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Comparison of stability changes of various palatal implants.

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ABSTRACT: Aim: The aim of the present study was to comparatively evaluate stability changes of palatal implants during the early stages of bone healing with chemically modified sandblasted/acid-etched (mod SLA) titanium surface compared with a standard sandblasted (SLA) titanium palatal implants.

Materials and methods: A statistically significant no. (n=40; 24 females and 16 males) of adult subjects who volunteered and have their informed consent for participating in the study were selected. These volunteers were randomly allocated to the experimental group (mod SLA surface) and to the control group (SLA surface) with 20 subjects in each group. Documentation of implant stability was done by assessing resonance frequency analysis (RFA) at implant insertion, followed by subsequent assessments each week till 12th week from baseline (1-12 weeks). Resonance frequency analysis (RFA) values were expressed as an implant stability quotient (ISQ).

Results: Immediately after installation of implant, the ISQ values for both surfaces tested were not significantly different and yielded mean values of 75.28 ± 5.23 for the control and 73.16± 4.81 for the test surface. In the first 2 weeks after implant installation, both groups presented only small changes and thereafter a reducing trend in the mean ISQ levels. In the test group, after 4 weeks a tendency towards increasing ISQ values was observed and 6 weeks after surgery the ISQ values corresponded to those after implant insertion. For the SLA-control group, the trend changed after 5th week and yielded ISQ values corresponding to the baseline after 9th week. After 12 weeks of observation, the test surface yielded significantly higher stability values of 78.68 ± 2.9 compared with the control implants of 75.5 ± 3.19 respectively.

Conclusion: The results undoubtedly support and validate the potential for chemical modification of the SLA surface to positively influence the biologic process of osseointegration and also a faster healing.

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

I. INTRODUCTION

Anchorage in orthodontics

Anchorage remains a challenging factor in orthodontics. Control of anchorage remains the preceding factor for determining the success of any orthodontic treatment. Angle in the year 1907 first introduced the concept of anchorage. It was later modified by Ottofy in the year 1923. Anchorage refers to the nature and degree of resistance to displacement of teeth that is offered either by an anatomic unit or intraoral or extraoral appliances in order to minimize or control the movement of certain teeth/anatomical unit, while completing the desired movement of other teeth. One of such devices are temporary anchorage devices. The use of temporarily placed anchorage devices (TAD) has been advocated by many in past few decades and thus, the orthodontic literature has come out with various research papers and case reports on the same.[1-7] These devices (TADs) have been frequently installed within the bone and once the desired orthodontic anchorage has been achieved they are removed carefully. The conventional limitations of orthodontic anchorage are thus overcome by the use of TADs. These devices also provide better compliance and acceptability by the patients.[1]

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 controlled trial was designed to prospectively assess implant stability changes of standard SLA palatal implants relative to implants having the same physical properties but a chemically modified surface. Clinical evaluation of implant integration over time was performed using resonance frequency analysis (RFA).

Subjects Forty adult volunteers (24 females and 16 males) were recruited and randomly allocated to the experimental group (modSLA surface) and to the control group (SLA surface). The mean patients' age was 26.9 years, ranging from 22.3 to 54.8 years. All participants were systemically healthy and had no contraindications for minor oral surgical procedures. The study protocol had been approved by the Institutional Ethical Review board Informed consent was obtained from all participants. Implant design and surface characterization All implants were manufactured from commercially pure titanium. 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.[8-9] 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.[10]

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.[11]

Methods of analysis The palatal implants' stability was monitored using RFA (Ostellt, Integration Diagnostics AB, Goteborg, Sweden).[12] 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 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 (o1% variation for individual implants).[12] 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[13] with secondary outcomes characterized by descriptive analyses.[14-15] 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

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analysis.[16] 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).

II. RESULTS

All 40 implants could be inserted with high primary stability, and a mean insertion torque of 40 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 counterclockwise torque had to be applied to remove the transfer piece. In the modSLAsurface 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 explanation. The mean ISQ values and standard deviation at baseline and in the subsequent time points of measurement are presented in Table 1a,b.

Table 1a, b. Mean ISQ values and standard deviation at baseline and subsequent time pointsfor SLA- and modSLA palatal implants

Table 1a

Control Group	Day		N	Minimum	Maximm	Mean	SD
SLA	0	ISQ	20	65.2	84.2	72.79	5.02
	7	ISQ	20	64.4	84	73.41	5.38
	14	ISQ	15	66.2	84.2	75.867	5.89
	21	ISQ	15	67.6	81	74	4.95
	28	ISQ	10	63.6	79	69.66	4.42
	35	ISQ	10	64.2	77	69.02	4.14
	42	ISQ	10	65.1	79	69.9	4.65
	49	ISQ	10	64.6	80	70.54	4.93
	56	ISQ	5	66.4	77	71.2	4.06
	70	ISQ	5	68.6	77	72.56	3.39

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	84	ISQ	5	69.4	79	74.48	3.90

Table 1b

Experimental Group	Day		N	Minimum	Maximum	Mean	SD
modSLA	0	ISQ	20	64	78.2	72.67	3.94
	7	ISQ	20	64	84	73.47	5.80
	14	ISQ	15	62.8	84.281	73	5.34
	21	ISQ	15	57.4	80	71.627	6.53
	28	ISQ	10	49.6	79.2	70.46	8.30
	35	ISQ	10	48	80.2	70.84	8.95
	42	ISQ	10	55	81.6	71.7	7.25
	49	ISQ	10	62.2	80.2	73.66	5.26
	56	ISQ	5	66.6	79	74	4.68
	70	ISQ	5	74	79	76.56	1.92
	84	ISQ	5	75	80	77.8	1.87

Immediately after installation of implant, the ISQ values for both surfaces tested were not significantly different and yielded mean values of 75.28 ± 5.23 for the control and 73.16 ± 4.81 for the test surface. In the first 2 weeks after implant installation, both groups presented only small changes and thereafter a reducing trend in the mean ISQ levels. In the test group, after 4 weeks a tendency towards increasing ISQ values was observed and 6 weeks after surgery the ISQ values corresponded to those after implant insertion. For the SLA-control group, the trend changed after 5th

week and yielded ISQ values corresponding to the baseline after 9th week. After 12 weeks of observation, the test surface yielded significantly higher stability values of 78.68 ± 2.9 compared with the control implants of 75.5 ± 3.19 respectively.

Both groups showed a fair homogeny in the individual ISQ values. Except for one palatal implant each of both groups, however, the changes over time differed significantly 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 modSLApalatal 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.

III. 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.[17] This transition period is crucial regarding early loading.[18-19] 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.[16] The technique has been demonstrated to be an accurate method for early assessment of osseointegration.[20] The significantly wider range in the ISQ values shown by the two palatal implants over time might be explained 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. The mean ISQ value, thereafter, started to decline significantly. 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 wettable characteristics enhancing the interaction between the implant surface and the biologic environment.[21] 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 goup and the control SLA group 21 days until biological stability occured. 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.[22] 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 Orthosystems palatal implant (Straumann AG) with a shoulder and a smaller diameter.[22] 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 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. 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.[10] 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[21] and leads to enhanced bone apposition.[10] 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. Similar findings of interarch variations in implant stability, with greater changes in stability in the mandible than the maxilla, have been reported previously.[23-24] However, this is in contrast to previous investigations, in which implants placed in less dense bone types tended to have greater changes in stability.[12,24] 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[24] which is in accordance with the characteristics of their bone quality. Dental implants, however, always deal with surrogate biological endpoints. Palatal implants, in contrast, are temporary anchorage devices and subsequently removed after therapy.

IV. CONCLUSION

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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