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Stability change of chemically modified SLA titanium palatal implants : a randomized controlled clinical trial

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Stability change of chemically modified SLA titanium palatal implants

A randomized controlled clinical trial

Inaugural-Dissertation

Zur Erlangung der Doktorwürde der Zahnmedizin
der Medizinischen Fakultät
der Universität Zürich

vorgelegt von
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Genehmigt auf Antrag von Prof. Dr. Timo Peltomäki
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1. Zusammenfassung

Ziel: Das Ziel dieser randomisierten, klinischen Studie ist die längerfristige Beobachtung der Stabilitätsveränderung von Gaumenimplantaten mit der chemisch modifizierten SLA-Oberfläche verglichen mit Kontrollimplantaten.

Material und Methoden: 40 freiwillige und erwachsene Probanden wurden rekrutiert, um an dieser Studie teilzunehmen. Sie wurden zufällig einer Testgruppe (chemisch modifizierte SLA-Oberfläche) und einer Kontrollgruppe (SLA® - Oberfläche) zugeteilt. Resonanzfrequenzmessungen wurden direkt nach der Implantation, sowie 1, 2, 3, 4, 5, 6, 7, 8, 10 und 12 Wochen nach der Operation genommen.

Resultate: Alle Implantate zeigten zu jedem Zeitpunkt klinische Stabilität. Der Wechsel von sinkender zu steigender Implantatstabilität konnte bei den Testimplantaten nach 4 Wochen und bei den Kontrollimplantaten nach 5 Wochen festgestellt werden.

Schlussfolgerung: Die Resultate dieser zufälligen, klinischen Arbeit zeigen das Wirkungsvermögen der chemischen Modifikation der SLA-Oberfläche, den biologischen Prozess der Osseointegration zu beeinflussen bzw. zu beschleunigen. Es konnte auch gezeigt werden, dass die Gegend der mittleren Gaumensutur ein für Tests geeigneter Implantationsort ist, vorausgesetzt man hat noch zusätzliche histologische Daten.

2. Introduction

Anchorage in orthodontics

Anchorage is one of the limiting factors in orthodontics and its control is essential for successful orthodontic treatment. The term orthodontic anchorage was first introduced by Angle (1907) and later defined by Ottofy (1923). Orthodontic anchorage denoted the nature and degree of resistance to displacement of teeth offered by an anatomic unit when used for the purpose of tooth movement. The principle of orthodontic anchorage has been implicitly explained already in the Newton's third law (1687) according to which an applied force can be divided into an *action* component and an equal and opposite *reaction* moment. In orthodontic treatment, reciprocal effects must be evaluated and controlled. The goal is to maximize desired tooth movement and minimize undesirable effects.

Basically, each tooth has its own anchorage potential as well as a tendency to move when force is applied towards the tooth. When teeth are used as anchorage, the inappropriate movements of the anchoring units may result in a prolonged treatment time and unpredictable or less-than-ideal outcomes.

Orthodontic anchorage is oriented to the quality of the biological anchorage of the teeth. This is influenced by a number of factors, such as:

- the size of the root surfaces available for periodontal attachment
- the height of the periodontal attachment
- the density and structure of the alveolar bone
- the turnover rate of the periodontal tissues
- the muscular activity
- the occlusal forces
- the craniofacial morphology

and the nature of the tooth movement planned for the intended correction (Diedrich 1993).

To maximize tooth-related anchorage, techniques such as differential torque (Burstone 1982), placing roots into the cortex of the bone (Ricketts 1976) and distal inclination of the molars (Begg & Kesling 1977, Tweed 1941) may be used. If the periodontal anchorage is inadequate with respect to the intended treatment goal, additional intraoral and/or extraoral anchorage may be needed to avoid negative effects. While the teeth are the most frequent anatomic units used for anchorage in orthodontic therapy, other structures such as the palate, the lingual mandibular alveolar bone, the occiputal bone and the neck are also alternatives.

Additional anchorage such as extraoral and intraoral forces are visible and hence, compliance-dependent and are associated with the risk of undesirable effect such as tipping of the occlusal plane, protrusion of mandibular incisors and extrusion of teeth.

Compliance dependent Anchorage Strategies

- extraoral: Headgear, chin-cap, reversed headgear ...
- intermaxillary: Cl II/III elastics, Herbst, Jasper, Eureka ...
- Gingiva, muscles, cortical bone: Plates, Nance-plate, lip bumper, transpalatal arch

The success of compliance dependent anchorage strategies relay on patient's cooperation. Based on a questionnaire of patients own reporting of headgear wear showed, that one third of the patients do not convey accurate information (Cole 2002). Monitoring the wearing time with a gauge with an electronic recorder did not significantly increase the compliance (56.7% to 62.7%) (Brandão et al. 2006).

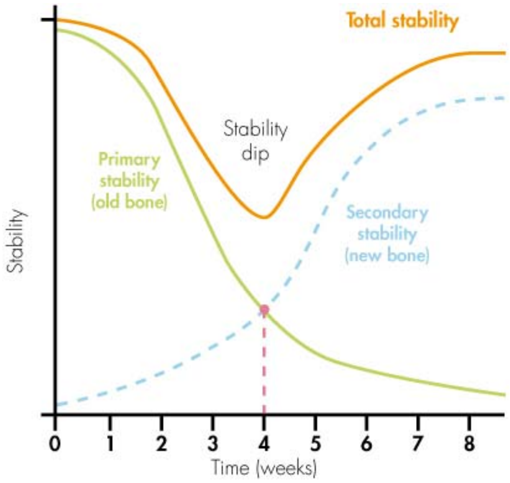
Implants, miniscrews and ankylosed teeth, as they are in direct contact with bone, do not possess a normal periodontal ligament. As a consequence, they do not move when orthodontic forces are applied (Melsen & Lang 2001) and hence, can be used for "absolute anchorage" that is independent of the patient's compliance.

Osseointegration process

The term osseointegration is based on histologic criteria as a direct contact between a loaded implant surface and bone without an intervening layer of fibrous tissue at light microscopic level (Brånemark et al. 1969). There is no minimal degree of bony contact for a bone-integrated implant. This implant-bone interface is created during the healing period immediately post surgery and is maintained in dynamic equilibrium over time.

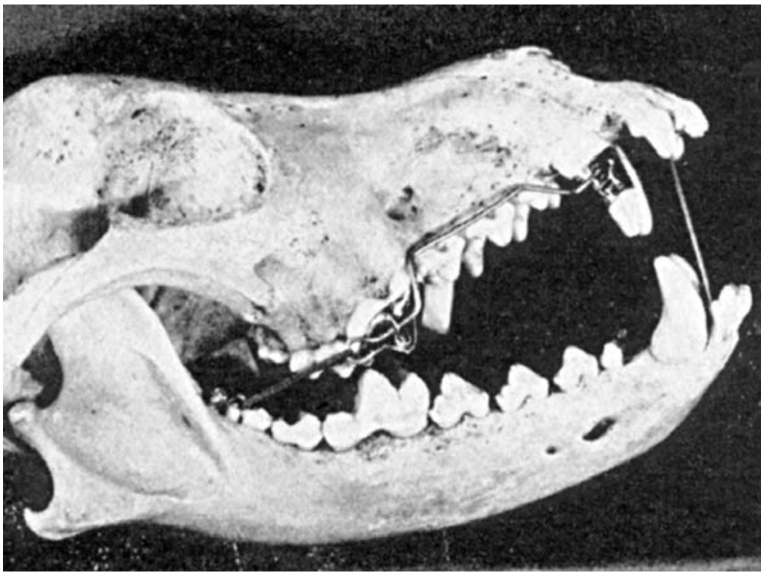
Following the placement of an endosseous implant, primary mechanical stability is gradually replaced by biological stability. The transition from primary mechanical stability, provided by the implant design, to biologic stability provided by newly formed bone as osseointegration occurs takes place during early wound healing (Berglundh et al. 2003). There is, therefore, a period of time during healing in which osteoclastic activity has decreased the initial mechanical stability of the implant but the formation of new bone has not yet occurred to the level required to maintain implant stability. During this critical period, a loaded implant would be at greatest risk of relativ motion and would theoretically be most susceptible to failure by osseointegration.

The most drop outs of implants are in the delicate early care phase between the 2nd and 4th week after implant insertion. In this phase there is a decrease of the primary stability in the old bone (osteoclastic activity) and the new bone has not yet reached the level required to maintain implant stability (Rhaghavendra et al. 2005).



Historical development of bone borne orthodontic anchorage

The first attempt to achieve skeletal anchorage was already made in 1945. Gainsforth & Higley (1945) placed vitallium (Vitallium: cobalt-chromium alloy) screws and stainless steel wires into the ramus of dog mandibles and applied elastics that extended from the screw to the hook of a maxillary arch wire to distally tip/retract the canine by immediate orthodontic loading. Even though the authors did not describe the development of infection, failures encountered may be attributed to infection and the lack of antibiotics at that time, as well as the early dynamic loading of screws. Although minor tooth movement was accomplished using basal bone for anchorage in two animals, an effective orthodontic force could not be maintained for more than thirty-one days.



Orthodontic appliance using vitallium screw anchorage.
(Courtesy of Gainsforth BL, Higley LB. A study of orthodontic anchorage possibilities in basal bone. Am J Orthod Oral Surg 31:406–416, 1945).

A generation later, skeletal anchorage systems have evolved from two directions. One such development originated from orthognatic fixation techniques used in maxillo-facial surgery. As pioneers, Creekmore and Eklund (1983) used a vitallium bone screw to treat one patient with a deep impinging overbite. The screw was inserted in the anterior nasal spine to intrude and correct the upper incisors using an elastic thread from the screw to the incisors for 10 days after the screw had been placed. Subsequently, Kanomi (1997) decribed a miniscrew specially designed for orthodontic use.

The second development originated from applications in implant dentistry. Linkow (1969) used blade implants for rubber band anchorage to retract teeth, but never presented longterm outcomes. Later, endosseous implant for orthodontic anchorage were suggested (Ödman et al. 1988, Shapino & Kokich 1988). As indicated in various animal studies, osseointegrated titanium implants remained positionally stable under orthodontic loading and thus could be used for orthodontic anchorage (Turley et al. 1980, 1988, Roberts et al. 1984, 1989, Wehrbein & Dietrich 1993, Wehrbein 1994, Wehrbein et al. 1998, De Pauw et al.1999, Majzoub et al. 1999). This resulted in the development of specially designed implants in the retromolar area (Roberts et al. 1990) and the palatal site of the maxilla (Triaca et al. 1992).

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 permits an independency of patient compliance (Creekmore & Eklund, 1983). In the early 1990ies special implants have been introduced to serve as temporary anchorage in maxillary bone for orthodontic reasons (Triaca et al. 1992; Wehrbein et al. 1996).

In orthodontic treatment the placement of implant as an absolute anchorage device facilitates and accelerates thereafter the therapy (Trisi & Rebaudi 2002). Even though, it remains an inactive waiting time of at least 3 months after insertion (12 week healing time (Wehrbein et al. 1996, 1998; Keles et al. 2003; Crismani et al. 2005a, 2005b) + referral time). Especially in adult patients there is a growing need to reduce this inactive waiting time and to reduce the risk of implant failure during early loading.

The aim of a clinical study by Crismani and co-workers (2006) was to investigate the behaviour of early loaded palatal implants and to asses whether shorter healing periods might be justified in order to accelerate the orthodontic treatment. Twenty patients received one palatal implant each because of orthodontic indication. All implants were of the same type: single-unit self-tapping made of pure titanium, length 4mm, diameter 3,3mm, SLA surface and a highly polished neck of 2,5mm (Orthosystem®, Institut Straumann). All measurements were carried out by one and the same investigator. 18 implants remained stable for the whole observation period. 2 implants were lost. The results of the study suggest the possibility of loading palatal implants earlier than recommended in the literature. An orthodontic loading of palatal implants 6 weeks post-surgery with a force up to 400 cN seems be justified.

In implantology, numerous efforts have been made to reduce this 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, acidetching, 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), and higher removal torque values in biomechanical testing (Wilke et al. 1990; Buser et al. 1999; Li et al. 2002). Based on these experimental results, clinical studies were initiated to load SLA implants after a reduced healing period of only 6 wks. The clinical examination up to 3 yrs demonstrated favorable results, with success rates around 99% (Roccuzzo et al. 2001; Cochran et al. 2002; Bornstein et al. 2003).

Besides surface topography, surface chemistry is another key variable for peri-implant bone apposition, since it influences surface charge and wettability (Kilpadi & Lemons 1994). Surface wettability is largely dependent on surface energy, and influences the degree of contact with the physiologic environment. Increased wettability thus enhances interaction between the implant surface and the biologic environment (Kilpadi & Lemons 1994). A certain similarity of clean hydrophilic titanium oxide surfaces to water can be assumed as a consequence of extensive hydroxylation/hydration of the oxide layer and a high wettability by water, leading to a gentle interaction of the surface with the water shell around delicate biomolecules such as proteins (Textor et al. 2001).

Therefore, the topography as well the chemistry of the surface affects the incipiently wettability and peri-implant bone apposition of implants. A modified, sand-blasted and acid-etched SLA surface (modSLA) is built by rinsing under N_2 atmosphere and after the acid etching it is immersing in an isotonic NaCl solution to anticipate contact with the molecules from the atmosphere. This process leads to a qualitative and quantitative enhancement of hydrophilicity of the modSLA implant surface and this surface rushes primary interaction with the aqueous biosystem. In comparison to other surfaces, the modSLA has a rectified protein-surface and cell-surface interaction. Albumin and fibronectin are important for the osseointegration process because they are the first blood components to come into contact with the implant. This greater protein adsorption on the modSLAsurface may lead to a greater and faster cellular adhesion and enhanced osseointegration (Seibl et al. 2005). Furthermore in a histological and immunohistochemical analysis of very early periimplant tissue reactions in dogs was found at day 4 around the modSLA implants collagen-rich and dense connective tissue as well as first indications of osteocalcin synthesis. These both phenomena’s are indications of a more rapid osseointegration which leads to a significantly enhanced bone apposition in the first weeks after the implant insertion (Buser et al. 2004). The standard SLA surface has already led to a reduction of healing periods in patients from 3 months to 6 weeks in implant sites with regular bone density (Roccuzzo et al. 2001; Cochran et al. 2002; Borstein et al. 2003). The modSLAsurface could offer a further reduction of the healing period following implant placement. This postulate is also supported by a study of Oates and co-workers (2007).

Clinical studies of dental implants, however, deal always with surrogate biological endpoints (Karoussis et al. 2004). Palatal implants, in contrast, are temporary anchorage devices and therefore subsequently removed after therapy. As a consequence, their loading time is shorter and defined by the preexisting treatment plan and the end of the need for additional anchorage (Männchen & Schätzle 2008). Palatal implants represent therefore the only implants in which explantation represent a clinical success. As they are removed including 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 stability patterns of palatal implants with chemically modified sandblasted/acid-etched (modSLA) titanium surface with enhanced wettability as compared with standard SLA surface, during 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.

3. Material & Method

This randomized trial was designed to prospectively asses implant stability changes of standard SLA palatal implants (Orthosystem ®, Insitut Straumann AG, Basel, Switzerland) relative to implants having the same physical properties but with 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, Savedalen, Sweden).

Subjects

40 adult volunteers (19 females and 21 males) 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 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 commercial 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 endossal part was 4.2mm in length.

The control implants revealed a standard SLA surface (sandblasted with large grits of 0.25 to 0.50 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 N_2 protection and continuously stored in an isotonic NaCl solution (Buser et al. 2004).

Clinical procedures

All endosseous implants were inserted in the maxillary bone in the midpalatal suture area by the same surgeon (R. M.) according the manufactures guidelines for the 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 one week. Mechanical tooth brushing was avoided in the surgical site for 2 weeks. After 1, 3, 7 or 12 weeks 5 implants were harvested by means of a standard trephine (5.5mm) for further histological analysis.

Methods of analysis

The palatal implants' stability was monitored by using the resonance frequency analysis (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 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 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 in every time interval. 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 outcome value was the change in implant stability (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 normal distributed (Kolmogorov Smirnov test). To decrease the patient-specific variability and to adjust for 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 analytic basis for 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 (Jonston et al. 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 have an earlier change of the direction of the test group (modSLA surface) with respect to the control group (SLA surface).

4. Results

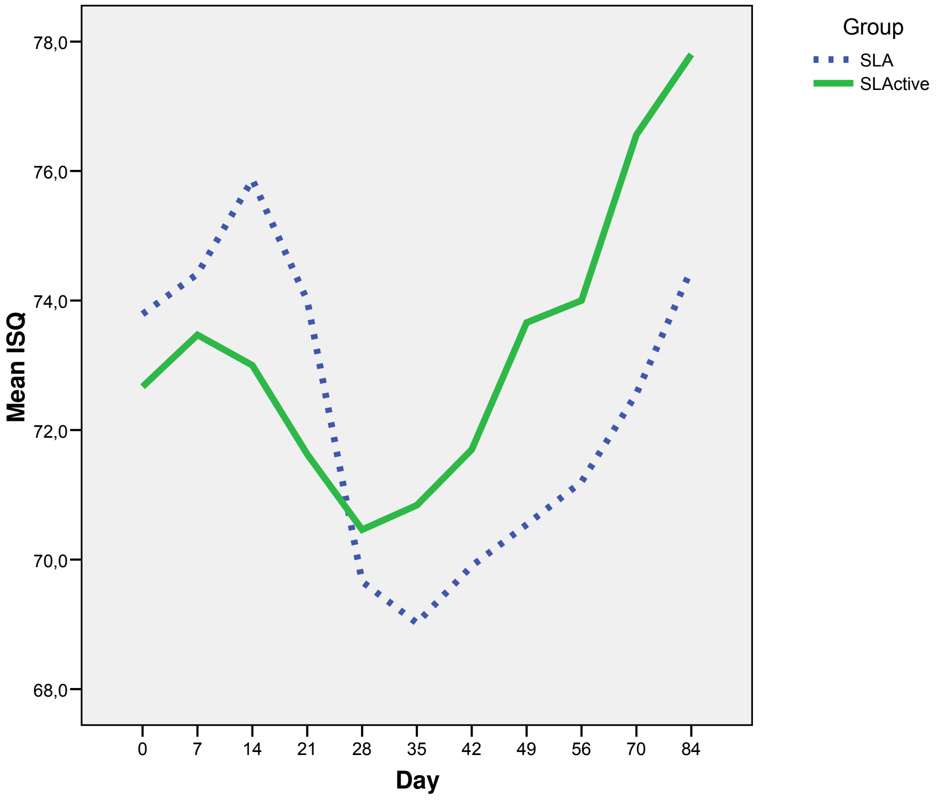
All 40 implants could be inserted with a high primary stability and a mean insertion torque of 39.25 Ncm (range: 30-55 Ncm) was applied. There was no correlation for insertion torque and ISQ-values irrespective of the implant surface. Before releasing the transfer piece in all but one SLA-surface palatal implant a counter-clockwise torque had to be applied to remove the transfer piece. In the modSLA-surface group, in contrast, in only one implant a counter-clockwise torque had to be applied to remove the transfer piece. 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.

The mean ISQ values and standard deviation at baseline and in the subsequent time points of measurement are depicted in Table 1 and Figure 1.

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

Group	Day		N	Minimum	Maximum	Mean	Std. dev.
SLA	0	ISQ	20	65,2	84,2	73,790	5,0214
	7	ISQ	20	63,4	85,0	74,410	5,3801
	14	ISQ	15	66,0	84,2	75,867	5,8908
	21	ISQ	15	65,6	81,0	74,000	4,9552
	28	ISQ	10	64,6	79,0	69,660	4,4222
	35	ISQ	10	64,2	77,0	69,020	4,1478
	42	ISQ	10	65,0	79,0	69,900	4,6516
	49	ISQ	10	64,6	80,0	70,540	4,9379
	56	ISQ	5	66,4	77,0	71,200	4,0669
	70	ISQ	5	68,6	77,0	72,560	3,3953
	84	ISQ	5	69,4	79,0	74,480	3,9079
modSLA	0	ISQ	20	64,0	78,2	72,670	3,9402
	7	ISQ	20	64,0	84,0	73,470	5,8097
	14	ISQ	15	62,8	81,0	73,000	5,3442
	21	ISQ	15	57,4	80,0	71,627	6,5356
	28	ISQ	10	49,6	79,2	70,460	8,3026
	35	ISQ	10	48,0	80,2	70,840	8,9581
	42	ISQ	10	55,0	81,6	71,700	7,2524
	49	ISQ	10	62,2	80,2	73,660	5,2688
	56	ISQ	5	66,6	79,0	74,000	4,6840
	70	ISQ	5	74,0	79,0	76,560	1,9204
	84	ISQ	5	75,0	80,0	77,800	1,8762

Figure 1: Mean ISQ values at baseline and subsequent time points for SLA- and SLAmod palatal implants



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 12 weeks of observation the test-surface reached significantly higher stability values of 77.8 ±1.9 compared to the control implants of 74.5 ± 3.9, respectively.

The individual ISQ vales for the SLA cohort as well as for the modSLA group are shown in Figure 2 and 3. Both groups showed a fair homogeny in the individual ISQ values. Except for one palatal implants of both groups, however, the changes over time differed significantly from the others. For the respective SLA palatal implant, the ISQ-changes over time yielded higher changes (-13.6 ISQ), but its ISQ-values remained within the range. For the SLAmod palatal implant, in contrast, the ISQ-changes over time yielded even higher changes (-18.6 ISQ) and its ISQ-values showed significantly lower values. After 12 weeks, both implants reached comparable stability-measurements.

Figure 2: ISQ-values separate for palatal implants with SLA surface over time

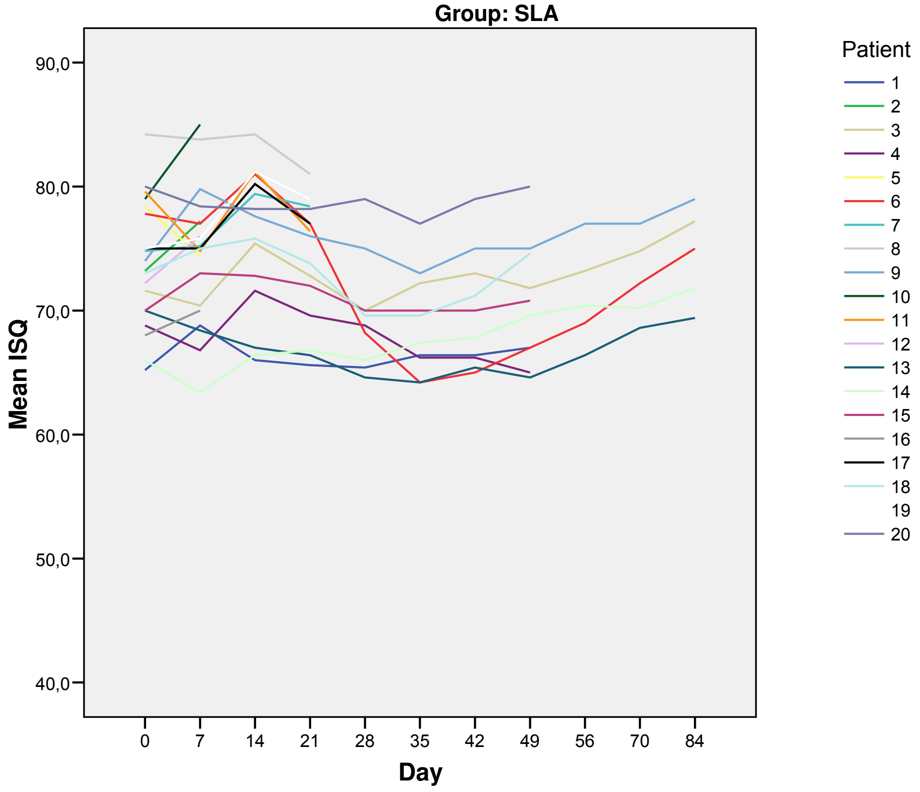
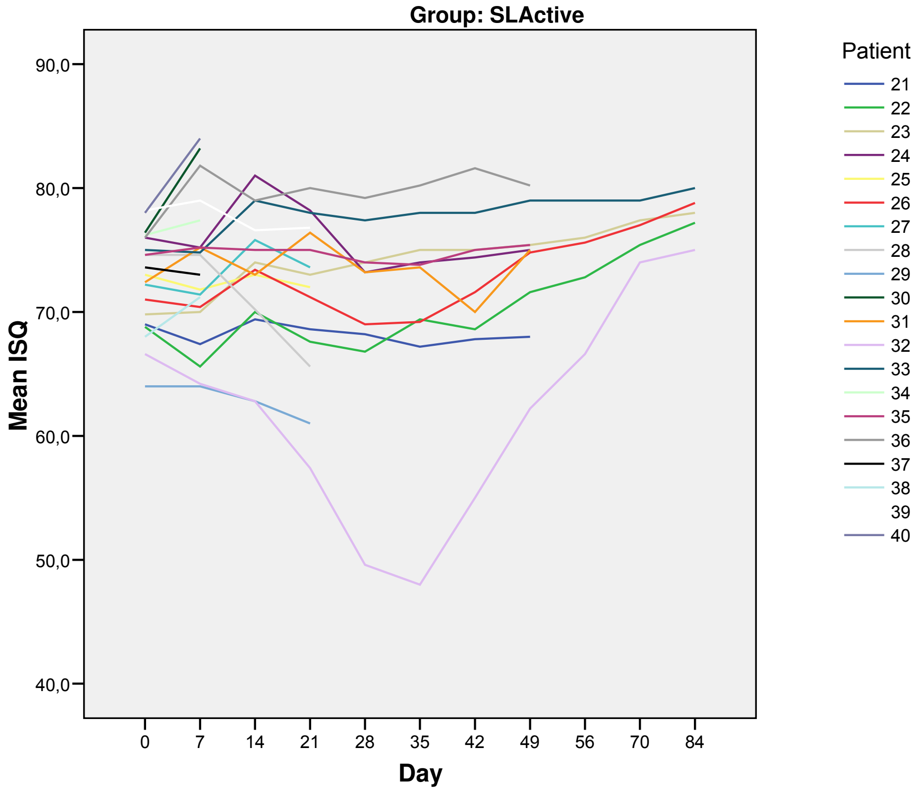


Figure 3: ISQ-values separate for palatal implants with SLAmod surface over time



As the absolute ISQ values were not of primary interest and had only minor clinical impact due to high individual influence, it is good clinical practice to monitor the changes over time by standardizing to the deviations of ISQ from baseline (Table 2 and Figure 4).

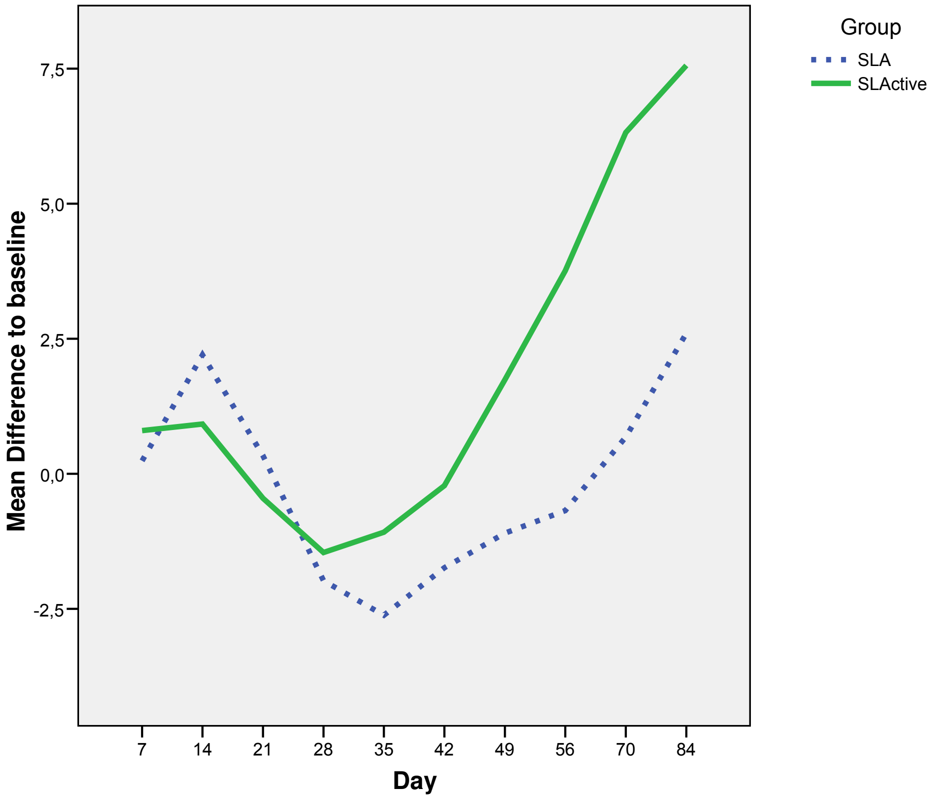
Table 2: Mean ISQ values changes and standard deviation for SLA- and SLAmod palatal implants by standardizing to the deviations from baseline.

Group	Day		N	Minimum	Maximum	Mean	Standard Deviation
SLA	7	Difference to baseline	20	-4,8	6,0	,240	3,1359
	14	Difference to baseline	15	-3,0	6,2	2,200	2,5467
	21	Difference to baseline	15	-3,6	4,0	,333	2,3924
	28	Difference to baseline	10	-9,6	1,0	-1,980	3,3045
	35	Difference to baseline	10	-13,6	1,4	-2,620	4,4974
	42	Difference to baseline	10	-12,8	1,8	-1,740	4,3889
	49	Difference to baseline	10	-10,8	3,6	-1,100	4,3279
	56	Difference to baseline	5	-8,8	4,4	-,680	5,4545
	70	Difference to baseline	5	-5,6	4,2	,680	4,1197
	84	Difference to baseline	5	-2,8	5,8	2,600	4,0125
modSLA	7	Difference to baseline	20	-3,2	6,8	,800	2,7690
	14	Difference to baseline	15	-4,4	5,0	,920	2,8484
	21	Difference to baseline	15	-9,2	4,0	-,453	4,0914
	28	Difference to baseline	10	-17,0	4,2	-1,460	5,9517
	35	Difference to baseline	10	-18,6	5,2	-1,080	6,6741
	42	Difference to baseline	10	-11,6	5,6	-,220	4,8511
	49	Difference to baseline	10	-4,4	5,6	1,740	3,0870
	56	Difference to baseline	5	,0	6,2	3,760	2,2865
	70	Difference to baseline	5	4,0	7,6	6,320	1,4464
	84	Difference to baseline	5	5,0	8,4	7,560	1,4519

In the first 2 weeks after implant installation, both groups showed only small changes in the ISQ values (0.24 to 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 -2.0 ±3.3 and modSLA-surface -1.5 ±6.0).

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

Figure 4: Mean ISQ values changes for SLA- and SLAmod palatal implants by standardizing to the deviations from baseline



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

5. Discussion

The purpose of this randomized controlled clinical study was to assess palatal implant stability over time for 2 SLA surfaces over the first 12 weeks following implant insertion. The main focus was set to the early stability changes corresponding to the transition from primary stability - provided by the implant design - to biologic stability provided by newly formed bone as defined as osseointegration (Berglundh et al. 2003). This transition period is crucial regarding early loading (Raghavendra et al. 2005; Glauser et al. 2004).

To clinically assess implant integration, resonance frequency analysis (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 two palatal implants showing a significantly wider range in the ISQ value over time might be explained by unscrewing the implant during the early healing period by installing the transducer. All the implants, however, were clinically stable at all time points und no movement was detected while performing the measurements.

The changes in implant stability expressed by ISQ-value differences over time may reflect the biologic events associated with the bone-implant interface. The mean ISQ value from insertion for the modSLA group to day 7 and for the SLA cohort from insertion to day 14 (SLA) was higher. The increase of the ISQ value after the implant insertion can 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 3.5mm while the implant diameter was 4.1mm. (Schenk & Buser 2000).

The mean ISQ value, thereafter, started to drop significantly (Figure 1). 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 1 week 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 (Kilpadi & Lemons 1994).

After a small decrease (ΔISQ = -1.5) (Figure 4) due to predominant resorptive processes in the adjacent bone, the stability of the test implants with modified SLA-surface began to reincrease after a time point of 4 weeks. For the control implants, however, the transition point from bone resorption to apposition corresponding to an increasing stability was evident 5 weeks after implant installation. Considering the different start points of resorptive processes, however, it lasted for both the modSLA-goup and control SLA-group 3 weeks until the biological stability prevailed. This change in stabilization pattern with transition points after 4 and 5 weeks is later than that reported in a previous clinical study using SLA palatal implants only, in which the transition was observed already after 3 weeks (Crismani et al. 2006).

The differences of the present study and the previously mentioned study might be interpreted with caution. The implants installed by Crismani and coworkers were the old Orthosystem® palatal implant (Straumann AG, Basel, Switzerland) with a shoulder and a smaller diameter. They have loaded their implants a few days after installation and showed lower ISQ values compared to 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 had a greater decrease (-4.8 ISQ) by reaching the transition point compared to those for the old Orthosystem® (approximately -1.5 ISQ). In both studies, it took almost 12 weeks to reach the initially measured values of the implant stability quotient, whereas for the mod SLA-surface the values were reached already after 6 to 7 weeks, documenting a significantly enhanced healing process.

As the design of the present Orthoystem® palatal implant is comparable to regular dental prosthetic implants, the changes in implant stability pattern during the early healing period might be rather comparable. A human clinical study comparing dental implants with SLA-surface (control) and modSLA-surface (test) showed no difference in the transition time points for these implants placed in the posterior maxillary area (Oates et al. 2007). The transition point was after 4 weeks for the test and the control group. In the mandible, however, different transition points after 4 and 2 weeks, respectively, could be found for the control and the test implants (Oates et al. 2007). The present findings correspond to these 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 (Figure 1). This fact may be explained by the increasing 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, since it influences the degree of contact with the physiologic environment. Increased wettability, thus, enhances 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 to 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 (ie, 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 based on placement of the implant in the maxilla or 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). However, this is in contrast to previous investigations, in which implants placed in less dense bone types tended to have greater changes in stability (Barewal et al. 2003; Meredith et al. 1996; Friberg et al. 1999). 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 similar results as the mandible (Oates et al. 2007) what is in accordance with characteristics of their bone quality.

Dental implants, however, deal always with surrogate biological endpoints (Karoussis et al. 2004). Palatal implants, in contrast, are temporary anchorage devices and subsequently removed after therapy. Palatal implants represent the only implants in which explantation represent a clinical success (Männchen & Schätzle 2008). As they are removed including 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 alter 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. As palatal implants, however, are temporary anchorage devices and usually removed including adjacent bone after use with a trephine, theses type of implant might be used for further clinical studies including human histological analysis.

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