34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Hermetic Electronic Packaging of an Implantable Brain-Machine-Interface with Transcutaneous Optical Data Communication

Martin Schuettler, *Member IEEE,* Fabian Kohler, *Student Member IEEE*, Juan S. Ordonez, *Member IEEE*, Thomas Stieglitz*, Senior Member IEEE*

***Abstract* — Future brain-computer-interfaces (BCIs) for severely impaired patients are implanted to electrically contact the brain tissue. Avoiding percutaneous cables requires amplifier and telemetry electronics to be implanted too. We developed a hermetic package that protects the electronic circuitry of a BCI from body moisture while permitting infrared communication through the package wall made from alumina ceramic. The ceramic package is casted in medical grade silicone adhesive, for which we identified MED2-4013 as a promising candidate.**

I. Introduction

Water-induced corrosion is a major hazard for complex electronic circuits that are implanted in the body. Although successful protection of electronics by vapour-permeable polymeric encapsulation is possible over decades of implantation time, sealing the electronic circuitry inside a hermetic package is easier in many cases, since the proof of hermeticity can be carried out by a simple measurement. In contrast, predicting lifetime of a polymer-packaged electronic implant is very complex, if possible at all.

Pacemaker fabricators have very successfully established technologies for hermetically sealing electronic circuits in metallic cans. However, these technologies are limited by the number of electrical contacts protruding through the wall of the can, connecting electronics and electrodes. New implant applications such as retina implants or brain-computer-interfaces (BCIs) require a large number of electrical feedthroughs in the range of some 10s or 100s, requiring the development of a new packaging technology. In the following, we describe our packaging concept of an implantable BCI system, named *BrainCon*, that is capable of electrically recording from multiple electrode contacts as well as electrical stimulation of neural areas. *BrainCon* is electrically powered by a magnetic field that alternates at radio frequency (RF), generated by an extra corporal unit, similar to a cochlear implant system. For data exchange, especially for transmitting the multichannel electro-corticogram (ECoG) through the skin to the extra corporal receiver unit, a high data rate is expected, which would exhaust the capability of modulating the existing inductive link. Instead, an optical data link is used. This paper does not go into details of the electronic circuitry but focuses on aspects of the assembly, hermetic packaging and rubber encapsulation of the implanted part of the *BrainCon* system that aims at assisting patients with locked-in syndrome, spinal cord injury or multiple sclerosis. We presume it will provide sufficient data for controlling a computer by thoughts, allowing the otherwise severely impaired users to communicate with their environment and to control devices such as TV sets, electric wheel chairs and mobile phones.

Manuscript received 27 March 2012.

The authors are with the Lab. for Biomedical Microtechnology, Department. of Microsystems Engineering, Univ. of Freiburg, Germany (schuettler@ieee.org). M. Schuettler and T. Stieglitz are associated to Cortec GmbH, Freiburg. T.Stieglitz is with the Bernstein Center Freiburg.

II. Materials and Methods

A. Investigation of Infrared Transmission

The infrared module used radiates and detects infrared light at wavelengths between 880 and 900 nm, communicating at 4 Mbit/s. It is a DC-powered (3.3 V) discrete electronic component, housed in a polymeric package. In order to protect it from water-induced corrosion once implanted, it is intended to be placed inside the hermetic package made from alumina ceramic, covered with polydimethylsiloxane (PDMS) and optionally with an additional layer of Parylene C. This requires the hermetic package to be sufficiently transparent for infrared light to allow robust communication. Hence the optical transmission of numerous alumina materials and the polymeric coatings were characterized using a Cary 50 Bio UV-visible spectrophotometer (Varian, Palo Alto, CA). In addition, the infrared communication was tested with the different ceramic materials placed between implant and external unit, allowing a distance between the two of at least 20 mm. Functionality or malfunction of the infrared data link was evaluated for each case. Unfortunately, we were not able to investigated transmission bit rate errors as a function of optical attenuation in more detail.

B. Hermetic Packaging

The fundamental concept and fabrication process of the packaging was established earlier in our group [1] and is based on the work by Donaldson [2]. It consists of two screen-printed alumina substrates that form a base and a lid. Additionally, we use a frame-shaped copper ribbon as a housing wall (see Fig. 1). Onto the base substrate, a fully assembled electronic printed circuit board (PCB, FR4-technology) is glued. Electrical connections between the PCB and the base are established using thermosonic gold wire bonding. The copper frame is soldered (Sn96Ag4 alloy) to the base and the lid is placed on top. Now the lid is

soldered to the copper frame, leaving out a 1 mm diameter puncture. The device is then transferred into a dedicated drying, helium-backfilling, and solder-sealing apparatus named *HERPES*, described elsewhere [3], in which the puncture is soldered shut, establishing a hermetic seal. Subsequently, potential gross leaks are visually detected by immersing the package in tap water inside a vacuum chamber (100 mbar absolute pressure). Leaking of helium at rates of 10^{-5} mbar·l/s or higher leads to visible bubble formation. After passing the gross leak test, fine leak tests using a mass-spectrometer based leakage tester (SmartTest HLT570, Pfeiffer Vacuum, Asslar, Germany) are carried out for characterisation of hermeticity and for allowing lifetime estimations based on mathematical models.

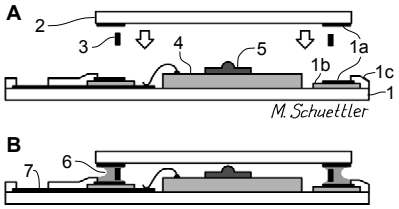

Fig. 1: Hermetic packaging concept of *BrainCon* implant before (A) and after (B) hermetic sealing. A base substrate (1) carries screen printed metal (1a) and insulation (1b) layers, which are partly covered by a glass layer (1c). A PCB (4), with electronic components (5) mounted on it is glued to the base substrate and connected to printed tracks by wire bonding. After assembly of the PCB, a screen printed lid substrate (2), is lowered to the base, using a 2.5 mm high copper frame (3) as spacer. For hermetic sealing, base, frame, and lid are joined by soldering (6). Electrode and RF coil wires are soldered to contact pads (7) on the base substrate.

C. Silicone Rubber Casting

The base substrate of the hermetic package contains 29 electrical feedthroughs, used for joining a radio-frequency (RF) receiver coil as well as for connecting the individual wires of the brain electrode array. For the purpose of electrical insulation of the individual contacts as well as for protecting the packaging materials from the harsh body environment, the entire assembly is casted in PDMS. Donaldson pointed out that a major requirement of a PDMS (silicone rubber) encapsulation for implant electronics is a hydrothermally stable adhesion to all encapsulated surfaces [4]. His favourite silicone was the one-part electronic casting compound DC3140 by Dow Corning. This material proved extremely reliable in many implants he built but comes with three disadvantages: 1.) As a one-part condensation cure rubber, it cannot be casted in a closed mould since it requires humidity to cure and while it cures it undergoes shrinking. 2.) Curing time cannot be accelerated and might take up to one week or more. 3.) DC3140 is not available in medical grade. Hence, we screened some medical grade adhesives supplied by NuSil (Carpinteria, CA, USA) with regard to the hydrothermal stability of their adhesion to badly adherent polymeric surfaces. It was identified earlier (unpublished) that from all present surfaces to be rubber casted (alumina, metal oxide, glass, polymer-insulation of wires), the weakest bond was established to polymers. Hence the adhesion of the rubbers to two potential polymeric wire insulators was investigated: Fluorinated ethylene propylene (FEP) and polyurethane (PU). As test specimens, stainless steel litz wire with FEP jacket ($\varnothing = 0.28$ mm) and PU-insulated copper wire ($\varnothing = 0.5$ mm) were used. The adhesion tests were prepared by pushing test specimens to a length of 10 mm in uncured silicone and then allowed it to cure according to the manufacturer's recommendations. A second batch of samples received a one minute plasma treatment before being rubber casted. The plasma parameters were chosen to be similar to those suggested in [5]: 300 W RF power, 50 sccm oxygen flow, 0.7 mbar chamber pressure, using a 13.56 MHz plasma reactor (model Nano UHP-RF–PC by Diener Electronic, Nagold, Germany). Four types of silicone adhesives were used: The technical silicone DC3140 (as reference) and the three medical grade silicones by NuSil: MED-1000 (low viscosity), MED-1037 (former Type-A, very common medical adhesive), and MED2-4013 (2-part adhesive). A quick overview of selected features of theses silicones is provided in Tab. 1. After curing, the samples were stored for 21 days in 60°C saline solution (0.9% NaCl). The final test consisted of pulling the wire out of the silicone bulk at 25 mm/min while measuring the required force using a pull tester (model BZ2.5/TN1S by Zwick, Ulm, Germany). The maximum pull force was identified and the arithmetic average of 8 identical samples of each material and pre-treatment combination was calculated.

Tab. 1: Overview of silicones investigated for package casting/moulding.

type	components	cure system	by-product	mould
DC3140	one	condensation	alcohol	open
MED-1000	one	condensation	acetic acid	open
MED-1037	one	condensation	acetic acid	open
MED2-4013	two	addition	none	closed

Two moulds were built, one open mould, suitable for casting of condensation cure silicone and one closed mould, allowing injection moulding of two-part addition cure silicones. The packaged and assembled implants were placed in the moulds and the rubber was casted and injected, respectively. MED-1000 was used as representative of acetoxy one-part medical grade silicone rubber instead of MED-1037 for two reasons: 1.) It is less viscous and hence is believed to cover the surfaces to be encapsulated better, and 2.) it is the identical material the electrode array is fabricated from, hence keeping the bill of materials used for implant production low. As control, DC3140 was used. Once filled in the mould, vacuum centrifugation (acceleration: ca. 100 G, 100 mbar absolute pressure, 45 min) was used to drive bubbles out of the silicone [6]. The two-part rubber was cured in an oven at 120°C for 30 minutes. The one-part rubbers were cured by placing the moulds at ambient temperature in a pressure chamber at 2 bar overpressure for one week, ensuring a humid air flow into the chamber while allowing cure by-products to leave the chamber via a bleeding valve. The relative humidity inside the chamber was adjusted to be around 60%. Pressurisation was used to avoid bubble formation during

the curing process [7]. Once curing was completed, the casted implants were removed from the moulds for visual inspection.

RESULTS

A. Infrared Transmission

The two polymers under test were found to be transparent to infrared light, allowing the transmission of 87.5% or more at layer thicknesses typical to our packaging concept. From all ceramic materials, sapphire is the most transparent, allowing to pass more than 40% of the light. The less crystalline High Temperature Co-Fired Ceramics (HTCC) supplied by ESL Europe (Reading, UK) as well as the Rubalit material (type 708S: 96% Al_2O_3; type 710: 99% Al_2O_3) supplied by CeramTec (Plochingen, Germany) showed low transmission rates between 1.5% and 2.45%. As last sample we found the transmission rate of a custom-made alumina lid of 2 mm thickness to be only 0.95%. This last sample was investigated as the only ceramic material under test that withstood a mechanical impact test as suggested in by the European Standard EN 45502-2-3 without breakage. Fig. 2 provides an overview of the relative optical transmission of all materials under test, including their thickness and their transmission rate at 890 nm.

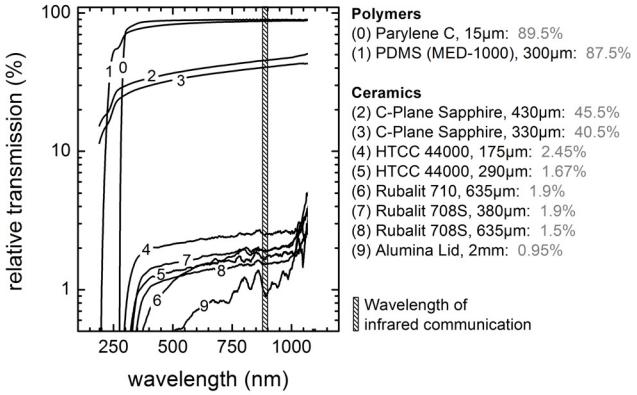

Fig. 2: Relative optical transmission of implant packaging materials. The percentage values in the legend refer to the relative transmission at the wavelength of infrared communication of the *BrainCon* system. Note: The two sapphire samples are products of two different suppliers which might explain why despite its layer thickness sample (2) has a higher transmission than sample (3).

Despite low transmission rates, the optical data link was functioning reliably with any of the aforementioned materials placed between two infrared modules. As a negative control, a piece of infrared opaque 535 µm thin silicon wafer (rel. transmission: 0.0%) was placed in the beam, causing the communication to break down.

B. Hermetic Packaging

Hermetic packaging using the *HERPES* apparatus lead to no detectable gross leak (Helium leakage rate below 10^{-5} mbar·l/s). Fine leak tests, however, revealed a leakage rate of 10^{-8} mbar·l/s. Fig. 3 shows a package before and after solder sealing.

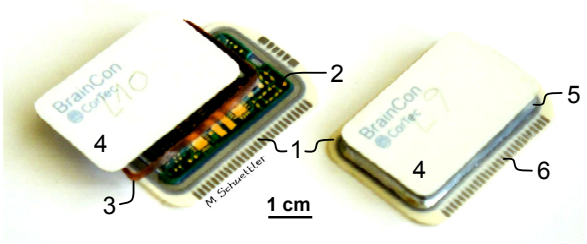

Fig. 3: Photograph of implant package before (left) and after (right) solder sealing. 1: Base substrate, 2: PCB, 3: copper frame, 4: lid substrate, 5: solder seal, 6: contact pads for electrode wires.

C. Silicone Rubber Casting

The pull tests of hydrothermally aged adhesive bond between different rubbers and PU / FEP clearly showed that of all rubbers, the two part MED2-4013 adheres best after 21 days. In case of adhesion to PU, the bond could not be broken. Instead, the 0.5 mm diameter copper wire broke at pull forces around 50 N. In general, the applied plasma pre-treatment did improve the adhesion slightly. An overview of the experimental results is given in Fig. 4 and Fig. 5, respectively. All rubbers adhered better to PU than to FEP, even when taking into consideration that the PU surface area was about double of the surface area of the FEP samples, due to different wire diameters.

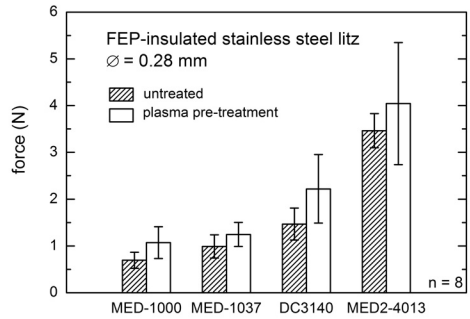

Fig. 4: Adhesion forces of different types of silicone adhesives to FEP. The error bars indicate max and min values

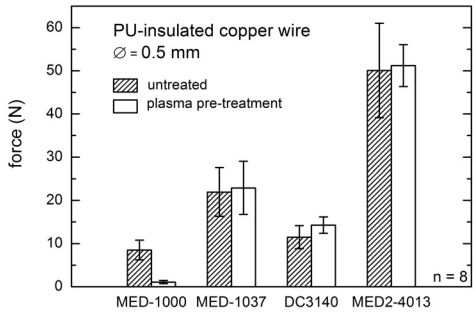

Fig. 5: Adhesion forces of different types of silicone adhesives to PU. The error bars indicate max and min values

Encapsulation of the package in MED2-4013 using a closed injection mould permitted comparably fast curing. Furthermore, the result was well defined in all geometrical dimensions by the mould. In contrast, the implants casted in open moulds showed variation of encapsulation thickness, dependent on the amount of silicone poured in the mould.

Also, the thicker the silicone layer, e.g. 5 mm inside the centre of the RF coil, vs. 0.5 mm on top of the ceramic package, the more pronounced was the effect of volume shrinkage during curing, leading e.g. to an indent in the centre of the coil. Vacuum centrifugation and pressure curing lead to (visually) void-free potting of all samples.

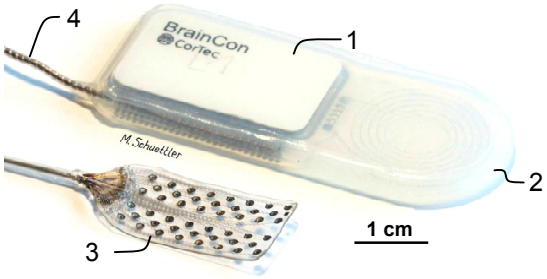

Fig. 6: Photograph of the assembled and PDMS encapsulated *BrainCon* implant prototype. The hermetic package (1) and the RF coil (2) are embedded in PDMS. The cortical electrode array (3) is connected to the hermetic package by a cable (4).

III. Discussion

Despite the bad infrared transmission performance of alumina, all materials under test permitted robust data communication during bench testing. Once implanted, additional layers of infrared absorbing tissue have to be bridged, further challenging the transmitter. Currently, 0.635 mm Rubalit 708S substrates are used since this is the material for which the firing procedure of the screen printing pastes is optimized. Future developments might consider the application of sapphire.

Using MED2-4013 instead of the established and very thoroughly investigated DC3140 proved to be easy and fast with respect to fabrication of the encapsulation. However, the reliability remains to be proven, e.g. in long-term measurements of hydrothermal stability to all materials involved, e.g. alumina, glass, solder, MP35N wire. Plasma-pre-treatment of these materials might not be necessary but will be investigated, too. The medical grade silicones investigated here are all of the type 'restricted to short-term implantation'. However, chemically identical (but more costly) versions are supplied by NuSil, suitable for chronic implantation.

The unsatisfactory hermeticity of the packages is currently under investigation and was rather surprising to the authors, since applying the identical fabrication process and materials resulted in excellent hermeticity below the detection limit (10^{-12} mbar·l/s) of our leakage tester in earlier sample fabrication [1]. Applying common mathematical models and presuming to enclose no humidity inside the package at the moment of sealing [8], it will take about one year and 9 months to reach a critical relative humidity of 5 000 ppm H_2O inside the package and about six years until 17 000 ppm are reached, which provides sufficient moisture for ongoing corrosive reactions [8] with potential catastrophic effect. This time period is considerably extended by the use of desiccants inside the package. Currently, the packages are suitable for animal experiments lasting for about one year. However, the final implant is intended to provide sufficient hermeticity to work within the human body for many decades. As electronic safety measure, the humidity inside the implant package is constantly monitored (already part of the implant circuitry), allowing the replacement the implant before critical levels of humidity are reached and potential hazardous conditions can occur.

The current *BrainCon* implant is intended to be chronically implanted subcutaneously in the area of the back of sheep. Preliminary acute sheep trials showed that powering and communication works well once implanted, covered by about 10 -15 mm tissue. In humans it will most likely be implanted behind the ear, requiring shrinking of the physical dimensions from today 5 mm thickness and an area of 34 mm x 78 mm to about 2/3 of the area, allowing to research BCI paradigms currently under investigation based on extra corporal recordings, e.g. [9].

IV. Conclusion

We developed a functional hermetic package for protecting the electronic circuitry of an implantable brain-computer-interface that is powered inductively and communicates via an optical infrared data link through the package wall.

V. Acknowledgements

The authors wish to thank German Federal Ministry for Education and Research for supporting our work within the research grand *BrainCon* (identifier 0316064C). Further acknowledgments go to Mrs Christina Hassler for measurement of the adhesion forces of silicone adhesives and Mrs Nora Haas for designing the silicone moulds.

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