

Implantable Hearing Devices



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Preface

Otolaryngologists are very lucky persons indeed, for we are the only medical specialty to be able to restore one of the five senses with the aid of a bionic device. With this revolutionary device, we are able to dramatically change a person's life for the better. Patients who have benefited from this technology may now be fully integrated into a hearing society, with prospects for full educational and employment opportunities.

History was made when the first cochlear implant in India was performed in Mumbai in August 1987 by Dr. Jack Pulec with Dr. Sandra de Sa Souza. I was present both as they screened for potential recipients and when the device was implanted. Dr. Pulec practiced in Los Angeles, California and was a very dynamic, energetic and skillful surgeon. Dr. de Sa Souza is among Mumbai's most talented and visionary surgeons.

At that time, in tandem with cochlear implants, nearly all the specialties experienced revolutions in radiological imaging, endoscopic sinus surgery and the like. It was a heady and exciting time full of discoveries and controversies.

Since then many others have started their own cochlear implant programs. The first device that was inserted, compared to the devices now available, was a primitive one. At that time, criteria for selection of candidates was unclear and the cost of the device was prohibitively expensive. As more and more patients received cochlear implants, results were found to be mixed and sometimes very disappointing. Then the device started evolving and criteria for implantation were more fully established. The results, as noted in recent medical literature, are just spectacular. Many issues though, still need resolving. Even though it is now well over 30 years since implants were introduced in India, many obstacles remain.

Uppermost is the cost of the device which sometimes equals a poor man's annual income. Next are related activities like mapping and instructing caregivers and patients on the careful maintenance of the device. And of course, rehabilitation. All these can prove to be formidable obstacles for patients especially those who have a limited supply of finance. In some Indian states the state government has stepped in and has funded the cost of the device as well as the cost of surgery. Many skilled and competent otologists have stepped forward and have energetically devoted their attention and time to helping those who would likely benefit from the device.

Cochlear implants represent just one of the many devices we have in our armamentarium to alleviate the problems that deafness brings. Now we have an array of devices like auditory brainstem implants, BONEBRIDGE, Vibrant Soundbridge and other active middle ear implants. This is a new and exciting field that will continue to evolve and become more and more sophisticated as time goes by.

The purpose of this book is to place in perspective the various devices available and the situations where they will be most effective. We have combined didactic literature with "how to" instruction in order to make the book come alive for the reader.

All the editors and authors of this book share their experience and knowledge knowing that in the years ahead there will be continued breakthroughs in understanding how we hear and how to better treat hearing impairment.

We hope that this sharing greatly benefits all those involved in the treatment of hearing impairment. This includes surgeons, patients, caregivers, and the companies that manufacture these wonderful and incredible devices.

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PART I
Cochlear Implants

1

History of the Cochlear Implant: An International Perspective

Matthew Gordon Crowson

Introduction

The development of the cochlear implant is one of the most fascinating medical device innovation stories of the 20th century. Through the hard work and trials of numerous investigators, industry, and brave patients around the world, the dream of hearing restoration for children and adults has been realized. While the technology for this innovation came to fruition in the 1960s and 1970s, early concepts of hearing restoration with the use of electricity had been considered at least 10 years earlier—conceivably as early as the 1800s.

Harnessing Electricity: A Romantic Era Eureka

Alessandro Volta, the namesake for the standard international unit of electromotive force, was an Italian physicist with a penchant for electricity.¹ In the late 1790s and early 1800s, he developed the electrolytic cell and began testing his new invention on a variety of tissues to assess the physiologic effects of electrostimulation.¹ He stimulated skin, tongues, the optic nerve, and finally the ear. He chose himself as a suitable test subject for stimulation of the ears, and

applied 50 volts of electricity via a metal rod in each ear. This audacious experiment generated a sensation that he described as noise.¹

Early Experimentation in the 1950s

Perhaps the earliest kindling of the cochlear implant began in France. André Djourno, an electrophysiologist, and the otolaryngologist Charles Eyriès had a chance meeting over a 57-year-old patient with bilateral cholesteatomas.² This patient had undergone radical temporal bone resections with labyrinthectomies and facial nerve resections.² Charles Eyriès had expertise in facial nerve grafting, and was introduced to Djourno through a mutual colleague who suggested that Eyriès allow Djourno to attempt to stimulate hearing at the same time a facial nerve repair was attempted. Intraoperatively, the cochlear nerve remnant was visualized and an active electrode was implanted into the remnant. Bursts of signal were administered and the patient reported being able to appreciate sound. Retrospective analysis of this momentous experiment suggested that perhaps the site of stimulation was the cochlear nucleus, and not the cochlear nerve remnant.² This was believed to be the case because Wallerian degeneration of the previously sectioned cochlear nerve

was thought to have rendered the remaining nerve fibers physiologically inactive.² However, this experiment laid the groundwork for the modern evolution of the idea of the cochlear implant.

The Modern Cochlear Implant: An International Effort

The purpose of this chapter is to examine the history of the cochlear implant from an international context. This is not the first written history of the cochlear implant, and interested readers should consult the excellent histories in the references cited in this chapter.³⁻⁸ As we hope to illustrate, the history of the cochlear implantation is a remarkable example of cross-border ingenuity with large contributions from investigators and industry in Austria, Australia, France, and the United States of America (Figure 1-1). With various corporations claiming world-firsts along the way, the work, in aggregate, has pushed the boundaries of the technology for hearing rehabilitation to provide meaningful benefit

for those afflicted by significant sensorineural hearing loss.

Austria (1975)

In 1975, Ingeborg and Erwin Hochmair began the development of cochlear implants at the Technical University of Vienna. It took two years to produce the world's first multichannel cochlear implant, and this first model was implanted in Austria by Professor Kurt Burian of Vienna. This early work would serve as the foundation for the establishment of a major manufacturer of cochlear implants—MED-EL.

1990s: The Establishment of MED-EL

The company now known as “MED-EL” was founded in Innsbruck, Austria, in 1989 by the Hochmair group. MED-EL's first cochlear implant system, called the “COMFORT,” utilized wave-shaped wires within the electrode to maximize structure preservation within the cochlea, a consistent theme for electrode development over the years. In 1991, MED-EL

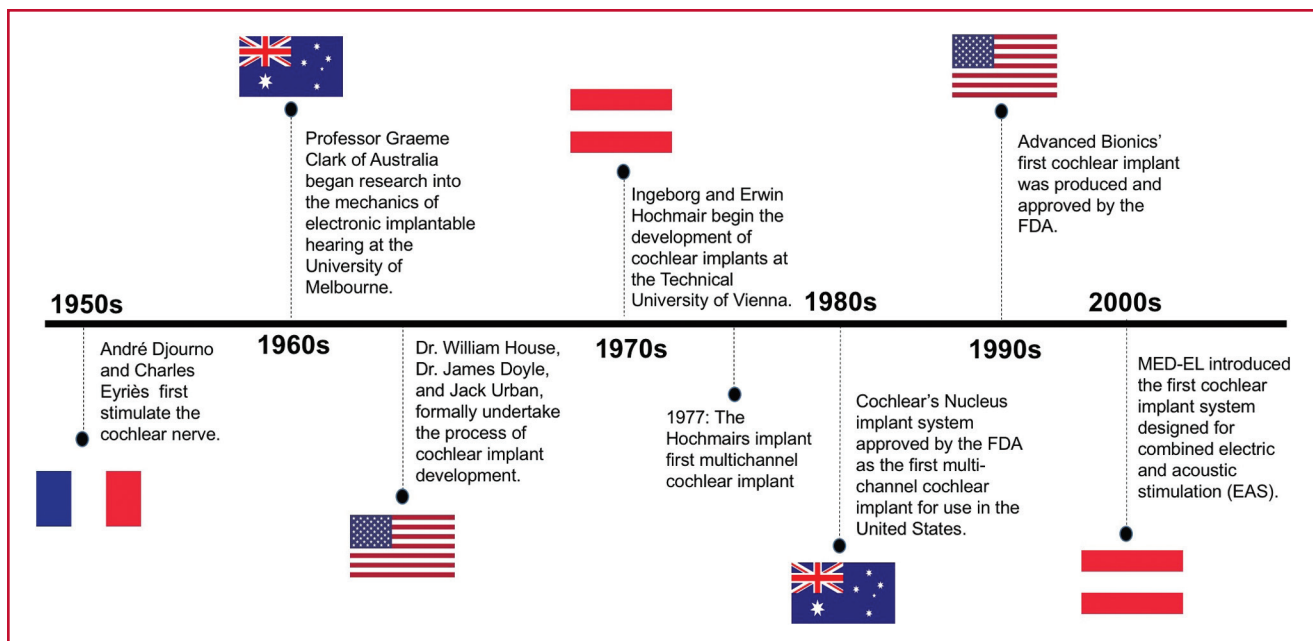


Figure 1-1. Timeline of international contributions and milestones in the development of the cochlear implant. Author-generated figure.

designed the world's first behind-the-ear (BTE) audio processor, followed shortly thereafter by the "CIS-PRO" pocket audio processor. The "COMBI 40" cochlear implant was introduced in 1994. These devices were the first to provide eight-channel, high-rate stimulation with the continuous interleaved sampling (CIS) sound processing strategy, as well as a new electrode design that was purported to have complete cochlear coverage. While the various sound encoding and processing techniques are beyond the scope of this brief review, it is worth mentioning that CIS developed by Blake Wilson and his team has become one of the most widely used speech processing strategies in cochlear implant processors.⁸ In 1996, the "CIS-PRO+" audio processor and "COMBI 40+" cochlear implant were introduced, which expanded the stimulation capabilities by providing 12 stimulation channels. In this same year, one of the world's first bilateral cochlear implantations was successfully completed using MED-EL cochlear implants and the accompanying audio processors. The first BTE audio processor to use a "CIS+" coding strategy was introduced in 1999, with a wearable option for children. MED-EL also developed the world's first use of combined electric and acoustic (EAS) stimulation in a cochlear implant recipient.

2000s: Middle-Ear Implants and MRI-Safe Cochlear Implants

The start of the 21st century saw the foundation of "VIBRANT MED-EL" in 2003. Through the acquisition of Vibrant from the San Jose-based (USA) company Symphonics Devices Incorporated, came the commercialization of the "Vibrant Soundbridge." At the time, it was the world's first middle-ear implant designed to assist those with moderate to severe sensorineural hearing loss. The device works by surgically coupling a transducer to the middle-ear ossicles, which are then vibrated upon stimulation from an external acoustic receiver and processor.⁹ Preliminary studies, both in Europe and the United States, demonstrated efficacy and safety of this device for patients with moderate to severe sensorineural hearing loss.⁹⁻¹³ While not a cochlear implant, these devices are an option for aural rehabilitation

for patients who are otherwise not able to utilize conventional hearing aids.

Over the remainder of the decade, MED-EL continued to refine its cochlear implants, electrodes, and processor systems. In addition to improvements to electrode design with a focus on hearing preservation, MED-EL introduced the first cochlear implant system designed for combined electric and acoustic stimulation (EAS) in 2005. More recently in 2013, the "RONDO" cochlear implant single-unit processor was made available, and MED-EL received FDA approval to be the first manufacturer with cochlear implants compatible with 1.5 and 3.0 tesla magnetic resonance imaging (MRI) scans without magnet removal in the United States. A cochlear implant had previously been a burden for patients who required an MRI, as the magnet contained within a standard cochlear implant was not MRI-compatible. Prior to the development of the MRI-compatible cochlear implant, elaborate safety precautions or in some cases, surgical removal of the cochlear implant magnet, were needed for patients who required an MRI after cochlear implantation.

Australia (1960s)

Electronic Implantable Hearing Devices: Innovation Down Under

Professor Graeme Clark of Australia began his research into the mechanics of electronic implantable hearing devices in his role as Professor of the Department of Otolaryngology at the University of Melbourne.¹⁴ In 1977, Professor Clark had a fortuitous encounter with a turban shell on Minnamurra Beach in New South Wales, Australia, where he introduced a blade of grass through the shell.¹⁴ This experience laid the groundwork for the concept of electrode introduction into and along the length of the cochlea. Alongside a few pioneering engineers, Professor Clark developed microchips for the sound processor, and just one year later, their first patient received a cochlear implant. A small medical device group named "Nucleus" caught wind of this re-markable experiment in 1979, and teamed up with Professor Clark, along with the Australian

Government, to develop and market a commercially viable cochlear implant. This partnership would be the beginning of the formation of a new company—Cochlear Limited.

1980s: The Establishment of Cochlear Limited

In 1982, Cochlear Limited was formed, and their first official headquarters was established in Sydney, Australia.¹⁴ The first cochlear implantation utilizing Cochlear's technology was completed in 1982 by Professor Clark, Drs Brian Pyman and Robert Webb of the University of Melbourne at the Royal Victorian Eye and Ear Hospital.¹⁵ Shortly thereafter in 1985, Professor Clark went on to perform successful cochlear implantations of two children in 1985. Around this time, Cochlear made a move to the United States of America to expand their global reach. In the same year that the two children were implanted in Australia, Cochlear's Nucleus implant system was approved by the FDA as the first multi-channel cochlear implant for use in the United States. Cochlear's global vision took them to Tokyo, Japan, in 1989, and in 1991, the Nucleus system was the first cochlear implant system approved for use in Japan.

1990s–2000s: Cochlear Limited's Quest to Perfect the Implant

As popularity of Cochlear Limited's Nucleus cochlear implant gained traction, the company's focus shifted to fine tuning and refining the design of the electrode, sound processor, and sound coding strategies. Innovations such as the "Softtip[®]" electrode, designed to preserve the inner strictures of the cochlea, were among the first designs to acknowledge the importance of hearing preservation with cochlear implantation.¹⁴ In 2008, Cochlear released their first hybrid implant—the Hybrid L24—which was designed for patients who suffered from high frequency hearing loss with residual low frequency hearing ability amenable to traditional hearing aid technology. The turn of the century also marked Cochlear's expansion of their osseointegrated hearing aid product line, coined the "Baha[®]." Osseointegrated hearing implants work by translating acoustic energy into vibratory stimuli that are transmitted

directly to the cochlea from the implant's position on the mastoid. In 2002, the Baha[®] was approved as an effective auditory rehabilitation aid for those who suffer from single-sided deafness.

United States of America (1960s)

Pioneering Efforts in Cochlear Implantation in Coastal California

In an unlikely twist of fate, Dr William House, an otolaryngologist in Los Angeles, California, learned of André Djourno and Charles Eyriès' electrical escapades through a piece of newsprint delivered to him by an interested patient.⁸ Shortly thereafter, House joined forces with Dr James Doyle, a neurosurgeon, and Jack Urban, an electrical engineer, to formally undertake the process of cochlear implant development.⁸ House's team's efforts resulted in the first cochlear implantation in 1961. In parallel, Dr Blair Simmons of Stanford began experimenting with cochlear implantation in animals as well as humans. In 1972, House and his team developed a commercially scalable cochlear implant and began formal clinical trials of this implant in 1973.¹⁶ Later in the 1980s, Dr House would partner with Jack Urban once again to produce a single channel cochlear implant with the 3M Company.³

An important milestone in the United States was the national recognition of the cochlear implant and its potential to help recipients. This recognition came in the form of a report commissioned by the National Institutes of Health (NIH) with Dr Robert Bilger of the University of Pittsburgh in 1977.⁸ The report, coined "The Bilger Report," demonstrated that the thirteen patients who had been implanted in the United States had measurable benefits in lip-reading and hearing ambient sounds in the environment around them.⁸ This report opened the dialog, as well as funding, for cochlear implantation as a legitimate therapy, in the eyes of the NIH.⁸

1990s: The Emergence of Advanced Bionics

Advanced Bionics (AB) came to fruition in 1993 under the direction of Alfred Mann.¹⁷ The begin-

nings of the company came from influences from the cardiac pacemaker and diabetic drug delivery pumps, in conjunction with cochlear implant expertise at the University of California in San Francisco that had been ongoing since the 1970s and 1980s. Their first cochlear implant produced by AB was approved by the FDA in 1996, and was purported to be the first multiprogram processor with a single headpiece design at the time. Over the next 10 years, AB would further refine their sound processors, electrodes, and speech enhancement technologies. In 2007, Sonova, a Swiss company, had merged with Phonak, a global leader in hearing aid technologies, and shortly thereafter acquired AB in 2009.¹⁸ With the acquisition of AB, Sonova has created a comprehensive portfolio of expertise in auditory rehabilitation technologies spanning the range of hearing aids to cochlear implants.

The Cochlear Implant in Other Countries

While the early beginnings of the cochlear implant may have been born primarily in the countries mentioned above, the technology has spread to benefit patients around the globe. After the first cochlear implant was performed in Cuba in 1998, the Cuban government formed a National Cochlear Implant Group in 2000 that focuses on public policy for cochlear implantation. This publically funded comprehensive program includes mechanisms for identification and patient selection, total surgical management coverage from preoperative evaluation through to postoperative care, as well as auditory rehabilitation programs throughout the patient's life. In nearby Latin America, Mexico, Argentina, Colombia and Ecuador also developed cochlear implant programs in the 1980s and 1990s.¹⁹ Overseas, Spain developed a national cochlear implant program in 1985, as did the small Greek island of Crete in 1997.²⁰ France developed and commercialized a cochlear implant device under the auspices of Neurelec, which was then purchased and is now marketed by Denmark's Oticon as the "Neuro One."²¹ In addition, Asia, Korea, Japan, and China have also implemented extensive cochlear implant programs.²²⁻²⁴ In Japan, health insurance initiated

coverage of cochlear implantation in 1994, and the annual cochlear implant volumes have steadily increased since this support began.²³ China began a pilot to support 1500 cochlear implants in 2009, and the central government launched a fully funded, centralized program in 2011 following the success of the pilot.²² More recently, collaborations between the University of California and investigators in China have resulted in the development of a low-cost, high-performance cochlear implant, now marketed as "Nurotron."²⁵ The mission of Nurotron is to introduce its cochlear implant to broaden access, including those in the developing world, where the need is potentially greatest.

As health care in the developed world can be expensive, it is not surprising to find reports of cochlear implantation being offered in some countries at lower expense. India is a widely known destination for 'medical tourism,' and a patient can obtain cochlear implantation and some related services at a cost approximately half of that quoted in the United States.²⁶ Although such arrangements may appear to offer a solution to high costs of care, caution is advised. Surgical implantation is merely the beginning of the process of aural (re)habilitation, and successful treatment requires full access to follow-up by specialists, such as audiologists, speech pathologists, and teachers of the hearing impaired, in the home country. This is best achieved with coordinated care by a team of specialists, from identification through (re)habilitation.

Conclusion

As of the writing of this chapter, three cochlear implant manufacturers have full US FDA approval—Advanced Bionics, Cochlear Corporation, and MED-EL.¹⁶ Technology continues to advance with the production of new electrode designs, electrode delivery, hearing preservation techniques, smaller and more powerful processors, as well as implant connectivity with mobile phones, and other electronic devices. In the near future, we may see totally implantable cochlear implants, robot-assisted and minimally invasive surgical implantation, as well as refinement of sound processing strategies to bring

the quality of audio perception closer to natural hearing.¹⁶ With a storied past as one of the most fascinating medical device developments to date, the future of cochlear implantation is bright with a significant opportunity to disseminate this technology to restore hearing to patients around the globe.

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