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Original Research Article

Rapid prototyping of molds for the encapsulation of electronic implants using additive manufacturing

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Abstract: Designing encapsulations for medical implants with integrated electronics is very challenging because a solution for several different and partly opposing requirements like biocompatibility, low water permeability, mechanical stability and small dimensions must be found. This work focusses on epoxy encapsulations, which are conventionally cast using silicone molds. For making these molds, a pattern must be CNC machined and the silicone mold must be cast from it. In this paper, a rapid prototyping method is proposed, which uses additively manufactured molds made by an inkjet 3D printer that operates with a silicone-based material. A proof of concept is presented for an electronic osteosynthesis implant, which is successfully encapsulated following the rapid prototyping method and compared to results obtained with the conventional method. The demonstrator was immersed in isotonic saline solution for three weeks without any negative effects on the functionality. The rapid prototyping approach required only 15% of the time needed by the conventional mold making process based on silicone casting and used less material. This shortens design cycles for the optimization of the encapsulation for electronic implants and enables to evaluate more design variations with little additional effort. Moreover, designs with more degrees of freedom are available in the additive manufacturing process. For casting the encapsulation, the same material as for the final implant can be used so that many properties like water permeability and mechanical stability can be evaluated in the early development phase.

I. Introduction

Integrating electronic components in medical implants to monitor physiological processes or even actively stimulate parts of the body is a promising approach in various treatments. Examples are artificial cardiac pacemakers [1], cochlear implants [2] or instrumented orthopedic implants [3], [4]. The integration of electronic components into implants poses specific challenges, because these devices have to be securely isolated from body fluids, which can cause short circuits or corrosion of the implants. This must be avoided, especially when the safety and health of the patients depend on the functionality of the implant. Moreover, the tissue surrounding the implants has to be protected from contact with the electronic components and the contained materials as these can lead to inflammations and other undesired reactions [5]. Typically, an encapsulating material is used to cover the electronic components, insulate them from the tissue and define the surface properties of the implant. The encapsulation has to be hermetic, biocompatible, inert and mechanically stable [6], [7]. In some cases, the encapsulation also has to be flexible or allow for the penetration of certain physical quantities like pressure or light if the implant is using such transducers. Many electronic implants also require wireless data or energy transmission [8], for which at least parts of the encapsulation material have to be transparent to electromagnetic fields in the used frequency spectrum. A common requirement for all devices that are implanted is that they should be small enough [9] to avoid negative effects on the surrounding tissue and restrictions for the patients as much as possible. This often requires to carefully trade-off the dimensions of the encapsulation with the aforementioned required properties and makes the design very challenging.

Depending on the application, different materials are used for encapsulating electronic implants. Typical solutions are titanium alloys [10], silicones [11], [12] or epoxies [13], [14], which all have specific advantages and disadvantages. Titanium based encapsulations are mechanically very robust, provide a high biocompatibility and low permeability for water. However, due to their high conductivity, even thin layers of metal prevent the penetration of electromagnetic fields, which is required for wireless data and energy transmission [6], [10]. Silicones like polydimethylsiloxane (PDMS) affect these fields only slightly, enable elastic encapsulations and can also be transparent to optical signals. However, PDMS has a comparatively high permeability to water [15]. Epoxy encapsulations have a significantly lower permeability to water than PDMS and have been reported to successfully seal electronic components immersed in water over several months [6], [13]. Moreover, cured epoxies provide a relatively high mechanical stability, can be transparent and do not shield electromagnetic fields. These properties are a good compromise for implants that require a rigid, mechanically stable encapsulation that also enables the use of wireless data transmission.

This work focusses on epoxy, which has successfully been used to encapsulate electronic implants under in-vivo conditions [3], [16]. Typically, epoxy encapsulations are realized by casting liquid epoxy resin into a mold made of silicone, polytetrafluoroethylene (PTFE) or some other material to which the epoxy does not stick very well so that it can be demolded easily [13], [14]. The fabrication of the molds is a complex process, which often requires CNC machining of the mold itself or a positive pattern from which a negative silicone mold is cast [6]. This makes design iterations very time-consuming and expensive. However, finding a trade-off for the requirements of the encapsulation, which partly oppose each other, often requires several design iterations and the experimental comparison of different design options. To overcome these limitations, a rapid prototyping approach is proposed in this paper, which utilizes additive manufacturing based on an inkjet process for the fabrication of silicone molds. A proof of concept is presented for the example of an electronically instrumented osteosynthesis implant and compared to the conventional mold making process.

Osteosynthesis implants typically consist of titanium or stainless steel and are used in the treatment of fractures to reposition and stabilize the bone fragments [17]. In [18] an electronic osteosynthesis implant was presented, which utilizes a strain gauge to measure the mechanical load acting on the implant to enable a monitoring of the fracture healing and to warn the patients if they overload the implant. The electronics module relies on a wireless inductive link for power supply to the implant and wireless data transmission based on Bluetooth Low Energy (BLE). Moreover, the module is placed on top of the conventional osteosynthesis plate and therefore requires mechanical protection from any forces that could affect and potentially damage it. For these requirements, epoxy is a fitting solution with its mechanical stability and relative transparency to electromagnetic fields.

II. Materials and Methods

For the proof of concept, a simplified version of the electronic osteosynthesis implant presented in [18] is used. The full version of the implantable electronics rely on an inductive power transfer at 125 kHz for supplying the implant and charging integrated super capacitors, which can then be used to autonomously operate the system. The simplified version on the other hand has two wires for conveniently providing the required supply voltage of 1.8 V to 3.3 V from a laboratory power supply or a battery. This simplifies the operation and testing of the implant, because no wireless charging device is required. The components required for wireless power reception are not assembled on the simplified demonstrator. For measurements of mechanical loads, a S1449 1.2 kΩ full-bridge strain gauge (Vishay Precision Group, Malvern, USA) is directly soldered to the printed circuit board (PCB). The wireless data transmission based on BLE operating at 2.4 GHz remains unaffected by any changes. A photo of the simplified demonstrator PCB with the connected wires for voltage supply and the strain gauge is shown in Fig. 1. For the encapsulation process, the strain gauge is folded to the bottom side of the electronics module. The PCB has total dimensions of 20 mm x 11 mm, which are slightly smaller than the ones for the implant version with full functionality.

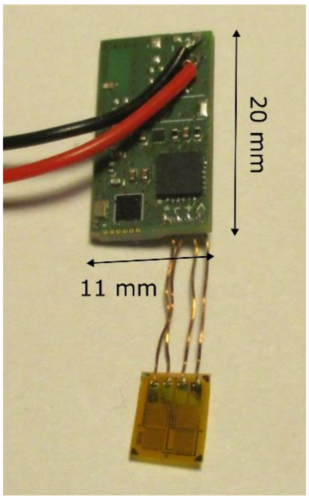

Figure 1: Photo of the electronics module of the osteosynthesis implant with the strain gauge connected at the bottom.

To precisely define the geometry of the encapsulation, a CAD model was designed as shown in Fig. 2. The dimensions of the electronics module were used as a reference to which a thickness of at least 250 µm in each direction was added. This is supposed to leave enough space to be filled by the epoxy during the casting and create thick enough walls to prevent fluids from leaking through the encapsulation. This demonstrator is only used as a proof of concept for the process. Therefore, the dimensions were chosen arbitrarily and are not yet optimized for long term reliability of the encapsulation. The geometry was however, chosen to resemble a shape that was used for electronic osteosynthesis implants before [16]. An important aspect is that there are no sharp edges at the implant, because these can damage muscles and tendons, which lie adjacent to the implant, or cause irritations. Therefore, all edges are rounded and the short edges are additionally chamfered to create a smooth surface along the length of the osteosynthesis implant.

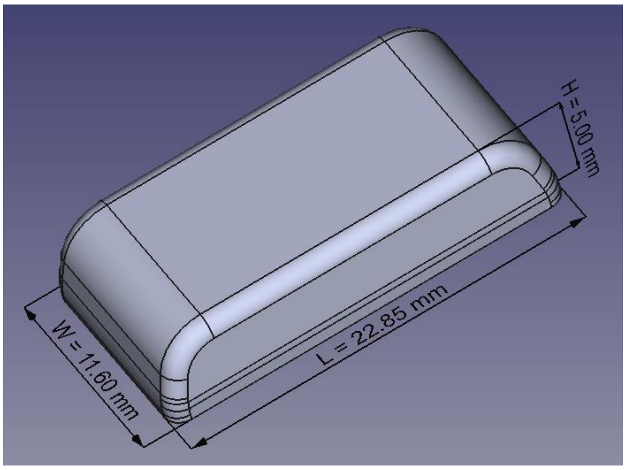

Figure 2: CAD model of the encapsulation including the maximum dimensions.

The CAD model depicted in Fig. 2 was utilized as the foundation for directly manufacturing the molds using the rapid prototyping method.

II.I. Encapsulation Using Molds Made by Silicone Casting

In this subsection, the procedure of making a mold from a CAD model using silicone casting is described. The steps are shown for the example of an older electronic osteosynthesis implant, which has previously been implanted successfully in 39 patients [3], [16].

Even though the functionality differs from the implant introduced in the previous section, their shape is very similar and in the context of mold making there is no significant difference. To create the negative mold, which can later be filled with epoxy, a positive pattern in the shape of the final encapsulation must be manufactured. For the electronic osteosynthesis implant this pattern was CNC machined on a Maho MH500W from an aluminum block, which was then repeatedly sanded to remove the tool marks and create a smooth surface.

The mold that is discussed here includes five cavities to encapsulate up to five implants in parallel. Two channels for inserting epoxy and letting air escape during the casting process are added to each cavity. The processed aluminum pattern for the upper half of the mold is depicted in Fig. 3.

The upper and lower half of the final mold are made by casting ELASTOSIL M4644 A/B silicone (Wacker Chemie AG, Munich, Germany) onto the aluminum pattern. Previously a PTFE block was CNC machined and added to the lower mold to provide a flat surface at the bottom of each electronics module to which the strain gauges can be attached.

The silicone takes about 12 h to cure and is then removed from the aluminum pattern. Fig. 4 shows the final negative silicone mold. To align both parts of the mold, metal pins are added in each corner.

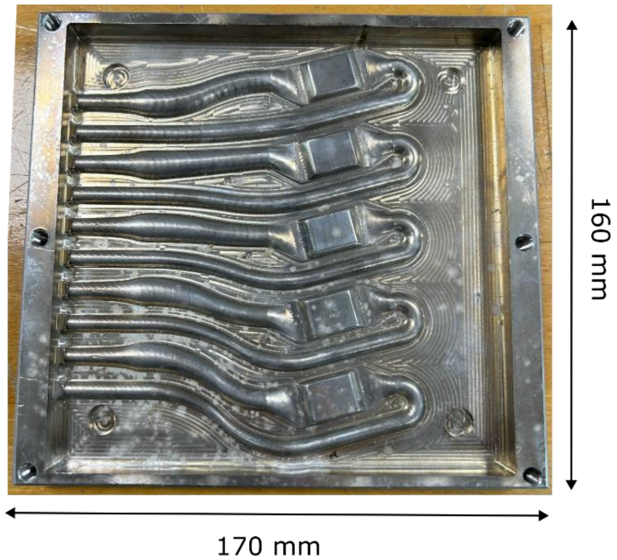

Figure 3: Aluminum pattern used for making the upper half of the mold by casting silicone onto it.

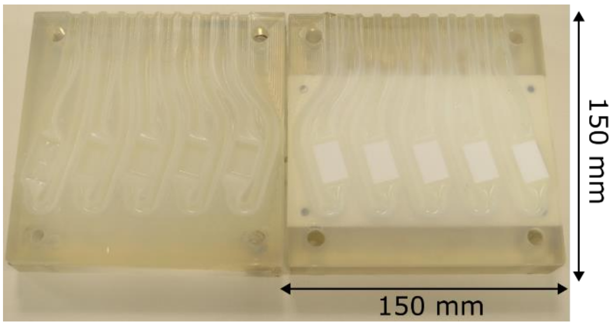

Figure 4: Conventionally manufactured silicone mold for casting up to five electronics encapsulations. On the left, the upper part of the mold is shown, while the lower part can be seen on the right. The lower part includes a white PTFE block. The remaining parts consist of silicone. In the corners, alignment pins are attached.

EPO-TEK MED-301 (Epoxy Technology Inc., Billerica, USA), a medical-grade two-component epoxy, which is also used for pacemakers and cochlear implants [19], was used for casting the encapsulation. As a first step, the strain gauge of the osteosynthesis implant is glued on the PTFE surface using the same epoxy, then the sensor is soldered to the PCB and the whole assembly is covered by both halves of the mold. The EPO-TEK MED-301 is then cast into the closed mold and a vacuum is applied to remove air bubbles, which can get trapped in the mold. The encapsulated implants are demolded after approximately 24 h to give the epoxy enough time to cure. When the silicone mold is used for about ten casting processes, it becomes too stiff for further application because residuals from the epoxy stick to the mold. When that happens, a new silicone mold must be cast from the aluminum pattern.

II.II. Encapsulation Using Additively Manufactured Molds

In this subsection, the rapid prototyping approach for fabricating the molds that is proposed in this work is described. To avoid the time consuming and costly process of CNC machining the pattern and casting the silicone mold, the mold is directly fabricated using additive manufacturing with a silicone-based material. Compared to the conventional method, not only the pattern for the encapsulation, but the complete negative mold has to be designed. Therefore, the CAD model shown in Fig. 5 was created by subtracting the object in Fig. 2 from a slightly larger rectangular cuboid.

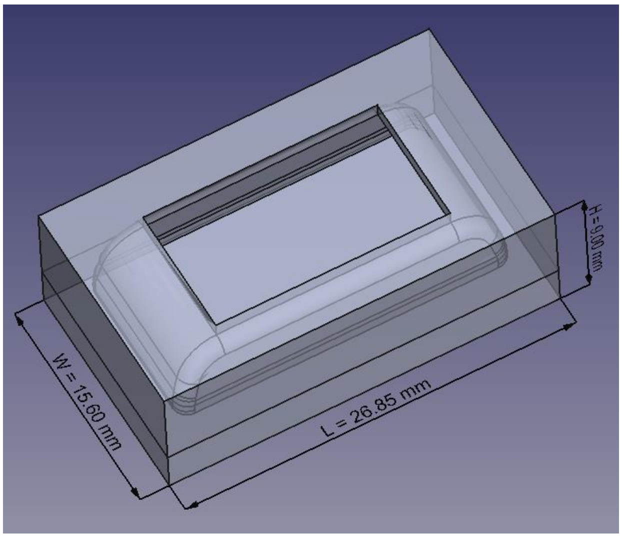

Figure 5: CAD model of the mold for additive manufacturing. The object is depicted transparently so that the geometry inside the mold can be seen.

In the top of the mold, a rectangular opening was left to be able to pour the epoxy into the mold and release the encapsulated electronics module when the epoxy is cured. Moreover, the wires for the supply voltage of the demonstrator fit through this opening. This shows another advantage of the additive manufacturing approach, because it allows to easily create different versions of the encapsulation, which can provide access to test signals for instance. To provide stability to the mold, the sheet under the encapsulation geometry was given a thickness of 3 mm, while the sheet above only has a thickness of 1 mm. The thinner top sheet improves the flexibility of the silicone mold, which helps with releasing the epoxy from the mold when it has cured. The sidewalls have a minimum thickness of 2 mm.

A Keyence AGILISTA-3200W 3D printer (Keyence Corporation, Osaka, Japan) was used for additively manufacturing the molds. The 3D printer uses a high-resolution inkjet process with UV-curable materials. AR-G1L (Keyence Corporation, Osaka, Japan) was used as the flexible printing material. It consists of 65% of silicone, 30-35% of an acrylate monomer, 1-5% of an organophosphorus compound and 1-5% of a phenone compound [20]. In addition, AR-S1 (Keyence Corporation, Osaka, Japan), which is a water-soluble support material, is used inside the cavity and around all walls of the mold. The CAD model was prepared for the printing process using the manufacturers Keyence Modeling Studio software. At a layer height of 30 µm the process for printing five molds in parallel took 1.5 h. Afterwards the support material had to be removed by cleaning the mold in water while using a small brush. Fig. 6 shows the printed mold after cleaning.

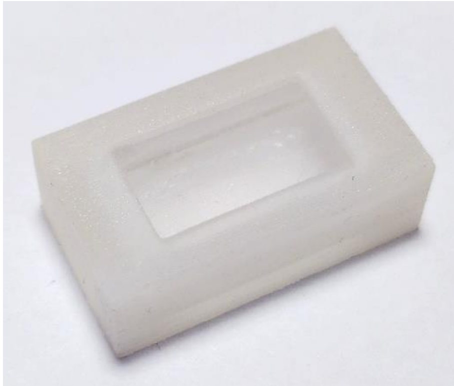

Figure 6: Additively manufactured mold.

As the demonstrator for an electronic osteosynthesis implant that serves as a proof of concept here is not meant to be implanted, a universally applicable epoxy was used for casting the test samples. The E45 (BBI-Trade GmbH, Berlin, Germany), a two-component epoxy was arbitrarily selected, because of its good availability and usability. First, the strain gauge of the PCB shown in Fig. 1 was folded under the PCB. Then a thin layer of epoxy was poured into the mold to cover the bottom surface. The PCB was then carefully pushed through the opening and the mold was filled completely with more epoxy. A lighter was lit closely above the open surface of the epoxy to remove air bubbles. After about 24 h, the encapsulated PCB was demolded by carefully separating the flexible walls of the mold from the cured epoxy.

To demonstrate the flexibility of the rapid prototyping approach and to investigate different design options, a second version of the mold was designed, which consists of two parts as shown in Fig. 7. The alternative design is based on the same geometry of the encapsulation, but has a removable lid, which is additionally held in place by one pin in each corner. This enables demolding the encapsulated electronics module without having to pull it through the small opening so that the handling of the mold is simplified. Compared to the design shown in Fig. 5, it is

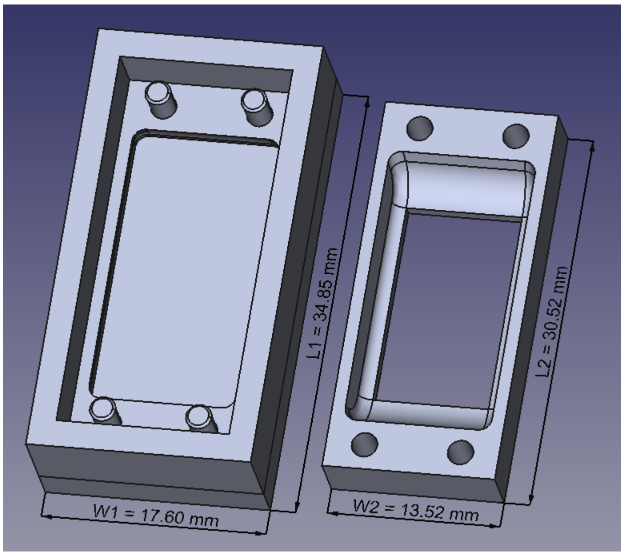

Figure 7: CAD model of an alternative design for the additively manufactured mold, which has a removable lid for easily demolding the encapsulated implant.

easier to clean the 3D-printed mold from support material because there are no overhangs, which cover areas of the mold.

III. Results and discussion

In this section, the results from the two processes of casting epoxy to encapsulate the electronics module of an osteosynthesis implant are presented. The encapsulated electronics modules from the different molds are qualitatively compared to each other. In Fig. 8 and 9 the encapsulated electronics modules for the conventionally silicone cast mold and the additively manufactured mold are shown respectively.

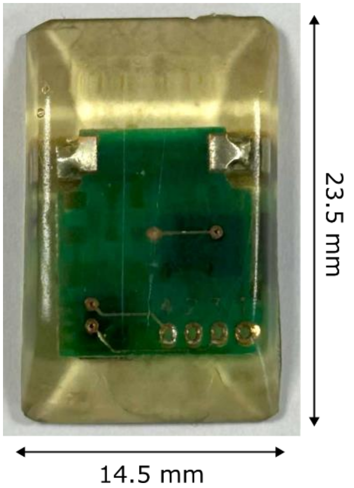

Figure 8: Encapsulation of an electronics module for an osteosynthesis implant made by epoxy casting following the conventional process described in section II.I.

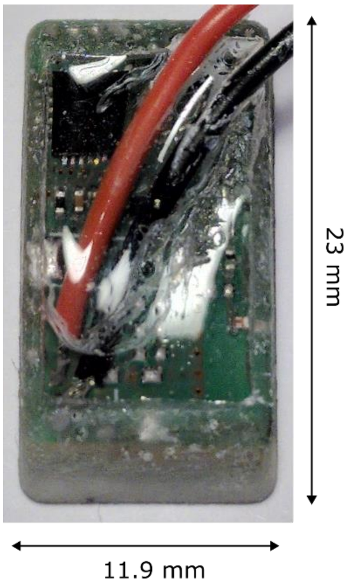

Figure 9: Encapsulation of an electronics module for an osteosynthesis implant made by epoxy casting following the rapid prototyping process described in section II.II. The cables for the supply voltage of the demonstrator are penetrating the top surface of the encapsulation.

Even though their geometry and the layout of the PCBs differ, it can be seen that the shape of the encapsulation is similar. The surface of the conventionally made encapsulation is very smooth, which also makes it easy to see the PCB through the transparent epoxy. While the rapidly prototyped encapsulation has a smooth top surface, on the other surfaces layer lines from the printing process are clearly visible. Moreover, a plateau was formed by the excess epoxy that filled the opening of the mold. To investigate the surface structure more in-depth, a sample was cast without inserting the PCB into the mold. The result is shown in Fig. 10. A detailed view of the clearly visible printing lines at the bottom of the sample is also depicted in Fig. 10.

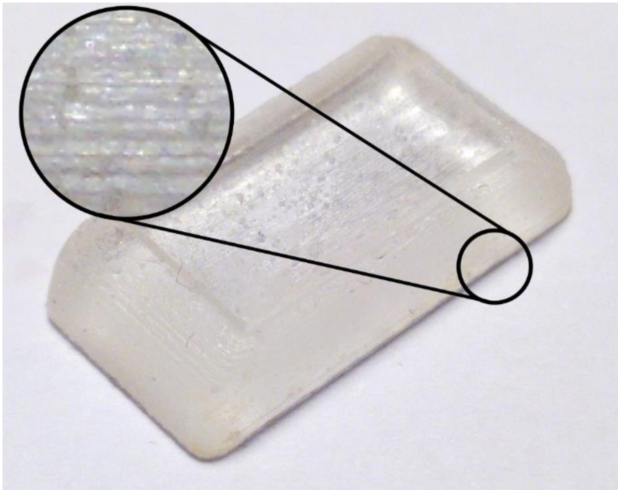

Figure 10: Sample of only epoxy being cast into the rapidly manufactured mold without an inserted PCB. The detail shows the clearly visible printing lines at the bottom surface of the encapsulation.

A comparison between Fig. 8 and 10 demonstrates that the surface quality of the rapidly prototyped encapsulation does not reach the same level of smoothness as the conventionally manufactured one. Nevertheless, the rapidly prototyped encapsulation is still fully covering the PCB of the osteosynthesis implant according to an optical inspection.

To investigate the manufacturing tolerances of the complete rapid prototyping process and the repeatability of the casting with the 3D printed molds, eight test samples were cast using four different molds. The length, width and height of each sample was measured and compared to the dimensions given in Fig. 2. The height was measured directly next to the plateau to avoid differences in the filling height during the epoxy casting to affect the measurements. The results are summarized in Table 1. The mean value and standard deviation across all samples were also calculated.

The results in Table 1 show that the variation of any dimension across the individual samples is relatively low with a maximum standard deviation of less than 100 µm. However, there seem to be systematic deviations between the nominal design values from the CAD model in Fig. 2 and the measured mean values of up to 210 µm in the length. In this specific example, the measured length and width tend to be larger than the design values while the height is lower than expected. With further investigations, it might be possible to compensate for these systematic offsets or reduce them by increasing the wall thickness for instance.

Table 1: Measured dimensions for eight test samples from four molds in comparison to the design parameters

Sample	Mold	Length [mm]	Width [mm]	Height [mm]
1	1	22.98	11.90	4.84
2	1	22.98	11.86	4.89
3	2	22.85	11.76	4.86
4	2	22.90	11.83	4.88
5	3	22.85	11.76	4.80
6	3	22.89	11.84	4.94
7	4	22.81	11.71	4.82
8	4	22.95	11.82	4.84
Mean value		22.90	11.81	4.86
Standard deviation		0.064	0.062	0.044
Nominal value		22.85	11.60	5.00

During the repeated casting of several samples, it was observed that the molds wear out relatively soon. For instance, cracks in the corners of the opening of some molds occurred already after two casting processes. Moreover, small pieces of the thin edges at the opening are sometimes torn from the mold during the demolding step. This indicates that the molds either have to be designed more robustly or have to be replaced at regular intervals.

One of the most important requirements of the encapsulation is to protect the implant electronics from the surrounding medium. To practically evaluate this property for the rapidly manufactured encapsulations, one electronics module was completely immersed in isotonic saline solution (water with 0.9% sodium chloride) after casting epoxy onto it. After three weeks in the isotonic saline solution, the electronics module was still fully functional. This indicates that the encapsulation does not have any leak and that the epoxy has a low enough permeability for water.

Table 2 summarizes the time required for the major steps in the mold making process in comparison between the conventional silicone casting and the proposed rapid prototyping approach. The set-up time of the CNC machine and the cleaning process of the additively manufactured molds partly depend on the experience and skills of the person performing the task, but both processes can probably be optimized to a similar degree. For manufacturing the aluminum pattern, a comparatively old CNC machine was used. On a more advanced machine this time can be reduced. Nevertheless, the comparison clearly shows the time savings in the rapid prototyping approach, which requires only 15% of the time that the conventional silicone casting process needs. The design of the CAD models is neglected here because the required time is highly dependent on the designer. Moreover, some smaller steps like the silicone casting or demolding are also neglected because they do not affect the total time significantly. However, considering them would probably increase the relative time saving of the rapid prototyping approach even more.

Table 2: Summary of the time required for the major mold making steps in comparison between the conventional silicone casting approach and the proposed additive manufacturing method. For a fair comparison, the manufacturing of five molds is considered in both cases.

Silicone-cast mold		Additively manufactured mold	
Set-up time	1 h	3D printing	1.5 h
CNC-machining	4 h	Cleaning	1 h
Silicone curing	12 h		
Total	17 h	Total	2.5 h

Fig. 11 shows the result of casting only epoxy into the alternative version of the additively manufactured mold shown in Fig. 7. The depicted sample is the second one that was made using this mold. It shows that epoxy was leaking into the gap between the lid and the lower part of the mold. This already happened with the first sample, but got worse when the lid was slightly damaged during demolding the first sample. In comparison, the original design for the additively manufactured mold produces better results. However, the demolding is easier with the removable lid and a thicker and more stable lid can most likely reduce the epoxy leaking. This should be investigated in further iterations of the design. Moreover, the thin epoxy brim around the sample can easily be removed in a post-processing step. Implementing the alternative design of the mold took about 30 min for the CAD design and then it was manufactured in parallel with the original design, which shows the versatility of the rapid prototyping approach for mold making.

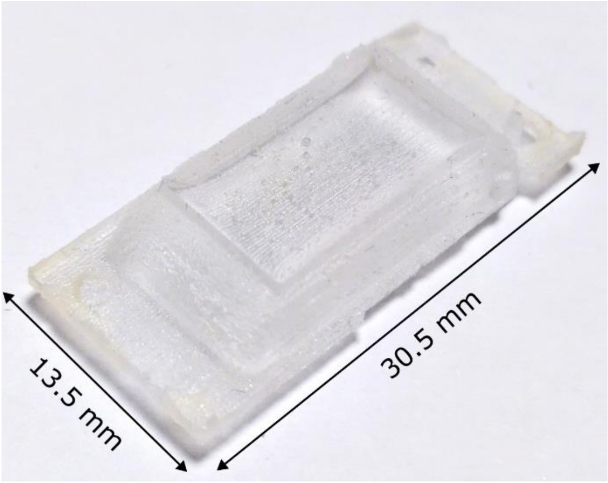

Figure 11: Sample of only epoxy being cast into the alternative version of the additively manufactured mold shown in Fig. 7. The sample was obtained from the second use of the mold and clearly shows that the fit between the lid and the lower part of the mold was not tight enough so that epoxy was leaking into this gap.

In Fig. 12, a complete demonstrator for an electronic osteosynthesis implant is shown. The electronics module was encapsulated by epoxy casting using the original version of the additively manufactured mold described in section II.II. It was then wet-sanded with grit sizes from 240 to 1200, polished and glued to a model of a conventional osteosynthesis plate with epoxy.

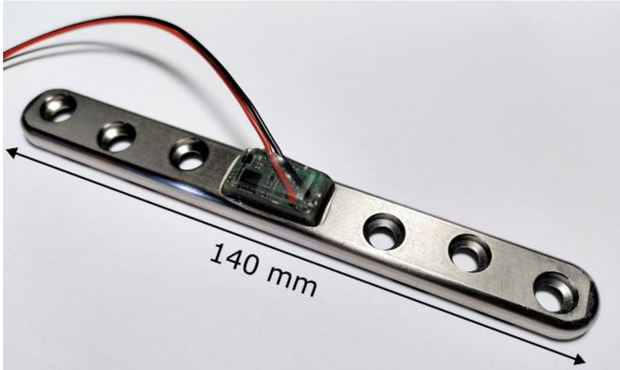

Figure 12: Fully assembled and encapsulated demonstrator for an electronic osteosynthesis implant. A model of an osteosynthesis plate for application at the tibia is shown. The wires connected to the PCB can be used to conveniently provide a supply voltage to the electronics module. The epoxy encapsulation was wet-sanded and polished.

IV. Conclusion

A rapid prototyping approach for making the molds for encapsulating electronic implants with epoxy casting is proposed in this paper. The new method utilizes an inkjet 3D printer with a silicone-based material to additively manufacture the mold directly instead of having to cast it with silicone from an aluminum pattern. An electronic osteosynthesis implant serves as a proof of concept that the rapid prototyping approach can be used to make molds from which fully functional epoxy encapsulations can be cast. The 3D printing approach requires only 15 % of the time that the conventional approach takes, in which a pattern must be machined and a silicone mold has to be cast from it. Moreover, it requires less material.

The rapid prototyping approach does not only save time and material, but it also enables more complex designs, because the 3D printing process, which uses water-soluble support material, offers more degrees of freedom than classical CNC machines. The main advantage is that this process allows to rapidly redesign an encapsulation and directly test it. Moreover, several different variations can be compared practically with minimal additional effort. Additional test ports can also be integrated. For instance, this can be used to conveniently provide a voltage supply to the electronics module as shown in the presented demonstrator, but it can also be used to easily get access to antennas or other radiofrequency components for characterizing them under realistic conditions. All these aspects support designers with the challenging task of finding the optimum trade-off between minimum dimensions of the encapsulation and other requirements like a low permeability for the surrounding medium or mechanical stability.

Even though the surface of the rapidly prototyped encapsulation is not as smooth as with the conventional mold, it is still possible to quickly manufacture fully functional test samples. Since the same material can be used as for the final implant, many properties like mechanical stability, biocompatibility and a low permeability can already be tested in the early prototyping phase. If a smooth surface is required, the samples can also be wet-sanded to get closer to the properties of the final implant.

In future, the design parameters for making the molds should be investigated more systematically to derive recommendations e. g. for the wall thickness. Moreover, it can be experimented with more complex molds consisting of several parts or different casting materials. Support structures for accurately positioning the PCB inside the mold could also improve the process. In the long term, it could be investigated if the encapsulations made from additively manufactured molds can even be used in the final implant. Therefore, effects of the silicone-based material or the printing lines have to be considered with respect to biocompatibility and other properties of the encapsulation. Investigating the biocompatibility of the materials involved in the 3D printing process is especially important for this step as they can be transferred from the mold to the encapsulation. The durability of the additively manufactured molds should also be improved by increasing the wall thickness for instance to avoid replacing them regularly.

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Author's statement

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

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