Original Article

Mini-implant stability at the initial healing period
A clinical pilot study

Manuel Nienkemper[a]; Benedict Wilmes[b]; Alexander Pauls[c]; Dieter Drescher[d]

ABSTRACT
Objective: To evaluate the changes of mini-implant stability over the initial healing period in humans.
Material and Methods: A sample of 19 consecutively treated patients (mean age 15.5 $\pm$ 7.3 years) was examined. In each patient, a mini-implant of a size of 2 $\times$ 9 mm was inserted into the anterior palate. Implant stability was assessed using resonance frequency analysis (RFA) immediately after insertion (T0), 2 weeks later (T1), 4 weeks later (T2), and 6 weeks later (T3). Insertion depth (ID) and the maximum insertion torque (IT) were measured. Data were tested for correlations between RFA, ID, and IT. All RFA values were tested for statistically significant differences between the different times.
Results: The mean ID was 7.5 $\pm$ 0.6 mm, and the mean IT was 16.8 $\pm$ 0.6 Ncm. A correlation was found between RFA and ID ($r = .726$, $P < .0001$), whereas no correlations between RFA and IT or between IT and ID were observed. From T0 to T1, the stability (36.1 $\pm$ 6.1 implant stability quotient [ISQ]) decreased nonsignificantly by 4.9 $\pm$ 6.1 ISQ values ($P > .05$). Between T1 and T2, the stability decreased highly significantly ($P < .001$) by 7.9 $\pm$ 5.9 ISQ values. From T2 on, RFA remained nearly unchanged (-1.7 ± 3.5 ISQ; $P > .05$).
Conclusions: Mini-implant stability is subject to changes during the healing process. During weeks 3 and 4, a significant decrease of the stability was observed. After 4 weeks, the stability did not change significantly. (*Angle Orthod.* 2014;84:127–133.)

KEY WORDS: Skeletal anchorage; Mini-implants; Stability; Resonance frequency analysis

INTRODUCTION

In recent years, orthodontic mini-implants have become very popular. New kinds of mechanics and treatment options became possible due to the new anchorage quality.[1–3] The anterior palate especially has been used more and more as an insertion site for mini-implants. This region is characterized by plenty of bone of high quality[4] covered with a thin mucosa, which allows a sufficient insertion depth.[5]

The first key factor to success in treatment is a sufficient primary stability.[6] In many studies, primary stability is determined by measurement of maximum insertion torque.[7,8] In addition, knowledge of the healing process at the bone-to-implant interface and the resulting changes in stability (ie, the transition to secondary stability) are important to apply an adequate clinical procedure.

The development of stability of dental implants has been studied thoroughly in animals, mainly relying on histological analysis of osseointegration rates. In humans, resonance frequency analysis (RFA) has proven to be an adequate method because of its noninvasiveness and contactless measurement method.[9]

RFA measurement requires a small magnet in an aluminum housing (SmartPeg, Gotenburg, Sweden) to be screwed on top of the implant's head. Electromagnetic pulses with frequencies ranging from 5 to 15 kHz are emitted by a handpiece toward the SmartPeg. The device detects the resonance frequency of the SmartPeg-implant unit in the bone (Figure 1). The unit

[a] Instructor, Department of Orthodontics, Heinrich-Heine-University, Düsseldorf, Germany.
[b] Associate Professor, Department of Orthodontics, Heinrich-Heine-University, Düsseldorf, Germany.
[c] Postgraduate Student, Department of Orthodontics, Heinrich-Heine-University, Düsseldorf, Germany.
[d] Professor and Department Chair, Department of Orthodontics, Heinrich-Heine-University, Düsseldorf, Germany.
Corresponding author: Dr Manuel Nienkemper, Department of Orthodontics, Heinrich-Heine-University, Moorenstr. 5, 40225 Düsseldorf, Germany
(e-mail: Manuel.Nienkemper@uni-duesseldorf.de)

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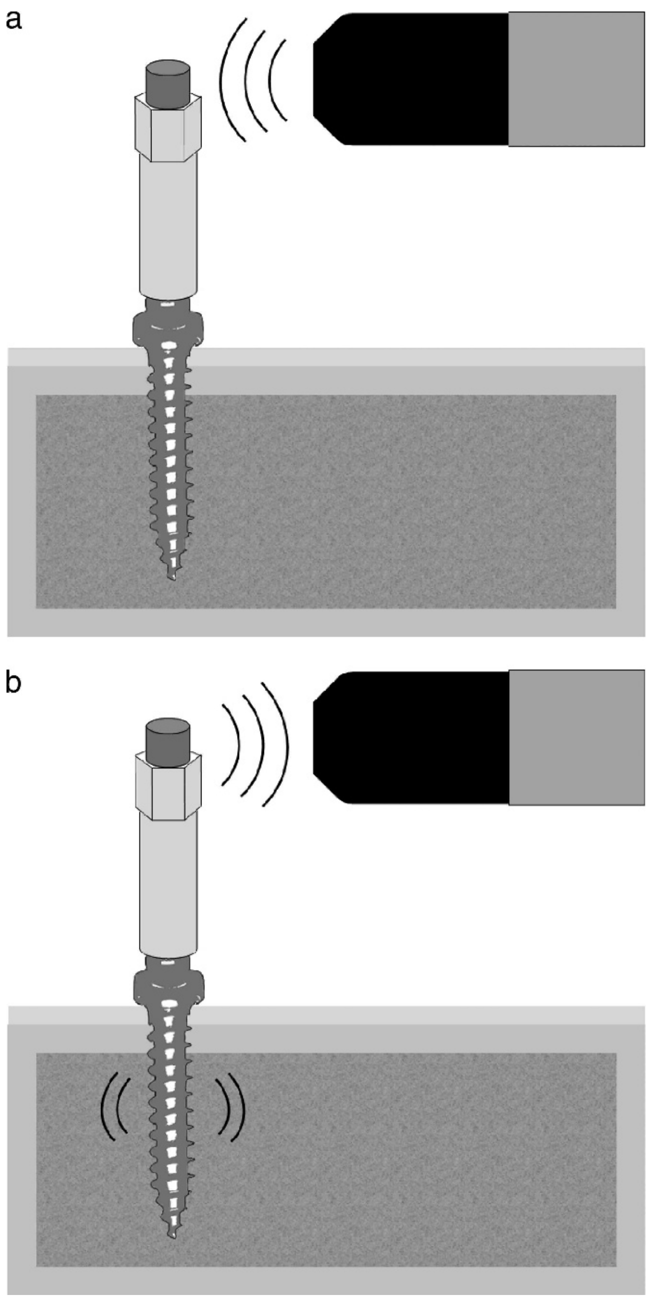

Figure 1. (a, b) Resonance frequency analysis measurement of an inserted mini-implant.

of measurement is the implant stability quotient (ISQ). RFA is regarded as the gold standard for clinical stability measurement of dental implants.[10] It was demonstrated that it can be used to assess implant stability any time after insertion.[11]

Mini-implants differ from current dental implants with respect to size, design, surface characteristics, insertion protocol, and insertion sites. As a consequence, results of RFA measurements are significantly affected by factors such as implant size and design.[12] To assess mini-implant stability, specially modified SmartPegs are used. It was shown that this way, RFA delivers reasonable results also for mini-implants.[13]

During the healing phase, the interface between bone and mini-implant is subject to changes due to the remodeling processes.[14] Until now, there has been no information as to how the healing process affects the stability of orthodontic mini-implants.

Hence, the primary aim of this clinical pilot study was to evaluate the development of mini-implant stability during the initial healing period. Secondary aims were to investigate the correlations between maximum insertion torque (IT), RFA, and insertion depth (ID) immediately after insertion and to evaluate the effect of measurement direction on RFA values.

MATERIALS AND METHODS

Subjects

Patients whose treatment plan comprised the insertion of a palatal mini-implant and who agreed to take part in the study were included. Exclusion criteria were presence of a systemic disease affecting bone metabolism or wound healing or poor oral hygiene. After insertion, data of patients who missed examination appointments or who developed a peri-implant inflammation were excluded.

Power Analysis

Calculation was performed using G*Power 3.1.5 (University of Kiel, Kiel, Germany). Due to the fact that of this study there was no publication available investigating the stability changes of mini-implants in humans, we had to resort to data obtained from a study on stability changes in beagle dogs.[15] In this pilot study, modified mini-implants were used to allow RFA using SmartPegs. The changes found in ISQ values and standard deviations over a 3-week period after insertion through keratinized tissue were chosen as a basis for sample size calculation for this study. Given a change of ISQ of 4.7 with a standard deviation of 4.7, an alpha level of .05 and a power of .90, the required sample size for the treated or control samples resulted in $n = 18$. Anticipating possible dropouts, 23 consecutively treated patients were examined. No further selection was performed.

During the observation period, four patients had to be excluded either due to signs of peri-implant inflammation or missed examination appointments. Hence, the test group comprised 19 patients, 11 males and 8 females of white ancestry with a mean age of 15.5 ± 7.3 years.

The prospective study was approved by the ethical committee of the University Clinics of Düsseldorf, Germany. It was performed according to the Declaration

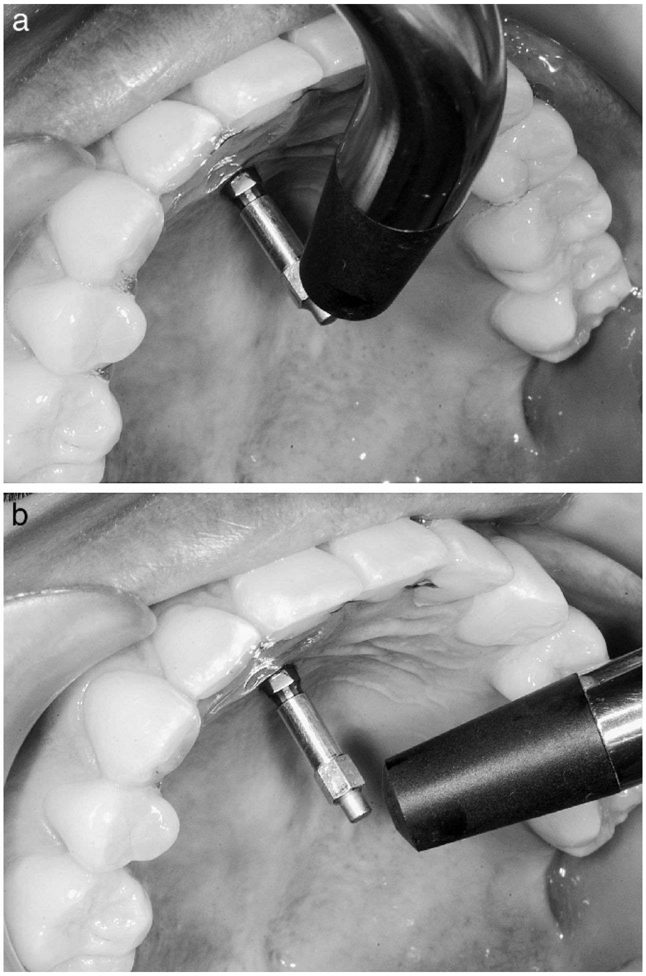

Figure 2. (a, b) Parallel and perpendicular resonance frequency analysis measurement.

of Helsinki guidelines on experimentation involving human subjects.

Insertion Protocol

The insertion site was defined as the midpalatal suture at the level between the third and fourth palatine rugae. After measurement of the soft tissue thickness using a dental probe with a silicon stop, predrilling was performed under water cooling using a 1.3-mm drill to a depth of 3 mm. A Benefit mini-implant (length: 9 mm; outer diameter: 2 mm; inner diameter: 1.35 mm; thread pitch: 0.75 mm; PSM Medical Solutions, Tuttlingen, Germany) was inserted rectangularly to the palatal surface until the mini-implant's head touched the soft tissue. Predrilling and insertion were performed using a surgical machine (ElcoMed SA 200C, W&H, Bürmoos, Austria).

Observation Protocol

The measurement of the soft tissue thickness, performed at the first appointment (T0), represents

Table 1. Initial Values for Resonance Frequency Analysis (RFA), Insertion Torque (IT), and Insertion Depth (ID)[a] and standard deviations

ID, mm	7.50	0.55
IT, Nmm	16.81	3.54
RFA, ISQ	36.14	6.08

[a] ISQ indicates implant stability quotient.

the implant's portion outside the bone since insertion was performed until the mini-implant's head touched the soft tissue surface. ID was calculated by subtraction of the soft tissue thickness from the total length of the thread part (9 mm). The surgical motor used for insertion recorded the maximum IT values.

RFA was performed three times both parallel and perpendicular to the midpalatal suture after insertion (T0), after 2 weeks (T1), after 4 weeks (T2), and after 6 weeks (T3; Figure 2). Mean values were calculated for perpendicular, parallel, and overall ISQ values for each mini-implant at each time. At each appointment, the peri-implant soft tissue was checked for signs of inflammation.

Statistical Analysis

The Shapiro-Wilk test showed a normal distribution regarding all ISQ values, maximum IT values, and soft tissue thicknesses. The Levene test showed equality of variances for the relevant ISQ values. Therefore, parametric statistics were applied. Significant differences between the ISQ values at T0, T1, T2, and T3 were tested with analysis of variance and Duncan post hoc test. A comparison between ISQ values parallel and perpendicular to the midpalatal suture was performed using the paired t test. Correlations between initial ISQ values, maximum IT values, and soft tissue thicknesses were calculated using Pearson correlation. In addition, linear regression analysis was performed. All statistical computations were performed with statistical software (SPSS 21.0, IBM, Chicago, Ill). Statistical significance was tested at $P < .05$ (*), $P < .001$ (**), and $P < .0001$ (***).

RESULTS

The mean thickness of the soft tissue at the insertion site was 1.5 $\pm$ 0.6 mm, resulting in an ID of 7.5 $\pm$ 0.6 mm. The IT recordings showed a mean value of 16.8 $\pm$ 0.6 Ncm. The RFA at T0 resulted in mean values of 36.1 $\pm$ 6.1 ISQ (Table 1). Pearson correlation showed no significant correlations between RFA and IT or between IT and ID. A significant correlation was found between RFA and ID ($P < .0001$) with a coefficient of $r = .726$ (Table 2; Figure 3).

The mini-implant's stability by means of ISQ values changed over time. Over the whole observation period of 6 weeks, there was a highly significant decrease of

Table 2. Correlations Between Resonance Frequency Analysis (RFA), Insertion Torque (IT), and Insertion Depth (ID)

	r	*P*	r^2
ID-IT	−.28	.25	.08
RFA-IT	.39	.1	.15
RFA	.73	<.0001	.53

the ISQ values by 13.6 ± 9.5 from 36.1 ± 6.1 at T0 to 22.5 ± 6.7 at T3 ($P < .0001$; Tables 3 and 4). During the first 2 weeks, stability decreased nonsignificantly by 4.9 ± 6.1 ISQ values ($P > .05$). Between T1 and T2, stability decreased highly significantly ($P < .001$) by 7.9 ± 5.9 ISQ values from 31.1 ± 5.6 to 24.2 ± 7.2. From weeks 4 to 6, RFA values stabilized, showing a nonsignificant change of −1.7 ± 3.5 ISQ ($P > .05$; Figure 4). The comparison between ISQ values parallel and perpendicular to the midpalatal suture showed no statistical differences at T0, T1, and T2. Only at T3 did the differences reach a low level of significance ($P < .05$), showing mean differences of 1.4 ± 2.1 ISQ (Table 3).

DISCUSSION

This pilot study is the first clinical investigation evaluating the stability changes of orthodontic mini-implants during the healing period. Since there were no respective data obtained from humans available, sample size calculation in this prospective study was based on the results of an animal study with a similar design.[15]

Even though four patients dropped out of the study, there was still a sufficient number of patients (19 patients) who could be examined during the healing period. The choice of statistical methods was based on a test for normal distribution for small sample sizes.

The surgical machine used for insertion has proven to be highly accurate with regard to the measurement of maximum IT values in an in vitro study.[16] The stability and reproducibility of the mini-implant Smart-Peg coupling as well as the proper functioning of the RFA device already had been tested in a previous investigation.[13]

Following the treatment protocol, a high primary stability could be achieved demonstrated by a mean maximum insertion torque of 16.8 ± 0.6 Ncm. No correlation was found between IT and RFA after insertion. Looking at the literature dealing with dental implants, there are contradictory results. Gonzalez-Garcia et al.[17] also found no correlation between the methods. Degidi et al.[18] observed a slight correlation, whereas Park et al.[19] reported a significant linear correlation. The observed correlation between ID and RFA was also investigated in in vitro studies by Kang

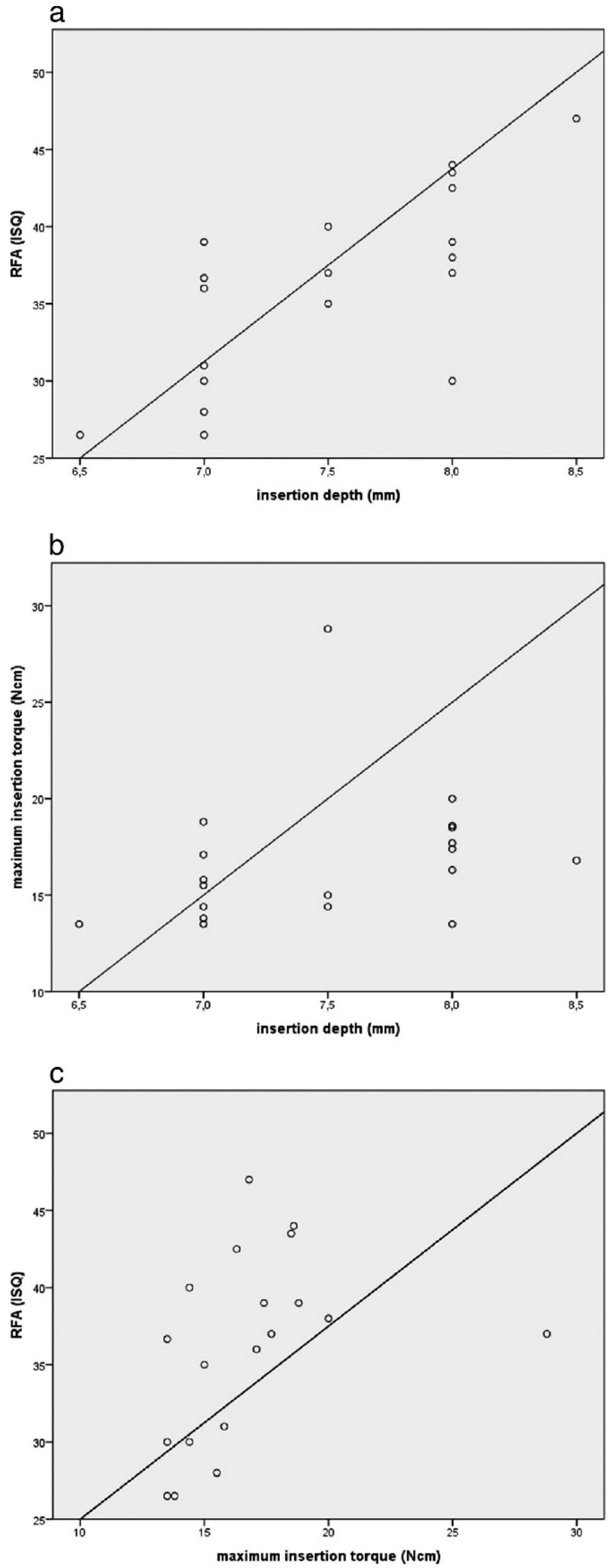

Figure 3. (a–c) Correlations between resonance frequency analysis, insertion depth, and maximum insertion torque with regression lines.

Table 3. Resonance Frequency Analysis Values (Implant Stability Quotient) at Each Measuring Point[a]

	T0		T1		T2		T3	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Overall	**36.14**	6.08	**32.11**	5.57	**24.23**	7.19	**22.51**	6.69
Length	36.18	6.34	32.46	5.47	24.53	7.38	23.61	6.47
Perpendicular	36.11	5.92	31.77	5.82	23.93	7.05	22.25	6.15
	ns		ns		ns		*	

[a] ns indicates not significant.
* $P < .05$.

et al.[20] for dental implants and by Pan et al.[21] for mini-implants. The IT did not correlate with ID. Also, Degidi et al.[18] summarized that IT and RFA appeared as two independent features of primary stability because of their different behavior toward affecting factors.

In the current investigation, there were only slight differences between the different measurement directions of RFA, although this implied measuring parallel or perpendicular to the midpalatal suture. Only at one measurement point did the differences reach a low level of significance. These results are in line with those of Park et al.,[22] who found no differences between the ISQs of dental implants when measuring from different directions, buccolingual and mesiodistal. Sim et al.[23] also reported no significant effect of different positioning of the RFA device.

Looking at clinical studies dealing with stability changes of dental implants, many used surface-treated implants without a control group. Development of ISQ values of time is similar in most of the investigations. Within the first weeks, stability decreased. The lowest stability was reported after three[24,25] or four[26,27] weeks. This phenomenon is explained by bone resorption due to osteoclast activity in the initial healing phase.[28] In these studies, the stability increased again afterward from 3 to 4 weeks after insertion. This is explained by the new bone formation with deep interlocking with the mostly rough surfaces.[29]

The current results show only slight changes of stability during the first 2 weeks followed by the typical decrease of stability from week 2 to week 4. The same was found by Schätzle et al.,[30] who investigated the healing period of palatal implants with SLA surface and 4.1-mm diameters inserted in the midpalatal region. They investigated a subsequent increase of ISQ values. A similar result was found by Ure et al.[15] for mini-implants in an animal study.

In this study, mini-implant stability did not change significantly after 4 weeks. One reason might be the relatively smooth machined surface, which leads to a significantly lower mechanical interlocking after healing compared with rough surfaces.[31] It is well known that implants with a machined surface stability do not reach the levels of stability of surface-treated implants. In fact, they do not even reach the level of primary stability after the healing period.[32]

Another reason for the relatively low secondary stability might be the typically small diameter of mini-implants. Being inserted into the midpalatal suture, the implant comes into contact not only with bone but also with the connective tissue of the suture, which might affect the healing process. Moreover, the implant primarily has contact with the cortical bone at borders of the suture and not so much to cancellous bone with its good blood supply.

With regard to the mini-implants' indications in orthodontic treatment, this kind of healing seems to be adequate. After initial healing, the stability remains unchanged on a sufficiently high level. Mini-implants are used as temporary anchorage devices and are removed easily after the orthodontic aims are achieved. The well-osseointegrated dental or palatal implants have to be removed by a trepan drill, leaving a bony defect. In addition, the reduced diameter of mini-implants bears the risk of an implant fracture when removal torque values become too high.[33]

Further clinical investigation regarding the factors that may affect healing and stability changes such as different mini-implant dimensions or insertion sites should be performed. Based on the results, different loading protocols could be tested regarding their influence on mini-implant healing. Further research based on the current methods should be performed elucidating the influence of mini-implant design,

Table 4. Changes in Mini-implant Stability Over Time Measured by Resonance Frequency Analysis Values (Implant Stability Quotient)

T1–T0		T2–T1		T3–T2		T3–T0	
Mean	SD	Mean	SD	Mean	SD	Mean	SD
−4.03	6.08	−7.89	5.92	−1.72	3.53	−13.63	9.49
ns		**		ns		***	

** $P < .001$; *** $P < .0001$.

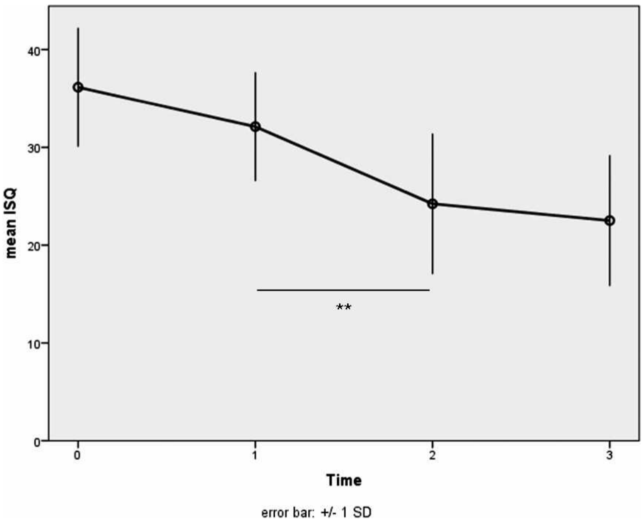

Figure 4. Development of mini-implant stability over 6 weeks by means of resonance frequency analysis (implant stability quotient).

insertion site, and loading protocols on stability changes during healing.

CONCLUSIONS

- Mini-implant stability is subject to changes during the healing process.
- During weeks 3 and 4, a significant decrease of stability was observed.
- After 4 weeks, the stability did not change significantly.
- Stability development seems to be adequate for temporary anchorage devices, which have to manage the balancing act of offering sufficient anchorage stability and allowing easy removal without fracturing.

REFERENCES

1. Wilmes B, Drescher D. Vertical periodontal ligament distraction–a new method for aligning ankylosed and displaced canines. *J Orofac Orthop*. 2009;70:213–223.
2. Wilmes B, Nienkemper M, Drescher D. Application and effectiveness of a mini-implant- and tooth-borne rapid palatal expansion device: the hybrid hyrax. *World J Orthod*. 2010;11:323–330.
3. Kanomi R. Mini-implant for orthodontic anchorage. *J Clin Orthod*. 1997;31:763–767.
4. Kang S, Lee SJ, Ahn SJ, Heo MS, Kim TW. Bone thickness of the palate for orthodontic mini-implant anchorage in adults. *Am J Orthod Dentofacial Orthop*. 2007;131:S74–81.
5. Kim HJ, Yun HS, Park HD, Kim DH, Park YC. Soft-tissue and cortical-bone thickness at orthodontic implant sites. *Am J Orthod Dentofacial Orthop*. 2006;130:177–182.
6. Meredith N. Assessment of implant stability as a prognostic determinant. *Int J Prosthodont*. 1998;11:491–501.
7. Javed F, Almas K, Crespi R, Romanos GE. Implant surface morphology and primary stability: is there a connection? *Implant Dent*. 2011;20:40–46.
8. Wilmes B, Rademacher C, Olthoff G, Drescher D. Parameters affecting primary stability of orthodontic mini-implants. *J Orofac Orthop*. 2006;67:162–174.
9. Meredith N, Alleyne D, Cawley P. Quantitative determination of the stability of the implant-tissue interface using resonance frequency analysis. *Clin Oral Implants Res*. 1996;7: 261–267.
10. Lachmann S, Laval JY, Jager B, Axmann D, Gomez-Roman G, Groten M, Weber H. Resonance frequency analysis and damping capacity assessment. Part 2: peri-implant bone loss follow-up. An in vitro study with the Periotest and Osstell instruments. *Clin Oral Implants Res*. 2006;17:80–84.
11. Quesada-Garcia MP, Prados-Sanchez E, Olmedo-Gaya MV, Munoz-Soto E, Gonzalez-Rodriguez MP, Valllecillo-Capilla M. Measurement of dental implant stability by resonance frequency analysis: a review of the literature. *Med Oral Patol Oral Cir Bucal*. 2009;14:e538–546.
12. Kang IH, Kim CW, Lim YJ, Kim MJ. A comparative study on the initial stability of different implants placed above the bone level using resonance frequency analysis. *J Adv Prosthodont*. 2011;3:190–195.
13. Nienkemper M, Wilmes B, Panayotidis A, Pauls A, Golubovic V, Schwarz F, Drescher D. Measurement of mini-implant stability using resonance frequency analysis. *Angle Orthod*. 2012; Epub ahead of print.
14. Gedrange T, Proff P, Bayerlein T, Landsberger P, Dietze S, Fanghanel J. Histological and fluorescence microscopic examination of the bone/implant interface in orthodontic miniscrews (Mondeal). *Folia Morphol (Warsz)*. 2006;65:70–71.
15. Ure DS, Oliver DR, Kim KB, Melo AC, Buschang PH. Stability changes of miniscrew implants over time. *Angle Orthod*. 2011;81:994–1000.
16. Pauls A, Nienkemper M, Drescher D. Accuracy of torque-limiting devices used for mini-implant placement—an in vitro study. *Journal of Orofacial Orthopedics*. 2013; in press.
17. Gonzalez-Garcia R, Monje F, Moreno-Garcia C. Predictability of the resonance frequency analysis in the survival of dental implants placed in the anterior non-atrophied edentulous mandible. *Med Oral Patol Oral Cir Bucal*. 2011;16: e664–669.
18. Degidi M, Daprile G, Piattelli A. Primary Stability Determination by Means of Insertion Torque and RFA in a Sample of 4,135 Implants. *Clin Implant Dent Relat Res*. 2010; epub ahead of print.
19. Park KJ, Kwon JY, Kim SK, Heo SJ, Koak JY, Lee JH, Lee SJ, Kim TH, Kim MJ. The relationship between implant stability quotient values and implant insertion variables: a clinical study. *J Oral Rehabil*. 2012;39:151–159.
20. Kang IH, Kim CW, Lim YJ, Kim MJ. A comparative study on the initial stability of different implants placed above the bone level using resonance frequency analysis. *Journal of Advanced Prosthodontics*. 2011;3:190–195.
21. Pan CY, Chou ST, Tseng YC, Yang YH, Wu CY, Lan TH, Liu PH, Chang HP. Influence of different implant materials on the primary stability of orthodontic mini-implants. *Kaohsiung J Med Sci*. 2012;28:673–678.
22. Park JC, Kim HD, Kim SM, Kim MJ, Lee JH. A comparison of implant stability quotients measured using magnetic resonance frequency analysis from two directions: a prospective clinical study during the initial healing period. *Clin Oral Implants Res*. 2010;21:591–597.
23. Sim CP, Lang NP. Factors influencing resonance frequency analysis assessed by Osstell mentor during implant tissue integration: I. Instrument positioning, bone structure, implant length. *Clin Oral Implants Res*. 2010;21:598–604.
24. Barewal RM, Oates TW, Meredith N, Cochran DL. Resonance frequency measurement of implant stability in vivo on implants with a sandblasted and acid-etched surface. *Int J Oral Maxillofac Implants*. 2003;18:641–651.

25. Han J, Lulic M, Lang NP. Factors influencing resonance frequency analysis assessed by Osstell mentor during implant tissue integration: II. Implant surface modifications and implant diameter. *Clin Oral Implants Res*. 2010;21: 605–611.
26. Balshi SF, Allen FD, Wolfinger GJ, Balshi TJ. A resonance frequency analysis assessment of maxillary and mandibular immediately loaded implants. *Int J Oral Maxillofac Implants*. 2005;20:584–594.
27. Huwiler MA, Pjetursson BE, Bosshardt DD, Salvi GE, Lang NP. Resonance frequency analysis in relation to jawbone characteristics and during early healing of implant installation. *Clin Oral Implants Res*. 2007;18:275–280.
28. Berglundh T, Abrahamsson I, Lang NP, Lindhe J. De novo alveolar bone formation adjacent to endosseous implants. *Clin Oral Implants Res*. 2003;14:251–262.
29. Rohner D, Meng CS, Hutmacher DW, Tsai KT. Bone response to unloaded titanium implants in the fibula, iliac crest, and scapula: an animal study in the Yorkshire pig. *Int J Oral Maxillofac Surg*. 2003;32:383–389.
30. Schatzle M, Mannchen R, Balbach U, Hammerle CH, Toutenburg H, Jung RE. Stability change of chemically modified sandblasted/acid-etched titanium palatal implants. A randomized-controlled clinical trial. *Clin Oral Implants Res*. 2009;20:489–495.
31. Buser D, Nydegger T, Oxland T, Cochran DL, Schenk RK, Hirt HP, Snetivy D, Nolte LP. Interface shear strength of titanium implants with a sandblasted and acid-etched surface: a biomechanical study in the maxilla of miniature pigs. *J Biomed Mater Res*. 1999;45:75–83.
32. Kim SJ, Kim MR, Rim JS, Chung SM, Shin SW. Comparison of implant stability after different implant surface treatments in dog bone. *J Appl Oral Sci*. 2010;18:415–420.
33. Wilmes B, Panayotidis A, Drescher D. Fracture resistance of orthodontic mini-implants: a biomechanical study in vitro study. *Eur J Orthod*. 2011;33:396–401.