

Geometrical Model Creation Methods for Human Humerus Bone and Modified Cloverleaf Plate

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Received 21 August 2016; revised 15 March 2017; accepted 17 May 2017

In the field of orthopaedic surgery, for the treatment of bone fractures orthopaedic surgeons use external and internal fixation methods, or combination of these two techniques. Geometrical 3D models of internal fixation implants and human bones are being created by various computer based methods and technical features. These methods include application of computer visualisation techniques like Medical Imaging, Computer-Aided Design, Finite Element Analysis, etc. This paper introduces newly developed methods for the creation of surface model of human humerus and parametric model of the modified cloverleaf plate. The geometrical properties and shape of the parametric model can be customized to match the morphology of humerus bone of the specific patient, by the application of parameter values acquired from medical images (X-Ray or Computerized Tomography). Such implant models can improve pre, intra, and post operative procedures in orthopedic surgery.

Keywords: Human Humerus, Geometrical Model, Cloverleaf Plate, Fixation, CAD, Reverse Engineering

Introduction

In healthcare systems there is a requirement to provide the best possible medical treatment for the patient involving the application of different procedures conducted by various experts in the field of medicine and other connected disciplines (engineers, software developers, materials experts, etc). In orthopedic surgery, for the treatment of bone fractures, orthopedic surgeons use methods of external and internal fixation, or combination of these two techniques^{1,2}. Internal fixation implants are made in the specific dimension range (sizes), in order to enable the application of these implants to bones belonging to different patients³. The application of predefined internal fixation implants to the specific patient may be problematic because of differences in the size and shape of the particular bone and the fixation implant. One of the solutions for this problem is the application of so-called customized implants. The geometry and topology of those implants are adjusted to the anatomy and morphology of the bone belonging to the specific patient by applying different techniques^{4,5}. Application of customized implants has

a positive effect on patients, but on the other hand requires more time for preoperative planning and implants manufacturing. For the proper creation of customized implants geometrical models it is important to acquire accurate geometrical models of the human bones, especially their surface models (because of the proper adjustment of implant position)⁵. In this paper authors present and propose new methods for the creation of the humerus bone surface model and modified cloverleaf plate parametric solid model (cloverleaf plate is a type of internal fixation implants)⁵. Presented method for the creation of the human humerus surface model is based on the Method of Anatomical Features (MAF), which is developed by the authors of this research, and which is already used for the creation of geometrical models of the human bones (femur and tibia)^{4,6}. Parametric model was designed and created by the newly developed method presented in this paper. Customization of the parametric model is achieved by the application of values of parameters which are measured on medical images (acquired from medical scanners, e.g. Computerized Tomography - CT, or X-ray). Geometrical model of the cloverleaf plate created by the application of the parametric model can be used as the basis for the production of the real

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model by the application of the conventional and additive manufacturing technologies⁷.

Geometrical models of human bones

The human humerus is a long bone and its geometry and anatomy is well known and described in literature^{8,9}. For the creation of geometrical models of the human long bones various methods are used¹⁰⁻¹⁴. These methods are in most cases based on volumetric data (from CT) and remodeling techniques applied in Medical software (Mimics, 3D Doctor) or in some other modeling software (i.e. Computer-Aided Design - CAD) and they can be applied for creation of geometrical model of any human organ and not just bones^{6,8}. Volumetric methods of scanning imply the use of scanner to form volumetric model by the application of different techniques and methods described in detail^{15,11}. This is the reverse engineering procedure and it consists of multiple steps. 2D image (slice) of human body is created on volumetric scanner, as a first step, and imaging processing techniques are performed¹⁶. By superposition of multiple slices a volumetric image of scanned patient is formed, composed of voxels (basic volumetric elements). Next process is segmentation, which represent a detailed bonding of anatomical entities along the volume of the scanned model^{17,18}. Segmentation can be a complex process and lots of researches have been done to resolve problems with feature extraction¹⁹. After the process of segmentation is completed, it is possible to create 3D model of the scanned object by the application of volumetric rendering methods²⁰. Volumetric rendering means shading of projected 3D scalar field onto 2D²¹. 3D scalar field can be used as the basis for the creation of a polygonal model of scanned object. The conversion process is done by the application of an adequate algorithm, such as marching cubes²². Polygonal model can be further used in CAD for construction of surface and volume models^{10,23}. Models constructed in this way are based on geometry of a specific patient, and thus they can be used to create implants adjusted to the patient, in preoperative planning, intra-operational navigation and so forth.

Internal fixation

In today's medicine various types of implants are used for the internal fixation of human bones fractures²⁴. The most common ones are plates and their variations. Appearance of LCP (Locking Compression Plate) has reduced usage of DCP

(Dynamic Compression Plate) which has to be mounted onto the periosteum (the tissue that lines the outer surface of all bones) and should be pressed onto the bone to achieve stability. Nevertheless, locked plating cannot completely replace conventional plating^{3,24}. A combination of plating techniques is possible and valuable²⁵⁻²⁷. Main problem with DCP is contact between plate and bone which could induce cortical bone porosis at that place, due to prohibited blood supply. However, certain doubts about this problem have been reported^{26,27} relating to the usage of plates with reduced contact area. According to references related to the biomechanical properties of unique plates (LCP) vs standard plates (DCP)²⁸ it was concluded that unique plates provide better fixation and they can withstand more load. In addition to the type of fixation, quality of reduction, soft-tissue handling and the characteristics of the injury, patient's general health status also has significant influence in the treatment results. There is no evidence that the use of LCP will overcome these other factors^{26-27, 29}. In this paper new method for the creation of modified cloverleaf plate parametric model is presented. It combines DCP fixation method and application of locking screws which are essential component of LCP fixation^{30,31}. It is based on the fact that DCP fixation needs direct contact between surface of the implant and periosteum³ to achieve stability of the bone. By changing the values of parameters, geometry of the implant (and contact surface between implant and bone) can be adjusted to the geometry (shape) of the bone, in the best possible way. In this way basic precontouring is done before the surgery. Also, application of the locking screws enables better positioning and stability of the fixation implant. The results presented in this paper are promising, but biomechanical and geometrical verification on more bone samples is needed for the final claim about model accuracy and dynamic stability.

Materials and methods

In this section the whole procedure for the creation of the humerus bone surface model and cloverleaf plate parametric model will be presented.

Material

For the purpose of this research two CT scans of human left arms were acquired. First scan was used as sample scan for the development of the method and second scan was used as test scan for testing the method. Both scan came from men, about 50 years

old, similar height and weight. Scanning was performed on Toshiba 64-slice scanner at Clinical Center in Nis, Serbia. Scanning parameters are defined according to the standard protocol defined 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 approximately 0.38 mm for sample scan and 0.40 for test scan, 16 bits allocated and stored. Software tool used for the creation and geometrical analysis of the developed models is DASSAULT SYSTEMS CATIA V5 R21 (CAD/CAM/CAE Software).

Overview of the surgical case

The bone trauma analyzed in this research is presented as a fracture of proximal part of a humerus bone. There are various types of bone fractures and they are defined by the adequate classification²⁹. As the fixation implant in the treatment of these fractures modified cloverleaf plate had been used^{29,32}. General process of patient's treatment regarding to the mentioned fracture(s) fixation contains several sub-processes. This process can be considered as a framework process and, because of that, not all sub-processes are presented. The main sub-processes presented in the order of performing are

Diagnostic procedure

In this procedure the bone fracture is defined through the verbal communication with the patient and by the analysis of medical images (or scans). Medical images can be analyzed with the computer software (e.g. Materialise Mimics for CT scans) or in the case of analog X-ray devices, manually.

Implant customization

In this process geometrical model of the customized fixation implant for the specific patient is created. This will be described in detail later in the manuscript.

Preoperative planning

Based on the constructed geometrical model of the implant, orthopaedic surgeon plans and simulates the orthopaedic intervention. This can be a very complex process and it involves planning of all surgical intervention steps which must be done in order to provide the best possible treatment for the patient. This process can be combined with previous process in order to better adjust of 3D implant model's geometry and topology. For this purpose various computer software can be applied (Vitrea, Mimics, etc.)⁴.

Manufacturing of the implant

The geometrical model of the customized implant can be used in CAM for the conventional manufacturing processes (e.g. CNC machines), for the manufacturing by the additive technologies or by the combination of both. In this case better solution for the manufacturing of the implant will be additive technologies because of the complexity of the implant's shape (free-form surface). The outcome of this process is a physical model of the customized implant, in the cases when it is made from biocompatible material.

Anatomy of the human humerus

Humerus, the longest and largest bone in the upper limb, has expanded ends and a shaft. The upper end consists of a large rounded head joined to the body by a constricted portion called the neck, and two eminences, the greater and lesser tubercles³⁴. The shaft is almost cylindrical in the upper half of its extent, prismatic and flattened below, and has three borders and three surfaces. The lower end is flattened from before backward and curved slightly forward; it ends below in a broad, articular surface, which is divided into two parts by a slight ridge³⁴.

Reverse modelling of the humerus bone

The reverse modelling procedure for humerus surface model creation contains several important steps and they are:

- Filtering point cloud model acquired from CT scanning⁴
- Creating polygonal model of the whole bone by the use of technical features implemented in CATIA software⁴
- Definition of the Referential Geometrical Entities (RGEs)^{4,23}
- Creation of spline curves referenced to the RGEs
- Creation of adequate surface models of the anatomical sections
- Merging individual surface models into the whole model.

Definition of the RGEs

The basic prerequisite for successful reverse modeling of a human bone's (humerus in this case) geometry is identification of RGEs, which represent an essential part of MAF. RGEs are unique geometrical elements, and they must be created for every individual bone. In this research RGEs are created for the human humerus. RGEs include characteristic points, directions, planes and views. For the creation of RGEs,

humerus geometric and morphometric definition was acquired from papers³⁵⁻³⁷. The definition of the coordinate system was acquired from the paper³⁸ where basic axes and planes (views) are defined. 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 – axis of the coordinate system. X axis is defined as a projection of the line which goes through tips of the epicondyles of the distal part of humerus³⁸ on the plane perpendicular to Z axis. Y-axis is the line normal to the plane formed by Z and X axes. Three important planes were defined: Anterior-Posterior plane (X-Z), Lateral-Medial plane (Z-Y), and Axial plane (Y-X). Created RGEs are presented in Figure 1.

Surface model of human humerus

In order to create surface model of the humerus, spline curves were created in cross-sections of planes parallel to axial planes, and polygonal model was created for three anatomical sections: proximal section, shaft section, distal section. The initial cross-section curves were adapted to the geometry and shape of humerus by inserting additional points, or deleting unnecessary points. The positions of the spline curves were adjusted to the anatomical landmarks of the adequate anatomical section of the humerus. The surface models of humeral anatomical sections together with constructed spline curves are presented in Figure 2. The proximal part and the shaft were created

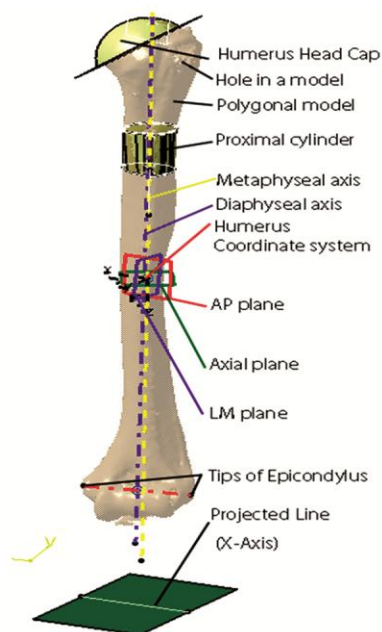


Fig. 1 — RGEs defined on polygonal model of humerus

by the use of splines created in the axial planes Figure 2a, and 2b. Distal section was created as an assembly of four surface parts. This is done because shape of the distal part is very complex. The upper part was created by the use of spline curves positioned in rotational planes, with the upper ending curve (closer to the shaft) constructed in axial plane. These planes follow the curvature of the distal part of the humerus. Right and Left bottom parts were created by the rotational curves and middle part was created by the parallel planes normal to the bottom ending plane of the upper part. The surface model of the distal part of the human humerus is presented in Figure 2c. The surface model of the whole humerus was created by the connection of constructed individual surfaces.

Geometrical accuracy of the humerus surface model

The deviation values measured in reference to the test polygonal model shows that created surface model is of adequate overall accuracy. Deviations are defined as follows:

- Minimum deviation of the created model is 0.4 mm in the shaft area.
- Maximal deviation is in range 0.811 - 1.216 mm (depends on the position of the measured point). In the area of proximal shaft and greater tubercle max. deviation is 0.494 mm (only one point).
- The deviation of about 90% of the measured points is defined in range 0.4-0.8mm

It should be noted that initially created surface model of human humerus had greater deviations – Maximal deviations were around 3 mm. The occurrence of these points can be explained through irregularities (e.g. holes) in the initial polygonal model (probably due to the osteoporosis), big change in curvature in the connected regions (e.g. head - neck). To correct these elements additional points were added on the basis of known data from medical literature³⁶ regarding to the bone shape in adequate areas and deviations were reduced as already stated. Orthopedic surgeons included in this research stated that these deviations are more than acceptable, especially because they are not in the region of interest for placement of the plate. In the area of interest deviations are under 0.5 mm enabling proper definition of the plate geometry and position. If there is a requirement to improve the accuracy of a resulting model it is possible to add more spline curves or to add more points to the existing spline curves in the areas of interest (e.g. humeral head area, or distal part of humerus).

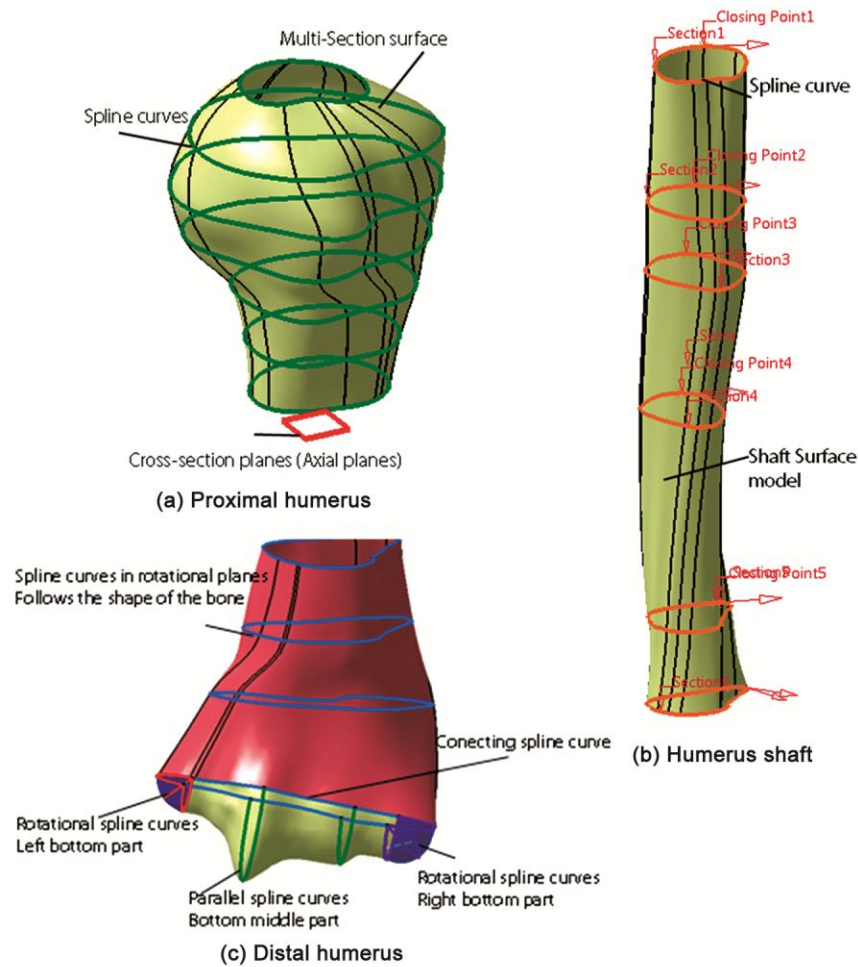


Fig. 2 — Spline curves and adequate surface models of the human humerus anatomical sections

Design process of the cloverleaf plate parametric model

Parametric model is a model which geometry and shape can be changed by the application of different values of parameters, while the topology of the model remains unchanged. All of the parameters and construction elements of the parametric model of cloverleaf plate are newly defined and constructed by following the suggestions and recommendations of the orthopedic surgeons included in this research. For the cloverleaf parametric model, parameters are defined as dimensions measured on the 3D model of the sample humerus. Construction elements are all geometrical entities (circles, arcs, axes, etc.) which are used for the creation of parametric model of the cloverleaf plate, together with additional technical features of CATIA. Dimensions which are measured are presented in the Figure 3 in AP plane together with 3D view of the sample model. These dimensions are defined as radiuses of circles (construction elements) defined in axial plane and they are measured in AP plane.

There are two important dimensions RD_{max} (distal part of plate) and RP_{max} (proximal part of plate). These dimensions represent maximal distance from the detected edge to the Anatomical axis of humeral body. RD_{max} and RP_{max} together with other defined radiuses enable creation of the profile curves which are used for the creation of initial plate surface model with multisection feature in CATIA. The radiuses of these curves (part of the circle in this case - arcs) are limited by the values of RP_{max} and RD_{max} respectively. For the sample set up, these values were: 23.3 mm (RP_{max}) and 13.4 mm (RD_{max}). In order to define the widest part of the proximal part of the plate (head) M_{width} dimension was set. M_{width} is defined as radius in AP plane, and it represents a circle chord which defines how wide plate envelops the outer surface of the proximal humerus. For the current setup values is 34 mm and it is presented in the Figure 3. All of these values are used for creation of initial surface model of the contact surface between plate

and bone, as already stated. Solid model of the plate is created by adding thickness to the surface and for the sample set up, value is 2mm (standard thickness) Figure 3. All of defined dimensions can be considered as parameters which values are changed according to the measurements acquired from medical images, so the model can be defined as parametric model. For testing the prototype model CT scan of the test humerus bone was used. AP Plane was defined for the test humerus bone and edge was constructed as the cross section of the bone model and AP plane (same situation as one presented in Figure 3). Dimensions are defined and measurement was performed. Maximal Values were: 21.2 mm (RPmax), 11.5 mm (RDMax), and 30.3 mm (Mwidth). Because of initial overlapping between humerus polygonal model and surface model of the plate adequate position transformations (by the use of technical features in CATIA), of the plate were applied. Plate contact surface was translated normally from the Lateral-Medial (Sagittal) plane for 1 mm, and rotated around its axis (Lateral-Medial Angle - LMA) about 11°. Plate axis is defined as the line between middle point of the widest part (Mwidth) of the proximal part of the plate and the middle point at the RDmax position

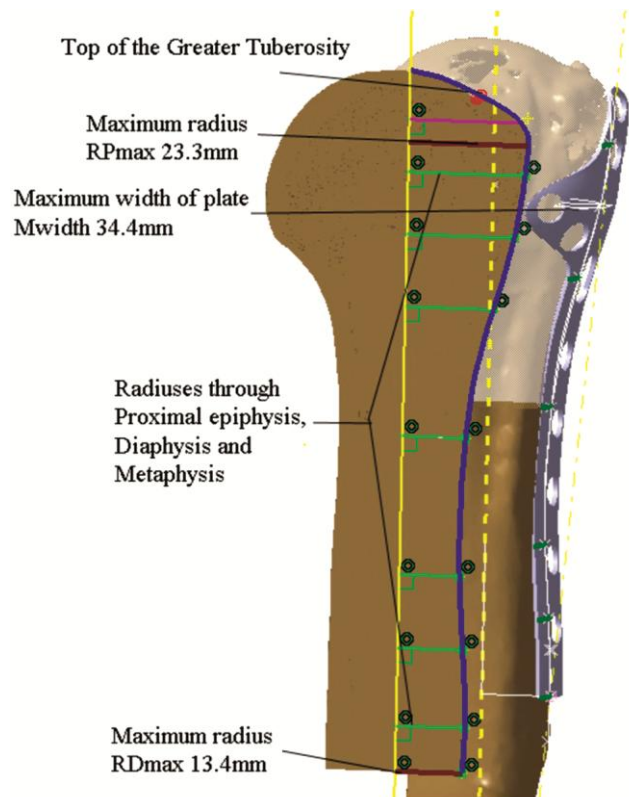
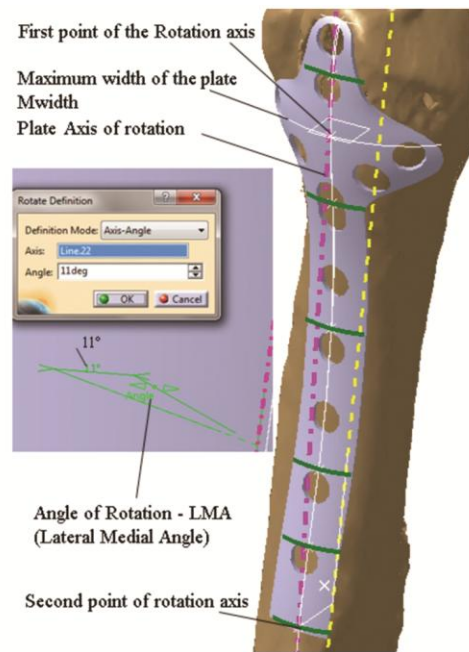
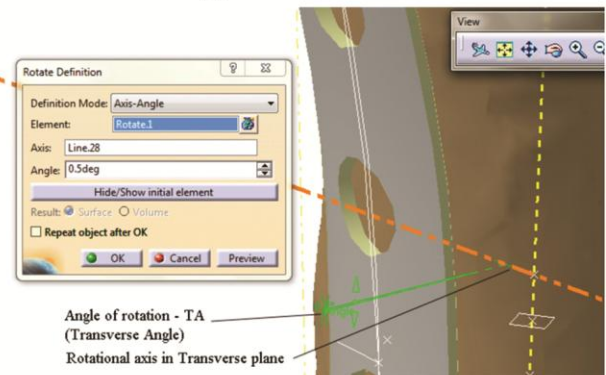


Fig. 3 — Definition of radiuses in AP plane

(distal end of the plate), and it lies in the LM (Lateral-Medial) plane of the humerus bone Figure 4a. Another rotation was performed about the axis which lies in Transverse (Axial) plane of Humerus positioned at the place just below the metaphysis. This axis passes through the point on anatomical axis and it is normal to AP plane. The angle of rotation is defined as Transverse Angle (TA) and its value is 0.5° Figure 4b. After that a thick surface is created by adding thickness of 2mm to the contact surface and solid model of the plate was created. Further, the surface model of humerus was created by the application of the developed procedure. At the end, the assembly of the customized plate solid model and surface model of the test humerus were created. There was no



(a) LMA angle definition



(b) TA angle definition

Fig. 4 — Defined angles of rotation for the cloverleaf plate – LMA and TA

intersection between models in assembly, and the plate inner surface follows the surface of the periosteum in the best possible way. If there is a requirement, surface of the plate can be adjusted to follow the shape of bone more or less by changing the values of radiuses (parameters).

Geometrical accuracy of the parametric model

Deviations were observed in AP plane between intersections of AP plane and plate and humerus surface models. Intersections were defined as spline curves and deviations were measured as normal distances between these two spline curves at adequate points. Maximum deviation in proximal epiphysis section is 2.267 mm, and maximum deviation in proximal diaphysis section is 2.44mm. These deviations are in the top and bottom area of the plate and they are quite satisfactory, as stated by orthopedics surgeons involved in this research. Also, the 70% of the plate contact surface is below 0.5 mm distance from the periosteum surface of the bone. The conclusion is that plate model in its current stage of development fits adequately with the test humerus model, and it can be used in DCP or LCP fixation. This means that the shape of the plate is adequately created and that the presented method provides good results. Of course, additional verification of the procedure needs to be done. The most important verification should be performed with application of X-ray image and that will be done in the future research.

Future work

In the next period additional activities concerning creation of humerus bone geometrical model and customization of cloverleaf plate geometrical model will be performed. The main tasks which will be analyzed and performed are

- Additional improvement of the plate and humerus bone geometry will be done with the application of more CT samples of patient's humerus bones.
- Definition of additional dimensions (parameters) – In order to enable better geometrical definition of the plate, additional dimensions should be investigated, analyzed and applied.
- Semi automatic or fully automatic registering of dimensions values from 2D medical images - The input for this process should be digitized X-ray image of the patient's humerus scanned in AP plane. Based on the edge detection algorithm(s)

applied in an open source software (e.g. GIMP), it is possible to acquire the edge of the proximal part of humerus and adequate values of dimensions can be measured. Values of measured dimensions should be stored in a textual file or Microsoft Excel file. These files can be used in CATIA for the customization of the parametric model.

The aforementioned tasks will be performed in order to create one complete information system which will help orthopedics surgeons for better preparing and performing of surgical interventions. This system should be important part of medical information system which is usually implemented in medical institutions.

Conclusion

The methods presented in this paper enable creation of humerus bone surface model and customized cloverleaf fixation plate parametric geometrical models (surface, solid). The main benefit of these methods application is the ability to create geometrical models of the implant customized for the specific patient. This means that shape, geometry, and topology of the implant geometrical model is adjusted to the patient's humerus. The level of adjustments can be controlled so that surgeon can make additional corrections to the geometrical model of the plate if there is such requirement (e.g. because of the patient's condition). Surface model of humerus and parametric model of modified cloverleaf plate can be used for: manufacturing of bone and plate models by the use of conventional or additive technology, creation of preliminary models for the Finite Element Analysis (FEA), preoperative planning in orthopedics and other possible applications in medicine and engineering. The results presented in this research concerning geometrical and anatomical accuracy of the human humerus surface model and parametric model of the cloverleaf plate are quite satisfactory. Authors are aware that the conducted research is still in prototype phase, so additional improvement of methods for models creation should be done in the future work.

Acknowledgements

The paper presents the case that resulted from application of multidisciplinary research in the domain of bioengineering in real medical practice. The research project (Virtual Human Osteoarticular System and its Application in Preclinical and Clinical Practice) is sponsored by the Ministry of Science and

Technology of the Republic of Serbia - project id III 41017 for the period of 2011-2015.

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