ACTION—Active Implants for Optoacoustic Natural Sound Enhancement

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The European project ACTION builds on the recent discovery that relatively low levels of pulsed infrared laser light are capable of triggering activity in hair cells of the partially hearing cochlea (optoacoustic stimulus). New implants based on this technology will rely on novel packaging concepts: miniature biocompatible and hermetic packages are required to protect the (VCSEL) light source. The challenge is to make them sufficiently small to fit inside the cochlea. Optoacoustic cochlear implants have the potential to provide better hearing quality than state of the art devices as they generate a sound wave inside the cochlea rather than electrically stimulating the nerves.

State of the art cochlear implants rely on electric signals to stimulate the auditory nerve fibers. These signals are provided by electrodes which are inserted in the cochlea. There are limiting challenges associated with this approach: High electric current densities can damage the tissue, electric interference with the environment may occur and high-frequency artefacts are introduced into electrical signals recorded during stimulation. Furthermore, the performance is limited by the extent to which the electric field can be controlled by the position of the electrode and by the field shaping capabilities of the device.

An optoacoustic (OA) single channel device has the potential to replace the hearing aid in electro-acoustic stimulation, freeing up the inner ear and offering the patient a greater degree of freedom. In patients with mixed hearing loss (conductive component), the OA -device can help too, as it bypasses the middle ear by generating the sound waves inside the intra-cochlear fluid.

The OA device requires that a VCSEL or other laser source be placed inside the body for a prolonged period of time. This poses the challenge of hermetically sealing the VCSEL in a biocompatible and long-term stable package (Figure 1). The space constraints in the cochlea further impose restrictions on the package with regard to size. To date, no packages are commercially available which would meet all the requirements. The challenges of the project are to develop such packages along with a flexible substrate, which carries the metal tracks needed to connect the VCSELs to the driver hardware. Development of the driver hardware and software are further tasks of the project.

CSEM focuses on the development of the hermetic package, the flexible substrate and contributes to the development of the hard- and software for the laser driver.

A first long term implantable hermetic package made from sapphire and Pt feedthroughs has been demonstrated. A similar package made from the same materials is being manufactured. Its outer dimensions are designed to be 0.6 mm x 1.2 mm laterally and 0.6 mm in height. This device will fit inside a cochlea (assuming a tubular structure) of 0.8 mm diameter. The internal components (VCSEL and focusing lens) are being developed by our consortium partners. In first lab tests we showed that acoustic waves inside an aqueous fluid can be generated with the output light of a VCSEL at around 1550 nm.

We further work on the development of a long term implantable flexible substrate. It provides electrodes to stimulate nerves and measure responses of nerves as well as space to accommodate hermetically packaged VCSELs for optoacoustic stimulation. Fabrication of the substrate is based on batch and automatable process steps. Figure 2 shows laser-structured electrodes which belong to an array of substrates. (Further process steps follow). These developments allow for reduced manufacturing costs. It also reduces the dependence on the availability of qualified and trained personnel as it reduces the number of manual intervention steps to a minimum.

The substrate comprises both distal and proximal end electrodes (metal structures), a flexible but non-stretchable member to protect the metal structure from strain, and a soft silicone coating to insulate the metal, protect the tissue from damage, and add robustness for handling. The substrate can also be equipped with bond sites for hermetically packaged VCSELs or sensors that need protection from the body. It is therefore possible to fabricate a substrate that combines stimulating/recording electrodes and active components in one device.

The joining of biocompatible and hermetically packaged VCSELs/sensors and flexible substrates opens up new potential treatment options through a combination of electrical and optical stimulation not just for hearing impaired but for patients who could benefit from neural stimulation.

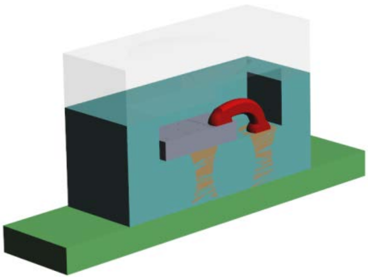

Figure 1: Sketch of a package with a cavity to accommodate a VCSEL (cross section). The package is made from a sapphire box (turquoise) and lid (translucent). The wire bond is represented by a red line. The feedthroughs (orange) connect the VCSEL to the flex substrate (green).

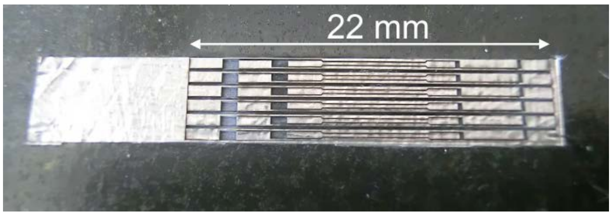

Figure 2: Array of substrate electrodes. Batch and automated processes are developed to manufacture new, reliable and flexible implantable substrates.

The research leading to these results has received funding from the European Union Seventh Framework Program FP7/2007-2013 under grant agreement n° FP7-ICT-611230.