

COCHLEAR IMPLANTS

*Audiologic Management and Considerations
for Implantable Hearing Devices*

Editor-in-Chief for Audiology
Brad A. Stach, PhD



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*Audiologic Management and Considerations
for Implantable Hearing Devices*

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Preface

All in One Place, for Audiologists

Almost 30 years ago, the multiple-channel cochlear implant was approved by the United States Food and Drug Administration (FDA) for clinical use with adults. Other implantable hearing devices, such as implantable bone conduction devices, middle ear implants, and auditory brainstem implants have been in clinical use for over 20 years. Over the past 20-plus years, these implantable hearing technologies have been covered in several excellent textbooks. However, no textbook has comprehensively addressed the audiologic considerations pertaining to each of the implantable hearing technologies available for children and adults with hearing loss. The objective of this textbook is to fill that void. Specifically, this textbook aspires to provide comprehensive coverage pertaining to the audiologic management of cochlear implants, implantable bone conduction devices, hybrid cochlear implants, middle ear implants, and auditory brainstem implants. This book is intended to serve as a text for AuD and PhD courses covering implantable hearing technologies and also as a resource to guide audiologists who are providing patient care in clinical settings. Although this book is primarily written for and by audiologists, it also will hopefully be helpful for other clinicians and researchers who are interested in implantable hearing technologies.

This book is intended to be a practical, “how-to” book. For each of the implantable hearing technologies discussed in this text, the author has sought to provide a summary of the assessment battery used to determine candidacy for the implantable hearing device, the audiologic procedures used to program the device to optimally meet the recipient’s unique needs, and the assessment battery used to evaluate the outcomes achieved with each type of implantable hearing device. Audiologic management of hearing technologies is discussed in general terms, but for implantable hearing technologies that are approved for commercial distribution by the United States FDA, detailed, manufacturer-specific information is also provided.

This textbook is also unique because it is primarily written by a single author who has substantial experience in both the clinical and research arenas associated with implantable hearing technologies. The potential advantage of a singular voice is to avoid redundancy across chapters while also avoiding the omission of information that is vitally important in regard to the audiologic management of implantable hearing technologies. Of note, however, the expertise of a handful of gifted clinicians was accessed to cover four topics that did not directly fall within the scope of the primary author’s personal experience including the medical aspects pertaining to cochlear implantation (which was authored by an experienced cochlear implant surgeon), considerations for radiologic imaging of implantable hearing device recipients (which was authored by a physician who is trained both as a medical radiologist and an otologist), considerations pertaining to the relationship of vestibular function and cochlear implantation (which was authored by an audiologist who specializes in the clinical and research aspects related to vestibular assessment and management), and the medical aspects pertaining to implantable bone conduction devices (which was authored by an otologic surgeon who has considerable experience with bone conduction implants).

The first chapter of this textbook summarizes the fascinating history of cochlear implant technology. The second and third chapters provide basic information pertaining to the physics and physiology associated with implantable hearing technology. Chapters 4 through 6 address matters associated with cochlear implant candidacy assessment. Chapters 7, 8, 14, 20, and 23 discuss basic principles pertaining to the management of cochlear implant recipients. Chapters 7, 8, 9, 15, 16, and 17 provide manufacturer-specific information regarding the hardware, signal processing, and programming of modern cochlear implant systems. Chapters 12 and 13 provide information pertaining to medical considerations associated with cochlear implantation. Chapter 18 provides a thorough overview of objective measures that may be used to evaluate the function of cochlear implant technology and the recipient’s auditory responsiveness.

to electrical stimulation from the cochlear implant, whereas Chapter 19 provides an excellent overview of the important points to consider regarding vestibular function and cochlear implantation. Chapter 24 provides a summary of electric-acoustic stimulation and hybrid cochlear implant technology. Chapter 25 provides a brief overview of the basics pertaining to auditory brainstem implants. Chapters 26 and 27 provide information pertaining to the assessment and management of recipients with implantable bone conduction devices. Chapter 28 provides a basic overview of middle ear implantable devices.

A relatively larger portion of this text is devoted to cochlear implant technology because the typical audiologist is more likely to encounter cochlear implant recipients than auditory brainstem implants or middle ear implant recipients. Although bone conduction implants are fairly commonplace, an argument can be reasonably made that the management of cochlear implant recipients is more complex than the management of bone conduction implant recipients. As a result, the author has made an attempt to

provide the reader with a thorough knowledge base that will facilitate the clinical management of recipients of each of the implantable hearing technologies discussed in this textbook.

Although no book can provide an exhaustive, detailed coverage of all of the information pertaining to implantable hearing technologies, it does provide comprehensive basic information that is supported by extensive references. The book certainly provides a robust foundation that will allow an audiologist to build a skillset that will capably serve recipients of implantable hearing technologies. However, the clinician should strive to stay current with advances that will inevitably occur with implantable hearing technologies. Medical knowledge is always evolving and advancing. The astute clinician never ceases to be an eager student. Finally, this book includes a tangible demonstration of clinical practices associated with implantable hearing technologies in a supplemental video that is available on a PluralPlus companion website.

Acknowledgments

Several of my former professors and mentors influenced the development of this book, either in the knowledge that they imparted over the past 20 years or in the support and encouragement they provided as I wrote the manuscript. I will always be grateful for my “audiology heroes,” a group of professors, researchers, and master clinicians who have shared their expertise with me. These generous and ingenious individuals include Stephen Painton, Richard Talbott, Michael Grim, J. Michael Dennis, James W. Hall III, Francis Kuk, Christine Jones, Stefan Launer, Rene Gifford, and Richard Seewald. I am grateful from Teresa Caraway, Stan Baker, and Mark Wood who coaxed me into working with children with cochlear implants and who continue to serve as valuable colleagues and friends today. I am also grateful to the countless pioneers and visionaries who have contributed to the development and refinement of the cochlear implant and other implantable technologies. Many of these surgeons, clinicians, and scientists are mentioned throughout this book.

I am also very indebted to a large group of people who have directly contributed to the development of this book. I am grateful for a host of talented healthcare professionals who have generously sacrificed their time and energy to share their expertise as chapter authors. Stan Baker, Mark Wood, and Anthony Alleman are gifted physicians who wrote excellent chapters summarizing the medical aspects associated with implantable hearing technologies. Jamie Bogle is one of the brightest young minds in vestibular assessment, and she was gracious enough to write a terrific chapter on the factors pertaining the vestibular function and cochlear implantation. Elizabeth Musgrave is a talented audiologist and electrophysiologist who co-authored an informative chapter on regulatory considerations pertaining to cochlear implantation. Also, my long-time colleague and friend, Professor Erin Schafer contributed to several chapters in this book. Dr. Schafer is one of the most intelligent audiologists I have ever known. I am fortunate to be able to work with her. Laura Schadt, Sarah McCullough, and Skyler Thompson are all students who study under Dr. Schafer. They were kind

enough to assist in the formatting of the references that were cited in this text. Without their help, this book may still be “in process.”

Several representatives from implantable hearing technology companies also helped to contribute information and images specific to each of their technologies. These helpful colleagues include Smita Agrawal, Erin Nelson, Sarah Downing, Leo Litvak, Darla Franz, Scott Hansson, Nathalie Davis, Amy Donaldson, Amy Popp, Pete Arkis, Aaron Parkinson, Leigh Ann Monthey, Christy Miller-Gardner, Jessica Ballard, Darren Knowles, George Cire, Phil Guyer, Kimberlee Griffey, and Chrissy Parlacoski. I also am thankful for Kalie Koscielak, Valerie Johns, and numerous other team members at Plural Publishing, Inc. for their tireless and capable efforts to bring this book to print.

I am continually thankful for the team of colleagues with whom I get to work at Hearts for Hearing. I know that I am biased, but I truly believe that I work with the best implantable hearing technology team in the world! Not a week goes by that I do not personally benefit from the talents and generosity of my excellent colleagues at Hearts for Hearing. I am also grateful for thousands of patients I have been privileged to serve. Without a doubt, much of the information in this book has been influenced by the lessons I have learned as I have strived to optimize the outcomes of recipients of implantable hearing technologies. Additionally, I am forever indebted to Joanna Smith, the Chief Executive Officer of Hearts for Hearing and my boss, friend, mentor, counselor, and colleague. Joanna has constantly encouraged me to shoot for the stars when working with recipients of implantable hearing technologies. She also continually inspires me to honor Him by maximizing the opportunities of individuals with hearing loss to listen and talk for a lifetime.

I owe a heartfelt thanks to my wonderful family. I am so proud of my three children, Hayden, Harper, and Henley. I love them with all of my heart, and I often felt like I should scrap the whole idea of this book because it interfered with time I could be spending with them. I appreciate their patience. I hope this book makes them proud of me and instills in them

the importance of making sacrifices and working hard to hopefully make life better for others. Finally, I am most grateful for and indebted to my soulmate, life partner, and wife, Lynnette, whose love, support,

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1

Basic Operation and History of Cochlear Implant Technology

Jace Wolfe

Introduction

The multiple-channel cochlear implant is the most successful sensory prosthetic device in the history of medicine. Many persons who develop severe to profound hearing loss in adulthood are able to achieve excellent open-set speech recognition (Gifford, Shallop, & Peterson, 2008; Helms et al., 2004), and many are also able to communicate over the telephone (Anderson et al., 2006; Wolfe et al., 2016a, 2016b). Additionally, children who are born with severe to profound hearing loss and receive a cochlear implant during the first year of life frequently develop age-appropriate spoken language abilities (Ching et al., 2013a; Dettman et al., 2016; Geers, 2004; Geers, Brenner, & Davidson, 2003; Geers, Moog, Biedenstein, Brenner, & Hayes, 2009). For instance, Dettman and colleagues (2016) evaluated spoken language outcomes in 403 children who used cochlear implants and were entering kindergarten and reported that almost 81% of those implanted before 12 months of age had normal vocabulary development.

Cochlear implants bypass the sensory function of the cochlea and stimulate the cochlear nerve directly. The primary function of the cochlea is to convert acousto-mechanical energy into neural impulses that may be delivered from the cochlear nerve to the auditory nuclei in the brainstem. Specifically, cochlear sensory cells, known as hair cells, serve as transduc-

ers that convert the hydrodynamic energy of cochlear fluid displacement (in response to acoustic stimulation) into neuro-electric impulses. In most cases of sensorineural hearing loss, the primary site of lesion is localized to the cochlear hair cells (i.e., auditory sensory cells) or to the structures that support the electrochemical environment within the cochlea that is necessary to allow for effective stimulation of the hair cells (e.g., genetic mutations that interfere with the development of the stria vascularis, which is instrumental in the production of K⁺ ions that maintain the highly positive endocochlear resting potential necessary for normal hair cell function).

The term “nerve deafness” is often used to describe sensorineural hearing loss, but this term usually does not accurately describe the primary underlying etiology of the hearing loss. The cochlear nerve is typically intact for the most part and functional, but in the case of severe to profound hearing loss and the concomitant loss of cochlear hair cells, the cochlear nerve does not receive adequate stimulation from the cochlear sensory cells. As a result, the cochlear nerve delivers a severely impoverished signal to the auditory nervous system. Cochlear implants are of substantial benefit to many persons with severe to profound hearing loss, because electrical stimulation is directly delivered to the functional cochlear nerve, resulting in the provision of a more robust auditory signal that includes components spanning the entire speech frequency range (Figure 1–1).

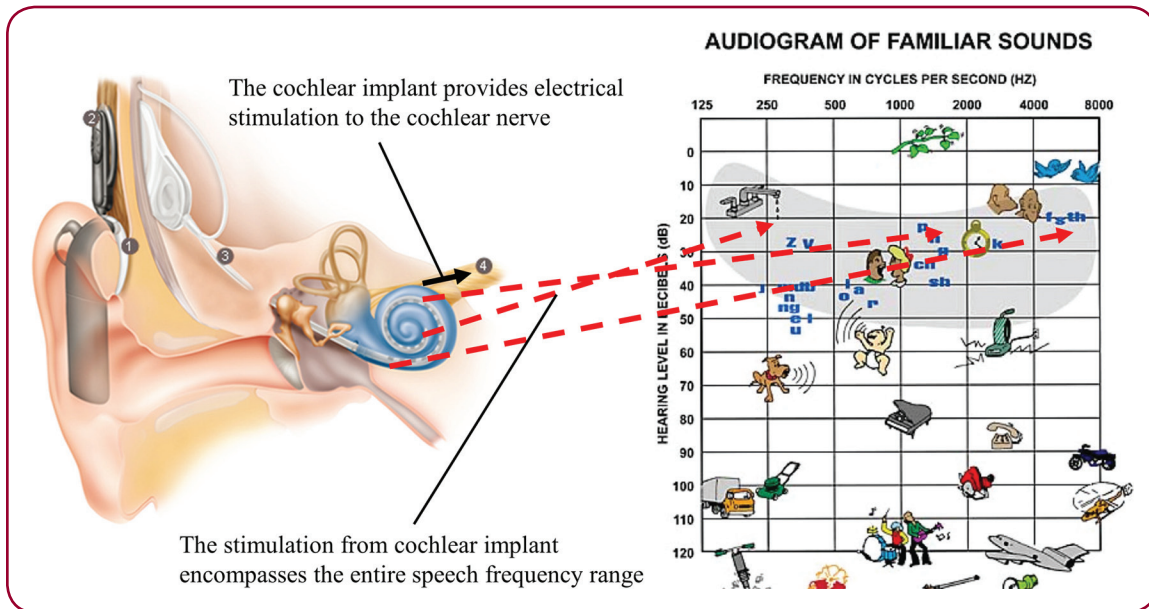


FIGURE 1-1. An illustration of a behind-the-ear cochlear implant sound processor and cochlear implant providing stimulation to the cochlear nerve so that audibility is restored throughout the speech frequency range. The image of the auditory system with cochlear implant is provided courtesy of Cochlear Americas, ©2018. The image of the familiar sounds audiogram is provided courtesy of Advanced Bionics, LLC.

It should also be noted that cochlear implants may also be beneficial for some persons who have cochlear nerve pathology. For instance, many researchers have shown that cochlear implants may provide significant improvements in speech recognition of persons with auditory neuropathy, many of whom likely have cochlear nerve abnormalities (e.g., demyelination of the cochlear nerve) (Ching et al., 2013b; Rance & Barker, 2008). In cases of demyelination of the cochlear nerve, it is possible that the high level of neural synchronization provided by electrical stimulation of the cochlear nerve results in a more robust signal than may be elicited by acoustical stimulation.

Furthermore, post-mortem studies have shown rather sparse populations of surviving spiral ganglion cells in some persons who achieved good benefit from and high levels of open-set speech recognition with a cochlear implant (Khan et al., 2005; Linthicum & Fayad, 2009). Additionally, research has shown that some (but certainly not all) children with deficient cochlear nerves, as indicated by magnetic resonance imaging (MRI), achieve open-set speech recognition and develop spoken language abilities after cochlear implantation, albeit with outcomes that are diminished compared with a child with a normally

developed cochlear nerve (Peng et al., 2017). Taken collectively, the studies mentioned in this paragraph suggest that it is possible to achieve a relatively modest amount of benefit from cochlear implantation in the presence of a fairly small population of functional cochlear nerve elements.

Basic Hardware of Cochlear Implants

There are certainly numerous differences in the hardware of cochlear implant systems produced by the various implant manufacturers, but all cochlear implant systems possess some basic components that are common across manufacturers. Every cochlear implant system comprises two general components: an external sound processor and the cochlear implant, which is sometimes referred to as the internal device. An example of external sound processors are shown in Figure 1-2, and an example of a cochlear implant is shown in Figure 1-3. Of note, the unique technologies and differences across cochlear implant manufacturers will be discussed in Chapters 9, 10, and 11.



FIGURE 1-2. A Nucleus CP1000 behind-the-ear sound processor. Image provided courtesy of Cochlear Americas, ©2018.



FIGURE 1-3. A Nucleus Profile cochlear implant. Image provided courtesy of Cochlear Americas, ©2018.

Cochlear Implant External Sound Processor

The external sound processor typically consists of five basic components: a microphone (or microphones), a digital signal processor, a power source (i.e., a battery), an external transmitting/receiving coil (i.e., external antenna), and an external magnet. The sound processor depicted in Figure 1-2 is behind the ear and, as shown, possesses a cable that exchanges information between the sound processor and the external coil. Sound processors are now available in a wide variety of configurations. Figure 1-4 provides examples of behind-the-ear, body-worn, and off-the-ear/single unit sound processors. As shown, the off-the-ear/single-unit sound processors do not contain a transmitting cable, because the microphone, digital signal processor, power source, and transmitting/receiving coil are housed in the same unit. Most sound processors are operated by lithium-ion rechargeable batteries. Lithium-ion technology has several advantages over other types of rechargeable batteries, including a flat voltage discharge curve, a long shelf life, a relatively robust voltage capacity, as well as the fact that it has little to no memory effect (i.e., it does not lose its ability to accept a full charge

if it is not charged from a mostly depleted state during each charging cycle). Of note, many modern sound processors may also be powered by zinc-air #675 hearing aid batteries or alkaline disposable batteries.

Cochlear Implant

The cochlear implant consists of six basic components, (1) the internal receiving/transmitting coil (i.e., internal antenna), (2) an internal magnet, (3) a digital signal processor, (4) a stimulator for electric pulse generation, (5) electrode leads, and (6) an electrode array. Together, the internal coil, digital signal processor, and stimulator are sometimes referred to as the receiver/stimulator. The digital signal processor and stimulator are housed in a biocompatible titanium case. Recently, there has been a general trend toward reducing the size (primarily the thickness) of the case in order to reduce the need for the surgeon to create a deep recession in the skull to accommodate the case as well as to reduce the tension/stretching placed on the skin that resides above the implant.

The electrode leads deliver the electric current from the stimulator to the electrode array that is

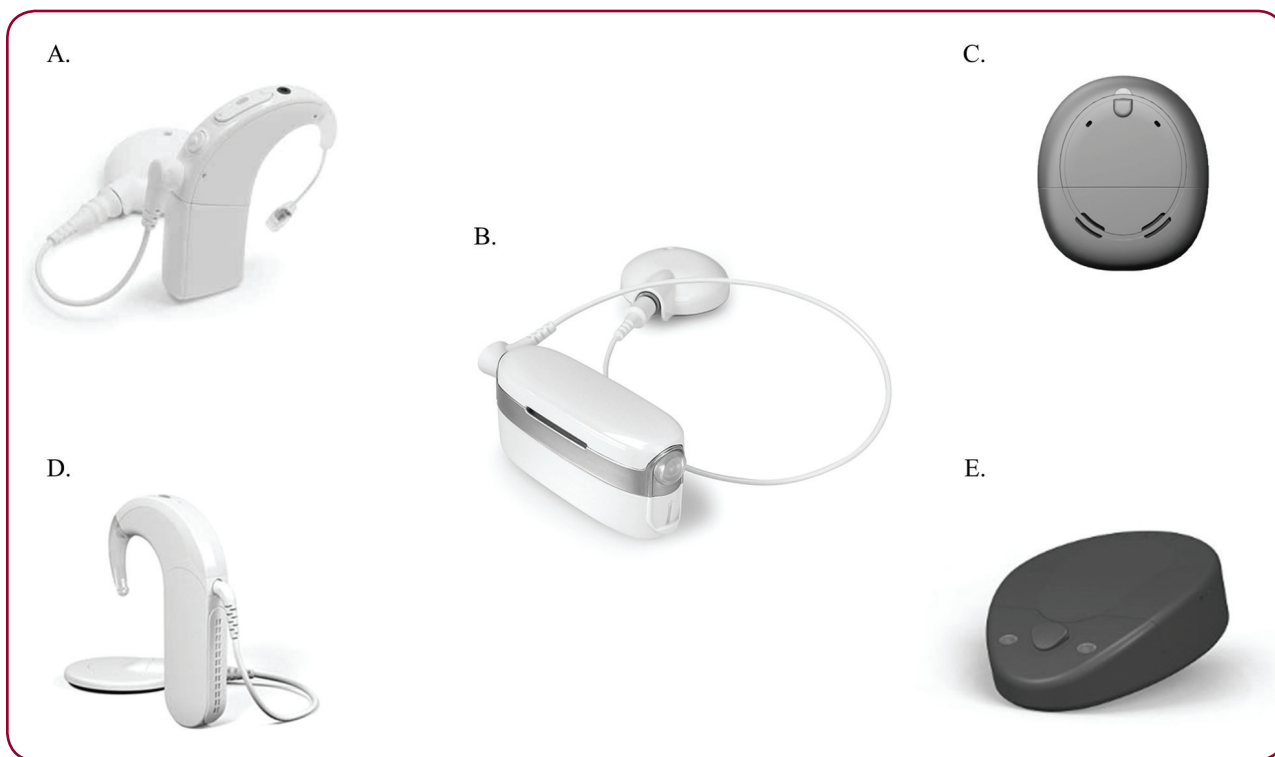


FIGURE 1-4. An illustration of several different types of cochlear implant sound processors including ear-level, body-worn, and on-the-head sound processors. **A.** Advanced Bionics Naida CI Q series sound processor, image provided courtesy of Advanced Bionics, LLC. **B.** Advanced Bionics Neptune sound processor, image provided courtesy of Advanced Bionics, LLC. **C.** Cochlear Nucleus Kanso sound processor, image provided courtesy of Cochlear Americas, ©2018. **D.** MED-EL SONNET sound processor, image provided courtesy of MED-EL Corporation. **E.** MED-EL RONDO sound processor, image provided courtesy of MED-EL Corporation.

housed within the cochlea. The electrode array consists of multiple (e.g., 12 to 22) electrode contacts. Collectively, the electrode leads and electrode array are sometimes referred to as the electrode.

There are numerous differences in the design and philosophy underlying the design of electrode arrays developed by the different cochlear implant manufacturers. Some electrode arrays are designed to be inserted close to the neural elements innervating the cochlea, whereas other electrode arrays are designed to be positioned remotely from the neural elements in an attempt to avoid trauma to the delicate sensory cells and supporting structures of the organ of Corti. Additionally, some electrode arrays are designed to be inserted to a relatively shallow depth in the cochlea (e.g., just beyond the first turn), while other electrode arrays are much longer and designed to be inserted toward the most apical end of the cochlea.

Basic Operation of Cochlear Implants

As with cochlear implant hardware, several differences exist in the way in which cochlear implant systems process and code incoming audio signals and provide stimulation to the cochlear nerve, but there are also some fundamental similarities in the manner in which cochlear implant systems operate. Figure 1-5 provides an illustration of the basic function of a cochlear implant system. The reader should note that the signal coding strategy described in Figure 1-5 and in the following paragraphs is a simplified explanation of the *Continuous Interleaved Sampling* (CIS) signal coding strategy, which essentially serves as a foundation for modern cochlear implant signal coding strategies. However, there are numerous differences between the original CIS signal coding strategies and signal coding strategies that are

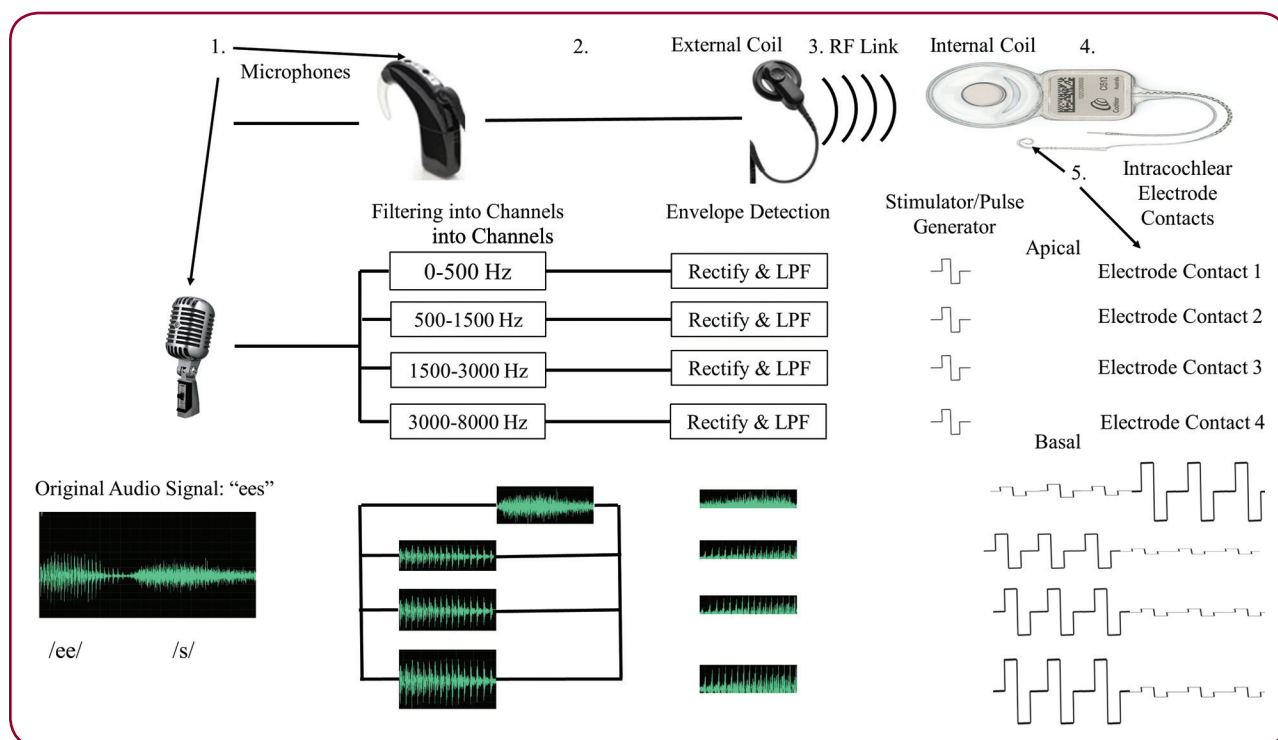


FIGURE 1-5. A block schematic of the Continuous Interleaved Stimulation (CIS) signal coding strategy.

used in most contemporary cochlear implant systems. The reader can find greater detail on cochlear implant signal coding strategies in Chapter 8.

As shown in Figure 1-5, the microphone(s) of the external sound processor captures the incoming audio signal and converts it into an electrical signal. The electrical signal is delivered to a preamplifier that increases the amplitude of the signal in order to improve the signal-to-noise ratio prior to further processing. The preamplifier typically provides a greater increase to the high-frequency components of the audio signal, because high-frequency speech sounds, such as /s/, are usually less intense and are more susceptible to masking from the relatively high-level, low-frequency speech and environmental sounds.

Next, the signal is analyzed by the sound processor's digital signal processor to determine the composition of the audio input in the frequency, temporal, and intensity domains. At this stage of operation, the signal is divided into different analysis bands (e.g., frequency bands or channels) to allow for frequency-specific processing and eventual stimulus delivery. The process of parsing the broadband input signal into spectral analysis bands is typically accomplished

with digital filtering (e.g., fast Fourier transformation, Hilbert transformation). During this stage of signal analysis, the sound processor may attempt to classify the signal as speech, noise, or some other type of acoustic signal, and signal processing may take place with the goal of optimizing signal delivery to the recipient (e.g., reduction in signal intensity in analysis bands mainly comprising noise along with an enhancement of the signal intensity within the analysis bands determined to primarily comprise speech). However, it is prudent to clarify that audio signal classification is not a component of the original CIS signal coding strategy.

It is important to note that prior to the recipient's use of the cochlear implant system, an audiologist typically programs the sound processor with the goal of determining the magnitude of electrical current required at each electrode contact (as noted later, an electrode contact usually corresponds to a particular analysis band associated with the contact in the spectral domain) to facilitate audibility as well as to produce a sensation that is loud but not uncomfortable, a process that is sometimes referred to as MAPPING (i.e., determining the implant recipient's electrical

dynamic range so that the desired range of acoustic inputs may be MAPPED into the recipient's electrical range of hearing with the end goal of restoring audibility and normalizing loudness).

After the audio signal has been spectrally analyzed and assigned to different analysis bands, the output from the different bands is subjected to rectification and low-pass filtering in order to capture the amplitude envelope (i.e., boundary across each of the spectral bands) of the input signal (note that Figure 1–5 depicts the process of rectification (i.e., only the components above baseline are preserved, but low-pass filtering has not yet been completed because the fine temporal structure of the original signal remains). Then, based on the information that was obtained during the MAPPING process, the sound processor determines the magnitude of stimulation that should be delivered to elicit audibility and a loudness percept that is appropriate for the input level of the audio signal).

Next, the digital signal processor converts the processed signal to a coded electrical signal that is delivered to the external coil, which delivers the signal across the recipient's skin to the internal coil of the cochlear implant via digital electromagnetic induction/radiofrequency (RF) transmission with a carrier frequency ranging from approximately 2.5 to 50 MHz. The signal delivered from the processor to the cochlear implant determines how the implant should deliver electrical stimulation to the cochlear nerve. Furthermore, the cochlear implant does not contain its own power source, so the RF signal delivered from the sound processor is also used to operate the cochlear implant.

Once the cochlear implant receives the digitized RF signal, it is analyzed by the digital signal processor of the implant. The cochlear implant possesses a stimulator that continuously produces biphasic electrical pulses at a fixed, moderate to fast rate (e.g., typically in the range of 800 to 1600 pulses per second) (the term “continuous” in CIS refers to the fact that electrical pulses are continuously delivered at a fixed rate). The amplitude of these electrical pulses is modulated (i.e., varied) by the magnitude of the amplitude envelope of the signal in each analysis band (see Figure 1–5). In other words, the amplitude of the electrical pulses is directly proportional to the magnitude of the amplitude envelope of the original signal (the term “sampling” indicates that the amplitude envelope of the original audio signal is captured or sampled and used to determine the magnitude of the stimulation delivered to the cochlear nerve).

Then, the amplitude-modulated electrical pulses are delivered to electrode contacts that correspond to a given analysis band. More specifically, multiple channel cochlear implants take advantage of the natural tonotopic organization that exists in the cochlea by delivering high-frequency signals to electrodes located toward the basal end of the cochlea and low-frequency signals toward more apical locations. As shown in the Figure 1–5, the electrical pulses delivered across each of the electrodes are slightly staggered in time so that an electrical pulse is never simultaneously delivered to two different electrode contacts, hence the term “interleaved.”

The History of Cochlear Implants

Antecedents to the Development of the Cochlear Implant

Advances in understanding electricity and basic electronics in the late 1700s and early 1800s led to rudimentary experiments in which physicists explored the potential to stimulate the auditory system with electrical current. In 1752, a physicist, Benjamin Wilson, described a rather crude attempt at electrical stimulation to elicit auditory sensation in a woman who was deaf:

The covered vial being electrised by two turns of the wheel only, I applied the end of a thick wire, which was fastened to the covering of the vial, to the left temple, just above the ear; then, I brought the end of that wire, which was in the vial, towards the opposite side of her head, and there ensued a small explosion. She was much surprised and perceived a small warmth in her head, but chiefly across it from ear to ear. I repeated the experiment four times and made the electrical shock stronger on each trial.

Quite obviously, Wilson's method of electrically stimulating the auditory system of a person with hearing loss is no longer in use in research laboratories or clinical settings today.

In the same vein, the noted Italian physicist Alessandro Volta (pictured in Figure 1–6), who is credited with the invention of the battery and for whom the SI unit of electrical force (i.e., volt) is named, also described a primitive attempt to electrically stimulate his own auditory system. Around the year 1800, Volta

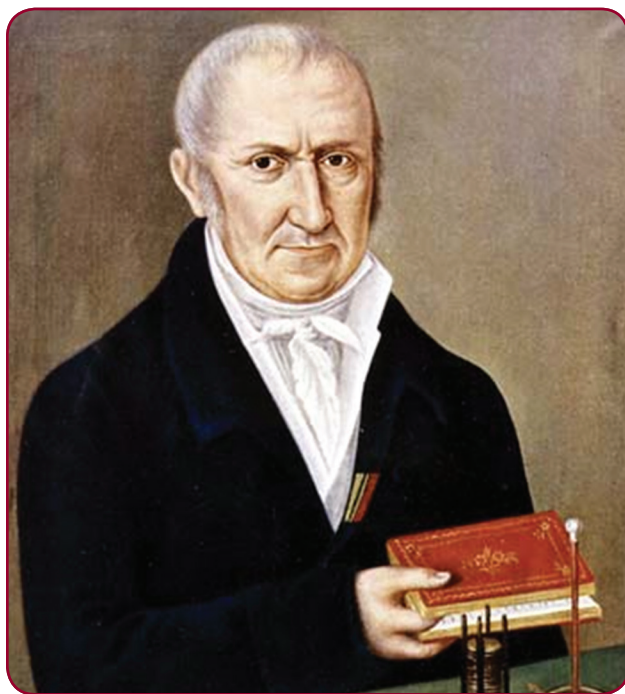


FIGURE 1-6. Alessandro Volta. Image provided courtesy of Encyclopedia Britannica, Inc.

inserted leads from each end of a 50-volt battery into each ear, completing a circuit for electric current to travel through his auditory system. He described the resulting experience as follows:

At the moment when the circuit was complete, I received a shock in the head, and some moments after, I began to hear a sound, or rather a noise in the ears, which I cannot well define: it was kind of crackling with shocks, as if some paste or tenacious matter had been boiling. . . . This disagreeable sensation, which I believe might be dangerous because of the shock in the brain, prevented me from repeating the experiment.

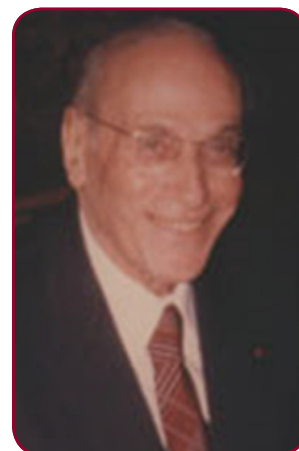
Volta's description of his experience with electrical stimulation of the auditory system seems far from pleasant, and indeed, there was a paucity of reports describing electrical stimulation of the ear for a considerable period of time.

The Nascent Stage of Cochlear Implantation

André Djourno and Charles Eyriès (pictured in Figure 1-7) are generally recognized as the first per-



A



B

FIGURE 1-7. A. Charles Eyriès. B. André Djourno. Images provided courtesy of Claude-Henri Chouard, M.D.

sons to develop an implantable prosthesis designed to electrically stimulate the cochlear nerve. Djourno was an electrophysiologist who developed an interest in the use of electrical stimulation for medical purposes. For instance, he explored the possibility of providing artificial respiration through electrical stimulation of the phrenic nerve. Additionally, his research focused on the use of implantable induction coils, which would allow for stimulation to be delivered electromagnetically across the skin (i.e., transcutaneously) to an implanted coil which would then deliver electrical current to peripheral nerves or muscles. An example of one of Djourno's induction coils is shown in Figure 1-8.

Eyriès was an otolaryngologist who developed an expertise in facial nerve reconstruction. In 1957, while Eyriès and Djourno were both working at the L'Institut Prophylactique in Paris, Eyriès sought to provide a facial nerve graft for a patient who had bilateral cholesteatomas requiring temporal bone resection and bilateral severance of the facial and cochlea-vestibular nerves. Eyriès visited the medical center's cadaver laboratory in search of tissue that could be used to support a facial nerve graft. While seeking suitable grafting tissue, Eyriès discussed the case with Djourno, who suggested implantation of an induction stimulator in order to provide electrical stimulation of the cochlear nerve. Considering the fact that the patient, who was deaf, had nothing to lose from this novel procedure conducted in conjunction with the facial nerve repair, Eyriès agreed to implant Djourno's device.



FIGURE 1-8. An example of induction coils used by Charles Eyriès and André Djourno. Image provided courtesy of Claude-Henri Chouard, M.D.

Upon examination of the cochlear nerve during surgery, Eyriès noted that most of the cochlear nerve had been resected, leaving a small stump near the brainstem. He placed the stimulating lead from Djourno's induction coil in the base of the remaining cochlear nerve and the ground electrode in the temporalis muscle. Following surgery, Djourno was able to deliver stimulation to the implanted device via electromagnetic induction. The patient was able to astutely distinguish changes in the intensity of stimulation but could only differentiate broad differences in the frequency of stimulation. Although the patient was enthused by the ability to be able to hear again, he was unable to understand speech presented in open-set without visual cues. Unfortunately, the device malfunctioned after a short period of use. Eyriès implanted a second device, which also quickly malfunctioned. Eyriès and Djourno parted company at that point.

To be completely accurate, Eyriès and Djourno's device was not a cochlear implant. First, the stimulating lead was not placed in the cochlea. Second,

because the cochlear nerve was essentially destroyed by the previous temporal bone resection, electrical stimulation was possibly provided directly to the cochlear nuclei in the brainstem rather than to an intact and functional cochlear nerve. However, their collaborative work represented the first successful endeavor in which an implantable device was used to electrically stimulate the auditory nerve. Furthermore, their work served as motivating impetus for William F. House and Claude Henri-Chouard, two persons who eventually became pioneers of cochlear implantation.

Development of the Cochlear Implant System

William F. House: The First Cochlear Implant Surgeon

William F. House earned degrees in dentistry and medicine. He was a successful otologist who was a pioneer in temporal bone surgery, including middle fossa approaches to access the internal auditory meatus. In 1958, a patient brought Dr. House a newspaper article that described how Eyriès and Djourno had created an implantable device that allowed persons with profound hearing loss to hear (House, 1974, 2011). Dr. House was very intrigued by Eyriès and Djourno's work and decided to explore the development of implantable hearing technology. In his memoirs, Dr. House noted,

I had seen deaf children with some residual hearing who could hear a degraded signal with a hearing aid and could learn lip-reading. It seemed possible that if an implant could give totally deaf children some hearing, they could learn lip-reading, be successful in an oral school, understand English language, and learn to read. (House, 2011, p. 67)

In January 1961, in collaboration with John Doyle, a Los Angeles neurosurgeon, Dr. House implanted a single wire into an opening anterior to the round window of a man who was profoundly deaf. The recipient was able to hear crude sounds when the wire, which protruded from the skin just behind the ear, was electrically stimulated, but the wire was removed after a few weeks because of concerns regarding infection. Another patient was implanted with a single wire in the cochlea and, once again, the recipient reported hearing sound upon stimulation, but the wire was removed after a short period of time for fear of infection. Of note, Dr. Doyle's brother, Jim Doyle, was an electrical engineer who assisted Drs.

House and Doyle in the development of instrumentation necessary to provide electrical stimulation to the cochlea (Mudry & Mills, 2013).

In February 1961, Drs. House and Doyle implanted a five-wire implant into the scala tympani of the first patient they had originally implanted a month earlier (House, 1976; House & Urban, 1973). The induction coils of the five-electrode system were seated in the skull just behind the auricle. The patient was able to detect different frequencies with stimulation to the different electrodes, which were placed at varying depths in the cochlea. The device was removed without complication in March 1961.

The positive initial experiences of House and the Doyles generated excitement among persons with hearing loss after the Doyles reported details of their cochlear implants to the media. Dr. House was upset with what he perceived to be the Doyle brothers' premature release of information about their preliminary experiences with electrical stimulation to the public. According to Dr. House (2011):

We began to be deluged by calls from people who had heard about the implant and its possibilities. The engineer who had constructed the implant exercised bad judgment and encouraged newspaper articles about the research we were doing.

Dr. House and the Doyles also disagreed on how the team should proceed toward commercialization of their cochlear implant work and who owned the intellectual property associated with their cochlear implant technology (Mudry & Mills, 2013). Dr. House also had concerns about the threat of infection and adverse reaction to the materials that were used in their early cochlear implants (Eshraghi et al., 2012; House, 2011; Hyman, 1990). As a result of these factors, Dr. House and the Doyle brothers ceased their collaborative endeavor. The Doyle brothers continued to implant patients until 1968, when a lack of finances prevented them from proceeding (Eshraghi et al., 2012). Dr. House did not resume his work to develop a cochlear implant until 1967. At that point in time, he was convinced that the success of other biomedical devices, such as pacemakers, which included hermetic sealing technology developed for the NASA space program and prevented body fluids from damaging electronic components, indicated that a cochlear implant could be created of materials and with methods that would allow for long-term durability of the device and safety of the recipient (House, 2011).

Dr. House began a collaboration with Jack Urban, an electrical engineer, in the late 1960s (Eshraghi et al., 2012; House, 1976; House & Urban, 1973; Mudry & Mills, 2013). They began implanting patients with a single-channel cochlear implant in 1969. At that time, their single-channel cochlear implant possessed a percutaneous plug that was implanted in the skull and protruded through the recipient's skin. Over the next several years, Dr. House implanted several patients with similar devices. In 1973, House and Urban reported on their early experiences with cochlear implantation in one patient in the journal *Annals of Otolaryngology, Rhinology, and Laryngology*. At this point in time, great interest in cochlear implantation was emerging in the otology and audiology communities, although many prominent clinicians, scientists, and researchers were skeptical that cochlear implantation could ever allow recipients to achieve open-set speech recognition. For example, noted otology surgeon Harold Schuknecht, M.D., Chief of Otolaryngology at the Massachusetts Eye and Ear Infirmary, attended the First International Conference on Electrical Stimulation of the Acoustic Nerve (held at the University of California San Francisco [UCSF]), where he saw videos of cochlear implant recipients responding to sound and heard case reports describing outcomes from early recipients. Dr. Schuknecht exclaimed (Henkel, 2013):

I interpreted the movies and the case presentations to confirm my suspicion that the prostheses as they are now designed are of very little use.

Schuknecht also stated (Wilson & Dorman, 2008):

I have the utmost admiration for the courage of those surgeons who have implanted humans, and I will admit that we need a new operation in otology, but I am afraid this is not it.

Merle Lawrence, a prominent hearing scientist, may have been even more skeptical than Dr. Schuknecht. Lawrence noted (Wilson & Dorman, 2008):

Direct stimulation of the auditory nerve fibers with resultant perception of speech is not feasible (Lawrence, 1964).

In spite of the skepticism surrounding his work and that of other pioneers conducting similar work in the 1960s and 1970s, Dr. House forged ahead. With the assistance of Jack Urban, in 1972, one of Dr. House's

patients became the first cochlear implant recipient to be provided with a wearable sound processor that could be used outside of the clinic (Figure 1–9). As a result of the fact that Dr. House was the first surgeon to implant an electrode into the cochlea as well as the first to assist in the development of a wearable cochlear implant system, he is often called the “father of cochlear implantation” (Eshraghi et al., 2012). Dr. House went on to lead several multicenter trials exploring the safety and efficacy of cochlear implantation in adults and children. Additionally, Dr. House and Urban partnered with the 3M Company to commercially develop the House/3M single-channel cochlear implant system (Figure 1–10). In 1982, the House/3M cochlear implant was the first cochlear implant to be evaluated in a multicenter U.S. Food and Drug Administration (FDA) clinical trial (Eisenberg, 2015). In 1984, the House/3M device became the first cochlear implant to be approved by the FDA for commercial distribution in the United States (Eisenberg, 2015).

Furthermore, Dr. House implanted his single-channel cochlear implant in a 3-year-old child in 1981, who at the time was the youngest child to receive a

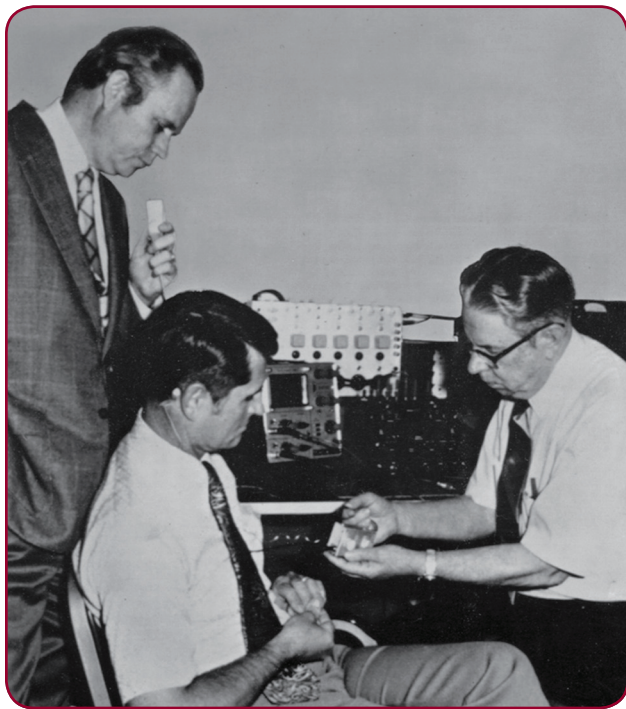


FIGURE 1–9. William F. House, M.D., cochlear implant surgeon, and colleagues at the House Ear Institute. Image provided courtesy of Laurie Eisenberg and the House Ear Institute archives.

cochlear implant (Eisenberg & House, 1982). Buoyed by his desire to assist children with profound hearing loss to listen to and develop spoken language, Dr. House led the first FDA trial exploring cochlear implantation in children. By 1985, the House/3M cochlear implant was provided to 164 children (Eisenberg, 2015). The average age of implantation of the children in the study was 8 years, and as a result, the benefits were modest. However, the study did demonstrate the safety and reliability of cochlear implantation for children with severe to profound hearing loss. By 1987, two hundred sixty-five children had been implanted with the House/3M cochlear implant (Berliner et al., 1990). The trial allowed investigators to learn that several factors influenced the benefit children obtained from cochlear implantation, including age of implantation, family involvement, mode of communication/intervention type, and child-specific factors (e.g., neuro-cognitive factors, additional disabilities, cochlear anatomy). In 1987, an FDA panel reviewed data from the large, multicenter pediatric cochlear implant trial led by Dr. House and recommended commercial approval of his device. The House/3M device was sold to another company in 1987, and final FDA commercial approval was never obtained (Eisenberg, 2015). Altogether, just over 1000 persons received a House/3M single-channel cochlear implant.

Contributions from Blair Simmons and the Stanford Cochlear Implant Team

In the 1960s, otolaryngologist Blair Simmons, M.D., explored the potential of treating deafness with electrical stimulation of the cochlear nerve in both animals and humans (Figure 1–11). In 1962, Dr. Simmons performed a posterior craniotomy and placed a single wire with an electrode on the tip on the cochlear nerve. The patient, who received a local anesthetic during the procedure, reported hearing sound with electrical stimulation of the cochlear nerve (Simmons et al., 1964). In 1964, Simmons implanted a six-wire/electrode device into the modiolus of a deafened adult. Simmons and colleagues performed extensive psychoacoustic testing with this recipient and determined that the recipient could detect different pitches with stimulation of different electrodes, which were placed at varying depths in the cochlea (Simmons, 1966). Also, Simmons showed that pitch changed with stimulation rate from about 30 to 300 electrical pulses per second. Additionally, the recipient reported that the device elicited a speech-like sound when broad-

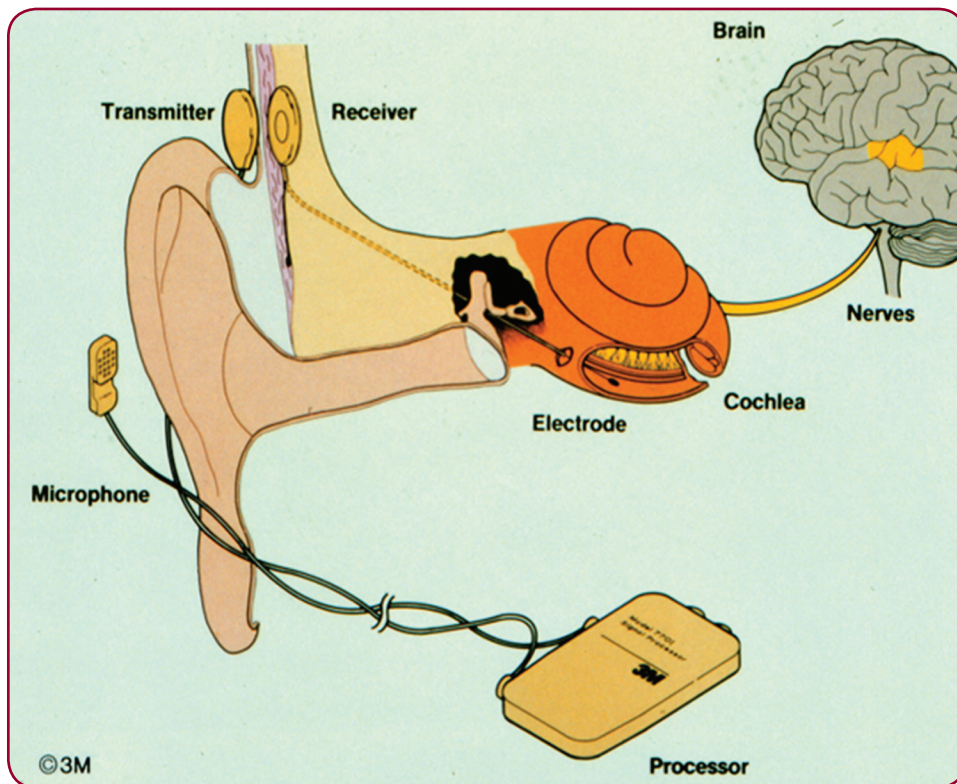


FIGURE 1–10. The House/3M single channel cochlear implant system. Image provided courtesy of Laurie Eisenberg and the House Ear Institute archives.

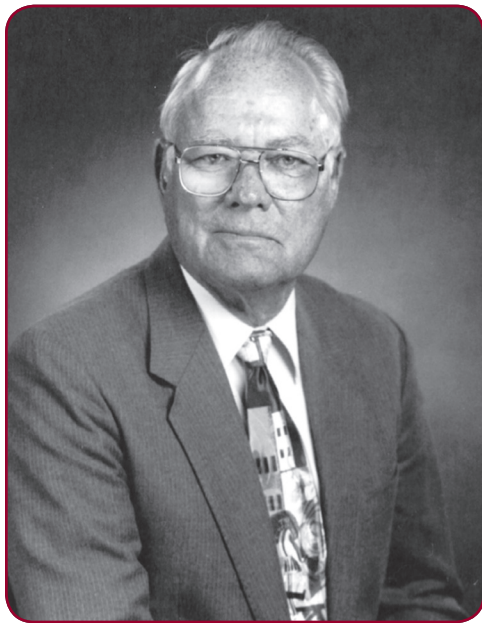


FIGURE 1–11. Blair Simmons, M.D., cochlear implant surgeon. Image provided courtesy of Stanford University's Department of Otolaryngology-Head & Neck Surgery.

band electrical stimulation was provided. However, the recipient was unable to understand speech presented in an open set, a fact that discouraged Simmons, who ceased evaluation of electrical stimulation in humans in the late 1960s. Of note, Simmons did present and publish throughout the mid to late 1960s on his findings with electrical stimulation of the auditory system, and he is believed to be the first person to use the term “cochlear implant” (Simmons, 1969).

Contributions from the University of California San Francisco Cochlear Implant Group

Robin Michelson, M.D., an otolaryngologist at UCSF, implanted several patients with a single-channel wire ensheathed in a silicone molding that was inserted into the basal end of the scala tympani in the late 1960s and early 1970s (Merzenich, 2015). Michael Merzenich, a physiologist, was recruited to UCSF in 1971 to collaborate with Dr. Michelson on the development of a multichannel device (Figure 1–12). Merzenich was initially skeptical that a cochlear implant could provide open-set speech recognition. However,



FIGURE 1–12. Michael Merzenich, Ph.D., physiologist and researcher. Image provided courtesy of Michael Merzenich.

he conducted psychophysical studies with some of Simmons' early recipients and was surprised to find that they could detect changes in frequency/pitch with changes in electrical stimulation rate through several hundred hertz. Merzenich felt that the low-frequency cues provided via changes in electrical stimulation rate could be paired with high-frequency place cues obtained from stimulation to several electrode contacts positioned throughout the cochlea (Merzenich, 2015).

Although Michelson's early recipients could not understand speech in open set, Merzenich was encouraged by the restoration of basic auditory abilities offered by the crude single-channel device. Merzenich conducted several studies to evaluate electrical stimulation of the cochlear nerve in cats in an effort to better understand the complexities involved in supporting speech recognition with cochlear implantation in humans. Merzenich's studies with animals and Michelson's early implant recipients convinced the San Francisco team to pursue development of a multi-channel cochlear implant system (Merzenich et al., 1973, 1974).

Otolaryngologist Robert Schindler, M.D., spearheaded the San Francisco group's efforts to develop a cochlear implant with biocompatible materials that would allow for a device that was safe to implant in the human body and that could function over the long term in an environment (i.e., the head) that was hostile to electronics (e.g., moist, mobile, susceptible to impact damage). Schindler was joined by scientist Birgitta Bjorkroth and anatomist Patricia Leake,

who also sought to identify safe methods to provide long-term electrical stimulation of the cochlear nerve (Merzenich, 2015). The group of researchers demonstrated that electrodes encased in silicone were safe to implant in the temporal bone. They also demonstrated that long-term charge-balanced electrical stimulation of the cochlear nerve in animals not only was safe (Leake-Jones, 1981) but actually promoted survival of cochlear neural elements (Wong-Riley, 1981).

Merzenich and colleagues collaborated with Blake Wilson and Charles Finley's team at the Research Triangle Institute (RTI) in North Carolina. Based on their collective findings in numerous research studies, they developed an eight-channel cochlear implant with independent/isolated channels (Merzenich, 2015). A CIS-type signal coding strategy was employed in the UCSF device. Much of the work conducted at UCSF and at the RTI was financially supported by the Neural Prosthesis Program (NPP) of the United States National Institutes of Health (NIH) (Wilson & Dorman, 2008). The results obtained with recipients who used the UCSF device and/or the RTI signal coding strategies were very encouraging, and as a result, the Storz Medical Instruments Company partnered with UCSF with the goal of developing a cochlear implant system for commercial/clinical use (Eshraghi et al., 2012). Storz produced a prototype of the UCSF cochlear implant system, but the device was plagued by issues with reliability. In 1986, UCSF entered into an agreement with another company, Minimed, which was owned by entrepreneur Alfred Mann, who provided substantial financial backing to the development of a commercial cochlear implant system (Eshraghi et al., 2012; Merzenich, 2015). Mann formed the Advanced Bionics Company, which eventually developed the Clarion cochlear implant system. The Clarion cochlear implant system was approved by the FDA for commercial distribution in the United States in 1996 for adults and in 1997 for children. Advanced Bionics was eventually acquired by the Boston Scientific medical manufacturer in 2004. Mann and colleague Jeffrey Greiner reacquired Advanced Bionics from Boston Scientific after the latter expressed concern about the profitability and quality control of the company. Mann and Greiner later sold Advanced Bionics to Sonova Holding AG in 2009.

Graeme Clark: The Father of the Modern Multiple-Channel Cochlear Implant

Graeme Clark, M.D., became an otolaryngologist after watching his father struggle with significant hearing

loss (Figure 1–13). Dr. Clark’s father was a pharmacist, and as a teenager, the junior Clark often assisted his father in his pharmacy clinic. Dr. Clark has often reminisced about the awkwardness that existed when his father’s clients would have to speak loudly about their private health needs so that his father could hear and understand his customers’ needs (Worthing, 2015).

Inspired to improve the lives of persons with hearing loss, Dr. Clark earned a medical degree and became a successful otolaryngology surgeon in Melbourne, Australia. His clinical practice was quite successful and provided considerable financial means for his wife and young daughters. By 1966, he had become the head of the clinic and the Royal Victorian Eye and Ear Hospital (Worthing, 2015, p. 68). In his clinical practice, he saw many patients who had severe to profound hearing loss. He lamented the fact that he was unable to provide them with substantial improvement in their communication abilities. Dr. Clark has acknowledged that the futility that he experienced when serving persons with severe to profound hearing loss served as an inspiration to develop the cochlear implant. An example of this

inability to provide help for persons with severe to profound hearing can be seen in a note written by one of Dr. Clark’s colleagues, Les Caust, M.D. (see the box below).

Toward the later part of 1966, Dr. Clark read of Dr. Blair Simmons’ work with cochlear implants, which was published in the *Archives of Otolaryngology*. After reading Simmons’ promising report, Dr. Clark conferred with his wife and trusted mentors about the possibility of moving to Sydney, Australia in order to pursue a Ph.D. and research electrical stimulation of the auditory system with the goal of treating deafness. In 1967, Dr. Clark commenced with his studies and his goal to develop a cochlear implant to allow persons with severe to profound hearing loss to hear and understand speech (Worthing, 2015).

Dr. Clark’s early research focused on answering basic questions such as could electrical stimulation reproduce the auditory system’s typical coding of frequency and intensity. In animal studies, he was able to demonstrate increases in the magnitude of the auditory system’s response with increases in electrical stimulation of the cochlear nerve. However, increases in the frequency of electrical stimulation

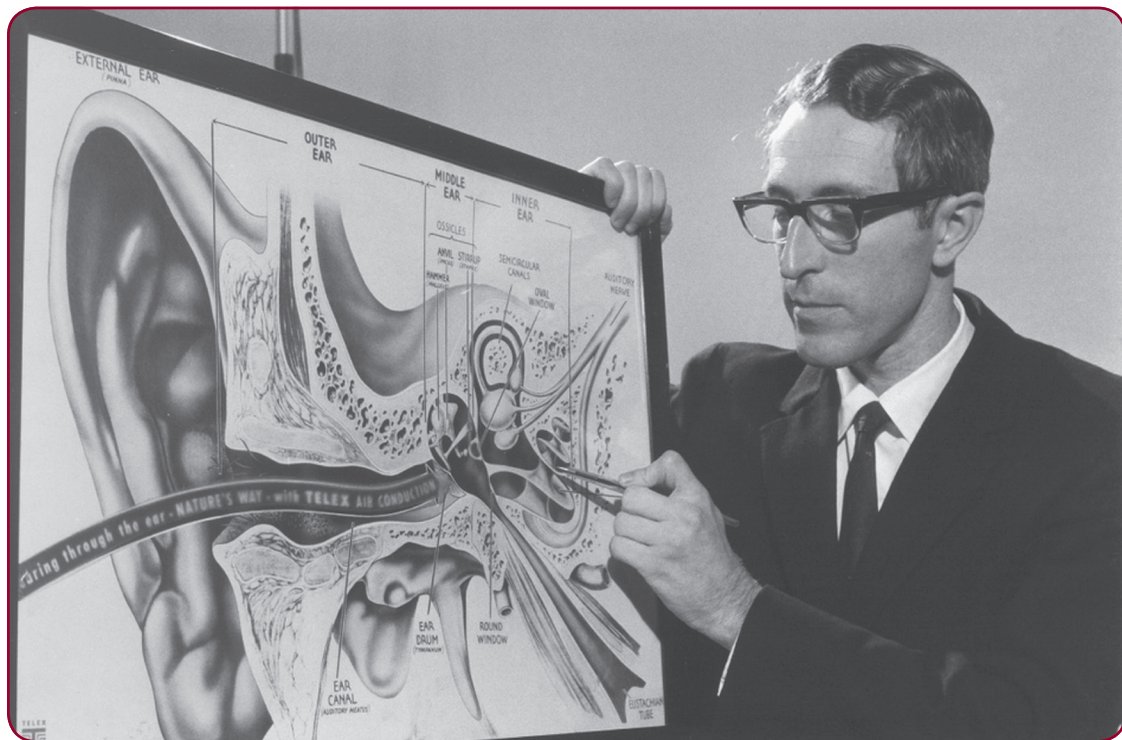


FIGURE 1–13. Graeme Clark, M.D., cochlear implant surgeon and co-developer of the multiple-channel cochlear implant. Image provided courtesy of Graeme Clark.

An example of a chart note written by Les Caust, M.D., one of Dr. Clark's medical colleagues. Dr. Clark noted that chart notes like these served as a motivator to create the cochlear implant. Provided courtesy of Graeme Clark.

4th April, 1967

Dear Mr. Kearton,

Thank you very much for going along to the Acoustic Laboratory and having their somewhat more sophisticated tests. . . .

It does appear that you have a complete bilateral sensori-neural hearing loss and that no surgical or any other attack would be of any avail to you. I would agree entirely with this that you rejoin the Australian Association for Better Hearing and I have enclosed a form for you to fill out to this end. It was disappointing that nothing surgical can help, but I'm sure with your perseverance and continued attack on it with the ability that you have got then you will make the most of a pretty bad lot.

(i.e., electrical pulses per second) could not be faithfully coded by the response properties of the cochlear nerve beyond about 400 Hz (Clark, 1969). Due to the limitations of temporal coding of frequency, Dr. Clark concluded that a multiple-channel cochlear implant would be required to support open-set speech recognition (Clark et al., 1977, 1978).

Dr. Clark's research and clinical experience made him aware of several obstacles that had to be surpassed in order for cochlear implantation to allow for a successful outcome. First, Clark's research indicated that the dynamic range of electrical hearing (i.e., range between threshold of electrical hearing and upper limit of tolerance to electrical stimulation) was much less (e.g., 5–10 dB) than the dynamic range of speech (Clark et al., 1978). Also, Dr. Clark postulated that in order to thoroughly represent the spectral range of speech across the cochlea, an electrode lead would have to be inserted at least 20 to 25 mm into the cochlea (Clark, 2015). Dr. Clark also acknowledged that there was no consensus regarding the proper coding strategy necessary to represent the spectral and temporal properties of speech to allow for open-set speech recognition.

After graduating with a Ph.D. from the University of Sydney in 1969, Dr. Clark accepted a position

as Chair of the Otolaryngology Department at the University of Melbourne. Dr. Clark formed a multi-disciplinary team of professionals (e.g., engineers, physiologists, audiologists) who worked to develop a multiple-channel cochlear implant that would be available for clinical use. Dr. David Dewhurst and Jim Patrick, both electrical engineers, provided the expertise necessary to develop signal coding strategies designed to electrically convey the necessary acoustic properties of speech and to develop the hardware of a multiple-channel cochlear implant system. Dr. Clark's team also included hearing science and audiology luminaries Field Rickards, Richard Dowell, and Yit Chow (Joe) Tong (Worthing, 2015).

Because Dr. Clark devoted the majority of his time to the development of administrative responsibilities within the academic department and to his cochlear implant research, funding for his research endeavors was in short supply. Dr. Clark led a grass-roots effort to raise money to fund his research with legend suggesting that he resorted to begging on the streets (Figure 1–14). He delivered numerous presentations describing his research and objectives to local organizations that may have been able to offer finan-



FIGURE 1–14. A cartoon depiction of Graeme Clark begging on the streets to raise money for his research to develop a cochlear implant. Image provided courtesy of Graeme Clark.

cial support. The Apex Club, a local service organization, donated \$2000 to support Clark's research, and the Australian Broadcasting Commission featured a story on the donation on the evening news. Sir Reginald Ansett, the founder of Ansett Airways and the owner of an Australian television station, saw the story on the news and offered to host a telethon on his station to raise money for cochlear implant research. Ultimately, Ansett hosted multiple telethons throughout the mid-1970s which not only raised considerable money to fund Dr. Clark's research but also enhanced public awareness of cochlear implantation as a means to improve hearing in persons who are deaf (Worthing, 2015).

Clark studied speech perception on a sabbatical in England from 1975 to 1976. Dewhurst, Patrick, and Ian Forster completed a bench version of a multiple-channel cochlear implant in 1976. Indeed, the work of developing the electronics necessary to support multiple-channel stimulation and signal coding to support speech recognition was tedious and required arduous study, but progress was steadily achieved. However, Clark noted that the team continued to struggle with the task of inserting an array of wires and electrode contacts 20 to 25 mm into the scala tympani of the cochlea. Specifically, Dr. Clark noted that his team explored the development of a suitable electrode array without success from 1975 throughout 1976. In 1977, Dr. Clark was on vacation with his family at a beach in Melbourne. While his

children were playing on the beach, Dr. Clark picked up a nearby snail shell and marveled at its structural similarities to the human cochlea. He then picked up a blade of grass and inserted it into the shell. He quickly noted that blades of grass that became progressively thinner from the base to the tip and progressively stiffer from the tip to the base easily slid into the shell (Figure 1–15). Unable to contain his excitement with his newfound discovery, he packed up his family and left their vacation two days earlier than planned. He then conveyed his observations to his team of engineers, who were able to develop an electrode array that could be inserted to the desired depth of approximately 25 mm into the cochlea (Worthing, 2015).

In August 1978, Rod Saunders was the first person to receive one of Dr. Clark's multiple-channel cochlear implants (Figure 1–16). Because the activation of Mr. Saunders' cochlear implant was the culmination of over 10 years of research, development, and fundraising, it was a big event that was covered by the Australian media, including the television station that hosted telethons to support the development of the cochlear implant. To everyone's dismay and disappointment, Saunders was unable to hear anything when Clark's team attempted to activate his cochlear implant. Saunders returned to the clinic a short time later, but once again, he was unable to hear when his cochlear implant was activated. Eventually, Clark's team discovered a faulty lead from the

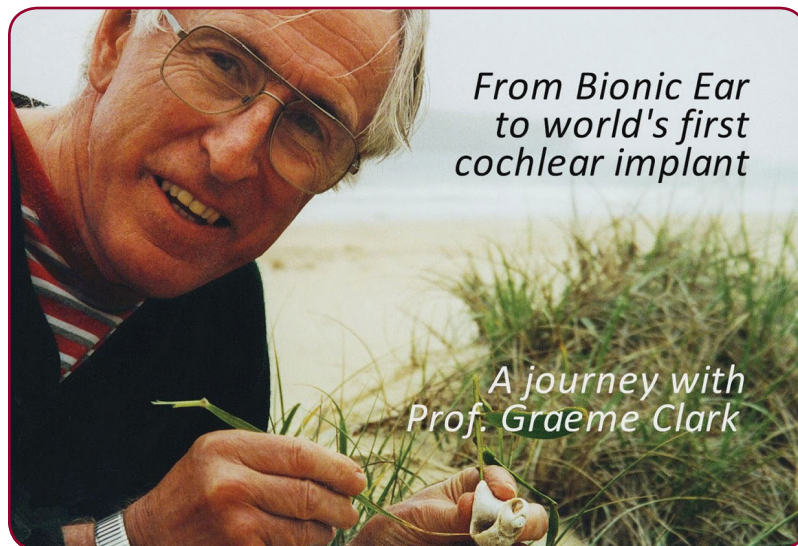


FIGURE 1–15. Graeme Clark inserting a reed of grass into a sea shell. Image provided courtesy of Graeme Clark.

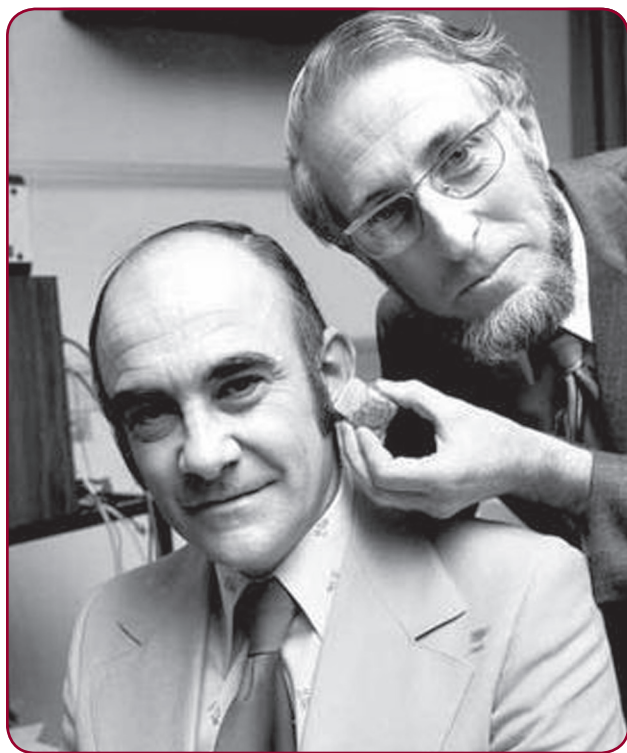


FIGURE 1–16. Graeme Clark with Rod Saunders, the first recipient of Clark’s multiple-channel cochlear implant. Image provided courtesy of Graeme Clark.

activating computer to the external transmitting coil of the cochlear implant. Ironically enough, one of the main culprits of faults in modern cochlear implants are faulty cables that deliver the signal from the recipient’s sound processor to the external transmitting coil. The faulty lead on Clark’s equipment was replaced, and Saunders returned for a third time for activation of his cochlear implant. As the old saying goes, the third time was the charm. Saunders’ cochlear implant was activated, and the Australian national anthem was played over a loudspeaker. Saunders, who was a veteran of the Australian armed forces, slowly but dramatically rose from his chair, stood at attention, and saluted to the sound of the anthem that he had not heard in years. Needless to say, Clark and his team were elated. It soon became apparent that Saunders was also able to understand speech presented in open set with the use of his cochlear implant. Dr. Clark describes his emotional reaction to the point in time at which he realized that all of his efforts and sacrifices to develop a cochlear implant had come to fruition and his new development that would allow persons with severe to profound hearing

loss, like his father, to hear sound and understand speech (Worthing, 2015):

It was the moment I had been waiting for. I went into the adjoining room and cried for joy.

Additional patients were implanted with Dr. Clark’s multiple-channel cochlear implant, and Clark became convinced that his device would allow for better hearing for persons with severe to profound hearing loss. He entered into a partnership with medical device manufacturer Telectronics, with the goal of manufacturing the multiple-channel cochlear implant for commercial distribution. Engineers at Telectronics initially expressed doubts that Clark’s cochlear implant could be commercially produced so that it possessed long-term reliability. Specifically, the pacemakers that Telectronics specialized in manufacturing had only one lead that had to pass through a hermetically sealed port from the pacemaker’s processor/stimulator. In contrast, Clark’s cochlear implant required 20 leads to pass from a ceramic-to-metal seal. Telectronic engineers worried that such a small device with so many leads could not be developed without the almost certain threat of body fluid entering into the cochlear implant and causing electronic failure (Worthing, 2015).

In his biography on the life and contributions of Graeme Clark, Mark Worthing (2015) described the dilemma and Clark’s response as follows:

So the company [Telectronics] hired a specialist engineer, Januz Kuzma, to work specifically on this problem. He worked for several months with no solution.

Graeme was becoming frustrated with the delays and the claims that it couldn’t be done, so he did what he always had done in such circumstances. He decided he would attempt to solve the problem himself. He asked his own engineer, Jim Patrick, to help him. Graeme got some clays and metals and fired up his pottery kiln at the back of his house in Eltham. About this time, Kuzma at Telectronics, who had heard that Professor Clark was attempting to do it himself in his backyard pottery kiln, began making some genuine progress and Graeme and Jim Patrick put their work on hold. Graeme likes to think that the risk of having amateurs working with a backyard kiln come up with a solution provided an added incentive to creativity. In any event, a ceramic solution to the problem was found.

In September 1982, Teletronics manufactured a commercial prototype of Clark's cochlear implant. Graham Carrick was the first recipient of a commercial version of Clark's device. Because the research and development of Clark's cochlear implant was now being funded by the Australian government, the activation of Carrick's implant was once again a significant event which was covered by the Australian media. Similar to the experience with Rod Saunders, Carrick was unable to hear with his new cochlear implant throughout the first 15 minutes of the activation session. Eventually, Carrick heard a sound through his implant. Carrick noted (Worthing, 2015):

It hit me, I heard a “ding dong” and I said to myself “bloody hell!” To get this sound was fascinating and mind boggling. Tears ran down my face.

By 1983, Clark's cochlear implant was being trialed by surgeons in Australia, the United States, and Europe. Clark's team developed methodical research studies to develop the data necessary to seek FDA approval for commercial distribution. Teletronics became known as Nucleus, which later developed a subsidiary company called Cochlear Limited. In short, Graeme Clark's multiple-channel cochlear implant became the Cochlear Nucleus 22 cochlear implant system. Cochlear Ltd. is now the world's largest manufacturer of cochlear implant technology. The FDA granted approval for commercial distribution of the Nucleus 22 cochlear implant for adults in 1985 and for children in 1990.

Contributions from Claude Chouard and Other French Cochlear Implant Researchers

In 1972, Claude-Henri Chouard, an otolaryngology surgeon in France, was informed of the advances that William House and Robin Michelson had made with their cochlear implant research (Figure 1–17). Inspired by the notion of developing a treatment for deafness, Dr. Chouard, who had previously served as a student in Charles Eyriès' laboratory during the time that Eyriès and Djourno explored electrical stimulation of the cochlear nerve, partnered with Patrick MacLeod to develop an interdisciplinary team to conduct research on and develop a multiple-channel cochlear implant (Chouard, 2015). Chouard and MacLeod made several significant contributions to the development of the cochlear implant. In their early efforts, they established a frequency map of almost the entire length of the human cochlea, which



FIGURE 1–17. Claude-Henri Chouard, M.D., cochlear implant surgeon. Image provided courtesy of Claude-Henri Chouard.

allowed researchers to determine where electrode contacts would need to be located to elicit a desired frequency/pitch percept.

Chouard and MacLeod also explored the biocompatibility of various materials that could be used to create a cochlear implant. In the 1970s, Chouard showed that Teflon-coated platinum-iridium electrode contacts and silicone Silastic™ insulation were safe to implant in the human cochlea and possessed physical characteristics that promoted long-term durability (Chouard, 2015). Chouard and MacLeod also explored signal coding strategies and were one of the first groups to suggest that sequential digital, pulsatile electrical stimulation may be preferable to analog stimulation because of the former's ability to lessen channel interaction (Chouard & MacLeod, 1976).

In September 1976, Drs. Chouard and Bernard Meyer implanted a patient with an eight-electrode cochlear implant (Meyer, 1974). Chouard noted that the performance of their early multiple-channel cochlear implant recipients was very favorable relative to results reported at the time for single-channel implant recipients (Chouard, 2015). Chouard and colleagues also reported on the need to determine signal parameters (e.g., stimulation levels) based on the electrophysiologic characteristics of each electrode contact, and they described rehabilitative strategies that facilitated a successful response to cochlear implantation (Chouard et al., 1983a). Furthermore, Chouard et al. (1983b) demonstrated the importance

of early implantation for congenitally deafened recipients by showing greater neural atrophy in the brainstems of guinea pigs implanted later in life relative to those implanted earlier.

Led by Chouard, the French cochlear implant group developed a 12-channel cochlear implant that was originally known as the Chlorimac-12. The early Chlorimac-12 implants were manufactured by Bertin[®], which later sold the patent for the Chlorimac-12 implant to the French company MXM Neurelec[®] (Chouard, 2015). In 2013, the MXM Neurelec cochlear implant was eventually acquired by the William Demant Group, the holding company of Oticon Medical and of the Oticon hearing aid company. At the time of this writing, the Oticon Medical cochlear implant had not been approved by the FDA for commercial distribution in the United States.

Contributions of the Vienna Cochlear Implant Group

Spurred by reports on electrical stimulation of the auditory system emerging from France and the United States, a team of researchers led by Ervin Hochmair at the Technical University of Vienna in Austria began work toward the development of a cochlear implant in the 1970s (Eshraghi et al., 2012). Ingeborg (Desoyer) Hochmair was also a promi-

nent member of the Vienna cochlear implant team (Figure 1–18). In 1975, The Hochmairs received a research grant to develop a multiple-channel cochlear implant, and within 18 months they had developed an eight-channel system complete with Teflon-insulated platinum electrodes encased in a silicone carrier. In 1977, a patient was implanted with the Vienna multiple-channel device. Initially, the Vienna team experimented with single-channel analog stimulation, but most recipients experienced difficulty understanding speech. Eventually, the Hochmairs collaborated with Blake Wilson at the RTI in North Carolina and incorporated CIS into their multiple-channel cochlear implant. Of note, the Hochmairs were convinced that a long electrode array (e.g., ~31 mm) would optimize speech recognition performance and sound quality by accessing the most apical regions of the cochlea, where low-frequency sounds are naturally coded. In 1990, the Hochmair team created the private company MED-EL to facilitate the commercial development of their multiple-channel cochlear implant. Ingeborg Hochmair left the University of Vienna to operate the MED-EL company, which is located in Innsbruck, Austria. In 2001, the MED-EL COMBI 40+ cochlear implant system was approved by the FDA for commercial distribution in the United States for adults and children.



FIGURE 1–18. Ervin and Ingeborg Hochmair, researchers and developers of the MED-EL cochlear implant. Image provided courtesy of Ingeborg Hochmair.

Contributions from the Utah Artificial Ear Project

Several researchers at the University of Utah contributed substantially to the development of modern cochlear implant technology. Michael Dorman and James Parkin (2015) have provided an excellent summary of the various contributions of the Utah Artificial ear project to the development of cochlear implant technology. The Dorman and Parkin (2015) review serves as the source of most of the information that is presented here in regard to the Utah Artificial Ear Project.

The University of Utah was home to the prolific Division of Artificial Organs, which was led by William J. “Pimm” Kolff, who developed the first artificial kidney. Kolff’s team was exploring the possible development of visual and auditory prostheses with initial interest directed toward stimulation of the auditory cortex. They eventually turned their interest toward intracochlear stimulation, because cochlear surgery was “less drastic” compared with implanting electrodes in the cerebrum, and they could potentially take advantage of the tonotopic organization that naturally exists within the cochlea.

The Utah group partnered with the Ear Research Institute in Los Angeles to pursue the development of a cochlear implant. The joint program included the Ear Research Institute surgeon Derald Brackmann and Utah’s James Parkin (surgeon), Michael Mladejovsky, (engineer), William Dobbelle (physiologist), Geary McCandless (audiologist), and Don Eddington (who was a graduate student in engineering at the beginning of the project). Work on the Utah Artificial Ear Project began in the early 1970s.

One of the early decisions made by the Utah group that was largely responsible for the impact it made on cochlear implant technology was the commitment to percutaneous signal delivery via an implanted pedestal. Most researchers at the time had chosen to develop cochlear implant systems that used electromagnetic induction to deliver signals across the skin (i.e., transcutaneous delivery) to the cochlear implant. Although transcutaneous systems have the benefit of housing all of the implantable components entirely underneath the recipient’s skin, there are constraints to the amount of information that may be delivered via electromagnetic induction/RF delivery.

In contrast, a percutaneous pedestal basically serves as an outlet to which an external processor may be connected to deliver stimulation directly to electrodes that are wired to the pedestal. As a result of this direct connection, there are essentially no lim-

its to the amount of information that may be delivered from an external processor to the implanted electrode contacts. Additionally, the electrode leads and contacts may be continuously monitored for faults, and there are no implanted electronics that could critically fail. Because of the inherent flexibility of the percutaneous design, the Utah Ear group was able to conduct a series of psychophysical studies designed to explore how recipients respond to electrical stimulation of the cochlear nerve. Of note, the Utah percutaneous implant was originally marketed by Symbion, Inc. under the name Ineraid. The Ineraid cochlear implant system is shown in Figure 1–19.

Utah’s Ineraid cochlear implant possessed six electrode leads that were coupled to the pedestal at the lateral end and to six electrode contacts at the medial end. The electrode leads were intended to be inserted into the cochlea at different depths in order to code six different frequencies/pitch percepts. Dr. Brackmann implanted two patients with the Ineraid device in 1975. Of note, one of these patients was

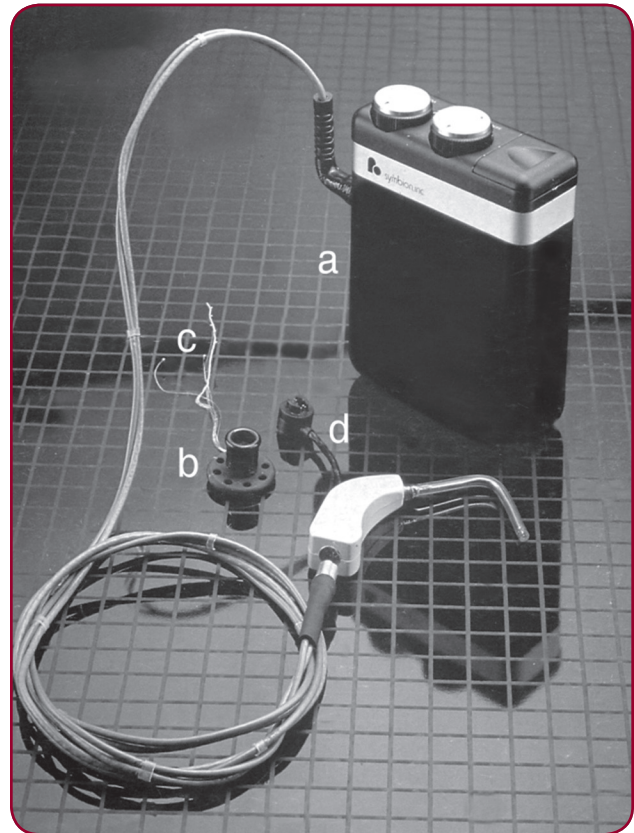


FIGURE 1–19. The Ineraid percutaneous cochlear implant system. Image provided courtesy of Michael Dorman.

bilaterally deafened and the other was unilaterally deafened. Two additional patients were implanted in 1977. The initial cohort of Ineraid implant recipients included persons who were prelingually deafened and others who lost their hearing as adults. The varied backgrounds of the Utah subjects allowed the researchers to gain keen insights into variables that influence outcomes obtained with a cochlear implant.

Eddington and Mladejovsky conducted exhaustive psychophysical studies with the initial Ineraid recipients. They were able to gain a preliminary understanding of many fundamental concepts pertaining to electrical stimulation of the cochlear nerve, including the relationship of place of stimulation (i.e., location/depth of the electrode in the cochlea) and pitch percept, the relationship of stimulus current amplitude, duration (pulse width), and rate to loudness percept, the pros and cons of bipolar versus monopolar electrode coupling, electrode impedance changes over time, etc. Their experiments greatly advanced the understanding of electrical stimulation of the human cochlea and the association to recipient experience.

Additionally, the Utah group capitalized on the unique opportunity afforded by the inclusion of a recipient with normal hearing in the non-implanted ear. Specifically, Eddington noted that they completed studies to match the pitch elicited by electrical stimulation at various depths in the implanted ear to the pitch elicited by pure tones presented to the opposite ear. Their measures confirmed that the implant place-to-pitch relationship corresponded to frequency-by-distance maps of the cochlea. The tonotopic information gleaned from the Utah group's research assisted other researchers in the development of multiple-channel cochlear implant systems and the application of pitch to electrode contact location.

In 1978, Eddington began to explore speech recognition obtained with single- and multiple-channel stimulation. At the time, there was still disagreement among researchers as to whether multiple-channel implants would allow for better performance than single-channel devices. In particular, some researchers contended that an electric current analogous to the acoustic input signal could be delivered to a single electrode contact in order to comprehensively provide the signal captured by the microphone. Eddington compared speech recognition obtained with a single channel to a four-channel stimulation (electric analog stimulation delivered in each condition). He reported that performance was unequivocally better with multiple-channel stimulation. However, the subjects were generally unable to understand speech

presented in open set, a finding that may have been attributed to the fact that a wearable processor was unavailable, so recipients were only able to hear with their cochlear implants when they came to the laboratory for research. As a result, they were unable to acclimate to electrical stimulation.

Between 1977 and 1984, no new patients were implanted with the Ineraid device. During that period, Eddington developed a wearable sound processor. Symbion, Inc. used Eddington's design to produce the first portable Ineraid sound processor, which was fitted to a recipient in 1983. Notably, the first recipient to use the Ineraid sound processor was implanted in 1977 and had gone six years with only being able to hear while visiting the laboratory for research sessions.

In 1984, the FDA granted permission to Symbion, Inc. to conduct a clinical trial of the Ineraid, and Dr. Parkin began to implant the Ineraid device at the University of Utah. Implantation of the Ineraid device eventually was performed at 19 different centers in the United States. Many recipients obtained substantial benefit and open-set speech recognition with the Ineraid implant. For instance, Scott Shepard was the first recipient of an Ineraid cochlear implant as part of the FDA clinical trial. Mr. Shepard achieved a score of 73% correct on the CNC monosyllabic word recognition test just a few months after the activation of his cochlear implant. Of note, these recipients were using a signal coding strategy that divided the input signal into four analysis bands centered at 500, 1000, 2000, and 4000 Hz, and an electric analog of the audio signal within each of the four bands was delivered to four electrode contacts located 4 mm apart within the cochlea.

In 1983, Blake Wilson and a team of his researchers located in North Carolina received funding from the NIH to develop signal coding strategies for cochlear implants. Wilson and colleagues were unable to effectively test many of their experimental strategies with recipients using implants with transcutaneous transmission, because at that time the electromagnetic link would not allow for delivery of the coded information. Consequently, Wilson began to study his new signal coding strategies with Ineraid recipients in 1989. The percutaneous connection of the Ineraid proved to be highly beneficial to Wilson's research, because Wilson and colleagues were able to deliver complex coded information to the Ineraid electrode contacts via the pedestal.

Wilson's work with the Ineraid recipients resulted in the development of the CIS signal coding strat-

egy mentioned earlier in this chapter. As previously noted, the CIS strategy served as the foundation on which all modern signal coding strategies were developed. Additionally, during their signal coding research with Ineraid recipients, Wilson and colleagues explored the potential benefit of other signal processing schemes that would eventually become mainstays in modern cochlear implant systems. Their work included assessment of *n-of-m* strategies, fine structure processing (FSP), current steering, and high-rate CIS stimulation.

Furthermore, researchers working with Ineraid recipients were able to make direct recordings of the compound action potential generated by the cochlear nerve in response to electrical stimulation. This research eventually led to the development of “on-board” systems in commercial implants to allow for measurement of the electrically evoked compound action potential (e.g., neural response telemetry [NRT]) (see Chapter 18). Also, because the Ineraid did not have the magnet necessary in transcutaneous implants, researchers were able to conduct functional MRI with Ineraid recipients and evaluate activity in the auditory cortex elicited by electrical stimulation from the implant.

Despite the numerous merits and contributions of the Ineraid system, the FDA never approved it for commercial distribution. In 1989, the FDA raised concerns regarding safety associated with a percutaneous pedestal. Specifically, the FDA was concerned that the percutaneous outlet would allow for infection in adjacent skin or in the brain. The FDA also expressed concern regarding “administrative issues” in the Symbion, Inc. company. Later, in the early 1990s, reports began to emerge of recipients experiencing a sensation of electric shock while using the Ineraid implant. Engineers determined that the check was likely arising from static electricity discharge collected at the long cable of the sound processor. In other words, the cable was essentially acting as an antenna to collect static electrical discharge. Design changes were made to the cable, and the problem was resolved. Also, a review of adverse effects associated with the Ineraid device indicated that there was no serious threat to complication, such as infection, with use of the percutaneous pedestal. Nevertheless, Symbion, Inc. grew weary of the process of seeking commercial approval from the FDA, and the Ineraid technology was sold to Cochlear Ltd. The pursuit of commercial approval was extinguished, but the remarkably positive legacy of the Ineraid implant (along with its designers, such as Don Eddington) and the positive

influence on modern cochlear implant technology are undeniable.

Prominent Milestones in the Development of Cochlear Implant Technology

The Neural Prosthesis Program (NPP) of the NIH was developed in 1970 and was under the leadership of Dr. F. Terry Hambrecht and later Dr. William J. Heetderks (Wilson & Dorman, 2008). Dr. Hambrecht hosted an annual workshop comprising scientists conducting research with neural prostheses. In 1973, Michelson, House, Merzenich, and Simmons shared their preliminary results from and experiences with their trials with electrical stimulation of the cochlear nerve in their patients with profound hearing loss. The outcomes were impressive enough to convince the NIH to provide federal funding of the research that was being conducted at the various sites in the United States.

In 1975, the NIH funded a study to evaluate the outcomes of 13 single-channel cochlear implant recipients. Eleven of these recipients were implanted by Dr. William House and two were implanted by Dr. Robin Michelson. The study was led by Robert Bilger, an audiologist and physiologist at the University of Pittsburgh. The 13 single-channel implant recipients were flown to the University of Pittsburgh for extensive assessment by Bilger and his colleagues. The findings of the study were published in a paper that is often referred to as the Bilger Report (Bilger & Black, 1977). In the summary, Dr. Bilger noted,

Although the subjects could not understand speech through their prosthesis, they did score significantly higher on tests of lipreading and recognition of environmental sounds with their prostheses activated than without them (Wilson & Dorman, 2008).

and

To the extent that the effectiveness of single-channel auditory prostheses has been demonstrated here, the next step lies in the exploration of a multichannel prosthesis (Mudry & Mills, 2013).

The Bilger Report was a watershed moment in the development of the cochlear implant, because it served to legitimize cochlear implantation in the scientific community, and it resulted in the provision of substantial NIH funding to researchers in the

United States, such as Michelson, Simmons, House, Blake Wilson, and so forth as well as Graeme Clark's program in Australia. The support of NIH for cochlear implantation was critical in advancing the state of the technology. At the time, there were still numerous opponents of the notion that electrical stimulation could prove to be beneficial for persons with severe to profound hearing loss. For example, in 1978, prominent auditory physiologist Professor Rainer Klinke said (Wilson, 2017),

From a physiological point of view, cochlear implants will not work.

The support NIH offered to fund cochlear implant research around the world fueled impressive advances that defied the expectations of skeptics. The NIH hosted a consensus conference in cochlear implants in 1988 and suggested that multiple-channel cochlear implants were likely to provide better performance than single-channel cochlear implants and that 1 in 20 recipients could understand speech in open set without speechreading. At a second consensus conference in 1995, the group concluded (NIH, 1995):

A majority of those individuals with the latest speech processors for their implants will score above 80% correct on high-context sentences, even without visual cues.

In the late 1980s, Richard Tyler, hearing scientist, traveled throughout the world to evaluate outcomes of recipients with a variety of different types of single- and multiple-channel cochlear implants. Tyler reported a wide range of outcomes across recipients but did show that good to excellent open-set speech recognition without visual cues was possible for some recipients (Tyler, Moore, & Kuk, 1989).

We would be remiss to discuss cochlear outcomes without inclusion of Margaret Skinner, an audiologist and hearing scientist at Washington University in Saint Louis, Missouri (Figure 1–20). Dr. Skinner was instrumental in the evaluation of cochlear implant outcomes in children and adults. She conducted research to show the benefits and limitations of cochlear implant technology in quiet and in noise for both children and adults. Her research was essential in identifying the variety of factors that influence outcomes experienced by cochlear implant recipients. She also developed the SPEAK signal coding strategy, and she explored the use of high-resolution CT scan assessment to evaluate the scalar position of cochlear implant electrode array. She was one of the first examiners to show the importance of electrode array placement in scala tympani (rather than dislocation in the scala vestibuli and/or scala media), and she demonstrated the benefit of close proximity of the electrode conducts to the cochlear neural elements in the modiolus (Holden et al., 2013).



FIGURE 1–20. Margaret Skinner, cochlear implant researcher. Images provided courtesy of Laura Holden.

Contributions from Blake Wilson and the Research Triangle in North Carolina

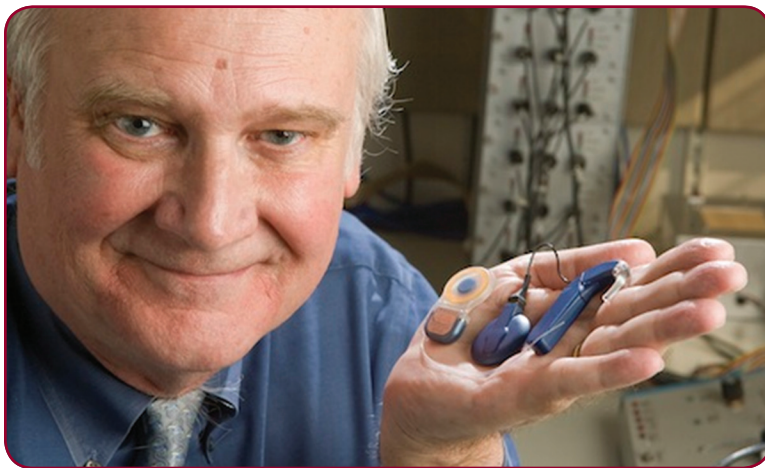
Any discussion of the history of cochlear implants would be incomplete without mention of the extraordinary contributions of Blake Wilson and colleagues at the Research Triangle Institute in North Carolina (see *Better Hearing with Cochlear Implants: Studies at the Research Triangle Institute* by Wilson and Dorman [2012] for a comprehensive review). In 1983, the RTI team received the first of numerous NIH funding awards to support the development of cochlear implant signal coding strategies. Of note, the RTI cochlear implant team had consecutive funding from the NIH for over 20 years. Throughout the next 25 years, Blake Wilson collaborated closely with several luminaries in the cochlear implant research arena, including Charles Finley, Don Eddington, Michael Dorman, Dewey Lawson, and more (Figure 1–21).

One of the most important contributions of the RTI cochlear implant group was the development of the CIS signal coding strategy in 1989. CIS, which serves as the foundation for most signal coding strategies found in modern cochlear implant systems, provided a sizable leap forward in the open-set speech recognition obtained by cochlear implant users in the early 1990s. Wilson and colleagues also developed

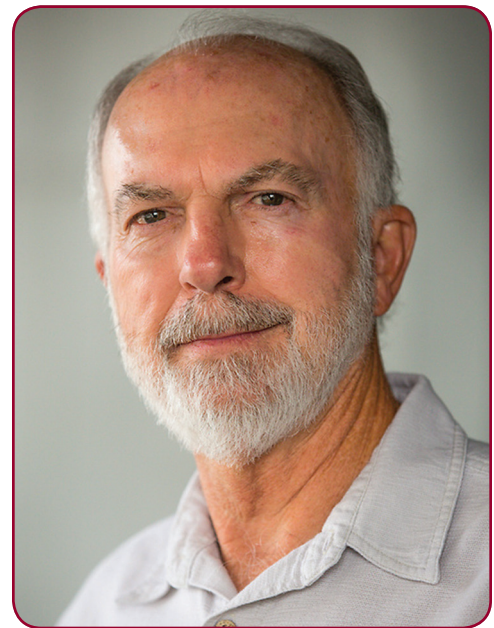
the so-called *n-of-m* signal coding strategy, which is the basis for what eventually became the *Advanced Combination Encoder* (ACE) signal coding strategy, which continues to be the primary signal coding strategy used in Cochlear Nucleus cochlear implants (see Chapter 8 for more information on signal coding). Furthermore, Wilson and colleagues developed the concept of electrical current steering to create “virtual channels/sites” of stimulation, a concept which figures prominently in modern Advanced Bionics and MED-EL signal coding strategies. Wilson et al. also explored the use of a roving stimulation rate across low-frequency channels in an effort to provide fine temporal structure cues, a concept that is prevalent in contemporary MED-EL signal coding strategies. Additionally, Wilson, Dorman, and colleagues have exhaustively explored the benefits and limitations of electric-acoustic stimulation for recipients who have preservation of low-frequency acoustic hearing following cochlear implant surgery (Dorman et al., 2008, 2015).

Expanding Cochlear Implantation to the Chinese Market and Other Developing Countries

At the time of this writing, several hundred thousand people with severe to profound hearing loss have received cochlear implants. Unfortunately, most of



A



B

FIGURE 1–21. A. Blake Wilson. B. Michael Dorman. Cochlear implant researchers and developers. Images provided courtesy of Blake Wilson and Michael Dorman.

these recipients have resided in the United States, western Europe, and Australia, whereas many persons with hearing loss in developing parts of the world have had limited access to cochlear implants. China was an example of a market that went quite some time without access to cochlear implant technology. Prominent cochlear implant researcher Fan-Geng Zeng, M.D., Ph.D., partnered with researchers and medical technologists in China and in the United States to develop the Nurotron cochlear implant system (Zeng et al., 2015). The Nurotron is a 26-electrode cochlear implant system which was developed with two objectives, to allow similar outcomes obtained with cochlear implants that are currently approved by the FDA for commercial distribution but to provide the system at a lower cost than existing cochlear implants. In 2011, the Nurotron cochlear implant received approval for commercial distribution in China by the Chinese equivalent of the Food and Drug Administration, and in 2012, Nurotron received the European Conformité Marketing designation. At the time of this writing, the Nurotron was not approved for commercial distribution in the United States by the FDA.

Key Concepts

- The multiple-channel cochlear implant is the most successful sensory prosthetic device developed in the field of medicine. A multiple-channel cochlear implant allows many adults with severe to profound hearing loss to develop open-set speech recognition abilities and to understand speech in occupational and social situations and when presented over the telephone and television. Cochlear implants also allow children who are born with severe to profound hearing loss to develop age-appropriate spoken language abilities.
- Published reports describing attempts to stimulate the auditory system date back to the 1700s and 1800s.
- Several researchers and surgeons worked around the globe in the 1960s and 1970s to develop the multiple-channel cochlear implant.

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