



**GUIDE to
HEARING LOSS
and
HEARING SOLUTIONS
with a focus on
IMPLANTABLE
DEVICES**

Second Edition 2018

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INTRODUCTION

WHY THIS GUIDE?

About one-third of Australian adults have some degree of hearing loss. That is about 3.5 million, of which some 2.5 million should have some form of hearing assistance but do not use it or have not tried any. Proportions are similar in other developed countries. In respect of cochlear implants, even in advanced economies, less than 10% of those who would benefit have done so.

Many people do not recognise their problem, others are in denial and some fear a stigma associated with a visible hearing solution. Myths include beliefs that hearing aids don't work, that cochlear implants are only for children, and that hearing devices make one look older or handicapped. This CICADA Guide therefore starts by summarising the numerous perceptions and misconceptions about hearing loss and the barriers to wider use of hearing solutions. The subsequent sections deal with what is involved in understanding hearing loss and potential solutions, then descriptions of the devices available and the ongoing technology advances.

The focus in this second edition is on implantable devices for several reasons: (i) hearing aids are long-established and well-known, with adequate overview and detailed comparative information available (ii) even the best-established of implantable devices - cochlear implants - are much less widely known, including across hearing professionals, with a lack of independent, comparative, accessible information (iii) technological and surgical advances have made some implantable devices much more routine, much more capable, and more widely applicable to different types and degrees of hearing loss (iv) a new myth, that implants can restore hearing and do so quickly, needs to be dispelled.

WHAT IS CICADA?

CICADA is a charity, originally established in 1984 as the Cochlear Implant Club and Advisory Association. CICADA now supports implant recipients and hearing-impaired Australians generally. As an independent, non-profit organisation CICADA Australia Inc. offers unbiased guidance through the difficult and emotional process of choosing and using hearing technology. CICADA is involved in

- Social events
- Guest speakers
- Technology expos
- National magazine
- State newsletters
- Interactive website
- Providing support from its members who have experience of all types of hearing aids and implantable devices.

WHO IS THIS GUIDE FOR?

Mainly for medical, audiological and other professionals in the hearing health field, along with some "consumers" - those who are hearing-impaired, their families and friends - who are interested and motivated to better understand the overall situation and their own options. We hope this Guide will help address the lack of awareness of the wide range of solutions available and the types and degrees of hearing loss that they apply to.

ACKNOWLEDGEMENTS:

Cicada Australia Inc. would like to acknowledge the following members for their contributions to this Guide.

Neville Lockhart - Content and editing:

As a toddler in Scotland after the war, Neville's hereditary deafness was quantified as total in the left ear and about 70% in the right ear. With hearing aids, years of speech therapy and continuous support from family, teachers and classmates, he progressed well at normal schools. In mid-teens there was a sudden loss of residual hearing along with tinnitus. Neville had to rely on lip-reading through the rest of school and at Strathclyde University. He undertook extensive library work to compensate for what he missed aurally, ending up with B.Sc in Chemistry followed by Ph.D in the solid state physics area, in both cases with the university medal and prize for top graduate. A teaching fellowship at the University of Nottingham followed, including research on electrical processes in biological materials.

Neville came to Australia in 1974 to join the Commonwealth Scientific and Industrial Research Organisation (CSIRO). He progressed to the senior research levels through the different fields of textiles, environment, coal and minerals that reflected changing government R&D needs. He then moved into management of R&D and technology. He became strategy and business development manager for the Division of Energy Technology and pulled together the Flagship Program "Energy Transformed" to address efficiency and greenhouse issues in the electricity generation, transport and energy end-user sectors. Neville was fortunate that facsimile machines, followed by mobile phone texting and emails, and then personal assistants helped him cope with the increasing communication requirements. He took early retirement in 2002 because of political and relocation issues, not deafness-related.

After his "retirement", Neville recalled visiting Prof Graeme Clark in 1983 and being advised he "heard" extremely well and it would be better to come back in 15-20 years when the cochlear implant was hopefully much better developed. He brought himself up to date, including attending CICADA functions and talking to many implant recipients. With the support of Judy and the children and grandchildren, Neville proceeded with the then newest cochlear implant (Freedom) in 2005 through SCIC and Prof Bill Gibson.

What a noisy world! But after 6 months he was achieving over 90% in sentence recognition tests in quiet without lip-reading, well above expectations for someone totally deaf for over 40 years. While he still has difficulties in noise and with the phone, the implant has been a great success, both socially and in work for CICADA. Neville was a committee member for 9 years. He became editor of the national newsletter (6 pages and 2000 circulation) and helped develop this into the 28 page glossy CICADA magazine with 20,000 circulation, filling a huge gap for the hearing-impaired and professionals in the hearing sector. The magazine was handed over in 2012 to the Tangello Group to further develop and expand as Hearing HQ magazine; Neville was a member of the Editorial Advisory Board. That magazine continued till 2016 when advertising pressures common to nearly all print media caused its cessation. Neville also helped with the revamp of the CICADA members newsletter Buzz and with material for the CICADA website.

Neville's technological management background in identifying unmet needs, along with his science communication experience, led him to attempt this CICADA Guide to Hearing Loss and Hearing Solutions. Neville welcomes the launch of this updated Guide on the CICADA website, which has been upgraded and further developed with Pat Mitchell as web-weaver.

Patricia Mitchell – Layout, Design and Graphics:

Pat is also CICADA Australia Inc. volunteer web-weaver. She was formerly a website designer and computer support staff member at La Trobe University IT Division, following many years in the private sector. She continues to develop websites in her retirement. Pat has been hearing-impaired for over 70 years, profoundly so for the last 20 years. She received her first cochlear implant in February 2014 and the second in February 2016. You can read more of Pat's story through this link as well as other personal stories: [What Price Hearing?](#)

In relation to the first edition of this Guide, CICADA is indebted to several professional reviewers

: Margaret Anderson:

A former audiologist and clinical development manager, Margaret retired in 2011 after 33 years with Australian Hearing. She has written and delivered many learning programs, is responsible for countless information brochures and articles related to hearing loss, plus tucked six years in publications and PR into her career. She now freelances as a Learning, Design and Development consultant to the hearing industry from her tree change 50 acres at Crookwell, NSW.

Marie-Louise (Muir) Hekel:

A thirst for excellence in communication, expression and understanding led her to Master degrees at Columbia University in Speech Pathology and Audiology. Ten years in hospital diagnostic and clinical casework angered her enough to push boundaries, create hearing aid legislation in New York, teach undergraduates and establish a private practice. After twenty-six years in the Australian hearing aid industry, education and a Collins Street practice specialising in *“Auditory Re-Awakening”*, she retired with her husband on 5 acres. Marie-Louise enjoys creative arts, sport, cooking and the friendship of many past clients.

Roberta Marino:

Roberta has 25 years experience as an audiologist with expertise in hearing aids, cochlear implants and other implantable hearing solutions. She is currently Senior Audiologist at Specialist Hearing Services and at Fiona Stanley Hospital, Perth and is Adjunct Research Fellow at the University of West Australia. She has presented at various national and international conferences and published papers in peer-reviewed international journals relating to cochlear and middle-ear implants.

Some of the experiences and insights of Margaret, Marie-Louise and Roberta have been incorporated as breakout boxes in appropriate parts of the text and carried over to this second edition.

1. Perceptions of Hearing Loss and Barriers to Hearing Solutions

The impact of hearing loss cannot be underestimated. It can be felt on a personal level, affecting development, education, self-esteem and socialisation, as well as on an economic level which can lead to unemployment, underemployment and lower incomes.

Research has also shown that hearing loss can negatively affect physical, cognitive, behavioural and social functions, and it has been linked to increased risks for depression and dementia. Yet only a small proportion of those who need or would benefit from a hearing solution actually have one or have even tried one. Of those who do obtain hearing aids, up to 40% do not wear them all of the time.

The barriers and perceptions are many:

- (I) Lack of Awareness
- (II) Denial
- (III) Unrecognised Impacts of Hearing Loss
- (IV) Misbeliefs and Unrecognised Value of Solutions
- (V) Poor Medical Guidance, Commercial/Vested Interests
- (VI) Stigma and Public Attitudes
- (VII) Cosmetics
- (VIII) Cost
- (IX) Inadequate Information
- (X) Fragmented Support Groups

(I) Lack of Awareness:

Many people are still unaware or apathetic about damage to hearing through exposure to excessive or prolonged noise or that the damage is cumulative and permanent. Many are not aware they have a hearing loss, even when it is more than a mild loss, especially when the onset is gradual and the person and their family/friends adapt to it often without realising they are adapting. Indifference to noise exposure and apathy apply to lots of people, with or without a hearing loss.

For example, do YOU find it hard to....

- Follow conversations?
- Understand family & friends?
- Notice soft sounds?
- Separate voices from background noise?
- Hear on the phone/mobile?

If you said yes to any of these questions, it may mean there is some hearing impairment. Hearing checks are widely available, including free telephone and website tests that one can carry out

oneself. Follow up quantification by professionals is covered in Section 3 of this Guide.

The most common reason for people getting their first hearing aid is that their 'hearing got worse' and they are experiencing increasing communication problems and embarrassments. At the other extreme, people have been motivated to seek a hearing solution after losing contracts or jobs due to misunderstandings. It is important to identify hearing loss earlier and not delay a solution.

Audiologist Comment 1

IF ONLY

If all individuals, from childhood to adulthood, would have REGULAR threshold testing - i.e. every 2 years for a child, every 3 years for a student, and every 5 years for an adult. - AND if all doctors, especially GPs, would understand and explain the social and psychological consequences of hearing loss on both the individual and their associates, much of the apathy and misconceptions could be eliminated.

Audiologist Comment 2

AH-HA MOMENTS

One of the most dramatic "Ah-Ha" moments in my client's lives (or the parents of hearing-impaired children) happens when I demonstrate the difference between listening to familiar, recorded music or speech or environmental noises, VIA SPEAKERS - FIRST with their natural hearing AND THEN with instruments set to correct adjustment for the loss. HEARING THE DIFFERENCE ALLOWS BELIEVING, - and with today's digital technology, this is easy and inexpensive.

Audiologist Comment 3

ASK for a PROFESSIONAL DEMO

of listening to the radio, or their loved one's voice, or a favourite recording, or recorded environmental sounds while wearing/using a hearing aid set to the correct prescription for someone's hearing loss IS NOT UNREASONABLE AND HIGHLY DESIRABLE.

(II) Denial:

Facing up to a loss of ability in an area of our lives can be difficult, and hearing loss is no exception.

Among the justifications:

- “I don’t have a problem” (though it is obvious to others),
- “my hearing loss is not severe enough”,
- “my loss too mild”,
- “I hear well in most situations”,
- “my hearing loss is not disruptive to my life”,
- “hearing aids are a hassle”,
- “other people mumble”.

There are many reasons why people won’t deal with fading hearing. Some people, struggling to admit there is a problem, may not want to confront their advancing age, or are afraid of how they will manage or afford a hearing aid. Some genuinely don’t realise there is an issue as their hearing is fading so gradually they haven’t noticed it. In fact, in most cases it is someone else who notices the hearing loss, not the person with the impairment.

(III) Unrecognised Impacts of Hearing Loss:

The Australian Hearing CRC and Access Economics in 2012 estimated the costs of untreated hearing loss at \$11.75billion annually, including 160,000 who would otherwise be employed and off welfare, and that costs to business are \$1880 per employee per year. US studies estimate reduced earnings potential of \$30,000pa for impaired employees. Importantly, in recent years hearing loss has been linked to Alzheimers and dementia. The greater the degree of (untreated) loss the greater the risk, while if hearing solutions are used the incidence falls to the same level as for the general population in the same age group. The link is not necessarily causative, but may be partly or wholly due to social isolation and lack of stimulation as a result of untreated hearing loss.

Audiologist Comment 4

DISCRIMINATION in PRACTICE

No matter if legislation exists which states that one cannot discriminate against the “disabled”, if an individual cannot hear subtle or soft information, cannot come across as being ‘an active, attentive, interested individual’ in the customer’s needs, they will not be hired or promoted. Simple!

Untreated hearing loss causes great problems in many relationships. “He won’t get a hearing aid.” “She won’t stop talking from another room”. Tension all round. Too often it is another family member who begs the hearing-impaired person to get an aid. “I had to force him to get hearing aids” is a common scenario in affected families. Audiologists often say “however hard it is for you, it’s harder for your family”. Most hearing aid wearers and recipients of implantable devices, agree with this, at least in hindsight.

(IV) Misbeliefs, Fear and Unrecognised Value of Solutions:

Common misbeliefs are that hearing aids don’t work, are not good enough or have too many problems; these are myths, certainly for modern technology. Another myth is that cochlear implants are only for children, or even that cochlear implants come from dead people or organ donors. Fear of surgery, necessary for all implantable devices, is also a barrier for some people, as is the fear “what if it does not work”. This is despite the relatively minor nature of most modern implant surgery and the very low incidence of complications. In addition, success rates are extremely high while many patients with profound hearing loss could rationalise any fears of failure in that they are no worse off!

Surveys of hearing aid wearers and implant recipients repeatedly demonstrate high levels of satisfaction with their devices. Objective assessment, unbiased advice and auditory rehabilitation to maximise the benefits are all important, along with realistic expectations. For example, hearing aids won’t cut out all unwanted noise, and cochlear implants do not restore hearing to normal. Nevertheless, nearly all hearing impairment has one or more solution options. For older children and adults who have had no hearing since birth, implants can at least help with environmental sounds and with lip reading, such that with prior counselling even signing deaf recipients can benefit.

(V) Poor Medical Guidance, Commercial/Vested Interests:

Many General Practitioners, specialists in Gerontology, even some specialists in Ear, Nose and Throat are not aware of some of the above factors, nor of the wide range of hearing solutions available and who would benefit from them.

Worse, some give incorrect information such as telling a patient:

- “you still have good hearing in one ear”,
- “you can converse in quiet”,

- “you’re fine, you understand me face-to-face in my rooms”,
- “your hearing loss is normal for your age”,
- “nothing can be done for nerve deafness” etc.

Hearing impairment can be misinterpreted as senility, while children can be misdiagnosed as slow, intellectually impaired, attention deficit etc. when these symptoms may be a consequence of hearing loss.

Another factor can be hearing aid clinics which offer a limited range of hearing aids and/or may be tied to one manufacturer, and have commercial/ vested interests in selling a solution that is not fitted properly or may not be the most appropriate device. To keep this in perspective, modern surveys also demonstrate high levels of satisfaction with professional services in this field. Dissatisfaction is greater with cut-price, one-size-fits-all approaches and on-line purchases.

This “competition among providers” issue does not apply to implantable devices, rather it is a case of too few specialists, for example less than 10% of audiologists in the USA classify themselves as a cochlear implant audiologist. Only half of all American children who could benefit from a cochlear implant actually receive one. Compare that to Europe, where nine in 10 receive implants.

Many American parents don’t know that cochlear implants are an option. That’s partially because information provided to parents of newborns who are deaf, particularly in some regions, comes from the Deaf cultural community and the network of schools for the deaf. So there is also no uniform and clear system or referral pathway to connect eligible candidates with cochlear implant specialists. Timeliness is critical because the best outcomes are achieved when children undergo implantation under age two — or even under age one. Some people who are Deaf and choose not to hear argue that cochlear implants and other advanced hearing technologies deprive children who are deaf of their rich Deaf cultural heritage, as well as immersion in the natural language of the deaf, American Sign Language. But more than nine in 10 parents of children who are deaf have normal hearing. They do not know sign language and are more comfortable with technology that can empower their child to speak, read, and write. Children with cochlear implants still need committed parents and supportive schools to reach their potential. Some will need to use multiple modes of communication, particularly if implanted late or because of other medical and social factors.

(VI) Stigma and Public Attitudes:

Some people reject hearing solutions because they believe it makes others feel they are less competent, unattractive, older, handicapped etc. This may be exacerbated by modern society being perceived as oriented towards youth, attractiveness, communication, and consumerism. But it is not hearing solutions that make one look older or incompetent, it is attitude, personality and other factors besides biological age.

It is the misinterpretation of conversations, need for repetition/clarification and withdrawing from social interactions that is more often the cause of a stigma. In a surprising twist, hearing technologies are now often thought to be AirPods and hands-free phone devices, making users of hearing aids look very technology savvy.

Audiologist Comment 5

INTIMACY

Often overlooked even by many professionals is to discuss with 'youthful - no matter what chronological age' clients, is the improvement in "INTIMACY". Sounds of intimacy, whether physically sexual or tenderness in words, are lost when the partner must raise their voice. It's wonderful with the use of amplification to catch those murmured "sweet nothings" again.

(VII) Cosmetics:

Cosmetic issues are no longer a barrier. Since the 1990s completely-in-the canal (CIC) devices provided virtual "invisibility". And if one needed a more powerful or suitable device, the in-the-canal (ITC) aids were only slightly larger. Public figures have commented along the lines that "people still think that you have to wear a huge contraption but, in fact, they can be colour matched to your hair and are very discreet". The argument goes 'Let's face it, you associate hearing loss with getting old and boring. But who says you can't be sexy and wear hearing aids?'

Ironically, a behind-the-ear instrument can be more cosmetically appealing than an in-the-ear device as current designs render them small and light, less visible, and physically more comfortable for the wearer. For many hearing-impaired clients, a custom-made ear mould is no longer required. Some hearing instruments communicate sound to the ear via a visually-transparent capillary tube or wire, connected to a miniature loudspeaker suspended in the open ear canal.

Advanced feedback cancellation technology has allowed the current generation of hearing instruments to use a more comfortable open ear fitting without any whistling. This design means that the ear is not blocked with a mould enabling it to breathe and does not impair the natural acoustics of the ear. Attractiveness is being addressed with professional fashion designers dealing with product imagery, and the cosmetic appeal of hearing aids has soared. Bone-anchored hearing devices are much less visible than conventional bone conduction hearing aids. Cochlear implants and other implantable devices may be more apparent, but can also be one piece and/or nearly invisible for females and others with longer hair.

(VIII) Cost:

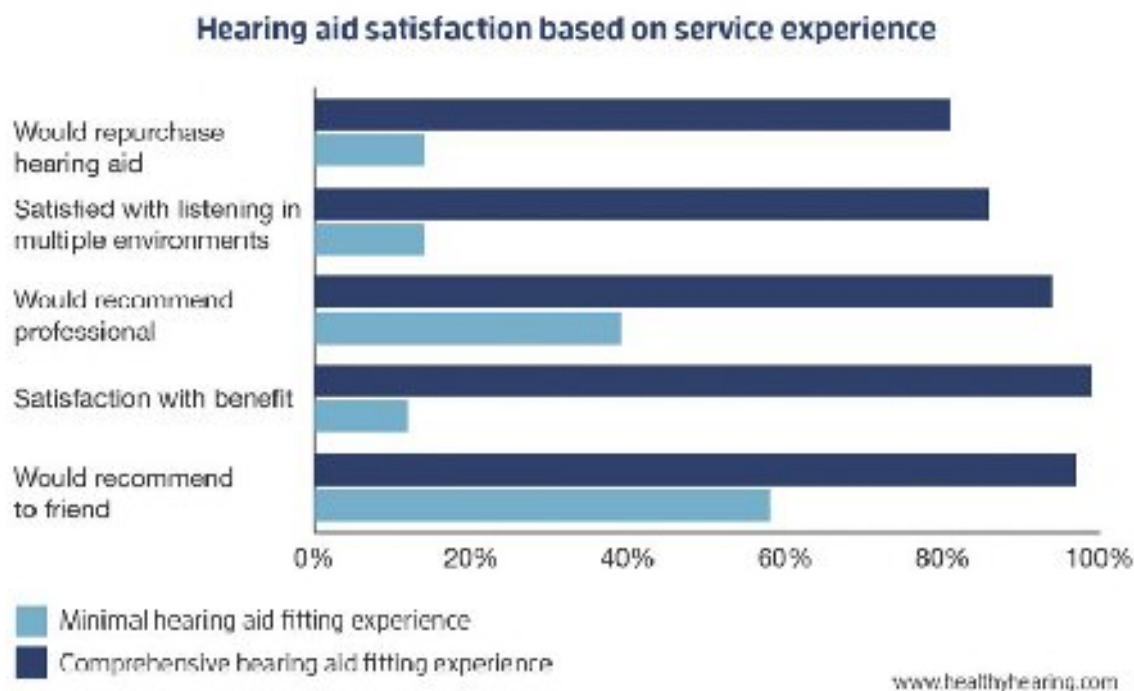
Costs, and government plus private insurance rebates, vary from country to country. In Australia, privately-purchased devices (excluding internet sales) range from \$1,500 for a basic hearing aid to \$12,000 for a pair of premium aids. There are usually many services included in the cost of hearing aids, such as hearing tests, expert assessment, initial fitting, follow up adjustments, cleaning and warranty. Also while the overall cost of hearing aids (and implants) have remained steady, the technology and sophistication at these same cost levels are much enhanced. A top-of-the-line aid a few years ago would be considered basic now. Cochlear implants with wireless accessories can range up to \$30,000 for a pair, plus surgical and rehabilitation costs.

Health insurance is available at reasonable cost to the general population. Most insurers provide at least partial reimbursement for hearing solutions, including any necessary upgrades and

replacements at intervals of several years. The Australian government provides fully subsidised hearing aids and services for children and young adults up to 26 years and for pensioners and war veterans. The majority of cochlear implants are supplied with little or no cost to the recipient, due to health insurance and other funding sources. The surgical component is covered by Medicare, private insurance and charity funding from donations.

The recent advent of the National Disability Insurance Scheme (NDIS) in Australia, now reaching nationwide rollout, provides an alternative or additional avenue for government funding. There is an ongoing campaign to make hearing one of the national health priorities. The NDIS is not covered in this Guide, pending more experience and certainty.

A consequence of the cost issue is the recent expansion of over-the-counter, on-line and mail order hearing aids. These can be OK but buyer beware. Readers are referred to a large survey by the Better Hearing Institute comparing satisfaction levels for those who had minimal services with those who had professional service protocols:



(IX) Inadequate Information:

There is plenty of information from manufacturers and clinics and on the internet. But that information is dispersed, often overlaid with marketing hype, and it is difficult and time-consuming to understand in any systematic way.

The wide variety of hearing aids across different manufacturers is now beginning to be reviewed independently and categorised according to the specific types and degrees of hearing loss that particular styles and models apply to - some references are provided in Section 6.

Implantable devices are much less well known, yet the types and applications are expanding, while comparative information remains hard to find. Furthermore, hearing aids and implantable devices are not compared, certainly not in any systematic way, despite the increasing areas of overlap and integration. CICADA hopes this guide and website information is a significant step towards overcoming this problem.

(X) Fragmented Support Groups:

There are numerous support groups for the hearing-impaired (as well as for the signing Deaf community) and many websites and other on-line resources. In Australia, the major and longest-established is Better Hearing Australia while the peak government body is Deafness Forum. Neither is strong on implantable devices. Many others have narrower or more specific aims, such as Aussie Deaf Kids, Parents of Deaf Children and Hear for You (aimed at teenagers and young adults).

Audiologist Comment 6

DEAF vs HEARING IMPAIRED

Of all the terms related to hearing, the term DEAF should only be used to denote true deafness, that is the absence of all hearing. The comparison is that someone who is BLIND, CANNOT BENEFIT FROM SPECTACLES/GLASSES. Those who wear glasses need correction with lenses. A majority of hearing LOSS OR IMPAIRMENT, is just that - an impairment - and can benefit from correction through a variety of instruments.

Conclusion: The key social and economic issue is that some 2.5 million Australians should have a hearing solution but do not. Statistics are similar in other countries. The Better Hearing Institute notes that more than 22 million people in the USA need but have not tried hearing solutions. Action on Hearing Loss (formerly RNID) estimates this figure at about 4 million for the UK. Furthermore, while over-the-counter hearing aids and their intended users – adults with mild to moderate hearing loss — generate headlines, the under-utilisation of cochlear implants (<1% up to only 8% of the adults who do meet the candidacy criteria in various countries) remains largely overlooked. This low uptake comes back to the lack of information and lack of awareness in the hearing health professions about recent advances in CI technology, candidacy requirements and potential benefits. This Guide is intended to help overcome the barriers and reflects CICADA's thrust: *Helping hearing-impaired Australians achieve the optimum, tailor-made solution to improve their hearing.*

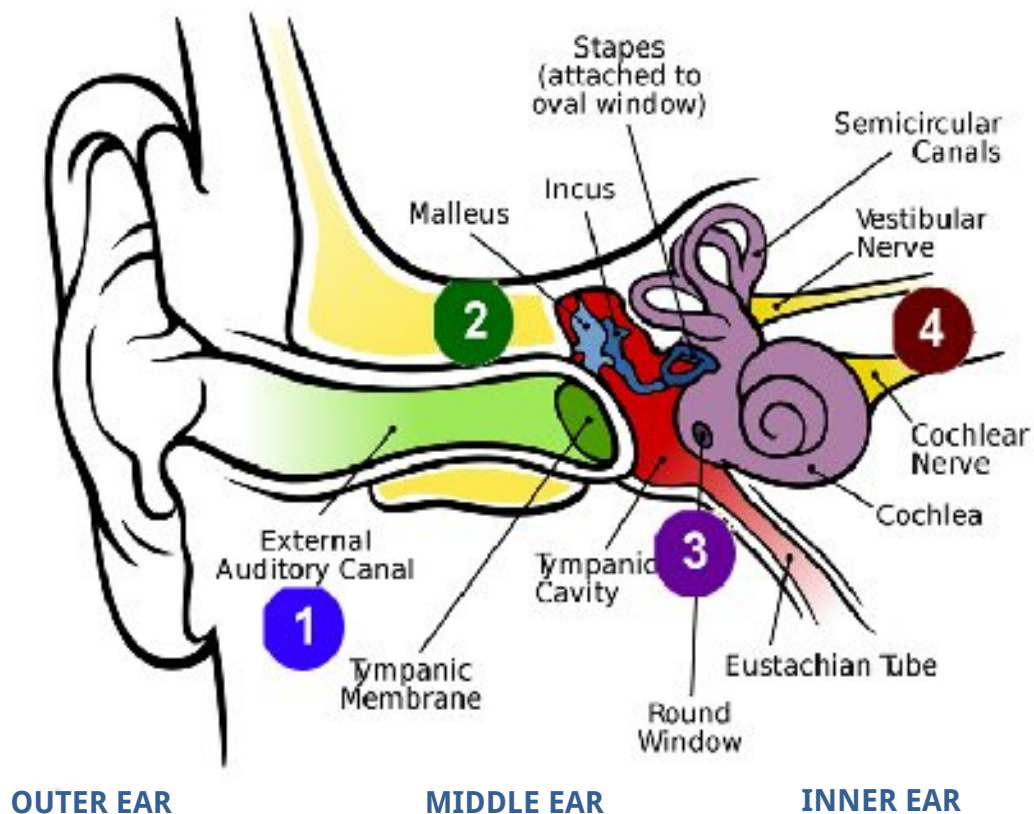
Sections 2 to 14 which follow, deal with what is involved in understanding hearing problems and investigating potential solutions. Many other topics that are relevant or interesting to hearing-impaired people are not included in order to maintain this focus and keep the Guide a reasonable length.

Many hearing-impaired people have outstanding achievements in business, academia, sport or other areas, in some cases while they were deaf and before they received hearing aids or implants. Such personal stories of the famous and not-so-famous are numerous and inspiring, but they too are not included for space and copyright reasons.

Conditions commonly associated with hearing loss such as Tinnitus and Meniere's Disease are mentioned only briefly, as are the specialised medical descriptions of hearing disorders and the exciting research or likely future developments. Interested readers are referred to the [CICADA Australia website](#).

2. HOW NATURAL HEARING WORKS

Sound enters our ear and sound waves funnel down the ear canal to the eardrum.



- 1** This is the outer ear.
- 2** The middle ear begins at the eardrum. Sound waves make the tympanic membrane vibrate like a drum (hence the term “eardrum”). Beyond the eardrum is an air-filled space containing three middle ear bones, the smallest bones in the body. These carry the vibrations to the inner ear.
- 3** The sound vibrations transfer to fluids in the cochlea, a snail-shaped structure containing “hair cells”. Fluid movement causes these tiny hair cells to bend. Hair cells at one end of the cochlea send low pitch sound information and hair cells at the other end send high pitch sound information.
- 4** The movement of the hair cells creates electro-chemical signals that are picked up by the auditory nerve. The auditory nerve sends signals to the brain where they are interpreted as sounds and given meaning.

The inner ear actually comprises two functionally separate sections:

The vestibular or balance part and the cochlea, which is the hearing part. The former helps us sense acceleration/deceleration in all directions, head position in relation to gravity, and to maintain sharp visual focus as we walk, run, ride, chew etc. Balance disorders, head noises (tinnitus) and hearing impairment are sometimes linked, such that some clinics deal with tinnitus, Meniere's disease and hearing loss in a holistic approach. Tinnitus does not cause hearing loss but is a common symptom, while the progression of Meniere's disease is usually accompanied by increasing hearing loss. Both tinnitus and Meniere's can be helped by hearing aids and implantable devices, but this Guide focuses on the hearing loss aspects.

Audiologist Comment 7

POSITIVE IMPACT on TINNITUS

All types of devices reduce the perception of tinnitus in most cases. TINNITUS by definition is the "Perception of a sound or noise within the ears or head IN THE ABSENCE OF AN EXTERNAL SOUND OR NOISE", THE FACT that this perception can be and is reduced with the use of hearing devices is VERY IMPORTANT and can be the very reason an individual uses amplification even if they do not accept they have that much of a communication problem. IF THEY CAN GET RID OF THEIR TINNITUS, they can CONTROL their life and improve their sleeping. (many tinnitus sufferers use their instruments all night and sleep much better)

3. HEARING TESTS and AUDIOGRAMS

The first step is recognising some of the tell-tale signs which can include:

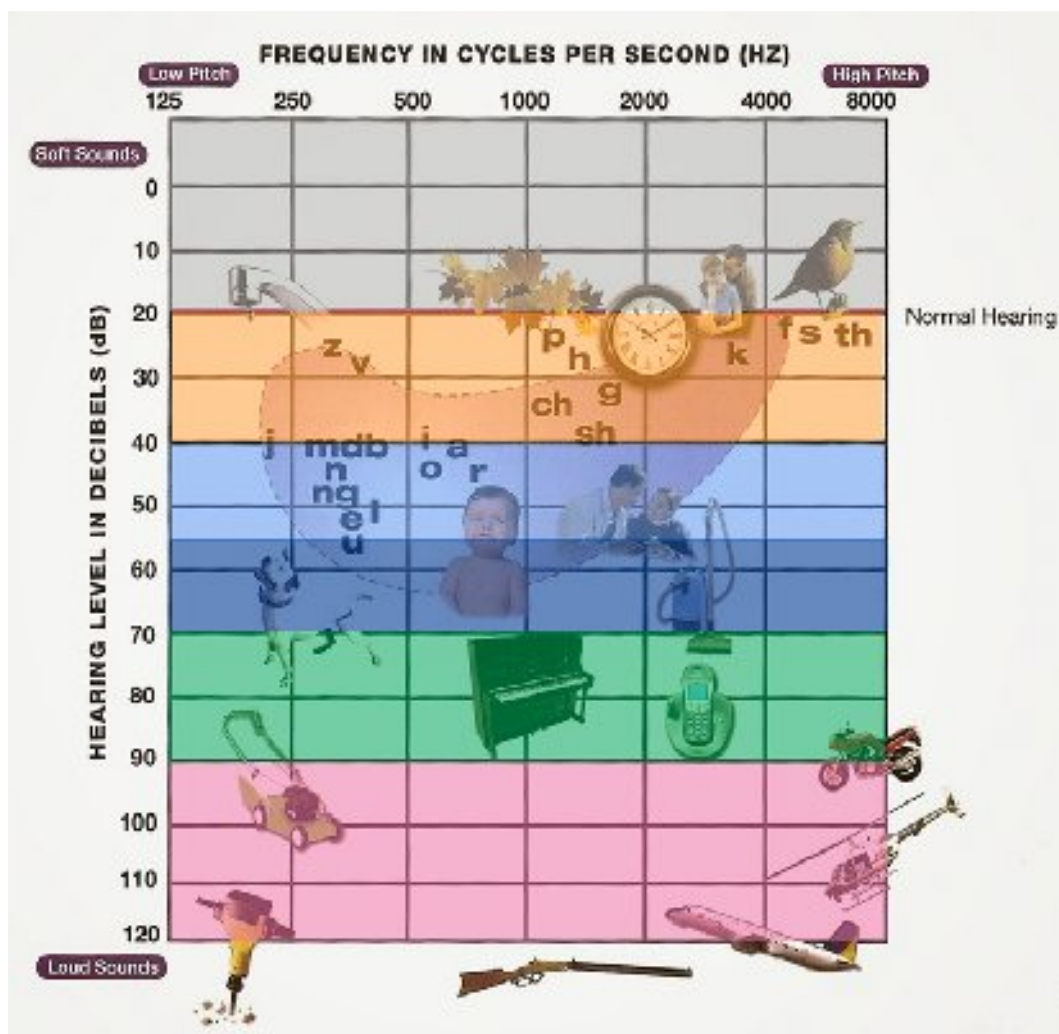
- mishearing words or asking people to repeat what they say
- finding them hard to understand when not facing you
- feeling people mumble or do not speak clearly
- greater difficulty in following conversations in noisy environments
- ringing, buzzing or other noises in the ears
- poorer understanding of, and/or a need to turn up the volume on the telephone, radio or TV
- problems identifying the direction sounds are coming from
- distortion of speech and music.

Simple hearing tests such as telephone checks offered by Australian Hearing are useful. Note that very few GPs routinely carry out hearing tests, and hearing problems are rarely recognised in the quiet one-to-one environment of a doctor's surgery!

The second step is to have a specialist (audiologist or audiometrist or ENT) quantify and classify the hearing loss. This starts with a case history – details of general health and specifics about the hearing loss. Next, a visual inspection of the ear canal and eardrum is performed with an otoscope (ear light) to check for any blockages or abnormalities in the outer ear. Then hearing is tested in a quiet room or sound-treated booth by presenting a series of tones through earphones to each ear.

The softest levels of each tone one can hear (the thresholds of hearing), across the frequency range in Hertz (Hz) units from 250Hz (very low pitch) to 8000Hz (very high pitch), are recorded on a graph.

This Graph is called an **audiogram**. On the decibel (dB) scale, 0dB represents extremely soft and 120dB extremely loud. The severity of hearing loss is described in terms of degree of disability or impact on everyday life. A mild hearing loss would cause mild problems, a severe hearing loss would cause severe disruption to communication and lifestyle. The chart below illustrates the various degrees of loss.



Normal hearing (Grey)-10dB to +20dB; Mild Loss (Orange) 20dB to 40dB;

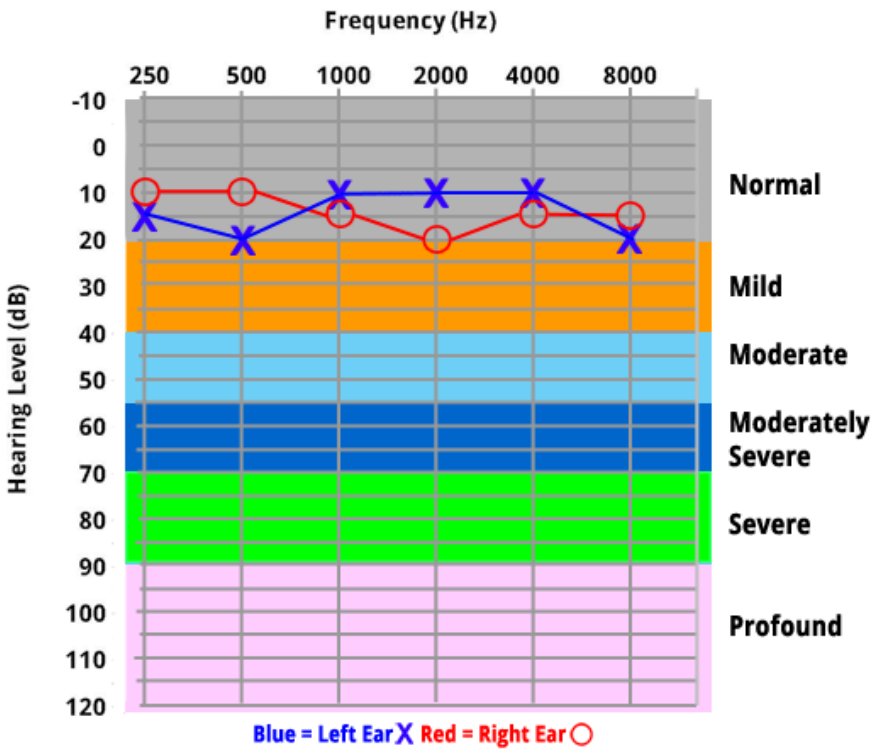
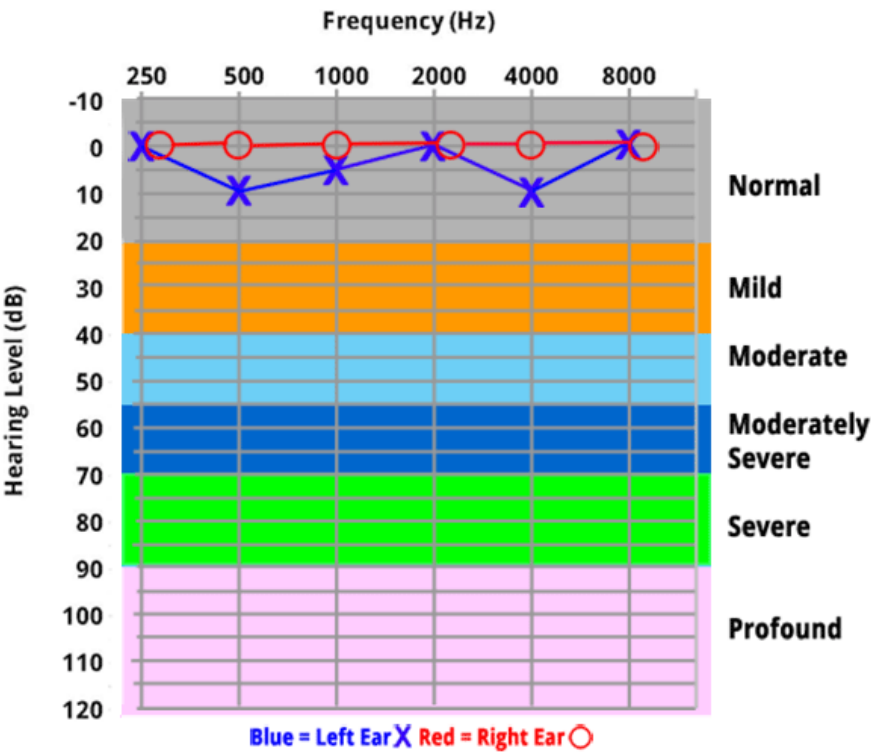
Moderate Loss (Light Blue) 40 to 55dB; Moderately Severe (Dark Blue) 55 to 70dB;

Severe (Green) 70 to 90dB; Profound (Pink) 90 to 120dB

The hearing test using earphones is referred to as air conduction. When this test reveals a hearing loss, it is supplemented with bone conduction testing. A small vibrator is placed on the mastoid bone directly behind the ear and sound is transmitted through the bones of the skull directly to the inner ear, bypassing the outer and middle ear.

On the audiogram, air conduction hearing thresholds (softest sounds heard) are shown as O for the right ear and as X for the left ear. The bone conduction hearing thresholds are represented by < and > respectively.

Examples of audiograms for hearing within normal range are shown below:



There is commonly some variation between individuals across the frequency range and between their right and left ears. Any response between -20 dB HL and +20 dB HL is considered within the normal range of hearing, that is, sufficient to allow for average communication to occur.

Audiologist Comment 8

NORMAL HEARING does NOT mean NO HEARING LOSS

If you have grown up with better than average hearing say 0dB, and are a healthy individual most of your life, and you begin to have trouble understanding (as opposed to hearing) certain speakers well, and you get tested - YOUR HEARING WILL BE CLASSIFIED NORMAL IF 20dB IS THE SOFTEST LEVEL YOU CAN HEAR ACROSS THE FREQUENCIES TESTED.

Unfortunately, you may have lost 20dB of your hearing and this means a significant loss of perception and your brain struggles to follow what you had no trouble with years before. THIS IS WHY SOME CHILDREN AND ADULTS CAN AND DO STRUGGLE WITH 20dB HEARING ACROSS THE ENTIRE FREQUENCY RANGE.

Audiograms representative of various degrees of hearing loss follow in Section 4. The difference or the lack of any difference between the air conduction (X and O) lines and the bone conduction (> and <) lines determines the nature of the hearing loss.

Hearing tests may extend further to:

- assessing ability to understand words or sentences, (before and after scores are a routine measure of the success of hearing aids or implants)
- tympanometry for the middle ear function and acoustic reflex for neural pathway
- otoacoustic emission testing which assesses the functioning of the inner ear
- auditory brainstem testing (ABR), which assesses the integrity of the auditory nerve pathway

Otoacoustic emission testing is the foundation for universal newborn hearing screening (UNHS) by which nearly all babies in Australia and most other developed countries are checked for hearing loss soon after birth. If the infant fails this screening test, it is followed up by a more detailed ABR test.

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HEARING CHECKS FOR CHILDREN

The time to have a hearing test is age 2 or 3 to set a baseline and testing should be as regular as eyesight tests.

Why - a mild or even worse hearing loss can be hard to pick up if a young child is bright or particularly alert. Some children are misjudged as slow learners, troublemakers, or learning-impaired. Some end up language-delayed and functionally-impaired because their loss was not identified.

Ear examination - If possible, seek out a professional who can make a photo of your ear canal and your ear drum on both ears. This equipment, called a Video-Otoscope, allows you to see what the examiner is seeing and has been around since the early 1990's. Being able to see your own ear canal and ear drum, especially when you may use a hearing aid, is of vital importance.

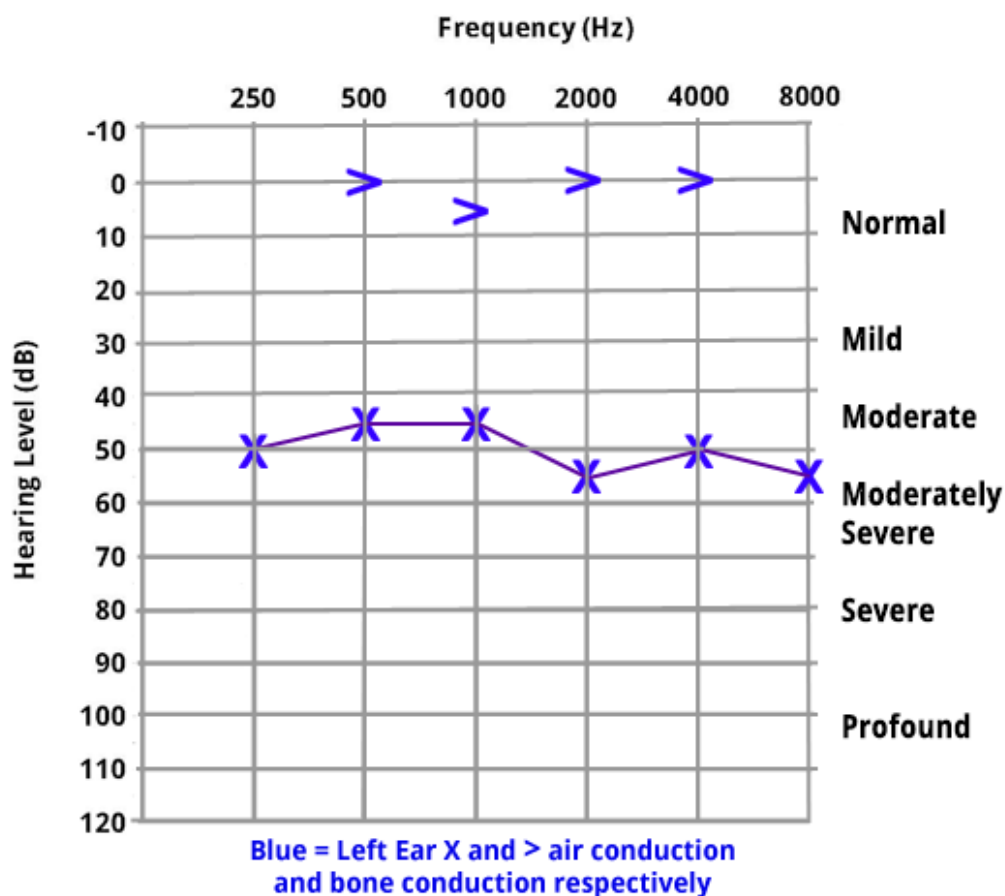
The other reasons for doing this is to show the health and condition of the outer ear and ear drum so to coordinate health records. This equipment also helps show and explain how the tip of any conventional hearing devices can get blocked with dirt, dust, dry skin, wax or fluids.

4. TYPES of HEARING LOSS with EXAMPLE AUDIOGRAMS:

- (I) Conductive Hearing Loss
- (II) Sensorineural Hearing Loss
- (III) High Frequency Sensorineural Hearing Loss
- (IV) Low Frequency Sensorineural Hearing Loss
- (V) Mixed Hearing Loss, Combinations
- (VI) Neural Hearing Loss

(I) Conductive Hearing Loss

The key feature is a bone conduction audiogram showing hearing in the normal range while the earphone (air conduction) test shows significant loss, as illustrated by the example audiogram below. The gap means that the hearing nerve function is better than the mechanical hearing. Conductive hearing loss is caused by a problem in the outer and/or middle ear that blocks sounds getting to the inner ear.



Common causes (from Healthy Hearing 2017) are:

Outer ear

- A narrowing of the ear canal (stenosis)
- Wax impaction
- Bone-like protrusions that can develop inside the ear canal and cause potential cause blockages
- Otitis externa (also known as swimmer's ear)
- Obstructions caused by foreign bodies inserted into the ear.

Middle ear

- A breach in the tympanic membrane caused by injury, ear infections or extreme and rapid air pressure changes
- A thickening of the tympanic membrane (tympanosclerosis)
- Otitis media or a buildup of fluid in the middle ear
- Blockages in the eustachian tube, which connects the middle ear to the back of the nose and throat
- Otosclerosis, a rare medical condition that causes movement of the middle ear bones to stiffen
- Abnormal growths or tumors that form within the middle ear
- Ossicular chain discontinuity, or a break in the connection between the bones of the middle ear, caused by injury or heavy trauma.

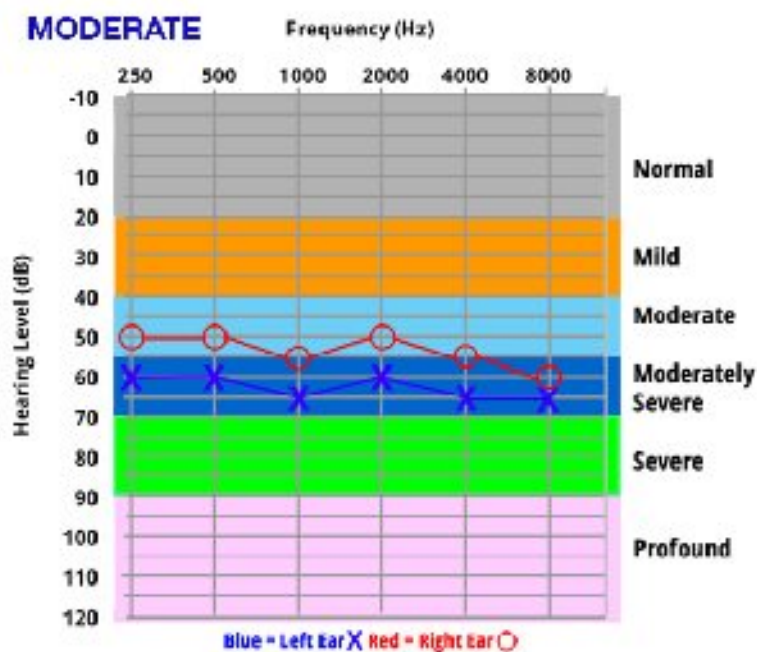
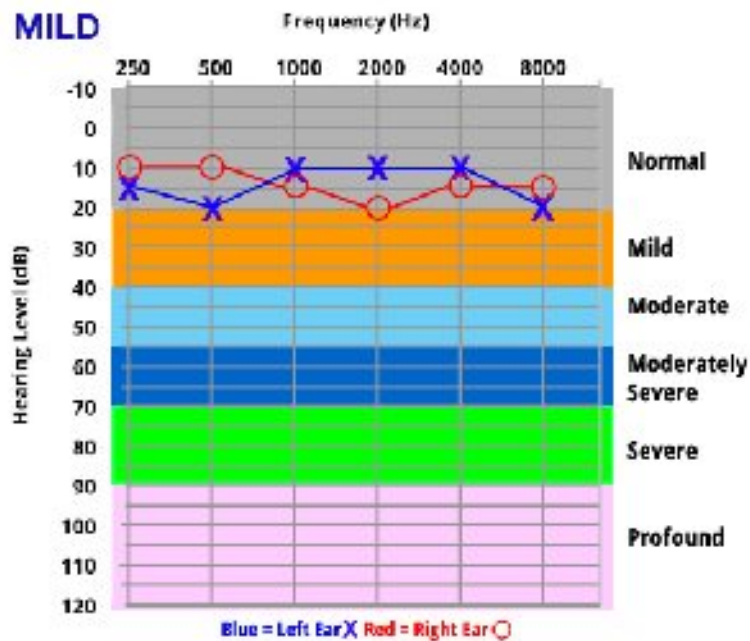
Approximately 10% of all hearing losses are conductive, which can range from mild to moderate in severity. Conductive hearing loss can often be medically or surgically treated, and in many cases, hearing can be restored or greatly improved.

(II) Sensorineural Hearing Loss

This is the most common type, applying to about 90% of all people with hearing impairment. The losses with the earphone and bone conduction tests are the same. If a child is born with sensorineural hearing loss, it is most likely due to a genetic syndrome or an infection passed from mother to fetus inside the womb, such as toxoplasmosis, rubella or herpes. When sensorineural hearing loss develops later in life, it can be caused by a wide variety of triggers, including:

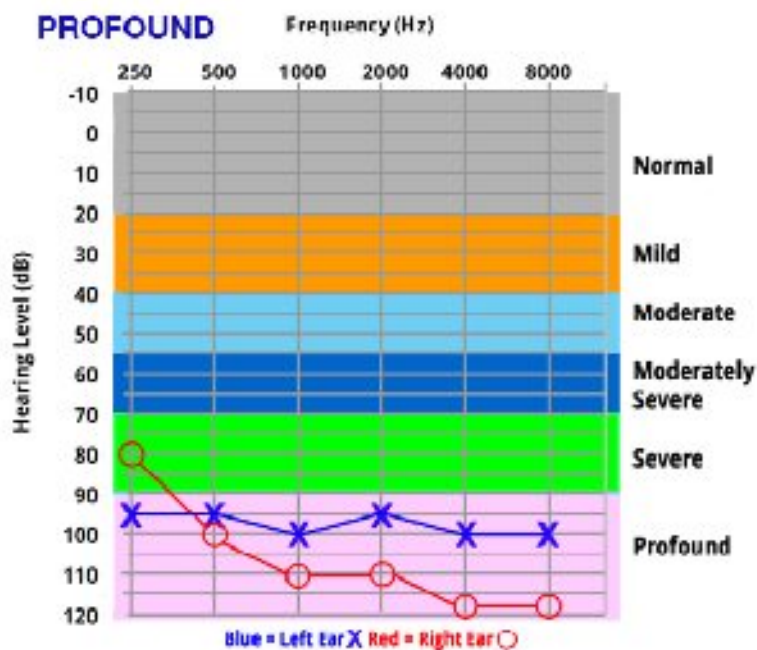
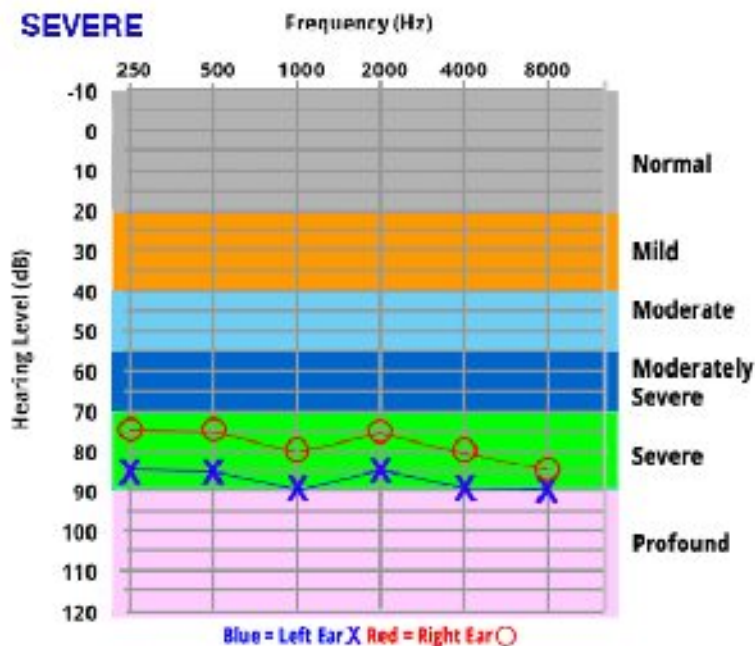
- Deterioration caused by age (presbycusis)
- Blood vessel diseases
- Auto-immune diseases

- Infections such as meningitis, mumps, scarlet fever and measles
- Traumatic injuries
- Noise exposure over extended periods of time
- Menieres disease
- Acoustic neuroma or other cancerous growths in the inner ear
- A side effect through the use of certain medicines



The hearing loss can be mild, moderate, severe or profound illustrated in the audiograms below.

Severe loss equates to not hearing conversational speech, hearing only shouting and loud noises like traffic. Profound loss means only very loud noises like pneumatic drills or planes taking off can be heard (or felt).

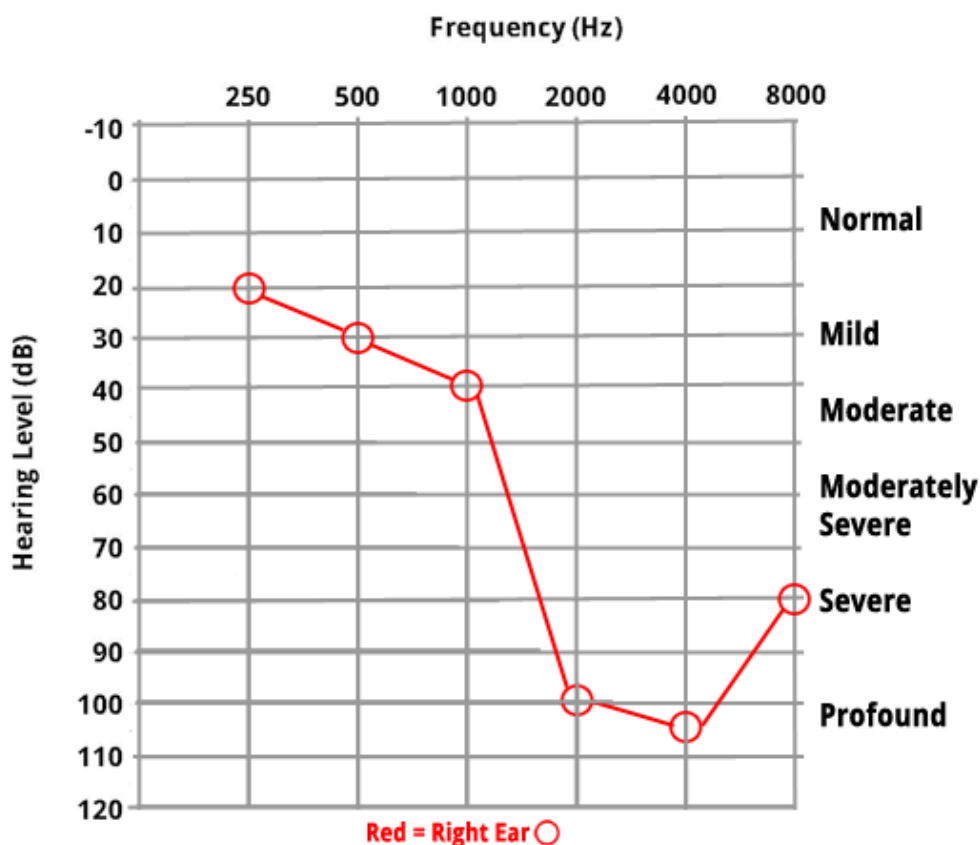


Sensorineural loss is a malfunction of the inner ear. The cause may be genetic, aging, exposure to excessive noise, viral infections, metabolic disturbances, medications, or accident/injury, or a combination. In many cases the cause is unknown, termed idiopathic. Sensorineural loss can be of any degree, is usually irreversible, permanent and not medically or surgically treatable. However future prospects include gene therapy and regeneration via stem cells, along with drugs that can prevent or aid recovery from instances of noise-induced hearing loss such as from loud concerts. Hearing aids and/or implantable devices are appropriate in nearly all cases.

(III) High Frequency Sensorineural Hearing Loss

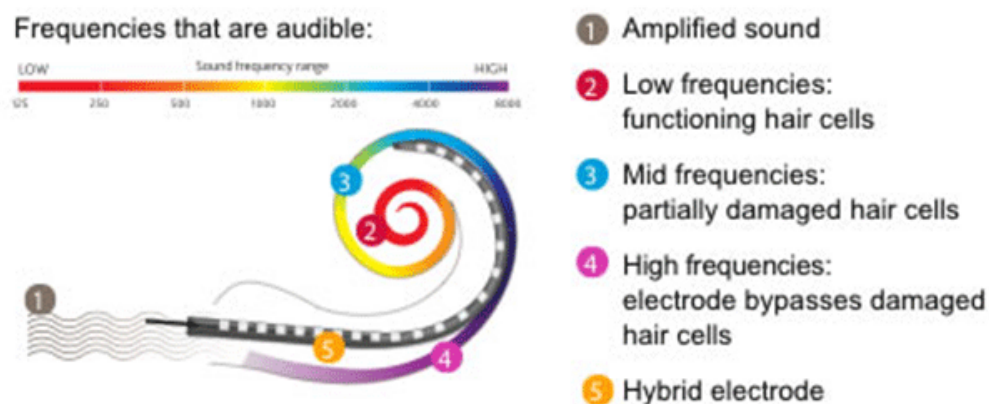
Most audiograms are not fairly flat like the examples above. They can be sloping down or up, or even U-shaped. One subcategory of sensorineural hearing loss is high frequency or “ski-slope” hearing loss; it is classified separately here because a recent device to address this loss has been a special combined hearing aid/cochlear implant.

A typical “ski-slope” audiogram, for an individual with a variable hearing loss that becomes profound at high frequencies, is shown below.



Many words begin and end with high frequency sounds, With high frequency hearing loss, words seem to merge together and become indistinguishable.

Cause of ski-slope hearing loss:

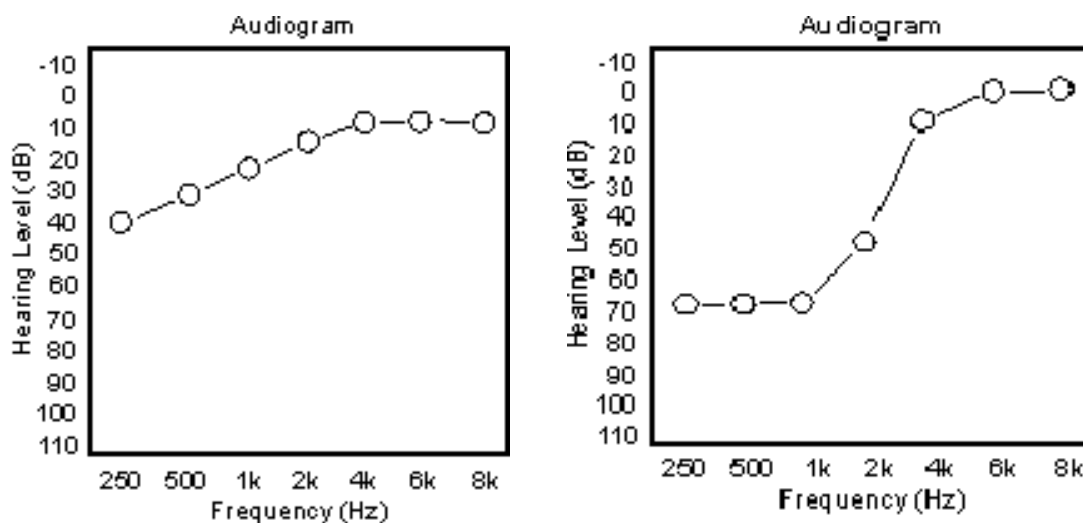


The cochlea diagram above (in the context of an electroacoustic implant) illustrates that low frequency sounds stimulate hair cells deep within the cochlea, whilst high frequencies stimulate those that are close to the entrance. The pitch most easily damaged by loud noises is ~4000Hz because of its proximity to the most intense vibrations. If high frequency hair cells are damaged and non-functioning, the brain will miss out on much of the clarity of words. Speech without the high frequencies is perceived as dull. You could compare it to an image perceived as black and white, as opposed to an image in full colour

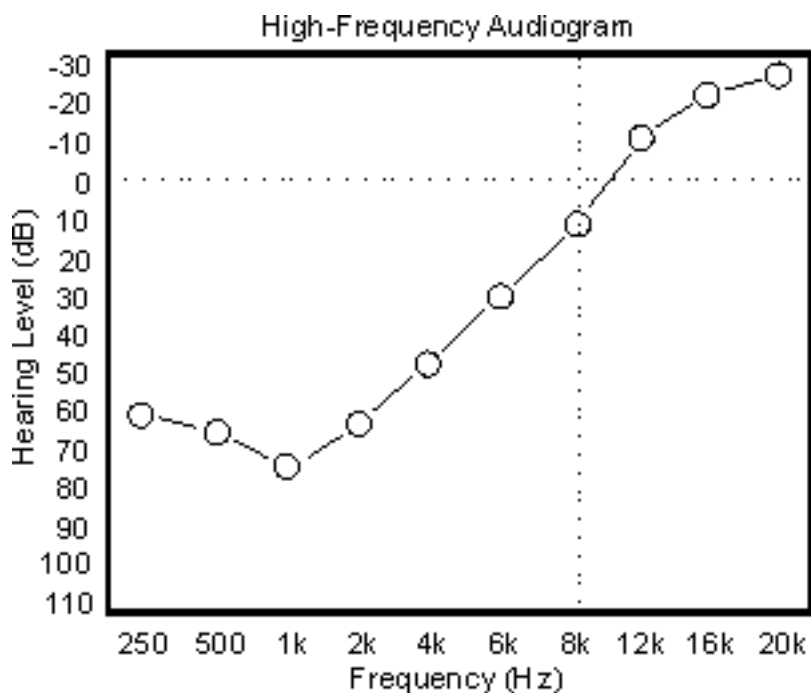
(IV) Low Frequency Sensorineural Hearing Loss

Much less common is hearing loss where the audiogram slopes up to the right. Some such people can't hear thunder rumbling overhead or a car motor running right beside them; yet they can hear a pin drop, or a whisper from across a large room. The most common name is actually reverse-slope (or reverse curve) hearing loss.

Below left to right are example audiograms - mild/moderate to good; moderate/severe to good; and severe to amazingly acute!



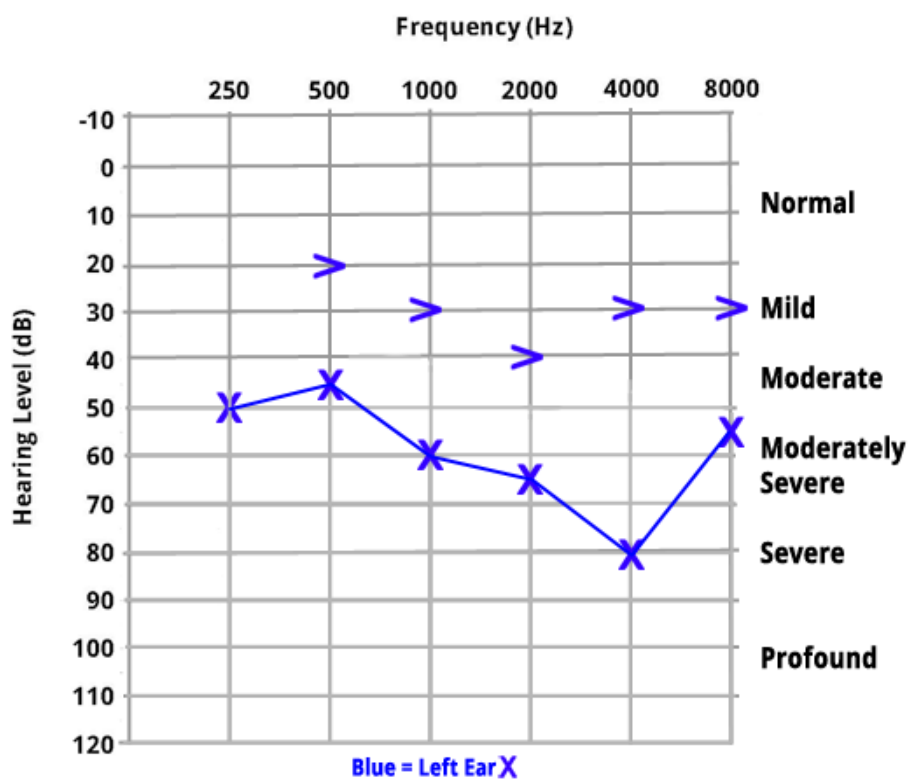
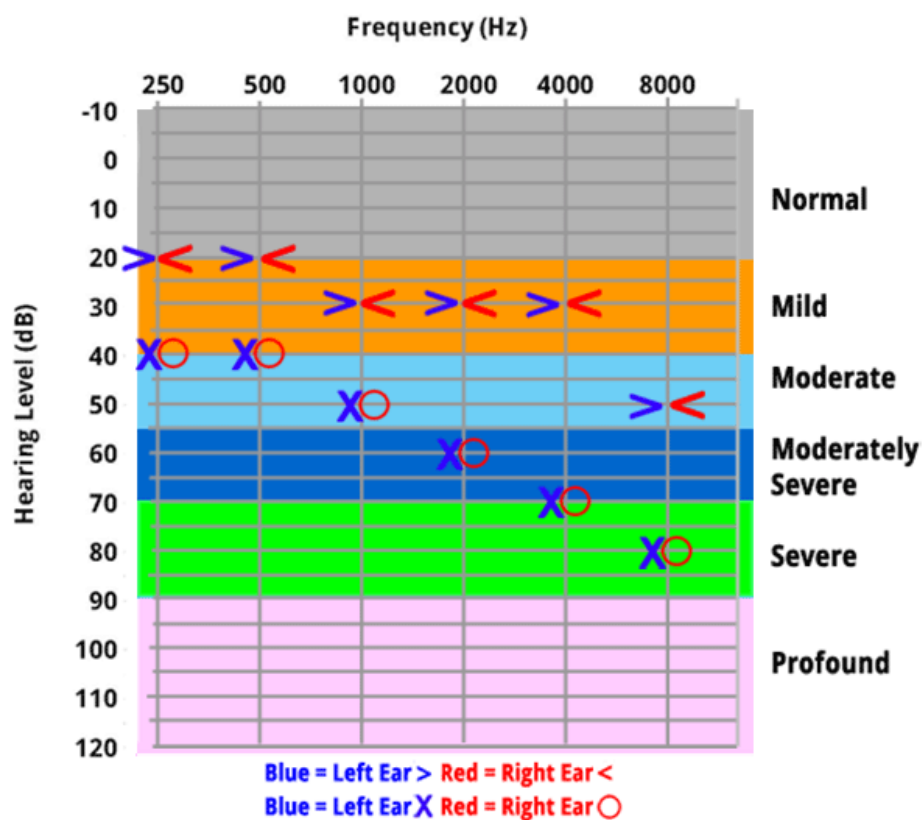
The last (below) belongs to the author (Dr Neil Bauman) of “The Bizarre World of Reverse-Slope Hearing Loss”, Centre for Hearing Loss Help, Jan 2015. He had amazingly acute hearing (-30dB) at 20kHz, where people with “perfect” hearing cannot hear at all. Reverse slope hearing loss is rare, particularly extreme cases like Bauman. The causes are mainly genetic or Menieres disease.



(V) Mixed Hearing Loss, Combinations

Sound can be blocked in multiple places along its path. When a hearing loss occurs from conditions in the outer and/or middle ear as well as the inner ear, this is known as mixed hearing loss. An example of mixed hearing loss may be someone with inner ear hair cell damage due to aging who at the same time has infected fluid in the middle ear due to an upper respiratory infection. The example audiograms below show two of the many variations that are seen.

There are also numerous combinations of mixed hearing loss - right only, left only and bilateral (both ears) mixed losses. (And of course right, left and bilateral conductive; right, left and bilateral sensorineural).



(VI) Neural Hearing Loss

This is another particular type of sensorineural hearing loss which is very rare. Sound enters the outer and middle ears and is processed correctly by the inner ear, but the auditory nerve is not able to transmit the nerve impulses to the brain. One cause is acoustic neuroma, a benign tumor that grows on the vestibular (balance) nerve and then presses against the auditory nerve. Ways of testing for neural hearing loss are the acoustic reflex, auditory brainstem response and MRI scans. Neural hearing loss usually results in a greater loss of speech discrimination than occurs with sensory hearing loss.

Because damaged nerve fibres aren't able to repair or regenerate themselves like some other parts of the body can, this type of hearing damage is currently permanent. Gene therapy and stem cells may however have long-term promise in this regard.

Recently-recognised conditions CAPD (Central Auditory Processing Disorder) and ANSD (Auditory Neuropathy Spectrum Disorder) also seem to derive from problems in the neural pathway, but not as defined or as severe as acoustic neuromas. CAPD is an umbrella term for a variety of disorders that result in a breakdown in the hearing process. The brain cannot fully understand the information contained in sound, although conventional hearing tests may well be "normal". Because the auditory signal is distorted in some way, the biggest problems experienced by individuals with CAPD is difficulty listening in background noise, and working out what direction certain sounds are coming from. CAPD is said to affect about two to five percent of children.

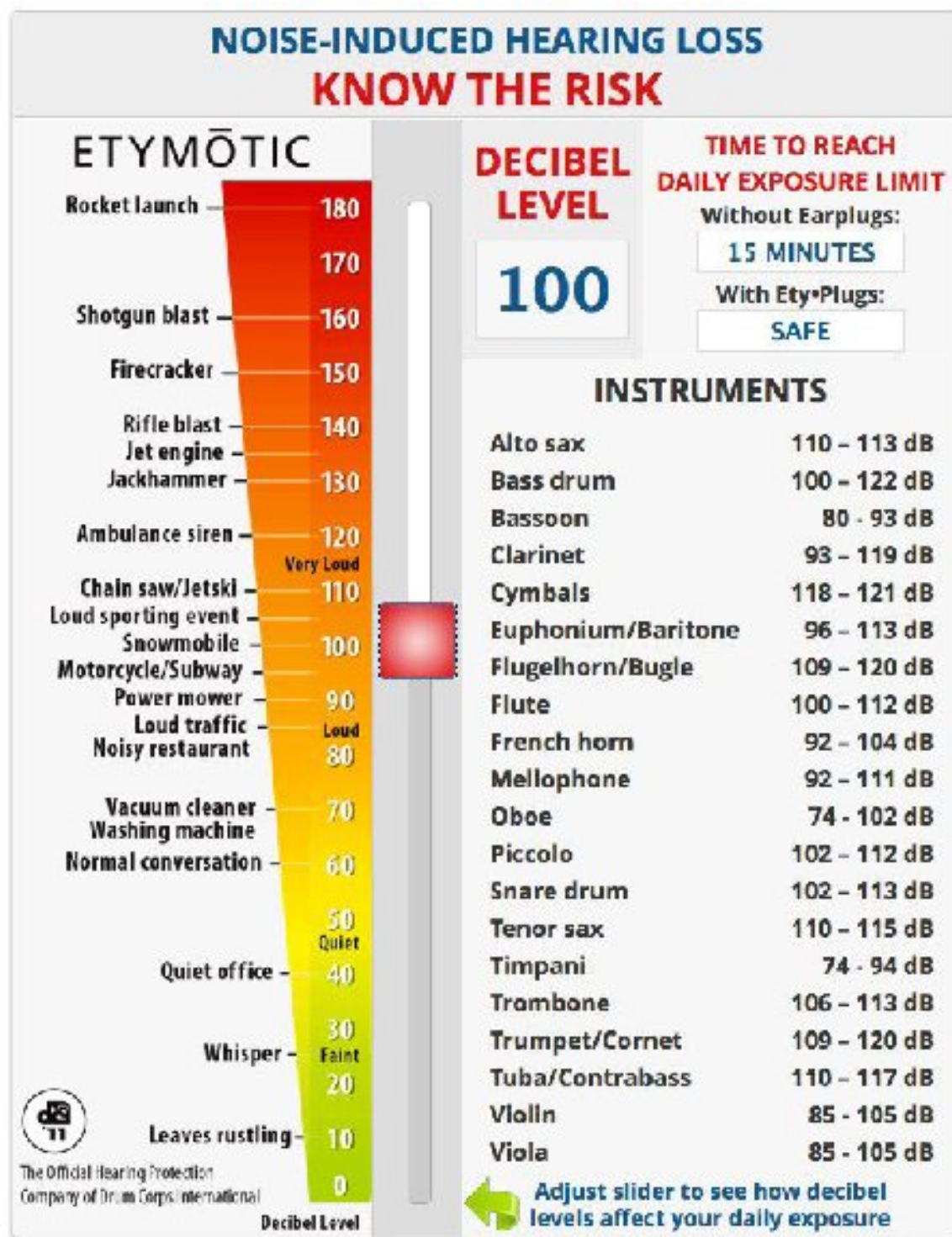
ANSD involves nerve dysfunction, commonly disruption of the timing of the electrical impulses. This results in distortion of sound and listeners often report that they "can hear but can't understand what is being said to them". Again listening in background noise is particularly affected. Localisation skills, the ability to judge where sounds are coming from, may also be affected. The most common form of AN is present from birth and occurs as a result of trauma. Babies with breathing problems and/or severe jaundice are particularly at risk. Progressive forms of AN also exist, often related to generalised neurologic diseases.

Diagnosing AN can initially be challenging, as people with the condition can have perfectly normal detection of sound. Tests that measure the function of the nerve and auditory pathways are required. These assessments are carried out routinely in babies, as part of Universal Newborn Hearing Screening programs, but are not standard in adult hearing tests.

Researchers in binaural auditory processing have studied "hidden" hearing loss in individuals whose standard audiograms reveal normal or close to normal hearing. Small neural losses for each individual ear can show only slight or even no measurable changes in audiograms, yet still produce a deficiency in the binaural auditory system. The brain compares what's going on in the left and right ear from a series of neural connections it receives from both. If anything diminishes the temporal precision of this system, it shows up in tests of the binaural system. Such testing is under development.

5. SOLUTION OPTIONS – LIMITATION and PREVENTION

The most preventable hearing damage is noise-induced hearing loss. Not unlike sun exposure, sunburn and skin cancer, exposure to loud and/or prolonged noise damages hearing and leads to cumulative and permanent degrees of hearing loss, as illustrated below:



Many Australians are regularly exposed to high levels of noise in nightclubs, pubs, music concerts and personal stereos.

The initial 'solution' to hearing loss is **Prevention and Limitation**. If you need to raise your voice or shout in order to be understood in background noise, then that noise is too loud. If you are listening to an audio device with personal earphones and do not hear people speaking, then that music is too loud. If your ears "ring" after being in noise, then that noise was damaging. Babies are very vulnerable; some baby toys can create extremely loud noises and this problem should not be overlooked or underestimated.

The prevention and limitation solution has the mnemonic CAT – Cover your ears, Avoid the noise or Turn it down. If you attend discos, pop concerts, car or motorbike races or fireworks displays, take correctly-fitting earplugs. Wear them when using or being close to mowers, blowers, mulchers, chainsaws, grinders, pneumatic hammers etc. Electronic hearing protection devices are available with Noise Reduction Ratios from 20 to 32dB. With peak clipping technology, when an unsafe sound is detected, the unit clips the sound. Compression technology takes an unsafe sound and reduces it to a safe level.

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EAR PLUGS

Many types are available from soft, coated foam for long hours of use to musicians custom made to allow quiet sounds in while dampening only loud music. **EAR PLUGS MUST BE FITTED CORRECTLY TO BE EFFECTIVE**

PEOPLE MUST BE NOT ONLY SHOWN HOW TO INSERT THEM, BUT BE OBSERVED TO INSERT THEM INTO THEIR OWN EARS CORRECTLY. This also means the users must understand how to maintain clean ear canals so as not to push in clumps of wax. Also it is important to know when to wear plugs and when to use muffs.

6. SOLUTION OPTIONS – HEARING AIDS

- (I) Behind the Ear (BTE)
- (II) In the Ear (ITE) to Completely In the Canal (CIC)
- (III) Receiver in the Ear (RITE)
- (IV) Contra-lateral Routing of Sound (CROS)
- (V) Spectacle Style
- (VI) Bone Conduction Types

The BTE, with earpiece or tube in the ear, is the most common style and is generally the most powerful, with a larger battery, more robust construction, easiest to use controls, and ideal for children.

ITE and CIC are smaller to very small one piece aids. RITE types are intermediate, with some of the electronics behind the ear and some inside the ear. CROS hearing aids can work for people who are deaf in one ear and have normal or near normal hearing in the other ear. The person wears what looks like two hearing aids in one of two styles—either BTE or a larger ITE type.

The spectacle style is still available from some suppliers, but its use has declined due to improved technologies in BTE and other styles. The bone-conduction category is specifically to overcome conductive hearing loss. Amplified sound is delivered to a vibrator which transmits through the bones in the skull, generally through the mastoid bone behind the ear. The sound thus bypasses any problem in the outer or middle ear. The output of bone conduction hearing aids is restricted compared to the air conduction hearing aids, particularly the more powerful BTE category.

Many people do not like CROS or bone conduction devices. Variations like the Soundbite - a removable dental insert that works with a small BTE microphone and transmitter to conduct sound through the teeth and jawbone - have not been particularly successful. Bone-anchored implants (next section) have had more impact.

Comprehensive and independent reviews of hearing aids are now available at both the overview level and the detailed specification level:

The Consumers Guide to Hearing Aids - The World's Independent Source 22nd Annual Edition 2017

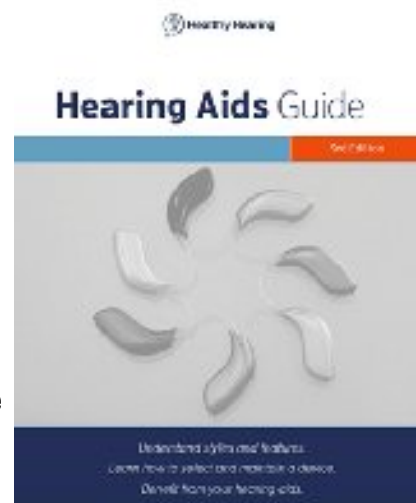


January 2018

Cooling is an Irish hearing aid blogger and has been involved with the hearing aid industry for over ten years.



Healthy Hearing (right) publishes a US Guide while the UK Guide above is from the Hearing & Mobility chain. Another example is Consumer Reports (consumer.reports.org) Hearing Aid Buyers Guide.



The state of the art for modern hearing aids, reflecting established technological advances, is categorised below. Most of this also applies to the sound processor component of implantable devices and so is implicit in Sections 7 to 11. This state of the art also leads into Section 12, covering the latest advances in consumer electronics and digital telecommunications that continue to be applied to hearing solutions.

The four basic parts - a microphone, a processor, a receiver and a power source - remain the same. The microphone picks up the sounds in the environment and passes it to the processor. The processor enhances the signal and delivers it to the receiver which sends the amplified signal to the ear canal. The power source - battery - drives the system.

The digital age has transformed these basic parts into four very sophisticated components. Digital instruments can perform multiple sound processing and management tasks efficiently and simultaneously. Automatic sound processing amplifies speech while reducing unwanted noise. Soft sounds are given more amplification, while very loud sounds are given little or no amplification. There is no need for external volume control wheels and the hands-free operation is simple and comfortable.

The same applies to implantable devices, where the sound processor components reflect similar features and advances to hearing aids. Variation in the electrical stimulation across the electrodes of an implanted component is equivalent to the differential amplification of hearing aids across the frequency range.

Hearing aid technology can be considered either basic or advanced, based on the sophistication of the processor. Basic digital hearing aids generally require the wearer to make some manual adjustments in certain listening situations; they may be computer programmable, but will have fewer or more limited adjustments available for fine tuning and customisation. As the level increases, hearing aids become more automatic and have more features to help in difficult listening situations. For example, there may be eight or more channels instead of two channels. This splits the signal into smaller frequency bands, providing a higher resolution of signal processing and flexibility in programming the frequency response to match the hearing loss profile. It also allows for multiple listening programs – different (customised) programs for specific listening situations including hearing in noisy situations, listening on the telephone, or to music.

A similar situation again applies to implantable devices, except there is no basic category!

Specifics follow:

Directional microphone systems are designed to give a boost to sounds coming from the front of the wearer and reduce sounds coming from other directions. Basic systems provide fixed directionality. Advanced MultiBand Adaptive Directionality systems work automatically and reduce the interference from multiple noise sources simultaneously, even if they are moving. This can significantly reduce the background noise to improve speech understanding.

Digital noise reduction systems analyse the signal, make the background or environmental noise less annoying and increase listening comfort. MultiBand Adaptive Noise management selectively reduces the volume in frequency regions where there is background noise and works together with the directionality system to reduce sudden, dominant noise without affecting speech.

Impulse noise reduction detects any transient loud noises, such as car keys rattling, typing on a keyboard or dishes rattling, and softens them.

Wind Reduction A particular problem outdoors is the wind. Wind noise reduction is an advanced technology that detects wind blowing across the microphones and avoids or reduces the amplification of it. Although fairly specific in its application, wind noise reduction can make a world of difference for those who spend time outdoors, like walkers, golfers, boaters, climbers etc.

Feedback management systems combat the whistling from feedback loops create an annoying whistling sound. Feedback management algorithms can be basic or advanced (Dynamic Feedback Cancellation), the latter able to reduce or eliminate whistling without affecting overall amplification.

Telecoil is a long-established wireless feature that picks up electromagnetic signals from compatible telephones or looped rooms. Because the signal of interest is directed to the sound processor without using the microphone, telecoil can improve the signal to noise ratio. Public performances, tours, exhibits and worship services are commonly made accessible via telecoil.

FM compatibility Frequency modulation (FM) compatibility is the general wireless feature that enables hearing aids to connect with FM systems. Like telecoil, FM systems improve the signal to noise ratio. FM compatibility is especially important in educational settings to ensure that the teacher's voice is heard clearly.

Bluetooth Connectivity allows connection to computers, TV and audio devices and more recently to smart phones. The audio can be streamed directly into the ear through the hearing device, without distortion or interference. Bluetooth interfaces can be added to non-Bluetooth devices such as landline phones.

Binaural processing means a pair of hearing devices communicates wirelessly via Bluetooth connectivity with each other. This mimics the brain's ability to process information coming from both ears and is most commonly used to keep the devices operating synchronously (such as switching from program 1 to 2 at the same time) or to stream auditory signals from one to the other.

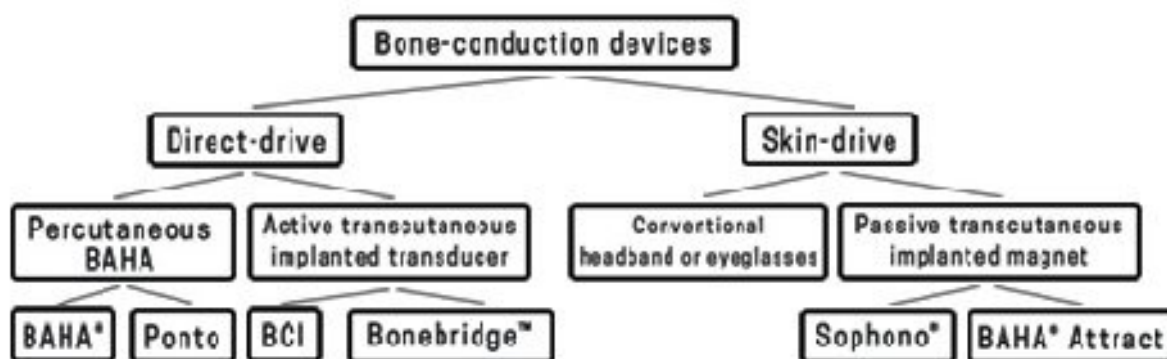
Data logging/Learning is a feature that stores data about the listening environments and wearer adjustments for programs, volume levels and other features. The information can be accessed by the hearing professional who can will use it to optimise the settings for the user, so that adjustments become more automatic. The ability to scan the sound environment and detect the presence of eg speech, background noise and wind noise may be used to change settings in the hearing device, such as the Adaptive Directionality and Noise Reduction. So hearing devices can automatically adjust to all kinds of soundscapes, such as a staff meeting, a crowded restaurant, or the chirp of cicadas or crickets on a late summer's evening.

Moisture Resistance Most hearing devices are now more water resistant and/or have accessories that allow them to be submerged. This feature particularly suits people who work in demanding environments, as well as those with active lifestyles—like swimmers, skiers, and sports enthusiasts.

Bluetooth connectivity is ongoing and the integration with mobile phones is so important and (especially for cochlear and other implants) so recent, that it is covered in detail in Section 12.

7. SOLUTION OPTIONS - BONE CONDUCTION DEVICES

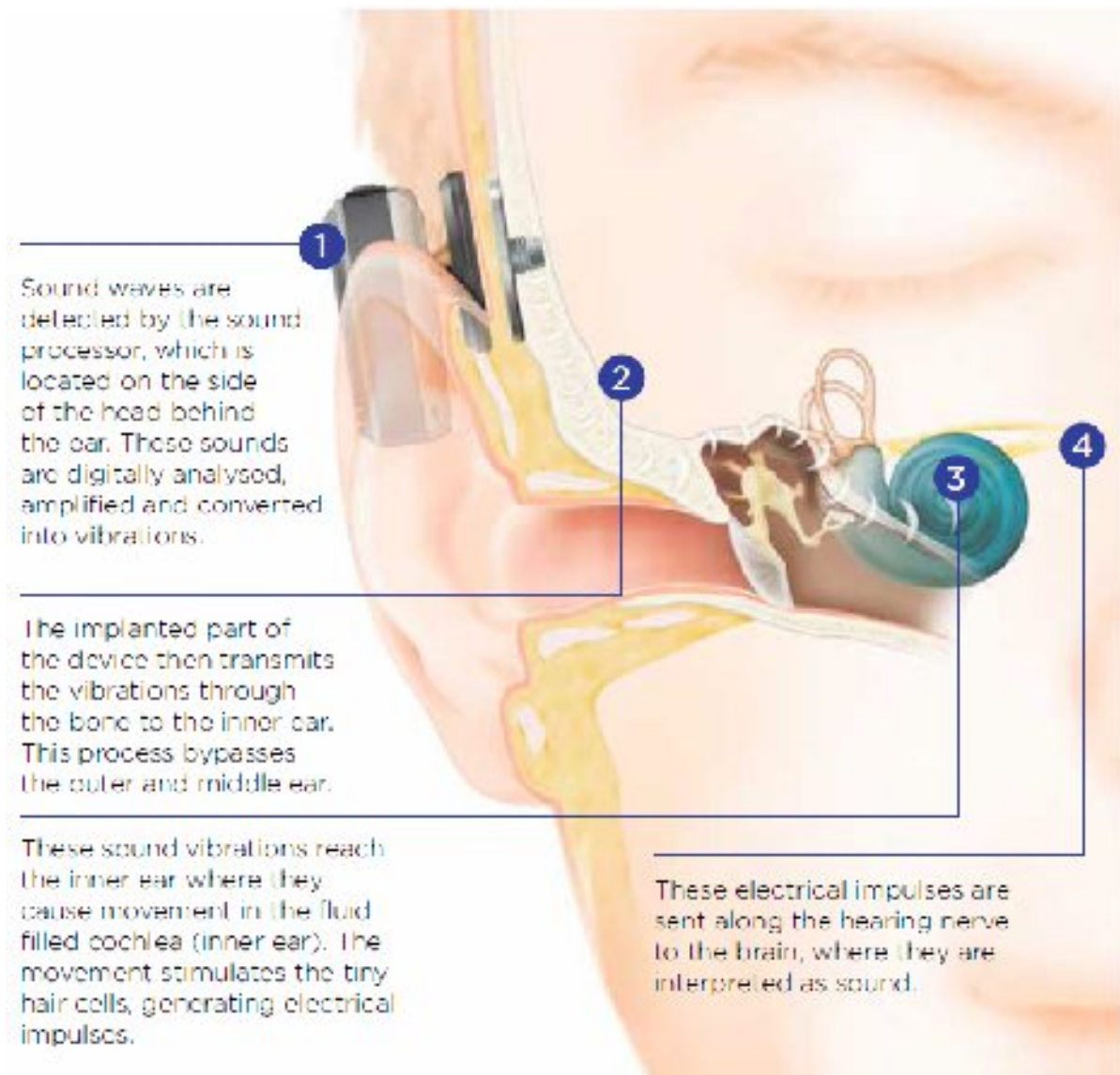
Like bone conduction hearing aids, these devices bypass impairments in the outer and middle ear. They involve converting sound waves into mechanical vibrations. There are two categories - those where vibration is through the skin and those where vibration is direct to the bone. Further subdivision can be into direct/active drive to the bone itself or passive drive through the skin, which may be intact (transcutaneous system) or surgically penetrated (percutaneous system).



The mechanism for a direct drive percutaneous device is illustrated below.

The diagram shows a device in an ear with conductive hearing loss.

So like bone conduction hearing aids, bone conduction implants address unilateral/bilateral conductive and mixed hearing loss, mild to moderately severe, arising from outer ear malformations, infections and discharges. The advantages over the conventional bone conduction hearing aids include improved appearance and comfort, and ability to assist conductive losses even when higher degrees of sensorineural loss are also present. Recipients have reported improved clarity of hearing in both quiet and noisy situations.



There are several bone-anchored devices available in Australia. The percutaneous type has a titanium screw placed in the mastoid bone with a skin-penetrating abutment.



Once this has settled (osseointegration), an external sound transducer is attached to the abutment. The Cochlear Baha Connect (left) and the Oticon Ponto (right) are shown below:



It was clear that directly stimulating the bone is more effective than stimulating through the skin. Percutaneous bone-anchored hearing aids (BAHA) were thus an important solution option that expanded over time to patients with unilateral hearing losses, both conductive and sensorineural. Cochlear's BAHA is thus a surgically implanted version of the CROS aid. Most people with unilateral hearing loss are enthusiastic about BAHA because it works very well and it is unobtrusive. Readers should note that the term Baha is often used to mean Bone- Anchored Hearing Aids generally and historically reflects the brand name of the Cochlear implanted device. The more general term BAHD is used here where appropriate.

People with normal hearing use timing differences between the ears to localise sound. This is not available in the BAHA because all sound ends up going to the good ear. The Ponto hearing implant by Oticon is a similar device that competes directly with the BAHA. There are models with different amplification power -the Ponto Plus and Ponto Plus Power - giving 45dB and 55dB respectively.

Despite being more commonly accepted than the conventional air conduction aids, BAHD do have a visible abutment, which can be associated with a proportion of soft tissue reactions or fixture failures as well as cosmetic issues. Different abutment shapes and lengths and Cochlear's hydroxyapatite coated abutment now minimise complications.

The more recent transcutaneous type has no skin-penetrating abutment, rather the external transducer is held by magnetic attraction to the implant under the skin. The vibrations are transmitted through the soft tissue, exemplified by the Cochlear Baha Attract (left) and the Medtronic Sophono Alpha (right)



The latter is a semi implantable system that relies on magnetic coupling between implanted and external magnets. Its output is 10-15dB lower than the percutaneous BAHD. The Sophono device provides about 45 dB of amplification at 2000Hz ranging to almost no amplification at 8000Hz, so it performs best at speech frequencies, but does not produce a “full spectrum” of sound. It is suited to less severe hearing loss than either the Baha Connect or the Ponto, but it is without the “stud”, making it cosmetically preferable as well as requiring less skin care to prevent infection. The Baha Attract, also by Cochlear, is similar - it has an implantable magnet that is attached to an osseointegrated titanium fixture. An external magnet is then coupled via the scalp.

Medel recently released a simple passive transcutaneous device - the AdHear - that uses an adhesive adaptor to couple the audio processor to the ear. It is gentle and suited to young children. The single-use adhesive can be worn for 3 to 7 days and is water-resistant during bathing, showering and other water-related activities.



Cochlear have also recently released a passive transcutaneous device aimed at children. This BAHA Sound Arc actually harks back to the original bone conduction hearing aid styles. Along with the Baha Softband, the Sound Arc is a first step in providing hearing to a child too young (under the age of five) or not yet ready for the bone conduction implant. It aims to help children with conductive hearing loss, mixed hearing loss or single-sided sensorineural deafness (SSD) get hearing performance and amplification to facilitate language development. As a child grows, it is natural to progress from a non-surgical hearing loss solution to an implantable solution.



- 1. Soft silicone tips and grips - provide a comfortable fit
- 2. Steel spring band - designed to fit most shapes and sizes
- 3. SoftWear Pad – for improved comfort and sound transmission
- 4. Baha 5 Sound Processor

In the case of adults with conductive hearing loss, mixed hearing loss, or SSD the Baha SoundArc can be used as a trial device to demonstrate how the Baha Sound Processor might sound before deciding on a Baha Implant System. The Ponto can also be simulated using headbands. Simulators look somewhat like headphones, but the sound is transmitted through the bone on the bad side.

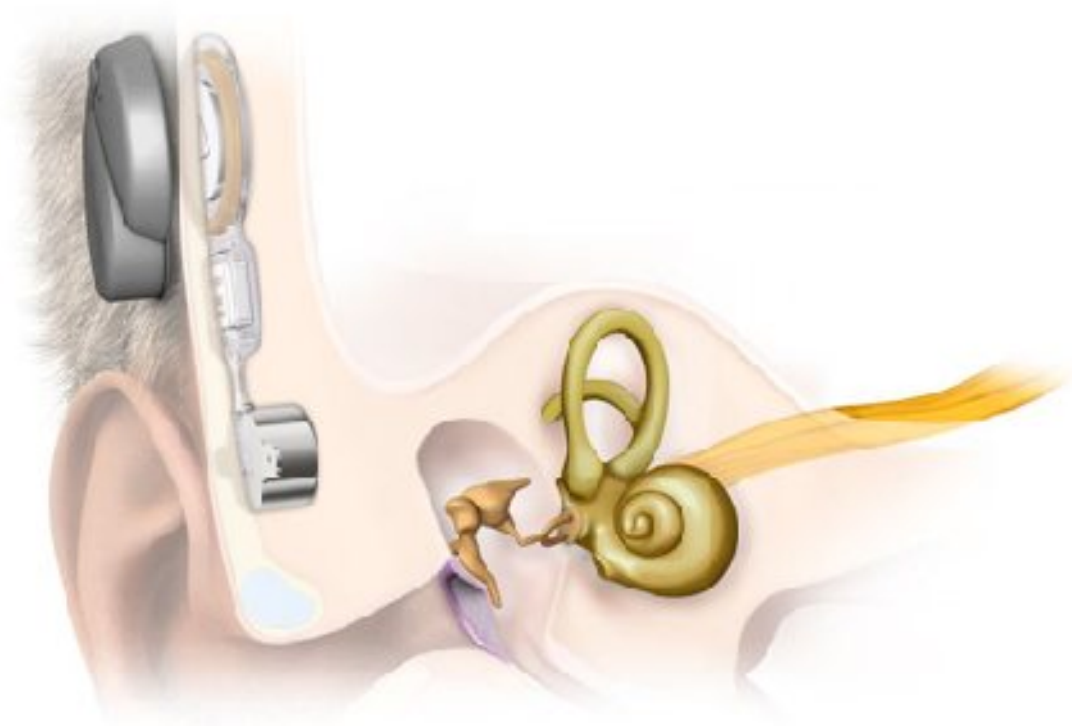
The Medel Bonebridge is a different transcutaneous device where the transducer (below, first image) is also implanted, allowing for a smaller external processor (below, second image).



The implantable floating mass transducer (FMT) is retained in the mastoid temporal bone by two screws. The external sound processor is coupled to internal magnets.



With nearly 20 years of experience with implantable FMTs, Med-EL offers power efficiency, high quality and long-term reliability.



Theoretically, this approach should reduce the dampening effect of the other transcutaneous devices. On the other hand the larger size of the implant component (left) requires adequate thickness of mastoid bone and may have higher risks of minor adverse effects - pain, tinnitus, skin infection.

A final point is that transcutaneous devices may be a relative contraindication in patients that require regular magnetic resonance imaging (MRI). A maximum of 3-Tesla scanners can be used with the Sophono™, and 1.5-Tesla scanners with the Baha Attract and the Bonebridge. If more detailed images are required then the magnet needs to be removed prior to imaging. As the devices are significantly larger than the percutaneous systems, a large artefact (up to 10 cm) can be seen on imaging. The titanium stud of the classic percutaneous BAHA device does not have any MRI issue, as it is not magnetic. Baha and Ponto Pro osseointegrated implants -- abutment and fixture are safe (up to 3-T) The implanted magnet of the Sophono Alpha 1 and 2 abutment-free systems are approved for 3-Tesla magnetic resonance (MR) systems.

8. SOLUTION OPTIONS - MIDDLE EAR IMPLANTS

These comprise a sound processor and an implant with electrical lead to a very small transducer that is attached to the middle ear structures by surgical techniques called Vibroplasty. In a similar way to bone conduction hearing devices, sound causes vibration, in this case to one of the ossicles, such that normal movement of these tiny bones is restored or amplified, and sound is then transmitted naturally to the inner ear.

A middle ear implant system is another alternative to conventional hearing aids. It is suitable for people with mild to moderately severe hearing losses whether conductive, sensorineural or mixed. For conductive or mixed loss, it is also an alternative to bone-anchored devices. While there are no speakers or ear moulds, the surgery and implant system is more complex and expensive than hearing aids. Recipients may be those not able to use hearing aids for medical reasons or who are dissatisfied with them.



The Medel Vibrant Soundbridge is the longest established (>20 years) and was recently approved for use with children three years and older; its placement is independent of skull growth. The implant (pictured above) is placed underneath the skin and contains a magnet to hold the audio processor over the implant. The key component distinguishing from other implantable devices is the Floating Mass Transducer (FMT) which is the little ball at the end of the wire. The FMT is the active component of the internal vibrating ossicular prosthesis and was originally intended to be clipped to the incus in an intact ossicular chain. More recently, coupling the FMT to the round window has expanded the audiological indications to include conductive and mixed hearing losses. The round window technique (VSB-RW) involves placing the FMT onto the round window membrane after cutting off the titanium clip and widening the round window niche.



Middle ear implant with round window application Medel Blog

The audio processor is attached to the head with a magnet and can be worn discreetly under the hair. It comprises the battery, microphone and electronics. The Samba is Med-El's latest and is the same as in its Bonebridge and other implants.

The first three steps in the process:

1. Sounds are picked up by the microphone of the audio processor
2. The audio processor converts environmental sounds into electrical signals
3. The electrical signals are transmitted across the skin to the implanted part are the same as for cochlear and bone conduction implants, but the next three steps differ:
4. The implant relays the signal down to the FMT
5. The FMT converts the signal into mechanical vibrations that directly stimulate a middle ear structure causing it to vibrate. This direct drive stimulation does not involve the ear canal.
6. These vibrations then conduct sound to the inner ear where they are passed on to the brain and are perceived as sound

There are two other middle ear devices, which are fully implantable. The Carina, developed by Otologics and now owned by Cochlear, is in its fourth generation. The processor is also implanted; there is nothing visible outside the ear. It can be placed in candidates as young as 14 years old.



It is used in Europe, Asia and Latin America. Some ten devices that have been given to British patients so far. 'With this device, people can go swimming or take a shower without having to remove anything. A hand-held remote control enables users to turn the Carina on and off as well as control the volume. The only other piece of external equipment is a small charger which connects wirelessly. The Carina requires just 30 minutes of charging daily.

The other fully implantable middle-ear implant is the Envoy Esteem implant, which has been available in the U.S. for about 10 years now. It is for bilateral sensorineural hearing loss at speech discrimination levels greater than 50%. The Esteem is an amplification system, analogous to conventional hearing aids, though entirely implanted. Unlike other middle-ear implants, which are based on electromagnetic stimulation, this is based on piezoelectric stimulation. The entire device is embedded. It uses no speaker or artificial microphone, no external components, and requires nothing in the ear canal. The Esteem is invisible, can be used 24 hours a day, 7 days a week. It enables a person to swim, shower, or exercise without worry of damage or discomfort. It is waterproof and safe for diving down to a depth of 10 metres. It requires no daily maintenance. The battery lasts between four-and-a-half to nine years. When it runs out, one has to remove the whole processing unit, which contains the battery.

Audiologist Comment 11

NEW DEVICES

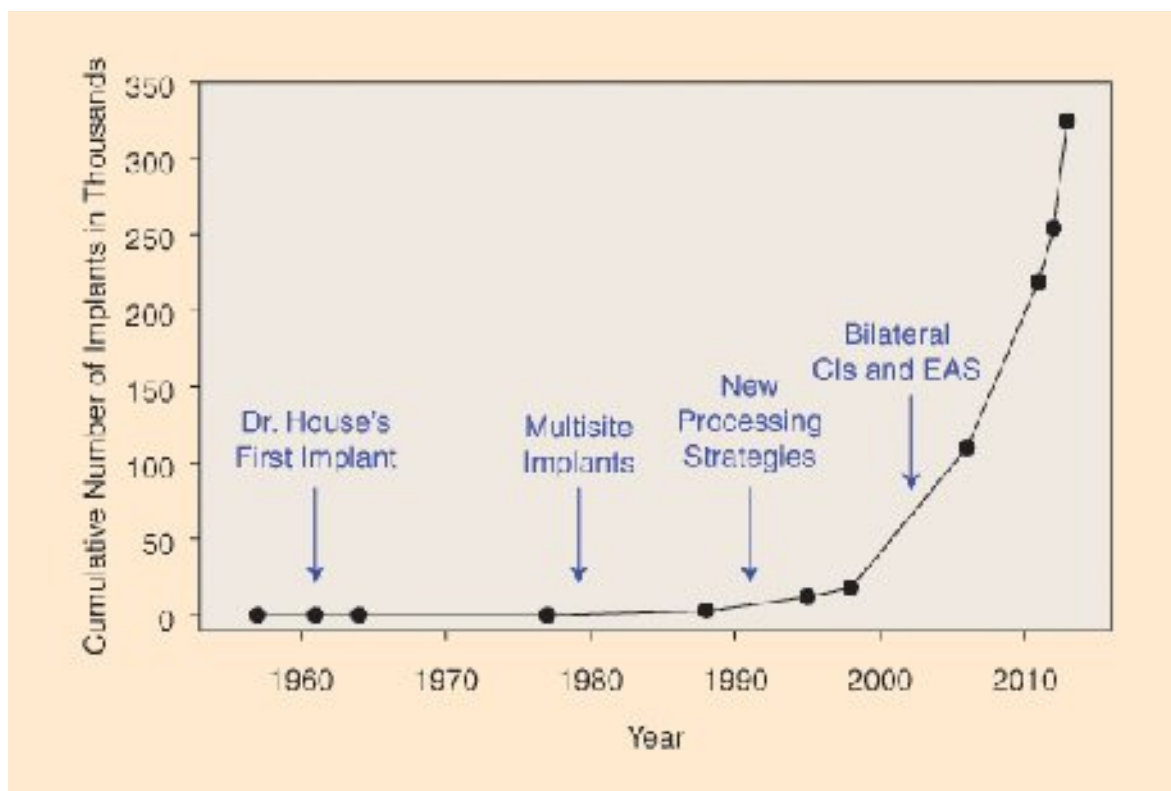
Middle Ear Implants are relatively new compared to Cochlear Implants and certainly hearing aids. They do not yet have track records to reveal performance and any risks for using them long-term. A few audiologists comment that attaching anything to middle ear bones adds weight to an already minute and fragile chain of bones.

9. SOLUTION OPTIONS - COCHLEAR IMPLANTS

Most people today have only heard of one kind of device which is surgically implanted into the skull to improve hearing - the cochlear implant (CI). Even for the CI there is little awareness that:

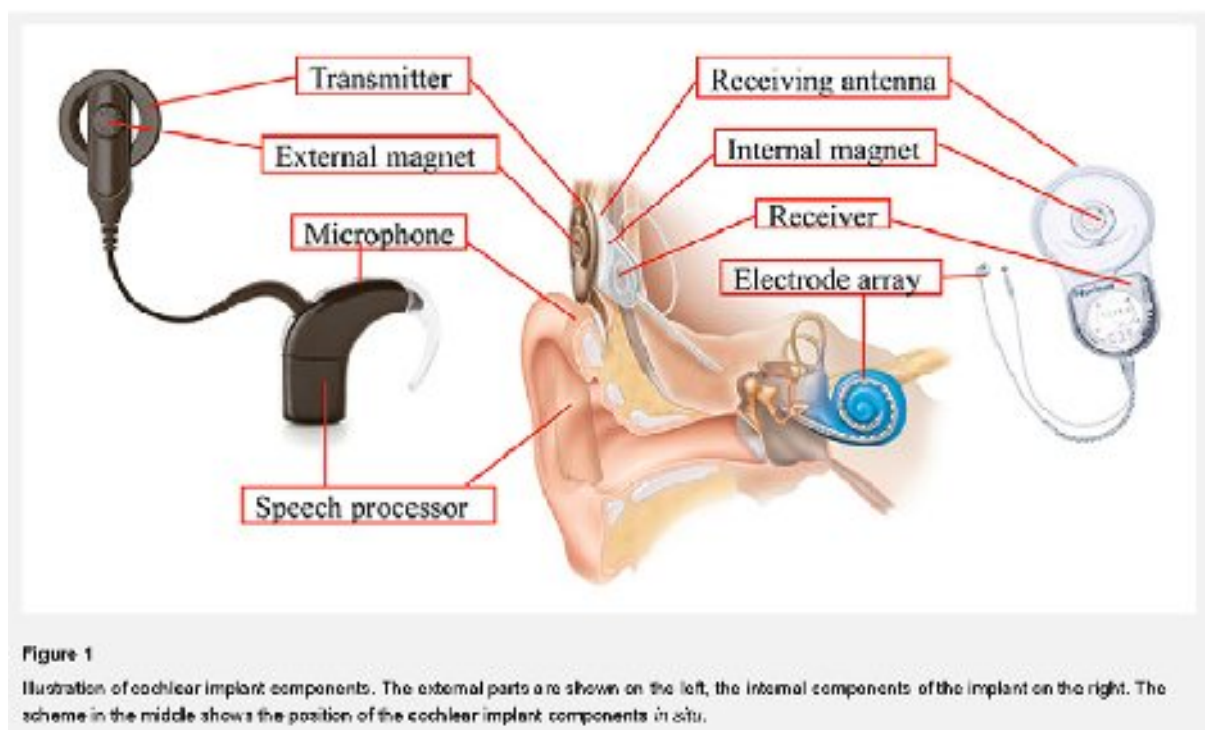
- CIs have been commercially available for 30 years
- CIs are well-established and long-accepted worldwide
- newborn screening, early implantation and auditory-verbal therapy (AVT) are becoming standard
- educational and social outcomes for children born even profoundly deaf are now commonly similar to those for their hearing peers if they get a CI early
- CIs mean special schools for deaf children are becoming redundant
- some in the signing Deaf community oppose CIs as “cultural genocide” because they see a major generational threat to their way of life.

The historical developments are illustrated below. An exponential fit to the data has a correlation higher than 0.99. If that exponential growth continues as expected, a million people will have received a CI or bilateral CIs by early 2020.



The basics common to all CIs : An external BTE Sound processor with transmission coil is held against an implanted receiver from which a flexible multi-electrode array is led to the inner ear where it coils into the cochlea. CIs have the following parts:

1. A microphone, which picks up sound from the environment
2. A speech processor, which selects and arranges sounds picked up by the microphone
3. A transmitter and receiver, which receive signals from the speech processor and convert them into electric impulses
4. An electrode array, which is a group of electrodes that collects the impulses from the stimulator and sends them to different regions of the auditory nerve.



The microphone, speech processor and transmitter (coil) are external components. The receiver is surgically embedded into the skull, and the electrode array is inserted into the cochlea.

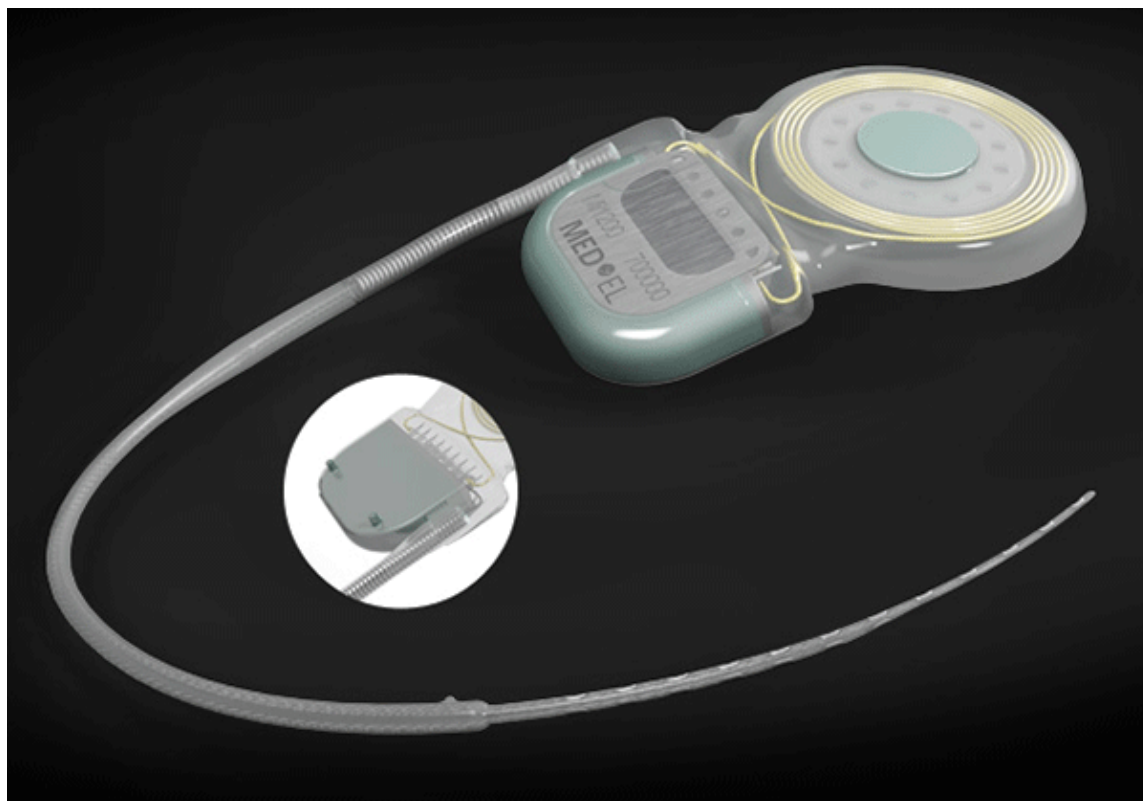
Cochlear, MedEl, Advanced Bionics (now part of the Sonnova group which includes Phonak) and Oticon (who took over Neurelec) are the main suppliers, with Cochlear (whose HQ is in Australia), having 70% of the world market. It has recently been reported that Nurotron, licensing technology from the University of California, is capturing much of the government tenders in China.

Illustrations of the latest implantable components from the four manufacturers follow:

Cochlear C1522



Medel Synchrony



AB Hi Res Ultra



The equivalent latest Sound Processors are Cochlear's Nucleus N7; Medel's Sonnet and AB's Naida series in BTE style.

Cochlear Nucleus 7 Sound Processor

Cochlear™ Nucleus® 7 Sound Processor



Medel's Sonnet

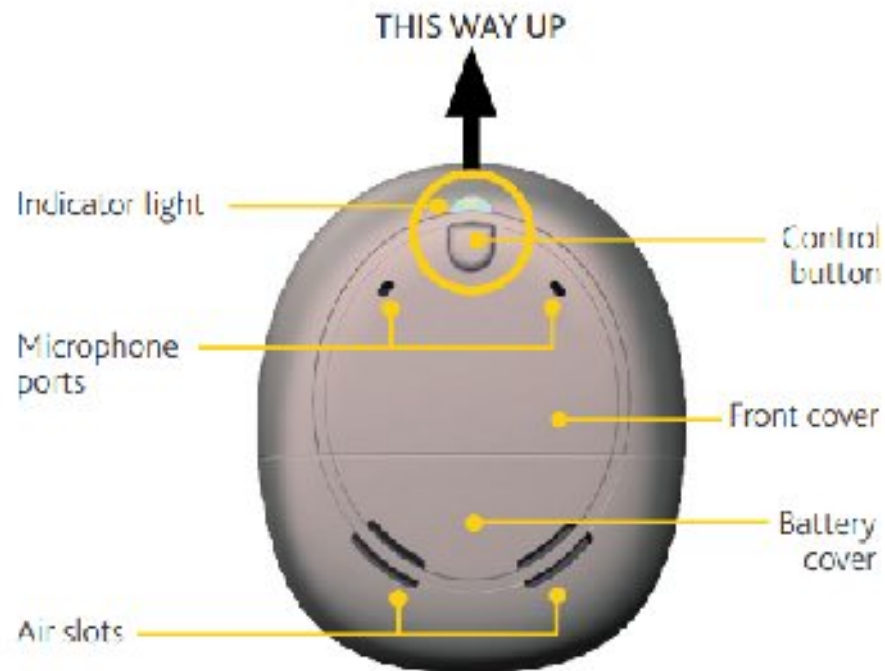


AB's Naida

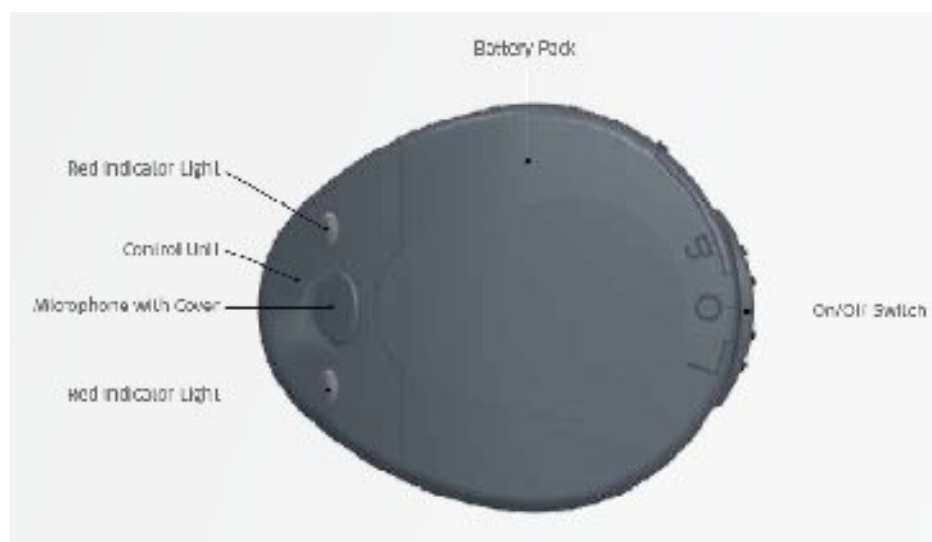


Followed by the all-in-one sound processors where everything is combined into a cable-free, compact and single-unit: Kanso (Cochlear); Rondo (Medel). It is worn on the ear against the implanted magnet, so is especially convenient for individuals who wear glasses.

Kanso



Rondo



10. SOLUTION OPTIONS - ELECTROACOUSTIC DEVICES (HYBRID HEARING AID and COCHLEAR IMPLANT)

This is essentially an integration of the features of a hearing aid into a cochlear implant. The BTE component is both a sound processor and amplifier, and it has both transmission coil and earmould connections. The implant component has a shorter electrode array, since it does not penetrate as far into the cochlea because its function is to stimulate the high frequency end only. The acoustic amplification acts on the inner hair cells, which are still functional and are not exposed to the small risk of damage that a full length electrode array insertion might entail.



Slim straight array for cochlear implants (left) and Hybrid L array (right).

New Cochlear Hybrid Hearing - Combining the Best of Both technologies.

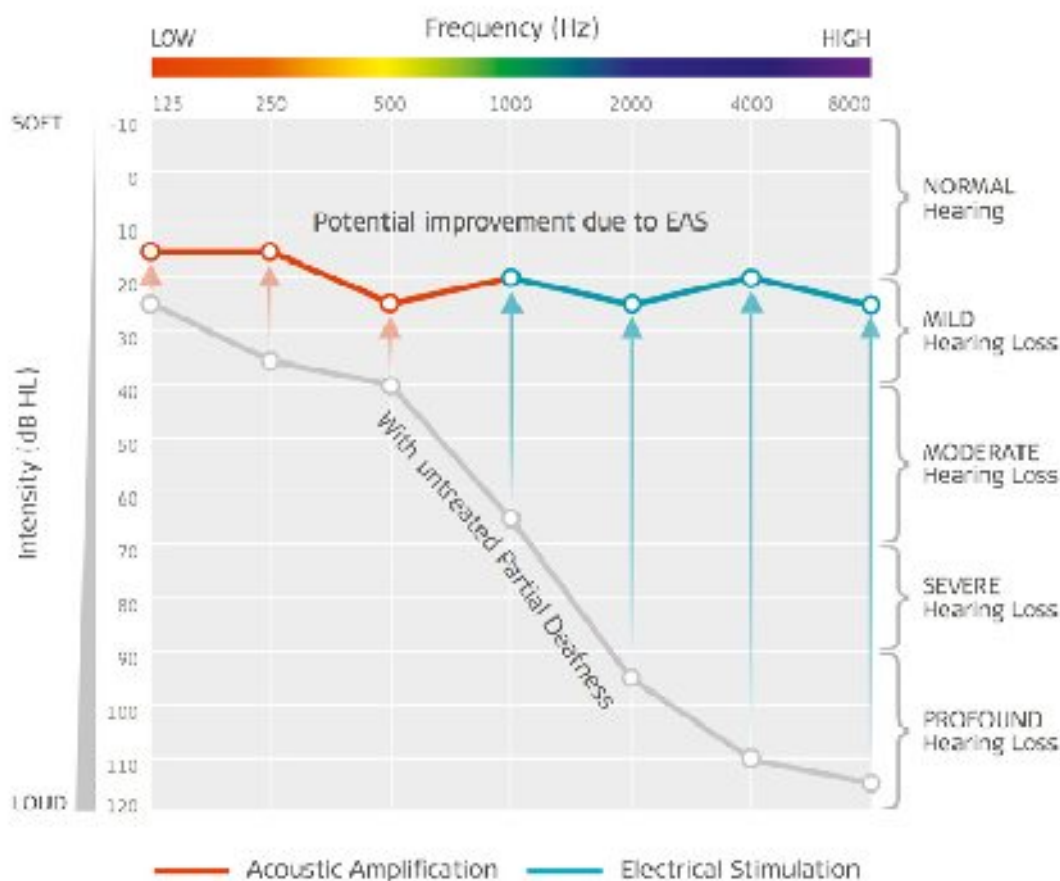


Medel's Sonnet EAS and Advanced Bionics Naida Q90 EAS are the other manufacturers latest versions; they appear very similar so are not reproduced here.

Frequencies that are audible:



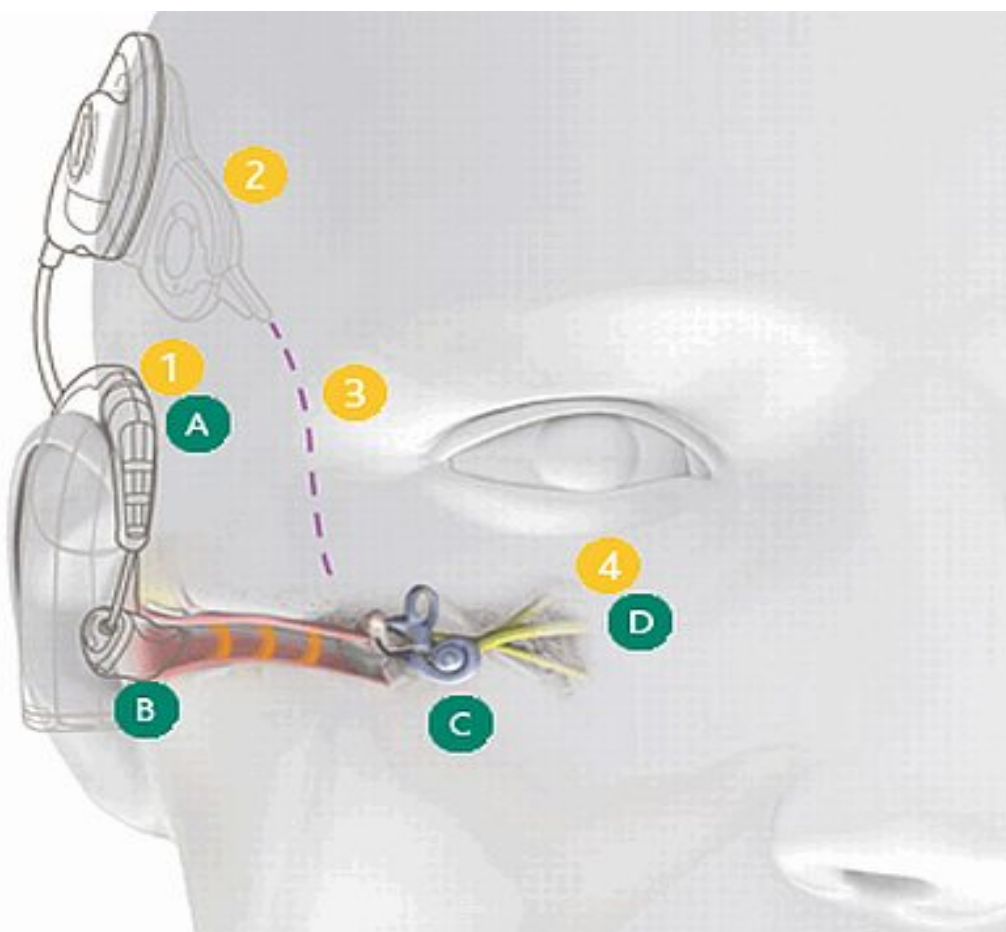
- 1 Amplified sound
- 2 Low frequencies: functioning hair cells
- 3 Mid frequencies: partially damaged hair cells
- 4 High frequencies: electrode bypasses damaged hair cells
- 5 Hybrid electrode



The electroacoustic system allows people with high frequency hearing loss to hear high frequency sounds which are so important for understanding speech and for successful communication. The acoustic component amplifies sound, strongly stimulating the low frequency hair cells deep inside the cochlea, and improving the perception of low frequency sounds in the brain. The implanted electrical component directly stimulates the high frequency hearing cells bypassing the damaged hair cells and creates the perception of high frequency sound in the brain. The red line shows how acoustic amplification can improve your residual hearing in the low

frequencies, and the blue shows the significant improvements in high-frequency hearing that electric stimulation provides.

Electrical pathway	Acoustic pathway
1 The external sound processor captures sound and converts it into digital signals	A The external sound processor sends low frequency sounds to the Acoustic Component
2 The sound processor sends digital high frequency signals to the implant	B The Acoustic Component amplifies the low frequency sounds and sends them via the normal hearing pathway
3 The implant converts high frequency signals into electrical energy, sending it to an electrode array inside the cochlea	C The amplified sounds activate the hearing nerves
4 The nerve hearing response caused by electrical and acoustic stimulation is sent to the brain which combines them into a perceived sound	D The nerve hearing response caused by electrical and acoustic stimulation is sent to the brain which combines them into a perceived sound

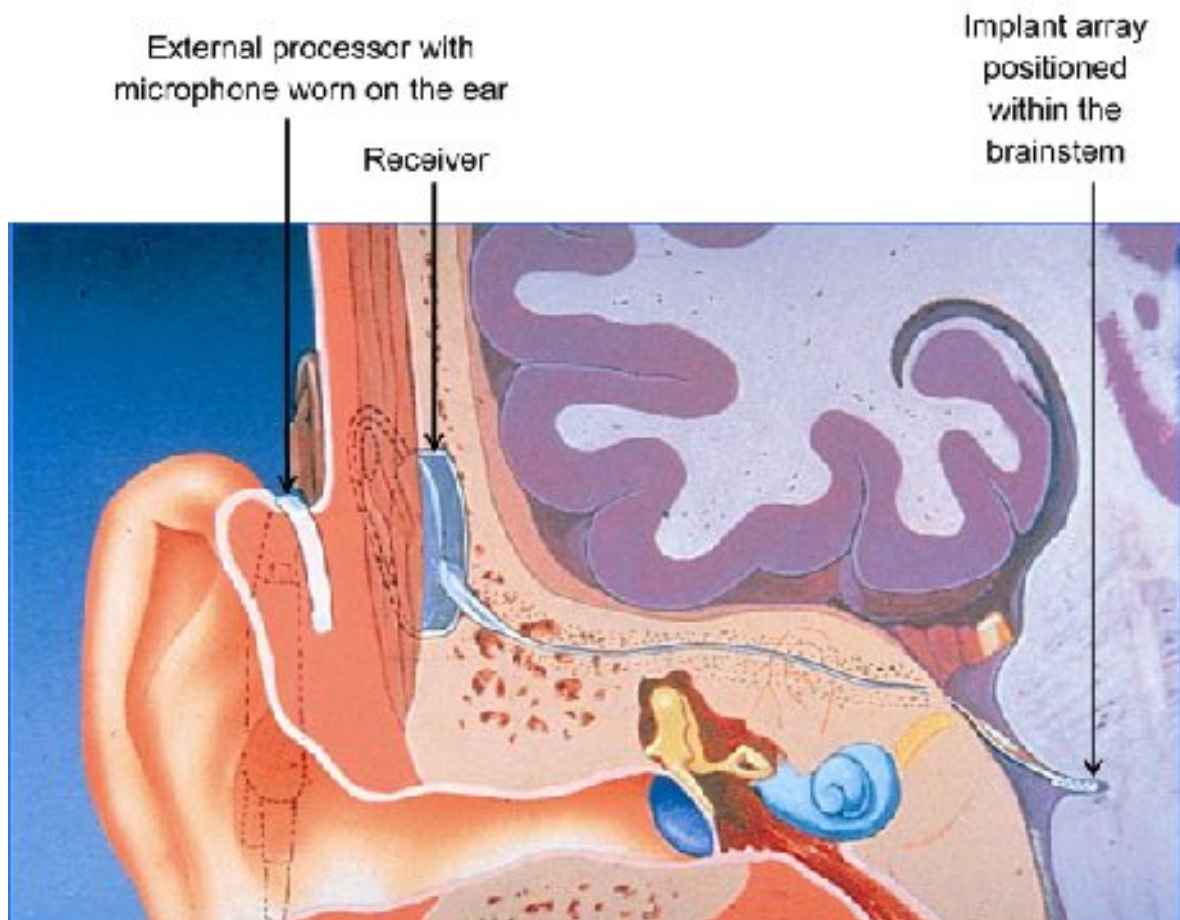


A final point regarding hybrid/EAS devices is that they can integrate with a conventional hearing aid in the other ear. Phonak and Advanced Bionics, both under the Sonnova umbrella, have been prominent in Bimodal Hearing Solutions. The Phonak hearing aid Naída Link integrates with the AB Naída Q90 CI with EAS sound processor.



11. SOLUTION OPTIONS - AUDITORY BRAINSTEM IMPLANT (ABI)

ABI is a small device that is surgically implanted in the brain of a deaf person whose auditory nerves are lacking or damaged. ABI uses similar technology to the cochlear implant but instead of electrical stimulation being used within the cochlea, it is used to stimulate the brain directly.



Cochlear and Medel offer ABI below



An ABI can provide hearing to people with hearing loss who cannot benefit from a cochlear implant. Most commonly this is when there is an absent or very small hearing nerve or severely abnormal inner ear (cochlea). The auditory brainstem implant directly stimulates the hearing pathways in the brainstem, bypassing the inner ear and hearing nerve. Originally developed for adults diagnosed with neurofibromatosis type 2 (NF2), a rare genetic condition that causes tumours to grow on nerves, the surgery is now considered for adults and children with other nerve and inner ear abnormalities.

In people with NF-2, the ABI usually is placed at the same time the nerve tumours are removed, so it is completed within one surgery. The ABI connects directly to the brainstem, bypassing the damaged cochlea and cochlear nerves. The microphone picks up sounds from the environment and digitally transmits them to the decoding chip under the skin. The chip stimulates the brainstem electrodes, allowing the patient to hear a variety of sounds.

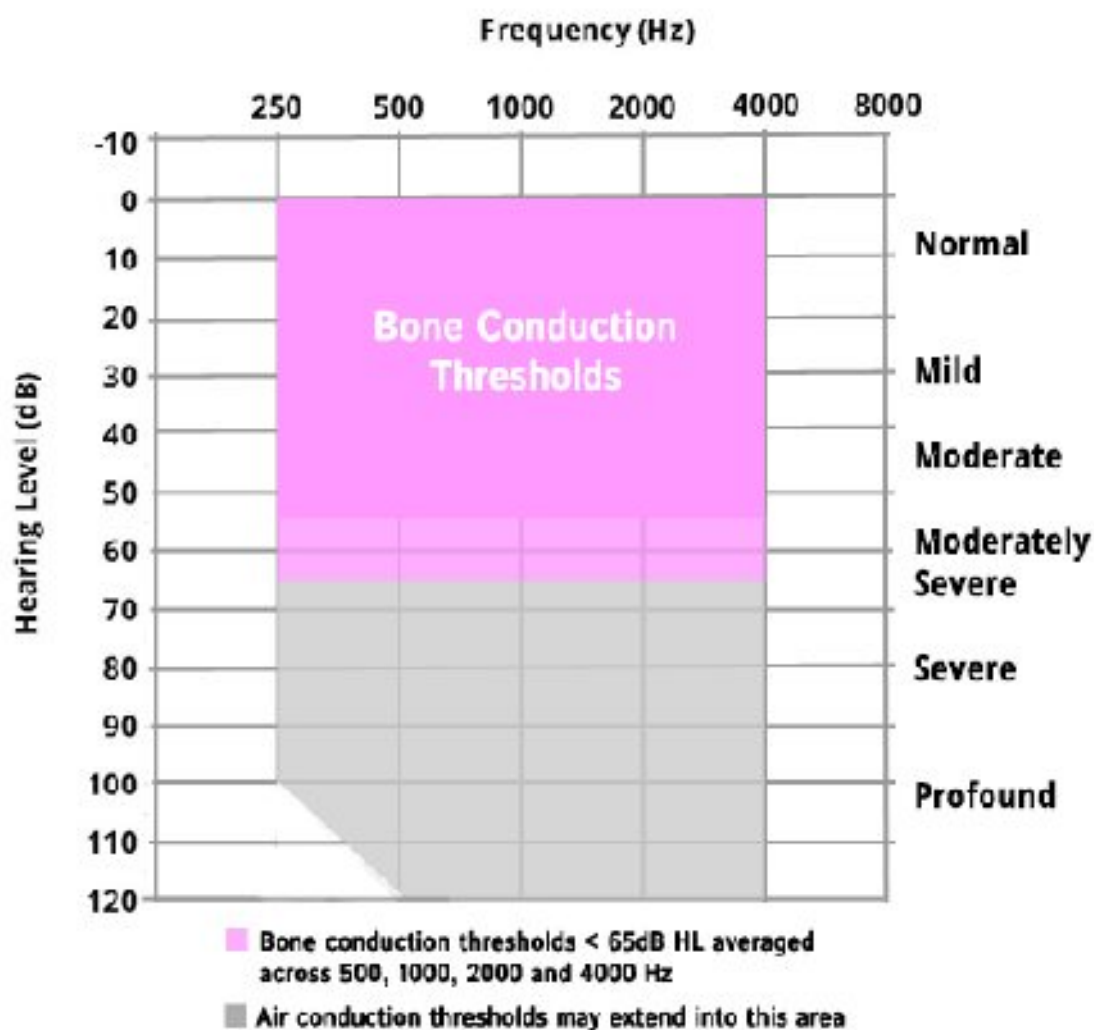
The device does not give the full range of hearing, but it provides increased environmental noise awareness. Most recipients are able to hear noises like a telephone ringing or horn honking, but the degree of hearing usefulness can vary greatly. Some people get good word recognition, while others get more general sound cues. In combination with lipreading, the cues help improve communication with others. Due to the brain surgery required for the implantation and the limited effectiveness of the implant, the number of ABI recipients is very small compared to the number of CI recipients. Consequently, like Middle Ear Implants, it cannot be considered mainstream, so the brief descriptions here suffice and any affected or interested reader can research further.

Finally, the neural disorder CAPD referred to Section 4 Types of Hearing Loss is not normally treated with implantable devices (or hearing aids) - rather a variety of therapies, training programs, and strategies help children and adults manage the condition. In the case of ANSD, in some cases - particularly in children who have the neonatal form of AN, hearing aids can help by making sound and speech more audible. In other situations cochlear implants can also provide some benefit by bypassing the regions in the auditory system that are damaged.

12. Expanding Criteria for Cochlear and other Implants

Initially **Bone Anchored Hearing Devices (BAHD)** were introduced for patients with bilateral conductive or mixed hearing losses (CHL) who were for practical reasons unable to wear conventional air conduction aids. These indications have expanded over time to benefit patients with unilateral hearing losses of both a conductive and sensorineural nature.

The audiogram below shows how a candidate's bone conduction thresholds need to fall within the coloured region. For single-sided sensorineural deafness the devices extend to profound hearing loss - the grey area.



General considerations are that patients likely to require MRI scans should only consider percutaneous BAHD. Specific criteria can be:

- For Single sided deafness at <20 dBHL Percutaneous or Transcutaneous device

- For Conductive Hearing Loss and mixed loss, unilateral or bilateral: at <20 dBHL Percutaneous or transcutaneous device; at 20-40 dBHL Percutaneous or transcutaneous device (or Vibrant Soundbridge Middle Ear Implant); at 40-55 dBHL Bone-Anchored or Vibrant Soundbridge

A middle ear implant is designed for individuals with mild to severe sensorineural hearing loss or conductive or mixed hearing loss, and is again an alternative to conventional hearing devices. The procedure is for patients with the following indications:

- outer ear condition that prevents the use of a conventional hearing aid
- a pure tone average (PTA at 0.5, 1.0, 2.0 and 4.0kHz) of less than 80 decibels hearing level (dBHL)
- bilateral, symmetrical hearing loss with PTA thresholds in both ears within 20 dBHL of each other
- speech perception discrimination of at least 65% correct for word lists with appropriately amplified sound
- normal middle ear · normal tympanometry · no other inner ear disorders.
- on audiometry, an air bone gap of less than 10dBHL across all frequencies

For example the Soundbridge has been used for patients who

- cannot tolerate foreign bodies in the ear canal for medical reasons, e.g., chronic ear canal inflammations or ear canal eczemas
- require a free ear canal for personal or professional reasons, e.g., musicians, singers or physicians who wish to hear harmonics free and undistorted by the occlusion effect
- rely on good perception of high frequency sounds.

Historically, **cochlear implants** had been confined to individuals with severe to profound hearing loss. The audiological criteria were a congenital or acquired profound sensorineural hearing loss; generally, a pure tone average (500, 1000, 2000 Hz) 90dB Hearing Loss or greater in both ears was indicated. There would be limited or no functional benefit from hearing aid amplification and indications like those following would still occur with hearing aids:

- Poor aided speech discrimination
- Reliance on lipreading
- Mishearing or incorrectly responding to questions
- Avoiding noisy situations and withdrawing from social occasions
- Turning the TV up louder than others may require and/or relying on subtitles
- Feeling stressed and annoyed from straining to hear or being unable to easily understand speech
- Feeling anxious about meeting new people or entering into new situations.

CIs have not only become the standard procedure for restoring substantial hearing in the profoundly deaf, but also the excellent performance of most recipients coupled with the rapid evolution of implant technology means candidacy now extends to (i) moderate preoperative speech recognition with hearing aids (ii) significant residual hearing (iii) single-sided deafness (iv) other conditions besides hearing loss (v) no lower or upper age limits. Many of these situations were actually regarded in the past as a clear contraindication to CI. Contra-indications that can still apply include:

- Long term hearing loss i.e. congenitally deaf who have never heard
- Hearing loss due to dysfunction of the acoustic nerve or central auditory pathways
- Otitis media or other active, unresolved ear problems
- Radiographic evidence of absent/abnormal cochlear development

Alternatives like brain stem implants and/or acceptance of lesser outcomes are possible.

The benefits people can receive from cochlear implants depend on a range of factors. One of the largest indicators is the duration of the severe to profound hearing loss. Early detection and intervention – both in children and adults – are crucial to minimising the impact of hearing loss. Children born deaf but implanted before the age of two, for example, have a 90 percent chance to follow mainstream education by the time they get to the age of 6 and have normal or near-normal development pathways.

Accurate assessment of hearing impairment by an audiologist remains a key factor. A pure tone audiogram should be complemented by acoustic reflex data and, when appropriate, auditory brainstem responses to both clicks and tonal stimuli. Current audiological criteria distilled from various sources, can be summarised as follows:

Adults (>18 years)

- Moderate to profound sensorineural hearing loss in both ears, sloping or flat
- Limited benefit from amplification - defined by preoperative test scores of $\leq 50\%$ sentence recognition in the ear to be implanted and $\leq 60\%$ in the other ear

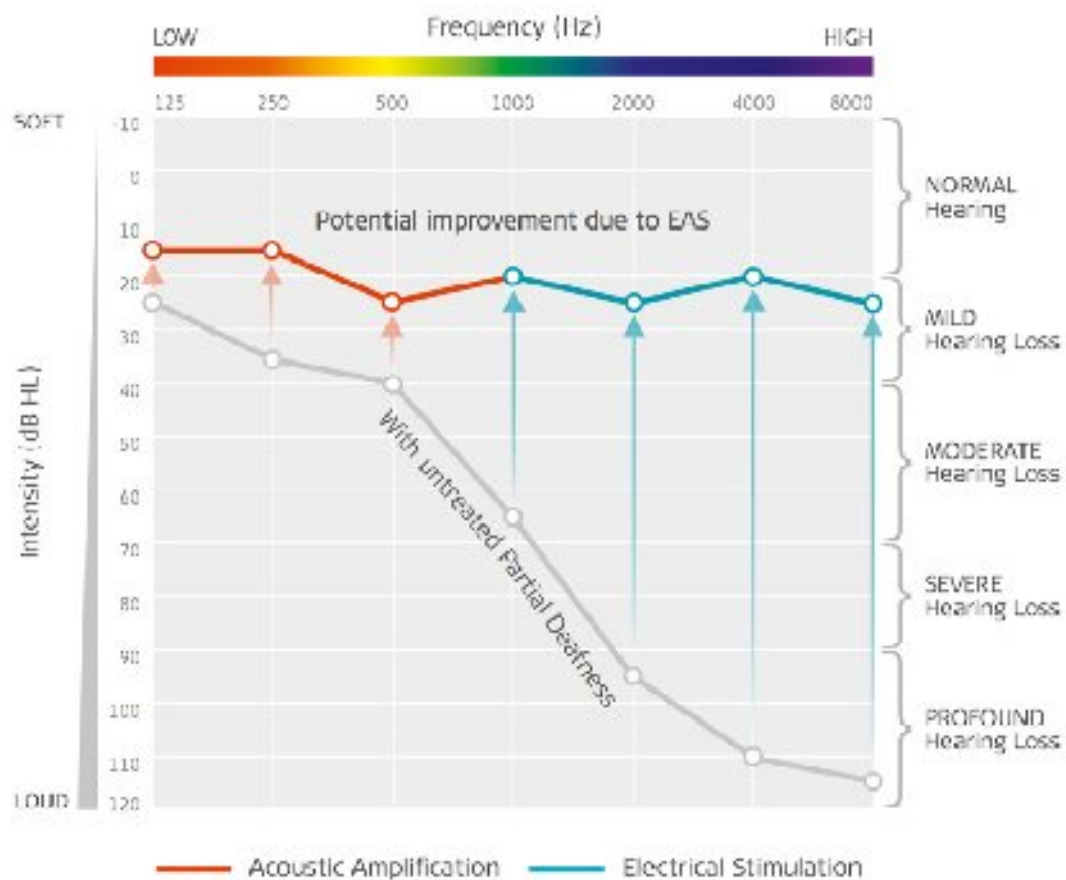
Children (2-17 Years)

- Severe to profound sensorineural hearing loss
- Limited benefit from binaural amplification; lack of progress in auditory skill development
- Less than 70% correct keywords on open-set pre-recorded sentence materials presented at 65 dB SPL in the best aided condition OR
- Less than 55% phonemes correct in the worse hearing ear and less than 75% phonemes correct in the better hearing ear on pre-recorded word material presented at 65 dB SPL

Children (12-24 Months)

- Profound sensorineural hearing loss
- Limited benefit from binaural amplification

With the technological advances and changes in surgical techniques that have improved the preservation of residual hearing, all the CIs available today are able to provide additional acoustic amplification for any preserved natural hearing, together with the electrical delivery of sound through the implant itself, making implants a viable intervention for individuals with low-frequency residual hearing. Thus the criterion for the CI or *EAS/Hybrid* is Bilateral steeply sloping hearing loss starting at ~ 1 kHz and becoming severe to profound towards higher frequencies. The benefit from the acoustic and electrical stimulation components compared to the original hearing loss is illustrated below:



Whatever implantable device is applicable, those who have hearing loss in both ears should wear two appropriate devices. The brain is wired to use input from both ears. Two devices thus reflect the natural hearing process, give better clarity/quality (like stereo vs mono), better sense of direction of sounds, no turning one's good ear towards the sound, better performance in noise and for music, and more relaxed listening with less straining or fatigue. Thus bilateral cochlear implants are now common, as are bimodal (CI + hearing aid) solutions and their advantages are

well demonstrated. Researchers in the USA actually developed candidacy guidelines for the hybrid CI system, bilateral CI and a bimodal arrangement, respectively. They determined that about three-quarters of the individuals who received one CI were a candidate for a hearing aid in the contralateral ear, because most do have adequate audible acoustic hearing in the low frequency region. Wireless communication allows two hearing devices to communicate and perform binaural processing.

The clinical evidence supporting the benefit of hearing with two ears means implantable devices have also become an option for people with Single-Sided Deafness (SSD) that can be associated normal or near normal hearing in one ear. Thus many people with significant hearing loss may now gain greater benefit from implantable devices than they might otherwise gain from hearing aids. Research shows that children with normal hearing in one ear and total hearing loss in the other, are ten times more likely to repeat a grade in school.

As well as the audiological criteria, candidates for implantable devices also require medical evaluation by an otolaryngologist, including history, physical examination and imaging studies of the temporal bone. The candidate should be free of active ear disease and have an intact tympanic membrane. High resolution computed tomography (CT) scan, magnetic resonance imaging (MRI), or both, are necessary to identify the implantable cochlea and internal auditory canal. Electrical promontory stimulation is indicated when auditory nerve integrity is in doubt. Balance assessment can also be an important consideration, for example if there is a choice between implanting an ear where the balance organs are impaired and the other ear with functional balance, the former would be chosen to ensure residual balance is preserved.

The assessment process should also use an age-appropriate combination of behavioural and psychological measures. While age is not a precluding factor for hearing implant technology, candidates need to be medically fit to undergo a general anaesthetic, have the ability to learn new skills and have realistic expectations of the device. The process may thus also cover speech, language, and general communication assessment, and counselling/expectations sessions. Indeed, an inability or lack of willingness to participate in post-implant aural rehabilitation remains a contra-indicator, though it is not common. Even after successful rehabilitation, realistic expectations remain important, particularly for those who have had long term profound hearing loss (although they could hear and develop language earlier in life) prior to implantation. Having said that, there are many such people who do well, so such long-term loss is not a contra-indication. In addition, such people have little to lose - if the outcomes are not great, they are rarely worse off!

Early detection and intervention – both in children and adults – are nevertheless ideal for minimising the impact of hearing loss. It is crucial for children born deaf, who can be implanted as early as a few months old. If implanted before the age of two, they have a 90 percent chance to follow main-stream education by the time they get to the age of 6 and have normal or near-normal development pathways.

Concluding Remarks

Although implantable devices have made enormous technological progress over the past few decades, these successes do not necessarily translate into greater activity or awareness within hearing loss clinics. In particular, despite expansion of the candidate population, and blurring of the lines between hearing aids and cochlear implants, CI uptake has remained relatively sluggish. Market penetration rates across countries range from 1% to ~ 8% of those who could benefit. Many individuals especially near the upper range of candidacy are not finding their way into a CI centre for evaluation, even in developed countries.

US researchers confirmed there are still many hearing aid users who could benefit from a CI that are not being referred, and only a low percentage of hearing professionals are qualified in implantable devices. It was suggested that in the emerging era of direct-to-consumer healthcare and deregulated hearing aid distribution, rank and file clinicians should get more involved in these proven, yet relatively unheralded solutions.

The US researchers went on to suggest that a self-report tool like the Speech and Spatial Qualities (SSQ) questionnaire, one that is seldom used in US clinics, might do a better job of measuring pre-CI performance with adults who currently use hearing aids. In the end, it is up to the individuals, who should not be afraid to get second or even third opinions, because many hearing professionals are still not familiar with cochlear implants. When considering what to do, the most important thing is to have all the information. This Guide will help.

13. Post-Implant Procedures

Self-fitting and tuning is possible with Personal Sound Amplifiers (PSAs) and cheaper hearing aids for those with mild to moderate hearing loss. But even if this market grows it will probably do so in tandem with the traditional market involving a hearing professional, which seems highly desirable if not indispensable for more advanced hearing aids.

Cochlear and related implants generally require continual training and adjustment by audiologists over long periods to maximise the outcomes and benefits. A not uncommon myth, propagated in part by internet videos of switch-ons, is that implants restore hearing immediately and that normal hearing is likely. To the contrary, training the brain to interpret the electrical signals as sounds, speech, music or whatever generally requires efforts over months, and longer for many with long-term post-natal profound deafness. The rare exceptions are usually adults who had good hearing that was lost suddenly, followed by early intervention with an implantable device.

Audiologists with expertise in the diagnosis (including the use of electrophysiological techniques), management, and habilitation of those with hearing loss are necessary to ensure competent provision of professional services by implant programs. The implant components and function, the risks, limitations, and potential benefits the surgical procedure, and the postoperative follow-up would be discussed with candidates, parents and if appropriate, the child. Ideally, children should be enrolled in educational programs that support the use of auditory prostheses and the development of auditory and speech skills, regardless of the particular communication method employed.

Ongoing management by an audiologist includes programming the implant parameters and monitoring device performance from electrical threshold and dynamic range data. Electrically evoked auditory brainstem responses (EABR), middle latency responses (MLR), or acoustic reflexes (EART) may be used intra-operatively with stimuli delivered to the cochlear implant prior to leaving the operating room or post-operatively on an outpatient basis to facilitate the fitting process. These objective measures can be particularly useful in children who are unable to respond consistently to the electrical stimuli used to program the speech processor.

This programming or MAPPING process is specific to each individual. Sound inputs can be enhanced to different degrees across the frequency range, so sound processors are adjustable for the particular type and degree of hearing loss in one or both ears. And also to reflect the individual's dynamic range (the difference between the softest sound that can be heard and the loudest sound that can be comfortably tolerated) which commonly also varies significantly with frequency.

Following mapping, learning to hear or rather to interpret sounds again is a gradual process. At first, sounds often seem unnatural, like from "Daleks", "Mickey Mouse" or "Submerged Divers". Rehabilitation focusses on the development of a wide range of listening behaviours within meaningful communication contexts. Particularly for those living on their own, talking books and internet audio training sources are helpful.

As the brain adjusts over time sounds become more natural. Whether it involves one or two devices, hearing aids or implants, mapping adjustments etc it usually takes weeks or months. No device provides natural hearing, nor allows hearing everything in every situation. People with normal hearing also miss things and generally have difficulties in noisy situations. Follow-up audiological evaluations assess improvement in sound and speech detection and understanding.

Ideally for children, there should be close interaction between the audiologist at the implant centre, the clinician who provides rehabilitative services, and educators working on a day-to-day basis with the child. Educators should have an understanding of device function and maintenance, as well as an appropriate level of expectation regarding the child's progress.

At the other extreme of not getting a hearing solution or not going through the rehabilitation process, people with untreated hearing loss have been shown to have a greater risk of dementia, which increases with the degree and duration of the untreated hearing loss. It is important to use hearing aids and implantable devices to keep the brain active. Indeed brain plasticity is such that people with a high degree and/or long duration of hearing loss who do receive implants seem to exhibit rewiring of the brain's auditory pathways and significantly reduce their risk of dementia.

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USE IT or LOSE IT

ALTHOUGH digital processing may indeed ensure precise replication of the original signal - IF THE USER HAS WAITED TOO LONG, THEIR BRAIN FORGETS WHAT THE SIGNAL REALLY SOUNDED LIKE. IT IS THE USE IT OR LOSE IT PRINCIPLE. Hearing aid users could be perceived as younger and more alert, if they used their instruments for all their awake hours.

A major development is *Real-Time Telecare, or Teleaudiology* which also arises from the telecommunications revolution. It is the remote mapping of cochlear implants or tuning and adjustment of hearing aids by professionals. Recipients do not have to attend a professional's office, rather it is done via the internet or secure cloud-based services from the hearing aid or implant manufacturers. Initially starting as a fine-tuning option on certain hearing aids, Telecare has expanded to allow professionals to make complete changes to the settings of the hearing aids and to send those changes to the devices via an app. Now full live remote servicing with video support is available. This changes everything about how the professional and the user interact.

Teleaudiology is especially valuable for those in remote areas or even in towns and cities where there are no specialist cochlear implant clinics. It avoids device users taking time off from work, pay for parking, or fight traffic and is a boon if a user doesn't drive or has to make special arrangements to travel. Streamlining can also occur by augmenting face-to-face visits with teleaudiology. Software and firmware updates are also being done via the cloud. A logical extension of the integration of hearing devices with mobile phones is servicing and adjustment over the phone from any location at any time.



Telecare has the possibility to change the business model of provision of hearing devices. It gives complete freedom to hearing aid users to decide how they want to be looked after. It means that a user can set-up a video call with a hearing professional and explain the issue. While connected, the hearing professional can tweak the device settings live and you can quickly assess if they are better.

It also offers professionals an opportunity to change how they work and what they offer. It is early days for Telecare and some hearing healthcare professionals are a little non-plussed about it. Many within the profession are still trying to get their heads around it and how they will use the service, while a few are already linking it to the selling of self-adjustable hearing aids. Phonak and Signia are releasing full featured remote assistance – where your clinician can access your hearing aids and adjust them via your smart phone.

Cloud technology, for example the Cochlear Link, helps connect healthcare professionals with manufacturers. That can assist with things like speeding up new or spare parts and even replacement devices, in case a user loses a sound processor. Continuing to build upon and enhance applications like this will open so many new opportunities especially as it relates to after-care. This can mean enhanced hearing performance monitoring, less travel to the clinic for device mapping, new rehabilitation processes and more.

Another area Cochlear is pursuing is Artificial Intelligence, involving a licensing and development agreement for FOX - Fitting to Outcomes eXpert. FOX's artificial intelligence assistant is to provide clinicians, no matter where they are in the world, a platform to speed up the cochlear implant fitting process while also helping them achieve the best possible patient outcome. This technology will change how cochlear implants are programmed as the audiologist can perform a set of simple, yet critical tasks, where the patient is an active participant. That provides the evidence for target-based fitting much like the well-established hearing aid verifications

Another area for development in post-implant procedures is music therapy. There is evidence that music training benefits not just musical skills but also speech perception and social participation for users of hearing aids and cochlear implants.

Finally, a minority of CI recipients achieve poor outcomes. More knowledge is needed of the underlying causal factors for variability in performance, of pre-implant indicators that link to such outcomes and of course of how to habilitate a CI user with a poor outcome.

A key limitation is that hearing loss not only decreases the overall level of neural activity, but also distorts the patterns of activity such that the brain is less able to recognise them. So the combined power of machine learning and large-scale electrophysiology may provide an opportunity for an entirely new approach to hearing aid design. This is covered in more detail in Section 14.

Similarly for the variability in CI outcomes, hearing loss is not only an ear issue, it is also a brain issue too reflecting close links between perception and action and brain, body and world working together as a functionally integrated information processing system. Deaf adults and children who are performing poorly with their CIs are not a homogeneous group and may differ in many different ways from each other, reflecting the dysfunction of multiple brain systems associated with both congenital and acquired deafness.

So an approach based on Neuro-cognitive hearing science and information processing theory seems worthwhile.

14. Advances in Technology: from Consumer Electronics and Communications into Hearing Solutions

- (I) General
- (II) Audio Linking, Bluetooth Connectivity & Wireless Accessories
- (III) Mobile Phone Integration
- (IV) Smart Phone Apps, Self-tuning, Self-Fitting
- (V) Convergence of Personal Sound Amplification Products (PSAPs) with Hearing Devices
- (VI) Future Advances - Health Tracking
- (VII) Future Advances - The Internet of Things (IOT)
- (VIII) Limitations

(I) General

Today just about all hearing solutions are miniature electronic devices using digital technology. All devices contain one or more microphones to pick up sound, a component that amplifies or processes sound, a receiver or speaker that sends the signal into the ear and a battery as the power source. These components are packaged into various styles. Incoming signals are converted into a series of numbers, which are then processed using mathematical equations, enabling complicated manipulation of signals, for example to help separate speech from noise. The sound processing chips can deal with enormous amounts of data. Complex algorithms can separate sound into different frequency regions and so allow each region to be amplified or processed selectively. Digital processing ensures a replication of the original signal with minimal distortion, resulting in good sound quality.

Most devices are “preventive/limiting” in reducing otherwise uncomfortably loud, wanted or unwanted, sounds and most offer feedback cancellation of steady noise sources.

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REDUCE LOUDNESS and DISCOMFORT

Some people are afraid that since they cannot tolerate ‘loud’ or ‘louder’ sounds, when a ‘normally hearing’ person can tolerate very loud sounds, they will be even more intolerant of loud sounds if they wear amplification. The fact that devices can and do **REDUCE THE DISCOMFORT** of loud sounds, while still allowing the user to perceive softer sounds, IS VERY IMPORTANT. Hearing aid wearers are, in many incidences, protected from day to day street noises, far better than those who do not use any devices and who must put up with extreme street noises or in the movies or theatre.

Basic, advanced and premium models of hearing aids reflect the degree of manual or automatic control, directional microphones, number of channels and hence capability of fine tuning, number of programs for different listening situations and for impulse and steady noise reduction, wind reduction and feedback management, telecoil, and cable or wireless connection to audio equipment.

Microchip technology, enabling more processing at the same or less cost and battery power, and wireless technology will continue to underpin future advances. It is said that what we are able to achieve now is just the beginning of what cochlear implants will look like five or 10 years down the road.

On the other hand, it is already hard for the layman to know which features in hearing aids actually make a real difference. Some, such as multiple channels, are easy to implement and look impressive on paper, but in reality do not make much difference in the hearing aid's actual performance to the average user. Some smaller manufacturers push these features as they tend to be lacking in the technically difficult features that really matter to user benefit. Thus one often sees multiple channels (32, 64 or even 196) advertised as one of the key features in "cheap" online hearing aids as they seem impressive. In reality 6-8 channels are all one really needs for an optimally performing hearing aid. That is why independent and objective assessments such as those listed in Section 6 are useful to help the user and their hearing professional make the "correct" choice for their needs and budget. Some of the important/desirable features from such assessments, that are **already available** are:

Automatic Directional Microphones – for better speech understanding in noise

Hearing aids have been able to effectively improve hearing in quiet situations pretty much since their inception. A much bigger challenge is improving hearing in noise. The only proven way to achieve this is through the use of directional microphones. This means you hear loudest from the direction you are looking at, while sounds next to and behind you are suppressed. Directional microphones are most effective when they automatically switch when interfering background noise is detected. There are several levels of directionality,

- Fixed - which is long-established and widely-available;
- Adaptive - which follows the one loudest noise behind you and reduces it;
- Multi-Band - which follows multiple noise sources behind you using 4 up to 48 bands in advanced models;
- Super Beam Forming.

The last wirelessly combines two microphones on one ear with the two on the other ear to form a four microphone array. This provides maximum pickup in a narrow beam in front of the hearing aid user, while offering maximum suppression behind the hearing aid user. Super Directionality is only available in limited brands and models. The better a hearing aid's directionality, the more expensive it tends to be. Not everyone requires top end directionality to do well however. The only way to know is to undergo a speech in noise test and have your score matched to a hearing aid's performance in noise. It is also critical you work with the hearing aid to get the most out of its directional microphones. Basically, keep noise to your back and the person you are listening to, to your front. Directionality requires hearing aid microphones to be spaced about 9mm apart to be effective. For this reason, it tends to be available only in hearing aids with sufficient space to house the microphones, ie BTE types.

Multi-Base Automatic Switching – for best automatic performance and less need for manual program changes.

Most manufacturers do not offer this feature. The reason for this goes back to the early days of digital hearing aids, when it was technically very difficult to create a multi-base automatic hearing aid without some serious performance issues. Most manufacturers chose single base automaticity as the foundation of their digital strategy. A few chose the more complex multi-base automatic system as their foundation. Multi-Base automaticity essentially switches the hearing aid automatically from one set of core features to another (automatic program switching). So not only can the adaptive features change, but the frequency response and core compression characteristics can change automatically. In the past, the biggest disadvantage was that hearing aid users could hear the hearing aid switch from one program to another, which was quite unsettling. With each generation, hearing aids became ever faster and new strategies, like the blending of programs, gradually got rid of the side effects all together. Today you can experience smooth transitions with optimal automatic functioning without compromise. The biggest advantages of modern Multi-Base Automatic hearing aids are that each automatic program can be changed independently of any other. This means, if you have difficulties in noise, the clinician can confidently change only that program without any concern of changes to programs that are working well. The clinician also has very little need to add manual programs, which in turn means less manual fiddling from the user.

Exceptional Sound Quality – Improved speech clarity, better music enjoyment and less distortion in loud environments

In the past, limitations in size, power usage and processing ability, limited the range of sound input that could be processed in a hearing aid. The limited resources available were then focussed on speech audibility at the cost of sound quality. This is changing. Big manufacturers have gradually been updating their hearing aid ranges with much more powerful processing, allowing them to deal with a wider range of incoming sound. This greatly improves their sound quality, especially for music. It also means less distortion in very loud environments.

Remote controls provide the user with easier programming, adjustment and troubleshooting. The features above are universally beneficial and would apply to any hearing aid or implant user. A combination of the features is better than any single one on its own.

Other features already available can be very helpful, but apply only to some users:

- Reduce tinnitus
- Dramatically improve hearing in Wind noise
- Address severe or greater hearing loss in the high frequencies via frequency shifting technology
- Improve Phone use - allows you to hear landline calls in both ears
- Greatly assist with Single Sided Deafness (Wireless CROS)
- Ability to upgrade to a higher level of hearing aid later on by upgrading the hearing aid software
- Wireless connectivity for hands-free mobile phone use, access to remote microphones and better television enjoyment
- Direct Connectivity to mobile phones

The last two features are detailed in the next subsections.

Coming Innovations

- Own Voice Processing (OVP) - used to process the hearing aid user's voice differently from anything else. One manufacturer has dedicated a completely separate computer processor on the platform to facilitate that. For new users of hearing aids the sound quality of their own voice can be off-putting, but it is usually something that they get used to. However, with this new feature problems with their own voice will be eliminated. This will mean that hearing aid users who traditionally would have to be fitted with open domes, can now be fitted with closed domes without causing auditory occlusion. Closed fittings are in fact a hearing aid brand's dream, it means that the full features and strategies they have designed can come into full effect to process the sound for a user. They spend vast sums and man-hours designing fantastic features to process sound, but are hobbled to a certain extent by the use of open fit tips which allow natural unprocessed sound in. Closing the ear canal will mean the end of that. This concept is likely to be adopted across all of the hearing aid brands over the next few years.
- Biometric Calibration, a system which uses the shape of your ear and its anatomy to make the function of hearing aids better. The outer ear naturally heightens some sounds and Phonak are the first hearing aid manufacturer to carefully map the outer ear to take advantage of its natural abilities. They will identify over 1600 biometric data points in and on your ear, which they use to deliver unique calibration settings that more reliably sense where a sound is coming from, thereby giving higher signal to noise ratios.
- Rechargeable Hearing Aids - while these are already available, the use of lithium-ion rechargeable batteries will see an expansion. These offer hearing aid manufacturers more and more power to run the features and strategies. Power usage has always been a problem for hearing aid brands, many of the really good features are power hungry. The lithium-ion battery offers outstanding levels of power without causing the user any hassle.
- Sensors in Hearing Aids - one manufacturer is introducing hearing aids with inertial sensors that track activity and detect falls and if a fall occurs, the hearing aids would report it. Going further, sensors will facilitate virtual assistant services like Siri and similar. These are already used widely outside the hearing loss context and Amazon has now integrated its assistant Alexa into hearing devices. More manufacturers will follow.

(ii) Audio Linking, Bluetooth Connectivity & Wireless Accessories

Historical

For more than a decade hearing aids and cochlear implants have become more alike than different. Both technologies have sophisticated sound processing strategies, Bluetooth streaming capability, and offer the user a variety of accessory options. Historically, hearing aids and implantable devices were linked to telephones by acoustic coupling or by telecoil coupling. The former is simply placing the telephone near the device microphone and is common practice for users with mild to moderate hearing loss. A telecoil picks up the electromagnetic energy emitted by the phone and delivers it directly to the device processor, bypassing its microphone. This was common for people with more advanced degrees of hearing loss. The telecoil may automatically switch on when it senses the electromagnetic field from the telephone or it may require manual switching into the telecoil or "T" mode.

Although a traditional household telephone usually won't generate much interference, digital or wireless phones are more prone to this. Since electromagnetic energy is transmitted through these phones, it can interfere with a hearing aid or implant when the phone is brought near the ear. So wireless phone providers are obliged to offer some models that are compatible with

acoustic or telecoil coupling to hearing devices. Other historically-established features of audio (telephone) linking include Volume Control, Incoming Call Alerts, Speaker Phone, and Speech-to-Text - captioned phones that may involve intermediaries who are hearing and translate for the user. Automatic conversion of speech to text is developing but would need to be better than currently-available options like Dragon and Siri that perform reasonably well. Of course texting by itself (SMS) is increasingly popular and does not require any of these features.

Telecoils and T switches also allow one to connect to radio frequency hearing loops in venues so that one can hear the speaker while not hearing background noise and other voices.

Recent trends have centred around Bluetooth, a standard protocol of the electronics and telecommunications industries. Bluetooth is not unique to a particular hearing device or manufacturer, so there is uniformity in the way that it works across all devices. The platform has been tested and refined through many years of application in mobile phones. The Bluetooth connection is secure and there is no interference.

A full implementation of the Bluetooth standard required a greater power supply than could be generated within the small footprint of a hearing device battery. However, a clever solution was wireless accessories. These assistive listening devices (ALD's) are usually now called streamers and are superseding most of the older ALD's. Streamers include remote microphones (sometimes called "spouse mics"), TV streamers and phone clips. Such wireless accessories have greatly elevated the hearing experience and enable hearing devices to double as highly-personalised, custom audio receivers.



The hearing device is paired with the streamer then the streamer is paired with external audio sources. The streamer picks up the Bluetooth signal (from the phone, TV or remote mic) and sends it to the hearing device via an FM signal or electromagnetic field, depending on the manufacturer's design. The streamer may be worn around the neck, placed in a pocket or plugged in to the TV audio. A remote mic would be placed on or near the speaker one wants to hear. Bluetooth accessories allow users to stream phone calls, music, and television programs directly to their sound processor with enhanced clarity. There are huge benefits in difficult listening situations, like a noisy classroom, auditorium or restaurant setting, where users can give the wireless mini-microphone to the person speaking and the sound then gets transmitted directly to their sound processor.

Audiologist Comment 14

AUDIO LINKING

Digital hearing instruments can be linked to Bluetooth devices, i-phones, radios and TVs usually through the use of a remote control. Active, tech-savvy people, even those with severe losses, can achieve an amazing degree of hearing and understanding.

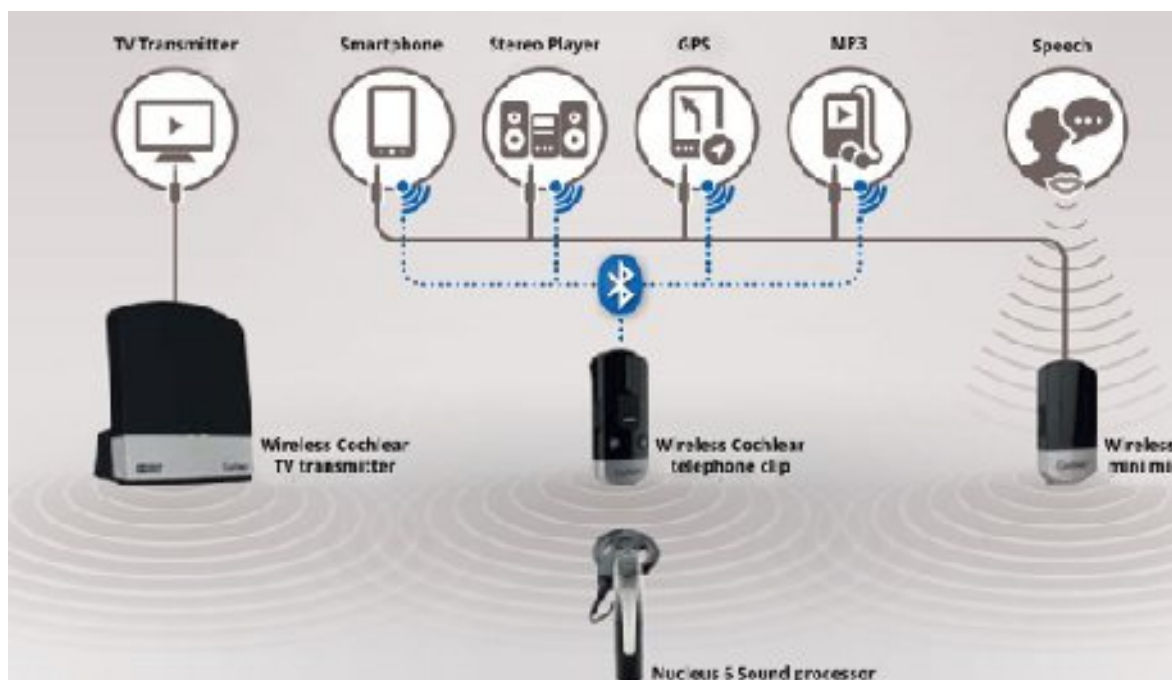
The figures below illustrate one example - the Cochlear suite of accessories (mini-microphone, TV streamer, phone clip)



Remote assistants or controllers - examples below - allow settings, functions and accessories to be managed without touching or removing the processor.



The connection and streaming possibilities are illustrated below:



Although using Bluetooth wireless accessories means carrying an additional device in order to more clearly access one's mobile phone or music player, a streamer provides many other opportunities previously unavailable. The audio signal can usually be set to stream to one or both hearing devices and the streamed signal can be amplified and shaped to match the hearing device's personalised settings. In the case of a music player, the hearing aids can become like a pair of wireless ear buds. For a phone, it may be desirable to stream the signal to just one hearing aid so as to keep the other one accessing the other sounds. This hands-free solution certainly beats the old method of trying to position a mobile phone receiver close to a hearing

aid microphone! Multiple devices can usually be paired to one streamer, so you can easily switch between different devices. For example, a streamer is able to interrupt or pause a music input from an audio device in order to connect with an incoming phone call.

(iii) Mobile Phone Integration

The latest development, wider connectivity and linking to Smartphones, already looks like partially superseding even the recent wireless accessories described above. Apple's push into making its devices more accessible to the hearing impaired began with 2013's launch of iOS 7, which also introduced the Made for iPhone hearing aid program. Its Bluetooth Low Energy Audio (BLEA) is, as the name implies, a way for devices to push sound around without guzzling power. BLEA has enabled a steady stream of iPhone-compatible hearing aids and cochlear implants to be released.

The key driver for the Made for iPhone program was how to improve the ability for someone with hearing loss to use an iOS device to do all the things everyone else does, from making phone calls to FaceTime to listening to music and apps like YouTube and watching movies.



Along with streaming sound from an iOS device, users can track the battery life of a hearing aid on an iPhone. They can adjust settings and volume through the iPhone instead of via the hearing aid, making the process more discreet. Audiologists help program presets for different sound

situations, like restaurants and concerts, and users can switch to the appropriate setting with a triple click on the iPhone home button. Geotagging automatically switches settings based on where the hearing aid users are, for instance it will turn on the restaurant or coffee shop setting. There's also a "find my hearing aid" feature on the phone. Another capability is Live Listen, that lets the iPhone act like a remote microphone so one can hear people on the other side of a crowded room or conference table -- wherever they place the iPhone.

Several hearing aid manufacturers released hearing aids that implement this Bluetooth technology and communicate directly with the iOS platform that runs iPhone, iPad and iPod Touch devices. The technology is designed to allow the devices direct connection without extreme stress on the battery power. The Made for iPhone-compatible hearing aids cut out the need for intermediary devices like streamers. Plus the use of hearing aids becomes less obvious, along with being stylish, wireless and high quality audio - all help remove the social stigma associated with hearing devices.

Phonak seems to be leading the way beyond Made for iPhone to Made for All Phones (MFA); its Audeo B-direct provides a hearing aid solution for the 85% of smartphones that are not iPhones. And not everyone has a smartphone, some just want a mobile phone that allows them to call people - the Phonak works for them too.



It functions just like completely wireless Bluetooth earbuds, using a 2.4 GHz Bluetooth chip, called SWORD (Sonova Wireless One Radio Digital) chip.

Moving on to implantable devices, when Cochlear and Apple collaborated on a made-for-iPhone cochlear implant sound processor, the CI space was very new to Apple and it was a steep learning curve. The outcome in 2017/2018 was the world-first Nucleus 7, which allows users to stream sound from iPhone, iPad and iPod touch directly to their sound processor. Users can also control, monitor and customise their hearing through its companion Nucleus Smart App, available to download for free from the App Store. Audio can be streamed directly to users'

implant without an intermediary device. It is as seamless as picking up the phone and answering the call immediately without having to fiddle around with any other settings. Users can also stream YouTube videos or music directly to their processor in crystal clear sound. Through the 'hearing tracker' feature on the app, users (or parents) can also monitor how often they have been exposed to speech and set goals for themselves (or their children). Plus, it records coil-offs time – that is, the time the sound processor coil does not detect the implant coil because it has, for example, fallen off a child's head.



Cochlear's Baha is another implantable device that follows Apple's program. It also lets users stream audio directly to their ears, much as one would with regular wireless Bluetooth headphones such as Apple's AirPods. An important safety angle emerges from stories like the emergency call dispatcher who now receives crystal-clear sound and the mountain climbing guide who uses his Apple Watch to adjust his hearing aids to dampen the sound of wind while still hearing his clients struggling 25 feet behind him.

With Phonak under the Sonova umbrella, Advanced Bionics is incorporating the SWORD chip and wireless radio technology into their portfolio of solutions. Current users of AB's latest sound processor, and future recipients, will be able to connect to any Bluetooth-enabled mobile phone. Cochlear is may also be moving towards a Made for All Phones device.

Phonak and AB also have a history of combining hearing aid and CI technologies. The Phonak Naída Link is the only hearing aid designed to treat sound in the same way as the AB Naída CI sound processor. Cochlear has entered a similar relationship with GN Resound. The third major CI manufacturer MED-EL has so far focussed on wireless charging rather than integration with Smartphones.

All these latest hearing aid and implantable device solutions offer real hands-free voice calling, even without the phone nearby, plus ability to take a phone call without touching your phone. The wearer can answer or reject a phone call by simply pressing a push button. The ringing of the phone is heard through the hearing device and once the call is accepted, the conversation is instantly streamed. Your voice is picked up by the device's intelligent microphone network and transmitted to the other caller similar to a wireless headset.

Some drawbacks - batteries do drain quicker. They can also be too complicated for the elderly. People in their 70s and 80s are much less likely to have smartphones than younger hearing device users. Just learning how to use a hearing device can be complicated enough. Bluetooth chips also limit how small hearing aids can be. But as the chips shrink, smaller versions will follow. All hearing aids and mainstream implantable devices will eventually connect to mobile phones.

(iv) Smart Phone Apps, Self-tuning, Self-Fitting

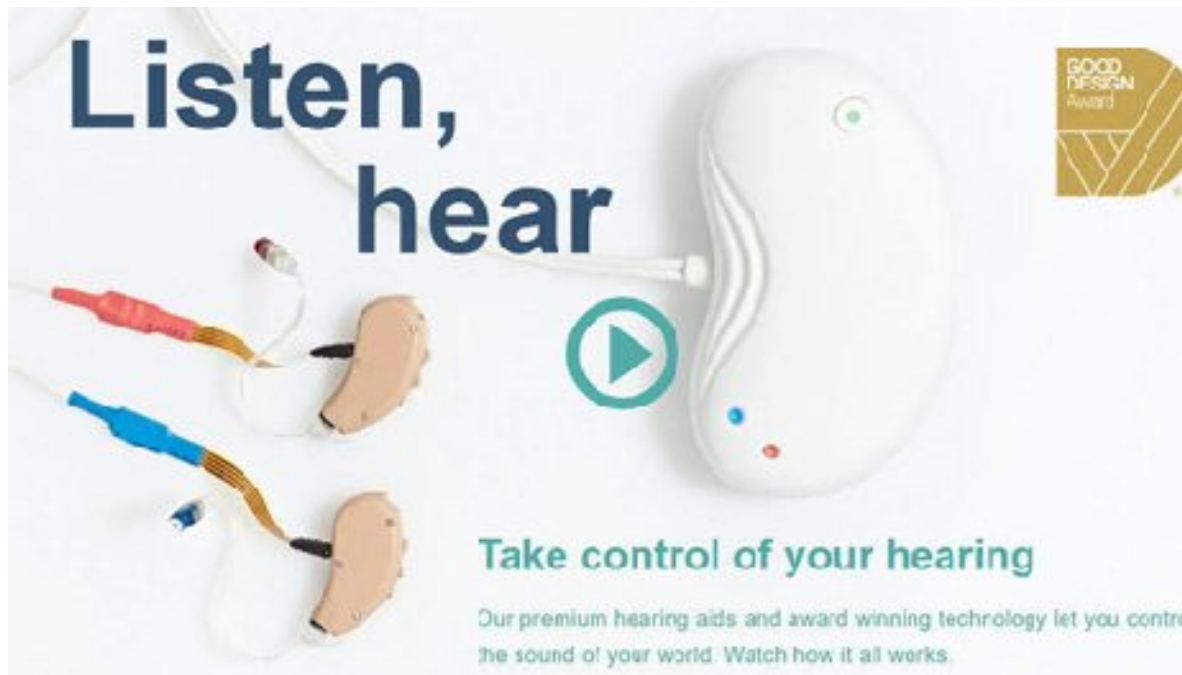


Preceding and in parallel with the integration of hearing devices with the iPhone were apps that provided hearing assistance. Some iOS apps like Fennex, Petralex and MyEar are said to help those suffering with hearing loss without using hearing aids at all. Third parties like Sonic Cloud customises sound on a phone call according to the unique needs of each person, through a hearing assessment tool, a cloud-based signal processing engine, and a VoIP calling service. An app from Earlogic called TSC Music first provides a hearing test for each ear on five different key frequency ranges. Then, it can play music from most streaming services like Spotify, SoundCloud and YouTube. A user's ability to hear should improve after just a few weeks.

Another approach has been **Self Fine Tuning** of actual Hearing Devices. One version is Mobile Ears, with a free iOS app downloadable from the iTunes App Store. This helps people with mild to medium hearing loss to hear clear speech and sound while watching TV, at meetings and conferences with just their phone and earbuds -- no need for expensive extra hearing devices or complex hearing tests. Mobile Ears gives speech clarity, noise cancellation, filtering and removal of unwanted background noise. The smartphone can be placed on the table or in front of the

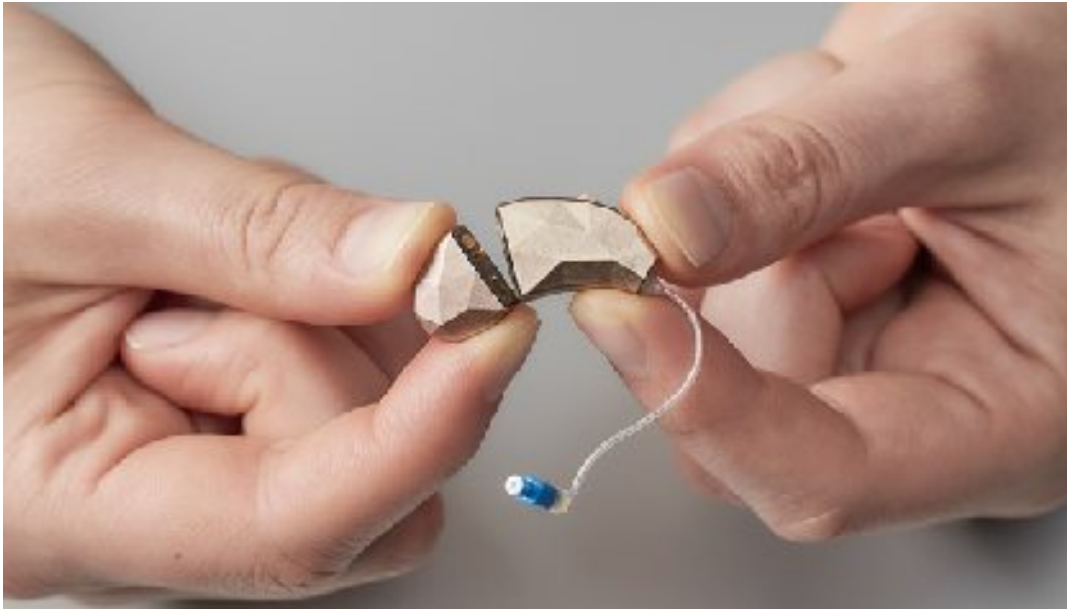
users. The app also works offline. It combines statistical analysis of hearing threshold data with a tailored individual user listening profile. Users can easily adjust the sound that suits their environment, whether a one-on-one conversation or television viewing, without needing to visit an audiologist or hearing specialist.

Yet another trend, **Self-fitting hearing aids**, have been available for some time in Australia. Blamey and Saunders have successfully offered self-fitting hearing aids, purchased online with a kit sent out to help fit them.



Self-fitting hearing aids have also become available in the US with the recent introduction of the iHear product line up, catalysed by the passage of the Over-the-Counter (OTC) Hearing Aid Act of 2017 in the USA. This addresses the accessibility and affordability of hearing aids, instructing the U.S. Food and Drug Administration to create a class of OTC hearing aids for people with mild to moderate hearing loss. The FDA must propose regulations within three years of enactment. By 2020, close to 45 million people in the United States will suffer from mild to moderate hearing loss, with 20 million of them aged 20 to 69. Yet traditional hearing aids have low adoption, with the penetration rate as low as 14 percent by some estimates. The Act will stimulate the above approaches ranging from use of Apps on phones without actual hearing devices, to self-tuning and self-fitting of basic hearing aids. For example, iHEAR Medical plans to launch advanced over-the-counter (OTC) hearing solutions in major drugstore chains and independent pharmacies across the United States, including their FDA-approved home hearing screening and test kit.

Blamey Saunders have also innovated within the traditional hearing aid price range. They have produced a modular aid that won the Australian 2018 Good Design Award of the Year and the CSIRO Design Innovation Award. Facett's design removes the stigma of hearing aids by drawing parallels to jewellery and wearable art.



As everyone's hearing is different, the device settings are adjustable through a system called I Hear You, via smartphone, tablet or Windows app. The device also boasts high resolution sound, filtered through 96 output channels, and technology that isolates speech and reduces background noise.

Furthermore, the device is powered by a rechargeable module, which magnetically clicks into place. The Facett features storing of two pairs of modules in a small portable drying and charging pod, to plug in at bedtime for overnight charging and the next day's listening.



Like other hearing aids and implantable devices with rechargeable batteries, this is an easier process than the small fiddly disposable batteries, especially for those with limited dexterity or in the dark.

(v) Convergence of Personal Sound Amplification Products (PSAPs) with Hearing Devices.

The OTC Act will also accelerate an already-established trend to PSAPs. Australia is becoming a powerhouse of audio equipment that users can personalise to match their hearing. Audeara, a start-up out of Brisbane, has released Bluetooth headphones that make up for any deficiencies in their owner's hearing, based on a conventional hearing test the wearer takes when they first set up the headphones. Nuheara, a start-up out of Perth, has released Bluetooth earbuds that do a similar thing, also via a hearing test, so can also act like hearing aids for the pub-deaf, pulling voices out of crowds and hiding the background noise. Nura, a start-up out of Melbourne, has released a pair of headphones that offer a more gentle adjustment to their sound, based around a hearing test similar to the test hospitals give newborn babies.

PSAPs were originally designed to accentuate sounds in specific listening environments for non-hearing impaired consumers. For example Nuheara's iQBuds, Bluetooth-connected earbuds, were not designed for the hearing-impaired. But people were using them to (like Mobile Ears above) to offset their hearing loss, because the alternative - hearing aids - were expensive, unattractive and did not necessarily process sound and boost voices as well as the iQBuds in noisy environments.



So the next edition, iQBudsBoost (above) was developed to effectively fit an audiologist in the box. It conducts a complete hearing test, applies the results to a hearing aid prescription formula (the same prescription formula used by all the major hearing aid companies around the

world). Nuheara's "Ear ID" assessment is deftly labeled (no one likes a test!) and easy to take: users tap a large blue button on the screen when they hear a tone. Results appear in colour-coded, concentric rings, instead of displaying the frequency numbers utilised on traditional audiograms—incomprehensible to many—the app labels sounds from “bird chirping” to “plane rumbling.”



The Nuraphones feature an earbud inside a headphone.

IQbuds BOOST hearing assessment results screen by Nuheara



These offerings are on top of others from the likes of JayBird, BlueAnt and BioConnected, all Bluetooth audio companies founded in or by Australians. This reflects Australia's long track record of expertise in the very skills coming to the fore in the era of Bluetooth headphones, dating back to the 1970s and the development of cochlear implant technology.

In summary, PSAPs can combine the utility of a hearing aid with the sound quality and ease of use of earbuds. However, unlike traditional hearing aids, PSAPs are not approved medical devices. But with the familiar functionality of streaming music and phone calls from smartphones, they do also augment users hearing. Their self-fitting technology and options for customisation empower consumers to manage their own listening experience, at attractive prices.

These Australian companies, along with overseas manufacturers like Bose, now also target audiologists and other clinical professionals who administer hearing tests, recommend hearing aids, and fit devices. So audiologists can determine whether and how to integrate the lower price points of PSAPs, about a tenth of that for hearing aids with smartphone connectivity, with their business model.

Thus PSAPs demonstrate how consumer listening devices and traditional hearing aid technology are colliding, for those with mild to moderately severe hearing loss. Tailored amplification, noise reduction, phone calls, and music listening now come packaged in one device, customisable with a smartphone app. Apps and PSAPs generally have fewer features and less functionality than hearing aids and are not subject to the same standards as hearing aids. Reviews suggest that with the right fit and adjustment, the higher-end models (still far cheaper than hearing aids) can help but the cheaper options do not measure up.

Apple itself has developed an audio product – AirPods. The wireless headphones include advanced low energy technology themselves, powered by the Apple-designed W1 chip. Apple's AirPods are making it acceptable, socially and at work, to wear such strange things hanging out of the ears while not being inattentive, quite the opposite. Spend a few hours in any major metropolitan area and one sees how pervasive AirPods have become.





Between the company's work in both accessibility and audio, Apple finds itself in a unique position to transform the market of hearing augmentation, using the AirPods as its own platform. While AirPods today don't offer sound amplification out of the box, they already contain advanced beamforming microphones and accelerometers that detect the source of one's voice and intelligently reduce background noise. The W1 chip found in AirPods also enables seamless pairing and connection with an iPhone, syncing the configuration to all iCloud--connected devices. Two people wearing AirPods could even speak directly to each other. The integration of a telecoil in AirPods would instantly make the headphones compatible with a large infrastructure already in place and in use by countless hearing aid users around the world. An iPhone connection also makes possible technologies like live translation and automatic transcription of conversations without any extra effort.

However, while Apple for example designed the shape of AirPods (and wired EarPods before them) based on 3D scans of hundreds of ears, no "one size fits all" product will fit as well as a custom solution. Many audiologists believe that even if a user is able to self-diagnose and pick out an appropriate device, there is little to no way to verify the device is optimal for their loss. Overall, while it is unlikely that Apple would receive clearance from the FDA to classify a product like AirPods as a hearing aid, Apple can have a big impact on PSAPs for the hearing-impaired.

(vi) Future Advances - Health Tracking

PSAPs play music, track fitness and allow a deeper and easier connection to audio devices. They are entering the medical tracking world, allow physicians to monitor the real-time health and fitness of their patients and to collaborate with other professionals involved in health care. The same trend or need applies to people who use hearing aids, who reflect society in becoming more active and health conscious. One manufacturer is developing a hearing aid with in-ear sensors. Another has a fitness app that pairs with its hearing aids.



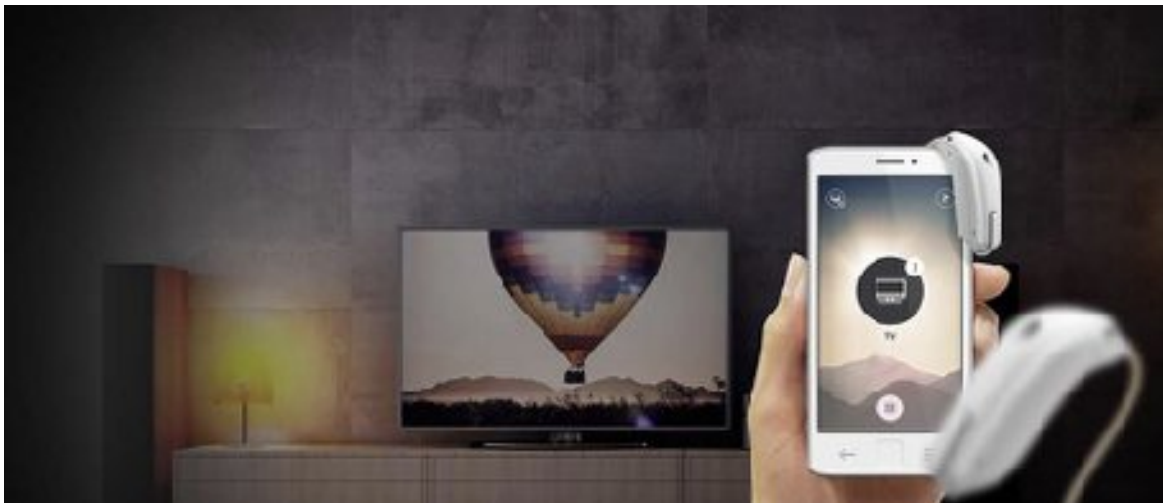
Oticon showed off a fitness app that pairs with the Opn hearing aids

Ear-level sensors can monitor vital signs like pulse and blood oxygen or glucose levels, even ECG! An accelerometer sensor can tell when someone has fallen and could set hearing devices to trigger a real time call for help. Artificial Intelligence can classify normal activities of the hearing aid user and send an alert to a doctor or relative if something seems out of place.

This type of feature could give older people with hearing loss and their families peace of mind and help them stay in their own homes for longer. Artificial Intelligence and real-time health monitoring is an opportunity for the hearing aid to transform itself.

(vii) Future Advances - The Internet of Things (IOT)

The IFTTT (If This, Then That) network is designed to allow one to set triggers, where by one action automatically triggers another. For instance, you can set up an IFTTT recipe that ensures everything you post on Twitter is automatically posted on Facebook. These recipes can also have real world applications that will just grow as the internet of things (IOT) grow. Already more and more devices in the home are becoming smart. For instance, if your thermostat is internet connected, you can programme a recipe to turn your heating on when the temperature outside reaches a certain point. In driving, GPS directions can be transmitted direct to the hearing device.



Oticon's Opn hearing aid can connect to other smart devices like light bulbs and a Nest thermostat.

Oticon's Opn hearing aid is designed to have access to the internet and the IFTTT network via its app on a smartphone. Oticon has actually designed some recipes including a notification being triggered by the doorbell being rung and lights in the house or the coffee machine coming on in response to one's hearing aids being turned on in the morning! In relation to health tracking above, an IFTTT could trigger weekly reports to be sent to relatives and/or a doctor.

While this type of thinking could allow a whole new future for hearing devices, it remains to be seen and will depend on how well adopted smart devices become in the home and smart sensors become in health tracking.

(viii) Limitations

Despite these technological advances and innovations and partly because of them, there are limitations. These latest products require the use of apps, mobile phones and internet, so users need computer competency, access to the hardware and software, and wi-fi connections to the Internet and between devices. Those who want or are willing to try these products may still be out of their comfort zone, at least initially - how many people are familiar with IOT and IFTTT? Expanded functionality also increases the level of user (and hearing professional!) education or training required to understand and operate the devices. There are many who will not want or are unwilling to try them. Some hearing device users just want something they put on and forget. In essence, some innovations appeal to some users. The issue is compounded by how much the innovations appeal to those who invent or provide them!

A more fundamental limitation is that most innovations refer to functions like wireless connectivity and phone linking, along with aesthetics and comfort. With respect to their primary function—improving speech perception—more needs to be done. For a sound to be audible, it simply needs to elicit a large enough change in auditory nerve activity for the brain to notice; almost any change will do. But for a sound to be intelligible, it needs to elicit a very particular pattern of neural activity that the language centres of the brain can recognise.

The key problem is that hearing loss not only decreases the overall level of neural activity, but also distorts the patterns of activity such that the brain is less able to recognise them. A good example is distortions: when a sound with two frequencies enters the ear, an additional sound is created by the cochlea itself at a third frequency that is a complex combination of the original two. These distortions are what we measure as otoacoustic emissions and their absence indicates impaired cochlea function. These distortions are not only transmitted out of the cochlea into the ear canal, they also elicit neural activity that is sent to the brain.

While a hearing device may restore sensitivity to the two original sound frequencies by amplifying them, it does not create the distortions and, thus, does not elicit the neural activity that would have accompanied the distortions before hearing loss. Such distortions may not be very relevant when listening to broadband sounds like speech, but they are representative of the complex functionality that hearing devices fail to restore. Without this functionality, the neural activity patterns elicited by speech are different from those that the brain has learned to expect.

A useful analogy is to think of the ear and brain as two individuals having a conversation. The effect of hearing loss is not simply that the ear now speaks more softly to the brain, but rather that the ear now speaks a new language that the brain does not understand. Hearing aids enable the ear to speak more loudly, but do not translate what the ear is saying into the brain's native language.

But there is reason for optimism. In recent years, advances in machine learning have been used to transform many technologies, including medical devices. In general, machine learning is used to identify statistical dependencies in complex data. In the context of hearing devices, it could be used to develop new sound transformations based on comparisons of neural activity before and after hearing loss. Machine learning is not magic; to be effective, it needs large amounts of data. Fortunately, there have also been recent advances in experimental tools for recording neural activity, allowing recordings from thousands of neurons at the same time and, thus, should be able to provide the required “big data.”

The combined power of machine learning and large-scale electrophysiology thus provide an opportunity for an entirely new approach to sound processor design. Instead of relying on simple sound transformations that are hand-designed by engineers, the next generation of hearing devices should have the potential to perform sound transformations that are far more complex and subtle. With luck, these new transformations will enable the design of hearing devices that can restore both audibility and intelligibility—at least to a subset of patients with mild-to-moderate hearing loss.