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EUROPEAN NETWORK FOR 3D PRINTING OF BIOMIMETIC MECHATRONIC SYSTEMS

MODULE 7 – 3D PRINTING

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Contents

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1. Introduction

Additive manufacturing technology (AMT), also known as 3D printing, has revolutionized various industries, including medicine. It is transforming the way medical devices and implants are manufactured, leading to significant advancements in patient care. 3D printing has the ability to create intricate and complex structures, which was not possible with traditional manufacturing techniques. This has opened up new possibilities for medical professionals and researchers to explore and improve upon existing treatments and procedures.

The medical applications of 3D printing are numerous and include the creation of prosthetics, implants, surgical tools, and even human tissues and organs. In the field of prosthetics, 3D printing allows for the production of custom-made, patient-specific devices that are designed to perfectly fit the individual. This has significantly improved the comfort and functionality of prosthetics, allowing patients to lead more active and fulfilling lives.

Another area where 3D printing is making a significant impact is in the creation of implants, such as spinal and joint replacements. Traditional implant manufacturing techniques have limitations, leading to standardized, one-size-fits-all devices. With 3D printing, implants can be created that are tailored to the specific requirements of each patient. This leads to improved patient outcomes and reduced recovery times, as the implant fits more precisely and functions better.

In the operating room, 3D printing is also playing a crucial role in the development of surgical tools and instruments. Surgeons can now create custom-made instruments that are specifically designed for the task at hand, improving the accuracy and efficiency of their procedures. Additionally, the use of 3D printing in surgical planning is allowing for more accurate preoperative simulations, allowing surgeons to visualize and practice complex procedures before they are performed on a patient.

One of the most exciting areas of research in the medical field is the development of 3D printed tissues and organs. Although still in its early stages, researchers have made significant progress in creating functional 3D printed tissues and even entire organs. The eventual goal is to provide patients with functional replacements for damaged or diseased tissues and organs, reducing the need for organ transplantation and improving patient outcomes.

3D printing is also revolutionizing the field of biomechatronics, which combines biomechanics and electronics to develop advanced prosthetics and exoskeletons. The

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aforementioned ability to create complex, custom-fit structures has opened up new possibilities for the design and manufacture of these devices.

One of the most significant benefits of 3D printing in biomechatronics is the ability to create prosthetics that are perfectly tailored to the individual patient. Traditional prosthetics have been limited by their standardized design and one-size-fits-all approach. With 3D printing, prosthetics can be designed and manufactured to meet the specific needs of each patient, leading to improved comfort and functionality.

Exoskeletons, which are wearable devices designed to enhance or augment human movement, are another area where 3D printing is making a significant impact. With 3D printing, exoskeletons can be designed and manufactured to be lighter, more comfortable, and more functional. This is particularly important for individuals with mobility impairments, who require exoskeletons to be as unobtrusive as possible.

This module presents basic knowledge on 3D printing. Some basic concepts and definitions have been presented, as well as some descriptions of fundamental and derivative processes. Along with basic knowledge, also examples of use in the field of personalized prosthetic and orthotic devices are presented.

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2. Basics of 3D Printing technology

2.1 Basic definitions

Below, some basic definitions and concepts pertaining to additive manufacturing are presented.

1. Additive Manufacturing: Also known as 3D printing, this is the process of creating a three-dimensional object by adding material layer by layer.
2. Rapid Prototyping: It is a main application of additive manufacturing - a process of creating a physical model of a product or part in a fast and efficient manner, typically using computer-aided design (CAD) data. The goal is to quickly produce a working model for testing, evaluation, and refinement.
3. Rapid Manufacturing: It is a manufacturing process that utilizes rapid prototyping technologies to produce end-use products in small to medium quantities. This method is faster and less expensive than traditional manufacturing methods and can be used to produce complex geometries and designs that are difficult or impossible to produce using other methods.
4. Rapid Tooling: It is the use of rapid prototyping techniques to produce tooling, such as molds, dies, and jigs, in a fast and cost-effective manner. This approach enables manufacturers to quickly produce low-volume production runs, test and refine designs, and reduce time-to-market.
5. 3D Modeling Software: This is software used to create 3D digital models that can be used in additive manufacturing.
6. Build Volume: This is the maximum size of the object that can be produced in a single build process.
7. Layer Height: This is the thickness of each individual layer that is added during the additive manufacturing process.
8. Resolution: This refers to the level of detail that can be achieved in the final product.
9. Post-Processing: This refers to the additional steps that may be required after the additive manufacturing process to achieve a finished product, such as sanding or polishing.

Basic scheme of additive manufacturing, by Gebhardt [1], is presented in Figure 2.1.

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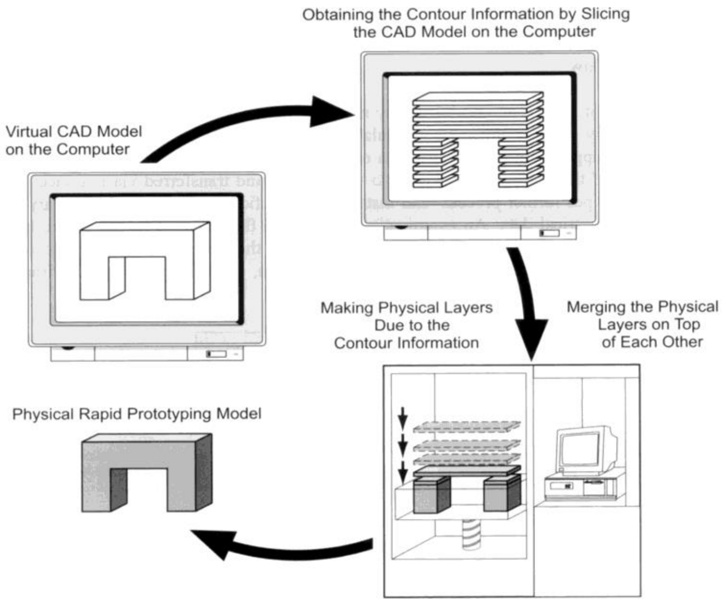

Figure 2.1. Basic scheme of additive manufacturing [1]

2.2 3D Printing technologies

2.2.1 Review of available technologies

The ISO/ASTM 52900 standard defines the following seven categories of additive manufacturing processes (Fig. 2.2):

- extrusion,
- sintering of powders (powder bed fusion),
- photopolymerization,
- material jetting,
- binder jetting,
- sheet lamination,
- directed energy deposition [2].

The first three categories are also the oldest. They gained their popularity on the consumer market mainly due to numerous patents expiring at the beginning of the 21st century by such companies as 3D Systems, Stratasys, MIT, HP, Hitachi.

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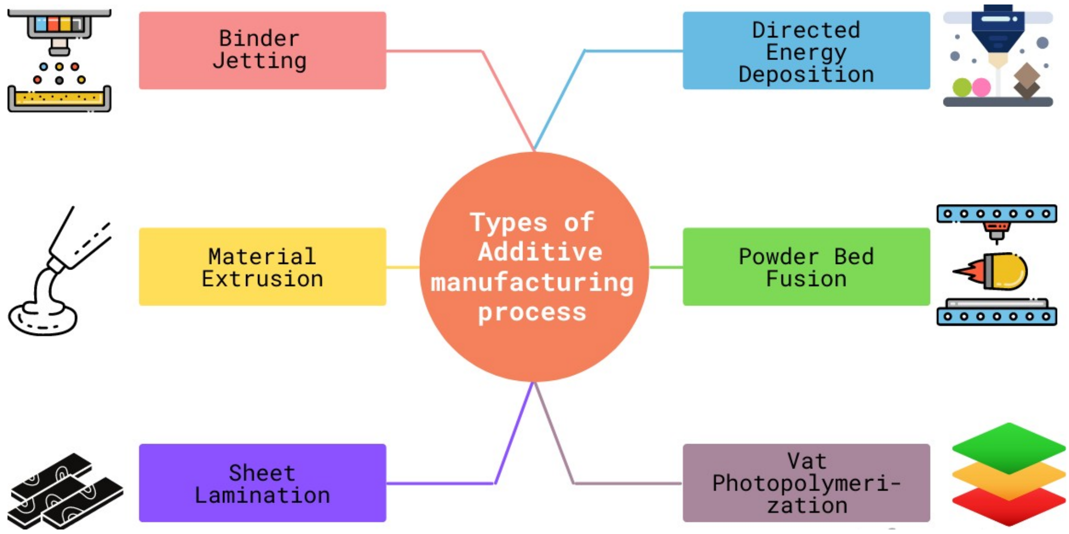

Figure 2.2.Categories of AMTs according to ISO 52900 standard [3]

Of each category, there are several or more distinctively named processes. Some processes are hybrid, i.e. they combine elements from two or more categories. The categories focus more on how the material is stored, deposed and finally joined and less on mechanical and kinematic aspects of realizing these functions. As such, machines realizing processes from one category might look (and also cost) entirely different, depending on the used approach. This is especially visible for the categories, in which original processes lost the patent protection and as such have become “free” technologies – such as Fused Deposition Modeling or stereolithography. These technologies can be implemented in either low-cost, hobby-like machines or in industrial-grade professional devices, ready to be placed in a factory floor or medical facility.

The most popular processes – historically and nowadays – are described in the following subchapters.

2.2.2 Fused Deposition Modelling

Fused Deposition modeling is a process consisting in layered deposition of plasticized build and support material supplied in form of a wire by an extrusion head (see fig. 1 for process schema). Numerically controlled device deposits build and support material on the model base, with data about head positioning coming from horizontal cross-sections of the part, prepared on the basis of the 3D CAD model. The ABS material is frequently used, other

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thermoplastics can be used too, depending on the machine and head type. Obtained models are considerably strong and can be subjected to further treatment by machining, gluing or painting, to obtain desired surface quality. Produced part is ready for use immediately after support material removal [4].

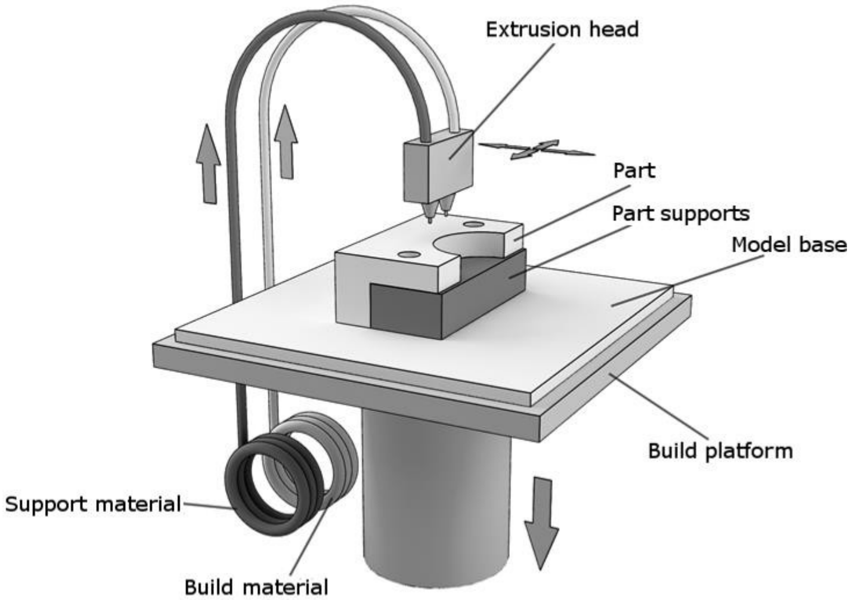

Figure 2.3. Scheme of FDM technology [5]

A very important feature of the FDM technology is the need to use supports. Unlike most additive technologies (e.g. stereolithography or powder methods), the created product does not have any natural supports, so in many cases the applied material could be deformed due to the force of gravity or table or head movements. Hence the need to build support structures that prevent deformation. The most commonly implemented method of building these structures is the use of a double head extruding the plasticized material - apart from the building material, it will be a special support material, usually a polymer material of a similar class, but with slightly different properties. The support must be removed at the end of the process and is the only finishing operation necessary in this manufacturing technique. Due to the method of removal, two types of supports can be distinguished - mechanically removed (by breaking) and soluble, removed by immersing the finished model together with the support in a special liquid.

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The process utilizes mostly thermoplastic materials, or composites based on them. Below, the most frequently used and specific materials are mentioned.

Standard:

- ABS - Acrylonitrile butadiene styrene, (poly(acrylonitrile-co-butadiene-co-styrene)) - the most popular, good strength properties,
- PLA - polylactide, polylactic acid - cheap, biodegradable, easily processed

Often used:

- PETG ("HD glass") - transparent, durable, easy to process,
- TPU ("flex") - thermoplastic polyurethane, flexible, soft
- PA12 (nylon) - abrasion resistant
- HDPE - polyethylene - cheap, available

Specialized:

- PC - polycarbonate – durable
- PPSF - polyphenylsulfone (polyphenylsulfone) - increased resistance
- PEEK (polyetheretherketone) - rigid, durable, resistant to high temperatures

Soluble supports:

- PVA - polyvinyl alcohol, soluble in water
- HIPS - polystyrene - soluble in limonene, can also be used as a building material

Figure 2.4 presents single anatomical product (hand orthosis) made of different materials using FDM technology.

Apart from the material, users of FDM technology can alter almost any parameter of the process, provided that the software and a given machine are open source. Basic parameters are layer thickness, internal filling level (stated in percentage of filling up single layer), velocities of head movement and material extrusion and temperatures of working table and printing nozzles. There are many other advanced parameters, able to be set up in the software. More expensive, industrial-grade machines have the process more automated, with only several choices to be made and other parameters adjusting automatically to a given material.

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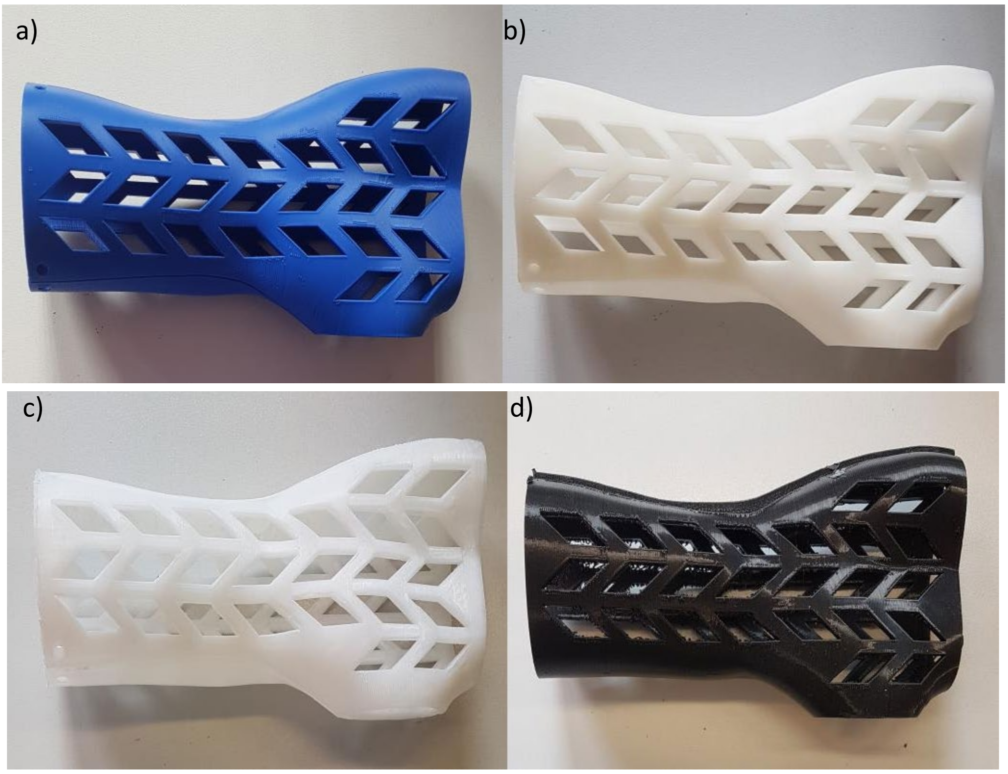

Figure 2.4. Orthosis manufactured in FDM technology, using: a) ABS; b) PLA; c) nylon; d) TPU

Compared to other additive manufacturing techniques with a similar cost and time to obtain a finished product (e.g. SLA, PolyJet, Layered Object Manufacturing), the FDM technique has the following advantages:

- speed of obtaining finished products - immediately after the machine is finished and the supporting structures are removed, the products are ready for use, without the need to keep them in the working chamber of the machine; also the layers are deposed relatively quickly,
- acceptable mechanical properties - products obtained with the FDM technique do not require finishing to obtain satisfactory mechanical properties,
- availability of build material - products are made of thermoplastics that are generally available, easy to process and recover through recycling.

One of the largest disadvantages of FDM is the relatively low mechanical properties of obtained products (tensile & bending strength, impact resistance, elongation at break and others) [6]. Apart from being lower than expected, these properties also often have uncertain,

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hard-to-predict values and are anisotropic on a macroscopic level [7]. The influence of the manufacturing process parameters on mechanical properties of products made using FDM, and economical coefficients of the process have been thoroughly studied worldwide [6-8].

2.2.3 Stereolithography and UV technologies

Stereolithography (SLA) is one of the basic and oldest methods of additive manufacturing. The SLA technology belongs to the group of additive manufacturing techniques that use the photopolymerization process (so-called "UV technologies"). The fabricated object is created as a result of selective hardening of the photopolymer resin with laser light, with the laser operating in a specific range of wavelength (ultraviolet). The resin is poured into the container, into which the work table is immersed. When the table is lowered to the bottom of the container to the height of the predetermined layer, the laser beam, which is focused on a predetermined path by means of a set of special mirrors (known as scanners), hardens the given layer of material. When this is complete, the platform rises to the height of the next layer and the process repeats. Basic scheme of the process is shown in Fig. 2.5.

After printing, the part is not fully cured, requiring repeated exposure. Carrying out additional processing (mainly re-exposure after the completion of the printing process) makes it possible to improve the mechanical and thermal properties of the printed model.

Unlike in the FDM technology, most of the parameters of the process are set automatically by the device manufacturers, without the possibility of changing them. Usually it's not possible to control intensity of the laser, its detailed movements and speed etc. Changeable parameters include the very basic ones: layer height and model position, which determines the location of its support structures. The supports are usually required to some extent, not as bulky as in the FDM, but rather openwork and easily disposable using simple mechanical tools, right after the process.

The typical layer height of the material is 25-100 µm, but both lower and higher values can be found in available systems. The use of lower layer thicknesses allows for better mapping of complex geometries, especially in comparison with the FDM technology – so-called staircase effect, eminent in FDM prints, is usually minuscule or unnoticeable in SLA prints. On the other hand, the manufacturing time is extended, and thus the cost of the production process. 0,1 or 0,05 mm are usual thicknesses of choice in the SLA process.

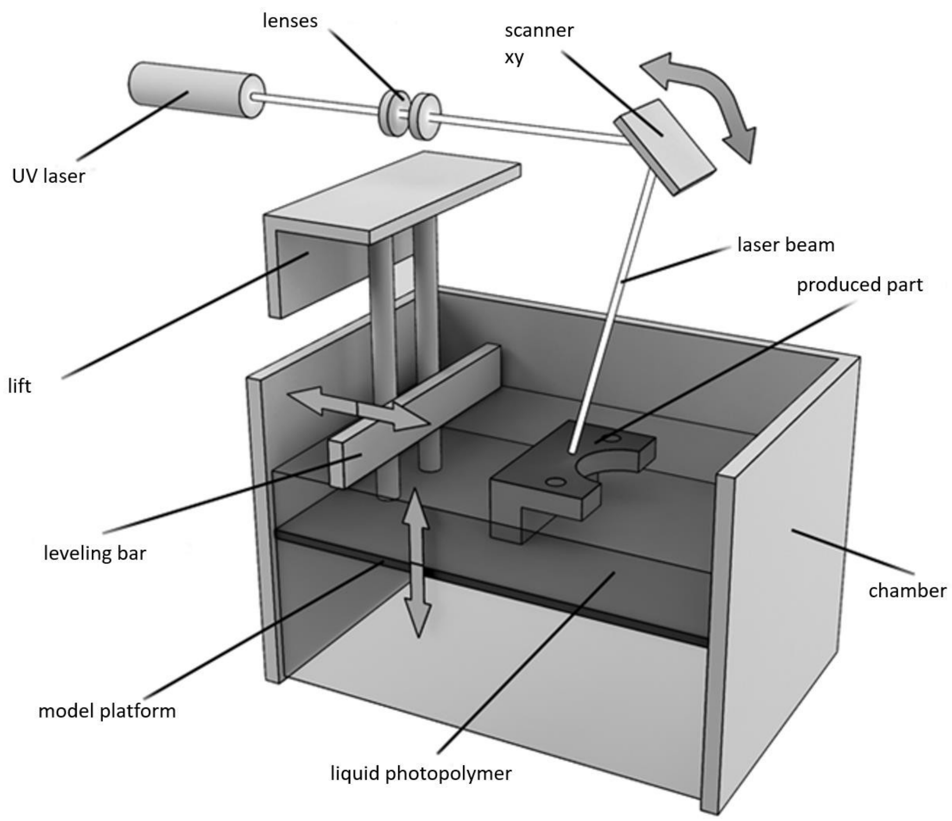

Figure 2.5. Scheme of SLA technology [5]

There are two main kinematic variants of SLA technology:

- standard process, in which laser is positioned above the resin tank (as presented in Fig. 2.5), and the model platform is going down after each layer,
- inversed process, in which laser is positioned below the resin tank and the model platform is rising up after each layer, with the product being fabricated upside down.

The standard process, more difficult to implement and costly, is a domain of professional, industrial printers. The inversed process can be found in most middle class or low-cost machines, offered by various producers. In the inversed process, the support structures are far more important than in the standard process, as they also enable safe and stable manufacturing, without disjoining of the model from the table due to gravity and increasing mass of the produced part.

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Examples of desktop SLA printers with setup are presented in Fig. 2.6. An example of SLA part of anatomical shape is presented in Fig. 2.7.

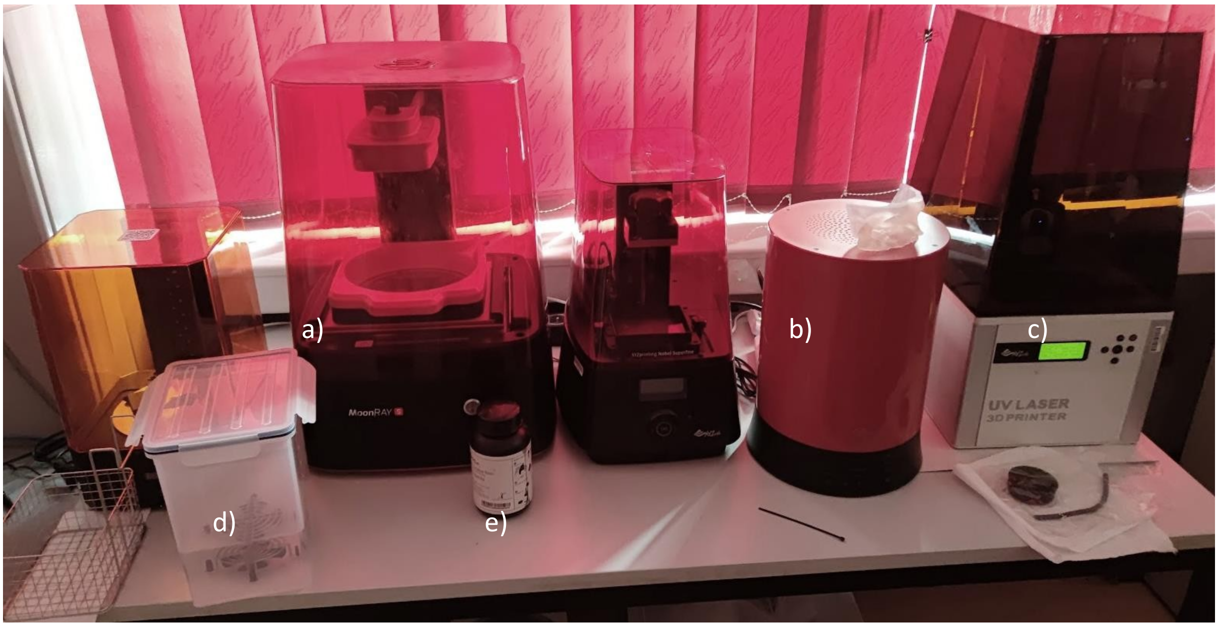

Figure 2.6. SLA technology setup: a) & c) desktop machines with inverse kinematics, b) post-curing station, d) cleaning tank, e) photopolymeric material

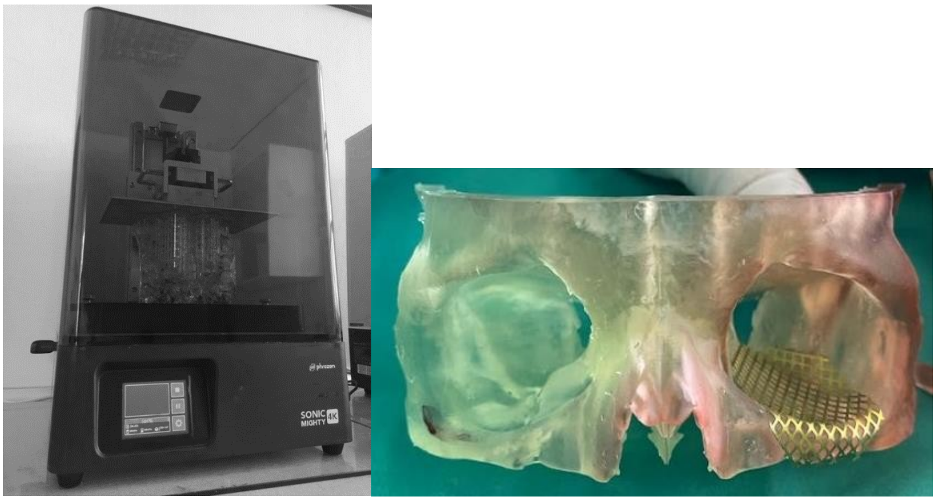

Figure 2.7. Anatomical part printed with SLA (inside the machine) and its clinical use for implant shape adjustment [9]

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Thanks to the use of SLA, it is possible to produce a model with a high degree of complexity of geometry, which has free surfaces with a wall thickness not less than the diameter of the laser beam used. This allows for a very high surface quality. Sterolithography has many advantages, but also weaknesses. SLA is a slow process, which, combined with the high cost of the building material, makes the use of this tool less economical compared to other methods (such as FDM). It should be remembered that during the polymerization process, volumetric shrinkage may occur, which will result in both dimensional and shape errors. However, modern materials and stable conditions of the manufacturing process allow to significantly reduce the risk of such errors. An additional problem may be the fact that elements made of photopolymers differ significantly in appearance and properties from typical engineering plastics. Due to the low mechanical strength, the models produced with the use of SLA mainly play the role of visual and conceptual prototypes, and are rarely used in functional tests [5].

The SLA technology is a basic UV process. There are, however, some variations even more useful than the original process. The most popular is the PolyJet technology, combining photopolymerization principle with kinematics more similar to FDM process, with moving head deposing the material in selected locations at the model table. This improvement allows using multi-material heads and obtaining models with combined properties, either pertaining to color or e.g. hardness or other properties. Basic scheme of the PolyJet process is presented in Figure 2.7. However, kinematics implemented in various machines can be different.

PolyJet technology is very useful for building multi-material, very detailed physical representations of complex intricate shapes, especially anatomical ones. It is suitable for representation of very thin structures and minor details, such as eye socket bone (Fig. 2.9) or arteries and nerves in a brain. Larger machines, such as MediJet J5 (Fig. 2.8) can be used to produce useful structures and objects, such as mechanisms of bioinspired prostheses, as well as large anatomical interconnected structures, such as liver or heart. PolyJet models need support, but as the process is conducted in low temperature, these supports are easily soluble under a jet of pressurized water, and as such are not a topic of concern as in FDM or even SLA. PolyJet is however an expensive technique and not as easily implementable in office or hospital conditions as relatively simpler FDM or SLA machines.

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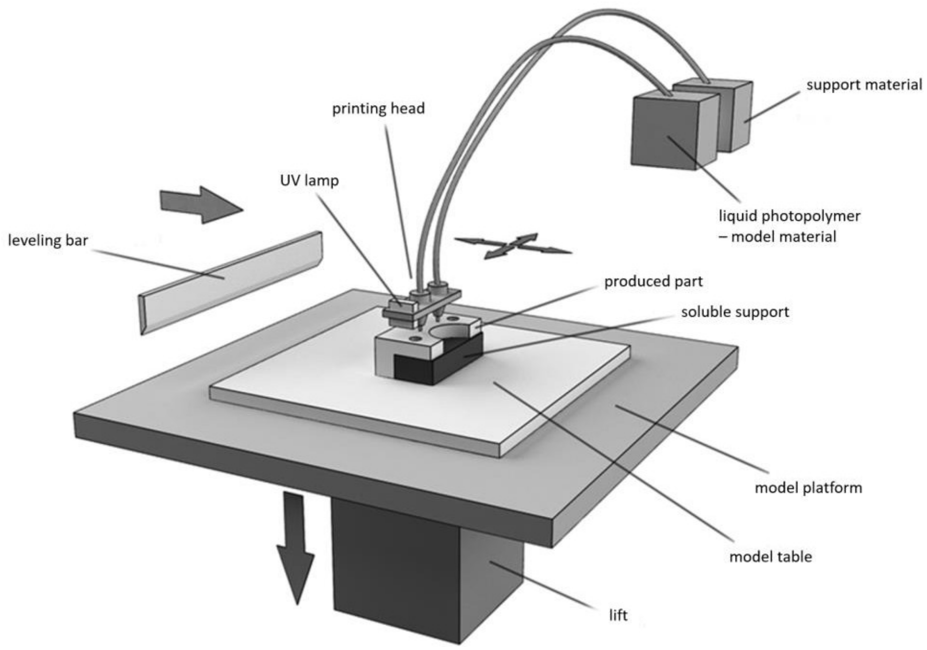

Figure 2.7. Scheme of PolyJet technology [5]

Figure 2.8. PolyJet machine – Stratasys MediJet J5

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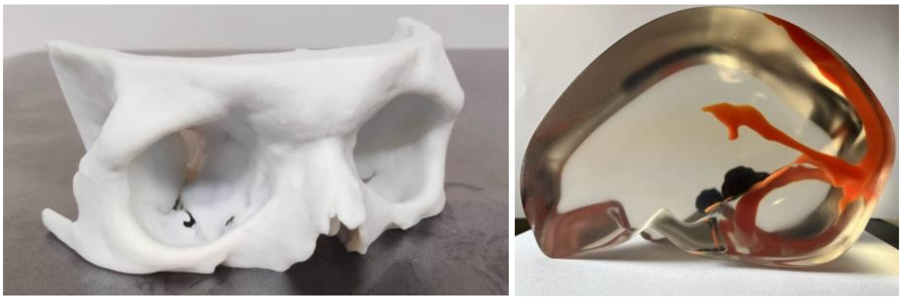

Figure 2.9. Example of anatomical models produced by PolyJet [9]

Another noteworthy example of UV technology is DLP, standing for Digital Light Processing. In this technology, idea of partial, point-like curing of liquid material has been replaced with curing of image of a whole layer at once, using special digital light projector (hence the name) and special brand of material, curable in the light of this projector. DLP technologies are often named as “layerless”, as there can be no defined layer thickness – the projector can smoothly project a section plane “traveling” through 3D object model along with corresponding vertical movement of build platform. Support structures are necessary as in the inverse kinematic SLA method, as the projector is located at the bottom of the resin tank (Fig. 2.10). DLP is a useful method for intricate shapes, but current generation of machines have very small build chamber and the process takes very long – its usability is therefore limited.

Figure 2.10 DLP machine and example of anatomically shaped product [10]

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2.2.4 Selective Laser Sintering

Selective laser sintering (SLS) is one of the basic additive manufacturing methods. It was developed at the University of Austin (United States), and the first successful commercial implementation took place in 1991. Intensive development work on the SLS method led to the creation of similar methods: Direct Metal Laser Sintering (DMLS) and Selective Laser Melting - SLM. All three methods are considered as one family. They differ mainly in the range of materials used, as well as in the fact that in the SLS and DMLS method only the outer layer of powder grains is melted, and in SLM the powder grains are fully melted (as in welding processes) [5].

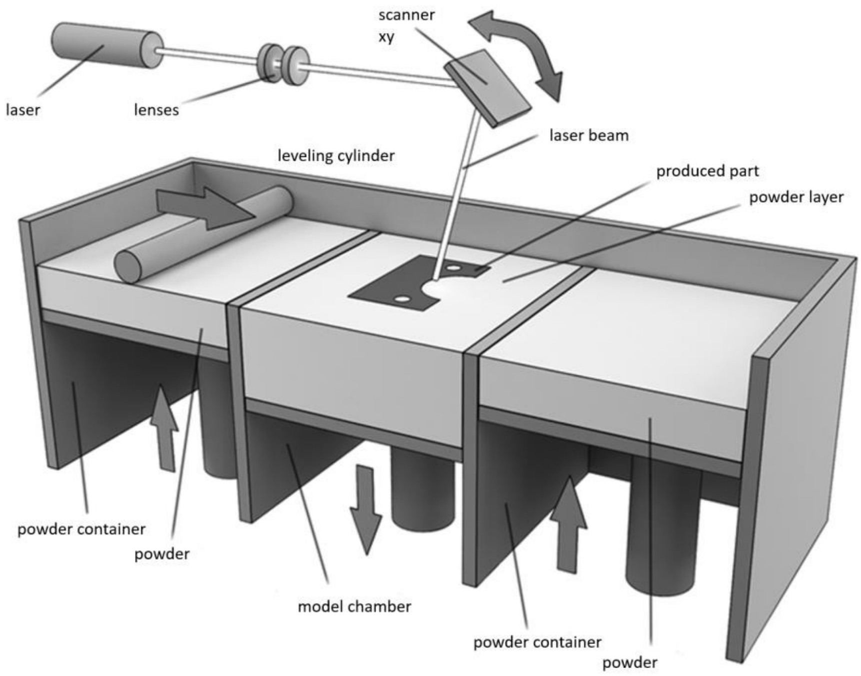

Figure 2.11. Scheme of SLS technology [5]

The additive sintering methods use high-power lasers - most commonly CO2 (carbon dioxide) for SLS and Yb (ytterbium) for DMLS/SLM - to deliver the necessary energy to the powdered material for fusion. The density of the produced prototypes depends mainly on the maximum instantaneous power that the laser can achieve, and not on the amount of energy delivered to the powdered material. Therefore, pulsed lasers are used, which can deliver short pulses of high power light. Among the materials used to build prototypes, one can find both

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plastics (nylon, nylon with glass microfiber, polypropylene, polystyrene, ABS) and metal powders (steel, stainless steel, tool steel, titanium, bronzes, aluminum, copper, nickel), depending on machine construction and laser type used. The SLS method uses both one-component powders and two-component powders - of which only one component material is a melting binder and the other is a filler. The size of a single grain is usually in the range of 20-70 micrometers, and the smaller it is, the better the strength properties and the greater the dimensional and shape accuracy of the manufactured element.

The temperature in the working chamber is only slightly lower than the melting point of the material from which the powder is made. Thanks to this, the bonding of successive grains requires the supply of a small amount of energy by a laser guided selectively on the surface of a given layer. This shortens the duration of the entire model building process. After the powder fusing process is completed, the produced parts must cool down, and then they are removed from the working chamber and cleaned of loose grains. The use of high-power lasers also necessitates the use of a protective atmosphere inside the working chamber. It is most often filled with nitrogen or argon (with minuscule amounts of oxygen, strictly controlled, desirably below 0,1% or even less), thanks to which there is no danger of ignition and explosion of the powder [5].

The great advantage of the described method is that there is no need to use supports for the elements protruding beyond the outline of the prototype base, because they are supported by the loose, unbound powder. The key advantage of the whole group of technologies is the possibility of using metallic powders, from which it is possible to build fully functional prototypes and series of usable products, such as personalized implants ready for implantation. The disadvantages of laser sintering include a much more complicated mechanical system of the device than in the case of other methods, leading to very high costs of purchase, implementation and maintaining the equipment. What's more, the obtained dimensional accuracy and surface quality of the prototypes is lower than in the case of stereolithography, and sometimes FDM [5].

Examples of anatomically shaped products 3D printed using SLS technique are presented in Figure 2.12.

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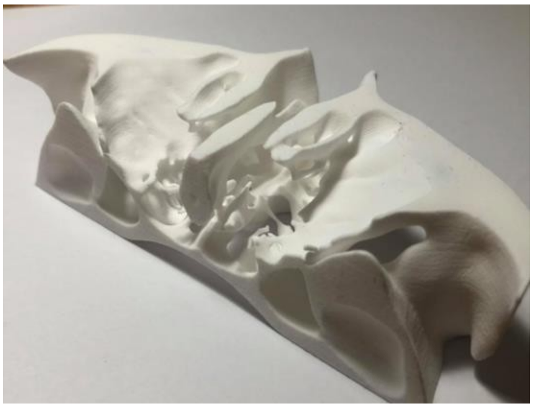

Figure 2.12. Example of anatomical object produced by SLS technique [11]

2.2.5 Other noteworthy technologies

Among literal dozens of other additive technologies available on the market, the following might be interesting from the viewpoint of producing biomimetic devices intended for medical use:

- 3D bioprinting is one of the additive manufacturing techniques (Additive Manufacturing) intended for medical applications and tissue engineering. It consists in the layered production of tissues (groups of cells). The produced tissues consist of living cells and specially selected support materials (organic or synthetic), ensuring process stability and shape rigidity. During the manufacturing process of one model, it is possible to use many different materials in its different areas. 3D bioprinting is currently used to test new drugs, study disease processes in a safe environment, and study blood flow processes in artificial vessels. In the future, it is planned to print tissues and complete organs for transplants based on the recipient's own cells. Basic bioprinting processes are based on known additive solutions: the main processes are inkjet printing, embossing, laser printing and stereolithography. The current generation of devices is used mainly for experimental purposes - the stability of the shapes obtained, cell survival, and the complexity and size of the obtained tissues are still not high enough to speak of a breakthrough in the field of tissue engineering and transplantology. However, 3D bioprinting technology can be described as the future of medical printing, especially in the field of biomimetic solutions.

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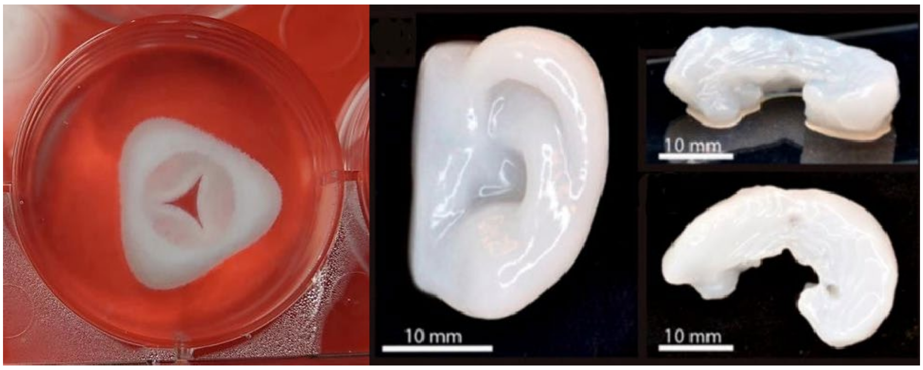

Figure 2.13. Examples of bioprinted objects [12] [13]

- laser powder forming - LPF - this is a group of methods which use a high-power laser beam to deposit metallic materials in a targeted manner. The obtained models do not have a porous structure, so their density is identical to that of elements cast from the same material. Thanks to the very good crystal structure, the strength properties may in some cases be better than for identical castings. The characteristic feature of the LPF is that it is the work table on which the model is formed that moves at most in the XY axes, and does not move in the Z axis. The input material is powder, which is supplied evenly along the circumference of the dosing head outlet opening, through which the laser beam also passes. The light beam is focused on the surface of a given layer of the model and supplies the energy necessary to melt the powder. The head rises in the Z axis after the material is applied in a given layer. In order to protect the applied material against the harmful effects of oxygen, and to facilitate the joining of successive layers, the manufacturing process can take place in a protective atmosphere. The metal powder is supplied to the head by gravity or in a gas stream [5].
- electron beam melting - EBM - allows for the production of models from metal powders melted using an electron beam in high vacuum conditions. The process is carried out at a high temperature (even up to 1000 degrees Celsius), which varies depending on the building material used, which gives a measurable benefit in the form of a model structure free of thermal stresses. Thanks to the presence of a very small amount of oxygen atoms in the working chamber, it is possible to produce models from easily oxidized materials (e.g. titanium). EBM is the most similar to

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SLM, because in both cases the powder is fully melted, thanks to which the elements do not have a porous structure and do not require further heat treatment. An additional advantage of this technology is the relatively high speed of operation and the minimum layer thickness of 0.05 mm. A typical application of this method are medical implants and aircraft engine turbine blades made of titanium alloys [5].

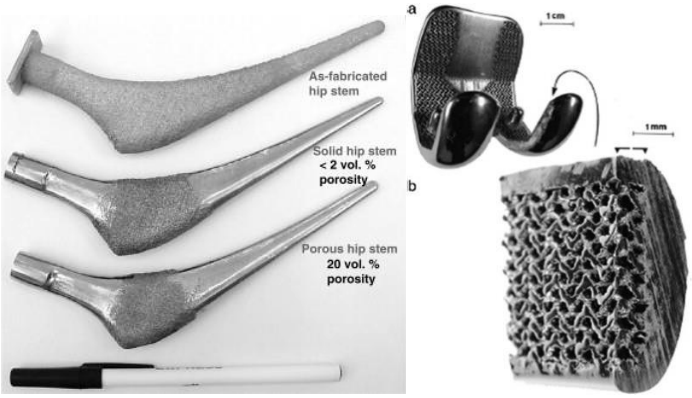

Figure 2.14. Products obtained by laser powder forming (a) [14] and electron beam melting (b) [15]

2.3 Preparing 3D printing processes

2.3.1 Data formats

There are several file formats that are directly related to the additive manufacturing [16]. They differ significantly from one another. Some additive manufacturing software can also import CAD-specific file formats, which is an ongoing trend. The selection of the appropriate data format to use frequently depends on the specific machine and the manufacturing technology. The file format used for 3D printing must accurately represent the design of the object, including its shape, size, and material properties. There are several file formats used in additive manufacturing, each with its own advantages and disadvantages. Currently, STL was still the most widely used data exchange format, developed in the 1980s and accompanying the first technology (stereolithography – hence the acronym, later altered to a different meaning).

STL (initially Stereolithography, now – Standard Triangulation Language) is the first and still one of the most widely used file formats for additive manufacturing. STL files are surface

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models, representing a 3D model as a mesh consisting of series of oriented triangles (facets), making it a faithful representation of a 3D object's geometry provided that these geometry contains straight lines. Otherwise, chordal error is introduced when converting arcs, circles and curves to triangles, but this can be nowadays managed by serious increase in density of tesselation. STL files are widely supported by most 3D printing software and hardware, making them an ideal choice for most applications. STL files are also default format for many optical 3D scanners, what is quite important and convenient in biomedical applications (change of formats during the processing is often not required).

STL is the simplest open-source file format. It supports ASCII encoding (bigger file size) and binary encoding (smaller file size, usually preferred). It can store only information about the geometry of a single object (no assemblies) and an additional 80 bytes of text information in the header. STL is not a topological format and it contains a lot of redundant information but no data on the connectivity of the triangles (this information is computed in real time during processing). STL also does not introduce any data correctness mechanisms by itself (e.g. it is not checked if geometry is “watertight” - object to be additively manufactured should have closed surface with positive volume). However, lots of free software is available for repairing and editing (as mentioned in Module 1 – CAD). Example of an STL file in ASCII encoding is shown in Fig. 2.15. Example of STL file during editing is shown in Fig. 2.16.

proteza00_Zosia__.stl

```
solid STL generated by MeshLab
  facet normal  9.994322e-03 -4.197675e-02 -9.990687e-01
    outer loop
      vertex  -5.937941e-01  3.377039e+01  3.400025e+01
      vertex  -8.860629e-01  3.359167e+01  3.400483e+01
      vertex  -1.287003e+00  3.360526e+01  3.400025e+01
    endloop
  endfacet
  facet normal  1.001812e-02 -4.128383e-02 -9.990972e-01
    outer loop
      vertex  -1.287003e+00  3.360526e+01  3.400025e+01
      vertex  -8.860629e-01  3.359167e+01  3.400483e+01
      vertex  -1.880865e+00  3.335046e+01  3.400483e+01
    endloop
  endfacet
  facet normal  1.019512e-02 -4.169602e-02 -9.990783e-01
    outer loop
      vertex  -1.287003e+00  3.360526e+01  3.400025e+01
      vertex  -1.880865e+00  3.335046e+01  3.400483e+01
      vertex  -1.906565e+00  3.345367e+01  3.400026e+01
    endloop
  endfacet
```

Figure 2.15. STL file structure – ASCII encoding

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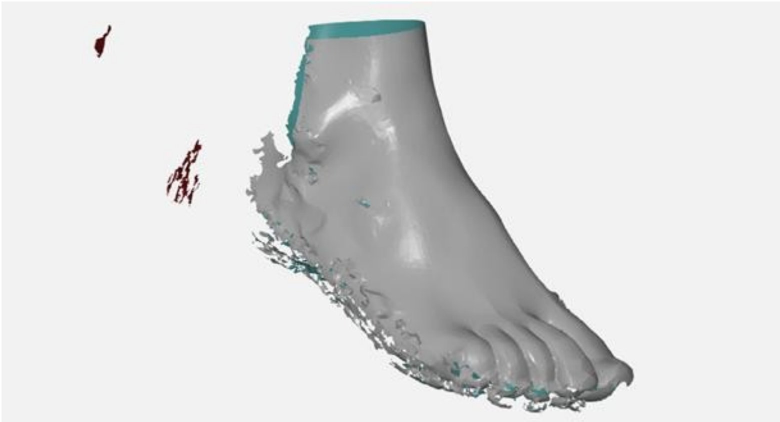

Figure 2.16. STL mesh editing process

OBJ (standing just for Object) is another widely used file format for additive manufacturing. OBJ files are similar to STL files, representing a 3D model as a series of triangles – but can also use polygons (quads) instead. OBJs also include additional information, such as color, texture, and material properties – for these additional MTL file is required (MTL standing for material template library). Also, many parts can be stored in a single file, allowing to process assemblies. OBJ files are widely supported by many 3D printing software these days, making them a good choice for applications that require more information than just the 3D geometry of an object – e.g. in PolyJet manufacturing, where different objects can have different colors or textures and be manufactured in a single process.

AMF (Additive Manufacturing File) is a newer file format that has been developed specifically for additive manufacturing, in 2011. It was called "STL 2.0", as it addresses to many of the shortcomings of the STL format. Despite the advantages of the format, the process of adaptation into additive manufacturing is relatively slow, mostly due to popularity and good usability of older formats in the most popular processes (FFF). AMF files are XML-based and contain a more detailed representation of a 3D object, including its geometry, material properties, and build parameters. In the AMF, 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. AMF files are becoming increasingly popular, as they provide a more comprehensive representation of a 3D object than STL or OBJ files.

It is also worth mentioning of another file format that is associated with additive manufacturing processes. It is G-Code. G-Code is a file format used primarily in the control of

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CNC (computer numerical control) machines, including 3D printers. G-Code files contain instructions for a machine to follow, including movements, speed, and temperature. G-Code files are not used to represent the 3D geometry of an object but are instead used to control the machine's movement and behavior during the printing process. Usually, software for slicing (CAM) deals with G-Code preparation and the user does not have to interfere or deal with the format in any way. However, there are scenarios in which editing the G-Code might be necessary for a process to succeed, especially if a given machine was customized for a specific purpose – certain instructions can be added or altered manually, to ensure correctness, especially in the beginning or end of the process.

2.3.2 Software – slicers

Slicer software is an essential tool for 3D printing, used to prepare 3D models for printing. It plays a crucial role in the planning and execution of the 3D printing process, as it divides the 3D model into hundreds or thousands of horizontal layers and generates the instructions for the 3D printer to build the model layer by layer, usually in form of NC code.

Slicer software usually allows to adjust various parameters that affect the final quality and accuracy of the 3D printed object, as well as course of the additive manufacturing process. Some of these parameters include layer height, infill density, print speed, and support structures. The sliced model can be also previewed and adjustments can be made if needed, which is particularly useful when working with complex models that require support structures or intricate details.

One of the most significant benefits of using slicer software is the ability to generate accurate estimates of print time and material usage, which can be useful for planning and budgeting purposes. This information can also be used to optimize the print process by reducing material waste and minimizing print time without sacrificing quality.

There are two main variations of slicers, depending on application range:

- universal – not made for any specific brand of machine or manufacturer, rather general and suitable for use for many types of devices,
- dedicated – usually created by manufacturer of a given machine, for that particular machine or a whole series of machines, not suitable for other devices.

The universal slicers usually allow more freedom in terms of selection of process parameters, but they also require more initial effort in order to properly set up and tune

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constant parameters for a given machine and material. The dedicated slicers have the machines and materials profiled from the start, so the user does not have to worry about details of parameter selection.

An example of universal slicer is Simplify3D software, that can be used for almost any FDM machine and material which is available on the market (Figure 2.17). An example of a dedicated slicer is Z-Suite software, made for machines made by Zortrax company, or MakerBot Print software, made for machines of the MakerBot brand (currently owned by Stratasys company).

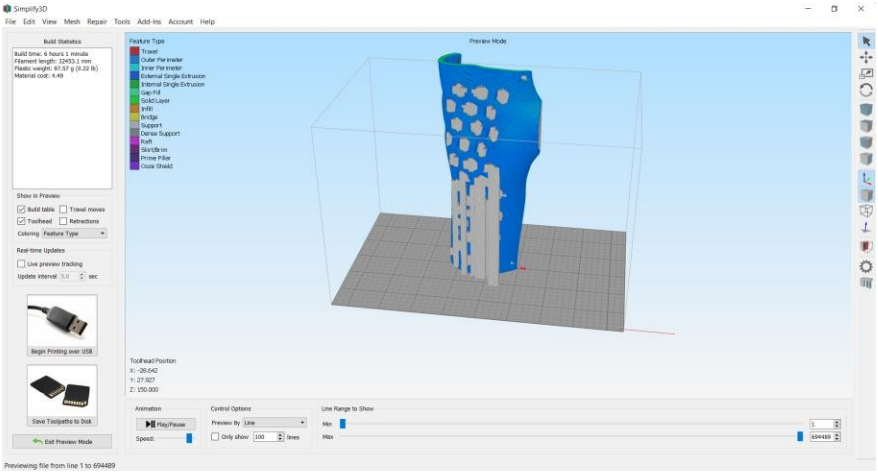

Figure 2.17. Simplify 3D slicer

A very important function of slicer software, mentioned above, is the ability to generate G-code, which is the machine language used by 3D printers to build objects. The G-code produced by the slicer software provides the 3D printer with the necessary information to control the movement of the print head, the extrusion of the filament, and other important aspects of the printing process.

There are many slicer software options available, including both open-source and commercial options. Some popular slicer software options include Cura, PrusaSlicer, and Simplify3D. Each of these options offers a range of features and benefits, and the best choice for a particular application will depend on the user's specific requirements and experience level.

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2.3.3 Guidelines for 3D printing of anatomical shapes

Below, a set of general guidelines is presented for 3D printing of anatomical shapes – including biomimetic products. These are just a general set of remarks, which have to be considered carefully, depending on a specific case of a product suited for people with special needs.

1. Accuracy: It must be ensured that the 3D model used for printing is accurate and has been verified by a medical professional (of a profession corresponding to a given subject, i.e. surgeon, orthopaedist, physiotherapist etc.). The model should have accurate proportions and details to ensure the best possible representation of the anatomy.
2. Material Selection: a material that is safe and appropriate for the intended use should be selected, ideally a biomaterial. Biocompatible materials such as polylactic acid (PLA) or polyamide (PA12, nylon) are commonly used in medical applications.
3. Layer Thickness: The layer thickness should be small enough to produce a smooth surface but not so thin that the print is weak and prone to breakage. A common layer thickness for biomedical and biomimetic applications is 0.1-0.2mm for the FFF technology, although use of very low thickness can result in lengthy prints.
4. Print Resolution: High-resolution prints produce better details and improved accuracy. Using a 3D printer with a high resolution capability should be considered to produce the best results.
5. Post-Processing: Depending on the intended use, it may be necessary to perform post-processing techniques such as sanding or polishing to improve the surface finish and accuracy, especially if surface of a product will be in touch with human body parts.
6. Sterilization: If the 3D print is intended for use in a medical setting, or for people with special needs (e.g. immunocompromised) it must be sterilized to eliminate any potential contaminants or microbes. Common methods of sterilization include autoclaving and exposure to ultraviolet light.
7. Quality Control: Quality control checks before using the 3D print in a medical setting must be performed, to ensure that it meets the necessary standards and

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specifications. This may include measurements, strength tests (static and dynamic), functional tests and material analysis.

8. Legal Considerations: It is important to consider any legal or regulatory considerations when 3D printing anatomical shapes. This may include obtaining necessary certifications and complying with applicable regulations. The 3D printed product must be classified to either class as stated in an appropriate regulation and then, if necessary, certification process should be realized if the product is intended for serious medical use with the patients. Otherwise it can be only used by volunteers in a course of a scientific experiment, but this also should be performed under specific regulations (usually approval of ethics committee is required).

In terms of guidelines for design of 3D printed parts, there are also plenty of things to consider, when switching from conventional manufacturing technologies into 3D printing, mostly regarding easier post processing, strength and usability of fabricated parts. Many guidelines are available in the community of 3D printing professionals, an example is shown in Fig. 2.18.

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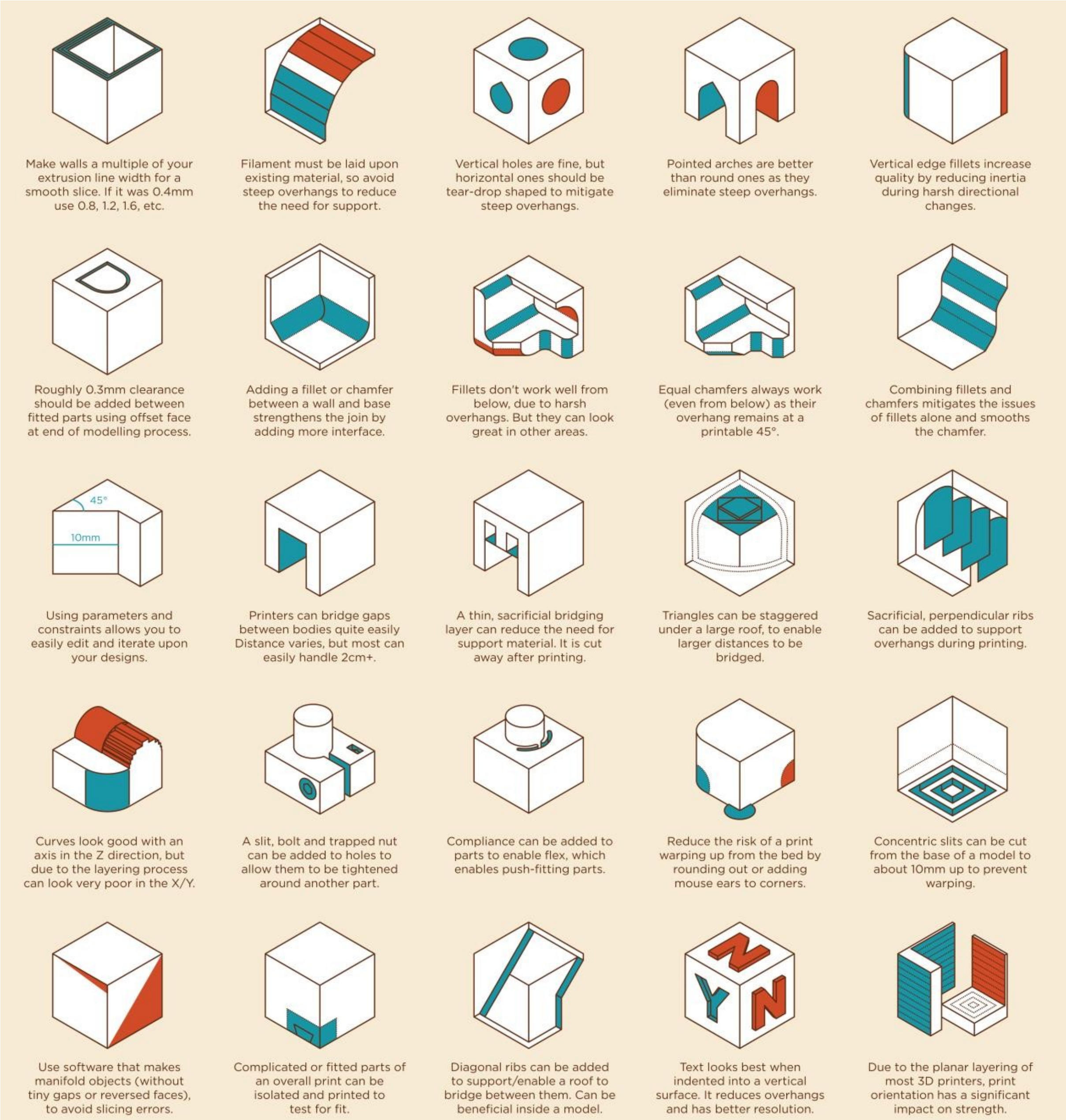

Figure 2.18. Example of guidelines for design for 3D printing [17]

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3. Examples of 3D printed biomimetic devices

3.1 Review of applications of 3D printing for biomimetic devices

3D printing and additive manufacturing, as already mentioned, has plenty of medical applications. Of these, building anatomically shaped and biomimetic devices seems to be a very promising direction, that surely will thrive in upcoming years. Here are several examples of 3D printed biomimetic devices:

1. Artificial Joints: 3D printing is increasingly used to produce customized artificial joints, such as hip and knee replacements, with shapes and structures that mimic the natural anatomy (Fig. 3.1).

Figure 3.1. 3D Printed knee personalized implant versus traditional implant [18]

2. Heart Valves: 3D printing has been used to produce heart valves with structures and materials that mimic the natural anatomy, offering improved functionality and personalization. For example, researchers at Minnesota University created patient-specific model, which includes the anatomy of the damaged leaflets of the aortic valve, where the replacement valve will be inserted. The model includes integrated sensors that helps to guide positioning of the replacement valve (Fig. 3.2) [19].

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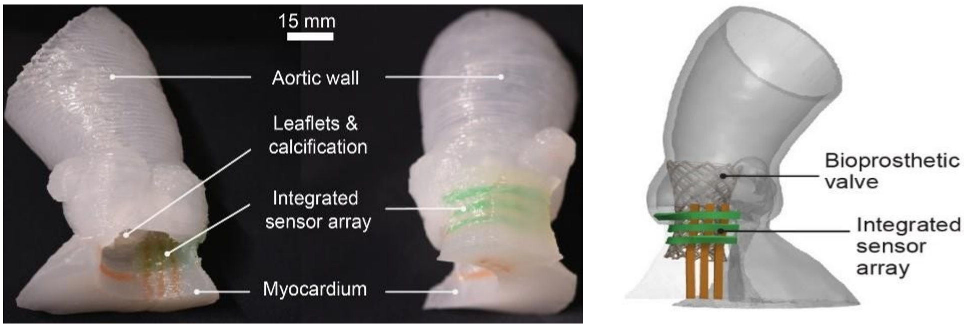

Fig. 3.2. 3D-printed model of a patient's aortic region [19]

3. Skin Tissue: Researchers have developed 3D printed skin tissue that mimics the structure and function of natural skin, offering a promising solution for burn victims and people with skin conditions [20].
4. Bones: 3D printing has been used to produce customized bones for use in medical procedures, such as spinal fusion and cranial reconstruction. The 3D printed bones mimic the structure and mechanical properties of natural bone, offering improved outcomes for patients, e.g. by infusing them with antibiotics (Fig. 3.3) [21]

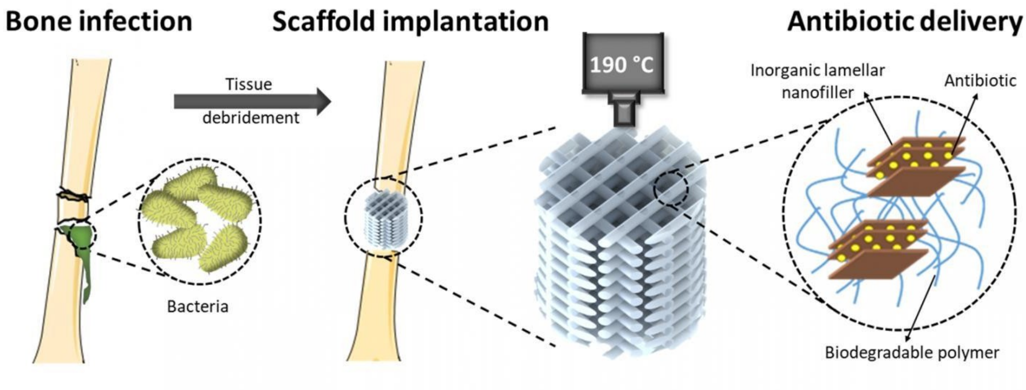

Fig. 3.3. 3D-printed bone scaffold with antibiotics [21]

5. Cartilage: Researchers have developed 3D printed cartilage that mimics the structure and function of natural cartilage, offering a promising solution for people with conditions such as osteoarthritis (Fig. 3.4) [22].

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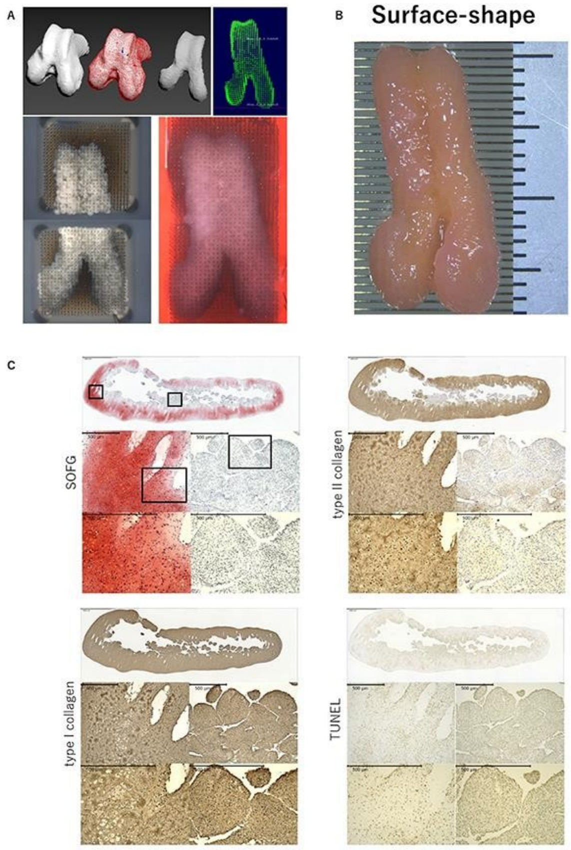

Fig. 3.4. Bio-3D printer design data and images of the articular surface-shape construct of cartilage tissue [22].

6. Blood Vessels: 3D printing has been used to produce functional blood vessels with a structure that mimics the natural anatomy, offering a promising solution for patients with cardiovascular disease [23].
7. Prosthetic Feet: 3D printing has been used to produce prosthetic feet with structures that mimic the natural anatomy, offering improved balance and stability for users [24].
8. Orthoses: 3D printing has been used to produce customized orthoses that mimic the shape and structure of the body, offering improved comfort and function compared to traditional equipment, often by implementation of mechatronic solutions [25].

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These are just a few examples of the many biomimetic devices that are being developed using 3D printing. The technology offers a wide range of possibilities for improving medical outcomes and developing new treatments for a variety of conditions. In the EMERALD project, the focus is on 3D printed mechatronic devices, with biological personalized shapes, made for external use – i.e. orthotics and prosthetics. An example of a 3D printed device taken as a case in the project is presented in the next subchapter.

3.2 Biomimetic example – therapeutic wrist hand orthosis

As a custom example of 3D printed product for people with deficits, a hand orthosis intended for realization of therapeutic and rehabilitation purposes will be described in this chapter. It can be used for wrist joint stabilization in time after an injury (fracture) or for patients with conditions that require stabilization, as rheumatoid arthritis, muscle atrophy and many others. The orthosis is customized on the basis of a 3D scan geometry of patient's hand and forearm. It can be 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. Basic information about design process of the orthosis are shown in Module 1 – CAD. Shape of the orthosis is shown in Fig. 3.5.

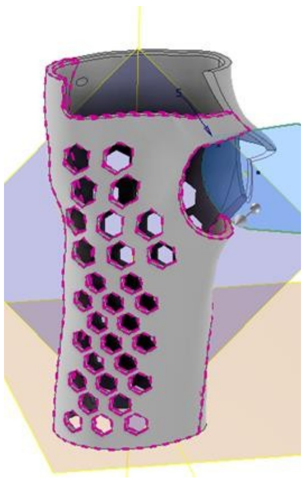

Figure 3.5. Shape of the wrist hand therapeutic orthosis

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For manufacturing of the orthosis, a case of a 13-year old patient is assumed. First of all, finishing the actual design stage, the two parts of the orthosis were exported to STL file format, with maximum detail in order to not lose shapes of geometrical details..

The first stage of the process of additive manufacturing of the orthosis in the FDM technology was the import of 3D models of the STL files to the selected slicer software in order to create instructions for the device in the form of a G-code file. Each part was oriented in the virtual workspace of the Simplify3D software for vertical fabrication, as generally better for this application. Of previous studies [26] it can be concluded the following regarding the orientation selection:

- vertical orientation is good in terms of accuracy and shape representation,
- horizontal orientation is worse in terms of surface roughness and comfort (without additional work-consuming post processing),
- vertical orientation is better economically – if the orthosis can fit vertically into selected machine's chamber – as it does not require high volume of support structures, which take time to build and later remove in post processing,
- vertical orientation is worse in terms of strength (bending test), although not in a way disqualifying the orthosis from daily use.

Considering all these factors, a default orientation was assumed as vertical, with lower predicted strength being the main drawback, however assuming the orthosis application scenario (several hours of therapeutic use daily), this should not pose a problem.

It was decided to make the prints of two materials: PLA (polylactic acid) by default and also TPU (thermoplastic polyurethane). The TPU orthosis was a proposed concept to obtain certain level of flexibility and easier use during therapeutic activities. Due to appropriate (low) size of the orthosis, a typical closed-chamber machine was used – FlashForge Creator Pro. PLA orthosis was printed in two design versions, with varying offset between patient's hand and orthosis inner surface (1 mm and 3 mm).

Processes for both materials were executed using similar parameters. Layer thickness of 0,25 mm was used and 30% of internal filling was applied with default pattern. 3D printing of PLA took approximately 4 hours per one part of the orthosis, with TPU taking above 7 hours. First printouts were not subjected to full post-processing, as they were only intended to check

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out the fitting and material – this is a standard way of conduct in low-cost 3D printing of personalized orthopedic equipment.

In Figures below, 3D printed orthoses are shown.

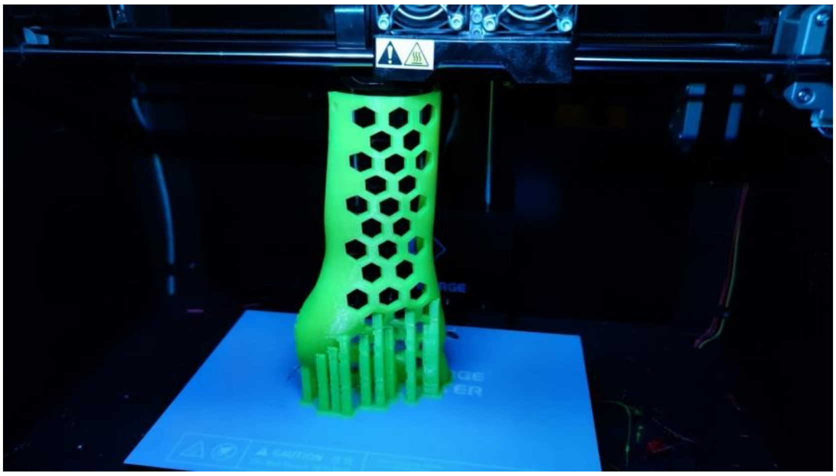

Figure 3.6. 3D printed orthosis (single part) in the machine chamber

Figure 3.7. 3D printed test orthoses, PLA (left) and TPU (right)

Improved final version of the orthosis was 3D printed only of PLA material, in a similar time, approximately 8 hours of continuous printing for both parts (one after another). Full post processing was applied, consisting of the following activities:

- removal of support,
- manual grinding, removing sharp edges,
- lining the orthosis with the EVA medical foam in specific places – mostly around the edges but also in locations where corrective shape of the orthosis would make it squeeze patient's muscle tissue.

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The two printouts of two separate materials were tested simultaneously. The procedure of fitting was performed with a physiotherapist, to ensure proper hand positions during fitting and therapeutic exercise simulation. The PLA orthosis was considered as the preferred variant by both patient and physiotherapist. Slight changes were also proposed in terms of geometry, to make the orthosis more functional and comfortable. Final version of the design was prepared and 3D printed. It was fully post processed and then given to the patient. Appropriate fitting and assembly was achieved.

Figure 3.8. presents the process of testing and fitting with the patient.

Figure 3.8. Tests of orthoses with the patient

The orthosis was evaluated as usable and helpful in therapy. After several months, the patient was 3D scanned again and another version was made, as the previous orthosis was too small (due to patient's growth). Also, orthoses for other patients with similar condition were made. The orthosis produced in this way is equal to, and in many respects even better than typical solutions. The first key aspect here is individualization, the 3D printed one described here is precisely adapted to the human body, which increases its rehabilitation effectiveness. Another important feature is the very short production time - only a week passed from the start of measurements to the first tests of the device by the patient. It also translates to reduction of costs, as the whole process of creating the orthosis costed approx. 50 EUR, including materials, use of machines and human operator time. 3D printing also enables the orthosis to be openwork and lightweight – which is a very important factor in terms of patients with limited muscle strength, typical orthoses are too heavy to operate effectively.

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4. Summary

In this e-learning module, 3D printing technologies were presented. Basic concepts, ideas and principles were described, along with context of biomedical applications, especially having in mind the main topic of the EMERALD project, which is production of biomimetic mechatronic devices using 3D printing. The performed review of processes and applications prove that it is fully justified to use the additive technology as means of fabrication of usable, anatomically personalized (biomimetic) devices for people with disabilities or other special needs.

Basic knowledge contained in this module, along with knowledge on CAD, computer programming and biomechatronics should allow the learner to get acquainted with basic set of technologies necessary in the work of modern biomedical engineer, dealing with design and production of customized mechatronic medical devices.

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