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Systematic and audiological indication criteria for bone conduction devices and active middle ear implants

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ABSTRACT

Certain patients with conductive or mixed hearing loss can benefit from bone-conduction hearing devices or active middle ear implants. Available devices differ in coupling site, energy transfer from the sound processor to the implant, and the active or passive actuator technology. The audiological benefit of those devices depends on the maximum stable power output and the noise floor of the device, the degree and expected stability of the sensorineural hearing loss and the coupling efficiency with the aim on achieving a minumum of 30-35 dB effective dynamic range. The choice of the device is often a trade-off between the optimal audiological solution with respect to the hearing loss, technical device-related parameters and the expected coupling efficiency, the optimal surgical solution with respect to patho-anatomical aspects, device dimensions and the coupling site, invasiveness or surgical risks, and other patient factors with respect to the patients' wish and expectations, social aspects, device usability and connectivity. This review article lists all currently available implantable and conventional bone-conduction hearing devices and active middle ear implants with respect to technical features like maximum power output, market availability, and the expected effective output dynamic range.

1. Introduction

This special issue of *Hearing Research* combines a selection of original work on new research findings on the development, prescription, application, and outcome measures of acoustic implants. For many patients, those devices provide a powerful treatment option besides conservative treatment, passive prostheses and conventional, sound-amplification hearing aids.

Active hearing implants are applied to close the air-bone gap in conductive or mixed hearing loss and to compensate sensorineural hearing loss by sufficient amplification of sound energy. They may be implanted on the basis of audiological and/or medical indications (Beutner et al., 2018). The choice of an active 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) considerations (Fig. 1). The selection of an appropriate device usually is a compromise between the optimal audiological solution and many other criteria and often a highly individual decision. For active middle ear hearing implants (AMEI), specific minimal standards for reporting the indication, application and outcomes in clinical trials have been published to enable better inter-study comparability (Maier et al., 2018).

In recent decades, a diversity of products with varying technologies and performance limits have been developed that allow a tailored, personalized treatment of individual otological-audiological problems. A current historical overview about AMEI has been provided by Banakis Hartl and Jenkins (2020). Very recently, a consensus involving ENT specialists, audiologists, health-policy scientists and representatives/technicians of the main companies in this field has been achieved providing a first framework for procedures and technical characterization to enhance effective communication between the various stakeholders, and thus, improving health care (Maier et al., 2021). This study focusses on the currently available devices and their audiological indication criteria.

2. Systematic of active hearing implants

Active hearing implants consist of an actuator that stimulates a specific anatomical structure by vibrating forces and an audio processor that contains microphones or an ossicle-coupled sensor, a signal processing unit and electric power supply. Fig. 2 shows an overview of the devices that are currently available on different markets worldwide. Bone conduction hearing devices deliver sound energy through a certain pathway to the skull (directly or

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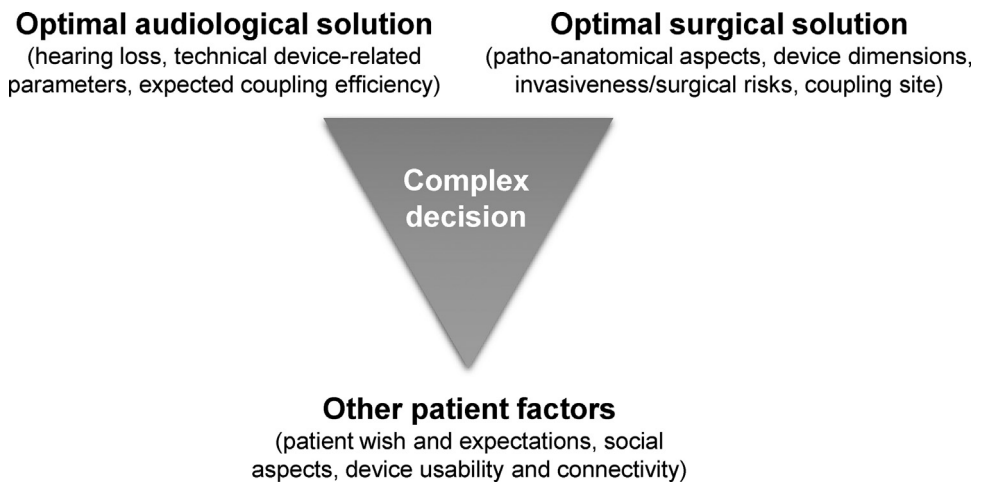

Fig. 1. Magic triangle of choice of an active hearing implant. The complex decision is based on and usually a compromise between an optimal audiological solution and many other objective (e.g. anatomical, surgical) and subjective (e.g. patient factors) considerations.

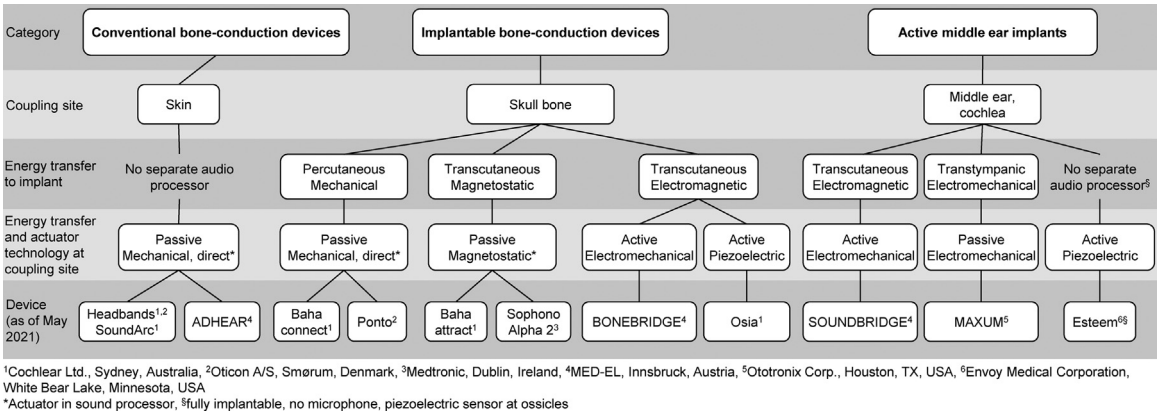

Fig 2. Systematic of currently available bone conduction devices and active middle ear implants.

coupled to the skin) while active middle ear implants stimulate mobile middle ear structures (i.e. ossicles, stapes footplate) or the cochlea via the round window membrane. The devices can thus be classified by the anatomical structure the actuator is connected to. Devices with actuators that drive the skin are no actual 'implants', however, they show significant similarities in design and indications, and are thus also discussed here.

The systems can also be characterized by the pathway of energy transfer from the audio processor to the implant. In percutaneous bone-anchored devices, the audio processor and the actuator are statically connected by an abutment that penetrates the skin and maintains a mechanical energy transfer (percutaneous-mechanical). Those implants are referred to as direct-drive bone-conduction devices. A passive ferromagnetic implant fixed to the skull can be driven transcutaneously by magnetic forces from the actuator located in the same housing as the audio processor placed on the skin (transcutaneous-magnetostatic). Those devices are referred to as skin-driven bone-conduction devices. Transcutaneous energy transfer can also be utilized as electromagnetic energy transfer (induction) from the audio processor coil to a receiver coil underneath the skin (transcutaneous-electromagnetic). The two components of the device are connected through magnetostatic forces of two permanent magnets. In non-implantable (conventional) bone conduction devices, the energy is also transmitted transcutaneously with the actuator placed on the skin to mechanically force the skin to vibrations that are further transmitted to the skull underneath the skin. A transtympanic, electromechanical energy transfer is used by a ferromagnetic implant that is driven by a sound processor within the external ear canal close to the tympanic membrane.

On the next level, the systems can be characterized by the energy transfer and the actuator technology at the coupling site. In passive devices, the actuator is directly connected to the implant by a static physical connection (direct mechanical) or magnetostatic forces. The vibration of the actuator directly follows the driving force. In active implants, actuators are transcutaneously connected by a radio frequency electromagnetic link to the sound processor. The implant decodes the acoustic information that is encoded in the electromagnetically transmitted signal so that electromechanical or piezoelectric actuators can generate vibrations. The specific, currently available devices for the respective energy transmission pathway are shown in Fig. 2 (bottom line).

2.1. Coupling to the skull

Transmission of sound to the skull bone is a very efficient pathway that bypasses the impaired middle ear function. The vibrations of the skull are conducted through different pathways to the cochlear capsule (Stenfelt, 2011). Its movement relative to the inner ear fluids then stimulates the sensory hair cells.

Typically, this type of energy transmission is obtained by fixing the actuator to the skull using screws with or without osseointegration. Due to its inertia, the acceleration of the skull bone requires large forces and works best when the moving mass of the actuator is large to have a resonance behavior similar to that of

the skull bone. Therefore, bone conduction stimulators are usually rather large and their maximum performance is limited.

In terms of maximum energy transfer, the optimal coupling site is close to the cochlea to be stimulated. Then, the transcranial attenuation to the contralateral cochlear achieves its maximum of around 10 dB (Claes et al., 2020; Dobrev et al., 2019; Rigato et al., 2019; Stenfelt, 2012). However, particularly in patients with asymmetrical sensorineural hearing loss, negative effects on the source separation, and thus hearing in noise and directional hearing, are expected.

In cases of percutaneous, mechanical energy transfer, the entire available energy is directly converted into vibration energy of the skull bone. Although such a technology is very effective, a direct penetration through the skin is required, that can cause skin irritation, inflammation or infection (Fritz et al., 2020; Shapiro et al., 2018). Currently available devices are the Baha 5 and Baha 6 connect systems (Cochlear Ltd., Sydney, Australia) (Kim et al., 2017; Kruyt et al., 2020), as well as the Ponto 3 and Ponto 4 systems (Oticon A/S, Smorum, Denmark) (Lagerkvist et al., 2020).

Transcutaneous energy transfer to the implant overcomes the limitations of the percutaneous (skin penetrating) implants. With analog electromagnetic signal transmission to the implant as used by the BONEBRIDGE (MED-EL, Innsbruck, Austria) (Seiwerth et al., 2021a; Sprinzl et al., 2021a) or the Osia (Cochlear Ltd., Sydney, Australia) (Goldstein et al., 2021; Willenborg et al., 2021), however, the induced voltage in the receiver coil is reduced with the distance between the induction coils (i.e., by the thickness of the skin) by about 1.5 dB / 2 mm (Taghavi et al., 2012). The risk of feedback loops is significantly reduced as compared with percutaneous signal transmission methods (Rahne, 2019). Some actuators, however, have relatively large footprints. Therefore, preoperative radiological planning has been recommended especially in small mastoids in malformations or children or in case of reduced bone volume after canal wall down mastoidectomy (Seiwerth et al., 2021b) and prompted companies to develop smaller actuators (Plontke et al., 2020; Wenzel et al., 2020).

2.2. Coupling through or via the skin

In cases when an invasive coupling to the skull has to be avoided, some bone-conduction actuators can be connected through the skin. With transcutaneous, magnetostatic energy transfer, the actuator is coupled to a ferromagnetic implant underneath the skin that is fixed to the skull. The elasticity of the skin attenuates the forces by about 10-20 dB (Gründer et al., 2008). Available devices are the Baha 5 Attract (Cochlear Ltd., Sydney, Australia) (Oberlies et al., 2020) and Sophono Alpha2 (Medtronic, Dublin, Ireland) (Bezdjian et al., 2017; Kohan and Ghossaini, 2019). The retention forces needed for an adequate energy transfer may cause pressure related side effects to the skin (Dimitriadis et al., 2016; Nevoux et al., 2018). Electromagnetic, transcutaneous energy transfer (see 2.1.) overcomes limitation of these implants, as electromagnetic waves are transmitted through the skin instead of magnetostatic or mechanical forces. Thus, the retention force can be reduced.

No magnet underneath the skin is needed if the device is coupled to the skin either by an adhesive ADHEAR (MED-EL, Innsbruck, Austria) (Dobrev et al., 2020; Zernotti et al., 2021) or by simple pressure (softband [Oticon A/S, Smorum, Denmark, Cochlear Ltd., Sydney, Australia] or BAHA SoundArc [Cochlear Ltd., Sydney, Australia]). Although they may use implant technology, these active bone conduction devices are not ‘implants’. Energy is directly transmitted transcutaneously, i.e., across the skin. The actuator mechanically forces the skin to vibrations that are further transmitted to the anatomically attached skull underneath the skin. An acoustic attenuation of about 10-15 dB results, that limits the performance of the entire system and may reduce speech perception (Gründer et al., 2008; Verstraeten et al., 2009).

2.3. Coupling to mobile middle-ear structures or the round and oval window

The most effective energy transfer is achieved if the actuator is coupled directly to mobile structures of the middle ear (ossicles, tympanic membrane) or to one of the cochlear windows. Energy can thus be transferred to the cochlea as ‘forward stimulation’ (e.g., incus, stapes, stapes footplate) or as ’reverse stimulation’ via the round window membrane (Beltrame et al., 2014; Colletti et al., 2006; Sprinzl et al., 2021b). Table 1 shows different coupling options of an active middle ear implant. Due to the small inertia of these structures, significantly less energy is required as compared with coupling to the skull or to the skin. Electromagnetic energy transfer is used by the SOUNDBRIDGE VORP 502 and VORP 503 (MED-EL, Innsbruck, Austria) active middle ear implant systems (Rahne et al., 2021; Song et al., 2021) or similarly to all cochlear implant systems.

Another middle ear implant (MAXUM, Ototronix Corporation, Houston, TX, USA) uses transtympanic, electrodynamic coupling of sound energy from the audio processor within the outer ear canal through the tympanic membrane to an actuator, that is attached to the intact ossicular chain at the level of a continuous incudomalleolar-stapedial joint (Pelosi et al., 2014).

All of the above-mentioned available implant systems are semi-implantable, i.e., the microphone, the audio processor, and the energy source are not implanted and worn externally. Fully implantable hearing systems are technologically challenging. Microphones underneath the skin are more sensitive to sound originating from the body than external microphones are. Sound processing algorithms have to deal with the attenuated external sound levels, body noises (e.g. chewing), and a significantly low feedback threshold (Tisch, 2017). In the last years, the Carina device (Cochlear Ltd., Sydney, Australia) was available as fully implantable middle-ear implant. Thus, future developments could again lead to fully implantable devices.

The piezoelectric actuator of the fully implantable hearing device Esteem (Envoy Medical Corporation, White Bear Lake, Minnesota, USA) is coupled to the stapes, while sound energy is picked up through a piezoelectric sensor attached to the malleus (Marzo et al., 2014). The necessary surgical interruption of the ossicular chain reduces the risk of feedback loops but also damages unaided hearing.

3. Audiological indication

In order to provide a balanced update about available active hearing implants, manufactures of implantable hearing devices were contacted and asked to provide information about market approvals, performance limits, and audiological indication criteria.

The vibratory output of an active hearing implant is air-borne sound energy that is amplified as function of the bone-conduction hearing threshold. It is reported in dB sound pressure level or dB force level. Since the gain of a device is limited, a maximum power output level (MPO) can be measured as function of the frequency for all systems. Occasionally, the term Maximum Power Output (MPO) is used synonymously as maximum of the MPO curve. When the maximum output level is reached, the device is in saturation. Thus, the MPO is the sum of the gain and the input sound pressure level at which saturation (and thus the maximum output level) is reached (Rahne and Plontke, 2016).

The performance of a hearing implant is often determined by the gain (difference between the unaided and aided sound-field thresholds and referred to as the ‘functional gain’ (Maier et al.,

Table 1
Coupling options for an active middle ear implant (VIBRANT SOUNDBRIDGE).

Stimulation	Coupling structure	Coupling elements	Typical indications§
Reverse	Round window membrane	Fascia, Cartilage, RW-coupler, RW-soft coupler, None (FMT direct)	*Mixed or conductive hearing loss:* e.g., in COM after CWD-procedures with very shallow middle ear cavity; footplate fixation (e.g., postinflammatory or otosclerosis); inaccessible OW in malformation; *Sensorineural hearing loss*
Forward	Incus (long process)	LP-coupler (L/R), Symphonix-Coupler (L/R)	*Sensorineural hearing loss*: medical contraindications for or complications with conventional hearing aids *Mixed or conductive hearing loss:* e.g., post-inflammatory meatal fibrosis (PIMF)
	Incus (body + short process)	SP-coupler	
	Stapes suprastructure	CliP-Coupler, Bell-Coupler	*Mixed or conductive hearing loss:* intact, mobile stapes; e.g., in COM w/wo CWD-procedure; malformation
	Stapes suprastructure	Stapes-Head Coupler, [Symphonix-Coupler*,**]	*Mixed or conductive hearing loss:* intact, mobile stapes; e.g., in COM w/wo CWD-procedure and very shallow middle ear cavity; malformation
	Stapes footplate	OW-coupler, Cartilage, [None (FMT direct)], [RW-coupler]	*Mixed or conductive hearing loss:* no stapes suprastructure, intact footplate with normal mobility, e.g., in COM w/wo CWD-procedure; malformation
	Incus (SP or LP) with additional stapes prostheses	LP- or SP-Coupler and stapes prosthesis	Otosclerosis with moderate-to-severe sensorineural hearing loss component; [malformation]
	Directly to vestibular perilymph through stapedotomy**	OW-Coupler**	Footplate fixation (postinflammatory, otosclerosis, malformation); up to moderate-to-severe sensorineural hearing loss component
	FMT placed in artificial promontorial window/ fenestration**	None (FMT direct)**	Selected indications (e.g., malformation)

COM: chronic otitis media: CWD: canal wall down: FMT: floating mass transducer; L: left; LP: long process (of the incus); OW: oval window; PORP: partial ossicular reconstruction prosthesis; R: right; RW: round window; TM tympanic membrane: w/wo: with or without; SP: short process (of the incus); TORP: total ossicular reconstruction prosthesis
*with modification by surgeon; **off -label; §Indications: usually after unsuccessful (multiple) middle ear surgery or insufficiently possible, unsuccessful ear canal reconstruction, or medical contraindications for conventional hearing aids

2021) and the MPO: At low input levels, the device with the larger gain is perceived as louder (and therefore more powerful). At high input levels, the device with the higher maximum output level appears louder. Thus, a pure evaluation of hearing implants on the basis of aided sound-field thresholds can be deceptive if devices are already saturated with moderate input levels. Instead of measuring 'functional gain', the 'effective' gain (difference between unaided (bone-conduction) and aided threshold) of a device should be measured to assesses the effectiveness of the device (Maier et al., 2021).

When evaluating the maximum output level taken from the manufacturer's data sheets with respect to an indication, it must be considered how 'usable' this performance is, taking into account the cochlear performance ('cochlear reserve'), the dynamic range, and the risk of acoustic feedback (maximum stable gain (Maier et al., 2021)). For implantable hearing systems, the bone conduction hearing threshold is usually used as a correlate of the 'cochlear reserve' and to determine the audiological indication for an active hearing implant (Carlsson and Håkansson, 1997; Rahne and Plontke, 2016).

The dynamic range of speech signals is around 70 dB (Stenfelt, 2011). According to Keidel and Neff (1974), however, it is sufficient to assume a target dynamic range of at least 35 dB in order to achieve an articulation index of 0.5, corresponding to a word recognition of 75% or a sentence recognition of 95%. In the case of bone conduction implants, due to the steeper loudness growth, the minimum required dynamic range can probably be reduced to 30 dB (Carlsson and Håkansson, 1997; Rahne and Plontke, 2016).

For the audiological indication, both the performance parameters of the implant systems and the audiological prerequisites of the patient must be considered. A large intrinsic dynamic range of the implant system, that is, a large MPO with low intrinsic noise, is potentially positive for the audiological result. Cochlear impairment (i.e., commonly measured as increased pure tone hearing threshold for bone conduction) as well as a potential transmission loss due to a decreased coupling efficiency, will reduce the available dynamic range and must therefore be considered.

Since the required dynamic range for the patient is a minimum of 30-35 dB, the MPO must therefore be at least 30-35 dB above the patient's bone conduction hearing threshold and the assumed deficit in coupling efficiency. Table 2 shows the reported (after beeing contacted by the first author) or published MPO data as well as the market approvals for nearly all currently available active hearing implants. For bone conduction devices, the audiological indication limits were derived from the MPO functions adjusted to a minimum dynamic range of 30 or 35 dB, respectively. The pure-tone averages (4PTA) were calculated as averaged thresholds at 0.5, 1, 2, and 4 kHz.

If the actuator is connected to the skin (ADHEAR [MED-EL, Innsbruck, Austria]), the reference equivalent threshold force levels, (RETFL (DIN EN ISO 389-3, 2016)) and correction values for the skin mediated attenuation (Gründer et al., 2008) were used to convert maximum force output levels to hearing levels. For bone-anchored hearing systems, up to 10 dB better thresholds as compared with the RETFL could be observed (Carlsson et al., 1995) and used as conversion levels for those implants ($RETFL_{dBC}$).

MPO data were not available for the MAXUM (Ototronix Corporation, Houston, TX, USA) and the Esteem (Envoy Medical Corporation, White Bear Lake, Minnesota, USA) systems. Both manufacturers did not reply to respective requests. Thus, pure-tone threshold-based indication criteria could not be derived. Clinical studies report a benefit for patients with sensorineural or mixed hearing loss (Chang, 2019; Hunter et al., 2016; Klein et al., 2012; Marzo et al., 2014; Pelosi et al., 2014).

Table 2.
Market approvals, frequency-specific maximum output levels and bone-conduction hearing threshold limits of currently available active hearing devices.

Device	Maxium output force level [dB re 1μN], *[dB SPL eq.]*					Skull simulator used	Maximum output hearing level [dB HL]						Indication limit: Maximum 4PTA BC threshold [dB HL]			Market authorities approvals
	0.5 kHz	1 kHz	2 kHz	3 kHz	4 kHz		0.5 kHz	1 kHz	2 kHz	3 kHz	4 kHz	4PTA	35 dB dynamic	30 dB dynamic	Manufacturer datasheet	
Cochlear Ltd.																
Baha 6 Max - Connect[a]	119	118	110	108	106	TU-1000[1]	71	73	84	80	79	77	42	47	55	CE, FDA
Baha 5 Superpower - Connect[a]	130	129	122	119	118	TU-1000[1]	82	84	96	91	91	88	53	58	65	CE, FDA, other
Baha 5 Power - Connect[a]	121	118	112	109	108	TU-1000[1]	73	73	86	81	81	78	43	48	55	CE, FDA, other
Baha 5 - Connect[a]	105	114	106	103	101	TU-1000[1]	57	69	80	75	74	70	35	40	45	CE, FDA, other
Baha 5 Superpower - Attract[a]	133	128	124	114	111	Artificial Mastoid[2]	85	83	98	86	84	87	52	57	65	CE, FDA, other
Baha 5 Power - Attract[a]	124	116	114	104	103	Artificial Mastoid[2]	76	71	88	76	76	78	43	48	55	CE, FDA, other
Baha 5 - Attract[a]	108	113	110	101	96	Artificial Mastoid[2]	60	68	84	73	69	70	35	40	45	CE, FDA, other
Osia[a]	113	116	112	105	104	TU-1000[1,ca]	65	71	86	77	77	75	40	45	55	CE, FDA
MED-EL																
ADHEAR[b]	105	114	101	98	95	SKS 10[3] and custom made[4]	44	65	61	48	37	52	17	22	25	CE, FDA, other
SAMBA 2 BB + BCI 602[b]	96	110	99	96	95	Custom made[4]	48	65	73	68	68	63	28	33	45	CE, FDA, other
SAMBA Lo + VORP 502[b]	*85*	*92*	*93*	*92*	*92*	not applicable[8]									25	CE, FDA, other
SAMBA Hi + VORP 502[b]	*111*	*111*	*111*	*111*	*111*	not applicable[8]									56	CE, FDA, other
SAMBA 2 Lo + VORP 503[b]	*83*	*93*	*91*	*91*	*91*	not applicable[8]									25	CE, other
SAMBA 2 Hi + VORP 503[b]	*109*	*110*	*110*	*110*	*110*	not applicable[8]									56	CE, other
Amade + VORP 502 (in vivo)[7]							75	83	90		80	82	47	52	56	[for comparison]
Medtronic																
Sophono Alpha 2 MPO[a]	88	111	107	100	85	Unknown	40	66	81	72	58	61	26	31	35-45	CE
Oticon A/S																
Ponto 3 Superpower / BHX implant[a]	119	129	119	115	112	Unknown[4,c]	71	84	93	87	85	83	48	53	65	CE, FDA, other
Ponto 4 / BHX implant[a]	108	120	106	102	100	Unknown[4,c]	60	75	80	74	73	72	37	42	45	CE, FDA, other
RETFL (DIN EN ISO 389-3)	58	42.5	31	30	35.5											
$RETFl_{dBC}$[5]	48	45.5	26	28	27.5											
Transcutaneous/percutaneous correction[6]	3	7	9	20	23											

[a]Datasheet, [b]Numerically provided from manufacturer, [c]Compensated for skull impedance, [ca]Compensated for skull impedance and for actuator position
[1]Håkansson & Carlssen, 1989, [2]DIN EN 60318-6, [3]Interacoustics, [4]IEC 60118-9:2019, [5]Carlssen et al., 1995., [6]Gründer et al., 2008, [7]Zwartenkot et al., 2014, [8]Laser Doppler Vibrometer (Dietz et al., 1997)

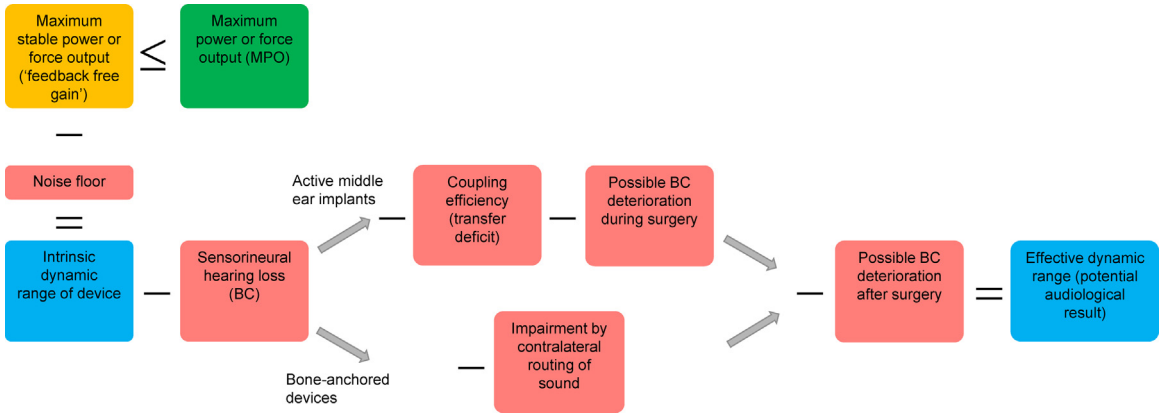

Fig 3. Flowchart for estimating the individual effective dynamic range for bone conduction devices and active middle ear implants.

The actuator of middle-ear implants is coupled to the ossicular chain (or remnants of it, e.g., the stapes footplate) or to the round window. The stability of those connections and thus the efficiency of coupling varies but is a prerequisite for efficient sound transmission and speech perception outcome. Poor coupling quality results in increased aided hearing thresholds or reduced signal quality (Müller et al., 2017; Rahne, 2019). For the SOUNDBRIDGE (MED-EL, Innsbruck, Austria) system, actuator coupling quality can be measured by acoustic evoked potentials (Fröhlich et al., 2020). Postoperatively, the measurement of in-situ thresholds (vibrogram) as direct thresholds is available as an unreferenced method of the manufacturer that correlates to the bone-conduction hearing thresholds. Increased vibrogram thresholds indicate a loss of coupling, which is also reflected in reduced speech understanding (Müller et al., 2017).

MPO measurement on skull simulators (DIN EN 60118-9, 2019; DIN EN 60318-6, 2009; Håkansson and Carlsson, 1989) is not possible for the SOUNDBRIDGE (MED-EL, Innsbruck, Austria) middle ear implant systems. Table 2 therefore shows the SPL equivalent MPO values according to Dietz et al. (1997). Since coupling quality varies, results of in-vivo measurements (Zwartenkot et al., 2014) were reported in Table 2. In the underlying experiment, the sound pressure level in the closed ear canal was measured as a function of the input sound pressure level, and the maximum output level was determined. The resulting audiological indication range is also shown in Table 2.

A possible pathway to estimate the suitability of a specific active hearing device for the individual patient is shown in Fig. 3. The intrinsic dynamic range can be estimated as the difference between the maximum stable power or force output ('feedback free gain') and the noise floor. A large intrinsic dynamic range of the implant system is potentially positive for the audiological result. The effective dynamic range can then be estimated by considering the sensorineural hearing loss (BC thresholds), a potential transmission loss (coupling deficit), and a worsening of bone conduction threshold due to an estimated natural or disease related progression or the surgery itself as a safety margin. For bone anchored devices, the contralateral routing of sound may limit the available intrinsic dynamic range due to interaction with the contralateral (better hearing) ear in the case of asymmetric BC thresholds. Therefore, the resulting effective dynamic range that determines the audiological result is – in the best case – just as large as the intrinsic dynamic range of the device, but rather almost always smaller.

Some of these considerations (e.g. coupling efficiency or BC deterioration) are directly related to the invasiveness and the surgical risks associated with different devices and surgical procedures. While coupling an actuator to mobile middle ear structures or the round window bears a certain risk of BC threshold deterioration, this is hardly the case with any of the bone conduction devices. Nevertheless, all implanted devices carry risks inherent to the specific surgical procedure. With respect to the exact rate of complications and risks, we expect a significant publication bias resulting in an underreporting.

Skin penetrating (percutaneous) devices naturally bear the inherent risks of skin reactions and infections. Fussey et al. reported that 77% of children experienced soft tissue complications that required treatment (Fussey et al., 2018). An earlier meta-analysis showed that these complications led to implant loss in 1.6–17.4% of patients (Kiringoda and Lustig, 2013). With the introduction of minimally invasive implantation techniques, however, and the avoidance of skin thinning with longer abutments, the complication rate has improved (Sardiwalla et al., 2018). Soft tissue complications associated with percutaneous bone conduction hearing implants can be avoided with transcutaneous systems. In devices with magnetostatic energy transfer through the skin, however, the retention forces needed may cause pressure related side effects to the skin (Dimitriadis et al., 2016; Nevoux et al., 2018), which is much lesser in devices with transcutaneous, electromagnetic energy transfer. For the latter, a recent meta-analysis on the BONEBRIDGE (model BCI 601, MED-EL, Innsbruck, Austria) reported minor adverse events in 7.7% and major adverse events in 1.7% of the cases (Magele et al., 2019). The optimized geometric design of the newer active bone conduction hearing implant BCI602 of the same company improved the fit of the implant to the bone even under challenging anatomical conditions (Plontke et al., 2020; Wenzel et al., 2020). Long-term follow up data for the newer Osia implant (Cochlear Ltd., Sydney, Australia) are sparse. A recent study reported explantations in 1 of 22 patients (4.5%) because of prolonged wound infection (Rauch et al., 2021). The surgical technique for the Osia involves a significantly larger skin incision than for the other implant with transcutaneous, electromagnetic energy transfer (Arndt et al., 2021).

With respect to the number of patients showing a decreased bone-conduction hearing threshold of at least 15 dB after SOUNDBRIDGE (MED-EL, Innsbruck, Austria) implantation, percentages of 11% (incus vibroplasty) and 20% (round-window vibroplasty) were reported (Spiegel et al., 2020). A deviation of 15 dB was considered clinically relevant in their study so that the percentage of patients with BC deterioration by more than 10 dB is potentially higher. In these patients, the cochlear reserve is poorer compared to the preoperative situation, i.e. when the device was chosen, which may lead to suboptimal audiological result. A device explantation rate was reported with of 10.2% (Brkic et al., 2019). The

findings on incus and round window vibroplasty (Spiegel et al., 2020) are in line with other studies, reporting an overall revision rate for the SOUNDBRIDGE ranging from 10.2% for different coupling strategies (Ernst et al., 2016) to 15.2% (Sprinzl et al., 2021b) or even 29% (Schraven et al., 2016) for round window coupling. The Esteem device (Envoy Medical Corporation, White Bear Lake, Minnesota, USA) requires the surgical interruption of the ossicular chain, which resembles a surgical procedure unique for this fully implantable hearing device. This risk, in combination with patient-related factors like previous surgeries, skin conditions or malformations, will also have to be considered when selecting an appropriate device for hearing rehabilitation.

4. Conclusions

Currently, bone conduction devices and active middle ear implants that sufficiently treat various pathologies of the ear with conductive and mixed hearing loss are available in many markets. The effective gain reached with different systems varies but allows to cover a certain degree of sensorineural and mixed hearing loss. To achieve a sufficient effective dynamic range, the upper indication limit can be derived from the MPO functions and in most cases is lower than the maximum indication range as provided by the manufacturer. Besides audiological indication criteria, there are several objective and subjective factors influencing the complex decision of selecting an appropriate device for an individual patient.

Authors' statement

All authors confirm that this review article does not include experiments with human subjects.

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