33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

Realization of an Active Book for Multichannel Intrathecal Root Stimulation in Spinal Cord Injury - Preliminary Results

Martin Schuettler, *Member IEEE,* Anne Vanhoestenberghe, Nooshin Saeidi*,* Xiao Liu, *Member IEEE*, Joe Evans, Cindy Colinge, *Senior Member IEEE,* Andreas Demosthenous, *Senior Member IEEE*, and Nick Donaldson

Abstract—**After spinal cord injury, electrical stimulation of the roots inside the spinal column at the level of the cauda equina is a safe and effective way to regain some degree of control over lower body function, e.g. bladder and bowel management and leg movement. The success of current systems used for so-called intrathecal stimulation is limited by the low number of stimulation channels, which are in consequence of the maximum acceptable number of transdural cables. In order to overcome this limitation, we developed an active electrode with integrated electronics, providing four individual stimulation channels that requires one cable only. This paper outlines the different elements of the so-called active book with the emphasis on its preliminary construction and assembly.**

I. Introduction

Since the 1970s, sacral anterior root stimulators have been implanted in patients suffering from spinal cord injury. These devices allow the users to control their bladder emptying and, in some of them, bowel evacuation. Most of the devices implanted are three channel stimulators. The corresponding electrodes are arranged as tripoles, multiple tripoles were grouped to a so-called *book*. The nerve roots (usually the efferent parts of S1 to S4) are placed between the pages of the book establishing electrical contact to the electrode tripoles. The book itself is placed inside the spinal canal, having multiple cables (usually three) connected to it, which leave the canal through the dura, sealed by a silicone grommet [1]. The cables are partly mechanically protected by the vertebral bone. Today, more than 2500 patients received such an implant [2]. In the 90s the technique of intrathecal lumbosacral anterior root (L2-S2) stimulation was applied for restoring lower limb mobility in spinal cord injured patients [3]. Although, the success of regaining standing and walking ability was limited, root stimulation permitted patients to do recreational cycling [4] or rowing. Presumably additional stimulation channels would provide more options for recovering functions including leg movement, bladder and bowel emptying. However, surgeons defined five as the maximum number of cables (highly reliable Cooper cables) that could enter the spinal canal and therefore, the number of stimulation channels was limited. In early 2008, our research consortium began to work on a new generation of book electrodes (called: *active book* [5]) that carries a programmable integrated circuit supplying stimulation current to four individual electrodes. Operating the active book requires an implanted control unit (to be located in the abdomen) which is connected to up to five active books, each using only one Cooper cable, thus allowing 20 stimulation channels to be used inside the spinal canal at maximum.

This paper focuses on the fabrication of the actual electrodes in the slots of the book, as well as on the assembly and interconnection technology, keeping the description of the stimulator chip and its hermetic packaging very short.

Manuscript received 25 March 2011.

M. Schuettler is with the Laboratory for Biomedical Microtechnology, Dept. of Microsystems Engineering - IMTEK, Univ. of Freiburg, Germany (schuettler@ieee.org). C. Colinge is with the Tyndall National Institute, Ireland. All other authors are with the University College London, UK.

II. Materials and Methods

A. Electrode Array

The active book has four electrode slots for insertion of nerve roots. Each slot carries a central stimulation cathode and two anodes arranged to a tripole. The slots are fabricated by a variation of an established laser process [6].

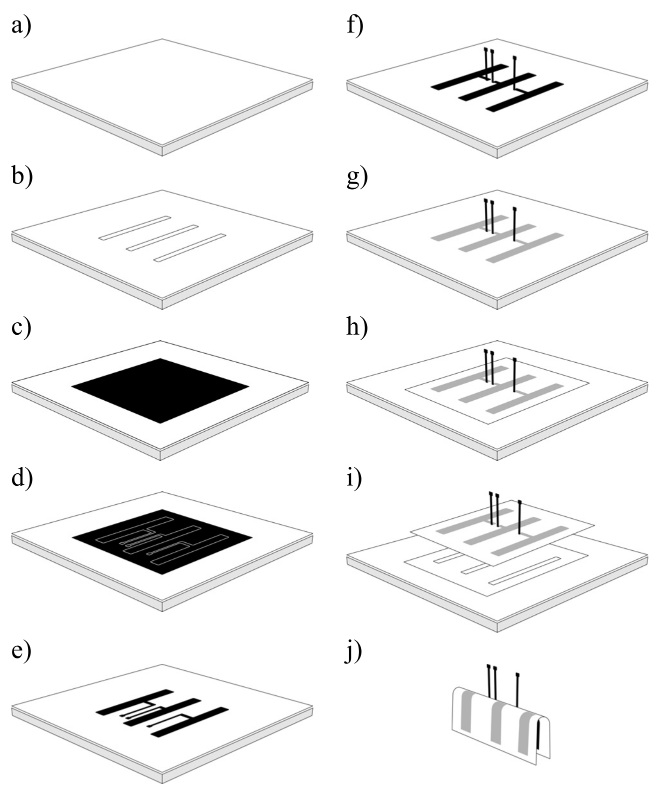

Fig. 1: Sketch of fabrication process of a single electrode slot.

2 x 2 inch² ceramic substrates are laminated with adhesive tape (type 4124, Tesa AG, Hamburg, Germany). Spin coating is applied to deposited a layer of n-heptane diluted MED-1000 medical grade silicone rubber (NuSil, Carpinteria, CA, USA, mixing ratio is 1:1 by volume, Fig. 1-a). The perimeters of the electrode contact openings (each 9 x 0.7 mm², pitch: 3.65 mm) are cut into the rubber using a Nd:YAG marking laser (DPL Genesis Marker, cab, Karlsruhe, Germany) as shown in Fig. 1-b. A 12.5 µm platinum foil (Goodfellow, Friedberg, Germany) is laminated to the rubber (Fig. 1-c) and the perimeter of electrode sites and contact 'fingers' is cut into the platinum (Fig. 1-d). Excess platinum is carefully removed using tweezers (Fig. 1-e) and the contact fingers are bent upwards (Fig. 1-f). A covering layer of silicone rubber is deposited by spin coating (Fig. 1-g) while care was taken that the contact fingers do not get coated with liquid rubber. A rectangle is laser-cut into the rubber (Fig. 1-h) and the rubber-metal-rubber structure is removed from the substrate and tape under the application of methanol (Fig. 1-i). Finally the structure is mounted in a PTFE-mould, reshaping the flat structure to an arch with contact fingers pointing upwards, the result is a single slot of a book electrode (Fig. 1-j).

B. Stimulator Chip

The stimulator chip was designed in a 0.6 µm CMOS process. It holds multiple current sources delivering up to 8 mA per channel at a maximum pulse width of 1 ms (18 V compliance voltage). After each stimulus, the electrodes are passively discharged. The stimulator circuit features various safety concepts including detection of direct current flow through electrodes or faulty cables. The chip is to be connected to a controller by a 5-wire cable, supplying power and permitting communication. The preliminary design of the stimulator chip is described elsewhere [7].

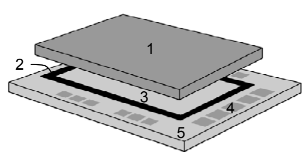

Fig. 2: Sketch of chip and lid; 1: lid, 2: metal frame, 3: area of active electronics, 4: contact pads, 5: silicon chip substrate.

C. Chip-Size Hermetic Package

In order to protect the stimulator circuitry from corrosive body fluids, it is hermetically sealed against the environment by a silicon lid. The lid (0.6 x 2.7 x 5.6 mm³ with 20 µm cavity) is placed over the area of the chip holding the actual active electronic circuitry and eutectically bonded [8, 9] to a gold frame deposited on the chip. Lidding is carried out on wafer level, that is, the entire stimulator chip wafer is aligned to 6-inch lidding wafer and the wafers are bonded using gold-silicon bonding technique. Subsequently, the bonded pair is diced to separate the sealed stimulator chips.

The hermeticity of the package of commercial electrical implants such as cochlear implants is tested by helium leakage tests. Based on the measured leak rate, the time-to-failure or at least the time-to-critical-moisture-levels can be estimated. This method cannot be applied to small volume micro packages as ours [10]. Instead an integrated capacitive humidity sensor will be included in the final stimulator chip. On request, the sensor will be used to measure the humidity under the lid coming from moisture potentially leaking into the package and send the data to the control unit [11].

D. Assembly and Interconnection

Four of the tripolar electrode arches (Fig. 1-j) with different position and lengths of the contact fingers are mounted in a PTFE mould.

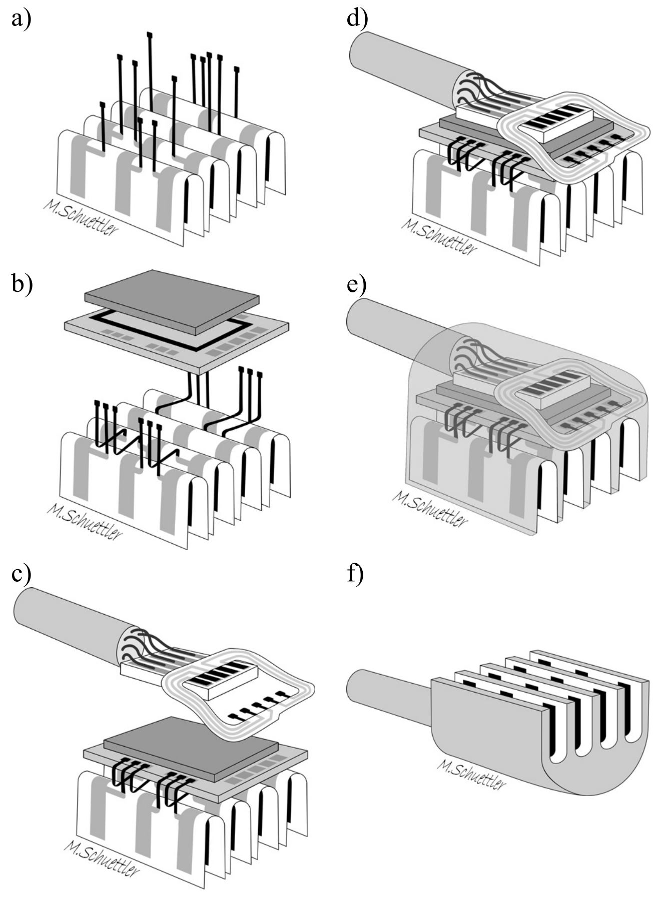

Fig. 3: Assembling the active book electrode

Fig. 3-a shows a sketch of the arrangement, not showing the actual PTFE mould. The contact fingers of the two central slots are bent to the sides, allowing the lidded stimulator chip to be placed above the slots (Fig. 3-b). After connecting the contact fingers to the pads of the chip by micro-riveting (Fig. 3-c, method described later), the cable is joined to the chip. This is done by soldering the individual wires of a 5-wire Cooper cable (Finetech Medical, Hertfortshire, UK) to Pt/Au tracks screen printed on a 380 µm thick 2.5 x 4 mm² Al_2O_3 ceramic substrate. A frame-like structure fabricated by laser-patterning of rubber and platinum foil using a process similar to the one described in section II-A is micro-riveted to the Pt/Au tracks as well as to the contact pads of the stimulator chip (Fig. 3-d). The assembly is transferred

into a PTFE mould and cast in silicone rubber using a vacuum centrifuge, electrically insulating all electrical contacts against each other and forming a mechanically robust body (Fig. 3-e). The result is a four-slot book with integrated stimulator on a 5-wire cooper cable (Fig. 3-f).

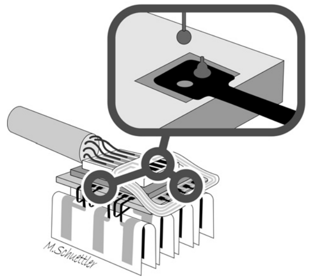

Fig. 4: Micro-riveting platinum foil to contact pads on the chip.

The method of micro-riveting, also know under the name 'micro flex' employs a thermosonic wire bonder. One end of a 25 µm gold wire is flamed to a ball, which is used for riveting the platinum foil contact finger through a 50 µm diameter hole to the underlying contact pad (Fig. 4). The riveting takes place at 150 C° while applying ultrasonic power [12]. A heatable jig was built that allows holding the chip in place just above the electrode slots. This jig was integrated into the wire bonder set up for assembly of the active book.

III. Results

Although, the development of the active book is not entirely completed yet, some encouraging preliminary results can be reported.

A. Electrode Arrays

Before casting, the laser-fabricated electrode structures have a thickness of about 120 µm. While the area of pure rubber is very flexible, the area with integrated platinum foil can be permanently deformed by bending or kinking. Fig. 5, left, shows an electrode slot before forming it to an arch. The right of Fig. 5 shows the upright contact fingers with the holes for the riveting process.

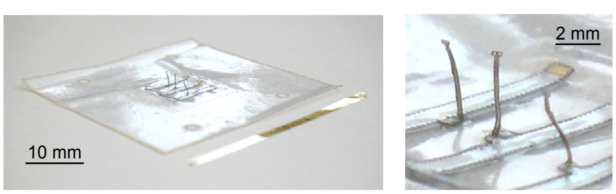

Fig. 5: Photo of laser-machined electrode slot before cutting the rubber to size and bending it to form an arch. Left: entire structure, Right: close up.

B. Stimulator Circuitry

The stimulator chip was fabricated on 6-inch wafers. Fig. 6 shows the layout of the stimulator chip. The total layout area is 3.8 x 6.1 mm². The active electronics is inside the frame for eutectic lid bonding. Outside this frame are the 17 contact pads (400 x 170 µm²).

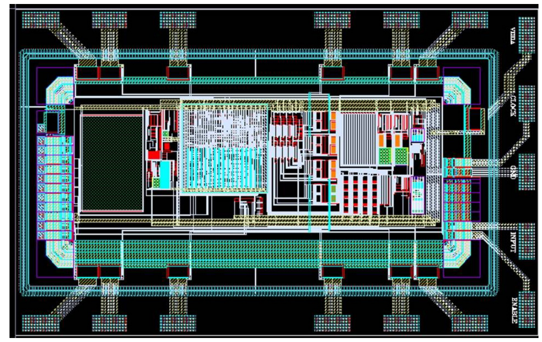

Fig. 6: Layout of the stimulator chip.

C. Chip-Size Hermetic Package

Numerous experiments on eutectic bonding have been successfully carried out on test wafers. However, the actual wafers are not lidded at the time this manuscript was completed since the lids were still in production.

D. Assembly and Interconnection

The screen printed ceramic substrate with Cooper cables soldered and a silicone/platinum frame riveted to it is shown in Fig. 7. Such a cable assembly is placed over the chip and lid and riveted to the corresponding contact pads(Fig. 8).

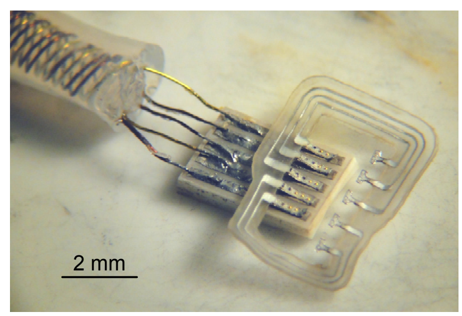

Fig. 7: Photo of screen printed ceramic substrate to which the wires of a Cooper cable are soldered and a laser-machined adapter frame was riveted.

Underneath the chip, four tripolar electrodes bent to slots can be identified (Fig. 8). Four of the contact fingers coming from the electrodes are not connected to the chip yet.

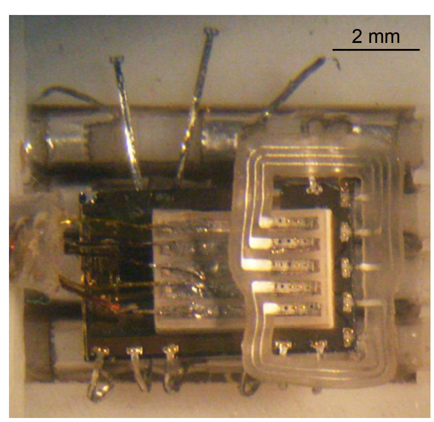

Fig. 8: Photo of intermediate step of assembly process. Note: a dummy chip without lid was used in this particular assembly.

Rubber-casting of electrode slots and Cooper cable shows the final shape of the active book electrode (Fig. 9). However, the sample in the picture is the result of a preliminary moulding experiment in which we did not incorporate chip, lid, ceramic adapter for cable assembly and the cable adapter frame.

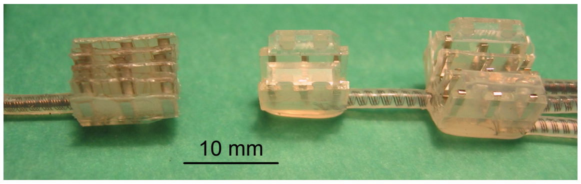

Fig. 9: Photo of active book electrode (dummy without chip) to the left and state-of-the-art sacral anterior root stimulator book electrode to the right.

IV. Discussion

The comparison of a state-of-the-art (inactive) book and the new active book shows obvious advantages of the active book design: Four slots are integrated in one book of the size of a traditional three-slot book. Fig. 9, right, discloses that four slots of the old design require two books and three cables and therefore almost double the space and three times the amount of cables breaking through the dura. However, the traditional design has proved that excellent reliability is possible at this site: no failure was reported in more than 1900 implant years [4]. The reliability of the much more complex active book remains to be investigated before clinical studies can be planned for testing the additional functions in patients.

This paper does not present the design of the active book control unit which supplies the book with power, programs the stimulator and reads humidity and other status data. This unit is currently under development.

V. Conclusion

Although the work on the active book is not finished at the time this manuscript was completed, we could show that some components have been developed and we are able to assemble them to an implantable active microdevice. Future work will address finishing the device and testing it, focussing on usability and reliability.

VI. Acknowledgements

The authors wish to thank the UK Engineering and Physical Science Research Council (EPSRC) for supporting this project under grant number EP/F009593/1.

References

[1] G.S. Brindley: "The first 500 patients with sacral anterior root stimulator implants: general description", Paraplegia. Vol. 32, No. 12, 1994, pp. 795-805.

[2] N.J.M. Rijkhoff: "Neuroprostheses to treat neurogenic bladder dysfunction: current status and future perspectives", Childs Nerv Syst, Vol. 20, 2004, pp. 75–86.

[3] D.N. Rushton, N. Donaldson, F.M.D. Barr, V.J. Harper, T.A. Perkins, P.N. Taylor, A.M. Tromans: " Lumbar Root Stimulation for Restoring Leg Function: Results in Paraplegia", Artificial Organs, Vol. 21, No. 3, 1997, pp. 180-182.

[4] T.A. Perkins, N. Donaldson, N.A.C. Hatcher, I.D. Swain, D.E. Wood: "Control of Leg-Powered Paraplegic Cycling Using Stimulation of the Lumbo-Sacral Anterior Spinal Nerve Roots", IEEE Trans Neural Systems and Rehab Eng, Vol. 10, No. 3, 2002, pp. 158-164.

[5] www.epsrc.ac.uk/newsevents/news/2010/Pages/spinalimplant.aspx, last visit: 14 January 2011.

[6] M. Schuettler, S. Stiess, B. King, G.J. Suaning: “Fabrication of Implantable Microelectrode Arrays by Laser-Cutting of Silicone Rubber and Platinum Foil”. Journal of Neural Engineering, No. 2, 2005, p. 121-128.

[7] X. Liu, A. Demosthenous, N. Donaldson: "Towards the Development of an Integrated Stimulator for Active Books", Proc IFESS, 2010 , pp. 34-36.

[8] N. Saeidi, M. Flynn, K. Y. Byun, R. Yu, I. Ferain, C. Colinge, A. Demosthenous, and N. Donaldson: “Developing a Wafer Level Gold-Polysilicon Eutectic Bond Process to Protect Sensitive Electronic Devices”, ECS Trans., Vol. 33, No. 4, 2010, pp. 83-92.

[9] M. Flynn, N. Saeidi, K. Y. Byun, R. Yu, I. Ferain, C. Colinge, A. Demosthenous, and N. Donaldson: “Characterization and Mechanical Reliability Evaluation of Gold Polysilicon Eutectic Bonded Wafers”, ECS Trans., Vol. 33, No. 4, 2010, pp. 103-112.

[10] A. Vanhoestenberghe and N. Donaldson: "The Limits of Hermeticity Test Methods for Micro-Packages", Proc. IFESS, 2010, pp. 25-27.

[11] N. Saeidi, A. Demosthenous, N. Donaldson, J. Alderman: "Design and fabrication of corrosion and humidity sensors for performance evaluation of chip scale hermetic packages for biomedical implantable devices," Proc. EMPC, 2009, pp.1-4.

[12] M. Schuettler, C. Henle, J.S. Ordonez, W. Meier, T. Guenther, T. Stieglitz: "Interconnection Technologies for Laser-Patterned Electrode Arrays". Proceedings of the IEEE EMBC Annual International Conference, 2008, pp. 3212-3215.