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A REVIEW OF ADDITIVE MANUFACTURING TECHNOLOGIES AND THEIR APPLICATIONS IN THE MEDICAL FIELD

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Abstract. *This review paper contains a literature survey about some additive manufacturing technologies and their medical use. Additive Manufacturing is a generic term referring to several technologies used to create physical models or prototype parts based on 3D drawings. Additive Manufacturing models can be used for various testing methods. The paper summarizes the application of Additive Manufacturing Technologies in medicine. It describes the main steps for how to create 3D models for medical applications. Some details can be found on the topics: Data acquisition using medical scanners; Data transformation; Creation of virtual 3D models; Surgical planning and simulation on the virtual 3D model; and Creation of Physical 3D Models for Additive Manufacturing Technologies. 3D physical models can be extremely useful in planning complex surgical interventions, which can be simulated on these models before the actual procedure.*
Keywords: *Additive Manufacturing; medical imaging; Selective Laser Sintering.*

1. Introduction

In the scientific literature, there are several classifications of the manufacturing technologies known and used until the early 1990s. One of these classifications [1] considers two main groups:

1. Material removal processing technologies. These technologies start with a large quantity of raw material, and by using conventional methods (turning, milling, grinding, etc.) or non-conventional methods (electroerosion, laser processing, ultrasound, etc.), the excess material is removed, resulting in the final piece.
2. Material redistribution processing technologies. These technologies start with the correct amount of raw material, which is redistributed into the required shape through deformation in the solid state (forging, stamping, drawing, extrusion, etc.) or redistribution in the liquid or semi-liquid phase (casting, injection molding, etc.).

In the 1990s, a third group of technologies emerged, Rapid Prototyping (RP) technologies (also known as Additive Manufacturing). This new technology is different from the existing ones because it uses a different principle for materializing parts, where material is added only where and as much as is needed. Due to the manufacturers' efforts to reduce the time from conception to market release and lower the costs of assimilating and producing new products, Rapid Prototyping technologies began to grow in importance [1].

Starting from a CAD description without the need for machine tools or specific devices, these systems can produce complex three-dimensional models.

Regardless of the chosen Additive Manufacturing technology, the part production algorithm remains the same [2]:

1. Modeling the part using a CAD software package.
2. Conversion to a*. STL format (Standard Triangulation Language), a format adopted as the industry standard for rapid prototyping production [3]. This format represents the 3D surface as a collection of flat triangles. The file contains the coordinates of the vertices and the outer normal direction of each triangle.
3. Slicing the *.STL file: A pre-processing program prepares the *.STL file for building. Various programs are available, and most allow the user to adjust layer size, placement, and orientation of the model. Depending on the construction technique, the pre-processing software slices the *.STL model into layers ranging from 0.01mm to 0.7mm [3]. The program can also generate a supporting structure for the model during the construction process. Each RP machine manufacturer provides its own pre-processing software.
4. Constructing the model "layer by layer." The material used for model construction varies depending on the chosen Rapid Prototyping technology (polymers, metal powder, paper).
5. Cleaning and finishing the model is the final step in the part-building algorithm (post-processing). This involves removing the prototype from the machine and detaching any supporting structures. After cleaning the model, a surface treatment can be applied to improve appearance and durability [4].

The most significant successes of RP system users are found in processes and technologies that justify their investment in these systems. They see RP systems as the basis for new technologies that allow them to function more efficiently and perform better compared to past methods [1].

In Figure 1, the upper curve refers to traditional manufacturing technologies, while the two lower curves refer to computer-aided manufacturing technologies. Computer-aided manufacturing is more flexible and efficient, regardless of the geometric complexity of the parts, involving significantly fewer tools [5].

Current rapid prototyping systems have become available to users, even though they were still in the experimental phase in the early 1990s. Initially, these systems required highly skilled personnel who understood and adjusted numerous parameters that characterized the operation of these systems and technologies. Today, adjusting these parameters has been simplified through standardization, making system operation easier and requiring less skilled personnel. From a mechanical point of

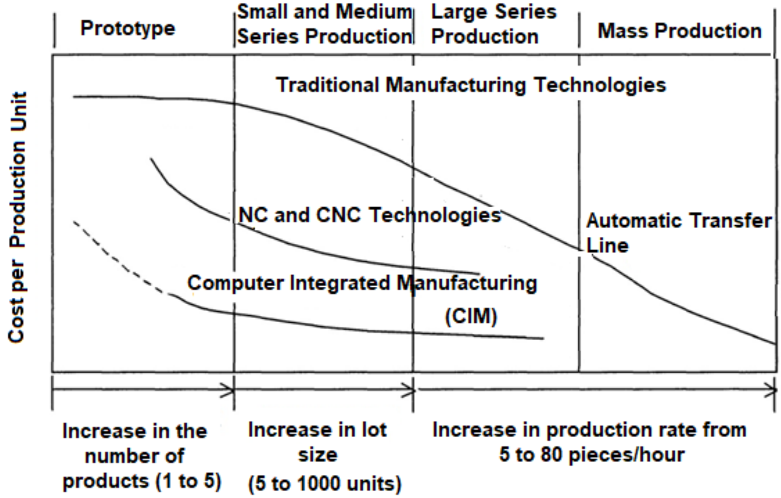

Figure 1.The impact of technology on the cost of production units, adapted from [5]

view, rapid prototyping systems are much more robust, reliable, and easy to maintain. Dimensional accuracy, surface quality, and deposition speed have all improved and continue to improve [1].

Since product development is a creative process, an algorithm must exist for the process. An example of an algorithm is presented in Figure 2. As with any design and development concept, this must be evaluated, preferably with the help of a prototype, thus allowing opportunities for product improvement to be identified. This cycle must be repeated until the final design and functionality are satisfactory. The main advantage of prototypes is that they offer various stakeholders (engineering, sales and marketing, manufacturing, suppliers and subcontractors, logistics) a visual representation of the future product and the possibility of modifying the product's characteristics according to stakeholder requirements [5].

Additive Manufacturing models can be successfully used for the physical visualization of the product. This can be done from the design phase of a new product or for the modernization of an existing one. By using this technology, communication between the manufacturer and the customer is improved. Thus, the product is developed in close collaboration with the customer.

Due to AM technology, manufacturers can sell products long before their actual production. By presenting AM models to customers, they can learn the characteristics of a new product. After such consultation and product acceptance, the manufacturer can begin production preparation [5].

Additive Manufacturing is a generic term referring to several technologies used to create physical models or prototype parts based on 3D drawings (files). Proposals for new products are studied and analyzed after being drawn up, but a physical model made of a certain material is much more convincing, especially if it is used in the environment in which it will function. Thus, AM models are used in the creation of mockups. The entire mockup is built piece by piece and then used to study shape, design, assembly, the space required, and even function. These mockups are often used in architecture or in the automotive industry [6].

These technologies rely on layered manufacturing, allowing the creation of a physical model at a low cost and in a short time.

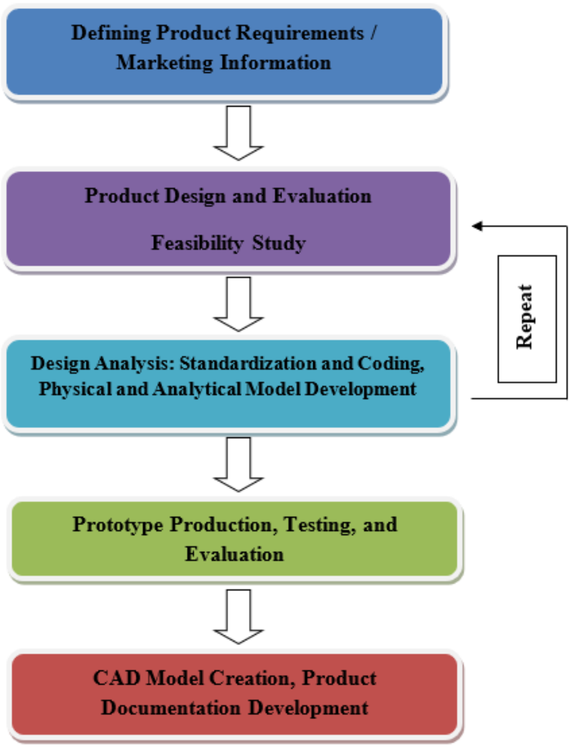

Figure 2. Product development algorithm, adapted from [5]

Additive Manufacturing models can be used for various testing methods. There are three factors that influence the testing of a product [1]:

1. Material: The material must be chosen according to the purpose of the test.
2. Model size: The size is conditioned by the capabilities of RP systems; the part should not have wall thicknesses smaller than 0.2mm (the average diameter of the laser beam); for sufficient rigidity during processing and testing, wall thicknesses of 1.5mm - 3mm are recommended.
3. Model design: This is critical for the solidification process or construction, along with the model's orientation during manufacturing. This factor can determine the appearance of shrinkage and deformations during or after construction.

These tests are used to verify the visual acceptance of the product, to understand its construction and functionality, as well as to finalize the final elements.

The most used tests are functional tests, simulation tests, manufacturing control, fixing and assembly, and packaging.

One of the advantages of these technologies is the reduction of time required to assimilate new products and the costs of creating new tools (devices and verification gauges) [6].

Rapid Tooling (RT) describes a process that combines Rapid Prototyping techniques with conventional processing practices to quickly produce a mold or parts of a functional model based on the CAD (Computer Aided Design) model in the shortest possible time and at the lowest possible cost compared to traditional methods.

There are two categories of Rapid Tooling: indirect and direct [7].

- In Indirect Rapid Tooling methods, parts created through AM processes are used as models for making molds, where the primary goal is not to obtain final parts. "Master" models made of wood, plastic, aluminum, steel, or cast iron are used to create a mold into which the material for the final model is cast. AM models can be indirectly used in several manufacturing processes. The most used indirect Rapid Tooling methods are vacuum casting, sand casting, investment casting, and injection molding [2].
- Direct Rapid Tooling involves directly obtaining the model by adding material layer by layer, often followed by post-processing operations to improve surface quality [5].

Rapid Prototyping technologies have and will continue to have a significant impact in many sectors, from industrial production to medicine, giving this technology strategic importance in companies that use RP [1].

2. Application of additive manufacturing technologies in medicine

In medical imaging, the introduction of X-ray computed tomography (CT), and magnetic resonance imaging (MRI) has broadened the general applicability of paraclinical investigation techniques, providing essential diagnostic justification for determining therapeutic interventions. These techniques are an important component of evidence-based medicine. Although the cost of these examinations remains high and access to the offered investigations is restricted due to economic factors, the benefits for actual interventions are significant for both the patient and the healthcare system. These non-invasive diagnostic techniques offer decision-makers the ability to plan appropriate and timely surgical interventions, including the surgical technique itself [8].

Additive Manufacturing Technologies assist designers in constructing physical replicas of virtual models created in CAD systems, providing a physical model that offers more information about the same object and is easier to understand. In medicine, medical imaging provides high-resolution images of internal structures of the human body. Based on this information, a physical model useful for preparing complex surgical interventions can be created [9].

These 3D models have three main uses [6]:

1. Surgical planning: 3D physical models can be extremely useful for planning very complex surgical interventions, which can be simulated on these models before the actual surgery. For example, in maxillofacial surgery, the greatest advantage of simulations is the ability to make decisions about bone fixation and to measure all intra- and post-operative bone movements.
2. Diagnostics: The 3D solid model can serve as a physical copy of a dataset and can form a solid basis for diagnosis, choosing the appropriate therapy, and teaching purposes. The model simplifies communication between members of surgical teams, between the radiologist and the surgeon, and between the doctor and the patient. This is important because the two-dimensional images provided by radiologists must be transformed into realistic 3D images that are extremely useful to the surgeon, allowing them to measure and simulate intraoperative situations.
3. Prosthetics: Creating a prosthesis is much easier with the existence of an accurate physical model of an existing structure. The model can be used as a negative or as a master model for making the implant. To reconstruct damaged parts in order to achieve symmetry, mirror images of healthy areas can be used. One forward-looking solution is to create these physical models directly on rapid prototyping systems using biocompatible materials with the human body.

These models produced by AM Technologies replace older models made using other technologies to understand various internal structures of the human body.

3. Steps to create 3D models for medical applications

Creating three-dimensional images involves the following steps [10]:

1. Data acquisition using medical scanners (CT, MRI, etc.).
2. Transferring data into DICOM format (Digital Imaging and

Communication in Medicine).
3. Creating virtual three-dimensional models.
4. Planning and simulation on virtual models (optional).
5. Creating physical three-dimensional (3D) models using Additive Manufacturing technologies.

These steps are visually summarized in Figure 3.

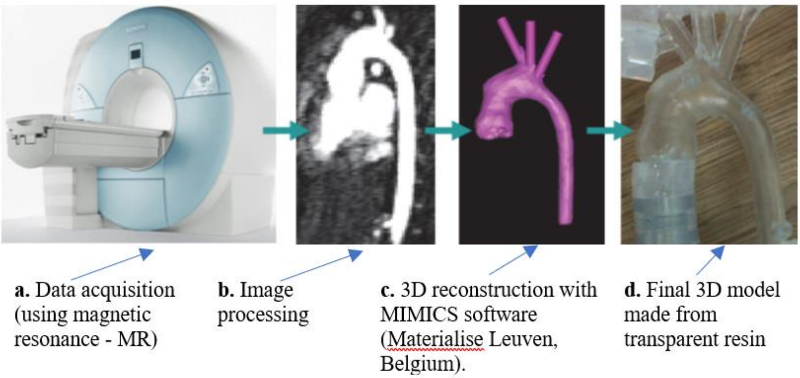

Figure 3. Visual synthesis of the stages of creating a patient's aortic arch [11].

3.1. Steps to create 3D models for medical applications

To obtain images, sensors are required to convert radiation energy into electrical signals. There is a wide range of sensors that detect radiation, from gamma rays, X-rays, ultraviolet rays, visible radiation (light), infrared radiation, microwaves, and radio waves.

Images can be captured sequentially using "linear" scanners, by scanning the object in one direction, or using cameras that directly produce a two-dimensional image. To obtain 3D information, which is increasingly in demand, scanners, or camera systems are arranged to capture spatial information. Most medical applications are based on images directly captured from the patient [12].

The informational content of medical images varies significantly depending on the image acquisition system used. Therefore, the first step in medical imaging is selecting the acquisition system appropriate for the intended purpose.

The informational support for creating 3D virtual models can be obtained through various types of medical scanning such as computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, etc. The most used methods for acquiring data for 3D models are computed tomography (CT), which provides accurate information about bone structures, and magnetic resonance imaging (MRI), which provides details about soft tissues. These two methods can be combined when 3D models are needed that include both the skeleton and soft tissues [10].

3.2. Transferring data into dicom format

Image processing has multiple applications in medicine, aimed at optimizing analysis and interpretation by the human observer of the information received from the external environment.

The human body includes an image analyzer for the external environment, represented by the human eye, responsible for capturing, transmitting, and converting light impulses into visual images.

In the technical field, the development of new image acquisition, storage, and transmission technologies finds application in diversifying equipment with medical applications.

Based on the visual sense, computer-assisted image processing attempts to create equipment capable of integrating visual facilities as simply as possible into electronic devices.

A digital image represents the numerical replication of an optical image. It can be stored in files with various formats, each adapted for specific uses (capture, processing, archiving, printing).

Images can be divided into two categories [13]:

1. Vector images (coordinate files).
2. Matrix images (composed of pixels).

Among matrix images, formats such as BMP, JPEG, GIF, and DICOM are common. In medical imaging, the most frequently used formats are DICOM and ANALYZE, which aim to store information related to slice thickness, voxels, the patient, the device used, and the medical facility where the images were obtained.

DICOM format (Digital Imaging and Communications in Medicine) is a standard created by the National Electrical Manufacturers Association (NEMA) to regulate the distribution and visualization of medical images obtained through CT, MRI, and ultrasound. Data in this format is included in a single file (*.dcm) that contains two parts: a header, intended for auxiliary information, and the other part for graphic data [14].

3.3. Creating virtual 3D models

Special programs are required for visualizing and performing additional operations (3D visualization, image modification, measurement, or exporting images in other formats).

In addition to proprietary programs for each medical scanner, there are many programs that can perform the operations (MIMICS, AGNOSCO, DICOM VIEWER, SANTE DICOM VIEWER, RADIANT DICOM VIEWER, WEASIS DICOM VIEWER, MITO MEDICAL IMAGING TOOLKIT, etc.). An example of Graphic user interface of the MIMICS application is shown in Figure 4.

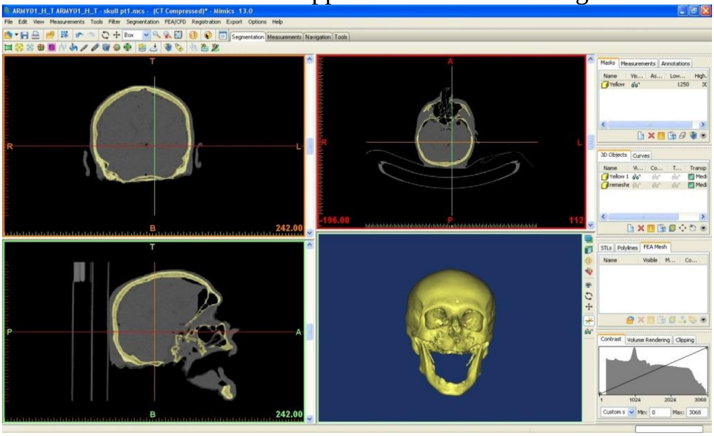

Figure 4. Graphic user interface of the MIMICS application [15].

Certain measurement techniques require pre-processing to obtain 3D coordinates of the scanned surface points. In the case of computed tomography, sections are obtained containing images with transverse densities and known distances between adjacent sections [5].

For the three-dimensional modeling of an anatomical system, three major steps are necessary:

1. Reading and processing input data.
2. Segmenting the input data to automatically identify objects in the images (useful when the goal is to detect and highlight areas of interest).
3. Three-dimensional reconstruction of anatomical models [16].

Processing images acquired through tomography is an essential step in obtaining valid *.STL models and then producing accurate physical models. For this purpose, the Belgian company Materialise created a specialized software package that simplifies the methodology of obtaining models within certain limits [1].

The MIMICS software includes several modules. Figure 5 shows the links between the main program and its various modules [17].

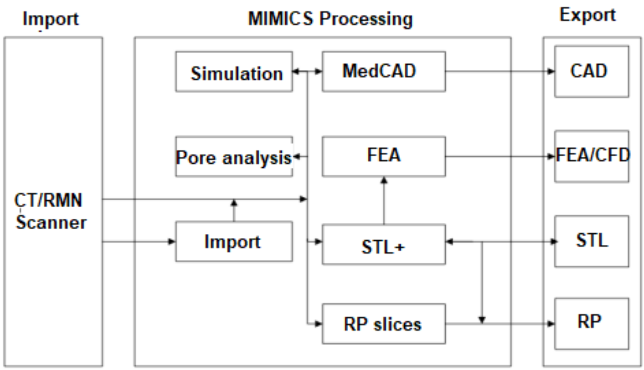

Figure 5. Modules of the MIMICS program, adapted from [17].

The MIMICS program displays image data in multiple ways, each providing unique information. MIMICS divides the screen into three or four windows, each offering a specific view or image:

1. The axial view of the image.
2. The processed coronal image.
3. The processed sagittal image.
4. A three-dimensional reconstruction view (Figures 6).

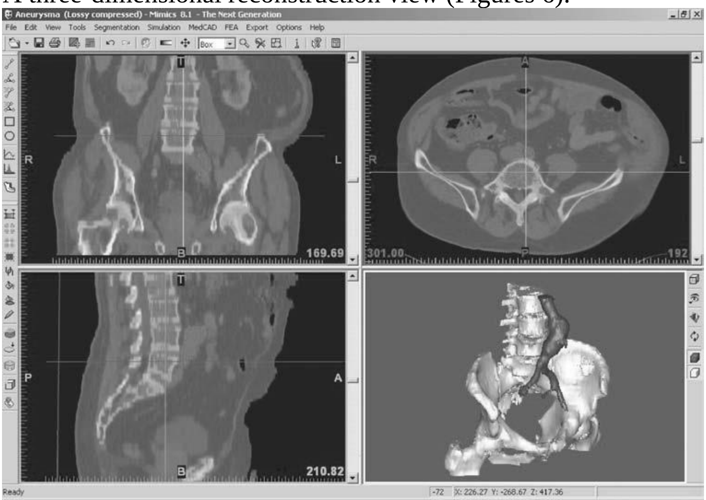

Figure 6. Results in the MIMICS program [18].

3.4. Surgical planning and simulation on the virtual 3D model

Three-dimensional visualization of the patient's internal anatomy before the surgical phase represented a significant leap in diagnosing and treating various conditions. Once the 3D model is created, it faithfully represents both the anatomy and pathology of the patient. It can be used for diagnostic purposes as well as for planning and simulating surgical interventions.

Software packages allow the surgeon to rotate the virtual model in all desired directions and to section it into different planes. This way, the diagnosis is precise, and the planning of the surgery can be done in detail [10].

3.5. Creation of physical 3D models for additive manufacturing Technologies

Using AM technologies, real models are transformed into physical models. The new techniques are based on CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing) processes and utilize special machines controlled by computers to generate physical 3D models using specific technologies. This technique is widespread globally, so much so that it can be said that most people use, in their daily activities, at least one product made by AM.

The main processes of AM are [1]:

- Stereolithography (STL)
- Fused Deposition Modeling (FDM)
- Laminated Object Manufacturing (LOM)
- Selective Laser Sintering (SLS)
- 3D Printing
- Wax Object Manufacturing (WOM)
- Model Maker Manufacturing System
- Stratoconception Manufacturing System

3.6. Selective laser sintering (SLS)

Selective laser sintering (SLS) is a very popular AM technique. Selective Laser Sintering (SLS) is a freeform fabrication process of components through the sintering of powders. This process is one of the most used for creating prototypes from various metallic and non-metallic powders [20].

SLS uses a laser beam directed by a computer over the surface of the powder bed to rapidly produce solid copies of virtual models. It is one of the few RP processes capable of producing durable and functional parts from a wide range of materials [5].

This process is based on materializing a CAD product by adding successive layers. The laser used in this process is typically a CO2 laser. The laser covers the entire surface of the section (point by point), sintering the fine layer of material deposited on the work platform [1].

Through this process, three-dimensional parts can be obtained by heating and bonding powders at temperatures below their melting points.

The laser system generates laser radiation, which is focused by a lens and directed through a system of mirrors to the surface of the work platform (Figure 7). At the beginning of the work process, the platform is in the upper position. A feed system deposits a thin layer of powder of controlled thickness on the surface of the platform. The laser beam scans the platform's surface according to the geometry of the first section of the workpiece. As a result of the scanning process, the laser radiation locally sinters the powder layer.

After the laser has scanned the entire surface of the first layer, the work platform lowers by a distance equal to the thickness of one layer. The feed system deposits a new powder layer over the previous one. Once again, the laser beam scans the current powder layer according to the geometry of the next section through the solid model of the workpiece.

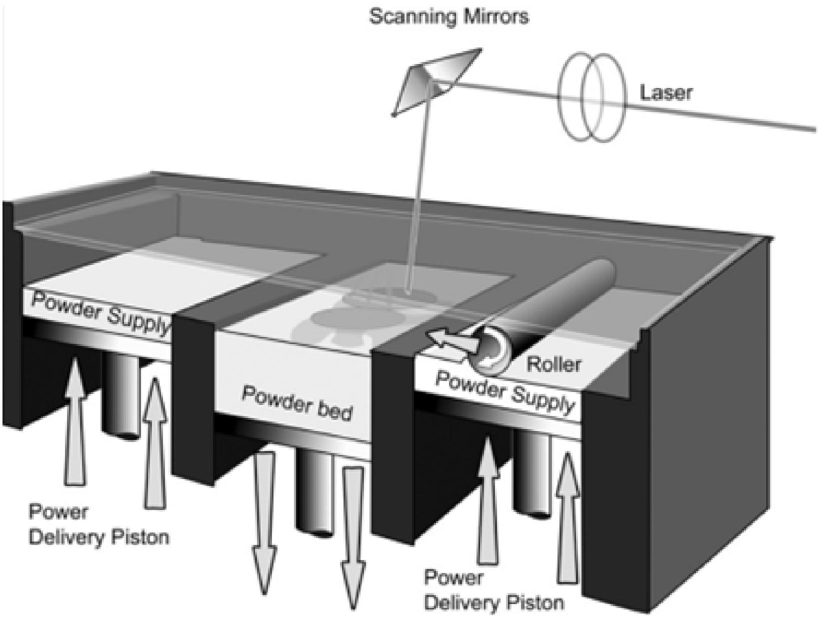

Figure 7. Schematic diagram of the Selective Laser Sintering process [21].

During the process, there is constant control over the thickness of the powder layer deposited on the platform, the distance between the sections created by the computer program through the model, and the distance moved by the work platform after each processed layer [1].

SLS systems are primarily produced by DTM Products Inc. in the USA and in Europe by Electro Optical Systems GmbH from Germany.

The materials used in the SLS process are very diverse, including a wide array of thermoplastics, such as polyamides, ABS, polycarbonates, and nylons, but also metal powders, quartz-based powders, or zirconium-based powders [22].

Selective Laser Sintering (SLS) offers multiple advantages such as high mechanical strength of the manufactured parts, recyclability of unused powders, and the ability to print large batches without support structures [23].

4. Conclusions

The main advantage of physical prototypes is that they provide various stakeholders (engineering, sales and marketing, manufacturing, suppliers and subcontractors, logistics) with a visual representation of the future product and the opportunity to modify the product characteristics according to needs.

AM models can be successfully used for physical visualization of the product, starting from the design phase of a new product or when modernizing an existing one.

Additive Manufacturing technologies allow the creation of physical models using layer-by-layer manufacturing, at a low cost and in a short timeframe.

3D physical models can be extremely useful in planning complex surgical interventions, which can be simulated on these models before the actual procedure.

Radiological images presented in two dimensions must be transformed into realistic 3D images that are extremely useful to the surgeon, as the models allow for measuring and simulating intraoperative conditions.

Creating a prosthesis is made much easier by having an accurate physical model of a structure. The model can be used as a negative or as a master model for creating the implant.

The physical model can be used both for diagnosis and for planning and simulating surgical interventions.

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ОГЛЯД ТЕХНОЛОГІЙ АДИТИВНОГО ВИРОБНИЦТВА ТА ЇХ ЗАСТОСУВАННЯ В МЕДИЧНІЙ СФЕРІ

Анотація. *Дана стаття містить огляд літератури щодо деяких технологій адитивного виробництва та їх медичного застосування. Адитивне виробництво — це загальний термін, що стосується кількох технологій, які використовуються для створення фізичних моделей або прототипів деталей на основі 3D-креслень. Моделі адитивного виробництва можуть використовуватися для різних методів тестування. У статті узагальнено застосування технологій адитивного виробництва в медицині. У ньому описані основні етапи створення 3D-моделей для медичних застосувань. Основна перевага фізичних прототипів полягає в тому, що вони надають різним зацікавленим сторонам (інженерія, продаж і маркетинг, виробництво, постачальники і субпідрядники, логістика) візуальне представлення майбутнього продукту і можливість модифікувати характеристики продукту відповідно до потреб. Моделі адитивного моделювання можуть успішно використовуватися для фізичної візуалізації продукту, починаючи з етапу проектування нового продукту або при модернізації вже існуючого. Технології адитивного виробництва дозволяють створювати фізичні моделі з використанням пошарового вирощування, з невеликими витратами і в стислі терміни. 3D фізичні моделі можуть бути надзвичайно корисними при плануванні складних хірургічних втручань, які можна змоделювати на цих моделях перед фактичною процедурою. Рентгенологічні зображення, представлені у двох вимірах, повинні бути перетворені на реалістичні 3D-зображення, які є надзвичайно корисними для хірурга, оскільки моделі дозволяють вимірювати та моделювати інтраопераційні умови. Створення протеза значно спрощується завдяки наявності точної фізичної моделі конструкції. Модель може використовуватися як майстер-модель для створення імплантату. Фізична модель може використовуватися як для діагностики, так і для планування та моделювання хірургічних втручань. Деякі подробиці можна знайти на теми: збір даних за допомогою медичних сканерів; трансформація даних; створення віртуальних 3D моделей; хірургічне планування та симуляція на віртуальній 3D моделі; створення фізичних 3D-моделей для технологій адитивного виробництва. 3D фізичні моделі можуть бути надзвичайно корисними при плануванні складних хірургічних втручань, які можна змоделювати на цих моделях перед фактичною процедурою.*

Ключові слова: *адитивне виробництво; медична візуалізація; селективне лазерне спікання.*