

Analysis of functional and aesthetic outcomes in external septorhinoplasty: study protocol

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ABSTRACT

Objective: In an otorhinolaryngology setting, a septorhinoplasty is frequently performed for both functional and aesthetic reasons. Therefore, pre- and postoperative evaluation of patient satisfaction regarding their nasal appearance and functional result is paramount.

Methods: This prospective observational, longitudinal outcome cohort study in a single private hospital center will involve 30 patients. All the participants, aged 18 years or over, are patients undergoing an external septorhinoplasty for both functional and aesthetic reasons. To assess the postoperative functional and aesthetic outcome in these patients, patient-related outcome measures (NOSE scale, FACE-Q, and Utrecht Questionnaire) as well as functional nasal measurements (nasal anterior rhinomanometry, acoustic rhinometry, and peak nasal inspiratory flow) will be carried out. In addition, the psychological profile of the patient will be measured by a specific screening tool (BDDQ-AS) regarding the presence or absence of a body dysmorphic disorder. The primary outcomes of this study include longitudinal postoperative changes in nasal obstruction and aesthetic satisfaction. Secondary outcomes include the correlation between the different patient-related outcome measures, the correlation of the Nasal Obstruction Symptom Evaluation (NOSE) scale with the functional tests and functional tests with the surgical methods used. The outcomes will be assessed at baseline (inclusion), and at 3, 6, and 12-months post intervention (postoperatively). In addition, the correlation between postoperative aesthetic satisfaction and the presence of body dysmorphic disorder will be assessed at 6 months post intervention.

Results: To our best knowledge, this is the first study correlating different patient-related quality of life questionnaires in septorhinoplasty, both aesthetic as well as functional, with all current types of objective nasal measurements. This study will also measure the impact of the psychological profile of the patient as related to body dysmorphic disorder on the aesthetic outcome.

Conclusion: The results of this study aim to provide a deeper insight into the functional and aesthetic satisfaction of patients undergoing an external septorhinoplasty.

Keywords: Body dysmorphic disorder, external septorhinoplasty, FACE-Q, NOSE scale, patient-related outcome measures, study protocol, Utrecht Questionnaire

Introduction

In an ENT (Ear Nose Throat) setting, septorhinoplasty (SRP) is performed for both functional and aesthetic reasons. One of the most difficult parts of SRP is to measure the outcomes after surgery (1). Patients who undergo this type of surgery frequently appreciate the aesthetic aspect of the procedure even though the initial indication was mainly the improvement of functional complaints (i.e. nasal blockage). It was found that meeting the aesthetic requirements, frequently not put forward by the patient preoperatively, was the single most important factor required for complete satisfaction, along with the overall surgical results, in this population (2). According to Saleh et al. (1), SRP is

a unique operation because the surgeon affects three aspects: shape, function, and psychological profile of the patient.

SRP procedures have considerably changed in the last decades from a standardized reduction procedure to a complex problem-oriented procedure (3). Surgical techniques for enhancing nasal airflow may have undesirable aesthetic consequences and vice versa. Therefore, pre- and postoperative evaluation of patients' 'total' satisfaction regarding their nasal appearance and functional result is paramount.

In recent years, there is an increasing trend to use health-related quality of life questionnaires (patient reported outcome

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measures: PROMs) after surgical procedures. The use of validated subjective scoring tools is strongly advised for future studies on this subject to enhance the reliability of conclusions concerning the correlation between objective and subjective outcomes (1, 4). Based on the systematic review of van Zijl et al. (5), the Nasal Obstruction Symptom Evaluation (NOSE) instrument, FACE-Q rhinoplasty module, and Utrecht Questionnaire (UQ) were chosen as questionnaires for patient satisfaction assessment on function and aesthetics respectively. Although none of the existing nasal questionnaires are completely adequate according to COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) standards, both NOSE and FACE-Q have sufficient structural validity and internal consistency to be used (5). UQ demonstrated a high construct validity and responsiveness, although its internal consistency and structural validity have not been tested yet (5).

COSMIN is an initiative of an international multidisciplinary team of researchers who aim to improve the selection of outcome measurement instruments both in research and in clinical practice by developing tools for selecting the most appropriate available instrument (6). In the United Kingdom, the Royal College of Surgeons Interspecialty Committee has also recommended the adoption of the FACE-Q for rhinoplasty (6, 7).

The FACE-Q is a multimodular PROM that includes a set of independently functioning scales and checklists designed to measure concepts that matter to people having any form of facial aesthetic treatment. FACE-Q scales are part of the Q-PROM series that also includes BREAST-Q and BODY-Q (8, 9). FACE-Q was developed by Klassen et al. (10, 11) in 2010 as a validated psychometric evaluation instrument for patients undergoing aesthetic surgery. In 2016 this questionnaire was also specifically validated for rhinoplasty outcome. In the present study, the FACE-Q rhinoplasty module for the appearance of the nose and nostrils have been used.

The Utrecht questionnaire has been developed by Lohuis et al. (12) and focuses on aesthetic SRP in female patients. According to Saleh et al. (1), two questions are in place to identify patients who suffer from body dysmorphic disorder (BDD). However, there is no evaluation between the BDD trick questions and formal assessments for BDD (1).

The NOSE score was developed by Stewart et al. (13) in 2004 as the first validated questionnaire for the assessment of subjective nasal obstruction. According to Menger et al. (14), there

is a significant correlation between the NOSE instrument on the one hand and peak nasal inspiratory flow and anterior rhinometry on the other.

The Body Dysmorphic Disorder Questionnaire-Aesthetic Surgery (BDDQ-AS) will be introduced to measure the psychological profile of the patients. Body dysmorphic disorder (BDD) is a well-established psychiatric disorder defined as an excessive concern about an imagined or slight defect in physical appearance, leading to significant distress and/or impairment in one or more important areas of functioning. Lekakis et al. (15) has recently published a validated screening tool for BDD in SRP patients. They had two main references: (1) Body Dysmorphic Disorder Questionnaire (BDDQ) and (2) BDDQ-Dermatology Version (BDDQ-DV). The BDDQ-AS was intended to be a screening instrument and not a diagnostic one. When compared to the results of the Rhinoplasty Outcome Evaluation (ROE) questionnaire and the visual analogue scale on assessing self-satisfaction with nasal appearance, they found that BDDQ-AS positive patients were less satisfied after surgery compared to BDDQ-AS negative patients.

Some PROMs, such as the Rhinoplasty Outcome Evaluation (ROE), Sino-nasal Outcome Test (SNOT-23), Functional Rhinoplasty Outcome Inventory (FROI-17), and Rhinoplasty Health Inventory and Nasal Outcomes (RHINO) have integrated questions on both functional and aesthetic domains in one sum score. However, it is preferable to measure functional and aesthetic outcome separately (5). As the initial context in an ENT or a plastic surgery practice may be different, most rhinoplasty practices focus on either construct rather than the two equally distributed.

Until now, the correlation between the outcomes found with objective nasal tests and an individual's subjective sensation of nasal patency remains uncertain (4). There is no consensus about the correlation between objective nasal measurements and subjective nasal patency symptoms.

It is important to understand that subjective and objective measurements determine different physical and biological properties. The different evaluation methods look at various aspects of nasal ventilation, and thus they must be viewed as complementary rather than contradictory (16). As stated by Braun et al. (17) and Menger et al. (14), all objective variables should be assessed in patients with nasal pathologies.

Since these objective tests have different informative value, we will apply all three tests on our patient population in this study:

Acoustic rhinometry (AR) is a static test.

1. Nasal active anterior rhinomanometry (NAR) and rhinore-sistometry (RRM) are low flow dynamic tests.
2. Peak nasal inspiratory flow (PNIF) is a high flow dynamic test (14).
3. In our daily practice, these measurements are also utilized as part of standard care.

By combining all currently available nasal measurements and PROMs, measuring both functional and aesthetic outcome as

Main Points:

- External septorhinoplasty affects shape, function of the nose and psychology of the patient.
- The effect of body dysmorphic disorder on the outcome of external septorhinoplasty will be analysed.
- Analyzing functional and aesthetic outcomes after septorhinoplasty could provide further recommendations and selection criteria for the evaluation and treatment of rhinoplasty patients.

well as a screening of the psychological profile of our patients, our aim is to gain a more profound understanding of the patient's profile in SRP.

Methods

The study design will be a prospective observational longitudinal outcome cohort study in a single private hospital center. This protocol has been registered at the Clinicaltrials.gov and approved by the Ethics committee from GZA hospitals (approval number: 190301ACADEM). Patients are recruited from the ENT outpatient department of the St. Vincentius Hospital in Antwerp, Belgium. All clinical procedures in this study are standard of care. All subjects undergo a standardized nasal history and physical exam including nasal endoscopy preoperatively and as required by their medical situation postoperatively.

Patients will be assessed for eligibility by one of the investigators. The eligible participants will receive information about the study protocol and written informed consent will be obtained. The investigator will explain the protocol verbally and answer the participants' questions before obtaining written informed consent. Participants eligible for external SRP will consecutively be enrolled in the study according to CONSORT guidelines (18). Those patients who do not meet the inclusion criteria will be excluded.

Inclusion Criteria

Participants included in this study will undergo an external SRP for both functional and aesthetic reasons, with symptoms of nasal obstruction for at least 1 year that is the result of an identifiable anatomical cause such as septal deviation, turbinate hypertrophy, internal or external valve collapse. Participants must be aged 18 years or over.

Exclusion Criteria

Participants will be excluded from this study for the following reasons: if they are mentally or physically incapable to answer the questionnaires; if they have had a nasal fracture or surgery in the past year; if they have used nasal cocaine in the past year; if they are younger than 18 years.

Sample Size

Previous studies concerning the effect of SRP surgery on PROMs such as the NOSE scale, Face-Q, and functional tests (NAR and AR), showed an effect size of approximately 1.5 SD (Cohen's D). Since the current study will be carried out on a very heterogeneous population, representing a mixture of different ages, ethnic groups, and socio-economic backgrounds, we need to account for a possible lower effect size than previously reported. Assuming an effect size of 0.75 SD in our population, a sample size of 25 individuals, of which both the pre- and post-measurements are available, would offer a power of 80% at a significance level of 0.01 in a paired t-test. Accounting for a possible drop-out of 20%, we would propose a sample size of 30 individuals to be followed up longitudinally. The sample size calculation was performed using program R version 3.5.3.

Patient Demographics

Age, gender, ethnic background, prior history of topical steroid

use, effect of topical steroids, smoking, nasal surgery, nasal fracture, and self-reported patient comorbidities (respiratory allergies, sinus problems, snoring, and/or obstructive sleep apnea with and without continuous positive airway pressure use) as well as the surgical report will be tracked prospectively in the data repository.

Surgical Data

This includes all the technical procedures undertaken during external SRP. External SRP was defined as a surgical procedure to repair defects or deformities of both the nasal septum and the external nasal pyramid through an external incision at the columella.

FACE-Q Rhinoplasty Module

The FACE-Q for rhinoplasty is a multidimensional measurement that evaluates appearance and adverse effects related to the nasal appearance after rhinoplasty (11). In the present study, two items of the FACE-Q instrument (satisfaction with nose and satisfaction with nostrils) will be used. It contains a 10-item satisfaction with nose scale and a 5-item satisfaction with nostrils scale, both of which measure the respondent's satisfaction with the size, width, length, and appearance of their nose and nostrils, respectively, in profile and photos. The FACE-Q is a self-administered questionnaire in which the evaluation can be performed in a paper-pencil format or via a secure web-based application. Items in both the satisfaction scales are responded to as 1) very dissatisfied, 2) somewhat dissatisfied, 3) somewhat satisfied, and 4) very satisfied. The scores of the subscales 'satisfaction with the nostrils' and 'satisfaction with the nose' are converted by a validated Rasch transformation table into a score: 5) between 0 (worst) and 100 (best).

Nose Obstruction Symptom Evaluation (NOSE) scale

NOSE scale is a disease-specific, self-completed questionnaire for the assessment of quality of life related to nasal obstruction. It was initially developed and validated to evaluate the treatment of nasal obstruction with a particular focus on assessing the effectiveness of septoplasty. The NOSE scale goes from 0 (no nasal obstruction) to 100 (severe nasal obstruction).

Utrecht Questionnaire (UQ)

The UQ measures the body experience regarding SRP and captures the answers to five concise questions including a visual analogue scale. The questions are responded to as: 1) not at all, 2) a little, 3) moderate, 4) much or often, and 5) very much or often. The visual analogue scale assessing self-satisfaction with nasal appearance ranges from very ugly [0] to very nice [10].

Body Dysmorphic Disorder Questionnaire-Aesthetic Surgery (BDDQ-AS)

The BDDQ-AS is a screening tool for BDD symptoms in an aesthetic SRP population with a sensitivity of 89.6% and a specificity of 81.4% to identify patients with at least moderate BDD symptoms (15). This questionnaire is given to a patient 6 months postoperatively to ensure that patient selection bias is not introduced preoperatively.

Acoustic Rhinometry

Acoustic rhinometry is based on the analysis of sound waves reflected from the nasal cavity. By sending a sound pulse

into the nose and recording and analyzing the reflected sound, a two-dimensional picture of the nasal cavity is created, from which the volume and the geometry of the nasal cavity can be deduced. The main benefit of acoustic rhinometry is its capacity to identify the narrowest part of the nasal cavity or minimal cross-sectional area (MCA). This usually corresponds to the nasal valve area or the head of the inferior turbinate.

Peak Nasal Inspiratory Flow (PNIF)

This measure is considered to be reliable, reproducible, inexpensive, fast, and easy to perform. The PNIF (L/min) is measured for each nostril separately. The patient must be encouraged to inhale as hard and fast as he can through the mask keeping the mouth closed starting from the end of a full expiration (residual volume method). Three satisfactory maximal inspirations are usually obtained and the highest of these results is taken as the PNIF. The measurement should be done while standing.

Nasal Anterior Rhinomanometry (NAR) and Rhinostometry (RRM)

The patient actively breathes through one nasal cavity while the transnasal pressure, or difference in pressure from the naris to the nasopharynx, is measured with a pressure probe placed in the contralateral nostril. The nasal airflow at 150 kPa is recorded for each nostril separately (mL/sec) as along with the nasal resistance (kPa/mL) at a flow of 250 mL/sec and the hydraulic diameter (mm) (19).

Primary Outcomes

Pre- and postoperative changes in aesthetic satisfaction using FACE-Q

- Pre- and postoperative changes in aesthetic satisfaction using UQ
- Pre- and postoperative changes in nasal obstruction using NOSE questionnaire
- Pre- and postoperative changes in nasal obstruction using acoustic rhinometry
- Pre- and postoperative changes in nasal obstruction using PNIF
- Pre- and postoperative changes in nasal obstruction using and rhinostometry

• Secondary Outcomes

- Correlation between NOSE questionnaire (PROM) and nasal functional tests (AR, NAR, RRM, PNIF)
- Correlation between the questionnaires measuring aesthetic satisfaction: FACE-Q and UQ
- Correlation between BDDQ-AS and postoperative aesthetic satisfaction as measured by FACE-Q and UQ
- Correlation between change of nasal functional tests (AR, NAR, RRM, PNIF) and surgical methods used

Data Collection and Management

Outcomes will be assessed preoperatively (baseline) and at 3, 6, and 12 months postoperatively. BDDQ-AS will be measured once at 6 months post intervention to avoid patient selection bias. All clinical data from the patients are stored in the electronic patient data system (EPD) on a secure server of the hospital. Patients' data are anonymized before they are entered into the subject data matrix of the data depos-

itory. The anonymization file is kept in a password secured file (MS Excel, Microsoft), saved on a secure hospital server and is only available to the research members of the present study. The anonymized dataset of the questionnaires and measurements will be stored in a secured MS Excel file. The anonymized surgical data will be stored in a database (Filemaker, Claris International Inc). Both datasets are stored on a secure hospital server. No information about individual participants will be reported in any publication and/or presentation. All analyses will be performed using the Statistical Package for Social Sciences version 25.0 software (IBM Corp.; Armonk, NY, USA) and R version 3.5.2. Standard descriptive analyses will be performed. For comparison of pre- and postoperative outcomes, a paired t-test will be used. P values less than 0.01 will be considered significant. The preoperative and postoperative mean of FACE-Q, UQ, and NOSE scores and functional measurements (NAR, AR, RRM, and PNIF) at various time points will be modeled using linear mixed models. The outcomes at different time points will be compared using a posthoc analysis with Tukey's correction for multiple hypothesis testing. The relation between the continuous variables will be modeled using linear regression and expressed using Pearson's correlation coefficient. Correlation analysis will be performed using Spearman's rank correlation and linear regression. To explore the relationship between functional results and surgical techniques, a cluster analysis will be performed.

Discussion

We have presented here the design and rationale for this trial. As SRP is one of the most frequently performed operations in facial plastic surgery, it is important to prove the success of the operation by validated measurable parameters. Patient satisfaction is of utmost importance in this instance than in any other type of operation. Till date, the study design and measurement instruments employed in research studies regarding SRP were remarkably diverse, yielding difficulties in the interpretation of data. Only one study appears to have compared objective nasal measurements with aesthetic results before and after SRP (20). However, the authors used only rhinomanometry as an objective test apart from NOSE and ROE questionnaires as patient-related outcome measures. As pointed out by van Zijl et al. (5), ROE has integrated questions on both functional and aesthetic domains in one sum score. However, it is preferable to measure functional and aesthetic outcomes separately (5).

Patient-reported outcome measures are increasingly being used to incorporate the perspective of the patient into the outcome assessments and are helpful to understand both physical and psychological concerns of the patient (21). For a better understanding of the patients' needs, this information hopefully will help us guide clinical management in the future. Quantifying patient satisfaction also allows the surgeon to compare different surgical techniques to assess which approach has the best outcome.

The strength of this study includes the combination of both subjective evaluation with different kinds of available questionnaires and extensive objective nasal measurements in relation to the psychological profile of the patient. The re-

sults of the present study will provide extensive knowledge on the 'total' satisfaction of patients undergoing an external SRP from a functional, aesthetic, as well as a psychological viewpoint. One of the main steps before SRP is to reveal the psychology of the patient and try and understand the demands of the patient. BDD should ideally be identified in all patients before surgery. This would be the most efficient way to avoid the situation of a dissatisfied patient and an unhappy surgeon (1). Only recently have large-scale studies confirmed the longstanding impression that BDD and BDD symptoms are much more common in patients seeking aesthetic treatment (22).

The prospective nature of this study will ensure accurate data collection as well as an appropriate follow-up time. The measurements performed in our study are standard care and used routinely in daily practice. However, there is still a debate on their usefulness, and there is no consensus on the use of these tests, either with respect to indications or normative values (16). The correlation of subjective sensation of nasal obstruction with objective tests such as AR, NAR, RRM, and PNIF remains controversial. Our study may provide further evidence of their use in SRP.

As reported above, this trial is focused on patient satisfaction. The physician's view, though important, is not included in the present study because of considerable estimator bias. Furthermore, the allocation of a control group would not be meaningful and probably even unethical in the present pre- and post-operative evaluation of SRP patients.

Although we are convinced that a follow-up of one year is appropriate, a longer follow-up period could be helpful to evaluate the long-term satisfaction of the patient.

External SRP is a unique operation because it affects three aspects: shape and function of the nose and psychology of the patient. This study includes a combination of both subjective aesthetic and functional evaluations and extensive objective nasal measurements in relation to his/her psychological profile as related to body dysmorphic disorder. The results of this study aim to provide a better understanding on the 'total' satisfaction of patients undergoing an external SRP. To our knowledge, this is the first study comparing different types of objective nasal measurements to patient-related quality of life measurements in this type of surgery. Analyzing functional and aesthetic outcomes after SRP could provide further recommendations and selection criteria for the evaluation and treatment of rhinoplasty patients in the future.

Ethics Committee Approval: Ethics committee approval was received for this study from GZA hospitals (Approval No: 190301ACADEM)

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – F.D., V.V.; Design – F.D., V.V.; Supervision – F.D.; Resources – F.D., Materials – F.D., V.V.; Data Collection and/or Processing – F.D., V.V., L.P., E.F.; Analysis and/or Interpretation

– F.D., V.V., E.F.; Literature Search – L.D., V.V., F.D.; Writing Manuscript – L.D., V.V., F.D.; Critical Review – F.D.

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