Hermetic Encapsulation of an Implantable Vision Prosthesis - Combining Implant Fabrication Philosophies

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Abstract—The design of an implantable neurostimulator for the restoration of visual percepts to the blind is discussed in terms of combining two engineering philosophies derived from different origins, yet sharing a common objective. We describe the production of a very small (12 mm diameter) nerve stimulator that exclusively utilises materials with a previous history of not only biological compatibility, but also regulatory approval and clinical application. The fabrication steps that involve laser micromachining, screen-printing, and material co-firing phenomena are illustrated via the example of a substrate for a hermetic electrical neurostimulation device for long-term implantation.

Index Terms—hermetic encapsulation, implant packaging, vision prosthesis.

I. INTRODUCTION

The design and fabrication of therapeutic neuroprostheses for long-term implantation present biomedical engineers and clinicians with substantial challenges. The two main areas of concern are: the efficacy of the interface between the device and the tissue through which therapeutic stimuli are to be conveyed; and the biological compatibility of the device within its host tissue. This paper deals primarily with the engineering of the latter, with life-long implantation in mind.

For more than four decades the Implanted Devices Group (IDG) at University College London has been designing, manufacturing, and implanting therapeutic neuroprostheses to treat various neurological disorders, and making both seminal and ongoing contributions to our collective understanding of these devices [1]. In basic terms, the implant design philosophy of the IDG as it relates to biological compatibility is as follows.

1) Polydimethylsiloxane (PDMS) or silicone rubber serves as an effective barrier to the transfer of relevant ions, but is permeable to water vapour.

2) Electronic components that are themselves inherently hermetic (e.g. resistors, diodes and capacitors) can be encapsulated within PDMS and co-exist with biological tissue in this state indefinitely [2].

3) Key to the longevity of circuitry comprising electronic components is the absence of conditions where corrosion can occur. In particular, the establishment of a bond between the rigid components of the device (e.g. the ceramic substrate) and the PDMS is essential [3].

4) Electronic components that may corrode if only encapsulated in PDMS (e.g. application-specific integrated circuits and their interconnecting bonds) must be sequestered away from exposure to water vapour by way of encasement within a leak-tight chamber [4].

5) Interconnecting circuitry and feedthrough contacts can be achieved by screen-printing metal and dielectric layers upon Al₂O₃ ceramic substrates.

Successful long-term implantation of devices fabricated following these practical considerations serves as testimony to the reliability that these design rules provide [5], [6].

Inherent conservatism in the medical device industry, and precedents set by the designs of cardiac pacemakers and, later, cochlear and deep-brain stimulators has led the Australian Vision Prosthesis Group (AVPG) to adopt their own set of design rules. While some of these rules have a scientific basis (and indeed are aligned with the IDG philosophy), others are influenced by perceptions and precedents that have led to de-facto standards in gaining regulatory approvals. These have been further refined so as to allow a modestly-funded laboratory to produce implantable devices with a plausible path to widespread clinical application by avoiding, wherever possible, expensive and time-consuming characterisation and “re-design for commercialisation” requirements following the first viable prototype. These rules are summarized as follows.

1) The material composition of the implant must be of “substantial equivalence” to other regulatory-approved implantable devices. This is a rather short (but by no means exhaustive) list of Pt, Ti, Al₂O₃, Pt/Ir, Parylene, PDMS and a small population of shape-memory alloys used for brazing.

2) PDMS is not considered a barrier between the tissue and the implant material (e.g. lead covered in silicone rubber is still to be considered only as lead).

3) The hermeticity of the device must be capable of being tested on an individual basis. PDMS coating should be avoided for such tests as it will swell in the presence of fluid and could conceivably mask a leak in hermeticity.

4) No connections within an electrical circuit that are exposed to tissue can be of dissimilar metals. One possible exception to this is Pt to Pt/Ir where a precedent is set in cochlear implant electrode manufacture.
5) The device must be capable of being sterilised - ideally in steam at $121^\circ C$.

While these rules differ in many ways from those of the IDG, this paper illustrates the results that occur when the principal attributes of each set are combined.

Intra-ocular placement of a stimulator for the restoration of rudimentary vision to the blind dictates that the package be of particularly small dimensions. To facilitate placement in the site of the lens, the device is chosen to be circular in shape, 12 mm in diameter and thinner than 6 mm.

The implant package described in this paper is designed to enclose the application-specific integrated circuit described by Wong et al. [7] and will be configured and powered by a tuned radio telemetry circuit. Electrodes attached to the package are fabricated through a slightly modified PDMS and Pt, laser micromachining process developed in our laboratories and previously described by Schuettler et al. [8]. A schematic view of the device is shown in Fig. 1.

II. METHODS

A. Combining fabrication philosophies

The IDG method includes screen-printing of tracks, bonding pads and interconnects on an $\text{Al}_2\text{O}_3$ substrate, soldering of components (typically in a “tombstone” configuration to avoid small cavities beneath the components) followed by thorough cleaning and, finally, encapsulation with PDMS for long-term adhesion. Components liable to corrosion are protected by placement within an “island” on the $\text{Al}_2\text{O}_3$ above which a cap is soldered thereby forming a hermetic chamber. Interconnects between the components within, and outside the hermetic chamber are achieved by burying tracks beneath the solder barrier using multi-layer conductor and dielectric structures.

The presence of discrete electronic components and the PDMS-encapsulated solder contravene the AVPG’s first and second rules above. Therefore, modifications to the IDG processes were explored. First, the hermetic “island” described in the previous paragraph must encompass all components other than those that comply with AVPG rule 1. Second, the solder that creates the barrier around the perimeter of the “island” must be replaced with a material compliant with the same AVPG rule 1. The result of the alignment of these two engineering philosophies is illustrated in Fig. 1.

B. Substrate fabrication flow

Implant manufacture where refractory materials are utilised requires careful consideration of the order in which particular heating steps occur. For instance, sintering of $\text{Al}_2\text{O}_3$ ($1500^\circ C$) clearly must take place prior to the incorporation of materials such as PDMS which can withstand only moderate temperatures. Eventually, the final sealing of the device must occur at a temperature that can be withstood by the full implant. For these reasons, a complex multi-step procedure is necessary where combined processes may appear more efficient.

The basic material of the implant package is $\text{Al}_2\text{O}_3$ ceramic. The lid may be cold pressed or machined in a solid alumina rod while the substrate is high temperature co-fired ceramic (HTCC). Tracks are produced by screen-printing a metallic conductor on the HTCC, Au for internal connections, Pt for connections “outside” of the hermetic barrier such as those connecting to the electrodes. For rapid-prototyping, printing stencils are made out of $50\mu m$ stainless steel sheets patterned by a laser (Nd:YAG Genesis Marker, CAB GmbH, Germany) according to a dxf (Drawing Exchange Format) vector file. A titanium ring is bonded to both alumina parts using a TiCuNi compound and, after substrate population and internal antenna connection, the implant package is closed by laser-welding the two Ti rings together. The use of the laser allows for very high energy to be delivered locally on the rings without over-heating the inside of the implant. The Pt electrode is connected to the Pt pads on the substrate using a novel Pt-Pt bonding method that will be described in a later publication.

C. Feedthroughs

Feedthroughs (paths crossing the hermetic barrier) are formed as described in Fig. 2. A via, filled with Pt, is created through a first layer of unsintered $\text{Al}_2\text{O}_3$ and is connected to a track in the buried plane which, at its opposite end, is connected to a second via that exposes the signal to the outside of the implant. This technique offers a number of advantages.

It has been shown that an extremely thin ($\sim$Angstrom) bond can be formed between ceramic oxides and several metals,
including Pt [9] [10]. While the mechanisms creating this bond, and indeed the nature of the bond itself, are not well-understood, it is known that a firm bond can be established between Pt and Al₂O₃ by application of moderate force at elevated temperature. For this reason, the buried track described above and shown in Fig. 2 and Fig. 3 is key to the formation of reliable, hermetic interconnects. Without the establishment of the Al₂O₃-Pt bond, the tendency, owing to unfavorable differential expansion coefficients (8.8 × 10⁶K⁻¹ and 8.5 × 10⁶K⁻¹ for Pt and Al₂O₃ respectively), is for a void to form at the Al₂O₃-Pt interface.

III. Results

Two-layer HTCC substrates were produced following the method described above. They are 350 µm thick with an inner diameter of 10 mm and carry 16 vias for 14 electrodes and 2 external antenna connections. The feedthrough resistance (tracks included) is below 1 Ω.

Fig. 3 shows the tip of an embedded platinum track at high magnification (1000x). The track appears intimately bonded with the alumina with no visible voids and the junction between the two Al₂O₃ cannot be seen after sintering, the alumina substrate has become a single, continuous, block.

IV. Discussion

Combining the experience of the Australian Vision Pros-thesis Group (Sydney) and the Implanted Devices Group (London), we have developed a novel method of packaging electronic circuits, typically aimed at chronic neurostimulation. The implants produced are very small and only require materials previously used for devices granted with either FDA or CE approval. This pre-requisite (AVPG rule 1) is expected to save a considerable amount of time and effort to secure approval prior to implantation and commercialisation. Another noticeable advantage of the method is that it allows the whole implant design process to remain "in house", providing a better control over the relevant parameters and potentially fewer issues of quality management from sub-contracting companies. The various technologies involved are all suitable for small scale prototyping and the cost of their implementation remains affordable for academic research laboratories. A further advantage derived from the fact that the processes do not require any dedicated tooling is their versatility. Implant packages of any size and shape may be produced with any new set of dxf files.

V. Conclusion

The designers of a medical implant for long-term human implantation must consider both scientific and regulatory constraints. For modestly-funded laboratories to contribute to this field, materials must be carefully chosen and advantage taken when established medical device manufacturers have set precedents in their utilisation. Finally, the development of in-house processes that offer versatility in prototyping should be encouraged wherever practical.

This paper illustrates how two different design philosophies may be aligned for the fabrication of a small hermetic implant package. Strengthening complementarities between designers of electrical stimulation devices benefits the development of future neuroprostheses.

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REFERENCES