A DETAILED ANALYSIS OF HEARING IMPLANT VERSIONS AND THEIR WORKING- A REVIEW

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Abstract:

The invention of hearing implants is a great benediction to people having impaired hearing. In this field, the FDA approved numerous institutional research and implants, allowing hearing-impaired individuals to live normal lives. In this paper, the thorough work done in many domains of hearing implants throughout a decade ending in 2021 is described in relation to cochlear implant users and people with normal hearing. There were many inventions that are closely related to different kinds of problems that pertain to variations in hearing capabilities. Some of them are based on the mixed type of hearing loss. Some of them are related to the underperformance of the various parts of the ear (i.e. outer, middle, inner). It mainly deals with, the length and strength of operations of those parts of the ear. According to each type of problem, different kinds of implants have been designed. The main issue is related to assessing the kind of medical test that can be performed after such kinds of implantation. The details related to these topics are presented in this paper in the form of facts and figures with respect to cochlear implant users.

Keywords: Cochlear Implant (CI), Electrode array, cochlear implant processor, cochlea, Magnetic resonance imaging (MRI).

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1. Introduction

The ear is an essential sensory organ of the human body that always remains engaged with some sort of sound. The sound is captured by the various components of the ear and interpreted by the brain correctly if all parts are working properly. Consequently, the research should focus on the various components of the ear, and their associated properties resulting in i.e. different kinds of hearing implants. Throughout the past 50 years, numerous research institutes have conducted a variety of hearing implant-related research and development. The development division has been technologically based. The constant evaluation of these technologies over the years is provided here [1].

2. The invention of the types of implants for hearing

One type of implant is known as the cochlear implant and the corresponding invention was carried out by Ingeborg and Erwin Hochmair in the year 1975.
As depicted in Fig-1, the cochlear implant consists primarily of two pieces, one exterior and the other internal. The exterior component contains the battery and converts analog to electrical signals. Using an electrode array, the internal component of the cochlear implant transmits these electrical signals to the brain [4].

2.1. The external part of the cochlear implant- The external part of the cochlear implant amendment is based on the number of channels, stimulation rate, coding strategy, and how the various external components can be integrated into one unit, etc. In the early days of the cochlear implant, multichannel functionality was not available. The first multi-channel cochlear implant was produced in 1977 with eight channels and a stimulation rate of 10,000 pulses per second per channel [1], [2], [3].

2.1.1 One special type of implant, which give the combined effect of hearing aids and cochlear implants - This kind of implant is known as Electric acoustic stimulation (EAS). 2005 saw the introduction of electric acoustic stimulation (EAS), which provides the user with a combined effect of acoustic and electric stimulation. Since 2009, the second-generation EAS has been accessible to users [1], [2], [3].
The exterior component of a cochlear implant is referred to as a sound processor. It is known as a body-worn speech processor, and it first appeared in 1980. Table 1 describes the evolution of the sound processor of the cochlear implant and EAS from 1970 to 2021 in relation to the problem with the ear's inner portion (cochlea).

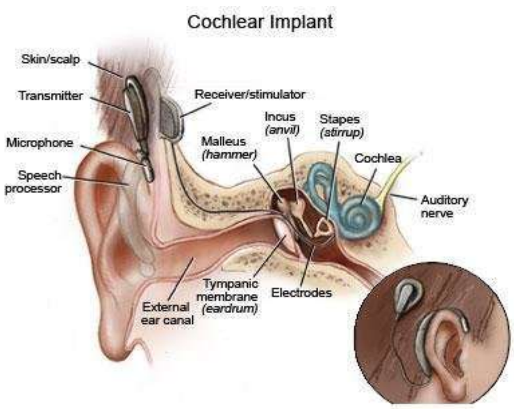
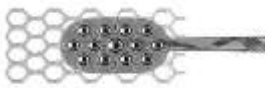


Fig-1 Cochlear Implant Placement in the Ear [25]
(courtesy of MEDEL Company)

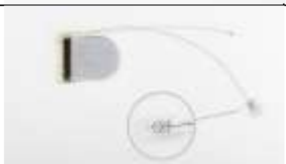
Table1: Detailed description of the cochlear implant outer parts [19]

Name &Year	**Image**	**Modification in the Sound Processor**
Body-worn speech processor (1980)		This is the first cochlear implant speech processor with all the necessary functionality. It provided open-set sentences to the CI users.
Comfort CI system (1989)		It gave the hermetically sealed ceramic housing of the coil with an ear-level microphone.
Behind the ear (BTE) speech processor (1991)		The size of the sound processor gets reduced and CI users can wear it behind the ear. In respect of speech understanding, it worked like body worn speech processor [1].
CIS Pro+ processor (1995)		It is using rectification with low pass filtering for the sound signals.
Tempo+ BTE (1999)		It is using Hilbert transform for envelope extraction of the speech signals. It is having a switch to change the volume and program [5].
Electric Acoustic Stimulation (EAS) system (2005)		It gives the combined features of a hearing aid and cochlear implant to the user.
Opus (2006)		It gives a switch-free and sleek design. It is using the FLEX series array in the internal part of the implant.
2nd generation EAS (2009)		It gives acoustic amplification in respect of a hearing aid and the stimulation of sound in respect of the cochlear implant with an upgraded version of EAS.
Opus2 (2010)		It can connect you to a device, like your phone and TV [6].

Maestro CI system (2010)		It is having the Opus2 sound processor with the Concerto internal part of the cochlear implant.
RONDO (2013)		It is providing all things in one compact sound processor like cable, control unit, and coil.
Synchrony CI system (2014)		It gives the facility of doing MRIs up to 3.0 Tesla.
Sonnet (2015)		It is light weighted and water-resistant processor [7], [18].
Wireless connectivity with sonnet (Sonnet2) (2017)		This processor allows users to connect its Roger wireless microphone to TV, and phone via processor sonnet [8].
RONDO2 (2017)		It can be charged wirelessly.
Expanded indication of ABI (2017)		It can be used for a 1-year child now.
RONDO3 (2020)		Users can use it with a hearing aid of any other kind of brand in another ear [1].

2.2 The internal part of the implant- It can be distinguished by the length, size, and kind of its electrodes. Combi 40 is the name of the first successful internal component of the cochlear implant, which was introduced in 1994. The voyage of the internal component of the Cochlear implant, from its inception to the most recent upgrade, is presented in tabular form in Table 2 below, beginning with the year of inception.

Table2: Detailed description of the cochlear implant internal parts [20], [21], [22]

Name &Year	Image	Modification in the internal part of the cochlear implant
Combi 40 (1994)		It carries 8 channels, using CIS speech coding strategy and its length is 31mm long which covers the entire length of the cochlea.
Combi 40+ (1996)		It carries 12 channels with an increased stimulation rate than combi 40.
Combi 40+ with split electrode (1997)		It is used basically when the user's ear fluid is converted into the bone, i.e. ossification cochlea. [1]
Pulsar (2004)		It is having ceramic housing and it is compatible with the future technology processor RONDO3 too.
Sonata (2006)		It is having titanium body with robust and impact-resistant features.
Concerto (2010)		It is lighter and smallest than others that are using titanium in the cochlear implant. It offers continuing reliability.
Concerto ABI (2010)		It gives combined features of CONCERTO & Auditory Brain Implant (ABI).
Synchrony (2014)		It is having a rotating, self-aligning diametric magnet. This feature allows MRI up to 3 Tesla without magnet removal.
Synchrony ST (2017)		It is providing the best MRI facility with the best reliability.
Synchrony 2 (2019)		It is the smallest implant till now with all the improved features. [9]

2.2.1. The invention is based on the electrode array of the cochlear implant- Users of cochlear implants will experience minimal harm and maximum performance due to its superior design. In this case, the shape of the electrode array has its own importance. Several types of electrodes exist according to technological advancements:

Wave-shaped Wires: This method utilized a platinum-iridium wire electrode array that was ultra-flexible. In comparison to straight wires, wave-shaped wires cause less tissue damage than straight wires. There are four types of electrode arrays: traditional (classical), Form, Flex, and Auditory brain implants.

Classic series: In this series, there are three types of electrode arrays called standard, medium, and compressed. All three types of electrode detail are depicted in Fig-2. The maximum array size is the regular array size, whereas the smallest array size is the compressed array size

Fig-2 Classic series electrodes detailed description (courtesy of MEDEL Company)

Form series: It is utilized when the cochlea is not functioning properly, such as when cerebrospinal fluid leaking is probable. It also has a seal indicating that the cochlea has closed. By this, a surgeon was able to close the cochlea with relative ease. They are of the Form24 and Form19 variety. Its details can be viewed in Fig-3.

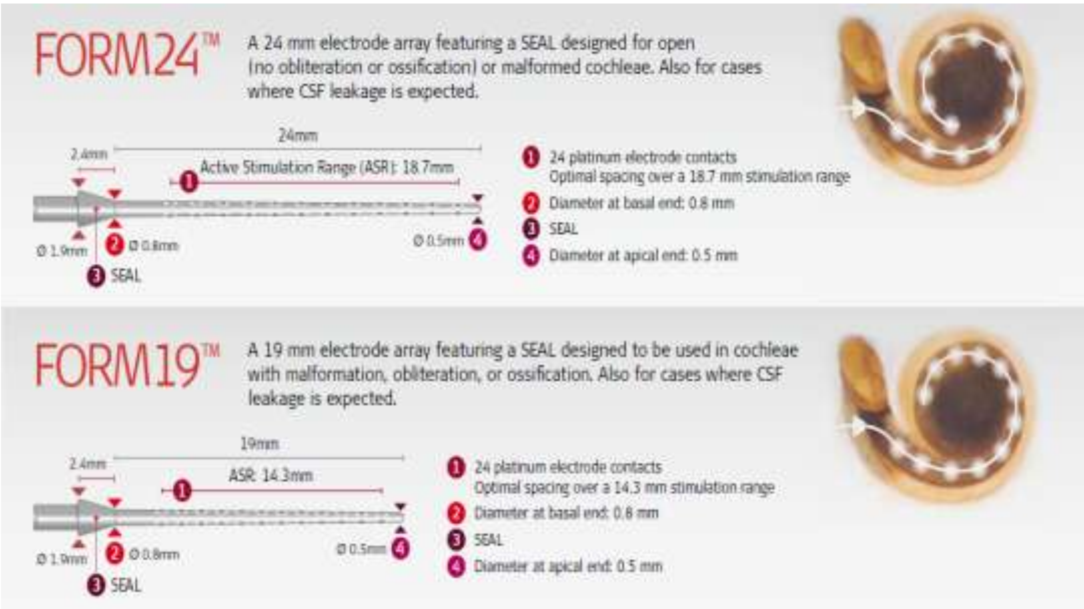


Fig-3 Form series electrodes detailed description (courtesy of MEDEL Company)

Flex series: This electrode array can be considered the most flexible and soft electrode array with flex tip technology. It is accessible to nearly all users. It is utilized for residual hearing preservation and building protection. This consists of Flexsoft, Flex28, Flex24, and Flex20 varieties. It provides comprehensive cochlea coverage (CCC). This type of electrode array stimulates all parts of the cochlea, from base to apex, for the best possible outcome for the user. Flexsoft has the longest length, while Flex20 has the shortest. All other characteristics and measurements are depicted in Fig-4.

Due to the presence of several electrode arrays. Using the diameter of the basilar turn, the user can select the appropriate electrode array. Using the modiolus as the centre point and the circular window to the opposite lateral wall, it is calculable [10].

3. Invention for some hearing nerve-related issues

In such cases, an implant can bypass the function of hearing (ear) and transmit sound directly to the brain, allowing the user to comprehend the meaning of the sound. An Auditory Brainstem implant describes this device (ABI). The work connected to ABI was initiated in 1994 by Professors Behr and Muller in Germany, in partnership with the University of Innsbruck in Austria. Professors Behr and Muller implanted the first ABI successfully in 1997.

Auditory brain implant: It is utilized for a specific purpose when the user's auditory nerves are not functioning properly or they have a tumor causing deafness.

ABI introduced the Combi 40+ internal components of the cochlear implant in 2003. Pulsar CI was introduced by ABI in 2005 as a response to the emergence of new technologies. In addition, it may accommodate additional internal components of the CI, such as CONCERTO, in 2010. It required four years to address the complex internal components of CI, namely SYNCHRONY [24].

Fig-4 Flex series electrodes detailed description (courtesy of MEDEL Company)

Any of these variations are feasible with a 15-year-old or older individual. It was advantageous for those with a tumour (neurofibromatosis) and deafness as a result of tumour excision. In 2017, an expanded indication for ABI was introduced. An Expanded indication of ABI is beneficial for a 1year child as well. Essentially, it is now advantageous for users who do not have neurofibromatosis disease [24]. Its shape, size, and travel are seen in Fig-5 and Fig-6, respectively.

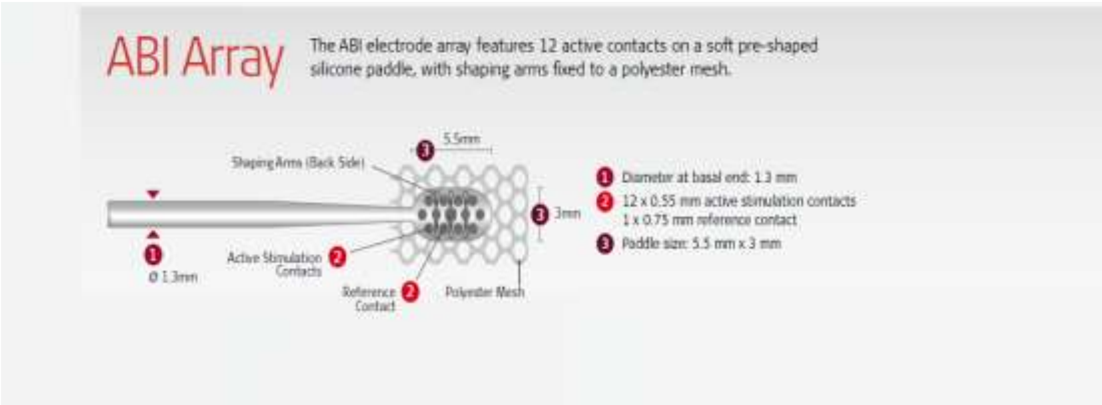


Fig-5 Auditory brain implant detailed description (courtesy of MEDEL Company)

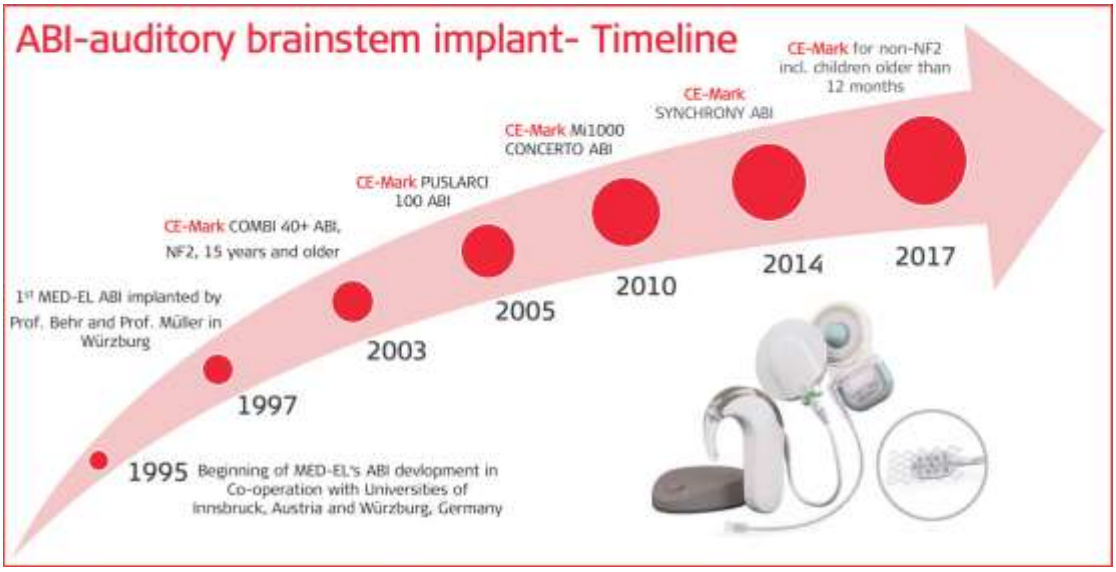


Fig-6 The detailed year-wise development of the ABI [24] (courtesy of MEDEL Company)

4. Implant for the outer and middle parts of the ear

When the user has problems with the outer and middle ear, there are additional implants that can be helpful.

4.1. Implant for the middle part of the ear- In such circumstances, a middle ear implant is inserted. The first middle ear implant, known as the VIBRANT sound bridge, was presented in 2003. Several new couplers are added to the soundbridge of the Vibrant, providing the surgeon with more amenities. 2014 marked the introduction of the newest version of soundbridge

4.2. Implant for the outer and middle ear- In 2012, a bone conduction implant was introduced to the market, which is useful when your outer and middle ear is not functioning properly. It collects the sound and transmits it to the inner ear through the skull bone. Table 3 provides every detail from the beginning time to the present time.

Table3: Detailed description of the middle ear and middle + outer ear implant [23]

Name &Year	Image	Working
Vibrant SoundBridge (2003)		It is known as a middle ear implant which is used in the case of mild-to-severe sensorineural hearing loss.
Vibrant SoundBridge (2008)		This year it added some new features i.e. it can be used for conductive and mixed hearing loss.
Amadé (2009)		It is an advanced version of Vibrant SoundBridge, in which users can be adults and child also.
Bone conduction implant (2012)		It is helpful when the outer and middle ear does not work properly. It takes sound around you and passes it to the internal part of the ear through the skull bones.
SOUNDBRIDGE (VORP 503) and SAMBA (2014)		It is an upgraded version of SoundBridge, with new Vibroplasty Couplers which help surgeons. It also provides an MRI facility to the user up to 1.5 Tesla.
SAMBA (2014)		It provides the combined functionality of SoundBridge and Bonebridge.
ADHEAR Bone Conduction System (2017)		It is helpful when the user is having conductive hearing loss or single-sided deafness.
BONEBRIDGE BCI 602 Implant (2019)		It is an advanced version of BoneBridge which provides less depth in drilling.
SAMBA2 (2020)		It gives a better hearing experience to bone conduction and middle ear implant users. [1]

Whenever an MRI examination is necessary, the user immediately perceives a problem. Users with cochlear implants were unable to undergo MRI examinations like other individuals; they needed special clearance from the surgeon to remove the magnet from the internal portion of the implant. After that, patients can get an MRI examination. In 2003, the FDA granted permission for only 0.2 Tesla MRI machines. This indicates that there is no need to remove the magnet from the implant if the MRI is 0.2 Tesla and the internal component of the cochlear implant is combi 40+. Later Pulsar, Sonata, and Concerto, which are internal components of cochlear implants, received FDA approval for 1.5 Tesla MRI without magnet removal. Synchrony, the most recent implant, received permission for a 3.0 Tesla MRI without magnet removal.

In synchrony, the magnet is distinct from others since it is initially fixed in the implant; therefore, when the MRI machine is turned on, the magnet is pushed on because its alignment differs from that of the machine magnet. Despite the fact that all magnets have a south and north pole, in contrast, the magnet in Synchrony is not stationary; it rotates in its titanium housing. Thus, it can make proper alignment from the machine itself. From 2021 onwards, research provides cochlear implant users with a lifetime MRI guarantee [11], [12],[13],[14],[15],[16],[17].

5. Conclusion

There was a continuous research effort in these areas, and it was fairly successful in supporting the requirements of implant functionalities. The sustained effort made people's life much easy. Nowadays they can choose any kind of implant, or electrode array according to their specific need. All kinds of implants are available in the market with systematically graded advanced technologies. The net result provides the best combinations in respect of the outer and inner parts of the implants.

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