Which Quality Makes the Difference?

Cosmetic Rhinoplasty

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ABSTRACT

There may be no field in which outcome is more obvious than in cosmetic nasal surgery. Both the quality of the procedure and the cosmetic quality of the result play an outstanding role in the arena of cosmetics. The expectations and interests of the surgeon are not always the same as those of the patient. Furthermore, with combination surgery, cost bearers focus independently on quality. This is often wrongly confused with economy. Objective criteria play a crucial role for the physician, but soft criteria are very important for patients. This is much more difficult, as everyone knows that beauty is in the eye of the beholder and must be compatible with functions such as breathing and smelling. There are many different quality standards, so that it is difficult for the patient to choose the right physician, particularly if he has to bear in mind the countless seals and certificates, and the influence of the internet and social media. But even the surgeon has to sift through a large number of congresses, courses, and symposia, if he is to achieve a minimum level of quality. Even though rhinosurgical techniques have greatly improved in recent decades, the patient always regards the quality of the outcome as being more important than the quality of the process. This paper presents a status report on the most objective quality indicators for cosmetic nasal surgery, as seen through the eyes of physicians, patients, and cost bearers, and in the context of changing surgical techniques.

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1. Introduction

When discussing the different areas of otorhinolaryngology, it is now crucially important to define quality parameters for efficacy. This applies particularly to aesthetic plastic rhinoplasty. This issue is not restricted to the benefit assessment criteria of the Federal Joint Committee of the Health Insurances (G-BA, Gemeinsamer Bundesausschuss) or to the regulatory instruments of the cost payers, but extends from guidelines up to evidence-based medicine. The concept of quality becomes even more important when defining the term of "evidence", as for the physician this incorporates the structure of service provision, the quality of training, overall previous treatment and follow-up, and the interdisciplinarity - which plays a crucial role in many treatment areas.

In 1990, the Institute of Medicine of the National Academy of Sciences, USA, developed the following definition of quality: "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge". For the patients, the particular aspect of this definition is that it is formulated in a patient-centred manner. The focus is not primarily placed on the outcome of medical services alone, but on the outcome perceived by the patient – as well as the patient's ideal outcome (Patient Reported Outcome, PRO) – but always based on sound state-of-the-art medical knowledge (guidelines, evidence). This aspect of PRO is particularly important in cosmetic rhinoplasty, as its whole purpose is to modify the external appearance.

The term "quality" is used frequently, but tends to be exaggerated and ill defined, particularly on advertising medical websites and social media portals, but even by cost payers and industry. This is also evident in the increasing number of certificates and quality labels. However, it is often unclear to the patient what this all means. What are the underlying principles and for how long are they valid? The measurement and assessment of the quality of medical treatment has been extensively studied, even though the methodology is rather difficult and prone to error and may be biased by subjective influences, especially in the field of cosmetics.

Perhaps no other field of otorhinolaryngology has been subject to more rapid changes in specific surgical techniques than has cosmetic rhinosurgery. There have been intensive discussion and assessment of the results of surgical techniques in interdisciplinary fora (meetings, publications, recommendations of well-known rhinoplasty surgeons). In addition, attempts are being made to define specific quality indicators for patients and referring physicians by objectifying the individual expertise (minimum quantities, lecturing/publishing activities etc.). In order to avoid possible deception, advertising with non-verified before/after pictures is generally forbidden. Registries or quality control mechanisms are currently either totally unavailable or inadequate information is provided. When rhinoplasty is advertised, the quality of the service is generally unclear. Since the patient may have to cover all the costs, they are mostly attracted by individual recommendations. Unfortunately, comparative studies like those in oncology are extremely rare in cosmetic surgery, particularly in rhinoplasty.

In the first part of this manuscript, the term of quality will be discussed in the context of rhinosurgery, including with requirements, its indicators and their control, and how these are maintained from the three main perspectives, i. e. those of the physicians, patients,

and cost payers. The second part will focus on quality development in cosmetic plastic rhinosurgery with different surgery methods.

2. Quality of Medicine in Rhinoplasty

2.1 Requirements for quality

2.1.1 From the physicians' point of view

Every physician is aware of the concept of quality and this is by no means a recent invention. The current understanding of quality was summarised in the original definitions of the ethical terms of medical activity (Hippocratic Oath: *"I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing"*). This basic principle has never changed. However, even the Hippocratic Oath could not ignore a "reformation" in the sense of how patients now see themselves. The new and revised version of the Oath was published in 2017 in the context of the 68th Plenary Meeting of the Medical World Association (WMA) in Chicago: The Physician's Pledge is now as follows: *"The health and well-being of my patient will be my first consideration and I will respect the autonomy and dignity of my patient"* [1].

The physician then strikes a balance between his claims, the new self-conception of the patients, and the interpretation of quality from the cost payer's point of view – that is nowadays increasingly confused with economic efficiency. Based on this development, several centres and institutes have been founded in recent decades under the aegis of different medical bodies and that illuminate, define, and further develop the term of quality from a medical point of view.

2.1.1.1 Medical Centre for Quality in Medicine (Ärztliches Zentrum für Qualität in der Medizin, ÄZQ)

The Medical Center for Quality in Medicine (Ärztliches Zentrum für Qualität in der Medizin, ÄZQ) is the centre of excellence of the German Medical Association (Bundesärztekammer, BÄK) and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV) for quality and knowledge transfer in the healthcare system. In 1995, it was founded as *"the Central Office of German Physicians for Quality Management in Medicine"*, with the aim of quality assurance of professional medical activity. In 2003, the name was changed to "Medical Centre for Quality in Medicine (ÄZQ)". The objective of the ÄZQ consists in supporting the BÄK and the KBV in fulfilling their tasks in the field of quality management in medical activity.

The fundamental objective of the BÄL and the KBV is quality improvement in healthcare services. The precondition is quality assurance and quality management (QA/QM), as designed and established in all service areas in an interdisciplinary manner. Furthermore, priorities have to be defined and the field of quality assurance and management has to be developed in a goal-oriented manner. Guidelines and principles of evidence-based medicine shall and must be developed in healthcare and patients have to be involved. Healthcare providers must create suitable structures for quality management in terms of staff and organisation, so that they can develop and enhance professionalisation in quality management, in cooperation with all contributing parties [2]. The work of the ÄZQ is founded on evidence-based medicine, patient safety, patient orientation, and transparency. These are all terms that will be discussed in the course of this paper in the context of quality.

Main focuses

The focuses may be classified into four key blocks.

- Medical guidelines (development, evaluation, distribution, methods)
  - Healthcare guides
  - Guidelines
  - Guideline clearing
- Patient information (development, evaluation, distribution, methods)
  - Patient information services
- Patient safety/error prevention in medicine
  - Online patient safety
  - CIRS
- Quality development in medicine

These four blocks show that we do not only include the physician's perspective, but also that of the patients and their information and safety.

This reflects the definition of the concept of quality that was published by the Institute of Medicine of National Academy of Sciences, USA, in 1990: *"Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"* [3].

The defining feature of this statement is that it is "patient-centred". It is not only the outcome of medical activity that is in focus, but also the result perceived and ideally desired by the patients.

In the literature, this aspect is defined as "patient reported outcome" (PRO) and must be measured on the basis of the sound knowledge of medicine expressed in guidelines and evidence. This topic will be described in more detail in Part 2 Chapter 12, as PROs are particularly important in aesthetic surgery and especially rhinoplasty.

2.1.1.2 Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF)

One of the first associations that aimed to define and assure the quality of medical activity was founded in 1962 as the Association of Scientific Medical Societies (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF). The German Society of Surgery then initiated a meeting of 16 scientific medical societies, mainly to implement specialisation in medicine and the introduction of specialist examinations. In the following 30 years, the AWMF has dealt with numerous issues in all scientific societies - such as the education guidelines for physicians (Weiterbildungsordnung für Ärzte) (1962, continuously since 1987), the regulation on licensing doctors (since 1970), quality management of the medical profession (since 1979 and continuously since 1993) etc.. Since then, it has been responsible for quality improvement in education by defining obligatory standards.

Today more than 150 scientific medical societies are represented in the AWMF that deal with the whole spectrum of scientific and research-related politics in the field of medicine. Together with other organisations such as BÄK, Medical Faculty Day (Medizinischer Fakultätentag), Association of University Hospitals (Verband der Universitätsklinika), and institutions of science promotion (e. g. German

Research Association, Deutsche Forschungsgemeinschaft), they are an important pillar in the entire German healthcare system. As a result, as early as 1995 the Council of Experts (Sachverständigenrat) for concerted action in healthcare assigned the AWMF the duty to promote and coordinate the development of standards, instructions, guidelines, and recommendations intended to enhance and define quality (▶ **Fig. 1**).

Guidelines

Three programmes have to be differentiated in the field of guidelines. The National Disease Management Guidelines (Nationale Versorgungsleitlinien) all correspond to the highest level of S3. The guideline program on "Oncology" is conducted in collaboration with the German Cancer Society (Deutsche Krebsgesellschaft) and German Cancer Aid (Deutsche Krebshilfe) and these guidelines also have the highest evidence-based level of S3; and thirdly, there are the guidelines of other specialist societies for verification of diagnostic and therapeutic approaches - that are classified from S1 to S3. Independently of the level of the guideline, they are a solid pillar in quality management, as will be discussed later in this contribution.

The AWMF defines the term of guideline as follows: *"Guidelines of Scientific Medical Societies are systematically developed to support physicians in making decisions in specific situations. They are based on current scientific knowledge and procedures that have proven to be successful in practice; and they lead to more safety in medicine, but also take into account economic aspects. The guidelines are not legally binding for physicians and therefore neither lead to nor relieve liability."*

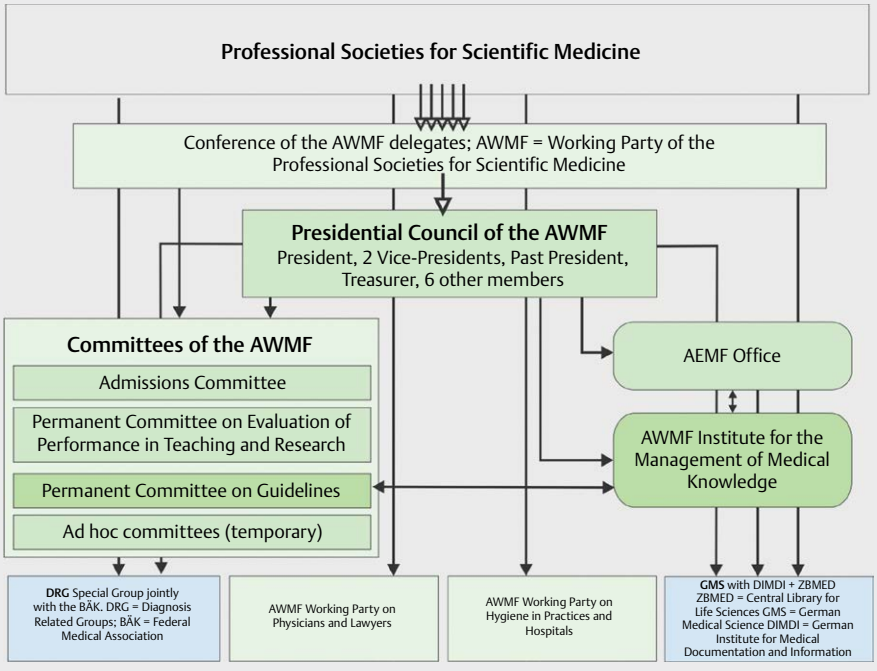
Under the leadership of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (Deutsche Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie, DGHNOKHC), 20 guidelines at different levels of evidence have been developed. In addition, the DGHNOKHC has contributed to the development and definition of a further 45 guidelines.

Among those 20 guidelines created under the egis of the DGHNOKHC, all levels of evidence are found - from S1 (e. g. oesophagoscopy, sudden hearing loss), via S2k (e. g. rhinosurgery and rhinosinusitis), S2e (e. g. sleep apnoea), up to S3 (e. g. laryngeal cancer, tinnitus). The guideline on rhinosurgery has the level S2k, which means that it is consensus-based. It will be discussed below in Chapter 3a. This is a significant step towards increasing quality in cosmetic plastic rhinosurgery.

2.1.2 From the patients' point of view

For patients, the quality of healthcare services is often of existential significance. National and international have been performed on patients' expectations for the quality of medical care; seven large areas may be summarised, whereby the last on the list is less important for rhinoplasty [4, 5].

- Restoration of health and physical well-being
- Respect of the patients' person, respect of their subjective values and ideas
- Sufficient and comprehensible information
- Emotional support and empathy
- State-of-the-art expertise of medical treatment, but also in other fields, e. g. nursing care
- Inclusion of partner, family, and friends
- Continuity of the treatment, understood as staff-related continuity within the medical institution, but also as continuity between the single healthcare services, e. g. support at the time of discharge from the hospital into the home environment



▶ **Fig. 1** Organisation chart of the AWMF. © AWMF online – Das Portal der wissenschaftlichen Medizin

Patients have an intense need for information about quality in healthcare services in these dimensions, as is evident in publications from the beginning of the 2000s [6].

Patients increasingly want to receive precise information about the institutions and physicians who will provide the highest quality. This desire is reflected in in the patients' new self-conception and self-confidence. They do not see themselves only as users of medical services, but they want to be understood as equal partners of the physicians. In the context of rhinoplasty, this is very important, as these patients are perceived as being extremely challenging.

There seems to be an increasing uncertainty about the situation in the quality of medical care. Even 18 years ago, two thirds (!) of the population stated that the situation for patients in healthcare services had deteriorated in recent years [7].

In comparison to other industrial nations, results for Germany for 2015 were a mixed bag. In some areas, Germany has a leading position (e. g. GP care), but one of five persons asked thinks that the German healthcare system needs to be completely revised [8].

Patients increasingly think that they should be able to retrieve transparent information about structural processes and a physician's and/or hospital's quality of results, particularly as this information is becoming more and more readily accessible in the internet or social media. Patients can gather additional information about medical treatment and quality from friends or practitioners. Patient satisfaction and experiences may also be published in social networks and the internet and these reports have excited increasing attention - even if their accuracy and authenticity generally cannot be verified.

According to a survey, one third of patients stated that they had chosen the medical institution in accordance with their physician's recommendation [9]. 20 % relied on the recommendations of relatives and friends; about 18 % had already experienced previous stays in the respective hospital; 17 % mentioned the general reputation of the institution as basis of their choice; for 12 %, the proximity to their home was decisive; 6 % selected the hospital based on internet information. Moreover, self-help groups are important information portals for their members and other interest groups.

Physicians who refer their patients to a colleague, directly or indirectly, give a direct or indirect recommendation to their patients. The physician's recommendation often results from their own experiences in collaboration with certain colleagues, departments, wards, or information retrieved from a professional network or the feedback of their own patients.

Studies on quality management and evidence-based healthcare have been performed in different medical fields. These confirm that it is not enough if the evaluation exclusively concentrates on a concentration of treatment methods, procedures for physical symptoms and treatment outcomes [10]. That is why the measurement of treatment efficacy focusses increasingly on the psycho-emotional characteristics of the physician-patient relationship, communication, and decision-making on a partnership basis (see above) [11, 12]. The physician should be aware of each patient's situation and value systems, how he experiences the disease and how he copes with it. Only then can the optimal treatment be identified [13]. From the patients' point of view, it is absolutely essential for therapy to establish a stable and confident relationship with the physician and that the physician understands his individual needs and requirements [14]. A self-confident patient expects that a competent physician will understand and be interested in his concerns, and will readily provide explanations, effective therapies, and specific information [15]. This trend is also observed in surgical disciplines. Therefore, the parameters of success are no longer restricted to the definition of evidence-based standards, but also in the patients' subjective assessment of therapeutic processes – and this is another important quality criterion [16]. This complex of communication, interaction, understanding, assessment etc. is most relevant for cosmetic rhinosurgery, as this modifies the shape of the nose – right in the middle of the patient's face. The patients' expectations have to be adequately assessed.

In the cosmetic context, the above mentioned subjective ratings (PROs) play a crucial role, as beauty is in the eye of the beholder and partially depends on fashion and the overall social situation. Furthermore, the assessment of the mentioned criteria provides knowledge about the actual quality standard of the service – both as perceived by the patients and in the subjectively experienced improvement in health status. At the same time, the assessment of the patients' needs is a consistently patient-oriented and effective instrument for quality assurance that provides a valid measure of the whole process and the outcome quality from the users' perspective. The resulting development into generic (general) and disease-specific subjective measurement instruments - so-called PROMs (patient related outcome measurements) – is underway and will be discussed later in Chapter 12 with a special focus on rhinoplasty.

2.1.3 From the cost payers' point of view

As regards cost payers, a distinction must be made between statutory and private health insurances as well as statutory accident insurances and employers' liability insurance associations (Berufsgenossenschaft, BG). These are described and defined in different social insurance codes (Sozialgesetzbuch, SGB). Their contents are defined differently - which is also expressed in different guiding principles.

2.1.2.1 Statutory health insurance (Gesetzliche Krankenversicherung, GKV)

One important pillar of the statutory health insurances is economic efficiency, as can be found in the first chapter of SGB V. According to chapter 2, §3, sentence 1, *health insurances provide the insured individuals with services, after taking into account the economic efficiency. Quality is only mentioned in the following paragraphs, in the statement that treatment methods, medication and therapeutic products of a specific treatment institution are not excluded. The quality and efficacy of the service have to observe generally accepted medical knowledge and medical progress.*

Service performance and the claim of efficacy are defined as follows in §12 (1): *The services have to be sufficient, appropriate and cost-effective; they must not exceed what is necessary. Services that are not necessary or effective may not be claimed by the insured individuals, the cost payers are not allowed to perform these services, and health insurances will not approve them.*

This shows the dilemma of the statutory health insurances, since all their services have to observe the claim of cost-effectiveness. The misinterpretation that cost-effectiveness is a quality parameter will have to be discussed later.

2.1.2.2 Private health insurances (Private Krankenversicherung, PKV)

In contrast, private health insurances are not defined in the social insurance code as a law, but the insurance relationship is constituted by a private contract. The principles are regulated in the insurance contract act and the insurance supervision act (Versicherungsvertragsgesetz, VVG; Versicherungsaufsichtsgesetz, VAG), both of which are generally applicable.

For private health insurances, the insured event is the medically necessary treatment. The explicit imperative of cost-effectiveness does not exist in private health insurances. It is rather the case that the single contract between the individual patient and the insurance company specifies the intensity and extent of the treatment costs to be borne.

2.1.2.3 Statutory accident insurance (Gesetzliche Unfallversicherung, GUV)

The definition of responsibility of the statutory accident insurances and the employers' liability associations is diametrically opposite to that of health insurances. In contrast to statutory health insurances, the maximum appropriate measures have to be taken. Their responsibilities and activities are regulated by law in the social security law (SGB VII). Their focus is not on the general provision of health service provisions, but on the prevention, rehabilitation, and compensation of the insured people.

Accordingly, the services must be of high quality so that the insured person can resume work as rapidly as possible. According to the social security code (SGB VII), the responsibility of statutory accident insurances is to restore the health and performance of the insured individuals after accidents at work or occupational diseases - with all appropriate measures and to compensate the patients or their surviving relatives by payments. No chapter explicitly mentions cost-effectiveness. In addition, quality is not mentioned clearly but automatically results from the special institutions of GUV and employers' liability associations - such as BG hospitals. These are highly specialised in the acute treatment and in rehabilitation of specific injury patterns.

3. Quality Indicators

3.1 Quality criteria and quality indicators

All investigations on the quality of provided services are based on the documentation and analysis of quality indicators. These aim to assess the quality level achieved by the service provided (aim achieved/aim partly achieved/aim not achieved). Quality indicators try to make the non-measurable conception of "quality in medical treatment" more tangible by checking single quality criteria for significant treatment aspects (e. g. laboratory, radiology etc.).

3.1.1 Aspects of treatment provision

The aspects of treatment provision include structures, processes, and outcomes of medical services that are highly relevant for the quality of medical treatment and which therefore should be assessed in the context of quality management. A series of suggestions have been made for the selection of aspects of treatment provision that should be included in medical quality management.

So treatments should be assessed that are known to be

- Performed with high frequency, represent a high risk for the patients, or are often associated with complications;
- Possibly associated with over-, under- or mistreatment;
- Subject to high treatment variability, if the treatment has recently changed significantly, that are of high financial relevance or where practical considerations are positive - such as the general measurability and variability as well as the acceptance by the group of affected individuals;
- Provide the possibility actually to improve treatment and health-related outcomes, are highly interesting for users or possibly improve the decision finding process (in favour or against a certain service provider);
- May serve as indicators for comprehensive treatment problems.

Except for the last aspect, all these are relevant to the field of internal and external nasal interventions. They are performed in high numbers and it is often unclear whether the therapy is adequate (e. g. the topic of septoplasty). Furthermore, there is great patient interest, since respiration and smelling are essential for the quality of life and because the effect is subject to a dynamism that can be measured. The cosmetic aspect is added because it does not primarily belong to the treatment aspect.

3.1.2 Quality criteria

Quality criteria for the assessment of service performance are those attributes that are expected to be typically fulfilled in the context of high quality medical treatment.

A list of such criteria has already been published in 1998 by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [17]. These criteria are still appropriate, as well as being internationally acknowledged and applied.

- Accessibility of care
- Appropriateness of care
- Continuity/coordination of care
- Efficacy of care (ideal conditions)
- Efficacy of care (treatment in healthcare practice)
- Efficiency of care (cost-effectiveness)
- Patient-orientation of care
- Safety of the care environment
- Timeliness of care

The WHO "World Health Report 2000" refers to these criteria and warns against applying these rather instrumental quality criteria to an overall assessment of healthcare systems. For such an overall assessment, the WHO mentions three key objectives of good healthcare: health, fair financing, and patient-orientation [18].

Quality criteria for single treatment aspects (e. g. rhinoplasty) might be used for example in internal quality management of an institution in order to define specific quality objectives.

Examples for quality criteria:

- Timeliness of diagnostic testing
- Information of the patients about their findings, planned treatment, their rights and obligations
- Training and education of the medical team
- Implementation of statistics about diagnoses and treatments
- Adequate use of diagnostic and therapeutic measures

- Waiting times (hospitalisation/before physician contact/ treatment/in hospitals or practices)

3.1.3 Quality indicators/reference range

Quality indicators are measures intended to make a difference between good and poor quality of structures, processes and/or outcomes of treatment. They are auxiliary parameters that indirectly depict the quality of a unit by numbers and ratios. They could also be called quality-related parameters.

The quality of a treatment is a very complex phenomenon that can be generally described by several indicators. Therefore, the overall quality of patient care, of a service provider, or of an institution cannot be assessed on the basis of a single quality indicator. Instead, single indicators only show partial aspects of quality. So to assess a certain treatment, it is reasonable to summarise several indicators or quality criteria in the form of indicator profiles

Indicators are suitable to influence the quality of patient care, or surgical treatment, and also the treatment outcome from the patients' perspective. Furthermore, quality indicators are useful to evaluate the objective achievement of medical treatment itself based on the outcome quality visible in the patient (evaluation function).

The evaluation is performed by means of previously defined values of "good quality", the so-called "reference ranges". The reference range is the interval in which the manifestation of a quality indicator is defined as "good" or "normal". In rhinoplasty, the assessment of good quality is rather difficult because the objective criteria of breathing and smelling have to be weighed against the subjectively perceived cosmetics. As is well-known, beauty is in the eye of the beholder and often varies between surgeon and patient.

Depending on various factors, different reference ranges may be assumed for a specific quality indicator. These factors are mainly patient-related (e. g. the extent of change, breathing, smelling) or surgeon-related (e. g. experience, number of operations, specialisation). In particular, the indicators for assessment of the outcome quality react sensitively to the above-mentioned factors. The discrimination of quality indicators and their respective reference ranges depend mainly on their sensitivity and specificity. If a reference range is optimally defined, nearly all quality problems are identified (high sensitivity) without producing too much unnecessary alarm (high specificity). The predictable positive and negative values then depend on the incidence of quality problems.

The realisation of programs for development and implementation of quality indicators is mainly influenced – as are the guidelines – by their quality, practicability, and financing. That is why "quality criteria" have been defined for quality indicators that partially correspond to quality criteria for guidelines (see Chapter 4.1.1.) [19, 20].

3.2 From the physician's point of view

Quality criteria that play a significant role in patient care from the medical point of view are mainly based on what physicians have seen and learned during their education as well as in exchanges with colleagues, during congresses, meetings, or information from scientific societies. It may be important to consider the type, intensity, and duration of the specialisation of their colleagues who are closely associated with the respective teaching hospital or special department. Furthermore, publications, lectures, or teaching activities may also influence quality indicators from the physicians' perspective. However, in the specific field of rhinoplasty, an increasing number of hands-on courses are available worldwide. It is possible to attend different meetings on this topic nearly twice per week. The quality of such courses is not controlled and minimum standards do not exist; the courses may be offered by any physician. Nonetheless, this is not a unique problem of rhinosurgery, but unfortunately is found in all disciplines of medicine. From all the single parameters and experiences, a physician generates his own personal quality indicators or criteria in order to rate other colleagues, which could be summarised in the sentence: "Where would I go? Who would I trust?"

In addition, the so-called specialist standard - based on two pillars - is crucial for quality analysis.

One pillar represents the number of treated diseases from a specific discipline (e. g. ENT) and thus the physician's experience in this discipline. The other pillar represents either the variation in the individual spectrum (e. g. general ENT) or the diagnostic and therapeutic specialisation of the physician and his expertise in this discipline (e. g. rhinosurgery, ear surgery, allergology, cancer etc.). These areas often lead to a low rate of side effects and complications and to a high outcome quality that is communicated to the referring physician by the patients and that is meanwhile even required by them and the cost payers.

In particular, the outcome concentrates on an optically good postoperative result – which does not say anything about the inside of the nose. Only an ENT specialist may confirm the quality by endoscopic examination. However, it must be mentioned that the objectively assessed outcome does not need to correlate with the patient's subjective perception, in particular in the field of breathing, smelling, and cosmetics. The experience of a surgeon in rhinosurgery is also reflected in the number of cases of revision and reconstruction, as experience and expertise with high case numbers and expertise are particularly important.

3.3 From the patients' point of view

Indicators for the choice of a physician are manifold and depend on the disease as well as on the discipline. The decision for an individual gynaecologist incorporates other priorities than that for a cancer surgeon. Nonetheless, patients too have indicators to help them to assess quality. Quality-conscious patients do not only assess the medical, therapeutic, nursing care provided and the outcome of the treatment, but also the information flow, communication with service providers, the impression of the staff (friendliness, reliability, competence, punctuality, waiting times), the interaction with all staff members of a practice or hospital, the access and the organisation of the practice as well as offers of support (see above) [21].

In this context, two relevant areas are seen that may be described as "hard" and "soft" factors. Hard factors are those that are objectifiable by facts or for which the patient can present objective arguments.

Hard factors are:

- Objective criteria:
  - Professional experience
  - Degree of education
  - Specialisation
  - Equipment of a practice
  - Staff

  - Hygiene
- Partly objective criteria:
  - Personal recommendation
  - Rating portals and fora
  - Online presentation
  - Seal of approval
  - Furnishing of the practice
  - Membership in scientific societies

On the other hand, there are so-called soft factors that correspond to the rather subjective perception of the patients.

- Soft factors:
  - Personality of the physician
  - Physician listens
  - Physician allows questions
  - Physician explains
  - Physician respects the individual patient and his problems as patient
  - Physician is interested in the patient's health-related problem
  - Physician takes his time
  - Confidence between physician and patient

Based on this perspective, BÄK, KBV, and ÄZQ published a general checklist for patients in 2015 that intends to illuminate and summarise this area [22].

In the preface, the following aspects are summarised: "You have to see a doctor but you do not exactly know where to go. Your physician should be competent and trustworthy. You want to be taken seriously, and you want to feel well cared for by the practice team. However, it is difficult to assess if a practice may meet all these expectations. That is why the checklist entitled "What are the criteria of a good doctor's office?" has been developed. This booklet will help you to find the right office for your needs. You may read what you can expect from a good practice. Whether a physician is actually the right one for you, finally depends on the confident relationship, which cannot be created by checklists but by a respectful and open interaction".

As assistance, the following questions might be asked:

1. Am I addressed in the medical office in a friendly and respectful way?
2. Does my physician take me and my concerns seriously?
3. Are my personality and my privacy observed?
4. Do I receive understandable and neutral information and consultation?
5. Do I receive hints about further reliable information sources and consultation offers?
6. Does my physician involve me and my wishes in all decisions?
7. Does my physician accept that I want to have a second opinion in cases of doubt?
8. How can I see if my physician and the team attend training courses and quality programs?
9. Is a highest level of security for my treatment observed in the practice?
10. Do I have access to my files without any problem?
11. Does the medical office cooperate with other physicians?

The problem is that patients are not informed about which aspects have to be understood as objective or subjective criteria and how they have to be classified. The list is more like a subjective general assessment. Unfortunately, the checklists give no information about experience, skills, specialisation, education etc.

For cosmetic rhinosurgery, other "quality indicators" are relevant for the patients that may result from objective criteria, but also very frequently come from subjective criteria.

The list below does not claim to be complete, but the following criteria play a major role – as often in the field of cosmetics:

- What is the surgeon's special field?
- Where did he learn rhinoplasty?
- Is he a member of a scientific society?
- How often does he perform this kind of surgery?
- Is he specialised in rhinosurgery?
- Is he specialised in revision surgery?
- What about the price of the operation?
- What do others report about this surgeon?
- What about the rating in the respective portals or fora?
- How informative is the homepage?
- How is his presence in social networks?
- Is the physician likeable?
- etc.

In this way, an accumulation of "facts" is created that consciously or unconsciously influence the patients in his choice of a surgeon and that are considered subjectively as quality indicators. In particular, emotional aspects that are confirmed by other people's statements – regardless of whether they can be verified or not - make any objective criterion obsolete, independently of the type of intervention.

3.4 From the cost payers' point of view

Since German reunification, cost payers have focused on cost-effectiveness. If a service provider works efficiently and effectively, the quality should be appropriate. This was the approach that cost payers have propagated since the beginning of the 1990s. They only focused on cost-effectiveness and the responsibility for the decreasing quality of medical care was attributed to the service providers [23].

However, this was too short-sighted, because medical care does not correspond to the industrial production of goods. Moreover, the cost payers had to acknowledge this fact after several years of cost savings, and other factors came more and more to the foreground that were more likely to be an indicator of quality than cost-effectiveness alone.

Structural specialisation to only a single disease or injury pattern and the associated "high" number of cases are now considered as possible indicators of high quality. For example, recent publications on the outcome quality of head and neck cancer therapy confirm that there is significant association between overall survival and the structural quality of the treatment centre with supposedly always the same therapy. These factors have only recently played a role in clinical trials [24].

Further examples for improved quality in organised and predefined structures are found in breast centres, burn centres, stroke units, or CI centres. This list could be continued endlessly for all dis-

ciplines. It is of course also the case that physicians have to employ the key terms of "minimum numbers" or "minimum quantities" in their annual negotiation with cost payers if they are to ensure adequate funding. This is eminently the case with plastic aesthetic rhinosurgery, as only a few physicians perform more than 30 complete inner and outer rhinoplasties per year.

The cost payers and the service providers thus have conflicting priorities in terms of comprehensive, adequate care of the population on the one hand and the requisite and currently high quality due to specialisation for specific diseases and injuries on the other. Specialisation reflects a higher level of experience and expertise and should be associated with fewer side effects or complications or better overall survival (see above).

In this way, the economic costs may be lower in the long term, due to shorter hospitalisation and partial displacement to outpatient care - which is less cost-intensive. This would then lead to greater cost-effectiveness - the declared primary goal of cost payers.

4. Control and Quality Assurance

4.1. Methods and instruments of quality management

When a quality problem has been identified and specific objectives have been defined to alleviate it, there are numerous methods of quality management (QM) to achieve these quality objectives [25]. The content, design and organisation of QM procedures should adequately consider the specific quality problem, the defined objectives, and the context of care. Quality management systems/procedures are often quite disparate with respect to structure and conceptual spectrum, so that a direct comparison of the criteria is difficult.

To be successful, QM procedures must be carefully and planned and their cost-effectiveness assured. Quality assurance instruments may encompass all or only some phases of the quality improvement cycle [26].

For quality management in medical care the following issues are of high priority:

- Quality circles with creation and/or revision of guidelines
- Ring trials
- Quality check in single cases (on a random basis)
- Second opinion procedures
- Data collection and evaluation of parameters (e. g. complications)
- Structured external comparison (e. g. benchmarking)
- Etc.

These procedures are not generally established in aesthetics.

4.1.1 From the physicians' point of view

4.1.1.1 Quality objectives for patient orientation from the physicians' perspective

Most regulations in medical quality assurance concern measures of structural quality. In individual areas of quality assurance, they generally lay down the physicians' qualification, education and training, as well as the required equipment. The guidelines define the details of the qualifications that a physician or his colleagues should have, or which technical equipment is approved in order to invoice certain services, but do not allow any statement about the quality of a medical service. Appropriate guidelines are completely missing in the field of rhinosurgery so that these interventions might also be performed by general surgeons etc. In cosmetic surgery, this is a general problem because there is no sufficient legal regulation defining and protecting these therapies and applications. Reports in the media about alternative practitioners who perform cosmetic interventions, internists performing surgeries etc. are well-known.

In a high number of quality assurance areas, quality management should check and control the quality of the procedure and outcome. The outcome quality is characterised by the verification of the success or outcome of the examination or treatment.

4.1.1.2 Practical implementation of patient orientation in QM

Thorough and understandable information

It is absolutely essential in quality management that the patients should be provided with detailed and comprehensible information, as this provides the basis for making informed decisions. The patient who comes to see a doctor and does everything the god in the white coat says without questioning him has become very rare (see above). More and more patients want to be informed about diagnostic and therapeutic measures and options, and who want to understand the implications, and finally make the decision together with their physician. This corresponds to the central statement of the concept of participative or shared decision making. On the basis of shared information, physician and patient make a joint decision; they enter into a "therapeutic alliance" [15]. In the field of self-payers and cosmetics, this is found comparatively frequently, as patients pay for the services out of their own pockets and thus expect high quality treatment.

Patients often understand only 50 % of the information they receive from their doctor [27]. Whether a patient understands the information given about the benefits and side effects of a suggested treatment option depends on how this information is provided [28, 29].

Even a very thoroughly conducted informative discussion is no guarantee that patients have understood the contents and will remember them. Many patients are not able to correctly recall the contents of a conversation when they leave the doctor's office. That is why patients should be able to take home everything they have learned about findings and possible therapy options - as well as further care - in the form of a piece of paper that summarises the information [22]. In rhinoplasty, processed pictures might help to visualise a desired outcome. However, the patient always has to be informed about the fact that this is a draft and not a guaranteed result.

What is important is that the patient takes something home that has been conceived individually for him. In this respect, quality is more important than quantity. An individual piece of information appears to be more professional and personalised than a photocopied plan or the usual information brochure.

Information about treatment options

For physicians and patients, making evidence-based decisions requires an understanding of probabilities. No examination is 100 % safe; no treatment is always and completely effective. So when making a decision, physician and patient always have to rely on probabilities. Experts assess benefit and risks in a different way from laypeople. Experts justify their evaluation for a clearly defined pa-

tient group (based on the according trial); patients are more likely to expect a yes/no decision. Another obstacle for the communication of benefit and risks is the so-called "framing effect". This means that the decision depends on the manner in which information/options are presented in a positive or negative way.

Quality of physician-patient communication

In order to have a successful physician-patient communication, various aspects have to be taken into account [30, 31]:

- Creating an undisturbed environment
- Establishing a confidential working relationship
- Empathy
- Conflict management
- Authenticity of the relationship
- Observance of the basics of communication science
- Identifying and communicating one's own limits

Patient care

- Orientation of the care to current scientific standards and guidelines
- Patient orientation, safety, collaboration, information, and consultation
- Structured treatment processes

Practice management/staff/organisation

- Regulation of the responsibilities
- Team orientation (e. g. safety at work, training and education)
- Practice management (e. g. appointments, data protection, hygiene, escape plan)
- Communication processes (internal/external) and information management
- Cooperation and management of the interfaces of care
- Integration of existing quality measures into the internal quality management

All these are areas that a rhinology patient regard as important, particularly in the communication of findings and therapy options. In most cases, the patient who deals with aesthetic correction of his nose is at least informed by the internet, and is influenced by other people's opinions and by the media with regard to the desired optical outcome – even more than he is aware.

4.1.1.3 Guidelines and quality management

For several years, the relevant literature has mentioned the close relationship between guidelines and quality management [32]. Guidelines are one of the most important tools of quality management. The integration of guidelines in QM programmes is one of the most effective strategies to implement guidelines.

In the context of quality management, guidelines further serve as basis for the work in quality circles [33], as reference for quality objectives, quality parameters and indicators [19], as the basis for process descriptions as well as working instructions, e. g. in the form of clinical treatment pathways [34]. The introduction of a working quality management system may assure the implementation of guidelines in practical routine and thus lead to the desired improvement in quality [35]. At the same time, guidelines are a relevant part of modern information management in medical work and may help patients to reach balanced and joint decisions (see above).

4.1.1.4 Intention and objectives of guidelines

In addition, guidelines are intended to present extensive current knowledge (scientific evidence and experience) of specific treatment problems, to assess their methodical and clinical aspects, to clarify contradictory perspectives, and to define the current process of choice by balancing potential benefits and harms.

The primary objective of guidelines is to improve the quality of medical care by communicating knowledge. After taking into account available resources, guidelines should aim at promoting good clinical practice and at informing the public, at finding a more rational basis for decisions in medical care, at strengthening the patient's position as partners in the decision making process, and at improving the quality of care.

Guidelines are the basis for defining parameters and indicators that make the quality of medical care measurable and allow differentiation between "good" and "improvement needed". Such quality indicators are an important tool for the evaluation of treatment services and outcomes in routine medical work, for internal quality management, and for external quality comparison.

4.1.1.5 Effectiveness and quality of guidelines

It has been demonstrated that guidelines have a favourable effect on the quality of both processes and outcomes in healthcare [35]. The efficacy and thus ultimately the benefit of an individual guideline, however, depends on its quality and implementation. Up-to-date criteria must be fulfilled by high quality guidelines and are internationally defined in a standardised way [32]. For Germany, these criteria of methodical quality are published in form of commented checklists - the so-called German Guidelines Assessment Instrument (Deutsches Leitlinien-Bewertungs-Instrument, DELBI) [36].

On the one hand, DELBI should help users of guidelines and other interested people to submit guidelines to a methodical check-up and thus to evaluate their validity. On the other hand, authors of guidelines ensure that the guidelines correspond to international standards, by checking their orientation to DELBI.

Three fundamental aspects are emphasised in this context:

- Composition of the guideline board: representation of the user community
- Evidence basis: systematic search, selection, and evaluation of the literature
- Methods of development: systematic evidence and consensus base

The evidence base is especially important for the scientific legitimation of a guideline, while the contribution of the users and structured consensus finding are crucial for acceptance and implementation. To help the user to achieve a broad view, four classes of guidelines are distinguished (see ▶ **Fig. 2**) [37]. The practicing physician must be able to recognise good (i. e. valid, current, practicable) guidelines. This is indeed a precondition for their use in evidence-based medicine.

Name	Characteristics	Scientific legitimation of the method	Legitimation for implementation
S1: Recommendation of experts	Consensus finding in an informal procedure	Low	Low
S2k: Consensus-based guideline	Representative institution, structured consensus finding	Low	High
S2e: Evidence-based guideline	Systematic research, selection, and evaluation of the literature	High	Low
S3: Evidence-based and consensus-based guideline	Representative institution, systematic research, selection, evaluation of the literature, structured consensus finding	High	High

▶ **Fig. 2** The S-classification scheme of the AWMF. © AWMF online – Das Portal der wissenschaftlichen Medizin

Legal aspects of guidelines

In contrast to directives, guidelines are not binding [38]. Before a specific recommendation is implemented, it must be confirmed that it is appropriate to the circumstances (e. g. comorbidities of the patient, available resources). The Federal Supreme Court (Bundesgerichtshof, BGH; sentence dated April 15, 2014 – VI ZR 382/12) has confirmed that guidelines are not legally binding, in particular because they cannot replace expert opinions. In principle, an active physician has to be informed about the guidelines that are relevant for his discipline. Furthermore, he should document justified deviations from guideline recommendations in individual cases - in the context of the patient's documentation. Deviating from a guideline alone will not be understood as negligence unless the respective procedure is so well established that no responsible physician would disregard it. However, this does not mean that a guideline could not have further consequences in a legal process - even if it is not normative for the confirmation of negligence. For example, it may lead to a reversal of the burden of proof, e. g. if a physician has not observed a guideline, he might be required to prove that the damage of the patient has not been caused by non-observance of the guideline.

Guidelines' significance in legal processes usually depends on several factors, especially on the extent to which they are scientifically proven, and whether they represent an expert consensus, and have been published by an authorised group or institution. Guidelines will not generally give final answers, even if they allow only a low level of flexibility in terms of their application. Medicine is progressing, the speed of development is extremely high so that every single guiding principle has to be assessed in the light of both the specific health problem as well as the particular circumstances of the respective patient. Sometimes competing guidelines are found, e. g. created in different hospitals or regions; in other cases, expert statements may be used in legal processes to question the authority of a guideline. For all these reasons, the courts will not automatically equate the observance of guidelines with good medical practice [36].

4.1.1.6. Use of guidelines in quality management – implementation of guidelines

The creation and publishing of guidelines alone is not sufficient to assure that they are applied in daily medical routine. Implementation of guidelines means the transfer of recommendations into individual action or behaviour of physicians, patients, relatives etc.

In order to assure that this transfer is successful, several complementary measures generally have to be taken that are specifically coordinated for the identified problem areas. These measures concern educational, financial, organisational and/or regulatory strategies [39].

For implementation, it is not only decisive that the guideline is available, but also that the users work according to the content and adapt it to their individual needs and circumstances. In the outpatient area, successful examples of such adaptations are performed in the context of quality circles [40, 41].

4.1.1.7. Implementation of guidelines in outpatient care

The observance of evidence-based guidelines is legally binding in several statutory healthcare programs, particularly for the structured treatment of chronic diseases (according to § 137f SGB V and since the amendment in April 2007 of the "Hausarztzentrierten Versorgung" (HZV) according to § 73b SGB V).

Structured treatment programs have to be based on consistent therapy recommendations, although the necessary evidence-based consensus guidelines are not available in Germany for all relevant diseases. With this background, the German Medical Association (Bundesärztekammer) initiated the so-called National Programme for Disease Management (Nationales Programm für Versorgungsleitlinien, NVL) in 2002 and published the first disease management guidelines (asthma, COPD, diabetes type 2, and coronary heart disease). The aim of this joint program of BÄK, KBV, and AWMF is the implementation of evidence-based guidelines in the context of structured healthcare. The recommendations reflect the interdisciplinary consensus of all medical societies and disciplines contributing to the care of a specific patient group, as based on the best

available evidence. The program of NVL contains targeted instruments and measures to distribute and implement NVL, in order to allow effective implementation in practice. One focus is on the fields of quality management, quality indicators, and education. If establishing NVL also has a demonstrable financial effect, it may be expected that legislation and cost payers will strive to implement them for all disciplines. This implies that medical therapeutic freedom is jeopardised.

Specific medical information for laypeople should be consistent with existing medical guidelines and provide people seeking advice with support when making decisions during all phases of medical care (diagnostic testing, therapy, follow-up). The information should provide valid data based on evidence-based medicine. In this context, patient information brochures are successful instruments for the implementation of guidelines.

4.1.1.8. Guidelines in rhinoplasty

The guideline that is relevant for rhinoplasty (AWMF registry n° 017/070) was written in June 2000 and revised in January 2016. It corresponds to the standard of S2k and will be revised again in January 2021. It was developed as a consensus paper under the authority of the DGHNOKHC by 11 physicians from the disciplines of otorhinolaryngology, plastic surgery, and maxillofacial surgery. Thus it meets the DELBI criteria in terms of the representation of the user circle (ENT, plastic surgery, maxillofacial surgery); moreover, it is structured and consensus based (S2k), and is being continuously developed (revision in 2021).

In the description of the objectives of the guideline, *it is stated that the aim of the guideline was to promote high quality specialist treatment of patients with malformation of the inner and outer nose associated with functional or relevant cosmetic impairment. It is intended to help to reduce associated, disease-related morbidity, to support the rational application of diagnostic and therapeutic procedures and to curb disease-related socio-economic factors. The objectives are to achieve reasonable and appropriate diagnostic testing and therapy based on the current state of scientific knowledge*.

This description of the objectives is essential because this also defines the minimum quality requirement from a medical perspective that is relevant for correction of the inner and outer nose or the functional and cosmetic elements. In the proper sense of the word, they are intended to "guide" the treating physician to develop the best concept for treating the patients. The S2k guideline on rhinosurgery has high legitimation with respect to implementation, due to the representative expert group and the structured consensus finding. On the other hand, its scientific legitimation is weaker, as no evidence is confirmed. In cases of S2e, the situation is inverted (▶ **Fig. 2**). In the long run, what we need is a higher level of classification, so that aesthetic plastic rhinosurgery can be established as S3, similarly to laryngeal cancer. However, this may also mean that "fond habits" can no longer withstand scientific analysis and have to be given up. This challenge has to be accepted by all ENT surgeons, in particular with regard to the changes in surgical techniques over the last 50 years (see part 2), which have significantly improved patient care. This should awake the interest of all physicians, as it reflects the benefits of medical progress – without which patients would still be treated as they were 50 years ago.

The well-informed patient also refers to guidelines and sometimes confronts the physician with the question as to whether the procedure corresponds to the guidelines. They are an integral part of the daily routine of rhinosurgeons and should be well-known. From an cosmetic point of view, they play a significant role that is explicitly requested by the patients. However, it should also be remembered that the quality of life is only mentioned in the section of the olfactory function in the rhinosurgical guideline and not in other areas (breathing, cosmetics etc.) of nasal function. Perhaps this aspect should be included in the revised version of 2021.

4.1.1.9. Quality and patient safety

All patient safety is aimed at preventing undesired events. The safety culture in each institution is then decisive. This safety culture can be established by specific measures and the commitment of individuals. There is an interaction between the safety culture and measures for improvement in patient safety. Safety culture in medicine means that an organisation (e. g. the doctor's office) permanently works on all levels so that patients do not experience any (avoidable) undesired event related to healthcare.

4.1.1.10. CIRS medical

CIRS medical is the reporting and learning system of German physicians for critical events in medicine. "CIRS" stands for Critical Incident Reporting System. It is anonymous, safe, and allows helps the user to learn from mistakes, errors and critical events. It is available to staff members in healthcare services. All safety-relevant events occurring in medicine may be reported by staff members of the healthcare services. These may be mistakes, near-accidents, critical events, or even undesired events. As examples, the "Manchester Patient Safety Framework" and the "Safety Attitudes Questionnaire" may be mentioned.

The reports must not contain data that allow the user to draw conclusions regarding the people or institutions involved (name, location etc.) [42, 43]. The author does not know of any such focused questionnaires in otolaryngology or plastic surgery.

For cosmetic rhinosurgery, one approach would be to anonymously collect undesired or critical events related to surgery and follow-up, and then to evaluate and discuss these. Specific conclusions could then be incorporated in order to draw specific conclusions that may enter in the guideline. This information should definitely be available to every specialist in this area of work.

4.1.2. From the patients' point of view

For patients, the last paragraphs of the last chapter are equally important. Quality management/quality assurance, questionnaires, and also reporting "critical" events are rated favourably, as patients know that medicine is a highly sensitive area where errors and mistakes happen. Therefore it is important to know how they are coped with – in the patients' interest.

4.1.2.1. Patient surveys in quality management

Surveys are an important instrument to collect feedback about the patients' satisfaction and to receive ideas for improvements. If possible, they should be conducted regularly with validated questionnaires.

The German questionnaire relating to satisfaction in outpatient care/quality from the patients' perspective ("Zufriedenheit in der ambulanten Versorgung – Qualität aus der Patientenperspektive";

ZAP) has been developed for anonymous written surveys of adult patients. By means of this questionnaire, patients who undergo specialist or general treatment and know the doctor's office, e. g. who had at least two treatment contacts, can rate the practice in the following areas: organisation, information, interaction, competence, participation in decision processes, confidence, treatment quality, and general satisfaction with the physician. It becomes obvious here how the so-called "hard" and "soft" factors described in Chapter 3.1.2. appear again and how they have been included by the G-BA.

4.1.2.2.Patient complaints as instrument of quality management

Complaints are not automatically a breach of confidence between the physician and the patient. Moreover, complaints can provide a significant source of information to improve the quality of treatment. Complaints expressed by patients are relevant feedbacks to all parties involved in medical treatment. Therefore, complaints have to be heard, evaluated, and answered. In addition, in cases of complaints or proposals, the treating physician has to be the contact person for the patient.

Individual patient complaints mainly require that the needs, anxieties, worries, annoyances etc. identified by the patients are registered and that someone tries to support them individually.

If the main issue is to find out the patients' opinion in support of treatment quality management possible options include: assessment of experiences and satisfaction collected by means of feedback (e. g. suggestion box) or standardised feedback based on systematic patient surveys. The patient rating depends on different dimensions, such as expectations and needs, ideas and assumptions about the treatment result, individual attitudes, social background, education, real experiences in a situation, and the health-related results; it is therefore reasonable to assess these parameters.

In rhinosurgery, these issues must not only be addressed in conversations and discussions prior to surgery, but explicitly in the follow-up. The patients' expectations and needs and ideas and assumptions are particularly important – as these are often diametrically opposed to the physician's perception. Even if the surgeon has clearly explained the limitations of a treatment and of a result or if the initial findings only allow limited options, these can collide with the expectations, wishes, assumptions, and imagination of the patients in the postoperative setting. Key factors include social background, circumstances, and education (see Chapter 12) [44].

For these reasons, it is essential to clearly formulate the questions and to take into consideration numerous other aspects (summarised in the literature) about the development of survey instruments. It is recommended to use already existing validated questionnaires that may be adapted to the needs and objectives of the respective treatment under qualified supervision [45].

4.1.3. From the point of view of the cost payer

Because of the increasing pressure on costs, and the patients' increasing demands for more information, there have been increased demands for more transparent health information (e. g. internet). To meet this need, different institutes have been established since 2000 that aim to determine and assure quality. In this context, we will discuss two institutions that directly or indirectly influence medical care and treatment.

4.1.3.1. Institute for Quality and Economy in Healthcare Services (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG))

Quality and economy – from the perspective of the cost payer, these are two decisive factors for a good and effective healthcare system (see above). In order to achieve this goal, it is important to objectively check the advantages and disadvantages of medical services for the patients. The IQWiG has the official mandate to evaluate the advantages and disadvantages of medical procedures, for example to compare different medications or surgical procedures. The IQWiG does not conduct its own clinical studies with patients. Moreover, the Institute systematically looks for those trials where the respective comparisons are described and that provide sufficient evidence-based and reliable results. On the basis of this systematic research, a summarising report is developed for the authorities. The institute publishes all results on its websites and addresses experts of the healthcare sector as well as the public. The mandates may only be assigned to the IQWiG by the G-BA or the Federal Ministry of Health. The results are published as reports, dossier evaluations or potential evaluations. The institute may also work independently on questions of general importance. Thus, the IQWiG creates reports about the benefit or additional benefit of medical measures from a medical and a cost-related perspective and may issue recommendations. The IQWiG, however, does not make decide whether the costs of a service have to be paid by health insurances. Only the G-BA is allowed to make these decisions.

4.1.3.2. Institute for Quality Assurance and Transparency in Healthcare Services (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen; IQTiG)

In 2014, the IQTiG was founded by the G-BA - in the context of the act about the development of financial structures and quality in statutory health insurance (Gesetz zur Weiterentwicklung der Finanzstruktur und der Qualität in der gesetzlichen Krankenversicherung; GKV-FQWG) - as an independent scientific institute for quality assurance and transparency in healthcare services based on § 137a SGB V. In accordance with the law on hospital structure (Krankenhausstrukturgesetz) and on behalf of the G-BA, it develops concepts for planning-relevant quality indicators, such as surcharges and deductions in quality-oriented remuneration, and evaluates quality contracts according to § 110a SGB V. Beside the development of quality assurance instruments, it is also guaranteed that current quality assurance procedures will be continued and developed. The development and implementation of procedures, the external quality assurance of the treatment, the setting of criteria for the assessment of certificates and quality labels as well as the publication of results are intended to ensure that quality is comparable in different hospitals. In 2019, the IQTiG conducted a total of 24 quality assurance procedures in the fields of visceral and vascular surgery, cardiology and cardiosurgery, transplantation medicine, hygiene and infection management, gynaecology, perinatal medicine, orthopaedics, trauma surgery and nursing care.

The quality assurance procedures compare and evaluate quality-related aspects in the fields of complications or undesired

events, revision interventions due to complications, and the survival of the patients. The principle aim of these procedures is to improve the procedures for these interventions, in order to enhance patient safety, reduce complication rates during and after the interventions, together with diseases caused by the intervention. In this way, costs can be reduced.

4.1.3.3. Quality and costs – the example of septorhinoplasty

The cost payers analyse single surgical methods based on quality-adjusted life years (QALY). By assessing the patient's subjective estimation before and after surgery by means of so-called PROMs (see Part 2 Chapter 12), an improvement or deterioration in the quality of life is estimated. A cost-benefit analysis is then derived. This consists of the quotient of the costs divided by the gain in the calculated quality of life. Analysis in the field of septorhinoplasty show a mean QALY gain of 0.04 points [46]. The significantly higher published values of 0.08 always referred to combined surgery of the nose including the paranasal sinuses [47]. In this way, the QALY in the area of rhinosurgery is very good in comparison to other interventions such as otology with 0.01 [48] or cochlear implantation with 0.035 [49]. Apart from the discipline of otorhinolaryngology, higher scores are only found in the fields of cardiac catheters and total hip replacement (0.1) [50].

For a state-wide base rate of € 3539,12 in 2019 for Baden-Württemberg and a valuation ratio of 1.139 for complex septorhinoplasties, revenue of up to 4031,6 EURO is earned. Taken in relation to the QALY gain of 0.04, the ICUR (incremental cost utility ratio) is calculated as about € 100,000 per gained QALY. This high ICUR is not due to the expensive therapy, but rather to the low QALY gain. Cost payers will increasingly include these calculations to help them to decide whether an intervention is economically justified or not. Similar developments are already seen in Great Britain, where specific interventions are no longer paid by the health insurances from a specific age (e. g. hip replacement) or the decisions are made individually in particular cases (e. g. septorhinoplasty) [51]. By implication, this means that from the cost payer's point of view the costs of the intervention have to be lower (lower DRG) or that the gained QALY would have to clearly increase with unchanged costs. One must always bear in mind that the QALY is the subjective perception of the patient and does not reflect the objective result. Thus, the medical quality only plays an indirect role because significant demographic features have an impact on the patients' perspective and these are distinct from the treatment and may influence the pre- and postoperative analysis (see Chapter 12) [44].

5 Evidence-based Medicine

5.1 Definition and background

The idea of evidence-based medicine originated in the second half of the 18th century when British physicians developed the concept of "medical arithmetic" [52]. For the first time, term was first used in an article entitled "An attempt to improve the Evidence of Medicine" published in 1793 by the Scottish physician George Fordyce [53]. In Great Britain, one of the first controlled clinical trials was conducted by James Lind who published the results of his attempt to treat scurvy in seamen with oranges and lemons as early as 1747.

In German-speaking countries, the Hungarian physician Ignaz Semmelweis (1818–1865), who was working in Vienna, was first author of the introduction of "systematic clinical observation" in medical research (1848).

In 1972, Professor Archie Cochrane, a British epidemiologist, published the book entitled "Effectiveness and Efficiency: Random Reflections on Health Services", which marks the beginning of current international efforts around "evidence-based medicine". His further publications led to increasing acceptance of clinical epidemiology and controlled trials. An international network on efficiency assessment in medicine was named in his honour – the Cochrane Collaboration [54]. Despite its historical roots, evidence-based medicine is a rapidly developing young discipline and its positive effects are currently proven. This evolution is in full swing and will achieve completely new dimensions, especially under the aspect of digitalisation and the worldwide collection and access of data, under the terms of "evidence-based" and "precision medicine" [55].

David Sackett is a pioneer of clinical epidemiology and scientifically substantiated healthcare. He defined "evidence-based medicine" (EbM), as practiced since the 1990s, in these words:

"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research"[56].

Individual clinical expertise means the skills and the discernment that physicians acquire by experience and clinical practice. A gain in expertise is reflected in many different ways, in particular, however, in making accurate diagnoses and in thoughtfully and empathically identifying and considering the particular situation, the rights, and preferences of patients in the context of clinical decision making during their treatment (see Chapter 3.1.2).

"Best available external evidence" describes the clinically relevant research - often basic medical research, but in particular patient-oriented research - on the accuracy of diagnostic procedures (including physical examination), on the relevance of prognostic factors, and on the effectiveness and safety of therapeutic, rehabilitative, and preventive measures. External clinical evidence leads to the re-assessment of formerly accepted diagnostic tests and therapeutic procedures and replaces them with those that are more effective, more accurate, and safer.

External clinical evidence may complement individual clinical experience but it will never replace it and vice-versa. It is especially this individual expertise that decides if external evidence can be applied in an individual patient and – if yes – how it can be integrated in the decision. In the same way, each guideline and each procedure has to be verified in terms of how and if it improves the clinical condition of the patients.

EbM is definitely no cookbook medicine. EbM requires a so-called "bottom-up approach" that combines best available external evidence with individual clinical expertise and the preferences of the patients. This means that the basic idea always consists in first solving circumscribed, detailed partial problems and, on this basis, then solving larger, higher ranking problems etc. The single partial solutions are combined "bottom-up" until the entire problem is solved. In conclusion, the concept of EbM is not compatible with strict adherence to a cookbook recipe for patient treatment.

But there are also critical voices expressing the fear that cost payers and politician make use of EbM to reduce expenses in healthcare (see above). This would not only be an abuse of the concept, but also a fundamental misunderstanding of the financial consequences. Physician who practice EbM will identify and apply the most effective procedures in order to maximise the quality and duration of life of their patients. This may tend to lead to an increase in costs instead of reducing them.

EbM is supported by the three pillars of individual clinical experience, values and desires of the patients, and the current state of clinical research.

The procedure in EbM is subdivided into five steps:

1. Translation of the clinical problem into a *question* that may be answered by scientific investigation.
2. Systematic *research of the literature* for adequate trials
3. Critical *evaluation of the evidence* over all identified trials
4. *Application* of the acquired knowledge in respect to the specific clinical situation
5. Self-critical *evaluation* and adaptation, if needed, of the current procedures

This five-step procedure requires training and it is not always feasible within the daily routine of patient care. The important element of EbM is the systematic, prompt, and unbiased consideration of study results (see above).

5.2 Levels of evidence

Evidence-based medicine should be understood as support for different therapeutic questions that allows sufficient room for the implementation of the physicians own clinical experiences. EbM is not only limited to randomised, controlled trials and meta-analyses. It also consists of the research for the best scientific evidence to answer the clinical question.

In order to learn more about the accuracy of a diagnostic procedure, well-conducted cross-sectional trials of patients are required who are clinically suspected to suffer from a certain disease – and no controlled trials.

For prognostic questions, methodically accurate follow-up studies of patients are needed who have been enrolled in the study in a uniform, early stage of their disease. The necessary evidence is sometimes found in basic disciplines such as genetics or immunology.

The study of therapeutic methods should avoid non-experimental approaches because they often lead to false-positive conclusions as regards the efficacy of treatments. Since randomised, controlled clinical trials and especially systematic reviews of these studies most probably provide correct data and false conclusions are less frequent, these are now the “gold standard” for answering the question of whether therapeutic measures do more good than harm. However, for some questions, no controlled trials are necessary (e. g. successful interventions compared to otherwise fatal situations) or when there is no time for clinical trials. If no controlled trial was conducted for the particular situation of the patients, the next best external evidence has to be found and taken into account.

According to the recommendations of the AHRQ (Agency for Healthcare Research and Quality), the levels of evidence of I to V are differentiated as well as grades that reflect the clinical perspective. Trials categorised as Ia have the highest level of evidence, trials classified V the lowest. The higher the level of evidence is, the better is the scientific justification for the resulting therapy recommendation (grading).

- **Level Ia**: at least one meta-analysis based on methodically high-quality RCTs
- **Level Ib**: at least one large, methodically high-quality RCT
- **Level IIa**: at least one high quality trial without randomisation
- **Level IIb**: at least one high quality trial of any other type (e. g. experimental trial)
- **Level III**: more than one methodologically high quality non-experimental trial such as comparative studies, correlation studies, or case control studies
- **Level IV**: opinions and convictions of reputed authorities (from clinical experience), expert commissions, descriptive studies
- **Level V**: case series or one or more expert opinions

Weighting and recommendation of levels of evidence with grading (modified according to AHCPR 1992, SIGN 1996).

Grade	Level of evidence
A	Ia or Ib, of first rate clinical importance
B	IIa, IIb, III, of second rate clinical importance
C	IV, of third rate clinical importance
D	V, of fourth rate clinical importance

5.3 Evidence-based medicine and rhinoplasty

As already described in the previous chapters, there have been few high quality controlled, randomised studies, even in the context of septal surgery. Only isolated publications are available on single procedures in rhinosurgery [57]. Multiple meta-analyses about different areas of rhinoplasty have been published (see part 2) that are based on single trials or results of single surgeons without randomisation or control. As in all surgical disciplines, it should be our motivation in rhinoplasty to face this challenge. Firstly, this would have to be organised at a national level and the results compared. This could then be followed by an international exchange. We may face this task with optimism, as there have been extremely positive developments in cosmetic and functional rhinosurgery in recent years, to the benefit of our patients and including the new S2k guideline. Furthermore, it should be mentioned that EbM has already been applied since the mid1990s in internal medicine, surgery, psychiatrics, and general medicine [58–60]. In this context, it must be recalled how - for example - the therapy of laryngeal cancer has completely changed during the last 20 years on the basis of evidence-based data [61].

6 Conclusion – Part 1

From the perspective of all three protagonists (physicians, patients, cost payers), the quality in healthcare must be transparent, permanent, scientifically proven, and cost-effective. To some extent, the focus is on very different areas. Physicians want to have the best care for their patients that is possible with their skills and knowledge. Patients want to have the best quality with least side effects, most pleasant outcome, and manageable costs – at least as self-payers. Cost payers want to have a quality that does not exceed the cost frame and that is compatible with efficiency and savings. This is a balancing act that can hardly be performed without underre-

presenting the one or other party. In order to find an agreement and to justify this with solid data, evidence-based data should also be developed for cosmetic rhinosurgery. However, this should be performed independently from financial influence, old habits, or unrealistic expectations and only pure data and facts should be presented and interpreted.

7. Part 2 – Quality of Surgical Methods in Rhinoplasty

The second part of this manuscript deals with transferring these results to the field of rhinosurgical interventions. Beside normal medical ethics, emotional and soft criteria play a major role in the patients' perception of changes in external appearance and shape.

Cosmetic rhinosurgery seems to develop in discrete eras, which are mostly initiated by pioneering publications describing new surgical techniques. A turning point in the last 40 years was the work entitled "Aesthetic Rhinoplasty" published by Sheen in 1978 [62]. Sheen heralded the first important paradigm shift since the publication of Jacques Joseph's book in 1931 [63], and helped to establish rhinoplasty as genuine cosmetic surgery with preoperative analysis, surgical planning, and performance. Joseph's reduction concept was replaced by balanced surgery combining resection and transplants; and the occasionally unattractive results that led to revisions could be significantly improved. Rhinosurgeons were no longer rated by the speed of surgery but by the cosmetic outcomes.

Until now, the classical disciplines such as physiology and anatomy have surprised us with new insights, despite the common idea that "everything has already been verified and examined" so that these new insights continuously improve our understanding of the shape and function of the nose and thus modify and refine surgical approaches. In general, the procedure for rhinosurgery has developed enormously and become more precise in recent decades. Important progress could be made by acknowledging the relationship between anatomy, nasal cosmetics, and surgical techniques. As an example, the nasal tip with its ligaments and the osteocartilaginous nasal dome have received new attention.

While open suture techniques for the nasal tip excited lively interest, Cakir succeeded in demonstrating that similar results could be achieved via a closed approach with better control and lower morbidity [64]. The aim was to preserve the nasal ligaments and to only minimally resect the cartilages. This was possible by a subperichondral access with less important postoperative swelling and reduced numbness, as well as less scarring - which would facilitate possible revision also for the future.

Other turning points in the philosophy of nasal tip surgery were the publications by Ozmen [65] and Gruber [66] who advocated sliding or the preservation of the alar cartilages, as until that time it had been common practice to generally resect the cephalic part. Based on these innovations, the so-called "alar notching" was less visible after surgery and "alar rim grafts" were more rarely applied. Another example is the problem of "alar malposition", that was considered as one of the most difficult deformities and had to be treated with "alar transpositioning" and "lateral crural strut grafts". Davis showed convincingly that "medial tensioning" was sufficient to meet the requirements without performing transposition or alar resection or using additional grafts [67].

Anatomical studies on the osteo-cartilaginous dome showed that the bony hump was only a small bony cap that could be removed, with preservation of the underlying cartilaginous dome [68]. The keystone area that was always in the focus turned out to be a type of semimobile cartilaginous joint that may be changed from being convex to straight by resecting the cartilaginous septal support [69].

In the focus of surgical quality, four areas will be illustrated that have been openly discussed at meetings and symposia for many years and that may be considered as relevant to quality.

- Open vs. closed access
- Costal vs. auricular cartilage
- Piezo vs. traditional osteotomy
- Preservation rhinoplasty vs. non-preservation

8. Open vs. Closed Access

Looking back in history, it is seen that even before World War II, open and closed accesses were practiced. By the end of the 19th century, open operations were performed, as a closed approach was impossible with the available lighting and instruments. Only after the technical development of surgical lights and headlamps after World War II, were closed techniques increasingly established because no scars were then visible, so that surgeons considered this approach to be more elegant. Nearly all rhinosurgeons who learned functional and cosmetic rhinoplasty in Europe from the 1960s employed a closed access. The introduction of endoscopic surgery further fostered the closed technique.

After World War II, the open technique was increasingly disregarded in Europe, but further developed step by step in the USA. After the closed access had reached its climax in popularity, another change in direction was triggered by articles published by Goodman at the beginning of the 1970s [70]. His results also convinced other rhinosurgeons in the USA, so that this technique was rapidly distributed in the literature [71–73].

In the 1990s, the open techniques - that had already been developed and established in Germany by Diefenbach and Joseph - returned to Europe and started their triumphant progress in the field of cosmetic rhinoplasty.

This surgical revolution was supported by three pillars:

1. Open access allowed better visualisation for analysis, surgical techniques, and teaching.
2. New surgical techniques such as nasal tip sutures, reconstruction of the inner vault or the septum were developed that were impossible or at least very difficult with a closed approach.
3. The open access reduced the learning curve for beginners, so that rhinoplasty became one of the most frequently performed cosmetic surgeries.

However, even in 1992, Aiach wrote that open surgery is only an option for revisions, difficult cases, or nasal tip surgery and should never become a standard procedure [74]. This view is now completely outdated since more than 70 % of all rhinoplasties are performed with an open access. Of course, some people considered that the open technique was a surgical setback to the 19th century and that it had to be considered as surgical cardinal sin [75]. But these voices have rapidly fallen silent for the above reasons.

A scientific quality analysis was not performed at that time for the two accesses - as would be required today - because the tech-

niques were presented at congresses, advocated by experienced surgeons of their time, and established in the hospitals in the context of medical teaching and education.

Quality was discussed - especially with respect to the scar at the columella, and whether the outer appearance was better or poorer with the one or other technique [76]. A discussion with regard to the quality of patient comfort, breathing, function, smelling, quality of life etc. took place only much later. Finally there was a consensus only in the perception that revisions, trauma noses or cleft nose deformities could be better analysed and operated through the open technique (see above).

8.1 Quality of the external or cosmetic outcome

During the "renaissance" of the open access, Friedman and Gruber postulated in 1988 that the long term results were better and longer lasting. Due to the open exposure of the anatomy, precision, accuracy, and the predictability of the outcome were superior to the closed approach. In their analysis, the focus was primarily placed on the nasal skeleton and the nasal tip. Even Gruber in his time considered that the aspect of the scar at the columella was no longer a problem, because optimised suture techniques led to significant improvement in the postoperative situation [77].

In 2017, Yagmur, Demir et al showed in 91 patients that the columella scar does not have a significant influence on the patients' satisfaction with regard to rhinoplasty in particular and physical perception in general [78].

Nonetheless, the learning curve and thus the existing risks and side effects of both techniques must not be neglected. In the context of a closed as well as an open access, there is the risk of an overresected nasal bridge or nasal tip, as well as the occurrence of a narrow inner nasal valve. In addition, further risks of a narrow or unstable outer nasal valve, open access may lead to an unstable nasal tip or a short nose. Furthermore, it must be mentioned that the number of patients with multiple rhinosurgeries with open access is significantly higher than with the closed technique [79].

When open rhinosurgery was being re-established, and beginners in rhinosurgery learned the open access without reluctance, they often had little experience in preparing the tissue in the area of the nasal tip. This led to previously unknown traumata and circulatory disorders, which initially reduced the quality of the open access. The advantage of the open exposition of the nasal tip and the nasal bridge was at the same time associated with severe disadvantages. Anatomical structures came to the fore that had been forgotten by the surgeons because the closed approach did not primarily touch these structures. Despite their influence on the function and cosmetics, the nasal ligaments have been overlooked for a long time [80].

As an example, the "Pitanguy ligament" had been described by Pitanguy in 1965, who emphasised its role in the context of the thick postoperative nasal tip [81]. Furthermore, the vertical Scroll ligament is known to stabilise the internal nasal valve by means of the transversal nasal muscle and supports the function of the nasal dome [68].

In addition, in 1996 Toriumi described the course of veins, arteries, and lymphatic vessels of the nose in a very interesting publication combining clinical evaluation, anatomical dissection, and histological examination [82]. Arteries, veins, and lymphatic vessels run in or over the muscular aponeurotic tissue layer of the nose. Thus, the risk of severe swelling of the nasal tip or even skin necrosis in this area was significantly reduced by strict preparation below the muscular aponeurotic layer, which led to improved quality.

8.2 Quality of the functional and endonasal outcome

As regards the function and the cartilaginous and bony architecture, the outcome depends on the severity of the deformity. Simple deviations, spurs etc. can be corrected without any problem via a closed modern septorhinoplasty; open access would mean clear overtreatment. More severe deformities of the inner nose may require extracorporeal reconstruction or restoration of the cartilaginous or bony nasal skeleton, and then the closed technique reaches its limits - so that open access is generally accepted as standard procedure. However, in 2016, Berghaus reported that there is still enough space for a closed access even in modern rhinoplasty and that this provides additional advantages [83]. In particular, in the context of the reconstruction of the septum, the inner and outer nasal valve, the anterior support, and the nasal tip, open access is superior to the closed approach, also due to the extensive use of cartilage transplants (grafts).

We know of no studies that compare the quality of the mere functional results. However, the superiority of the open access in reconstruction and revision surgery has been demonstrated and is generally acknowledged (see above).

8.3 Quality of the subjective perception of the patients

Interestingly, despite scientific discussions over many years that even extend to today, there have been no significant changes in the subjective perception of the patients. Various scores and questionnaires (NOSE, ROE, DAS-24) do not show significant differences. A recent article from 2019 published by Gökce Kütük and Ok with more than 90 patients showed that the psychosocial stress level of patients after successful rhinoplasty was significantly reduced [84]. This value, however, was completely independent of the type of access (open vs. closed), the indication (cosmetic vs. functional), or the type of intervention (primary vs. revision). Together with other prospective follow-up trials in this context, this makes it clear that the approach is not decisive but the outcome is - especially in the perception of the patients [85]. The repeated significance of the quality of the outcome vs. the quality of the procedure becomes very obvious.

9. Costal vs. Auricular Cartilage Transplant

One important pillar of traditional rhinoplasty was dorsal resection with destruction of the keystone area, followed by immediate reconstruction by means of osteotomies and dome reconstruction. Despite all surgical improvements in the context of cosmetics and nasal function, smaller revisions or even larger second or third interventions cannot be totally avoided, even now. Apart from trauma history, there are revisions where costal or auricular cartilage is used in the reconstruction of the nasal bridge or the nasal tip. The technique of preserving the area of the nasal bridge could probably reduce the number of nasal bridge revisions and minimise the necessity of dome reconstruction (see Chapter 11) [86].

Although numerous improvements have been achieved, we may still repeat Rollin Daniel's question: "Why are we doing an operation that can produce such a destructive result that a rib graft reconstruction becomes necessary following a primary case performed by an experienced surgeon?" [87]

Cartilage grafts may be taken (for example) from the rib, followed by primary reconstruction of the base and subsequent reconstruction of the secondary structures is an accepted procedure. Structures that resist contraction forces in the long term play a major role [88].

In order to allow a more detailed assessment, rib grafts and auricular grafts have to be analysed separately. Rib grafts may then be subdivided into autologous and irradiated homologous cartilage. Furthermore, the surgical development has to be taken into account, as well as the dicing type, either with (diced cartilage in fascia, DCF) or without fascia (free diced cartilage, FDC). Since a complete description of the cartilage grafts for the entire nasal architecture would go far beyond the scope of this manuscript, the focus has been placed on the nasal bridge.

9.1 Quality of the external and/or cosmetic outcomes

9.1.1 Autologous cartilage chips (ACC)

The harvest of the autologous rib cartilage is one of the oldest procedures to reconstruct the nasal bridge. The first publications on this subject appeared at the end of the 1960s [89] and in the mid1970s [90]. Meanwhile, this technique has been established and refined. With rib cartilage for augmentation of the nasal dorsum, results from very long observational periods are now available that give a good overview of the external results. A meta-analysis encompassing 10 studies with nearly 500 patients and a mean follow-up period of nearly three years showed that the complaints related to deviation, hypertrophic scars, and revision [91]. This aspect is worth being mentioned because these three aspects are perceived both by patients and their environment. The deviation (3.1 %) of the chips is often disappointing for the patients. The hypertrophic scar (5.5 %) at the corpus is a stigma and a cosmetically limiting sequela of the lifting intervention, especially for females. Other complications - such as resorption, infection, shifting of the rib chip etc. - only play a minor role and amounted to less than 0.6 %. A revision rate of 14 %, one in seven 7 (!), must raise the question as to whether there was no other option. This aspect will be discussed later in the manuscript.

9.1.2 Irradiated homologous cartilage chip (IHCC)

The first article published on IHCC appeared in 1961. Dingham et al. illustrated the possibility of conserving homologous costal cartilage chips by means of irradiation [92].

In 1993, Kridel reported excellent results with irradiated homologous cartilage chips in more than 120 augmentations of the nasal dorsum [93]. Kridel published additional results in 2009 [94] and 2017 [95] that confirmed that the sum of side effects in 943 patients was only 3.25 %. The percentage of resorption was 1.01 % and of deviations 1.06 %. Kridel's overall conclusion was positive, as the rates of side effects were very low, there were no lifting comorbidities and IHCC is less expensive than ACC.

A large retrospective comparative study including histological examinations of ACC and IHCC, was also published in 2017 [96] and investigated 83 patients in follow-up. Costal chips were applied measuring 30–40 mm in length, 4–6 mm in thickness, and 8 to 10 mm in width. A 10-fold higher resorption rate (30 %) was observed in cases of IHCC. This was of course also reflected in the optical outcome, which was significantly inferior to ACC. In contrast to Kridel's publications, these numbers are consistent with the general literature that reported resorption rates between 1.4 % and 75 % for IHCC, depending on the follow-up period. The differences in deviation or infection were not statistically significant. No objective differences were observed in the functional outcome.

9.1.3 Quality of the subjective perception of the patients regarding ACC and IHCC

The above mentioned results are reflected in the quality of the treatment as subjectively perceived by the patients. In Kridel's publication of 2009 [94], the high subjective rating improved for the internal and external outcome from 91.3 % to 94.2 % in the mean follow-up period of 7.8 years.

In a study published by Wee et al. more than 75 % of patients in both groups reported that they were "satisfied" or "very satisfied" by the postoperative outcome [96]. However, due to the high resorption rate of IHCC, the intergroup score was significantly lower in cosmetics. There was no significant difference between the groups with respect to function. In this respect, satisfaction amounted to 95 %, as in Kridel's cohort. Once again, this confirms that patient satisfaction depends primarily on the outcome and not on the method itself.

9.1.4 Diced cartilage in fascia (DCF)

After 10 years of experience, Erol published the method of diced cartilage for the nose as so-called "Turkish delight" [97]. He wrapped the cartilage in Surgicel® and not in fascia. In their publication of 2004, Daniel and Calvert also reported clinical difficulties and explained this by a foreign body reaction on Surgicel® - that had been used until then [98]. After 2006, fascia was used, as Calvert could prove histologically that diced cartilage in fascia was superior to Surgicel®[99]. More recent publications experiment with cellulose instead of fascia, however, the application in humans still needs to be approved [100].

In the long-term observation after 25 years, Erol came to the conclusion that the method was optimal with Surgicel®, as there were no side effects – even though the method with fascia had by then been widely used [101]. In a further development, Tasman replaced the fascia with fibrin glue and blood components, in order to stabilise the dices. He achieved satisfying outcomes in more than 100 patients [102]. For all further developments of the classic costal cartilage chip, it must be said that patients perceive the application of diced cartilage – independent of the type of wrapping – as being more comfortable than rigid chips. This is due to the lesser rigidity and deviation [103].

9.1.5 Free diced cartilage (FDC)

Gubisch et al. have further developed the procedure by using "free diced cartilage" (FDC, 2017) [104]. To enhance both augmentation and camouflage, they compared the application of FDC either

without any wrapping including fibrin or with fascia or as classic DCF. The revision rate in the DCF group was five times as high as in the FDC group. This may certainly also be due to the fact that FDC has to be diced in smaller and thinner parts than DCF - nearly like powdered sugar. FDC is a good option - in particular for covering irregularities and for the final touch up. Because of its recent introduction, patient ratings are not yet available.

9.1.6 Auricular or concha cartilage

As early as 1984, Münker suggested that the use of auricular cartilage as double or triple sandwich may be an alternative to costal chips for the augmentation of the nasal bridge [105].

However, problems occurred from cartilage luxation, with unfavourable external outcomes. Furthermore, due to the reduced donor quantity, the augmentation of the nasal dorsum was limited. Therefore, for auricular cartilage too the way was paved for diced cartilage, as it had been proved in animal experiments that preservation of the perichondrium led to better vascularisation and stabilisation of the transplant [106]. In addition, with auricular cartilage, a harvesting morbidity is observed that is mainly characterised by keloids or hematoma. According to recent studies, this amounts to about 2.4 % [107]. In animal experiments, there was no difference in quality with the type of cartilage (rib vs. ear) or origin of the fascia (autogenic vs. allogeneic). Minor differences were only observed in ossification and calcification, but had no impact on the outcome [108].

9.1.7 Quality of subjective perception of the patients with costal and auricular cartilage

Since the implementation of the "diced cartilage" technique, regardless of the type, patient satisfaction and quality perception have significantly improved, because deviation is now improbable. Moreover, the rigidity is no longer rated as disturbing by the patients because the other forms are clearly softer in terms of their haptics [103]. As regards the harvesting morbidity, this certainly depends on the surgeon's experience. Most recent investigations show that patients do not perceive any difference between auricular or costal cartilage [109] and this is reflected in the outcome quality.

10. Ultrasound-based vs. Conventional Osteotomy

In the course of recent decades, conventional osteotomy has been modified, especially by switching from the closed to the open access. This technique was originally performed endonasally with the Walter osteotome; external, lateral, transversal, and paramedian osteotomy were then introduced, as first described by Goria in 1955 and published by Straatsma in 1961 [110, 111].

Its clinical superiority with respect to swelling, bleeding, and mucosal damage were demonstrated in several trials with continuous or perforating fracture line – in the sense of a greenstick fracture – also in cadaver interventions [112, 113]. Generally, these studies were focused on describing the handling and short-term results but not the middle- and long-term improvement of the patients' postoperative quality of life.

Technical progress led to the implementation of other methods. In other disciplines, such as dentistry, osteotomy with ultrasound was established long before being used in rhinosurgery. Robiony et al. first described the application of piezo surgery in rhinosurgery in 2007 [114]. They now enjoy the longest experience worldwide, but only in percutaneous use. Their 10-year follow-up, which was published in 2019, describes piezo osteotomy with no or mild swelling in more than 90 % of 183 patients. The further development goes in the direction of piezo-navigated access, but has not been established yet [115]. In contrast, Gerbault, Daniel et al. perform ultrasound osteotomy via an enlarged open access with widely prepared soft tissue mantle [116]. In his retrospective study published in 2019, Berghaus came to the conclusion that the piezo technique in rhinoplasty is a safe and precise procedure for bone modelling and osteotomy [117].

In an animal model, Kurt Yazar et al. showed that - in contrast to percutaneous or endonasal osteotomy - piezo techniques leads to fewer mucosal lesions and undesired fracture lines [118]. This corresponds to the reported experiences of regular users of this osteotomy technique. Long-term results are currently not available for all conducted trials. At least currently published data do not show any apparent disadvantage of this technique, even if significant advantages could not be shown either. With regard to the patients' quality of life, there have been no investigations that would allow a comparison.

10.1 Quality of external and/or cosmetic results

In 2017, Kocak et al. reported a prospective trial of 49 patients. They found that swelling on the first two postoperative days was significantly lower than with conventional osteotomy [119]. However, this significance rapidly disappeared until the seventh postoperative day at the latest. Since the reduced swelling is only described for the first 48 hours in both piezo methods (open vs. percutaneous), this effect cannot be due to the extent of soft tissue preparation. In cases of ecchymosis, piezo surgery is significantly superior to conventional osteotomy in the complete follow-up interval. This could also be confirmed in a systematic literature analysis performed by Währmann et al. in 2019 [120]. However, it remains unclear if the relatively minor pains that were described were really alleviated or if this was only a consequence of the patients' impression of decreased ecchymosis. The authors correctly describe these results as a trend, as they have not been verified statistically and long-term results are completely missing in all areas.

10.2 Quality of the functional and/or endonasal results

Even after 10 years of follow-up, scientific papers on the functional and/or endonasal results are not available. However, this would be desirable, in particular with regard to the described minor mucosal lesions. No studies have been performed to compare endonasal and percutaneous osteotomy, although external osteotomy is said to be superior with respect to mucosal lesions.

10.3 Quality of the subjective perception of patients

No valid investigation has yet been conducted. Only the significantly reduced swelling in the short postoperative interval (up to 2 days

postoperatively) and the lower degree of ecchymosis have been verified and described by the investigators (see above). With regard to the quality of life or functional impairment, no valid data or trials are available, although this will certainly be made good. However, Baumann et al. showed that there is no difference in the subjective perception of the patients or the quality of life with respect to internal or external osteotomy [85]. There is only one established difference between different osteotomy techniques – the lesser pain reported by the patients after piezo osteotomy.

11. Preservation vs. Traditional Rhinoplasty

There is a lively discussion on preservation rhinoplasty. This is not a new approach in the field of rhinoplasty. In 1899, J.L. Goodale was the first to publish this technique in the Boston Medical Surgical Journal under the title of "A new method for the operative correction of exaggerated roman nose" for the area of the nasal dorsum [121]. Although even then the preservation of the keystone area was postulated, this knowledge was lost over time, as often occurs in medicine, especially after Joseph described reduction techniques with removal of the hump in the keystone area in 1931 [63].

The re-discovery of preservation shows that interest in the preservation of anatomical structures has been revived. Since the publication of Sheen's book in 1978 (see above), rhinoplasty has developed from resection to reshaping. Now the development seems to be from reshaping to preservation of anatomical structures. This is possible mainly due to newly acquired knowledge of the anatomy and physiology of the nose (see above), improved suture techniques and refined surgical techniques.

The first results of so-called "push down preservation" rhinoplasty were described by Barelli in 1975 [122]. Yves Saban re-discovered this technique and evolved it for closed access [123]. This technique now involves either complete preservation of all structures or partial preservation of specific structures (skin/nasal dorsum, skin/nasal tip, nasal tip/nasal dorsum). In 2018, Yves Saban et al. published a trial of 320 patients, in which they compared the let-down technique (LDT) and the push-down technique (PDT) [86].

The basic difference is that PDT is indicated in cases of smaller humps of up to 4 mm, when the fully mobilised nasal pyramid is "pushed down". It has become clear that the keystone area is the semi-mobile cartilaginous joint [69]. During LDT, the nasal pyramid is "let down" after an additional incision in the area of the maxillary processes; this is indicated for humps over 4 mm. The same preservation technique can be used for closed and open access. In 2019, Rollin Daniel published 100 cases that underwent exclusively open surgery with a follow-up of one year [124]. He considered that this technique represented a new paradigm shift that preserves the dorsal soft tissue mantle and the ligament structures of the nose – especially in the area of the nasal tip (see above). However Saban and Daniel emphasise that the patients have to be selected very carefully and that this technique cannot be applied in all kinds of hump noses.

11.1 Quality of external and/or cosmetic results

All surgeons consistently describe an accelerated postoperative healing phase with lower swelling tendency and that the external results are very satisfactory. A combination of preservation and piezo technique is meanwhile in the testing and was published as a case report by Göksel and Saban in 2019 [125].

11.2 Quality of functional and/or endonasal results

Corresponding results with short- or long-term observation are completely missing. This is certainly on the agenda of future projects, in order to emphasise the relevance of preservation on breathing quality too.

11.3 Quality of subjective perception of the patients

The patient statements reported by the surgeons have been positive. Unfortunately, the corresponding PROMs have not been performed and only these can lead to verified results in the assessment of a long-term analysis.

12. Patient Reported Outcomes (PROs)

The parameters for clinical effectiveness are typically reflected in the outcomes that are important for the patients, such as symptoms, function, optics, or morbidity.

It is fortunate that in recent decades the concept has been established that treatments need not only be clinically effective and profitable, but also acceptable and indeed desirable for the patients. Measurements of clinical efficacy cannot tell us anything about the patients' feelings, thoughts, or what they want to achieve with the treatment. Measuring this element of acceptance requires patient-based evidence that includes the well-being regarding the treatment and the outcome.

For this purpose, the focus is increasingly placed on the development of patient-reported outcomes (PROs) that centre on the perception of a disease and its treatment by the patients. Patient reported outcome measures (PROMs) are tools that are used to measure and assess data of PROs and since 2011 they have given rise to many publications [126].

In general, for all PROMs two categories are differentiated. Firstly, there are the general PROM instruments (e. g. SF-36, EQ-5D) that measure the general health-related quality of life and may be applied independently of the disease. The results are comparable over different patient and population groups. Secondly, there are disease-specific PROM tools (e. g. ROE, FROI-17, Oxford Knee Score) that measure the severity of a specific disease or a certain aspect of a disease or organ [127].

The specific survey possibly shows relevant details that would not have been assessed by generic tools. Whether a generic or specific instrument is selected depends on the objective and the question.

Patient reported outcomes are important because they provide the patients' perspective of the treatment and the outcomes that is not recorded by the clinic alone. However, it is just as important for the patients as the scientific result.

Typically, the following dimensions are systematically assessed [128]:

- Achieved health status
- Process of recovery (time, quality of the treatment chain)
- Sustainability

In contrast to clinical standard results, PROs give a unique insight into which impact a certain therapy or surgery may have on the patients, especially regarding the outcome after rhinoplasty.

People with exactly the same health conditions, diagnoses, or sensitivities have different perceptions, since every individual perceives different factors contributing to the satisfaction with a specific result. PRO data are important because they reflect more exactly the real benefit that is relevant for the patients.

The ability to measure well-being as result is greatly important in clinical situations where the primary goal is the treatment of the patients' well-being (e. g. rhinoplasty) and not the prolongation of life expectancy. The use of PROMs before, during, and after treatment shows changes in the individual patient level, e. g. improved physical functions, higher quality of life [129].

PROs have to be defined thoroughly so that they assess the information that is relevant for the patients. This information must be precisely measured and if possible in a way that makes them comparable to other results. By implication, this means that it is relevant *how* a question is formulated, *when* the questions are asked, *how* the answers are assessed, and *how* the data are interpreted. This means, the more precisely and specifically the question is formulated, the better is the detailed information from the patients' perspective. The definition of the PROs determines the measurement objective such as a symptom, an effect, or an external characteristic etc. [130, 131].

The most important concepts measured by means of PROs are:

- Health-related quality of life (HRQoL)

The HRQoL is multidimensional and represents the patient's opinion of a disease and its treatment in daily life, including the physical, mental, social function and emotion, well-being, vitality, health status etc.

- Patient satisfaction

The rating of the outpatient or inpatient institution as well as single treatments, service providers including all staff members of health-related professions etc.

- Physical functions

Physical impairment and limitations at rest and during activities, including self-care and other daily activities such as walking, mobility, sleep, sex etc.

- Mental condition

Positive or negative emotions, cognitive thinking including anger, attention, self-esteem, well-being, sorrow etc.

- Signs and symptoms

Reports about physical and mental symptoms or feelings that are not directly visible including physical power and fatigue, nausea, irritability etc.

- Social competence

Impairment at work, in school, with friends and family interaction etc. as well as active participation in social life.

- Therapy adherence (postoperative after-care)

Reports and observations about active postoperative compliance.

- Usefulness

The usefulness or serviceability is the beneficial condition for the satisfaction of needs. In health economy; the patients' preference is measured on the basis of usefulness, e. g. how important different factors are for the patients, such as symptoms, pain, and mental health. In this way, the impact of new treatment methods on these factors and thus on the quality of life can be investigated. It is a common approach to evaluate new therapy approaches as well as to assess if treatments should be paid by the cost bearers.

A high quality PROM tool is valid, provides consistent and reproducible data on the effect of the treatment and reacts to changes. In the selection of the PROM tool, it is important that the characteristics of the group of people on which the evidence is based (age, gender, disease etc.) is comparable with the group to be examined. For development, evaluation, implementation, and reporting of PROMs, multiple manuals and publications are available. But this also means that the changes in the quality of life are not always optimally reflected in PROMs because often the trials do not have a cohort, are not prospective, and cover only a short follow-up period [126, 132–134].

12.1 Quality of the external and/or cosmetic results and the quality of life

In the field of rhinoplasty, quality analyses mostly encompass a combination of inner and outer outcome with focus on the postoperative function. The one exception in the disease-specific area is the "Rhinoplasty Outcome Evaluation (ROE)", which focusses on the external appearance. The ROE was published in 2001 by Alsaraf et al. [135].

Currently, the ROE is the only disease-specific PROM focusing on the external result of rhinoplasty. However, it must be mentioned that the questionnaire also has disadvantages, as it only contains six questions and five of these are related to external appearance. This means that the ROE has definite weaknesses in terms of sensitivity and specificity and does not optimally meet the abovementioned requirements of a disease-specific PROM.

Two retrospective publications found a mean improvement of 36.7 points in the ROE after five [136] and after 36 months [137].

In one of the largest follow-up papers (60 months), Bulut and Baumann et al. confirmed that the ROE after one and after five years showed significant postoperative improvement in the outer appearance and quality of life [138]. This is the only study that evaluated this long follow-up period for the field of septorhinoplasty. The data reflect the finding that retrospective trials show similar results to prospective analyses, but the validity of prospective trials is clearly greater than that of retrospective studies ("response shift bias", see below).

Among the PROMs, the FACE-Q has an intermediate position, as it is not focused on the nose but on changes in the face and thus is also applied to eyelid surgery, face lifting etc. [139].

This makes sense because the nose is in the middle of the face and dominates everything else in the patients' perception. In the further development of the FACE-Q, a nose module is presented that encompasses 19 questions. Ten of these are related to the nose, 4 questions focus on adverse effects of surgery, and 5 on the nostrils. On this basis, the conclusion could be drawn that the outward changes in the face had a significantly positive effect on all areas (appearance, quality of life, mental well-being etc.) [140].

The general PROM entitled "Short-Form 36 Health Survey (SF-36)" that analyses the general physical condition [141] reveals improvements one year after surgery in the fields of role-specific effect and cognitive health. Five years after surgery, significant improvements from the preoperative findings were found in the areas of physical functioning, role-specific effect, cognitive health, bodily pain, vitality, and social functioning. However, the SF-36 did not show significant changes between the 12th and 60th postoperative

months. This is striking, as an improvement was identified compared to the preoperative status, which might lead to the conclusion that the SF-36 reaches its limits for postoperative assessment. A correlation between SF-36 and ROE could not be found for all evaluated periods (▶ **Fig. 3**). This might be due to the very unspecific questions and the low number of questions of ROE; this also reveals its weakness as a disease-specific PROM (see above).

12.2 Quality of the functional and/or endonasal outcome and quality of life

Two PROMs play a major role in the function after rhinoplasty: NOSE and FROI-17. NOSE (Nasal Obstruction Symptom Evaluation) was established in 2004 by Stewart et al.. It primarily illustrates the functional and obstructive aspect and confirmed improvement in the quality of life after surgical treatment of obstructed nasal breathing [142].

Another PROM was presented in 2018 that has a strong correlation to NOSE but does not have the same impact in the cosmetic area. SCHNOS is mentioned here for the sake of completeness. As it has only recently become available, further data are needed for evaluation. The questionnaire includes four questions on breathing, five on the shape of the nose, and one question on the patients' self-esteem [143].

FROI-17 was initiated and established by Baumann et al. in 2014 [144]. It is intended to be a general assessment, as it also takes into account optical and functional data. The analysis of functional results revealed a significant change in the patients' perception of nasal function 12 and 60 months postoperatively [138]. Furthermore, the authors confirmed that patients with a preoperative crooked nose were significantly more satisfied after surgery than patients with a straight preoperative nose. In addition, a correlation between the general PROM SF-36 and the disease-specific PROM FROI-17, in contrast to ROE, was found (see ▶ **Fig. 3**) [85].

These data of the FROI-17 trials of the inner and outer nose are clearly important, as this is a prospective trial and therefore has less risk of bias than a conventional retrospective study, which incorporates a retrospective assessment of the preoperative situation (response shift bias).

The overall conclusion is that - from the patients' perspective – these is a significant long term improvement in quality of life, with respect to both the internal and external nose.

12.3 Quality of the subjective patient perception of PROM in rhinoplasty

First, as for all cosmetic treatments, the patients' perception of their own bodies has to be taken into consideration. An improvement in mental health after cosmetic interventions was already demonstrated in the mid1990s [145]. The most frequently observed mental disease that is seen in plastic surgery is body dysmorphic disorder. Recent meta-analyses showed that a mean of 15 % of all patients wishing external changes suffer from body dysmorphic disorder. This would be more than one patient of six. In rhinoplasty, this amount is even higher - 21–48 %.

Of course, this aspect is also reflected in the results and the interpretation of PROMs [146]. Picavet et al. confirmed a clear correlation between disturbed body perception and the wish for rhinoplasty [147]. In addition, Felix et al. showed that patients with body dysmorphic disorder benefit from rhinoplasty, but that they

	Preoperatively		1-year postoperatively		5-year postoperatively		*p* (preop vs. 1-year)	*p* (preop vs. 5-year)	*p* (1-year vs. 5-year)
	Mean	SD	Mean	SD	Mean	SD			
FROI-17									
Overall score	32.2	17.5	20.2	18.3	13.7	17.3	**<0.0001**	**<0.0001**	**0.048**
Nasal symptoms	31.7	17.0	21.5	19.7	14.7	18.8	**0.001**	**<0.0001**	0.05
General symptoms	32.9	22.8	20.0	20.7	12.9	17.9	**0.0002**	**<0.0001**	**0.043**
Self-confidence	30.8	26.5	16.9	21.8	14.3	23.7	**0.0002**	**<0.0001**	0.55
ROE									
Overall score	39.8	15.2	68.5	17.8	75.1	24.0	**<0.0001**	**<0.0001**	0.15
SF-36									
Physical functioning	84.0	19.4	91.4	13.3	94.4	13.3	0.05	**0.001**	0.23
Role-functioning physical	75.5	35.7	89.1	23.7	90.1	25.6	**0.02**	**0.004**	0.85
Bodily pain	80.3	26.5	83.6	23.2	89.5	22.7	0.49	**0.026**	0.26
General health	66.0	21.0	70.9	20.0	66.4	19.5	0.24	0.90	0.31
Vitality	53.1	19.6	57.2	19.6	62.8	19.7	0.30	**0.004**	0.20
Social functioning	76.0	25.2	80.5	24.6	87.5	20.7	0.38	**0.003**	0.18
Role-functioning emotional	80.2	33.4	85.4	31.6	88.7	26.9	0.43	0.09	0.63
Mental health	61.8	19.2	70.6	18.4	71.0	18.2	**0.024**	**0.004**	0.90

SD standard deviation, *p p* value, *vs* versus

▶ **Fig. 3** Preoperative assessment by means of ROE, FROI-17, and SF-36 compared to one and five years after surgery, also comparison between one and five years after surgery. ©: Bulut OC, Wallner F, Oladokun D et al. Long-term quality of life changes after primary septorhinoplasty. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation 2018; 27: 987-991.

have significantly poorer scores pre- and postoperatively compared to the control group without this mental disorder [148]. Furthermore, the evaluation of all questionnaire tools has to take into account that most rhinological patients are female, young, and healthy usually without having other health problems. Therefore the improvement in physical findings has a more direct impact on all areas of life. In a demographic analysis, Schwitzer et al. reported that the satisfaction about an improvement in external appearance and quality of life depends on age, gender, race, and income. White, female patients younger than 35 years were clearly more satisfied with their postoperative quality of life and their external appearance than all other groups [44].

In addition, the timeline of the follow-up is a relevant aspect in the analysis of the PROMs. The positive change in bodily and mental perception and the quality of life is especially obvious in the first 12 months after surgery [149]. A meta-analysis performed by Yang et al. in 2018 verified this in a review of all rhino-specific PROMs and confirmed the improved quality of life, in particular in the first 12 months and in young patients [150].

In a more restricted prospective study, Sarver et al. confirmed that the positive change after cosmetic surgeries in general (nose, eyelid, breast etc.) primarily takes place in the first 3 months, independently of the patient population [151]. As yet, no improvement in the quality of life has been demonstrated after 60 months [152].

On one hand, the functional and optical improvements are positively reflected in the questionnaires (SF-36, FROI-17, and ROE), especially in shorter follow-up periods of one year. However, the functional improvements on re-socialisation, self-confidence, and self-esteem clearly appear later, as reflected in the long-term data of the FROI-17. This is in contrast to the ROE - that failed to confirm any positive long-term improvement. This is consistent with the findings of Bulut et al. that the type of procedure does not affect the quality of life or bodily perception in any way. This is particularly interesting, as two thirds of their patients underwent closed and one third open surgery, which is contrary to the current general trend [153].

13. Conclusion

1. The quality of cosmetic plastic rhinoplasty depends on many different factors.
2. As in all types of surgery, rhinoplasty is influenced by institutions, cost bearers, patients, and media (primarily internet and social media).
3. Measurable and tangible quality is defined and expected in different ways by the single groups.
4. Cost-effectiveness and quality do not exclude each other but they are definitely not mutually dependent.
5. As regards changes in external appearance, the quality of rhinoplasty often depends on soft factors and the cosmetic taste of the patients.
6. According to current knowledge, the quality of rhinoplasty does not depend on the type of access, technique of osteotomy, or other single steps but on the outer and functional outcome, as reflected in general and disease-specific PROMs.
7. The quality of the outcome is more important than the quality of the procedure.
8. Quality assurance and quality confirmation for all areas and institutions can only be established by means of scientific evaluation of the studies. This will encourage the use of guidelines and evidence-based data.
9. The objective should be the serious implementation of prospective comparative studies as is usual in drug or cancer therapy. This would enhance the surgeon's position in relation to cost bearers and decrease dependency on the influences of industry.

Conflict of Interest

The author declares that there is no conflict of interest.

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