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Design and 3D-printing of a rinsing chamber for hydrostatic high-pressure treated allogeneic tissues

M. Lorenz[1*], C. Drobek[2], D. Schwerdt[1], R. Bader[3] and H. Seitz[2]

[1] *Faculty of Engineering, Hochschule Wismar, Wismar, Germany*
[2] *Chair of Microfluidics, University of Rostock, Universität Rostock, Rostock, Germany*
[3] *Department of Orthopedics, Biomechanics and Implant Technology Research Laboratory, Rostock University Medical Center, Rostock, Germany*
[*] *Corresponding author, email: mathias.lorenz@hs-wismar.de*

Abstract: Nowadays, the use of additive manufacturing processes is widespread in the area of medical applications due to the advantages such as the wide variety of materials and the flexibility regarding the unique or single-part production to fabricate, for example, implants, surgical devices and guides as well as prostheses. As part of a joint project, our research groups have developed a rinsing system for allogeneic tissues and printed all relevant components by using stereolithography. The results presented in this scientific work show the use of this technology to fabricate biocompatible and steam sterilizable chambers and tissue holders for the rinsing system.

I. Introduction

The increasing demand for tissue replacement materials for surgical tissue reconstruction, which are preferably taken from other individuals of the same species (allogeneic) due to the reduced donor side morbidity have to be costly processed by various methods to prevent a severe immune reaction after transplantation [1, 2]. A new promising approach in clinical applications is to process various tissues by hydrostatic high-pressure (HHD), whereby cells are devitalized without affecting the extracellular matrix [3]. After HHD treatment, cells and cellular components have to be flushed out of the allograft in order to achieve a high grade of decellularization (DC). As part of the joint project "HOGEMA", novel approaches for the DC, such as ultrasound and fluid jet, were examined with regard to their effectiveness. The results of the DC by sonication in a centrifugation tube have already been published in [4]. For the transfer in clinical use a tissue rinsing chamber as the central part of an automated rinsing system was necessary, which fulfills the high requirements such as biocompatibility, temperature and chemical resistance.

Additive Manufacturing (AM) such as Selective Laser Sintering (SLS), Direct Metal Printing (DMP) and Stereolithography (SLA) have been used in medicine for years to fabricate, for example, prostheses, implants, orthoses and surgical devices [5, 6]. The recently developed Low Force Stereolithography (LFS), (Formlabs Inc., Sommerville, MA, USA) is a similar process variant of the well-known stereolithography process and offers high geometric accuracy, smooth surfaces and biocompatible materials. For this reason, we decided to use this technology to print all relevant components for our research project. This paper illustrates the results of the design and manufacturing process of an additively fabricated rinsing chamber with tissue holders.

II. Material and methods

To investigate the novel approaches, a rinsing chamber for the application of ultrasonic treatment and a fluid jet as well as a self-rotating tissue holder had to be developed. After designing with SolidWorks (Dassault Systèmes, Waltham, MA, USA), the (.stl) files have to be imported into Preform 3.15.2 Software (Formlabs Inc, Somerville, USA). The material-dependent printing parameters and slicing was done according to the manufacture settings with a corresponding layer thickness of 100 microns. For the 3D printing we utilized a Form 3B and a resin Surgical Guide V1 (Formlabs Inc., Sommerville, MA, USA), so the printed parts were biocompatible and could be sterilized by steam after post processing. We chose the highest resolution of 100 microns in order to be able to print the threads as well as the fine and challenging structures on the holders. After the printing process, support structures, as well as remaining liquid photopolymer, had to be removed manually through isopropanol bath cleaning. In addition, there was the need for a 30 minutes post-curing process in the UV light box Form Cure (Formlabs Inc., Sommerville, MA, USA) at a temperature of 70°C to finish the polymerization process, followed by steam sterilization.

III. Results and discussion

The chamber with a diameter of 26 mm and a height 50 mm has a 14 mm port for a sonotrode including an O-ring as

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well as an inlet for a fluid jet, consisting of a female Luer Lock and a nozzle 1.2 mm directly behind (Fig. 1). To insert the tissue holder in the chamber, we selected the two-part design, which are screwed together via a GL32 thread and sealed with another O-ring.

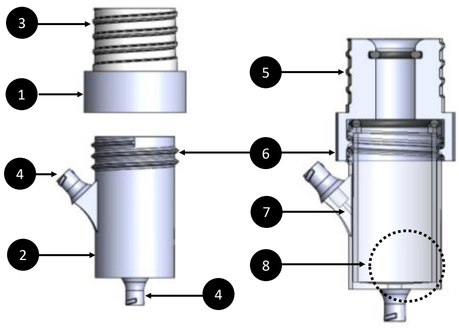

Figure 1: Computer-Aided Design (CAD) drawing of rinsing chamber: 1- upper part, 2- lower port, 3- external thread for fixation, 4- Luer Lock fittings, 5- port for Sonotrode, 6- GL 32 thread, 7- nozzle, 8- tissue holder.

Furthermore, to fix the rinsing chamber on the DC set up [4], an external thread of an original 50 ml centrifugation tube (i.e. Greiner Bio One 50 ml, Greiner, Kremsmünster, Österreich) was included in the upper part. In order to ensure continuous treatment of all sides of the tissue during the rinsing process without manual intervention, a self-rotating holder was developed for various allografts (bone cubes of 5x5x5 mm, cartilage cylinders of 0.5x11 mm), shown in Fig. 2.

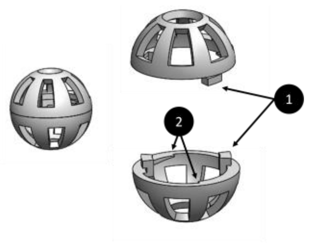

Figure 2: CAD drawing tissue holder: Two identical halves from a ball with 1. claws and 2. lugs.

The identical halves of the ball have two claws and lugs that interlock when they were put together and closed by turning, so that the ball is firmly closed. Moreover, large openings were added for proper flushing during the rinsing process.

The rinsing chambers and holders could be printed without any problems. Fig. 3 shows the rinsing chamber consisting of the upper and a lower part, which are equipped with a standard GL32 thread and female Luer Lock fittings.

Figure 3: 3D-printed rinsing chamber fabricated with Form 3B and resin Surgical Guide V1.

The print quality of the surface and the threads was very good, only occasional small remnants of the support structure had to be removed by light grinding. The port for the sonotrode with a diameter of 14 mm, the integrated nozzle of 1.2 mm and the designed section for the O-rings were dimensionally accurate. Fig. 4 shows a tissue holder with a diameter of 18 mm for bone and cartilage allografts after post processing. The print quality of the balls with the fine structures of the claws and lugs were very good, so that the halves of the ball could be assembled without further grinding. In addition, the surface of the balls was very smooth and without any significant defects.

Figure 4: 3D-printed tissue holder fabricated with Form 3B and resin Surgical Guide V1.

IV. Conclusions

In this work we showed the design and fabrication of a rinsing chamber and tissue holder for hydrostatic high-pressure treated allogeneic tissues. An SLA process was utilized to generate biocompatible and steam sterilizable parts. First visual examinations of the printed parts showed that the surfaces were very smooth without significant defects, which will be confirmed by further investigations. The results, presented in this research work, show that additive manufacturing processes can meet the highly challenging requirements in medicine for sterility by means of steam sterilization and biocompatibility.

Acknowledgments

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Author's statement

The Authors state no conflict of interest.

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