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Parylene-based integrated wireless single-channel neurostimulator

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ABSTRACT

This paper presents the design, fabrication, and functional testing of a fully implantable, flexible, Parylene-enable neurostimulator that features single-channel wireless stimulation capability [1]. This system comprises a fold-and-bond microelectromechanical systems (MEMS) coil for wireless power and data transmission, a BION 1-3 CMOS stimulator chip, discrete capacitors, as well as a carrier substrate with two platinum stimulating electrodes and interconnections for system assembly. The physical geometries of the devices are designed for use in retinal implantation with the specifications determined from the implantation results in canine eyes. The coil and carrier substrate are separately fabricated using a Parylene–metal skin technology. The unique properties of Parylene C allow these MEMS devices to be flexible and biocompatible, facilitating surgical procedure. The system assembly is achieved by interconnecting individual components together on the carrier substrate with a biocompatible silver epoxy. A 10 μm layer of Parylene C is selectively deposited on the integrated system to protect it from corrosive eye environment. The system functionality is verified using a telemetry link setup, and single-phase pulses with amplitudes ranging from 7 to 8.5 V are detected.

1. Introduction

Nervous system damages (e.g. brain trauma, spinal cord injury, and retinal diseases) result in permanent physical disabilities to millions of people worldwide [2,3] and are presently incurable conditions. Potential treatments such as neural transplantation and stem cell therapy [4–6] are promising but their implementation faces great challenges due to the lack of clinical practice protocols, high costs, and political issues. Artificial neural prostheses, which utilize electronic devices as interfaces to central and peripheral neural systems, have been increasingly accepted to partially treat neurological disorders and diseases. Many different approaches have been investigated, using electrical signal to stimulate neurons and muscles for controlling of limbs and organs, or to elicit sensory sensation for feeling, hearing, or seeing. Numerous applications include limb prostheses for spinal cord injury and stroke, sacral nerve stimulations for bladder emptying, deep brain stimulation (DBS) for essential tremor and the tremor of Parkinson's disease, cochlear prostheses for restoring hearing, and retinal prostheses for outer retinal degenerative diseases such as age-related macular degeneration (AMD) and retinitis pigmentosa (RP), to name just a few [7–11].

In recent decades, integrated wireless microsystems emerge and provide breakthrough opportunities for implantable neural prosthesis. Microfabrication technologies can effectively increase the degree of miniaturization and system complexity. Wireless power and data signal transmission through electromagnetic fields avoids batteries or permanent wired connections, and thus reduces surgical complexity as well as undesired physical damages to patients. Among the aforementioned examples of neural prostheses, an epiretinal prosthesis is one of the most prominent prosthetic interfaces that will benefit from wireless microsystem technologies. An epiretinal implant system typically comprises (1) radio-frequency (RF) coils for transferring power and data between intraocular units and external data acquisition units, (2) integrated circuitry for converting signal and providing stimulus to retina, and (3) a multielectrode array for stimulating neural cells on the inner retina (Fig. 1). For applications that involve completely intraocular implantation in human eyes, the following requirements on the system and encapsulation method are critical: (1) sufficiently high spatial selectivity, (2) biocompatibility and low cytotoxicity, (3) enough flexibility to conform to anatomical curvatures of eyeballs, minimize tissue damage, and facilitate surgical procedure. Current technologies using flexible polymer-based microsystems

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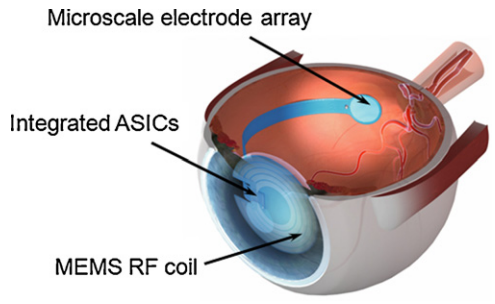


Fig. 1. Conceptual schematic of an epiretinal prosthesis showing main components and their placement.

for epiretinal implants are still in developmental stage [12–14] and few have actually been transferred to the clinical practice due to challenges with respect to material selection, device miniaturization, as well as fabrication and integration methods.

Our goal is to address these existing issues, by integrating Parylene-based microelectromechanical systems (MEMS) devices (microcoils and electrode arrays) with other discrete components (application specific integrated circuits (ASICs), capacitors, etc.) to develop flexible and biocompatible wireless neural implants. In this work, we present the first completely Parylene-based functional neural stimulator, which consists of a MEMS coil and an electrode array integrated with a single-channel stimulator chip. For the first prototype, MEMS devices are made separately, and assembled with other system components using biocompatible silver epoxy. A Parylene–metal skin technology has been developed, which allows us to microfabricate RF coils and high-density multi-electrode arrays in a process compatible way [15,16]. Parylene C is chosen as the main substrate and packaging material because of its favorable properties, such as flexibility (Young's modulus ~4 GPa), optical transparency, chemical inertness, and biocompatibility [17]. In fact, Parylene C is an ISO 10993 and United States Pharmacopeia (USP) Class VI biocompatible material, the highest biocompatibility and implant clearance among plastics. Upon intraocular implantation in two rabbits for 6 months, Parylene C is shown to generate no detectable immune response affecting their retinas [18]. These results indicate that Parylene C is a biocompatible material suitable for long-term intraocular retinal prostheses.

2. System design

Fig. 2 depicts the system schematic of the single-channel simulator, which consists of a complementary metal–oxide–semiconductor (CMOS) chip, two capacitors, a specially designed RF MEMS coil, and a carrier substrate. The chip is a single-channel stimulator which was initially developed by Loeb and co-worker to mimic muscle spindle function for patients with muscle paralysis [8]. When implanted into paralyzed muscles, power and command signals can be delivered to the chip through inductive coupling over a 480–500 kHz power carrier generated in an external personal trainer. Then the chip can emit precisely timed stimulation pulses with a highly regulated amplitude and pulse-width. Fig. 3 shows a BION 1–3 chips used in our experiments, and the pad functionalities are described in the right hand table. This chip has physical dimensions of ~1 mm in width, ~2.33 mm in length, and ~257 μm in thickness. There are five pads on the BION chip approximately 120 μm by 74 μm in size, and the distance between adjacent pads is about 110 μm.

A dual-metal-layer coil is designed as the main component for wireless power and data transmission. The self-inductance of such a MEMS coil is limited by its small dimensions, and can be calculated using the following equation [19]:

$$L_s = 2\pi d N^2 \times 10^{-9} \left[\left(\ln \frac{4d}{t} \right) \left(1 + \frac{t^2}{24d^2} \cdots \right) - \frac{1}{2} + \frac{43t^2}{288d^2} \cdots \right] \text{(Henry)}, \quad (1)$$

where N is the total number of turns, d (in cm) is the mean diameter of the coil, and t (in cm) is the coil width. Two ceramic chip capacitors (AVX Corporation, Myrtle Beach, SC, USA) are also incorporated into the system for circuit function, as shown in Fig. 2. C_1 is a frequency tuning capacitor in parallel with the receiving coil to achieve a resonant frequency of ~500 kHz, and C_2 is a charge storage capacitor which has a capacitance of ~22 nF. The size of these capacitors is approximately 1 mm in length, 0.5 mm in width, and 0.56 mm in thickness. Finally, the carrier substrate is designed for system assembly, which comprises a flexible cable, interconnection leads and contact pads, and two stimulus electrodes of which one serves as the signal terminal and the other as the floating ground.

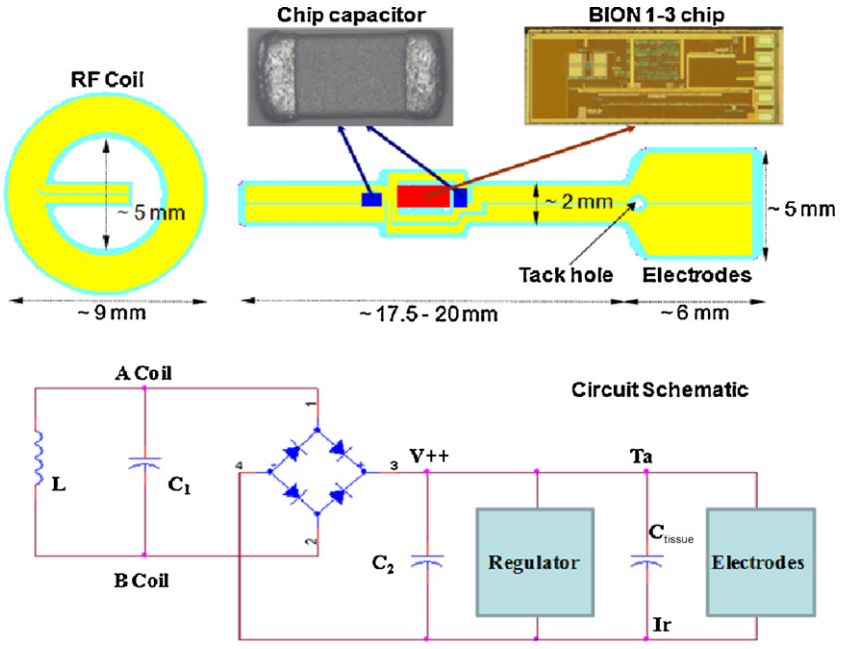
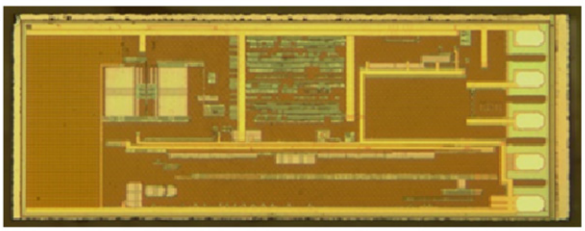


Fig. 2. System schematic of the single-channel stimulator and the corresponding circuit layout, showing the connections between individual components.

(a)



(b)

Name	Functionality
V++	Rectifier output
A Coil	Coil terminal
B Coil	Coil terminal
Ta	Stimulation output
Ir	Common ground

Fig. 3. (a) Microscope image of a BION 1-3 chip. (b) Pad function of the chip.

Overall physical dimensions of the MEMS coil and the carrier substrate need to meet specifications used in retinal implantation. Due to the small volume and complex anatomy of eyes, it is necessary to evaluate possible geometries in eyes prior to finalizing the designs of the devices. It is also important to verify the robustness of the devices and materials under surgical manipulation. Thus, mechanical models with various dimensions are first fabricated and implanted in canine eyes to study the system geometrical feasibility inside the eye, as shown in Fig. 4. In this experiment, carrier substrates are made of Parylene C thin films (PDS 2120 system, Special Coating Systems, Indianapolis, IN, USA) using a photoresist mask and oxygen plasma etching in a reactive ion etching (RIE) system (Semi Group Inc. T1000 TP/CC). Plastic dummy coils and chips are then glued onto the carrier substrates using biocompatible epoxy EPO-TEK 301-2 (Epoxy Technology, Billerica, MA, USA), simulating the system integration of various key components. The animal surgery is operated at the Keck School of Medicine of the University of Southern California. During the implantation, the coil site is placed right beneath the cornea, in the anterior chamber of canine eyes, less than 1 mm from external air. After lens extraction, the flexible cable is passed through the anterior and posterior lens capsule into the vitreous cavity, leaving the chip site floating in the vitreous cavity. Vitrectomy is then performed and the electrode array site is attached on top of the inner retina using a retinal tack modified by the addition of a PDMS washer. Based on preliminary surgical results, optimal device dimensions for canine eyes are determined as indicated in Fig. 2. Devices for human implantations can be simply modified by reducing the cable length in order to accommodate the smaller space of the vitreous cavity in human eyes.

3. Fabrication

In order to reduce fabrication complexity, the coil and the carrier substrate are fabricated and calibrated respectively. Then the system is assembled by interconnecting individual components on the carrier substrate with a conductive silver paste. Detailed fabrication is divided into three steps and described in the following sections.

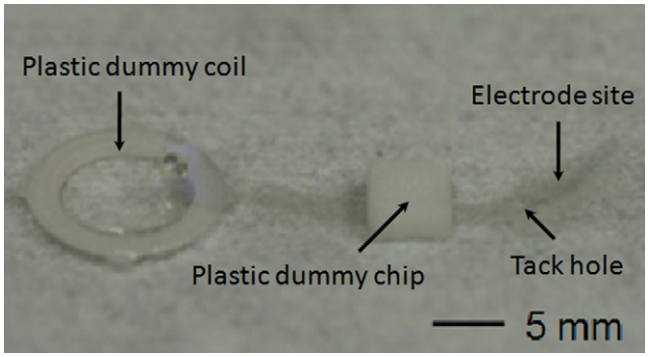


Fig. 4. A dummy structure for canine implantation.

3.1. Carrier substrate fabrication

To build the flexible substrate, a 200 nm layer of metal is e-beam (SE600 RAP, CHA Industries, Fremont, CA, USA) evaporated on a Parylene C coated silicon substrate. Then the metal is patterned using a lift-off method to form connection pads, interconnection leads, and electrode array [16]. Platinum is selected as the primary electrode material due to its optimal stimulation capability and biocompatibility. Parylene C-based arrays of thin-film platinum electrodes have shown excellent biostability when chronically implanted in contact with canine retinas for 6 months [16]. Furthermore, platinum and Parylene are known to have good adhesion, requiring no additional adhesion metal layer during fabrication. After metal patterning, another layer of Parylene C is deposited to seal the entire structure, followed by oxygen plasma etching with a photoresist mask to define the contour of the carrier substrate, as well as to open the electrode sites and the contact vias. Finally, the device is peeled off from the silicon substrate in a water bath and dried in air. Fig. 5 illustrates the detailed process for making the carrier substrate, where steps (b)–(d) describe the lift-off technology for platinum patterning.

Fig. 6 presents a fabricated carrier substrate. This device has a total thickness of approximately 10 μm. Three extra pads are added on the chip site for testing purpose and can be removed after system integration. The microscope image in Fig. 6 shows a special chip site design where Parylene ribbons are etched in a way such that the chip can be held in place and self-aligned to the contact vias on the substrate during system assembly. The array site contains a 450 μm diameter tack hole so that it can be attached to the retina with the retinal tack during implantation.

3.2. RF MEMS coil fabrication

A fold-and-bond technology is involved in the MEMS coil fabrication [20]. First, a planar Parylene–metal–Parylene sandwich structure is built with two coils arranged in series (Fig. 8). The fabrication process is show in Fig. 7. Briefly, a 3 μm layer of gold is deposited on a Parylene coated substrate and patterned with metal etching process. Then Parylene deposition is performed on top of metal, followed by oxygen plasma etching to open contact vias. Photoresist serves as a sacrificial layer so the structures can be released from the substrate by dissolving photoresist in acetone.

After the planar structure is microfabricated, it is folded into two layers and stacked together with the assistance of two glass slides. Aluminum sheets are inserted between the Parylene surface and the glass slides to prevent Parylene from sticking to glass. External pressure is applied by stacking a ~2 lbs metal plate on top of a 75 mm × 50 mm glass slide, allowing Parylene-to-Parylene bonding at modest temperatures. After that, the whole unit is placed in a vacuum oven (T-M Vacuum Products, Inc., Cinnamin-

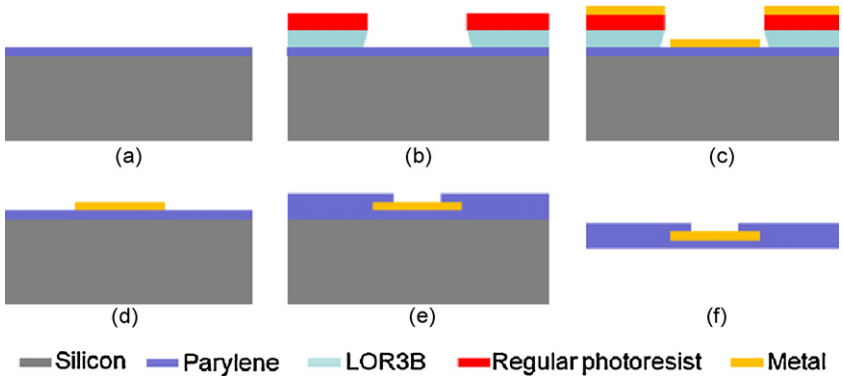


Fig. 5. Fabrication process of the Parylene-based carrier substrate.

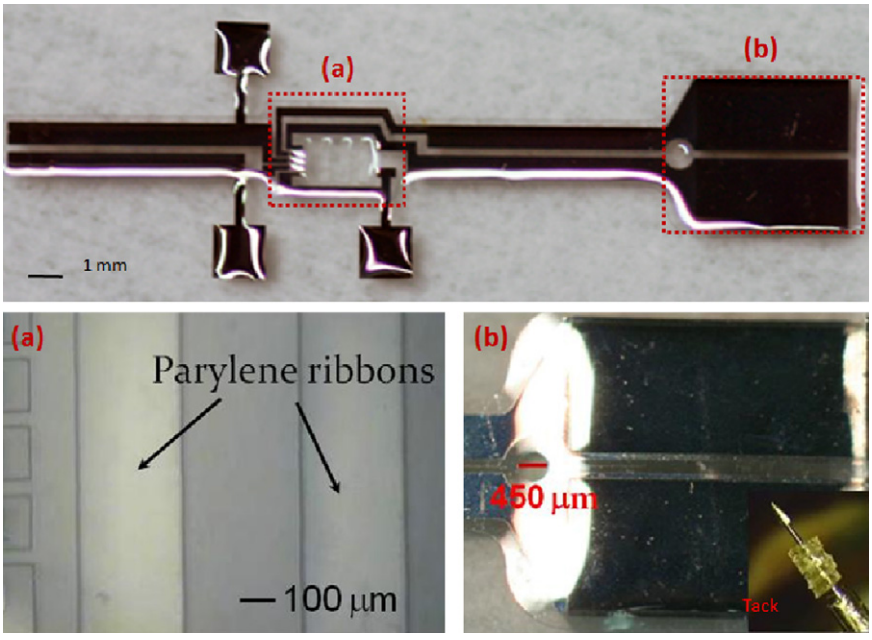


Fig. 6. A fabricated carrier substrate with electrodes, interconnection leads and contacts. (a) Parylene ribbons for holding the BION chip. (b) A 2-electrode array with a tack hole.

son, NJ, USA) with the chamber pressure of ~10 Torr for bonding. The oven temperature ramps from room temperature to bonding temperature, and then soaks at the bonding temperature for 2 days, followed by slowly cooling to the room temperature. Nitrogen backfill is introduced to the chamber in order to equalize the chamber temperature. Experiments are performed at a setting temperature range of 180–250 °C, and bonding results are evaluated by visual inspection. The results demonstrate that the vacuum pressure of 10 Torr can prevent Parylene from undesired oxidation at elevated temperatures so that the device can remain flexible after bonding. It is also found that good Parylene-to-Parylene bonding occurs in samples annealed at temperatures higher than 230 °C. It should be noted that the bonding temperature has to be lower than the melting temperature of Parylene C (290 °C), as strong recrystallization can happen beyond this point [21].

A fabricated coil is shown in Fig. 8, comprising two layers of metal with 10 turns in each layer. In-and-out leads are connected to the carrier substrate from the center to facilitate the surgical procedure. Through vias are designed to overlap with the contact pads so that the interconnections to the carrier substrate can be formed from either side. The electrical properties of this coil are measured with an Agilent 34401A multimeter and the HP 4192A LF impedance analyzer (HP/Agilent Technologies Inc., Santa Clara, CA, USA), showing an inductance of approximately 2.24 μH and a DC resistance of approximately 15.82 Ω. A Q factor of 0.45 is calculated at the operation frequency of 500 kHz. Theoretically, thicker metal can lower the intrinsic resistance of the coil to achieve higher Q

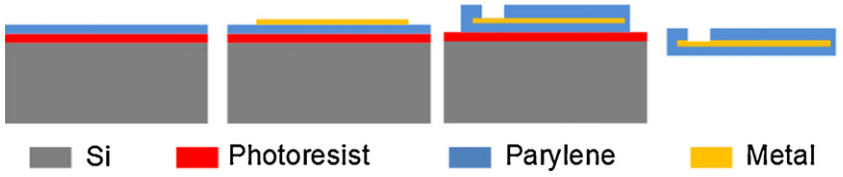
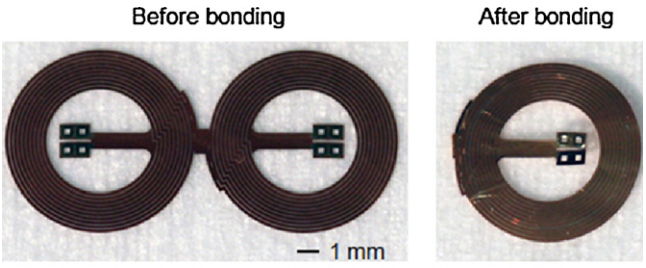


Fig. 7. Fabrication process of Parylene–metal–Parylene sandwich structure.



Inductance	DC resistance	Q at 500kHz
2.24 μH	15.82 Ω	0.45

Fig. 8. A fabricated fold-and-bond coil with two layers of metal. The electrical characteristics are measured and given in the table.

factor and better performance, but e-beam evaporated metals are often limited in film thickness due to process cost.

3.3. System assembly and packaging

For hybrid system assembly, discrete components (the BION chip, the coil and the capacitors) are aligned to corresponding interconnection vias on the carrier substrate. A small amount of biocompatible silver epoxy EPO-TEK H20E is then applied on the contacts and cured at 80 °C for 3 h in a convection oven. The conductive epoxy serves two purposes: to form the interconnections between the components as well as to bond the components onto the substrate. Fig. 9 shows an assembled single-channel stimulator system, and close-up views of the interconnections for each component.

Because the BION chip used in our experiment has only five pads, hand assembly can be used as a temporary solution for fast integration. However, a major problem of manual assembly is the inability to control epoxy dosage when applied by hand. Short circuits can be created if too much epoxy is applied, and epoxy reflow can also happen during high temperature curing, resulting in short circuits between adjacent pads. For circuitry with high-density pad layouts, this hand assembly is no longer feasible, and thus a wafer level integration technology becomes necessary [22].

Another big concern is the isolation of the silver epoxy from the eye environment. Human eye is known as a delicate and sensitive organ. Any toxin released from the epoxy can cause inflammation and infection. In addition, eye fluids are corrosive to exposed metals [23], which can reduce the durability of silver epoxy bonding, and finally result in open circuits. To overcome these challenges, ~10 μm Parylene C is coated over the entire system just leaving the electrode sites open to protect the circuitry from corrosive eye fluids. The packaging performance of Parylene C has been studied using accelerated-lifetime soak tests in related work [24]. Preliminary results indicate that Parylene C protected metal can remain

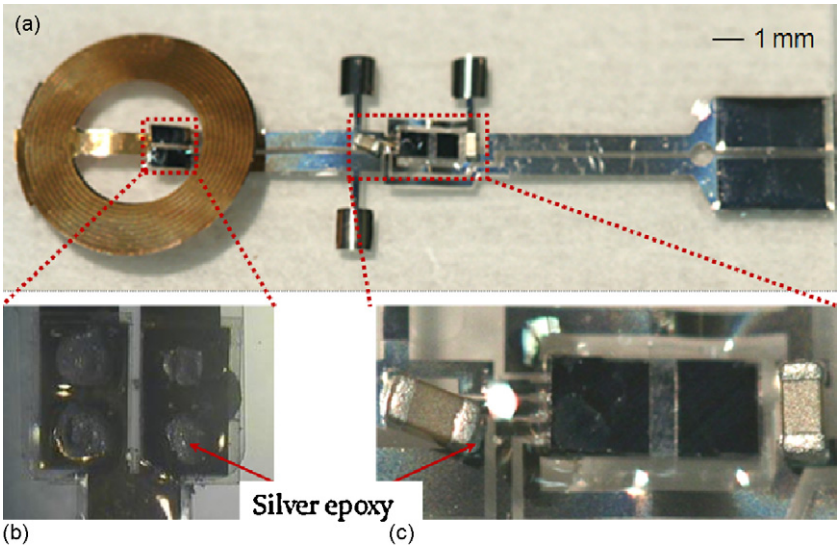


Fig. 9. (a) An assembled BION system. (b) Interconnects of coil contacts formed with biocompatible conductive silver epoxy. (c) Interconnects of chip and capacitor contacts formed with biocompatible conductive silver epoxy.

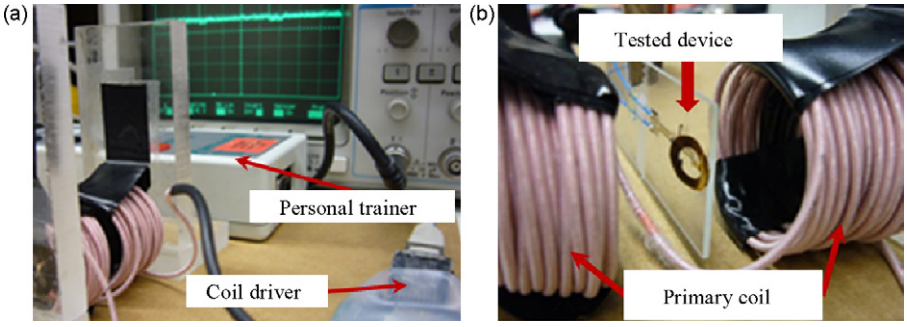


Fig. 10. (a) A telemetry setup for functionality test of the assembled BION system. (b) A close-up image showing the tested system placed between the primary coil.

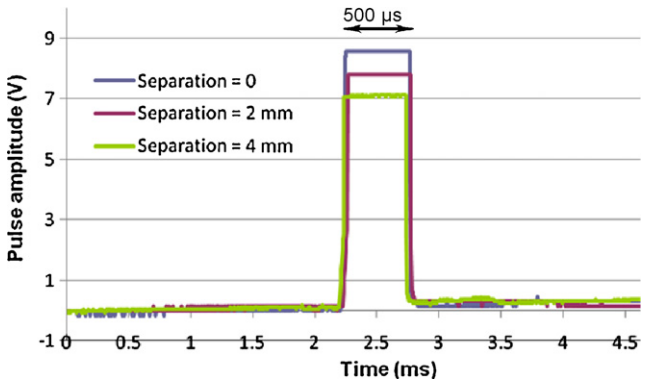


Fig. 11. Recorded stimulation pulses at different separation distances between two coils.

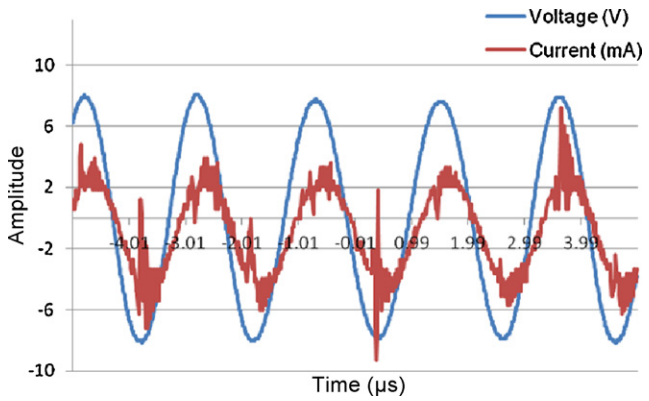


Fig. 12. Typical waveforms of transferred voltage and current to the chip.

intact in saline (0.9% NaCl) at body temperature (37 °C) for over 20 years, which is very promising for our application.

4. Test results and discussions

The system functionality is verified using a telemetry link setup (Fig. 10). The primary stage, which comprises a personal trainer unit, a class-E coil driver, and a hand-wound transmitting coil, can generate a power carrier of approximately 500 kHz. The personal trainer stores command programs personalized for individual subjects, records the time and duration of treatment, and transfers this information to an external computer for real time monitoring. Upto three programs can be preloaded into the memory of the personal trainer [25]. The coil driver is connected to the personal trainer through a custom made adapter. The transmitting coil has an inductance of ~46.4 μH and a *Q* factor of ~118 at 500 kHz. Litz wires 1025-44 SPN are used for winding the primary coil in order to reduce the skin effect and proximity effect losses. The transmitting coil is built in a solenoid shape to establish a more uniform electromagnetic field inside the coil. It is also known that the induced voltage at the receiving coil increases proportionally with the increase of magnetic flux going through the inductive link. Therefore, ferrite cores are incorporated in the transmitting coil to magnify electromagnetic field and improve voltage transfer efficiency,

In vitro measurements have been conducted in air using this setup, and output signals of the integrated stimulator are monitored by connecting two electrodes directly to an HP 54645A oscilloscope. The distance between the two coils is varied during testing, and a maximum detectable range of ~4 mm is found. The operation range is relatively short, suffering from the low *Q* factor of the receiving coil as expected. The recorded stimulating pulses at the different separation distances are given in Fig. 11, showing a pulse width of approximately 500 μs, and amplitudes varying from 7 to 8.5 V.

In order to estimate the power transfer capability of the MEMS coil, voltage across the receiving coil terminals and current delivered to the chip are measured. Fig. 12 shows typical waveforms of the transferred voltage and current, indicating a resonant frequency of ~505 kHz and a ~25° phase drift between voltage and current. As mentioned earlier, the tuning capacitor is a commercially available chip capacitor, which has limited options for capacitance values. Therefore, it is difficult to fine tune the resonant circuit to achieve precise synchronization. Delivered power at different separation distances is also investigated, as shown in Fig. 13. It can be seen that our MEMS coil can transfer a maximum power of ~43 mW through this inductive link at a separation distance of 1 mm. As the separation distance increases to 2 mm, the power drops dramatically by 62%, mainly due to the divergence of electromagnetic field. When delivered power is less than 10 mW, no stimulating pulse can be detected from the output.

Similar power transfer measurements have also been performed by immersing the integrated stimulator in regular saline solution to simulate *in vivo* conditions. Preliminary experimental results have shown that the maximum detectable range of this telemetry link is decreased to approximately 2 mm. This significant reduction (~50%) is attributed to a substantial environmental permittivity change in the liquid medium as compared with air, which results in the increase of magnetic energy losses into the saline and a low *Q* factor of the MEMS coil [26].

Typical detection distance for retinal prostheses in current clinical applications is estimated to be approximately 15 mm, which is defined as the coaxial separation distance between the implanted coil and the external coil. In our system, the internal coil is placed right beneath the cornea, and the limiting factor in reducing this distance is the large separation of external coil from eye surface for safety reason. To accommodate such requirements and increase the practicality of our stimulator, further improvement can be made to increase the detectable range by optimizing coil design, such as increasing metal thickness and/or the number of metal layers, to enhance the coil *Q* factor and the power transfer efficiency. Particularly, for a fold-and-bond coil used in this integrated system, the coil *Q* factor is proportional to the number of folds and can be enhanced by *n*-times when *n* single layers of Parylene–metal thin films are stacked and bonded together [20].

The functionality of the integrated system has been successfully demonstrated in both air and saline. Some efforts have been carried out to test the mechanical reliability of the integrated system in rabbit eyes, as well as to optimize the surgical procedure. Fig. 14 shows an example of the acute implantation, in which an integrated system is implanted in a rabbit eye. After implantation, the

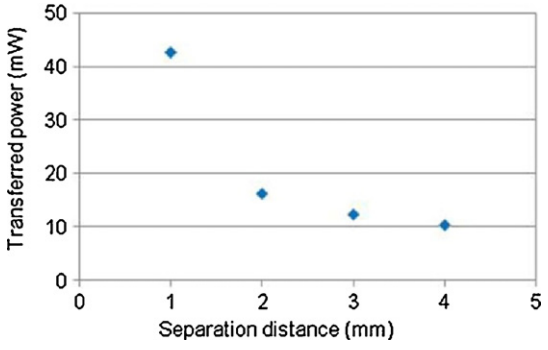


Fig. 13. Transferred power at different separation distances between two coils.

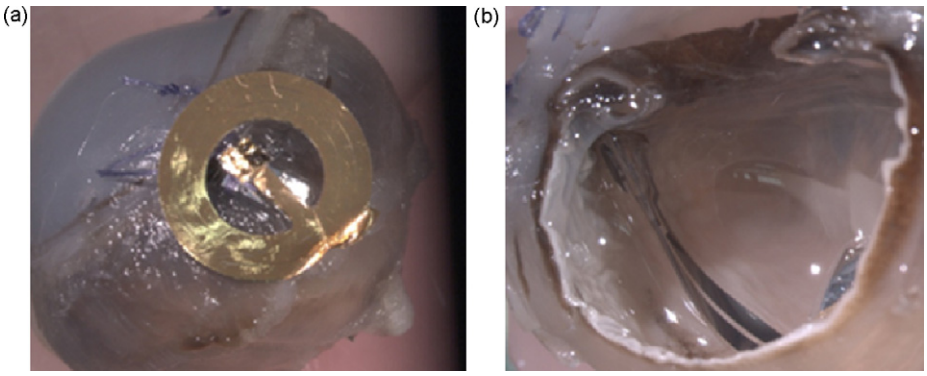


Fig. 14. Acute implantation images of an integrated system in a rabbit eye, showing: (a) the coil sitting in front of the iris; (b) the flexible cable and array implanted in the vitreous cavity.

subject is sacrificed and its eyeball is soaked in forming solution for 1–2 weeks to maintain the eyeball shape. Then the eyeball is removed from the solution and cut into halves in order to examine the implanted device. Preliminary outcomes suggest the implanted device can mechanically withstand the surgical procedure fine. Future work will aim to improve the power transfer performance of the telemetry link as well as to verify the system functionality and biostability using *ex-vivo* testing and *in vivo* implants in rabbit subjects.

5. Conclusion

A Parylene-based single-channel neural stimulator has been designed, and the first prototype has been successfully microfabricated and assembled. *In vitro* active measurements are performed to verify the functionality of the integrated system. The test results demonstrate that the BION chip can be driven by the MEMS coil within a 4 mm separation distance in air. Output pulses with ~500 μs pulse width and greater than 7 V amplitude are detected from the stimulating electrode. Preliminary animal implantation result indicates that the integrated system is mechanically reliable and surgically compatible. We are expecting to implant the device in animal subjects to further characterize its system performance *in vivo*. Although specifically tailored to the needs of retinal prostheses, this system integrates Parylene-based MEMS devices with discrete electrical components and ASICs, and thus enables a new range of true system solutions for both biomedical and non-biomedical applications.

Acknowledgments

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