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PATIENT SATISFACTION AFTER USING A REVERSE FLOW BASED FACIAL ARTERY MUSCULOMUCOSAL FLAP (FAMM) VERSUS A PALATAL PEDICLED FLAP FOR CLOSURE OF RECURRENT SMALL AND MEDIUM-SIZED ORONASAL FISTULA (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

Patient Satisfaction After Using a Reverse Flow Based Facial Artery Musculomucosal Flap (FAMM) versus a Palatal Pedicled Flap for Closure of Recurrent Small and Medium-Sized Oronasal Fistula: A Randomized Clinical Trial

Objectives: To evaluate the clinical success and patient satisfaction of FAMM for closure of recurrent small to medium oronasal fistula in comparison to the palatal pedicle flap.

Patients and Methods: 24 patients with recurrent small and medium-sized oronasal fistula failed after several trials to close, up to 10 mm were recruited. Patients were equally divided into two groups; G1: had surgical closure using FAMM flap and G2: had a Palatal Pedicle flap. Success is determined by the degree of patient satisfaction and healing, as well as the lack of complications.

Results: Clinical results showed that in the 2nd and 4th week, the percentage of healed fistula was 100% in the FAMM group and 75% in the palatal flap group while in the 2nd and 3rd month, the percentage of patients with healed fistula was 100% in FAMM and 75% in the palatal flap groups. Regarding mouth opening results showed that at the 2nd and 4th week, the percentage of patients with normal oral competency was 91.7% in the FAMM group, compared to 75% in the palatal flap group while at the 2nd and 3rd month the percentage of patients with normal oral competency was 100% in the FAMM group compared to 75% in the palatal flap group with no statistically significant differences.

Conclusion: The FAMM flap and palatal pedicle flap are effective choices for reconstructing small to medium-sized recurrent ONF due to their reliability and versatility. Both flaps yield satisfactory functional outcomes. Truly, FAMM flap is preferred over palatal flap.

KEYWORDS: **Musculomucosal, Palatal, Flap, Oronasal, Fistula**

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INTRODUCTION

Oronasal fistula (ONF) is a common and significant complication that can arise after cleft palate repair. These fistulas can negatively impact speech and result in food exiting through the nose during eating. To address these issues, a second surgery is often required when an ONF is present. However, this secondary procedure entails considerable pain, suffering, and medical expenses. Consequently, ONF following cleft palate repair is an important outcome in the field of cleft surgery and is utilized as a measure of surgical quality on both national and international scales [(1)].

Closing a fistula presents a considerable challenge for surgeons. Despite the introduction of various surgical techniques over the past two decades, such as using tong flaps, orbicularis oris musculomucosal flaps, free flaps, buccal mucosal grafts, or acellular dermal matrix, there is still a high likelihood of fistula recurrence after the initial repair [(2)].

One technique, known as the palatal flap, is an axial flap that relies on the greater palatine artery. This flap can be employed as a rotational flap or an interpolated flap with an intervening bridge of oral epithelium. In a study conducted by Parvini and colleagues in 2018, favorable outcomes were reported for oroantral fistulas treated with a palatal rotation advancement flap[(3)]. The advantages of this technique include its proximity to the defect site, similarity to the surrounding tissue, good blood supply, preservation of sensory innervation, appropriate thickness, minimal complications at the donor site, straightforward anatomy, and short procedure duration [(4)].

The facial artery musculomucosal flap (FAMM) is a versatile intraoral flap covered by the mucosa of the cheek. This flap can be pedicled either inferiorly or superiorly, based on the facial artery or angular artery, respectively. The superiorly based pedicle has been used in several reports for reconstructing defects of the hard palate or nasal cavity [(5)]. Ayad et al. conducted a systematic review of the indications and outcomes associated with FAMM flaps, drawing data from various studies. The authors concluded that the primary indications for these flaps included reconstruction following tumor removal in the oral cavity or pharynx, closure of fistulas in the oral cavity or nasal area, and treatment of osteoradionecrosis [(6)]. Hence, the objective of the present study is to compare the utilization of the FAMM flap with the palatal pedicled flap in closing recurrent oronasal fistulas.

MATERIALS AND METHODS

Ethical Consideration

The study's protocol was reviewed and approved by the institutional review board (IRB) and the ethics committee at the Faculty of Dentistry of Cairo University and was registered on clinicaltrials.gov with an I.D. number NCT04814901.

Study Design and Study Setting

The present study was a two-arm, parallel, randomized, single-center, open-label trial with a follow-up period of three months. Eligible patients were randomized and allocated in a 1:1 ratio among the two groups. All the patients were selected from the Outpatient Clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University, Egypt.

Grouping

Surgical closure of patients with recurrent small to medium-sized oronasal fistula was done either by using the Facial Artery Musculomucosal Flap "FAMM" (Group I) compared to using the Palatal Pedicle flap (Group II).

Sample Size Calculation

A non-probability consecutive sampling method was employed for participant selection. Initially,

30 patients were screened for potential inclusion in the study; however, six patients were excluded due to ipsilateral surgery, and two patients declined to provide written informed consent. Consequently, a total of 24 patients were included in the analysis and assigned to the study group. The allocation of participants was carried out randomly using the minimization method with electronic data capture. No blinding procedures were implemented in this particular study. The effect size was calculated using Cohen's d method, resulting in a value of 1.17.

Eligibility Criteria

Patients of an age range between 18-60 years of both genders with recurrent small and medium-sized oronasal fistula failed after several attempts of closure, up to 10 mm regardless of the number of recurrence and position of the fistula were enrolled. Recruited patients accepting consent for extracting one tooth in the surgical field if needed without having any contraindications to surgical intervention with a patent facial artery course assessed using the doppler study were able to participate in the study. Patients with ipsilateral radiation, previous ipsilateral surgery or with ipsilateral carotid ligation were excluded.

Preoperative Data Collection

Case history including personal data, medical, surgical and family history was recorded. After clinical examination, the Maximum Interincisal mouth opening (MIO) was recorded and a preoperative identification and mapping of the facial artery was performed using Doppler.

Preoperative Preparations

All patients under general anesthesia were infiltrated with lidocaine 2% + epinephrine 1:200,000 (Septodont, USA) followed by probing around the fistula to demarcate the bone defect before starting the surgical steps of each group.

FAMM Flap Surgery

To prevent accidental injuries, the course of the facial artery was marked using a handheld Doppler, along with the identification and marking of the parotid duct. Following Sahoo et al., 2016, the flap was marked in a medial position to the duct, which determined the posterior limit of the flap. The anterior marking of the flap began 1 cm behind the oral commissure, and its size was adjusted proportionally to the size of the defect. However, to avoid tension during donor site closure, the width of the flap was kept at 2-2.5 cm as shown in Fig. (1,2) [7].

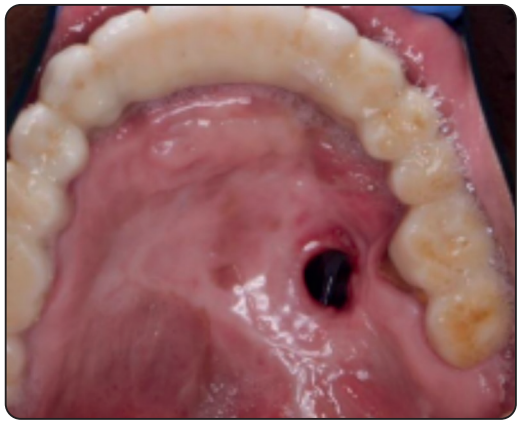

Fig. (1) Right preoperative recurrent oro-nasal fistula

Fig. (2) Anterior incision 1 cm posterior to oral commissure to prevent inward retraction of commissure

An initial incision was made 1 cm posterior to the oral commissure to locate the superior labial artery, which could be traced back to the facial artery. The incision was then deepened through the buccal mucosa, submucosa, and the underlying muscles (buccinators and a small portion of the orbicularis oris near the commissure) until reaching the layer of buccal fat. The artery was ligated proximally, and the flap was swung over a pivot at the base of the pedicle to cover the defect. Careful attention was given to prevent kinking or twisting of the pedicle. Once the surgical site was fully prepared, the flap was inserted, and the donor site was closed primarily using interrupted sutures of 4-0 polyglactin (Vicryl) (Ethicon, Scotland) Fig. (3,4) [7].

Palatal Pedicled Flap

Paramedian subperiosteal incisions were made on the palate to create a full-thickness palatal flap, providing a clear view of the bone defect measuring approximately 2 cm in diameter. The flap was outlined to extend from the palatal mucosa opposing the permanent second molar to the permanent canine anteriorly. After the incision, the flap was raised, pedicled over the greater palatine artery, rotated toward the oronasal fistula, and secured in place using interrupted sutures of 4-0 Vicryl (Ethicon, Scotland) Fig. (5,6) [7].

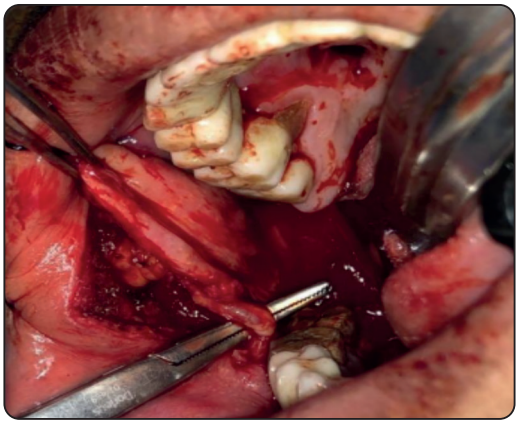

Fig. (3) Dissection begins along the anterior margin through mucosa; submucosa, and buccinator muscle. The superior labial branch of the facial artery is first identified just above the height of the commissure and then ligated.

Fig. (4) The elevated flap is then rotated and sutured into position and the cheek is closed primarily by using 4-0 vicryl absorbable suture leaving a small open area around the base of the pedicle to prevent compression and allow for donor site drainage.

Fig. (5) Pre-operative fistulous tract on the left side of the palate

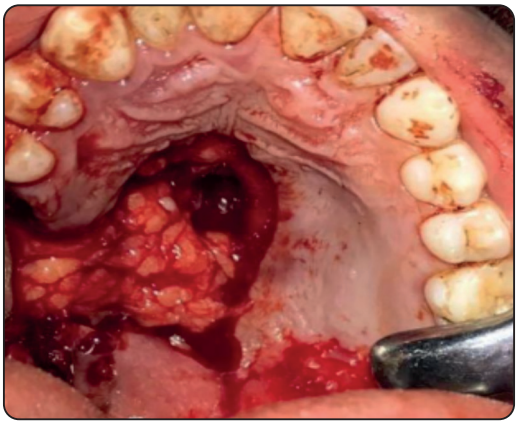

Fig. (6) Resection of the fistulous tract

Post-operative Care

Before being discharged within 48–72 hours after the surgical operation, postoperative medications, including antibiotics (amoxicillin 1g capsules b.d.s.) and analgesics (diclofenac potassium 50 mg as needed), were prescribed to the patient in addition to strict postoperative oral hygiene instructions. Patients were asked to remain on a soft diet for one week and then were examined after two weeks for ischemia or pedicle detachment in the FAMM group. Patients were encouraged to adhere to successive follow-ups to assess the achieved anatomical continuity. Participants in the FAMM group were not given a dental block piece.

Outcome Measures

Patient satisfaction was evaluated using the 10-mm visual analog scale (VAS) to quantify improvements in function and quality of life following surgical repair of the previously unsuccessfully operated defect. Each patient completed a questionnaire based on word articulation and chewing, providing values ranging from 1 to 10. A score of 1 represented the least satisfaction, while 10 represented the most satisfactory result. The results on the VAS were categorized as very good (8-10), good (6-8), fair (4-6), or poor (<4). Secondary outcomes focused on clinical assessment, including measuring postoperative maximum interincisal opening (MIO) using a digital caliper and observing the healing pattern visually for any breakdown, dehiscence, or infection. Facial nerve function was evaluated and graded as intact if there was no sialorrhea and the patient could hold air with a gentle mouth squeeze.

Statistical Analysis

Data were collected and entered into the SPSS (Statistical Package for Social Science) program for statistical analysis. Quantitative data were presented as mean, standard deviation (SD), and range, while qualitative data were expressed as frequency and percentage with a 95% confidence interval (95% CI). The chi-square test and Fisher exact test were used to assess associations between categorical variables. A p-value less than 0.05 was considered statistically significant.

RESULTS

Only one patient out of 24 had a tooth extraction during the surgical procedure. In one case in the FAMM group, there was a suture line dehiscence. However, the flap was successfully advanced and resutured. The results (Table 1) showed that there was no statistically significant difference between both groups at different time intervals after two weeks, one month, two months, and three months with p-values of 0.54, 0.63, 0.18 and 0.17 respectively.

TABLE (1) The distribution of patients' satisfaction categories

Time period	Palatal Flap (N =12) No. (%)	FAMM (N= 12) No. (%)	P-value
Two weeks			
- Very Good	3 (25%)	6 (50%)	
- Good	5 (41.7%)	4 (33.3%)	0.54
- Fair	1 (8.3%)	1 (8.3%)	
- Poor	3 (25%)	1 (8.3%)	
One Month			
- Very Good	5 (41.7%)	7 (58.3%)	
- Good	3 (25%)	5 (41.7%)	0.63
- Fair	3 (25%)	0	
- Poor	1 (8.3%)	0	
Two Months			
- Very Good	6 (50%)	8 (66.7%)	
- Good	3 (25%)	4 (33.3%)	0.18
- Fair	0	0	
- Poor	3 (25%)	0	
Three Months			
- Very Good	7 (58.3%)	9 (75%)	
- Good	2 (16.7%)	3 (25%)	0.17
- Fair	0	0	
- Poor	3 (25%)	0	

Data are presented as mean ±SD, median (Range), or number (%).

As for mouth opening (Table 2), results showed that there was a statistically significant difference between the two groups after two weeks as well as after one month at p-values of 0.005 and 0.028, respectively. Normal mouth opening was observed in 100% of the cases of the palatal flap at both time intervals compared to 50% and 66.7% of the FAMM group. 100% regain of normal mouth opening was obtained in both groups at two months follow-up and onwards.

TABLE (2) The distribution of mouth-opening categories

Time period, No. (%)	Palatal Flap (N =12)	FAMM (N= 12)	P-value
Two weeks			
Normal	12 (100%)	6 (50%)	0.005
Reduced	0	6 (50%)	
One Month			
Normal	12 (100%)	8 (66.7%)	0.028
Reduced	0	4 (33.3%)	
Two Month			
Normal	12 (100%)	12 (100%)	---
Reduced	0	0	
Three Month			
Normal	12 (100%)	12 (100%)	---
Reduced	0	0	

Data are presented as mean ±SD, median (Range), or number (%).

Fig. (7) 3-month follow-up after fistula closure using FAMM flap.

Wound healing and closure of fistula (Table 3) showed a 100% healing of the FAMM group after two weeks onward while 75% only showed complete healing in the palatal flap group with no statistically significant difference between both groups Fig. (7,8).

TABLE (3) The distribution of the healing pattern

Time period, No. (%)	Palatal Flap (N= 12)	FAMM (N= 12)	P-value
Two weeks			
Healed	9 (75%)	12 (100%)	0.064
Wound breakdown	3 (25%)	0	
One Month			
Healed	9 (75%)	12 (100%)	
Wound breakdown	3	0	---
Two Months Healed	9 (75%)	12 (100%)	
Wound breakdown	3	0	---
Three Months			
Healed	9 (75%)	12 (100%)	
Wound breakdown	3	0	---

Data are presented as mean ±SD, median (Range), or number (%).

Regarding oral competency, better results were shown in the FAMM group with no statistically significant difference between both groups at the different time intervals as shown in Table (4).

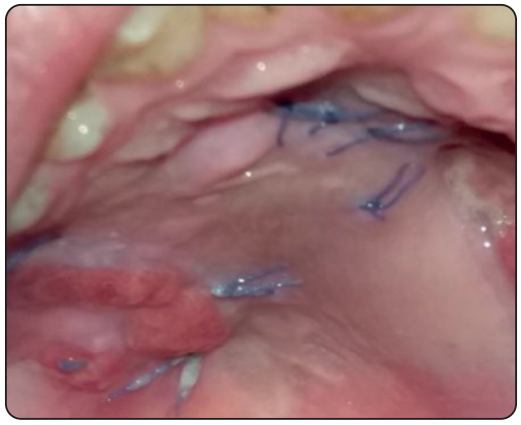

Fig. (8) 3-month follow-up after fistula closure using palatal pedicle flap

TABLE (4) The distribution of oral competency

Time period, No. (%)	Palatal Flap (N =12)	FAMM (N= 12)	P-value
Two weeks			
Normal	9 (75%)	11 (91.7%)	0.27
Reduced	3 (25%)	1 (8.3%)	
One Month			
Normal	9 (75%)	11 (91.7%)	0.27
Reduced	3 (25%)	1 (8.3%)	
Two Month			
Normal	9 (75%)	12 (100%)	0.064
Reduced	3 (25%)	0	
Three Month			
Normal	9 (75%)	12 (100%)	0.064
Reduced	3 (25%)	0	

Data are presented as mean ±SD, median (Range), or number (%).

DISCUSSION

After undergoing cleft palate repair, the development of oronasal fistulas (ONFs) is a significant and troublesome complication. Previous studies have reported the incidence of ONF to range from 4% to 35%. Several factors contribute to ONF formation, including repair under tension, intraoperative bleeding, postoperative infection, type of cleft palate, and surgical technique. ONFs can lead to clinical symptoms such as nasal fluid and food regurgitation, hyper-nasal speech, malodor, hearing loss, and nasal catarrh. They can also cause psychosocial and behavioral issues, significantly impacting the patient's overall well-being [8].

The size of ONFs is categorized as small (<3 mm), medium (3-5 mm), or large (>5 mm). Actually, spontaneous healing may occur for defects with a breadth of less than 3mm. In order to achieve closure, it is necessary to employ rotating and sliding flaps or the use of bone graft for communications that exceed a width of 5 mm, which was applied in our study [9]. The success of closure might be influenced by the site of the oroantral fistula. The location of the fistula within the oral cavity might have an impact on the surgical strategy and the feasibility of using nearby tissue for closure. Fistulas that are situated in proximity to the alveolar ridge or the hard palate tend to be more easily reachable and may exhibit a greater likelihood of success in comparison to those placed in more problematic regions, such as the posterior maxillary sinus or the tuberosity region. The feasibility and effectiveness of fistula closure are influenced by factors such as the closeness of the fistula to neighboring anatomical structures and the quality of the local tissues [10].

Closing ONFs presents a great challenge for surgeons, especially in the presence of scar tissue, which often differs in quality and vascularity compared to healthy tissues. Scar tissue in the palate tends to be less flexible, less elastic, and may have compromised blood supply as shown in a past case report [11]. Despite the introduction of various surgical techniques over the past two decades, such as tongue flaps, orbicularis oris musculomucosal flaps, free flaps, buccal mucosal grafts, or acellular dermal matrix, there remains a high probability of recurrent fistulas after primary repair [3].

The palatal flap is an axial flap based on the greater palatine artery. It can be used as a rotation flap or an interpolated flap with an intervening bridge of oral epithelium. Its initial description was credited to Ashley in 1939 [12]. Since then, numerous authors have demonstrated the efficacy of this flap and its modifications in closing oronasal fistulas, oropharyngeal fistulas, and various small to medium-sized ablative defects. The advantages of the palatal flap include its proximity to the defect site, similarity to the surrounding tissue, good vascularity, preservation of sensory innervation, adequate thickness, minimal donor site morbidity, straightforward anatomy, and short procedure time[13].

Alternatively, due to wound contraction and the presence of scar tissue surrounding the fistula, it is preferable to use a regional flap that provides fresh, unscarred, and well-vascularized tissue. Pribaze et al. [14]. introduced the facial artery musculomucosal (FAMM) flap, which is an axial pattern flap based on the facial artery. Unlike most free flaps, the FAMM flap offers mucosal coverage instead of skin. It is a reliable and versatile flap that has been successfully utilized in palatal reconstruction following ablative surgery, trauma, and cleft surgery [15].

The FAMM flap, approximately 5 mm thick, consists of buccal mucosa, submucosa, and the buccinator muscle, along with its feeding vessels and vascular plexus. The donor site can usually be closed directly without causing deformity or scarring. This flap is particularly suitable for covering small to medium-sized defects due to its tissue characteristics and ease of performance. The technique has shown effectiveness, providing advantages such as tension-free palatal closure, robust muscular reconstruction, lengthening of the nasal layer, and closure of the palate without leaving exposed areas [16].

To the best of our knowledge, no previous studies have compared the outcomes of the palatal flap and FAMM flap in patients with recurrent small to medium-sized ONFs. Therefore, the objective of this study was to assess the impact of using the FAMM flap for closure of such ONFs on patient satisfaction, in comparison to the utilization of the palatal pedicled flap.

Depending on the degree of functional impairment, oronasal fistulas (ONFs) can have psychological, social, and developmental consequences and therefore require repair [3]. In our randomized controlled trial, we focused on patients' satisfaction as the primary outcome. We found that the FAMM group had higher patient satisfaction regarding feeding practice compared to the palatal group, although the difference was not statistically significant. Specifically, in the second week, fourth week, second month, and third month of follow-up, the FAMM group showed numerically higher patient satisfaction percentages (50% versus 25%, 58.3% versus 41.7%, 66.7% versus 50%, and 75% versus 58.3%, respectively).

These findings are consistent with a case reported by Ariffuddin et al. [17] where a previously repaired ONF was effectively closed using an inset FAMM flap, resulting in satisfactory feeding practice at the end of the follow-up. Similarly, Ayad et al. [6] conducted a systematic review on FAMM flap outcomes in oronasal defects and found that 81% of patients who underwent FAMM flap reconstruction for cleft palate had resolution of nasal regurgitation. Another study by Sumarroco et al. [18] reviewed the results of FAMM flap procedures performed between 2006 and 2014. The study was conducted on 20 patients and 20 FAMM flaps were done. The flaps were divided to 16 right and 9 left as (64%) and (36%) respectively. They reported satisfactory oral function and ingestion in all patients.

These positive outcomes can be attributed to the fact that the FAMM flap has minimal or no aesthetic sequelae compared to tunneled nasolabial flaps, as there are no external scars. Additionally, the FAMM flap allows reconstruction using histologically similar mucosal tissue, which typically leads to better functional results [18]. Conversely, the lower satisfaction observed in the palatal pedicle flap group may be attributed to the disadvantages of this technique, including denudation of the palatal surface, pain, and the subsequent appearance of roughness and deepening in the area due to secondary epithelization over a period of two to three months.

In the present study, we found that the normal oral competency, as a measure of facial nerve function, was numerically higher in the FAMM group compared to the palatal pedicle flap group at the second week (91.7% versus 75%), fourth week (91.7% versus 75%), second month (100% versus

75%), and third month (100% versus 75%). The reduced facial nerve function in the palatal regional flap group can be explained by air escape from the fistula rather than true facial nerve affection. The superiority of the FAMM flap in this aspect could be attributed to the fact that the facial nerve branches are located more superficially than the facial artery, and they are usually not included in the dissection plane, minimizing the risk of nerve injury.

Donor site morbidity is minimal with the FAMM flap, and no complications related to the donor site were encountered in our study. This finding aligns with other published papers on FAMM flaps, which also reported no issues with donor sites [19]. Removing a strip of muscle and mucosa from the buccal surface does not affect mouth opening. Although there may be a slight reduction in mouth opening immediately after the surgery, it returns to normal within three months. In one case in this study, there was a suture line dehiscence, possibly due to the thinned mucosa to which the flap was sutured. However, the flap was successfully advanced and resutured, leading to uneventful healing of the fistula.

The FAMM flap does have certain limitations. The maximum width that can be obtained is 2.5-3 cm, which allows for closure of the donor area and use in anterior hard palate fistulas. Additionally, an open alveolar cleft is necessary for the flap to access the anterior palate. To prevent patients with teeth from biting the pedicle, a dental block piece needs to be placed in the immediate postoperative period. Another limitation is the vascular anatomy of the flap. The facial artery has a tortuous course in this region, so careful attention must be paid to include the arterial axis in the flap. The relationship between the artery and vein can also vary, with the vein following the course of the artery at a distance of up to 23 mm. Therefore, there is a risk associated with isolating the flap and maintaining a mucosal layer over the pedicle increases the likelihood of including venous tributaries [20].

CONCLUSION

In conclusion, both the FAMM flap and the palatal pedicle flap are valid choices for reconstructing small to medium-sized recurrent oronasal fistulas (ONFs). These flaps offer reliability and versatility in addressing such complications. They have demonstrated favorable outcomes with minimal complications and satisfactory functional results. Therefore, both the FAMM flap and palatal pedicle flap are suitable options for reconstructing ONFs located at the anterior hard palate and between the soft and hard palate, which are commonly affected sites following cleft palate repair. Our comparative analysis showed that FAMM had more favorable outcomes in terms of patients' satisfaction and facial nerve function. Thus, FAMM may be favored over palatal pedicle flap when the healthcare facility is well-prepared for FAMM. There is a vital need for the development of individualized interventions for the management of recurrent ONF. Nevertheless, further large-scale studies are still needed to confirm our findings.

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