Biodegradable polyurethane for closure of oroantral communications
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Introduction

Pathogenesis, incidence and treatment of oroantral communications

Oroantral communications (OACs) are open connections between the maxillary sinus and oral cavity. OACs are usually caused by extraction of maxillary posterior teeth. Although the incidence is relatively low, OACs are frequently encountered due to the high number of dental extractions.

Nowadays, closure of OACs is usually performed by means of a buccal or palatal flap procedure. In case of a small OAC, suturing the gingiva might be sufficient to close the perforation. It is stated in literature that OACs smaller than 5 mm heal by themselves. Evidence for this statement is lacking as the size of an OAC is difficult to measure accurately in the clinical situation. Surgical treatment, preferably within 24 hours, is therefore recommended in many cases to minimize the risk of maxillary sinusitis and subsequent fistula formation. The selection of the surgical technique depends on the size of the communication, the time of diagnosis and the presence of an infection. The amount and condition of the tissue available for repair and prosthetic planning, including the possible placement of dental implants also have influence on the surgical decisions.

Treatment strategies for oroantral communications

A wide range of surgical treatment strategies for OACs has been established throughout the years. In Chapter 2 a literature review concerning this topic is presented. The goal of this review was to establish whether the buccal flap still is the treatment of choice 20 years after the last review. Secondly, it provided an overview of the common surgical treatment strategies of OACs, as well as the alternative treatment techniques including their advantages and disadvantages. The treatments were divided into techniques using autogenous soft tissue flaps or autogenous bone grafts, allogeneic grafts, xenografts and synthetic materials or metals.

It was concluded that only a few techniques to close OACs have gained wide acceptance. Some proposed new techniques proved to be too expensive. Other alternatives did not offer any simplification compared with the standard surgical closure. Surgical closure of OACs by means of a buccal or palatal flap remains the treatment of choice.

Success percentages of frequently used surgical techniques can be found in literature. However, prospective randomized comparative studies that provide evidence for the superiority of one of the techniques have not been published. Little information could be found about the (general) complication rate associated with surgical closure of OACs in terms of recurrence of the OACs. Chapter 3 provides new information on this subject. A cohort of all patients treated for an OAC in 2004 - 2008 was reviewed retrospectively. The recorded data included patient age and gender, location and duration of the OAC, method of removal of the (pre)molar, presence of maxillary sinusitis, disturbed wound healing, and the surgical treatment method. Multivariate regression analysis showed a 15 times higher risk of a recurrence in case of a maxillary sinusitis at the follow-up appointment. The presence of a maxillary sinusitis at the follow-up appointment can therefore be considered an important determinant of the treatment outcome of OAC repair.

The overall results of the study showed that in about 1 out of 10 patients the OAC recurs and requires a second intervention after surgical closure. New treatment strategies should result in an equal or better treatment outcome to be considered a suitable alternative to standard surgical treatment.

The development of a new strategy for OAC treatment

As with any surgical procedure, the use of a buccal or palatal flap results in postoperative pain and swelling. The use of a buccal flap also has the risk of permanently decreasing the buccal sulcus depth which could hinder the fitting of a dental prosthesis in the future. Up to now it seems that the drawbacks of surgical closure of OACs are accepted because useful alternatives are not available. Ideally, a new treatment method for surgical closure of OACs gives predictable results, and overcomes the drawbacks of conventional surgical closure. It should be easy and quick to perform, making it possible for a dentist to treat an OAC by him/herself. The latter would also be interesting from a socio-economical point of view.

Biodegradable polyurethane (PU) foam is a fully synthetic biodegradable product that offers the right characteristics for a new treatment strategy for OACs. This highly porous PU foam has excellent elastic and mechanical properties, allowing adaptation to the extraction socket.

A new and easy to perform treatment for closure of OACs, using synthetic biodegradable polyurethane (PU) foam is presented in Chapter 4a. This PU foam is composed of hard urethane segments, and soft segments made of D/L lactide (50/50), ε-caprolactone and 5% polyethylene-glycol (PEG). The composition of this specific PU foam was optimised in preceding in vivo and in vitro studies. To evaluate the use of PU foam for this application, OACs were created in the edentulous part of the maxilla in 21 New Zealand White rabbits, and subsequently closed with PU foams. Results showed complete healing of the oral mucosa after 4-10 weeks, healing of the antral mucosal lining after 6 months and complete bony regeneration after 1 year. No reopening of the defects occurred and no maxillary sinusitis was observed. Degradation of the PU foam had not yet reached completion 1 year after implantation. It was concluded that PU foam with 5% PEG provided adequate closure of an OAC in the rabbit model to support healing of the oral and maxillary sinus mucosa. Also, it was found that longer time intervals are needed to assess the complete degradation of the PU foam.

Time intervals up to 4 years (Chapter 4b) demonstrated that the OACs recovered uncomplicatedly in all rabbits, concerning both soft tissue and bony regeneration.
The degradation process was not fully completed after 4 years but a decreasing number of macrophages with internalized PU and the aspect of the internalized PU suggest further degradation in time to an ultimate end stage.

Human studies were implemented for the further development and evaluation of this new treatment strategy of OACs (Chapter 5 and 6). A feasibility study to assess the feasibility of biodegradable polyurethane (PU) foam for closure of OACs was carried out in 10 consecutive patients with fresh oroantral communications (existing < 24 hrs) (Chapter 5a).

Closure was obtained in 7/10 patients without further surgical intervention. Three patients developed maxillary sinusitis. Based on this feasibility study it was concluded that closure of OACs with biodegradable polyurethane foam is feasible. The complications were possibly related to the fitting of the foam and the size of the defects. Therefore, a second human pilot study (Chapter 5b) was conducted with 2 alterations made to the treatment protocol. First, the cylindrical shape of the PU foam was changed into a conical contour. This conically shaped PU foam was thought to improve adaptation to the extraction socket. Secondly, it was decided that a so called “safety suture” had to be applied to the PU foam prior to its placement into the extraction socket. The latter ensured that the PU foam could easily be removed in case it had accidentally been pushed through the OAC into the maxillary sinus. The conical PU foam was used in 10 consecutive patients with fresh OACs and permanent closure was obtained in 8 of 10 patients. The results obtained were more favourable than in the previous feasibility study and therefore the alterations in the treatment protocol were maintained for additional research in a large number of patients (Chapter 6). A prospective clinical trial was set up to analyze the effectiveness of (conical) PU foam for closure of OACs in terms of recurrences. As stated earlier, treatment of OACs with a buccal or palatal flap is considered the golden standard and results in a success percentage of 90%. In order to consider a new treatment strategy for OACs a valid option, its success percentage should be comparable. It was hypothesized that closure with PU foam was at least as effective as surgical closure in terms of the percentage of recurrence.

Thirty six consecutive patients with OACs existing less then 24 hours were treated with PU foam. In 19 patients the OAC was closed successfully without any complication. In 16.7 % of the patients the OAC recurred and required additional surgical closure. Statistical analysis proved that the results of PU treatment of OACs are significantly inferior to conventional surgical closure (P < .05). Based on this data it can be concluded that closure of OACs with biodegradable PU foam is not a suitable alternative for conventional surgical closure.

In conclusion, it seems that surgical closure of OACs therefore still is the golden standard, and perhaps will remain in the near future. The reason for this is not its superiority because there are indeed drawbacks associated with surgical closure as mentioned above. It seems these drawbacks are taken for granted because new treatment strategies, including the PU closure investigated in this thesis may be quick and easy to perform, but also have a worse outcome in terms of recurrences and sinusitis.

As for the PU material, this thesis confirms its status of a safe biodegradable material, which makes alternative applications of the PU in biomedical implants possible.

In Chapter 7 the results and conclusions from the previous chapters are compared and discussed.