Introduction

Personalized medicine involves the use of technologies to seriously acquire and assess an individual's own data for only their own treatment. It has been a field under development for the past years, which has moved its way forward and across our daily interaction with healthcare, at the same time that innovations like Artificial Intelligence (AI) or Machine Learning have struck their way into our society. However, today in this paper we will assess how another type of innovation in technology has helped to indeed push this concept further. With the advancement of design and manufacturing technologies in the last decades, more and more high-value added personalised medical products have been successfully developed, and brought in well-recognised benefits for patients [1]. This involves methods for rapid prototyping, along with other tools, and how methods in the early stages of the developments of these products have enhanced a smooth and solid launching and implementation of this concept in our lives.

We will state what are the products available today, in terms of personalised product developments, what are the tools currently used for this and how the process of developing a functioning unit goes.

Current Products Available

The current trend in Personalised Healthcare Technologies is about personalizing and tailoring medical treatment to the patient. Personalized medicine is still a young, but a rapidly expanding field of healthcare which helps healthcare professionals to select treatments based on patients genetic profile which can lead to more successful results and be less cost effective compared to “trial and error” approach in disease treatment. Current advances in science and technology have made diagnostics more smart, targeted, and accessible. [2]

Some of the uses of personal healthcare technologies include:

- Personalised implants for bone reconstruction - Designed specifically for the patient case considering personal anatomy structure, these implants are the best solution for bone reconstruction. Personalised implants take less time to be implemented during the operation and have better cosmetic results than traditionally manufactured implants. [1]

- Surgical tools - Personalised tools and implants are a good combination, because tools allow surgeons to access necessary places in the human body and pre-designed implants installed in the same operation. Previously it was divided in two operations, therefore personalised surgical tools reduce operation time and post treatment of the patient. [1]

- Dental implants are currently widely used since 3D scanning, modeling and printing came to the healthcare field. These products support false teeth and are usually fused with the jawbone. Modern implants based on 3D technologies have better cosmetic results. [1]

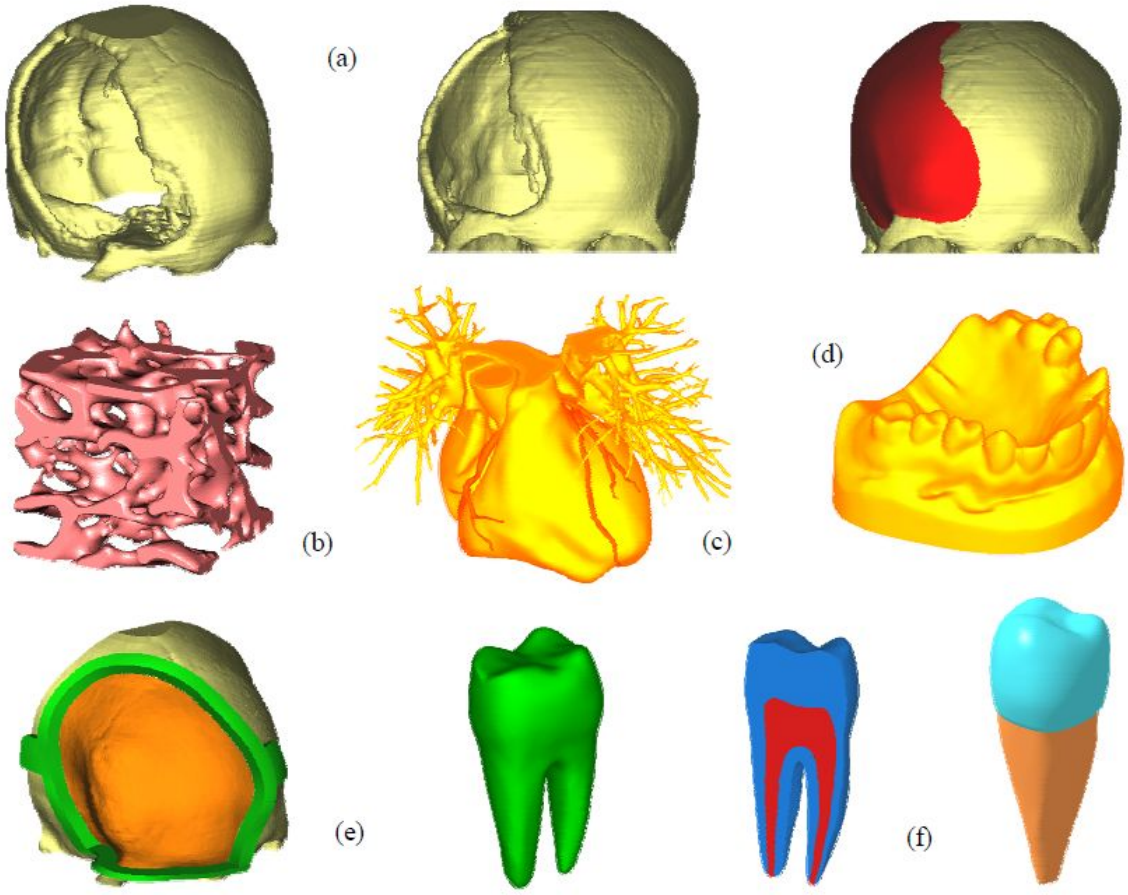

Figure 1: 3D Design and modeling for medical product development [1]

Another promising usage of personalized medicine includes cancer treatment. Personalized cancer medicine studies the human genes and how they affect different cancers. Tumors usually have different underlying genetic causes and therefore behave differently in different patients. Typical cancer therapy is overly simplified and therefore it can result in ineffective and expensive treatment which can be possibly harmful for the patient. Therefore, precision and personalized medicine is a growing interest amongst cancer research and treatment. Biological data is gathered from the patient and analyzed, in the hope of identifying mutations and biomarkers. One example of an emerging personalized cancer medicine product includes organoids. [3]

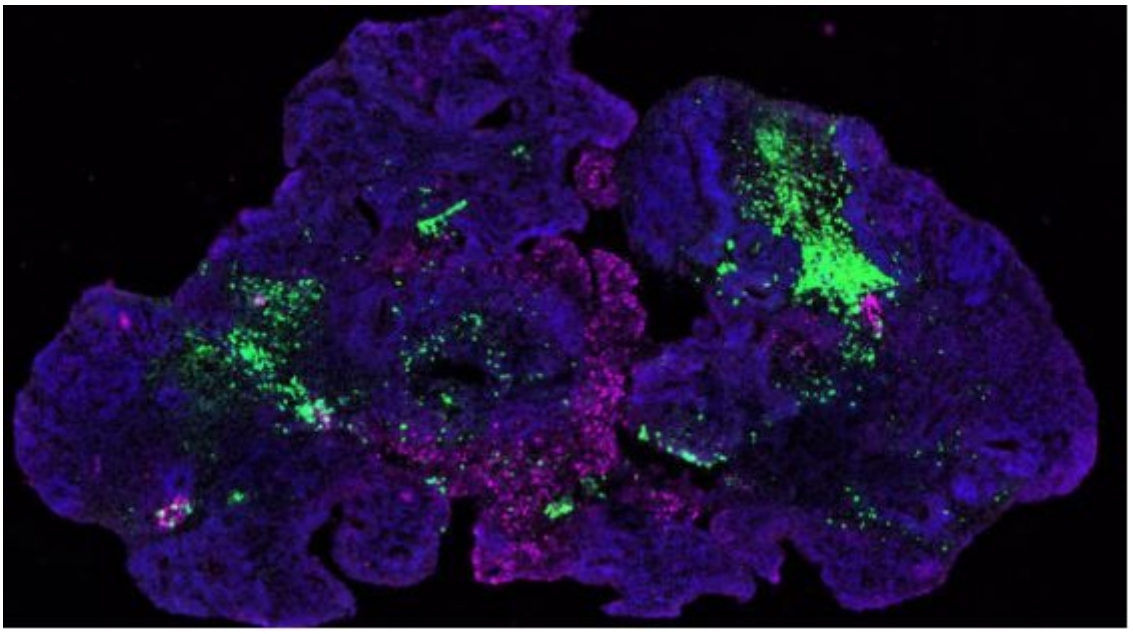

Figure 2: Section of a brain organoid after three months of cultivation [4]

Organoids are small, self-organized three dimensional tissues that are derived from stem cells and produced in vitro environment. Researchers have been able to produce organoids that are similar to the brain, kidney, liver and other tissues and organs. Organoids can range in size from less than the width of a hair to to five millimeters. The organoids gives the scientist important and detailed information on how organs form and grow, this enables also important research in how different drugs interact with different organs which helps develop personalized medicines. [4]

Current Tools for Product Development

- Medical Image Processing techniques:
  - Magnetic Resonance Imaging (MRI) - technique and process of creating visual representations of the interior of a body for clinical analysis and medical intervention, as well as visual representation of the function of some organs or tissues,
  - Computerized Tomography (CT) - medical imaging technique that uses computer-processed combinations of multiple X-ray measurements taken from different angles to produce tomographic images of a body, allowing the user to see inside the body without cutting,
  - Positron Emission Tomography/CT (PET/CT) - imaging technique that uses radioactive substances known as radiotracers to visualize and measure changes in metabolic processes, and in other physiological activities including blood flow, regional chemical composition, and absorption,
  - Optical Coherence Tomography (OCT) - imaging technique that uses low-coherence light to capture micrometer-resolution, two- and three-dimensional images from within optical scattering media. It is used for medical imaging and industrial nondestructive testing,
- Molding techniques such as negative casting,
- 3D modeling and simulation software: Computer Aided Design softwares (CAD), Computer Aided Manufacturing softwares (CAM), and 3D scanning techniques,
- Manufacturing techniques: 3D printing, Rapid Prototyping, Electron Beam Melting (EBM), Direct Laser Sintering (DMLS), sometimes CNC. [1]

Personalized Development Process

The four steps for the development of personalised healthcare products are:

1. Collection of data from the patient,
2. 3D modeling of anatomical structures - Designer works with the Doctor/Surgeon to plan surgery/treatment,
3. Evaluation and optimization of the design,
4. Manufacturing - Rapid prototyping and manufacturing technologies help to develop modern surgical tools and implants as well as other devices in the medical field. [1]

Below we will explain in more detail how this steps lead to one and other, as well as setting some real examples:

The design process for the majority of personalised medical products begins with collecting the data about the patient with Medical Image Processing technologies. That is the starting point for the product design and further development of the personalised medical device. [1]

The development of personalised medical products requires relevant software, hardware, and other specialised equipment. Depending on the patient case, a suitable technique of Medical Image Processing is chosen to obtain the medical image, which is then converted into a 3D model. The suitable methods of obtaining the medical image are chosen in a way that ensures the best quality of the 3D model. For example for treatment of bone fracture and reconstruction, the best quality for 3D modeling of the bone structures is obtained when using CT (Computerized Tomography) images. Similarly, MRI (Magnetic Resonance Imaging) provides the best quality of data for 3D reconstruction of soft tissues. However, in eye imaging and 3D reconstruction of the eye shapes, four different methods are widely used (CT, MRI, OCT, and RE), but their use is highly dependent on the required accuracy and clinical constraints, which differs in every patient case. In cases where direct scanning and imaging is not possible, molding techniques and negative casts are used, for example rapid tooling and dental casts are used for modeling the teeth and foot for development of dentures and orthotics. [1]

In order for the product design and development's time to be minimised, the surgeons/doctors and the designer of the medical device shall be able to work collaboratively, and to transfer the design data quickly and conveniently for both parties. It is often the case that the patient, the hospital, and the product design & development center are located in various geographical locations. For that reason data transfer and overall communication between all the parties need to be taken into account during the product development process. Usually, data acquisition is done in a hospital, then that data is sent via the internet to centers for personalised medical product development. For the development of personalised medical products, the surgical planning and the procedures for diagnosis and treatment are normally required. The planning is usually done by surgical teams in the clinical constraints. However, the technical specifications of the medical device need to be taken into account as well. In order to combine those two aspects, the surgeon plans with technical specifications, the designers need to also have a good level of knowledge in Biomedical Engineering. Since most of the personalised medical products have rather complex shapes and require to be made from special materials, it needs to be carefully considered in every single case what design and manufacturing techniques to use. [1]

Before the design can be forwarded to the manufacturing phase, the 3D model of the medical device needs to be carefully checked and evaluated by the designer and doctors/surgeons involved in the process. For personalised implants the design of the device needs to be evaluated also biomechanically with doctors/surgeons. If needed, the design can be further optimized and altered.

This part of the product development is time-consuming especially if the designer and doctors/surgeons are not in the same location. [1]

Once the design is accepted, the personalised medical device can be manufactured. The cost of the final product, and the needed treatment/surgery for the patient, is heavily dependent on the technologies used during the design and manufacturing phases. [1]

Conclusion

Paper [1] states the following:
“In order to be convenient for translation of knowledge into clinical practice, there is a need for better and more efficient ways and working environments to help hospitals and product design centres or companies to work collaboratively and efficiently. A robust decision support and information management tools as well as intelligent database and expert systems could be useful; and they should also be integrated into the personalised medical product design and development systems.”

The reason this is quoted as a matter of concluding this research, is to demonstrate that a need indeed exists to develop the methods and practices of the early stages of the product development process of personalised healthcare products. It is a field with a lot of open room for research and innovation, which will only have a beneficial impact in our everyday lives and health. However, methods for more efficient collaboration between the parties involved in the product development have to be developed, as well as the importance of the correct data management established. The purpose of all of this is merely to ensure an optimal delivery of the personalised service to the end user, also considering that when it comes to healthcare, processes have to be extremely efficient and accurate.

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