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van Eekeren, P.J.A.	

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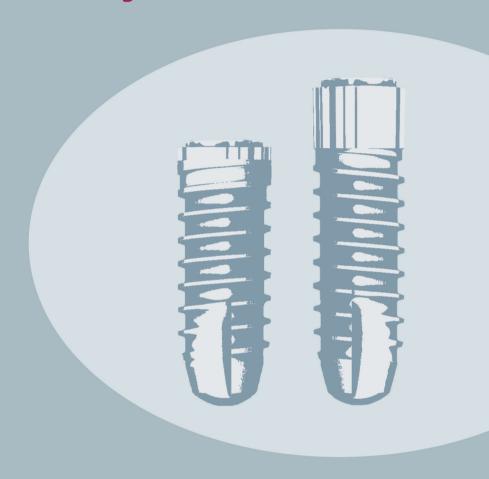
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Chapter 4

Resonance Frequency Analysis & Osseointegration



Resonance frequency analysis of thermal acid-etched, hydrophilic implants during the first 3 months of healing and osseointegration in an early loading protocol

van Eekeren PJA, Said C, Tahmaseb A, Wismeijer D.

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Abstract

Purpose: Safe loading of dental implants requires an optimal osseointegration. This osseointegration process during healing could be analyzed by resonance frequency analysis (RFA). The purpose of the study is to evaluate RFA changes during healing in splinted, early loaded, thermal acid-etched, hydrophilic implants over time.

Materials & Methods: Patients received a minimum of 2 implants: an implant with the prosthetic abutment connection at the crestal bone level (MC, bone level) and one with the prosthetic abutment connection 2,5 mm supra crestal (LC, soft tissue level). Implant stability (RFA) was measured at weeks 0, 2, 3, and 12 using the Osstell™ device.

Results: 76 implants were placed in 32 patients. Early loaded soft tissue level implants showed a significant drop in ISQ values by 2.2 ± 3.6 ISQ (P < 0.001) by week 2. Changes in ISQ values were significant between weeks 3 and 12, and also between weeks 0 and 12, with mean differences of 4.2 (P < 0.001) and 2.8 ISQ (P < 0.001) respectively. Early-loaded bone level implants show a significant change in ISQ by 2.3 ± 3.7 ISQ at week 2 (P < 0.01) and at T12 when compared to T3 of 2.9 ± 4.9 ISQ (P < 0.01). Bone level implants achieved higher ISQ values compared to soft tissue level implants in weeks 0, 2, 3 and 12, with mean differences of 3.8 ± 5.5 ISQ (P < 0.01), 3.8 ± 6.1 ISQ (P < 0.01), 3.7 ± 6.7 ISQ (P < 0.01), 2.3 ± 5.8 ISQ (P < 0.05) respectively.

Conclusion: A significant dip in ISQ values was observed, with the lowest point at week 2. ISQ values remained higher in bone level implants throughout the process of healing and osseointegration.

Resonance frequency analysis of thermal acid-etched, hydrophilic implants during the first 3 months of healing and osseointegration in an early loading protocol

Introduction

Immediate implant stability has increased significantly with the introduction of acid-etched implants (Bornstein et al. 2009). Proceedings of the third International Team for Implantology (ITI) consensus meeting defined loading categories according to the time of implant placement (2004) and were similar to earlier published data by the Sociedad Española (Aparicio et al. 2003). Conventional: a minimum of 3 months, early: at least 48 hours and no later than 3 months and immediate: within 48 hours after implant placement (2004) (Aparicio et al. 2003). The early loading definition was however 'tenuous' as the span in time could make a significant difference in stages of healing and was in need of further accurate descriptions in the future (Attard & Zarb 2005). Further, it has been suggested that when using implants with hydrophilic properties, the healing period shortens and treatment predictability increases (Bornstein et al. 2010).

Implant stability is critical to the long-term success of osseointegrated implants (Anil & Al Dosari 2015). Initially, the stability is provided by macro retention to the bony walls. Resorption of bone takes place within a few days of implant insertion resulting in a loss of mechanical retention (Terheyden et al. 2012). Further, the loss of mechanical retention and the process of osseointegration do not occur simultaneously, thus causing a temporary decrease in implant stability (Raghavendra et al. 2005, Barewal et al. 2012, Sim & Lang 2010, Zembic et al. 2010).

Several factors are believed to influence the existence and pattern of a dip in stability, such as the quality of bone (Herekar et al. 2014), insertion torque (Filho et al. 2014), and more importantly, the implant design (Simunek et al. 2012). Surface topography, chemistry, charge, and wettability are important factors that determine the design of an implant (Bornstein et al. 2009, Buser et al. 2004, Ferguson et al. 2006, Oates et al. 2007, Schwarz et al. 2007). To measure implant stability, resonance frequency analysis (RFA) can be used (Herekar et al. 2014). With RFA, it is possible to assess changes in implant stability over time, in a clinical and non-invasive manner (Anil & Al Dosari 2015). RFA is used to measure the axial stabil-

ity of the implant. It yields a measurement scale called the implant stability quotient (ISQ). ISQ values range from 1 to 100 (Filho et al. 2014). Higher ISQ values indicate higher implant stability. Clinically stable implants generally demonstrate ISQ values between 40 and 80 (Andersson et al. 2013, Aparicio et al. 2006, Barewal et al. 2012, Bogaerde et al. 2010, Herekar et al. 2014, Manresa et al. 2014, Schwarz et al. 2009). Ideally, ISQ values reveal information about the stiffness of an implant within the surrounding bony walls but do not necessarily reflect the actual BIC (Anil & Al Dosari 2015, Manresa et al. 2014).

An ISQ value is not a predictor of osseointegration, but gives some information about the stability of an implant (Herekar et al. 2014). Therefore, to gather useful information about osseointegration, ISQ values of individual implants should be measured over a period of time. By studying the changes that occur in the ISQ values, conclusions can be drawn about the pattern of osseointegration of individual implants.

Related studies (Andersson et al. 2013, Bogaerde et al. 2010, Stoker & Wismeijer 2011, Zembic et al. 2010) have only measured the ISQ values directly after implant placement and after healing of the implant. This does not provide adequate information to determine the pattern in which implant stability develops. More frequent measurements are necessary to ascertain this information. The occurrence and timing of the dip in implant stability, the duration thereof, and the extent of decrease can be useful during treatment planning in case of early loading protocols.

The aim of the present study was to examine the pattern of development of implant stability during osseointegration in splinted, early loaded, acid-etched dental implants with hydrophilic surface characteristics. Other objectives during this research were to determine whether there was a difference in stability between implants with the prosthetic abutment connection at the crestal bone level or 2,5 mm above during osseointegration, and to analyze whether there was a correlation between ISQ at placement and insertion torque.

Materials & Methods

All procedures were performed at the Department of Implantology, Academic Centre of Dentistry Amsterdam (ACTA) and approved by the medical ethics committee of the Free University. (METc VUMC registration number 2009/221). Patients were referred by their respective dentists to the ACTA for implant-supported 3-unit fixed restorations in the posterior maxilla or mandible. This study was performed between November 2012 and June 2013.

Patients aged between 25 and 85 years were eligible for inclusion in the study on fulfilling all the following criteria: (1) requirement of a 3-unit fixed dental prosthesis supported by 2 implants in the molar/premolar area, (2) adequate bone height for implant placement without any bone regeneration, (3) agreeable to visiting every 3 months for a strict oral hygiene protocol, (4) adequate oral hygiene, and (5) willing to sign the informed consent.

Patients were excluded from the study if they fulfilled any of the following criteria: (1) medical conditions that contraindicate surgery, e.g., severe cardiac and pulmonary disorders, uncontrolled diabetes or chronic liver disease, (2) suffering from periodontitis, or (3) problematic substance users

The patients were then prospectively followed-up over a period more than 1 year. Thereafter, 32 patients (19 women and 13 men) were selected, with a mean age of 61 (range 36–85) years.

At the time of inclusion in the study, patients were advised regarding the nature of the study, and the clinical procedures and possible risks involved.

A week before the surgery, all patients received a precise overview of the treatment and signed the informed consent. The oral hygiene was examined according to the Dutch periodontal screening index (DPSI). The patients received a prescription of chlorhexidine 0.2% oral rinse to be used post-surgically for 1 min, 3 times a day. General surgery-related instructions were provided and the patients were again advised about the procedure and risks involved.

Implant placement was performed under local anaesthesia (articaine hydrochloride 4% with epinefrine 1:100000; Ultracain ds forte, Aventis). Prior to the surgery, patients were instructed to rinse their mouth with chlorhexidine 0.2%. Implant placement was carried out according to the manufacturer's guidelines.

All patients received at least 2 SPI-ELEMENT implants with a thermal acid-etched surface (INICELL®) (Thommen Medical AG, Grenchen, Switzerland). Implants were conditioned chair side to achieve a hydrophilic implant surface (APLIQUIQ®). One implant was placed with the prosthetic abutment connection at the crestal bone level (bone level; MC). The other implant with the prosthetic abutment connection 2,5 mm supra crestal (soft tissue level;

LC). The position (whether anterior or posterior) was determined by random selection. The position of the implants was decided such that a fixed dental prosthesis with three premolar sized units could be placed post surgically. All implants were placed one-stage.

At the time of implant placement, the insertion torque for both the implants was assessed using the torque wrench (MONO, Thommen Medical AG, Grenchen, Switzerland)) provided in the surgery kit. All implants were intended to be loaded within 3 weeks after implant placement (early). If the insertion torque of one of the implants was lower than 10 Ncm both the implants were loaded after 3 months (conventional).

ISQ values were measured by attaching an abutment with a magnet (Smartpeg; Osstell, Gothenberg, Sweden) into the implant and using the contact-free probe of the Osstell™ device (Osstell, Gothenberg, Sweden) for measurement. The ISQ values were assessed immediately after implantation (T0). Thereafter, healing abutments were seated, wounds were sutured with polypropylene 6/0, and postoperative instructions were given.

Two weeks after surgery, sutures were removed, ISQ values were assessed (T2), and impressions for the 3-unit fixed dental prosthesis were obtained.

In the third week after surgery, ISQ values were again measured (T3), and the porcelain-fused-to-metal fixed dental prosthesis was mounted. The screw-access holes were closed temporarily using a Teflon tape and temporary filling material (Cavit-W; 3M ESPE, Seefeld, Germany) for easy access after 12 weeks (T12).

After 3 months (T12), the screw-retained fixed dental prosthesis was removed, ISQ values were measured and the implants were now restored permanently. All restorations were screw-retained. The screw-access holes were covered using a Teflon tape and composite resin (Filtek Supreme XTE; 3M ESPE, Seefeld, Germany).

Statistical Analysis

One fixed partial denture was randomly selected to account for the dependency when patients received multiple constructions. Using intent to treat analysis would fill in the missing data in patients when early loading was not possible and the implants were conventional loaded. The data would be missing at week 2 and 3, as these RFA measurements are not

possible. This would give a statistical and methodical error and it was decided to analyze this group of patients separately.

The repeated measures ANOVA test was performed to determine whether the changes in ISQ over time were statistically significant. The Pearson sample *t*-test was then used to identify the ISQ measurements between which the differences were statistically significant. For the comparison of ISQ values in bone and soft tissue level implants, the independent samples *t*-test was used. The Pearson's correlation was performed to determine whether there was a correlation between ISQ at baseline (T0) and the insertion torque. P levels of < 0.05 were considered to be significant. For statistical analysis, the SPSS statistical package (SPSS 21, SPSS Inc., Chicago, IL) was used.

Results

A total of 76 SPI-ELEMENT implants – 38 bone level (MC) and 38 soft tissue level (LC) implants – were placed in 32 patients. Totally 20 implants were placed in the maxilla and 56 in the mandible.

4 implants showed insertion torque values lower than 10 Ncm. In accordance with the study protocol, these implants were loaded by the conventional method. In these cases, it was possible to assess ISQ values only at the time of implant placement and after 3 months. One patient lost a mandibular bone level implant owing to an infection in week 3. This patient was excluded from the research. All other implants – 66 placed in 27 patients – showed no signs of infection or loss of retention (98.6%) and were loaded early, at 3 weeks. 3 patient's received 4 implants and one patient received 8 implants.

ISQ values of the 27 early-loaded implants soft tissue level (LC) implants ranged from 64 to 80 with a mean 74 ± 4.2 ISQ at baseline ISQ measurements at week 2 (T2) were significantly lower (P < 0.01) than at T0, with a mean difference of 2.2 ± 3.6 (95% CI, 0.8 to 3.7 ISQ). Between T2 and T3, the ISQ values increased by 0.8 ± 3.1 (95% CI, -2.0 to 0.4 ISQ), however, this was not significant. By T12, the ISQ values had increased by 4.2 ± 3.1 (95% CI, -5.9 to -2.5 ISQ) and were significantly higher than those at T3 (P < 0.001). ISQ measurements at T12 were significantly higher than the baseline values T0 (P < 0.001), with a mean difference of 2.8 ± 3.7 (95% CI, -4.3 to -1.4 ISQ). Bone level implants (MC) showed a significant mean difference of -2.3 ± 3.7 (95% CI, 0.8 to 3.7 ISQ) (P < 0.01) between T0 and T2 and ranged at baseline 60 to 86 with a mean 77.8 ± 6.0 . Comparing T2 with T2, a difference of 0.7 ± 2.4

(95% CI, -1.6 to 0.2 ISQ) ISQ was observed, which was not significant. T3 and T12 showed a increase of 2.8 \pm 4.9 (95% CI, -4.8 to -1.0 ISQ) reflecting significantly higher ISQ values (P < 0.01). The measurements obtained at T12 showed no significant mean difference of 1.3 \pm 4.7 (95% CI, -3.2 to 0.6 ISQ) compared to those at T3. (table 1 & 2 & figure 1)

Table 1: Descriptive statistics on ISQ values						
	N	Minimum	Maximum	Mean	Std. Deviation	
Soft tissue level T0	27	64,0	80,0	74,0	4,2	
Soft tissue level T2	27	60,0	78,0	71,8	4,6	
Soft tissue level T3	27	60,0	80,0	72,6	5,0	
Soft tissue level T12	27	66,0	83,0	76,8	4,1	
Bone level T0	27	60,0	86,0	77,8	6,0	
Bone level T2	27	63,0	84,0	75,6	5,4	
Bone level T3	27	63,0	84,0	76,3	5,9	
Bone level T12	27	60,0	86,0	79,1	4,8	
Valid N (listwise)	27					

Significantly lower ISQ values at baseline were found in soft tissue level implants (LC) when compared to bone level implants of 3.8 \pm 5.5 (95% CI, -6.0 to -1.6 ISQ) (P < 0.01). After 2 weeks a mean difference of 3.8 \pm 6.1 (95% CI, -6.2 to -1.4 ISQ) (P < 0.01) was seen. At T3 bone level implants showed 3.7 \pm 6.7 (95% CI, -6.3 to -1.0 ISQ) (P < 0.01). The mean difference at T12 in bone level implants was still significantly higher 2.3 \pm 5.8 (95% CI, -4.6 to 0 ISQ) (P < 0.05) (table 3).

4 patients with the conventional loading were measured at baseline and at T12. The mean difference in bone level implants was not significant with a mean change of 5.0 ± 4.4 (95% CI, -12.0 to -2) ISQ. Soft tissue level implants show a significant increase of 17.3 \pm 8.6 (95% CI, -30.9 to -3.6 ISQ) P < 0.05. (table 4 & 5)

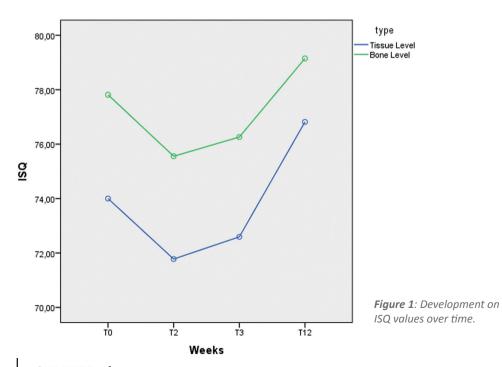
All the 76 implants originally selected for this study were used to determine the correlation between the insertion torque and ISQ values measured directly after implantation. A highly significant correlation of $r^2 = 0.801$ was found (P < 0.001).

Table 2: Paired-samples test						
		Paired Differences				
		Std.	95% Confide of the Di	Sig.		
	Mean	Deviation	Lower	Upper	(2-tailed)	
Soft tissue level T0-T2	2,2	3,6	,8	3,7	,004	
Soft tissue level T2-T3	-,8	3,1	-2,0	,4	,177	
Soft tissue level T3-T12	-4,2	4,3	-5,9	-2,5	,000	
Soft tissue level T0-T12	-2,8	3,7	-4,3	-1,4	,000	
Bone level T0-T2	2,3	3,7	,8	3,7	,004	
Bone level T2-T3	-,7	2,4	-1,6	,2	,134	
Bone level T3-T12	-2,9	4,9	-4,8	-1,0	,005	
Bone level T0-T12	-1,3	4,8	-3,2	,6	,159	

Table 3: Paired-samples test on the difference in time per implant type						
	Paired Differences					
		95% Confidence Interval of the Difference		Sig.		
	Mean	Deviation	Lower	Upper	(2-tailed)	
Soft tissue level - Bone level T0	-3,8	5,5	-6,0	-1,6	,001	
Soft tissue level - Bone level T2	-3,8	6,1	-6,2	-1,4	,004	
Soft tissue level - Bone level T3	-3,7	6,7	-6,3	-1,0	,009	
Soft tissue level - Bone level T12	-2,3	5,8	-4,6	,0	,046	

Table 4: Descriptive statistics on ISQ values conventional loading								
	N Minimum Maximum Mean Std. Deviat							
Soft tissue level T0	4	37,0	58,0	49,8	9,3			
Soft tissue level T12	4	60,0	78,0	67,0	8,1			
Bone level T0	4	58,0	78,0	70,0	8,8			
Bone level T12	4	65,0	85,0	75,0	8,5			
Valid N (listwise)	4							

Table 5: Paired-samples test in the conventional loading protocol						
		Std.	95% Confidence Interval of the Difference		Sig.	
		Deviation	Lower	Upper	(2-tailed)	
Soft tissue level T0 – Soft tissue level T12	-17,3	8,6	-30,9	-3,6	,028	
Bone level T0 – Bone level T12	-5,0	4,4	-12,0	2,0	,107	



Discussion

Two weeks after implant insertion; a drop of 2.2 ISQ indicates a statistical significant dip in implant stability. This dip in stability would correspond to the process of loss of mechanical retention during the early phase of healing (Terheyden et al. 2012). Thereafter, ISQ values seemed to increase at week 3, although this was not significant. This increase in stability would indicate new bone formation. After 3 months, ISQ values had risen and were significantly higher compared to not only values at week 3, but also to the baseline measurements.

For successful osseointegration, a functional connection between bone and the implant surface is needed. The newly formed bone ensures this biological bonding with the implant surface (Manresa et al. 2014, Sim & Lang 2010). When analyzing the quality of the connection between bone and the implant surface, several factors can be assessed, for e.g., the bone to implant contact (BIC), effective implant length (EIL), and bone volume density (BVD). These parameters, however, can only be used in histological studies due to their invasive nature (Manresa et al. 2014, Sim & Lang 2010). As clinical, non- invasive, but not as accurate alternatives, insertion torque and RFA are used. Assessment of insertion torque is easy, but can only be performed at implant placement. The assessment of ISQ values, however, can be done even after implant placement.

In an animal study (Manresa et al. 2014), however, no correlation was found between RFA and BIC. Research by Park et al. using rabbit tibia showed a correlation between ISQ values directly after implant placement and the percentage of BIC after 4 weeks of healing. ISQ measurements assessed later in the process of healing showed no correlation with the percentage of BIC (Park et al. 2011). During the current research, we analyzed the development in ISQ values during healing, to draw conclusions about the pattern of osseointegration. To obtain reliable information about the BIC, however, histological evaluation is needed (Park et al. 2011). Thus, while RFA does not reflect the actual BIC, it gives us information about the implant stability (Han et al. 2010).

In our study, the dip in stability was highest at week 2. Generally, in implants with no hydrophilic surface, the dip in stability is at its lowest point during weeks 3 and 4 (Makary et al. 2012, Simunek et al. 2012). A study by Buser et al. also reported promising results when using implants with hydrophilic properties. They observed faster healing periods and enhanced bone apposition. They also found higher BIC within the first 4 weeks and 60% more

bone within 2 weeks, in comparison to the regular sandblasted acid etched surfaces (Buser et al. 2004).

The modified implants reached stability values similar to those at baseline after 6 to 7 weeks, in contrast to the regular implants which needed 12 weeks to reach baseline ISQ values (Schatzle et al. 2009). During this study, significantly higher ISQ values were observed at week 12 compared to the measurements at baseline, suggesting a shorter healing period for the implants researched during this investigation, compared to the healing period of regular implants.

Although promising results have been reported in literature, there is still no consensus on whether the process of osseointegration is indeed faster in chemically modified implants. Han et al., for instance, found no difference between the healing periods of SLA and SLActive implants. Moreover, both implants had their lowest point of the dip at week 3 (Han et al. 2010). Furthermore, there are studies that don't report a dip in implant stability at all (Simunek et al. 2012). This, however, might be the result of insufficient number of measurements per implant over time.

During this investigation, implants were loaded 3 weeks after insertion, thus representing an early loading protocol. However, in 8 cases, it was decided to delay loading because of low insertion torque values of 4 implants. In the literature, while the importance of good primary stability is reported, the importance of good implant stability during healing is also highlighted (Herekar et al. 2014, Makary et al. 2012). All these implants were placed in the maxilla. It is mentioned that the quality and quantity of bone are important factors in the success of implant therapy and that the bone in the mandible is of better quality and quantity than that of the maxilla (Filho et al. 2014, Turkyilmaz et al. 2007). Compared to the mandible, bone in the maxilla is softer and of smaller volume (Balleri et al. 2002, Friberg et al. 1999). The current literature shows that higher ISQ values directly after placement can be found in type II bone compared to type IV bone (Balleri et al. 2002, Filho et al. 2014, Friberg et al. 1999, Manresa et al. 2014, Moon et al. 2010). Generally, type II bone can be found in the mandible and type IV in the maxilla. It has been observed that implants in the maxilla generally present with ISQ values of less than 60, and implants in the mandible demonstrate ISQ values of 60 or more (Friberg et al. 1999). It has been said that higher bone quality is related to higher implant stability in the period following surgery (Filho et al. 2014, Herekar et al. 2014, Moon et al. 2010). It has also been stated that the quality of bone can influence

the pattern of the dip in stability and therefore affect the success rate of the treatment (Huang et al. 2002, Simunek et al. 2012). Further, it has been suggested that implants with low implant stability at placement show less than adequate osseointegration (Friberg et al. 1999). Moreover, a higher occurrence of failure was observed in the maxilla, especially when implants were loaded early (Balleri et al. 2002, Friberg et al. 1999, Turkyilmaz et al. 2007). Therefore, it was advisable to prolong the healing period before loading under these circumstances, considering that implant stability increases over time.

In the current study, bone level implants yielded significantly higher stability at weeks 0, 2, and 12, compared to soft tissue level implants. However, during healing, the development of implant stability did not differ significantly between bone level and soft tissue level implants. This might indicate that for the process of osseointegration, the design of the implant is not of influence. Nonetheless, it is interesting to note that the bone level implants yielded significantly higher ISQ values throughout this process.

The difference found in implant stability between bone and soft tissue level implants might be explained by the height of the collar of the implant. The bone level implants used in this study had a short collar of 0.5 mm and were, as a consequence, placed in a more crestal position. The soft tissue level implants, on the other hand, had a collar height of 2.5 mm, and were therefore placed in a supra crestal position. In the bone level implants, the distance between the shoulder of the implant and the alveolar ridge was smaller compared to that of the soft tissue level implants, conceivably resulting in a more rigid connection between the bone crest and the implants at the time of measuring the ISQ. In soft tissue level implants, however, the collar was partially extended above the bone crest, possibly resulting in more flexibility of the implant. This could explain why soft tissue level implants showed lower ISQ values than bone level implants. However, further research is needed to fully comprehend the mechanism behind the difference in ISQ values between bone and soft tissue level implants as there are no publications discussing this subject.

The high correlation between insertion torque and implant stability that was found during this study suggests that implants with high insertion torque values generally have higher implant stability. Insertion torque is generally seen as an indirect indicator of implant stability immediately after surgery (Filho et al. 2014, Makary et al. 2012). It has, however, been suggested that insertion torque can also be seen as an indicator of the local bone quality (Turkyilmaz et al. 2007). A significant correlation of $r^2 = 0.853$ (P < 0.001) between ISQ values

after placement and insertion torque values was observed (Turkyilmaz et al. 2007). This corroborates the results found during this investigation ($r^2 = 0.801$, with a significance level of P < 0.001). A similar significant correlation was also reported (Makary et al. 2012). Further, the researchers also found a positive correlation between insertion torque and the process of osseointegration. This corresponds with the findings that lower implant stability is achieved when implants are placed in bone of lower quality and quantity, such as in the maxilla. Regarding the limitations of this study, the criteria for patient selection were stringently adhered to, so as to ensure that no other factors, such as systemic diseases or periodontitis, could influence the outcomes. Furthermore, all implant insertions were performed by the same operator (PVE), as were all the prosthodontic procedures and ISQ measurements. Measurements were repeated in order to decrease the risk of errors. The literature shows that ISQ measurements have a high degree of repeatability, and a variation of less than 1% can be found when measuring ISQ values of an implant (Schatzle et al. 2009).

Conclusion

A drop in ISQ values by 2.2 in soft tissue level and 2.3 in bone level implants after 2 weeks of implant insertion indicates a significant dip in implant stability. After osseointegration, significantly higher implant stability was seen compared to the stability directly after placement.

During healing, no differences in the development of ISQ values between bone and soft tissue level implants were observed, indicating no differences in the process of osseointegration between the two types of implant design.

Furthermore, the high correlation between insertion torque and implant stability at placement suggests that implants with high insertion torque values generally have higher implant stability at placement. On the basis of the insertion torque values, 91% of the implants were loaded after 21 days of healing. This early loading concept using Thommen Medical implants has been shown to be predictable when torque values are above 10 Ncm and crowns are splinted.

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