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Some contributions to the design of osteosynthesis implants

Ciprian Radu[a] and Ileana Roşca[b]

[a] Mechanical Engineering Faculty, Transylvania University of Braşov, 13 Barbu Lautaru, Bl. 26, Sc. C., Ap. 15, Braşov, 500423 Romania; ciprian1_radu@yahoo.com
[b] Mechanical Engineering Faculty, Transylvania University of Braşov, 29 Eroilor Avenue, Braşov, 500036 Romania; roscaileana@yahoo.com

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Abstract. The main purpose of this paper is to develop a new adapted osteosynthesis implant, used for transsindesmotic fibula's fracture. We have chosen to design this medical implant, because the lateral malleolar fracture represents from 40% to 45% of skeletal fractures. At the present moment, orthopaedic screws and metallic plates do the osteosynthesis of this region, but the results are not satisfactory. In order to reduce the healing time of the fractured bone, we have considered optimizing the geometrical shape of the existing osteosynthesis metallic plate, thus to fulfil two major functionalities such as implant's capacity to adapt to the bone surface and keeping the periosteum vascular circulation in the contact region. The proposed solution is based on a method, which combines the medical image processing techniques and CAD modelling.

Key words: implant, fracture, fibula, tomography, CAD.

1. INTRODUCTION

There are two types of medical treatments for lateral malleolar fractures such as medical conservator fixation using gypsum and 6–8 weeks immobilizations, and surgical internal fixations using orthopaedic screws, Kirschner wires, wire cerclaje and metallic orthopaedic plates. Today, the most used method for fractured bone osteosynthesis is surgical internal fixations, because the heeling time is shorter and bone reduction is much better than with the other method. Even the method that uses orthopaedic plates is not sufficient to obtain a good osteosynthesis and a short healing time. The existing implant surface is plain, although the bone surface is irregular. Doctors use some special tools, named clamping dies, which allow them to bend and twist the implants. This process takes time and needs a lot of experience [1,2].

Considering these aspects, the main objective of our study is to design a new implant of different geometrical shape and thickness for osteosynthesis of trans-sindesmotic fibula's fracture. This medical implant follows all the bone irregularities, having a predefined geometrical shape. This approach allows the implant surface to be in permanent contact with the bone tissue, leading to the elimination of micromovements from the focal fracture, which offers stability to the osteosynthesis. It is true that the bone irregularities are not the same for all human subjects, but having the predefined shape we have shortened the shape adapting process [2].

To design the new implant, we have used a method, which is already used in implant design practice, a method that combines the medical image processing techniques and CAD modelling. For the medical image processing we have used medical imaging software, which is a software that performs the segmentation of the anatomy through sophisticated three-dimensional selection and editing tools. For the CAD modelling process we have used SolidWorks software, where the virtual model of the medical implant was obtained by using complex operations like extrude, sweep, revolve [3].

2. DESIGN METHODOLOGY

Our design methodology of the medical implant includes three major stages: 1) medical image processing, performed by MIMICS software, 2) CAD modelling of the medical implant, performed by SolidWorks software, and 3) finite element analysis of the assembly, formed by the implant, bone and screws, performed by Ansys Workbench.

2.1. Medical image processing

Medical image processing is the first major stage in our design methodology, used to obtain the 3D model of the anatomical area under investigation (ankle joint and fibula bone) by using tomographic slices of the area. This process is broadly split into four steps: 1) importing and processing of the input data, 2) analysis of the tomographic slices and automatic identification of the objects, 3) three-dimensional reconstruction of the anatomical segment, and 4) CAD modelling technique of the fibula [3].

Importing and processing of tomographic images is an essential step to obtain the virtual model of the ankle–foot anatomical system. For this technique medical imaging software (MIMICS) has been used that converts 2D images into the 3D ones [4].

Input data of the modelling process are 73 tomographic slices in DICOM format, every 512×512 pixel slice having 2 mm thickness [1]. The 73 tomographic slices were obtained for a 25 years old male person with a body weight of 84 kg [1,3].

The second step includes the threshold method, which means that the segmentation object (visualized by a collared mask) contains only those pixels of the

image with a value higher than or equal to the threshold value. The detection of bone tissue has been obtained by using the optimal grey value, established between minimum value of 1628 and maximum value of 3056 Hounsfield units (HU) [5]. These two values have been chosen after few successive attempts.

The next step we followed was the three-dimensional reconstruction of the investigated anatomical parts. Using suitable selection of the threshold values, all the pixels belonging to the defined interval are attributed to one coloured mask. The mask had the role to create an individual 3D model for each region of interest. During the three-dimensional reconstruction processes, each pixel of the formed mask is converted into a voxel. The value of each voxel depends of the scanning distance between images [1,3]. The main problem, which we met, was the interpolation between 2D tomographic sections. The virtual model, obtained from the 2D slices without the interpolation between them, presents a rough surface, with precipitous gaps in all the three directions *Ox*, *Oy*, *Oz* (the so-called "scale effect" is present, the size of the gap is equal to the distance between two consecutive sections on the *Oz* direction and equal to the size of the pixel in *Ox* and *Oy* directions [5]). As it can be seen in Fig. 1a, the 3D model is poor in details and there is a possibility that it may provide wrong virtual and tactile information. The main advantage of MIMICS software is the possibility to perform the interpolation between sections using the "cube algorithm" [5].

Using tomographic slices and smoothing parameters, we have obtained the gross model of the ankle–foot anatomical system (Fig. 1b) and the individual model of each bone of the investigated anatomical system (Fig. 1c).

The fourth step was CAD modelling of the fibula bone. This technique is the link between the 3D model of the anatomical part and the osteosynthesis implant's 3D model [1]. Using this technique we have obtained the model of the fibula bone in IGES format, which afterwards is used as the reference model in SolidWorks software, to design an osteosynthesis implant for fibula fracture. In this case, the IGES model can be described as a surface, which "wraps" and copies all the irregular parts of the natural bone. The transfer from the solid to the surface is done by polylines, which determine the exterior bone contour (Fig. 2).

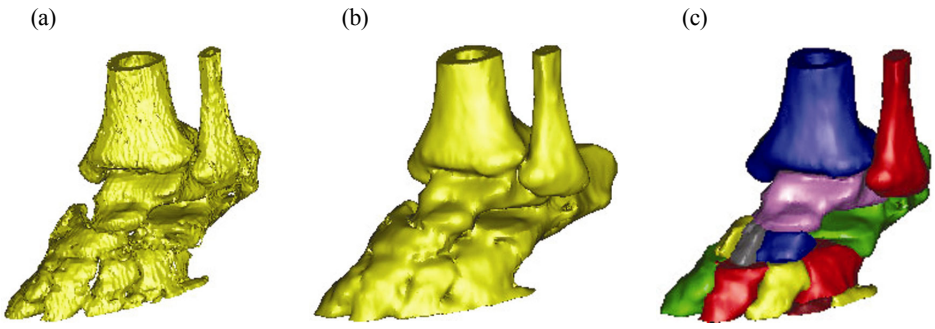

Fig. 1. The 3D model of the ankle–foot area that presents the scale effect (a) before (b) and after the editing process (c).

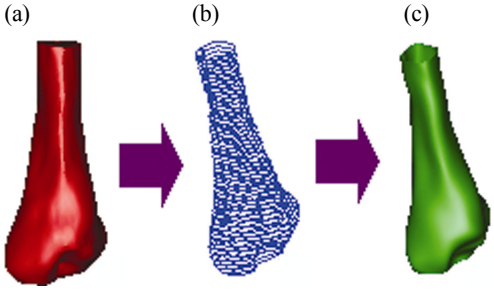

Fig. 2. The stages from the solid model to the IGES model: (a) fibula's solid model; (b) polylines model; (c) IGES surface of the fibula bone [1].

For each section a polyline has been generated. So for 73 tomographic slices we have obtained 73 polylines and the IGES model is obtained by inserting a tangent surface to the polylines [6].

2.2. CAD modelling of the medical implant

Using conventional techniques, available in SolidWorks 2007 software, CAD modelling of the fibula and medical implant have been carried out. Using this technique, our goal was to obtain a precise transfer of the anatomical shape details of the fibula for the optimization of the adapted implant. This approach allows the implant surface to be in a permanent contact with the fibula bone and the micromovements due to fracture are almost eliminated. In order to obtain a virtual assembly, formed by the bone structure, implant and fixation screws, we have made the following steps [5,6]: 1) modelling of different bone structures of the fibula (periosteum, compact bone and spongious bone) and of the trajectory of bone fracture, 2) modelling of a new adapted osteosynthesis implant, 3) modelling of the fixation screws and 4) realization of the bone-implant-screws assembly.

The base structure, used for CAD modelling, was the IGES surface of the fibula bone, obtained using the MIMICS software. Thus, using in Solid Works software theoretical data from special literature, we have obtained the 3D model of the fibula bone, shown in Fig. 3. Also, we have modelled the bone fracture trajectory, with an inclination angle of 40° at 43 mm distance from the inferior part of fibula [7].

In order to reduce the healing time of the fractured bone, we have considered optimizing the shape of the existing osteosynthesis metallic plate (Fig. 4a), to fulfil two major functionalities, the implant's capacity to adapt to the bone surface and keeping the periosteum vascular circulation in the contact region [2]. In order to determine the implant thickness we have used the relation of fracture strength for compression and tension of axial loaded beams [7]

$$\sigma_{r_t} = \frac{F}{A}, \tag{1}$$

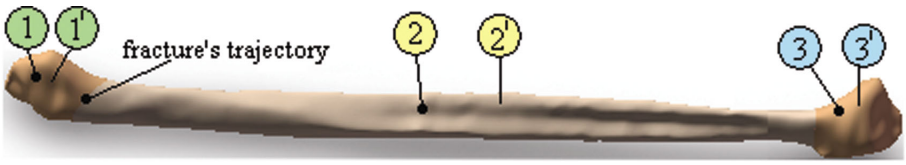

Fig. 3. 3D model of the fibula bone, formed from six bone components: 1 – periosteum of lower epiphysis, 1′ –spongious bone of lower epiphysis, 2 – periosteum of dyaphisis, 2′ – compact bone of dyaphisis, 3 – periosteum of upper epiphysis, 3′ – spongious bone of upper epiphysis.

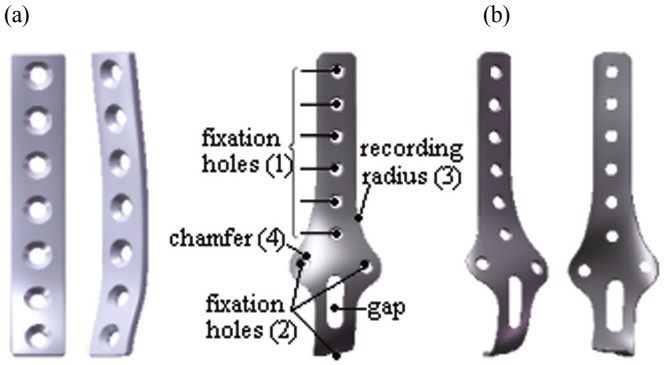

Fig. 4. The existing osteosynthesis implant used already in medical practice (a) and the new proposed osteosynthesis implant (b).

where σ_{r_t} is the fracture strength of the transversal section (517 MPa for austenitic stainless steel), F is applied force in axial direction ($F = 124.53$ N); F represents the tensile force, which acts on the fibula bone in vertical direction during the last contact stance of the foot to the ground, in case of a human subject with a body weight of 89.71 kg, and A is the area of the transversal section, mm^2. Knowing the force F, fracture strength of the transversal section σ_{r_t} and using Eq. (1), we can determine the area of the transversal section of the osteosynthesis implant as follows [7]:

$$A = \frac{F}{\sigma_{r_t}} = \frac{124.53}{517 \times 10^6} = 0.24 \text{ mm}^2.$$

Taking into account the relationship

$$A = Lh, \tag{2}$$

where h is the height of the section and L its length, which in our case is 12.8 mm, we can determine the admissible thickness of the osteosynthesis implant as [7]:

$$h_{\min} = \frac{A}{L} = \frac{0.24}{12.8} = 0.019 \text{ mm}.$$

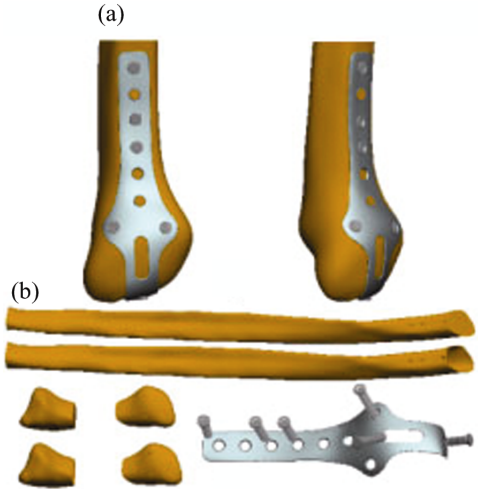

Fig. 5. Bone-implant-screws assembly: different views (a) and the assembly's components (b).

Using a safety factor of 42, the thickness of the implant is 0.8 mm. Figure 4b depicts the new osteosynthesis implant for transsindesmotic fibular fracture.

Seven fixation screws have been used for the fixation of the osteosynthesis implant to the fibula bone. For the compact bone of the fibula's dyaphisis we have modelled a metric 3.5 mm screw having a small thread and a reduced height of the course of thread. In case of a spongious bone of the lower fibula's epiphysis, we have modelled a metric 4.0 mm screw having a high thread and a high height of the course of thread. Having all the elements we have modelled an assembly formed by 6 bone components, one metallic plate and six fixation screws, as depicted in Fig. 5 [1,8].

2.3. Finite element analysis

In order to be sure that our designed implant is better then the implant that is used already in medical applications, we have numerically analysed both assemblies, the proposed and the existing one. To evaluate the tension, deformation and contact state, both assemblies have been analysed in the same stress conditions in four distinct stages [8]:

– importing the CAD models of the bone-implant-screw assemblies;
– attributing the materials to the assembly's components;
– discretization of the assemblies (that is made automatically by software);
– visualization and data interpretation.

In the first stage, the 3D assembly model of fibula-implant-screws, which has been obtained using SolidWorks software, is imported into the finite analysis program ANSYS Workbench 10. The model is imported as ACIS format (Fig. 1) [9]. To obtain concluding results we have modelled in SolidWorks environment a fibula model that is almost identical with the natural one. According to literature,

long bones have three distinct concentric layers: 1) periosteum layer, which is the first layer of bone (it is about 0.3 to 0.5 mm thick), 2) compact bone layer, and 3) endosteum layer, of about 0.1 mm thickness [2,7]. We have decided to neglect the inner layer (endosteum), because it is very thin and its mechanical properties are not known. As a conclusion, we have decided to use only two bone layers, first, periosteum with a thickness of 0.5 mm and the second one, compact bone. We have modelled the bone fracture trajectory with an inclination angle of 40° and at 43 mm distance from the inferior part of the fibula [2]. Also, in the first stage we have established the materials for all components: austenitic stainless steel for implant and fixation screws, spongious bone for the inferior layer of lower fibula's epiphysis, periosteum for the superficial layer of fibula and compact bone for the inferior layer of fibula's dyaphisis (Table 1).

The next step was the discretization of both assemblies using finite elements. The discretization has been realized automatically, using 10-node tetrahedral structural solid element; for the proposed assembly we have obtained 158 481 nods and 164 230 elements, and for the existing assembly 139 259 nods and 141 430 elements.

The 3D model of the assembly is constrained on the upper face of fibula bone and subjected to two forces, vertical force of 150 N and horizontal force of 50 N. The vertical force represents 1/6 of the total reaction force that acts in an ankle's joint of a human subject with a total body weight of 84 kg in dynamic conditions (in the fifth stance phase of foot during normal walking). The horizontal force represents the total reaction force that acts in the horizontal direction, in the ankle's joint in the same condition as the vertical force. On the lower part of fibula bone acts also a rotation moment of 15 Nm, which represents the total rotational moment that acts in the human ankle joint during normal walking [1]. During movement, the lateral malleolus (lower part of fibula bone) has a slight lateral movement of 2 mm against the talus bone. To implement that, we applied to our bone model a 2 mm lateral movement [7]. For the second medical implant, which is already used in medical practice, we have used the same conditions as for the implant we have designed (Fig. 6).

In the next phase, the finite element solution is executed computationally, a process usually involving little or no direct interaction with the user. Then follows the phase, where the FEA solution's output is used to compute variables of interest and the selected information is displayed graphically [3] (Fig. 7).

Table 1. Mechanical properties of different bone layers and austenitic stainless steel [10]

Type of bone	Young modulus *E*, GPa	Poisson's ratio	Density ρ, Kg/mm^3
Compact bone	2×10^4	0.29	6.82×10^{-6}
Spongious bone	85×10^2	0.27	3×10^{-6}
Periosteum	17×10^3	0.29	6.82×10^{-6}
Stainless steel	2×10^5	0.3	7.85×10^{-6}

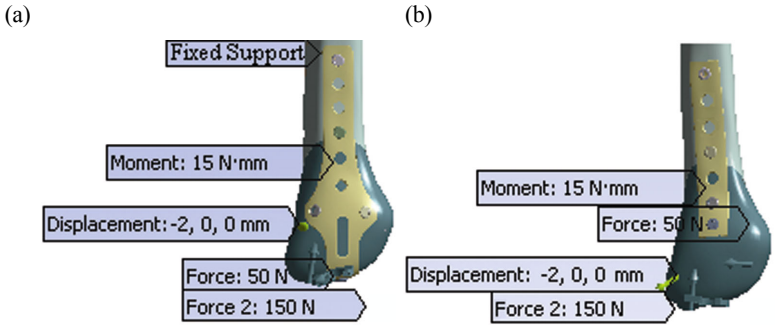

Fig. 6. Constraints and loads applied to the implant model designed by the authors (a), implant model already used in medicine practice (b).

Starting with Fig. 7, there are slight differences between equivalent stresses of both models and they appear in the same places. In case of the proposed assembly the maximum equivalent stresses appear in the metallic implant while in the existing assembly the equivalent stresses appear in a cortical fixation screw. The higher are tensions in the fractured region the higher is the risk for bone dislocation and the healing time is longer [10,11]. In Fig. 7c, d the specific deformations of the proposed and the existing assembly are depicted. As it can be seen, there are big differences in deformations, especially in the fractured zone. The differences can be explained by the high rigidity of the existing implant, which had a thickness of 2.2 mm [8]. In Fig. 7e, f the contact status of both assemblies between implant and bone tissue is described. Our designed implant keeps full contact with the bone surface while with the existing implant there is no full contact with the bone surface in some places, especially on the inferior part of the bone fracture. This phenomenon has to be avoided, because it can induce high tensions and micromovements in the fractured zone [11].

3. CONCLUSIONS

It can be concluded that the proposed osteosynthesis implant, used for fibula's transsindesmotic fracture, is more efficient than the existing one, used already in medical practice. It means that the new implant keeps permanent contact with the bone surface, leading to the elimination of micromovements from focal fracture, which offers stability to the osteosynthesis. The next goal is to obtain the implant prototype by using Rapid Prototyping technology and to propose it for medical practices.

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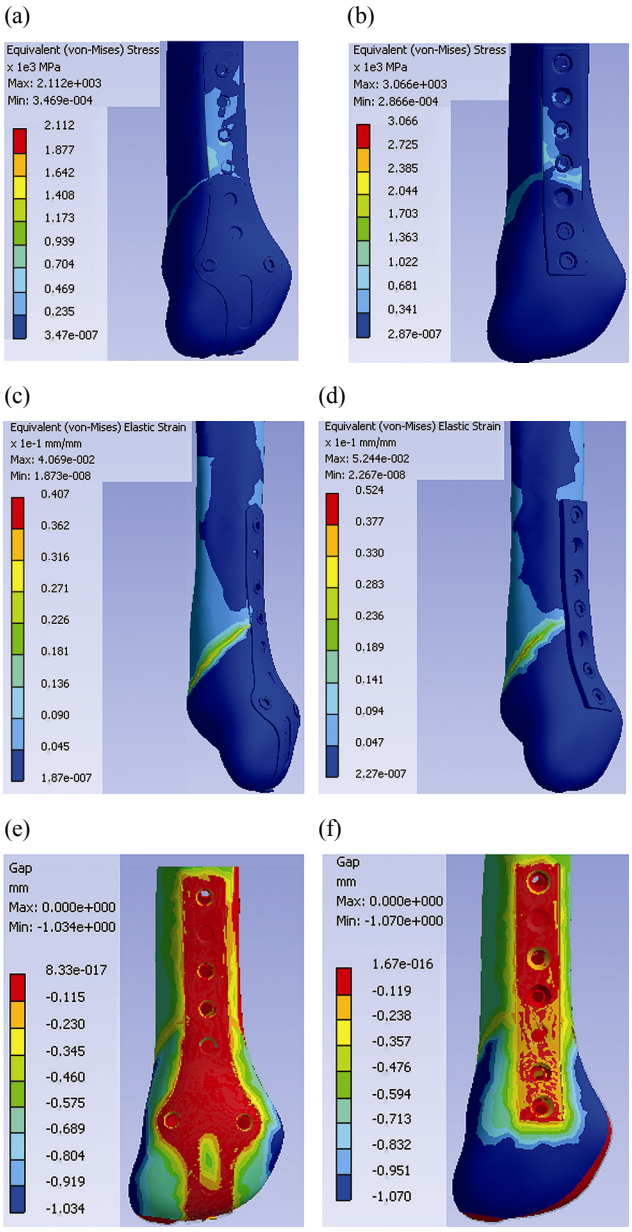

Fig. 7. Graphical representation: equivalent stresses of the proposed assembly (a) and of the existing assembly (b); specific deformations of the proposed assembly (c) and of the existing assembly (d); the contact state of the proposed assembly (e) and that of the existing assembly (f).

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Osteosünteesi implantaatide modelleerimise edasiarendused

Ciprian Radu ja Ileana Roşca

On esitatud pindluu murru puhul kasutatava osteosünteesi implantaadi modelleerimise uus kontseptsioon. See meditsiiniline implantaat on oluline, kuna luumurdudest 40–45% moodustavad lateraalsed pahkluuvigastused. Seniajani on kasutatud selle piirkonna osteosünteesi puhul ortopeedilisi kruvisid ja metallplaate, kuid need ei anna alati rahuldavaid tulemusi. Murdunud luu paranemisaja lühendamiseks on artikli autorid optimeerinud olemasoleva osteosünteesi metallplaadi geomeetrilist kuju, tagamaks kaht põhilist funktsionaalsust: implantaadi kohanemisvõime luupinnaga ja kontaktpiirkonnas luuümbrise vaskulaarse tsirkulatsiooni võimaldamine. Pakutud lahendus põhineb meetodil, mis kombineerib meditsiinilise pilditehnika CAD modelleerimisega.