BRIGHT

Erasmus+ strategic partnership for Higher Education

BOOSTING THE SCIENTIFIC EXCELLENCE AND INNOVATION CAPACITY OF 3D PRINTING METHODS IN PANDEMIC PERIOD

MODULE 6

Process optimization and software control

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Content

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1 Introduction

Biomedical engineering (BME), or medical engineering (ME) is a contemporary science field, which includes many different science branches such as: medicine, engineering, mathematics, computer graphics, materials, etc. To properly understand the learning materials presented in this course, which are highly related to BME, it is important to understand the basic topics and terms used throughout the presented chapters. Four general topics are described, concerning Computer Graphics, Medical imaging, Medical devices, and Organ and process modelling. These topics will provide initial information which is needed to properly acquire thematic knowledge, presented in later chapters.

1.1 Computer graphics

Computer graphics is a field in computer science in which visual content is created, with the application of appropriate methods and with the use of computer technology. Computer graphics involves the visualization of two-dimensional content (e.g., photographs, images), as well as three-dimensional content (e.g., 3D display of objects). Some of the terms used in computer graphics are as follows:

Computer model - Computer representation of physical objects. A computer model can be the visualization of a physical object shape (e.g., a 3D model of a house displayed on a monitor screen) or for example a graphical presentation of a change in temperature in area over a period of time.

Geometrical modelling - A scientific field in which the application of various methods and algorithms defines a mathematical description of the geometry, topology, and shape of physical objects.

Geometrical models - Geometric models are a special group of computer models created through the application of geometric modelling. The basic division of geometric models is into 2D models that allow the display of objects in 2D space and 3D models that allow 3D visualization of physical object shapes. 2D models are widely used in mechanical engineering (e.g., technical drawings), construction (e.g., building plans), electronics (e.g., electrical diagrams). 3D models are applied in CAx (CAD / CAM / CAE), but also in construction (e.g., 3D visualization of houses, buildings) and entertainment industries (e.g., computer games, movies).

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- **Computer-Aided Design (CAD)** - Methods involving the use of computer techniques to create, modify, optimize, and analyse different types of designs. In mechanical engineering, the term CAD refers to the creation of geometric models of machine elements and assemblies, both in 3D and in 2D. Software packages used to create such models are CATIA, Solid Works, PRO / Engineer, etc.
- **CAD models** - Geometric models created using CAD methods. There are several types of such models and some of them are:
  - **Point cloud model** - A model in 2D or 3D space whose boundaries are defined by points. Each point is defined by coordinates in Euclidean space.
  - **Wireframe model** - A special type of model that defines the edges (lines) between points in space. This model can be used as a preview of more complex types of models, because it takes up fewer computing resources.
  - **Polygonal model** - A model in which the boundary surfaces of an object are defined by polygons. Polygons are defined as planar objects bounded by edges. A set of polygons defines a polygonal model. Polygons are usually of the triangle type, but they can also be defined with several edges. Polygonal models nowadays, in addition to their application in mechanical engineering, are also widely used in computer graphics in the entertainment industry (computer games, movies).
  - **Surface model** - A model that describes the boundary surfaces of objects. NURBS curves, polygonal models and Subdivision Surfaces are commonly used as elements to enable this.
  - **Volume model** - A model that defines the volume of an object covered by boundary areas, i.e., solid model. This type of model has a wide application in the analysis of stress states in elements in mechanical engineering and construction.

Computer-Aided Manufacturing (CAM) - Methods that involve the use of computer techniques and computer equipment to control the operation of machine tools, in order to process machine and other parts. The main purpose of the mentioned methods is to improve the accuracy of processing and on the other hand to speed up the whole process of production of parts.

Computer-Aided Engineering (CAE) - Methods that involve the use of computer techniques and equipment in the implementation of various engineering activities. Analysis of machine and building constructions, assistance in the realization of production activities, construction and optimization of products in appropriate software packages, are all areas in which the mentioned methods can be applied.

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Medical Imaging (MI) - Methods that include the use of radiological devices and various methods that allow scanning of patients, analysis of the obtained data, as well as defining the treatment process. As a result of the application of this process, images of the internal organs of the human body are obtained, which can be analysed in the appropriate software (Materialise Mimics, 3D Doctor, etc.)

Medical Image Processing (MIP) - A set of methods and algorithms that can be used to process medical images obtained by radiological methods. By applying these methods, it is possible to obtain a volumetric model of the human musculoskeletal system, in which the patient is scanned using computed tomography.

1.2 Medical imaging

Medical imaging is a technique and procedure of imaging the inside of the body for clinical analysis and medical intervention, as well as a visual presentation of the function of some organs or tissues (physiology). Medical imaging seeks to reveal the internal body structures, as well as to diagnose and treat diseases. Furthermore, medical imaging allows the creation of a database of normal anatomy and physiology to enable the detection of abnormalities. Medical imaging devices can be grouped by the technologies that they use (X-Rays, Ultrasound) and may include X-ray radiography, magnetic resonance imaging, ultrasound, endoscopy, elastography, positron emission tomography (PET) and single photon computed tomography (SPECT). It may also include measurement and recording techniques that are not primarily intended for imaging, such as electroencephalography (EEG), magnetoencephalography (MEG), electrocardiography (ECG). Medical imaging procedures result in various data which can be stored for later use. For example, CT devices can provide large amounts of information for the whole human body as visual 3D representation of the organs (Figure 1.1). Another example can be MRI, which uses magnetic fields to create 3D visualization of organs.

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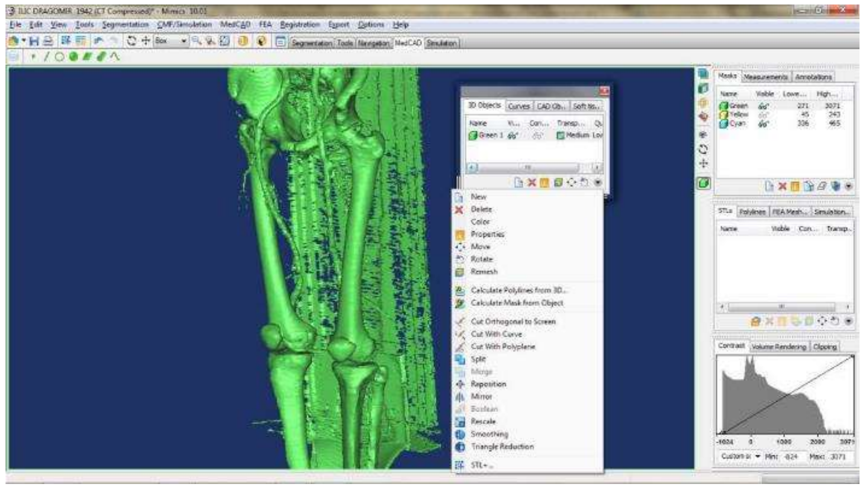

Figure 1.1 CT image in Mimics software[1] (Trial version)

1.3 Devices for diagnostics, monitoring and therapy

Radiology can be defined as the science of radiation, where radiation includes emissions of different types of waves (gamma rays, X-rays, etc.), with application for medical purposes for diagnosis and therapy of the patient.

Radiological methods - There are various radiological methods used to diagnose the condition of patients and some of them are**:**

- X-ray - The most common form of acquisition of patient body data when X-rays are used to create images. The procedure is invasive and it is not desirable for regular check-ups, because X-rays are ionizing. During imaging, the patient is placed between the emitter and the detector. Recording is performed by emitting a short X-ray pulse, whereby the detector captures different levels of energy transmitted through the patient's body. In the resulting image, organs that absorb more X-ray energy are shown in a lighter (white level) shade of grey (e.g., bone), and those that have less ability to absorb X-rays are represented as a darker shade of grey (e.g., soft tissue, Figure 1.2).

[1] https://www.materialise.com/en/medical/mimics-innovation-suite

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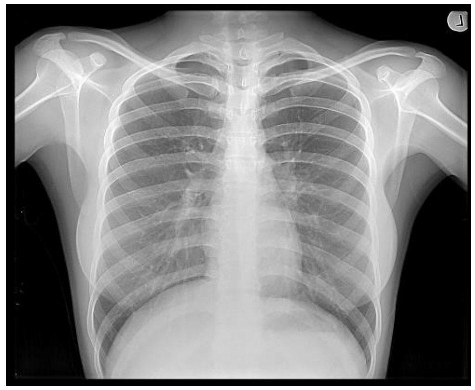

Figure 1.2 Chest Radiograph[2]

- Computed Tomography (CT) - A method of medical imaging that provides information about the internal structure of the human body. The patient is imaged on a CT scanner, which uses X-rays to acquire data about the patient's body. The recording process is performed by rotating the X-ray source and the receiver around the patient's body (during which it is possible to move the table on which the patient lies, so-called spiral scanning, Figure 1.3) and by recording the amount of absorbed energy as in the case of classic X-ray machines. During the scanning process, many individual 2D images (cross-sections) of the patient's body (or a certain part) are formed, based on which a virtual 3D model can be created with the use of appropriate software. Due to the use of X-rays, CT is one of the invasive radiological methods.

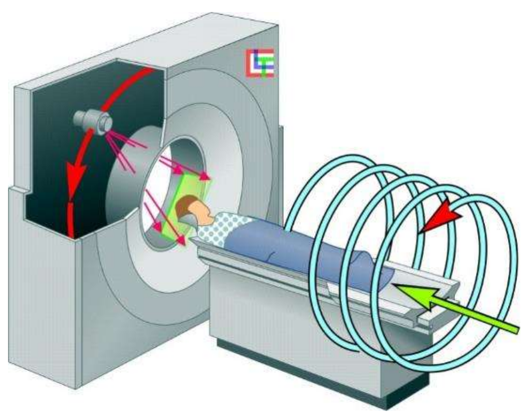

Figure 1.3 spiral CT[3]

[2] Copyright 2010 by PRI X-RAY - http://prixray.com/
[3] www.lookfordiagnosis.com, All rights reserved,

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- Magnetic Resonance Imaging (MRI) – Has a principle of data acquisition that is very similar to tomography (2D images of cross-sections of the patient's body are also formed), with the important difference that instead of X-rays, this technique uses magnetic fields and radio waves (Figure 1.4). Due to the nature of the waves that are used, MRI unlike CT is not an invasive method. MRI is mainly used for imaging soft tissues, but it is also possible to use MRI for imaging bones (although it is better to use CT for the bone and joint system).

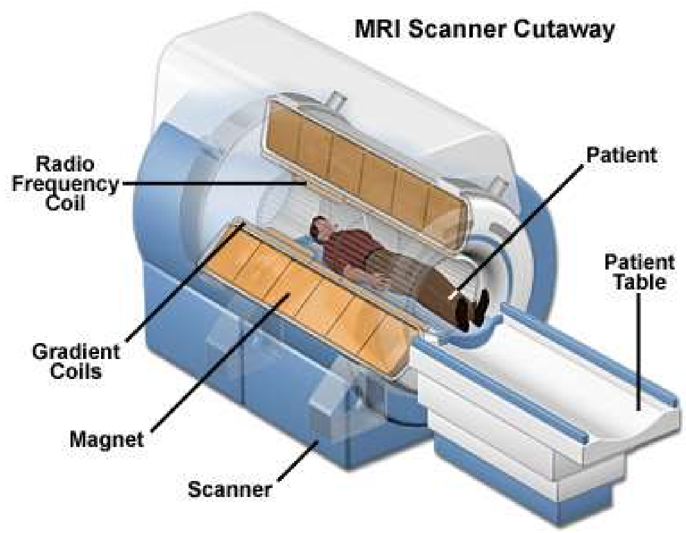

Figure 1.4 MRI device[4]

1.4 *Organ and process modeling*

Organ and process modelling is based on the application of Medical and CAD software for the creation of a medical process model, or a 3D CAD model of the organ. Furthermore, organ modelling can be defined through the creation of a 3D model of a human organ by using geometrical modelling software, like CAD, and a specific method of model creation. The most used method here is the reverse modelling method which is based on the medical imaging outputs. This method is a part of reverse engineering (RE, will be explained in detail through the following

[4] © Copyright 2006 - 2014 Biomedresearches, all rights reserved, http://www.biomedresearches.com/root/pages/researches/epilepsy/mri.html

sections of this course), which can often be applied in medicine. It is important to note, that RE method is highly dependent on the output from medical imaging methods (i.e., the better the input model is, the better the output CAD model will be). The resulting models (CAD or other) can be used for various purposes, such as: diagnostics, preoperative planning, Computer Assisted Surgery, etc.

Process simulation can be carried out in software for Finite Element Analysis (FEA) like ANSYS, e.g., biomechanical model of bone torsion or bending. The CAD model of the human organ, which can be used for the simulation of the process, is usually acquired from CAD software, or in some cases from Medical software. Materialise Mimics as medical software has the capabilities to perform basic meshing of models for later FEA analysis. Process modelling can also be used for modelling the cardiovascular or other dynamic systems, when there is a requirement to simulate blood flow, or implant insertion (like stent).

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2 Fundamentals of anatomy

In this chapter basics of human anatomy and morphology will be described. The reader will be introduced to the human body and its main structures, the skeletal system, soft tissue, etc. Basic concepts of morphology, and functional morphology will also be presented.

2.1 Basics of Human anatomy

Human beings are complex organisms with many functions. The human body is composed of billions of smaller structures of four major kinds[5]:

- Cells - Cells are the simplest units of living matter that can maintain life and reproduce themselves.
- Tissues - Tissues are more complex units than cells, and by definition, a tissue is an assembly of many similar cells with different amounts and kinds of intercellular substance.
- Organs - An organ is an assembly of several different kinds of tissues. Organs can perform a unique function. For example, the stomach is a combination of muscle, connective, epithelial, and nervous tissues.
- Systems - A system is an assembly of varying numbers and kinds of organs, for the purpose of performing complex functions for the body. Ten major systems compose the human body: Skeletal, Muscular, Nervous, Endocrine, Cardiovascular, Lymphatic, Respiratory, Digestive, Urinary and Reproductive.

Human skeleton

The human skeleton (Figure 2.1) serves as a support system for the body. This system consists of many different bones and cartilages. There are is also fibrous connective tissue: ligaments and tendons which are in close relationship with parts of the skeleton. This section is concerned primarily with the gross structure and function of the skeleton of a normal human adult. The main functions of the skeleton are: support, protection and motion.

[5] https://www.britannica.com/science/human-body

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These functions can be separated into: Giving the body shape and structure; Providing protection to the major organs; Allowing movement through muscles which are attached to bones via tendons. When muscles contract, they exert force on bones; Production of red and white blood cells within the bone marrow, which is a spongy substance found in the cavities of long bones. Red blood cells carry oxygen and white blood cells are important for fighting disease and infection. Platelets aid blood clotting when the skin is damaged; Storage of calcium and phosphorous, these minerals make bones and teeth strong.

Human Soft tissue

Soft tissue (Figure 2.2) is all the tissue in the body that is not hardened by the processes of ossification[6]. Soft tissue connects, surrounds or supports internal organs and bones, and includes muscle, tendons, ligaments, fat, fibrous tissue, lymph and blood vessels, fasciae and synovial membranes.

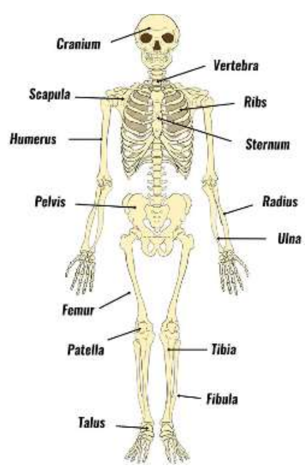

Figure 2.1 Human skeletal system[7]

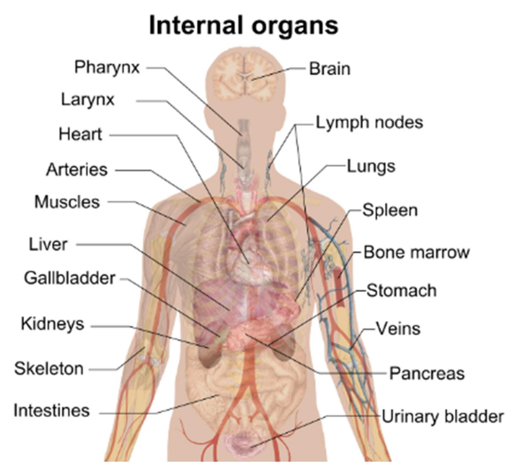

Figure 2.2 Human body internal organs[8]

2.2 *Morphological-functional features*

Morphology, as defined in biology is the study of the size, shape, structure and relationships between constituent parts of animals, plants and microorganisms. The term refers to the general aspects of biological form and functional assembly of the parts. The term anatomy is more focused on study of the details of either gross or

6 "Soft tissue". Retrieved 13 July 2020.

7 https://www.teachpe.com/anatomy-physiology/the-human-skeleton

8 Häggström, Mikael (2014). "Medical gallery of Mikael Häggström 2014". WikiJournal of Medicine 1 (2).

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microscopic structure. In practice however, the two terms are used almost synonymously. Generally, morphology is used to describe the shape of the human organ(s), and anatomy is used to describe the properties and internal structure of the organ(s).

Functional morphology

Functional morphology defines the relationships between the structure of an organism and the function of different parts of the organism. The function of an organ dictates its shape. The primary task of functional morphology is to observe living organisms to see how they live and function. Theoretical morphology tries to determine the boundaries of the form that enable the existence of real organisms. Functional morphology studies the patterns in which structures such as muscles and bones are applied to form various patterns of behaviour, including movement, feeding, struggle, and reproduction. Functional morphology integrates concepts from physiology, evolution, development, anatomy, and the physical sciences and synthesizes different ways in which biological and physical factors interact in the lives of organisms. Functional morphology and biomechanics allow scientists not only to observe and quantify how skeleton systems and joints move and how muscles work, but also how these things relate to the diversity of living beings' behaviours[9].

[9] https://www.encyclopedia.com/science-and-technology/biology-and-genetics/biology-general/functional-morphology; Curtis, Helena, and N. Sue Barnes. Biology, 5th ed. New York: Worth Publishing, 1989.

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3 Geometrical models and their application in medicine

Geometrical models and their properties are already described in the introduction chapter. In this chapter additional model structures and formats will be presented. The geometrical models of organs will be described for soft and hard tissue. Implant models will be presented for selected bone and plate implants. Models used for biomechanical analysis and simulation will be presented (FEA models).

3.1 Geometrical models of organs

Geometrical models of organs can be created by using different procedures. Two general procedures will be presented in this chapter. The first procedure is based on the application of reverse engineering techniques, and the second is based on the use of template models for the creation of human organ models.

Reverse Engineering procedure (Figure 3.1) is based on the application of medical imaging software for gathering and pre-processing data about the organ and CAD software which is usually used for additional processing and creation of models. These models are used for: preoperative planning, creation of presentation models, FEA simulation, prototyping, rapid tooling of moulds, etc. The procedure generally consists of the following steps:

- Medical imaging by using CT (for hard and soft tissue), and MRI (mainly for soft tissue)
- Pre-processing (Segmentation) in medical software which enables creation of adequate organ models, e.g., hard or soft tissue. Segmentation is usually done by using, Hounsfield scale, named after Sir Godfrey Hounsfield[10]. This is a quantitative scale for describing radiodensity, and it is often used in CT scans, where its value is also known as the CT number. By using this scale different organs can be extracted from the radiograph.
- Exporting a 3D model from medical imaging software to an adequate format. The usual export format is the STL format which is widely used in RE, 3D printing and generally Computer graphics. This format describes 3D models as a set of triangles, with additional information about their normal. It is a very plain format, and easy to use.

[10] De Vos, W.; Casselman, J.; Swennen, G.R.J. (June 2009). "Cone-beam computerized tomography (CBCT) imaging of the oral and maxillofacial region: A systematic review of the literature". International Journal of Oral and Maxillofacial Surgery. 38 (6): 609–625. doi:10.1016/j.ijom.2009.02.028. PMID 19464146.

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- Importing and processing the 3D model in CAD software, which can be a very demanding and complex task, which mainly depends of the imported organ. The processing in CAD is based on the following: additional filtering of bad data, tessellation and creation of a polygonal model, creation of geometrical entities, creation of different types of models (e.g., polygonal, surface, solid), depending on their application.

Template models (Figure 3.2) are generally models created as Free Form Deformation models, which use different methods to adapt their shape and geometry to the personalized organ model. Another model type are the parametric bone models[11], which are used for the creation of personalized bone models based on the morphometric and other values acquired from medical images.

The following models are used in general:

- Data Model (DICOM) - A model based on DICOM (Digital Imaging and Communications in Medicine). The model in DICOM format is most often created on medical scanning devices (CT, MRI) and as such is significantly used in software packages that serve to visualize the obtained data (Materialise Mimics, 3D Doctor, Vitrea and others).
- Point cloud model - A model used in CAD software packages. It usually defines the whole of the model (bone, muscle), and consists of spatially distributed points.
- Polygonal model - The most commonly used model in computer graphics. It is characterized by polygons that are defined between points (vertices). This model can be formed on the basis of a previously defined point cloud, but it does not have to be. From the point of view of computer data processing, this model is the most optimized because computer graphics cards are designed to work with this model.
- Surface model - Models that are defined through a mathematical (numerical) function and describe the whole of an objects'' real surface. They can be created based on a polygonal model, but they don't have to be. For example, the surface model of a ball is a function that defines a sphere in three-dimensional space.
- Volume models - Models that, in addition to the area, define the volume that the area covers. Volume models can be defined by volume elements (parallelepiped, tetrahedron, etc.) and have the greatest use in additive technologies for prototyping, finite element analysis, medicine to show the inside of bones, muscles and the like.

11 Majstorovic, V., Trajanovic, M., Vitkovic, N., Stojkovic, M., 2013, Reverse engineering of human bones by using method of anatomical features, CIRP Annals - Manufacturing Technology, Vol. 62, No. 1, pp. 167-170

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- Parametric models - A parametric model is a geometric model that is based on morphometric parameters, as well as other geometric parameters relevant to a particular bone, and allows the creation of a specific type of geometric model adapted to the bone of a particular patient. It is essentially a model that has been known and successfully applied in CAD for many years. In this case, the parametric model is defined as a model consisting of points whose coordinates are defined by parametric functions.

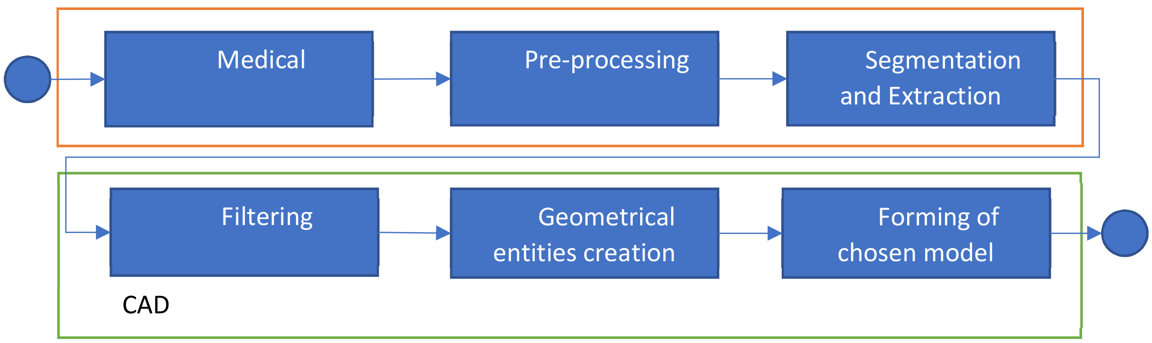

Figure 3.1 Reverse Engineering (modelling) procedure

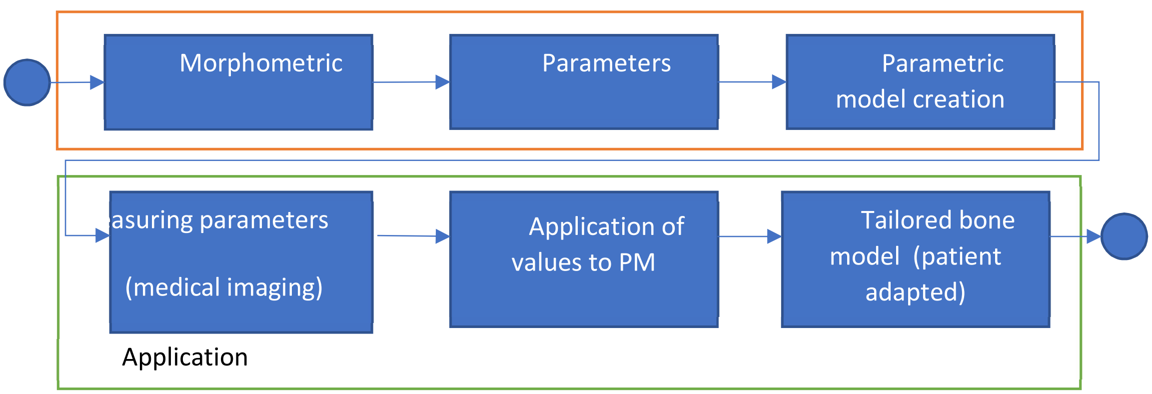

Figure 3.2 Reverse Engineering (modelling) procedure

3.2 Implants and their application

In this chapter hard tissue implants (bones) will be covered and scaffolds for soft tissue. Geometrical model of the human bone is not usually enough to perform intervention. If a physician plans to apply internal fixation for the treatment of a bone, several tasks need to be performed:

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- Selection of adequate plate implant (standard or personalized)[12].
- If a standard plate is used then the decision about the usage of pre-tailored or other standardized plates (e.g., angular, reconstruction) must be made.
- Creation of a plate geometrical model for the personalization.
- Production of personalized plate which is adapted to the patient's bone.
- Special tasks. like: plate position and orientation, screw selection, etc.

The simplification of the whole process is done, in order to clearly define possible problem(s). Next the pre-bending of standardized plates, or application of pre-contoured plates is done, depending on plate type, fracture type and position (this is not always required). If customization of the plate implant is needed, then surgeons and engineers must work together in order to manufacture a plate implant and apply it to the specific patient. This entails selecting the material of the implant, geometrical model creation, physical model manufacturing, plate implantation, monitoring the post-operative recovery, etc.

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 join of the bone fragments, like forming the visible callus[13]. The main tasks for the internal fixation are to enable mechanical stability to the bone and surrounding tissue, to preserve blood supply, and finally to prevent possible fracture diseases like infection in the area of trauma[14]. In the process of internal fixation two stability patterns exist: absolute stability (results in direct bone healing), and relative stability (results in indirect bone joining). Absolute stability presumes no moving between bone fragments, and relative stability means that bone fragments can create relative motion during their union. To enable proper healing of the bone, surgeons apply various mechanical parts which provide mechanical and functional stability to the bone during the healing/recovery process. The main components which are used for internal fixations are: wires, pins, screws and plates.

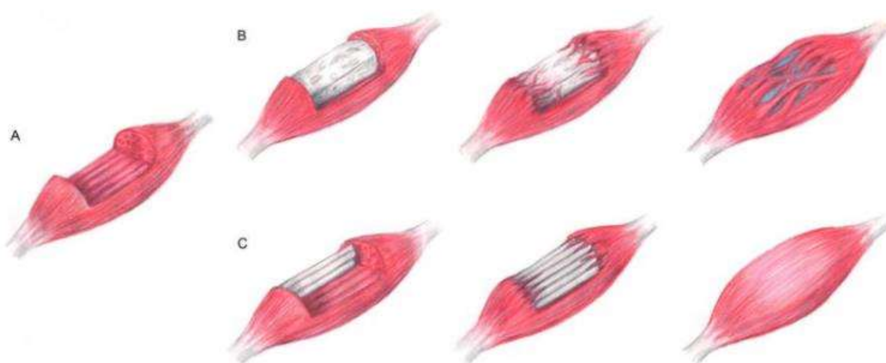
[12] Mohhamed Mizal Rashid, Doctoral Disertation, , "Parametric models of the plate implants for humerus bone", 2018, Serbia

13 Musuvathy, S., Azernikov, S., Fang, T., 2011, Semi-automatic customization of internal fracture fixation plates, Engineering in Medicine and Biology Society, EMBC, 2011 Annual International Conference of the IEEE, Boston MA, Aug. 30 2011-Sept. 3, pp. 595 – 598 doi:10.1109/IEMBS.2011.6090132

14 Lešić, A., Zagorac, S., Bumbaširević, V., Bumbaširević, M., 2012, The development of internal fixation: Historical overview, Acta chirurgica iugoslavica, 59 (3), pp. 9-13

Beside plates, sometimes it is required to implants scaffolds into bones[15] and soft tissue[16], in order to enable support for cell growth, and also provide some mechanical stability to the bone. If additional stability is required, then it is possible to combine plate and scaffold. Soft tissue engineering has been introduced as a new strategy for healing damaged or diseased soft tissues and organs, in order to overcome the limitations of current therapies. Since most of soft tissues in the human body are usually supported by collagen fibres to form a three-dimensional microstructure, fibre-reinforced scaffolds have the advantage to mimic the structure, mechanical and biological environment of natural soft tissues, which benefits for their regeneration and remodelling.

Tissue engineering can be simply defined as preparing a living tissue construct by expanding cells ***in vitro*** and incorporating the cells into a temporary scaffold to mimic the structure and function of the native tissue. Extracellular matrix (ECM) with specific appearances and functions plays a pivotal role in promoting cell growth and differentiation, following the growth patterns and rules found in natural tissues and organs. ECM in native tissue is a three-dimensional (3D) network whose composition and structure can interact with cells continuously to provide structural support (Figure 3.3), transfer mechanical forces and transmit chemical signals in native tissues. In general, scaffolds for tissue engineering should possess sufficient mechanical properties, biocompatibility and appropriate morphology to support inward cell growth, and have high porosity and interconnection to transmit regulatory chemical signals, nutrients, oxygen and metabolic wastes.



15 Jelena Milovanovic, Milos Stojkovic, Milan Trifunovic, Nikola Vitkovic, Review of bone scaffold design concepts and design methods, FACTA UNIVERSITATIS-SERIES MECHANICAL ENGINEERING, UNIV NIS, 0354-2025, 10.22190/FUME200328038M, Nov2020.

16 Pei B, Wang W, Fan Y, Wang X, Watari F, Li X. Fiber-reinforced scaffolds in soft tissue engineering. Regen Biomater. 2017;4(4):257-268. doi:10.1093/rb/rbx021

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Figure 3.3 Schematic representation of scaffold mediated repair of volumetric muscle loss (VML). (A) VML injuries span large portions of the muscle belly, and (B) can be repaired using bulk scaffolds to fill this void space. These scaffolds support tissue repair, but functional regeneration is limited by disorganized myofiber and scar tissue formation. (C) Scaffolds with precisely engineered topographic cues to direct aligned tissue growth, such as micro threads, will guide organized myofiber formation for more robust functional tissue regeneration.[17]

3.3 Biomechanical analysis and simulation

The first phase in creating a model of the organ for the needs of a finite element analysis (FEA) is based on a CAD model through modelling of characteristics of Its internal structures. When modelling bones, two approaches are mainly used:

1. Assigning material characteristics to each finite element, by correlating with the density of the material which is determined on the basis of CT recording,

2. Zoning the bone, by dividing the bone into segments to which different materials are assigned.

The first method is often used in practice, because it allows for the FEA model to be created in a very short time. In doing so, major mistakes can be made especially if the dimensions of the finite elements are significantly greater than the thickness of individual bone segments. For example, the outer layer of the femur (cortical bone) can be very thin in some places, especially in the case of elderly people, because of osteoporosis. In the presented approach zoning is chosen as the method for FEA model material assignment. FEA analysis results based on a zoned model are presented in Figure 3.4 and Figure 3.5 a and b.

[17] Grasman JM, Zayas MJ, Page RL, Pins GD. Biomimetic scaffolds for regeneration of volumetric muscle loss in skeletal muscle injuries. Acta Biomaterialia. 2015 Oct;25:2-15. DOI: 10.1016/j.actbio.2015.07.038.

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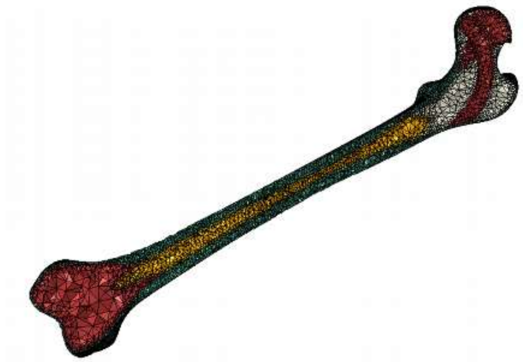
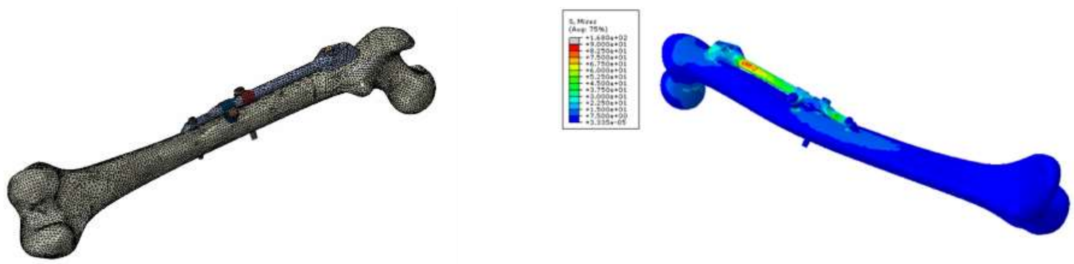


Figure 3.4 The inside look of an FEA model of the femur



a) FEA model of the Femur-implant plate assembly

b) The equivalent stress gained through preliminary analysis

Figure 3.5 FEA model and analysis of the femur-plate assembly

Biomechanics of human soft tissue has been an emerging and very important research field since the 1981 publication of the book Biomechanics: Mechanical Properties of Living Tissues by Yuan-Cheng Fung. Since then, a lot of research has been performed in order to propose biomechanical models of the body parts. For example, modelling human bone deformations requires an accurate geometrical, topological and material structure. By modelling brain deformations and its mechanical interactions with the skull surface and surgical tools it is possible to assist a surgical procedure, through determining how one can compensate for the brain shifting during tumour resection.

Human soft tissues are complex structures that can show nonlinear, time dependent, inhomogeneous, and anisotropic behaviours. Modelling such behaviours is usually carried out with partial differential equations (PDE) of continuum mechanics that are numerically solved through the Finite Element Analysis procedure. The procedure for creating FEA models is a complex task, and it includes: (1) collecting geometrical data, (2) definition of a constitutive

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model and estimating its parameters for the organ soft tissues, (3) defining boundary conditions which describe mechanical limitations and interactions (4) solving the PDE with the FE method, using 3D meshing and a numerical calculation. Subject-specific 3D geometry of the organ (mainly using segmentation techniques applied to 3D images such as CT or MRI) and solving the PDE (using dedicated FE software) are now quite straightforward tasks. The choice for a constitutive model of the organ is still an open question posed by many researchers, and mainly it depends on the goal of the analysis.[18]

[18] Biomechanics of Living Organs, Louise Springthorpe, 2017; Book: Biomechanics of Living Organs, Editors: Yohan Payan, Jacques Ohayon, https://doi.org/10.1016/C2015-0-00832-2

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4 Software solutions in additive technologies supported medicine

4.1 Software solutions for medical image processing

The medical software is a growing market, and it is expected to reach USD 3,876 million by 2022[19]. There are different types of software in medical imaging and diagnostics, and they can be divided by using the following factors:

- By price: Commercial, Free, Open Source
- By Type: Integrated Software, Standalone Software
- By Image Type: 2D Imaging, 3D Imaging, 4D Imaging
- By Modality: Traumatic Brain Injury (TBI), Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), Single-photon Emission Computed Tomography (SPECT), Ultrasound Imaging, 2D Ultrasound Imaging, 3D/4D Ultrasound Imaging, Doppler Imaging, Radiographic Imaging, Combined Modalities, PET/CT, SPECT/CT, PET/MR
- By Application: Orthopaedics, Dental Application, Neurology, Cardiology, Oncology, Obstetrics and Gynaecology, Mammography, Respiratory Applications, Urology and Nephrology,
- By End User: Hospitals, Diagnostic Centres, Research Centres, Higher Education Institutions

In the sense of additive manufacturing the highest importance lies with software for medical imaging, which can provide 3D models of human organs, or even preparing a model directly for 3D printing (Materialise Mimics). Software that can "analyse" data obtained from medical images is called medical image analysis software. The analysis can be used in diagnosis, by comparing images between patients or within the same patient at different time points to assess disease progression and prognosis. Along with the improvement of imaging technology, great strides are being made in the analytical capability of medical imaging software, in an effort to create software capable of independently detecting clinical anomalies in medical images. Some basic characteristics of medical imaging software are:

[19] https://www.marketsandmarkets.com/Market-Reports/medical-image-analysis-software-market-846.html

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Image Segmentation which is used to distinguish tissues, one from another, and to provide boundaries between different organs (if it is possible, based on the applied algorithms and image quality).

Image registration is a process that allows images to be aligned in the correct manner. In this technique, the computer is acquainted with a series of 'target' images. When it is fed a new image, this new 'source' image is transformed to become similar in alignment to the target image. Image registration can be achieved using three methods: transformation models, similarity functions, and optimization procedures[20].

Image Visualization which presumes creation of 3D models from 2D images, by applying adequate techniques (like marching cube algorithm[21]). The most known medical imaging software are (but not limited to): Materialise Mimics[22] and 3D Doctor[23]. Their scope is beyond this course, but some applications of Mimics (trial version) will be presented in the following chapters.

Example - Model manipulation and processing in Materialise Mimics (10.0, Trial Version)

Materialise Mimics is a software intended for medical image processing, which also enables CAD, as well as FEA (Finite Element Analysis). The package consists of several modules, the combination of which can be used to create a complete 3D model of the organs of the human body, including implants. More about the software at https://www.materialise.com/en/medical/mimics-innovation-suite/mimics.

The software can import medical images via the corresponding wizards and DICOM, TIFF or BMP formats, as well as images in RAW format. Most often, medical images are imported in DICOM (CT, MRI) format and they can be processed in different software, such as: 3D Doctor, 3D Slicer and others. The DICOM format itself contains image data for each recorded examination (e.g., CT section), but may also contain other patient data (e.g., textual data with data on height, weight, etc.). After opening / creating a new project and selecting the option to import images, a dialog for selecting a folder containing patient data (images) in DICOM format opens, Figure 4.1.

[20] https://www.postdicom.com/

[21] Lorensen, William E.; Cline, Harvey E. (1 August 1987). "Marching cubes: A high resolution 3D surface construction algorithm". ACM SIGGRAPH Computer Graphics. 21 (4): 163–169. CiteSeerX 10.1.1.545.613. doi:10.1145/37402.37422.

[22] https://www.materialise.com/en/medical/mimics-innovation-suite/mimics

[23] https://www.3d-doctor.com/

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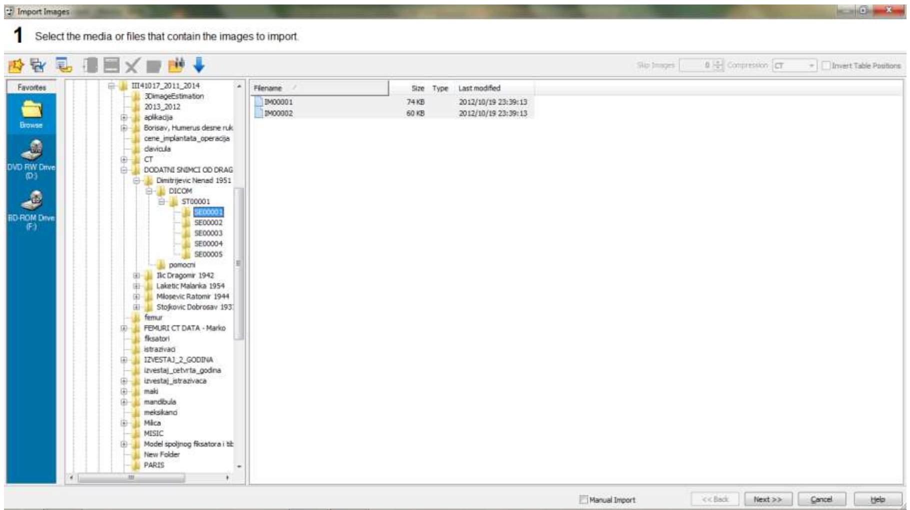

Figure 4.1 CT data import

After selecting the appropriate files, the next window opens, displaying the data recorded in the DICOM file. Regarding the scan parameters, the cross-sectional thickness as well as the scan resolution are very important. The thinner the cross-section, and the higher the resolution, the better the image and the better the segmentation of the image. On the other hand, higher resolution implies a higher dose of radiation, so care should be taken not to over-irradiate the patient. In recent times, with the development of technology and software solutions, it is possible to obtain images of higher quality than was previously the case. Selecting the image conversion option transfers the images to a format that matches Mimics and moves on to further options that allow volumetric display of the scanned data. These options allow you to select the position of the body when scanning in several directions (Figure 4.2.): top (up), bottom (down), left (left), right (right), anterior (front), posterior (back).

After defining the position of the patient, the scanned data is displayed in the form of a 3D representation of the human body. The given volumetric representation is shown through three projections, namely Anterior projection, Right projection, and Top projection. In the lower right window, which is currently empty, it is possible to display a 3D model obtained by processing volumetric data, such as a polygonal model. If there is an error in the orientation of the model, it is possible to use File - Change Orientation commands to change the orientation of the patient model. If you need to remove an image from a group of images, or make another modification, you need to select the command File - Organize Images and reorganize the images, as shown in Figure 4.3.

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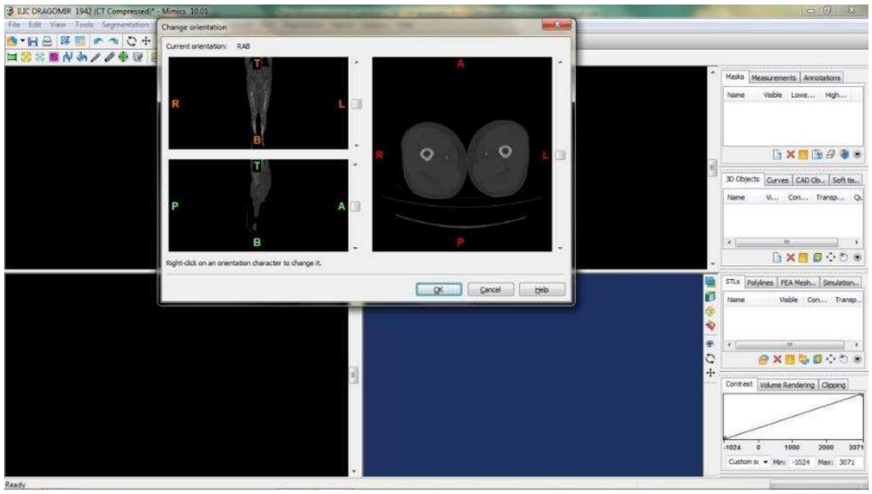

Figure 4.2. Mimics 10 Workspace window

As can be seen from Figure 4.3, it is possible to show all images created on CT scanner, and manipulate them: erase, change contrast and alike.

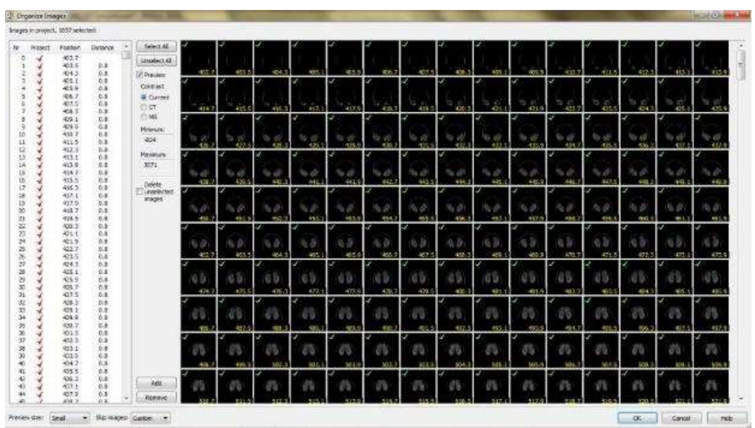

Figure 4.3 Manipulation of loaded images in Mimics software

Defining thresholds

Mimics is a software that defines objects through appropriate masks. Segmentation masks are masks that are defined as sets of pixels between, or across boundary values. It is possible to create many such masks, or as many as needed. Low limit values enable the selection of soft tissues, while higher values enable the selection of bones, i.e.,

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body parts of higher density. This basically means that if it is necessary to create a whole-body model, it is better to define a lower limit value of pixel colour intensity. Defining the limit value in Mimics is performed via the Thresholding command defined in the Segmentation toolbar (Toolbars - Segmentation), as a green rectangle. Depending on the values defined as minimum and maximum, the corresponding masks will be marked in the model projections. Figure 4.4 shows a mask defined in green indicating values between 226 and 3072 which corresponds to Bone (CT). In the drop-down list where the predefined limit values are located, it is possible to select the appropriate value range, Figure 4.5. If Soft Tissue is selected as the set of values, then the minimum value is included in the mask -700 and the maximum 225 Hounsfield units.

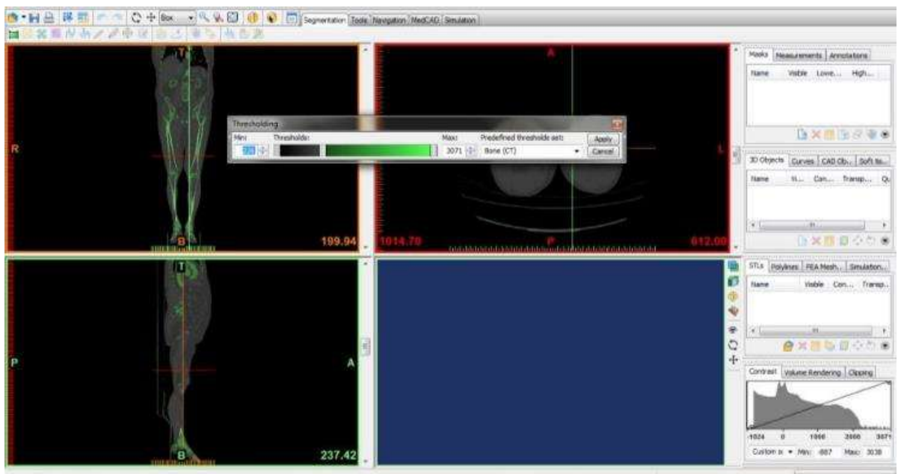

Figure 4.4. Thresholding for hard tissue (bones)

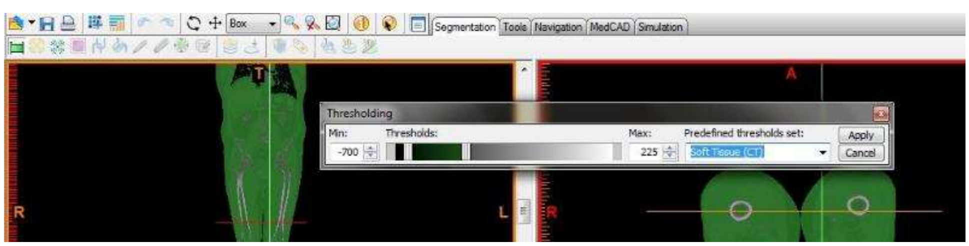

Figure 4.5. Thresholding for soft tissue

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When the process of determining the value range is completed, the user creates a green mask with a confirmation, which includes the given value range.

Creating a 3D model

Based on the image segmentation, it is possible to create a polygonal model that can be used for further processing in Mimics, or for subsequent processing in a CAD package. By selecting the Calculate 3D command, Mimics creates a volumetric presentation of the segmented mask, which is shown in Figures 4.6 and 4.7. It can be noticed that in the Project Management - 3D Object palette, a new object is displayed, i.e., the one that was created. The quality of the object can be defined in several levels, all depending on the need. Figure 4.8 shows possibilities that can be achieved with a 3D object. It is possible to apply transformations (rotation, translation), show volume shading, and alike. As for the mask, by clicking on the button at the end of the list in the panel, it is possible to select some other options for manipulation, which are shown in Figure 4.8 It is possible to cut a 3D object with certain lines, make a mirror image, etc.

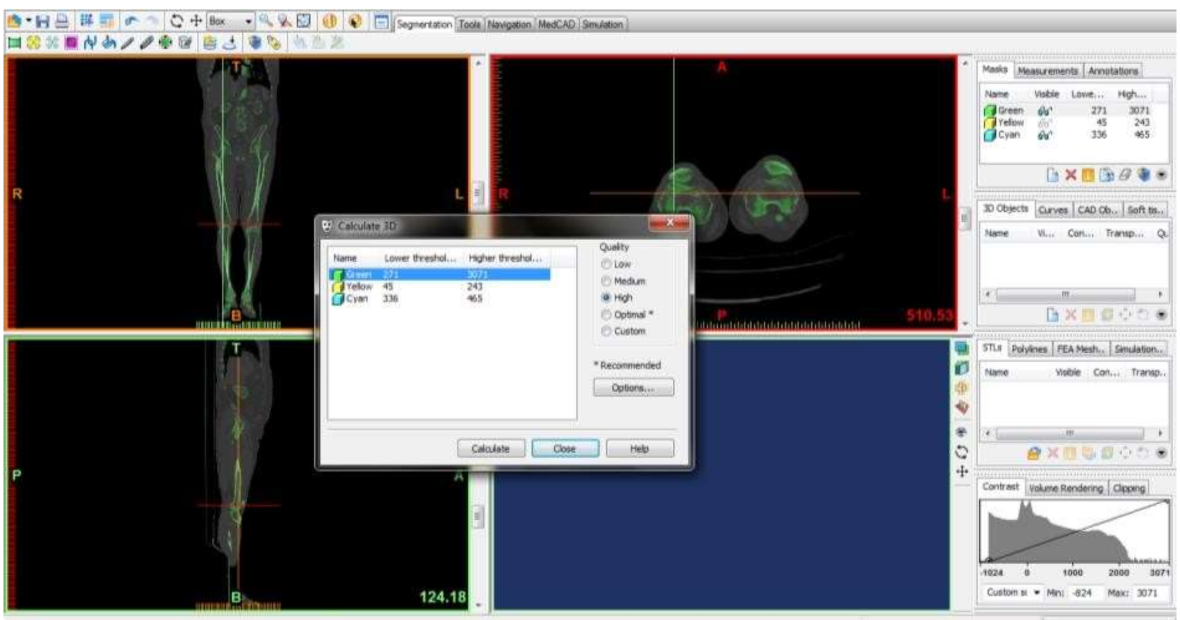

Figure 4.6 Forming the volumetric model

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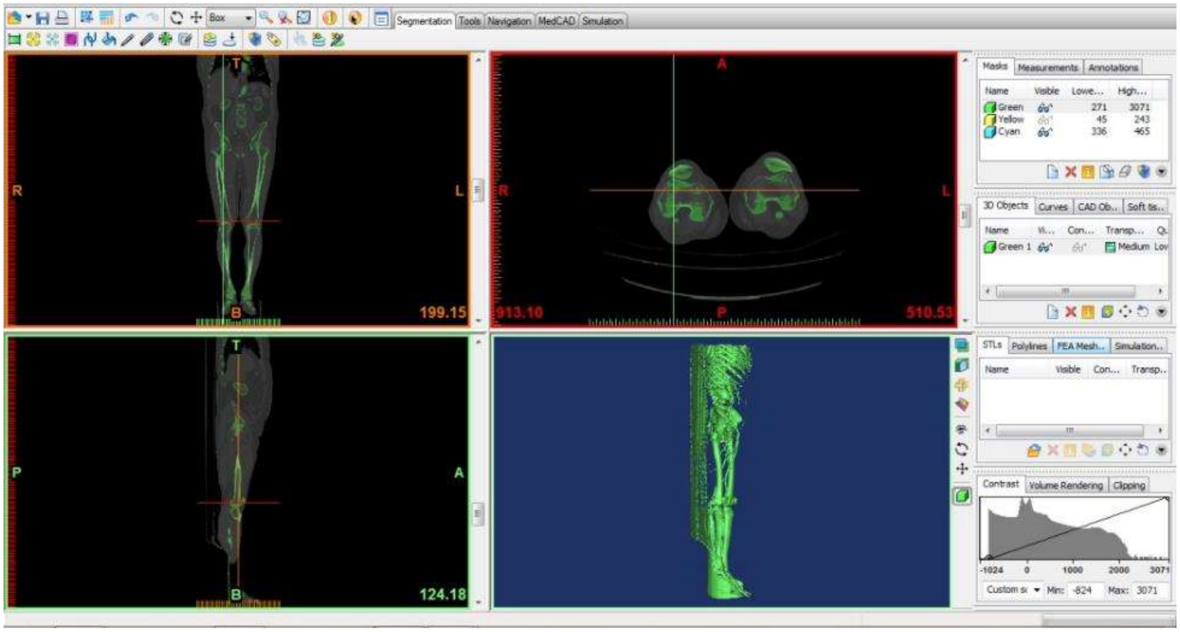

Figure 4.7 Volumetric model

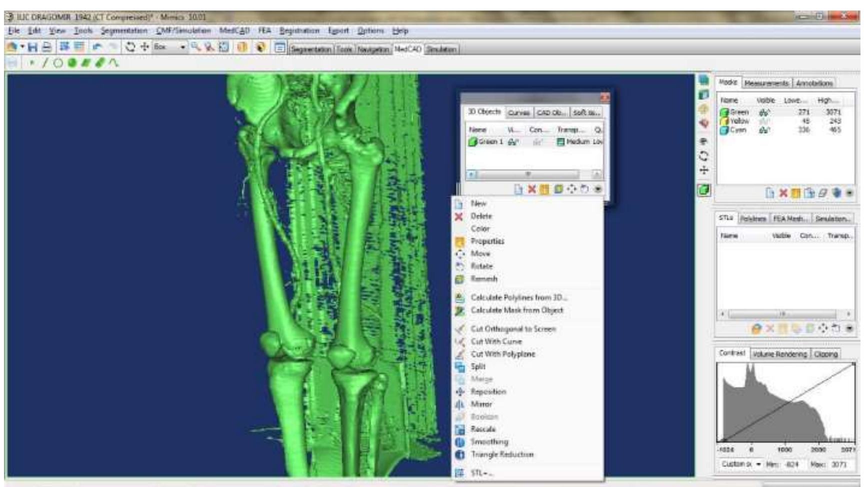

Figure 4.8 3D model manipulation

By clicking on the STL + button, the volumetric model is exported to the STL model, which is suitable for further processing in CAD packages. By clicking on the selected mask and selecting the Add option, the output model is formed in the form of an STL file. The model is created in a folder that is defined by default. If a higher quality model is needed, then it is necessary to edit settings for a high-quality object.

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4.2 Software solutions for creation and application of 3D geometrical models

Medical imaging software is used for processing medical images coming from different devices (e.g., radiographs). Their capabilities can be expanded for the creation of 3D models (Mimics), usually polygonal, but sometimes other types can be created, like solid model. The initial purpose of this software is to provide output model (STL, OBJ) for the application in CAD/CAM software for further processing and application, e.g., 3D printing. Software packages which are used for processing such models are standard CAx (CAD/CAM/CAE) software packages, or other computer graphic software packages, because they process the input, and the source is not important.

This procedure is known and already presented as Reverse Engineering (the model processing procedure is the same, and does not depend on the source, i.e., if it is laser scanning of the mechanical part, or CT of a human bone). The result, on the other hand, differs. When processing models of the human organs it is of crucial importance to define the application of that model, and by using that as a guidance apply proper modelling techniques. If model application is for teaching purposes, then anatomical correctness is important, but geometrical accuracy is not so important. If there is a requirement for implant creation, then anatomical and morphological correctness and geometrical accuracy are very important. Any software with surface modelling can be applied for this purpose, and some of them are: CAx – Solid Works, Catia, Fusion 360, Rhino, etc.; Graphics – Blender, Maya, 3D Studio max, etc. The application of CATIA for bone remodelling will be presented in following chapters.

4.3 Software solutions for the application of additive technologies

Additive technologies (usually called 3D printing, but not limited to it) are technologies which were firstly used for creation of product prototypes. Nowadays it is possible to use additive technologies (AT) for the manufacture of functional products. In medicine, additive technologies can be used for the creation of hard and soft tissue implants, plate creation, scaffold creation, etc. As there are different software packages which can be applied for creating models (CAD)[24], there are also different software solutions available for AT machine g-code creation. These are also known as slicing programs in additive manufacturing (used for print settings preparation) such as: Simplife3D[25] or Cura[26] for 3D printing/FDM. A division can be done by pricing, where some of the software packages are completely free and others are commercial. The user must look carefully in the license agreement to see what he is using, and

[24] https://wohlersassociates.com/software.html
[25] https://www.simplify3d.com/
[26] https://ultimaker.com/software/ultimaker-cura

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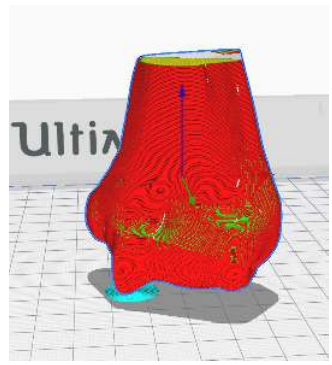
the possible costs. The model can be fully prepared in CAD, but final adjustments are done in specialized software solutions, and they are usually provided with the machine (applied technology), but as stated, there are software packages which can be used for more than one technology, like PreForm[27], or Formware 3D[28] (DLP, SLA or LCD). The most important part is that the selected software supports the available additive machine (to control prints), and that slicing and support can be done properly. An application example of FDM printer use for prototyping plate implants for humerus bone is presented in Figure 4.9 (Cura software).

a) 3D models of distal humerus in CATIA

b) Surface model of distal humerus in CATIA



c) Sliced model in Cura

Figure 4.9 Different representation of 3D models in CAD (CATIA) and Slicer software (Ultimaker Cura)

[27] https://formlabs.com/software/#preform
[28] https://www.formware.co/

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5 Creation of 3D geometrical models

In this chapter, two main methods for 3D model reconstruction will be presented. First, method(s) based on the scanned data, usually by using volumetric scanners (CT, MRI), and second, method(s) which uses template or parametric models for the creation of tailored (personalized) models of human organs.

5.1 Creating 3D models using methods based on medical data

The techniques presented in this course are part of the Method of Anatomical Features (MAF) which introduces a new approach to describe geometrical entities of human bones, and it enables creation of various geometrical models of the human bones. MAF is a complex method, and because of that, Structured Analysis and Design Technique (SADT) is used for its description. SADT diagrams are used for the graphical representation of system processes, and they enable detail analysis of system and involved resources. The main components of SADT diagrams are input elements, resources, control elements, and output elements. In order to apply SADT on MAF, it was essential to define main components of the method. Analysis of MAF was performed and main components were defined as:

1. Input elements – labelled with capital I: Volumetric images of the patient (bone) created by CT or MRI; 2D images of the patient (bone) usually created by the application of X-ray.
2. Mechanisms (Resources) - labelled with capital M: Doctor – surgeon; Designer – Expert in CAD and medical software; Software packages: Materialise Mimics, CATIA
3. Control elements - labelled with capital C: Medical knowledge; Rules and limitations of applied methods in MAF; Morphometric rules – Rules about morphometric parameters;
4. Output elements - labelled with capital O: Geometrical models of human bones – polygonal, NURBS (surface), solid, models for Finite Eleventh Analysis (FEA), etc.

MAF (Figure 5.1.1) contains basic and additional processes (Figure 5.1). Basic processes are presented in Figure 5.2 and additional processes are presented in Figure 5.3. Basic processes enable complete geometrical and anatomical definition of the specific human bone, and they are:

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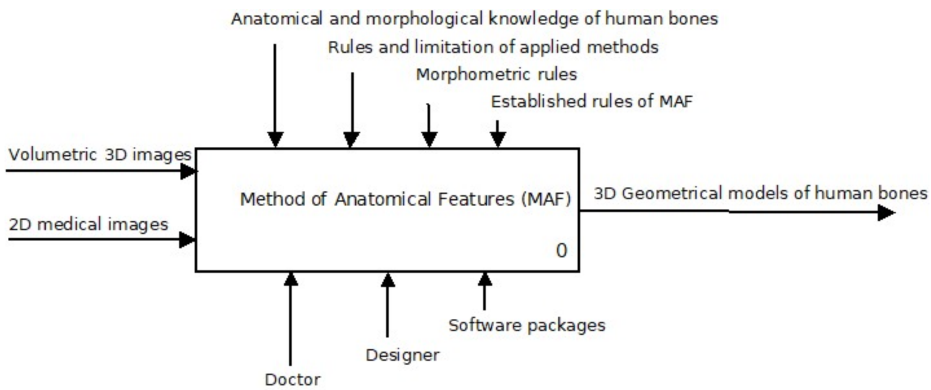

Figure 5.1 Basic components of MAF - A-0

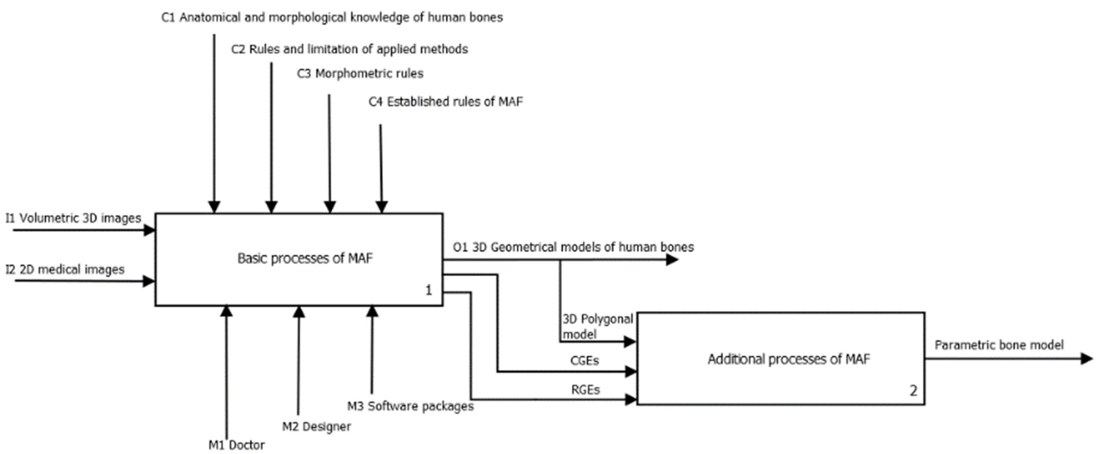

Figure 5.2 Basic and additional processes of MAF

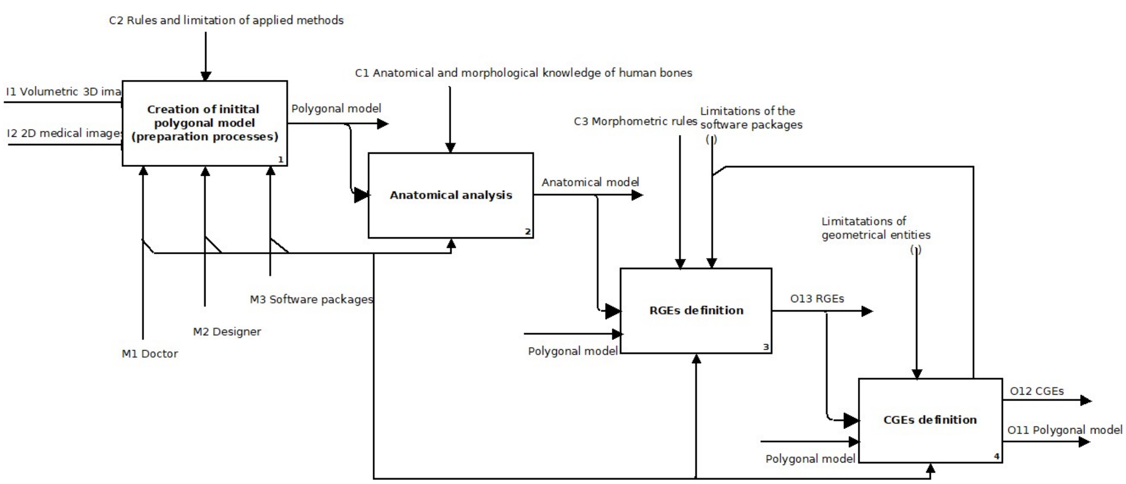

Figure 5.3 Basic processes of the MAF – A1

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- Creation of initial polygonal model (A11) – This process contains several procedures, which must be performed in sequential order: Scanning of human bone by the application of CT scanner; Segmentation of the acquired images; Forming of the polygonal model and its conversion to STL format - creation of the initial point cloud; Cleaning of the point cloud; Creation of the tessellation model; Additional processing of the tessellated model (filling holes, fixing irregularities in model.
- Anatomical analysis (A12) – The process of anatomical analysis presumes anatomical and morphological analysis of the human bone in order to create the anatomical model of the human bone. This model is a semantic model which connects geometrical elements on the polygonal bone model with anatomical and morphological terms, which are already defined in medical literature.
- Definition of Referential Geometrical Entities (RGEs) (A13) – RGEs are geometrical entities (points, lines, planes, axes, etc.) which are created on the polygonal model of the human bone. These entities represent basic geometry which is used for the creation of all other geometrical elements, e.g., surfaces.
- Creation of Constitutive Geometrical Entities (CGEs) (A14) – RGEs are the basis on which CGEs are created. These entities are called constitutive because they are used for the creation of surface and solid models of the human bones, and parts of the bones, in accordance with bone morphology.

Processes which are used for the creation of parametric bone model are called additional processes of MAF (Figure 5.4) and they are:

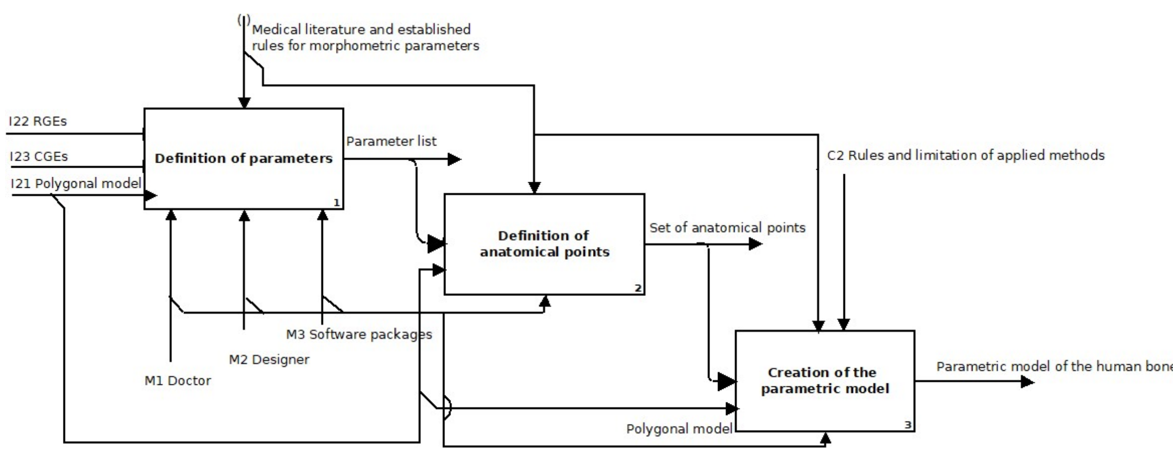

Figure 5.4 Additional processes of MAF – A2

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- Definition of parameters (A21) – The first step in this process is to define morphometric parameters, which are clearly visible and measurable dimensions in medical images, and also defined in medical literature, and by traditional morphometrics. These parameters are defined individually for each human bone.
- Definition of anatomical points (A22) – Anatomical points are defined on CGEs or other important anatomical landmarks (true, pseudo and semi landmarks) on polygonal model, in relation to anatomical model of specific human bone and defined morphometric properties. This set of anatomical points must be defined for each bone in an input set. It is important to note for landmark geometric morphometrics states that number of landmarks should correspond to the number of specimens, but in this research that is not the case, because, reversed principle is applied, i.e., landmark points are created on the CGEs which are geometric elements used to describe bone shape, and not on the bone itself.
- Creation of the parametric model (A23) – The last step in the parametric model definition is to measure coordinates of points and morphometric parameters for each created polygonal model in a set. Measured values are applied in statistical analysis, and as a result, parametric functions with morphometric parameters as arguments, are created. These functions define values for coordinates of anatomical points in relation to morphometric parameters. Each coordinate (X, Y and Z) of every anatomical point can be calculated by the application of parametric functions width input arguments defined as values of morphometric parameters measured for specific patient. In the first iteration of the MAF, multiple linear regression was chosen as statistical functions, but other statistical methods can be applied also.

5.2 Reconstruction of a 3D model based on a volumetric image

Input data

The radiology image of the tibia bone (Figure 1), which is often called raw data in CAD terminology, represents input data for reverse modelling (RM). The sample of tibia was scanned by CT (computer tomography) in resolution of 0.5mm. The raw data, that is the coordinates of points on scanned bone, were imported into appropriate CAD software for reverse modelling. The CT scans were obtained fast, but in a low resolution (in terms of RM). That had effects on accuracy of some details in the 3D digital model, but not on accuracy of the total bone morphology. In addition, CT scans contained internal bone tissue structures, as well as the other type of the surrounding soft tissues. That is the reason why these scans required considerable time for model post processing (“for cleaning and healing the model”).

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Reverse modeling

Reverse modelling of a human bone's geometry using CAD software means generating digital 3D model of bone's geometry from radiology images (X-Ray, CT, MRI). In this case, CATIA V5 R21 CAD software and its modules were used. Importing the raw data into the CAD system results in the generation of one or more clouds of points (discrete points of the bone, which are scanned by some of radiology methods). In the next phases of reverse modelling, the geometrical features of higher order (curves and surfaces) are designed.

1. The process of creating the tibia model was based on the processes that are described in[29], and also[30].
2. Importing and editing (filtering, aligning, etc.) of clouds of points.
3. Tessellation of polygonal model (mesh) by creating a huge number of small triangular planar surfaces between the points in the cloud, as well as editing of polygonal model.
4. Recognition and defining the Referential Geometrical Entities (RGEs) and its correlation with tibia anatomy Figure 5.5 and 5.6
5. Creating anatomical points and spline curves in the defined planes Figure 5.7a.
6. Creating the 3D surface model of tibia using obtained spline curves Figure 5.7b.
7. Creating 3D Solid model of human tibia

The geometrical models of the human tibia

Situated at the medial side of the leg, tibia is the longest bone of the skeleton after the femur. It is made up of a shaft and two extremities, proximal and distal. The proximal end of the tibia has a broad superior articular surface which articulates with the femur. The shaft has a prismoid shape with three surfaces and three margins. The anterior margin, the most prominent of the three, commences above at the tuberosity, and ends below at the anterior margin of the medial malleolus. Distal end of the tibia, much smaller than the upper, is prolonged downward on its medial side as a strong process, the medial malleolus. Its inferior articular surface is quadrilateral, and smooth for articulation with the talus Figure 1.

29 Stojkovic, M., Trajanovic, M., Vitkovic, N., Milovanovic, J., Arsic, S., Mitkovic, M. (2009) Referential Geometrical Entities for Reverse Modeling of Geometry of Femur, WIPIMAGE, Porto, Portugal, Proceedings, pp 189-194

30 Vitkovic, N., Trajanovic, M., Milovanovic, J., Korunovic, N., Arsic, S., Ilic, D. (2011) The geometrical models of the human femur and its usage in application for preoperative planning in orthopedics, 1st - International Conference on Internet Society Technology and Management / ICIST, Kopaonik, pp 13

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Recognition and defining the RGEs

In the case of the tibia, the mechanical axis is a line from the centre of the tibia plateau (interspinous intercruciate midpoint) extending distally to the centre of the tibia plafond[31].The tibia plateau (proximal/superior articular surface) was approximated with an ellipse, which was the best solution when compared with all other tested entities: circles, spline curves, etc. The first point of the mechanical axis is in the centre of the ellipse, which is approximately equal with the centre of tibia spines notch. The second point is in the centre of the tibia plafond (distal/inferior articular surface) which was approximated with adequate lower cross-section of distal end of tibia, Figure 5.6.

Figure 5.5 Right tibia and fibula, a) Anterior view, 1. Medial condyle, 2. Lateral condyle, 3. Tibia tuberosity, 4. Lateral surface, 5. Anterior margin of tibia, 6. Medial surface, 7. Lateral margin of tibia, b) Posterior view, 1. Intercondylar tubercles of intercondylar eminence, 2. Fibula, 3. Medial margin of tibia, 4. Posterior surface, 5. Medial malleolus, 6. Lateral malleolus [3]

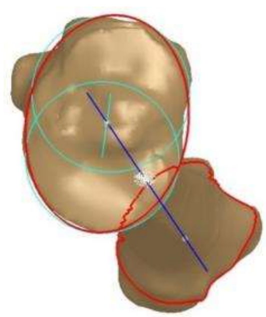
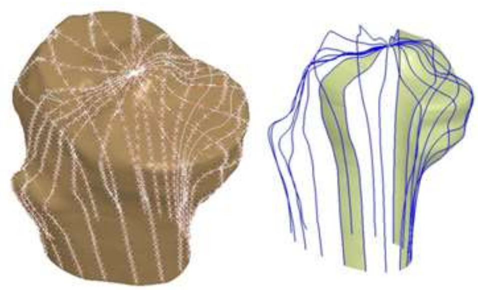


Figure 5.6 RGEs on polygonal model of the right tibia



a) Points and spline curves on proximal end of tibia

b) Creation of the 3D surface model of the proximal end of tibia

Figure 5.7 Definition of basic geometry and human tibia 3D surface

31 Cooke, D., Sled, E., Scudamore, A. (2007) Frontal Plane Knee Alignment: A Call for Standardized Measurement, The Journal of Rheumatology, Vol.34, No 9, pp 1796-1801

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Creating 3D surface and solid model of human tibia using the characteristic regions method

Ten planes based on the defined mechanical axis and anatomical landmarks of tibia, were created. These planes were used for the creation of the cross-sections. The intersections of planes and polygonal model of tibia produces contour curves (cross-section contour). These curves were used for creating points and spline curves (Figure3a). Obtained spline curves were used for creation of the proximal end of tibia surface model Figure3b. The expanded proximal end is a bearing surface for body weight, which is transmitted through the femur. It consists of medial and lateral condyles, with intercondylar eminence and anterior and posterior intercondylar area between and the tibia tuberosity, on the anterior surface. The same procedure, only with a set of eight planes, was applied in the creation of a 3D surface model for the distal end of tibia Figure 5.8. The slightly expanded distal end of the tibia has anterior, medial, posterior, lateral and distal surfaces. It projects inferomedially as the medial malleolus. The distal end of the tibia, when compared to the proximal end, is laterally rotated (tibia torsion). The short thick medial malleolus has a smooth lateral surface with a crescentic facet that articulates with the medial surface of the talus. For tibia shaft, set of nineteen planes was used. These planes are perpendicular to the mechanical axis. The shaft is triangular on the cross section and has three surfaces: medial, lateral and posterior, separated with three margins: anterior, lateral and medial. A 3D surface model of tibia was created by merging 3D surfaces of proximal end, shaft and distal end of tibia. The solid model was obtained by filling the volume of surface models using known features from the CATIA. Problem whit this approach is alignment of these tibia parts during merging. This requires approximations of 3D surface models of tibia parts on places where they should be connected.

Creating 3D surface and solid model of human tibia using the rotational planes method

Another possible method for creating a 3D surface model of the human tibia is based on contour cross-sections of the whole tibia. In this case cross-sections were created by intersecting four rotational planes with the human tibia polygonal model. The angles between these planes are forty-five degrees. As well as in the previous approach obtained cross-sections were used to create points, spline curves and adequate models.

Figure 5.8 3D surface model of the right tibia

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5.3 Reconstruction of a 3D model using template models

The MAF method enables creation of template/parametric models which are based on the anatomical points defined on B-spline curves made over the 3D model in the CAD program, as shown in the Figures 1c and 1d. In this way, the points have been defined on the bone model in the three-dimensional space as they would be defined in nature by the simple touch of probe onto the bone surface. The MAF comprises many processes which can be generally split into the preparatory processes and the modelling processes. The MAF preparatory processes have been shown (Figure 5.9a.). At the end of the preparatory processing, a STL (mesh) model is created. This model represents input data for the geometrical model processing, which starts with tessellation and creation of polygonal model. The following procedure is referential geometry definition - RGE (planes, lines, axes, points, and alike), which is defined on polygonal human bone model in accordance with its anatomical and morphological features. RGEs are used as the basis for the creation of geometrical entities, Figure 5.9b. These entities are mostly spline curves and they are defined to follow the bone geometry and topology as best as possible. At the end of the geometrical processing, points on geometrical entities are defined. These points define the boundary of certain anatomical regions on the polygonal model (anatomical points) as presented on Figure 5.9c and 5.9d. Parameters (dimension) defining is done regarding the RGE, as presented in Figure 5.10a and 5.10b. Parameters are defined separately for each type of human bone in relation to its anatomical and morphological features and are mainly related to clear and easily noticeable geometrical entities on a bone, which is what RGE represent. Parameters may be: femur head radius, angle between the anatomical and mechanical axis of femur, and alike. Currently, six parameters are defined for femur and four for tibia. In order to successfully perform the process of statistical analysis, it is necessary to define the same anatomical points and parameters on a certain number of examples of polygonal models of the same type of human bones of various patients. After this, it is necessary to measure coordinates of these points and parameters values on each model separately and to create the corresponding vectors. Coordinate system is positioned at the Centre of Femoral Head or at Tibia Plate, and oriented with A-P (Anterior-Posterior) and L-M (Lateral-Medial) planes. Through the defined vector values of point coordinates and parameters, statistical analysis is done by application of multiple linear regression.

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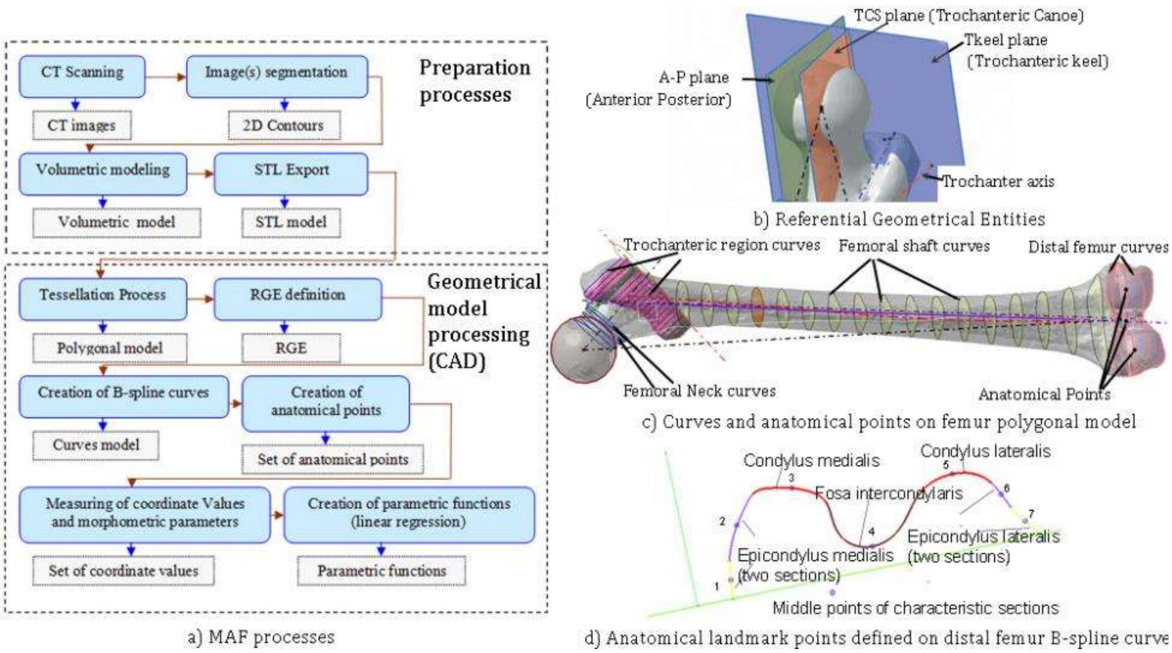
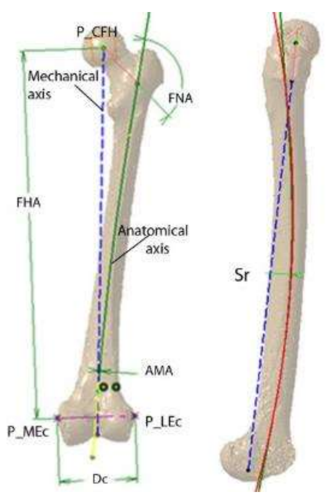
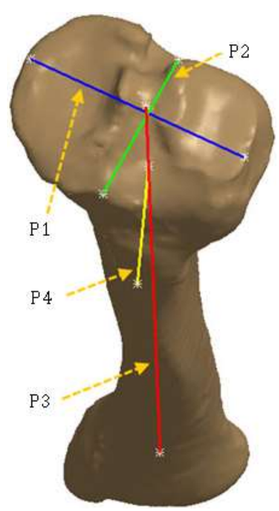


Figure 5.9. The process of creation 3D geometrical models of human long bones



P_LEc - The point of the lateral epicondyle.
P_MEc - The point of the medial epicondyle.
P_CFH - Femoral Head Center.
FHR - Femoral Head Radius.
FNA – Femoral Neck Angle.
FHA – Distance between P_CFH and line connecting P_MEc and P_LEc.
DC – Distance between P_MEc and P_LEc.
AMA – Angle between Anatomical and Mechanical Axis.
Sr – Shaft radius.



P1, P2 - Dimensions between the furthest points in A-P (Anterior-Posterior) and L-M (Lateral-Medial) planes of tibia plate.
P3 –Distance between the points determining mechanical axis of tibia.
P4 - Tuberosity: Distance from mechanical axis to the most prominent tibial tuberosity point.

a) Parameters defined on femur polygonal model b) Parameters defined on tibia polygonal model

Figure 5.10. Morphometric parameters defined on femur and tibia polygonal models

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As a result of regression application, parameter functions that give linear functional dependence between coordinates of points and parameters are created. The parametric function with six parameters for point 1 on curve 1 which belongs to a distal part of femur is presented in (1).

$$X_{f11} = 9.168 + 0.033 \cdot D_{ci} - 0.033 \cdot FHA_i + 0.041 \cdot FNA_i + 0.002 \cdot AMA_i + 0.055 \cdot S_{ri} - 0.033 \cdot FHR_i \quad (1)$$

Parametric functions may be created with variable number of parameters32. If the values of all the parameters are not legible due to the incomplete data acquired from the medical images of the human bone, it is possible to apply the parametric functions with the number of parameters which are available.

Example of the parametric function with three parameters for the same point is presented in (2)

$$X_{f11} = 11.4509 - 0.0325\,Dc - 0.0007\,FNA - 0.0197\,FHA \quad (2)$$

32 Vitković, N., Milovanović, J., Korunović, N., Trajanović, M., Stojković, M., Mišić, D., Arsić, S., 2013, Software system for creation of human femur customized polygonal models. Computer Science and Information Systems, Vol. 10, No. 3, pp. 1473-1497

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6 CAD model and its application in additive technologies

6.1 Topological and geometrical optimization of CAD models

Design for Manufacturing (DFM)[33] regroup different approaches and Design for Additive Manufacturing is one of them (DfAM)[34]. It is the ability to produce designs specifically for 3D printing. Designs produced for 3D printing are quite different from traditional designs, developed for other manufacturing techniques. Creating a design for additive manufacturing, a technique consisting into building parts layers by layers, is different from subtractive manufacturing methods or injection molding. Design for additive manufacturing enables a new way of thinking but you also must keep in mind that 3D modeling and design for additive manufacturing are two different things. While designing for 3D printing, you create a file that must be understood by a 3D printer. Moreover, 3D printing technologies all have their specificities, from FDM to Selective Laser Sintering or Selective Laser Melting technologies, which must be taken into consideration during the designing process. Getting the perfect 3D model will allow you to make the most of digital manufacturing. Methods such as topology optimization, creation of innovative structures, or even customization, can be a real asset. DfAM is not just a matter of converting an existing design to produce it with additive manufacturing. It goes further, DfAM is about recreating the part, optimizing, and improving it, without the manufacturing constraints of traditional manufacturing methods such as injection molding or CNC machining. But it is not only about the part; it is also about the process: with thoughtful design you can reduce assembly time and the number of components to save time and money. The two important features which DfAM brings to the industry:

- Design freedom - Thanks to the additive manufacturing process, it is becoming possible to create parts perfectly adapted to physical constraints. One of the main advantages of additive manufacturing is design freedom, you can create any idea you are thinking of. This

[33] Wiberg, A., Persson, J. and Ölvander, J. (2019), "Design for additive manufacturing – a review of available design methods and software", Rapid Prototyping Journal, Vol. 25 No. 6, pp. 1080-1094. https://doi.org/10.1108/RPJ-10-2018-0262;

[34] https://www.sculpteo.com/en/3d-learning-hub/3d-printing-business/design-for-additive-manufacturing/

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technology allows to push the boundaries of manufacturing, and you will be free from the constraints of traditional manufacturing techniques, in terms of structure and design.

- Adaptability and flexibility - Design for Additive Manufacturing can make your business more adaptable. 3D printing offers the opportunity to produce on-demand.

Topology optimization[35] is one of the structural optimization techniques that optimizes material distribution for given loads and boundary conditions while meeting the product performance requirements. Most topology optimization techniques are performed by common CAD and FEA concepts and different optimization algorithms considering different manufacturing techniques as shown in the topology optimization process in Figure 6.1[36]. The use of CAD in topology optimization is to create a rough / initial product model to be optimized, while FEA is used to determine the stress and strain distribution throughout the product. Topology optimization is performed in order to remove areas of the product that are not sufficiently subjected to loads and deformations and do not affect the functioning of the product. Based on the requirements of the design problem, various optimization algorithms are used to remove a part of the material in the product in which a certain stress value has not been surpassed. Moreover, topology optimization is performed to meet certain design goals and maintain design constraints. Based on a given problem, the goal could be to minimize the flexibility of the product, i.e., maximizing the stiffness of the product, because flexibility is the opposite of stiffness; while a constraint could be a defined value for maximum allowable deformation, and so on. Topology optimization tools generate a complex natural shape that shows the removal of material based on the goals and constraints set in the design problem. The design is then finalized in CAD software in order to obtain a smooth part following the shape generated in the topology optimization process. After this, the final optimized design is validated using FEA tools. This is done in order to check if it meets the design requirements. Dedicated software used for the topology (and geometry) optimization are:

[35] Sofiane Belhabib, Sofiane Guessasma,Compression performance of hollow structures: From topology optimisation to design 3D printing,International Journal of Mechanical Sciences,Volume 133, 2017, Pages 728-739, ISSN 0020-7403,https://doi.org/10.1016/j.ijmecsci.2017.09.033.

[36] Gebisa A. W., Lemu H. G., “A case study on topology optimized design for additive manufacturing”, IOP Conference Series: Materials Science and Engineering, Volume 276, Stavanger, 2017.

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- nTopology: Next-generation Design & Engineering Software (https://ntopology.com/topology-optimization-software/),
- Altair OptiStruct™ (https://www.altair.com/optistruct/),
- Ansys (https://www.ansys.com/),
- Solid Works (https://www.solidworks.com/), etc.

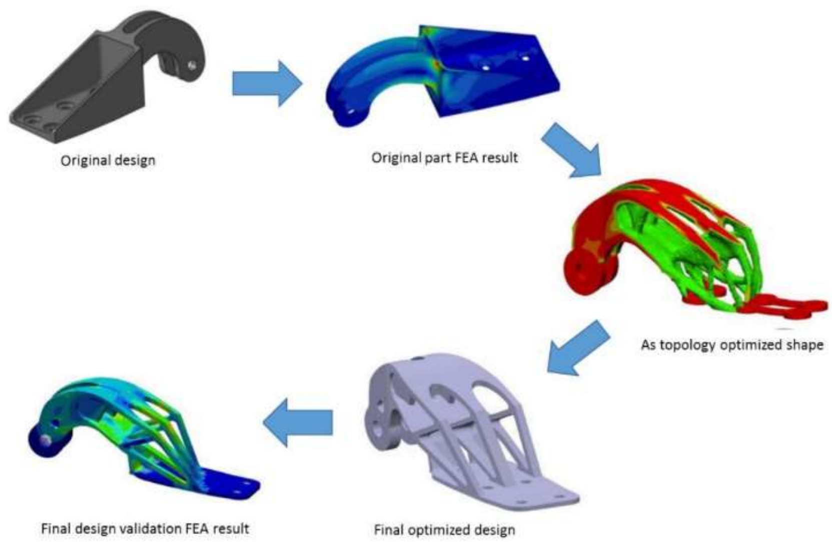

Figure 6.1 Topology optimization process[37]

Parts consolidation[37]

Due to the constraints of traditional manufacturing methods, some complex components are usually separated into several parts for the ease of manufacturing as well as assembly. This situation has changed by the use of additive manufacturing technologies. Some case studies have been done to shows some parts in the original design can be consolidated into one complex part and fabricated by additive manufacturing processes. This redesigning process can be called parts consolidation.

[37] Kim, S.; Moon, S.K. A Part Consolidation Design Method for Additive Manufacturing based on Product Disassembly Complexity. Appl. Sci. 2020, 10, 1100. https://doi.org/10.3390/app10031100

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Lattice structures[38]

Lattice structures are a type of cellular structures (i.e., open). These structures were previously difficult to manufacture, hence they were not widely used. Thanks to the free-form manufacturing capability of additive manufacturing technology, it is now possible to design and manufacture complex forms. Lattice structures have high strength, low mass and multifunctionality. It has been observed that these lattice structures mimic atomic crystal lattice, where the nodes and struts represent atoms and atomic bonds, respectively. They obey the metallurgical hardening principles (grain boundary strengthening, precipitate hardening etc.) when undergoing deformation.

Thermal issues in design[39]

For AM processes that use heat to fuse powder or feedstock, process consistency and part quality are strongly influenced by the temperature history inside the part during manufacture, especially for metal AM. Thermal modelling can be used to inform part design and the choice of process parameters for manufacture[40]

6.2 Optimization of CAD models for additive manufacturing

The novel methods presented in this course for the geometry optimization of medical implant for human mandible are based on the unit cell[41] approach, but with the implementation of two important improvements.

- The first and most important improvement is the application of Method of Anatomical Features for the definition and creation of the scaffold 3D model.
- The second important modification is the application of parametrically defined nucleus elements. A nucleus is a straight or curved bar limited by two nodes (Figure 6.2a), and it

[38] W. Tao and M. C. Leu, "Design of lattice structure for additive manufacturing," 2016 International Symposium on Flexible Automation (ISFA), 2016, pp. 325-332, doi: 10.1109/ISFA.2016.7790182.

[39] Dowling, L.; Kennedy, J.; O'Shaughnessy, S.; Trimble, D. (2020). "A review of critical repeatability and reproducibility issues in powder bed fusion". Materials and Design. 186: 108346. doi:10.1016/j.matdes.2019.108346.

[40] Yavari, R.; Cole, K. D.; Rao, P. K. (2019). "Design Rules for Additive Manufacturing – Understanding the Fundamental Thermal Phenomena to Reduce Scrap". Procedia Manufacturing. 33: 375–382. doi:10.1016/j.promfg.2019.04.046.

[41] Habib Fatah N., Nikzad Mostafa, Masood Syed Hasan, and Saifullah Abul Bashar M., 2016, Design and Development of Scaffolds for Tissue Engineering Using Three-Dimensional Printing for Bio-Based Applications, 3D Printing and Additive Manufacturing, 3/2:119-127.

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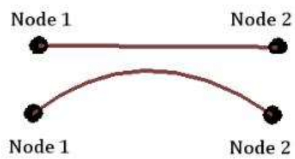
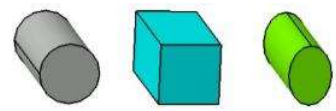
represents a basic building block for scaffold modelling. Nucleuses can be created with the application of different shape and size of cross-sections, and with different lengths, as presented in Figure 6.2b.



a) Straight or curved nucleus



b) cross-section shapes

Figure 6.2. Shapes and cross-sections of nucleus elements

The nucleus cross-section and length dimensions, applied in presented examples, are arbitrary. For each individual patient, they should be personalized. The first developed method is a Curve Based Method (CBM), and second is a Pattern Based Method (PBM). As a result of the application of both methods, scaffold 3D models are created. Both models are based on the nucleus elements, but the difference is in a manner of model construction.

- For the CBM model, the defined nucleus parametric model is used as a basic construction element for the definition of scaffold architecture, as presented in Figure 6.3.
- For the PBM model, the nucleus element was used as a basic component for the construction of the unit cell, which was defined as a 3D cross (Figure 6.3 and Figure 6.5c).

The use of both methods involves performing three groups of processes: preparation process, shared processes, and method specific processes, as presented in Figure 6.4.

The preparation process is a process which is performed in advance, and it enables the definition of the initial structure of scaffold components. Both methods include the process of nucleus length and cross section definition. To properly define a nucleus model as a parametric model, three entities were introduced: cross-section shape, cross-section dimension(s), and nucleus length. As presented in Figure 6.2, for each entity, one or more parameters were defined, or more specifically: the parameter cross-section shape; the cross-section dimension defined for adequate shape (e.g., radius

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for circle); the nucleus length. To conclude, the nucleus parametric model is defined as the function of three entities, as described in (1).

parametric_nucleus_model = f (cross-section shape, cross-section dimensions, nucleus length) (1)

Shared processes are very important because they enable creation of the boundary surface of the missing part of the bone. Among three shared processes, only the selection of points in the affected area requires involvement of surgeons because only they may decide where boundaries of resection are. Two other shared processes are done automatically in CATIA as shown in [10-12].

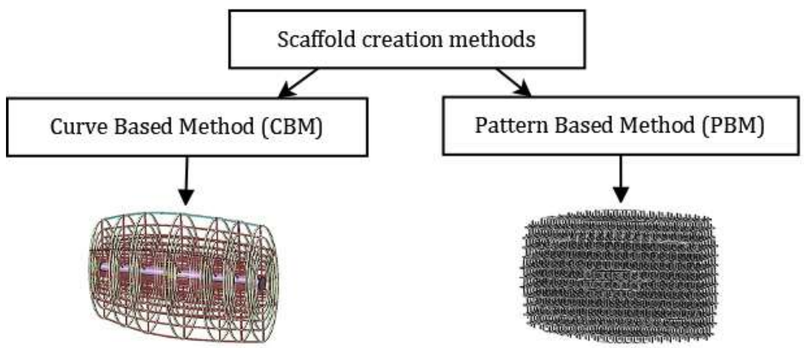

Figure 6.3. Scaffold design methods

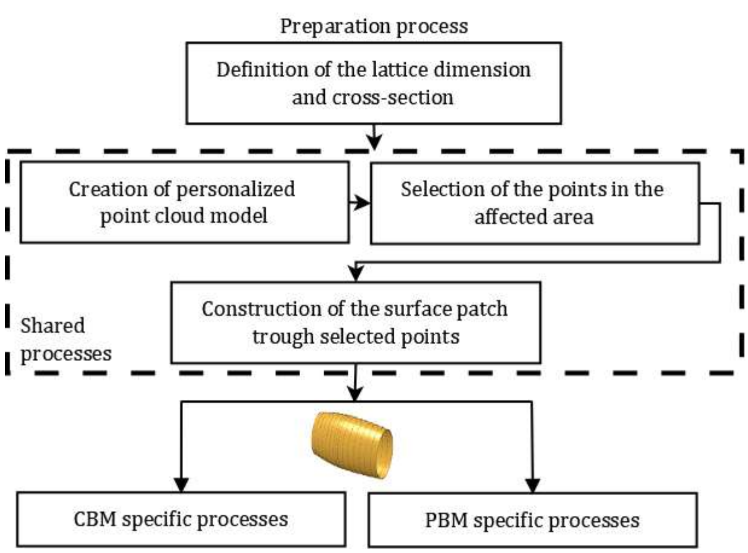

Figure 6.4. Preparation, shared and specific processes for presented methods

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Curve Based Method (CBM)

This approach uses interpolated splines as guiding curves for grid construction. The first step is the definition of boundary radial splines, which are created as intersections between planes and the boundary surface of the missing part of the bone. The position of the planes mainly depends of the bone type. The planes are created in respect to Referential Geometrical Entities (RGEs), which are the essential part of MAF, and they are defined as geometrical entities (lines, axes, planes, etc.) which represent basis for the creation of bone geometrical models. Basic anatomical entities of the mandible are presented in Figure 6.5a.

The next step is to construct scaled curves, as presented in Figure 4b. Scaling and the following steps are done by the use of script created by authors, and defined in VBScript in CATIA. In this step the scale factor is calculated according to the minimal defined nucleus length in radial direction. In this case, the minimal nucleus length is set to 5mm, so the maximal calculated scale factor for the presented case is 0.6 - 0.8. The scale factor is calculated by using the gravity centre point for each curve and points on curves, for each model.

Homogeneous coordinates were used for the definition of points and for the scale calculations. Curves are planar, so scaling is done in plane, and only two coordinates are required: X and Y. The scale factor has the same value for both coordinates (sx = sy = s). Equidistant points were created on the original and scaled curves. These points were used for the creation of axial curves in axial direction, Figure 6.5b. In radial direction, curves were created by using these points and gravitational centers. Both radial and axial curves were used as support elements for scaffold model construction. If scaling cannot produce adequate curves, the other option is to use a parallel curve tool from CATIA.

A sweep feature was used for the creation of axial and radial nucleuses. For each nucleus a circular cross section was used (R = 0.5 mm) as the sweep profile, and the spline curve was used in the radial and axial direction as the guiding curve. By merging nucleuses, a personalized scaffold 3D model was created (6.5c). In order to connect the CBM model with the rest of the mandible bone, supporting shell elements were created. These elements were merged with the CBM model at both

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sides of the mandible, as presented in Figure 6.5b. By using these elements and adapted fixation plate (created by extended MAF), the CBM model is connected to the rest of the mandible bone.

Pattern Based Method (PBM)

In this approach a combination of nucleus elements is used to form a shape of a unit cell. A nucleus element is defined as a cylinder with parametrically defined geometry and shape. In the presented case a circle was chosen as a cross-section shape with the radius of r= 0.5mm, and the length of cylinder of L = 2.5mm, but these values can be different for different clinical cases. A basic unit cell is defined as 3D cross, with nucleus elements positioned in four (4) directions, as presented in Figure 6.1.6c. Different unit cells can be created and used to acquire different porosities values (P), and the surface-area-to-volume ratio(R), as defined in (2).

$$P = 1 - \frac{V_s}{V_t}; \quad R = \frac{S}{V_s} \tag{2}$$

Vs – Volume of scaffold material, Vt – Total volume contained by scaffold, S – Surface area defined by scaffold volume.

3D pattern architecture composed of unit cells is formed by multiplication of the unit cell throughout the volume model of the missing part of the bone (Figure 6). This pattern structure is used as an intersecting operand for the Boolean operation intersection, with boundary volume as the base object. To perform this operation, another VBScript in CATIA was developed, and it enables the creation of:

- Maximal volume for the creation of the unit cell pattern. This volume is defined as a box in which the volume of the affected bone part can be inscribed.
- Pattern architecture by multiplication of the unit cell (3D cross) throughout 3D space (rectangular pattern tool). This operation creates a volume model composed of unit cells.
- Boolean operation of intersection between the base object (boundary volume of the missing part of the bone), and the pattern volume model (intersecting operand). This operation creates a personalized model of scaffold, as presented in Figure 6.5

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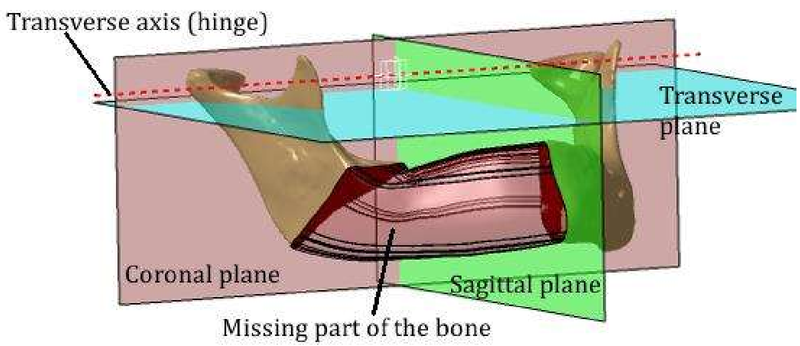
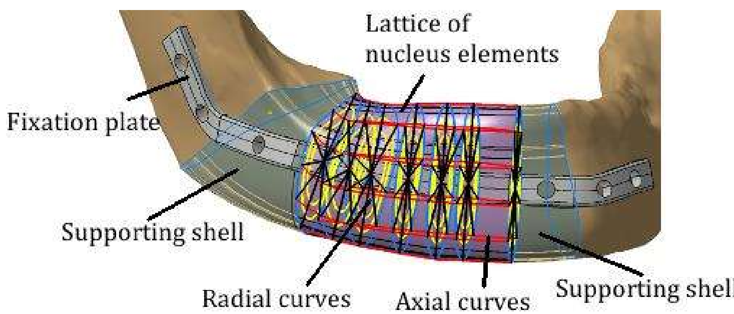
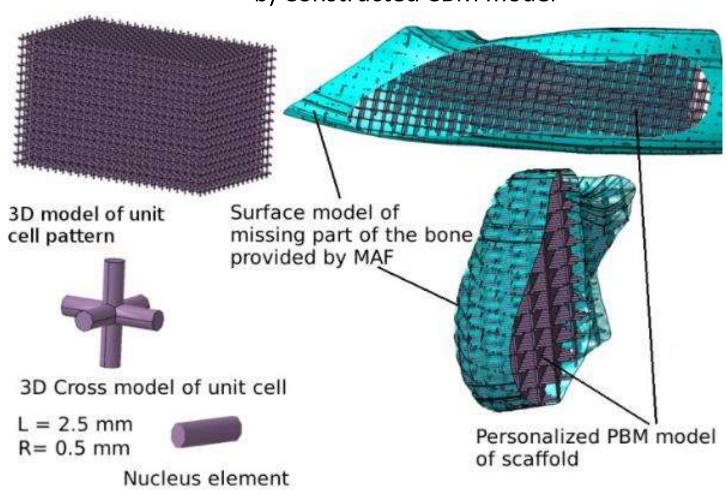
It is important to note that in any case if there is a requirement for additional support, plate implants can be inserted and add stability to the assembly of mandible, and scaffold.



a) RGEs and volume module of missing part of the mandible



b) Constructed CBM model



c) Forming process of predefined scaffold pattern

Figure 6.5 Different approaches for the creation of optimized scaffold structure

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7 Optimization in additive technologies

7.1 Introduction to optimization

There can be many optimization goals related to:

- Reduced 3D printing time
- Reduced 3D printing costs
- Improving the quality of the finished product in terms of:
    - Finishing surface (surface quality)
    - Geometry (dimensional accuracy)
    - Topology (surface accuracy)
    - Functionality (functional quality)
    - Mechanical properties (strength, flexibility)
    - Other defined requirements

To achieve these goals, a 3D optimization process can (must) be performed. There are three general elements that influence the choice of the optimal 3D printing process:

- Materials – Additive technologies can vary in materials, and each technology has a number of materials to work with. Figure 7.1
- Aspects of the finished product (functionality and visualization)
    - It is very important to define which aspect of the finished product is of the greatest importance
    - The desired aspect significantly influences the choice of the appropriate 3D printing technology
    - Two general aspects of finished products are:
        - Functionality - Requirements for the design of functional parts, assemblies and prototypes.
        - Visual appearance - Visual representation of the work (final surface, transparency, etc.)

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- Productivity (possibility of production with adequate technology) -Choosing write technology for the product and defined material, geometry and topology.

Functionality (Figure 7.2)

- When designing a part or prototype that is used / assembled with other components, it is important to define the required level of tolerance.
- The overall strength of the work depends on different mechanical and physical properties. To simplify selection, the tensile strength of the material can be used as a guide.
- When high strength and rigidity are required, 3D metal printing or FDM printing with a material reinforced carbon fibres can be used.
- 3D printing materials are available with properties such are heat resistance, flame resistance, chemical resistance. They can also be certified as biocompatible materials.
- Flexibility can be defined as high elongation, in thermoplastics such as TPU in SLS and FDM, or as low hardness, in materials with a rubber feel for SLA / DLP and Material Jetting.

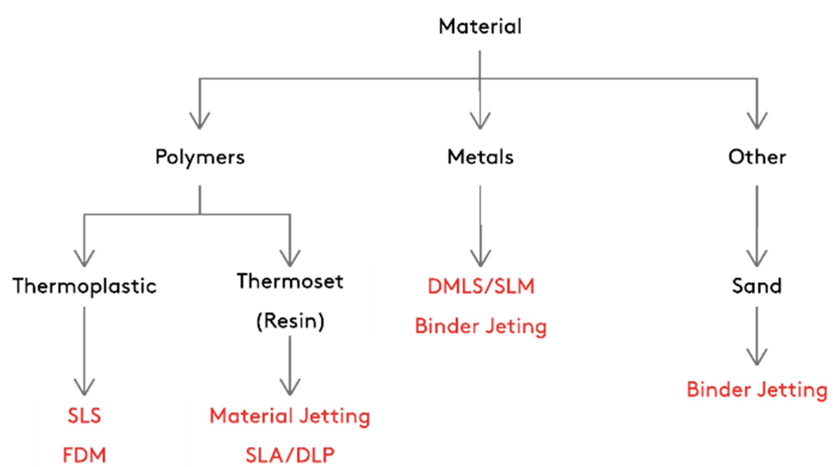

Figure 7.1 Additive manufacturing technologies and applicable material

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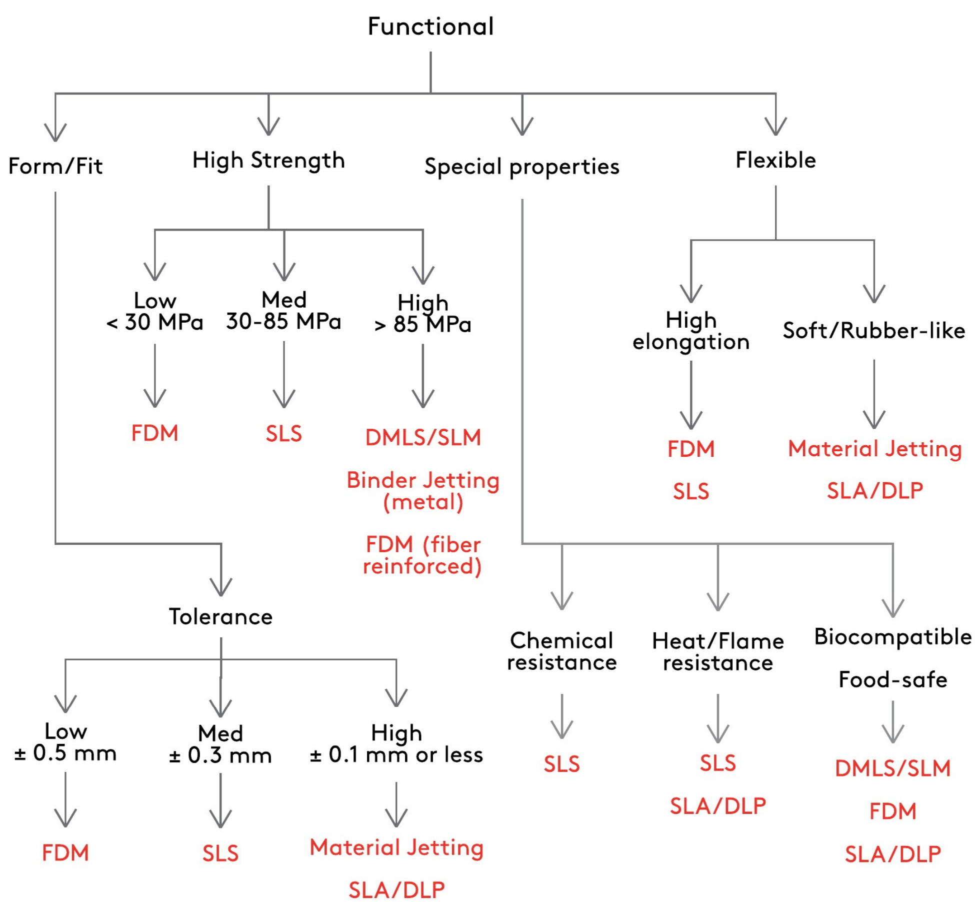

Figure 7.2. Functional requirements and printing process selection[42]

Visual display (Figure 7.3)

- SLA / DLP and Material Jetting can produce parts with a smooth finish that matches the surface obtained by injection molding.
- Material Jetting produces completely transparent parts, while SLA / DLP printed parts are semi-transparent and can be subsequently processed to be almost 100% permeable.

[42] https://www.hubs.com/knowledge-base/selecting-right-3d-printing-process/

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- Parts with a special texture, such as wood or metal finish, can be printed using wood or metal filament (FDM).
- The softness of the parts can be achieved by using rubber.
- Material Jetting and Binder Jetting are the only 3D printing processes that currently offer the possibility of full color printing.
- Another option is to move both models after printing or use a dual-extrusion FDM printer (for two colors only).

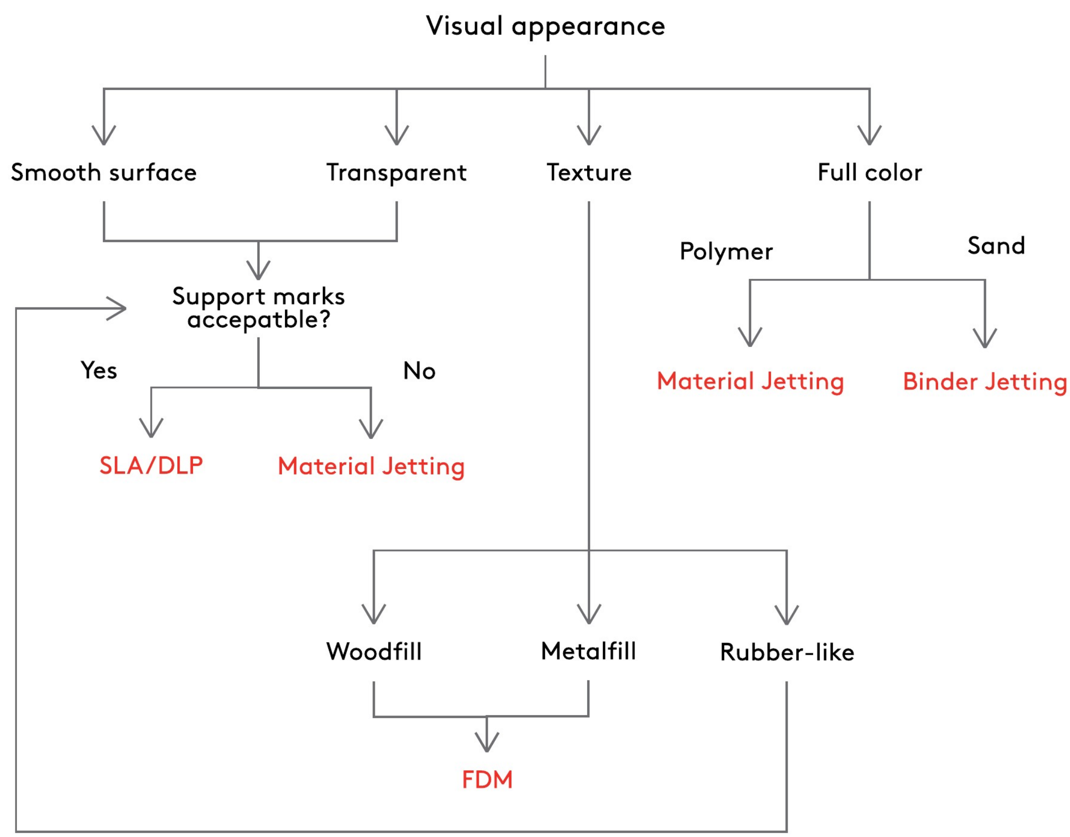

Figure 7.3 Visual appearance and 3D printing method selection[42]

Process selection based on production capabilities

The three main characteristics of 3D printing that influence the choice of technology are:

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- Dimensional accuracy which is related to the level of detail that the printing process can achieve and to the quality of the 3D printer. Processes that provide greater precision can usually create parts with finer characteristics, but sometimes the costs can be higher.
- The size of the construction determines the maximum dimensions of the part that the printer can produce.
- The need for support structures (support structures or support, hereinafter support). Support determines the level of design freedom, and can lead to design limitations, so it is important to consider technologies that do not require support or where support can be easily removed after the process.

Table 1[42]. Manufacturing capabilities of processes

	Dimensional accuracy	Typical build size	Support
FDM	± 0.5% (lower limit ± 0.5 mm) - desktop ± 0.15% (lower limit ± 0.2 mm) - industrial	200 x 200 x 200 mm for desktop printers Up to 900 x 600 x 900 mm for industrial printers	Not always required (dissolvable available)
SLA/DLP	± 0.5% (lower limit: ± 0.10 mm) - desktop ± 0.15% (lower limit ± 0.05 mm) - industrial	145 x 145 x 175 mm for desktop Up to 1500 x 750 x 500 mm for industrial printers	Always required
SLS	± 0.3% (lower limit: ± 0.3 mm)	300 x 300 x 300 mm (up to 750 x 550 x 550 mm)	Not required
Material Jetting	± 0.1% (lower limit of ± 0.05 mm)	380 x 250 x 200 mm (up to 1000 x 800 x 500 mm)	Always required (always dissolvable)
Binder Jetting	± 0.2 mm (± 0.3 mm for sand printing)	400 x 250 x 250 mm (up to 1800 x 1000 x 700 mm)	Not required
DMLS/SLM	± 0.1 mm	250 x 150 x 150 mm (up to up to 500 x 280 x 360 mm)	Always required

Basic rules to follow:

- Determine the priority, e.g., functionality or visual appearance.
- Wisely choose adequate AT, based on the properties and cost-efficiency, especially in cases where product can be manufactured with more different technologies.

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- For functional polymer parts, use thermoplastics (SLS or FDM).
- For better visual appearance, thermosets (SLA/DLP or Jetting) are the better (best) option.
- DMLS/SLM are applicable for metal parts and for high-performance applications. Binder Jetting for lower cost and larger parts.

7.2 Optimization for Additive manufacturing

The design rules mainly depend on quality and costs of the process, but also some limitations for adequate method exists, and optimization in geometry and shape should be implemented. Following graphics from hubs provide guidance for design rules for selected additive manufacturing technology. Beside optimization in the pre-printing and during printing phase, some optimization technique will be presented for post-process optimization.

Some typical design recommendations valid for all technologies:

Overhangs

All 3D printing processes create parts by applying layer by layer of material. Overhangs are areas of the model that are partially supported by the bottom layer or not supported at all, mostly protruding beyond the basic volume of the material. There is a limit to the maximal angle that any printer can produce without the need for auxiliary materials (e.g., for FDM and SLA about 45 degrees). It is necessary to minimize the use of overhangs, because they are generally difficult to make without the help of additional/supporting material.

Wall thickness

Wall thickness is a very important aspect of 3D printing, which primarily depends on the material being printed, but if the minimum value is 0.8 mm, then all printing procedures and different materials can be applied.

Warping

Warping is bending a model during printing, because of large printing surface, non-equal temperature distribution, and low thickness of the walls in the flat areas. When printing, large flat areas should be avoided, bed temperature should be adequate, and use of a round corners is recommended.

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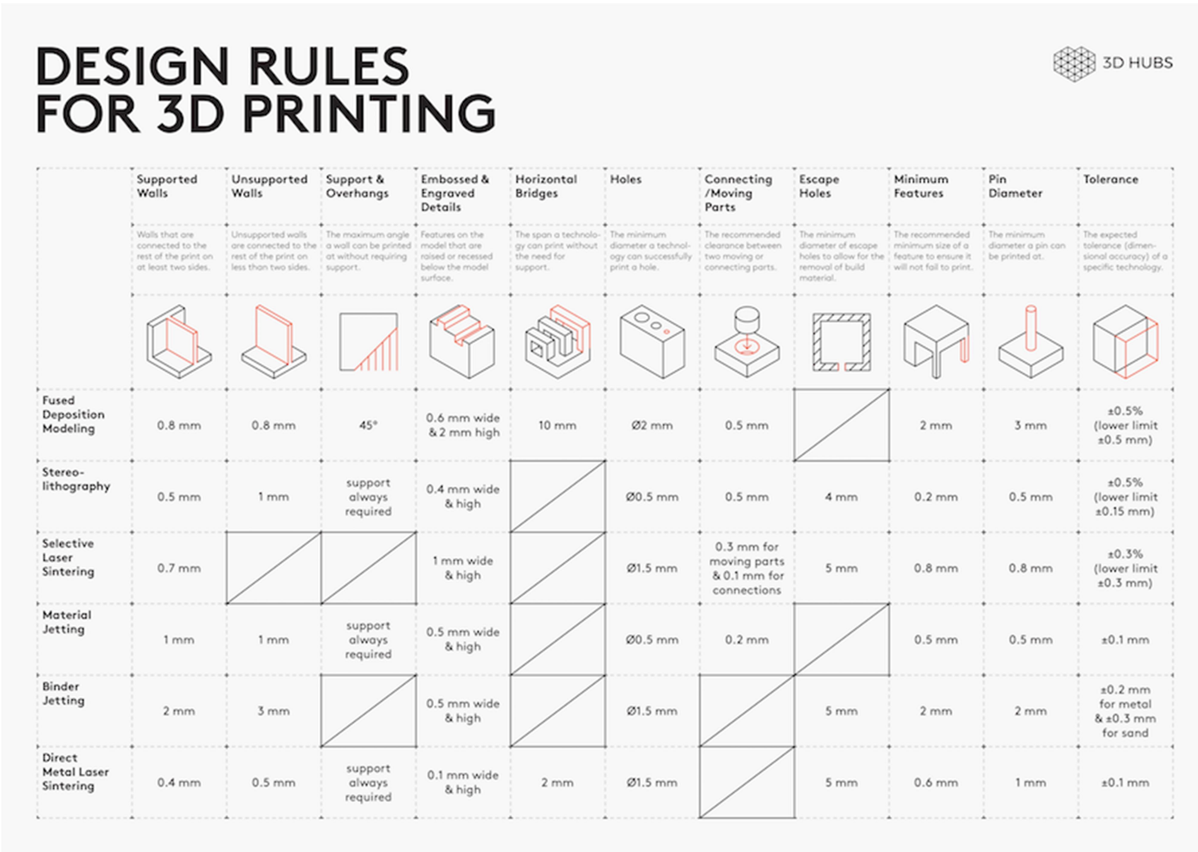
For specific design rules (Fig. 7.4) and technologies specifications and recommendations visit https://www.hubs.com/.


DESIGN RULES FOR 3D PRINTING

3D HUBS

	Supported Walls	Unsupported Walls	Support & Overhangs	Embossed & Engraved Details	Horizontal Bridges	Holes	Connecting /Moving Parts	Escape Holes	Minimum Features	Pin Diameter	Tolerance
	Walls that are connected to the rest of the print on at least two sides.	Unsupported walls are connected to the rest of the print on less than two sides.	The maximum angle a wall can be printed at without requiring support.	Features on the model that are raised or recessed below the model surface.	The span a technology can print without the need for support.	The minimum diameter a technology can successfully print a hole.	The recommended clearance between two moving or connecting parts.	The minimum diameter of escape holes to allow for the removal of build material.	The recommended minimum size of a feature to ensure it will not fail to print.	The minimum diameter a pin can be printed at.	The expected tolerance (dimensional accuracy) of a specific technology.
Fused Deposition Modeling	0.8 mm	0.8 mm	45°	0.6 mm wide & 2 mm high	10 mm	Ø2 mm	0.5 mm		2 mm	3 mm	±0.5% (lower limit ±0.5 mm)
Stereo-lithography	0.5 mm	1 mm	support always required	0.4 mm wide & high		Ø0.5 mm	0.5 mm	4 mm	0.2 mm	0.5 mm	±0.5% (lower limit ±0.15 mm)
Selective Laser Sintering	0.7 mm			1 mm wide & high		Ø1.5 mm	0.3 mm for moving parts & 0.1 mm for connections	5 mm	0.8 mm	0.8 mm	±0.3% (lower limit ±0.3 mm)
Material Jetting	1 mm	1 mm	support always required	0.5 mm wide & high		Ø0.5 mm	0.2 mm		0.5 mm	0.5 mm	±0.1 mm
Binder Jetting	2 mm	3 mm		0.5 mm wide & high		Ø1.5 mm		5 mm	2 mm	2 mm	±0.2 mm for metal & ±0.3 mm for sand
Direct Metal Laser Sintering	0.4 mm	0.5 mm	support always required	0.1 mm wide & high	2 mm	Ø1.5 mm		5 mm	0.6 mm	1 mm	±0.1 mm

Figure 7.4 Design recommendations for additive manufacturing technologies[43]

2.2.1. Postprocessing of the created parts[44]

In order to achieve the required characteristics of final product, it is almost always necessary to perform additional processing. In order to achieve the right properties such as surface quality, geometric accuracy and mechanical properties, almost all AM components require post-processing, like: heat treatment, separation of components from supporting structures and beds, and surface

[43] https://www.hubs.com/knowledge-base/key-design-considerations-3d-printing/

[44] Peng, X.; Kong, L.; Fuh, J.Y.H.; Wang, H. A Review of Post-Processing Technologies in Additive Manufacturing. J. Manuf. Mater. Process. 2021, 5, 38. https://doi.org/10.3390/jmmp5020038

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finishing. Heat treatment is required to relieve stress on the components. Finishing surface treatment may include grinding and polishing, in order to achieve high-quality surfaces. The surface quality of AM parts is commonly lower because of the layering and the staircase effect. Also, different AM processes will create product surfaces with different quality, usually rough. It is important to perform mechanical tests on produced parts, because the characteristics defined by design and those of a produced part can differ, due to various cracks, holes, non-continuity in material. Sometimes it is required to apply a layer of coating in order to improve surface strength and quality there by enabling successful application of the manufactured part.

7.3 Application and Optimization for medical application

In this section an introduction to the application and optimization of AT for medical application will be presented. The direct creation of the models and manufacturing optimization will be described in the last two chapters of the course.

In 3D printing materials which can be used for implantation are strictly regulated. Different companies develop metal, plastic, ceramic, and other bio-compatible materials to resolve various issues. Plastic and ceramic are usually implemented in dental or prosthetics, a combination of plastic and metal is commonly used for knee or joint replacements. In recent news published by 3D Printing Industry research on hybrid polymer, Lucas Albrecht, Stephen Sawyer and Pranav Soman, from Syracuse University in New York, showed that materials like PLA, PCL, PCL+HA and PCL+PLA can be implemented to print scaffolds and create engineered tissues.

The main optimization of implants is conducted in concern to strength and biocompatibility, but also through implant topology and shape optimization. In some cases when implants are combined together with fixation plates it can be possible to use biocompatible material with less strength, but materials that can be absorbed in the organism, while at the same time enabling growth of new tissue. These kinds of materials are known as Bone cements and they have been used very successfully to anchor artificial joints (hip joints, knee joints, shoulder and elbow joints) for more than half a century.

Regarding the healthcare field, the future of medical devices and medicines is going to be personalized for different patients which exploits AM features. According to literature, FDM is the

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only used method for designing personalized catheters with promising results. FDM[45] is a potential method for manufacturing of surgical instruments, implants, orthoses, and prostheses.[46]

Inkjet printing is applicable for both polymer and ceramic biomaterials such as polyethylene glycol (PEG), hydroxyl aprtite (HA), bioglasses, polycaprolactone (PCL), polylactic acid (PLA). There is a wide range of applications of inkjet printing in healthcare such as controlled drug delivery, personalized medicine, and prostheses.

Regarding the capability of SLA to produce large-sized objects with submillimetre errors, several patients' products have been successfully prepared so far such as Invisalign®, which is an orthodontic device, and hearing aid tools. Moreover, due to resolution development, broadening of the applicable materials, controlling the porosity, and producing patient-specific devices, SLA has proved its capability to be used as a potential manufacturing technique for tissue engineering[47].

Concerning optimization and manufacturing of personalized implants it is important to know which type of implant is used, e.g., locking plate or standard plates like compression plates. This is important because in the case of compression plates it is required to adjust surface of the bone with a plate contact surface, while locking plates, do not require that condition, and the shape can be standardized. Locking means that the screw head has a thread, which removes the possibility of unlocking.

Currently, the main areas of interest include patient-specific implants and instruments, smart bioactive implants, tissue engineering, sensory equipped implants, 4D imaging techniques as well as process chain optimization and standardization. Results indicate, that rapid prototyping benefits patient-specific treatments of complex conditions in orthopaedics, improves surgery planning and risk assessment, while minimizing long-term complications through individualization and monitoring. However, as technologies are evolving rapidly, procedures are lacking in standardization as well as

[45] Saeideh Kholgh Eshkalak, Erfan Rezvani Ghomi, Yunqian Dai, Deepak Choudhury, Seeram Ramakrishna, The role of three-dimensional printing in healthcare and medicine, Materials & Design, Volume 194, 2020, 108940,

ISSN 0264-1275,https://doi.org/10.1016/j.matdes.2020.108940.

[46] Mohd. Javaid, Abid Haleem, Additive manufacturing applications in medical cases: A literature based review,

Alexandria Journal of Medicine, Volume 54, Issue 4, 2018, Pages 411-422, ISSN 2090-5068, https://doi.org/10.1016/j.ajme.2017.09.003.

[47] N.A. Chartrain, C.B. Williams, A.R. Whittington A review on fabricating tissue scaffolds using vat photopolymerization Acta Biomater., 74 (2018), pp. 90-111, 10.1016/j.actbio.2018.05.010

inter-disciplinary routine and need highly skilled personnel. Moreover, limitations in object size, structural strength as well as the time and cost, limit its feasibility for some medical applications. Data science, 4D imaging methods, connected smart implants and biomaterial printing are expected to play a major role for the technology's future expansion[48].

General Classification of additive manufacturing application in medicine (but not limited to):

- Medical models;
- Implants;
- Tools, instruments and parts for medical devices;
- Medical aids, supportive guides, splints and prostheses;
- Biomanufacturing.

Hearing aids[49], this is a perfect case study for 3D printing where the desire for personalization meets the low volume required for each particular item. Additive manufacturing is perfect for creating the organic shapes specific to each user which then house the stock electronic assembly.

One of the applications of additive manufacturing within medicine (which is already having a big impact) is the ability to practice before procedures. Surgeons can use prototype (or real) models to perform surgical planning, and to define the procedure.

The dental industry is also one of the biggest users of 3D printing. Using scans taken from the actual patient's mouth, dentists and dental laboratories are able to build accurate and tailored solutions to fix dental problems. Use cases include 3D printed aligners which slowly move the teeth into a desired position as well as 3D printed crowns and bridges. Additive manufacturing is a massive and growing player in the dental industry and there are already a number of machines and materials built specifically for this market.

Prosthetics nowadays are a very important part of 3D printing for medical applications. The possibility to create personalized product, which geometrically correspond to a patient is a

[48] Mika Salmi, Additive Manufacturing Processes in Medical Applications, Materials 2021, 14, 191. https://doi.org/10.3390/ma14010191

[49] https://www.manufacturingtomorrow.com/article/2018/10/additive-manufacturing-in-the-medical-industry/12281, James Murphy | HLH Mold Tech Co Ltd

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remarkable achievement even if it is only a prototype, because it can be used as a template for future production. Of course, additive technologies can also be used to create completely finished products and not just prototypes. The application is wide, from humans to animals.

With prosthetics it is very important to create lightweight assisting devices, which have the ability to withstand load, and to adjust to the patient. Topological and shape optimization is very important for prosthetic devices, especially in the case of limb replacements.

Another application of 3D printing lies within printing organs, especially if printing is achieved by using the persons' tissue (cells). This will mean, that we will be able to repair or replace damaged organs and to perform personalized healthcare.

The full application of existing and possible future additive technologies is yet to be determined, but, considering the current state of research, the future looks more than promising.

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8 Clinical case – personalized sternum model (geometry and production optimization)

From the data obtained by CT scanning the patient and with the help of CT scans of healthy patients' sternum, using appropriate medical software, the part affected by the disease was extracted and processed. Based on the plan, the operation was defined in order to connect the surfaces of healthy part of the patient's bone. Using a specific reverse modelling method in the CATIA V5 software package, a polygonal model was created based on the point clouds, then a volumetric model of the affected part of the sternum and ribs was created. Based on that reconstructed 3D geometric model of the sternum and by using 3D printing as one of the methods for rapid prototyping, a prototype implant was created that completely corresponded in shape and dimensions to the parts of the sternum and ribs affected by cancer. Based on this prototype, a mould was created in which an implant was casted of a suitable biocompatible mixture. For the first time in the world, one patient was implanted with a personalized sternum implant.

8.1 Reverse modeling procedure

The reverse geometry modelling procedure begins by obtaining digital image data of the affected region with the help of a CT scanner, and transforming them into a point cloud, which is then loaded into the appropriate CAD software (CATIA V5), Figure 8.1.

Subsequent processing of such entered data creates a polygonal model (Figure 8.2) which is necessary for recognizing and defining RGE - reference geometric entities of the observed bone (which represent the essence of this method of reverse modelling), and which is also the basis for geometric modelling.

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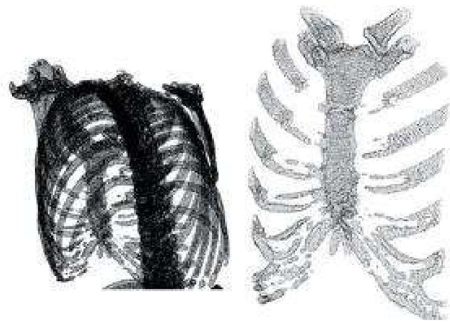

Figure 8.1 Medical image and resulting point cloud

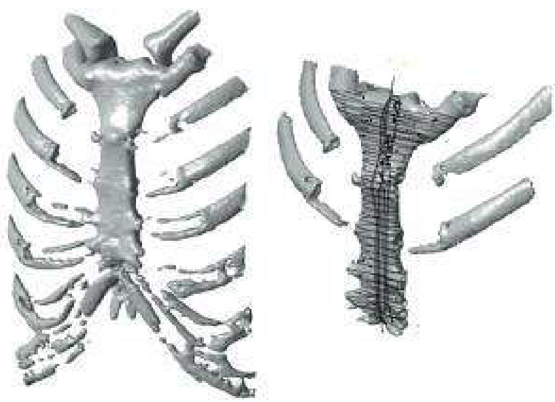

Figure 8.2 Sternum polygonal model

In this particular case, it was necessary to make a simplified version of the geometry based on CT scanning of the diseased part of the sternum and the ends of the sternum that were not affected by cancer, as well as on the basis of CT images of patients with healthy sternums. The main goal was to create a geometric model that must, on the one hand, preserve the structural functionality of the sternum, and on the other hand, enable simpler and more economical mould making with one opening direction (through one divided surface).

2.2.2. 3D bone model

In this case, the procedure of reverse modelling of the sternum part begins with the identification of the junction of the cartilaginous extension of the second and third ribs and the sternum as well as the 3D curves of the rib guides. After a series of steps at the end of this part of the

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procedure, a volumetric model of the ribs (Figure 8.3) and cartilaginous extensions towards the sternum was created.

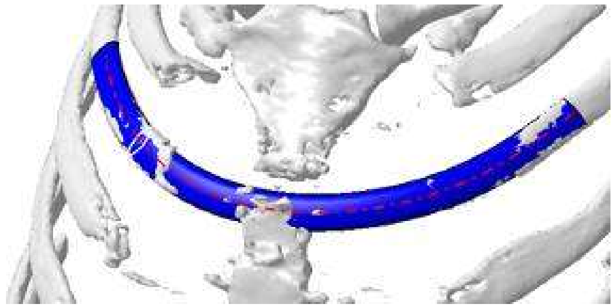

Figure 8.3 Forming the ribs volume model

The process of reconstruction of a part of the sternum begins with the creation of parallel sections on a polygonal model along the body of the sternum. Also, a spatial curve of the guide along the body of the sternum was created on a polygonal model. Using the guide curve and plane curves obtained in the intersection of the plane and the polygonal model, a volumetric model of the sternum and manubrium was created (Figure 8.4).

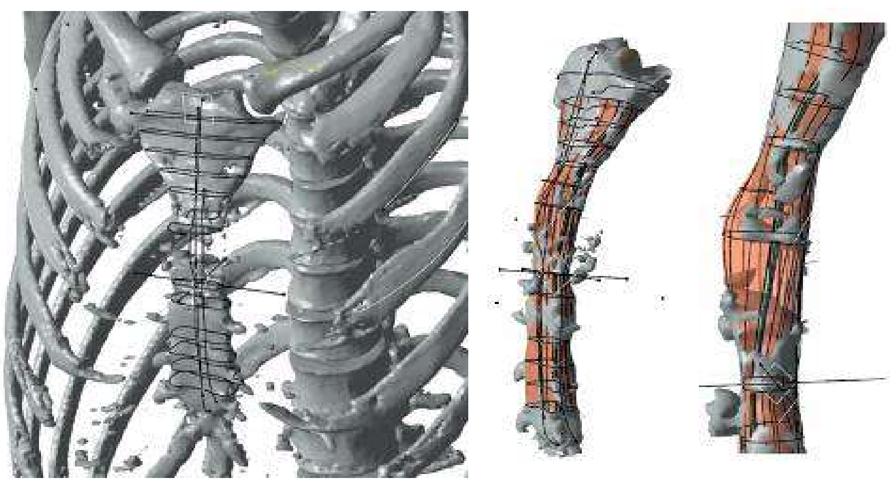

Figure 8.4 Spatial guide curve of the sternum and volume of the sternum body

The missing part of the sternum affected by cancer was reconstructed by analysing a model of a healthy sternum and comparing it with the model of a sternum affected by cancer.

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After the obtained model was analysed, it was concluded that the model was too complex for mould creation, and that it is necessary to simplify the geometry and topology of the sternum model.

Each individual plane curve based on which the volume model of the sternum was created is simplified, in that the interpolation curves (splines) are replaced by approximate curves made of lines and arcs, wherever possible, considering the structural functionality of the created model (Figure 8.5). After modifying the curves, a volumetric model of the sternum and ribs was re-created. In the final phase of model preparation, a dividing surface was created that separates the parts of the mould for making implants (Figure 8.6).

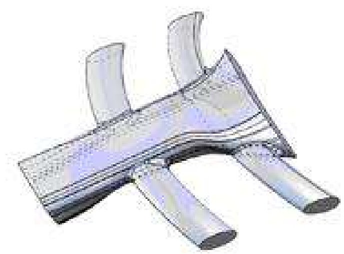

Figure 8.5 Volumetric model of simplified geometry and topology

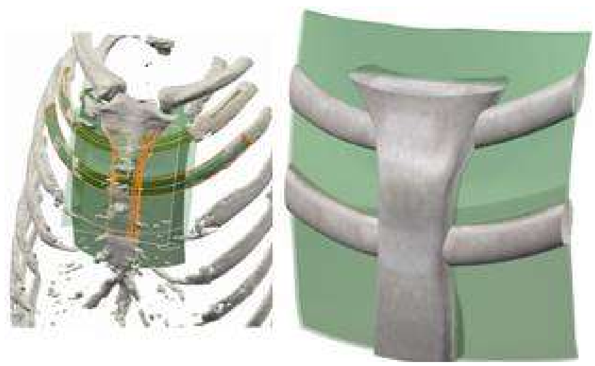

Figure 8.6 Final adjustment of the model to mould making

8.2 Prototype manufacturing by 3D printing

Based on the 3D model created in the Dassault Catia software, the export in STL format resulted in a model suitable for 3D printing. Due to the specifics of the post-processing, another auxiliary model was made, which, in addition to the main geometry, also contains a divided surface (which also has a thickness of about 2 mm), in order to form the mould more easily. These models were then loaded into dedicated ZPrint software so that they could be produced on the ZCorporation ZPrinter 310 System 3D printer. The model and the device on which it was made are shown in Figure 8.7.

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Figure 8.7 Model in ZPrint software (left) and 3D printer (right)

Before starting the production, it was necessary to determine the printing parameters. This specifically refers to the choice of working material and binder (in this case the powder was ZP130, and the binder ZB58), as well as to the thickness of the layer that affects the surface quality. Considering that the printed part in this case was the original for making the mould, it was of great importance that the quality of the surface was as good as possible, for the sake of making and separating the mould more easily. A layer thickness of 0.088 mm was chosen, which caused a slightly longer production time. In addition, the models are positioned in the working volume in a way that maximizes the surface quality and strength of the finished parts. The production process and the printed original are shown in Figure 8.8.

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Figure 8.8. The process of making the original

The printing process itself took a little over 2 hours, and then the parts were left to harden for another 45 minutes before being removed from the powder. After the parts were removed from the powder, the excess powder was removed with compressed air. In order to achieve the best possible mechanical characteristics and shorten the drying time, the parts were placed in an oven at 100 ° C for 90 minutes. The final product of 3d printing is shown in Figure 8.9.

Figure 8.9. Finished originals obtained by 3D printing

8.3 Mold manufacturing

Since the presented originals are not safe for direct use for prosthetic purposes, it was necessary to create a mould from which a sternum made from medically tested prosthetic material would be produced. A special type of polyurethane plastic was used to make the mould, which has the hardness required for casting acrylates, which make up the largest percentage of the mentioned material (75% methyl methacrylate-styrene-copolymer and 15% polymethylmethacrylate). First, the

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lower part of the mould was cast in the box, using an auxiliary model with a "sheath", and then, using the original, the upper part of the mould was made in Figure 8.10. The auxiliary model was destroyed during the molding process, while the original remained undamaged.

Figure 8.10 Made mould

The result of this procedure is given in Figure 8.10, as well as the procedure of filling the mould with prosthetic material of Figure 8.11.

Figure 8.11 Filling the mould with prosthetic material

The prepared prosthetic material was applied to the cavities of the mould and, after expansion, filled the mould (Figure 8.12). After the time allowed for the prosthetic material to harden, the implant was removed from the mould.

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Figure 8.12 Implant cast in a mould before finishing

In the end, mechanical finishing of the implant was necessary, which was done with tools for cutting and grinding, as well as cold sterilization of the final product.

8.4 Application of produced sternum model

On a patient with a preoperative working diagnosis of sternal tumour with infiltration of the anterior segment of the right upper lobe of the lung, a resection of the sternum of the second, third and fourth costal cartilage was performed. In addition to this a wedge resection of the anterior segment of the right upper lobe was performed. With the GIA STAPLER the implant was placed, and then fixed with wires to the remaining parts of the bone and ribs on both sides of Figure 8.13.

Figure 8.13 CT image and implant insertion with wiring

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The control MSCT of the chest, one year after the operation, showed that the implant was in an ideal position and that there was no movement of the implant. The conclusion is that this method enables the reconstruction of the chest wall, which is maximally adjusted to the individual needs of the patients.

The clinical case participants[50]:

Direct development:

Faculty of mechanical Engineering, University of Nis, Serbia

Faculty of Engineering University of Kragujevac, Serbia

Medical faculty in Kragujevac, Serbia

User:

Clinical Centre Kragujevac, Serbia

50 Stojković M., Milovanović J., Vitković N., Trajanović M., Grujović N., et al., 2010, Reverse modeling and solid free-form fabrication of sternum implant, Australasian Physical & Engineering Science in Medicine, Vol. 33, No. 3, pp. 243-250

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9 Project-based learning - Reverse modelling of the humerus bone and plate customization

9.1 Reverse modelling procedure

The reverse modelling procedure for humerus surface model creation contains several important steps: Filtering point cloud model acquired from CT scanning; Creating polygonal model of the whole bone by the use of features implemented in CATIA software; Definition of the Referential Geometrical Entities (RGEs); Creation of spline curves referenced to the RGEs; Creation of adequate surface models of the anatomical sections; Connecting individual surface models into the whole model; Plate selection; Plate parameters definition; Plate model creation;

3D Bone model

The basic prerequisite for successful reverse modeling of a human bone's (humerus in this case) geometry is the identification of RGEs. RGEs include characteristic points, directions, planes and views. For the creation of humerus RGEs geometric and morphometric definition was acquired from literature[51].' The definition of the coordinate system was acquired[52], where basic axes and planes (views) are defined. The Anatomical axis of the proximal part of the humerus (metaphyseal axis) is defined as the axis of the cylinder that is formed in the upper part of the humeral shaft. It is set as the Z axis of the coordinate system. The X axis is defined as a projection of the line which goes through tips of the epicondyles of the distal part of humerus 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 9.1.

[51] Expert Consult, Gray's Anatomy, https://expertconsult.inkling.com; Boileau P & Walch G, The three-dimensional geometry of the proximal humerus implications for surgical technique and prosthetic design, J Bone Joint Surg Br, 79 (1997) 857-865

[52] Roberts S, Foley A, Swallow H, Wallace A, Coughlan D, The geometry of the humeral head and the design of prostheses, J Bone Joint Surg Br, 73 (1991) 647-650

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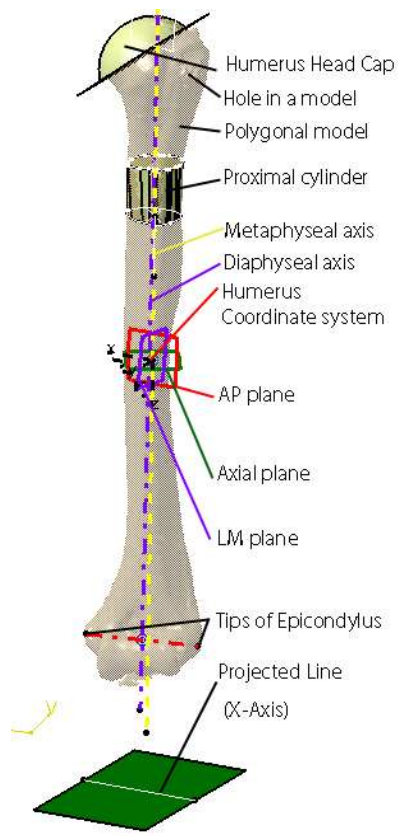

Figure 9.1 RGEs of the humerus bone

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 a 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 sections of the humerus. The surface models of humeral anatomical sections together with constructed spline curves are presented in Figure 9.2. The proximal part and the shaft were created using splines created in the axial planes (Figure 9.2a, and 9.2b). The distal section was created as an assembly of four surface parts.

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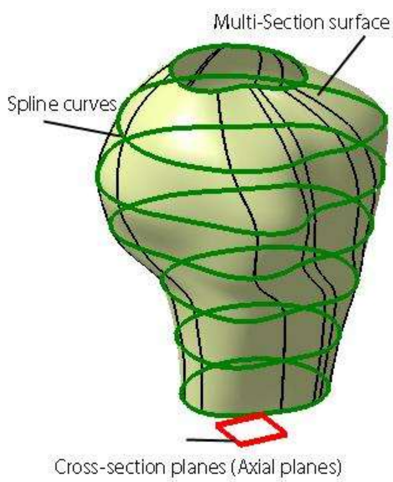
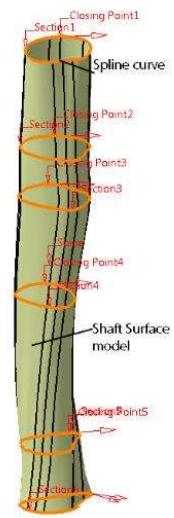
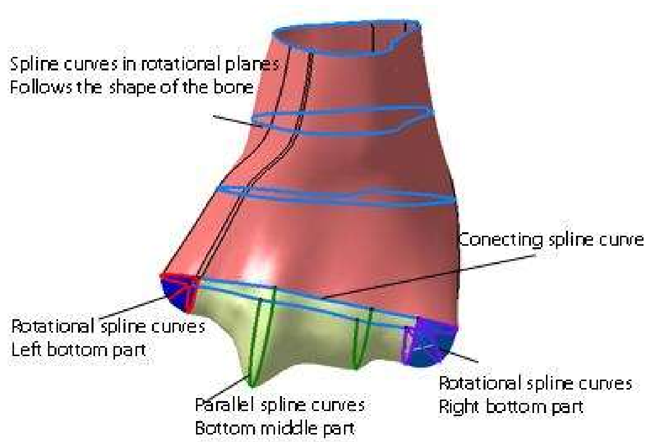
This is done because shape of the distal part is very complex. The upper part was created using spline curves positioned in rotational planes, with the upper ending curve (closer to the shaft) constructed in the axial plane. These planes follow the curvature of the distal part of the humerus. The right and the left bottom parts were created by the rotational curves and the middle part was created with 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 9.2c.



a)



b)



c)

Figure 9.2 Spline curves and adequate surface models of the human humerus anatomical sections. a) proximal section, b) shaft section, d) distal section

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Discussion of the geometrical accuracy of the surface model

The surface model of the whole humerus was created by the connection of constructed individual surfaces. The complete model is presented in the Figure 9.3a.

The deviation values measured in reference to the input sample polygonal model shows that the created surface model is of adequate overall accuracy (Figure 9.3b). It can be seen that overall accuracy of the model is around 0.4-0.8 mm. Maximal deviation is in the range of 0.811 - 1.216 mm. In the area of proximal shaft and greater tubercles max. deviation is 0.494 mm (one point, Figure 9.3c). It should be noted that the initially created surface model of the 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 information from medical literature 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).

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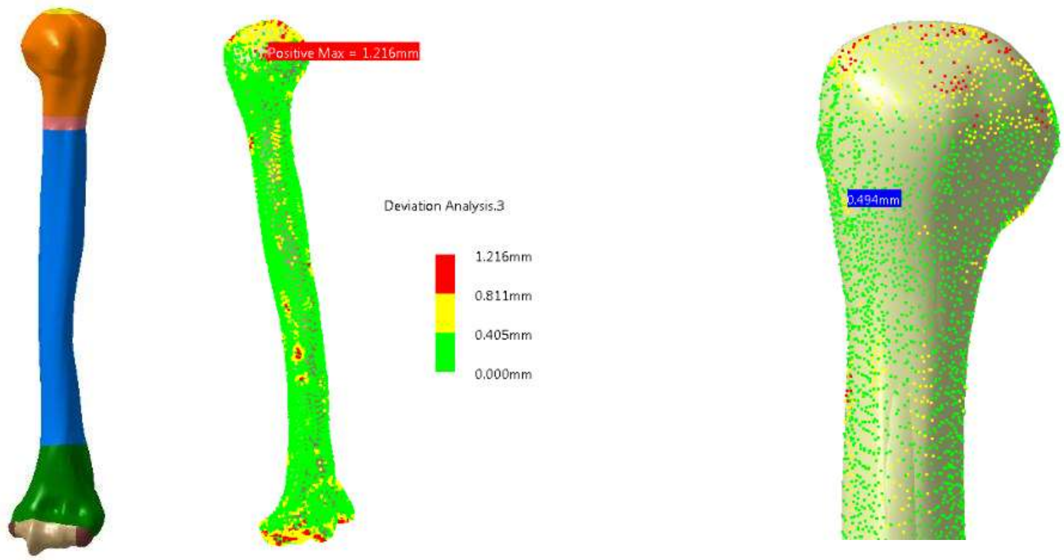

a) *b)* *c)*

Figure 9.3 Humerus bone surface model and deviation analysis. a) Humerus Surface model, b) Deviation analysis between input sample polygonal model and created surface model (Surface based) c) Proximal part and supporting surface for plate positioning with deviation points

9.2 Customized implant 3D model (cloverleaf plate)[53]

In this process a geometrical model of the customized plate for the specific patient is created. Parameters are defined as dimensions measured on the 3D model of the sample humerus. The dimensions which are measured are presented in the Figure 9.4 in AP plane with 3D view of the sample model. There are two important dimensions RDmax (distal part of plate) and RPmax (proximal part of plate). These dimensions represent maximal distance from the detected edge to the Anatomical axis of humeral body.

[53] Rashid, M M., Husain, K N., Vitković, N., Manić, M.,Trajanović, M., Mitković, M.B., Mitković, M. M., (2017). Geometrical Model Creation Methods for Human Humerus Bone and Modified Cloverleaf Plate, JSIR-Journal of Scientific Industrial Research, 76(10), 631-639.

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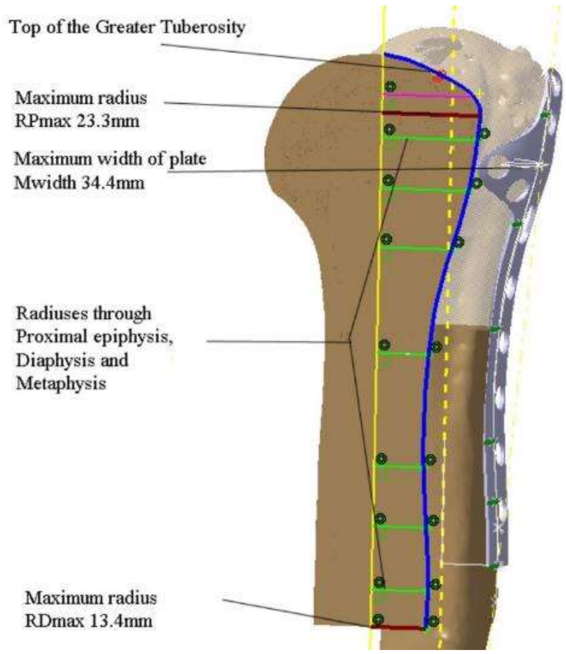

Figure 9.4 Definition of radiuses in AP plane

RDmax and RPmax together with other defined radiuses enable the 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) are limited by the values of RPmax and RDmax respectively. For the sample set up these values are: 23.3mm (RPmax) and 13.4mm (RDmax). In order to define the widest part of the proximal part of the plate (head) dimension Mwidth is set. It is based on the defined radius in AP plane and it represents a circle chord which defines how wide the plate envelops the outer surface of the proximal humerus, for the current setup it is 34mm. All of these values are used for the creation of the initial surface model of the contact surface between plate and bone, as already stated. The solid model of the plate is created by adding thickness to the surface and for the sample set up its' value is 2mm (standard thickness) (Figure 9.4).

All 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 a 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 an edge was constructed as the cross section of the bone model and AP plane. Dimensions are defined and measurement was performed. Maximal Values

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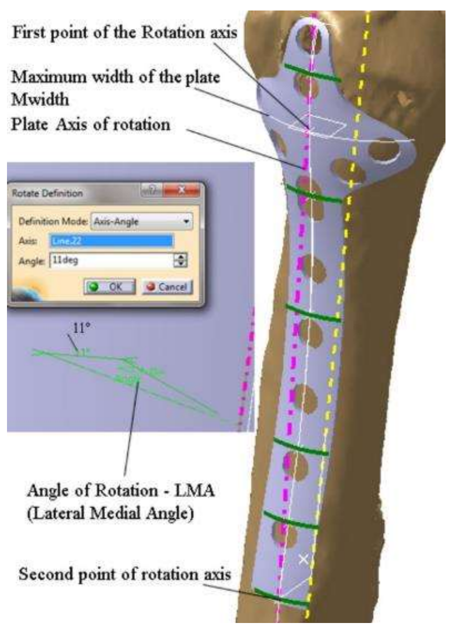
were: 21.2 (RPmax), 11.5 (RDMax), 30.3 (Mwidth). Based on the defined procedure, a surface model of the plate contact surface was created.

3D model optimization in CAD software (accuracy definition)

Because of initial overlapping between the humerus polygonal model and the surface model of the plate, adequate position transformations of the plate were applied. Plate contact surface was translated normally from the Lateral-Medial (Sagital) plane for 1 mm, and rotated around its axis (Lateral-Medial Angle - LMA) about 11º. Plate axis is defined as the line between the middle point of the widest part (Mwidth) of the proximal part of the plate and the middle point at the RDmax position (distal end of the plate), and it lies in the LM (Lateral-Medial) plane of the humerus bone (Figure 9.5a).

Another rotation was performed around 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 the anatomical axis and it is normal to AP plane. The angle of rotation is defined as the Transverse Angle (TA) and its value is 0.5º (Figure 9.5b). After that, a thick surface is created by adding a thickness of 2mm to the contact surface after which a solid model of the plate was created.



a) Mwidth and LMA angle definition

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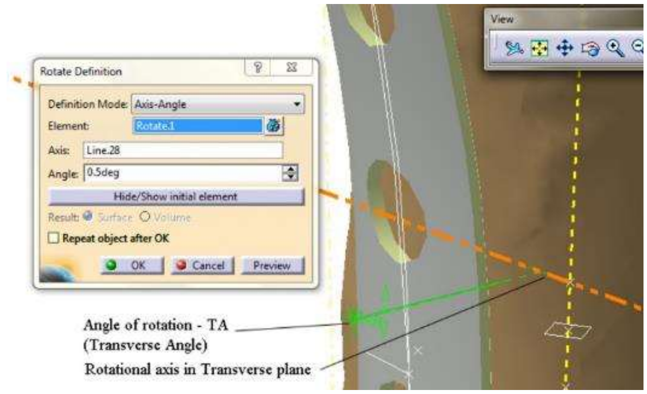

b) TA angle definition

Figure 9.5 Defined Mwidth dimension and angles of rotation for the cloverleaf plate – LMA and TA

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 (Figure 9.6). There was no 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 need, surface of the plate can be adjusted to follow the shape of the bone by changing the values of radiuses (parameters).

Deviations were observed in AP plane between intersections of AP plane and plate and humerus surface models. Maximum deviation in proximal epiphysis section is 2.267 mm, and maximum deviation in proximal diaphysis section is 2.44mm (Figure 10). These two deviations are in the top and bottom area of the plate and they are quite satisfactory, as stated by orthopedic surgeons involved in this research. The 89% of the plate contact surface is below 1 mm distance from the periosteum surface of the bone.

Plate implant prototype creation by using FDM (FFF)

For prototyping purposes plate implants were produced on Wanhao 3D printer (Figure 9.7). Layer width of 0.1mm, infill 70%. The overall geometry and shape were in accordance with the dimension of the bone. Additionally, it would be possible to print the bone model and to pair it with the plates, after which further optimization of both geometries and printing parameters can be considered.

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Figure 9.6 Assembly of the plate solid model and surface model of the test humerus bone

Figure 9.7 Creation of personalized 3D cloverleaf plate

9.3 Conclusion

The methods presented here enable the creation of a 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 to 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 (optimization) can be controlled so that surgeon can make additional corrections to the geometrical model of the plate if there is such a requirement (e.g., because of the patient's condition).

The surface model of humerus and the parametric model of the 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.

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