Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, Vol 1, No 1, 2019, Article ID S02T03

Infinite Science | Publishing

3D-printing technology as a tool for medical implantable electronic devices

P. Mendoza Ponce[1,2*], L. Abu-Saleh[1], W. H. Krautschneider[1], M. Kuhl[1]

[1] *Institut für Integrierte Schaltungen, Technische Universität Hamburg, Hamburg, Germany*
[2] *Electronics Engineering Department, Tecnológico de Costa Rica, Cartago, Costa Rica*
[*] *email: pablo.mendoza@tuhh.de*

Abstract: Medical implantable electronic devices (IMD) are of great use to research and in the treatment of various health conditions. 3D printing technology is proving to revolutionize multiple industries, including IMDs, by allowing rapid research, development and production. This paper presents how 3D printing technology was utilized during the modeling, prototyping and fabrication process of the first version of an implantable device intended for interstitial pressure monitoring.

I. Introduction

Implantable medical devices (IMD) have benefited from advances in microelectronics, which has allowed them to be reduced in size while their complexity and functionality has increased. Thanks to these developments, IMDs are finding their way into more areas of medical research and illness treatment, thus increasing demand and pressuring designers and manufacturers to accelerate the introduction of new devices.

The research and development of implantable medical devices is a multidisciplinary task that requires cooperation between engineers and physicians to produce a functional product. In particular, and based on our experience, 3D printing technology greatly facilitates working together on the process of defining and optimizing the mechanical and volumetric specifications.

This paper discusses the use of 3D-printing technology in the prototyping and development of a deeply implantable medical device for the monitoring of pressure ([1], [2]). Also, an outlook of the ways emerging techniques can improve production and development of IMDs is briefly presented.

II. Prototyping of Implantable devices

Given the complexity of the human body (and also that of any test animal), defining the correct dimensions, as well as physical and mechanical properties, of the IMD is of high importance. Therefore, the input from medical researchers is critical in the early stages of the project.

To this end, in the developed IMD, 3D printing was used to provide the physicians with models of the proposed device. Fig. 1 shows the initial and final models of the design. For this prototype, the tip (indicated in Fig. 1.d) contains the sensors and so must remain in a precise position without being affected by the movements of the test subject. In the first iteration, the design had two rings that were designed to enable suturing (Fig. 1.a,b) of the implant to provide the required mechanical stability. Several configurations of the rings were proposed and considered (not shown in Fig. 1). Furthermore, various wire lengths were tested.

The final version (Fig. 1.c) of the model does not include the rings. The decision to remove them was made after several trials with previous models in dead mice indicated that the system could be used effectively without the need for suturing the implant (which simplified the medical procedure for implantation). This entire process took around two months, a relatively short time, since change requests were processed and tested rapidly thanks to the 3D printing of the models.

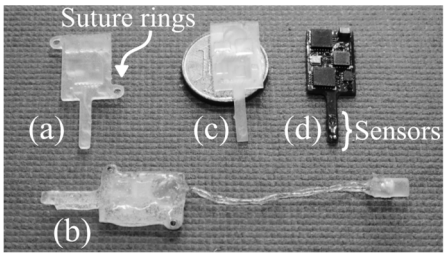

Figure 1: 3D models produced and real IMD prototype. (a) First model produced. (b) First model with wire after a test of silicone encapsulation. (c) Final IMD 3D model. (d) Real IMD board.

Each 3D model reflected the dimensions of the actual components used for the IMD. The final version of the model was then used by the physicians for improving and practicing the implantation procedure while the real IMD (Fig. 1.d) was produced.

III. Instrument fabrication for IMD assembly

Since IMDs are in direct contact with internal tissue and fluids, there is a need for encapsulation with biocompatible materials to protect both the electronics and the subject that carries the device. In the case of the developed system, a layer of biocompatible silicone [3] was used as encapsulation.

For the application of the silicone, molds were required to ensure the thickness and geometry of the final system were controlled and consistent. Again, 3D printing was instrumental in developing and testing various designs, and further adjustments were made as the coating process was refined. This custom method also provided flexibility in case any implant dimension had to be changed at a later

DOI: 10.18416/AMMM.2019.1909S02T03

stage (e.g. wire length). Fig. 2.a shows one of the molds generated and the resulting implantable device (Fig. 2.b).

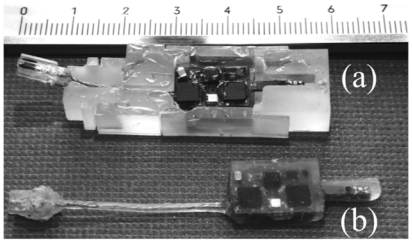

Figure 2: (a) 3D printed mold for applying the silicone coating to an IMD. (b) IMD coated in medical grade silicone.

IV. Fabrication of components for IMDs

An additional challenge in developing IMDs is to obtain needed mechanical components that fit the small dimensions required. The use of an external manufacturer means relying on their 'off the shelf' products which often leads to compromises in the IMD specifications, or to spending large amounts of time and money for getting custom made parts in a small quantity, a service not always offered.

Due to the aforementioned problems, 3D printing was used to manufacture some mechanical parts for the first prototype of the IMD. Specifically, a connector and port set was necessary since a wired setup (reduced development time when compared to a wireless setup) was acceptable for proving the IMD concept in animal tests.

Fig. 3 shows the final version of the developed connectors. This set consists of a small female connector that is attached to the implant by a wire (Fig. 3.a), a port with a protective cap (Fig. 3.b) and a male connector which is used to connect the system to the reader hardware (Fig 3.c). The connectors were shared with the physicians together with the IMD models for evaluation and were also subject to design changes in order to improve their mechanical stability and to reduce the stress on the animals used in the experiments.

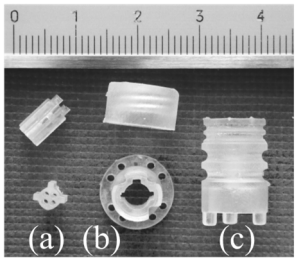

Figure 3: (a) IMD miniature male connector. (b) Port (bottom) and protective cap (top). (c) Reading hardware male connector.

V. Considerations of the utilized materials

Several problems regarding the various materials used had to be solved during the development of the IMD. The first issue confronted was the heat resistance of the material used for the mold [5] (Fig. 2.a.). The solution was to refabricate the final mold design with a Teflon substrate after testing (of the 3D printed molds) confirmed the correct dimensions.

The material used for 3D printing the connectors is not certified as biocompatible [4] and so presented an additional challenge. For the final setup, therefore the surfaces which would be in contact with the animal tissue were covered with a thin layer of the biocompatible silicone coating [3]. This solution, however, was not perfect as silicone is permeable to moisture [6] which interferes with the pressure measurement, so a further external layer of Parylene was applied as in [7].

VI. Conclusions and outlook

The use of 3D printing in the development of the presented IMD allowed for a rapid prototyping flow. By fabricating models with real dimensions it was possible to obtain input from the physicians during the initial phases of development. Also, these models were useful as training tools for the implantation surgical procedure. The packaging of the IMD benefited from 3D printing as well, by allowing changes to the dimensions of the molds as the process was optimized. Finally, 3D printing enabled the rapid and inexpensive production of some specific components required by the IMD such as the miniature connectors presented.

Future 3D printing technologies are going to further revolutionize IMD development and manufacturing. Biocompatible printing materials and emerging technologies that allow printing around existing structures [8] (such as the IMD circuit board) can eventually be used for rapid IMD packaging. These technologies might also permit new mechanical features for IMDs (e.g. micro channels embedded in the packaging for differential pressure measurement in miniaturized implants).

AUTHOR'S STATEMENT

Research funding: This work has been partially supported by a grant from Instituto Tecnológico de Costa Rica with number 37-2015-D and also by the German Exist program and Europan Social Funding with number 03EFKHH024. Ethical approval: The research related to tests in animals complies with the relevant German regulations, institutional policies, approved by the animal ethical committee with number: N-086/201.

REFERENCES

[1] R. Ranjan, B. John, D. Schroeder and W. H. Krautschneider, *Capacitance to Digital Converter ASIC with Wireless Energy and Wireless Data Transmission for a Medical Implant*, ANALOG 2016; 15. ITG/GMM-Symposium, pp. 1–5, Sept. 2016.

[2] P. Mendoza-Ponce, B. John, D. Schroeder and W. Krautschneider, *Super-capacitors for implantable medical devices with wireless power transmission*, in: 2018 14th Conference on Ph.D. Research in Microelectronics and Electronics (PRIME), pp. 241–244, July 2018

[3] Avantor (2018). *MED4-4420 Data sheet.* [Data Sheet] Retrieved on May 2019 from https://nusil.com/services/downloadfile.ashx?productcode=MED4-4420&originalname=MED4-4420.pdf

[4] Formlabs (2016). *Clear Photoreactive Resin for Form 1, Form 1+, Form 2 - Safety data sheet.* [Material safety data Sheet] Retrieved on May 2019 from https://archive-media.formlabs.com/upload/Clear-SDS_u324bsC.pdf

[5] Formlabs (2017). *Material data sheet - Standard.* [Data Sheet] Retrieved on May 2019 from https://archive-media.formlabs.com/upload/Clear-DataSheet.pdf

[6] B. Ratner, A. Hoffman, F. Shoen and J. Lemons. *Biomaterials science: an introduction to materials in medicine*. (third ed.) Academic Press, 2013

[7] A. Shapero and Y. Tai, *Parylene-oil-encapsulated low-drift implantable pressure sensors*, 2018 IEEE Micro Electro Mechanical Systems (MEMS), Belfast, pp. 47-50, 2018

[8] B. Kelly, I. Bhattacharya, H. Heidari, M. Shusteff, C. Spadaccini and H. Taylor. *Volumetric additive manufacturing via tomographic reconstruction*. Science. Vol 363. pp. 1075-1079, AAAS, 2019