



ROLAND MÄNNCHEN

The Palatal Orthodontic Implant

Healing Process, Clinical Application, Biomechanics,
Success, Risk Factors, Indications and Limits



ACADEMIC DISSERTATION

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ACADEMIC DISSERTATION

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To Catherine and Werner
In memory of my parents

ABSTRACT

Temporary anchorage devices (TAD), fixed to bone, have been gaining increasing importance in orthodontics in the last 15 years. They are independent of the patient's compliance, overcome some of the limits of classical anchorage devices and expand the orthodontic treatment possibilities. But only very little is known about the healing process after insertion, success and survival rates, risk factors, adequate handling and biomechanics and, as a consequence, indications and limits of the different TADs used nowadays.

The aim of the series of studies was to examine the different aspects of the palatal orthodontic implant as one representative of contemporary TADs and to compare them to other TADs.

The healing process of two different implant surfaces (Straumann SLA® and a new hydrophilic SLActive®-surface) has been tested in humans using resonance frequency analysis. It was found that the transition point from primary to secondary stability occurs after 5 weeks for SLA® and after 4 weeks for SLActive® surfaces and that the baseline stability is re-established after 9 weeks for SLA® and after 6 weeks for SLActive®, respectively. It is suggested that palatal implants may be loaded after 2 month or 1.5 months, respectively. No conclusive statement can be made for miniscrews, as the surface characteristics are completely different.

An individualised multifunctional supraconstruction for palatal implants is presented. With this, teeth can be stabilized or forces and moments in all three dimensions of space can be applied. With miniscrews, in contrary, a direct line of force is required, as miniscrews cannot tolerate significant torque moments.

The survival rate of osseointegrated loaded Orthosystem® palatal implants with the mentioned supraconstruction was found to be 98.6% after 25.2 months and the corresponding success rate 98.4% after 24.6 months in a prospective longitudinal clinical trial.

A systematic review on TADs revealed in meta-analysis that the failure rate for onplants was 17.2%, for palatal implants 10.5% (95% confidence interval: 6.1% - 18.1%), for miniscrews 16.4% (95% CI: 13.4% - 20.%) and 7.3% for miniplates (95% CI: 5.4% - 9%). Miniplates and palatal implants, representing torque resisting temporary anchorage devices, when grouped, showed a 1.92 fold (95% CI: 1.06 – 2.78) lower clinical failure rate than miniscrews did. For the onplants the surgical procedure and the anatomical situation represent the highest risk for early failure. For Orthosystem® palatal implants, the surgical insertion procedure including the special design of the emergence profile represented the highest risk factors. This emergence profile has been changed in the new Straumann palatal implant®. For miniscrews, screw diameter, implant placement torque, mandibular placement, mobility, the patient's right side and inflammation (due to oral hygiene and weak non-keratinized gingiva) were associated with an increased miniscrew failure rate. As miniplates are fixed to bone by two or more mini screws, these TADs face similar risk factors such as inflammation due to weak non-keratinized mucosa or inadequate oral hygiene. Their failure rate due to mobility was higher in growing patients than in adults.

In conclusion, the palatal orthodontic implant has proved to be a stable and reliable tool for absolute anchorage and it is therefore indicated for major tooth movements and movements of the whole dental arch in the upper jaw, whereas miniplates are the system of choice in the lower jaw. Miniscrews are only indicated for minor tooth movements, as the odds ratio with multiple screw placement is too poor, especially in the mandible. The onplant is obsolete as the palatal implant is more reliable and easier to handle.

Nevertheless it must be kept in mind, that classical anchorage strategies are usually preferable in growing children, as TADs have no influence on the skeletal growth pattern except for autorotations of the mandible due to vertical manipulations of the posterior teeth.

TIIVISTELMÄ

Luuhun kiinnitettävät väliaikaiset ankkurointilaitteet (suulaen implantti, minilevyt ja -ruuvit) ovat saavuttaneet lisääntyvästi suosiota oikomishoidossa viimeisen 15 vuoden aikana. Niiden käyttäminen ei vaadi potilaan yhteistyötä ja niiden avulla voi tehdä hoitotoimenpiteitä, mitkä eivät olisi mahdollisia normaaleilla ankkurointimenetelmillä. Paranemisprosessista, onnistumisesta, riskitekijöistä, adekvaatista käsittelystä, biomekaniikasta, indikaatiosta ja käytön rajoituksista on kuitenkin vain vähän tutkittua tietoa olemassa.

Tutkimuksen tarkoituksena on tutkia yhden modernin luuhun kiinnitettävät väliaikaisen ankkurointilaitteen eli suulaen implantin käyttöön liittyviä kysymyksiä sekä verrata tätä muihin luuhun kiinnitettäviin väliaikaisiin ankkurointilaitteisiin.

Kahden pintarakenteeltaan erilaisen suulaen implantin (Strauman SLA® ja SLActive®) luuhun kiinnittymistä tutkittiin satunnaistetusti vapaaehtoisilla yksilöillä käyttäen resonanssi frekvenssi –analyysiä. Primäärinen stabiliteetin muutos sekundääriseksi tapahtui 5 viikon kuluttua implantoinnista niillä yksilöillä, joilla oli SLA® implantti ja 4 viikon kuluttua SLActive® koskien. Alkutilanteen stabiliteetti saavutettiin SLA® implantilla 9 viikon kuluttua ja SLActive®:lla 6 viikon kuluttua. Havainnoista voidaan päätellä, että SLA®-implanttia voidaan rasittaa 2 kk ja SLActive® 1.5 kk kuluttua asettamisesta.

Suulaen implanttia varten kehitettiin yksilöllinen ja monikäyttöinen jatkorakenne, jonka avulla ankkuri-hampaat voidaan stabiloida tai hampaiden siirroissa tarvittavat voimat ja momentit kohdistaa optimaalisesti kaikissa suunnissa. Miniruuveja hyväksikäyttäen voidaan käyttää ainoastaan suoria voimia, koska ko. ruuvit eivät kestä kiertäviä voimia.

Prospektiivisessä kliinisessä tutkimuksessa havaittiin, että luuhun integroituneiden suulaen implanttien eloonjäämismäärä (survival rate) käyttäen hyväksi suunniteltua jatkorakennetta oli 98.6% 25.2 kuukauden käytön aikana ja vastaava onnistumisprosentti 98.4% 24.6 kuukauden aikana.

Luuhun kiinnitettäviä väliaikaisia ankkurointilaitteita koskeva meta-analyysi osoitti, että luun päälle asetettavien implanttien (onplant) epäonnistumismäärä oli 17.2%, suulaen implanttien 10.5% (95% luottamusväli: 6.1-18.1%), miniruuviin 16.4% (95% luottamusväli: 13.4-20.1%) ja minilevyjen 7.3% (95% luottamusväli: 5.4-9.9%). Kiertäviä voimia vastustavien ankkurointilaitteiden (minilevyt ja suulaen implantit) yhdistetty epäonnistumisriski oli 1.92 kertaa vähäisempi kuin miniruuveilla. Luun päälle asetettavilla implanteilla kirurginen toimenpide ja suulaen anatominen rakenne aiheuttivat korkeimman riskin varhaiselle epäonnistumiselle. Orthosystem® suulaen implanttia koskien kirurginen implantin asettaminen johtuen implantin rakenteesta osoittautui suurimmaksi riskiksi varhaiselle implantin menetykselle. Implantin rakennetta onkin tämän vuoksi muutettu (Strauman palatal implant®). Miniruuveja koskien ruuvien läpimitta, asettamisvoima, liikkuvuus, alaleukaan asettaminen, etenkin potilaan oikealle puolelle, ja tulehdus johtuen huonosta suuhygieniasta ja vähäisestä kiinnittyneestä ikenestä lisäsivät miniruuviin epäonnistumista. Koska minilevyt kiinnitetään luuhun kahdella tai useammalla miniruuvilla, on näiden ankkurointilaitteiden riskitekijöitä samat kuin miniruuveja koskien. Minilevyjen epäonnistumismäärä oli suurempi liikkuvuudesta johtuen kasvavilla yksilöillä kuin aikuisilla.

Yhteenvetona todetaan, että suulaen implantti on osoittautunut stabiiliksi ja luotettavaksi absoluuttiseksi ankkurointilaitteeksi. Siksi sitä voidaan suositella käytettävän oikomishoidossa kun tarvitaan suuria hampaiden siirtoja tai koko ylähammaskaarta koskevia siirtoja. Minilevyt ovat sitä vastoin hyvä menetelmä alaleuassa. Miniruuvit ovat käyttökelpoisia vain pienissä hampaiden siirroissa, koska epäonnistumisriski on suuri etenkin alaleuassa käytettynä. Luun pinnalle asetettavilla implanteilla on vain vähäisiä käyttöindikaatioita, koska suulaen implantti on helpompi käsitellä ja luotettavampi.

Kaikesta huolimatta tulee muistaa, että perinteiset ankkurointimenetelmät, kuten erisuuntaiset ekstraoraalivedot, ovat edelleen suositeltavia kasvavilla potilailla. Luuhun kiinnitettävillä väliaikaisilla ankkurointilaitteilla ei ole mahdollista vaikuttaa kasvuun paitsi alaleuan rotaatioon muutettaessa yläleuan poskihampaiden vertikaalista asemaa.

LIST OF ORIGINAL ARTICLES

The presented study is based on the following original publications:

- I. Schätzle M, **Männchen R**, Balbach U, Hämmerle CHF, Toutenburg H, Jung RE (2009) Stability change of chemically modified SLA titanium palatal implants. A randomized controlled clinical trial. Clin Oral Impl Res 20:489-95.
- II. **Männchen R** (1999) A new supraconstruction for palatal orthodontic implants. J Clin Orthod 33: 373-382.
- III. **Männchen R**, Schätzle M (2008) Success Rate of Palatal Orthodontic Implants - A prospective longitudinal study. Clin Oral Impl Res 19: 665-669.
- IV. Schätzle M, **Männchen R**, Zwahlen M, Lang NP (2010) Survival and failure rates of orthodontic temporary anchorage devices: a systematic review. Clin Oral Impl Res 20: 1351-9.
- V. **Männchen R**, Schätzle-Mayor K, Schätzle M, Peltomäki T, Suuronen R (2010) Risk factors associated with orthodontic temporary anchorage device failures. A systematic review. Eur J Orthod (submitted)

Roland Männchen and Marc Schätzle contributed equal parts to the publications I and IV.

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1 INTRODUCTION

The principle of orthodontic anchorage has implicitly been indicated already in Newton's third law (1687) according to which an applied force can be divided into an action and an equal and opposite reaction component. Until today, there is no evidence, though, about the exact relation between an applied force and the velocity of the induced tooth movement.

Nevertheless, reciprocal effects must be evaluated and controlled in orthodontic treatment. The goal is to maximize desired tooth movements and minimize undesirable effects (Proffit, 2000).

The anchorage potential of teeth is influenced by many factors and often limited. Therefore, a multitude of "classical" anchorage strategies have been developed to achieve a maximum and safest possible amount of anchorage. Among these, extraoral (Kingsley 1880) and intermaxillary (Steward et al. 1978) anchorage appliances are the most common. But also differential application of moments in the sagittal dimension (Burstone 1982, Begg & Kesling 1977, Tweed 1941), moving the roots of the anchor teeth into the buccal cortical bone (Ricketts 1976) or using the support of the gingiva or perioral soft tissues (Osborn et al. 1991) are used.

Many of these methods have undesired side effects like protrusion and gingival recession of the lower incisors, root resorptions or rotations of the occlusal plane and/or they depend on the patient's compliance. Patients may have to face prolonged treatment time, unnecessary extraction concepts or orthognathic surgery due to inadequate or insufficient anchorage.

Titanium implants, like ankylosed natural teeth, are (partly) in direct contact with the surrounding bone and do not possess a periodontal ligament. As a consequence, they do not move when orthodontic forces are applied to a certain extent (Melsen & Lang 2001) and hence, can be used for "absolute anchorage" that is independent of the patient's compliance.

As there is usually not enough space to incorporate an implant in the alveolar process in patients with full dentitions, alternative insertion sites such as the trigonum retromolare (Roberts et al. 1990, Trisi & Rebaudi 2002) and the palate have been proposed (Triaca et al. 1992, Block & Hoffmann 1995, Wehrbein et al. 1996a+b).

Miniscrews or miniimplants, having been introduced first in 1983 by Creekmore & Eklund and further promoted by Kanomi in 1997, can be incorporated in the alveolar process in certain areas (Schnelle et al. 2004).

Besides the above mentioned, modified osseo-synthesis plates can be used, which are usually placed in the canine or premolar area, stabilised by two or three screws apically of the roots. They penetrate the mucosa into the oral cavity in order to serve there as an anchorage location (Umemori et al. 1999, De Clerck et al. 2002).

Although all the so called temporary anchorage devices (TAD) have been used for almost two decades, very little is known about the healing procedures, survival and success rates, supraconstruction and biomechanics, ad-

vantages and disadvantages as well as indications and limits of the different TAD systems.

2 REVIEW OF THE LITERATURE

2.1 The Problem: Actio = Reactio

In 1687, Sir Isaac Newton's formulated the third law of motion (Newton 1726):

„Lex III. Actioni contrariam semper et aequalem esse reactionem: sive corporum duorum actiones in se mutuo semper esse aequales et in partes contrarias dirigi.“

According to this law of equilibrium an applied force can always be divided into an action and an equal and opposite reaction component. Newton had discovered that there is no way of exerting a force on an object without the object exerting an equal but opposite force on the actor.

2.2 Anchorage: A Major Issue in Orthodontics

The principle of orthodontic anchorage has therefore implicitly been indicated already in Newton's third law. Ever since dentists began to mobilize teeth within dental arches by means of force, they, in fact, have been attempting to circumvent this law. Edward Hartley Angle was the first to use the term "orthodontic anchorage" in 1907. He thereby wanted to describe the problem of controlling undesired tooth movements while desired tooth movements are performed.

The term orthodontic anchorage was later defined by Ottofy (1923) as the nature and degree of resistance to displacement of teeth offered by an anatomic unit when used for the purpose of tooth movement. Until today, there is no evidence, however, about the exact relation between an applied force and the velocity of the induced tooth movement (Ren et al. 2003).

Nevertheless, reciprocal effects must be evaluated and controlled in orthodontic treatment. The goal is to maximize desired tooth movements and minimize undesirable effects (Proffit, 2000).

The anchorage potential of teeth is influenced by a large number of factors such as size of the root surfaces available, height of the periodontal attachment, density and structure of the alveolar bone, turnover rate of the periodontal tissues, muscular activity, occlusal forces, craniofacial morphology and nature of the tooth movement planned for the intended correction (Diedrich 1993). But only in the presence of an ankylosis (De Pauw et al. 1999), teeth offer an infinite resistance potential and therefore absolute anchorage.

A multitude of strategies have been developed to achieve a maximum and safest possible amount of anchorage. These strategies are called "conventional orthodontic anchorage devices" (COADs, Sandler et al. 2008, Feldmann & Bondemark 2008).

The reaction component can for example be transferred to extraoral places such as the back of the head, the neck, chin or forehead by means of (reversed) headgears or chin-caps. Extraoral anchorage has been efficiently

used since Norman Kingsley published the headgear therapy in 1880. These principles are unchanged until today.

The reaction can also be transferred to the opposite jaw in order to achieve synergistic tooth movements by means of intermaxillary elastics (Steward et al. 1978), functional appliances (Teuscher 1978), Herbst appliance (Pancherz & Fischer 2003), Jasper Jumper (Jasper & McNamara 1995), Eureka-spring (DeVincenzo 1997) or similar.

Besides these methods, tooth born anchorage can additionally be reinforced by differential application of moments in the sagittal dimension (Burstone 1982, Begg & Kesling 1977, Tweed 1941), by moving the roots of the anchor teeth into the buccal cortical bone (Ricketts 1976) or by using the support of the gingiva or perioral soft tissues by means of plates or lip bumpers (Osborn et al. 1991, Nevant et al. 1991, Grossen & Ingervall 1995, Ferro et al. 2004).

Many of the mentioned methods have undesired side effects like protrusion and gingival recession of the lower incisors, root resorptions or rotations of the occlusal plane and/or they depend on the patient's compliance (Nanda & Kierl 1992). So patients may have to face prolonged treatment time, unnecessary extraction concepts or orthognathic surgery due to inadequate or insufficient anchorage.

2.3 Temporary Anchorage Devices

The term "temporary anchorage device" (TAD) was introduced by Daskalogiannakis in 2000. TADs are devices fixed to bone for the purpose of enhancing orthodontic anchorage or overcoming the limitations of traditional anchorage and subsequently removed after use.

The first attempt to incorporate artificial gold roots in the alveolar bone was made in the early 19th century (Maggiolo 1809). But also other experimental designs such as platinum-iridium cage like roots (Greenfield 1913), steel spirals (Formoggini 1947) or vitallium screws (Lubbit & Rappaport 1949) were not very successful on a long-term basis. Instead of intraosseous implants, subperiosteal implants have been used as prosthetic anchors with acceptable success for quite some time (Strock 1939). Gainsforth and Higley (1945) were the first who tried to use vitallium screws for the purpose of skeletal anchorage. They tried to advance the mandible and retract the upper canines at the same time by the use of retromolar implants in the lower jaw in a dog experiment (Fig. 1). As vitallium screws do not osseointegrate, this method was too ambitious, but in any case some retraction of the canines could be achieved before the implants failed.

In the late sixties so called blade vent intraosseous implants, by which the load was distributed on a much larger area (Linkow 1969, 1971, Linkow & Mahler 1974, Viscido 1969) have been developed. Still, these implants did not osseointegrate. New biocompatible materials and techniques for successful implant installation have been developed by Brånemark and co-workers (1969), so that an implant in bone has become increasingly stable and 'osseointegrated'. Such implants are extensively used in prosthetic dentistry today.

With the development of these endosseous titanium implants, the idea of using implants as orthodontic anchorage was revitalized in the late seventies and eighties in animal experiments (Sherman 1978, Turley et al. 1980, Gray 1983, Roberts et al. 1984, 1989, Sennerby et al. 1993, Wehrbein & Dietrich 1993, Wehrbein 1994, De Pauw et al. 1999, Majzoub et al. 1999) and further in the late eighties and nineties in humans (1994, Shaphiro & Kokich 1988, Higuchi & Slack 1991, Kokich 1996, Wehrbein et al. 1998, Wehrbein & Merz 1998). The effect of osseointegrated implants on craniofacial growth in terms of reduced alveolar bone growth has been studied in both, clinical and animal experiments (Ödman et al. 1988, Ödman et al. 1991, Thilander et al. 1992, 1994, 1999, Thilander 1995).

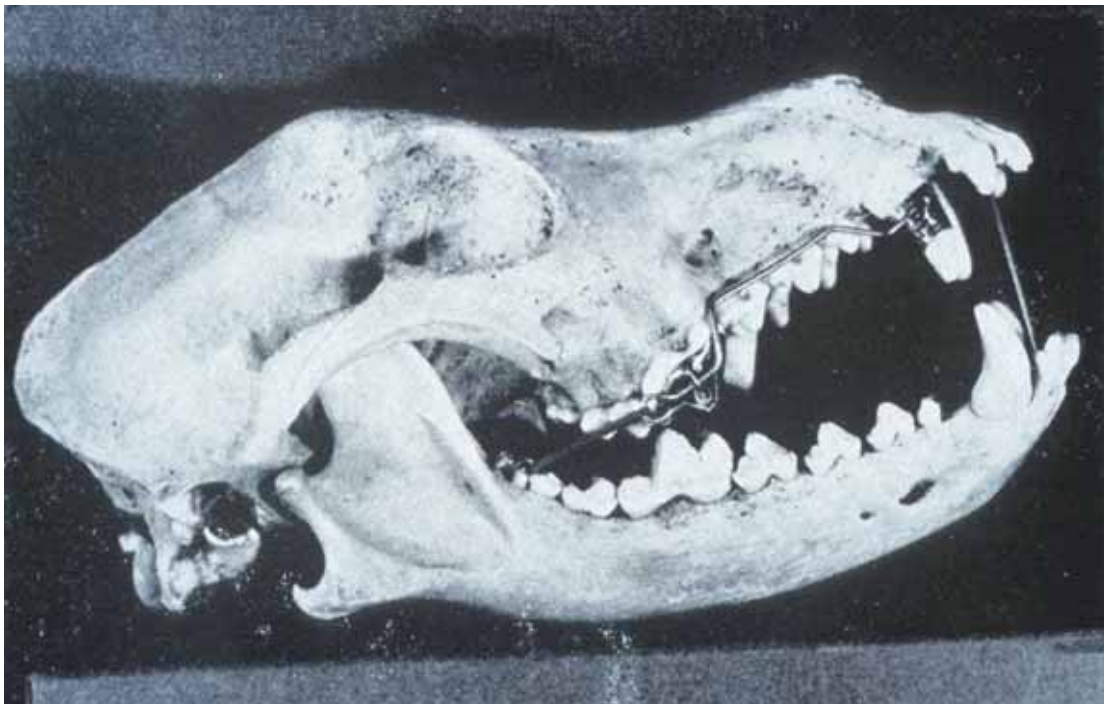


Fig. 1 Macerated skull of a beagle dog as published by Gainsforth and Higley (1945)
Note the implant in the ramus ascendens. The canine is banded and was retracted by the use of an elastic between the implant and a stainless steel sectional archwire fixed to the canine and guided by a buccal flange at the 1st molar.

Titanium implants, comparable to ankylosed natural teeth (Rozenzweig & Rozenzweig 1989), are (partly) in direct contact with the surrounding bone and do not possess a periodontal ligament. As a consequence, they do not move when orthodontic forces up to a certain extent are applied (Melsen & Lang 2001) and hence, can be used for "absolute anchorage", that is independent of the unpredictable patient's compliance (Nanda & Kierl 1992).

As there is usually not enough space to incorporate an implant in the alveolar process in patients with full dentitions, alternative insertion sites such as the trigonum retromolare (Roberts et al. 1990, Trisi & Rebaudi 2002) and the palate have been proposed (Triaca et al. 1992, Block & Hoffmann 1995, Wehrbein et al. 1996a+b).

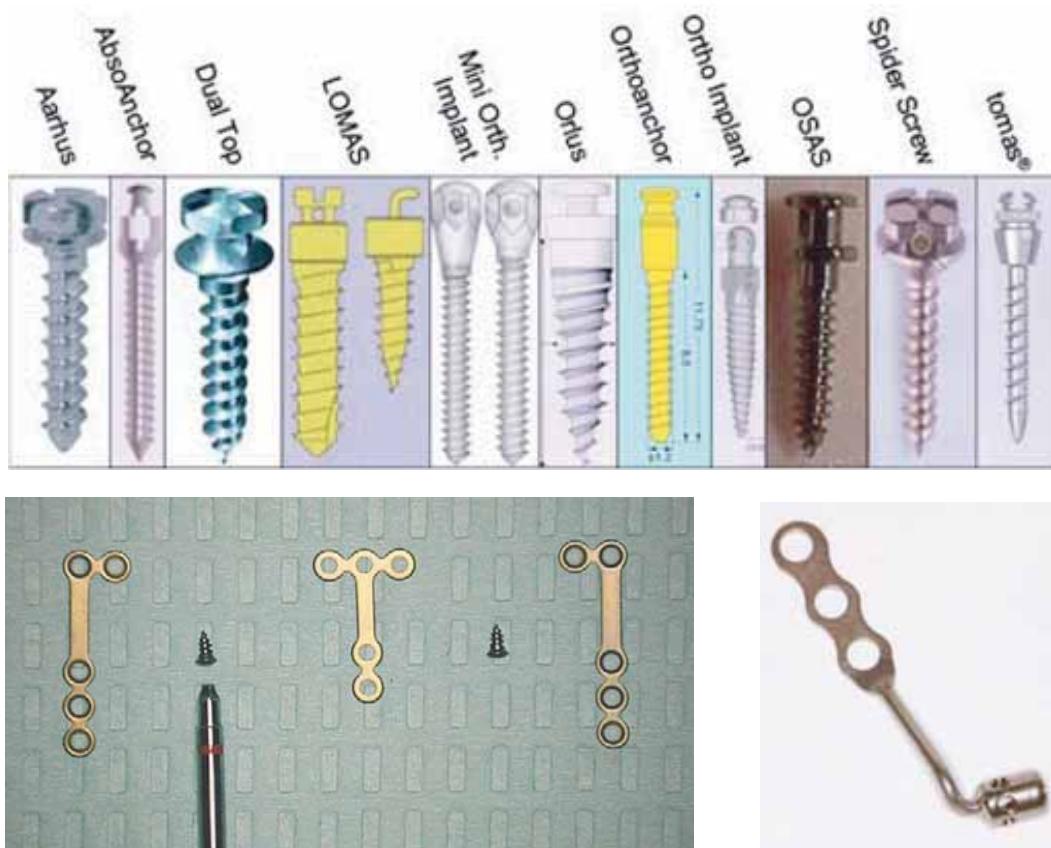


Fig. 2 Alternative Temporary Anchorage Devices
 2a: Different Miniscrew-systems (from Wehrbein & Göllner, 2007)
 2b: Miniplate System by Stryker/Leibinger (from Sherwood, 2007)
 2c: Surgitec bone anchor miniplate (from Heymann & Tulloch, 2006)

Miniscrews or miniimplants (Fig. 2a), having been introduced first in 1983 by Creekmore & Eklund and further promoted by Kanomi in 1997, can be incorporated in the alveolar process in certain areas (Schnelle et al. 2004) and used for orthodontic anchorage, but do not seem to be stable under all conditions (Liou et al. 2004). Except for one stainless steel system (Orthodontic Mini Implant, Leone S.p.A., Italy), miniscrews are made of titanium type IV or V (Papadopoulos et al. 2007). The different types refer to different amounts of Oxygen, Nitrogen and Iron included in the titanium and have an impact on the mechanical properties of the material.

Besides the above mentioned, modified osseosynthesis plates (Fig. 2b+c) are used, which are usually placed in the buccal canine or premolar area in the lower or in the zygomatic crest area in the upper jaw, stabilized by two or three screws apically of the roots. They penetrate the mucosa of the vestibulum into the oral cavity in order to serve there as an anchorage location (Umemori et al. 1999, De Clerck et al. 2002).

The huge variety of skeletal anchorage devices available on the market nowadays can usually be described as one of the following:

- Palatal implants with a rough surface and a diameter of at least 3 mm, which are placed in the midsagittal or paramedian area,

- Palatal onplants, which are placed between the periosteum and the bone in the lateral areas of the palatal vault,
- Mini- or microscrews with a machined surface and a maximum diameter of 2.3mm, which are placed in the alveolar processes between the roots,
- Anchorage plates of different designs fixed to the basal jawbones by two or three miniscrew above/below the apices of the roots.

2.4 History of the Palatal Implant

The placement of a midsagittal palatal implant has first been described by Triaca and co-workers in 1992 (Fig. 3a). They wanted to establish a bone borne anchorage outside the alveolar process and the anterior palate seemed to be the only area in the maxilla with sufficient bone for the incorporation of an implant. The supraconstruction was quite rudimentary. It consisted of a .032 x .032" slot for the accommodation of a transpalatal bar of the same dimensions. This was fixed by the use of a steel ligature.

1993 to 1996 a more sophisticated design was developed at the university of Zürich in collaboration with Unor Switzerland. A flat screw with a diameter of initially 7 and later 5mm and a height of 3mm was used in several test persons. A supraconstruction cap (Fig. 3b) was screwed on the implant and incorporated an .032 x .032" slot. Due to problems with the second fabrication batch, which resulted in an increased failure during the healing phase, this project was stopped.

Another interesting approach was the use of an implant made of polygalactan instead of titanium (Glatzmeier et al. 1995). As TADs are used only for a limited period of time, it would be ideal to have a system, which is resorbed after completion of the orthodontic treatment. The BIOS (bioresorbable implant for orthodontics system, Fig. 3c and d) was able to initially withstand 50N of horizontal force. Unfortunately, the degradation of the polygalactan matrix was too fast, resulting in insufficient anchorage. There have never been any further reports.

The first Straumann Orthosystem® came on the market in 1996 (Wehrbein et al. 1996a+b). It had an ortho-cap, which was not stabilized against rotation and yielded the same slot retention for the transpalatal bar as the Unor system and BIOS (Fig. 3e). No asymmetrical sagittal movements could be performed.

In 1998, Brånemark flange fixtures, which had originally been used for epithelial purposes, have been investigated in a multi-centre study. Epiplants have been inserted in seven test persons in Zürich. The implant was submerged and the abutment was connected after 3 month of healing time. As the implant had a smooth "machined" surface, its torque load capacity was low, resulting in loosening of 4 out of 7 implants during abutment connection with applied moments of 20 to 30 Ncm (see also page 78: torque load considerations). The Viennese group published a survival rate of 85.7% in 21 patients (Bernhart et al. 2001). Nevertheless, its supraconstruction parts were secured against rotation and a new supraconstruction design was published (Study II).

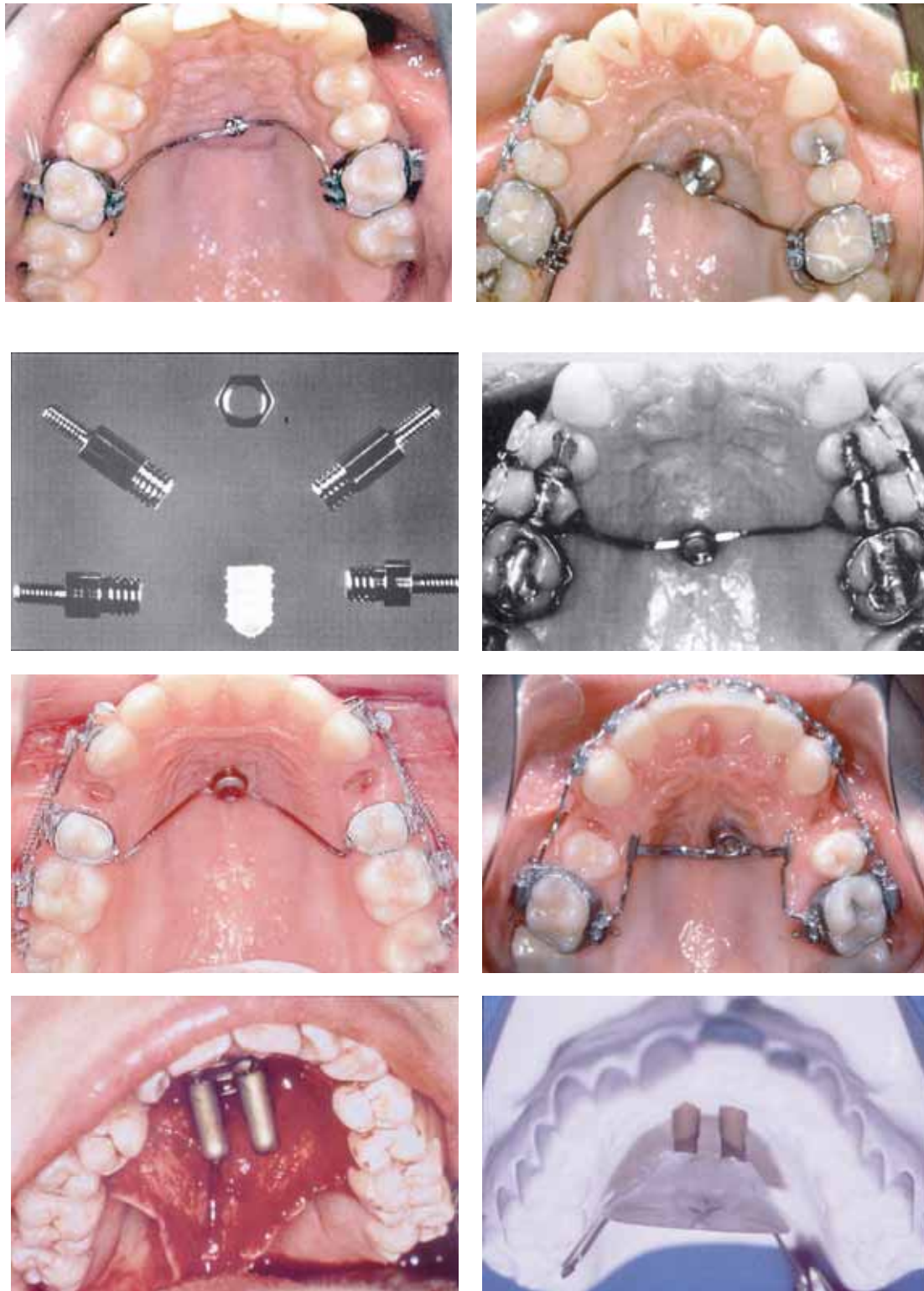


Fig. 3 History of the palatal implant.
3a: Flat screw implant (Triaca et al. 1992).
3b: Unor® experimental implant (Zürich, 1993).
3c: BIOS: Polygalactan implant and supraconstruction (Glatzmeier et al. 1995).
3d: BIOS: Supraconstruction with .032 x .032" transpalatal bar.
3e: Straumann Orthosystem® with supraconstruction (Wehrbein et al. 1996a).
3f: Brånemark Epiplant® with supraconstruction (Männchen 1999).
3g: GISP: Flap surgery for insertion (Byloff et al. 2000)
3h: GISP: Pendulum appliance.

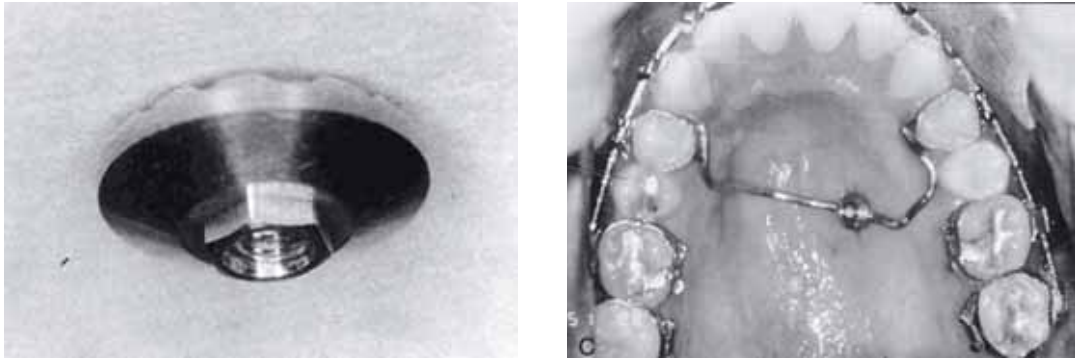


Fig. 3 History of the palatal implant.
3i: Brånemark Onplant® (Blocks & Hoffmann 2001)
3j: Onplant Supraconstruction

This concept has been taken over in the Straumann Orthosystem from the year 2000 on. A rotationally stable ortho-cap with an internal octagon (see Fig. 9) has been developed. From 2002 on, the pitch of the thread of the implant has been increased to reduce the risk of overwinding the implant due to excessive insertion moments.

To reduce the side effects of pendulum appliances, a modified osteosynthesis plate with two cylinders has been proposed (Byloff et al. 2000, Fig. 3g and h). Major flap surgery was mandatory for the insertion and removal of the GISP (Graz implant supported pendulum).

A titanium disc with the same abutment parts like with the Brånemark epiplant is placed under the periosteum of the lateral palatal vault with the Onplant® system (Blocks & Hoffmann 2001, Fig. 3i and j). No hole needs to be drilled, but flap surgery is required for insertion and removal.

Also conventional prosthetic implants have also been used (Tosun et al. 2002) for palatal anchorage.



Fig. 4 Construction characteristics of Straumann Orthosystem® and Palatal Implant®

In 2006, the Straumann Palatal Implant® as a successor of the Orthosystem® was introduced (Jung et al. 2009). The shoulder was replaced by a tulip shaped polished neck (Fig. 4) and the octagon by a vertically reduced triangle. This allows less rotational tolerance of the suprastructure.

2.5 Healing Process

The early healing process after implant insertion is crucial. Before the introduction of biocompatible non-biologic implant materials, no direct contact between implant material and bone could be achieved on a long term, even if there had been a direct contact immediately after implant insertion. Bone remodelling after implant installation resulted in a withdrawal of the surrounding bone with soft tissue encapsulation of the implant. Titanium was the first non-biologic material with the ability to induce bone formation on the implant surface (Albrektsson et al. 1981).

It has been stated, that the primary (mechanical) stability of a titanium implant is reduced and a secondary stability (new bone) is established during the early healing period (Berglundh et al. 2003). During this time, the implant stability is reduced to a minimum (the so called transition point), after which the stability increases again, passing through the baseline level and achieving higher values than the initial stability on a long term. This transition period is crucial regarding early loading of the implants (Raghavendra et al. 2005, Glauser et al. 2004).

Numerous efforts have been made to simplify clinical procedures and to reduce the healing period by using new titanium surfaces that have the potential to shorten and improve the osseointegration process (Buser et al. 2004; Oates et al. 2007; Bornstein et al. 2008). Especially in adult patients, there is a growing need to reduce this inactive waiting time and to reduce the risk for implant failure during early loading. There are several studies that have reported a successful outcome of early/immediate loaded conventional dental implants placed in the alveolar ridge (Calandriello et al. 2003; Rocci et al. 2003; Bischof et al. 2004; Gallucci et al. 2004; Glauser et al. 2004; Jaffin et al. 2004).

In detail, the main goal of these experimental studies has been to determine, whether bone apposition can be enhanced by microrough titanium surfaces such as titanium-plasma-sprayed (TPS) as compared with the original machined implant surface. Sandblasting, acid-etching, or combinations, have been used to produce microrough titanium surfaces to modify surface topography (Wieland et al. 2000). Implants with sandblasted and acid-etched (SLA) surface have demonstrated enhanced bone apposition in histomorphometric studies (Buser et al. 1991; Cochran et al. 1998), higher removal torque values in biomechanical testing (Wilke et al. 1990; Buser et al. 1999; Li et al. 2002) and favourable results in clinical applications (Roccuzzo et al. 2001; Cochran et al. 2002; Bornstein et al. 2003).

Healing processes have not been studied in humans, as inserted implants cannot be removed for examination because they are usually needed for prosthetic purposes. The use of human edentulous alveolar bone areas as test sites is not possible for ethical reasons, as a removal of fixtures leads to a

serious loss of bone. Temporary anchorage devices, in contrary, are only needed for a limited period of time and removed thereafter anyway. They are usually not placed in the region of the alveolar processes and subsequent loss of bone does not play a major role. The palate is therefore an ideal test site for the healing process of different types of implants with different surfaces conditions.

2.6 Supraconstruction and Clinical Handling

The palatal implant can be used not only to enhance anchorage of teeth during orthodontic therapy, but also to allow direct active movement of the teeth to which it has been connected. Therefore, the fabrication of an appropriate supraconstruction to the palatal implant to allow these both functions has been a long standing challenge. Initially, a yoke-formed cast appliance fixed by soldered bands to the first or second premolars has been used to stabilize these teeth. Active sectional wires were then applied to the buccal side to mobilize the first and second molars. When these were in desired positions, another palatal bar had to be fabricated to anchor the molars (Fig. 5) so that correctional adjustment of the premolars, canines and incisors could follow. The casting of the supraconstruction requires the assistance of a prosthetic technician whose familiarity with orthodontic appliances is sometimes limited. If only stabilization of the molars is required, some orthodontists tend to fix the anchor-teeth for too long a period so as to avoid fabricating an additional supraconstruction. Such practices make the system very ineffective.

There has been a proposition (Crismani et al. 2002) to replace the cast appliance by a chairside bent transpalatal arch, which is subsequently soldered to the supraconstruction. Although this procedure is cheaper and less time consuming, its versatility is also minimal. The supraconstruction recommended for the Orthosystem® (Wehrbein et al. 1996a+b) includes a .032" square archwire placed in a transverse slot of the supraconstruction and banded or bonded, by a soldered mesh, to the palatal surface of the premolars. However, the connection of the wire to the implant has been found to be quite unstable (Fig. 6). Furthermore, this device must also be fabricated twice if molar distalization is required.

A .032" square helical spring placed in the implant-slot and a .032"-bracket soldered onto the palatal side of the molar bands can be used as a variation. But this device is very difficult to adjust. The pendulum appliance proposed by Byloff and co-workers (2000) is much easier to be handled. But the coverage of the gingival by the pendulum plate causes significant inflammation on the other hand.

One case report each have been presented, in which a modified distal jet appliance was anchored by the use of a palatal implant (Keles et al. 2003) or a miniscrew and fixation to the first premolars (Karaman et al. 2002).

It is generally held that an ideal supraconstruction should; (i) be easy to use and adjust, (ii) allow stabilization and active movements of the attached teeth in all three dimensions without the need for changing the construction and (iii) be easy to fabricate by an orthodontic technician.



Fig. 5 Cast appliance to stabilize the molars; additional temporary reconstruction of right central incisor. Picture courtesy of Dr. Michele Antonini, Zürich.



Fig. 6 Stability of the first Straumann Orthosystem® ortho-cap. Minor sagittal forces cause a major displacement of the bonding mesh as the torque hold of the cap is not stable enough. The transpalatal bar is pre-welded to the ortho-cap with the new Palatal Implant system, in contrast.

The biomechanics of orthodontic tooth movement in combination with a temporary anchorage device are slightly different to normal tooth borne orthodontic biomechanics. No publications regarding this problem are available so far.

2.7 Survival and Success Rates of the Palatal Implant

The majority of literature regarding temporary anchorage devices reflects only a short period of supervision after loading of the fixture (Crismani et al. 2006, Luzi et al. 2007, Motoyoshi et al. 2007, Wiechmann et al. 2007, Jackson et al. 2008, Jung et al. 2009). To really fulfil the requirements of a sufficient orthodontic anchorage, it must be stable during the whole treatment time, because a change of the treatment plan is often impossible after a certain treatment time.

The term “survival rate” is derived from prosthetic dentistry (Gunne et al. 1992). There is no exact definition of success in prosthodontics, as there is no end point of the function or loading of an implant, except for the patient’s death.

In orthodontics, in contrary, there is a clear end point of the use of a TAD, which is the end of treatment or end of anchorage need. So here, the term “success rate” is rather meaningful.

The survival rate of a TAD after a certain time is the percentage of non-failed, but still loaded TADs divided by the total number of TADs in the investigated group. The success rate of a TAD is the same quotient, but after completion of the orthodontic treatment or anchorage need, respectively. For the indication of a success or survival rate, the indication of the corresponding time period is essential. The clinical significance of a success rate is superior to survival rates.

Numerous case reports and clinical trials have been published documenting the possibilities of the use of temporary anchorage devices (Abels et al. 1999, Armbruster & Block 2001, Bae et al. 2002, Bae & Kyung 2006, Baek et al. 2008, Böhm & Fuhrmann 2006, Bousquet et al. 1996, Carano et al. 2005, Celenza 2003, Chae 2006, 2007, Chang et al. 2004, Chaushu et al. 2008, Chen et al. 2006a+b, Chhatwani & Schneider 2006, Cho 2006, Choi et al. 2007a+b, Chung et al. 2004, 2005, 2007, 2008, Costa et al. 1998, 2006, Deguchi et al. 2008, Gedrange et al. 2006, Giancotti et al. 2003a+b, 2004a+b, 2005, Gracco et al. 2007, Hong et al. 2005a+b, Janssens et al. 2002, Jeon JM et al. 2006, Jung & Kim 2008, Karaman et al. 2002, Kim et al. 2006, 2008, 2009, Kinzinger et al. 2006, Ko et al. 2006, Kokitsawat et al. 2008, Kook & Kim 2008, Kravitz & Kusnoto 2007a+b, Kyung et al. 2003a+b, 2004, 2005a+b, 2009, Lee et al. 2001, 2004, 2007, Lim & Hong 2008, Lim et al. 2008, Lin et al. 2006, 2008, Ma et al. 2008, Mavreas 2006, McGuire et al. 2006, Melo et al. 2008, Merli et al. 2007, Mimura 2008, Nagaraj et al. 2008, Nocini et al. 2004, Ohnishi et al. 2005, Paik et al. 2003, 2006, 2007, Papadopoulos 2008, Park et al. 2001, 2002, 2003, 2004a/b/c/d, 2005a/b/c, 2006c, Park 2006, Roth et al. 2004, Sari & Uçar 2007, Sohn et al. 2007, 2008, Suzuki & Suzuki 2007, Takano-Yamamoto & Kuroda 2007, Upadhyay et al. 2008, Wehrbein & Merz 1998, Wu et al. 2006, Xun et al. 2007, Yanosky & Holmes 2008, 2008, Youn 2006, Young et al. 2007, Yao et al. 2005, Yun et al. 2005).

Although palatal implants have been used for more than a decade (Wehrbein et al. 1996a+b), there existed only one prospective study of nine patients demonstrating successful osseointegration and stability in all patients (Wehrbein et al. 1999a). Bantleon and collaborators (2002) published a sub-

jective report of 40 Orthosystem® palatal implants and indicated a 92% early success rate of osseointegration and loading, but never published any further details and/or results. Only very recently, two prospective clinical trials have been conducted, analyzing long time survival. In these, conventional orthodontic anchorage has been compared to palatal implant anchorage (Benson et al. 2007, Sandler et al. 2008) and to palatal implant and onplant anchorage (Feldmann & Bondemark 2008).

2.8 Survival Rates and Risks Factors for Failure of Different TADs

In contrast to prosthetic oral implants, the literature exploring the risk factors associated with early failures of orthodontic TADs has not been evaluated systematically. The dynamics of TAD loss (loss over time) is an important factor for choosing the appropriate anchorage device and for decision making in orthodontic treatment planning like extraction of permanent teeth or the decision of an orthodontic approach only vs. a combined orthodontic-surgical procedure. TAD failures during orthodontic treatment may make a change of the treatment plan difficult or impossible.

Retrospective studies cannot establish causal or temporal relationships, but may point to factors influencing the failure of TADs, and may be considered “risk indicators”. However, the determination of true risk factors requires prospective longitudinal studies. A true risk factor is a component, which is known to be associated with failure related conditions on the basis of epidemiological evidence. Such an attribute may be associated with an increased probability of occurrence of a particular event (failure of a TAD) without necessarily being a causal factor. A risk factor may also be modified by interventions thereby reducing the likelihood for the development of a particular disease or failure (Beck 1994).

3 AIM OF THIS STUDY

The general purpose of this study is to evaluate different aspects of the palatal orthodontic implant.

The specific aims of the study are:

- to study the initial healing process of palatal implants with different surface characteristics and provide guidelines for the ideal loading time.
- to present an ideal supraconstruction and clinical handling of the palatal implant and give biomechanical guidelines.
- to study long time survival and success rates of the palatal implant loaded for orthodontic purposes.
- to study survival and failure rates of different TADs.
- to study risk factors for failures of different TADs.
- and to deduct clinical indications and limitations of the different TADs.

It is the hypothesis, that palatal implants have a significantly higher success and survival rate as well as a lower odds ratio for clinical complications compared to other TADs and that there is a difference of biomechanical force application, what would make palatal implants the TAD of choice in the upper jaw, especially if major tooth movements have to be performed.

4 PATIENTS, MATERIALS AND METHODS

4.1 Healing Process of the Palatal Implant

A prospective randomized trial was designed to assess implant stability changes of standard SLA® palatal implants (Orthosystem®, Insitut Straumann AG, Basel, Switzerland) relative to implants with identical design but a chemically modified surface (SLActive®, Institut Straumann AG, Basel, Switzerland). Clinical evaluation of implant integration over time was performed using resonance frequency analysis (RFA) (Osstell; Integration Diagnostics, Save-dalen, Sweden).

4.1.1 Subjects

40 adult volunteers (19 female and 21 male) were recruited and randomly assigned to the test group (modSLA-surface) and control group (SLA-surface). The mean patients' age was 27.9 years, ranging from 21.3 to 51.8 years. All participants were in good general health condition and presented no contraindications for minor oral surgical procedures. The study protocol was approved by the local Ethical Committee (SPUK ZZMK 06/04), State of Zurich, Switzerland. Informed consent was obtained from all participants.

4.1.2 Implant Design and Surface Characterization

All implants were manufactured from commercially pure titanium (Institut Straumann AG, Basel, Switzerland). The implants were characterized by an identical cylindrical shape of the commercially available palatal implants and had an outer diameter of 4.1mm. The enossal part was 4.2mm in length (Fig. 4, page 23).

The control implants were provided with the standard SLA® surface (sand-blasted with large grits of 0.25 to 0.50 mm and acid etched with HCl/H₂SO₄) used in clinical practice today (Rocuzzo et al. 2001; Cochran et al. 2002; Bornstein et al. 2003; 2005). Test implants with the modSLA surface were produced with the same sandblasting and acid-etching procedure like the SLA surface but were rinsed under constant N₂ protection and continuously stored in an isotonic NaCl solution (Buser et al. 2004).

4.1.3 Clinical procedures

All palatal implants were inserted into the maxillary bone in the midpalatal area of the suture by the same person (R.M.) according to the manufacturer's guidelines. The implants are provided by the manufacturer with a transfer piece, which serves as a connection between the implant and insertion tool and has to be removed after implant insertion in order to give acces to the implant for healing cap placement. Patients were instructed to avoid any trauma in the insertion site and to rinse the mouth with 0.2% chlorhexidine solution twice a day for one week. Mechanical tooth brushing was abandoned for the surgical site for 2 weeks. After 1, 3, 7 or 12 weeks, 5 implants each were ran-

domly harvested by means of a standard trephine (5.5mm) for histological analysis.

4.1.4 Methods of analysis

The palatal implants' stability was monitored by using resonance frequency analysis (RFA) (Ostell™, Integration Diagnostics AB, Göteborg, Sweden) according to Meredith et al. (1996). The RFA was performed at implant insertion, 1 ($N=40$), 2 ($N=30$), 3 ($N=30$), 4 ($N=30$), 5 ($N=30$), 6 ($N=30$), 7 ($N=20$), 8 ($N=10$), 10 ($N=10$) and 12 ($N=10$) weeks after surgery. At each measurement session, the healing cap was removed in order to give access to the implant. To avoid excessive torque-moments and thus loosening an implant, a standardized torque of 10 Ncm was applied with a torque-controlled ratchet when connecting the transducer (Smart Peg Type 9, Integration Diagnostics AB, Göteborg, Sweden) to the palatal implant. RFA produced an implant stability quotient (ISQ), which was recorded five consecutive times for each implant in every time point. ISQ values indicate clinical stiffness with a range from 1 to 100, with implant stability increasing as the ISQ value increases. It has been found that ISQ measurements show a high degree of repeatability (less than 1% variation for individual implants) (Meredith et al. 1996).

The primary value of interest was the change of ISQ from the baseline measurement for each implant. All measurements were performed by one investigator (M.S.).

4.1.5 Statistics

The response variable ISQ (with values between 0 and 100, like a percentage) is continuous and its normal distribution was identified by using the Kolmogorov Smirnov test. To decrease the patient-specific variability and to adjust for patient-specific situation, the original response was transformed to differences "observation – baseline" (ISQ difference). The normal distribution of this continuous variable was again tested (Kolmogorov Smirnov test).

The time-dependent stability patterns for each of the implant types has been analysed using a generalized linear model, the Chow test (Chow 1960), with secondary outcomes characterized by descriptive analyses (Jonston & DiNardo 1997; Toutenburg 2002)

There are two main fixed factors TREATMENT and TIME (baseline through 12 weeks) with a possible interaction and the random factor PATIENT. The linear mixed model was used to evaluate the significance of these overall effects.

4.2 Supraconstruction and Clinical Handling of the Palatal Implant

4.2.1 Design

The aim was to create a rigid supraconstruction that is primarily not attached to any teeth. It would be used as a platform for simple sectional wires that provide stabilization and/or active movement. The sectional wires can be easily adapted to the actual clinical situation.

The construction consists mainly of a yoke-formed palatal bar (Fig. 7, #3) with rectangular tubes (.022 x .028", Fig. 7, #4) at both ends. In addition, Damon® self-ligating brackets (.022", Fig. 7, #5) are welded to the palatal aspect of the molar bands. The bracket-attachments to the molars, when closed, would provide the stability and control of a tubular structure and the ease of handling of a bracket when opened. The molars can be stabilized, moved or rotated in all three dimensions in almost any clinical situation by just adjusting the sectional wires (Fig. 7, #6) that connect the molars to the bar-tubes (Fig. 7, #4).

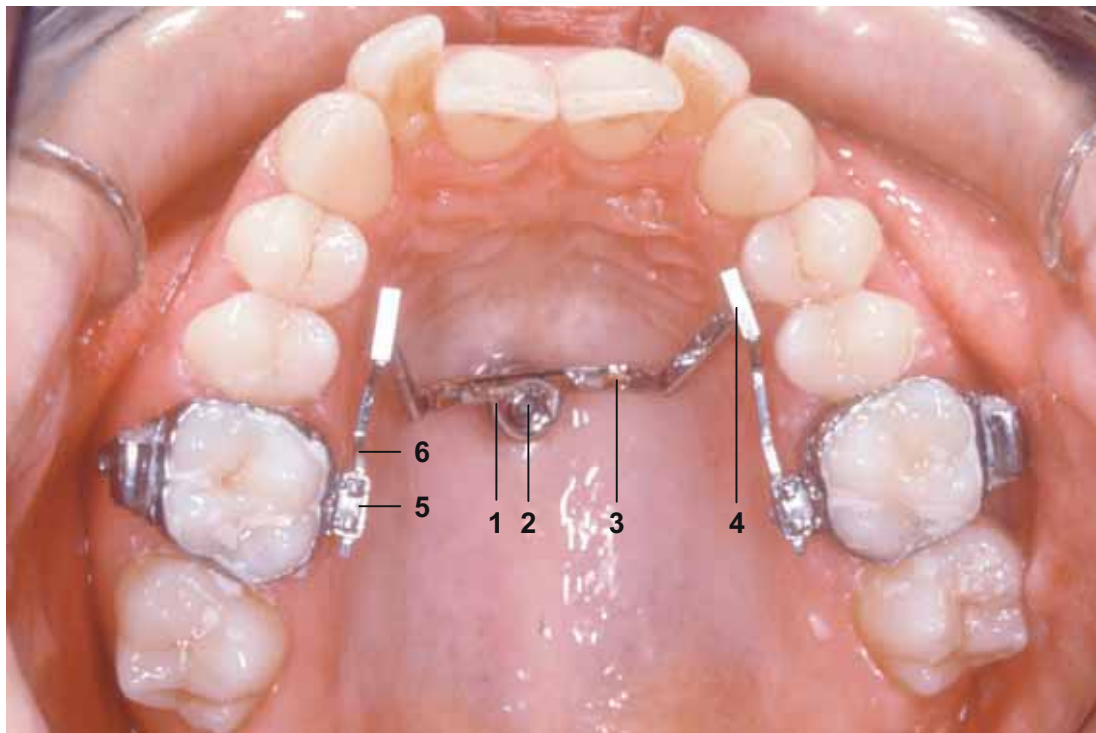


Fig. 7 A clinical picture of the supraconstruction in situ showing the ortho-cap (#1), fixation screw (#2), yoke-formed palatal bar (#3), .022" x .028" bar-tubes (#4), Damon® self-ligating brackets (#5) and sectional wires (#6)

4.2.2 Clinical Steps

For the clinical trial of the supraconstruction described, the Straumann Ortho-system® was used, which is not mandatory. Three months after implant placement (Fig. 8a), the impression coping is inserted (Fig. 8b) and the molar

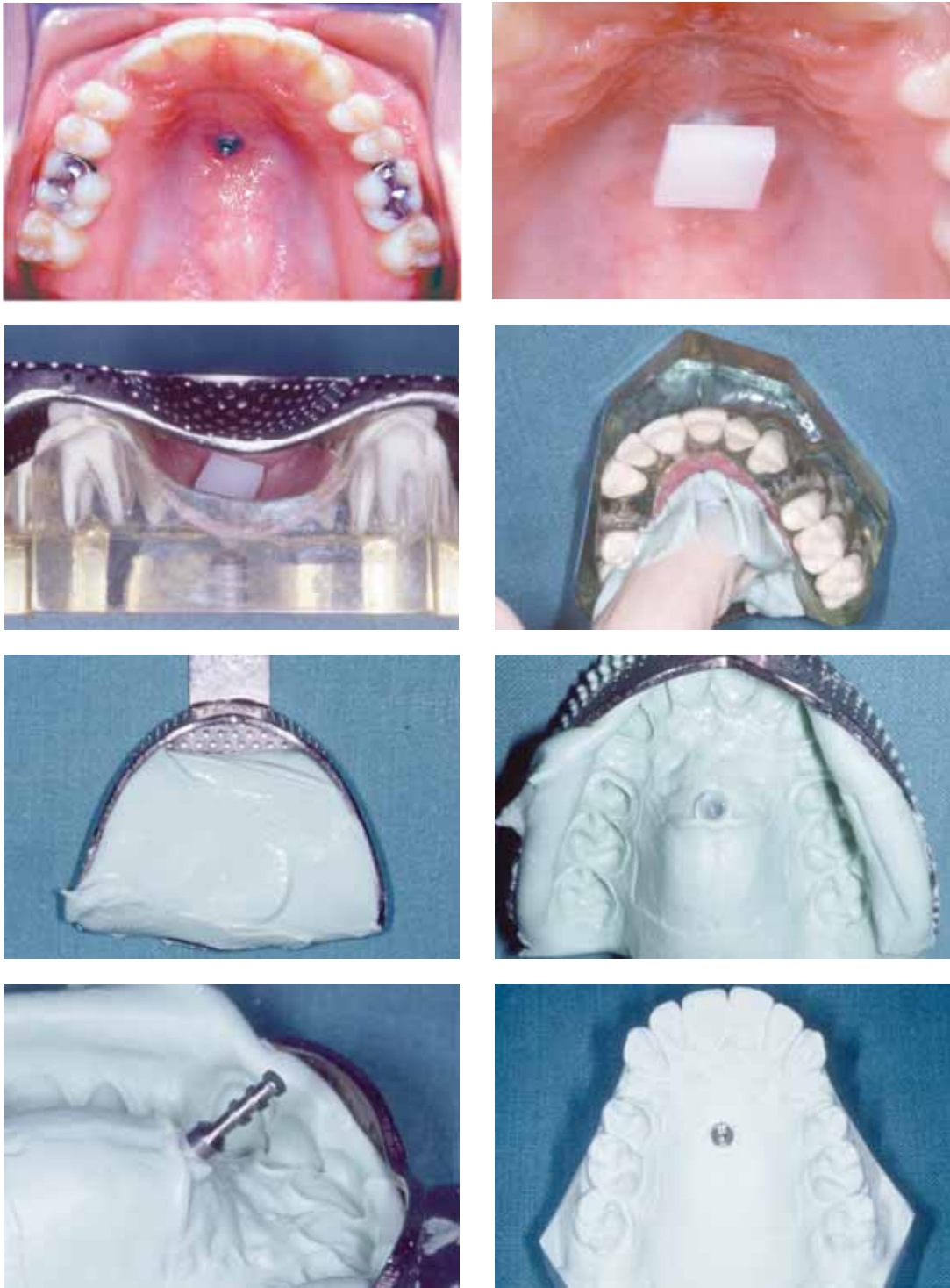


Fig. 8 Clinical Steps:

- 8a:** Implant before impression, healing cap removed.
- 8b:** Impression coping fixed to the implant; the edges of the retention must not touch the gingiva.
- 8c:** There is enough space between the impression tray and the coping.
- 8d:** Alginate is pressed under the retention.
- 8e:** The incisal area of the tray is not filled with alginate.
- 8f:** Tray removed after setting of the alginate.
- 8g:** Abutment replica fixed to impression coping.
- 8h:** The finished model cast.

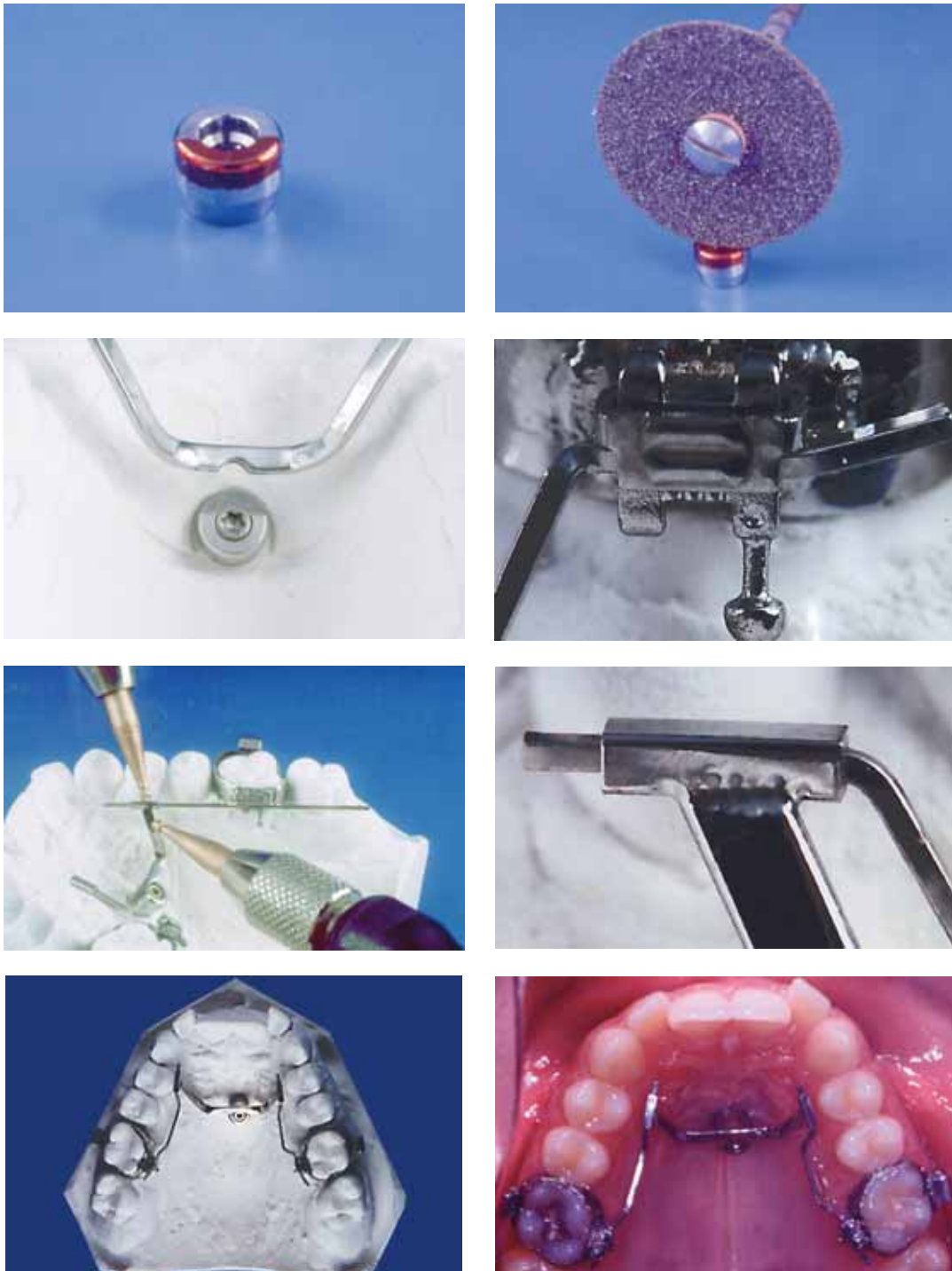


Fig. 9 Laboratory work:
9a: The ortho-cap before milling reduction.
9b: Milling of the red parts.
9c: Palatal bar, with a 'cut-back' for the occlusal screw, before laser welding to the ortho-cap.
9d: Detail of the laser-weld between a Damon® bracket and the molar band, sectional wire in position within the closed bracket.
9e: Point welding of the bar-tube; straight connection and identical torque situations are ensured by an .021 x .025 sectional wire.
9f: A close-up of the laser-weld between the palatal bar and a bar-tube.
9g: The completed supraconstruction in position on the model.
9h: A clinical view of the supraconstruction *in situ*.

bands are seated. The impression coping is fixed by friction of a tiny packing ring overlapping the implant shoulder by 1mm. Special care must be taken, that the packing ring is not destroyed when the coping is inserted and that the edges of the retention do not touch the palatal gingiva. If so, the edges have to be shortened with a bur. There is enough space between the impression coping and alginate tray in the vertical dimension as displayed in Fig. 8c. The mouth set-up is then ready for an impression. As the impression does not require the high standards needed for crowns and bridges, impressions with alginate would suffice. It is important to place some alginate under the retentions before inserting the tray (Fig. 8d) in order to guaranty a secure hold of the coping in the impression material when the tray is removed. As the incisors are not parallel to the implant's long axis, the incisor area of the tray should not be filled with alginate (Fig. 8e). Thereby only the incisal edges will be covered during the impression. Once the tray is removed (Fig. 8f), the molar bands are repositioned in the alginate and waxed. Then the technician's abutment replica is fixed to the impression coping (Fig. 8g). Special care must be taken so that the position of the impression coping is not altered during this procedure. Thereafter, the plaster model with the abutment is fabricated (Fig. 8h).

4.2.3 Fabrication of the Supraconstruction in the Laboratory

The ortho-cap (Fig. 9a) that has an internal octagon fitting to the implants octagon (with the new Straumann palatal implant® it is a star fitting on a rounded triangle) has to be reshaped (Fig. 9b). This milling work of 1.9 x 0.9mm is done in order to accommodate the palatal bar (Fig. 9c), which is made of a 0.9 x 1.9mm quenchable stainless steel wire (Remaloy®, Dentaurum Inc., Germany). The bar can be manually bent and stiffened by heat-treatment. A 'cut-back' is done in the palatal bar so as to create enough space for the occlusal screw to pass (Fig. 9c). The so prepared palatal bar is next laser-welded (or soldered) onto the modified ortho-cap. .022" Damon® self-ligating brackets (Roth-system, upper first premolar of the opposite side; Ormco, USA) are welded to the palatal aspect of the molar bands (Fig. 9d). Then the rectangular tubes (.022" x .028", length: 4.5mm; Leone, Italy) are welded to both ends of the palatal bar by means of a straight .021" x .025" wire (Fig. 9e,f) in order to ensure identical torque situations at the bar-tube and molar bracket. The sectional wires (.021" x .025" for stabilization and .018" x .025" for active movements) are also pre-fabricated by the orthodontic technician. Fig. 9g shows the completed supraconstruction. It may be pointed out that all laser-welded parts can be done by soldering as well.

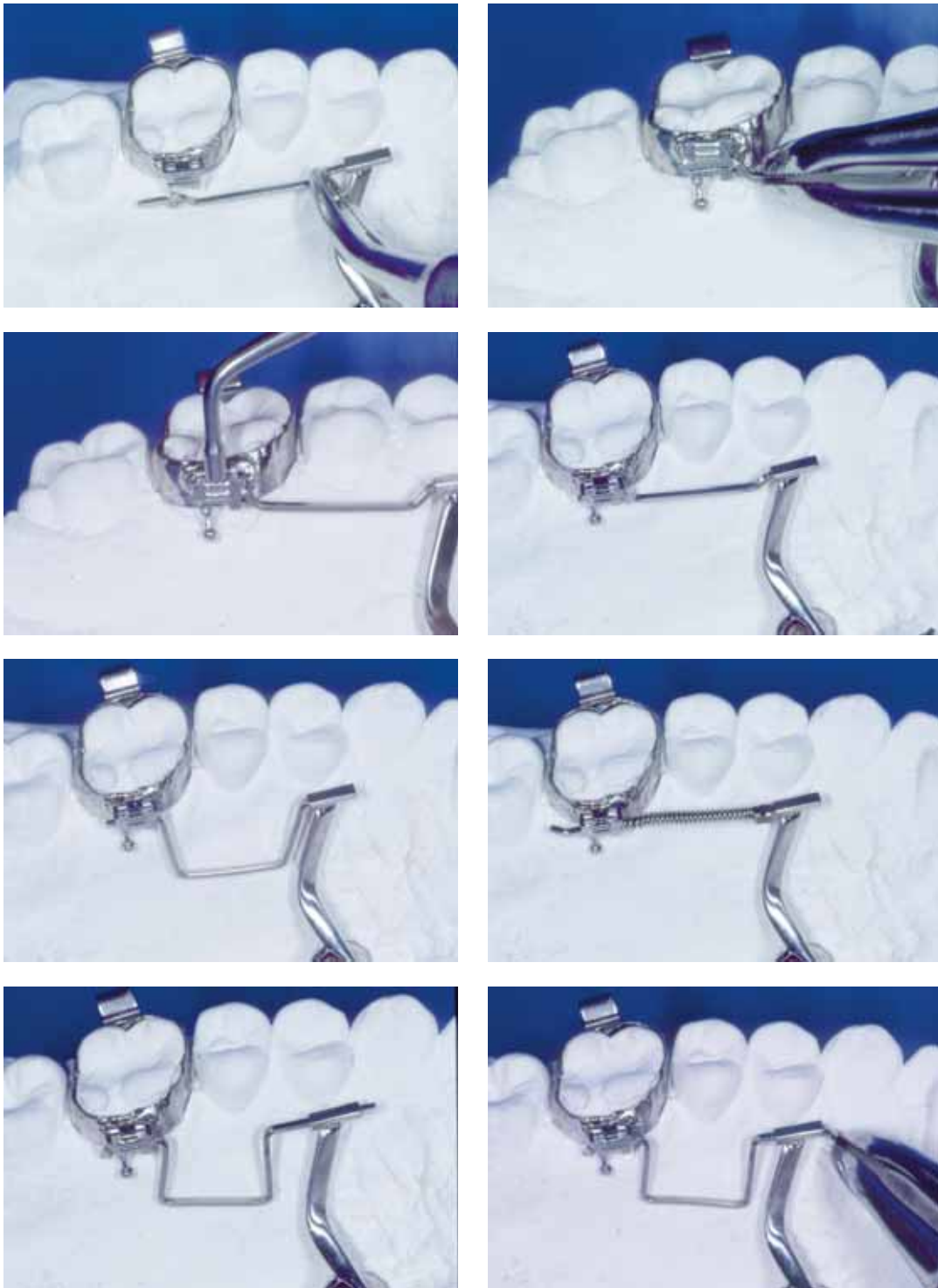


Fig. 10 Handling (a-c) and applications (d-h) of the sectional wires:

- 10a:** Insertion of the mesial end of the wire into the bar-tube from its distal opening.
- 10b:** Positioning of the distal end into the Damon® bracket from the palatal side.
- 10c:** Damon® bracket is being closed to a tube shape.
- 10d:** Passive set-up (.021" x .025") to stabilize molars: note the short vertical legs of the loop, serving as sagittal stops.
- 10e:** Active set-up (.018" x .025") for molar distalization with a pre-activated delta-loop-sectional-wire in position.
- 10f:** Active set-up for molar distalization with a straight sectional wire and push-coil (with a welded or crimpable stop) as an alternative to the set-up in figure 9e.
- 10g:** Set-up for molar mesialization before activation: note the bend distal to the molar bracket.
- 10h:** The wire is activated by pulling at the mesial end and making a Mexican "tie-back".

4.2.4 Handling and Applications

The orthodontist can adjust the prefabricated sectional wires according to the clinical situation. For insertion, the sectional wire is first introduced into the distal end of the bar-tube (Fig. 10a). This can be easily done if the end of the wire is filed beforehand. As the 'tube' of the Damon® bracket can be opened, it is accessible from the palatal side. The distal end of the sectional wire is then placed in the molar bracket from the palatal aspect (Fig. 10b). Finally, the Damon® bracket is closed to its tube-shape with the aid of an exclusive closing device (Ormco, USA) or with a normal band seating instrument (Fig. 10c). To use the implant for absolute anchorage of the molars, a passive set-up using a .021" x .025" stainless steel wire is ideal (Fig. 10d). In order to get a firm connection between the supraconstruction and the molar, the vertical legs of the sectional wire should be as short as possible. The latter serve solely as sagittal stops.

The supraconstruction is also planned for active distalization or mesialization of teeth. Distalization is done either with sagittally preactivated delta loops (with long vertical legs, Fig. 10e) or with 'straight' wires and push-coils (Fig. 10f). Then it is recommended to weld or crimp a stop onto the sectional wire distal to the bar-tube so as to prevent the wire from free sagittal sliding. A wire dimension of .018" x .025" is ideal for both purposes.

The same delta loop as described above, but preactivated in the opposite direction, can be used for mesialization of the molars. An additional bend has to be made distal to the molar-bracket (Fig. 10g). The loop is activated by pulling it mesially out of the bar-tube and by making a Mexican 'tie-back' (Fig. 10h).

4.2.5 Biomechanics

When a molar is distalized as described above, it will rotate mesially in, because the applied force is palatally eccentric to the centre of resistance. A compensation is needed to prevent this rotation. Therefore, a β -antirotation-bend (or 'toe in bend') is made at the molar site. If only this bend is placed, equilibrium requires another couple in the opposite direction, which is found as a buccal force at the molar and a palatal force at the implant. As the implant would not react, only the molar would move buccally. This is usually undesired and should be compensated by an α -bend of the same angle in the opposite direction at the bar tube (Fig. 11a). If the molar is distalized with a 'straight' wire, these local compensation bends are replaced by a 'sweep', which is a continuous curvature along the wire (Fig. 11a).

The problem is similar in the second order dimension (Fig. 11b), where the applied forces are also eccentric. Therefore, compensation bends are needed. With the delta loop, a crown tip forward bend (β -bend) at the molar and an α -bend at the bar-tube are made to prevent intrusion of the molar, if this is not desired. With the 'straight' wire, these bends are replaced by a sweep in the appropriate direction.

For mesialization of the molars, all the forces, couples, bends and sweeps are to be applied in the opposite direction as those described for distalization.

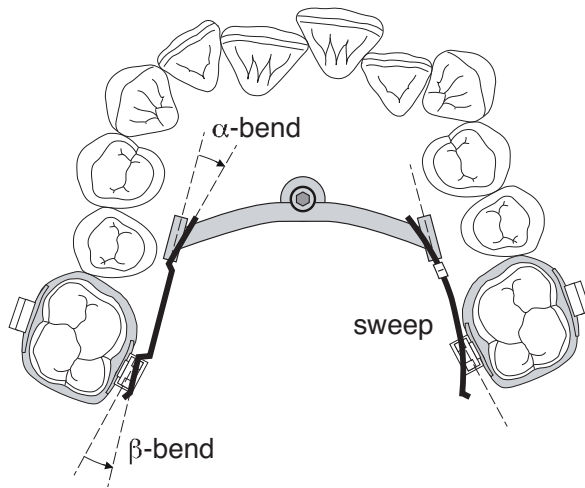


Fig. 11a: Schematic drawing of the 1st-order-compensations needed for molar distalization:

Note the delta-loop-sectional-wire of the right side of the patient showing a β -bend at the molar site to prevent it from rotating mesially in during distalization and an opposite α -bend at the bar-tube to avoid transversal side effects of the molar. Alternatively, a 'sweep' compensates for the rotational and transversal side effects in a 'straight wire' set-up (patient's left side; the coil spring is not drawn for clarity).

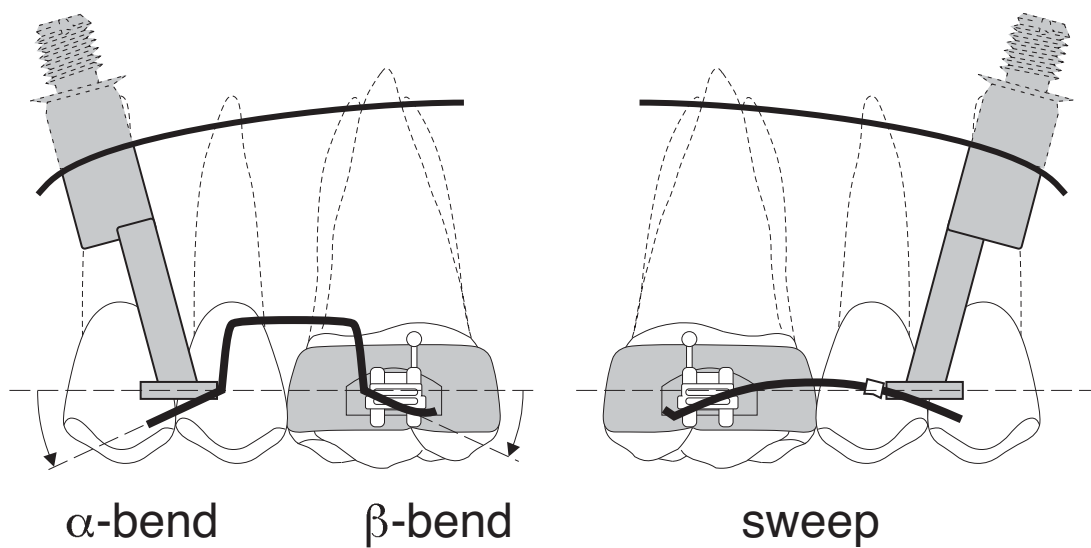


Fig. 11b: Schematic drawing of the 2nd-order-compensations needed for molar distalization (lingual view):

Note the delta loop wire of the right side of the patient showing a β -bend at the molar site to prevent the molar from tipping distally during distalization. An opposite α -bend at the bar-tube avoids intrusion of the molar. Alternatively, a 'sweep' compensates for the tipping and intrusion of the molar in a 'straight wire' set-up (patient's left side; the coil spring is not drawn for clarity).

4.3 Long Time Clinical Survival and Success Rates of the Palatal Implant

4.3.1 Patients

Seventy-two consecutive patients (59 female, 13 male) (Table 3, Chapter 5.3.4) receiving Orthosystem® palatal implants (Straumann AG, Basel, Switzerland) for orthodontic treatment purpose from March 1999 to November 2006, were included in this prospective study.

The indication for palatal implant use was established according to the required anchorage situation in order to achieve the intended orthodontic treatment goal. Before placing the palatal implant, the vertical bone volume along the palatal suture was assessed with a lateral cephalogram (Wehrbein et al. 1999b) (Fig. 12). In one case of reduced bone volume and an impacted upper canine, CT-scans were obtained to evaluate feasible insertion sites (Bernhart et al. 2000).

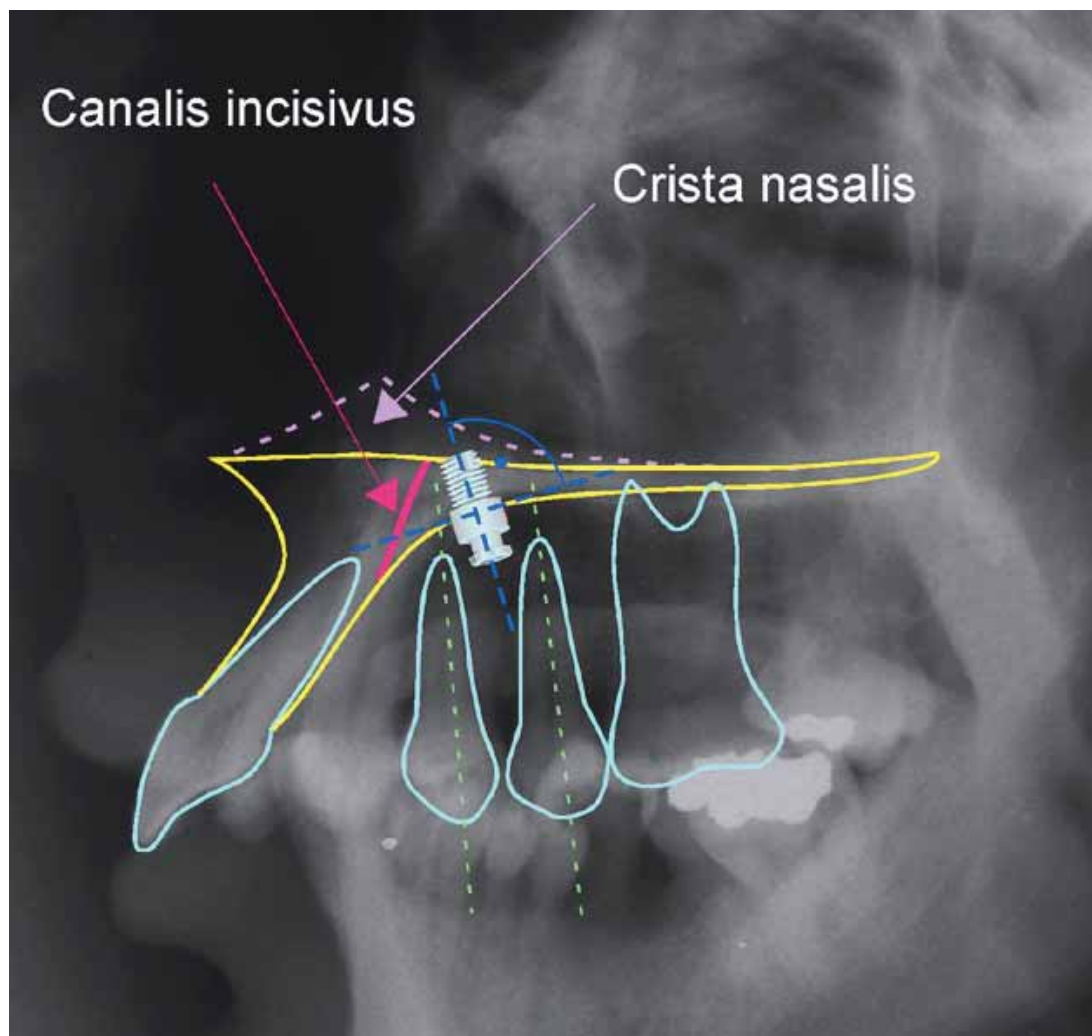


Fig. 12 Entry point into the cortical bone is between the anterior-posterior level of the premolars – perpendicular to the palatal surface.

All implants were placed by the same orthodontist (RM) according to the manufacturer's guidelines. After local anaesthesia and chlohexidine rinsing, the palatal mucosa was removed with a punch and an elevator. The cortical bone was marked in the centre of the intended implant site with a round bur, the hole for accommodating the implant was drilled by the use of spiral burs (2.2mm and 2.8mm) and the shoulder was prepared with the ortho-profile drill. The self-tapping implant was inserted by hand with a ratchet and guide instrument. In growing patients the palatal implants were inserted in the paramedian, in adults usually in the median region (Table 3, Chapter 5.3.4). Sagittally, the implants were placed perpendicular to the bone surface in the region of the premolars. In the more anterior region, there is greater vertical bone volume, but there is also a danger of interference with the canalis incisivus and the incisor roots. Based on stability criteria (immobility, percussion sound; Buser et al. 1990), all implants, which were primary stable after installation, were considered for further evaluation.



Fig. 13 Supraconstruction consisting of a yoke shaped palatal bar made of 0.36 x 0.72" heat-treatable Remaloy (Dentaurum Inc., Germany) stainless steel with 4.5mm 0.022 x 0.28" rectangular tubes at each end and 0.22" Damon® (Ormco Cooperation, Glendora, CA, USA) brackets welded to the palatal aspect of the molar bands. Tubes and brackets are interconnected by sectional wires.

After a healing period of two to three months, an alginate impression of the implant and maxillary dentition was taken in order to obtain a master cast for

designing the supraconstruction, including orthodontic mechanics. This customized construction was fixed to the abutment in a rotationally stable manner using the internal hexagon of the ortho-cap fitting to the hexagon of the fixture with a tolerance of $-0/+0.02\text{mm}$. The orthodontic mechanical forces either affected the implant directly (0.018"x.025" stainless steel sectional wires) or indirectly via the stabilized molars (0.021"x.025" stainless steel sectional wires) (Fig. 13).

All implants were of the same type: single-unit, self-tapping, made of pure titanium, length 4mm or 6mm, diameter 3.3mm or 4mm, grit-blasted and acid-etched intraosseous surface (SLA®) and a highly polished neck of 2.5mm (Orthosystem®, Institut Straumann, Switzerland) (Table 3, Chapter 5.3.4).

After completion of orthodontic treatment the palatal implants were removed using a standard trephine of 5.5mm diameter. One patient refused the removal of the palatal implant after successful treatment.

Osseointegration was defined successful when at the time point of taking the alginate impression for the supraconstruction, the implant showed absence of mobility and the patient had no complaints (Buser et al. 1990).

The loading time was calculated based on the time period between insertion of the supraconstruction and the end of May 2009 or the removal of the latter after achieving the treatment goal, respectively.

The survival rate was calculated for all loaded implants and the success rate only for patients with completed orthodontic treatment on the basis of absence of mobility throughout the entire loading time.

4.3.2 Statistics

Descriptive statistics for patient age and sex, implantation site, type of load, healing and loading time were performed after grouping the implants into three groups: all implants inserted, successfully osseointegrated implants and implants with completion of the intended orthodontic anchorage purpose.

4.4 Systematic Literature Reviews on TADs

4.4.1 Survival Rates of Different TADs

A MEDLINE (PubMed and Ovid) search from 1966 to the end of January 2009 was conducted for English-language articles. The keywords were: 'human', 'mini screw', 'miniscrew', 'micro screw', 'microscrew', 'micro implant', 'micro-implant', 'mini implant', 'miniimplant', 'palatal implant', 'miniplate' or 'onplant'.

Manual searches of the bibliographies of all full-text articles and related reviews, selected from the electronic search were also performed. Furthermore, manual searching was applied to the following journals for the years 2004 to January 2009: Clinical Oral Implants Research, European Journal of Orthodontics, American Journal of Orthodontics and Dentofacial Orthopedics, Angle Orthodontist, Journal of Clinical Orthodontics, Journal of Orofacial Orthope-

dics, Journal of Adult Orthodontics and Orthognathic Surgery and International Journal of Oral and Maxillofacial Implants.

From this search, it was obvious that no randomized controlled clinical trials (RCTs) were available comparing all different types of TADs at once. There were 2 randomized clinical studies comparing TADs (onplants and palatal implants) to compliance dependent COADs (Sandler et al. 2008, Feldmann & Bondemark 2008) and one comparing two different miniscrew types (Wiechmann et al. 2007).

4.4.1.1 Inclusion criteria

In the absence of RCTs comparing all different types of TADs to each other, the present systematic review was based on the available limited randomized clinical trials and all prospective or retrospective cohort studies. The additional inclusion criteria were:

- Mean TAD loading time of at least 12 weeks or 3 months,
- Included patients had been examined clinically at the follow-up visit, i.e. publications based only on patient records, questionnaires or interviews were excluded,
- Details of the screw types were described.

4.4.1.2 Selection of studies

Titles and abstracts of the MEDLINE searches were initially screened by two independent reviewers (R.M. and M.S.) for possible inclusion. The full text of all possible studies was then obtained for independent assessment by the two reviewers. Any disagreement was resolved by discussion.

Fig. 14 describes the process of identifying the 27 studies selected from an initial yield of 390 titles.

4.4.1.3 Data extraction

Information on the survival rates and corresponding incidence of biological and technical complications was retrieved of the included 27 studies. Biological complications included disturbances in the function of the anchorage device characterized by a biological process affecting the supporting tissues and leading to an early removal of the anchorage device prior to the end of the intended orthodontic treatment or observation period. Healing failures were also included in this category. Technical complications were not reported in any of the studies and could therefore not be assessed separately.

From the included studies the survival and failure rates were calculated.

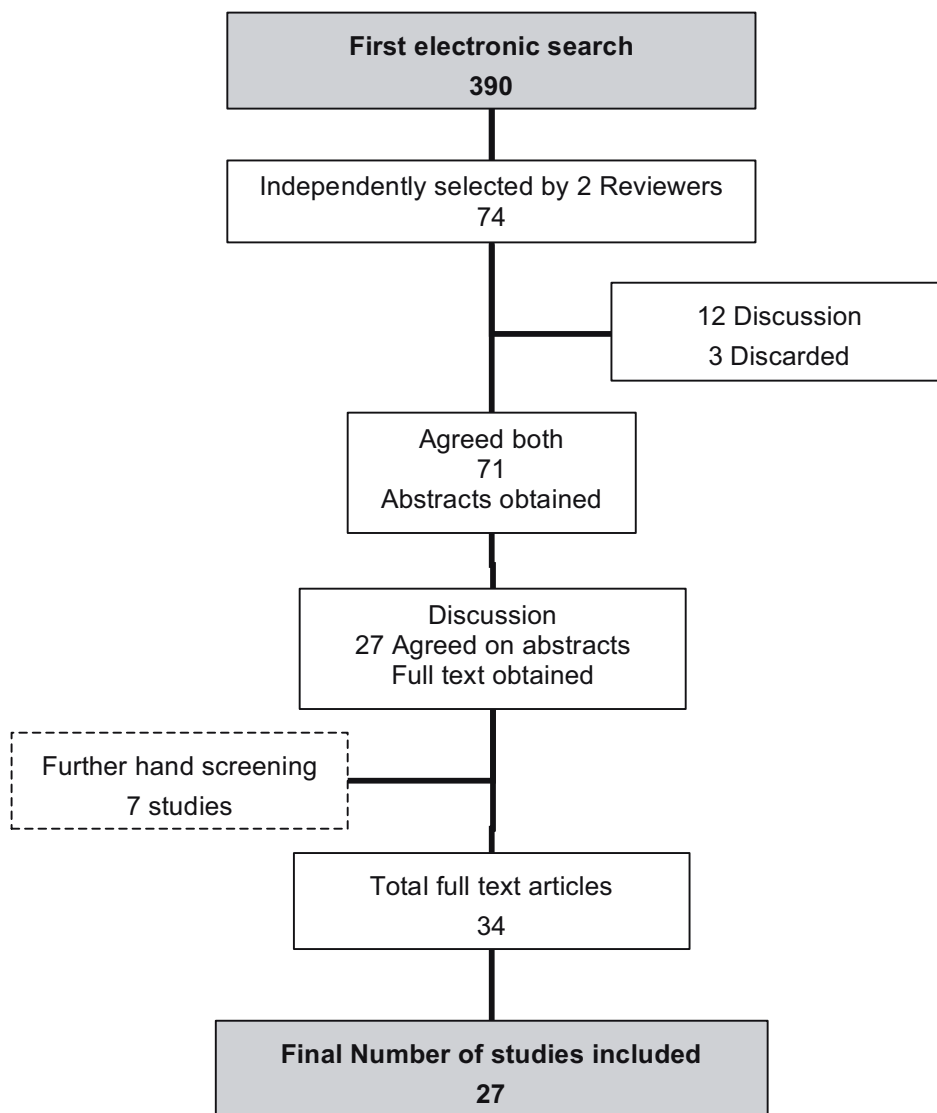


Fig. 14 Search strategy

4.4.1.4 Statistics

Failure rates were calculated by dividing the number of events (failures) after at least 12 weeks of orthodontic loading by the total number of each anchorage type. For further analysis, the total number of events was considered to be Poisson distributed for a given number of TADs, and Poisson regression with a logarithmic link-function and total number of TADs per study as an offset variable was used. To assess heterogeneity of the study-specific event rates, the Spearman goodness-of-fit statistics and associated P-value were calculated. If the goodness-of-fit P-value was below 0.05, indicating heterogeneity, random-effects Poisson regression (with γ -distributed random effects) was used to obtain a summary estimate of the event rates. Summary failure rate estimates and 95 percent confidence intervals (95% CI) are reported.

To provide anchorage on either side of the maxilla, only one palatal implant or onplant is needed, whereas at least two fixtures have to be installed if mini-

plates or miniscrews are used. If the whole dentition should be moved in the same direction, even four miniscrews are required as a minimum due to interferences with the moving roots.

To evaluate the possible failure of at least one out of two fixtures, it was assumed that failures of these objects may occur independently. The probability to remain free of failure was therefore calculated by multiplying the probability of the two objects to remain free of failure: $(1-\text{risk}_{\text{object1}}) \cdot (1-\text{risk}_{\text{object2}})$. Therefore, the probability to encounter at least one failure for two fixtures becomes $1-(1-\text{risk}_{\text{object1}}) \cdot (1-\text{risk}_{\text{object2}})$.

The 95% CI limits for survival proportions were calculated by using the 95% confidence limits of the event rates. All analyses were performed using Stata®, version 10.1 (Stata Corporation, College Station, TX, USA).

4.4.2 Risk Factors Associated with TAD Failures

Based on the results of the systematic review on the survival and failure rates of orthodontic TADs (Publication IV) covering the period from 1966 to January 2009, it was obvious that no randomized controlled clinical trials (RCTs) were available comparing all the different types of TADs.

In the previous study (4.4.1), the survival and failure rates were of interest, whereas in this study, the clinical risk factors leading to failure were analysed.

4.4.2.1 Inclusion criteria

This systematic review was based on the available limited randomized clinical trials and all prospective cohort studies. The additional inclusion criteria for study selection were:

- Publications reported in English
- Mean TAD loading time of at least 12 weeks or 3 months
- Included patients had been examined clinically at the follow-up visit, i.e. publications based only on patient records, on questionnaires or interviews were excluded.
- Details of the screw types were described.
- Details on the risk factors associated with the failures were reported.

4.4.2.2 Data extraction

Information on the risk factors and odds ratios of failures was retrieved of the included 10 prospective studies / RCTs included in the systematic review (Publication IV).

5 RESULTS

5.1 Healing Process of the Palatal Implant

All 40 implants could be inserted with a high primary stability. A mean insertion torque of 39.25 Ncm (range: 30-55 Ncm) was applied. There was no correlation between insertion torque and ISQ-values irrespective of the implant surface. Before releasing the transfer piece in all but one SLA-surface palatal implants, a counter-clockwise torque had to be applied to loosen the transfer piece. In the modSLA-surface group, in contrast, in only one implant a counter-clockwise torque had to be applied. In all cases, the counter-clockwise torque was considerably lower than the insertion torque. All installed implants remained stable at all time points of observation up to the point of explantation.

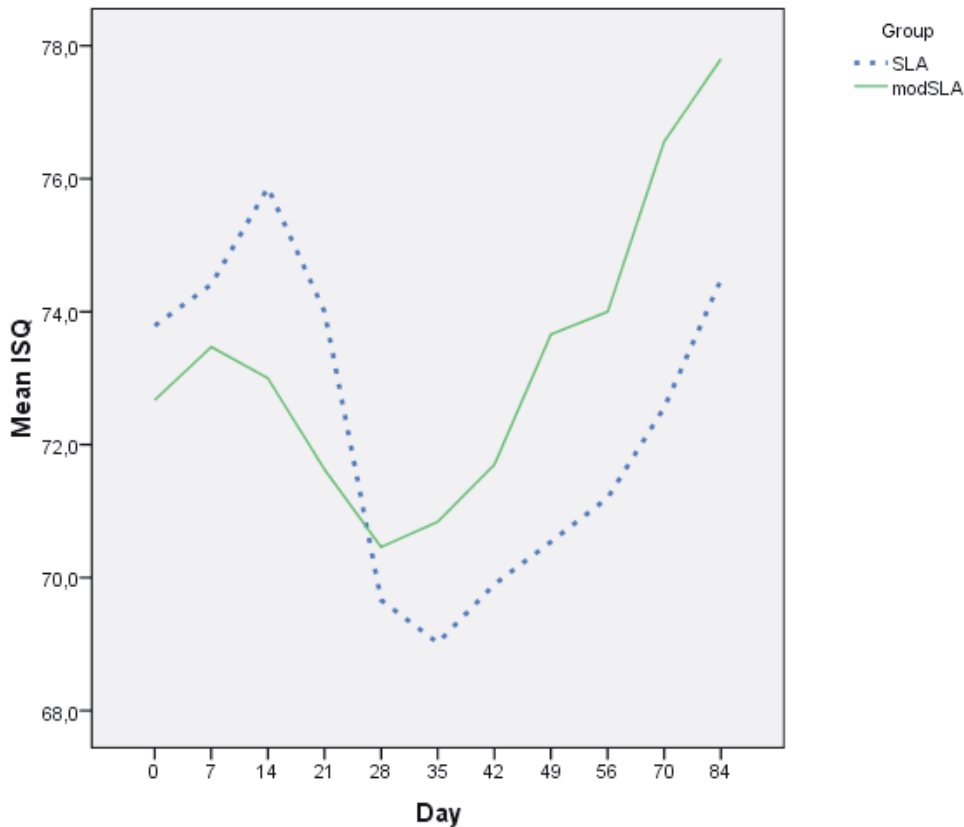


Fig. 15 Mean ISQ values at baseline and subsequent time points for SLA- and modSLA palatal implants.

The mean ISQ values and standard deviation at baseline and in the subsequent time points of measurement are depicted in Table 1 and Fig. 15. At baseline, the stability quotients for both surfaces tested were not significantly different and yielded mean ISQ values of 73.8 ± 5 for the control implants and of 72.7 ± 3.9 for the test implants, respectively. After 84 days (12 weeks) of observation the test-surface implants reached significantly higher stability values of 77.8 ± 1.9 compared to the control implants of 74.5 ± 3.9 , respectively.

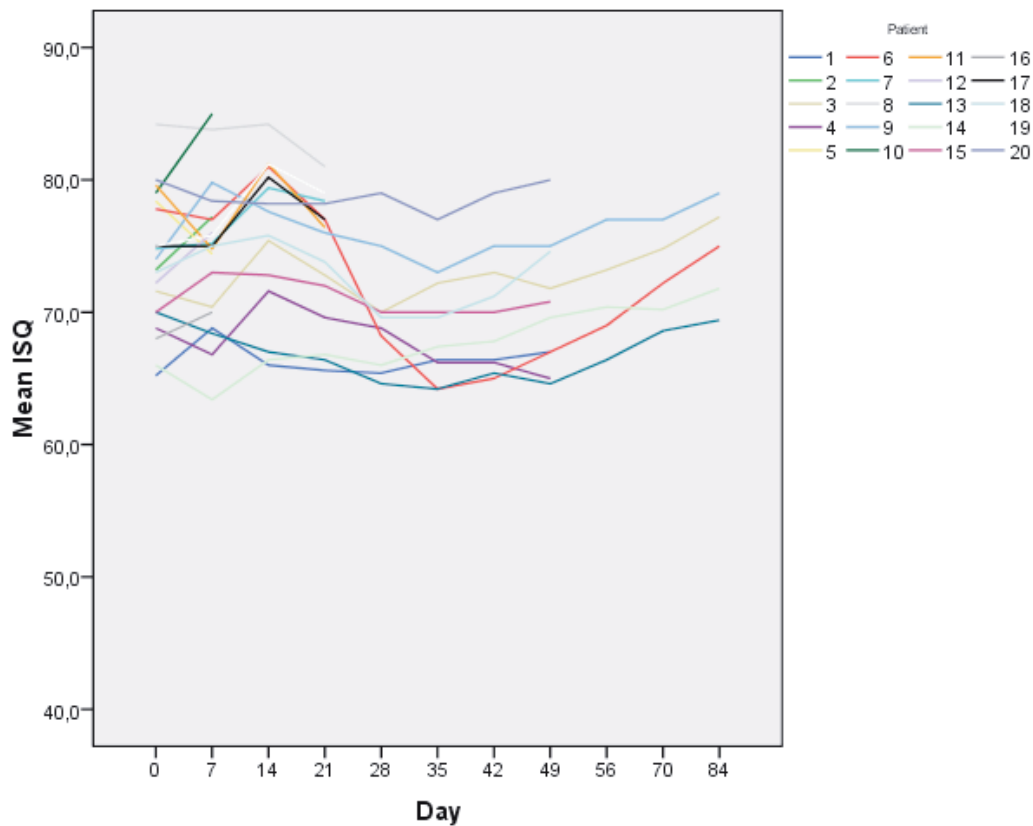


Fig. 16 Individual ISQ-values separate for palatal implants with SLA surface over time.

The individual ISQ values for the SLA implants and for the modSLA ones are shown in Fig. 16 and Fig. 17. Except for one implant of both groups, the individual ISQ values showed a fair homogeneity over time. For the one atypical SLA palatal implant, the ISQ-changes over time yielded higher changes (-13.6 ISQ), but all its ISQ-values remained within the range of those of the other implants. For the one modSLA palatal implant, in contrast, the ISQ-changes yielded even higher (-18.6 ISQ) and the ISQ-values were significantly lower than those of the other implants of the group. But after 84 days (12 weeks), both atypical implants re-established stability values comparable to the other implants.

As the absolute ISQ values were not of primary interest and have only minor clinical impact due to high individual variability, it is good clinical practice to monitor the changes over time by standardizing the ISQ values as deviations from the baseline (Table 2 and Fig. 18). During the first 14 days after implant installation, both groups showed only small changes in the ISQ values (+0.24 to +2.2). Thereafter, both groups revealed a decreasing trend of mean ISQ level reaching significantly lower values (difference from baseline for the control surface -2.0 ± 3.3 and modSLA-surface -1.5 ± 6.0). In the test group, however, this transition point of the ISQ values was observed at 28 days after implant installation. For the SLA-control group, the trend changed one week later, after 35 days. After the transition points of ISQ differences, the ISQ

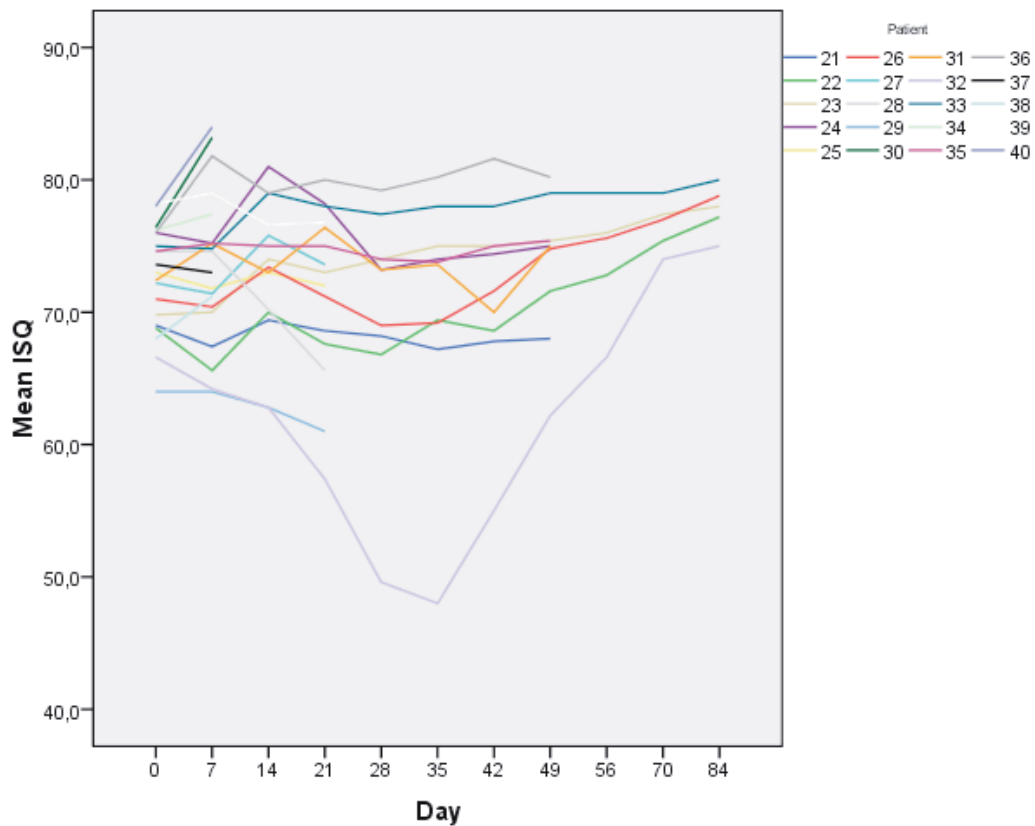


Fig. 17 Individual ISQ-values separate for palatal implants with modSLA surface over time.

increased significantly more over time for the test than the control group. 42 days after installation the modSLA-surface reached ISQ values corresponding to those immediately after palatal implant installation, whereas for the SLA-surface, it took significantly longer, approximately 63 days. The ISQ-difference values as well as the mean ISQ values for the SLA-surface after 84 days (12 weeks) corresponded to the values of the modSLA-surface reached after 56 days (8 weeks). The Chow test, however, did not show a sufficiently statistically significant difference between the groups.

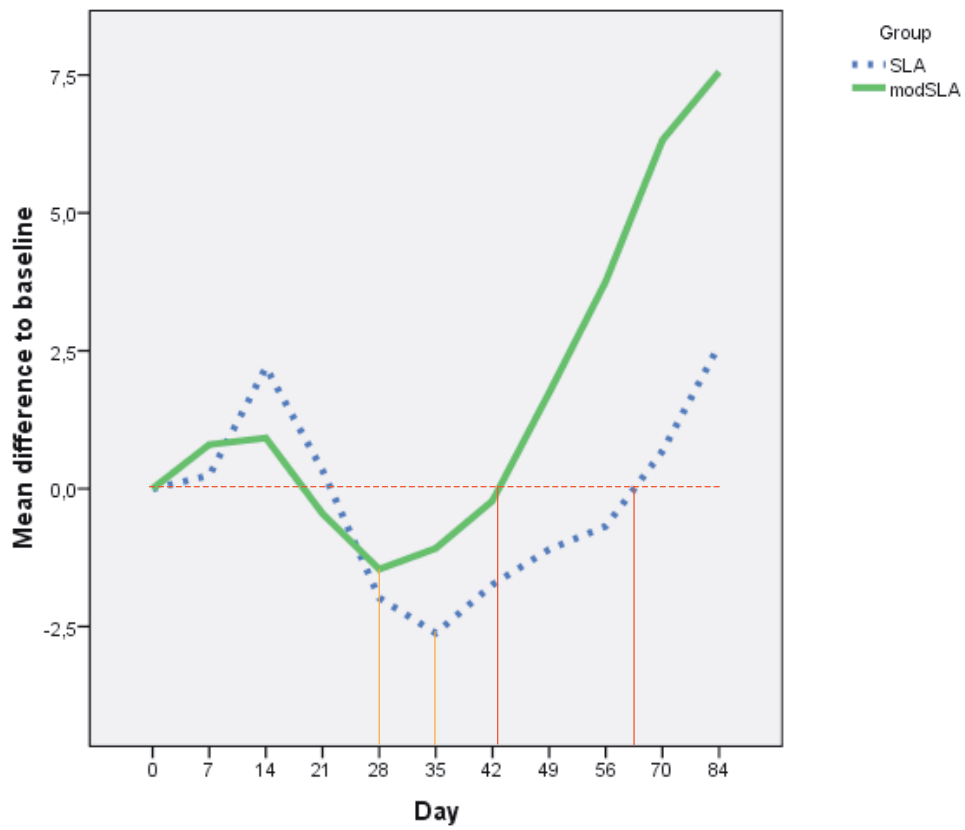


Fig. 18 Mean ISQ values changes for SLA- and modSLA palatal implants by standardizing to the deviations from baseline. Transition points after 28 and 35 days. Baseline re-establishment after 42 and 63 days.

5.1.1 Tables

Table 1. Mean ISQ values and standard deviation at baseline and subsequent time points for SLA- and modSLA palatal implants.

Day	N per group	SLA			modSLA		
		Minimum	Mean \pm SD	Maximum	Minimum	Mean \pm SD	Maximum
0	20	65.2	73.790 \pm 5.0214	84.2	64.0	72.670 \pm 3.9402	78.2
7	20	63.4	74.410 \pm 5.3801	85.0	64.0	73.470 \pm 5.8097	84.0
14	15	66.0	75.867 \pm 5.8908	84.2	62.8	73.000 \pm 5.3442	81.0
21	15	65.6	74.000 \pm 4.9552	81.0	57.4	71.627 \pm 6.5356	80.0
28	10	64.6	69.660 \pm 4.4222	79.0	49.6	70.460 \pm 8.3026	79.2
35	10	64.2	69.020 \pm 4.1478	77.0	48.0	70.840 \pm 8.9581	80.2
42	10	65.0	69.900 \pm 4.6516	79.0	55.0	71.700 \pm 7.2524	81.6
49	10	64.6	70.540 \pm 4.9379	80.0	62.2	73.660 \pm 5.2688	80.2
56	5	66.4	71.200 \pm 4.0669	77.0	66.6	74.000 \pm 4.6840	79.0
70	5	68.6	72.560 \pm 3.3953	77.0	74.0	76.560 \pm 1.9204	79.0
84	5	69.4	74.480 \pm 3.9079	79.0	75.0	77.800 \pm 1.8762	80.0

Table 2. Mean ISQ value changes and standard deviations for SLA- and modSLA palatal implants relative to their individual baselines.

Day	N per group	SLA			modSLA		
		Minimum	Mean \pm SD	Maximum	Minimum	Mean \pm SD	Maximum
7	20	-4.8	+0.240 \pm 3.1359	+6.0	-3.2	+0.800 \pm 2.7690	+6.8
14	15	-3.0	+2.200 \pm 2.5467	+6.2	-4.4	+0.920 \pm 2.8484	+5.0
21	15	-3.6	+0.333 \pm 2.3924	+4.0	-9.2	-0.453 \pm 4.0914	+4.0
28	10	-9.6	-1.980 \pm 3.3045	+1.0	-17.0	-1.460 \pm 5.9517	+4.2
35	10	-13.6	-2.620 \pm 4.4974	+1.4	-18.6	-1.080 \pm 6.6741	+5.2
42	10	-12.8	-1.740 \pm 4.3889	+1.8	-11.6	-0.220 \pm 4.8511	+5.6
49	10	-10.8	-1.100 \pm 4.3279	+3.6	-4.4	+1.740 \pm 3.0870	+5.6
56	5	-8.8	-0.680 \pm 5.4545	+4.4	0.0	+3.760 \pm 2.2865	+6.2
70	5	-5.6	+0.680 \pm 4.1197	+4.2	+4.0	+6.320 \pm 1.4464	+7.6
84	5	-2.8	+2.600 \pm 4.0125	+5.8	+5.0	+7.560 \pm 1.4519	+8.4

5.2 Supraconstruction of the Palatal Implant: Case Presentation

The developed supraconstruction has been used in all 72 patients who received palatal implants in the prospective study (study III). In two patients, a failure of the closing mechanism of the Damon® bracket occurred which was not a major problem as the mechanism could be replaced by a steel ligature.

Two cases are presented as an illustration.

5.2.1 Case 1

This 28-year-old patient attended the clinic because she was concerned about the large overjet. Before treatment, she showed a 3/4 class II intercuspation with slightly vertical open bite, hyperdivergency, crowding of the lower incisors, some gingival recession and crossbite of the left first molars (Fig. 19a-c). If two premolars would have been extracted in the lower jaw, an acceptable overjet and overbite situation would never have been reached by orthodontic means only. It was therefore decided to extract two upper premolars, stabilize the upper molars by a palatal implant and level the lower arch after interdental stripping with additional aid of a lip bumper. The supraconstruction was 14



Fig. 19 Case 1: Bilateral space closure, incisor retraction and vertical blockage of the molars in a 28 year old female patient:

19a: Frontal view with a slight vertical open bite before treatment.

19b: Lateral view of the left buccal segment: 3/4 class II intercuspation, crossbite of the first molars, crowding of the lower incisors.

19c+d: Overjet before and after treatment. The first upper premolars have been extracted, interdental stripping and levelling with additional aid of a lip bumper was performed in the lower dental arch.

19e: Lateral view of the left buccal segment after treatment. Note the change of the canine's position.

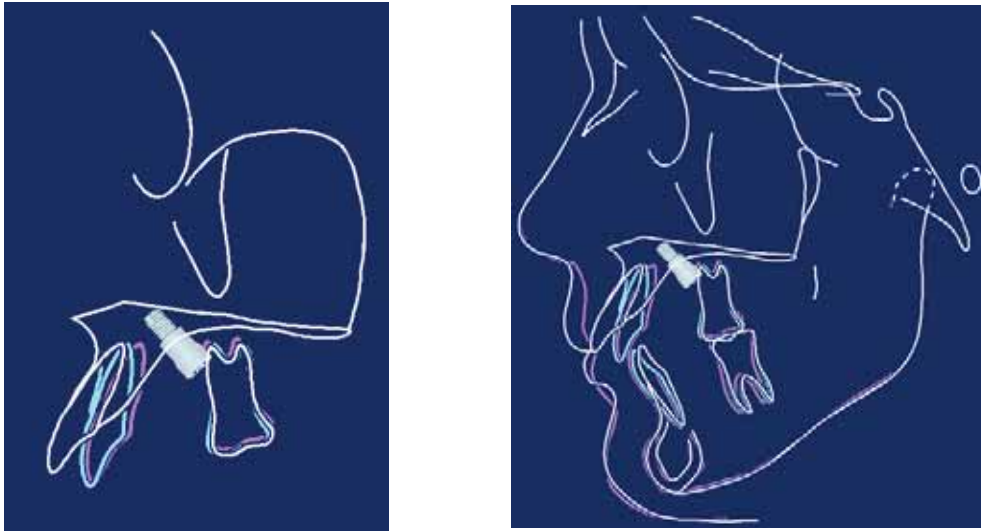


Fig. 19 Case 1: Bilateral space closure, incisor retraction and vertical blockage of the molars in a 28 year old female patient:
 19f: Structural superposition of the maxilla. Almost absolute sagittal molar anchorage was achieved. Additionally a minor intrusion of the molars can be observed.
 19g: Although the patient was quite hyperdivergent, the y-axis was rather closed than opened during treatment, probably because of the molar intrusion in the upper jaw. White: before, blue: during, pink: end of treatment.

months in place, whereas the whole treatment time lasted for 2 years. The outcome of treatment is displayed in Fig. 19d and e. Fig. 19f and g show the local and total structural superposition of the pre- and post-treatment cephalograms. The y-axis slightly closed, due to a minor intrusion of the molars, which is typical for palatal implant anchorage. There was no sagittal anchorage loss of the molars.

5.2.2 Case 2



Fig. 20 Case 2: Unilateral molar mesialization in a 16 year old female patient:
 20a: Occlusal view. The left first molar had to be extracted after an accident. Single sided supraconstruction for mesialization of the second molar.
 20b: Occlusal view after implant removal (treatment time: 13 months). No other orthodontic appliance has been used. The wisdom tooth erupted later in a correct position.

Conventional orthodontic treatment had just been finished, when this 16-year-old female patient broke one cusp of the left upper first molar in an accident. The fracture reached into the pulp and above the alveolar crest. Extensive endodontics, periodontal surgery and prosthetic reconstruction would have been needed to restore this tooth. In presence of a wisdom tooth, it was decided to extract the first molar and mesialize the second by the use of a palatal implant. There was no prospective interference of the roots with the maxillary sinus. Compensations according to Fig. 11 (page 39) have been bent into the sectional arch wires. The mesialization was achieved within 13 months (Fig. 20).

5.3 Long Time Survival and Success Rates of the Palatal Implant

5.3.1 Osseointegration Rate

Initially, 73 consecutively admitted patients were recruited for this study (14 males and 59 females). One male person was excluded due to smoking abuse and severe wound healing disorder after molar extraction. In two out of the 72 included patients, the implants had to be removed 10 and 19 days after installation due to inadequate primary stability. In these individuals, new implants were successfully placed in a slightly different location after a healing period of 4 months. Nevertheless, these two implants are interpreted as failures and were not considered for further evaluation.

One or 1.4% of the 70 primary stable palatal implants did not successfully osseointegrate and was lost before loading. This 4mm in length and 3.3mm in diameter implant was lost spontaneously approximately 2 months after implant insertion (Table 3). During the healing period, this patient complained about pain in the incisal region. The overall success rate of osseointegration of the 70 implants was 98.6%.

5.3.2 Loaded Implants (Survival Rate)

In all 69 patients (mean age: 22 years 6 months \pm 10 years 9 months) with successfully osseointegrated palatal implants after a mean healing time of 12.7 (\pm 3.8) weeks (Table 3), an alginate impression was taken in order to obtain a master cast for designing the individualised, rotationally stable supraconstruction. After installation of this, 27 implants or 39.1% were loaded actively, 33 implants or 47.8% were used for passive stabilisation and 9 implants (13.0%) were used for both purposes, respectively (Table 4).

By May 2009 and after a mean loading time of 25.2 months, all but 1 or 98.6% of the 69 osseointegrated palatal implants remained stable under orthodontic loading.

The overall survival rate in the patient cohort ($N=72$) was 94.4%. It has to be kept in mind, however, that 5 patients still were in orthodontic treatment at the completion of the study.

5.3.3 Implants at the Removal of the Supraconstruction (Success Rate)

By the time of re-evaluation, 5 Orthosystem® implants were still in situ and under orthodontic loading. In 64 patients (mean age 22 years 4 months ± 10 years 2 months), the supraconstruction had been removed due to completion of the orthodontic anchorage need or implant failure after successful osseointegration (Table 5). One patient refused the removal of the palatal implant after treatment.

By analyzing the 64 successfully loaded Orthosystem® palatal implants after completion of orthodontic therapy only, the overall success rate was 98.4% for a mean loading time of 24.6 months.

5.3.4 Tables

Table 3. Frequency distribution of mean age (± SD), sex, implantation site and healing time before orthodontic loading for installed implants

Implant dimension (mm)	N	Mean age ± SD	Sex		Implantation site		Mean healing time in weeks ± SD (before orthodontic loading/failure)	
			Male	Female	Median	Paramedian		
Length: 4 Diameter: 3.3	20*	24-7 ± 10-4 median: 22-6	3	17*	5*	15*	12.5 ± 3.7	Minimum 2 Maximum 20
Length: 4 Diameter: 4	10	23-9 ± 11-5 median: 20-9	2	8	1	9	12.2 ± 2.1	Minimum 8 Maximum 15
Length: 6 Diameter: 3.3	42	20-9 ± 10-6 median: 16-5	8	34	5	37	12.9 ± 4.1	Minimum 3 Maximum 25
Total	72	22-3 ± 10-7 median: 17-2	13	59*	11*	61*	12.7 ± 3.8	Minimum 2 Maximum 25

*Three out of 72 (4.2%) installed implants (1 median, 2 paramedian) did not successfully osseointegrate.

Table 4. Frequency distribution of mean age (± SD), sex, implantation site and mean loading time for successfully loaded implants (survival rate).

Implant dimension (mm)	N	Mean age ± SD	Sex		Implantation site		Type of load			Mean loading time of the supra- construction in month ± SD	
			Male	Female	Median	Param.	active	passive	both		
Length: 4 Diameter: 3.3	17*	26-1 ± 10-6 median: 26-7	3	14*	4	13*	8*	7	2	26.9 ± 16.0	Minimum 5 Maximum 70
Length: 4 Diameter: 4	10	23-9 ± 11-5 median: 20-9	2	8	1	9	5	4	1	28.6 ± 13.7	Minimum 16 Maximum 62
Length: 6 Diameter: 3.3	42	20-9 ± 10-6 median: 16-5	8	34	5	37	14	22	6	23.6 ± 9.3	Minimum 9 Maximum 43
Total	69	22-6 ± 10-9 median: 17-6	13	56	10	59	27*	33	9	25.2 ± 11.9	Minimum 5 Maximum 70

*One implant of 4 mm length and 3.3mm diameter in a female patient lost its stability after a 5 month unilateral loading time and had to be removed.
One or 1.4% of 69 successfully osseointegrated implants did not remain stable under loading.

Table 5. Frequency distribution of mean age (\pm SD), sex, implantation site and *mean loading time* for successfully loaded implants with removal of the supraconstruction due to completion of the orthodontic anchorage need or implant failure (success rate).

Implant dimension (mm)	N	Mean age \pm SD	Sex		Implantation site		Type of load			Mean loading time of the supra-	
			Male	Female	Median	Param.	active	passive	both	construction in month \pm SD	
Length: 4 Diameter: 3.3	16*	26-10 \pm 10-4 median: 27-0	3	13*	4	12*	7*	7	2	26.1 \pm 16.1	Minimum 5 Maximum 70
Length: 4 Diameter: 4	9	24-9 \pm 11-7 median: 22-7	2	7	1	8	4	4	1	28.4 \pm 14.5	Minimum 16 Maximum 62
Length: 6 Diameter: 3.3	39	19-10 \pm 9-3 median 16-2	7	32	3	36	13	21	5	23.1 \pm 9.4	Minimum 9 Maximum 43
Total	64	22-4 \pm 10-2 median 17-6	12	52*	8	56*	24*	32	8	24.6 \pm 12.0	Minimum 5 Maximum 70

*One implant of 4 mm length and 3.3mm diameter in a female patient lost its stability after a 5 month unilateral loading time and had to be removed.
One or 1.6% of 64 removed implants did not remain stable under loading.

5.4 Systematic Literature Reviews on TADs

5.4.1 Survival Rates of Different TADs

5.4.1.1 Onplants®

One article fulfilling the inclusion criteria concerning onplants (Feldmann & Bondemark, 2008) could be found. In this prospective RCT, 5 out of 29 onplants (17.2%) failed (Table 6).

5.4.1.2 Miniscrews, Miniimplants and Microimplants

17 studies provided data on the survival of 31 different types of miniscrews (Table 7). A total of 2374 miniscrews inserted in 1196 patients with 363 (15.3%) of failures could be analyzed. Seven studies reported results of prospective clinical trials, whereas the remaining 10 assessed their results retrospectively. Data of one prospective RCT could be extracted comparing two different screw types (Wiechmann et al. 2007). Due to the lack of precise data in all these studies no conclusive statement of survival and/or failure rate of a specific screw type (length and diameter) regarding its favourable indication, insertion location, insertion technique and type of loading could be made.

Some reports provided detailed data on diameter and length of the inserted miniscrews while others pooled the results of a specific miniscrew diameter with various lengths. The mean follow-up time ranged between 120 days and more than 1 year or completion of the intended orthodontic treatment.

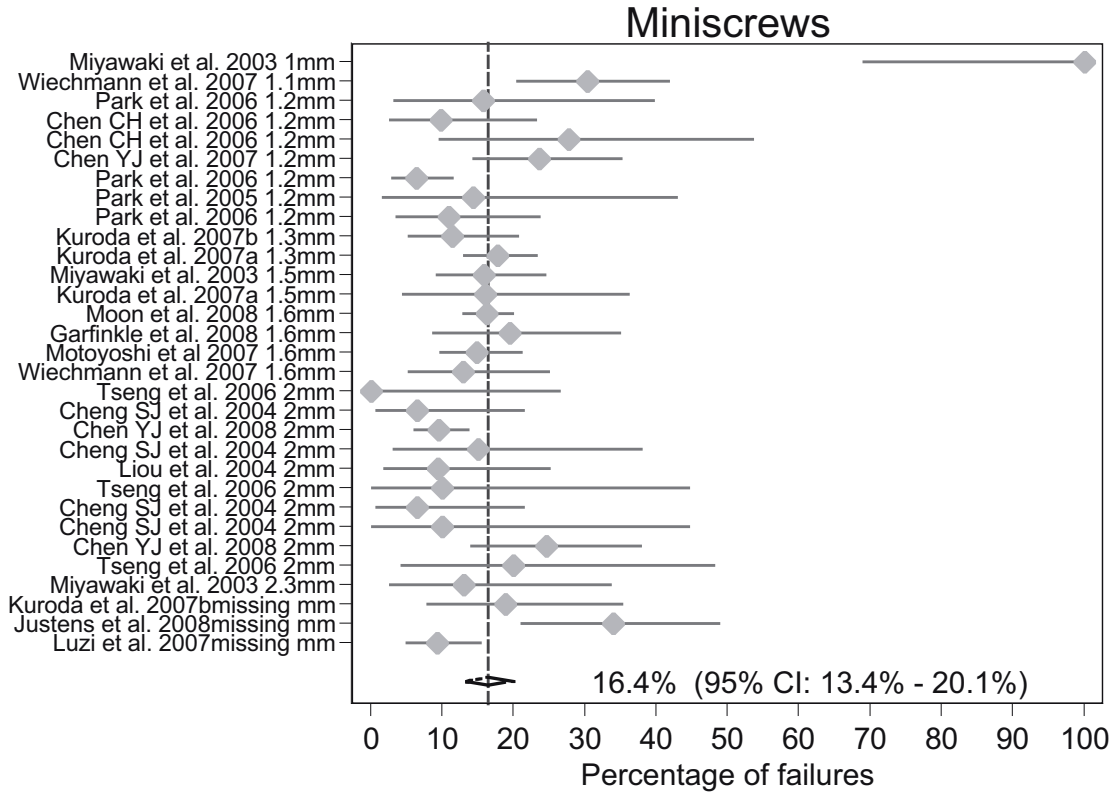


Fig. 21 Failure rates of miniscrews and summary estimate from meta-analysis and their 95% confidence intervals by study and diameter.

By meta-analysis, the failure rate (Fig. 21) was estimated at 16.4% (95% Confidence Interval 13.4%-20.1%). By analyzing the influence of screw length and diameter, only the data of screws with detailed characteristics were considered. 3 groups of diameter were created which basically separate 3 clouds of diameter (1.2mm or less, 1.5 or 1.6mm, 2mm or more) and length types as seen in Fig. 22. The miniscrews with a diameter of 2mm or more showed a significantly 1.78-fold lower risk (95% C.I. 1.05-3.01) to fail than miniscrews of a diameter of 1.2mm or less.

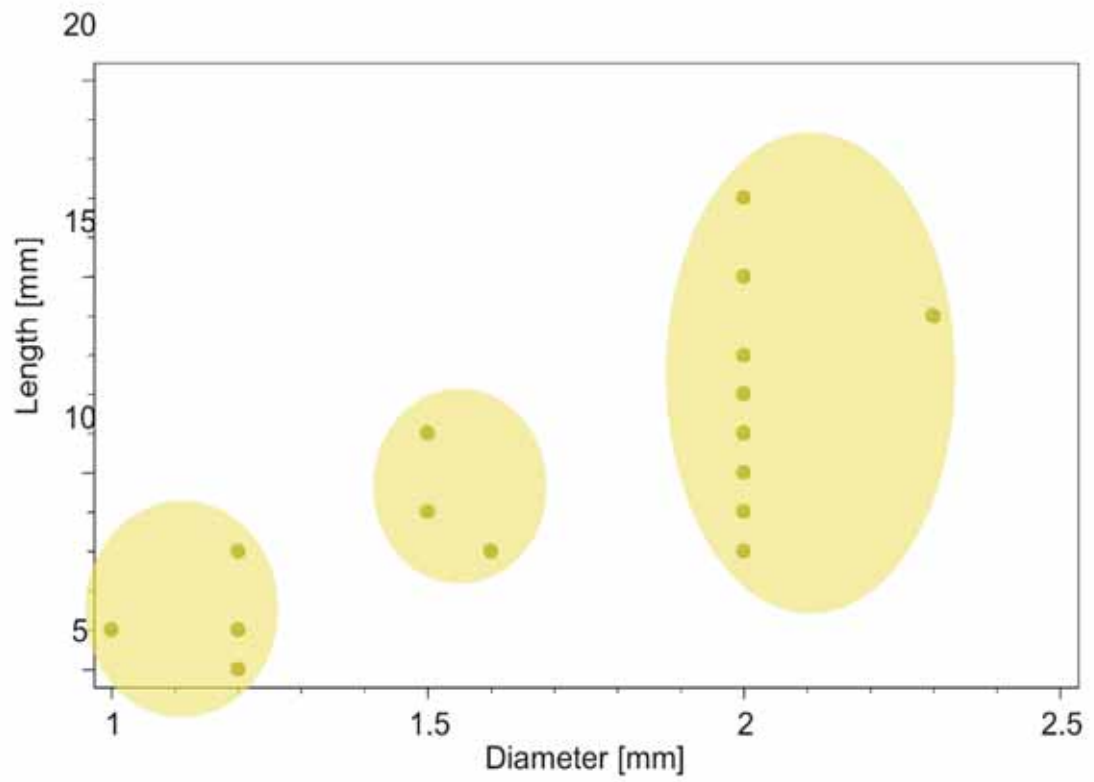


Fig. 22 Description of screws by length by diameter forming 3 clouds.

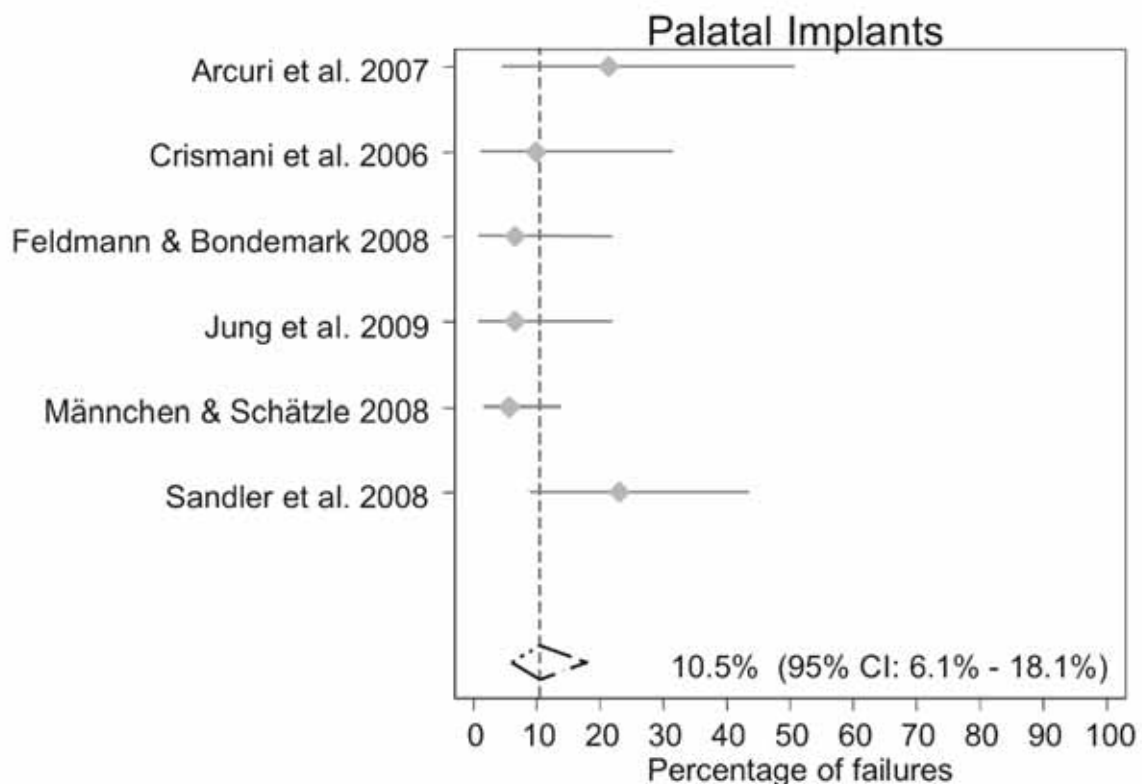


Fig. 23 Failure rates of palatal implants and summary estimate from meta-analysis and their 95% confidence intervals by study.

5.4.1.3 Palatal implants

One retrospective and five prospective clinical studies provided data fulfilling the inclusion criteria on the survival and failure rate of palatal implants (Table 8). Two out of these were RCTs comparing palatal implants to compliance-dependent conventional orthodontic anchorage devices (COAD) only (Sandler et al. 2008) or to COADs and onplants (Feldmann & Bondemark 2008). But only one report evaluated the clinical outcome of a larger number of palatal implants (Study III). Data of a total of 190 palatal implants with a follow-up time of at least 12 weeks up to more than 22 months or completion of the intended orthodontic treatment could be assessed. Nineteen or 10% out of 190 palatal implants did not provide sufficient anchorage and were lost early or before the time point of evaluation. In meta-analysis, the failure rate was estimated at 10.5% (95% C.I: 6.1%-18.1%) (Fig. 23).

5.4.1.4 Miniplates

Seven out of the 27 included reports provided data on the survival and failure rate of miniplates (Table 9). Two were prospective clinical trials, the remaining five evaluated the material retrospectively. A total of 586 miniplates in 406 patients could be followed for at least 120 days up to 1.5 years or completion of the intended orthodontic treatment, respectively. 43 or 7.3% out of these did

not remain stable and had to be removed. In meta-analysis, the failure rate (Fig. 24) was estimated at 7.3% (95% CI: 5.4%-9.9%).

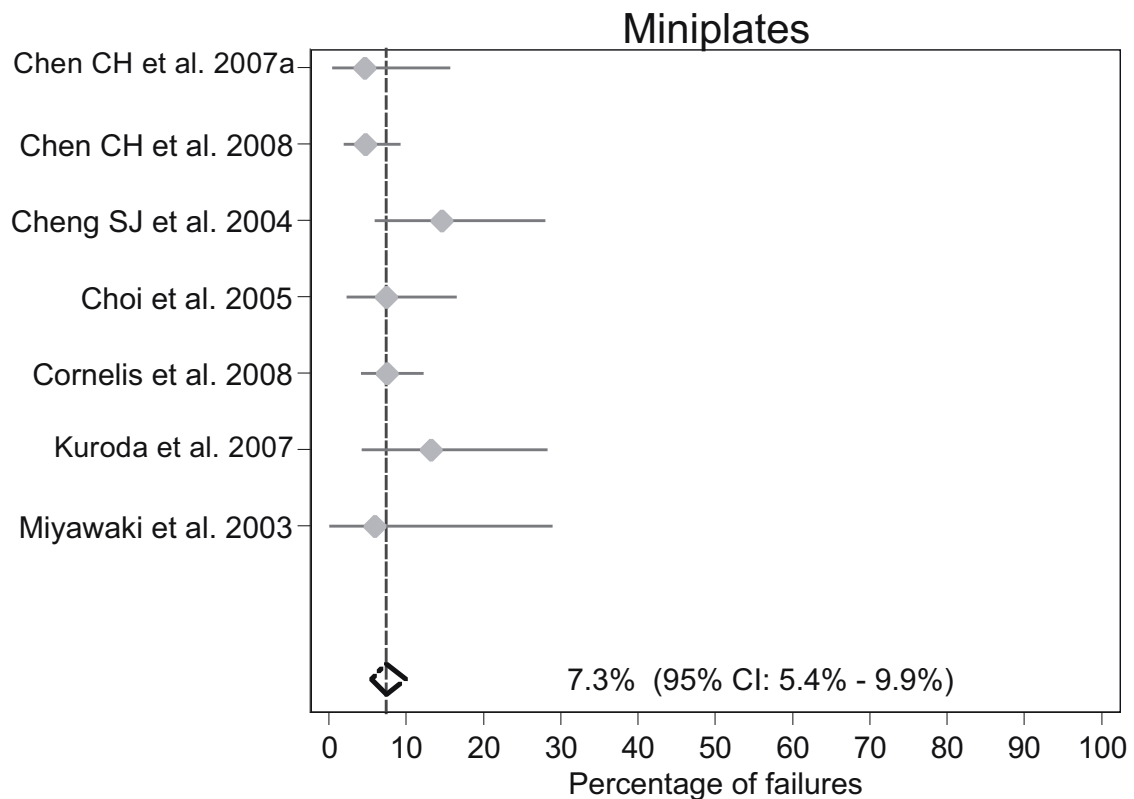


Fig. 24 Failure rates of miniplates and summary estimate from meta-analysis and their 95% confidence intervals by study.

By comparing miniplates, palatal implants and miniscrews to each other, none of them showed statistically significant better survival rates due to the wide scattering within the groups. But when miniplates and palatal implants, representing torque resisting devices, were grouped together, they showed a statistically significant 1.9-fold (95% CI: 1.06 – 2.78, $p=0.0048$) lower clinical failure rate than miniscrews.

To achieve the same clinical anchorage on both sides of the arch as with a palatal implant (10.5% failure rate, 95% C.I.: 6.1%-18.1%) 2 miniscrews or miniplates have to be inserted. The probability to have at least one failure, when 2 of these TADs are installed in the maxilla, is 14.1% (95% C.I. 10.5% - 18.8%) for miniplates and 29.4% (95% C.I. 24.3% - 36%) for miniscrews, respectively.

5.4.2 Risk Factors Associated with TAD Failures

5.4.2.1 Onplants®

There was one article fulfilling the inclusion criteria concerning onplants, reporting a failure rate 17.2% (Table 10). (Feldmann & Bondemark, 2008). One of 29 onplants failed to osseointegrate during the healing period and was removed before the orthodontic treatment. Furthermore, due to narrow and high palates, another 2 onplants became tilted during the healing period and could therefore not be accessed for the supraconstruction and were thus removed. Two other failures were attributed to the loss of anchorage (>1mm) and poor oral hygiene.

5.4.2.2 Miniscrews, Miniimplants and Microimplants

Four studies provided prospective data on factors associated with an increased risk for early miniscrew failures (Park et al. 2006b, Wiechmann et al. 2007, Motoyoshi et al. 2006, Garfinkle et al. 2008, Table 11).

In the randomized clinical trial included in this study, the survival and failure rates of two different screw diameters were assessed (Wiechmann et al. 2007). The survival of the 1.6mm diameter micro-implants was significantly higher than for the 1.1mm diameter, identifying screw diameter as a risk factor (odds ratio (OR) 2.9 (95% C.I.: 1.2-7.4)). Additionally, the failure rates differed significantly depending on the insertion site independent of the screw diameter. The survival of both micro-implants systems was significantly higher in the maxilla than in the mandible. Miniscrews placed in the mandible had a more than 5-times increased risk for failure (OR 5.1 (95% C.I.: 2.2-12.1)). The failure rate of implants inserted lingually into the mandible was significantly higher than in all other localizations (OR 13.5 (95% C.I.: 3.9-46.6)).

The cohort study by Park et al. (2006b), comparing various lengths of different miniscrews of the same diameter showed a significantly higher failure rate of implants placed in the mandible than those placed in the maxilla (OR 5.3 (C.I. 95%: 1.7 – 16.7)). This factor was not confirmed in the two other prospective studies investigating the same factors (Motoyoshi et al. 2006, Garfinkle et al. 2008). The right patient side had significantly higher failure than the left side (OR 6 (C.I. 95%: 1.6 – 21.7)).

For procedure management factors, the screw heads intentionally covered by overlying soft tissue tended to have higher survival rates than screw heads exposed in the oral cavity. However, the difference was not statistically significant (Park et al. 2006b). The screw implants in the upper palatal alveolar bone between the first and second molars showed higher survival rates than those in other locations, although there was no statistical significance again (Park et al. 2006b). There was no significant correlation of failure rate in relation to the method of force application or placement angle (Park et al. 2006b).

For environmental management factors, miniscrews with inflammation or mobility during treatment showed significantly lower survival rates (OR 4.8 (95% C.I.: 1.7-13.9) and OR 24.4 (C.I. 95%: 4.8 – 125), respectively).

In the study by Motoyoshi et al. (2006) assessing risk factors associated with miniscrews of 1.6mm diameter and 8mm length no difference between maxillary and mandibular placement was found. But in this cohort study, implant placement torque (IPT) was identified as a risk factor for early screw failure. The survival rate for implants with an IPT between 5Ncm and 10Ncm was significantly higher than that for maxillary implants with IPT below 5Ncm or above 10Ncm and higher than the survival rate of all maxillary and mandibular miniscrews combined. The odds ratio for failure of the mini-implant anchors with IPT below 5 or above 10Ncm was 11.7 (95% C.I.: 3.1-44.4) when compared with those within this range.

5.4.2.3 Palatal implants

Five prospective studies provided data fulfilling the inclusion criteria for palatal implants (Table 12). Two out of these were RCTs comparing palatal implants to compliance dependent conventional orthodontic anchorage devices (COAD) only (Sandler et al. 2008) or to COADs and onplants (Feldmann & Bondemark 2008).

All but two of the palatal implants failures were due to surgical failures during the healing phase leading to an early loss prior to loading (Crismani et al. 2006, Männchen & Schätzle 2008, Sandler et al. 2008, Feldmann & Bondemark 2008, Jung et al. 2009). One palatal implant was judged as a failure, even though it remained stable during the whole treatment, as the supracost-structure did not provide sufficient anchorage (anchorage loss more than 1mm) (Feldmann & Bondemark 2008). One implant did not remain stable after successful osseointegration attributed to a unilateral heavy and excessive orthodontic loading (Study III).

5.4.2.4 Miniplates

One prospective cohort study out of the 10 included reports provided data on risk factors associated with increased failure rates of miniplates (Cornelis et al. 2008, Table 13). In this report, 15 bone plates out of 200 had to be prematurely removed. Most (73.3%) failures occurred in growing patients. Increased mobility was more frequently reported in the mandible than the maxilla, possibly related to the flap design. The initial mandibular surgical protocol was therefore modified during the study and the releasing incision was placed in the attached gingiva instead of the sulcus. Unfortunately, the corresponding odds ratios were not assessed in detail.

5.4.3 Tables

Table 6. Study and patient characteristics of the reviewed study of onplant survival.

Author	Kind of Study	Manufacturer	Diameter	Length	N Patients	Mean Age \pm SD	N TAD	N Failure	Loading Time
Feldmann & Bondemark 2008	Prospective RCT	Nobel Biocare	7.7-mm titanium disk	-	29	14.0 years \pm 1.53	29	5	Completion of treatment

Table 7. Study and patient characteristics of the reviewed studies of mini-/microscrew survival.

Author	Kind of Study	Manufacturer	Diameter	Length	N Patients	Mean Age (\pm SD)	N TAD	N Failure	Loading Time
Chen YJ et al. 2008	Retrospective	Mondeal	2mm	8 to 14mm	194	25.1years \pm 8.7	57	14	During 3 years
Chen YJ et al. 2008	Retrospective	BioRay	2mm	5 to 21mm	194	25.1years \pm 8.7	264	25	During 3 years
Chen YJ et al. 2007	Retrospective	AbsoAnchor	1.2mm	4 to 10mm	129	24.5years \pm 7.1	72	17	Completion of treatment
Chen CH et al. 2006a	Retrospective	AbsoAnchor	1.2mm	6 mm	29	29.8 years	18	5	Completion of treatment
Chen CH et al. 2006a	Retrospective	AbsoAnchor	1.2mm	8mm	29	29.8 years	41	4	Completion of treatment
Cheng SJ et al. 2004	Prospective CT	Leibinger / Mondela	2mm	9mm	44	29 years \pm 8.9	31	2	Completion of treatment
Cheng SJ et al. 2004	Prospective CT	Leibinger / Mondela	2mm	11mm	44	29 years \pm 8.9	31	2	Completion of treatment
Cheng SJ et al. 2004	Prospective CT	Leibinger / Mondela	2mm	13mm	44	29 years \pm 8.9	20	3	Completion of treatment
Cheng SJ et al. 2004	Prospective CT	Leibinger / Mondela	2mm	15mm	44	29 years \pm 8.9	10	1	Completion of treatment
Park et al. 2006b	Prospective CT	Stryker Leibinger	1.2mm	5mm	10	15.5 years \pm 8.3	19	3	Completion of treatment
Park et al. 2006b	Prospective CT	Ostomed	1.2mm	6 to 10mm	67	15.5 years \pm 8.3	157	10	Completion of treatment
Park et al. 2006b	Prospective CT	AbsoAnchor	1.2mm	4, 6, 7, 8, 10mm	16	15.5 years \pm 8.3	46	5	Completion of treatment
Wiechmann et al. 2007	RCT	AbsoAnchor	1.1mm	5, 6, 7, 8, 10mm	49	26.9 years \pm 8.9	79	24	120 days
Wiechmann et al. 2007	RCT	Dual Top	1.6mm	5, 6, 7, 8, 10mm	49	26.9 years \pm 8.9	54	7	120 days
Liou et al. 2004	Prospective CT	Leibinger	2mm	17mm	16	22-29 years	32	3	9 months
Park et al. 2005c	Prospective CT	Osteomed	1.2mm	6 mm	7	17.9 years \pm 5.7	14	2	13.2 months
Kuroda et al. 2007b	Retrospective	AbsoAnchor	1.3mm	6, 7, 8, 10, 12mm	110	22.5 years \pm 8.1	237	42	>1 year or completion of treatment
Kuroda et al. 2007b	Retrospective	Martin	1.5mm	9mm	110	22.5 years \pm 8.1	25	4	>1 year or completion of treatment

Kuroda et al. 2007b	Retrospective	KeSei Medical Ind.	2.0 / 2.3mm	7 / 11mm	18	21.8 years	37	7	>1 year or completion of treatment
Kuroda et al. 2007b	Retrospective	AbsoAnchor	1.3mm	6, 7, 8, 10, 12mm	40	21.8 years	79	9	>1 year or completion of treatment
Luzi et al. 2007	Retrospective	Aarhus-Miniscrew	1.5 / 2mm	9.6 / 11.6mm	98	34.3 years	140	13	120 days
Motoyoshi et al. 2007	Prospective	Biodent	1.6mm	8mm	57	20.8 years	169	25	>6months
Tseng et al. 2006	Retrospective	Stryker Leibinger	2mm	8 mm	25	29.9 years	15	3	completion of treatment
Tseng et al. 2006	Retrospective	Stryker Leibinger	2mm	10mm	25	29.9 years	10	1	completion of treatment
Tseng et al. 2006	Retrospective	Stryker Leibinger	2mm	12mm	25	29.9 years	12	0	completion of treatment
Miyawaki et al. 2003	Retrospective	Not specified	1mm	6mm	3	21.8 ± 7.8 years	10	10	>1 year or completion of treatment
Miyawaki et al. 2003	Retrospective	Not specified	1.5mm	11mm	31	21.8 ± 7.8 years	101	16	>1 year or completion of treatment
Miyawaki et al. 2003	Retrospective	Not specified	2.3mm	14mm	10	21.8 ± 7.8 years	23	3	>1 year or completion of treatment
Garfinkle et al. 2008	Prospective CT	Ostomed	1.6mm	8mm	13	14.83 years	41	8	Space closure
Justens et al. 2008	Retrospective	Dual Top	1.6 / 2mm	8 / 10mm	21	21.4 years	50	17	Completion of treatment
Moon et al. 2008	Retrospective	Dual Top	1.6mm	8mm	209	20.3 years	480	78	8 months

Table 8. Study and patient characteristics of the reviewed studies of palatal implant survival.

Author	Kind of Study	Manufacturer	Diameter	Length	N Patients	Mean Age (± SD)	N TAD	N Failure	Loading Time
Jung et al. 2009	Prospective CT	Straumann	4.1 mm	4.2 mm	30	19.7 years	30	2	6 months
Sandler et al. 2008	RCT	Straumann	3.3 or 4mm	4mm	24	15.7 years	26	6	2.15 years ± 0.59
Feldmann & Bonde-mark 2008	RCT	Straumann	3.3mm	4mm	30	14.6 years ± 1.99	30	2	Completion of treatment
Männchen & Schätzle 2008	Prospective CT	Straumann	3.3 or 4mm	4 or 6mm	70	22.5 years ± 10.8	70	4	18.8 ± 10.7 months
Arcuri et al. 2007	Retrospective	Straumann	3.3mm	4 or 6mm	14	>20 years	14	3	22 Month 25 days
Crismani et al. 2006	Prospective CT	Straumann	3.3mm	4mm	20	26.4 years	20	2	12 weeks

Table 9. Study and patient characteristics of the reviewed studies of miniplate survival.

Author	Kind of Study	Manufacturer	Diameter	Length	N Patients	Mean Age (\pm SD)	N TAD	N Failure	Loading Time
Chen CH et al. 2008	Retrospective	Mondeal / Leibinger	2mm	5 to 9mm	194	25.1years \pm 8.7	171	8	During 3 year period
Cornelis et al. 2008	Prospective CT	Surgi-Tec / KLS Martin		5 or 7mm	97	23.7 years	200	15	1.5 \pm 0.7 years
Chen CH et al. 2007a	Retrospective	Leibinger	2mm	5 or 7mm	25	27.5 years	44	2	15 months
Kuroda et al. 2007	Retrospective	KeSei Medical Ind.	2.0 / 2.3mm	7 or 11mm	22	21.8 years	38	5	>1 year or completion of treatment
Choi et al. 2005	Retrospective	Martin	2mm	5mm	17	21.2 years	68	5	At least 6 months
Cheng SJ et al. 2004	Prospective CT	Leibinger / Mondeal	2 / 2.3 mm	5 or 7mm	44	29 years \pm 8.9	48	7	Completion of treatment
Miyawaki et al. 2003	Retrospective	Not specified	2mm	5	7	21.8 \pm 7.8	17	1	>1 year or completion of treatment

Table 10. Study and patient characteristics of the reviewed study of onplant risk factors.

Author	Kind of Study	Manufacturer	N TADs	N Failures	% Failures	Risk Factors	Estimated relative risk
Feldmann & Bondemark 2008	RCT	Nobel Biocare	29	5	17.2%	Surgical failure (1) Sensitive for anatomic restrictions (2) Poor oral hygiene (1) Loss of anchorage (1)	Not assessed

Table 11. Study and patient characteristics of the reviewed studies of mini-/microscrew risk factors.

Author	Kind of Study	Manufacturer	Diameter	Length	N TADs	N Failures	% Failures	Risk Factors	Estimated relative risk
Park et al. 2006b	Prospective	Stryker Leibinger	1.2mm	5mm	19	3	15.8%	Mandible > Maxilla	5.3 (95% C.I.: 1.7-16.7)
Park et al. 2006b	Prospective	Ostomed	1.2mm	6 to 10mm	157	10	6.4%	Inflammation Mobility within 8 month of loading	4.8 (95% C.I.: 1.7-13.9) 24.4 (95% C.I.: 4.8-125)
Park et al. 2006b	Prospective	AbsoAnchor	1.2mm	4, 6, 7, 8, 10mm	46	5	10.9%	Right site > left site	6.0 (95% C.I.: 1.6-21.7)

Wiechmann et al. 2007	RCT	AbsoAnchor	1.1mm	5, 6, 7, 8, 10mm	79	24	30.4%	Diameter (1.1mm > 1.6mm) Mandible > Maxilla	2.9 (95% C.I.: 1.2-7.4) 5.1 (95% C.I.: 2.2-12.1)
Wiechmann et al. 2007	RCT	Dual Top	1.6mm	5, 6, 7, 8, 10mm	54	7	13%	Lingually of the mandible > all other insertion sites	13.5 (95% C.I.: 3.9-46.6)
Motoyoshi et al. 2006	Prospective	Biodent	1.6mm	8mm	169	25	14.8%	5cm< Implant placement Torque<10 Ncm Maxilla = Mandible	11.7 (95% C.I.: 3.1-44.4) 2 (95% C.I.: 0.7-5.6)
Garfinkle et al. 2008	Prospective	Ostomed	1.6mm	8mm	41	8	19.5%	Early loading (within 1 week) = delayed loading (3-5 weeks) Maxilla = Mandible Direct placement > cortical notching	0.9 (95% C.I.: 0.2-4.4) 0.8 (95% C.I.: 0.2-4.2) 2.9 (95% C.I.: 1.1-7.6)

Table 12. Study and patient characteristics of the reviewed study of palatal implant risk factors.

Author	Kind of Study	Manufacturer / System	N TADs	N Failures	% Failures	Risk Factors	Estimated relative risk
Jung et al. 2009	Prospective	Straumann Palatal Implant®	30	2	6.7%	Surgical failures (2)	Not assessed
Sandler et al. 2008	RCT	Straumann Orthosystem®	26	6	23.1%	Surgical failures (6)	Not assessed
Feldmann & Bondemark 2008	RCT	Straumann Orthosystem®	30	2	6.7%	Surgical failures (1) Loss of anchorage >1mm (1)	Not assessed
Männchen & Schätzle 2008	Prospective	Straumann Orthosystem®	70	4	5.7%	Surgical failures (3) Heavy unilateral loading (1)	Not assessed
Crismani et al. 2006	Prospective	Straumann Orthosystem®	20	2	10%	Surgical failures (2)	Not assessed

Table 13. Study and patient characteristics of the reviewed study of miniplate risk factors.

Author	Kind of Study	Manufacturer	N TADs	N Failures	% Failures	Risk Factors	Estimated relative risk
Cornelis et al. 2008	Prospective	Surgi-Tec / KLS Martin	200	15	7.5%	Mandible (6/47) > Maxilla (9/153) Growing patients (11) > Adult patients (4) Incision in sulcus (3) > in attached gingiva (0)	2.3 (95% CI: 0.8-7.0) Not assessed Not assessed

6 DISCUSSION

6.1 Healing Process of the Palatal Implant

A randomized controlled clinical study was conducted to assess palatal implant stability over time for 2 different SLA surfaces during the first 84 days (12 weeks) following implant insertion.

To clinically assess implant osseointegration, resonance frequency analysis (RFA) was used to measure implant stability. This technique was proven to be capable of characterizing alterations in implant stability during early healing and it is sensitive enough to identify differences in longitudinal implant stability based on bone density at the implant recipient site (Barewal et al. 2003). The technique has also been demonstrated to be an accurate and valid method for early assessment of osseointegration (Huang et al. 2003).

Palatal implants in two test persons showed a significantly wider range of ISQ values over time than the others. This might be explained by an unscrewing of the implants during the early healing period when installing the transducer for RFA analysis. All the implants, however, were clinically stable at all time points and no movement was detected while performing the measurements. The reason for wider ISQ-variability of the two test persons thus remains open.

The changes in implant stability expressed by ISQ-value differences over time reflect the biologic events associated with the bone-implant interface. The mean ISQ values increased from insertion to day 7 for the modSLA group and from insertion to day 14 for the SLA cohort. These higher ISQ values after the implant insertion may be explained by primary mechanical stability, achieved by the press fit of the implant with a larger diameter (4.1mm) compared to the diameter of the last drill of 3.5mm (Schenk & Buser 2000).

In both groups, the high mean ISQ levels indicative of mechanical stability started to drop after one to two weeks after installation (Fig. 15). It can be assumed that the decrease in ISQ values corresponds to bone resorption, whereas an increase would be associated with bone formation. The faster decrease, just 7 days after implant installation of the modSLA-surface might be explained by its surface wettable characteristics enhancing the interaction between the implant surface and the biologic environment and thereby accelerating the biological processes also including earlier resorption (Kilpadi & Lemons 1994). Though, this difference could only be observed for the mean absolute ISQ-values, but not for the mean ISQ-value *changes* and may be interpreted with precaution.

After a small decrease (Δ ISQ = -1.5) (Fig. 18), the stability of the test implants with modified SLA-surface began to re-increase after 28 days (4 weeks). For the control implants, this transition point from bone resorption to apposition corresponding to an increasing stability occurred a week later, i.e. at 35 days after implant installation. The found change in the stabilization pattern with transition points after 28 and 35 days is later than reported in a previous clinical study using SLA palatal implants only, in which the transition was observed already after 21 days (Crismani et al. 2006). The difference in the findings has to be interpreted with caution and may be related to the different re-

search protocol and type of implants used. Crismani and co-workers used the old Orthosystem® palatal implants (Straumann AG, Basel, Switzerland) with a shoulder and a smaller diameter (see Fig. 4, page 23). Furthermore, the implants were loaded one week after installation and showed lower ISQ values compared to the present study. Unlike in the present study, the measurements were performed with a transducer long arm directly connected to the implant. The ISQ values of the SLA-type implants in the present study started at a higher level and had a greater decrease (-4.8 ISQ) by reaching the bottom line at transition point compared to those for the old Orthosystem® whose decrease was approximately -1.5 ISQ. In both studies, it took about 84 days (12 weeks) to reach the initially measured values of the implant stability quotient. For the mod SLA-surface, the values were reached already after 42 to 49 days (6 to 7 weeks), documenting a significantly enhanced healing process.

As the design of the latest palatal implant (see Fig. 4, page 23) is comparable to regular dental prosthetic implants, the changes in implant stability pattern during the early healing period might therefore be comparable. In a human clinical study using dental implants with SLA-surface as control and modSLA-surface as test implants, no difference in the transition time points were found when the implants were placed in the posterior maxillary area (Oates et al. 2007). For both types of fixtures the transition point was at 28 days. In the mandible, however, different transition points after 28 and 14 days, respectively, could be found for the control and the test implants (Oates et al. 2007). The present findings are in line with the clinical findings of dental implants in the mandible.

During the time period between the transition point and 84 days (12 weeks) after palatal implant insertion, the mean ISQ-value increased in both groups (Fig. 18). This finding can be explained by the increasing reinforcement by mature lamellar bone gradually replacing the initial woven bone thus providing secondary implant stability (Schenk & Buser 2000).

The old gold standard for the healing time up to load application used to be 3 months with the SLA implants. The same ISQ level is reached after 7 to 8 weeks with the mod-SLA implants (Fig. 18). After transition, mod-SLA implants re-established the initial ISQ-level much faster (42 days) than SLA implants did (63 days). It can therefore be assumed that a healing period of 2 months for SLA and 1.5 months for SLActive palatal implants is sufficient.

Several authors tried to investigate the effect of immediate loading on the stability of the implant and the corresponding bone to implant contact (BIC) rate. 8 implants have been inserted in 4 shepherd dogs and immediately loaded (Borbély et al. 2008). The BIC rate was higher after 6 months than after 4 weeks. Due to the small number of implants and dogs, the differences were not statistically significant. It is also questionable if the time intervals of bone healing in shepherd dogs are comparable to humans. Göllner and co-workers (2009) found 8.3% of failure in a group of 36 patients with immediate indirect loading with 3 N, whereas there was only one failure in a group of 40 patients loaded with the same protocol after 12 weeks. The BIC ratio was higher in the delayed loading group, but the differences again were not statistically significant. Also no statistical significance could be detected by Borsos and co-

workers (2008), as there were only 8 patients per group. But again, the BIC ratio was higher in the delayed group.

In a setup with immediate direct loading of the implants with a simple force of 2 N (Jackson et al. 2008), the ISQ level was significantly lower than at baseline, whereas it was significantly higher than baseline in a non-loaded control group.

Taking into account that there was a tendency of lower BIC rates of immediately loaded in all investigations, that there was also a higher failure rate of immediately loaded implants and that the ISQ levels were lower than at baseline, it seems to be advisable not to immediately load the implants, especially if direct forces or even direct moments are applied.

It was a challenge to find an appropriate statistical model for the evaluation of the healing process. From repeated measurements, the mixed model analysis appeared to be modelling an overall treatment effect of a structural change in the data over time. The Chow test is designed to be able to detect this special treatment effect (i.e., a decrease and subsequent increase in ISQ) and so was chosen as the most appropriate statistical model. Similar statistical analysis was used in a previous study (Oates et al. 2007). The findings from that analysis demonstrated differences in implant stability and healing process based on placement of the implant in the maxilla or mandible. This finding is suggestive of differences in bone quality between upper and lower arch that are affecting implant stability. Similar findings of interarch variations in implant stability, with greater changes in stability in the mandible than the maxilla, have been reported previously (Bischof et al. 2004; Oates et al. 2007). However, this is in contrast to previous investigations, in which implants placed in less dense bone types tended to have greater stability changes (Barewal et al. 2003; Meredith et al. 1996; Friberg et al. 1995). The contrasting findings remain to be elucidated. Based on the present findings, it could be demonstrated that the palatal area tends to show similar results as the mandible (Oates et al. 2007), which is in accordance with characteristics of the corresponding bone qualities.

In conclusion, the study supports the potential for chemical modifications of a roughened implant surface to positively influence biologic events during the early osseointegration process by increased wettability (Kilpadi & Lemons, 1994). This property seems to be associated with an enhanced bone apposition (Buser et al. 2004), which may lead to alterations in clinical loading protocols for dental implant therapy. Deducting from the presented results, it may be suggested, that SLA® type implants could clinically be loaded after 2 months and SLActive® types after 1.5 months. If an immediate loading of the implants has an impact on the time point of transition, must be evaluated in the future.

6.2 Supraconstruction and Clinical Handling of the Palatal Implant

The here presented supraconstruction is applicable for diverse orthodontic clinical situations by just adjusting the shape of the sectional wires that connect the supraconstruction to the molar attachments. The overall design can be easily adapted to any implant system whose supraconstruction is protected

against rotation. The appliance is easy to be fabricated and applied on patients in an orthodontic practice. It fulfils all the requirements listed in the introduction. Its versatility, which claims for only one single laboratory procedure, is superior to any other supraconstruction. However, the laboratory procedure is more complicated than with other methods (Crismani et al. 2002) and it might not be as efficient like other supraconstruction for single specific applications. A pedulum appliance with a sagittal screw for reactivation (Wehrbein & Göllner, 2008) is probably more efficient for molar distalisation, whereas a lingual power-arm (Wehrbein & Göllner, 2008) or a transpalatal arch (Jackson et al. 2008) with a direct line of force might be more efficient for molar protraction.

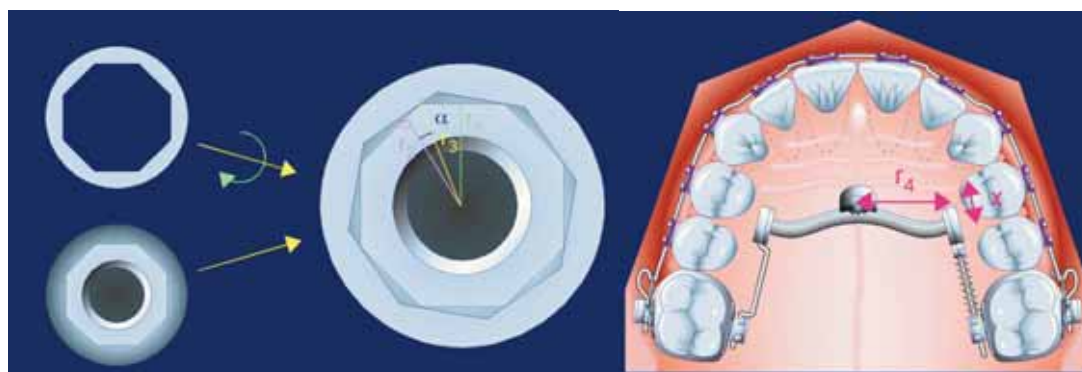


Fig. 25 Sagittal play due to manufacturing tolerances.

In some patients, a sagittal play of the supraconstruction was detected. This can be attributed to the manufacturing tolerances. The diameter tolerance of the implant is $+0/-20\mu\text{m}$, of the ortho-cap $+20\mu\text{m}/-0$. Therefore are r_1 and r_2 in extremis:

$$r_1 = 1.49\text{mm} \quad r_2 = 1.51\text{mm}$$

r_3 is the radius to the edges of the implants octagon.

$$r_3 = \frac{r_1}{\cos(22.5^\circ)}$$

$$\cos(\alpha) = \frac{r_2}{r_3} = \frac{r_2}{r_1} * \cos(22.5^\circ)$$

The maximum play β of the ortho-cap is:

$$\beta = 22.5^\circ - \alpha = 1.94^\circ$$

If r_4 is about 15mm, then

$$x = 2 * r_4 * \sin(\beta) \approx 1.0\text{mm}$$

If absolute anchorage of the molars is required, a slight sagittal pre-activation of the sectional wires is mandatory in order to avoid anchorage loss because

of manufacturing tolerances. The same applies to the new Palatal Implant®, which has a rounded triangle of the implant and a star for multiple positions of the ortho-cap.

With the Palatal Implant®, a supraconstruction cap with pre-welded transpalatal arch is also available. This can be adjusted chair-side and bonded to the palatal aspect of the premolars or molars. Only passive anchorage can be established and indirect forces need to be applied on the teeth to be moved. A slight pre-activation is then recommended, as the transpalatal arch is slightly resilient.

6.3 Survival and Success Rates of the Palatal Implant

Despite the small dimensions, orthodontic anchoring implants should remain stable under orthodontic loading in order to serve as absolute anchorage. Therefore, osseointegration is a prerequisite. Histological examination of bone specimens of explanted human palatal orthodontic implants revealed that osseointegration is indeed maintained during long-term orthodontic loading under clinical conditions (Wehrbein et al. 1998). This confirms the clinical experience that an adequate anchorage to withstand orthodontic loading is achieved with these small implants. In some cases, however, a premature loss of the implant before orthodontic loading has been noted and reported. In the present thesis (study I and III) this occurred in 4 cases out of a total 112 palatal implants. Premature loss may be attributed to the lack of adequate primary stability, which causes connective tissue encapsulation around the implant and consequently premature loss of the implant (Friberg et al. 1991; Lioubavina-Hack et al. 2006).

There is a substantial difference between orthodontic forces to palatal implants and occlusal forces to dental implants. While orthodontic forces are mainly continuous and horizontal or oblique, occlusal loads are intermittent and expected to be mainly vertical along the long axis of the implants/teeth. Naturally, the orthodontic forces should not have a negative impact on the peri-implant bone and impair the long-term stability of the implant. In experimental animal study, dental implants were inserted and subjected to well-defined continuous loading (Melsen & Lang 2001, Hsieh et al. 2008). None of the implants lost osseointegration, but loading significantly influenced the turnover of the alveolar bone in the vicinity of the implants. When the strain exceeded a certain threshold level, the remodelling of the bone resulted in a net loss. It can be speculated that the reason for the one and only failure of an initially successfully osseointegrated implant in the present study was due to a unilateral heavy and excessive orthodontic loading.

In addition to the difference on loading pattern between palatal and dental implants, there is also a substantial difference how success of a prosthetic vs. orthodontic implant can be judged. Most of the studies reporting on survival and failure rates of implant deal with surrogate biological endpoints (Karoussis et al. 2004) or technical failures (Pjetursson et al. 2007). As prosthetic implants have an undefined clinical endpoint (death of the patient), a clinical success starts with installation of the prosthetic unit after the healing period.

On the other hand, palatal implants are temporary anchorage devices and are in most cases removed after use. Their loading time is shorter and is defined by the treatment plan and the end for anchorage need. Success is not achieved by the installation and loading, but by the removal of the supraconstruction due to finished anchorage need. Therefore, comparison of survival and success rates of prosthetic dental implants with those of temporary anchorage devices has a limited value. Early failures during the healing period can however be directly compared between prosthetic and orthodontic implants. In the present study, one implant did not fulfil the criterion of success at the completion of the healing period. This low failure rate is consistent with the result reported for prosthetic implants (Buser et al. 1997).

The present study revealed a survival rate of 98.6% after more than two years (Table 4) of orthodontic loading. This rate is higher than the 90% survival rate of 20 similar but early loaded Orthosystem® palatal implants (Crismani et al. 2006) and the 84.8% for 21 short epithetic implants with a machined surface loaded for approximately 23 months (Bernhart et al. 2001). The report by Bantleon et al. (2002) of 40 Orthosystem® palatal implants indicated a 92% early survival rate of osseointegration and loading.

As the survival rates of the above mentioned studies are based on ongoing patient data, the present study is the first analyzing 64 successfully loaded *and* removed Orthosystem® palatal implants at completion of the orthodontic anchorage need. The success rate of the 64 patients was 97.1%. Two implants were lost; one during early healing phase, one under loading.

Although the palatal implants used in this study had slightly smaller dimensions than traditional dental implants, it could clinically be shown that they are able not only to resist forces but also moments in the horizontal dimension.

Orthodontic palatal implants with a rough surface and rotation resistant supraconstruction provide a versatile option in orthodontic anchorage as they reduce the need for patient compliance and offer increased clinical flexibility and effectiveness. These temporary anchorage devices provide reliable absolute orthodontic anchorage and hence, can be considered to be superior to other orthodontic tooth-borne anchorage devices. Nevertheless, it must be kept in mind that skeletal anchorage in general has no skeletal growth modification potential and must therefore be carefully considered against extraoral or functional appliances in growing individuals.

6.4 Insertion Site of the Palatal Implant

In the presented long time survival study (study III), the majority (85%, Table 3, page 55) of the implants were placed in the paramedian region to avoid possible disturbance of the palatal suture. This is of interest mainly in growing patients (Glatzmaier et al. 1995; Wehrbein et al. 1996a+b, Asscherickx et al. 2005). It is suggested from animal experiments (Asscherickx et al. 2005, 2008) that the placement of an implant in the median palatal suture would impair transversal maxillary growth. Although, this yields only 0.3 to 0.5mm per year during puberal growth spurt in humans (Björk & Skieller 1974, 1977, Korn & Baumrind, 1990, Gandini & Buschang 2000) or a total of about 1.6mm

between 6 and 18 years of age (Işeri & Solow 2000). From this point of view, a median placement is possible from the age of 18.

But the sutural area should also be avoided because residual connective tissue could compromise implant stability during the conversion from primary to secondary stability (Cafiero et al. 2008). In the RFA analysis study, all implants were placed in the median suture. The incisal nerve channel has been found to reach rather far distal, especially in hypodivergent patients. This is an additional argument for paramedian placement. But as this data has not been systematically collected, it must be the topic of further investigation.

A paramedian placement of the implant should be performed on the respective side, on which major sagittal anchorage is needed during orthodontic therapy. Thereby, the axial moments acting on the implant are reduced by lever arm reduction.

Vertical growth of the maxilla is not affected by any placement of an implant in the palate. The most important vertical growth changes are the result of displacement of the maxillary complex and subsequent sutural growth and surface remodelling processes. The sutural lowering of the maxillary complex as well as the apposition at the orbital floor and at the infrazygomatic crest are not affected by implant installation in the palate. The resorptive lowering of the nasal floor around the implant, however, and the increase of the maxillary alveolar bone height might be influenced, especially, if teeth are attached to the implant. This might result in an anterior rotation of the mandible, which is favourable in high angle, but contraindicated in hypodivergent patients. However this growth impairment is limited to values of less than 1mm per year during growth spurt (Björk 1977).

For prosthetic implant insertion, dental computer tomography has been proposed by several authors (Smalley 1995, Smalley & Blanco 1995, Lindh et al. 1995). For palatal implant presurgical diagnostics, lateral cephalograms (Giancotti et al. 2003a, Arcuri et al. 2007) and dental computer tomography (Bernhart et al. 2000, Gahleitner et al. 2004, Wexler et al. 2007) have been used, partly in combination with surgical stents. In the anterior region of the palate, bone volume is greater (Crismani et al. 2005), but there is a danger of damaging incisor roots or penetrating the incisal nerve. In the posterior region, this danger is small, but bone height is reduced. The greatest mean thickness was identified to be about 6 to 9mm posterior to the incisal foramen in the mid-sagittal plane (Bernhart et al. 2000). Avoiding the midpalatal suture, the area suitable for implant placement is, therefore, located 6 to 9 mm posterior to the incisal foramen and about 3mm lateral to the mid-sagittal plane. If the necessary bone volume for an orthodontic implant installation is defined as 4 mm or more (Bernhart et al. 2000), 95% of the patients present adequate vertical bone volume for accommodating palatal implants. This is in agreement with other clinical reports (Schiel et al. 1996).

For all but one of the 112 palatal implants inserted in this thesis (study I and III), lateral cephalograms have been the only diagnostic tool, and no stents have been used. Computer tomography and a surgical stent were mandatory in only one case with reduced vertical bone height and an impacted canine.

6.5 Survival Rates of Different TADs

The systematic review of the literature for the evaluation of survival and failure rates of skeletal anchorage devices such as onplants, miniplates, palatal implants and mini- or microscrews after a loading time of at least 12 weeks showed that no RCTs were available comparing all types of these TADs. Excluding other languages than English did not have a major impact on the data collection as there were only 4 purely chinese and one purely german article to be found. The german article was a case presentation and would have been excluded in the further procedure.

RCTs comparing the four different TAD types at once are very difficult to conduct and will probably never be done. Therefore a lower level of evidence, i.e. RTCs comparing some TADs to conventional orthodontic anchorage devices (COAD), prospective and retrospective cohort studies were included. Before TADs were developed, COAD offered the only possibility to provide anchorage for controlling unwanted tooth movements. A major disadvantage of many of these strategies, such as extraoral traction or intermaxillary elastics, is patient cooperation, which is unpredictable (Nanda & Kierl 1992). Hence, the comparison of survival and failure rates of all the different types of TADs is of great prognostic value in orthodontic treatment planning. But it has to be remembered that TADs are usually inappropriate in growing patients in whom craniofacial growth modification is often additionally needed.

There were only two randomized clinical trials (Feldmann & Bondemark 2008; Sandler et al. 2008) comparing the efficacy of COAD to TADs (palatal implants or onplants) within their patient cohorts. Sandler et al. (2008) reported significantly higher proportions of failed palatal implants than Feldmann & Bondemark (2008). It is noteworthy that most of the failed palatal implants had been placed during the initial phase of the investigation. Therefore the surgeons had probably been at an early phase of the learning curve of this “relatively new” technique (Sandler et al. 2008), inherent with high failure rates. The same problem was also reported in a retrospective study by Arcuri et al. (2007). In contrast to conventional dental implants, the emergence profile of the Orthosystem® implants had a 90-degree shoulder offering a danger to over-wind with a subsequent loss of the primary stability (Fig. 4, page 23). This feature of the Orthosystem® caused indeed major surgical sensitivity. If not considering the two above-mentioned studies with increased failure rates due to the learning curve of the surgeons, palatal implants showed a failure rate of only 6.7%.

For the current Straumann palatal implants® (Fig. 4, page 23), the emergence profile has been modified to a slightly concave, tulip-shaped conical design, which reduces the risk of over-winding the implant during installation. The only prospective study available on this new generation palatal implant (Jung et al. 2008) reports very favourable survival rates (93.3%). In our own experimental human study (Study I), no problems were observed as all inserted palatal implants yielded a high primary stability and remained stable during the whole observation period. When summing up all studies in meta-analysis, the failure rate of the palatal implant was estimated at 10.5% (95%C.I: 6.1%-18.1%) (Fig. 23).

Compared to COADs (headgear, transpalatal bar), palatal implants provided equal (very compliant patients, Sandler et al. 2008) or statistically significant better clinical anchorage reinforcement (Feldmann & Bondemark 2008). There were more technical problems and a significantly higher failure rate with the Onplant® system and therefore the palatal implant was considered the anchorage system of choice in the maxilla (Feldmann & Bondemark 2008). Additionally, the palatal implant was better tolerated than the onplant in terms of pain intensity, discomfort and analgesic consumption (Feldmann et al. 2007) as there is no need for mucoperiosteal flap surgery for its insertion and removal.

After an observation period of at least 12 weeks, miniplates showed a higher survival rate of 543 out of 586 (92.7%) compared to palatal implants. Again, it has to be realized that the difference was mainly due to early surgical failures in two palatal implant studies (Arcuri et al. 2007, Sandler et al. 2008). Unfortunately, no studies are available comparing the efficacy of miniplates with palatal implants. Furthermore, it has to be kept in mind that for achieving the same anchorage in the maxilla, 2 miniplates have to be installed instead of one palatal implant, which increases the risk for failure per jaw to 14.1% (95% C.I. 10.5% - 18.8%) for the miniplates.

Even though the majority of the included studies deal with miniscrews, none of the studies disclose why a certain screw length or diameter had been chosen based on clinical or diagnostic criteria. Only Wiechmann and his co-workers (2007) randomized clinical trial compares two different screw diameters (1.1 and 1.6mm) of various lengths to each other. Screw diameter was found to be one decisive factor for success or failure. This is in accordance with findings from this systematic review, showing a approximately 2-fold increase failure rate for miniscrews of a maximum diameter of 1.2mm compared to miniscrews of a diameter of 2mm or more, and two other retrospective studies (Chen et al. 2007a, Miyawaki et al. 2003). But in contrast to two other retrospective study (Chen et al. 2006a, Tesng et al. 2006) those RCTs failed to identify the screw length as a possible risk factor. Too many different screw diameters and insertion sites had been included provoking a wide scattering of the data.

Several other reviews on temporary anchorage devices have been published in the last years. Unfortunately, most of them give only an overview, but do neither include a systematic data collection nor a meta-analysis (Heyman & Tulloch 2006, Papadopoulos et al. 2007, Sherwood 2007, Wehrbein & Göllner 2007, 2008, Lee et al. 2008, Leung et al. 2008, Rossouw & Buschang 2009).

There are four reviews with systematic data collection. In contrast to the present investigation, Janssen et al. (2008) also included animal studies in their review. Janssen et al. (2008) as well as Hoste et al. (2008) did not describe any inclusion or exclusion criteria. Crismani et al. (2010) included german literature as well but included studies only with a minimum of 30 miniscrews and data on the patients and fixture's characteristics. Reynders et al. (2009) used the *Cochrane Handbook for Systematic Reviews of Interventions* and restricted the inclusion criteria to a minimum of 10 fixtures per study, clear definition of success, a minimum of 3 months of fixture loading and miniscrews with a diameter smaller than 2.5mm.

They mentioned that 6 out of 19 included studies were lacking clarity and had poor methodology. Therefore they did not include a meta-analysis. Nevertheless they concluded, that most studies report a miniscrew success rate of higher than 80% if mobile and displaced implants were included as successful. Janssen et al. (2008) indicated a wide range of success of miniscrews between 70% and 100% instead of doing a meta-analysis. The only meta-analysis that was performed on miniscrews (Crismani et al. 2010), found an average success rate of $83.8\% \pm 7.4\%$, which is almost identical to the present findings. The inclusion criteria in the study of Crismani were quite comparable. Unfortunately, no other TADs were examined.

Although some authors report significantly higher success rates of miniscrews in the maxilla than the mandible (Cheng et al. 2004, Park et al. 2006b, Chen et al. 2006a), the present meta-analysis could not detect a significant difference due to the scattering of the data in the other publications examined. This supports Reynders' (2009) view. Cheng et al. (2004) did not differentiate between freestanding miniscrews and miniscrews used for miniplate fixture. Park et al. (2006b) found 86.4% of success for single miniscrews in the mandible and 96.0% in the maxilla, whereas Chen et al. (2006a) found 81.3% in the mandible and 86% in the maxilla. Combining the data of the last two studies, there was 91.6% success in the maxilla and 85.2% in the mandible.

Palatal implants as well as miniplate systems allow changes of the force vectors without the need for repositioning of the TAD and they tolerate significant moment application. Palatal implants and miniplates are associated with a statistically significant 1.9-fold lower risk (95% C.I. 1.06-2.78) for failures than miniscrews. This is supported by Janssen and co-workers (2008), who found about 10% difference of success between miniplates and single miniscrews. This difference was not statistically significant, though. Cheng et al. (2004) additionally found a clear tendency for shorter survival times of single miniscrews versus miniplates. The Kaplan-Meier analysis displayed new failures even after one year of loading. After such a long period of time, a change of treatment concept due to anchorage failure might be impossible and the treatment goals are thus endangered.

As there is a risk that miniscrews do not remain stationary under orthodontic forces, a safety zone for root or nerve proximity is required (Liou et al. 2004, Wang & Liou 2008). This could further restrict possible insertion sites, limit the amount of tooth movement and/or miniscrews have to be repositioned several times during treatment, further decreasing the success rate. TADs are expected to be in place for a long time if patients are undergoing extensive orthodontic corrections. During this time, force vectors may need to be varied or the roots of the teeth to be moved may need to slide past the anchors. Palatal implants or miniplates should be the TADs of choice in such cases.

It seems that all TADs have the potential to provide almost absolute anchorage, which enables orthodontic tooth movements that are almost impossible with conventional anchorage methods. In addition, the problem of patient compliance is simplified.

6.6 Risks Factors Associated with TAD Failures

Retrospective studies by nature cannot establish causal or temporal relationships, but may point to factors influencing early failures of TADs, and may be considered “risk indicators”. Many risk indicators for TAD failures such as inflammation (Miyawaki et al. 2003, Choi et al. 2005, Park et al. 2006b, Chen et al. 2008), cortical bone thickness (mandibular plane angle, placement torque) (Miyawaki et al. 2003, Motoyoshi et al. 2006, Chen et al. 2008), mandibular arch (Park et al. 2006b, Chen et al. 2008), non-keratinized mucosa (Cheng et al. 2004), root proximity (Kuroda et al. 2007), and patients age (Chen et al. 2007b) have been described in the literature. There also seems to be some evidence that miniscrews with a delayed loading protocol (Chen et al. 2008) show higher and with flap surgery insertion (Herman et al. 2006) a lower survival rate. However, the determination of true risk factors requires prospective longitudinal studies.

No randomized controlled clinical trials were available comparing all different types of TADs. Therefore, studies with a lower level of evidence, i.e. RTCs comparing some TADs to conventional orthodontic anchorage devices (COAD) and prospective cohort studies were included in this systematic review. In contrast to study IV, no retrospective studies were allowed in order to evaluate true risk factors.

The knowledge of risk factors leading to an early loss of TADs is an important factor for decision making in orthodontic treatment planning.

The risk factors identified in these studies could be divided into screw/implant factors, host factors, procedure and environmental management factors.

6.6.1 Onplants®

There was only one study fulfilling the inclusion criteria for onplants (Feldmann & Bondemark 2008). Onplants are placed subperiostally and are supposed to adhere to bone. Due to the fact that an onplant is initially just stabilized by the pressure of the soft tissue and the periosteum, it may not remain stable during the healing process and therefore not osseointegrate. Narrow and high palates can cause an inappropriate contact of the disc shaped base of the attachment to the bone surface. As a consequence onplants may become tilted during osseointegration and they might therefore not be usable due to mal-positioning. The Onplant®-system appeared to be more sensitive for anatomic restrictions and surgical technique. Improper contact to the bone surface and insufficient adhesion make this anchorage type also sensible to forces during manipulation of the suprastructure. However, once osseointegrated, they remain stable during treatment.

6.6.2 Miniscrews

Even though miniscrews have been used for more than a decade, only one randomized clinical trial (Wiechmann et al. 2007) and three prospective cohort studies (Park et al. 2006b, Motoyoshi et al. 2006, Garfinkle et al. 2008) provided data on risk factors associated with an increased failure rate.

The only significant factor influencing the failure rate of miniscrews was the diameter. A decrease in diameter was associated with a decrease in the cumulative survival rate, whereas the length of implants had no statistically significant effect on implant failure rates (Wiechmann et al. 2007). Two studies (Chen et al. 2006a, Tseng et al. 2006) showed a tendency for longer screws to be more stable than shorter ones, though.

The simple force load capacity of an implant is proportional to the contact area to the surrounding bone (Büchter et al 2005). But hardly any publications deal with the torque load resistance of miniscrews. Concerning this type of axial moment application, Buser et al. (1999b) tested the removal torque values of osseointegrated implants with different surface conditions in the minipig after 4, 8 and 12 weeks of healing. The removal torque values found (13 - 26 Ncm for machined surfaces) are much higher than the ones generated in clinical orthodontics. Still, miniscrews are significantly smaller than the investigated design of 4.05mm of diameter.

The removal torque value of a cylindrical fixture is proportional to the maximum sharing stress τ_{\max} at the bone-implant-interphase and equals the maximum tangential sharing force F_{\max} divided by the area A of the interphase:

$$\tau_{\max} = \frac{F_{\max}}{A}$$

The interphase A is proportional to the screw diameter D and length L , whereas the maximum sharing force F_{\max} is proportional to the screw diameter D only:

$$A \propto D * L \qquad F \propto D$$

Putting these equations into the first, the maximum sharing stress τ_{\max} becomes proportional to the square diameter of the screw but only linearly proportional to the length:

$$\tau_{\max} \propto D^2 \qquad \tau_{\max} \propto L$$

It is therefore comprehensible, that the length of the screw is not detected as a significant risk factor. Naturally, the above theoretical calculation is valid in a homogenous environment, which bone does not represent. Probably the compact bone is more important for the stability of a miniscrew than the spongy bone. Buser et al. (1999b) also found that the bone density shows local variation and hence also differences in the implant removal torque values.

When the removal-torque values for machined surfaces (13 Ncm for an implant of 8mm length and 4.05mm diameter) reported by Buser and co-workers (1999b) are re-calculated by the use of the deduced formulas, removal-torque values for miniscrews can be calculated as shown in the Fig. 26.

Length of a miniscrew

		4	5	6	7	8	9	10	11	12	13	14
Diameter of a miniscrew	1.0	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4
	1.1	0.5	0.6	0.7	0.8	1.0	1.1	1.2	1.3	1.4	1.6	1.7
	1.2	0.6	0.7	0.9	1.0	1.1	1.3	1.4	1.6	1.7	1.9	2.0
	1.3	0.7	0.8	1.0	1.2	1.3	1.5	1.7	1.8	2.0	2.2	2.3
	1.4	0.8	1.0	1.2	1.4	1.6	1.7	1.9	2.1	2.3	2.5	2.7
	1.5	0.9	1.1	1.3	1.6	1.8	2.0	2.2	2.5	2.7	2.9	3.1
	1.6	1.0	1.3	1.5	1.8	2.0	2.3	2.5	2.8	3.0	3.3	3.6
	1.7	1.1	1.4	1.7	2.0	2.3	2.6	2.9	3.1	3.4	3.7	4.0
	1.8	1.3	1.6	1.9	2.2	2.6	2.9	3.2	3.5	3.9	4.2	4.5
	1.9	1.4	1.8	2.1	2.5	2.9	3.2	3.6	3.9	4.3	4.6	5.0
	2.0	1.6	2.0	2.4	2.8	3.2	3.6	4.0	4.4	4.8	5.2	5.5
	2.1	1.7	2.2	2.6	3.1	3.5	3.9	4.4	4.8	5.2	5.7	6.1
	2.2	1.9	2.4	2.9	3.4	3.8	4.3	4.8	5.3	5.8	6.2	6.7
	2.3	2.1	2.6	3.1	3.7	4.2	4.7	5.2	5.8	6.3	6.8	7.3
	2.4	2.3	2.9	3.4	4.0	4.6	5.1	5.7	6.3	6.8	7.4	8.0
	2.5	2.5	3.1	3.7	4.3	5.0	5.6	6.2	6.8	7.4	8.0	8.7
	2.6	2.7	3.3	4.0	4.7	5.4	6.0	6.7	7.4	8.0	8.7	9.4
	2.7	2.9	3.6	4.3	5.1	5.8	6.5	7.2	7.9	8.7	9.4	10.1
	2.8	3.1	3.9	4.7	5.4	6.2	7.0	7.8	8.5	9.3	10.1	10.9
	2.9	3.3	4.2	5.0	5.8	6.7	7.5	8.3	9.2	10.0	10.8	11.7
3.0	3.6	4.5	5.3	6.2	7.1	8.0	8.9	9.8	10.7	11.6	12.5	
3.1	3.8	4.8	5.7	6.7	7.6	8.6	9.5	10.5	11.4	12.4	13.3	
3.2	4.1	5.1	6.1	7.1	8.1	9.1	10.1	11.2	12.2	13.2	14.2	
3.3	4.3	5.4	6.5	7.6	8.6	9.7	10.8	11.9	12.9	14.0	15.1	
3.4	4.6	5.7	6.9	8.0	9.2	10.3	11.5	12.6	13.7	14.9	16.0	
3.5	4.9	6.1	7.3	8.5	9.7	10.9	12.1	13.3	14.6	15.8	17.0	
3.6	5.1	6.4	7.7	9.0	10.3	11.6	12.8	14.1	15.4	16.7	18.0	
3.7	5.4	6.8	8.1	9.5	10.9	12.2	13.6	14.9	16.3	17.6	19.0	
3.8	5.7	7.2	8.6	10.0	11.4	12.9	14.3	15.7	17.2	18.6	20.0	
3.9	6.0	7.5	9.0	10.5	12.1	13.6	15.1	16.6	18.1	19.6	21.1	
4.0	6.3	7.9	9.5	11.1	12.7	14.3	15.9	17.4	19.0	20.6	22.2	

Fig. 26 Re-calculations of the removal-torque values for “machined” surfaces found by Buser et al. (1999b). The colours indicate different torque ranges: red < 1Ncm < orange < 2Ncm < yellow < 3Ncm < white < 4Ncm < blue < 5Ncm < green

The red framed cells correspond to the 20, 10, 0 and 0% failure rates found by Tseng et al. (2006).

If for example a miniscrew with a diameter of 1.6mm and a length of 6mm is used, the calculation is:

$$13Ncm * \left(\frac{1.6mm}{4.05mm}\right)^2 * \left(\frac{6mm}{8mm}\right) = 1.5Ncm \text{ (see Fig. 26)}$$

The red framed cells indicate the failure rates of the study by Tseng et al. (2006). They used miniscrews with a diameter of 2mm and found 20% of failure for the length of 8mm, 10% of failure for 10mm, and 0% of failure for 12 and 14mm. This might indicate, that there is a critical threshold moment level of about 4Ncm. In a preliminary study (Chen et al. 2006c), 50 % of the removed miniscrews yielded a removal torque of 8.7Ncm. But in this study, very long miniscrews (up to 17mm) have been used and a large difference between maxillary and mandibular removal torques was noted. Therefore, no conclusive statement can be made at this time. It nevertheless would be advisable to use the thickest and longest possible screw (without contacting neighbouring roots). Bi-cortical insertion could eventually further increase the stability.

Primary stability of a miniscrew, as a prerequisite for osseointegration, is not only affected by the screw diameter (Holmgren et al. 1998), but also by the bone stiffness (Meredith 1998). This points to a correlation of the implant placement resistance and bone density (Friberg et al. 1995). In some cases there is an early failure of miniscrews shortly after installation and orthodontic loading. This loss may be caused by the lack of sufficient primary stability which causes an inappropriate healing (Friberg et al. 1991, Lioubavina-Hack et al. 2006). Additionally, hoop stresses, which are generated around the dental implant threads during insertion, may be beneficial in enhancing the primary stability of the implant (Meredith 1998). However, it must be kept in mind that such stresses can be excessive, resulting in ischemia and local necrosis of the bone. Using 1.6-mm diameter mini screws of 8mm length the ideal implant placement torque (IPT) was identified to be within a range from 5 to 10Ncm (Motoyoshi et al. 2006). IPT values below or above these thresholds were associated with an 11.7-times higher risk for early failure. In situations with excessive IPT due to the bone stiffness and cortical bone thickness, pre-drilling or cortical notching might be considered (Motoyoshi et al. 2006, Garfinkle et al. 2008).

Excessive implant placement torque might also be the reason for the 5-times higher risk for failure in the mandibular when compared to maxillary insertion sites found in two studies (Park et al. 2006b, Wiechmann et al. 2007). The lower jaw has a thicker and more dense cortical bone than the maxilla (Park 2002) carrying the risk for overheating of the bone during drilling or causing excessive stress during miniscrew installation. In addition, miniscrews placed in the posterior part of the mandible can easily be irritated by food during chewing. These factors might negatively affect the clinical survival of miniscrews (Park et al. 2006b). Two other evaluated prospective cohort studies (Motoyoshi et al. 2007, Garfinkle et al. 2008) were not able to confirm these findings, though.

Despite of any critical loading or tipping force, some mini screws became loose after a certain period of loading. The applied forces should, however, not have a negative impact on the peri-implant bone and impair the long-term prognosis of the mini screw. Büchter et al. (2005) showed that excessive tipping moments at the bone edge may lead to screw loosening and early failure. Once a mini screw has become mobile, there is an almost 25-time likelihood of the screw to fail. Therefore, controlled clinical trials are encouraged taking the applied tipping moments at the bone level into account.

Management factors include compromised oral hygiene and consequently inflammation or infection and excessive load. Only inflammation was identified to increase the risk for failures by 4.8 times (Park et al. 2006b). To ensure success, it is important to prevent inflammation around the miniscrews. Screws placed in the patient's left side showed a 6 times lower failure risk than placed on the right side. This might be comprehensible by better hygiene on the left side of the dental arch by right-handed patients, who are most of the population (Tezel et al. 2001). Oral hygiene did not directly affect survival, but local inflammation around the screw implants did. Not only bad oral hygiene but also weak non-keratinized soft tissue around the neck of the screw implant can cause local inflammation. Once inflammation arises, it tends to persist in non-keratinized mucosa areas (Park et al. 2006b).

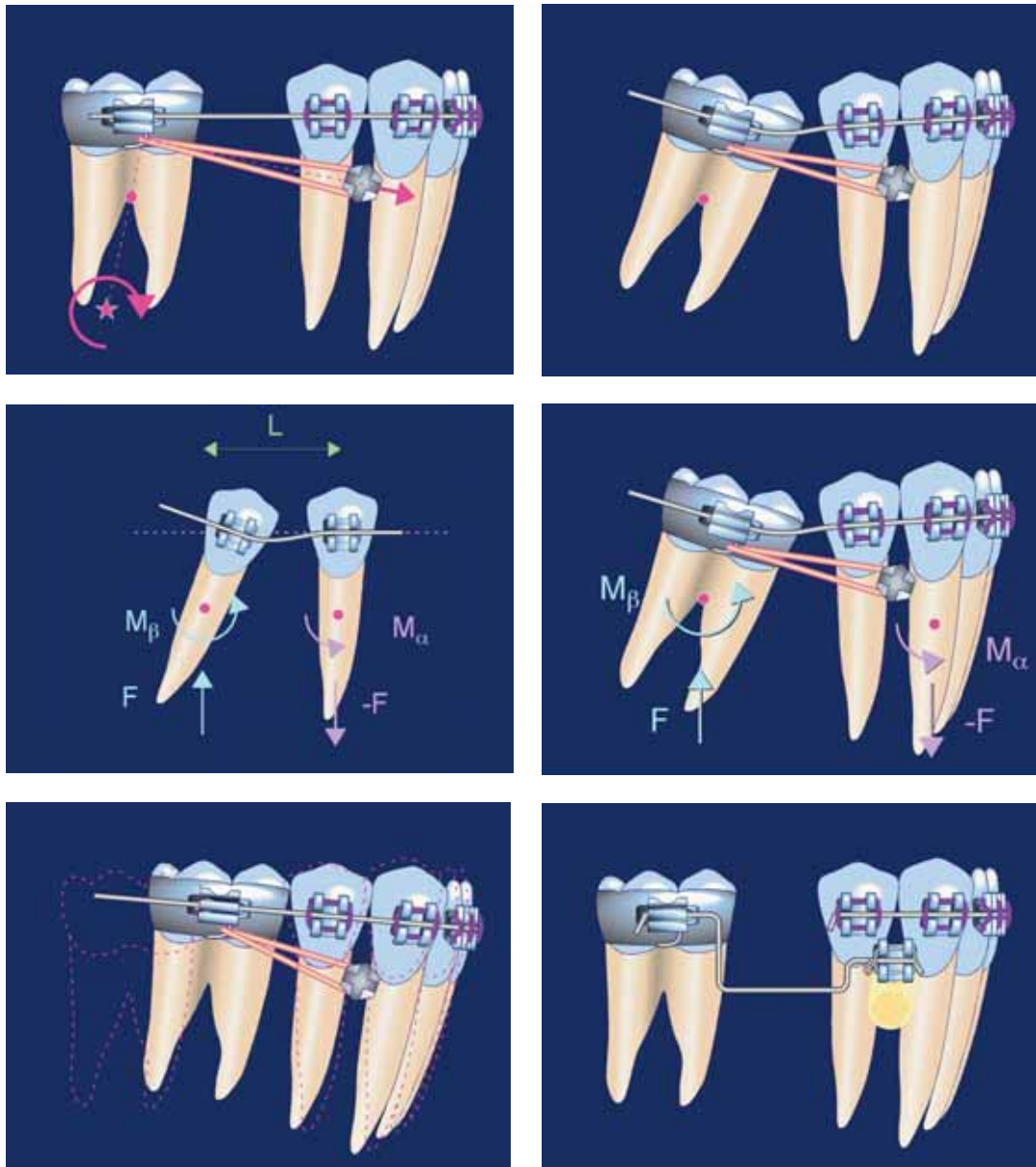


Fig. 27. Biomechanical side effects of space closure with a single miniscrew.

- 27a: If a molar is to be protracted and the force is applied above the centre of resistance, a mesial tipping will be the consequence.
- 27b: The arch wire is deflected and continuously (stiff wire) or subsequently (resilient wire) counteracts this tipping.
- 27c: The setup corresponds to a Burstone class III mechanical system.
- 27d: Uprighting of the molar will result in an extrusive force acting on the molar and an intrusive force acting on the anterior teeth. There is no biomechanical difference between a continuous and subsequent uprighting.
- 27e: Setup after molar uprighting. The created molar extrusion will cause a premature contact resulting in an additional bite opening by mandibular autorotation.
- 27f: Two primary interconnected miniscrews can tolerate moments to a certain extent and can therefore be used to control the vertical position of the molar without side effects on the anterior teeth.

Miniscrews are often used to close agenesis spaces in the lower jaw. Besides the fact that this requires a lot of secure anchorage, which cannot be guaranteed by a miniscrew system (Wehrbein & Göllner, 2008), there can be additional vertical side effects as displayed in Fig. 27. If the sagittal force is



Fig. 28. Clinical setups for molar Mesialization with multiple miniscrews.
28a: Two primary interconnected miniscrews with a bonded bracket for molar mesialization without extrusion.
28b: Detail of the bonded part.
28c: X-ray of the two screws. The space between the roots is a limiting factor.
28d: Slicing of the deciduous second molar in order to allow further protraction.
28e: Final position of the molar in class I after extraction of the second deciduous molar.
28f: Occlusal view of the same situation.
28g: Alternative setup with one miniscrew mesial and one distal of the anchor tooth.
28h: Occlusal view of the same setup (Pictures g and h courtesy of Dr. P. Goellner, Bern)

applied eccentric (Fig. 27a) to the centre of resistance (either because an application of a power arm is impossible or because the orthodontist is not aware), a mesial tipping (and mesial rotation) of the molar will be the consequence (Fig. 27b). The archwire either continuously (when a very rigid wire is used) or subsequently (in case of a more resilient wire) counteracts this

mesial tipping by developing a β -uprighting moment. No matter if the uprighting is continuous or subsequent, it corresponds to a Burstone class III system (Smith & Burstone 1984, Fig. 27c). This is the reason why the molar is extruded and the anterior teeth intruded during the molar mesialization (Fig. 27d). The extruded molar will cause a premature contact (Fig. 27e) with a subsequent additional autorotation of the mandible aggravating this problem. Reynders et al. (2009) state: "Mini-implants have been proposed as an alternative for certain orthognathic surgical procedures, but could also be its cause when uncontrolled biomechanics area applied." Even if the first premolar is primarily attached to the screw and the force only indirectly exerted on the molar, the consequences will be the same, as miniscrews cannot sufficiently tolerate axial moments (Chen et al. 2006c). A primary blockage of two miniscrews (Fig. 27f) transforming the necessary α -moment to a couple of simple forces, can tolerate the moment to a certain extent and is therefore capable of counteracting the molar extrusion.

The clinical application (Fig. 28a to f) and an alternative setup (Fig. 28g and h) are displayed. If these setups of primary screw blockage provide a higher level of success, must be the topic of further investigation.

6.6.3 Palatal implants

In the present study, only one loaded palatal implant was lost under heavy unilateral, orthodontic loading (Study III). All other failed implants were lost during the healing phase prior loading and are considered as surgical failures (Table 12). It seems that the surgical procedure of the palatal implant insertion including the special 90° shoulder design of the emergence profile of the Straumann Orthosystem® represented the highest risk factors for early loss. But the danger of "over-winding" the implant during installation with a subsequent loss of the primary stability is overcome in the new Palatal Implant® (slightly concave, tulip-shaped conical emergence profile; Straumann AG, Basel, Switzerland). From a clinical point of view, once osseointegrated, palatal implants remain stable during treatment and proved to well resist orthodontic forces and moments. Neither host nor management factors have been identified as risk factors in the five evaluated studies.

6.6.4 Miniplates

As miniplates are fixed to bone by two or more mini screws, these TADs face similar risk factors as single mini screws. Increased mobility has more frequently been reported in the mandible than the maxilla, possibly related to the flap design (Cornelis et al. 2008). The initial mandibular surgical protocol was therefore modified during the study and the releasing incision was placed in the attached gingiva instead of the sulcus. No further failures were observed after this change.

It is apparent that soft tissues play an important role in implant stability. Mucosal penetration of the miniplate arm at the mucogingival junction or 1 mm within the attached gingiva enables tight closure of the tissues, which appears to be necessary for good soft-tissue healing. On the other hand, placement of

a miniplate so that the attachment arm is localized in the non-keratinized gingiva increases the risk for inflammation and eventual early failure. Proper oral hygiene is also a pre-requisite for success (Cornelis et al. 2008).

The failure rate due to mobility was reportedly higher in growing patients than in adults. Although the surgeons were instructed to place the attachment arm penetrating the tissue at the mucogingival junction, this was found to be more difficult in young patients, because the alveolar height tends to be still shallow, the width of attached gingiva less, and therefore access to the bone restricted.

6.6.5 Conclusions

On the basis of the systematic review it is concluded that the surgical procedure and the anatomical situation represent the highest risk for early failure of onplants. For miniscrews, screw diameter (Wiechmann et al. 2007), implant placement torque (Motoyoshi et al. 2006), mobility, the patient's right side and inflammation (due to bad oral hygiene and weak non-keratinized gingiva; Park et al. 2006b) were associated with an increased miniscrew failure rate. The mandible was identified as risk factor in two studies (Park et al. 2006b, Wiechmann et al. 2007). In all Orthosystem® studies, the surgical insertion procedure including the special design of the emergence profile represented the highest risk factor for early loss. However, a new modified implant with the purpose of reducing these risks has been introduced and showed very favourable clinical results (Jung et al. 2008). For miniplates, installation in non-keratinized gingiva, in the mandible and growing patients were associated with an increased risk for failure.

There is only one single systematic review trying to assess the risk factors of TADs (Hoste et al. 2008). The mentioned risk factors were general risk factors like tobacco smoking, placement in the midpalatal suture at an early age, risk of endocarditis, diabetes and juvenile idiopathic arthritis; local risk factors like gingivitis and periodontitis, reduced mouth opening capacity, bone quality and radiotherapy; surgical risk factors like insufficient primary stability, immediate loading, breakage of the miniscrew due to insufficient pilot hole drilling. Unfortunately, only systematic data collection, but no systematic evaluation of the risk factors was performed. Additionally, retrospective studies were included, therefore not presenting real risk factors but only indicators.

The dynamics of TAD loss (loss over time) is an important factor for decision making in orthodontic treatment planning. The Kaplan-Meier analysis of a prospective RCT comparing miniscrews with 2 different diameters (1.1mm and 1.6mm) (Wiechmann et al. 2007) showed that the majority of the miniscrew failures occurred within 100 to 150 days after the start of orthodontic loading. In another prospective study (Garfinkle et al. 2008) most failures occurred within the first several months after placement. But still, there are failures even after one year of loading (Cheeng et al. 2004). At this point of time, a change of the treatment plan nevertheless may be difficult or impossible. With respect to palatal implants, reports indicate that implant loss occurs predominantly in the unloaded healing period (Arcuri et al. 2007, Study III, Sandler et al. 2008). This means that once a palatal implant has osseointegrated, no implant loss has to be expected.

It is clear that the placement and removal of a miniplate or palatal implant is a more complex procedure than that of a miniscrew. But the surgical intervention for both devices is tolerated from the patients (Kuroda et al. 2007, Cornelis et al. 2008) and the pain intensity after surgical installation of a palatal implant is less than that after premolar extraction (Feldmann et al. 2007). It seems that the greater flexibility and torque resistance provided by palatal implants and miniplates is an advantage under many circumstances.

Miniscrew anchorage is subjected to many risk factors and a single screw cannot tolerate significant torque moments (Chen et al. 2006c). This demands a direct line of simple force application, which is often problematic due to interferences with the roots to be moved or due to insufficient space for the placement of a screw in the desired region. If a whole dental arch should be moved, usually four screws are required as a minimum. If, for example, the upper dentition is to be distalized, two screws are placed in the anterior region, stabilising the premolars and anterior teeth in order to distalize the molars. Thereafter, two new screws are placed in the molar region to retract the anteriors against the now stabilized posterior teeth. The probability P , to encounter a failure in at least one of these four screws is:

$$P = 1 - (1 - risk_{Miniscrew})^4$$

This probability is about 50%, which means, that at least one out of four miniscrews fails in every second patient. If the combined success rates of Park et al. (2006b) and Chen et al. (2006a) are used instead of the general miniscrew failure rate, the probability is still 30% in the maxilla and 50% in the mandible.

When miniplate anchorage is used, one plate on each side of the jaw is usually needed. The probability per jaw is therefore:

$$P = 1 - (1 - risk_{Miniplate})^2, \text{ which equals } 14\%.$$

The placement of a palatal implant in the upper jaw or two miniplates in the lower jaw would therefore be preferable to miniscrew anchorage during en-masse movement of an entire dental arch of more than two millimetres. The palatal implant is superior to all other TADs in the maxilla as only one anchorage per patient is needed.

Reynders et al. (2009) tried to evaluate in their review the variables associated with the success rate of the 19 included studies. The implant-related factors were: implant type, diameter and length. Patient-related factors were: sex, age, mandibular plane angle, temporomandibular symptoms, crowding and sagittal relation. Local factors were: bone quality, cortical bone thickness, mucosa type, exposed vs. closed procedure, maxilla vs. mandible, lingual or anterior mandible, left vs. right patient's side and root proximity. Surgery-related factors were: flap, direction of placement, placement torque and self-drilling vs. self-tapping. Orthodontic-related factors were: magnitude of force, timing of force application, duration, type and direction of force and type of tooth movement. Implant maintenance factors were: Antibiotics, chlorhexidine, oral hygiene, control of inflammation and mobility. But any investigation, that tried to document a relation of success rate with one of these factors, was rejected because one or several of the other factors were not controlled.

In Studies IV and V, no such detailed quality assessment of the included publications was performed in order to at least be able to receive some information. At the moment, only very few can be reported in terms of variables influencing success or failure, especially of miniscrew anchorage. In order to evaluate relative effectiveness, efficiency and indications of different temporary anchorage devices, more prospective controlled studies have to be performed with proper recording of all influencing factors.

6.7 Indications and Limitations for Different TADs

Considering the survival rates and risk factors of the different TADs and looking at the biomechanical options, the palatal implant is the TAD of choice in the maxilla, especially if major anchorage is needed or if the whole dental arch is to be moved. The palatal implant is a reliable tool and the presented supraconstruction offers a multitude of clinical treatment possibilities.

6.7.1 Indications for palatal orthodontic implants

- 1) (Partial) stabilization of the upper dentition in relation to the maxillary base:
 - Prevention of movement of the reactive unit during space closure:
 - Extraction in the upper jaw only with full class II (posterior anchorage; Wehrbein et al. 1996a/b, 1998, 1999a, Bernhart et al. 2001, Wehrbein & Göllner 2007)
 - Closure of agenesis spaces in the upper jaw with class I (anterior anchorage)
 - Prevention of molar extrusion in open bite patients / hyperdivergency (vertical anchorage) or in class II patients
- 2) Active movements of the upper dentition in relation to the maxillary base:
 - Distalization of molars (class II; Study II, Wehrbein & Göllner 2007)
 - Mesialization of molars (space closure in the upper jaw with class I; Study II, Wehrbein & Göllner 2008)
 - Asymmetrical sagittal dental movements (Study II)
 - Vertical movements (open bite, deep overbite, retained canines)
 - Transversal movements (expansion and compression)
 - Unilateral rotations of the molars without transversal side effects
 - Tipping of the molars (compensation of the β -moment after vertical manipulations of the incisors)
- 3) Special tasks:
 - Protraction of the maxilla with a facemask application directly on the implant (Wehrbein & Göllner 2007)
 - Fixture of a provisional partial denture, especially after bony build-up of the alveolar ridge or waiting for implantation age

6.7.2 Limitations of palatal orthodontic implants

- 1) No skeletal effect on the maxilla with the implant only
- 2) No effect on the mandible or lower dentition, except possible autorotation of the mandible due to vertical manipulations of the buccal segments

6.7.3 Indications for mini-/microscrews

- 1) Minor tooth movements / anchorage such as:
 - Intrusion, extrusion, tipping or rotations of single teeth (Creekmor & Ecklund 1983, Roth et al. 2004, Da Costa Filho et al. 2004, Lee et al. 2004, Yao et al. 2004, Onishi et al. 2005, Bae et al. 2006, Lin et al. 2006)
 - Uprighting of mesially tipped molars by distal traction of the crown (Giancotti et al. 2004)
 - Minor sagittal / vertical passive anchorage or intrusion of the molars (Paik et al. 2003, Chang et al. 2004, Kuroda et al. 2004)

6.7.4 Limitations of mini-/microscrews

- 1) No skeletal effects on the maxilla or the mandible, except possible autorotation of the mandible due to vertical manipulations of the buccal segments
- 2) Insufficient interradicular spaces in the desired line of force or blocking of the desired tooth movements by the screw(s) (Schnelle et al. 2004)
- 3) Need for significant moment anchorage, especially around the long axis of the screws (Chen et al. 2006c). (Two primary interconnected screws can support axial moments to a certain extent; see Fig. 28)

6.7.5 Indications for miniplates

- 1) Maxilla: only if a direct skeletal anchorage is needed on the buccal sides (e.g. skeletal class III elastic application; Cevitanes et al. 2009)
- 2) Mandible: Stabilisation or active movements:
 - Prevention of movement of the reactive unit during space closure:
 - Closure of agenesis spaces with class I (anterior anchorage)
 - Posterior anchorage during space closure in class III-patients
 - Prevention of molar extrusion in open bite patients / hyperdivergency (vertical anchorage) or in class II patients
 - Mesialization of the molars (space closure in the lower jaw with class I)
 - Asymmetrical sagittal dental movements
 - Vertical movements (open bite, deep overbite; Umemori et al. 1999, Sugawara et al. 2002, Sherwood et al. 2003, Paik et al. 2003, Everdi et al. 2004, Kuroda et al. 2004, Chang et al. 2004, Sherwood & Burch 2005)

- Unilateral rotations of the molars without transversal side effects
- Uprighting / tipping of molars (uprighting of second molars after loss of the first, compensation of the β -moment after vertical manipulations of the incisors)

6.7.6 Limitations of miniplates

- 1) No skeletal effects on the maxilla or the mandible by the appliance only, except possible autorotation of the mandible due to vertical manipulations of the buccal segments
- 2) Insufficient bone height to place the screws below/above the roots
- 3) Flap surgery is required for the placement and removal.

Although an absolute anchorage can be achieved with many TADs, active movements of the dentition may sometimes be limited, especially in the following situations:

- Distalization in the upper jaw when the 2nd molars have erupted
- Root movements through the maxillary sinus
- Sandglass shaped alveolar bone
- Expansion of the upper arch without opening of the suture
- Vertical manipulations (danger of relapse)
- Large skeletal discrepancies with insufficient bone support in the direction of the desired tooth-movements

As TADs have no influence on craniofacial growth pattern, which is often an elementary part of orthodontic treatment, classical anchorage strategies like headgears and/or functional appliances are usually preferable in growing children.

7 CONCLUSIONS

On the basis of this series of investigations, literature search and clinical experience, the following conclusions can be made:

The healing process of the hydrophilic SLActive®-surface is faster than that of the conventional SLA®-surface. Palatal implants with these surfaces can be loaded after 1.5 months or 2 months, respectively.

A versatile supraconstruction fulfilling all clinical requirements and guidelines for its handling and application of proper biomechanics is designed and presented.

The survival rate of osseointegrated loaded Orthosystem® palatal implants with the specified supraconstruction is 98.6% after 25.2 months and the corresponding success rate 98.4% after 24.6 months in a prospective longitudinal clinical trial.

The hypothesis is proven that the survival rates of the palatal implants are superior to miniscrews and onplants. The survival rate of the palatal implant and miniplates are comparable, but the clinical reliability is superior as usually two miniplates are needed per jaw.

There are different risk factors for failure for different TADs. For the onplant, these are anatomic restrictions, surgical technique and mobilisation during the healing phase. Miniscrews are sensitive for small diameter and short length, patient's right side, inflammation, non-keratinized gingiva, mandibular placement and excessive placement torque. The only risk factor for the palatal implant is the insertion technique, especially with the Orthosystem's 90° shoulder. Miniplates are sensitive for mandibular placement, growing patients, non-keratinised gingiva, inflammation and surgical technique.

The palatal orthodontic implant is a stable and reliable tool for absolute anchorage and it is therefore indicated for major tooth movements and movements of the whole dental arch in the maxilla. Miniplates are the anchorage system of choice in the mandible. Miniscrews are indicated for minor tooth movements, as the probability of failure with multiple screw placement is too poor, especially in the mandible.

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Stability change of chemically modified sandblasted/acid-etched titanium palatal implants. A randomized-controlled clinical trial

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Key words: implant stability, implant surface, randomized clinical trial, resonance frequency analysis, surface topography

Abstract

Aim: The aim of this randomized-controlled clinical study was to examine stability changes of palatal implants with chemically modified sandblasted/acid-etched (modSLA) titanium surface compared with a standard SLA surface, during the early stages of bone healing.

Materials and methods: Forty adult volunteers were recruited and randomly assigned to the test group (modSLA surface) and to the control group (SLA surface). The test and control implants had the same microscopic and macroscopic topography, but differed in surface chemistry. To document implant stability changes resonance frequency analysis (RFA) was performed at implant insertion, at 7, 14, 21, 28, 35, 42, 49, 56, 70 and 84 days thereafter. RFA values were expressed as an implant stability quotient (ISQ).

Results: Immediately after implant installation, the ISQ values for both surfaces tested were not significantly different and yielded mean values of 73.8 ± 5 for the control and 72.7 ± 3.9 for the test surface. In the first 2 weeks after implant installation, both groups showed only small changes and thereafter a decreasing trend in the mean ISQ levels. In the test group, after 28 days a tendency towards increasing ISQ values was observed and 42 days after surgery the ISQ values corresponded to those after implant insertion. For the SLA-control group, the trend changed after 35 days and yielded ISQ values corresponding to the baseline after 63 days. After 12 weeks of observation, the test surface yielded significantly higher stability values of 77.8 ± 1.9 compared with the control implants of 74.5 ± 3.9 , respectively.

Conclusion: The results support the potential for chemical modification of the SLA surface to positively influence the biologic process of osseointegration and to decrease the healing time.

Traditionally, orthodontists have used teeth, intraoral and/or extraoral appliances to control anchorage – minimizing the movement of certain teeth, while completing the desired movement of other teeth. In the past decades, the orthodontic literature has published numerous case reports and scientific papers documenting the possibility of using several different types of temporarily placed anchorage devices (TAD)

(Creekmore & Eklund 1983; Roberts et al. 1990; Triaca et al. 1992; Bousquet et al. 1996; Kanomi 1997; Umemori et al. 1999; De Clerck et al. 2002). These TADs are anchored within the bone and subsequently removed after they have been used for the purpose of enhancing orthodontic anchorage or overcoming the limitations of traditional anchorage. The anchorage, by means of a TAD, allows an independence

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in terms of patient compliance (Creekmore & Eklund 1983). In the early 1990s special implants were introduced to serve as temporary anchorage in the maxillary bone for orthodontic reasons (Triaca et al. 1992; Wehrbein et al. 1996).

In orthodontic treatment, the placement of implants as an absolute anchorage device facilitates and accelerates therapy (Trisi & Rebaudi 2002), although a healing period of at least 3 months is required after implant insertion before orthodontic loading (Wehrbein et al. 1996, 1998; Keles et al. 2003; Crismani et al. 2005a, 2005b). Especially in adult patients there is a growing need to reduce this healing period.

In implantology, numerous efforts have been made to simplify clinical procedures and to reduce the healing period by using new titanium surfaces that have the potential to shorten and improve the osseointegration process (Buser et al. 2004; Oates et al. 2007; Bornstein et al. 2008).

The main goal of these experimental studies was to determine whether bone apposition could be enhanced by new microrough titanium surfaces as compared with the original implant surfaces utilized in implant dentistry, such as machined or titanium-plasma-sprayed (TPS) surfaces. Various techniques have been used to produce microrough titanium surfaces, including sandblasting, acid-etching or combinations thereof, to modify surface topography (Wieland et al. 2000). Among these new surfaces, the sandblasted and acid-etched (SLA) surface demonstrated enhanced bone apposition in histomorphometric studies (Buser et al. 1991; Cochran et al. 1998), higher removal torque values in biomechanical testing (Wilke et al. 1990; Buser et al. 1999; Li et al. 2002) and demonstrated favourable results in clinical examinations (Roccuzzo et al. 2001; Cochran et al. 2002; Bornstein et al. 2003).

Clinical studies of dental implants, however, always deal with surrogate biological endpoints (Karoussis et al. 2004). Palatal implants, in contrast, are temporary anchorage devices and are therefore subsequently removed after therapy. As a consequence, their loading time is shorter and is defined by the preexisting treatment plan and the end of the need for additional anchorage (Männchen & Schätzle 2008). Palatal implants therefore represent the only

implants in which explantations are affected after clinical success. As they are removed along with a small amount of adjacent bone with a trephine after therapy, palatal implants may offer the potential of studying the early pattern of osseointegration in humans including later histological analysis.

The aim of this randomized-controlled clinical study was to examine the stability patterns of palatal implants with a chemically modified sandblasted/acid-etched (modSLA) titanium surface with enhanced wettability as compared with a standard SLA surface, during the early stages of bone healing. The study hypothesis was that there would be a difference in palatal implant stability between implants with test and control surfaces during the early healing period (12 weeks) following placement.

Material and methods

This randomized trial was designed to prospectively assess implant stability changes of standard SLA palatal implants (Orthosystem[®], Institut Straumann AG, Basel, Switzerland) relative to implants having the same physical properties but a chemically modified surface (SLActive[®], Institut Straumann). Clinical evaluation of implant integration over time was performed using resonance frequency analysis (RFA) (Osstell; Integration Diagnostics, Savedalen, Sweden).

Subjects

Forty adult volunteers (19 female and 21 male) were recruited and randomly assigned to the test group (modSLA surface) and to the control group (SLA surface). The mean patients age was 27.9 years, ranging from 21.3 to 51.8 years. All participants were in a good general health condition and had no contraindications for minor oral surgical procedures. The study protocol had been approved by the local Ethical Committee (SPUK ZZMK 06/04), State of Zurich, Switzerland. Informed consent was obtained from all participants.

Implant design and surface characterization

All implants were manufactured from commercially pure titanium (Institut Straumann). The implants were characterized by an identical cylindrical shape of the

commercially available palatal implants and had an outer diameter of 4.1 mm. The enossal part was 4.2 mm in length.

The control implants revealed a standard SLA surface (sandblasted with large grits of 0.25–0.5 mm and acid etched with HCl/H₂SO₄) used in clinical practice today (Roccuzzo et al. 2001; Cochran et al. 2002; Bornstein et al. 2003, 2005). Test implants with the modSLA surface were produced with the same sandblasting and acid-etching procedure as the SLA surface but were rinsed under N₂ protection and continuously stored in an isotonic NaCl solution (Buser et al. 2004).

Clinical procedures

All endosseous implants had been inserted into the maxillary bone in the midpalatal area of the suture by the same blinded surgeon (R.M.) according to the manufacturer's guidelines for respective palatal implants. Patients were instructed to avoid any trauma around the areas of surgery and to rinse the mouth with 0.2% chlorhexidine solution twice a day for 1 week. Mechanical tooth brushing was avoided in the surgical site for 2 weeks. After 1, 3, 7 or 12 weeks, five implants were harvested using a standard trephine (5.5 mm) for further histological analysis (Schätzle et al. 2010).

Methods of analysis

The palatal implants' stability was monitored using RFA (Ostell[™], Integration Diagnostics AB, Göteborg, Sweden) according to Meredith et al. (1996). The RFA was performed at implant insertion, 7 (*n* = 40), 14 (*n* = 30), 21 (*n* = 30), 28 (*n* = 30), 35 (*n* = 30), 42 (*n* = 30), 49 (*n* = 20), 56 (*n* = 10), 70 (*n* = 10) and 84 (*n* = 10) days after surgery. At each measurement session, the healing cap had been removed in order to provide access to the implant. To avoid excessive torque moments and thus loosening of an implant, a standardized torque of 10 N cm was applied with a torque-controlled ratchet when connecting the transducer (Smart Peg Type9, Integration Diagnostics AB, Göteborg, Sweden) to the palatal implant. RFA produced an implant stability quotient (ISQ), which was recorded five consecutive times on each implant at every time interval. ISQ values indicated clinical stiffness with a range from 1 to 100, with implant stability

increasing as the ISQ value increased. It has been found that ISQ measurements show a high degree of repeatability (<1% variation for individual implants) (Meredith et al. 1996).

The primary outcome value was the change in ISQ from the mean baseline measurement for each implant. All measurements were carried out by one-blinded investigator (M.S.).

Statistical analysis

The response variable ISQ (with values between 0 and 100 like a percentage) is continuous and might be considered as normally distributed (Kolmogorov–Smirnov test). To decrease the patient-specific variability and according to the patient-specific situation, it is a good clinical and statistical practice to transform the original response to differences ‘observation – baseline’ (ISQ difference). This continuous variable is again normally distributed (Kolmogorov–Smirnov test).

The aim of this study was to determine whether there is a difference in the time-dependent stability patterns for each of the implant types. Therefore, analysis was performed using a generalized linear model, the Chow test (Chow 1960), with secondary outcomes characterized by descriptive analyses (Johnston & DiNardo 1997; Toutenburg 2002).

There are two main fixed factors Treatment and Time (baseline through 12 weeks), with a possible interaction, and the random factor Patient. The linear mixed model was used to evaluate the significance of these overall effects. However, because ISQ values decrease after implantation before they begin to increase, the main statistical problem to be tested in this study was not amenable to a linear mixed model analysis (Barewal et al. 2003). The objective is to attain an earlier change of the direction of the test group (modSLA surface) with respect to the control group (SLA surface).

Results

All 40 implants could be inserted with high primary stability, and a mean insertion torque of 39.25 N cm (range: 30–55 N cm) was applied. There was no correlation between insertion torque and ISQ values

irrespective of the implant surface. Before releasing the transfer piece in all but one SLA-surface palatal implant, a counter-clockwise torque had to be applied to remove the transfer piece. In the modSLA-surface group, in contrast, a counter-clockwise torque had to be applied in only one implant to remove the transfer piece. In all cases, the counter-clockwise torque was considerably lower than the insertion torque. All the installed implants remained stable at all time points of observation up to the point of explantation.

The mean ISQ values and standard deviation at baseline and in the subsequent time points of measurement are presented in Table 1 and Fig. 1. At baseline, the stability quotients for both surfaces tested were not significantly different and yielded mean ISQ values of 73.8 ± 5 for the control implants and 72.7 ± 3.9 for the test implants, respectively. After 84 days (12 weeks) of observation, the test surface attained significantly higher stability values of 77.8 ± 1.9 compared with the values of the control implants of 74.5 ± 3.9 , respectively. The individual ISQ values for the SLA cohort as well as for the modSLA group are shown in Figs 2 and 3. Both groups showed a fair homogeneity in the individual ISQ values. Except for one palatal implant each of both groups, however, the changes over time differed signif-

icantly from the others. For the respective SLA palatal implants, the ISQ changes over time yielded higher changes (-13.6 ISQ), but their ISQ values remained within the range. For the modSLA palatal implant, in contrast, the ISQ changes over time were even higher (-18.6 ISQ) and their ISQ values showed significantly lower values. After 84 days (12 weeks), both implants reached comparable stability measurements.

As the absolute ISQ values were not of primary interest and had only minor clinical impact due to the high individual effect, it is good clinical practice to monitor the changes over time by standardizing to the deviations of ISQ from the baseline (Table 2 and Fig. 4). In the first 14 days after implant installation, both groups showed only small changes in the ISQ values (0.24–2.2 ISQ). Thereafter, the SLA surface as well as the modSLA surface showed a decreasing trend in mean ISQ levels, reaching significantly lower values (difference from baseline for the control surface of -2 ± 3.3 and modSLA surface of -1.5 ± 6).

In the test group, however, a transition point in the ISQ values was observed at 28 days after palatal implant installation. For the SLA-control group, however, the trend changed 1 week later, at 35 days. After the transition point of ISQ differences,

Table 1. Mean ISQ values and standard deviation at baseline and subsequent time points for SLA- and modSLA palatal implants

Group	Day	N	Minimum	Maximum	Mean	Standard deviation		
SLA	0	ISQ	20	65.2	84.2	73.79	5.0214	
	7	ISQ	20	63.4	85	74.41	5.3801	
	14	ISQ	15	66	84.2	75.867	5.8908	
	21	ISQ	15	65.6	81	74	4.9552	
	28	ISQ	10	64.6	79	69.66	4.4222	
	35	ISQ	10	64.2	77	69.02	4.1478	
	42	ISQ	10	65	79	69.9	4.6516	
	49	ISQ	10	64.6	80	70.54	4.9379	
	56	ISQ	5	66.4	77	71.2	4.0669	
	70	ISQ	5	68.6	77	72.56	3.3953	
	84	ISQ	5	69.4	79	74.48	3.9079	
	modSLA	0	ISQ	20	64	78.2	72.67	3.9402
		7	ISQ	20	64	84	73.47	5.8097
		14	ISQ	15	62.8	81	73	5.3442
21		ISQ	15	57.4	80	71.627	6.5356	
28		ISQ	10	49.6	79.2	70.46	8.3026	
35		ISQ	10	48	80.2	70.84	8.9581	
42		ISQ	10	55	81.6	71.7	7.2524	
49		ISQ	10	62.2	80.2	73.66	5.2688	
56		ISQ	5	66.6	79	74	4.684	
70		ISQ	5	74	79	76.56	1.9204	
84		ISQ	5	75	80	77.8	1.8762	

ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

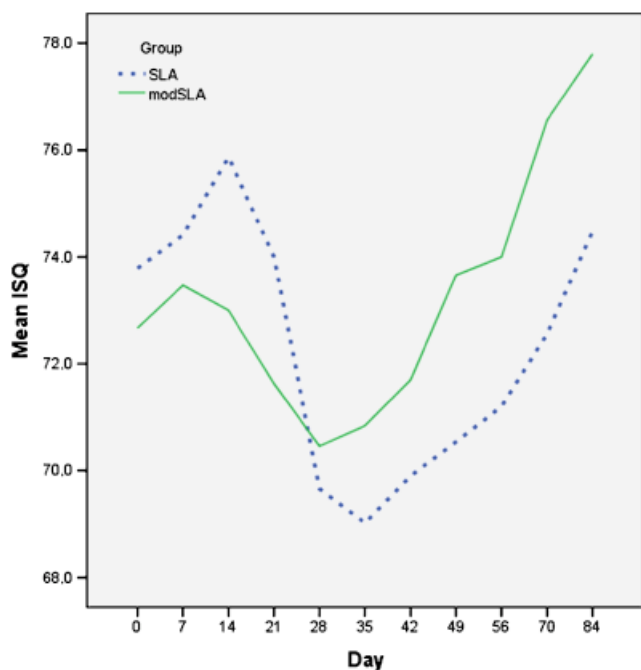


Fig. 1. Mean ISQ values at baseline and at subsequent time points for SLA- and modSLA palatal implants. ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

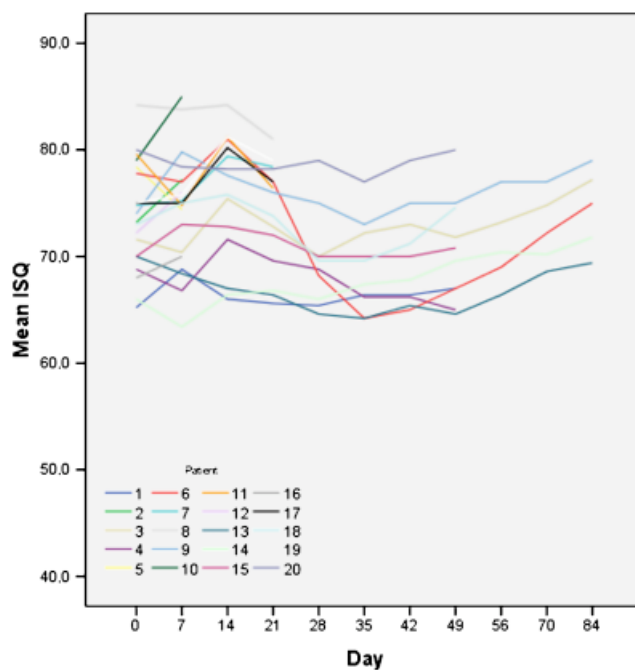


Fig. 2. ISQ values differ for palatal implants with the SLA surface over time. ISQ, implant stability quotient; SLA, sandblasted/acid-etched.

Table 2. Mean ISQ values changes and standard deviation for SLA- and modSLA palatal implants by standardizing to the deviations from baseline

Group	Day		N	Minimum	Maximum	Mean	Standard deviation
SLA	7	Difference to baseline	20	-4.8	6	.24	3.1359
	14	Difference to baseline	15	-3	6.2	2.2	2.5467
	21	Difference to baseline	15	-3.6	4	.333	2.3924
	28	Difference to baseline	10	-9.6	1	-1.98	3.3045
	35	Difference to baseline	10	-13.6	1.4	-2.62	4.4974
	42	Difference to baseline	10	-12.8	1.8	-1.74	4.3889
	49	Difference to baseline	10	-10.8	3.6	-1.1	4.3279
	56	Difference to baseline	5	-8.8	4.4	-.68	5.4545
	70	Difference to baseline	5	-5.6	4.2	.68	4.1197
modSLA	84	Difference to baseline	5	-2.8	5.8	2.6	4.0125
	7	Difference to baseline	20	-3.2	6.8	.8	2.769
	14	Difference to baseline	15	-4.4	5	.92	2.8484
	21	Difference to baseline	15	-9.2	4	-.453	4.0914
	28	Difference to baseline	10	-17	4.2	-1.46	5.9517
	35	Difference to baseline	10	-18.6	5.2	-1.08	6.6741
	42	Difference to baseline	10	-11.6	5.6	-.22	4.8511
	49	Difference to baseline	10	-4.4	5.6	1.74	3.087
	56	Difference to baseline	5		6.2	3.76	2.2865
70	Difference to baseline	5	4	7.6	6.32	1.4464	
84	Difference to baseline	5	5	8.4	7.56	1.4519	

ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

the ISQ increased significantly more over time in the test than in the control group. Forty days after installation, the modSLA surface reached ISQ values corresponding to those immediately after palatal implant installation, whereas for the SLA surface it took significantly longer, approximately 63 days.

The ISQ-difference values as well as the mean ISQ values for the SLA surface after 84 days (12 weeks) corresponded to the values of the modSLA surface attained after 56 days (8 weeks). But the application of the Chow test did not show sufficient statistically significant difference.

Discussion

The purpose of this randomized-controlled clinical study was to assess palatal implant stability over time for two SLA surfaces over the first 84 days (12 weeks) following implant insertion. The main focus was on the early stability changes corresponding to the transition from primary stability – caused by the implant design – to biologic stability provided by newly formed bone defined as osseointegration (Berglundh et al. 2003). This transition period is crucial regarding early loading (Glauser et al. 2004; Raghavendra et al. 2005).

To clinically assess implant integration, RFA has been used to measure implant stability. This technology was proven to be capable of characterizing alterations in implant stability during early healing and is sensitive enough to identify differences in longitudinal implant stability based on bone density at the implant recipient site (Barewal et al. 2003). The technique has been demonstrated to be an accurate method for early assessment of osseointegration (Huang et al. 2003).

The significantly wider range in the ISQ values shown by the two palatal implants over time might be explained

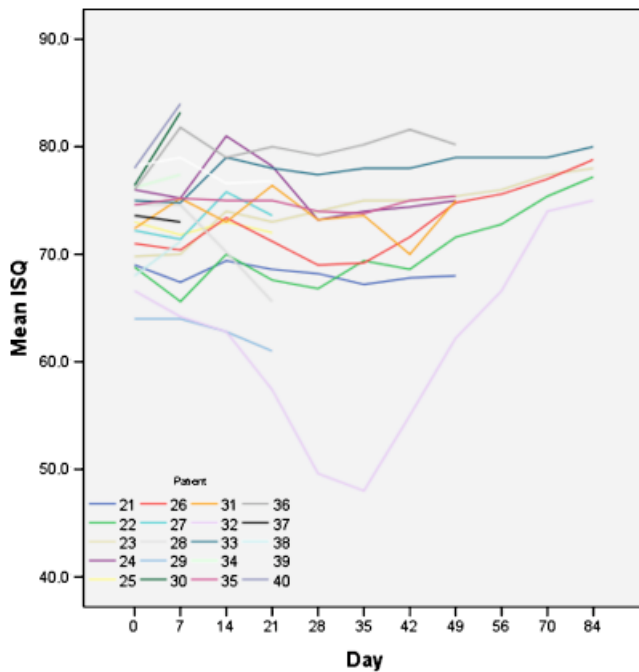


Fig. 3. ISQ values differ for palatal implants with the modSLA surface over time. ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

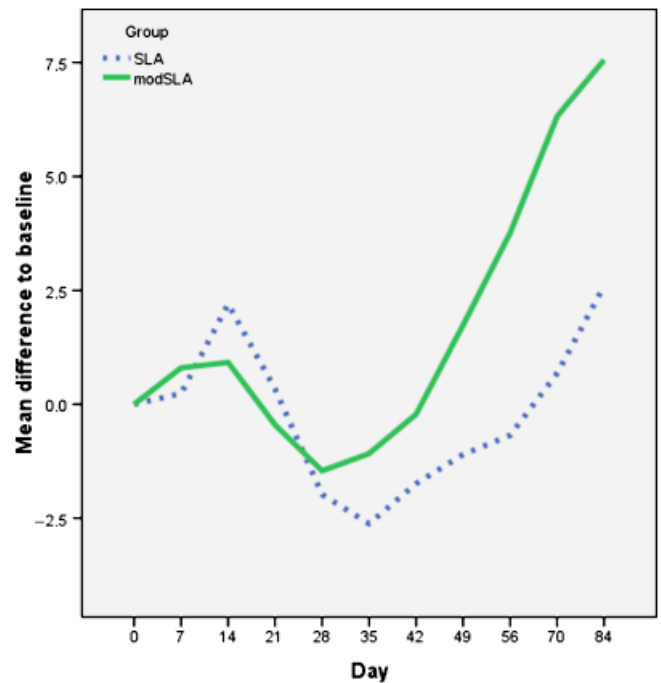


Fig. 4. Mean ISQ value changes in SLA- and modSLA palatal implants onstandardization to the deviations from the baseline. ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

by unscrewing of the implant during the early healing period on installing the transducer. All the implants, however, were clinically stable at all time points and no movement was detected while performing the measurements.

The changes in implant stability expressed by ISQ-value differences over time might reflect the biologic events associated with the bone-implant interface. The mean ISQ values increased from insertion to day seven for the modSLA group and from insertion to day 14 for the SLA cohort. These higher ISQ values after the implant insertion might be explained by primary mechanical stability, achieved by the press fit of the implant with a larger diameter (4.1 mm) compared with the diameter of the last drill (3.5 mm), while the implant diameter was 4.1 mm. (Schenk & Buser 2000).

The mean ISQ value, thereafter, started to decline significantly (Fig. 1). It might be assumed that the decrease in ISQ values would correspond to bone resorption, whereas an increase would be associated with bone formation. The faster decrease, just 7 days after implant installation of the modSLA surface, might be explained by its surface wettability characteristics enhancing the interaction between the implant sur-

face and the biologic environment (Kilpadi & Lemons 1994).

After a small decrease (Δ ISQ = -1.5) (Fig. 4) due to predominant resorptive processes in the adjacent bone, the stability of the test implants with the modified SLA surface began to increase again after a time point of 28 days (4 weeks). For the control implants, however, the transition point from bone resorption to apposition corresponding to an increasing stability was evident 35 days (5 weeks) after implant installation. Considering the different starting points of resorptive processes, however, it lasted for both the modSLA group and the control SLA group 21 days until biological stability occurred. This change in the stabilization pattern with transition points after 28 and 35 days is later than that reported in a previous clinical study using SLA palatal implants only, in which the transition was observed already after 21 days (Crismani et al. 2006).

The differences in the present study and the previously mentioned study should be interpreted with caution. The implants installed by Crismani and coworkers were the old Orthosystem[®] palatal implant (Straumann AG) with a shoulder and a smaller diameter. They have loaded their

implants a few days after installation and showed lower ISQ values compared with the present study. In contrast to the present study, the measurements were performed with a transducer long arm directly connected to the implant. The ISQ values in the present study started at a higher level and showed a greater decrease (-4.8 ISQ) by reaching the transition point compared with those for the old Orthosystem[®] (approximately -1.5 ISQ). In both studies, it took almost 84 days (12 weeks) to reach the initially measured values of the ISQ, whereas for the mod SLA surface the values were reached already after 42-49 days (6-7 weeks), indicating a significantly enhanced healing process.

As the design of the latest Orthosystem[®] palatal implant is comparable to regular dental prosthetic implants and, therefore, the changes in the implant stability pattern during the early healing period might be rather comparable. In a human clinical study using dental implants with an SLA surface (control) and a modSLA surface (test), respectively, no difference was found in the transition time points for the implants placed in the posterior maxillary area (Oates et al. 2007). The transition point was after 28 days for the test and the control group. In the mandible, however,

different transition points after 28 and 14 days, respectively, could be found for the control and the test implants (Oates et al. 2007). The present findings correspond to the clinical findings of dental implants in the mandible and support the potential for chemical modifications in a roughened implant surface to alter biologic events during the early transition from primary to secondary stability.

Within the time period between the transition point and 84 days (12 weeks) after palatal implant insertion, the mean ISQ value increased (Fig. 1). This may be explained by the increase in reinforcement of the preformed woven bone scaffold by lamellar bone. Later, the bone quality is improved because of the replacement of the initially formed bone by mature lamellar bone, which provides secondary implant stability (Schenk & Buser 2000). This would confirm that surface chemistry is a key variable for peri-implant bone apposition, because it influences the degree of contact with the physiologic environment. Increased wettability, thus, enhances the interaction between the implant surface and the biologic environment (Kilpadi & Lemons 1994) and leads to enhanced bone apposition (Buser et al. 2004).

The working hypothesis was that chemically modified SLA implants have increased healing potential when compared with standard SLA implants. The challenge was to find an appropriate statistical model for evaluation. From repeated measures, the mixed model analysis appeared to be modelling an overall treatment effect

of a structural change in the data over time. The Chow test is designed to be able to detect this special treatment effect (i.e., a decrease and a subsequent increase in ISQ) and so was chosen as the most appropriate statistical model. Similar statistical analysis was used in a previous study (Oates et al. 2007). The findings from that analysis demonstrated differences in implant stability and healing based on placement of the implant in the maxilla or the mandible. This finding is suggestive of differences in bone quality between arches affecting implant stability. Similar findings of interarch variations in implant stability, with greater changes in stability in the mandible than the maxilla, have been reported previously (Bischof et al. 2004; Oates et al. 2007). However, this is in contrast to previous investigations, in which implants placed in less dense bone types tended to have greater changes in stability (Friberg et al. 1991; Meredith et al. 1996; Barewal et al. 2003). The contrasting findings between studies are suggestive of unique aspects of bone quality that affect bone metabolism beyond clinical assessments of bone density or implant stability and remain to be elucidated. Based on the present findings, it could be demonstrated that the palatal area tend to show results similar to those of the mandible (Oates et al. 2007), which is in accordance with the characteristics of their bone quality.

Dental implants, however, always deal with surrogate biological endpoints (Karoussis et al. 2004). Palatal implants, in contrast, are temporary anchorage de-

vices and subsequently removed after therapy. Palatal implants represent the only implants in which Palatal implants represent therefore the only implants in which explanation are effected after clinical success (Männchen & Schätzle 2008). As they are removed along with a small amount of adjacent bone with a trephine after orthodontic loading, palatal implants may offer the potential of studying the early pattern of osseointegration in humans including later histological analysis. Therefore, a randomized-controlled clinical study was designed to elucidate the pattern of osseointegration and stability change. The present results could confirm the palatal area as a potential experimental human implant site.

In conclusion, this study supports the potential for chemical modifications in a roughened implant surface to positively influence biologic events during the early osseointegration process. These alterations may be associated with an enhanced healing process, which may lead to alterations in clinical loading protocols for dental implant therapy. However palatal implants, are temporary anchorage devices and usually removed along with adjacent bone after use with a trephine, these types of implant can be used for further clinical studies including human histological analysis.

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Success rate of palatal orthodontic implants: a prospective longitudinal study

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Key words: human, loading, orthodontic implant, palatal implant, success rate, survival rate

Abstract

Aim: The purpose of this prospective cohort study was to assess the survival and success rates of palatal implants.

Material and methods: Seventy patients (56 female, 14 male; age $25-6 \pm 10-8$ years) receiving Orthosystem[®] (Straumann AG, Basel, Switzerland) palatal implants from March 1999 to November 2006 were included. The indication was established according to the required anchorage for orthodontic therapy. All implants were placed in a mid-sagittal, median or paramedian palatal location by the same surgeon. They were orthodontically loaded after a healing period of 8–16 weeks (Mean: 12.8 weeks).

Results and discussion: Of the initially 70 consecutively admitted patients, two implants in two patients were not primary stable after installation and had to be removed. Of the 70 initially installed palatal implants, 67 implants or 95.7% osseointegrated successfully and were loaded actively and/or passively for approximately 19 months. Only one implant of the 67 osseointegrated implants lost its stability under orthodontic loading. By the time of re-evaluation, 20 palatal implants were still used for orthodontic therapy, while 46 implants had been removed after completed orthodontic therapy. By only analyzing those, the success rate of the initially installed implants was 92%.

Conclusions: Orthodontic palatal implants with a rough surface are predictable and highly reliable devices for a multitude of maxillary orthodontic treatment options. The survival and success rates for palatal orthodontic implants are comparable to dental implants installed for dental prostheses.

Numerous case reports and clinical trials have been published documenting the possibility of using different types of temporarily placed anchorage devices (TAD) fixed to bone, which are subsequently removed after their use for the purpose of enhancing orthodontic anchorage or overcoming the limitations of traditional anchorage. The anchorage by means of a TAD permits an independency of patient compliance (Creekmore & Eklund 1983) either by supporting the teeth of the reactive unit or by obviating the need for a reactive unit altogether.

Because regular orthodontic patients have a full dentition or extraction sites to be closed, no edentulous alveolar bone sections are available for the insertion of an implant. As a consequence, implants for orthodontic anchorage purposes must be placed in other topographical regions. In the early 1990s special implants have been introduced to serve as temporary anchorage in maxillary bone for orthodontic reasons (Triaca et al. 1992; Block & Hoffmann 1995; Wehrbein et al. 1996). Both the mid-sagittal (Triaca et al. 1992; Wehrbein et al.

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1996) and paramedian (Bernhart et al. 2000, 2001) regions of the hard palate have been proposed for this kind of implant placement.

Even though palatal implants have been used in orthodontic treatment for more than a decade (Wehrbein et al. 1996), there exists only one prospective study of nine patients demonstrating successful osseointegration and stability in all patients (Wehrbein et al. 1999). Moreover, Bantleon et al. (2002) published a subjective report of 40 Orthosystem® palatal implants and indicated a 92% early survival rate of osseointegration and loading. So far, there is only one scientific report on the success rate of loaded palatal implants ($n=4$) that were removed after completion of the orthodontic treatment (Wehrbein et al. 1998). Results on any larger number of palatal implants have not been published.

The aim of the present prospective study was to assess the rates of osseointegration as well as the survival rates of loaded palatal implants.

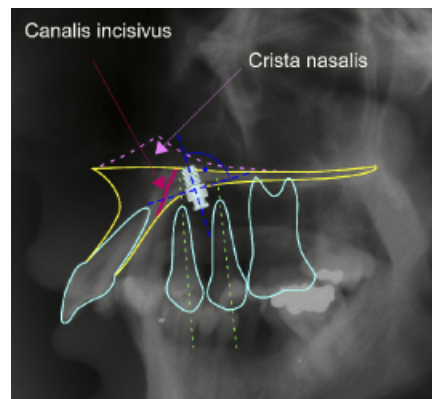


Fig. 1. Most implants are clinically stable when their entry point into the cortical bone is between the anterior-posterior level of the maxillary first and second premolars – perpendicular to the palatal surface.

Material and methods

Seventy-one consecutively admitted patients (56 females, 15 males) (Table 1) receiving the first generation of Orthosystem® palatal implants (Straumann AG, Basel, Switzerland) for orthodontic treatment purposes from March 1999 to November 2006 were included in this prospective study.

The orthodontic indication for implant placement was established according to the required anchorage situation in order to achieve the intended treatment goal. Before placing palatal implants, the vertical bone volume along the palatal suture was assessed in lateral cephalograms (Fig. 1) (Wehrbein et al. 1999). Only in one case of reduced palatal bone height and an impacted upper canine, CT-scans were performed to evaluate possible insertion sites (Bernhart et al. 2000).

All endosseous implants were placed by the same surgeon (R.M.) according to the Straumann® guidelines for respective palatal implants. After injecting a local anesthesia, the palatal mucosa was removed with a punch and an elevator. The cortical bone was marked in the center of the intended implant site with a round drill, the hole for accommodating the implant was drilled by the use of spiral drills (2.2 and 2.8 mm) and the shoulder was prepared with the ortho-profile drill. The self-tapping implant was inserted by hand with a ratchet. In growing patients the palatal implants were inserted in paramedian regions to avoid possible developmental disturbances of the palatal suture (Glatzmaier et al. 1995; Wehrbein et al. 1996; Asscherickx et al. 2005) (Table 1). Based on stability criteria (Buser et al. 1990), all implants that were primary stable after

installation were considered for further evaluation. 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.

After the healing period, an alginate impression of the implant and maxillary dentition was taken in order to obtain a master cast for designing the supraconstruction, including the orthodontic mechanics. This customized construction was fixed on the abutment in a rotationally stable manner using the internal hexagon of the ortho-cap. The orthodontic mechanical forces either affected the implant directly (active movement of the first molars by the use of 0.018×0.025 in. stainless steel sectional wires) or indirectly via the stabilized molars (0.021×0.025 in. stainless sectional wires) (Männchen 1999) (Fig. 2).

All implants used in these patients were of the same type: single-unit self-tapping

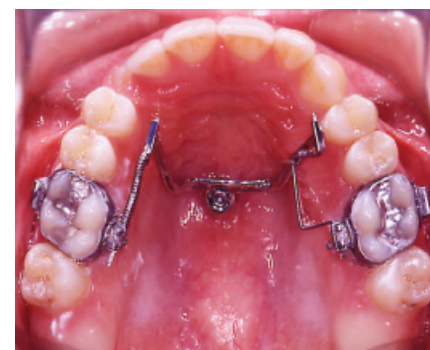


Fig. 2. Supraconstruction consisting of a yoke shaped palatal bar made of 0.36×0.72 in. heat-treatable Remaloy (Dentaurraum Inc., Ispringen, Germany) stainless with $4.5 \text{ mm } 0.022 \times 0.28$ in. rectangular tubes[†] at each end and $0.22''$ Damon (Ormco Cooperation, Glendora, CA, USA) brackets welded to the palatal aspect of the molar bands. Tubes and brackets are interconnected by sectional wires. (Männchen 1999).

Table 1. Frequency distribution of mean age (\pm SD), sex, implantation site and healing time before orthodontic loading for installed implants

Implant dimension (mm)	N	Mean age \pm SD	Sex		Implantation site		Mean healing time in weeks \pm SD (before orthodontic loading/failure)	
			Male	Female	Median	Paramedian		
Length: 4 Diameter: 3.3	18*	26-1 \pm 10-6 median: 26-7	3	15*	4	14*	12.5 \pm 3.7	Minimum: 2 Maximum: 20
Length: 4 Diameter: 4	10	23-10 \pm 11-5 median: 20-9	1	9	1	9	12.2 \pm 2.1	Minimum: 8 Maximum: 15
Length: 6 Diameter: 3.3	42	20-9 \pm 10-6 median: 16-5	10	32	5	37	12.9 \pm 4.1	Minimum: 3 Maximum: 25
	70	22-6 \pm 10-8 median: 17-6	14	56	10	60	12.7 \pm 3.8	Minimum: 2 Maximum: 25

*Three out of 70 (4.3 %) installed implants did not successfully osseointegrate.

made of pure titanium with a length of 4 or 6 mm, a diameter of 3.3 or 4 mm, grit-blasted and acid-etched intraosseous surface and a highly polished neck of 2.5 mm (Orthosystem[®]) (Table 1).

After completion of the orthodontic treatment the palatal implants were removed using a standard trephine of 5.5 mm.

Osseointegration was defined as *successful* when at the time of taking an alginate impression for the supraconstruction, the implant showed absence of mobility and absence of persistent subjective complaints (Buser et al. 1990).

The *loading time* was calculated based on the time period between insertion of the supraconstruction and its removal after achieving the intended anchorage needed or the end of November 2006, respectively, if the implant was still in use.

The *success rate* was calculated for patients with *removal of the supraconstruction* on the basis of absence of mobility throughout the entire loading time.

Statistical analysis

Descriptive statistics for all clinical parameters were performed after grouping the implants into three groups: all implants inserted, successfully osseointegrated implants and implants with completion of the intended orthodontic anchorage purposes.

Results

All implants inserted

Initially 71 consecutively admitted patients were recruited for this study (15 males and 56 females). One male person could not be included into the study due to smoking abuse and severe wound healing disorders after a molar extraction. Out of the 70 patients included, two implants in two patients had to be removed 10 and 19 days after installation due to inadequate primary stability. These were replaced in a slightly different location after a healing period of 4 months. Osseointegration thereafter was successful. Nevertheless, these two implants are interpreted as failure and hence are not considered for further evaluation.

Only one or 1.5% out of the 68 primary stable palatal implants did not successfully osseointegrate and was lost before loading. This 4 mm in length and 3.3 mm in diameter implant was lost spontaneously ap-

proximately 2 months after implant insertion (Table 1). During the whole healing period, this patient complained about pain in the incisal region. The overall survival rate of osseointegration of the 68 implants was 98.5%.

Successful osseointegration

In all 67 patients (mean age 22 years 6 months \pm 10 years and 9 months) with successfully osseointegrated palatal implants that were clinically stable after a mean healing time of 12.7 (SD: 3.9) weeks (Table 1), an alginate impression was taken in order to obtain a master cast for designing the individualized, rotationally stable supraconstruction. After installation of this, 25 implants or 37.3% were loaded actively, 29 implants or 43.3% were used for passive stabilization and 13 implants (19.4%) were used for both purposes, respectively.

By November 2006 and after a mean loading time of 18.8 months, all but one or 98.5% of the 67 osseointegrated palatal implants remained stable under orthodontic loading.

Implants at the removal of the supraconstruction (success rate)

By the time of re-evaluation, 20 Orthosystem[®] implants were still *in situ* and under orthodontic loading. In 47 patients (mean age 23 years 4 month \pm 10 years 3 month), the supraconstruction had been removed due to completion of the orthodontic anchorage needed or implant failure after successful osseointegration (Table 3). One patient refused the removal of the palatal implant after treatment.

The overall survival rate in this patient cohort ($n=70$) was 94.3%. It has to be kept in mind, however, that 20 patients still were in orthodontic treatment at the completion of the study.

By analyzing the 46 implants successfully loaded and removed Orthosystem[®] palatal implants after completion of orthodontic therapy only, the overall success rate was 92% for a mean loading time of 21.4 months (two lost implants: one in the early healing phase, one under loading).

Discussion

The purpose of this study was to assess the survival rate of osseointegration and load-

ing of palatal implant and the success rate of palatal implants with removal of the supraconstruction after completion of the intended orthodontic treatment.

Despite the small dimensions, orthodontic implant anchoring devices must maintain positional stability under orthodontic loading in order to serve as absolute anchorage. Therefore, osseointegration is a prerequisite. Histological examination of explanted human palatal orthodontic implant bone specimens revealed that osseointegration is maintained during long-term orthodontic loading under clinical conditions (Wehrbein et al. 1998). This suggests that an adequate anchorage to withstand orthodontic loading can also be achieved with these small implants.

In some cases, there may be a premature loss of the implant before orthodontic loading. This loss may be attributed to the lack of adequate primary stability. Insufficient primary stability causes connective tissue encapsulation and the possible premature loss of the implant (Friberg et al. 1991; Lioubavina-Hack et al. 2006).

There are substantial differences between orthodontic forces and occlusal loading applied to implants. Orthodontic forces are continuous and horizontal or oblique. Occlusal loads, in contrast, are discontinuous and expected to be mainly along the long axis of the implants/teeth. Therefore, the effect of orthodontic loading to the adjacent bone of the implant is of great interest. The applied forces should not have a negative impact on the peri-implant bone and impair the long-term prognosis of the implant. In an experimental study, oral implants were inserted in monkeys and subjected to well-defined continuous loading (Melsen & Lang 2001). None of the implants had lost osseointegration after 11 weeks of loading, but loading significantly influenced the turnover of the alveolar bone in the vicinity of the implants. When the strain exceeded a threshold, the remodeling of the bone resulted in a net loss. It may be speculated that the reason for the one and only failure of a successfully osseointegrated implant in this study could be attributed to a unilateral heavy and excessive orthodontic loading.

Most of the implant studies reporting on survival and failure rates of implants, deal with surrogate biological endpoints (Karoussis et al. 2004) or technical failures

Table 2. Frequency distribution of mean age (± SD), sex, implantation site, type of load and mean loading time for successfully loaded implants

Implant dimension (mm)	N	Mean Age ± SD	Sex		Implantation site		Type of Loading			Mean loading time of the supraconstruction in month ± SD	
			Male	Female	Median	Paramedian	Active	Passive	Both		
Length: 4 Diameter: 3.3 mm	16	26.7 ± 10.6 median: 27.0	3	13*	3	13*	8*	6	2	21 ± 11.1	Minimum: 5 Maximum: 50
Length: 4 Diameter: 4	9	24.6 ± 11.9 median: 22.7	1	8	1	8	5	1	3	23 ± 15.3	Minimum: 1 Maximum: 56
Length: 6 Diameter: 3.3	42	20.9 ± 10.6 median: 16.5	10	32	5	37	12	22	8	17.1 ± 9.31	Minimum: 1 Maximum: 37
	67	22.8 ± 10.6 median: 17.6	14	53	9	58	25	29	13	18.8 ± 10.7	Minimum: 1 Maximum: 56

*One implant of 4 mm diameter and 3.3 mm length in a female patient lost its stability after a 5 month unilateral loading time and had to be removed. One or 1.5% of 67 successfully osseointegrated implants did not remain stable under loading.

Table 3. Frequency distribution of mean age (± SD), sex, implantation site, type of load and mean loading time for successfully loaded implants with removal of the supraconstruction due to completion of the orthodontic anchorage need or implant failure

Implant dimension (mm)	N	Mean Age ± SD	Sex		Implantation site		Type of Loading			Mean loading time of the supraconstruction in months ± SD	
			Male	Female	Median	Paramedian	Active	Passive	Both		
Length: 4 Diameter: 3.3	13*	25.4 ± 10.3 median: 24.1	3	10*	4	9*	7*	5	1	23.9 ± 10.1	Minimum: 5 Maximum: 50
Length: 4 Diameter: 4	7	23.8 ± 13.2 median: 18.11	1	6	1	6	2	4	1	22.4 ± 6.1	Minimum: 16 Maximum: 31
Length: 6 Diameter: 3.3	27	22.3 ± 9.8 median: 17.7	6	21	3	24	5	16	6	20.6 ± 7.6	Minimum: 9 Maximum: 37
	47	23.4 ± 10.3 median: 18.11	10	37	8	39	14	25	8	21.4 ± 8.4	Minimum: 5 Maximum: 50

*One implant of 4 mm diameter and 3.3 mm length in a female patient lost its stability after a 5 month unilateral loading time and had to be removed. 20 of 67 successfully loaded implants are still in use and therefore not considered for this evaluation. One or 2.1% of 47 removed implants did not remain stable under loading.

(Pjetursson et al. 2007). But there are substantial differences between a success of prosthetic implants and temporary anchorage devices. As prosthetic implants have an uncertain clinical endpoint (death of the patient), a clinical success starts with the installation of the prosthetic unit.

Palatal implants, however, are temporary anchorage devices and usually removed after use. As a consequence, their loading time is shorter and defined by the pre-existing treatment plan and the end of the need for additional anchorage. Success is not achieved by the installation and loading over time, however, but by the removal of the supraconstruction. Therefore, the comparison of survival and success rates of prosthetic dental implants with those of temporary anchorage devices is limited.

Concerning these limitations, just the 'early failures' during the healing period can be directly compared with prosthetic implants. In the present study, one implant did not fulfill the criterion of success at the completion of the healing period. This low failure rate is consistent with results

reported for short epithetic implants (Bernhart et al. 2001) and prosthetic implants (Buser et al. 1997).

The long-term success rates for dental implants are generally indicated between 88% and 96% after 6–14 years (Berglundh et al. 2002).

This report documented a successful loading rate of 98.5% after approximately 19 months (Table 2) of orthodontic use of palatal implants. This rate is higher than the 90% success rate of 20 similar and early loaded Orthosystem[®] palatal implants (Crismani et al. 2006) and for 21 short epithetic implants with a machined surface loaded for approximately 23 months (84.8%) (Bernhart et al. 2001). There is one report of 40 Orthosystem[®] palatal implants indicating a 92% early success rate of osseointegration and loading (Bantleon et al. 2002).

As there is no existing study analyzing the successfully loaded implants with completion of the orthodontic treatment, the present study is the first analyzing 46 successfully loaded and removed Orthosys-

tem[®] palatal implants and reporting a success rate of 92% (two implants lost: one during early healing phase, one under loading, Table 3).

During the last decade, an increasing number of articles have been published on the use of micro-implants or mini-screws (Kanomi 1997; Costa et al. 1998). This type of anchorage is not suitable for the application of anchorage moments. Only simple forces may be applied demanding a perfect positioning in relation to the desired tooth-movement. Although the palatal implants used in this study had slightly smaller dimensions than traditional dental implants, it could clinically be shown that they are able not only to resist forces but also moments in the horizontal dimension. This shows their superiority to the micro-implants in the maxilla.

In conclusion, orthodontic palatal implants, such as the Orthosystem[®] (Straumann AG), with a rough surface and rotation resistant supraconstruction provide a new dimension in orthodontic anchorage as they reduce the need for patient

compliance and offer increased clinical flexibility and effectiveness. These temporary anchorage devices are providing reliable absolute orthodontic anchorage and hence,

are considered to be superior to any orthodontic tooth-borne anchorage device. Nevertheless, it must be kept in mind that this kind of skeletal anchorage has

no skeletal growth modification potential and must therefore be carefully considered vs. extraoral or functional appliances in growing individuals.

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A New Supraconstruction for Palatal Orthodontic Implants

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When osseointegrated implants were developed for prosthetic dentistry, orthodontists began to explore the possibilities of using them as anchorage devices.¹⁻¹⁴ The idea of an implant in the median maxillary suture, originally proposed by Triaca and colleagues,¹⁵ seems to have prompted investigators to explore other anchorage sites, such as the trigonum retromolare^{16,17} and the alveolar bone.

Most orthodontic patients are too young to have fully developed alveolar bones. This problem can be circumvented by inserting a miniature implant buccolingually into the alveolar bone, between the roots of the adjacent teeth,¹⁸ or by affixing "onplant" plates to the bone surface.¹⁹

The maxillary suture would seem to be a more reliable location for anchorage in adolescent orthodontic patients. Unfortunately, research data on the effectiveness of implants used for orthodontic anchorage are available only from animal studies,²⁰⁻³⁰ and only one of these used implants in the median maxillary sutures.³⁰

Furthermore, the fabrication of a supraconstruction—the palatal arch attached to the implant—has been a longstanding problem, especially if active movement of the anchor teeth is desired.^{31,32} The ideal supraconstruction should

be easy to fabricate by an orthodontic technician, should be simple to use and adjust, and should allow stabilization and active movement of the attached teeth in all three dimensions, without refabricating the appliance. This article describes a new supraconstruction that meets these requirements.

Design and Fabrication

The basic principle of the appliance is to provide a rigid platform that is not attached primarily to any single tooth. A yoke-shaped palatal bar made of .036" × .072" heat-treatable Remaloy* stainless steel wire has 4.5mm .022" × .028" rectangular tubes** attached on each end (Fig. 1). Sectional wires connect these tubes to .022" Damon SL*** brackets welded to the palatal sides of the molar bands. The sectional wires are used to stabilize, move, or rotate the molars in any plane of space, depending on the clinical situation.

The working cast is constructed as follows:

*Registered trademark of Dentaaurum, Inc., 10 Pheasant Run, Newtown, PA 18940.

**LeoneAmerica, 1200 Stellar Drive, Oxnard, CA 93033.

***Registered trademark of Ormco/A Company, 1717 W. Collins Ave., Orange, CA 92867.



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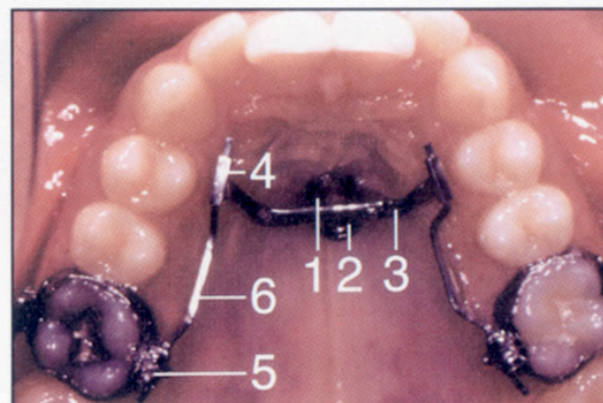


Fig. 1 New supraconstruction, showing remodeled impression coping (1), gold fixation screw (2), yoke-shaped palatal bar (3), rectangular tubes (4), Damon SL molar brackets (5), and sectional wires (6).

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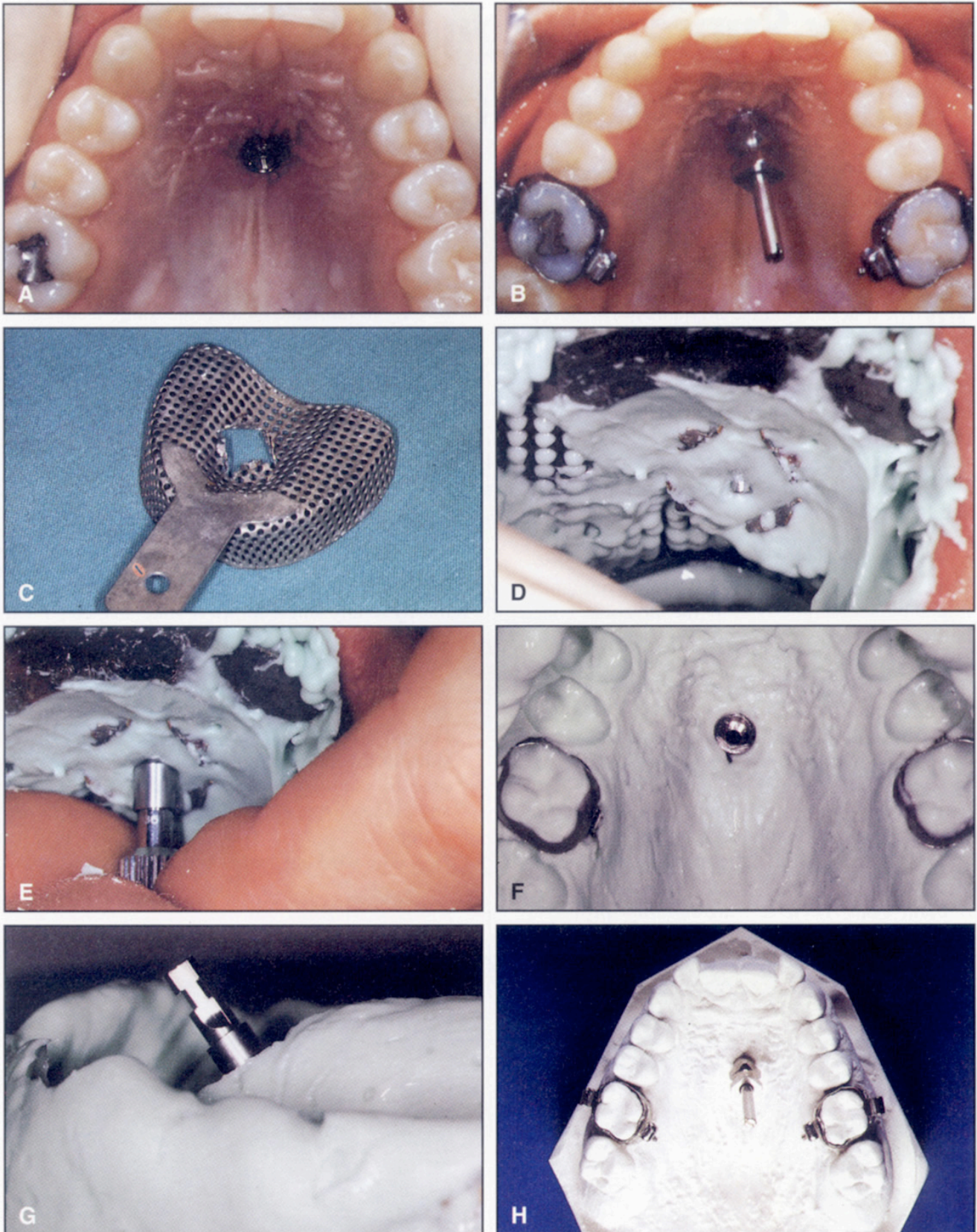


Fig. 2 A. Implant after connection of abutment. B. Impression coping fixed with guide pin and molar bands seated. C. Hole cut in impression tray for coping and guide pin. D. Excess alginate removed from top of guide pin. E. Guide pin unscrewed after alginate has set. F. Molar bands positioned in alginate. G. Replica of abutment attached to impression coping with guide pin. H. Finished cast with molar bands and impression coping in place.

1. After surgical placement of the implant and connection of the abutment (Fig. 2A), the impression coping is inserted and fixed with a guide pin (a long-headed screw, Fig. 2B). In the clinical trials pictured here, two weeks elapsed between these steps; the same procedure can be accomplished in one appointment.
2. The molar bands are seated.
3. An x-shaped slot is cut into the impression tray at the implant site. The triangles thus created are bent lingually, and the edges are curled to prevent injury to the tongue (Fig. 2C).
4. Since the model does not need the high degree of accuracy required for crowns and bridges, an alginate impression is sufficient. The tray is inserted, and the excess alginate covering the guide pin is removed (Fig. 2D).
5. After the alginate has set, the guide pin is unscrewed with the tray still in place (Fig. 2E).

The tray is then removed.

6. The molar bands are positioned in the alginate (Fig. 2F) and waxed.
7. A technician's replica of the abutment is attached to the impression coping with the guide pin, taking care not to move the impression coping (Fig. 2G).
8. The impression is poured in plaster (Fig. 2H).

The supraconstruction is then constructed as follows:

1. The guide pin is replaced by a gold fixation screw. The impression coping is cut to the height of this screw, and its square edges are milled into a round shape (Fig. 3A).
2. The coping is further milled with an .036" × .072" slot to accommodate the palatal bar (Fig. 3B).
3. The Remaloy palatal bar is heat-treated so it can be manually bent and stiffened into the prop-

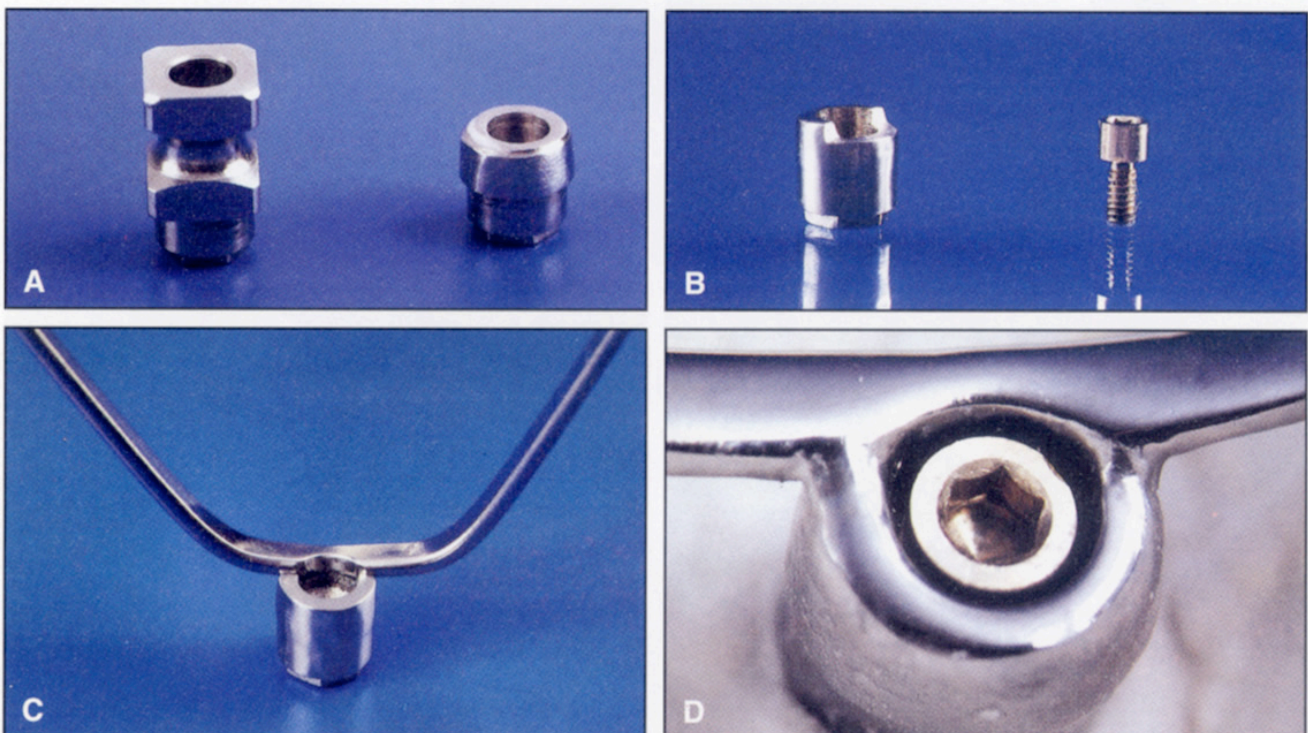


Fig. 3 A. Impression coping (left) cut to height of gold fixation screw and milled into round shape (right). B. Impression coping (left) milled with slot for palatal bar and ready to accommodate gold screw (right). C. Palatal bar trimmed back to allow space for gold screw. D. Palatal bar laser-welded to impression coping (continued on next page).

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er yoke shape. The wire is shaved back in the center, where it meets the impression coping, to allow enough space for the gold screw (Fig. 3C).

4. The palatal bar is laser-welded to the impression coping (Fig. 3D). (All laser-welded parts can be soldered if desired.)

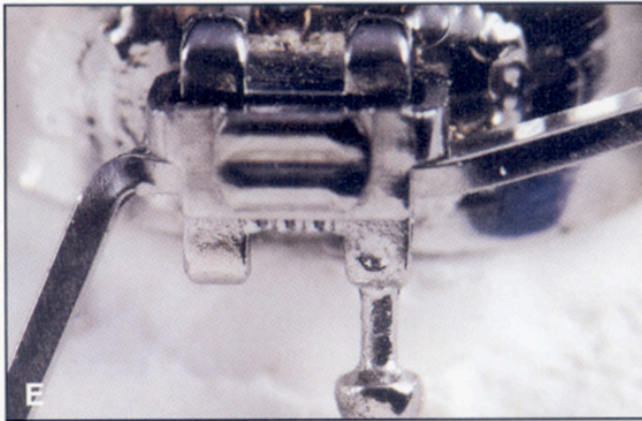


Fig. 3 (cont.) E. Damon SL bracket welded to palatal side of molar band, showing sectional wire in closed bracket. F. Rectangular tube welded to palatal bar, with sectional wire in place. G. Completed supraconstruction on cast. H. Mesial end of sectional wire inserted into distal end of rectangular tube. I. Distal end of sectional wire inserted into palatal side of Damon SL bracket. J. Bracket closed into tube with band-seating instrument.

5. Damon SL .022" brackets (Roth prescription, maxillary first premolar of opposite side) are welded to the palatal sides of the molar bands (Fig. 3E).

6. The .022" × .028" rectangular tubes are welded to the ends of the palatal bar (Fig. 3F), with a straight .0215" × .028" wire inserted in each tube to stabilize it during welding. Care must be taken to ensure identical torque in the tubes and the molar brackets.

7. Sectional wires can also be prefabricated by the technician (Fig. 3G) and later adjusted in the mouth by the orthodontist. The mesial ends of the sectional wires can be filed down to facilitate insertion into the distal ends of the rectangular tubes (Fig. 3H). The Damon bracket slots are opened to allow insertion of the distal ends of the sectional wires from the palatal side (Fig. 3I). The slots are then closed into tubes, using the

special Damon tool or a band-seating plier (Fig. 3J).

Clinical Applications

The palatal implant provides absolute anchorage of the molars in a passive setup using .021" × .025" stainless steel sectional wires (Fig. 4A). The vertical legs of the sectional wires should be as short as possible, serving only as sagittal stops.

Either distal or mesial movement of the molars is possible, although the former is usually desired. Distalization can be accomplished either with sagittally preactivated delta loops and long vertical legs (Fig. 4B) or with straight sectional wires and push-coil springs (Fig. 4C). If straight wires are used, stops should be crimped or welded distal to the rectangular tubes to pre-

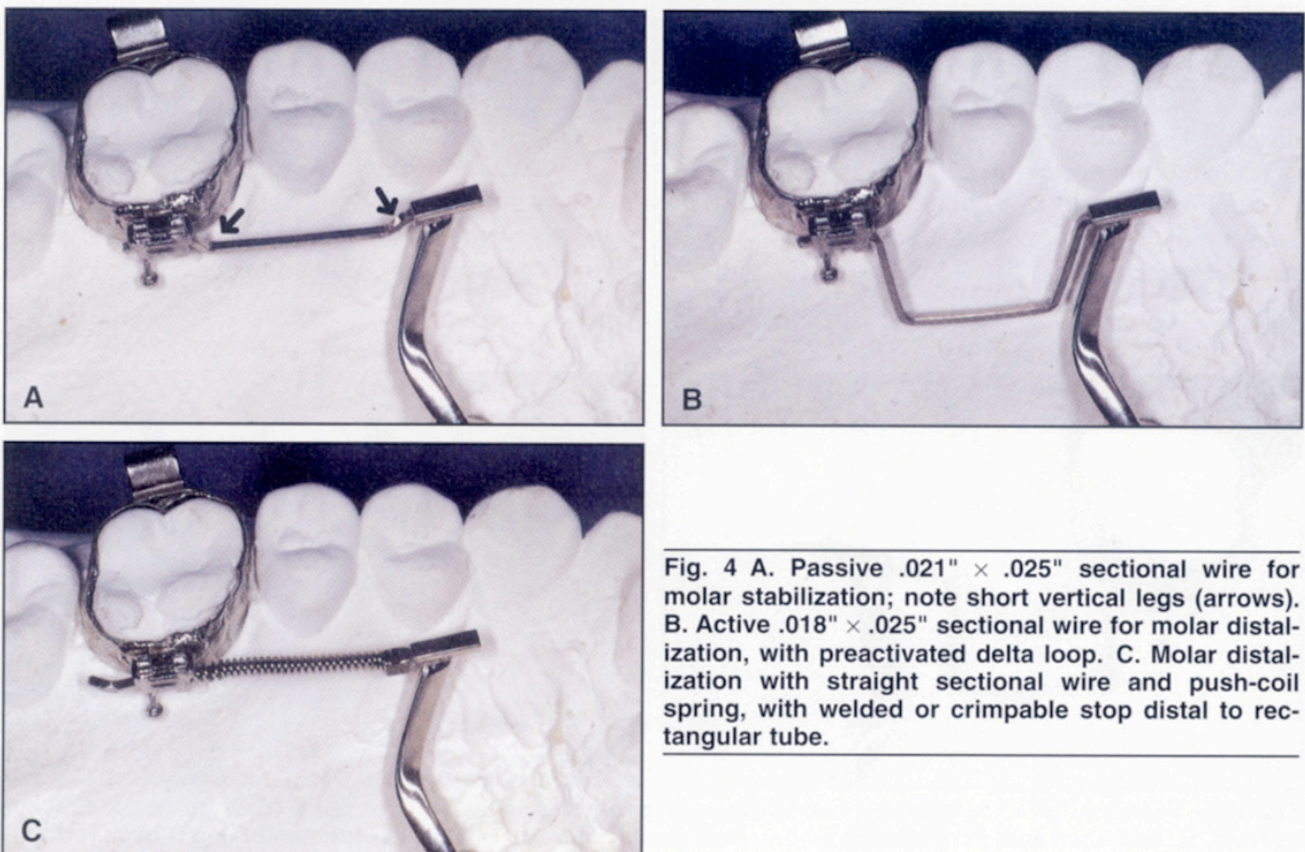


Fig. 4 A. Passive .021" × .025" sectional wire for molar stabilization; note short vertical legs (arrows). B. Active .018" × .025" sectional wire for molar distalization, with preactivated delta loop. C. Molar distalization with straight sectional wire and push-coil spring, with welded or crimpable stop distal to rectangular tube.

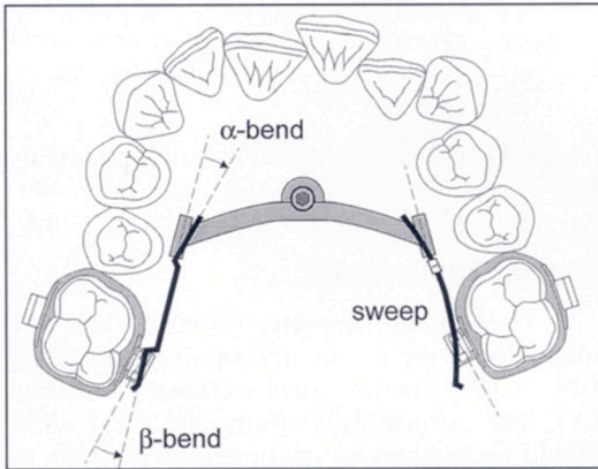


Fig. 5 1st-order compensations needed for molar distalization. With delta-loop sectional wire (patient's right side), β -bend at molar bracket prevents mesial molar rotation, and opposite α -bend at rectangular tube prevents undesirable transverse side effects. With straight sectional wire (patient's left), bends are made in continuous "sweep" (coil spring is omitted from drawing for clarity).

vent free sagittal sliding. In either case, .018" \times .025" stainless steel sectional wires seem to be ideal.

Because the applied force is palatal to the center of resistance, the distal movement will tend to rotate the molars mesial-in and tip them distally. Therefore, compensatory 1st- and 2nd-order bends are needed.

When delta-loop sectional wires are used, antirotation (toe-in) β -bends are made at the molar brackets (Fig. 5). Equilibrium then re-

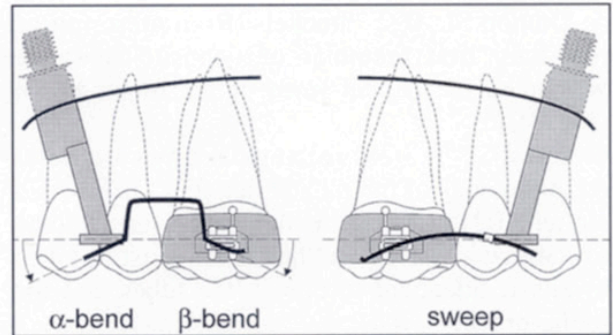


Fig. 6 2nd-order compensations needed for molar distalization. With delta-loop sectional wire (patient's right side), β -bend at molar bracket prevents distal tipping, and opposite α -bend at rectangular tube avoids molar intrusion. With straight sectional wire (patient's left), bends are made in continuous "sweep" (coil spring is omitted from drawing for clarity).

quires a couple in the opposite direction—a buccal force at the molars and a palatal force at the implant. Since the implant will not move, the molars will move buccally. To avoid this undesirable side effect, α -bends of the same angle should be placed in the opposite direction at the rectangular tubes.

Second-order compensation involves crown-tip-forward β -bends at the molars, with α -bends at the rectangular tubes to prevent intrusion of the molars, if that is not desired (Fig. 6).



Fig. 7 A. Sectional wire for mesial molar movement prior to activation; note bend distal to molar bracket (arrow). B. Sectional wire activated by pulling mesial end through rectangular tube and tying it back (arrow).

When straight sectional wires are used for distalization, the bends described above are replaced by "sweeps" or continuous curvatures in the appropriate directions. These curves allow free movement of the coil springs.

Mesial molar movement can be produced with the same type of delta loop, preactivated in the opposite direction. The sectional wire must be bent down distal to the molar bracket (Fig. 7A). The loop is then activated by pulling the wire mesially through the rectangular tube and tying it back (Fig. 7B). Compensatory bends are applied in the opposite directions as those for distal molar movement.

Case 1

A 12-year-old male presented with a full Class II molar relationship on the right and a one-and-a-half-step Class II on the left (Fig. 8A). Even with extraction of the maxillary first premolars, the maxillary incisors could not be retracted into a normal overjet, nor could the midline be corrected, as long as the left canine was hindered from moving into a Class I relationship.

Therefore, the maxillary left first molar was distalized with a palatal implant and a straight sectional wire and push-coil spring as described above (Fig. 8B). The required distal movement was achieved in two months (Fig. 8C,D).

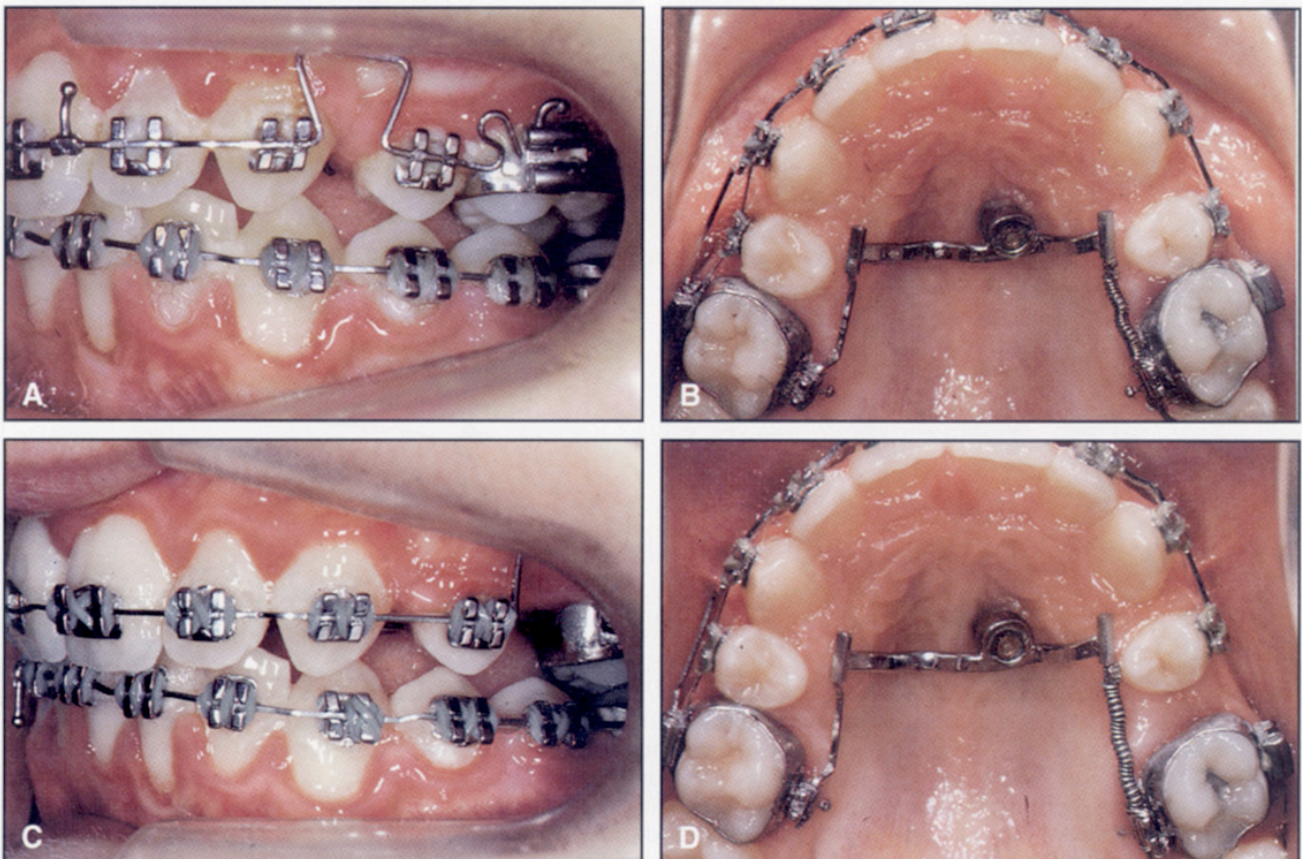


Fig. 8 Case 1. A. 12-year-old male with one-and-a-half-step Class II relationship on left side. B. Supra-contruction with push-coil spring for distalization of left first molar. Molar is not connected to rest of maxillary dentition. Note placement of implant lateral to raphe. C. Molars in Class II relationship after two months. D. Left first molar has been moved 4mm distally, without movement of premolar.

A New Supraconstruction for Palatal Orthodontic Implants

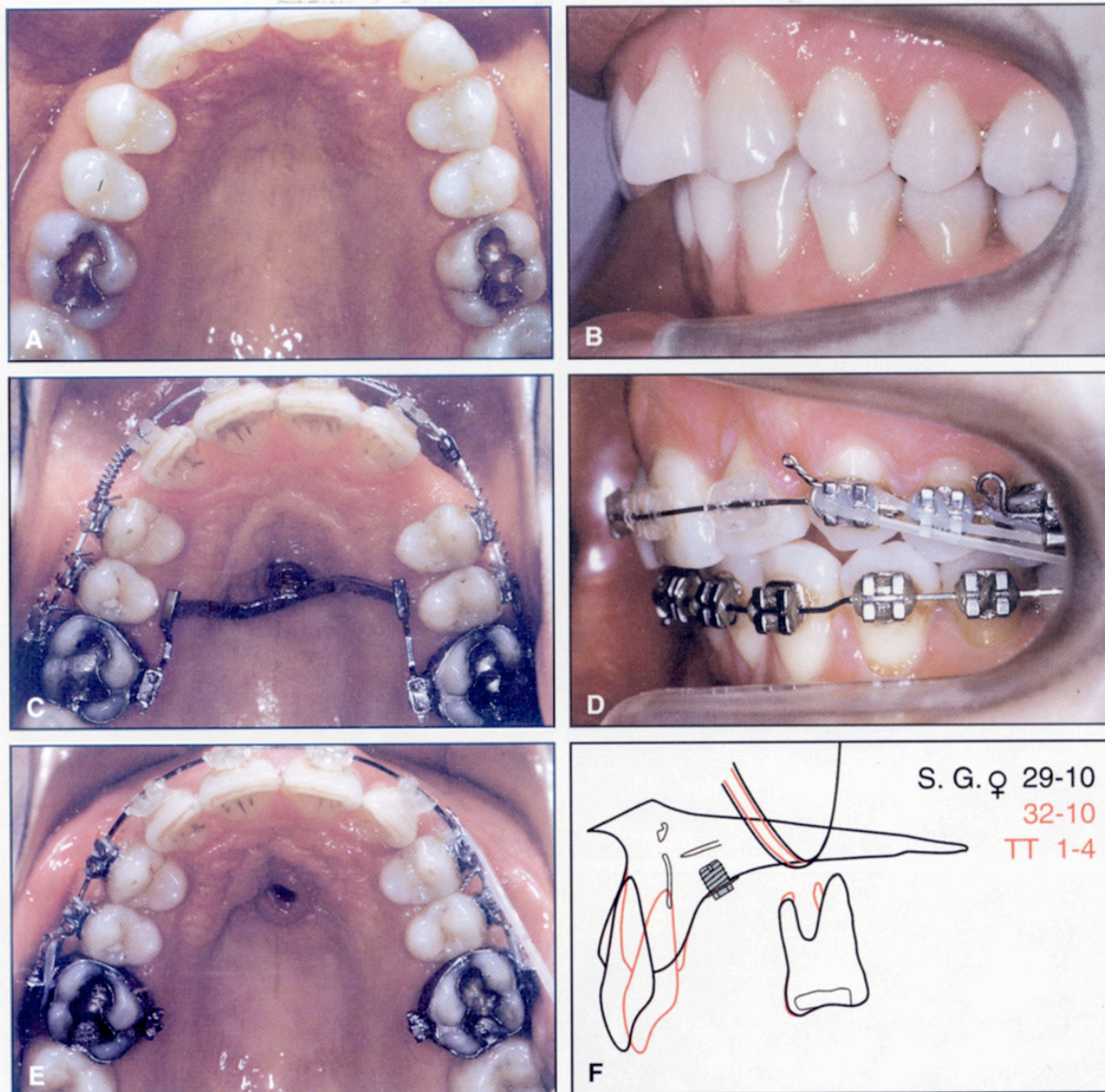


Fig. 9 Case 2. A,B. 29-year-old female with three-quarter-step Class II relationship on each side. Maxillary midline shift to right and retrusive incisors were due to extractions of maxillary right canine and mandibular incisor in previous orthodontic treatment. C. Supraconstruction with .021" × .025" sectional wires for absolute anchorage of molars on both sides. After extraction of maxillary left canine, incisors were shifted to left along archwire, using push-coil spring on right and pull-coil spring on left. D. Class II elastic used for finishing adjustments. E. After removal of implant. F. Structural superimposition of maxilla, showing 7° torquing of incisor and 2.5mm retraction of incisal edge, with no molar movement.

Case 2

A 29-year-old female had a maxillary midline shift to the right and retrusive incisors, due to extractions of the maxillary right canine and a mandibular incisor in previous orthodontic treatment (Fig. 9A). The premolar and molar relationships were three-quarter-step Class II on both sides (Fig. 9B).

The maxillary left canine was extracted because it is larger than the first premolar, and thus would reduce the arch-size discrepancy caused by the extracted mandibular incisor. The maxillary incisors then had to be retracted and shifted to the left, with a substantial amount of palatal root torque.

Although only a little anchorage was needed on the right side, a considerable amount was required on the left. A palatal implant was placed, with a supraconstruction using .021" × .025" sectional wires for molar stabilization (Fig. 9C). The incisors were moved along the archwire with a push-coil spring on the right and a pull-coil spring on the left. After spaces had been closed equally on both sides (Fig. 9D), the implant was removed (Fig. 9E).

Maxillary superimposition showed that the incisors were torqued 7°, so that the incisal edge was retracted 2.5mm and the apex 5mm (Fig. 9F). Virtually no change in molar position occurred.

Conclusion

The supraconstruction described in this article can be adapted to numerous clinical situations simply by adjusting its sectional wires. The overall design can be adapted to any implant system in which the supraconstruction is protected against rotation. The appliance is easy to fabricate and install.

Clinical observation thus far has shown favorable stability, effectiveness, and patient comfort. The long-term reliability of implants in the median palatal suture still needs to be confirmed by further investigation.

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Survival and failure rates of orthodontic temporary anchorage devices: a systematic review

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Key words: failure, human, skeletal anchorage, survival, systematic review

Abstract

Aim: The purpose of this study was to systematically review the literature on the survival rates of palatal implants, Onplants[®], miniplates and mini screws.

Material and methods: An electronic MEDLINE search supplemented by manual searching was conducted to identify randomized clinical trials, prospective and retrospective cohort studies on palatal implants, Onplants[®], miniplates and miniscrews with a mean follow-up time of at least 12 weeks and of at least 10 units per modality having been examined clinically at a follow-up visit. Assessment of studies and data abstraction was performed independently by two reviewers. Reported failures of used devices were analyzed using random-effects Poisson regression models to obtain summary estimates and 95% confidence intervals (CI) of failure and survival proportions.

Results: The search up to January 2009 provided 390 titles and 71 abstracts with full-text analysis of 34 articles, yielding 27 studies that met the inclusion criteria. In meta-analysis, the failure rate for Onplants[®] was 17.2% (95% CI: 5.9–35.8%), 10.5% for palatal implants (95% CI: 6.1–18.1%), 16.4% for miniscrews (95% CI: 13.4–20.1%) and 7.3% for miniplates (95% CI: 5.4–9.9%). Miniplates and palatal implants, representing torque-resisting temporary anchorage devices (TADs), when grouped together, showed a 1.92-fold (95% CI: 1.06–2.78) lower clinical failure rate than miniscrews.

Conclusion: Based on the available evidence in the literature, palatal implants and miniplates showed comparable survival rates of $\geq 90\%$ over a period of at least 12 weeks, and yielded superior survival than miniscrews. Palatal implants and miniplates for temporary anchorage provide reliable absolute orthodontic anchorage. If the intended orthodontic treatment would require multiple miniscrew placement to provide adequate anchorage, the reliability of such systems is questionable. For patients who are undergoing extensive orthodontic treatment, force vectors may need to be varied or the roots of the teeth to be moved may need to slide past the anchors. In this context, palatal implants or miniplates should be the TADs of choice.

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Anchorage is one of the limiting factors in orthodontics, and its control is essential for successful treatment outcomes. The term 'orthodontic anchorage' denotes the nature and degree of resistance to displacement offered by an anatomic unit. According to the intended treatment goals, desired tooth

movements should, therefore, be maximized, and undesirable effects should be minimized. Traditionally, orthodontic therapy used teeth, extraoral and/or intermaxillary appliances for anchorage. Since a patient's cooperation is not always optimal (Nanda & Kierl 1992), temporary anchorage

devices (TAD) (Daskalogiannakis 2000) have been introduced. TADs are anchored in bone and removed after completion of the intended orthodontic tooth movement. They are designed to overcome the limitations of conventional orthodontic anchorage devices (COADs). Anchorage by means of TADs allows independence in relation to patient compliance (Creekmore & Eklund 1983) either by supporting the teeth of the reactive unit or by obviating the need for a reactive at large.

Usually, orthodontic patients present a complete dentition or with extraction sites to be closed. No edentulous alveolar bone ridges are generally available for the insertion of TADs. As a consequence, these must be placed in topographical regions distant to the main area of action.

New additional insertion sites have been offered by the introduction of length-reduced mid-palatal orthodontic anchorage devices such as titanium flat screws (Triaca et al. 1992), resorbable orthodontic implant anchors (Glatzmaier et al. 1995), T-shaped orthodontic implants (Wehrbein et al. 1996) (Orthosystem[®], Institut Straumann, Waldenburg, Switzerland) and the Graz implant-supported pendulum (Byloff et al. 2000). Diameter-reduced temporary orthodontic anchorage devices such as miniscrews (<2 mm) in various lengths (Kanomi 1997; Costa et al. 1998) and titanium pins (Bousquet et al. 1996) are inserted into the alveolar bone and L-shaped miniplates with the long arm exposed into the oral cavity (Umemori et al. 1999), and bollard anchors (De Clerck et al. 2002) are fixed by bone screws in supra-apical regions. Another device, the Onplant[®] (Nobel Biocare, Zurich, Switzerland) (Block & Hoffman 1995), placed subperiostally, was supposed to adhere to bone.

Having used these TADs for more than a decade, numerous case reports and scientific papers have been published documenting the clinical feasibility of the TADs mentioned. In contrast to prosthetic oral implants, the literature exploring the survival and failure rates of orthodontic TADs has not been evaluated systematically.

Therefore, the aim of the present systematic review was to determine the survival and failure rates of palatal implants, mini screws, miniplates and onplants. The focused question to be answered was: 'What are the survival and failure rates of

the orthodontic TADs after a functional period of at least 12 weeks.'

Material and methods

A Medline (PubMed and Ovid) search from 1966 up to and including January 2009 was conducted for English language articles limited to human studies published based on the following searching terms: 'mini screw', 'miniscrew', 'micro screw', 'micro-screw', 'micro implant', 'microimplant', 'mini implant', 'miniimplant', 'palatal implant', 'miniplate' and 'onplant'.

Manual searches of the bibliographies of all full-text articles and related reviews, selected from the electronic search, were additionally performed. Furthermore, the following journals were searched manually for the years 2004 to January 2009: *Clinical Oral Implants Research*, *European Journal of Orthodontics*, *American Journal of Orthodontics and Dentofacial Orthopedics*, *Angle Orthodontist*, *Journal of Clinical Orthodontics*, *Journal of Orofacial Orthopedics*, *Journal of Adult Orthodontics and Orthognathic Surgery* and *International Journal of Oral & Maxillofacial Implants*.

From these searches, it was obvious that there were no randomized-controlled clinical trials (RCTs) available comparing all the different types of TADs. However, there were two RCTs comparing TADs (Onplants[®] and palatal implants) with compliance-dependent COADs (Feldmann & Bondemark 2008; Sandler et al. 2008) and one RCT comparing two different miniscrew types (Wiechmann et al. 2007).

Inclusion criteria

In the absence of RCTs comparing all different types of TADs with each other, this systematic review was based on the few (three) available RCTs with limited impact and all prospective or retrospective cohort studies. The additional inclusion criteria for study selection were:

- mean TAD loading time of at least 12 weeks;
- publications reported in English;
- included patients had been examined clinically at the follow-up visit, i.e. publications based on patient records only, on questionnaires or interviews were excluded;

- reported details on the screw types used.

Selection of studies

Fig. 1 describes the search strategy used to identify relevant studies selected for this review. Titles and abstracts of the Medline searches were initially screened by two independent reviewers (R.M. and M.S.) for possible inclusion. From a yield of 390 titles, 71 were selected for abstract screening (Fig. 1). The agreement between the reviewers using κ -statistics was 96.2%. The full text of all studies of possible relevance (34) was then obtained for independent assessment by the two reviewers. Any disagreement was resolved by discussion.

Data were extracted independently by the same two reviewers using a data extraction form.

Excluded studies

Of the 34-full-text articles retrieved, seven were excluded from the final analysis. The main reasons for exclusion were a mean observation period of <12 weeks, loading time was not clearly indicated, less than 10 units per modality in the study and multiple publication of the same cohort in different scientific journals at different time points.

Data extraction

Information on the proportions of biological and technical complications was retrieved on the 27 studies included. Biological complications included disturbances in the function of the skeletal anchorage device leading to any early removal of the anchorage device before the end of the intended orthodontic treatment or observation period. Healing or incorporation failures were also included in this category. Technical complications were not reported in any of the studies, and therefore could not be assessed separately.

From the 27 included studies, the number and percentage of failures was extracted. Disagreement regarding data extraction was resolved by consensus.

Statistical analysis

Failure rates were calculated by dividing the number of events (failures) after at least 12 weeks of orthodontic loading in the

numerator by the total number of each TAD type in the denominator. For further analysis, the total number of events was considered to be Poisson distributed for a given number of TADs, and Poisson regression with a logarithmic link function and total number of TADs per study as an offset variable was used. To assess the heterogeneity of the study-specific event rates, the Spearman goodness-of-fit statistics and associated *P*-value were calculated. If the goodness-of-fit *P*-value was below 0.05, indicating heterogeneity, random-effects

Poisson regression (with γ -distributed random effects) was used to obtain a summary estimate of the event rates. Summary failure rate estimates and 95% confidence intervals (CI) are reported.

To provide anchorage on either side of the maxilla, only one palatal implant or Onplant[®] was needed, whereas at least two fixtures have to be installed if miniplates or miniscrews are used.

To evaluate the possible failure of at least one out of two fixtures, it was assumed that failures of these objects may occur

independently. The probability to remain free of failure was therefore calculated by multiplying the probability that each object remains free of failure: $(1 - \text{risk}_{\text{object1}}) \times (1 - \text{risk}_{\text{object2}})$. Therefore, the probability of encountering at least one failure becomes $1 - (1 - \text{risk}_{\text{object1}}) \times (1 - \text{risk}_{\text{object2}})$.

The 95% CI limits for survival proportions were calculated using the 95% confidence limits of the event rates. All analyses were performed using Stata[®], version 10.1 (Stata Corporation, College Station, TX, USA).

Results

Onplants[®]

There was only one article fulfilling the inclusion criteria concerning Onplants[®] (Feldmann & Bondemark 2008). In this RCT, five out of 29 onplants or 17.2% (95% CI: 5.9–35.8%) failed (Table 1).

Microscrews/Microimplants and Miniscrews/Miniimplants

Seventeen studies provided data on the survival of 31 different types of miniscrews (Table 2). A total of 2374 miniscrews inserted in 1196 patients with a total of 363 or 15.3% failures could be analyzed (Table 2). Seven studies reported results of prospective cohort studies, whereas the remaining 10 assessed their results retrospectively. Data of only one RCT could be extracted comparing two different screw types (Wiechmann et al. 2007). However, due to the lack of precise data reporting in all these studies no conclusive statement of survival and/or the failure rate of a specific screw type (length and diameter) regarding their favorable indication, insertion location, insertion technique and type of loading could be made.

Some reports provided detailed data on the diameter and length of the inserted miniscrews, while others pooled the results of a specific miniscrew diameter with various lengths (Table 2). The mean follow-up

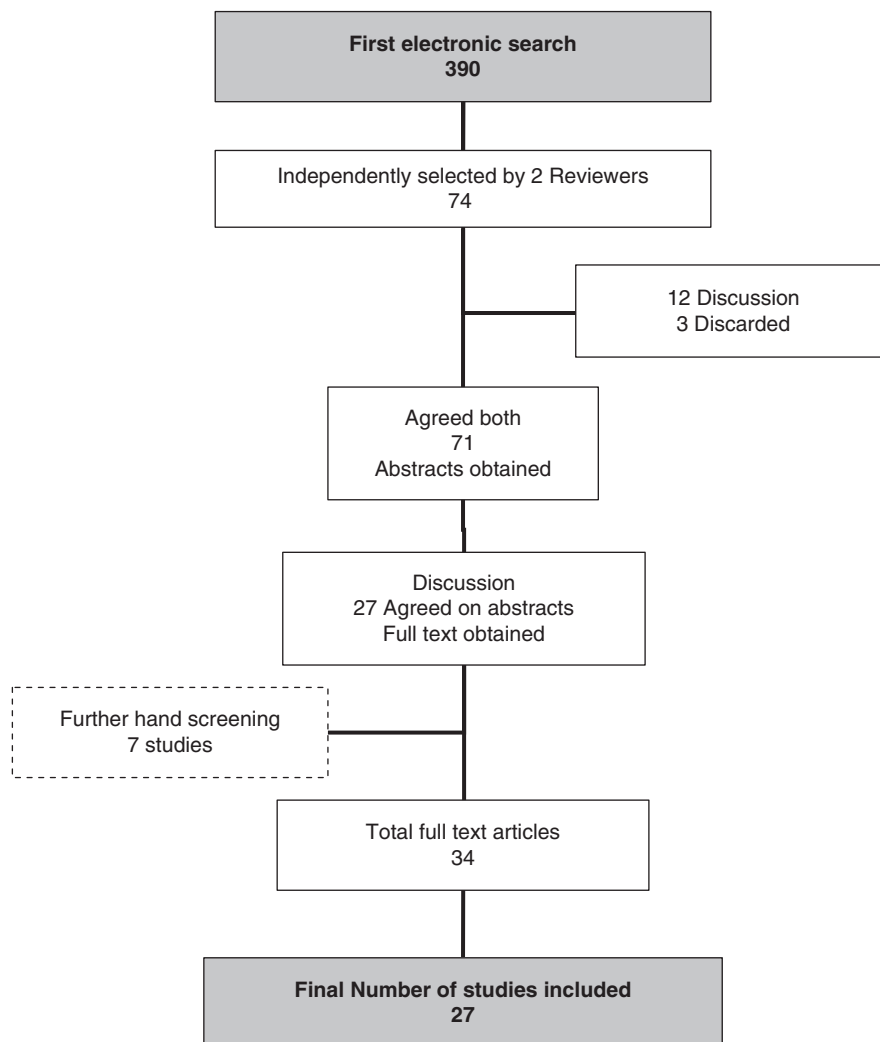


Fig. 1. Search strategy.

Table 1. Study and patient characteristics of the reviewed study of Onplants[®]

Author	Kind of study	Type of TAD	Manufacturer	Diameter	Number of patients	Mean patient's age (years)	Number of TADs	Number of failures	Percent of failures	Loading time
Feldmann & Bondemark (2008)	RCT	Onplant [®]	Nobel Biocare [®]	7.7 mm titanium disk	29	14 ± 1.53	29	5	17.2%	Completion of treatment

TAD, temporary anchorage devices; RCT, randomized controlled clinical trials.

Table 2. Study and patient characteristics of the reviewed studies of miniscrews/microscrews

Author	Kind of study	Type of TAD	Manufacturer	Diameter (mm)	Length (mm)	Number of patients	Number of Mean patient's age (years)	Number of TADs	Number of failures	Percent	Loading time
Chen et al. (2008)	Retrospective	Miniscrew	Mondeal, Tuttlingen, Germany	2	8–14	194	25.1 ± 8.7	57	14	24.6	Within 36 months
Chen et al. (2008)	Retrospective	Microscrew	Bioray, Taipei, Taiwan	2	5–21	194	25.1 ± 8.7	264	25	9.6	Within 36 months
Chen et al. (2007)	Retrospective	Miniscrew	AbsoAnchor, Dentos, Daegu, Korea	1.2	4–10	129	24.5 ± 7.1	72	17	23.6	Completion of treatment
Chen et al. (2006)	Retrospective	Miniscrew	AbsoAnchor	1.2	6	29	29.8	18	5	27.8	Completion of treatment
Chen et al. (2006)	Retrospective	Miniscrew	AbsoAnchor	1.2	8	29	29.8	41	4	9.8	Completion of treatment
Cheng et al. (2004)	Prospective	Miniscrew	Leibinger and Mondela, Mondeal Tuttlingen, Germany	2	9	44	29 ± 8.9	31	2	6.5	Completion of treatment
Cheng et al. (2004)	Prospective	Miniscrew	Leibinger or Mondela	2	11	44	29 ± 8.9	31	2	6.5	Completion of treatment
Cheng et al. (2004)	Prospective	Miniscrew	Leibinger or Mondela	2	13	44	29 ± 8.9	20	3	15	Completion of treatment
Cheng et al. (2004)	Prospective	Miniscrew	Leibinger or Mondela	2	15	44	29 ± 8.9	10	1	10	Completion of treatment
Park et al. (2006)	Prospective	Miniscrew	Stryker/Leibinger, Leibinger, Mülheim-Stelten, Germany	1.2	5	10	15.5 ± 8.3	19	3	15.8	Completion of treatment
Park et al. (2006)	Prospective	Miniscrew	OstoMed, Addison, TX, USA	1.2	6–10	67	15.5 ± 8.3	157	10	6.4	Completion of treatment
Park et al. (2006)	Prospective	Miniscrew	AbsoAnchor	1.2	4, 6, 7, 8 or 10	16	15.5 ± 8.3	46	5	10.9	Completion of treatment
Wiechmann et al. (2007)	RCT	Miniscrew	AbsoAnchor	1.1	5, 6, 7, 8 or 10	49	26.9 ± 8.9	79	24	30.4	4 months
Wiechmann et al. (2007)	RCT	Miniscrew	Dual Top, Jeil Medical, Seoul, Korea	1.6	5, 6, 7, 8 or 10	49	26.9 ± 8.9	54	7	13	4 months
Liou et al. (2004)	Prospective	Miniscrew	Leibinger, Mülheim-Stelten, Germany	2	17	16	22–29	32	3	9.4	9 months
Park et al. (2005)	Prospective	Miniscrew	Oesteomed	1.2	6	13	17.9 ± 5.7	30	3	10	12.3 ± 5.7 months
Kuroda et al. (2007a)	Retrospective	Miniscrew	AbsoAnchor	1.3	6, 7, 8, 10 or 12	110	22.5 ± 8.1	237	42	17.7	> 12 months or completion of treatment
Kuroda et al. (2007a)	Retrospective	Miniscrew	Gebrüder Martin GmbH, Tuttlingen, Germany	1.5	9	110	22.5 ± 8.1	25	4	16	> 12 months or completion of treatment
Kuroda et al. (2007b)	Retrospective	Miniscrew	KeiSei Medical Ind., Tokyo, Japan	2 or 2.3	7 or 11	18	21.8	37	7	18.9	> 12 months or completion of treatment
Kuroda et al. (2007b)	Retrospective	Miniscrew	AbsoAnchor	1.3	6, 7, 8, 10 or 12	40	21.8	79	9	11.4	> 12 months or completion of treatment
Luzi et al. (2007)	Retrospective	Miniscrew	Ashus-Miniscrew, Medicon, Tuttlingen, Germany	1.5 or 2	9.6 or 11.6	98	34.3	140	13	9.3	4 months
Motoyoshi et al. (2006)	Prospective	Miniscrew	Biodent, Tokyo, Japan	1.6	8	57	20.8	169	25	14.8	> 6 months
Tseng et al. (2006)	Retrospective	Miniscrew	Stryker Leibinger	2	8	25	29.9	15	3	20	Completion of treatment
Tseng et al. (2006)	Retrospective	Miniscrew	Stryker Leibinger	2	10	25	29.9	10	1	10	Completion of treatment
Tseng et al. (2006)	Retrospective	Miniscrew	Stryker Leibinger	2	12	25	29.9	12	0	0	Completion of treatment
Miyawaki et al. (2003)	Retrospective	Miniscrew	Not specified	1	6	3	21.8 ± 7.8	10	10	100	> 12 months or completion of treatment
Miyawaki et al. (2003)	Retrospective	Miniscrew	Not specified	1.5	11	31	21.8 ± 7.8	101	16	15.8	> 12 months or completion of treatment
Miyawaki et al. (2003)	Retrospective	Miniscrew	Not specified	2.3	14	10	21.8 ± 7.8	23	3	13	> 12 months or completion of treatment
Garfinkle et al. (2008)	Prospective	Miniscrew	Osteomed	1.6	8	13	14.83	41	8	19.5	Space closure
Justens & De Bruyn (2008)	Retrospective	Miniscrew	Dual Top	1.6 or 2	8 or 10	21	21.4	50	17	34	Completion of treatment
Moon et al. (2008)	Retrospective	Miniscrew	Dual Top	1.6	8	209	20.3	480	78	16.3	8 months

TAD, temporary anchorage devices; RCT, randomized controlled clinical trials.

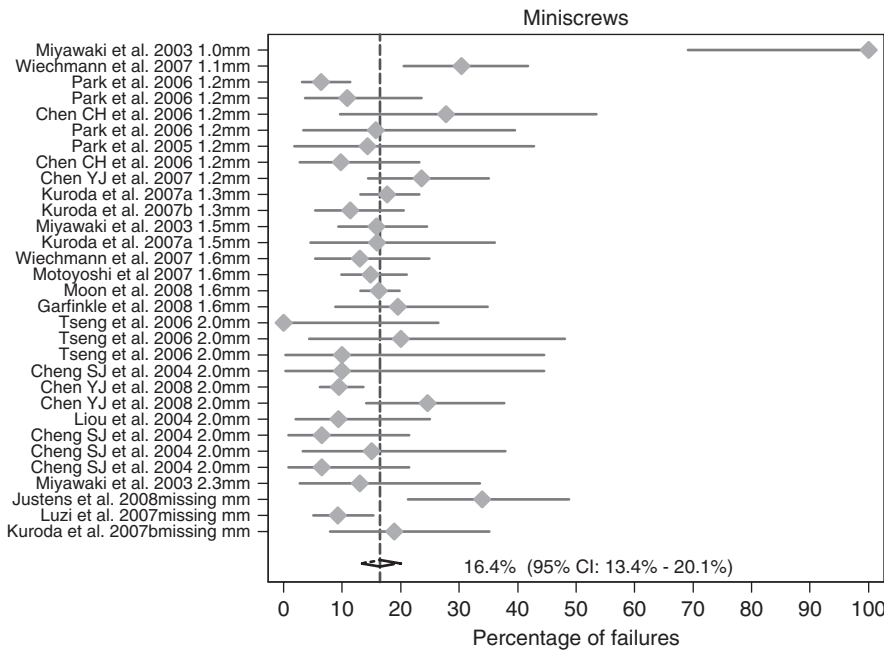


Fig. 2. Failure rates of miniscrews and summary estimate from meta-analysis and their 95% confidence intervals (95% CI) by study.

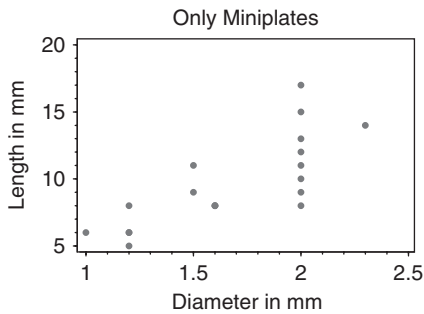


Fig. 3. Distribution of screw length by screw diameter.

time ranged between 120 days and more than 1 year or completion of the intended orthodontic treatment.

By meta-analysis, the failure rate (Fig. 2) was estimated at 16.4% (95% CI 13.4–20.1%). By analyzing the influence of screw length and diameter, only the data of screws with detailed characteristics were considered. Three groups of diameter were created, which basically separate these three ‘clouds’ of diameter and length types (Fig. 3). The miniscrews with a diameter of 2 mm or more showed a significantly 1.8-fold lower risk (95% CI: 1.1–3) of failing than miniscrews of a diameter of 1.2 mm or less.

Palatal implants

One retrospective and five prospective cohort studies provided data fulfilling the

inclusion criteria on the survival and failure rate of palatal implants (Table 3). Two out of these were RCTs comparing palatal implants with conventional compliance-dependent orthodontic anchorage (CDOA) (Sandler et al. 2008) only or with CDOA and Onplants® (Feldmann & Bondemark 2008). However, only one report evaluated the clinical outcome of a larger number of palatal implants (Männchen & Schätzle 2008). Data of a total of 190 palatal implants with a follow-up time of at least 12 weeks up to more than 22 months or completion of the intended orthodontic treatment could be assessed. Nineteen or 10% out of 190 palatal implants did not provide sufficient anchorage and were lost early or before the time point of evaluation. In meta-analysis, the failure rate for the whole group of studies was estimated at 10.5% (95% CI: 6.1–18.1%) (Fig. 4).

Miniplates

Seven studies out of the 27 included reports provided data on the survival and failure rates of miniplates (Table 4). Two were prospective cohort studies, and the remaining five evaluated the material presented retrospectively. A total of 586 miniplates in 406 patients could be followed for at least 120 days up to 1.5 years or completion of the intended orthodontic treatment, respectively. Forty-three or 7.3% out of

Table 3. Study and patient characteristics of the reviewed studies of palatal implants

Author	Kind of study	Type of TAD	Manufacturer	Diameter (mm)	Length (mm)	Number of patients	Mean patient's age (years)	Number of TADs	Number of failures	Percent of Failures (%)	Loading time
Jung et al. (2009)	Prospective	Palatal implant	Straumann	4.1	4.2	30	19.7	30	2	6.7	6 months
Sandler et al. (2008)	RCT	Palatal implant	Straumann	3.3 or 4	4	24	15.7	26	6	23.1	25.8 ± 7 months
Feldmann & Bondemark (2008)	RCT	Palatal implant	Straumann	3.3	4	30	14.6 ± 2	30	2	6.7	Completion of treatment
Männchen & Schätzle (2008)	Prospective	Palatal implant	Straumann	3.3 or 4	4 or 6	70	22.5 ± 10.8	70	4	5.7	18.8 ± 10.7 months
Arcuri et al. (2007)	Retrospective	Palatal implant	Straumann	3.3	4 or 6	14	>20	14	3	21.4	22.8 months
Crismani et al. (2006)	Prospective	Palatal implant	Straumann	3.3	4	20	26.4	20	2	10	3 months

TAD, temporary anchorage devices; RCT, randomized controlled clinical trials.

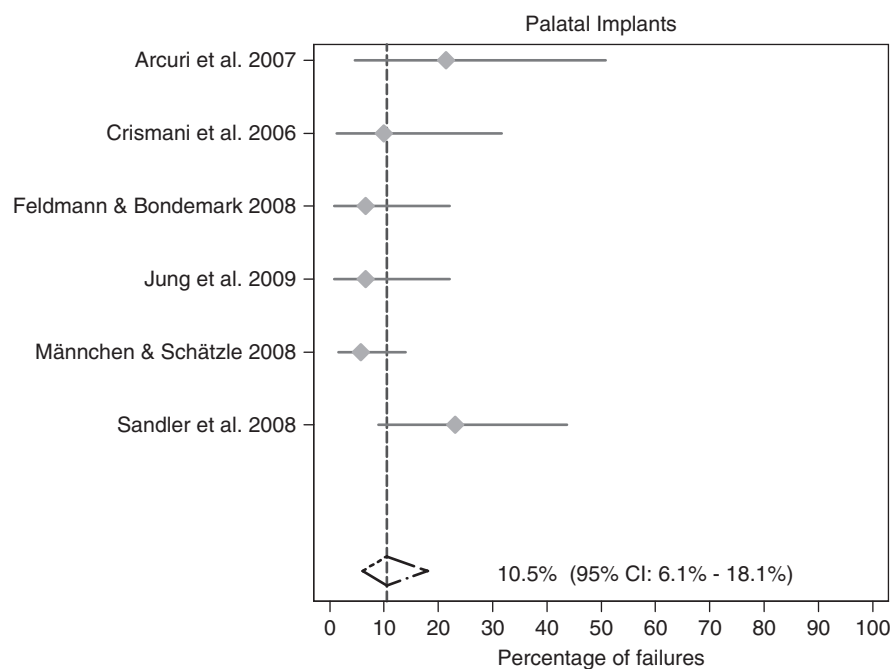


Fig. 4. Failure rates of palatal implants and summary estimate from meta-analysis and their 95% confidence intervals (95% CI) by study.

these did not remain stable and had to be removed early. In meta-analysis, the failure rate (Fig. 5) was estimated at 7.3% (95% CI: 5.4–9.9%).

On comparing miniplates, palatal implants and miniscrews with each other, none of them showed statistically significantly higher survival rates than the other due to the wide scattering within the groups. However, when miniplates and palatal implants representing torque-resisting TAD were grouped together, they showed a statistically significant 1.9-fold (95% CI: 1.1–2.8, $P = 0.005$) lower clinical failure rate than did miniscrews.

To achieve the same clinical anchorage on both sides of the arch as with a palatal implant (10.5% failure rate, 95% CI: 6.1–18.1%), two miniscrews or miniplates have to be inserted. The probability of having at least one failure, when two of these TADs are installed in the maxilla, was 14.1% (95% CI: 10.5–18.8%) for miniplates and 29.4% (95% CI: 24.3–36%) for miniscrews, respectively.

Discussion

The purpose of this systematic review was to evaluate the survival and failure rates of skeletal TADs such as Onplants[®], miniplates, palatal implants and mini- or micro-

screws after a loading time of at least 12 weeks. No RCTs were available comparing all types of these TADs. RCTs comparing these four treatment modalities may be difficult to conduct both from a logistic as well as an ethical point of view since this anchorage is usually chosen on specific patient indications. In the absence of these kinds of RCTs, a lower level of evidence, i.e. RCTs comparing some TADs with COAD and prospective and retrospective cohort studies were included in this systematic review. TAD survival and failure rates are only meaningful if anchorage is provided at least for the major part of orthodontic therapy. Hence, a minimal period of 12 weeks of functional anchorage was chosen in the evaluation.

Before the use of TADs, COADs offered the only possibility for sufficient anchorage to control undesired tooth movements. The main disadvantage of many of these devices was the fact that treatment outcomes depended to a high degree on patient compliance (Nanda & Kierl 1992). Hence, the comparison of survival and failure rates of the different types of TADs is of great prognostic value in future orthodontic treatment planning. But it has to be remembered that TADs are usually inappropriate in growing patients in whom influencing the skeletal growth is additionally indicated.

Table 4. Study and patient characteristics of the reviewed studies of miniplates

Author	Kind of study	Type of TAD	Manufacturer	Diameter (mm)	Length (mm)	Number of patients	Mean patient's age (years)	Number of TADs	Number of failures	Percent of failures	Loading time
Chen et al. (2008)	Retrospective	Miniplates	Mondeal or Leibinger	2	5–9	194	25.1 ± 8.7	171	8	4.7	During 36 months period
Cornelis et al. (2008)	Prospective	Miniplates	Surgi-Tec or KLS Martin	2	5 or 7	97	23.7	200	15	7.5	12 ± 8.4 months
Chen et al. (2008)	Retrospective	Miniplates	Leibinger	2	5 or 7	25	27.5	44	2	4.5	15 months
Kuroda et al. (2007)	Retrospective	Miniplates	KeSei Medical Ind.	2 or 2.3	7 or 11	22	21.8	38	5	13.2	> 12 months or completion of treatment
Choi et al. (2005)	Retrospective	Miniplates	Martin	2	5	17	21.2	68	5	7.4	At least 6 months
Miyawaki et al. (2003)	Retrospective	Miniplates	Not specified	2	5	7	21.8 ± 7.8	17	1	5.9	> 12 months or completion of treatment

TAD, temporary anchorage devices.

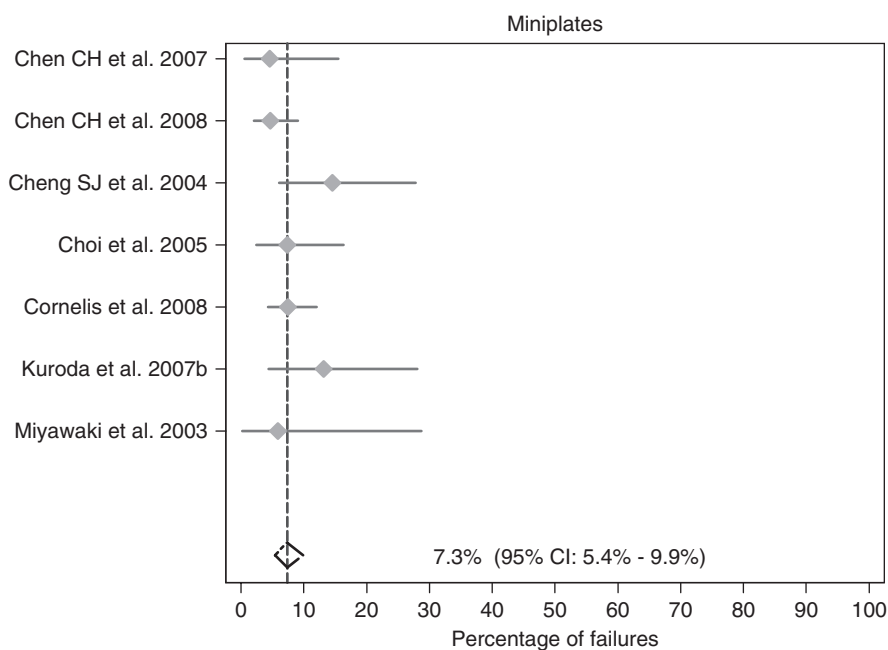


Fig. 5. Failure rates of miniplates and summary estimate from meta-analysis and their 95% confidence intervals (95% CI) by study.

There were only two RCTs (Feldmann & Bondemark 2008; Sandler et al. 2008) comparing the efficacy of COADs with TADs (palatal implants or Onplants[®]) within the same patient cohort. One of these studies reported significantly higher proportions of failed palatal implants than the other (Sandler et al. 2008). Most of the failed palatal implants had been placed during the initial phase of the investigation, representing the results of a learning curve of the surgeons involved with this 'relatively new' technique. Similar problems were encountered in one retrospective study (Arcuri et al. 2007).

In contrast to conventional oral implants, the orthodontic anchorage implants of the time such as palatal implant yielded an emergence profile with a 90° shoulder. This bore the danger of 'over-winding' 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. If the two studies mentioned are eliminated from the analysis, palatal implants showed a failure rate of only 6.7%. This is slightly below that reported for miniplates [7.3% (95% CI: 5.4–9.9%).

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 over-winding the implant during installation (Orthoimplant[®], Straumann AG, Basel, Switzerland). To date, only one prospective cohort study is available on this new generation of palatal implants (Jung et al. 2009) reporting very favorable survival rates (93.3%) (Table 3). Furthermore, a recently published experimental human study on palatal implants with this novel design (Schätzle et al. 2009) yielded a high primary stability and a 100% survival for the whole observation period. Considering all studies on palatal implants, the meta-analysis presented a mean failure rate of 10.5% (95% CI: 6.1–18.1%), rendering this treatment a reliable option with sufficient predictability for routine clinical use (Fig. 3).

Compared with COAD (headgear, transpalatal arch), palatal implants provided equal (compliant patients, Sandler et al. 2008) or statistically significantly better clinical anchorage reinforcement (Feldmann & Bondemark 2008). There were more technical problems and a significantly higher failure rate with the Onplant[®] system and hence the palatal implant may be considered the anchorage system of choice for TAD (Feldmann & Bondemark 2008). Palatal implants were better tolerated than Onplant[®] devices as well as extraction of premolars in terms of patient-centered outcomes (pain intensity,

discomfort and analgesic consumption) (Feldmann et al. 2007).

After an observation period of at least 12 weeks, miniplates showed a slightly higher success rate of 92.7% than palatal implants (89.5%). It has to be realized, however, that this difference was mainly caused by early surgical failures in two studies mentioned above (Arcuri et al. 2007; Sandler et al. 2008). A direct comparison of the efficacy of miniplates with that of palatal implants with respect to survival has not been performed. Considering the fact that two miniplates have to be installed instead of one palatal implant to achieve the same anchorage in the maxilla, the presumptive risk for failure for the miniplates has to be assumed at 14.1% (95% CI: 10.5–18.8%) for the miniplates.

Even though the majority of the studies included in this review deal with miniscrews, there was no study describing clinical or diagnostic criteria in relation to screw length or screw diameter. Only one RCT (Wiechmann et al. 2007) directly compared two different screw diameters (1.1 and 1.6 mm) of various lengths with each other. A small screw diameter was identified as a risk factor for failure. These findings are in accordance with the results of this present systematic review. An approximately two-fold increased failure rate was identified for miniscrews with a diameter of ≤ 1.2 mm compared with miniscrews with a diameter of 2 mm or more. Moreover, two other single retrospective studies (Miyawaki et al. 2003; Chen et al. 2007) came to the same conclusion. But in contrast to another retrospective study (Chen et al. 2006), this RCT (Wiechmann et al. 2007) failed to identify screw length as a possible risk factor for failure. Too many different screw lengths and insertion sites had been included in the study, resulting in a wide scattering of the data. However, it seems to be important that the tipping moment at the bone edge be considered (Büchter et al. 2005). These findings are in accordance with data from two experimental implant studies dealing with different force levels (Melsen & Lang 2001; Hsieh et al. 2008). Therefore, controlled clinical trials with clear selection criteria for screw length and diameter including the applied tipping moments should be encouraged.

The dynamics of TAD loss (loss over time) is an important factor for decision

making in orthodontic treatment planning. The Kaplan–Meier analysis of Wiechmann et al. (2007) showed that the major miniscrew failures occurred within 100–150 days after the start of orthodontic loading. At this point, a change in the treatment plan may be difficult or impossible. With respect to palatal implants, reports indicate that implant loss occurred predominantly in the unloaded healing period (Arcuri et al. 2007; Männchen & Schätzle 2008; Sandler et al. 2008). This in turn means that once a palatal implant is osseointegrated, no implant loss is to be expected.

It is clear that the placement and removal of a miniplate or a palatal implant is a more complex procedure than that associated with the installation of a miniscrew. The surgical intervention for both devices is generally well tolerated by the patients (Kuroda et al. 2007b; Cornelis et al. 2008) and pain intensity after surgical installation of a palatal implant is less than that after premolar extraction (Feldmann et al. 2007). It seems that the greater flexibility and torque resistance provided by palatal implants and miniplates provides an advantage.

For example, during ‘en-masse’ movement of an entire dental arch of >2 mm, placing a palatal implant in the maxilla or two miniplates in the mandible would be preferable to choosing miniscrew anchorage. Palatal implants as well as miniplate systems allow changes of the force vectors without the need for repositioning of the TAD. Palatal implants and miniplates are

associated with a statistically significant 1.9-fold lower risk (95% CI: 1.06–2.78) of failure than miniscrews. Moreover, as there is a chance that miniscrews do not remain stationary under orthodontic forces, a safety zone for root or nerve proximity might be required (Liou et al. 2004; Wang & Liou 2008). This could further restrict possible insertion sites, limit the amount of tooth movement and/or miniscrews have to be repositioned several times during treatment, further increasing the risk for failures. For patients who are undergoing extensive orthopedic corrections or other treatments (maxillary/mandibular protraction or intrusion), the TADs are expected to be in place for a long time. During this time, force vectors may need to be varied or roots of the teeth to be moved may need to slide past the anchors. In this context, palatal implants or miniplates should be the TADs of choice.

It seems obvious that all TADs have the potential to provide some kind of anchorage, which enables orthodontic tooth movements that might be impossible with conventional anchorage methods. However, no orthopedic effects can be achieved in growing children, except for autorotation of the mandible due to vertical manipulations of the buccal segments or in combination with compliance-dependent extraoral or intermaxillary forces.

In conclusion, the use of TADs really expands the envelope of discrepancies in which orthodontic treatment might be suc-

cessful. On the basis of this systematic review it is concluded that for the maxillary arch, palatal implants are a clearly superior treatment option compared with all other skeletal anchorage devices, whereas in the mandible, miniplates yielded the most favorable results. Both palatal implants as well as miniplates offer safe and effective anchorage possibilities with a high survival rate (>90%), with few side effects or problems during treatment. Palatal implants as well as miniplates might simplify orthodontic treatment and enhance the possibility of treatments that might have been considered unfeasible without skeletal anchorage. However, the relative effectiveness, efficiency and indication list of all different TADs used for various clinical problems need to be evaluated further in prospective controlled studies.

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