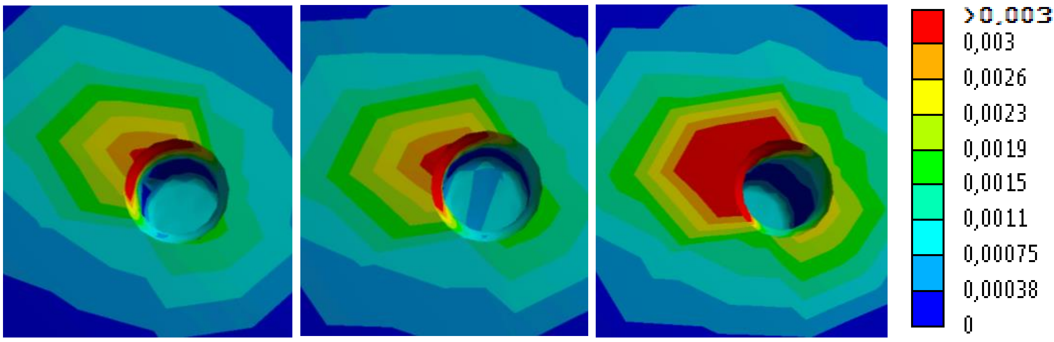

Fig. 66: Equivalent (Von Mises) strain for PEEK *wide implant* holes load by force (left), force and ICP (middle) and just ICP (right).

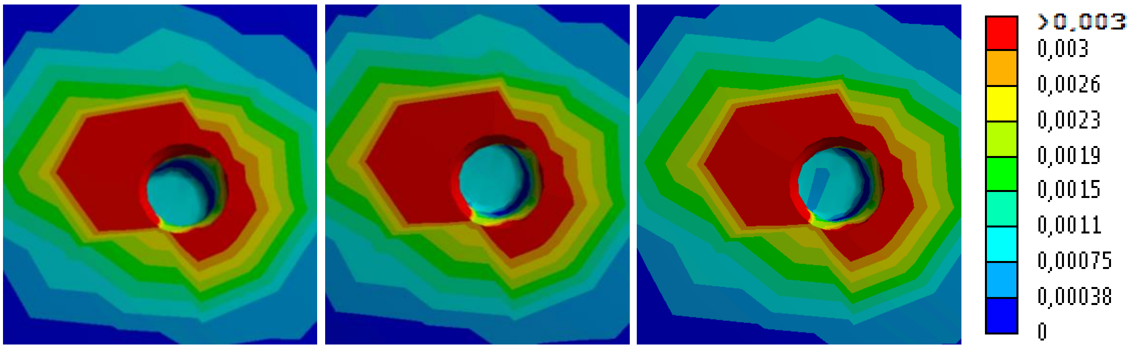

Fig. 67: Equivalent (Von Mises) strain for Titanium *wide implant* holes load by force (left), force and ICP (middle) and just ICP (right).

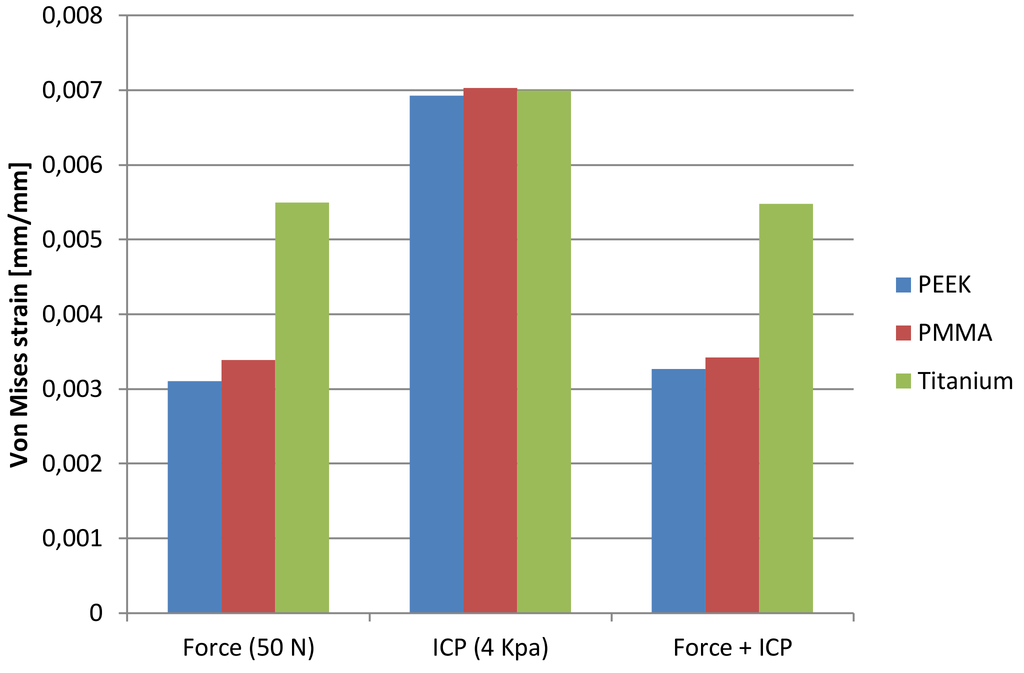

Fig. 68: Comparison of equivalent (Von Mises) strain in skull using *thin implant.*

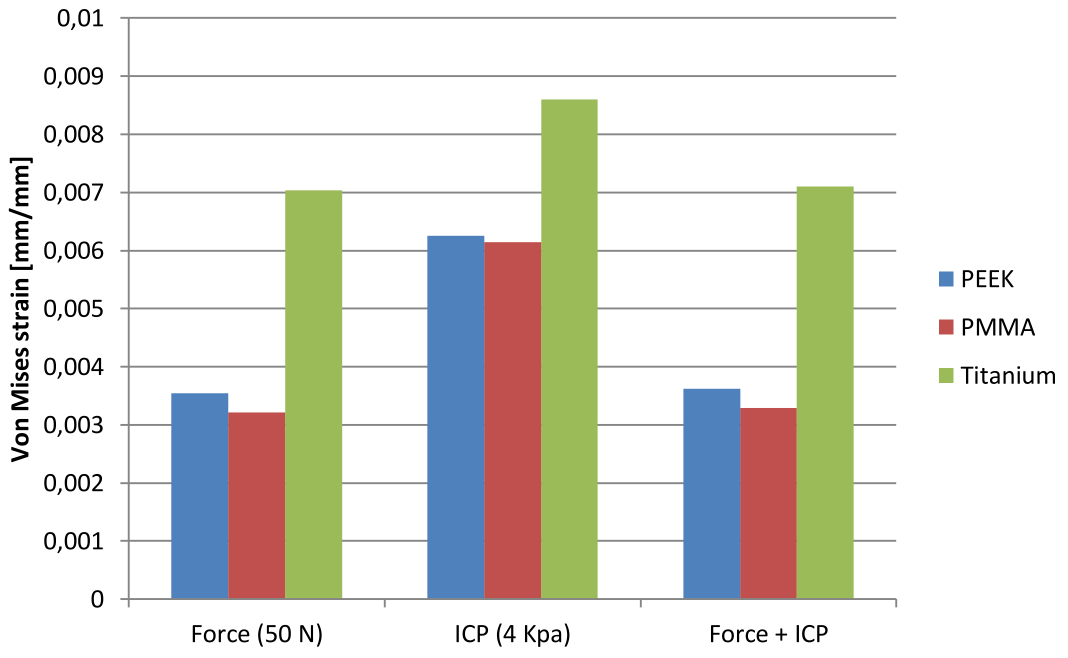

Fig. 69: Comparison of equivalent (Von Mises) strain in skull using *medium implant.*

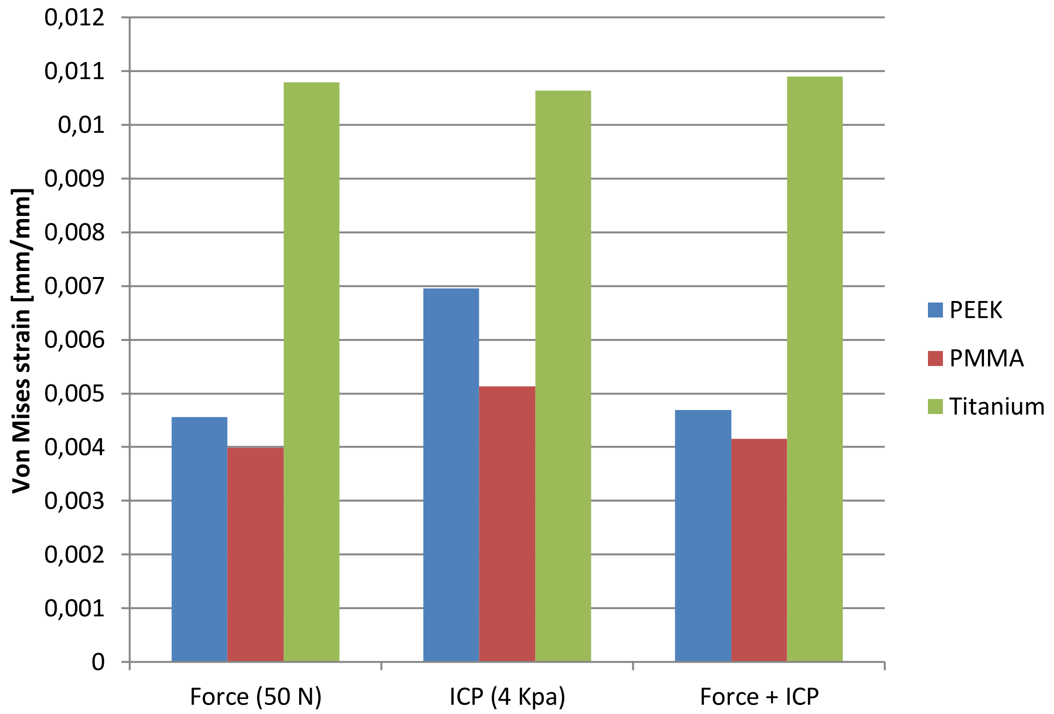

Fig. 70: Comparison of equivalent (Von Mises) strain in skull using *wide implant.*

Tab. 10: Results of maximum value of equivalent (Von Mises) strain is skull.

Material	Load	Strain in skull [mm/mm]		
		Thin implant	Medium implant	wide implant
PMMA	Force (50 N)	0.003	0.003	0.004
	ICP (4 kPa)	0.007	0.006	0.005
	Force + ICP	0.003	0.003	0.004
PEEK	Force (50 N)	0.003	0.004	0.005
	ICP (4 kPa)	0.007	0.006	0.007
	Force + ICP	0.003	0.004	0.005
Titanium	Force (50 N)	0.005	0.007	0.011
	ICP (4 kPa)	0.007	0.009	0.011
	Force + ICP	0.005	0.007	0.011

Due to Frost's Mechanostat* hypothesis, process of (re)modeling is based on loading forces. This forces causes strain in skull bone [55], [56]. If the value of strain is higher than 0.003, bone is overloaded. Micro-fractures may occur, which activate osteoclasts. In case that strain is higher than 0.004, bone tissue is pathologically overloaded and bone start to produce new bone matter. It leads to decreasing of strain, but loosing elasticity. Skull bone starts to be hard and rigid [57], [58].

This hypothesis was proved by some clinical research, although it is not considering important factors, such as diet, genetics and so on.

** = Mechanostat is a model parables to thermostat with a feedback.*

As it was mentioned before, highest values were in holes for screws. Values are written in table 9. In case of using 3 fixators, skull bone is in 22 % cases overloaded and in 78 % pathologically overloaded. In case of using 4 fixators, strain in skull bone decrease under the threshold 0.003 in a case of wide implant, this means decreasing about more than 50 %. Only Titanium alloys implant, values of strain in skull are above 0.003, but less than 0.004.

In case of 5 fixators, strain for loading by force and together force and ICP does not changed. Loading by ICP without force caused decreasing strain in skull, when PMMA and PEEK implants were used and increasing strain in skull, when Titanium alloy implant was used. PMMA and PEEK has worse mechanical properties than cranial bone, on the other hand Ti6Al4V has better mechanical properties. Comparison is shown in figure 71 and table 11.

In case of using 4 fixators, the highest strain was located in hole 3. For 5 fixators, it was situated in hole 1 (description of hole numbering is in figure 58).

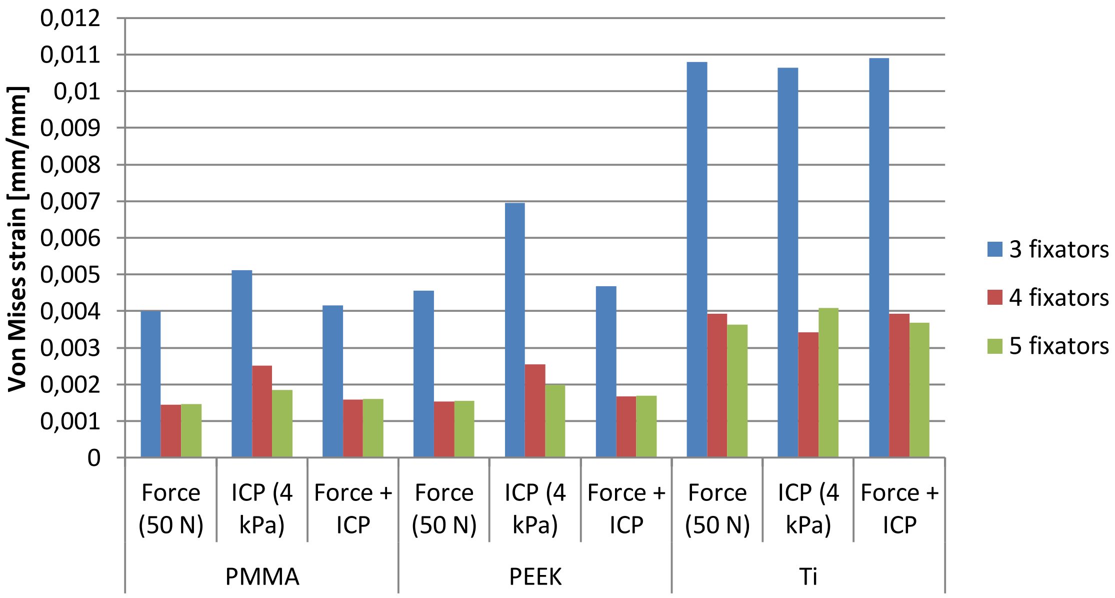

Fig. 71: Comparison of maximum values of strain (Von Mises) in skull using wide implant and 3, 4 and 5 fixators.

Tab. 11: Results of maximum values of equivalent (Von Mises) strain in skull using different quantity of fixators.

Material	**Load**	**Strain in skull**					
PMMA	Force (50 N)	**3 fixators**	0.004	**4 fixators**	0.001	**5 fixators**	0.001
	ICP (4 kPa)		0.005		0.003		0.002
	Force + ICP		0.004		0.002		0.002
PEEK	Force (50 N)		0.005		0.002		0.002
	ICP (4 kPa)		0.007		0.003		0.002
	Force + ICP		0.005		0.002		0.002
Ti	Force (50 N)		0.011		0.004		0.004
	ICP (4 kPa)		0.011		0.003		0.004
	Force + ICP		0.011		0.004		0.004

12.4. Overall effects of implant thickness and quantity of fixators

For overall evaluation, how thickness of implant and number of fixators influence overall results, PMMA implant is chosen, because it is the most used material for cranial implants and the properties are comparable to PEEK.

This analysis was made disregarding holes in implant, because the holes are significant stress concentrator.

12.4.1. Thickness influence

Stress in implant rises with the thinning of implant, which is shown in figure 75 and table 12. Difference between wide implant (thickness same as bone) and thin implant (thickness around 2 mm) is in case of loading by force more than 60 % and force with ICP more than 50 %. In case of loading by ICP, the difference is less evident, it is around 10 %. The difference of stress distribution is shown in figures 72 to 74.

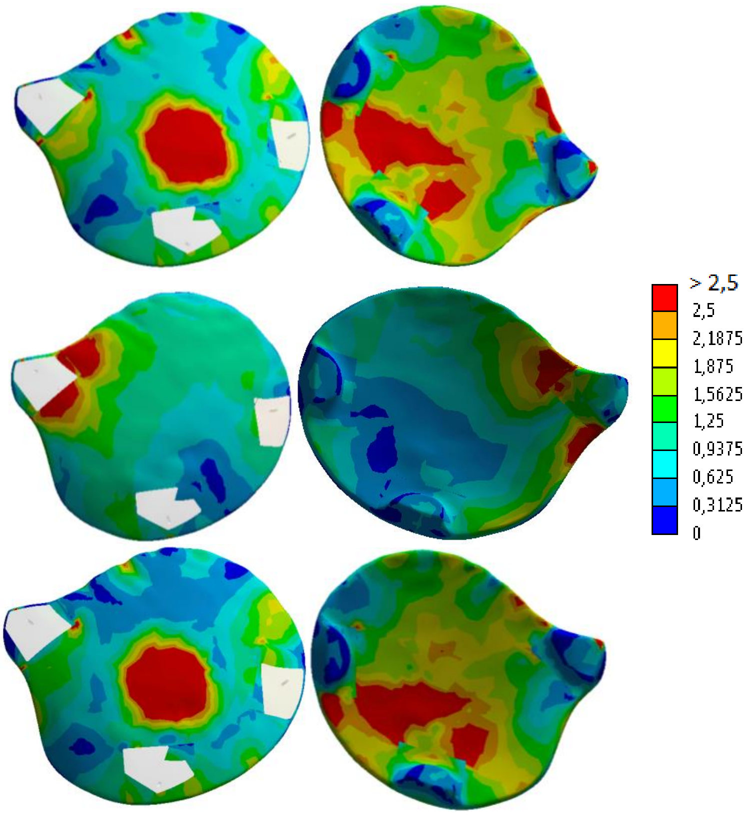

Fig. 72: Equivalent (Von Mises) stress [MPa] in thin PMMA implants (disregarding holes) loaded by force (top), ICP (middle) and force with ICP (bottom).

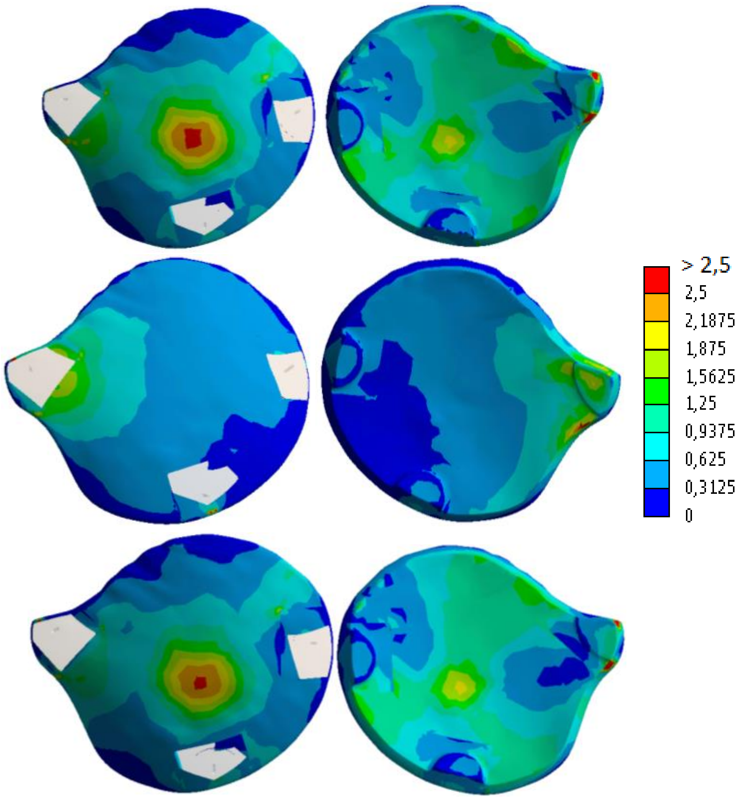

Fig. 73: Equivalent (Von Mises) stress [MPa] in medium PMMA implants (disregarding holes) loaded by force (top), ICP (middle) and force with ICP (bottom).

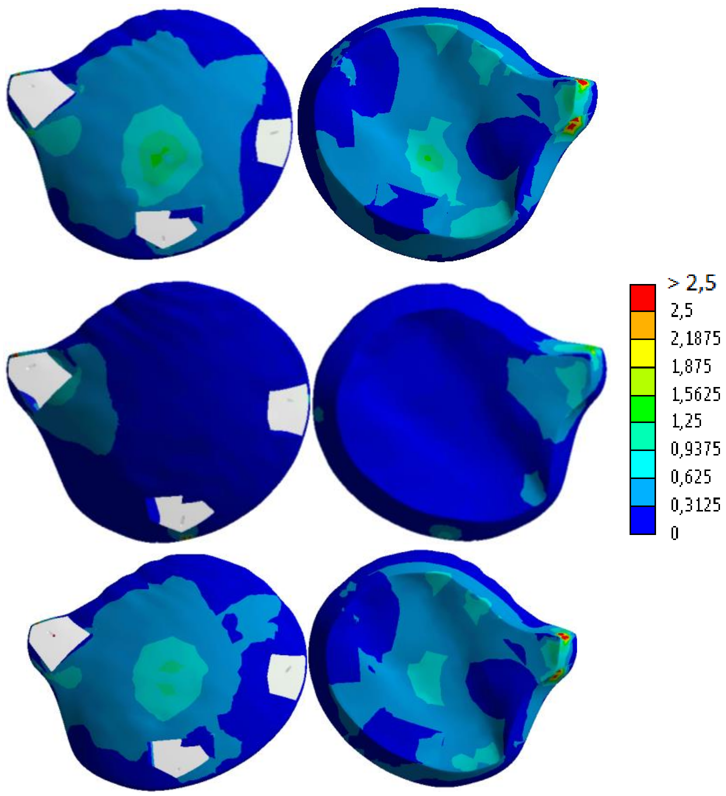

Fig. 74: Equivalent (Von Mises) stress [MPa] in wide PMMA implants fixed with 3 fixators (disregarding holes) loaded by force (top), ICP (middle) and force with ICP (bottom).

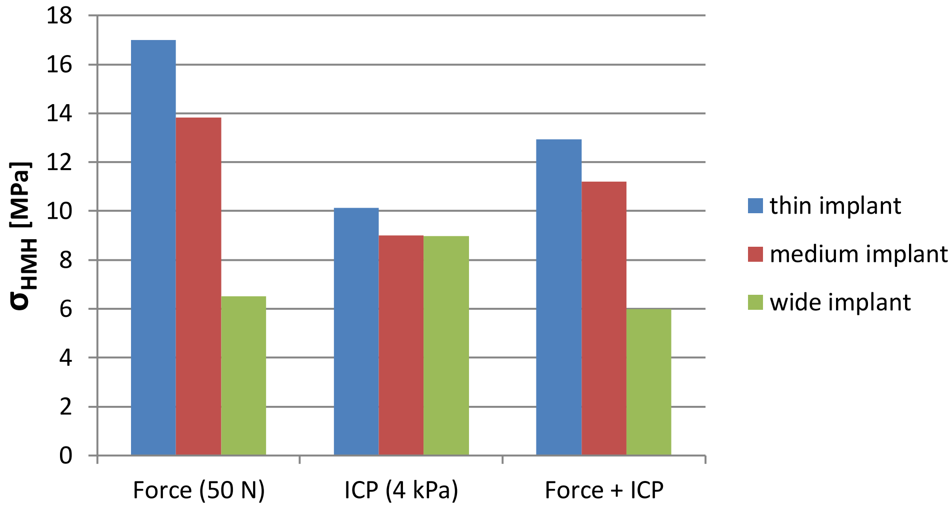

Fig. 75: Thickness influence to maximum value of equivalent (Von Mises) stress.

12.4.2. Fixation influence

Based on results, stress in implant rises with more fixators. More fixators not allow fixator to move as a unit so higher stresses and deformation occur. On the other hand, strain in skull is significantly lower (as shown in chapter 12.3.). Distribution of stress in implants with different amount of fixators is shown in figures 74, 76 and 77. Comparison of stress values is shown in figure 78 and table 12.

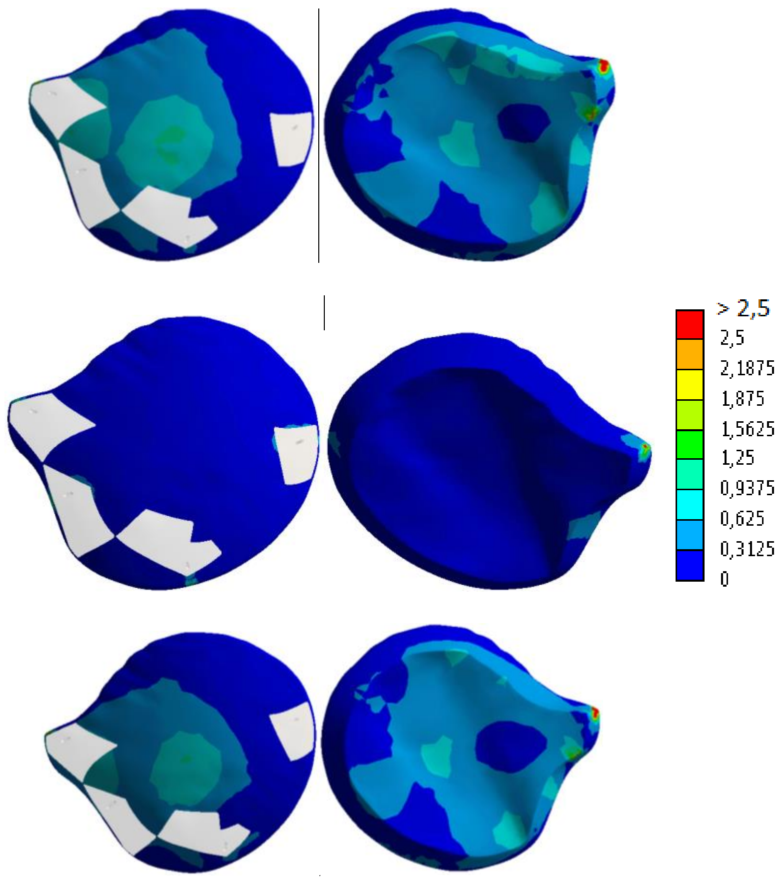

Fig. 76: Equivalent (Von Mises) stress [MPa] in wide PMMA implants fixed with 4 fixators (disregarding holes) loaded by force (top), ICP (middle) and force with ICP (bottom).

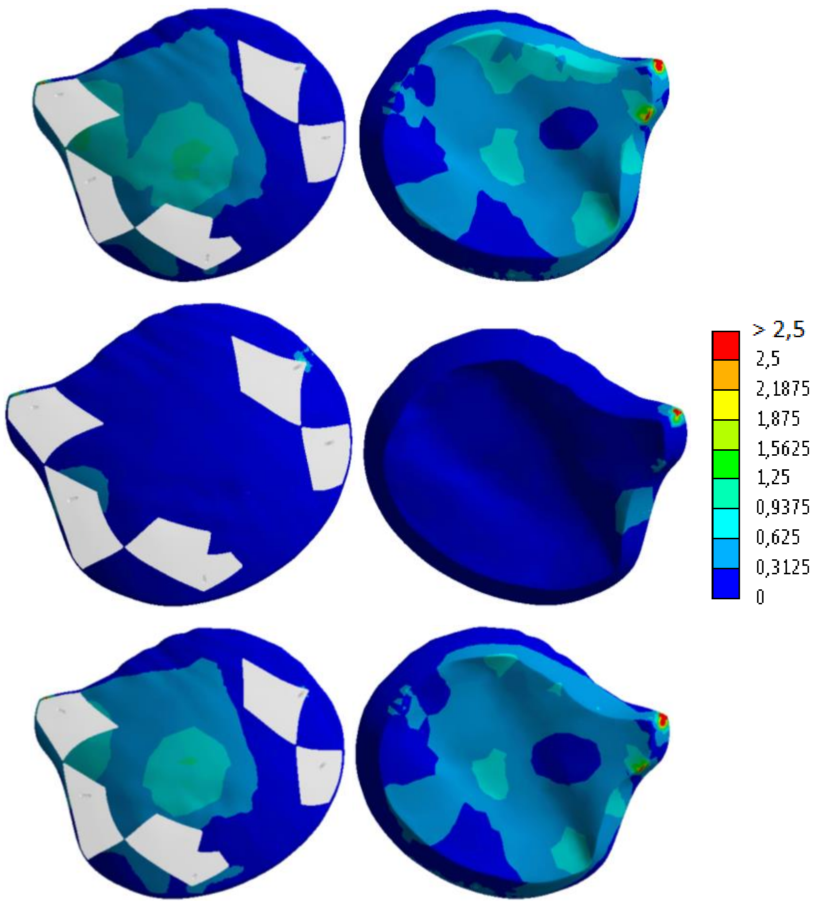

Fig. 77: Equivalent (Von Mises) stress [MPa] in wide PMMA implants fixed with 5 fixators (disregarding holes) loaded by force (top), ICP (middle) and force with ICP (bottom).

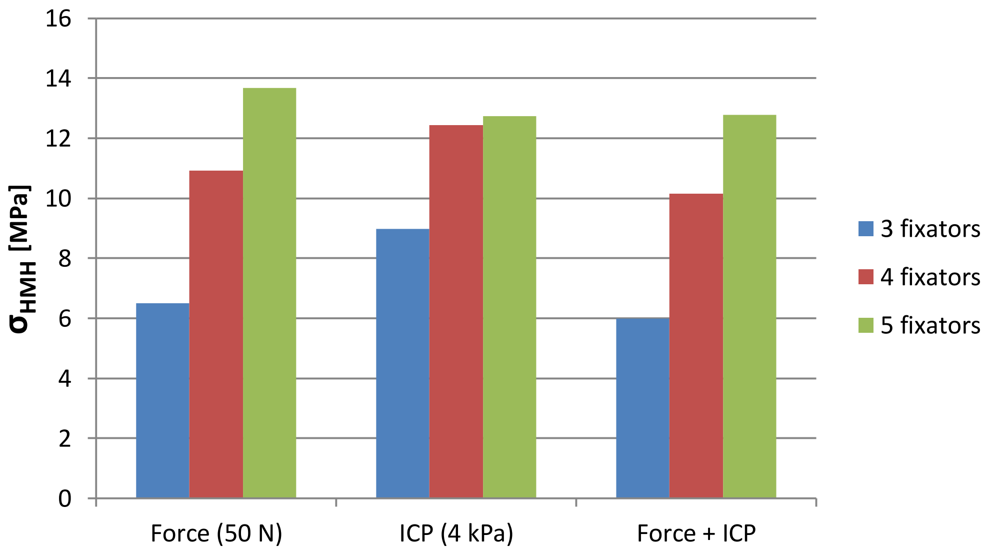

Fig. 78: Fixation influence to maximum value of equivalent (Von Mises) stress using wide PMMA implant (excluding holes, including other concentrators).

Tab. 12: Maximum equivalent (Von Mises) stress in PMMA implant.

PMMA Implant			HMH stress [MPa]
thin implant	3 fixators	Force (50 N)	17
		ICP (4 kPa)	10
		Force + ICP	13
medium implant		Force (50 N)	14
		ICP (4 kPa)	9
		Force + ICP	11
wide implant		Force (50 N)	7
		ICP (4 kPa)	9
		Force + ICP	6
	4 fixators	Force (50 N)	11
		ICP (4 kPa)	12
		Force + ICP	10
	5 fixators	Force (50 N)	14
		ICP (4 kPa)	13
		Force + ICP	13

Table 12 shows that maximum values of equivalent (Von Mises) stress are higher with increasing of number of fixators. Only the most significant stress concentrators (holes) were removed from the model. These results show just the situation in critical places (sharp part of the implant – described in figure 32), which are less significant, but they distort overall results. Maximum values of equivalent (Von Mises) stress in implant, which are not influenced by stress concentrators, are shown in table 13 and figure 79.

Tab. 13: Maximum values of equivalent (Von Mises) stress in PMMA wide implant not influenced by stress concentrators.

			HMH stress [MPa]
Wide PMMA implant	3 fixators	Force	1.5
		ICP	0.9
		Force + ICP	1.1
	4 fixators	Force	1.1
		ICP	0.4
		Force + ICP	1
	5 fixators	Force	1.1
		ICP	0.5
		Force + ICP	1

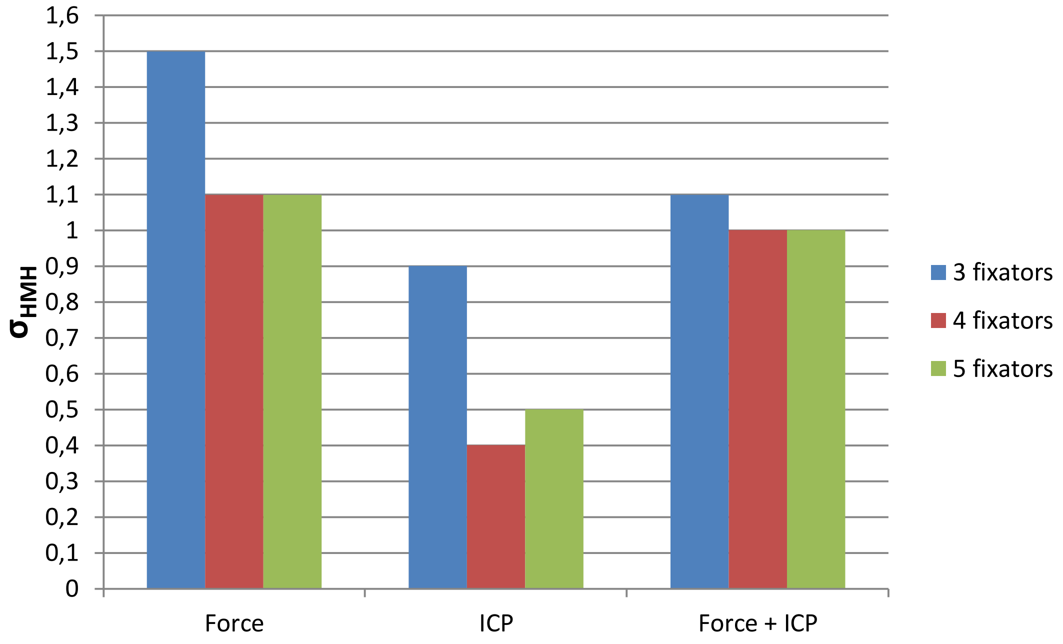

Fig. 79: Fixation influence to maximum value of equivalent (Von Mises) stress using wide PMMA implant (excluding all concentrators).

12.5. Submodeing

Submodeling is a way of modeling, which provides more accurate results in submodel area. It is usually used in places, where stress concentrators are. In the submodel area, soft mesh can be generated and solution if faster than solution of whole model with the same mesh. It is necessary to define special boundary conditions on surfaces, which were cut out from the coarse model. These special boundary conditions are counted from coarse model. The most often, these boundary conditions are displacements on surfaces.

Submodeling is based on St. Venant's principle, which says, that force system π can be replaced with equivalent force system π_e, whereas the stress in model is the same except of very surroundings of a submodel. This is the limitation of submodeling, analyzed data has to be far enough from very surroundings of submodel [54].

In this thesis, submodel of area around one fixator, which was considered to be most problematic, is analyzed (as shown in figure 80). The submodel is upgraded by screws with thread (as shown in figure 81). In coarse model, screws are modeled as threadless cylinders. Contacts between screws and implant or screws and bone are not bonded (as in coarse model), but frictionless. The only boundary condition is imported deformation on surfaces, which were cut out from coarse model (as shown in figures 82 and 83). Values of imported constraint and total deformation have to be similar. Deformation in submodel after recalculation using new boundary condition is shown on figure 84.

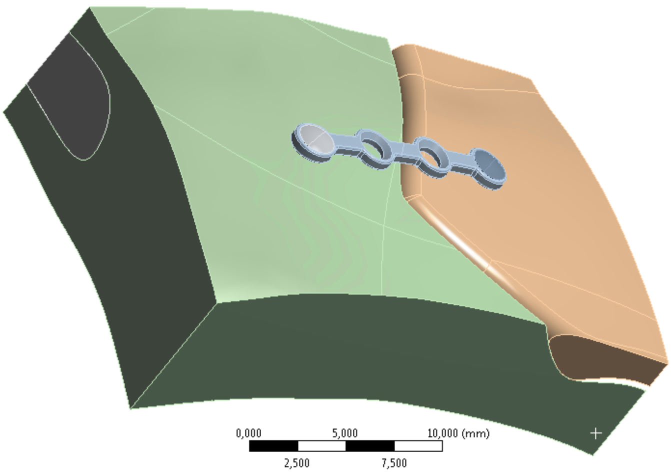

Fig. 80: Submodel.

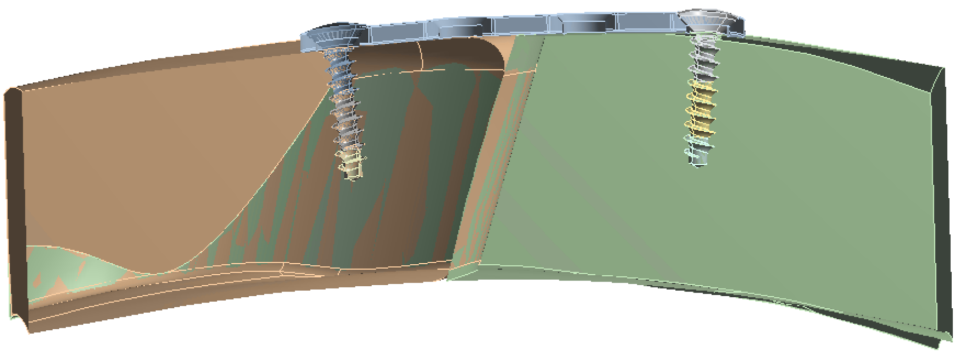

Fig. 81: Screw with threads in submodel geometry.

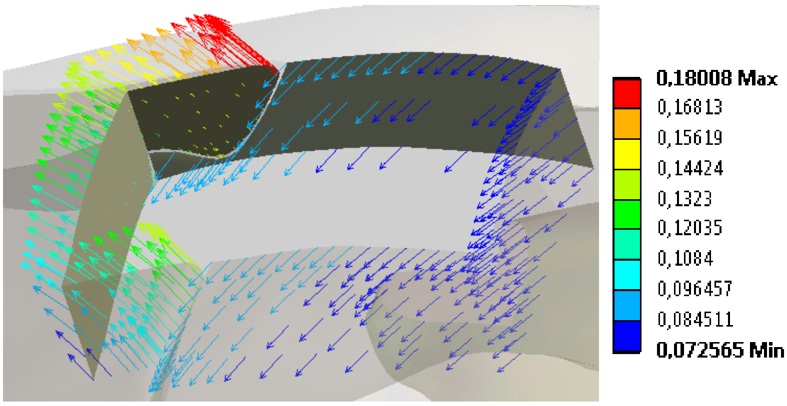

Fig. 82: Total deformation [mm] in coarse model, used as boundary constraints.

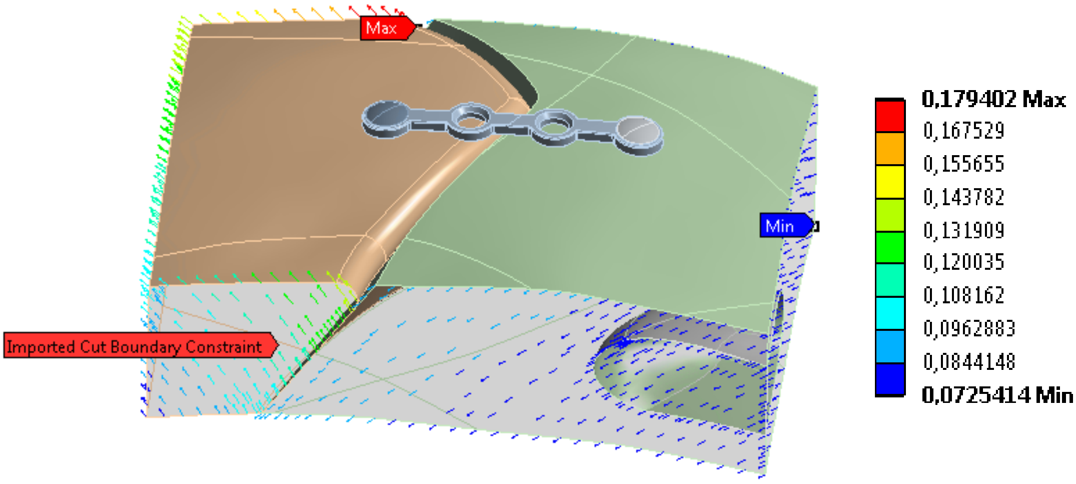

Fig. 83: Imported boundary constraints (deformation [mm]) on submodel.

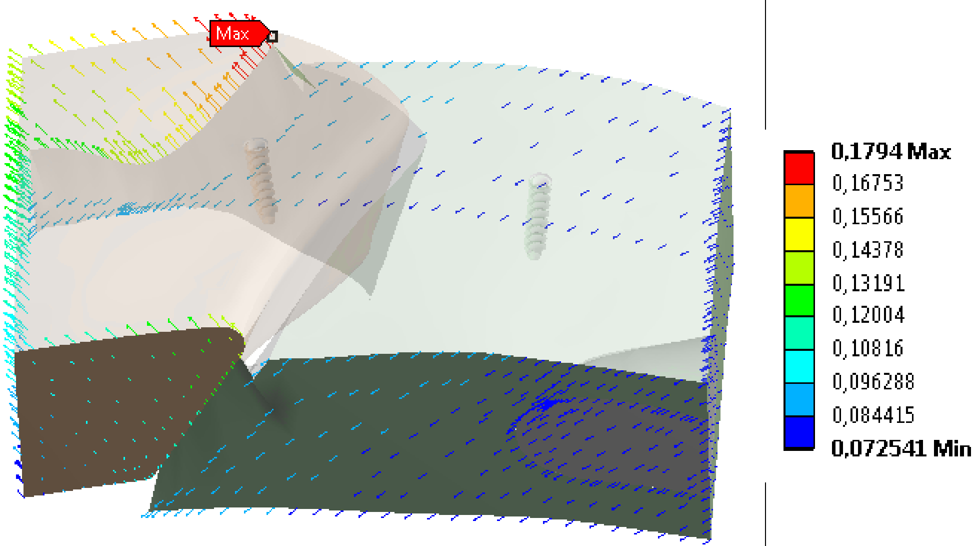

Fig. 84: Deformation [mm] in submodel after recalculation.

The results from submodeling shows, that stress in implant decrease with increasing of thickness (as shown in figure 85). In figure 85, there is also shown displacement with scaling 10 and stress distribution in fixators, which are less stressed in implants, which are fixed with more fixators. Also displacement is lower in case of using more than 3 fixators.

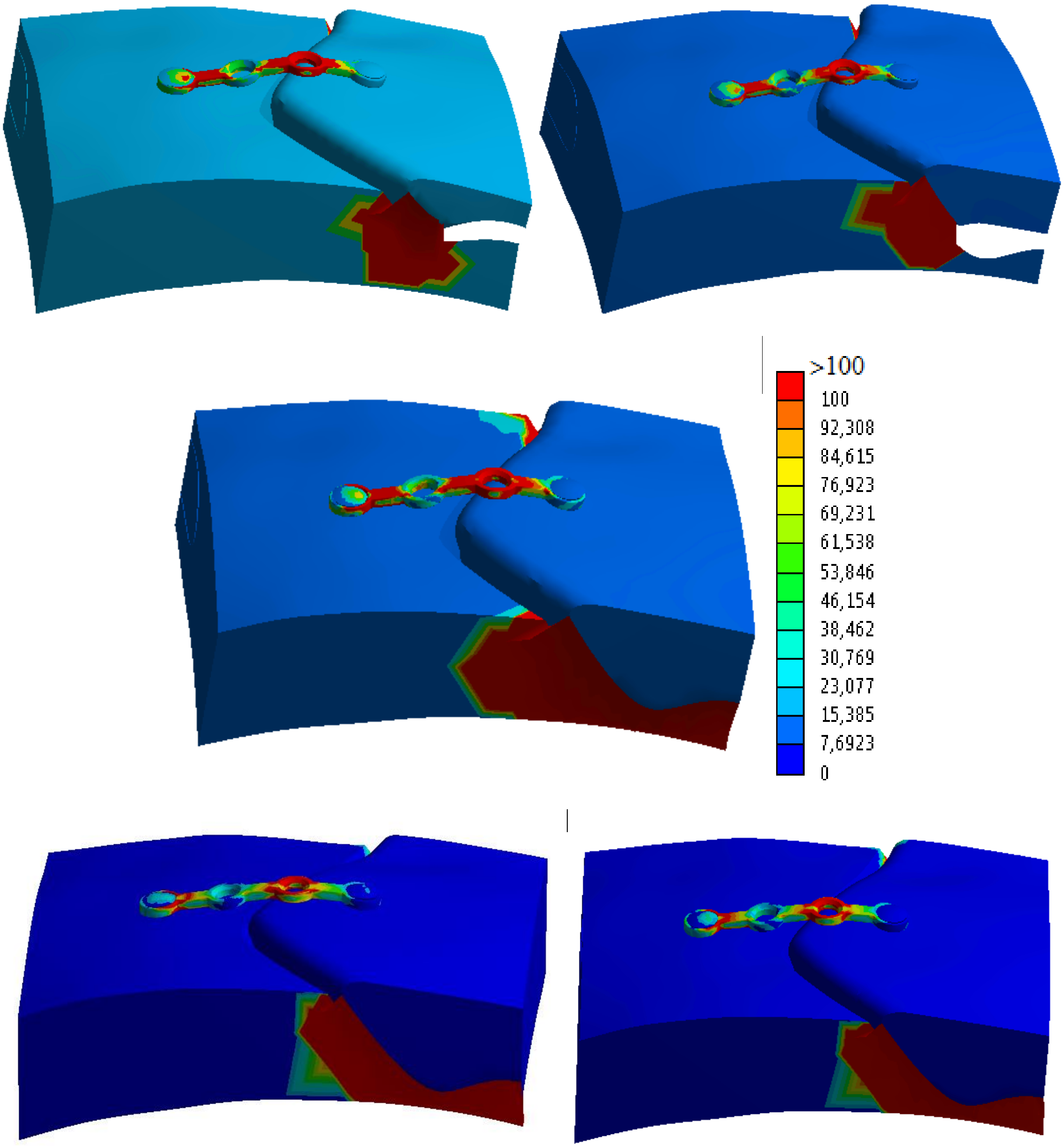

Fig. 85: Distribution of equivalent (Von Mises) stress [MPa] in PMMA thin (top left), medium (top right) and wide implants. Wide implant was fixed by 3 (middle), 4 (bottom left) and 5 (bottom right) fixators. Deformation (scaling 10) was used to demonstrate movement.

Distribution of stress in fixators calculated using submodel is shown in figure 86. With increasing of number of fixators, the value and distribution decrease. There is not big difference between stress distribution fixing by 4 and 5 fixators.

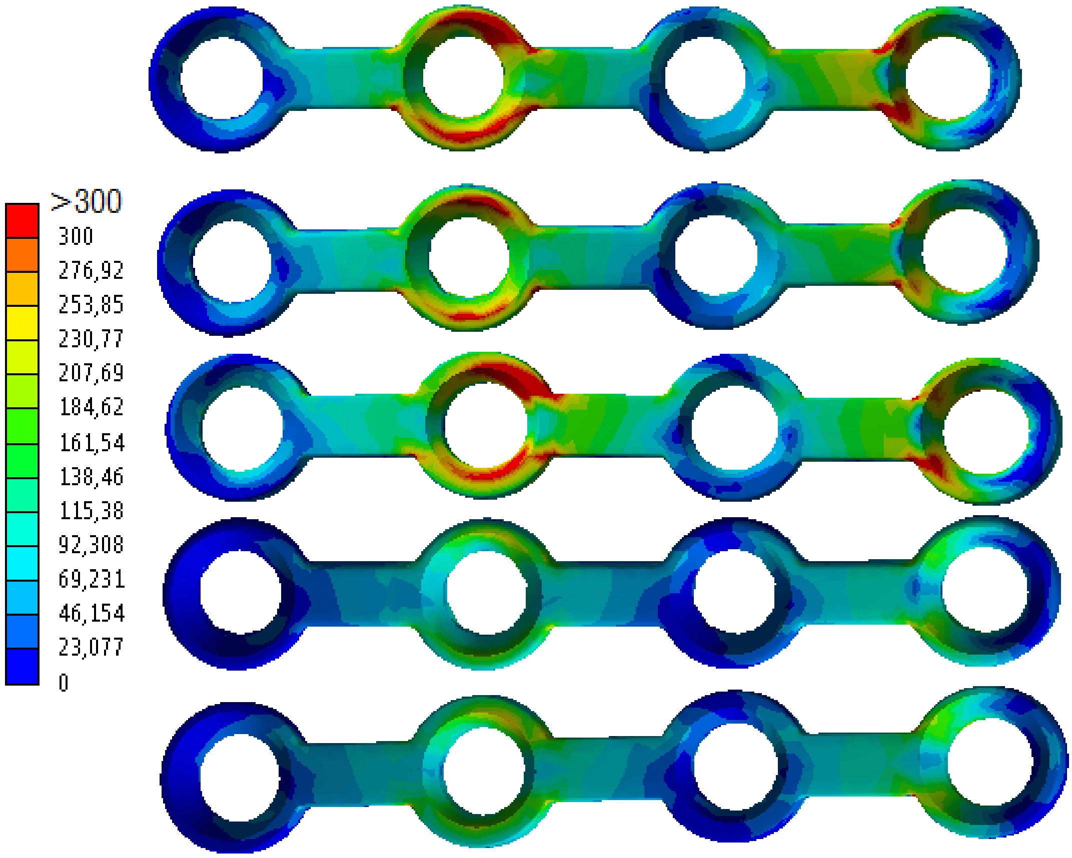

Fig. 86: Distribution of equivalent (Von Mises) stress [MPa] in fixator using PMMA thin (top), medium (the 2nd from the top) and wide implants. Wide implant was fixed by 3 (3rd - middle), 4 (4th) and 5 (5th – bottom) fixators.

CONCLUSION

The goal of this Master thesis, which deals with cranial implants, was to analyze system skull – implant body – fixators, comparison of different thicknesses, materials and number of fixators. The analysis is done on skull, which includes spongy part of cranial bones. The analysis was solved using computational approach.

In research part, types and materials of implants and fixators were characterized. There is also shown elementary anatomy of cranio - maxillofacial system and described, how ICP increases and its values.

For a computational approach, it is necessary to have suitable model. The model is designed based on CT scans in software STL Model Creator, Catia and SolidWorks. One model was done for skull and one for spongy part. Then spongy was placed inside the skull. It is necessary to be able to define different material properties for compact bone and spongy bone. The Finite element analysis was done in software ANSYS Workbench 16.2. In ANSYS Workbench 16.2 influence of thickness of implant, its material and way of fixation was tested. Stress in implant and fixators, strain in skull and directional deformation in direction of loading force was investigated. The shape of implant was without critical places except of one sharp parts, where the stress were concentrated (as described in figure 32 and shown in figures 72 – 74, 76 and 77).

Results, which are more detailed described in chapter 12, show, that:

- the highest stress in implant is in holes for screws, which are significant stress concentrators;
- the highest equivalent (Von Mises) stress in implant is in case loading with ICP;
- the lowest stress is in implant, made from PMMA, the highest is in implant from Ti6Al4V (for all thicknesses);
- directional deformation of the implant in loading force direction (in the force activity location) was the lowest for fixation using 3 fixators, because more than 3 fixators don't enable implant to move as a unit;
- maximum values of directional deformation was in implant fixed with 3 fixators on bone – implant contact;
- values and distribution of directional deformation for 4 and 5 fixators was similar;
- the highest values equivalent (Von Mises) stress in fixators are situated to the border between hole for screw and connections;
- the highest values equivalent (Von Mises) stress in fixators are observed in case wide implant is used, the lowest are for thin implant;
- bone is overloaded for large defects (large implants) using 3 fixators (value of strain in skull is higher than 0.003;
- using at least 4 fixators for large implants decrease the value of strain in skull under the threshold 0.003 (only implant made from Ti6Al4V has higher values);
- in case of excluding significant stress concentrators from implant (holes etc.) maximum value of equivalent (Von Mises) stress and its distribution is in implant fixed with 3 fixators.

Based on results from this thesis, using 4 fixators showed better results than using 3 fixators, which is nowadays standard. In case of large implants 4 fixators decrease values of stress and directional deformation in implant and strain in skull, which is important, because of overloading of skull bone. Values of all investigated results are almost similar for fixation using 4 and 5 fixators. Using 5 fixators extend surgery time and it is more expensive.

Results for model, which includes diploe were different on average about 2 %* than for model made just from compact bone. In some cases it was about 5 – 6 %. The fact, that there is a difference between model with and without diploe part, shows, that diploe influences results and it have to be considered to the calculation. With increasing of loading force, the difference would be even higher.

The topic, this thesis is focused on is not much explored, so there is plenty research and calculation to do in future. Possible future work, I would like to do is for example:

- analyzing Ti6Al4V implant with some % of porosity, where the bone tissue would ingrown to the implant;
- define the size for implants, which are better to fix with more than 3 fixators;
- analyzing bone – implant contact area (BIC), with a regard to inaccuracies;
- analyzing skull – implant – fixator system using different screw length or fixator shape.

** = it was tested on wide PMMA implant using 3, 4 and 5 fixators.*

LIST OF UNITS

Unit	Description
N	Newton
Kg	Kilogram
mmHg	Millimeter of mercury
kPa	Kilopascal
%	Percent
GPa	Giga Pascal
MPa	Mega Pascal
HU	Hounsfield's units
mm	Millimeter
min	Minute

LIST OF ABBREVIORS

Abb	Description
Abb	Abbreviors
BC	Before Crist
CAD	Computer aided design
CAM	Computer aided manufacturing
FEM	Finite element method
PMMA	Polymethylmethacrylate
CT	Computed tomography
CF	cerebral blood
CSF	cerebrospinal blood
CMF	Cranial and Maxillofacial
STL	Stereo lithography (file format)
3D	3 dimensions
PEEK	Polyether ether ketone
HA	Hydroxyapatite
MRI	Magnetic resinance imaging
S - I – F	Skull – implant body – fixators
BUT	Brno University of Technology
BIC	Bone – implant contact surface

LIST OF TABLES

Unit	Description
Tab. 1	Several mechanical properties of cranial bone
Tab. 2	Values of Hounsfield’s units for selected tissue and references for CT – HU transformation
Tab. 3	Properties of PMMA
Tab. 4	Properties of PEEK
Tab. 5	Properties of Ti6Al4V
Tab. 6	Materials used for implant and fixators and their defining parameters
Tab. 7	Results of maximum value of HMH stress in implant
Tab. 8	Results of maximum and minimum values of directional deformation and value in force sphere of activity
Tab. 9	Results of maximum value of HMH stress in fixator
Tab. 10	Results of maximum value of equivalent (Von Mises) strain is skull
Tab. 11	Results of maximum value of equivalent (Von Mises) strain is skull using different quantity of fixators
Tab. 12	Stress in PMMA implant
Tab. 13	Maximum values of equivalent (Von Mises) stress in PMMA wide implant not influenced by stress concentrators or critical places

LIST OF FIGURES

Number	Description
Fig. 1	Human head
Fig. 2	ICP dependence on time
Fig. 3	Analyzed system Skull – Implant
Fig. 4	Skull including spongy part
Fig. 5	A lateral view of a skull
Fig. 6	Scalp
Fig. 7	Cross-section of skullcap bone
Fig. 8	Values of ICP during head injury (1), standing – vertical position (2) and normal value (3)
Fig. 9	Patient specific approach
Fig. 10	Biocompatibility of material for given function (yellow color in the picture)
Fig. 11	Titanium cranial implant
Fig. 12	Comparison of Ultimate Tensile strength
Fig. 13	HA cement placed on Titanium mesh
Fig. 14	Fixators and screw from company KLS Martin
Fig. 15	Fixators and screw from company Medtronic
Fig. 16	Fixators and screw from company Aesculap
Fig. 17	Unusual types of fixators
Fig. 18	System skull – implant body – fixators.
Fig. 19	Computed tomography picture of skull using Hot/cold color map
Fig. 20	CT picture of skull (on the left) and binarised crop of cranial bone without diploe
Fig. 21	Plot of part of the skull without diploe part
Fig. 22	CT picture of skull (on the left) and binarised crop of diploe part of cranial bone
Fig. 23	Plot of diploe part of a skull, shown in figure 21
Fig. 24	Volumes od skull and spongy made in software CATIA
Fig. 25	Spongy part, placed inside the skull in software CATIA
Fig. 26	*Wide*, *medium* and *thin* implants designed in software SolidWorks.
Fig. 27	Screw, designed in software SolidWorks
Fig. 28	Fixator, designed in software SolidWorks
Fig. 29	Loads (50 N force and 4 kPa ICP)
Fig. 30	Mesh
Fig. 31	Modifications of system Skull bone tissue – Implant – Fixators, which are calculated in this thesis
Fig. 32	Equivalent (Von Mises) stress in implant
Fig. 33	Equivalent (Von Mises) stress for PMMA *thin implant* holes load by force, force and ICP and just ICP
Fig. 34	Equivalent (Von Mises) stress for PEEK *thin implant* holes load by force, force and ICP and just ICP
Fig. 35	Equivalent (Von Mises) stress for Titanium *thin implant* holes load by force, force and ICP and just ICP
Fig. 36	Equivalent (Von Mises) stress for PMMA *middle implant* holes load by force, force and ICP and just ICP
Fig. 37	Equivalent (Von Mises) stress for PEEK *middle implant* holes load by force, force and ICP and just ICP
Fig. 38	Equivalent (Von Mises) stress for Titanium *middle implant* holes load by force, force and ICP and just ICP

Fig. 39	Equivalent (Von Mises) stress for PMMA *wide implant* holes load by force, force and ICP and just ICP
Fig. 40	Equivalent (Von Mises) stress for PEEK *wide implant* holes load by force, force and ICP and just ICP
Fig. 41	Equivalent (Von Mises) stress for Titanium *wide implant* holes load by force, force and ICP and just ICP
Fig. 42	Equivalent (Von Mises) stress for *thin implant.*
Fig. 43	Equivalent (Von Mises) stress for *medium implant*
Fig. 44	Equivalent (Von Mises) stress for *wide implant*
Fig. 45	Differences between using 3, 4 or 5 fixators on *wide PMMA implant*
Fig. 46	Maximum values of directional deformation for wide implant fixed using 3, 4 and 5 fixators
Fig. 47	Minimum values of directional deformation for wide implant fixed using 3, 4 and 5 fixators
Fig. 48	Values of directional deformation in a place of force sphere activity for wide implant fixed using 3, 4 and 5 fixators.
Fig. 49	Wide PMMA implant fixed using 3, 4 and 5 fixators loaded by force, ICP and combination of force and ICP
Fig. 50	Wide PEEK implant fixed using 3, 4 and 5 fixators loaded by force, ICP and combination of force and ICP
Fig. 51	Wide Titanium implant fixed using 3, 4 and 5 fixators loaded by force, ICP and combination of force and ICP
Fig. 52	Equivalent (Von Mises) stress for *thin implant* fixators from PMMA, PEEK and Titanium loaded by force, force and ICP and just ICP
Fig. 53	Equivalent (Von Mises) stress for *medium implant* fixators from PMMA, PEEK and Titanium loaded by force, force and ICP and just ICP
Fig. 54	Equivalent (Von Mises) stress for *wide implant* fixators from PMMA, PEEK and Titanium loaded by force, force and ICP and just ICP
Fig. 55	Equivalent (Von Mises) stress for fixator using *thin implant*
Fig. 56	Equivalent (Von Mises) stress for fixator using *medium implant*
Fig. 57	Equivalent (Von Mises) stress for fixator using *wide implant*
Fig. 58	Equivalent (Von Mises) strain in skull
Fig. 59	Equivalent (Von Mises) strain for PMMA *thin implant* holes load by force, force and ICP and just ICP.
Fig. 60	Equivalent (Von Mises) strain for PEEK *thin implant* holes load by force, force and ICP and just ICP.
Fig. 61	Equivalent (Von Mises) strain for Titanim *thin implant* holes load by force, force and ICP and just ICP.
Fig. 62	Equivalent (Von Mises) strain for PMMA *medium implant* holes load by force, force and ICP and just ICP.
Fig. 63	Equivalent (Von Mises) strain for PEEK *medim implant* holes load by force, force and ICP and just ICP.
Fig. 64	Equivalent (Von Mises) strain for Titanim *medium implant* holes load by force, force and ICP and just ICP.
Fig. 65	Equivalent (Von Mises) strain for PMMA *wide implant* holes load by force, force and ICP and just ICP.
Fig. 66	Equivalent (Von Mises) strain for PEEK *wide implant* holes load by force, force and ICP and just ICP.
Fig. 67	Equivalent (Von Mises) strain for Titanim *wide implant* holes load by force, force and ICP and just ICP.
Fig. 68	Comparison of equivalent (Von Mises) strain in skull using *thin implant*

Fig. 69	Comparison of equivalent (Von Mises) strain in skull using *medium implant*
Fig. 70	Comparison of equivalent (Von Mises) strain in skull using *wide implant*
Fig. 71	Comparison of equivalent (Von Mises) strain in skull using wide implant and 3, 4 and 5 fixators
Fig. 72	Equivalent (Von Mises) stress in thin implants (disregarding holes) loaded by force, ICP and force with ICP.
Fig. 73	Equivalent (Von Mises) stress in medium implants (disregarding holes) loaded by force, ICP and force with ICP.
Fig. 74	Equivalent (Von Mises) stress in wide implants (disregarding holes) loaded by force, ICP and force with ICP.
Fig. 75	Thickness influence to equivalent (Von Mises) stress
Fig. 76	Equivalent (Von Mises) stress in wide implants fixed with 4 fixators (disregarding holes) loaded by force, ICP and force with ICP.
Fig. 77	Equivalent (Von Mises) stress in wide implants fixed with 5 fixators (disregarding holes) loaded by force, ICP and force with ICP.
Fig. 78	Fixation influence to maximum value of equivalent (Von Mises) stress using wide PMMA implant (excluding holes, including other concentrators)
Fig. 79	Fixation influence to maximum value of equivalent (Von Mises) stress using wide PMMA implant (excluding all concentrators)
Fig. 80	Submodel
Fig. 81	Screw with threads in submodel geometry
Fig. 82	Total deformation in coarse model, used as boundary constraints
Fig. 83	Imported boundary constraints on submodel
Fig. 84	Deformation in submodel after recalculation
Fig. 85	Distribution of equivalent (Von Mises) stress in PMMA thin, medium and wide implants. Wide implant was fixed by 3, 4 and 5 fixators. Deformation (scaling 10) was used to demonstrate movement
Fig. 86	Distribution of equivalent (Von Mises) stress in fixator using PMMA thin, medium and wide implants. Wide implant was fixed by 3, 4 and 5 fixators

REFERENCES

[1] PŘEMYSL JANÍČEK. *Systémové pojetí vybraných oborů techniky.* Brno: Akademické nakladatelství CERM, 2007. ISBN 978-80-214-3544-5.

[2] ABRAHAMS, Peter H. *Jak pracuje lidské tělo: [ilustrovaná encyklopedie anatomie a funkcí všech částí lidského těla].* 1. vyd. Praha: Svojtka & Co., 2014. ISBN 978-80-256-1160-9.

[3] Anatomie – Springer Medizin. [online], [cit. 2016-02-05], Available from: http://agentur-focus.de/Lightboxen/ANGEBOTE/FEATURES/2013/Medizin/SPLSpringerMedizin1/index.html

[4] History – Implantology: [online], [cit. 2016-04-13], Available from: http://pagesperso-orange.fr/drgauthier/histoire.htm

[5] CHAMRAD, Jakub, Petr Marcián, Libor Borák and Jan Wolff. *Finite element analysis of cranialimplant*. Engineering Mechanics 2016: 22nd International Conference. ISBN 978-80-87012-59-8.

[6] CZOSNYKA, Marek, John D. Pickard. *Monitoring and interpretation of intracranial pressure*. Neuroscienceforneurologists. 2004, 75:813-821 DOI:10.1136/jnnp.2003.033126. Available from: http://jnnp.bmj.com/content/75/6/813.long

[7] Abouthealth: Craniotomy vs. Craniectomy: [online], [cit. 2016-03-05], Available from: http://surgery.about.com/od/proceduresaz/qt/CraniotomyCraniectomy.htm

[8] Lebka: Princip stavby a vývoje. Přehled kostí neurocrania a splanchnorania: [online], [cit. 2016-03-05], Available from: http://anat.lf1.cuni.cz/souhrny/lekzs08a.pdf

[9] PÁČ, Libor a Ladislava HORÁČKOViÁ. *Anatomie člověka*. 1. vyd. Brno: Masarykova univerzita, 2009, 146 s. ISBN 978-802-1049-536.

[10] Ivnducsocal: Bones of skull: [online], [cit. 2016-03-06], Available from: http://rocountdopo.blogspot.cz/2012/06/bones-of-skull.html

[11] MCELHANEY, James H., John L. FOGLE, John W. MELVIN, Russell R. HAYNES, Verne L. ROBERTS and Nabih M. ALEM. *Mechanical properties of cranial bone*. Journal of Biomechanics. 1970, vol. 3, issue 5, s. 495-511. DOI: 10.1016/0021-9290(70)90059-X. Available from: http://www.sciencedirect.com/science/article/pii/002192907090059X

[12] MOTHERWAY, Julie A., Peter VERSCHUEREN, Georges VAN DER PERRE, Jos VANDER SLOTEN a Michael D. GILCHRIST. *The mechanical properties of cranial bone: The effect of loading rate and cranial sampling position.* Journal of Biomechanics. 2009, vol. 42, issue 13, s. 2129-2135. DOI: 10.1016/j.jbiomech.2009.05.030. Available from: http://www.sciencedirect.com/science/article/pii/S0021929009003285#

[13] Bone Tissue: [online], [cit. 2016-03-05], Available from: https://www.studyblue.com/notes/note/n/chapter-7-bone-tissue/deck/11431494

[14] NEČAS, Emanuel. *Patologická fyziologie orgánových systémů*. 2. vyd. Praha: Karolinum, 2009, s. 381-760. Učební texty Univerzity Karlovy v Praze. ISBN 978-802-4617-121.

[15] GANONG, William F. *Přehled lékařské fyziologie*. 20. vyd. Praha: Galén, c2005, 890 s. ISBN 80-726-2311-7.

[16] PROCHÁZKOVÁ, Silvie. *Úroveň znalostí všeobecných sester o problematice intrakraniálního tlaku* [online]. Olomouc, 2011 [cit. 2016-04-06]. Available from: http://theses.cz/id/pdpvu2/00152107-821282340.pdf. Bakalářská práce. UNIVERZITA PALACKÉHO V OLOMOUCI, Fakulta zdravotnických věd.

[17] PEREZ-BARCENA, Jon, Juan Antonio LLOMPART-POU a Kristine H. O'PHELAN. *Intracranial Pressure Monitoring and Management of Intracranial Hypertension. Critical Care Clinics* [online]. 2014, vol. 30, issue 4, s. 735-750 [cit. 2016-04-08]. DOI: 10.1016/j.ccc.2014.06.005. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0749070414000517

[18] SAMEŠ, Martin. Neurochirurgie: učebnice pro lékařské fakulty a postgraduální studium příbuzných oborů. 1. vyd. Praha: MAXDORF, 2005, 127 s. ISBN 80-734-5072-0.

[19] Medscpe: Decompressive Craniectomy:[online], [cit. 2016-03-17], Available from: http://www.medscape.com/viewarticle/559009_2

[20] Internal documents Tampere University of Technology from lectures. Subject: *Biomaterials*. Teacher: Niina Ahola. Available from: https://moodle2.tut.fi/course/search.php?search=Biomaterials

[21] Internal documents Tampere University of Technology from lectures. Subject: *Research & Productization*. Teacher: Timo Allinniemi. Available from: https://moodle2.tut.fi/course/search.php?search=Research+%26+Productization

[22] The Free dictionary: Medical dictionary: [online], [cit. 2016-04-16], Available from: http://medical-dictionary.thefreedictionary.com/osteointegration.

[23] HARRIS, Dominic A., Abigail J. FONG, Edward P. BUCHANAN, Laura MONSON, David KHECHOYAN a Sandi LAM. *History of synthetic materials in alloplastic cranioplasty*. Neurosurgical Focus [online]. 2014, vol. 36, issue 4, E20- [cit. 2016-04-08]. DOI: 10.3171/2014.2.FOCUS13560. Available from: http://thejns.org/doi/abs/10.3171/2014.2.FOCUS13560

[24] JARDINI, André Luiz, Maria Aparecida LAROSA, Rubens Maciel FILHO, CecíliaAmélia de Carvalho ZAVAGLIA, Luis Fernando BERNARDES, Carlos Salles LAMBERT, Davi Reis CALDERONI a Paulo KHARMANDAYAN. *Cranial reconstruction: 3D biomodel and custom-built implant created using additive manufacturing*. Journal of Cranio-Maxillofacial Surgery [online]. 2014, vol. 42, issue 8, s. 1877-1884 [cit. 2016-03-15]. DOI: 10.1016/j.jcms.2014.07.006. Available from: http://linkinghub.elsevier.com/retrieve/pii/S1010518214002303

[25] EL HALABI, F., J.F. RODRIGUEZ, L. REBOLLEDO, E. HURTÓS a M. DOBLARÉ. *Mechanical characterization and numerical simulation of polyether–ether–ketone (PEEK) cranial implants*. Journal of the Mechanical Behavior of Biomedical Materials [online]. 2011, vol. 4, issue 8, s. 1819-1832 [cit. 2016-03-17]. DOI: 10.1016/j.jmbbm.2011.05.039. Available from: http://linkinghub.elsevier.com/retrieve/pii/S1751616111001470

[26] VAN DER MEER, Wicher J., RuudR.M. BOS, Arjan VISSINK a Anita VISSER. *Digital planning of cranial implants*. British Journal of Oral and MaxillofacialSurgery [online]. 2013, vol. 51, issue 5, s. 450-452 [cit. 2016-03-29]. DOI: 10.1016/j.bjoms.2012.11.012. Available from: http://linkinghub.elsevier.com/retrieve/pii/S026643561200616X

[27] PIKIS, Stylianos, Jacob GOLDSTEIN a Sergey SPEKTOR. *Potential neurotoxic effects of polymethylmethacrylate during cranioplasty*. Journal of Clinical Neuroscience [online]. 2015, vol. 22, issue 1, s. 139-143 [cit. 2016-04-08]. DOI: 10.1016/j.jocn.2014.06.006. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0967586814003233

[28] CAE DS – Injection MouldingMaterials: Poly(methylmethacrylate) (PMMA): [online], [cit. 2016-04-11], Available from: http://webhotel2.tut.fi/projects/caeds/tekstit/plastics/plastics_PMMA.pdf

[29] EL HALABI, F., J.F. RODRIGUEZ, L. REBOLLEDO, E. HURTÓS a M. DOBLARÉ. *Mechanical characterization and numerical simulation of polyether–ether–ketone (PEEK) cranial implants*. JournaloftheMechanicalBehaviorofBiomedicalMaterials [online]. 2011, vol. 4, issue 8, s. 1819-1832 [cit. 2016-03-28]. DOI: 10.1016/j.jmbbm.2011.05.039. Availablefrom: http://linkinghub.elsevier.com/retrieve/pii/S1751616111001470

[30] BALLARE, Josefina, Inderchand Manjubala, Wido H. Schreiner, Juan C. Orellano, Peter Fratzl, Silvia Ceré. *Improving the osteointegration and bone–implant interface by incorporation of bioactiveparticles in sol–gel coatings of stainless steel implants.* Acta Biomaterialia. 2009, Volume 6, Issue 4, Pages 1601–1609 DOI:10.1016/j.actbio.2009.10.015. Available from: https://www.researchgate.net/profile/Josefina_Ballarre/publication/38017194_Improving_the_osteointegration_and_bone-implant_interface_by_incorporation_of_bioactive_particles_in_sol-gel_coatings_of_stainless_steel_implants/links/0f31752fa39466cc8b000000.pdf

[31] YONG, Li, WeiYang, Li Xiang, Xing Zhang, Cairu Wang, Xiangfei Meng, Yifeng Pei, Xiangli Fan, Pingheng Lan, Chunhui Wang and Zheng Guo. *Improving Osteointegration and Osteogenesis of Three-Dimensional Porous Ti6Al4V Scaffolds by Polydopamine-Assisted BiomimeticHydroxyapatite Coating.* ACS Appl. Mater. Interfaces, 2015, 7 (10), pp 5715–5724 DOI: 10.1021/acsami.5b00331. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25711714

[32] MIT Material Property Database. Massachusetts Institute of Technology [online]. 2004 [cit. 2016-04-01]. Available from: http://www.mit.edu/~6.777/matprops/pmma.htm

[33] SCHMIDT, M., D. POHLE a T. RECHTENWALD. 2007. *Selective Laser Sinteringof PEEK.* CIRP Annals - Manufacturing Technology [online]. 56(1): 205-208 [cit. 2016-04-16]. DOI: 10.1016/j.cirp.2007.05.097. ISSN 00078506. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0007850607000510

[34] LETHAUS, Bernd, Yara SAFI, Mariel ter LAAK-POORT, Anita KLOSSBRANDSTÄTTER, Frans BANKI, Christian ROBBENMENKE, Ulrich STEINSEIFER a Peter KESSLER. *Cranioplasty with Customized Titanium and PEEK Implants in a Mechanical Stress Model*. Journal of Neurotrauma [online]. 2012, 29(6): 1077-1083 [cit. 2016-04-17]. DOI: 10.1089/neu.2011.1794

[35] Carlos Oldani and Alejandro Dominguez. Titanium as a Biomaterial for Implants, ISBN: 978-953-307-990-5, InTech, Available from: http://www.intechopen.com/books/recent-advances-in-arthroplasty/titanium-as-a-biomaterial-for-implants

[36] Azomaterials: PEEK: [online], [cit. 2016-04-17], Available from: http://www.azom.com/properties.aspx?ArticleID=1882

[37] NIINOMI, Mitsuo. *Mechanical properties of biomedical titanium alloys.* Materials Science and Engineering: A [online]. 1998, 243(1-2): 231-236 [cit. 2016-04-16]. DOI: 10.1016/S0921-5093(97)00806-X. ISSN 09215093. Available from: http://linkinghub.elsevier.com/retrieve/pii/S092150939700806X

[38] STAFFA, Guido, Andrea BARBANERA, Andrea FAIOLA, Marco FRICIA, Paolo LIMONI, Ruggero MOTTARAN, Bruno ZANOTTI a Roberto STEFINI. *Custom made bioceramic implants in complex and large cranial reconstruction: A two-year follow-up.* Journal of Cranio-Maxillofacial Surgery [online]. 2012. 40(3): e65-e70 [cit. 2016-04-09]. DOI: 10.1016/j.jcms.2011.04.014. ISSN 10105182. Available from: http://linkinghub.elsevier.com/retrieve/pii/S1010518211001053

[39] AO Foundation: Cranial Vault & Skull Base – Special considerations: Cranioplasty (bone versus alloplast): [online], [cit. 2016-03-15], Available from: https://www2.aofoundation.org/wps/portal/surgery?showPage=redfix&bone=CMF&segment=Cranium&classification=93-Special%20considerations&treatment=&method=Special%20considerations&implantstype=hidden&approach=&redfix_url=1289999576062&Language=en

[40] Craniomaxillofacial Surgery: Titanium Osteosynthesis. KLS Martin Group [online]. 2015 [cit. 2016-03-18]. Available from: http://www.klsmartin.com/products/implants-andimplant-systems/cmf/titanium-osteosynthesis/?L=2

[41] Cranial RepairProducts. Medtronic [online]. 2015 [cit. 2016-03-18]. Available from: http://www.medtronic.com/for-healthcare-professionals/productstherapies/neurological/cranial-repair-products/index.htm

[42] Cranial Fixation. Aesculap [online]. 2015 [cit. 2016-03-18]. Available from: https://www.aesculapusa.com/products/neurosurgery/cranial-fixation

[43] Orthopedics Skull Lock Cranioplasty Cranial Titanium Plate: [online], [cit. 2016-03-08], Available from: http://cn-hos.en.alibaba.com/product/1365102050-218162828/Orthopedics_Skull_Lock_Cranioplasty_Cranial_Titanium_Plate.html

[44] MARCIANO, Frederick, A. Giancarlo VISHTEH. *Fixation techniques for cranial flap replacement. Operative Techniques in Neurosurgery* [online]. 1998, 1(1): 50-56 [cit. 2016-03-18]. DOI: 10.1016/S1092-440X(98)80008-X. ISSN 1092440x. Available from: http://linkinghub.elsevier.com/retrieve/pii/S1092440X9880008X

[45] SYRETT, B.C and A. ACHARYA. *Corrosion and degradation of implant materials: a symposium sponsored by ASTM committee F-4 on metal and surgical materials and devices, and ASTM committee G-1 on corrosion of metals,* American society for testing and materials, Kansas City, Mo., 22-23 May 1978. Philadelphia, Pa.: ASTM, 1979, 356 s. ASTM special technical publication 684.

[46] Interaktivní studijní podpory předmětu Biomechanika II zaměřené na tvorbu výpočtových modelů: [online], [cit. 2016-04-15], Available from: http://biomechanika.fme.vutbr.cz/index.php?option=com_content&view=article&id=88%3Ainteraktivni-studijni-podpory-pedmtu-biomechanika-ii-zamene-na-tvorbu-vypotovych-model&catid=38%3Aopory&Itemid=97&lang=cs

[47] NARRA, Nathaniel, Jiří VALÁŠEK, Markus HANNULA, Petr MARCIÁN, George K. SÁNDOR, Jari HYTTINEN a Jan WOLFF. *Finite element analysis of customized reconstruction plates for mandibular continuity defect therapy*. Journal of Biomechanics [online]. 2014, 47(1): 264-268 [cit. 2016-04-16]. DOI: 10.1016/j.jbiomech.2013.11.016. ISSN 00219290. Available from: http://www.sciencedirect.com/science/article/pii/S002192901300568X

[48] HUOTILAINEN, Eero, Risto JAANIMETS, Jiří VALÁŠEK, Petr MARCIÁN, Mika SALMI, Jukka TUOMI, Antti MÄKITIE a Jan WOLFF. *Inaccuracies in additive manufactured medical skull models caused by the DICOM to STL conversion process*. Journal of Cranio-Maxillofacial Surgery [online]. 2014, vol. 42, issue 5, 259-265 [cit. 2016-04-18]. DOI: 10.1016/j.jcms.2013.10.001. Available from: http://www.sciencedirect.com/science/article/pii/S1010518213002862

[49] Ridwan-Pramana, A., Marcián, P., Borák, L., Narra, N., Forouzanfar, T. &Wolff, J. (2016) *Structural and mechanical implications of PMMA implant shape and interface geometry in cranioplasty – a finite element study*. Journal of Cranio-Maxillofacial Surgery [online] 2015, vol. 44, issue 1, 34-44 [cit. 2016-03-07]. Available from: http://www.sciencedirect.com/science/article/pii/S1010518215003546

[50] 3Ders – 3D printer and 3D printing news: [online], [cit. 2016-04-15], Available from: http://www.3ders.org/articles/20150603-medical-first-in-brazil-3d-printed-titanium-skull-successfully-implanted-in-23-year-old-woman.html

[51] ASM Aerospace Specification Metals Inc.: *Titanium*: [online], [cit. 2016-05-08]. Available from: http://asm.matweb.com/search/SpecificMaterial.asp?bassnum=MTP641

[52] Boedeker.com: *PEEK (PolyEtherEtherKetone) Specifications*: [online], [cit. 2016-05-08] Available from: http://www.boedeker.com/peek_p.htm

[53] Joon B. Park, Roderic S. Lakes, *Biomaterials an introduction*.Springer Science & Business Media, 1992. ISBN: 978-0-387-37879-4

[54] ANSYS. v13.0 producthelp

[55] Ichim, I., Swain, M., Kieser, J. A.: Mandibular Biomechanics and Development of the Human Chin, Journal of Dentistry Research, 85 (2006) 638-642.

[56] Jee, W. S. S., Principles in bone fysiology, Review Article, *Journal of musculoskeletal & neuronalinteractions*, 1(2000) 11-13.

[57] Brianne, M., Mulvihill, A., Prendergast, P. J.: An algorithm for bone mechanoresponsiveness: implementation to study the effect of patient-specific cell mechanosensitivity on trabecular bone loss, *Computer Methods in Biomechanics and Biomedical Engineering*, 11 (2008) 443-451.

[58] Frost, H. M., Does bone design intend to minimize fatigue failures? A case for the affirmative, *Journal of Bone and Mineral Metabolism*, 18 (2000) 278-282.

[59] K. Smith *et al*., "Automated measurement of pediatric cranial bone thickness and density from clinicalcomputedtomography," *2012 Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, San Diego, CA, 2012, pp. 4462-4465. DOI: 10.1109/EMBC. 2012. 6346957.

[60] McElhaney, James H., Fogle, John L., Melvin, John W., Haynes, Russell R., Roberts, Verne L., Alem, Nabih M. (1970/10).*Mechanical properties of cranial bone*. Journal of Biomechanics 3(5): 495-496. Available from: http://hdl.handle.net/2027.42/32686

[61] Motherway, Julie A., Verschueren, Peter, Van der Perre, Georges, Vander Sloten Jos, Gilchrist, Michael D., Lim, C. T., Goh, J. C. H. *The Mechanical Properties of Cranial Bone*. 6th World Congress of Biomechanics (WCB 2010). August 1-6, 2010 Singapore. 978-3-642-14515-5. Available from: http://link.springer.com/chapter/10.1007%2F978-3-642-14515-5_197