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Different encapsulation strategies for implanted electronics

Comparison of titanium, ceramic and silicone material for implant body

Abstract: Recent advancements in implant technology include increasing application of electronic systems in the human body. Hermetic encapsulation of electronic components is necessary, specific implant functions and body environments must be considered. Additional functions such as wireless communication systems require specialized technical solutions for the encapsulation.

In this paper 3 different implant strategies based on the material groups silicone, ceramics and titanium alloys are evaluated. With the background of a specific application the requirements for the encapsulation are defined and include the implementation of electrical feedthroughs, wireless communication and wireless energy transfer as well as biomedical specifications such as hermetic sealing, mechanical stability and biocompatibility. The encapsulations are manufactured and qualified experimentally.

Keywords: implant, encapsulation, titanium, silicone, ceramics

https://doi.org/10.1515/cdbme-2017-0153

1 Introduction

A complex hand prosthesis system as outlined in Figure 1 contains extracorporal parts as well as components to be implanted into the human body. Encapsulation is necessary for electronic components such as application specific integrated circuits (ASICS) or capacitive energy buffers.

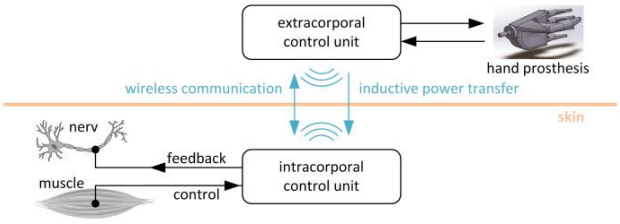

Figure 1: Components of hand prosthesis system

As part of the hand prosthesis system a single housing contains all electronic components. Several specifications such as hermeticity, long-term stability and biocompatibility must be matched. Beside the basic encapsulation function an electrical feedthrough for the connection to the muscles and nerves is required. The encapsulation system must allow for inductive energy transfer and data communication. All specifications are explained in detail in the following chapter.

Three different encapsulation concepts based on three material groups are evaluated experimentally. Each concept holds specific advantages and disadvantages with respect to the specifications und functions of the encapsulation.

2 Requirements and boundary conditions for encapsulation

The implant as part of the hand prostheses system must match medical requirements and provide several technical functions. The implant functions are illustrated in Figure 2.

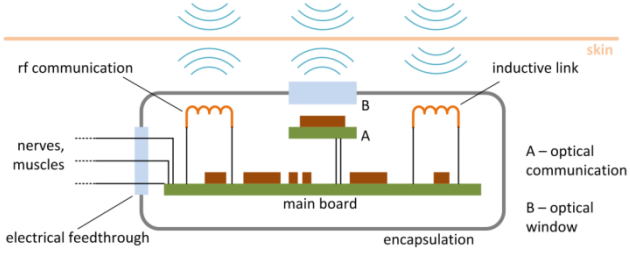

Figure 2: Illustration of implant functions

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The main board controls all functions of the implant. Electrical energy is delivered over an inductive link. For data communication with the extracorporal control unit the implant is equipped with an rf communication link and an infrared-based optical communication link. Although the communication systems are redundant, both options are evaluated. In order to connect the implant with the nerves and muscles an electrical feedthrough with 35 contacts is required.

Depending on the material the encapsulation interacts with the radiation for communication and energy transfer. If the encapsulation material is nontransparent for infrared radiation, the optical communication cannot be used or an additional optical window is required. If a metal housing is used the rf radiation and the electromagnetic field for the inductive link may cause heating of the housing and suppression of the rf signals.

Besides the technical functions the encapsulation must provide for long-term hermetic sealing. All materials with contact to the body environment need to be biocompatible. Because the implant may be located in the arm with low distance to the skin surface, the housing must withstand mechanical forces from the outside of the body.

3 Silicone encapsulation

PDMS is a common material for the non-hermetic encapsulation of implants, especially for the functional evaluation in animal models. Silicone casting is a relatively uncritical process, whereby it is suitable for rapid prototyping. In this work, we used a two-part, low viscosity silicone, which was casted in a mold under vacuum atmosphere and kept in this atmosphere to eliminate entrapped air. To realize a good adhesion between the implant electronics and the PDMS material, the PCB was treated with an adhesion promoter before encapsulation. The good adhesion is important to avoid free space inside the package, in which water vapor can condense to liquid water, which can damage the electronics. The long-term stability of such silicone encapsulations was demonstrated in other studies, where a silicone encapsulated implant circuitry was stable in a primate for over one year [2].

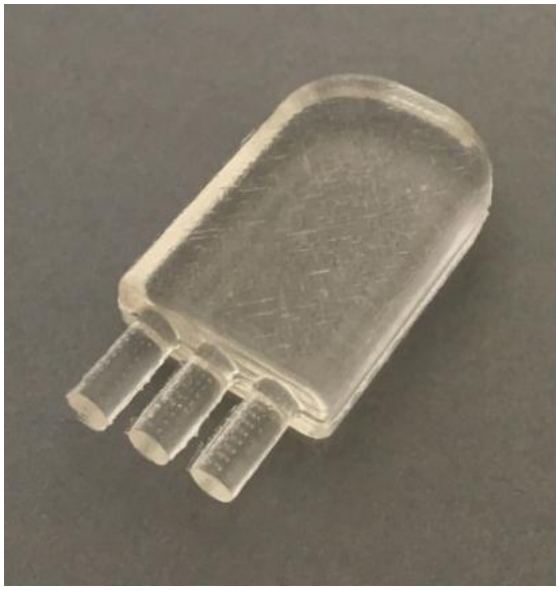


Figure 3: Silicone casting in the form of the final implant (without internal PCB)

4 Ceramic encapsulation

The ceramic material Al2O3 is widely used for medical implants because of its biocompatibility and hermeticity [3]. The package was manufactured in two parts, in which the lower part is a flat ceramic substrate, on which feedthroughs are realized by screen printing. After printing an isolation layer, a second metallization in the shape of the lid is also screen printed, which is the connection part to the cover. The upper part is a top cover whose boundaries lie bear on the metallized frame of the lower part and which also has a metallized area at the border (Figure 4). So both parts can be connected through soft-soldering. Additionally, an epoxy preform inside the housing at the rim of the ceramic lid causes an additional sealing of the housing and prevents the penetration of gases inside the package, which occur during the soft-soldering process (Figure 5). Previous to the closure of the package, all components were placed on a hotplate to remove residual moisture, especially present in the polymeric parts of the electronic components. The sealing takes place on a hotplate in a dry nitrogen atmosphere to avoid high moisture levels inside the package. In addition, the moisture level in the package can be reduced by integration of water getters inside the package, so the lifetime of the implant can be increased.

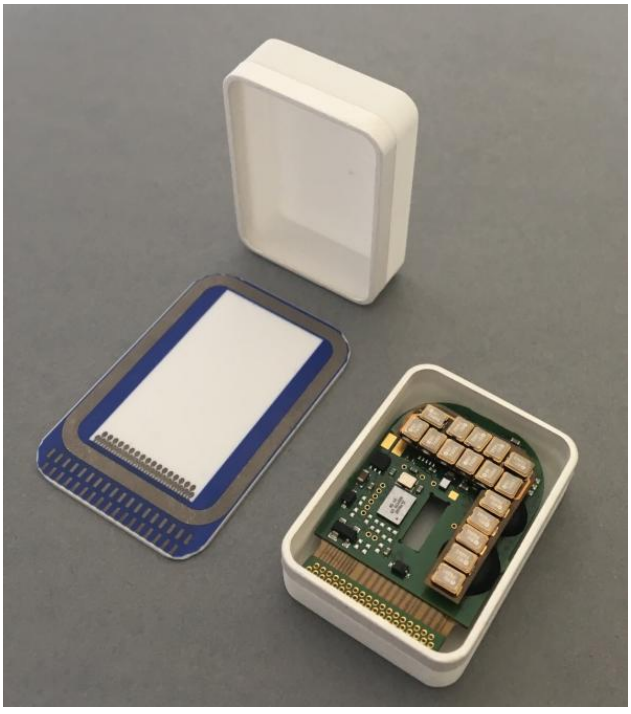


Figure 4: Ceramic implant consisting of a ceramic substrate with feedthroughs and a ceramic cover with internal implant electronics

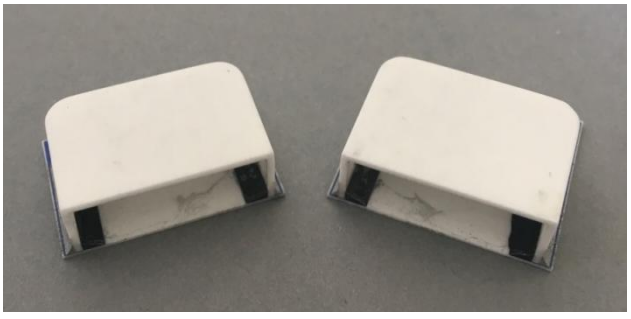


Figure 5: Cross section of a closed ceramic implant to see the internal sealing with molten epoxy

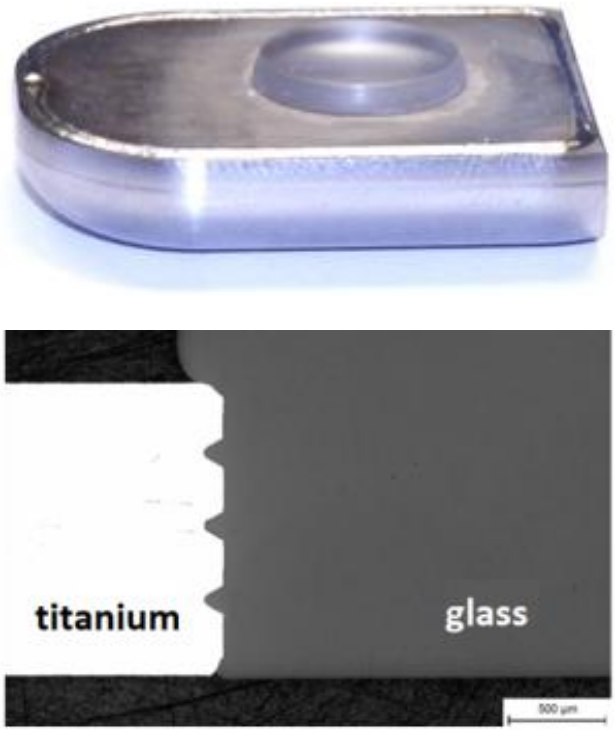
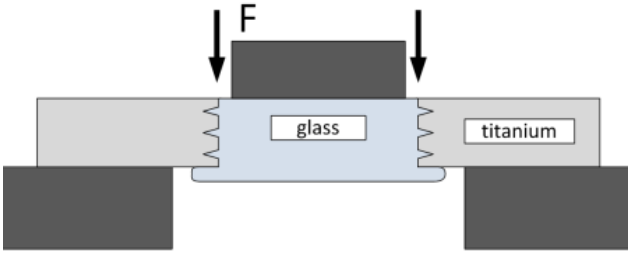


Figure 6: Titanium implant with optical window (top) and SEM image of titanium-glass-interface (bottom)

The optical window provides for infrared communication between the implant and the extracorporal control unit. By passing through the skin and body tissue the infrared signal quality is strongly reduced. Therefore, the transmission through the glass window was tested experimentally resulting in a sufficient transmission coefficient of more than 85%.

The quality of the bond between glass and titanium is crucial for the mechanical stability of the implant. The bond strength was characterized by applying force to the glass window until failure of the bond (Figure 4). In all experiments the window resisted a force of at least 1 kN.



5 Titanium based encapsulation

Titanium and its alloys are widely used for medical implants because of their biocompatibility. The titanium alloy TiAl6V4, also known as Titanium Grade 5, was selected as encapsulation material due to its superior mechanical properties [4, 5]. The housing was manufactured in two parts by precision cutting. For the optical window (Figure 3) the biocompatible glass type N-F2 was chosen. The glass-to-metal seal was produced in a vacuum-based high-temperature glass forming process. After assembly of the electronic components the titanium parts were bonded by laser welding.

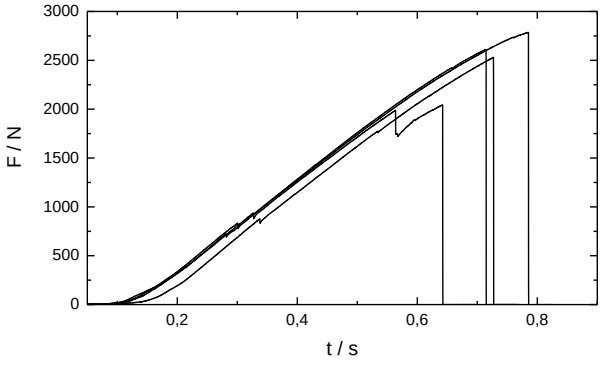


Figure 7: Determination of mechanical stability of optical window: experimental setup (top) and results for 4 glass windows (bottom)

6 Conclusion

In this paper 3 different implant strategies based on the material groups silicone, ceramics and titanium alloys were evaluated with the background of a specific application. The encapsulations were manufactured and qualified experimentally.

Silicone encapsulations allow a rapid prototyping, but they are not hermetic. Because of the good adhesion between substrate and PDMS, it can be used for animal experiments and is found to be stable for over a year. The titanium (TiAl6V4) encapsulation shows very good mechanical stability, but difficulties arise during the realization of feedthroughs from the PCB to the outside. The ceramic (Al2O3) encapsulation doesn't influence the energy and data transmission, but is rather fragile. This could be minimized by an additional silicone coating.

Both hermetic encapsulation methods persist of two parts, so the critical location of the interface exists at both implant housings. Further research and development work concentrates on the elimination of the respective restrictions, in order to realize a demand-oriented encapsulation of the implant.

Acknowledgment: The work was developed as part of the Fraunhofer pilot project Theranostic Implants - Approval-relevant development of key technologies for medicine. We would like to gratefully thank the Fraunhofer-Gesellschaft for its support.

Author's Statement

Research funding: The authors state no funding involved. Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent is not applicable. Ethical approval: The conducted research is not related to either human or animals use

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