A Comparison of Stability between Delayed versus Immediately Loaded Orthodontic Palatal Implants

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ABSTRACT

Introduction: Control of anchorage is a fundamental problem in orthodontics. Conventional means of controlling anchorage are characterized by potential disadvantages and inconveniences: visibility, compliance dependence, risk of undesirable side effects, and injury. Titanium implants have evolved as a potential clinical alternative in overcoming the limits of conventional dental orthodontic anchorage.

Methods: This project was designed as a prospective observational study on 20 patients whose treatment plans required maximum (stable) anchorage during orthodontic treatment. The patients received palatal implants (Institut Straumann AG, Waldenburg, Switzerland: length of implant 4–6 mm, diameter 3.3 mm), which were placed into the midpalate. The goal of this study was to evaluate if the implant could be loaded immediately, or if time should be allowed for integration. Patients were randomized into two groups; one group had their implants loaded immediately with a coil spring, and the second group remained nonloaded, with an annealed coil spring, for the 8-week experimental period. Measurement of implant stability was taken using resonance frequency analysis on both groups at the time of implant placement and at 8 weeks post-placement.

Results: This study demonstrated that immediate loading of the Straumann orthodontic implant is possible, based on the clinical success observed in both groups. However, compared with the nonloaded group, the stability of the immediately loaded implant was significantly less at 8 weeks. The mean implant stability quotient (ISQ) of the nonloaded group was 38.7 kHz at baseline and 47.3 kHz after 8 weeks. The mean ISQ of the loaded group was 42.0 kHz at baseline and 38.4 kHz after 8 weeks. Statistical analysis showed a significant difference between the group that was loaded and the nonloaded group after 8 weeks ($p < 0.05$).

Conclusion: Based on the results of this study, an unloaded healing period provides for increased stability of the implants compared with immediately loaded palatal implants.

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CLINICAL SIGNIFICANCE

Patients often like to have their orthodontic treatment begin as soon as possible. This study examined if palatal implants could be loaded immediately after placement so overall treatment time could be decreased. It appears that this is possible based on the results of the study; however, an unloaded healing period results in a more stable implant.

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INTRODUCTION

Orthodontic anchorage can be defined as the resistance to unwanted tooth movement. The goal of orthodontics is always to maximize desired tooth movements while minimizing undesirable effects. When stationary anchorage is required in the course of orthodontic treatment, a loss of stability of the anchoring teeth often leads to unfavorable occlusal relations and unsatisfactory outcomes. Conventional methods of stabilizing anchorage are with the use of extraoral and intraoral appliances, such as headgear and elastics. Class II elastics have been associated with some side effects, such as loss of lower anchorage and proclination of lower incisors. They have also been coupled to increased vertical dimension and extrusion of the upper incisors. Headgear use also has its inherent disadvantages relating to compliance, duration of wear, unacceptability by adults, and risks of injury.

Orthodontic treatments that do not rely on patient compliance or foster negative side effects appeal to both orthodontists and patients. Endosseous implants comprise a specific subgroup of this orthodontic armamentarium because they offer maximal anchorage by virtue of their osseointegration.[1] Favero and colleagues in 2002 published a comprehensive review of the literature on the theoretical aspects of such fixtures for orthodontic anchorage. In general, orthodontic implants are indicated when a large amount of tooth movement is required, or dental anchorage is insufficient because of hypodontia, tooth loss, or periodontal disease.[2]

Control of anchorage is a fundamental aspect of orthodontics and dentofacial orthopedics. Osseointegrated implants have been shown to provide anchorage in a reliable fashion. This has been demonstrated in orthodontics with the use of prosthodontic implants inserted for orthodontic purposes.[3] More recently, implants have been introduced that serve as temporary anchorage in orthodontics. One example is the Straumann Orthosystem (Institut Straumann AG, Waldenburg, Switzerland). Arguably, the most widely available commercial palatal orthodontic implant system, the Orthosystem (Institut Straumann) was developed jointly by the University of Aachen in Germany and the Straumann Institute in Switzerland.[4] This titanium implant has three distinct sections. The first is the self-tapping endosseous body, which is 3.3 mm in diameter and either 4- or 6.0-mm long. The second is the smooth cylindrical neck, which has a 4.1-mm diameter and is either 2.5- or 4.5-mm long, and the final section is the octagonal head, which is used for intraoral attachments. These were the dimensions of the Orthosystem as used during the study. Recently, the dimensions have been modified slightly to a body of 4.1 and 4.8 mm in diameter, and 6.0 mm in length. The implant relies on primary (mechanical) stability at the time of insertion and subsequent integration between its sand-blasted, large-grit, and acid-etched surface (SLA) and the surrounding bone.[5] This implant is placed in the midsagittal area of the palate. Owing to the reduced bone height available in the palate, only short implants (<9 mm) can be considered; surface enlargement by

texturing and the achievement of good primary stability are prerequisites for success.[6] Minimal surgical treatment, combined with maximal anchorage, distinguishes this promising treatment modality for the orthodontist collaborating with a surgeon.

As implant design has changed and surface treatments have evolved, the healing time required of an implant has decreased. The traditional Branemark restorative implant protocol required a stress-free healing period of 3 to 8 months before loading.[7] Roberts in 2002 showed that "endosseous implants can be provisionally loaded at about 18 weeks, but full maturation of the interface requires approximately 1 year."[8] Hermann and colleagues reported that bone remodeling occurs rapidly during the early healing phase after implant placement.[9] Cochran and colleagues showed that approximately 6 weeks is consistent for implant success when an SLA surface is utilized.[10]

Implant stability is an important criterion for osseointegration, and therefore, implant treatment success.[11] The methods for assessing stability level are divided into invasive methods and noninvasive methods. The latter is most applicable to human cases. Noninvasive methods include percussion and the Osstell device. Percussion with two mirror handles is difficult to quantify. The Periotest, a percussion device, measures mobility of teeth. Teerlinck and colleagues revealed that the Periotest measurement value does not have enough sensitivity for detecting the stability level.[12] The Osstell device is a resonance frequency analyzer. It is the newest noninvasive quantitative measuring device of stability and presumed osseointegration of implants. Resonance frequency analysis (RFA) value was reported to be correlated with bone-to-implant stability change.[13–15] These investigators showed that the RFA value changes are related to the increase in stiffness of an implant in the surrounding tissues. These reports support the RFA as a useful device for assessing changes in the healing period of an implant.

The Osstell Mentor is the newest RFA device to measure dental implant stability in the oral cavity. The Osstell Mentor is a portable, handheld instrument that involves the use of the noninvasive technique. The system includes the use of a Smartpeg, which is a magnet, attached to the implant or abutment by means of an integrated screw. The Smartpeg is excited by a magnetic pulse from the measurement probe on the handheld instrument. The resonance frequency, which is the measure of implant stability, is calculated from the response signal. In both in vitro and in vivo studies, this system has proved valuable when it comes to recording changes in implant stability.[15]

The result of a recent histomorphometric study suggested that RFA values correlate well with the amount of bone–implant contact.[16] These findings support the use of RFA in assessing changes in the bone healing and osseointegration process following implant placement. Gedrange and colleagues used RFA to determine the primary stability of orthodontic palatal implants. They examined 4- and 6-mm implants placed in the palatal suture. During their histologic and radiologic examination, they found that one can accurately measure implant stability by investigation of the bone available and density around the implant. They concluded that the short implant (4 mm) gives sufficient bone fixation, independent of location.[17]

RFA evaluation in vivo to date has been performed predominantly on implants placed for restorative purposes. It is therefore unknown what the pattern is for palatal implants. Questions that remain unaddressed in the orthodontic implant field include: Is it possible to load orthodontic implants immediately by virtue of the fact that light forces are used (<300 g)? Will loading the implant immediately influence the healing of the

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implant as judged by RFA? The goal of this study was to begin to address some of these questions regarding palatal orthodontic implant stability and time of loading.

Implant stability quotient (ISQ) is a measure of implant clinical stiffness with a range of 1 to 100. As ISQ values increase, implant stability increases. Inversely, as ISQ values decrease, the lower the stability of the implant in the supporting bone and soft tissue. The ISQ measurement shows a high degree of accuracy (±1%).[13] Classically, ISQ has been found to vary between 40 and 80; the higher the ISQ, the higher the implant stability.[15] In 2003, Barewal and colleagues used resonance frequency measurements to characterize the stability of 26 unloaded Straumann SLA (sand-blasted, large-grit, and acid-etched) implants placed for tooth restoration. Their findings demonstrated that implants placed in type I bone had a small decrease in stability, whereas implants placed in type IV bone had the greatest decrease in stability and hence, the greatest change in ISQ.[18]

MATERIALS AND METHODS

This human clinical trial was designed as a randomized prospective study to measure implant stability with an RFA device (Osstell Mentor) at the time of implant placement and 8 weeks postplacement. The study sample consisted of dental patients seeking orthodontic treatment, and those in which an orthodontic implant was deemed necessary for treatment by their orthodontist. The target was a sample of 20 patients with both of their maxillary first molars erupted and present. At the initial screening appointment, the patients' medical and dental histories were reviewed and inclusion/exclusion criteria confirmed. The Institutional Review Board-approved protocol was explained to the patient, and informed consent was obtained from the patient or parent.

Clinical and radiographic screenings were used to limit the study to patients with sufficient bone quantity to completely encase a palatal implant. Implant selection (Straumann: length of implant 4 or 6 mm, diameter 3.3 mm) for each patient was based on the vertical height of the anterior plate as determined by the lateral cephalogram taken for the orthodontic treatment planning. The implant length selection was made by the surgeon. In certain cases, the surgeon requested tomograms to help determine the appropriate location to place the implant within the palate.

Preparation of the site for implantation was performed according to surgical procedures prescribed by the manufacturer: Institut Straumann AG, Waldenburg, Switzerland. First, intraoperative probing of the implant site was performed to detect any bony perforation to the nasal cavity. After local anesthesia was injected in adequate amounts, a trephine or tissue punch was used to remove a 5-mm-diameter area of palatal mucosa (Figure 1). An excavator was used to fully release the soft tissue. The center of the exposed cortical plate was indented with a small round bur to help locate the profile drill. Next, the profile drill was selected, according to the prescribed implant intraosseous length, and used to prepare the implant bed (Figure 2). The selected implant was inserted manually and rotated clockwise until fully seated, often with the assistance of a ratchet. The patients were instructed to use a chlorhexidine digluconate mouth rinse perioperatively and then postoperatively for 2 weeks. The patients were also asked to not manipulate the implant with their tongue in any way, and to clean their implant with a toothbrush during regular cleanings after the seventh postoperative day.

Group designation obtained by randomization was revealed to the primary investigator on the day of the surgery. RFA was accomplished using the Osstell Mentor

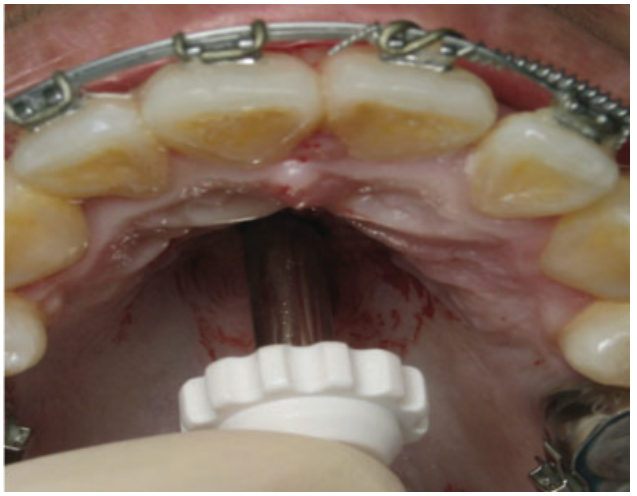

Figure 1. Tissue punch used to remove the palatal mucosa.

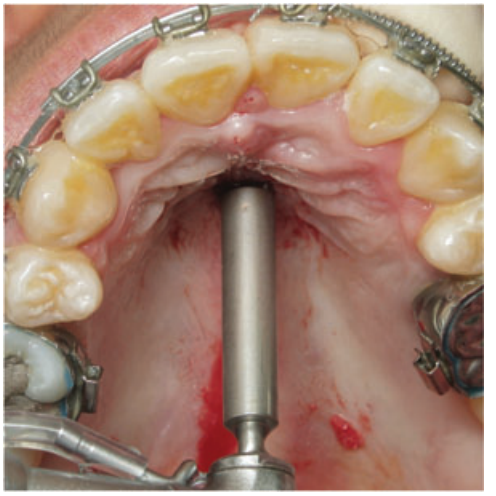

Figure 2. Drill used to prepare the implant bed.

immediately after implant placement, and before delivery of the transpalatal arch (TPA), and then at the 8-week time point. At each of the two time points, the transducer was calibrated before and after the RFA readings. After the first calibration, three RFA readings were taken at the same angle, with loosening and tightening of the Smartpeg between successive readings.

The 5-mm, 200-g nickel titanium coil spring, which is designed to deliver constant and continuous force at any length, was measured with an intraoral ruler and activated to 7 mm. Those patients randomized to the nonloaded group received a coil spring that had been annealed, therefore, not applying any force (Figure 3). After the 8-week reading, the TPA was removed, and the patient proceeded with the orthodontic treatment as planned.

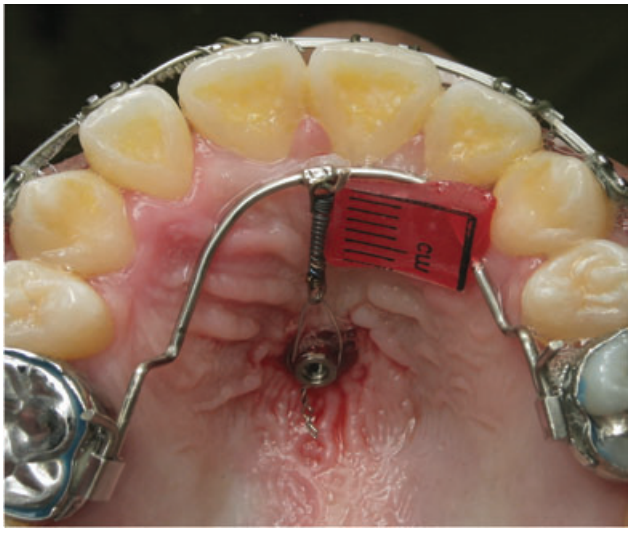

Figure 3. Transpalatal arch, with a nickel titanium coil spring attached to the Orthosystem implant.

Statistical Analysis

All patients in the study were randomized to either immediately loaded or nonloaded treatments using the method of randomly permuted blocks. The randomization scheme was generated by using the website Randomization.com, http://www.randomization.com.

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Using the randomization scheme, a third party volunteer sealed the treatment assignment for each participant in a brown envelope, which was opened immediately prior to placement of the midpalatal implant.

The resonance frequency of the implant/transducer system is calculated by the Osstell Mentor device from the peak amplitude of the signal, and an ISQ value between 1 and 100 was derived via a mathematical formula that took into account the resonance frequency measurement and the calibration parameters for each transducer. Specification and selection of the transducer used are available on the internet: http://www.osstell.com.

SPSS for Windows release 14.0.1 (SPSS, Inc., Chicago, IL, USA) software was used to perform all statistical analyses. Prior to analysis, all data were screened for outliers and for gross departures from normality, and after the final model fitting, residuals were examined graphically and statistically. ISQ data were analyzed using two-way, factorial, mixed models analysis of covariance (SPSS mixed models procedure) with one between the patients' factor, corresponding to treatment (immediate versus nonloaded), and one within the patients' (repeated measures) factor, corresponding to time (baseline versus 8-week follow-up). Implant length (4 or 6 mm) served as the covariate. An unstructured covariance matrix was assumed. The primary null hypothesis, that mean change in ISQ (adjusted for implant length) from baseline to 8-week follow-up is unequal under immediate and delayed loading, was tested by the treatment × time interaction effect. Following a significant result, this interaction was decomposed to examine the simple effects of time within each treatment group and treatment at each time. The mean age and the distribution of male and female patients were compared within immediate and delayed treatment groups at baseline using one-way analysis of variance and Fisher's exact test, respectively. Two-sided tests with statistical significance defined as $p < 0.05$ were used for all statistical testing. ISQ measurements were reported as adjusted means ± 1 standard error.

The within session repeatability of the ISQ measurements was estimated by calculating the intraclass correlation coefficient (ICC) taken over the three measurements obtained at baseline and at follow-up. A two-way model was used with both patients and repeated ISQ measurements modeled as random effects. A further assumption was made that three repeated ISQ measurements are aggregated by taking the mean and that absolute agreement is the repeatability standard. The reliability of the results was measured at both baseline and follow-up. The repeatability of readings taken at baseline (ICC = 0.94) and at the 8-week reading (ICC = 0.98) was excellent. On a scale of 0 to 1.00, this is highly reliable.

RESULTS

Twenty-one patients enrolled in the study, with one patient dropping out because of implant failure. Of the 23 Straumann orthodontic implants placed into the midpalate, three implants (13%) failed during the 8-week experimental period. Two of the implants were 6 mm in length, whereas the remaining implant was 4 mm. Each failed implant was subsequently removed, and the site was allowed to heal. Of the implants that failed, two were in the nonloaded group on the same patient, whereas the remaining one was in the immediately loaded group. The patient with the two implant failures eventually completed the study with a successful implant. Statistical analysis was carried out on the 20 successfully osseointegrated implants over 8 weeks. Seven of the 20 implants were 4 mm in length, five of those were in the loaded group and two in the nonloaded group. The remaining 13 implants were 6 mm in length, five in the loaded group and eight in the nonloaded group (see Table 1).

TABLE 1. DISTRIBUTION OF THE NUMBER OF PATIENTS, NUMBER OF IMPLANTS, AND THE LENGTH OF IMPLANTS PLACED.

	Loaded	Nonloaded	Total Implants per Length
Implant length			
4 mm	5 (50%)	2 (20%)	7
6 mm	5 (50%)	8 (80%)	13
Total implants per group	10	10	20

TABLE 2. IMPLANT STABILITY QUOTIENT (ISQ) VALUES OF THE LOADED AND NONLOADED GROUPS AT BASELINE AND AT 8 WEEKS.

	Baseline ISQ	8 Weeks ISQ	Significance from Baseline
Implant			
Nonloaded	38.7 ± 2.4	47.3 ± 1.7	0.000*
Loaded	42.0 ± 2.4	38.4 ± 1.7	0.057
p	0.358	0.002*	

Significance ($p < 0.05$); values are given as mean ± SD.
*Significant difference ($p < 0.05$).

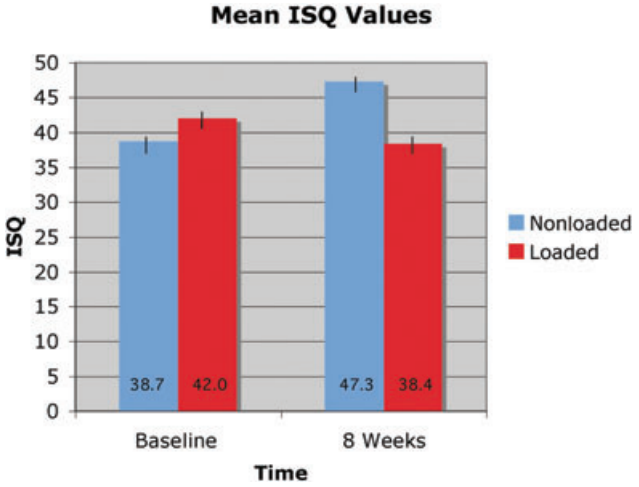

Figure 4. The mean implant stability quotient (ISQ) values obtained at baseline and at 8 weeks for the loaded and nonloaded groups.

Ten patients were randomized to the nonloaded group, whereas the other 10 were in the immediately loaded category. The age range of the patients was 13 to 48, with 12 females and 8 males participating.

Initial examination evaluated the 20 successfully integrated implants, adjusted for length. Mean ISQ values for immediately loaded implants were compared with the mean ISQ values for nonloaded implants at the time of surgery and at the 8-week follow-up. Comparing the two groups, there was an average increase in ISQ values from the surgical date to the 8-week interval in the nonloaded group, and an average decrease in ISQ values for the loaded group. Table 2 and Figure 4 illustrate the mean change in ISQ values of the midpalatal implants that were placed and immediately loaded and those that were nonloaded from placement to 8-weeks later. The table illustrates the fact that the two groups were very similar in their mean baseline ISQ and were significantly different at 8 weeks. Nonloaded implants showed about a 15 to 20% increase in stability from the first to eighth week, which was a significant change ($p < 0.05$). In contrast, the loaded implants decreased in stability by 10 to 15% over this same time period, which was nonsignificant ($p > 0.05$).

The two implant lengths (Straumann Orthosytsem: length of implant 4 and 6 mm) were compared from surgical placement to the 8-week interval (see Table 3). The ISQ values of the 4-mm implants remained practically unchanged ($p > 0.05$), whereas the 6-mm implants increased in ISQ values at the 8-week reading ($p < 0.05$). Table 3 compares the mean ISQ values of the 4- and

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TABLE 3. MEAN IMPLANT STABILITY QUOTIENT (ISQ) VALUES FOR THE 4- AND 6-MM IMPLANTS AT BASELINE AND 8 WEEKS.

	Mean ISQ Baseline	Mean ISQ 8 Weeks	Significance from Baseline
Implant length			
4 mm	36.6 ± 7.2	34.0 ± 9.3	0.308
6 mm	42.4 ± 7.3	47.6 ± 4.9	0.039*
p	0.105	0.000*	

Significance ($p < 0.05$); values are given as mean ± SD.
*Significant difference ($p < 0.05$).

6-mm implants. The 6-mm readings demonstrated an average higher reading than the 4-mm implants. The difference between the 4- and 6-mm groups at 8 weeks was significant ($p < 0.05$).

DISCUSSION

The results support the hypothesis that there is a statistically significant difference in the stability of orthodontic palatal implants that receive a constant orthodontic load immediately after placement compared with implants that are not loaded until 8 weeks after placement. Immediate loading of midpalatal implants at the same appointment as the surgical placement had lower RFA readings at the 8-week time point as compared with the nonloaded group (15–20% increase versus 10–15% decrease). However, it does not support the hypothesis that there is a clinically significant difference in the success rate between the two groups. Eighty-seven percent of the implants placed exhibited clinical success. Clinical success was defined as the ability to use the implant in the course of orthodontic treatment. However, because the sample size was small and there was only one patient in each group with implant failures, the results cannot be interpreted as a recommendation to load the implants immediately. Furthermore, it is not known if the force delivered through the TPA was the same, given the difference in implant stability between groups.

This study was designed to examine if there was a difference between the immediately loaded and the nonloaded groups. In addition, a secondary goal was to determine if the 12-week healing period suggested by the manufacturer was necessary. This information coupled with an implant that was not clinically usable would support a longer healing period. First, biologic principles must be understood to support the different RFA readings that were evident between the two experimental groups.

Osseointegration is a strain-dependent highly dynamic process. It is defined as a direct and stable anchorage of an implant by the formation of bony tissue without growth of fibrous tissue at the bone–implant interface.[19] One defining feature of osseointegration is that osteoblasts and mineralized matrix contact the implant surface even when loads are applied. Cochran and colleagues showed that an implant is in contact with the bone when the implant is placed into the bone.[10] This is called primary bone contact and represented approximately 70% at the time of implant placement. The percentage of the original bone contact with the implant, primary contact, decreased over time, from 70 to 5%, indicating an increase in the secondary bone contacts. This was interpreted as a sign of ongoing bone remodeling at the bone–implant interface. This has been reinforced more recently by Buchter and colleagues who showed that the bone is in contact with the implant surface from day one of implant insertion, as quantified by undecalcified histologic sections.[20]

Three of the implants placed failed and required removal before the completion of the study. Implant failure can be the result of many factors. The first implant that failed exhibited good primary stability at surgical placement as

evidenced by a large RFA reading (ISQ > 40) and the absence of mobility. However, when the patient came in for his later RFA readings, it was loosened by the primary investigator when unwinding the screw that held the healing cap in place. Two days later, the patient had the implant manually removed by the surgeon because of excess mobility. Subsequent to that, a second implant was placed in the same patient 4 weeks later, with a low initial RFA reading (ISQ < 30). This second implant in the same patient also failed. It is plausible that the palatal bone did not have enough time to heal between the two procedures. The third implant that failed during the course of the investigation also exhibited poor primary stability as evidenced by a low RFA reading (ISQ < 30) and implant mobility. One reason for early implant failure is thought to be because of excessive mechanical load applied to the implant, coupled with lower stability at implant placement.[21] It is possible that this third implant that failed never attained a good bone to implant contact and that the orthodontic appliance undermined the process through application of a continuous load. Insufficient primary stability is associated with poor healing and the premature loss of an implant.[22]

The results obtained with the two implant lengths (4 and 6 mm) were consistent with a previous publication by Gedrange and colleagues[23] that the ISQ values of the 6-mm implants were higher when compared with the 4-mm implants. According to the RFA findings, there was a significant increase in the 6-mm group from baseline to 8 weeks; and a significant difference between the 4- and 6-mm groups at 8 weeks. Two parameters are particularly useful when evaluating implant stability with RFA. The first is the location of the implant in the bone. The second is the stiffness of the implant in the surrounding tissue. There are three factors that are important for stiffness. The first one is the stiffness of the implant components themselves. The second is the stiffness of the implant/bone interface, the bond between the surface of the implant and the surrounding bone. The third is the stiffness of the bone itself, determined by the trabecular/cortical bone ratio and the bone density.[17] These parameters show the importance of the length and type of the implant and the preparation technique depending on bone quality and quantity. It is possible that, because of the increased length of the 6-mm implants, they were bicortically stabilized by reaching the cortical layer of the nasal floor. Bicortical placement would decrease the trabecular/cortical ratio and with the increased density of both cortices, higher RFA values would be expected.

CONCLUSION

In summary, this is the first prospective clinical trial evaluating the stability patterns of midpalatal implants under immediate loading. It supports the empirical notion that orthodontic implants can be loaded immediately because of the relatively light forces that are used in orthodontics as compared with the heavy loads that are placed on restorative implants. It reinforces earlier findings that the unloaded Orthosystem implants increase in stability from surgical placement, which is considered time one (primary stability) to time two (secondary stability)[17] and that the 6-mm implants have higher ISQ values compared with the 4-mm implants, implying higher stability. In addition, the objective of determining the stability of nonloaded midpalatal implants 8 weeks after placement and comparing them with the immediately loaded implants for use as orthodontic anchorage was accomplished. These results demonstrate that delaying the load on an implant by 2 months results in a higher RFA reading, but that loading the implants immediately did not result in less implant success. It is possible that a decrease in RFA readings, which can be critical for implants used for tooth replacement, is not as critical for orthodontic implants because of the light forces that are used during orthodontic traction (100–200 g).

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Based on the study results, and the clinical success observed in the nonloaded and loaded groups, it suggests that once primary stability is observed at the time of implant placement, it is possible that the implant can be loaded and successfully used for orthodontic purposes. Primary stability, and therefore, lack of mobility, appears to be an important parameter governing the clinical success of the palatal implants used for orthodontic purposes. If lack of mobility (good primary stability) is observed at the time of placement, loading the implants at that time will allow the orthodontist to save valuable treatment time and pass along to the patient a cost/time benefit advantage. However, the clinical success observed in this study will need to be corroborated with a larger sample size. Recently, Straumann has introduced palatal implants with slightly different dimensions. It is possible that these new dimensions may yield different results and warrant future investigation.

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