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Hermetic diamond capsules for biomedical implants enabled by gold active braze alloys

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ABSTRACT

As the field of biomedical implants matures the functionality of implants is rapidly increasing. In the field of neural prostheses this is particularly apparent as researchers strive to build devices that interact with highly complex neural systems such as vision, hearing, touch and movement. A retinal implant, for example, is a highly complex device and the surgery, training and rehabilitation requirements involved in deploying such devices are extensive. Ideally, such devices will be implanted only once and will continue to function effectively for the lifetime of the patient. The first and most pivotal factor that determines device longevity is the encapsulation that separates the sensitive electronics of the device from the biological environment. This paper describes the realisation of a free standing device encapsulation made from diamond, the most impervious, long lasting and biochemically inert material known. A process of laser micro-machining and brazing is described detailing the fabrication of hermetic electrical feed-throughs and laser weldable seams using a 96.4% gold active braze alloy, another material renowned for biochemical longevity. Accelerated ageing of the braze alloy, feedthroughs and hermetic capsules yielded no evidence of corrosion and no loss of hermeticity. Samples of the gold braze implanted for 15 weeks, *in vivo*, caused minimal histopathological reaction and results were comparable to those obtained from medical grade silicone controls. The work described represents a first account of a free standing, fully functional hermetic diamond encapsulation for biomedical implants, enabled by gold active alloy brazing and laser micro-machining.

1. Introduction

The medical bionics field is currently in a very exciting stage of growth. The success of the cochlear implant, restoring hearing to hundreds of thousands of patients by electrically stimulating sensory neurons in the auditory pathway, has been a major inspiration in the field. Newer generations of implanted devices, such as visual prostheses, aim to interact with neural tissue in complex ways, with hundreds or even thousands of stimulating electrodes [1–3], based on the premise that higher electrode density and number will confer more information to the nervous system. Experience with the cochlear implant has also shown that the individual control of electrodes is essential, as tuning of each electrode is key to providing patients an optimised experience with their device. Accordingly, Bionic Vision Australia is currently developing a high acuity visual prosthesis with the aim of up to 1024 individually controlled stimulating electrodes.

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Unfortunately, the momentum towards high electrode counts in implantable prostheses have created a major materials design problem. The electronic components in bionic implants, which are at risk of leaching unsafe materials into the tissue, and of suffering corrosion damage from exposure to moisture and ions, must be isolated within a hermetic encapsulation. It is commonly acknowledged that hermetic encapsulation is one of the major challenges for high resolution visual prostheses [4–7]. The most common approach to hermetic encapsulation, a vessel of titanium or ceramic with a ceramic feedthrough plate containing an array of brazed wires, is reaching its natural limit in electrode density. The risk of brittle cracking failure for each penetrating feedthrough increases as the feedthroughs get smaller and closer together [8]. Some are addressing this limitation by improving the ceramic technology, using screen-printing and co-fired ceramics to make high-density feedthrough arrays [9–11]. These arrays can be hermetic with densities up to 2500 channels per square centimetre [10], but they do not address the other obstacle of having high electrode counts: the flexible cable joining the feedthrough to the electrodes. A cable carrying hundreds or thousands of wires becomes an untenable prospect, due to issues such as stiffness and the risk of breakage in the fine wires. As the current materials of encapsulation are unlikely to provide an outlook for next generation hermetic miniaturised bionic implants, a new paradigm is required. Any new materials for encapsulation must be able to demonstrate their hermeticity to protect electronics, their durability to remain functional during chronic implantation, and their biocompatibility for safe and comfortable implantation.

Diamond has been hailed as the biomaterial of the 21st century [12]. While its high hardness, wear resistance and thermal conductivity are well known, recognition is now spreading for its chemical inertness which confers both biocompatibility [13–16] and biostability [17]. Diamond is also highly impermeable, as it is intrinsically non-porous, and diamond films grown by chemical vapour deposition (CVD) are pinhole-free after several hours of growth [17]. Xiao et al. showed that diamond films were provided a hermetic seal over silicon wafers which were not degraded after three months of implantation in the retinae of rabbits. Other advantages that diamond can offer for an implantable encapsulation are low density, so that capsules are light when fixed to fast-moving tissue such as the wall of the eye, and high strength, so that capsule walls can be thin for the sake of miniaturisation.

During the development of the Bionic Vision Australia's (BVA's) high acuity epiretinal prosthesis we have reported modification of and stimulation of retinal ganglion cell nerves with an activated form of nitrogen included ultananocrystalline diamond (N-UNCD) [18,19]. We have also previously reported the use of N-UNCD to generated high density, hermetic feedthrough arrays suitable for direct integration with surface mount electronics and leading directly to a high density array of N-UNCD stimulating electrodes [20]. This paper describes a method to hermetically join a diamond capsule to our previously described diamond electrode array [20] using a gold based active braze alloy. Furthermore we show that the gold braze can also be used to generated low impedance feedthroughs in the box, suitable for data and power transfer to internal electronics. The components of the BVA stimulator capsule are illustrated in Fig. 1 (a) and laser welding in (b).

Finding a sealant material for diamond is challenging principally because of the inertness that makes it so attractive as a biomaterial [2,9]. Whilst growing a diamond film over the joint between capsule and electrode array would form a robust hermetic seal, the growth temperatures inside a CVD reactor are too high (400 °C–1000 °C) and would destroy modern CMOS electronics [21,22]. The abrasives industry makes use of active brazing to join synthetic diamond pads to metallic tool surfaces. Active brazes differ from conventional brazes by the inclusion of a metal solute that can chemically react with and bond to the target substrate. In the case of active brazes for diamond, this is typically a metal that can form carbides such as titanium, chromium, or vanadium. The carbide layer is credited with improving bond strength by mitigating stresses developed through mismatch of coefficients of thermal expansion between the diamond ($\sim 1 \times 10^{-6}\ \mathrm{K}^{-1}$) [23] and braze alloy ($15–20 \times 10^{-6}\ \mathrm{K}^{-1}$) [24]. Active brazing is also used by the medical device industry to form hermetic seals between feedthrough array and capsule using conventional ceramic materials.

The diamond/gold hermetic encapsulation reported here makes use of active braze materials in two distinctly different ways.

(i) Formation of a low number of low resistance hermetic feedthroughs in the capsule for the purposes of power and data transfer to and from the encapsulated ASIC (indicated in Fig. 1).
(ii) Formation of inlaid braze lines for hermetically joining two diamond components (indicated in Fig. 1).

The high electrical resistivity of diamond is an advantage for low resistance feedthroughs as conducting feedthroughs can be formed directly in the diamond, without the need for an electrically insulating insert as normally required to isolate feedthroughs in metallic encapsulation materials. For hermetically joining diamond, braze rings are formed in the two surfaces to be joined. The electronics cargo is shielded from the high temperatures of brazing by introduction to the capsule cavity after the braze process is complete, and the capsule is sealed in a final step at ambient temperatures using laser microwelding of the braze layers. To the authors' knowledge, there is no literature showing that braze joints in diamond can be hermetic or biocompatible. Here we show a method to make weldable braze layers and conductive vias in diamond capsules and demonstrate their hermeticity, durability and biocompatibility.

2. Methods

2.1. Fabrication of diamond capsule, inlaid braze lines, and braze feedthroughs

Polycrystalline diamond (PCD) plates, either 0.25 or 0.5 mm in thickness, were patterned using a 2.5 W Nd:YAG, 532 nm wavelength, nanosecond pulsed laser micromachining system (Oxford Lasers). For testing of hermetic feedthroughs, 0.25 mm thick diamond plates were prepared with four identical 150 μm diameter holes positioned near the centre of the plate. For inlaid braze lines, 50 μm deep square grooves were cut into the PCD. Graphite debris, formed during laser cutting, was removed by etching in a hydrogen plasma or by boiling in a mixture of $\mathrm{NaNO_3/H_2SO_4}$ (conc) 1 mg/mL. An adhesion layer was created by melting Silver-ABA paste (Ag 92.75%, Cu 5%, Al 1%, Ti 1.25%, Wesgo Ltd.) over the PCD surface on a resistively-heated element under vacuum of at least 10^{-5} mbar. After the braze was observed to melt and spread (approximately 950 °C), the temperature was raised to ~1000 °C and held to evaporate excess Silver-ABA. The evaporation rate of Silver-ABA was monitored with a quartz crystal monitor. The sample temperature was reduced slowly once the evaporation rate dropped to near zero. The thickness of the Silver-ABA adhesion layer was measured by scanning electron microscopy (SEM, JEOL JSM 510) of a cross section of the interface between Silver-ABA and PCD. Samples for cross sectional imaging were prepared using a focused ion beam scanning electron microscope (FIBSEM, FEI XT Nova NanoLab 200) or the abovementioned laser cutter. Gold-ABA paste (Au 96.4%, Ni 3%, Ti 0.6%, Wesgo Ltd.) was brazed over the adhesion layer in a vacuum (10 min, 1000 °C). For feedthroughs, a 120 μm diameter Pt/Ir wire (A-M Systems) was threaded through a laser-machined 150 μm diameter hole. The wire was brazed into the hole using Gold-ABA over a Silver-ABA adhesion layer as described above. Excess braze was removed by mechanical polishing to leave braze in the groove or feedthrough holes only. For the hermetic capsule, inlaid braze lines were prepared in a flat lid component and a box component. The box cavity was excavated by laser milling, and the weldable gold braze edge exposed by laser cutting through the centre of the inlaid braze line. The process of forming a laser weldable inlaid braze line and a hermetic feedthrough is depicted in Fig. 2.

2.2. Laser welding of inlaid braze lines

Inlaid gold braze lines were aligned beneath a 5 W Nd:YAG, 1064 nm wavelength, microsecond pulsed laser welder with 10 μm tolerance. All laser welding was