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DESIGN OF 3D MODEL OF CUSTOMIZED ANATOMICALLY ADJUSTED IMPLANTS

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Abstract. *Design and manufacturing of customized implants is a field that has been rapidly developing in recent years. This paper presents an originally developed method for designing a 3D model of customized anatomically adjusted implants. The method is based upon a CT scan of a bone fracture. A CT scan is used to generate a 3D bone model and a fracture model. Using these scans, an indicated location for placing the implant is recognized and the design of a 3D model of customized implants is made. With this method it is possible to design volumetric implants used for replacing a part of the bone or a plate type for fixation of a bone part. The sides of the implants, this one lying on the bone, are fully aligned with the anatomical shape of the bone surface which neighbors the fracture. The given model is designed for implants production utilizing any method, and it is ideal for 3D printing of implants.*

Key Words: *Custom Implants, Bones Fixation, CT Scan, 3D Bone Model*

1. INTRODUCTION

In orthopedic surgery there is a range of fixation methods for treating various bone fractures or other traumas. In the case of an internal fracture fixation treatment, it is of particular importance to utilize internal fixation whose geometrical and topological characteristics fully correspond to the shape and size of the patient's bone since this ensures improved recovery [1]. This paper focuses on the implants which are not of a standardized shape and size, but are adjusted to the patient's specific needs (customized, personalized implants) [2]. The term 'customization' in medicine mainly refers to the use of the treatments which are adjusted to a specific patient. There are not many examples of

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applying this principle when designing orthopaedic implants. In this paper, we will describe the method for enabling the design of the orthopaedic implants which are adjusted to a specific patient (customized implants) and of both shape volumetric and plate type. The patient's specific implants, i.e. custom designed implants for an individual patient, are growing in popularity.

The geometry and topology of those implants are adjusted to the anatomy and morphology of the bone and fracture of the specific patient. Their application has a positive effect on patients, but on the other hand, it requires more time for preoperative planning and manufacturing. Therefore, they are used in the areas where the application of predefined fixators can lead to complications in the surgical interventions or in the process of recovery [3].

Internal fixation of medical devices are used as a support to treat damaged or disease-infected bones brought about as a consequence of old age, disease or an accident. They are made of different kinds of biocompatible materials [4]. There are two kinds of internal fixations – intramedullary and extramedullary.

Intramedullary nails are used to treat various long bones (e.g. tibia). The nails are inserted into the bone by using the bone's intramedullar canal, after which screws are inserted to fix the nail to the bone [5].

Extramedullary devices take the form of plates that are fixed to the bone with screws. (Fig. 1). These kinds of implants are placed on the external surface of the fractured part of the bone [4, 6]. In this way, the fractured bone fragments are connected into a whole, the transport capacity of the joint is created and position and direction of the fragments are kept.

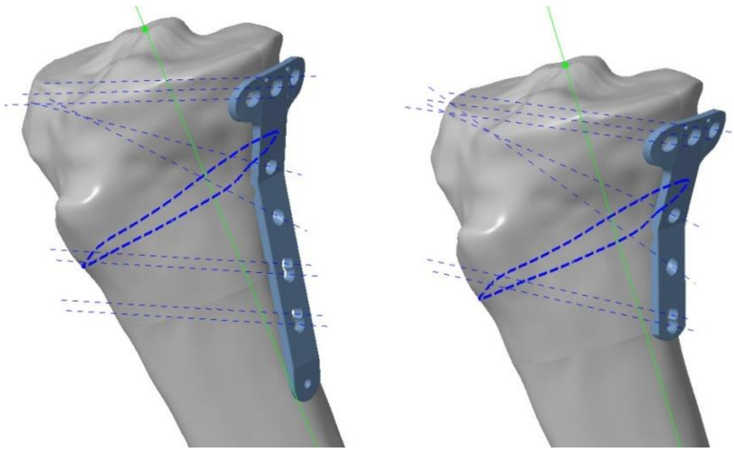

Fig. 1 Insertion of a tile for the upper part of tibia

There can be found only few described examples of the methods for creating a 3D model of anatomically adjusted internal implants which correspond to the bone contour in the literature.

Papers [7] and [8] present a method for designing customized implants with a CAD system by modifying standard implants, based on a patient's bones. The Finite Element Analysis is then used to evaluate and compare the proposed design of a custom femoral component with a conventional design.

Papers [9] and [10] present an example of designing a fixation with tile shape, as well as the dynamic screw bolt of a hip.

In [11] the description of a method and procedure of designing an internal fixation with tile shape type “medially locking plate” (MLP) is described, which is used for treating fractures of the femur from its lateral side. As a basis for design a 3D femur model is used. The position of a tile related to the femur is defined by creating a datum plane. Medial sketch of the MLP is created on the sagittal plane. The sketch is then extruded in both normal directions. The inner sides of the fixator are approximated by polygons, and try to follow the bone surface.

In [12] and [13] the method which is used for designing an internal fixation according to Mitkovic type TPL (tibia-plato-lateral) is shown. The suggested method is based on the application of the MAF - Method of Anatomical Features and newly developed techniques for designing fixation supporting surfaces. The result of the application of this method is a parametrical fixation model whose shape and geometry could be changed with a change of parameters. With this approach it is allowed to change the shape of a fixation in order to adjust it to the patient’s bone shape, in this case tibia, based on parameters values (dimensions) read from a suitable X-ray or CT - Computer Tomography – scan.

Many methods for creating customized implants try to create a mirror image 3D model of a sound part of the patient’s bone. After mirroring those methods use engineering tools (spline techniques) to create implants.

The case related to reverse engineering of sternum (chest bone) body presented in the paper [14] brings out a method for creating customized implants. The missing part of the sternum, affected by cancer, was redesigned in accordance with the virtual model of the sternum bone that was generated from preceding geometrical analyses of the healthy sternum samples which were geometrically and dimensionally similar to the diseased one. The geometrical analyses of healthy samples were used for generating the characteristic shape pattern of the transversal and sagittal cross-sections of the sternum as well as to identify the specific geometrical and dimensional constraints and relations.

2. Design of Customized Implants

An implant is a medical device manufactured to replace a missing biological structure, support a damaged biological structure, or fix an existing biological structure.

Conventional implant manufacturing methods provide only standard parts in a standard size and shape. This means that the implants do not respond to the patient’s specific needs, and the post-operative recovery is more difficult.

What is of highest importance during the process of implants insertion is to create a minimal direct contact between the fixation and the bone surface, while at the same time ensure that fixation follows the bone contours. The stress created when the device rests on the bone should be avoided since it can damage the periosteum which covers the bone surface and nourishes the bone through blood vessels in it.

The implant modeling is performed using a Computer-Aided product development system which, beside geometry and topology, enables integration of product knowledge and applied technologies restrictions for some forms in a virtual model of a product.

Methods include use of CAD software to design internal implants and these methods are based upon the ideas of orthopedic surgeons and engineers. The basis for creating a 3D geometrical model of an internal fixation is an outline of its contour defined in a suitable position in relation to the bone surface.

The general engineering techniques for design, analysis and manufacturing of customized implants, for specific bones, used in this research, include several tasks [15] (Fig. 2).

1. Creating a 3D parametric model of bones.
2. Creating a 3D parametric model of a fracture using a CT scan of the patient's fractured bones.
3. Selecting the places on the bone where the implant will be placed.
4. Adjusting the geometry of the implant according to the requirements of the surgeon.
5. Creating a customized 3D model of the implant.
6. Simulation of implant placement to bones.
7. Analysis and optimization of the shape and dimensions of implants.
8. Implant manufacturing.

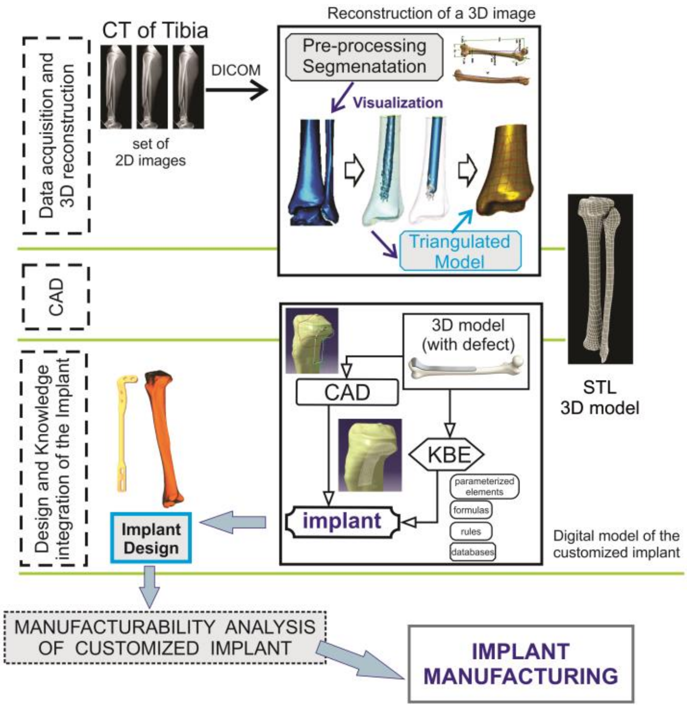

Fig. 5 Phases for designing and manufacturing of customized implants

This methodology gives the opportunity to create a custom implant design adjusted to the patient's bone anatomy. 3D models of implants can then be used for the production of implants, after manufacturability analysis.

The creation of 3D models of customized and anatomically adjusted implants is based on the 3D models of the patient bones and 3D parametric model of fracture which is made on the 3D model of the bone.

The typical design process of anatomical adjusted customized implants, used in this paper, is shown in Fig. 3.

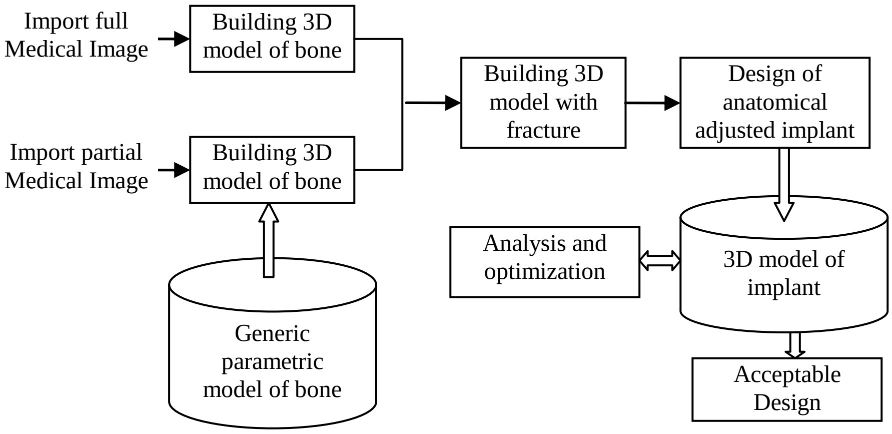

Fig. 3 Typical design process of anatomical adjusted customized implants

For this purpose, the first step is to create a 3D model of a selected bone.

The creation of geometrically accurate 3D models of human bones utilizes a number of different techniques and presents a unique challenge, because their geometry and form are very complex. These types of shapes can be modeled by using surface patches represented by Bezier or B-spline surfaces, or by using NURBS patches, which are commonly used in traditional CAD applications, e.g. CATIA [16].

The output of CATIA is presented in the STL (Stereolithography) format, which allows it to be directly transferred into an RP (Rapid Prototyping) machine.

Reverse engineering of human bones implies the use of some kind of medical imaging device for the acquisition of medical data (Computer Tomography – CT, Magnetic Resonance Imaging – MRI), then processing the data in medical or CAD software, and, finally, creating a valid geometrical model (surface, volume).

2.1. Creating 3D parametric model of bones

Within the project VIHOS (Virtual human osteoarticular system and its application in preclinical and clinical practice) [17] which is carried out at the Faculty of Mechanical Engineering and the Faculty of Medicine at the University of Niš, the 3D parameterized geometrical bone models are developed. For that purpose the Method of Anatomical Features (MAF) is developed.

The goal of this method is to find the best possible solution for the creation of a parametric point model of the human bone in a sense of its best application in medical imaging and preoperative planning in orthopedics. With application of this method it is possible to create patient specific geometrical models (polygonal, surface, and volume) and parametric (predictive) models of the human bones. Parametric models enable creation of geometrical models even in the cases when the geometrical data about specific bone is incomplete (e.g. bone fractures or diseases). In these situations geometrical models are created by applying the values of parameters measured on the medical images in the parametric functions. A more detailed description of the MAF and its various applications are presented in [18, 19, 20, 21]. The MAF consists of several procedures which enable the creation of geometrically precise and anatomically correct geometrical models of the human bones.

1. Importing and editing point cloud acquired from medical imaging device,
2. Tessellation of point cloud and creation of polygonal model (mesh),
3. Anatomical and morphological analyses of a selected bone,
4. Identification of RGEs (Referential Geometrical Entities) which are based on the anatomical and morphological characteristics of a selected bone (points, directions, planes and views),
5. Creating and editing the curves on a polygonal model of the selected bone, in accordance with the RGEs, and,
6. Creating and editing the surface model of the selected bone's outer surface by sweeping, lofting, blending, and trimming the curves.

The developed method can possess multiple benefits (or uses), in medicine and technology. The most important characteristic of the created parametric model is its ability to conform to the individual human dimensions of bone, which brings vast benefits in the sense of: preoperative planning (adequate implant for the analogous bone fracture can be selected, implant(s) position on the bone can be defined with greater accuracy, fixation pin positions can be easily determined), for the creation of solid model for structural analysis by FE, for RP of implant prototypes, for manufacturing presentation models, etc.

2.2. Creating 3D parametric model of fracture

By using bone a 3D model and spline design techniques in CAD system, according to CT scan of fractured bones, it is possible to create a 3D parametric model of fracture. From a CT scan of the patient's fracture and the surgeon suggestions, the characteristic points of fracture are measured and transmitted to the 3D bone model. By connecting them, the outside contour of fracture is obtained. The complete model of fracture is created using adequate engineering techniques for free form surfaces and spline modeling.

For this purpose AO/OTA Fracture and Dislocation Classification [22] is used for creating a UDF (User defined feature) for each type of fracture. Some examples of created 3D model of tibia's fracture are shown in Fig. 4.

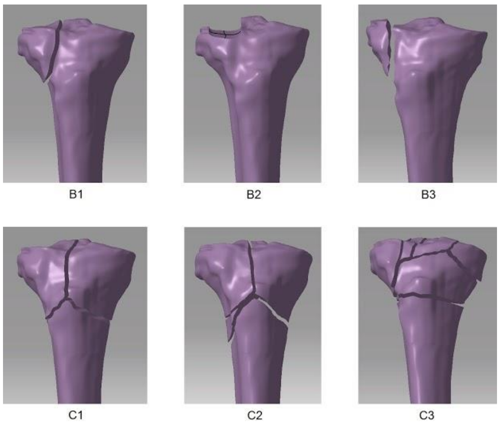

Fig. 4 3D model of a fracture

3. Design of Anatomically Adjusted Implants

The aim of our research is to develop a design method and technique for creating several types of customized implants (Fig. 5). The design method for a scaffold is presented in [23].

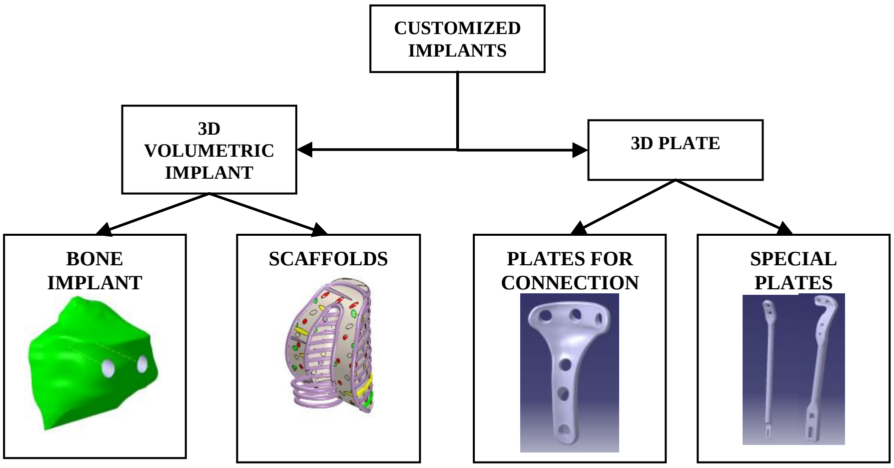

Fig. 5 Different types of customized implants

The principle of anatomical adaptability implies that the internal fixation with its contact surface fully corresponds to the surface of the part of a bone where the fracture is located. In this paper, we present the process of designing anatomically adjusted 3D volumetric implants for long bones, and type plate, by using CATIA V5 software package. For both designs of implant the first step is to create the parametrical 3D geometrical model of bone or a part of bone, made on the basis of the patient's CT scan [18, 19, 20, 21].

3.1. Designing technique of an anatomically adjusted 3D volumetric implants

According to a CT scan of the patient's fracture, and the surgeon's suggestions, the model of fracture is created, using adequate engineering techniques for free form surfaces and spline modeling (Fig. 6).

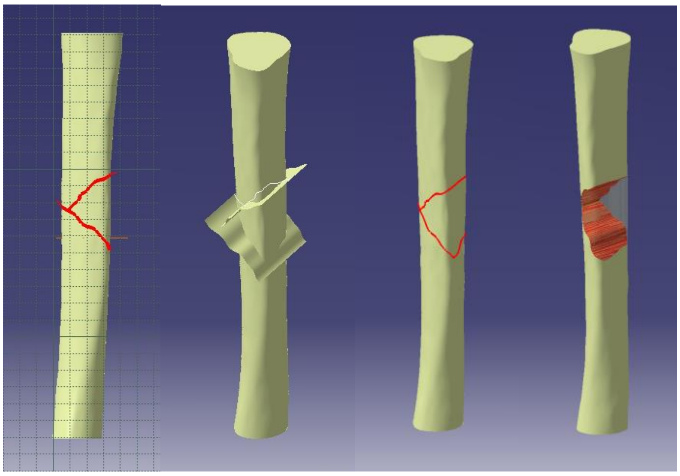

Fig. 6 3D model of fracture

When the fracture is created and its surfaces satisfy the surgeon's needs, the healthy bone fragments that do not belong to the implant are removed (Fig. 7). By removing the desired bone fragments a basic 3D model of the implant is created. By using advanced engineering techniques for free form modeling, the initial model of implant can be modified. For instance, bevels, rounding and additional screw holes can be added and everything else that is needed for the implant's production and implementation.

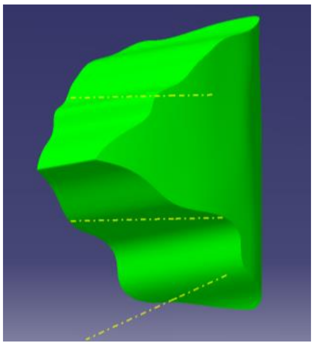

Fig. 7 Basic 3D model of volumetric implant

3.2. Designing technique of an anatomically adjusted implants type plate

Designing procedures at the beginning are very similar as previously described ones, for 3D volumetric implants. The first step is creating a model of the fracture (Fig. 8).

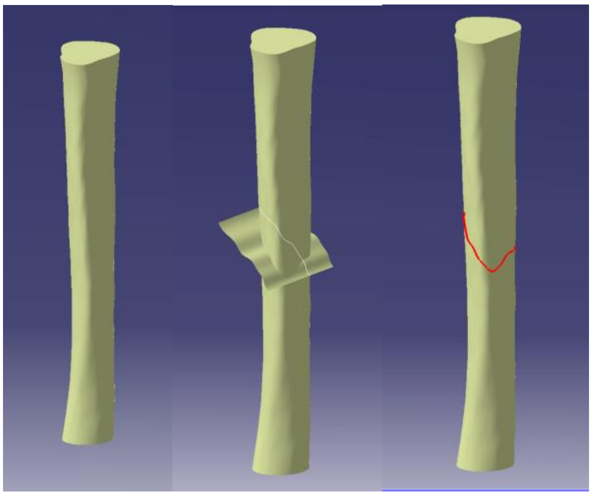

Fig. 8 A 3D model of fracture

Close to the model of the fracture, a datum plane, not far from the lateral surface of bone, is created, which is placed opposite the contour of the fracture (Fig. 9). The surgeon suggests and defines the position and orientation of this plane. Inside it, the contour of the proximal part of the plate is drawn.

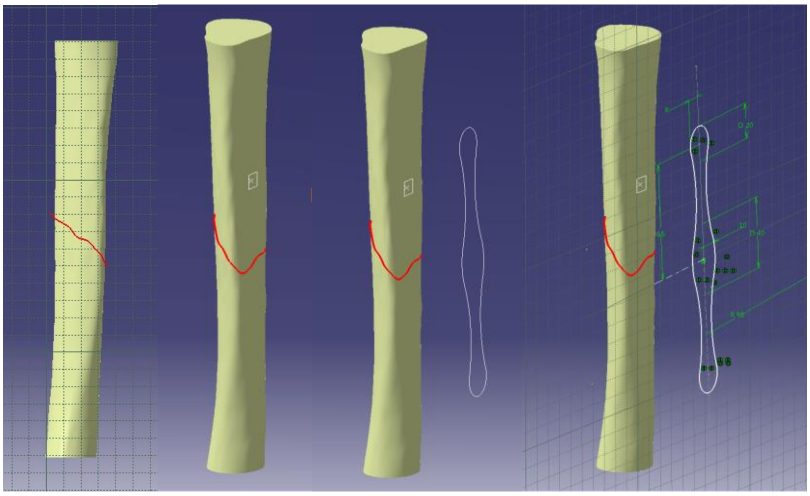

Fig. 9 Creating the plane for contour drawing, and creating the contour of the proximal part of the plate

Following that, the contour extrusion in the direction of the lateral bone side is performed so as to ensure that the extruded contour surface penetrates the bone surface (Fig. 10).

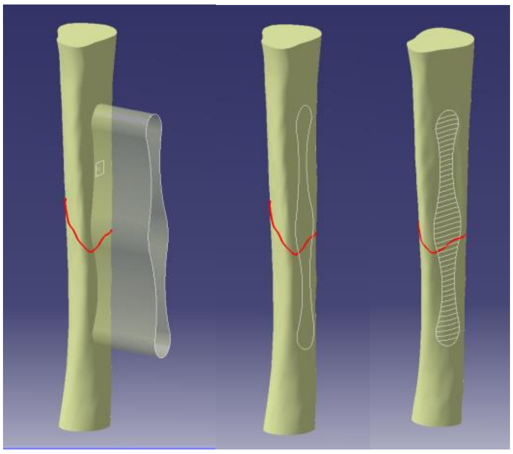

Fig. 10 Extrusion of the contour and its penetration through the bone

The intersected closed contour of the plate's internal side is created in this way. Inside of that contour, the curve drawing of the 3D splines that follow the bone contour is performed. After this step, the moment comes when all the surfaces are removed and the only surface left is the one that actually presents the internal side of the plate that is put directly on the bone (Fig. 11). Now this surface is extruded to transform it into a full model. With this process completed, we get a full 3D model of a proximal fixation plate that is completely anatomically adjusted to the surface of the proximal part of the bone (Fig. 11).

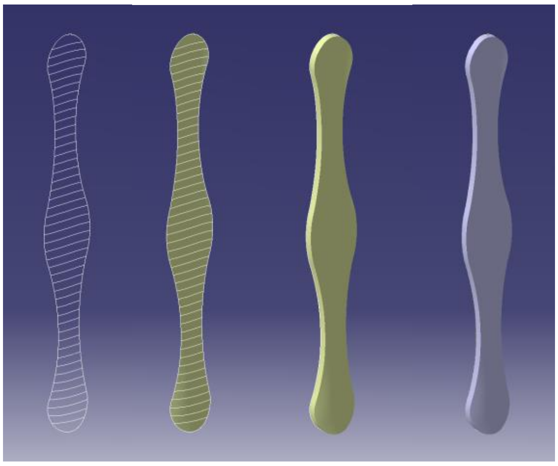

Fig. 11 Intersecting contour, 3D splines inside of the contour, extruded surface

The remaining parts of the internal fixator plate type are made with standard technical elements. After the plate has been shaped, the creation of the screw holes on the proximal side of plate part is performed. According to the orthopedist request, an additional scheme of concentric circles with points for screw holes production is created (Fig. 12). The process of screw holes creation is based on projection points and created tangent planes and is performed on the part of the proximal plate surface.

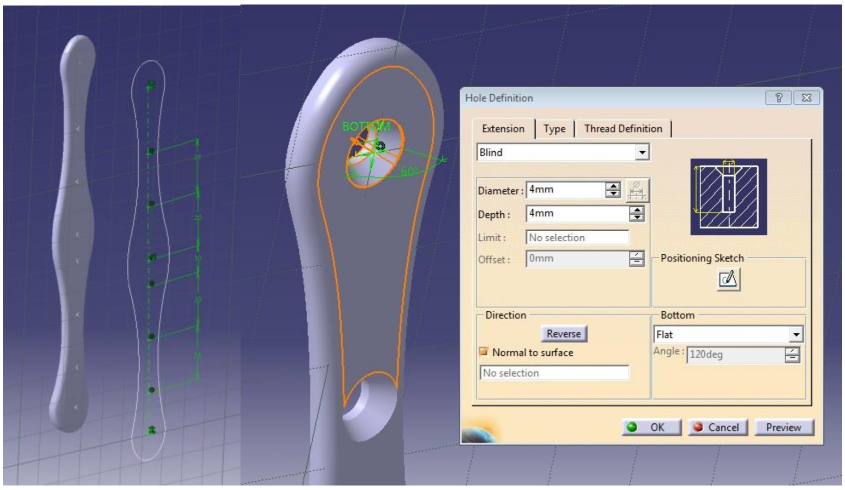

Fig. 12 Creating a full model of plate

The final model of the internal customized fixator type plate is shown in Fig. 13.

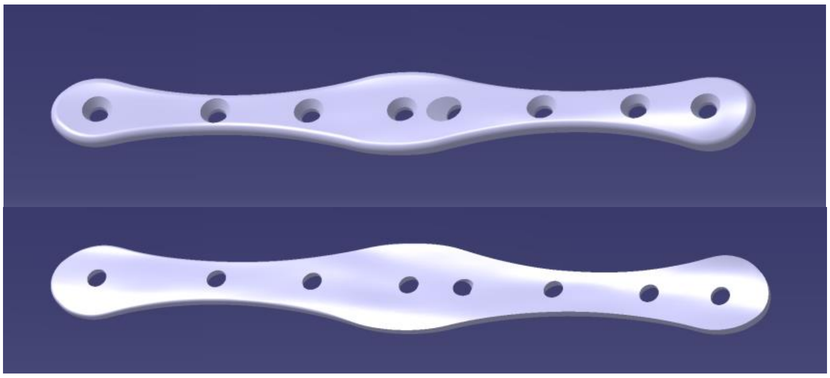

Fig. 13 Final model of customized plate

The assembling module of CAD system can be used to check whether the implant model plate type is appropriate by creating a set – a bone part, plate and fixation elements (Fig. 14). In this way, we can check the model, seating, the number of necessary screws, etc. Furthermore, this 3D model of a set can be used for FE analysis and dimension and shape optimization.

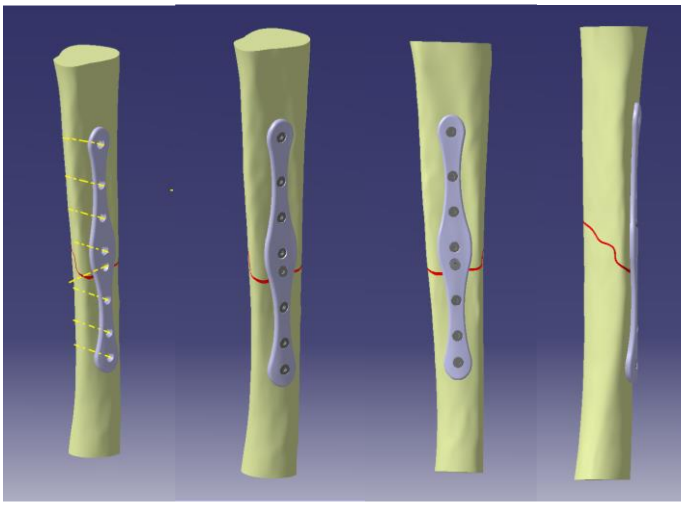

Fig. 14 Bone and plate set

By combining two previously described techniques a 3D volumetric implant and a tile for its fixation can also be made. Moreover, a set bone-volumetric implant-fixation tile-bonding elements can be designed. The designed set is used for implementation simulation and all the other analyses (FEM etc.). This process is illustrated on Fig. 15.

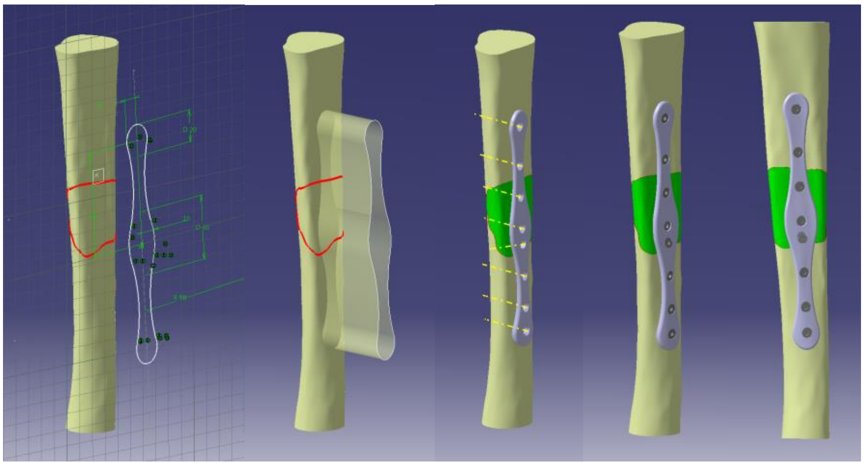

Fig. 15 Set bone-volumetric implant-fixation tile

4. Conclusion

The presented method is based on designing implants directly on a patient's parametric three-dimensional (3D) bone model. When this is finished, further model adjustments to the patient's bone and manufacturing methods are performed. When a 3D model is created in this way, it can be used for the production of implants or plates. The method presented in this paper can be used for various kinds of internal fixators, which are directly attached to any bone surface.

The method presents the designing process of a 3D model of customized anatomically adjusted internal implants, both volumetric and plate type. The internal surfaces lying on the bone are fully aligned with the bone surface and fracture surfaces. In this way, it ideally lies on the bone. This method provides the possibility to create a 3D model of positioning and insertion of the implant and tiles and it can also be used as a simulation model. Furthermore, it can be used for a full analysis and shape and dimension optimization of fixation material.

The method developed and described in this paper is applicable to various other implants of tile type and for any human bone. The requirement that must be fulfilled is the existence of a 3D bone model with imprinted fracture.

This method has significantly improved the technique for production of anatomically adjusted internal fixations.

The created 3D model of implants and plates is ideal for 3D printing or their production using a CNC machine.

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