Results and Quality of Life after Implantation of Active Middle Ear Implants

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ABSTRACT

The provision of implantable hearing aids represents an area with high development and innovation potential. On the one hand, this review article provides an overview of current indication criteria for the treatment with active middle ear implants. On the other hand, outcome parameters as well as functional results after implantation of active middle ear implants are demonstrated and discussed. The focus is mainly placed on audiological results as well as the subjective health status. "Patient Reported Outcome Measures" (PROMs) have become an integral part of the evaluation of hearing implant treatment. Due to low evidence level criteria, the study situation regarding audiological as well as subjective outcome parameters is not satisfactory. The lack of an international consensus on accepted outcome parameters makes a meta-analytical evaluation of results immensely difficult. In the studies published to date, patients with sensorineural hearing loss and patients with conductive or mixed hearing loss offered better speech recognition after implantation of an active middle ear implant compared to conventional hearing aids. Current analyses show a significant improvement in general as well as hearing-specific quality of life after implantation of an active middle ear implant. To date, no validated, hearing-specific quality-of-life measurement instruments exist for assessing the success of fitting in children. Especially in children with complex malformations of the outer and the middle ear, excellent audiological results were shown. However, these results need to be substantiated by quality-of-life measurements in future.

Contents

1. Introduction

Nowadays, active middle ear implants are an integral part of the concept of personalized hearing rehabilitation. During the past decades, many efforts have been undertaken with regard to research and development to provide active middle ear implants with most different mechanisms of action and indications. In Germany, the indication was focused on patients who cannot use conventional hearing aids for medical reasons or who would not satisfactorily benefit from conventional hearing aids because of mixed hearing loss (MHL). The technological challenges for an implantable device on one hand and on the other hand the currently low market percentage compared to cochlear implants led to the fact that only few active middle ear implants achieved a stable position in the last 20 years.

Due to the increased significance of "patient-reported outcome measures" (PROMs) for the evaluation of therapies and the healthcare process in clinical trials, the assessment of the subjectively perceived therapy success also in the provision of hearing implants was placed more and more in the focus. PROMs may extend the significance of clinical trials beyond the traditional clinical endpoints by including further patient-related endpoints. The increasing significance of these PROMs in the context of approval and reimbursement decisions is also reflected in international and national guidelines. Hereby, the subjective and audiological outcome of a treatment with active middle ear implants must not only be measured by comparing the situation with unaided hearing conditions. Moreover, it is recommended that the outcome quality is comparable of other possible alternative hearing solutions (e. g., bone conduction hearing systems or conventional hearing aids) or preferably improved so that the provision with active middle ear implants can be justified towards the individual patient as well as the cost bearers.

While former articles published in the context of Annual Meetings of the German ENT Society preferably dealt with the methods of stimulation, indications as well as advantages and disadvantages of the single active middle ear implants that had been developed up to then [1–3], the present submission will focus on the clinical outcome of treated patients consistent with the motto of the 93rd Annual Meeting of the German ENT Society, namely "Interface – Focus on human individual in the age of high tech medicine and technology". At the beginning, the present article will define the indication range of active middle ear implants because the treatment outcome is mainly determined by correct, possibly evidence-based indication. Then, audiological outcome parameters and PROMs will be illustrated, which are suitable to comprehensively describe and rate the treatment outcome. Afterwards, the findings that have already been assessed in clinical trials will be displayed and discussed. The consensus about generally accepted outcome parameters that is currently not found on an international scale and the missing standard of reporting massively complicates the comparability of the studies so that investigations based on meta-analyses do only have limited significance. Furthermore, this article will discuss factors that might have an impact on the audiological outcome or even the PROMs and an outlook to open questions will be given.

2. Indications for the treatment with active middle ear implants

The S2k guideline on implantable hearing aids is the national basis of current definition of an indication for active middle ear implants [4]. According to the guideline, an indication for an active middle ear implant is given when provision of conventional hearing systems is not sufficiently possible due to medical or audiological reasons or when a permanently improved hearing ability may be expected by means of a middle ear implant taking into account the individual cochlear reserve and the performance characteristics of the implant.

Primarily, active middle ear implants have been developed for actor coupling to the intact ossicular chain (especially to the incus) and thus for hearing rehabilitation in cases of sensorineural hearing loss (SNHL). The development of coupling elements in analogy to passive middle ear implants as well as the verification of coupling to the round window membrane for "reverse stimulation" of the cochlea led to a broader spectrum of indications for conductive hearing loss (CHL) and patients with MHL.

In particular patients with multiple revision surgeries due to chronic otitis media, impaired middle ear ventilation and/or post-inflammatory chain (mainly stapes) fixation do not achieve satisfactory hearing results after classic reconstruction of the ossicular chain by means of passive prostheses so that especially these patients must be treated with a hearing system because of their impaired speech perception. Treatment with conventional hearing

▶ **Table 1** Overview about commercial active middle ear implants.

	Implant	Manufacturer	Possible actor target structures	Mechanism	Indication	Functional results	
						WRS 65 dB (implanted)	Functional Gain
Partly implantable	Vibrant Soundbridge	MED-EL (Innsbruck, Austria)	Incus, stapes head, stapes footplate, round window	Electro-magnetic	Moderate SNHL, moderate to severe MHL/CHL	MHL/CHL: 62–99 % SNHL: 66–80 % [83–88]	MHL/CHL: 12–43 dB SNHL: 11–28 dB [83–88]
	Middle Ear Transducer *	Cochlear (Sydney, Australia)	Incus, stapes head, stapes footplate, round window	Electro-magnetic	Moderate to severe SNHL or MHL	63–86 % [69–71]	15–45 dB [69–71]
	Codacs Direct Acoustic Cochlea Implant *	Cochlear (Sydney, Australia)	Perilymphatic coupling	Electro-magnetic	Severe to profound MHL	55–85 % [204–207]	48–50 [205–207]
	MAXUM System	Ototronix LLC, (Houston, USA)	Stapes head	Electro-magnetic	Moderate to severe SNHL	65–82 % [63, 72, 73, 82]	39–60 dB [63, 72, 73, 82]
Fully implantable	Carina *	Cochlear (Sydney, Australia)	Incus, stapes head, stapes footplate, round window	Electro-magnetic	Moderate to severe SNHL or MHL	MHL: 62–95 % SNHL: 62–69 % [64–68, 79–81]	MHL: 29–39 dB SNHL: 19–28 dB [64–68, 80–81]
	Esteem	Envoy Medical Corporation (White Bear Lake, USA)	Incus (sensor), stapes head (actor)	Piezo-electric	Moderate to severe SNHL	68–70 % [74–76]	20–27 dB [74–77]
	TICA *	Implex AG (Munic, Germany	Incus	Piezo-electric	Moderate to severe SNHL	72–78 % [78]	30–30 dB [78]

WRS: Word Recognition Score; SNHL: sensorineural hearing loss, CHL: conductive hearing loss, MHL: mixed hearing loss; * no longer available.

aids is often in vain for these patients because high amplification performances and output levels are necessary to overcome the air-bone gap (ABG). In this situation, active middle ear implants provide a solution since they circumvent the stiffness and absorption of a poorly vibrating tympanic membrane or ossicular chain reconstruction as vibromechanical bypass and thus they allow direct entering of the sound into the inner ear using a "bypass". In this way it is possible to acoustically stimulate the cochlea over the entire speech range.

In the past years, several active middle ear implants have been developed (▶ **Table 1**) that vary regarding the mode of action, surgical procedure, performance characteristics, and thus their spectrum of indications. Some of these implants did not prevail in the clinical routine and disappeared from the market because of only low numbers of implantations.

3. Outcome parameters

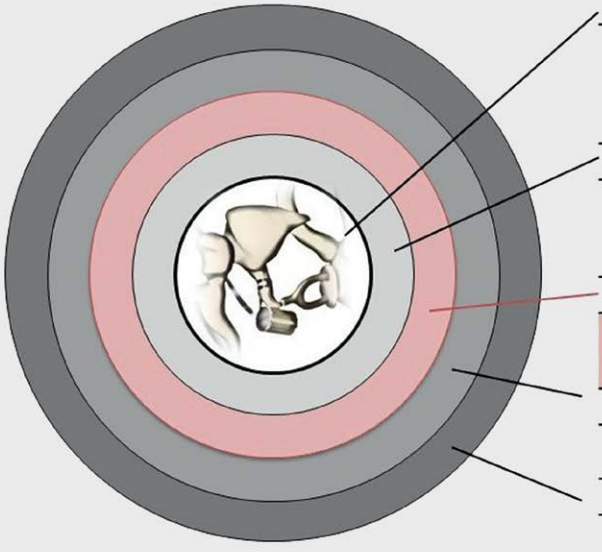
The objective of outcome analyses is the evaluation of the outcome quality in medical healthcare provision. The outcome quality refers to the result of a medical intervention and includes all current or future changes of the patient's health status after intervention [5]. The outcome comprises different dimensions of the merely medical change of the health status via the impact on social, caring, and psychological functions of the patient up to health-related changes of the consciousness, knowledge, and behavior as well as the patient and life satisfaction [6]. Based on this definition, it is obvious that a comprehensive assessment (▶ **Fig. 1**) requires the outcome evaluation from the physician's as well as the patient's perspective [7].

The medical assessment of the treatment process with hearing implants traditionally focuses on the analysis of audiological target parameters. The evaluation of the outcome from the patient's point of view includes factors like quality of life, expectations, negative affections, social stigmatization, and coping strategies.

3.1. Audiological target parameters

For audiological evaluation of the treatment outcome with an active middle ear implant, threshold- and speech-related parameters must be considered. These parameters are assessed in the clinical process and are also suitable as target parameters for clinical trials. Due to methodical and evaluation differences on an international level regarding audiometric examination techniques, direct comparisons of the results and their inclusion in meta-analysis are hardly possible [8].

Threshold-related parameters The measurement of the pre- and postoperative bone conduction threshold allows estimating the cochlear reserve and serves as medical control regarding postoperative cochlear depression. The measurement of the aided threshold in the free field (functional gain) by means of narrow band noise or warble tones does not allow interpretations of the resulting speech perception but it documents the shift of the hearing curve into the "speech-perceived" area [9]. By means of different weightings of single frequencies, the articulation index may be



Evaluation level	Possible method	Statement
1 Intraoperative evaluation		
Classification of coupling, verification of the quality of coupling, description of the reconstruction technique	Surgery report, classification of vibroplasty, intraoperative monitoring	Integrity of the implant and the coupling
2 Evaluation of the hearing outcome		
Hearing and ear history, clinical and audiological findings	Audiology (speech comprehension, effective and functional hearing gain), in situ thresholds	Hearing function
3 Holistic patient assessment		
Quality of life, impairment due to hearing disorders	Disease-specific, hearing-specific, and generic QoL measurement tools	Individual
4 Evaluation in trials		
Assessment of defined endpoints in trials	Statistical evaluation	Cohort
5 Evidence		
Significance of trials	Systematic research (meta-analyses, Cochrane analyses, review articles etc.)	Evidence

▶ **Fig. 1** Model representation of the evaluation levels in the provision process of active middle ear implants, modified according to Neudert and Zahnert, 2017 [7]: The simultaneous application of different methods or perspectives for outcome evaluation after implantation of an active middle ear implant and the assessment of possibly valid data allows a comprehensive consideration of the outcome of the healthcare process. As of level 3, patient-reported outcome measures (PROMs) must be included in the consideration.

calculated based on the aided threshold in order to assess speech perception [10].

The parameter of functional gain defined as difference between the aided and unaided threshold was taken from conventional hearing aid provision. However, in patients with MHL or CHL, this parameter can only insufficiently describe the actual amplification performance of active middle ear implants due to the additional ABG. A realistic evaluation of the amplification of the active middle ear implant is achieved by determining the effective gain as difference between aided threshold in the free field and bone conduction threshold because hereby the different manifestations of the ABG in MHL/CHL are not significant [11]. Negative values allow assuming an increase of the free field threshold over the bone conduction (overclosure). The measurements of the direct thresholds via the implant and their comparison with the bone conduction threshold allows conclusions regarding the coupling efficiency. The corresponding measurement algorithms are specific for each manufacturer (e. g., Vibrant Soundbridge, MED-EL Company, Innsbruck, Austria: Vibrogramm; Carina, Cochlear Company, Sydney, Australia: OC Direct). Frequently, all threshold-related parameters are averaged according to the recommendations of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) at test frequencies of 500, 1,000, 2,000, and 3,000 Hz while in European countries 3,000 is often replaced by 4,000 Hz [12, 13]. But in order to present the frequency-specific performance characteristics of the implant, a description of the mentioned threshold-related parameters depending on the frequencies may be helpful.

Speech-related parameters In analogy to conventional hearing systems, the evaluation of the outcome of the treatment with active middle ear implants is mostly performed by comparing the preoperatively unaided speech perception in quiet with aided speech understanding. For evaluation, the word recognition score is measured at determined sound pressure levels (SPL; e. g., 60 dB SPL, 65 dB SPL, 80 dB SPL) or also the speech reception threshold (SRT) for numbers or monosyllables [14]. The assessment of speech perception in noise gives information about the benefit of the hearing aids in daily routine. The applied test procedures are not only different with regard to the test material (sentence test, monosyllables test) and in the configuration of the signal or noise, but also in the measurement methods (adaptive measurement, non-adaptive measurement). The permutation of these parameters leads nationally and internationally to a high heterogeneity of the presentation of the outcome parameters [8]. For the treatment with active middle ear implants, the AAO-HNS recommends the measurement of speech perception at 40 dB SPL over SRT and the presentation in a scattergram containing also the pure tone average (PTA) as target parameter [12]. In particular for patients with MHL leading to important threshold losses, the measurement at 40 dB SPL over SRT must be considered as unusable because the limits of conventional audiometry are reached directly [14].

In a consensus paper of 2018, German-speaking audiologists and otologists published recommendations for a minimum reporting catalogue (▶ **Table 2**), independently from scientific societies and working groups. They defined a minimum follow-up period of 12 months while reports about audiological results were considered as justified even 6 months after first fitting [15].

▶ **Table 2** Audiological target parameters for evaluation of the outcome quality after implantation of active middle ear implants [15].

Pre- and perioperative characteristics	
Demographic parameters	**Surgical parameters**
▪ Implanted side ▪ Year of birth ▪ Sex ▪ Type of hearing loss ▪ Etiology ▪ Type and extent of a malformation ▪ Previous interventions ▪ Number of revision interventions ▪ Current otologic findings ▪ Fulfillment of indication criteria ▪ Rationale for implantation	▪ Date of surgery ▪ Date of activation ▪ Patient's age at the time of surgery ▪ Time of first fitting ▪ Surgical approach ▪ Coupling technique ▪ Coupling elements ▪ Additional materials
Audiological parameters	
▪ Tone audiogram including air (0.25–8 kHz) and bone conduction (0.5–6 kHz) before and after surgery ▪ Preoperative speech audiogram at 65 dB and 80 dB, if possible, max. word recognition score ▪ Preoperative free field threshold without hearing implant (possibly with hearing aids) at 0.25–8 kHz and after surgery (with implant) ▪ Preoperative speech perception in quiet at 65 dB in the free field without implant (possible with hearing aids) and after surgery (with implant) ▪ Preoperative speech perception in noise (adaptive speech understanding threshold with a noise of 65 dB SPL) without implant (possible with hearing aids) and after surgery	
Assessment of complications	
Perioperative, up to 12 months after surgery, more than 12 months after surgery	
Patient Reported Outcome Measures	
Preoperative APHAB as well as 6 and 12 months postoperatively	
Description of the fitting algorithm	

3.2. Patient Reported Outcome Measures (PROMs)

The term of PROMs includes different concepts for measuring subjectively perceived therapeutic effects. All these methods of PROMs have in common that the individual patient estimates the own health status or its changes at a certain time [16]. PROMs are based on a psychometric approach aiming at measuring perceived symptoms, abilities, behavior, or mental constructions. Single dimensions can be summarized to complex concepts such as health-related quality of life. Standardized, valid, and reliable PROMs allow comprehensively displaying intervention effects of specific therapies from the patients' perspective [17].

The PROMs that are helpful to assess the treatment success after implantation of an active middle ear implant include tools measuring the hearing capacity from the patient's point of view in different situations and tools measuring the quality of life. The latter ones are subdivided into generic and disease-specific or function-specific measurement instruments (▶ **Fig. 2**).

3.2.1. Definition and concept of health-related quality of life

The term of "quality of life" (QoL) was introduced at the beginning of the 1980ies. Since then, efforts are undertaken not only to assess the quality of life in doctor-patient conversations and consultations, but also to make it measurable and thus available for scientific purposes [18].

Based on the multidimensional definition of the WHO of health as "… state of complete physical, mental and social well-being and not merely the absence of disease or infirmity …" [19], the shift from the merely biomedical perspective of health to an extended biopsychosocial model (▶ **Fig. 3**) is justified [20]. The health-related quality of life is considered as multifactorial construction that focuses on four dimensions in the context of scientific investigation: Beside physical complaints, the mental condition, functional impairment in daily routine as well as impairment in the building of interpersonal relationships and social interactions that are primarily due to a disease are analyzed from the subjective perspective of the patient [21]. The health-related quality of life is determined by the expectations and experiences of the patients and varies between the single individuals. It is subject to changes in the time course which justifies the necessity to assess the subjective patient's point of view by means of measurement tools and not by external parties [22, 23].

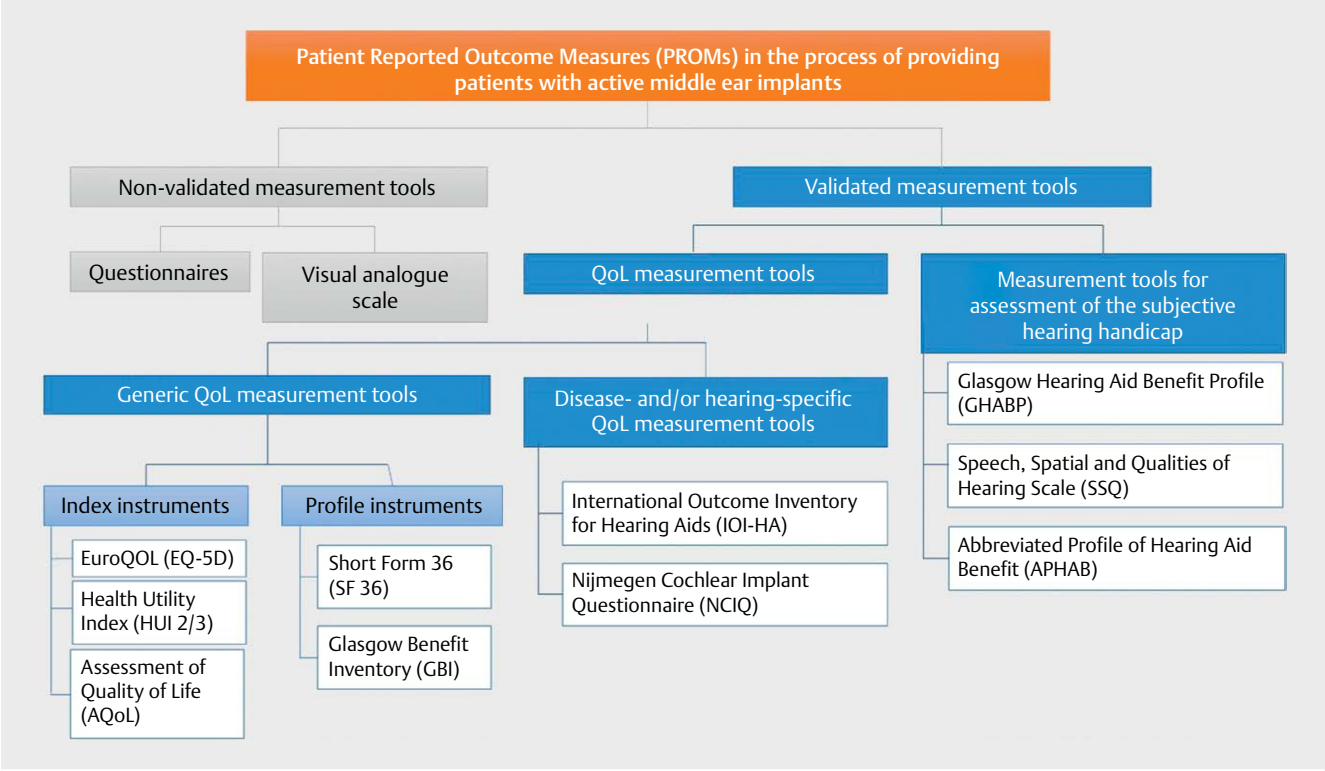
The objectives of assessing the quality of life are not only the description of well-being and functionality (epidemiological perspective) but also the evaluation of treatment outcomes (clinical perspective), the analysis of quality and treatment costs (health-economic perspective), and the optimization of healthcare pathways (healthcare policy) in order to finally achieve tailored individualized therapies for each individual patient [24].

At the beginning, the research on quality of life mainly focused on oncological issues as well as chronic diseases. Only at the beginning of the 2000s, the quality of life for audiological and otological issues was identified as important indicator in addition to merely biomedical parameters.

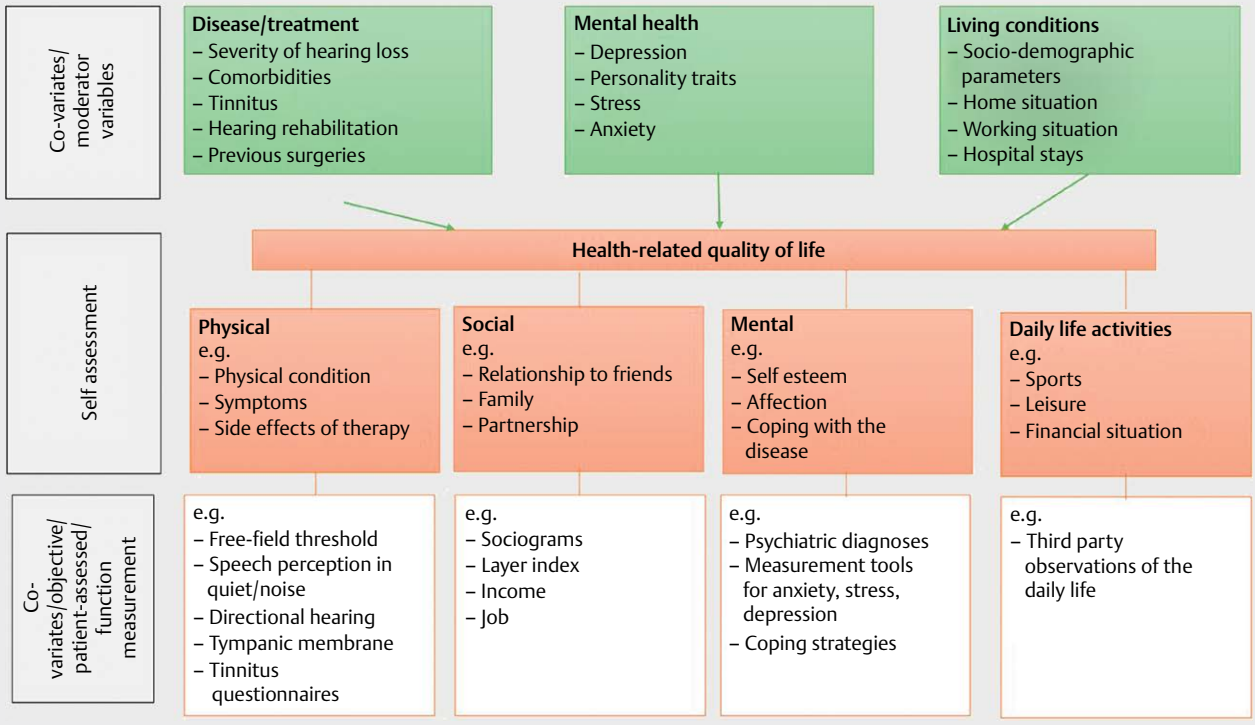
3.2.2. Quality criteria of the measurement tools

Precondition for a scientifically high-quality analysis of quality-of-life parameters is the availability and evaluation of suitable measurement tools. Self-conceived symptom lists have to be strictly differentiated from quality-of-life measurement tools that meet all criteria of a quality indicator. In the literature, several recommendations are found regarding criteria to assess the methodological quality of QoL measurement tools. A short and easily applicable list of criteria was suggested by Fitzpatrick et al. (▶ **Table 3**) [25].

Since the beginning of the 2000s, the focus in audiology and otology was initially placed on the development of new, possibly disease-specific measurement tools as we all on checking if already existing tools may be applied taking into account the mentioned quality criteria. Only in the last years, also therapy- and patient-associated factors were increasingly placed in the focus of QoL investigations.



▶ **Fig. 2** Overview of patient-reported outcome measures (PROMs) for characterization of the therapy success after implantation of active middle ear implants.



▶ **Fig. 3** Biopsychosocial model of hearing implant provision: Consideration of dimensions and co-variates of health-related quality of life.

▶ **Table 3** Criteria for evaluating the methodical quality of quality of life measurement instruments [25].

Category	Description	Parameter
Appropriateness	The data collected with a QoL measurement instrument are suitable to answer the questions of the trial.	Content- and method-related characteristics
Acceptability	The measurement instrument has to be accepted by the participant.	Extent, required time, content of the measurement instrument
Feasibility	The feasibility describes how simple and easy it is to practically apply and evaluate the measurement tool.	Required efforts, evaluation algorithms, digitization
Validity	A measurement tool is considered as valid when measures what it is intended to measure.	Validity of the content, discrimination, congruence
Reliability	Under the same conditions, the measurement tool must allow reproducible results.	Internal consistency (Cronbach α), test-retest reliability
Responsiveness	This criterion allows to assess if and how suitable a tool is to depict changes of the quality of life in the time course.	Standardized Response Mean, SRM
Precision	The instrument needs to have a sufficient number of items and possible answers in order to reliably assess the differences in the evaluation.	Number of measurement values, (sub)scales
Interpretability	The scores of the measurement tool need to have a certain significance.	Comparison with other trials and norm data, Minimal Clinically Important Difference (MCID)

3.2.3. Generic quality of life and measurement tools

QoL measurement instruments are differentiated into disease-specific and disease-spanning (generic) questionnaires. Furthermore, the difference must be made between uni- and multidimensional questionnaires. Unidimensional measurement tools contain global questions and indexes, multidimensional profiling tools are based on the psychometric approach of QoL research, describe QoL in a more detailed way, and may reflect even conflicting effects in the different QoL dimensions.

While predominantly the Short-Form 36 (SF-36) and the Euro-QOL (EQ-5D) are applied as generic measurement instruments in the European countries, the Health Utility Index (HUI) and the Assessment of Quality of Life (AQoL) in the North American space represent the standard measurement instruments. In addition, the

Glasgow Benefit Inventory (GBI) is used globally in oto-rhino-laryngology to assess the generic QoL. Generic QoL measurement instruments do not only vary with regard to their extent and assessed domains but also to the evaluation algorithms (▶ **Table 4**). While the SF-36 and the GBI are multidimensional profiling questionnaires, the HUI, the EQ-D, and the AQoL are classified as benefit-oriented index instruments that are applied for disease-related health-economical considerations. In this context, the calculations based on the QALY concept must be mentioned that analyze therapeutic methods based on the quality-adjusted life years (QALY). Based on the improvement or deterioration of the QoL after intervention, a cost-benefit analysis is made by establishing the quotient from the costs and the additional benefit of the calculated QoL.

A multitude of other generic QoL measurement instruments exist, however, in the following paragraphs the focus is placed on the mentioned five ones because they have already been applied in clinical investigations to assess the healthcare quality after implantation of active middle ear implants.

Short-Form 36 (SF-36) The SF-36 consists of a questionnaire with 36 items. Each item is either an own scale or is part of a scale [26, 27]. The reply categories of the SF-36 vary from questions with binary response options (yes-no) up to ratings from 1 to 6. The SF-36 comprises 8 subscales: physical functionality, physical role function, emotional role function, and mental well-being. A validated short-form with 12 items is available as SF-12, however, the precision is lower than the one of the original version due to the reduced number of items. The German translation of the SF-36 is validated [18]. For this measurement instrument, also standard data are available for evaluation [28].

Glasgow Benefit Inventory (GBI) The Glasgow Benefit Inventory (GBI) was already validated in 1996 for quantifying the post-interventional benefit after oto-rhino-laryngological procedures. So, it is a benefit-related questionnaire. Based on 18 items that are 5-level Likert scaled, an overall score and three subscores are established. The single score values reach from − 100 (severe deterioration) to + 100 (important improvement); a score of 0 means no change of the QoL. The GBI was conceived in that way that a percentage may be given on which proportion of the patients reports improvement, no change, or deterioration of the health-related condition after an intervention. The German version has been validated based on benefit measurements after tympanoplasty [29].

Health Utility Index Beside the already described QoL questionnaires of SF-36 and GBI, also the Health Utiliy Index (HUI) is one of the most frequently applied measurement tools. The first version of the HUI was established in the early 1980s for investigation of the sequelae of underweight neonates. The further developments of HUI-2 and HUI-3 are able to reflect 24,000 and 972,000 health conditions, respectively, based on 7 and 8 dimensions. The HUI measurement instruments are mostly applied in the Canadian and

▶ **Table 4** Overview of generic quality of life measurement tools.

		Short Form 36 (SF 36)	EuroQOL (EQ-5D)	Health Utility Index (HUI 2/3)		Assessment of Quality of Life (AQoL-8D)	Glasgow Benefit Inventory (GBI)
Items		36	5	15		35	18
Validity/reliability of the original version		Yes	Yes	Yes		Yes	Yes
Validity and reliability of the German version		Yes	Yes	No		No	Yes
				HUI-2	HUI-3		
Subscales	Somatic dimension	▪ physical pains	▪ pains	▪ pains	▪ pains	▪ pains	▪ physical health
	Functional dimension	▪ physical functionality ▪ vitality	▪ mobility	▪ fertility	▪ hearing ability ▪ articulation ▪ visual ability ▪ mobility ▪ fine motor skills	▪ senses/perception	
	Psychological dimension	▪ mental well-being ▪ emotional role function	▪ anxiety ▪ depression	▪ mood ▪ memory	▪ mood ▪ memory	▪ satisfaction ▪ mental health ▪ coping with disease ▪ self esteem	
	Social dimension	▪ social functionality				▪ social relationships	▪ social support
	Impairments in daily routine	▪ physical role function	▪ routine activities ▪ self-sufficiency	▪ self-sufficiency		▪ autonomous life	
	Overall assessment	▪ general health					▪ general benefit

American space to define the generic QoL in clinical trials with long-term follow-up, in economical evaluations as well as in sociological population analyses. The HUI allows reporting disease-spanning aspects as unidimensional index value which is specifically relevant for health-economic questions and thus justifies its application for the economic evaluation of hearing implants. The health-related QoL may achieve a maximum of 1.00 corresponding to the best possible health status. The HUI-2 ranks from − 0.03 to 1.00, HUI-3 from − 0.36 to 1.00. Death is classified as 0.00. This means that negative values represent a health status that is perceived as worse than death.

EuroQOL (EQ-5D) – European Quality of Life Questionnaire The EQ-5D questionnaire has been developed and validated initially in the English-speaking space by the EuroQoL workgroup [30]. Currently, it is available in more than 70 translations as validated measurement instrument. The German version has also been verified regarding feasibility, validity, and reliability [31]. By means of only five items and a visual analogue scale, the dimensions of mobility, self-care, general activities, pains/physical complaints, and anxiety/depression are displayed. The health-related QoL is summarized as single index so that the EQ-5D is appropriate for health-economic questions like the HUI and especially for cost-benefit analyses. Standard values are available on the basis of random population samples for the QoL index score.

AQoL (Assessment of Quality of Life) The AQoL (Assessment of Quality of Life) in its different iterations (for adults − 4D and − 8D) is a multidimensional, validated, and reliable measurement instrument for assessing the generic QoL. It has already been applied for evaluating the QoL after implantation of active middle ear implants. The AQoL-8D is the enlarged version of two former instruments, the "AQoL" (or AQoL-4D) and the AQoL-6D. The resulting tool contains 35 items focusing on eight dimensions. Three dimensions (pain, senses/perception, and self-determined life) refer to a mental "superdimension" and the remaining five (satisfaction, mental health, coping strategy, social relationships, self-esteem) to a psychosocial superdimension [32]. The measurement instrument is particularly sensitive for psychosocial disorders and weights them comparably higher. For the AQoL, also sex- and age-related standard data are available [33].

3.2.4. Disease- and function-specific quality of life and measurement of the subjective hearing

Since patients are treated with active middle ear implants due to manifold reasons of hearing loss (chronic otitis media, otosclerosis, malformations of the outer or middle ear, chronic otits externa), function- or hearing-specific QoL measurement instruments are integrated in the healthcare process instead of disease-specific QoL measurement tools. Several of the usually applied questionnaires have been taken from conventional hearing system provision. Thus, some of these measurement instruments (▶ **Table 5**) are rather suitable for subjective assessment of the hearing ability than presenting the actual health-related quality of life. These measurement instruments include the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, the Glasgow Hearing Aid Benefit Profile (GHABP), and the Speech, Spatial, and Quality of Hearing Scale (SSQ). At least one global question of the International Outcome Inventory for Hearing Aids (IOI-HA) assesses the aspect of QoL. The only multidimensional measurement instrument for QoL evaluation after hearing implant provision that is currently available is the Nijmegen Cochlear Implant Questionnaire (NCIQ) that, however, had been developed and validated for the cochlear implantation process.

This article will not deal with available disease-specific measurement tools that do not contain relevant aspects of device-related hearing rehabilitation; review articles on this topic can be referred to [34] because they have not been used for subjective assessment of the provision of active middle ear implants.

Abbreviated Profile of Hearing Aid Benefit (APHAB) In 1995, Cox and Alexander published the APHAB as further developed "Profile of Hearing Aid Benefit (PHAB)" questionnaire. It is the most frequently applied measurement instrument in conventional hearing system provision to assess the benefit of a hearing system [35]. This tool is available in 18 translations; the German version has been validated and standardized [36]. The patients are invited to rate on a seven-level scale how they perceive the impairment due to their hearing loss in a specific situation. Low values correspond to a low subjective impairment.

The questionnaire comprises three scales for assessment of hearing in specific hearing situations (EC scale [ease of communication, simple hearing situations without background noise], BN scale [background noise], RV scale [reverberation, hearing in large spaces with echo or reverberation situations]) as well as one scale for characterization of reactions on environment noise (AV scale [aversiveness of sounds, hearing perception of loud situations]). In the context of hearing aid testing according to the guideline on auxiliary means, the APHAB questionnaire has obligatorily been used in Germany for many years.

Speech, Spatial and Qualities of Hearing Scale (SSQ) The SSQ inventory comprises 49 questions assessing the hearing capacity in specific hearing situations [37] including 14 items on speech perception, 17 items on spatial hearing, and 18 items on the hearing quality. Two additional questions focus on the hearing effort and the hearing at rest. Higher scores correspond to a better subjective hearing performance. The German version has also been evaluated and validated [38]. Furthermore, a German validated short-form with 12 items (SSQ-12) is available [38]. The questionnaire was primarily conceived for the quality assessment of conventional hearing system provision; however, it is also used for the evaluation of the provision of active middle ear implants as well as cochlea implants. The SSQ inventory does not contain any item on the specific assessment of the QoL.

Glasgow Hearing Aid Benefit Profile (GHABP) The GHABP as partially open inventory assesses hearing in four predefined and four individually selected hearing situations [39]. It contains six subscales inquiring different factors in the context of hearing systems. The first two scales ask the patients about their hearing impairment and the influence on daily life. The other four subscales refer to the condition after treatment. The GHABP was originally developed for hearing acoustics, but it is also applied for evaluation

▶ **Table 5** Overview about hearing-specific measurement tools to assess the subjective benefit of hearing implants.

		Abbreviated Profile of Hearing Aid Benefit (APHAB)	**International Outcome Inventory for Hearing Aids (IOI-HA)**	**Glasgow Hearing Aid Benefit Profile (GHABP)**	**Speech, Spatial and Qualities of Hearing Scale (SSQ)**	**Nijmegen Cochlear Implant Questionnaire (NCIQ)**	**Hearing Device Satisfaction Scale (HDSS)**
Items		24	7	24	49	60	21
Validity/reliability of the original version		Yes	Yes	Yes	Yes	Yes	No
Validity/reliability of the German version		Yes	Yes	Yes	Yes (as short form SSQ-12)	No	No
Subscales	Comfort	–	▪ Duration of use	▪ Duration of use	–	–	▪ comfort ▪ handling
	Satisfaction	–	▪ Benefit ▪ Satisfaction	▪ Benefit ▪ Satisfaction	–	–	–
	Functional dimension	▪ Hearing in quiet ▪ Hearing in noise ▪ Hearing with echo ▪ Discomfort	–	–	▪ Speech perception ▪ Spatial hearing ▪ Quality of hearing	▪ Elementary sound perception ▪ Perception of speech and music ▪ Control of the own voice quality	▪ Improved hearing ▪ Sound
	Impairment of routine activities	–	▪ Residual impairment of activity/disability	▪ Impairment before the use of hearing aids ▪ Impairment in daily routine ▪ Residual disability	–	▪ Activity behavior	–
	Social impairment	–	▪ Residual impairment of participation/ handicap ▪ Impact on others	–	–	▪ Social contacts	–
	Psychological dimension	–	–	–	–	▪ Psychosocial consequences	–
	Assessment of the quality of life	–	▪ Quality of life	–	–	–	▪ Improved quality of life

of the treatment quality with hearing implants. For the validated English original version of the GHABP, standard data are available for comparative evaluation [40]. However, it is often difficult for the patients to fill out the questionnaire due to the complexity of the single items.

International Outcome Inventory for Hearing Aids (IOI-HA) The IOI-HA as result of an international consensus process covers the most important dimensions of the subjective perception of hearing systems. With seven items it represents a compromise between desirable and feasible options [41]. Furthermore, it contains one global item to assess the quality of life. Due to its multidimensional approach, it is very close to the mentioned requirements of a psychometric measurement instrument. Additional psychological and somatic and/or functional aspects to determine the QoL would be helpful. The inventory is available and standardized in more than 20 translations [42]. The German version has been verified and validated [43]. Higher overall scores correspond to more favorable outcomes.

Nijmegen Cochlear Implant Questionnaire (NCIQ) The NCIQ has been specifically developed and validated to assess the quality of life after cochlear implantation [44]. A German translation is available; however, it has not yet been evaluated regarding the psychometric characteristics [45]. The physical, mental, and social condition of the patients is assessed by means of 60 items. This questionnaire is currently the most significant QoL measurement instrument after cochlea implantation. It is increasingly used for evaluating the disease-specific quality of life and the hearing quality of patients treated with active middle ear implants. Some items seem to be less appropriate for the assessment of the treatment outcome so that perspectively a revision and statistically justified item reduction and/or adaptation for patients with active middle ear implants should be pursued.

3.2.5. Non-validated measurement instruments and evaluation of satisfaction

In this context, the Hearing Device Satisfaction Scale (HDSS) questionnaire must be mentioned that was made available by Symphonix Devices Company (San Jose, USA) in order to estimate the handling and hearing quality after treatment with an active middle ear implant compared to conventional hearing systems [46]. The psychometric properties of the original version comprising 21 items as well as the German translation have not yet been evaluated. The HDSS questionnaire assesses the categories of comfort, sound, handling, improved hearing, and improved quality of life.

Another method to characterize the subjective benefit of hearing implant provision is the application of visual analogue scales (VAS). VAS as valid, reliable, and sensitive measurement instrument are an important part of the determination of pain intensities [47]. Furthermore, their validity and reliability in the context of tinnitus have been confirmed [48]. The psychometric properties of VAS are not verified for the application in hearing implant provision to characterize the quality of life and subjective descriptions of hearing loss so that their use in clinical trials must be questioned critically. At least, in contrast to self-conceived, non-validated questionnaires they allow statistical evaluations and thus a certain comparability of the collected data.

3.2.6. Particularities of QoL measurement in children

Also in children and adolescents, the use of medical resources in the fields of prevention, therapy, and rehabilitation does not only have an impact on somatic but also on emotional and social aspects so that it is necessary to focus on the quality of life from a children's and adolescents' perspective [49]. Differences in the definition of the term of "health" between children and adults lead to differences in the dimensions of QoL assessment which makes it necessary to develop own QoL measurement instruments for children and adolescents [50]. Beside the QoL dimensions mentioned at the beginning, the assessment of the subjective well-being of children and adolescents must also include additional aspects like self-perception/self-esteem, the perceived quality of the relationships regarding parents and friends, and the well-being at school [51]. For assessment of the quality of life, generally the patients should provide the information themselves in order to get valid statements. Since there might be doubts regarding the reliability of children's responses, especially younger children, third party questionnaires are still the standard. The assessment is mostly performed by the parents. While parents are in the position to evaluate externalized (behavior-related) aspects, an estimation of internalized (emotion-related) problems is rather difficult [49]. Therefore, the parents' statements must be considered as additional information to physical symptoms. The actual disease experience and feeling of the children cannot be reflected. Beside mental, social, and physical dimensions of the quality of life, specific contexts such as family, friends, school, and sports have to be considered in children [52]. It must be observed that the evaluation of these dimensions changes in the course of their development [53]. Due to this fact, the development of child-appropriate, development-related QoL measurement instruments is still in the focus of QoL research. In particular for younger children, computer-based interviews by means of interactive graphs, pictures, and audio contents provide a useful tool [54]. In this context, it must be mentioned that children as of the age of eight years are mostly able to evaluate their own quality of life, in cases of younger children an additional third party evaluation by the parents seems to be appropriate [55].

Currently, the Child Health and Illness Profile (CHIP) questionnaire that has been developed in the American space and the measurement instruments of KIDSCREEN and DISABKIDS in the European countries are available as generic tools [56–58]. The Glasgow Children's Benefit Inventory provides a validated measurement instrument to assess the postinterventional quality of life of children and adolescents after ENT-specific interventions. It is the adaptation of the GBI that has been modified especially for preschool children and retrieves information about emotions/feelings, physical health, learning behavior and vitality/activity based on 24 items [59]. The single questions are answered by the parents. The German version was validated in 2007 by Schwentner et al. [60].

Despite increasing numbers of implantations of active middle ear implants in children and adolescents, child-adapted validated measurement instruments have not been used so that currently no statements can be made regarding QoL changes after treatment with active middle ear implants from the patients' point of view in

this age group. Although an increasing number of disease-specific measurement tools has been provided in pediatrics during the last years, it must be criticized that no hearing-specific tool is available to measure the quality of life of children and adolescents. Another approach to assess the health-related quality of life of pediatric patients is to involve the parents in the QoL measurement. Hereby, the parents do not only evaluate their children's quality of life as representatives but they rate how they feel as caregivers in the context of their child's disease [49]. In otology, this procedure is established mainly for children suffering from otitis media with effusion [61]. In the treatment process with active middle ear implants, non-validated questionnaires have been specifically created [62].

4. Results

4.1. Audiological results

4.1.1. Hearing improvement after treatment with active middle ear implants

The hearing improvement after implantation of an active middle ear implant compared to the unaided hearing constellation has been confirmed in several trials (▶ **Table 1**) and presented in systematic review articles [34, 63–87]. In a meta-analysis, Ernst et al. could quantify for patients with MHL/CHL who had been treated with a Vibrant Soundbridge (VSB, MED-EL Company, Innsbruck, Austria) an average functional gain of 29.6 dB (range: 12.5–43.4 dB) [88]. The speech perception in quiet improved significantly to 62–99 % in the investigated 45 patients. The eight trials included in the meta-analysis, however, were highly heterogenic with regard to the test material and the design. Another meta-analysis published by Kließ et al. based on 42 trials included all available active middle ear implants. It did not reveal significant differences of speech perception in quiet between patients with SNHL or MHL/CHL [89]. As expected, the functional gain was higher in the group of patients with MHL/CHL (functional gain of 33.58 dB; 95 % confidence interval: 29.14–38.02) compared to the patient group with SNHL (functional gain of 26.24 dB; 95 % confidence interval: 22.33–30.14). It must be observed, however, that the functional gain only describes the improvement of the free field threshold for patients and not the amplification of the system. In particular, patients with mere conductive hearing loss or patients with only low-grade sensorineural component do not need an amplification or only a moderate one because the hearing gain is achieved by bypassing the poorly vibrating tympanic membrane or a (reconstructed) ossicular chain. The term of "gain" in this context may be misleading.

4.1.2 Active middle ear implants versus conventional hearing systems

In addition to assessing the hearing improvement compared to the unaided hearing situation, a comparison of the functional results with an alternative treatment is necessary which is for most patients initially a conventional hearing aid. A meta-analysis including all clinical trials about treatment with active middle ear implants until June 2020, identified 16 investigations that compared the speech perception with a conventional hearing system in patients with CHL, MHL, and SNHL with the one of an active middle ear implant [90]. Patients with CHL/MHL had a significantly improved speech understanding compared to previous conventional hearing aids. Also, patients with SNHL had a significantly better speech recognition score in quiet with an active middle ear implant than with the conventional hearing aid (▶ **Fig. 4**).

A systematic review compared the functional outcome of treatment with active middle ear implants with the one of previous conventional hearing systems in cases of SNHL and revealed an average improvement of the functional gain of 8.1 dB (range: − 8.4 dB to + 13 dB) [91]. Furthermore, an improvement of the speech perception of 9.2 % was found (range: − 9.8 to + 22.6 %) with an active middle ear implant compared to the previously used conventional hearing aid.

These investigations are subject to a selection bias because only patients who could not be treated satisfactorily with conventional hearing aid underwent implantation of an active middle ear implant and had the function of their own control group in the analyzed clinical trials.

4.1.3 Active middle ear implants versus bone anchored implants

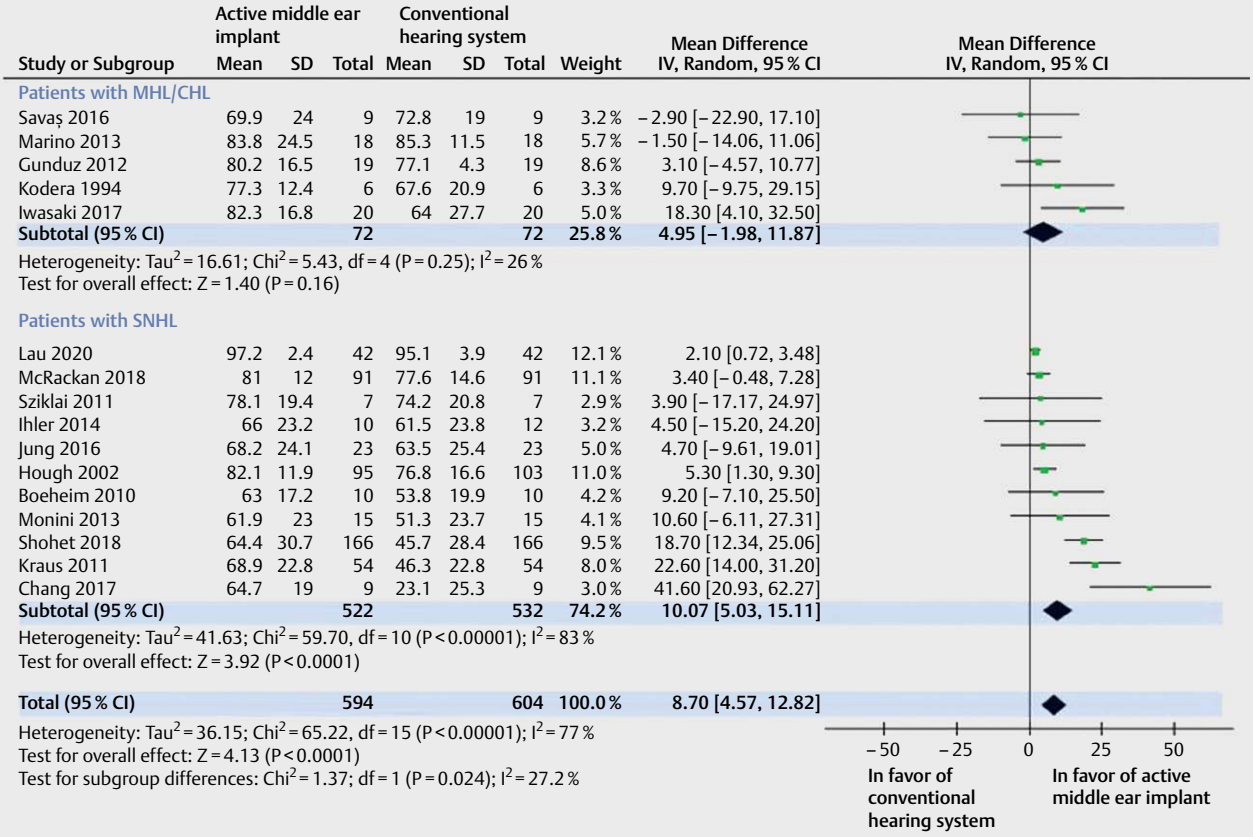
In particular for patients with MHL/CHL, bone anchored hearing systems may be an alternative that is suitable in cases of difficult anatomical conditions. The team of Hannover included 12 patients (6 patients per group) with similar audiological and clinical basic findings in a clinical trial. The patients had either a bone conduction hearing system (Bone Anchored Hearing Aid, BAHA, Cochlear Company, Sydney, Australia) or a VSB that was coupled to the round window membrane [92]. The speech recognition score in quiet of the VSB group was significantly better with 82 % at 65 dB SPL compared to the BAHA group (56 %). This fact was also confirmed in the Oldenburg sentence test that quantified a signal-to-noise ratio (SNR) of − 1.3 ± 2.2 dB for the VSB patients and of 0.6 ± 1.4 dB for the BAHA patients. The results were underlined by the same team based on a retrospective analysis of audiologic parameters of 48 patients (24 patients per group). In the context of the analysis, the speech comprehension with BAHA and VSB was analyzed in dependence on the preoperative bone conduction threshold. While BAHA could only achieve the target criterium (75 % speech perception in quiet at 65 dB SPL) up to a bone conduction threshold of 35 dB, this was still possible for VSB patients up to a conductive hearing loss of up to 50 dB [92].

A retrospective patient study analyzed the speech audiometric results of patients treated with VSB who previously had a BAHA system carried via a soft headband. All patients experienced a significantly better speech perception in quiet and in noise as well as an improved functional gain in high frequencies with the VSB compared to the previously used BAHA [93], which could partly be explained by the limited contact pressure of the soft headband.

The evaluation of these results shows an audiological advantage of active middle ear implants compared to bone anchored hearing systems.

4.1.4 Active middle ear implants in pediatric audiology

The VSB is the only active middle ear implant that is approved for implantation as of the age of 5 years and thus for rehabilitation in children and adolescents. In particular for children with complex malformations of the outer and the middle ear, VSB represents an



▶ **Fig. 4** Meta-analysis for comparison of speech perception with an active middle ear implant versus conventional hearing system: For patients with SNHL as well as for patients with MHL/CHL, an advantage after implantation of an active middle ear implant could be proven compared to conventional hearing aids. Target parameter was the proportional understanding of monosyllables. A total of 16 studies that had been published until 06/2020 were included. Figure modified according to Nikdad et al., 2021 [90].

alternative for treatment with conventional hearing systems or bone anchored hearing aids (▶ **Fig. 5**). Due to the low incidence of such malformations that amounts to 1:3,300–1:10,000 [94, 95], the numbers of cases in clinical trials that focus on audiological outcomes after VSB implantation in children are often very low [96–104]. All currently available clinical trials (▶ **Table 6**) could confirm a satisfactory speech recognition score in quiet of 80–100 % at 65 dB SPL.

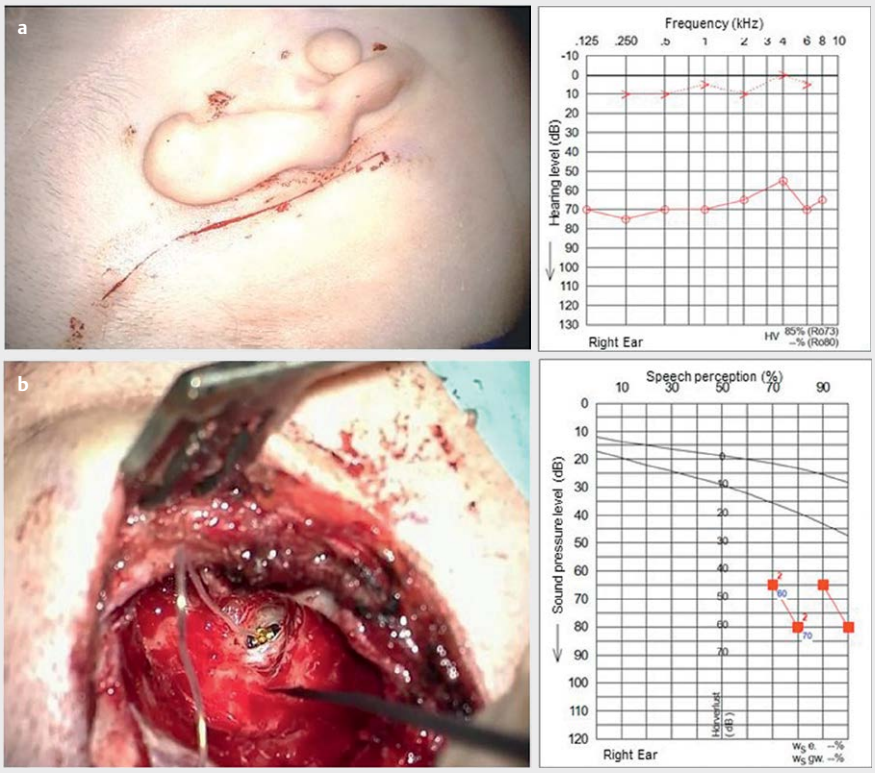
A larger retrospective multicenter study about the benefit of active middle ear implants in children and adolescents analyzed the speech perception of 55 children and adolescents before and after VSB implantation. An improvement of the speech recognition score in quiet at 65 dB SPL from 24.5 ± 25.4 % (unaided situation) to 86.4 ± 13.4 % could be identified. Two of the 55 patients had to undergo revision surgery because of a dislocation of the floating mass transducer (FMT), one child was classified as non-user [105].

The majority of children with unilateral hearing loss does not show deficits in the speech development, general development, or intellectual skills [106, 107] and has already developed sufficient compensation strategies in daily life [108] so that the acceptance of device-related hearing rehabilitation is often rather low. However, in audiological examinations of this patient group, deficits become obvious regarding directional hearing, speech perception in noise, and binaural processing [109, 110] which justifies the necessity of early and consequent hearing rehabilitation of unilateral, even low-grade hearing loss in children in order to avoid late consequences concerning neurophysiological and psychosocial development disorders [111–113]. Consequently, an assessment of the hearing ability especially in complex hearing situations is required to assess the individual benefit of treatment with an active middle ear implant.

Three clinical trials investigated the speech perception by means of everyday simulating sentence tests with basic noise level and adaptive speech levels (Oldenburg sentence test or Oldenburg children's sentence test). Even in this context, the positive effect could be confirmed with an improved SNR of 4–6 dB [99, 101, 104].

4.1.5 Impact on directional hearing

In order to localized sound sources, interaural transit time differences especially for frequencies below 1,000 Hz and interaural intensity or level differences at frequencies above 1,500 Hz are neuronally measured. In contrast to bone anchored hearing systems for which low transit time differences can be expected due to the bilateral cochlear stimulation, active middle ear implants may achieve an optimized directional hearing due to the unilateral coch-



▶ **Fig. 5** Implantation of a Vibrant Soundbridge System for hearing rehabilitation of pediatric conductive hearing loss: Because of the high-grade conductive hearing loss **b**, a 5-year-old child with auditory canal atresia and auricular dysplasia **a** underwent implantation of a VSB with coupling of the FMT to the round window membrane **c**. After first activation, speech perception of 90 % with 65 dB could be achieved based on the Göttingen speech test for children (part 2) **d**; curve 2 shows the measurement in noise.

lear stimulation. This benefit has not yet been sufficiently investigated in patient studies.

The effect of the treatment with active middle ear implants on directional hearing was analyzed exclusively in children and adults with congenital auditory canal atresia. While Vogt et al. and Takahashi et al. revealed an improved ability of localizing the sound source after VSB implantation, Zhao et al. could not confirm these results [100, 103, 114]. In this context, the duration of hearing loss, the duration of hearing aid implantation and the time of use should be considered because training effects contribute to the development of spatial hearing of patients with unilateral deafness. Furthermore, patients with congenital unilateral CHL due to auditory canal atresia are expected to have development disorders of central auditory processes that are essential for directional hearing, even if these children have possibly been treated early with bone anchored hearing aids. Already at the age of 5 years, the development of the ability of localize sound sources are similar to the one of adults [115]. Taking these findings into account, it is most probable that congenital hearing loss interrupts or delays this maturation and thus leads to impaired performance of the sound localization even if the affected person has used hearing aids since early childhood [116]. The results found in the investigations cannot be easily transferred to patients with acquired hearing loss, in particular adult patients. Further studies are necessary that consider also signal pre-processing strategies and/or microphone technologies of current speech processors that allow focusing on sound sources as well as reducing noise. Finally, also the hearing status of the contralateral ear must be included in the observations of directional hearing. An analysis of the benefit of binaural treatment with active middle ear implants showed that sound localization was more precise in comparison to unilateral treatment when both VSBs were used [117]. A patient group with bilateral hearing loss revealed that only unilateral use of the speech processor led to deterioration of directional hearing compared to the unaided hearing constellation which may be explained by a significant distortion of the binaural information by the induced asymmetry. Therefore, the development of current speech processors focuses on the maintenance or improvement of binaural information.

4.1.6 Effect on tinnitus

Overall, only few data exist on the effect of treatment with active middle ear implants on the perception of tinnitus. Three clinical trials were conducted to investigate the influence of VSB implantation on tinnitus based on subjective evaluation documents. However, the data were collected from only few cases. Seo et al. compared the subjective tinnitus evaluation of 11 patients with VSB with 16 cochlear implant patients [118]. In both patient groups a significant reduction of the tinnitus severity could be found by

▶ **Table 6** Results of implanting children with active middle ear implants.

Author	n	Functional Gain	WRS 65 dB SPL		SNR at 65 dB noise		Directional hearing	Subjective assessment
			unaided	with VSB	unaided	with VSB		
Frenzel 2009 [96]	7	45,5 dB	0 %	99 %	No data	No data	No data	No data
Mandalà 2011 [97]	14	No data	14 ± 5 %	90 ± 10 %	No data	No data	No data	No data
Hempel 2013 [104]	12	38 dB	No data	90–100 %	No data	− 4,4–6,8 dB	No data	GCBI: 93 % of the children benefit from implantation
Clarós 2013 [98]	22	30,7 dB	19 %	97 %	No data	No data	No data	No data
Frenzel 2015 [99]	19		19–29 %	89–96 %	0,34–2,79 dB	− 3,6–4,9 dB	No data	No data
Leinung 2016 [208]	16	14,5–23,75 dB	No data	No data	No data	No data	No data	Highest parent satisfaction regarding ▪ acceptance of use ▪ hearing effort ▪ esthetics ▪ handling
Vogt 2018 [100]	14	No data	No data	No data	No data	No data	Improved directional hearing	No data
Hempel 2019 [101]	31	26–32 dB	17 ± 23 %	89 ± 12 %	2,38 ± 4,31 dB	− 4,51 ± 1,49 dB	No data	HDSS: all patients have been satisfied with the implant
Célérier 2019 [102]	3	34–38 dB	10–70 %	100 %	No data	No data	No data	No data
Lailach 2020 [105]	55	No data	25 ± 25 %	86 ± 13 %	No data	No data	No data	No data
Takahashi 2021 [103]	4	No data	50 % *	80 % *	No data	No data	Improved directional hearing	No data

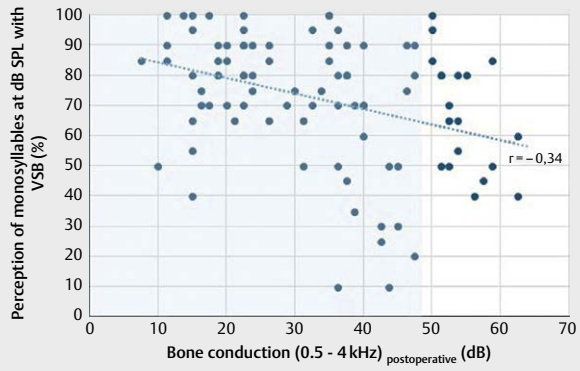
n: number of cases; SNR: Signal-noise ratio; WRS: Word Recognition Score; HDSS: Hearing Device Satisfaction Scale; GCBI: Glasgow Children's Benefit Inventory; * measurement in noise (60 dB); [a] measurement set-up with 24 loudspeakers, [b] measurement set-up with 9 loudspeakers.

means of the Tinnitus Handicap Inventory (THI). At the same time, 73 % of the VSB patients reported a reduction of their depression which was evaluated by means of the Beck Depression Inventory (BDI) and a reduced stress perception was shown in 55 % of the patients by the Brief Encounter Psychosocial Instrument (BEPSI). A Korean research team revealed a significant reduction of the tinnitus perception by means of the THI in 16 patients treated with VSB [119]. Marino et al. also analyzed the impact of VSB on existing tinnitus in 10 treated patients [120]. Four of them who had preoperative tinnitus confirmed a reduction of the tinnitus-related stress.

4.1.7 Consideration of potential influencing factors on speech perception

Preoperative hearing constellation After treatment with active middle ear implants, the postoperative speech understanding of the patients is highly heterogenous. The broad interindividual spectrum leads to the question of appropriate pre- and intraoperative predictors. In this context, the cochlear reserve plays a crucial role in patients with SNHL as well as with MHL. For patients with only SNHL, the value of preoperative air conduction threshold and the maximum recognition score of monosyllables via earphones must be analyzed. One positive predictor for better speech understanding with an active middle ear implant in cases of SNHL compared to conventional hearing aids turned out to be the speech perception gap with a conventional hearing system at a basic speech level (50 dB or 65 dB SPL) and the maximum speech understanding measured via earphones [63, 121, 122]. The maximum word recognition score in the speech audiogram should nearly be achieved at 65 dB with a conventional hearing system. In clinical routine, however, the speech understanding achieved with a conventional hearing system is mostly 10–20 % below the max. word recognition score [123]. The mentioned investigations could show that in particular patients in whom the speech understanding with conventional hearing systems at 50 dB or 65 dB significantly deviated from the max. word recognition score could benefit from the treatment with an active middle ear implant. The authors explain these finding mainly by feedback problems in the treatment with conventional hearing aids. Especially in patients with moderate to high-grade hearing loss of high frequencies, feedback problems limit the functional gain of conventional hearing systems in high frequencies which may lead to an unsatisfactory speech comprehension [122].

In this context, only the preoperative bone conduction threshold is a significant preoperative audiological indicator for patients with MHL. The measurement of the maximum recognition score of numbers or monosyllables via bone conduction transducer is an established procedure in some institutions, however, it often fails because of missing standardization and the limitations of audiometers in cases of high threshold losses. Surprisingly, former clinical trials could only present moderate correlations of speech comprehension with the averaged bone conduction hearing curve [124]. This could also be confirmed by the author's own evaluation of the speech perception of 94 patients who had been treated with VSB (▶ **Fig. 6**) [125]. Considering the performance data of VSB, Rahne et al. calculated a bone conduction hearing loss of up to 48 dB (0.5–4 kHz) as highest indication spectrum in order to guarantee a basic dynamic range of at least 35 dB [126].



▶ **Fig. 6** Influence of the bone conduction threshold averaged at 0.5–4 kHz on the understanding of monosyllables at 65 dB SPL after VSB implantation: With a correlation coefficient of r = – 0.34, only a moderate linear dependence of the speech perception from the cochlear reserve is found. The indication range according to Rahne et al. [126] is marked in blue.

Coupling

Determination of coupling Another influencing factor is the coupling of the actuators to the ossicular chain or the round window membrane. A stable connection between actor and anatomical structure is the precondition for good signal transmission over all frequencies. A coupling deficit leads to higher hearing thresholds, deficient speech comprehension or even reduced signal quality [127]. While a coupling deficit can often be compensated by the amplification performance of the implant in cases of low-grade bone conduction component, patients at the lower edge of the indication spectrum dispose only of a low dynamic range so that a non-optimal coupling is more important and leads to an unsatisfactory audiological result.

Based on the knowledge gained from LDV (laser doppler vibrometry) measurements of the temporal bone and simulated calculations regarding an optimal coupling of the FMT it is easy to understand the wish for a measurement method for intraoperative evaluation of the coupling efficiency [128–131].

By means of the transducer loading assistant software (Cochlear Company, Sydney, Australia) indirect measurements for coupling of the actuator could be performed intraoperatively for the Carina system that were compared with the postoperative measurements in the further course. Based on an impedance measurement, the quality of the coupling could be concluded indirectly from the difference between the frequency and quality of the impedance curve before and after coupling. In the context of VSB implantation, the intraoperative evaluation of the coupling is predominantly based on the subjective estimation of the ear surgeon. Promising approaches for the use of acoustically evoked potentials as intraoperative monitoring procedures are currently still in the trial phase [132–134]. Furthermore, procedures have been described for objectification of the FMT coupling that measure the sound pressure in the external auditory meatus in cases of intact ossicular chain as well as intra- and postoperative LDV measurements [135, 136].

Postoperatively, the coupling efficiency can be determined by means of the difference between in situ thresholds and the bone conduction threshold in the context of fitting. The measurement methods of the in-situ thresholds are manufacturer-specific and unfortunately it is not comprehensively documented. The measurement requires the patient's cooperation and thus cannot be performed intraoperatively under general anesthesia. It might be possible to use this measurement procedure under infiltration anesthesia in the context of revision surgeries to improve the coupling in case of cooperative patients.

In an investigation performed by Müller et al., patients with a significant difference between bone conduction ($4PTA_{BC}$) and direct threshold ($4PTA_{Vibrogram}$) at 0.5–4 kHz which documents an unfavorable coupling, showed an important deviation of the speech perception at 65 dB SPL compared to the preoperatively measured max. word recognition score that was defined as target value for successful VSB provision. The difference of $4PTA_{BC\text{-}Vibrogram}$ should not exceed 20 dB in order to allow a word recognition score of more than 75 % at 65 dB SPL [124].

Clinical aspects of coupling in the context of intact ossicular chain In cases of morphologically intact ossicular chain, the incus is the primary target structure of the actor of an active middle ear implant. Hereby, the vibrating direction should correspond to the natural vibrating direction of the ossicular chain so that an optimal functional result may be achieved.

Due to the defined angle, this is only partly possible when the T2 transducer of the Carina system (Cochlear Company, Sydney, Australia) is applied that was primarily conceived for coupling to the incus and is firmly anchored in the bone. Therefore, efforts to optimize the coupling in cases of intact chain are undertaken. In temporal bone experiments, differences of the performance between coupling to the incus and coupling to the long process of the incus via a clip mechanism could not be revealed [137]. However, the frequently performed procedure of creating a small cavity in the incus by means of laser to insert the actuator did not have an impact on the efficiency of the system [137]. Clinically, there are currently not comparative studies analyzing the efficiency of different types of coupling to the incus for the T2 transducer. The extension of the surgical intervention with additional posterior tympanotomy and the associated more complex alignment of the actuator speak against a standard coupling to the long process of the incus.

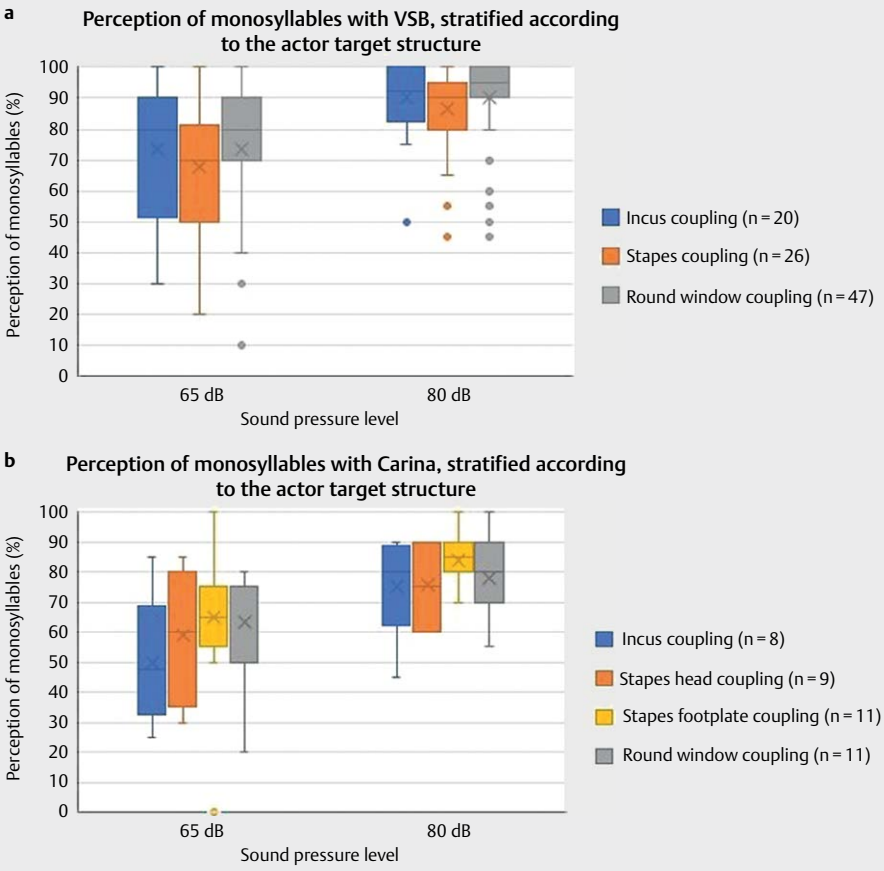
In contrast, the VSB was primarily developed for coupling to the long process of the incus. In the last years, however, the coupling to the short process of the incus turned out to be the standard coupling in cases of intact ossicular chain. In meanwhile more than one third of all VSB implantations, the FMT is coupled to the short process of the incus [138]. Coupling to the short process of the incus is more favorable due to the significantly shorter duration of the surgery compared to the coupling to the long process of the incus (85 ± 29 minutes versus 113 ± 43 minutes) because drilling of the chorda facialis angle is not necessary to create the posterior tympanotomy [139]. Especially in children with auditory canal atresia and intact ossicular chain, the short process of the incus is a very well accessible coupling site without jeopardizing the often atypically running facial nerve. In a direct comparison, Schraven et al. showed in LDV assisted temporal bone experiments better results of average 5 dB for coupling to the long process of the incus versus coupling to the incus body [140]. In the clinical setting, contradictory results were revealed in the audiological outcome comparing both coupling techniques. While Schraven et al. achieved a significantly better understanding of monosyllable at 65 dB SPL for coupling to the short process of the incus (76.1 ± 16.1 %) compared to the classic coupling (66.2 ± 23.5 %) [139] in 42 patients, two retrospective studies could not confirm these results. Since no significant differences between both coupling options to the incus could be revealed in the context of understanding monosyllables, effective gain, and functional gain, there is no clear preference of one of the coupling types from an audiological point of view [141, 142]. However, the easier surgical procedure speaks for coupling the FMT to the short process of the incus.

Clinical aspects of coupling in cases of defective ossicular chain In the context of defective ossicular chain, the mobile stapes as well as the round window membrane are possible coupling target structures for an active middle ear implant.

Based on temporal bone experiments, coupling to the stapes is preferred for VSB implantation. Coupling to the round window membrane may lead to losses of 10–15 dB in low frequencies [143, 144]. Furthermore, the temporals bone experiment revealed a higher efficiency of 10–20 dB for the T2 actuator of the Carina system when it was coupled to the stapes [137].

In clinical trials, differences in speech perception stratified according to the actor target structure could not be revealed, neither for the Carina system nor for the VSB (▶ **Fig. 7**), which may also be due to very heterogenous peer groups and the large spectrum of the results [125, 139, 141, 145–147]. Only an investigation performed by Rahne showed an inferiority of round window coupling regarding speech perception compared to incus coupling [141]. Favorable results in high frequencies speak for coupling of the actor to the mobile stapes, as well as the surgical procedure that is known from classic tympanoplasty and the mechanical stability, especially in cases of coupling to the stapes head, and the clinically easier assessable pretension [148, 149].

In cases of prolapsing facial nerve or fixed stapes due to sclerosis, the round window membrane represents a well accessible coupling structure. Especially for fixed stapes, there were intense discussions for many years if the additional creation of a compensatory opening ("third window") of the cochlea is necessary [150]. Zhang et al. could show in a simulation model that the additional creation of a further opening could reduce the transmission losses of > 30 dB to max. 5–7 dB [151]. However, it cannot be reliably confirmed based on the currently available trials if patients with sclerotic stapes have inferior outcomes compared to patients with mobile stapes with regard to speech comprehension or effective hearing gain after implantation of a VSB. A study with a very low number of cases compared the functional outcome of patients with mobile (n = 7) and fixed (n = 5) stapes after round window vibroplasty. The researchers found a slightly lower functional hearing gain for the patient group with fixed stapes [152]. The analysis of the results observed in the author's department concerning round window coupling by means of soft coupler in comparison of patients with mobile (n = 11) and fixed (n = 14) stapes footplate could not reveal significant differences in the effective gain (6.4 ± 7.1 dB versus



▶ **Fig. 7** Influence of the actor target structure on the speech understanding after active middle ear implant: The figure depicts the understanding of monosyllables at 65 dB SPL and 80 dB SPL six months after implantation of active middle ear implants. **a** after VSB implantation; **b** after Carina implantation, stratified according to the coupling site [125, 146]. The influencing factors known from experimental investigations are reflected in the proportional understanding of monosyllables because of the heterogeneity of the patient population.

6.0 ± 11.1 dB), the difference of $4PTA_{BC\text{-}Vibrogram}$ (12.6 ± 13.6 dB versus 11.8 ± 9.2 dB), and speech perception at 65 dB SPL at rest (75.4 ± 17.9 % versus 77.7 ± 11.2 %).

The clinical results of the round window vibroplasty, show a broad spectrum because a multitude of influencing factors have to be considered in the context of coupling to the round window. On one hand, the coupling surface of the FMT should correspond to the round window membrane that itself is highly variable. Temporal bone studies could show an optimized coupling by interposing fascia between the FMT and the round window membrane [153]. However, contrary results become apparent in the direct application in patients. Rajan et al. could reveal a higher coupling efficiency without interposition of fascia (− 2.0 to − 8.4 dB) which was determined by means of the difference of direct and bone conduction threshold, compared to a patient group with fascia interposition (1.5–118 dB) [154]. The relatively high rate of revision surgeries due to dislocation of the FMT that amounts to 50–71 % according to the literature and that can often be explained by an atrophy of the inserted interposition material emphasizes the necessity of standardized coupling also to the round window by appropriate coupling elements [154, 155]. Even if patient studies could not reveal audiological advantages for the application of coupling elements versus the direct contact of the FMT to the round window membrane for the average word recognition score in quiet (80 % versus 85 %) as well as for the functional gain with a difference of 2.0 dB (250 Hz) to 5.8 dB (4,000 Hz) [156], the complete drilling of the round window niche, as it is certainly required for FMT coupling without coupler, must be critically discussed because of the risk of noise trauma.

Due to its conic shape, the currently available commercial soft coupler allows standardized coupling without damping by contact with the bony limitation. In this way, the necessary drilling of the round window niche is reduced. A comparison in an experimental setting of the silicone-made coupler versus the previous hemispherical coupler made of titanium did not reveal frequency-specific differences in the stimulation of the cochlea [157]. Currently, no audiological investigations are available that evaluate directly the differences in the outcome of the various types of coupling to the round window. In all studies no clinically relevant differences between the application of the soft coupler and the titanium coupler could be identified neither for the word recognition score in

quiet at 65 dB SPL (71 versus 73 %) nor for the functional gain (36 dB versus 34–43 dB) [141, 145, 155].

Beside the coupling surface of the FMT, the contact pressure of the FMT plays a crucial role in round window vibroplasty. Hereby, a visual and tactile control by the surgeon is only possible to a limited extent. For optimal coupling between round window membrane and coupler, a contact pressure of 4–20 mN is recommended [158]. Typically, it is achieved by backward support with cartilage discs. In order to achieve a standardization of the contact pressure, research focuses on the development of a specific coupling element with a mechanical spring for backward support and thus controllable preload [158, 159]. The effective gain of using such a coupling element amounts to 0.6 to − 25 dB [160–162] which is higher than the values that could be achieved until now with former couplers, especially in the frequency range of > 500 Hz [141, 147]. In these small case series, the word recognition score at 65 dB SPL amounted to 79–83 %, which is in the area of the results achieved with established couplers (63–80 %) while the trials were all highly heterogeneous [125, 145, 160, 161, 163].

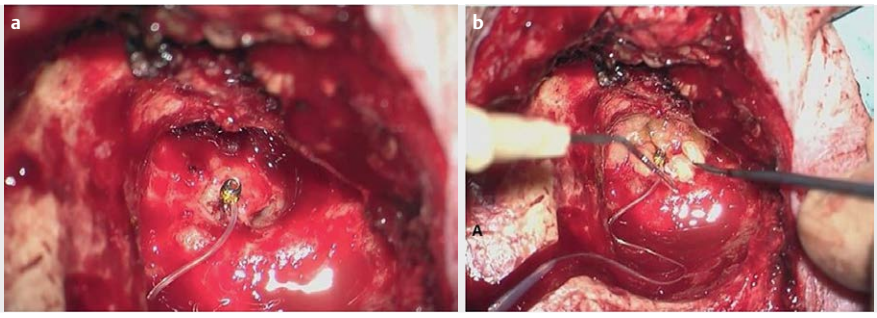
Ventilation disorders, obliteration During the last years, MHL or CHL that is difficult to treat with conventional hearing aid turned out to be the main application of active middle ear implants. This situation is typically found in patients with chronic otitis media after several attempts to reconstruct the ossicular chain with passive protheses and patients with permanently impaired middle ear ventilation.

A temporal bone experiment with simulated negative pressure conditions, the Carina system revealed a high stability of the actuator coupling efficiency in cases of simulated positive and negative pressure for the coupling to the incus [137, 164]. The differences amounted to less than 5 dB in the frequencies below 1 kHz. In contrast, it is meanwhile known for the VSB that negative pressure situations in the middle ear lead to a poorer transmission behavior for stapes coupling in low frequencies due to an increased pretension of the annular ligament [148, 165]. In this context, it is obvious that patients with ventilation disorders benefit from the necessity of safe tympanic membrane reconstruction with thick cartilage because it carries most of the charge and consecutively leads to a lesser charge of the annular ligament. On the average, the transmission losses amount to less than 5 dB in cases of ventilation disorder and thick cartilage reconstruction of the tympanic membrane (thickness of about 300 µm) [165]. In the clinical setting, the influence of the ventilation disorder on the audiological outcome cannot be verified because of the important heterogeneity of the patient populations. Since there is no difference in the speech perception of patients with chronic otitis media and stapes coupling and the speech perception of other patient groups after implantation of an active middle ear implant and since the functional gain and the effective gain are not poorer in patients with regular middle ear conditions, there is no hint for an opposite effect [125, 146, 149, 166, 167].

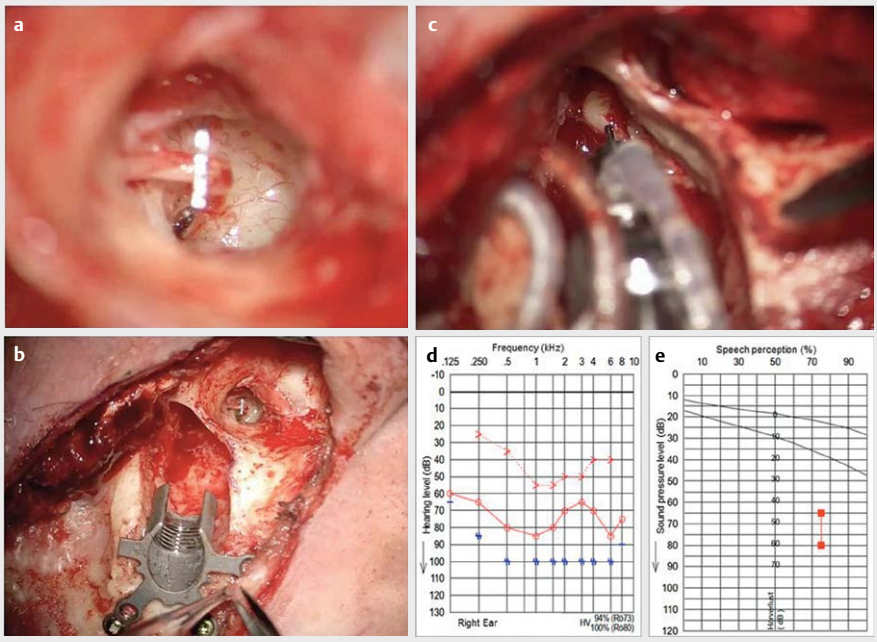
In the context of patients with chronic otitis media, active middle ear implants should only be implanted in the inflammation-free interval in order to avoid secondary infections. Especially regarding long-lasting wound healing disorders of open mastoid cavities or recurrent middle ear pathologies, subtotal petrosectomy with abdominal fat obliteration (▶ **Fig. 8**) may be an alternative treatment strategy [168]. In these cases, additional damping forces due to the inserted obliteration material must be discussed. Experimental investigations on the impact of obliteration revealed that the transmission losses amount to only 1–2 dB for the FMT as well as the T2 transducer of the MET and the Carina system [169]. With 34–46 dB, the average functional gain for VSB implantation and simultaneous abdominal fat obliteration was in the range of the results [170–172] that could also be achieved for VSB implantations without obliteration (12–43 dB) [88]. A comparative analysis even revealed a better effective gain in the group with obliteration (− 15.1 ± 21.2 dB) than in the group without obliteration and preserved posterior auditory canal wall (− 7.2 ± 11.4 dB). The speech perception was comparable in both patient groups (77.9 ± 20.8 % versus 83.3 ± 13.6 %) [172]. After Carina implantation and simultaneous belly fat obliteration, a small patient group revealed a speech perception that did not significantly deviate from the one of patients with intact posterior canal wall (50–85 % versus 50–100 %) [79].

4.1.8 Active middle ear implants for intracochlear mechanical stimulation

In particular patients with MHL and sclerotic annular ligament as well as (partly) ossified round window membrane benefit from perilymphatic coupling of an active middle ear implant for intracochlear mechanical stimulation by bridging the impedances of the annular ligament or the round window membrane for hearing rehabilitation in cases of MHL. After the only commercial Codacs Direct Acoustic Cochlea Implant (Cochlea Company, Sydney, Australia) had been taken from the market, the most frequently applied



▶ **Fig. 8** Implantation of a Vibrant Soundbridge with simultaneous subtotal petrosectomy **a** and abdominal fat obliteration **b**. The FMT was coupled to the stapes head.



▶ **Fig. 9** Power stapesplasty: Combination of conventional stapesplasty **a** with an active middle ear implant coupled to the incus (Carina, **b**, **c**), preoperative pure tone audiogram (**d**), postoperative understanding of monosyllables with Carina in the Freiburg monosyllabic test (**e**).

method in daily life for intracochlear mechanical stimulation is the combination of conventional stapesplasty with an active middle ear implant coupled to the incus ("power stapesplasty", ▶ **Fig. 9**). This option of hearing rehabilitation requires the mechanical opening of the inner ear, which is associated with the risk of inner ear damage due to the mechanical trauma, bleedings, or infections. Thus, it is reserved for patients with irritation-free middle ears and regular ventilation as it is typically found in patients suffering from otosclerosis. Especially when after conventional stapesplasty an additional sensorineural problem requires the use of conventional hearing aids, the additional implantation of an active middle ear implant may allow sufficient hearing rehabilitation in cases of chronic disorders of the auditory canal. Case series analyzing the audiological results after this combination therapy with only few patients reveals consistently positive outcomes [173–175].

The combination of conventional stapes surgery and subsequent application of high-performance hearing systems allows satisfactory hearing rehabilitation for the majority of patients with otosclerosis. A clinical trials that analyzed 322 patients with MHL, however, could identify a subgroup of patients with otosclerosis (15 %) who did not sufficiently benefit from this combination therapy [176]. In this subgroup, no satisfactory speech comprehension could be achieved despite the use of high-performance hearing systems because the sensorineural component and the postoperatively remaining ABG summed up to thresholds for which even the most advanced technical hearing systems could not provide an adequate benefit due to the limited amplification and/or performance. For this patient population, the intracochlear mechanical stimulation seems to be suitable; in the future, however, the development of stronger active middle ear implants may be expected in order to finally close the indication gap for cochlea implantation in patients with otosclerosis and high-grade inner ear component. If primary "power stapesplasty" provides an audiological advantage for patients with MHL and otosclerosis compared to conventional stapesplasty with following hearing aid use, cannot be satisfactorily assessed based on the current data situation because according comparative trials are missing. In this context, analyses of the quality of life and subjective estimation of hearing in complex hearing situations might be helpful. Recently, a clinical investigation could show that patients with otosclerosis and a bone conduction threshold of > 40 dB did not have a gain in quality of life after stapesplasty despite the use of hearing aids [177] so that for this patient population also primary provision of an active middle ear implant combined with stapesplasty may be discussed.

4.2 Complications

The quality evaluation regarding the treatment with active middle ear implants is primarily based on the assessment of an improvement of the health status, which can be measured by means of optimized audiological parameters and the quality of life. In clinical routine, however, it is the risks and complications associated with surgery that make patients critical of implantation. Single case reports and retrospective analyses of patient populations who have been treated with active middle ear implants provide first hints to the occurrence probability of complications in the treatment process. But also in this context, the numbers of cases are very small so that a sound statement about complication incidences and their prospective course would require a desirably international implant registry.

Not all complications occurring after implantation are suitable for specific quality assessment. The development of cholesteato-

ma recurrences or tympanic membrane perforations should be excluded because they are primarily caused by the basic middle ear disease and not by implantation. Furthermore, the association of a deterioration of the cochlear reserve in the longer course should not be rated as immediate complication of implantation. Beside the complications defined as major and minor complications of middle ear surgery in the article [178], implantation-specific risks must be mentioned like implant infections, defective implants, implant failures, dislocation of the actor as well as cable extrusions into the outer auditory canal. Up to now, exclusively retrospective data on the incidence of complications are available assessed by means of patients' records. Due to the long intervals of assessment amounting from three months to more than 20 years, the significance of these data is limited. Fortunately, the occurrence of major complications is rather low. Deafness resulting from VSB implantations has not been reported up to now. Transient facial paresis occurred only in one of 12 patients in a trial published by Lassaletta et al. [179]. In the further course, dislocations of the FMT were observed in 1.8–8 % of the patients treated with a VSB [84, 105, 180–185]. The incidence of revision varied between 4 and 27 % [84, 105, 180–182, 184–186]. Exposed cables in the externa auditory canal led to revision in 10–33 % of the patients with chronic otitis media [179, 185]. Maier et al. determined a decline of 0.42 dB per year for the bone conduction curve of patients treated with a VSB, which was not different from the unaided contralateral side with a deteriorated bone conduction of 0.57 dB per year. In the long-term course, 2–11 % of the VSB patients received an alternative treatment with a cochlear implant [181, 182, 185]. The failure rate of the implant varied between 1.7 and 5 % [182–184].

For other active middle ear implants, only sporadic data are available on the incidence of complications. Regarding the Carina implant, which had initially been distributed by Otologics Company (Boulder, USA), Bruschini et al. reported about one implant infection, one actuator dislocation, and two wound infections requiring revision in a total of 32 implanted patients [65]. An American team observed for the same implant generation wound infections in two patients and implant failures in three cases of a total of 58 implantations [67]. Martin et al. reported about one case of deafness, two implant infections, and one implant failure in 11 patients [68]. After treatment with the Carina generation distributed lastly by Cochlear Company, a multicenter analysis of 42 patients identified three wound infections [187]. Furthermore, two patients received a cochlea implant after three years due to increasing inner ear component; one patient had a brain abscess because of a defect of the laterobase. Another multicenter investigation reported about revision surgery because of severe feedback problems in a total of 16 implantations [188].

4.3. Patient-Reported Outcome Measures (PROMs)

4.3.1. Generic quality of life

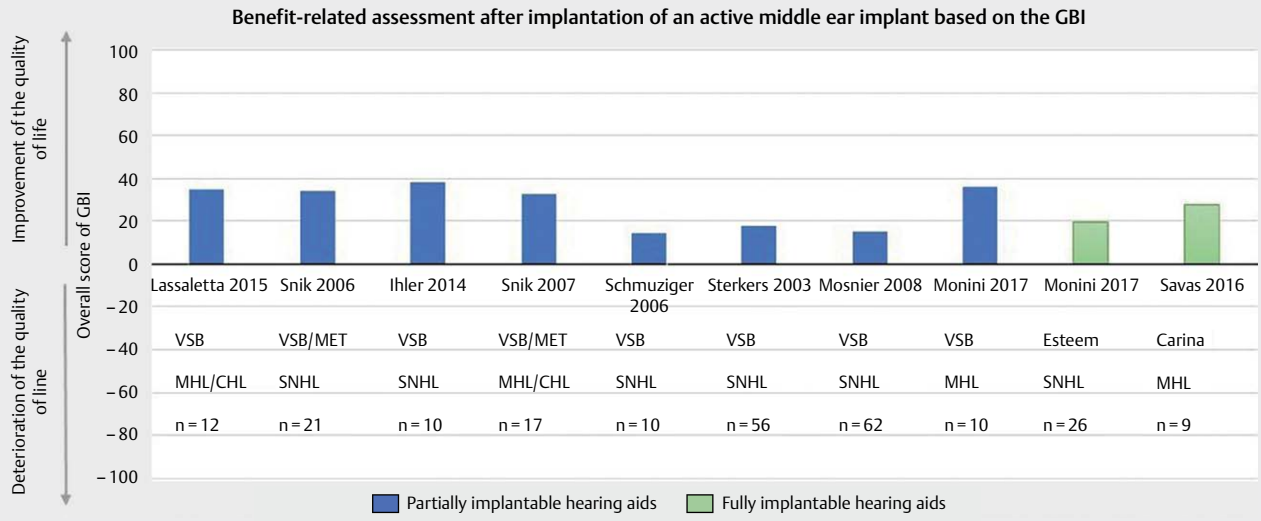
Investigations assessing the generic quality of life before and after intervention in the treatment process with active middle ear implants are rarely conducted. Three studies could be identified that assessed the generic quality of life and included it in health economic considerations. By means of the AQoL, Edlinger et al. could confirm a positive effect of implantation of an active middle ear implant on the generic quality of life. The resulting postoperative overall index of 0.75 ± 0.16 was not significantly different from the index of a healthy control group with the same age and gender distribution (0.81 ± 0.02) [142]. The subjective benefit of the implantation correlated strongly with the proportional understanding of monosyllables at 65 dB SPL (r = 0.84).

In a northern European multicenter trial, Edfeldt et al. showed a non-significant improvement in the HUI-3 of 0.57 ± 0.20 to 0.66 ± 0.23 [189]. Snik et al. revealed a significant deterioration in the physical subscore (0.51 ± 0.09 versus 0.48 ± 0.1) and an improvement of the mental sum score (0.49 ± 0.1 versus 0.53 ± 0.07) of the SF-36 [190]. Edfeldt et al. calculated a cost effectiveness of 7,260 €/QALY for patients with SNHL as well as 12,503 €/QALY for patients with CHL/MHL. Snik et al. calculated a cost effectiveness of 16,085 €/QALY in the Dutch healthcare system. For comparison, the cost-benefit effectiveness of treatment with BAHA amounts to 20,505 €/QALY [191], the one of cochlear implantation to about 11,000 €/QALY [192]. In the USA, England, and Canada, medical interventions are considered as effective when the cost-benefit effectiveness is below 29,632 €/QALY [192]. The Institute for Quality and Efficiency in Healthcare in Germany (IQWIG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen), the definition of such a limit value is still not accepted.

The change of the generic quality of life by treatment with active middle ear implants is in the focus because in former studies, conventional middle ear interventions did not have an effect on the generic quality of life [193, 194].

4.3.2. User-oriented assessment of the quality of life

In some trials, the implantation of active middle ear implants led to a significant improvement of the quality of life of the patients (▶ **Fig. 10**), which is reflected in the user-oriented evaluation by means of the GBI [64, 83, 86, 179, 184, 190, 195–197]. Overall, the general benefit was rated higher than the improvement of the physical health and the social support [64, 83, 86, 179, 184, 195–197]. For partially implantable active middle ear implants, all patients reported a benefit measured with the GBI [179, 195]. Regarding the evaluation of the general benefit, 94–100 % of the patients reported a benefit, for the improvement of social support there were 33–47 % of the patients. An improved physical health was reflected by only 0–35 % of the patients. An investigation on the impact of the implantation of the fully implantable Carina on the general quality of life showed a benefit in the overall score after three months in 8 of 9 patients compared to previous conventional hearing aids; the general benefit was rated positively by 8 patients [64]. Eight patients reported a positive influence on their physical health and five patients confirmed a positive effect on the social support. Ihler et al. compared a patient group that was treated with VSB for SNHL with a patient group with conventional hearing aid treatment [83]. The analyzed patients were equal regarding the severity of the average hearing loss. In comparison to the conventional hearing system group, the VSB patients achieved a higher benefit of device-related hearing rehabilitation in the overall score (38.3 ± 32.3 versus 24.8 ± 22.2). Even in the subscores of "general benefit" and "physical health", the benefit was higher in the VSB group; regarding the subscore of "social support", the groups were not different. Based on 16 patients, a multicenter study from Austria showed that patients with bilateral hearing loss and bilateral VSB provision ex-



▶ **Fig. 10** Benefit-related assessment of the quality of life after active middle ear implant based on the Glasgow Benefit Inventory (GBI). Positive values allow assuming a gain in quality of life after implantation of an active middle ear implant.

perienced a further gain in quality of life after implantation of the second VSB [198]. The improvement of the proportional understanding of monosyllables after implantation of the second VSB correlated significantly with the overall score of the GBI (r = 0.727).

Regarding the evaluation of the results of the GBI, it must be taken into account that the assessment of a postinterventional benefit is a retrospective evaluation of the patient of the condition before implantation. A distortion due to response-shift effects that have not yet been elaborated for hearing implant treatment has to be considered. Furthermore, a correlation of the audiologically measurable benefit with QoL parameters would be desirable for further trials.

4.3.3. Hearing-specific quality of life

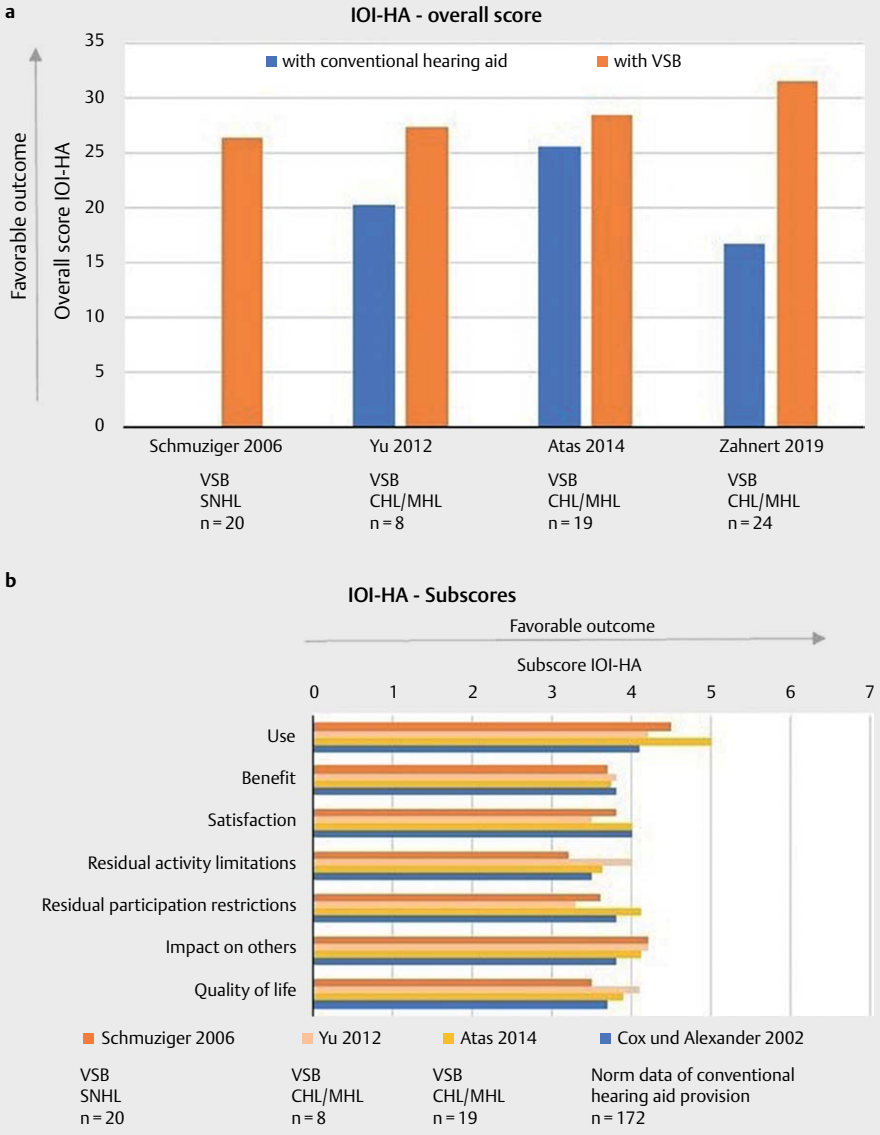
In all clinical analyses evaluating the treatment quality after VSB implantations by means of the IOI-HA, an overall score was identified to determine the benefit compared to the previous treatment with conventional hearing aids [163, 184, 199, 200]. This aspect, however, is subject to a significant selection bias because mainly patients who did not benefit from hearing systems had been provided with an active middle ear implant. The single data of the evaluated items were compared to the standard data for patients with conventional hearing aids assessed in the original article by Cox et al. for validation of the IOI-HA (▶ **Fig. 11**) [42]. For all single items, the benefit achieved by the VSB implantation is within the range of the available standard values. Especially for patients with MHL/CHL, an improvement of the quality of life could be identified while the assessment shows methodical weakness in only one item of the IOI-HA. At this point, it would be interesting to conduct a comparison with according audiological results which should be the topic of further analyses. For the item of "duration of use", it must be mentioned that it is mainly influenced by the existing hearing loss and less by the satisfaction with the respective hearing system.

A multidimensional assessment of the hearing specific quality of life was performed in only two clinical analyses. For twelve patients with radical cavities after VSB implantation, Lassaletta et al. could show an improvement in all six subscores of the NCIQ [179]. Snik et al. confirmed the improvement of the quality of life in the three superordinate main domains of the NCIQ for assessment of the psychological, physical, and social impairments [190]. In the context of this clinical investigation, the quality of life of 21 patients with chronic otitis media and SNHL was evaluated before and after treatment with an active middle ear implant (MET and VSB).

4.3.4. Assessment of the subjective hearing

In some patient studies, the subjective hearing after treatment with an active middle ear implant was assessed by means of the APHAB (▶ **Fig. 12**) [65–68, 195, 201–203]. A direct comparison with conventional hearing systems, however, was only performed in two patient trials [67, 201]. Hereby, an advantage of the treatment with an active middle ear implant compared to pre-existing conventional hearing system could the revealed for the three specific hearing situations, while even here the selection bias has to be considered. The assessed APHAB data did not show significant deviations compared to standard data collected in the context of the validation process of the APHAB for patients treated with conventional hearing systems [35].

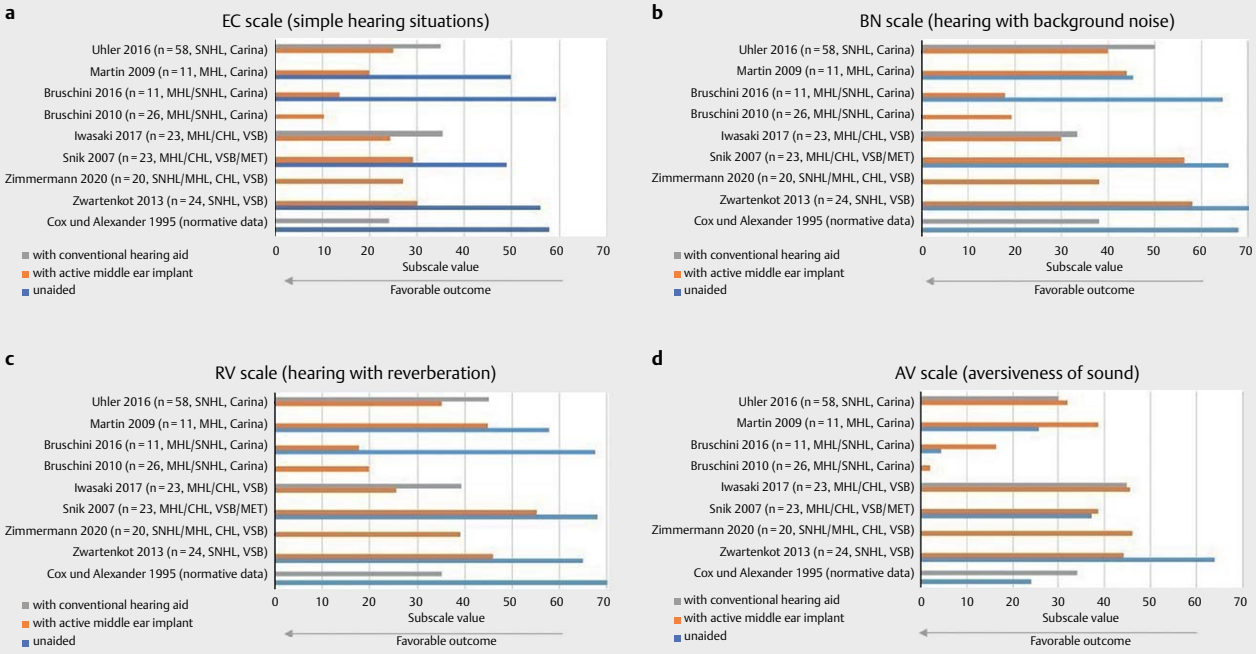
Deficits with therapeutic dimension may be elaborated in a targeted way by means of the APHAB, for single patients as well as for the development of the hearing system or implant. While a subjective evaluation of the hearing can be displayed for simple hearing situations after treatment with an active middle ear implant that is within the normal range, especially for the speech comprehension in noise as well as hearing with echo an improvement potential may be identified regarding microphone technology and noise adaptation. For both hearing situations, however, the knowledge of the treatment condition of the contralateral side would be inter-



▶ **Fig. 11** Hearing-specific quality of life measured by means of the International Outcome Inventory for Hearing Aids (IOI-HA). Based on the overall score, a better subjective outcome after implantation of a Vibrant Soundbridge (VSB) in comparison to conventional hearing systems **a**. The results of the single subscores **b** do not differ from the norm data assessed in the validation process of the IOI-HA by Cox and Alexander [41] for a patient cohort with conventional hearing systems.

esting because a bilateral treatment allows expecting an improvement. The hearing sensation of loud background noises is not importantly changed by the use of active middle ear implants. Overall, it must be considered as positive that only one investigation found that the perception of loud noise was rated as more discomfortable after implantation of an active middle ear implant. In this context, further influencing factors like long-term hearing deprivation due to insufficient hearing systems should be analyzed.

In addition, deficits may be identified with the APHAB that are not necessarily apparent based on the methods of the aids guidelines. This aspect may be confirmed by the data assessed in the context of a clinical trial comparing the audiological and subjective benefit of the alternative use of the speech processor in 20 patients treated with VSB [203]. While the speech audiometric examinations could not reveal an advantage of the new speech processor generation (Samba, Med-El Company, Innsbruck, Austria), the patients consistently rated them as positive in the APHAB for all hearing situations compared to the previous models (Amadé, Med-El, Innsbruck, Austria). These results could also be confirmed in the SSQ questionnaire where the patients rated the Samba speech processor entirely as better in the three subscales of “speech perception”, “spatial hearing”, and “hearing quality” compared to the previously used Amadé speech processor.



▶ **Fig. 12** Assessment of subjective hearing after implantation with active middle ear implants based on the Abbreviated Profile of Hearing Aid Benefit (APHAB). An advantage becomes obvious with an active middle ear implant compared to previous conventional hearing aids. For comparison, the norm data for hearing aid users are presented as well [35]. For simple hearing situations **a** the scores after implantation with middle ear implants amount to nearly normal data for hearing aids. In complex hearing situations **b**, **c** the regular values could not be achieved in all trials. Concerning the evaluation of discomfort caused by noise (**D**), sometimes a deterioration compared to the non-implanted situation or to previous hearing aids.

4.3.5. Quality of life in pediatric patients

Investigations about the subjective assessment of the treatment with active middle ear implants in children and adolescents are only scarcely available. A recent multicenter trial on the benefit of VSB implantation in children estimated the subjective satisfaction of nine children by means of the non-validated HDSS that was filled out by the parents. The average duration of use amounted to 9.9 hours. All patients were satisfied with the hearing implant. Only the subcategories of "speech perception in noise" and "feedback" did not achieve the maximum scores [101].

Another trial assessed the benefit of auricular reconstruction by means of porous polyethylene and the simultaneous VSB implantation in twelve children by asking the parents based on the Glasgow Children's Benefit Inventory. In eleven of twelve children, the parents reported values of more than 0, which corresponds to a positive effect of the intervention. The most important benefit was achieved for the subscores of "learning behavior" (average of 37.1, median of 41.7) and "vitality" (average of 21.2, median of 16.7). Leinung et al. evaluated the parents' satisfaction in 16 children who received a VSB due to auditory canal atresia by means of a self-conceived, non-validated questionnaire. The highest parents' satisfaction was identified for the categories of "using acceptance", "hearing effort", "esthetics", and "handling". The evaluations with regard to "satisfaction and quality of life" as well as "behavior" were comparatively lower [62].

At this point, also the determination of the gain in quality of life after treatment with active middle ear implants versus previously used transcutaneous bone conduction hearing systems would be helpful in order to generate further evidence for this treatment process. In addition, a longitudinal assessment of the quality of life of implanted children in their further development stages should be established, possibly by applying self-assessment tools, in order to identify changes of the subjective perception and thus to better consult patients and/or parents. In this context, the availability of child-adapted measurement tools would be required for multidimensional assessment of the hearing-specific quality of life.

4.3.6. Open questions in QoL measurement

Significant deficits of the previous research on the subjective outcome of the treatment with active middle ear implants can mainly be found in the type of operationalization of health-related quality of life. In most investigations, the assessment of the quality of life was equated with the measurement of the subjective hearing handicap. Only a very small part of the studies actually assessed the quality of life in a multidimensional way, i. e. in the context of physical, emotional, mental, social, and behavior-related well-being.

All mentioned investigations focused on a comparison of the subjective hearing handicap or the quality of life before and at a certain time after implantation or on a singular postoperative measurement of the subjective benefit. Currently long-term evaluations are not available that measure the quality of life at different times and display their dynamism. Up to now, no data have been published on the assessment of patient-related influencing factors (duration of hearing loss, personality, depressiveness, so-

cio-economic status) on the estimation of the postinterventional benefit in order to investigate their interaction in a biopsychosocial concept. Furthermore, future studies should also analyze the association of the audiological parameters measured in the treatment process with the subjective estimation of the patient.

In all previous investigations, the measured change of the quality-of-life indicators must be critically interpreted. The question has to be asked if the assessed "statistical significance" and the "clinical relevance" can be compared. For the parameters measured by means of the APHAB and IOI-HA, at least a comparison with the reference values for conventional hearing systems could be performed. For all other measurement tools, further studies are needed to determine the relevance. Hereby, the parameter of the "minimal clinically important difference" (MCID) for the single measurement instruments must be elaborated.

5. Closing remarks

In the last years of hearing implant outcome research, increasing efforts have been undertaken to integrate PROMs in the outcome assessment. In order to allow international comparability, the availability of the IOI-HA, translated and validated in several languages, is an important step. The measurement of a disease-specific quality of life of patients with active middle ear implants, however, is made difficult by the fact that these devices do not treat the basic disease in the sense of healing but compensate a functional deficit. Unfortunately, a validated measurement tool is currently not available allowing the multidimensional assessment of the function-specific quality of life with consideration of particularities of treatment with active middle ear implants. A next step might be the adaptation of existing measurement tools from conventional hearing systems and a subsequent re-validation.

Up to now, the study situation is not satisfactory regarding audiological as well as subjective outcome parameters measured with evidence-level criteria. Only rarely, the publications have a high evidence level because in most cases an adequate control group is missing. Furthermore, achieving a higher quality level requires also a standardized reporting and outcome parameters. Due to the manifold factors that may determine the outcome of a treatment with an active middle ear implant, a detailed description of findings and implantation- as well as fitting-associated parameters is essential. With a consensus paper for standardized reports in cases of active middle ear implants that is prepared for publication, a first basis has been created. The numerous influencing factors and their characteristics as well as nationally and internationally low numbers of implantations make inter-hospital and long-term assessment for evaluation of outcome and influencing parameters necessary. Therefore, data collection and high-quality evaluation can only be achieved by implementing a practical and hospital-wide assessment system (registry).

Conflict of Interest

The authors received research support, travel support, and honoraria for speaking engagements from MED-EL Elektromedizinische Geräte Deutschland GmbH and Cochlear Deutschland GmbH.

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