Randomized controlled trial: hybrid technique using balloon dilation of the frontal sinus drainage pathway

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Background: **The objectives of this study were as follows: (1) to evaluate frontal sinus ostial patency following balloon dilation with the Ventera® Sinus Dilation System, compared with frontal sinusotomy (Draf 2a); and (2) to compare mean blood loss and mean surgical time for frontal sinusotomy using balloon dilation compared with traditional surgical methods.**

Methods: **A single blinded, randomized, controlled, prospective study was performed at St. Paul's Sinus Center, Vancouver, a tertiary referral rhinology center. Thirty patients undergoing functional endoscopic sinus surgery (FESS) for chronic rhinosinusitis (CRS) were randomized to a hybrid approach with exposure of the frontal recess using standard instrumentation and then balloon dilation of 1 frontal sinus drainage pathway and traditional frontal sinusotomy for the opposite side. Blood loss and surgical time for opening the frontal sinus drainage pathway was recorded for each side. Patients acted as their own controls. Ostial patency and size were assessed 5 weeks and 3 months postoperatively using endoscopy. Ostial patency was also recorded at 1 year following surgery.**

Results: **All frontal sinus ostia in both groups (n = 30) were successfully opened and were patent with both techniques 3 months postoperatively. All frontal sinus ostia assessed at 1 year (73%) remained patent and none required revision frontal surgery. Balloon dilation showed a mean surgical time of 655 seconds compared to 898 seconds for traditional FESS ($p = 0.03$). Mean blood loss was less with balloon dilation (58 mL vs 91 mL; $p = 0.008$).**

Conclusion: **A hybrid balloon technique successfully dilates the frontal sinus drainage pathway with reduced blood loss. Also, short-term patency appears to be comparable to traditional frontal sinusotomy.** © 2014 ARS-AAOA, LLC.

Key Words:
frontal sinusotomy; balloon dilation; chronic rhinosinusitis; frontal sinusitis; functional endoscopic sinus surgery

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Chronic rhinosinusitis (CRS) affects approximately 100 million people worldwide each year.[1] When medical treatment for CRS fails, functional endoscopic sinus surgery (FESS) is the surgical procedure of choice.[2] In FESS, the diseased or hypertrophic tissue and/or bone are resected under endoscopic visualization. The sinus ostia can be enlarged to restore normal drainage of the sinuses.[3] As with most surgical procedures, when tissue is removed there is a subsequent period of healing involved as well as surgical risks such as infection, bleeding, scarring, and re-stenosis. In a small but significant number of patients, particularly those undergoing frontal sinusotomy, revision FESS may be required to remove scar tissue and prevent re-stenosis.

In 2005, balloon catheter technology for the management of paranasal sinusitis was introduced.[4] This technology has been known to other specialties such as cardiology and gastroenterology for decades. The balloon can dilate sinus ostia by compressing the surrounding mucosa and causing microfracture of the circumferential bone.[5,6] It has been

FIGURE 1. Ventera sinus dilation system.

argued that balloon dilation may enhance mucosal preservation, reduce local trauma, and restore the natural sinus drainage pathways resulting in effective relief of symptoms.

This is the first study to investigate the safety and efficacy of one of the latest balloon dilation catheters, the Ventera® Sinus Dilation System (Ventera SDS; ENTrigue Surgical Inc., San Antonio, TX) (Fig. 1). It has a reusable handle with a ratchet mechanism to adjust the angle of the disposable balloon allowing it to be used on multiple sinuses (eg, sphenoid and frontal). It does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery (a hybrid technique). To date, there have been no clinical studies evaluating the effectiveness of the Ventera SDS in frontal sinus drainage pathway dilation.

Materials and methods

Study design

A single-blinded, randomized controlled trial was designed to evaluate the efficacy of this balloon dilation device (Ventera SDS). Ethics approval was obtained from the University of British Columbia and Providence Health Care Research Ethics Board. Subjects were randomized to receive conventional FESS with frontal sinusotomy (Draf 2a) for 1 frontal sinus and a hybrid technique using balloon dilation for the opposite frontal sinus. They had equal probability to have the left or right side receiving balloon dilation. Each subject acted as his or her own control. The randomization sequence was computer generated and closed, nontransparent envelopes were used to ensure treatment allocation remained concealed. The principal investigator performing the procedure could not be blinded to which frontal sinus was to receive the hybrid or conventional method. However, the clinician evaluating each frontal sinus and patency during postoperative assessments were not aware of treatment allocation.

Adult patients over the age of 19 years, diagnosed with CRS (including bilateral frontal sinus disease), with or without nasal polyposis (CRSwNP or CRSsNP, respectively), refractory to medical treatment according to the Canadian Clinical Practice Guidelines for Acute and Chronic Rhinosinusitis, waitlisted to receive bilateral FESS, and with no previous history of sinus surgery were eligible to participate in this trial. Patients were excluded if they had previously received sinus surgery; exhibited unilateral frontal sinus disease; had a coagulopathy; used anticoagulants; had cystic fibrosis, ciliary dysfunction, osteoneogenesis, Paget's disease, fibrous bony disease, or sinonasal tumors; or had a history of facial trauma with distorted sinus anatomy. Informed consent was obtained prior to surgery from designated research staff.

Procedure

The left side was operated on first (using either a hybrid approach with balloon dilation of the frontal sinus drainage pathway or conventional frontal sinusotomy depending on the randomization) unless there was difficult access due to a septal deviation. In these cases, the procedure was commenced on the more open side first and the other side was operated on following an endoscopic septoplasty. Our operative approach to the frontal recess and frontal sinus is performed in a back-to-front manner. That means the ethmoid sinuses are opened and the skull base is identified. This is followed anteriorly until the anterior ethmoid artery is identified, marking the posterior border of the frontal recess. Intraoperatively, the time taken to open the frontal sinus drainage pathway on each side was started as soon as the anterior ethmoid artery was identified and continued until the frontal sinus ostium was free of obstruction and visualization of the frontal sinus with an angled endoscope was possible. The amount of blood lost during this time was recorded. When the anterior ethmoid artery was identified all blood was cleared from the nose and a measurement was taken in the suction bottle. The frontal procedure then continued until the frontal sinus ostium was clearly visualized. The blood loss was then re-measured in the suction bottle and the blood loss during the frontal sinus part of the procedure was calculated by the difference between the 2.

On the hybrid side, once the ethmoid sinuses had been fully opened and the anterior ethmoid artery identified using standard instrumentation, the balloon was inserted into the frontal recess. Image-guidance was used to confirm that the balloon was in the frontal sinus and not a frontal cell. The guide tip of the device is 2 mm in diameter and the balloon itself is 10 mm in length and 6 mm in diameter. It was inflated to 10 atmospheres for 10 seconds. Further insertions of the balloon with repeat inflations were carried out as necessary to create an acceptable opening to the frontal sinus drainage pathway and the frontal sinus ostia was adequately visualized and dilated. Any loose debris following dilation was removed with standard instrumentation but no further dissection was performed in the frontal recess on the balloon side. The Draf 2A procedure was performed using a mucosal sparing technique using standard frontal sinus instruments. A single, experienced endoscopic sinus surgeon performed all of the procedures (A.R.J.). The ostium of the frontal sinus was measured in both groups using a 2-mm outer diameter suction aspirator. Adverse events such as cerebral spinal fluid (CSF) leak, orbital injury, bleeding requiring nasal packing, device malfunctioning (eg, balloon rupture), and re-stenosis were recorded intraoperatively and during subsequent clinic visits.

All patients received a 1-week course of oral prednisolone (10 mg once daily) and were instructed to carry out nasal saline rinses starting on the first postoperative day containing a single budesonide respule (0.5 mg) into each side. As per conventional protocol at our institution, they were seen 1 week postoperatively for general debridement. No measurements were taken at the first visit. The postoperative evaluation for patency was performed at the 5-week and 3-month visits by a single clinician. If there was edema present the 2-mm-diameter suction was not pushed through the edema but the patency of the frontal sinus ostium was measured. If edema was fully obstructing the ostium this was recorded as not patent. In addition to the original study protocol, frontal sinus ostia patency was also assessed at 1 year following surgery. The evaluating clinician was unaware of the side that the balloon was used on. Endoscopic assessment was made using direct visualization with a 30-degree and 70-degree endoscope and patency of the frontal sinus ostia confirmed. A 2-mm outer diameter curved suction was also passed into the frontal sinus ostia to confirm patency. Frontal ostia size was measured in the anterior-posterior and medial-lateral dimensions using the curved suction of 2-mm diameter under direct vision. Also, using the validated Philpott-Javer endoscopic scoring system, the mucosa was graded postoperatively on both sides.[7]

Statistical analysis

An a priori sample size calculation was completed indicating that 30 frontal sinuses would be required in each arm. A 2-proportion sample size calculation was powered to detect an effect size of 75% and accounting for Type I error of 5% and Type II error of 20%. A total of 60 frontal sinuses were required, consisting of 30 frontal sinuses per arm. We decided to evaluate a large effect size between the experimental and conventional method as this was the first clinical trial to evaluate this particular balloon dilation instrument and previous comparisons had not been made.

Baseline characteristics were collected preoperatively; these included age, sex, disease severity (Lund-Mackay [LM] scoring system), and presence of nasal polyposis (yes/no). Measures of central tendency (mean, conventional deviation) for continuous variables (age, disease severity) and proportions for categorical variables (sex, nasal polyposis) were reported. As patients received both interventions, total side-specific and frontal sinus-specific disease severities were compared between groups to ensure randomization resulted in balanced groups. The primary outcome of frontal sinus ostium patency was reported as a dichotomous outcome variable (yes/no). Secondary outcome variables of operating time (seconds), blood loss (mL), anterior-posterior and medial-lateral ostium size (mm) and endoscopic score (Philpott-Javer system 0-9) were reported as continuous outcome variables. Intention to treat analysis was completed for this statistical analysis. Subjects lost to follow-up and withdrawals were considered treatment failures. Observations of patency, operating time, and blood loss were considered independent for this statistical analysis, as each frontal sinus was treated separately. The 2-proportion test was used to compare the proportion of frontal sinus patency between intervention groups. The parametric Student *t* test was used to compare the mean estimates of operating time and procedural blood loss. A probability value less than 0.05 was considered statistically significant and all statistical tests were 2-sided. Statistical analysis of data was conducted using GraphPad Prism Version 5.0a (GraphPad Software Inc, La Jolla, CA).

Results

A total of 30 patients (60 frontal sinuses) were enrolled and participated in the study. The average age was 49.8 years consisting of 18 (60%) males and 12 (40%) females. Twelve (40%) patients had CRS with nasal polyposis. There was no significant difference in sinonasal disease severity between both groups when comparing total score per side (8.0 ± 2.3 vs 8.0 ± 2.5 hybrid LM score) and frontal sinus-specific scores (1.3 ± 0.5 vs 1.4 ± 0.5 hybrid LM score). Table 1 shows the different frontal sinus cell types present in each group.

On average, 1.8 dilations were required to open the frontal sinus drainage pathway receiving the hybrid method. One (3%) device rupture was experienced, which occurred on the second dilation after the ostium receiving treatment was unobstructed. There were no serious adverse events or intraoperative complications encountered during the use of the balloon dilation device. The proportion of patent frontal sinus ostia at 5 weeks postsurgery was the

TABLE 1. Frequency and absolute proportion of frontal cell types stratified by frontal sinus procedure

	Study sample (n = 30)			
	Hybrid group (n = 30)		Traditional group (n = 30)	
Frontal cell types	n	%	n	%
Kuhn frontal cell categorization				
Type 1	0	0	0	0
Type 2	8	26.7	8	26.7
Type 3	4	13.3	5	16.7
Other cell types				
Intersinus septal cell	6	20.0	14	46.7
Supraorbital ethmoid cell	0	0	0	0

TABLE 2. Intraoperative results comparing conventional and hybrid methods

Secondary characteristics	Conventional (mean ± SD)	Hybrid (mean ± SD)	95% CI	*p*
Time (seconds)	898 ± 504	655 ± 279	30.9–454.5	0.03[a]
Estimated blood loss (mL)	91 ± 51	58 ± 42	8.8–57.5	0.008[a]
Device malfunction	–	1 rupture	N/A	N/A
Mean dilations	–	1.8 per case	N/A	N/A

[a]Student *t* test performed.
CI = confidence interval; N/A = not applicable; SD = standard deviation.

same in both groups (29/30, 97%). At the 3-month assessment, 30/30 (100%) of frontal sinus ostia in both groups were found patent. There was no statistically significant difference in the proportion of patent sinuses between study groups at 5-week and 3-month assessment ($p = 1.0$). The single subject (1/30, 3%) with bilateral nonpatent frontal sinus ostia at 5 weeks could not be visualized due to mucosal edema. This patient was prescribed topical budesonide (Pulmicort Respules 2 mg of 0.5 mg/mL) administered by the Mucosal Atomization Device (MAD; Wolfe-Tory Medical, Salt Lake City, UT) twice a day until the final study assessment into both sides. Bilateral frontal sinus patency was observed in this patient at the 3-month assessment.

Secondary outcomes of operating time, blood loss, and ostium size were compared between study groups (Tables 2 and 3). Operating time for the frontal procedure was statistically significantly less for the hybrid approach than the conventional method (655 vs 898 seconds; $p = 0.03$; Fig. 2). Blood loss was significantly less during the hybrid approach than the conventional method (58 vs 91 mL; $p = 0.008$; Fig. 3). Anterior-posterior and medial-lateral measurements of frontal sinus ostia were

TABLE 3. Comparison of ostium size and endoscopic score between conventional and hybrid techniques

Frontal ostium characteristics	Conventional (mean ± SD)	Hybrid (mean ± SD)	*p*	95% CI
Anterior-posterior ostium size (mm)				
Intraoperative	5.6 ± 1.7	5.5 ± 1.5	0.82	−0.75 to 0.95
5 weeks	4.1 ± 1.7	4.3 ± 1.6	0.75	−0.98 to 0.71
3 months	4.8 ± 1.4	4.3 ± 1.6	0.18	−0.24 to 1.31
Medial-lateral ostium size (mm)				
Intraoperative	5.3 ± 1.4	5.0 ± 1.3	0.45	−0.43 to 0.96
5 weeks	4.2 ± 1.7	4.0 ± 1.5	0.61	−0.62 to 1.05
3 months	3.8 ± 1.3	3.5 ± 1.5	0.41	−0.42 to 1.02
Endoscopic score (Philpott-Javer scale 0–9)				
5 weeks	2.1 ± 2.2	2.4 ± 2.8	0.61	−1.64 to 0.97
3 months	1.2 ± 2.1	1.8 ± 2.3	0.30	−1.73 to 0.53
1 year	1.6 ± 2.5	1.4 ± 2.1	0.77	−1.2 to 1.6

CI = confidence interval; SD = standard deviation.

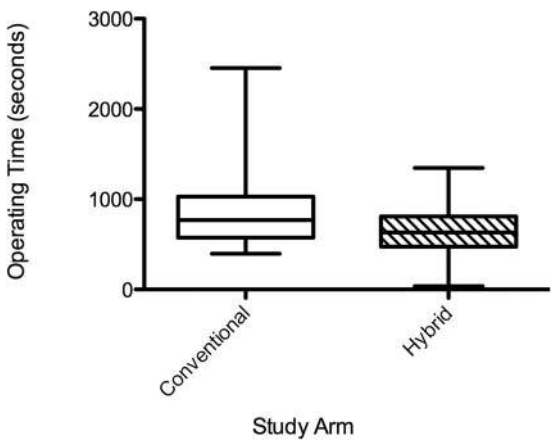

FIGURE 2. Operating time for each surgical technique.

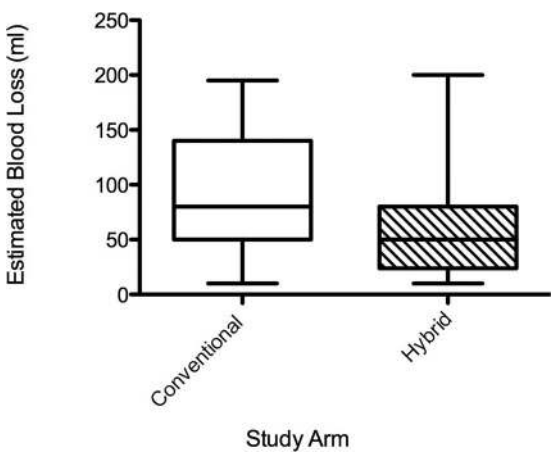

FIGURE 3. Blood loss for each surgical technique.

evaluated intraoperatively, 5 weeks, and 3 months postintervention. Frontal sinus mucosal edema was also assessed endoscopically at 5 weeks and 3 months (Table 3). There was no significant difference between the frontal sinus ostia measurements or frontal mucosal edema for each surgical technique at all time points assessed. Outside the original study protocol, 73% (22/30) of the study patients were followed up 1 year following surgery. One hundred percent (100%) of frontal sinus ostia assessed at 1 year were patent (44/44 frontal sinus ostia in total, 22/22 in each technique) and no patient required revision frontal sinus surgery. There was no significant difference between endoscopic frontal mucosal edema scores between the 2 techniques at 1 year (traditional 1.6 ± 2.5; hybrid 1.4 ± 2.1; $p = 0.77$).

CRS patients were stratified by nasal polyposis to determine the effect of the hybrid method on this patient group. Results for CRSwNP and CRSsNP are summarized in Table 4. Frontal sinus patency was the same for both surgical techniques at 5 weeks and 3 months post-surgery. Operating time and blood loss were lower for the hybrid group compared to the conventional approach for patients with and without nasal polyposis, however this was only significant for blood loss in the nasal polyp patients. There was no difference in endoscopic scores or ostial size between the 2 techniques in either CRSwNP or CRSsNP patients ($p > 0.05$).

Discussion

This is the first randomized controlled trial to demonstrate the safety, feasibility, and short-term patency using the Ventera SDS balloon as part of a hybrid procedure for dilation of the frontal sinus drainage pathway. The Acclarent balloon (Menlo Park, CA) was the first catheter-based system used for the dilation of the paranasal sinuses to be released on the market in September 2005. It was marketed as a standalone tool. Its safety and clinical improvement was established in a large, multi-institutional, prospective, nonrandomized study, known as the CLEAR trial.[8] This study looked at 115 patients (358 sinuses) with CRS who had failed medical management and required FESS. Fifty-nine patients had a "hybrid" procedure whereas 56 had sinuplasty alone. This cohort of patients was followed up at 1 and 2 years,[9,10] with both studies demonstrating significant improvements were maintained in Lund-Mackay computed tomography (CT) scores and symptom scores. This demonstrated that balloon sinuplasty is feasible and results in a significant improvement in symptoms that are maintained over a period of 2 years. There were, however, many questions remaining unanswered. The CLEAR and follow-up studies do not clearly define the patient population or their preoperative management, and the mean Lund-Mackay CT scores were low, suggesting mild disease, meaning it was unclear how applicable this study group is to other CRS patients.

More recently, the Ventera SDS was introduced and marketed as an adjunct to be used as a surgical tool to assist with traditional FESS methods rather than a standalone technique. Our results show that the Ventera balloon can be safely used as an adjunct to traditional FESS when dilating the frontal sinus drainage pathway. When compared with traditional frontal sinusotomy, hybrid balloon

TABLE 4. Comparison of CRS with or without nasal polyps by surgical technique

Characteristics	Conventional CRSwNP	Hybrid CRSwNP	*p*	95% CI	Conventional CRSsNP	Hybrid CRSsNP	*p*	95% CI
Patients	12/30 (40%)	12/30 (40%)	–	–	18/30 (60%)	18/30 (60%)	–	–
Total cavity disease severity (Lund-Mackay score)	9.7 ± 2.4	9.7 ± 2.5	1.0	−2.1 to 2.1	6.9 ± 1.5	6.8 ± 1.8	0.8	−1.0 to 1.2
Frontal sinus–specific disease severity (Lund-Mackay score)	1.7 ± 0.5	1.7 ± 0.5	1.0	−0.4 to 0.4	1.1 ± 0.3	1.2 ± 0.4	0.6	−0.3 to 0.2
Patency								
5 weeks	12/12	12/12	–	–	17/18	17/18	–	–
3 months	12/12	12/12	–	–	18/18	18/18	–	–
Time (seconds)	1045 ± 578	714 ± 318	0.1	−63.9 to 725.7	800 ± 438	616 ± 251	0.1	−58.3 to 426.0
Estimated blood loss (mL)	100 ± 50	61 ± 28	0.02	5.4 to 73.8	85 ± 53	56 ± 50	0.1	−6.2 to 63.9
Endoscopic score (Philpott-Javer 0–9)								
5 weeks	2.7 ± 2.0	3.8 ± 3.2	0.3	−3.3 to 1.2	1.7 ± 2.3	1.6 ± 2.1	0.8	−1.4 to 1.7
3 months	2.0 ± 2.4	2.9 ± 2.7	0.4	−3.1 to 1.2	0.6 ± 1.7	1.0 ± 1.6	0.5	−1.5 to 0.7

CI = confidence interval; CRS = chronic rhinosinusitis; CRSsNP = CRS without nasal polyposis; CRSwNP = CRS with nasal polyposis.

dilation of the frontal sinus was achieved in 100% of cases and was just as effective, resulting in a 100% frontal sinus ostia patency in both groups at 3 months postoperatively. Furthermore, there was a statistically significant reduction in intraoperative blood loss and operating time in the hybrid group with no clear difference in the physical size of the frontal sinus ostium. The reduction in blood loss and operating time for the hybrid group was present in both CRSwNP and CRSsNP patients, although when divided into these subsets the numbers are small and the difference is not statistically significant. However, the overall difference in time for frontal surgery of 4 minutes (243 seconds) between the 2 techniques, although statistically significant, is not necessarily clinically significant. The reduction in time with the hybrid technique is not going to significantly reduce operating time in theatre. However, it does suggest that using the balloon as a tool as part of a hybrid frontal procedure may be time efficient and reduce blood loss. Our results compare favorably with other studies using balloon dilation of the frontal sinus. Plaza et al.[11] performed the only other randomized controlled trial, using a different balloon system, opening the frontal recess in patients with CRS and nasal polyps. They found 80.76% of frontal recesses were successfully dilated in a hybrid balloon group compared to 91.7% in a FESS-only group.[11] Patency was confirmed endoscopically at 1 year in 73.07% in the hybrid group and 62.5% in the FESS group. Four patients required revision surgery, 1 in the balloon group (6.25%) and 3 in the FESS group (18.75%). No measurement of frontal sinus ostia size was made in this study. In our study, 100% of frontal sinuses were successfully opened in both groups and all frontal sinus ostia assessed at 1 year were patent. Only 73% of patients were reviewed at 1 year in our study but no patients required revision frontal surgery.

We believe that this hybrid approach, identifying the frontal recess and then using the balloon to open the frontal drainage pathway, is one that is applicable and potentially useful to all endoscopic sinus surgeons. Frontal sinus anatomy can be complex and frontal sinus surgery requires specialist instrumentation and skills to perform successfully. However, the use of balloon technology enables the frontal sinus to be approached safely and effectively, with reduced blood loss and a possible reduction in operative time.

There are limitations associated with this study. Both CRSwNP and CRSsNP patients were included. These patient groups do have inherent differences that may affect patency rates. However, because this is the first study to investigate the use of this device in a hybrid technique to dilate the frontal sinus drainage pathway, we wanted to include all patients with CRS, with or without nasal polyps, undergoing bilateral frontal surgery. Now that the safety and feasibility of this device has been demonstrated in both of these patient groups, future research will look at the 2 patient populations in isolation. Also, only 73% of patients were followed up at 1 year following surgery. This was outside the original study protocol and although 100% of the frontal sinus ostia assessed in both groups remained patent, 8 patients were lost to follow up at 1 year. All 30 patients completed a period of 3 months of follow up, which is relatively short and only provides information about early postoperative patency. However, the study has established the safety and feasibility of the device used in this manner with successful intraoperative dilation in all cases and a reduction in blood loss and possibly operating time. Other recent studies looking at frontal sinus ostial stenosis following ESS have used a 3-month postoperative follow-up period to assess early outcomes.[12] However, to establish longer-term patency rates, further studies are required. The method used to measure frontal sinus ostia size may also be criticized for being imprecise. We looked at a number of alternative techniques to accurately measure ostial size, including postoperative CT scanning, but we felt that the small associated risk of radiation exposure was not warranted. Other recently published studies have used similar techniques to measure frontal sinus ostia size.[12] In this study the size of the ostium is a secondary outcome and we used the best method available to accurately measure the size. Our primary outcome measure was patency, as is the case in the majority of other balloon studies, and this was easily confirmed under direct visualization using a 70-degree endoscope. The evaluation of patency was made by a single clinician, who was also the operating surgeon. This is a potential source of bias as there may be memory of the techniques used on a given side for a given patient. Also, there may be a different endoscopic appearance on the Draf 2A traditional side compared to the hybrid where small residual partitions may not have been removed. These differences in appearance could bias the clinician taking measurements and determining patency. Also, there was a higher proportion of frontal intersinus septal cells present in the traditional group and this therefore may have contributed to slightly more complex dissection and increased time and blood loss.

Balloon dilation of sinus ostia has emerged as another viable tool in the armamentarium of endoscopic sinus surgeons. Despite its widespread use in the United States, few randomized controlled trials have demonstrated convincing evidence that balloon dilation is as effective as traditional methods. A recent Cochrane review demonstrated the paucity of evidence to support the use of endoscopic balloon sinus ostia dilation compared with conventional surgical methods in patients with CRS.[13] Balloon technology has met criticism for its cost, and its "halo effect," whereby the "perception of efficacy is based on technical sophistication which creates a cognitive bias that can distort outcomes through rose-colored glasses."[13] New technologies do not always translate into better results, particularly since the existing techniques have proven to be very effective. We have successfully demonstrated that the use of balloon dilation of the frontal sinus drainage pathway as part of a hybrid procedure can improve operating efficiency without compromising safety or outcomes.

In a healthcare system with limited resources, the additional cost incurred by adding balloon technology can become a significant hindrance. Addition of such technology needs to be effective and needs to improve efficiency in order to become widely acceptable. Any reduction in operating time may compensate for the additional cost of using a balloon, although such a calculation was not carried out for this study.

Conclusion

The Ventera® Sinus Dilation System is safe to use as part of a hybrid procedure, once the frontal recess has been exposed, to successfully dilate the frontal sinus ostia. The use of this balloon device as a tool in frontal sinus surgery may reduce time and blood loss compared to traditional endoscopic frontal sinusotomy. The short-term patency appears to be comparable to traditional frontal sinusotomy although the long-term outcomes for this device are not established and this is something that requires further study.

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