



Recreating the microscopic direct access Draf 2a frontal sinusotomy in the endoscopic era and comparison to an angled instrument approach

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Abstract

Purpose Microscopic Draf 2a frontal sinusotomy relied on direct access. However, the modern-day endoscopic approach is hindered by the anterior–posterior dimensions of the frontal recess. The nasofrontal beak, angled endoscopes, and variable frontal recess anatomy make the surgery challenging. Carolyn's window frontal sinusotomy removes the limitation of anterior–posterior dimensions and is an endoscopic version of the microscopic Draf 2a. This study aims to compare the perioperative outcomes and morbidity from endoscopic direct access Draf 2a compared to angled access Draf 2a.

Methods Consecutive adult patients (> 18 years) seen at a tertiary referral clinic who underwent Draf 2a frontal sinus surgery using either endoscopic direct access (Carolyn's window) or endoscopic angled instrumentation were included. Patients who underwent Carolyn's window were compared to those with angled Draf 2a frontal sinusotomy.

Results One hundred patients (age 51.96 ± 15.85 years, 48.0% female, follow-up 60.75 ± 17.34 months) were included. 44% of patients used Carolyn's window approach. 100% [95% CI 98.2–100%] of patients achieved successful frontal sinus patency. Both groups were comparable for early morbidities (bleeding, pain, crusting, and adhesions) and late morbidities (retained frontal recess partitions). There were no other morbidities in the early and late postoperative periods.

Conclusion The endoscopic direct access Draf 2a, or Carolyn's window, removes the anteroposterior diameter limitation. The frontal sinus patency and early and late surgical morbidities of direct access Draf 2a were comparable with the angled Draf 2a frontal sinusotomy. Surgical modifications, often with drills and bone removal, can be successfully made to enhance access in endoscopic sinus surgery without concern for additional morbidity.

Keywords Endoscopic endonasal surgery · Frontal sinus · Frontal sinusitis · Paranasal sinus diseases · Sinusitis

Introduction

Frontal sinus surgery is a challenging component of endoscopic sinus surgery due to the intricacy and variability of frontal recess and sinus anatomy [1, 2]. The thickness of the nasofrontal beak, and a limited anterior–posterior dimension of the frontal recess, make the Draf 2a frontal sinus surgery with angled endoscopy and instrumentation visually difficult and requires skilled dexterity [1, 3]. Additionally, the postoperative frontal visualization of the frontal sinus requires angled endoscopy. This vertical angulation of the frontal recess also influences topical therapy delivery to the

frontal sinus [4, 5]. Microscopic frontal sinus surgery, as initially described by Draf, was performed via a direct corridor, drill, and microscope [6, 7]. Removal of the nasal process of the frontal bone and the frontal process of the maxilla create excellent visualization of the frontal recess and sinus. Additionally, thinning the bone lateral to the insertion of the middle turbinate and palpating the bur movement through the skin of the nasal dorsum was Draf's technique to guide the surgeon [6]. Later, in the endoscopic era, several techniques, including an axillary flap with the removal of bone from the anterior agger nasi [8] and the agger nasi punch-out procedure [9], were described to improve visualization and instrumentation of the frontal recess. However, angled endoscopes and instrumentation were still required to navigate

the nasofrontal beak and the anterior–posterior dimensions of the frontal recess [6].

The direct access or Carolyn's window approach to the frontal recess replicates Draf's technique via the endoscopic approach. The approach utilizes only the 0° endoscope, making the visualization and instrumentation of the frontal sinus and recess easy. Removal of the "axilla" of the middle turbinate or agger nasi to facilitate dissection is well documented, but the concept of an "axillectomy" is integral to Carolyn's window approach. The axilla, including the entire frontal process of the maxilla, agger nasi and nasal process of the frontal bone, is removed with a high-speed drill [10]. This bone complex has been referred to by other researchers as the axilla-agger nasi-maxillary-frontal process complex [11]. Exposed bone created by drilling is covered with a lateral mucosal wall flap (modified-Woodworth flap) and free mucosal grafting [10]. This technique is distinct from "axillotomy" or removing the anterior wall of the agger nasi of angled Draf 2a frontal sinusotomy. The frontal process of the maxilla and the nasofrontal beak is preserved in the angled Draf 2a and ensures the need for angled endoscopy and instruments.

The expanded middle meatus created after Carolyn's window technique allows direct visualization of the frontal sinus. The goal for most patients is to visualize all walls of the frontal sinus via a seen-through 0° endoscope. This post-operative view predicts better irrigation access and drainage of the frontal sinuses [11]. Carolyn's window approach as a Draf 2a technique overcomes the anterior–posterior distance and dexterity needed for angled instrumentations. However, concerns regarding the potential morbidity of the additional drilling and bone exposure are valid. This study aims to assess endoscopic direct access Draf 2a in creating patent frontal sinusotomy and associated perioperative morbidity compared to endoscopic Draf 2a frontal sinusotomy with an angled endoscope and instrumentation. The null hypothesis was that outcomes and morbidity are similar between the techniques.

Material and methods

A retrospective cohort study was conducted of patients who underwent frontal sinus surgery using either direct access Draf 2a frontal sinusotomy (Carolyn's window) or angled Draf 2a frontal sinusotomy. This study received ethics approval and patients provided informed consent for research data collection. The cohort was created by a shift in the technique used over time at the institution, rather than by the selection of individual patients.

Consecutive adult patients (> 18 years) seen at a tertiary referral clinic, who underwent frontal sinus surgery using either direct access Draf 2a or angled Draf 2a frontal

sinusotomy with an angled endoscope and instrumentation as part of the endoscopic management for both inflammatory and neoplastic diseases were included. Frontal sinus surgery was performed for either inflammatory/diffuse chronic rhinosinusitis or neoplastic disease in which the frontal sinus anatomy needed to be defined as part of the procedure. Angled Draf 2a frontal sinusotomy was performed in a period ranging from September 2015 to December 2017 by a tertiary rhinologist. Similarly, the same rhinologist performed direct access Draf 2a frontal sinusotomy from January 2018 to April 2020. Patients were excluded if they had less than 6 months of follow-up. Patients were categorized into the "direct access Draf 2a" group or "angled Draf 2a" group based on the surgical techniques utilized for frontal recess surgery.

Surgical techniques for direct access Draf 2a frontal sinusotomy (Carolyn's window)

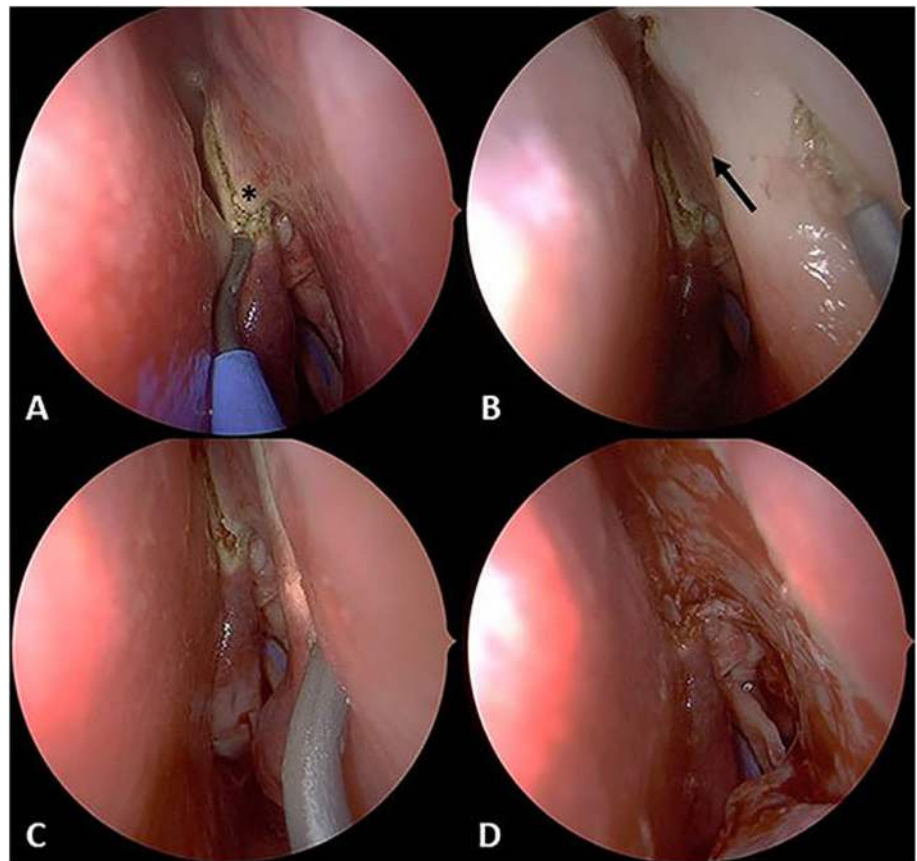
Carolyn's window is commonly used in conjunction with sphenoethmoidectomy or "full-house" surgery. The first step involves creating a modified-Woodworth flap, an inferior-based lateral wall mucosal flap, by making posterior incision to the bone starting above the axilla at the nasal roof, utilizing needle-point diathermy, setting 12 (0016AM Megadynne, NJ, USA), and extending vertically down to the middle turbinate insertion. The superior incision is carried out at the apex of the nasal cavity, extending forward to the pyriform aperture, and vertically down behind it to almost the midpoint of the middle meatus. The axilla and lateral wall bone are then exposed by subperiosteally elevating the inferior-based lateral wall mucosal flap [10] (Fig. 1).

Drilling is done using a 4-mm 15° diamond burr, at 30,000 revolutions-per-minute (Straightshot M5 Microdebrider, Medtronic, FL, USA) and a 0° endoscope to remove the axilla-agger nasi-maxillary-frontal process complex. The periosteum of the frontal process of the maxilla bone and the nasolacrimal sac are identified as the lateral limit, and the entire axilla is removed from the lateral side of the middle turbinate insertion. The triangular bone in front of the frontal recess is removed until the "blue lining" of the frontal recess mucosa is visible, preserving the frontal recess. Drilling continues vertically to the apex of the frontal sinus to remove the nasofrontal beak, followed by removal of the frontal recess partitions with 2.5-mm 45° cutting forceps and 4.3-mm quadcut straight microdebrider (Straightshot M5 Microdebrider, Medtronic, FL, USA). The 5-mm 70° Hosemann frontal sinus punch, which is used with a 0° endoscope, can completely eliminate bone edges. Finally, all frontal sinus walls are visualized through the 0° endoscope, creating a huge middle meatus [10] (Fig. 2).

The lateral wall is then covered by returning the inferior-based mucosal flap to its original position, and any

Fig. 1 The inferior-based lateral wall flap creation.

Representative intraoperative endoscopic imaging of the left nasal cavity. **A** The posterior incision starts from a point high above the axilla (asterisk) at the nasal roof and then goes straight down to reach the middle turbinate. **B** The superior incision is carried out at the apex of the nasal cavity, extending forward to the pyriform aperture (black arrow). **C** The anterior incision is made vertically downward, just behind the pyriform aperture, until it reaches a level approximately in the middle of the middle meatus. **D** The inferior-based lateral wall mucosal flap is raised subperiosteally and then folded downward



exposed bone is covered with a thin free mucosal graft from the tail of the inferior turbinate. The middle meatus is stented with hyaluronic acid gel (Bioregen, Changzhou, China) and Merocel (Medtronic, FL, USA) finger glove spacer, without additional packing material [10] (Fig. 3).

Surgical techniques for angled Draf 2a frontal sinusotomy

Draf 2a frontal sinusotomy is performed where the agger nasi cell and all other ethmoid partitions are removed from the middle turbinate medially to the lamina papyracea laterally. A 70-degree endoscope is used for visualization with through-cutting instruments, and the Hoseman punch is used to dissect all clefts and partitions within the frontal recess in an effort to modify the final boundaries as follows: posterior, ethmoid skull base and anterior ethmoid artery; anterior, frontal beak; lateral, medial orbital wall (lamina papyracea); and medial, middle turbinate. The axilla of the middle turbinate is partially removed with a Kerrison rongeur without any drilling. The middle meatus is stented with Merocel (Medtronic, FL, USA) finger glove spacer with no other packing [4, 5].

Postoperative care

The spacers were left in place for 7–14 days, and saline irrigation was started on the first day after surgery. Patients were discharged within the same day. Amoxicillin/clavulanic acid was prescribed for 10 days, and prednisone was given at a maximum dose of 25 mg per day for 7–21 days, depending on the pathology, to reduce inflammation and congestion.

Baseline characteristics

Patient demographic data were obtained from electronic medical records, including age, gender, smoking status, atopy status, serum eosinophil count level, prior sinus surgery, disease characteristics, and follow-up duration. Active smoking was defined as cigarette use within the last 12 months. Atopic status was determined by automated immunoassay (ImmunoCap®) to detect serum-specific Immunoglobulin (Ig) E antibodies to the following four aeroallergen mixes: (1) grass mix; (2) dust mite; (3) mold and (4) animal epithelium. A serum-specific IgE level greater than 0.35 KU/L for any of these aeroallergen mixes was considered a positive result. Prior sinus surgery was self-reported by the patient. Disease

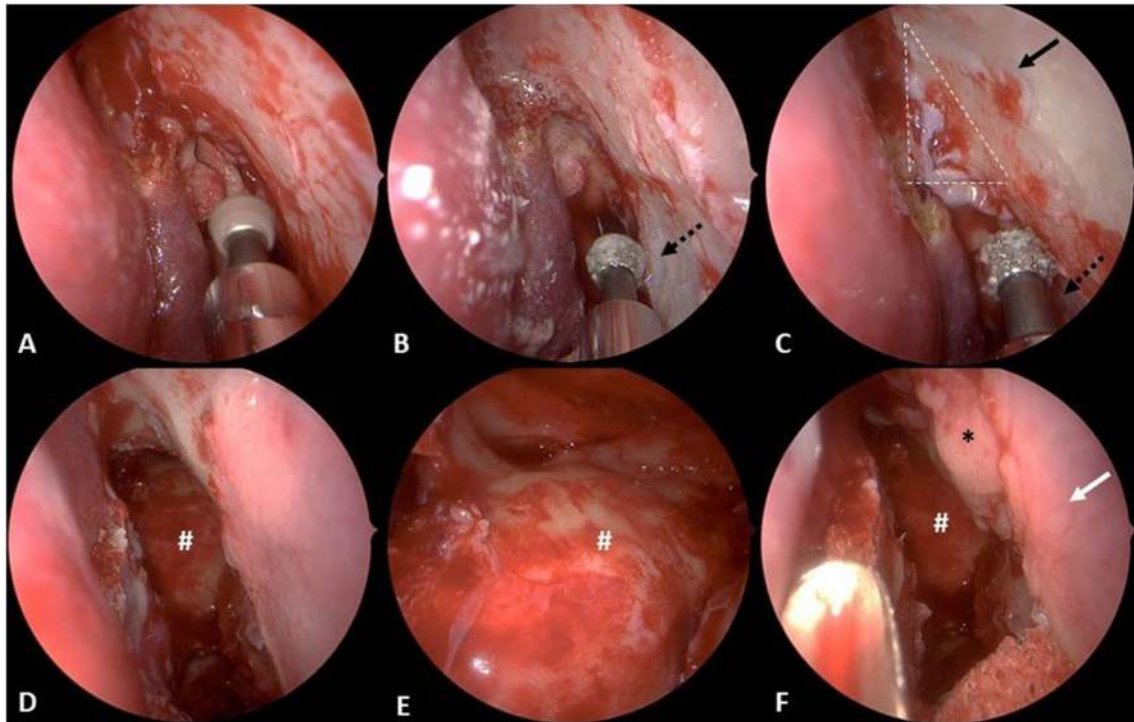


Fig. 2 Axillectomy and the inferior-based lateral wall mucosal flap and free mucosal graft placement. Representative intraoperative endoscopic imaging of the left nasal cavity. **A** The axilla and lateral wall bone are exposed by subperiosteally elevating the inferior-based lateral wall mucosal flap. **B, C** The lateral boundaries are determined by the periosteum of the frontal process of the maxilla bone (black arrow) and the periosteum of the nasolacrimal sac (black dash arrow). **C** Drilling removes the triangular bone anterior to the

frontal recess (dash line triangle) and lateral to the middle turbinate. **D, E** Creating a giant middle meatus allows for visualization of all frontal sinus walls through a 0° endoscope. **F** The inferior-based mucosal flap (white arrow) is repositioned to cover the lateral nasal wall, and any exposed bone is covered by a thin, free mucosal graft (asterisk) taken from the inferior turbinate tail. Posterior table of the frontal sinus (number sign)

characteristics were classified based on the European Position Paper on Rhinosinusitis and Nasal Polyps 2020 (EPOS 2020) [12] if the diagnosis was an inflammatory disease.

Perioperative outcomes

Data on perioperative outcomes were obtained from patient medical records. The primary outcome measure was frontal sinus patency after three months post-operative. Secondary outcomes were surgical morbidity, defined as early (< 90 days) or late (> 90 days). Early morbidity included bleeding (requiring intervention), pain (requiring additional analgesia), crusting (requiring additional post-op visit), adhesions (any), cerebrospinal fluid leak, periorbital edema or hematoma, skin changes, and inferior-based lateral wall mucosal flap necrosis. Late morbidity included epiphora, smell reduction from baseline, retained frontal recess partitions, and any external cosmetic change.

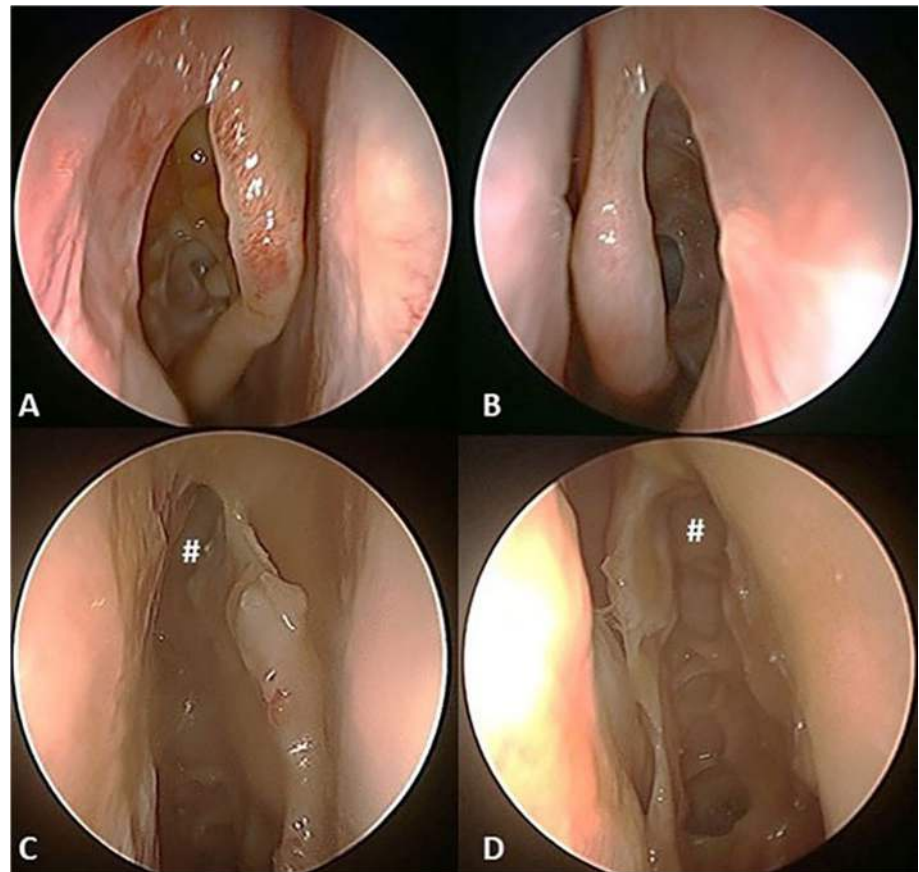
Statistical analysis

Comparisons between patients who underwent frontal sinus surgery using direct access Draf 2a and patients using the angled Draf 2a were performed. Statistical analysis was performed using SPSS Statistics v28 (IBM, Chicago, IL, USA). Parametric results were expressed as mean \pm standard deviation. Non-parametric results were expressed as median (interquartile range). Continuous data were assessed with independent samples t test and proportional data were assessed with a Chi-square or Fisher's exact test (where two or more groups were < 5). All p values were 2-tailed, and a value of $p < 0.05$ was considered statistically significant.

Results

A total of 100 patients (age 51.96 ± 15.85 years, 48.0% female) who underwent frontal sinus surgery using either direct access Draf 2a or angled Draf 2a were included. 23.0% were active smokers, 54.0% were atopic, and 32.0%

Fig. 3 3-month postoperative view of Draf 2a with the 0° endoscope. Postoperative view of the angled Draf 2a frontal sinusotomy, with limited visualization of the right (A) and left (B) frontal sinus. Postoperative view of Carolyn's window approach, with the enlarged right (C) and left (D) middle meatus and frontal sinus that can be seen through the 0° endoscope. Posterior table of the frontal sinus (number sign)



had prior sinus surgery. The serum eosinophil count level was $0.23 \times 10^9 \pm 0.2 \times 10^9$ cells/L and the follow-up duration was 60.75 ± 17.34 months. 78 patients (78%) had chronic rhinosinusitis and 22 (22%) had neoplastic diseases. 44

patients (44%) underwent frontal sinus surgery using direct access Draf 2a approach and 56 (56%) underwent angled Draf 2a frontal sinusotomy with an angled endoscope and instrumentation.

Table 1 Baseline characteristics of direct access Draf 2a frontal sinusotomy compared with angled Draf 2a frontal sinusotomy

	Endoscopic endonasal technique		P-value
	Direct access Draf 2a	Angled access Draf 2a	
n	44	56	
Age (years), mean (SD)	49.77 (17.82)	53.68 (14.03)	0.22
Gender, %F (n)	50 (22)	46.43 (26)	0.72
Smoking, % (n)	36.36 (16)	12.5 (7)	0.01
Allergic, % (n)	50 (22)	57.14 (32)	0.48
Neoplastic diseases, % (n)	25 (11)	21.43 (12)	0.67
CRS, % (n)	75 (33)	78.57 (44)	0.67
Disease characteristics			
Primary CRS, % (n)	68.18 (30)	66.07 (37)	0.38
Diffuse CRS, % (n)	70.45 (31)	66.07 (37)	0.18
Type 2 Diffuse CRS, % (n)	68.18 (30)	48.21 (27)	0.95
Prior sinus surgery, % (n)	40.91 (18)	25 (14)	0.09
Serum eosinophil count ($\times 10^9$ cells/L), mean (SD)	0.21 (0.19)	0.24 (0.21)	0.42
Follow-up duration (months), mean (SD)	43.39 (7.17)	74.39 (8.38)	<0.001

n = number of patients, F = female, SD = standard deviation, CRS = chronic rhinosinusitis

A comparison of patient characteristics between the direct access Draf 2a and the angled Draf 2a groups was presented in Table 1. Smoking status was higher in direct access Draf 2a than in the angled Draf 2a group (36.36% vs 12.5%, $p = 0.01$). The follow-up duration of angled Draf 2a was longer than the direct access Draf 2a group (74.39 ± 8.38 vs 43.39 ± 7.17 months, $p = < 0.001$). There was no significant difference regarding age, gender, atopy status, disease characteristics, prior sinus surgery, and serum eosinophil count levels.

For the entire group, all 100 patients (100% [95 CI 98.2–100%]) had successful frontal sinus patency with no difference between direct access Draf 2a and the angled Draf 2a groups. All 88 inferior-based lateral wall mucosal flap sites (100% [95 CI 95.9–100%]) showed no evidence of flap necrosis in the direct access Draf 2a group. A comparison of surgical morbidities between patients using direct access Draf 2a and the angled Draf 2a approach was summarized in Table 2. Both groups were comparable for early morbidities, including bleeding, pain, crusting, and adhesions. For late morbidities, retained frontal recess partitions were similar in both groups. There were no other morbidities in the early (cerebrospinal fluid leak, periorbital edema or hematoma, and skin changes) and late (epiphora, smell reduction from baseline, and any external cosmetic change) perioperative periods.

Discussion

To improve surgeon orientation, many attempts have been made to classify the frontal sinus cell and the extent of frontal sinus surgery due to complex frontal sinus anatomy [1, 3]. However, surgical consensus is that the thickness of the nasofrontal beak and the anterior–posterior dimensions of the frontal recess are essential factors in addition to frontal sinus cell variability [1]. These two factors force the surgeon to use angled endoscopy and instrumentation and require skilled hands. Several previous techniques, including an axillary flap with the removal of bone from the anterior agger nasi [8] and the agger nasi punch-out procedure [9], were designed for using less angled endoscopy and instruments. These techniques remove the front wall of the agger nasi cell but not the entire nasofrontal beak and angled endoscopy/instrumentation are still required to complete Draf 2a frontal sinusotomy.

Draf's original description of microscopic endonasal frontal sinus surgery was to allow visualization for the microscope and overcome the thickness of the nasofrontal beak and the anterior–posterior dimensions of the frontal recess [6, 7]. However, 30 years later, the endoscopic Draf 2a angled endoscope and instrumentation replaced Draf's original technique [6]. Early endoscopic instrumentation was limited, and the high-speed burrs that are available now were not in the early endoscopic surgeons' tool kit. With new high-speed burrs, Carolyn's window approach replicated the microscopic technique of Draf in the endoscope era.

Table 2 Surgical morbidities of direct access Draf 2a frontal sinusotomy compared with angled Draf 2a frontal sinusotomy based on frontal recess sites

	Endoscopic endonasal technique		P-value
	Direct access Draf 2a	Angled access Draf 2a	
n	88	112	
Early (< 90 days)			
Bleeding (requiring intervention), % (n)	1.14 (1)	0 (0)	0.44
Pain (requiring additional analgesia), % (n)	1.14 (1)	0.89 (1)	1.00
Crusting (requiring additional post-op visit), % (n)	2.27 (2)	0.89 (1)	0.58
Adhesions (any), % (n)	4.55 (4)	3.57 (4)	0.73
Cerebrospinal fluid leak, % (n)	0 (0)	0 (0)	
Peri-orbital edema or hematoma, % (n)	0 (0)	0 (0)	
Skin changes, % (n)	0 (0)	0 (0)	
Inferior-based lateral wall mucosal flap necrosis, % (n)	0 (0)	N/A	
Late (> 90 days)			
Epiphora, % (n)	0 (0)	0 (0)	
Smell reduction from baseline, % (n)	0 (0)	0 (0)	
Retained frontal recess partitions, % (n)	0 (0)	0.89 (1)	1.00
External cosmetic changes, % (n)	0 (0)	0 (0)	

n = number of frontal recess sites, N/A = not applicable

Direct access Draf 2a frontal sinusotomy or Carolyn's window is a straightforward and robust approach for performing Draf 2a frontal sinusotomy. This approach aims to eliminate the nasofrontal beak and overcome the limitation of the anterior–posterior dimension. A 0° endoscope and nearly straight instruments are used throughout the procedure, which provides excellent visualization of the frontal sinus and recess. Straight power instruments (15°) are typically sufficient, and high-speed drills can efficiently remove the axilla-agger-nasi complex. Furthermore, straight microdebrider blades with straight edges can be used to preserve the frontal recess and sinus mucosa.

After axillectomy, the use of Carolyn's window approach resulted in a significant increase in the size of the middle meatus. This approach enables an excellent view of the frontal sinus through a zero-degree endoscope, which helps to improve surgical instrumentation, post-surgical access, and postoperative irrigation [10]. Furthermore, topical irrigation delivery to the frontal sinus was superior in that the frontal sinus can be visualized with zero-degree endoscopic visualization than angled Draf 2a frontal sinusotomy [11].

The result of this study confirms that Carolyn's window is a vigorous approach and has comparable outcomes with the angled Draf 2a frontal sinusotomy. The baseline characteristics between Carolyn's window and the angled Draf 2a approach were similar except for the smoking status and the follow-up duration. The chi-squared analysis between direct access Draf 2a and angled Draf 2a frontal sinusotomy groups was 68.18% v 48.21%, ($p=0.95$) for the 'polyp' or type 2 diffuse group, showing a similar proportion of 'polyp' patients. Carolyn's window is a technique that was started in 2018, so the follow-up duration was shorter than the angled Draf 2a frontal sinusotomy that was done before. Additionally, both techniques' surgical morbidities in early and late perioperative periods were very low and comparable.

Rates of frontal sinus patency in the previous literature were 67.6–92% [13]. Patency rates in recent years have been more reliable since surgical techniques and instrumentation have evolved over that time [13]. This study shows the high rates of frontal sinus patency due to the evolution of surgical techniques and aggressive management in the postoperative period, including crusting and adhesion removal and topical therapies. There was a paucity of literature examining the perioperative morbidity outcomes data of Draf 2a frontal sinusotomy [14]. One previous Draf 2 frontal sinusotomy case series reported postoperative complications, including early: burn of nostril (6%), headaches and eye edema (3%) and late: chronic sinusitis (3%), adhesions (19%), and recurrent mucocele (3%) [15]. The morbidities in this study are very low when compared with the previous case series [13], including bleeding (0.5%), pain (1%), crusting (1.5%), adhesions (4%), and retained frontal recess partitions (0.5%). However, surgical techniques and instrumentation have evolved over the last 20 years.

Bone exposure, which can predispose to neo-osteogenesis and adhesions, occurs at the anterior wall only in both approaches. Mucosal preservation of the remaining walls of the frontal recess and sinus is paramount to both approaches. Whereas angled Draf 2a frontal sinusotomy, without drilling, exposes minimal bone, some bone anterior does become exposed through the use of angled punches and articulating Kerrison rongeurs. In direct access, it is important to completely remove the bone from the axilla-agger-nasi-maxillary-frontal process complex. This minimizes the area exposed, and the inferior-based lateral wall mucosal flap (modified-Woodworth flap) and free mucosal graft help provide repaid remucosalization as described in Carolyn's window approach [10]. These mucosal flaps prevent neo-osteogenesis and adhesion. Additionally, the flap based inferiorly is advantageous for the surgeon because it remains outside the surgical field during drilling. The large flap simplifies its preservation and repositioning, and no flap necrosis was observed.

This study supports that modifying anatomy by bone removal and drilling, to improve access, does so without significant additional morbidity. Carolyn's window is ideal for addressing the frontal sinus hypopneumatization that necessitates upper ethmoid access, but where a Draf 3 procedure is not feasible. The authors utilize it for managing sinus barotrauma, central compartment atopic disease [16], or benign tumors in the frontal sinus. However, this approach does not remove the frontal sinus floor, superior part of the nasal septum, and frontal sinus septum, which are completed in a modified endoscopic Lothrop procedure [17, 18]. Therefore, a Draf 3 is still utilized for lateral frontal access or hyper-secretory conditions like eosinophilic chronic rhinosinusitis requiring a wider common frontal sinusotomy [16].

This study has several limitations. Carolyn's window is a new technique that requires some learning curve; however, the primary and secondary outcomes are comparable. The retrospective cohort was created from a change in practice pattern rather than case selection. Additionally, this study aims to compare patent frontal sinusotomy in terms of anatomical outcomes and associated perioperative morbidity between Carolyn's window and angled Draf 2a frontal sinusotomy. Due to the heterogeneity of pathologies being treated, patient-reported outcome measures were not included. This study was on surgical techniques and not disease management.

Conclusion

The endoscopic direct access Draf 2a, or Carolyn's window, removes the anteroposterior diameter limitation. Frontal sinus patency and early and late surgical morbidities of direct access Draf 2a were comparable with the angled Draf 2a frontal sinusotomy. The 0° endoscope visualization and bone removal with a high-speed drill facilitates

the dissection. Anatomical modifications, often with drills and bone removal, can be successfully made to improve access in endoscopic surgery without concern for additional morbidity.

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Declarations

Conflict of interest Richard J. Harvey is consultant/advisory board with Medtronic, Novartis, Glaxo-Smith-Kline and Meda pharmaceuticals. He has been on the speakers' bureau for Glaxo-Smith-Kline, Astra-zeneca, Meda Pharmaceuticals and Seqirus. Larry Kalish is on the speakers' bureau for Mylan and Seqirus Pharmaceuticals. Raewyn G. Campbell is on the speakers' bureau for Medtronic, Seqirus, GSK and Viatrix. All other authors have no personal, financial, or institutional interest in any drugs, materials, or devices described in this article.

Ethical statement This study received ethics approval from the St. Vincent's Hospital Research Ethics Committee (2019/PID13822).

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