Working On The Design Of New Medical Implants

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This report on work currently underway on innovative implants describes the progress being made with wireless communication and the lessons learned after one year of development of an artificial sphincter and an intracranial pressure sensor.

Major funded project
In the past 10 years there has been a lot of discussion about new medical implants, yet there are still very few widely available on the market. In 2003, the European Commission funded a major project called “Healthy Aims” to develop a range of medical implants. This 26-partner, €26-million project has just completed its first year and has produced some incredible results. It has also revealed some challenges that need to be overcome if the products are going to be commercialised in the future. Some of these are technical, others relate to commercial and clinical issues.

Technology developments
The Healthy Aims project has produced a number of technology developments that are applied directly to medical products. These are
- radio frequency (RF) communications from within the body to 3-m away
- microelectrodes
- micropackaging
- biomaterials
- a power source
- sensors and actuator
- an inertial measuring unit.

The medical products being developed under the project are
- a cochlear implant
- a retina implant and glaucoma sensor
- functional electrical stimulator (FES) initially targeted at upper-limb movement
- an artificial intraurethral sphincter and sphincter sensor
- an intracranial pressure sensor.

Defining specifications for the technologies proved difficult because they are dependent on the product requirements. Working closely with the product designers enabled draft outline specifications to be produced in the first three months and technology development to start.

Wireless communication
From the RF communications aspect, the overall requirement is for data to be transmitted from the implant to an external unit up to 3-m away. However, it was found that each implant has different performance requirements. Some such as the retina implant require a high-speed, high-density data transfer; others such as the intracranial pressure sensor only transmit short bursts of data on an occasional basis. In addition, the initial specification to transmit data at the medical frequency of 402–405 MHz was not suitable for all applications, because two of the devices, the glaucoma sensor and the intracranial-pressure sensor were using inductive coupling for power and preferred to use the same system for data transfer.

To accommodate these varying requirements, microelectronics company, Zarlink, (Caldicot, UK, www.zarlink.com) has developed a range of solutions. The company applied its ultra-low power RF design expertise to the low-frequency inductive systems and helped source the required hardware. For those products, namely the cochlear implant and the FES, that can work at 402–405 MHz, the system has been configured to accommodate the highest data rate, and software was developed to minimise the power consumption for products transmitting at a low data rate.

Customised in-body antennae
In-body antenna design is another factor that requires a unique approach for each product. Each device is implanted and thus compact size is an important consideration. Designers also have to consider the effects of human tissue on wireless signals. Various tissues within the human body such as muscle, fat and skin have unique characteristics that will attenuate the signal, alter its path and may even cause it to reflect back onto itself (Figure 1). Therefore, a generic antenna design is only suitable for the development phase and must then be
followed by a specific design for each product.

Data-transfer protocol
A final point that relates to in-body RF communications is that there is no standard protocol for data transfer. The Medical Implant Communication System (MICS) only defines the frequency, power limits, spectral aspects and how the device is used in communications mode (Table 1). However, MICS is quickly becoming the standard governing implant communications for the Federal Communications Commission and the European Telecommunications Standards Institute. Moreover, with so few medical implants with integrated RF links, there is no major industrial driver to force the commercial development of a protocol. The Healthy Aims project intends to develop a large percentage of implants using the MICS standard.

Solutions for other applications
At the end of its first year, Healthy Aims has highlighted difficulties associated with developing a common body area network linking implants to a base station up to 3-m away. The determination of all the parties involved has enabled the work to progress on each of the products, and solutions will be realised. Moreover, the solutions found to date should meet other product requirements in the future. On the product side, some equally difficult challenges have been met over the past year. These have related to the combination of clinical, commercial and technical aspects.

Artificial sphincter
This implant is a good example of one of the most challenging products. The original concept was to develop a disposable intrarectal catheter for long-term catheter users. Combining all components into a device to fit into the urethra was always going to be an extremely difficult technical challenge. However, as with any concept design, when preparing the system-requirements specification, the original outline specification was extended. Initially, this was to increase the number of days of usage from 30 to 90 days, inline with operational practices and competitive pressures, which are anticipating a regulatory review of urinary catheters. In addition, the cost target was reduced to take into account the difficulties experienced with selling existing incontinence devices. Finally, the clinical teams reduced the volume from year one of the Healthy Aims project? Certainly it can be said that specifications are critical before any design work is undertaken. Also, to help ensure the long-term commercial viability of any new product, a design and development team should not be scared of altering the specifications to accord with clinical and commercial needs. This may lead to radical design changes, but providing these align the product so that a realistic exploitation plan can be written, then it is likely to achieve long-term success on the market. This is the approach being followed in the Healthy Aims project, rather than simply developing technically challenging products that have little chance of commercial success.

Intracranial pressure sensor
Another product that raised interesting commercial challenges is the intracranial pressure sensor. This Class III passive implant will be the first commercial product of its type and, therefore, requires an innovative company to obtain CE-marking and subsequently exploit the product. The Healthy Aims team is keen to include new commercial partners to exploit this and similar product innovations and is planning to put out a tender this year (www.healthyaims.org).

Learning from experience
So, what are the major lessons learned from year one of the Healthy Aims project? Certainly it can be said that specifications are critical before any design work is undertaken. Also, to help ensure the long-term commercial viability of any new product, a design and development team should not be scared of altering the specifications to accord with clinical and commercial needs. This may lead to radical design changes, but providing these align the product so that a realistic exploitation plan can be written, then it is likely to achieve long-term success on the market. This is the approach being followed in the Healthy Aims project, rather than simply developing technically challenging products that have little chance of commercial success.

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