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Otology

Implantable hearing devices in clinical practice. Systematic review and consensus statements

Protesi acustiche impiantabili nella pratica clinica. Revisione sistematica della letteratura e dichiarazioni di consenso

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SUMMARY

Objective. Implantable hearing devices represent a modern and innovative solution for hearing restoration. Over the years, these high-tech devices have increasingly evolved but their use in clinical practice is not universally agreed in the scientific literature. Congresses, meetings, conferences, and consensus statements to achieve international agreement have been made. This work follows this line and aims to answer unsolved questions regarding examinations, selection criteria and surgery for implantable hearing devices.

Materials and methods. A Consensus Working Group was established by the Italian Society of Otorhinolaryngology. A method group performed a systematic review for each single question to identify the current best evidence on the topic and to guide a multidisciplinary panel in developing the statements.

Results. Twenty-nine consensus statements were approved by the Italian Society of Otorhinolaryngology. These were associated with 4 key area subtopics regarding pre-operative tests, otological, audiological and surgical indications.

Conclusions. This consensus can be considered a further step forward to establish realistic guidelines on the debated topic of implantable hearing devices.

KEY WORDS: implantable hearing devices, consensus statement, bone conduction devices, middle ear implants, hearing loss

RIASSUNTO

***Obiettivo**. Le protesi acustiche impiantabili rappresentano una soluzione moderna e innovativa per la riabilitazione uditiva. Nel corso degli anni, lo sviluppo tecnologico di questi dispositivi è stato di particolare rilievo, eppure il loro impiego nella pratica clinica non è uniformemente riportato in letteratura scientifica. L'argomento è stato discusso nel corso di congressi, incontri, dichiarazioni di consenso al fine di poter raggiungere un accordo internazionale sul loro utilizzo. Su questa scia, il presente lavoro ha lo scopo di rispondere alle domande irrisolte che riguardano esami preoperatori, indicazioni cliniche e chirurgiche riguardanti le protesi impiantabili.*

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Materiali e metodi. Il lavoro è stato condotto da un gruppo di lavoro nominato dalla Società Italiana di Otorinolaringoiatria e Chirurgia Cervico Facciale. Un gruppo di ricerca ha effettuato una revisione sistematica della letteratura per identificare le migliori evidenze riguardanti l'argomento e per poter guidare un pannello di esperti nello sviluppo delle indicazioni.
Risultati. Ventinove dichiarazioni di consenso sono state approvate e raggruppate in 4 categorie principali: esami pre-operatori, indicazioni otologiche, audiologiche e chirurgiche.
Conclusioni. Il presente lavoro rappresenta un ulteriore e necessario passo avanti nello stabilire linee guida realistiche sul dibattuto tema delle protesi acustiche impiantabili.

PAROLE CHIAVE: *protesi acustiche impiantabili, dichiarazione di consenso, protesi impiantabili a conduzione ossea, protesi dell'orecchio medio, sordità*

Introduction

In recent decades, a wide range of implantable hearing devices have been developed. These innovative devices have increasingly powerful technologies and performances that offer an alternative solution to conventional hearing aids (CHAs) and cochlear implantation. Along with their development, audiologists and otologists have sought and experimented with new applications for these implantable devices. Currently, however, there is no universal agreement in the scientific literature [1]. Congresses, meetings, conferences, and consensus statements have been organised internationally to achieve this goal. The choice of a specific hearing implant is a complex decision based on many factors; besides audiological indication criteria, there are objective (e.g. anatomical, surgical) and subjective (e.g. expectations) issues to consider.
Recently, consensus was reached involving otolaryngologists, audiologists, health policy scientists and representatives/technicians of the main companies in this field. It provides a first framework for clinical, surgical, and audiological procedures on implantable devices. The aim was to deliver a technical characterisation of these devices to enhance effective communication between the various stakeholders, and thus improve health care [1]. The consensus underlines that the scientific literature does not lead to comprehensive results for these devices. Moreover, the lack of standardised formats of study designs, results reporting, and nomenclature hinder the compilation of meta-analyses [1]. The aim of the present work is to build on the recommendations laid down by the previous consensus and carry on the process of defining clinical, audiological indications and pre-operative and surgical recommendations.
On these bases, a tailored, personalised treatment of otological-audiological treatment is looming on the horizon.

Current state of art

"Implantable hearing devices" is a broad denomination under which we consider any semi- or fully implantable device available on the market: bone conduction devices (BCDs), middle ear implants (active and passive), cochlear implants (CI), auditory brainstem implants (ABI) and electroacoustic stimulation (EAS). However, CI, ABI and EAS systems are generally considered as separate categories of implantable hearing devices. Likewise, passive middle ear implants including partial ossicular replacement prosthesis (PORP) and total ossicular replacement prosthesis (TORP) do not feature the conversion of an electric signal into a mechanical stimulus, and therefore will not be considered in the present consensus exercise.
Given these premises, we will look further into the technical aspects regarding BCHIs, also traditionally defined as bone-anchored hearing aids, and active middle ear implants (AMEI) (Fig. 1).

Bone conduction devices (BCDs)

Bone conduction is a very efficient hearing pathway that bypasses impaired external and middle ear structures. Acoustic signals are transformed into mechanical vibrations that are sent directly to the inner ear (direct-drive BCD) or through the intact skin (skin-drive BCD) [2].
Therefore, BCDs are conceived for patients with conductive hearing loss (CHL) but might also be useful in cases of mixed hearing loss (MHL) or in those who suffer from single-sided deafness (SSD).
BCDs can be divided into two main categories: 1) percutaneous BCDs that require a titanium screw permanently penetrating the skin and the bone coupled with an external audio processor attached to the end of the screw; 2) transcutaneous BCDs that require an external part coupled with the internal part through a magnetic field, with intact skin. When the transducer is positioned externally, it is defined as passive, while, when the transducer is directly coupled to the bone, under the intact skin, the system is described as active.

Percutaneous BCDs

Percutaneous BCDs were the first bone-anchored hearing aids to be introduced into clinical practice in 1977 [3]. They were indicated for patients with CHL or MHL who did not benefit from or could not be fitted with CHAs, i.e. patients with external ear canal closure, ear malformations, surgical

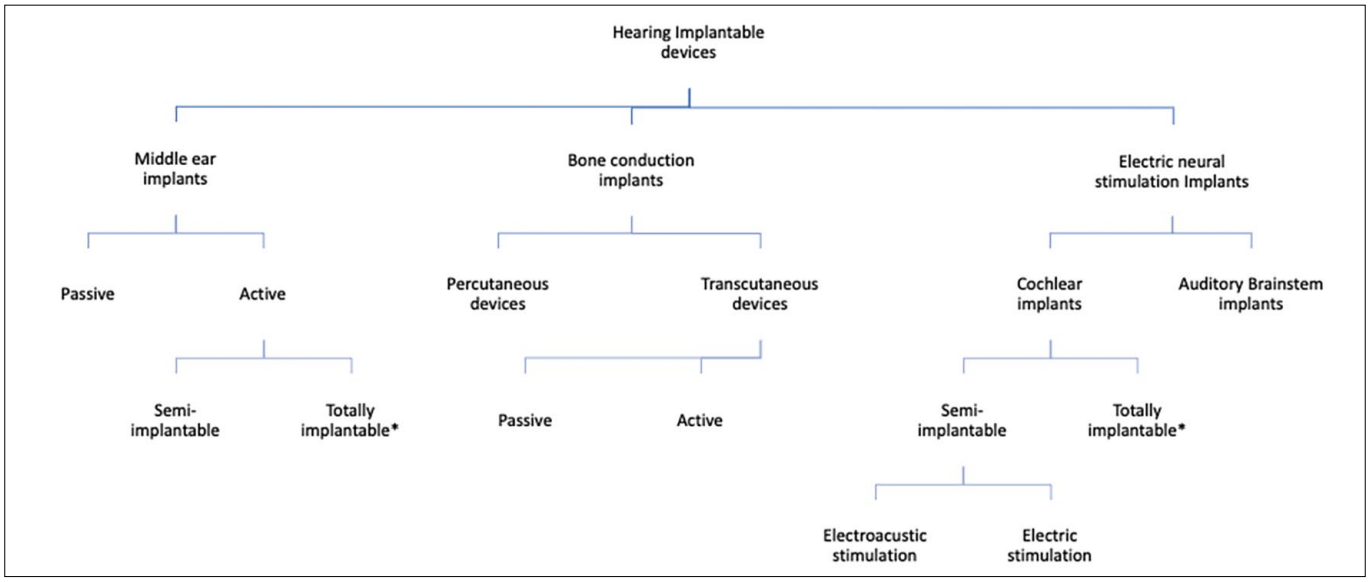

Figure 1. Currently implantable hearing devices. *Not available in the European market.

mastoid cavities, or recurrent otitis. Since their introduction, percutaneous BCDs have undergone many technological improvements, refining the surgical technique and expanding their clinical indications, as in SSD scenarios [4]. The main advantage of percutaneous systems is the efficient transmission of the sound directly to the inner ear, avoiding skin and subcutaneous attenuation of the vibration. However, these devices require osseointegration of the screw, the failure of which will affect the performance of the device. The main disadvantages of these devices are related to the daily hygiene of the implant, the aesthetic aspect, and a non-negligible rate of overall complications that emerges from the literature [5].

Transcutaneous BCDs

Transcutaneous BCDs have been developed to overcome the weaknesses of percutaneous devices by preserving skin integrity and maintaining an acceptable aesthetic level. In this category of devices, the abutment is replaced by an internal part housed into the skull. As previously mentioned, if the transducer is placed outside the body it is referred to as a passive system, while if the transducer is placed on the bone it is referred to as an active system.

The external part of a passive transcutaneous device contains the transducer and a magnet, the vibration of which induces a subsequent vibration (indirect) of the internal implanted magnet. The main audiological disadvantage is the attenuation of vibrations caused by the skin impedance of about 10-20 dB [6]. Transcutaneous active BCDs avoids the skin attenuation effect as the implanted transducer, that does not require osseointegration, and directly vibrates onto the mastoid bone (transmastoid placement). Alternatively, it can be safely implanted in various positions of the skull such as retrosigmoid and suprameatal placements [7]. Environmental sounds are picked up by the external microphone, and then digitally compressed and modified. The signal, as well as the energy to drive the internal part, are transmitted transcutaneously to an internal coil via an inductive link. However, due to the analogue electromagnetic signal transmission, the greater the distance between the induction coils, the lower the voltage induced in the receiver coil (about 1.5 dB/2 mm) [8].

Active middle ear implants (AMEIs)

AMEIs stimulate mobile middle ear structures (i.e., ossicles, stapes footplate) or the cochlea via the round window membrane. These devices were introduced in the late ’90s and were intended for patients with mild-to-severe sensorineural hearing loss (SNHL) who are unable to tolerate CHAs. The Vibrant Soundbridge (VSB) (MED-EL, Innsbruck, Austria) is the only currently available AMEI on the market. More recently, audiological indications have been extended to CHL or severe-to-profound MHL. In cases of MHL, the VSB bypasses the middle ear structures and overcomes the conductive component of the hearing loss, an additional stimulation provided by the audio-processor that presumably also improves the bone conduction threshold [9].

Aside from audiological indications, otological indications for AMEIs are still a source of debate. Details will be discussed herein [10].

Materials and methods

In February 2022, the Italian Society of Otorhinolaryngology called "Società Italiana di Otorinolaringoiatria e Chirurgia Cervico Facciale" (SIOeChCF) proposed a Consensus Working Group (CWG) consisting of five Italian experts in implantable hearing devices. The CWG was elected by the Board of SIOeChCF with the aim of establishing a consensus regarding implantable hearing devices (Fig. 2).

To reach this goal, the CWG had to achieve different steps, namely: evaluate the suitability of the implantable acoustic devices as the subject of a clinical consensus statement, find a method group to supervise and approve all the steps of the consensus, define the questionnaire, recruit the panel, vet potential conflict of interests among proposed panel members, evaluate the results, follow the work of the panel, draft preliminary statements after consensus, write the draft of the manuscript and publish and promote the consensus.

Evaluation of the literature and systematic reviews on this topic have underlined that implantable acoustic devices are an ideal subject for consensus statements. Many questions about preliminary tests, surgical indications and procedures are not yet well defined in the scientific literature.

In February/March 2022, the laboratory of systematic reviews and guidelines production of the Mario Negri Institute for pharmacological research IRCCS of Milan was identified as the method group.

At the same time, the CWG identified a multidisciplinary panel of 16 experts that was approved by the SIOeChCF. The members of the panel were otolaryngologists (n = 13), audiological physicians (n = 2) and 1 patient.

The panellists were asked to be actively involved in all stages of the modified Delphi consensus process. CWG and panel members disclosed their conflicts of interest.

A questionnaire consisting of 29 multiple choice questions was written by the CWG. The questions regarded pre-operative tests, indications for implantable device use and surgical procedures. This questionnaire was evaluated and validated by the SIOeChCF. Afterwards, the method group performed a systematic review relative to each single question to identify the best evidence and guide the panel in developing clinical statements that could help fill evidence gaps and assist otolaryngologists in the management of devices. The systematic literature search was conducted in Medline/Pubmed, Embase and Cochrane Library from their inception up to June 2022 with the assistance of a professional database search consultant and included systematic reviews, randomised and non-randomised controlled trials and non-controlled studies. Methodological quality of the included reviews was assessed using AMSTAR 2 [11], randomised controlled tri-

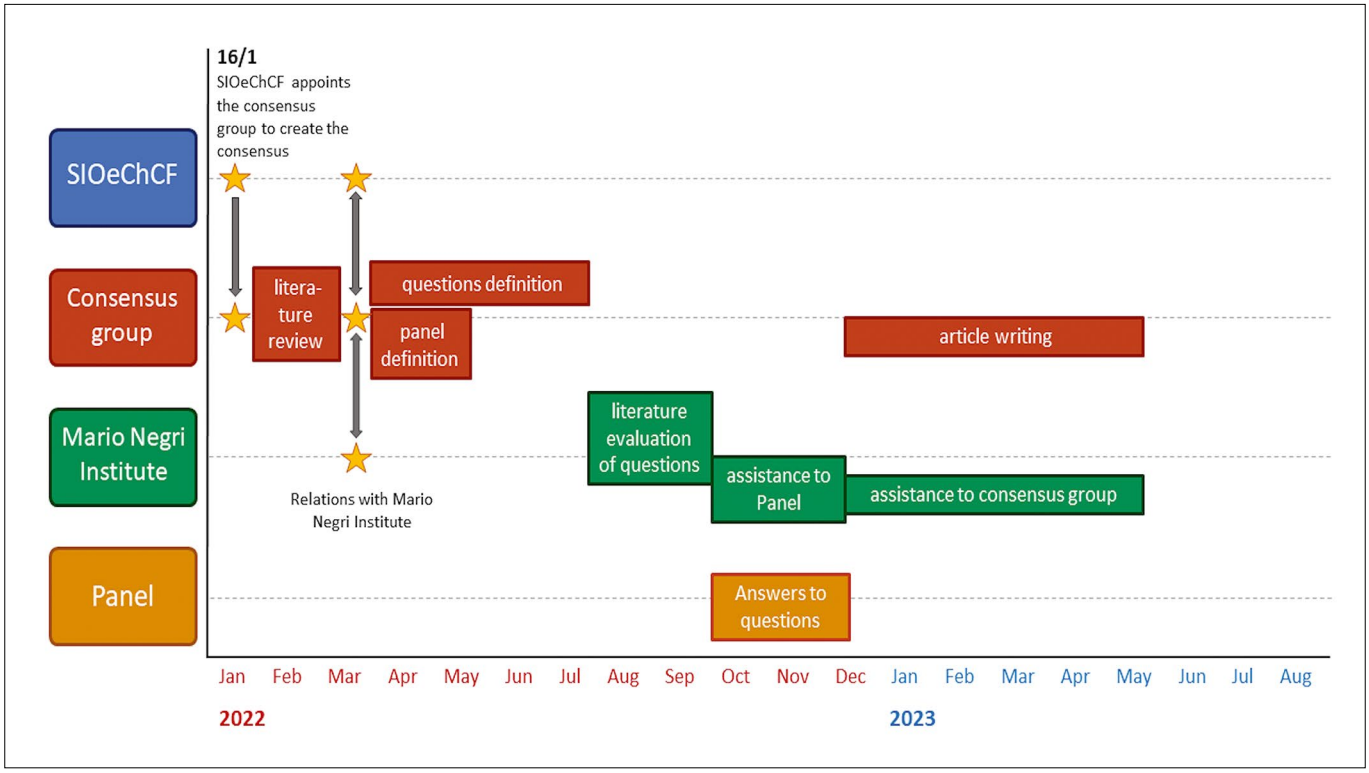

Figure 2. Gantt diagram of consensus development.

als was assessed using the Cochrane Criteria [12], non-randomised controlled studies with the Newcastle-Ottawa scale [13], and uncontrolled case series quality was assessed using The National Institutes of Health quality assessment tool for case-series study [14]. These criteria were listed in the evidence tables and summary documents. All panellists received a summary of the results of the searches and the data taken from the included studies, evidence tables (one per study) containing the main characteristics of each included study/review, the keywords used to build the bibliographic search string, the results of the search, the number of excluded/included studies with reasons for exclusion, and the evaluation of the risk of bias/methodological quality of each included study/review.

From October to December 2022, a modified Delphi process [15] was used to reach a structured consensus on each question. Summaries of the results of the Delphi rounds were anonymous. The panel members were asked to select one or more answers, when appropriate, for each question. Accepting a statement required a predetermined minimum of 70% consensus from all panellists. The statements which did not reach 70% consensus were subjected to a second round of voting. Thereafter, for the residual statements without a consensus, a third round was done. At the end, all 29 questions gained 70% consensus and were accepted as consensus statements.

If a panel member did not answer a question, it was either because they abstained or did not feel qualified to answer. Panellists who responded that they were unqualified to answer a given question were not considered for measurement of agreement for that statement.

With the panel responses the statements were defined. Subsequently, based on these, manuscript for international disclosure was drafted. Consensus statements were associated with 4 key area subtopics: 1. Pre-operative tests (2 consensus statements); 2. Otological indications (5 consensus statements); 3. Audiological indications (13 consensus statements); 4. Surgical indications (9 consensus statements).

Results

Table I shows the consensus results with the round and percentage of approval by the panel. The appendix document contains the evidence tables, search strategy, PRISMA flow diagram, and list of excluded studies for each statement.

Pre-operative tests

Statement 1. Audiological tests, imaging and questionnaires are necessary for the pre-operative evaluation in candidates for surgery.

According to the evidence found in the systematic review, candidates for the placement of BCDs and AMEIs require audiological tests including pure tone audiometry, speech audiometry also in free field, in aided and unaided conditions [9,16-18].

Radiological evaluations must include petrous bone high-resolution computed tomography (HR-CT) without contrast enhancement and gadolinium-enhanced magnetic resonance imaging (MRI) of the brain. They provide an accurate anatomical study for the positioning of the device, identification of possible malformations conditioning surgical complications, and detection of incidental lesions requiring MRI follow-up [19]. Finally, it is essential to carry out accurate pre-operative counselling to evaluate the patient's goals and expectations, and the presence of adequate compliance both with surgery and post-operative rehabilitation (repeated fittings, speech therapy rehabilitation, etc.). A psychologist as well as the use of specific questionnaires are part of pre-operative counselling (A1 in Appendix, pp. 2-7).

Considering all the aspects described so far, the panel believes that the above-mentioned audiological and radiological examinations, questionnaires, and counselling are necessary as pre-operative evaluation.

Statement 2. Audiological tests with soft band are useful only for BCDs candidates and not for AMEI candidates.

When considering BCDs, pure tone and speech audiometry in free field with a bone vibrator positioned using softband can be useful [20]. These techniques allow to define the cochlear reserve and predict the post-operative effective gain [21]. They also assist the patient's choice by simulating the auditory sensation after surgery (A2 in Appendix, pp. 8-10).

On the contrary, the panel believes that the softband is not a useful pre-operative examination for AMEI candidacy.

Clinical and surgical indications

Otological indications

Statement 3. For the treatment of chronic otitis media, implantation of BCDs is recommended only after failure of other surgical treatments.

In cases of chronic otitis media with or without cholesteatoma, the main surgical goal is eradication of the disease, while restoration of hearing is desirable but not always achievable. As reported by Lucidi et al. [22] in 2022, higher post-operative hearing thresholds correlate with worse outcomes on most questionnaires assessing quality of life. Percutaneous BCDs require the insertion of an abutment in a reliable and simple procedure. Four of the studies identified in the systematic review concluded that these devices are an effective option to restore hearing [23-26]. Similarly, active transcutaneous BCDs proved their efficacy in two other studies [23,25]. As shown by the quality-of-life questionnaires,

Table I. Consensus statements with results in voting rounds 1, 2 and 3.

Consensus statements	Voting round 1	Voting round 2	Voting round 3
Pre-operative tests			
Statement 1. Audiological tests, imaging and questionnaires are necessary for the pre-operative evaluation in candidates for surgery.	Consensus statement reached ≥ 70% agreement (75%)		
Statement 2. Audiological tests with soft band are useful only for *BCDs* candidates and not for AMEI candidates.	Consensus statement reached < 70% agreement (60%). Round 2 was necessary	Consensus statement reached < 70% agreement (69%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (75%)
Otological indications			
Statement 3. For the treatment of chronic otitis media, implantation of *BCDs* is recommended only after failure of other surgical treatments.	Consensus statement reached < 70% agreement (60%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (86%)	
Statement 4. Implantation of an AMEI (VSB) is recommended only after years of recovery from chronic otitis media (dry ear, imaging of the middle ear free from cholesteatoma).	Consensus statement reached < 70% agreement (57.1%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (86%)	
Statement 5. Percutaneous *BCDs* are useful for the treatment of CHL/MHL due to otosclerosis. These devices are recommended only in cases of surgical failure, or in cases in which a surgical revision exposes the patient to a high risk of deafness and CHAs cannot be fitted.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (80%)	
Statement 6. AMEIs are useful for the treatment of severe/profound MHL due to otosclerosis, placed during or after stapes surgery.	Consensus statement reached < 70% agreement (46.1%). Round 2 was necessary	Consensus statement reached < 70% agreement (64%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (73%)
Statement 7. CHL in children, especially if bilateral and greater than 35 dBHL, should be treated surgically (e.g., by placement of ventilation tubes) or by CHAs in order to treat the hearing impairment that adds to the patient's cognitive disabilities.	Consensus statement reached ≥ 70% agreement (71.4%)		
Audiological indications			
Statement 8. *BCDs* are a second treatment option after contralateral routing of signals (CROS) system or CI for the treatment of the SSD.	Consensus statement reached < 70% agreement (57.1%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (93%)	
Statement 9. In SSD the percutaneous *BCD* should be used in order to optimise sound conduction and to reduce retroauricular incision that can lead to problems for a future CI positioning.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (79%)	
Statement 10. CHAs are the best choice for asymmetric SNHL when CIs are not indicated.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached < 70% agreement (60%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (80%)
Statement 11. In asymmetric hearing loss, if you decide to use a bone conduction device, percutaneous *BCDs* should be used in order to optimise the sound conduction and to reduce retroauricular incision that can lead to problems in future CI positioning.	Consensus statement reached < 70% agreement (42.8%). Round 2 was necessary	Consensus statement reached < 70% agreement (53%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (80%)
Statement 12. In case of CI treating a severe hearing loss, and contralateral moderate-to-severe hearing loss without the possibility of fitting a conventional hearing aid, the best choice is a bimodal stimulation with CI in the worse ear and an AMEI or *BCD* in the better ear.	Consensus statement reached < 70% agreement (66.7%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (93%)	
Statement 13. *BCDs* are indicated in children affected by a permanent unilateral CHL/MHL because without the rehabilitation of the weak ear, the neurologic pathway of binaural hearing does not develop, and the child will never be able to reach the binaural advantages such as localisation and speech in noise.	Consensus statement reached < 70% agreement (46.1%). Round 2 was necessary	Consensus statement reached < 70% agreement (67%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (73%)

continues ▶

Table I. Consensus statements with results in voting rounds 1, 2 and 3 *(follows)*.

Consensus statements	Voting round 1	Voting round 2	Voting round 3
Statement 14. AMEIs are indicated in children affected by a permanent unilateral CHL/MHL because without the rehabilitation of the weak ear, the neurologic pathway of binaural hearing does not develop, and the child will never be able to reach the binaural advantages such as localisation and speech in noise.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached < 70% agreement (60%), Round 3 was necessary	Consensus statement reached ≥ 70% agreement (80%)
Statement 15. In adults affected by unilateral CHL/MHL, *BCDs* are not able to restore the binaural hearing due to reduction in transcranial attenuation.	Consensus statement reached < 70% agreement (46.7%). Round 2 was necessary	Consensus statement reached < 70% agreement (60%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (80%)
Statement 16. In adults affected by unilateral CHL/MHL, AMEIs are indicated because thanks to the selective stimulation of the deaf ear they allow retention of the binaural cues.	Consensus statement reached < 70% agreement (42.8%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (71%)	
Statement 17. In cases where implantable hearing devices are indicated, binaural fitting is strongly recommended for both AMEIs and *BCDs* to treat permanent symmetric bilateral CHL or MHL in children.	Consensus statement reached < 70% agreement (53,8%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (93%)	
Statement 18. In cases where implantable hearing devices are indicated, binaural fitting is strongly recommended for both AMEIs and *BCDs* to treat symmetric bilateral CHL or MHL in adults.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (93%)	
Statement 19. Implantable devices are indicated in patients with temporary stabilisation of progression of hearing loss when audiological/radiological features allow the correct fitting.	Consensus statement reached < 70% agreement (53,3%). Round 2 was necessary	Consensus statement reached < 70% agreement (67%). Round 3 was necessary	Consensus statement reached ≥ 70% agreement (80%)
Statement 20. Auditory deprivation could negatively influence binaural cue rehabilitation, but it is not a contraindication for the implantable devices.	Consensus statement reached < 70% agreement (66.7%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (86%)	
Surgical indications			
Statement 21. Age limits on placing an implantable device are related to the kind of anaesthesia (local or general anaesthesia) and to the anatomical contraindications (e.g., thickness of the skull) but not to the devices.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (93%)	
Statement 22. Surgical procedures for percutaneous *BCDs* may be performed under local anaesthesia in adults.	Consensus statement reached < 70% agreement (60%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (86%)	
Statement 23. Surgical procedure for percutaneous *BCDs* must be performed in an operating theatre.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (73%)	
Statement 24. Surgical procedure for transcutaneous *BCDs* may be performed under local anaesthesia with sedation in adults.	Consensus statement reached < 70% agreement (50%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (73%)	
Statement 25. Surgical procedure for transcutaneous *BCDs* must be performed in an operating theatre.	Consensus statement reached ≥ 70% agreement (76.9%)		
Statement 26. Surgical procedure for AMEIs must be performed under general anaesthesia.	Consensus statement reached < 70% agreement (41.7%). Round 2 was necessary	Consensus statement reached ≥ 70% agreement (78%)	
Statement 27. Surgical procedure for AMEIs must be performed in an operating theatre.	Consensus statement reached ≥ 70% agreement (84.6%)		

continues ▶

Table I. Consensus statements with results in voting rounds 1, 2 and 3 *(follows)*.

Consensus statements	Voting round 1	Voting round 2	Voting round 3
Statement 28. In case of concomitant need for reconstruction of the auricle, the implant should be placed in a more postero-superior location than normal so as not to injure the skin flap and compromise subsequent reconstruction of the auricle/placement of the epithesis.	Consensus statement reached ≥ 70% agreement (92.3%)		
Statement 29. In case of malformities of the middle ear, it is recommended to perform middle ear surgery by reconstructive procedures on the ossicular chain with CHAs if socially useful hearing is not achieved.	Consensus statement reached ≥ 70% agreement (71.4%)		

AMEI(s): active middle ear implant(s); BCD(s): bone conduction device(s); CROS: contralateral routing of signals; CHAs: conventional hearing aids; CHL: conductive hearing loss; CI(s): cochlear implant(s); MHL: mixed hearing loss; SNHL: sensorineural hearing loss; SSD: single-sided deafness; VSB: vibrant soundbridge.

these implants provide an overall improvement in quality of life [24,26] (B1.1 in Appendix, pp. 11-16).
The panel of experts consider it worthwhile to recommend BCDs only after the failure of other surgical treatments. Thus, if multiple surgical procedures are not able to restore the hearing threshold, BCDs can improve hearing loss.

Statement 4. Implantation of an AMEI (VSB) is recommended only after years of recovery from chronic otitis media (dry ear, imaging of the middle ear free from cholesteatoma).
According to the evidence found in the systematic review, in cases of MHL due to chronic otitis media, VSB with the floating mass transducer placed on the ossicular chain or on the round window membrane is effective [27]. The clinical stability of the middle ear is essential for long-term tolerance and the correct coupling of the implant. Therefore, the VSB is not recommended in cases of chronic otitis with active inflammation [27] (B1.2 in Appendix, pp. 17-18).
Consequently, the panel states that middle ear implants are recommended in chronic otitis media without active inflammation (dry ear) or cholesteatoma recurrences only after a reasonable time of stability of the chronic disease. The exact amount of time required cannot be established based on current literature, and as such it should be based on current clinical best practice and the clinician's judgement.

Statement 5. Percutaneous BCDs are useful for the treatment of CHL/MHL due to otosclerosis. These devices are recommended only in cases of surgical failure, or in cases in which a surgical revision exposes the patient to a high risk of deafness and CHAs cannot be fitted.
Stapes surgery has an overall high rate of success; in fact, a post-operative air bone gap closure up to 10 dB is achievable in over 90% of cases during primary surgery [28]. However, some individuals may require revision surgery in which the success rate falls to 78% during the first surgical revision and to 21% during the second revision [29]. Moreover, deafness risk appears to be five times higher after revision surgery than primary surgeries (0.5% or below) [29].
Percutaneous BCDs are not an alternative treatment for otosclerosis, but may provide a third option for a group of patients who are unwilling or unable to benefit effectively from stapedectomy and/or CHAs rehabilitation [23,26]. Quality of life questionnaires show a good result overall using bone implantable device rehabilitation for otosclerosis [26] (B2.1 in Appendix, pp. 19-21).
In agreement with these results, the panel recommends the use of percutaneous BCDs after one or more surgical failures in otosclerosis and when surgical revision exposes the patient to a high risk of deafness and CHAs cannot be fitted.

Statement 6. AMEIs are useful for the treatment of severe/profound MHL due to otosclerosis, placed during or after stapes surgery.
The VBS improves the movement of the ossicular chain in a mobile chain, with a working and correctly positioned piston prosthesis. In advanced otosclerosis, the conductive component of the MHL can be treated by performing a stapedioplasty, while the sensorineural component can benefit from CHAs or from the use of an AMEI such as the VBS [27,30]. The surgical procedure requires stapes surgery and the placement of the floating mass transducer of the device on the incus in a single or two-step procedure [27]. In single-step surgeries, it is recommended to place the transducer on the incus first and then perform the stapedioplasty to avoid misplacement of the prosthesis (B2.2 in Appendix, pp. 22-23).
The panel states that AMEIs are useful in severe/profound MHL due to otosclerosis when placed simultaneously or sequentially with stapes surgery.

Statement 7. CHL in children, especially if bilateral and greater than 35 dBHL, should be treated surgically (e.g., by placement of ventilation tubes) or by CHAs in order to treat the hearing impairment that adds to the patient's cognitive disabilities [31-34].
Otitis media with effusion is the most common cause of hearing impairment in children in developed nations. It is responsible for learning difficulties (speech and reading),

delayed response to auditory input, limited vocabulary, and disturbances in attention [35]. Clinicians should evaluate, at 3- to 6-month intervals, children with chronic otitis media until the effusion is no longer present. If chronic otitis media with effusion persists, surgery is recommended, consisting of tympanostomy tubes and/or adenoidectomy [36]. The bone conduction device, even applied with softband, can be applied to restore hearing impairment after many surgical procedures although there are no clear indications on this from the scientific literature (B3 in Appendix, p. 24).
The panel recommends that chronic otitis media should be treated surgically (e.g., by placement of ventilation tubes) or by CHAs in order to treat the hearing impairment that adds to the patient's cognitive disabilities.

Audiological indications

Statement 8. BCDs are a second treatment option after contralateral routing of signals (CROS) system or CI for the treatment of the SSD.
SSD is another disease where rehabilitation is critical and BCDs can play a pivotal role [37]. The systematic review of the literature reveals that in SSD, BCDs provide improvement in speech perception by reducing the head shadow effect when the acoustic signal comes from the impaired ear [38]. Some authors report better results with BCD and not only with CROS system in summation, but there is no improvement of speech perception in noise when signal-to-noise ratio is different in the two ears [39-41]. Speech recognition seems to be significantly better in the speech poorer ear condition for CROS over BCDs [42].
The literature also reveals that 36.4% of SSD patients rehabilitated with a BCD are non-users. In another review with moderate methodological quality by Wendrich et al. [43], 178 of 471 patients (38%) abandoned their BCD. Better satisfaction and hearing outcomes are reached in cases of mild CHL in the better ear [44] (B4.1 in Appendix, pp. 25-35).
The panel states that BCDs are a second treatment option after CROS system or CI. Therefore, patients should be offered CHAs and cochlear implantation first, and then BCDs.

Statement 9. In SSD the percutaneous BCD should be used in order to optimise sound conduction and to reduce retroauricular incision that can lead to problems for a future CI positioning.
If a BCD is chosen for SSD, the implant should be preferentially percutaneous. As much as all bone implants have few post-operative complications, percutaneous devices minimise the retroauricular surgical approach in preparation for possible reintervention [45-49] (B4.2 in Appendix, pp. 36-41).
The panel states that the percutaneous BCDs must be preferred to optimise sound conduction and to reduce retroauricular incisions that can create problems for future CI positioning.

Statement 10. CHAs are the best choice for asymmetric SNHL when CIs are not indicated.
Treatments for patients with asymmetric SNHL include the use of bilateral CHAs, bilateral routing of signals (BiCROS) systems, BCDs, and CIs [49]. All these therapeutic approaches can be distinguished as treatments that bypass or stimulate the impaired ear. The BiCROS system collects the sound from the poorer ear affected by severe SNHL and sends the acoustic signals to the hearing aid placed on the better hearing ear. However, BiCROS does not restore binaural hearing. Similarly, BCDs behave like a CROS system, stimulating the contralateral better ear via bone conduction, thus precluding true binaural hearing [49]. Cross-stimulation improves sound awareness for sounds coming from the poorer ear, but speech understanding in noise and localisation benefits are limited because both require binaural cues [50]. On the contrary, bilateral CHAs or bimodal stimulation with CI in the worse hearing ear and conventional hearing aid in the contralateral ear may provide binaural hearing, stimulating the most impaired ear as well [49]. Supporting the panel's recommendation, as reported by Marx et al. around 50% of patients chose CHAs as the preferred treatment in asymmetric SNHL [51]. The systematic review, in contrast, shows that BCDs seem to be a good solution for treatment of asymmetric CHL/MHL [52]. Alternatively, BCDs can be placed in the worse ear with a conventional hearing aid in the better ear [53] (B5.1 in Appendix, pp. 42-46).
Based on literature data, in cases of asymmetric SNHL in which CIs are not indicated for audiological or clinical/otological or anatomical reasons, the Delphi consensus panel recommends the use of bilateral CHAs.

Statement 11. In asymmetric hearing loss, if you decide to use a bone conduction device, percutaneous BCDs should be used in order to optimise the sound conduction and to reduce retroauricular incision that can lead to problems in future CI positioning.
The consensus panel states that the ideal bone conduction device to use in asymmetrical hearing losses is the percutaneous BCD. The abutment maximises sound transmission and reduces retroauricular incisions; it does not interfere with possible future middle ear surgery or CI placement (B5.2 in Appendix, pp. 42-46).

Statement 12. In case of CI treating a severe hearing loss, and contralateral moderate-to-severe hearing loss without the possibility of fitting a conventional hearing aid, the best choice is a bimodal stimulation with CI in the worse ear and an AMEI or BCD in the better ear.

Bilateral input to the auditory system enhances the potential for binaural processing which relies on head shadow, binaural squelch, binaural summation and localisation abilities [54-56]. In asymmetrical hearing loss, in case of severe-to-profound hearing loss in the poorer ear and better hearing in the other ear, the best choice is a bimodal stimulation with a CI in the poorer ear and the fitting of a conventional hearing aid in the better ear [57]. In these cases, bilateral input is provided with acoustic amplification from one ear and electric stimulation from the opposite ear. In case of surgical sequelae or a draining ear, the hearing aid cannot be fitted (B6 in Appendix, pp. 47-48).
Based on the literature findings, the panel believes that in the above-mentioned situation, the best choice is a bimodal stimulation with a CI in the worse ear and an AMEI or BCD in the better ear in place of the CHAs.

Statement 13. BCDs are indicated in children affected by a permanent unilateral CHL/MHL because without the rehabilitation of the weak ear, the neurologic pathway of binaural hearing does not develop, and the child will never be able to reach the binaural advantages such as localisation and speech in noise.
BCDs stimulate both the ipsilateral and contralateral ear due to the limited transcranial attenuations of bone conducted sound propagating through the skull. Therefore, cross stimulation is expected to affect sound localisation performance and squelch effect. This could compromise the development of binaural processing even with a correct hearing rehabilitation with a BCD. According to the literature of the systematic review, BCD in unilateral CHL or MHL does not improve sound localisation [38,58]. Regarding speech in noise, Priwin et al. [58] did not find any improvement with speech and noise coming from a source in front of the patient, while other authors found the greatest gain with speech discrimination when noise and speech were separated in some cases only for head shadow reduction [59,60].
These data, even if not definitive because of contrasting results, suggest that the effect of cross stimulation does not preclude binaural cues completely and that BCDs still give good audiological results [61,62] (B7.1 in Appendix, pp. 49-56). For this reason, the panel concludes that BCD fitting is recommended to try to develop the neurologic pathway of binaural hearing in children.

Statement 14. AMEIs are indicated in children affected by a permanent unilateral CHL/MHL because without the rehabilitation of the weak ear, the neurologic pathway of binaural hearing does not develop, and the child will never be able to reach the binaural advantages such as localisation and speech in noise.
The systematic review found that there are only a few articles in the scientific literature [60,63], but the results agree (B7.2 in Appendix, pp. 57-59).
The panellists agree that AMEIs are recommended to develop neurologic pathway of binaural hearing to reach the binaural advantages such as localisation and speech in noise in children.

Statement 15. In adults affected by unilateral CHL/MHL, BCDs are not able to restore the binaural hearing due to reduction in transcranial attenuation.
In this section we deal with the cross-stimulation issue in adults. To approach this topic, it is fundamental to differentiate congenital from acquired unilateral CHL scenarios. Moreover, hearing outcomes must consider different aspects of binaural hearing. According to the systematic review of the literature, these aspects are investigated only by Agterberg et al. [64]. The results show that in congenital unilateral CHL, binaural summation effect was present, but binaural squelch could not be proven. A possible explanation for these poor results relies on two main factors: first, the lack of a fundamental development period might affect binaural hearing abilities; second, crossover stimulation, considered as an additional stimulation of the contralateral cochlea to the BCD side, might deteriorate binaural hearing in patients with unilateral CHL. Crossover stimulation, due to the reduction of the transcranial attenuation in bone conduction, is not the same for all subjects, and the range at each frequency is up to 40 dB [65].
In patients affected by acquired CHL, Agterberg et al. [60] reported better outcomes in binaural summation and an improvement was found in the directional hearing test in aided conditions.
In one other study, by Pfiffner et al., speech perception benefit was reported without analysing binaural hearing aspects [64]. Other authors reported an improvement of sound localisation [67] and a decrease in the handicap scores [68,69] (B8.1 in Appendix, pp. 60-64).
According to the literature findings, in adults affected by unilateral CHL, the panellists recommend fitting a BCD. However, BCDs are not always able to restore binaural hearing, which relies on differences in the inputs to the 2 cochleae; in bone conduction stimulation there is a difference in the inputs to the two ears depending on the transcranial attenuation of the single subject. Obviously, the greater the transcranial attenuation, the more efficient the BCD binaural hearing. Therefore, a hearing test with a softband before considering the BCD fitting seems necessary.

Statement 16. In adults affected by unilateral CHL/MHL, AMEIs are indicated because thanks to the selective stimulation of the deaf ear they allow retention of the binaural cues.

AMEIs can be used in unilateral hearing loss in adults. The systematic review identified only one study on this topic [70]. Zhao et al. concluded that sound localisation ability does not improve in aided conditions with the VSB. No data on speech perception is available (B8.2 in Appendix, pp. 65-66). To develop this consensus statement, the committee supplemented the data with their personal experience concluding that AMEI rehabilitation is recommended, because the selective stimulation of the affected ear allows the retention of binaural cues in adults.

Statement 17. In cases where implantable hearing devices are indicated, binaural fitting is strongly recommended for both AMEIs and BCDs to treat permanent symmetric bilateral CHL or MHL in children.

As much as unilateral implantation provides good audiological results, bilateral BCDs for adults and children have been proposed for binaural listening [71]. Den Besten et al. specifically evaluated bilateral implantation with BCD. They found that both lateralisation and sound localisation were better with bilateral BCDs than with unilateral aided conditions [72]. Roman et al. reported the results of VSB in monaural and bilateral applications (2 cases). All patients wore the device daily with benefit, but the authors did not compare the unilateral versus bilateral application [63]. Although there are few publications on this topic, the consensus was high (B9.1 in Appendix, pp. 67-70); the presenters strongly agree that, in cases where implantable hearing devices are indicated, binaural application is strongly recommended for both AMEIs and BCDs in children.

Statement 18. In cases where implantable hearing devices are indicated, binaural fitting is strongly recommended for both AMEIs and BCDs to treat symmetric bilateral CHL or MHL in adults.

In the systematic review by Colquitt et al. [73], the topic of cross-stimulation is examined. Considering unilateral versus bilateral percutaneous BCDs, in three studies it was demonstrated that bilateral percutaneous BCDs produced better results compared to unilateral percutaneous BCD when noise was presented from the baffle/best side (the side with the percutaneous BCD in the unilateral condition). However, when noise was presented from the shadow side (the side opposite to the percutaneous BCD in the unilateral condition), bilateral stimulation was not superior to unilateral stimulation; a possible explanation is that the percutaneous BCD placed on the shadow (noise) side, increases noise transmission to both ears. Three studies demonstrated that localisation of sound was improved with bilateral percutaneous BCDs. Two studies suggested that bilateral percutaneous BCDs enable binaural hearing.
On the other hand, the recent literature agrees on the bilateral fitting of BCD, also demonstrating better speech results in the squelch setting (noise presented from the shadow side). This is attributed to the enhanced performance of the new generation of auditory processors [74].
Similar results are reported with the VSB AMEI [75,76] (B9.2 in Appendix, pp. 71-74).
Due to the high literature agreement on the topic, the panellists state that in cases where implantable hearing devices are indicated, binaural fitting is strongly recommended both for AMEIs and BCDs in adults.

Statement 19. Implantable devices are indicated in patients with temporary stabilisation of progression of hearing loss when audiological/radiological features allow the correct fitting.

Several papers report good functional results after fitting an AMEI in SNHL [77-79]. Barbara et al. showed that the adoption of an AMEI in unconventional indications could also be beneficial for patients affected by severe-to-profound SNHL. In some cases, it can be a temporary hearing solution before performing CI surgery [80,81] (B10 in Appendix, pp. 75-81).
Based on the literature findings, the panellists agree that implantable hearing aids are also indicated in those patients with temporary stabilisation of progression of hearing loss when audiological/radiological features allow correct fitting.

Statement 20. Auditory deprivation could negatively influence binaural cue rehabilitation, but it is not a contraindication for the implantable devices.

The duration of deafness influences auditory rehabilitation results. A review by Bernhard et al. [10] reported that auditory deprivation lasting more than 12 years leads to poorer performance after CI surgery. In CHL there is not complete sound deprivation; the cochlea is reached by the patient's own voice by bone conduction [65] and there is an evolution of the hearing pathway on that side. However, the asymmetry of the two hearing thresholds does not allow the development of signal processing in the brainstem and precise analysis of the difference of the input that reaches the 2 cochleae (B11 in Appendix, pp. 82-83). These patients will have the advantage of bilateral hearing with a reduction in hearing due to the head shadow effect, but they could have poorer results in binaural hearing.
Based on this knowledge, the panel recommend that auditory deprivation could negatively influence the binaural cue rehabilitation, but it is not a contraindication for implantable devices.

Surgical indications

Statement 21. Age limits on placing an implantable device are related to the kind of anaesthesia (local or general anaesthesia) and to the anatomical contraindications (e.g., thickness of the skull) but not to the devices.

Age does not appear to be a limiting factor for AMEIs, according to the literature [82-84] (B12 in Appendix, pp. 84-88). The indication that emerges from the opinion of the panellists of the consensus is that there are no age limitations for implantable hearing devices. Contraindications are related to anaesthesiologic requirements or anatomical variations (e.g., thickness of the skull).

Statement 22. Surgical procedures for percutaneous BCDs may be performed under local anaesthesia in adults.
The surgical placement of percutaneous BCDs is a procedure where great care must be taken in all steps of the implantation. Precise drilling and placement of the titanium fixture in the temporal bone is paramount to accomplish firm osteointegration.
Since the mid 1990s, the implantation of percutaneous BCDs has usually been performed as a one-stage procedure for both percutaneous BCDs and passive transcutaneous BCDs. The procedure, for both devices, might be performed under local anaesthesia in adults and requires general anaesthesia in children [85,86] (C1.1 in Appendix, pp. 89-91). This now-established finding in the international literature for percutaneous BCDs was also confirmed by the expert panel.

Statement 23. Surgical procedure for percutaneous BCDs must be performed in an operating theatre (C1.2 in Appendix, pp. 89-91)**.**

Statement 24. Surgical procedure for transcutaneous BCDs may be performed under local anaesthesia with sedation in adults. (C2.1 in Appendix, pp. 92).

Statement 25. Surgical procedure for transcutaneous BCDs must be performed in an operating theatre (C2.2 in Appendix, pp. 92)**.**

Statement 26. Surgical procedure for AMEIs must be performed under general anaesthesia.
Regarding the type of anaesthesia, the consensus panel suggests local anaesthesia with sedation for transcutaneous BCDs and general anaesthesia regarding AMEIs (C3.1 in Appendix, pp. 93).

Statement 27. Surgical procedure for AMEIs must be performed in an operating theatre.
The surgery is performed in an operating room with regular sterility precautions [87]. However, an operating room does not seem to be strictly necessary for the placement of percutaneous BCDs. One study reported that the insertion of the percutaneous abutment can be quickly performed in an outpatient setting in a safe and less expensive manner. However, the author recommends considering this option in selected patients [85,86]. On the contrary, the expert panel does not consider an outpatient setting adequate for surgery. Based on the experience of the consensus panel, placing a percutaneous BCDs in an operating room setting is recommended. An operating room is deemed necessary for all kinds of implantable devices by the expert panel, including transcutaneous BCDs and AMEIs (C3.2 in Appendix, pp. 93).

Statement 28. In case of concomitant need for reconstruction of the auricle, the implant should be placed in a more postero-superior location than normal so as not to injure the skin flap and scompromise subsequent reconstruction of the auricle/placement of the epithesis.
Implantable devices are indicated in the case of malformations of the external ear, microtia and/or aural atresia [88-90]. Two main problems arise: the need for cosmetic reconstruction of the external ear and achievement of optimal audiological results.
Regarding the hearing problem, BCDs technology is strongly recommended for children with bilateral aural atresia to support speech and language development [91]. An International Consensus published in 2019 recommends a careful HR-CT scan of the temporal bones, accurate audiological evaluation and test of pre-operative motivation with the softband. The placement of the BCDs or of an AMEI should not interfere with microtia reconstruction. It can be performed after autologous rib graft microtia repair or in combination with ear elevation [91,92] (C4 in Appendix, pp. 94-99). In accordance with the indications of the "International Consensus Recommendations on Microtia, Aural Atresia and Functional Ear Reconstruction", the consensus panel suggests placing the device in a more postero-superior location than normal so as not to injure the skin flap.

Statement 29. In case of malformations of the middle ear, it is recommended to perform middle ear surgery by reconstructive procedures on the ossicular chain with CHAs if socially useful hearing is not achieved.
Congenital aural atresia is a birth defect that is characterised by hypoplasia or aplasia of the external auditory canal, often in association with dysmorphic features of the auricle, middle ear, and, occasionally, inner ear structures. The classification of congenital aural atresia differentiates between stenosis, partial atresia and total atresia. In the last two forms, the tympanic membrane and ossicular chain are often missing, and thus surgical reconstruction is difficult. On the contrary, patients with external auditory canal stenosis display a wide range of ossicular abnormalities, such as fixation of the ossicular chain, which results in a mild-to-moderate CHL. Hearing can be restored in these patients with tympanoplasty and/or canaloplasty procedures. Hearing improvement has been reported in 56% to

82% of patients following such surgeries [93-96]. Generally, an improvement of approximately 15 dB in the air bone gap is observed post-operatively; nevertheless, the hearing improvement presumably depends on the severity of the ossicular deformity and the narrowness of the tympanic membrane/external auditory canal (C5 in Appendix, pp. 100-108). Based on this, in case of mild malformations, the panel suggests to restore hearing with ossicular chain reconstructive surgery and to use CHAs if socially useful hearing is not achieved [88,97-99].

Discussion

In addition to CHAs and CIs, implantable prostheses complete the range of hearing solutions for persons who are deaf. To date, the otolaryngologist or audiologist can choose between three products to treat different types of deafness. However, clinical/audiological indications for these devices often overlap, making it difficult to suggest the best choice to hearing-impaired patients. Sometimes the choice relies upon the specialist or the patient's opinion rather than evidence-based clinical/audiological indications. Over the years, several authors have proposed to define their correct application, but in a way that can be ambiguous. This prompted us to develop consensus statements on implantable prostheses and define precise indications. Twenty-nine consensus statements were developed and approved by the Delphi consensus group. These consensus statements review best practice in diagnosis, clinical and audiological indications, and surgery. They mark a first step toward more precise identification of potential candidates. Thanks to these consensus statements, many unclear aspects in the international scientific literature have been defined. The scientific literature does not specify which pre-operative examinations should be carried out for candidates for an implantable device, while the panel defined, already in the first round of voting, that all audiological examinations, imaging, and questionnaires are necessary to evaluate candidates for surgery. Also, the panel peremptorily stated that implantable hearing devices cannot replace "traditional" surgery. BCDs are indicated only when surgical treatment of chronic otitis or otosclerosis has failed, while AMEI can be used only in the case of dry ear, free from cholesteatoma, or for advanced otosclerosis together with stapedial prosthesis. According to the panel, implantable hearing aids are not the treatment of choice for SSD and asymmetrical hearing loss, and this is in line with the recent scientific literature [39,52,100]. In contrast, in CHL/MHL, implantable hearing aids are useful in adults and necessary in children for adequate cognitive development. Finally, in the case of bilateral symmetrical hearing loss, bilateral fitting of implantable hearing aids is indicated. The consensus statement also addressed some aspects of surgery. According to the expert panel, there are no absolute age limits for implantable device recommendation. Age limits are only related to surgical feasibility, the type of anaesthesia, and anatomical contraindications. In conclusion, the panel believes that the operating room is always the best scenario to place implants and that only percutaneous BCDs can be applied under local anaesthesia in adults.

Conclusions

Consistent guidelines are needed for implantable hearing devices. This consensus marks a first important step in this direction. However, we believe that further studies are required to optimise management and to increase the use of these effective hearing solutions.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

LB, PC, AC, EC, AL formed the Consensus Working Group (CWG). The Authors equally contributed to the design of the consensus statement, wrote the draft of the manuscript, critically revised and gave important intellectual content and final approval of the version to be published; MM, MC formed the method group: they performed a systematic review of literature and guided the panel to develop the statements; MB, MAB, RB, LB, BC, DC, CDF, ADV, FD, PM, AMai, AMar (being part of the panel in quality of patient), EO, EP, GR, NiQ, were members of the panel. All panellists critically examined the literature and selected the answers for each question.

Ethical consideration

Not applicable.

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