Effectiveness of the lateral pedicled endonasal flap for prevention of restenosis in frontal sinus drillouts*

René Fischer[1], Caroline T. Seebauer[1], Florian Zeman[2], Christopher Bohr[1], Werner Hosemann[3], Rainer Weber[4], Christian Rohrmeier[5], Thomas S. Kuehnel[1]

[1] Department of Otorhinolaryngology, University of Regensburg, Regensburg, Germany

[2] Centre for Clinical Studies, University of Regensburg, Regensburg, Germany

[3] Helios Clinic Stralsund, Stralsund, Germany

[4] Städtisches Klinikum Karlsruhe, Department of Otorhinolaryngology, Karlsruhe, Germany

[5] Faculty of Medicine, University of Regensburg, 93042 Regensburg, Germany and ENT medicinal office, Straubing, German

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Abstract

Background: Frontal sinus median drainage according to Draf is an established procedure for achieving maximum drainage of the frontal sinus. Despite great efforts and several modifications, restenosis of the neo-ostium is still a persistent problem. This study presents an approach by implementing local mucosal flaps to prevent restenosis and compares it with the conventional technique without using the flap.

Methods: Description of endonasal, lateral pedicle mucosal flap. A Draf III procedure was performed on 156 patients between 2012 and 2021. Data for 123 of the included patients were retrospectively analyzed in terms of surgical indication, technique, postoperative aftercare and patency of the drainage pathway. The follow-up observation period was between 3 and 24 months.

Results: Treatment with the pedicle mucosal flap took place in 86 cases. 37 patients were treated as a control group without this flap. The analysis showed a significant association to the event "total closure of the drainage pathway" for surgical technique, as well as in the case of the presence of an allergy and the existence of Samter's triad. Furthermore, there was a significant association between the onset of "near total closure of the frontal sinus ostium" and Samter's triad, CRS and revision surgery was involved.

Conclusions: Use of an endonasal lateral pedicle flap for reconstruction of mucosal defects in frontal sinus surgery improves the long-term chances of a patent drainage pathway. Bone exposed by drilling was covered with a local mucosal flap for a faster epithelialization, healing and less scarring.

Key words: Draf III procedure, frontal sinus surgery, modified Lothrop procedure, mucosal flap, stenosis

Introduction

Extended frontal sinus surgery is largely used in challenging clinical settings: for revision surgery in cases of extensive polyposis, after failed frontal sinus surgery with consecutive stenosis of the outflow tract due to scarring, for extensive mid-face bone injuries, traumatic [(1)] or congenital skull base defects and in endonasal surgery of frontobasal tumors. Median drainage of the frontal sinus is also being increasingly recommended as primary surgery in regular chronic rhinosinusitis with nasal polyps, when there are risk factors present (asthma and polyposis, small ostium, imaging features of extensive disease) [(2)]. The decisive impetus for maximized drainage of the frontal sinus came from Draf in 1991 [(3)]. Since then the technique has been modified and the indications have been the subject of much debate [(4,5)].

In extended endonasal frontal sinus surgery, the floor of the frontal sinus is removed through to the nose to a variable extent. This creates a much larger opening between frontal sinus and nose, when compared to the natural ostium. A Draf type IIb drainage procedure involves resecting the frontal sinus floor between orbit and nasal septum, whereas in type III the entire floor of both frontal sinuses is resected between the orbits. The widest possible opening is created to counteract the tendency

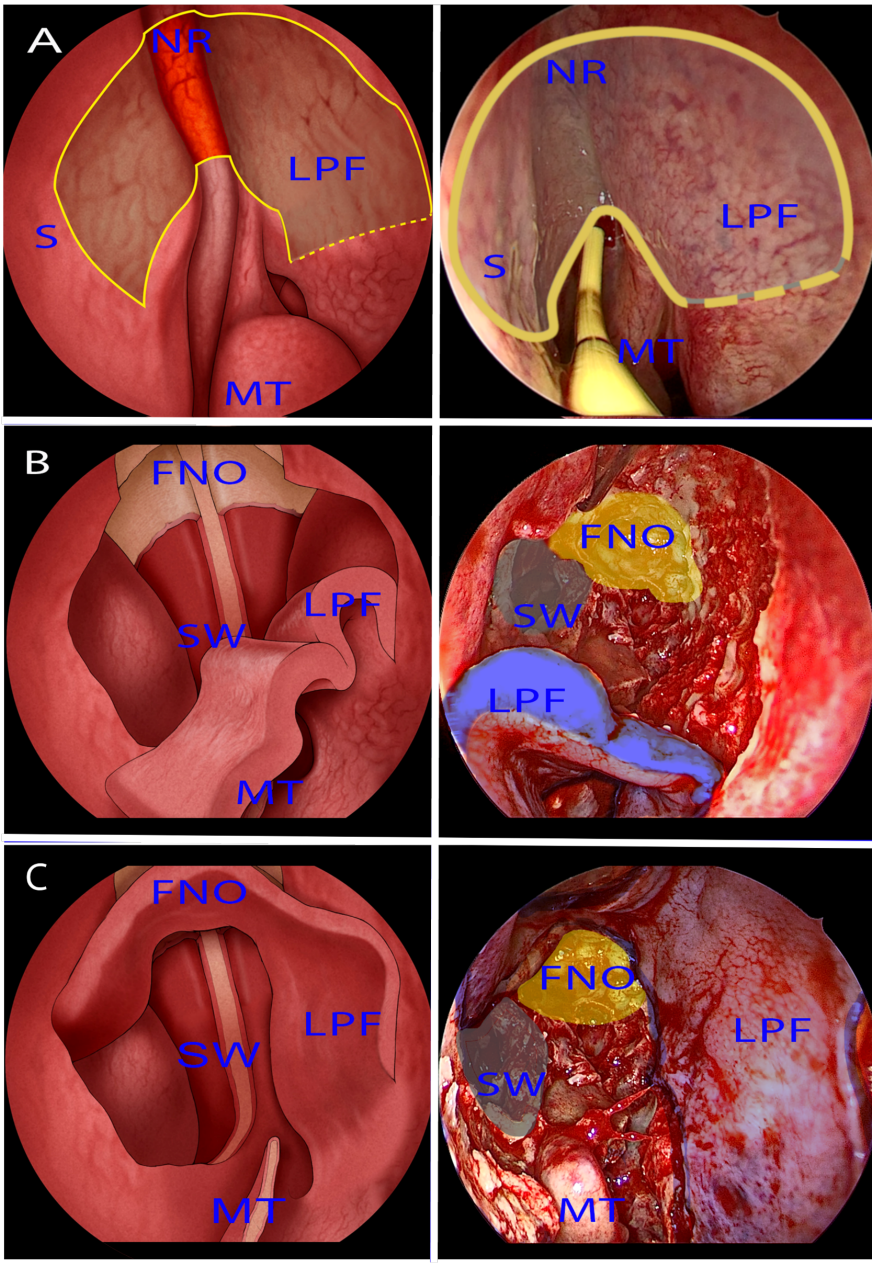

Figure 1. Surgical steps: Use of a lateral pedicle mucosal flap. Shown schematically and as part of an operation: (A) the landmarks for dissecting the lateral pedicle flap (LPF), S = nasal septum, NR = nasal roof and MT = middle turbinate. Incise around with a monopolar electric precision needle (right figure side) and trim the middle turbinate, then perform Draf III procedure. Finally, the frontal neo-ostium (FNO) is visualized, SW = nasal septal window (B). The final step is to place the transposition flap onto the bare bone of the frontal sinus neo-ostium (C).

to scarred stenosis of the frontal sinus neo-ostium. These techniques represent the last escalation level in endonasal frontal sinus surgery once the functional techniques (Draf I and IIa) have proved inadequate [6]. Despite large accesses and to some extent high success rates of 81% to 97% [7,8], significant restenosis is bound to be observed in some cases [9,10]. The bone areas denuded by the drilling work regularly tend to osteitic changes and delayed wound healing. The causes are extensive and only incompletely clarified. Among others, correlations to chronic rhinosinusitis as well as to allergy are described [11,12]. Over time considerable scarring may often be observed, which not uncommonly results in renewed closure of the frontal sinus neo-ostium [11,13]. To ensure effective and fast wound healing by covering the bone with autologous nasal mucosa at an early stage, a variety of techniques were proposed in the past [13-17]. Flap necrosis ensued in 11% of these tested techniques [18].

A new technique was to minimize the risk of flap necrosis and promote rapid wound healing. Endonasal dissection of a lateral pedicled mucosal flap provides new mucosal covering for the Draf type III frontal sinus neo-ostium. This offers an alternative to

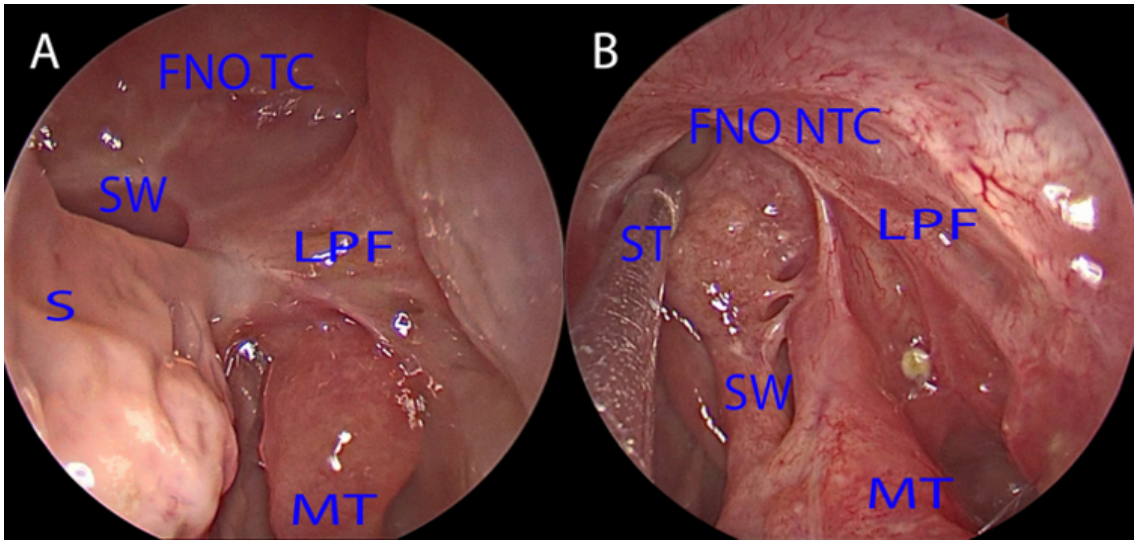

Figure 2. Endoscopic follow-up findings. Shown is a total closure of the frontal sinus drainage pathway (FNO TC) with the landmarks, the lateral pedicle flap (LFP), S = nasal septum, SW = septal window and MT = middle turbinate (A). The second result (B) shows a near total closure (FNO NTC). In addition, a 5 mm curved suction tube (ST) was used as described in the method section.

the free mucosal flap in this area, as proposed by Hildenbrand [19].

This study was designed to investigate whether the newly developed surgical technique offers an advantage over conventional techniques applying no specific mucosal covering and whether the expected improvements in local wound healing can reduce the restenosis rate of the neo-ostium following frontal sinus drill out.

Materials and methods

The retrospective cohort study was approved by the local Ethics Committee (University of Regensburg, no. 20-2085-101) and was performed in accordance with the ethical standards laid down in the Declaration of Helsinki.

Patients

A modified Lothrop procedure was performed by the same surgeon on 156 patients in a period between 2012 and 2021. All patients aged at least 18 years with a clinical follow-up period of at least 3 months were included. Accordingly, patients with a follow-up period < 3 months were excluded.

Since a relevant proportion of restenosis occurs in the first two years after surgical treatment, the study period was limited to 24 months [19, 20].

Retrospectively, the patients were divided into two groups, an intervention group (using a lateral pedicle mucosal flap for reconstruction of the mucosal defect) and a control group (frontal sinus drillout without specific mucosal reconstruction). Generally, there were no fixed criteria for the choice of the alternative surgical procedures in the individual patient. However, there was a trend towards use of the flap over the course of the study.

Surgical technique using a lateral pedicled mucosal flap in the context of a Draf type III procedure

This operation involves drilling out the floor of the frontal sinus extensively and additionally resecting the cranial septum caudally of the frontal sinus floor. Instead of the mucosa in this area being discarded, dissection of a lateral pedicled flap, which can be raised on both sides without giving rise to relevant secondary defects, is recommended. After identifying the area of the nasal septum to be resected under the frontal sinus floor, a low-energy, monopolar electric precision needle was used to incise around the mucosal flap at the septum from basal to cranial (Figure 1). The two parallel incisions are extended over the nasal roof onto the lateral wall of the nose. It is important to ensure the flap pedicle is kept wide enough and ends at the lateral nasal wall anterior of the middle turbinate. To expose the frontal maxillary process clearly for the eventual drilling work, continue the anterior mucosal incision along the pyriform aperture in a caudal direction as far as the inferior turbinate. Use a sharp dissector to develop this subperichondrally at the septum and subperiostally at the agger nasi. Dissection in the roof of the nose is difficult because the mucosa here is thin and firmly fused to the underlying bone and because there is limited space for manipulation. The rest of the dissection then becomes straightforward and effortless, provided it is kept within the correct (subperichondral or subperiosteal) layer. As the long and thin flap will be at risk from the drill, it is advisable to position it close to the lateral nasal wall in a caudal direction or, better still, to deposit it in the maxillary sinus. It will remain in this parked position until the end of the procedure. A 70° bur (Medtronic, 30k bur, 4mm x130mm; Medtronic GmbH, Germany) was used for resection of the bone. Once all drilling work is completed, the flap can be

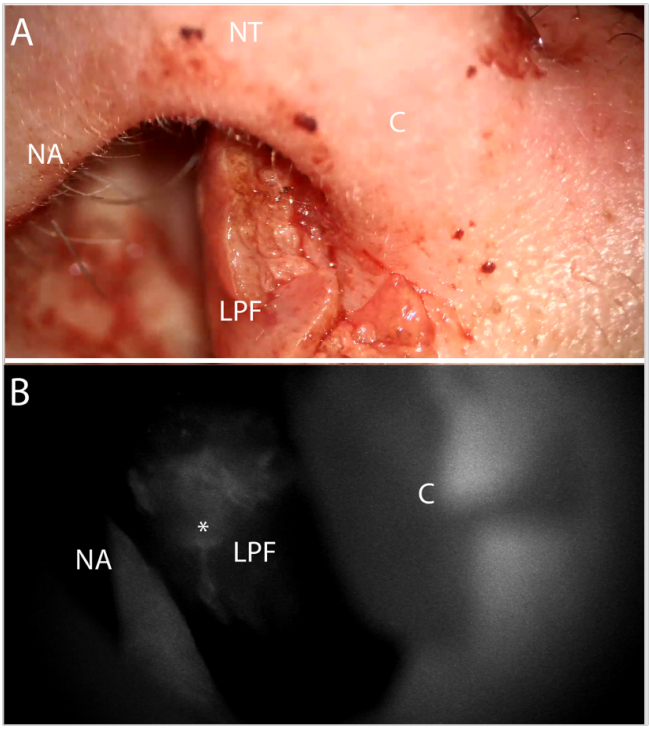

Figure 3. Perfusion of the periphery of the lateral pedicle mucosal flap (LPF) is depicted by means of indocyanine green (ICG)-based flow analysis. For the time of the examination, the tip of the flap was positioned at the nasal vestibule. Shown for overview: C = columella, NT = nasal tip and the NA = nasal alae. (A) Before intravenous administration and (B) after delivery of ICG using Flow 800 software to demonstrate an adequate peripheral blood supply (*). (Kinevo; Carl Zeiss, Oberkochen, Germany).

easily reflected cranially and spread over the bare bone in the frontal sinus neo-ostium. So as not to jeopardize the outcome of the procedure in the immediate postoperative phase, the flap is covered in its new position by resorbable gelatine foam. This prevents the flap from becoming dislodged by suction or rinsing during postoperative care.

Checking perfusion of the lateral pedicle mucosal flap

The presented mucosal flap corresponds to a random pattern flap. Indocyanine green (ICG)-based flow analysis (Kinevo; Carl Zeiss, Oberkochen, Germany) was used in selected cases to visualize blood flow at the periphery of the flap. During this examination, the flap was first dissected as described; the free end was then transposed for a short time to the nostril to improve visualization. Positioning of the microscope was followed by intravenous administration of ICG (0.2 mg/kg) in consultation with the anesthesia team and analysis using Flow 800 software (Carl Zeiss).
Within the scope of the examination, it could be shown that the blood circulation, especially around the periphery of the flap, is sufficient (Figure 3).

Follow-up

The non-blinded follow-up examinations took place in a non-specified but regular time interval in the department. After decongestion of the turbinates with xylometazoline hydrochloride (1 mg/ml), a nasal endoscopy was performed (Storz, 30°, 4mm, Storz Germany) and the width of the frontal sinus neo-ostium was determined during patient aftercare The findings recorded were classified as "open", "near total closure" and "total closure". "Near total closure" means that a 5 mm curved suction tube (Karl Storz SE & Co. KG, Tuttlingen, Germany) could not pass the neo-ostium unhindered (Figure 2).
Clinical endpoints were total closure on the one hand and near total closure of neo-ostium on the other hand.

Statistical analysis

Data are presented as mean ± standard deviation (SD) or as absolute and relative frequencies. By use of the phi coefficients, a possible correlation between the variables studied and the surgical technique performed was analyzed (Table 1). The impact of surgical technique and the further clinically relevant covariates (revision surgery, surgical indications, presence of an allergy or the Samter's triad) on the endpoints total closure and near total closure was analyzed by using log rank tests and is graphically presented by Kaplan-Meier Plots. Due to the limited number of events, no multivariable regression models were calculated. A p-value <0.05 was considered as statistically significant. All analyses were performed using SPSS statistical software (IBM SPSS Statistics 26; Chicago, IL, USA).

Results

123 patients (83 male, mean age at time of surgery 52.6 ± 12.9 years, 18 – 85 years) were followed up for a minimum period of 3 months postoperatively up to a maximum of 83.2 months (mean 31.8 ± 22.6 months). Regular follow-up was performed for at least 12 months in 102 of all included patients. 65 patients were followed up for at least 24 months.

An endonasal lateral pedicled mucosal flap (intervention group) was used in 70% (N = 86) of all the modified Lothrop procedures performed. In 16 cases, the mucosal flap was prepared on both sides. 37 operations (30%) involved the conventional Draf III technique without reconstruction of the mucosal defect (control group).
Eighty-seven (87) of all 123 operations corresponded to revision surgery because of stenoses in the frontal sinus ostium, whereby in no case was an already existing maximally endonasal frontal sinus median drainage revised.

There was an almost equal distribution of surgical indications in both the intervention group and the control group (Table 1). The leading indication for the Draf III procedure was chronic

Table 1. Patients' profiles with relative frequencies in the patient groups and examination of an interrelationship between the surgical technique performed and the variables studied (p-value).

Parameter	All patients (n=123)	With flap (n=86)	Without flap (n=37)	p value
Age (years)	52.6 ± 12.9	52.2 ± 13.3	53.6 ± 12.0	0.84
Sex (male), n (%)	83 (67.5)	58 (67.4)	25 (67.6)	0.99
Revision surgery, n (%)	87 (71.1)	62 (72.1)	25 (67.6)	0.61
Allergie, n (%)	32 (26.0)	24 (27.9)	8 (21.6)	0,47
Samter's triad	15 (12.2)	9 (10.5)	6 (16.2)	0.37
Smoking, n (%)	45 (36.6)	35 (40.7)	10 (27.0)	0.15
Indications				
Chronic rhinosinusitis, n (%)	69 (56.1)	51 (59.3)	18 (48.6)	0.28
Post-traumatic, n (%)	21 (17.1)	13 (15.1)	8 (21.6)	0.38
Encephalocele, n (%)	5 (4.1)	5 (5.8)	- (0.0)	0.13
Tumor, n (%)	28 (22.8)	17 (19.8)	11 (29.7)	0.28

rhinosinusitis, followed by skull base tumors and post-traumatic interventions.

32 (26,0%) of the patients studied were suffering from nasal allergy. 15 (12,2%) patients suffered from Samter's triad (CRSwNP, bronchial asthma and aspirin intolerance) (Table 1).

Total obstruction of the frontal sinus ostium after surgery occurred after 22.6 months in one case only of 86 patients in the group where the pedicled flap was used. Using bilateral flaps, there was no total closure. In the control group, without the use of a mucosal flap, total closure occurred in 3 cases of 37 patients, after 4.9, 9.6 and 14.9 months (Table 2). All affected patients had chronic rhinosinusitis. Three out of 4 patients with a total obstruction of the frontal sinus neo-ostium had undergone previous surgery, in 3 cases there was a history of allergy, 2 suffered from Samter's triad.

Total closure

The log-rank test showed a significant association to the event total closure for surgical technique considering the use of a lateral pedicled mucosal flap (p = 0.048) (Figure 4).
The studied covariates with presence of an allergy (p = 0.028) and the existence of Samter's triad (p = 0.040) were also significant with the endpoint total closure of the drainage pathway. The other variables (revision surgery, chronic rhinosinusitis) showed no significant association.

Near total closure

The endpoint near total closure of the frontal sinus drainage pathway was found in 16 patients. Such a finding was found in the follow-up in 11 of 86 patients from the intervention group (in 2 cases bilateral mucosal flaps were used) and 5 of 37 from the control group. (Table 2). There was no significant difference between the two groups regarding the surgical technique studied (p = 0.939) (Figure 4).

The majority from the treated group (87.5%) suffered from rhinosinusitis (CRS), and 15 patients (93.8%) had already had previous surgery. Six cases had a history of Samter's triad.

There was a significant association between the onset of near total closure of the frontal sinus ostium and the covariates Samter's triad (p = 0.003) and CRS (p = 0.007). Furthermore, the fact that revision surgery was involved (p = 0.046) was also significant. Other variables showed no significant association.

Discussion

Despite advances in technical capabilities, obstructions of the frontal sinus drainage pathway occur frequently [9,10,20]. Last but not least, exposed areas of bone in conjunction with impaired wound healing appear to have an influence on this outcome [11,13,21]. This provided the impetus for analyzing the technical performance of the modified Lothrop procedure and studying potential new approaches.
The modified Draf III procedure described in this article, using a lateral pedicled mucosal flap, has a few key advantages. The mucosa on the nasal septum utilized for the transposition flap is resected and hence remains unused in the conventional technique. Furthermore, the modified Draf III procedure involves a pedicle flap without an axial vessel. Random pattern flaps, as in this case, have perforating vessels which can arise in external skin subdermally for example from the periosteum and thus guarantee the blood supply [22,23]. In terms of ensuring a blood flow

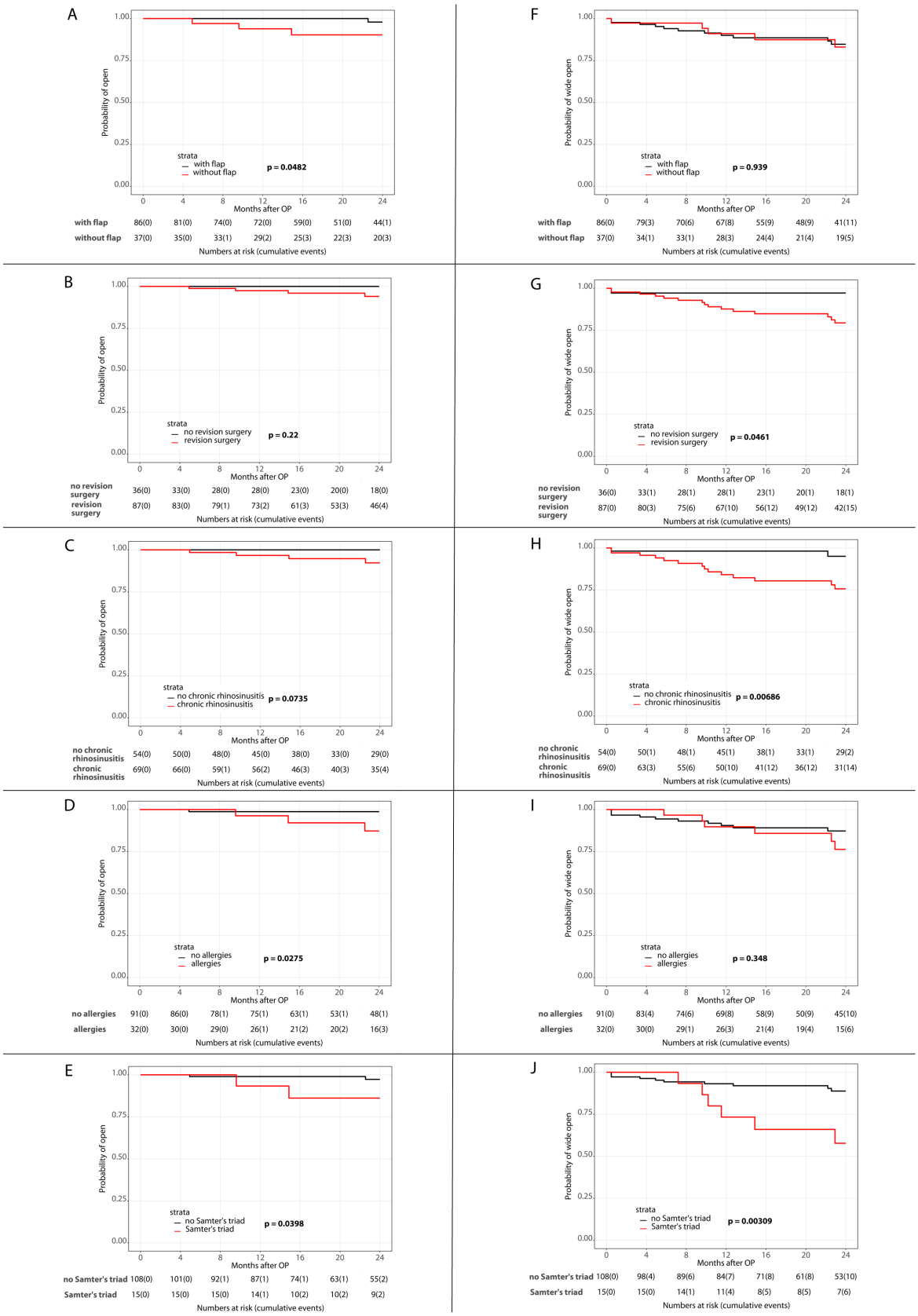

Figure 4. Time-to-event analysis; shown on the ordinate: the probability of "open" (A-E) or "wide open" (F-J) of the drainage pathway , statistical end-point: total closure (A-E) and near total closure (F-J) of the frontal sinus ostium as a function of the surgical technique (A, F), revision surgery (B, G), concomitant chronic rhinosinusitis (C, H), allergies (D, I) and the presence of Samter's triad (E, J).

Table 2. Overview of patients with total/near total restenosis

No.	Age at surgery (years)	Sex (m/f)	Date of surgery (R for revision surgery)	Use of pedicle flap (yes/no)	Date of (near) total closure of the drainage pathway	Allergy (yes/no)	Samter's triad (yes/no)	Surgical indication: CRS, post-traumatic (PT), tumor (T)
Total closure								
1	56	f	09/13/2013-R	no	12/11/2014	yes	yes	CRS
2	60	f	03/08/2016	no	08/04/2016	no	no	CRS
3	70	f	10/02/2018-R	yes	08/20/2020	yes	no	CRS
4	62	m	10/05/2019-R	no	07/23/2020	yes	yes	CRS
Near total closure								
5	42	m	11/28/2013-R	yes	03/10/2014	no	no	CRS
6	62	f	07/23/2014-R	yes	07/09/2015	no	yes	CRS
7	63	f	01/13/2016-R	yes	06/09/2016	no	no	CRS
8	40	m	04/19/2016-R	no	03/16/2018	yes	yes	CRS
9	61	m	07/11/2017-R	yes	05/16/2019	no	no	T
10	55	m	10/09/2017-R	no	08/16/2018	no	yes	CRS
11	46	m	02/20/2018-R	yes	12/16/2018	yes	no	CRS
12	49	f	09/04/2018-R	yes	04/11/2019	no	yes	CRS
13	71	f	06/21/2019-R	yes	04/07/2019	no	no	CRS
14	55	m	01/31/2020-R	yes	07/23/2020	yes	no	CRS
15	72	f	03/09/2020-R	yes	04/01/2021	no	no	CRS
16	52	m	02/17/2021	yes	03/04/2021	no	no	T

with oxygenation of the peripheral end of the flap, the width-to-length ratio of the flap pedicle should be generally taken into consideration [24]. Assessment of perfusion of the flap periphery seems even more important since anatomical conditions inside the nose, where maneuverability is poor, make it impossible to maintain an optimum ratio. Following neurosurgical methods [25] a specialized analysis technique made it possible to demonstrate a blood supply after intravenous administration of ICG (Figure 3).

Use of the described surgical technique means that the flap can be dissected on both sides of the nose, and it is long enough to extend into the frontal sinus. Thus, the mucosal defect can be covered almost entirely. It is hence possible to promote wound healing with healthy mucosa positioned on the inflamed bone areas and to avoid restenosis [11].

Data for 123 patients were analyzed and compared to achieve high quality and informative value with respect to the effect of the newly established surgical technique. The roughly equal distribution in the study groups was a key factor in the comparability of the results (Table 1). In addition, all the operations were performed by the same surgeon.

The leading indication for surgery was CRS (56.1%), followed by tumors (22.8%) and post-traumatic causes (17.1%). The majority of all the revision procedures were in turn performed because of CRS. This supports the theory of its association with restenosis [26]. A significant proportion of restenosis seem to occur mainly in the first two years after surgical treatment [26,27]. Other authors even report that the majority of all stenoses present within the first year after treatment [11,12,28]. For this reason and because of the high density of follow-up examinations, a period of up to 24 months was chosen in this study. Nevertheless, long-term aftercare of such patients for several years is essential [11].

In the described total population, 4 patients had a complete restenosis, which reflects a high success rate (96.8%) compared to other studies [7,8,12]. Considering patients with pronounced narrowing of the neo-ostium or the presence of subtotal stenosis, the success rate fell to 87.0%. It should be noted, however, that no patients who had a residual ostium experienced any symptoms. This phenomenon is also observed in other studies [26]. No clear-cut definition of the criterion of stenosis is given in the current literature [11]. Anderson used the need for frontal sinus revision surgery as the decisive criterion of failure for 612 patients [10], while other authors define stenosis via the clinical findings, partly dependent on symptoms [12,19,26].

In terms of the surgical technique employed, the rate of

complete stenoses in this study, when using a lateral pedicle mucosal flap as part of a Draf III procedure, proves significantly lower than with the classic technique (Figure 4). A subgroup analysis with bilaterally prepared flaps was not performed separately due to the small number and uneven distribution. In the study period one patient out of 86 had a freshly appeared complete stenosis in the group treated with a pedicle mucosal flap, whereas 3 people had complete obstruction among the 37 patients who underwent the standardized Draf III procedure. On the other hand, regarding narrowing of the drainage pathway ("near total closure"), no relevant advantage of either of the two techniques can be identified (11/86 versus 5/37 patients). Unfortunately, the retrospective analysis does not reveal any possible causes of this interesting result.
Presumably other factors, which can lead to a deterioration and hence to restenosis, play a decisive role in this finding.

Among other things, it was demonstrated that patients suffering from CRS had rather a tendency to a deterioration in their postoperative findings. From the total group of all 16 (near) total closure findings, 14 patients suffered from CRS, 14 had already undergone frontal sinus surgery in the past. Another significant criterion associated with stenosis is the presence of Samter's triad. Those affected tended significantly more frequently not only to near total closure, but also unfortunately to total closure after undergoing frontal sinus median drainage. These findings partly coincide with those of Tran [11] and Casiano [12]. The fact that patients with a history of allergy (including to pollen) also tend to stenosis, as shown in this study, is a matter of some debate. Casiano [12] reports on 21 cases with a previous history of allergy and an association with respect to the stenosis rate, which Schlosser et al. [28] refuted in their own case series of 44 patients.

A technically similar method but with a shorter follow-up period and fewer patient numbers was described by Khoueir et al. [21]. Their success rate is roughly the same at 93.75% (15/16 patients with patent drainage pathway). The authors did not perform a classification of the endoscopic findings into "near total closure" or "total closure". AlQahtani et al. also described a similar approach in the context of a cadaver analysis in the laboratory [29]. A use of this technique in operative care was not investigated.

The study presented here, as well as describing the modified Draf III procedure, also investigated what effect the additional dissection of a lateral pedicle mucosal flap has on the outcome for the patients concerned: considering the results, the new technique can be seen as a worthwhile working step during a frontal sinus median drainage operation. This broadens the range of therapeutic options for counteracting obstruction of the drainage pathway around the frontal sinus.

Furthermore, additional treatment approaches to improve the surgical outcome and/or to reduce the inflammatory process could be discussed. For instance, methods such as steroid-releasing paranasal sinus implants have recently been mentioned [30].

Conclusion

The endonasal stabilization of the neo-ostium after frontal sinus surgery still poses a surgical problem nowadays. Mucosal covering of the bare bone by means of a new lateral pedicle mucosal flap for frontal sinus drainage after a modified Lothrop procedure improves wound healing and thus prevents complete stenoses due to scarring and osteitis when compared to the conventional technique.

Authorship contribution

RF., TK designed the study. TK performed the surgeries. RF, CS, TK examined the patients. RF, CS, FZ analyzed the data. FR, CR, TK designed the figures. RF, TK wrote the paper. CB, WH, RW revised and edited the manuscript critically. All authors have read and agreed to the published version of the manuscript.

Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the Ethics Committee of the University of Regensburg (no. 20-2085-101) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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René Fischer, MD
Department of Otorhinolaryngology
University of Regensburg
93042 Regensburg
Germany

Tel: 0049-941-944-9401
Fax: 0049-941-944-9402
E-mail: rene.fischer@ukr.de