Technology Development for Medical Implants

D. Hodgins
European Technology for Business Ltd, Codicote, UK

Work on new technologies for biomaterials and an implantable power source for implants is described here. Common requirements have been identified to start the development of technological solutions that can be applied to a range of products.

In search of improved interaction
Healthy Aims is a four-year project funded by the European Commission’s Framework 6 Programme to develop a range of medical implants. In its first year, considerable effort has been put into developing the technologies to be used in these products. This article focuses on developments in biomaterials and power sources.

Any device that is to be implanted into the body will interact with the living environment around it. Understanding this interaction is crucial to ensure optimum performance of the device and to minimise unwanted effects to the body. By developing new biomaterials, the project hopes to direct and improve that interaction.

Requirements for a biocompatible coating
From the outset, it became clear that although each device had a requirement for a biocompatible biomaterial coating, the specific needs of each differed according to the three-dimensional (3D) form of each device and the environment into which it is to be sited. The common requirements were identified and collated to produce a specification document from which the types of materials to be developed could be agreed and work could begin. It is, however, recognised that materials proven in the laboratory are not likely to complete, within the lifetime of the project, the clinical trials necessary for use in implantable device coatings. The agreed main requirements were:

- The need for a biocompatible, impermeable material able to encapsulate complex 3D geometries and prevent the ingress of moisture and leaching of potentially toxic components from within the device.
- While remaining biocompatible, the material must prevent the cell and protein adhesion that causes biofouling of devices; the prevention of bacterial infection would also be useful.
- Prevention of biofouling at the active electrode surface would minimise the impedance between the electrode and nerve allowing more efficient devices with reduced power needs.

Environmental concerns
The specific needs of each device are often dictated by the biological system with which they integrate. The site of implantation within the body is important because the different cell types, for example, those of the nervous system or muscle, behave in different ways. The extracellular environment can also be different; for example, the composition of urine is not the same as that of fluids in the retina. The lifespan of the device will also impose specifications. Cochlear implants can be in place for up to 20 years, while other devices may be implanted for only 24 hours for testing purposes.

The general requirements and the individual-specific requirements collated by the biomaterials experts have formed the basis of their investigations in year one. To date, an approach has been defined and material families have been identified that address these issues. Each family has been tailored to adhere to the different base materials of each device. The synthesis of the polymer coatings is underway and their analysis has begun. During the second year of the project, these materials will be developed and tested before being applied directly to the product components. Trials will then be conducted, initially in simulated...
environments. The results from these trials will be used to focus the work and ascertain if one material is suitable for all applications or if a range of materials is required.

**Bone implants**

One example that INEX (www.inex.org.uk) and the University of Newcastle upon Tyne (www.ncl.ac.uk) are associated with is the development of a stable interaction between bone and implants. This is essential to secure the long life span required for joint replacements. Biomaterials with modified surface features have been examined to investigate their interactions with bone cells or osteoblasts. Figure 1 shows osteoblast cells growing across a biomaterial surface structured with subcellular scale columnar features. These physical cues can influence cell adhesion and alignment. Cell nuclei are visible in blue (stained with Dapi) and the actin cytoskeleton of the cell is labelled in green (labelled with phalloidin).

The development of biomaterial technology for the Healthy Aims implant applications demonstrates the difficulty of developing a single approach for a range of product applications. This is also true for microelectrodes and micropackaging work. A similar methodology has been used with biomaterials and radio-frequency communications to develop the specification based on the common product requirements while considering the individual needs of each end product.

**Power-source developments**

A slightly different approach has been taken in the development of a power source. Only one secondary cell was to be developed, thus it is essential that this meets the requirements of all devices requiring a rechargeable, implantable power source, in this case, for the cochlear implant and the Functional Electrical Stimulator (FES). It was critical to consider the required number of hours of use and the charging and total lifetime of the battery. Fortunately, the cochlear and FES require a minimum of 10 years and ideally 16 hours of use and <8 hours for charging. It has also been agreed that the battery measuring 3–5 mm × 10 mm × 20 mm will be encapsulated within the implant, producing just one sealed unit (see Figure 2). This considerably simplified the packaging and biomaterial coating requirements.

Work is now focussing on developing a lithium-ion composition that will withstand more than 3500 charges without losing more than 30% of the original capacity. Recharging is another extremely important parameter that has to be considered. The charging circuit needs to be inductively coupled to the implant, the heat generated must produce a temperature rise of no more than 2°C, and there must be no outgassing.

The charging circuit is being developed jointly with the battery developers Saft (www.saftbatteries.com) and CEA/Liten (www.ceafrench.fr), and the two end users, CTC (www.cochlear.com) and Finetech Medical (www.finetechnical-medical.co.uk). At the end of the project, Saft intends to have a qualified battery that can be commercially exploited into other medical implants.

The Healthy Aims team is also interested in developing longer-term solutions. An alternative power source would be a biofuel cell that provides renewable energy derived from recently living organisms or their metabolic byproducts. The biofuel cell is being investigated for use with low-power devices. Development is still at an early stage and it will be another year before a proof of concept is available.

**Long-term perspective**

Although technology development has revealed difficulties in applying common strategies to complex problems, it is clear that it is possible to develop technologies for a range of products. It is hoped that the solutions that develop from this work will be applied to other medical implants in the future. Thus, in the long term it is believed that the Healthy Aims project will help the future development of existing implants and drive the development of new ones to the benefit of all.

The Healthy Aims Project is looking for new partners to extend the project in certain areas. Calls for tenders will be on the Healthy Aims website for

- clinical experts with medical applications for electrical stimulation, including urinary incontinence
- a company to provide mobile communications from the Body Area Network
- a technology/product roadmap for micro- and nanotechnology applications in medical devices
- an end manufacturer to exploit the intracranial pressure sensor.

To find out more, visit www.healthyaims.org

**Dr Diana Hodgins**

is Managing Director of European Technology for Business Ltd, Codicote Innovation Centre, St Albans Road, Codicote SE4 8WH, UK, tel. +44 1438 822 822, fax +44 1438 822 811, e-mail info@etb.co.uk www.etb.co.uk and Project Co-ordinator for Healthy Aims www.healthyaims.org