

Success Rate of Second-Generation Palatal Implants

Preliminary Results of a Prospective Study

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ABSTRACT

Objective: To analyze the clinical outcome of a prospective two-center study of second-generation palatal implants 6 months after functional loading.

Material and Methods: From 2005 to 2006, 30 patients aged 12 to 41 years were included in the study. In all patients, orthodontic treatment required stationary anchorage. The palatal implants (Straumann, Basel, Switzerland) were placed in the median region of the anterior palate.

Results: All implants were initially stable at the time of placement. However, two (6.7%) were lost during the unloaded healing period. The remaining 28 (93.3%) were subjected to functional loading after a mean healing period of 12 weeks. Typical signs of slight superficial inflammation were observed in the peri-implant mucosa (n = 28). During the orthodontic loading phase, the implants were equipped with either a modified pendulum appliance for distalization or a transpalatal arch for stationary anchorage to the posterior teeth. No implant loosening or loss was registered during the active treatment period.

Conclusions: The failure rate of palatal implants of the second generation was low (6.7%). Slight inflammatory reactions of peri-implant tissue caused neither implant loss nor pain. (*Angle Orthod.* 2009;79:85–90.)

KEY WORDS: Endosseous orthodontic anchorage elements; Palatal implants

INTRODUCTION

Orthodontic anchorage, defined as “the capacity to dissipate undesirable reactive forces,”¹ was first reported by Angle² and has evolved into a major factor in the treatment of dental and skeletal dysgnathia. Depending on the individual goal of treatment, the orthodontic treatment plan is critically dependent on the biologic anchorage quality of the teeth.^{3,4}

The theoretical concept of “ideal orthodontic an-

chorage” includes complete interception of all undesirable side effects by means of stationary anchorage. This concept seems to have been realized today in the form of endosseous implants. In the last years, a large body of clinical and experimental evidence has confirmed the reliability and success of endosseous implants for the purpose of orthodontic and orthopedic anchorage.^{5–11} An overview of the most commonly used means of skeletal anchorage was recently published by Heymann and Tulloch.¹²

Palatal implants were developed as temporary orthodontic skeletal anchorage elements, particularly for the maxilla. Compared to implants loaded with masticatory forces, they are significantly reduced in length. The first-generation palatal implants have been successfully applied in several studies.^{8,13–16} However, no data on the clinical performance of the second generation of palatal implants (Figure 1), which came onto the market in 2004, have been available until now.

Therefore, in the present paper we report on the osseointegration and clinical parameters of a “new” type of implant in a prospective study. In this communication, we present initial results observed 6 months after functional loading of these implants.

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Accepted: March 2008. Submitted: January 2008.

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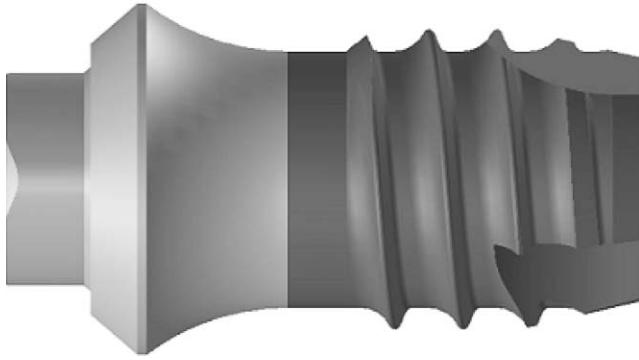


Figure 1. Schematic illustration of the second-generation palatal implant. The diameter and length of the endosseous portion are 4.1 and 4.2 mm, respectively.

MATERIALS AND METHODS

Study Design

The investigation was designed as an open, prospective, uncontrolled, two-center study. Patients were treated at two study centers: one in Berne, Switzerland, and the other in Mainz, Germany. Local statutory board approval was obtained from the ethics committees of the provincial medical societies of Rheinland-Pfalz and Switzerland.

Figure 2 provides the schedule of the clinical study from recruitment of patients to conclusion of the study. The primary end point of the initial phase of the study was clinical stability at 6 months after functional loading. Loss or implant mobility was assessed at this time. The following parameters were analyzed as secondary

end points: wound healing, peri-implant soft tissue reactions, and local mechanical complications secondary to the presence of orthodontic appliances.

Patients

The study period ranged from 2005 to 2006 and included 30 patients (17 female and 13 male patients) aged 12 to 41 years. Inclusion criteria were as follows:

- Orthodontic indication for skeletal anchorage (stationary anchorage was necessary)
- Age ≥ 12 years
- Sufficient bone, as judged on the lateral radiograph, for placement of a palatal implant
- Written informed consent of the patient and/or the parent(s) or custodian

Patients with cleft lip and palate or other syndromic craniofacial abnormalities were excluded. Further exclusion criteria were immune system compromise; diseases requiring steroid treatment, irradiation, or chemotherapy; bone metabolism diseases; drug or alcohol abuse; and pregnancy.

Palatal Implant

Palatal implants of the second generation (Orthoimplant, Institut Straumann, Basel, Switzerland; Figure 1), were used in the present study. The endosseous portion (length, 4.2 mm; diameter, 4.1 mm) includes a self-tapping thread and has a sandblasted acid-etched surface. Compared to the implants of the first gener-

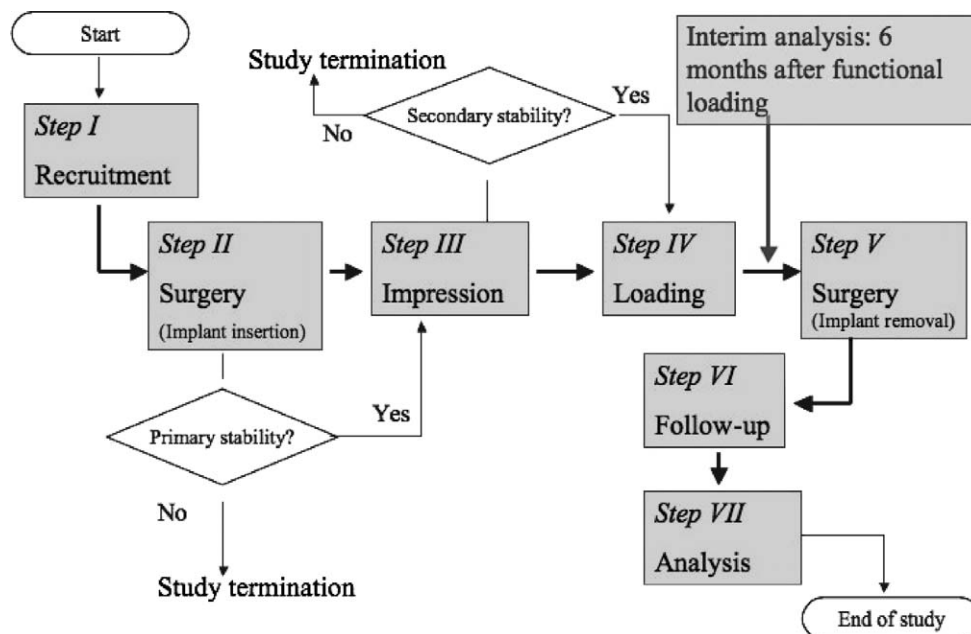


Figure 2. Course of the study from patient recruitment to its conclusion. If either primary stability was not achieved or loosening of the implant was seen, the implant was considered a “failure” and the patient was excluded from the study.

ation, the thread has a greater load-bearing depth, and the emergence profile has been modified from a 90-degree shoulder to a slightly concave, tulip-shaped conical design. A triangular device was developed to improve rotational stability in the connection between the implant and the orthodontic device. For orthodontic treatment, the implant is fitted with a steel cap (height, 3.5 mm; diameter 4.8 mm), onto which orthodontic arches can be fixed by laser welding.

Site of Insertion and Surgical Insertion

All implants were placed in the median region of the anterior palate by one experienced surgeon per center. Surgical placement was performed under local anesthesia at approximately the level of the first or the second premolars, perpendicular to the bone surface. The palatal mucosa at the insertion site was removed with a mucosal punch. A round bur was used to create a slight bony groove. The implant site was prepared using an ascending sequence of spiral drills up to 3.5 mm. The self-tapping implant was placed with a ratchet and then sealed with a healing cap.

Postoperative clinical controls were performed after 1, 2, 6, and 12 weeks. The patients were instructed to rinse their mouth three times per day with a chlorhexidine digluconate solution during the first 10 days post-surgery. Thereafter they were advised to clean the implant in a circular fashion with a soft toothbrush. The mean duration of the unloaded healing phase was 12 weeks.

Orthodontic Treatment, Suprastructure, and Force Systems

According to the manufacturer's instructions, plaster casts were obtained after a minimum of 10 weeks after

implant placement by alginate impressions using pre-fabricated transfer copings. At this time the implants were not subjected to functional loads. The impressions were made without applying pressure.

Customized palatal suprastructures were manufactured for each patient. Both direct anchorage (force system between the anchorage implant and the teeth that were to remain mobile) and indirect anchorage (rigid connection [orthodontic wire] between the anchorage implant and the teeth) were used. For direct loading we often used an implant-supported quadruple pendulum device to distalize the molars (Figure 3a). The lever arms (springs) of this device exerted a force of 1.5 N per spring. The basic component for indirect loading was a transpalatal arch (Figure 3b). Force magnitudes of segmented arches for intrusion/extrusion and torque movements of anterior teeth ranged between 0.8 and 1 N. The force magnitude of open- or closed-coil springs or elastic chains ranged between 1.5 and 2 N (eg, the amount of force used for mesial movement of posterior teeth). Force magnitudes were measured chairside during insertion of the force systems by the use of a spring balance (Correx, Haag Streit, Switzerland). Functional orthodontic loading of the implants was started no earlier than 12 weeks after implant placement.

Assessment of Implant Stability and Mobility

Primary stability was assessed intraoperatively by the surgeon. Secondary stability was measured before and during functional loading through the percussion resonance of the implant. Implant mobility was tested indirectly by the presence of undesired movements of orthodontic suprastructures using the instrumental grip technique.



Figure 3. Clinical aspects of direct anchorage of the palatal implant. (a) Anchorage by means of a modified pendulum appliance to distalize the lateral teeth. (b) Anchorage through a modified transpalatal arch.



Figure 4. (a and b) Mild mucositis around the Orthoimplant. (c) Pendulum appliance in situ. In the peri-implant region there is a mild hyperplastic reaction, and in the region of the pendulum loops there is mild irritation of the palatal mucosa.

Assessment of Peri-Implant Soft Tissues

Peri-implant soft tissues were assessed during orthodontic control appointments, based on the following classification: grade 0 = no visible hyperplastic reaction in the peri-implant region; grade 1 = visible soft tissue hyperplasia.

Statistical Evaluation

Absolute and relative frequencies were given for the primary and secondary end points of the study.

RESULTS

Implant Mobility and Loss

From 2005 to 2006, 30 implants were placed in patients aged 12 to 41 years. Fourteen patients were younger than 16 years of age, and 16 patients were at least 16 or older. The patients' mean age was 19.7 years. One implant was placed in each patient. To date, there have been no dropouts from the study.

At the time of placement, all implants (30/30) were stable. However, during the healing phase two (6.7%) implants were lost (both at the eighth week postinsertion). In these patients there was marked implant mobility and a dull percussion resonance at the time of removal. The remaining 28 implants (93.3%) became osseointegrated and were subjected to functional loads after 12 weeks. At the time of this interim analysis, these 28 implants had been subjected to orthodontic loads for at least 6 months and were marked by a high tone on percussion and an absence of mobility. None of the implants ($n = 28$) had to be removed. No patient had reported pain in connection with orthodontic devices.

Wound Healing, Peri-Implant Findings, and Local Mechanical Complications

During the healing phase and at 6 months after functional loading, all implants showed mild mucositis in the peri-implant region (Figure 4a, b). In one patient the inflammation was resistant to local treatment for more than 4 months; in all other patients, the inflammation ceased after local treatment with a chlorhexidine digluconate solution. In spite of grade 1 soft tissue hyperplasia, impression taking was not impaired in any cases ($n = 28$). Neither mucositis nor the hyperplastic reaction in the peri-implant region caused pain or impaired the stability of the implants.

Four of 28 patients received a modified pendulum appliance to move posterior teeth distally. Two of these patients had impaired oral hygiene because of the appliance, which caused a mild irritation of the palatal mucosa at the site of the pendulum body and in the region of the pendulum loops (Figure 4c). However, this tissue reaction subsided spontaneously after distal tooth movement had been accomplished. Twenty-four patients received a transpalatal arch. Oral hygiene problems were not encountered with this type of device. To date, no mechanical complications such as loosening or fractures of bars or wires have been observed.

DISCUSSION

It was the aim of this communication to report on the clinical performance of the "second-generation" palatal implants. The implants were inserted in the midline, since anatomic¹⁷ and radiologic investigations^{16,18,19} have demonstrated sufficient dimensions and quality of bone at this site.

In addition to primary stability, the report of Asscherickx et al²⁰ has recently raised the issue of growth in-

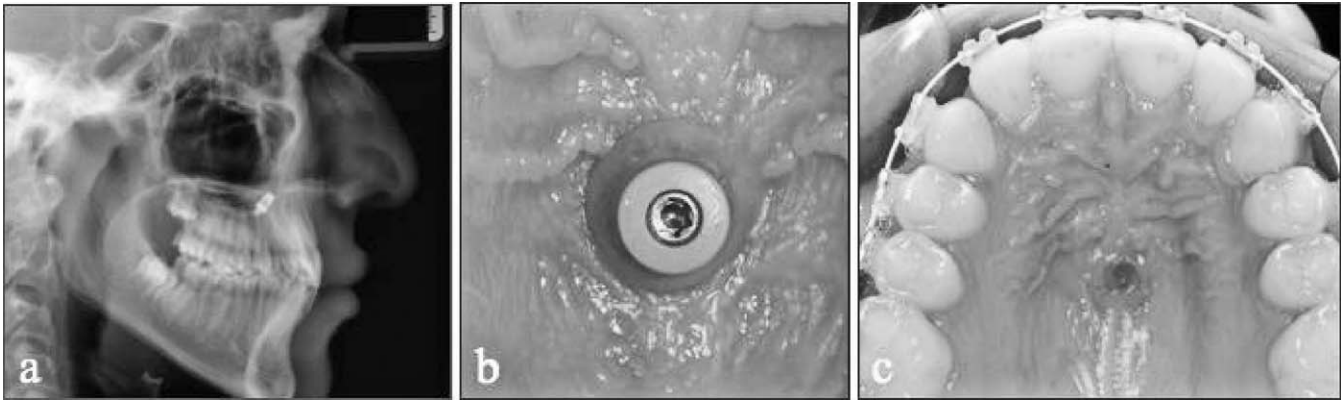


Figure 5. (a) Lateral radiograph obtained after insertion of a palatal implant. This implant was lost at 8 weeks postinsertion. (b) Magnification of the peri-implant region shows marked mucosal hypertrophy and the formation of a soft tissue margin in the peri-implant region. (c) Intraoral photograph of the maxilla of another 18-year-old patient shortly after surgical removal of the loosened palatal implant shows only mild soft tissue hyperplasia.

terference. In fact, experimental data obtained from growing beagle dogs provided an initial suspicion of disturbed transverse growth following median-sagittal insertion of palatal implants.²⁰ The significance of these findings for the human skeleton remains to be explored. However, based on the data of Björk and Skieller,²¹ a clinically relevant effect seems to be highly unlikely. Moreover, the question of potential impairment of growth after paramedian insertion has not been answered conclusively. Therefore, we used the well-established concept of median palatal insertion and did not change the implant site even after the results of Asscherickx et al²⁰ were published in 2005.

Regarding positional stability, the success rate in this study was 93.3%. Two of 30 implants were lost during the healing phase, prior to functional loading. These were lost early in the healing phase in patients aged 13 and 18 years. Although somewhat speculative, one might claim parafunctional activity of the tongue was responsible for these implant losses. In such cases, the use of a cover plate may be helpful to prevent application of undesired forces to the implant. Given the small number of losses, however, we did not recommend such plates on a routine basis. Failure of palatal implants may potentially occur owing to a large quantity of connective tissue in the median suture and insufficient interdigitation of the palatal plates,^{16,22} bacterial infection,²³ or technical problems during surgical placement. None of these was recognized in the cases described here. Intraoperatively, the implants were stable and technical problems did not occur. Figure 5a shows the lateral radiograph of a 13-year-old patient shortly after surgical insertion of the palatal implant. This implant was lost early (eighth week postinsertion) and showed a marked hyperplastic reaction (grade 1) before surgical removal (Figure 5b). On the other hand, the clinical investigation of an-

other patient (18 years old) shortly after removal of the palatal implant showed only a mild hyperplastic reaction (Figure 5c). The remaining 28 implants are clinically stable at 6 months after functional loading and have shown no signs of implant mobility.

The difference between this implant and the previous system is its macrostructure (ie, larger load-bearing depth of the thread, tulip-shaped passage through the mucosa) and the standardized drilling instruments. With respect to the surgical insertion, the drill is not equipped with any additional cutting edges. Thus, surgical insertion is rendered simpler and is designed to prevent marked weakening of cortical bone. Given the same healing period (minimum of 12 weeks), loss rates for palatal implants of the first generation were between 0% and 15%.^{8,15,22} The most commonly reported reason for loss was peri-implant infection during the orthodontic loading phase. In a few cases the implants were lost during the healing phase. Tinsley et al²² reported three lost implants (out of 20 placed) during the healing phase after median insertion of the implants; the reasons for the losses were not clear.

A further aspect concerning the hygiene of palatal implants was noted in the present study. The implants and suprastructures placed were generally easily accessible for cleaning purposes during the orthodontic treatment, with the exception of the pendulum appliance. Repeated exposure of the implants as described for the first-generation implants¹⁵ was not required in this study. In this respect, the altered design of the abutment components (triangular, tulip-shaped) of the second-generation implants appears to exert a particularly favorable effect on peri-implant soft tissues. The implants in the present investigation showed only mild mucositis (28 cases of grade 1 peri-implant soft tissue hyperplasia). However, this neither affected the stabil-

ity of the implants nor interfered with technical steps of orthodontic treatment.

CONCLUSIONS

- The failure rate of palatal implants of the second generation was low (6.7%).
- Mild mucositis or a hyperplastic reaction around the implant was common but caused neither implant loss nor pain.

ACKNOWLEDGMENT

We would like to thank Institut Straumann, Basel, Switzerland, for supplying the implant material and funding this clinical study.

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