A Polymer-Metal Two Step Sealing Concept for Hermetic Neural Implant Packages

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Abstract— **In this paper, we introduce a technique for double-sealed ceramic packages for the long-term protection of implanted electronics against body fluids. A sequential sealing procedure consisting of a first step, during which the package is sealed with epoxy, protecting the implant electronics from aggressive flux fumes. These result from the application of the actual moisture barrier which is a metal seal applied in a second step by soft soldering. Epoxy sealing is carried out in helium atmosphere for later fine leak testing. The solder seal is applied on the laboratory bench. After the first sealing step, a satisfactory barrier for moisture is already achieved with values for helium leakage of usually $L_{He} = 6 \cdot 10^{-8}$ mbar l s^{-1}. After solder sealing, a very low leakage rate of $L_{He} \leq 1 \cdot 10^{-12}$ mbar l s^{-1} was found, which was the lower detection limit of the measurement setup, suggesting excellent hermeticity and hence moisture barrier. Presuming an implant package volume of V ≥ 0.5 cm³, the time to reach a critical humidity of p = 5000 ppm $_{H2O}$ inside the package will be longer than any anticipated average life of human patients.**

I. Introduction

In the development of active medical implantable devices (AIMDs), intended to stay functional within the human body for many years, three packaging aspects are of outstanding importance. First, to design a package which has the fundamental capability to withstand the hazardous surrounding of body fluids, disallowing moisture ingress into the implant. Second, a robust process to properly seal the designed package and last, a method to evaluate the quality of the seal and linked to that a prediction of the implant lifetime. There is a general consensus for packaging engineers that this can only be achieved by a hermetic housing. A guideline for hermeticity and testing of the same is given by military standards MIL-STD-883 (method 1014.13) and MIL-STD-750 (method 1071). However, limits stated within these are often not sufficient for implant lifetimes in the range of decades, this is especially true for small internal volumes [1]. But not only size matters. Even if the package is large enough, the mixture of materials and their different behavior in leakage tests might influence the result and hence lifetime predictability.

Manuscript received April 7, 2014. Work is funded by the German Federal Ministry for Education and Research, BrainCon project (research grant identifier 0316064C). It is also part of the research supported by the BrainLinks-BrainTools Cluster of Excellence (DFG grant no. EXC 1086).
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II. Materials & Methods

To advance our implantable brain-computer interface (BCI), first presented in 2012 [2], we modified the existing housing concept aiming for a miniaturized package and improved hermeticity. Sealing of the former three-part package, consisting of ceramic lid and base with a metal ribbon in between was done by manual soft soldering. Followed by helium-backfilling with a specially developed sealing apparatus [3] which allowed precise closing of a puncture in the frame in inert helium atmosphere.
The new package introduced in this paper was reduced to a two-part assembly, hoping to minimize possible leakage paths. It consisted of a ceramic base substrate, providing electrical feedthroughs and therefore hosting several functional screen-printed layers, and additionally a pre-shaped ceramic lid. The concept for sealing had to be modified as well. Since a hole in parts made of ceramic had to be avoided, predominantly in order not to compromise mechanical stability, a new sealing procedure together with functional tools had to be developed. Moreover, the implementation of a protective barrier for hazardous flux contaminants and fumes from the soldering process was desired [4].

A. Sealing Concept Comparison

The sealing process as it was performed in former implant studies as well as its modification for our first BCI generation is described elsewhere in detail [2, 5]. However for an illustrative description and for better contextual understanding the former process is depicted alongside to the new one (Fig. 1). Initially, a circle (Ø = 30mm) was laser-scribed into a 0.635 mm thick Al_2O_3 ceramic substrate (Rubalit 708 S, CeramTec, Marktredwitz, Germany) as perimeter of the later package base. Screen-printing was utilized to add conductive tracks and pads, isolation layers and a solderable frame. A glassy protection was finally screen-printed for two reasons, additional covering of possible leakage paths and to serve as an improved adhesive layer for intended silicone rubber over-molding of the whole package. A printed circuit board (PCB) populated with discrete electronic components was glued to the center of the ceramic disk which was fractionized from the substrate beforehand. Electrical connection between PCB and screen-printed tracks on the ceramic was provided by ball-wedge wire bonding utilizing 25 µm gold wire. Such populated base substrates (Fig.1 - top), together with a ceramic lid (ID = 19 mm) which possessed pre-metallized AgPt sidewalls were transferred to a glovebox (SG1200/750TS, Vigor Tech. Co.

Ltd., Houston, USA), which provided a controlled dry atmosphere of 100% helium gas (p_{rel} = *5-10 mbar*). Lid and base were both placed on a hotplate within the glovebox and dried at 110°C for at least 12 h to remove residual moisture (Fig. 1 - 2a)), especially present in polymeric parts of the electronic components. The evaporating humidity could be monitored with the control unit of the glovebox.

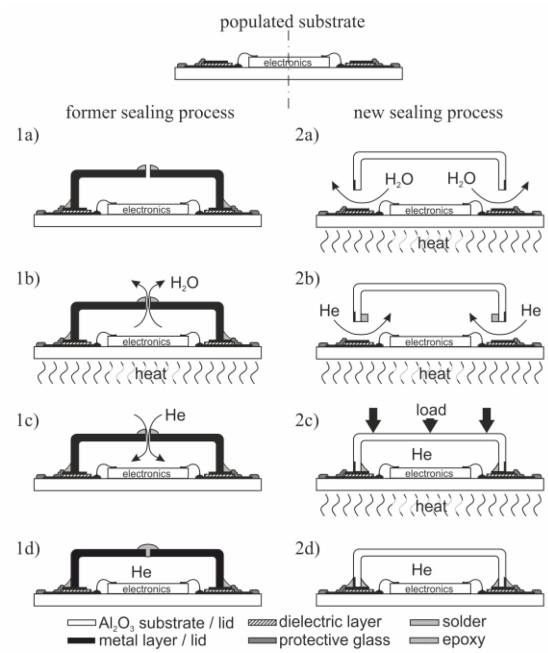

Figure 1: Comparison of the former sealing process steps 1a - d), as developed in [3] and the new procedure, implementing steps 2a - d).

After drying, the lid was removed from the hotplate. Once cooled down, two preform-rings (OD = 19 mm, ID = 16 mm, height 1 mm each) made from flexible epoxy adhesive F08 (Multi-Seals Inc., Manchester, USA) were stacked at the lower rim of the ceramic lid (Fig. 1 - 2b)). The lid was centrically placed on the base substrate and loaded with a 5 kg weight. Simultaneously, the hotplate was set to 130°C for at least one hour to ensure proper melting (T_m = *96°C*) and curing of the epoxy (Fig. 1 - 2c)). The epoxy-sealed packages were passed through the glovebox' lock to be eventually sealed by means of manual soft-soldering (Sn60Pb38Ag2, T_m = *183°C, F-SW34, solder iron at 350°C, hotplate at 120°C*), the outer metallization of the lid to the screen-printed frame on the base (Fig. 1 - 2d)).

B. Alignment Tool for Pre-sealing

To facilitate handling of the drying procedure and especially to accurately center the ceramic lid to the base substrate during the epoxy-sealing step, a compact alignment tool (bottom footprint: 20 x 7 cm²) to be operated in a standard laboratory glovebox was developed (Fig. 2).
The apparatus possessed a hotplate (60 x 46 mm²) with a cavity which accommodated the ceramic base substrate throughout the whole sealing procedure. The hotplate was heated by a 33 W heating element and offers closed-loop temperature control, utilizing a PT100 sensor element. For placement of the epoxy preforms (compare Fig. 1 - 2b)), the ceramic lid was mounted in an adjustable clamp on the apparatus' alignment lever (compare Fig. 2). The lid was automatically held in place by a metal spring (0.23 N/mm) attached to the clamp. Turning the lever down towards the hotplate enabled a concentric alignment of lid and base. The flattened back of the lever was suitable for placing additional weights if necessary, leading to an increased force that pushes the cap to the base during sealing, ensuring a minimal gap size between cap and base.

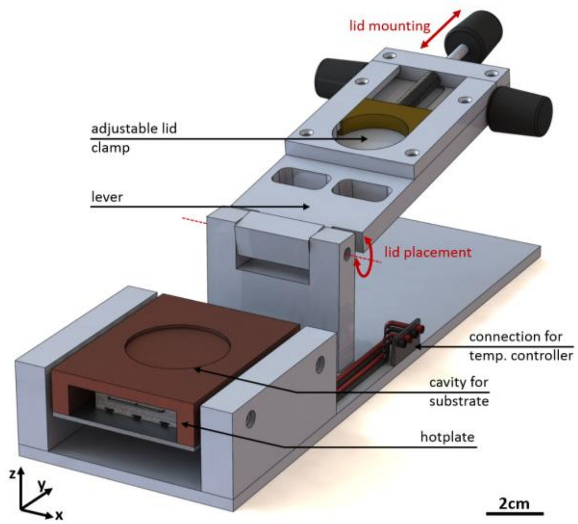

Figure 2: CAD Drawing of the alignment tool for precise centering of lid and base and subsequent epoxy curing with an integrated hotplate.

C. Process Analysis

The sealing procedure with the alignment apparatus was characterized by mounting a thermocouple (type K) on base and lid, respectively. A typical process was executed to determine possible temperature delays for each package component. The temperature was recorded with a thermo logger Voltcraft K202 (Conrad Electronic, Hirschau, Germany) at a sampling rate of 0.5 Hz. For illustrative reasons the duration of the drying period was reduced from 12 h to one hour in the exemplary process presented in the results section.

D. Package Hermeticity & Helium Adsorption

The hermeticity of orderly fabricated packages was measured by means of gross and fine leak testing according to MIL-STD-883. Three test packages solely sealed with F08 epoxy from the inside were tested for gross leaks, i.e. visual bubble formation after submersion in a water bath under vacuum (p_{abs} = *200 mbar*). Successfully tested packages were transferred to a fine leak tester (SmartTest HT570, Pfeiffer Vacuum Technologies, Asslar, Germany) to record the actual helium leak rate L_{He}. After that, the packages received their final sealing by manual soft-soldering, followed by another cleaning step and re-testing in the HT570.
Helium is quickly (seconds to minutes) adsorbed in all porous and polymeric materials even at low pressure [6]. It was thus mandatory to evaluate this effect to avoid false leak rate detection, i.e. virtual leaks resulting from helium desorption of materials utilized for the package. Several

samples were prepared and exposed to the glovebox' helium atmosphere for 30 min. Samples under test were pre-tinned solder frames (SnPbAg), protective glass printed on Al_2O_3 substrates and loose F08 epoxy rings. The samples were tested for their virtual leak rate in the fine leak tester. Measurements were repeated hourly until the detection limit (L_{He}.= 10^{-12} mbar l s^{-1}) was reached.

E. *Characterizing the Seal*

The quality of the seal and practicality of the process were evaluated by three measures: visual inspection of the seal in a polished cross-section, hermeticity testing and surveillance of moisture ingress into the packages.

For visual inspection a package without electronic components was fabricated according to the standard procedure. The package was cleaned, implying removal of solder fluxes and grease by brushing the surfaces with de-flux (Servisol 160, CRC Ind., Somerset, UK), followed by an isopropanol and subsequent deionized water rinse. After drying (*T = 80°C, 1 h*), the package was embedded in acrylic resin (DuroCit, Struers GmbH, Willich, Germany), which was cured for one hour and cut in half using a diamond blade buzz saw. The two cross-sections were grinded and polished to reduce visual scratches. It is well known, that most polymers, including epoxies, form a poor moisture barrier and are hence unsuitable as hermetic sealing [7]. However it was interesting to know how fast humidity rose in solely epoxy-sealed packages in ambient atmosphere to determine the time-frame until a proper metal sealing had to be applied. For that purpose, combined humidity and temperature sensors (SHT15 by Sensirion, Steafa, Switzerland) together with a 100 nF buffer capacitor were placed in test packages, which were afterwards epoxy-sealed according to part A of this paper. Six packages were fabricated in total and two of each stored in differently tempered water baths (room temperature, 37°C and 60°C) to investigate an accelerated aging effect on the seal. To monitor the moisture development within the packages, they were periodically taken out of their baths, cooled-down and humidity was measured.

III. Results

A. *Process Analysis*

The drying phase (Fig. 3 - 1) progressed without notable fluctuations besides the ± 1 K oscillations of the temperature controller.

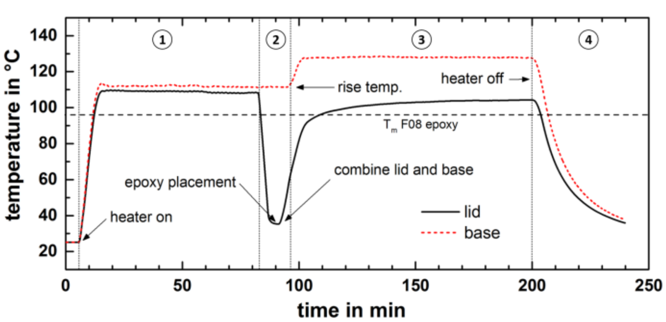

Figure 3: Typical temperature profiles recorded separately for lid and base using the sealing tool shown in Fig. 2.

The temperature for the base was slightly higher compared to the lid since it was embedded in the cavity ensuring optimized heat transfer. The lid in turn was placed next to the base substrate on the hotplate, upper side facing towards the heater. Removing the lid from the hotplate and placing it in the clamp caused it to cool down rapidly (Fig. 3 - 2), hence epoxy placement was easily manageable without premature melting. The peak temperature for the lid in the subsequent melting phase (Fig. 3 - 3) was 20 - 30°C lower compared to the base, which must be attributable to the thermocouple position on top of the lid plus an additional cooling effect of the bulk material of the alignment lever. After the heater was switched off, both temperatures declined as expected.

B. *Package Hermeticity & Helium Adsorption*

The hermeticity for epoxy-sealed packages reached their first limit after two hours at L_{He} ~ $6 \cdot 10^{-8}$ mbar l s^{-1} (Fig. 4). The measurement of virtual leaks between 10^{-5} mbar l s^{-1} and 10^{-7} mbar l s^{-1} was likely within the first hour after exiting the samples from the glovebox, especially due to helium desorption of the epoxy. Later, the epoxy helium desorption was lower compared to the package leak. When the packages were eventually solder-sealed the leak rate dropped below the detection limit of the leakage tester.

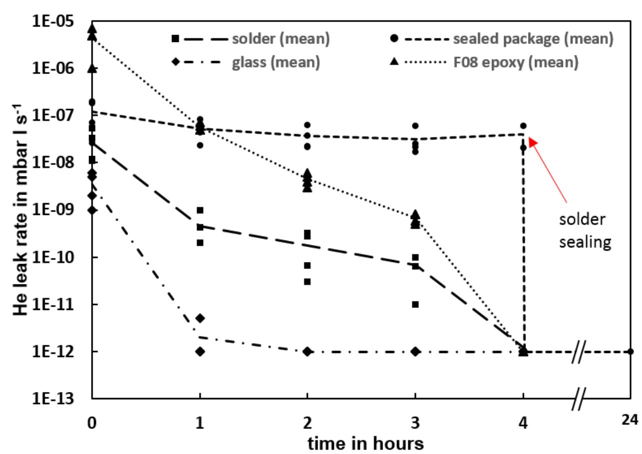

Figure 4: Helium outgassing for different materials utilized for the double-seal packaging process.

Helium desorption in solder and screen-printed glass were negligible, since their virtual leaks developed below the actual leak rate of the package almost from the start. This effect was not surprising since, both materials possessed almost no porosity. The virtual leak of the ceramic substrate was almost identical to the progression of glass. It was not plotted in Fig. 4 due to avoid too much overlapping.

C. *Characterizing the Seal*

Visually inspecting the cross-sectional view of the seal showed a proper sealing of both interfaces, out- and inside the package (Fig. 5). Wetting of the outer metallization with solder (Fig. 5 - a)) and of the inner ceramic wall to the F08 epoxy (Fig. 5 - b)), respectively, was homogeneous, forming evenly shaped menisci. The contact angle to wall and base substrate was always smaller than 90° for solder and epoxy.

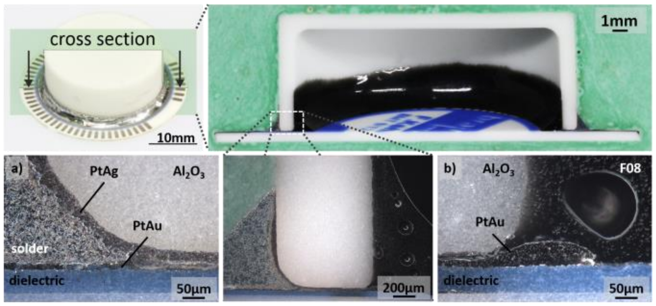

Figure 5: Full-view (top left) and polished cross-section (top right) of a double-sealed package (without electronics). Different magnifications depict details - a) outer solder seal, b) inner epoxy seal.

However individual bubbles scattered within the bulk epoxy seal were discovered. No continuous leakage path which could jeopardize the barrier function was visible. The humidity within packages stored at room temperature (RT) did not rise within the first 12 days of measurement (Fig. 6 - circular marks). Accelerated aging caused the packages to fail earlier. Storage at 37°C reduced the time until the humidity started rising to half (approx. six days). For samples stored at 60°C, humidity values were already increased at first measurement after less than one day. The humidity at 37°C was calculated using a mathematical model according to [5].

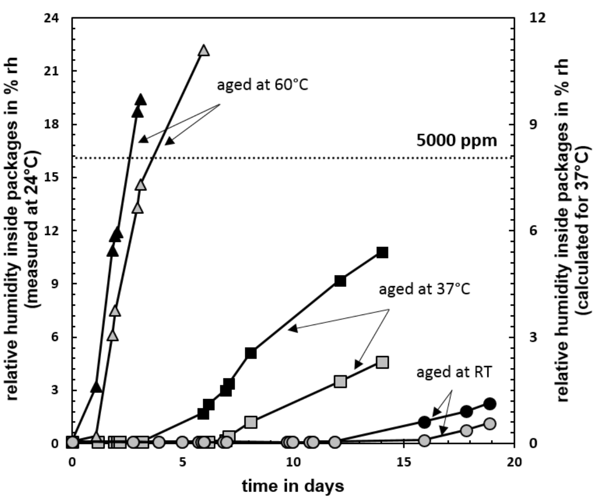

Figure 6: Moisture ingress into epoxy-sealed packages which have seen different aging conditions. Two packages for each aging setup are plotted (grey and black).

IV. Discussion

The introduced procedure is a reliable and reproducible method for sealing neural implant housings in helium atmosphere using a laboratory glovebox. The process is simple and easy to manage even with thick rubber gloves that permit manipulating objects inside the glovebox from outside. The inner epoxy seal provides a reasonable barrier so that the package can be transferred to an external solder station where it is then finally solder-sealed. The time-frame until this has to happen is in the range of weeks. If fine leak testing as a measure for hermeticity is desired, helium outgassing of package materials, such as solder, glass and especially epoxy should be awaited. However, after two hours all outgassing rates have dropped and the true leak of the package is measurable. The bubble formation within the epoxy should be investigated in greater detail to determine whether the package's hermeticity is posed at risk. Further experiments should also focus on actual barrier properties of the utilized epoxy against solder fumes. A disadvantage of the sealing apparatus lies in the necessity of loading the sealing lever with additional weights to build up enough pressure to cause the epoxy not to exit the package through small crevices between lid and base. An improved version of our packager would hence implement a spring load which is able to apply the necessary pressure without additional elements. Focusing on the humidity development inside sensor equipped packages certifies a reasonable time until a durable und true hermetic metal sealing has to be done. The minimal mathematically extrapolated time to failure (referring to the popularly stated 5000 ppm limit [8], i.e. 8.87 % rh at 37°C) for packages stored at room temperature incl. 2% sensor error in this regime is 58 days. This matches theoretical calculations where a package ($V = 1.7\ cm^3$) reaches the 5000 ppm limit after 58.4 days if a mean leak rate of $6{\cdot}10^{-8}$ mbar l s^{-1} is assumed. Aging of solely epoxy-sealed packages speeds up non-linear degradation effects of the polymer. A reliable prediction of the implant's failure hence becomes questionable. Despite all that, sealing to true hermeticity (soldering) needs to be done as soon as possible since a humidity increase inside the package cannot be stopped once initiated. Additionally, water which diffuses into the epoxy over time forms a dangerous source of humidity even if the package is tightly sealed.

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