

Editorial

Electronic implants: a new challenge in the treatment of old diseases and functional disorders

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Micro-engineering, microelectronics and related technologies are the sciences involved in the development of a constellation of new devices, the use of which is yielding promising results in the treatment of a series of different diseases and disorders with a great social impact. They mostly act to replace, improve or enhance simple impaired functions such as heart pacing, urinary and faecal continence, gastric emptying, but also more complex functions such as the production and chrono-modulated delivery of insulin. Furthermore, specially designed implants may reverse the loss of senses such as deafness (well established technology) or blindness (research in progress).

All these devices have been developed and are implanted not only with a curative intent, which obviously remains the main endpoint of such research lines, but also with the intent to improve the patient's quality of life which is strongly affected by the impairment of physiological functions.

Some of the clinical applications of the electronic implants mentioned above are thoroughly described in the topic articles of this MITAT issue.

Finally, there is a field of application where electronic implants have been designed not to replace a function but yet to improve the patient's quality of life: the treatment of chronic pain. As for other neurostimulation procedures the technique uses a small system that is surgically placed under the skin to send controlled mild electrical pulses to targeted areas of the nervous system. The electrical pulses block pain signals from reaching the brain: they work in the specific areas of the nervous system where

the pain signals travel and therefore can be directed to cover the areas of the body where patients feel pain. There is a number of studies concerning spinal cord stimulation in the treatment of chronic, intractable low back pain [1, 2] and also chronic reflex sympathetic dystrophy (complex regional pain syndrome) [3] in selected patients: all of them showed that electrical stimulation of the spinal cord may reduce pain, improve quality of life [1, 3] and that the initial healthcare acquisition costs of implantation are consistently offset by reduction in post-implant healthcare resource demands and costs [2].

A side effect of the implant of electrodes into the spine and use of electrical pulses for pain-relief was found by chance by researchers of Piedmont Anesthesia and Pain Consultants in North Carolina: the possibility to cure orgasmic dysfunction in women (source: BBC News Online).

In the wide spectrum of neuromodulation and neurostimulation, brain stimulation has also been used to treat specific neurological disorders. Deep brain stimulators (electrodes inserted deep into the left and right movement areas of the brain) have been successfully employed for curing Parkinson's Disease symptoms with improvement of tremors, slowed movements and involuntary movements (source: Massachusetts General Hospital Peripheral Neuropathy Web Forum).

A common denominator of almost all implants for neurological stimulation is their counter-position to other treatment options, mainly surgical procedures, with great invasiveness and often poor results. On the opposite, neuro-stimulators only require minimally

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invasive surgical procedures: thus, the surgical approach, while diminishing overall treatment invasiveness, further contributes to improve post-treatment quality of life.

Impairment of different neurological functions (sexual, urinary, intestinal) may have an iatrogenic pathogenesis. A word apart is needed to stress the importance of preventing nerve injuries during abdominal and pelvic surgery responsible for most such postoperative dysfunctions. In this respect a major contribution has been made over the last years by the work of M. Possover from Cologne, the results of which are reported in this issue's article on "laparoscopic neuro-navigation".

Future progress

Research in the field of electronic implants is expanding. We have already mentioned the implants used to restore impaired senses: the first cochlear implant was developed and inserted in an ear by Graham Clark of the Melbourne University in 1978 [4]. Since the implantation of this rather primitive device, new multi-channel implants have been developed and implanted even in children under two years of age with severe to profound hearing loss.

Eye implants have been designed to take the place of light-sensitive cells in the retina in an attempt to reverse blindness. Existing devices are chips that convert light into electronic impulses. Those are then fed to the brain through the optic nerve. Another new and more attractive way to achieve that is obtained with devices that work chemically rather than electronically: in such a case the light strikes the chip, causing it to release neurotransmitters that will stimulate retinal nerve cells.

Electronic implants have been used to treat patients with diabetes. This is a more complex technology used to continuously monitor glucose levels in the human tissues and deliver insulin as requested. The ultimate aim of such a combination of a sensor with an electronic delivery pump is to have an implantable artificial pancreatic beta-cell substitute.

Electronic sensors have also been integrated in knee prostheses to monitor forces and better understand the load-carrying capability of bone and prosthesis when the patient walks, climbs stairs or exercises. This new technology, developed by researchers of the Scripps Clinic Center for Orthopaedic Research and Education, consists of an electronic knee containing a transducer, a micro-transmitter and an antenna that allow transmission of force measurements into a computer-readable format. Data are thus transmitted in real-time to

clinicians and researchers. In such a case electronics is used not to cure but to give a better knowledge on how to design prostheses for knee replacement in the future (source: www.scripps.org/scrippsnews).

Future advances also come from the possibility to miniaturize electronic devices. A new class of implants is made possible by the use of monolithic electronic design and implant packaging. These devices are small enough to be implanted by percutaneous injection through large gauge hypodermic needles with no need for surgical manoeuvres. These micro-modules which may act as micro-stimulators are designed for functional neuromuscular stimulation. Their future employment encompasses the following: stimulation of paralyzed muscles, conventional neuromuscular stimulation and neuromodulatory functions such as laryngeal stimulation and sleep apnea [5].

Advances in this field are often consequential to advances in related technology areas. An example of that is given by the technology needed for the construction of interfaces with living tissues. Materials, shapes and bio-compatibility are of utmost relevance and therefore continuously under evaluation to improve the effectiveness of electronic implants. Brain implants such as those introduced into the movement areas mentioned above or into the hypothalamus to treat specific cephalic pains may benefit from further developments in interface design and manufacturing. Polymer surface could improve the efficiency of electrodes implanted in the brain: rough surfaced, fuzzy polymers with various grooves and depressions have been designed to mesh better with neurones, thus diminishing the risk of blocking the signal by losing contact with tissue (source: University of Michigan).

The topic section of the MITAT December issue is a spotlight on some of the many present therapeutic uses of electronic implants with the aim to introduce the reader to them and show their actual results. We are sure that ongoing investigations on the electronic implants under development and their clinical application and a deeper analysis of the technologies in this area not covered in this issue will be most likely a matter for the topic section of our journal in the years to come.

One of the plenary sessions of the annual Conference of the Society for Medical Innovation and Technology (the 16th in a row), which will be held this year in Rome from December 16 to 18, is going to focus on new frontiers of electronic implants. The architecture of this session and all the others of the scientific program will follow the philosophy of

the last Conference in Amsterdam. The aim is to try and combine lectures on the most sophisticated technologies with lectures on their present and future clinical applications, offering to the audience a wide and balanced spectrum of advanced technology research lines and high-tech multidisciplinary treatments of benign and malignant diseases.

The 2004 conference has two more aims. One is to enhance the exchange of experiences and ideas between scientists who work in the field of technology and clinical sciences. Thus, the basic technology sciences and research should be made less abstract for the majority of physicians who are attending a medical congress; on the other hand engineers, physicists, and informatics experts will be made aware of the actual problems to be overcome in the clinical field.

The last and more challenging aim is to make the 2004 SMIT conference an attractive meeting for young surgeons, radiologists, physicians, engineers and all other scientists coming from all over the world. Our society is rather young, needs to grow up and be joined by young researchers. The annual conference

is our window and we will do our very best to make this 3-day event in Rome appealing and above all scientifically fruitful!

References

- 1 Ohmeiss DD, Rahsbaun RF. Patient satisfaction with spinal cord stimulation for predominant complaints of chronic, intractable low back pain. *Spine J* 2000;1: 358–63.
- 2 Taylor RS, Taylor RJ, Van Buyten JP, Buchser E, *et al.* The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. *J Pain Symptom Manage* 2004;27:370–8.
- 3 Kemler MA, Barendse GA, van Kleef M, de Vet HC, *et al.* Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med* 2000;24:1811.
- 4 Clark GM, Tong YC, Bailey QR, Black RC, *et al.* New TA multiple-electrode cochlear implant. *Journal of the Otolaryngological Society of Australia* 1978;4:208–12.
- 5 Troyk PR. Injectable electronic identification, monitoring and stimulation systems. *Annu rev bioeng* 1999;1:177–209.