The integration of bio, micro and nano technologies to produce a range of Medical Implants from the Healthy Aims Project

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Abstract – This paper describes how new medical implants are being developed under the Healthy Aims Project, integrating a range of technologies.

INTRODUCTION

New intelligent implantable medical devices integrate a wide variety of technologies, processes and materials. Often the development of these new medical products extend the state of the art in these areas, and provide the necessary market pull for future exploitation.

Healthy Aims is an EC project, funded under the FP6 1st programme, defined in ref. [1]. The aim of this project is to produce intelligent medical implants by developing technologies beyond the current state of the art, and integrating these into exploitable products.

TECHNOLOGIES

The technologies being pursued are:

- Local body area network for data communication from in the body to a base unit up to 3m away.
- Micro and nano-electrodes to link nerves and muscles in the body.
- Micropacking techniques to encapsulate the active implants in the smallest space envelop available.
- Biomaterials for coating the implant and enhancing the electrical path from the electrodes to the nerves.
- Implantable power source that can power the active implant for up to 25 yrs.
- Implantable sensors that are required to monitor specific parameters in the body over a period of time.
- Motion sensing system to provide trigger mechanism for one implant

MEDICAL PRODUCTS

The intelligent implants and sensor listed were chosen because they will extend these technologies.

- Cochlear implant
- Retina implant
- Functional electrical stimulation (FES) implant
- Intra-cranial pressure sensor implant
- Glaucoma and sphincter sensor
- Artificial sphincter

ACTIVITIES RELATING TO THE TECHNOLOGY DEVELOPMENT

One year into the project the specifications for all the products have been produced, and from this the technologies specifications have been developed. Of particular interest is how each implant requires a slight variation on the technology. For example, a biocompatible material that prevents any growth on the surface is a generic requirement. However, brain fluid has different characteristics to urine, upper arm tissue and body fluid etc. Similarly, enhancing conductivity possibly by cell growth in the eye, cochlear and upper arm may not result in one unique solution. Figure 1 shows how neurite growth can be encouraged to grow in particular directions as defined by grooves at the μm scale.

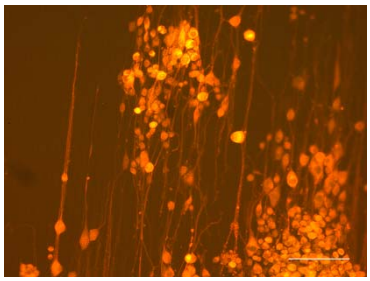


Fig 1: Neurite growth on 3D grooves 10μm wide

The discussions highlighted the main requirements:

- The need for a biocompatible, impermeable material able to encapsulate complex three dimensional geometries; preventing 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 bio-fouling of devices. The prevention of bacterial infection would also be useful.
- Prevention of bio-fouling at the active electrode surface would minimize the impedance between the electrode and nerve making for more efficient devices with reduced power needs.

The specific needs of each device are often dictated by the biological system that they integrate with. The site of implantation within the body is important as the different cell types of, for example, the nervous system and muscle behave

in different ways. And the extracellular environment can also be different; the composition of urine is not the same as that of the fluids within the retina. The lifespan of the device will also impose specifications. Some cochlear implants are in place for more than 20 years, while other devices may be implanted for only 24 hours for testing purposes.

Defining the different specific needs has possibly revealed why bio materials companies have so far not been keen to develop new materials. A considerable amount of research is required to establish first a family and then specific material(s) that may meet all the requirements. Once proven in the lab environment the material must undergo first in vitro and then in vivo trials) in order to validate these materials for human implants. This then qualifies the material(s) for the specific applications but not for general use. Most biomaterials companies are extremely cautious from entering these markets as they are high risk, low volume niche applications, compared to on the body applications. It is, however, anticipated that at the end of this project the material selection, which is currently restricted to titanium or silicone, will be extended and these new materials will be commercially available.

Implantable secondary power sources are essential for active implants, yet these are not commercially available. The aim within this project was to develop a suitable device that could be used for a variety of new intelligent active implants, and Saft were keen to develop this product within the project. In year 1 when developing the specifications it became clear that power requirement, time of use between charging and charging time all vary, and yet it was necessary to develop one specification to meet all the known requirements, compromising some aspects of each product design. The development work has focussed on the electrochemistry selection, based on Li-ion technology, since this has a major impact on the lifetime charging/ discharging parameters. Charging is also important for in body applications, as significant temperature rises are obviously not allowed. Accelerated aging tests and cycling has so far revealed one material combination that looks likely to be acceptable for long term in body usage. At the end of the 4 year project the chosen design will have completed all the necessary qualification tests and Saft will then start the process of commercially exploiting the product for other new active implant applications.

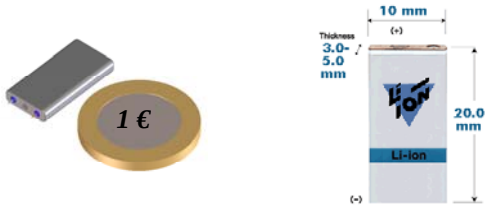


Fig 2: target size for the secondary cell

In the longer term it is believed that implantable biofuel cells, will be able to transform internal body energy to electrical energy. The work in the first year has revealed that time stability is one technology challenge to overcome, and the second is power. Preliminary results indicate that a short life, low power device may be achievable, either using an enzymatic or direct biofuel cell design.

For the communications aspect the overall requirement was for data to be transmitted from the implant to an external unit up to 3m away, at the allocated frequency for medical products of 402-405MHz, as defined in Table 1, and shown schematically in Figure 3[Ref 3].

Downlink Data Rate *(Basestation to Implant)*	250 kbit/s
Uplink Data Rate *(Implant to Basestation)*	500 kbit/s
Output Power	Limited to 25 μW EIRP
Range	1.5 – 3.0 metres

Table 1: Specification for the MICS chip

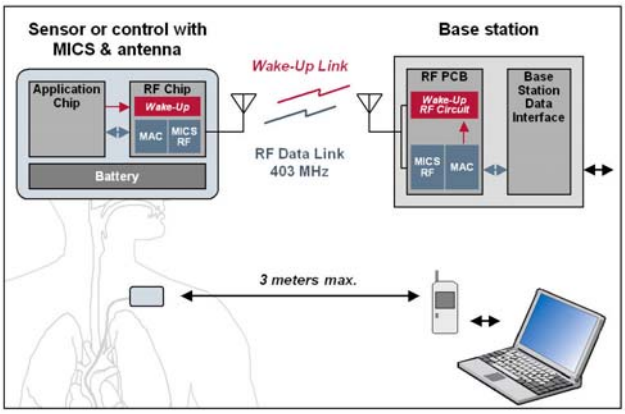
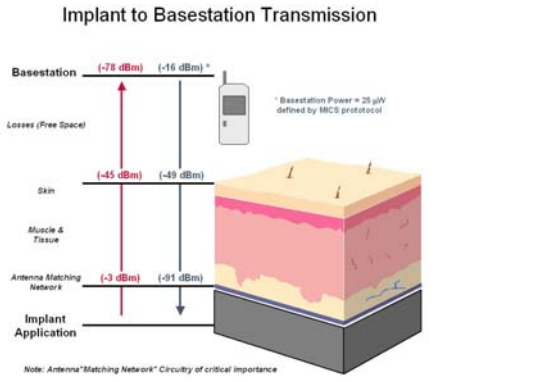


Fig 3: Schematic of the complete RF communications system

It was revealed during the specification phase that each implant has differing specific requirements, particularly in terms of data rate and density of data transfer. Another factor that requires a different solution for each of the products is the antenna design. Each device is implanted and must therefore transmit through different parts of the anatomy, and has a different space envelop available. Figure 4 shows schematically the losses expected through the body and air from the implant to the Base station.



Thus a genetic design is only suitable for the development phase, and must then be followed by a specific design for each product. Zarlink, the partner responsible for developing this aspect of the system, has focused their effort on developing a suitable antenna system, including the antenna matching network. This is a critical aspect of the design to ensure that enough power is to be received by the implant and from the implant to the base station. The Medical Implant Communications Service (MICS) stipulated that the power from the base station to the implant must not exceed 25µW. Zarlink are confident from preliminary trials in year 1 that their proposed solution will be suitable for these and future implant applications. A final point that relates to the in-body RF communications is that there is no standard protocol for data transfer. The Medical Implant Communication Service (MICS) only defines the frequency, power limits, spectral aspects and how the device is used in communications mode. However, MICS is fast becoming the de facto standard governing implant communications for the FCC (Federal Communications Commission) and ETSI (European Telecommunications Standards Institute).

SUMMARY

This paper has highlighted some of the technology challenges which are being addressed in order to develop new medical implants. These cover micro and nano technology, biomaterials, RF comms, power sources and sensors. Some specific examples relating to the activities in the first year of the project have been presented in this paper. Over the next 3 years new challenges will be revealed, and solutions developed. The ultimate aim is to have a range of new technologies and new medical implants by the end of the 4 year project. Further details of the project can be found in ref. [2].

REFERENCES

[1] Sixth framework programme priority 1.1.2 Information Society Technologies

[2] Healthy Aims Website www.healthyaims.org

[3] Working on the design of New Medical Implants