

Marc Schätzle
Roland Männchen
Ulrike Balbach
Christoph H. F. Hämmerle
Helge Toutenburg
Ronald E. Jung

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

Authors' affiliations:

Marc Schätzle, Roland Männchen, Ulrike Balbach, Clinic for Orthodontics and Pediatric Dentistry, Center for Dental and Oral Medicine and Cranio-Maxillofacial Surgery, University of Zurich, Zurich, Switzerland

Christoph H. F. Hämmerle, Ronald E. Jung, Clinic for Fixed and Removable Prosthodontics and Dental Material Science, Center for Dental and Oral Medicine and Cranio-Maxillofacial Surgery, University of Zurich, Zurich, Switzerland

Helge Toutenburg, Institute of Statistics, Ludwig-Maximilians University, Munich, Germany

Correspondence to:

Dr med. dent. et Odont. Dr Marc Schätzle
Clinic for Orthodontics and Pediatric Dentistry
Center for Dental and Oral Medicine and Cranio-Maxillofacial Surgery
Plattenstrasse 11
CH 8032 Zürich
Switzerland
Tel.: +41 44 634 3214
Fax: +41 44 634 4304
e-mail: marc.schaetzle@zzmk.uzh.ch

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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.

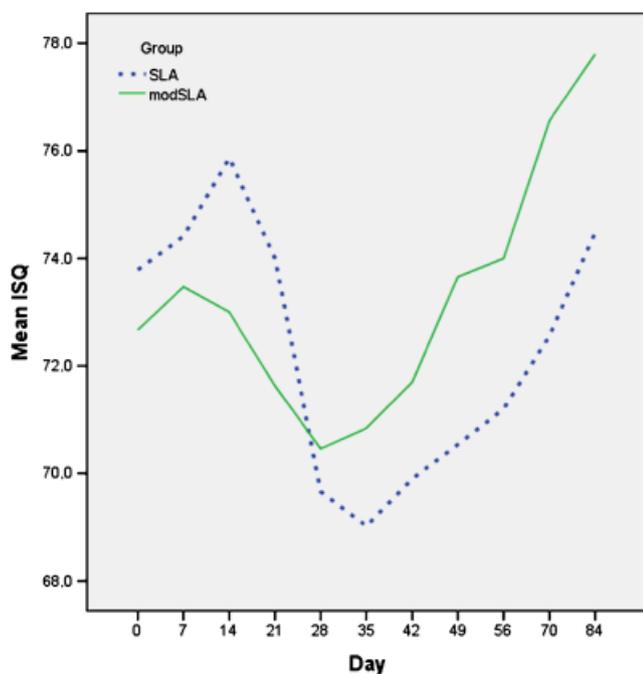


Fig. 1. Mean ISQ values at baseline and at subsequent time points for SLA- and modSLA palatal implants. ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

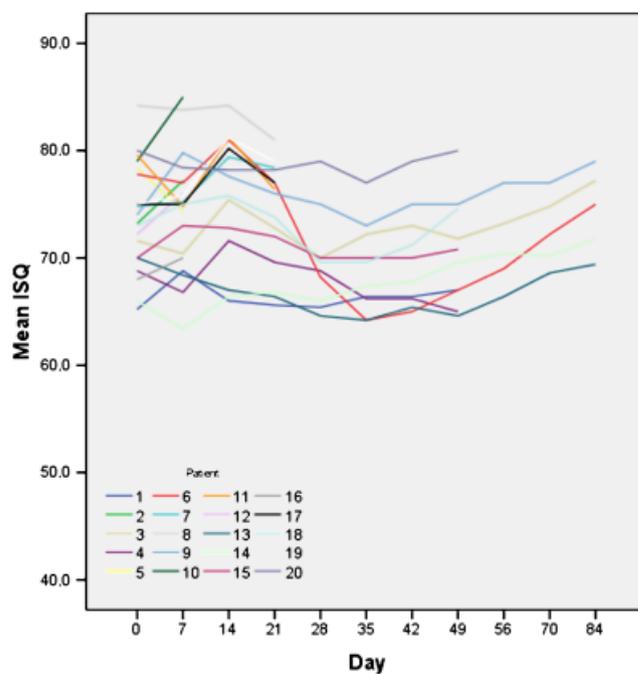


Fig. 2. ISQ values differ for palatal implants with the SLA surface over time. ISQ, implant stability quotient; SLA, sandblasted/acid-etched.

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

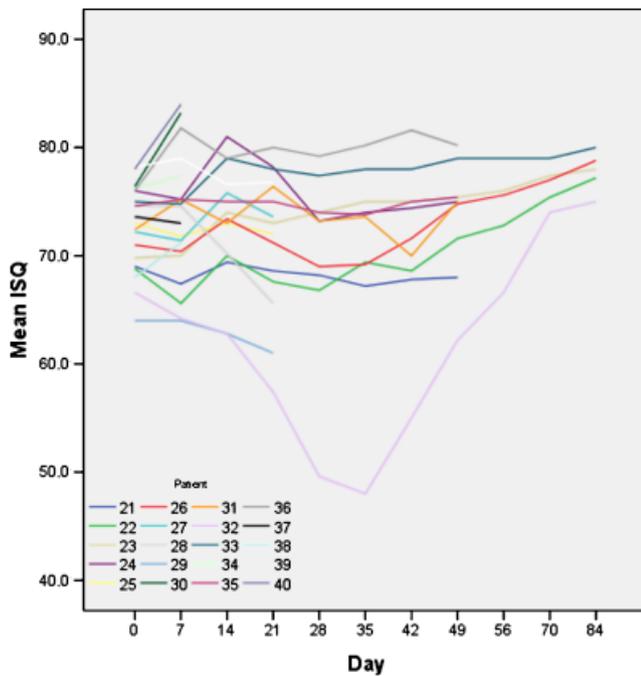


Fig. 3. ISQ values differ for palatal implants with the modSLA surface over time. ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

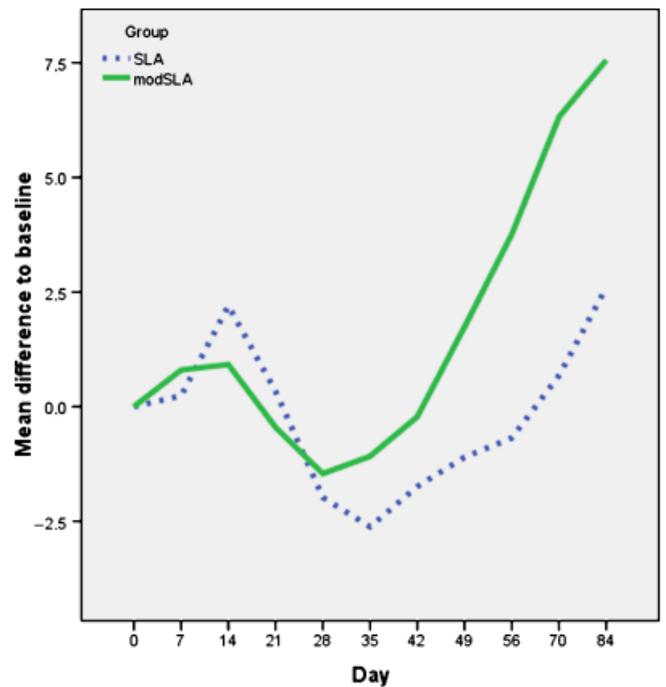


Fig. 4. Mean ISQ value changes in SLA- and modSLA palatal implants onstandardization to the deviations from the baseline. ISQ, implant stability quotient; modSLA, modified sandblasted/acid-etched.

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 explantation 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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