Institution: University of Nottingham

Unit of Assessment: UoA4 - Psychology, Psychiatry and Neuroscience

Title of case study: Adoption of new engineering solutions to reduce the patient experience of intense acoustic noise during Magnetic Resonance Imaging (MRI)

1. Summary of the impact

Reduction of unpleasant ambient noise during MRI has been enabled through innovative engineering solutions developed at the Medical Research Council Institute of Hearing Research (MRC IHR). Intellectual property was licensed to Optoacoustics Ltd and the resulting OptoActive™ active noise-cancelling headphones for MRI are the only one of their type commercially available, enabling free conversation between patients and clinicians. The product was formally launched in September 2012 and has worldwide sales including in the USA, Europe, Asia and the Middle East.

2. Underpinning research

The MRC IHR (Professor Alan Palmer Director), in collaboration with Professor Deborah Hall (Nottingham Hearing Biomedical Research Unit), has established Nottingham as a world leading centre for auditory functional magnetic resonance imaging - developing novel technologies to optimise detection of activity in the auditory brain in the hostile and noisy environment of the MR scanner. The Magnetic Resonance Imaging (MRI) scanner is extremely noisy when in operation. In the hospital setting, the ambient noise leads to patient discomfort and prevents communication between clinician and patient.

The MRC IHR is located on the main University of Nottingham campus with many of its senior staff holding honorary appointments with the University of Nottingham and co-supervising PhD students with University research active staff. From 1998-2009, Professor Palmer led a small team of engineers at the MRC IHR in the development of innovative hardware and software technologies, using the latest methods in digital signal processing, to achieve active noise reduction of the high-level ambient noise generated during magnetic resonance imaging[1,2]. For some types of MRI scan, the noise level can reach 130 dB sound pressure levels[3], which far exceeds safe noise dosage guidelines, and so novel solutions for improving the patient experience are required.

Professor Hall led the neuroimaging team at MRC IHR, which provided the crucial acoustic, psychophysical, and neuroimaging measurements of the effectiveness of the prototype system for active noise reduction during auditory functional magnetic resonance imaging. These novel experimental results confirmed that active noise cancellation offers substantial benefits during MRI scanning. The prototype system has demonstrated excellent sound reduction (35 dB of acoustic attenuation measured at the patient's ear[4]), improved audibility and listening quality[5] and enhanced ability to detect sound-related brain activity in the hostile environment of the MR scanner [4,5]. Her work was conducted in collaboration with physicists at the Sir Peter Mansfield Magnetic Resonance Centre (University of Nottingham) where the research prototype has been installed.

The system offers a number of important advantages - it safely cancels Echo Planer Imaging (EPI) main gradient noise; it allows quiet two-way communication during a scan; it records sound as the patient hears it; it is self-calibrating with Sound Pressure Level (SPL) monitoring in real time; it enables use of high fidelity audio stimuli; it provides instant control over performance with a digital touch display and it allows multiple concurrent audio inputs

The research reports the technical design of the active noise-cancellation system and provided convincing evidence that active noise reduction offered substantial benefits for communication during noisy MRI scanning. The original engineering project was viewed as supporting the MRI group at the MRC IHR, however, conventional noise reduction systems were clearly not applicable in the MRI environment as the sound paths were too short. Overcoming such problems involved devising a novel noise reduction system, entailing recording and playback of the scanner noise with adaptive cancellation algorithms. Evaluation of the effectiveness of the cancellation was achieved by careful psychoacoustic testing of subjects within the scanner and quantification of the changes in their brain activation[6].

Key researchers

Professor Alan R Palmer (1986 - present), Director, MRC Institute of Hearing Research
Professor Deborah Hall, Programme Leader Scientist, MRC Institute of Hearing Research (until 2009); now Director, National Institute for Health Research (NIHR) Nottingham Hearing Biomedical Research Unit
Mr John Chambers, Engineer, MRC Institute of Hearing Research (left in 2008)
Mr Dave Bullock, Engineer, MRC Institute of Hearing Research (left in 2008)

3. References to the research

1. Chambers J, Akeroyd MA, Summerfield AQ, Palmer AR (2001). Active control of the volume acquisition noise in functional magnetic resonance imaging: method and psychoacoustic evaluation. *Journal of the Acoustical Society of America* 110:1-14. http://dx.doi.org/10.1121/1.1408948. IF: 1.55; Citations: 45

2. Chambers J, Bullock D, Kahana Y, Kots A, Palmer AR (2007). Developments in active noise control sound systems for magnetic resonance imaging. *Applied Acoustics* 68:281-295. DOI:10.1016/j.apacoust.2005.10.008. IF: 1.233; Citations: 23

3. Foster JR, Hall DA, Summerfield AQ, Palmer AR, Bowtell RW. (2000) Sound-level measurements and calculations of safe noise dosage during EPI at 3T. *Journal of Magnetic Resonance Imaging* 12(1): 157-163. DOI: 10.1002/1522-2586(200007)12:1<157::AID-JMRI17>3.0.CO;2-M. IF: 2.7; Citations: 69

4. Hall DA, Chambers J, Foster J, Akeroyd MA, Coxon R, Palmer AR (2009). Acoustic, psychophysical, and neuroimaging measurements of the effectiveness of active cancellation during auditory functional magnetic resonance imaging. *Journal of the Acoustical Society of America* 125(1):347-359. DOI: 10.1121/1.3021437. IF: 1.55; Citations: 18

5. Blackman G, Hall DA (2011). Reducing the effects of background noise during auditory functional magnetic resonance imaging of speech processing: Qualitative and quantitative comparisons between two image acquisition schemes and noise cancellation. *Journal of Speech, Language and Hearing Research* 54:693-704. DOI: 10.1044/1092-4388(2010/10-0143). IF: 1.971; Citations: 5

6. Talavage TM, Hall DA (2012) How challenges in auditory fMRI led to general advancements for the field. *NeuroImage*. Special issue "Twenty Years of Functional MRI: The Science and the Stories". 62(2): 641–647. DOI: 10.1016/j.neuroimage.2012.01.006. IF: 7.063; Citations: 13

Selected Funding

1999 MRC 5-year programme grant to MRC Institute of Hearing Research (Palmer and Hall, co-applicants). **£15,000,000**

2004 MRC IHR intramural programme 2004-2009 "The Auditory Brain". (Palmer and Hall, co-applicants). **£15,000,000** including a specific contribution to the 3 T MR scanning facility of **£500,000**

4. Details of the impact

Development of the IMROC system and prototype agreement from Optoacoustics

The IMROC (Interventional MR Optical Communication) System makes MRI communications simple and effective. Incorporating lightweight fibre optical headphones, it allows hands-free, full duplex communications between MRI scanner and control room. Using IMROC, doctors can speak with technicians and patients in any MRI environment. It is especially suited to advanced interventional and interoperational MRI suites, where clear, full duplex communications are absolutely critical. Radiologists and technologists have praised IMROC for improving personal productivity and clinical throughput (http://www.webwire.com/ViewPressRel.asp?aId=149468#.UfKOtJwvyZQ).

In September 1998, as part of the development process, researchers at MRC IHR contacted Optoacoustics Ltd (a leading designer and manufacturer of optical fibre-based microphones, headphones and sensing systems for medical applications) about their optical microphone technology. Optoacoustics had developed optical noise-cancelling microphones which were ideal for MRI because their operation was unimpaired by the high magnetic field, although the company did not yet have a complete active noise-cancellation system for the MRI market. The company provided MRC IHR with a set of optical microphones which were incorporated into our research prototype MRI active noise-cancellation system. The prototype was installed and evaluated using the Phillips 3 Tesla MRI scanner at the Sir Peter Mansfield Magnetic Resonance Centre, University of Nottingham in 2006.

In February 2006 Dr. Yuvi Kahana, CEO of Optoacoustics Ltd, visited Nottingham to experience the fully operational prototype system and to informally discuss the technical specification. Following subsequent negotiations, the intellectual property was exclusively licensed to the company through a formal contract drawn up by MRC Technology - the exclusive technology transfer agent for the MRC. The licensing agreement provided Optoacoustics Ltd with the mechanical design, hardware and software of the prototype and was signed on August 2008[a]

Translation of proof of concept work to commercial system

The company devoted 10 years and considerable financial resources to turn MRC IHR's proof-of-concept work into a commercial system for wider MRI applications. Dr. Kahana and his team redesigned the IMROC system for use during MRI; with the OptoActive™ active noise-cancelling headphones component of the IMROC system based on the original MRC IHR innovation. The OptoActive™ component uses adaptive filtering to attenuate MR acoustic gradient noise, with three selectable modes to fit every scenario. MRC IHR is acknowledged in the OptoActive product as licensing a portion of the Active Noise Cancellation algorithm supporting real-time algorithmic, out-of-phase harmonic active noise cancelling using proprietary Digital Signal Processing. Many of the system's other features (unsurpassed sound clarity, quiet two-way communication, self-calibrating with sound pressure level monitoring in real time, and high fidelity audio stimuli capability) are also characteristics of the MRC IHR research prototype.

Siemens AG financed compatibility testing in one of their major USA imaging centres (North Carolina). In April 2011 Siemens AG declared that Optoacoustics' OptoActive™ headphone system, IMROC system and FOMRI noise-cancelling microphone were compatible and safe for use in Siemens AG MRI systems worldwide, specifically in the MAGNETOM family of MRI systems[b].

The IMROC system has been evaluated by several development partners at leading interventional MRI research centres (University of Texas M. D. Anderson Cancer Center (MDACC), National Institutes of Health (NIH), Johns Hopkins University School of Medicine, University of Utah School of Medicine, and Klinikum Coburg, Germany) and in November 2011, Siemens promoted the system at the Radiological Society of North America (RSNA) 2011 conference in Chicago, USA[c]. Optoacoustics' CEO Dr. Yuvi Kahana said: "We're honored and thrilled to be invited by Siemens to join them in promoting the IMROC system at RSNA 2011. We look forward to seeing IMROC become an integral part of every Siemens MRI suite''.

FDA approval and Optoacoustics system brought to market

In May 2012, Optoacoustics' OptoActive™ system was cleared for marketing in the US by the federal Food and Drug Administration (FDA)[d]. Receipt of 510(k) clearance enables broader sales and distribution of this unique flagship device in advanced MRI, interventional MRI and functional MRI facilities. In marking the FDA approval, Optoacoustics' CEO Dr. Yuvi Kahana said, "The FDA clearance for our leading medical division products opens up an exciting new era for Optoacoustics. I expect that we'll see very keen interest from MR professionals in the US. Now they can dramatically expand their research and work more efficiently without EPI noise."

In September 2012, Optoacoustics formally launched the fully wireless IMROC system at the 9th Interventional MRI (iMRI) symposium at Harvard Medical School, Boston, USA[e]. The company has so far installed six systems worldwide and has already received 10 major orders for Optoacoustics' OptoActive™ systems from companies in the USA, Germany, Begium, South Korea, Finland and Israel[f].

5. Sources to corroborate the impact

a. Licensing agreement with Optoacoustics

b. Siemens test certificate. 15 April 2011: Test of influences on MRI systems caused by non-Siemens products. Test number 10207. Document Identifier number 10519276 ASD FR1 02.
www.optoacoustics.com/sites/default/files/medical/imroc/pdfs/siemens-ag-test-certificate-2011_optoacoustics-imroc.pdf

c. Press release. Nov 2011: Optoacoustics Brings Advanced IMROC™ Multi-Channel MRI Communication System to Siemens at RSNA 2011
www.optoacoustics.com/sites/default/files/documents/pr_siemens-rsna_imroc_nov-11.pdf

d. FDA review statement K12 1239. 18 May 2012: 510(k) clearance summary
www.accessdata.fda.gov/cdrh_docs/pdf12/K121239.pdf

e. OptoActive™ brochure (page 6 for Nottingham citation)
www.optoacoustics.com/sites/default/files/documents/optoactive_brochure-web_sep-2012.pdf

f. Letter from CEO. Optoacoustics Ltd corroborating Nottingham's product development, uptake of product and sale worldwide