Functional endoscopic dilatation of the sinuses: Patient satisfaction, postoperative pain, and cost

Michael Friedman, M.D.,*# Paul Schalch, M.D.,*# Hsin-Ching Lin, M.D.,#§ Narges Mazloom, B.S.,# Marci Neidich, B.S.,*# and Ninos J. Joseph, B.S.#

ABSTRACT

Background: *The purpose of this study was to determine how functional endoscopic dilatation of the sinuses (FEDS) compares with functional endoscopic sinus surgery (FESS) in a select group of patients with respect to (1) elimination of symptoms, (2) patient satisfaction, (3) postoperative narcotic use, and (4) cost. A retrospective study was performed of 70 patients with chronic rhinosinusitis who underwent FEDS or FESS as primary or revision treatment.*

Methods: *Symptoms and satisfaction based on the Sino-Nasal Outcome Test (SNOT-20) questionnaires and global patient assessment, postoperative narcotic use, and costs were compared after 3-month follow-up.*

Results: *SNOT-20 change scores indicated that both FEDS and FESS had clinically meaningful treatment responses. Patient satisfaction was higher and postoperative narcotics usage was less with FEDS. The cost for primary procedures was similar, whereas the cost for revision surgery using FEDS was considerably less. Turbinate lateralization and scarring was more common in the FEDS group, particularly early in the study. The incidence of recurrent sinus infections during the follow-up period was similar for both groups. Only one patient in the FEDS group required a repeat intervention within the short-term follow-up period.*

Conclusion: *Both FEDS and FESS resulted in significant improvement in SNOT-20 scores for selected patients with mild disease. Patient satisfaction and postoperative narcotic use of FEDS compare favorably with FESS. Cost of FEDS was comparable with FESS for primary procedures but was less than FESS for revision procedures. Long-term efficacy and final cost of FEDS remain to be addressed, taking into account the need for revision procedures after initial FEDS, by means of long-term studies and objective outcome measures.*

(Am J Rhinol 22, 204–209, 2008; doi: 10.2500/ajr.2008.22.3155)

Key words: Balloon dilatation, balloon sinusplasty, cost, endoscopic dilatation of the sinus, endoscopic sinus surgery, patient satisfaction, quality of life, rhinosinusitis

Balloon Sinuplasty, henceforth referred to as functional endoscopic dilatation of the sinuses (FEDS), was recently introduced as a minimally invasive tool to treat chronic rhinosinusitis (CRS). The system follows the principles of over-the-wire, catheter-based balloon dilatation, commonly used in vascular and urological surgery, as well as in interventional cardiology. What this system accomplishes specifically for CRS is the dilatation of the sinus ostia by advancing balloon catheters under fluoroscopic guidance to the narrowed segment and inflating them with high pressure.[1] FEDS provides a new set of tools, designed to dilate the natural ostia without tissue removal but with possible tissue injury. Because FEDS is a technique suitable only for selected patients, it is not a substitute for functional endoscopic sinus surgery (FESS) but may be a valuable tool used either as a supplement or a substitute to classic tools in select patients.

Only long-term studies ultimately will determine whether this novel strategy results in the same disease control rate as classic FESS. Although a 1-year efficacy study has only just been completed, this technology is already in widespread clinical use. The enthusiasm for FEDS is based on anecdotal experience or on the perception that the procedure is less aggressive and, therefore, more acceptable to patients, when comparing it with classic FESS. Promoters of the technology claim that its use may result in less pain and a quicker postoperative recovery. Currently, there are no data to substantiate these assertions. In addition, the relative cost of using this technology instead of the instruments for the classic technique is unknown.

The purpose of this study was to compare a group of patients treated with FEDS with a comparable group of patients who underwent classic FESS with respect to the postoperative Sino-Nasal Outcome Test (SNOT-20) score level, patient satisfaction, narcotic pain medication usage, and cost. In addition, this is the first reported series of patients who underwent FEDS under local anesthesia.

METHODS

Study Design

A retrospective chart review of a prospective data set of patients, following Institutional Review Board approval, was conducted in 70 adult patients with CRS who underwent FEDS or FESS from December 2005 to May 2006. All patients undergoing surgery fill out pre- and postoperative SNOT-20[2] surveys to determine baseline symptom status (before treatment) and improvement (if any) after intervention. Patients

*From the *Department of Otolaryngology and Bronchoesophagology, Rush University Medical Center, Chicago, Illinois, #Department of Otolaryngology, Advanced Center for Specialty Care, Advocate, Illinois Masonic Medical Center, Chicago, Illinois, and §Department of Otolaryngology, Chang Gung Memorial Hospital–Kaohsiung Medical Center, Chang Gung University College of Medicine, Kaohsiung, Taiwan*

Presented at the annual meeting of the American Rhinologic Society, Toronto, Ontario, Canada, September 16, 2006

This study was sponsored in its entirety by the principal investigator (M.F.); there are no financial relationships to disclose with the manufacturers of the Balloon Sinuplasty/Relieva catheter systems, Acclarent, Inc.

Address correspondence and reprint requests to Michael Friedman, M.D., 30 North Michigan, Suite 1107, Chicago, IL 60602

E-mail address: hednnek@aol.com

also fill out a Global Patient Assessment (GPA) questionnaire, designed to monitor satisfaction after undergoing a procedure. Only those patients who completed preoperative and postoperative SNOT-20 surveys and postoperative GPA forms at least 3 months after the procedure were enrolled.

Patient Selection

The charts and billing records of all adult male and female sinus patients treated surgically during the study period were reviewed. Patients with missing preoperative SNOT-20 data were eliminated from the study and those patients with missing postoperative surveys only were contacted to complete their data at a minimum 3-month follow-up. Thirty-five consecutive patients with Lund-McKay scores ≤12, who had undergone FEDS, were selected for the study. Thirteen of these FEDS cases were revision procedures. For comparison, 35 consecutive adults who had undergone FESS and who also had Lund-McKay scores of ≤12 were selected, 12 of which were revision cases. In general, patients met criteria for surgical intervention if they had a history of recurrent rhinosinusitis despite antibiotic therapy, topical nasal steroids, and allergic management.[1] In addition, patients must have had either a persistently abnormal computed tomography (CT) after at least 4 continuous weeks on antibiotics or an abnormal CT during treatment, with posttreatment normalization and three or more recurrences per year.[1] Patients with severe disease, Lund-McKay scores of >12, significant nasal polyposis, sinus osteoneogenesis, or systemic disease were excluded, because data suggest that these patients require more aggressive interventions, offered through conventional FESS instruments.[1,3] During the time period under consideration, all patients with Lund-McKay scores of ≤12 without polyps were given the option to choose between classic FESS or FEDS, after being informed of the specifics of each procedure, as well their respective potential benefits, side effects, potential complications, and risks. In addition, patients who had undergone surgery using a combination of both FESS and FEDS were excluded from the study.

Surgical Procedures

All procedures were performed by the senior author (M.F.). The surgical procedures, FESS, and FEDS were performed according to previously described techniques.[1,4] The Balloon Sinuplasty System, including the Relieva catheters, guidewires, guiding catheters, balloon inflation devices, and other necessary equipment was used for all FEDS procedures (Acclarent, Inc., Menlo Park, Ca). All patients undergoing surgery with FESS technology were performed under general anesthesia. Of the 35 patients treated with FEDS, 24 had general anesthesia and 11 had local anesthesia with sedation (8 patients) or without sedation (3 patients).

Assessments and Study End Points

Patient surveys were conducted pre- and postsurgical intervention using the validated SNOT-20,[2] a measure of rhinosinusitis health status, to assess short-term treatment effectiveness. All surgical candidates were given surveys before any surgical intervention. Patients who underwent either FESS or FEDS were followed at a minimum of 3 months postoperatively. Pre- and postoperative SNOT-20 scores were calculated for each patient, with a possible range from 0 to 5 (the mean item score for all 20 items), a higher score indicating a greater rhinosinusitis-related health burden.[2] To assess the impact of treatment, the difference between pre- and postoperative SNOT-20 scores was calculated to determine the SNOT-20 change score; a change score >0.8 was used to assess clinically significant improvement.[2]

At 3-month postoperative follow-up, patients also were administered a GPA questionnaire, which subjectively assessed patient satisfaction (1) by asking, if given the choice, would the patient choose to undergo the same procedure (yes/not sure/no), and (2) by asking the patient to rank their overall experience on a scale of +5 to −5 (+5 being the best outcome possible and −5 being the worst outcome possible). Although the GPA questionnaire contained additional parameters, we arbitrarily selected these two for the study before data collection and analysis.

Severity of postoperative pain was assessed by the number of days the patient used narcotic pain medications. Postoperative patients are routinely prescribed 1–2 tablets of acetaminophen/hydrocodone (500/5 mg) every 4–6 hours as needed for pain. The number of days a patient uses narcotics is routinely recorded in our postoperative follow-up. The number of narcotic days was recorded for each patient and used to quantify the persistence of pain postoperatively. Records were not precise enough to assess the actual doses of narcotic pain medication used on a particular day.

Cost of the procedures was compared for patients undergoing FEDS versus FESS. Cost analysis was based on charge from the perioperative period (24 hours) only and do not reflect preoperative or postoperative (after discharge) care. The cost represents preoperative laboratories, operating room, anesthesia, and postanesthesia care unit (PACU) charges. In addition, charges related to 23-hour overnight admission for those patients who required or requested admission were included. Charge for use of the C-Arm for FEDS patients and charge for use of the image-guided system for FESS cases were included.

Statistics

The sample size calculation was based on a primary outcome incidence of major and minor complications using results of previously reported FESS studies for an estimation of control and experimental incidence. Setting $\alpha = 0.05$, 80% power, a probability of 0.4 in FESS, and 0.1 in FEDS, a projected enrollment of 32 FEDS and 32 FESS was considered an adequate sample size for detecting a significant change in the primary outcome.

All statistical analyses were performed using SPSS Version 11.0.1 (SPSS, Inc., Chicago, IL). Continuous data are displayed as mean ± SD. Statistical significance was accepted when $p < 0.05$. The Levine's Test for Equality of Variances was used to determine statistically significant variances. The paired Student's *t*-test was used to compare preoperative versus postoperative mean values within each group. The two-tailed independent Student's *t*-test was used to compare differences between groups. The χ^2 and the Fisher's exact tests were used to test the association between categorical variables.

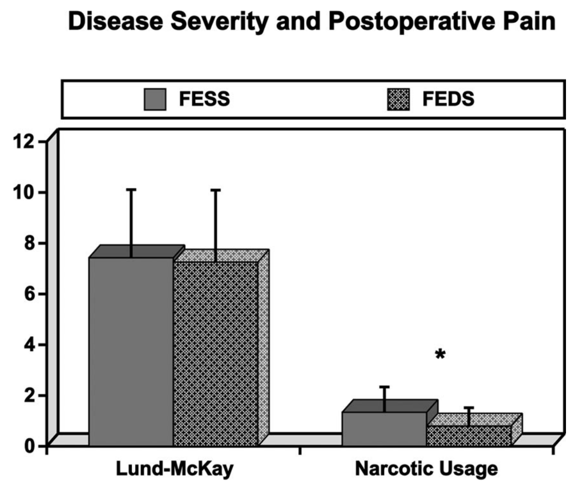

*Figure 1. Comparison of CT findings and severity of postoperative pain (narcotic use) after FESS or FEDS treatment of CRS (*significant difference between FESS and FEDS treatment groups; statistical significance accepted when $p < 0.05$).*

RESULTS

Forty male patients and 30 female patients, with a mean age of 43.0 ± 11.7 years (range, 18–74 years) were studied. These 70 patients included 35 treated with FEDS and 35 treated with FESS. Lund-McKay scores, based on preoperative sinus CT scans, were comparable ($p = 0.796$) for the FEDS and FESS groups (ranging from 3 to 12 and 1 to 12, respectively; Fig. 1). Fifty-nine patients underwent classic FEDS or FESS under general anesthesia in the operating room (OR), and 11 patients (all FEDS) had procedures done under local anesthesia with or without sedation.

Thirty-five subjects (23 men and 12 women) underwent FEDS as either primary ($n = 22$) or revision ($n = 13$) surgery, 24 subjects under general and 11 subjects under local anesthesia. Thirty-five subjects (17 men and 18 women) underwent FESS as either primary ($n = 23$) or revision ($n = 12$) surgery, all under general anesthesia. FEDS or FESS was performed on one to four sinuses (Table 1). In the FEDS group, 46 maxillary, 36 frontal, and 18 sphenoid sinuses were operated on. In the FESS group, 56 maxillary, 12 frontal, 27 ethmoid, and 13 sphenoid sinuses were operated on.

Paired *t*-test analysis revealed improvement in SNOT-20 scores following both FEDS and classic FESS ($p < 0.0001$ for both) from baseline (Fig. 2). Preoperative SNOT-20 scores were not different (2.8 ± 0.52 versus 2.70 ± 0.85 for FEDS and FESS, respectively), indicating well-matched groups. The mean 3-month postoperative SNOT-20 scores after FEDS (0.78 ± 0.55) was less than FESS postoperative SNOT-20 scores (1.29 ± 0.87; $p = 0.006$; Fig. 2). To determine if the treatment response was clinically meaningful, the SNOT-20 change scores were calculated (preoperative minus postoperative SNOT-20 score); a change score of ≥0.8 was used to determine clinical significance.[2] The SNOT-20 change score of both FEDS and FESS equally showed clinically significant improvement of health status and quality of life because both groups resulted in scores >0.8 (1.99 ± 0.66 for FEDS versus 1.41 ± 0.98 for FESS; $p = 0.005$).

Patient satisfaction with each treatment strategy was measured using the 3-month follow-up GPA form questionnaire; 91.4% of FEDS patients responded with "yes" to having the same procedure done again, compared with 48.6% of post-FESS patients. Additionally, 2.9% of FEDS patients responded with "no" and 5.7% were "not sure" when faced with the same question, versus 5.7 and 45.7% of the post-FESS patients, respectively ($p = 0.0001$; Fig. 3). The measure of patient satisfaction using the GPA survey was based on patient rating of their overall experience with the procedure, based on a −5 ("worst outcome I could have expected") to +5 ("best outcome I could have expected") scale. Data revealed a significantly better mean score of +3.71 ± 1.20 for patients that underwent FEDS versus +2.94 ± 1.39 for FESS ($p = 0.016$; Fig. 2).

Postoperative pain was quantified using the number of days a patient used narcotic pain medication. Postoperatively, FEDS patients had a mean duration of postoperative narcotic pain medication usage of 0.80 ± 0.72 days, which was statistically shorter than the mean number of days of narcotic pain medication use in the group of patients treated with FESS (1.34 ± 0.99; $p = 0.011$; Fig. 1).

Cost analysis was based on charges for time and equipment; charges may not reflect actual payment. FEDS requires the use of the balloon set at a cost of $ 1500; C-Arm use varied between $500 and $1000. On the other hand, FESS cases sometimes required the image-guided system charge at $500 and microdebrider use and blades average approximates of $500. In addition, each 15 minutes of OR time costs $600 and each 15 minutes of PACU time costs $300. Although equipment charges are higher for FEDS, revision cases were considerably shorter with FEDS and recovery and OR time were considerably shorter for patients undergoing surgery with local anesthesia versus general anesthesia.

The average cost of FEDS (22 primaries and 13 revisions) was approximately $12,656.57 ± $3,184.08 versus $14,471.14 ± $2,743.68 for FESS (23 primary and 12 revisions). This difference was significant ($p = 0.013$). However, when only primary procedures were considered the cost of FEDS and FESS was

Table 1 **Numbers of sinuses per patient treated with either FESS or FEDS**

	Number of Sinuses Treated				
	1	2	3	4	Total
FESS	0 (0%)	11 (31.4%)	10 (28.6%)	14 (40.0%)	35 (100%)
FEDS	2 (5.7%)	7 (20.0%)	16 (37.1%)	10 (28.6%)	35 (100%)

Data shown as count (%). No patient had more than four sinuses operated in this study.

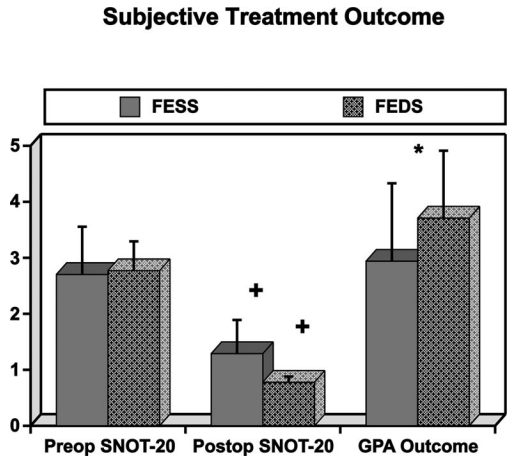

*Figure 2. Comparison of preoperative and postoperative SNOT-20 survey scores and GPA experience outcome as a measure of overall satisfaction after FESS or FEDS treatment of CRS (*significant difference between FESS and FEDS treatment groups; $^{+}$significant change in postoperative total SNOT-20 score when compared with preoperative score; statistical significance accepted when $p < 0.05$).*

not different ($14,021.82 ± $2,200.55 for FEDS versus $13,574.35 ± $2794.74 for FESS; $p = 0.555$). Consequently, the significant difference in cost of revision procedures using FEDS ($10,346.15 ± $3324.32) and FESS ($16,190.00 ± $1,653.11; $p < 0.0001$) contributed to the difference seen in the overall cost of the two procedures (Fig. 4).

Eight patients that underwent FEDS had turbinate lateralization or scarring whereas only three patients who underwent FESS had the same. Turbinate lateralization was more common in the FEDS group. However, this was not significantly different based on the two-sided Fisher's exact test ($p = 0.188$). No other major or minor complication occurred in either group. Six FEDS-treated patients (17.1%) and nine FESS-treated patients (24.6%) had one to four recurrent sinus infections during the follow-up period. There was no statistical difference between these incidences ($p = 0.646$) and therefore the cost of treating postoperative infections was not studied. One patient in the FEDS group required revision surgery secondary to persistent infection within the 3-month follow-up. None of the FESS patients required revision surgery during the short follow-up.

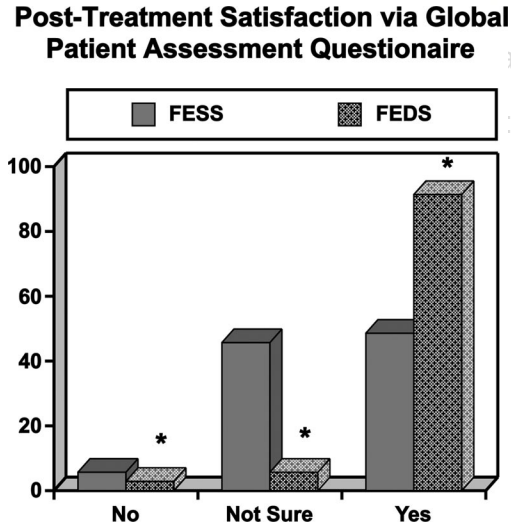

*Figure 3. Comparison of patient satisfaction (Would you undergo this same procedure again?) between patients treated with either FESS or FEDS for CRS using the GPA survey (*significant difference between FESS and FEDS treatment groups; statistical significance accepted when $p < 0.05$).*

DISCUSSION

FEDS has become increasingly popular since being introduced as an alternative to classic FESS in some patients, even before studies have become available that evaluate the value of this new technology. Because efficacy can not be assessed with 3-month follow-up, this study specifically avoided drawing conclusions about efficacy. Nevertheless, ongoing studies are essential to determine if balloon dilatation technology is worthy of continued clinical use. The feasibility of FEDS has been established by a study involving only 10 patients.[3] Its popularity is based on the perception of improved patient satisfaction and decreased pain, without increased cost. The present study, by virtue of a larger patient population, confirms these early reports on feasibility of FEDS.

The one criterion to judge any new technology is its ability to eliminate disease and control symptoms. Although studies are needed to examine the long-term efficacy of this new technique, only short-term results are available to assess FEDS at this time. This short-term evaluation will provide validity to the technique as well as allow for future comparison of early versus long-term outcomes.

In this study, we attempted to compare SNOT-20 improvement scores, patient satisfaction, postoperative narcotic use, and cost between FEDS and FESS. The SNOT-20 was used as a guide, as measured by the patient's perception of severity of disease, and to its improvement after treatment. The results showed that preoperative scores were comparable for the two matched groups. Using the mean SNOT-20 change scores to measure treatment response, results showed that both post-FEDS and post-FESS patients had scores >0.8 and therefore

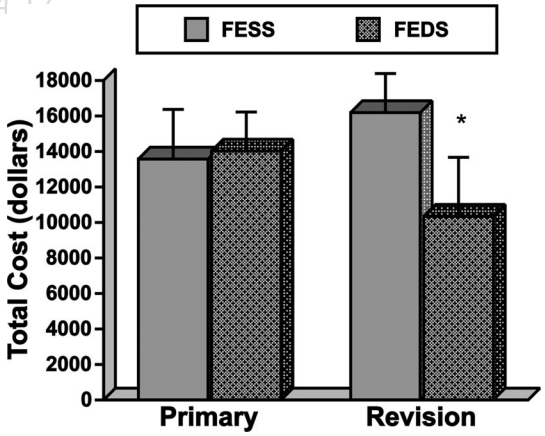

*Figure 4. Comparison of cost for primary and revision cases between patients treated with either FESS or FEDS for CRS (*significant difference between FESS and FEDS treatment groups; statistical significance accepted when $p < 0.05$).*

both procedures proved to provide clinically significant CRS-related sinonasal symptoms improvements.

Favorable results also were evident for measurements of patient satisfaction. Assessment of patient satisfaction was measured on the GPA form using the two parameters of (1) patient responses to whether they would undergo the same procedure again (Fig. 3) and (2) patient ranking of overall experience with their procedure (Fig. 2). Results for both parameters revealed that patient satisfaction was significantly greater for patients undergoing FEDS versus patients undergoing FESS.

As stated earlier, pain was assessed using the number of days of narcotic pain medication use. Results indicated decreased narcotic use associated with FEDS when compared with FESS (Fig. 1). However, the limitation of this study was its inability to measure the pain qualitatively. Also, the lack of records regarding amount of narcotics used each day may have prevented accurate measurement of total narcotic use, which may contribute to possible altered statistics. However, because both sets of patients were measured in the same method, any significant difference in the amount of narcotics used between one patient and another can be assumed to be distributed evenly among the two groups, therefore preventing any significant variation in the results.

This study has many limitations. It is not meant as endorsement of the FEDS technique, because a 3-month study can not prove efficacy. In addition, the fact that one of the FEDS patients required revision surgery in that period is of concern. The procedure by its nature does not allow for visual inspection of the ostia to determine patency. The purpose of this study was to determine if the perceived benefit of improved patient satisfaction is indeed true. This would provide the impetus to make additional long-term studies worthwhile. Also, the cost analysis is important in using new technology.

An important critique to note is that this study was not blinded. The patients who had elected to undergo FEDS in preference to FESS may have anticipated better results with the perception of a minimally invasive, en vogue procedure, and this may have contributed to possible partiality with the foregoing assessments. This procedure had received intensive media coverage. To eliminate possible partiality, an ideal study would be prospective and single blinded to patient knowledge of procedure type. Perhaps the most significant limitation of this study is that a direct comparison between both techniques is difficult, because FEDS, unlike FESS, does not include ethmoidectomy, and the patients selected for each group were by no means randomized. Therefore, our conclusions are limited to the results obtained in the short-term patient satisfaction outcome, which is not necessarily an objective outcome measure.

The value of any treatment option is not solely determined by cost. However, cost must be taken into consideration when treatment options are compared. The cost of a surgical procedure is dependent OR time, disposable supplies consumed, equipment used, and time in the PACU among other factors. When calculating in the cost of the supplies and equipment to the OR time, the total average cost of FEDS was slightly less than FESS. However, the cost difference between FEDS and FESS, for revision surgery in particular, was very significant (Fig. 4). Of the 25 patients that underwent revision procedures, FEDS was used in 13 patients and FESS was used in 12 patients. Three common causes of recurrent sinusitis that require revision surgery include (1) recurrent polyposis, (2) scarring of nonoperated sinuses, and (3) scarring of previously operated sinuses. Patients who have developed postoperative iatrogenic frontal, maxillary or sphenoid sinusitis after previous endoscopic maxillary sinusotomy and/or ethmoidectomy may be excellent candidates for FEDS. In our study, 13 patients fit this profile. These procedures had short operative times resulting in reduced cost. As stated previously, the cost saving was significant for FEDS revision procedures when compared with revision with FESS. This series is the first reported cases of FEDS performed under local anesthesia. Many of the revision procedures were extremely short and were done without general anesthesia. In addition to improved patient satisfaction, this results in considerable cost savings. However, it should be noted that cost-effectiveness, particularly for surgical interventions for recurrent chronic sinusitis, is also a function of the need and the frequency for revision surgery. This can be addressed only in a long-term follow-up study.

Complications of turbinate lateralization and scarring were more common in the FEDS group. However, this was present in the early group of patients and probably represents a technical error on the surgeon's part. In classic FESS, no packing is generally placed between the turbinate and lateral nasal wall. After the initial complication of lateralization and scarring in the FEDS group, absorbable gel is placed between the turbinate and retained uncinate. The complication rate of turbinate lateralization after initial experience has been reduced.

Incidence of recurrent sinus infection was comparable among the groups. Analysis of these measures revealed that six FEDS-treated patients (17.1%) and nine FESS-treated patients (24.6%) had one to four recurrent sinus infections during the follow-up period. There was no statistical difference between these incidences ($p = 0.646$). The major weakness of FEDS as it compares with FESS in this study is that one patient who underwent treatment with FEDS required a second surgical procedure within 3 months secondary to persistent infection. None of the FESS patients required revision surgery during the short follow-up. Although, patients undergoing sinus surgery understand and accept the risk of revision surgery, only long-term studies will determine whether this is indeed going to be statistically more common after FEDS procedures.

This study did not include information about postoperative endoscopic findings in either post-FESS or post-FEDS patients. Examination of the ostia in the post-FEDS patient is difficult because of the retained uncinate process, which impairs visualization.[3] Because this objective data could not be easily obtained among all FEDS patients, endoscopic findings were excluded collectively among all patients. Otherwise, valid comparisons could not be made between the two groups. Despite this, the evaluation of the short- and long-term effectiveness of FEDS and how it compares to FESS goes beyond the scope of this study. Ultimately, the best use of balloon dilatation may be to combine it with uncinate removal in selected patients.

CONCLUSION

FEDS is already in widespread use for the treatment of frontal, maxillary, and sphenoid sinuses. Our study indicates that, when compared with classic FESS during a 3-month follow-up period, FEDS had comparable clinically significant improvement in SNOT-20 scores. However, FEDS had significantly better results for patient satisfaction and postoperative narcotic use. On the other hand, FEDS resulted in a higher rate of turbinate lateralization and revision surgery. The cost between the two procedures was comparable for primary procedures, while revision FEDS procedures were significantly less costly when compared with conventional FESS. Although long-term results are necessary to evaluate the role of FEDS in the treatment of CRS, as well as the cost-effectiveness as a function of the need for revision surgery, this study provides data to justify ongoing study of this new tool. In addition, this study shows the feasibility of performing FEDS under local anesthesia.

REFERENCES

1. Friedman M, and Schalch P. Functional endoscopic dilatation of the sinuses (FEDS): Patient selection and surgical technique. Op Tech Otolaryngol Head Neck Surg 17:126–134, 2006.
2. Piccirillo JF, Merritt MG, and Richards ML. Psychometric and clinimetric validity of the 20-item sino-nasal outcome test (SNOT-20). Otolaryngol Head Neck Surg 126:41–47, 2002.
3. Brown CL, and Bolger WE. Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: A preliminary investigation. Ann Otol Rhinol Laryngol 115:293–299, 2006.
4. Friedman M, Landsberg R, Schults RA, et al. Frontal sinus surgery: Endoscopic technique and preliminary results. Am J Rhinol 14:393–403, 2000. □