Rhino(septo)plasty Informed Consent. Consensus by the European Rhinoplasty Course Faculty – EUFOREA

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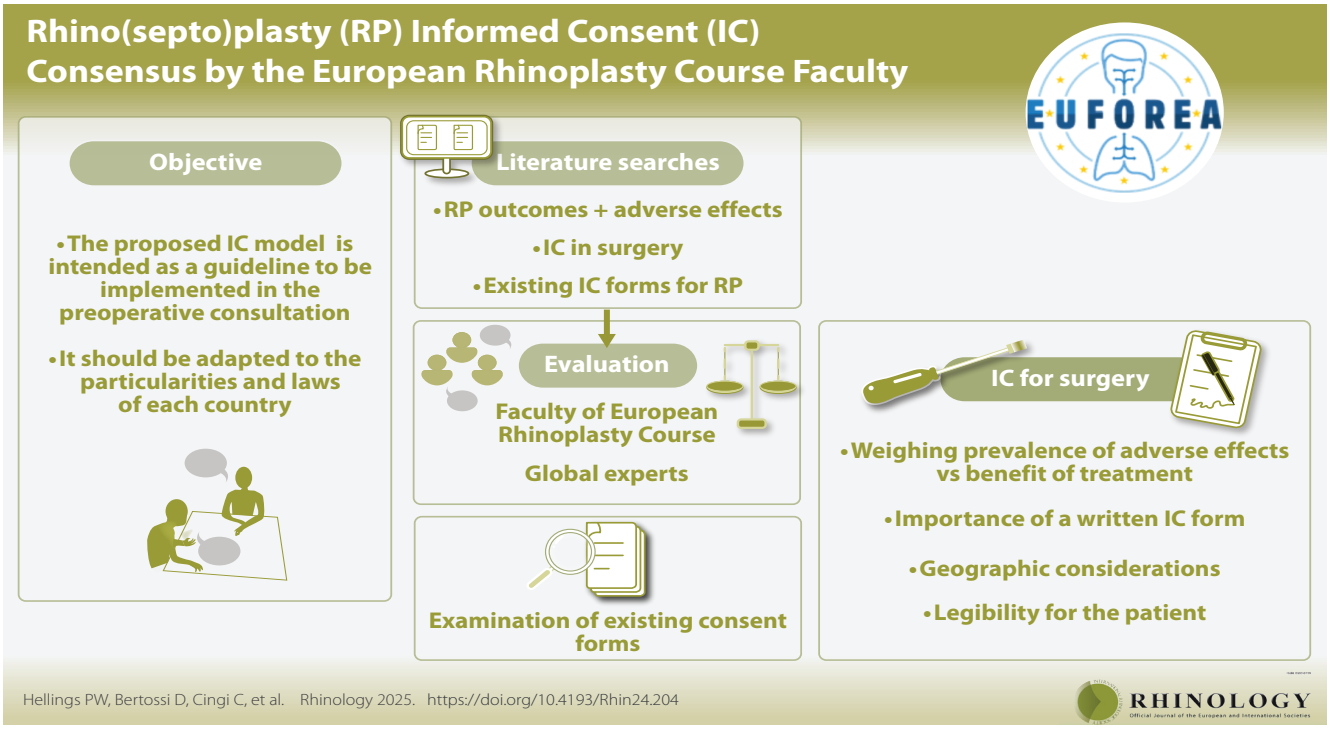

Abstract

Background: Patients seeking rhino(septo)plasty need to be adequately informed by their surgeon or surgical team members about the procedure, the expected outcomes, complication risks and post-operative care, and the available alternatives. A consensus on the content of an informed consent in rhino(septo)plasty is currently lacking despite the high unmet need.

Methodology: The extended international faculty of the European Rhinoplasty Course in Brussels organized by EUFOREA has generated an overview of the current literature on rhinoplasty outcomes and complication rates, and available informed consents. A proposal for informed consent was elaborated, consensus reached and checked for legal validity.

Results: An overview of reported outcomes and complication rates of rhino(septo)plasty are provided. Additionally, contents of existing consent forms for rhino(septo)plasty surgery are compared with requirements found in literature on informed consent, leading to a proposal of informed consent including relevant information according to expert consensus.

Conclusions: An informed consent form for rhino(septo)plasty is proposed by the international faculty of the European Rhinoplasty Course, that might serve rhinoplasty surgeons in the development of their informed consent documents.

Key words: rhino(septo)plasty, rhinoplasty, informed consent, rhinoplasty surgeon

Introduction

The legal doctrine of informed consent (IC) can be traced back to the post-World War II Nuremberg Code [1-3], a set of guidelines created to ensure that unethical "medical" experiments were no longer carried out in the name of science. This doctrine is based on the general principle that an adult person with a sound mind has the right to determine what may be done to his or her body. Whenever a patient is subjected to a procedure that he/she does not consent to, the physician performing the procedure may be held responsible for medical malpractice.

IC is not only a legal obligation but also a cornerstone of the patient-physician relationship. Despite its paramount importance, several medical articles still mention the medicolegal consequences of its non-use or inappropriate use [4]. Perhaps most striking is that its importance is still not properly developed in the legal medicine departments of medical schools. In some countries, its development is the responsibility of the medical associations or scientific societies of each specialty, so there is no common basic rationale and even less agreement on how to extrapolate it to the common needs of all medical centers.

Although all surgical procedures nowadays are a result of a shared decision between patients and surgeon, a formal informed consent (IC) by the patient is a legal requirement in all domains of medicine, including rhino(septo)plasty (RP). The ethical, legal and personal aspects of an IC are of paramount importance for both patients as well as surgeons dealing with RP, given the delicate nature of a RP with the combined functional and aesthetic aspects of the nose. By being able to redefine and explain the aims of RP, the risk of complications and suboptimal outcomes, the alternatives and all logistical aspects of RP, patients can give their voluntary and well-informed permission to plan a RP. Of note, the shared-decision making process as part of an IC enhances physician-patient relationship, with expected better outcomes. IC documents also serve as a medico-legal document that reduces the liability of a surgeon [5].

There are several ways to gain an IC from a patient. Oral information and explanation of goals, results and risks is the most frequently way of obtaining an IC, with/without written notification of the information orally provided by the surgeon. Unfortunately, patients' ability to recall such information is low and decreases over time [6,7]. Risk recall improves significantly when patients receive written information accompanied by illustrations as opposed to verbal information [8,9]. In the ideal world, an IC should be obtained in a written way and contain all relevant information that will be included in the proposed IC.

Until 2024, there have no attempts been made to propose an international consensus for IC for RP. Given the unmet need of an international consensus on IC for RP, and the extended international faculty of the European Rhinoplasty Course in Brussels, the authors aimed to join forces to propose a draft IC for RP that might be used and/or adapted to the needs of individual centres in Europe. It has been the goal of the European Rhinoplasty Course faculty to make a consent form that meets the needs of both patients and surgeons in different EU member states. It is acknowledged by the group that a uniform approach to all cases is not feasible, as individualities and particular considerations cannot be disregarded. Consequently, the present document is intended to provide recommendations and guidance on what the group considers to be essential.

Based on the current literature on consent and on complications and outcomes of RP, a draft IC is proposed with consent of a legal advisor (TVS).

Materials and methods

The approach of development of an IC for RP consisted of several steps. As a first step, literature searches have been conducted evaluating outcomes and adverse effects of RP, ICs in relation to nose surgery and RP, and a comparison of existing consent forms on rhinoplasty. First, a literature search on outcomes and adverse effects of rhinoplasty was performed. PubMed was searched with the terms "Outcomes AND rhinoplasty" and "Quality of life AND rhinoplasty' and "Rhinoplasty AND complications". Results were limited to articles in English language. References of selected articles were screened for additional relevant articles. Second, a literature search on IC in surgery was performed. The PubMed database was explored with the search term "Informed consent AND surgery OR rhinoplasty". Only articles written in English languages were included. The Cochrane online library was searched on articles about informed consent. Additionally, the references from articles found through this literature search were screened for additional relevant articles.

Third, Google was searched for existing consent forms for rhinoplasty using the search terms "informed consent AND rhinoplasty". Patient information leaflets were excluded.

As a second step, the proposed outcomes and proposed IC have been subject to 2 rounds of evaluations by the faculty of the European Rhinoplasty Course in 2023 and in 2024. Global rhinoplasty experts from 11 countries have been asked to critically revise, to suggest changes and to approve the content. A preliminary virtual meeting was convened in October 2023, followed by a second meeting in March 2024, with the objective of finalising outstanding issues and achieving a consensus.

Due to the unique nature of this initiative and the objective of establishing a precedent for genuine equality of voices, the methodology employed by the group has been to submit each step for voting and to proceed in accordance with the majority decision.

In this sense, the bibliography under consideration, the definitions regarding the resolution of differences of opinion, as well as the practical aspects related to the composition and editing of this document and its appendices, have been collaboratively derived from the opinions of the aforementioned experts, under

the premise of advancing in accordance with the consensus reached by the majority.
This group believes that this approach has not only been comprehensive but also ensures that all voices have equal weight and are heard and valued equally.

Results

Outcomes of rhino(septo)plasty

Rhino(septo)plasty aims to improve or at least preserve (if the other improves) both nasal form and function, depending on the goal of the procedure in relation to the concern of patients. The goals of RP need to be clearly discussed with the patients before the surgery, as is the estimated impact of RP on the function as well as the appearance of the nose [10].
It is obvious that preserving nasal patency in major reduction rhinoplasty with tip refinement and deprojection can be challenging [11] and that surgeons sometimes need to prioritize either nasal function or aesthetics in particular cases like in cleft lip RP [12]. Maintaining or improving nasal function should be the primary goal, although the effects of reducing nasal patency should not be underestimated.
To assess postoperative outcomes, both nasal aesthetics and function are of clinical importance.

Nasal patency after rhino(septo)plasty

The preservation or preferably improvement of nasal function during rhinoplasty is of paramount importance. A recent systematic review of nasal patency after functional rhinoplasty showed a substantial reduction in subjective nasal obstruction after functional rhinoplasty [13,14]. The subjective relief of nasal obstruction after surgery is of most clinical relevance for the patient and may differ substantially result obtained with nasal patency measurements, like acoustic rhinometry or rhinomanometry [15,16]. As such, the relevance and value of objective measures of nasal patency before and after nasal surgery is subject to debate, given the anatomic, mucosal and chemosensory mechanisms involved in the subjective feeling of nasal patency [17]. In this context, the use of validated patient-reported outcome measures that address nasal function such as the NOSE [18,19] and SCHNOS [20,21] scales takes on more value. Both, along with acoustic rhinometry or rhinomanometry, are of capital functional importance.
Having said this, reducing nasal patency, because of improved aesthetics, should not be done except in exceptional circumstances and then should be very carefully discussed with the patient and included in int IC.

Nasal appearance after rhino(septo)plasty

Patient satisfaction with nasal appearance is of clinical relevance after RP. The Rhinoplasty Outcome Evaluation scale (ROE) is currently accepted as a validated quality of life instrument reflecting patient satisfaction with the nasal appearance after RP [13,14,22-24]. Using their outcomes, various studies have shown a significant improvement in patient satisfaction after aesthetic rhinoplasty, reflecting an improvement in quality of life [25]. One study shows a patient satisfaction score of more than 90% [26]. The same can be said for cleft lip patients undergoing revision rhinoplasty [27]. Furthermore, studies on outcomes of revision rhinoplasty also show high and long-standing patient satisfaction scores [28], but with several caveats in the interpretation of data as patient selection is key to success. Several factors related to the nasal deformity, the patient, and the surgeon all determine the selection of patients taken for RP [29]. It is important to evaluate body dysmorphic disorder symptom severity before the surgery, as severity is inversely correlated with postoperative patient satisfaction [30,31].

Revision rate

A recent large retrospective cohort study from the United States showed that the overall revision rate for (septo)rhinoplasty was between 1.1% and 3.3% [32-36]. Primary rhinoplasty had an overall revision rate of 3.1%, while secondary rhinoplasty had a higher revision rate of 11% [32]. Both functional as well as aesthetic reasons may underly the indication for a revision RP. Other have shown that revision rates are higher, mostly related to the complexity of the cases [37]. Overall, and despite the lack of real-life data and the probably higher percentage of (minor) real-life reviews given the advent of social networking [38], satisfaction rates after RP are lower than other facial procedures like blepharoplasty, face lift, otoplasty and/or chin augmentation [38]. Revision rates of RP depend on multiple factors related to the patient, the surgeon, the nose and the surgery performed and the postoperative care. Literature is limited in relation to revision rates, most likely given the delicate nature of the topic and the limited investment in long-term outcome studies in RP.

Complications of rhinoplasty

Rhinoplasty is a delicate procedure with some predictable and unpredictable complications.
Despite the low incidence, complications do occur. Table 1 [39-46] provides an overview of complications following rhinoplasty, divided into those with minor and major impact on the patient. Patient dissatisfaction cannot be considered a complication; however, its incidence is estimated at 15-17% [39]. Literature on complication rates following rhinoplasty is scarce and varies greatly in study periods. Historically, complication rates vary widely, ranging from 1.7% to 18% [39]. The most frequent complications were infection (0-15%), wound dehiscence (5%), and epistaxis (0.5-2%) [39]. The following is a brief discussion of different rhinoplasty complications and their incidence rates, adapted from recent literature.

Table 1. Rhinoplasty complications [39-42].

Table 1: Rhinoplasty complications

COMPLICATION	MINOR Complications	MAJOR Complications
Bleeding	Minor epistaxis	• Major epistaxis requiring surgical exploration • Septal hematoma
Infection	Mild cellulitis	• Severe cellulitis requiring hospitalisation • Septal abscess • Toxic shock syndrome • Cavernous sinus thrombosis • Implant infection
Trauma	Transient epiphora due to soft tissue oedema	• L-strut fractures • Lacrimal duct injury resulting in epiphora • Intracranial injury • Cerebrospinal fluid leak
Functional issues	• Transient nasal obstruction • Intranasal synechiae • (Asymptomatic) septal perforation • Temporary hyposmia	• Residual or new nasal obstruction • Anosmia • Persistent reduced nasal function • Chronic rhinitis • Numbness of the face / upper lip (larger area)
Aesthetic issues	Minor nasal deformities	• Implant extrusion, distortion, resorption • Postoperative deformities of the nose
Skin and soft tissue complications	• Prolonged oedema • Visible transcolumellar scar • Contact dermatitis	• Tissue necrosis • Post-rhinoplasty cysts

Bleeding and infection

A recent prospective cohort study in the United States on almost 5000 patients reported an overall major complication rate of 0.7% [47,48]. The most common complication was bleeding (epistaxis and septal hematoma), followed by infection ([48]. Both had an incidence of approximately 0.2% [48]. These findings are consistent with incidence rates from recent literature, where the incidence of serious bleeding after rhinoplasty is reported as being less than 1% [40]. Reported infection rates are between 0 and 3% [41,48,49]. Septal hematoma can lead to septal perforation and saddle-nose deformity.

Functional complications

It has been reported that 10% of patients complain about residual or new breathing problems after primary RP [50-52]. In most cases however, RP does not worsen nasal patency [40]. Nasal obstruction can occur due to problems related to the nasal septum, nasal valve or healing of the mucosa with scarification. Given the chemosensory aspects of nasal patency, also these extra anatomical reasons might underly the feeling of suboptimal patency of the nose after RP [15].

Hyposmia after rhinoplasty is mostly temporary due to postoperative swelling of the mucosa, with permanent anosmia being only rarely reported. The overall risk of (temporary) hyposmia or anosmia after rhinoplasty is estimated at approximately 3% [53-55].

Numbness of the facial skin after rhinoplasty is common. This occurs because of injury of the external nasal nerve, which supplies the sensation of the nasal tip and adjacent upper columella [31,47,56]. Historically, incidence rates of 65.3% were cited, with resolution of the numbness in 68.3% of the patients within three months post-surgery [42,47,57,58]. A more recent study by Jaberoo et al. reported an incidence of 26.2%, with 15.4% short-term numbness and 10.8% long-term numbness [42,47,59].

Skin and soft tissue complications

Post-rhinoplasty skin issues related to persistent swelling, numbness, acne, discoloration/hyperpigmentation, persistent dark circles in the lower eye lid, fat or skin necrosis, telangiectasis, scarification of the skin with/without skin defects, and even cysts over the dorsum/tip might occur [47,60].

Aesthetic complications

Postoperative deformities, irregularities and asymmetries of the nose can result in patient dissatisfaction and therefore an unsatisfactory result, both shortly after the rhinoplasty (within the first year) or on the long term (after more than 5 years). The rate of nasal asymmetry is variable, but has been reported in 3.52% of cases, while the rate of post-operative dissatisfaction is 4.98% [41,42,47]. In 5-15% of the cases, this leads to revision rhinoplasty [41,42,47]. Polly beak deformity, irregular dorsum and/or residual asymmetries are one of the most common postoperative deformities after primary reduction RP [59].

When using implants, surgeons can choose between alloplastic implants or autologous cartilage. Alloplastic implant infection,

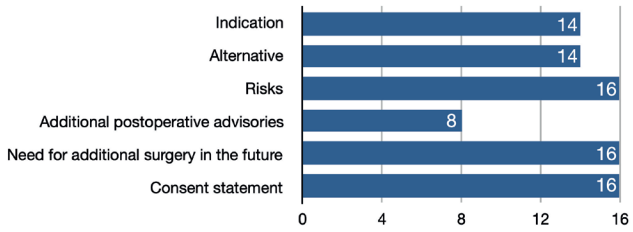

Figure 1. Overview of consent form contents.

extrusion, distortion and resorption have been reported ranging from 1 to 8% [41,61]. When using autologous costal cartilage (ACC), complication rates are reported to be 14% [57]. Complications related to the donor site, such as hypertrophy of the scar or keloid, occurred in 7% of all patients [62]. No difference in outcomes was found between autologous and homologous costal cartilage grafts, including rates of warping, resorption, infection, contour irregularity or revision in patients undergoing dorsal augmentation rhinoplasty [63].

Given the dynamic changes of the soft tissue envelope of the ageing nose, aesthetic changes of the nose may occur long time after rhinoplasty.

Trauma and others

L-strut overresection and/or fractures may occur leading to saddle nose deformity or underprojected nasal tip. In a retrospective review on intraoperative fractures of the L-strut, Gunter et al. reported an overall incidence of 1.2% [64].

Epiphora mostly occur because of compression of the nasolacrimal duct due to oedema, but nasolacrimal duct injuries have also been reported [51].

Other complications are rare, and include toxic shock syndrome [65], cerebrospinal fluid leak [66], sinus cavernosus thrombosis [67], and intracranial injury [68].

Informed Consent for surgery

The general requirements of IC include a description of the indication of the procedure, a short description of the procedure, the risks and the expected outcomes. Furthermore, the possibility of not performing surgery or proposing alternative treatments need to be discussed. Aside from the legal requirements, it is important to address patients' wishes regarding the contents of a consent form.

Defining which risks are relevant to mention is probably the most crucial aspect of the IC form. There are no specific European laws that elaborate on this matter. In the recent history of medical litigation, the Bolam principle was used to determine if a physician was guilty of negligence [69]. This principle states that the physician in question cannot be deemed negligent if he can prove that he has disclosed all information that a reasonable body of peers would have disclosed [69,70]. In the last 10 years, there has been a shift from this principle of 'the reasonable doctor' to 'the reasonable patient': any physician has to disclose material risks, that is, adverse effects that a 'reasonable patient' would find significant [69,70].

The detail in which complications are discussed varies amongst different European countries. In Germany, every complication that is specific to the surgery or will surprise the patient is discussed, regardless of the incidence [71,72]. In Sweden, France, Belgium and the Netherlands, surgeons discuss the main results and risks of the operation, then note down that consent is obtained in the electronic health record without further specification [71-73]. In the United Kingdom, the unwritten rule is to only mention complications with an incidence of 1% or more and complications that are severe enough to discourage a patient from electing surgery [71,74].

Patients prefer a qualitative probability of risks rather than a quantitative one [75]. When a surgeon does decide to discuss complication rates with a patient, it is preferable to use their own results and figures, as this would more accurately represent one's personal experience and data found in literature are only estimates [76]. A template, listing complications without further explanation, is insufficient [77]. The list of complications preferably needs to contain an explanation of the further management [73].

Literature has shown that risk recall is higher in patients that received written information compared to those who received only verbal information [78]. This underlines the importance of a written consent form.

Although one can argue that providing patients with a list of rare complications can provoke undue anxiety, it only rarely results in withdrawal from surgery [79]. Literature on avoiding nocebo-effects has emphasized the importance of focusing on the positive effects of treatment [80]. Furthermore, it is crucial not to overestimate the prevalence of adverse effects and to make sure that negative phrasing during consent process is avoided as much as possible [80].

Regarding outcome, it is crucial to discuss realistic outcomes to prevent postoperative dissatisfaction. It is advised to inform about a possible revision preoperatively [41].

Literature points out that patients wish non-surgical treatment options would be discussed more frequently, and the same accounts for postoperative procedure and recovery time [81].

Last, consent forms often contain difficult, medical or legal language, that some patients fail to fully understand [5]. Discrepancy in knowledge of anatomy and procedures can complicate the consent process [81]. Therefore, a valid consent form should be written in plain language that the patient can understand, following the recommendation by the WHO/NIH that all educational materials are written at the 6th grade reading level or lower [82,83].

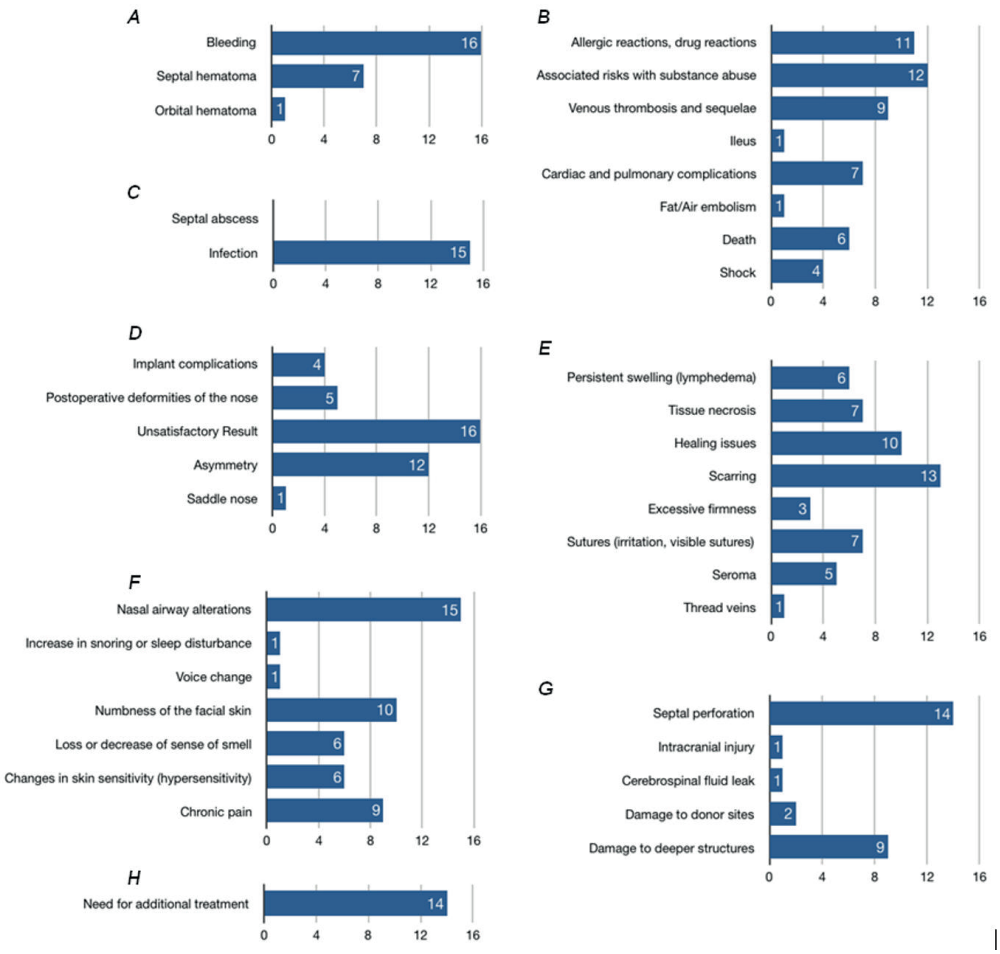

Figure 2. Specific complications mentioned by consent forms. A: Bleeding, B: Systemic complications, C: Infection, D: Aesthetic complications, E: Skin and soft tissue complications, F: Functional complications, G: Trauma, H: Other.

Content of existing consent forms

Sixteen different consent forms for rhinoplasty were found online, used in different countries. Ten forms came from the United States of America, four from Europe, one from Africa and one from Oceania. We must note, however, that there were many more rhinoplasty surgeons in the USA listing consent forms, but they all used the template provided by the American Association of Plastic Surgeons and therefore were not separately listed. The general requirements of informed consent include a description of the indication of the procedure, a short description of the procedure, the risks and the expected outcomes. Furthermore, the possibility of doing nothing or alternative treatments need to be discussed. A comparison of existing consent forms was made regarding the general content (Figure 1).

Risks were discussed in detail by all the forms. Half of the forms contained additional postoperative advisories, such as activities to avoid and lifestyle measures for the first postoperative weeks. Remarkable is that all the forms address the possibility of need for additional treatment in the future.

The specific complications each of the documents reported where also extensively studied. These results are shown in Figure 2.

Complications were grouped according to type of injury, corresponding with the grouping of complications in Table 1. The complications that were mentioned the most are bleeding, unsatisfactory result, nasal airway alterations, septal perforation and need for additional treatment. Rare complications, such as orbital hematoma, intracranial injury, cerebrospinal fluid leak, ileus and fat/air embolism where only mentioned in one consent form. Very specific complications such as increase in snoring or sleep disturbance, voice change and thread veins were also only mentioned in one form. Saddle nose was only specifically mentioned in one consent form, but postoperative deformities of the nose were mentioned in five other forms. Septal abscess was not mentioned at all.

Discussion

What is known from literature on the consent requirements was compared with the content of consent forms currently available online. This information was used to design the proposed

Table 2. Risks of rhinoplasty.

TABLE 2: RISKS OF RHINOPLASTY

Type of injury	Intraoperative risks	Postoperative risks
Bleeding	Bleeding	• Epistaxis • Septal hematoma • Orbital hematoma
Infection		• Local infection of the nose (tip, septum, dorsum) • Implant infection • Toxic shock syndrome • Cavernous sinus thrombosis
Trauma	• Damage to donor sites • Damage to deeper structures • L-strut fracture • Lacrimal duct injury • Cerebrospinal fluid leak • Intracranial injury	Septal perforation
Functional issues	Complete off treatment	• Nasal airway alterations • Hyposmia or anosmia • Changes in facial skin sensitivity (numbness, hypersensitivity) • Epiphora • Increase in snoring or sleep disturbance • Voice change • Chronic pain
Aesthetic issues	Complete on treatment	• Unsatisfactory result • Postoperative deformities of the nose • Implant extrusion, distortion, resorption • Asymmetry
Skin and soft tissue complications		• Tissue necrosis • Post-rhinoplasty cysts • Lymphoedema • Healing issues • Scarring • Excessive firmness • Sutures (irritation, visible sutures) • Seroma
Systemic complications	• Shock • Death	
Other complications		Need for additional treatment or surgery

consent form.

As stated before, consent forms should contain several general contents, and the language used needs to be understandable. The basic requirements are indication, procedure, alternatives, outcomes, complications and patient statement.

The general indication for rhinoplasty is twofold. Rhinoplasty can improve both the appearance of the nose and nasal breathing. It is important to tailor the surgery to the specific needs of the patient.

This consent form does not intend to replace the preoperative consultation but serves as a template with hallmarks that guide the surgeon and patient through the consultation. Therefore, the surgical aspects of rhinoplasty were not comprehensively explained, but only the most important points were mentioned. Rhinoplasty is a very effective procedure with good outcome on function and form of the nose in a high percentage of patients. Even though, it is important to stress the possibility of unsatisfactory results and even the possibility of additional surgery in the future.

We chose not to address the alternatives specifically. It is important to stress that the procedure is elective, and the patient can choose to have no surgery at all or to try a non-surgical option instead, such as fillers. Because the form is not intended to educate patient on the possible alternatives, no further information about this is included in the form.

The most critical component of any consent form is the list of complications. The heterogeneity in discussion of complications throughout Europe is reflected in the existing consent forms. We decided to combine the complications mentioned in literature and the complications mentioned in the consent forms studied and divided those risks in preoperative or postoperative risks (Table 2).

Postoperative pain, limited swelling and bruising after rhinoplasty are normal, thus cannot be called a risk of complication. Because of this reason this was not included in the consent form. Since most institutions have a separate informed consent for anaesthesia, risks related to anaesthesia were not included in the consent form. These risks include blood transfusion and the concurrent risk of hepatitis or other infections, allergic reactions, drug reactions, reactions to fluid or wetting solutions, venous thrombosis and sequelae, ileus, cardiac and pulmonary complications, fat embolism and air embolism. Instead, patients were encouraged explicitly to discuss these specific risks with the anaesthesia staff.

The risk on thread veins and contact dermatitis was not mentioned because in our opinion, these are not risks specific to rhinoplasty surgery, but rather pre-existing conditions.

A blank space was left so that physicians can add complications to their own preference.

Considering patients prefer qualitative terms, a differentiation between frequent adverse events was made in qualitative terms, analogous to the ones used in medication patient information leaflets. The term 'common' was used for a prevalence between 1/10 and 1/100, 'occasional' for a prevalence between 1/100 and 1/1000, 'rare' for a prevalence between 1/1000 and 1/10.000, and 'very rare' for a prevalence of less than 1/10.000. Risks were divided in these categories according to the available information on complication rates.

Complications were classified in these groups according to the incidence rates found in literature. When no incidence rate was found, they were listed as 'unknown'. As previously stated, it is important not to overstate the prevalence of adverse effects.

Information on the postoperative stay and recovery time is different for every institution, and should therefore be mentioned in the preoperative consultation, not in the consent form.

The purpose of this document is to serve as a framework that can be adapted to suit the requirements of local practice. However, it is not feasible to create a single document that can account for the various local laws and the unique complexities of each case. While the group acknowledges that some surgeons may elect to utilise the form in its original state, it is strongly

recommended that the option of individual modification be considered to ensure its suitability for every possible scenario.

Limitations

This study has several limitations, which need to be addressed in future research.

First, there is a shortage of recent data on complication incidences. This study was based on one recent study; other complication rates were found in older literature.

Second, it would be preferable to quote one's personal complication rates instead of numbers found in literature. To address this limitation, we suggest that the physician using the consent form can tailor the emphasize on specific risks according to their own experience. Furthermore, if the physician thinks the patient is prone to specific risks, they can accentuate these, and in this way, tailor the consent to the patient's needs.

Third, the small number of different consent forms that were studied and the fact that more than half were from US authors or centres, limits the conclusions drawn from these data. While this could be seen as a limitation in generalising this approach, this initiative has sought to include a variety of voices sufficient to serve as a guide.

Last, although the legal aspect of informed consent is important, it is crucial to understand that the consent process is more than the simple signing of a consent form. Patients need enough time and clinical contact with their physician to outbalance the benefits versus risks. The consent form needs to be accompanied by a good explanation in understandable language. Furthermore, patient leaflets or videos can help expand the knowledge of the patient and prevent nocebo-effects. An alternative could be a video-assisted informed consent to enhance and overcome limitations to the traditional verbal consent process (84,85).

Conclusion

This study seeks to provide a patient´s-based consent form that can function as a guideline for modification and utilisation by rhinoplasty surgeons throughout Europe. This is a first step in improving the consent process. The consent form seeks to expand the knowledge of patients, and at the same time, provide a useful tool to prevent medico-legal issues.

Abbreviations

ACC: Autologous costal cartilage; IC: Informed Consent; ROE: Rhinoplasty Outcome Evaluation scale; RP: Rhino(septo)plasty.

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None.

Authorship contribution

All the authors have made substantial contributions to the conception or design of the work, the acquisition, analysis, and interpretation of data for the work. They have drafted the work and revised it critically for important intellectual content, have provided approval for publication of the content, and have agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors contributed to the article and approved the submitted version.

Conflict of interest

PWH: Is recipient of consultancy/lecture fees or unrestricted research grants from Sanofi/Regeneron, Novartis, GSK, Medtronic and Viatris. DMC: Serves as Academic Manager at the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA) and as Review Editor at Frontiers in Allergy, Rhinology Section. WJF: Received grants for research in Rhinology from: ALK, Allergy Therapeutics, Chordate, Novartis, EU, GSK, MYLAN, Sanofi-Aventis, and Zon-MW. Further received consultation and/or speaker fees from Dianosic, GSK, Novartis and Sanofi-Aventis/ Regeneron and is chair of EPOS and board member of EUFOREA. PG: Has participated in advisory boards and received speaker fees from ALK-Abelló, Argenx, Astra-Zeneca, Genentech, GSK, Novartis, Regeneron, Roche, Sanofi Genzyme, and Stallergenes-Greer.

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