

Rhino(septo)plasty Informed Consent

REVIEW

Rhino(septo)plasty Informed Consent

Consensus by the European Rhinoplasty Course Faculty – EUFOREA

P.W. Hellings^{1,2,3}, D. Bertossi⁴, C. Cingi⁵, S. Claeys⁶, J. Constantinidis⁷, D.M. Conti^{8,9}, A. D'Souza¹⁰, F. Declau^{11,12}, H. Foda¹³, W. Fokkens¹⁴, P. Gevaert³, W. Gubisch¹⁵, S. Halewyck¹⁶, P. Lekakis^{17,18}, G. Liva¹⁹, A. Mesbahi²⁰, C. McIntosh²¹, G. Nolst Trenité²², V. Picavet^{23,24,25}, E. Prokopakis¹⁹, E. Robotti²⁶, S. Vandembroeck^{17,18}, A. Van Hoolst^{17,27}, T. Vansweevelt²⁸, W. Wagner²⁹.

¹Allergy and Clinical Immunology Research Unit, Department of Microbiology and Immunology, KU Leuven, Leuven, Belgium.

²Clinical Department of Otorhinolaryngology, Head and Neck Surgery, University Hospitals Leuven, Leuven, Belgium.

³Department of Otorhinolaryngology, Laboratory of Upper Airways Research, University of Ghent, Ghent, Belgium.

⁴Unit of Maxillo Facial Surgery Head & Neck Department, Università degli Studi di Verona, Verona, Veneto, Italy.

⁵Department of Otorhinolaryngology, Faculty of Medicine, Eskişehir Osmangazi University, Eskişehir/Turkey.

⁶Department of Otorhinolaryngology, Ghent University Hospital, Ghent, Belgium.

⁷1st Academic Otolaryngology Department, AHEPA University Hospital, Aristotle University of Thessaloniki, Kiriakidi 1 Str, 546 21, Thessaloniki, Greece.

⁸The European Forum for Research and Education in Allergy and Airway Diseases Scientific Expert Team Members, Brussels, Belgium.

⁹Escuela de Doctorado UAM, Centro de Estudios de Posgrado, Universidad Autónoma de Madrid. Calle Francisco Tomás y Valiente, nº 2. Ciudad Universitaria de Cantoblanco, 28049 Madrid, Spain.

¹⁰Department of Head and Neck, Facial Plastic and Reconstructive Surgeon, University Hospital Lewisham, London, United Kingdom.

¹¹Department of ENT, Head and Neck Surgery, GZA-ziekenhuizen, Campus Sint-Vincentius, Antwerp, Belgium.

¹²Department of ENT, Head and Neck Surgery, Antwerp University School of Medicine and Health Sciences, Antwerp, Belgium.

¹³Department of Otolaryngology, Alexandria Medical School, Alexandria, Egypt.

¹⁴Department of Otorhinolaryngology and head/neck surgery, Amsterdam University Medical Centres, location AMC, University of Amsterdam, Amsterdam, The Netherlands.

¹⁵Department of Facial Plastic Surgery, Marienhospital Stuttgart, Boeheimstrasse 37, 70199, Stuttgart, Germany.

¹⁶Department of Otorhinolaryngology - Head and Neck Surgery Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel Brussels Belgium.

¹⁷Department of Otorhinolaryngology Head and Neck Surgery, Katholieke Universiteit Leuven, Leuven, Flanders, Belgium.

¹⁸Department of Otorhinolaryngology Head and Neck Surgery, Regional Hospital Tienen, Flanders, Belgium.

¹⁹Department of Otorhinolaryngology, University of Crete, School of Medicine, Heraklion, Greece.

²⁰Facial Plastic Surgery Clinic, Fars Province, Shiraz, Iran.

²¹Facial Plastic Surgery, Edge Day Hospital, Port Elizabeth, South Africa.

²²Jan van Goyen Medical Center, Amsterdam, the Netherlands.

²³ENT, Praxis für Ästhetik/HNO, Ludwigstrasse 7, Augsburg, Bavaria, Germany.

²⁴ENT, MVZ Moser Gehrking Sauter und Partner, Augsburg, Bavaria, Germany.

²⁵ENT Praxis Hasselbacher-Picavet & Partner, Donauwörth, Bavaria, Germany.

²⁶Department of Plastic Surgery, Villa Sant'Apollonia Private Health Clinic, Bergamo, Lombardia, Italy.

²⁷Department of Otorhinolaryngology Head and Neck Surgery, Regional Hospital Leuven, Flanders,

Belgium.

²⁸Faculty of Law, University of Antwerp, Antwerp, Belgium.

²⁹Municipal Hospital of Munich, Munich, Germany. Kölner Platz 1, 80804 Munich.

SUMMARY

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/Principal: *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.

Up until 2024, there has been no attempts 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

1. 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.

1.1. 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, as a result 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.

1.2. 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).

1.3. 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.

2. 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.

2.1. 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.

2.2. 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).

2.3. 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).

2.4. 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, 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.

2.5. 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⁾.

3. 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).

4. 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 of the forms. Half of the forms contained additional postoperative advisories, such as activities to avoid and life style measures for the first postoperative weeks. Remarkable is that all of 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 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 more or less 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 particular 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 in order 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).

CONCLUSIONS

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

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

Hellings P.W.: Is recipient of consultancy/lecture fees or unrestricted research grants from Sanofi/Regeneron, Novartis, GSK, Medtronic and Viatis.

Bertossi D.: No conflict of interest to declare in relation to this initiative.

Cingi C.: No conflict of interest to declare in relation to this initiative.
Claeys S.: No conflict of interest to declare in relation to this initiative.
Constantinidis J.: No conflict of interest to declare in relation to this initiative.
Conti D.M.: 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.
D'Souza A.: No conflict of interest to declare in relation to this initiative.
Declau F.: No conflict of interest to declare in relation to this initiative.
Foda H.: No conflict of interest to declare in relation to this initiative.
Fokkens W.: The department of Otorhinolaryngology of the Amsterdam University Medical centre, location AMC received grants for research in Rhinology from: ALK, Allergy Therapeutics, Chordate, Novartis, EU, GSK, MYLAN, Sanofi-Aventis, and Zon-MW. Wytse Fokkens received consultation and/or speaker fees from Dianotic, GSK, Novartis and Sanofi-Aventis/ Regeneron and is chair of EPOS and board member of EUFOREA.
Gevaert P.: Has participated in advisory boards and received speaker fees from ALK-Abelló, Argenx, AstraZeneca, Genentech, GSK, Novartis, Regeneron, Roche, Sanofi Genzyme, and Stallergenes-Greer.
Gubisch W.: No conflict of interest to declare in relation to this initiative.
Halewyck S.: No conflict of interest to declare in relation to this initiative.
Lekakis P.: No conflict of interest to declare in relation to this initiative.
Liva G.: No conflict of interest to declare in relation to this initiative.
Mesbahi A.: No conflict of interest to declare in relation to this initiative.
Mcintosh C.: No conflict of interest to declare in relation to this initiative.
Nolst Trenité G.: No conflict of interest to declare in relation to this initiative.
Picavet V.: No conflict of interest to declare in relation to this initiative.
Prokopakis E.: No conflicts of interest to declare related to this initiative.
Robotti E.: No conflict of interest to declare in relation to this initiative.
Vandenbroeck S.: No conflict of interest to declare in relation to this initiative.
Van Hoolst A.: No conflict of interest to declare in relation to this initiative.
Vansweevelt T.: No conflict of interest to declare in relation to this initiative.
Wagner W.: No conflict of interest to declare in relation to this initiative.

FUNDING

Not applicable.

REFERENCES

1. SIMMONS FB. REGARDING THE NUREMBERG CODE. Arch Otolaryngol. 1964 Jul;80:118-9. doi: 10.1001/archotol.1964.00750040122024.
2. Moreno JD, Schmidt U, Joffe S. The Nuremberg Code 70 Years Later. JAMA. 2017 Sep 5;318(9):795-796. doi: 10.1001/jama.2017.10265.
3. Weindling, Paul. "The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code." *Bulletin of the History of Medicine*, vol. 75 no. 1, 2001, p. 37-71. *Project MUSE*, <https://dx.doi.org/10.1353/bhm.2001.0049>.
4. Pallocci M, Treglia M, Passalacqua P, Tittarelli R, Zanovello C, De Luca L, et al. Informed Consent: Legal Obligation or Cornerstone of the Care Relationship? Int J Environ Res Public Health. 2023 Jan 24;20(3):2118. doi: 10.3390/ijerph20032118.
5. Vansweevelt, T., Glover-Thomas, N. (eds.), Informed consent and health. A

global analysis, Edward Elgar publishing, 2020.

6. Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. *BMJ*. 1993 Apr 3;306(6882):885-90. doi: 10.1136/bmj.306.6882.885.
7. Burns P, Keogh I, Timon C. Informed consent: a patients' perspective. *J Laryngol Otol*. 2005 Jan;119(1):19-22. doi: 10.1258/0022215053222860.
8. Kinnersley P, Phillips K, Savage K, Kelly MJ, Farrell E, Morgan B, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database Syst Rev*. 2013 Jul 6;(7):CD009445. doi: 10.1002/14651858.CD009445.pub2.
9. Chan Y, Irish JC, Wood SJ, Rotstein LE, Brown DH, Gullane PJ, Lockwood GA. Patient education and informed consent in head and neck surgery. *Arch Otolaryngol Head Neck Surg*. 2002 Nov;128(11):1269-74. doi: 10.1001/archotol.128.11.1269.
10. Picavet VA, Grietens J, Jorissen M, Hellings PW. Rhinoplasty from a rhinologist's perspective: need for recognition of associated sinonasal conditions. *Am J Rhinol Allergy*. 2012 Nov-Dec;26(6):493-6. doi: 10.2500/ajra.2012.26.3816.
11. Patel PN, Abdelwahab M, Most SP. A Review and Modification of Dorsal Preservation Rhinoplasty Techniques. *Facial Plast Surg Aesthet Med*. 2020 Mar/Apr;22(2):71-79. doi: 10.1089/fpsam.2020.0017.
12. Hens G, Picavet VA, Poorten VV, Schoenaers J, Jorissen M, Hellings PW. High patient satisfaction after secondary rhinoplasty in cleft lip patients. *Int Forum Allergy Rhinol*. 2011 May-Jun;1(3):167-72. doi: 10.1002/alr.20023.
13. Floyd EM, Ho S, Patel P, Rosenfeld RM, Gordin E. Systematic Review and Meta-analysis of Studies Evaluating Functional Rhinoplasty Outcomes with the NOSE Score. *Otolaryngol Head Neck Surg*. 2017 May;156(5):809-815. doi: 10.1177/0194599817691272.
14. Verkest V, Pingnet L, Fransen E, Declau F. Multidimensionality of Patient-Reported Outcome Measures in Rhinoplasty Satisfaction. *Facial Plast Surg*. 2022 Oct;38(5):468-476. doi: 10.1055/a-1760-1422.
15. Lam DJ, James KT, Weaver EM. Comparison of anatomic, physiological, and subjective measures of the nasal airway. *Am J Rhinol*. 2006 Sep-Oct;20(5):463-70. doi: 10.2500/ajr.2006.20.2940.
16. Snoeks S, Velasco E, Talavera K, Hellings PW. Nasal Obstruction: Overview of Pathophysiology and Presentation of a Clinically Relevant Preoperative Plan for Rhino(Septo)plasty. *Facial Plast Surg*. 2024 Jan 15. doi: 10.1055/s-0043-1777850.
17. André RF, Vuyk HD, Ahmed A, Graamans K, Nolst Trenité GJ. Correlation between subjective and objective evaluation of the nasal airway. A systematic review of the highest level of evidence. *Clin Otolaryngol*. 2009 Dec;34(6):518-25. doi: 10.1111/j.1749-4486.2009.02042.x.
18. Justicz N, Gadkaree SK, Fuller JC, Locascio JJ, Lindsay RW. Preoperative characteristics of over 1,300 functional septorhinoplasty patients. *Laryngoscope*. 2020 Jan;130(1):25-31. doi: 10.1002/lary.27955.
19. Aksakal C. Surgical Outcomes of Bony Batten Grafting Through Endonasal Septoplasty in the Correction of Caudal Septum Deviation. *J Craniofac Surg*. 2020 Jan/Feb;31(1):162-165. Doi: 10.1097/SCS.0000000000000602.
20. Moubayed SP, Ioannidis JPA, Saltychev M, Most SP. The 10-Item Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS) for Functional and Cosmetic Rhinoplasty. *JAMA Facial Plast Surg*. 2018 Jan 1;20(1):37-42. Doi: 10.1001/jamafacial.2017.1083.

21. Patel PN, Kandathil CK, Abdelhamid AS, Buba CM, Most SP. Matched Cohort Comparison of Dorsal Preservation and Conventional Hump Resection Rhinoplasty. *Aesthetic Plast Surg*. 2023 Jun;47(3):1119-1129. doi: 10.1007/s00266-022-03156-3.
22. Alsarraf R, Larrabee WF Jr, Anderson S, Murakami CS, Johnson CM Jr. Measuring cosmetic facial plastic surgery outcomes: a pilot study. *Arch Facial Plast Surg*. 2001 Jul-Sep;3(3):198-201. doi: 10.1001/archfaci.3.3.198.
23. Pingnet L, Verkest V, Fransen E, Declau F. Dutch Translation and Validation of the FACE-Q Rhinoplasty Module. *Facial Plast Surg*. 2021 Jun;37(3):296-301. doi: 10.1055/s-0040-1721099.
24. Pingnet L, Verkest V, Saltychev M M, Most SP, Declau F. Translation and validation of the standardized cosmesis and health nasal outcomes survey in Dutch. *B-ENT* 2022;18(3):170-175.
25. Yang F, Liu Y, Xiao H, Li Y, Cun H, Zhao Y. Evaluation of Preoperative and Postoperative Patient Satisfaction and Quality of Life in Patients Undergoing Rhinoplasty: A Systematic Review and Meta-Analysis. *Plast Reconstr Surg*. 2018 Mar;141(3):603-611. doi: 10.1097/PRS.00000000000004102.
26. Ors S, Ozkose M, Ors S. Comparison of Various Rhinoplasty Techniques and Long-Term Results. *Aesthetic Plast Surg*. 2015 Aug;39(4):465-73. doi: 10.1007/s00266-015-0497-5.
27. Hellings PW, Nolst Trenité GJ. Long-term patient satisfaction after revision rhinoplasty. *Laryngoscope*. 2007 Jun;117(6):985-9. doi: 10.1097/MLG.0b013e31804f8152.
28. Hens G, Picavet VA, Poorten VV, Schoenaers J, Jorissen M, Hellings PW. High patient satisfaction after secondary rhinoplasty in cleft lip patients. *Int Forum Allergy Rhinol*. 2011 May-Jun;1(3):167-72. doi: 10.1002/alr.20023.
29. De Greve G, Adriaensen GFJPM, Constantinidis J, Prokopakis E, Lekakis G, Hellings PW. Reasons for rejection of rhinoplasty seeking patients: a multicentre observational study. *Rhinology*. 2024 Feb 1;62(1):82-87. doi: 10.4193/Rhin22.378.
30. Picavet VA, Prokopakis EP, Gabriëls L, Jorissen M, Hellings PW. High prevalence of body dysmorphic disorder symptoms in patients seeking rhinoplasty. *Plast Reconstr Surg*. 2011 Aug;128(2):509-517. doi: 10.1097/PRS.0b013e31821b631f.
31. Picavet VA, Gabriëls L, Grietens J, Jorissen M, Prokopakis EP, Hellings PW. Preoperative symptoms of body dysmorphic disorder determine postoperative satisfaction and quality of life in aesthetic rhinoplasty. *Plast Reconstr Surg*. 2013 Apr;131(4):861-868. doi: 10.1097/PRS.0b013e3182818f02.
32. Spataro E, Piccirillo JF, Kallogjeri D, Branham GH, Desai SC. Revision Rates and Risk Factors of 175 842 Patients Undergoing Septorhinoplasty. *JAMA Facial Plast Surg*. 2016 May 1;18(3):212-9. doi: 10.1001/jamafacial.2015.2194.
33. Youn GM, Shah JP, Wei EX, Kandathil C, Most SP. Revision Rates of Septoplasty in the United States. *Facial Plast Surg Aesthet Med*. 2023 Mar-Apr;25(2):153-158. Doi: 10.1089/fpsam.2022.0009.
34. Shah JP, Youn GM, Wei EX, Kandathil C, Most SP. Septoplasty Revision Rates in Pediatric vs Adult Populations. *JAMA Otolaryngol Head Neck Surg*. 2022 Nov 1;148(11):1044-1050. Doi: 10.1001/jamaoto.2022.3041.
35. Wells MW, DeLeonibus A, Barzallo D, Chang IA, Swanson M, Guyuron B. Exploring the Resurgence of the Preservation Rhinoplasty: A Systematic Literature Review. *Aesthetic Plast Surg*. 2023 Aug;47(4):1488-1493. Doi: 10.1007/s00266-023-03345-8.

36. Santamaría-Gadea A, Sevil-Serrano C, Buendía Pérez J, Mariño-Sánchez F. Nonsurgical Rhinoplasty after Rhinoplasty: A Systematic Review of the Technique, Results, and Complications. *Facial Plast Surg Aesthet Med*. 2024 Sep 4. doi: 10.1089/fpsam.2024.0116.
37. Youn GM, Shah JP, Wei EX, Kandathil C, Most SP. Revision Rates of Septoplasty in the United States. *Facial Plast Surg Aesthet Med*. 2023 Mar-Apr;25(2):153-158. doi: 10.1089/fpsam.2022.0009.
38. Khansa I, Khansa L, Pearson GD. Patient Satisfaction After Rhinoplasty: A Social Media Analysis. *Aesthet Surg J*. 2016 Jan;36(1):NP1-5. doi: 10.1093/asj/sjv095.
39. Rohrich RJ, Ahmad J. Rhinoplasty. *Plast Reconstr Surg*. 2011 Aug;128(2):49e-73e. doi: 10.1097/PRS.0b013e31821e7191.
40. Cochran CS, Landecker A. Prevention and management of rhinoplasty complications. *Plast Reconstr Surg*. 2008 Aug;122(2):60e-67e. doi: 10.1097/PRS.0b013e31817d53de.
41. Rettinger G. Risks and complications in rhinoplasty. *GMS Curr Top Otorhinolaryngol Head Neck Surg*. 2007;6:Doc08. Epub 2008 Mar 14. PMID: 22073084; PMCID: PMC3199839.
42. Heilbronn C, Cragun D, Wong BJF. Complications in Rhinoplasty: A Literature Review and Comparison with a Survey of Consent Forms. *Facial Plast Surg Aesthet Med*. 2020 Jan/Feb;22(1):50-56. doi: 10.1089/fpsam.2019.29007.won.
43. Shin CH, Jang YJ. Factors Affecting the Complication Rate of Septoplasty: Analysis of 1,506 Consecutive Cases of Single Surgeon. *Facial Plast Surg*. 2023 Aug;39(4):387-392. Doi: 10.1055/a-1990-2818.
44. Alghamdi FS, Albogami D, Alsurayhi AS, Alshibely AY, Alkaabi TH, Alqurashi LM, Alahdal AA, Saber AA, Almansouri OS. Nasal Septal Deviation: A Comprehensive Narrative Review. *Cureus*. 2022 Nov 10;14(11):e31317. Doi: 10.7759/cureus.31317.
45. Taha HI, Elgendy MS, Ezz MR, Tolba K, El Safty M, Azzawi MADA, Katamesh BE, Albazee E. Septoplasty versus non-surgical management for deviated nasal septum: a systematic review and meta-analysis of randomized controlled trials. *Eur Arch Otorhinolaryngol*. 2024 Sep 4. Doi: 10.1007/s00405-024-08937-x.
46. Oleck NC, Cason RW, Hernandez JA, Marcus JR, Phillips BT. Defining Our Terms: Are Postoperative Complications Adequately Defined in the Rhinoplasty Literature? *Aesthetic Plast Surg*. 2023 Jun;47(3):1155-1161. doi: 10.1007/s00266-022-03155-4.
47. Surgical correction of the nose (Rhinoplasty). Information in the Thieme Compliance System. Published by Thieme Compliance GmbH, Am Weichselgarten 30a, 91058 Erlangen, www.thieme-compliance.de.
48. Layliev J, Gupta V, Kaoutzanis C, Ganesh Kumar N, Winocour J, Grotting JC, Higdon KK. Incidence and Preoperative Risk Factors for Major Complications in Aesthetic Rhinoplasty: Analysis of 4978 Patients. *Aesthet Surg J*. 2017 Jul 1;37(7):757-767. doi: 10.1093/asj/sjx023.
49. Georgiou I, Farber N, Mendes D, Winkler E. The role of antibiotics in rhinoplasty and septoplasty: a literature review. *Rhinology*. 2008 Dec;46(4):267-70. PMID: 19145993.
50. Yoo DB, Peng GL, Azizzadeh B, Nassif PS. Microbiology and antibiotic prophylaxis in rhinoplasty: a review of 363 consecutive cases. *JAMA Facial Plast Surg*. 2015 Jan-Feb;17(1):23-7. doi: 10.1001/jamafacial.2014.1021.
51. Beekhuis GJ. Nasal obstruction after rhinoplasty: etiology, and techniques for

- correction. *Laryngoscope*. 1976 Apr;86(4):540-8. doi: 10.1288/00005537-197604000-00010.
52. Sidle D, Hicks K. Nasal Obstruction Considerations in Cosmetic Rhinoplasty. *Otolaryngol Clin North Am*. 2018 Oct;51(5):987-1002. doi: 10.1016/j.otc.2018.05.011.
53. Adamson P, Smith O, Cole P. The effect of cosmetic rhinoplasty on nasal patency. *Laryngoscope*. 1990 Apr;100(4):357-9. doi: 10.1288/00005537-199004000-00005.
54. Allis TJ, Leopold DA. Smell and taste disorders. *Facial Plast Surg Clin North Am*. 2012 Feb;20(1):93-111. doi: 10.1016/j.fsc.2011.10.011.
55. Champion R. Anosmia associated with corrective rhinoplasty. *Br J Plast Surg*. 1966 Apr;19(2):182-5. doi: 10.1016/s0007-1226(66)80030-9.
56. Goldwyn RM, Shore S. The effects of submucous resection and rhinoplasty on the sense of smell. *Plast Reconstr Surg*. 1968 May;41(5):427-32. doi: 10.1097/00006534-196805000-00002.
57. Bafaqeeh SA, al-Qattan MM. Alterations in nasal sensibility following open rhinoplasty. *Br J Plast Surg*. 1998 Oct;51(7):508-10. doi: 10.1054/bjps.1997.0296.
58. Thompson AC. Nasal tip numbness following rhinoplasty. *Clin Otolaryngol Allied Sci*. 1987 Apr;12(2):143-4. doi: 10.1111/j.1365-2273.1987.tb00177.x.
59. Jaberoo MC, De Zoysa N, Mehta N, Prasad V, Heywood R, Saleh H, Marais J. A twin-center study of nasal tip numbness following septorhinoplasty or rhinoplasty. *Ear Nose Throat J*. 2016 Feb;95(2):E18-21. doi: 10.1177/014556131609500206.
60. Tracy LE, Badran K, Siaghani P, Wong BJ. Dorsal nasal mucocele: a delayed complication of rhinoplasty. *Aesthetic Plast Surg*. 2014 Feb;38(1):100-103. doi: 10.1007/s00266-013-0233-y.
61. Giacomini PG, Topazio D, Di Mauro R, Mocella S, Chimenti M, Di Girolamo S. Unusual postrhinoplasty complication: nasal dorsum cyst. *Case Rep Otolaryngol*. 2014;2014:617424. doi: 10.1155/2014/617424.
62. Christophel JJ, Park SS. Complications in rhinoplasty. *Facial Plast Surg Clin North Am*. 2009 Feb;17(1):145-56, vii. doi: 10.1016/j.fsc.2008.09.012.
63. Vila PM, Jeanpierre LM, Rizzi CJ, Yaeger LH, Chi JJ. Comparison of Autologous vs Homologous Costal Cartilage Grafts in Dorsal Augmentation Rhinoplasty: A Systematic Review and Meta-analysis. *JAMA Otolaryngol Head Neck Surg*. 2020 Apr 1;146(4):347-354. doi: 10.1001/jamaoto.2019.4787.
64. Gunter, J. P., & Cochran, C. S. (2006). Management of intraoperative fractures of the nasal septal "L-strut": Percutaneous Kirschner wire fixation. *Plastic and reconstructive surgery*, 117(2), 395-402. <https://doi.org/10.1097/01.prs.0000200804.16112.7b>
65. Liang X, Wang K, Malay S, Chung KC, Ma J. A systematic review and meta-analysis of comparison between autologous costal cartilage and alloplastic materials in rhinoplasty. *J Plast Reconstr Aesthet Surg*. 2018 Aug;71(8):1164-1173. doi: 10.1016/j.bjps.2018.03.017.
66. Holt GR, Garner ET, McLarey D. Postoperative sequelae and complications of rhinoplasty. *Otolaryngol Clin North Am*. 1987 Nov;20(4):853-76. PMID: 3320872.37. Hallock GG, Trier WC. Cerebrospinal fluid rhinorrhea following rhinoplasty. *Plast Reconstr Surg*. 1983;71(1):109-13.
67. Casaubon JN, Dion MA, Larbrisseau A. Septic cavernous sinus thrombosis after rhinoplasty: case report. *Plast Reconstr Surg*. 1977 Jan;59(1):119-23. doi: 10.1097/00006534-197701000-00027.
68. Lawson W, Kessler S, Biller HF. Unusual and fatal complications of

- rhinoplasty. *Arch Otolaryngol*. 1983 Mar;109(3):164-9. doi: 10.1001/archotol.1983.00800170030008.
69. Wheeler R. The evolution of informed consent. *Br J Surg*. 2017 Aug;104(9):1119-1120. doi: 10.1002/bjs.10520.
70. Oosthuizen JC, Burns P, Timon C. The changing face of informed surgical consent. *J Laryngol Otol*. 2012 Mar;126(3):236-9. doi: 10.1017/S0022215111003021.
71. Lund VJ, Wright A, Yiotakis J. Complications and medicolegal aspects of endoscopic sinus surgery. *J R Soc Med*. 1997 Aug;90(8):422-8. doi: 10.1177/014107689709000803.
72. Hosemann W, Draf C. Danger points, complications and medico-legal aspects in endoscopic sinus surgery. *GMS Curr Top Otorhinolaryngol Head Neck Surg*. 2013 Dec 13;12:Doc06. doi: 10.3205/cto000098.
73. Re M, Magliulo G, Romeo R, Gioacchini FM, Pasquini E. Risks and medico-legal aspects of endoscopic sinus surgery: a review. *Eur Arch Otorhinolaryngol*. 2014 Aug;271(8):2103-17. doi: 10.1007/s00405-013-2652-4.
74. Wolf JS, Malekzadeh S, Berry JA, O'Malley BW Jr. Informed consent in functional endoscopic sinus surgery. *Laryngoscope*. 2002 May;112(5):774-8. doi: 10.1097/00005537-200205000-00002.
75. Mazur DJ, Hickam DH. Patients' preferences for risk disclosure and role in decision making for invasive medical procedures. *J Gen Intern Med*. 1997 Feb;12(2):114-7. doi: 10.1046/j.1525-1497.1997.00016.x.
76. Sharp HR, Crutchfield L, Rowe-Jones JM, Mitchell DB. Major complications and consent prior to endoscopic sinus surgery. *Clin Otolaryngol Allied Sci*. 2001 Feb;26(1):33-8. doi: 10.1046/j.1365-2273.2001.00394.x.
77. Snissarenko EP, Church CA. Informed consent process and patient communication after complications in sinus surgery. *Otolaryngol Clin North Am*. 2010 Aug;43(4):915-27. doi: 10.1016/j.otc.2010.04.015.
78. Bowden MT, Church CA, Chiu AG, Vaughan WC. Informed consent in functional endoscopic sinus surgery: the patient's perspective. *Otolaryngol Head Neck Surg*. 2004 Jul;131(1):126-32. doi: 10.1016/j.otohns.2004.02.027.
79. Colloca L. Tell Me the Truth and I Will Not Be Harmed: Informed Consents and Nocebo Effects. *Am J Bioeth*. 2017 Jun;17(6):46-48. doi: 10.1080/15265161.2017.1314057.
80. Lekakis G, Claes P, Hamilton GS 3rd, Hellings PW. Three-Dimensional Surface Imaging and the Continuous Evolution of Preoperative and Postoperative Assessment in Rhinoplasty. *Facial Plast Surg*. 2016 Feb;32(1):88-94. doi: 10.1055/s-0035-1570122.
81. Wolf JS, Chiu AG, Palmer JN, O'Malley BW Jr, Schofield K, Taylor RJ. Informed consent in endoscopic sinus surgery: the patient perspective. *Laryngoscope*. 2005 Mar;115(3):492-4. doi: 10.1097/01.mlg.0000157835.69121.f8.
82. Eltorai AE, Ghanian S, Adams CA Jr, Born CT, Daniels AH. Readability of patient education materials on the american association for surgery of trauma website. *Arch Trauma Res*. 2014 Apr 30;3(2):e18161. doi: 10.5812/atr.18161.
83. Examining the Reading Level of Internet Medical Information for Common Internal Medicine Diagnoses. Hutchinson, Nora et al. *The American Journal of Medicine*, Volume 129, Issue 6, 637 - 639
84. Hakimi AA, Standiford L, Chang E, Wong BJ. Development and Assessment of a Video-Based Intervention to Improve Rhinoplasty Informed Consent. *Facial Plast Surg*. 2021 Oct;37(5):585-589. doi: 10.1055/s-0041-1722912.
85. Theeling T, Djouder C, Laurens H, Preyra JH, Shire CME, Van Staeyen E,

Hellings, 10 May 2024

Conti DM, Scadding GK and Hellings PW (2024) Nasal polyp syndrome: a patient-centred term for CRSwNP by EUFOREA. *Front. Allergy* 5:1372919. doi: 10.3389/falgy.2024.1372919.

CORRESPONDING AUTHOR

Prof. Dr. Peter W. Hellings
University of Leuven
Herestraat 49
3000 Leuven, Belgium
+32 16 33 23 40
peter.hellings@kuleuven.be

E-mail and ORCID ID:

Hellings P.W.: peter.hellings@kuleuven.be / 0000-0001-6898-688X
Bertossi D.: dario.bertossi@univr.it / 0000-0002-8635-9967
Cingi C.: ccingi@gmail.com / 0000-0003-3934-5092
Claeys S.: Sem.Claeys@UGent.be / 0000-0001-6195-5618
Constantinidis J.: janconst@otenet.gr / 0000-0002-2369-993X
Conti D.M.: diego.conti@kuleuven.be / 0000-0002-8896-495X
D'Souza A.: ad@londonfacialsurgery.org /
Declau F.: nko@telenet.be / 0000-0001-6969-1565
Foda H.: dr.hossam.foda@gmail.com
Fokkens W.: w.j.fokkens@amsterdamumc.nl / 0000-0003-4852-229X
Gevaert P.: philippe.gevaert@ugent.be / 0000-0002-1629-8468
Gubisch W.: wolfganggubisch@t-online.de / 0000-0002-2692-7993
Halewyck S.: Stijn.Halewyck@uzbrussel.be / 0000-0002-4465-0588
Lekakis P.: philio.lekakis@gmail.com
Liva G.: Georgialiva21@gmail.com / 0000-0001-9050-447X
Mesbahi A.: alirezamesbahi@hotmail.com / 0000-0003-3870-1374
Mcintosh C.: cameron@drcameronmcintosh.com / 0000-0001-9448-754X
Nolst Trenité G.: nolsttrenite@gmail.com /
Picavet V.: valerie.picavet@gmail.com / 0000-0002-2441-8159
Prokopakis E.: eprokopakis@gmail.com / 0000-0002-1208-1990
Robotti E.: dr@enricorobotti.it / 0000-0001-5196-8212
Vandenbroeck S.: sebastian.vandenbroeck@gmail.com
Van Hoolst A.: annavanhoolst@hotmail.com / 0000-0001-9579-0743
Vansweevelt T.: thierry.vansweevelt@uantwerpen.be / 0000-0003-1788-2233
Wagner W.: wolfgang.wagner@muenchen-klinik.de

FIGURES

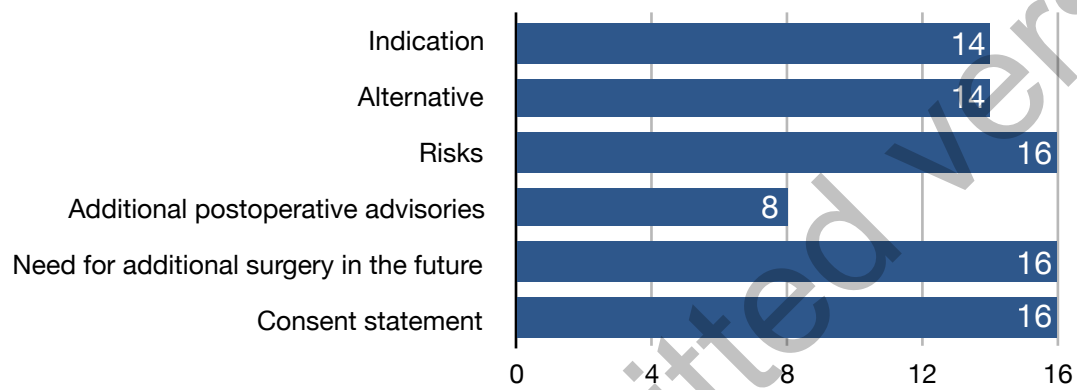


Figure 1. Overview of consent form contents.

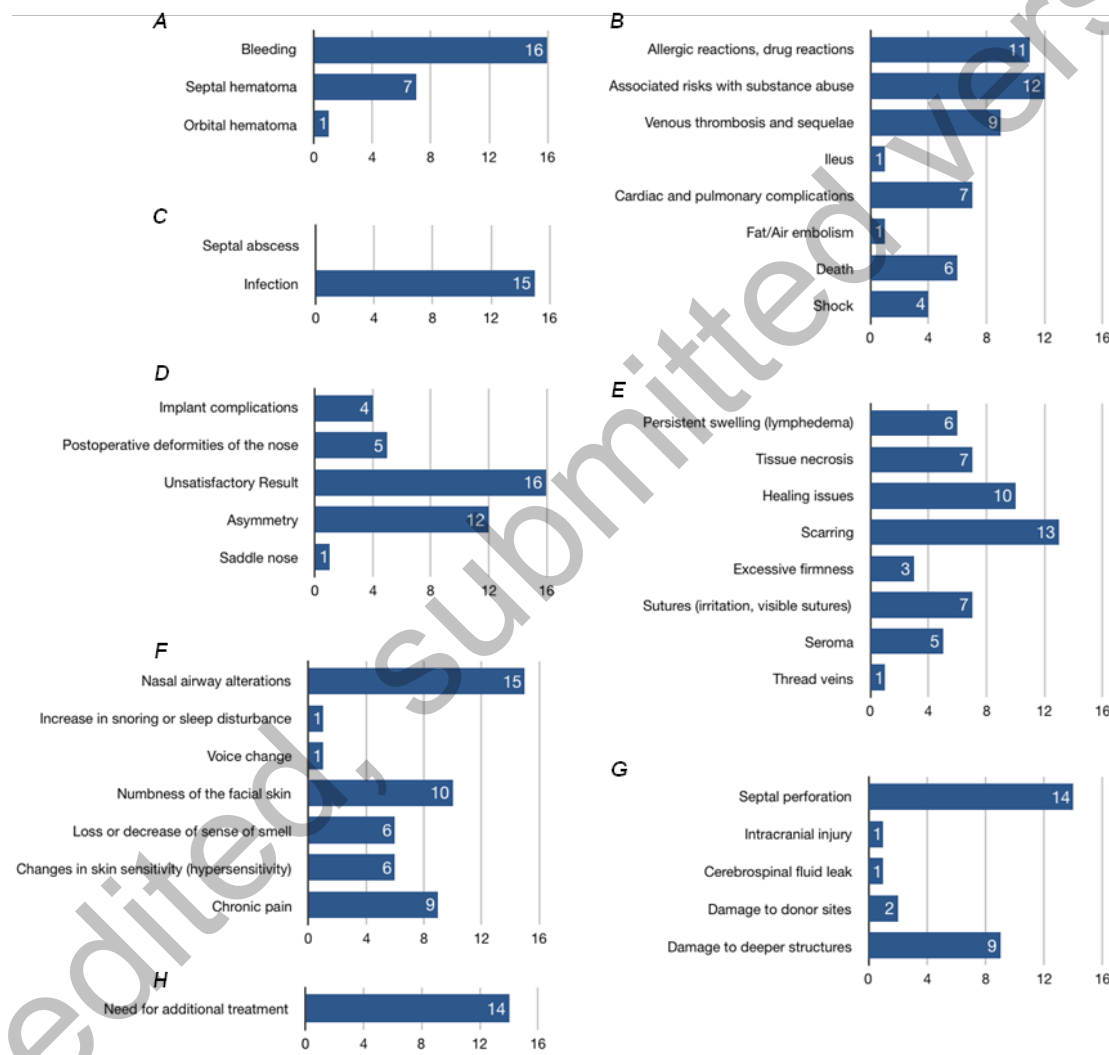


Figure 2. Specific complications mentioned by consent forms. A: Bleeding, B: Systemic complications, C: Infection, D: Aesthetic complications, E: Skin and soft tissue complications, F: Functional complications, G: Trauma, H: Other.

TABLES



Table 1:
Rhinoplasty
complications

COMPLICATION	MINOR Complications	MAJOR Complications
Bleeding	Minor epistaxis	<ul style="list-style-type: none"> Major epistaxis requiring surgical exploration Septal hematoma
Infection	Mild cellulitis	<ul style="list-style-type: none"> Severe cellulitis requiring hospitalisation Septal abscess Toxic shock syndrome Cavernous sinus thrombosis Implant infection
Trauma	Transient epiphora due to soft tissue oedema	<ul style="list-style-type: none"> L-strut fractures Lacrimal duct injury resulting in epiphora Intracranial injury Cerebrospinal fluid leak
Functional issues	<ul style="list-style-type: none"> Transient nasal obstruction Intranasal synechiae (Asymptomatic) septal perforation Temporary hyposmia 	<ul style="list-style-type: none"> Residual or new nasal obstruction Anosmia Persistent reduced nasal function Chronic rhinitis Numbness of the face / upper lip (larger area)
Aesthetic issues		<ul style="list-style-type: none"> Implant extrusion, distortion, resorption Postoperative deformities of the nose
Skin and soft tissue complications	<ul style="list-style-type: none"> Prolonged oedema Visible transcolumellar scar Contact dermatitis 	<ul style="list-style-type: none"> Tissue necrosis Post-rhinoplasty cysts

Table 1. Rhinoplasty complications ⁽³⁹⁻⁴²⁾.

**TABLE 2: RISKS OF RHINOPLASTY**

Type of injury	Intraoperative risks	Postoperative risks
Bleeding	Bleeding	<ul style="list-style-type: none"> • Epistaxis • Septal hematoma • Orbital hematoma
Infection		<ul style="list-style-type: none"> • Local infection of the nose (tip, septum, dorsum) • Implant infection • Toxic shock syndrome • Cavernous sinus thrombosis
Trauma	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Unsatisfactory result • Postoperative deformities of the nose • Implant extrusion, distortion, resorption • Asymmetry
Skin and soft tissue complications		<ul style="list-style-type: none"> • Tissue necrosis • Post-rhinoplasty cysts • Lymphoedema • Healing issues • Scarring • Excessive firmness • Sutures (irritation, visible sutures) • Seroma
Systemic complications	<ul style="list-style-type: none"> • Shock • Death 	
Other complications		Need for additional treatment or surgery

Table 2. Risks of rhinoplasty.