Biodegradable polyurethane for closure of oroantral communications

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Document Version
Publisher’s PDF, also known as Version of record

Publication date:
2016

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

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Chapter 5b

Feasibility of conical biodegradable polyurethane foam for closure of oroantral communications.

Susan H Visscher, Baucke van Minnen, Rudolf RM Bos

Edited version of:
Abstract

To assess the feasibility of a conically shaped biodegradable polyurethane (PU) foam for closure of oroantral communications (OACs).

In 10 consecutive patients, fresh OACs (present for <24 hours) were closed with PU foam. Standardized evaluations were performed at 2 and 8 weeks after closure of the OAC. Success was considered permanent closure of the OAC.

No complications were observed in 7 of the 10 patients. Of the other 3 patients, 1 developed a maxillary sinusitis that was successfully managed with antibiotics and the OAC recurred in 2 patients.

Permanent closure of the OAC using PU foam was accomplished in 8 of 10 patients. The results obtained in the present study were more favorable than in a previous feasibility study. Therefore, the alterations in the treatment protocol were maintained for additional research of this new and straightforward treatment strategy. In general, closure of OACs with biodegradable PU foam is feasible and has the potential to make surgical treatment unnecessary for a large number of patients with OACs.

Introduction

The apices of the lateral segments in the upper jaw, and especially the molars, are in very close relationship to the floor of the maxillary sinus. Upon extraction this may result in an oroantral communication (OAC). The incidence of oroantral communications is about 13 % (1). OACs usually occur in association with maxillary dental extraction. Since dental extractions are performed on a regular basis by both dentists and maxillofacial surgeons, an incidence of 13 % results in relatively high numbers of OACs. Amongst others, Punwutikorn and co-authors (2) found that OACs occur the most in the first molar.

Preferably, closure is accomplished within 24 - 48 hours after establishment of the OAC, to minimize the risk of oral bacteria invading the maxillary sinus and causing acute sinusitis, or on the longer term, the development of an epithelial fistula. Suturing the gingiva might be sufficient for closure of small OACs, but a study by von Wowern (3) demonstrated a high frequency of failure associated with primary suture alone. Otherwise, a surgical procedure involving a buccal advancement flap or a palatal rotational advancement flap are commonly used to achieve permanent closure.

Like in any surgical procedure, the use of the buccal or palatal flap gives rise to postoperative pain and swelling. This is especially true for the palatal flap in which the donor area requires secondary healing. Furthermore, the buccal flap has an additional risk of permanently decreasing the buccal sulcus depth (4) which may hamper the fitting of a dental prosthesis in the future. Also, in most cases, the patient has to be referred to a maxillofacial surgeon for surgical treatment.

Other alternative treatment strategies for closure of OACs have been described in literature but none of these proposed techniques seem to have gained wide acceptance.

Ten patients with fresh oroantral communications were treated with PU foam in an earlier feasibility study, from October 2007 to January 2008 in the Oral and Maxillofacial Surgery outpatient department at the University Medical Centre Groningen (5). Closure was achieved in 7/10 patients without the need for further surgical intervention. Based on this study it was concluded that closure of OACs with biodegradable PU foam is feasible. However, a few alterations were made to the treatment protocol. Firstly, the shape of the PU foam was changed from cylindrically shaped to a conically contour, to enhance the adaptation of the PU foam in the extraction socket. Secondly, it was decided that in the future a “safety suture” needs to be applied to the PU foam prior to its placement in the extraction socket. By doing so, the PU foam might easily be removed in case it is accidentally pushed through the OAC into the maxillary sinus as occurred twice in the previous study.

The purpose of the present study was to assess the closure of oroantral communications using the modified PU foam treatment protocol.
Patients, material and methods

All patients were fully informed before giving their written consent. All procedures, including the material, were approved by the medical ethical committee of the University Medical Centre Groningen (UMCG).

The biodegradable polyurethane foam (Polyganics B.V., Groningen, the Netherlands) used in this study, consists of hard urethane segments for mechanical strength and soft segments made of (50/50) D/L lactide and ε-caprolactone. Five percent polyethyleneeglycol (PEG) was added to the polyester soft segment to make the PU foam more hydrophilic and more rapidly degradable. The foam retains its mechanical properties for a period of 2 weeks.

The urethane segments were synthesized with 1,4-butanediisocyanate and 1,4-butanediol. Chain extension was performed, resulting in a PU with urethane segments with a uniform length of 5 urethane moieties. The overall PEG content was 5 Wt. %. The polyurethane was dissolved in 1,4-dioxane, resulting in a concentration of 4 Wt. % polyurethane. Water (7.5 Wt. %) was then added to obtain an interconnected pore structure after which the solution was poured in a conically shaped mould. After cooling down the solution to -18 °C, it was freeze dried to remove the dioxane and water crystals. The porosity of the resulting foam was 94 %. Two sizes of PU foam were synthesized, i.e. 8 x 10 x 5 mm and 11 x 10 x 7 mm (Figure 1). Prior to the study the foams were sterilized using ethylene oxide.

A PU foam was selected that resulted in a tight fit. Next, a safety suture (4.0 Vicryl® Rapid, Ethicon, Amersfoort, the Netherlands) was attached to the PU foam to facilitate removal of the foam in case it might have been accidentally pushed through the OAC. The PU was then fitted in the perforation. Gingival margins were approximated without attempting to accomplish complete mucosal closure, only to ensure the PU foam would stay in place. An overview of the treatment procedure is presented in Figure 2.

All patients were instructed to avoid nose blowing. Postoperative analgesics (Ibuprofen 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 prescribed beforehand. Patients were evaluated 2 weeks and 8 weeks after the procedure. Remaining sutures were removed after 2 weeks. Intraoral photographs were taken to document the tissue healing (Figure 3A-D).

Success was considered as permanent closure of the OAC, and the conventional surgical flap procedure was used to close the OAC in case it recurred.
Ten patients aged between 20 – 55 years were treated in this study. The mean age was 35.3 years. Six males and four females were included (Table 1).

In 7 patients, closure of the OAC was performed following on its establishment because the OAC was either created at the outpatient department (Pt No. 1-3, 8, 9), or patients were immediately referred by their dental practitioners (Pt No. 4, 5). Three patients were also referred but had their OAC treated the day after establishment (Pt No. 6, 7, 10).

In 8 patients, the OAC was closed successfully, meaning that the OAC did not recur.

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**Table 1** Overview of the clinical data of the 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 root</th>
<th>Indication for extraction</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>m</td>
<td>25</td>
<td>yes</td>
<td>right third molar</td>
<td>distobuccal</td>
<td>carious</td>
</tr>
<tr>
<td>2</td>
<td>f</td>
<td>50</td>
<td>no</td>
<td>left third molar</td>
<td>palatal</td>
<td>non-functional</td>
</tr>
<tr>
<td>3</td>
<td>f</td>
<td>29</td>
<td>no</td>
<td>left third molar</td>
<td>all, fused roots</td>
<td>non-functional</td>
</tr>
<tr>
<td>4</td>
<td>m</td>
<td>26</td>
<td>yes</td>
<td>right first molar</td>
<td>distobuccal</td>
<td>non-functional</td>
</tr>
<tr>
<td>5</td>
<td>m</td>
<td>38</td>
<td>no</td>
<td>left second molar</td>
<td>mesiobuccal</td>
<td>carious</td>
</tr>
<tr>
<td>6</td>
<td>f</td>
<td>20</td>
<td>no</td>
<td>right first molar</td>
<td>distobuccal</td>
<td>endodontic</td>
</tr>
<tr>
<td>7</td>
<td>m</td>
<td>37</td>
<td>yes</td>
<td>right second premolar</td>
<td>palatal</td>
<td>carious</td>
</tr>
<tr>
<td>8</td>
<td>m</td>
<td>26</td>
<td>yes</td>
<td>right third molar</td>
<td>mesiobuccal</td>
<td>non-functional</td>
</tr>
<tr>
<td>9</td>
<td>m</td>
<td>47</td>
<td>yes</td>
<td>right first molar</td>
<td>distobuccal</td>
<td>periodontal</td>
</tr>
<tr>
<td>10</td>
<td>f</td>
<td>55</td>
<td>no</td>
<td>right first molar</td>
<td>mesiobuccal</td>
<td>carious</td>
</tr>
</tbody>
</table>

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

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**Table 2** Characteristics of the treatment results

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Size OAC (mm)</th>
<th>Size PU (mm)</th>
<th>VAS-Pain 2 weeks</th>
<th>VAS-Pain 8 weeks</th>
<th>Antibiotics</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≤ 5</td>
<td>8 X 10 X 5</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>none</td>
</tr>
<tr>
<td>2</td>
<td>≤ 5</td>
<td>8 X 10 X 5</td>
<td>3</td>
<td>0</td>
<td>Yes</td>
<td>sinusitis</td>
</tr>
<tr>
<td>3</td>
<td>≤ 5</td>
<td>11 X 10 X 7</td>
<td>5</td>
<td>*</td>
<td>Yes</td>
<td>recurrence OAC</td>
</tr>
<tr>
<td>4</td>
<td>≤ 5</td>
<td>8 X 10 X 5</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>none</td>
</tr>
<tr>
<td>5</td>
<td>≤ 5</td>
<td>11 X 10 X 7</td>
<td>0</td>
<td>0</td>
<td>Yes</td>
<td>wound healing</td>
</tr>
<tr>
<td>6</td>
<td>≤ 5</td>
<td>8 X 10 X 5</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>none</td>
</tr>
<tr>
<td>7</td>
<td>≤ 5</td>
<td>11 X 10 X 7</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>none</td>
</tr>
<tr>
<td>8</td>
<td>5 - 7</td>
<td>11 X 10 X 7</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>none</td>
</tr>
<tr>
<td>9</td>
<td>≤ 5 (2x)</td>
<td>8 X 10 X 5 (2x)</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td>none</td>
</tr>
<tr>
<td>10</td>
<td>5 - 7</td>
<td>11 X 10 X 7</td>
<td>0</td>
<td>0</td>
<td>Yes</td>
<td>recurrence OAC</td>
</tr>
</tbody>
</table>

* VAS-pain score is missing because the OAC recurred before the 8 weeks follow-up appointment took place. Abbreviations: OAC; oroantral communication, PU; polyurethane, VAS; visual analogue scale.

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Figure 3A Perioperative view of patient 5, oroantral communication located at mesial buccal root of the left second molar. Arrow indicates polyurethane foam in extraction socket.

Figure 3B Perioperative view with suture applied to prevent loss of polyurethane foam.

Figure 3C Follow-up visit 2 weeks postoperatively showing oral mucosa has almost completely grown across the defect. Note normal depth of the buccal sulcus.

Figure 3D Follow-up visit 8 weeks postoperatively with oral mucosa fully restored.
Patient No. 5 however, returned 4 days after treatment because of mild swelling of the buccal fold near the OAC. Antibiotics were started out of precaution and the complaints resolved without further intervention (Figure 3A-D). Patient No. 2 developed a maxillary sinusitis 1 week after treatment that was conservatively managed with antibiotics.

Extraction of the right first molar resulted in OACs of both buccal roots in patient No. 9. Both OACs were subsequently closed successfully using 2 PU foams.

Extraction of the left third molar gave rise to an OAC in patient No. 3. The positioning of this molar was rather problematic, resulting in a complicated OAC that covered a large area of the maxillary sinus floor. Shortly after the procedure the patient developed a sinusitis that responded well to antibiotics initially. However, the OAC recurred after 4 weeks and needed surgical closure.

In patient No. 10 the OAC recurred. The extraction of the right first molar by the dentist had been rather difficult in this patient. Above this, she got the flu shortly after treatment and had ongoing complaints of both maxillary sinuses since then. At first she responded well to the antibiotics. Nevertheless, the symptoms associated with the right maxillary sinus returned and 8.5 weeks after treatment a recurrence of the OAC was observed. In the end, the OAC was successfully closed with a buccal flap according to the protocol.

On average no pain or discomfort was reported in the follow up appointments (Table 2). Higher pain scores were reported in cases with marked complications (Pt No 2 and 3). Pt No 10 scored 0 on the pain score on both follow up visits, because her complaints were ongoing but relatively mild at these moments.

Discussion

In this feasibility study we treated 10 patients with fresh OACs using degradable polyurethane foam. The goal of this study was to assess the changes made to the treatment protocol; i.e. a conically shaped PU foam instead of a cylindrically shaped foam, and application of a safety suture prior to placement. Eight of 10 patients were successfully treated in this study, meaning that the OAC did not recur after closure with PU foam. Based on the present study, it was concluded that the alterations to the protocol were beneficial to the treatment, and will therefore be maintained in further use.

Most OACs in this study were caused either by extraction of the third molar or first molar. This can be explained by the high number of (impacted) third molar extractions at the Oral and Maxillofacial Surgery outpatient department. Furthermore, the high number of first molars inducing OACs is in line with other studies (3,6-8) as the maxillary sinus has a very close relationship to the root apices of the first molars. Similar to the retrospective study by Abuabara (9), the decade of life with the highest incidence of OACs in the current study was the third decade, probably also because of the rather high number of referral for (third molar) extractions in this period of life.

In 2 out of 10 patients the OAC recurred. Neither of these 2 patients were smokers. This is in contrary to the previous study in which the recurrences of OACs (3 in total) were recorded in heavy smokers. Besides the negative influence of smoking on oral tissue healing (10,11), this difference might be explained by the difference in shape of the polyurethane foams. It can be imagined that the cylindrically shaped PU, as used in the first study, dislodges more easily in comparison to a conically shaped PU. This seems especially true for smokers, who are probably more likely to put load on the PU foam while in- and exhaling smoke.

The other alteration in the treatment protocol was the use of a safety suture. This suture was applied to facilitate removal of the PU foam in case it was dislocated into the sinus, which occurred twice in the previous study. In the present study none of the foams dislodged into the sinus.

In patient No 3 extraction of the left third molar resulted in a problematic OAC that recurred after 4 weeks. To our opinion, the only likely reason for the recurrence of the OAC may be found in ill fitting of the PU foam due to the extended and complex outline of the OAC. Specifically, this molar was positioned along the border of the maxillary sinus and upon extraction a rather large part of the sinus floor was lost. Besides this fact, all conditions were in favour of good healing: a cooperative young and healthy patient, good oral hygiene and closure of the OAC immediately after extraction of the molar.

In patient No. 10, closure of the OAC was accomplished the day after the extraction was performed by the dentist. The OAC unfortunately recurred after 8.5 weeks. It is not exactly clear why the OAC recurred, but it is probably a summation of unfavourable circumstances: the dental extraction and the postoperative healing course were troublesome, the patient was referred with remaining radices of the molar in situ, she got the flu with generalized sinusitis with persisting complaints of the right sinus despite antibiotic treatment, and a bone sequester came loose from the extraction site. After treatment of the sinusitis the recurred OAC was surgically closed with a buccal flap.

In our opinion, these specific failure cases do not seem to justify narrowing of the suitability of PU foam for closure of for example large OACs or OACs without an intact extraction socket. All the more because looking back it appeared difficult to predict on clinical and radiographic grounds which cases were prone for complications or failure. Cases of which we thought that could be problematic, for example because of the absence of an intact alveole or a thin sinus floor, healed perfectly and vice versa.

VAS-scores were obtained from all patients to document the pain levels associated with the PU treatment. In general no pain (VAS score 0) was reported at both follow-up visits. Logically, patients with complaints such as maxillary sinusitis reported higher pain scores. In addition, VAS scores were obtained directly after the procedure but these did not seem to be of further value, because the treatment took place under local anesthesia. At the first follow-up visit, patients were also asked for the pain expe-
rienced in the days following the procedure, but obviously it was difficult to discrimi-
nate between pain caused by the extraction or by the PU treatment. It did become
clear that difficult extractions (Pt No. 3, 4, 8, 10) gave rise to more pain and discomfort.

Apart from the VAS-scores, all patients found the PU procedure quick and had a
positive overall opinion. In the future, VAS pain scores should preferably also be re-
corded after standard surgical closure, in order to compare the discomfort associated
with both treatment modalities.

In conclusion, taking the small number of treated patients in mind, the results of
this study concerning fitting of the PU foam and dislocation into the maxillary sinus
were more favourable than in the previous feasibility study. Therefore, the alterations
in the treatment protocol as used in this study will be maintained for further research
on this new strategy for closure of OACs. Nevertheless, a retrospective study will also
be performed to look into the complication rate associated with surgical treatment
of OACs. To our knowledge, this information is not yet available in literature, probably
because the surgical treatment is the golden standard and associated complications
are therefore taken for granted.

However, a success percentage of 80 % seems acceptable to proceed with further
research on this new strategy, as closure of OACs with biodegradable polyurethane
foam has the potential to make a surgical treatment unnecessary in a large number
of patients.

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

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