Biodegradable polyurethane for closure of oroantral communications
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Chapter 5a

Closure of oroantral communications using biodegradable polyurethane foam: a feasibility study

Susan H Visscher, Baucke van Minnen, Rudolf RM Bos

Edited version of:
Abstract

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

Ten consecutive patients with fresh oroantral communications (existing < 24 hrs) were treated with PU foam. Standardized evaluations were performed at 2 weeks and 8 weeks after closure of the OAC.

In 5 patients the OACs were closed successfully without complications. 3 patients developed a 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 reoccurred and was surgically closed with a buccal flap after thorough irrigation.

Closure of OACs with biodegradable polyurethane foam is feasible. Closure was achieved in 7/10 patients without further surgical intervention. The complications may be related to the fitting of the foam and the size of the defects. Taking the complicating factors into account, further studies will be implemented to optimize this treatment strategy.

Introduction

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

OACs may close spontaneously, especially when the defect has a size below 5 mm (5). It is, however, difficult to determine the size of the OAC clinically and therefore, it is difficult to predict whether an OAC will heal uneventfully without intervention. To prevent chronic sinusitis and the development of fistulas, it is therefore generally accepted that all of these 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. Firstly, the patient often has to be referred to a maxillofacial surgeon for surgical closure of the OAC. Secondly, the patient suffers from more postoperative pain and swelling after surgical closure compared to an uneventful extraction (7). Thirdly, on the long term, the depth of the buccal sulcus may permanently decrease, thereby hindering the construction of a well-fitting dental prosthesis (8;9).

Because of the disadvantages of surgical closure, several alternative treatment modalities have been described in literature, including third molar transplantation, hydroxyapatite blocks, bioabsorbable root analogue and the Bio-Oss-Bio-Gide sandwich technique (10-13). Nevertheless, these methods all have their specific disadvantages and are not frequently used in clinical practice because either they are not effective, no simplification of the standard method, or too expensive.

The goal of this feasibility study was to evaluate a new, straightforward and safe strategy for the closure of oroantral communications with biodegradable polyurethane foam. As a result of its biodegradability, the foam does not have to be removed from the body after it has performed its function, which is considered a major advantage over non-degradable materials. In our opinion, the PU foam should make treatment of oroantral communications easier and additionally, it will take the need for special equipment and surgical expertise away. This should make it possible for the general dentist to treat an OAC himself, instead of having to refer the patient to the maxillofacial surgeon or another colleague trained in closing such defects. Besides, it means a simple method for closure of OACs for maxillofacial surgeons as well. Lastly, at all times the attending physician can fall back on the standard surgical procedure in case the PU foam unexpectedly does not result in adequate closure.
Materials and methods

All procedures and materials were approved by the medical ethical committee of the University Medical Centre Groningen (UMCG).

Biodegradable polyurethane foam (Polyganics B.V., Groningen) has been developed for the closure of OACs, 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 consisted of (50/50) D/L lactide/ε-caprolactone and polyethylene glycol (PEG). The polyethylene glycol was added to the soft segment to make it more hydrophilic and more rapidly degradable. Chain extension was performed resulting in polyurethane segments with a uniform length of five urethane moieties and an overall PEG content of 5 w/w%.

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

The final product is a cylindrically shaped foam with a diameter of app 5 mm and a height of approximately 7 mm (Figure 1). The porosity of the foam is app 95%. The foam remains 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 PU foams as medical devices for tissue regeneration (14-17). An in vitro degradation study showed that the foams remained mechanically stable for two weeks (17), and animal experiments proved that it enables mucosal overgrowth (18). Altogether, the results indicated that the PU foam can be used safely as a biodegradable implant and showed no different biocompatibility compared to the commercially available materials.

For this feasibility study, 10 consecutive patients with oroantral communications were included. Inclusion took place from October 2007 to January 2008 at the Department of Oral and Maxillofacial Surgery of the UMCG. 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, patients on antibiotic prophylaxis, or patients with acute sinusitis were excluded. Standardized evaluations were performed at 2 weeks and 8 weeks after closure of the oroantral communication. Recorded data included patient sex, age, smoking, medication, aetiology, reason for extraction, location and (any) complications.

Success was considered as permanent closure of the OAC. In case of a recurrence of the OAC, 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 carried out under local anaesthesia with 4% articain and 1:100,000 epinephrine (Aventis Pharma BV Hoevelaken). The approximate size of the perforation was estimated and a cylindrically shaped polyurethane foam selected that resulted in a tight fit. Secondly, the PU foam was fitted in the perforation. Gingival margins were approximated with a 4.0 Vicryl® Rapid suture (Ethicon), without complete mucosal closure to ensure the PU foam stayed in place (Figure 2a and 2b). All patients were advised against nose blowing. Postoperative analgesics (Ibuprophen and/or paracetamol) and 0.2% chlorhexidine mouth rinses 2-3 times daily were prescribed. As in accordance with the Dutch guidelines, antibiotics or decongestants were not routinely prescribed. Remaining sutures were removed after 2 weeks. Intraoral photographs were taken to document the tissue healing.

Figure 1 PU Foam with electron microscope detail, showing interconnected pore structure.
### Results

#### Table 1  Overview of clinical data of included patients

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Sex (m/f)</th>
<th>Age (years)</th>
<th>Smoker (yes/no)</th>
<th>Location OAC</th>
<th>Affected roots</th>
<th>Indication</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>f</td>
<td>47</td>
<td>no</td>
<td>left second molar</td>
<td>distobuccal</td>
<td>carious</td>
</tr>
<tr>
<td>2</td>
<td>m</td>
<td>48</td>
<td>no</td>
<td>right third molar</td>
<td>mesiobuccal</td>
<td>carious</td>
</tr>
<tr>
<td>3</td>
<td>f</td>
<td>22</td>
<td>no</td>
<td>right third molar</td>
<td>distobuccal</td>
<td>non-functional</td>
</tr>
<tr>
<td>4</td>
<td>f</td>
<td>44</td>
<td>yes</td>
<td>right first molar</td>
<td>palatal/mesiobuccal/distobuccal</td>
<td>carious</td>
</tr>
<tr>
<td>5</td>
<td>m</td>
<td>25</td>
<td>no</td>
<td>right third molar</td>
<td>mesiobuccal</td>
<td>preventive</td>
</tr>
<tr>
<td>6</td>
<td>f</td>
<td>72</td>
<td>no</td>
<td>right first molar</td>
<td>palatal</td>
<td>total tooth extraction</td>
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<tr>
<td>7</td>
<td>m</td>
<td>46</td>
<td>yes</td>
<td>left first molar</td>
<td>distobuccal</td>
<td>carious</td>
</tr>
<tr>
<td>8</td>
<td>m</td>
<td>42</td>
<td>yes</td>
<td>left second molar</td>
<td>mesiobuccal/distobuccal</td>
<td>pain</td>
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<tr>
<td>9</td>
<td>m</td>
<td>43</td>
<td>no</td>
<td>left third molar</td>
<td>mesiobuccal/distobuccal</td>
<td>non-functional</td>
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<tr>
<td>10</td>
<td>m</td>
<td>28</td>
<td>no</td>
<td>left third molar</td>
<td>all (fused roots)</td>
<td>non-functional</td>
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</table>

Abbreviation: m; male, f; female, OAC; oroantral communication

#### Table 2  Characteristics of the treatment results

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Wound infection</th>
<th>PU lost</th>
<th>Sinusitis</th>
<th>Reoccurrence OAC</th>
<th>Antibiotics</th>
<th>Surgical intervention</th>
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<tbody>
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<td>-</td>
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<td>-</td>
<td>+</td>
<td>-</td>
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<td>-</td>
</tr>
</tbody>
</table>

Abbreviation: PU; Polyurethane
Ten consecutive patients with oroantral communications were treated with PU foam (6 males, 4 females). The mean age was 41.7 years (range 22 to 72 years). An overview of the patient data is given in Tables 1 and 2.

The treatment with PU foam was well tolerated by all patients. In general, it was observed that the extraction wounds had decreased in size after 2 weeks, with the PU still visible in the perforation (Figure 3). After 8 weeks the wound had closed completely (Figure 4). Soft tissue healing was uncomplicated in all 10 patients. Five patients showed uneventful healing, according to this scheme (No 1-3, 5, 6). Two patients (No 9 and 10) were treated with antibiotics and decongestives because of presumed maxillary sinusitis after respectively 5 days and 2 weeks. The diagnosis was based on radiographic findings, although clinical signs were not apparent.

Two patients required a surgical procedure because of a recurrent OAC. In 1 of these 2 patients (No 4) the PU foam was pushed through the perforation into the maxillary sinus. A second PU foam was placed to close the perforation. No attempt was made to remove the PU foam that was 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 patient No 7 the OAC required surgical closure using a buccal flap because it reopened spontaneously after 6 weeks, despite uncomplicated healing in the first weeks post-procedure. In patient 8 the OAC did not reopen spontaneously, but a sinusitis developed that required intervention. Therefore, the sutures were removed to allow drainage and irrigation. After the sinusitis resolved, the OAC was secondarily closed surgically with a buccal flap.

Discussion and Conclusions

In this study the closure of OACs with biodegradable polyurethane foam was investigated. The study showed that closure of OACs with a biodegradable foam, consisting of hard urethane segments and soft segments made of D/L lactide/ε-caprolactone and polyethyleneglycol, is feasible. In 7 of 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 there is hardly any data in literature about the healing of non-treated OACs, we assume that the presence of the PU foam facilitates the closure of the communication. The PU foam reinforces the blood clot and protects it from displacement. Secondarily, this reinforced coagulum enables mucosal overgrowth of the perforation, both on the oral and antral side. As Skoglund et al (19) already stated, the healing of OACs is entirely dependent on the presence of a stable non-infected blood clot.

Sinusitis was diagnosed in 5 out of 10 patients, despite of the fact that only fresh OACs (existing < 24 hrs) were included. Nevertheless, it may well be that in some
cases the sinusitis has been misdiagnosed. Two patients (pt No 9 and 10) were diagnosed with maxillary sinusitis, after 5 days and 2 weeks, respectively. Although clinical signs of maxillary sinusitis were not apparent in both patients, it was decided to start antibiotics and decongestives in both cases because of radiographic signs of maxillary sinusitis. However, the radiographic signs might be mistaken for maxillary sinusitis. As a study by von Wowern (20) showed; the frequency of false positive radiographs is high in cases without clinical signs or symptoms of maxillary sinusitis (22 % - 63 %).

Furthermore, the porous structure of the PU foam might be seen as a potential cause of sinusitis. However, although the PU foam has a very porous structure, it is assumed that it forms a solid barrier against oral bacteria invading the sinus. In animal experiments it has been demonstrated that the PU foam completely fills itself with blood upon placement (18).

Care should be taken when the PU foam is placed, because the risk of pushing the PU foam through the perforation has proven to be considerable. In this study, the PU foam was actually displaced into the maxillary sinus twice. In one patient (No 4) the foam was already pushed through during the procedure, and immediately closed with a second PU foam to close the perforation.

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

It is anticipated that the PU foams will disintegrate and eventually leave the sinus through ciliair movement. Therefore, no attempt has been made to remove the dislocated PU foams. Until now, no complications have been reported by the patients concerning the PU foams in the maxillary sinus.

Other alternative minimally invasive methods for closure of OACs have been described throughout the years, including both autogenous grafts as well as alloplastic implants.

The PU foam treatment appears to have some advantages beyond the standard surgical closure and the use of alloplastic implants. An important advantage of PU foam is the fact that it is quick and requires no additional surgical expertise, making it possible for general dentists to close oroantral communications created by themselves, without referral to a maxillofacial surgeon. This is interesting from a socio-economical point of view. Moreover, the PU foam is a fully synthetic product which implies complete absence of the risk of transmitting pathogens like in animal derived products. Lastly, in this study the gingival margins are only approximated, to prevent drop out of the PU foam. Therefore, there is no risk of decreasing vestibular sulcus depth.

Degradation of the PU foam is a slow but steady process. After 3 years, light microscopic evaluation showed no PU remnants. Observations with the electron microscope showed only very little intracellular PU fragments, pointing out 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 10 patients no surgical procedure was necessary to close the OAC. At this moment it is difficult to state whether this is an acceptable success percentage. To our knowledge, there is no information in literature about the complication ratio after surgical closure of oroantral communications. Probably, a 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.

Interestingly, in contrast to the other 7 patients who are non smokers, the 3 patients who needed a surgical procedure for closure of the OAC are all smokers (Table 1). Besides the known negative influence of smoking on (oral) tissue healing (21;22), it may well be that in these patients the smoking habit has mechanically influenced the positioning of the foam, and consequently the treatment outcome.

In this study no bone formation or bone quality was assessed. The objective of this study is solely to evaluate the feasibility and safety of the PU foam for closure of OACs. However, animal studies did show bony bridging across the defect in time (18). It is therefore anticipated that bone formation will take place.

In conclusion: closure of OACs with biodegradable PU foam is feasible. As the treatment procedure is simple it seems a valuable alternative for the standard surgical closure. The reported complications are related to the fitting of the PU, the size of the defect and probably our reserve with the use of antibiotics. These aspects will be addressed in a second clinical study in our centre. On the long term, a randomized prospective multicenter trial will be implemented to evaluate this new straightforward treatment strategy in a larger population.

The polyurethane foams were kindly provided by Polyganics BV, Groningen, The Netherlands.


