Original Investigation

Assessment of Surgical Results in Patients With Empty Nose Syndrome Using the 25-Item Sino-Nasal Outcome Test Evaluation

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IMPORTANCE Empty nose syndrome (ENS) is an iatrogenic disorder, which severely affects the normal nasal breathing function. People affected by ENS may experience decreased productivity and lifestyle disruption. The 20-Item Sino-Nasal Outcome Test (SNOT-20) is a validated quality-of-life measurement and can be used to compare before and after intervention outcomes.

OBJECTIVES To evaluate the effectiveness of the Medpor implant (Porex Surgical Inc) to improve the disease-specific quality of life in patients with ENS and to validate the 25-Item SNOT (SNOT-25) as an assessment tool in patients with ENS.

DESIGN, SETTING, AND PARTICIPANTS We prospectively enrolled 24 patients from our hospital who received inferior turbinate reconstruction surgery after drug therapy failed to improve their symptoms.

INTERVENTIONS All the patients underwent submucosal Medpor implant surgery to reconstruct their inferior turbinate.

MAIN OUTCOMES AND MEASURES Patient assessments were based on the SNOT-25 questionnaire prior to surgery and at 3, 6, and 12 months after surgery.

RESULTS The total scores of the SNOT-25 declined postoperatively, showing a significant difference at 3, 6, and 12 months after surgery compared with their initial visit ($P = .045$, $P < .001$, and $P < .001$, respectively). The 5 items most frequently reported by patients as important at their initial visit were "fatigue," "reduced concentration," "sadness," "dryness," and "nose is too open." The mean overall scores for these 5 important items also declined, showing statistically significant decreases compared with their initial visit ($P < .05$) and indicating that the items patients believed were important had improved.

CONCLUSIONS AND RELEVANCE Medpor implant surgery in patients with ENS is associated with statistically significant improvements in disease-specific quality of life measures. The modified version of SNOT-20 Health Survey Scales, the SNOT-25, may be a useful measurement tool in patients with ENS.

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Empty nose syndrome (ENS) is an iatrogenic disorder most often recognized by the presence of paradoxical nasal obstruction despite an objectively wide nasal fosse.[1] Patients may experience ENS after undergoing inferior turbinate resection or middle turbinate resection; however, ENS is also associated in individuals who have normal turbinate tissue and intranasal volume. Not every patient undergoing a radical turbinate procedure experiences the debilitating symptoms of ENS, but once it occurs, ENS severely affects the normal breathing function of the nasal cavity. As in patients with atrophic rhinitis, patients with ENS experience primarily mucosal dryness, nasal congestion, facial pain and headache on inspiration, and excessive crusting and discharge, although the severity of these symptoms varies substantially among individuals.[2,3] Empty nose syndrome contributes to a significant number of sick days missed from work, decreased productivity, and lifestyle disruption.

Quality of life (QOL) is different from one's health status. Quality of life is the unique personal experience that reflects not only one's health status, but also other factors and circumstances pertaining to the patient's life that only he or she can describe.[4] Currently, the assessments of clinical outcome of ENS treatments mostly depend on objective indicators, such as computed tomographic scans and endoscopic or electronic nasopharyngoscopy imaging. There are few subjective assessments of the changes in QOL, which greatly limits the overall evaluation of ENS treatments. A specific instrument to measure QOL related to ENS is needed to evaluate morbidity, disease progress, and therapy impact more precisely. A health-related and disease-specific instrument for QOL evaluation called the 20-Item Sino-Nasal Outcome Test (SNOT-20) was created and validated for use to evaluate the impact of a variety of situations such as cystic fibrosis, otitis media, obstructive sleep apnea, and rhinosinusitis.[5-9] The SNOT-20 is a validated 20-item survey that examines general nasal symptoms and can be used to compare preintervention and postintervention outcomes. It describes the health burden of ENS and is sensitive to clinical changes. The SNOT-20 measures physical problems, functional limitations, and emotional consequences by asking participants to score 20 symptoms including the need to blow the nose, sneezing, runny nose, cough, postnasal discharge, thick nasal discharge, ear fullness, dizziness, ear pain, facial pain or pressure, difficulty falling asleep, waking up at night, and lack of sleep. The SNOT-25, developed by Houser in 2001,[8] is a modification of the SNOT-20 that measures 5 additional factors: "dryness," "difficulty with nasal breathing," "suffocation," "nose is too open," and "nasal crusting." This study used the SNOT-25 survey because the 5 additional items may evaluate the symptoms of patients with ENS better.[8] A variety of surgical procedures currently exist to relieve the symptoms of ENS[10-12]; however, few studies have been carried out that have investigated the association between surgical treatment and QOL of patients with ENS using a disease-specific questionnaire. The aim of present study was to assess the association between surgical treatment and disease-specific QOL of ENS patients using the SNOT-25 questionnaire.

Methods

Patients

In accordance with the current bioethical norms, all patients signed a written informed consent form to take part in the study, which was approved by the Institutional Ethics Board of Shanghai Jiao Tong University School of Medicine. We retrospectively reviewed 24 patients (18 men and 6 women) who underwent inferior turbinate surgical reconstructions with a Medpor implant (Porex Surgical Inc) and were followed up for a minimum of 3 months to a maximum of 2 years. The median follow-up period was 10.5 months. None of the patients referred to the study had absolute contraindications to surgery, and hence, all were included. The mean (range) age of the patients was 32.4 (18-64) years.

Enrollment criteria included (1) the characteristic symptoms of excessive airflow, paradoxical obstruction, nasal or facial pain on inspiration, excessive crusting or discharge, and depression; (2) a history of partial or total turbinectomy; and (3) partially or totally absent inferior turbinate tissue and abnormally wide nasal cavities, as revealed by endoscopic examination, and enlargement of the nasal cavities with destruction of the lateral nasal wall and bony destruction of the inferior turbinate, as revealed by computed tomography. Exclusion criteria included age below 18 years, pregnant and lactating patients, having systemic or localized diseases that might compromise the patient's health, and previous turbinate surgery less than 2 year prior to enrollment in this study.

Surgical Technique

Implantation was performed with local anesthesia (lidocaine, 1%, and epinephrine, 5 μg/mL), which was administered at the submucosa of the inferior turbinate and/or lateral nasal wall and/or nasal septum opposite the nasal concha. To create a submucosal pocket, an incision was made at the inferolateral side of the lateral nasal wall, just below the inferior turbinate remnant. For some seriously affected patients, the incision also extended to the mucosa of the nasal floor and/or nasal septum, opposite the site of the missing inferior turbinate. In these patients, the graft was placed at the septum or floor anteriorly. Care was taken not to obstruct the integrity of the submucoperiosteal flap in order to ensure good vascular supply, which promotes the survival of the implants. After elevating the submucoperiosteal flap, a pocket was filled with the surgical Medpor implant to create a neoturbinate. To simulate an inferior turbinate, the graft was also placed at the septum or floor anteriorly. The Medpor implants can be cut into different sized strips from a 13 × 38 × 3-mm piece depending on the volume of missing tissue to rebuild an appropriate inferior turbinate. On the basis of each individual's requirements, we implanted 1 to 4 pieces (3-13 × 20-38 × 3 mm) in each cavity. The implant was carefully positioned under endoscopic surveillance, and the pocket was closed with 1-0 silk braided sutures to keep it in position. Vaseline gauze packing was placed on it for 2 days, and the patients received prophylactic antibiotics for 1 week following implantation.

Health Outcome Measures

The SNOT-20 consists of 20 items to assess 10 symptoms and 10 social and emotional consequences of ENS. The mean total score ranges from 0 (no symptoms) to 5 (severe symptoms) and is calculated by averaging an individual's responses to all questions. In addition to the standard SNOT-20, we also included the 5 additional items from Houser (2001),[8] which are particularly relevant for patients with ENS. The participants completed the SNOT-25 at the initial visit and at each subsequent clinic visit (3, 6, and 12 months after surgery). The sum of all items scores gives each patient a summary score, the total SNOT-25 score. We also evaluated the 5 important items that were reported to be the most severe symptoms among the 25 items and their variations at 3, 6, 12 months after operation.

Statistical Analysis

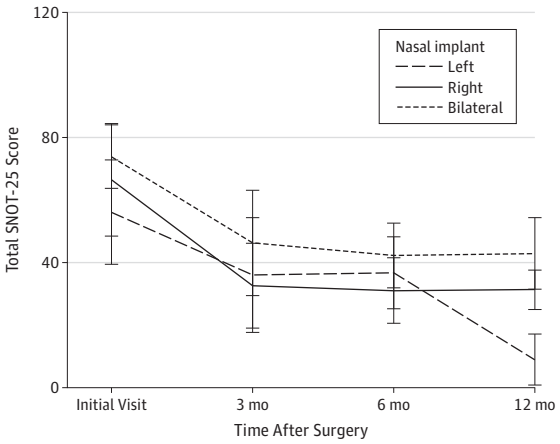
Comparisons between groups were performed with 1-way analysis of variance (ANOVA) or ANOVA on ranks (in cases of nonnormally distributed outcomes). Internal consistency reliability was estimated by Cronbach α and by test-retest reliability of the questionnaire in a subset of 15 patients who completed an additional SNOT-25 evaluation approximately 2 to 4 weeks after their 6-month evaluation (Wilcoxon signed-rank test and Spearman rank correlation coefficient).[12] An α value of .05 was considered statistically significant for all statistical tests. Data analysis was performed using SPSS 19.0 (SPSS Inc, IBM).

Results

Of all 24 patients, 23 (96%) completed the SNOT-25 approximately 3 months after the initial visit, 20 (83%) completed the SNOT-25 approximately 6 months after the initial visit, and 15 (63%) completed the SNOT-25 approximately 12 months after the initial visit.

There were 5 patients with left nasal implants, 4 patients with right nasal implants, and 15 patients with bilateral nasal implants. The SNOT-25 scores of all patients gradually decreased, indicating that continued improvement was achieved after Medpor implant surgery (**Figure**). The overall Cronbach α value was .90, suggesting good internal consistency within the SNOT-25. A subset of 15 patients who completed the SNOT-25 at 6 months was contacted by e-mail, and they completed the SNOT-25 approximately 2 and 4 weeks later. The mean difference between the SNOT-25 scores was 0.2. Pearson correlation analysis revealed a high degree of correlation between the scores at 2 and 4 weeks (r = 0.9; P < .001). The mean (SD) total SNOT-25 score was higher at the initial visit 68.31 (23.83) vs 49.60 (29.80) at 3 months after surgery, vs 30.69 (26.90) at 6 months after surgery, and vs 27.75 (14.88) after 12 months. The total SNOT-25 scores of the patients were significantly different at 3, 6, and 12 months after surgery compared with their initial visit (P = .045, P < .001, and P < .001, respectively). The difference between the initial visit and the 3-month visit was 18.71 points, the difference between the initial visit and the 6-month visit was 37.62 points, and the difference between the initial visit and the 12-month visit was 40.56 points.

Figure. Mean Total SNOT-25 Scores at Initial Visit (Before Surgery) and at 3-, 6-, and 12-Month Follow-up Visits



Error bars represent standard deviation. SNOT-25 indicates 25-Item Sino-Nasal Outcome Test.

Table 1 summarizes the mean change for each item accessed by the SNOT-25 from the initial visit to the 3-, 6-, and 12-month visit after surgery. The 5 items most frequently reported as important at the initial visit were "fatigue," "reduced concentration," "sadness," "dryness," and "nose is too open." The mean overall scores for these 5 important items were significantly decreased over time compared with the initial visit, indicating that patients reported greater improvement for important items (**Table 2**). The change in "dryness" average overall scores was not significantly different at 3 months after surgery compared with their initial visit (P = .74). However, the differences were significant at 6 and 12 months after surgery (P < .001). No new symptoms seemed to develop after implantation.

Discussion

Empty nose syndrome is typically not diagnosed because most rhinologists are trained to look for physical signs of dryness and atrophy after turbinectomies, and hence they may disregard the patients' subjective complaints of nasal obstruction or shortness of breath.[13,14] It is difficult to diagnose ENS clinically because there are no reliable objective tests, hence the otolaryngologist must rely on the patient's subjective symptoms. We used the SNOT-25 as a comprehensive assessment tool to aid in the evaluation of turbinate reconstruction surgery effects in ENS because it encompasses such complaints in detail and it can be accomplished in only 2 minutes.[15] The reliability of any instrument can be assessed by its internal consistency and the maintenance of the score over time when the patient's condition does not change. The internal consistency of the SNOT-25 was assessed by how well each item related to the instrument against the other items and against the final score. The Cronbach α value of .90 demonstrated a high internal consistency and a level necessary for clinical application. The test-retest reliability was validated by applying the

Table 1. The SNOT-25 Sores Reported by Patients at Initial Visit and at 3, 6, and 12 Months After Surgery

Item	SNOT-25 Score, Mean (SD)			
	Initial Visit (n = 24)	3-mo Visit (n = 23)	6-mo Visit (n = 20)	12-mo Visit (n = 15)
Need to blow nose	2.04 (1.89)	1.55 (1.13)	1.27 (1.10)	1.18 (0.98)
Sneezing	1.04 (1.33)	0.78 (0.97)	0.36 (0.50)	0.36 (0.50)
Runny nose	1.52 (1.65)	1.22 (1.09)	1.09 (0.94)	0.63 (0.67)
Cough	1.47 (1.73)	1.89 (2.15)	0.73 (1.01)	0.45 (0.93)
Postnasal discharge	2.17 (1.80)	1.56 (2.07)	1.27 (1.68)	1.27 (1.74)
Thick nasal discharge	1.48 (1.65)	1.89 (1.54)	0.73 (1.01)	0.63 (1.21)
Ear fullness	1.09 (1.31)	1.33 (1.58)	0.72 (1.01)	0.27 (0.47)
Dizziness	2.82 (2.08)	1.11 (1.27)	1.54 (1.75)	0.82 (0.98)
Ear pain	1.52 (1.73)	0.89 (1.27)	0.64 (0.92)	0.36 (0.67)
Facial pain/pressure	1.74 (1.86)	1.00 (1.32)	0.91 (1.38)	0.73 (1.42)
Difficulty falling asleep	3.22 (1.95)	2.22 (2.17)	1.36 (1.86)	1.00 (1.00)
Waking up at night	3.39 (1.88)	1.67 (2.00)	1.36 (1.86)	0.91 (1.22)
Lack of good night's sleep	3.36 (1.94)	2.11 (2.20)	1.54 (1.75)	0.63 (0.67)
Waking up tired	3.39 (1.85)	2.00 (1.80)	1.63 (1.75)	1.00 (0.77)
Fatigue	3.69 (1.66)	2.44 (2.07)	1.64 (1.36)	0.91 (0.83)
Reduced productivity	3.74 (1.57)	2.78 (2.05)	1.64 (1.29)	1.54 (1.21)
Reduced concentration	3.91 (1.44)	2.67 (2.06)	1.36 (1.36)	1.54 (1.13)
Frustration/restlessness/irritability	3.65 (1.77)	2.55 (2.18)	1.36 (1.36)	1.64 (1.21)
Sadness	3.65 (1.77)	2.00 (2.00)	0.91 (1.30)	1.36 (1.29)
Embarrassment	3.04 (1.82)	2.00 (1.94)	1.64 (1.50)	0.55 (0.69)
Dryness	3.91 (1.62)	3.00 (1.58)	1.18 (1.17)	1.36 (1.57)
Difficulty with nasal breathing	3.09 (1.89)	2.00 (1.87)	0.91 (1.04)	0.91 (1.14)
Suffocation	2.22 (2.00)	0.78 (1.09)	0.54 (0.82)	0.18 (0.40)
Nose is too open	3.96 (1.55)	1.33 (1.73)	1.18 (1.33)	1.45 (1.29)
Nasal crusting	2.91 (1.76)	2.33 (1.80)	1.36 (1.20)	1.54 (1.51)

Abbreviation: SNOT-25, 25-Item Sino-Nasal Outcome Test.

Table 2. The Mean Overall Scores for the 5 Highest-Ranked Items as Assessed at Patient Initial Visit Compared With Values Reported at 3, 6, and 12 Months After Surgery

Item	*P* Value[a]		
	3-mo Visit	6-mo Visit	12-mo Visit
Fatigue	.046	.001	<.001
Reduced concentration	.04	<.001	<.001
Sadness	.01	<.001	<.001
Dryness	.74	<.001	<.001
Nose is too open	<.001	<.001	<.001

[a] *P* values were calculated by 1-way analysis of variance between initial visit and 3, 6, and 12 months after surgery.

SNOT-25 at different times and analyzing the correlation between the scores. The study results ($r = 0.9$; $P < .001$), suggest a satisfactory test-retest reliability. These results were similar to those obtained in the reliability and validity studies for sinusitis.[16]

A healthy nose provides about half of the resistance of the entire respiratory tract. A serious decline in this resistance may considerably disrupt the balance of resistance needed for deep pulmonary inspiration and result in shortness of breath.[17] The nasal resistor has been cited as centrally important in providing wider opening of the peripheral bronchioles and enhancing alveolar ventilation.[18] This claim is strengthened by clinical research that indicates that normal rates of nasal resistance to expiration help to maintain lung volumes and may indirectly determine arterial oxygenation.[19] Elad et al[20] and Zhao and Dalton[21] have elegantly demonstrated such airflow disruption after inferior turbinate resection in a computer model of airflow through the nose. Loss of turbinate tissue ultimately disrupts and destroys the meatal structure, causing turbulent, less efficient, and less sensate air flow.[22,23] The meatus that are formed by turbinates, septum, and nasal floor walls are very narrow, offering a mechanism of resistance and thereby limiting the total amount of airflow. Thus, in patients with ENS lacking turbinates, airflow resistance is substantially decreased. These patients seem to be in a constant state of dyspnea and may describe the sensation as suffocating. The constant abnormal breathing sensations cause these patients to be consistently preoccupied with their breathing and nasal sensations, and this often leads to the inability to concentrate, chronic fatigue, frustration, irritability, anger, anxiety, and depression. This also points out that ENS is not a single disease entity. In the present study, the symptoms that pa-

tients reported as most troubling before implantation were "fatigue," "reduced concentration," "sadness," "dryness," and "nose is too open." Among these symptoms, "dryness" and "nose is too open" are ENS-specific questions, whereas "fatigue," "reduced concentration," and "sadness" are emotion-specific questions. Our findings were thus similar to previous studies that reported subjective factors as the most troubling in patients with ENS before implantation: "fatigue," "facial pain or pressure," "dryness," and "nose is too open."[24] Individuals with ENS experience considerable discomfort in their daily lives owing to the severe impairment of normal breathing functions. Saafan[24] reported the SNOT-25 values related to depression (sadness, irritability, reduced productivity, reduced concentration, embarrassment, and difficulty sleeping) tended to improve after implantation.[24] Our data, consistent with the findings by Saafan,[24] suggested that the change in the average overall "fatigue," "reduced concentration" and "sadness" items scores were statistically lower at the 3, 6, and 12-month follow-up visits compared with the initial visit ($P < .05$). We conclude that inferior turbinate reconstruction surgery led to a significant improvement in nasal symptoms as well as the psychological problems in patients with ENS. Although the psychological problems do not have the specificity of diseaselike symptoms, the changes in these indicators reflected disease occurrence and outcome in a sense. The improvement in psychological problems provides support for the effectiveness of implantation surgery. Implantation surgery had a positive impact on psychological restoration.

Saafan[24] conducted a prospective randomized blind clinical study comparing the efficacy and safety of acellular dermal (alloderm) grafts vs silastic sheets submucosal implants for management of ENS. The SNOT-25 scores showed that both groups experienced a significant improvement after surgery, and there was no statistical evidence for a significant difference between the 2 groups. The data in the present study showed that the overall SNOT-25 scores of our 24 patients' declined postoperatively, which indicates that the QOL in patients with ENS was greatly improved after reconstruction of the inferior turbinate with the Medpor implant. Another prospective study by Houser,[13] in which acellular dermis (alloderm) was surgically implanted into a submucoperichondrial or submucoperiosteal plane or into the submucous layer in 8 patients to simulate missing turbinate tissue, found that most patients reported a statistically significant improvement in their symptom scores for the SNOT-25. We therefore suggest that a nasal implant can be useful because when the airflow is shifted toward more sensate tissue, less crusting occurs with a reduced dry air stream, and the airflow pattern is normalized when a pseudoturbinate was created. The rationale of narrowing the nasal lumen is that a decreased amount of airflow will occur with inspiration, thereby resulting in less drying, crusting, and subsequently less damage to the nasal mucosa.[25,26]

Limitations of our study include the fact that some participants failed to complete our forms during the 1-year postoperative follow-up period. These lost data could have led to a potential source of bias if the patients who withdrew did so for reasons related to their treatment or outcome.

Conclusions

The SNOT-25 tool is easy for patients to complete and can be used in routine clinical practice to inform clinicians about a full range of problems associated with ENS. Medpor implant surgery had a positive association with QOL in patients with ENS, as seen in the statistically significant differences observed in SNOT-25 scores before and after surgery. Change in SNOT-25 score can be combined with other outcome measures, such as computed tomographic scan, nasal endoscopy examination, and acoustic rhinometry to monitor effects over time and to provide a more complete outcome description. The SNOT-25 can also aid researchers in assessing the degree and effect of ENS on health status in addition to estimate treatment responses.

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