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BRIGHT

Erasmus+ strategic partnership for Higher Education

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

MODULE 1
CAD

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Contents

1 Introduction 4

2 CAD design basics 5

2.1 Basic definitions 5

2.2 Types of 3D modelling and basic methods 6

2.2.1. Wireframe modelling 6
2.2.2. Solid modelling 7
2.2.3. Surface, mesh and hybrid modelling 8
2.2.4. Assembly 9

2.3 Review of CAD software 10

2.3.1. Autodesk Inventor 10
2.3.2. CATIA v5 11
2.3.3. SolidWorks 12
2.3.4. Fusion 360 13
2.3.5. Altair Inspire 18

3 Methodology of CAD design of medical parts for 3D printing 22

3.1 Basic concepts 22

3.1.1. 3D printed products for medicine – basic concepts and examples 22
3.1.2. Medical imaging techniques (CT, MRI, 3D scanning) 25
3.1.3. Data formats (DICOM, STL) 27

3.2 Software review 29

3.2.1. 3D Slicer 29
3.2.2. InVesalius 33
3.2.3. MIMICS 35

3.3 Design of 3D printed mid-surgery supplies 43

3.2.1. Design methodology and use cases 43
3.2.2. CT data processing 45

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3.2.3. CAD design process examples 47

3.4 Design of orthopaedic and prosthetic equipment 60

3.3.1. Process methodology 60
3.3.2. 3D scanning and data processing 61
3.3.3. CAD design of orthopaedic supplies 66
3.3.4. Selected cases 67

4 Preparation of medical CAD models for 3D printing 74

4.1 Good practices in design for 3D printing 74

4.2 File types related to additive manufacturing 77

5 Summary 81

6 References 82

7 Figure list 86

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1 Introduction

Wide possibilities of the still developing methods of additive manufacturing have also been adapted to the needs of medicine. The ability to recreate complex and non-standard lumps and shapes allowed for an individualized approach to a specific patient, both at the stage of planning the operation and educating about the existing problem, by implementing surgical tools and templates dedicated to the patient, ending with individually matched (patient specific) implants or prostheses. In addition, rapid manufacturing methods have been used in tissue engineering as an element of bioprinting using living cells. The continuous development of additive manufacturing methods provides newer solutions in the field of materials used, obtained textures, colors and properties of the final product.

However, before any medical part becomes manufactured, it first must be designed – 3D printing processes require full digital representation of printed objects, in form of 3D models, usually prepared in computer-aided design (CAD) systems. Concerning the non-anatomical 3D printed parts – such as surgical tools, operating room equipment, protection devices and so on – the design can be performed in a standard way, utilizing solid, surface or hybrid modelling methods in selected CAD systems, on the basis of requirements and available ready solutions. This, however, is not a usual use of 3D printing technologies, as they are suited for more individualized and intricate shapes. The task becomes more difficult if a 3D printed part must be based upon real human anatomy, either internal (organs) or external (limbs). It requires gathering the anatomical data, via simple or more sophisticated measurement techniques – e.g. medical imaging. This data must be appropriately processed and used as an input to CAD software, to design individualized medical parts.

The most important trends covered in modern literature are as follows:

- 3D scanning and reverse engineering in medicine [1],
- medical parts design using CAD systems [2],
- automation of CAD modelling [3],
- processing of medical imaging for 3D printing [4],
- design optimization towards 3D printing processes [5].

This module covers some of the above mentioned problems, presenting basic and advanced knowledge – current state of the art – regarding the design of medical parts for 3D printing.

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2 CAD design basics

2.1 Basic definitions

Design is a set of activities undertaken by engineers in order to create a new product or improve an existing one, fulfilling the requirements of a specific recipient or group of recipients.

Design is a beginning part of product lifecycle (Figure 2.1) and it can be divided into concept preparation and engineering design. This module focuses on the latter, presenting how engineers can work towards 3D printed medical parts.

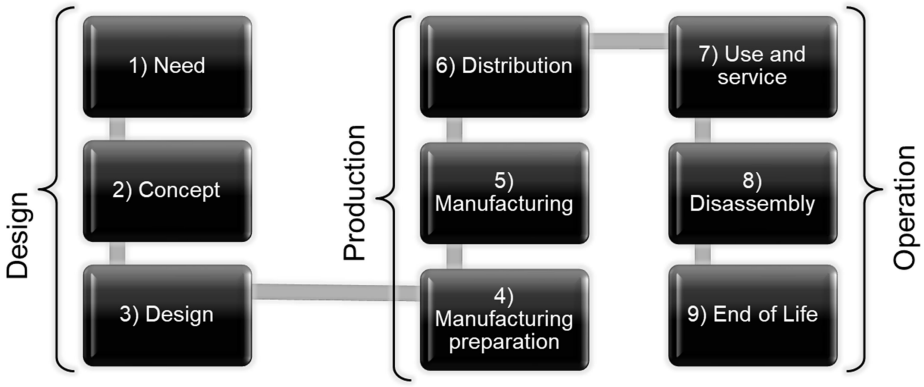

Figure 2.1 Product lifecycle stages [6]

Computer Aided Design (CAD) is use of computer technology to help the engineers prepare a design of a new or improved product. CAD is a part of the whole family of CAx systems, helping engineers and manufacturers to bring a product to life. The other systems are, e.g. CAM (Computer Aided Manufacturing), CAE (Computer Aided Engineering), CAPP (Computer Aided Process Planning) and many others. There are many book publications, widely explaining definitions and practice of use of CAx systems – e.g. [7], so it will not be covered here in great detail. Popular CAD systems include CATIA, Inventor, SolidWorks, NX, SolidEdge and many others.

3D modelling, for the sake of this module, will be considered as a process realized in CAD software, focusing on formulating a three-dimensional shape of a designed product. The 3D modelling realized in CAD systems is usually **parametric**, meaning that the shape is governed

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by a set of dimensional and geometrical constraints, allowing the simplest elements of a given shape to be connected to one another (e.g. a line can have a dimensional constraint of length and a geometrical constraint of being perpendicular to another line). The 3D models also often have history, meaning that all the operations are stored in a linear order, allowing to trace and modify any operation at any given time. Idea of parameterized 3D modelling with history is shown in Figure 2.2.

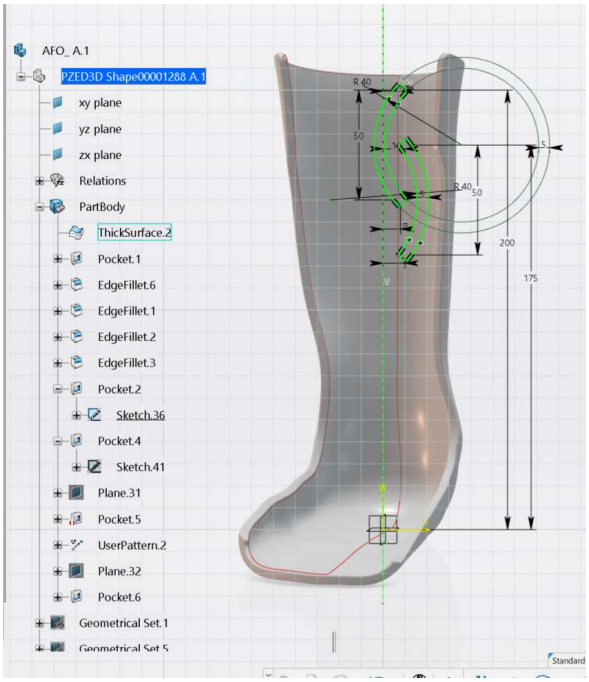

Figure 2.2 Parameterized 3D modelling in a CAD system [own work]

2.2 Types of 3D modelling and basic methods

2.2.1. **Wireframe modelling**

A wireframe model is a skeletal description of a 3D object. There are no surfaces in a wireframe model; it consists only of points, lines, and curves that describe the edges of the object. Wireframe models can be created by positioning 2D (planar) objects anywhere in 3D space. Some 3D wireframe objects are also provided, such as 3D polylines and splines. Because each object that makes up a wireframe model must be independently drawn and positioned, this type of modeling can be the most time-consuming [8].

In wireframe modelling, the following operations are the most commonly used:

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- create a point (by coordinates or in relation to other element),
- create a line (as above),
- create a curve (2D or 3D) – spline, circle, ellipse, helix and others,
- create a plane,
- multiply and transform elements: mirror, array, translation, rotation.

Wireframe modelling is usually used as a complementary technique, aiding the surface or solid modelling. For example, to create a spring, helix must be first modelled, then a circular or other shape can be extruded along it, obtaining a solid model.

2.2.2. **Solid modelling**

Solid modelling is a mathematical technique for representing solid objects. Unlike wireframe and surface modeling, solid modeling systems ensure that all surfaces meet properly and that the object is geometrically correct, hence making it the most robust technique for 3D printing (where geometrically incorrect objects cannot be manufactured properly). Solid modeling is the easiest type of 3D modeling to use. With the solid modeler, 3D objects can be made by creating basic 3D shapes: boxes, cones, cylinders, spheres, wedges, and tori (donuts). These shapes can be then combined to create more complex solids by joining or subtracting them or finding their intersecting (overlapping) volume. However, solid are most frequently created by sweeping a 2D object (usually a closed curve, named a sketch in many popular CAD systems) along a path or revolving it about an axis [8].

Parametric 3D solid modelling in modern CAD systems usually consists of the following steps:

1. Designate a place for a sketch.
2. Draw a sketch.
3. Add 3rd dimension by extrusion or rotation.
4. Add non-sketch modifications or transformations.
5. Repeat until model is ready.

The following operations can be distinguished in solid modelling:

1) single sketch based features – extrusion (3rd dimension by linear sweep) or rotation (3rd dimension by angular sweep), both positive and negative effect (add or remove material),
2) two or more sketch based features – rib (sweep a 2D closed curve along a 3D curve – closed or open) and multi-section solid (create an advanced shape as blend between

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many closed curves usually placed on parallel planes), with adding or removing material,

3) non-sketch based features – fillet, chamfer, shell (thin-walled solid) and others,
4) transformations and multiplications – rectangular array, circular array, symmetry, translation, rotation,
5) boolean operations – subtract, add, intersect.

There are also systems, in which the so-called free modeling is available. Starting from a certain primitive shape (cube, sphere, cylinder, cone), steering curves and points can be manipulated in order to obtain a more advanced shape in a so-called digital sculpting process.

2.2.3. **Surface, mesh and hybrid modelling**

Surface modelling is a mathematical technique for representing solid-appearing objects. Surface modeling is a more complex method for representing objects than wireframe modeling, but not as sophisticated as solid modeling. Surface modeling is widely used in CAD (computer-aided design) for illustrations and architectural renderings. Although surface and solid models appear the same on screen, they are quite different. Surface models cannot be sliced open as can solid models. In addition, in surface modeling, the object can be geometrically incorrect; whereas, in solid modeling, it must be correct [9].

CAD software packages use two basic methods for the creation of surfaces. The first begins with construction curves (splines) from which the 3D surface is then swept (section along guide rail) or meshed (lofted) through. The second method is direct creation of the surface with manipulation of the surface poles/control points. From these initially created surfaces, other surfaces are constructed using either derived methods such as offset or angled extensions from surfaces; or via bridging and blending between groups of surfaces. Freeform surfaces do not have rigid radial dimensions, unlike regular surfaces such as planes, cylinders and conic surfaces; control points of a surface define its shape.

Mesh modeling, or mesh processing, is another type of modeling, not exclusive to CAD systems, but available also in many other software packages, such as MeshLab, GOM Inspect, MeshMixer and many more. The mesh, in this case, is either a point cloud or a triangular mesh, in STL format (the formats are explained in the next chapter). The mesh is usually created as a result of a reverse engineering process (3D scanning or medical image processing). Mesh processing involves selection and manipulation of triangles – manually or

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semi-automatically, filling holes, smoothing the surface, repairing defects and removing unwanted artifacts etc., basic shaping tools are also available to make certain manipulations and create new geometries.

Difference between 3D modelling types are presented in Figure 2.3.

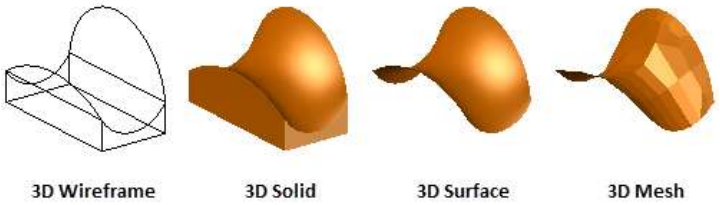

Figure 2.3 Types of 3D models [10]

Hybrid modelling is a technique, in which wireframe, surface and solid modelling are combined within a single model. Part of the model can be surface modelled, part can be wireframe and the other part could be solid. This is frequently found in reverse engineering, where measured points and surfaces are imported and a solid model is built upon them (see Figure 2.4). This also applies to medical applications – a surface representing patient's limb can be used to develop a solid 3D model of a prosthesis or orthosis.

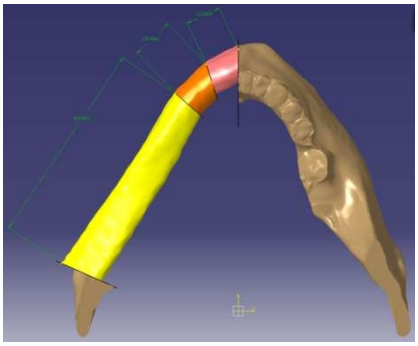

Figure 2.4 Hybrid 3D model of a mid-surgery template - CT-based surface joined with solid parts [11]

2.2.4. **Assembly**

Assembly is a process, in which a complex model of a device is created by putting together models of its components (parts), created by 3D modelling techniques (Figure 2.5).

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In order to create an assembly, at least two parts must be inserted into it and linked together by means of geometrical and dimensional constraints.

Assembling parts together in a desired arrangement can be achieved by utilizing the following constraints:

- line/plane contact,
- offset/distance,
- angle,
- concentricity,
- coincidence (point/line),
- symmetry.

The assembly is usually fully parameterized, so changing values of constraints can allow for controlling the parts arrangement. Assembly is usually a separate module of any given CAD system. Any inserted part can be edited on the spot, adding new features to the part itself (replicated in any assembly where the part is used) or – sometimes – features specific to a given assembly (e.g. a hole through two or more parts or a weld between them).

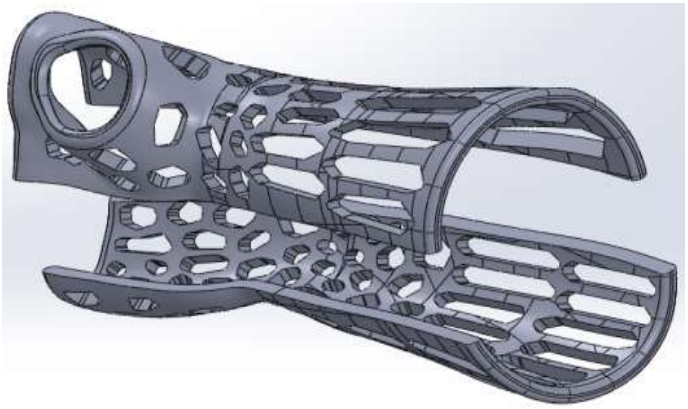

Figure 2.5 Assembly - two parts of an orthosis [12]

2.3 Review of CAD software

2.3.1. **Autodesk Inventor**

Autodesk Inventor is a 3D CAD program used primarily for the mechanical design of parts and assemblies and the preparation of technical documentation based on them. It is focused mainly on creating multi-element assemblies and has an extensive Content Center tool aimed at this eventuality, enabling effective import of a wide selection of standardized

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elements. Inven-tor, due to its competitive price and free access to student versions of the software, has been widely used in the educational sector and small and medium-sized enterprises with an engineering profile.

Autodesk Inventor can import STL files of any size. In order to convert a mesh to a parametric model, it is necessary to install the Mesh Enabler add-on, which allows you to convert the model in a short operation. The processing time depends on the computational capabilities of the computer and the complexity of the output model.

By design, Autodesk Inventor is not a program dedicated to making complex surface models, but it is nevertheless equipped with tools that allow you to perform basic operations, such as creating surfaces by extrudes. The efficiency of work with the program depends on the computational capabilities of the computer and the complexity of the design task. Due to the small number of tools intended for advanced modeling, in some cases it is not possible to complete the design task in full [13].

2.3.2. **CATIA v5**

CATIA V5 is an integrated system that, in addition to modules responsible for 2D and 3D modeling, has tools for planning machining processes, product life cycle management, numerical analyzes, or creating digital product mock-ups. Due to its complexity and wide possibilities in the field of engineering activities, CATIA has found application in the design of highly complex products [13].

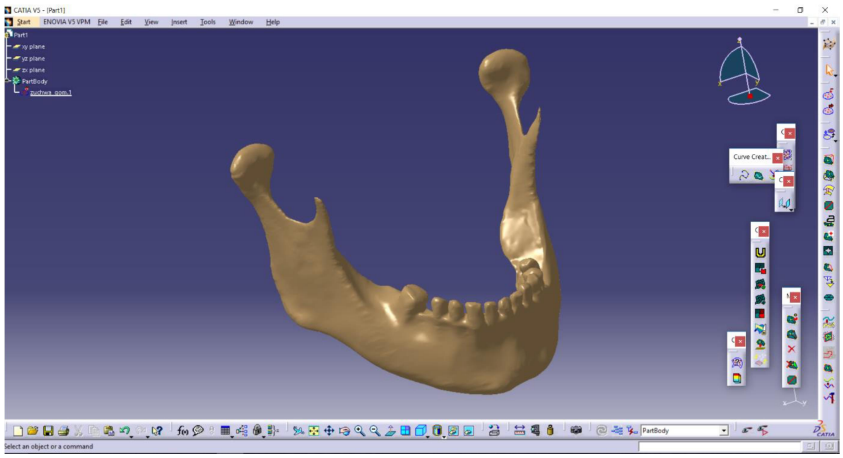

Figure 2.6 CATIA V5 software [13]

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CATIA V5 allows to import an STL file of almost any size - the success of the operation depends on the computing capabilities of the computer, mainly the size of the RAM memory. It is possible to convert a polygon mesh to a parametric model using the DMU Optimizer module, which results in a model that the program is able to interpret as part of (.CATpart). In addition, the Digitized Shape Editor module offers a set of file editing tools at the polygon mesh level. The program does not perform automatic model diagnosis, therefore all checking activities should be performed separately.

The program has a whole set of modules for surface modeling, including Geneative Shape Desingn and FreeStyle. The tools available in the modules allow for the production of almost any surface models, including those with higher quality and aesthetic requirements (the so-called A-class surfaces). [13]

2.3.3. **SolidWorks**

SolidWorks is one of the most popular 3D CAD programs available on the market. In addition to standard functions related to 3D modeling, it has tools for technical documentation management, electrical design, FEM simulation and kinematic analysis. It is also widely used in enterprises in the design of technological processes and tools for plastic working and processing of plastics.

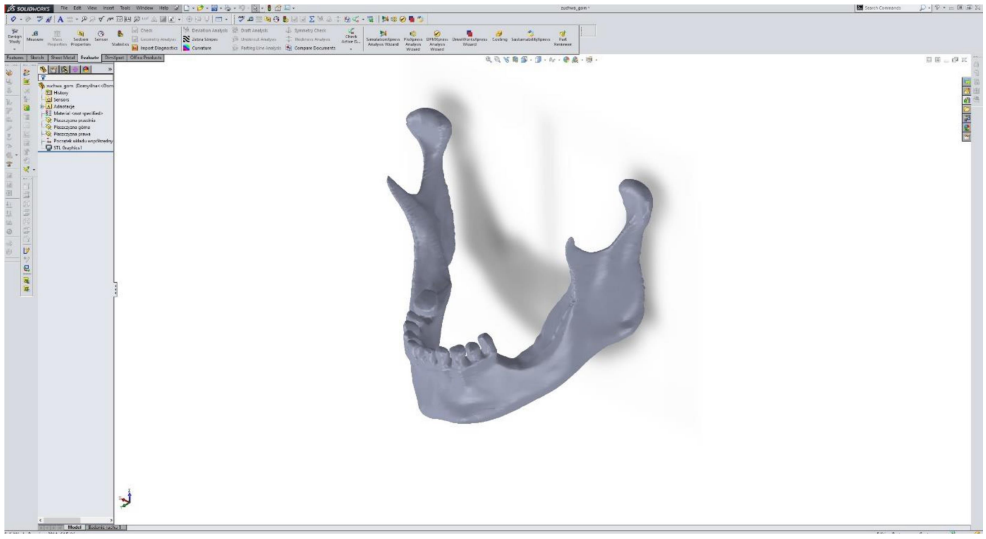

Figure 2.7 SolidWorks software [13]

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The easy-to-use and intuitive interface is one of the main advantages of SolidWorks. All functions are gathered in the main tabs which, when expanded, form ribbons in the upper part of the main window. The operations tree is a separate block that can be expanded or hidden depending on your preferences. The program has a help system at the software level and a knowledge and instruction base available on the Internet.

Each time an import of a file in the STL format is associated with the indication of the type of the output file. You can choose between a graphical model with very limited editing options, surface or solid. At the time of import, the program performs an automatic diagnosis of the file and suggests performing basic corrective actions using a special wizard. The disadvantage of working with STL files in the SolidWorks program is the much greater demand for computer computing power than in other 3D CAD programs. SolidWorks has a set of tools that allow you to perform a limited number of surface modeling activities. The program allows you to create simple linear and unfolding surfaces, as well as more complex NURBS (Non-Uniform Rational B-Spline) surfaces [13].

2.3.4. **Fusion 360**

Fusion 360 is a Cloud based collaborative product development program from the AutoDesk company [14-15]. It's an all in one package, mainly used for mechanical engineers and product designers, that combines all the phases throughout the entire engineering life cycle, from the planning stage, prototyping, testing all the way to final production. Fusion 360 eliminates the need of utilizing multiple different softwares in the development of new products or upgrade of existing ones. Having all the solutions in one software facilitates the making of various iterations to the design, as no data needs to be transferred to different softwares, and all of the Fusion 360 modules collaborate with each other. This software can be used as a tool for parametric CAD modeling, machining (CAM programming), simulation and analysis (FEM), creation of generative design, visualization (rendering), animation and 3D printing. It also allows real time collaboration between people involved in the same project, updating the models to all the participants.

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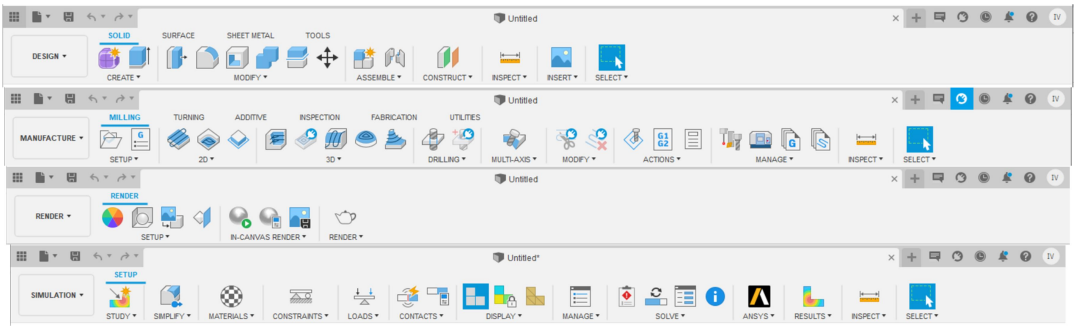

Figure 2.8 Fusion 360 toolbar on different working modules

The program is free to use for educational purposes and startups with less than $100k of revenue per year. The user can switch through different modules in the upper left corner. Fusion 360 CAD module is called DESIGN, and it is very easy to use for begginers new to CAD modeling. It has all the tools that are standard for other CAD programs, and it allows importing other 3D models made in different CAD softwares. The biggest difference is the simplicity of which assembly works in Fusion 360. Unlike Solidworks that works with Mates, Fusion 360 has Joints, which allows the user to combine two different components using just one reference point.

There are different types of Joints that can be used depending on the articulation needed (Rigid / Revolve / Slider/ Cylindrical / Planar etc…). All the Joints of the assembly can be found in the Browser window.

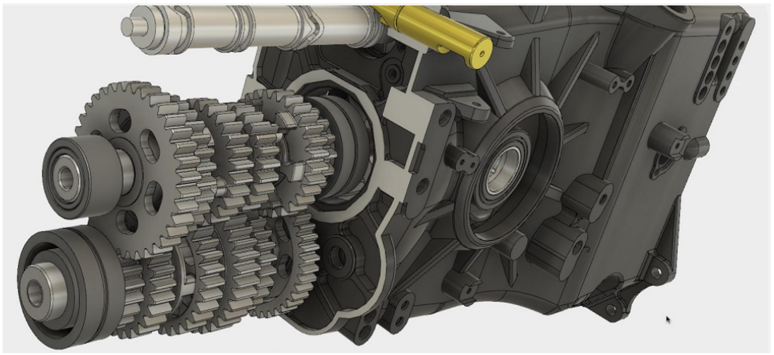

Figure 2.9 Fusion 360 Computer Aided Design (CAD) [14]

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The working interface consists of the Data Panel, Toolbar, Browser, View Cube, Timeline, Navigation and Display Bar, Profil & Help. The workspace as well as the toolbar with the list of commands changes when passing through different modules.

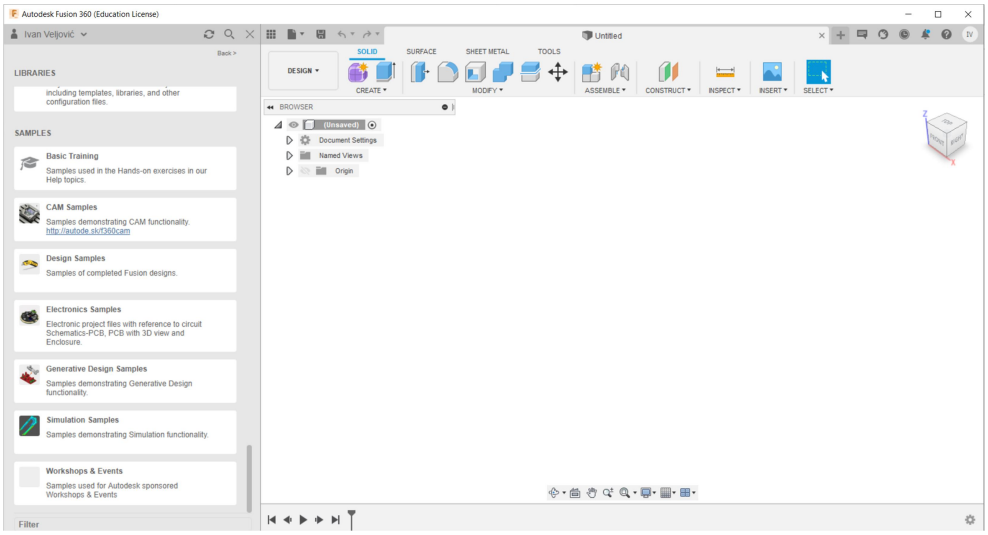

Figure 2.10 Fusion 360 working interface

Navigation in Fusion 360 is simple, and it can be adjusted to simulate the navigation in other CAD programs to facilitate the user experience. Navigating around the workspace can be done with:

- The use of the navigation bar (orbit / pan / fit / zoom icons)
- View Cube (by clicking on the cube sides, edges and corners we access various standard views)
- Keyboard and Mouse (scroll the mouse to zoom in or zoom out / click and hold the middle mouse button while moving the mouse rotates the model / holding SHIFT and the middle mouse button while moving the mouse pans the model)

The methodology of working with Fusion 360 is very simple, allowing all the standard CAD forms of designing: top-down, bottom-out and middle-out. Being a Cloud based software, the user doesn't have to worry about other models or components outside the main assembly as they can be easily imported and all the changes to the models are implemented in real time. All of the assembly components are stored in one single file, but it is also possible to link multiple files together for even bigger subassemblies and assemblies.

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Once the product is designed, we can use the Fusion 360 CAM module called MANUFACTURE in order to perform the cutting operations and program toolpaths based on the part geometry. In the CAM module we can specify cutting parameters such as cutting speed, pierce delay, and lead-in geometry and Fusion will export these toolpaths as a G-code file that can be read by the machines controller software. We can also define our stock material, choose different tools, coolants and everything that is necessary for our manufacturing process.

If we want to perform simulation and analysis of our components, we can access the Fusion Finite Element Method module called SIMULATION. Under this module we can choose from various simulations including:

- Static Stress Analysis - used to analyse displacement, stresses, and common failure criteria.
- Modal Frequencies - used to determine the modal frequencies of the model.
- Thermal - determine how the model responds to Heat Loads and Thermal Boundary Conditions under steady state conditions.
- Structural Buckling - determine the Buckling modes of the model. The Results include Buckling Modes and their corresponding Load Multipliers.
- Nonlinear Static Stress - determine the static stresses and deformation throughout the model caused by structural loads and boundary conditions while considering nonlinear material properties and large deformations.
- Event Simulation and more - determine how the design responds to motion (including initial velocities), impacts, and time-dependent loads and constraints. The results include displacements, stresses, strains, and other measurements throughout a specified time period.

Another significant part of the Simulation module is the ability to perform shape optimization and generative design. These two segments have similar goals but are performed in different ways, and the input variables are different. The shape optimization module generates a new model from the boundaries of the previous one, based on the direction of stress movement in the model. Every simulation can evaluate only one material at the time. With this module, we can prevent the over dimensioning of the model. Unlike

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shape optimization, with the generative design multiple iterations of the model are automatically created based on inputs like different materials, manufacturing methods, boundary limits and so on. The generative design iterations are not limited by the boundaries of the original model, and the results can be very different from the initial concept.

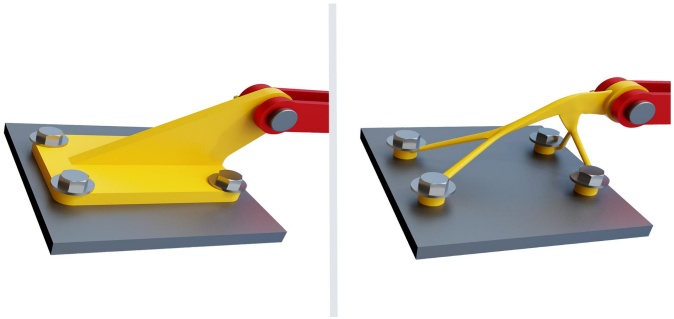

Figure 2.11 Fusion 360 Topology Optimization (Shape Optimization) [17]

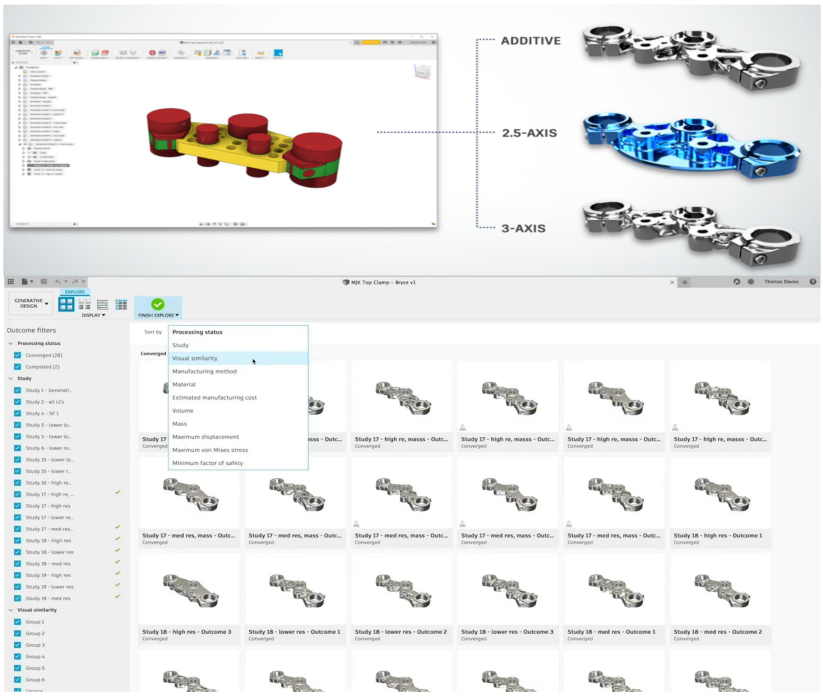

Figure 2.12 Fusion 360 Generative Design [18]

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Some of the advantages of using Fusion 360 are:

- Cloud based program
- User friendly interface and intuitive command selection
- Fast and easy modeling process
- Easy to make changes
- Simple unit conversion
- Seven different models of work environment (CAD / CAM / FEM / Generative Design / Render / Animation / Technical Drawings)
- Compatible with other CAD softwares

2.3.5. **Altair Inspire**

Altair Inspire Studio is a new flexible solution for mechanical engineers and product designers, allowing for a fast production of CAD model, FEM analysis, topology optimization and generative design [19]. The tools used for creating 3D models as well as the workflow, are optimized for maximizing the efficiency of the product development and design experience. Some of the main features that makes Altair Inspire Studio greate for begginers and advanced CAD drafters are:

- Historical based modeling - like many other CAD softwares it has a historically based modelling, that enables simply reverting to an earlier design phase to reuse or modify objects from past phases in real time.
- Sketching - Technical sketches can be created and edited by applying geometric relationships between components. Sketches are used to extract a 3D model from them.
- Surfaces and Curves - ability to use uneven curves and surfaces for precise and flexible design of the most complex shapes.
- Rendering and animations - high quality photorealistic images and animations, with a physical global light mechanism.

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- Toolbar - user friendly toolbar design allows the access to all modeling and rendering tools with one click, bringing any functionality directly to the user. The toolbar can be customized to suit the user needs.
- Production and assembly drawings - detailed 2D drawings of complex 3D models and assemblies from multiple perspectives can be created. Functionalities include one-click view creation, cross-sectional and detail views, linear, angular, radial, and coordinate dimensions, as well as notes.
- Parametric modeling - the creation of 3d models using parametric modelling allows for an easier and faster process in creating various design iterations.
- Geometrical modeling - complex geometries can be edited in a simple, intuitive and interactive way, either at the global part level or by applying local modifications to the model.

As with most other CAD programs, the working interface at Altair Inspire Studio consists of:

1. Toolbar
2. Timelines and browsers
3. ViewCube
4. Work space

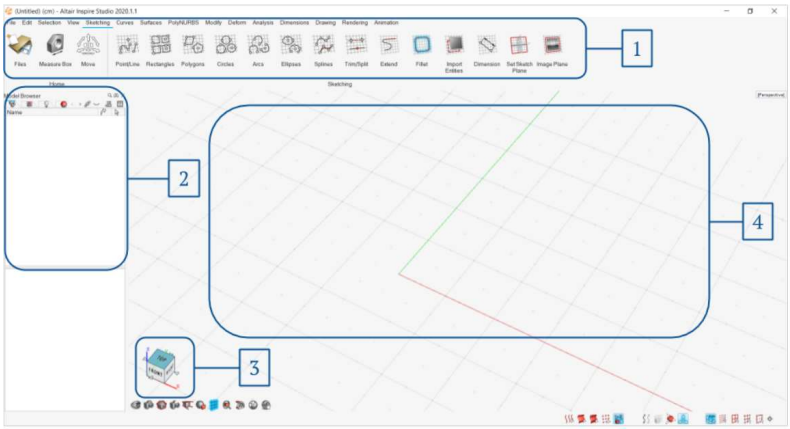

Figure 2.13 Altair Inspire Studio working interface

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The interactive Toolbar provides a unique approach, to bring the necessary commands closer to the workspace. To access the toolbar inside the workspace simply hold down the ALT key and right-click on the keyboard. The interactive toolbar can be customized to the needs of the user.

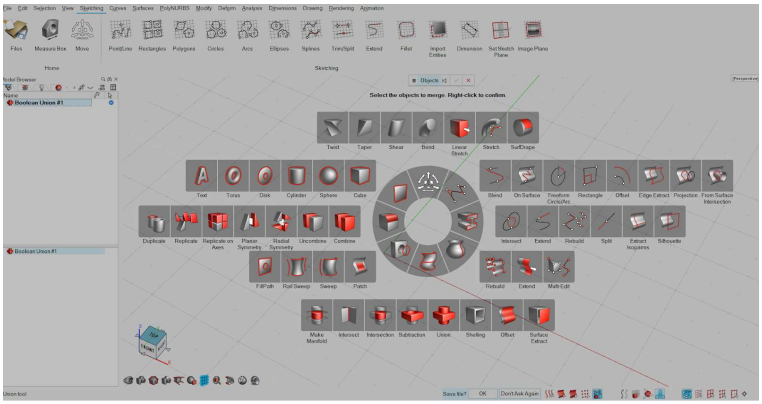


Figure 2.14 Altair Inspire Studio interactive toolbar

Navigation in Altair is simple, and it can be adjusted to simulate the navigation in other CAD programs to facilitate the user experience. Navigating around the workspace can be done with:

Pan the model:

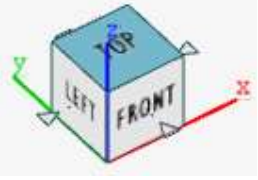
Right mouse click and move the mouse

Zoom mode:

Scroll the mouse wheel

Rotate the model:

ViewCube



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Click on the faces, edges or corners of the ViewCube

Click the scroll wheel and move the mouse

Altair has many different modules that can be upgraded to the basic module, some of which are represented in the figures below.

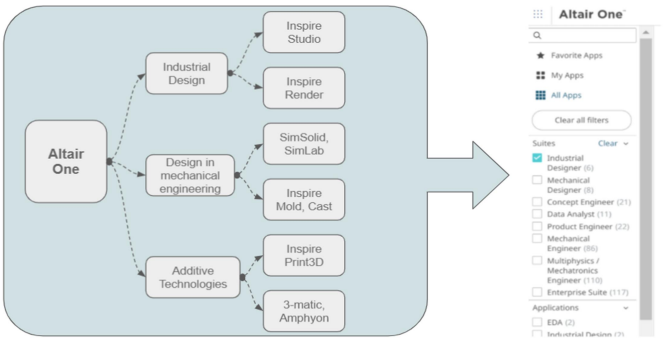

Figure 2.15 Display of part of the Altair software solutions [19]

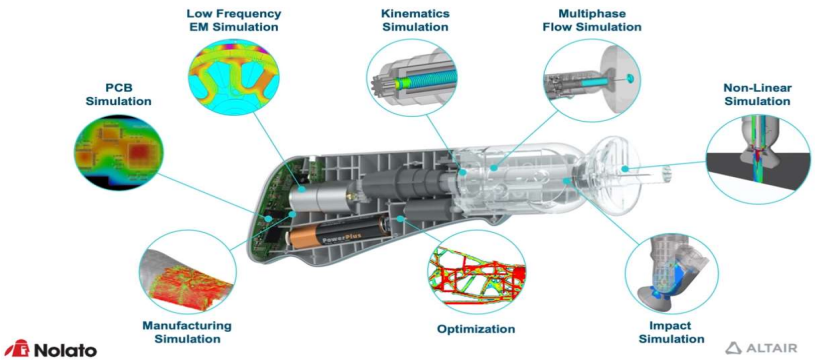

Figure 2.16 Altair software solutions in product development [20]

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3 Methodology of CAD design of medical parts for 3D printing

3.1 Basic concepts

3.1.1. 3D printed products for medicine – basic concepts and examples

3D printing is a technology which is particularly well suited for medical uses. It's relatively easy to manufacture intricate, organic, anatomical shapes using 3D printing. Moreover, there are no confinements with the limits of serial or mass production – a 3D printer can produce one object and then shift to another, without any additional cost. There is no need to prepare any molds, tools or whatever. So there is big potential in personalized medicine – producing objects tailored for a specific patient – implants, orthoses, prostheses. Non-personalized products can be manufactured (or prototyped) too.

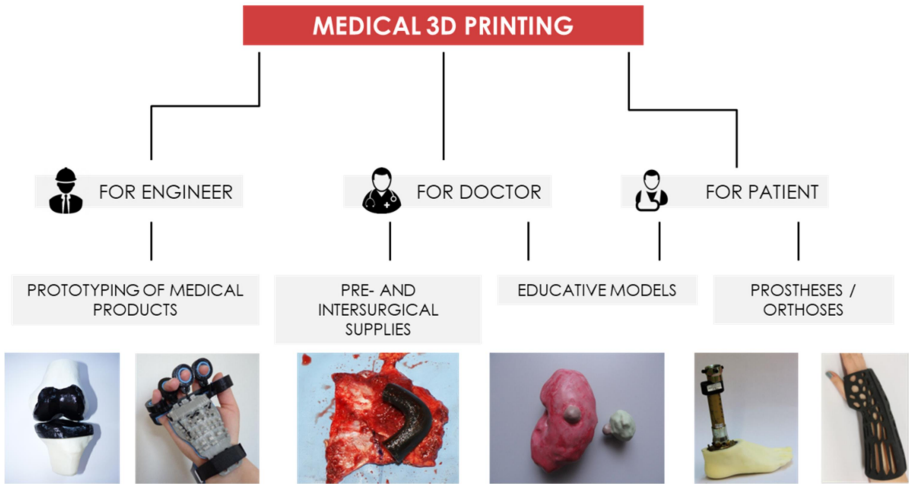

Figure 3.1 Groups of applications of medical 3D printing [own work]

In general, there are three main groups of applications of individualized 3D printing in medicine (Figure 3.1). First, a biomedical engineer can use it – for example, they design a new wheelchair, exoskeleton, prosthesis or surgical tool – 3D printing can be used to quickly prototype if their design is correct. Second, a doctor can use it, more specifically – a surgeon. 3D printed supplies can be used before or during a surgery. The third group is 3D printing for patients, so a product that comes out of 3D printer is directly used by patient during the

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treatment process, or sometimes for lifetime. This includes orthoses, prostheses, implants and other personalized medical devices, which can be custom made for a specific patient.

Non-individualized medical equipment possible to be 3D printed involves:

- protective gear,
- parts and connectors for medical devices,
- surgical tools,
- small equipment for surgery room,
- prototypes of new medical devices.

Each particular product must be designed first. In the case of non-individualized products, this is a rather typical engineering process of design, involving use of CAD systems and combining engineering and medical knowledge to create new designs of devices. The real point of interest of this module are individualized parts – such as implants, prostheses etc., that firsthand require measurement of a specific geometry in order to be designed. This will be described in the further part of this chapter.

Below, some typical examples of 3D printed, CAD designed medical products are presented.

3D Printed Surgical Instruments

George et al., [21] have used package Solid Works to design a surgical set including hemostats, needle driver, scalpel handle, retractors and forceps. The authors claim that the advantages compared to traditional production methods do not involve an increase in costs due to increased complexity, accelerated design to production time and specific modifications surgeons. Figure 3.2 shows surgical instruments: scalpel handle, hemostats, needle drivers, forceps presented in [21].

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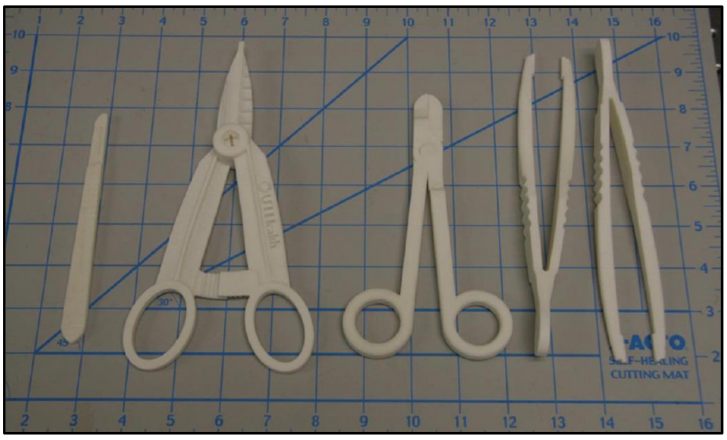

Figure 3.2 Scalpel handle, hemostats, needle drivers, forceps [21]

CAD for construction for bone regenerative

Cioccaa, De Crescenzio, Fantini and Scotti [22]. developed a model for testing new bone constructs to replace spare skeletal segments that are derived from new generation scaffolds for bone marrow-derived mesenchymal stem cells. They used computed tomography data, scaffolds were defined using computer-aided design and computer-aided manufacturing for rapid prototyping by three-dimensional printing. Cioccaa et al. developed a surgical guide system to accurately reproduce virtually planned bone sectioning procedures in animal models to get an ideal fit through surgery. Figure 3.3 shows a digital model of the defective mandible.

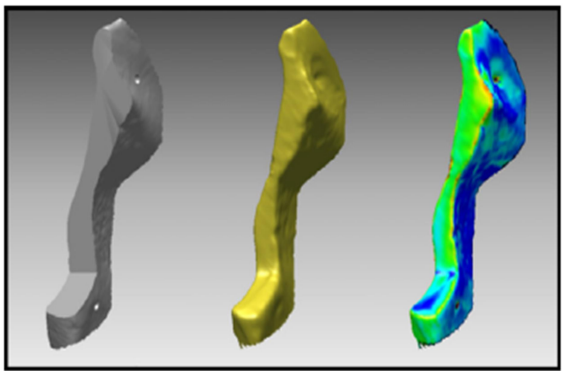

Figure 3.3 Digital model of the defective mandible (left), scanned model of the actually cut bone (center), and the distance deviation color map between the two superimposed models (right) [22]

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Computer-aided tissue engineering

Computer-aided design has many important biomedical applications, particularly in tissue engineering, this is made possible thanks to imaging technologies and reverse engineering techniques supported equally by both hardware and software technologies.

In tissue engineering computer-aided design-based bio-tissue IT model provides information on the biochemical , biophysical, biological and properties of tissues for designing, modeling , and fabricating tissue replacements (Sun, Starly, Nam and Darling [23]). Sun et al. presented the use of bio- computer-aided design models for the description of morphology, heterogeneity and organizational structure of tissue anatomy. Figure 3.4 shows the process of heterogeneous tissue block assembly for the kidney.

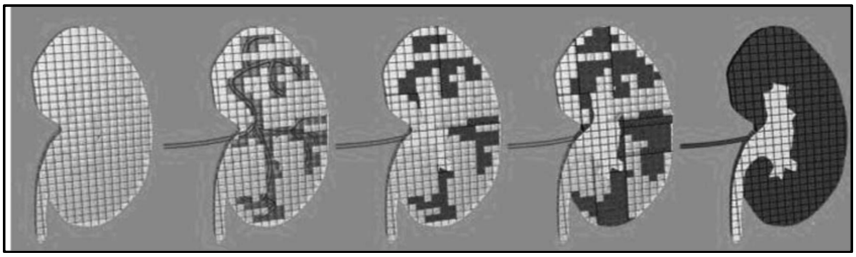

Figure 3.4 Computer-aided tissue engineering: process of heterogeneous tissue block assembly for kidney [23]

3.1.2. Medical imaging techniques (CT, MRI, 3D scanning)

Anatomically adjusted medical products manufactured by 3D printing must be based on measurements of patient's anatomy. Depending on the level of individualization, the measurement can apply to each single patient, representatives of certain groups of patients (e.g. children, or adults with specific features etc.) or one, exemplary patient (as in design of protective equipment). In a very simplistic approach, the measurement can be made manually, using simple tools or templates (rulers, tape measures etc.), but it is not very precise.

General overview of methods of digital measurement is presented in Figure 3.5. Selected methods are shortly characterized below.

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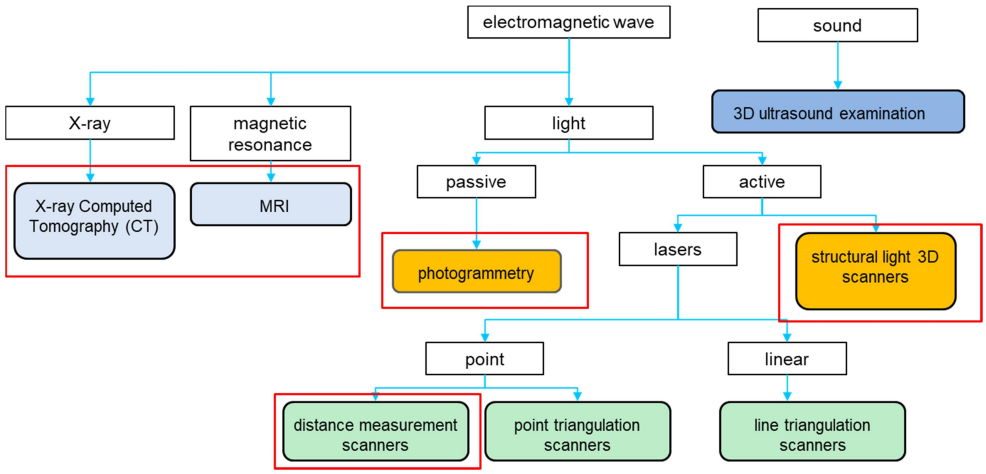

Figure 3.5 Methods of contactless measurement – methods used in medicine marked in red [own work]

Medical and industrial X-ray tomographs are characterized below.

- the measurement consists in registering many tomographic images (sections) of the examined object (flat shots in different positions of the object), and then reconstructing the 3D spatial model
- data in DICOM format (sections)
- the ability to measure the geometric features of external surfaces and the internal structure of the object
- better imaging of hard tissues (bones, cartilage)

In terms of photogrammetry, the short range version is usually utilized in engineering. It has the following features:

- measurement consists in registering a series of many images of the same object taken from different positions and their mutual positioning on the basis of common points
- basic measuring device - camera
- the result is a point cloud representing common / characteristic points
- photogrammetric systems can act as optical coordinate measuring devices due to their high accuracy - 0.01mm (industrial systems only)
- quick contactless measurement, motionlessness required during shooting

There are two basic methods of photogrammetric analysis:

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- recognition of markers stuck to the tested object (industrial systems, few points, very accurate measurement)

- generating an approximate point cloud of the entire object (any camera, many points, low accuracy and detail of the measurement)

Laser scanning can be described as following:

- infrared or green light emitted by the laser is reflected by a rotating mirror mounted on a rotating base

- the distance of each point from which the laser beam is reflected and returns to the sensor is recorded

- the surroundings are scanned in the range of 360 degrees horizontally and from 270 - 300 degrees vertically

- the advantages include high measurement speed and the ability to scan large areas

- the disadvantages include the low resolution of points (from 2 to 4 mm)

- laser scanners are increasingly replacing non-engineering short-range photogrammetry

- scanning range varies from 0.6 to 130m

3.1.3. Data formats (DICOM, STL)

The basic information about the measurement results in engineering techniques (3D scanning, photogrammetry) is the point cloud. Each point is defined in space by three real numbers describing its position in the Cartesian coordinate system.

- Disordered point cloud

Points do not connect with each other and it is not known in what order they were registered. It is also not known in which direction the measured object is in relation to the point and from which direction the point was registered

- Ordered point cloud

The points are placed in the order of their registration and the set of curves with which they can be connected will present the contours of the measured object. Point cloud files are usually saved with the TXT, XYZ or ASC extension - this is a text format compatible with the ASCII code. File structure - each consecutive point is written on one line using the x, y coordinates and with real numbers separated by commas or spaces. Additionally, lines can contain additional data, e.g. colors of points (values of r, g, b components for each point). An example of a point cloud is shown in Figure 3.6.

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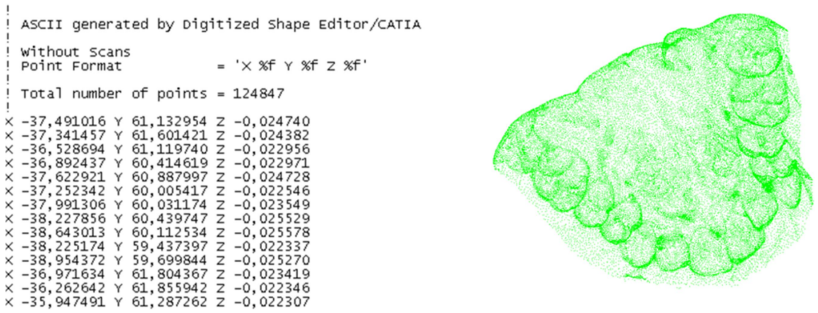

Figure 3.6 Point cloud of a medical 3D scan [own work]

The medical imaging (CT, MRI) techniques usually store their measurements in form of series of sections – flat images, that can be connected to form a 3D cloud. The most popular form of storing these images is DICOM.

DICOM (Digital Imaging and Communication in Medicine) is a universal standard for exchanging medical data that is used all over the world. It was created to enable communication and a smooth flow of information between medical units and unify data from various diagnostic devices. Files in the DICOM standard are sets of cross-sections of the examined structure, resulting from the digitization of data collected during computed tomography, magnetic resonance, or other examinations from the group of medical imaging techniques. There are many free and commercial programs compatible with the DICOM standard. It is also possible to edit them later in 3D CAD environments [24, 25].

The output file from the program enabling segmentation and mesh generation is a file in STL format. The term extension is an abbreviation of the name of the method of stereolithography (STereoLithography), although it is currently adopted as the development of Standard Triangulation Language [26]. It is the universal format recognized by software that controls the printing process in additive technologies. The mesh is created as a result of the surface approximation of the generated model. If the triangles are very small, the approximation of the surface is very accurate. However, with very complex geometry, this involves large file sizes. To simplify the model and facilitate its processing, the number of triangles is reduced. Example of STL mesh containing medical data is presented in Figure 3.7

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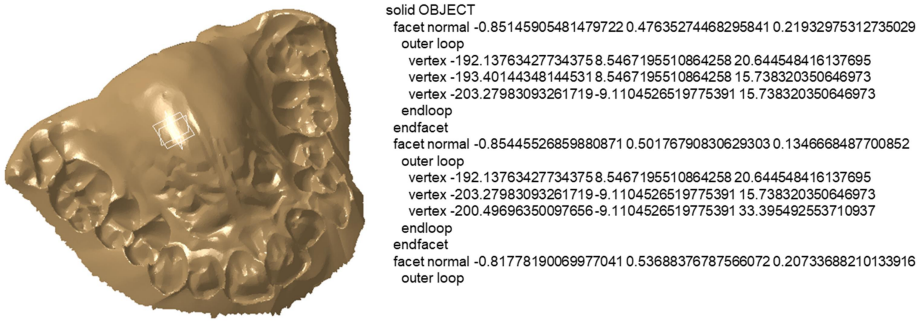

Figure 3.7 STL mesh - medical example [own work]

3.2 Software review

The primary function of programs dedicated to editing and analyzing DICOM files is to enable a relatively simple and effective work with data from a diagnostic device. When assessing the functionality of the program, it is worth using the following criteria:

- Intuitive interface: it should be user-friendly and clearly display the most important available tools.
- Possibilities and forms of automation of the segmentation process: the most advantageous option is the availability of a tool that will efficiently and comprehensively guide the user through the segmentation process with little time.
- The degree of expansion of the support system: the number of training materials guaranteed by the manufacturer and the forms of technical support for the user at the software level.
- Availability: preferable applications are free and compatible with as many operating systems as possible.
- Effectiveness and efficiency: the possibilities of the program related to obtaining by the qualified user the best possible results of work in the shortest possible time.

3.2.1. **3D Slicer**

3D Slicer is the most popular free program designed to work with DICOM data (Figure 3.8). It is dedicated mainly to educational and research purposes, but the bundle of functions available in it allows for a complete DICOM-STL transformation. 3D Slicer is subject to

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continuous and dynamic development, thanks to which it has received many additions in the form of applications for, among others, for making measurements, analyzing data collected utilizing PET tomography, or direct communication with programmatic environments.

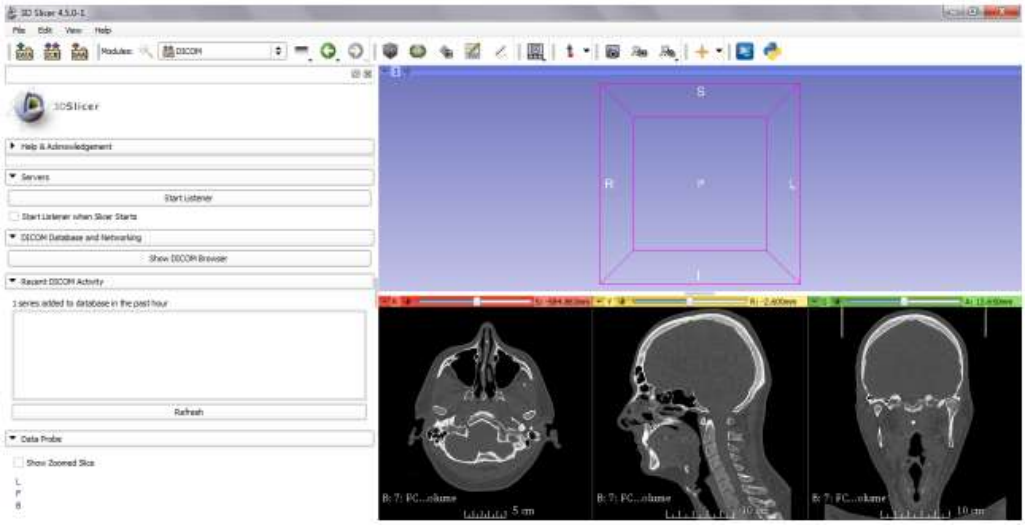

Figure 3.8 3D Slicer window with imported DICOM data [13]

The program has a modular structure. Regardless of the selected module, all available functions are located in the panel on the left side of the main window - this is an advantageous solution as the working space is always fully visible. Moreover, the essential functions, including quick selection of the view type, are also highlighted on the ribbon at the top of the main window.

3D Slicer has several tools for automatic segmentation and manual segmentation support. Among them, the following functions can be mentioned:

- Autodetection of islands (Level Tracing Effect) (Figure 3.9): Consists in supporting the manual marking of the structure by detecting the vicinity of the extracted object corresponding to its shade of grey. It is an ineffective tool - segmentation should be performed separately for each section. Additionally, the activity should be repeated several times for a single layer due to the presence of discontinuities in the structure. The labour consumption of the method increases with the degree of the geometric complexity of the object. The cost-effectiveness of

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applying island auto-detection is limited to working with low-resolution datasets and the extraction of compact, discontinuous areas.

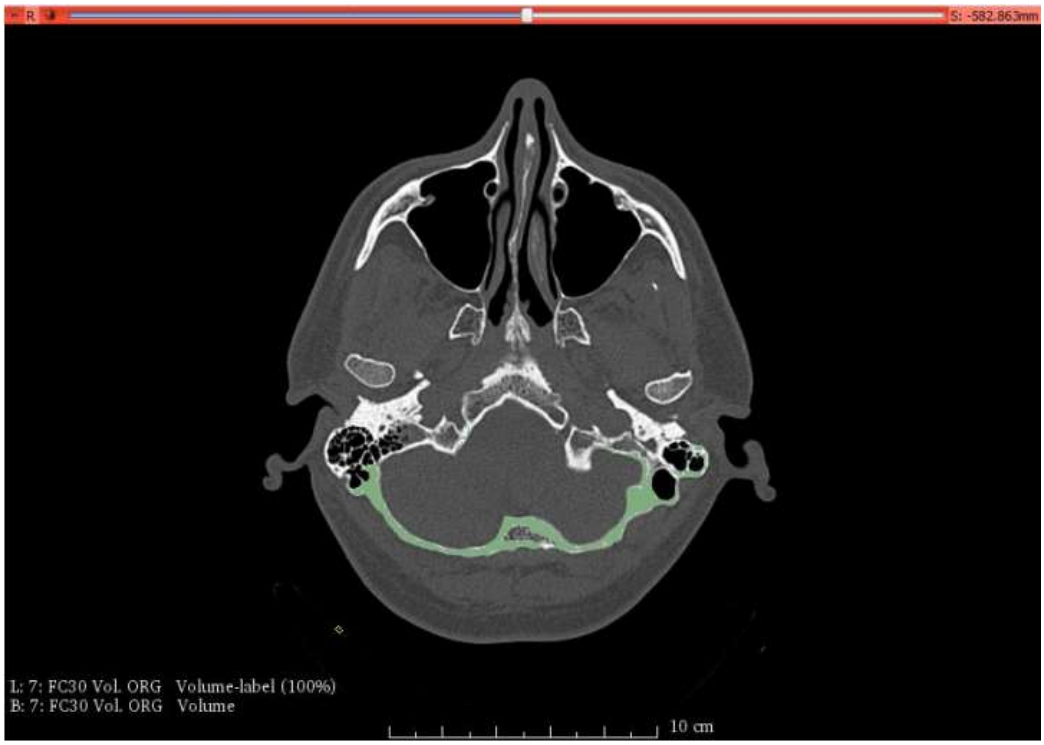

Figure 3.9 3D Slicer segmentation with the use of island auto-detection, the maximum area possible to be determined in a single operation is marked in green [13]

- Threshold Effect (Figure 3.10): the function takes advantage of the fact that, depending on the source of the DICOM data (CT, MRI), it is possible to assign one of the shades of grey to a specific tissue. In the 3D Slicer software, the thresholding can be performed in two ways: by manually entering the limits of the threshold range or by controlling the limits with a slider and observing the changes taking place in the preview. The thresholding tool works automatically. One-time operation results in marking the area on all sections. The method is the more effective the greater the contrast between the given tissues; is mainly used when working with data from a computer tomograph.

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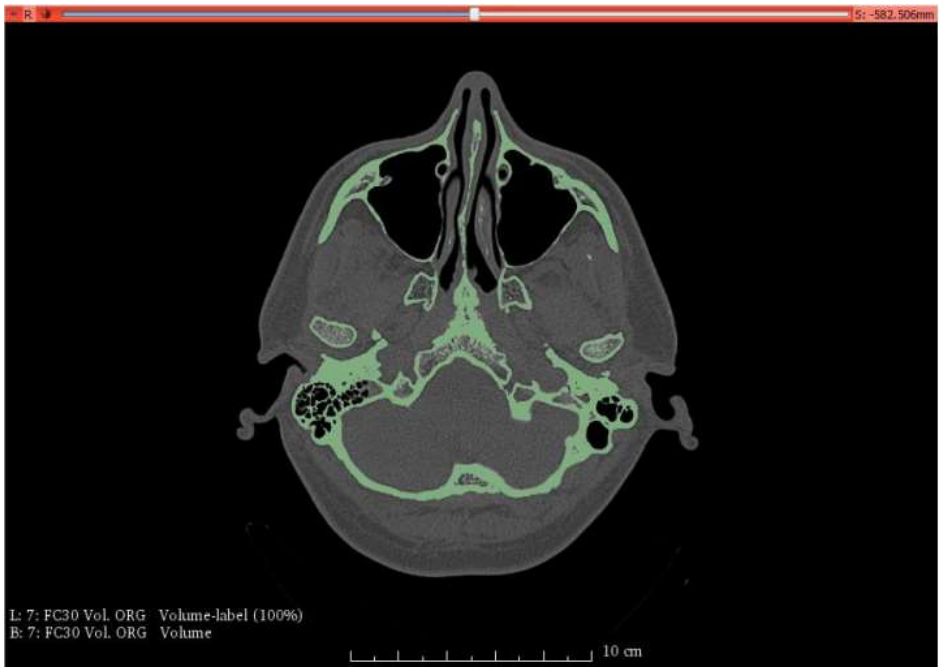

Figure 3.10 3D Slicer segmentation with thresholding, the areas of bone tissue were extracted with green [13]

- The Grow Cut Effect (Figure 3.11): Consists in defining two input areas - the foreground (constituting the tissue to be extracted) and the background, by marking with samples of any shape and color. If there are n elements of a given tissue within the cross-section, n areas should be defined analogously. The growth algorithm, based on the markings made, automatically calculates the size and shape of the area of interest and fills it with the foreground colour, while the rest of the pixels are filled with the background colour. In order to extract the tissue that is the subject of the work, one can use the layer editing function and define the background as transparent. The profitability of using the growth algorithm increases with the decrease in the number of defined foreground elements, and it reaches maximum efficiency in the case of segmentation of compact structures, e.g. tumours or organs.

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Figure 3.11 3D Slicer segmentation with the use of the growth algorithm, the area automatically extracted by the program is marked in green [13]

Technical support is provided through the SlicerWiki platform, where, in addition to the basic issues related to the operation of the program, one can find several manuals, publications and sample applications. Using the help requires access to the Internet.

3D Slicer is free and available to the public. It develops based on the idea of open source and creates excellent opportunities for adding own applications and algorithms as well as modifying the existing ones. It is compatible with all the most popular operating systems (Windows, MacOS X, Linux).

The number of possible segmentation methods allows the qualified user to select the one with the most favourable ratio of working time to the quality of the obtained model. Thanks to this, as new user gain experience in working with the program, the effectiveness of his actions also increases.

3.2.2. **InVesalius**

InVesalius is an entirely free software designed to work with DICOM data, created and promoted by the Research and Development Center of the Brazilian Ministry of Science and Technology (MCT). The source code of the program is freely available and can be modified by

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users in any way, however, InVesalius is also successfully used in its original version by medical units from all over the world (Figure 3.12) [27, 28].

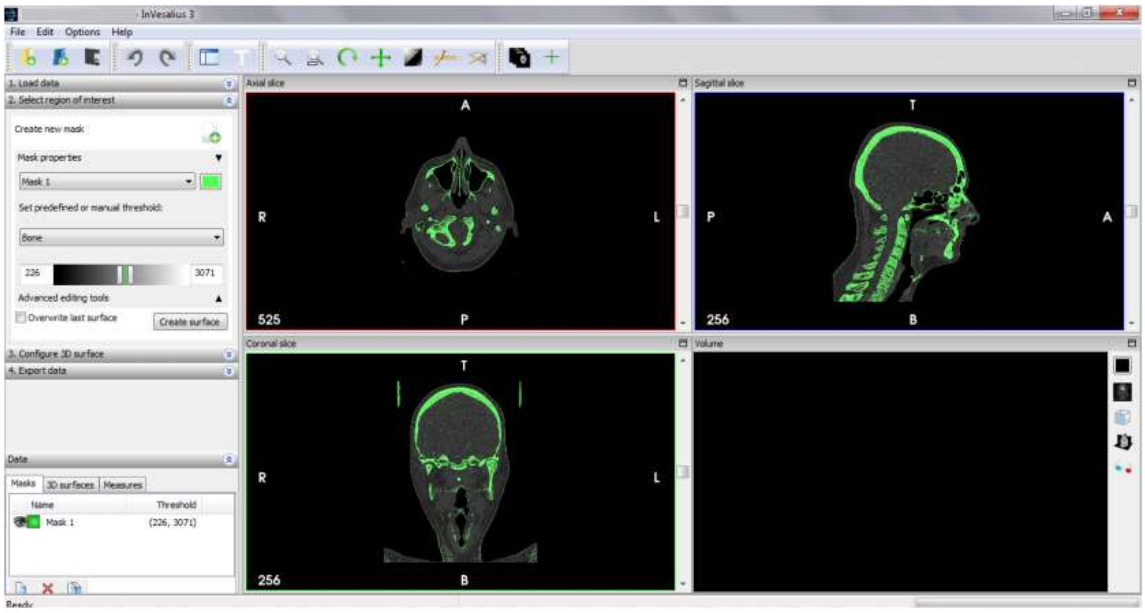

Figure 3.12 InVesalius window with imported DICOM data [13]

The number of tools available in the InVesalius environment is small, so the operation of the program is not problematic. On the left side of the main window, there is a drop-down menu with tabs, and on the ribbon at the top of the window, there are buttons with the most essential functions such as zoom or rotation of the view.

The program has a tool for segmentation through thresholding. The user can use predefined options that enable fully automatic extraction of various types of tissues, including bone, adipose or muscle tissue (Figure 3.13). If necessary, it is possible to designate your own threshold range or modify the existing one. Performing the extraction for a single cross-section result in taking into account segmentation for the entire data set, thanks to which the segmentation process takes place in a very short time.

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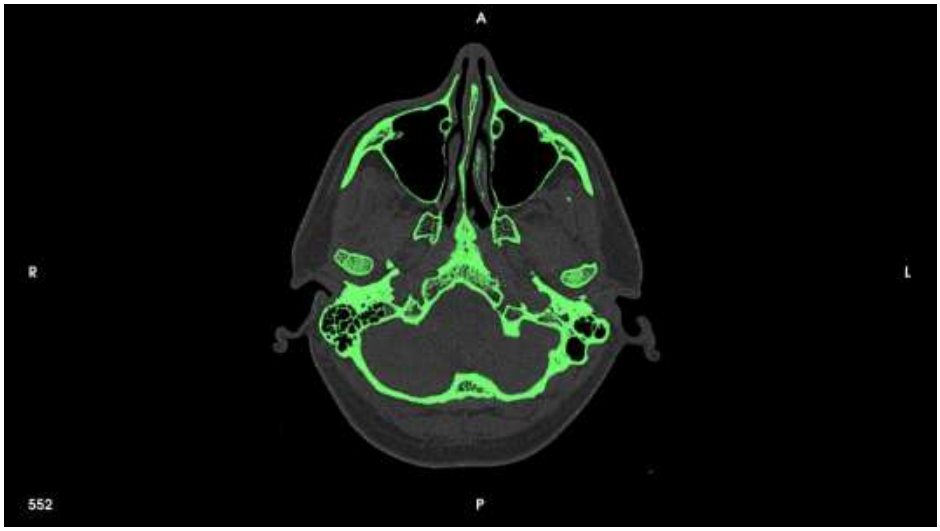

Figure 3.13 InVesalius segmentation using thresholding, the area of bone tissue has been extracted with green.

The program comes with instruction in the form of a text file, which explains the use of the functions available in the program, using examples. It is fully written in Portuguese. InVesalius is a program that is completely free and flexible in terms of making changes to the source code. The manufacturer provided versions compatible with Windows, Linux and selected versions of MacOS X.

Due to the ease of use of the program, work efficiency does not depend on the user's advancement level. The effectiveness of the operations, however, depends on the input data, as the available tools in many cases can make the segmentation process ineffective or impossible to perform.

3.2.3. **MIMICS**

Materialize Mimics is 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 can be found at its website [29].

The software can import medical images via the corresponding wizards and images in DICOM format, images in TIFF or BMP format, as well as images in RAW format. Most often,

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medical images are imported in DICOM (CT, MRI) format and it can be processed in different software, such are: 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 heights, weights, 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 3.14.

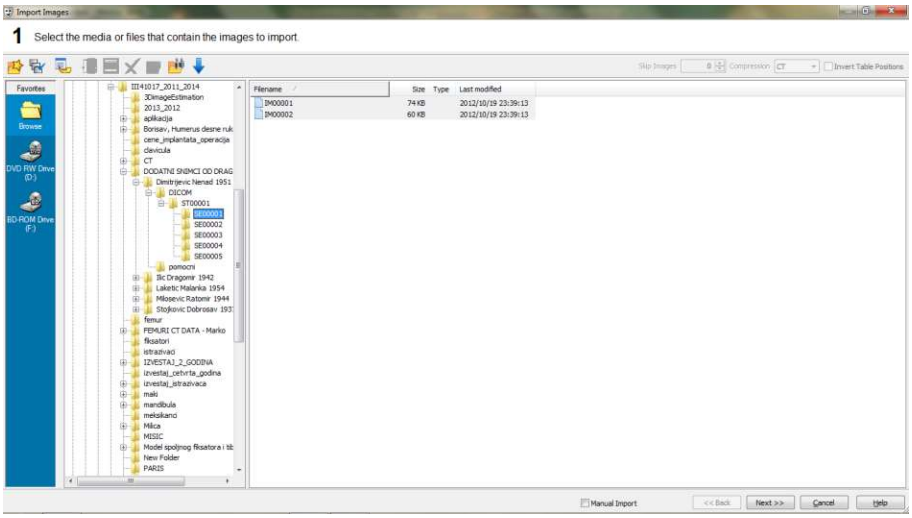

Figure 3.14 CT data import

After selecting the appropriate files, 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 3.15): top (up), bottom (down), left (left), right (right), anterior (front), posterior (back).

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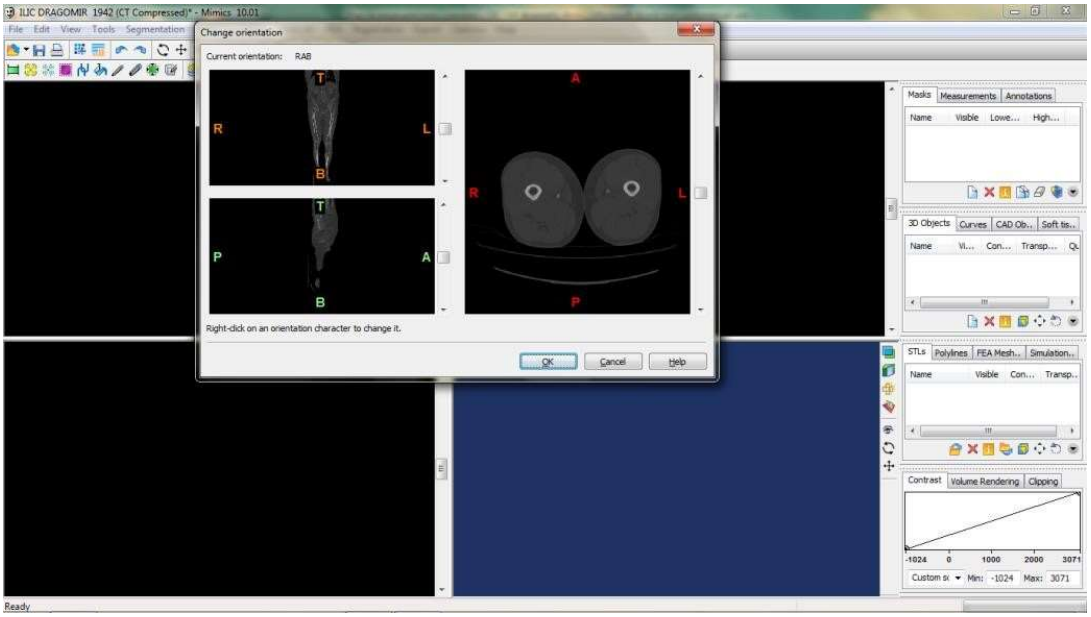

Figure 3.15 Mimics 10 Workspace window

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 3.16. As can be seen from Figure 3.16, it is possible to show all images created on CT scanner, and manipulate them: erase, change contrast and the like.

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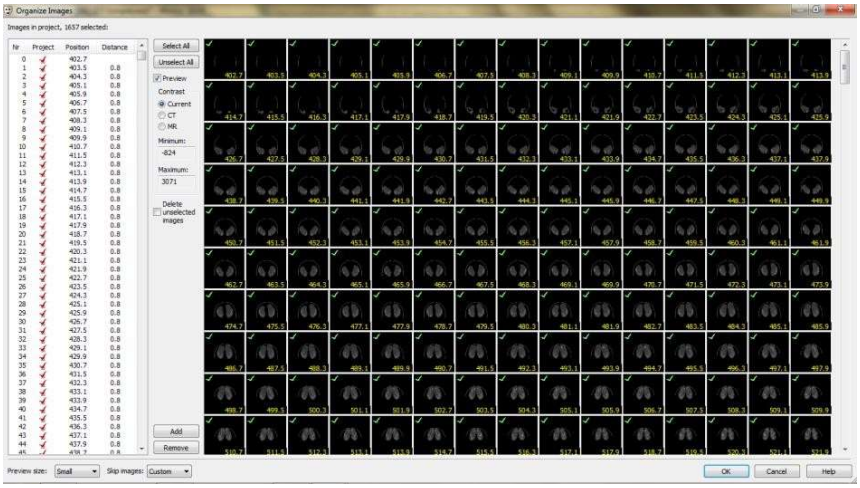

Figure 3.16 Manipulation of loaded images in Mimics software

Defining image contrast (Windowing)

The contrast that defines the grayscale intensities in the projections is defined by the histogram in the frame Project Management window. The histogram defines the variation of gray that it represents Hounsfield units between certain boundaries. Anything below the minimum is shown as black, and everything above the maximum is defined as white, Figure 3.17. Range of Hounsfield unit can be adjusted in several ways , by histogram using a window of a certain projection, or to choose a predefined range of sizes, and a third to simply enter data into the appropriate fields.

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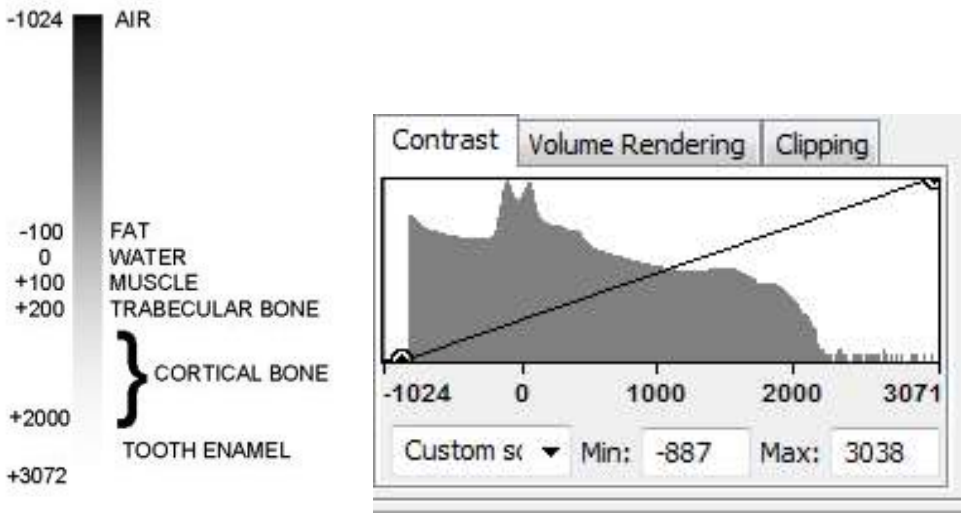

Figure 3.17 Hounsfield values for appropriate materials and histogram

Defining thresholds

Mimics is 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., 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 color 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 3.18 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 3.19. 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.

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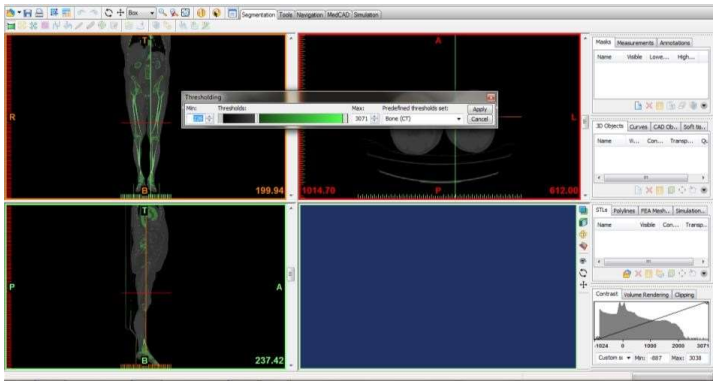

Figure 3.18 Thresholding for hard tissue (bones)

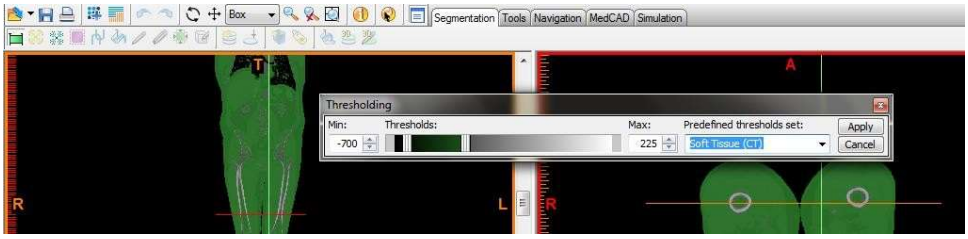

Figure 3.19 Thresholding for soft tissue

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.

Another way to define the range of values that define the mask is via the Profile command. Selecting this option allows you to define a set of values as a profile line drawn in appropriate projection. This command is in the Tools menu. After selecting the given command, it is necessary to draw a line in the appropriate projection by left clicking on the starting point and then the end point. By moving the horizontal line in the diagram, it is possible to define the range values. When the user is satisfied with the achieved, by choosing End Thresholding, process is completed. The user should pay attention to the following: When moving a line there is a change in the minimum and/or maximum limit value as seen in the Thresholding window, which can influence on the created mask. When the process of determining the range of values is completed, a green mask that covers a given range of values is created. The given mask and profile window can be seen in Figure 3.20.

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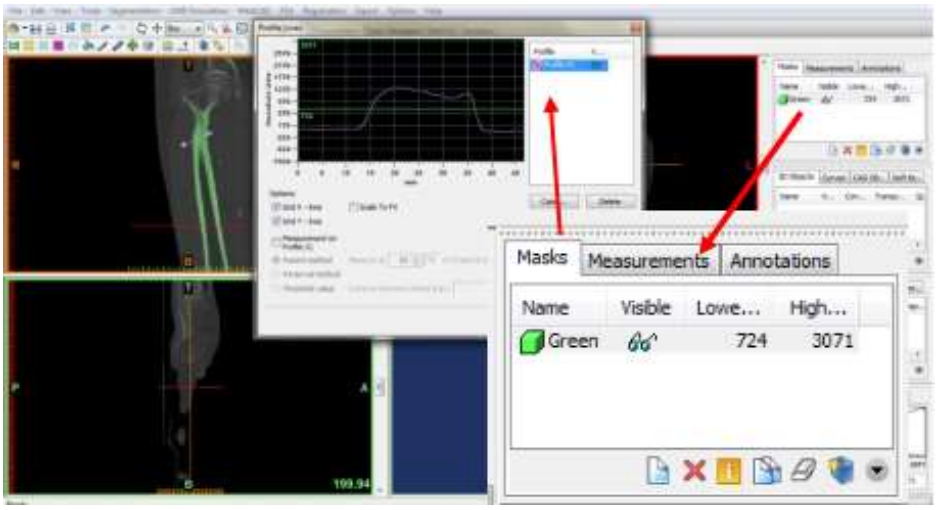

Figure 3.20 Forming the green mask

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 Figure 3.21 and Figure 3.22. 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 3.23 shows the possibilities that can be done with a 3D object. It is possible to apply transformations (rotation, translation), show volume shading, and the like. 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. It is possible to cut a 3D object with certain lines, make a mirror image, etc.

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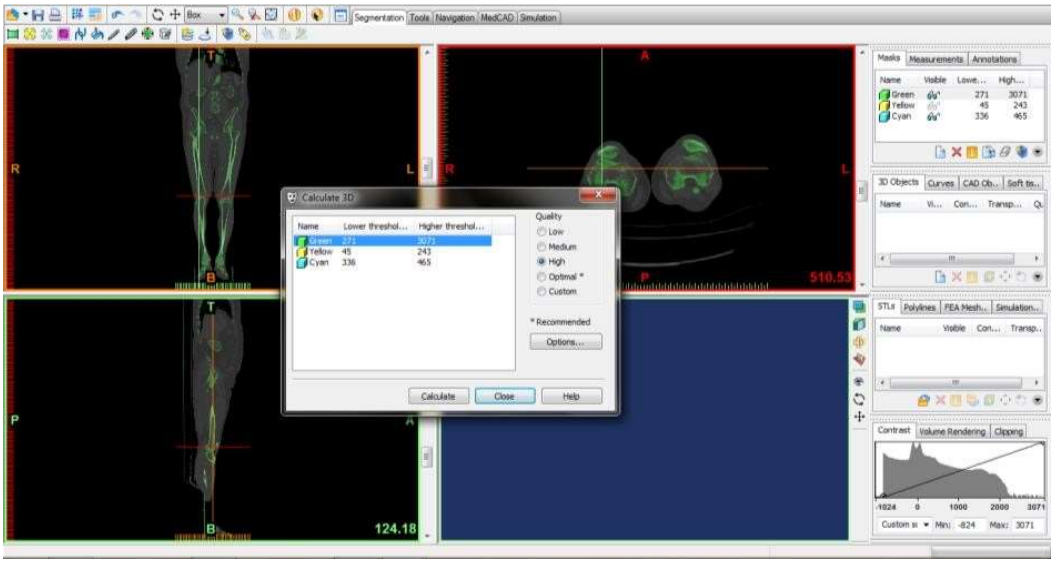

Figure 3.21 Forming the volumetric model

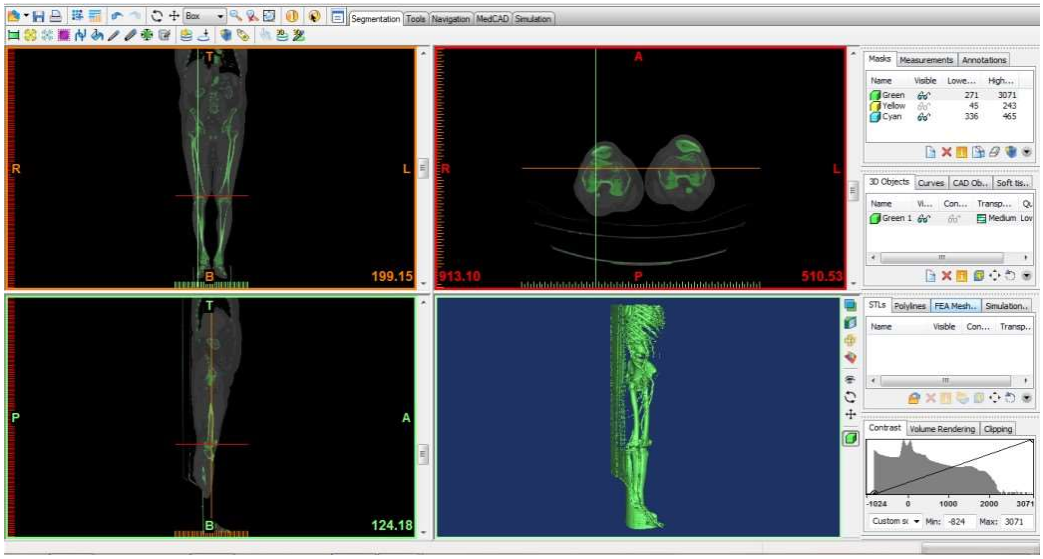

Figure 3.22 Volumetric model

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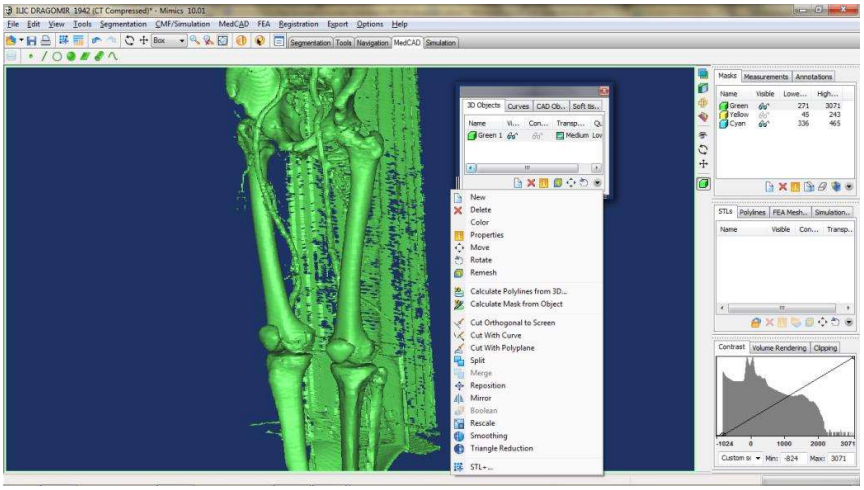

Figure 3.23 3D model manipulation

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 set that when creating a 3D object, a high-quality object is created.

3.3 Design of 3D printed mid-surgery supplies

3.2.1. Design methodology and use cases

The proposed methodology is based on general methodologies available in literature [26, 30]. However, the authors have expanded the existing methodologies with the aspects of clear indication of required skills and involved people and indication of proposed software at each stage, mostly aiming at freeware or open-source software. It can be applied to any type of product created on the basis of measurements of human's internal organs via medical imaging.

Eight consecutive stages can be distinguished, that require at least three separate competence areas: medical technician (stages 1 and 8), biomedical engineer (stages 2-4) and 3D printing technician (stages 5-7). The most demanding stage in terms of skills and time is Stage 4, where a surface and/or solid model must be created. Stage 4 can be especially demanding when Stage 2 is conducted improperly [4]. Stage 3 also requires a large amount of skills of manual processing of 3D mesh.

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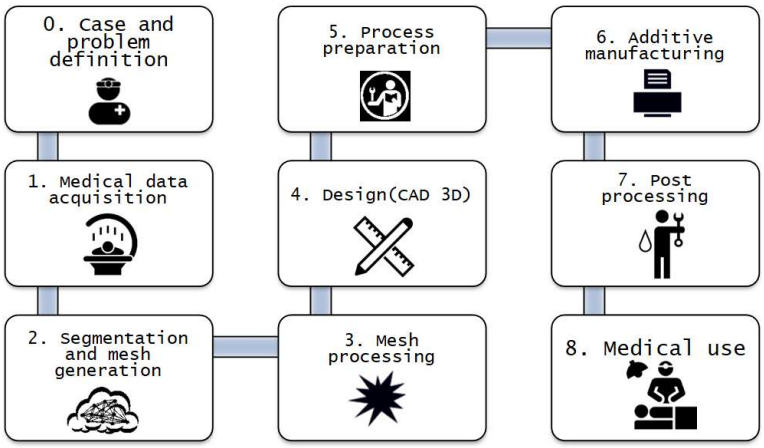

Figure 3.24 Methodology of design and 3D printing of surgical supplies [30]

In this particular module, stages 1-4 are described in greater detail. The other stages are described in other modules – 3D printing, testing etc.

Use cases of this methodology include all the mid- and pre-surgery supplies which could be utilized in order to help a surgeon before or during an operation. The examples include:

- mid-surgery templates for jaw reconstruction surgery [11,30]
- pre-surgery models for eye socket surgery [31]
- knee implant prototype [32]

The first two examples, designed in CATIA, are shown in Figure 3.25 and Figure 3.26. The third example is presented in greater detail in the last subchapter of this section.

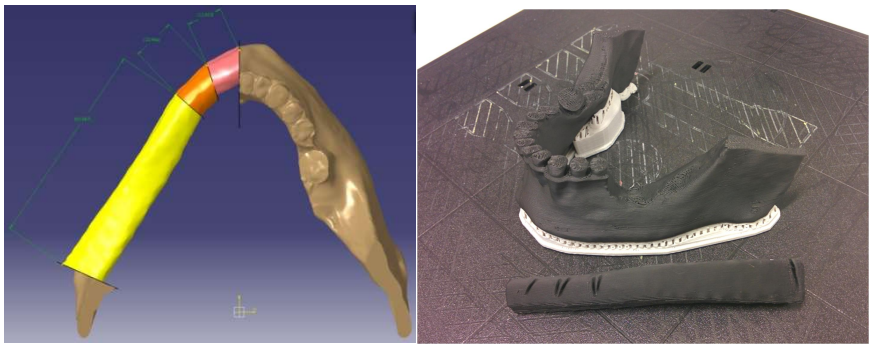

Figure 3.25 Mid-surgery supplies for jaw reconstruction [11, 30]

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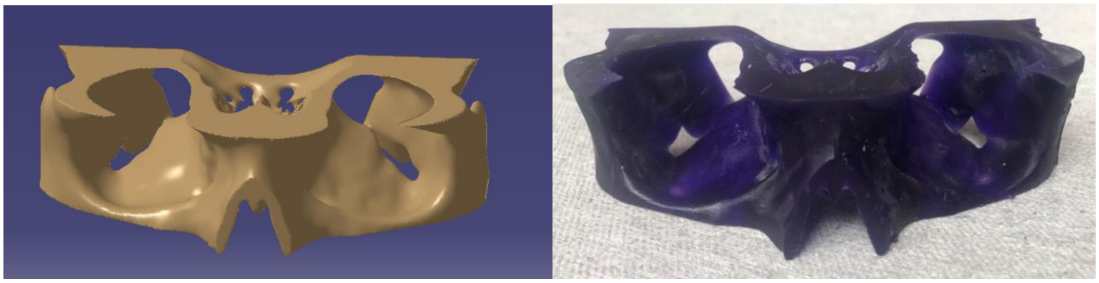

Figure 3.26 Pre-surgery supplies for eye socket reconstruction [31]

3.2.2. CT data processing

The first step in creating virtual 3D models of anatomical structures is to collect input data. These data are most often a digital representation of a diagnostic test, and their quality is primarily determined by the resolution - the higher it is, the smaller the discrepancy between the generated model and the actual anatomical features of the examined structure. The required thickness of a single layer is determined by the complexity of the geometry of the object and its size - for example, for models intended for maxillofacial surgery, the thickness should be between 0.5 and 1 mm. The obtained images are initially saved in the DICOM standard (Figure 3.27).

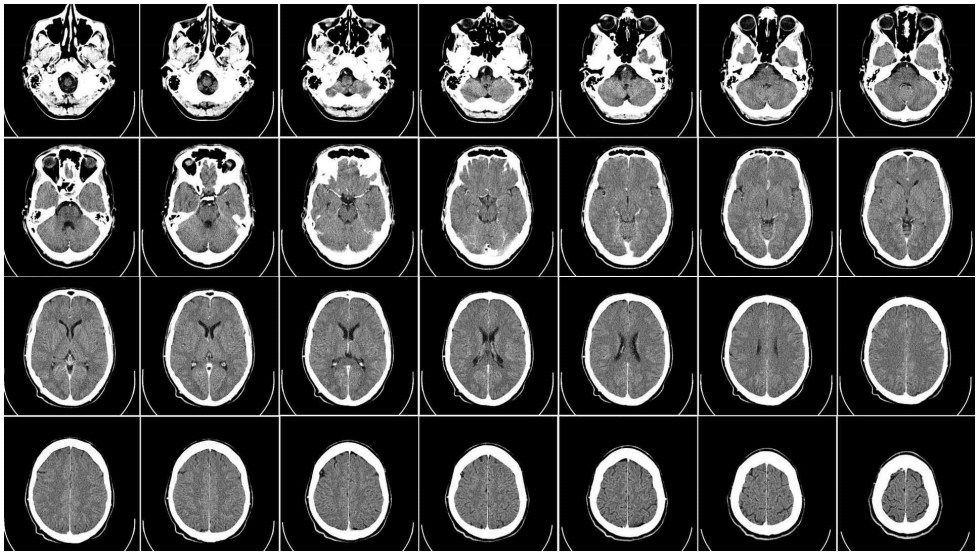

Figure 3.27 Sample DICOM data - head tomography [33].

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Segmentation is a key step in generating 3D anatomical models. Its purpose is to isolate and extract the tested structure from an available data set, which, depending on the work environment, may be automatic or manual. Bringing together the sequence of sections of the specified object results in the generation of a volumetric model (Figure 3.28), Where the quality of a given model depends on the resolution with which the test was performed. Therefore, it can be said that the smaller the distance between individual cross-sections, the obtained the volumetric model more accurately represents the structure being the subject of the work. Such a model, for the purposes of further activities, is transformed into a surface mesh of polygons, most often triangles. This activity is performed by dedicated tools and results in smoothing the surface of the model [26].

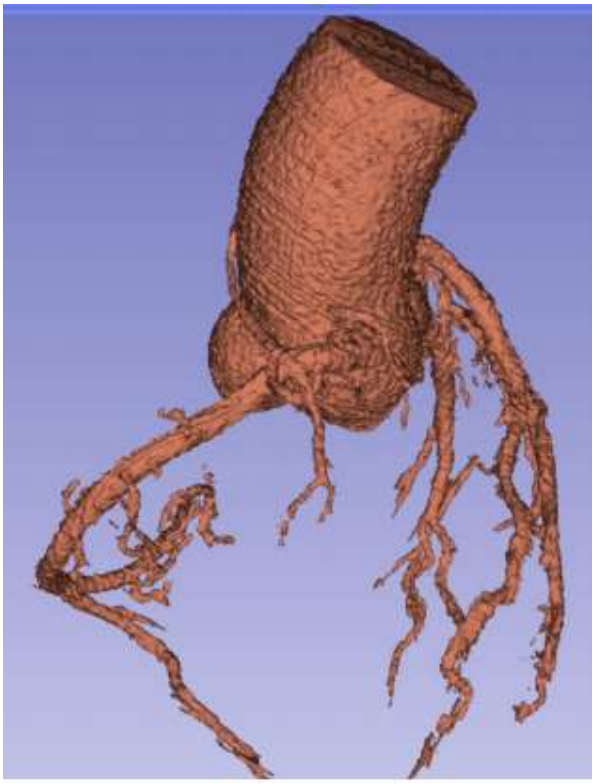

Figure 3.28 Volumetric model - example [34].

It should be remembered that the mesh obtained by segmentation often requires a series of activities, which, depending on the quality of the output model, may include, e.g.

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for removing artefacts, eliminating mesh errors, or eliminating fragments that are not of direct interest. These activities are aimed at the best possible preparation of the model to perform project tasks, the scope of which depends on the specificity of a given case. Due to the difficulties of working with polygon meshes, it is practised to perform transient conversion of the mesh into a solid or surface model for the needs of performing activities typical for working with parametric models in CAD software [35].

3.2.3. CAD design process examples

The first example will be a model of a knee endoprosthesis, on the basis of CT scan. The 3D Slicer software was used for segmentation and mesh generation (Figure 3.29). The obtained mesh was exported to STL format and used as an input data for the design process. The whole process presented in this chapter was realized in Poznan University of Technology and described in the work [32].

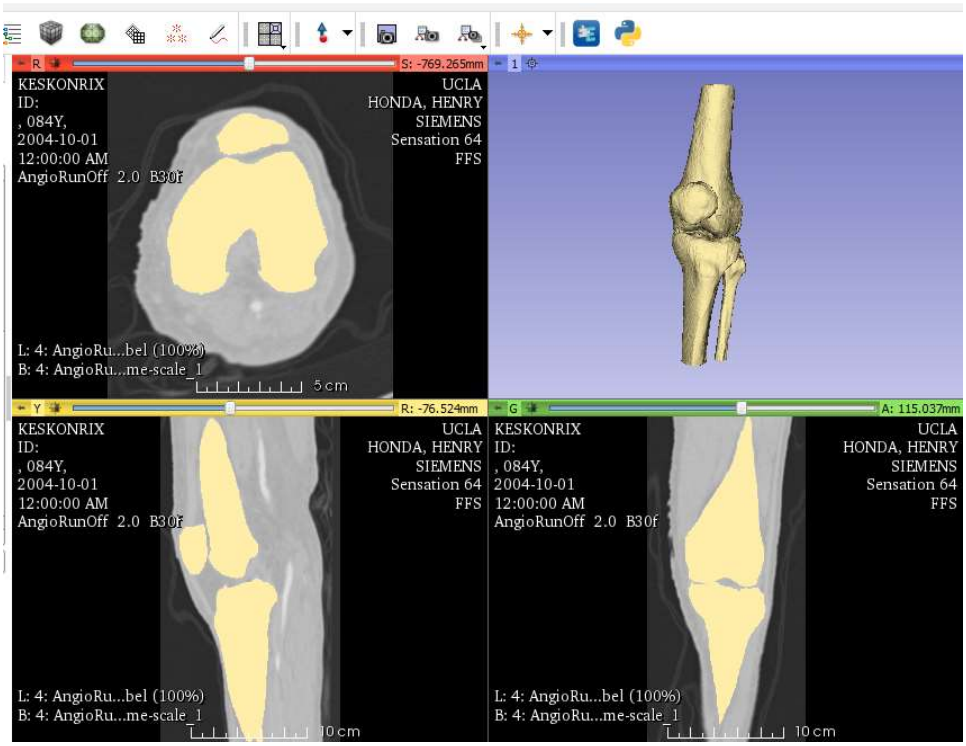

Figure 3.29 Knee mesh on the basis of CT data [32]

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In order to extract two separate models of the femur and tibia from the entire knee joint, the following activities were performed:

- import of a file in STL format,
- removing unnecessary triangles and bones,
- division of the model with a plane,
- removal of triangles related to the mesh of the separated bone, but constituting the remains of the cut out,
- closing the resulting openings,
- repair of a distorted mesh,
- smoothing the surface,
- reduction of the number of triangles,
- file export to STL format.

The GOM Inspect software in the V8 version was used to process the obtained model. It is a free software designed to control and process the mesh obtained by 3D scanning or segmentation of computed tomography data.

Knee prostheses are used to replace the articular surfaces of the femur and tibia, so only models of these two elements were needed for further editing. In this case, the segmentation resulted in all bones in the joint area, therefore the kneecap and fibula should be removed. The first step is to check if these items are related to the others. This can be verified by selecting the Select Patch option and clicking on the desired die. If only the selected item's color changes, it means that it has no connection with the rest, and therefore, it is possible to quickly, automatically delete it using the Ctrl + Delete keyboard shortcut. However, if the color of the selected element and other elements adjacent to it change, it means that the objects are related and must be separated manually. In this model, only the kneecap was not connected to the rest, the remaining bones had to be separated by hand.

In order to obtain separate models of the femur and tibia, perform the Delete By Plane operation (Figure 3.30), available from the context menu Operations-> Mesh-> Other. Operation options allow you to select from among the available planes, set their position and the direction of removal. It is possible to create your own plane beforehand, but with the model oriented in this way, it is suggested to use base planes, in this case it will be the Z plane. After selecting the planes, the divided object must be defined using the Select Patch tool.

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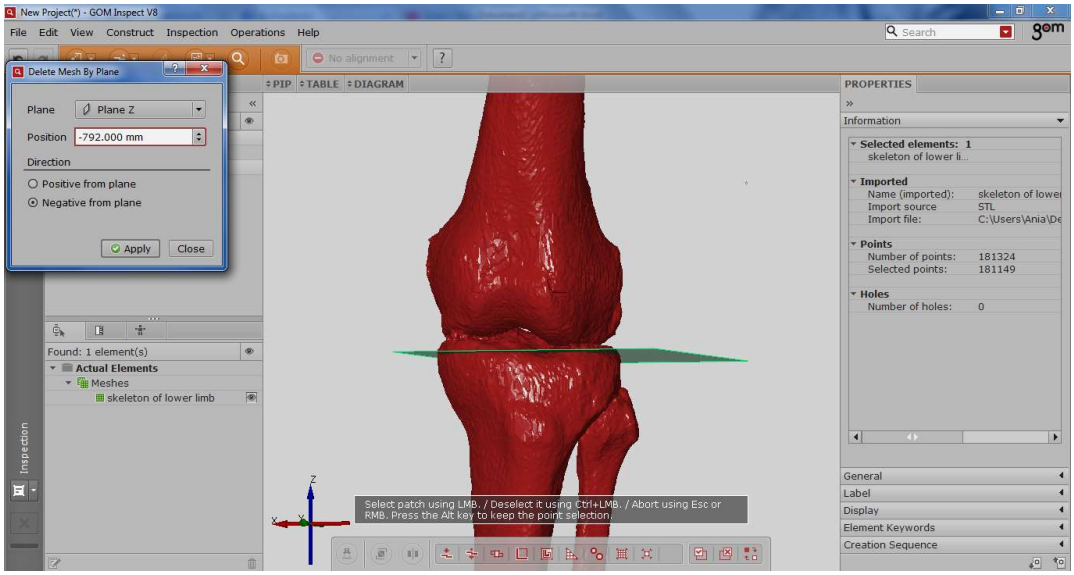

Figure 3.30 Division of two areas in GOM Inspect by "Delete by Plane" function [32]

After the division is made, a model of the femur is obtained with openings and redundant tibia elements. The first step is to remove the allowance using the tools available on the toolbar at the bottom of the screen, mainly: Select / Deselect on Surface, Select / Deselect Through Surface and Select Triangle. Using these options, select and delete triangles belonging to the tibia. After removing the excess triangles, close the openings created during editing. First, however, you need to remove the "free" triangles not related to the model. To do this, the femur is selected using the Select Patch tool, and then the selection is inverted using Insert Selection, allowing you to remove all unnecessary, unbound elements. After that, check the number of holes on the property tab and proceed to closing them. This can be done in two ways available from the context menu Operations-> Mesh-> Close Holes. The first is to use the Close Holes Automatically tool, i.e. the automatic closing of holes. It is possible to adjust it according to the user's preferences. Typically, however, this tool is only useful for closing small holes. The second way is to use the Close Holes Interactively option, which allows the creation of "bridges" connecting the edges of large holes and thus dividing them into smaller ones (Figure 3.31). The last step before exporting the file to STL format is smoothing the surface. Use the Smooth tool to improve the surface

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quality. The work in GOM Inspect ends with exporting the mesh to the STL format. The procedure for obtaining the tibia is analogous to that described above for the femur.

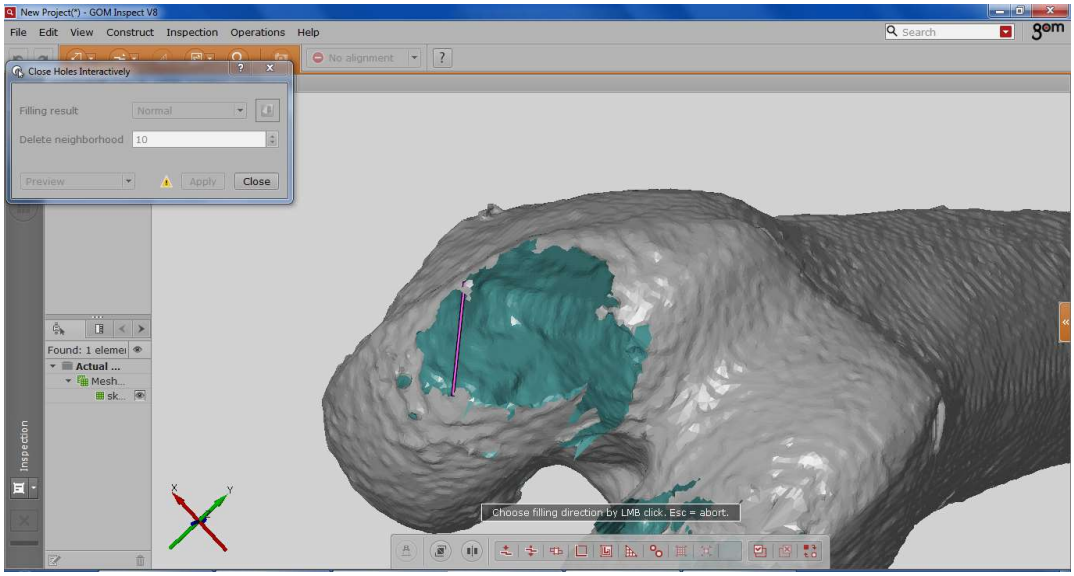

Figure 3.31 Closing holes in the mesh [32]

The endoprosthesis modeling process in the CAD environment is as follows:

- import of a file in STL format,
- conversion to a solid model,
- use of planes to divide the model into bone and implant component,
- creation of pins fixing the endoprosthesis in the place of implantation and the corresponding holes in the bone model,
- export of parts to STL format.

Implant modeling was performed in Autodesk Inventor Professional. The program version was used with the Mesh Enabler plug-in installed, which enables the conversion of STL files into a surface or solid model.

After loading the STL file, it is not possible to perform any editing or mesh measurement operations. To use the original bone geometry, you must convert to a solid model. This is possible thanks to the Mesh Enabler plug-in by adding the Convert to Base Feature to the context menu (available after right-clicking on the mesh). After performing this operation, a solid model is obtained on the femoral mesh. Next, use work points to determine the locations that will be used to create the axis, and then the division planes of the solid. It

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should be remembered that the modeled endoprosthesis should completely replace the damaged articular surfaces (Figure 3.32).

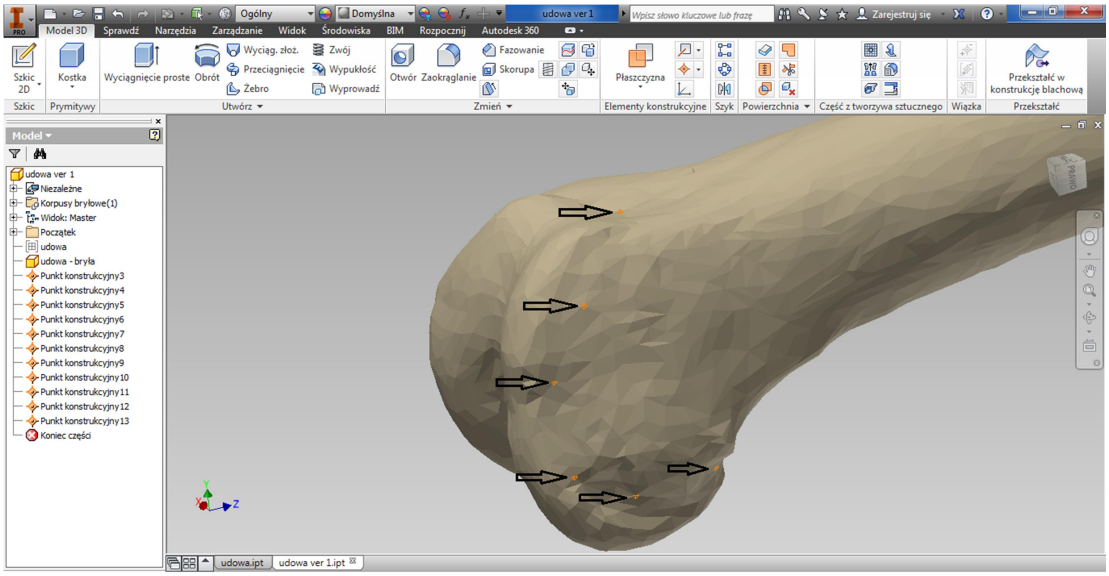

Figure 3.32 Adding points on the imported mesh in the Inventor software [32]

The designated points are used to create construction axes on which the planes will be stretched. The first axis is formed by two selected points, each next axis should be created using the "Parallel to line through point" function.

After the construction axes are properly created, stretch the planes on them by selecting the "Two coplanar edges" option, and then resize them to the area defined by the axes. Using the "Divide" function, separate the solid into a bone and an endoprosthesis component, with the division tools being the previously created construction planes. The number of planes determines the number of division operations. In this case, 5 planes were used, i.e. 5 divisions were made (Figure 3.33). In order to merge the 5 elements that make up the femoral component of the prosthesis, the operation "Create combination" should be performed. This will allow for permanent connection of the implant elements and treating them as one solid.

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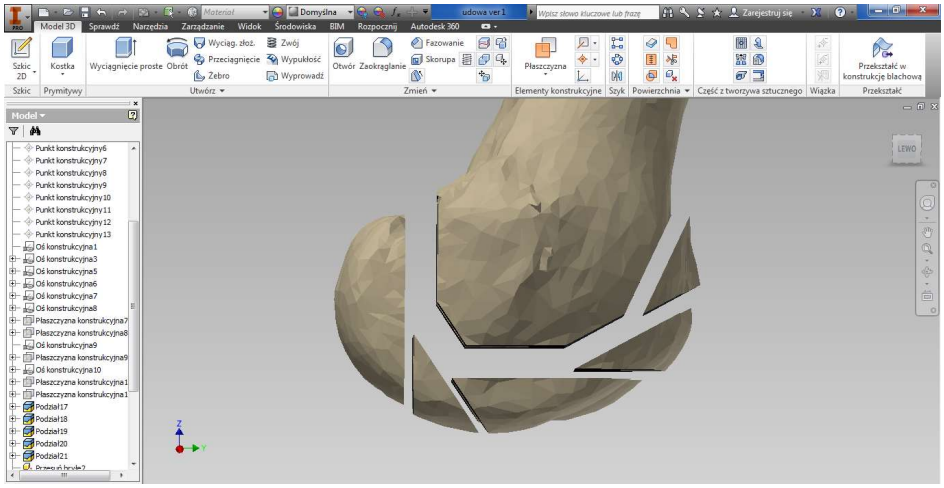

Figure 3.33 Division of the mesh using defined construction elements [32]

The next step is to make the pins securing the endoprosthesis. To do this, make a sketch on a plane perpendicular to the bone axis and draw two circles. Then you use the "Extrude" operation to obtain the selected height of the pins, and "Fillet" with a radius equal to the radius of the previously drawn circles to edit their top surface (Figure 3.34).

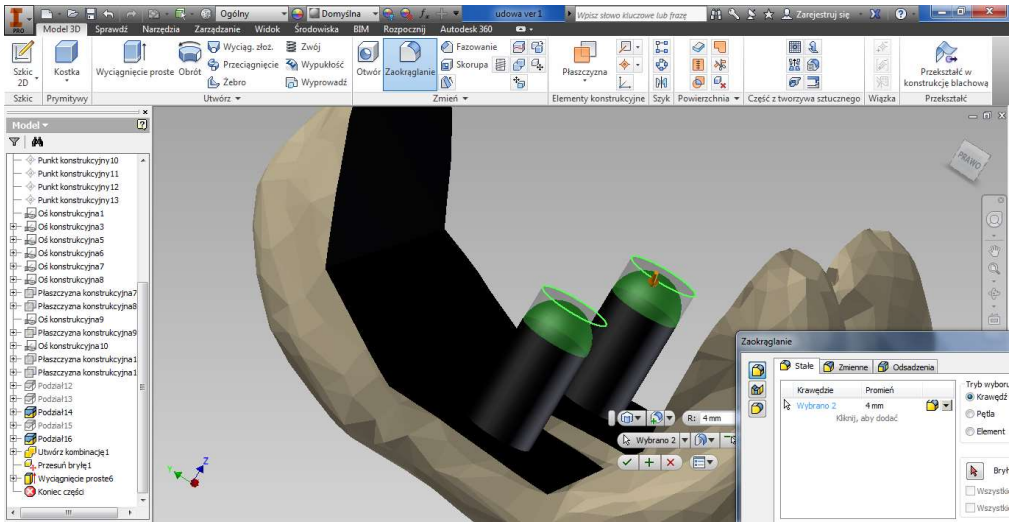

Figure 3.34 Creation of pins for assembling the endoprosthesis with a bone [32]

The modeled retaining bolts must match the holes in the bone. To correctly determine their position, you should create a sketch on a parallel surface, located on a bone model, and

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use the "Project geometry" function to project pins on it. Using the centers of the created circles, outline the holes with a slightly larger diameter (approx. 1 mm), which will allow the elements to fit together also in the event of a slight inaccuracy of the print, and also provide space for the application of bone cement. The hole sketches should be drawn to a depth that is at least greater than the height of the bolts and rounded by the value of their radius.

Due to the large height of the bone model, the solid is divided with a plane, thanks to which a smaller object is obtained, and thus, the estimated printing time will be shortened and the amount of material used will be reduced. The finished models are shown in Figure 3.35.

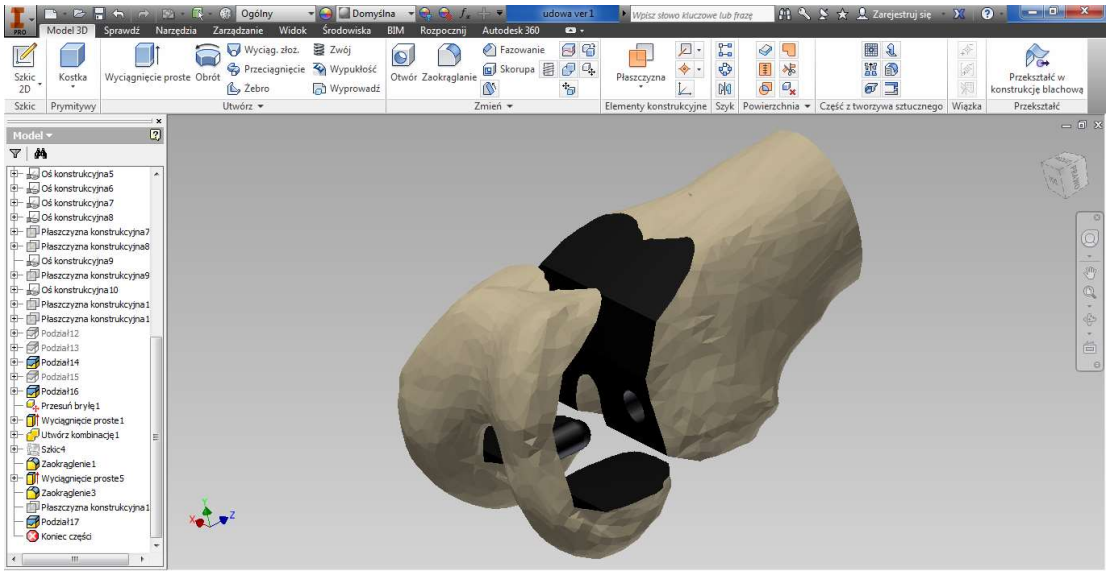

Figure 3.35 Finished model of the femoral bone implant [32]

The methodology of operation for the tibia is the same as described above, therefore only operations that are slightly different will be discussed. The tibia solid model is divided using two construction planes parallel to each other and bone cross-sectional areas. At this stage, it is possible to determine the thickness of the tibial component and the sliding insert.

Create a fastener sketch on the face of a metal component adjacent to a bone. In this case, a pin has been designed with two truncated cuboids, which will fix the position of the implant in the bone. As with the femur, the tibia opening is made by projecting geometry onto its surface. Be sure to design the play in each direction. Connecting the sliding insert with the tibial component is achieved by using the cross-sectional geometry projected onto

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the plane, reduced by the "Scale" function and extended towards the implant part in order to cut the appropriate shape. The same should be done in order to model the insert fixing element in the component, with the difference that the projected geometry must be made on a minimally smaller scale and extended to a height less than the hole depth. As a result, this connection also has a play that allows for inaccuracies in execution and also allows the use of bone cement to connect the two elements. The obtained elements are shown in Figure 3.36.

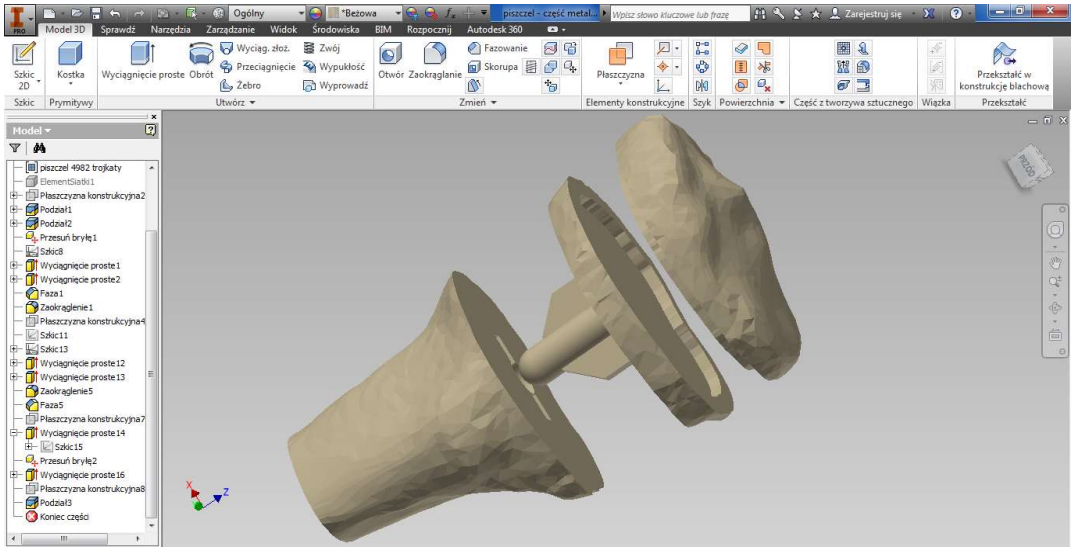

Figure 3.36 Elements of the knee implant – tibia [32]

The whole was printed from ABS material using FDM technology. The assembled implant prototype - potentially for use in the process of bone surgical development - is shown in Figure 3.37.

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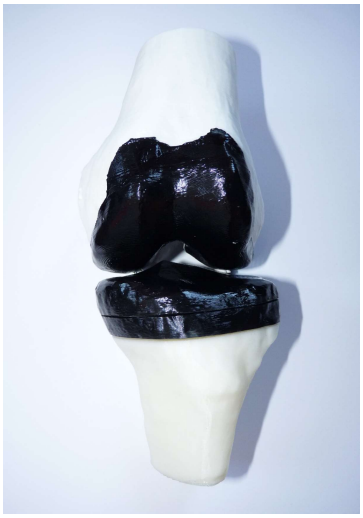

Figure 3.37 Result of the work – 3D printed implant prototype [32]

The second example will be a bone model. Based on the point clouds obtained by using image diagnostic methods and Mimics, the CATIA software package was used for the creation of initial 3D polygonal mode. The whole process of initial processing of point clouds is performed in the Shape module - Digitized Shape Editor, which is shown in Figure 3.38.

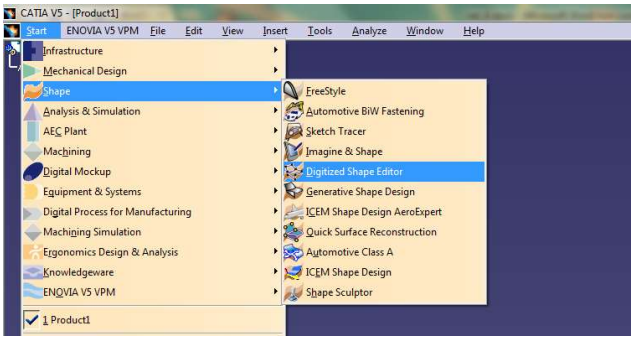

Figure 3.38 Digitized Shape Editor

The first step is to import the STL model into CATIA. The option that enables this is the Import Cloud Option in the Import palette. Imported models can be in the form of point clouds, but they can also be polygonal models (in this text we will use the point cloud as the general name). After the import of point cloud, the next process is processing the point

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cloud model in terms of removing unnecessary points, filling holes and the like. The first step involves removal of points located outside the border area of the femur. It is possible to remove points on the whole model or to use Activate option to select only a specific group of points on the cloud point or triangles on a polygonal model. Points are removed using Filters intended for processing imported point clouds. One of the filters is a filter that removes excess points (Remove option) and is shown in Figure 3.39.

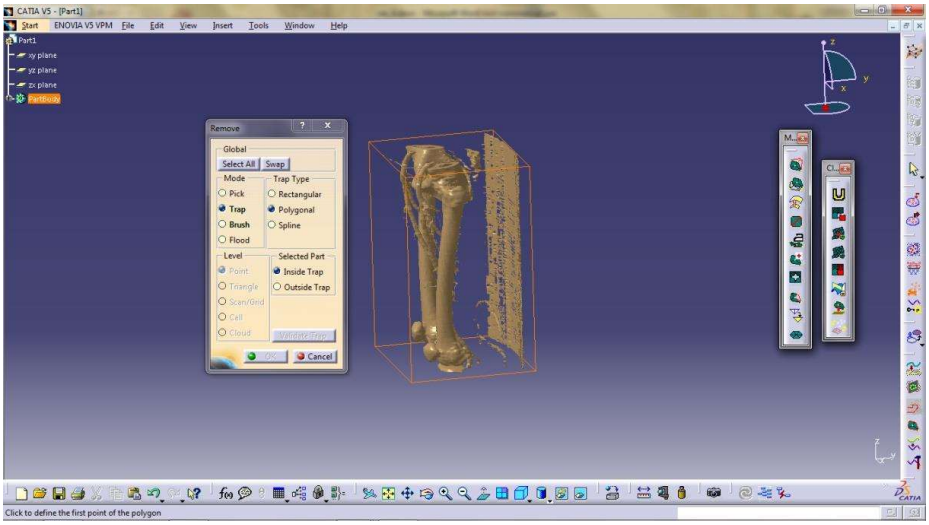

Figure 3.39 Filtering point cloud (Removing unnecessary points)

This filter allows to select the area to be removed by selecting Mode, which may be:

- Pick - This is the only mode in which it is possible to select directly by clicking the mouse on the screen a certain element, which can be: point, triangle, scan, grid, cloud
- Trap - Include a part of the point cloud that needs to be discarded
- Brush - Same purpose as in image processing programs. It is removed with a brush stroke of unwanted points. The size of the brush radius is defined from the context menu (right mouse click)
- Flood - Removes all associated (connected) triangles starting with the selected triangle. Which triangles will be selected depends on the angle between their normals. The angle is defined from the context menu. If the angle is not defined then all connecting triangles will be removed.

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Trap Type - Defines how triangles or points in the cloud will be selected points. It is possible to select a rectangular selection, via a polyline or via a spline curve. All the above options also apply to the Activation command which is selected from the the Cloud Edition toolbar. It is important to note that whether activating or removing part of the point cloud, it is possible to select several parts of the imported point cloud in one step. For each selection, it is possible to select Validate Trap and thus the previously selected selection is placed in memory. It is also possible to replace the selected part of the point cloud with the Swap command. The Remove / Activate dialog is shown in Figure 3.40.

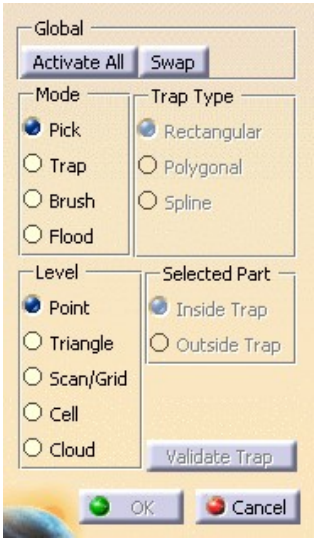

Figure 3.40 Manipulating points in the model

After filtering the initial imported model, the process of tessellation, i.e. creation of polygonal/triangle model is performed. This procedure is performed by the technical element Mesh Creation, and it is presented in Figure 3.41.

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Figure 3.41 Creating a polygonal model with the technical element Mesh Creation

The options of this technical element are:

- 3D Mesher - Creates a 3D polygonal model based on the selected point cloud or initial polygonal model. Intended for processing complicated point shapes.
    - The sag option allows you to filter out too dense point clouds. Shape is preserved, but points below the defined value are removed.
- 2D Mesher - An option designed to create polygonal models from simpler ones point clouds. In principle, it works great with continuous surfaces, as well as those which can be projected on one plane.
- If 3D mesh is selected, pay attention to segmentation, and if 2D is selected, the proper projection plane should be chosen.
- Neighborhood value defines the longest side of the triangle, ie the largest distance between two points in a triangle.
- The display option affects the model display or light calculation. For complex polygonal models, it is desirable to turn off the display of triangles and include shading.
- The constrained option is intended for post-processing of a polygonal model, like adding additional points, and can also be used to connect multiple polygons.

In principle, when creating complex polygonal models, it is possible to use activation to define only individual parts, then connect them as constrained, or to connect via Merge

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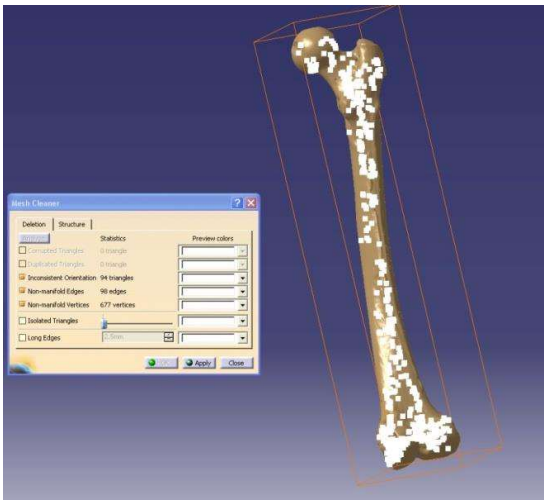
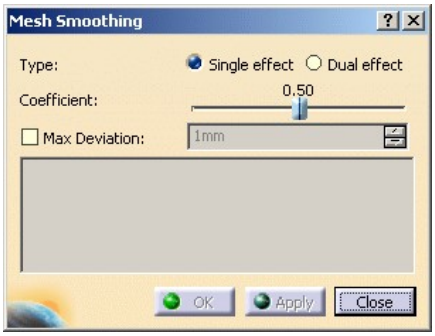
Meshes technical element. There are some other options that can improve the final polygonal model, and they are: Fill Holes -

Hole Filling (Figure 3.42a), Mesh Cleaner – Adjusting the Polygonal Model, like make it manifold (Figure 3.42b), Mesh smoothing – Softening the polygonal model (Figure 3.42c)

a) Fill holes



b) Mesh cleaner



c) Mesh Smoothing

Figure 3.42 Different operations with a polygonal (mesh) model

After healing of the polygonal model (Figure 3.42), the model is ready for further processing, i.e., to generate other model types (surface, volume). At the end of the process, model like one shown in Figure 3.43 can be obtained. Additional processing can be done in other CATIA modules.

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Figure 3.43 Formed Model

3.4 Design of orthopaedic and prosthetic equipment

3.3.1. Process methodology

The solution presented in this chapter is a part of a project focused on rapid manufacturing of orthoses and prostheses, named "Automation of design and rapid manufacturing of individualized orthopedic and prosthetic products on the basis of data from anthropometric measurement". A concept of the methodology behind the work of a prototype system is presented in Figure 3.44, as well as in publications [36, 37]. The process is a modern one – as opposed to a traditional process of manufacturing orthopaedic equipment, which is manual, the modern process relies on digital data. The proposed process could be used to produce any type of individualized orthopaedic or prosthetic device.

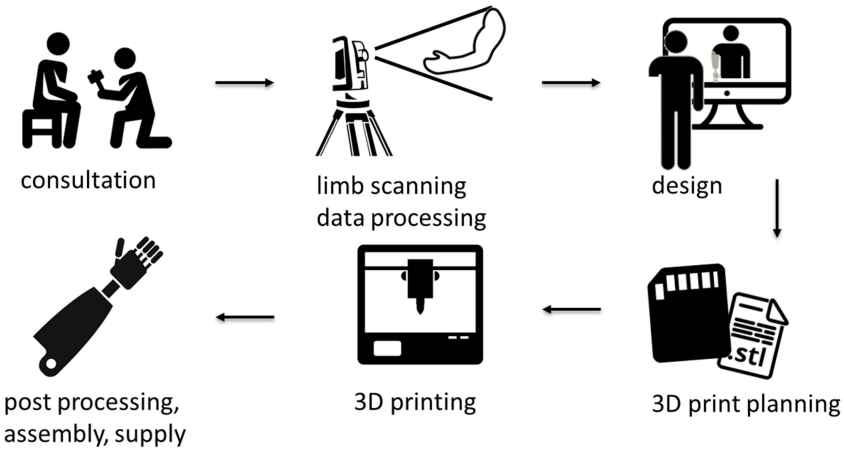

Figure 3.44 Methodology of design of 3D printed orthotic and prosthetic supplies [36]

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The process starts with measurement. Most of measurements are made digitally, by 3D scanning of patient's limbs. Then, the measurement data is processed to obtain a digital image of a full limb. This is an input to a computer aided design software, where a parameterized 3D model of a prosthesis, or orthosis is created. The patient also should be able to customize the product, as in selecting the color or material.

The model could be parameterized for design automation – the basic parameters can be stored in an external file (e.g. Excel spreadsheet), so if we supply a set of measurements from another patient – it automatically reshapes itself with no further action needed in a CAD system. After the design is finished, the parts are send for 3D printing.

The types of orthopaedic devices made this way could be prosthetics or orthotics – examples are shown in Figure below. The further subchapters describe the data processing and design of the orthopaedic supplies.

Figure 3.45 Examples of orthopaedic supplies made by 3D printing on the basis of 3D scanning [37]

3.3.2. 3D scanning and data processing

The 3D scanning of patient's limbs can be realized using manually operated 3D scanners or stationary, larger scanners. The two variations are presented in Figures below.

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Figure 3.46 Manual 3D scanning of patient limb (EinScan Pro)

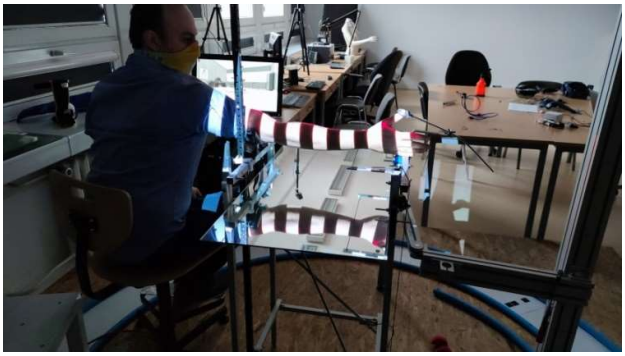

Figure 3.47 Semi-automated 3D scanning using a stationary scanner (David SLS-3 on a custom-made automated trolley)

The data processing is shortly presented in Figure 3.48 and illustrated in Figure 3.49. In general, it focuses on obtaining a clean representation of a selected fragment of a given limb, of which data can be extracted for further design in a CAD system.

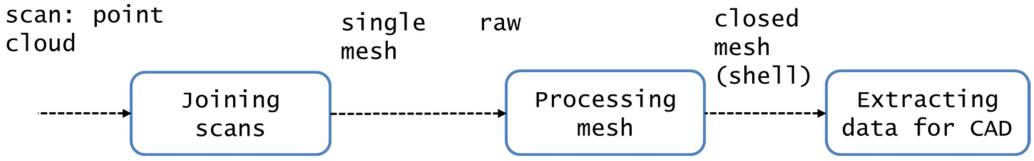

Figure 3.48 3D scanning data processing

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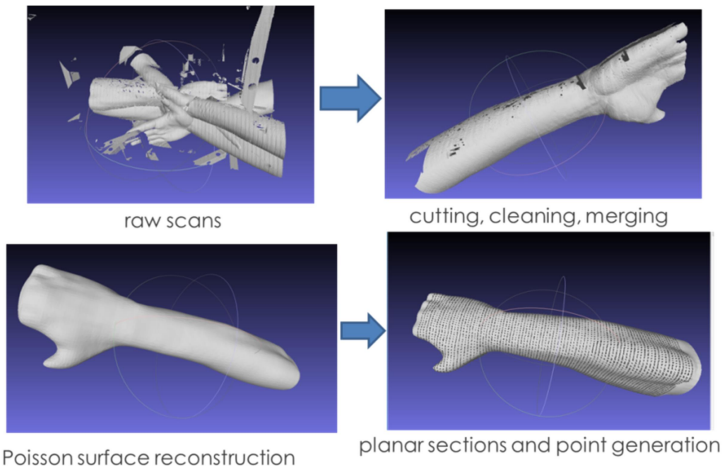

Figure 3.49 3D scan processing (MeshLab)

The process consists of the following stages:

1. Combining scans
    - background cleaning,
    - geometric transformations (rotations, translations, mirror),
    - best fit.
2. Cleaning and processing the resulting scan (Figure 3.50, Figure 3.51)
    - deleting unnecessary data,
    - closing holes,
    - smoothing,
    - removing artifacts, repairing
    - triangle reduction, reconstruction (optional).
3. Data extraction (Figure 3.52)
    - manual and automated measurements,
    - creating sections,
    - save to txt and workbooks (Excel).

The subsequent stages are illustrated on the Figures below.

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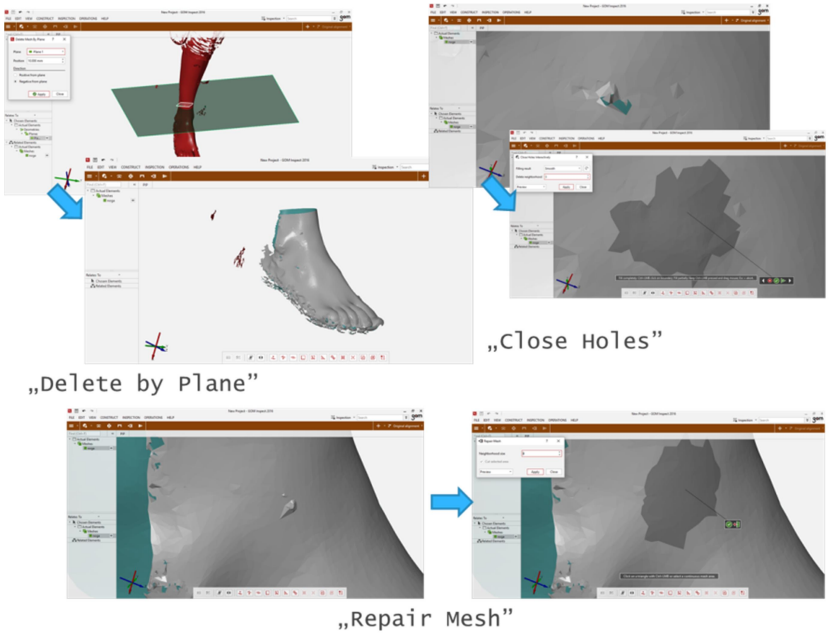

Figure 3.50 Mesh processing – cleaning, repairing (GOM Inspect)

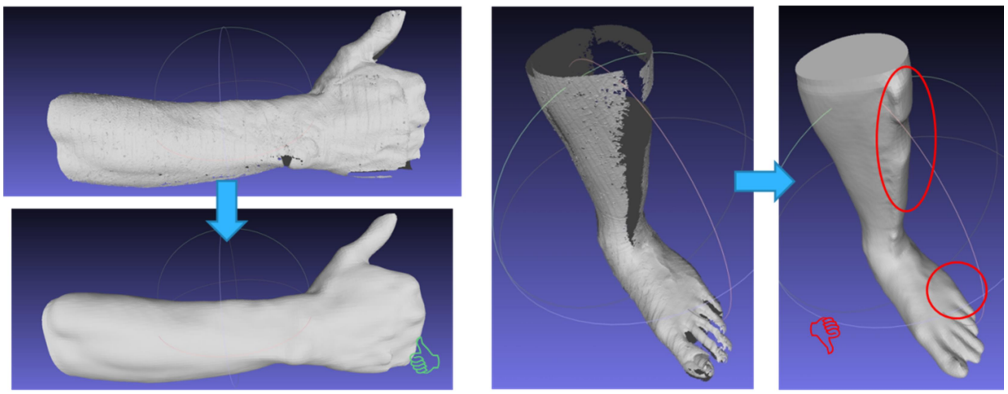

Figure 3.51 Mesh processing – limb reconstruction, successful – to the left, failed – to the right (wrong/missing scan data)

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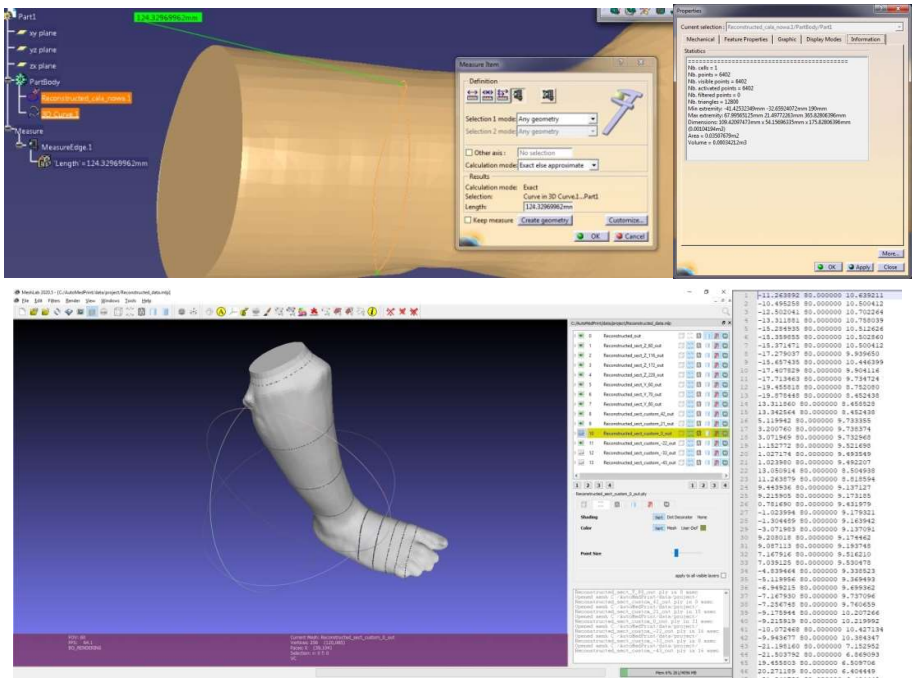

Figure 3.52 Data extraction – manual/automated measurements (CATIA), creating and exporting sections (MeshLab)

The first stage could be done entirely automatically by scanners' software, especially in more expensive 3D scanners. If it isn't, it must be done manually, which is often the case when cheaper or custom scanners are involved. There is a number of available tools in software such as GOM Inspect or MeshLab, allowing geometrical transformations and some semi-automated algorithms ("best fit").

The second stage could be fully automated (cleaning via predefined planes, removing all isolated mesh patches, cleaning errors and wrongly placed vertices/triangles, cleaning all holes) or done manually (selection of triangles in a given area and applying specific filters, such as smoothing or repairing). Some CAD systems allow to perform these operations – e.g. CATIA V5 in its Digitized Shape Editor, as shown previously in the chapter 2.

The second stage finishes in generation of a closed shell, which could be converted into a solid. It could be achieved by thorough cleaning and closing holes, or by reconstruction (e.g. Poisson reconstruction algorithm), which is also good for reducing mesh size, albeit can result in shape errors (as visible in Figure 3.51).

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The third stage is related to the way of conduct. There are three possible solutions – the reconstructed closed mesh can be used as a base for CAD modelling (converted to surface or solid – in which case no other actions are taken at this stage), certain point data could be extracted to create a parametric limb representation in CAD or measurements of the limb (lengths, widths, circumferences) can be used selectively as input parameters (dimensional constraints) for building CAD models. The latter does not involve creating limb's representation in CAD, so in many ways it is a regular CAD design process (with predefined constraints). The first two are presented in the next subchapter.

3.3.3. CAD design of orthopaedic supplies

Basing on the 3D scan processed data, a 3D model of an orthosis or prosthesis can be created in CAD software. There are 2 possible approaches in the design of anatomically fit devices:

• non-parametric ("shell") - conversion of the mesh (e.g. of a hand) into a „dumb" 3D model,

• parametric ("spline") - parametric reconstruction of anatomy in the form of a surface or solid model using a series of closed spline curves obtained as a result of mesh sections.

The resulting solid (parametric or non-parametric) is subjected to offset and further modeling operations in the CAD system.

Data needed in the "shell" approach:

• complete, closed, „waterproof" STL mesh,

• characteristic distances - dimensions, distance range,

Data needed for the "spline" approach:

• a series of selected coordinates of points that control spline curves,

• characteristic distances - distances of planes with curves.

The two approaches are presented in greater detail in Figures below.

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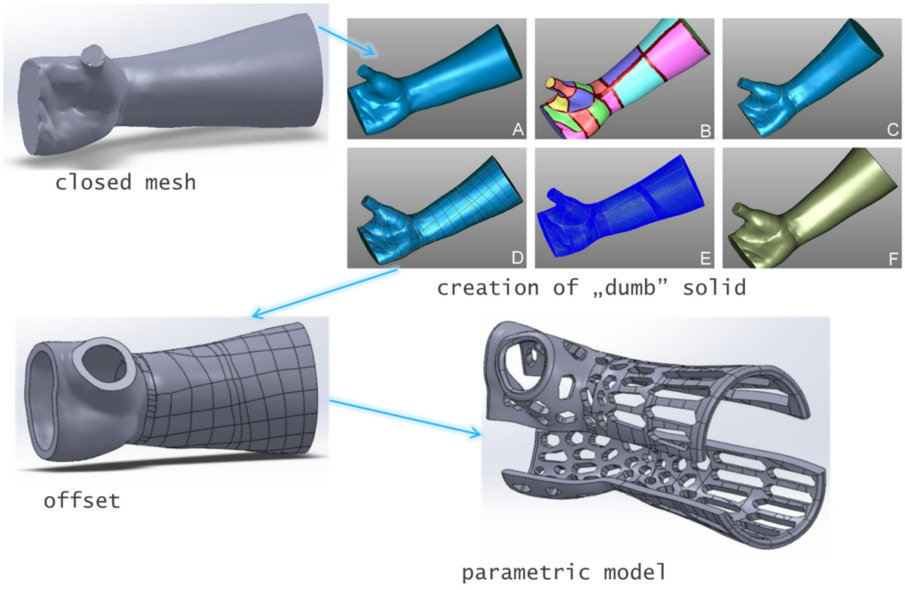

Figure 3.53 The "shell" approach to design of individualized orthoses

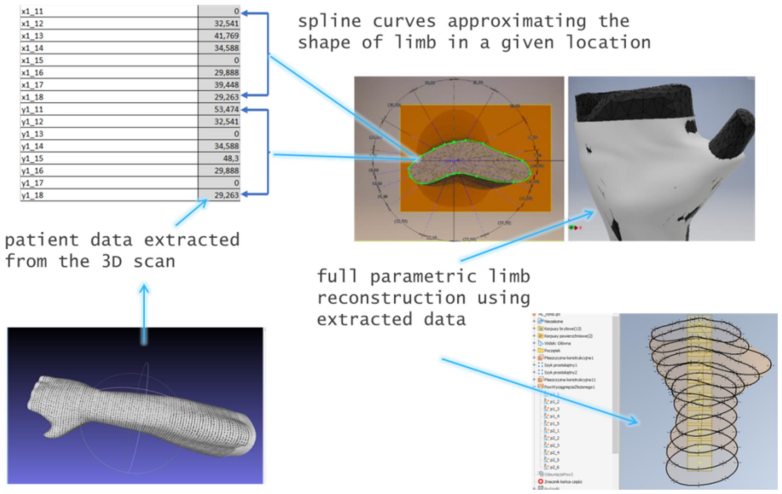

Figure 3.54 The "spline" approach to design of individualized orthoses

3.3.4. Selected cases

The first case is a model of a wrist hand orthosis (WHO), on the basis of the "spline" approach. The model is fully parameterized and its parameters are stored in an external

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Excel sheet, to which data is supplied by extraction of section points from a reconstructed limb model.

The following assumptions were made in the construction of the auto-generating model of WHO orthoses:

1) The basis for creating the outline of the orthosis is the so-called multi-section solid, ie a 3D solid spread over a group of spline curves (spline), placed on planes parallel to each other (Figure 3.55). These curves are made of points whose coordinates come directly from the measurement data, i.e. a 3D scan of the patient, processed with the MeshLab software and an automated Excel spreadsheet.

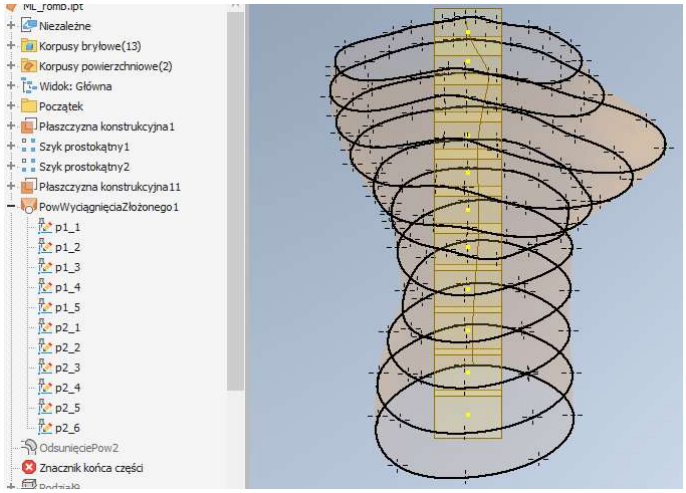

Figure 3.55 Multi-section solid for the WHO orthosis - visible outlines of sketches and planes

2) Cross-sections made in the MeshLab software are created at a distance of 2 mm. From all the sections, 11 representative sections are then selected - 5 representing the forearm and 6 - the wrist and hand. Sections are selected based on manual forearm measurements entered into the software (Scan Assistant) during the 3D scan or later to the patient data file or directly to the Excel spreadsheet. The measurements are made in accordance with the diagram shown in Figure 3.56.

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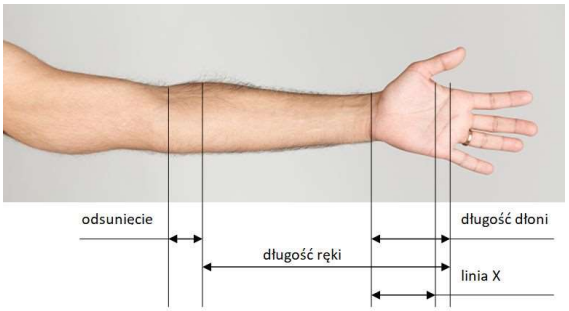

Figure 3.56 Diagram of auxiliary manual measurements of the forearm for the design of the WHO orthosis

3) For the 5 sections representing the forearm, curves consisting of 8 points are created, and for the remaining 6 sections - curves consisting of 18 points, as shown in the examples in Figure 3.57.

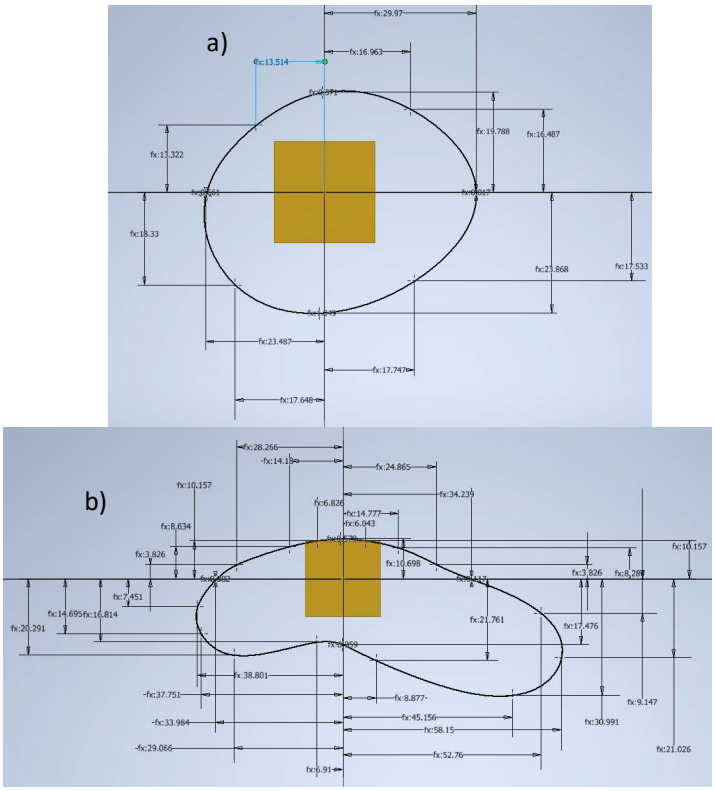

Figure 3.57 Examples of sketches in the WHO brace model - a) 8-point (forearm) b) 18-point (palm)

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4) On the basis of the base body, the orthosis shell is created - the contour moved away from the base body by a controllable distance (play) within the range of 0.5 - 3 mm. The shell is cut with planes to create a full contour of the orthosis (Figure 3.58). The standard accepted thickness of the orthosis is 4 mm.

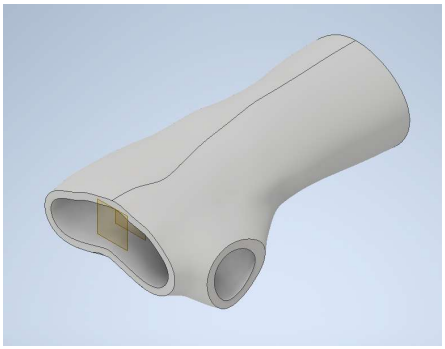

Figure 3.58 The shell of the WHO orthosis

5) The outline of the orthosis is divided into two halves in such a way that the division is in the thumb hole (Figure 3.59).

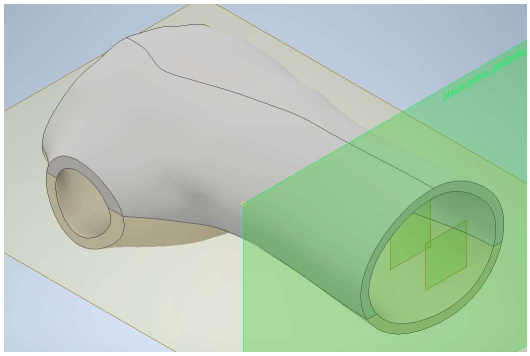

Figure 3.59 The shell of the WHO orthosis divided into two halves

6) The openwork is parametric and can take one of three forms: standard curvilinear, rhomboid and hexagonal (Figure 3.60). In special situations, the openwork may be completely disconnected, and a monolithic orthosis is obtained (e.g. for therapeutic purposes, if it is made of a flexible material, such as TPU).

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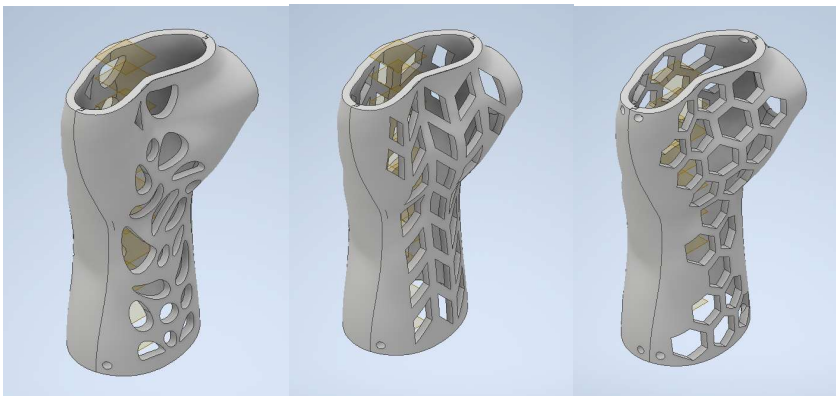

Figure 3.60 Three types of openwork in the WHO orthosis, from the left: curvilinear, rhomboidal, hexagonal

7) The two halves are joined by a form fit - a groove is generated in one of the halves, and a projection in the other with the same course (along the dividing line) as shown in Figure 3.61. In addition, the halves of the orthosis have holes that allow them to be attached to the patient's hands with disposable polymer clips.

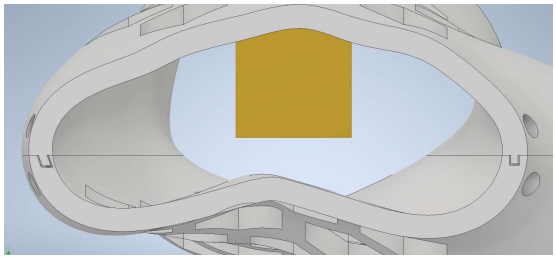

Figure 3.61 The method of joining the orthosis halves - groove and slot in both halves, holes for polymer clips are also visible

8) The edges of the model are rounded to eliminate uncomfortable sharp edges in use (especially in the area of the thumb - Figure 3.62).

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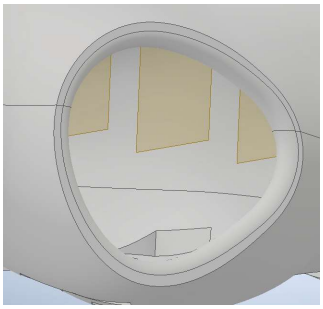

Figure 3.62 Filleting the WHO orthosis model in the area of the thumb

9) The orthosismodel has a max. 140 mm long - the size is selected depending on the patient's height (for patients below 160 cm it is 120 mm, in the range 160-190 - 130 mm, over 190 - 140 mm). The correctness of the model execution is assumed for patients over 12 years of age (the autogenerative model was tested on this target group).
10) All parameters of the auto-generating model are saved in a dedicated Excel sheet (Figure 3.63). In addition to the coordinates of the points of individual curves, it also contains parameters such as offset (clearance), orthosis thickness or openwork parameters. The sheet is linked to the orthosis model saved in a single file in .ipt (Inventor Part) format.

	A	B	C
1	reka	1	
2	dlugosc_reki	262	
3	ilosc_pl_reki	5	ul
4	dlugosc_dloni	90	
5	ilosc_pl_dloni	6	ul
6	liniax	78	
7	odsuniecie	2	
8	ods_od_plaszczyzny_poczatkowej	192	
9	azur_odleglosc_od_bryly	0	
10	gr_ortezy	4	
11	srednica_otworów_malych	2	
12	srednica_otworow_duzych	4	
13	odleglosc_od_linii_z_dla_otworow_malych	3	
14	odleglosc_od_linii_z_dla_otworow_duzych	5	
15	wyciecie	30.60368	
16	dlugosc_drukarki	155	
17	minimum_x5	24.273	
18	minimum_x8	12.4034	
19	minimum_x7	18.70653	
20	minimum_x3	30.20767	
21	minimum_x2	16.63621	
22	x1_11	1.048798	
23	x1_12	17.94269	
24	x1_13	31.17091	
25	x1_14	20.91756	
26	x1_15	0.858414	
27	x1_16	20.80217	
28	x1_17	26.58439	
29	x1_18	13.70978	
30	y1_11	20.58852	
31	y1_12	16.76995	
32	y1_13	0.470688	
33	y1_14	18.76618	
34	y1_15	26.39968	

Figure 3.63 Excel sheet with the parameters of the WHO orthosis (excerpt)

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11) There is one orthosis model, originally for the right hand. In the case of the left limb orthosis, the mirror image operation is used. The reflection takes place twice - the first time when the triangle mesh is processed (so that all activities are carried out for the limb in the right version), the second time - after generating files ready for printing.

After generating the appropriate data sheet and the user finishes working with the product configurator, where the type of openwork, material, color and manufacturing parameters are selected, the CAD system is opened in the background and the model is updated (which takes a few minutes). After a successful update, files with the halves of the orthosis are generated in the triangle mesh (STL) format to be printed on an additive manufacturing device. After generating the files for printing, the information is transferred to the software controlling the operation of the additive manufacturing device. The end result - an example of an orthosis - is shown in the Figure 3.64 below.

Figure 3.64 3D printed orthosis example

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4 Preparation of medical CAD models for 3D printing

4.1 Good practices in design for 3D printing

Additive manufacturing technologies are a collection of very diverse manufacturing methods. Each of them has its own limitations that must be taken into account by the designer. The issue of designing with additive manufacturing in mind is so extensive that it would require writing a separate book. This chapter will present only the most important aspects to keep in mind when designing products to be manufactured with the FDM method on a machine equipped with a standard (0.4-0.5 mm) nozzle diameter and heated bed table.

The first point concerns the layered nature of additive manufacturing. This results in the quantized dimensions of the Z-axis (the direction of model division into layers), while dimensions in the X and Y axes can be mapped smoothly. For example, assuming that the model of height (in Z-axis) h equal to 2 mm will be made with the thickness of the applied layer t equal to 0.25 mm, it is necessary to apply eight layers of material. The error in producing this dimension should be close to zero. In the case where the produced element is to have a height h equal to 2.8 mm, the number of applied layers with the same thickness t equal to 0.25 mm is 11.2. The number of layers must be an integer. Therefore, the program controlling the machine will round it, most often it will be a round upwards. In this particular case, the manufactured object will have twelve layers. The dimension error will be 0.2mm. Important dimensions, e.g. of mating surfaces, must be generated in the XY plane. If this is not possible, we should design dimensions that are multi-portions of the layer with which we intend to produce the prototype. It is also worth considering the total manufacturing time. The longest time is to produce with the FDM method in the Z-axis, so when designing a new element, try to orient most of its features to the production "flat" (fewer layers means faster manufacturing at the same volume needed to extrude).

The minimum layer thickness that can be used during production may, together with the nozzle diameter, determine the maximum detail of the geometry that the FDM 3D printer is able to reproduce. When designing a product with a view to production on a specific machine, avoid containing too fine geometries. They will not be produced correctly anyway,

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and at the same time, they increase the weight of the STL file, make it more difficult to process and store.

All sharp edges, if not necessary, should be blunted by chamfering (e.g. 0.5 mm or two layer thicknesses).

Models with large surfaces adjacent to the worktable tend to buckle. This is especially true for manufacturing from thermoplastics with high thermal shrinkage. It is good practice to round off all corners in the XY plane, thus limiting the point stress concentration (Figure 4.1). Sometimes it is worth considering dividing large elements into smaller ones and their fixing (glueing/twisting with screws) in post-processing. The division of the CAD model into several smaller elements may also result from the limited space in the 3D printer's working chamber.

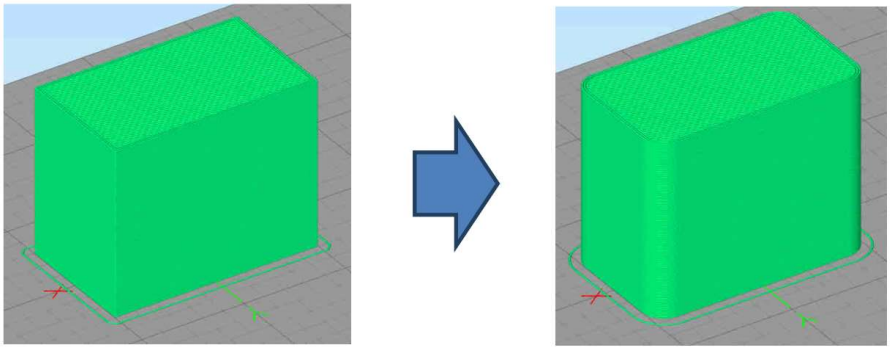

Figure 4.1 Rounding corners in the layer adjacent to the worktable.

Manufacturing by the FDM method requires the use of supports in places where the next extruded layer cannot be supported by the material extruded in the previous layer. The necessity to use supports results in the extension of the total production time increased waste material consumption and the need for additional post-processing. Moreover, in general, the surface adjacent to the supports loses its quality. The geometry of the product can often be optimized by transitioning to a vertical wall with a chamfer (under the entire surface) at least 45 degrees (for ABS material) or 65 (for PLA material) (Figure 4.2). In this case, we will avoid material overhang, and there will be no need for additional supports.

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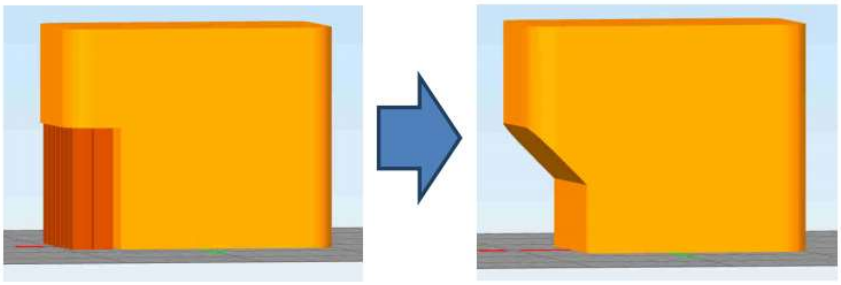

Figure 4.2 Avoidance of unnecessary supports.

In products manufactured by the FDM method, "printed" threads should design as geometry feature only for sizes M14 or larger, maintaining the appropriate clearance. For smaller threads, a better solution is to use a screw tap (select the hole diameter in accordance with the recommendations for pre-tap drill diameter). When using thread forming screws for plastic, the diameter of the screw hole should be approx. 0.3 mm smaller than the screw diameter.

The minimum diameter of the cylinder feature (eg. fixing pins) is 2 mm, safer is 3-4 mm. If the cylinder is high (above 10-15 mm for minimum diameter) or will be loaded, it is worth applying reinforcement by rounding at its base or an additional reinforcing rib. Proceed in the same way for high thin walls - strengthen them with ribs.

All form-fit connections (between different 3D printed parts) should have a clearance of at least 0.2 mm. The smaller the nominal size, the greater the clearance that needs to be applied. The value of the clearance is often selected experimentally as the quality of the joint will depend on the quality of the FDM machine and its proper calibration.

A minimum wall thickness of 1.5 mm should be used. The safe thickness is 2 mm - it depends on the geometry of the product, especially the height of the wall and its curvature. Generally, every FDM fabricated wall should consist of at least four contiguous contours (Figure 4.3). The use of an extrusion nozzle with a larger diameter may require the walls to be thickened.

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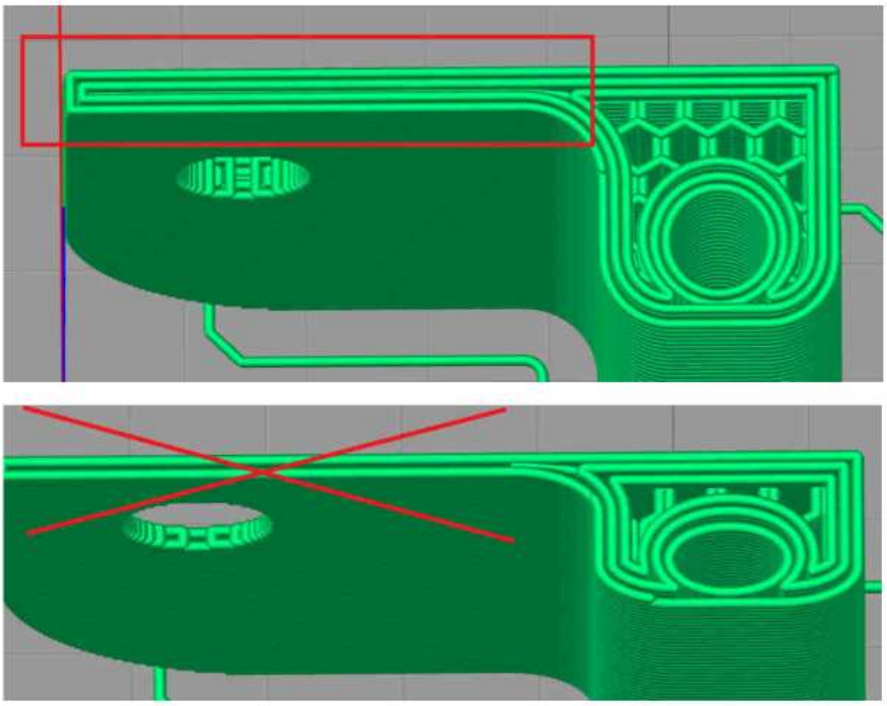

Figure 4.3 Minimal contours number for slim walls.

4.2 File types related to additive manufacturing

There are several file formats that are directly related to the additive manufacturing [38]. They differ significantly from one another. The most common files types are STL, OBJ, AMF and 3MF. Some additive manufacturing machine software can also load and work with CAD-specific file formats. The selection of the appropriate data format to use depends very much on the machine and the manufacturing method. At the beginning of 2021, STL was still the most widely used data exchange format, which was developed in the 1980s by the creator of the first machine for additive manufacturing - stereolithography.

The STL format can be characterized as follows:

- its full name is "Standard Tessellation Language" or "Standard Triangulation Language"
- is the simplest open-source file format

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- supports two encodings: ASCII (bigger file size) and binary (smaller file size)
- can store only information about the geometry and an additional 80 bytes of any text information in the header
- uses a mesh of triangles to represent the surface of the geometrical object
- every triangle is represented by three vertices and one normal vector
- triangles can be made arbitrarily small to approximate curved regions (the more triangles, the larger the file and the more difficult its processing)
- can be imported and exported in almost any CAD software (however, it is challenging to edit directly)
- it does not carry information about the scale of the object, but only about its proportions (unit-less format)
- is not topological, hence stores a lot of redundant information but no information about the connectivity of the triangles (software needs to compute this information ad hoc)
- does not enforce any data correctness mechanisms (e.g. "water tightness" of geometry - object to be additively manufactured should have closed surface with positive volume), but there is a lot of free and paid software for file repairing

The second file format that has been introduced to additive manufacturing is OBJ. It was originally used by graphics designers and it later adopted by the additive manufacturing community. The main reason for adoption was its ability to transfer information of different colours within the same geometry. This allowed for the full use of the possibilities of multi-colour 3D printers. The OBJ format can be characterized as follows:

- its full name is just "Object" file
- it is simply to work with an open-source licensed
- supports both ASCII and binary encodings
- can store information about colours, materials and textures using a companion file format called Material Template Library (MTL)
- can use not only triangle, but any polygons to covers object surface
- geometry data is topological
- it is a unit-less format

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- support also advance schemes like free-form surface, which can encode a curved geometry without any information being lost
- corrupted file repair is complicated and there's not many tools that can help with
- is not as widely supported as STL in CAM software, but most of CAD software can import/export OBJ

The next file format, dedicated directly to additive manufacturing, was AMF - introduced in 2011. It was called "STL 2.0", as it addresses to many of the shortcomings of the STL format. Despite the many advantages of the new format, the process of implementing it into additive manufacturing is relatively slow. The AMF format can be characterized as follows:

- its full name is "Additive Manufacturing File" format
- it is an open standard (ISO / ASTM52915 - 20)
- it uses XML format to encode data, hence ensures that the file is easy to read, write and process
- geometry is described with triangular mesh (same as STL), but triangles can be curved, so file size can stay low in volume with only a small loss to mapping accuracy of nonlinear geometry
- it supports texture mapping, colours, gradients and substructures
- an object can be described in any scale (different design units)
- it supports constellations which helps to significantly reduce the size of a file with repeating geometrical patterns
- XML can be updated with new metadata fields, including names, tolerances, manufacturing parameters etc.

The format that was presented last was developed by a large computer company. Microsoft, the creator of the new 3MF format, developed it with the vision to implement it in its operating system. As an easy to use tool 3MF was aimed to give a high-quality experience for 3D printing for non-professional customers. By introducing other well-known companies in the additive manufacturing industry into development work (establishing 3MF Consortium), Microsoft has facilitated technical development and the future adoption of the new format. Like the AMF format, 3MF breaks the limits of the STL format and can be characterized as follows:

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- its full name is "3D Manufacturing Format"
- is an open-source file format
- it uses XML format to encode data, so it has all the same advantages as AMF
- has full tray support for direct machine preparation
- supports viewing and printing in Microsoft Windows
- uses the same compression as a ZIP archive (file can be smaller to send and store)
- ensures that the files are 100 % manifold with no cracks or overlapping triangles, avoiding problems
- it can encapsulate different parts of a more complex product, which can be produced by various manufacturing processes

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5 Summary

This module presents basic, intermediate and advanced knowledge on design of medical parts for 3D printing, in various aspects. The most popular modelling techniques and software systems were reviewed. Detailed methodologies of creating 3D models and preparing them for 3D printing were also presented, with full examples of authors' experience or based on available, up-to-date literature. The main goal of this module was to present the possibilities and main ways of preparing printable 3D models of individualized medical parts, with lots of effort put into processing of medical data. The knowledge presented here is, however, nowhere near being complete, mostly due to volume constraints – on the basis of shown literature, the reader can go further and extend their knowledge and skills. Many useful information are provided in the publications referenced in this document, especially review papers such as [39-42].

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7 Figure list

Figure 2.1 Product lifecycle stages [6] 5
Figure 2.2 Parameterized 3D modelling in a CAD system [own work] 6
Figure 2.3 Types of 3D models [10] 9
Figure 2.4 Hybrid 3D model of a mid-surgery template - CT-based surface joined with solid parts [11] 9
Figure 2.5 Assembly - two parts of an orthosis [12] 10
Figure 2.6 CATIA V5 software [13] 11
Figure 2.7 SolidWorks software [13] 12
Figure 2.8 Fusion 360 toolbar on different working modules 14
Figure 2.9 Fusion 360 Computer Aided Design (CAD) [14] 14
Figure 2.10 Fusion 360 working interface 15
Figure 2.11 Fusion 360 Topology Optimization (Shape Optimization) [17] 17
Figure 2.12 Fusion 360 Generative Design [18] 17
Figure 2.13 Altair Inspire Studio working interface 19
Figure 2.14 Altair Inspire Studio interactive toolbar 20
Figure 2.15 Display of part of the Altair software solutions [19] 21
Figure 2.16 Altair software solutions in product development [20] 21
Figure 3.1 Groups of applications of medical 3D printing [own work] 22
Figure 3.2 Scalpel handle, hemostats, needle drivers, forceps [21] 24
Figure 3.3 Digital model of the defective mandible (left), scanned model of the actually cut bone (center), and the distance deviation color map between the two superimposed models (right) [22] 24
Figure 3.4 Computer-aided tissue engineering: process of heterogeneous tissue block assembly for kidney [23] 25
Figure 3.5 Methods of contactless measurement – methods used in medicine marked in red [own work] 26
Figure 3.6 Point cloud of a medical 3D scan [own work] 28
Figure 3.7 STL mesh - medical example [own work] 29
Figure 3.8 3D Slicer window with imported DICOM data [13] 30
Figure 3.9 3D Slicer segmentation with the use of island auto-detection, the maximum area possible to be determined in a single operation is marked in green [13] 31
Figure 3.10 3D Slicer segmentation with thresholding, the areas of bone tissue were extracted with green [13] 32
Figure 3.11 3D Slicer segmentation with the use of the growth algorithm, the area automatically extracted by the program is marked in green [13] 33

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Figure 3.12 InVesalius window with imported DICOM data [13] 34
Figure 3.13 InVesalius segmentation using thresholding, the area of bone tissue has been extracted with green. 35
Figure 3.14 CT data import 36
Figure 3.15 Mimics 10 Workspace window 37
Figure 3.16 Manipulation of loaded images in Mimics software 38
Figure 3.17 Hounsfield values for appropriate materials and histogram 39
Figure 3.18 Thresholding for hard tissue (bones) 40
Figure 3.19 Thresholding for soft tissue 40
Figure 3.20 Forming the green mask 41
Figure 3.21 Forming the volumetric model 42
Figure 3.22 Volumetric model 42
Figure 3.23 3D model manipulation 43
Figure 3.24 Methodology of design and 3D printing of surgical supplies [30] 44
Figure 3.25 Mid-surgery supplies for jaw reconstruction [11, 30] 44
Figure 3.26 Pre-surgery supplies for eye socket reconstruction [31] 45
Figure 3.27 Sample DICOM data - head tomography [33]. 45
Figure 3.28 Volumetric model - example [34]. 46
Figure 3.29 Knee mesh on the basis of CT data [32] 47
Figure 3.30 Division of two areas in GOM Inspect by “Delete by Plane” function [32] 49
Figure 3.31 Closing holes in the mesh [32] 50
Figure 3.32 Adding points on the imported mesh in the Inventor software [32] 51
Figure 3.33 Division of the mesh using defined construction elements [32] 52
Figure 3.34 Creation of pins for assembling the endoprosthesis with a bone [32] 52
Figure 3.35 Finished model of the femoral bone implant [32] 53
Figure 3.36 Elements of the knee implant – tibia [32] 54
Figure 3.37 Result of the work – 3D printed implant prototype [32] 55
Figure 3.38 Digitized Shape Editor 55
Figure 3.39 Filtering point cloud (Removing unnecessary points) 56
Figure 3.40 Manipulating points in the model 57
Figure 3.41 Creating a polygonal model with the technical element Mesh Creation 58
Figure 3.42 Different operations with a polygonal (mesh) model 59
Figure 3.43 Formed Model 60
Figure 3.44 Methodology of design of 3D printed orthotic and prosthetic supplies [36] 60
Figure 3.45 Examples of orthopaedic supplies made by 3D printing on the basis of 3D scanning [37] 61
Figure 3.46 Manual 3D scanning of patient limb (EinScan Pro) 62
Figure 3.47 Semi-automated 3D scanning using a stationary scanner (David SLS-3 on a custom-made automated trolley) 62

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Figure 3.48 3D scanning data processing..... 62
Figure 3.49 3D scan processing (MeshLab)..... 63
Figure 3.50 Mesh processing – cleaning, repairing (GOM Inspect)..... 64
Figure 3.51 Mesh processing – limb reconstruction, successful – to the left, failed – to the right (wrong/missing scan data)..... 64
Figure 3.52 Data extraction – manual/automated measurements (CATIA), creating and exporting sections (MeshLab)..... 65
Figure 3.53 The “shell” approach to design of individualized orthoses..... 67
Figure 3.54 The “spline” approach to design of individualized orthoses..... 67
Figure 3.55 Multi-section solid for the WHO orthosis - visible outlines of sketches and planes..... 68
Figure 3.56 Diagram of auxiliary manual measurements of the forearm for the design of the WHO orthosis..... 69
Figure 3.57 Examples of sketches in the WHO brace model - a) 8-point (forearm) b) 18-point (palm)..... 69
Figure 3.58 The shell of the WHO orthosis..... 70
Figure 3.59 The shell of the WHO orthosis divided into two halves..... 70
Figure 3.60 Three types of openwork in the WHO orthosis, from the left: curvilinear, rhomboidal, hexagonal..... 71
Figure 3.61 The method of joining the orthosis halves - groove and slot in both halves, holes for polymer clips are also visible..... 71
Figure 3.62 Filleting the WHO orthosis model in the area of the thumb..... 72
Figure 3.63 Excel sheet with the parameters of the WHO orthosis (excerpt)..... 72
Figure 3.64 3D printed orthosis example..... 73
Figure 4.1 Rounding corners in the layer adjacent to the worktable..... 75
Figure 4.2 Avoidance of unnecessary supports..... 76
Figure 4.3 Minimal contours number for slim walls..... 77

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