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# 3D Printed Biocompatible Enclosures for an Implantable DBS Microdevice

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**Abstract**

A number of methods have been used to make electronic medical microdevices biocompatible. This paper presents a novel approach for design and fabrication of biocompatible silicone enclosures for implantable medical microdevices. The approach involves design and formation of a 3D model of the enclosure using a computer-aided design software tool, followed by 3D printing of the enclosures using a bioplotter. Three different implantable enclosure designs are presented. The fabrication of the three enclosures is given. An evaluation of the suitability of the enclosures for implantation of a deep brain stimulation microdevice is discussed through submersion and operation tests. The evaluation results are presented and discussed.


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*Keywords:* 3D printing, biocompatibility, medical microdevices, DBS.

## 1. Introduction

In deep brain stimulation (DBS), a microdevice delivers electrical signals to a target region of the brain through an electrode. The electrical stimulation of the brain tissue can treat symptoms of several neurological disorders.

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Moreover, BDS is used to model and study the pathophysiology of the neurological disorders in preclinical murine models [1-4]. In pre-clinical studies, DBS devices are used with small laboratory animals to study the therapeutic mechanisms of DBS over time. However, most existing DBS devices involve sophisticated circuitry that are large in size and weight. Thus, uninterrupted animal behavioral tests have been difficult. Therefore, a miniature implantable DBS device can boost the outcome of research studies that aim to discover the therapeutic mechanisms of DBS.

Kouzani et al. [5-6] have developed a variety of DBS microdevices for pre-clinical applications. One of their latest devices has been designed to be implantable under the animal's skin. The device comprises a low-power microcontroller, an adjustable current source, an n-channel metal–oxide–semiconductor field-effect transistor, a micro pushbutton, an LED, two capacitors, two resistors, a coin-cell battery, a battery holder, battery and electrode wires, and an electrode. A miniature two-layer printed circuit board is designed to host the components of the DBS device. The length and the width of the board are 12 mm and 5.5 mm, respectively. The shape of the board is chosen in such a way to allow the board to be secured under the animal's skin. However, the response of the animal's body to the device would be in a way to get rid of it due to the lack of biocompatibility. Biocompatibility is defined as "compatibility with living tissue or a living system by not being toxic, injurious, or physiologically reactive and not causing immunological rejection" [7].

A number of methods have been employed to make an electronic device, which includes a printed circuit board and electronic components that are mounted on it, biocompatible. One popular method has been to cover the device with a biocompatible material. Accordingly, the device would not harm the animal when used as an implant, and at the same time it is protected from the animal's body fluids. A widely used material is medical grade silicone which is silicone evaluated for biocompatibility and are appropriate to be used for medical applications.

Beyond to its elasticity, flexibility, and resilience, silicone is one of the most widely evaluated and utilised biomaterial which is popular for its inherent biocompatibility property [8]. Thus far, silicone has been used to make a device biocompatible through two approaches: dipping or molding. In the former, a silicone coating is produced on the device. A device consisting of a printed circuit board and electronic components is coated with a silicone film. In the latter, on the other hand, a mandrel is produced from metal, glass, or other materials in the figure of the biocompatible enclosure for the device. While the former is low-cost and suitable for low-volume applications, the formation of coating is not highly controllable, and that there is lack of repeatability and consistency. On the other hand, while the latter is suitable for high-volume production, it is expensive and not suitable for low-volume applications.

This paper presents a novel approach for the design and fabrication of biocompatible silicone enclosures for implantable microdevices. The approach involves design and formation of the 3D model of the enclosure using a 3D computer-aided design software tool such as SolidWorks. Next, the generated 3D model is fed into a 3D bioplotter which is capable of printing multiple materials using pressure. The materials range from viscous pastes to liquids including medical grade silicone.

## 2. 3D Bioplotter

The EnvisionTEC GmbH Bioplotter is a rapid prototyping system [9] for processing a great variety of biomaterials within the process of computer aided printing from 3D CAD models to the physical 3D objects with a designed and defined outer form and an open inner structure. Multiple materials are deposited in three dimensions using pressure. They range from viscous pastes to liquids, and are inserted using syringes moving in three dimensions. Pressure is applied to syringes, which then deposit a strand of materials for the length of movement, and the time that the pressure is applied. Parallel strands are printed in one layer. For the following layer, the direction of the strands is turned to the centre of the object, creating a mesh with good mechanical properties, and mathematically defined porosity. The features of the system include 3-axis positioning system with high movement accuracy, cell printing with up to five types of cells per object, high flexibility in the choice of materials, fast printing speed, a large building volume, and flexible inner structure design.

## 3. Methods

The enclosures designed and fabricated in this paper will enable the 12 mm × 5.5 mm × 1 mm DBS device to be surgically implanted into the laboratory rat. In order to successfully implant the DBS device the enclosure must have minimal impact on the animal allowing for as close to normal behavior as possible while the device is operational.

### *3.1. CAD Models*

Three different implantable enclosure designs are presented which are differentiated by the position of the DBS device in the enclosure and the outer profile of the enclosure. All of the 3D printed models are developed in Solidworks (Dassault Systemes SolidWorks Corporation, Velizy, France), and designed to be 3D printed without the need for a support material. Support material was avoided due to a limitation in the fabrication method being used.

The first design as shown in Fig. 1 (a) is a simple two piece rectangular design where each piece is 14 mm × 10 mm × 3.5 mm with sides 90° to the base. Each piece of this enclosure has an inner cavity 11 mm × 7 mm × 2 mm to house the DBS device. The key objective of this enclosure design is ease of manufacture using the 3D printing process, for this reason the design has vertical sides and a rectangular profile. The top and bottom sections of this enclosure are identical in design, and the DBS device is positioned between them in order to physically isolate it from the surrounding tissue and body fluids. In order to seal the two pieces of this design, same silicone is be used in order to bond the top and bottom parts sealing the DBS device from the tissue surrounding the implant.

The second design as shown in Fig. 1 (b) is an altered version of the first design with a rounded outer contour radius 4 mm to eliminate the 90° edges. The key objective of this enclosure design is to make a more implant friendly version of the first design with less sharp edges. The flat side of this enclosure is kept from the first design to maintain the manufacturing process simple. The DBS device is positioned within the enclosure similarly to the first design and the enclosure is sealed in the same manner.

The third and final design as shown in Fig. 1 (c) is a 14 mm tall cylinder with a base diameter of 8 mm, the inner cavity in this design is 13 mm × 7 mm × 3 mm. The aim of this design is to create a functional enclosure out of a single piece, not requiring a printed lid. This reduces the number of surfaces to be sealed after fabrication and should provide better isolation from the tissue surrounding the implant. The DBS device is placed into the inner cavity which is then sealed using the silicone.

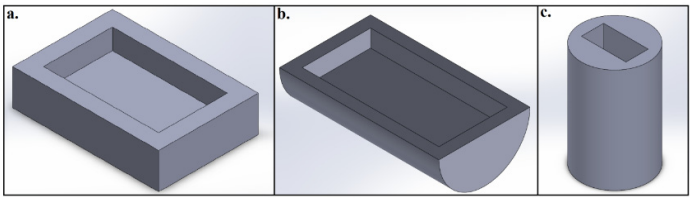



Fig. 1. Three enclosure designs, (a) design 1, (b) design 2, and (c) design 3.

### *3.2. Fabrication*

All of the models were printed in commercial grade silicone on an EnvisionTEC GmbH Bioplotter (EnvisionTEC, Gladbeck, Germany) shown in Fig. 2. The bioplotter was chosen to produce these designs over a more traditional 3D printer due to the ability to accurately print using biocompatible silicon. By keeping the silicon at a constant 20°C and using a syringe as the extrusion system, the material deposit was consistent and predictable.

The operating parameters of the Bioplotter was determined through the manufacturer's procedure [9]. Table 1 shows the determined operating parameters for printing the silicone. This mix of material volume and deposit speed meant that the designs could be produced rapidly (under 5 minutes per design) while still allowing for a high level of bonding between the layers. In order to fabricate the enclosures the following procedure was followed:

- Load the 3D Model into the Bioplotter RP software.

- Select the appropriate build area and material (100 mm × 100 mm, and 250 µm silicone).
- Reposition the model into a location where it can be successfully printed.
- Slice the model into layers with the appropriate thickness.
- Export to the Visual Machine plotting software.
- Turn on the Bioplotter.
- Assign the appropriate material (250 µm silicone) to the part.
- Assign the appropriate internal pattern to the part.
- Save the part.
- Insert the material cartridge and the needle tip into the printing head.
- Assign the appropriate material and needle tip to the print head in the Visual Machine software.
- Calibrate the print head.
- Purge and clean the print head.
- Start the print.

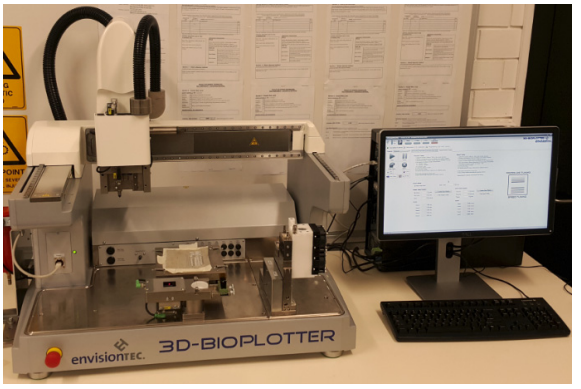



Fig. 2. EnvisionTEC GmbH Bioplotter.

Table 1. Bioplotter settings.

| Parameter | Value |
|---|---|
| Plastic tip size | 250 µm |
| Speed | 30 mm/s |
| Pressure | 3.5 bar |
| Temperature | 20$^{o}$C |
| Pre-flow delay | 0.05 s |
| Post-flow delay | -0.05 s |

Following this procedure, the three enclosures were all printed successfully and in a repeatable manner. Fig. 3 shows samples of the three printed enclosures, together with the printed circuit board of the DBS device.

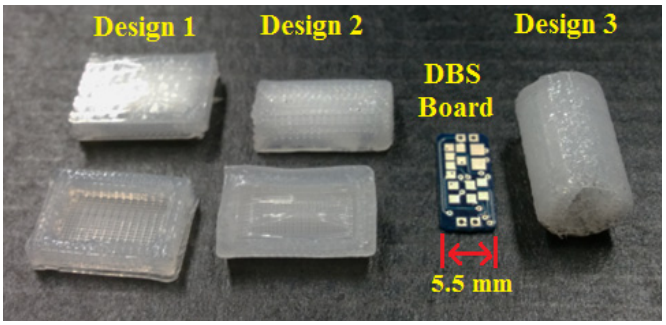



Fig. 3. The three printed enclosures.

## 4. Evaluation

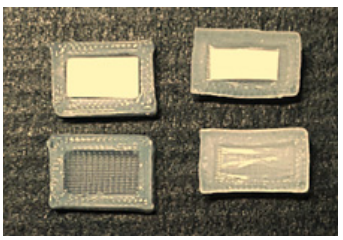
In order to assess the suitability of the 3D printed enclosures for implantation, two tests were conducted: submersion, and operation.

### *4.1. Submersion Test*

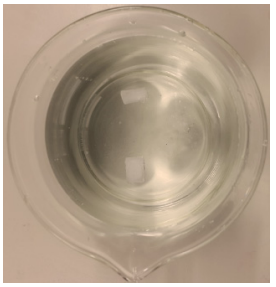
The submersion test was performed on both of the two piece enclosures of Design 1 and Design 2 to gauge if they were waterproof when submerged for an extended period of time. A piece of copy paper was placed into the each device cavity in order to observe if the enclosure will leaked during the submersion test (see Fig. 4 (a)). Silicone was then used to attach the pieces of the two piece enclosures together. After the enclosures were sealed with the papers inside, the enclosures were submerged under approximately 10 cm of water. An image of the submerged enclosures is shown in Fig. 4 (b,c).

The cylindrical two piece design (Design 2) was removed from the water after 1 hour of submersion and the exterior was dried. The enclosure was then opened with a scalpel to remove the paper. The paper when removed from the enclosure showed no signs of moisture which indicated that the device cavity remained watertight over the period of submersion. The paper is shown in ff.

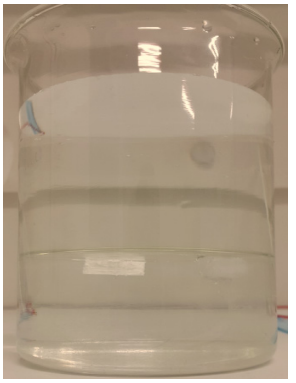
The rectangular enclosure (Design 1) was removed from the water after 5 hours of submersion and the exterior was dried. The enclosure was opened with a scalpel and the paper removed. The paper in this enclosure also showed no signs of moisture which indicates that the device cavity remained watertight over the 5 hours of submersion.



(a)



(b)



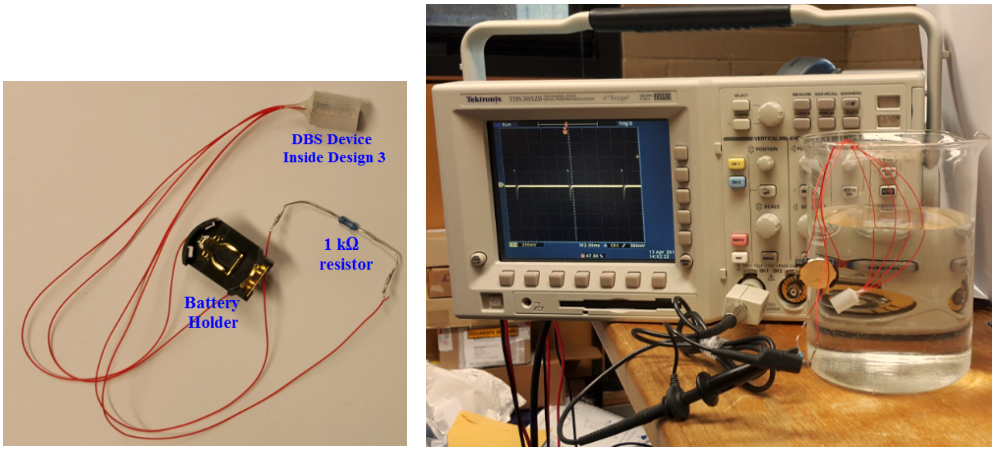
(c)

Fig. 4. (a) Insertion of paper in two enclosures before submersion test. (b) Top view of submersion test. (c) Front view of submersion test.

### *4.2. Operation Test*

The operation test was performed with the single piece enclosure to ensure that an active DBS device could be submerged and remain active with no change in output. The DBS device was placed into the enclosure and the opening was sealed with silicone (see Fig. 5 (a)). A coin cell battery was then connected to the power wires and the device was activated. The output was connected across a 1 kΩ resistor which emulates the brain tissue, and the output pulses were observed with an oscilloscope. The device and enclosure were then submerged in water and the operation of the device was similarly tested. As can be seen in Fig. 5 (b), the device was still active and producing DBS signal pulses even though it was completely submerged.

The results of the two tests clearly show that there is significant potential in using this method of producing implantable enclosures to house medical microdevices.




(a) (b)

Fig. 5. (a) DBS device sealed in the enclosure (Design 3). (b) Operation test while the DBS device is submerged in water.

## 5. Conclusion

The paper presented an approach for design and fabrication of biocompatible silicone enclosures for an implantable DBS microdevice. Design and creation of a 3D model of the enclosure was done using a CAD software tool. Then, 3D printing of the enclosures was performed using a bioplotter. An evaluation of the suitability of the enclosures for implantation of the DBS microdevice was discussed through two tests. The results demonstrated that there is significant potential in using this method for producing implantable enclosures to house medical microdevices.

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