The Combination of a Buccal Trapezoidal Flap With a Palatal Connective Pedicle Flap for the Closure of Oro-Antral Fistulae

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Abstract: Various surgical techniques have been developed for the closure of oro-antral fistulae (OAF), all of them presenting some limitations. Nineteen consecutive patients with a clinical diagnosis of OAF were enrolled in the present case series study. The technique being tested included the reflection of a buccal trapezoid flap with the OAF at its center. The lesion was then fully exposed and debrided. A palatal pedicle connective graft was split from the overlying mucosa and it was rotated over the lesion and under the buccal flap, thereby double-sealing the fistula. The superficial layer of the palatal flap was left at its primary position and sutured, thus ensuring primary intention healing of the palate. The patients were followed for 30 days. No patient showed residual oro-antral communication by the end of the follow-up period. The pain level was highest at the end of the first follow-up week, with a median visual analog scale of 4, which decreased to 3 in the second week, and to 0 in the fourth week. The same trend could be observed for Discomfort. The combination of a buccal flap with a split palatal connective tissue flap is an effective surgical technique with good predictability and high patient satisfaction levels.

Key Words: connective tissue, OAF closure, oro-antral fistula, palatal flap, pedicle flap

(*J Craniofac Surg* 2022;33: 00–00)

Oroantral communication (OAC) is an abnormal pathologic connection between the oral cavity and the maxillary sinus.[1,2] The term oroantral fistula (OAF) is used to indicate a communication lined by epithelium that may be filled either with granulation tissue or with polyposis of the sinus membrane.[3] OAC may develop into OAF, if both, it remains open during the first 48 to 72 hours, and it becomes epithelialized: OAFs persisting beyond 3 weeks are regarded as "chronic."[4] Due to the local interruption of the mucoperiosteum barrier, there is a higher chance of sino-nasal infections caused by anaerobes and oral species ascending from the oral cavity.[5]

OACs fall within the surgical complications of tooth extraction, infections, sinusitis, osteomyelitis, trauma, and/or implant placement. Oroantral fistula is associated with variable degrees of rhinosinusitis, and it is 1 of the most common causes of odontogenic maxillary sinusitis.

Although odontogenic maxillary sinusitis has been traditionally related to dental conditions, more recently a broader definition was proposed, with the attempt to integrate both implant-related and sinus augmentation-related sinonasal conditions into the definition of "sinonasal complications of dental disease or treatment".[6] Clinical symptoms would include unilateral cheek pain with nasal obstruction, purulent rhinorrhea, foul odor, foul taste, headaches, anterior maxillary tenderness, and postnasal drip.[1]

The successful management of OAFs dwells on early clinical and instrumental diagnosis. In any case, the therapeutic goal is to restore the functio lesa, thus sealing again the oral cavity from the maxillary sinus.

OAC dimensions might represent a key-factor when choosing the treatment strategy. OAC smaller than 3 mm in diameter may heal spontaneously, whereas flap procedures are recommended in presence of wider lesions.[7,8]

The buccal flap approach, the oldest and most widely used procedure, finds its clinical indication in presence of small- and moderate-size defects[9–10]; conversely, it has been suggested that wider OACs might need the adjunctive displacement of a buccal fat pad reflection.[11,12] Among other surgical approaches, the palatal-based rotational flap, recently widespread, is raised full-thickness and it includes the greater palatine artery in its width.[12,13] Albeit a good vascular supply is guaranteed to the OAC, the overall healing process is jeopardized by a wide palatal second intention healing area, which causes great discomfort and pain for the patient.

To overcome those limitations, subepithelial connective pedicle flaps have been described. Their applications mainly include reconstructive procedures[14–16] and oroantral communications management,[17,18] and they are precisely aimed at avoiding second intention healing associated sequelae.

The aim of the present case series is to describe the clinical performance of a modified surgical approach for the closure of oroantral communications by means of 2 overlapping flaps: a buccal trapezoidal flap secured over a connective pedicle flap, which is rotated from the palate. Success is established on the clinical assessment of OAC closure and patients' related outcomes.

MATERIALS AND METHODS

Individuals representing the reference population for the present single center, prospective, case series were consecutively enrolled

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Received January 23, 2022.

Accepted for publication February 7, 2022.

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The study was reviewed and approved by the Area Vasta ethical committee (ODO002, 26/06/2020).

The authors report no conflicts of interest.

Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jcraniofacialsurgery.com).

ISSN: 1049-2275

DOI: 10.1097/SCS.0000000000008617

from patients in need of posterior maxillae tooth extraction at the Department of Medical Biotechnologies, unit of Oral Surgery, University of Siena, Italy. The study was reviewed and approved by the Area Vasta ethical committee (ODO002, 26/06/2020).

Eligible population was defined by dentate individuals more than 18 years, systemically healthy, with a diagnosis of clinically frank oro antral communication (OAC) or with a reasonable pre-extractive radiographic suspicion of potential OAC, and eventually associated symptoms (varying among cheek pain with nasal obstruction, purulent rhinorrhea, foul odor, foul taste, headaches, anterior maxillary tenderness, and postnasal drip). Patients were excluded if they: (i) received antibiotic therapy in the last 3 months (ii) requiring anticoagulation therapy (iii) had systemic diseases that could interfere with oral tissue healing process/bleeding (iv) were using bisphosphonates (v) were pregnant (vi) had mental/physical disabilities (vii) underwent radiation treatment to the head or neck region.

Patients who were willing to participate were asked to sign a written informed consent, in which scopes and methods of the current protocol were detailed. All study procedures complied with the principles stated in the Declaration of Helsinki "Ethical Principles for Medical Research Involving 'Human Subjects'," adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and as amended most recently by the 64th World Medical Assembly, Fontaleza, Brazil, October 2013.

OAC Diagnosis

The experimental sample has been defined according to the clinical diagnosis of OAC: first, the lesion was probed (University of North Carolina [UNC] 15), second, the patient was asked to perform the Valsalva maneuver. One of the latter criteria must be fulfilled to consider the patient eligible. Two different clinical conditions were considered for this protocol: delayed OAC/OAFs (they occurred within 1 week from the surgical extraction), or immediate (they occurred immediately after tooth extraction).

Pre-Experimental Procedure

All patients, before the experimental procedure, have been screened with a complete periodontal evaluation. With the aid of a periodontal probe UNC 15, at 6 sites per tooth, probing pocket depth, clinical attachment level, full mouth plaque score, and full mouth-bleeding score were assessed. Thereafter, patients were treated accordingly and were instructed on order to improve self-performed oral hygiene. Experimental intervention was postponed until patients showed proper periodontal tissue stability.

The day of the experimental procedure, prophylactic Systemic Antibiotic regimen (Amoxicillin+Clavulanic acid 2 grams) was started 2 hours before surgery.

Immediately before the surgery, patients were asked to rinse with a 0.12% chlorhexidine solution for 1 minute.

Surgical Treatment

The surgical procedure for oroantral communication closure was a combination between a buccal trapezoidal flap and a palatal connective pedicle flap (Fig. 1). All surgeries were carried out by the same expert operator (NB) at the oral surgery subunit facilities, Department of medical Biotechnologies, Siena.

Under local anesthesia, using maxillary block and vestibular infiltration, the OAC/OAF was carefully probed and assessed (Fig. 2A).

The flap design consisted of a trapezoidal flap reflected on the buccal surface of the communication, and completed by 2 vertical beveled releasing incisions on the mesial and distal teeth apart the OAC. Once the OAC/OAF was cleaned and epithelial scar tissue into the fistula was carefully removed, the alveolar dimensions of the communication (mesio-distal and buccal-palatal distances) were recorded using a periodontal probe (UNC 15) (Fig. 2B). Thereafter, the OAC was rinsed with several hydrogen peroxide and rifampicin lavages (Rifocin, Sanofi-Aventis, Milan, Italy).

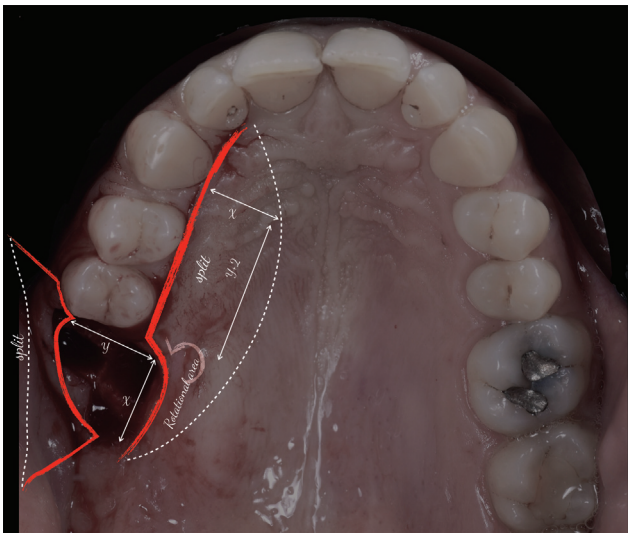

FIGURE 1. Schematic diagram of the surgical technique: the 2 main incisions are depicted in red, the buccal trapezoid flap outline on the left, and the palatal trap outline on the right. *X* and *Y* segments represent the dimensions of the lesion. *X* and *Y* are flipped in the palatal surface to determine the required length and width of the rotational flap.

A split thickness incision was performed in the inner apical portion of the buccal flap, at the level of the mucogingival line: buccal periosteum was left in place and muscular insertions were dissected to obtain an adequately tension-free flap, large enough to cover the lesion.

In the palatal side, a para-marginal incision was performed, not involving the anatomical papillae. Then, a pedicle connective tissue flap was prepared: the surgeon split the thickness of the palatal mucosa, and, after, harvested a connective tissue lingula, making his way from the medial to the distal side, whereas keeping the pedicle flap anchored at its distal edge (Fig. 2C). The pedicle flap's dimensions were reported using the periodontal probe as explained

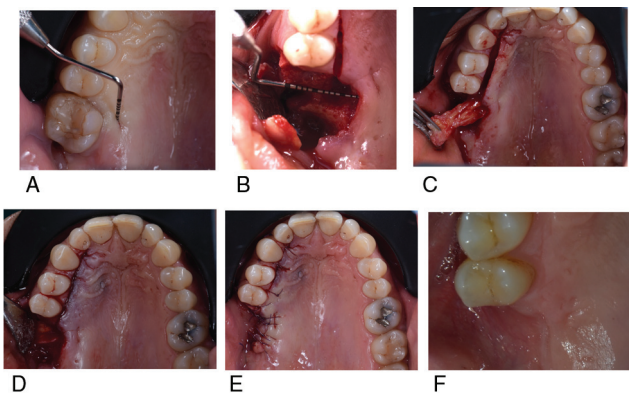

FIGURE 2. Case presentation: (A) oro-antral fistula in the right molar area; (B) after tooth extraction and flaps incision, the OAC is exposed and dissected at the bony level; (C) deep connective palatal layer extended over the OAC; (D) connective layer folded buccally; (E) flap sutured in its primary position; (F) tissue healing at 4 weeks after surgery.

in Figure 1. The flap was then fully rotated to completely cover the OAC area.

Once the connective palatal flap was fully rotated over the OAC without tension, then, it was anchored at the buccal periosteum, in the deepest portion of the buccal flap (Fig. 2D). In the end, the buccal flap was sutured above the rotated connective tissue flap, thus ensuring a double layered closure of the communication (Fig. 2E). The residual mucosal palatal flap was sutured back at its original position, thus favoring first intention healing of the palatal side. Tissue healing was documented with intraoral digital photographs at 2 and 4 weeks after surgery (Fig. 2F).

An example of the full clinical surgical course is presented in Figure 2.

Postsurgical Care

Antibiotic therapy was continued for 5 days after the surgery. Patients were asked to avoid blowing from the nose during the first week after. Analgesic and anti-inflammatory regimen was established for the very first 3 days (Ibuprofen 600 mg 2 times per day) and then pro re nata.

No provisional removable restoration was allowed during the first week of healing.

Clinical and Patient Outcomes Measures

Intra-surgical measure of OAC dimension was performed by the same experienced surgeon who deployed the surgical treatment.

The clinical success in terms of OAC complete closure was recorded as the primary outcome of this study. OAC patency was evaluated by a blinded operator (MV) at day-30 using a double check procedure: clinically probing the soft tissue in the treated area using a periodontal probe (UNC 15) and then performing the Valsalva's maneuver. If at least 1 of the 2 procedures revealed the presence of residual OAC/OAF, the surgical intervention was considered as a failure.

The secondary outcome of the study was to assess patient's discomfort and pain by a ten-grade visual analog scales (VAS) diagram. Personnel not directly involved in the surgical procedure delivered the psychometric scales at day-3, day-7, day-14, and day-30 after the surgical intervention.

All patients were asked to complete VAS diagrams concerning their discomfort and pain after the surgical intervention. Patients' evaluation was requested as an overall judgment of the surgical treatment in terms of discomfort and pain at 3-, 7-, 14-, and 30-day follow-ups. The scale had verbal anchor descriptors at each extreme.

The VAS consisted of a 10 cm long line representing the spectrum of evaluation from 0% (no discomfort at all) to 100% (very relevant discomfort); the distance from the left extremity of the VAS to the mark made by the patient was measured to the nearest millimeter and reported as a value (0 up to 10).

Intrasurgical and postsurgical complications during follow-up were also recorded by the same operator.

Duration in minutes of the surgical procedure starting from the first incision to the last suture was recorded. In those cases where the communication was found after tooth extraction, the recorded time started once the extraction was performed. A clinician (MT), not involved in the surgical procedure, recorded the surgical times.

Data Analysis

Data were entered and proofed for errors. Descriptive and inferential analysis were performed using R version 4.0.4. Characteristics of the sample populations ($n = 19$) were described as means and 95% confidence interval. Discomfort and pain were assessed by means of VAS. The VAS reading was taken as the measurement from the left endpoint to the subject's mark, and it was normalized to lie in the interval [0,1]. Visual analog scales medians with their interquartile range were assessed for each experimental time and they were evaluated and graphically displayed as boxplots. To evaluate the changes of both VAS values as a function of time and other covariates, a continuous ordinal model was built. The ocm function within the ordinalCount package in R was used. The package ordinalCont implements a regression framework for a response variable that is a recorded perception on a visual analog scale, of an underlying latent variable, which is difficult or impossible to observe or measure. To check the model fit, we looked at the histogram of the quantile residuals and the quantile residual normal Q-Q plot. The Pearson correlation test was used to assess the eventual association among the other explanatory variables once normal distribution was confirmed for all of them. Last, the F1-LD-F1 design from the nparLD package was used to assess group and time effects on both primary and secondary outcomes: in particular, the longitudinal effect of the type of OAF management (whether immediate or delayed) and the longitudinal effect of the presence of infection at the moment of surgery were evaluated. Alpha error was set at <0.05 for all analyses.

RESULTS

Nineteen patients were enrolled and accepted to participate (14 males and 5 females, mean age 55.9 ± 14.0 years). Baseline clinical characteristics of the included sample are described in Supplementary Digital Content, Table 1, http://links.lww.com/SCS/D978. OAC mean dimensions were 6.22 ± 2.53 mm and 6.61 ± 2.65 mm, respectively, for mesio-distal and buccal-palatal length, whereas the OAC mean area was $46.9 \pm 41.9\,mm^2$.

The healing period was uneventful for 13 patients. For 1 patient, a severe bleeding from the buccal flap was reported during surgical intervention. Five patients, during the first postsurgical week, reported slight complications (a case of hematoma and 4 cases of epithelial necrosis in the palatal tissue).

The mean duration for surgeries was 31 ± 13.7 minutes and this measure seemed moderately related to the extension of the lesion, according to the Pearson correlation test (cor 0.59).

According to the main outcome variable, complete closure of OAC/OAF was observed at day 30 in all the experimental sample. Therefore, the success rate of the described technique was 100% by the end of the evaluation period.

The longitudinal evolution of VAS measures for Patients' reported outcome for Discomfort and Pain was assessed implementing a model, which is an extension of the cumulative logistic ordinal regression model for discrete ordinal responses and is general in the sense of incorporating parametric and smoothing terms, as well as random effects. The model showed a perfect fit for both variables (Fig. 3) and suggested that both Discomfort and Pain behaved as a function of time for the entire cohort. The Supplementary Digital Content, Table 2, http://links.lww.com/SCS/D979 presents average values for both discomfort and pain. At 3 days, median patient reported Discomfort was 4 and median patient reported Pain was 4 as well. Pain reported values decreased to zero faster than discomfort, which was present until 14 days after surgery for patients who run into post-operatory complications.

Pain and discomfort did not differ according to the presence or absence of infection, nor depending on the type of surgical management of the lesion (immediate or delayed).

DISCUSSION

The present case series study reported the clinical efficacy of a modified surgical approach for the closure of OAC/OAF. The success rate for the above-described technique was 100% at a

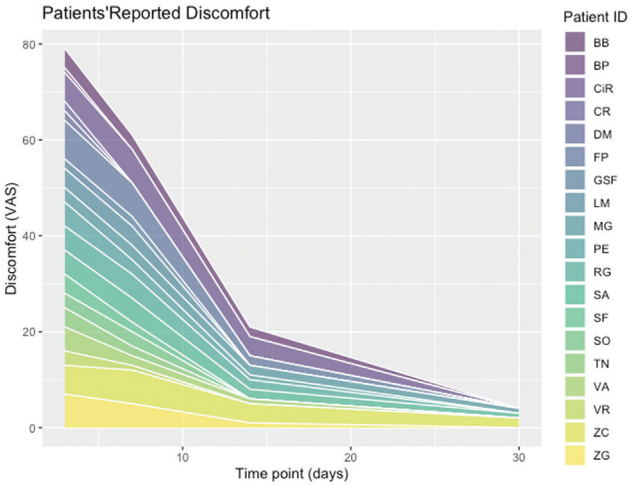

FIGURE 3. Stacked area chart displaying the evolution of discomfort for all patients.

30-day evaluation. The proposed surgical approach is a combination of 2 local flaps, buccal and palatal: its main advantages are represented by the double closure of the communication that guarantees a safe healing, and very low patient discomfort. Furthermore, the palatal incision is designed to respect the anatomical papillae and to ensure primary intention healing of the palate.

Local flaps are a group of surgical procedures for the treatment of small and moderate OAC/OAFs[19] and many studies described their clinical success.[20–22]

However, current evidence did not support any superior technique.[2] A recent retrospective study reported similar outcomes in terms of closure success using either buccal flaps, palatal flaps, or buccal fat pad flaps.[23] Some failures were reported in those studies where only the buccal flap was performed: most of those cases needed an adjunctive surgery by means of a buccal fat pad transposition in order to close the OAC.[16]

A clinical problem related to the buccal approach, namely, the Rehrmann flap, is the reduction of the buccal vestibulum after surgery, and unpredictable flap shrinkage.[24] Thus, in those cases where implant treatment would be possible, an apical repositioning flap or an apical repositioning flap combined with a free gingival graft may be better recommended.

Authors suggested that the addiction of a palatal flap could increase the thickness of the soft tissues along with their quality.[25] However, the most significant disadvantage of the palatal approach is flap necrosis at donor site. The classic palatal rotation flap, the 1 including the greater palatine artery, is associated with many complications that can affect the wound healing process: flap necrosis, pain, exposed bony surface, surface irregularities related to secondary epithelialization.

In order to avoid secondary healing of the palatine surface, subepithelial connective pedicle flaps have been introduced. Ito and Hara[17] documented a wide flap where the whole palatal surface was opened on the side of the OAC and a connective pedicle flap was prepared and rotated to close the communication. Dergin approach[18] introduced a H-type incision in the palate in order to harvest the connective pedicle flap and achieve primary closure of the wound.

Recently, Blal and colleagues[26] reported the outcomes of a new approach, similar in method and outcomes to the 1 presented here: a trapezoid full-thickness flap extending from the palatal area to the buccal gingiva is raised, including the fistula at its center. The palatal free-end side is split into 2 layers and the deep periosteal layer is folded deep under the flap and over the bony defect, thereby sealing the fistula. The superficial layer is then returned to its primary position and sutured.

The present technique includes a palatal incision that does not involve the anatomical papillae; this approach has the advantage of harvesting a wider surface of connective tissue starting from the alveolar margin to the palatine vault. The flap is easy to be sutured to the papillae that are not reflected. The clinical success of this technique might be attributed to the proliferative potential of the palatal periosteal connective tissue, as it is well known that adipose-rich connective tissue displays huge tendency to metaplasia.[27]

This surgical approach might be at risk for hemorrhage due to the lesion of the greater palatine or its smaller branches. The position of the greater palatine foramen has to be located before starting the surgery, and great attention should be paid to the reflection of the split thickness flap for the exposure of the palatal connective flap.

It must be highlighted, among the limitations of the described technique, that it should be reserved to moderate-dimension OAFs, as greater lesions might be difficult to manage, given the constrained dimensions of the palatal flap.

In 4 patients, 22% of the surgical procedures, an epithelial necrosis at donor site was found at day-7 and at day-14 follow up. This complication is common for those techniques, including this 1, where connective tissue grafts are harvested from the palate using a trap-door approach.[28] However, all wounds were debrided and secondary healing occurred eventually. Only chlorhexidine mouth rinses were prescribed. No lesion was found at day-30 follow up for any patient.

The present case series reported the clinical efficacy of a modified surgical approach for OAC closure, with 100% healing rate at 30-day evaluation and favorable patients related outcomes. The combination of a buccal flap with a split palatal connective tissue flap is an effective surgical technique with good predictability and high patient satisfaction levels and it merits further investigation.

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