Advancing Binaural Cochlear Implant Technology

The Context of the Project and the Main Objectives

Hearing loss is the most common sensory deficit; one in seven of the global population has a hearing problem and with this population increasingly ageing, the issue of hearing loss and its financial and health cost to society is increasingly evident. Deaf and hard-of-hearing people are often socially isolated, preferring not to mix in social gatherings where background noise makes communication impossible. To this end, the advent of cochlear implantation, or electrical hearing, has revolutionized the lives of the severe and profoundly deaf. Cochlear implants (CI) restore sound perception by directly stimulating residual auditory nerve fibres with patterns of electrical pulses delivered via an electrode array implanted into the cochlea – the hearing organ of the inner ear. Employing up to 22 electrode contacts, CIs attempt to replace the function of all, or nearly all, of the 3000 or so sensory cells of the inner ear that are damaged or absent in individuals with severe and profound hearing loss.

Despite its undoubted success, much remains to be achieved if CI listeners are to perform adequately in even moderately-challenging listening conditions, especially so as CI is largely a ‘monaural’ technology at present, with CI listeners unable to exploit the known benefits of binaural (‘two-eared’) hearing. Binaural hearing refers to the brain’s ability to compare information about sounds arriving at the two ears, is essential for locating the source of a sound and a vital component of ‘cocktail party’ listening (understanding speech in noisy environments); monaural listeners are at a distinct disadvantage under such conditions, being unable effectively to segregate speech patterns originating from different talkers. Currently, even where CIs are provided to both ears (bilateral implantation) they remain independent devices, incapable of exploiting the important differences in sounds at the two ears that render cocktail party listening possible. Oticon Medical is the only manufacturer of CIs that deliver synchronized signals to the two ears, using one processor serving both cochleae. This provides the opportunity of generating synchronised signals to the two ears (truly binaural) compared with using two unsynchronized monaural devices (bilateral). Nevertheless, exploiting the great potential of such technology has not yet been fully realized, including the possibility of exploiting specific binaural processing strategies that make use of the brain’s remarkable ability to compare small timing differences in sounds at the two ears to hear out speech in noisy conditions. The CI prototype to be developed will for the first time provide true binaural stimulation.
ABCIT has 5 main objectives that move the outcome of the project beyond the state-of-the-art:-

1. to develop the ability to exploit the full range of binaural hearing cues in cochlear implantation (CI), and to gear stimulation strategies towards enhancing binaural information

2. to develop a research platform, including a speech pre-processing module, to enhance the development of CI processors

3. to adapt currently successful hearing-aid (pre-processing) algorithms to meet the special demands of cochlear implants

4. to develop the means of measuring from the auditory brain neural signals that will provide an objective means of assessing binaural performance in CI users. This goes far beyond the capabilities of all current CI systems, and is based on Oticon Medical’s unique implant design

5. to develop a low-power, wireless audio link between the devices at both ears so as to enhance users’ access to binaural information

The outcome of meeting these objectives by the end of the programme will be the development of a prototype ‘second generation’ binaural CI device that will eventually be brought to market, providing the possibility of true binaural hearing in CI users.

Project Objectives for the period and work performed so far

The ABCIT programme of work was divided into 7 work packages (WPs), including those of dissemination and administration (WP7).

The aim of WP1 was to deliver a portable, binaural, real-time CI research platform including research environments for the development of sound pre-processing (“speech processing”) and stimulation strategies. This WP was fundamental to the developments and practical evaluations proposed in the other WPs. The main objective by M18 was to deliver a working research platform and this objective has been met. Specifically, the entire research platform that integrates the Master Hearing Aid (MHC) of Hoertech, with the Oticon Medical CI technology has been implemented and hardware developed to interface the devices in ‘real-time’.

WP2 was concerned with developing a simulation tool – a model of the cochlea and the spread of electrical current within it in response to CI stimulation - to better understand, and aid the development of, electrical stimulation strategies for CI devices. A one-dimensional model and a more complete three-dimensional model were developed, and the spread of current assessed in these models. The major goals of WP2 have been achieved, in that simulations of the response to binaural cochlear stimulation can be computed to design the new stimulation strategies (WP3, which starts in M18). The simulation tool has already being used in the R&D assessment of CI stimulation power consumption. Being able to compute such accurate specification is key in the future completion of WP6 for which quantitative predictions are necessary to prototype development.
WP3 is due to start in M18, and provisions are in place for this to commence. This work package focuses on animal and human experimentation to assess neural responses to the new devices and stimulation strategies.

WP4 exploits the unique design of Oticon Medical’s current and next-generation binaural implant; with its galvanic connection across both sides of the brain, the binaural implants enable, in principle, the recording of electrically evoked auditory brainstem responses (eABRs) utilising the implant device itself without the need to position additional, external electrodes on the skin. To date, work at UOL has implemented standard eABR paradigms employed by other devices and has gone beyond this to establish the first multi-(61)-channel eABR setup. It has also generated the first ever data employing binaural eABRs to aid CI fitting, such as interaural electrode pairing and on an EEG study using the frequency following response. Work at UCL has been dedicated to devolving custom EEG recording software, and piloting a novel objective measure of sensitivity to interaural time differences (ITDs), initially, in normal hearing subjects but with the aim of applying this to CI users.

The aim of WP5 is to assess speech pre-processing algorithms currently employed in hearing aids, and to develop new ones for the binaural CI, that improve speech understanding and spatial processing. Early assessment of currently available algorithms was performed in the first 3 months of the project, and these algorithms were subsequently implemented in the real-time research platform (WP1). Further evaluation of these is currently underway, including their functionality once transferred to a device that exploits electrical stimulation (cochlear implants) compared to amplified sound.

WP6 due for delivery in M36, aggregate all results and knowledge from WPs 1-5 in order to develop the prototype of the next-generation binaural cochlear implant system with ECAP and EABR recording capabilities. Although the deliverable for WP6 is the final stage of the project significant advances have been made in the system architecture, high-density feed through, wireless microphone components.

WP7 aims to provide an efficient, effective and transparent management structure for ABCIT as well as a clear dissemination and exploitation plan for the project result. During this period, beside effective management, the project website has been set up, a dissemination strategy has been laid out and project leaflets have been distributed.

**Expected final results and impact of the project**

The final result of ABCIT will be a prototype of a new binaural cochlear implant (CI) device that will ultimately bring about the delivery of a new binaural CI device to the market. This will impact on the lives of the severe and profoundly deaf who will, for the first time, have access to technology that restores critical attributes of normal hearing, such as locating the source of a sound and better hearing in background noise through binaural listening. A critical outcome of ABCIT will be its innovative perspective in bringing a ‘Master Hearing Aid’ platform to the development and assessment of CI pre-processing and stimulation strategies. This perspective lies at the cutting edge of discovery science and translational research in the field of sensory therapies. The excellent track
record of Hoertech and Oticon Medical in developing new knowledge to the delivery of new technologies will be combined with the latest discovery science in the field of binaural and spatial hearing to revolutionizing the expected standard (i.e. delivery of true binaural hearing potential) of cochlear implantation. The relatively informal links between UOL and UCL will be significantly strengthened with a formal aim of employing their combined expertise and know-how in the delivery of an innovative medical technology that, through its superior financial impact (Oticon Medical’s binaural device is considerably more effective in terms of cost) and in terms of performance (providing the possibility of true binaural hearing) than alternative devices, will impact significantly on the hearing health of CI recipients and on Oticon Medical’s position within the global CI market. Also consistent with key requirements of the call, the sharing of resources between organisations, countries and the public and private/commercial sectors is a critical element of ABCIT. Sharing the expertise of Hoertech in hearing aid and pre-processor design with a CI company, and enabling fast-tracking of the assessment of the device physiologically and behaviourally with leading academic partners has significant potential to improve European competitiveness and to address major societal needs within Europe and beyond. The combination of a vigorous SME (Oticon Medical) whose potential for advancing considerably the only therapeutic solution for a significant and growing proportion of the population (and doing so in a more cost-effective manner than other CI companies can do, at a time of economic uncertainty in health-care provision) is strongly concordant with the desired aims of the FP7-HEALTH-2012-INNOVATION-2 call. The advances being targeted include: tools to improve rapidly the design of cochlear electrodes and stimulation strategies, the development and testing of new CI-specific speech processing algorithms, the development of specific binaural algorithms for Oticon Medical’s existing and future-generation binaural devices, and investigations into the use of objective measures (e.g. advanced CAP analysis and EABR) for automated fitting - something that is now (within the last 5 years) considered essential for continued operation in the paediatric implant market. Ultimately, the goal is to gear these solutions towards improving hearing health outcomes, improving Oticon Medical’s current market position, and expanding into the US market, a market from which Oticon Medical is currently completely absent. The time-to-market for these solutions comes in two stages: (1) New input algorithms or binaural algorithms could be implemented in year 2 of the programme, following the development and testing of the algorithms by HörTech/Oticon Medical. These advances are also potentially backwards compatible to current generation CIs. If next generation implants are required, the benefits will follow the timeline of those releases (typically new processors released every 3 years). (2) The development of new electrode arrays and measurement of objective responses would benefits next-generation implant users at 3 years.