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3D printing of active medical implants

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Abstract: *For the fabrication of customized silicone rubber-based implants, e.g. cochlear implants or electrocortical grid arrays with high resolution, 3D printing it is not only a great option but also a challenging one. 3D printing of medical approved silicone will enable highly personalized medicine. The introduction of electronics, conductors and electrodes which are needed for creating active implants includes some challenges but will allow them to be more unique and compatible with the users. These are the printing of the high viscous non-Newtonian medical approved silicone rubber. It is also required to develop high speed curing systems, which vulcanize the silicone rubber systems to prevent extensive spreading of the viscous silicone rubber materials during vulcanization. The introduction of active electronics and the conductors and the sealing of it against body fluids is another challenge. Here, the steps towards a high resolution printing of medical approved silicone rubber are presented. This includes the understanding of the non-Newtonian behavior of the silicone during the printing process.*

I. Introduction

Flexible silicone-rubber-based implants can be used to treat or to diagnose neuronal diseases. For instance, hearing of deaf patients can be restored with cochlear implants, and epileptic foci can be localized with electrocortical grid arrays [1]. Several standard sizes of these implants are available for different anatomical environments, but they do not perfectly fit individual anatomy due to their stiffness and inflexibility. Due to this, conventionally available implants are limited by means of resolution and sensitivity caused by large distances between the electrode contacts and the target nerve cells, for example, in cochlear implants or electrocortical grid arrays.

II. Challenges

II.I. Printing Principle

To overcome these limitations, we present a fabrication approach for the direct fabrication of individually tailored silicone-rubber-based implants using typical medical-grade silicone rubber in conjunction with a 3D printing setup. This consist in an extruder for the two-component silicone rubber and an X-Y-Z table. As commonly used ultraviolet-curable silicone rubbers for additive manufacturing are not approved for medical implant fabrication, it is required to use conventionally established heat-curing mechanisms for implant fabrication.

II.II. Ultra-Fast Laser Curing

Since these silicone rubbers are thermal-curing liquids that undergo a low-viscosity region during the time-consuming heat curing process, a spreading of the silicone rubber can be expected. As the spreading would result in fabrication inaccuracies, we developed a high-speed-curing system to prevent the silicone rubber from spreading extensively. The system uses the strong infrared (IR) absorption properties, in the long-wave infrared region for heat transfer [2].

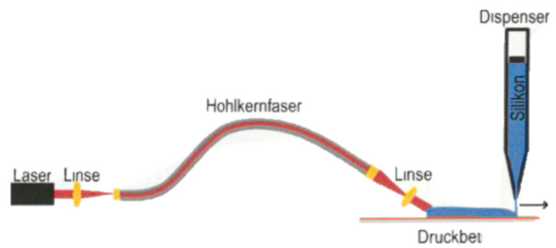

Figure 1: principle of printing silicone rubber with ultra-fast laser curing [3]

Figure 1 show a schematic of the system and its components. The dispenser is moved over the printing bead. A focused laser spot initiates the ultra-fast curing of the extruded silicone. Tests were carried out to investigate the spreading of the material and to investigate the material properties after this curing method. The ultra-fast laser curing minimizes the spreading and has no influence on the material properties including its biocompatibility [4]. With this setup printing resolution of about 300 µm was achieved [3].

III. Towards higher resolution

The basic principle of printing medical approved silicone with a voxel diameter of 300 µm was already shown. To achieve the goal of 50 µm voxel diameter the design of the extruder needs to be redone. A size reduction from 300 µm to 50 µm is due to the physics of polymer rheology not feasible (according to the Hagen-Poisseulle-law the nozzle diameter scales with the power of 4. Thus, a 6 times smaller nozzle opening will lead to 1296 times higher pressure). Due to this fact a total redesign of the extruder nozzle is needed. This redesign needs a full understanding of the liquid to generate a model that can be used for numerical validation of the design. Fig. 2 shows two measurements of the viscous behavior of the Silpuran 2430, one was given by Wacker AG the other was made by Stieghorst [3].

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The viscosity curve shows a nonlinear behavior. This nonlinearity and the minimum of the viscosity will be used to design the extruder nozzle with the needed diameter. The idea is to use local viscosity minimization by shear rate maximization. For this a total understanding of the viscosity curve is needed.

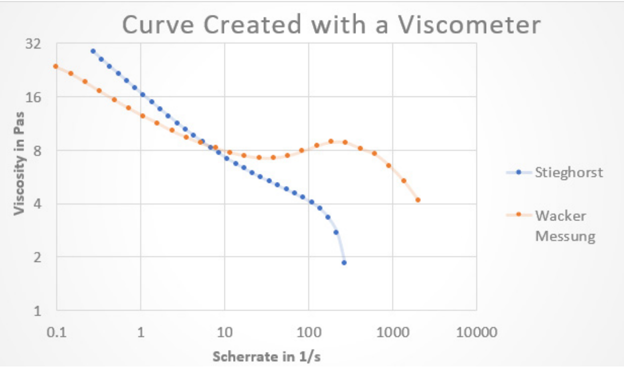

Figure 2: Viscosity measurements in relation with the sheer rate of the silicon rubber

III. Results and discussion

For the evaluation of the silicon behavior a test stand, figure 3, was used. For this experiment a nozzle was connected to a syringe using a luer lock connection to ensure stability.

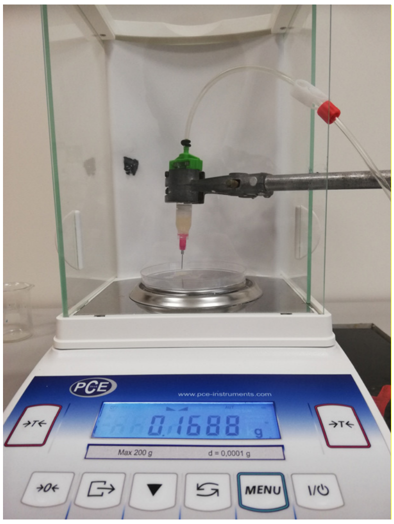

Figure 3: Test Stand for flow rate measurements of the silicon rubber.

Different pressure values where applied and the flow rates where measured using the data collected by the electronic scale, all recorded with the aid of LabView.

Using this method, it was possible to record and study the viscosity of the material under different shear rates simply by changing the pressure and the nozzle size. The achieved viscosity data will be used to perform numerical analysis. With this test stand measurements under conditions close to the final extruder could be performed.

Several commercially available nozzles with diameters from 200 µm down to 50µm were tested in a pressure range from 1 to 12 Bar. It could be seen that a reliable measurement of the flow rate was only possible down to 100µm nozzle diameter. The 50µm nozzle showed non-repeatable flow behavior. This leads us to the conclusion that a sophisticated nozzle design is needed. This design will be created with the help of the collected viscosity data and numerical methods.

IV. Conclusions

The 3D printing of silicone rubber based active implants is a challenge. Several topics needs to be addressed. A research consortium is planned to achieve this goal. At the Jade University of Applied Sciences the design of the printer nozzle with the needed diameter will be done. To achieve the goal of 50 µm voxel diameter printing the behavior of the printed liquid needs to be fully understood. Measurements to verify the viscosity model and to test different nozzles are presented here. The results shown that the goal of such a small nozzle size can only be reached by a sophisticated nozzle design.

AUTHOR'S STATEMENT

The authors state no funding involved and no conflict of interest. Informed consent has been obtained from all individuals included in this study.

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