Application of Innovative Hydroxyapatite Materials in 3D Printing for Biocompatible Voice Implants

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The paper presents the possibility of using an innovative hydroxyapatite filament Ca10(PO4)6(OH)2 for printing in 3D printers of bone implants and the possibility of using it during implantation with voice prostheses. The introduction of an additional colloidal silver composite in voice implants will contribute to the reduction of bacterial infections, fungal infections and granulomatous hyperplasia. The creation of a stable external ring of the vocal fistula will remove complications associated with it with enlargement of the fistula and leakiness of voice implants. The ability to print with a hydroxyapatite filament will allow digital pre-surgery modeling of bone implants suited to the needs of surgical procedures.

Keywords: 3D printing, hydroxyapatite, voice prosthesis, silver nanomaterials, artificial bones

Printing three-dimensional elements has been used in medicine.

Initially, organ models were made for educational purposes. The models were made in the form of folded, layered elements, which allowed visualization of subsequent layers of organs. Figure1 shows a layered heart model printed on a 3D printer and a 3D printer.

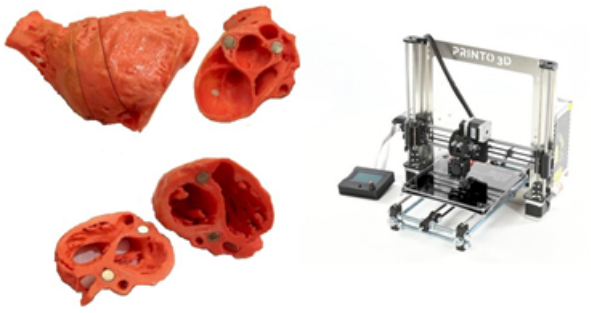

Fig.1. Layered heart model 3D printing and 3D printer

It should be noted that the printout of elements, at a small scale of production, is significantly lower than during the traditional method using injection of plastic material into the mold. The implementation of a small, single injection mold is estimated at an average of 2,000 EUR. We must remember that if an organ section is made, several such forms should be made. The cost of such an operation is a sum of 20,000 EUR. The return of the investment takes place only after the execution of several thousand items.

The next step was to print the organs or parts of the body to visualize the operations performed later. It can be said that this is a form of training before the actual surgery is performed. Currently it is the one from procedures for complicated surgery [1]. The previous visualization of the shape of organs, their location and location of blood vessels or nervous system significantly increases the patient's safety and reduces the risk of complications during and after surgery [2]. These activities were helpful in face transplantation and reconstruction of maxillo-facial bones, separation of siamese twins, a heart model was performed to simulate cardiac valve surgery to practice further surgery or to perform limb prostheses.

All presented surgical procedures did not introduce implants made by 3D printing into the body. Figure 2 Shows the reconstruction of the bones of the skull.

Fig. 2. Reconstruction of the facial bone model before and after. Source: Centrum Onkologii- Instytut im. Marii Sklodowskiej-Curie Oddzial w Gliwicach and author

An effective hydroxyapatite medical filament for 3D printers must meet several basic physical and medical functions. According to our assumption, it is supposed to stay in the body permanently and should constitute a compatible part of it [3].

The basic parameter in this case is its biocompatibility. While staying in the body permanently, it can not negatively

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affect the immune system. Hydroxyapatite is considered to be ceramics, biocompatible. In living organisms is a natural component of bones and teeth.

It must be characterized by high mechanical strength properties. It fulfills the function of the scaffolding responsible for the mechanical strength of the framework. The basic implant before use in the body does not have to fulfill this assumption. During rehabilitation, we assume a natural improvement in parameters by combining it with the body. Hydroxyapatite naturally overgrows bone tissue.

After a period of rehabilitation and penetration of bone tissue, it is supposed to fulfill the function of a natural bone. Obstruction with bone tissue is to eliminate the need for bone cement, which over time degrades and loose, which can cause pain in patients.

During manufacture, the sterility and cleanliness of the implant should be ensured.

The use of composite material in the form of colloidal silver in the part of the vocal implant, is to contribute to the reduction of bacterial infections, fungal infections and granulomatous hyperplasia.

Experimental part

During the production of a test bone implant, we used:

- A hydroxyapatite filament with a hydroxyapatite gel connector
- A modified 3D printer based on the Prius Cyberbiomed construction.
- Thermal Cyberbiomed vacuum dryer.
- Cura test software, Free Designspark Mechanical.

A bone structure design was carried out based on assumptions: the structure of the constructed object must be characterized by mechanical resistance. A uniform longitudinal structure corresponding to the structure of microfibrils [4]. supported on hexagonal scaffolds giving transverse mechanical reinforcement, was used. Figure 3 shows the shape of the applied structure.

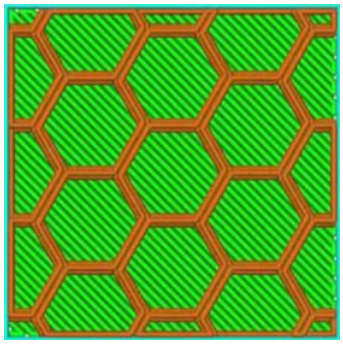

Fig. 3. The shape of the applied structure

At the same time, three types of filling with gradations of 25, 50 and 70% were adopted in order to subject them to tests of mechanical strength and permeability of physiological fluids. It was necessary to consider the permeability of the structure giving the possibility of natural fouling with bone tissue both inside and outside the structure.

During the design, skeletal structure shrinkage after evaporation of the hydroxyapatite gel and its effect on the distal contact points of the structure were taken into account.

Preservation of cleanliness and sterility of the structure.

After execution, the project was processed with a slicer program and entered into the printer. The hydroxyapatite feeders and the printing system were then loaded.

After about 1 hour, the structure element was printed. It was subjected to thermal vacuum treatment and another hydroxyapatite gel reinforcement. The operation of thermal vacuum drying was repeated until a dry structure was obtained.

The mechanical and structural properties of the print were preliminarily assessed and the structure was qualified for further testing.

The next stage of the research work was the creation of a colloidal silver structure on the external rings of the vocal implant. The defined medical problem consisted in frequent fungal infections (Candida albicans) [5-7] and bacterial infections (Chlamydophila pneumoniae, Mycoplasma pneumoniae and others) [8,9] occurring in the area of the voice fistula performed in laryngectomized patients using vocal implants [10-13]. Contact of the vocal fistula with food on the esophagus side and direct contact of the exposed structure of the trachea on the other side of the implant in many medical cases led to the development of infection and the need to close the fistula to eliminate the cause of the infection [14].

The closure of the fistula is associated with a complete closure after suturing, while the wound heals and cures the infection [15, 16]. During treatment and rehabilitation, the patient is fed with a probe inserted through the nose, as shown in figure 4.

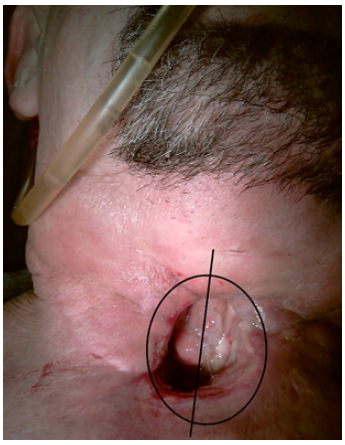

Fig. 4. Probe feeding food through the patient's nose

The inconvenience of feeding by using the probe takes about 3 weeks [17-29].

In order to reduce the possibility of infection, it has been proposed to use aseptic silicone with colloidal silver particles released during permanent implant use. The release time and aseptic effect occur throughout the entire time of use of the voice implant [8, 9, 22].

The implant was made by double injection of the obtained silicone with silver nanoparticles to the previously made form. Figure 5 shows the prototype of the implant made.

Fig. 5. Prototype of the implant with silver nano composite

In order to obtain the appropriate mechanical and chemical parameters, the element was treated in a pharmaceutical vacuum dryer. The implant was tested for the presence of silver nano particles in the outer wall structure and release during mechanical abrasion. In both

cases, the occurrence of silver nano particles was recorded. The implant was sent for further medical research.

Conclusions

Using the 3D printing method, making bone implants, we can say

that it is reasonable to continue further research and develop production methods. It should be noted that the use of 3D printing with hydroxyapatite, other elements or whole bones can significantly contribute to the development of new methods of implant surgery and bring tangible results to patients.

Positive results of using silver nano inserted in the structure of the vocal implant and the aseptic action known to us, will undoubtedly improve the patient's health safety and reduce the possibility of bacterial, viral and fungal infections in the vicinity of the vocal fistula.

Correlation of the vocal implant and fistula with an implanted hydroxyapatite ring has been directed to further research work for use in implantology.

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Manuscript received: 15.10.2017