Deve/oping Innovative Implantable Medical Devices

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The market for electronically driven implantable devices is set to expand significantly. This article examines the current potential and some of the products under development.

Hindrances to innovation
Currently there are few implanted, electronically driven medical devices available for citizens in the European Union (EU) and worldwide. There are a number of reasons for this. From the technology point of view, these include
■ limited materials available for encapsulation in the human body
■ no long-life implantable batteries
■ packaging and interconnect systems have not been developed for flexible three-dimensional (3D) microstructures
■ data and power communications from in body to on, or close to, the body are limited
■ microstructures, microsensors and microactuators have not been developed for medical applications.

From the clinical point of view, the reasons are simply that the system concepts developed by clinicians often cannot be produced because of a lack of resources or a lack of access to the relevant technology providers.

Perhaps most importantly from the commercial point of view, the reasons are:
■ The application volumes are often low and hence are not of interest to large organisations.
■ The time to market as a result of clinical trials and regulatory approval is long, which discourages large organisations and makes it difficult for small-medium enterprises (SMEs) to invest in product development.
■ The regulatory procedure for obtaining approvals requires the highest quality standards within all organisations involved in the development of the product and is extremely labour intensive.

Furthermore, developing these products is often prohibitively expensive, particularly for SMEs, and the risk is high.

Route to product development
Looking at the available products today, most focus on applications relating to the heart and blood system, for example, pacemakers. This is because research activities, including clinical research, have been well funded in this area and the potential market is reasonably large. As a result, the main players are large organisations.

There are also a few other implants available, including a cochlear implant for the profoundly deaf and a bladder stimulator for people with no bladder control. More recently, two types of artificial urethral sphincters for people with manual dexterity have become available and a simple two-channel functional electrical stimulator (FES) implant for “dropped foot” sufferers. These are mostly produced by SMEs in Europe and have demonstrated that smaller high-risk niche markets can be successfully addressed by SMEs.

How can the number be increased of electronically driven medical implants developed? This question was put to the NEXUS Medical Devices User Supplier Club (USC) in 2002 (www.nexus-mems.com). The USC has approximately 100 members. These include academics and design groups with specialist expertise in micro- and nanotechnology, biomaterial experts, component manufacturers, medical device end-user manufacturers and clinicians/surgeons. With this mix of skills and expertise the members were able to
■ define what the end user, namely, citizens in the EU and worldwide, require
■ determine how the concept could be presented as a system
■ break the system down into components
■ design the components
■ build the components into a system
■ test the system in labs/animal trials/clinical trials
■ obtain approvals
■ market the product.

The next phase brought the members together to discuss the different
potential medical implants that are not currently on the market and next to ascertain which concepts would make most commercial sense to the members. This procedure is shown schematically in Figure 1. A number of meetings took place when different concepts were discussed, as shown in Figure 2.

Defining core technologies
During the discussions, it became clear that there were a range of electrically driven medical implants focusing on the nervous system that would utilise similar technologies. As a result, it was agreed that a consortium would be put together to develop the core technologies for a specific range of implants. The core technologies were defined as:

- radio frequency communications suitable for implanting into the human body
- an implantable power source
- biocompatible materials that would include addressing the problem of maintaining electrical connectivity to the body in a stable manner for extended periods
- microelectrodes to connect the power source to the nerves
- microassembly techniques for 3D, flexible structures requiring coating with biomaterials
- sensors and actuators to fit inside the body.

The products chosen were:
- a cochlear (enhancement of existing high-cost, low-resolution system)
- a retina
- FESs for upper and lower limbs (enhancement over simple two-channel “dropped foot”)
- an artificial intraurethral sphincter
- a sphincter sensor
- a pressure sensor for long-term implant (>10 years)
- a glaucoma sensor.

The Consortium was developed to address the entire project needs from basic research through to clinical trials and subsequent regulation approvals. Complementary skills in the core technologies were included to ensure that the products did not focus on using one technology, but would develop a range of methodologies using knowledge from a number of important research areas.

Success is a structured partnership
The 26-partner Consortium from nine countries was successful in the first call for funding under the European Community Sixth Framework Programme, Information Society Technologies, Microsystems. The Healthy Aims project started on 1 December 2003 and will run for four years. At the end of the four years some of the products will have completed pilot clinical trials and others will be ready for trials. It is anticipated that as the project progresses, new products will emerge using the core technologies developed in the project. It is also anticipated that the Consortium will be able to embrace the process of obtaining regulatory approvals for new electrically operated implants far better than individual companies are able to do at present.

This project is an excellent example of how a well-structured partnership with experts in each of the areas can tackle highly innovative, high-risk topics. The medical sector is one area where the market place is well defined and predictable. With new emerging technologies such as microsystems, nanotechnology and biomaterials, the opportunities for developing a range of new medical implants is high. The Healthy Aims Consortium firmly believes in this goal and four years from now will have a range of products to prove it.

The Healthy Aims project is also a prime example of how a network can produce strong partnerships, which will ultimately bring new products to the market. Partnerships like this one include SMEs, large enterprises and academics with no main driving force from any one sector. It is hoped that the networks developed within other NEXUS USCIs, including pharmaceutical, will be able to build and strengthen their partnerships to address other applications. Other complementary networks such as the United Kingdom Medical Devices Faraday Partnership (www.medical-devices-faraday.com) can also exploit this model for other medical applications and provide a dissemination vehicle for the Healthy Aims deliverables/outcomes.

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