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A 232-Channel Retinal Vision Prosthesis with a Miniaturized Hermetic Package

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Abstract — **Miniaturization of implantable devices while drastically increasing the number of stimulation channels is one of the greatest challenges in implant manufacturing because a small but hermetic package is needed that provides reliable protection for the electronics over decades. Retinal vision prostheses are the best example for it. This paper presents a miniaturized 232-channel vision prosthesis, summarizing the studies on the individual technologies that were developed, improved and combined to fabricate a telemetrically powered retinal device sample. The implantable unit, which is made out of a high temperature co-fired alumina ceramic package containing hermetic feedthroughs, electronic circuitry and a radio frequency coil for powering is manufactured through a modified screen-printing/lasering process. The package is sealed with solder glass to provide unaffected inductive coupling to the telemetric transmitter. A 0.05 cc inner volume allows helium leak testing and mathematical lifetime estimations for moisture-induced failure of up to 100 years. The feedthroughs contact a thin-film polyimide electrode array that utilizes DLC and SiC coatings for improved interlayer adhesion of the metallic tracks to the polymer carrier. Two metal layers allow integrated wiring of the electrode array within the very limited space.**

I. INTRODUCTION

We identified two basic aspects in implant manufacturing that turn the miniaturization of neuro-stimulators/recorders with an increased number of active contacts into a major challenge: 1. Thin-film electrodes, if fabricated with inert, biocompatible materials suffer from delamination of the metallic layer from its carrier polymer with catastrophic consequences. 2. The established, traditional hermetic feedthrough technologies provide the required reliability, but are limited to only 10 to 30 channels per implant package. Opposite to pacemakers, neuromodulators or cochlear implants where a) the implantation site allows the fabrication of rather large devices and b) successful restoration of function is achieved with a moderate amount of stimulating channels, is the space inside and in the surroundings of the eye very limited and restoration of vision to a meaningful extent requires at least about a hundred channels [1]. No marketed feedthrough technology can be implemented to fabricate a small device with the required hermeticity. The last is a very critical factor in small packages, for as the volume of the package decreases, the faster a given leak for water vapor leads to water condensation followed by corrosion of electronics. Furthermore, interfaces and discontinuities in the substrate material are introduced with every feedthrough, increasing the probability of fabricating leak channels with every contact protruding through the substrate. There are many approaches for fabricating hermetic packages for retinal prostheses [2][3]. However, no device small enough to be implanted into the eye or its surroundings containing over a hundred channels has been yet presented. By taking existing technologies and looking cautiously into the aspects, which might lead to failure, we established a miniaturized implant concept made out of traditional implant materials, focused on what we believe are the most critical aspects for long lifetime assurance, tested the individual pieces of each technology and put together a device to share the technology and experience with the implantable devices community. Advantageous of the presented implant concept is its ease of adaptability to different stimulating electronics, larger amount of stimulation channels, circuitries, and electrode designs while maintaining the small dimensions of the package.

II. MATERIALS AND METHODS

A. Implant design and concept

The implant package was designed to fit a 232-channel application-specific integrated circuit (ASIC) [4], which is inductively powered with capabilities of replacing it by a much more advanced stimulating device as presented in [5]. An AC-operated photodiode [6] sitting in the optical path for the extra corporal unit, close to the stimulation sites on the epi-retinal electrode array receives digitally coded data and passes it on to the ASIC which decodes and activates targeted stimulating channels. The photodiode is encapsulated in silicon rubber adhesive while the ASIC and some discrete resistors and capacitors (surface mounted devices, SMD: 0402 or 0201 housing) are placed inside the hermetic package. The hermetic package also contains the coil for radio frequency (RF) powering of the device. A polyimide (PI) thin-film electrode array has been developed [7] using two metal layers and silicon carbide (SiC) and diamond-like carbon (DLC) layers to improve metal to polyimide adhesion, permitting to keep the array's dimensions minimal. The back-end of the electrode array contacts a robust high temperature co-fired ceramic (HTCC) alumina substrate with hermetic feedthroughs, electrically

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contacting the inside and the outside of the package. A polyimide-based thin-film printed circuit board re-routes the feedthrough channels inside the package to the ASIC. The substrate contains minor electronic circuitry fabricated through a combination of laser ablation and screen-printing techniques [8],[9]. The lid and the substrate are hermetically sealed with solder glass [10], avoiding the fabrication of metallic rings that would compromise the inductive coupling efficiency of the device. A small opening through a metallic pad on the lid allows the capsule to be thoroughly dried and helium backfilled before being solder-sealed. The dimensions of the package are such that the best results of the helium leak tester ($1\cdot 10^{-12}$ $\mathrm{atm\cdot cm^3/s}$) permit a lifetime estimation of up to 100 years until critical humidity levels (5 000 ppm H_2O) inside the package are reached. The assembled device is then encapsulated in silicone rubber (poly-dimethylsiloxane; PDMS). The individual aspects of the system, as well as their fabrication procedure are discussed below.

B. *Substrate, feedthrough and circuitry*

The substrate was chosen to be out of HTCC alumina for its capability of being structured and co-fired with superficial and embedded platinum metallization. The sintered bio-compatible alumina substrate can be combined with other metallic layers through screen-printing as it has been successfully implemented in implant fabrication since the 1960s [11]. However, reaching the desired integration in a small device density is not possible with current methods. By applying a modified screen-printing method involving laser structuring of the green alumina tape and of the metallic pastes it was possible to reach integration densities comparable to those of photolithographic methods while maintaining the use of robust bulk materials [8],[9].

The process for substrate fabrication (Fig. 1) starts by fixing a piece of the green alumina tape (type 44000 by ESL Europe, Reading, UK) onto a sintered alumina carrier with the shape of a frame. This allows a double-sided laser structuring of the tape without detaching the green alumina tape from the carrier (Fig. 1 – a). For clarity purposes, the carrier substrate is left out of the process illustrations, but it was used from step a to d. Using a Nd:YAG Laser (DPLGenesis Marker, cab Produkttechnik GmbH & Co KG, Karlsruhe, Germany), through-holes (vias) and grooves were laser structured from the top side into the HTCC tape which will form an embedded pad for the feedthroughs. The back of the HTCC tape was structured with grooves for tracks, footprints for electronic elements and the coil. Platinum conductor paste (type 5574, ESL Europe) was globally screen-printed onto the top of the structured HTCC tape parts. Vacuum was applied from below during screen-printing to support the viscous paste to fill out the vias (Fig 1 – b). After the paste had leveled-out and dried, desired structures were created by laser-patterning (Fig 1 – c). Two corresponding parts were aligned and laminated into one stack according to the manufacturer's indications (Fig. 1 – d). This multi-layer system was co-fired at 1500°C yielding a 96 % Al_2O_3 substrate with embedded horizontal Pt barriers (Fig. 1 – e). The surfaces of the sintered substrates were globally covered with a Au paste (type 8844-G, ESL Europe) on the tracks and Pt/Au paste (type 5837-G, ESL Europe) on the solder pads via screen-printing, dried and fired at 1000 °C (Fig 1 – f). The surfaces of the substrate were grinded down using a fine diamond rotary disc (MD-Piano 1200, Struers GmbH, Willich, Germany) to expose the buried structures (Fig. 1 – g). Finally, solder glass (4026-G, ESL Europe) was screen-printed onto the outer ring of the lid and substrate (Fig. 1 – h). The glass was fired at 600 °C to remove the solvents and the organic binder off the printable paste, forming a homogeneous glass layer hermetically joined to the ceramic. The final substrate consists of a ~ 450 µm laminate cut into a disc with 10 mm in diameter. The laser fabrication procedures allow feature sizes of down to 25 µm.

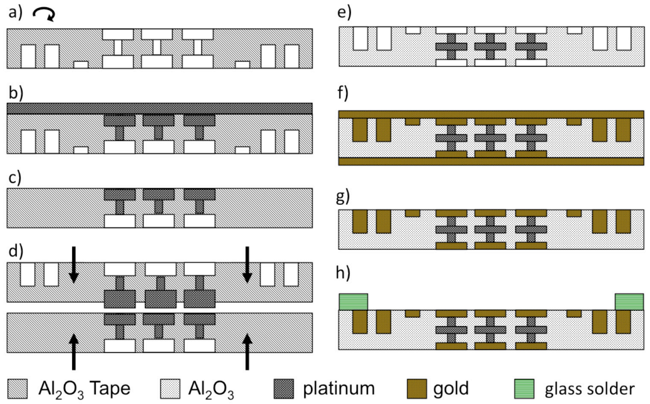

Figure 1: Process of substrate fabrication for hermetic feedthroughs and circuitry for connecting the coil to the electronic components.

C. *Lid*

To create a miniature lid while keeping the material's combination simple and compatible with the substrate, the same Al_2O_3 tape, solder glass and Pt/Au paste were used. The lid was dimensioned to fit 0402 SMD components (or smaller) and a silicon chip inside the chamber.

The tape was laminated to form a 1 mm stack. Using the same marking laser as for the substrate the alumina tape was ablated on both sides to create the cavities and cut to the desired shape. The tape with lid-shape was sintered at 1500 °C. Pt/Au was screen-printed onto the surroundings of the top cavity of the lid and fired. The lid opening permitted drying and helium backfilling of the capsule once the lid and substrate had been joined. The metallization provided a small pad with a puncture reaching through the lid, which allowed it to be soldered shut for final package sealing as presented in [12]. As a last step, solder glass was screen-printed onto the bottom of the lid and sintered at 600 °C to remove the solvents and the organic binder of the printable paste. Further details can be extracted from [10].

D. *Electrode*

Polyimide (BPDA-PPD, U-Varnish S, UBE America Inc., New York, USA or PI 2611 from HD Microsystems, New Jersey, USA) has shown very promising results for the fabrication of microelectrode arrays. U-Varnish-S was chosen for the fabrication of the arrays in this study. However, delamination with dramatic consequences hampered the long-term application of these devices so far.

The authors took a closer look at the aspects leading to delamination of metal from polyimide, studied the adhesion over accelerated aging [13] and proposed a thin-film system with improved adhesion and long-term stability. An exhaustive fabrication description is presented in [7]. In the following, we focus on some design aspects of the electrode array.

While the electrode contacts were intended to be facing towards the retina, the photodiode had to be assembled on the opposite side of the polyimide substrate. To avoid sophisticated two-sided fabrication process, the polyimide substrate array carries a flap which is flipped over to the backside of the array and tempered into position at 350 °C under nitrogen atmosphere allowing the photodiode to look to the opposite side of the stimulating contacts. Openings on the end of the flap allow mechanical fixation of the folded part after PDMS coating of the photodiode. The back end of the polyimide structure that is to be connected to the hermetic package consists of radially positioned contacts with a large opening in the center of the array. The radial design allows 3 things: 1) the top and the bottom layer are spatially detached from each other. The bottom layer covers one half of the contacts while the upper layer sits on the opposite half, allowing relative motion of the lower layer towards the substrate without introducing mechanical stresses, during the assembly process 2) relatively large pitch between the pads allows a better rubber casting and at the same time underfilling through the center of the array. To avoid air trapping, small openings (Ø 20 µm) around the interconnection pads allow on the one hand air to escape during underfilling and on the other hand mechanical interlocking of the polyimide structure with the rubber. 3) By maintaining the feedthroughs on the surroundings of the substrate it is possible to position the SMD components close to the center of the substrate, which is good during sealing of the device. The coil is located in the periphery beyond the pads. Two electrode designs were produced, one with openings for µFlex interconnection, a modified ball-bumping technique [14] and one with gold electroplated pads for more automated flip-chip assembly in the future.

The 232 channels were fed along an integrated 4 mm wide ribbon on two metallization layers down to the actual electrode array, which is only 5 mm in diameter. To reduce capacitive coupling between the tracks of the top and the bottom layers the parallel wiring of both layers runs in offset. The stimulation contacts were coated with sputtered iridium oxide (SIROF) to provide adequate charge injection capacity during stimulation.

E. *System assembly*

Substrate, lid and electrode are fabricated individually. The electrical components are mounted and connected to the substrate and to the flexible circuitry. The lid is attached taking precaution not to overheat the inner of the capsule. The package is dried, helium backfilled and closed with a small solder seal and tested for leaks. The electrode (with already folded flap) is attached to the bottom of the package and the photodiode is bonded into position. Eventually, the photodiode and the package are coated with PDMS.

III. RESULTS

To prove the fabrication procedure a test circuitry (not for stimulation purposes) was fabricated. The device consists of an alumina substrate with hermetic feedthroughs and some basic metallic wiring, including a footprint for a solderable light emitting diode (LED) and some representative 0201 SMD components. For demonstration purposes, the coil was integrated in the bottom of the substrate and was connected via feedthroughs in the ceramic directly to the solder pads for the LED (Figure 2 a - d). The successful attachment of the electrode array through µFlex ball bumping is presented on Figure 2 – e. Due to the size of the LED and its temperature sensitivity, it was not possible to seal the device according to the presented methods in [10]. However, the sealing of separated packages containing no electronics inside showed leak rates of < $1 \cdot 10^{-12}$ atm·cc/s, which is the detection limit of the leak tester (SmartTest HLT570 by Pfeiffer Vacuum Technologies, Asslar, Germany).

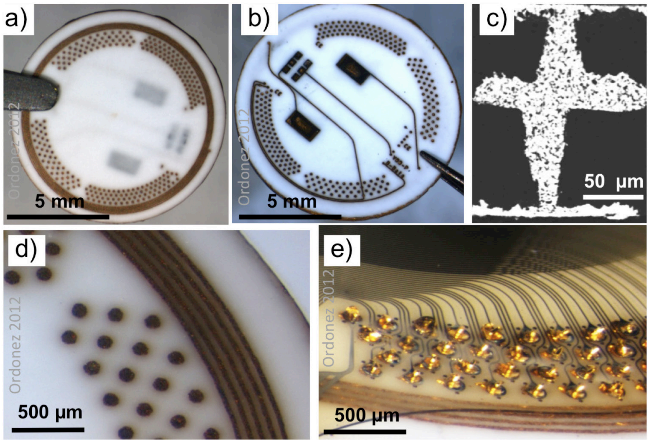

Figure 2: Back (a) and top (b) view of the substrate containing a coil for RF communication sitting on the bottom side (d) which is attached to the electrode array through µFlex (e). A single feedthrough in cross-section is presented in (c).

The 'simple' telemetry unit with the LED as a receiver (not a visual prosthesis power and data transmission unit) was used to prove the wireless powering of the device. However, the resistance of the coil was too high (10 Ω) to allow power transmission over distances larger than 1 cm. By increasing the depth of the coil in the ceramics the resistance could be dropped below (1.5 Ω). Based on ongoing work on this aspect, it can be expected to reach the required power transmission over at least 5 cm distance between the sender and receiver.

The µFlex interconnects showed excellent results (Fig. 2 e, Fig. 3 b). The reproducibility was successful on three devices. Important for the success was the placement of gold bumps on the feedthrough contact pads previous to electrode mounting. This duplicated the required amount of gold bumps and as a consequence the failure probability of the interconnections. However, the used Au paste showed excellent bondability if the bond pads are designed properly (> 40 µm wider than the bonding capillary, Ø 100 µm). A further advantage of this technology is that the tail of the gold bumps can be used as aids to mount the electrode onto the substrate. Figure 3 shows a partially bonded polyimide circuitry foil on the inside of the package.

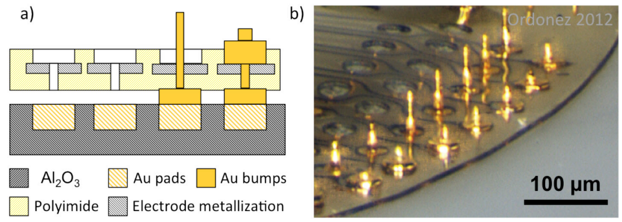

Figure 3: (a) Simplified cross-section sketch showing the bonding pads and the situation on (b), with a partially connected polyimide circuitry foil on the inside of the package. The back 2 rows show the contacting openings on polyimide as fabricated while the middle row shows the tail of the bumps threaded through the openings in the polyimide foil. The outer row shows fully contacted µFlex interconnections.

IV. DISCUSSION AND CONCLUSION

By combining recently developed and improved fabrication methods and technologies, we established a system concept for miniaturized high-channel implantable prostheses and exemplified the fabrication procedure on a retinal prosthesis with 232 stimulating channels (Fig. 4). The two most critical issues concerning long-term stability of an implant were the hermeticity of the package and the stability of the electrode array. Both have been proven successfully by the authors [7],[8],[10]. The combination of these individual parts permitted the system concept presented here: a hybrid assembly of a retinal implant with inductive energy supply.

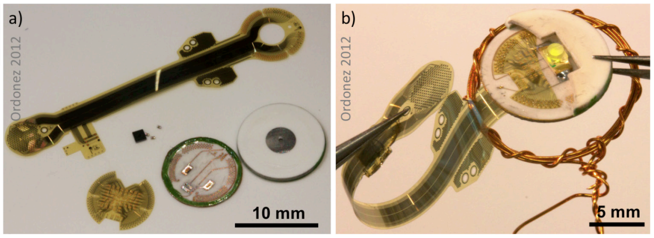

Figure 4: (a) individual parts for the presented device including the electrode, flexible circuitry for the inside of the package, the substrate, the photodiode and SMD components (0201 series). (b) shows an assembled device (electrode, photodiode and substrate) with an open lid for demonstration purposes. The coil on the back of the substrate receives power through an RF link. Hermetic feedthroughs contact the coil with the inside of the package. The glowing LED proves the wireless power transmission.

A large advantage of the fabrication procedure is the capability of doing a Helium leak testing on the package previous to electrode attachment and rubber casting, allowing an early detection of a defective device. The volume of the package is minimal still allowing a prediction of up to ~ 100 years lifetime of the electronic components if leak rates of $(1\bullet10^{-12})$ are detected. This assumes that the PDMS coating provides enough protection and thus no biodegradation of the package takes place. Additionally, there would be enough space to include water getters as safety measure to significantly improve the lifetime of a device stored in a humid environment such as the body [15]. The use of robust materials for the package is of benefit as the stability of the same is provided along the assemblage of the device. Applying ultrasonic bonding for the attachment of the electrode array could be considered a critical step, as repeated application of pressure and ultrasound might cause micro cracks in the glass seal, leading to early failure of the device. However, annealing (considered best at one third to half of the melting temperature of the treated material) can take place after electrode attachment since the complete device (previous to casting in PDMS) is capable of withstanding prolonged temperatures of 200 °C. This is based on the considerations that the ASIC and SMD components are either assembled by wire bonding or high - temperature solders. Beyond this, the integration capabilities of the applied technologies are far from being exhausted, permitting an increase in the number of stimulating channels without affecting the reduced dimensions of the device. Future tests will analyze the long-term stability of the fully assembled device *in vitro* during long-term stimulation with the real electronic components before validating the results in *in vivo* studies.

V. ACKNOWLEDGEMENTS

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