The use of polylactide-coated β-TCP

Closure of oroantral communications

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_Abstract

Methods for the closure of oroantral communications that occur occasionally after tooth extraction are invasive and laborious. Here, we assessed a simple and efficient technique to close such perforations in nine patients. The oroantral communication at the bottom of the extraction socket was covered with oxygenized, degradable cellulose and the coronal two thirds of the socket were filled with in-situ hardening polylactide-coated β-tricalcium phosphate (β-TCP). An airtight, stable barrier could be established in all cases, and wound healing was uneventful. The novel procedure was minimally invasive and patient-friendly. Soft tissue covered the material after two weeks, and the biological width was reestablished after two months. Hard and soft tissue structures were preserved. The bone substitute has been partially replaced by alveolar bone at the end point of this case-cohort study. A complete regeneration of the alveolar bone can thus be expected.

_Background

Oroantral communications (OACs) may occur after the extraction of the upper first molars and—less frequently—after extraction of premolars or second and third molars (Ehrl 1980; Amaratunga 1986). Left untreated, this may result in the formation of oroantral fistulae and chronic infection of the sinus cavities (Amaratunga 1986). An immediate and complete closure of the communication is thus indicated if the sinus cavities are not already infected (Kraut and Smith 2000; Greenstein et al. 2008).

Frequently, soft tissue flaps are used to close the communications, with good results (Lambrecht 2000). However, flap mobilization involves slitting of the mucosa and the periost and is rather invasive, post-operative swelling and pain are thus common (Gacic et al. 2009). Furthermore, the procedure leads to displacement of tissue and scarring. As a consequence, relocation procedures become necessary in most cases. Oroantral communication closure with tissue transplants and membranes represent an alternative to the flap-based methods. These surgical methods can be combined with augmentative measures to preserve the dimensions of the alveolar ridge (Becker et al. 1987; Watzek 2008). Membrane-based techniques and soft tissue transplantations are characterized by good alveolar hard- und soft tissue preservation and thus are becoming more popular (Schwarz et al. 2006; Cardaropoli and Cardaropoli 2008; Fickl et al. 2008). Nevertheless,

Fig. 1_OAC in region 26.
Fig. 2_Closure of the perforation with oxydized cellulose.
Fig. 3_The extruded bone graft substitute is flatted at its front.

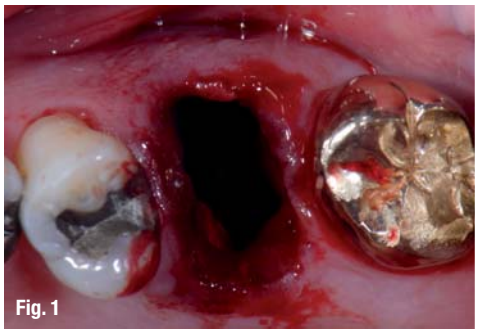


Fig. 1

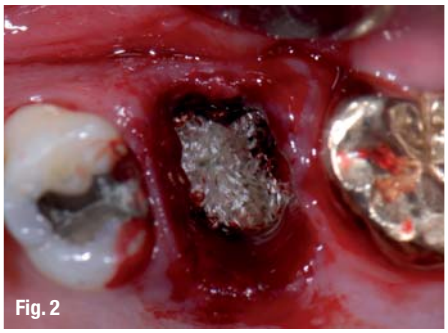


Fig. 2

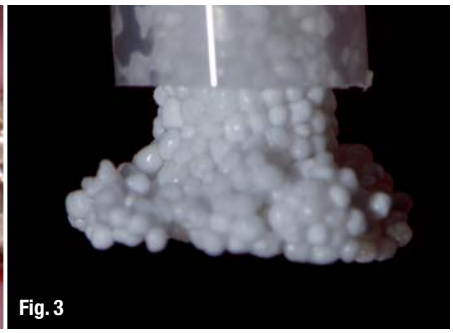


Fig. 3

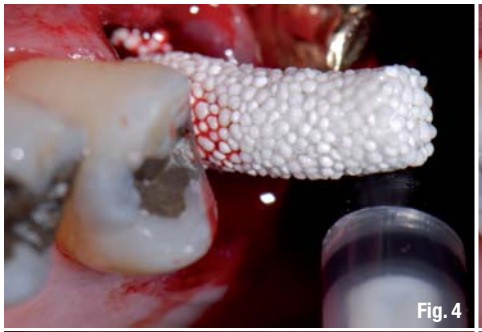


Fig. 4


Fig. 5


Fig. 6


Fig. 7


Fig. 8a


Fig. 8b

these techniques are also intricate and invasive, and there is always a risk for dislocation of graft material into the sinus cavity (Thoma et al. 2006).

Frequently, the occurrence of an oroantral communication is not anticipated and therefore the intervention to close the perforation was not scheduled in advance. An easy, efficient and minimally invasive method would represent a benefit for both patients and clinicians alike. Communication closure by insertion of root analogs made chair-side from a porous β-tricalcium phosphate (β-TCP) composite fulfills these criteria (Thoma et al. 2006). The technique was shown to be fast and easy. Furthermore, less pain and swelling were observed compared to the patients that were treated with a buccal flap (Gacic et al. 2009). However, the fabrication of root analogs is only possible with unfractured roots as templates (Thoma et al. 2006).

Here, we present a template-independent technique for oroantral communication closure that uses a moldable polylactide-coated β-TCP. The initially soft bone substitute hardens in the defect and thereby forms a barrier between the oral and the nasal cavities. In this pilot study, we addressed the question whether the novel method is successful in closing the oroantral communications that have occurred in nine patients after tooth extraction. The safe establishment of a barrier, healing and regeneration of hard and soft tissue structures were evaluated.

_Materials and methods

Subject population and clinical situation

All patients with an oroantral communication after tooth extraction between June 18, 2007, and October 17, 2008, in a private dental practice were treated with the described method. The study included 5 female and 4 male patients who were between 21 and 86 years old. The occurrence of oroantral communications was routinely checked by asking the patient to pressurize his or her nasal cavity. Positive findings were verified visually and with a blunt probe. Subjects were excluded from the study if the anamnesis or mucous nasal discharge indicated an acute infection of the maxillary sinus or if the residual height of the buccal plate was below 3 mm, which may interfere with stable fixation of the graft material. Based on these criteria, no patient had to be excluded. The dimensions of the extraction sockets were measured by probing, radiographically and on clinical pictures (Figs. 1 & 2). The extraction defects measured 6 to 14 mm in the mesio-distal and 8 to 12 mm in the bucco-oral direction. The height of the buccal plate in the socket was between 3 and 11 mm. All extraction sockets were surrounded by intact gingiva.

Closure of the oroantral communication

In a first step, the site of the perforation at the bottom of the extraction socket was covered with of oxygenized cellulose (Tabotamp, Johnson&Johnson Medical, Gargrave, United Kingdom) (Fig. 2) in order to pre-

Fig. 4_Bone graft substitute in the defect.
Fig. 5_The defect is filled up to the ginigival level.
Fig. 6_Sligth expansion of the augmentate one day after the operation.
Fig. 7_Superficial degradation of the bone graft substitute in the height of the biological with after two weeks.
Figs. 8a & b_Complete soft tissue closure, occlusal view after 3 (left) and 8 months (right).

Region	18	17	16	15	14	24	25	26	27	28
OAC	1	–	1	1	–	1	–	3	2	–

Tab. 1_Localization of the OACs after tooth extraction.

vent a displacement of the graft material into the nasal cavity. Only after the formation of a stabilized coagulum the socket was filled with a fully synthetic bone graft substitute (easy-graft®, Degradable Solutions AG, Schlieren, Switzerland) to the gingiva level. The material consists of porous β-TCP granules that are coated with a 10 µm thin film of a polylactide. By mixing the granulate in the syringe with a liquid plasticizer, the polymer layer is softened and the granulate is transformed into a moldable mass. Excess liquid has to be discarded prior to graft application by pressing it carefully into a sterile swab. The bone graft substitute was applied directly from the syringe into the defect. In cases of larger perforations, the putty-like mass was flattened at its front end in order to prevent compression or displacement of the cellulose-stabilized coagulum (Fig. 3). The bone substitute was pressed gently into the defect and adapted to the socket walls with a sharp spoon (Fig. 4). The putty-like material hardens in contact with blood and other aqueous liquids into an inherently stable, porous, defect-analog body within minutes (Fig. 5). The soft tissue was not sutured. Complete closure of the communication was verified by asking the patients to pressurize his or her nasal cavity. Defect filling was assessed radiographically. In order to minimize pressure onto the implant material, the patients were advised not to blow their nose at the day of the operation and to eat with care in order not to put a mechanical strain on the defect site. Six patients took a broad-spectrum antibiotic during 3 to 8 days; the other three patients declined the use of antibiotics for antibiotic prophylaxis (Table 2).

_Follow-up

Recall appointments were scheduled after one day, seven days, two weeks and five weeks. More appointments were fixed if the medical situation demanded close monitoring of the patient. One patient did not appear for the one-week control, two patients were not available for the two- and the five-week controls. All patients were seen at least once between week one and week two, and all but one patient were followed up for four weeks or more. Oroantral communication closure, healing and clinical outcome were documented photographically and radiographically. In one case, soft and hard tissue samples taken during the placement of a dental implant were subjected to histological analysis.

_Results

Occurrence of oroantral communications

Mostly, the oroantral communications have occurred after extraction of the first molar (4/9), two oroantral communications were opened up due to extraction of the second molar, the remaining three oroantral communications were observed after removal of a first and a second premolar and a wisdom tooth, respectively.

Surgery and healing

The graft material hardened within minutes to an inherently stable body in the extraction socket. All subjects were able to pressurize the nasal cavities, which indicated a complete closure of the perforation. The patients reported weak pain on the first day after the operation and a weak sensation of warmth in the region where the perforation has been closed. Swelling was not observed in the operated region in any of the patients. Bloody nasal discharge, which would be a sign of bleeding into the nasal cavity, was not observed. The bone graft substitute material formed a stable block that was well adapted to the wound contours. The β-TCP composite swells slightly due to water uptake. The graft was thus tightly fixed in the extraction socket and protruded slightly above the gingiva level (Fig. 6). Within two weeks, the graft material was covered with soft tissue. Single β-TCP granules have been integrated into the covering tissue layer (Fig. 7). The vertical dimension of the material decreased due to the ongoing degradation procedure. However, the material always remained at the height of the biological width. After four to six weeks, a complete regeneration of the soft tissue could be observed. A collapse of the alveolar ridge could be prevented. After nine months, the initially convex buccal plate has receded slightly and appeared straight in the occlusal view (Figs. 7 & 8), indicating a marginal reduction in the width of the alveolar ridge. Nevertheless, the vertical and horizontal dimensions of the well-attached gingiva were maintained nearly completely (Fig. 9).

Figs. 9a & b_Complete soft tissue closure, lateral view after 3 (left) and 8 months (right).
Fig. 10_Radiograph after OAC-closure.


Fig. 9a


Fig. 9b

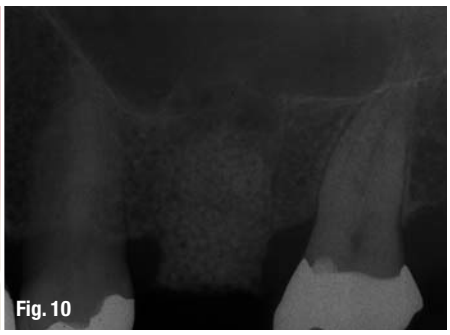


Fig. 10

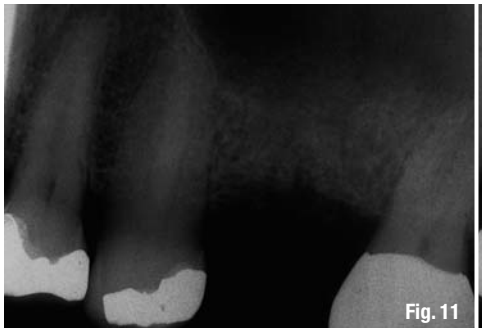


Fig. 11

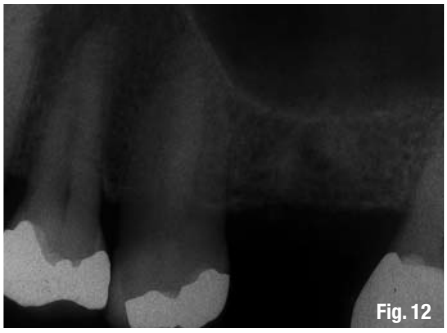


Fig. 12

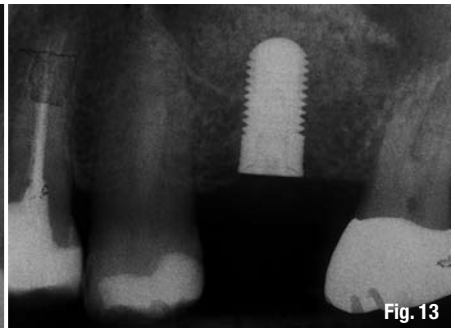


Fig. 13

Radiography

After closure of the oroantral communication, the bone graft substitute in the coronal two thirds of the extraction socket but not the oxygenized cellulose in the bottom of the extraction socket could be detected radiographically (Fig. 10). After three to four months, the outlines of the graft particles appeared blurred, the formation of a tissue radiologically identical to bone could be observed in the periphery of the graft material (Fig. 11). The vertical dimensions of the marginal bone structures were not altered (Figs. 10 & 12). Even after 18 months, variations in the radiopacy could be observed in the center of the former extraction socket (Figs. 12 &13). However, an implant could be inserted at the former extraction site with sufficient primary stability (Fig. 13).

Histological analysis

In the hard tissue sample taken after 18 months, capillary structures in the central part and a rather compact lamellar bone of various mineralization grades were detected (Fig. 14). The histological analysis of the soft tissue sample showed a connective tissue that is covered with an unkeratinized, stratified squamous epithelium Remnants of graft material were not observed in either sample, which was expected given that the material was described to resorb completely within three to 14 months (Nair et al. 2006; Rothamel et al. 2007).

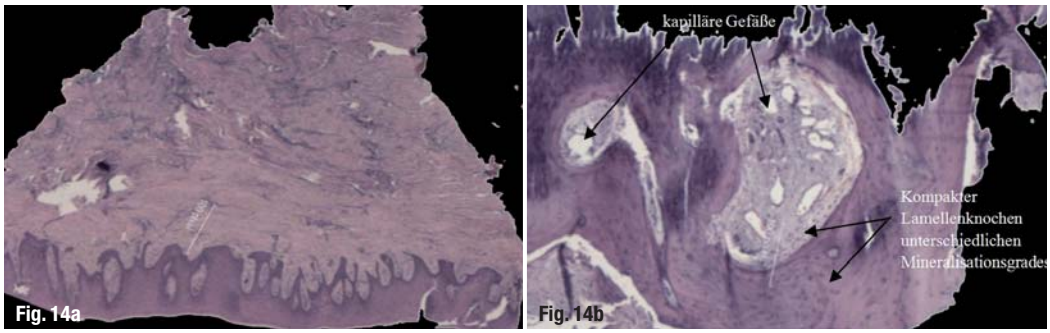
_Discussion

It has been shown that the incidence rate of oroantral communications after extraction of upper teeth ranges between 0.3 and 4.7% (Thoma et al. 2006). If the maxillary sinus is not already infected, immediate closure of the perforation is indicated in order to prevent contamination of the sinus cavity and a subsequent infection. The flap-based techniques according to Rehrmann-Wassermund or Axhausen are rather invasive and entail surgical tissue relocation procedures due to structural tissue changes. The results are often

Fig. 11_Blurring of the outlines of the graft material after 3 moths.
Fig. 12_Central remodelling after 18 months.
Fig. 13_Sinus floor elevation and insertion of an Aesthura® Classic implant in region 26 after 19 months with 25 Ncm.

Tab. 2_Patient overview.

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9
Age (y)	52	37	21	43	53	62	49	54	86
Sex	f	f	f	m	m	m	f	m	f
Region	15	26	26	16	26	27	24	18	27
Amount of easy-graft	1 x 0.4 ml	2 x 0.4 ml 1 x 0.15 ml	2 x 0.15 ml	1 x 0.4 ml	2 x 0.4 ml	1 x 0.4 ml	1 x 0.15 ml	1 x 0.4 ml	1 x 0.4 ml
Antibiotics	–	Isocillin 1.2 Mega	Isocillin 1.2 Mega	Sobelin 300 mg	Isocillin 1.2 Mega	–	–	Isocillin 1.2 Mega	Isocillin 1.2 Mega
Antibiotic intake	–	3 x 1 daily, 4 days	3 x 1 daily, 4 days	3 x 1 daily, 4 days	3 x 1 daily, 8 days	–	–	3 x 1 daily, 4 days	3 x 1 daily, 4 days



Figs. 14a & b_Histological analysis of soft (left) and hard tissue (right). Harvesting and preparation artifacts are visible.

Fig. 14a

Fig. 14b

not satisfying from an esthetic point of view. Therefore, a membrane-based approach in combination with a method to preserve the alveolar ridge after tooth extraction is favored. The perforation can be closed with a membrane and/or a tissue transplant and the extraction wound is filled with a material suitable for socket preservation (Becker et al. 1987; Watzek 2008). Finally, the wound is sealed towards the oral cavity with another membrane and/or soft tissue transplant. However, this technique is laborious, costly and is mastered mainly by experienced oral surgeons. Membrane-independent, minimally invasive subantral augmentation methods are simple and efficient one-step procedures for closure of oroantral communications (Thoma et al. 2006). The method presented in this case-cohort study critically depends on the unique features of the novel synthetic graft material. Initially it is moldable, and can be inserted into defects of any shape. In contact with blood, the material hardens and forms an inherently stable but openly porous body. Most likely, coagulated blood in the interconnected pores and the underlying, stabilized coagulum supports the formation of an air-tight barrier. During the first days, the polymer layer that mediates the formation of a stable scaffold takes up water, which results in a slight volume increase and guarantees a tight contact between the defect walls and the graft material. The β-TCP composite is tissue-friendly and the phase-pure β-TCP is degraded in parallel with bone formation (Nair et al. 2006; Rothamel et al. 2007; Gläser 2009). Unlike other methods, the described subantral augmentation procedure does not inflict further damage to the soft- and hard tissue surrounding the defect site. Pain, swelling and increased risk of infection that results from soft tissue and periost slitting and the exposure of the underlying bone are avoided, which represents a major patient benefit. It took two weeks for the graft material to be covered with soft tissue whereas defect closure is immediate with other techniques. It could be argued that the delayed coverage with soft tissue may increase the risk of infection. However, neither in the present study nor in a larger study that used an identical, thermally molded β-TCP composite for oroantral communication closure did such infections occur (Gacic et al. 2009; Thoma et al. 2009). Further studies will need to compare larger patient groups to address this issue in more detail. The clinical and radiographic controls showed an almost complete preservation of soft and hard tissue structures similar to membrane-based surgical techniques. Expansion of the sinus cavity towards the alveolar ridge was observed in one case 18 months after tooth extraction, making a sinus lift for stable implant placement necessary (Fig. 12). The β-TCP composite is replaced by bone that is subjected to physiological bone remodeling. Expansion of the sinus cavity thus occurred like it would be the case in any non-augmented edentulous setting.

The described minimally invasive method for oroantral communication closure is well suited for oroantral communications that are located above unproblematic extraction sites. However, it should not be applied if the size or the geometry of the defect does not allow stable anchorage of the material. Alternative methods should be considered in patients with very large oroantral communications that may result from the extraction of two or more molars. In such cases, the graft material may be lost or displaced into the sinus cavity by mastication forces. Also, safe anchorage of the material and efficient closure of the oroantral communication may not be given in shallow extraction sockets, e.g. if the buccal lamella is missing. A perforation with only 3 to 5 mm remaining vertical bone height could be successfully closed during this study. This patient was monitored more closely than described in the protocol. Defects shallower than this certainly should be treated with an alternative method.

In conclusion, the described minimally invasive method for closure of oroantral communications has several obvious advantages over conventional techniques. It is fast and efficient and does not inflict damage to the surrounding tissue since no additional surgery is needed. Nevertheless, alternative methods should be considered if an unsuitable defect geometry jeopardizes stable graft anchorage. Soft and hard tissue structures were mostly preserved, and no complications or failures to close the perforations were recorded during this retrospective case cohort study._

Article scheduled for publication, based on the article "Der Einsatz von polylactid-beschichtetem β-Tricalciumphosphat zum MAV-Verschluss", published in Quintessenz 08.

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