Infinite Science | Publishing

Application-specific software supporting engineers and physicians to manage risks in 3DP

M. Herzmann[1*] , S. Leonhardt[1]

[1] *Kumovis GmbH, Munich, Germany*
[*] *Corresponding author, email: martin.herzmann@kumovis.com*

Abstract: To allow easier judgement about successfully 3D printed parts Kumovis develops a proprietary software as guiding instrument for physicians and engineers operating the filament printer R1 to manufacture surgical guides, instruments and implants. The software takes multiple parameters into account to manage the risk of failed print jobs and provides a Go / NoGo decision for the printer operator. Aim of the software is the raise of success rate per printed parts in a regulated market and reduction of failed print jobs.

I. Introduction

The large variety of additively manufactured medical devices make risk management a complex topic which is, however, urgently needed when medical markets meet additive manufacturing. This paper provides a solution for risk management for 3D printed cranial implants commonly used in craniomaxillofacial- and neurosurgery [Fig.1]. The risk analysis is based on a parameter set which is relevant for Kumovis R1 printer hardware which features a filament printing with an integrated clean room environment [1]. The printer is installed either at point of care or in industrial environment.

To ensure a high satisfaction rate for printing, minimal waste and optimal resource efficiency each print shall be as successful as possible and the risk for failed print jobs shall be reduced.

Figure 1: Example for a 3D printed cranial implant representing a lateral defect. Sizes, shapes and geometries will vary for each implant.

Risks to failed print jobs are influenced by parameters which partly can be analyzed mathematically. However, risks are also defined by non-mathematical parameters which are listed in the described solution tailored to Kumovis R1, too.

I.I. Implant parameters to consider

In order to specify an implant and define the risks related to its manufacturing mathematical data provides clear borders and criteria which allow categorization of the risk. Mathematical parameters such as implant volume, size, geometries such as overhangs, wall thickness and material define the implant precisely.

These parameters can partly be influenced during the design-process and partly be influenced during the build job itself (such as print speed). Fig. 2 shows three examples of different parts and gives an impression of the parameter set which defines the risk. The larger the size the higher the risk. However, some parameters have larger impact on the risk than others and must be valued accordingly.

While the printer Kumovis R1 has more than 50 integrated sensors (e.g. print-bed temperature, build chamber temperature, print head temperature, humidity, bed leveling, material processing, etc.) not all of these sensor data have an influence on the risk management system to produce reliable medical devices. However, these parameters allow insights during the print job which have additional information for the engineer running the machine and building an implant and the manufacturer taking ownership and responsibility for a successful part.

DOI: 10.18416/AMMM.2020.2009033

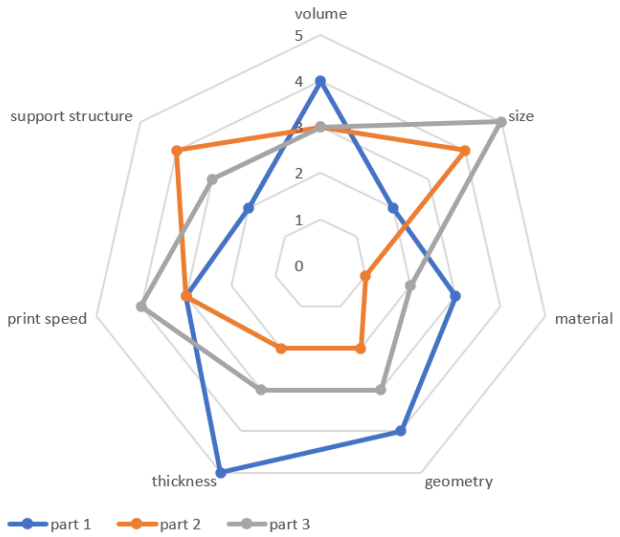

Figure 2: Example for visual impression on different parameters which can have impact on the success rate of printing of cranial implants. The parameters actually taken into account are more than shown in this graphic.

I.II. Human parameters

Beside mathematical and metrically measured data the human factor also plays a role when risk management for cranial implants is discussed. Haptic validation of the surface, optical impression on the color, the overall look and feel and the interdisciplinary discussion with the surgeon who needs the implant must be considered as a crucial parameter for risk management. Additive manufacturing requires an engineering skill set. Risk management requires both engineer`s understanding and cultural and human skillset.

II. Material and methods

Kumovis has developed a software tool to analyze the risk of failure for cranial implants built on the filament printer Kumovis R1. This tool will allow engineers to validate the quality of the printed part and will cluster numerous parameters into a Go or NoGo scenarios. NoGo scenarios represent a risk which is estimated too high to release the printed part as medical device. Go scenarios allow the engineer operating with the printer to trust the quality of the part given the validated parameters described above.

To ensure that this tool covers the majority of cranial implants requested by physicians and healthcare providers Kumovis works with statistical shape models (SSM) of implant designs for neurosurgical and craniomaxillofacial patients manufactured from polymers. In the first iteration the tool relies on data for an SSM based on more than 20 implant designs in PEEK [2].

The printer Kumovis R1 is able to process different high performance polymers, however, the first generation of this software focuses on PEEK (Polyetheretherketon) which is an accepted and widely used polymer. Future developments will consider further high performance polymers such as PPSU and PEKK.

These polymers require different material handling during the print process and therefore need separate specifications.

During the development process it became visible that the implant design varies from each designer and different medtech companies and manufacturer`s philosophies. Therefore, a continuous re-evaluation of the statistical shape model will be required to cover the majorities of surgical requests and clinical needs.

III. Results and discussion

The current quantity of implant datasets influencing the statistical shape model and risk assessment must grow to a quantity which provides an even higher certainty for both implant manufacturer and physician. The software tool gives clear indications for a Go / NoGo scenario and allows healthcare professionals to rely on technology which is difficult to understand in detail. Kumovis software tool opens up a pathway for both hospitals printing at point of care and medtech industry to establish filament printing on a reliable and industrial level. Following initiatives will allow the tool to become even more reliable:

- Additional PEEK cranial implant designs
- Additional metric and soft parameters to granulate the decision tree further and result in improved Go / NoGo decisions for the printer and the healthcare professional
- Comparison studies to prove the technology scientifically

IV. Conclusions

Additive manufacturing in medicine will grow in both markets: hospital and industrial. To allow users not focusing purely on 3D printing to benefit from this advanced technologies, supporting tools will be needed to raise acceptance amongst users. Intelligent decision support tools will benefit both the printer manufacturer and the user and allow users in the regulated medical market to install further printers backed up with clinical needs and build a sustainable installed base in medical environment. Further investigation and more patient data and experience will be needed to establish the described software tool in the medical market.

AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: Does not apply.

REFERENCES

[1] https://www.fabbaloo.com/blog/2020/5/21/kumovis-updates-on-medical-3d-printing

[2] https://corporate.evonik.com/en/evonik-launches-implant-grade-peek-filament-for-medical-applications-in-3d-printing-129905.html