■ REVIEW

Review of Audiometric Criteria in Treatment of Neurosensorial Deafness With Hearing Aids and Implantable Hearing Devices

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Sensorineural hearing loss has a high incidence in our population; as a matter of fact, 50% of people over 75 years of age suffer this impairment.
Due to the advances in the devices to alleviate this condition and their verified efficacy, it is now appropriate to review the indications for these devices and provide a detailed description of the audioprosthetic systems used.
These systems can be classified as external non-implantable devices (hearing aids) and implantable prostheses. The latter can be sub-divided into active implants in the external ear or middle ear, cochlear implants, and auditory brainstem implants (ABI).
Indications for each group are determined by the type and location of the underlying condition as well as by the anatomic, functional, and social characteristics of each patient. It must be stressed that the selection and monitoring of the treatment is up to the specialist. Generally speaking, an attempt is made to facilitate the integration of the hypoacusic patients to their sound setting by enhancing their understanding of the spoken word and restoring binaurality, while at the same time, seeking to retain the plasticity of central auditory routes through the stimulation provided by any of these systems.
In the course of this review, we refer to newly-emerging indications in both the field of cochlear implants (bimodal stimulation, implantation in patients with residual hearing, bilateral implants, etc) and in the area of ABI in patients with tumoural disease previously treated with radiosurgery or patients with non-tumour pathologies presenting malformations or bilateral cochlear ossification.

Key words: Hearing loss. Hearing aids. Auditory implants.

Revisión de los criterios audiométricos en el tratamiento de la hipoacusia neurosensorial mediante audífonos y prótesis auditivas implantables
La hipoacusia neurosensorial tiene alta incidencia en nuestra población. Sirva de ejemplo que el 50% de las personas mayores de 75 años tiene este tipo de discapacidad.
Los avances en los dispositivos utilizados para su tratamiento paliativo y su eficacia comprobada hacen necesaria la revisión de sus indicaciones y la descripción detallada de los sistemas audioprotésicos empleados. Éstos pueden ser clasificados en prótesis externas no implantables (audífonos) y prótesis implantables. El grupo de las prótesis implantables se subdivide a su vez en implantes activos de oído externo, implantes activos de oído medio, implantes cocleares e implantes auditivos de tronco cerebral (IATC).
Las indicaciones establecidas para cada grupo audioprotésico se definen por la tipología y la topología de la enfermedad subyacente y por las características anatomofuncionales y socioculturales de cada paciente. En esta cuestión debe hacerse hincapié en el protagonismo del especialista a la hora de elegir y seguir el tratamiento. Como norma general, se procura favorecer el acceso del paciente hipoacúsico a su entorno sonoro realzando la comprensión de la palabra hablada restableciendo la binauralidad y, a la vez, se busca mantener la plasticidad de las vías auditivas centrales a través de la estimulación proporcionada por cualquiera de estos sistemas.
Se expone las indicaciones emergentes, ya sea en el campo de los implantes cocleares (estimulación bimodal, implantación en pacientes con audición residual, implantaciones bilaterales, etc.) o en el campo de los IATC, en pacientes con afección tumoral previamente tratada con radiocirugía y en pacientes con trastornos no tumorales afectos de osificación coclear bilateral o malformaciones.

Palabras clave: Hipoacusia. Audífono. Implantes auditivos.

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INTRODUCTION

The current treatment for sensorineural deafness is palliative and based on implantable hearing aids and devices. There are several reasons why it would interesting to review the indications for these systems.

The first reason is the high incidence of sensorineural deafness in Spain. A more than sufficient example of this is the incidence of presbycusis, which is the most frequent form of sensorineural deafness, affecting 45% of people over the age of 65; this percentage is higher in people even older than that and climbs to around 50% of people over the age of 75.[1] All this makes this condition one of the most frequent reasons for seeking medical advice from an ENT specialist.

Secondly, the results using these treatment methods for sensorineural deafness are becoming more and more satisfactory. If we add to this the exponential growth in the number and different forms of devices used then an updated review of their indications, to help otorhinolaryngologists choose the most appropriate therapeutic path for each particular patient, is completely justified.

DESCRIPTION AND CLASSIFICATION

Non-Implantable Hearing Aids or Devices

A hearing aid is basically made up of a microphone, an amplifier, and a speaker. Its goal is to produce an acoustic amplification that allows for an audiometric curve to be reached that is as close to normal as possible as well as provide good understanding of spoken words and avoiding, as much as possible, any type of distortion.

Below is a summary of the different types of hearing aids available[2]:

– Behind-the-ear hearing aids: these are placed behind the ear. They may be used for any type of hearing loss

– In-the-canal hearing aids: these are placed in the external ear canal and are used for slight and moderate hearing loss

– Belt or pocket hearing aids: the microphone and amplifier are located in a type of "box" and through a wire are connected to an earpiece that is placed just inside the ear. These are used less and less and cover the same types of hearing loss as the behind-the-ear hearing aids

If we look at the technical features of hearing aids then there are 3 types: *a*) analogically controlled analogue hearing aids; *b*) digitally controlled analogue hearing aids; and *c*) digital hearing aids.

Implantable Hearing Devices

Outer-Ear Implants

These implants are made up of a system of small titanium tubes that allow the retroauricular region to communicate with the lumen from the outer ear at the cartilage-area level. At the end of this tube a small hearing aid is placed, almost totally hidden in the retroauricular region. This system means the external auditory canal is not obstructed, thus avoiding feedback effects. This totally reversible implant is done during a simple surgery, with local anaesthesia.[3]

Active Middle-Ear Implants

Active middle-ear implants (AMEI) are electronic devices that are surgically implanted, either completely or partially, in order to correct hearing loss by vibration excitation of the ossicular chain.[3] Basically, an active middle-ear implant consists of a microphone, an audioprocessor, a battery, a receptor (in those completely implantable systems these last 3 items are known as the main module) and a transducer. The main types of AMEI[4-12] are shown in Table.

These devices have several virtues: they avoid feedback problems, no matter how intense the stimulation, they provide natural hearing with acceptable levels of discrimination in noisy settings, they avoid the discomfort or contraindications presented by diseases affecting the external auditory canal (since they are not placed there) and a large number of patients, mostly women, find the results aesthetically pleasing, particularly completely implantable systems. However, AMEIs do have some downsides: a surgical procedure is needed to put them in place, more often than not requiring general anaesthesia; the implant poses a potential risk of damage to the ossicular chain since, in the event of a technical failure in the implanted elements, further surgery is needed to replace the implant; some devices limit the use of magnetic resonance imaging as well as electroconvulsive therapy and radiotherapy of the head.

Cochlear Implants

They basically work by transforming sounds and ambient noise into electricity, which in turn affects the cochlear nerve afferences to produce an acoustic sensation.[3,13]

Main Types of AMEI

Transducer	*Researchers*	*Company*	*Implantation*
Piezoelectric	Yanagihara et al[4]	Rion	Partial
Piezoelectric	Welling et al[5]	St. Croix Medical	Total
Piezoelectric	Zenner et al[6]	IMPLEX	Total
Electromagnetic	Kartush et al[7]	Smith Nephew Richards	Partial
Electromagnetic	Perkins[8]	Resound	Partial
Electromagnetic	Maniglia et al[9]	Wilson Greatbach	Partial
Electromagnetic	Baker et al[10]		Partial
Electromechanical	Gan et al[11]	Vibrant Sound Bridge	Partial
Electromechanical	Frederickson et al[12]	Otologics	Partial-total

Basically a cochlear implant consists of a microphone, which is located in a housing similar to a hearing aid and sits behind the ear, or is sometimes placed within the transmitter. The signals picked up are transmitted to a processor, which may be inside the same housing as the microphone (behind-the-ear processor) or may be a different element connected by a wire (body processor). Together with this processor is a container to hold the batteries providing the system's energy. The job of the processor is to encode the signals and send them to a transmitter or coil located on the surface of the skin in the temporoparietal region, which is kept in place by 2 magnets: one in the transmitter and another in the receiver-stimulator. The transmitter emits signals by modulated radiofrequency that goes through the skin and in turn are picked up by an antenna and a receiver-stimulator placed surgically on the cranial bone surface previously under the skin of the retroauricular region. This element decodes the message and sends it to each of the electrodes, usually placed within the cochlea, so as to stimulate the cochlear nerve.

There are different types of cochlear implants, which can be classified into 3 groups: *a)* by location of the electrodes (intracochlear or extracochlear); *b)* the number of stimulation channels (1 or more); and *c)* the way in which the sound is handled (coding strategies based on whether or not acoustic formants and the human voice are extracted).

Auditory Brainstem Implants

The idea of this device is similar to that of the cochlear implant except that the design of the electrodes and the surgical technique used for placing it are aimed at the cochlear nuclei, instead of the cochlear tympanic scale.[3]

This device is made up of a group of electrodes, a receiver-stimulator, an antenna (all of which are internal or implanted elements), a transmitter, a speech processor, and a microphone (which are external, or non-implanted elements). Even though the components of this device are similar to those used in a cochlear implant the main difference between them resides in the electrodes.

Their shape adapts to the anatomy of the cochlear nuclei and the electrodes are fitted on a rectangular or oval electrode holder.

INDICATIONS

Non-Implantable Hearing Aids or Devices

There are no standard guidelines for deciding the level of hearing loss that absolutely requires using one of these devices (taking into account the information from the tonal threshold audiometry). For children it is felt to be completely indicated when middle-ear hearing is ≤40 dB HL in the better ear, with frequency thresholds averaging between 500 and 2000 Hz on the tonal threshold audiometry. However, in adults, with communicative and cognitive development already acquired, hearing aids are recommended for moderate-to-high degrees of hearing loss (41-70 dB HL), are considered necessary for severe cases (71-90 dB HL) and absolutely essential for profound hearing loss (>90 dB HL).[14] For this last case, the option of using a cochlear implant should clearly be considered (Figure 1).

The re-establishment of hearing and, in this case, the adjustment of hearing aids should be done as soon as possible. This is especially important during the first years of life, as patients' development of acoustic areas in the cortex as well as normal language acquisition depend on whether or not adequate acoustic stimuli are received.[15,16] This is why hearing aids and, generally speaking, any type of hearing prosthesis should be used done as soon as hearing problems are found to meet the audiometric criteria previously mentioned for them to be indicated. Lafon points out that serious learning problems may arise if profound, severe and mid-range hearing loss is not treated before 24, 24, and 36 months of age, respectively.[17]

As a general rule, binaural hearing should be re-established. Some of the advantages that may be achieved with binaural versus monaural adaptation are: better sound localization, absence of the head shadow effect, better language discrimination (especially in noisy places), and a summation effect of around 3 dB.

Bilateral stimulation, especially during infancy, allows preservation of the hearing paths and auditory centres in both hemispheres of the brain.

Adaptation will be binaural as long as the dynamic range and the degrees of discomfort in each ear are similar, the levels of verbal discrimination are practically the same and the thresholds of pure tones by way of the bone do not differ by more than 30 dB HL. For those cases in which the above requirements are not met, monaural adaptation should be planned.[18]

The compensation provided by the device must bring the audiometric curve as close as possible to a normal one, with the aim of understanding spoken language well. However, it is necessary to consider that when the percentage of initial discrimination is lower than 60%, it is estimated that adaptation to the device will be difficult, with limited results[17] (Figure 1).

A series of contraindications exist for an air-conduction hearing aid, which can classified into the following groups[17]:

1. Related to the external auditory meatus (EAM):

– Absolute: EAM agenesis
– Relative: congenitally narrow EAM or with exostosis, scarring problems, or protrusions from the jaw condyle
– Temporary: EAM obliteration (wax build-up, epidermal plug) or EAM intolerance due to chronic dermatitis

2. Related to the tympanic membrane and areas of the middle ear:

– Relative: open mastoidectomy cavity
– Temporary: active non-marginal perforation from an infectious-inflammatory point of view and marginal perforation with or without cholesteatoma formation

Hearing aids should be prescribed by ENT specialists, who should also monitor the progress of those patients who have adapted to this type of hearing device. Hearing aid adaptation is done by specialized professionals (hearing aid providers) who should choose the device, make any necessary adjustments and arrange any check-ups necessary to determine it is working properly.[17] It is recommended that hearing aid adaptation centres should meet a series of requirements (established by a committee of experts) to ensure adaptation quality.

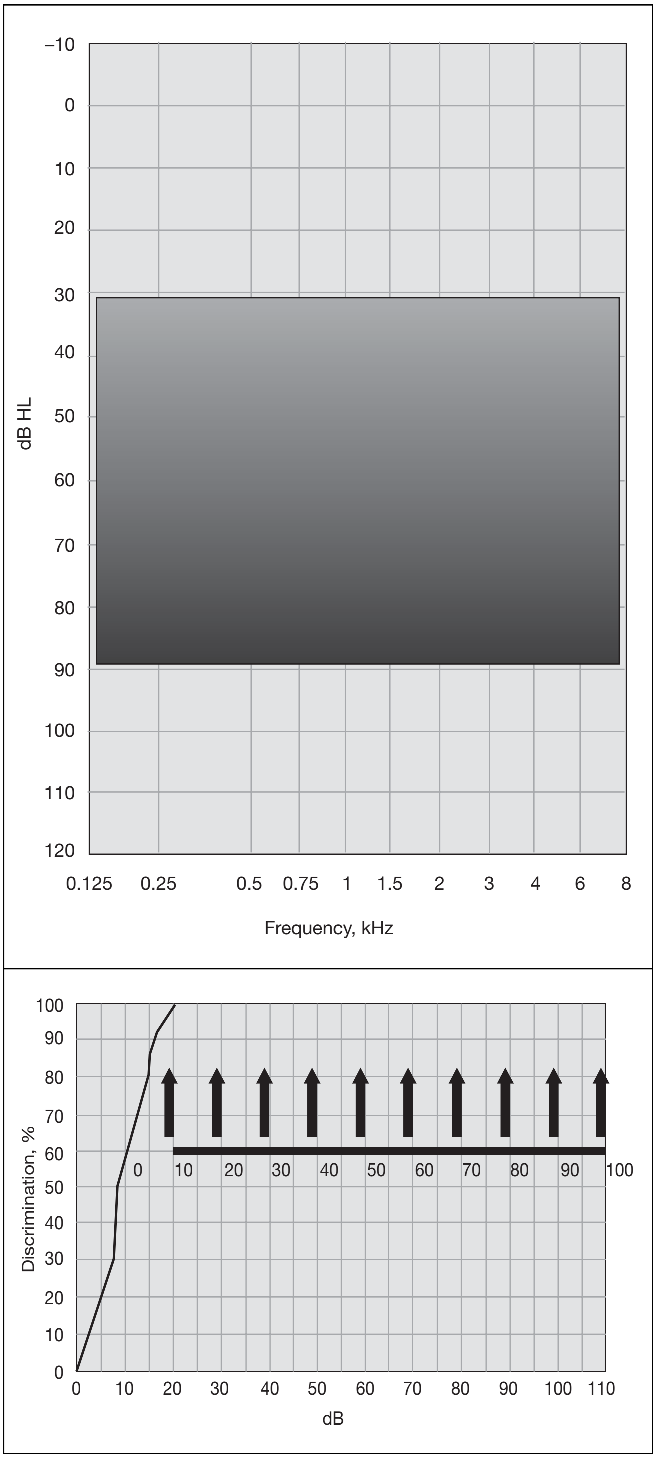


Figure 1. Audiometric criteria for hearing aid indication. An area where the air-conduction thresholds (determined by a tonal threshold audiometry) should be found is superimposed on the audiogram. At the same time, the logoaudiometry graph shows the percentage of discrimination from which the prognosis of audio-prosthetic adaptation is favourable.

Outer-Ear Implants

Outer-ear implants have a maximum frequency compensation between 2000 and 6000 Hz and therefore are devices designed especially for hearing loss mostly with loss of the high-tone frequencies and with a good degree of hearing preservation in the middle and lower-tone frequencies (Figure 2).

The main contraindications are: fluctuating hypoacusis, very narrow auditory canals, skin disease of the area, chronic otorrhea, the need to use hearing protection, and tasks in very contaminated areas.

Active Middle-Ear Implants

The main indications to keep in mind are moderate-to-severe sensorineural deafness. Following the recommendations from the "International consensus on

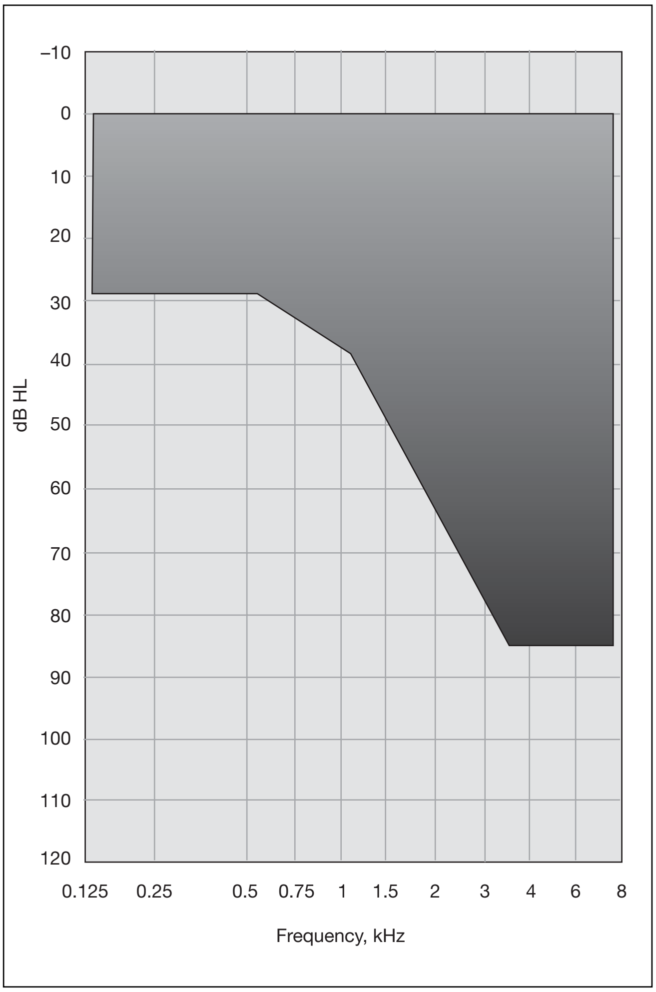


Figure 2. Audiometric criteria for indicating outer-ear implants. An area where the air-conduction thresholds (determined by a tonal threshold audiometry) should be found is superimposed on the audiogram.

middle ear implants,"[19] which took place in Valencia in 2004,[19] it was considered inappropriate to prescribe these if the patient did not benefit from an air-conduction acoustic stimulation hearing device.

The main requirements for prescribing these devices are: the patient must be over 18, have bilateral sensorineural deafness with air-conduction thresholds within the moderate-to-severe range, the differential air-bone threshold for the 500, 1000, 2000, and 4000 Hz frequencies must not be over 10 dB for 2 or more of these frequencies, language discrimination above 50% using the 2-syllable word list, normal functioning, and anatomy of the middle ear, no previous surgeries of the middle ear, no evidence of retrocochlear alterations in the ear canal, and proven dissatisfaction with hearing aids for at least 6 months in the ear to be implanted. Since these implants do not produce an occlusion of the external auditory canal their indication should be considered especially for those patients with chronic infections of the outer ear, such as chronic external otitis and in those cases in which the expectations are realistic and there are no vestibular alterations.[19-21]

As mentioned, these active middle-ear implants are indicated for moderate-to-severe sensorineural deafness. However, the audiometric criteria may present certain variations for each particular device. The audiometric criteria requirements for those devices marketed in Europe with the CE mark are shown in Figure 3.

Cochlear Implants

Most authors coincide in affirming that cochlear implants are indicated for those patients with profound bilateral sensorineural deafness, who do not see much improvement with the use of hearing aids. This condition is due to a wide array of congenital or acquired causes that may occur in the pre-speech, peri-speech, and post-speech phases of language development.

Clinical progress following implantation depends on several factors. These include the stage of onset of hearing loss, the age at which the implant was inserted, the anatomical conditions of the cochlea, and the technology of the cochlear implants. Over time the latter has changed the criteria for indicating a cochlear implant.

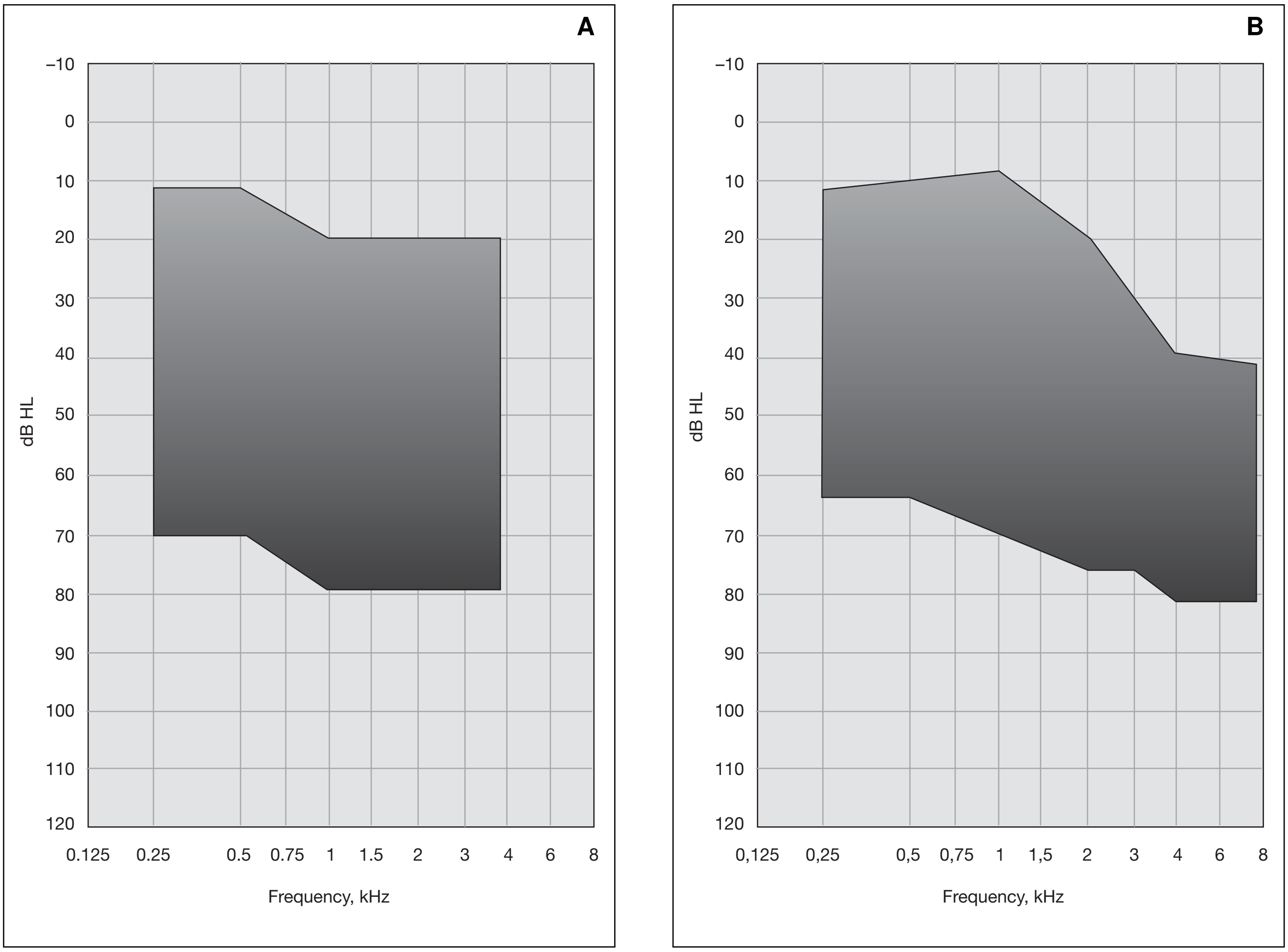


Figure 3. Audiometric criteria for indicating active outer-ear implants. Areas where the air-conduction thresholds (determined by a tonal threshold audiometry) should be found are superimposed on each audiogram for the Otologics MET (A) and Vibrant Sound Bridge (B) devices.

Audiometric criteria are still the most important parameter in deciding whether or not a patient is a candidate for a cochlear implant. The established criteria are given below, together with emerging criteria that may be useful reference points in clinically differentiated situations.

Established Audiometric Criteria

Taking into account the population of adults with acquired language skills and according to the US Food and Drug Administration, a cochlear implant is indicated for bilateral sensorineural deafness with acoustic thresholds >70 dB for the mean of the 500, 1000, 2000, and 4000 Hz frequencies, with free-field tonal audiometry with a hearing aid above 55 dB at the same frequencies and with a discrimination of less than 40% using open word lists and adequate audio-prosthetic equipment at a stimulation intensity of 64 dB HL.[22]

For children, according to the same organization, the audiometric criteria are more restrictive than for adults. Cochlear implants are indicated for bilateral sensorineural deafness with average losses above 90 dB HL (500, 1000, 2000, 4000 Hz).[22] The FDA recommends placing the implant after the child reaches 12 months of age. The reasons for this are the difficulty in performing hearing canal tests, the non-existence of objective evidence to evaluate the acoustic thresholds for the entire frequency range, the limited amount of time testing is done with the hearing aid and concomitant middle ear diseases. All of these can make it difficult to diagnose the degree of hearing loss before 18 months. However, as experience with cochlear implants increases and diagnostic methods improve, it is clear that the age trend tends to lean toward younger ages. This is the determining factor for results following implant placement due to the existence of a critical period for acquiring language, namely during the first few years of life. This means that the current minimum age limit is marked by diagnostic certainty in order to determine the degree of hearing loss.[23]

There is a large number of "traditional candidates" that meet these audiometric requirements. However, for some of them it is necessary to place special detailed emphasis on the final indication of the implant since very important prognostic factors are involved. Such is the case with:

– Teenagers and adults with hearing loss that appeared in the pre-speech phase[24]

– Patients with congenital inner ear malformation or with different degrees of cochlear ossification[25,26]

– Candidates with other disabilities related to hearing loss[27]

Emerging Audiometric Criteria

Bimodal stimulation. Following a series of clinical trials, there is a tendency to place implants in patients with severe sensorineural deafness in one ear and profound deafness in the other. Clinical experience has shown that these patients simultaneously use a cochlear implant in the ear with the higher degree of deafness and a hearing aid in the other. This stimulation paradigm is called the bimodal strategy. Through this strategy, these patients have been shown to reach stereophony and improved language discrimination, both in quiet as well as noisy situations, in comparison with the results obtained using only hearing aids or a cochlear implant.[28,29]

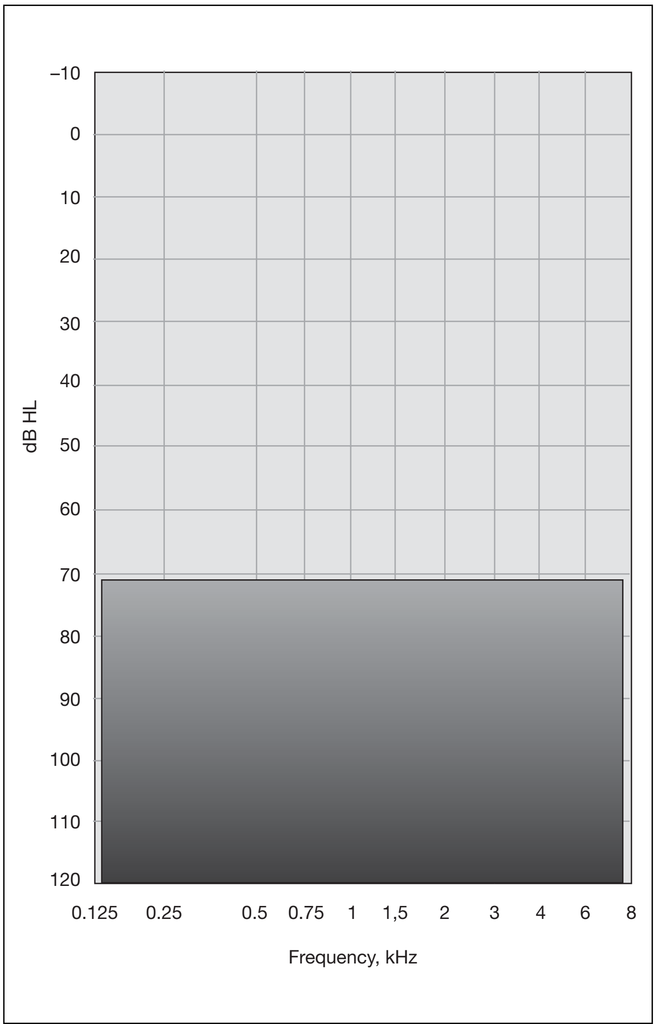
The audiometric criteria used will be as follows: profound sensorineural deafness in one ear and severe (71-90 dB) in the other. The cochlear implant will be placed in the ear that is worse[30] (Figure 4).

Implantation in patients with residual hearing. There are patients that have good residual hearing at lower-tone frequencies and abrupt hearing drops at middle and high-tone frequencies. This group of patients usually has poor spoken language discrimination that does not substantially improve with hearing aid use. In these patients, by using special electrode guides and a refined surgical technique known as "atraumatic" surgery, it is possible to preserve what is left of the hearing in the implanted ear. This circumstance allows, within the same ear and simultaneously, for electrical stimulation with the cochlear implant and acoustic stimulation with the hearing aid (hybrid stimulation). The results with this stimulation paradigm indicate that the patients are capable of hearing significantly better, especially in noisy settings, and can reach a satisfactory level of musical perception.[31] Even though this method of treatment is still in the experimental stages, and there are no standard criteria, we would be able to include patients in this method when they meet the following criteria: *a)* patients must be over 18; *b)* they must have post-speech phase sensorineural hearing loss for frequencies over 1500 Hz and slight to moderate post-speech phase sensorineural hearing loss for frequencies over 500 Hz, with no audiometric restrictions for the contralateral ear (Figure 5); *c)*the duration of the hearing loss must be under 30 years; and *d)* they must be able to recognize disyllabic words with assistance (correctly adjusted device) between 10% and 50% in the ear due to receive the implant, both in situations of silence and at 65 dB SSPL.

Bilateral cochlear implants. Several studies show clear benefits for patients undergoing bilateral implantation since it allows them to localize sounds, obtain a summation effect, avoid the head shadow effect and improve language discrimination in noisy settings.[28,32] The most widely-used audiometric criterion for simultaneous or sequential indication of a bilateral cochlear implant is profound sensorineural deafness in both ears, with little discrimination of 2-syllable words (less than 40%) with the use of adequately adapted hearing aids.

Auditory Brainstem Implants

The selection criteria for candidates for an auditory brainstem implant (ABI) have changed over time. For years it was mostly indicated in patients as a treatment for tumorous formations at the level of the 2 acoustic nerves within a context of a type II neurofibromatosis. For these cases, the accepted criteria for indicating a ABI were based



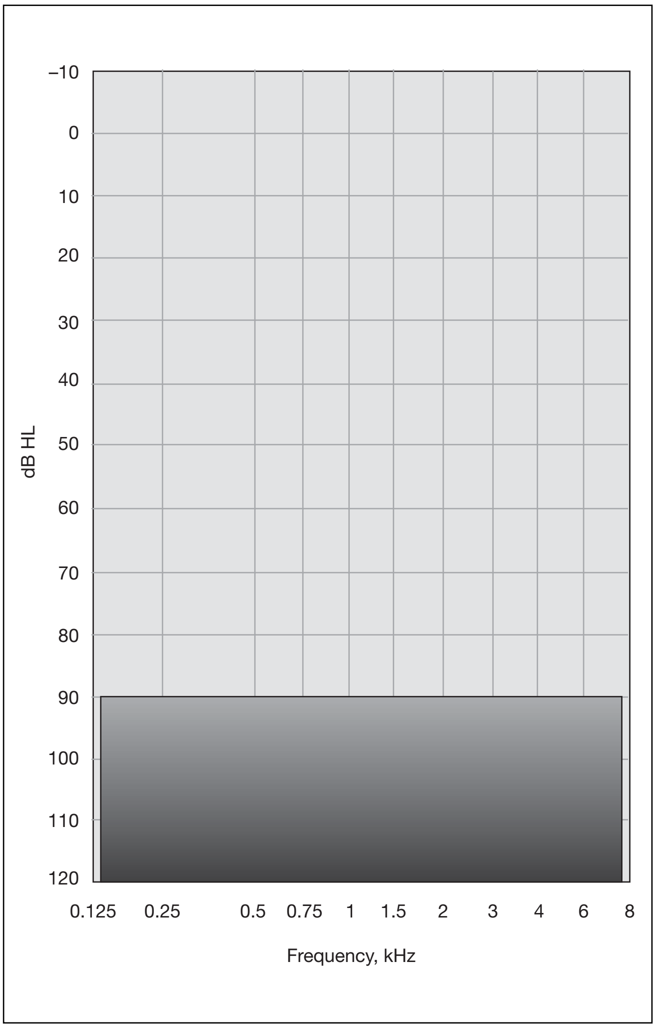


Figure 4. Audiometric criteria for indicating a cochlear implant for bimodal stimulation cases. Audiograms from both ears can be seen. Areas where the air-conduction thresholds (determined by a tonal threshold audiometry) should be found for the cochlear implant (thresholds >90 dB HL) and the hearing aid (thresholds of 70-90 dB HL) are superimposed on each one.

on the following: *a)* patients diagnosed with type II neurofibromatosis that led to a severe bilateral dysfunction of the acoustic nerve; *b)* patients who were over 15 years of age; *c)* implantation could take place during initial surgery to remove a tumour, or in subsequent surgery on the other side, or following bilateral extirpation of tumours, or after diagnosis of bilateral trauma-induced dysfunction of the acoustic nerve; less frequently the implantation could be done during follow-up surgery following the extirpation of the neurofibromas in the initial surgery; *d)* the candidates must meet medical and psychological requirements that allow for the surgery to be performed with general anaesthesia and adequate collaboration during the acoustic recovery process following surgery; *e)* the patients must be prepared and motivated to participate in the scheduled programming, evaluation and follow-up sessions; and *f)* audiological criteria are not specified due to the fact that the natural progression of tumours located in the cerebellopontine angle, the usual translabyrinthine approach used for extirpation, and the traumatic origin of the bilateral lesion of the VIII pair in themselves cause deafness in the patient. However, in those patients with useful hearing levels, considering the Briggs-Brackmann[33] and Doyle-Nelson[34] criteria, a selective approach for our indications can be used by following this outline:

– Bilateral tumour <1.5 cm with normal bilateral hearing: conservative unilateral resection surgery through the middle fossa. An ABI will be implanted during a second procedure in the light of the results from the first surgery and tumour control

– A tumour that is <1.5 cm associated with a contralateral tumour larger than 23 cm, with useful hearing: surgery for resection of the larger tumour by way of a translabyrinthine approach with an ABI and observation of the second tumour and therapeutic decisions made in view of the progress observed

– Bilateral tumours >23 cm: hearing alterations are frequently seen in these cases. Resection is performed using the translabyrinthine approach as well as placement of an ABI

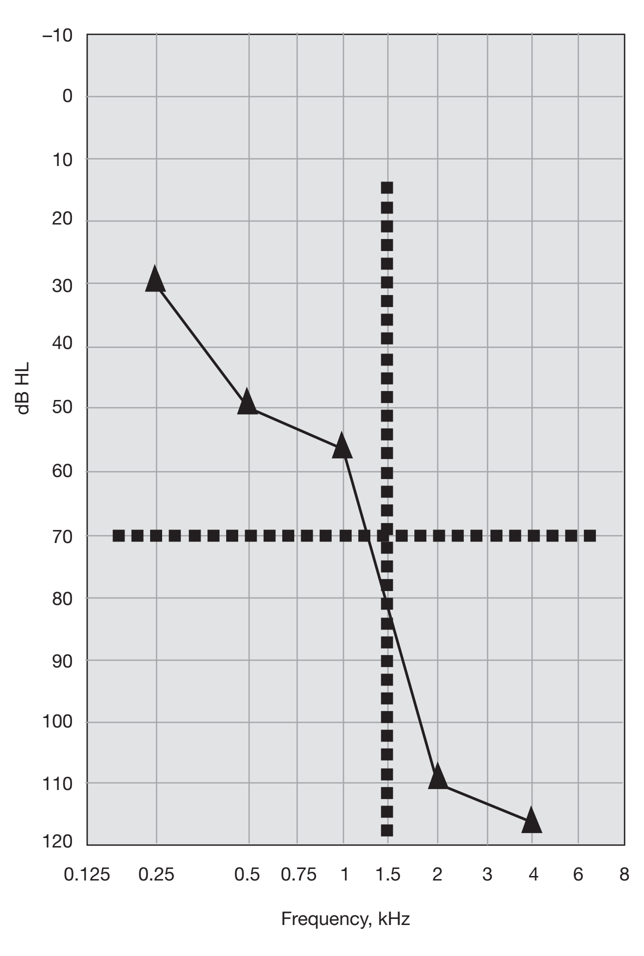


Figure 5. Audiometric criteria for indicating a cochlear implant for residual hearing cases. The airway of a severe-to-profound hearing loss at frequencies above 1500 Hz and slight-to-moderate hearing loss at frequencies above 500 Hz is shown on the audiogram for the ear that will receive the implant.

Emerging Indications

Tumours previously treated with radiosurgery. Initially, this group of patients already treated with radiosurgery was excluded from the indication of an ABI due to the potential deterioration the radiation might induce in the cochlear nuclei.[35-37] However, this criterion is under review in the light of the experience of other authors who have obtained results following implantation in these patients that are comparable with those recorded in other patients not previously treated with radiotherapy.[38,39]

Total bilateral cochlear ossification. Generally speaking, there are not many results regarding patients who underwent cochlear implants presenting situations of complete cochlear ossification linked to a meningitic labyrinthitis.[40] This is due to the difficulties in the normal insertion of the electrodes of the cochlear implant and especially the relevant decrease of stimulatable neurons at the spiral ganglion level. Some authors have shown a relevant improvement in language perception in an open context, in patients treated with an ABI in the same ear that previously had a cochlear implant.[41,42] This information, aside from opening up a new indication for ABI in ears with very advanced labyrinthitis ossificans, provides very satisfactory clinical results in stimulation of an unaltered auditory pathway, such as with cases of type II neurofibromatosis. Because of this, new expectations arise regarding the use of these systems for non-tumorous sensorineural deafness from congenital malformation of the cochlea (agenesis or severe hypoplasia), aplasia of the cochlear nerve, and total ossification of both cochleae with a negative promontorial stimulation test.

Bilateral agenesis of the cochleae and/or cochlear nerves. Despite the fact that this is one of the most hotly-debated emerging indications, the results found and the absence of therapeutic alternatives for restoring hearing led to the first ABI implants being carried out in children suffering from these malformations.[43] The results published so far are very encouraging and no severe complications related with the use of these devices in children have been seen so far. Undoubtedly long-term follow-up of these patients is absolutely essential before any generalizations can be made or the use of ABI in children confirmed.

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