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Consensus Statement on Bone Conduction Devices and Active Middle Ear Implants in Conductive and Mixed Hearing Loss

Hannes Maier, Thomas Lenarz, Parwis Agha-Mir-Salim, Martijn J. H. Agterberg, Andreas Anagiotos, Susan Arndt, Geoffrey Ball, Manohar Bance, Maurizio Barbara, Uwe Baumann, Wolfgang Baumgartner, Daniele Bernardeschi, Dirk Beutner, Arjan Bosman, Robert Briggs, Susan Busch, Marco Caversaccio, Markus Dahm, Ernst Dalhoff, Arnaud Devèze, Azadeh Ebrahimi-Madiseh, Bernard Fraysse, Henning Frenzel, Javier Gavilán, Mohammad Ghoncheh, Bo E. V. Hakansson, William Hodgetts, Myrthe Hol, Julian Holland, Marcus Holmberg, Alexander M. Huber, Herman Jenkins, Roulla Katiri, Kiana Kheirkhah, Assen Koitschev, Martin Kompis, Cris Lanting, Luis Lassaletta, Bob Lerut, Rudolf Leuwer, Thomas Linder, Hubert Löwenheim, Lawrence Lustig, Rishi Mandavia, Manuel Manrique, Jorge Humberto Martins, Griet Mertens, Robert Mlynski, Hamidreza Mojallal, Simonetta Monini, Peter Monksfield, Alexander Müller, Emmanuel Mylanus, Hideko Nakajima, Marcus Neudert, Erwin Offeciers, Flurin Pfiffner, Markus Pietsch, Stefan K. Plontke, Nils Prenzler, Milan Profant, Torsten Rahne, Gunesh Rajan, Anna Ratuszniak, Stefan Raufer, Jaydip Ray, Sabine Reinfeldt, Christof Röösli, Tove Rosenbom, Rolf Salcher, Matthias Schönermark, Burkard Schwab, Henryk Skarżyński, Piotr H. Skarżyński, Hillary Snapp, Georg Sprinzl, Michael Spearman, Stefan Stenfelt, Christof Stieger, Stephane Tringali, Eric Truy, James Tysome, Paul Van de Heyning, Nicolas Verhaert, Thomas Wesarg, Patrik Westerkull, Barbara Wollenberg, Thomas Zahnert, Andrzej Zarowski, Ad Snik*

Nowadays, several options are available to treat patients with conductive or mixed hearing loss. Whenever surgical intervention is not possible or contra-indicated, and amplification by a conventional hearing device (e.g., behind-the-ear device) is not feasible, then implantable hearing devices are an indispensable next option. Implantable bone-conduction devices and middle-ear implants have advantages but also limitations concerning complexity/invasiveness of the surgery, medical complications, and effectiveness. To counsel the patient, the clinician should have a good overview of the options with regard to safety and reliability as well as unequivocal technical performance data. The present consensus document is the outcome of an extensive iterative process including ENT specialists, audiologists, health-policy scientists, and representatives/technicians of the main companies in this field. This document should provide a first framework for procedures and technical characterization to enhance effective communication between these stakeholders, improving health care. **Key Words:** Active middle ear implants—Auditory system—Bone conduction devices—Consensus statement—Health policy—Mixed hearing loss—Multi-stakeholder approach—Rehabilitation—Surgery—Technical data.

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Address correspondence and reprint requests to Hannes Maier, Ph.D., Department of Otorhinolaryngology, Medical University Hannover, Carl-Neuberg-Str. 1, 30625 Hannover, Germany; E-mail: Maier.Hannes@MH-Hannover.de

*Authors and their affiliations are listed in the section Authors and Affiliations at the end of the article.

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Since the mid-80 s, several different types of implantable acoustic hearing devices have been developed for patients with conductive and mixed hearing loss. They are proven, indispensable treatment options for hearing impaired patients who cannot use conventional, non-implantable hearing devices or do not profit sufficiently from fitting such devices. Thanks to innovative researchers and manufacturers, several types of these technologically sophisticated devices are on the market. Hence, for each candidate, a choice has to be made out of many. In order to facilitate the clinician in counseling candidates and to initiate the development of a common framework clinicians, researchers and manufactures developed this consensus document in partnership. This document is based on expert opinions in the field of surgical, audiological, technical and political/economic issues.

If reconstructive middle ear surgery is not feasible, or long-term outcomes of the usual surgical approaches are expected to be poor (see review by (1)), or if fitting of conventional hearing devices is contraindicated (e.g., the use of behind-the-ear devices and nonsurgical bone conductors) or is expected to give unsatisfactory outcomes (2,3) implantable hearing devices are a valuable alternative. Available implantable devices as of 2021 can be divided into two broad categories: bone-conduction devices (BCD) and active middle ear implants (AMEI). Currently available devices include percutaneous BCDs (Baha® Connect device, Cochlear BAS, Gothenburg, Sweden and the Ponto system (4), Oticon Medical AB, Askim, Sweden), transcutaneous passive BCDs (Baha® Attract device, Cochlear BAS, Gothenburg, Sweden and the Sophono device, Medtronic, Jacksonville, FL) and transcutaneous active BCDs with an implanted actuator (Bonebridge device, Med-El, Innsbruck, Austria and Osia device, Cochlear BAS Gothenburg, Sweden). The other option is the use of AMEI with its actuator directly coupled to a portion of the ossicular chain or one of the cochlear windows (Vibrant Soundbridge device or VSB, Med-El, Innsbruck, Austria).

There are several significant differences in each of these implantable devices with regard to medical and audiological issues, including indications, invasiveness of surgery, and relative output (gain). The decision which device to choose must be made on the basis of published evidence if available. In addition, results from treatments should be prospectively collected and reported in a standardized format that can be used to provide and extend the evidence of factors crucial for success: the optimal choice of device or class of device, medical issues (complexity of the surgery, safety, adverse events, and stability), audiological issues (assessment procedures, fitting procedure) and the evaluation of the outcomes.

To choose the best amplification option for an individual patient, systematic reviews of the literature might be helpful. Such reviews are popular but have been criticized as they might interfere with a self- critical attitude (4) of clinicians, especially as most of the systematic reviews in this field report on just a single device (5–7). Systematic reviews that are not device-specific are more useful for the clinician, but unfortunately scarce (8). Moreover, the lack of standardized formats of study designs, reporting results and nomenclature hinder the compilation of metaanalyses.

The intention of this work was to initiate the creation of a first framework for clinical procedures (surgical and audiological) and health care issues in order to optimize counseling of patients. The main focus was to agree on a set of device characteristics presented in a uniform and verifiable way, to build evidence and to enable the comparison of different technologies and their results.

Therefore, Consensus Statements Are Needed

During the last several years, there has been a shift from practitioner-centered to patient-centered care (9). Patients should be empowered and encouraged to take an active role in their relationship with clinicians, and clinicians should assist the patient using shared decision making (10). Consensus statements could facilitate this process. An additional impetus for consensus statements is that outcomes vary widely between clinics, irrespective of the type of implantable device used (11). Finally, consensus statements may help clinicians and healthcare providers to discuss reimbursement issues with insurance companies, patients or hospital administrations or other health authorities.

The initiative to develop this consensus report was taken by the first two and the last author, in 2017. The initial meeting and the following public meetings on conferences in the EU and US, where everyone interested in the subject could declare his or her participation, were organized by the same group as well as the compilation of written input.

A concept report was produced that was discussed during the first meeting by invitation, in November 2017. A large group of potentially interested stakeholders; clinicians, health-economists and the manufacturers, were invited. Those who could not participate were invited to comment by mail. We asked all potential participants whether they would like to support further activities and whether they could recommend other experts in the field to support the initiative. Based on the input, an updated version was distributed to all members of the supporting working group, and a Round Table discussion was organized during the International conference on Cochlear Implants and other Implantable Auditory Technologies in Antwerp Belgium (June 2018). With the comments gathered, a second updated version was produced and distributed, and another Round Table was organized during the Osseo meeting in Miami (Osseo 2019; December 2019). After evaluation of all the comments, a third and final version was sent around with the question whether or not the text was adequate and acceptable and whether or not, the recipient, as a member of the supporting group, wanted to be included as a coauthor.

As stated in the title, the present document aims at the application of acoustic implants for patients with conductive or mixed hearing loss; more specifically unilateral application in bilateral hearing loss. It is assumed that the alternatives, surgical reconstruction

and the use of conventional nonimplantable hearing solutions, have been considered and rejected because of medical reasons or (expected) poor outcomes in terms of hearing abilities and speech recognition. In other words, the application of an acoustic implant might be—but is not necessarily—a last resort solution. With regard to surgical reconstruction, Nadaraja et al., recently published a systematic review of the literature showing that, on the average, hearing thresholds after atresia repair were significantly worse than those reported after application of a percutaneous BCD (1). Furthermore, it has been shown that discharging ears, occluded by the ear mold of a conventional device, dry up better after application of a percutaneous BCD (12). Application of the BCD resulted in less otological interventions (13), which is an important advantage in terms of cost-benefit as well as in the patient's convenience. Furthermore, studies indicate that patients with an air-bone gap of more than 30 dB PTA (the mean threshold of 0.5, 1, 2, and 4 kHz) will benefit significantly more from a bone-anchored device than a conventional hearing aid (2,3,14). Similarly it was recently demonstrated that an active acoustic implant with sufficient output can overcome the technical limitations of current conventional hearing aids in cases of severe mixed hearing loss (15).

Bilateral application of hearing devices is not considered in this consensus document. Neither the application of acoustic implants in patients with unilateral hearing impairment, such as unilateral conductive or mixed hearing loss or profound unilateral hearing loss (also commonly referred to as SSD [single-sided deafness]). Furthermore, the focus is on adults and adolescents; the specific needs and challenges of treating young children with conductive hearing loss are not addressed.

Terminology: In this consensus statement, we state mandatory and optional actions (in the opinion of the authors) using the following convention (see e.g., (16)):

- ''Must'' indicates an action or condition which the authors consider mandatory, a necessary prerequisite for successful treatment
- ''Should'' indicates an action or condition which the authors recommend, but do not consider essential for successful treatment
- ''Will'' indicates an action or condition which the authors predict will happen in the future, without implying any obligation to make this happen.

Classes of Devices on the Market for Patients with Conductive or Mixed Hearing Loss

Many new devices to treat hearing deficits are available today, each having new properties and stimulation principles and even more with new features will appear on the market. Therefore, proper definition of devices into classes with comparable properties enables adequate class specific standards for comparison and testing procedures. Although new solutions are currently under development (auditory brain stem implants, auditory mid brain implants) or imaginable (opto-genetic stimulation), the following definitions only comprise classes that are clinically available in 2021. Hence, these definitions are not intended to be complete and have to be extended when new devices become clinically available.

Nonimplantable Solutions

Conventional hearing aids: Devices that stimulate the ear acoustically by air conducted sound (e.g., behind-the-ear devices).

Conventional Bone-Conduction Devices (BCD): Devices that stimulate (vibrate) the skull. The actuator is coupled to the skull by a headband/softband (e.g., Baha or Ponto), or an adhesive fixation (e.g., ADHEAR).

Implantable Systems

Percutaneous BCD: BCD coupled to the skull bone by a skin-penetrating abutment (e.g., Baha device and Ponto system). Also referred to as direct-drive BCD (17).

Transcutaneous BCD: In principle a conventional BCD with a magnetic coupling by an implanted subcutaneous magnet, also referred to as a *transcutaneous passive BCD* or skin-driven BCD (17) (e.g., Sophono device and Baha Attract).

Active transcutaneous BCD refers to a system with an implanted actuator, which communicates wirelessly with the external sound processor over the skin by an inductive link using an RF (radio frequency) transmission technique (e.g., Bonebridge or Osia device).

Active Middle Ear Implants (AMEI), also known as Implantable Middle Ear Hearing Devices: Devices that stimulate mobile structures of the middle ear (ossicles, tympanic membrane) or, directly, one of the cochlear windows by a vibratory stimulus (Vibrant Soundbridge).

Cochlear Implants (CI): Devices that electrically stimulate neural structures of the inner ear.

Requirements for Implant Teams

As rehabilitation with implantable devices involves a high level skill set in several areas, the structure of the multidisciplinary team involved is essential. For proper function of the entire treatment, organizational aspects are crucial.

Following Gavilan et al. (18), the implant team is responsible for the comprehensive treatment, which includes device selection, surgery, device fitting, follow-up, and evaluation. At minimum, this team must consist of an otologist and an audiologist. The otologist provides the medical management of the hearing loss and, is responsible for the implantation. He/she must have advanced experience in otology and implant surgery.

The audiologists/coordinator working either in the implant center or as a local service partner should preferably be qualified to postgraduate level, holding an accredited MSc or similar qualification. He/she should have extensive experience with the fitting of conventional hearing aids and/or implantable devices as well as with validation and verification procedures. Other rehabilitation professionals such as speech language therapists might be also needed, particularly in

meeting the rehabilitation and speech development needs of children.

In a multidisciplinary approach, both the otologist and audiologist must be involved in the selection and evaluation process to continuously optimize the patient selection, surgical procedures and device fitting.

As discussed by Gavilan et al. (18) quality issues and control are essential to successful hearing loss management. We recommend using the statements in their paper entitled ''Quality standards for bone conduction implants'' for all the implantable devices that are discussed in the present paper where they apply. For evaluation of results, a minimum evaluation protocol has previously been developed for AMEI, which enables comparisons between studies and pooling of data (19), and applicable parts should be used for all devices included in this statement.

STATEMENTS

Patient-Centered Issues

The World Health Organization describes patient-centered care as putting the comprehensive needs of people and communities, not only diseases, at the center of health systems, and empowering people to have a more active role in their own health (20). The central point in a patient-centered approach is shared decision making. The implant team must provide comprehensive unbiased counseling to facilitate informed decision making (10). The patient must be given information on all noninvasive and implantable treatment options and on their advantages and disadvantages, including reimbursement issues. The patient must be given an explanation as to why they have been offered a particular device, or choice of devices. Written information on the device(s) offered must also be made available (18).

The implant team must ensure the patient has an appropriate understanding of the information provided before proceeding with the treatment. At minimum counseling should include a review of the following:

- What are realistic expectations for speech perception and sound quality (e.g., music)? How can they be optimized and what are the preferences if one of the qualities has a trade-off with another?
- What is the burden of the surgery, anesthesia, and aftercare, what are the risks and complications, how safe is the treatment, and what are the future consequences (e.g., MRI compatibility)? What about the stability and reliability of the implant and its longevity?
- Personal preferences should be discussed, such as cosmetics, handling of the device, lifestyle, occupational needs, sports with a high risk of impact to the device both the internal and external parts, etc. as well as reimbursement issues.
- Performance over time (i.e., expected life time of the device, compatibility with progressive hearing loss etc., necessity of additional surgeries, e.g., battery exchanges).
- Whenever possible, a pre-surgical trial with a bone conduction or air-conduction hearing device must be performed (BCD on headband or conventional hearing aid). The outcome of the trial should be documented along with audiological tests and hearing-specific questionnaires. Regarding middle ear implants, appropriate test devices that allow a realistic impression of the possible outcome are desirable but not yet available.

If applicable, the candidate should be offered the opportunity to talk with an experienced implant user preferably by the mediation of a patient support group to avoid bias. If the patient already has hearing aids, the appropriateness of the devices and the fitting must be evaluated (18).

Clinical-Audiological Issues

Closely linked to patient-centered care is the audiologist's counseling, based on available evidence. To choose the appropriate device and sound processor, technical specifications are essential for evidence-based decisions. The audiologist must have an overview of those characteristics in relation to the degree of hearing loss, to choose the appropriate solution (see section Technical Specifications).

Selection and Fitting of the Device

When choosing any intervention, indication and contraindication criteria as recommended by the manufacturer must be observed. Amongst others, the sensorineural hearing loss (SNHL) component (bone conduction thresholds) must fall well within the indication range as defined by the manufacturer. Equally crucial for optimal results is that surgeons, audiologists and technical specialists must undergo obligatory training if and as specified and offered by manufacturers to ensure safe and optimal results.

Both a BCD stimulating the skull bone and an AMEI with its actuator coupled to one of the cochlear windows directly stimulate the cochlea, bypassing the impaired middle ear. The selection of BCDs and AMEIs can thus be made according to the procedures developed for the application of conventional hearing devices in pure sensorineural hearing loss. Consequently, the gain (amplification) provided by the implanted device is the difference between the cochlear thresholds (i.e., bone-conduction thresholds) and the aided thresholds with the device implanted, which in the literature is referred to as ''bone-conduction gain'' (21) or the ''effective gain'' (22). Therefore, the effectiveness of the treatment depends only on how well the cochlear loss (as expressed by the bone-conduction thresholds) is ''compensated,'' as for pure sensorineural hearing loss. This implies that if the SNHL component is absent or small, such as in primarily conductive hearing loss (CHL) cases, compensation of the air-bone-gap or even a negative ''effective

gain'' may be sufficient for an effective treatment result (elaborated in the Appendix).

Problems related to determining the ''bone-conduction gain'' or ''effective gain'' may arise from different sources:

The accurate measurement of the cochlear thresholds (bone-conduction thresholds)

For proper application of an AMEI, well-masked bone-conduction thresholds are essential to be sure that the cochlea of the implanted ear is sensitive enough for successful application of the implant; proper measurement of bone-conduction thresholds might be complicated owing to masking problems. On the other hand, for the application of a BCD, masked bone-conduction thresholds are of importance for the selection of the ear to be implanted. However, *unmasked* bone-conduction thresholds of the to-be-treated ear are required for programming the BCD. Because of the limited transcranial attenuation, the cochlea with the best bone-conduction thresholds is stimulated by the BCD; either the ipsilateral or contralateral cochlea (23). Therefore, (any type of) BCD fitting should be based on the unmasked bone-conduction thresholds or in situ thresholds (see remarks next page).

Proper measurement of sound field aided thresholds. Aided thresholds might be affected by nonlinear processing of the sound processor as well as internal noise (24)

A limitation of any device is the level of internal noise. (A) Input noise such as intrinsic microphone noise may mask soft sounds and thus affects measured aided thresholds. To deal with microphone noise, expansion (viz. minimizing the gain for low input levels) can be used to make that noise inaudible (24,25). However, this has a similar effect as input noise, artificially increasing measured aided thresholds, leading to erroneous aided thresholds. This is a common problem when fitting any type of hearing aid. However, patients with predominantly conductive hearing loss might be more likely to hear the noise, owing to their normal cochleae. (B) Device output noise is harder to deal with and leads to a restricted application range (the bone-conduction threshold must be higher than the noise floor) as advocated by the manufacturers. Output noise can be reduced by attenuating the output signal either in specific-build low-noise processors or with integrated switchable attenuators, which, in turn, have the trade-off of an equally reduced maximum power output (MPO).

The other limitation of BCDs and most AMEIs as well as hearing aids, is their limited MPO, which restricts the aided dynamic range of the patient's hearing. To deal with that, a limiting compressor (often referred to as output compression: high compression ratio at high output level) might be used as well as wide-dynamic range compression. Wide-dynamic range compression, however, affects the aided thresholds (elaborated in the Appendix).

Regarding AMEI, output and MPO are also affected by coupling efficiency of the actuator to the cochlea (see section Additional performance specifications). Similarly, the exact placement of the active transcutaneous BCD transducer affects the output and MPO (26). However, in percutaneous BCDs the surgical procedures are well standardized and variation in coupling efficiency is, therefore, less of an issue.

Fitting of the Sound Processor

Fitting rules, limitations of the dynamic range and output measurements.

The main input parameters for fitting the acoustic implant are the bone-conduction thresholds. The first step in the fitting procedure is to choose and apply a fitting rationale (rule), to determine the desired gain and the desired output (25). Fitting rules as used by the manufacturers are e.g. the NAL (National Acoustics Laboratories), DSL (Desired Sensation Level) as well as proprietary prescription rules. After fitting the sound processor, the outcome should be verified, for example, by measuring the aided thresholds and comparing these to the desired aided thresholds as prescribed by the fitting rule (25). Alternatively, the measured effective gain might be compared to the prescribed gain. Discrepancies might occur, owing to specific limitations of AMEIs and BCDs in terms of noise level, variability in coupling efficiency and limited MPO.

Any type of fitting rule requires an input-output relationship with defined input sensitivities and output levels. In devices that have an external sound pick-up, such as BCDs and partially implantable AMEIs, microphones provide an input of well characterized sensitivity and input noise level. Regarding the output levels, for percutaneous BCDs, standardized skull simulators are available (with an abutment input) enabling characterization of the output of these devices (IEC 60118-9 (27)). The output of transcutaneous BCDs can be determined in a similar way on a skull simulator according to IEC 60118-9. However, the so-determined output of a transcutaneous device in terms of hearing level (dB HL) is influenced by individual factors (position of the vibrator, type of attachment) and consequently a dedicated fitting procedure is still missing (see appendix). In contrast to percutaneous BCDs, (active) transcutaneous devices permit the separation of the stimulation position (the implanted actuator) from the processor location and new stimulation sites with different coupling efficiency (see section Additional performance specifications), for example, closer to the cochlea become imaginable. In implantable AMEIs, a well-defined and accepted measurement procedure has been developed to determine the output experimentally when the ossicular chain is stimulated in the forward direction (28). However, even experimental results obtained under controlled conditions in human temporal bones are subject to variability. Here, measures considering the inter-individual variability, such as the concept of coupling efficiency (see section Additional performance specifications) may help

to deal with inter-individual variance and to implement dedicated fitting procedures in the future. The situation becomes also more difficult in fully implantable AMEIs, when even the input sensitivity and noise floor of the implanted microphone might vary between individuals. Consequently, methods to measure the individual microphone sensitivity need to be developed.

- The audio processor must be fitted and programmed by experienced audiologists who have been well trained and are up-to-date with the current evidence and fitting approaches. The device should be fitted and programmed according to the manufacturer's recommendations. Fine-tuning and verification of the fitting should be considered to maximize benefit and sound quality.

Audiological Measurements to Evaluate the Fitting of the Sound Processor

The use of a standardized audiological test battery is highly recommended and tests should be carried out before the treatment and after an acclimatization period of at least 4 weeks including:

- Bone-conduction thresholds, masked and unmasked, pre surgery to assess if the patient is within the indication range, and after surgery to assess whether or not cochlear thresholds remained unchanged, furthermore, these bone-conduction thresholds are the main input for device fitting (see Appendix).
- Direct hearing thresholds1Most implants today have so-called *direct threshold* (also known as *in-situ threshold)* measurements implemented that permit the determination of device specific thresholds using the device as stimulator. to assess coupling efficiency (section Additional performance specifications) and for base-line purposes.
- Aided sound-field hearing thresholds (using warble tones or narrow-band noise2Feedback cancellation systems affect the gain of devices, therefore to obtain valid aided threshold one typically need to disable the automatic feedback cancellation system. Alternatively the frequency sweep and modulation can be modified to leverage the feedback cancelation off.) to determine the ''effective gain.''
- Aided sound-field speech reception thresholds (SRT**)** and/or aided speech scores (e.g., words) presented at normal conversational level, for example, 65 dB SPL.
- Aided speech-in-noise SRTs in an adaptive procedure at appropriate speech and noise presentation levels (29) to determine valid SRT in noise.
- Maximum stable gain (feedback free gain) for the devices where it is available. We encourage all manufactures to implement tools to determine it, see section Additional performance specifications.

Furthermore, the setting of the fitting parameters should be documented.

Determination of the Gain of the Device

Often, the ''gain'' of a device is assessed by taking the difference between the unaided and aided sound-field thresholds, referred to as the ''functional gain.'' However, by definition, in conductive and mixed hearing loss, ''functional gain'' is simply the sum of the above introduced ''bone-conduction gain'' or ''effective gain'' and the air-bone gap. In most cases, that classical ''functional gain'' is dominated by the width of the air-bone gap and, therefore, ''functional gain'' is not assessing the effectiveness of the device, in contrast to the ''effective gain.''

Instead, using ''**effective gain**'' is advocated as it is independent of the air-bone gap and assesses the effectiveness of the treatment, which depends on how well the cochlear loss is compensated. The ''effective gain'' should equal the gain prescribed by the applied fitting rule, thus verifying whether or not the fitting and device are adequate. If the cochlear sensitivity is near normal (predominant conductive hearing loss), the ''effective gain'' might be zero (virtual closure of the air-bone gap) or even negative as indicated before and elaborated in the Appendix (11)).

Additionally, **functional improvement** should be used instead of the term ''functional gain'' with the same definition as given above, but with measurements defined as the pre-intervention unaided hearing thresholds minus the postintervention aided hearing thresholds. In the case of conductive or mixed hearing loss, ''functional improvement'' sums up the overall hearing benefit experienced due to the intervention. In contrast to a postintervention on-off determination of the ''functional gain'' with the device, it comprises the audiological benefits and trade-offs. ''Functional improvement'' might be equally useful in comparing the outcomes of surgical treatments.

An alternative approach might be to compare the pre intervention SRT to that obtained after the treatment with the device, which might be closer to the real world benefit of the patient than tone thresholds.

Surgical Issues

Following audiometric evaluation and the clinical/otological, treatment options emerge. As the various implantable devices have different surgical aspects to them, it is of importance to include these issues in the shared decision-making. Anatomy may play a role and therefore, it may be necessary to perform imaging specifically of the temporal bone region. The implantation procedure is an important link in the chain of care.

Regarding the choice of the device to be implanted

The device offered to the patient:

- Should have a proven track record of safety and reliability.
- Must be a system that the implant team is experienced with. If not, the team must have been trained and experts from the manufacturer and/or another more experienced clinical center should be on-site at the clinic during the surgical and fitting procedure.

- It should be MRI compatible at least up to 1.5 T
- Must have clinical and technical support available from the manufacturer.
- Aftercare service (repairs, etc.) should be guaranteed by the manufacturer.

Regarding the counseling of the implantation procedure and postoperative care

Surgery is often worrisome to the patient, so good preimplantation counseling comes down to informing the patient about all aspects of the surgery, including, if needed, any surgical interventions before the actual implantation (e.g., subtotal petrosectomy or tympanoplasty), the implantation procedure, the risks involved intra-and postoperatively, the postoperative care, the stability of the system, revision surgery and MRI compatibility. In practice:

- Patient information must be given before surgery: information about the different devices, their principle of action, their advantages and disadvantages, longevity, sustainability, upgrade-options and MRI compatibility. Written information about the device(s) should be made available to the patient before surgery.
- The surgical procedure must be explained and all minor and major complications that may occur. The patient should be informed about the length of the clinical admission period. If applicable, any intraoperative monitoring, measurements or imaging should be explained.
- The patient must be given the available information by the clinic (e.g., principle of the surgery, safety of the surgery, invasiveness, occurrence and rate of complications, stability of the device, guaranty terms and conditions for long term support) on the device(s) planned for implantation and possible alternative approaches that may become necessary during surgery.
- All coupling options for his/her specific case should be explained to the patient, as far as known preoperatively.
- Postoperative care must be discussed with the patient. The patient should be informed of financial consequences including repair and future upgrades of the external components.
- Patient consent containing the above information must be obtained and documented in accordance with local rules.

Regarding the implantation procedure

- Surgical techniques employed and perioperative medical care must be safe. Clinicians must stay current in their knowledge of the use of devices (employing continuing education).
- Surgical techniques should be adapted to the device-specific conditions of the patient, for example, head growth, proximity of the dura mater or vascular structures like the sigmoid sinus, congenital malformations of the temporal bone, and thickness of the skin and subcutaneous tissue.
- If applicable, perioperative testing of the device must be performed, as it is an important part of the full procedure to verify the functional status of the device and to distinguish technical from medical complications.
- Surgical technique, implant and coupling type, implant serial number, and surgical complications and findings must be documented in the surgical files.

Intra-and postoperative testing of the device is an important part of the full procedure to verify the functional status of the device, the possibility of detecting failures and to distinguish technical from medical complications. The surgeon must continue to monitor the patient's progress during the postoperative period, and be responsible for dealing with postoperative issues that may arise in relation to the implant.

Health Policy Issues and Device Benefit

Conventional BCDs as available in the nineteen eighties were limited by several medical and technical factors in the management of conductive and mixed hearing loss, thus restricting their utility. These transcutaneous nonsurgical BCDs required the use of a headband to couple the processor's actuator to the mastoid bone, resulting in issues of comfort, esthetic appearance, but also limited output. The first implantable BCD, introduced in the late eighties, was more comfortable to use and more powerful, owing to its (more efficient) percutaneous coupling (30). For patients with mixed hearing loss, health authorities in several countries accepted the within subject, pre-post intervention studies as convincing evidence for reimbursement. Since then, several new types of BCDs have been developed.

As an alternative, AMEIs have been applied to circumvent the normal sound transmission route of the middle ear stimulating the inner ear by, for example, a round window approach (31). This approach opened a new range of applications for AMEIs, which were approved for use in sensorineural hearing loss only, by demonstrating that they can be used to substitute the middle ear and deal with the sensorineural hearing loss component, if present.

Pragmatic judgment of a specific technology or device in comparison to other options is necessary to provide not only evidence for differential indication criteria but also reimbursement. One-to-one comparisons are the most meaningful. However, these can be difficult to conduct in the fast-evolving field of implants. In the case of a new device, comparisons should be ideally made to alternative state-of-the-art hearing solutions. Even if medical conditions may be the decisive choice factor, such comparisons help to estimate the trade-off.

From a clinical perspective, it is important that ''patient-relevant'' endpoints are used. This is helpful when explaining different treatment options to patients in

the spirit of shared decision-making. Mere audiological parameters might be regarded as surrogates with no or limited patient relevance by health technology assessment bodies. Therefore, standardized and validated instruments that measure quality of life are indispensable in clinical studies investigating the benefit of new BCDs or AMEIs (e.g., using the communication-sensitive HUI3 (Health Utility Index) generic 'quality-of-life questionnaire and the treatment-oriented GBI (Glasgow benefit inventory, (32)).

Equally important is the collection of reliable information concerning the use, subjective benefit and audiological properties during the first years of application and beyond. That remains essential for investigating the real-world benefit of such devices (e.g., by using the disability-specific APHAB (Abbreviated Profile of Hearing Aid Benefit) questionnaire (33)). Both, the APHAB and the GBI are the most frequently used questionnaires for mixed hearing loss (34).

Clinicians are encouraged and should contribute to post-market surveillance programs in the interest of generating a large body of valid external data, which can then be used to optimize outcome prediction, detect possible discrepancies between predicted and observed clinical benefit, and guide future device development. While acoustic implants have been widely adopted, registry data on their applications are still lacking. From their systematic review and qualitative study on acoustic implant registry development, Mandavia et al. (35,36) concluded that ''stakeholders, policy-makers and patients have recognized that, in the absence of registry data, it is difficult to regulate acoustic implants, monitor clinical and cost-effectiveness, and ultimately develop appropriate guidelines and policy'', affecting shared decision making and evidence based patient care. Local, national and device related registries are being developed, (37,38), however, the successful development and maintenance of registries face challenges. Some of the key requirements for developing a successful registry of acoustic implants include:

- Definition of clear objectives by stakeholders (clinicians, patients, industry, academics, insurances and specialist societies), reaching a balance between dataset comprehensibility and simplicity to maximize data input whilst keeping the registry meaningful. Registries solely focusing on safety and reliability may miss specific audiological data to provide evidence for effectiveness and differential indications.
- Registry planning with a dedicated registry leadership and management structure in place, planning for sufficient registry funding, as well as identifying who/which organization will own the registry data.
- Clear regulation of the ownership of data and access to data. Analyzed and interpreted clinical evidence must be provided to practitioners in peer- reviewed publications, requiring rules for authorship.
- To establish a registry, a sustainable funding of the IT-infrastructure and possible monitoring is required. Without a clear incentive to contribute data and acknowledgement, voluntary contributions will be insufficient. Involving all stakeholders throughout the registry development process will help maximize buy-in and data completion. Cost and time for obligatory contributions must be taken into account in reimbursements.

Although the creation of registries faces significant challenges that are beyond the scope of this publication, we strongly encourage the creation of implant-and application specific databases. Solid evidence on performance and device reliability provides practical relevant information to clinicians for their daily practice. As the scope of single clinics and academic institutions is usually locally limited and rarely crosses country borders, a broad collaboration between all players is essential to gather and report growing clinical experience short and long term. Only a strong alliance between clinicians, academics, manufacturers, and health care providers can generate reliable evidence and establish a reliable reporting infrastructure that is accessible to decision makers in the form of registries.

Manufacturers

Manufacturing and certification of implantable devices requires significant effort and responsibility from manufacturers. As many of the devices are (relatively) new and information for clinical decision making is initially limited, this requires the structured collection of clinical data. Here, the focus must be on real-world benefit to provide evidence-based information for differential indication criteria and optimized clinical quality standards. In the next sections, the systematic collection of experiences and data from preclinical and clinical results are discussed.

Market Release of a New Implantable Device

During clinical trials and first use in humans under very controlled conditions in accordance with for example ISO 14155 (39), evidence for safety and efficacy is collected and demonstrated to regulators. At market release, manufacturers confirm the safety of the device under all normal and expected operating conditions, which are followed up by a post-market-clinical-follow up. Information regarding the technical specifications of different AMEIs and BCDs must be available at market release when devices become accessible to a broader community to enable independent judgment on the performance of these devices. At its core, the data needed in this phase is included in the section Technical Specifications and encompasses the MPO and noise floor. Here, it is equally important to clearly specify the source and method of how these basic properties were determined, and measurements should follow standards where applicable, for example, IEC60118–9 (27) or ASTM F2504–05 (28). This is even more important for the indication

range of any device, as clinical decision and inclusion of patients mainly relies on indication ranges that specify the possible hearing loss (thresholds) of those patients where a sufficient benefit can be expected. The basic properties MPO and noise floor determine the device's indication range, which is of utmost importance, as it determines the proportion of the patient's dynamic range of hearing that can be covered with the device. The dynamic range of hearing covered by the device, assumed for the calculation of the audiological indication criteria in terms of threshold-to-MPO range, is an essential element to give professionals the possibility of predicting outcomes and to define differential indication criteria between devices. This applies equally to BCDs and AMEIs.

During the First Years of Clinical Experience

During the clinical trial and certification of a newly introduced device, the training standards regarding surgical, audiological and device fitting are usually well controlled and monitored. However, the transition to clinical routine makes devices available to a broader community that is more heterogeneous and where procedures are less controlled. Here, the manufacturer must offer adequate training for surgeons, audiologists, and technical specialists to ensure safe and optimal results. Nevertheless, offering training is only one crucial element and clinicians must undergo these trainings. As the years of first experience are a continuous learning process, manufacturers, who have the best overview on the use and distribution of a product, are legally required to monitor the proper use, safety, and implant stability issues. As this gathered information might not be easily accessible to clinicians, information concerning safety and performance should be made available to clinics to enable decisions based on the most current information. The verification of indication criteria is of importance for proper differential indication and optimizing surgical procedures. As the broadest database possible is crucial for meaningful decision criteria, clinicians, researchers and manufacturers are equally responsible to gather, analyze and distribute clinical evidence. In the absence of registries all parties should endeavor to contribute to peer-reviewed publications of single-and multicenter studies.

Over the Entire Time of Clinical Use

The creation of evidence from clinical experience on a short and long-time scale beyond claims and narrative reporting is of utmost importance. The new medical product regulation (MDR) (40) was recently implemented in the EU (41) and will apply for implantable and class III devices at the end of May 2021. Although, the MDR requires the collection of relevant information on devices, it may not suite the needs of health care professionals. It places stricter requirements on clinical evaluation, technical documentation and post-market clinical follow-up to assess product safety and performance. Furthermore, it requires better traceability of devices through the supply chain. The implementation had a transition period of 3 years that was extended by 1 year. Devices certified before May 2021, under the Medical Device Directive (MDD, (42) can be marketed and put into service until recertification under the MDR is required. Although the MDR requires the establishment of databanks to collect information evaluation of the long-term safety and performance databases for only a few categories of devices are under development or planned. Although this is an important step forward, information penetration of such data sources and accessibility in clinics is generally not widespread today. To support clinical decision making with relevant evidence, tools have to be developed to make information easily accessible to clinicians, researchers, and developers.

Once more, we strongly emphasize the importance of implant-and application specific databases on audiological performance and device reliability.

The Role of Manufacturers in Aftercare and Repair

Depending on the complexity of the device, the procedure or the adjustment of the software (fitting), manufacturers are responsible for offering training and/or certification to professionals.

Manufacturers are responsible for service and the repair of the sound processors. Beside the legally required warranties on the implant and external components the company must provide a statement of the minimal duration of availability for guaranteed service, such as repair and exchange of external components to clinics and patients. Regarding long-term support another important issue is backwards compatibility. Companies introducing new processors should enable patients with older implants to participate in new features and signal processing developments. Manufacturers should enable the implant team to technically check basic functioning of sound processors including the output sound quality. In case of failure of the sound processor, the processor is repaired under the responsibility of the manufacturer. In the meantime, spare parts and sound processors should be available as per warranty and repair procedures. In cases where the patient depends on the device to participate in essential social activities, such as school attendance in children, the replacement equipment should ''be issued or dispatched on the same or the next working day'' following Gavilan et al. (18). If an internal device failure is suspected (AMEI or transcutaneous active BCD), a representative from the manufacturer should be available at the patient appointment to provide support, on request by the clinic.

Adequate service is especially important for implantable systems because (1) the market is limited and (2) patients often have no choice as only one system may provide sufficient benefit for their problem. As the patient depends on a few or even a single provider, guaranteed services must be clearly communicated to the patient by the clinic. However, as the clinic acts as a mediator between the patient and the

manufacturer or the insurance, ensuring the protection of sensitive health- related data, clear procedures for communication between the clinic and manufacturer must be established.

Technical Specifications

To select a treatment option, clinicians must be enabled to evaluate the audiological needs of the patient and match with the technical capabilities of each device. Therefore, a minimum set of technical performance parameters must be provided by the manufacturer and presented in a uniform and comparable manner. For conventional hearing aids, this has long been standard practice and is defined in the relevant standards (25). For BCD, a corresponding standard exists (27) and should be followed by the manufacturers. The standard covers conventional BCDs, percutaneous BCDs, as well as transcutaneous and active transcutaneous BCDs, and describes the measurement of the output under standard conditions on a skull simulator. However, the clinical implications of these measurements are only well established for percutaneous BCDs.

Determination and Verification of Specifications in Patients

Even if preclinical results provide reliable results on device performance, clinical verification is indispensable as clinical conditions during implantation may differ from experimental conditions and some results can only be determined in patients. However, when measuring aided thresholds or other aided loudness percepts in a recipient of a hearing implant, care must be taken to avoid interference from advanced signal processing features in the hearing implant, such as anti-feedback algorithms, wide dynamic range compression, noise cancellers, etc. In particular, for devices with implanted microphones, the potential for masking of test signals by the microphone, internal noise must be taken into account (24).

Performance Specifications

Datasheets must specify the following performance measures at least for the frequency range of 200 to 8,000 Hz.3This range exceeds the minimum required for publications on AMEI from a previous publication (14). This also is in accordance with IEC60118−8 for hearing aids and IEC60118−9 for percutaneous BCDs. Although, only frequencies up to 5000 Hz are required in IEC60118−9 for transcutaneous BCDs according to the authors opinion datasheets should enable proper decision in clinics and have to go beyond what is minimally required for pooling data from publications. However, we encourage that scientific publications are not limited to the minimum data set and use the range suggested here, allowing retrospective verification of datasheets from clinical application. Reporting measures of amplification outcomes or MPO only as a multi-frequency average is inadequate, because both the patient's audiological needs and the device performance may vary widely across frequencies:

Maximum Power Output (MPO) expressed as equivalent hearing level, that is, as the highest output level above the normal hearing threshold that the device can produce. The use of MPO for a device in hearing level (dB HL) facilitates the assessment of a device for a specific individual's hearing function and enables the comparison between devices. The maximum output in hearing level (MOHL) incorporates the function of the device itself as well as the sound transmission efficacy from the device output to a hearing sensation. Although, in percutaneous BCDs the Maximum Force Output (MFO) is better established and common, we recommend the use of MPO as described above for clinical applications as it simplifies comparison between different types of devices (e.g., transcutaneous BCD vs. AMEI) and the creation of differential indication criteria. Note that the vibrator of an active transcutaneous device can be more flexibly positioned as the processor location is separated from the site of stimulation. Different vibrator placements, attachments and load impedances will lead to sitespecific MOHLs.

Output noise level at minimum gain expressed as equivalent sound pressure level.

Additional Performance Specifications

Once there is clinical experience with a device, it is desirable that additional performance measures in patients are collected and published, either by manufacturers or by independent academic institutions.

Coupling efficiency is a crucial factor in devices that underlays significant transmission variability at the biological interface and is specifically for AMEI essential. Even if it is not obligatory, most implants already have so-called *direct* threshold measurements systems that determine the threshold of a patient when stimulated with the device. Although direct thresholds units cannot be easily related to hearing thresholds, these devicespecific direct thresholds are a useful descriptor of the transmission of this specific device to the patient. By measuring an individual frequency-specific coupling efficiency (bone-conduction thresholds minus direct thresholds) for a device and comparing that to the usually achieved coupling efficiency, limits can be defined where, for example, a surgical re-intervention becomes necessary. Although direct thresholds are in arbitrary units, they can often be converted to physically meaningful units such as Volt input to the actuator.

Although MPO can be determined with various methods, preclinically and clinically, it usually has a pronounced variability amongst implanted subjects even under controlled surgical conditions. As the knowledge of the variability of MPO is essential to predict the outcome in candidates it is required that statistical descriptors of the range of expected MPO are published as soon as sufficient clinical experience is available. The minimum data necessary to describe clinical MPO

outcomes are the frequency specific (250 Hz to 6 kHz) 25th and 75th quartiles and the median. However, these specifications of clinically obtained results may be updated when more reliable surgical procedures have reduced the variability of MPO.

Maximum stable gain (or feedback-free gain) is another important factor that may impair the clinical performance of a device. The measurement of maximum stable gain is a common feature in conventional hearing aid fitting software. The occurrence of feedback may limit the possible gain below the technically feasible gain of the device in the clinical application. The maximum stable gain is dependent on available feedback cancellation systems and will be subject to software versions and later updates. Nevertheless, the maximum stable gain (with a specific software version) is essential data that can be obtained from available clinical data to be included in technical specifications for indication. The maximum stable gain may vary substantially in patients and its frequencyspecific level and variability must be published either by the manufacturers or clinics as soon as clinical experience of it is available. As maximum stable gain is a property of the feedback pathway in specific patients, knowledge of achievable gain will help (1) to identify preoperatively patients who are unlikely to receive required gain, (2) to define limits for insufficient gain that require a revision surgery and (3) to identify conditions that lead to limitations in maximum stable gain.

Bone Conduction Devices (BCDs)

For air-conduction hearing aids, the conditions for measuring parameters are well defined and standardized using, for example, a 2 cc coupler (25); for percutaneous BCDs, a skull simulator is available, which can be used interchangeable with a 2 cc coupler, enabling the (standardized) measurement of the maximum force output level (MFO), gain as a function of input level, harmonic distortion and internal noise (see datasheets by Cochlear and Oticon Medical). The MFO as measured with the skull simulator in ''dB force-level,'' can be expressed in dB HL, using the RETFLdbc transformation (21). As the percutaneous coupling is standardized and implantations are usually performed at the same position, the variability in coupling efficiency is limited. Thus, the gain and output expressed in dB HL, can be assessed with sufficient accuracy from the skull simulator measurements (43).

Acquiring MPO is less obvious in transcutaneous BCDs, where the output is determined under standard conditions on a skull simulator. However, transcutaneous BCDs permit a more flexible placement of its vibrator and might differ in their attachment to the skull. Hence, the output in terms of hearing level at the cochlea depends on factors, such as the position of the vibrator (44) and type of fixation. In these cases, at least the preclinical estimates should be verified in patients during clinical application and the individual factors need to be identified.

Active Middle Ear Implants

Since middle ear implants bypass the middle ear and therefore, the predicted performance is independent of air-bone-gap, appropriate performance measures must refer to the sensorineural hearing loss component, not to air-conduction hearing loss. Furthermore, in contrast to percutaneous BCD, coupling efficiency might vary significantly between patients and will depend on the method and site of coupling (22,45).

Preclinical methods to determine device and application specific specifications. For middle ear implants where the output is coupled to an ossicular structure, the preferred method is described in the ASTM F 2504–05 ''Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices'' (28), and is already in widespread use in the professional community and well established. Measurements of the actuator equivalent sound pressure transfer function H_{ET} as defined in ASTM F 2504–05 section 3.4.26 can be combined with knowledge about the frequency specific maximum electrical output of the implant to calculate the MPO (28). A statistically sufficient number of preclinical experiments may also help to estimate the expected variation. However, conditions in experiments may be more optimal than in the surgical situation where limited time, anatomical restrictions and other clinical issues may contribute to less favorable real- world outcomes. Consequently, preclinical estimates of MPO and variability must be verified in clinical routine.

Although, the ASTM F 2504–05 only applies to stimulation of ossicular structures in the forward direction, this approach based on Laser Doppler vibrometry of the stapes footplate can be substituted by an approach based on the measurement of intracochlear pressure differences (46,47) in other cases. However, as this method is less established and experimental experience is limited, clinical validity must be demonstrated in the future.

Determination and verification of specifications in patients with AMEI. For middle ear implants, methods for determining the MPO include, but are not limited to, the following:

In the case of an intact middle ear, Snik et al. (48) describe a method for recording sound pressure in the external ear canal while the device is operating, with increasing input sound level until the ear canal sound pressure saturates. The input level at that point can be converted to output level, by adding the ''effective gain.'' However, this approach is not applicable in many cases of CHL and MHL.

An alternative approach that is independent of the type of hearing loss uses the coupling efficiency. It describes the threshold in device specific units for a hypothetically normal hearing subject. The maximum output level in an individual ear can be calculated by combining: (1) the coupling efficiency, (2) the frequency specific relationship between the actuator input voltage and the direct threshold units, and (3) the maximum electrical output of the implant (47).

Minimum requirements for BCD and AMEI specifications in data sheets. In a phase when only technical, preclinical and data from a clinical trial with a limited number of patients and centers are available, technical specifications and data sheets of devices must contain the following:

- The MPO or MFO must be included, specified as a function of frequency and its variability. The method used must be referenced or explained in the publication.
- The output noise levels should be presented. For BCDs only a standardized method to determine the equivalent input noise level is described (27). Although, in percutaneous BCDs audible noise and variability in coupling is less of an issue, variability in coupling efficiency in transcutaneous BCDs and AMEI may impact the minimum output noise level in patients.
- An indication/application range must be specified (in dB HL); the method used to determine that range must be specified and what dynamic range4-**Dynamic range** is the range of hearing of a patient between his/her hearing thresholds and the loudness discomfort levels (LDL). Preferably the MPO of a fitted hearing device should be above but close to the LDLs in order to use the full dynamic range of hearing. of hearing to be covered was assumed for the calculation of that indication range.

If clinical data are available

- Measured MPO values and clinical variability. The method or reference how these results were obtained has to be given, including the appropriate statistical descriptors (e.g., average, median, quartile or percentile range, number of cases) and the selection criteria for the reference cohort.
- Maximum stable gain and variability, with, optionally, a criterion for revision surgery
- Variability of output noise levels
- Coupling efficiency and variability, with, optionally, a criterion for revision surgery

CONCLUDING REMARKS AND THE FUTURE

Limitations of the Study

This Consensus Statement on Bone Conduction Devices and Active Middle Ear Implants in Conductive and Mixed Hearing Loss is a result of comprehensive analysis of the literature and opinions from a large expert group of multidisciplinary stakeholders. The strength of these consensus statements is that the main stakeholders were involved in the development. Competent multidisciplinary opinions of experts (clinicians, audiologists, health care specialists, and manufacturers) with experience in acoustically stimulating devices was combined. Scientific conferences were used to discuss the statements and to recruit participants for the working group, fostering consensus based decision-making. One limitation of this setup is that patients were not included as part of the working group. The present consensus aimed to provide a framework for procedures and technical characterization. Future upgrades of the consensus should focus more on patient- oriented outcomes and should involve patients to address those needs more wholly. Secondly, although the consensus was designed as an open project, geographical representation of the authors is somewhat limited. Future updates to the consensus should include a more diverse and more adequate representation of expert opinions globally.

Concluding Remarks

Acoustic implants are proven, indispensable treatment options for hearing impaired patients that cannot use conventional hearing devices or do not benefit sufficiently from such devices. Thanks to innovative researchers and manufacturers, several different types of these technologically sophisticated devices are on the market, so, for each candidate, a choice has to be made. This field of rehabilitating hearing impaired patients is still evolving and more alternative treatments can be expected.

Future

To facilitate the creation of evidence and differential indication criteria, the present consensus document with a primary scope on efficacy was developed. However, this can be only an attempt as other aspects require a more careful structure, developed in collaboration between stakeholders such as clinicians, patients, manufacturers, decision-makers and researchers.

What is urgently needed and must be developed:

- Firstly, standardized methods, equipment and procedures to measure the characteristics of **all** devices (see sections Clinical-audiological issues, Health policy issues and device benefit, and Technical Specifications).
- Secondly, to increase our knowledge on best clinical practice, the creation and use of (local, national) registries comprising surgical and audiological outcomes (2.4). Problems to set up and effectively use such registries have been acknowledged (37,38). To establish and maintain a registry encompassing clinically relevant information faces major challenges, for example, the definition of clear objectives, the regulation of contribution, ownership of data and access to data. In the meantime, clinicians are encouraged and should contribute to post-market surveillance programs in the interest of generating a large body of clinical experience (see sections Market release of a new implantable device-Over the entire time of clinical use).
- Thirdly, equally important is continuous education on surgical and clinical standards. This requires an organizational structure that is adapted to fast-evolving knowledge and technical possibilities, developed and agreed upon in a partnership between the stakeholders.

- Fourthly, regarding efficacy of the devices, mere audiological parameters need to be complemented by ''patient-relevant'' endpoints adequate for the complex aspects of implantable hearing devices and ''added value'' by generally accepted standardized and validated instruments that measure the benefit of all classes of hearing instruments (see section Health policy issues and device benefit).

Therefore, this consensus document should be regarded as a starting document and guidance that will be subject to updates and reviewed regularly.

APPENDIX (MEASUREMENTS OF THE MPO)

Importance of the MPO and Verification of the Device Fittings

In 1990, Gatehouse and Browning (49) published their study on the output characteristics of an implantable BCD (the Audiant device). They used both psychophysical tests and measurement of the head vibrations, induced by that BCD, to study the input-output behavior. Both tests showed similar, significantly limited maximum output levels, leading to a narrow aided dynamic range of hearing.

Some years later, Carlsson et al. (21) addressed the same issue, viz. measurement of device characteristics of, in their case, percutaneous BCDs and developed a simulator (skull simulator). They reported, amongst others, on the (full-on) gain, noise level, and the MFO (maximum force output level). The MFO can be expressed in dB HL, using the RETFLdbc (a look-up table, for details, see (21)). Nowadays, the electro-acoustic characteristics of all types of percutaneous BCDs are available in the form of data sheets.

More recently, the input–output behavior of BCDs (percutaneous and transcutaneous devices) has also been studied in patients. Head vibrations have been studied by using an accelerometer (50) as well as by measuring the level of the sound radiated by the vibrating skull bone with a microphone, either in an occluded cavity, for example, an ear canal or nostril (50,51) or in a temporarily created cavity (forehead-mounted surface microphone (52). In this way, input-output curves have been determined and the (frequency-dependent) input level at which the device saturates.

The MPO has been used to compare the capacity of different types of implantable devices; for this, the devices were temporarily programmed linearly. Under these conditions, the MPO is the sum of the input level at which the device saturates plus the effective gain (in dB SPL, to be converted to dB HL) (e.g., Zwartenkot et al. (53), Rahne et al. (54), van Barneveld et al. (51)).

Additionally, measuring input-output behavior has been used to optimize the individual fitting of (percutaneous) BCDs. To this purpose, Hodgetts et al. (52) adapted an existing fitting rule, the DSL rule. Electroacoustic verification of their DSL based BCD fittings was based on skull simulator measurements. To that purpose, the (mean) RETFLdbc values were individualized with a correction factor, which was determined for each patient. In this way, the patient-dependent coupling efficiency was dealt with.

On average, the MPO value obtained from measuring head vibrations was in accordance with that obtained with standard skull simulator measurements (which concerned percutaneous BCDs). Therefore, it was concluded that measuring head vibrations could be applied to assess the (individual) MPO of other types of BCDs as well, which is especially important for fitting (all types of) transcutaneous BCDs (51).

Alternatively, the MPO of all classes of devices, including AMEIs can be determined in individuals by an approach suggested by Grossöhmichen et al. (47). Essential is that the device provides the possibility to determine the direct thresholds by the device so that coupling efficiency is taken into account. However, to determine the MPO of a device with this method in a subject or group of subjects, the input voltage to the transducer at threshold and the maximum input voltage provided by the device has to be available, to be provided by the manufacturer, or has to be determined with a sample device.

Verification of the Fittings of (Any Type of) Implantable Device

According to fitting protocols, after hearing assessment and device fitting using some fitting rationale, the outcomes must be verified (e.g., (50)). For percutaneous devices, using the DSL procedure, the outcome of the fitting can be verified electro-acoustically (52). For other devices, comparing prescribed and measured aided thresholds is advocated for verification/validation purposes.

Just one fitting rule has been applied and evaluated thoroughly in patients with mixed hearing loss, namely the NAL-RP rule (25). From their study, the authors concluded that, obviously, in predominant conductive hearing loss, the first 20 dB of hearing loss can be ignored. Snik et al. evaluated that rule with the proposed adaptation (11) using published studies in patients with predominant conductive hearing loss fitted with BCDs or MEIs. Using the original NAL-RP rule, a discrepancy between the measured and NAL-RP prescribed aided thresholds of 11 dB was found, which reduced to 3 dB when using the adapted rule (2 kHz data; accepting a margin of 5 dB (11)). The table below presents the desired aided thresholds and desired (effective) gain as a function of the unaided thresholds applying that adapted NAL-RP rule. The values in the table should be considered as a first-order approximation. Owing to technical limitations of certain implants, the measured outcomes might vary; therefore, the margin of 5 dB was introduced (11). As the effective gain is the difference between unaided (bone-conduction) and aided thresholds, obviously, it is zero or negative if the bone-conduction threshold is $\leq$ 20 dB HL.

Note that it is not suggested to use the adapted NAL-RP rule instead of proprietary fitting rules as used in the companies' fitting software.

TABLE 1. *Device independent desired aided thresholds and the desired gain as a function of frequency (separated by a slash), in multiples of 5 dB HL*

	Aided Threshold [dB HL] / Gain [dB]			
Unaided Threshold [dB HL]	0.5 kHz	1 kHz	2 kHz	4 kHz
0	20/−20	20/−20	20/−20	20/−20
10	20/−10	20/−10	20/−10	20/−10
20	20/0	20/0	20/0	20/0
30	25/5	20/10	20/10	20/10
40	30/10	20/20	20/20	25/15
50	35/15	25/25	25/25	30/20
60	40/20	30/30	30/30	35/25
70	45/25	35/35	35/35	35/35
80	45/35	40/40	40/40	40/40

The data presented in the Table are valid for patients with conductive and mild/moderate cochlear hearing loss and with flat or gradually sloping audiograms.

Note. As addressed in the section Clinical-audiological issues, aided sound-field thresholds are often used to verify the fitting of a hearing device. However, aided thresholds have limitations as a verification tool (50). They might be elevated owing to noise floor effects (device noise or ambient noise) especially in patients with near normal cochlear sensitivity, which results in aided thresholds to be worse than expected. Further limitations are due to the possible use of nonlinear signal processing (24). Also the presentation of (warble) tones during sound field measurements might activate an automatic feedback cancellation system, which results in elevated aided threshold. Narrow-band noise stimuli or higher modulation frequency and/or range might be the better option. This adapted NAL-RP rule is rather insensitive for disturbance by ambient noise assuming that ambient noise in the sound booth is within the norms. Typically, noise and/or expansion might lead to hearing thresholds not better than 20 to 25 dBHL, in subjects with predominant conductive hearing loss, where lower aided thresholds were expected.

Compression might have been used to deal with a limiting MPO. Taking compression into account (e.g., by using the NAL-NL rule instead of the NAL-RP rule; (55); software version 1.1) thresholds were 5 dB better (lower) than those listed in Table 1. Using wide dynamic range compression is not the first option to deal with a limiting MPO as long as more powerful devices are available. It should be mentioned that the consideration on the target above in Table 1 can act as rule-of-thumb.

AUTHORS AND AFFILIATIONS

Hannes Maier, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany; Thomas Lenarz, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany; Parwis Agha-Mir-Salim, HNO-Heilkunde, Hörzentrum Berlin, Vivantes Klinikum im Friedrichshain, Berlin, Germany; Martijn J. H. Agterberg, Department of Biophysics, Donders Institute for Brain, Cognition and Behaviour, Radboud University, Nijmegen, Netherlands; Andreas Anagiotos, Department of Otorhinolaryngology, Nicosia General Hospital, Nicosia, Cyprus; Susan Arndt, Department of Oto-Rhino-Laryngology and Implant Center, Medical Center-University of Freiburg, Freiburg, Germany; Geoffrey Ball, MED-EL Medical Electronics, Innsbruck, Austria; Manohar Bance, Department of Otology and Skull Base Surgery, University of Cambridge, Cambridge, UK; Maurizio Barbara, Otorhinolaryngology, University Hospital Sant'Andrea, Rome, Italy; Uwe Baumann, Klinik für HNO-Heilkunde, Universitätsklinikum Frankfurt, Frankfurt a. M., Germany; Wolfgang Baumgartner, ENT Department, Medical University of Vienna, Vienna, Austria; Daniele Bernardeschi, Department Otology, Auditory Implants and Skull Base Surgery, Pitié-Salpêtrière-Hospital, Paris, France; Dirk Beutner, Department of Otorhinolaryngology, Head and Neck Surgery, University Medical Center Göttingen, Göttingen, Germany; Arjan Bosman, Department of Otorhinolaryngology, Radboud University Medical Center Nijmegen, Nijmegen, Netherlands; Robert Briggs, Department of Otolaryngology, The University of Melbourne, East Melbourne, Australia; Susan Busch, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany; Marco Caversaccio, Department of ENT, Head and Neck Surgery, lnselspital, Bern University Hospital, Bern, Switzerland; Markus Dahm, St. Vincent's Private Hospital, Melbourne, Australia; Ernst Dalhoff, Department of Otolaryngology-Head & Neck Surgery, University of Tübingen Medical Center, Tübingen, Germany; Arnaud Devèze, Ramsay Gènèrale de Santè, Clairval Hospital, Ear and Skull Base Institute, Marseille, France; Azadeh Ebrahimi-Madiseh, The University of Western Australia, Ear Science Institute Australia, Subiaco, Australia; Bernard Fraysse, ORL, Clinique Rive Gauche, Toulouse, France; Henning Frenzel, ENT-Centre-Lue- beck, Luebeck, Germany; Javier Gavilán, Department of Otorhinolaryngology, La Paz University Hospital, Madrid, Spain; Mohammad Ghoncheh, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany; Bo E. V. Hakansson, Electrical Engineering, Chalmers University of Technology, Gothenburg, Sweden; William Hodgetts, Institute for Reconstructive Sciences in Medicine and University of Alberta, University of Alberta, Edmonton, Alberta, Canada; Myrthe Hol, ENT Department, Universitair Medisch Centrum Groningen (UMCG), Groningen, Netherlands; Julian Holland, Gilgit Road Specialist Centre, Epsom, New Zealand; Marcus Holmberg, Oticon Medical AB, Askim, Sweden; Alexander M. Huber, Department of Otolaryngology, University Zurich, Zurich, Switzerland; Herman Jenkins, Otolaryngology-Head and Neck Surgery Department, University of Colorado, School of Medicine, Aurora, USA; Roulla Katiri, Department of Audiology, Mater Misericordiae University Hospital, Dublin, Ireland; Kiana Kheirkhah, Department of Biophysics,

Donders Institute for Brain, Cognition and Behaviour, Radboud University, Nijmegen, Netherlands; Assen Koitschev, Abt. Kinder-HNO und Otologie, Olgahospital, Klinik für Hals-, Nasen, Ohrenkrankheiten, Klinikum Stuttgart, Stuttgart, Germany; Martin Kompis, Universitätsklinik für Hals-, Nasen-und Ohrenkrankheiten, Hals-, Kiefer-und Gesicht- schirurgie, Inselspital, Bern, Switzerland; Cris Lanting, Department of Otorhinolaryngology, Radboud University Medical Center Nijmegen, Nijmegen, Netherlands; Luis Lassaletta, Department of Otolaryngology, La Paz University Hospital (IdiPAZ). Centro de Investigatión Bio- médica en Red de Enfermedades Raras (CIBERER-U761), Madrid, Spain; Bob Lerut, Department of Ear, Nose and Throat, AZ Sint-Jan Brugge-Oostende, Brugge, Belgium; Rudolf Leuwer, Helios Region West, HELIOS Kliniken GmbH, Krefeld, Germany; Thomas Linder, Department of Otorhinolaryngology-Head & Neck Surgery, Luzerner Kantonsspital, Luzern, Switzerland; Hubert Löwenheim, Department of Otolaryngology- Head & Neck Surgery, University of Tübingen Medical Center, Tübingen, Germany; Lawrence Lustig, Department of Otolaryngology-Head & Neck Surgery, Columbia University Irving Medical Center & New York Presbyterian Hospital, New York, USA; Rishi Mandavia, evidENT, UCL Ear Institute, Royal National Throat, Nose and Ear Hospital, London, UK; Manuel Manrique, ENT Department, University Clinic of Navarre, Pamplona, Spain; Jorge Humberto Martins, ENT Department, Centro Hospitalar Universitário de Coimbra, Coimbra, Portugal; Griet Mertens, University Department of Otorhinolaryngology, Head and Neck Surgery and Experimental Laboratory of Translational Neurosciences and Dento-Otolaryngology, University of Antwerp, Edegem, Belgium; Robert Mlynski, Department of Otorhinolaryngology, Head and Neck Surgery ''Otto Koerner'', Rostock University Medical Center, Rostock, Germany; Hami- dreza Mojallal, MED-EL Medical Electronics, Innsbruck, Austria; Simonetta Monini, Department of Otorhinolaryngology, Sapienza University, Medicine and Psychology, Rome, Italy; Peter Monksfield, Department of Otolaryngology, University Hospitals Birmingham, Birmingham, UK; Alexander Müller, Vivantes Hearing Center Berlin (HZB), Department of Otorhinolaryngology, Head & Neck, Plastic and Cosmetic Surgery, Friedrichshain Clinic, Berlin, Germany; Emmanuel Mylanus, Department of Otorhinolaryngology, Radboud University Medical Center Nijmegen, Nijmegen, Netherlands; Hideko Nakajima, Department of Otolaryngology, Head and Neck Surgery, Harvard Medical School, and Massachusetts Eye & Ear, Boston, USA; Marcus Neudert, Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Carl Gustav Carus at the Tech- nische Universität Dresden, Dresden, Germany; Erwin Offeciers, Neus Keel Oorziekten, St. Augustinus Antwerpen-European Institute for ORL-HNS, Wilrijk, Belgium; Flurin Pfiffner, Department of Otorhinolaryngology, Head & Neck Surgery, University Hospital Zürich, Zürich, Switzerland; Markus Pietsch, Department of Otorhinolaryngology, Helios Klinikum Hildesheim, Hildesheim, Germany; Stefan K. Plontke, Department of Otorhinolaryngology, Head and Neck Surgery, Martin Luther University Halle-Wittenberg, University Medicine Halle, Halle (Saale), Germany; Nils Prenzler, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany; Milan Profant, Department of Otorhinolaryngology, Univerzitná Nemocnica Bratislava, Bratislava, Slovenská republika; Torsten Rahne, Department of Otorhinolaryngology, Head and Neck Surgery, University Medicine Halle, Halle (Saale), Germany; Gunesh Rajan, Klinik für Hals, Nasen, Ohren, Luzerner Kantonsspital, Lucerne, Switzerland; Anna Ratuszniak, Oto-Rhino-Laryngology Surgery Department, World Hearing Center, Kajetany/Warsaw, Poland; Stefan Raufer, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany, Hannover, Germany; Jaydip Ray, ENT Department, University of Sheffield, Sheffield, UK; Sabine Reinfeldt, Electrical Engineering, Chalmers University of Technology, Gothenburg, Sweden; Christof Röösli, Department of ENT, Head and Neck Surgery, University Hospital Zürich, Zürich, Switzerland; Tove Rosenbom, Clinical Affaires, BAHS, Oticon Medical, Smoerum, Denmark; Rolf Salcher, Department of Otorhinolaryngology, Medical School Hannover, Hannover, Germany; Matthias Schönermark, SKC Beratungsgesellschaft mbH, Hannover, Germany; Burkard Schwab, Department of Otorhinolaryngology, Helios Klinikum Hildesheim, Hildesheim, Germany; Henryk Skarżyński, Oto-Rhino-Laryngology Surgery Clinic, World Hearing Center, Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany, Poland; Piotr H. Skarżyński, Teleaudiology and Screening Department and Institute of Sensory Organs, World Hearing Center, Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany, Poland; Hillary Snapp, Department of Otolaryngology, University of Miami, Miami, USA; Georg Sprinzl, Universitätsklinik für Hals-, Nasen-, Ohrenkrankheiten, Universitätsklinikum St. Pölten-Lilienfeld, St. Pölten, Austria; Michael Spearman, Ototronix, LLC, St. Paul, USA; Stefan Stenfelt; Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden; Christof Stieger, Department of ENT, University of Basel Hospital, Basel, Switzerland; Stephane Tringali, Department of ENT, Lyon Sud Hospital, Hospices Civils de Lyon, Universitè Lyon 1, Pierre-Bènite, France; Eric Truy, Department of Otorhinolaryngology, Centre Hospi- talier Universitaire de Lyon, Lyon, France; James Tysome, ENT Department, Cambridge University Hospitals, Cambridge, UK; Paul Van de Heyning, Department of Otorhinolaryngology and Head and Neck Surgery, Antwerp University Hospital, University of Antwerp, Edegem- Antwerp, Belgium; Nicolas Verhaert, Department of Otorhinolaryngology, Head and Neck Surgery and Department of Neurosciences, UZ/KU Leuven, Leuven, Belgium; Thomas Wesarg, Klinik für Hals-, Nasen-und Ohrenheilkunde, Universitätsklinikum Freiburg, Freiburg, Germany; Patrik Westerkull, Otorix

AB, Askim, Sweden; Barbara Wollenberg, Klinikum rechts der Isar, Technische Universität München, Munich, Germany; Thomas Zah- nert, Klinik und Poliklinik für HNO, UNI-Klinikum Carl Gustav Carus, Dresden, Germany; Andrzej Zarowski, Neus Keel Oorziekten, St. Augustinus Antwerpen, Wilrijk, Belgium; Ad Snik, Department of Biophysics, Donders Institute for Brain, Cognition and Behaviour, Radboud University, Nijmegen, Netherlands.

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