



Evolution of Cochlear Implant Technology over the Last 35 Years

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Anandhan Dhanasingh and Sandra DeSaSouza

3.1 Introduction

Cochlear Implant (CI) is the *state-of-the-art* treatment option for severe-to-profound sensorineural hearing loss (SNHL) conditions worldwide. In the early 1990s, only *severe-to-profound* bilaterally deaf hearing loss subjects were considered for CI. But with the advancements in CI technologies in the last 35 years, the indications of CI and the minimum age limit have been expanded liberally. Patients with partial deafness in the high-frequency region who do not benefit from conventional hearing aids (HA) are now considered candidates for CI [1]. Single-sided deafness (SSD)/asymmetric hearing loss (AHL) is another group of patients who are currently treated with CI in many developed countries [2]. With the advancements in the surgical steps, newborn babies as young as <12 months old are now treated with CI [3]. With the advancements in the preoperative image analysis tools, the anatomies of the various inner ear malformation types are now well understood, and these patients are also treated with CI and the results are convincing [4]. The advancements in CI technologies, surgical skills, accessory tools like preoperative image analysis tools are all contributing to the success in safely expanding the CI for various indications

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A. Dhanasingh (✉)
MED-EL Medical Electronics, Innsbruck, Austria
e-mail: Anandhan.dhanasingh@medel.com

S. DeSaSouza
ENT Municipal Hospital, Mumbai, Maharashtra, India
ENT Department, Jaslok Hospital, Mumbai, Maharashtra, India
Breach Candy Hospital and Desa Hospital, Mumbai, Maharashtra, India

and age groups. While the surgeons might be aware of the advancements in the surgical steps/skills, it is important to bring out the advancements in the CI technologies. With that aim, this chapter will detail the technological advancements over the last 35 years in the implantable and external components of a CI from a general perspective.

3.2 Components of a Cochlear Implant

The *microphone* in the audio processor picks up the acoustic signal from the surrounding environment and the *audio processing unit* breaks it down to digital signals using a *sound-processing algorithm* which will be transmitted to the *receiver stimulator* via an inductive link. Briefly, the inductive link works through an interaction between the external and the receiving antenna when the external transmitter is placed over the *implant magnet*. The implant electronics then convert these signals to electric impulses and transfer them to the inner ear through the intracochlear *electrode array*. All these components of the CI along with the signal processing algorithms have undergone tremendous improvements over the last 35 years and this chapter will bring it to your attention. Figure 3.1 shows the components of a modern CI.

3.3 Technological Evolution of the Implant Stimulator Case

One of the key requirements for the overall success of CI is the hermeticity of the implant stimulator. The electronics inside the implant case should be kept dry at all times and any ingress of body fluid could fail the implant electronics. In the late 1970s, the investigational CIs were fabricated using medical-grade epoxy resin to encapsulate implant electronics. In the late 1980s, the epoxy encapsulation of the implant electronics was changed to ceramic housing. The ceramics used in medical applications are commonly based on aluminum oxide (Al_2O_3). The advantage of the

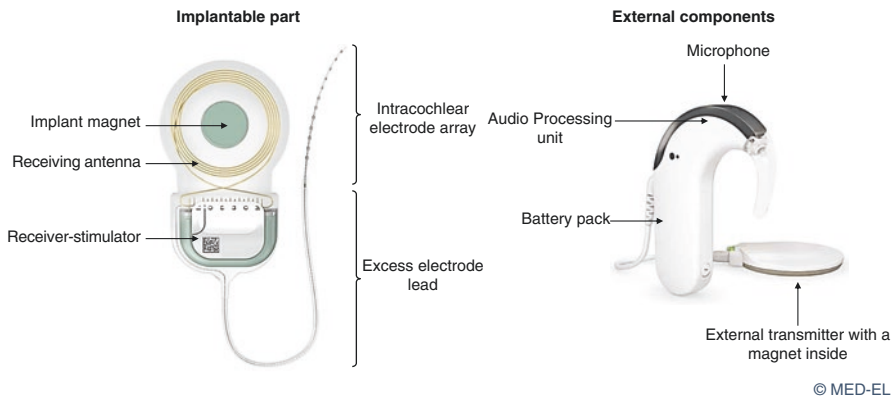


Fig. 3.1 Components of a modern cochlear implant

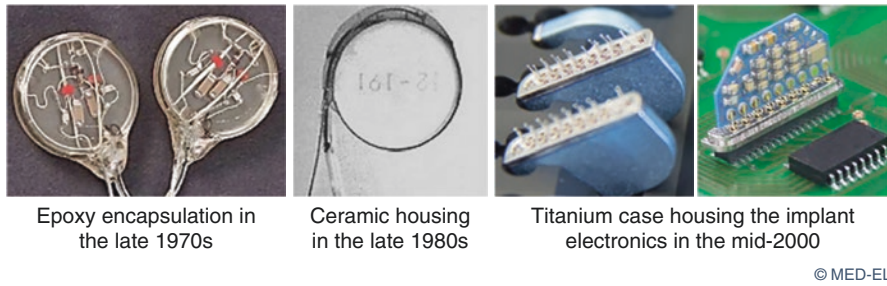


Fig. 3.2 Different materials used in the fabrication of implant stimulator case over time

ceramic housing is that the receiver coil can be placed within the casing, as ceramics do not greatly affect signal transmission. However, the material is more brittle than titanium and thus more prone to breakage under significant mechanical stress [5]. Figure 3.2 shows the different materials used to encapsulate implant electronics over time.

It is reported that the titanium housing has an impact resistance of up to 2.5 J [6]. Figure 3.2 shows implant electronics casing based on different materials that have evolved over time. Till today (2021), titanium is the *state-of-the-art* material used in the implant case. Recalls from the CI manufacturers due to implant failures are reported from time to time. Cochlear Corporation has recalled its implants in the year 1995 due to internal power supply failure issues and in the year 2011 due to hermeticity failure. Advanced Bionics has recalled in 1995 due to cracked ceramic cases, in 2002, due to suspicion of electrode array positioner being correlated to the risk of meningitis, in 2004, due to moisture trapped inside the implant at the time of manufacturing, in 2006, due to hermeticity failure, in 2010, due to latent short circuit in substrate and in 2020, due to moisture entering the implant causing a decrease in hearing performance [7].

3.4 Technological Evolution in the Implant Magnet

The implant magnet plays a key role in keeping the external transmitter in place over the implant, thereby relaying the signals from the external audio processor to the implant. The design of the implant magnet plays a major role in the safety of the CI patient. In the presence of an external powerful magnetic field like a magnetic resonance imaging (MRI) system, the implant magnet could react. If the implant magnet has no freedom to align itself to the external magnetic field, it can pop out of the implant case depending on the implant design, or it can cause the overall implant to shift its location causing pain sensation to the patient depending on the surgical fixation, or the magnet could lose its magnetism [8].

A magnet design with a self-aligning property in response to the external magnetic field could solve several issues. In the absence of a self-aligning magnet design, the magnet can be surgically removed prior to the MRI session, but at the cost of additional surgery and even some damage to the implant.

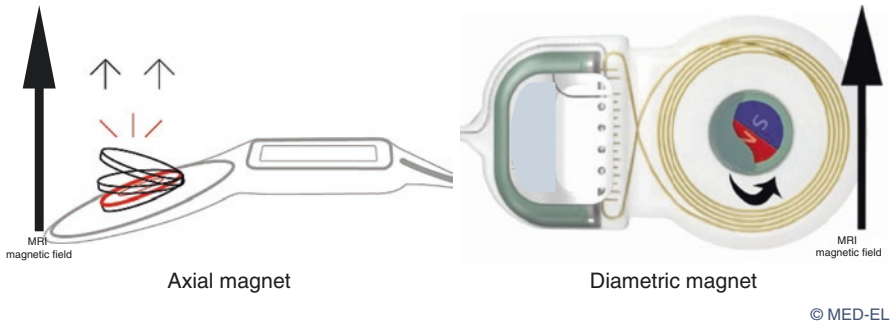


Fig. 3.3 Implant magnet design. Axial magnet is a regular cylindrical magnet with two magnetic poles on either face of the magnet and could be pulled toward the external magnetic field. The diametric magnet has both the magnetic poles on the same face of the magnet making it to rotate inside the magnet case in response to the external magnetic field (video clip)

In 2014, MED-EL introduced a self-aligning diametric magnet design that revolutionized the CI field when it comes to MRI procedures as shown in Fig. 3.3 (Video 3.1). The diametric magnet design allowed for an unparalleled MRI safety at 3.0 T without the need for magnet removal through an additional surgical procedure [9, 10]. Advanced Bionics and Cochlear Corporation, which are the other two CI manufacturers also came up with a self-aligning magnet concept in the year 2018.

3.5 Technological Evolution in the Intracochlear Electrode

Intracochlear structure preservation was not the aim when the first-generation electrode arrays were designed. The first generation of CI electrode arrays were bulky and were designed with ball contacts that protruded out of the electrode array as shown in Fig. 3.4. This was purposefully made with the aim of bringing the stimulating electrode contacts closer to the modiolus wall of the cochlea where the spiral ganglion cell bodies (SGCBs) are housed. It was reported several years after implantation of this first-generation electrode, that the ball contacts were broken and stuck inside the fibrous tissue encapsulation during explantation due to device failure. This warns us that the protruding ball contacts are not the optimal electrode design for CI applications.

Electrode with a positioner pushing the stimulating contacts closer to the modiolus wall was another electrode concept that came into existence in early 2000 [12]. In 2002, the Food and Drug Administration (FDA) reported about 87 cases of meningitis in patients implanted with CI and a total of 17 deaths have resulted mainly in patients implanted with positioner electrodes [13] as shown in Fig. 3.5. After this tragic incident, this electrode type was removed from clinical practice.

Pre-curved modiolar hugging electrode was another concept that was introduced by Advanced Bionics in 1995 and Cochlear corporation in 1999 to the best of author's knowledge. The design of the pre-curved electrode aims at hugging the

Fig. 3.4 Electrode with ball contacts protruding out of the electrode surface. Image adapted from Rebscher et al. [11]

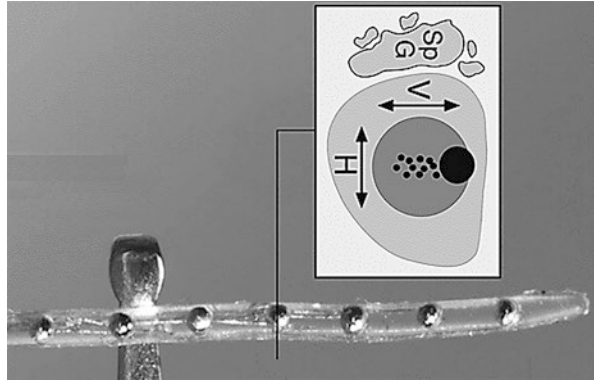
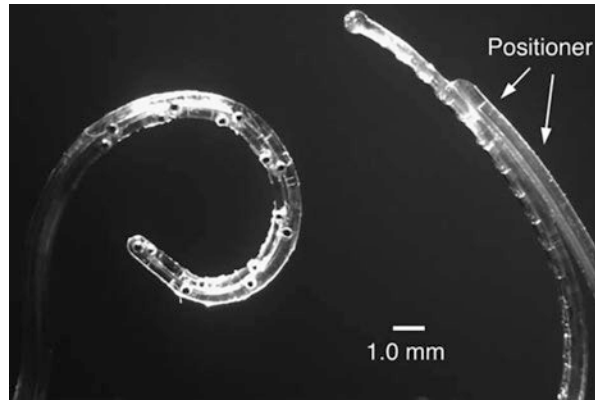


Fig. 3.5 Electrode with positioner [12]. Image reproduced by permission of Elsevier B.V.



modiolus wall of the cochlea bringing the stimulating electrode contacts close to the SGCs. These earlier versions of pre-curved electrodes were made bulky with no thoughts on the intracochlear structure preservation but rather on bringing the stimulating electrode channels closer to the SGCs and on the easiness of insertion fully inside the cochlea. Till today (2021), all the commercially available pre-curved electrodes as shown in Fig. 3.6 are available in a length mainly to cover only the basal turn of the cochlea and not beyond that [14]. This leaves us with the question if pre-curved electrodes have any manufacturing limitations that prevents them to be fabricated longer than what it is now to cover beyond the basal turn of the cochlea with electrical stimulation. The question was answered with yes, in the year 2018 as per the report by Dhanasingh et al. [15].

Since the beginning of MED-EL, its philosophy was to cover the entire population of the neural elements or in other words the entire frequency range with electrical stimulation in profound deaf cochlear conditions and therefore it developed the straight free fitting lateral wall electrode array of length 31.5 mm. Since 2004, MED-EL has introduced electrodes in 31.5 mm, 28 mm, 26 mm, 24 mm, and 20 mm array lengths with the aim of providing electrode solution to any cochlear size and

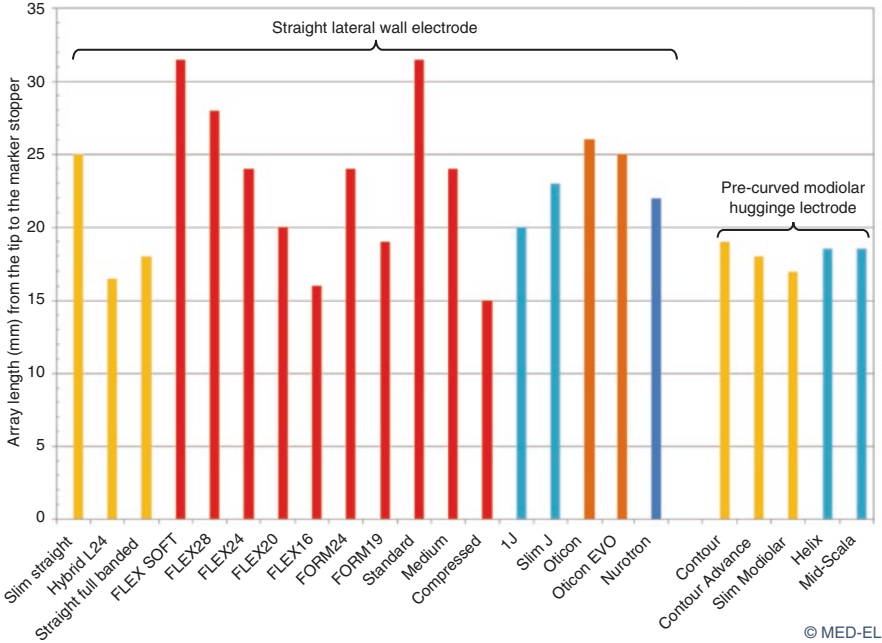


Fig. 3.6 Chart displays both lateral wall and pre-curved electrode array from all five CI brands. There are 19 lateral wall and 5 pre-curved electrode variants that were developed altogether by all five CI brands. Video clip shows the insertion of a flexible lateral wall electrode goes inside the cochlea



Fig. 3.7 SPLIT electrode with two branches. The short branch has five channels to be placed in the upper basal turn stimulating the low frequencies and the long branch with seven channels to be placed in the lower basal turn stimulating high frequencies

hearing level [16]. The other CI brands have some varieties on the length of the electrode array within straight lateral wall electrode type to offer different electrode insertion depths. Figure 3.6 captures the electrode types and their variants that are in current (2021) commercial use.

For severely ossified cochlear conditions, any of the regular CI electrode arrays mentioned in Fig. 3.6 may not be suitable. SPLIT electrode is a special electrode design that facilitates the placement of the SPLIT electrode by drilling two channels in the ossified cochlea as shown in Fig. 3.7.

3.6 Technological Evolution in the Method of Testing Auditory Nerve

The auditory nerve (AN) must be intact for hearing perception with a CI. In cases of tumor removal from the internal auditory canal (IAC) or in cases with severely malformed cochleae (e.g., hypoplastic cochlear type or hypoplastic IAC, as shown in Fig. 3.8), it may be necessary to assess the viability of the AN to predict the outcome of cochlear implantation [17]. Recording electrically evoked auditory brain-stem responses (eABR) via surface electrodes or placing an Intracochlear electrode is a well-established method for determining the integrity of the auditory pathways [18]. This section canvasses through the evolution of such systems over time.

The promontory stimulation test was first conceived by House and Brackmann in 1974, to predict the electrical response of surviving spiral ganglion nerve fiber populations to a cochlear implant. The generation of auditory sensations by preoperative electrical stimulation of the promontory was believed to verify a functioning cochlear nerve and appeared to be predictive of auditory perception following cochlear implantation [19].

The early-days promontory stimulation was performed preoperatively using a trans-tympanic needle electrode placed directly on the promontory at a location close to the round window opening. Electrode impedance confirm the contact with the promontory and the reference electrode was placed on the ipsilateral earlobe.

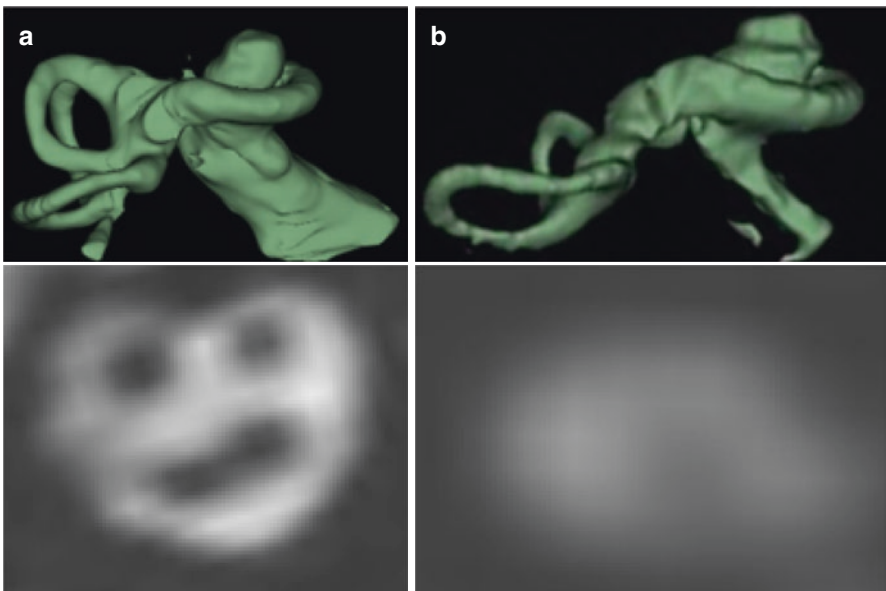


Fig. 3.8 Three-dimensional (3D) images of normal anatomy and the cross-section of the IAC showing four nerve bundles (a) and hypoplastic cochlea and cross-section of the IAC showing just one nerve bundle (b)

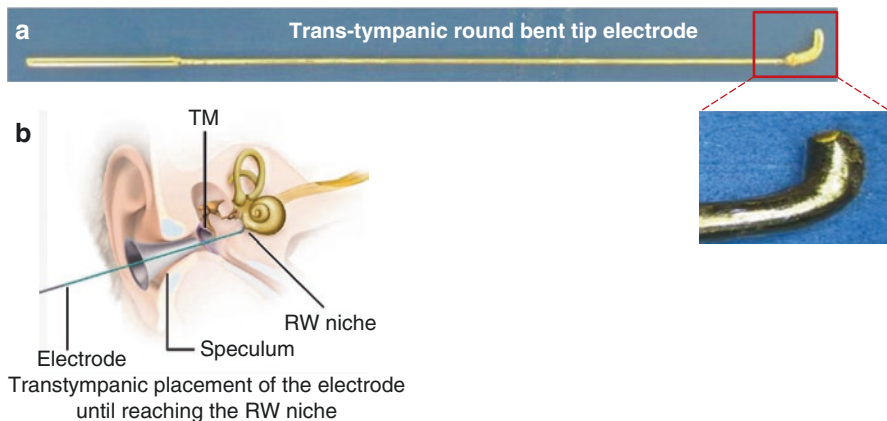
Promontory thresholds at low frequencies correlate with the percentage of surviving neural elements and therefore it is wise to deliver AC current at frequencies of 50 and 100 Hz. Patients subjectively respond if the electrical stimulation produced a sensation of sound and the data were collected on the smallest current detected [17]. One of the key disadvantages of the subjective promontory test is if the patient is congenitally deaf and how the first hearing sensation can be differentiated from sensation resulting from the side effects of electrical stimulation. The spread of excitation can cause “co-stimulation” affecting the facial nerve or vestibular nerve branches. Some patients will not be able to distinguish a vibrotactile sensation from an electrical auditory sensation, which makes the subjective interpretation of this test difficult.

To overcome the downsides of the subjective promontory test, the objective promontory test was introduced in the late 1980s and in the early 1990s. Objective promontory uses the electrically evoked auditory brainstem response (eABR) to verify the function of the auditory system from the auditory nerve response elicited either from the promontory stimulation or via cochlear implants.

As a further fine-tuning of the objective promontory test, the needle electrode was modified to a golf-club type electrode to be atraumatically placed at the RW as shown in Fig. 3.9. This was originally conceived by Dr. Peter Gibson in the early 1990s. This golf club electrode along with eABR recording makes the objective promontory test safer and more reliable.

In situations where an individual shows no response or is expected to have no response to the sound, and where imaging tests show normal or abnormal anatomy, or where the individual has already been selected for either a CI or an ABI, as an advanced method, an intraoperative test of nerve functionality is currently used. This test includes placement of the cochlear test electrode into the scala tympani (ST) to provide electrical stimulation followed by the eABR recordings.

MED-EL recently developed its own auditory nerve test system (ANTS) as shown in Fig. 3.10. The intracochlear test electrode contains four electrode contacts.



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Fig. 3.9 The “golf club” electrode used in the promontory stimulation (a), Illustration of the placement of golf club electrode on the RW niche through the external ear canal (b)

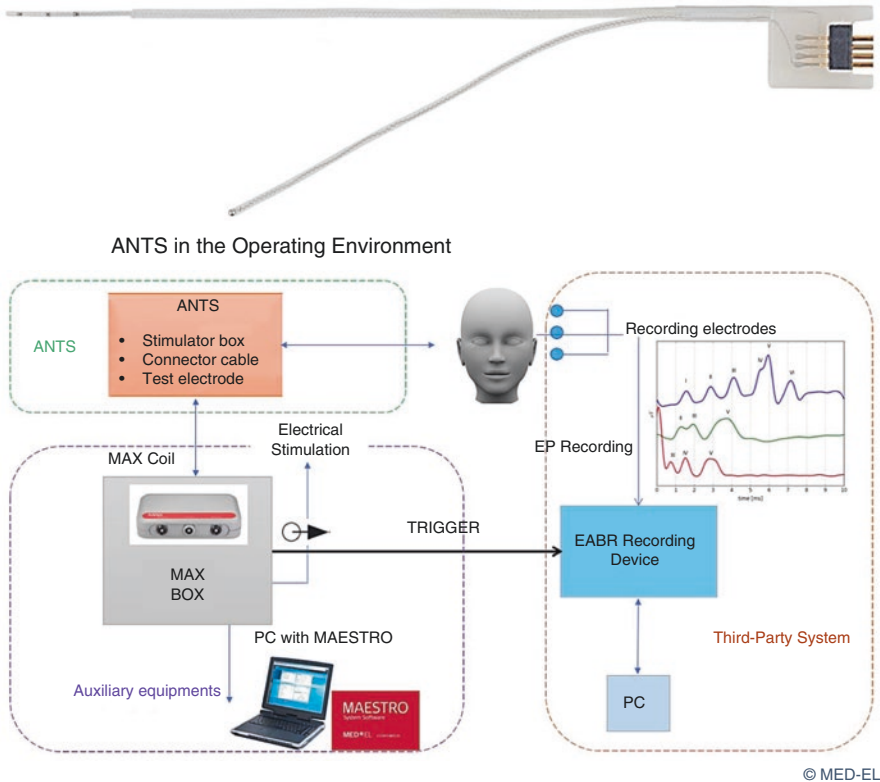


Fig. 3.10 Intracochlear test electrode and test set-up in recording the eABR responses

It is intended to be inserted into the ST during surgery. The length of the electrode is 18 mm, as indicated by the marker ring. Three of the electrode contacts are placed directly into the ST, and the fourth electrode contact is placed under the temporalis muscle. Biphasic pulses are generated using the MAX interface and delivered to the cochlea. At the time of stimulation, the MAX interface triggers the evoked potential, and eABR response is obtained from the surface electrode as depicted in Fig. 3.10.

This tool is suitable for individuals with questionable functionality of the auditory nerve, individuals with a narrow internal auditory canal and patent or malformed cochlea, in tumor patients to monitor nerve functionality during tumor removal, or in situations where any other tests/methods failed to show CI candidacy, including the use of eABR with the objective promontory stimulation system.

3.7 Technological Evolution in the Audio Processor

The routine usage of the audio processor by the CI recipients depends much on the cosmetic look and the design of the audio processor offering wearing comfortableness. Since the beginning of the modern CI, the audio processor is one element of

CI that has advanced a lot over time both in terms of advanced features and the cosmetic look. This section will cover the technological evolution from the early experimental device till 2021.

The very first experimental CI device in the year 1979 had an audio processor in the size of a mini-suitcase as shown in Fig. 3.11. The CI user was made to try a number of speech coding strategies and stimulation field configurations for fundamental research on nerve stimulation.

The audio processor from the mini-size suitcase transformed into a much smaller-sized body-worn type in the year 1979 as shown in Fig. 3.12. The microphone that picks up the audio signal in the body-worn audio processor type is in a different position than the ear pinna. The external transmitter coil is connected to the hear



Fig. 3.11 Mini-suitcase-sized investigational audio processor

Fig. 3.12 First version of body-worn audio processor

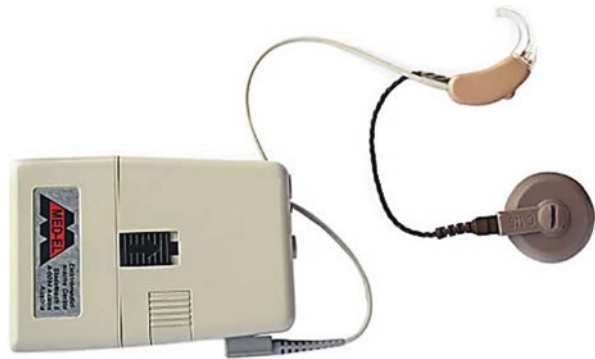


hook to be placed much closer to the implant to communicate with the implant stimulation via an inductive link. Still, it was an investigational device and it lacked a magnet in the external transmitter coil to have a focused inductive link with the implant stimulator.

The first commercial CI audio processor still had the body-worn type having the battery pack and the processing unit. The microphone was however brought to the ear level mimicking ear pinna as shown in Fig. 3.13. The external transmitter coil was designed with the magnet to have a focused inductive link with the implant stimulator. It took 10 years of research and development to bring an audio processor that was more practical to use. This audio processor used an AA battery as the signal processing strategy was high power consumption.

Soon after the development of the first commercial audio processor, the signal processing strategy was fine-tuned to consume less power. As a result, the AA batteries were replaced with zinc-air smaller size batteries allowing miniaturizing the whole audio processor into a much practical and comfortable behind-the-ear (BTE) processor (Fig. 3.14). In 1991, the world's first BTE processor was developed by

Fig. 3.13 First commercially available body-worn type audio processor



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Fig. 3.14 World's first BTE audio processor



Fig. 3.15 World's first single-unit audio processor

MED-EL and for the next 20 years, BTE processor was *state-of-the-art*. Dual microphone was one advancement within the BTE processor enhancing the CI recipient to better localize the sound source. Direct audio streaming from external audio devices like mobile phones and media players into the audio processor was a further advancement making the audio processor more practical and up-to-date with the general technological advancement.

Single-unit audio processor is the latest technological advancement in the audio processor that combined the battery pack, signal processing unit, and external transmitter coil as shown in Fig. 3.15. If placed under the hair, it will be highly invisible. In 2013, the world's first single-unit audio processor was introduced by MED-EL, and soon after Cochlear Corporation followed it. Within the single-unit audio processor, wireless charging of batteries, Bluetooth connectivity, water protection case was some of the technological advancements making it more practical to use. The microphone position is shifted from the ear level to more posterior but that did not have any significant effect on the hearing performances as per the published scientific reports [20].

3.8 Technological Evolution in Signal Processing Algorithms

Signal processing is a topic that is often seen as difficult to understand. It is the hidden component of the CI and it drives the whole CI system. In simple words, signal processing breaks the acoustic sound signal into frequency-specific smaller components and are converted into electrical signals to be delivered through the individual electrode contacts of the electrode array into the cochlea in a tonotopic pattern.

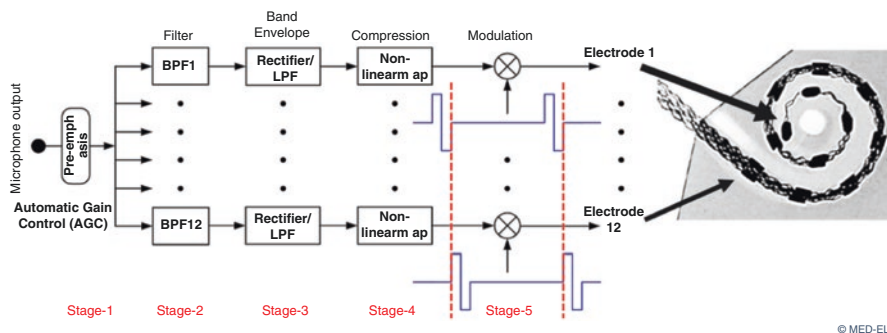
1991 was an important year in the field of CI, as Prof. Blake Wilson and his colleagues from the Research Triangle Institute in the USA developed the Continuous

Interleaved Sampling (CIS) strategy [21]. Before the introduction of the CIS strategy, it was mainly simultaneous multichannel analog stimulation was in use in which, all the stimulating channels in the electrode array were stimulated at the same time making it highly difficult for the brain to extract information from the stimulation impulse. Therefore, the simultaneous stimulation strategy did not succeed in bringing the complete acoustical input into the cochlea.

In the classic CIS sound coding strategy, the microphone signal is first processed through a pre-emphasis filter that attenuates strong components in the speech above 1.2 kHz and emphasizes signals that are below 1.2 kHz, as the speech information that is needed for normal conversation is around that frequency (stage 1). The output of the pre-emphasis is further passed through multiple channels of processing that include bandpass filters (BPF) (stage 2) for splitting the broadband signal into different frequency bands, rectification, as well as lowpass filtering for envelope extraction (stage 3). The envelope signals are compressed into the narrow dynamic range of electrically evoked hearing (stage 4). Trains of charge-balanced biphasic pulses are sequentially interleaved in time across electrodes to eliminate any overlap across channels, as shown in Fig. 3.16 by the red dotted vertical lines. The pulse amplitudes derive from the envelopes of the bandpass filter outputs and are directed to intracochlear electrodes (EL-1 to EL-12) (stage 5).

All the signal processing strategies that are available in today's CI system from various CI brands are based on the CIS strategy but with some modifications making it compatible with their implant electronics and the number of electrode channels.

The acoustic signal from the ear pinna reaches the middle ear and then to the inner ear where it is converted to electrical potentials by the Organ of Corti and



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Fig. 3.16 Block diagram of the CIS strategy. The pre-emphasis filter (pre-emp)/automatic gain control attenuates strong components in the speech above 1.2 kHz. This filter is followed by multiple channels of processing, with each channel including stages of bandpass filtering (BPF), envelope detection, compression, and modulation. The envelope detectors generally use a full-wave or half-wave rectifier (Rect.), followed by a lowpass filter (LPF). Carrier waveforms for two of the modulators are shown immediately below the two corresponding multiplier blocks (circle with an x mark). The outputs of the multipliers are directed to intracochlear electrodes (EL-1 to EL-12). The inset shows an X-ray image of the implanted electrode (in a cochlear model) to which the outputs of the speech processor are directed. Scheme created from Wilson et al. [21]

reaches the auditory cortex where it is perceived as sound. This whole process takes a few milliseconds and it is called traveling wave latency. Whereas with CI, the intracochlear electrode array bypasses the external and the middle ear and reaches the inner ear directly. This makes CI hearing to reach the auditory cortex bit earlier than natural hearing. The latest advancements in the signal processing strategy include a delay compensation feature [22] to adjust for the traveling wave latency making the CI hearing and natural hearing to reach the auditory cortex at the same time, if the patient is using CI in the ipsilateral side and having natural hearing on the contralateral side. This is very crucial in single-sided deafness (SSD) patients.

Conventional hearing aids (HA) take an even longer time to process the acoustic signal and to amplify it. If the patient uses HA on one ear and CI on the other ear, then the mismatch in time delay will be much higher. Bimodal Delay Compensation is a new feature in the signal processing strategy that allows unilateral CI users with HA on the contralateral ear to enjoy much-balanced hearing in both ears.

3.9 Future Technologies

Total Implantable Cochlear Implants (TICI) is one concept that carries a lot of potential and was first reported by Cochlear Corporation as a research device in the year 2008 [23]. However, it was never made commercially available till the time of writing this chapter in 2020. In 2020, MED-EL reported their first TICI device implanted in patients within Europe. If TICI is commercially available, the hearing loss will then be completely made invisible and it may not be far from achieving it soon.

The CI electrode array loaded with corticosteroids is another future concept that could come into commercial use soon as there are several research studies on the intracochlear application of corticosteroids by major CI manufacturers [24].

Robot-assisted CI surgery has already come into clinical practice and more than 20 patients are reported to have received a CI using the minimally invasive robot-assisted CI surgical approach [25]. While this robot-assisted surgical approach is limited to mastoid drilling to reach the cochlea, insertion of the electrode was still done manually. HEARO™ is the name of the robotic-assisted surgical system developed by a Swiss company named CAScination in collaboration with MED-EL. ROBOTOL is a robotic arm capable of inserting an electrode array into the cochlea and it was reported recently that few CI surgeries were performed applying ROBOTOL clinically [26]. This was developed by a French company named Collin Medical.

Further miniaturization of the whole CI would be another aim of every CI manufacturer, and something along this line can be expected in the near future. Complete reversing of hearing loss is the aim of some pharmaceutical companies. They are highly active in synthesizing novel molecules that could regenerate the neuronal elements that were either missing by birth or degenerated over time due to several medical conditions. Along this line, research on combining CI with stem cell were reported [27]. Predicting future hearing loss through gene testing is currently in

clinical practice in some hospitals and Prof. Shin-Ichi Usami from Matsumoto University in Japan is one of the active pioneers in this topic [28].

Through a mutual collaboration between the clinicians and the CI companies, the future of CI is certainly going to be very exciting as there exists a healthy competition between the CI companies.

3.10 Conclusion

Cochlear Implantation field is unique in its way that there are only three manufacturers worldwide who have received food and drug administration (FDA) approval for their CI devices. Every segment of the CI device has advanced tremendously in the last 35 years and thanks to the strong scientific collaboration between the clinicians and the CI manufacturers that made it possible to bring out the innovation reaching the patients. Continuous engagement of the CI manufacturers with the clinicians is essential as the clinicians could provide valuable feedback on how to further improve the CI device as they are the ones who handle it during and after the CI surgery. While the CI technology has reached its maturity in terms of functionalities after 35 years of dedicated research efforts, the near future will focus on evaluating the patient-related factors that affect the uniformity in hearing performance across CI recipients.

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