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Parametric models of the plate implants for humerus bone

DOCTOTAL DISSERTION

Niš, 2018

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МАШИНСКИ ФАКУЛТЕТ

Мохаммед.М.Расхид Ал-Ријебат

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Data on doctorial dissertation

Doctoral Supervisor:	Dr. Miodrag Manić, Full professor,University of Niš, Faculty of Mechanical Engineering
Title:	Parametric models of the plate implants for humerus bone
Abstrac:	In the field of orthopaedic surgery the main goal is to find the best treatment for the person with bone fracture or other trauma. In the treatment of the fractures of the bones, surgeons apply techniques of internal and external fixation. External fixation is a surgical technique used for stabilization of bone fragments with the fixator positioned outside of the human body (only pins and screws go inside the body). The alignment of the external fixator can be adjusted externally to provide optimal position of the bone and bone fragments during the recovery process. Internal fixation presumes use of osteofixation material (screws, pins, plate implants) inside the human body, in order to stabilize the bone fracture. Both internal and external fixation can be used for the healing of the bone fracture, but internal fixation is preferable, since there is better functional recovery of the bone. Plate implants are the most used internal fixators for the surgical treatments of the bone fractures. They are made in the various sizes and shapes, in order to be used for different patients. The application of such implants for the treatment of the unique patient bone may initiate problem because the bone and the plate implant may be different in size and shape.. In such cases it is hard to find proper position of the plate, the patient's treatment may be hampered due to inadequate transfer of load during bone healing process, etc. The problem can be reduced if the implants known as the personalized implants (PPIs) are used. The geometry and shape of PPIs are customized to the anatomy and morphology of the bone of the particular patient. Positive effects on patients are present but there is the need for more preoperative planning and production. PPIs are used in the situations when, if the predefined implant are used, it can lead to both intra-operative and post-operative complications.
Key Words:	personalized implants ,Method of Anatomical Features (MAF) , manufacturing ,Plate implan , fixators
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Подаци о докторској дисертацији

Ментор:	Др Миодраг Манић, редовни професор, Универзитет у Нишу, Машински факултет
Наслов:	Параметарски модели плочастих имплантата за кост хумеруса
Резиме:	U oblasti ortopedske hirurgije glavni cilj je pronalaženje najboljeg tretmana za osobu sa prelomom kostiju ili drugom traumom. U lečenju preloma kostiju, hirurzi primenjuju tehnike unutrašnje i spoljne fiksacije. Spoljašnja fiksacija je hirurška tehnika koja se koristi za stabilizaciju fragmenata kostiju s fiksatorom postavljenom izvan pacijentog tela (samo uglavci i vijci ulaze unutar tela). Poravnanje vanjskog fiksatora može se izvaditi spolja kako bi se osigurala optimalna pozicija dijelova kostiju i kostiju tokom procesa oporavka. Unutrašnja fiksacija podrazumijeva korištenje osteofiksacionog materijala (vijci, igle, implantati ploča) unutar pacijentog tijela, kako bi se stabilizirao fraktura kostiju. I unutrašnja i spoljna fiksacija mogu se koristiti za lečenje preloma kostiju, ali je poželjna unutrašnja fiksacija, jer postoji bolji funkcionalni oporavak kosti. Implant ploče su najčešće korišćeni unutrašnji fiksatori za hirurške tretmane preloma kostiju. Napravljene su u različitim veličinama i oblicima, kako bi se koristile različitim pacijentima. Primena takvih implantata za lečenje jedinstvene kosti pacijenta može pokrenuti problem jer se implantata kosti i ploča mogu razlikovati po veličini i obliku .. U takvim slučajevima teško je pronaći odgovarajuću poziciju ploče, tretman pacijenta može biti otežani zbog neadekvatnog prenosa opterećenja tokom procesa zarastanja kostiju itd. Problem se može smanjiti ako se koriste implantati poznati kao personalizovani implanti (PPI). Geometrija i oblik PPI-a su prilagođeni anatomiji i morfologiji kosti određenog pacijenta. Pozitivni efekti na pacijente su prisutni, ali postoji potreba za preoperativnim planiranjem i proizvodnjom. PPI se koriste u situacijama kada, ako se koristi predefinisani implant, može dovesti do intraoperativnih i post-operativnih komplikacija
Научна област:	Машинско инжењерство
Научна дисциплинаК	Производни системи и технологије
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Abstract

In the field of orthopaedic surgery the main goal is to find the best treatment for the person with bone fracture or other trauma. In the treatment of the fractures of the bones, surgeons apply techniques of internal and external fixation. External fixation is a surgical technique used for stabilization of bone fragments with the fixator positioned outside of the human body (only pins and screws go inside the body). The alignment of the external fixator can be adjusted externally to provide optimal position of the bone and bone fragments during the recovery process. Internal fixation presumes use of osteofixation material (screws, pins, plate implants) inside the human body, in order to stabilize the bone fracture. Both internal and external fixation can be used for the healing of the bone fracture, but internal fixation is preferable, since there is better functional recovery of the bone.

Plate implants are the most used internal fixators for the surgical treatments of the bone fractures. They are made in the various sizes and shapes, in order to be used for different patients. The application of such implants for the treatment of the unique patient bone may initiate problem because the bone and the plate implant may be different in size and shape.. In such cases it is hard to find proper position of the plate, the patient's treatment may be hampered due to inadequate transfer of load during bone healing process, etc. The problem can be reduced if the implants known as the personalized implants (PPIs) are used. The geometry and shape of PPIs are customized to the anatomy and morphology of the bone of the particular patient. Positive effects on patients are present but there is the need for more preoperative planning and production. PPIs are used in the situations when, if the predefined implant are used, it can lead to both intra-operative and post-operative complications.

Problem Description

Two different problems can occur in creating bone models and their proper forming which are based on the date obtained from medical scanners. The both problems are in direct connection with data or morphology geometry of human bone since they can be incomplete. There are different reasons for the insufficient data.

There are some circumstances when volumetric scanner cannot be used: high level radiation must not be applied on some patients, or some patients have metal implants or there is no adequate scanner in some institutions and so on. The result of this can be one or two 2D images (if we use digital device) or film (if we use x-ray device). It was very hard to complete the 3D bone visualization if 2D data are used, so to create 3D geometrical bone models which are constructed on one or more 2D images are possible since some methods are available today.

The second problem is incapability to create a complete bone image. This is not in the connection with the obtaining bone data from medical images (sometimes it is the problem) but it depends on the patient's health condition. These conditions are: osteoporosis, multiple bone fractures, other diverse acute and chronic diseases and such.

In both cases it is essential to create valid geometrical model of the human bone. Valid geometrical model means that it provides enough geometrical, topological and morphometric data for the surgeon to plan and perform intervention and post-operative recovery process.

Geometrical model of the human bone is not enough to conduct surgical intervention. If surgeon plans to apply internal fixation for the treatment of the bone, than plate implant and other fixation elements must be properly defined. This presumes several tasks: Selection of proper plate implant (standard or personalized).

If standard plate is used than decision about application of pre-contoured or other standard plates (e.g. angular, reconstruction) must be made.

Creation of plate geometrical model if personalization or pre-bending needs to be done.

Pre-bending of standard plate or Production of personalized plate which are adapted to the patient bone.

Other tasks like: plate position, screws selection, screwing order, etc. Of course, the simplification of whole process is done, in order to clearly define possible problem(s). The pre-bending of standardized plates, or application of pre-contoured plates, depends on plate type and fracture type and position, and it is not always necessary. But, if personalization and customization of the plate implant is required, than surgeons and engineers must work together in order to manufacture plate implant and apply it to the specific patient. This presumes selecting the material of the implant, creation of the geometrical model, production

of the physical model, implantation of the plate in the patient body, monitoring the post-operative process, etc.

This research had four main goals:

- The first goal of the dissertation was to improve existing Method of Anatomical Features (MAF) [3] which can be used in construction of complete geometrical model of human humerus, which foundation can be both complete and incomplete input data, and which would greatly improve the process of preparation, planning and execution of orthopaedic surgeries.
- The second goal was to create novel method which will enable personalization of the plate implant geometrical model for proximal and distal humerus. In other words it was necessary to construct parametric geometrical model of the plate implants, and to improve method(s) for its production.
- Next goal was to develop User Defined Feature elements for the creation of personalized plate implant models
- Last main goal was to define manufacturing procedure for the production of the plate implants personalized to specific patient.

Developed solution

The improved MAF method is developed and applied in the case of human humerus reconstruction process. The improvement is done in the area of Referential Geometric Entities (RGEs) [9] definition. New complex surfaces are constructed and served as basis for the definition of other geometry on the bone model.

Since we wanted to improve the pre-, intra-, and post-operative procedures in the treatment of the distal humerus fractures author propose application of the PPI created by the new technique presented in this thesis. This technique enables construction of the geometrical prototype of the PPI whose contact surface with the bone is adapted to bone's geometry and morphology. For this purpose, parametric model of the PPI is created. Parametric model can be made if the toplogy is not changed but the geometry can be adjusted if the value of parameters (specific dimensions) is changed. This model is constructed by the application of the Method of Anatomical Features (MAF) which enables creation of fully geometrically defined anatomical surfaces of the human bones [10-12]. Parametric model can be used as an

elementary model for the manufacturing of the PPI by implementation of the specific and ordinary manufacturing procedures. For the purpose of PPI model application, User Defined Feature (UDF) was created in CATIA software package. This UDF enables automatic creation of personalized plate model for the specific bone fracture or other trauma, in accordance with values of morphometric parameters measured on medical images. UDF application was tested against real clinical case, and the results are more than promising, which will be presented in the later section of the thesis.

Solution Discussion

The plate implants are necessary orthopaedic equipment, and their design and ways of production should be constantly improved. As already stated, plates play very important role in bone healing process.

In this thesis are presented the methods which make the creation of human bones possible as well as cloverleaf fixation plate for each patient and geometrical models for distal plate.

The main advantage of usage of these methods is that it is possible to make geometrical models of the implant modified (personalized) for each patient individually. If the shape, geometry and topology of the implant which is used as a geometrical model are adjusted, it is done in the terms of the terms of shape, geometry and topology of patient's humerus. A surgeon can control adjustments by making more corrections of the geometrical prototype of the plate(s) if it is necessary (e.g. the patient's health situation requirements).

The base for this approach is the application of the MAF method. More precisely, it represents extensions of the aforementioned method by introducing and defining the corresponding parameters for the purpose of creating a parametric model of the plate. Pre-contouring i.e. adaptation of the plate is achieved by inserting and changing the value of the existing parameters, according to the dimensions values acquired from the 2D or 3D model of the humerus bone, while topology remains unchanged. Adaptation of the plate model is possible through the UDF application, which is created in CATIA. UDF enables inserting the parameters values and as a consequence, shape and geometry of the plate models are personalized to the specific patient. UDF application is presented on the use case defined through the clinical case, which is publically available on the internet. Results show that presented requirements can be fulfilled quite satisfactory.

The possibility of plate adaptation before surgery, improves preoperative processes, shortens the time of intervention as well as improves stability of the fracture and satisfies functional properties of the bone and joints. It is very important to consider that the importance of this approach for plate models creation lies down in its flexibility for adaptation. It is not always important to just make geometrically accurate plate model, yet, it is important to create flexible model. If parametric model can be flexible enough to conform to the specific case, than surgeon shall not need to use bending during the surgery and that will shorten the surgery time, which is crucial for the patient health. Plate models created in presented way, are flexible by default.

Deviation analysis between plates contact surface and bone outer shows that plate shape can be adapted to the patient specific bone in accordance with standard recommendations in clinical practise, or to the requirements of the specific medical case.

Created geometrical models can be applied in production of bone and plate models by using ordinary and specific technologies, making of preliminary prototypes for the Finite Element Analysis (FEA), in preparation in orthopaedics before operations and the wide range of usages in both medicine and engineering. The results which are presented in this study of geometrical and anatomical accuracy of the human humerus are parametric plate models are quite acceptable.

Contents

1. Introduction

CAOS (Computer Assisted Orthopaedic Surgery) is a scientific and technical discipline where computer technology is applied for the treatment of the patients in the field of orthopaedic surgery. CAOS brings together various fields of science and technology, like medicine, engineering, mathematics, robotics, computer vision, information systems, and other [1, 2]. The main requirement of CAOS is to provide the medical treatment which is as good as possible to the patient. It includes all the stages of the treatment: pre-operative, intra-operative and/or post-operative procedures. One of the elements which greatly influence on the outcome of applied CAOS procedures are accurate geometrical models of human bones. The geometrical accuracy, topological similarity, anatomical and morphological correctness of these models are required goals of every procedure applied for theirs creation. With these models it is possible to better perform pre-operative procedures, or to conduct intra-operative tasks with greater accuracy. Also, such models enable creation of customized bone implants and fixators using additive and/or other manufacturing technologies [3, 4].

In orthopaedic surgery there is need to deliver the medical treatment as good as possible for the patient not only with the bone fracture but with any other bone trauma as well. In the treatment of the fractures of the bones surgeons apply methods of internal and external fixation. External fixation is a surgical technique used for stabilization of bone fragments with the fixator positioned outside of the human body (only pins and screws go inside the body) [5]. The alignment of the external fixator can be adjusted externally to provide optimal position of the bone and bone fragments during the recovery process. Internal fixation presumes use of osteofixation material (screws, pins, plate implants) inside the human body, in order to stabilize the bone fracture [6-9]. Both internal and external fixation can be used for the healing of the bone fracture, but internal fixation is preferable, because it contributes to better functional recovery of the bone [6].

Plate implants are the most used internal fixators for the surgical treatments of the bone fractures. They are made in the various sizes and forms, in order to be used for different patients [8]. The application of such implants for the treatment of the unique patient bone may initiate a problem, because the size and the form of the bone and the plant implant can be different. In such cases it is hard to find proper position of the plate, the patient's treatment

may be hampered due to inadequate transfer of load during bone healing process, etc. This problem can be reduced by the application of the implants known as personalized plate implants (PPIs). The geometry and shape of PPIs are modified to the anatomy and morphology of the particular patient's bone [9-12]. Application of PPIs has a positive outcome on patients, but at the same time it needs more time for preparations before operation and their production [12]. This is the reason why PPIs are used in cases when the predefined implants application can cause the both intra-operative and post-operative complications.

Distal Humerus fractures are common fractures of the human arm (elbow), and that's why they are the main centre of attention of the research conducted in this thesis. It is of great importance to properly stabilize the elbow while the patient is in the recovery process [13, 14]. For this purpose pre-contoured plates are used. If the quality of the bone is poor (osteoporotic bone), then pre-contoured angular stable plates are used [14]. In the cases when standard plates are applied for fixation of the distal humerus fractures, then, the plate must be adapted to the shape of the patient bone (e.g. bending of the plate during the surgery, or pre-bending before surgery) [14, 15].

1.1 Problem description

Two different problems can occur in creating bone models and their proper forming which are based on the date obtained from medical scanners. The both problems are in direct connection with data or morphology geometry of human bone since they can be incomplete. There are different reasons for the insufficient data.

There are some circumstances when volumetric scanner cannot be used: high level radiation must not be applied on some patients, or some patients have metal implants or there is no adequate scanner in some institutions and so on. The result of this can be one or two 2D images (if we use digital device) or film (if we use x-ray device). It was very hard to complete the 3D bone visualization if 2D data are used, so construction of 3D geometrical bone prototypes which are founded on one or more 2D images are possible since some methods are available today.

The second problem is incapability to create a complete bone image. This is not in the connection with the obtaining bone data from medical images (sometimes it is the problem) but it depends on the patient's health condition. These conditions are: osteoporosis, multiple bone fractures, other diverse acute and chronic diseases etc. Surgeons are not in the situation

to plan surgical procedures based on a partial image appropriately; as the result of this, some surgical decisions and alternatives have to be made during the surgery itself.

In both cases it is essential to create valid geometrical model of the human bone [16]. Valid geometrical prototype means that it provides enough geometrical, topological and morphometric data for the surgeon to plan and perform intervention and post-operative recovery process.

Geometrical model of the human bone is not enough to conduct surgical intervention. If surgeon plans to apply internal fixation for the treatment of the bone, than plate implant and other fixation elements must be properly defined. This presumes several tasks: Selection of proper plate implant (standard or personalized).

- If standard plate is used than decision about application of pre-contoured or other standard plates(e.g. angular, reconstruction) must be made.
- Creation of plate geometrical model if personalization or pre-bending needs to be done.
- Pre-bending of standard plate or Production of personalized plate which are adapted to the patient bone.
- Other tasks like: plate position, screws selection, screwing order, etc.

Of course, the simplification of whole process is done, in order to clearly define possible problem(s). The pre-bending of standardized plates, or application of pre-contoured plates, depends on plate type and fracture type and position, and it is not always necessary. But, if personalization and customization of the plate implant are required, than surgeons and engineers must work together in order to manufacture plate implant and apply it to the specific patient. This presumes selecting the material of the implant, creation of the geometrical model, production of the physical model, implantation of the plate in the patient body, monitoring the post-operative process, etc.

1.2 Goal of the research

This research had four main goals:

- The first goal of the dissertation was to improve existing Method of Anatomical Features (MAF) [3] to enable creation of complete geometrical model of human humerus, based on both complete and incomplete input data, and which would also

make better and easier the procedures of preparation, planning and execution of orthopaedic surgeries.

- The second goal was to construct novel method which will enable personalization of the plate implant geometrical model for proximal and distal humerus. In other words it was necessary to construct parametric geometrical prototype of the plate implants, and to improve method(s) for its production.
- Next goal was to develop User Defined Feature elements for the creation of personalized plate implant models
- Last main goal was to define manufacturing procedure for the production of the plate implants personalized to specific patient.

1.3 Research Subject

The subject of this research of the dissertation are methods of Reverse and Biomedical Engineering, that are used to get 3D geometrical models of the human long bones, and to enable production of the personalized plate implant.

1.4 Developed solution

The improved MAF method is developed and applied in the case of human humerus reconstruction process. The improvement is done in the area of Referential Geometric Entities (RGEs) [9] definition. New complex surfaces are constructed and served as basis for the definition of other geometry on the bone model.

In order to make better and easier the pre-, intra-, and post-operative procedures in the treatment of the distal humerus fractures author propose application of the PPI created by the new technique presented in this thesis. This technique enables construction of the geometrical prototype of the PPI whose contact surface with the bone is adapted to bone's geometry and morphology. For this purpose, parametric model of the PPI is created. Parametric model can be made if the topology is not changed but the geometry can be adjusted if the value of parameters (specific dimensions) is changed. This model is constructed by the application of the Method of Anatomical Features (MAF) which enables creation of fully geometrically defined anatomical surfaces of the human bones [10-12]. Parametric model can be used as an elementary model for the manufacturing of the PPI by implementation of the specific and ordinary manufacturing procedures. For the purpose of PPI model application, User Defined Feature (UDF) was created in CATIA software package. This UDF enables automatic

creation of personalized plate model for the specific bone fracture or other trauma, in accordance with values of morphometric parameters measured on medical images. UDF application was tested against real clinical case, and the results are more than promising, which will be presented in the later section of the thesis.

2 Literature review

Literature review will cover three important research subjects:

- Bone remodeling techniques: CAD techniques; Reverse Engineering techniques and procedures; Types of geometrical models; and other.
- Plate implants: History of human bone treatments; Types of fixations; Types of fixators and implants; Design techniques; Application of plate implants; and other.
- Biomaterials: Applicable materials; Advantages and Disadvantages of adequate materials; Production of plate implants; and other.

2.1 Bone remodeling

In order to create geometrical models which fulfil requirements defined by today's clinical practice, various methods are applied. These methods can be separated: by the type of model which they create, by the type of scanning device which is implemented for the acquisition of medical (bone) data, or by the techniques which are implemented, etc. In general, two types of models can be created and they are three-dimensional (volumetric) and two-dimensional. Volumetric models represent models which are defined in 3D space and they can be separated as boundary/surface (point cloud, wireframe, polygonal, etc.) and solid models (various CAD models, Finite Element Analysis Models, etc.). They can be created by the application of various techniques (Direct modelling, Parametric modelling, etc.) which are generally known and presented in [3, 16-18]. 2D models provide much less information then 3D models and they are used (created) in the cases where there is need for fast reaction from medical practitioners, or volumetric models are not available. In most cases these models are created by two-dimensional scanning of the patient with X-ray or Ultrasound devices [19]. As already stated, volumetric models provide more detailed geometrical and topological information then 2D models, and because of that it is essential to develop methods which can provide precise 3D models of the human bones. Accurate 3D models of human bones are in the majority of cases created on the basis of the geometrical data acquired from the three-

dimensional medical scanning devices (like Computer Tomography – CT, 3D Ultrasound), or on the basis of two or more 2D images from two-dimensional scanning devices (X-ray or Ultrasound) [3, 19, 20]. As a result of the application of these methods various types of geometrical models of human bones are created.

Geometrical modeling of human bones will be presented on the process of creation of human humerus surface geometrical model. The geometry and anatomy of the human humerus is well known and described in literature [21, 22]. The modeling procedures applied for the creation of the geometrical model of human humerus are presented in [19, 23-24]. These procedures are mostly based on CT data and techniques used for remodelling in Medical software (Mimics, 3D Doctor) or in some other software which are used for remodeling (i.e. CAD), and they are used for construction of geometrical prototype of any organ in a human body, and not just humerus bone [3,19]. These are standard procedures which involves standard modeling techniques (meshing, free-form modeling) and they provide geometrical models of human bones of satisfying quality. In this paper authors propose application of newly developed Method of Anatomical Features (MAF) for the construction of the surface of geometrical model of the humerus bone. MAF has been already used for the modeling of the surface geometrical prototypes of the human femur and tibia bone as presented in [3, 21]. MAF provides: geometrical definition of anatomical sections of the human bone, geometrical definition of the morphometric parameters of the human bone, polygonal and surface models of the human bone, parametric point cloud model of the human bone, and other elements described in [3,22]. The resulting model presented in this paper shows that MAF can be used for the construction of geometrical prototype of the human humerus of good geometrical accuracy and anatomical correctness.

2.2 Introduction to humerus fractures

The location of the fracture and the type of the fractures are used to classify them. A fraction can occur on three locations: the top of the humerus close to the shoulder is known as the proximal location, at the shaft of the humerus is the middle location and at the bottom part of the humerus close to the elbow is the distal location. [23] One of the four types of fractures which are based on the displacement of the greater tubercle, the lesser tubercle, the surgical neck and the anatomical neck are proximal fractures. These are four parts of the proximal humerus and their fracture displacements are considered to be no less than one centimetre of separation or measurement of angles more than 45º. One-part fracture is without

displacement of any part of humerus, two-part fracture is a fracture is a fracture with one part displaced comparable to the other three, three-part fracture is a fracture with two displaced fragments and four-part fracture is a fracture when all the fragments are displaced from one another. Fractures of the humerus shaft can be divided into four groups of fractures: transverse, spiral, ''butterfly'' and pathological fractures. ''Butterfly'' fractures are both transverse and spiral fractures at the same time. The fourth group of the fractures which has been mentioned above as pathological fractures is caused by some diseases. Split between supracondylar fractures are distal fractures, which are transverse fractures above the two condyles at the bottom of the humerus, and intercondylar fractures, which involve a T- or Y-shaped fracture that splits the condyles [23].

To evaluate humerus injures, it is very important to classify them if there is need for that, to reduce and immobilize them and to ask for orthopaedic consultation. Since 80% of proximal humerus fracture are without displacement or with minimal displacement, they can be treated without operation. [23] Patients who suffer from osteoporosis commonly have associated injures as well. Ipsilateral proximal forearm fractures are in the connection with distal humeral fractures. Direct trauma to the arm or shoulder can be the reason and can cause humerus fractures or if the axial loading is transmitted through the elbow. Attachments from pectoralis major, deltoid, and rotator cuff muscles impact the level of displacement of proximal humerus fractures. Humeral stress fractures can appear when the patient does the overhead throwing and sometimes if fierce muscle contractions are performed. These categories of fractures are very common in sports such is baseball. As with other stress fractures, other reasons for these conditions are: an increase in activity, stress on a bone which is not mature enough or if it is an unconditioned bone.

Humeral diaphyseal fractures take part with 1.2% of all fractures [24]. Proximal humerus fractures take part with 5.7% of all fractures [24]. Proximal humeral fractures are more frequent among elderly people, who are approximately 64.5 years old [25, 26], and they are the third most common fractures. The first two groups of common fractures are hip fractures and distal radius fractures. Humeral diaphyseal fractures are more common among a little bit younger population, with the average age of 54.8 years [25].

Fracture patterns are similar for all ages, though older people suffer more from fracture because of osteoporosis. If the humerus fracture occurs with a child who is not prone to it, it should be suspected that the child is abused. Young patients who have humeral diaphyseal

fractures after high-energy injuries often have multiple injuries. There are approximately 5% of these patients who have diaphyseal fractures present with spinal fractures or complex foot fractures, and about 4% present have pelvic or proximal tibial fractures [25]. Older patients suffer more from other fractures in the ipsilateral arm and they are mostly distal radius fractures [26].

2.2.1 AO/OTA Classification of humerus fractures

This classification is founded on fracture location and the existence of impaction, angulation, translation, comminution, or dislocation. Every fracture type is further placed in a subgroup according to displacement, valgus or varus angulation of the humeral head, comminution and the presence and direction of glenohumeral joint dislocation [27].

1. Type A: extra-articular, unifocal, associated with a single fracture line, lowest avascular necrosis (AVN) risk
    - A1: greater tuberosity fracture
    - A2: surgical neck fracture with metaphyseal impaction
    - A3: surgical neck fracture without metaphyseal impaction
2. Type B: extra-articular, bifocal, associate with two fracture lines, higher AVN risk
    - B1: surgical neck fracture with metaphyseal impaction and a displaced fracture of either the greater or lesser tuberosity
    - B2: nonimpacted surgical neck fracture with a displaced fracture of either the greater or lesser tuberosity
    - B3: surgical neck fracture with a displaced fracture of either the greater or the lesser tuberosity and glenohumeral dislocation
3. Type C: articular fracture, involving either the humeral head or anatomic neck, most severe, highest AVN risk
    - C1: Anatomic neck fracture with slight displacement
    - C2: Anatomic neck fracture with marked displacement
    - C3: Anatomic neck fracture with glenohumeral dislocation

AO/OTA classification of long bones fractures are presented in Fig. 1a and 1b.

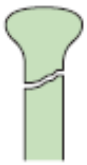
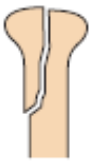
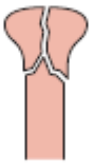
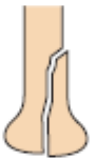
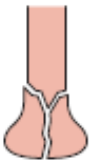
Segment	Type		
	A	B	C
1 Proximal			
	Extraarticular No involvement of displaced fractures extending into the articular surface	**Partial articular** Part of the articular component is involved, leaving the other part attached to the meta-/diaphysis	**Complete articular** Articular surface involved, metaphyseal fracture completely separates articular component from the diaphysis
2 Diaphyseal			
	Simple One fracture line, cortical contact between fragments exceeds 90% after reduction	**Wedge** Three or more fragments, main fragments have contact after reduction	**Complex** Three or more fragments, main fragments have no contact after reduction
3 Distal			
	Extraarticular No involvement of displaced fractures extending into the articular surface	**Partial articular** Part of the articular component is involved, leaving the other part attached to the meta-/diaphysis	**Complete articular** Articular surface involved, metaphyseal fracture completely separates articular component from the diaphysis

Figure 1.1AO/OTA classification of long bones fractures - www2.aofoundation.org

2.2.1.1 Subtypes classification

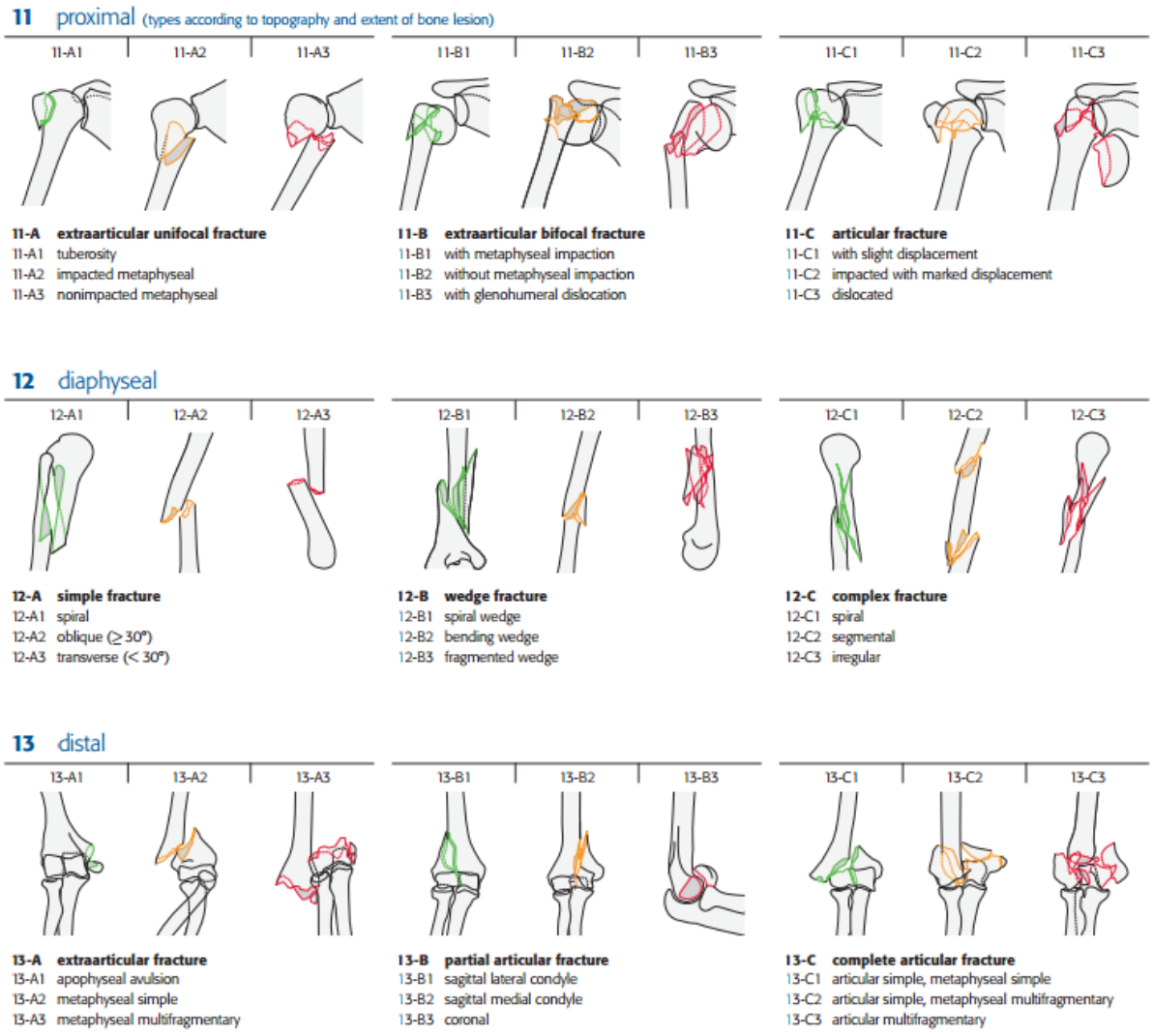


Figure 2.AO/OTA Subtype classification of humerus -www2.aofoundation.org

2.3 Introduction to reduction and fixation in orthopaedic surgery

In the field of orthopaedic surgery there is the need to deliver the medical treatment as good as possible for the person with bone fracture. In the treatment of the fractures of the bones surgeons apply techniques of internal and external fixation. External fixation is a surgical technique used for stabilization of bone fragments with the fixator positioned outside of the human body (only pins and screws are implanted inside the body) [28]. The alignment of the external fixator can be adjusted externally to provide optimal position of the bone and bone fragments during the recovery process. Internal fixation presumes use of osteofixation

material (screws, pins, plate implants) inside the human body, in order to stabilize the bone fracture [29-32]. Both internal and external fixation can be used for the healing of the bone fracture, but internal fixation is preferable, because there is better functional recovery of the bone when these two types of fixation are used [29].

Plate implants are the most used internal fixators for the surgical treatments of the bone fractures. They are made in the various sizes and shapes, in order to be used for different patients [31]. The application of such implants for the treatment of the unique patient bone may initiate a problem, because the bone and the plate implant can have different size and shape. In such cases it is hard to find proper position of the plate, the patient's treatment may be hampered due to inadequate transfer of load during bone healing process, etc. This problem can be reduced by the application which is known as Patient Specific Plate Implants (PSPIs). The geometry and shape of PSPIs are customized to the anatomy and morphology of the bone of the particular patient [3, 32-34]. Usage of PSPIs has a good outcome on patients, but it requires more time for preoperative preparation and their manufacturing [34]. That is the reason why PSPIs are used in cases where the usage of predefined implants possibly leads to both intra-operative and post-operative complications.

Distal humerus fractures are common fractures of the human arm (elbow). It is of great importance to properly stabilize the elbow while the patient is in the recovery process [35, 36]. For this purpose plates which are previously contoured are used. If the quality of the bone is poor (osteoporotic bone), then angular stable plates are used [36]. In the cases when standard plates are applied for the fixation of the distal humerus fractures, then, the plate must be adapted to the shape of the patient bone (bending of the plate during the surgery) [36, 37].

2.3.1 The history and principles of bone fractures treatment

Fractures were treated traditionally during the centuries in the past [40-44]. The most long bone fractures were treated by bracing, casting or splinting a joint above and below the fracture. All these treatments were not applicable to femur fracture, so traction was the main treatment procedure. It was not possible to apply these standard treatment procedures with open fractures of ballistic wounds since they were accompanied with soft tissue injures and there was the danger of sepsis, so the only solution was amputation.

Gyps immobilisation

At the end of 19th century gypsum, became a leading medium for the immobilization in Europe. Certain types of gypsum immobilisation methods were familiar with the Arabs, and they were used in the Islamic countries. In the year 1967, method of functional gypsum immobilization (Sarmiento method) was introduced. The actual treatment was applied on the fracture which is known as „crus fracture“, and it is significant to mention that this treatment was not the standard treatment when a knee gypsum boot is applied; opposite to it, physician Sarmieto used the „moment device“, (i.e. the pattelar – tendon – Bearing cast). [40,41].

Traction

“Traction is described as the method that helps in the process of reposition and it prevents the healing of the fracture with fragment dislocation and shortening of extremities by the influence of the muscle fiber force” [40].Scientist Galen (130 – 200 A.D.) was the first to implement traction treatment – blossoming treatment. Mr. Quven (14th century) (1300 – 1307) was using the traction treatment method and he gave a good description of it in his book titled, “ Chirurgic Magna”. Surgeon Herr. Albot Hoffa (1859- 1907) used the traction treatment for the reposition of humerus and femur bone. Josh Crosby and other surgeons used the traction and additionally to it, in order to create traction and sustention, they used: the adhesive tapes, bandages and set of weights. “It is important to note that the traction can be replaced by a gypsum immobilization as a permanent solution, just following the relative fracture consolidation” [40].Modern traumatology nowadays applies the process of the traction intra operation by applying the tables with the specific structure, and by this kind of surgical approach, osteosynthesis can be achieved. This is primarily the case in hand surgery, where cross skin extensions are applied (something like a glove). [40-42]

Internal fixation

Internal fixation must follow three main principles: To enable movement of muscles and joints in the area of fracture; To provide complete restoration of the bone; To enable direct union of the bone fragments without visible deformation in other areas of tissue (like forming the visible callus) [9,43]. The main tasks for the internal fixation were to enable stability to the bone and surrounding tissue, to maintain blood supply to the bone, and finally to prevent possible fracture diseases like infection in the area of trauma [44]. In the process of internal

fixation surgeon can invoke two patterns of stability, which will influence the kind of bone healing that will appear: absolute stability (results in direct bone healing), and relative stability (results in secondary or indirect bone union). Absolute stability means that there is no movement between bone fragments, and relative stability means that bone fragments can create motion during their union with the main bone or with each other [9,45].

In order to enable proper healing of the bone, surgeons use various mechanical components which provide mechanical and functional stability to the bone during recovery process. The main components which are used for internal fixations are: wires, pins, screws and plates [43 - 46].

Brief history of Plates in internal fixation

For more than a century orthopaedic surgeons have been using plates for internal fixation of fractures. The first usage of this metal plate was in 1895. by Lane. This plate was abandoned because of corrosion. Lambotte and after him, Sherman introduced their versions of the internal fracture fixation plate in 1909. The corrosion resistance of the plate was improved because of the improvement in the metallurgical formulation. The both designs had one weakness and it was their insufficient strength [8]. Eggers continued the development of the fracture plate design during 1948. This plate was with two long slots so that screw heads could slide and in that way compensate the resorption of the fragment ends. The problem with this plate was in inadequate stability of fixation elements, due to the structural weakness. Müller introduced one more design which enabled interfragmentary compression by tightening a tensioner in 1965. That tensioner was temporarily to the bone and the plate for some time. “With this design, Müller and his group set the stage for the rigid plating of fractures that resulted in a mode of bone healing characterized by the absence of periosteal callus formation” [10]. By the time the use of the tensioner was rejected and replaced by oval holes which have a design which has no difference from Bagby plate. This altered construction which is known as a dynamic compression plate (DCP) was created and it was believed that it was without awareness of Bagby and Jone’s development. Two members of Swiss group of researchers, Schenk and Willenegger, referred to the compression technique supported by Bagby and Janes in 1967. They named this plate as a dynamic compression plate (DCP) [46] but it was possible to recognize only one static compression at the time.

A new plate design was developed by the Swiss group. They wanted to reduce the plate’s contact with cortical perfusion and in that way to reduce cortical porosis. This design was

named the limited contact-dynamic compression plate (LC-DCP) [8, 47]. Intent of this design was to reduce bone-plate contact by approximately fifty percent (50%).

One study [42] measured the bone-plate contact area for both DCPs and LC-DCPs which were fixed to cadaveric bone and it found “no apparent differences in interface contact area attributed to bone plate design.” This contradicts the assertion by Gautier and Perren who claimed that the LC-DCP reduces the contact area by 50%. [8,48]

The cortical blood flow with laser Doppler flowmetry of canine tibias fixed with a DCP or LC-DCP, was measured in [48]. These findings supported the results presented in [48].Conclusion was made that “the LCDCP is not advantageous in fracture healing or restoration of cortical bone perfusion to devascularized cortex.”

Wires and Pins

Kirschner wire fixation (K-wires) is a method of fixation in which metal wires with sharp points are applied in a place of fracture. The diameter of the K-wires can be from 0.6 - 3.0 mm [49]. They can provide temporal and conclusive fracture fixation. The resistance to bending is reduced to the smallest level, so they are mostly used with other types of fixation (methods of stabilization). The important characteristics of the K-wires are that damage to the bone and surrounding tissue is minimal [49].

Steinmann pins (diameter: 3-6 mm) are very similar to K-wires, and they are used for the same purpose. The main difference is in size; Steinmann pins are made in larger dimensions. Pins and wires are made in different lengths and end tips can be different in size and shape. The most common pointed ends are a three-sided trocar tip (for penetrating corticular bone) or a two-sided chisel (for penetrating endosteal surface of the bone’s cortex or for lodging in cancellous bone). The K-wires and Steinmann pins can be fully threaded, partially threaded at the end tip, or unthreaded. In each case it is significant to slowly insert pins or K-wires into the soft tissue and bone, and if it is possible to use image intensifiers for correct positioning and alignment [50, 51].

In order to provide stability of the fracture K-Wires and pins are used in assembly with other fixation components like screws or plates. If there is need K-Wires and pins can be used for skeletal traction. This happens in the situations when the skin traction cannot stand the force which is exerted, or when it is found that the skin traction is not suitable for the part of the body which is treated. With the use of tensioners, components can be pre-strained in order to support more bending load during treatment [49, 50].

It is important to plan pin and wire placement in order to avoid possible permanent fixation device. If it is achievable, pins should be located parallel to screws which are used for fracture compression. According to the diameter, pins can be considered as guide wires for cannulated screw fixation as well [52]. Pin or wire fixations are frequently applied for fractures of the phalanges, metacarpals, metatarsals, proximal humerus, and wrists [52]. K-wires very often supplement tension-band wire constructs at olecranon, patella, and medial malleolus fractures. Pin and wires are presented in Fig. 3.

Figure 3. *3Pins and wires*[1]

Screws

An elementary part of modern internal fixation is bone screws and it is possible to apply them separately or with some specific kinds of implants [52-54]. They consist of tip, shaft, thread and head. On the thread several elements should be recognized: thread diameter, shaft diameter, pitch and lead (Fig. 4).

The screw's resistance to breakage or tensile strength is determined by the root diameter. Pitch impacts purchase strength in bone. If the pitch increases it increases the bone material between the threads but it decreases the number of threads per unit of distance at the same time. The lead means the distance which a screw achieves with a complete turn. Lead is the same as pitch if the screw is single threaded, and lead is twice the pitch if the screw is double-threaded (faster screw insertion).

[1] Securos Surgical, © 2010 Securos, Europe http://www.securos-europe.eu/products/pin-wire-management/?L=1

Screws can be of different shapes and sizes and they can be classified according to: design (e.g. locking head), dimension (e.g.3.5 mm); traits (e.g. self-tapping, self-drilling), area where they are applied (e.g. cortex bone, cancellous bone) and function or mechanism [45,54].

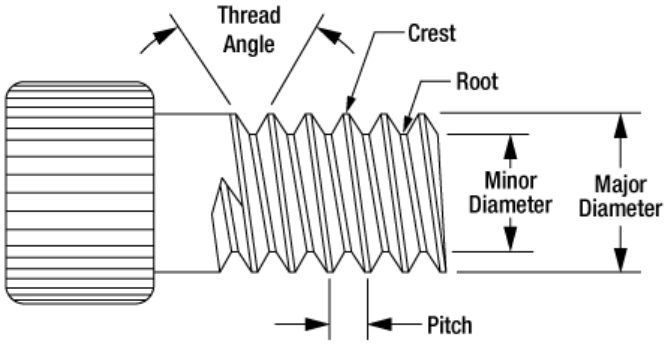


Figure 4.Screw thread parameters[2].

There are two types of screws which are used for fixation of the bone fragments, and which are defined by the bone density (or area of application): cortical screws, constructed for compact bone, and cancellous screws, constructed for the trabecular bone [52]. A cortical screw has smaller pitch, and bigger minor diameter then cancellous screws, because compact diaphyseal bone is stronger than trabecular metaphyseal bone. Some types of screws are presented in Fig. 5.

[2]ThorLabs, Copyright 1999-2016 Thorlabs, Inc., https://www.thorlabs.com/tutorials.cfm?tabID=37745

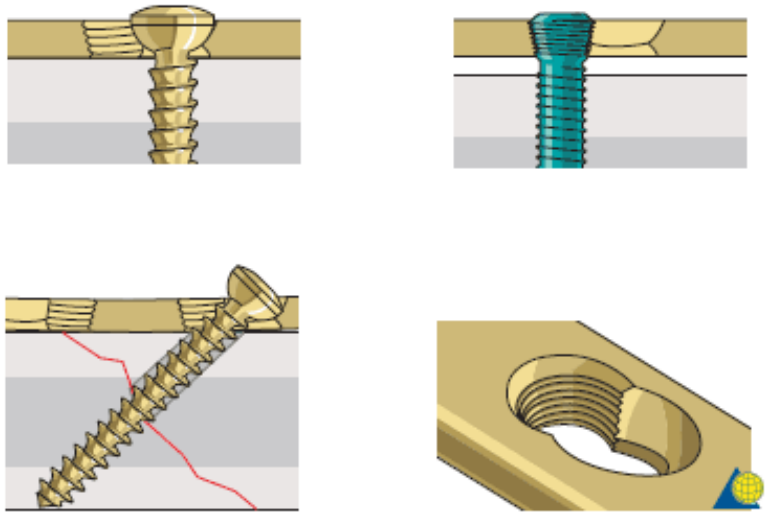


Figure 5. *Locking and convetional Screw -Both can be used in Locking compression Plates combination holes [43]*

For compression of a fracture surface (lag screw), for fixation of a plate bone by making impression between the plate and the bone (plate screw), a screw can be applied just as it may be used for fixation of internal fixator (locking head screw) to a bone (Fig.3). Two fragments are held by a position screw together without compression. It is possible to use lag screws separately which are inserted through a plate. The expression lag screw is not used to depict the screw morphology, but it is used as a term which defines the function of compression of two fragments.

It is important to mention that since locking head screws are applied in orthopaedic surgery all other screws are named conventional [45, 53, 54].

2.4 Plates

When the human bones fracture occurs it is possible to use different types of implants. [55]. Plates and their variations are mostly used today. The very often ones are plates and their variants. The one of the first plates were compression plates which use various designs and external devices to enable compression of bone fragments [55]. Compression plates with oval holes made introduction to the Dynamic Compression Plates (DCP) [56]. Oval holes were used in order to provide interfragmentary compression during screw tightening. DCP incorporates specially designed oval holes similar to the ones described in [55], in order to compress bone particles while a screw is being fastened. The benefits of the DCP are low incidence of malunion, stable internal fixation, and there is no necessity for external immobilization which allows immediate movement of neighbouring joints [56, 57]. To

provide adequate stability and to enable functional requirements of the bone, DCPs have to be placed onto the periosteum (the tissue that lines the outer surface of all bones) and should be pressed onto the bone. [55-58]. This requirement rises one important issue and that is cortical bone porosis at the site of placement, because of prohibited blood supply. There are some questions since this problem was reported.[58, 59]. This problem was connected to the plates with small contact area. Refracture after plate removal, was another problem with DCPs. In order to prevent refracture it was highly recommended that the plate should not be taken out 15–18 months at least [55] in order to eliminate fracture gap between bone fragments. Different studies analysed the reasons for refracture and the conclusion was that refracture was a effect of cortical necrosis [50,60].

In order to lower the plate's contact with cortical perfusion the new plate was designed which decreased cortical porosis. The construction was named the limited contact-dynamic compression plate (LC-DCP) [55]. LC-DCP make less surface to surface contact with the periosteum of the bone in comparison with the DCP. In this way necrosis of cortical bone and osteopororsis under the bone were reduced. Also, LC-DCP is constructed with plate-hole symmetry, which enables dynamic compression from either side of the hole with different intensity [55]. It should be noted that some studies [60,8] were conducted which shows that LC-DCP does not improve blood flow to the bone, or biomechanical properties of the bone-implant assembly.

Today, nearly all of the mentioned plate implants were substituted with plates which are capable for both locking and unlocking functions, such as Locking Compression Plates (LCP). It is not possible that conventional plating can be replaced by locked plating. [55].It is possible to use both techniques as a combination. It is possible to use both techniques as a combination and should be performed whenever it is possible [55, 57-59]. LCP gives better fixation and they can bear more load compared to standard plates (DCP) [61]. To choose the best fixation for the particular patient it is necessary to take in account quality of reduction, soft-tissue handling, the kind of injury and the ovrall condition of health of the patient which all together have the most important impact on the final successful recovery. DCP and LCP fixation methods are based on anatomically precontoured plates, reducing or eliminating intra-operative (in-situ) plate modification (usually bending). LCP does not require precise contouring because the plate does not need to touch the bone with all its surface-it is not

required when locking screws are used. In such cases plate acts more like fixator rod. However, greater distance between the plate and the bone can cause a problem [61-63].

It is important to mention that reconstruction plates which are constructed with deep notches among the holes can be contoured (bend) in three planes to fit complex surfaces. Reconstruction plates are different in straight and they are a bit thicker and stiffer precurved lengths. Their screw holes are oval, like mentioned compression plates, and they allow potential limited compression [64]. Plates are presented in Fig. 6.

The new objective in plates design and production is to achieve maximum stabilization with minimum damage to the blood supply during fracture healing. Also, there is a need for extremely rigid fixation during the healing of fractures, and less rigid fixation during later bone remodelling.

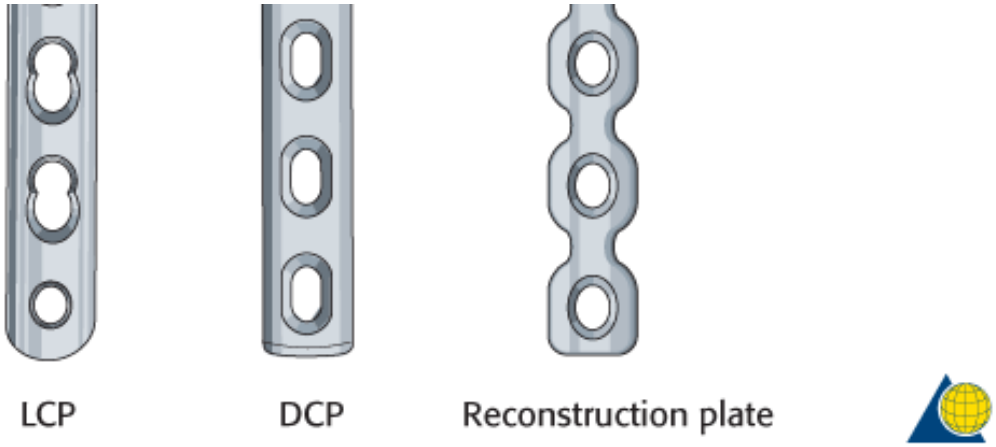


Figure 6*.Various types of plates used for bone healing*

2.5 Biomaterials

All materials which are synthetic that can be used to substitute or re-establish function to a body tissue is a biomaterial [65-98. A biomaterial can constantly or periodically be in connection with body fluids. This definition is restrictive in a way, since materials which are used as instruments used in surgical or dental procedures cannot be used in these circumstances. These instruments are in contact with body fluids, but they do not substitute or increase the function of human tissue. When we say that biomaterials are exposed to body fluids that means that the biomaterial is placed within the interior of the body, and because of that there are a few strict limits on materials which can be considered as a biomaterial. Foremost and the most important, a biomaterial has to be biocompatible which means that it mustn't provoke an adverse reaction from the body, and otherwise. It mustn't be toxic and non-carcinogenic. Those demands exclude many manufacturing materials that are obtainable. Next, the biomaterial is supposed to have appropriate physical and mechanical characteristics to work as enhancement or substitution of body tissues. For practical reasons a biomaterial should be easily handled and easily used in the terms of forming and fabricated into shapes and at the same time it should be cheap and available at all the time. Some archaeologists claimed that biomaterials were used thousands of years ago since they found some metal dental implants which had been used before 200AD. Today, biomaterials are defined as "artificial or natural materials used in the manufacturing structures for replacing the lost or diseased biological structure to restore its form and function". Two main characteristics of biomaterials are biofunctionality and biocompatibility [65 - 72].

The perfect material or combination of materials should have the following characteristics;

- It should be of chemical composition which is biocompatible in order to avoid adverse reaction of the tissue;
- Excellent resistance to degradation (it means that metals should be resistant to corrosion or polymers should be resistant to biological degradation);
- Adequate level of intensity to bear periodic loading endured by the joint;
- A low modulus to reduce bone resorption;
- High wear resistance to minimize wear-debris generation;

Possibility of biomaterials application is defined through next factors: osteoinduction, growth degree of cells, and degradation degree of the biomaterials in case of non-permanent

scaffolds [65, 68]. It is possible to classify biomaterials and these groups are: into bio-inert, bio-active, bio-degradable, and materials with a possibility of bimolecular incorporation [71, 63], as is presented in Table 1.

"Bio-inert biomaterials decrease the potential for a negative immune response to the implant, while bioactive materials interact in a positive manner with the body to promote localized healing" [65]. Bio-active and Bio-inert materials are used broadly in manufacturing orthopaedic and that means bone plates as well. [65,74]. It is generally known that any upgrade in biomaterials which are used for manufacturing of bone plates directly influence improvements in techniques of bone plates implementation.

Table 1.Biomaterials cassifiication [66]

Table 1 Implant materials can be classified based on the type of material used and the biologic response they elicit when implanted[3]

Biodynamic activity	Chemical composition		
	Metals	Ceramics	Polymers
Biotolerant	Gold		Polyethylene
	Co-Cr alloys		Polyamide
	Stainless steel		Polymethylmethacrylate
	Niobium		Polytetrafluroethylene
	Tantalum		Polyurethane
Bio inert	Commercially pure titanium	Al oxide	
	Titanium alloy (Ti-6AL-4U)	Zirconium oxide	
Bioactive		Hydroxyapatite	
		Tricalcium phosphate	
		Bio glass	
		Carbon-silicon	

2.5.1 Bio-metals

Bio-metals are the most common biomaterials used in medical practise for fabrication of medical devices which means bone plates as well [65]. Bio-metals are inorganic metallic biomaterials. They are not biodegradable, but some researches are currently undertaken in order to create alloys with biodegradable properties. Stainless steel, cobalt alloys and titanium alloys are the bio-metals which are mostly used in orthopaedic surgery.

Stainless steel is the mostly used biomaterial for fabrication of bone plates since it has some characteristics which are very important for this purpose. These characteristics are: cost, mechanical firmness, fabricating implants, and misshaping of implant during surgery /

bending or pre-contouring. Stainless steel AISI 316L (ASTM F138 & F139) is mostly used in biomedical applications in medical practise since it has better fatigue firmness, more ductility and better workability. One drawback for the application of this alloy is that contains Nickel which can be toxic. Stainless steel is generally suitable for application in implant devices which are not applies permanently. Facture plates, screws and hip nails are some of them.

ASTM International is an international standards organization that develops and publishes technical standards for a variety of materials, products, systems, and services, and their recommendation are four types of cobalt-chromium (Co-Cr) alloys which can be used in surgical implant implementation including cast Co-Cr-Mo alloy (F75), wrought Co-Cr-W-Ni alloy (F90), wrought Co-Ni-Cr-Mo alloy (F562) and wrought Co-Ni-CrMo-W-Fe alloy (F563) [71]. Predominantly, cobalt based alloys are highly impervious to fatigue and breaking because of the corrosion [71-82], especially caused by chloride within crevices [82], they may fail because of fatigue fracture.

Only four grades of commercially pure titanium (cpTi) are recognized as good materials for medical implementation (ISO 5832-2) [83]. ASTM F67 and Ti-6Al-4V ELI alloy, are commonly used for biomedical implementation [84, 85]. However, the firmness of cpTi is inadequate, and the metals of vanadium (V) and Aluminum (Al) in Ti-6Al-4V ELI alloy are toxic. So Ti alloys which have no toxic were developed not long ago [86]. Also, some studies [67] are carried out to enhance the wear resistance of Ti-based materials. This is why the alloys of Titanium and Zirconium (Ti-Zr) are recommended since they response well in terms of bio-functionality and biocompatibility [79].

Shape memory alloys (SMA) have ability to return to their memorized shape and all that they need for this is an alternation of temperature. SMAs have been considered for medical applications because of their can recover their genuine shape after exposition to mechanical load and because they can maintain the deformed shape all the time while they are heated [85-88].

2.5.2 Polymers and bio-composites

Bio-metals are mostly unresolvable and can cause toxicity because of corrosion. They can cause early failure because of heterogeneous stress distribution, because modules of the implant are more elastic in comparison with bone [65]. That is the reason why numerous studies [65] have been made in which the main subjects are organic biomaterials and

biocomposites: Polymethyl-methacrylate (PMMA), Poly lactic acid (PLA), Poly glycolic acid (PGA), LPLA (PLLA), D-PLA (PDLA), Polyglycolic acid (PGA), Polycaprolactone (PCL), Polyhydroxybutyrate (PHB), poly ether–ether-ketone (PEEK), Poly (2-hydroxy-ethylmethacrylate) (PHEMA), and Polydioxanone (PDS). These studies proved that instead of metallic orthopaedic implants, implants made of biocomposites and biopolymers can be used. Despite of it, they are not commonly used in practice because of their poor mechanical characteristics and they are used only in dental implants and in small flexible internal fixators. In early 1970s there were some studies which tried to improve carbon fiber-reinforced-epoxyresin as a material which can be used in bone plates.

"Generally, studies on biocomposites, bioglass fibers, Carbon/PEEK composite material, nonhomogenous stiffness graded (SG) and flexible Kevlar/BCP (biphasic calcium phosphate) demonstrate that the mechanical properties of the biocomposites plates are comparable with Bio-metals. Additionally, biodegradable polymers should be seriously considered in the design of new plates. Finite element studies acknowledge these results. According to findings, stress shielding in bone SG plate is less compared to Stainless Steel plate. Since SG plates are more flexible, they permit more bending of the fractured bone, higher compressive stress at the fractured interface which induces accelerated healing and higher tensile stress in the intact portion of the bone" [65].

2.5.3 Bioceramics

Bioceramics are categorized as inorganic biomaterials [65]. Bioactive ceramics are Alumina, Zirconia, Yttria-stabilized Zirconia (Y-TZP), (HA) and Hydroxy Carbonate Apatite (HCA), tricalcium phosphate (TCP), Bioglass® (BG), and glass ceramic (A-W G-C1) and they have been studied for orthopaedic applications [81-88]. They have low tensile strength and lower fracture toughness in comparison to the human cortical bone and for these reasons it is impossible to use them solitarily to substitute a bone or a bone plate in a joint which bears high loads especially in the situations when very porous ceramics is used. Although bone in-grow is promoted and induced prosthesis stabilization as well, they are not recommended in load bearing applications. For covering other bioiner materials, e.g. titanium alloys [65,96] bioceramics is usually used. Characteristics very similar to the bone recommend calcium phosphate biomaterials. On the other hand, there are some disadvantages in their applying in coating. [82] these disadvantages are delamination and decomposition if they are used for a

longer time, porosities which impact biological properties, toughness and low crack resistance. [82] Z-TZP is the toughest and the strongest among bio-ceramics used nowadays but on the other hand, it is not stable enough when it is implemented for longer time, [82] so it cannot be applied as a permanent implant. “In general, currently bio-ceramics are not suitable for bone plates unless for coating or composition with other biomaterials” [65].

3 Manufacturing of metal medical implants

3.1 Introduction

There are several stages for developing of medical implants and fabricating is merery based on in-vitro tests and computer numerical simulations. The first step is to define the problem which is based on requirements and goals of the working environment. The acceptable action is standardization of resembling fracture. The next step is to give preliminary ideas and to create preliminary design. This design is based on computer tomography (CT) or magnetic resonance imaging (MRI)scans. These scans are employed to create the medical images with high resolution and accuracy which is necessary for the reconstraction of contours (3D prototype). In the third step of the procedure is this prototype as a base for numerical analysis (Finite Element Analysis – FEM) which is a prototype which is going to be improved and its fabricating on a CNC mashine according to the elaborated program. When the prototype is finished, it is tested with various tests: mechanical, chemical, histological and cadavar test (in vitro tests). In this way we verify its performance and functionality. If the tests are positive, the prototype is tried-out on patients (in-vivo) tests. That is the fifth stage. The last stage is clinical use of the developed implant.

3.2 General processing of metal materials

Generally, the initial process of metals includes the process ingot to mill products if the subjects are wrought alloys, and casting process if ther subject is a cast alloy. Powder metallurgy can produce the primary products of metals. Production of implant alloys is considered to be very expensive since there are very complex processes. This is very true for production of Ti alloy. Since the alloys are very reactive, a special operation is neccessary in order to mange finishing of the process of production successfully. This means that there is a need to introduce some new materials which are not so difficult to deal with. [99] There are a

few processes which may be taken into consideration as advanced processes in the fabrication of the materials for implants. These orocesses are: superplastic deformation, isothermal forging and direct metal desposition. Their applying enables better process of production and the products are of better quality. Superplastic deformation (SPD) is an advanced process of forming where is applied deformation of higher degree to form products which have complex shape whereas forming process of the low rate is necessary (Krishna, 1997). Dual phase materials are treated by SPD process because they have potential for that with the additionaly materials are required to have ultra-fine grain composition. This superplasticity, i.e. in duplex stainless steel, is due to dynamic recrystallization assisted grain boundary sliding where, in order to achieve an optimum superplasticity different rate of sliding for the other kind of grain boundary is necessary. There are a few methods of severe plastic deformation processes for production of ultra-fine grain structure such as equal channel angular pressing (ECAP), accumulative roll-bonding (ARB), high pressure torsion (HPT) and others processes similar to this. For superplastic deformation and diffusion bonding processes superplasticity is used nowadays. There is one more advanced process known as isothermal forging where the higher temperature is applied for dies maintaining and therefore reduces die chill and increases metal flow (Campbel, 2006). It is preferable to use rather low strain rate rate in to provide superplasticity state and because of that it is possible to achieve high degree uniform deformation after the procedure. This process delivers longer lifetime of dies a more uniform microstructure and dectreases the step of process in order to get near net form of product. It is more expensive to apply this process because it is more expensive to use high temperature dies material than dies for standardized forging process. One more near net form process is directed metal deposition. Usage of this process reduces the costs of Ti parts production particularly because it saves the utilized material. In the process of complex shape production there is higher material saving. [5].

3.3 Personalized implant manufacturing

In this chapter manufacturing technologies used for the production of plate implants will be presented.

3.3.1 CNC machining (milling)

In fabrication of titanium alloys are applied conventional mashining processes (turning, milling, drilling, high-speed cutting), forming processes (cold and hot forming, hydroforming, forging) and substitutional machining processes (laser cutting, water-jet cutting, direct metal laser sintering, targetz metal deposition technology). Those technics are very challenging since titanium alloys have very high tensite strenght, low ductile yield, 50% lower modulus of electricity (104 Gpa) and about 80% lower thermal conductivity zhan alloys made of steel. Greater “spring back“ may be caused by the lower moduls of ealsticity and deflaction of the object of process. That means that the tools of greater clearnes and more rigid setups should be used. In the yones of the tool contact high temperatures and pressures can arise (the tool-to-workpiece inteface). Laminar chips can remove no more than 25% of te heat and the rest is eliminated through the tools. Conditioned by this phenomenon, it is possible to treat titanium alloys at relatively low cutting speeds. If titanium alloys are treated on higher temperatures which are caused by friction, titanium is more chemically reactive and it can “weld“ to the tool parts during the process. If the surface become over-heated, the interstitial pickup of oxygen and nitrogen can occur. The result of this is the production of a hard and brittle alpha case. For cutting titanium during these operation it is advisible to use carbides with high WC-Co content (K-grades) and high-speed steels with high cobalt content. Cutting depths of turning operations should be as large as it is possible, speed of cutting Vc from 12 to 80m/mm and almost 50% lower than the tools of high-speed steel (HSS) are used. Large volums of cooling lubricants should be used to remove the generated heat. In the presence of clorine, titanium can be susceptible to stress corrosion failures so it is better not to use chlorinated cutting fluids. Since the titanium is very reactive at high temperature, any kind of hot working or forging operation should not be performed above 925%. [100].

3.3.2 Metal forming

Many factors affect titanium alloys in terms of deformability. These factors can be: temperature, structure, chemical composition and strain velocity. One of these factors is a way of deformation. The main reasons why plastic working of titanium alloys is considered to be difficult are: susceptibility to creation of the build-ups on the tools(adhesive wear) and low thermal conductivity, high friction coefficient, high reactivity with gases (oxygen, nitrogen, hydrogen), especially in higher temperature. This means that these parameters of deformation should be chosen according to the process specificity [101].

3.3.2.1 Forging

Forging of titanium and its alloys is the most frequent applied plastic working process in implant production. Different kinds of endoprothesis stems are produced by forging. These stems are mainly knee or elbow joints or stems of the hip. The basic element of each joint of endoprosthesis is a stem. Endoprosthesis stem transfers complex, variable in cycles mechanical loads for 10-15 years. Nowadays only forged stems are used because there was a very negative experience with the casting stems for many years. Forging process of Ti6Al4V titanium alloy is performed in the span of temperature 1000-800ºC. The main influences on the properties of the forged elements have temperature and strain velocity. Because of the high sensitivity to strain velocity, it is more appropriate to use the hydraulic presses than the hammers for forging of titanium . If hydraulic presses are used the alloys formability increases of about 10-12%. Since titanium has low thermal conductivity and because of the high coefficient of friction between the deformed metal and tool, strain heterogencity may occur. The result of this is structure and properties heterogencity. There are some problems and obstacles in hot forging of titanium alloys because of the strong affinity with hydrogen, oxygen and nitrogen. Gascous diffusion causes some changes on the top layer of the product in both microstructure and chemical constitution. These changes are not acceptable when we talk about endoprothesis stems so there is a need to overcome them. It is possible if we overcome three “technological barriers“. These obstacles are: to protect forging surface against gascou diffusion while it is being heated till the forging temperature is reached; between the deformed metal and the tool is fractional resistance which needs to be decreased; the third “barrier“ is proper heat treatment (homogenizing treatment) after the process of forging. This implies that the adequate protective atmosphere has to be provided while the

slug forging (rods) are being heated. At the same time it is necessary to use the adequate technological lubricant. These lubricants have double role: lubricating and protection.[101].

3.3.2.2 Stamping of titanium alloys

To produce some elements for the knee endoprothesis (e.g. clamping plates of the polyethylene inserts, ondyle elements of the sled endoprostheses)the process which is used is stamping. Stamping technology is used in some other productions such as different kinds of castings: for the artificial heart chamber, endoprothesis accelerator cups. Some tools such as forceps are produced by stamping etc.

The adequate plastic properties (annealed state) and microstructure are necessary at the titanium sheets which are applied for draw-parts. It is possible to perform the forming process of titanium sheets in room and higher temperature (semi-hot forming). Semi-hot stamping requires temperature of 350-400ºC. Decreasing the numbers of operations and increasing accuracy of the work sheet-titanium forming in higher temperature is performed. It is considered that it is much more difficult to perform sheet-titanium forming process, especially of Ti6A14V alloy than performing the process of sheet-steel forming. The difficulty rises from high strain hardening, high yield point, tensile strength and susceptibility to creation of the titanium "build ups" on the surface of the steel tools and high frictional resistance, high value of the Re/Rm. Applying of the intermediate annealing have to be in cold stamping process. Stress relief annealing has to be applied on the final products to remove internal stresses. Both annealings: intermediate and stress relief annealing must be performed in the atmosphere which is considered to be protective. The criteria for determination sheet ability to deep drawing operation is limit drawing coefficient m=d/D. When cold stamp process of Ti6A14V titanium alloy is applied m=0.83÷0,76 and when the hot stamp process is applied m=0.83÷0.63. The main impact on process of forming of sheet-titanium has strain velocity, so it is preferable to apply the use of the hydraulic press for titanium sheets forming with the velocity lower than 0.25m/s. In Fig.7 some examples stamping products have been shown.

Figure 7. Some examples of titanium product made by stamping process [101]

3.3.2.3 Die shearing, re-striking

Die shearing process is the process which is mainly used in production of surgical instrumentarium and implants. The starting material in this production is cold-rolled annealed titanium sheets. The next stage is shaping of the blanks applying restriking (to get work hardening in the surface layer) and machining (holes are drilled and milled). Next, after restriking and machining, the next stage of the process is polishing of the implant surface with the aim to get adequate quality of the surface. Die shearing restriking and milling are used in the production of different precise surgical tool (e.g. tweezers).
For cutting of titanium sheets often are used some conventional methods (a guillotine or a blanking tool).

3.3.3 Additive manufacturing in medicine

3.3.3.1 Introduction

Some of the medical technology goals are maintaining, assisting and restoring of a patient's mobility. In many cases, doctors and patients have to rely on custom-made designes or individualized small series of the productions of medical devices. Production of the devices and materials have to be of the best quality. There are smoe other important things for

applying of these products: their economical price and availability. Some of the requirements of the additive manufactoring follows [102]:

- Individualization

  A patient can suffer from long and stressful adoptation phase when a customized prosthetic is applied before a satisfactory effect is obtained. This can often cause high (extra) costs together with the patient's requirement for the desigh of personalized product.

- Complex geometries

It is hard to produce free-form structure by conventional manufacturing methods such as casting, milling and turning. Nowadays, there is an evolving requirement to replicate the successful products used by nature and, for example, to use bionic principles to design and fabricate an implant.

- Functional integration

After manufacturing, many products used as medical devices which meet one or more functions require considerable assembly work. This is the reason why the goal for the manufacturing and development of the products is to incirporate as fwe elements as possible for multiple function.

- Reduced costs

New and innovative products reduces the time of process, so it reduces the pressure on both patient and healthcare system. If a patient is cared for better that means that the financial expenditure for the hospital is lower not only during the process of healing, but the costs are lower for follow-on-treatments.

- Rapid availability

Many medical innovations cannot reach patients for years. On the other hand, if a medical innovation is used and applied faster, patient's benefit is evident. That means that it is very important to speed up the development process of products and their manufacturing.

Every human body is different so the main aim is orthopaedics is to design a product which flts perfectly, which is accepted by body faster and that results in patient's long-term life quality. If we examine individual patient's history we can find out that standardized orthopaedic solutions are not satisfactory enough.

The additive manufacturing provides answer to those requirements:

- Improved patient care

Additive Manufacturing enables production of the lattice structure which remarkably speeds up the process of healing following the implant in the body. Since there is a large, rough surface which can be defined during the fabricating, it enables better bone ingrowth. 3D CAD data of the patient can be used for making the customized implants. This means optimized treatment, shorter hospital stays and minimazied unwanted side-effects.

- Cost-effectiveness for the hospital

  Implants which are patient customized have to meet both needs: of the hospital and of the patient as well. There is the requirement for individualization, but there is the requirement for the economical cost. Additional Manufacturing makes it possible to produce small quantities at reasonable prices. This method enables a high degree of flexibility because if 3D CAD data are used, an implant can be optimized and adopted quickly.

3.3.3.2 Types of additive technologies

Additive Technologies which are common in medicine are Selective Laser Sintering, Fused Deposition Modeling, Multi-Jet Modeling and Stereolithography. The prototype here is made layer after layer according to 3D contour date. The additive technology in comparison to subtractive techniques ca produce promptly complex structures and cavities [103]. Since 2010, the American Society for Testing and Materials (ASTM) group "ASTM F42 – Additive Manufacturing", set a group of standards that classify the Additive Manufacturing processes into 7 categories according to Standard Terminology for Additive Manufacturing Technologies. These seven processes are [104]:

1. Vat Photopolymerisation
2. Material Jetting
3. Binder Jetting
4. Material Extrusion
5. Powder Bed Fusion
6. Sheet Lamination
7. Directed Energy Deposition

3.3.3.2.1 Vat Photopolymerisation

Vat Photopolymerisation method is the base for 3D printer which has a container which is filled with photopolymer resin. The photopolymer resin is hardened with UV light source, Fig 8.

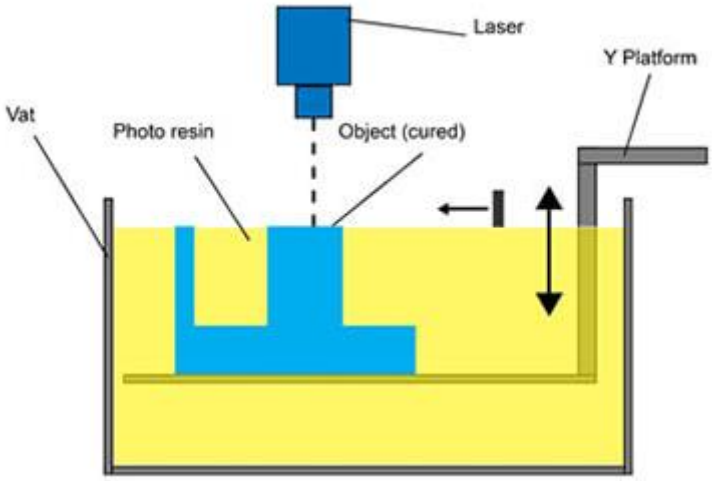


Figure 8. Vat photopolymerisation process[104]

Stereolithography (SLA) is frequently used technology in this process. Layers are built one at a time by using this technology which employs a vat liquid ultraviolet curable photopolymer resin and an ultraviolet laser. The laser beam traces a cross-section of the part pattern on the surface of the liquid resin for each layer. The pattern traced on the resin is cured and solidified by exposure to the ultraviolet laser light and that structure is joined to the layer which is placed under the previous one. After the structure has been traced, the SLA's elevator platform descends by the same distance which is, in fact, the thickness of each layer, typically 0.05 mm to 0.15 mm (0.002″ to 0.006″). Then, a resin-filled blade sweeps across the cross section of the part, re-coating it with new material. On this new liquid surface, the following layer structure is traced, joining the previous layer. This project forms the complete 3D object. Since the object floods in the basin which is filled with liquid resin, there is the need for supporting structures for stereo lithography. These supporting structures bind the part of the elevator platform and hold the object. These structures are eliminated manually but not before the object is finished. Charles Hull invented this technique in 1986. 3D System Company was founded by him as well.

3.3.3.2.2 Material Jetting

This process is very similar to the function of ordinary inkjet paper printer. Material is supplied in droplets through a small diameter nozzle. Material is supplied layer-by-layer to build platform making a 3D object. After that, it is hardener by UV light, Fig.9.

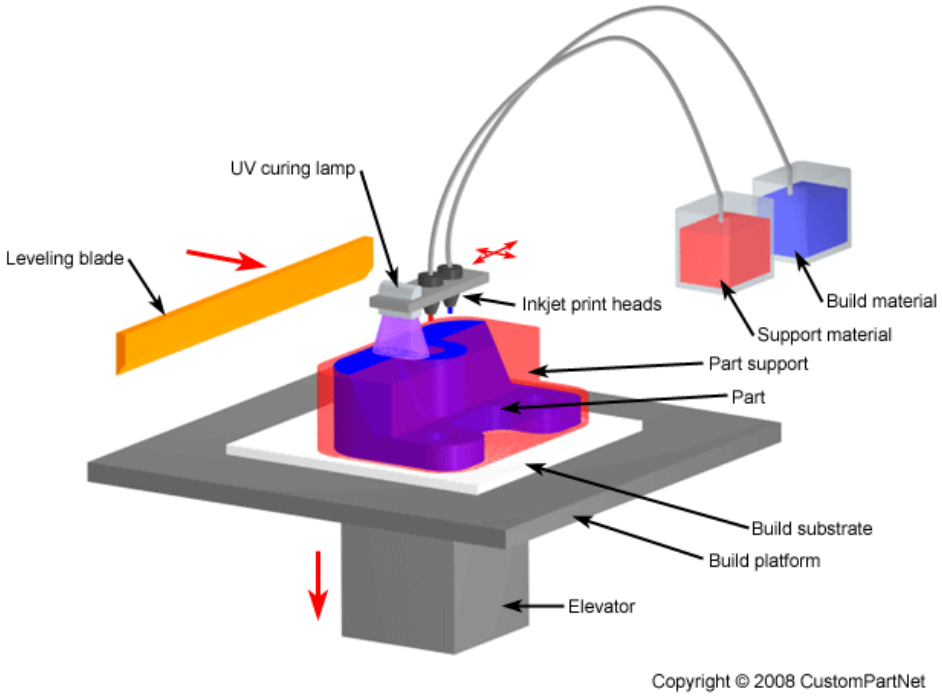


Figure 9.Material Jetting Process [104]

3.3.3.2.3 Binder Jetting

Powder base material and a liquid binder are used with binder jetting. Fig.10. powder is spread in the build chamber in equal layers. Binder is supplied through jet nozzles and the powder particles are ”glued” in the configuration of the programmed 3D object. The completed object is ”glued together” by binder remains in the container with the powder base material. The powder which remains after the print is completed is cleaned and it can be used for the next object 3D printing. Massachusetts Institute of Technology developed this technology for the first time in 1993. Z Corporation got an exclusive licence in 1995.

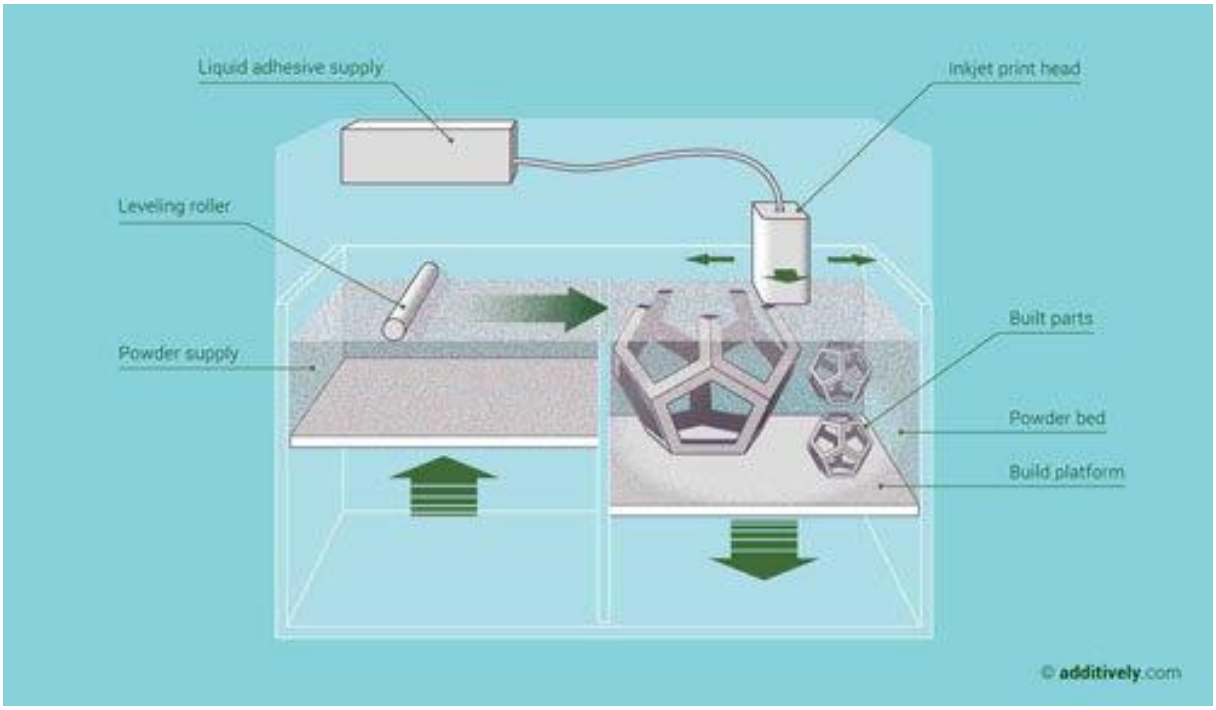


Figure 10. Binder Jetting Process [104]

3.3.3.2.4 Material Extrusion

Fused deposition modeling (FDM) is the most frequently used technology in material extrusion. Fig.11. The FDM uses a plastic filament or metal wire. This metal wire is unwound from coil and it supplies material to an extrusion nozzle. The nozzle has the possibility to turn on and off the flow. This nozzle is heated in order to melt the material and it is possible to move it in both directions: horizontal and vertical by a mechanism which is numerically controlled. It can be controlled and by a computer-aided manufacturing (CAM) software package. When melted material is extruded, it forms layers because the material is hardened instantly and the object is produces. Two plastic filament material types are commonly used in these technologies:

ABS (Acrylonitrile Butadiene Styrene) and PLA (Polylactic acid) but there are other materials which are available ranging in properties from wood filed, conductive, flexible etc.

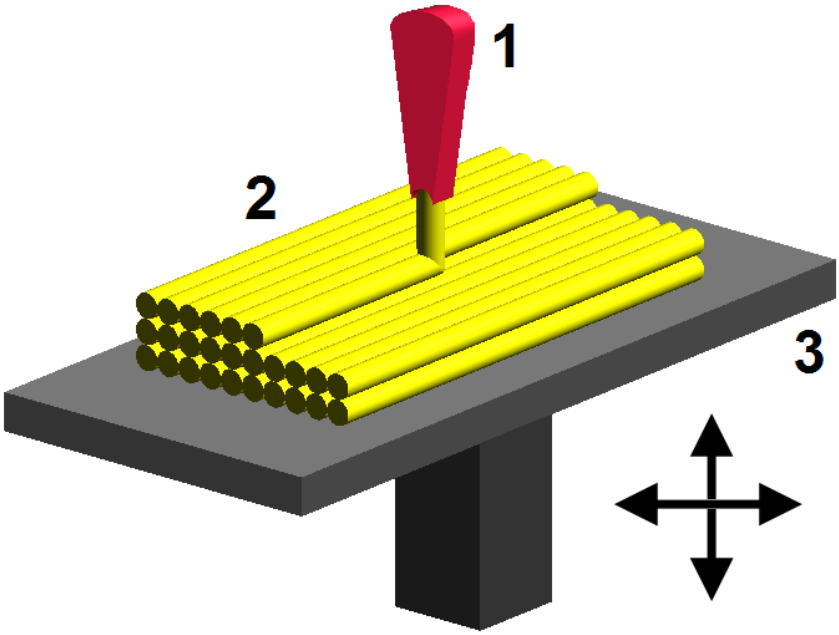


Figure 11. Fused deposition modeling(FDM), ,a method of rapid prototyiping:

1 – nozzle ejecting molten material (plastic), 2 – deposited material (modeled part), 3 – controlled movable table. [104]

Scott Crump invented FDM in the late 1980s he patented this technology and after that he founded the company Stratasys in 1988. If support structures are required they are automatically generated by the software which goes with this technology. There are two materials depended by this machine: one is for the prototype and the other is for a disposable support structure. The term fused deposition model and the abbreviation FDM are Stratasys's Inc trademark. The absolutely equal term, fused filament fabrication (FFF) was invented by the RepRap project and it is legally in use.

3.3.3.2.5 Powder Bed Fusion

In this process the most frequently used technology is Selective Laser Sintering (SLS), Fig. 12.

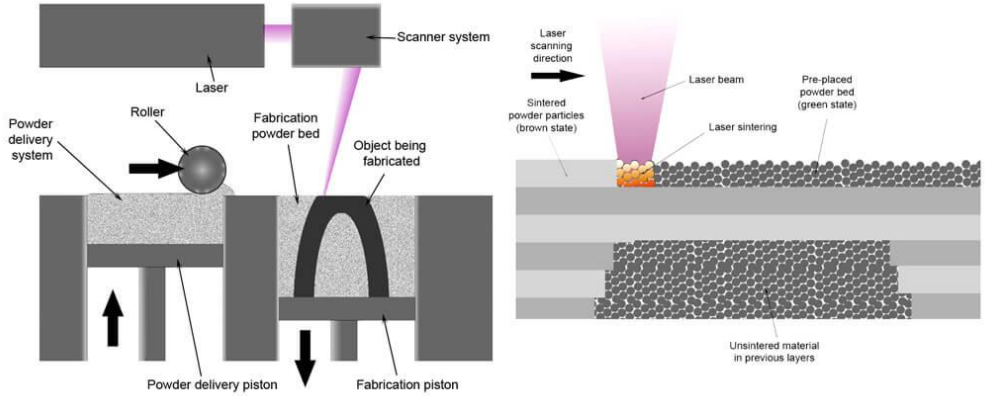


Figure 12.SLS Process [104]

This laser fuses small particles of metal, glass powders, ceramics and plastic into a mass with the dimensional shape which is required. The powdered materials are fused selectively by the laser. They are fused by scanning the cross-section of layers which is obtained by the 3D modeling program on a powder bed's surface. Powder bed becomes lower after every cross-section is scanned. It is decreased for the thickness of one one-layer. The new layer of material comes on the top and the whole operation is done again. This process continues until the object is finished.

A support structure for the object is all untouched powder which remains unchanged. This is the advantage of SLS and SLA since no support structure is required in these process.

3.3.3.2.6 Sheet Lamination

External force is used to bind the sheets together. These bounded sheets are involved as material in sheet lamination. These sheets can be made of paper, metal or they can be in a form of polymer. If paper sheets are used, adhesive glue is used to glue them together and precise blades are used to cut them in required shapes. Mcor Technology is the leading company in this area. Ultrasonic welding is applied to weld the metal sheets and after that the proper shape is obtained by CNC milling. Fig. 13.

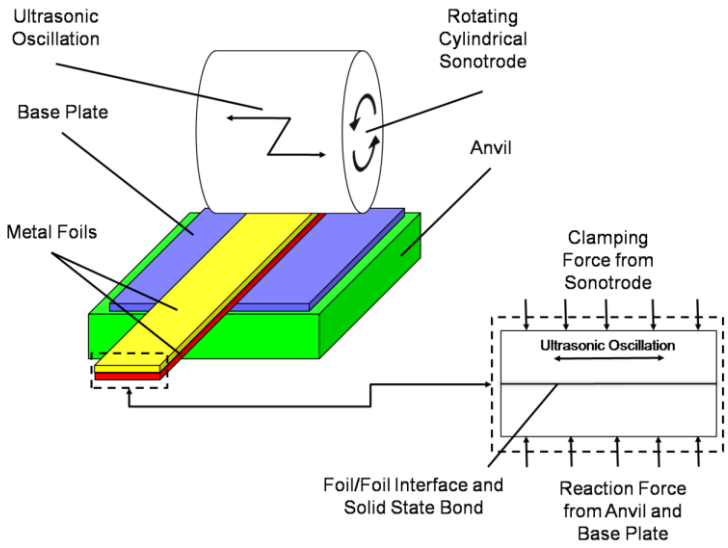


Figure 13.Simplified model of ultrasonic sheet metal 3D Printing[104]

3.3.3.2.7 Directed Energy Deposition

In the high-tech metal industry is mostly used this process. It is used in rapid manufacturing applications as well. In this process usually is used the 3D printing apparatus which is attached to a multi-axis robotic arm. It has a nozzle which deposits wire or metal powder on a surface. To form a solid object an energy source (laser, electron beam or plasma) melts the material

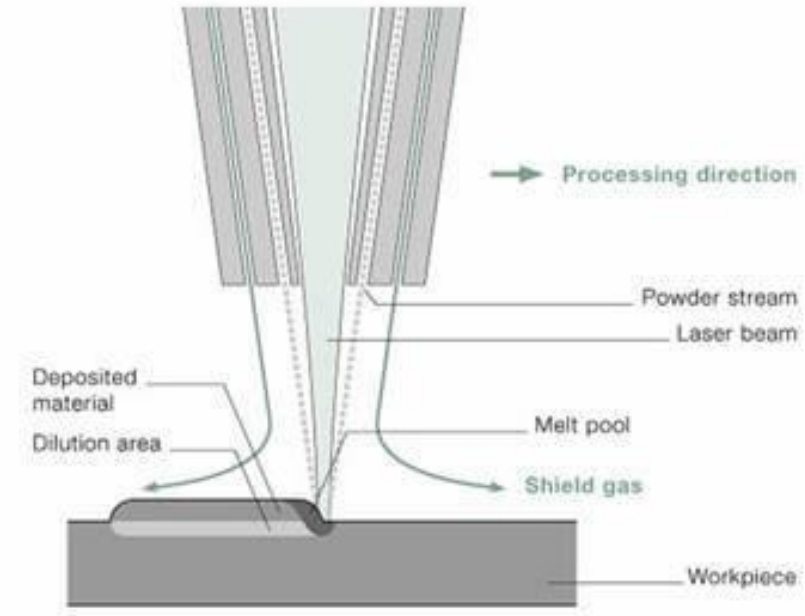


Figure 14.Direct Energy metal powder and laser melting. Image source: Merlin project [104]

In the Table 2 different additive technologies separated by the categories, with applicable material are presented.

Table 2 Additive technologies and applied materials

Type	Technologies	Materials
Extrusion	Fused deposition modeling (FDM) or Fused Filament Fabrication (FFF)	Thermoplastics, eutectic metals, edible materials, Rubbers, Modeling clay, Plasticine, Metal clay (including Precious Metal Clay)
	Robocasting or Direct Ink Writing (DIW)	Ceramic materials, Metal alloy, cermet, metal matrix composite, ceramic matrix composite
Light polymerised	Stereolithography (SLA)	photopolymer
	Digital Light Processing (DLP)	photopolymer
Powder Bed	Powder bed and inkjet head 3D printing (3DP)	Almost any metal alloy, powdered polymers, Plaster
	Electron-beam melting (EBM)	Almost any metal alloy including Titanium alloys
	Selective laser melting (SLM)	Titanium alloys, Cobalt Chrome alloys, Stainless Steel, Aluminium
	Selective heat sintering (SHS)	Thermoplastic powder
	Selective laser sintering (SLS)	Thermoplastics, metal powders, ceramic powders
	Direct metal laser sintering (DMLS)	Almost any metal alloy
Laminated	Laminated object manufacturing (LOM)	Paper, metal foil, plastic film
Wire	Electron Beam Freeform Fabrication (EBF)	Almost any metal alloy

3.4 Criterions for evaluation of technological processes

3.4.1 Optimization of technological processes

Technological processes of making products are characterized by different solutions in all its phases, and operations. These characteristics are caused by input data, techno-economic conditions and subjective commitment designers of technological processes. Each variant of the technological process seems logical set of appropriate technological operations making the solutions depend on the decisions of previous and subsequent operations. Multiple variance solutions technological process of product or group of products for the given conditions based on the capabilities of different solutions in terms of:

- The type of pre-form,
- The types of machining processes,
- The order of operations,
- The structure of operations,
- machining and technological systems,
- tools, accessories, measuring instruments, etc.

When designing the technological processes a detailed analysis of the interplay between selected elements of technology, and also the impact on the overall quality of the technological process, seeking those solutions that provide the necessary concordance between the elements of the technical and economic level.

3.4.2 Expert evaluation of the variants of technological solutions

In general, the selection of the best varieties of technological solutions can be made on the basis of evaluations rating by different methods. Correctly determining the value of rating is based on estimations of experts by using the predetermined criteria, which are of major importance for the techno-economic level value of the technological process. For the expert assessment of the technological processes in a collaborative system the following criteria are provided [105]:

- technological cycle TIME,

• The QUALITY of the technological process,
• FLEXIBILITY of technological processes,
• Utilization of MATERIALS and
• COSTS in production environment.

Each criteria is evaluated from 1 - 5. Orientation recommendations are presented in Table 3:

Table 3. Values recommendation for specific criteria

Ocena	**TIME**	**QUALITY**	**FLEXIBILITY**	**MATERIAL**	**EXPENSES**
1	>150 min.	Bad quality, average reliability	Extremely difficult adjustment	Production waste >100% finished product	Very high expenses of equipment and production
2	50-150 min.	Average quality	Slow adjustment	Production waste 50-100% finished product	High expenses of equipment and production
3	10-50 min.	Average to Good quality	Average adjustments and average time of preparation	Production waste 10-50% finished product	Relatively low expenses of equipment and production
4	2-10 min.	Good to best quality	Fast adjustments	Production waste <10% finished product	Low expenses of equipment and production
5	<2 min.	The best quality	The preparation time does not exists	Production waste can be neglected	Without equipment expenses

The criteria for evaluating variations of technological solutions can be changed depending on the strategic interests of the parent company, which are adjusted to market requirements. In addition, the importance of these criteria evaluates experts in the evaluation of technological

processes, which also greatly influences the choice of the best variant of technological process.

3.4.3 Expert assessment of the criteria importance

Ranking the importance of criteria for evaluation of technological processes in a collaborative system can be done in two ways:

- Fuller triangle method and
- Explicit definition of the criteria.

Method of Fuler's triangle represents partial-add method of comparison, whereby making gradual mutual comparison of two criteria. In each comparison expert gives his opinion on what criteria is more important, with the possibility to add to both criteria an equal importance. Total number of pairs that are being compared is n (n-1) / 2 where n is a number of criteria for assessing the technological process. Given that in a collaborative system five evaluation criteria are defined, the total number of pairs in Fuller's triangle is defined by expression:

$$\frac{n(n-1)}{2} = \frac{5 \cdot 4}{2} = 10$$

Fuller triangle (FT) was chosen for weight assignment because of the simple and fast use. Every pair - consists of two parameters which are compared – has one point and that point is awarded to the most important parameter (then encircled). If they are equally important – each parameter gets a half point (that pair is put in a rectangle). When the evaluation is completed, the points are awarded to the parameters are summed up. That sum stands for their weights. Explicit evaluation of criteria defined by the experts, directly influence the weight of each criteria, whereby the percentage increase in the influence of one criteria reflects the percentage of reduction in the impact of one or several other criteria.

Product of the importance of criteria and corresponding expert assessment relating to the criteria, the real assessment of variants of the technological process is provided.

4 Creation of the geometrical models of the human humerus and plate implants

In this section of the thesis, the process for the humerus surface model creation will be presented. Also, the design process for the creation of geometrical models (solid) of two plate implants (cloverleaf plate and personalized reconstruction plate) will be shown. The geometry and shape of these implants are personalized for the specific patient, as it is presented in the following sections.

4.1 Material

For the purpose of the development of the parametric models of plates, two CT scans of human left arms were obtained. Several things should be noted, about used samples. First, these scans are used only for the initial development and testing processes. For additional verification of the models, more samples were used. Second, it must be noted, that these models do not need to be totally accurate (sometimes they must deviate from the surface at longer distances), just accurate enough, because, as already stated, the goal is to shorten the time of preoperational planning and surgery, and that is already achieved by the presented process. It is important to show that established parameters enable geometry and shape modification to fulfil different requirements of medical case, and surface-to-surface accuracy is just one of them.

To develop the method it was used the first scan as a sample scan and to test the method the second scan was considered as a test scan. We took the both scans from the men who were of the same age (50-year-old) and they were almost of the same height and weight. We used the scanner at Clinical Centre in Nis, Serbia. The scanner was Toshiba 64 slice scanner.

Scanning parameters that we used are determined according to the standard protocol which was determined by manufacturer: radiation of 120 kVp, current of 150 mA, rotation time of 0.5 s, exposure time of 500 ms, rotation time 0.5 s, slice thickness of 0.5 mm, image resolution 512 × 512 px, and pixel size about 0.38 mm for sample scan and 0.40 for test scan, 16 bits allocated and stored.

4.2 Overview of the surgical case

The fracture which we analysed as a bone trauma is known as a fracture of proximal part of a humerus bone. We can define different groups of bone fractures and which are determined by the appropriate categorization, as already stated in previous sections. As the fixation implant in the treatment of these fractures modified cloverleaf plate had been used [14,106]. Universal procedure of applying of the mentioned fracture(s) fixation used in patient's treatment is shown in Fig. 15. Since the process that is the subject of this research is believed to be a framework process, not all sub-processes are shown. The order of the main processes is:

Diagnostic procedure – To define the bone fracture we use the patient's statement and we analyse medical images. It is possible to analyze them by the computer software (e.g. Materialise Mimics for CT scans) or if we use an analog x-ray device, visually.

Implant Customization – When we reach this step, we create the geometrical prototype of the customized fixation implant for the particular patient. Detailed description will be in found in the further text.

Process before operation – Orthopaedic intervention is planned and stimulated by orthopaedic surgeon after the geometrical model of the implant had been constructed. The crucial point is to plan all surgical intervention steps to provide the best possible way to treat a patient which can be a very complex process. It is considered that it is very advisable to connect this process with the previously mentioned one. In that way there will be better adjustment of geometry of the 3D implant model and its topology. There are many different computer software which can be used in this purpose. (Vitrea, Mimics, etc.) [3].

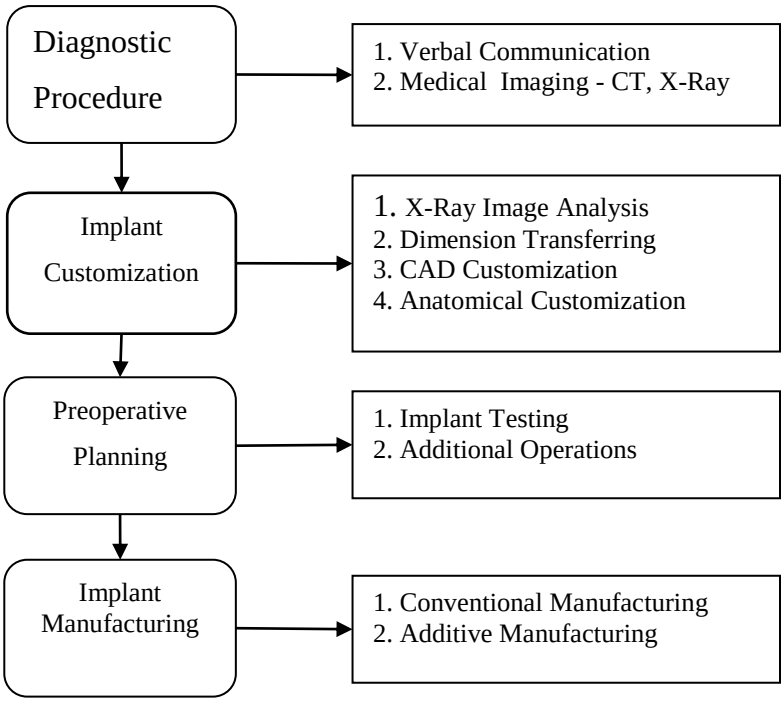


Figure 15.Schme of the process [surgical case]

Manufacturing of the implant – The last step is manufacturing by using the geometrical prototype of the customized implant. Conventional manufacturing can be used in this purpose, but there can be used some specific procedures if necessary or, if there is a need it is possible to combine the both technologies. Since the implant's shape is very complex (frre form surface) it is advisable to use additive technologies. The final result, if we use biocompatible material, is physical model of the customized implant.

4.3 Anatomy of the human humerus

Humerus is the longest and largest bone in the upper limb. It has expanded ends and a shaft. Rounded head is positioned on the proximal (upper) end, medially (internal side) and forms an enarthrodial joint with the glenoid cavity of the adjacent bone called scapula. The lesser tubercle is positioned close to the head, on the anterior (frontal) side of humerus and is limited on its lateral (external) side by a well-marked groove. The distal (lower) end is adapted to the forearm bones at the elbow joint. The anatomical landmarks are presented in the Fig. 16.

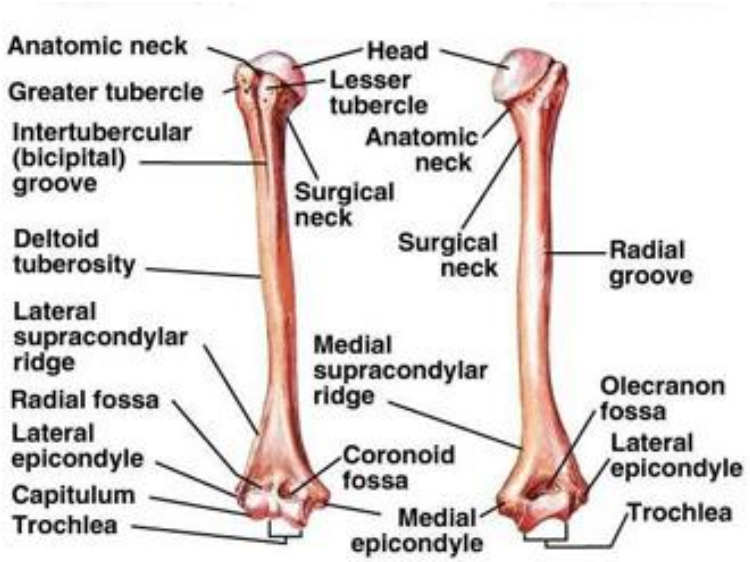


Figure 16.Anatomical andmarks and sections of humerus bone

The capsule of elbow joint is attached anteriorly to the upper limits of the radial and coronoid fossae, so that both these bony depressions are intracapsular. Medially it is attached to the medial non-articular lip of the trochlea and to the root of the medial epicondyle. Posteriorly (back side) it ascends to, or almost to, the upper margin of the olecranon fossa, which is therefore intracapsular. Laterally it skirts the lateral borders of the trochlea and capitulum, lying medial to the lateral epicondyle. With the arm by the side, the medial epicondyle lies on a plane which is posterior to that of the lateral epicondyle, so that the humerus appears to be rotated medially. In this position the head of the humerus is directed almost equally backwards and medially, and the posterior surface of the shaft faces posterolaterally. Since the glenoid fossa of the scapula faces anterolaterally, the humerus is not rotated medially relative to the scapula in this position of rest, but regarding to the conventional anatomical position it is rotated in that way. This position of the bone must be remembered when movements of the arm and forearm are considered [109-111].

4.4 Reverse modeling of the humerus bone

There are a few steps which have to be followed to provide the reverse modeling procedure and create humereus surface model. These steps are:

1 To acquire filtering point cloud obtained from CT scanning; [3]

2 To create the whole bone polygonal model, the technical features which are implemented in CATIA softer are used;
3 To define Referential Geometrical Entities (RGEs) [3, 11]
4 To create spline curves which are referenced to the RGEs
5 To create anatomical sections surface models which are adequate for the requirements of the procedure,

4.4.1 Definition of the RGEs

The identification of RGEs is the fundamental step for the successfully accomplished geometric of the reverse human bone modelling (humerus in this case). There are characteristic points, directions, planes and views which RGEs includes. To create RGEs humerus geometric and morphologic definition we obtained data from the papers.[109-111]. We obtained the definition of the coordinate system which was obtained from the papers [109, 110] where are defined basic axes and planes (views). The Anatomical axis of the proximal part of the femur (metaphyseal axis) is defined as axis of the cylinder formed in the upper part of the humeral shaft.

This is Z axis is axis of the coordinate system. A projection of the line which passes through tips of the epycondulus of the distal part of humerus on the plane perpendicular to Z axis was used to define X axis. The line which is normal to the plane which is formed by Y abd X axes is Y axis. We defined three important planes: Anterior-Posterior plane (X-Z), Lateral-Medial plane (Z-Y), and Axial plane (Y-X). Created RGEs are presented in Fig. 17.

4.4.2 Surface model of Human humerus

We created spline curves in cross-section to create surface model, and for three anatomical sections: proximal, shaft and distal section. we created polygonal model. By inserting some supplemental points or by removing some points which are not necessary, we managed to adopt cross-section curves to the geometry and form of humerus. To acquire the spline curves position, they were modified according to the anatomical major points of the appropriate humerus' section. The surface prototypes of humeral anatomical sections and built spline curves are shown in Fig. 18. Using of splines which were created in the axial panes made it possible to create proximal part and the shaft (Fig. 18a, and 18b).

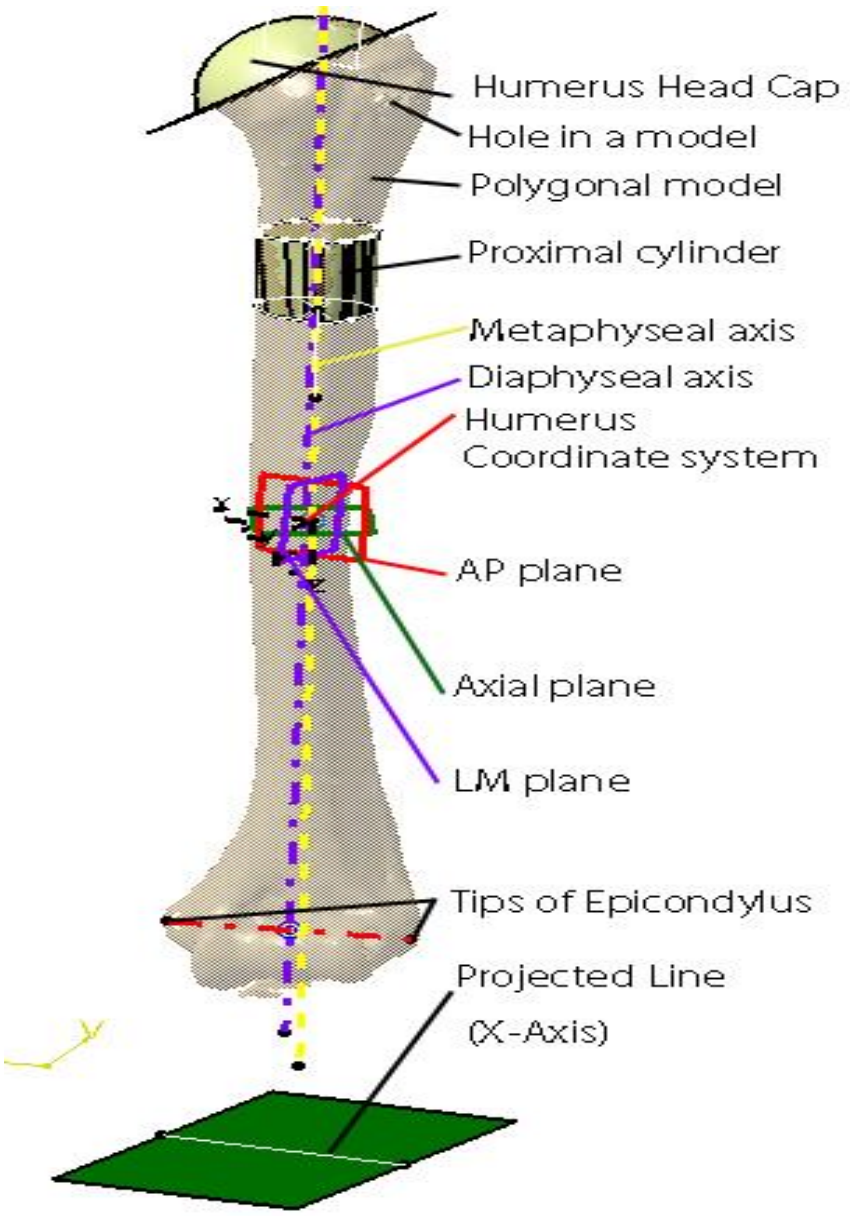
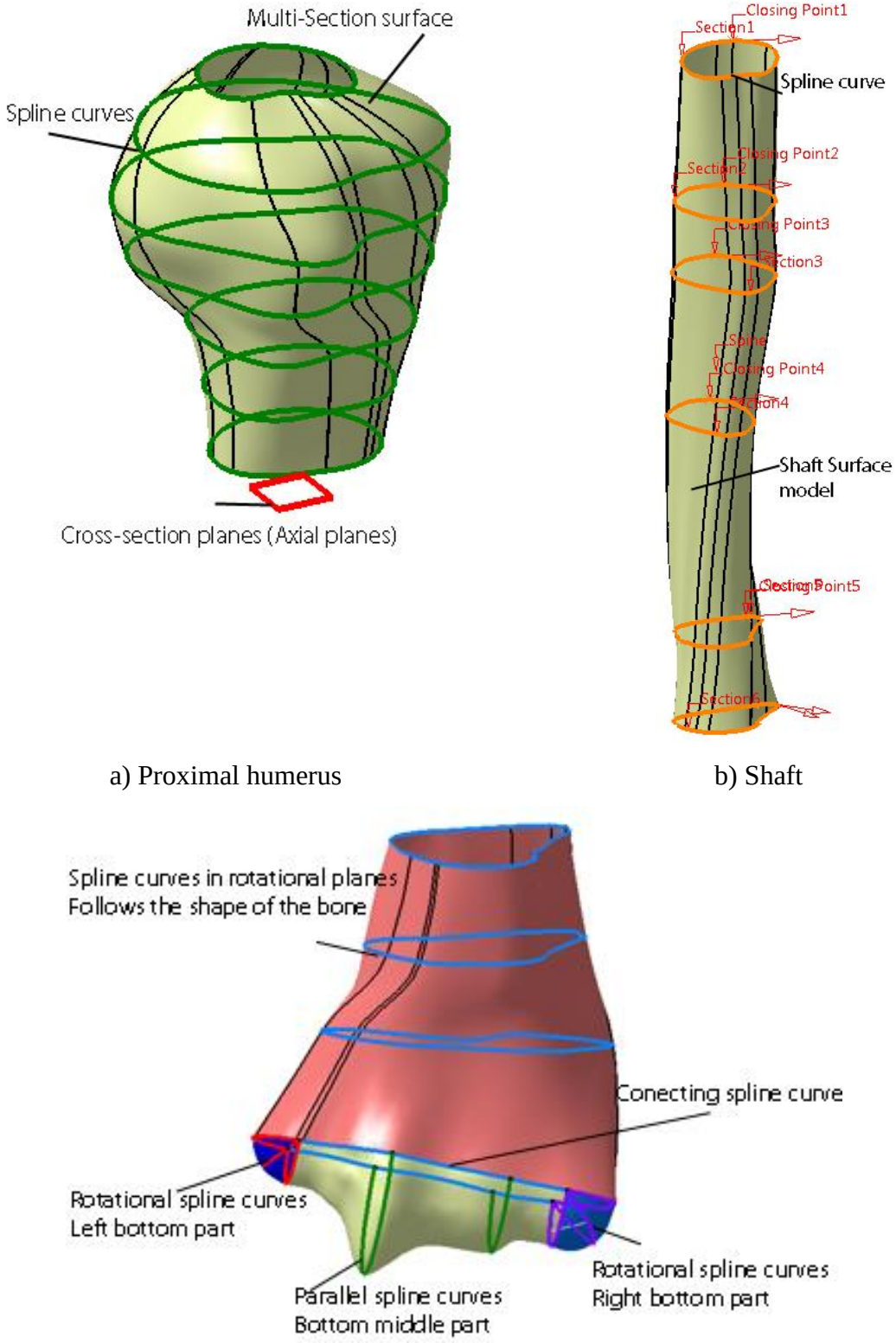


Figure 17.Created RGEs

An assembly of four surface parts was built by using the distal section. We did this because the shape of the distal part is considered to be very complex. We managed to create the upper parts by the usage of spine curves which were placed in rotational planes, and the curve of the upper ending (closer to the shaft) was built in axial plane. It is possible because these planes follow the curves of the distal part of the humerus. To create Left and Right bottom segments we used the rotational curves and for the middle parts we used the parallel planes normal to the bottom ending plane of the upper segment. We presented the surface model of the distal segment of the human humerus in Fig.18c.



a) Proximal humerus

b) Shaft

c) Distal humerus

Figure 18.Grometrical models of the individual parts of the humerus bone

4.4.3 Discussion of the geometrical accuracy of the surface model

We constructed individual surfaces and connected them to create the surface prototype of the whole humerus.. The complete model is presented in the Fig. 19a.

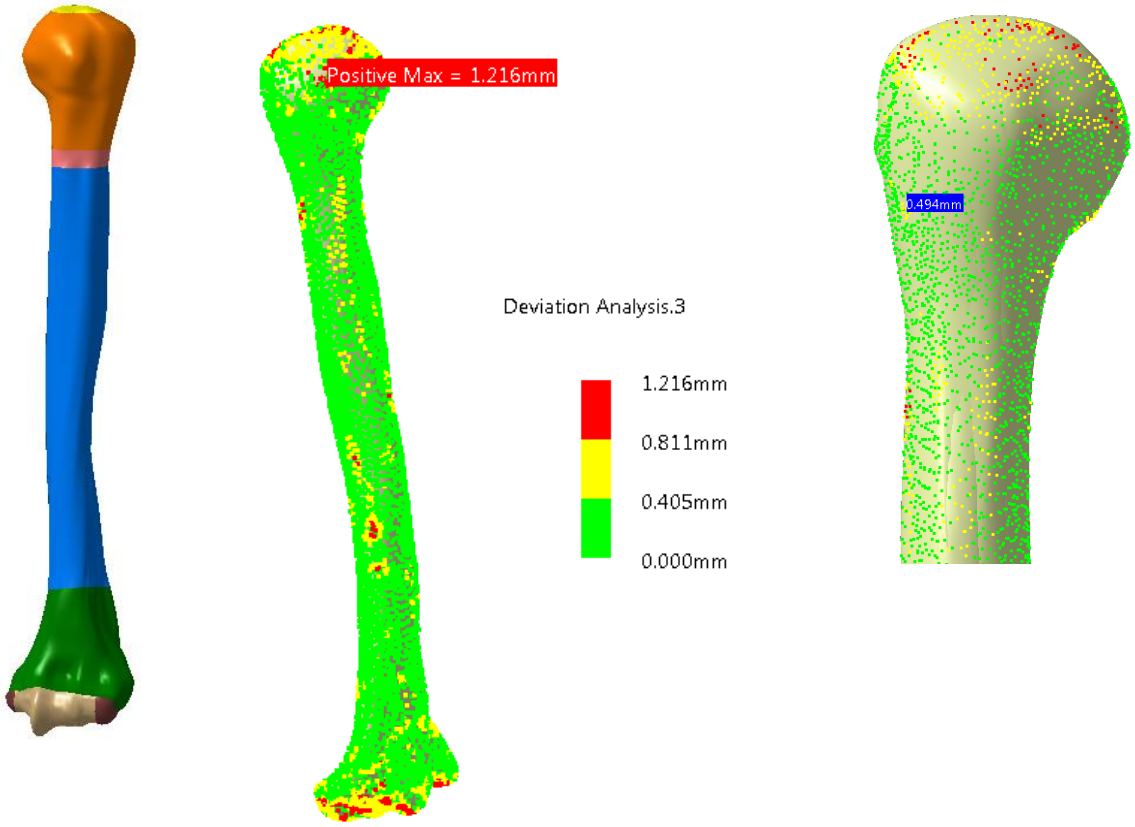
The deviation values which were measured in reference to the input sample polygonal prototype showed that the created surface prototype is of appropriate and suitable overall accuracy (Fig. 19b). There can be seen that complete accuracy of the model is around 0.4-0.8 mm. The range of maximal deviation is 0.811 - 1.216 mm. If we speak about the max deviation in the section of proximal shaft and greater tubercle, it is 0.494 mm (one point, Fig. 19c). It should be remarked that the surface prototype of human humerus which was create in the beginning had greater deviations – maximal deviations were about 3 mm. This model had irregularities (e.g. holes) in the first polygonal model (e.g. caused by osteoporosis), big differences in curves in the regions which were connected (e.g. head-neck) and they are the main reason for occurrence of these deviations. We used information from medical literature concerning the bone shape to add some new points in order to correct these elements and in that way we managed to decrease the deviations which have been already mentioned.

Orthopaedic surgeons who took part in this research stated that these deviations are more than sustainable, especially since they are not in the location of interest for placement of the plate. In this section deviations are under 0,5mm which enables the correct definition of geometry and position of the plate. If a need to raise the accuracy of a resulting prototype exists, we can include some additional spline curves which have already existed in this area which is the object of our interest (e.g. distal part of humerus or humeral head area).

4.4.4 Design process of the cloverleaf plate parametric model

During this process we create the geometrical model of the customized plate for a particular patient. We define parameters according to the dimensions which are measured on the 3D model of the humerus which is used as a sample. The measured dimensions are shown in the Fig.20 in AP plane and we can see 3D view of the model which is the sample model asa well. It has to be remarked that two important dimensions: RDmax (distal part of the plate) and Rpmax (proximal part of the plate) are always determined. Rdmax and Rpmax are maximal distance which begins at the detected edge of the Anatomical axis of humeral body. These two dimensions combined with other radiuses which are defined, too, make it possible

to create the profile curves. These profile curves are used to create initial plate surface model with multisection feature in CATIA.



a) *b)* *c)*

Figure 19. Surface model of the humerus and deviation analysis between created and input model

When we mention curves in this case, they are part of the circle. They have their limits which are determined as the values of the both RPmax and RDmax. The vastest part of the proximal section of the plate (head) can be defined when the dimension Mwidth is set. Its base is defined radius in AP plane and it is a circle chord which defines the span of the plate which covers the outer surface of the proximal humerus. The present set up value is 34mm and it is shown in the Fig.20. To create initial surface prototype of the contact surface between plate and bone, all these values are used, as it was already mentioned. To create solid prototype of the plate it is necessary to add thickness to the surface. For the sample which is set up, the standard is 2mm. (Fig.20)

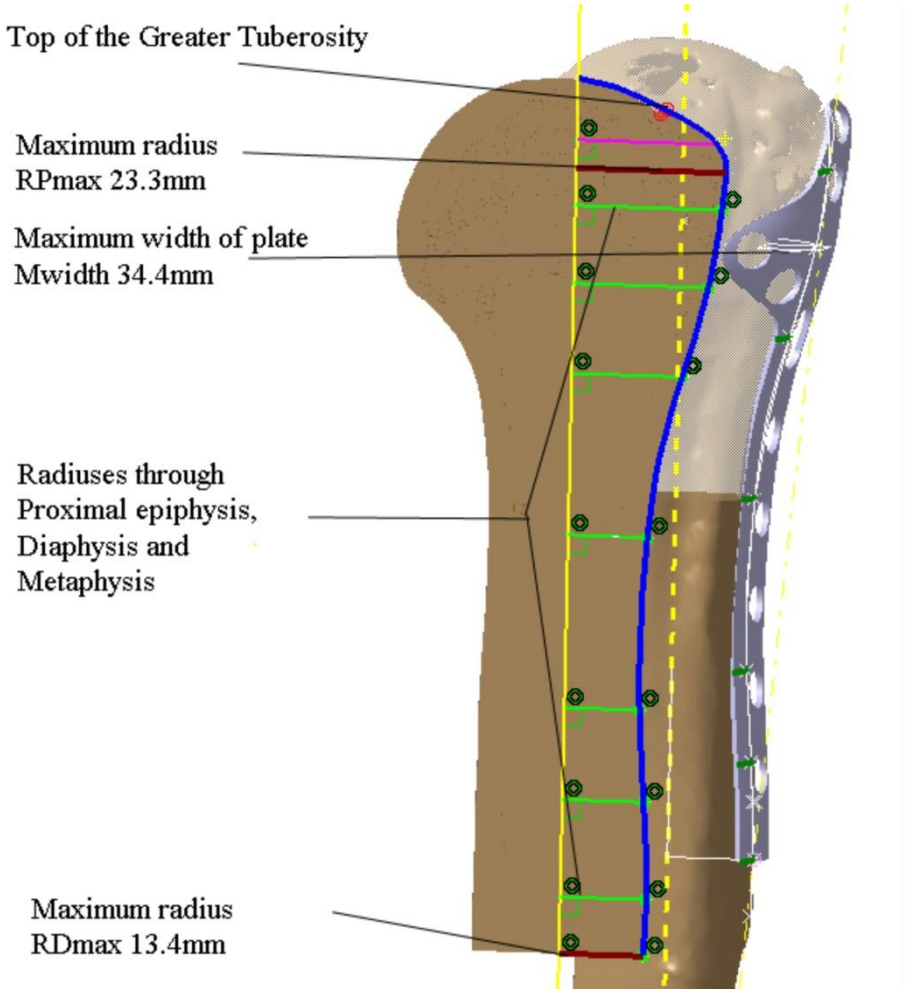


Figure 20. Defined dimensions (parameters) of the humerus bone presented in AP plane

We can consider the defined dimensions as parameters and their values are changed because of the measurements which are obtained from medical images. According to this, that prototype can be considered as a parametric prototype. The prototype model CT scan of the test humerus bone was applied in testing. It was plane that was considered as the test humerus bone and the construction of the edge was the cross section of the bone prototype and AP plane. Firstly, definition of the dimensions was performed which enabled the measurements. Maximal values were: 21.2 (RPmax), 11.5 (RDmax). In that case, construction of the surface model of the plate contact surface was based on the defined procedure. (Fig. 21).

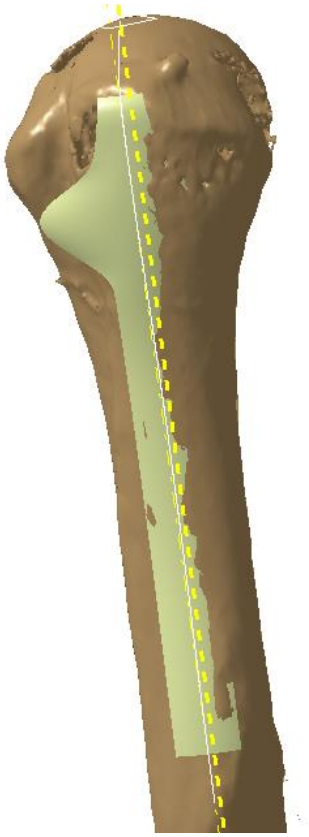
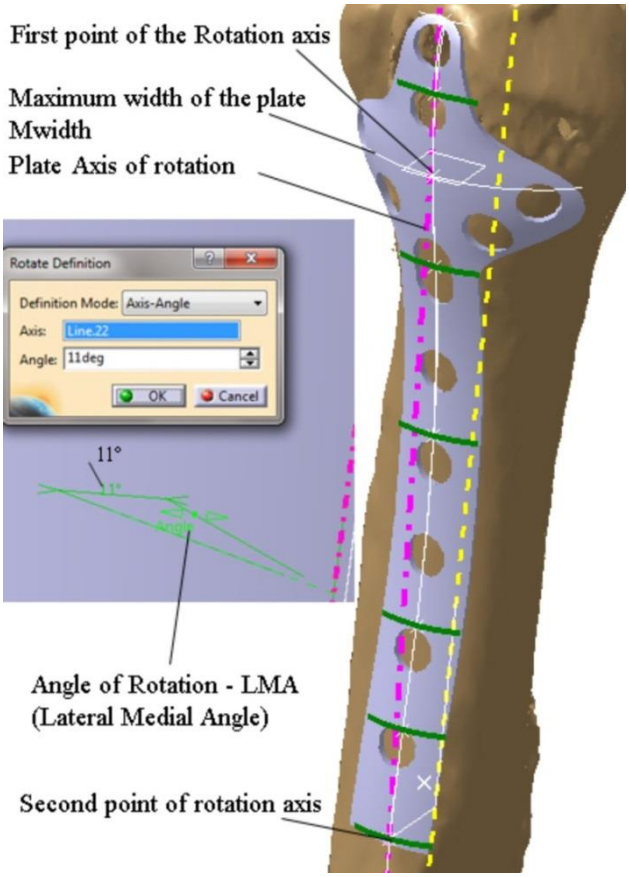


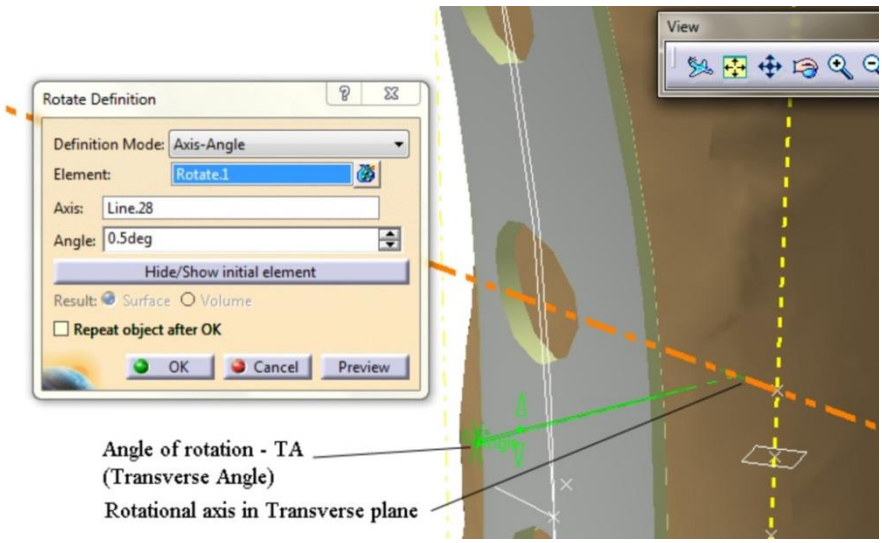
Figure 21.Surface model of the plate contact surface

There was the overlapping which occurs at the beginning between humerus polygonal prototype and the surface prototype of the plate so the appropriate transformation of the location of the plate had to be applied. We translated the plate contact surface normally from the Lateral-Medial (Sagital) plane for 1mm and it was rotated around its axis (Lateral-Medial Angle-LMA) about 11°. The line between middle point of the vastest part (Mwidth) of the proximal section of the plate and the middle point at the RDmax location (distal end of the plate) is defined as the plate axis and it is positioned in the LM (Lateral-Medial) plane of the humerus bone (Fig.22a)

We performed one more rotation about the axis that is positioned in Transverse (Axial) plane of humerus and which is located at the place just below the metaphysic. This axis passes through the point on anatomical axis and it is normal to AP plane. Transverse Angle is the angle of rotation and it is 0.5º (Fig.22b). to make the surface thicker we added thickness of 2mm on the contact surface and in that way we created the solid model of the plate.



a) Mwidth and LMA angle definition



b) TA angle definition

Figure 22.Parameters difinition

The developed process was applied for building of the surface model of the test humerus. Finally, we succeeded in the creation of the assembly of the customized plate solid model but we created the surface model of the test humerus as well. (Fig. 23) the models were connected and any intersections between them didn't exist so it was the best possible way for the inner surface of the plate to follow the surface of the periosteum. It is possible, if there is a need for that, to adjust the surface of the plate to follow the form of bone less or more and it can be done by changing the values of radiuses (parameters).

Figure 23. Assembly of the customized plate solid model and surface model of the test humerus

4.4.5 Discussion of the geometrical accuracy of the parametric model

There were some deviations between intersections of AP plane and the plate which we observed. This deviation was maximum 2.267mm in proximal epiphysis section and the one which was observed in proximal diaphysis section was maximum 2.44mm (Fig.24). The

orthopedic surgeons who took part in this research found that these two deviations which were located on the top and bottom area of the plate were completely acceptable. Since the 89% of the contact surface of the plate is under 1mm distance from the periosteum surface of the treated bone.

We can state that the current stage of evolution of the model of the plate is suitable enough and it fits satisfactorily with the test prototype of humerus and it is possible to apply it in DCP and LCP fixation. The result is that the form of the plate was appropriately constructed and the described method can be applied with very satisfactory result. There is still a need for an additional verification. In the future research the most important verification which is necessary is the application of x-ray images.

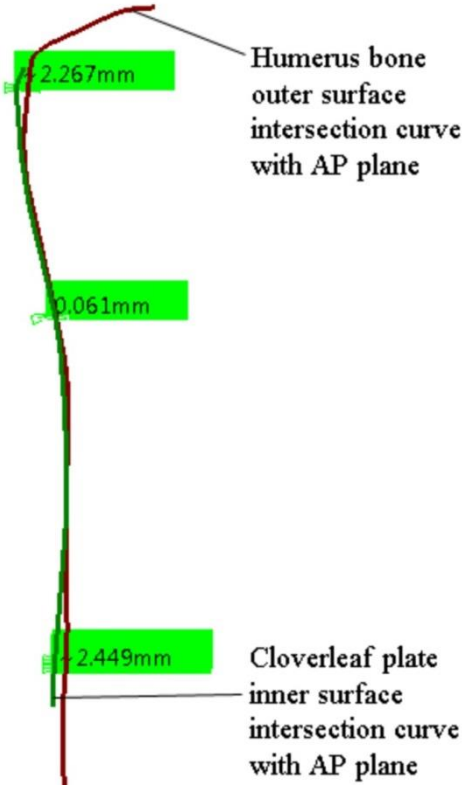


Figure 24.*Deviatins in AP Plane between intersections of AP plane and plate surface model, and humerus surface model*

4.4.6 Creation of plate implant geometrical model for distal humerus

In this section of the thesis the model of distal humerus was improved in order to provide more geometrical precision for the placement of personalized reconstruction plate. This is very important because distal humerus is essential part of elbow, so it is of great significance to properly reconstruct its size and shape. In Fig. 14, humerus surface model together with original model acquired from CT scan (Toshiba Acqulion 64 scanner, Slice thickness: 0.5mm, resolution: 512x512px) and previously created surface model are presented. Models were created in Dassault Systems CATIA V5 R21 software. As it can be seen from the Fig. 25, new surface model closely follows the original input model from CT.

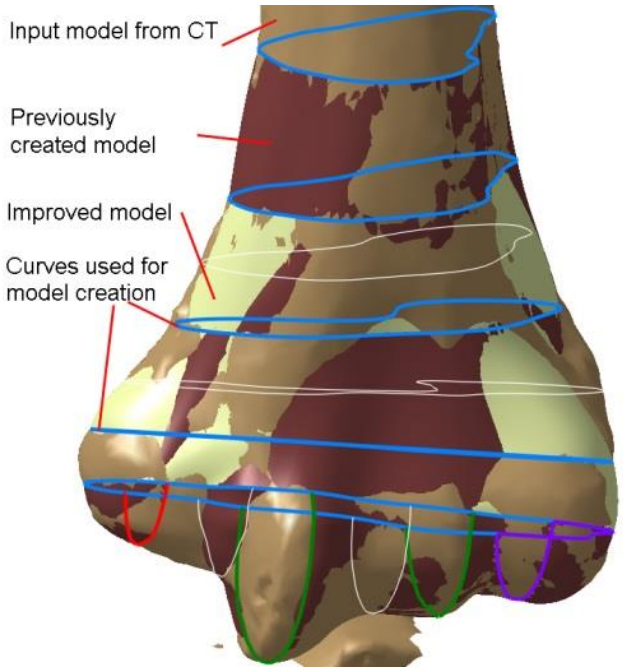
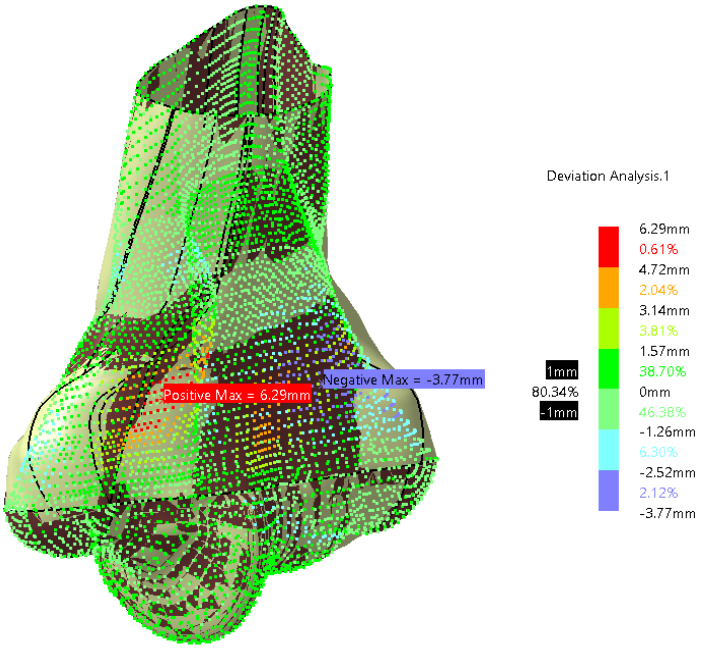


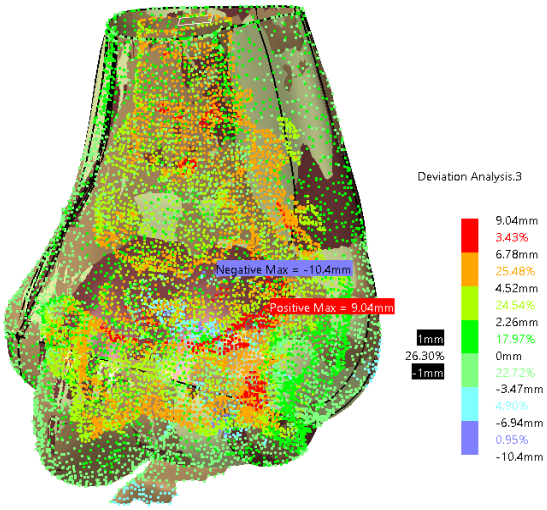
Figure 25.*Surface models and spline curves of the distal humerus*

Deviation analysis presented in Fig. 26 shows that deviation range for most of the surface points of the newly created surface model is around 1mm (Fig. 26c). It should be noted that, for the analysis, only points which lie on the periosteum surface of the bone are included, since input polygonal model had lot of points which belongs to the inner structure of the bone (e.g. points with deviation above 3.14 mm for newly created surface model of the distal humerus). Deviation analysis between newly created surface model and previously created surface model of the distal humerus shows that in 80.34%, distance between points is below 1 mm. In regions of bone with greater curvature, maximum deviation is 6.29 mm, which

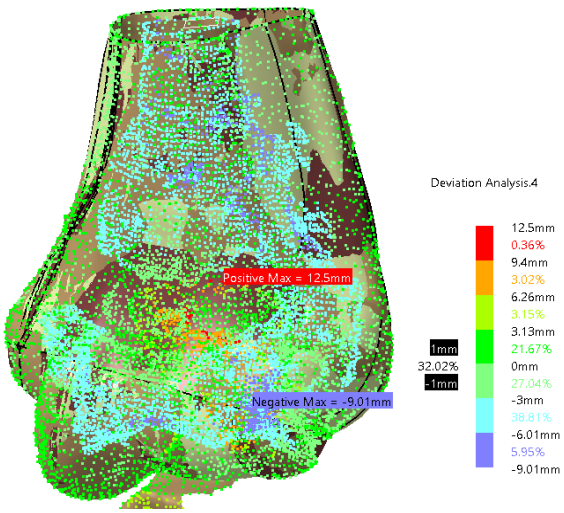
confirms that additional curves were necessary for the creation of geometrically precise model of that area.



a) Deviation analysis between created surfaces



b) Deviation analasys between input polygonal model and previously created surface



c) Deviation analasys between input polygonal model and newly created surface

Figure 26, *Devaiation analysis*

4.4.7 Creation of Geometrical Model of Bone-Plate Contact Surface

As [14] stated reconstruction plates are used for the fixation of the distal humerus on the lateral and medial side. On the lateral side, the plate can be placed distally onto the posterior aspect of the capitellum. On the medial side, the plate is usually bent around the epicondyle. The focus of this research was to develop and propose new method for the creation of the one specific type of medial reconstruction plate model. Proposed method was developed in order to improve process of plate adaptation to the bone, which is essential for the healing process of bone fracture [14]. In the future research method will be tested with more bone samples in order to prove that it is applicable for use in orthopaedic surgery. By the application of additive technologies (e.g. 3D printing) this model can be manufactured and possibly used in orthopaedic surgery.

MAF was used for the construction of plate geometrical model. Curves which were used for the construction of the surface model of the distal humerus were used for the construction of the parametric prototype of the reconstruction plate. Four radiuses were defined and one medial curve was created as helper curve for surface orientation. Radiuses were defined on spline curves which were applied for the construction of the surface model of the distal humerus. Each radius defines one arc of adequate length. Arc length is a changeable parameter and it defines width of plate (it can be constant). Each arc length is defined by four corresponding arc angles. One more parameter was defined, and that was the angle of bending in the lower part of the medial plate. Defined radiuses (R1…R4), angles (α1…α4), medial curve and bending angle (Bending Angle) are presented in Fig. 27. The values of parameters for this specific patient are presented in Table 4. These values of parameters were applied for the construction of the surface prototype of the plate contact surface. That surface was at right distance from the bone surface and the intersection with the surface of the bone was minimal and only at the end of the bended part.

Deviation analysis between surface model of the distal humerus and plate contact surface is shown in Fig. 28. It can be concluded that maximum deviation is 0.707 mm, in outer region of the plate surface – closer to edges. Deviation range is from 0.177 to 0.707 which is pretty accurate concerning the requirement that plate contact surface should correspond to bone

outer surface as maximum as possible [10]. Analysis confirms that nine parameters were enough for the definition of fixator surface shape with respect to the defined requirement.

It should be mentioned that during the real surgical intervention, a surgeon can manipulate with the plate. Surgeon can rotate, move and perform additional bending (amount of applied bending would be much smaller) in order to adapt the plate to the bone.

The solid prototype of the reconstruction plate was constructed applying of the thick surface feature in CATIA (thickness was defined as 3mm), and it is presented in Fig. 29.

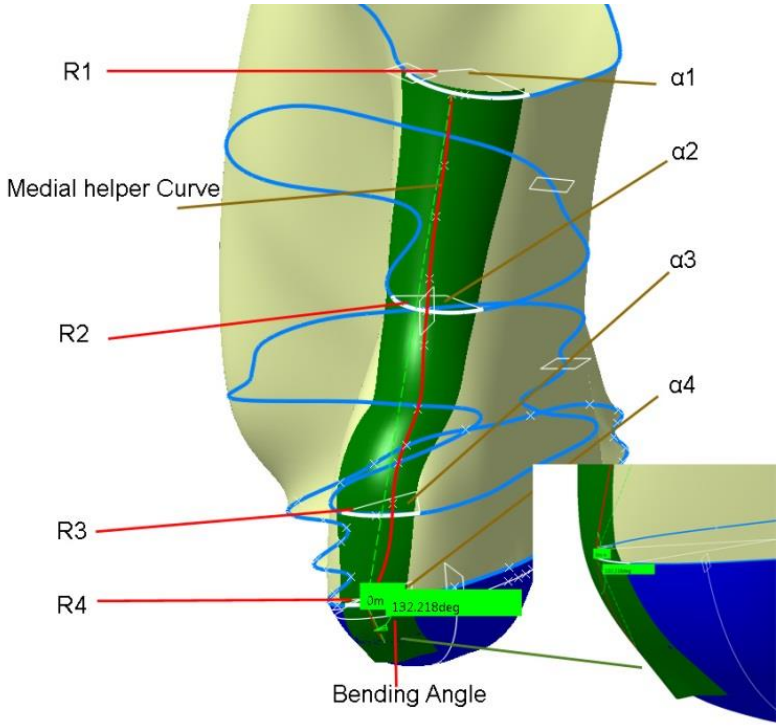


Figure 27*.Difined parameters and surface model of the bone-plate contact surface*

Table 4.*Values parameters measured for the specific patient*

R1 [mm]	R2 [mm]	R3 [mm]	R4 [mm]	Bending Angle [°]
5.3	3.7	6.1	5.7	132.2°
α1 [°]	α2 [°]	α3 [°]	α4 [°]	
109.2	126.6	58.6	54.5	

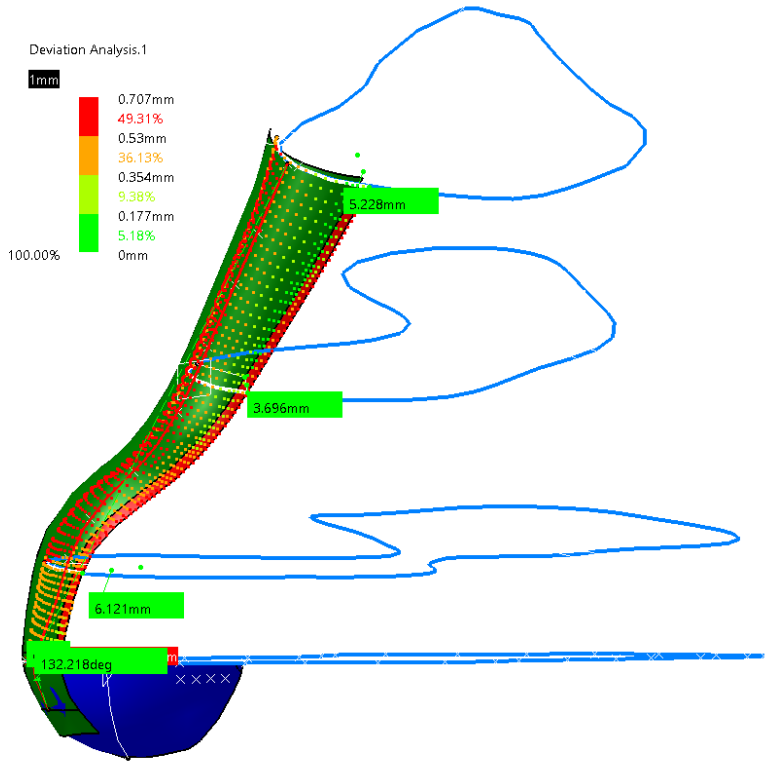


Figure 28 *.Deviation analysis between plate contact surface and bone outer surface*

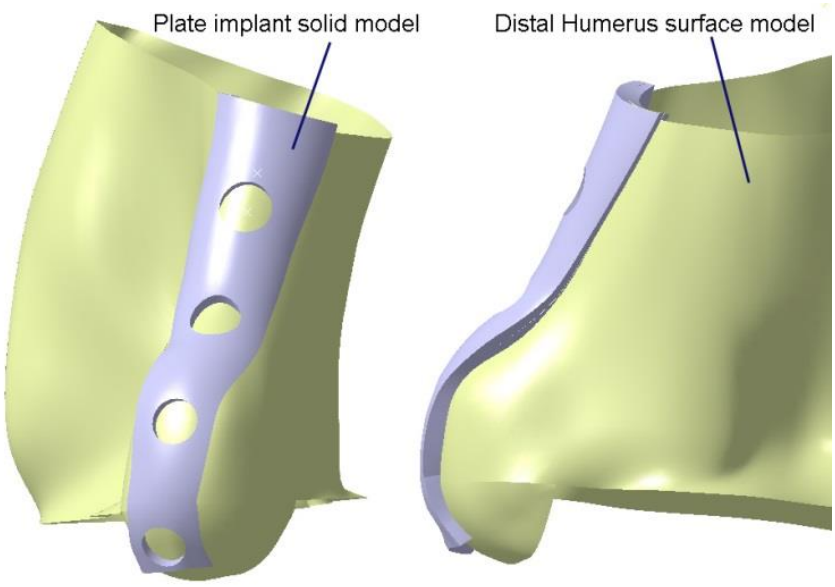


Figure 29 *Example of plate implant solid model*

5 Creation of the User defined Feature for the PPI application

Geometrical prototype of the customized cloverleaf plate for the particular patient is constructed as a parametric model. Parameters are already defined in previous parts, but in order to be clear, they will be presented in this section of the thesis, as well. Parameters presented in the Fig. 20 in AP plane of the humerus bone. Rdmax (distal part of the plate) and Rpmax (proximal part of the plate) are two dimensions which are very important. They are dimensions of the maximal distance from the edge which is detected to the Anatomical axis of the body of the humeral RDmax, RPmax and other radiuses which were defined enable the procedure of the construction of the profile curves which are applied for the construction of initial plate surface model with multisection feature in CATIA.

As we have already mentioned, radiuses of the curves which are the part of the circle in this case, have their limits because of the values of Rpmax and Rdmax both at the same time. Mwidth is set because it is necessary for the definition of the vastest part of the proximal part of the plate (head) dimensions. In this way we can use it to define how wide plate covers the outer surface of the proximal humerus. To create the initial surface model of the contact surface between the bone and the plate we use all these values. To construct the solid model of the plate, thickness was added to the surface and the set up of the sample was 2mm (standard thickness) (Fig. 20).

These dimensions which are defined are considered as parameters and their values are changeable due to the measurements which were obtained from the medical images, so it is possible to consider this model as a parametric one.

The assembly of the customized plate solid prototype and surface prototype of the test humerus were constructed and presented in Fig. 2, and described in [112]. The model properly fits the bone outer surface, but if it is necessary, it is possible to adjust surface of the plate to follow the form of the bone more or less since it is possible to change the values of parameters.

5.1 User Defined Feature created for the parametric plate model

On the basis of the created parametric model User defined Feature (UDF) in CATIA was created. User Defined Feature is a template feature that works at the part level. From a collection of features (geometry, literals, formulas, constraints, etc.), own feature can be

created and applied as any other feature from CATIA. The created feature can be saved in a catalogue , and reused later. In order to create UDF geometry of the parametric model is extracted and created in specific geometric set under body entity, Fig 30.

In order to create adequate UDF feature, only three elements were required as Components inputs: First Origin (Axis system), Second Origin (Axis System), Transversal Plane and Anterior Posterior (AP) plane. First and Second origin was selected as input elements to properly position the plate model. First origin respond to the gravity centre of the bone, and second origin respond to the distance of the model from the centre, i.e. distance vector. Transverse and AP plane are used to properly orient plate model in space.

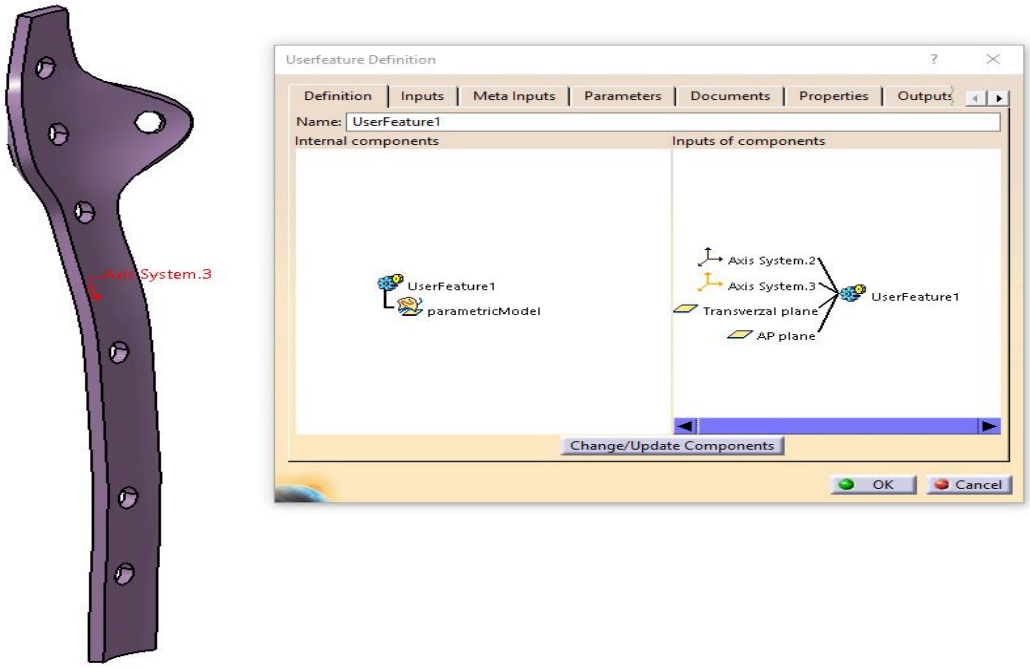


***Figure 30**. User Defined Feature for the modified cloverleaf plate*

All input components are created when specific bone model is created, so in order to apply UDF it is essential to have proper personalized 3D bone model, with defined Referential Geometrical Entities (RGEs) [112]. That kind of model can be created by using any known method, and of course MAF.

To properly create UDF it is not just enough to set input components. It is also important to specify which model modification parameters are available to the user at the time of model creation. If these parameters are not defined, UDF user will not be able to modify plate 3D model, and benefits of UDF application will be lost. For the first UDF presented in Fig 30,

these parameters were radiuses and Mwidth. This is generally quite correct UDF definition, but in the testing phase, some issues raised. The most important issue was proper positioning of the individual arcs – it was not possible. Only radiuses values could be changed. If the user wanted to change geometry and shape of the plate model by moving arcs trough space, it was not possible. For some bone models, this was required.

To address this issue, modified parametric model was created with little adjustments in geometry definition. Of course, original model with defined radiuses (Fig. 20) and Mwidth is still possible to use as separated UDF. In order to gain more control over the shape of the model, some adjustments to the basic building geometry of the plate implant were introduced. Main difference opposite to the original model is that individual circle arcs, were defined as arcs with two points and arc angle (not just radiuses). Originally, points still lie in AP plane and they define radiuses, but they can be translated to another position if there is a requirement. Added arc angle is a parameter which defines plate width at each circle arc, as presented in Fig. 4. In this way position of each circle arc in 3d space is better defined, with four, instead of just one parameter. Support plane (fourth parameter) is a plane created by using Transverse and AP plane, as presented in Fig 31, so the whole plate geometry is generally defined, and ready to be used.

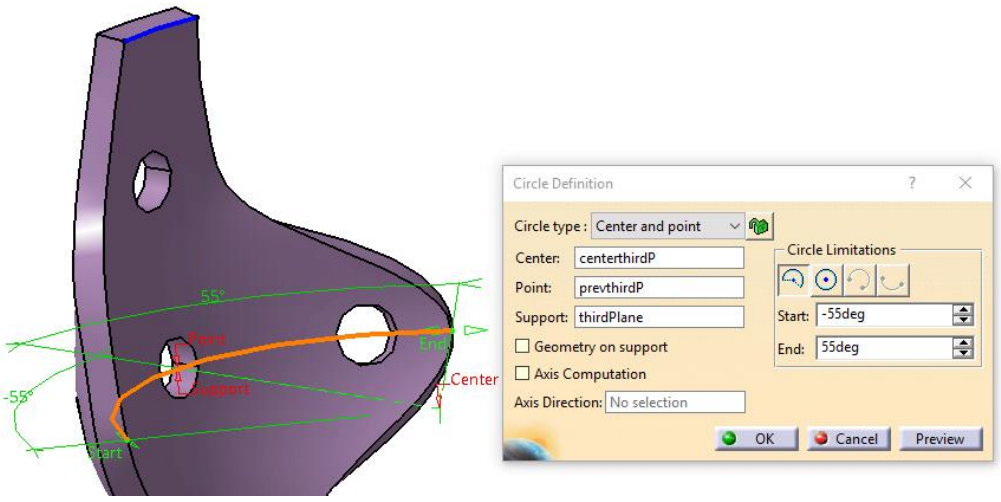


***Figure 31**. Circle arc definition with Start and End point, and arc angle.*

This procedure was performed for every originally defined radius parameter, and these parameters (Start point, End Point and Arc angle) were available to the UDF user for later use. In Fig. 32 Model

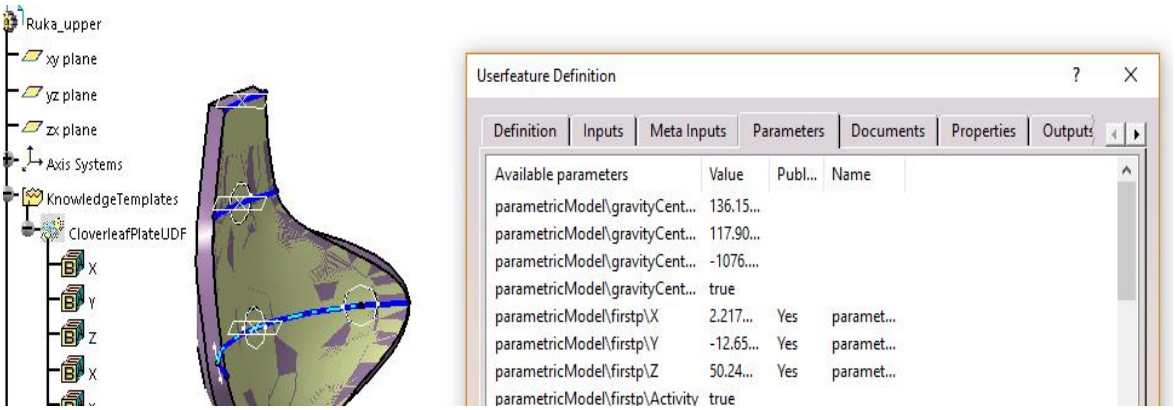
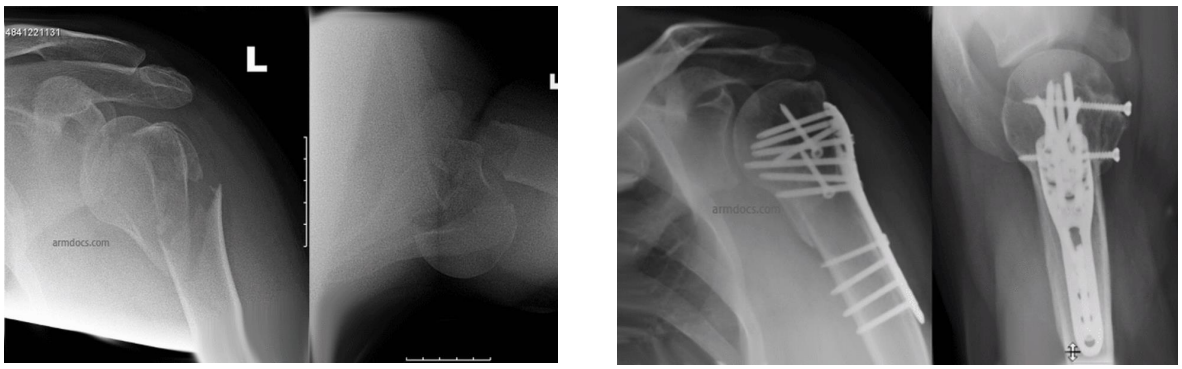


***Figure 32**. Plate UDF with published parameters*

The both UDFs (original and improved) were tested by changing the parameters values and various shapes were acquired, with no topology errors, so for the current stage of the research UDF definition can be marked as valid.

5.2 Application of the parametric model on the sample use case

Sample use case which represents reduction and fixation of the proximal humerus was acquired from [113], and shown in Fig 33.



a) Humerus fracture – X-ray Image b) Plate fixation of humerus fracture

***Figure 33.** X-ray images of proximal humerus fracture with plate fixation*

This use case was chosen because whole procedure for the treatment of the fracture was performed, from diagnostics to aftercare. In order to perform plate personalization four processes were performed. These processes are presented in the Fig. 34

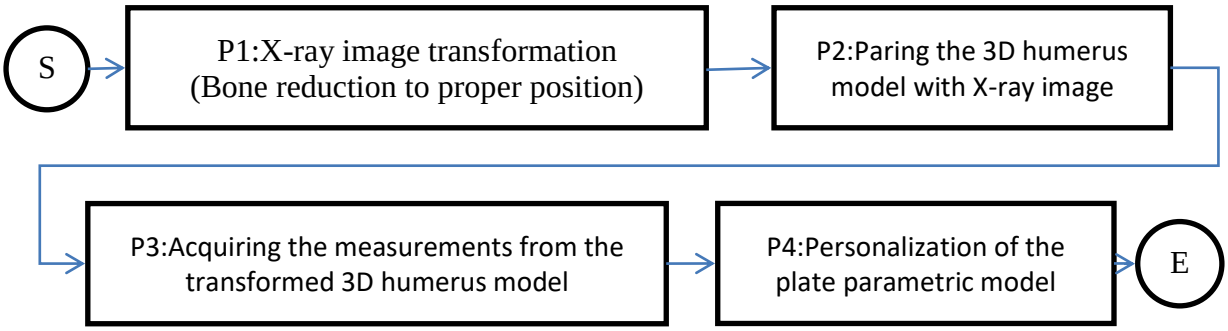
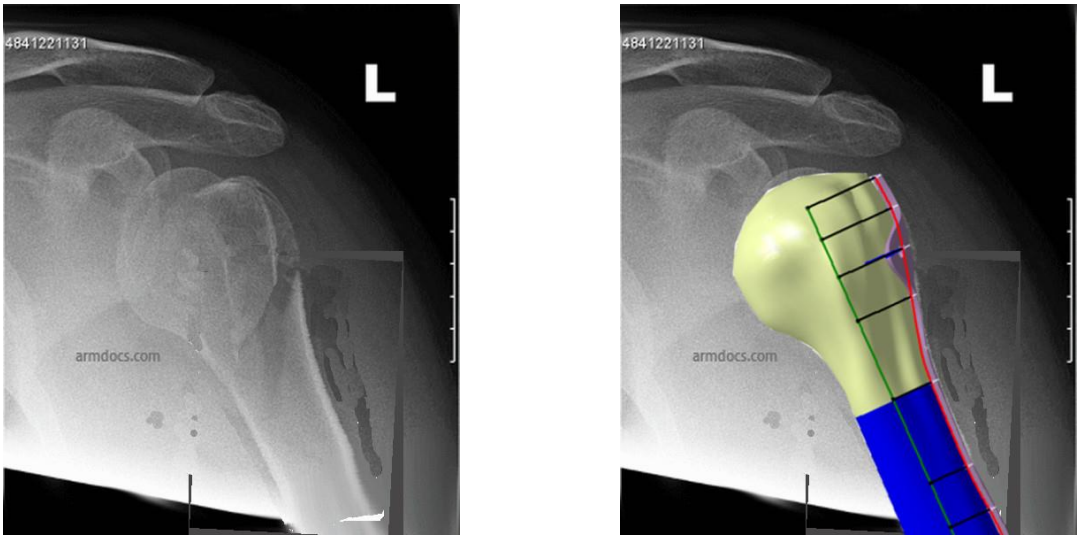


Figure 34 *Process for the creation of the personalized plate model for the humerus bone.*

Process P1 was undertaken because proper reduction of the bone was required in order to accurately acquire parameters from the X-ray image. To simulate bone reduction, transformation of 2D image parts was done in GIMP software, and presented in Fig 35a. Correctness of image transformation (procedure) was checked against image of already fixated bone (Fig 33b), and presented in Fig 35b.



a) Reconstruction of the bone parts by using image transformation tools in GIMP

b) Acquiring parameters values from the X-ray image using defined scale.

Figure 35. *Definition of the plate geometry by using X-ray scan and created plate parametric model*

Processes P2 and P3 were performed by using already created 3D model of humerus and plate. The assembly of plate and bone is paired with transformed image in order to get required parametric values for the personalization of the parametric model.

In the process P3, all measurements were performed in AP plane, i.e. the plane of the X-ray image. This plane corresponds to the AP plane created on the 3D humerus model in CATIA software. Measured values were scaled according to the established etalon presented in X-ray image (Fig 8b).

Measured values and positions of the corresponding points were transferred to the CATIA and parametric model was transformed and personalized to the specific bone – process P4, by using already created UDF. It is possible to manufacture Personalized 3D model by the use of additive technologies, or standardized machining and applied for the real surgical case.

5.3 User Defined Feature (UDF) implementation

In order to implement UDF, user form was created which enables application of UDF in part or assembly module of CATIA. UDF form enables:

- Direct insertion of UDF element into the part or assembly model – button “Insert UDF plate”
- Repositioning of the UDF in the part space – button “Define Position of UDF”
- Acquiring values for parameters from design table in Excel – button “Get Data From Database”.

UDF form is presented in the Fig 36, and UDF form application for the specific humerus bone (input sample from Clinical Center Nis) in Fig 37.

Figure 36. *UDF form*

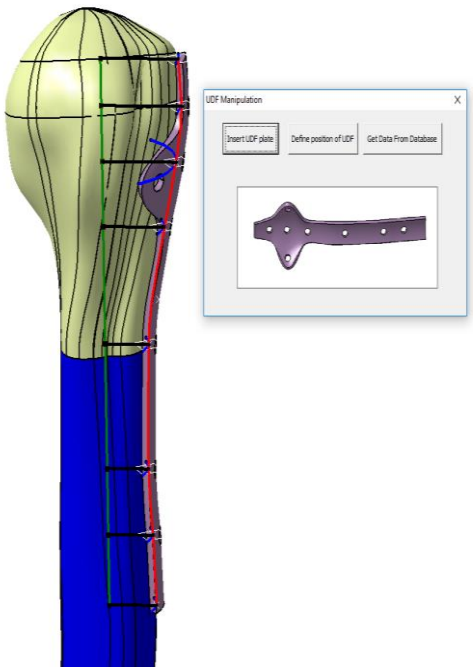


Figure 37. *UDF application*

5.4 Personalized plate manufacturing

3D printing was applied for the production of personalized plates. 3D model of the plates were adapted to the dimensions acquired from the medical doctors. The personalized plates were modified by using created UDFs, and they are presented in the Fig. 38 (proximal) and 39. (distal). Customized bone model is presented in Fig. 40.

Figure 38 *Personalized plate for proximal humerus*

Figure *39 Personalized plate for distal humerus*

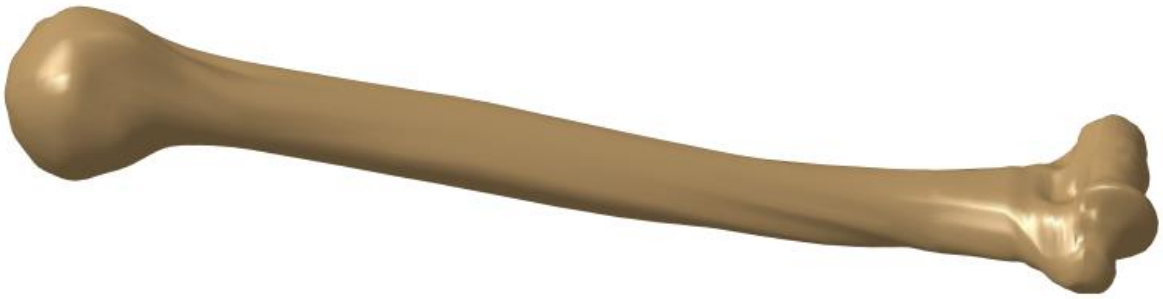


Figure 40 *Personalized 3D model of humerus*

3D printing of personalized plates was performed on the CraftBot Plus 3D printer by using PLA material. The resulting models are presented in Fig 41.

Figure 41 .*Plate models created by 3D printing.*

6 Techno economic analysis and manufacturing processes for the selected cloverleaf implant

The use case is already defined in Chapter 5, but in order to make it more clear, process scheme will be presented again in Fig. 38.

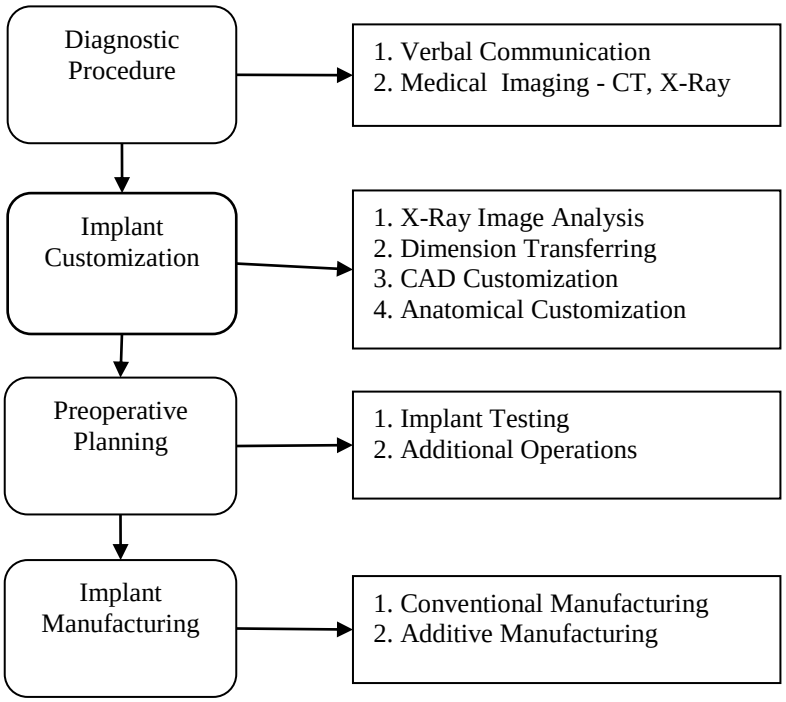


***Figure** 42 Patient's treatment processes*

6.1 Techno economic analysis of the manufacturing processes of the customized fixator

For the purpose of the production of the proposed fixator (implant) three manufacturing processes are defined, and presented in Fig. 39.

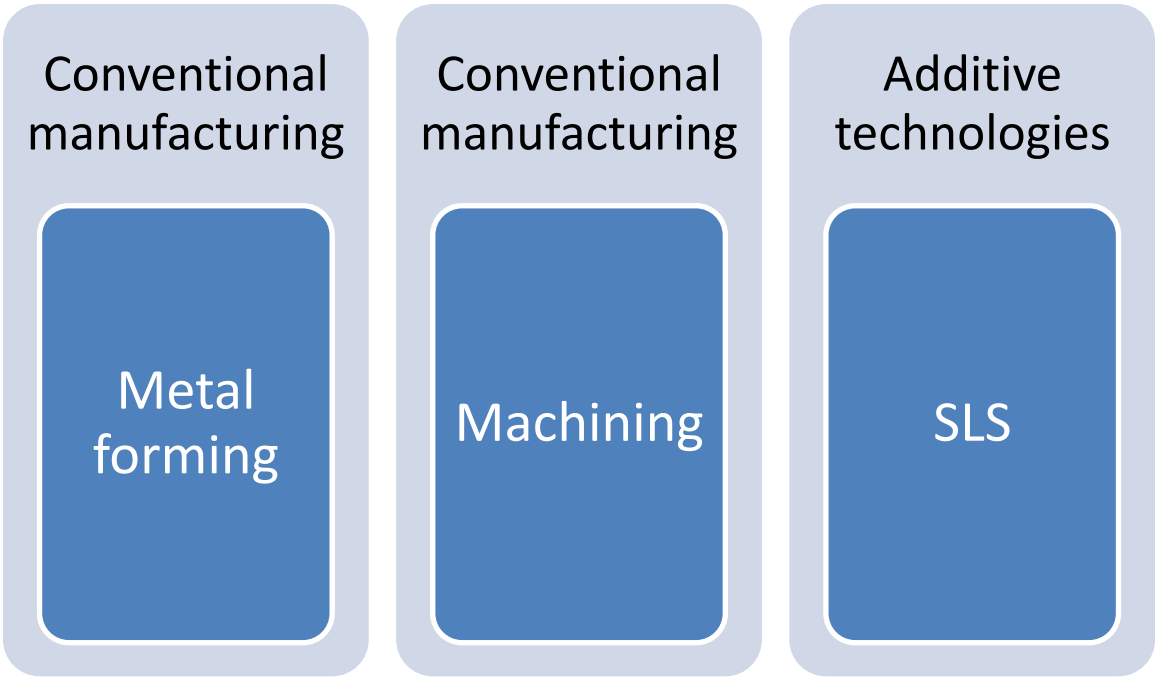


Figure 43 *.Proposed manufacturing processes for the production of the customized plate (Ti6Al4V)*

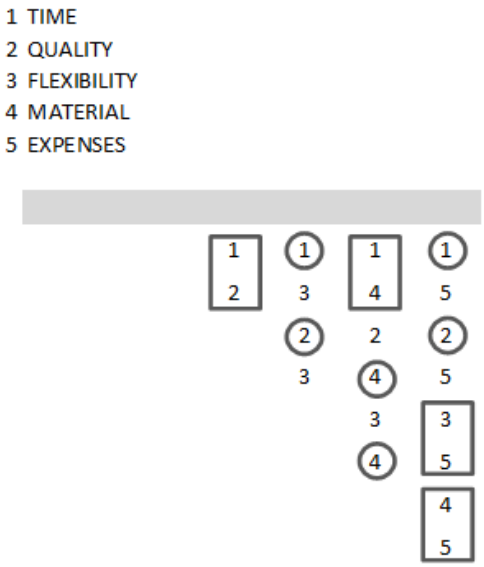
The technological processes are defined in Table 5. In Table all the operations for the adequate technology are presented

Table 5. *Manufacturing processes for the production of the customized plate (Ti6Al4V)*

Metal forming	Machining	Selective laser sintering (SLS)
1. Definition of the stock (panel sheet) 2. Stock cutting to adequate size 3. Bending in the adequate tool 4. Making adequate holes in the same tool 5. Grinding of the external and internal edges	1. Definition of the stock (panel sheet) 2. Surface Milling of the defined geometry (from both sides) 3. Hole drilling 4. Grinding of the external and internal edges	1.Preparing the model geometry in CAM software 2. Creation of the fixator model at the SLS printer.

6.1.1 Multi criteria analysis

For the multi-criteria analysis of the manufacturing processes Fuuler Triangle is defined for all the defined criterion and presented in Fig.40. For the definition of values two experts are consulted. For the five criterions 10 pairs triangles are defined with value of each criterion defined as 10%. All of the values of the criterions are defined for proposed technologies and presented in Table 7. The Final criterion values are calculated as product of importance of the criteria and specific value of criterion for each proposed manufacturing technology. Arithmetic mean of individual grades was calculated for both experts.



TIME	QUALITY	FLEXIBILITY	MATERIAL	EXPENSES
1	2	3	4	5
		%		
30	25	5	30	10

Figure 44 Fuller triangle method for the defining the importance of each criterion

6.1.2 Specific Values defined by first expert

Table 6 .Criterion values for the adequate manufacturing technology for first expert

Metal Forming	**Specific Value**
TIME	4
QUALITY	3
FLEXIBILITY	3
MATERIAL	4
EXPENSES	1
Machining	**Specific Value**
TIME	3
QUALITY	4

FLEXIBILITY	3
MATERIAL	3
EXPENSES	3
SLS	**Specific Value**
TIME	4
QUALITY	5
FLEXIBILITY	4
MATERIAL	4
EXPENSES	3

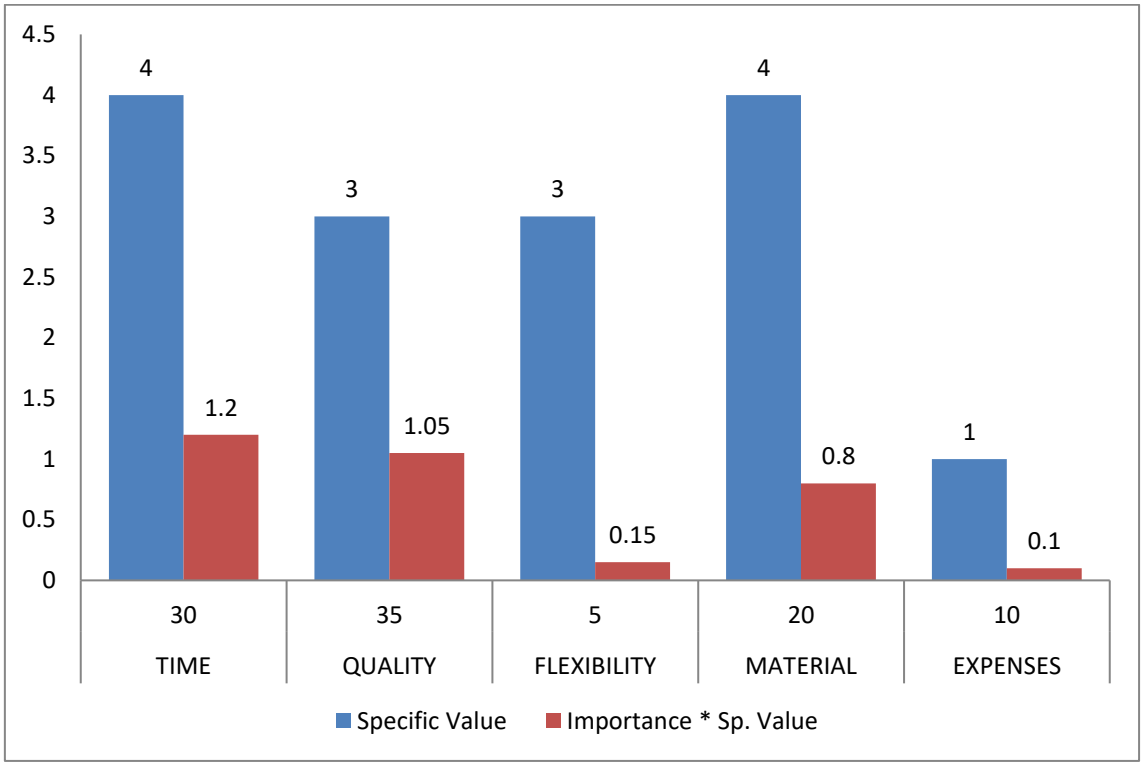


Figure 45. *Graphic representation of criterions importance values for Metal Forming*

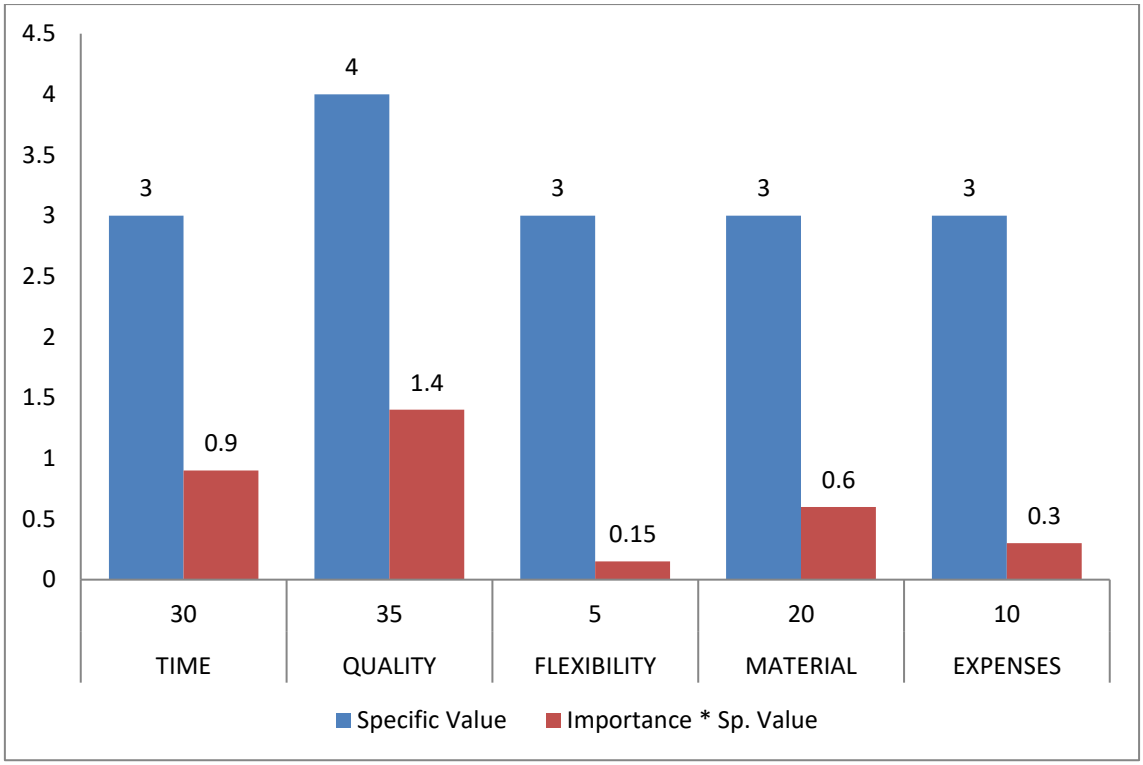


Figure 46 *.Graphic representation of criterions importance values for Machining*

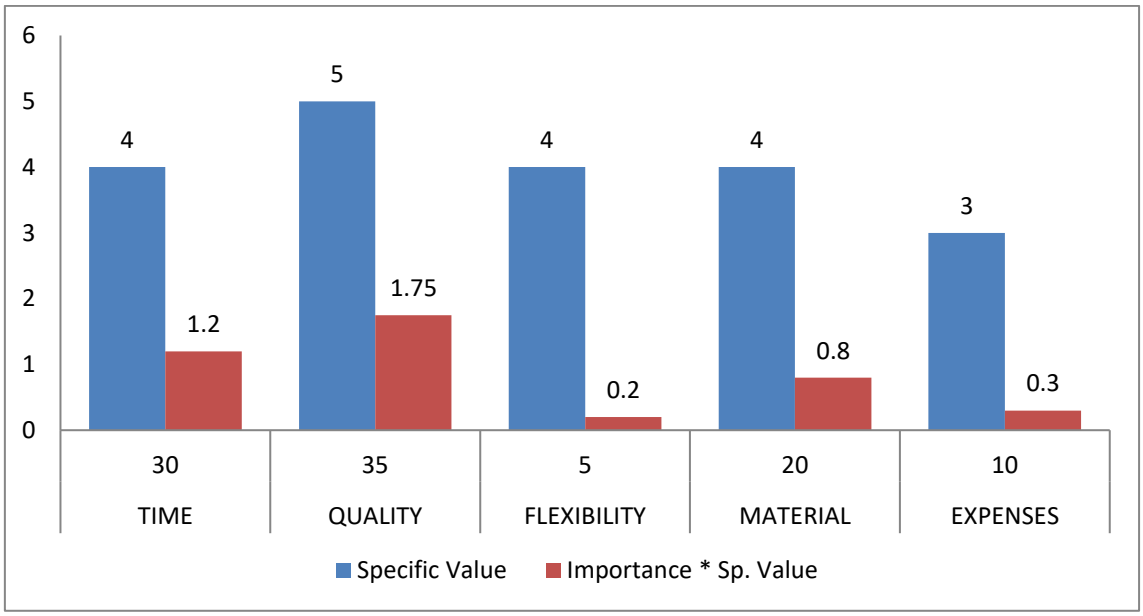


Figure 47 *.Graphic representation of criterions importance values for SLS*

***Table 7**. Calculated values for defined criterions and manufacturing technology (importance values * specific values)*

Manufacturing technology	TIME	QUALITY	FLEXIBILITY	MATERIAL	EXPENSES
Metal forming	1.2	1.05	0.15	**0.8**	**0.1**
Machining	0.9	**1.4**	**0.15**	0.6	**0.3**
SLS	**1.2**	**1.75**	**0.2**	0.8	**0.3**

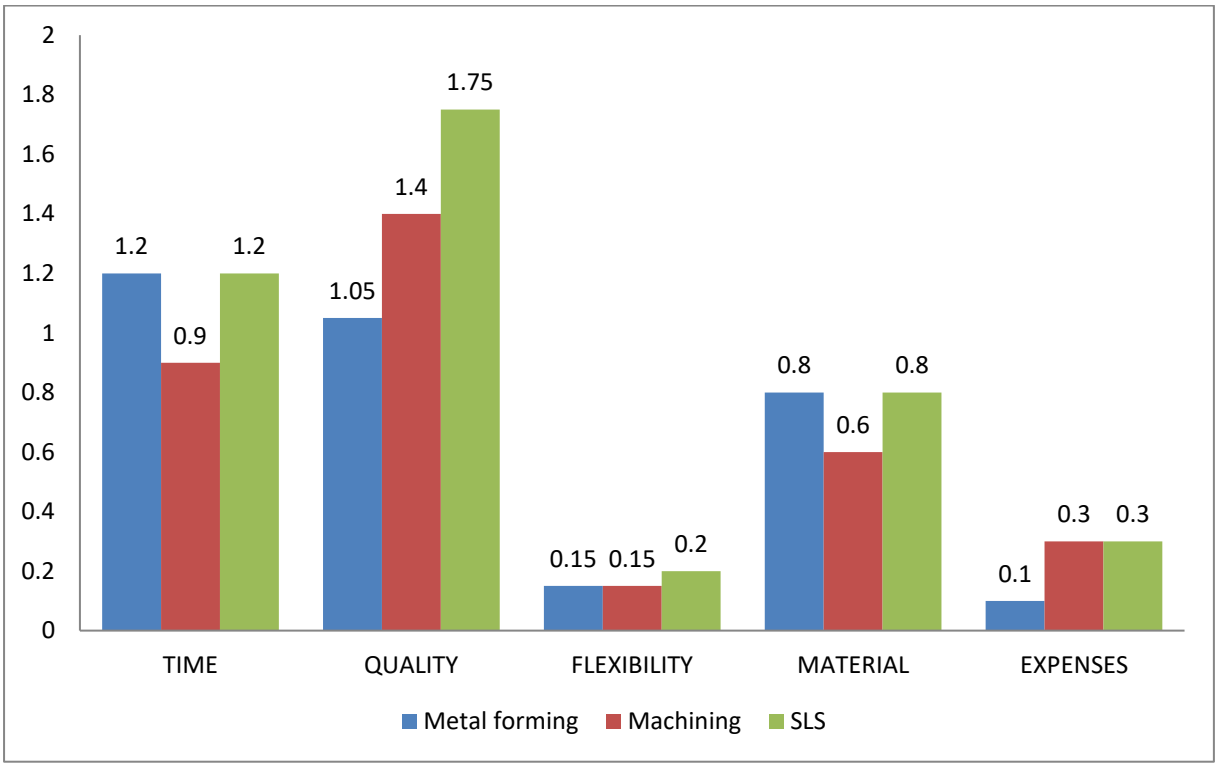


***Figure 48** .Graphic representation of calculated values (importance values * specific values)*

6.1.3 Specific Values defined by second expert

***Table 8** .Criteria values for the adequate manufacturing technology for second expert*

Metal Forming	Specific Value
TIME	3
QUALITY	3
FLEXIBILITY	3
MATERIAL	4
EXPENSES	2

Machining	**Specific Value**
TIME	4
QUALITY	4
FLEXIBILITY	3
MATERIAL	2
EXPENSES	4
SLS	**Specific Value**
TIME	5
QUALITY	4
FLEXIBILITY	5
MATERIAL	4
EXPENSES	3

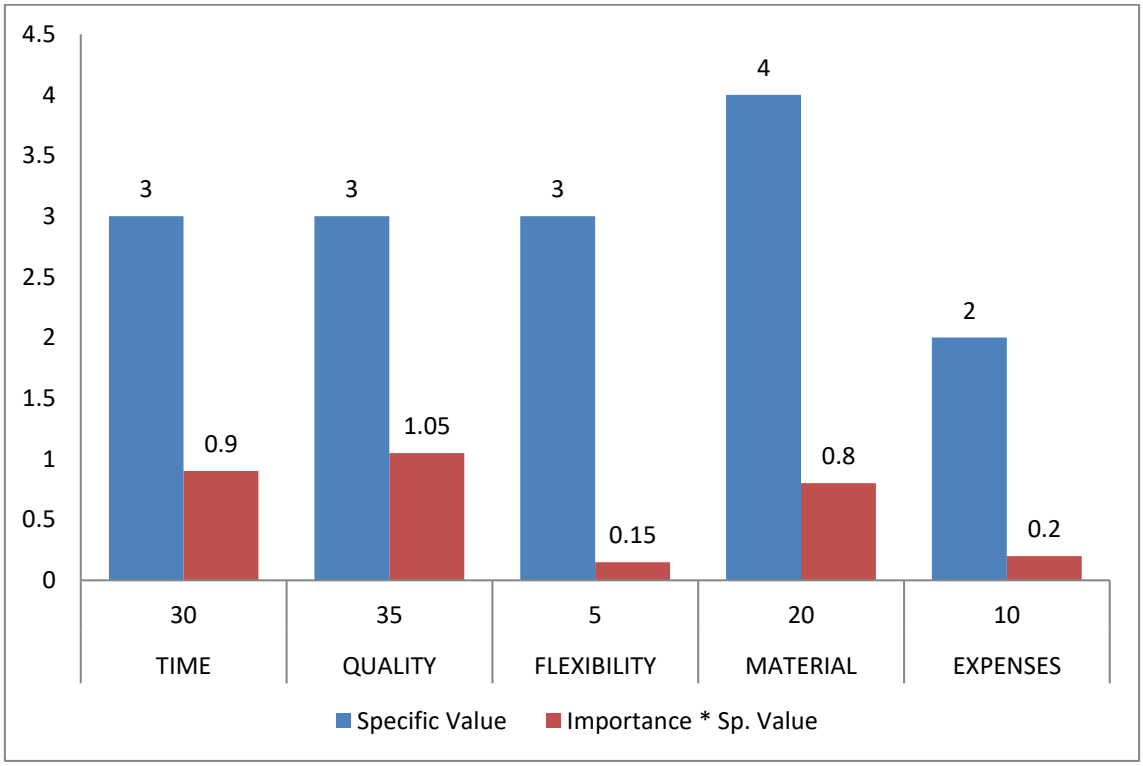


***Figure 49**. Graphic representation of criterions importance values for Metal Forming*

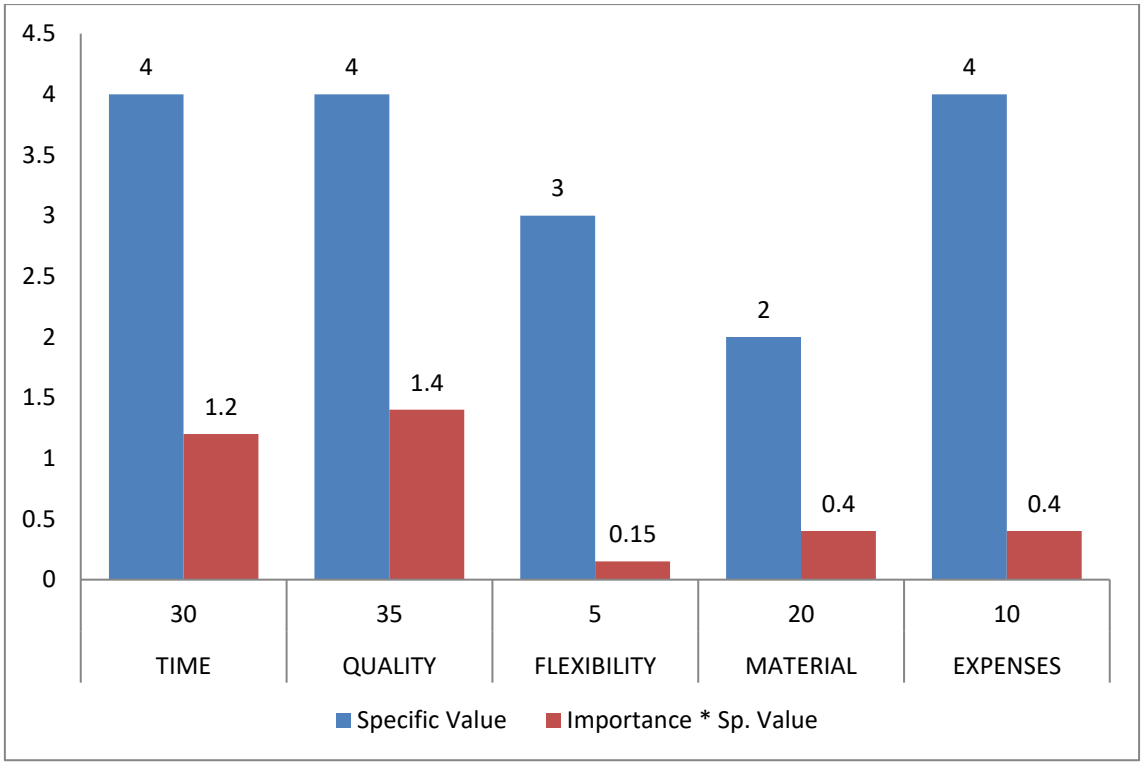


Figure 50 Graphic representation of criterions importance values for Machining

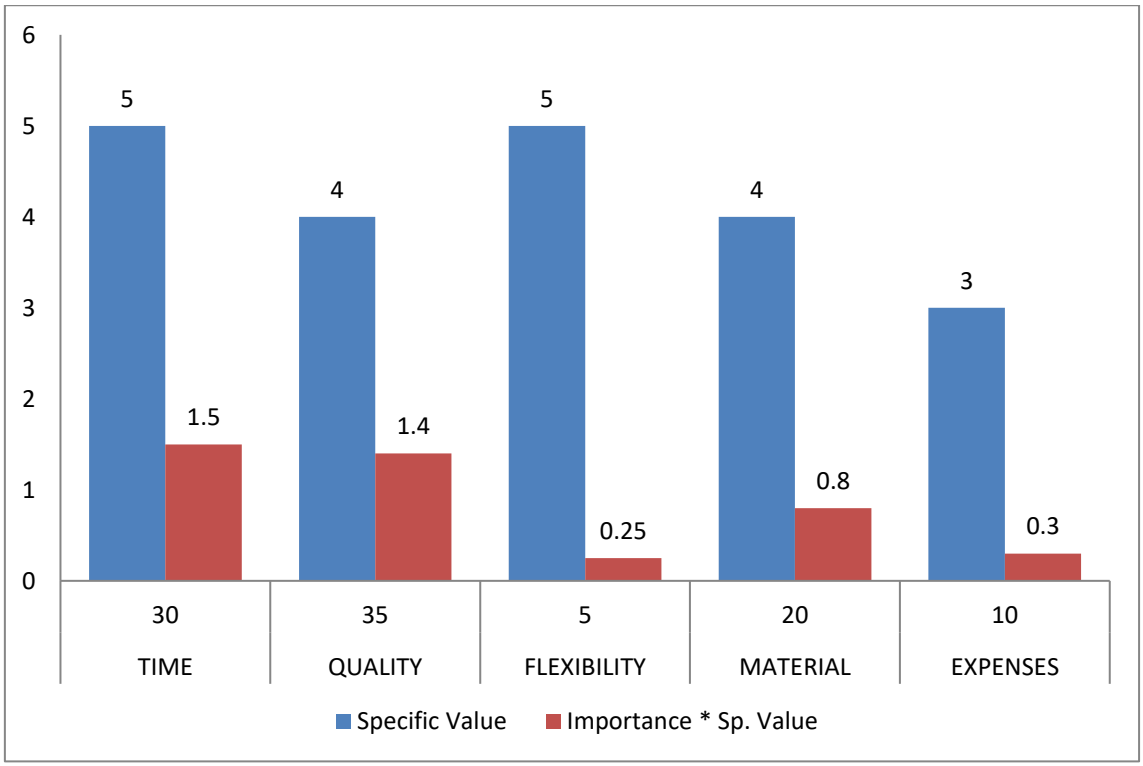


Figure 51. Graphic representation of criterions importance values for SLS

*Table 9 Calculated values for defined criterions and manufacturing technology (importance values * specific values)*

Manufacturing technology	TIME	QUALITY	FLEXIBILITY	MATERIAL	EXPENSES
Metal forming	0.9	1.05	0.15	**0.8**	**0.2**
Machining	1.2	**1.4**	**0.15**	0.4	**0.4**
SLS	**1.5**	**1.4**	**0.25**	0.8	**0.3**

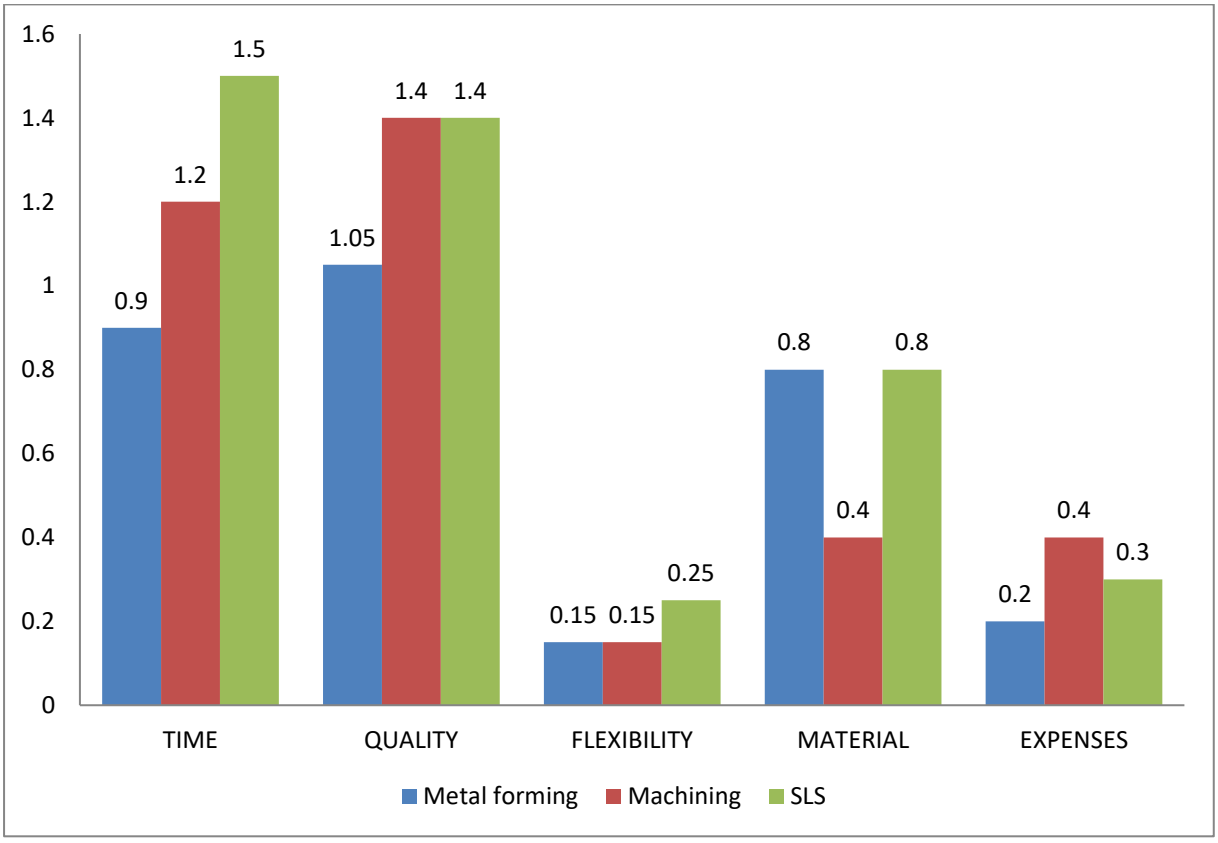


Figure 52 *.Graphic representation of calculated values (importance values * specific values)*

Table 10. *Mean values for defined criterions and manufacturing technology (importance values * specific values) for both experts*

Manufacturing technology	TIME	QUALITY	FLEXIBILITY	MATERIAL	EXPENSES
Metal forming	1.05	1.05	0.15	0.8	0.15
Machining	1.05	1.4	0.15	0.5	0.35
SLS	1.35	1.575	0.225	0.8	0.3

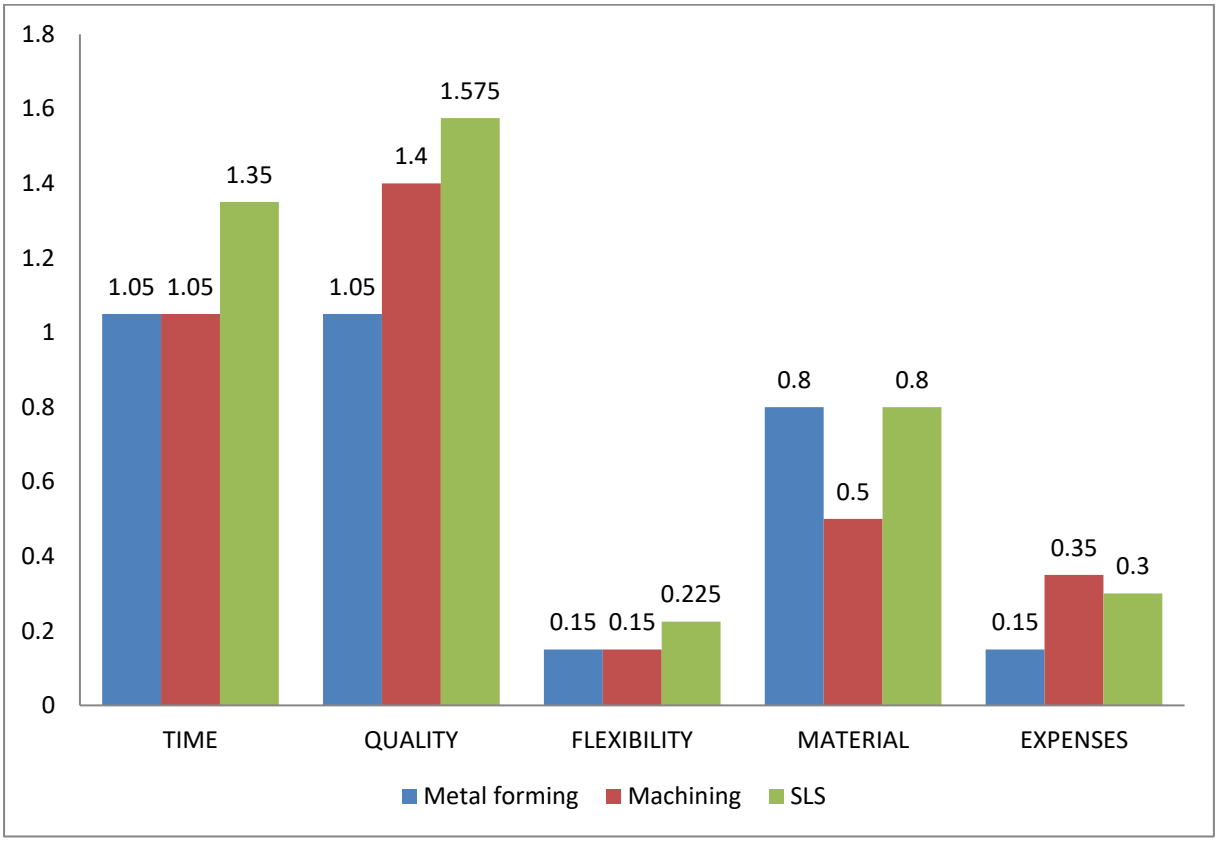


Figure 53 .Graphic representation of mean calculated values (importance values * specific values) for both experts

6.1.4 Discussion of the results

In Table 11 calculated values are presented for all defined manufacturing technologies and defined criterions. Values are self explanatory but some remarks should be noted:

- **Time** is lowest for SLS technology. This is normal because parts can be made fast if everything is prepared accordingly.
- **Quality** is best for SLS technology, but very close to machining. Any factors influence this, so much deeper analysis should be performed in some other research.
- **Flexibility** is the best for SLS, but this is not so important for customized plates.
- **Material** (production waste) is big for machining, while SLS and metal forming have less waste. But, this is questionable because there are lot of factors which influence this criterion (type of stock, design intent, etc).
- **Expenses** are high for metal forming because the tool for forming operation can be very expensive, in a case when only one implant should be created. That's why machining and SLS are cheaper.

6.2 Manufacturing of customized plate implant

For the manufacturing of the customized plate implant four manufacturing technologies were analyzed:

- Milling of the customized implant
- Milling of the core and cavity of the mold for molding the implant
- SLS - Selective Laser Sintering
- DMLS - Direct Metal Laser Sintering

Six parameters were analyzed to find the best technology which can be applied for the manufacturing of the customized plate implant.

- Surface quality
- Surface Tolerances
- Time
- Strength
- Possibility of production
- Cost

Implant properties:

- Volume: V = 0.0002 m^3
- Surface: S = 0.003 m^2
- Height: Z = 0.118 m
- Density: D = 4.43 g/cm^3

6.2.1 Milling

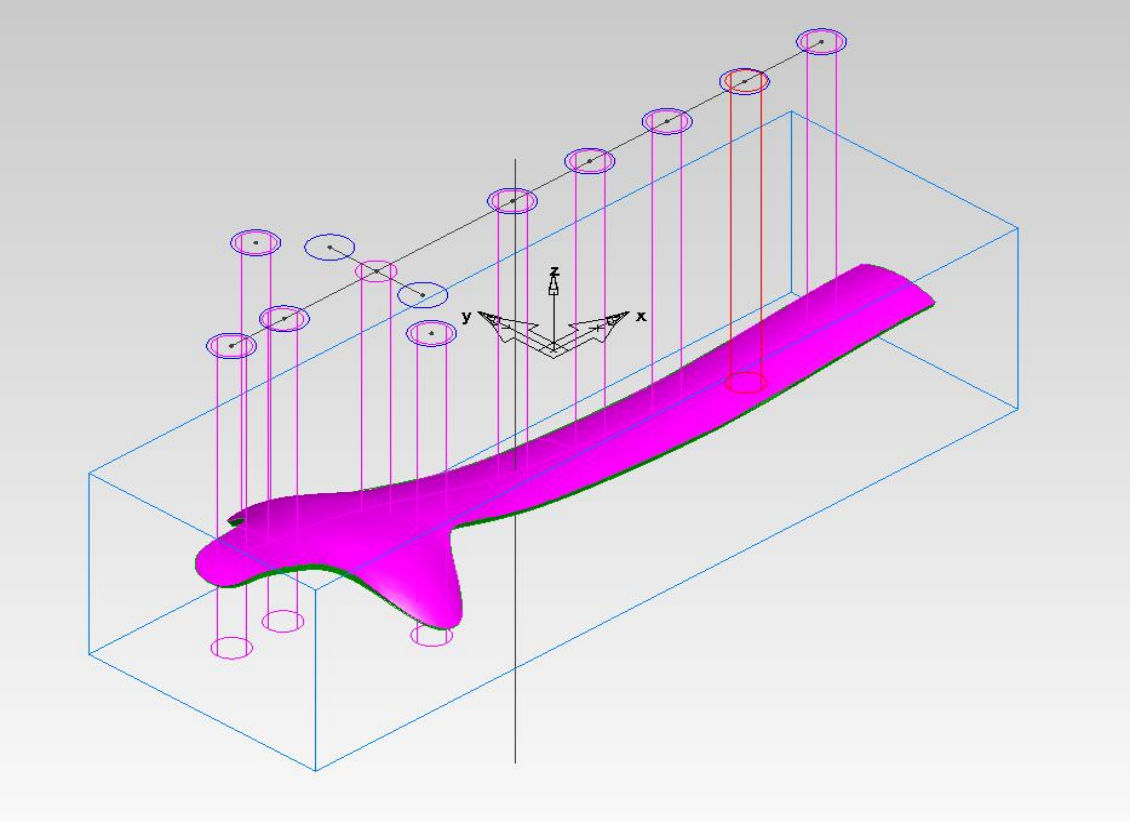


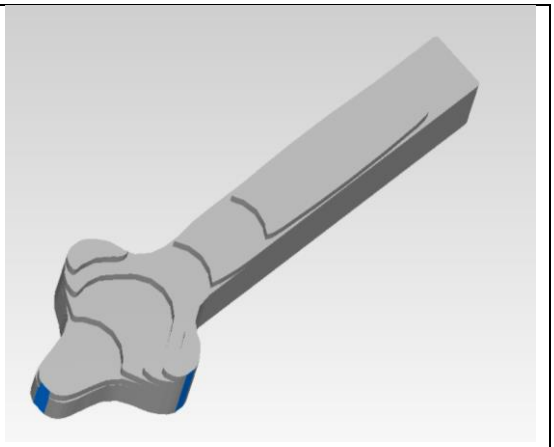
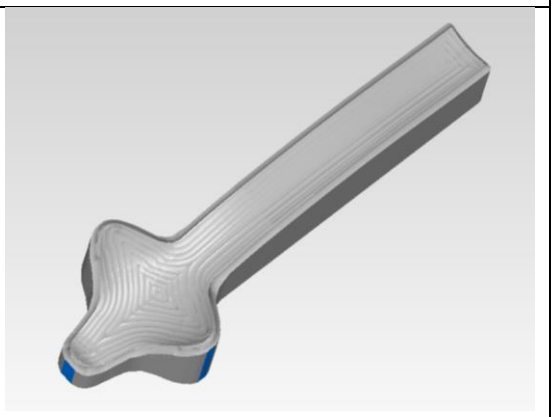
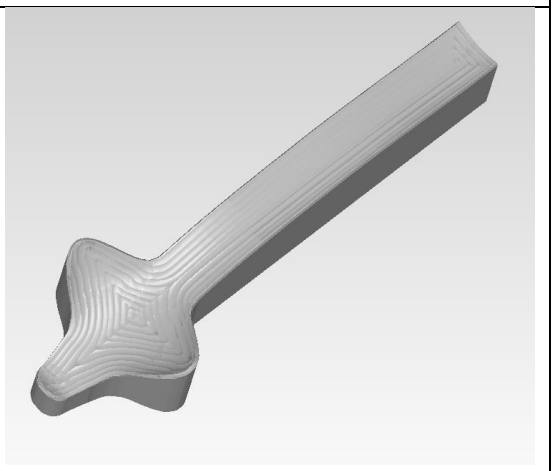
Figure 54. Implant plate model in the CAM software

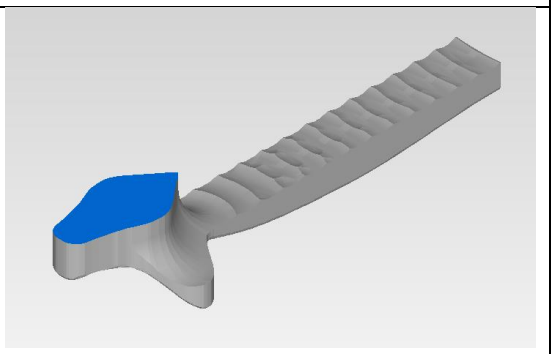
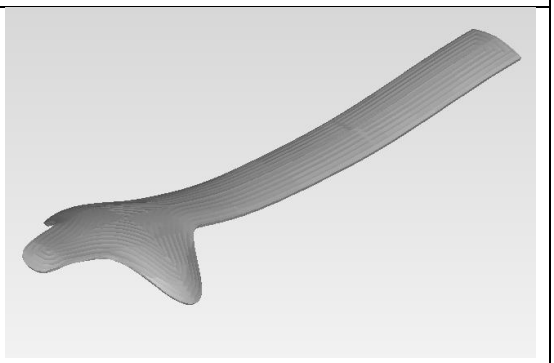
MANUFACTURING OPERATION SHEET

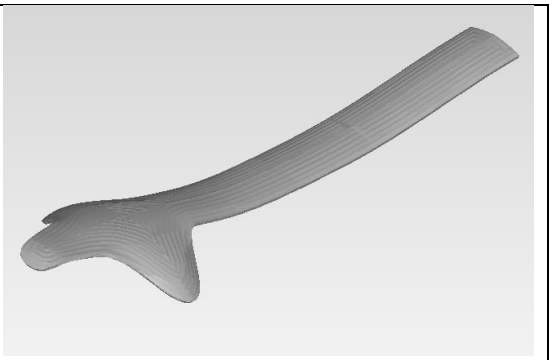
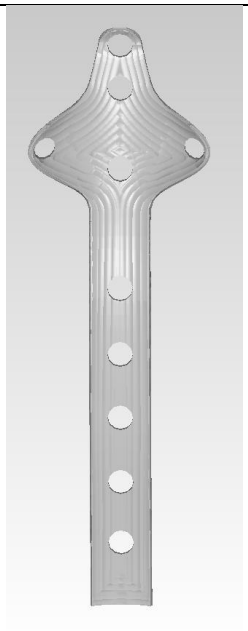
Part: plate implant
Time: **17:21:35.1**
Stock: L 119.879 mm x W 38.719 mm x T 30.000 mm
Mat: TITANIUM, 111.00 Brinell, 7.92 kN/mm^2

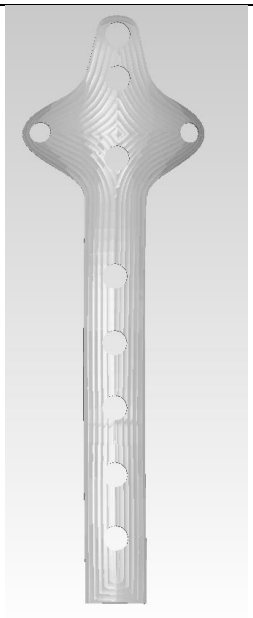
NC Software: Bridgeport Operating Software Systems 9 (Inch).
Bridgeport machines with BOSS9 control software.

Setup: Setup1
Fixture: 1
Origin: X 59.940 mm, Y 19.359 mm, Z 0.000 mm

Op: 1 srf_mill1 (rough1, z level), Fixture 1 F/S: 161 RPM, 35 MMPM (0.054 MMPT) Tool: #1 (endmillM1800:4reg, 18.000 mm) Depth: 3.000 mm Other: Stepover: 5.994 mm Allowance: 1.250 mm, Tolerance: 0.100 mm Time: 4:12:36.0 Power: 0.08 (est. 0.08) kW	
Op: 2 srf_mill1 (finish3, spiral3d), Fixture 1 F/S: 646 RPM, 31 MMPM (0.012 MMPT) Tool: #2 (endmillBM0600:4reg, 6.000 mm) Other: Stepover: 1.250 mm Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 1:37:27.6	
Op: 3 srf_mill1 (finish4, z level), Fixture 1 F/S: 646 RPM, 31 MMPM (0.012 MMPT) Tool: #2 (endmillBM0600:4reg, 6.000 mm) Other: Stepover: Adaptive Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 4:25:54.5	

Op: 4 stop1 (stop), Fixture 1 Time: 0:00.0	
Setup: Setup2 Fixture: 2 Origin: X -59.940 mm, Y 19.359 mm, Z 30.000 mm	
Op: 5 srf_mill2 (rough1, z level), Fixture 2 F/S: 161 RPM, 35 MMPM (0.054 MMPT) Tool: #3 (endmillBM1800:4reg, 18.000 mm) Depth: 18.000 mm Other: Stepover: 5.994 mm Allowance: 1.250 mm, Tolerance: 0.100 mm Time: 1:37:17.4	
Op: 6 srf_mill2 (finish3, spiral3d), Fixture 2 F/S: 352 RPM, 31 MMPM (0.022 MMPT) Tool: #4 (endmillBM1100:4reg, 11.000 mm) Other: Stepover: 1.250 mm Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 1:48:19.1	

Op: 7 srf_mill2 (finish4, z level), Fixture 2 F/S: 352 RPM, 31 MMPM (0.022 MMPT) Tool: #4 (endmillBM1100:4reg, 11.000 mm) Other: Stepover: Adaptive Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 3:04:48.2	
Op: 8 hole1 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: -54.938 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:35.9 Op: 9 hole2 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: -30.228 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.5 Op: 10 hole3 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: -6.981 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.5 Op: 11 hole4 (spot drill), Fixture 2	

F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: 19.386 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.6 Op: 12 hole5 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: 45.753 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.6 Op: 13 hole6 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: -35.797 mm 15.000 mm 28.239 mm Depth: 5.039 mm Time: 0:25.0 Op: 14 hole7 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: -35.797 mm -15.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.6 Op: 15 hole8 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: -46.142 mm 0.000 mm 28.239 mm Depth: 5.039 mm	

Time: 0:24.4 Op: 16 hole9 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: 6.351 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.8 Op: 17 hole10 (spot drill), Fixture 2 F/S: 559 RPM, 0.036 MMPR Tool: #5 (center_M1000-0400, 5.200 mm) Center: 32.876 mm 0.000 mm 28.239 mm Depth: 5.039 mm Time: 0:24.6 Op: 18 hole1 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: -54.938 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:12.9 Op: 19 hole2 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: -30.228 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole	

Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:01.6 Op: 20 hole3 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: -6.981 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:01.6 Op: 21 hole4 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: 19.386 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:01.6 Op: 22 hole5 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: 45.753 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm	

Time: 3:01.6 Op: 23 hole8 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: -46.142 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:02.2 Op: 24 hole9 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: 6.351 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:01.9 Op: 25 hole10 (drill), Fixture 2 F/S: 582 RPM, 0.035 MMPR Tool: #6 (TD_M0500:J, 5.000 mm) Center: 32.876 mm 0.000 mm 28.239 mm Depth: 52.002 mm Other: Pecks: 20, Cycle: Deep Hole Other: Steps: 5.000 mm 2.500 mm 2.500 mm Time: 3:01.6	

Op: 26 hole6 (drill), Fixture 2 F/S: 727 RPM, 0.028 MMPR Tool: #7 (TD_M0400:J, 4.000 mm) Center: -35.797 mm 15.000 mm 28.239 mm Depth: 51.602 mm Other: Pecks: 25, Cycle: Deep Hole Other: Steps: 4.000 mm 2.000 mm 2.000 mm Time: 3:16.2 Op: 27 hole7 (drill), Fixture 2 F/S: 727 RPM, 0.028 MMPR Tool: #7 (TD_M0400:J, 4.000 mm) Center: -35.797 mm -15.000 mm 28.239 mm Depth: 51.602 mm Other: Pecks: 25, Cycle: Deep Hole Other: Steps: 4.000 mm 2.000 mm 2.000 mm Time: 3:05.2	

Tools:

Crib: tools
Tool Name: endmillM1800:4reg
Tool Slot No.: 1
Tool Comp. No.: 1
Tool Offset No.: 1
Tool Material: HSS
Tool Finish: BRIGHT
Tool End: SINGLE
Cutting Type: CENTER
Flute Angle: STANDARD
Flute Number: 4
Diameter: 18.000 mm
Shank Diameter: 15.880 mm
Length: 41.280 mm
Exposed Length: 59.300 mm

Overall Length: 95.250 mm
End Radius: 0.000 mm

Tool Name: endmillBM1200:4reg
Tool Slot No.: 2
Tool Comp. No.: 2
Tool Offset No.: 2
Tool Material: HSS
Tool Finish: BRIGHT
Tool End: SINGLE
Cutting Type: CENTER
Flute Angle: STANDARD
Flute Number: 4
Diameter: 12.000 mm
Shank Diameter: 12.000 mm
Length: 25.000 mm
Exposed Length: 37.000 mm
Overall Length: 75.000 mm
End Radius: 6.000 mm

Tool Name: endmillBM1800:4reg
Tool Slot No.: 3
Tool Comp. No.: 3
Tool Offset No.: 3
Tool Material: HSS
Tool Finish: BRIGHT
Tool End: SINGLE
Cutting Type: CENTER
Flute Angle: STANDARD
Flute Number: 4
Diameter: 18.000 mm
Shank Diameter: 18.000 mm
Length: 38.000 mm
Exposed Length: 56.000 mm
Overall Length: 100.000 mm
End Radius: 9.000 mm

Tool Name: center_M1000-0400
Tool Slot No.: 4
Tool Comp. No.: 4
Tool Offset No.: 4
Tool Material: HSS
Tool Finish: BRIGHT
Type: Center
Diameter: 4.000 mm
Body Diameter: 10.000 mm
Length: 4.000 mm
Exposed Length: 37.500 mm

Overall Length: 50.000 mm
Angle (included): 118 deg.

Tool Name: TD_M0500:J
Tool Slot No.: 5
Tool Comp. No.: 5
Tool Offset No.: 5
Tool Material: HSS
Tool Finish: BRIGHT
Diameter: 5.000 mm
Shank Diameter: 5.000 mm
Length: 62.000 mm
Exposed Length: 68.500 mm
Overall Length: 92.000 mm
Angle (included): 118 deg.
Tool touch off at the tip

Tool Name: TD_M0400:J
Tool Slot No.: 6
Tool Comp. No.: 6
Tool Offset No.: 6
Tool Material: HSS
Tool Finish: BRIGHT
Diameter: 4.000 mm
Shank Diameter: 4.000 mm
Length: 54.000 mm
Exposed Length: 59.200 mm
Overall Length: 83.000 mm
Angle (included): 118 deg.
Tool touch off at the tip

Cost of the process:
Material Cost: 4.86$/kg * M = 4.86 * V * density = 4.86 * 0.0002 * 4430 = **4.3$**
Machining per/hour was approximated and data was used from the internet:

- machine cost
- machine maintenance cost
- tooling cost
- project risk
- customer panic factor
- labor, rent, etc

For standard CNC 3-acix milling machine around 150$/h

Machining Cost: Machining/ hour * Hours = 150 * 17.35 = **2581.5$**

Cost = 2585.8$

Second Attempt

Actions:

- Remove one finish
- Change finish process tool path from spiral to parallel

Process time reduced to 9:17:41.0

Time reduced by 90%. Surface quality dropped, additional work needed.

Machining cost: 150 * 9.35 = 1402$

Cost: 1406.3$

Third Attempt

Actions:

- Remove one finish

Process time reduced to 16:22:29.9

Time reduced by 7%. Surface quality remains the same.

Machining cost: 150 * 16.367 = 2455.05$

Cost: 2459.35$

Conclusion - More time needed for the better quality surface.

6.2.2 Manufacturing of core and cavity for the customized plate implant - Milling

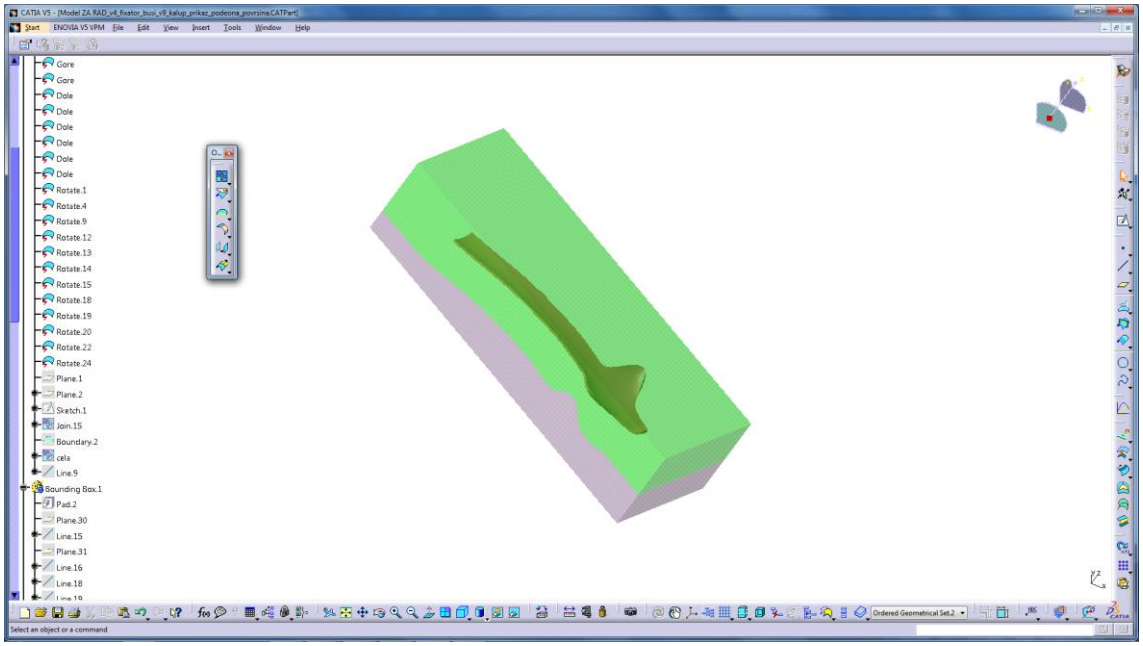


Figure 55. MOLD with plate implant model

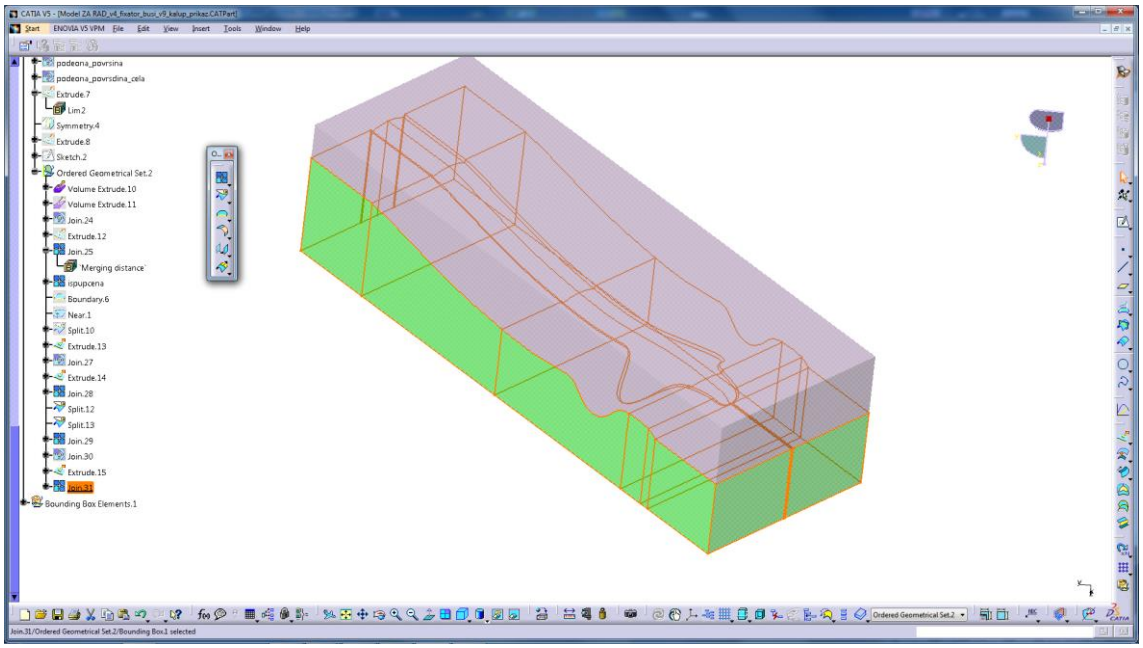


Figure 56. CATIA - CORE and CAVITY design

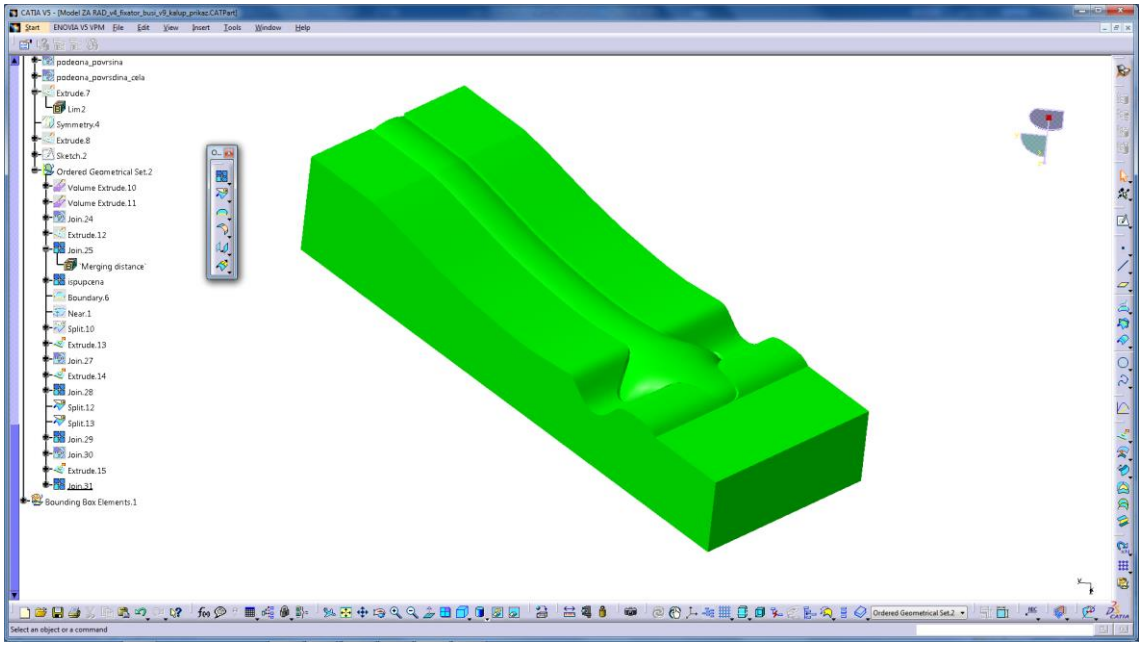


Figure 57. CATIA - CORE design

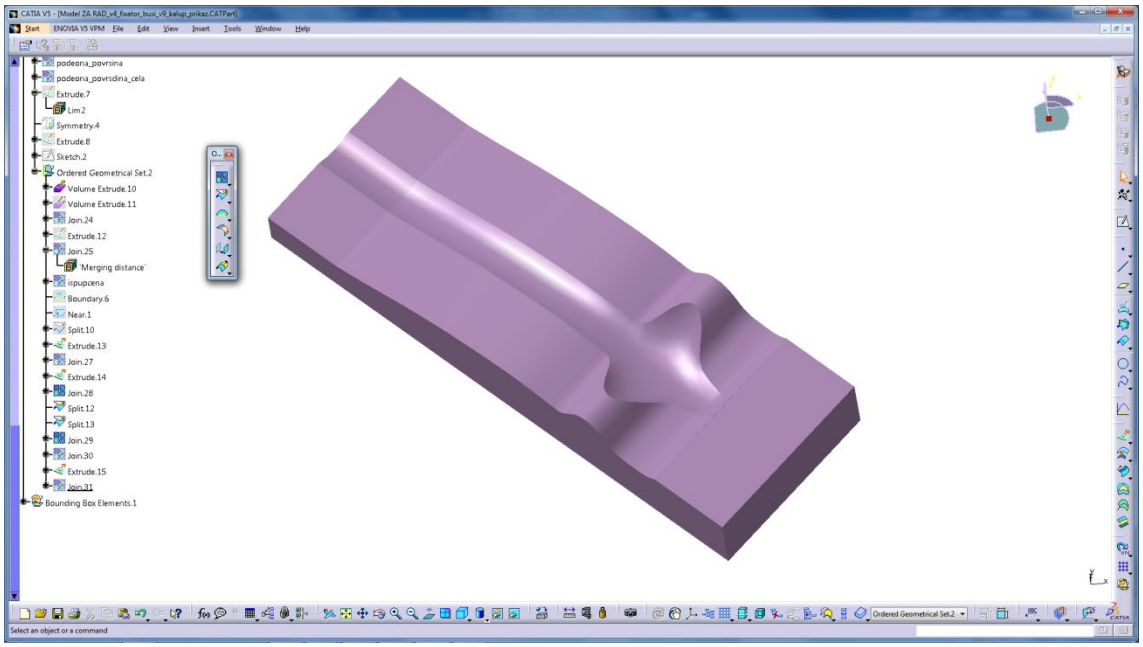


Figure 58 .CATIA - CAVITY design

Core Manufacturing

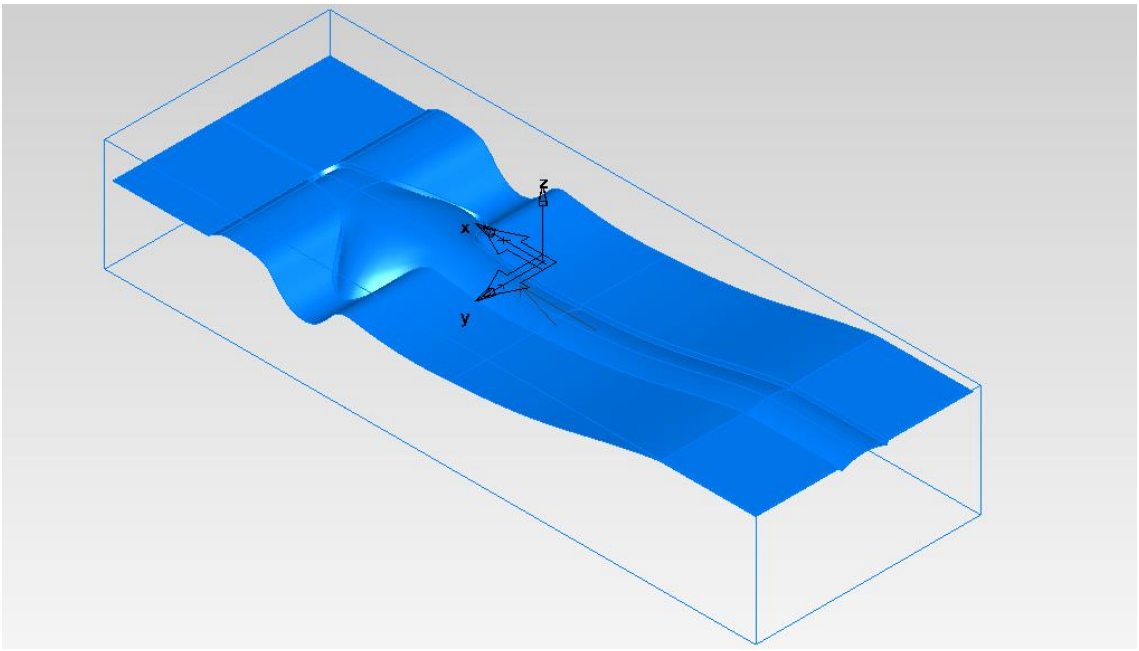


Figure 59. CORE Prepared for Manufacturing

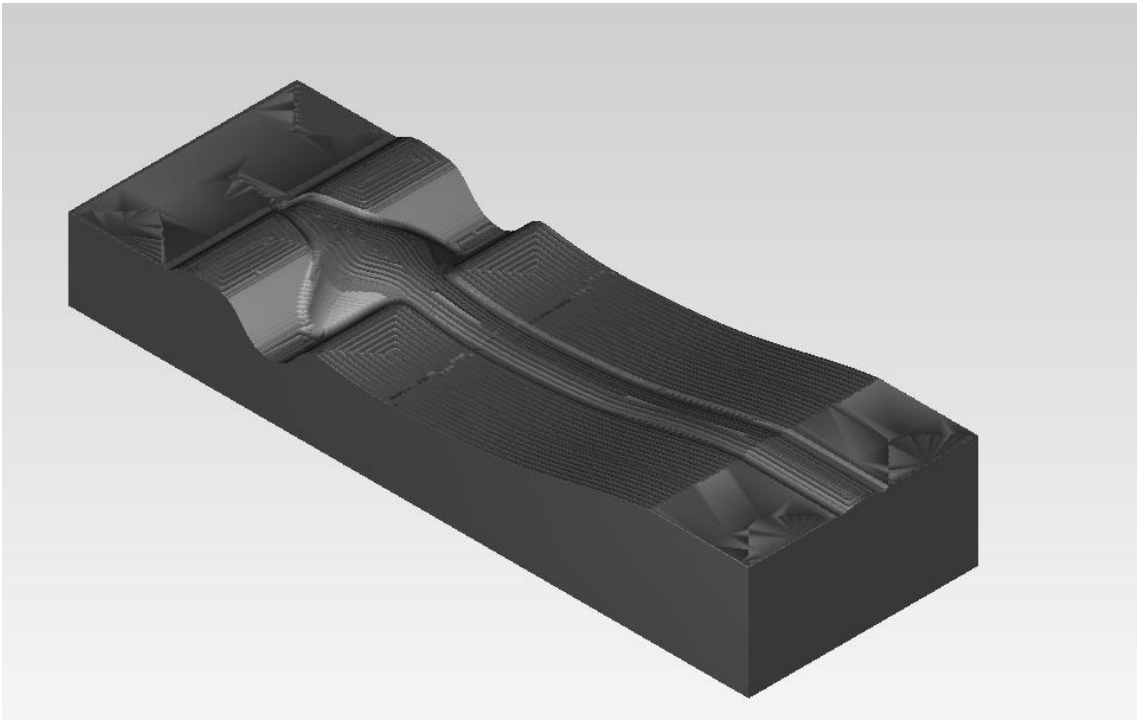
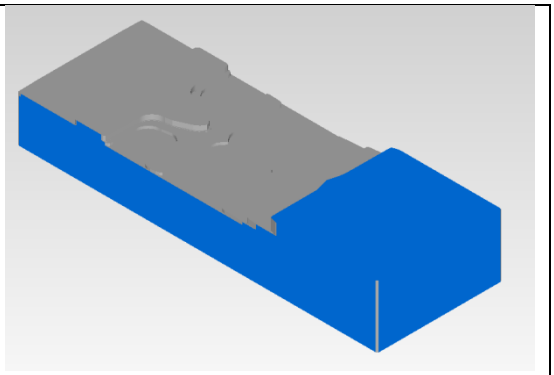
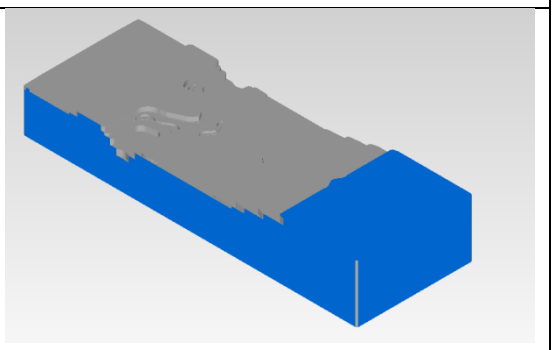
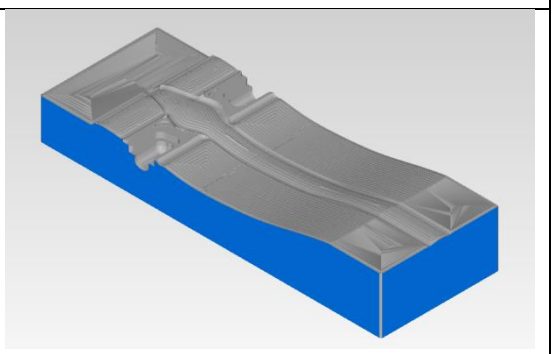
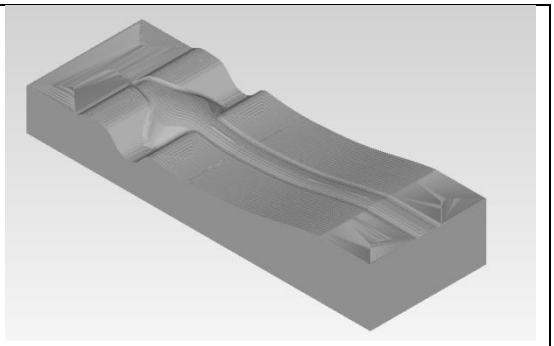


Figure 60 Manufactured CORE

Part: CORE for implant plate
Time: 6:46:04.0
Stock: L 170.133 mm x W 58.785 mm x T 29.369 mm
Mat: STEEL-41XX, 217.00 Brinell, 3.82 kN/mm^2

Op: 1 srf_mill2 (rough2, z level), Fixture 1 F/S: 657 RPM, 152 MMPM (0.058 MMPT) Tool: #1 (endmillM1200:4reg, 12.000 mm) Depth: 12.000 mm Other: Stepover: 3.996 mm Allowance: 1.250 mm, Tolerance: 0.500 mm Time: 44:36.7	
Op: 2 srf_mill2 (rough3, z level), Fixture 1 F/S: 1315 RPM, 76 MMPM (0.029 MMPT) Tool: #2 (endmillM0600:reg, 6.000 mm) Depth: 3.000 mm Other: Stepover: 1.998 mm Allowance: 1.250 mm, Tolerance: 0.500 mm Time: 13:03.6	
Op: 3 srf_mill2 (finish5, spiral3d), Fixture 1 F/S: 1894 RPM, 119 MMPM (0.016 MMPT) Tool: #3 (endmillBM0500:4reg, 5.000 mm) Other: Stepover: 1.250 mm Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 1:17:14.7	

Op: 4 srf_mill2 (finish6, z level), Fixture 1 F/S: 1894 RPM, 119 MMPM (0.016 MMPT) Tool: #3 (endmillBM0500:4reg, 5.000 mm) Other: Stepover: Adaptive Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 4:31:02.1	

Crib: tools

Tool Name:	endmillM1200:4reg
Tool Slot No.:	1
Tool Comp. No.:	1
Tool Offset No.:	1
Tool Material:	HSS
Tool Finish:	BRIGHT
Tool End:	SINGLE
Cutting Type:	CENTER
Flute Angle:	STANDARD
Flute Number:	4
Diameter:	12.000 mm
Shank Diameter:	12.700 mm
Length:	31.750 mm
Exposed Length:	43.800 mm
Overall Length:	82.550 mm
End Radius:	0.000 mm

Tool Name:	endmillM0600:reg
Tool Slot No.:	2
Tool Comp. No.:	2
Tool Offset No.:	2
Tool Material:	HSS
Tool Finish:	BRIGHT
Tool End:	SINGLE
Cutting Type:	CENTER
Flute Angle:	STANDARD
Flute Number:	2
Diameter:	6.000 mm
Shank Diameter:	9.530 mm
Length:	12.700 mm

Exposed Length:	18.700 mm
Overall Length:	61.910 mm
End Radius:	0.000 mm

Tool Name:	endmillBM0500:4reg
Tool Slot No.:	3
Tool Comp. No.:	3
Tool Offset No.:	3
Tool Material:	HSS
Tool Finish:	BRIGHT
Tool End:	SINGLE
Cutting Type:	CENTER
Flute Angle:	STANDARD
Flute Number:	4
Diameter:	5.000 mm
Shank Diameter:	6.000 mm
Length:	16.000 mm
Exposed Length:	21.000 mm
Overall Length:	50.000 mm
End Radius:	2.500 mm

Cavity Manufacturing

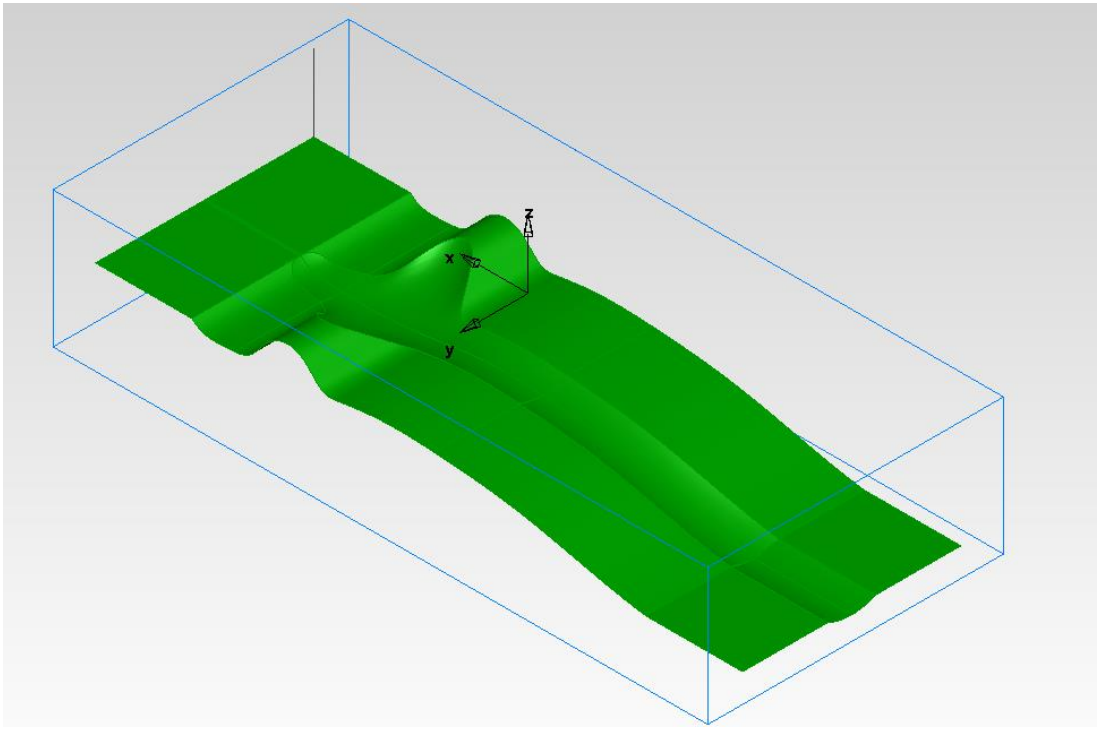


Figure 61. CAVITY prepared for manufacturing

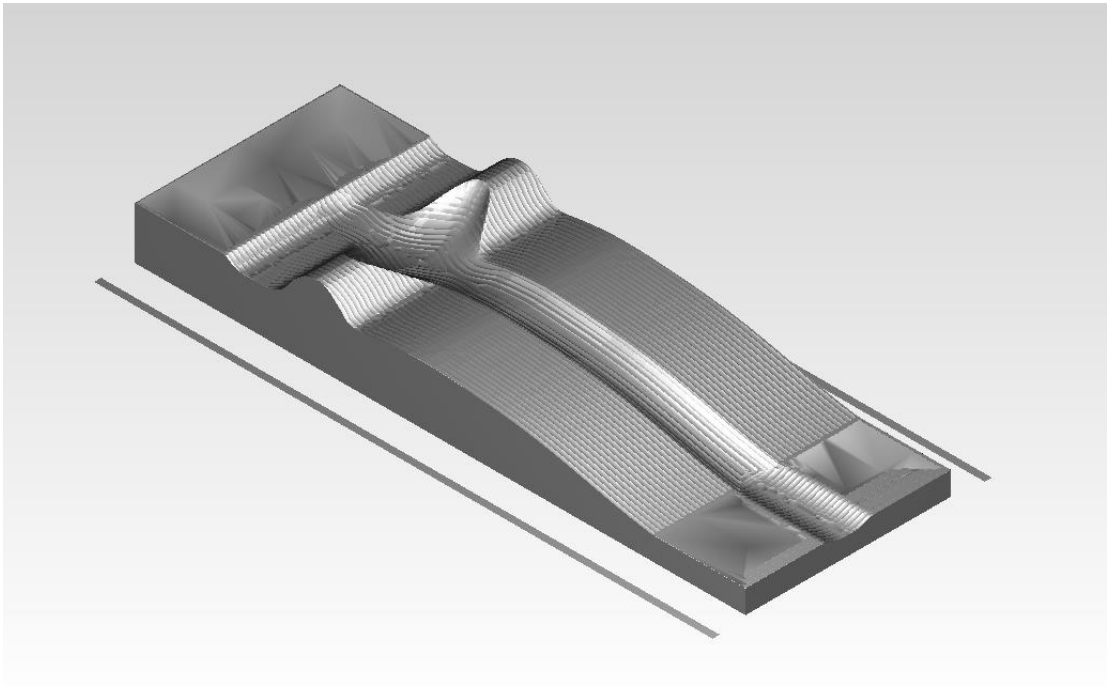
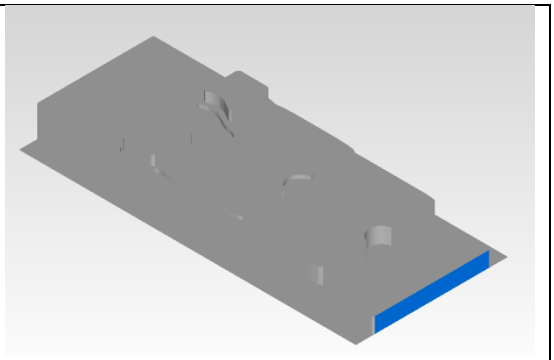
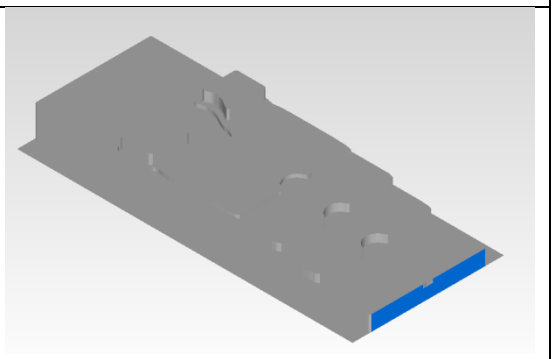
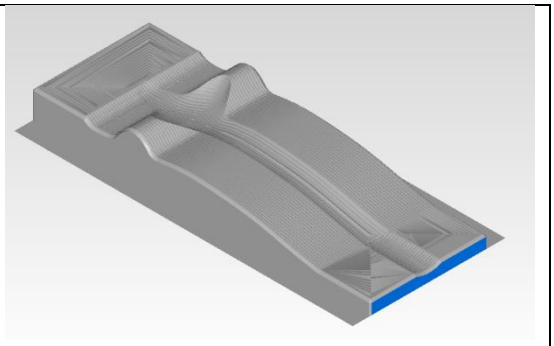
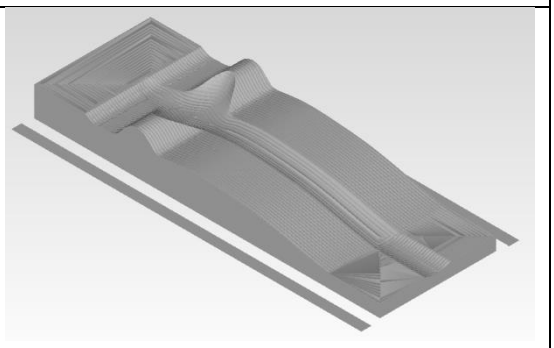


Figure 62 .Manufactured CAVITY

Part: Model ZA RAD_v4_fixator_busi_v9_kalup_prikaz_podeona_povrsina
Time: 3:06:50.8
Stock: L 170.133 mm x W 76.814 mm x T 35.388 mm
Mat: STEEL-41XX, 217.00 Brinell, 3.82 kN/mm^2

Op: 1 srf_mill1 (rough2, z level), Fixture 1 F/S: 848 RPM, 244 MMPM (0.072 MMPT) Tool: #1 (endmillM1200:4reg, 12.000 mm) Depth: 12.000 mm Other: Stepover: 3.996 mm Allowance: 1.250 mm, Tolerance: 0.100 mm Time: 1:14:50.8	
Op: 2 srf_mill1 (rough3, z level), Fixture 1 F/S: 848 RPM, 244 MMPM (0.072 MMPT) Tool: #1 (endmillM1200:4reg, 12.000 mm) Depth: 6.000 mm Other: Stepover: 3.996 mm Allowance: 1.250 mm, Tolerance: 0.100 mm Time: 2:58.0	

Op: 3 srf_mill1 (finish5, spiral3d), Fixture 1 F/S: 2444 RPM, 191 MMPM (0.020 MMPT) Tool: #2 (endmillBM0500:4reg, 5.000 mm) Other: Stepover: 1.250 mm Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 50:12.7	
Op: 4 srf_mill1 (finish6, z level), Fixture 1 F/S: 2444 RPM, 191 MMPM (0.020 MMPT) Tool: #2 (endmillBM0500:4reg, 5.000 mm) Other: Stepover: Adaptive Allowance: 0.000 mm, Tolerance: 0.025 mm Time: 58:41.9	

Crib: tools

Tool Name: endmillM1200:4reg
Tool Slot No.: 1
Tool Comp. No.: 1
Tool Offset No.: 1
Tool Material: HSS
Tool Finish: BRIGHT
Tool End: SINGLE
Cutting Type: CENTER
Flute Angle: STANDARD
Flute Number: 4
Diameter: 12.000 mm
Shank Diameter: 12.700 mm

Length: 31.750 mm
Exposed Length: 43.800 mm
Overall Length: 82.550 mm
End Radius: 0.000 mm

Tool Name: endmillBM0500:4reg
Tool Slot No.: 2
Tool Comp. No.: 2
Tool Offset No.: 2
Tool Material: HSS
Tool Finish: BRIGHT
Tool End: SINGLE
Cutting Type: CENTER
Flute Angle: STANDARD
Flute Number: 4
Diameter: 5.000 mm
Shank Diameter: 6.000 mm
Length: 16.000 mm
Exposed Length: 21.000 mm
Overall Length: 50.000 mm
End Radius: 2.500 mm

Cost of the process:
Material Cost: 4.45$/kg * M = 4.45 * V * density = 4.45 * 0.00027 * 8030 **= 9.65$**
Machining per/hour was approximated and data was used from the internet:

- machine cost
- machine maintenance cost
- tooling cost
- project risk
- customer panic factor
- labor, rent, etc

For standard CNC 3-acix milling machine around 150$/h
Machining Cost: Machining/ hour * Hours = 150 * 9.89 = **1483.5$**

Cost = 1493.15$

6.2.3 Additive Technologies

Two Technologies SLS and DLMS were chosen for the comparison. The both techniques provide excellent surface quality, build time is similar, both of them can build parts of complex geometry (DMLS can build parts with moving sections)

Problem as stated on http://www.lasersintering.com/ can be in size of the parts. They stated:"The largest build chamber size for plastic laser sintering (SLS) is 29” x 21.65” x 29.53”. Standard tolerances are +/- 0.005” for the first inch and +/- 0.003” for each inch thereafter. The build chamber for metal laser sintering (DMLS) is 9.85” x 9.85” x 8”. Standard tolerances can range from 0.010” to as fine as 0.003”.

6.2.4 Build Time

Build Time approximation defined in [14]. This function is defined for SLA, but it is just geometrically based, so as it is stated in [14] it can be used for other additive technologies as a approximation.

$T = 0.0341 + 2 * Z + 2.17 * V + 0.018 * SA$ [14]

Z - Height of the part. $Z = 0.118$ m

V - Volume of the part $V = 0.004$ m^3

SA - Surface Area $SA = 0.003$ m^2

$T = 0.0341 + 2 * 0.118 + 2.17 * 0.004 + 0.018 * 0.003 = 0.28$ h

Surface Tolerances (http://www.protolabs.com/ and https://www.stratasysdirect.com)

SLS	0.25 - 0.0015mm/mm
DLMS	0.12 - 0.05 mm/mm

Surface quality (https://www.stratasysdirect.com)

SLS	8 µm
DLMS	8.75 µm

Cost

SLS	269$
DLMS	269$

Based on data acquired from https://i.materialise.com/

6.2.5 Discussion

Based on the presented results it seems that SLS and DLMS are good choice for the production of customized implant because quality is acceptable, but there is one big problem. SLS and DLMS provide good results for smaller parts. When parts are bigger structural strength is much lesser then for smaller parts and geometrical precision of the obtained model is questionable [14]. Considering milling of the part or the mold, the conclusion follows: The cost of milling compared to additive technologies is much higher, but that is logical because working hour is much more expensive for CNC machines. Of course with different feeds and speeds time for machining can be reduced. The author suggests to mold the implant in the core and cavity produced by the milling process presented in this paper. One more reason for mold production is that mold can be used again, for some different patient. Some general marks about parameters for the manufacturing technologies are presented in following table 11.

Table 11 *.Manufacturing parameters*

Manufacturing technology	Surface Quality	Time	Tolerances	Strength	Possibility of production	Cost per part
Milling (part)	+	-	+	+	/	**2459.35$**
Milling (Core and Cavity)	+	-	-	+	+	**1493.15$**
SLS	+	+	+	-	/	**269$**
DLMS	+	+	+	-	/	**269$**

Conclusion

The plate implants are necessary orthopaedic equipment, and their design and ways of production should be constantly improved. As already stated, plates play very important role in bone healing process.

In this thesis we presented the methods which make possible the construction of humerus bone, and personalized cloverleaf fixation plate and distal plate geometrical prototype (surface, solid).

The crucial advantage of usage of this method is that it is possible to make geometrical models of the implant modified (personalized) for each patient individually. If the shape, geometry and topology of the implant which is used as a geometrical model are adjusted, it is done in terms of the shape, geometry and topology of patient's humerus. A surgeon can control adjustment by making some more corrections of the geometrical prototype of the plate(s) if it is necessary (e.g. the patient's health state requirements).

This approach is founded on the usage of the MAF method. More precisely, it represents extensions of the aforementioned method by introducing and defining the corresponding parameters for the purpose of creating a parametric model of the plate. Pre-contouring i.e. adaptation of the plate is achieved by inserting and changing the value of the existing parameters, according to the dimensions values acquired from the 2D or 3D model of the humerus bone, while topology remains unchanged. Adaptation of the plate model is possible through the UDF application, which is created in CATIA. UDF enables inserting the parameters values and as a consequence, shape and geometry of the plate models are personalized to the specific patient. UDF application is presented on the use case defined through the clinical case, which is publically available on the internet. Results show that presented requirements can be fulfilled quite satisfactory.

The possibility of plate adaptation before surgery, improves preoperative processes, shortens the time of intervention as well as enables firmness of the fracture and satisfies functional properties of the bone and joints. It is very significant to state that the importance of this approach for plate models creation lies down in its flexibility for adaptation. It is not always important to just make geometrically accurate plate model, yet, it is important to create flexible model. If parametric model can be flexible enough to conform to the specific case, than surgeon shall not need to use bending during the surgery and that will shorten the surgery time, which is crucial for the patient health. Plate models created in presented way,

are flexible by default. Deviation analysis between plates contact surface and bone outer shows that plate shape can be adapted to the patient specific bone in accordance with standard recommendations in clinical practise, or to the requirements of the specific case.

Created geometrical models can be applied in production of bone and plate models by using ordinary and specific technology, making initial prototype for the Finite Element Analyses (FAE), in planning in orthopaedics before operations and the wide range of applications in medicine and engineering. The results which are obtained and described in this study of geometrical and anatomical precision of the human humerus and parametric plate models are quite acceptable.

For the purpose of the demonstration, one example of techno-economic analysis of the cloverleaf plate manufacturing processes is presented in this thesis. This example covers application of classical manufacturing (CNC machining, metal forming) and application of additive technologies. It clearly shows importance of the application of the additive technologies in manufacturing the personalized physical models of the plates. In the cases when valid 3D geometrical model is created, physical model can be created in a just few steps. Of course, traditional manufacturing techniques like CNC machining can be also used, but, by the author opinion they are more suitable for the production of standard plates, which are used for the groups of patients.

Future work will cover several steps. First, it is of crucial importance to increase number of surgical cases or trauma examples, in order to test the validity of the selected parameters. This includes: number, type, and position of parameters. Second, full accessibility of the UDF to all kinds of medical and educational institutions will be enabled. For that purpose, it is crucial to remove commercial applications included in the research, and to enable application of open source software solutions. This can be done by using free (open source) CAD software like Free CAD with adequate scripts added to it. Third, it is important to create a database of developed solutions (plate models), because, it can be used for various purposes: open data repositories, for presentational purposes, for applications in real surgical cases, for educational purposes, etc. In order to fulfill requirements of this step, first step needs to be done.

Literature

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Figure:

Table:

Изјава 1.

ИЗЈАВА О АУТОРСТВУ

Изјављујем да је докторска дисертација, под насловом:

„Параметарски модели имплантата типа плочице намењених раменој кости“

која је одбрањена на Машинском факултету Универзитета у Нишу:

- резултат сопственог истраживачког рада;
- да ову дисертацију, ни у целини, нити у деловима, нисам пријављивао/ла на другим факултетима, нити универзитетима;
- да нисам повредио/ла ауторска права, нити злоупотребио/ла интелектуалну својину других лица.

Дозвољавам да се објаве моји лични подаци, који су у вези са ауторством и добијањем академског звања доктора наука, као што су име и презиме, година и место рођења и датум одбране рада, и то у каталогу Библиотеке, Дигиталном репозиторијуму Универзитета у Нишу, као и у публикацијама Универзитета у Нишу.

У Нишу, 28-11-2018

Потпис аутора дисертације:

Мохаммед Ал-Ријабет

Изјава 2.

ИЗЈАВА О ИСТОВЕТНОСТИ ЕЛЕКТРОНСКОГ И ШТАМПАНОГ ОБЛИКА ДОКТОРСКЕ ДИСЕРТАЦИЈЕ

Наслов дисертације:

„Параметарски модели имплантата типа плочице намењених раменој кости“

Изјављујем да је електронски облик моје докторске дисертације, коју сам предао/ла за уношење у **Дигитални репозиторијум Универзитета у Нишу,** истоветан штампаном облику.

У Нишу, 28-11-2018

Потпис аутора дисертације:

Мохаммед Ал-Ријабет

Изјава 3:

ИЗЈАВА О КОРИШЋЕЊУ

Овлашћујем Универзитетску библиотеку „Никола Тесла“ да у Дигитални репозиторијум Универзитета у Нишу унесе моју докторску дисертацију, под насловом:

„Параметарски модели имплантата типа плочице намењених раменој кости“

Дисертацију са свим прилозима предао/ла сам у електронском облику, погодном за трајно архивирање.

Моју докторску дисертацију, унету у Дигитални репозиторијум Универзитета у Нишу, могу користити сви који поштују одредбе садржане у одабраном типу лиценце Креативне заједнице (Creative Commons), за коју сам се одлучио/ла.

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5. Ауторство – без прераде **(CC BY-ND)**
6. Ауторство – делити под истим условима **(CC BY-SA)**[3]

У Нишу, 28-11-2018

Потпис аутора дисертације:

Мохаммед Ал-Ријабет