NHMRC

The cochlear implant restores hearing: Case Study

Hearing loss can have a wide range of adverse effects on individuals and their families. Cochlear implants offer the only effective treatment for those with severe-to-profound sensorineural hearing loss. NHMRC-funded researchers at The University of Melbourne developed the type of cochlear implant that is in widespread use today. In partnership with leading Australian medical device firm Nucleus Ltd, their work led to the development of Cochlear Limited, a successful Australian company and the world's leading cochlear implant provider.

Origin

Impaired hearing can lead to many adverse outcomes for those affected, including a loss of social contact and risks to personal safety. For children, it also impedes language development, and educational and economic attainment.[1]

In 1946, the Commonwealth Acoustic Laboratories, at that time part of NHMRC, began designing hearing aids for use by deaf children.[2] Hearing aids amplify sounds so that they may be detected by those who are 'hard of hearing', but cannot help those who are profoundly deaf.

During the 1960s, Melbourne-based ear, nose and throat (ENT) surgeon Graeme Clark was becoming increasingly aware of the challenges faced by people with profound hearing loss. Commencing in 1967, Clark undertook research at The University of Sydney – within the NHMRC-funded team of Dr Colin Dunlop – to explore the possibilities of restoring hearing through direct electrical stimulation of the auditory nerve.

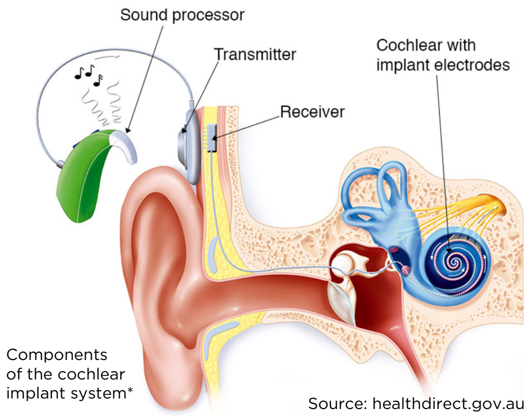
To accomplish this, an external microphone would need to capture sound and send it to a speech processor that would then send signals to electrodes implanted in the spiral-shaped inner ear (cochlea). These signals would stimulate the auditory nerve which would then send information to the brain that would be interpreted as sounds.

Work to develop single-electrode cochlear implants had already been undertaken at a number of laboratories internationally.[3] However, the prevailing opinion within the medical community was that such devices could not adequately mimic the complex processes used by the ear to convert speech information and send it to the brain. Clark's research revealed that a multi-channel approach would be essential in order to convey to the brain the broadest possible range of sound (and particularly speech) information.

Investment

Commencing in 1971, Clark and colleagues at The University of Melbourne – Peter Seligman, Jim Patrick, Ian Forster, Joe Tong, Peter Blamey, Richard Dowell, Hugh McDermott, Collette McKay, Lois Martin, Field Rickards, David Dewhurst and many others – were supported by NHMRC grants to develop a cochlear implant. Also, informed by advice from NHMRC, the Australian Government provided four rounds of funding through the Industrial R&D Incentives (IRDI) Scheme from 1979 to 1985 to support commercialisation of the cochlear implant.[4]

Clark and his team engaged in extensive independent fundraising, including through televised appeals for funding ('telethons'). Other sources of funding for their work included: the Lions, Rotary and Apex Clubs; The Felton Bequest and other philanthropy; The Government of New South Wales; US National Institutes of Health (NIH); the Australian Research Council; and the Cooperative Research Centres (CRC) Program.



Source: healthdirect.gov.au

Research

To make a functional cochlear implant, Clark and a multi-disciplinary group of researchers had to answer some key research questions, including:

- can a functioning inner ear, containing thousands of sense receptors, be replaced by electrodes stimulating groups of nerve fibres?
- would an implant in the inner ear damage the nerves it was supposed to stimulate?
- can speech information be effectively presented to the hearing part of the brain by electrically stimulating nerve fibres? If so, how?
- do children who are born deaf, and those with long-term hearing loss, have enough nerve connections to brain cells for electrical stimulation to give adequate hearing?

To address these and other related questions, Clark's team undertook research and development in areas such as biomedical, electronic and software engineering, audiology and speech science, surgery and surgical training.

They investigated various speech coding strategies and programmed the sound processing device to emphasise different types of speech information – including pitch, loudness, timing and formants (the frequency spectra of speech) – according to the individual needs of the user.

They demonstrated that a multi-channel approach was essential for the implant to be successful and that the electrodes had to be placed along the length of the coiled tube of the cochlea. They also discovered how to do this safely and effectively.

In 1978, Clark implanted the first multi-channel cochlear implant prototype at the Royal Victorian Eye and Ear Hospital. In January 1979, the Australian Government announced the availability of an IRDI grant to allow commercial development of the cochlear implant developed by Clark's team.

Commercialisation

In 1977, Clark began discussions with Paul Trainor, the owner of Nucleus Ltd, about a project to develop the cochlear implant. In 1979, Nucleus was chosen to participate in the IRDI funded project because of its expertise in medical devices and also because Telectronics Pty Ltd, a Nucleus subsidiary, was a world-leading producer of pacemakers. A key feature of the Telectronics pacemaker was its hermetically-sealed design that protected the electronics for the lifetime of the patient, and this feature was incorporated into the cochlear implant.

In 1981, the first employees were assigned to the 'Cochlear Project' at Nucleus. In 1983, the project was incorporated, becoming Cochlear Limited in 1985. Telectronics engineers, in collaboration with Clark's team, entirely redeveloped the implant so that it would use less power, be simpler and less expensive to produce and work effectively with a series of constantly improved external speech processors. They also redesigned the processors themselves to be more portable.

In 1982, the new device was ready to undergo clinical trials. These took place in Australia, Europe and the United States, where the implant had been approved for clinical trials by the Food and Drug Administration (FDA). Clark and his team evaluated the device after it was implanted in six patients.

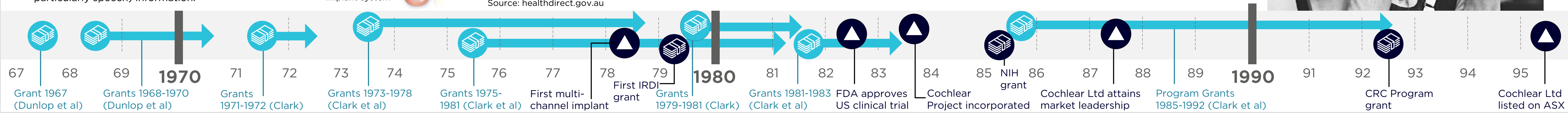
In 1985, Cochlear was the first organisation to have a multi-channel cochlear implant approved by the FDA. Sales of Cochlear devices increased from 409 in 1987 to 596 in 1988. By March 2001, Cochlear had sold over 30,000 implants.[5] This figure now stands at over 650,000. Cochlear's multi-channel device more effectively improved speech understanding and was more reliable than competing devices.[6,7] It was also more effectively promoted globally to audiologists and ENT surgeons. As a consequence, Cochlear gained market leadership by 1987.

Outcomes and Impact

Cochlear implants have now become an accepted clinical tool for patients who are living with moderately severe to profound sensorineural hearing loss. They provide a highly effective and reliable treatment for sensorineural hearing loss in children and adults.[8] Over time they have become smaller, lighter, more effective and reliable.

Cochlear implantation in children before 24 months of age can promote speech understanding and before 12 months can support speech intelligibility and language outcomes on par with normal-hearing peers. Cochlear implants significantly improve overall and hearing-specific quality of life in adults with bilateral severe, profound or moderate sloping to profound sensorineural hearing loss.[9,10]

Cochlear implants are now a global commercial enterprise with a number of major manufacturers producing various types of cochlear implant approved for use in many countries. Cochlear Limited, which was listed on the Australian Stock Exchange (ASX) in 1995, is still the market leader, accounting for over 60% of the global market.[11] In 2021, Cochlear Limited sold 36,456 cochlear implants.[12]



Note on diagram: The electrode of a cochlear impant usually extends from 1 to 1.5 turns of the cochlea

Prof Graeme Clark AC

Graeme Milbourne Clark trained in medicine at The University of Sydney then worked as an ENT surgeon in hospitals in London and Bristol (in the United Kingdom) and in Victoria, Australia. After completing Masters and PhD degrees at The University of Sydney (1968-1969), Clark became Professor in Otolaryngology at The University of Melbourne (1970 2004). Clark established the Cochlear Implant Clinic at the Royal Victorian Eye and Ear Hospital and was surgeon in charge (1985-2004). He founded and then directed the Bionic Ear Institute (1984-2005). Clark was made an Officer (1983) and then a Companion (2004) of the Order of Australia.

Paul Trainor AO

Paul Murray Trainor (1927-2006) began his working life at Watson Victor Ltd, an Australian company specialising in importing and manufacturing medical imaging (principally X ray) equipment. In 1964, Trainor established his own medical device company – Nucleus – which in 1967 acquired a controlling interest in pacemaker firm Telectronics. The 'Nucleus group' went on to include other firms such as Ausonics (diagnostic ultrasound), BGS Medical (implantable bone graft stimulators), Domedica (dialysis and blood processing) and Medtel (cardiac monitors and defibrillators) as well as Cochlear Ltd. Trainor was made an Officer of the Order of Australia in 1986.

Prof Peter Seligman

Peter Seligman is a biomedical engineer at the Bionics Institute and an associate of the Melbourne Energy Institute. Seligman worked at Nucleus/Cochlear Ltd from 1983-2009 focusing on speech processor miniaturisation and improvement.

Prof Jim Patrick AO

James (Jim) Finlay Patrick was a Senior Research Fellow at The University of Melbourne (1975-1981) who became Cochlear Ltd's Chief Scientist (1981-2016). He was made an Officer of the Order of Australia in 2015.

Prof Ian Forster

Ian Forster is Senior Principal Research Fellow in the Ion Channels and Human Diseases Laboratory at The Florey Institute of Neuroscience and Mental Health in Melbourne. Forster has worked at the Institute of Neurology in London and at the University of Zurich.

Joe Tong

Yit Chow (Joe) Tong was a graduate student in mechanical engineering at The University of Melbourne who worked at the Department of Otolaryngology and was then a senior staff member at the Human Communications Research Centre (1988-1993).

Prof Peter Blamey

Peter Blamey was a Principal Research Fellow (1989 2002) and a Professorial Fellow (2002 2019) at The University of Melbourne. He was co inventor on 25 patent families and established several companies.

Other contributors

Key contributions to the development of the cochlear implant were also made by: Richard Dowell, Hugh McDermott, Collette McKay, Lois Martin, Field Rickards and David Dewhurst; patients who received implants; other staff at the The University of Melbourne, the Bionic Ear Institute, Nucleus Ltd, and Telectronics Pty Ltd.

How the ear works

A functioning ear consists of an outer ear which collects and then channels soundwaves through the ear canal to the middle ear. Here, the ear drum vibrates, causing fluid to vibrate within the inner ear (the cochlea, a coiled tube). The cochlea contains thousands of hair cells, each connected to an auditory nerve fibre. The hair cells transform the vibrations that they receive into electrical energy that causes the auditory nerve fibres to send signals to the brain that are interpreted as sound. Each hair cell is tuned to certain sound frequencies according to its location within the cochlea, with the highest frequencies received at the beginning of the tube and low frequencies at the end.

Australian Government
National Health and Medical Research Council

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The information and images from which impact case studies are produced may be obtained from a number of sources including our case study partner, NHMRC's internal records and publicly available materials.

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