Quality in Middle Ear Surgery – A Critical Position Determination

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ABSTRACT

When evaluating the outcome of reconstructive middle ear surgery, it is insufficient to use only the achieved improvement of audiometric measurement results. Although, as functional parameters, they occupy a central position in the therapeutic assessment of the ear as a sensory organ, they must be supplemented by a number of modern quality control factors. Different perspectives for assessment of quality must be taken into account. What is important from the patient's point of view may not be the same factors as to the physician, while the physician places a high value on factors that are less significant for the medical insurance company. The international otological community, who would like to draw conclusions from middle ear surgery data, might set different criteria altogether for assessing quality of surgery.

Hence, we propose to adapt the general concept of quality to middle ear surgery. This must be implemented on different levels and surgical therapy of middle ear diseases must be understood as a process.

This means that quality assessment must comprise additional aspects, which include a structured description and recording of disease-specific symptoms, findings, and outcome of treatment. Furthermore, in today's world the use of internationally recognized classification systems must be regarded as a quality feature, in order to make results not only publishable but also capable of meta-analysis. Internationally developed and recognized reporting systems are available for this purpose. Their use in routine care not only makes the collected data internationally comparable, but also enables systematic evaluation within the institution for quality description and control.

In addition to audiological measurement results, surgical quality indicators are considered. We also focus on emerging complications and the value of systematic and structured evaluation and documentation systems. Validated measuring instruments are already available for patient benefit assessment, the use of which should no longer be limited to scientific studies. In summary, quality assessment of surgery should be extended to include not only the "patient as a whole", but also to the "therapy process as a whole", incorporating features of structural and process quality.

Contents

1. Introduction

In the context of this collection, the term of quality is illustrated in many ways. It becomes obvious that different fields of medicine have very individual definitions of the term. Regarding therapy of a sensory organ, the quality of treatment is primarily measurable with the preservation or restoration of its function. Some quality indicators seem to be apparent. For instance, if the objective of a surgical intervention is hearing improvement, audiological examination results are significant when comparing the situations before and after surgery. They allow "objective" measurement (taking into account the limitations of psycho-physical measurement procedures) of the surgery success and indirectly of its quality. Extending the spectrum of assessed and possible parameters raises the question of meaningfulness – is "more" really a "more" of significance? And if so, what would be an appropriate set of parameters to sufficiently describe the quality of a therapy procedure in middle ear surgery?

Other quality indicators, however, have entered in the assessment of the outcome only recently because they are difficult to measure and to establish in an academic environment that is moved by evidence and objectivity. The measurements of the health-related, disease-specific quality of life gives us as treating physicians the possibility to measure the quality that is subjectively perceived by the patient. Under certain circumstances, this may differ from the quality assessment of the therapist. This change of perspective can also be applied when evaluating the quality of treatment for a patient cohort, rather than a single patient. Adequate tools and procedures are necessary to process and analyze the rapidly growing data quantities. Especially in the last years, the call for prospective trials became urgent which would increase the requirements regarding the documentation quality in medical treatment. If the data gained in everyday treatment routines are used and evaluated for scientific purposes, standardized assessment and documentation instruments are essential. High additional efforts are usually made to establish and manage this data, with little regard to time or money required.

Nonetheless, these methods are needed to embark on the path of empirical medicine to scientifically justified and sound therapy.

In the following, the attempt is made to summarize established and new quality indicators that are directly and indirectly suitable for a description of the treatment quality in middle ear surgery. The focus will also be placed on how primary data is processed and evaluated. Especially in times of "post-truth politics", the commitment to serious, honest, and detailed collection, processing, and description of outcomes is more important than ever, since it also reflects on the quality of the otologic community.

2. Definition of "quality"

Since the 2000s, the concept of quality has gained presence and significance in medicine. Nowadays, entire departments are responsible for quality management, and quality management officers work on the creation and management of quality manuals, process descriptions, and audits. Without discussing here the usefulness of a development that could not be reversed in any case, the concrete question regarding the implications for middle ear surgery will be asked, since using the terms of "management" and "assurance" means that the object of what can be managed or assured is clearly defined. This requires knowledge about the type of data to be assessed, under which circumstances it was collected, and which limitations prevail in the context of measurement, documentation, and analysis. Furthermore, the data has to be classified in the overall context of evaluation and reasonably weighted [1].

In order to systematically work on this topic, the categorization suggested by Donabedian into structural, process, and outcome quality should be used since it has proven to be suitable [2–4]. The spectrum of established and possible future quality indicators that may be identified in middle ear surgery can be mostly classified into

the last-mentioned category of outcome quality. This is obvious, because in the end only the achieved treatment outcome is important for the patients. The evaluation of structural and process quality, however, is significantly more difficult because it depends on the local structural circumstances and the individual processes under which therapy takes place and thus outcomes are produced.

Nonetheless, it is possible to find ways and tools to at least sufficiently describe the existing structural and process variables in this area, even if they are not minimized or eliminated. This is the focus of controlled trials that attempt to investigate a question defined as exactly as possible with exclusion of all uncontrolled influences [5]. Healthcare, however, is a clinical routine claiming to provide highest quality of treatment and it does not depend on a specific design of a randomized controlled trial, being instead oriented on guidelines and ethical and moral principles of medical activity.

2.1 Categories of the term of quality in middle ear surgery

Which quality indicators may be identified under the mentioned aspects in middle ear surgery?

2.1.1 Quality of the outcome

The term of quality of the outcome summarizes all quality indicators that focus on the result of an intervention and describe it or make it measurable. They include the classic functional parameters of audiometry but also the different extents of "graft take rate" (GTR), i. e. the percentage of transplants and implants that are successfully integrated in the body. In the last years, the category of health-related quality of life (HRQoL) became more and more important for the evaluation of the outcome. It reflects the disease-specific impairment that is subjectively perceived by the patients. If we think quality "backwards", the absence of complications may also be understood as quality indicator. Figuratively, the specific complication rates are reciprocal parameters of the outcome quality. Therefore, this chapter will also describe generally acknowledged complications of middle ear interventions and analyze the probabilities of their occurrence retrieved in the available literature.

2.1.2 Structural quality

Structural quality summarizes the description of the basic conditions, the characteristics of the staff-related and material resources that are available for the treatment (service). On the other hand, they also encompass organizational aspects such as available working concepts. We can therefore describe the provision and use of documentation systems that may be used for the standardized description and effect evaluation and assessment of patient data. In middle ear surgery, they obtain a more and more important role because they contain clear definitions and categories that allow superordinate evaluation of therapy data.

Structural quality also includes knowledge, skills, competences, and qualifications as well as the level of education and training of staff members. In this context, surgical training models and programs that improve the surgeons' skills, structured education and courses are mentioned. However, only few measurable parameters that present a quality indicator are available. In addition, the field is too large to be exhaustively assessed in the context of this manuscript.

2.1.3 Process quality

The process quality encompasses all medical and administrative activity that contributes directly or indirectly to the treatment process. For middle ear surgery, the handling and implementation of established standards, classifications, and good scientific practice are mentioned. This aspect is closely related with the mentioned aspects of structural quality and can be subsumed together with it as quality of documentation. This term is not defined in the quality dimensions of Donabedian; it comprises the quality with which the indicators of outcome quality are described in the literature. The quality of documentation directly influences the significance of the described results, and thus represents a decisive principle of the outcome quality.

3. Quality of the Result

Measuring the quality based on the result or outcome of a measure is understandable and effective. In the context of middle ear surgery, several outcome parameters may be defined that measure the quality of treatment and care.

3.1 Graft take rate

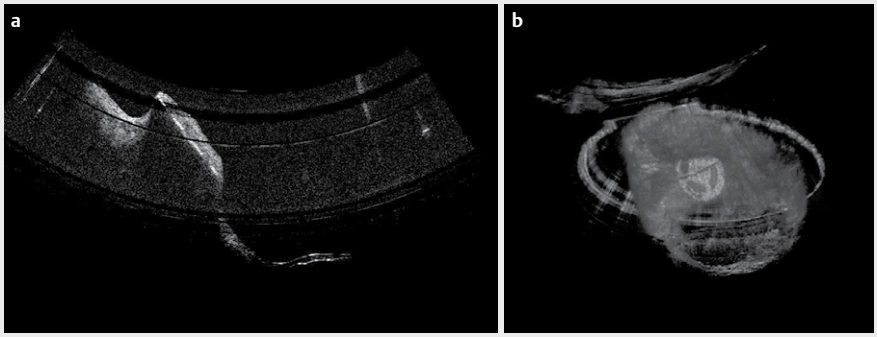
The percentage of patients or surgeries where an inserted transplant or implant remains in the body and is integrated and not rejected, is called graft take rate (GTR). In middle ear surgery, this may refer to the success of reconstruction of the tympanic membrane, inserted ossiculoplasty, and the remaining obliteration material in mastoid cavities. In every aspect, primary targets are found that ought to be achieved, such as a stable and permanent closure of the eardrum when reconstruction of the tympanic membrane was performed. In this context, suitable parameters for measuring success are the percentage of recurrent perforations, retractions, or – limitedly – the postoperative conductive hearing loss (air bone gap [ABG]). Single factors that have to be considered for high-quality middle ear surgery will be illuminated more in detail below.

3.1.1 Reconstruction of the tympanic membrane

Objectives:	stable, permanent closure of the eardrum, maximum sound absorption
Measurement parameters:	GTR, ABG, (vibration behavior)

The objective of reconstructing the tympanic membrane is the permanent closure of the eardrum in order to reconstitute the physiological middle ear compartment and to achieve both a maximum sound absorption and at the same time highest possible stability. The development of GTR and re-perforation rate should be inverse.

A recent meta-analysis (214 studies, 26 097 patients) reveals a 12-month GTR of 86.6 % independently from age, perforation size, and reconstruction material [3]. The analysis of single factors shows a failure rate in children that is 5.8 % higher. Furthermore, smaller perforations (< 50 % of the surface of the eardrum) have a 6.1 % better prognosis; and cartilage as reconstruction material turned out to be superior in comparison to fascia with a 2.8 % higher closure rate. This difference regarding cartilage and fascia could by confirmed by another meta-analysis (11 prospective and 26 retrospective trials, 3,606 patients), in which a GTR of 92 % was achieved with cartilage and 82 % with fascia ($p < 0.001$). Differences in the percen-



▶ **Fig. 1** Optical Coherence Tomography (OCT) for display of the tympanic membrane. It is the optical two-dimensional section through the eardrum level in the posterior upper quadrant. (**a**) The prosthesis plate (2.5 mm titanium clip prosthesis, type Dresde, Kurz Company, Dusslingen) is well displayed in the longitudinal section. (**b**) The prosthesis plate is well seen in the three-dimensional reconstruction. The vibration analysis (not displayed) allows statements about the amplitude of the tympanic membrane and the prosthesis plate.

tage of a postoperative ABG < 10 dB could not be revealed between the groups. The isolated analysis of prospective trials, however, showed a significant advantage of fascia reconstruction ($p = 0.02$). Quite the opposite was observed regarding the GTR where cartilage reconstruction had significantly better results ($p = 0.001$) [6].

Otorrhea seems to have a negative effect only in the short-term analysis (2–6 months), where 94.4 % of the dry ears were closed compared to 84.8 % of the actively inflamed ones ($p = 0.002$). In the long-term interval (> 12 months), no differences could be identified with regard to the GTR [3, 7, 8].

Early assessment (< 12 months) of the GTR leads to false-positive closure rates [8]. A prospective analysis of 837 ears that underwent surgery in a single center showed a GTR of 93.0 % after 2–6 months post-op that decreased to 86.6 % after 12 months ($p < 0.001$). This effect was also confirmed with a mean decrease of 6.0 % after adjustment for all examined prognostic factors. An assessment interval of at least 12 months is necessary for a reliable value of the GTR and a comparison with the international literature.

Regarding the large data base on which the above-mentioned results are based, they may be considered as proven with high probability. The two instruments of meta-analysis and database system are required for the generation of these results.

An assessment of the vibration capacity is currently not available by means of established diagnostics. A possible approach to measure the postoperative vibration capacity of the (reconstructed) tympanic membrane is optic coherence tomography (OCT) [8–10].

Beside the general accessibility and assessment of the tympanic membrane with OCT, a vibration analysis of the eardrum was performed in one patient including the visible prosthesis plate (▶ **Fig. 1**). In this experiment, the decrease of the vibration amplitude of the prosthesis plate matched the measured conductive hearing loss in pure tone audiometry (Morgenstern et al. 2019 [in press]). Although this is a single case analysis with high processing efforts, this procedure might enlarge the spectrum of middle ear diagnostics by detailed *in vivo* vibration analysis.

3.1.2 Ossiculoplasty

Objective:	good and permanent sound transmission
Measurement parameters:	ABG, prostheses extrusion rate, (vibration behavior)

The outcome after reconstruction of the sound conduction system is influenced by many factors. In this context, the fields of biomechanics of the middle ear [12–15], of the material of the prostheses [16–18], and of the surgery and reconstruction techniques [13, 15, 16, 19, 20] have already been illustrated in detail. In the clinical course, the question of successful ossiculoplasty may be reduced to the 2 indicators of postoperative ABG and failure rate, in these cases the extrusion rate of middle ear prostheses. Even if, in experimental investigations, single reconstruction techniques and materials seem to have advantages regarding transmission behavior, disturbing factors often lead to a reduction of such differences in the pathologically altered ear [21].

Again, the use of meta-analysis provides the possibility to summarize effects from several suitable trials and to assess them in a combined way. In 2013, the question of qualitative differences between partial (PORP) and total prostheses (TORP), related to the postoperative ABG and the extrusion rate was investigated in a meta-analysis of 40 studies (4311 patients; 2344 PORP, and 1067 TORP) [22]. Here, the PORP revealed a constantly lower ABG (< 20 dB) compared to the TORP, even when differentiated by surgery technique, prosthesis material, and follow-up interval. The authors emphasize the significance of the stapes superstructure for stable reconstruction. The same goes for the extrusion rate: PORP were significantly less affected by prostheses extrusions and thus superior to TORP.

A direct comparison of titanium prostheses and non-titanium prostheses was made in another meta-analysis of 12 trials (1388 patients; 621 titanium prostheses and 767 non-titanium prostheses) and did not reveal any difference regarding the postoperative ABG and the extrusion rate [23]. In the context of this analysis, a remaining ABG of < 20 dB was considered to indicate successful ossiculoplasty. In addition, the categorization into PORP and TORP did not show any differences in the hearing outcome of the groups.

The same was observed for prostheses extrusions where again no differences in the group and subgroup analyses were noted.

In several trials, the additional padding of the prosthesis head plate with cartilage reduced the extrusion rate of titanium prostheses [23–29] and can thus be considered as standard.

The authors of both analyses openly discuss the limitations of their investigations. However, these are found mainly in the source data of the meta-analyses, i. e. in the primary studies taken for analysis, rather than in the methods. Generally prospective trials and a sufficient description of the study populations are notably missing.. It must also be mentioned that numerous studies could not be taken into consideration because the data in their presentation were not suitable for meta-analysis.

3.1.3 Mastoid cavity obliteration

Objective:	small volume of the cavity, dry ear, self-cleaning
Measurement parameters:	Otorrhea, infections, visit to doctors, vertigo, HRQoL

A “good cavity” is as small as possible, manageable, and self-cleaning [30–32].

The creation of an open mastoid cavity by removing the posterior auditory canal wall (“canal wall down”, CWD) is often a necessary practice and performed frequently in restoring ear surgery. Independently from the applied surgical strategy, the cavity is preferably obliterated in the same session or later. First technical descriptions used bone grafts and bone meal for obliteration [33, 34]. Numerous reasons justify the obliteration of open mastoid cavities. Most important for the patients are less extensive follow-up treatments due to self-cleaning of the cavity [35–37] and less thermal side effects because of wind, water, and suction maneuvers for cleaning [38]. Audiologically, obliterated mastoid cavities achieve better results because sound transmission in open cavities and thus maximally enlarged auditory canal lead to a lower sound pressure in front of the eardrum [39–41]. This results in poorer hearing outcomes of up to 10 dB [37, 42, 43]. Furthermore, obliterated mastoid cavities do no longer play a role in pressure regulation in the middle ear and therefore have no negative influence due to the resulting mucosal surface reduction [44–46]. For this reason, obliterations are also performed in the context of preservation of the posterior canal wall [47–49]. Finally, the economic advantage of successful obliteration must be mentioned because less visits to doctors and local treatments or even revision surgeries are needed [50, 51].

Successful and stable mastoid obliteration is a quality indicator for restoring ear surgery; and the obliteration technique as well as the selection of the material directly influence the outcome. In addition to autologous materials, today a range of alloplastic materials are available which are clearly advantageous, especially in cases of revision surgery and biologically low-quality endogenous tissue. Because of resorption processes, connective tissue [33] or fat [52, 53] for obliteration are associated with significant volume reductions which could even nullify the obliterating effect [54–56]. Muscle-fascia-connective tissue flaps, predominantly shaped from the temporalis muscle [55, 57–63] have a lower shrinking tendency, at the long term, however, partial atrophy and volume reductions cannot be avoided [51, 63–65].

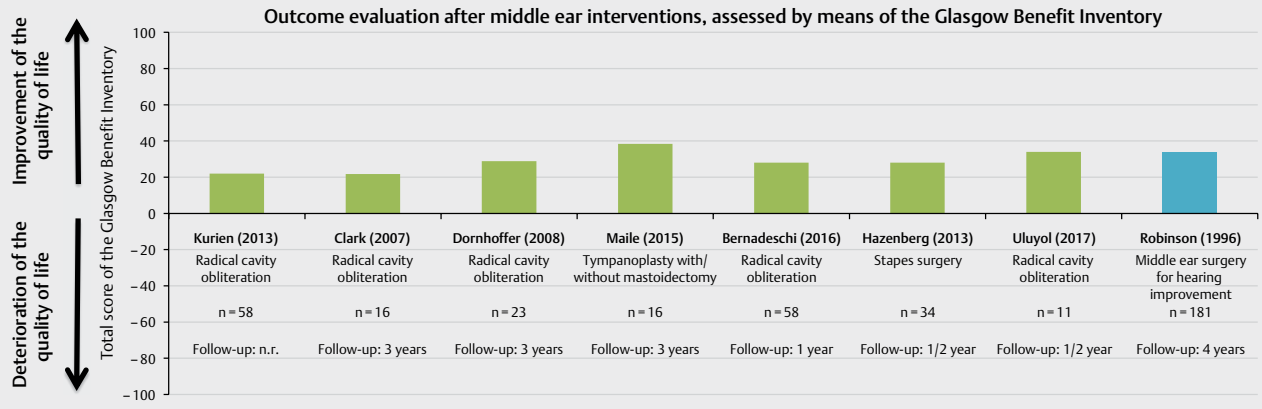
Other endogenous biological tissue collected during surgery may be used, such as bony material in form of bone meal (bone pâté, bone dust) or chips [54, 64, 66–74], or cartilage from the tragus and/or the cavum conchae [75–78]. When using autologous bone material, the success rate of permanent obliteration is decisively influenced by the collection parameters and the donor constitution. The bone gained by means of a mill is decomposed into a pasty mixture of cells, collagen components, water, blood, and extracellular matrix. The capacity for mineralization depends on the quantity of vital cells in the mixture. Contamination with cholesteatoma tissue must be avoided. Depending on the mill geometry (diameter and blade distance), bone grafts of different sizes may be gained in a chipping procedure. Due to the resulting heat, the pressure, rotational speed, and cooling also determine the percentage of vital cells in the bone meal. Big (7.0 mm) and coarse mills that are used with not more than 15 000 revolutions per minute (RPM) show the highest percentage of vital cells in the native bone meal in histological examinations [79]. Alternatively, larger bone particles may also be collected and crushed in a bone mill. In animal experiments, radiological and histological examination both confirmed that defects of non-critical size obliterated with carefully gained autologous bone material showed the best osteogenic enforcement two weeks after surgery [80]. Since donor-specific factors such as age, hormone status, and metabolic diseases may also negatively influence the quality of autologous bone transplants, partial rejection or resorption cannot always be avoided even after careful and controlled collection of bone material [71, 72, 81–85].

For this reason, the use of a high mill diameter and coarse blade geometry with a controlled speed of a maximum of 15 000 RPM is essential for the collection of high-quality material for autologous bone meal obliteration. The addition of antibiotics to the bone meal before re-implantation may reduce the risk of infections. Directly postoperative infections of the implanted bone meal may be due to improper collection with high percentages of avital tissue or an inappropriate site. Possibly because of its higher cell contents, cortical bone provides better prerequisites for obliteration. In this way, Walker and colleagues were able to reduce the postoperative infection rate from 10 % (9/90) to 3.6 % (7/195) [86].

Endogenous cartilage may be applied alone or in combination with bone meal or other materials. The biological and mechanical properties allow its use as stable reconstruction material or as flexible but nonetheless sealing coverage in addition to other material. Prominent edges and steps must not occur in order to avoid squamous cell invaginations [51].

Naturally, alloplastic materials compete with autologous material in the operating room, the biocompatibility, availability, cost-efficiency, and acceptance by patients and surgeons of which are undisputed. Therefore, alloplastic materials have to provide significant advantages that make their application attractive. Among others, ceramics [81, 83–85, 87–97], methylmethacrylate [98], silicone [99], hydroxyapatite [58], and bioactive gas (BAG S53P4, BonAlive®) [100–103] are applied.

Measuring the success of an obliteration by postoperative inflammation control, respectively otorrhea, up to 97 % of complaint-free ears (n = 37/38) ears may be achieved after obliteration with bone meal and cartilage [87]. In a retrospective, direct comparison



▶ **Fig. 2** Outcome evaluation after middle ear interventions, assessed by means of the Glasgow Benefit Inventory. The Glasgow Benefit Inventory (GBI) displays improvements and deteriorations (scaled to a maximum of 100 points each). In the mentioned trials, a positive benefit after interventions was given by the patients [35, 36, 105, 107, 108, 140, 199, 200].

of obliterated and non-obliterated mastoid cavities after resection of the posterior canal wall, Harun and co-workers could achieve dry conditions in 77.8 % (14/18) and 71.1 % (41/45) (p = 0.590) after six months. In the further course, these values increased to 88.9 % (16/18) and 91.1 % (41/45) (p = 0.786) so that no significant advantage of obliteration could be confirmed with regard to the dry ear. Also after stratification into primary and secondary obliterations, no significant difference could be achieved [104]. There also was no difference between the two groups in the number of postoperative medical consultations.

Another aspect that is important for patients is the management of vertigo. In this context, obliterations have a clearly positive effect because in up to 56 % of the cases vertigo does not occur after obliteration in caloric stimulation due to everyday events [38, 66].

The Glasgow Benefit Inventory (GBI) shows that patients perceive a benefit due to obliteration [36, 105–108] (▶ **Fig. 2**). This measurement tool for the assessment of the benefit after ENT specific interventions is presented in Chapter 3.7.

3.2 Recurrence rate (recurrent/residual cholesteatoma)

Objectives: Eradication of the disease
Measurement parameters: Residual and recurrence rate

In the past years, the question of the “right” strategy or surgery method in cholesteatoma treatment has been intensively dealt with in the literature. In this context, the problem arose that the classification of the techniques was not clearly delineated. The definitions based on the condition of the preserved (canal wall up, CWU) and removed (canal wall down, CWD) posterior canal wall prevailed over the years. Furthermore, the new classification of tympano-mastoid surgery will contribute to more transparency in the definition of procedures and description of surgical techniques [109].

Currently, the most exhaustive investigation is a meta-analysis from 2013. It evaluates 13 trials (4720 patients; 2761 CWU and 1959 CWD) [110]. In summary, the recurrence rates reach from 9 to 70 % in CWU and from 5 to 17 % in the CWD group. This means a nearly triple risk to develop recurrence if the posterior canal wall was left intact (CWU) compared to the CWD group. The limitations of the study and additional influencing factors were intensively discussed by the authors, in particular the differences in the follow-up intervals, the often missing differentiation between recurrence and residual cholesteatoma, and the performance of 2nd look interventions. The authors ultimately come to the conclusion that the CWD technique should be applied more generously, however, and it should also be preferred. This also led to the recommendation that the follow-up should include at least 2 and preferably 5 years for final assessment of cholesteatoma recurrences/residuals [35, 109–111].

Special attention has to be paid to the single session obliteration in the context of CWD because there is the risk of dissemination of cholesteatoma tissue into the obliteration. Regarding the occurrence of residual or recurrent cholesteatoma, the single session mastoid obliteration seems to have a positive effect [114]. In the systematic comparison of 13 trials with a total of 1,534 ears, a recurrence rate of 4.6 % (0–12 %) and a residual rate of 5.4 % (0–12.5 %) could be identified in obliterated mastoid cavities, independent from an open (CWD) or closed (CWU) technique. In contrast to this, recurrence and residual rates of 4–17 % must be mentioned in open surgery (CWD) and 9–70 % in trials with closed surgery technique [104]. It cannot yet be finally clarified if the application of autologous or alloplastic material makes a difference in the development of residual or recurrent cholesteatomas. The residual rates were nearly identical with 5.5 % (n = 73; autologous obliteration) and 4.7 % (n = 10; alloplastic obliteration) while the recurrence rates amounted to 5.3 % (n = 70; autologous obliteration) and 0.5 % (n = 1; alloplastic obliteration). However, the number of cavities with alloplastic obliteration (212 patients in 3 trials [110, 115, 116]) might indicate a bias. In summary, the current trial situation leads to the conclusion that a single session obliteration of the mastoid cavity in the context of cholesteatoma surgery does not influence the residual and recurrence rates in comparison to two session.

3.3 Hearing outcomes

Naturally, documentation of the hearing outcomes plays a key role in the description of the results of middle ear surgeries. Thus, audiological results have proven to be appropriate quality indicators of middle ear surgery, and they have internationally been established as such. The quality of therapy can partly be measured by the change in hearing performance. The part of hearing impairment that can be influenced primarily by middle ear surgery is conductive hearing loss, in the description of which the following objectives are pursued (modified according to [117]):

1. Prognosis of success for patient and physician
2. Assessment of a surgery method or reconstruction technique
3. Comparison of the results with other case series and studies
4. Creation of a database for future meta-analyses.

High-quality reporting and documentation standards that are comparable on a national and international level should meet the following requirements.

1. Applicability: The definition of the parameters has to take into account the proportionality of desired knowledge gain to economically feasible implementation. This increases the acceptance and the application of a documentation standard.
2. Validity: The defined parameters have to demonstrably depict the success of the intervention. This is especially true for psychometric measurement tools.
3. Completeness: If possible, all parameters should be assessed that have an impact on the outcome of the intervention and/or reflect it. This requires a combination of evaluation criteria and measurement methods (anamnestic, clinical, and intraoperative findings, functional results).
4. Transferability: The parameters used to describe the success should contain common international parameters in order to be able to discuss them in an international context. This applies to measurement methods, instruments, and standards in the outcome calculation and description.
5. Comparability: The study populations have to be described as exactly as possible so that comparisons of the success parameters do not lose their value because of too important differences in the cohort composition.

In most cases, the hearing changes following middle ear interventions are evaluated based on the change in conductive hearing loss. This can be measured easily by pure tone audiometry. Thus, the pure tone audiogram is still the most important psychoacoustic measurement instrument. Its intuitively interpretable result in form of air and bone conduction hearing thresholds (measured in dB) can be easily displayed, evaluated, and calculated with mathematical comparison. Furthermore, its tonal character allows comparing statements beyond language borders which makes pure tone audiometry irreplaceable in the international literature. Also, due to the proven validity, it is taken as correlation basis for other outcome parameters [118]. Speech audiometry has some particularities for the assessment of the benefit of middle ear surgery that justifies explanations regarding its application.

3.3.1 Pure tone audiometry

The calculation of the difference between bone and air conduction hearing threshold (so-called air-bone gap, ABG) is the aspect of hearing impairment that can be influenced by tympanoplasty. Regarding the measurement technique, both thresholds may generally be measured easily and so the ABG, averaged over the applied frequencies can not only be rapidly calculated but is a key parameter for quality assessment. However, the application must not be uncritically done because a decrease of the ABG may also be observed in cases of postoperative increase of the bone conduction threshold with unchanged air conduction (AC) [117–119].

In order to exclude this false-positive decrease of the ABG, either the change of the bone conduction threshold (bone conduction, BC) in the pre- and postoperative comparison should be mentioned or an additional calculation must be performed subtracting the *preoperative* bone conduction threshold from the *postoperative* air conduction threshold ($ABG_{eff} = AC_{post} - BC_{pre}$) [122].

Furthermore, it has to be taken into account that the change of the air conduction plays the most decisive role for patients because it is the net performance of hearing improving surgery. While ABG is of interest from a surgical point of view, from the patients' perspective, the resulting air conduction must also be considered as a defining quality indicator because it significantly influences the resulting quality of life.

For the sake of international comparability of the results, the selection of the test frequencies should be based on the recommendations of the American scientific society (American Academy of Otolaryngology – Head and Neck Surgery; AAO-HNS) and consequently include 0.5, 1, 2, and 3 kHz [123]. The mean value and standard deviation of the pure tone average (PTA) are mentioned. In the German speaking countries, 4 kHz is commonly used instead of 3 kHz. In times of digital data processing, it should be possible without any problem to give both mean values as well as a value averaged over all frequencies. Since the selection of the considered frequencies has an impact on the outcome [124], their choice has to be mentioned in any case.

3.3.2 Speech audiometry

The results of speech audiometry are only of limited value for the assessment of conductive hearing loss. A parameter of speech audiometry that might be compared to the ABG of pure tone audiometry does not exist up to now. Similar to the air conduction threshold, the results of speech audiometry summarize multiple aspects of hearing that are relevant for the assessment of the functional impairment or restoration of hearing [125].

Due to differences in methods and evaluation, preclude direct international comparisons. The word recognition score that is preferred in Anglo-American countries, measured at 40 dB beyond the individual speech understanding threshold [126, 127] must be classified as methodically unsuitable. In the context of individual and thus variable definition of the sound pressure, either the discomfort threshold or the level limit of the audiometer is reached or the results do not correspond to the maximum speech understanding due to the severity of the identified hearing impairment [128, 129]. By way of contrast, the changes of speech understanding at constant sound pressure level provide significantly higher differences, which in concrete terms means that the percentile comprehension

value of the Freiburg monosyllables test at 65 dB and 80 dB must be considered as being methodically superior [128].

Therefore, the inclusion of speech audiometric results for quality description of hearing improving middle ear surgeries is generally desirable, however, the national as well as international methodical differences limit their value. Against this background, especially the modification of the AAO-HNS recommendations on the reporting standard [130] performed in 2012 must be valued very critically. According to these, hearing results should always be displayed as two-dimensional parameter combination of tone and speech audiometric results (so-called scattergram). The abovementioned explanations, however, seem to already dismiss the methodical precondition (measurement at 40 dB SL) as not suitable to reliably display changes after hearing improving surgeries [128]. Furthermore, the question must be asked how a case number estimation for clinical trials may be performed based on the propagated scattergram. Its binding use as precondition for publications with several journals must be considered as questionable.

3.3.3 Times of assessment

Beside the obligatory preoperative measurement, the timing for postoperative assessment of audiometric results is poorly standardized. The AAO-HNS recommendations provide an interval of 12 months for significant hearing results [123]. A consensus regarding defined intervals distinguishing between short-term and long-term results does not exist. Intervals >36 to >60 months, however, may be valued as relatively reliable long-term statement, similar to cholesteatoma surgery [37, 111–113].

In clinical routine, the first weeks and months after surgery are best documented, which also goes for audiometry and is due to the comparably close binding of the patients to the surgeons in this time. Thus, functional verifications often exist for the time of tamponade removal or shortly afterwards. But because of wound healing that is not yet finalized, the reliability of these results is rather low and is expected to be poorer than the final evaluation. From clinical experience, an interval of three months seems to be more practical. As with any other parameter, the information about the reported time interval is essential in any case.

As often observed, unfortunately the efforts for complete documentation fail because of the circumstances of healthcare reality. As will be seen in the chapter on "Assessment and documentation systems", the quantity of missing data is directly proportional to the length of the postoperative follow-up interval. This phenomenon can only be compensated to a limited extent by increased efforts of the surgeons in medical offices or hospitals because the patients' compliance is directly proportional to the severity of the complaints, respectively to the level of suffering [8]. In addition, this leads to a bias in the data pool in the sense of overrepresented display of particularly long courses with sometimes high rates of complications. The affected patients remain in clinical observation for longer times and receive more frequently functional examinations than the regularly recovering control group.

3.4 Quality of life

The number of measurement tools for the quality of life that may assess the impairment of patients and the therapy success of treated ear patients is considerable and still increasing [131]. Even if the multitude of the described tools seems to be unnecessary at first glance, it is nonetheless required for a differentiated evaluation. In the past, original questionnaires have often been developed for patients and symptom documentation lists were used to supplement objective and functional parameters [131–135]. It is both reasonable and correct to make efforts to assess and make measureable such factors that are not represented by ABG or percentile healing rates using such lists. However, they do not meet the quality criteria of scientific measurement instruments and have only a complementary value.

Thus, the introduction of validated measurement instruments is a logical consequence and enriches the description of the outcome quality. For ear surgery, the "Chronic Ear Survey" (CES) published in 2000 was the first ear-specific measurement instrument in English language to measure the quality of life [136]. The COMOT-15 (Chronic Otitis Media Outcome Test 15) was the first German equivalent developed in 2009 [132].

3.4.1 General and specific measurement instruments

In contrast to general measurement instruments for the quality of life, disease-specific tools focus on physical symptoms and mental impairments that are caused by a certain disease. Therefore, another inventory of questions is needed for the structured assessment of complaints in the context of otosclerosis [137] than for chronic otitis media. Furthermore, this specificity also explains why ear disease-related impairments mostly cannot be depicted in general QoL measurement instruments because these are conceived too broadly.

The general measurement instruments applied in otolaryngology for the overall spectrum of diseases, the Short Form 36 (SF-36) and the GBI must be mentioned. Even if the SF-36 could not confirm an improvement of the HRQoL in previous trials on middle ear surgery, patients with chronic otitis media reveal significant impairments in 4 subscales (of a total of 8) [138–140]. Especially because of its comprehensive characteristic, which goes beyond the ENT discipline, the additional application of the SF-36 is recommended for the valuation of middle ear diseases. Thus, under certain circumstances a classification of middle ear-specific impairments and/or changes after therapy is not only longitudinal but also encompasses other entities.

The GBI has also been developed as an overall measurement tool regarding diseases and therapies in order to measure the general benefit of ENT-specific interventions [140]. Originally, the display of the results was conceived with numerals reaching from -100 (significant deterioration) to +100 (significant improvement) in order to reveal the relative change due to the intervention. Often, however, the data measured by means of GBI are given with the statistical measures of mean value and standard deviation. Nonetheless, it is also suitable to show the benefit or the change achieved by middle ear surgical interventions and to draw comparisons with GBI measurements of other interventions. It must also be mentioned that the German version of the GBI is currently not yet validated for the benefit measurement after tympanoplasty. In middle ear surgery, the GBI was used for the assessment of radical cavity revisions and stapes surgeries. ▶ **Fig. 2** compares trials in which the benefit was measured by means of the GBI.

3.4.2 HRQoL measurement instruments in middle ear surgery

In the context of valuating the benefit of middle ear surgeries, one may also differentiate between the evaluation of the sense of hearing and the disease-specific impairments. Some of the disease-specific measurement instruments have integrated subscales for hearing evaluation.

The valuation of hearing loss or a post-interventional change is the subject of the evaluation of surgical procedures such as tympanoplasty but also of treatment with hearing systems. Measurement instruments that valuate hearing loss specifically were predominantly applied in the past in order to describe the benefit of conventional hearing aid provision as well as hearing implants. Their strength is that they allow an assessment of the actual individual impairment that is caused by limited hearing. In this way, they complement psychophysical test procedures and must not be considered as surrogate parameters. In the past years, some of them have already been applied to determine the hearing improvement after middle ear interventions.

For mere assessment of the hearing loss, among others the following inventories and measurements are available.

- Hearing Satisfaction Scale (HSS)
- (modified) Amsterdam Inventory of Auditory Disability and Handicap ((m)AIAD)
- Hearing Handicap Inventory for Adults (HHIA)
- Abbreviated Profile of Hearing Aid Benefit (APHAB).

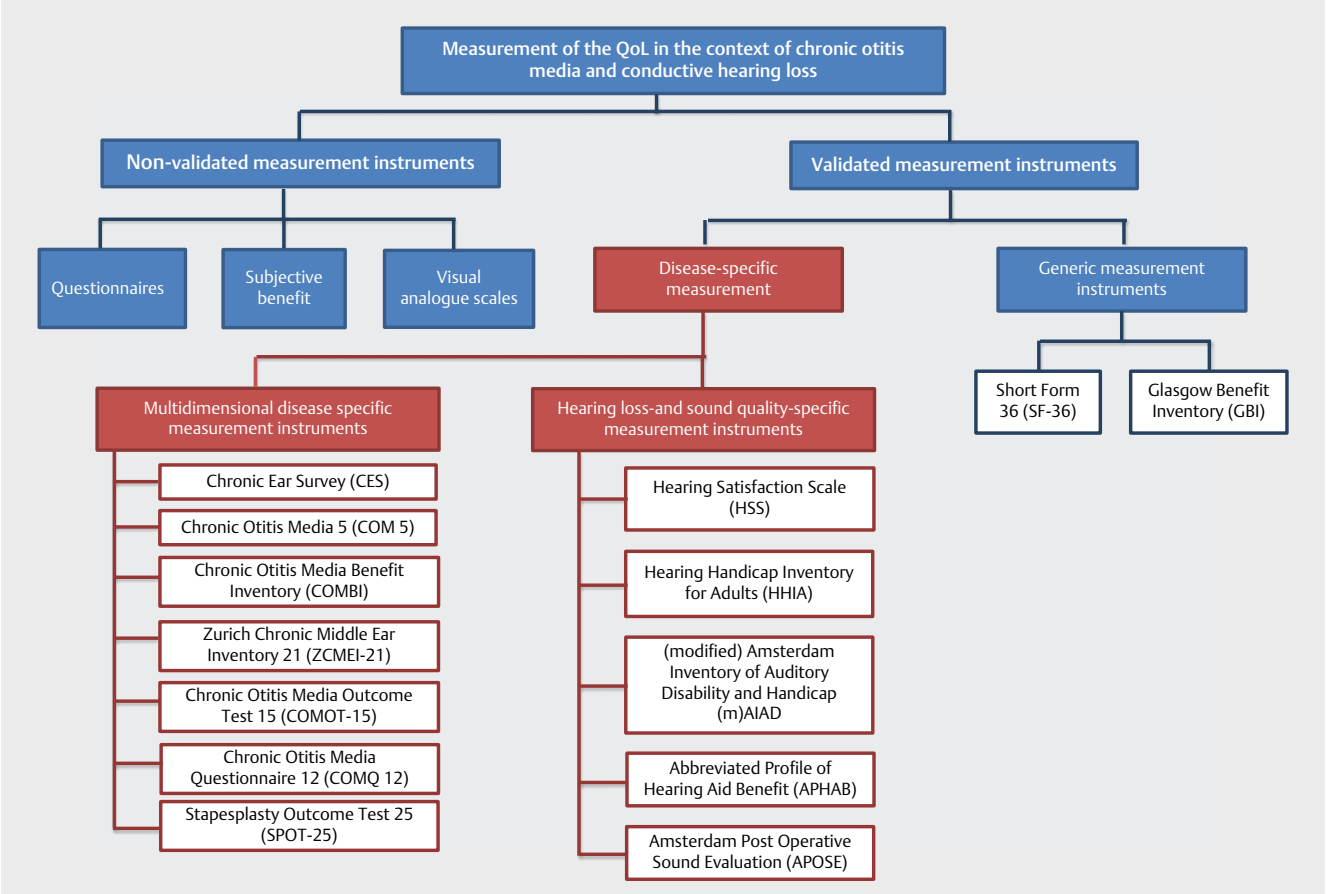
Furthermore, the perceived sound quality may be assessed by means of the

- Amsterdam Post-Operative Sound Evaluation (APOSE)

In order to be able to measure the subjective impairment caused by a specific ear disease, the use of multi-dimensional disease-specific assessment instruments is required. Like all measurement instruments that have been described, their application is useful to display the actual status. This makes them a valuable tool in clinical routine. The respective item lists enquire the specific symptoms of the disease and are thus correlated closely with systematic history taking and complement it by the dimension of subjective scales valuating the impairment.

Additionally, there is the option of the individual longitudinal application to compare the pre- versus postoperative changes. In analogy to the outcome assessment of the surgery success of hearing improving surgery based on the ABG decrease, the subjectively perceived impairment caused by the symptoms of the disease may be valued and evaluated.

▶ **Figure 3** gives an overview of the available measurement instruments that may be applied for assessment of the subjective impairment in the context of middle ear diseases, and which are at



▶ **Fig. 3** Measurement instruments for benefit assessment of middle ear surgeries.

the same time suitable for the benefit assessment of therapeutic measures.

3.4.3 Further factors influencing the HRQoL

The observation that patients value the outcome of their surgery differently despite well comparable objective results leads to the question of additional, possibly superordinate influencing factors. In particular opposite valuations with good values of objectifiable outcome parameters (closed eardrum, dry ear, and ABG < 10 dB) and nonetheless severely impaired specific quality of life allows the assumption that HRQoL measurements are subject to an intraindividual bias. An investigation about the influence of mental health on the disease-specific HRQoL in patients with chronic otitis media showed that depression was the main influencing factor for the postoperatively perceived benefit of middle ear surgery [141].

With the COMOT-15 and the ZCMEI-1, one hundred patients with OMC revealed significant improvements in the pre-/postoperative comparison with unchanged generally measured quality of life (SF-36). After stratification according to the preoperatively measured depression, the HRQoL was more severely impaired in patients with depressive symptoms over all measurement instruments. Even after adjustment to the change of the absolute hearing threshold, the severity of middle ear pathology, and the somatic comorbidities, this statistically significant correlation persisted. Thus, preoperative depression symptoms may prospectively be considered as associated with a poorer disease-specific quality of life six months after restoring middle ear surgery (▶ **Fig. 3**).

Since, according to these results, patients with increased depressiveness value the postoperative HRQoL as significantly poorer (also independently from somatic comorbidities, the severity of middle ear pathology, and the postoperative air conduction threshold), the necessity of further investigations to identify additional influencing factors such as characteristics of personality becomes obvious. At the same time, the data illustrate the complexity regarding the application of psychometric measurement instruments that – like other measurements as well – always have to be considered in the overall context of the measurement conditions. For consultation of the patients and for realistic expectancies in patients and physicians, these correlations might provide an important contribution.

3.4.4 Recommendations for the selection and application of HRQoL measurement instruments

Up to now, national or international recommendations do not exist regarding the selection and application of measurement instruments. Selection and application are decided upon locally and distribution is not wide-spread even on a national level.In the German language alone, competing tools seem to be available such as the COMOT-15 and the ZCMEI-21 for chronic otitis media. Due to deviations in both item inventories, there is a difference in the weighting of the significance which is emphasized by authors and users in the respective publications and considered as beneficial for their cases. Nonetheless, the individual preferance for one measurement tool or another leads to the fact that the results can no longer be compared. This situation is aggravated by individual translations of other, preferably English measurement instruments that are not yet validated and published in German.

As otologic community, we will have to cope with a development that faces an increasing diversity which at the same time counteracts national and international connectivity of the results. From the perspective of quality assurance, the elaboration of recommendations for the selection and application of measurement instruments for the quality of life is urgently required. Only in this way, high-quality study results may be produced that are comparable on a national as well as on an international level. Regarding the application of HRQoL measurement tools for the assessment of the benefit of middle ear surgery, the following aspects may be summarized:

- Routine use of HRQoL measurement tools for assessment of the impairment and valuation of the individual treatment outcome
- Selection and application of a general and a disease-specific measurement tool which is validated in as many languages as possible
- Application before and at least 6 months after surgery
- Adjustment with psycho-physical audiometric measurement results (pure tone audiometry)

HRQoL measurement tools enlarge the perspective and complement the disease assessment of an individual by correlating specific complaints with a measurable and comparable scaling. In this way, the gap between measurable functional impairments and subjectively perceived disease-related impairment is closed [142].

3.5 Absence of complications as outcome quality (a paradigm shift)

The valuation of a therapy is instinctively based on the improvement of an impaired health status. So far, this manuscript has likewise dealt primarily with indicators under this aspect, to consider and measure the success and the quality of treatment based on their improvement. Although each measured parameter may also display a deterioration after therapy, a priori it is an improvement of the condition that is anticipated to indicate a successful treatment.

Quite another perspective, which in fact is a paradigm shift in the assessment, is the definition of the term of quality by focusing on the absence of undesired side effects or complications. Interestingly, in daily routine it is the fear of occurring complications that cause patients to develop a critical view of surgery. A large part of the medical consultation is also dedicated to explanations and realistic estimation of the probability that complications occur. Therefore, such a paradigm shift is not only understandable but very much necessary.

Detailed publications exists about instructions on how to proceed in cases of complications during as well as immediately after surgery [143–145]. In their article on risks of ear surgery and surgery of the lateral skull base published in 2013, Schick and Dlugaiczyk emphasized possible complications of ear surgeries [144]. This article and others have significantly contributed to the development of openly discussing complications and failures. In this context, it shall also be mentioned that it was for the first time in 2013 that the program of the annual meeting included a section of “failures and risks” and “learning based on case examples”.

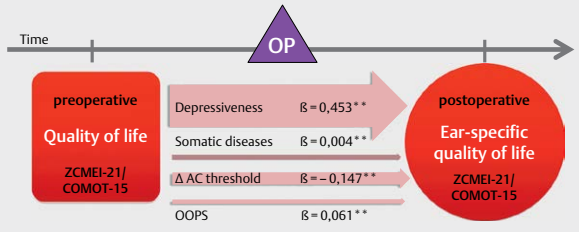
In summary, this development must be fully approved. As a consequence of this positively developing failure culture, the desire to routinely assess complications in a standardized and prospective manner, because all sources that are quoted in the review articles

are experience reports, single case descriptions, or retrospective analyses of patient populations. Of course, they may be used for identification of possible complications and they may also give first hints to the probability or incidence of complications that might occur. In a next step, however, prospective investigations are essential that provide possibly unbiased results based on a standardized assessment of all surgeries performed and the identification of courses associated with complications.

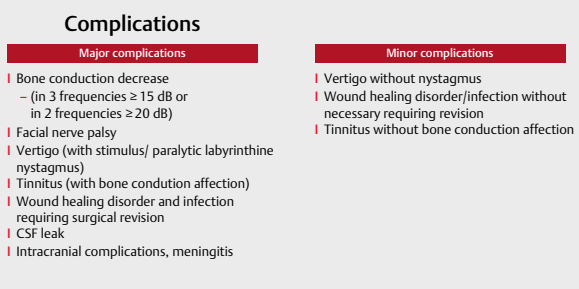
3.5.1 Definition of the terms of "failure" and "complication"

At this point, the terminology must be briefly defined because in daily routine, the terms of "complication" and "failure" are often uncritically used as synonyms. The wish to support the scientific discussion with standardized nomenclature was met by the elaboration of the glossary on patient safety and failures in medicine (Glossar Patientensicherheit/Fehler in der Medizin) by the Medical Center for Quality in Medicine (Ärztliches Zentrum für Qualität in der Medizin). In 2005, this glossary that was elaborated by experts from Germany, Switzerland, and Austria summarized and explained the terms that are used commonly on the national and international level in the field of patient safety and failures in medicine[146].

Complication: Unplanned and/or unexpected course that complicates, impairs, or prevents healing (also undesired event). A complication may also occur as fateful course of a disease, e. g. aggravation of a disease or as consequence of a diagnostic or therapeutic measure.



▶ **Fig. 4** Influencing of the HRQoL by mental health. Itemized according to the influencing factors, depression represents the major part of postoperatively perceived quality of life. The decrease of the air conduction threshold as well as additional somatic diseases have a clearly lower impact. (ZCMEI-21: Zurich chronic middle ear inventory 21; COMOT-15: Chronic otitis media outcome test 15; OOPS: Ossiculoplasty outcome staging index, ΔAC hearing threshold: change of the air conduction threshold).



▶ **Fig. 5** Depiction of the defined major and minor complications.

Failure: A correct plan is not realized as described or the event is due to a false plan. In this context, further difference must be made between treatment error, incidents, and active failure.

However, in the scope of this manuscript, neither a legal nor a semantic excursion is possible or intended. The general differentiation is of higher importance because the next paragraphs will exclusively focus on "unplanned" and "unexpected" courses. In the English literature, sometimes other terms are used with deviating definition, which again leads to different classifications and thus inevitably to missing clarity of discussion. These classifications and definitions of "sequelae", "failure to cure", and "complications" are also controversially discussed [147, 148], just as in the German literature [144, 145].

Nonetheless, the focus must be placed on those courses of events where the undesired event occurs unpredictably. Examples include facial nerve palsy without drilling or manipulation in the topographic neighborhood of the nerve, the decrease of the bone conduction threshold without working at the ossicular chain, or postoperative bleeding despite thorough intraoperative coagulation. In this moment of medical action, the technically, ethically, and morally impeccable way of acting is immanent. Especially these courses will be summarized and discussed using the term of complications.

3.5.2 Specific complications after ear surgery

Not all complications that might possibly occur after middle ear surgery are suitable for specific quality assessment. Without any doubt, the high occurrence of postoperative deep vein thromboses allows a statement about the quality of perioperative management. Nonetheless they are not directly associated with the specific surgical measure of middle ear surgery. On the other hand, postoperative bleeding and wound infection are not specific for ear surgery, but as locally appearing undesired events with timely and causal relation to surgery, they are suitable to assess the specific treatment outcome.(▶ **Fig. 4**)

Furthermore, all recurrences, e. g. newly occurring perforation, retraction, or cholesteatoma etc., are excluded from the discussion about complications. They are dealt with as independent parameters of quality assessment, rather in the sense of the mentioned failure to cure.

3.5.3 Retrospective discussion and prospective assessment of complications

▶ **Figure 5** summarizes important complications that might occur after middle ear surgeries. A detailed classification into complications developing early (< 48 h after surgery) and in the further course (> 48 h postop) is useful.

As already mentioned, there are no prospective studies on this topic. To the best of our knowledge, none of the published data has been generated by means of prospective and structured registration of a populationof surgeries and the appearing incidence distribution of complications. Thus, the incidences and distributions always refer to retrospective analysis of patients' files. Linder and Lin summarized the problems and significance in a concise way: "It does not suffice to only evaluate predefined surgery checklists. Since nearly nobody takes the time to thoroughly read all surgery reports (and assess the most important aspects from these texts written by someone else), many long-term trials with high case

▶ **Table 1** Complications after middle ear surgeries. Complications after middle ear interventions.

	Percentage of all middle ear surgeries (n = 419) from September 1, 2019, to May 30, 2019 (9 months)		Completely regressive		Partly regressive		Not regressive	
	n =	%	n =	%	n =	%	n =	%
major	46	11 %	24	5.7	10	2.4 %	12	2.9 %
Bone conduction decrease	32 *	7.6 % *	14	3.3 %	7	1.7 %	11	2.6 %
Vertigo with stimulus/ paralytic labyrinthine nystagmus or SPN	11	2.6 %	9	2.1 %	1	0.2 %	1	0.2 %
Facial nerve palsy	3	0.7 %	1	0.2 %	2	0.5 %	0	
minor	18	4.3 %	17	4.1 %	1	0.2 %	0	
(retroauricular) hematoma	7	1.7 %	7	1.7 %	0		0	
Tinnitus	6	1.4 %	5	1.2 %	1	0.2 %	0	
Post-op bleeding	1	0.2 %	1	0.2 %	0		0	
Taste disorder	0		0		0		0	
Vertigo without nystagmus	4	1 %	4	1 %	0		0	
Late complications (>48 h post-op or after the inpatient stay)								
	n =	%	n =	%	n =	%	n =	%
major	22	5.3 %	13	3.1 %	1	0.2 %	8	1.9 %
Bone conduction decrease	14 *	3.3 % *	7	1.7 %	1	0.2 %	6	1.4 %
Tinnitus	4	1.0 %	3	0.7 %	0		1	0.2 %
Facial nerve palsy	3	0.7 %	3	0.7 %	0		0	
Deafness	1	0.2 %	0		0		1	0.2 %
minor	57	13.6 %	51	12.2 %	2	0.5 %	3	0.7 %
Stenosis	25	5.9 %	22	5.2 %	0		3	0.7 %
Wound infection without necessary revision	17	4.1 %	15	3.6 %	2	0.5 %	0	
Dehiscence	5	1.2 %	5	1.2 %	0		0	
Otorrhea	7	1.7 %	6	1.4 %	0		0	
Sensation of numbness (auricle, tongue)	1	0.2 %	1	0.2 %	0		0	
Vertigo without nystagmus	1	0.2 %	1	0.2 %	0		0	
Wound infection or healing disorder requiring surgical revision	1	0.2 %	1	0.2 %	0		0	
Total	143	34 %	105	25 %	13	3.1 %	22	5.3 %

Direct complications (0–48 h post-op or during the inpatient stay). Here mentioned: definition of bone conduction decrease: 3 frequencies >15 dB or 2 frequencies >20 dB decrease.

numbers degenerate to poorly significant banalities" (translated from German) [145].

Due to these and other limitations, the author's institution meanwhile registers all ear surgeries. Hereby, all courses with complications or undesired events are marked based on a standardized scheme of parameter assessment. Their selection was the result of a first retrospective analysis in which the complications were classified into major and minor complications (▶ **Fig. 5**). In this context, 377 middle ear surgeries were evaluated over 12 months and analyzed with regard to the occurrence of complications within the first 6 weeks postop. Furthermore, risk factors were assessed in this trial and their correlation with the occurrence of major and minor complications was investigated. These risk factors were taken from the literature about general surgery [149]. It was shown that the risk factors known from general surgery played a subordinate role in ear surgery. For the defined major complications in ear surgery, principally no statistical evidence of risk factors could be identified. Only arterial hypertonia turned out to be a risk factor for postoperative bone conduction decrease (RR = 2.2; p = 0.041).

▶ **Table 1** shows a summary of the occurrence, the incidence, and the course of single complications, based on the mentioned *prospective* assessment over an interval of 9 months. The combina-

tion with the evaluation of the courses gives a differentiated focus to the data of mere incidence. For example, 32/419 patients (11 %) were identified with bone conduction decrease (defined as decrease in 3 frequencies > 15 dB or 2 frequencies > 20 dB) in the immediate postoperative phase, but at the time of analysis n = 21/419 had completely or partly recovered. In n = 11/410 (2.6 %) of the cases, the bone conduction decrease persisted until the time of analysis. Complete hearing loss was not observed, neither was the affection of the facial nerve. All three affections that had occurred completely or at least partly disappeared within the observation period of 9 months. Due to the further follow-up, regression of the partly still visible palsies is expected.

The classification into early (< 48 h postop) and late complications (> 48 h postop) clearly shows that some of the observed adverse courses only occur after discharge. Further n = 14/419 (3.3 %) BC decreases were seen, n = 8 of them were completely or partly regressive and n = 6/419 (1.4 %) persisted until the end of the analysis. From 419 middle ear surgeries performed in this collective, a total of n = 46 (419 (10.9 %) developed postoperative bone conduction affections, 17/419 (4.0 %) turned out to be persisting. No complete hearing loss was identified among all registered cases.

Thus, the routinely performed prospective and structured assessment of complications shows that major complications occur rather rarely and a relevant percentage of undesired courses is regressive. In comparison to the few published retrospective data, it can be stated that similarly detailed summaries are not available. ▶ **Table 2** shows that the selection of the parameters is comparably low. With regard to bone conduction decreases, Kazikdas et al. described n = 18/51 cases (35 %) [150]. Phillips et al. provided retrospective data on facial nerve palsies, vestibular affections, and tinnitus as well as wound healing and gustatory disorders. The differences observed in this context may most likely be explained by the retrospective study design. From our own experience, the well-known limitations of such clearly affects research results, and this emphasizes the necessity of implementing permanent registration and assessment of undesired courses in clinical routine. Only in this way, valid quality evaluations may be performed that at best may be taken as self-generating parameters within a department at any time.

Beside the mentioned and further developing failure culture, prospective assessments of complications within a department or hospital may significantly contribute to a direct increase of the documentation quality and indirectly to an improvement of the treatment quality.

4. Process and Structural Quality

This category summarizes the provision and use of reporting and documentation systems.

4.1 Quality of documentation

The quality of reporting and documentation is an essential pillar of clinical healthcare and scientific analysis of clinical results. Therefore, it is the quality of how indicators of outcome quality are described that directly decides the reliability of formulated statements. Since a multitude of factors influence the outcome in clinical research, the description of the basic and trial conditions plays a central role. All previously described quality indicators of middle ear surgery depend mainly on the quality of their assessment, description, and evaluation, as well as on their interpretation.

4.1.1 Differences in healthcare and research

Non-standardized measurement and documentation conditions may beless important for individual patients if systematic influencing factors are kept constant and “only” individual courses are longitudinally investigated. However, even the evaluation of original, manageable patient cohorts must be based on a detailed and thus standardized characterization in order to be able to make statements about individuals. For clinical trials with the claim of generating evidence, the main influencing factors have to be clearly defined.

We have found the following minimum documentation criteria for reconstructive middle ear surgery:

- Study population (type and severity of the treated pathology)
- Intervention (type and extent of treatment/surgery)
- Analysis of the outcome (type, extent, and time of assessment)

In short, the basic principles of good scientific practice must be observed, which define the “what”, “how”, and “when” certain tasks are performed and events recorded. Even if medicine is often called an “inexact” science, this statement should be based on the consideration of scattering individual deviations in the biological system of “humans” and not on negligence in the assessment and the analysis of data and measurement results. The application of fundamental scientific knowledge in the context of outcome description can be expected after graduating from a university. So at first glance, the routinely performed documentation in healthcare seems to deviate from the requirements of scientific practice, but really only at first glance. For medico-legal reasons, the above-mentioned aspects must be implementedhere as well, however, generally not always in such a detailed and structured way as for the scientific analysis of results. On the one hand, this leads to the known problems of retrospective trials that can only include data that have previously been documented. All aspect that have not been described in the documents have to be excluded. On the other hand, numerous lists with symptoms, findings, and procedures have been conceived everywhere. Due to the unstandardized classification, extent, and interpretation, they can only be compared in a limited way or even not at all.

Very soon, this has prompted the establishment of classification and evaluation systems. Since 1956, the classification according to Wullstein [151] exists for reconstructive middle ear surgery that contained also the hearing outcome observed independently from the description of the reconstruction types of the middle ear. In 1969, Bellucci also described a dual evaluation system which measures the chance of successful tympanoplasty based on the presence or likeliness of middle ear infections [152]. Numerous others followed.

The transition from documentation in clinical routine of patient care to the evaluation of the results for scientific purposes is fluent. In general, there are always three objectives: (1) the analysis of the surgical method or reconstruction technique (or prosthesis), (2) the comparability of the results with other case series and studies, and it (3) serves for the outcome prognosis (for patients and physicians) [117, 122].

▶ **Table 2** Comparison of prospective and retrospective complication assessment.

	Major complications									
	n	**Bone conduction decrease**	**Facial nerve palsy**	**Vertigo with stimulus/ paralytic labyrinthine nystagmus or SPN**	**Tinnitus (with bone conduction affection**	**Wound healing disorder (with revision surgery)**	**CSF leak**	**Intracranial complications**	**Hearing loss**	**Total**
Retrospective										
Lailach et al. 2019 [148]	377	29 (7.5 %)	14 (3.7 %)	9 (0.3 %)	0	1 (0.3 %)	1 (0.3 %)	0	0	54 (14.3 %)
Kazikdas et al. 2015 [149]	51	18 (35 %)	–	–	–	–	–	–	–	18 (35 %
Özgür et al. 2015 [185]	53	–	1 (1.9 %)	–	–	–	–	–	–	1 (1.9 %)
Salvinelli et al. 2004 [186]	580	–	7 (1.2 %)	–	–	–	–	–	–	7 (1.2 %)
Safdar et al. 2006 [187]	219	–	1 (0.9 %)	–	–	–	–	–	–	1 (0.9 %)
Kuo & Wu 2017 [188]	131	–	0	–	–	7 (5.3 %)	–	–	–	7 (5.3 %)
Zhou et al. 2015 [189]	1420	–	16 (1.1 %) *	–	–	–	–	–	–	16 (1.1 %)
Jolink et al. 2018 [190]	61	–	1 (1.6 %)	–	–	–	–	–	–	1 (1.6 %)
Fiedler et al. 2013 [191]	1037	–	55 (5.3 %)	116 (11.1 %)	31 (3 %(	26 (2.5 %)	–	1 (0.1 %)	81 (7.8 %)#	282 (27.2 %)
Prospective										
Complication registry of the University Hospital of Dresden, Germany	419	43 (10.3 %)	7 (1.7 %)	12 (2.9 %)	0	1 (0.2 %)	0	0	0	63 (15 %)
James 2017 [192]	267	–	–	–	–	3 (1.1 %)	–	–	–	3 (1.1 %)
Yiannakis et al. 2018 [193]	103	–	1 (1.0 %)	–	–	–	–	–	1 (1.0 %)	2 (1.9 %)
Phillips et al. 2015 [194]	495	–	0.0 %	0.4 %	0.6 %	–	–	–	–	1 %
Berglund et al. 2019 [195]	3775	–	–	–	–	–	–	–	–	–
Meta–analysis										
Bae et al. 2019 [196]	17461	–	111 (0.6 %)	–	–	–	–	–	–	111 (0.5 %)

▶ **Table 2** (Continued)

	Minor complications								
	n	**Vertigo (without nystagmus)**	**Wound healing disorder (without revision surgery)**	**Tinnitus (without bone conduction affection)**	**Stenosis**	**Deshiscence**	**Taste disorder**	**Otorrhea**	**Total**
Retrospective									
Lailach et al. 2019 [148]	377	–	–	–	–	–	–	–	110 (29 %)
Kazikdas et al. 2015 [149]	51	–	–	–	–	–	–	–	–
Özgür et al. 2015 [185]	53	–	–	–	1 (1.9 %)	–	1 (1.9 %)	–	2 (3.8 %)
Salvinelli et al. 2004 [186]	580	–	–	–	–	–	–	–	–
Safdar et al. 2006 [187]	219	–	–	–	–	–	–	–	–
Kuo & Wu 2017 [188]	131	–	7 (5.3 %)	–	–	3 (2.3 %)	0	–	10 (14.5 %)
Zhou et al. 2015 [189]	1420	–	–	–	–	–	–	–	–
Jolink et al. 2018 [190]	61	1 (1.6 %)	3 (4.9 %)	–	–	–	2 (3.3 %)	–	6 (9.8 %)
Fiedler et al. 2013 [191]	1037	–	–	–	–	–	–	–	–
Prospective									
Complication registry of the University Hospital of Dresden, Germany	419	5 (1.2 %)	16 (4.1 %)	10 (2.4 %)	25 (6.0 %)	5 (1.2 %)	1 (0.2 %)	7 (1.7 %)	70 (16.7 %)
James et al. 2017 [192]	267	–	2 (0.75 %)	–	–	–	–	–	2 (0.75 %)
Yiannakis et al. 2017 [193]	103	4 (3.9 %)	7 (6.8 %)	1 (1 %)	–	–	1 (1%9	–	13 (12.6 %)
Phillips et al. 2015 [194]	495	–	1.4 %	–	–	–	1.2 %	–	2.6 %
Berglund et al. 2019 [195]	3775	–	–	44 (1.2 %)	–	–	10 (0.5 %)	–	54 (1.4 %)
Meta-analysis									
Bae et al. 2019 [196]	17461	–	–	–	–	–	–	–	–

* only late pareses (7.4 ± 1.8 days postop.). #sensorineural hearing loss. -no parameters

4.1.2 Standards of description and documentation

The classifications according to Wullstein and Bellucci have already been mentioned. In the following years, numerous others were added with different impacts and presence in the literature on ear surgery. The better known ones are the SPITE criteria by Black [153], the Austin classification most often in their modification according to Kartush [154] that developed to the Middle Ear Risk Index, MER index, or abbreviated MERI [155, 156]. The only statistically justified index, the OOPS index (ossiculoplasty outcome parameter staging index) must be mentioned [157]. Classification systems are also available for specific aspects of reconstruction of the tympanic membrane with cartilage [158] and endoscopic ear surgery [159].

Recently, the existing classifications for cholesteatomas were reviewed in an article [160] that will not be discussed here in detail. The current European classification of the European Academy of Otology and Neurotology in cooperation with the Japanese Otologic Society (EAONO/JOS) dates from 2017 [161]. It encompasses the definition, classification, and staging (examination) of cholesteatoma. The elaboration and conclusion were done before, during, and after the 10th International Cholesteatoma and Middle Ear Surgery meeting in 2016 (Chole2016). Finally, the definition was accepted by 89 % of the international delegates, the classification by 98 %, and the staging by 75 %. The foundation of an International Otology Outcome Group (IOOG) was planned for elaboration of a general minimum reporting standard for application of the international otologic community.

The most recent publication is the one about categorization of tympano-mastoid surgery elaborated by the mentioned IOOG [109]. In a similar procedure, a consensus was found on the description of middle ear surgery. The abbreviation of SAMEO-ATO represents the evaluation categories. A major advantage might be the simultaneous illustration of the defined characteristics because the scope of interpretation is being limited. This consensus was also finally concluded by a group of international delegates with a clear majority (95 % [20/21] to 100 % [21/21] depending on the parameter).

These two processes designed as Delphi procedures show very well how complex and difficult consensus-finding may be in an international context. The upcoming years will show if the propagated consents will prevail. With regard to the high number of existing, suggested, and described systems, the consensus for an international standard is a beneficial facilitation. The success of the project depends on the international otologic community because only this community may consequently apply the agreed consensuses and make them a success. The logical consequence is to accept the new classification and categorization, independently from documentation schemes that may have already been locally established. Especially in this context, opposition may be anticipated at the working level because the necessary "re-coding" from one classification to a new one is potentially work-intensive or technically not feasible. In addition to the technical challenges, personal sensitivities may be expected if an International Otology Outcome Group or a steering committee propagates a consensus, the development of which can never include everyone and which can never consider all opinions. Therefore, the approval of both consensuses is also an appeal to the international otological community to put individual opinions in second place and to work for the joint objective.

4.1.3 Application of classification systems and reporting standards

Looking at the seemingly small partial aspect of reporting standards of surgeries for therapy of conductive hearing loss, the recommendations of the AAO-HNS from 1995 may be considered as minimum criteria catalogue [123]. Similar to the above-mentioned categorization systems regarding cholesteatoma and tympanomastoid surgery, the attempt was made to define a standard for outcome description. In contrast to both consensus processes, this was a proposal of the AAO-HNS.

The acceptance and impact of the recommendations was described in a critical analysis of the literature from 2005 to 2015 that was performed on "hearing results after middle ear surgeries" [162]. It revealed that there are significant deficiencies even in the description of the methodological condition of the trials. In a scientific discipline, one could expect the application of mathematic and test-statistics basics for the specification of hearing results and their changes in the form of mean values with standard deviations. Nonetheless, the analysis of 169 publications (all of them published in peer-reviewed journals) revealed that the postoperative ABG was given in this form only in 56 % of the articles. Furthermore, information about the applied statistical methods were missing in 17 %. The test frequencies recommended by the AAO-HNS were applied in less than half (46 %) of the publications and in 15 % the information was not given at all. Strictly speaking, because of these flaws, sound statements cannot be derived from the results of these trials. Considering the application of the 10 criteria of the AAO-HNS standard of 1995, none of the publications applied them correctly and in 5 % (9/169) they were not applied at all. A correlation between correctly applied criteria with the impact factor of the journal could not be found ($r = 0.008$; $p = 0.3$).

Another study on the application and description of speech audiometry in studies about hearing improving middle ear surgeries, implantable hearing systems, and therapy of tumors of the cerebellopontine angle (performed between 2012 and 2016) confirmes the essence of the present problem (Morgenstern and Lailach et al., 2019, under review). In 20 % of the publications (56/279) statements on statistical test procedures were missing, in 11 % (32/279) and in 4.3 % (12/279) no information was given about the prospective character or the study design. In particular the information about the highly sensitive parameter of the measurement of speech understanding was alarmingly incomplete. 90 % (252/279) of the studies applied this parameter, but in 60 % (167/279) information was missing about the offered sound pressure and the measurement conditions which makes the respective statements nearly completely useless. In addition, this is an example of the interesting effect of "continued imprecision". In 45 % of the studies about the treatment of vestibular schwannoma, the description referred to audiometric functional testing mentioned in a publication of Gardner and Robertson from 1988 [163]. However, the quoted original article does not describe any audiological measurement procedure, but a classification with the categories of hearing that is suitable or not suitable for everyday situations. The authors recommend the application of their classification as an additional means besides according audiological test procedures. More recent reporting standards can only be considered and implemented in the literature with a certain delay [164]. In sum-

mary, it can be said that there is no lack of reporting and documentation standards but they are not or only sometimes applied.

At this point it is interesting to ask about the reasons and consequences of this knowledge. The reasons might be based on the practicability and/or quality of a reporting standard itself. Some authors might critically see a certain standard or even completely refuse it. However, this does not explain the flaws regarding the application of methodical basics. Therefore, also the uncomfortable question about the usefulness and the benefit of peer review procedures must be asked. It does not only show that the authors should work more soundly and thoroughly but also that the review procedure is sometimes ineffective [162].

4.2 Assessment and documentation systems

Historically grown, middle ear surgery is not a particular case regarding the scientific justification of specific therapy and surgery strategies. The decision basis is often empiric and based on clinical observations and experiences that have been collected since the beginnings of middle ear surgery until now [165, 166]. This condition could be met by prospective, controlled, and randomized trials that apply the principles of good scientific and clinical practice and include a representative number of patients. The reasons are manifold why this was difficult to realize also in the last years.

1. **Evaluation and classification systems:** The existing evaluation and classification systems and the published reporting standards [165, 167–169] are applied only sometimes or not at all [133, 170]. Since anamneses or surgery reports assessed retrospectively as free tests cannot be transferred validly into standardized evaluation tools, the description of a homogenous study population is difficult or impossible. This inevitably leads to the fact that statements generated in this way have the character of individual outcome reports.
2. **Nomenclature:** The nomenclature is various and provides much room for interpretations that are opposed to clear descriptions of findings and procedures.
3. **Multitude of influencing factors:** The individual middle ear pathology is influenced by a multitude of additional factors so that the statistically required control of single or more factors is nearly impossible in patient populations. Thus a rather respectable number of patients can be rapidly reduced to a small patient population which makes statistical evaluations impossible.
4. **Surgeon as influencing factor:** In addition to the individual pathology, major differences are observed regarding the surgical strategies and expertise between different sites. This fact is even multiplied by the number of involved surgeons in a department. Because of this, even within a single department the comparing of outcome evaluations is complicated.
5. **Retrospective study design:** The retrospective design of the majority of the studies limits the data quality (among others also due to the above-mentioned aspects) and presents a high risk for design-based bias.
6. **Additional documentation efforts:** Only in very few centers the most important influencing factors and predictors for the treatment outcome are systematically assessed in the routine. The implementation of datasets for statistical evaluation for scientific investigation requires enormous additional efforts for the clinical routine which is already overloaded with documentation work.
7. **Database systems:** The "Würzburg Ear Form" [171] was developed in the 1990s and certainly provides one of the first useful computer-based tools for standardized assessment of ear surgeries. Even preceding this, standardized data on ear surgeries has been collected and assessed in Germany [172, 173], at that time with punch card systems and the former possibilities of computerized information technology [174]. With the Würzburg Ear Form, more than 10 000 ear surgeries were assessed at that time, mostly including audiogram and follow-up examinations in an MS DOS-based database system of a single site. At the time of its development, this was a path-breaking development that unfortunately was made obsolete by the progressing computer technology. The fact that it was never adapted to more current operating systems illustrates the limitations of in-house, non-commercial solutions.

   Meanwhile, free-access database systems are available that allow the entry and evaluation of data via internet. This also allows for cross-departmental evaluation of results, which is the most important feature in the sense of evidence-orientation. Unfortunately, these databases are only rarely used [175]. Beside the above-mentioned additional time effort, resentments are often observed regarding the provision and availability of "own" datasets. The reason might be the possible traceability, a general fear of abuse of anonymized patient data to third parties, or other aspects.

The mentioned aspects reveal the difficulties that are associated with the quality claim regarding the generation of scientifically sound outcome evaluations. On the other hand, this problem can only be solved by routinely performed systematic and prospective assessment and collection of disease and therapy data. Therefore, the core aspect seems to be the availability and application of database systems and thus reflections on data protection and the efforts associated with the use, time, and costs. A more of quality must be equated with a more of documentation efforts that have to be implemented in daily routine. There is no need to mention that these additional efforts are not displayed in the refinancing concept of our healthcare system. Nonetheless, this is the only way a higher degree of evidence will be made possible.

Pursuing these objectives, a number of different cross-department database systems have already been developed and varyingly distributed. Some of them will be presented here.

4.2.1 Common Otology Audit Database

Founded in 2004 and published in 2005 as "International Otologic Database" [176], this database is the first international cross-country and cross-department database for middle ear interventions. In the pilot phase, three of the authors implemented 50 datasets each for otosclerosis surgeries. Based on this experience, the data entry was considered user-friendly and rapid (about 2 min per dataset), and according to the authors all users agreed with this statement [176]. The data assessment is divided into two categories. The basic database entry only assesses some criteria and consequently evaluates limited outcome parameters. In contrast, the

evaluation via category 2 allows for a detailed analysis based on extensive parameter entries. It encompasses preoperative anamnestic data about the pathology and the symptoms, intraoperative findings, and performed measures and allows postoperative follow-up in defined intervals. Furthermore, pre- and postoperative pure tone audiometry values of air and bone conduction thresholds may be entered so that the ABG is automatically calculated. The allocation occurs via an entry identification number with reference to the anonymized patient as well as to the surgeon. The system provides the possibility for every contributing surgeon to classify his/her results according to the categories of stapes surgery, myringoplasty, ossiculoplasty, and cholesteatoma surgery (children and adults) and have them displayed with consideration of the entire sum of entries (benchmark database). The data is available for scientific evaluation since it can be exported into common spreadsheet and statistics software.

At the time of manuscript writing, 27 otologists from 12 countries, the so-called "European Otology Database Project Group", have agreed to the standardized dataset for assessment, German representatives among them.

4.2.2 Standardized Korean Ear Surgery Database

In 2001, the "Korean Otologic Society" established a standardized database for middle ear surgical interventions [177]. This national project contained the standardization of a middle ear surgical nomenclature and recommendations for the postoperative outcome reporting. Nine ear surgeons of seven universities were involved in the process of consensus finding. They not only defined standards for the outcome evaluation, but also established a standardized nomenclature. International comparative publications were used here as orientation, for example from Japan [178], Europe [176], but also other classifications [166, 179, 180]. As with other documentation systems, the challenge here was also the maintenance of the database. Due to the fact that the documentation lists were in Korean, the application of this system on an international scale is limited.

In 2012, this database was used to evaluate a series of 2,312 surgeries of one single surgeon between 1989 and 2009 for therapy of chronic otitis media [181]. Due to the fact that this database was only developed in 2005, the data was implemented subsequently, which is associated with all limitations of retrospective data transfer. Nonetheless, this example impressively demonstrates the possible benefits of database systems. The authors showed that the function of the auditive tube, the presence of a cholesteatoma, and the severity of ossicular destruction (mainly of the stapes) influence the postoperative outcome.

4.2.3 Oto Database

In 2002, a group of Dutch authors from Rotterdam described their in-house database that is used for internal collection and evaluation of ear surgeries [182]. Beside the detailed description of documentation lists, they intensively and critically discussed the benefit and efforts of electronic data assessment. On average, a documentation time of 2–3 min was needed for the entry of surgery data. Out of 1009 datasets at the time of publication, the surgery report form was filled out in 89 % of the cases. Regarding the outpatient follow-up examinations, this rate dramatically decreased to 2 %. The authors mainly emphasize the value of the outcome assessment for the individual feedback to the surgeons and the department. Structural data are discussed and analyzed in detail. There seem to be no further publications about the use of this database system.

4.2.4 Otology-Neurotology Database

In 2006, R. Vincent and colleagues presented the Otology-Neurotology Database (ONDB) [183] as a commercial software package that had been developed in their department. It was based on the reporting format standard of the AAO-HNS 1995 and an international scientific committee was founded for further development and consultation. At the time of presentation, the application only included the registration of otologic patients and findings, however, it was planned to extend it not only to neurotologic diseases but also to the entire field of otolaryngology. Already at that time, the software was conceived for multicenter application with data pooling within an institution and beyond. With the inauguration of the database system, the same publication evaluated the considerable number of 3,050 stapes surgeries in the time between 1991 and 2004.

4.2.5 Oto Kir Database

The Oto Kir database was developed in Copenhagen, Denmark [8]. Comparable to the Würzburg Ear Form, it is an internal database allowing the assessment of interventions and outcome-specific influencing factors. An automatized interface allows the import of audiometry data if it is available electronically. The authors emphasize the significant user-friendliness, but critical consideration reveals certain limitations. In many aspects, the registration is performed in parallel to the hospital information system, the surgeons have to do additional, sometimes double documentation, and the import of external sources, for example audiometric data, has to be arranged via interfaces. It must be mentioned positively that the database of the Danish Association of Ear Surgeons is set to be applied nationwide and developed further [8]. Furthermore, it can be freely installed on the level of the operating system.

4.2.6 Swedish National Quality Registry for Myringoplasty

The Swedish Myringoplasty Registry was introduced in 1997 [184]. It is actually not a database system in the proper sense of the word, but since all 33 Swedish ENT departments have contributed in the course of time, we will be describing it as an example of a national quality initiative. It is not explicitly mentioned in which way the data assessment is performed. After the establishment phase, a total of 6334 procedures have been registered between 2002 and 2012. Beside anamnestic data, audiological data (pure tone audiometry) and information about the surgery technique were included. The amount of registered data was consciously limited in order to achieve a high compliance for data entry, which was performed at 4 times (1 preoperatively, 3 postoperatively). The data regarding the GTR are congruent with the data presented in Chapter 3.1.1 with 89.5 %.

According to the authors, the benefits of the registry are the facilitation ofdata exchange and pooling between the participating centers as well as quality control. They see the advantage of a national learning process and a continuous improvement of the Swedish healthcare system.

▶ **Table 3** Overview of database systems for assessment and evaluation of middle ear surgeries.

Name	Language	Year	Described in	Commercial	Publication
Common Otology Audit Database	English	2004	[176]	N	[175, 186–189]
Standardized Korean Ear Surgery Database	Korean	2005	[190]	N	[181]
Oto Database	Danish	2002	[182]	N	[182]
Otology-Neurotology Database	English	2006	[183]	Y	[183, 188, 191–194]
Oto Kir Database	English	2004	[8]	N	[8, 195–196]
ENT statistics	German	2004		Y	
Swedish National Quality Registry	Swedish	2004	[184]	N	[184, 197–198]

4.2.7 ENT statistics

The software tool called ENT statistics of the Innoforce Company is a commercial database for the administration of ear and other ENT-specific surgeries. It communicates with the hospital information system and the audiometry software via corresponding interfaces. Questionnaires of HRQoL measurement instruments and other survey lists can be integrated. Furthermore it is possible to pool data from different users and to filter targeted parameters. Due to the commercial use, the database maintenance and servicing are assured. Publications on the application of the system for middle ear surgeries are currently not available. An application in the field of cochlear implantation was reported by authors from Heidelberg [185].

A number of publications already use and analyze results that have been extracted from the above mentioned database system (▶ **Table 3**). This clearly shows the advantages: the consequent application leads to large case numbers that even after filtering in terms of certain parameters provide respectable population sizes for statistical evaluations. If additionally, cross-user data pooling is possible, the way is paved for detailed analyses in form of prospective multicenter trials. However, it is also obvious that the multitude of already existing local and/or national, sometimes self-conceived systems does not help the cause. In contrast, the purchase, integration into the hospital information structure, care, and maintenance of commercial solutions are expensive and cannot be easily justified in a limited investment budget.

The requirements for a documentation system can be summarized as follows:

- Cost-effective or adequate cost-benefit relation
- Uncomplicated data transfer to the hospital information system
- Uncomplicated data transfer from data sources (audiometry, HRQoL, parameterized hospital information system forms)
- Professional maintenance of the database
- Possibility of retrieving individual data and evaluation of multiple parameters
- Information structure for processing and evaluation of cross-site scientific questions with observance of data protection and ethical aspects.
- Unproblematic integration of new classification systems with the option of subsequent re-coding of already existing database entries.

5. CONCLUSION

A statement by Aristotle seems to be an adequate summary: “We are what we repeatedly do. Quality, then, is not an act, but a habit.” (Aristotle [384–322 B.C.]). The term of quality is mentioned explicitly here. Especially in middle ear surgery, achieving a higher quality level seems to be inevitably associated with the routine performance (habit) and the description of symptoms, therapy modalities, and evaluation parameters. The manifold influencing factors and differences in the findings and therapy make long-term and cross-center data collection necessary in order to generate sufficiently large populations for significant studies. Without any doubt, it requires the commitment of the scientific world to use existing assessment systems, to prospectively and routinely collect and manage data. With regard to the current work load and the perception of increasing work density in all areas, this requirement may sound presumptuous because it means (even) more documentation. On the other hand, this is the only way the advantages of digital data processing can be fully utilized. Therefore, the implementation of adequate classification and documentation systems in daily routine is the actual challenge that we have to face.

Conflict of Interest

The author declares that there is no conflict of interest.

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