CLINICAL ORAL IMPLANTS RESEARCH

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Complications and adverse patient reactions associated with the surgical insertion and removal of palatal implants: a retrospective study

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Abstract

Objectives: The purpose of this study was to assess the frequency and variety of surgical complications and adverse patient reactions associated with the implantation and explantation of palatal implants.

Materials and Methods: The implantations and explantations of palatal implants in 146 patients who had undergone orthodontic treatment using a palatal implant for anchorage in the time period 1999–2010 were evaluated retrospectively. All complications and adverse patient reactions associated with the surgical intervention of implantation and explantation of the implant were assessed.

Results: Of the 146 palatal implants reviewed, 104 implantations and 44 explantations met the inclusion criteria and their data could be extracted. Of the 104 implantations, 25 (24.0%) surgical complications and adverse patient reactions could be documented. They consisted of lack of primary stability: 7 (6.7%), prolonged pain: 7 (6.7%), secondary bleeding: 6 (5.8%), perforation of nasal floor: 2 (1.9%), necrotic mucosa anterior of the implant: 2 (1.9%) and sensory impairment of the anterior palate: 1 (1%). The respective incidents for the 44 explantations were: disturbed wound healing: 3 (6.8%), perforation of nasal floor: 1 (2.3%), secondary bleeding: 1 (2.3%) and fracture of the implant: 1 (2.3%).

Conclusions: A wide spectrum of surgical complications and adverse patient reactions after palatal implant insertion and removal was found. All complications were of minor severity and duration except after one implantation, where a prolonged hypoesthesia of the anterior palate was found. Although only a small risk of a permanent sensory impairment of the anterior palatal region remains, patients must be well informed accordingly.

Anchorage is of central importance for predictable orthodontic tooth movement. Most of the anchorage strategies are reliant on patient's cooperation. But patient's cooperation is not predictable and might be insufficient (Nanda & Kierl 1992). With the introduction of temporary anchorage devices (TADs) (Daskalogiannakis 2000) a new kind of anchorage became available for orthodontic therapy (Triaca et al. 1992; Glatzmaier et al. 1995; Bousquet et al. 1996; Wehrbein et al. 1996; Kanomi 1997; Costa et al. 1998; Umemori et al. 1999; Byloff et al. 2000; De Clerck et al. 2002). These TADs were developed to overcome some disadvantages of conventional anchorage, namely patient cooperation (e.g., headgear) and relative stability (e.g., teeth). In a recently performed systematic review on the survival rate of four different TADs (palatal implants, onplants, miniplates and miniscrews), palatal implants and miniplates have shown the highest survival rate of more than 90% and can therefore be considered as a reliable skeletal anchor in the maxilla (Schätzle et al. 2009b). The simplicity in use, minimal stress experienced during surgical implant installation and removal, as well as the reliable success rates of palatal implants (Jung et al. 2007, 2009, 2012a; Männchen & Schätzle 2008; Schätzle et al. 2009b) are prerequisites for the high acceptance of this treatment by the orthodontic patients. A randomized clinical study with 120 patients on pain intensity and discomfort following palatal implant placement and premolar extraction showed, that pain intensity after surgical installation of an Orthosystem® implant was significantly

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lower than after premolar extraction (Feldmann et al. 2007).

So far, there have been only studies in the literature focusing on specific issues of palatal implant treatments like pain and discomfort (Feldmann et al. 2007), acceptance (Gündüz et al. 2004) or the impossibility to remove the implant after treatment because of its close proximity to the front teeth (Nicolas & Bart 2008). However, in contrast to the numerous reports on side effects in miniscrews (Motoyoshi et al. 2006; Maino et al. 2007; Chen et al. 2008; Briscено et al. 2009; Gracco et al. 2010), there is no report assessing the spectrum of surgical problems and adverse patient reactions arising during implant installation and removal. As the majority of palatal implants are placed in the anterior median or paramedian palate region, the surgical interventions may cause damage to the incisal nerve, damage to the roots of neighboring teeth, endodontic complications (Nicolas & Bart 2008) or may lead to a perforation of the nasal floor. The aim of this study was to evaluate all the complications and adverse patient reactions during the surgical procedure of installing and explanting palatal implants.

Materials and methods

The data of the retrospectively evaluated implantations and explantations were obtained from the patient records of the Department of Orthodontics and Paediatric Dentistry, Center of Dental Medicine, University of Zurich, Switzerland. One hundred and fourty six consecutive patients, receiving a palatal implant (Orthosystem®; Institut Straumann AG, Basel, Switzerland) during the time period 1999–2010 for orthodontic purposes to achieve the intended treatment goal, were identified and considered for possible inclusion. The orthodontic indication for implant placement was established according to the required anchorage situation to achieve the intended treatment goal.

The inclusion criteria were as follows:

- Implantation performed by an experienced surgeon:
  As surgeon's experience (>10 implant insertions) was identified as a significant prognostic marker, the respective limitation was done to reduce the influence of the implant specific learning curve (Jung et al. 2012a). All endosseous implants were placed according to the Straumann® guidelines for respective palatal implants. After injecting a local anesthesia, the palatal mucosa was either removed with a punch and an elevator or the insertion occurred under visual control by an open flap technique. After marking the center of the intended implant site with a round drill, the hole for accommodating the implant was drilled by the use of respective spiral drills, and for the older palatal implants (Ø 3.3 and 4 mm), the shoulder was prepared with the ortho profile drill for the respective implants. The self-tapping implant was inserted by hand with a ratchet.

  After completion of the orthodontic treatment, the palatal implants were removed using a standard trephine of 5.5 mm and an implant cylinder for guidance.
- The following data had to be available: age, gender, type of implant, installation region (median, paramedian), operation procedure and surgeon. If one or more variables were missing, the respective implantation/explantation was not considered for evaluation.
- Good general health condition of patients and no contraindications for minor oral surgical procedures.
- The non-stable implants were removed, and palatal implants were, again, inserted at a later date. However, such non-stable but replaced implants were eliminated from further evaluation.

Of all the implantations and explantations fulfilling the inclusion criteria, the following data were extracted: age, gender, type of implant, installation region (median, paramedian), operation procedure, surgeon and all complications associated with the surgical intervention of the insertion and/or removal of the implant.

Figure 1 illustrates the data collection used to identify all implantations and explantations fulfilling the selection criteria. Twenty seven implantations and 4 explantations with incomplete data had to be excluded for assessment of complications and adverse patient reactions associated with the surgical insertion and removal of palatal implants.

Results

By end of December 2010, 146 patient records were reviewed by one of the investigators (R.F.) and out of these, 104 implantations [33 male/71 female, mean age 19.5 years (median 17.2 years)] and 44 explantations [9 male/35 female, mean age 22.8 years (median 20.7 years)] fulfilled the inclusion criteria and could be analyzed. The surgical complications and adverse patient reactions are depicted in Tables 1 and 2.

Complications while/after palatal implant insertion:

In seven out of the 104 evaluated implantations, the inserted palatal implant was not primary stable or its stability was considered as critical. Three of those implants without or critical primary stability, however, were maintained *in situ* but were lost during the early healing phase. In two cases, a so-called

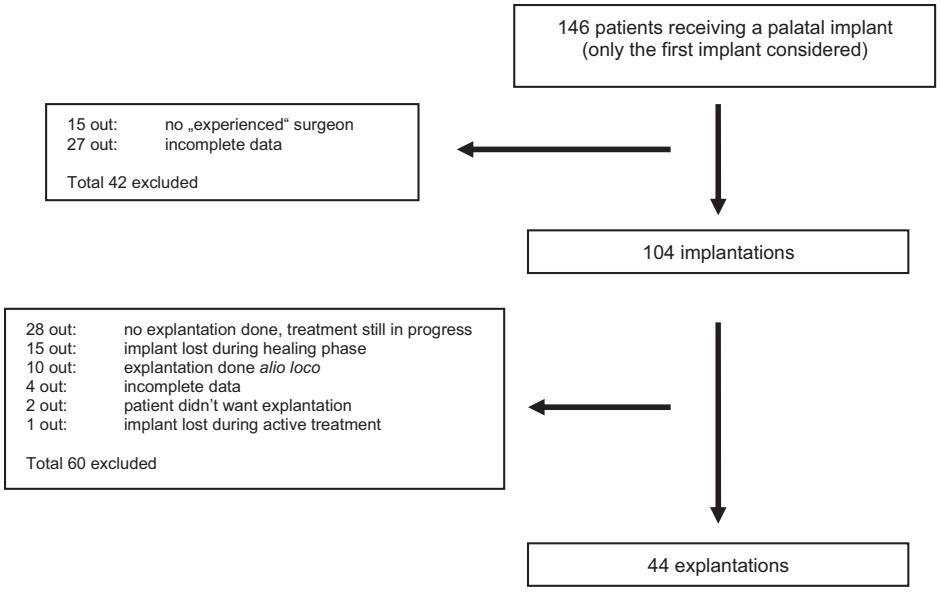

Fig. 1. Data collection.

Table 1. **Complications associated with the implantation (N = 104)**

Complication	N (%)	Age (years): mean median range	Gender (m/f)	Implant type	Location	Procedure	Surgeon
No primary stability	7 (6.7)	17.0 15.3 11.8–33.5	4/3	Ø 3.3 mm, length 6 mm: 3 Ø 4.0 mm, length 4 mm: 1 SLA Ø 4.1 mm, length 4.2 mm: 3	median: 4 paramedian: 3	standard: 5 flap: 2	A: 1 C: 1 D: 3 E: 2
Prolonged pain	7 (6.7)	21.9 20.5 14.6–34.9	0/7	Ø 3.3 mm, length 4 mm: 1 Ø 3.3 mm, length 6 mm: 1 SLA Ø 4.1 mm, length 4.2 mm: 4 SLA Ø 4.8 mm, length 4.2 mm: 1	median: 4 paramedian: 3	standard: 5 flap: 2	A: 2 B: 4 C: 1
Secondary bleeding	6 (5.8)	25.8 24.7 12.7–41.6	2/4	Ø 3.3 mm, length 6 mm: 1 SLA Ø 4.1 mm, length 4.2 mm: 5	median: 4 paramedian: 2	standard: 4 flap: 2	A: 2 B: 0 D: 1 E: 3
Perforation of nasal floor	2 (1.9)	22.4 22.4 11.5–33.3	1/1	Ø 3.3 mm, length 4 mm: 2	paramedian: 2	standard: 1 flap: 1	A: 1 C: 1
Necrotic mucosa	2 (1.9)	28.8 28.8 15.9–41.6	0/2	Ø 3.3 mm, length 6 mm: 1 SLA Ø 4.1 mm, length 4.2 mm: 1	median: 1 paramedian: 1	flap: 2	A: 2
Sensory impairment	1 (1)	18.5 - -	0/1	SLA Ø 4.1 mm, length 4.2 mm: 1	median: 1	standard: 1	B: 1

Table 2. **Complications associated with the explantation (N = 44)**

Complication	N (%)	Age (years): mean median range	Gender (m/f)	Implant type	Location	Surgeon
Disturbed wound healing	3 (6.8)	23.3 24.4 16.5–28.9	1/2	Ø 3.3 mm, length 6 mm: 2 SLA Ø 4.1 mm, length 4.2 mm: 1	median: 2 paramedian: 1	B: 2 C: 1
Perforation of nasal floor	1 (2.3)	30.0 - -	0/1	Ø 3.3 mm, length 6 mm: 1	median: 1	F: 1
Secondary bleeding	1 (2.3)	19.1 - -	0/1	Ø 3.3 mm, length 6 mm: 1	median: 1	A: 1
Fracture of the implant	1 (2.3)	30.0 - -	0/1	Ø 3.3 mm, length 6 mm: 1	median: 1	F: 1

"rescue implant" (palatal implant with a larger diameter) was placed and osseointegrated successfully thereafter. In two implantations, another implant bed was prepared, and a respective implant was inserted at a different location. All subsequently placed implants were not considered for further evaluation.

In three of the seven implantations after which patients were reporting prolonged pain, pain was felt in the anterior front teeth. In one of these three patients, dolor persisted until the implant got loose and was removed subsequently. One patient felt pain while blowing one's nose. For the remaining three patients, no further information was available.

In four of the six implantations with secondary bleeding, the incident was noted during the first day immediately after implantation. One patient suffered from prolonged secondary bleeding for 3 days. In one patient, no further information was available in the respective record.

Accidental perforation of the nasal bone floor was noted during the drilling procedure in two implantations by means of a blunt probe. However, a significant perforation of the respective mucosa was not diagnosed. Nevertheless, the respective implants were placed without any complications and osseointegrated successfully thereafter. By the explantation of these two implants, no perforation was observed.

In two implantations, an adverse patient reaction in terms of necrotic mucosa anterior of the implant was detected. In one of them, even the underlying bone was exposed. Both implantations were performed with an open flap surgery.

After one implantation, the respective patient noticed a numb sensation in the anterior palate for 3 weeks.

Complications while/after palatal implant explantation:

There were only very rare complications and adverse patient reactions while and after explantation of the palatal implant.

After one explantation, an ostitis sicca developed, whereas after two other explantations, a bone sequestrum led to a disturbed wound healing. No information about possible smoking habits, may influencing this event, was available.

During one explantation, the respective palatal implant fractured and had to be removed surgically. In the same explantation also, the nasal floor was perforated and an oronasal fistula developed during the subsequent wound healing, which had to be closed surgically. In one patient immediately after the explantation, an intense bleeding was noted and finally was stopped by means of electrocautery.

Discussion

Since the introduction of bone borne TADs, orthodontists are no longer dependent on non-predictable and often insufficient patient's cooperation (Nanda & Kierl 1992). From all TADs, orthodontic palatal implants, such as the Orthosystem® (Institut Straumann AG), are providing reliable absolute

orthodontic anchorage and hence are considered to be superior to any orthodontic tooth-borne anchorage device (Schätzle et al. 2009b). Although palatal implants are now successfully used for almost two decades (Triaca et al. 1992; Wehrbein et al. 1996), there is no study assessing the spectrum of possible surgical complications or risks during palatal implant insertion and removal.

Lack or insufficient primary palatal implant stability is assessed to be the major surgical problem during implant insertion. Insufficient primary stability causes connective tissue encapsulation and the possible premature loss of the implant (Friberg et al. 1991; Lioubavina-Hack et al. 2006). This might be the reason why the three palatal implants with insufficient primary stability post-insertion did not osseointegrate and were lost early. Insufficient primary stability might be caused by poor quality of bone, insufficient bone quantity, imprecise implant bed preparation or overwinding during implant installation. Concerning the first aspect, two histomorphometric studies (Stockmann et al. 2009; Wehrbein 2009) assessed the bone quality of the median palate in the anterior–posterior dimension. Bone quality was found to be sufficient for orthodontic implantation in all respective sites. However, both studies had small sample sizes (22 and 10, respectively). Nevertheless, it should be kept in mind that according to an animal study, implants that are placed in bone of soft quality always show high micromotion (Trisi et al. 2009). Therefore, it can be assumed that also in human bone of soft quality, primary stability might be negatively affected. Concerning the second aspect, bone quantity obviously varies among patients and must, therefore, be evaluated individually with respect to the planed implantation site. The precision of implant bed preparation may be dependent on the surgeon's skills. This would be in agreement with a retrospective study that evaluated prognostic parameters such as age and gender, vertical bone height along the prospective implant axis, implant type and surgeon's experience contributing to palatal implant failures, in which only surgeon's experience was associated with a better implant survival (Jung et al. 2012a). As a treatment alternative, if primary stability is unfavorable, the use of a so-called "rescue implant", slightly larger than the regular palatal implant, might be used to achieve the mandatory primary stability for implant success. Furthermore, the former palatal implant yielded an emergence profile with a 90-degree shoulder. This bore the danger of overwinding the implant during installation with a subsequent loss of the primary stability. It is obvious that such designed features made the installation of palatal implants technique sensitive (Männchen & Schätzle 2008).

In this study, some surgeons inserting the palatal implant performed therefore the installation in open flap technique having better visual control to reduce the danger of overwinding. However, a necrotic mucosa anterior of the implant was only found in those cases where a flap surgery was performed. In recent years, a new palatal implant (with a modified, slightly concave, tulip-shaped conical emergence profile) was developed with the purpose of reducing the risk of overwinding the implant during installation (Orthosystem®, Institut Straumann AG). A recently published experimental human study on palatal implants with this novel design (Schätzle et al. 2009a) yielded a high primary stability and a 100% survival for the whole observation period. Since then, the respective implant bed preparation might be performed with a stent or similar devices without performing flap exposure, and therefore, this complication should not be seen any longer.

Another complication might be the perforation of the nasal floor. This might be detected either visually, with a probe or with a radiography. On wire-marked skulls, the highest bony demarcation of the palatal complex seen radiographically largely coincided with the nasal floor rather than with the midsagittal nasal septum that offers additional vertical bone height (Wehrbein et al. 1999). Hence, it was suggested that the vertical bone heights in the anterior and middle thirds of the hard palate were at least 2 mm higher vertically than identified on lateral cephalograms. The vertical dimension on lateral cephalometry reflects therefore the minimum quantity of bone, which is usually seen in the parasagittal plane, and not the maximum quantity of vertical bone in the median plane. Therefore, an indication for a preoperative CT or CBCT only exists when lateral cephalometry reveals a marginal quantity of bone (Jung et al. 2011, 2012b). In a study of human cadaveric maxillae, it could be shown that 20% of palatal implants projecting beyond the nasal floor in the lateral cephalogram were false-positive records and may not be related to actual penetrations into the nasal cavity (Crismani et al. 2005). According to their investigation, usually the true anatomical nasal floor lies about 0.8 mm higher than it is projected in the lateral cephalogram. Furthermore, even when the bone is perforated up to 1.3 mm, the covering nasal mucosa was not necessarily perforated.

In our investigation, the two patients in whom a perforation was detected during the implantation, no further complications were seen afterward, even after explantation. On the other hand, when a perforation of the nasal floor happened during the explantation, an oronasal fistula persisted in one patient and a spontaneous closure did not happen. Perforation of the nasal floor seems to be more critical after explantation than after implantation.

But also the relation to the adjacent teeth located anterior to the palatal implant must be considered, especially when performing an en masse retraction with maximum anchorage. The intended final root position must be taken into account otherwise possible root damage of the incisors might be a clinical consequence or the palatal implant must be remained *in situ*. In an experimental human study (Schätzle et al. 2009a), by explantation the nerve–vessel thread of an upper incisor was found to be damaged and caused gray tooth discoloration and temporary reduced reaction to sensibility testing. In the present patient cohort, however, possible damages to the roots of the incisors as mentioned by Nicolas & Bart (2008) were not detected or may have been left unnoticed.

Prolongation of pain phenomenon was the most common adverse patient reaction in the implantation group and most often felt in the anterior front teeth. Pain may result from the press-fit of the palatal implant generated after implant installation. This may explain why no entry about pain was found in the patients chart after explantation. Regarding gender, only women were reporting pain. This is in agreement with a study about the perception of pain as a result of orthodontic treatment with fixed appliances (Scheurer et al. 1996). In all but one case, pain was felt only transitionally. In this patient, pain lasted permanently until the implant got lost. This might have been caused by a direct compression/contact of the incisal nerve. The finding that one patient felt pain while blowing one's nose was may be due to an unnoticed perforation of the nasal floor. However, a randomized controlled trial showed that at the first evening after palatal implant insertion, pain intensity and the consumption of analgesics 1 week after the installation were significantly lower in the Orthosystem® group than after premolar extraction (Feldmann et al. 2007).

Even though there is a couple of information on the bony palatal region, no data exist about the course of the nasopalatine canal and it's probably underlying relation to the skeletal pattern. One patient suffered from a prolonged hypoesthesia of the anterior palate.

This may have been due to a direct injury of the incisal nerve or its compression. The difficulties for implant placement in the anterior maxilla in context with the nasopalatine canal are known to oral surgeons and different studies already investigated the anatomical topography of the nasopalatine canal (Mraiwa et al. 2004; Bornstein et al. 2011). Its palatal opening is the incisive foramen. At the level of the nasal floor often 2 (Y-canal morphology), but sometimes 3 or 4 openings can be observed. In particular cases, the canal showed up as a cylinder with only one nasal opening (Mraiwa et al. 2004). Despite the variety of the canal morphology, it would be interesting to assess the inclination of the nasopalatine canal in relation to the nasal floor as the facial type might have an impact on the skeletal characteristics (Masumoto et al. 2001).

To the authors' knowledge, no study reported of secondary bleeding after palatal implant installation. Prolonged bleeding normally might be simply stopped by compression only (for example, with a swab). If this procedure is not successful, constriction of the respective bleeding vessel with a suture or stop bleeding with electrocautery might be necessary.

In three explantations, the wound healing did not happen normally. The reason for this can only be guessed. The ostitis sicca may have been due to excessive rinsing after the explantation, non-diagnosed wound healing disorder or smoking habits (not assessed). The bone sequester found in two patients might be a result of disrupted bone due to the forces produced during the explantation or may be due to inappropriate water cooling and consequently increased temperature during the drilling procedure. For implantations, the temperature changes in different bone depths with different irrigation temperatures were investigated (Sener et al. 2009). It could have been shown that without irrigation, the maximum temperature was 50.9°C at a depth of 3 mm. With cooling of a 25°C saline solution, maximum temperature was found to be 37.4°C in a depth of 12 mm. Above this, all temperatures were below body temperature. However, these results hold true for the implantation, where cooling might be easier through the bore canal than compared to the explantation, where the rinsing solution has to enter through the thin space between the implant and the surrounding bone.

No study or report so far has reported of fractures of palatal implants. The implant that broke was 3.3 mm in diameter and 6 mm in length.

Due to the small sample size, however, the frequencies of the different surgical complications and adverse patient reactions found must be interpreted with care.

Conclusions

A wide spectrum of surgical complications and adverse patient reactions after palatal implant installation and removal was found. In all but one implantation, respective incidents were of transitional manner and minor severity. Only in one patient, a prolonged hypoesthesia of the anterior palate was found after implantation. Nasal floor perforation seems to be rather crucial during explantation and might need to be closed surgically to prevent a persisting oronasal fistula. Although only a small risk of a permanent sensory impairment of the anterior palatal region or damage of the nerve–vessel thread remains, the patients must be well informed accordingly.

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