# Enhanced Implant Stability with a Chemically Modified SLA Surface: A Randomized Pilot Study

Thomas W. Oates, DMD, PhD[1]/Pilar Valderrama, DDS, MS[2]/Mark Bischof, Dr Med Dent[3]/
Rabah Nedir, Dr Med Dent[3]/Archie Jones, DDS[1]/James Simpson, PhD[4]/
Helge Toutenburg, PhD, DSc[5]/David L. Cochran, DDS, PhD[6]

***Purpose:*** *Chemical modification to a sandblasted, large-grit, acid-etched (SLA) implant surface has been shown to enhance the rate of osseointegration. The goal of the present study was to examine changes in stability for implants with a chemically modified SLA surface and to compare their outcomes to those of control implants.* ***Materials and Methods:*** *A randomized controlled trial was conducted with 31 patients. Each patient received 2 implants with the same physical properties but with surfaces that were chemically different. The control implants had a standard SLA surface, while the test implants had a chemically modified surface. Resonance frequency analysis was assessed weekly over the first 6 weeks following implant placement.* ***Results:*** *All implants proved clinically successful, allowing for restoration. Most implants were placed in the mandible (50 of 62). A shift in implant stability from decreasing stability to increasing stability (P < .001), occurred after 2 weeks for the test implants and after 4 weeks for the control implants.* ***Conclusion:*** *The findings from this pilot study provide clinical support for the potential for chemical modification of the SLA surface to alter biologic events during the osseointegration process and demonstrate levels of short-term clinical success similar to those observed for implants with an SLA surface.* Int J Oral Maxillofac Implants 2007;22: 755–760

**Key words:** *clinical trial, implant stability, implant surface chemistry, resonance frequency analysis*

Osseointegration of titanium implant surfaces is dependent upon both physical and chemical properties.[1] The influences of physical properties such as surface topography and roughness on osseointegration have translated to shorter healing times from implant placement to restoration.[2] The biologic basis underlying these clinical improvements continues to be explored.[3,4]

[1]Associate Professor, Department of Periodontics, University of Texas Health Science Center at San Antonio.
[2]Graduate Student, Department of Periodontics, University of Texas Health Science Center at San Antonio.
[3]Private Practice, Clinique Dentaire de Chauderon, Lausanne, Switzerland.
[4]Director of Clinical Research, Institut Straumann, Basel, Switzerland.
[5]Professor, Institut für Statistik, Ludwig-Maximilians-Universität Munich, Germany.
[6]Professor, Department of Periodontics, University of Texas Health Science Center at San Antonio.

**Correspondence to:** Dr Thomas W. Oates, Department of Periodontics, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900. Fax: +210 567 6858. E-mail: oates@uthscsa.edu

Surface chemistry has the potential to alter ionic interactions, protein adsorption, and cellular activity at the implant surface.[5,6] These modifications may subsequently influence conformational changes in the structures and interactive natures of adsorbed proteins and cells. Furthermore, within the complexities of an in vivo environment containing multiple protein and cellular interactions, these alterations may differentially regulate biologic events. For example, the serum proteins albumin and fibrinogen showed less organized secondary structure upon adsorption onto a hydrophobic surface than a hydrophilic one.[7] Therefore, modifications to the implant surface chemistry may lead to alterations in the structure of adsorbed proteins and have cascading effects that may ultimately be evident at the clinical level.

Recent in vivo evidence has supported the use of alterations in surface chemistry to modify osseointegration events. Specifically, an investigation utilizing 2 sandblasted, large-grit, acid-etched (SLA) surfaces that were chemically different but had the same physical properties was conducted to assess bone-implant contact (BIC) as a measure of osseointegration. The chemically enhanced SLA surface demon-

strated significantly enhanced BIC during the first 4 weeks of bone healing, with 60% more bone than the standard SLA surface after 2 weeks.[8] The chemical modifications for the test SLA surface resulted in increased wettability (ie, in a hydrophilic surface rather than a hydrophobic one). Water contact angles of 0 degrees were seen with the chemically enhanced surface compared to 139.9 degrees for a standard SLA surface, and the hydrophilicity was maintained after drying. The chemical composition of the surface was also altered, including a 50% reduction in carbon concentration compared with the control implant surface.[9]

The increase in BIC observed with a chemically modified SLA surface suggests the potential for enhancement of implant integration that would be evident at the clinical level. To clinically assess implant integration, resonance frequency analysis (RFA) has been used to measure implant stability. This technology has proven capable of characterizing alterations in implant stability during early healing and sensitive enough to identify differences in longitudinal implant stability based on bone density at the implant recipient site.[10] Early investigations have shown that RFA can also be related to the stiffness of an implant and the level of peri-implant bone.[11,12] The technique has been shown to be more precise than damping capacity assessment for predicting implant stability[13] and has been demonstrated to be an accurate method for early assessment of osseointegration.[14]

The objective of the present investigation was to compare dental implant stabilization patterns over time for 2 SLA surfaces over the first 6 weeks following implant placement and to evaluate the short-term clinical experience of the implants with the modified surface. The study hypothesis was that there would be a difference in patterns of implant stabilization between implants with test and control surfaces during the early healing period (6 weeks) following placement.

## MATERIALS AND METHODS

This 2-center randomized controlled pilot trial was designed to prospectively evaluate implant integration of standard SLA implants (Straumann, Basel, Switzerland) relative to implants having the same physical properties but a chemically modified surface (SLActive). Clinical evaluation of implant integration over time was performed using RFA (Osstell; Integration Diagnostics, Savedalen, Sweden) and outcomes based on standard success criteria.[15]

### Study Population

The study population included 31 adult patients who were missing at least 2 posterior teeth in either the mandible or maxilla. Edentulous areas were required to have 4 months of healing following tooth extraction, with no previous bone grafting and an indication for implant-supported, fixed prosthetic single tooth replacement. Informed consent was obtained from all patients in accordance with the ethical policies and procedures for human research at both study centers (The University of Texas Health Science Center at San Antonio and Clinique Dentaire, Vevey, Lausanne, Switzerland). Inclusion and exclusion criteria have been previously described.[2]

### Treatment

Sixty-two implants having either a diameter of 4.1 mm or 4.8 mm and a length of 8 or 10 mm were placed in 31 patients. Two implants were placed per patient, with 1 implant having a standard SLA surface (control) and the other implant having a chemically modified SLA surface (SLActive, test). The dimensions of the test and control implants were matched on a per-patient basis, with implants placed in the same arch in each patient. Test and control sites were determined using a randomization scheme established prior to the start of the study and applied after implant osteotomies for both sites were prepared. Implants were placed in a nonsubmerged manner. All implant procedures were performed according to the manufacturer's guidelines.

RFA was carried out and clinical success criteria were recorded at 0, 1, 2, 3, 4, 5, and 6 weeks following surgical implant placement. RFA produced an implant stability quotient (ISQ), which was recorded in triplicate. ISQ indicates clinical stiffness with a range from 1 to 100, with implant stability increasing as the ISQ value increases. ISQ measurements show a high degree of repeatability (less than 1% variation for individual implants).[11]

Each visit entailed removal of the healing cap or restorative abutment and standardized placement of the transducer perpendicular to the arch. The transducers were calibrated using an implant fixed in a plaster block at the start and completion of each patient visit. In addition, each implant was evaluated at all visits for mobility and signs of infection, pain, or suppuration.

The primary outcome value was the change in implant stability (ISQ) from the mean baseline reading for each implant. Secondary outcome measures included the nature and frequency of adverse events or complications, defined as persistent or irreversible pain, inflammation or parasthesia, peri-implant infection, peri-implant radiolucency, or lateral or rotational implant mobility.

**Table 1 Mean RFA Values (ISQ) Overall and by Arch**

| | | Overall | | Maxilla | | Mandible | |
|---|---|---|---|---|---|---|---|
| | n | Mean | SD | Mean | SD | Mean | SD |
| Baseline | | | | | | | |
| Control | 27 | 63.6 | 6.6 | 55.4 | 3.8 | 65.5 | 5.5 |
| Test | 29 | 61.8 | 7.3 | 52.4 | 7.4 | 64.2 | 5.0 |
| 1 week | | | | | | | |
| Control | 26 | 61.8 | 6.3 | 54.0 | 2.6 | 64.2 | 5.0 |
| Test | 28 | 60.7 | 6.7 | 51.9 | 5.2 | 63.1 | 4.9 |
| 2 weeks | | | | | | | |
| Control | 27 | 61.2 | 7.6 | 55.1 | 4.5 | 63.0 | 7.4 |
| Test | 29 | 59.4 | 6.3 | 52.1 | 6.9 | 61.3 | 4.6 |
| 3 weeks | | | | | | | |
| Control | 27 | 60.5 | 7.5 | 54.2 | 2.6 | 62.2 | 7.6 |
| Test | 28 | 60.1 | 6.8 | 51.7 | 5.4 | 62.4 | 5.2 |
| 4 weeks | | | | | | | |
| Control | 27 | 60.2 | 7.6 | 56.3 | 3.0 | 61.3 | 8.1 |
| Test | 28 | 59.9 | 5.9 | 53.3 | 5.0 | 61.7 | 4.9 |
| 5 weeks | | | | | | | |
| Control | 27 | 61.0 | 6.4 | 55.8 | 2.5 | 62.6 | 6.4 |
| Test | 29 | 61.2 | 6.6 | 53.3 | 4.3 | 63.3 | 5.5 |
| 6 weeks | | | | | | | |
| Control | 24 | 61.3 | 5.5 | 57.0 | 2.8 | 62.8 | 5.4 |
| Test | 27 | 61.8 | 5.9 | 53.5 | 5.3 | 64.1 | 3.5 |

### Statistical Analysis

The primary response variable, ISQ (with values between 0 and 100), was continuous and identified as normally distributed (Kolmogorov-Smirnov test). To decrease the patient-specific variability and to adjust for patient-specific situations, the response variable was transformed to normalize differences relative to baseline readings, as "observation minus baseline" (ISQ difference).

Two main fixed factors, treatment (test versus control) and time (baseline through 6 weeks); the fixed factor arch; and the random factor patient (each patient received 1 test and 1 control implant) were evaluated. The linear mixed model was used to evaluate the significance of these overall effects. However, because ISQ values decrease after implantation before they begin to increase, the main statistical problem to be tested in this study was not amenable to a linear mixed model analysis.[10]

The analytic basis for 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, with secondary outcomes characterized by descriptive analyses.[16–18]

## RESULTS

The study population consisted of 22 female patients (71%) and 9 male patients ranging in age from 30 to 83 years, with a mean age of 61.1 ± 13 years. Of the 62 study implants placed in the 31 patients, 50 (in 25 patients) were placed in the mandible and 12 in the posterior maxilla sextants. Bone type scoring was equivalent at both sites in 25 of the patients, with 49 of the 62 implants placed in bone types 2 or 3, 10 of 62 implants placed in type 1 bone, and 3 implants (2 in test, 1 in control) placed in type 4 bone.[19] Of the 31 patients enrolled in this study, 2 patients were excluded from RFA analysis because of protocol violations. In addition, 2 control implants in 2 patients were excluded from RFA analysis because 3 or more readings were not carried out because of rotational movement. However, all 62 implants were included in secondary outcomes assessments.

### Implant Stability

Overall, stability at the time of placement was not significantly different for the control implants (mean ISQ, 63.7 ± 6.9) than the test implants (mean ISQ, 61.7 ± 7.6). Both implant types showed decreases in mean stability levels through the 2-week time point and had similar levels of stability after 6 weeks (Table 1).

**Table 2 Normalized Mean RFA Values (Difference from Baseline)**

| | Maxilla | | | Mandible | | | Overall | |
|---|---|---|---|---|---|---|---|---|
| | n | Mean | SD | n | Mean | SD | Mean | SD |
| Baseline | | | | | | | | |
| Control | 6 | 0.0 | 0.0 | 21 | 0.0 | 0.0 | – | – |
| Test | 6 | 0.0 | 0.0 | 23 | 0.0 | 0.0 | – | – |
| 1 week | | | | | | | | |
| Control | 6 | −1.4 | 3.5 | 20 | −1.0 | 2.4 | −0.7 | 2.4 |
| Test | 6 | −0.5 | 2.8 | 22 | −1.1 | 4.1 | −1.1 | 4.0 |
| 2 weeks | | | | | | | | |
| Control | 6 | −0.3 | 1.0 | 21 | −2.5 | 3.8 | −2.4 | 3.8 |
| Test | 6 | −0.3 | 1.3 | 23 | −2.9 | 4.8 | −3.1 | 4.6 |
| 3 weeks | | | | | | | | |
| Control | 6 | −1.1 | 1.6 | 21 | −3.2 | 5.2 | −3.1 | 5.1 |
| Test | 6 | −0.7 | 4.2 | 22 | −1.8 | 4.8 | −2.2 | 4.8 |
| 4 weeks | | | | | | | | |
| Control | 6 | 0.8 | 1.9 | 21 | −4.2 | 7.3 | −4.2 | 7.0 |
| Test | 6 | 0.9 | 4.6 | 22 | −2.5 | 5.2 | −3.4 | 6.0 |
| 5 weeks | | | | | | | | |
| Control | 6 | 0.3 | 2.0 | 21 | −2.9 | 4.6 | −2.9 | 4.8 |
| Test | 6 | 0.8 | 5.2 | 23 | −0.9 | 7.0 | −0.9 | 6.9 |
| 6 weeks | | | | | | | | |
| Control | 6 | 1.5 | 1.1 | 18 | −2.3 | 4.2 | −2.4 | 4.3 |
| Test | 6 | 1.0 | 6.8 | 21 | 0.4 | 4.8 | −0.1 | 5.5 |

Initial evaluation of the effects of time, implant surface (test/control), and arch (maxilla/mandible) on ISQ levels showed no significant interaction between these factors, which enabled independent assessment. Overall, implant surface was not significant ($P = .073$), while time ($P < .017$) and arch ($P < .001$) were found to be significant factors in implant stability. Therefore, changes in implant stability (primary outcome) were considered independently for each arch relative to time (Table 2). In addition, the study center was found to have no significant effect.

In the mandible, relative to baseline levels, control implants had decreased levels of stability throughout the 6-week evaluation period, whereas test implants showed stability levels decreased below baseline levels through the first 5 weeks of evaluation. In the maxilla, both implant types had stability levels greater than baseline after 4 weeks (Table 2). Evaluation of the stabilization patterns over time for the mandibular implants showed a significant change ($P < .001$) in the pattern of stability for the test implants at the 2-week time point from decreasing stability to increasing stability (Table 3). This is in contrast to the control implants, in which a similar ($P < .001$) change in the pattern of stability was identified at the 4-week time point (Fig 1). In the maxilla, a significant change in the pattern of stability was noted for the test implants at week 3, but no significant change in stabilization pattern was noted for the control implants (Table 3).

## Implant Success Rate and Complications

All 62 study implants were successfully integrated at the 6-week time point and restored. Twenty adverse events were reported. The most common adverse event was rotational movement of an implant during RFA assessment. This occurred with 7 of the 62 implants, with all occurrences in mandibular implants. The remainder of the adverse events were inconsequential to patient treatment or study results, for example, postoperative discomfort, ulcerations, or loosened healing caps. Although implants were lost to analysis because of rotational mobility, none of the adverse events altered the clinical therapy for the implants.

Interestingly, 5 of the implants with rotational movement were found in the control group. All instances of rotational movement occurred between weeks 1 and 4, and most (4 of 7) occurred at week 3. Although it is likely that the rotational movement and subsequent alterations in implant stability are reflective of overall differences between implant types, secondary analysis of the data was done excluding these implants. In contrast to the overall findings, significant effects were identified for arch ($P < .001$) and for implant type ($P < .001$); the effects of time were insignificant ($P = .062$). Again separating the mandibular and maxillary implants for analysis, implant type was a significant factor in both the maxilla ($P < .001$) and the mandible ($P < .01$). Time was found to be a significant factor in the mandible ($P < .05$) but not in the maxilla ($P = .329$).

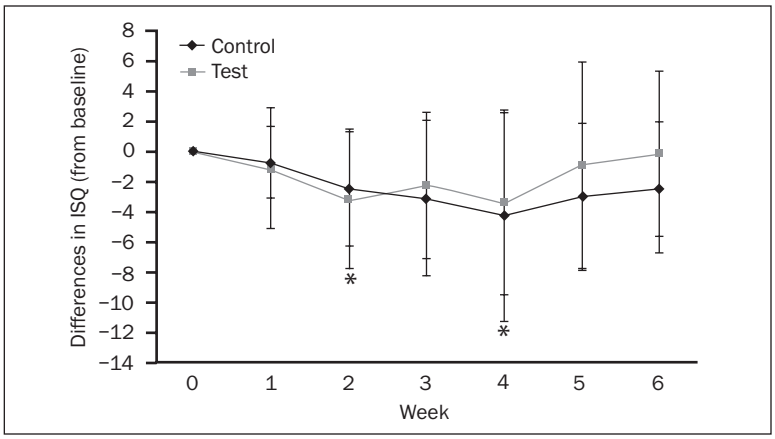


**Fig 1** Mean differences in ISQ values from baseline for implants placed in the mandible, with an asterisk indicating significant ($P < .001$) breakpoints.

Evaluation of the changes in implant stability relative to initial stability and excluding the implants with rotational movement showed a significant change in the pattern of stability for test implants at the 2-week time point in both the mandible ($P < .01$) and in the maxilla ($P < .001$). This is in contrast to the control implants, in which no significant change in the pattern of stability was identified over the 6-week healing period (data not shown).

**Table 3 Changes in Pattern of Stability**

| | Breakpoint | Significance* |
|---|---|---|
| Test | | |
| Maxilla | 3 weeks | < .001 |
| Mandible | 2 weeks | < .001 |
| Control | | |
| Maxilla | 3 weeks | 0.643† |
| Mandible | 4 weeks | < .001 |

*Chow test.
†Not significant.

## DISCUSSION

The objective of this investigation was to compare dental implant stabilization patterns over time for 2 SLA surfaces over the first 6 weeks following implant placement and to evaluate the short-term clinical experience of the test implants. The most interesting finding of this study was the earlier change in the pattern of stability with the modified SLA surface. The stability of the test implants began to increase after the 2-week time point. Although this was evident only for implants placed in the mandible, this finding is in contrast to the findings for the control implants, in which this transition from decreasing stability to increasing stability was evident after 4 weeks. This transition after the 2-week time point is also earlier than that reported in a previous investigation using the control-surface implants, in which the transition was evident after 3 weeks.[10] Furthermore, the clinical success of the modified implant was similar to that of the control implant (SLA); all implants were clinically restored and loaded.

The changes usually observed in implant stabilization over time are thought to be reflective of the biologic events associated with the bone-implant interface (ie, increasing stability is associated with bone formation). The identification of a transition point from decreasing implant stability to increasing implant stability is suggestive of a change in the overall bone metabolism associated with the implant surface from predominantly resorptive to predominantly formative in nature. These findings suggest an enhanced healing process associated with the modified implant surface consistent with findings obtained using an animal model.[8]

Although one of the apparent benefits of the modified implant surface was a shift in the transition point from 4 weeks to 2 weeks, these results must be considered within the broader scope of implant stabilization during the healing process. The difference in stability levels (ISQ) on a 100-point scale was approximately 2 points between the test and control surfaces. The clinical significance of the difference in stability between the 2 implant surfaces remains to be determined.

All implants were successfully restored; the rotational movement observed was not associated with any clinically significant events. Although there were 7 documented events of rotational movement, 5 of these events occurred in the control implants. This finding is consistent with an enhanced healing process for the modified-surface implants.

The working hypothesis, therefore, was that chemically modified SLA implants heal more quickly than standard SLA implants. The challenge was to find an appropriate statistical model for evaluation. From

repeated measures, the mixed model analysis appeared to be modeling an overall treatment effect of a structural change in the data over time. The Chow test is designed to be able to detect this special treatment effect (ie, a decrease and subsequent increase in ISQ) and so was chosen as the most appropriate statistical model. The findings from this analysis demonstrated differences in implant stability and healing based on placement of the implant in the maxilla or mandible. This finding is suggestive of differences in bone quality between arches affecting implant stability. Similar findings of interarch variations in implant stability, with greater changes in stability in the mandible than the maxilla, have been reported previously.[20] However, this is in contrast to previous investigations, in which implants placed in less dense bone types tended to have greater changes in stability.[10,12,21,22] 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.

## CONCLUSION

In conclusion, this study supports the potential for chemical modifications in a roughened implant surface to alter biologic events during the 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.

## ACKNOWLEDGMENT

This study was supported by Institut Straumann (Basel, Switzerland).

## REFERENCES

1. Sul YT, Johansson C, Wennerberg A, Cho LR, Chang BS, Albrektsson T. Optimum surface properties of oxidized implants for reinforcement of osseointegration: Surface chemistry, oxide thickness, porosity, roughness, and crystal structure. Int J Oral Maxillofac Implants 2005;20:349–359.
2. Cochran DL, Buser D, ten Bruggenkate CM, et al. The use of reduced healing times on ITI implants with a sandblasted and acid-etched (SLA) surface: Early results from clinical trials on ITI SLA implants. Clin Oral Implants Res 2002;13:144–153.
3. Kim HJ, Kim SH, Kim MS, et al. Varying Ti-6Al-4V surface roughness induces different early morphologic and molecular responses in MG63 osteoblast-like cells. J Biomed Mater Res A 2005;74:366–373.
4. Lossdorfer S, Schwartz Z, Wang L, et al. Microrough implant surface topographies increase osteogenesis by reducing osteoclast formation and activity. J Biomed Mater Res 2004; 70A:361–369.
5. Schliephake H, Scharnweber D, Dard M, Sewing A, Aref A, Roessler S. Functionalization of dental implant surfaces using adhesion molecules. J Biomed Mater Res B Appl Biomater 2005;73:88–96.
6. Ellingsen JE, Johansson CB, Wennerberg A, Holmen A. Improved retention and bone-to-implant contact with fluoride-modified titanium implants. Int J Oral Maxillofac Implants 2004;19:659–666.
7. Roach P, Farrar D, Perry CC. Interpretation of protein adsorption: Surface-induced conformational changes. J Am Chem Soc 2005;22:8168–8173.
8. Buser D, Broggini N, Wieland M, et al. Enhanced bone apposition to a chemically modified SLA titanium surface. J Dent Res 2004;83:529–533.
9. Rupp F, Scheideler L, Olshanka N, de Wild M, Wieland M, Geis-Gerstorfer J. Enhancing surface free energy and hydrophilicity through chemical modification of microstructured titanium implant surfaces. J Biomed Mater Res A 2006;76A:323–334.
10. 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.
11. 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.
12. Meredith N, Book K, Friberg B, Jemt T, Sennerby L. Resonance frequency measurements of implant stability in vivo. A cross-sectional and longitudinal study of resonance frequency measurements on implants in the edentulous and partially dentate maxilla. Clin Oral Implants Res 1997;8:226–233.
13. Lachmann S, Laval JY, Jager B, et al. 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.
14. Huang HM, Chiu CL, Yeh CY, Lin CT, Lin LH, Lee SY. Early detection of implant healing process using resonance frequency analysis. Clin Oral Implants Res 2003;14:437–443.
15. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: A review and proposed criteria of success. Int J Oral Maxillofac Implants 1986;1:11–25.
16. Chow GC. Tests of equality between sets of coefficients in two linear regressions. Econometrica 1960;52:211–222.
17. Johnston J, DiNardo J. Econometric Methods. McGraw-Hill, 1997.
18. Toutenburg H. Statistical Analysis of Designed Experiments (ed 2). New York: Springer-Verlag, 2002.
19. Lekholm U, Zarb GA. Patient selection and preparation. In: Brånemark P-I, Zarb GA, Albrektsson T (eds). Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago: Quintessence, 1985:199–209.
20. Bischof M, Nedir R, Szmukler-Moncler S, Bernard JP, Samson J. Implant stability measurement of delayed and immediately loaded implants during healing. Clin Oral Implants Res 2004; 15:529–539.
21. Friberg B, Sennerby L, Linden B, Grondahl K, Lekholm U. Stability measurements of one-stage Brånemark implants during healing in mandibles. A clinical resonance frequency analysis study. Int J Oral Maxillofac Surg 1999;28:266–272.