# Survival of Splinted Mini-Implants After Contamination with Stainless Steel

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***Purpose:*** *Dental practitioners are instructed to avoid any type of contact with implant surfaces prior to their insertion. However, the probability of contaminating the surface is high, especially when placement of implants necessitates the use of precise surgical guides. The aim of this study was to evaluate the 2-year survival rate of splinted mini-implants that came into contact with stainless steel prior to their insertion.* ***Materials and Methods:*** *During the clinical portion of the study, initiated over a 3-day period, 90 mini-implants were inserted into the anterior mandible of 45 totally edentulous patients; 46 were inserted using a prefabricated stainless steel guide (group 1, bar) and 44 were placed without a guide (group 2, ball). A flapless surgical protocol was used. All implants were immediately loaded with mandibular overdentures, and follow-up was conducted for up to 2 years. The Kaplan-Meier method was used to analyze implant survival in each group, with a confidence level of 95%. In the in vitro phase of the study, five mini-implants were contaminated for 20 seconds with a stainless steel surgical guide. They were then observed using scanning electron microscopy and energy dispersive spectroscopy to identify contaminants and to determine qualitatively the chemical composition of the surface. As a control, five mini-implants recently extracted from their original containers were analyzed.* ***Results:*** *During the 2-year follow-up, one implant failed (97.8% survival rate) in group 1 and four failed in group 2 (90.9% survival rate). The in vitro analysis revealed carbon and oxygen on all implants. On the implants that were in contact with stainless steel, additional elements were identified, including silica, calcium, iron, and chromium.* ***Conclusions:*** *Contact between mini-implants and stainless steel surgical guides does not seem to generate contamination that compromises the survival of splinted mini-implants.* Int J Oral Maxillofac Implants 2010;25:351–356

**Key words:** *contamination, edentulous mandible, mini-implants*

The response of bone tissue to biomaterials depends partly on the surface characteristics of the material inserted.[1] The high biocompatibility of commercially pure titanium used in conventional dental implants is associated with the reactive oxide layer that forms rapidly in the presence of oxygen.[2]

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A strict cleaning procedure is recommended for titanium components at the end of the manufacturing process, as is strict control over the implant surface composition, even after autoclaving.[3] These recommendations attempt to minimize surface contamination and ensure good contact with the bone tissue.[1,4] This criterion is also a requirement for titanium-aluminum-vanadium (Ti-6Al-4V) implants.[5] However, the risk of contamination during implant insertion is high. In vivo animal studies have been done to determine how contamination affects the healing process. Ivanoff et al[6] demonstrated that prior contact between the implant surface and soft tissues does not affect osseointegration. Nonetheless, and although the degree of bone formation was not significant when compared with uncontaminated surfaces, the authors indicated that surface contamination should be avoided until further studies determined its clinical relevance. Likewise, Kolonidis et al[7]

found that osseointegration was possible on implant surfaces previously contaminated with plaque and cleaned in different manners; however, these results have not been confirmed by prospective clinical studies.

Recently, mini-implants have been reported as an alternative treatment for patients with completely edentulous mandibles[8–11] and have been approved for the long-term treatment of edentulous patients (US Food and Drug Administration, 2003-510(k) number K023067). Contamination risks can increase considerably when precise surgical guides are necessary for proper implant insertion, as in cases of severe alveolar atrophy. The effect of contamination on Ti-6Al-4V surfaces is not known.

The purpose of this study was to evaluate the 2-year survival rate of splinted mini-implants made of Ti-6Al-4V that came into contact with stainless steel prior to their insertion.

## MATERIALS AND METHODS

The survival rate of the mini-implants at the 2-year follow-up was assessed during a clinical trial (primary outcomes). The implant survival rate was evaluated based on failed implants. Implant failure was defined as the total loss of the implant.

### Clinical Trial

This descriptive study was part of a 2-year randomized trial comparing the bone loss of splinted versus nonsplinted mini-dental implants in edentulous patients (Jofre, unpublished data). Forty-five edentulous people were selected at a public health center in Concepción, Chile. Every participant received oral and written trial information prior to signing an informed consent document to participate. The study protocol was approved by the University's Ethics Committee and the National Commission on Scientific and Technological Research in Chile. During the design of the trial, the research team was unaware that the mini-implant needed to touch the stainless steel surgical guides during insertion. This fact was only analyzed at a later stage, intended to improve the design of the steel guide. It was not the intent of the researchers to knowingly contaminate the implants.

The study included edentulous men and women between 45 and 90 years of age who had a persistent loss of stability and retention of their conventional mandibular dentures, no temporomandibular disorders, and an Angle Class I jaw relationship. Exclusion criteria were uncontrolled systemic disease (eg, hypertension, diabetes), severe osteoporosis (bone mineral density > 2.5 SD below the young adult reference mean and 1 or more fragility fractures) and/or current bisphosphonate therapy, mental disorders, and/or administration of radiotherapy in the 18 months prior to the study. The baseline participant characteristics (eg, gender, age, morbid conditions) were recorded to ensure comparability between study groups.

During a 3-day period, 90 mini-implants (Ti-6Al-4V; 1.8 × 15 mm; Sendax MDI, IMTEC) with treated surfaces were placed (two per patient) in the anterior mandible. An electronic OsseoCare DEC600 motor (Nobel Biocare) and a flapless surgical protocol were used in all patients. An infiltrative technique was used for nerve blocking in the area, and an initial spiral drill of 1.1 mm was used to prepare the implant site with a transmucosal perforation. Allocation of the implants and the prosthetic system (ball or bar) was performed in a simple random fashion by an independent collaborator who allocated the patients to their groups according to a list of random numbers. Forty-six mini-implants were inserted; for 20 seconds during the insertion process, these came into contact with a prefabricated guide made of surgical steel (Fig 1). This group received a retention system consisting of a bar cemented to the implants with a prosthetic attachment (clip) (group 1, bar). The remaining 44 mini-implants were inserted using the same protocol, but without the use of a guide (Fig 2) and with individual balls (O-ring) as prosthetic attachments (group 2, ball). Implant insertion for the prefabricated bar group required the use of a surgical guide as standard protocol. In group 2, the surgical guide was not needed. Just after insertion, all implants were immediately loaded with mandibular overdentures.

In the case of group 1 patients who lost one implant, the bar was removed and the remaining implants were adjusted with a soft liner. In group 2, the retention system of the failed implant was removed from the denture, which was relined with a soft liner.

### In Vitro Phase

Qualitative identification of contaminating elements on mini-implants was done during an in vitro phase (secondary outcome). To identify the contaminating elements, the chemical composition of a Ti-6Al-4V mini-implant (1.8 mm diameter, 15 mm long; Sendax MDI, IMTEC) was determined qualitatively using a scanning electronic microscope (SEM) with electron dispersive spectroscopy (EDS) (JSM 6380LV, Jeol). The implants were analyzed either after touching the implant surface with a stainless steel surgical guide for 20 seconds, using similar conditions to that applied during implant insertion (n = 5), or directly after removal from the commercial package (n = 5). Samples were mounted on a device that could rotate

**Fig 1** *(left)* Insertion of a mini-implant in contact with the internal surface of a prefabricated stainless steel guide.

**Fig 2** *(right)* Insertion of a mini-implant without a guide and no metal contamination.

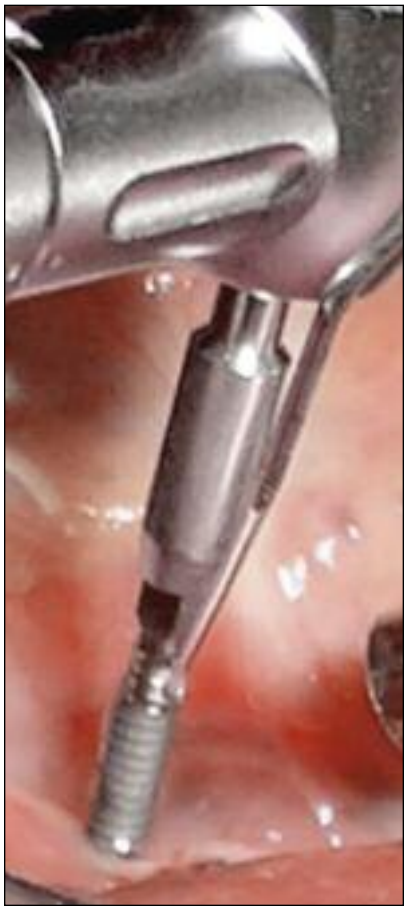
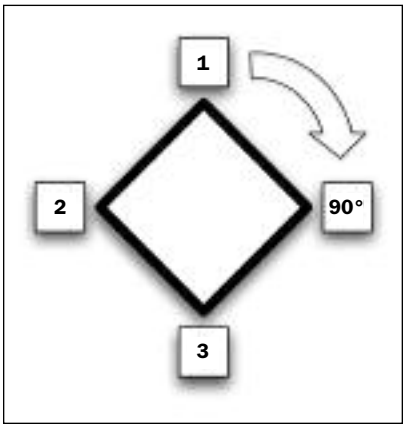


**Fig 3** *(left and below)* Mini-implant on a slide for SEM observation and a diagram showing how all four sides of the implant were examined.




360 degrees (Fig 3). The implants were then rotated 90 degrees four times to perform a complete SEM scan; the authors searched for signs of deformation, particulate matter, or contamination.

To standardize the observations, the implant surfaces were divided into three sections (apical, middle, and basal). After observation by SEM, the 12 systematically varied areas from each implant that showed deformation or particles, along with unaltered contiguous areas, were analyzed using EDS to determine the chemical composition of the surfaces.[12]

### Statistical Analysis

The mini-implant survival rate in each group was determined after 2 years of follow-up. Data were analyzed using SPSS version 15.0 (SPSS). Categorical variables (eg, baseline characteristics) were compared using the Fisher exact test, and continuous variables were examined with the Student *t* test. Statistical significance was considered if $P \leq .05$. The Kaplan-Meier method was used to analyze implant survival at 2 years using a confidence level of 95%. The analysis was by intention-to-treat and involved all patients.

**Table 1 Baseline Patient Characteristics**

| | Group 1 | Group 2 | Difference between groups* |
|---|---|---|---|
| Sex (F/M) | 14/9 | 13/9 | NS |
| Age (y) | 73 ± 9.6 | 69 ± 8.7 | NS |
| Comorbid conditions | | | |
| Diabetes | 3/23 | 2/22 | NS |
| Osteoporosis | 0/23 | 1/22 | NS |
| Smoking | 1/23 | 1/22 | NS |

*Categorical variables were compared using the Fisher exact test and continuous variables using the Student *t* test. A statistically significant difference is considered if $P \leq .05$. NS = nonsignificant difference.

## RESULTS

### Clinical Trial

The groups were comparable with respect to baseline characteristics of the participants (Table 1). One patient did not return for the follow-up examination and another died before the end of the study, reducing the number of participants in group 2 to 20.

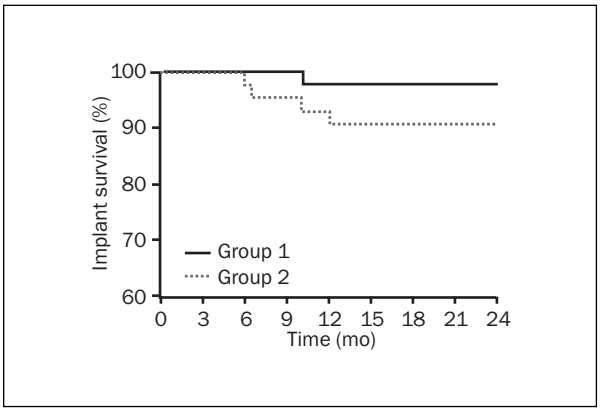



**Fig 4** Mini-implant survival rates at the 2-year follow-up (n = 90). The survival rate for group 1 was 97.8% and for group 2 it was 90.9%.

After 2 years of follow-up, one implant failed (1/46) in group 1 and four implants (4/44) in group 2 failed. After 2 years, the survival rates for these groups were 97.8% and 90.9%, respectively (Fig 4).

### In Vitro Findings

EDS, a technique for qualitative chemical analysis, was done on five mini-implants immediately after they were removed from the commercial package, revealing the presence of titanium, vanadium, aluminum, carbon, and oxygen (Figs 5 and 6). The implants that came into contact for 20 seconds with the guide (n = 5) were also found to have these elements, plus silica, calcium, iron, and chromium. Figures 7 to 9 show SEM images from both groups and the corresponding EDS spectra. Note that, because of the characteristics of the method, the height of the peak in the spectrum is not related to the concentration (or amount) of the element.

## DISCUSSION

Chemical analysis of the mini-implants showed clear surface contamination with carbon and oxygen. Both were adsorbed from the atmosphere and normally occur in SEM analyses. Furthermore, oxygen is an unavoidable element when titanium and other reactive metal surfaces are exposed to the environment.[5] Although the implant surfaces are also thought to contain nitrogen, the EDS technique is not able to detect this element.

For the in vitro study, the mini-implants were contaminated manually, and the contamination conditions were possibly more severe than those of a standard clinical procedure. Thus, slight plastic deformation was observed along the edges of the mini-implant threads. Calcium, chrome, and iron were detected in these areas (Fig 8).

The presence of iron and chrome could have come from the stainless steel surgical guide, which is made up of 0.03% carbon, 2% manganese, 2% silica, 18% chromium, 14% nitrogen, and 2% to 3% molybdenum; the remainder is iron. Likewise, calcium probably came from the implant, as reported previously by Lausmaa.[13] These contaminants were not detected in other areas of the implant, suggesting that the total amount of contaminant on the implant is very low and located only in the areas around the plastic deformation—that is, where the contact between the implant and the guide was more severe.

Conversely, silica was found in some other areas of the implant (Fig 9). The presence of silica could be related to a leaching process of the crystal vials used to store the mini-implants.[14,15] This form of contamination is external to the surgical procedure. Therefore, silica was found on previously contaminated implants (group 1) as well as on the uncontaminated implants (group 2).

Several studies have proposed that, in terms of implant osseointegration and long-term prognosis, avoiding implant contamination by foreign elements is of vital importance.[1,4] During the early healing phase, gigantic multinuclear cells are present on the implant surfaces and then disappear when the mineralized bone approaches the surface. It has been proposed that these gigantic multinuclear cells are activated by the presence of contaminating elements and could lead to the production and release of inflammatory mediators, which could negatively influence the bone healing process.[16] Nonetheless, despite the friction contact between mini-implant surfaces and the stainless steel surgical guides during insertion in the clinical phase of this study, most of the mini-implants were clinically stable after the healing phase.

A study by Mouhyi et al,[17] done with conventional implants, showed important atomic modifications in the composition of the titanium oxide layer when the surface was contaminated over time with plaque, simulating conditions of peri-implantitis. In the present study, the decreased exposure time and contact surfaces may have resulted in the insignificant atomic modification of the mini-implant titanium oxide layer. Even if it is assumed that the foreign elements observed in the in vitro phase of this study were present at the time of implant insertion with a surgical guide, this contamination cannot be used to explain

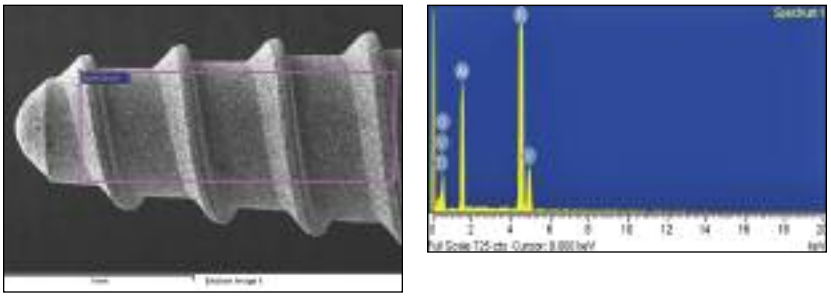


**Fig 5** SEM panoramic view of the implant and result of EDS analysis, showing the presence of titanium, vanadium, and aluminum, the elements of which the implant was made. The presence of oxygen was a result of exposure of the implant to the environment.

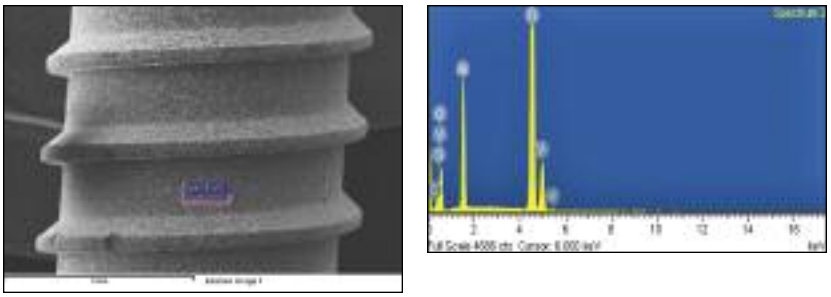


**Fig 6** A close-up section of an uncontaminated implant and EDS analysis of the section showing titanium, vanadium, and aluminum, as well as foreign elements such as carbon and oxygen.

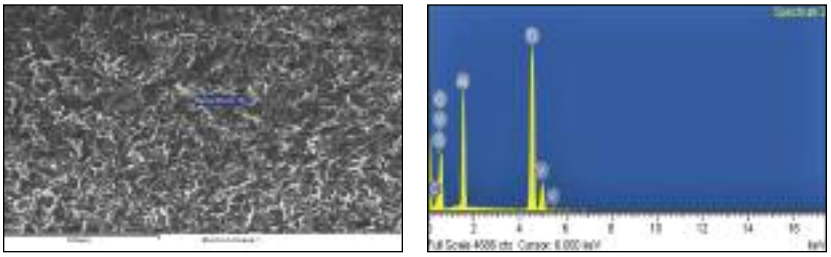


**Fig 7** Analysis of an area contiguous to the plastic deformation, showing titanium, vanadium, aluminum, and foreign elements such as carbon and oxygen.

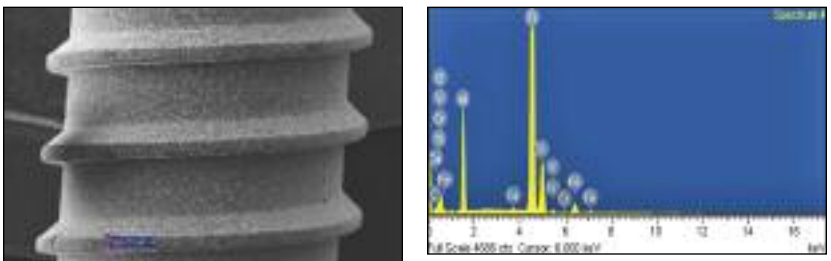


**Fig 8** SEM and EDS analysis of the area of plastic deformation of a mini-implant. Contamination with oxygen, carbon, calcium, chrome, and iron was detected.

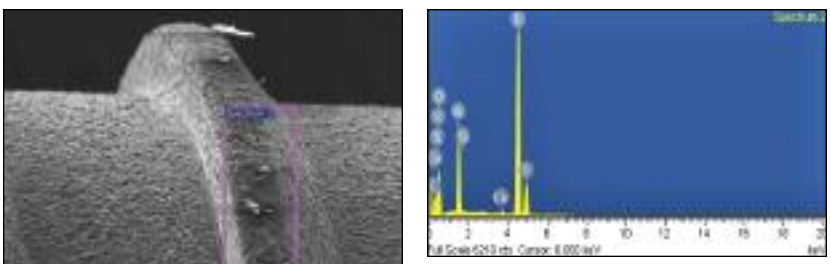


**Fig 9** Detail of contamination from the stainless steel guide observed with SEM, showing contaminating elements on a thread of a mini-implant.

implant failures through interference in the osseointegration process, since the first failures occurred after the sixth month of implant insertion, when the initial healing stage had already ended.[18,19] Also, more implants were lost in the uncontaminated group than in the group whose implants had come into contact with stainless steel. However, it was not possible to compare the two groups because of their different loading conditions, which might mask or overestimate the true difference between groups.

Esposito et al[14] and Shibli et al[20] found titanium oxide and variable quantities of additional elements on all lost implant surfaces; carbon dominated in many cases, and nitrogen, sodium, calcium, phosphorus, chlorine, sulfur, and silicon were found in some instances. In spite of this, these authors suggested that the implants failed not because of the implant material, as no significant changes were observed in the composition of the titanium oxide, but because of problems during the healing process, asymptomatic infection, or overloading. The present results support this theory, suggesting that variables such as bone quality and overloading play a more important role in mini-implant survival than surface contamination. Further studies are necessary to evaluate other variables that might play a more decisive role in mini-implant success and/or failure.

## CONCLUSIONS

Contact with stainless steel surgical guides does not seem to generate contamination that compromises the survival of splinted mini-implants.

## ACKNOWLEDGMENTS

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## REFERENCES

1. Albrektsson T, Brånemark PI, Hansson HA, Lindstrom J. Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. Acta Orthop Scand 1981;52:155–170.
2. Kasemo B, Lausmaa J. Aspects of surface physics on titanium implants. Swed Dent J Suppl 1985;28:19–36.
3. Lausmaa J, Kasemo B, Hansson S. Accelerated oxide growth on titanium implants during autoclaving caused by fluorine contamination. Biomaterials 1985;6:23–27.
4. Adell R LV, Brånemark P-I. Surgical procedures. In: Brånemark P-I, Zarb G, Albrektsson T (eds). Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago: Quintessence, 1985:211–232.
5. Massaro C, Rotolo P, De Riccardis F, et al. Comparative investigation of the surface properties of commercial titanium dental implants. Part I: Chemical composition. J Mater Sci Mater Med 2002;13:535–548.
6. Ivanoff CJ, Sennerby L, Lekholm U. Influence of soft tissue contamination on the integration of titanium implants. An experimental study in rabbits. Clin Oral Implants Res 1996;7:128–132.
7. Kolonidis SG, Renvert S, Hammerle CH, Lang NP, Harris D, Claffey N. Osseointegration on implant surfaces previously contaminated with plaque. An experimental study in the dog. Clin Oral Implants Res 2003;14:373–380.
8. Christensen GJ. The 'mini'-implant has arrived. J Am Dent Assoc 2006;137:387–390.
9. Balkin BE, Steflik DE, Naval F. Mini-dental implant insertion with the auto-advance technique for ongoing applications. J Oral Implantol 2001;27:32–37.
10. Shatkin TE, Shatkin S, Oppenheimer BD, Oppenheimer AJ. Mini dental implants for long-term fixed and removable prosthetics: A retrospective analysis of 2514 implants placed over a five-year period. Compend Contin Educ Dent 2007;28:92–99.
11. Bulard RA, Vance JB. Multi-clinic evaluation using mini-dental implants for long-term denture stabilization: A preliminary biometric evaluation. Compend Contin Educ Dent 2005;26: 892–897.
12. Shibli JA, Theodoro LH, Haypek P, Garcia VG, Marcantonio E Jr. The effect of $CO_2$ laser irradiation on failed implant surfaces. Implant Dent 2004;13:342–351.
13. Lausmaa J. Surface spectroscopic characterization of titanium implant materials. J Electron Spectrosc Relat Phenom 1996;81: 343–361.
14. Esposito M, Hirsch J, Lekholm U, Thomsen P. Differential diagnosis and treatment strategies for biologic complications and failing oral implants: A review of the literature. Int J Oral Maxillofac Implants 1999;14:473–490.
15. Esposito M, Lausmaa J, Hirsch JM, Thomsen P. Surface analysis of failed oral titanium implants. J Biomed Mater Res 1999;48: 559–568.
16. Sennerby L, Thomsen P, Ericson LE. Early tissue response to titanium implants inserted in rabbit cortical bone. J Mater Sci Mater Med 1993;4:240–250.
17. Mouhyi J, Sennerby L, Wennerberg A, Louette P, Dourov N, van Reck J. Re-establishment of the atomic composition and the oxide structure of contaminated titanium surfaces by means of carbon dioxide laser and hydrogen peroxide: An in vitro study. Clin Implant Dent Relat Res 2000;2:190–202.
18. Roberts WE, Marshall KJ, Mozsary PG. Rigid endosseous implant utilized as anchorage to protract molars and close an atrophic extraction site. Angle Orthod 1990;60:135–152.
19. Roberts WE, Nelson CL, Goodacre CJ. Rigid implant anchorage to close a mandibular first molar extraction site. J Clin Orthod 1994;28:693–704.
20. Shibli JA, Marcantonio E, d'Avila S, Guastaldi AC, Marcantonio E Jr. Analysis of failed commercially pure titanium dental implants: A scanning electron microscopy and energy-dispersive spectrometer x-ray study. J Periodontol 2005;76:1092–1099.