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Clinical workflow in medical additive manufacturing

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Abstract: Additive Manufacturing allows for the personalized production of medical models, surgical guides and implants. While the potential for AM in medicine is well known, the implementation of AM in clinical settings remains a challenge since it involves multiple independent parties, technologies and software tools. Recent advances in digitalization allow for more cohesive processes in the AM workflow. We review possible workflow implementations involving state-of-the-art printing technologies and materials, highlighting communication and legal issues.

I. Introduction

Additive Manufacturing (AM) is a generative process in which parts are built from various materials layer-by-layer. To date medical AM is most commonly used for the fabrication of patient-specific models, surgical guides and implants. However, serial production of non-personalized implants such as acetabular cups is becoming more common.

Successful personalized additive production requires the implementation of multiple process steps, which all require specialized equipment and know-how. Due to the increase in demand new, innovative workflow solutions are sought. More specifically a more cohesive interplay of the different processes in medical AM is necessary.

The basis for setting up such an advanced AM workflow is the further development of each technology currently used in the fabrication process. Since some of these technologies have now reached a technical readiness level (TRL) of 8 to 9, it is time to close the gaps in the process chain to create a holistic, coordinated workflow. The aim of this study is to give an overview of the involved steps, the participating parties and possible workflow models.

II. Material and methods

To obtain data for this study, interviews were conducted with experts from all included process steps. These included surgeons and medical engineers from different companies and hospitals [4]. In the following section, we list and explain all processes necessary for the generation of an individualized medical device. We then name all parties involved in these processes. Finally, we construct and discuss various possible workflows, naming advantages and challenges.

III. Results and discussion

In Fig. 1 is a schematic representation of the current medical workflow.

III.I. PROCESS STEPS

The workflow begins when a patient enters a hospital and is examined. In certain cases, the physician decides that the patient requires an individualized implant. The costs for such treatments are currently covered by healthcare providers under Diagnosis Related Groups in Germany as well as in the US [5][6].

Figure 1: Schematic representation of the processes that take place in the fabrication of personalized medical products.

All individualized medical products are based on patient-specific anatomy/region of interest. In order to visualize the anatomy of interest different imaging acquisition techniques can be applied: CT and X-Ray imaging are used for bony structures, MRI for soft tissues. Ultrasonic imaging is gaining in importance due to the lower exposure to radiation. Prior to surgery it is important to define the best scanning parameters for the region of interest. The parameters are very important since they influence factors like the resolution, contrast and signal-to-noise ratio which subsequently affect the quality of the printed medical device. [1]

The generated DICOM file contains more information than is needed for the AM process. Thus, segmentation is used to discard unnecessary information and cluster the desired voxels into distinct regions of interests (ROIs) [2]. In the assigned ROIs, DICOM data are converted into small triangles to create an STL file [3]. This STL model is used to design the individualized medical device using Computer Aided Design (CAD) software. The finished design is saved as an STL-file.

In order to produce a medical part, both the AM technology and the material need to be carefully chosen. Currently the most popular AM techniques used in medicine are Stereo-Lithography (SL), Selective Laser Sintering (SLS) and Selective Laser Melting (SLM). To date, a plethora of different materials including

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biocompatible titanium and polyamide (PA 12) are available for medical printing. For the fabrication of titanium parts, additional support structures have to be designed and implemented.

It is important to choose the correct printing technology prior to starting the AM workflow. Depending on the desired usage, the medical device must fulfill different requirements, such as mechanical characteristics and biocompatibility. After printing, most parts require post-processing. Depending on the printing technique, the parts must be either separated from the building platform or removed from excess building material. Tedious manual work is often required to remove such support structures. The final finishing of the parts may involve chemical, mechanical or thermal treatment to achieve the desired properties.

III.II. PARTICIPATING PARTIES

Besides the patient and the healthcare provider, there are three main parties involved in the current medical workflow. The hospital, the production facility and - in case of class II or III devices (surgical guides and implants) - the legal manufacturer. The legal manufacturer is "the natural or legal person with responsibility for the design, manufacturing, packaging, and labeling of a device before it is placed on the market under its own name. A legal manufacturer is liable for the product [5]."

III.III. POSSIBLE WORKFLOW MODELS FOR MEDICAL AM IN CLINICAL SETTINGS

The following factors influence the medical AM workflow: The location at which each step is executed, as well as the parties involved in each of the aforementioned steps.

It is theoretically possible for all steps including the production to be performed in hospital settings. This allows for direct and uncomplicated communication between doctors and engineers. All experts can collaborate easily to obtain optimal results. Short routes of transport enable quick delivery. To realize this, hospitals must however invest in 3D printers and technical experts.

A second workflow hence business model would be to exclude the production steps, but keep all other steps within the hospital. As the design takes place in the hospital, direct communication between the surgeon and the designer is ensured. It is important that the production facility meets the legal specifications.

In a third model, only the medical examination takes place in the hospital. The production facility designs and produces the medical device. The hospital does not need specialized in-house knowledge, which may be a suitable situation for smaller or peripheral hospitals. This model has the advantage that each domain is specialized to its assigned process step. In order to avoid potential difficulties, excellent means of communication and coordination must be established between the surgeons, the designers, and engineers. As the design process is undertaken outside of the hospital, a feedback loop between radiologists and designers is hard to establish.

Another major issue is data conversion and exchanges between multiple parties which can cause data loss. The use of one software package for the whole workflow would be advantageous. Furthermore, machine learning techniques can improve the individual processing steps needed in the AM workflow. For example, convolutional networks can significantly speed up the process of CT image segmentation [7]. Thereby operating errors and interfaces are reduced.

III.IV. CERTIFICATION

Unlike anatomical models surgical guides and implants need certification. Liability for medical products can be granted by the hospital, a production facility or a third party. Either of these parties are capable of taking the role of a legal manufacturer and are thus responsible for ensuring appropriate quality. Most interviewed companies were reluctant to take the role of a legal manufacturer. An important issue that was addressed by the companies was the lack of knowledge in quality control and the absence of quality guidelines for certification. To date a legal manufacturer must be certified in accordance with the Medical Devices Directive in order to sell printed medical implants.

IV. Conclusions

This study described the current medical AM workflow and the different stakeholders involved in the manufacturing process. The results revealed that the communication between doctors and engineers is pivotal in the AM process and that hospitals should preferably have a production facility on site and act as legal manufacturers. The use of machine learning and one dedicated software package could minimize errors and reduce production time in medical AM.

AUTHOR'S STATEMENT

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