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EUROPEAN NETWORK FOR 3D PRINTING OF BIOMIMETIC MECHATRONIC SYSTEMS

MODULE 1 – CAD

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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 [Farhan et al. 2021; Wichniarek et al. 2020; Baronio et al. 2017],
- medical parts design using CAD systems [Dal Maso & Cosmi 2019; Ciocca et al. 2009; Sun et al. 2005; Górski et al. 2022; George et al. 2017],
- automation of CAD modelling [Górski et al. 2020; Portnoy et al. 2020],
- processing of medical imaging for 3D printing [Marro et al. 2016; Huotilainen et al. 2014],

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- design optimization towards 3D printing processes [Wojciechowski et al. 2019; Buonamici et al. 2019; Krishnanand et al. 2016].

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 of biomimetic devices

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 first technical stage 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.

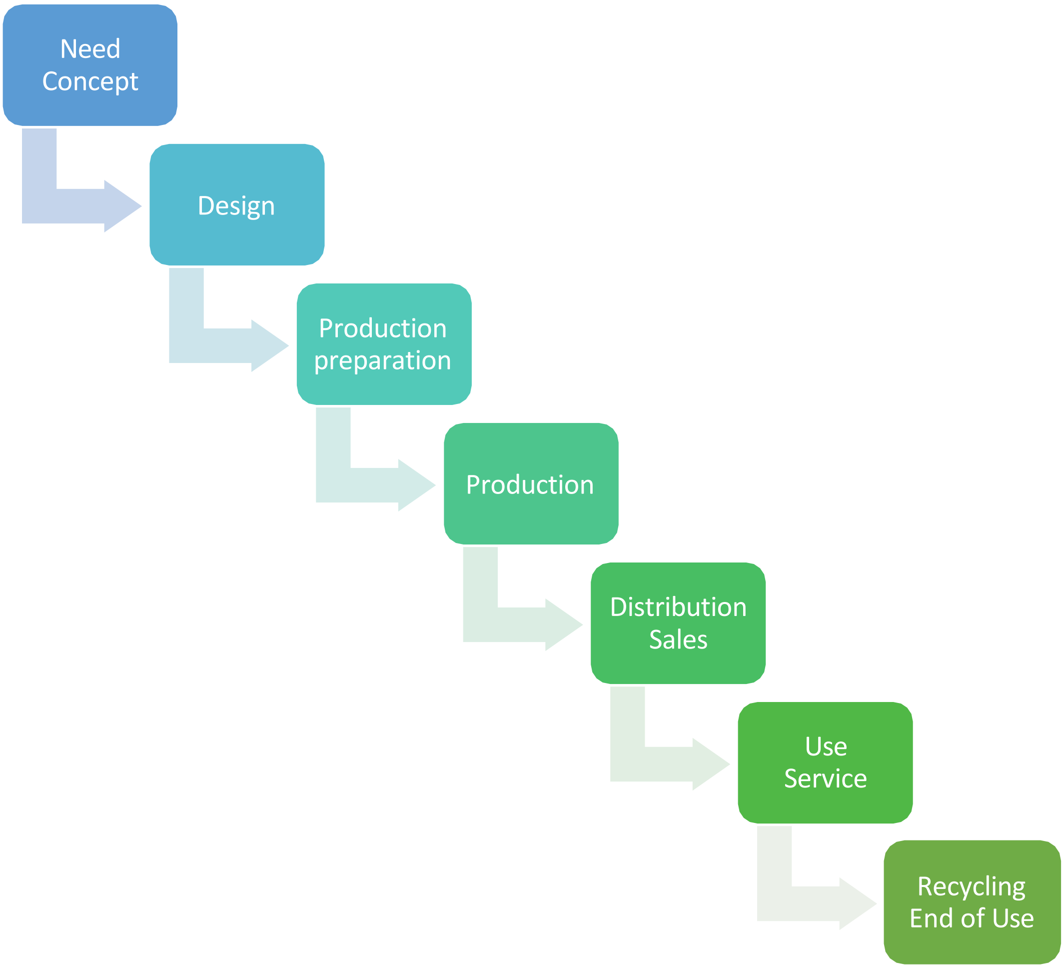

Figure 2.1 Product lifecycle stages including design

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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. 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 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. Example of parametric 3D model is shown in Fig. 2.2.

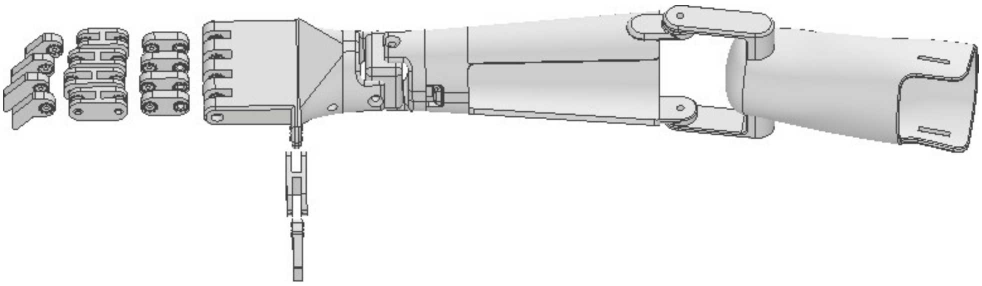

Figure 2.2 Parametric 3D model example – biomimetic arm prosthesis [Komorowska 2022]

In medical engineering, preparation of patient-specific, anatomically adjusted biomimetic devices falls under the range of **Engineering-To-Order** (ETO) and individualized design. Engineering-To-Order is creating a new product directly for a given client (or a group of clients) or patient, in the case of medical design. Individualized design is creating a new variant of an already known product, adjusted to the needs of a given client / patient. Individualization can be based on selectable features – then it can also be named customization. It can also be performed on geometrical (anatomical) level, using patient's digitized anatomy to create a shape of a product.

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Products of such organic shapes are often named as biomimetic. **Biomimetics** or biomimicry is human-made technology with ideas copied from nature, or directly inspired by it. By this definition, any device with anatomical shapes can be considered as biomimetic, as well as one representing similar working principles, as works of nature (e.g. artificial arm containing joints of the same capabilities as in arm of a living human).

Examples of biomimetic products are shown in Fig. 2.3.

Figure 2.3 Biomimetic product examples [blatchfordmobility.com] [kaylenekau.com]

2.2 3D modelling types

2.2.1 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 [Kurland 2007].

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

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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 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.

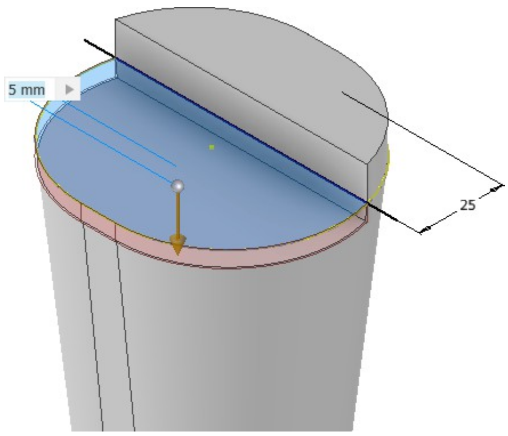

Figure 2.4 Solid modelling – extrusion, Inventor software [Komorowska 2022]

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2.1.1. Surface 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 [pcmag.com].

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.

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. 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.

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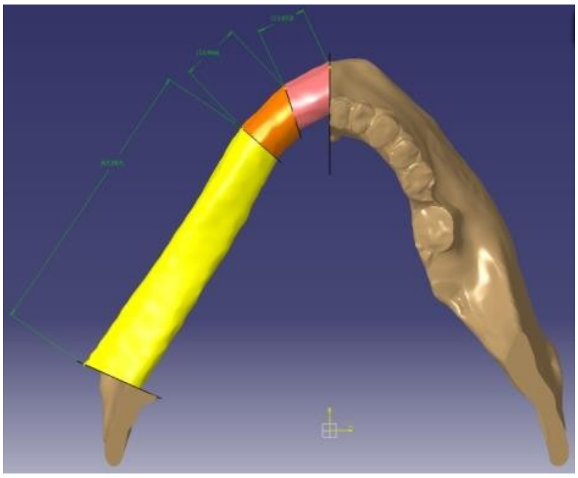

Figure 2.5 Hybrid modelling – CATIA software [Banaszewski et al. 2018]

2.1.2. 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 [Kurland 2007].

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

- 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.

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2.1.3. Mesh processing

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 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 (Fig 2.6).

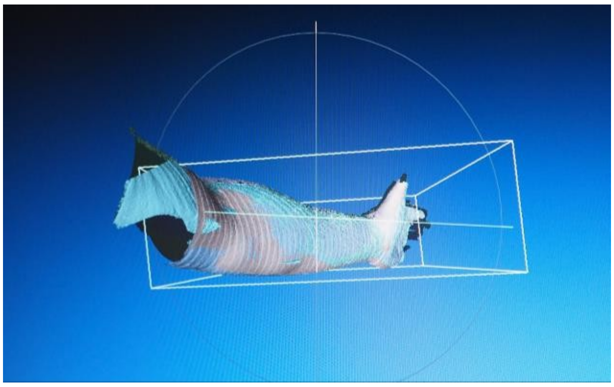

Figure 2.6 Mesh processing – human hand 3D scanned geometry

2.1.4. 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). 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,
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- angle,

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- 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).

2.3. CAD Software review

2.3.1. 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 (fig. 2.7.). It is focused mainly on creating multi-element assemblies and has an extensive Content Center tool aimed at this eventuality, which enables the effective import of a wide selection of standardized elements. Inventor, due to its competitive price and free access to student versions of the software, has been widely used in the education sector and small and medium-sized enterprises with an engineering profile [bright-project.eu].

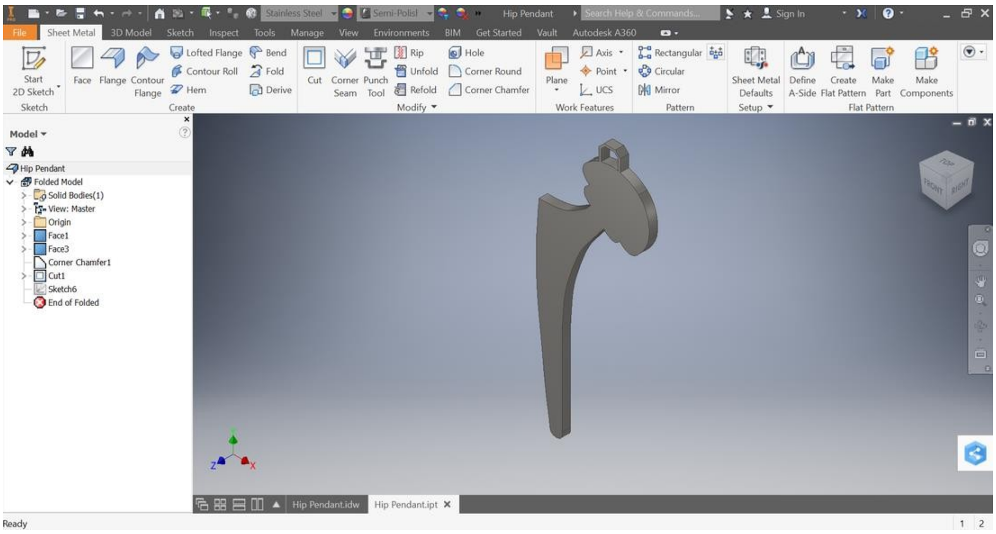

Figure 2.7 Inventor main window – hip implant

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The program has a ribbon structure of the main window with drop-down tabs in the upper part and an operation tree in the form of a block. Some functions are hidden in sub-tabs available after expanding a specific group of commands. In addition to the standard online help and support system, Autodesk Inventor 2014 and higher comes with a set of tutorial videos and educational animations that open when you move the cursor over the tool icon.

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 activities, such as creating surfaces by extrudes.

The software enables automation through the use of product configuration tools, component generators and calculators, and automatic modifications of parts and components. It also has automation tools in the design of assemblies combining mechanical and electrical components, or installation.

The efficiency of work with the program includes the computational capabilities of the computer and the complexity of the design task. Due to the small number of tools for advanced modeling, in some cases it is not possible to complete a design task in full.

2.3.2. SolidWorks

SolidWorks is one of the most popular 3D CAD programs available on the market (fig. 2.8). In addition to standard functions related to 3D modelling, it has tools for technical documentation management, electrical design, FEM simulation and kinematic analysis. It is also widely used in enterprises for the design of technological processes and tools for plastic working and processing of plastics [bright-project.eu].

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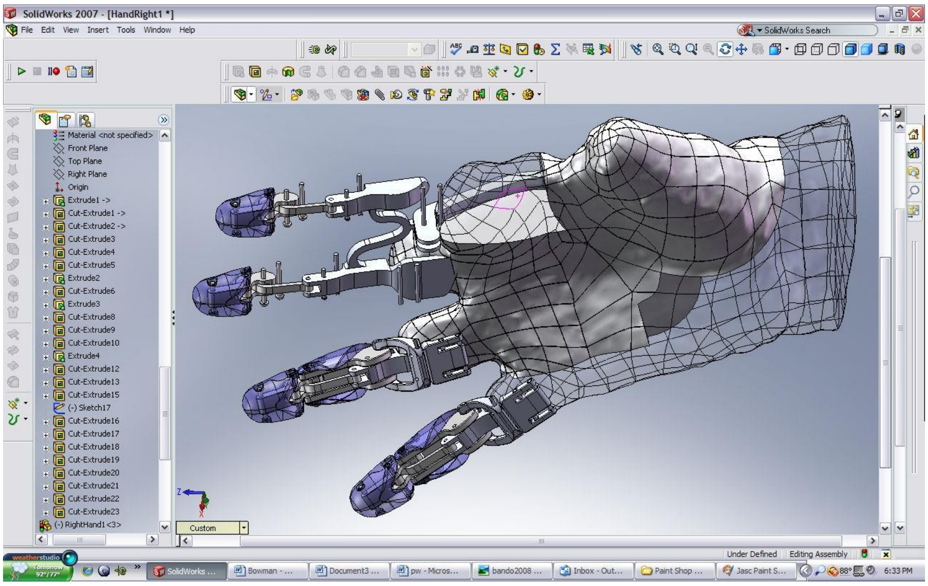

Figure 2.8 SolidWorks window view [solidsmack.com]

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 software-level help system as well as a knowledge and instruction base available on the Internet.

Each time, importing a file in the STL format is associated with indicating 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 proposes basic repair actions with the use of 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 enables the creation of simple linear and unfolding surfaces, as well as more complex NURBS (Non-Uniform Rational B-Spline) surfaces [Turostowska 2016].

Automation of model generation in the SolidWorks program is achieved by add-ins, which are a set of macros used to assign specific properties to components. The manufacturer authorized add-on is MacroSolid, which is not an integral part of the software.

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The high demand for computing power in the case of SolidWorks is a problem not only for importing STL files, but also for working with large data sizes or with complex assemblies. As a result, regardless of the user's level of advancement, it is difficult to optimize work with the program, which translates into a decrease in efficiency. The main factor that affects the efficiency of project tasks is hardware capabilities.

2.1.5. Fusion 360

Fusion 360 is a Cloud based collaborative product development program from the Autodesk company [autodesk.com]. 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 [bright-project.eu]. The program is free to use for educational purposes and startups with less than $100k of revenue per year.

The methodology of working with Fusion 360 is relatively 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. Fusion 360 is similar in principles and interface to Inventor software, so users of Inventor can usually easily switch between the two and vice versa.

Some of the advantages of using Fusion 360 are:

- Cloud based program

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- 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

Fusion 360 is frequently used in open source projects for medical 3D printing – e.g. for 3D printed hand prostheses, as demonstrated via representatives of the e-Nable hub (see Fig. 2.9).

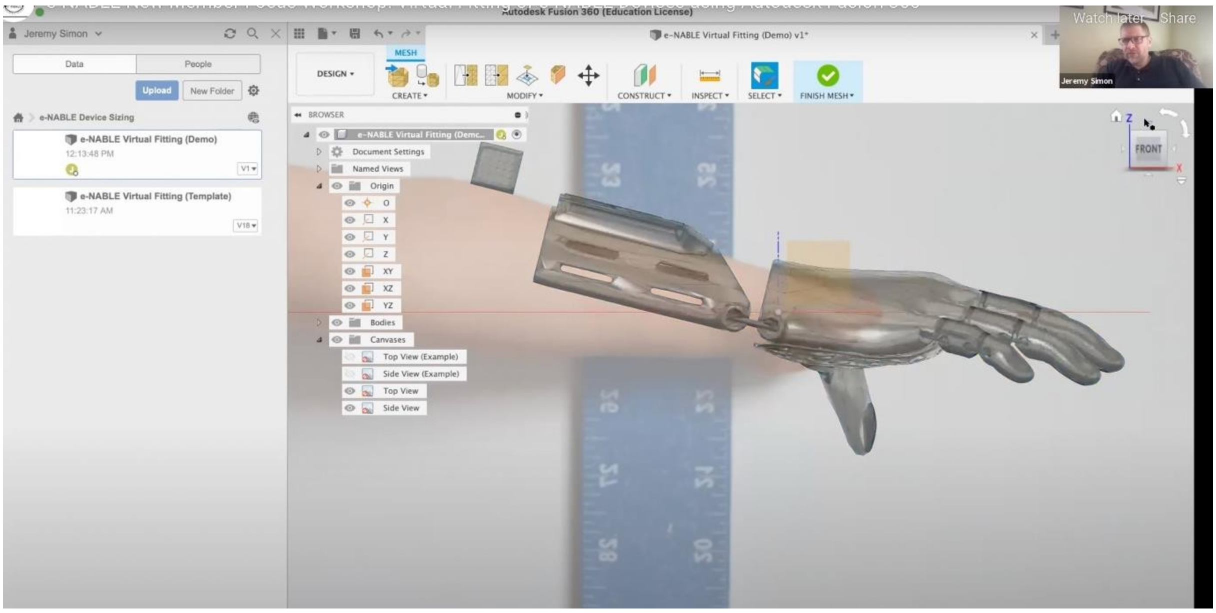

Figure 2.9 Use of Fusion 360 for prosthesis design [e-nable.com]

2.4. Mesh processing software review

2.4.1. MeshLab

MeshLab is an open source software for processing and editing of 3D triangular meshes, as well as point clouds and raster objects. The tool is dedicated to processing large unstructured triangle meshes and includes a set of tools. It allows editing, cleaning, healing, inspecting, rendering, texturing and converting meshes. It processes raw data produced by 3D

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digitization tools/devices and for preparing models for 3D printing [meshlab.net]. The tool is in active development by the Visual Computing Lab of ISTI-CNR (Italy) since 2005. There are new versions released in year 2022.

As a mesh viewing application, MeshLab allows 3D objects (saved in various formats) to be loaded and interactively inspected in a simple way, by dragging and clicking the mesh itself. User can work on a loaded mesh owing to interactive tools or a large set of parametric filters (e.g. Fig. 2.10a), which perform automatic tasks on selected parts or whole meshes. A distinctive feature of MeshLab is a very large range of these filters, allowing to perform very advanced operations, often based on complex mathematic algorithms. A unique feature of MeshLab is automatic recording of the filter usage - auto-creation of macros, which can be saved to a hypertext file and then re-used, both manually (via script interface – Fig. 2.10b) or through console-based tool (originally MeshLab Server, in late versions replaced by PyMeshLab).

Main usage of MeshLab involves the following work:

1) Basic align of 3D scanned / medical imaging data in form of point clouds and triangle meshes. MeshLab provides a set of tools for moving the different meshes into a common reference system (Fig. 2.10d). The alignment can be performed on meshes and point clouds coming from several sources, including active (both short- and long-range) scanners and 3D-from-image tools.
2) Basic mesh processing: transformation, rotation (Fig. 2.10a), mirror, scaling; selecting and removing vertices, triangles and whole surfaces via manual or semi-automated algorithms; automated mesh error removal and cleaning.
3) Advanced cleaning: hole filling, removal of unwanted artifacts, partial or total repair of meshes. Mesh division, simplification, refinement or remeshing.
4) Mesh reconstruction. The process of transforming independent acquisitions, or point clouds, into a single-surface triangulated mesh can be fulfilled with different algorithmic approaches. MeshLab provides several solutions to reconstruct the shape of an object, ranging from volumetric (Marching Cube) to implicit surfaces (Screened Poisson – Fig. 2.10e).
5) 3D printing oriented features: offsetting (creating inner shells), resampling/remeshing, automatic closing of holes to obtain “waterproof” meshes, flattening the bottom area and more.

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6) Measurement and analysis: manual measurement on the mesh surface, automated geometric and topological computations (center of mass, inertia tensor, bounding box size etc.). Planar sections in form of points, polylines or planar surfaces. Comparing different meshes for geometrical and topological differences.

7) Conversion and interchange – a number of 3D and 2D formats supported, both for export and import.
8) Raster image use – possibility of use of raster layers with 2D imagery or other forms of 2D data.

Figure 2.9c presents an example of an interactive filter. Whereas the engineer drags the mouse over the mesh, the local smoothing is performed on the touched part of the mesh in real time. An example of a rotation operation leading to the matching of two hand scans is shown in Figure 2.10d. The process can run separately or together following a flat approach based on layers [Cignoni et al. 2008].

The rich variety of filters make MeshLab a very important software for mesh-based operations, competing with applications such as MeshMixer or GOM Inspect. It can be utilized with advantage in the medical sector, for processing data from 3D scanning of patients (e.g. limbs) or processing of 3D data extracted of medical imaging (e.g. dental CT scans, MRI and others, after conversion of DICOM into STL, which is done in other software).

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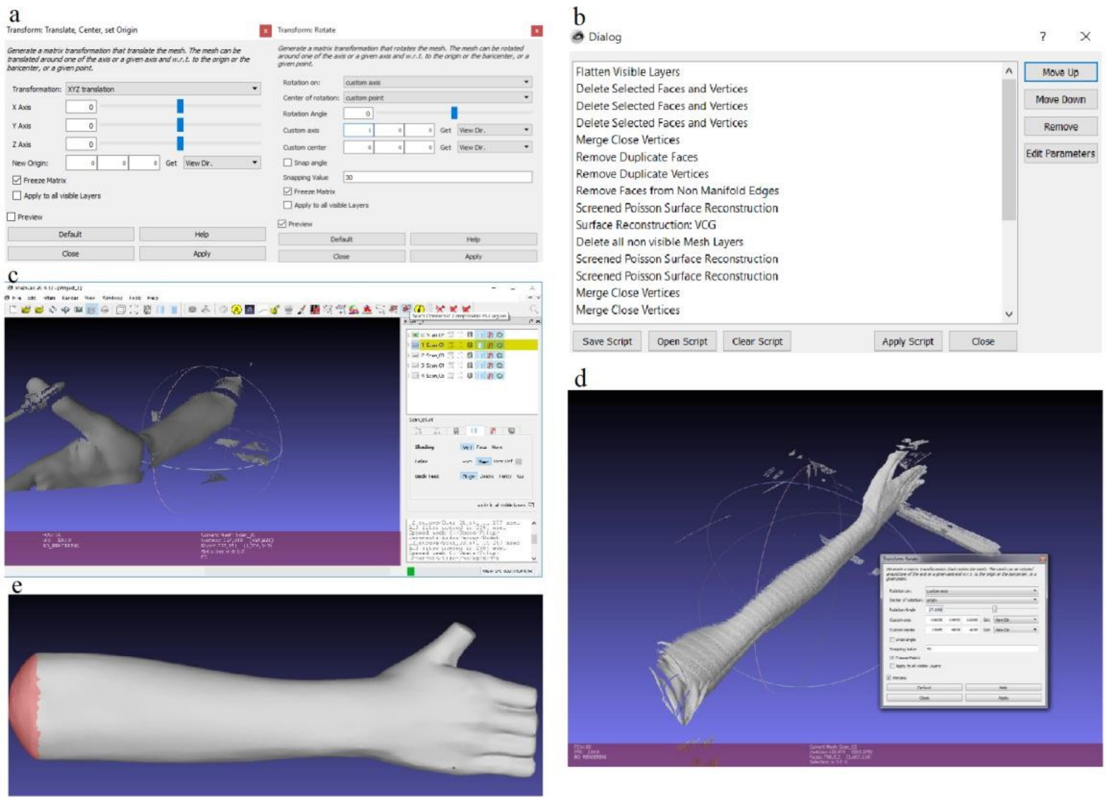

Figure 2.10 MeshLab exemplary features (a) translation and rotation operation, (b) list of operations, (c) mesh processing from the scan, (d) fitting two scans, (e) model after reconstruction [Górski et al. 2020]

MeshLab is operated using a Graphical User Interface, consisting of several windows and toolbars. The main part of the window is 3D viewer, where meshes and other objects can be inspected in 3D space (rotation, zoom and panning operations are available, as well as switch between perspective/orthographic camera, plus a number of possible visualization options – both global and per layer). All the meshes are organized in named layers, usually representing separate files. A project with multiple layers can be saved, referring to multiple files in various formats. Layers can be duplicated, hidden, frozen, renamed and reordered freely.

File, view, align, selection and basic measurement operations are available from the toolbar. All the filters allowing the advanced features are available from the Filters menu. Each of more than a hundred filters has its own interface and unique capabilities (filters are usually contained within external DLL files). The Filters menu also contains simple script editor, allowing preview and basic edition of macros generated by use of filters. Each use of a filter

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creates additional entry to the script, all the entries can be edited – i.e. modified, removed, reordered, duplicated and so on.

MeshLab is generally known for not being a super user-friendly. Its interface is bulky and somehow difficult to get acquainted with. The filters are very advanced, but their descriptions are usually vague and features aren't always intuitive. That is why MeshLab is not recommended as a tool for beginners, unless detailed use instructions are given. However, MeshLab creators, as well as the user community, have prepared a number of video tutorials, instructions and scientific papers on its use, so it is a good start for learning the software. MeshLab main advantages over competing software (MeshMixer, GOM Inspect and others) are:

- Very large quantity of available filters for mesh processing, some of them unique to MeshLab
- Advanced algorithms for mesh measurement, analysis and comparison
- Easy automation of tasks on various level (complete automation possible)
- Open source – free to use, code freely available
- Optimized engine – rapid work, possibility of use on computers with lower computing power
- High range of possible file formats available for import/export

2.4.2 GOM Inspect

GOM Inspect is software for the processing and analysis of 3D data. It enables comprehensive analysis of grids or clouds of points from 3D scanners or computer tomographs. The program allows to generate geometric meshes, with the possibility of smoothing them, filling holes, reducing the number of triangles forming the mesh and optimizing their edges. It also allows to edit the mesh by selecting data to extract a specific structure and remove the rest of the model. In the previous editions, it was a free (also for commercial purposes) version of GOM Professional, delivered in a package with professional devices for 3D scanning and reverse engineering by GOM. Currently, only 14-day free trial is offered [gom.com], but previous versions are still available.

The GOM Inspect software has tools to carry out both rough processing, which consists in cutting the mesh model along the X, Y, Z axis, and fine processing. More precise processing of

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the model consists in removing unnecessary or damaged parts of the mesh by selecting individual triangles.

GOM Inspect allows to carry out work of a similar nature to other mesh processing software (e.g. MeshLab). Due to the origin and original purpose of the program, it contains many tools that facilitate alignment of geometry in relation to each other, assigning coordinate systems and generating inspection reports for e.g. for product quality control, i.e. the compliance of the scan with the model CAD model.

Many different data formats can be imported into the GOM Inspect software - in addition to the standard STL, also incl. STEP representing 3D solids. STL files are transferred to the GOM Inspect program using the dedicated Import tool. Example of an anatomical mesh imported into the software is shown in Fig. 2.11.

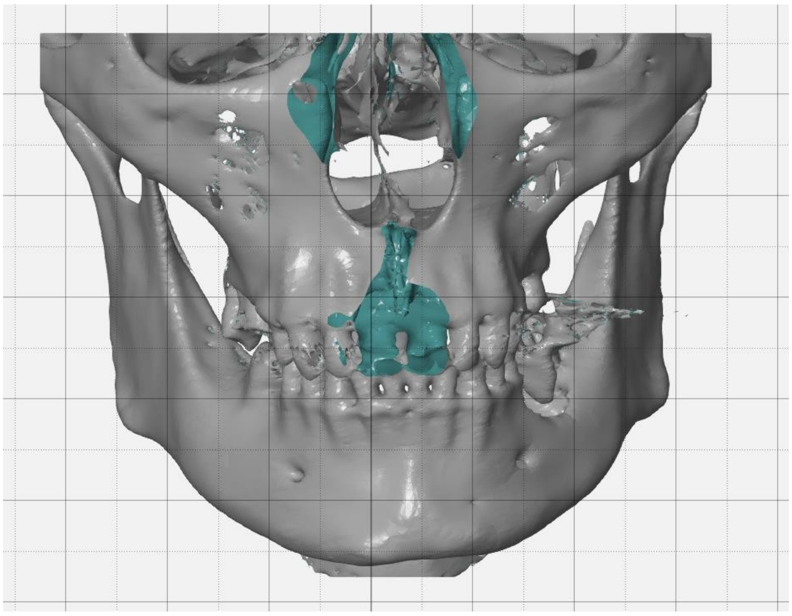

Figure 2.11 GOM Inspect software – anatomical mesh model

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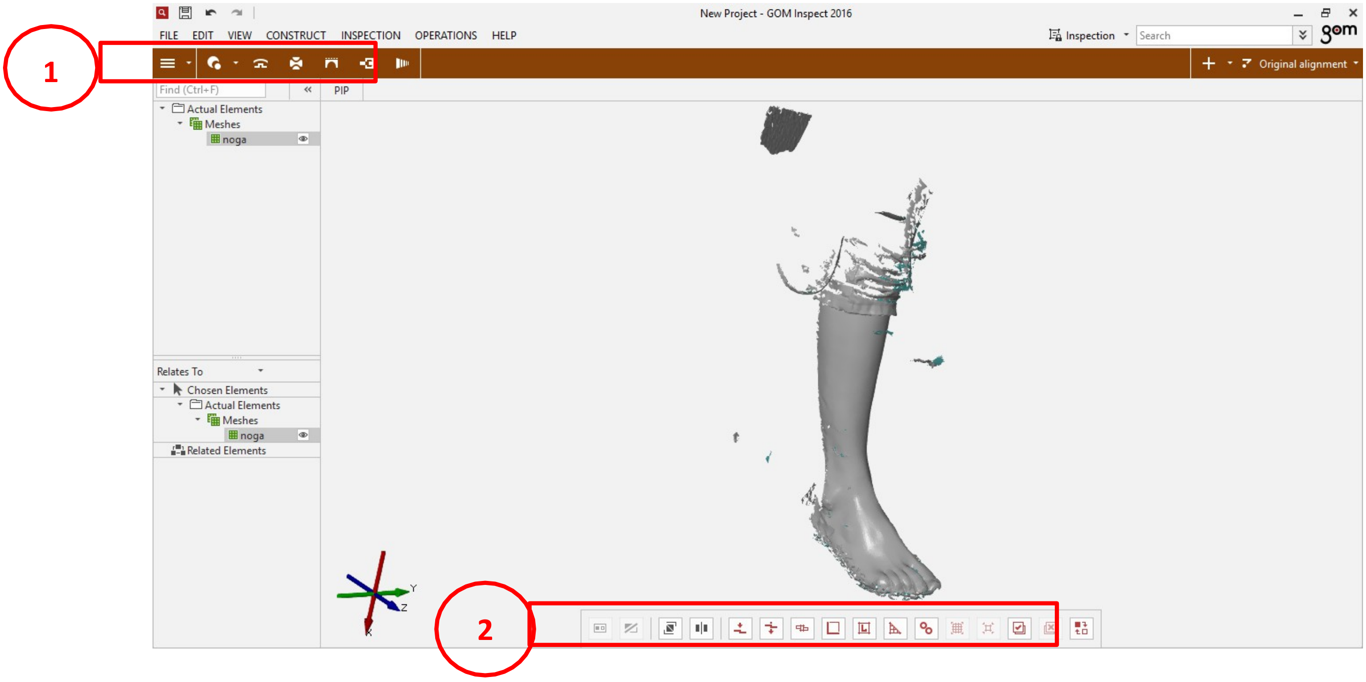

Figure 2.12 GOM Inspect software GUI

GOM Inspect has an intuitive Graphical User Interface (Fig. 2.12), allowing easy selection and performing of some quite advanced tasks. The bar marked as number 1 (available after selecting the Mesh Editing option from the drop-down list) enables the following operations:

- Close Holes - filling holes;
- Smooth Mesh - mesh smoothing;
- Thin Mesh - thinning out the mesh;
- Create Mesh Bridge - creating mesh bridges;
- Repair Mesh - fixing the mesh;
- Refine Mesh - mesh refinement.

Bar number 2 contains options for adjusting the view, selecting a specific area, and manipulating the selection area. Bottom bar tools looking from the left:

- Switch Camera - switch the camera;
- 3D Measuring View Off - turn off the 3D Measuring View;
- Clipping Cube - hide the area beyond the indicated cube;
- Clipping At Plane - hide the area beyond the indicated plane;

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•Select / Deselect On Surface - select / deselect the surface;

- Select / Deselect Throught Surface - check / uncheck through;
- Select Patch - select a separate, unconnected item;
- Select Boundary - mark the boundaries;
- Select Along Line - select along the drawn line;
- Select Triangle - select a single triangle;
- Select Reference Points - select reference points;
- Increase Selected Area -increase the selection area;
- Decrease Selected Area -reduce the selection area;
- Select All - select all;
- Deselect All - select all;
- Invert Selection - invert the selection.

In addition to the above-mentioned basic tools for processing triangle meshes, GOM Inspect also has tools for conducting inspections and generating measurement reports (i.e. overlaying meshes from a 3D scan on a nominal CAD model and generating color deviation maps). It is also possible to base meshes on parametrically defined features (line, point, cylinder, plane, etc.), also in relation to imported solid models. The software also enables the diagnosis and automatic repair of damaged (containing errors) meshes, sometimes impossible to open by other software (eg MeshLab). Unfortunately, scripting and automation is impossible in the free version of the software (only available in the Professional version that comes with 3D scanners). The main advantages of the GOM Inspect program over competing programs are listed below:

• clear and friendly interface,

• a lot of options for precise marking of geometry on the mesh,

• quick and effective implementation of basic operations: patching holes, cleaning, reconstruction and repair,

• the ability to generate measurement reports and color deviation maps,

• easy homing and changing the coordinate system.

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3. Methodology of CAD design of 3D printed biomimetic mechatronic devices

3.1. Basic concepts of design of biomimetic products

Basic methodology of design of biomimetic products is a process, which is different to a classical computer aided design of mechanical devices. Biomimetic component of a designed device usually comes from a digital representation of anatomical features of a certain organism (usually – a human one). Also, biomimetic devices are usually medical ones, so they require medical consultation and diagnosis before any engineering work is done. As such, the process includes the following stages:

0. Medical diagnosis / consultation (non-engineering stage). Here the patient is diagnosed and / or prescribed with a certain medical product (orthosis, prosthesis, implant etc.).
1. Measurement / reverse engineering of organic anatomical features. This is usually done by 3D scanning or other form of medical imaging. Acquired imagery is then processed to obtain basic dataset for design engineering.
2. Design – here CAD systems are used to create a 3D parameterized (or non-parametric, in some cases) model of a desired biomimetic device. Very often, all types of modelling are utilized – starting from mesh, through wireframe/surface and finally – solid.
3. Planning of 3D printing processes – here CAD geometry is exported to appropriate file types and NC programs for selected 3D printers are prepared, assuming appropriate parameters of material processing and layer deposition.
4. 3D printing – at this stage, actual layer deposition is performed by 3D printing machines, usually automatically without supervision of a human operator.
5. Post processing, assembly and supply – at that stage, parts are processed (with scope depending on selected 3D printing process and material used) and assembled. Try-on with the patient/user is necessary to obtain feedback and possible re-design guidelines.

The above-mentioned process is presented in Fig. 3.1.

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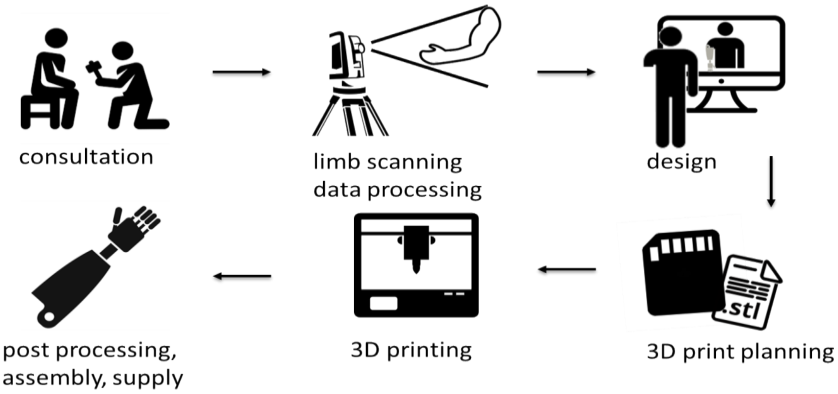

Figure 3.1 Design and manufacturing of 3D printed anatomically shaped devices

If a given biomimetic device is also a mechatronic one, additional sub-process needs to be utilized, with selection, design and programming of appropriate electronic components, mostly Printed Circuit Boards (PCBs). Basics of design of PCBs for medical purposes is described in another chapter.

The design can be based on different premises. On a basic level, there are 2 possible approaches:

- 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.

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.

Both design approaches are shown in Figures 3.2 and 3.3. The "spline", parametric approach is the desired one, allowing quick reconfiguration of a given model basing on different datasets for different patients. In the non-parametric approach, it is difficult to easily change the model for another patient – the whole process must be repeated from the scratch

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on another dataset. As such, the "shell" approach is advisable only in term of "one-shot" problems, where a specific device is unique and created only for one, particular patient, with non-repeatable features.

The "shell" approach converts the 3D scan into a solid, and further work assumes performing offsets, extrusions, cutouts, fillets, holes etc. in this particular solid. As such, it can be considered as "carving" in the anatomical features.

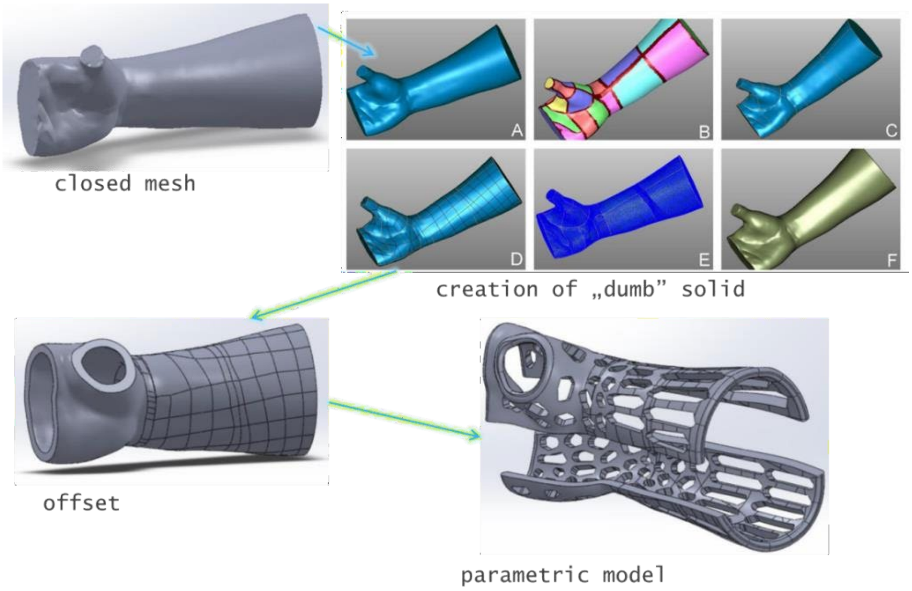

Figure 3.2 "Shell" approach [Górski 2021]

The "spline" approach usually starts with the splines (or other curves), based on points extracted from a mesh model representing anatomical features that need to be recreated in the device model. On the basis of the splines, a multi-extrusion is performed. The basic solid is then appropriately cut, divided and additional features can be added by various techniques of solid and/or surface modelling, if necessary.

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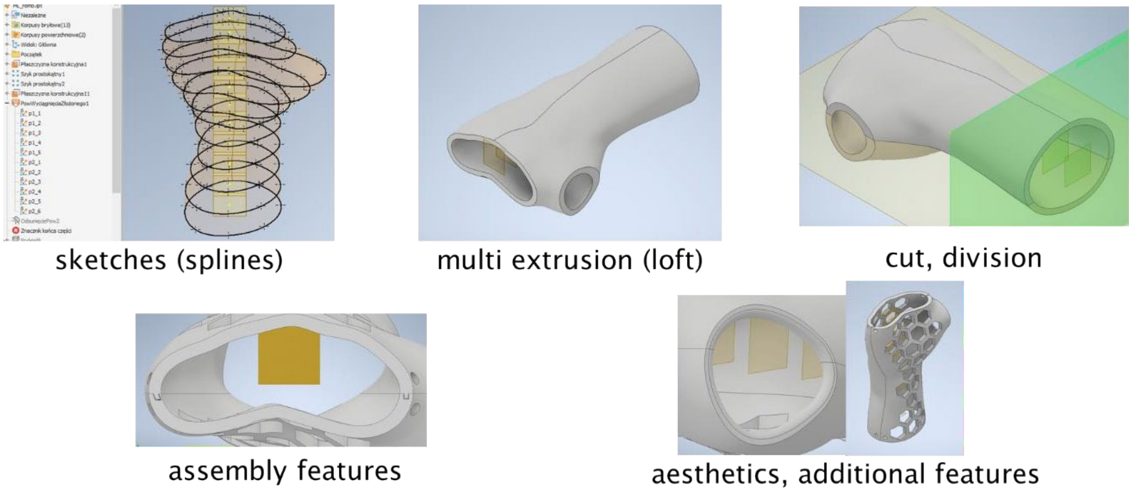

Figure 3.3 "Spline" approach [Górski 2021]

3.2. Automation of design of medical products

Automation of design is a concept introduced alongside the mass customization [Fogliatto et al. 2012]. It assumes that the so-called intelligent CAD models re-configure themselves, on the basis of design parameters entered by the clients. As such, workload of design engineers is significantly reduced, even from weeks to hours or from days to minutes [Chapman & Pinfold 2001, Kulon et al. 2006]. This concept has been successfully introduced in classical mechanical engineering branches, e.g. in automotive [Chapman & Pinfold 2001] or aeronautical [Stokes 2001] engineering.

In design of biomimetic devices, representing anatomical shape of a given human patient, the challenge is much more difficult, as the geometry is usually created of complex shapes, or is non-parametric at all. Aside from that, most of the production of such devices (e.g. limb orthoses or prostheses) still relies on manual processes, in which there is no digital layer. As such, transforming typical design/production process into an automated one, two big steps are required – first introducing the digital process, based on 3D scanning, CAD and 3D printing. This modern process is now known in literature [Cha et al. 2017] but it did not replace the traditional process, mostly because costly and difficult work of technicians has been replaced with also costly work of skilled biomedical engineers. The second big step is automation of design, which is very difficult and possible only in selected cases. Design automation assumes that all the basic stages are performed automatically, or at least without the need of work

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with a specialized software, such as CAD. Main idea of these transformations is presented in Figure 3.4.

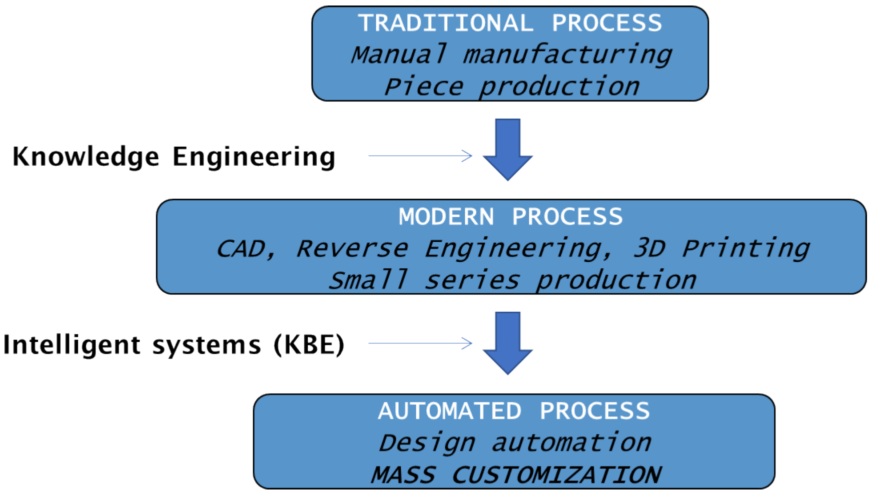

Figure 3.4 Design automation – transformation stages [Górski 2021]

The central component of design automation is usually an intelligent model. Intelligent CAD model is a digital model, in which geometry is enriched with knowledge about:

- functional and structural features,
- relations between these features,
- rules describing selection of these features.

The model is usually linked to an external „design table". Design table is often an Excel sheet, containing all parameters about a given product variant. In the case of biomimetic devices, it contains anatomical data (e.g. points extracted from mesh, based on 3D scan or medical imagery) mixed with technical data (hole diameters, thicknesses, lengths etc.).

Basic ideas of intelligent CAD models is shown in Figure 3.5. Figure 3.6 contains example of a design table for a biomimetic hand prosthesis, along with a model of such prosthesis.

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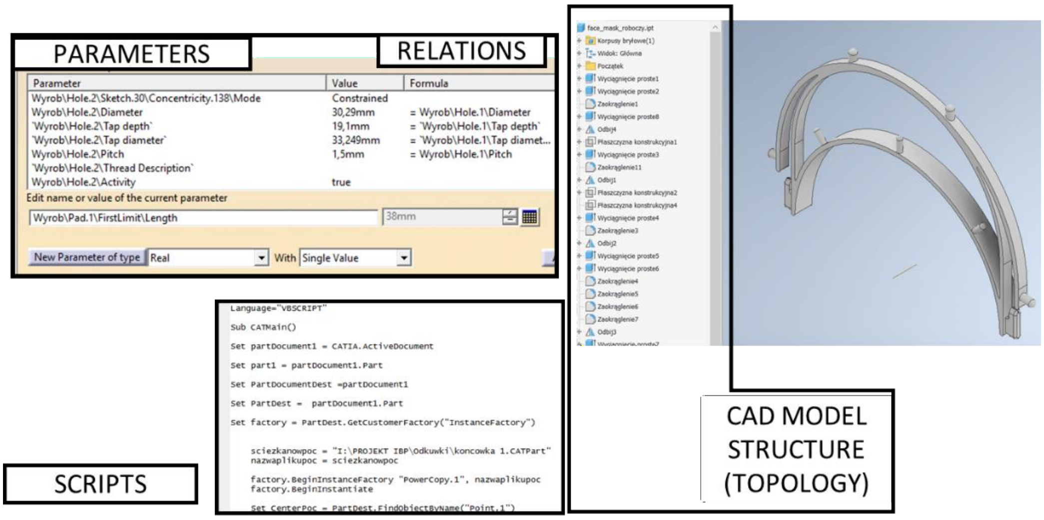
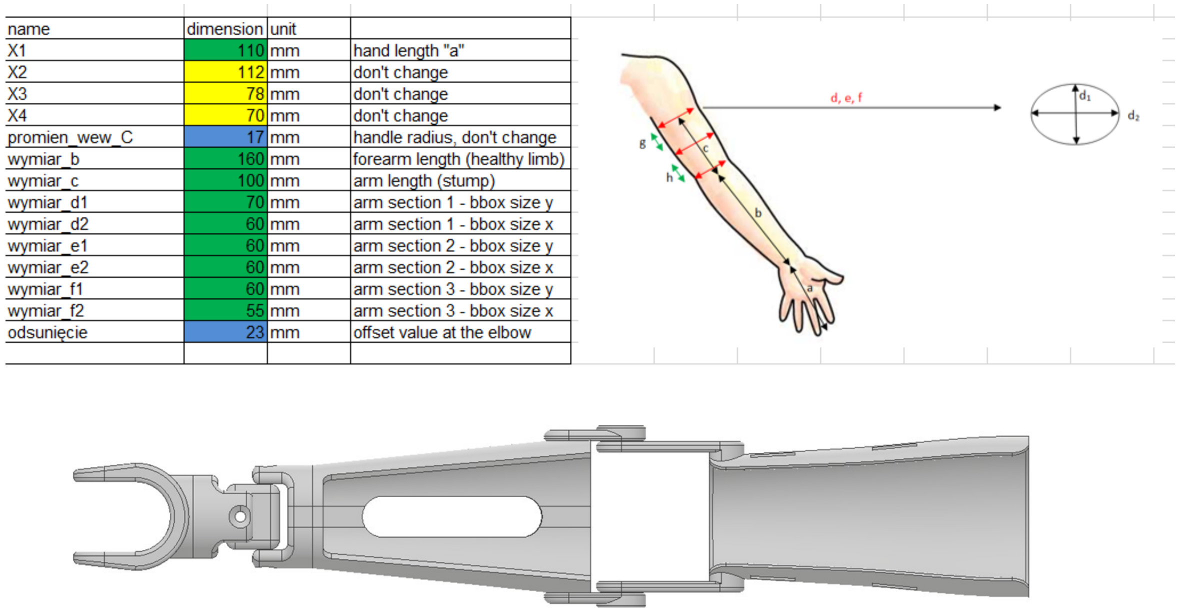


Figure 3.5 Basic ideas of intelligent CAD models [Górski 2021]



name	dimension	unit	
X1	110	mm	hand length "a"
X2	112	mm	don't change
X3	78	mm	don't change
X4	70	mm	don't change
promien_wew_C	17	mm	handle radius, don't change
wymiar_b	160	mm	forearm length (healthy limb)
wymiar_c	100	mm	arm length (stump)
wymiar_d1	70	mm	arm section 1 - bbox size y
wymiar_d2	60	mm	arm section 1 - bbox size x
wymiar_e1	60	mm	arm section 2 - bbox size y
wymiar_e2	60	mm	arm section 2 - bbox size x
wymiar_f1	60	mm	arm section 3 - bbox size y
wymiar_f2	55	mm	arm section 3 - bbox size x
odsunięcie	23	mm	offset value at the elbow

Figure 3.6 Design table of an arm prosthesis [Górski 2021]

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3.3 CAD design of electronic circuits for mechatronic and medical purposes

3.3.1. Basic introduction

Printed Circuit Board is a plate made of insulating material with electrical connections, the so-called tracks and with solder points called pads. Designed for the assembly of electronic components. Different requirements are imposed on them depending on the purpose of electronic systems, e.g. in the automotive industry, electronic systems must have high resistance to vibrations. In the case of medical applications, this may be:

- EMC compatibility,
- no harmful effects of electromagnetic fields, including those of high frequency
- use of lead-free assembly
- no use of harmful ingredients (lead)
- securing the power supply against unauthorized access,
- use of low voltages and currents flowing in the circuits.

At this point, a distinction should be made between systems that are installed directly on the patient's body (or inside) and devices that work independently, for example for medical imaging.

The composition of a PCB involves layering one material on top of another. The thickest, middle part of the board is an insulating substrate (usually FR4). On either side is a thin layer of copper, through which our electrical signals pass. To isolate and protect the copper layers, we cover them with a thin layer of varnish - soldermask, which gives the board its color (green, red, blue, etc.). Finally, to complete the look, we add a layer of screen printing similar to ink, which allows us to add text and logos to the PCB.

PCBs can be divided on:

- single-sided (one copper layer),
- double-sided (two copper layers on both sides of one substrate layer),
- multi-layer (outer and inner layers of copper).

The most important CAD programs for professional and amateur PCB design include:

- Altium Designer (paid license, trial 30 days)
- Eagle Layout Editor (free license for a specific PCB size and non-commercial use, so-called student version)
- Design Spark (free license)

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−KiCAD

The basic types that can be divided into electronic components from the assembly point of view are:

- through-hole components
- SMD components

3.3.2. PCB design procedure

Creating a PCB design in CAD software application is usually a two-step process. In the first stage, we create the so-called electrical schematic (schematic). It defines the elements used in the electronic circuit being created, their parameters and how they are connected to each other. When the electrical schematic is ready, we proceed to design a printed circuit board based on it. The elements used in the schematic will automatically be available in the PCB design. In addition, you will also receive information about the connections of these elements. Thus, it is enough to properly arrange the elements and connect them with paths to get an image of the circuit board, which will then be used to make the board itself. There are companies on the market that accept PCB designs made in Eagle and make professional PCBs based on them. The cost usually depends on the area and number of boards (the more, the cheaper) and ranges from a few tens of dollars upwards. The advantage of entrusting the making of a board to a professional company is that you won't have to bother making it yourself and the result will always be good.

The design procedure steps:

a) design assumptions - determining the purpose, type of power supply, electrical protection, determining whether the devices should be portable or not
b) creating a schematic diagram
c) creating a CAD SCH scheme

Schematic design is a two-step process. First, you must add all the parts to the schematic sheet, and then those parts must be wired together. You can mix these steps - add a few parts, wire a few parts, and then add a few more - but since we already have a reference design, we able to add parts and wires at once. On figure below example of power supply scheme is presented.

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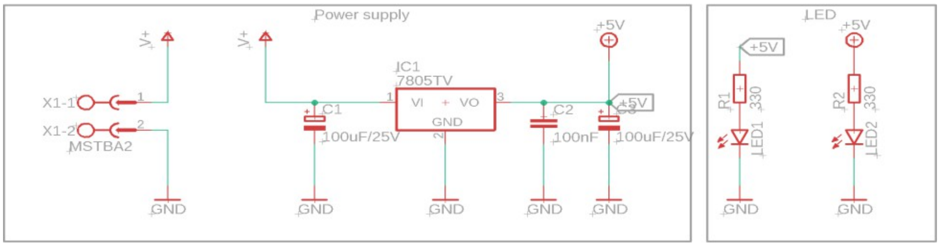

Fig. 3.7 Example of SCH scheme of power supply

d) creation of a BRD scheme

When designing circuit boards, you need to know and understand the basic terminology involved, preferably in English. The basic unit of measurement here is miles (1/1000th of an inch). Electronic circuits developed in Anglo-Saxon countries, and there the non-metric system of measurement is (or was) in effect. 1 inch is 25.4 mm, so 1 mil = 0.0254 mm. On a printed circuit board, paths (tracks) are created along which current flows. These tracks have widths in mils, such as 12, 16, 32, 40.

The thickness of the path depends on the expected electric current that will flow in this path. In the case of digital technology, these currents are usually small and you won't have to be particularly concerned about this. However, in order to comply with formal requirements, I give below a table that determines the widths of paths depending on the current they conduct.

When arranging components on a circuit board, you must take care that there is adequate space between them, otherwise they will not fit. The Eagle program makes it easy for you to do this, because in its database it contains enclosure views for all available electronic components. Here is a sample PCB design, corresponding to SCH schematic:

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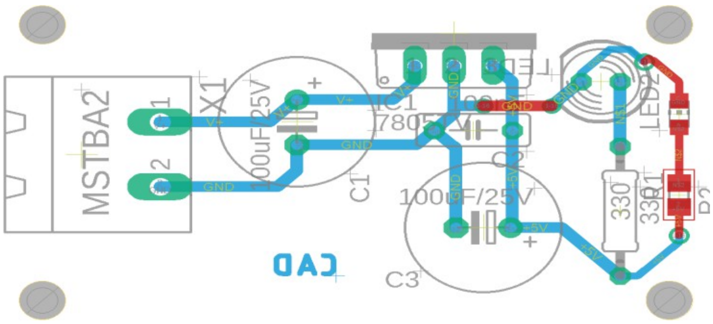

Fig. 3.8 Example of BRD scheme of power supply

e) PCB making
f) Assembly of electronic circuits by soldering
g) System programming (if required)
h) Function test (power supply, individual modules)
i) verification of design assumptions and possible return to one of the previous points.

For prototypes, PCBs can be made using one of three methods:

- Thermal transfer
- Phototransfer
- Mechanical milling.
- Most often, however, the tiles are ordered outside (outsourced) and made by external companies

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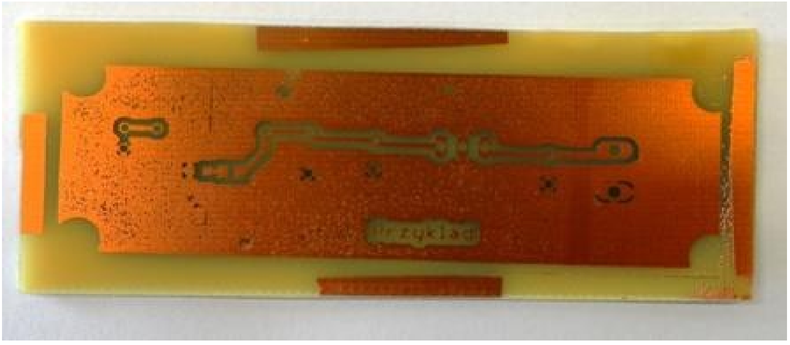

Fig. 3.9 Example of thermal transfer PCB

Example of PCB making using the phototransfer method

Basic rules for the implementation of the BRD layer:

a) Before starting work, set the grid on which the elements are to be placed. Due to the dimensioning of the electronic component housings, it is recommended to set inches or mills as the main unit.

b) The wire should be as simple and short as possible, especially in analogue and digital circuits, including some communication interfaces, e.g. SPI (impedance and the parasitic effect of connections have a special impact on the operation of the electronic system).

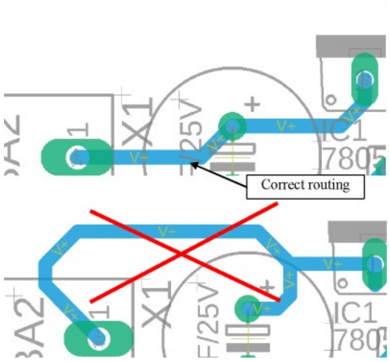

Fig. 3.10 Example of correct and bad routing

c) Wires should be routing at an angle of 45 degrees or at an angle of 90 degrees

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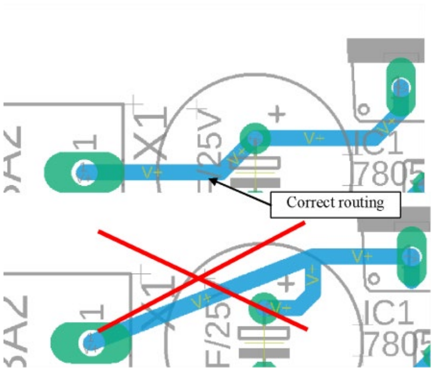

Fig. 3.11 Example of correct and bad angles

d) Electronic components should be placed differently to the edge of the plate, at an angle of 90 degrees to each other

e) Remember to add power connectors, which should be placed on the periphery of the PCB, preferably at one edge

f) The ground plane has several tasks in the case of PCBs: They are:

- reference for all voltages within the board
- provides a noise shield and / or heat sink.
- reduces the inductance of parasitic circuits and increases the capacitance

The basic rule is that it should occupy the largest possible PCB surface - preferably the entire one layer of the PCB. In multilayer boards, the ground plane and the power plane are dedicated to the inner layers, while the signal paths lead to the outer ones. In the case of the much more common two-layer panels, it is recommended that at least 75% of the layer's surface be allocated to the test range.

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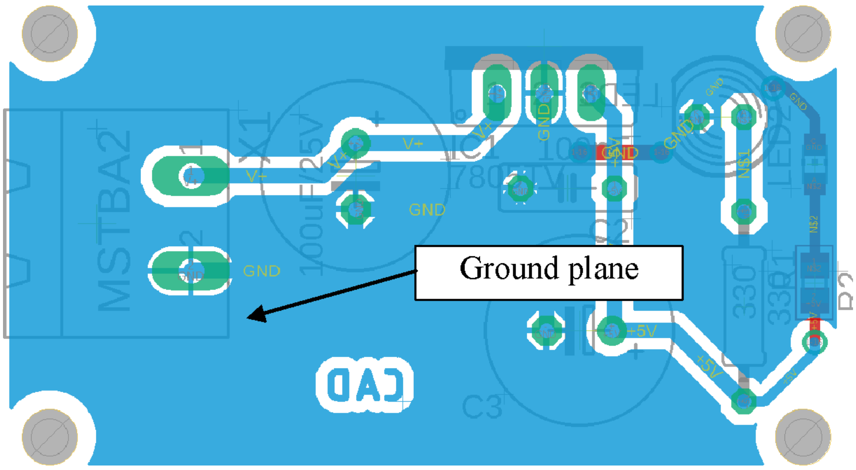

Fig. 3.12 Example of ground plane on bottom layer of PCB

g) Testing the board for correctness according to predetermined parameters (Design Rule Check). It might look like this:

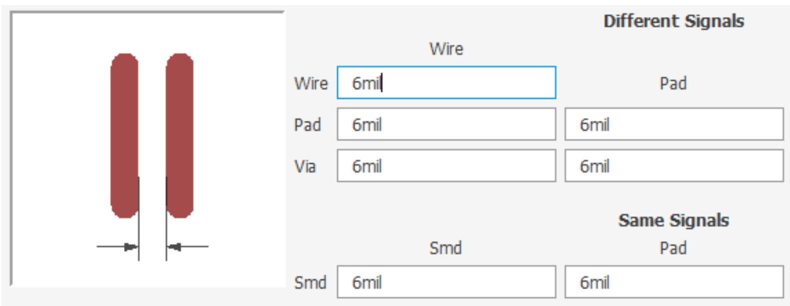

Fig. 3.13 Example of signals settings

h) Use of information imprints

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Fig. 3.14 Example of text in bottom copper layer

i) Grouping of cooperating components - dependent elements should be placed as close to each other as possible

j) Using as many of the same components as possible - this applies especially to passive components, such as resistors, capacitors, etc. Using components with values from the series, including the same housing sizes, the same within the board, simplifies the list of components and facilitates assembly. These elements can also be used in other projects.

k) Placing test points on the PCB

l) pay attention to paths that must be symmetrical and of the same length, e.g. paths connecting quartz with a microcontroller

3.3.3. Production files - GERBER format

The standard of printed circuit board production documentation is the so-called Gerber format. It allows to vector save the image of the design layers:

- paths,
- mosaics,
- masks,
- descriptions.

There are two versions of the format:

- older Standard Gerber (RS-274D)
- contemporary Extended Gerber (RS-274X).

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Layer files in the Extended Gerber format (RS-274X) contain the complete set of data for design processing - coordinates and aperture definitions.

Machining parameters such as drilling and milling are most often used in the Excellon format (version 2). A program of this type for CNC drilling or milling operations should include:

- definition of the diameters of the tools used.
- also store information about the format of the coordinates and the units of measurement used.

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3.4 *Examples of 3D printed biomimetic devices*

3.4.1. Bicycle prosthesis

The first product example is a 3D printable mechanical prosthesis, intended for use with personal transportation devices, such as bicycles or scooters (Fig. 3.15). The prosthesis is a mechanical device, anatomically adjusted to a specific patient by a set of constraints and dimensions. It is intended for patients with transradial amputations or defects (above or at the elbow level), although patients with a short forearm stump could also possibly use it.

Fig. 3.15 [automedprint.put.poznan.pl]

The prosthesis is printable of any material – PLA and PET-G are recommended as being known for proper behavior in contact with user's skin. PLA is suitable for children version, while more durable materials, such as PET-G, are recommended for adult users. ABS and other materials could also be used, provided that there is no direct skin contact (e.g. foam is used) or sterilization is performed before and also after use. 3D printing of the whole prosthesis in children version lasts approx. several hours, depending on the material and printer used. It could be realized simultaneously, as the prosthesis contains few larger parts and several smaller parts. Standard nuts and bolts are used for assembly, along with straps and EVA foam for lining of socket's insides.

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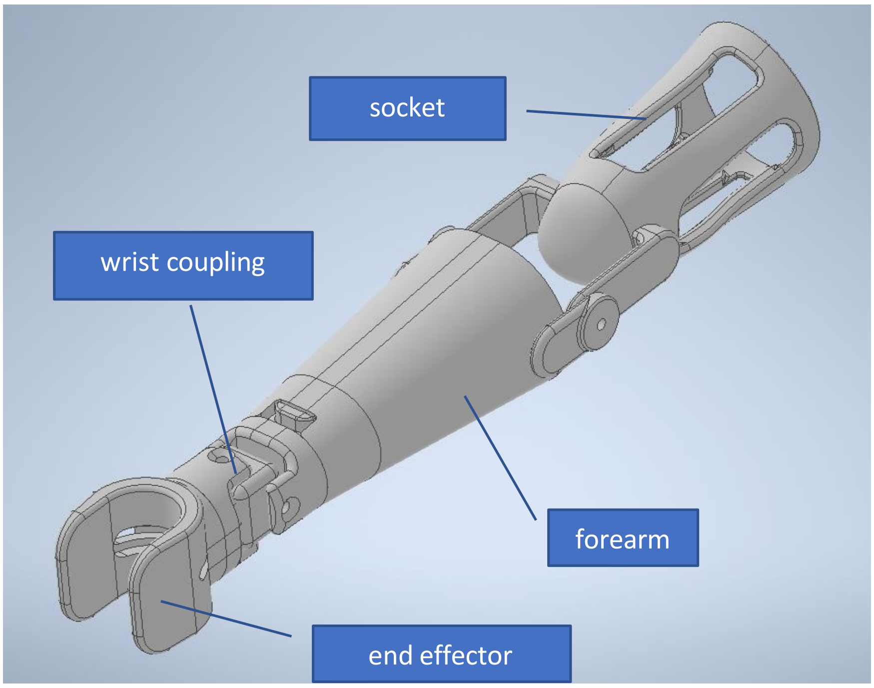

Fig. 3.16 Basic parts of the bicycle prosthesis

The prosthesis consists of basic parts (as visible in the figure above):

- socket (stump part) with elbow coupling,
- forearm part,
- wrist coupling (4 parts),
- elbow coupling,
- end effector.

The prosthesis is a biomimetic device, having two joints resembling human elbow and wrist joint, as well as a customizable socket of anatomic shape, using compression and release of muscle tissue to keep the prosthesis locked on patient's limb. All the basic parts are modular and can be replaced with different parts.

The prosthesis was designed using Autodesk Inventor software. Thanks to use of modularity and implemented iLogic rules, it is possible to obtain a large number of variants for a single patient (examples in Fig. below).

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The model is impossible to use without aid of MeshLab software, which is needed to obtain data necessary to feed the model with patient-specific anatomical features. MeshLab software is also used to check fit of the prosthesis after it is generated (Fig. 3.17).

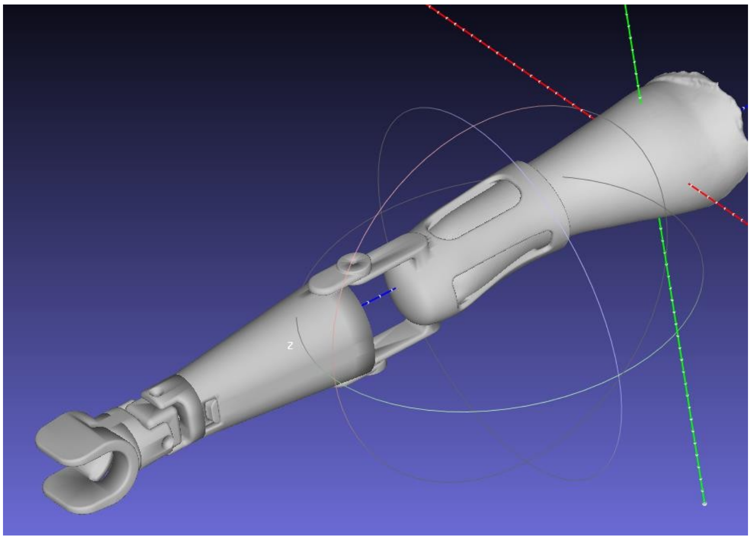

Fig. 3.17 Fitting check in MeshLab software

3.4.2. Therapeutic hand orthosis

The product is an orthosis used for wrist joint stabilization in time after an injury (e.g. Colles fracture) or for patients with conditions that require stabilization (rheumatoid arthritis, muscle atrophy and many others) – Fig. 3.18. The orthosis is openwork, to enable skin access in both comfort and hygienic reasons. Rehabilitation orthosis (used in the event of muscle paralysis, damage to the hand nerves, etc.) is designed to stabilize the hand in a position where active rehabilitation of the hand occurs. In this way, it supports the correct positioning of the hand and allows to perform exercises supporting the patient in the rehabilitation process.

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Fig. 3.18 Examples of use of the Wrist Hand Orthosis [automedprint.put.poznan.pl]

The orthosis is customized on the basis of a 3D scan geometry of patient's hand and forearm. It is 3D printed using one of the basic FDM technology materials: PLA, ABS, PET-G and PA-12 (nylon), of which PLA and PA-12 are recommended due to proper combination of mechanical and processing properties, as well as no known issues with skin irritation. The 3D printing takes approx. 3-4 hours for one part of the orthosis, for an adult patient.

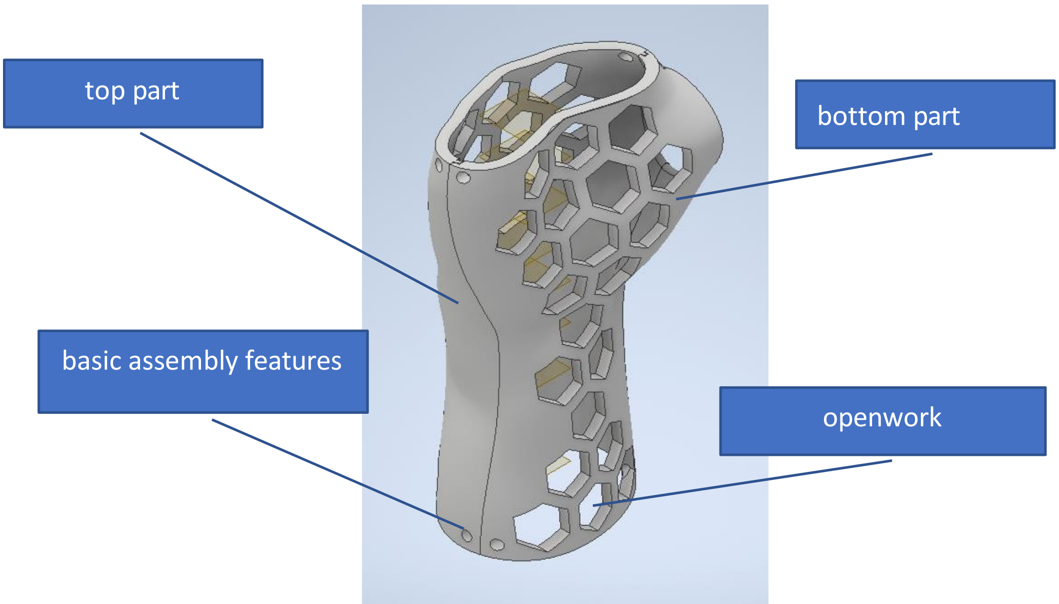

Fig. 3.19 Wrist hand orthosis – basic parts [Górski 2021]

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The orthosis consists of basic parts (as visible in the figure above):

- bottom part (in contact with palm),
- top part (in contact with back of the hand),
- optionally – the bottom and top part could be transversally divided if orthosis too long for a given 3D printer (could be 4 parts instead of 2) .

Complete model of a customizable orthosis was made in Autodesk Inventor. The parameters (dimensions) are stored in an Excel spreadsheet (which could be edited using MS Excel with VBA macro support). A new set of anatomical measurements is created for every single patient, using a batch file involving a set of algorithms, based on MeshLab, Excel VBA and a custom application for selection of basic section plane positions. Then, these measurements stored in an Excel file, must be used to customize the orthosis and any errors or inconsistencies must be repaired to obtain a functional orthosis.

If the orthosis is set to be functioning not only as a corrective, but also therapeutic device, it needs to have certain cutouts, to allow grasping movement. Examples of these features are shown in Figure below.

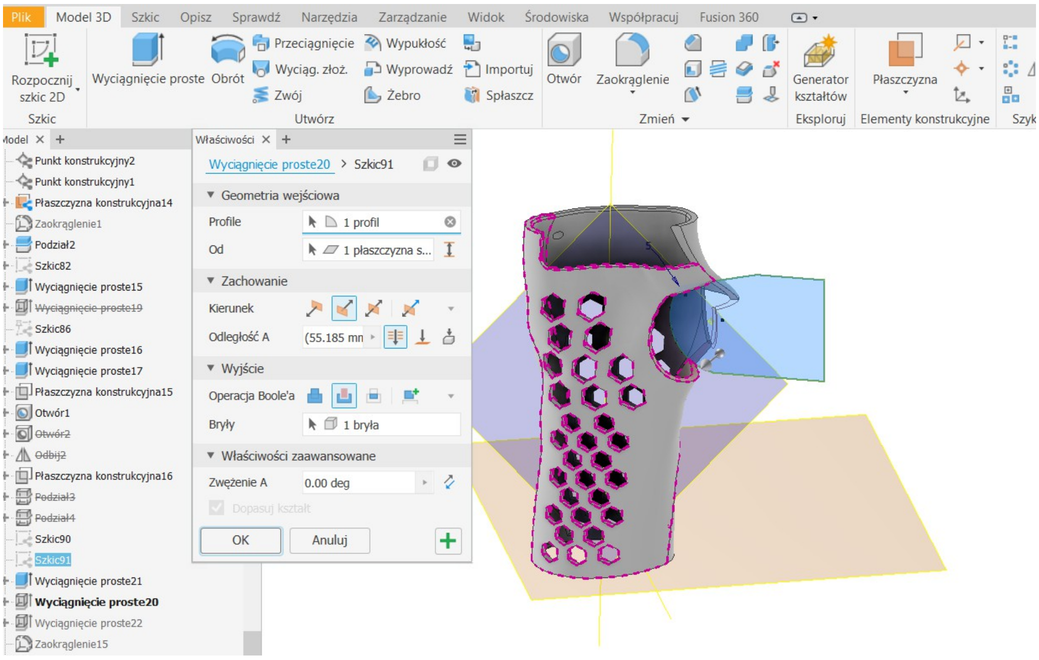

Fig. 3.20 Conversion of standard orthosis into therapeutic orthosis in Inventor

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As in the case of the bicycle prosthesis, it is important to use MeshLab software to generate the set of patient data, as well as check proper fitting at a later stage (Fig. 3.21).

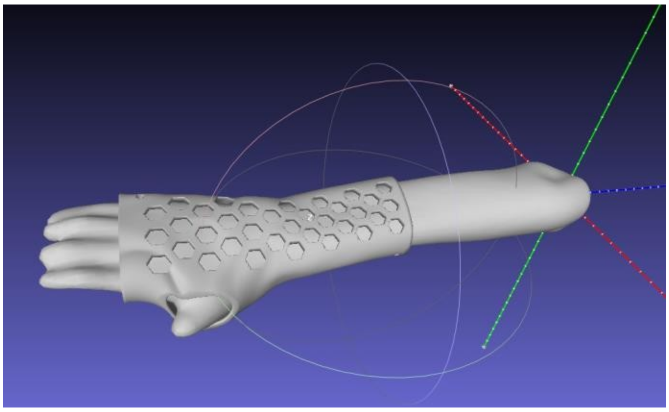

Fig. 3.21 Orthosis fitting check in MeshLab

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4. Summary

In this module, basic knowledge about computer aided design of 3D printed biomimetic mechatronic products for people with special needs was presented. The most important takeaways have been summarized below:

- using digital technologies can make design for medicine much faster and also more robust,
- 3D printing helps faster iteration of design, as well as easier obtaining of organic, anatomical shapes,
- designing individualized medical products requires anatomical data processing in several types of software,
- design for medicine requires participation of doctors at the beginning and often end of the process,
- some, if not most operations in the design process of medical parts can be automated for greater efficiency,
- functional, specialized, biomimetic prostheses can be 3D printed for a fraction of a cost of a traditional, expensive one – but the design can be time consuming,
- design changes can be introduced anytime, as many times as feedback is gathered from patients,
- 3D printed prostheses and orthoses could be converted into mechatronic devices by adding sensors and actuators, helping in therapeutic or daily activities.

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