

# A surgeon's perspective on the challenges facing cochlear implantation in children

BY IAIN A BRUCE

Cochlear implantation in children offers a different set of challenges and goals to adult practice. In this article, **Iain Bruce**, Professor of Paediatric Otolaryngology in Manchester, UK, explains some of the current clinical and research challenges in paediatric cochlear implantation, from the surgeon's perspective.

## Introduction

Cochlear implantation (CI) is now well established as a potentially life-changing intervention for children and young people who have a severe-to-profound hearing loss. Technological and (re)habilitation advances have improved efficacy, and our understanding of factors influencing outcome continue to evolve. Innovation and increased understanding generate new dilemmas for clinicians, as we strive to ensure that the maximum number of children and young people benefit from cochlear implantation.

This article discusses some of the important challenges faced by clinicians involved in paediatric CI. Whilst the topics have been subdivided into clinical and research challenges, they are co-dependent with some of the content being equally applicable to CI in adults.

## Clinical challenge: supporting expansion in candidacy criteria

Whilst candidacy criteria for CI in the UK were defined by NICE in 2009 (TA166, 'louder than 90dBHL at frequencies of 2 and 4kHz'), improved outcomes of CI have driven CI to be offered to children with less severe types of hearing loss, providing they are not making the anticipated developmental progress. Recent work by Vickers et al. has suggested that

consideration should be given to changing audiological criteria to 4 frequency average poorer than or equal to 80dBHL, or 2 frequency average poorer than or equal to 85dBHL [1]. Likewise, this uncertainty in candidacy is demonstrated by the variability in audiological criteria between countries and geographical regions.

Evolution and expansion in the application of any such medical technology is inevitable as clinicians strive to help the maximum numbers of patients, and with increased understanding of the consequences of applying and withholding the intervention. However, the available evidence to support best practice has lagged behind this expansion in candidacy, and largely comprises single-centre case series. Two examples of areas of unmet research need are the role of CI in post-lingually deafened young people and determining benefit in children with cognitive impairment. Neither clinical scenario necessarily lends itself to meaningful evaluation of benefit using commonly used outcomes, or existing measurement instruments [2].

## Clinical challenge: maintenance of residual natural hearing

Cochlear implantation with attempted preservation of residual natural low frequency hearing is now well established. CI with hearing preservation (HP) led to the development of novel CI technologies that enable patients to hear 'electrically' in some hearing frequencies and either naturally, or with a conventional hearing aid in others. It also focused surgeons on developing 'atraumatic' surgical techniques to limit intra-cochlear inflammation and scarring. Despite significant advances in outcome and understanding of CI with HP, success rates continue to vary widely between surgeons and within individual surgeon's practice.

The maintenance of preserved hearing is brought into greater focus when considering children, young people and younger adults, who may live for decades following initial implantation.

Progress is being made in the field of biotechnology-assisted CI where drugs, genes or cells are delivered into the cochlea at the time, or after surgery, with the aim to preserve, maintain or even restore hearing function. Complementing these advances, robotic CI aims to decrease electrode array insertion forces, ultimately seeking to reduce variability in outcome, invasiveness, intra-cochlear trauma and operator error inherent in the conventional manual procedure for CI, with or without HP.

## Factors of likely importance/areas for development in CI with HP

- Minimising intra-cochlear inflammation
  - Pharmacological, e.g. electrode array as drug delivery system (steroid)
- Minimising and standardising intra-cochlear trauma
  - Electrode design, e.g. physical characteristics
  - Robotic CI insertion
- Enhancing preserved hearing
  - Drug-based therapies (neurotrophic factors (NTFs), gamma-secretase inhibitor)
  - Cell-based therapies (human stem cells, [www.otostem.org](http://www.otostem.org))
  - Gene-based therapies (CGF166, Columbia)

## Research challenge: maximising the impact of research

Resources in healthcare are limited both in terms of financial support and time available for dedicated clinicians to

**"Beyond preserving residual hearing during CI, the aim is to maintain and enhance natural hearing after CI."**

undertake clinical research. Systematic reviews can be a powerful tool to support evidence-based practice, if sufficient primary data exists and there is homogeneity in the use and reporting of outcome measures. The process of combining data from CI studies is currently hindered due to heterogeneity in the outcomes measured in effectiveness studies [3].

A recent editorial in the British Medical Journal has emphasised the critical importance of, "establishing and requiring core outcomes to enable combination of data from multiple studies" under the banner of promoting the benefits of 'big data'. Ultimately, it is envisaged that, "... studies that are designed, conducted, and reported using a common language will have a greater scientific value because the datasets can be truthfully combined" [4]. The concept of Core Outcome Sets (COS) (<http://www.comet-initiative.org>) offers a potential solution to the problems resulting from variation in choice of outcomes and corresponding measurement instruments. A COS is an agreed minimum set of outcomes that should be measured and reported in all trials in a specific condition. The ideal COS for CI would combine both 'user' and clinician opinion and would be used in the

design of subsequent clinical effectiveness studies of novel technologies and extended applications of existing technologies. A COS would include a recommendation of 'what' should be measured and reported in all future clinical effectiveness studies. Accompanying the domains in the COS should be an appropriate method to quantify the outcome (the measurement instrument set) – 'how' – in addition to a recommendation for the timing of its use – 'when'. Studies are currently in development to co-produce standardised sets of bespoke outcomes for CI, incorporating the perspectives of children, young people, parents, adults and clinicians. Methodology to ensure full participation of children and young people in such consensus exercises will be of fundamental importance.

The solutions to many of the problems facing paediatric CI clinicians include improvements in data collection, standardisation in outcome reporting and ensuring that the perspectives of patients and parents are central to the design, delivery and meaningful interpretation of effectiveness studies. Advances in CI technology demand corresponding improvements in the evidence underpinning best practice.

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