Closure of Oroantral Communications Using Biodegradable Polyurethane Foam: A Feasibility Study

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Purpose: The aim of this study was to assess the feasibility of biodegradable polyurethane (PU) foam for closure of oroantral communications (OACs).

Patients and Methods: Ten consecutive patients with OACs (existing <24 hours) were treated with PU foam. Standardized evaluations were performed at 2 weeks and 8 weeks after closure of the OAC.

Results: In 5 patients, the OACs were closed successfully without complications. Three patients developed sinusitis, which was conservatively managed with antibiotics in 2 cases. In 1 case the sinus was reopened for irrigation, after which a buccal flap procedure was performed. In 2 patients the OAC recurred and was surgically closed with a buccal flap after thorough irrigation.

Conclusion: In this feasibility study, closure was achieved in 7 of the 10 patients without further surgical intervention. Complications of the procedure using PU foam may be related to the fit of the foam in the socket and the size of the perforation. In general, closure of OACs with biodegradable polyurethane foam is feasible and has the potential to spare a large number of patients with OACs a surgical procedure. Furthermore, in case the treatment with PU foam fails to close the OAC, the attending physician can always fall back on the standard surgical procedure.

J Oral Maxillofac Surg 68:281-286, 2010

Oroantral communications (OACs) are usually caused by extraction of the maxillary posterior teeth.[1,2] Although the incidence is relatively low (5%), OACs are frequently encountered owing to the high number of extractions.[3,4]

OACs can close spontaneously, especially when the defect is less than 5 mm.[5] It is, however, difficult to determine the size of the OAC clinically; therefore, it is difficult to predict whether an OAC will heal uneventfully without intervention. To prevent chronic sinusitis and the development of fistulas, it has generally been accepted that all such defects should be surgically closed within 24 to 48 hours.[5]

Surgical closure of OACs is commonly performed with a mucoperiosteal buccal flap.[5,6] Nevertheless, the use of a buccal sliding flap has several disadvantages. First, the patient often must be referred to a maxillofacial surgeon for surgical closure of the OAC. Second, the patient experiences more postoperative pain and swelling after surgical closure than after an uneventful extraction.[7] Finally, in the long term, the depth of the buccal sulcus can permanently decrease, hindering the construction of a well-fitting dental prosthesis.[8,9]

Because of the disadvantages of surgical closure, several alternative treatment modalities have been reported, including third molar transplantation, hydroxylapatite blocks, bioabsorbable root analog, and the Bio-Oss-Bio-Gide sandwich technique (Osteohealth, Shirley, NY).[10-13] Nevertheless, these methods all have their specific disadvantages and are not frequently used in clinical practice, because either they are ineffective, not a simplification of the standard method, or too expensive.

The goal of the present feasibility study was to evaluate a new, straightforward, and safe strategy for the closure of OACs using biodegradable polyure-

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0278-2391/10/6802-0008$36.00/0
doi:10.1016/j.joms.2009.07.019

thane foam. Because of its biodegradability, the foam does not have to be removed from the body after it has performed its function, a major advantage over nondegradable materials. We believe the use of polyurethane foam will make the treatment of OACs easier and also will eliminate the need for special equipment and surgical expertise. This should make it possible for the general dentist to treat an OAC, instead of having to refer the patient to the maxillofacial surgeon or another colleague trained in closing such defects. Additionally, it is a simple method for closure of OACs for maxillofacial surgeons. Finally, at all times, the attending physician can use the standard surgical procedure in cases in which the polyurethane foam unexpectedly does not result in adequate closure.

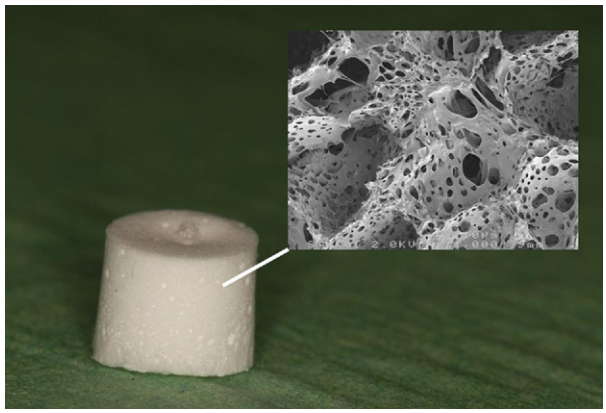

FIGURE 1. Polyurethane foam with electron microscopic detail showing interconnected pore structure.

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Materials and Methods

The medical ethical committee of the University Medical Centre Groningen approved all procedures and materials.

A biodegradable polyurethane foam (Polyganics BV, Groningen, The Netherlands) has been developed for the closure of OACs. It is made of hard urethane segments for strength and soft segments made of D/L lactide and ε-caprolactone. The polyester soft segments were synthesized first and consist of 50/50 D/L lactide/ε-caprolactone and polyethylene glycol. The polyethylene glycol was added to the soft segments to make them more hydrophilic and more rapidly degradable. Chain extension was performed, resulting in polyurethane segments with a uniform length of 5 urethane moieties and an overall polyethylene glycol content of 5 Wt/Wt%.

The polyurethane was dissolved in 1,4-dioxane, resulting in a concentration of 4 Wt/Wt% polyurethane. Water was added to obtain an interconnected pore structure, after which the solution was poured into a mold. After cooling the homogenous solution to −18°C, it was freeze-dried to remove the water and dioxane crystals. Before use, the foams were sterilized with ethylene oxide.

The final product is a cylindrically shaped foam with a diameter of approximately 5 mm and a height of approximately 7 mm (Fig 1). The porosity of the foam is approximately 95%. The foam retains its strength for about 2 weeks. The highly interconnected pore structure of the product is designed for optimal tissue ingrowth.

In vivo and in vitro experiments were performed to investigate the use of polyurethane foams as medical devices for tissue regeneration.[14-17] An in vitro degradation study showed that the foams remained mechanically stable for 2 weeks,[17] and animal experiments proved that it enables mucosal overgrowth.[18] Altogether, the results indicated that the polyurethane foam can be used safely as a biodegradable implant and showed no different biocompatibility compared with the commercially available materials.

For the present feasibility study, 10 consecutive patients with OACs were included. Inclusion occurred from October 2007 to January 2008 at the Department of Oral and Maxillofacial Surgery, University Medical Centre Groningen. The cause of the OAC was tooth extraction in all selected patients. All OACs were closed by the same maxillofacial surgeon and resident. Patients with a history of chronic sinusitis, taking antibiotic prophylaxis, or with acute sinusitis were excluded. Standardized evaluations were performed at 2 and 8 weeks after closure of the OAC. The recorded data included patient gender, age, smoking history, medication use, etiology, reason for extraction, location, and complications, if any. Success was considered permanent closure of the OAC. In the case of a recurrence, the standard surgical procedure was used to achieve closure.

The OAC was confirmed by nose and mouth blowing. In all patients, obliteration of the antral perforation with the foam was performed with the patient under local anesthesia using 4% articaine and 1:100.000 epinephrine (Aventis Pharma BV, Hoevelaken, The Netherlands). The approximate size of the perforation was estimated, and a cylindrically shaped polyurethane foam was selected that resulted in a tight fit. Second, the polyurethane foam was fitted into the perforation. The gingival margins were approximated with 4.0 Vicryl Rapid suture (Ethicon, Somerville, NJ), without complete mucosal closure to ensure the polyurethane foam stayed in place (Figs 2A,B). All patients were advised against nose blowing. Postoperative analgesics (ibuprofen and/or paracetamol) and 0.2% chlorhexidine mouth rinses 2 to 3 times daily were prescribed. In accordance with the Dutch guidelines, antibiotics or decongestants were not routinely prescribed. The remaining sutures

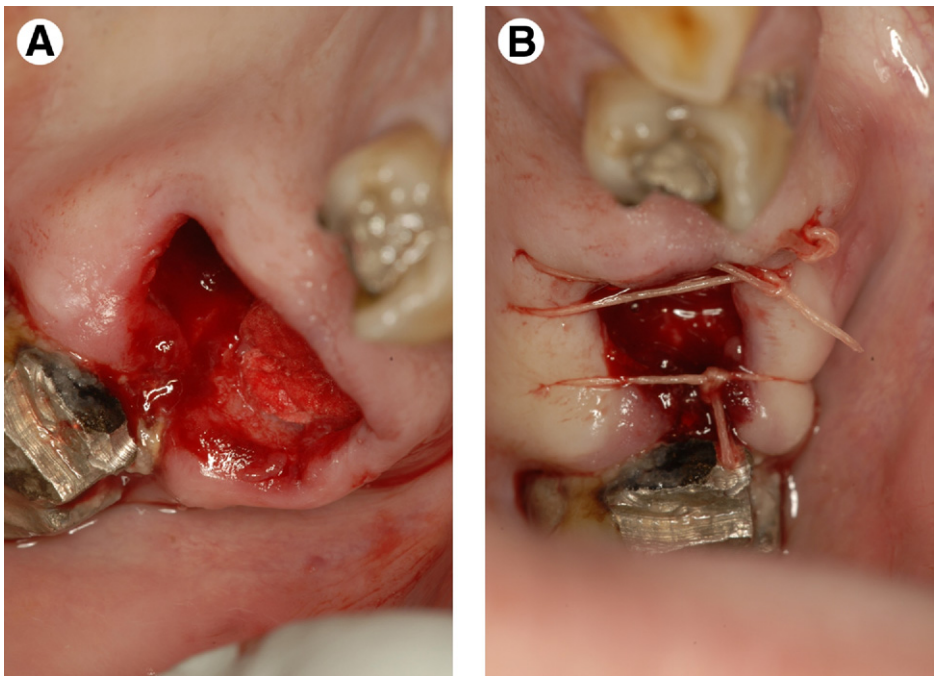

FIGURE 2. *A,* Patient 7 with polyurethane foam placed in oroantral perforation. *B,* Patient 7 with polyurethane placed in oroantral perforation and gingival margins approximated with 2 sutures.

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were removed after 2 weeks. Intraoral photographs were taken to document tissue healing.

Results

A total of 10 consecutive patients with OACs were treated with polyurethane foam (6 men and 4 women). Their mean age was 41.7 years (range, 22 to 72). An overview of the patient data is given in Tables 1 and 2.

The treatment with polyurethane foam was well tolerated by all patients. In general, the extraction wounds had decreased in size after 2 weeks, with the polyurethane foam still visible in the perforation (Fig 3). After 8 weeks, the wound had closed completely (Fig 4). Soft tissue healing was uncomplicated in all 10 patients. Of the 10 patients, 5 had uneventful healing (patients 1 through 3, 5, and 6) and 2 (patients 9 and 10) were treated with antibiotics and decongestives because of presumed maxillary sinusitis after 5 days and 2 weeks, respectively. The diagnosis was determined from the radiographic findings, although clinical signs were not apparent.

Of the 10 patients, 3 required a surgical procedure because of a recurrent OAC or infection. In 1 of these 3 patients (patient 4), the polyurethane foam was pushed through the perforation into the maxillary sinus. A second polyurethane foam was placed to

Table 1. OVERVIEW OF CLINICAL DATA OF INCLUDED PATIENTS

Pt No.	Gender	Age (yr)	Smoker	OAC Location	Affected Roots	Indication
1	Female	47	No	Left second molar	Distobuccal	Carious
2	Male	48	No	Right third molar	Mesiobuccal	Carious
3	Female	22	No	Right third molar	Distobuccal	Nonfunctional
4	Female	44	Yes	Right first molar	Palatinal, mesiobuccal, distobuccal	Carious
5	Male	25	No	Right third molar	Mesiobuccal	Preventive
6	Female	72	No	Right first molar	Palatinal	Total tooth extraction
7	Male	46	Yes	Left first molar	Distobuccal	Carious
8	Male	42	Yes	Left second molar	Mesiobuccal, distobuccal	Pain
9	Male	43	No	Left third molar	Mesiobuccal, distobuccal	Nonfunctional
10	Male	28	No	Left third molar	All (fused roots)	Nonfunctional

Abbreviations: Pt No., patient number; OAC, oroantral communication.

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Table 2. CHARACTERISTICS OF TREATMENT RESULTS

Pt. No.	Wound Infection	Polyurethane Lost	Sinusitis	OAC Recurrence	Antibiotics	Surgical Intervention
1	No	No	No	No	No	No
2	No	No	No	No	No	No
3	No	No	No	No	No	No
4	No	Yes	Yes	Yes	Yes	Yes
5	No	No	No	No	No	No
6	No	No	No	No	No	No
7	No	No	Yes	No	Yes	Yes
8	No	Yes	Yes	Yes	Yes	Yes
9	No	No	Yes	No	Yes	No
10	No	No	Yes	No	Yes	No

Abbreviations as in Table 1.

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close the perforation. No attempt was made to remove the polyurethane foam that had pushed into the sinus. The OAC reopened after 3 weeks, resulting in sinusitis. After thorough antral irrigation, the recurrent OAC was closed with a buccal flap.

In the second patient (patient 7), the OAC required surgical closure using a buccal flap because it had reopened spontaneously after 6 weeks, despite uncomplicated healing in the first weeks after polyurethrane foam placement. In the third patient (patient 8), the OAC did not reopen spontaneously; however, sinusitis developed that required intervention. Therefore, the sutures were removed to allow drainage and irrigation. After the sinusitis had resolved, the OAC was secondarily closed surgically with a buccal flap.

Discussion

In the present study, we investigated the closure of OACs with biodegradable polyurethane foam. The results have shown that closure of OACs with a biodegradable foam, consisting of hard urethane segments and soft segments made of D/L lactide/ε-caprolactone and polyethylene glycol, is feasible. In 7 of the 10 patients, the OAC was closed without surgical treatment. In the other 3 cases, the OAC was successfully closed secondarily with a surgical procedure.

Although hardly any data are available regarding the healing of untreated OACs, we believe the presence of the polyurethane foam facilitates closure of the communication. The polyurethane foam reinforces the blood clot and protects it from displacement. Additionally, this reinforced coagulum enables mucosal overgrowth of the perforation, on both the oral and the antral side. As Skoglund et al[19] stated, the healing of OACs is entirely dependent on the presence of a stable noninfected blood clot.

Sinusitis was diagnosed in 5 of the 10 patients, even though only fresh OACs (present fewer than 24 hours) were included. Nevertheless, it could well be that in some cases the sinusitis was misdiagnosed. Two patients (patients 9 and 10) were diagnosed with maxillary sinus-

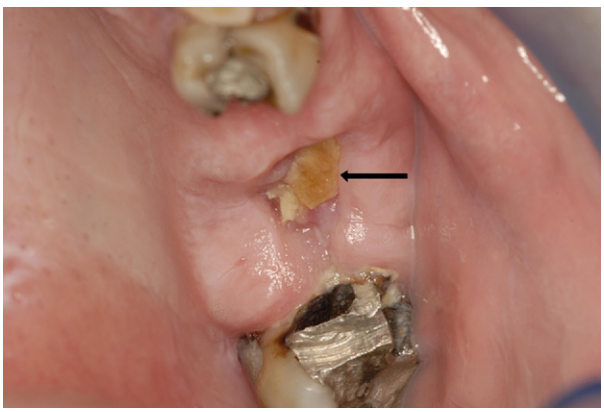

FIGURE 3. Patient 7 showing OAC 2 weeks after closure with polyurethane foam in situ *(arrow)*.

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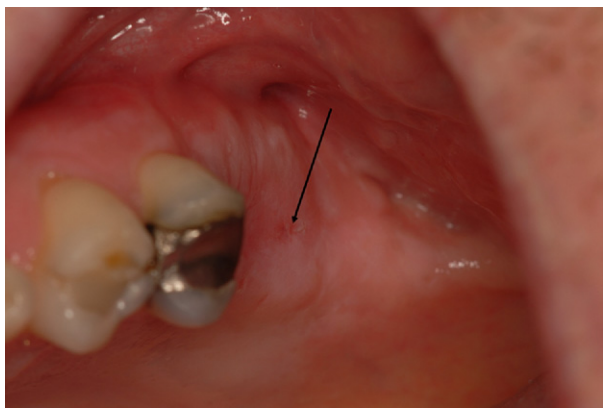

FIGURE 4. Patient 9 at 8 weeks after closure with wound fully closed *(arrow)*.

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itis, after 5 days and 2 weeks, respectively. Although clinical signs of maxillary sinusitis were not apparent in either patient, it was decided to start antibiotics and decongestives in both cases because of radiographic signs of maxillary sinusitis. However, the radiographic signs might have been mistaken for maxillary sinusitis. As a study by von Wowern[20] showed, the frequency of false-positive radiographic findings is high in cases without clinical signs or symptoms of maxillary sinusitis (22% to 63%).

Furthermore, the porous structure of the polyurethane foam could be seen as a potential cause of sinusitis. However, although the polyurethane foam has a very porous structure, it is believed that it forms a solid barrier against oral bacteria invading the sinus. In animal experiments, it has been demonstrated that the polyurethane foam is completely filled with blood on placement.[18]

Care should be taken when the polyurethane foam is placed, because the risk of pushing the polyurethane foam through the perforation has proved to be considerable. In the present study, the polyurethane foam was actually displaced into the maxillary sinus twice. In 1 patient (patient 4), the foam had already been pushed through during the procedure, and the OAC was immediately closed with a second polyurethane foam placed to close the perforation.

Selection of polyurethane foam with the correct dimensions (ie, not too small) will probably lower the risk of displacement into the maxillary sinus. Furthermore, applying a suture onto the foam before placement will facilitate removal of the foam in case it is accidentally pushed through the defect.

It is anticipated that the polyurethane foam will disintegrate and eventually leave the sinus through ciliary movement. Therefore, no attempt has been made to remove the dislocated polyurethane foam. To date, no complications have been reported by the patients concerning the presence of polyurethane foam in the maxillary sinus.

Other alternative minimally invasive methods for closure of OACs have been previously described, including autogenous grafts and alloplastic implants.

The polyurethane foam treatment appears to have some advantages compared with standard surgical closure and the use of alloplastic implants. An important advantage of polyurethane foam is that it is quick and requires no additional surgical expertise, making it possible for general dentists to close OACs themselves, without referral to a maxillofacial surgeon. This is interesting from a socioeconomic viewpoint. Moreover, the polyurethane foam is a fully synthetic product, implying a complete absence of the risk of transmitting pathogens such as can occur with animal-derived products. Finally, in the present study, the gingival margins were only approximated, to prevent drop out of the polyurethane foam. Therefore, there is no risk of decreasing the vestibular sulcus depth.

Degradation of the polyurethane foam is a slow but steady process. After 3 years, light microscopic evaluation showed no polyurethane remnants. Observations with an electron microscope showed only very little intracellular polyurethane fragments, revealing that the resorption had not stopped after 3 years. It is thus very likely that the material will ultimately be totally resorbed.

In 7 of the 10 patients, no surgical procedure was necessary to close the OAC. At present, it is difficult to state whether this is an acceptable percentage of success. To our knowledge, no information is available regarding the complication rate after surgical closure of OACs. Probably, surgical closure is the only completely adapted treatment modality. Therefore, it is difficult to compare our results with the commonly accepted surgical treatment of OACs.

In contrast to the 7 patients who were nonsmokers, the 3 patients who required surgical correction for closure of the OAC were all smokers (Table 1). In addition to the known negative influence of smoking on oral tissue healing,[21,22] it could well be that in these patients the smoking habit mechanically influenced the positioning of the foam and, consequently, the treatment outcome.

In the present study, no bone formation or bone quality was assessed. The objective of the present study was solely to evaluate the feasibility and safety of polyurethane foam for closure of OACs. However, animal studies did show bony bridging across the defect with time.[18] It is therefore anticipated that bone formation will occur.

In conclusion, closure of OACs with biodegradable polyurethane foam is feasible. Because the treatment procedure is simple, it seems a valuable alternative to standard surgical closure. The reported complications were related to the fitting of the polyurethane, the defect size, and, probably, our reserved used of antibiotics. These aspects will be addressed in a second clinical study at our center. In the long term, a randomized prospective multicenter trial will be implemented to evaluate this new straightforward treatment strategy in a larger population.

Acknowledgment

The polyurethane foam was kindly provided by Polyganics BV, Groningen, The Netherlands.

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