Implantable Flexible Electrodes for Functional Electrical Stimulation

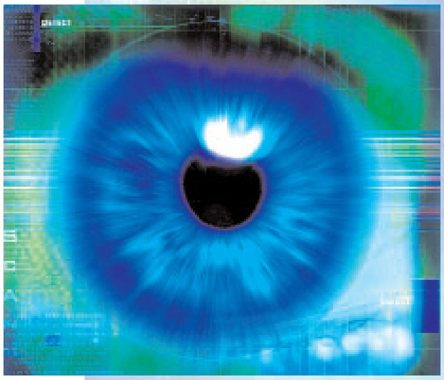

Image: Digital Vision

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A manufacturing technology has been developed to fabricate microelectrode systems with reportedly high numbers of electrodes and high reproducibility. The approach leads to flexible microimplants without the need for heavy and large titanium or ceramic housings.

Biological and technical interface

Neural prostheses are technical systems that partially substitute for the neural functions of the body that have been lost after traumatic lesions or neurological disorders. Different serious disease patterns such as apoplexy and retinitis pigmentosa and traumatic lesions lead to damage or impairment of parts of the nervous system and loss of body functions. This loss can be partially replaced by devices that stimulate the remaining intact nerves. The most well-known examples of implantable devices for functional electrical stimulation (FES) are cardiac pacemakers and cochlear implants. This article focuses on one of the core elements of implantable devices for electrical stimulation: the electrodes that build the interface between the biological and the technical world.

Implantable devices

The history of implantable devices for FES in clinical practice started in the 1960s with the development of the first heart pacemakers to replace the autonomic rhythm of the heart. Today, approximately 600 000 pacemakers are implanted per year.[1] Systems for bladder stimulation that allow paraplegics to control voiding voluntarily followed in the 1980s.[2] In cochlear implants, a complex system consisting of microphone, speech processor, transmitting unit, implantable stimulator and tubular electrode array replaces the damaged hair cells by stimulating the still-functioning auditory nerve of the patient.[3] The most recent examples of active implants for FES are stimulators to treat pain in patients with tumours and trembling caused by Parkinson's Disease, and to restore the grasp function in tetraplegics.

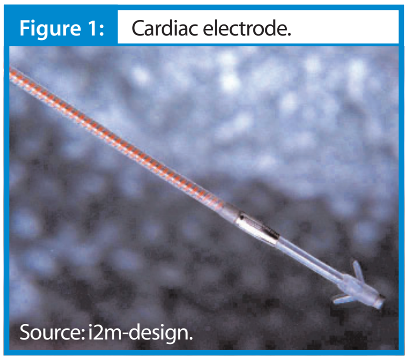
All these systems need electrodes that establish a direct contact to biological tissues such as muscles or nerves. Epimysial electrodes are sewn onto muscles, intramuscular electrodes are placed near or into the muscle tissue for heart pacemakers (Figure 1), and book-shaped electrodes are used in bladder stimulators to embed roots of the sacral nerves into the electrodes.

Electrode manufacturing

Tomorrow's implantable devices such as retinal implants or implants for lower-limb stimulation for gait and stance need a new approach for electrode systems and thus new manufacturing technologies. This is because it has been found that

- higher numbers of electrode sites and stimulation channels allow a better spatial selectivity of peripheral and central neural implants and an easier adaptation of the implant function to the patient's anatomical and physiological preconditions
- when contacting nerves, lowest weight, highest flexibility and

Figure 1: Cardiac electrode.



Source: i2m-design.

smooth edges are essential to prevent undesired tissue reactions and damage to the nervous system ■ smaller-scale electrode systems allow the use of minimally invasive surgery to minimise the stress for the patient and achieve shorter rehabilitation periods.

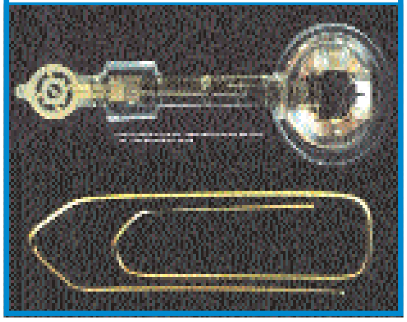
A manufacturing technology has been developed, which is based on micromachining technologies such as dry etching, to fabricate microelectrode systems with high numbers of electrodes and high reproducibility. This system approach, which is a combination of flexible micromachined substrates with hybrid assemblies of electronics and well-known encapsulation materials such as parylene and medical silicone rubber, leads to flexible microimplants without the need for heavy and large titanium or ceramic housings.

Manufacturing flexible systems

The core element of these electrode systems is a polyimide substrate, PI 2611, (HD Microsystems, www.hdmicrosystems.com) with monolithically integrated electrodes for recording and stimulation purposes, interconnection cables and connection pads for plugs, electronic circuitry and electronic components. Polyimide is used because it is flexible and lightweight, has a low water uptake of below 0.5% and can be patterned with standard microsystems technologies such as photolithography, dry etching and reactive ion etching using oxygen plasma.[4]

In these electrode systems one or more metal layers are sandwiched between layers of polyimide 5-μm thick, which serve as substrate and insulation material at the same time. The use of a dry-etching process allows openings for electrodes, connection pads and outer shapes in an arbitrary geometry arrangement. In this process, an aluminium mask protects the polyimide except for the envisioned openings for electrode sites and connection pads; the chemical and physical reactions generated by the reactive gas ions in the gas plasma remove the material from these unprotected regions. Gold is used for conducting tracks, and platinum or iridium is deposited as functional electrode material to optimise the stimulation and recording characteristics at the interface to the biological tissue. The geometrical surface area of the electrodes decreases with the square of the electrode diameter and limits the reversible charge injection over the electrodes during stimulation. By electroplating the platinum on the electrodes with a rough surface texture, the so-called platinum black is obtained; this is a coating with small grains and a roughness from which almost no light is reflected, hence the surface appears completely black. It lowers the impedance of the electrode site by approximately two decades to allow low noise recordings and increases the reversible charge injection and electrical capacity for stimulation by a comparable magnitude.[5]

Figure 2: Microimplant for epiretinal stimulation of the ganglion cells.



Polyimide-based devices have been designed and fabricated, which differ in number and geometry of electrodes and integration of electronic components.

Assembly and encapsulation

The polyimide structures can be assembled to functional systems using hybrid-assembling technologies. Surface-mount devices such as capacitors, diodes or coils are soldered or glued with conductive epoxy resin to the relating connection pads on the substrate. Application-specific integrated circuits (ASICs) are assembled with a modified stud-ball bonding technique known as MicroFlex Interconnection.[6] This technique creates "microrivets" that mechanically assemble and electrically interconnect silicon-based electronic circuitry with the interconnect pads of the flexible tapes to the same level of integration density of the interconnects. It combines the advantages of the integration density of flip chip (the integrated circuit is turned over and the connection pads point towards the substrate) or ball-grid array approaches with the advantages of wire bonding (the components are bonded on the top of the part) such as visual inspection and there is no need for an additional metal layer on the connection pads (integrated circuits dies can be used directly).

For encapsulation of the systems, Parylene C is deposited from the gas phase. The electrode areas are protected with natural rubber that is released after the vapour deposition. Another possibility is the deposition of the complete device and the opening of the electrodes by means of an excimer laser or by means of another dry-etching step. Pilot experiments show that the surface energy and roughness of the Parylene C coating could be adjusted by means of oxygen or a mixture of oxygen and tetrafluorcarbon plasma. In some applications, parts of the implant have been encapsulated with silicone rubber to obtain haptic areas that feel like tissue; these are the parts of the implant that contact tissue and achieve stability, for example, the anterior chamber of the eye.

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Biocompatibility

New technologies often involve the use of new materials as in this case for these polyimide-based electrodes. The micromachined polyimide electrodes proved to be noncytotoxic according to ISO 10993.[7] The structural biocompatibility, long-term stability and functionality of the polyimide-based electrodes were proven in chronic implantations in rat animal models.[8]

Applications

Different polyimide-based devices have been designed and fabricated, which differ in outer shape, number and geometry of electrodes, tracks and pads, integration of electronic components and combination of medical silicone and coating. Two applications are described below.

System for retinal stimulation. The polyimide and hybrid assembly technology has been successfully used in an electrode system for retinal stimulation. These stimulators, which are a joint effort of the epiretinal research group in Germany, consist of a coil for inductive signal and energy transmission, a decoder and a stimulator ASIC and 24 electrode sites (Figure 2). The electrode sites are coated with platinum black to decrease the impedance of the electrode sites and thereby achieve better stimulation results. At present, systems for retinal stimulation are being tested in in vivo experiments.

Figure 3: Polyimide sieve electrode with silicone guidance channels (inner diameter of the guidance channel is approximately 1.4mm) for contacting peripheral nerves for the control of artificial limbs.

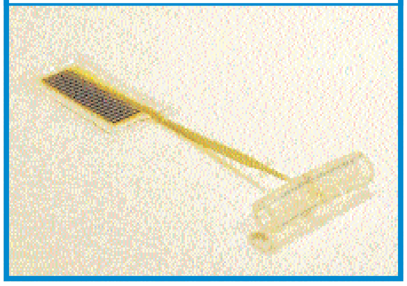
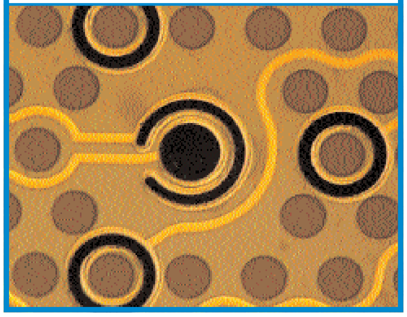


Figure 4: A polyimide-based electrode system with holes (40 μm in diameter) for regenerating peripheral nerves and circular electrode for stimulation and recording purposes.



System to control artificial limbs. Sieve electrodes based on polyimide have been fabricated by micromachining for the control of artificial limbs after amputation. This electrode system consists of a polyimide foil that contains numerous holes and 19 circular electrode sites around some of them (Figures 3 and 4). All the electrodes are coated with platinum black. While the regenerating peripheral nerves grow through the holes, afferent nerves can be stimulated to give the patient sensory feedback, and signals from efferent nerves can be recorded to control artificial limbs. Artificial arms with a myoelectrically controlled gripping function (muscle signals are used as control input for the artifical limb) already exist on the market and devices with higher functionality and sensory feedback are in the research and development phase.

Acknowledgement

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References

1. "Microsystems and Nanotechnology in the Medical and Biomedical Market," Technology for Industry Ltd, Littleport, Ely, UK, 2002.
2. G.S. Brindley, *Paraplegia*, **32**, pp.795, 1994.
3. P.H. Van de Heyning et al., "Cochlear Implantation: An Overview of Existing Implants," *Acta Otorhinolaryngol Belg.* **52(2)**, pp.91–103, 1998.
4. T. Stieglitz et al., "Micromachined, Polyimide-Based Devices for Flexible Neural Interfaces," *Biomedical Microdevices*, **2**, pp.283–294, 2000.
5. A. Staiger, M. Schuettler and T. Stieglitz, "Impedanzsenkung flexibler Mikroelektroden durch galvanische Abscheidung von Pt Black und Iridiumoxid," *Biomedizinische Technik*, **46, Suppl.**, pp.500–501, 2001.
6. J.-U. Meyer et al., "High Density Interconnects and Flexible Hybrid Assemblies for Active Biomedical Implants," *IEEE Transactions on Advanced Packaging*, **24**, pp.366–374, 2001.
7. T. Stieglitz et al., *Biomaterials*, submitted 2003.
8. F.J. Rodríguez et al., "Polyimide-Cuff Electrodes for Peripheral Nerve Stimulation," *J. Neuroscience Methods*, **98**, pp.105–118, 2000. mdt

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