# Clinical Parameters Associated with Success and Failure of Single-Tooth Titanium Plasma-Sprayed Cylindric Implants Under Stricter Criteria: A 5-year Retrospective Study

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Purpose: The purpose of this study was to determine the clinical parameters associated with long-term success and failure of single-tooth titanium plasma-sprayed (TPS) cylindric implants. Materials and Methods: Thirty-nine implants in 39 subjects were followed for 5 years. The following data were collected: subject age and gender, implant length, implant location, bone density, and implant position in relation to crestal bone. Assessments made at recall intervals included: Gingival Index (GI), probing depth, relative attachment level, and standardized radiographs. Failure was defined as a mean annual attachment loss rate (ALR) of  $\geq$  0.25 mm after the first year of implant function. Between-group differences were assessed nonparametrically using the Mann-Whitney and chi-square tests. Results: Nineteen implants were considered successes and 20 were considered failures with respective mean ALRs of 0.12 ± 0.07 mm and 0.42 ± 0.19 mm. The following factors were associated with success: longer implants (P < .001), lower GI (P < .001), higher bone density (P < .0001), and implant position at the crest or supracrestally (P < .0001). Age, gender, probing depth, and implant location were not related to outcome. Conclusions: A model using attachment loss as a parameter for success and failure has not been previously utilized. Longer implants, lower GI, higher bone density, and implant position at the crest or supracrestally were clinical factors associated with long-term success of single-tooth TPS cylindric implants in this patient population. INT J ORAL MAXILLOFAC IMPLANTS 2005;20:687-694

Key words: alveolar bone loss, attached gingiva, dental implants

Osseointegrated dental implants have become a predictable and effective modality for the treatment of single missing teeth.<sup>1,2</sup> Long-term esthetics, comfort, and function of the implant are often the patient's criteria for a satisfactory outcome. The key

element in the success of dental implants is maintenance of the integration between intraoral tissues and the implant.<sup>3,4</sup> Studies have shown that breakdown of the tissue-implant interface initiates in the crestal region of otherwise successfully integrated implants.<sup>5,6</sup> This early bone loss can be as much as 1.6 mm in the first year,<sup>7</sup> an amount that may undoubtedly lead to esthetic compromise. This initial loss may be self-arresting or may continue at a rate of up to 0.2 mm annually.<sup>8</sup> Hypotheses that have been postulated as reasons for these bony changes include bacterial colonization of the coronal implant surface or sulcus,<sup>5,9,10</sup> surgical trauma,<sup>11,12</sup> the position of the implant's rough-smooth border in relation to the crest of the bone,<sup>13,14</sup> the size of the microgap between implant and its abutment,<sup>15,16</sup> the influence of biomechanical forces on bone resorption,<sup>5,7,9</sup> and the establishment of a "biologic width."<sup>17,18</sup>

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Even small amounts of bone loss around functional implants can be problematic for clinicians because of the increased focus on soft tissue esthetics. Therefore, traditional implant failure criteria such as 33% bone loss, <sup>19</sup> peri-implant radiolucency,<sup>20</sup> implant mobility,<sup>20</sup> infection, <sup>19,20</sup> and pain<sup>20</sup> may not be critical enough to distinguish differences in small losses of the attached gingiva that could result in esthetic compromises. Consequently, it may be necessary to raise the standard of what is considered success.

The purpose of this study was to determine which clinical parameters are associated with the long-term success or failure of single-tooth implants, using criteria of success stricter than those commonly used, based on attachment loss rate (ALR) after the first year of function.

## **MATERIALS AND METHODS**

#### **Patient Enrollment and Clinical Procedures**

The following study involved the retrospective analysis of 3i implants (Implant Innovations, Palm Beach Gardens, FL) placed as part of a larger prospective project designed to evaluate the long-term effectiveness of titanium plasma-sprayed (TPS) hexed cylinder implants (Fig 1). The project was approved by the university's institutional review board. Criteria for inclusion (18 years of age or older, willing to participate for the duration of the study, willing to provide informed consent, edentulous in either the maxilla or mandible, absence of soft tissue, oral or dental pathologies, in good general health, and enough available bone to fully accommodate the implant) and exclusion (uncontrollable metabolic disease, immunocompromise, uncompensated systemic disease, mental illness, prior radiation treatment of the **Fig 1** (*Left*) Externally hexed TPS cylindric implant (3i/Implant Innovations).

Fig 2 (*Right*) Florida probe and a customized template.

surgical site, history of drug abuse or alcoholism, smoking, previous implant placement or graft of the surgical site, debilitating temporomandibular disease, pregnancy, prisoner status, less than 5 mm of bone width based on oral examination, and less than 10 mm of bone height based on radiographic examination) have been previously reported.

Only patients with implants replacing a single missing tooth were selected from the group to be included in this study. Data from 39 patients fitting the aforementioned selection criteria were collected for a period of 5 years, and all implants were considered successes according to the following criteria set forth by the original study protocol: immobility of the implant, absence of consistent pain, and no periimplant radiolucency or significant damage to adjacent structures. Furthermore, according to the original success criteria, the implant had to be load-bearing and meet prosthetic needs, and bone loss had to be stabilized and could not exceed 30% of the implant length. In addition to a thorough medical history, the following data were collected for each patient: age, gender, implant length, and implant location. The surgical protocol was documented in detail; information gathered included bone quality<sup>21</sup> and final position of the implant shoulder in relation to the crest of the bone (subcrestal, flush, or supracrestal).

None of the implants analyzed required any bone or soft tissue grafting procedures at the time of placement or during the follow-up period. After placement, the implants were allowed a healing period of at least 3 months in the mandible and 6 months in the maxilla. Following the nonloaded healing period, the implants were uncovered, and a healing abutment was placed. An additional 2-week healing period was allowed before the prosthesis was fabricated. Assessments were made at delivery of the prosthesis, 3 months, and 6 months and at 6month intervals thereafter. Each assessment included the following: gingival health as quantified by the Gingival Index (GI), probing depth (PD), relative attachment level (RAL), standardized radiographs, and a comprehensive prosthodontic examination. During each recall visit, oral prophylaxis was performed and oral hygiene instructions were reinforced.

#### **Clinical Recordings**

- Gingival Index: Gingival inflammation was evaluated on the buccal side on a scale of 0 to 3 as defined by Löe and Silness.<sup>22</sup>
- Probing Depth and Attachment Level: In 35 cases where the restorations were screw retained, the crown was removed to measure PD and RAL to the nearest 0.1 mm mesially and distally using a customized acrylic resin template and a 0.2-N standard pressure electronic probe (Florida Probe, Gainesville, FL) (Fig 2). For the 4 cemented restorations, each of the mesial and distal measurements was an average of their respective buccal and lingual readings. The average of the mesial and distal measurements became the PD and RAL for each assessment visit.

## Radiographic Recordings and Bone Level Measurements

All radiographs were exposed and developed in a standardized manner. The developed films were scanned on an Epson Perfection 2450 photo scanner (Epson, Long Beach, CA). The size of the image was standardized at 800 dpi, with an average resulting size of 2,550  $\times$  3,510 pixels and 256 scales of gray. The resulting digital images were analyzed and measured using ImageJ (National Institutes of Health, Bethesda, MD). Bone levels were measured from the implant shoulder to the first radiographically apparent bone-to-implant contact. Bone level measurements for each implant were made mesially and distally. The average of the mesial and distal bone level measurements was defined as the RBL for each assessment visit. Radiographs obtained at the 1-year and 5-year follow-ups for each implant were standardized by calibrating the program to the known implant length or width. All measurements were performed by the same investigator (JE) to the nearest 0.1 mm. Intraexaminer reliability of RBL was determined by repeated measurements on 20 implants. An intraclass correlation coeffcient of 0.998 was obtained, with upper and lower coefficients of 0.999 and 0.995, respectively.

#### **Attachment and Bone Loss Rates**

ALR was defined as the difference in RAL between year 1 and year 5, annualized. ALR was calculated using the formula

$$ALR = \frac{RAL \text{ year } 5 - RAL \text{ year } 1}{4}$$

Bone loss rate (BLR) was defined as the difference in RBL between year 1 and year 5, annualized. BLR was calculated using the formula

$$BLR = \frac{RBL \text{ year } 5 - RBL \text{ year } 1}{4}$$

#### **Bone Type and Implant Position**

Bone quality was determined by the surgeon, who subjectively graded the patient's bone density on a scale from 1 to 4 during implant placement. For the final position of the implant shoulder in relation to the crestal bone, implant shoulders placed at or above the crest were grouped into 1 category (Fig 3), while those placed subcrestally were grouped into another category (Fig 4). When categorizing implant location, the most coronal point of bone-implant contact was considered.

#### **Criteria for Success/Failure**

After a thorough review of longitudinal implant studies, <sup>1,8,23–26</sup> for the purposes of this study, "failed" implants were defined as those having an ALR  $\ge$  0.25 mm after the first year of function (group A). Implants having an ALR < 0.25 mm after the first year of implant function were considered "successes" (group B).

#### **Statistical Evaluation**

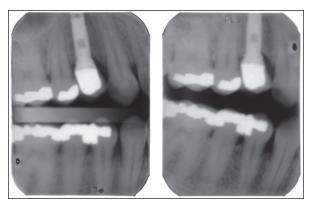
Differences in age, PD, length, GI, and bone quality were evaluated by the Mann-Whitney test. Differences in gender, implant location (area and jaw), and implant position were analyzed using the chi-square test. Correlation between ALR and BLR was assessed using the Spearman correlation coefficient. The threshold for differences to be considered statistically significant was set at P < .05.

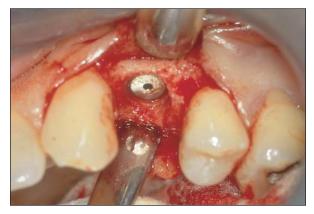
### RESULTS

The patient pool consisted of 22 women and 17 men with a mean age of 49.2 years. Twenty-one of 39 implants were placed in posterior sites (distal to the canine position), while 18 were placed anteriorly (in intercanine or canine positions). Twenty-five implants were placed in the maxilla; 14 were placed in the

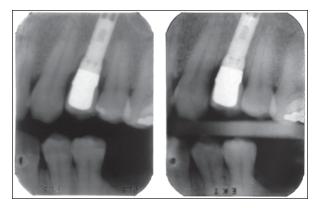


**Fig 3** Supracrestal placement of an implant, with follow-up radiographs (*below*). Baseline image on left; 5 years postrestoration on right.





**Fig 4** Subcrestal placement of an implant, with follow-up radiographs (*below*). Baseline image on left; 5 years postrestoration on right.



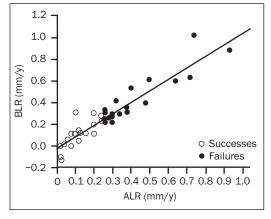


Table 1     Attachment and Bone Loss Rates									
	Mean	SD	Median	Quartile range	Minimum	Maximum			
All implants (N = 39)									
ALR	0.27	0.21	0.26	0.28	0.02	0.93			
BLR	0.27	0.24	0.26	0.22	-0.13	1.02			
Group A (N = 20)									
ALR	0.42	0.19	0.36	0.20	0.26	0.93			
BLR	0.43	0.22	0.33	0.29	0.22	1.02			
Group B (N = 19)									
ALR	0.12	0.07	0.10	0.14	0.02	0.24			
BLR	0.11	0.12	0.11	0.19	-0.13	0.31			

Fig 5 Correlation between ALR and BLR.

mandible. At the 5-year examination, all 39 implants were stable and functioning. All implants were without suppuration or major prosthetic or periodontal complications. According to the modified success criteria, failures (group A, n = 19) had a mean ALR of  $0.42 \pm 0.19$  mm/year, compared to  $0.12 \pm 0.07$  mm/year for the successes (group B, n = 20). The combined mean ALR for the 2 groups was  $0.27 \pm 0.21$ 

mm (Table 1). BLR was comparable, at 0.43  $\pm$  0.22 mm/year for group A and 0.11  $\pm$  0.12 mm/year for group B, with a combined mean BLR of 0.27  $\pm$  0.24 mm (Table 1). The correlation between ALR and BLR for all implants was statistically significant (Spearman correlation coefficient = 0.91, *P* < .001) (Fig 5).

Implant length, GI, bone quality, and implant shoulder position in relation to crestal bone were

Table 2     Differences Between Implant Groups (Continuous Variables)												
		Group A (n = 20)					Group B (n = 19)					
	Mean	SD	Median	Minimum	Maximum		Mean	SD	Median	Minimum	Maximum	<b>P</b> *
Age	51.10	9.69	53.50	25.00	65.00		47.21	8.40	45.00	36.00	62.00	.1287
Probing depth	3.51	1.40	3.15	1.60	6.50		3.53	0.73	3.40	2.50	5.00	.4730
Length	11.30	2.11	10.00	10.00	15.00		14.00	1.37	15.00	10.00	15.00	.0003
Gingival Index	2.00	0.65	2.00	1.00	3.00		0.47	0.61	0.00	0.00	2.00	< .0001
Bone quality	2.90	0.31	3.00	2.00	3.00		1.79	0.71	2.00	1.00	3.00	<.0001

\*Mann-Whitney test used.

significantly different between groups A and B (Tables 2 and 3). Implant length was significantly associated with success of implants (P < .001). The mean length was  $11.30 \pm 2.11$  mm and  $14.00 \pm 1.37$  mm for groups A and B, respectively (Table 2). Group A had a mean Gl of  $2.00 \pm 0.65$  compared to  $0.47 \pm 0.61$  for group B (P < .001) (Table 2). The mean bone quality was  $2.90 \pm 0.31$  and  $1.79 \pm 0.71$  for groups A and B, respectively (Table 2). In Group A and B, respectively (P < .001) (Table 2). In Group A, 2 implants were placed subcrestally or at the crest, while 18 were placed subcrestally or at the crest. The difference between the 2 groups was statistically significant (P < .001) (Table 3).

Patient gender, age, implant PD, and site of implant placement (maxilla/mandible, anterior/posterior) were not significantly associated with implant success or failure as defined in this study (Tables 2 and 3).

### DISCUSSION

Numerous longitudinal studies have reported on the overall success rate of implants and the long-term interaction between the implant and the soft and hard tissues, 1,8,23-26 but few have analyzed the determinants of the transformation of this interaction, which provides the integrity and stability of esthetics over the lifetime of the implant. Studies on patient self-reported satisfaction with dental implants<sup>27,28</sup> have shown that implant position, restoration shape, chewing capacity, effect on speech, and overall appearance were critical for patient acceptance of the treatment. This study was undertaken to evaluate which clinical parameters collected during implant placement, restoration, and follow-up visits were essential to the maintenance and stability of the implant-tissue relationship to the predictability and patient acceptance of treatment. Within the limits of this retrospective study, the results indicate that longer implants, lower GI, higher bone density, and placement of the implant shoulder at the crest or

## Table 3Differences Between Implant Groups(Nominal Variables)

	Gro	oup A	Group	В
	n	%	n	% <b>P</b> *
Gender				
Female	9	45.0	13 6	8.4
Male	11	55.0	6 3	1.6 .1404
Area				
Anterior	11	55.0	7 3	6.8 .2556
Posterior	9	45.0	12 6	3.2 .2556
Jaw				
Maxilla	14	70.0	11 4	2.1 .4304
Mandible	6	30.0	8 5	7.9 .4304
Position				
Above	2	10.0	19 10	0.0 < .0001
Below	18	90.0	0	0.0

\*Chi-square test.

supracrestally are significantly associated with limited attachment loss over a period of 5 years around TPS externally hexed cylindric implants.

In the present study, an annual attachment loss rate of < 0.25 mm over 5 years of function was considered "success." This criterion was based on a review of longitudinal implant studies.<sup>1,8,23–26,29</sup> A few single-implant studies have used 0.2 mm of mean annual bone loss as the threshold for success of implants. In 1996, Avivi-Arber and Zarb<sup>8</sup> found that 9 of 49 Brånemark System implants followed from 1 to 8 years exceeded that threshold. No factors that may have influenced success or failure were discussed in this study, but the authors stated that any differences which may have been present reflect an obvious need to fine tune success and failure criteria. In a similar study,<sup>30</sup> in which the same implant system was analyzed over a period of 5 years, all 30 implants had a mean bone loss of less than 0.2 mm per year. The authors attributed implant success to their consideration of the prevention of occlusal overload. Another study<sup>1</sup> evaluated 107 Brånemark System implants and found that after disregarding 3 implants that had failed during the first year of function, the total marginal bone loss during the 5-year period did not exceed a mean of 1 mm for all implants analyzed. A closer look at the data revealed that, in some cases, the individual implant bone loss rate reached more than 1 mm per year. The authors pointed out that the measurement methods used were crude and that a significant problem in abutment loosening may have skewed the results. In the present study, attachment loss was measured with a constant force probe utilizing a customized template.

Implant length has been shown to affect success. In a 7-year life table analysis of 187 single-tooth replacement implants, Romeo and colleagues<sup>31</sup> had failures in the short (10 mm or less) implant category only. In another retrospective study of 742 implants with various types of restorations, 28 of 30 failures were implants 10 mm or less in length.<sup>25</sup> In comparison, 16 (80%) of the failures reported in the present study were 10-mm-long implants. In contrast to the present study, the aforementioned studies defined failure as removal of the implant.

Cross-sectional studies indicate that inflammation and poor oral hygiene can be direct contributors to implant failure.<sup>32,33</sup> The present longitudinal study found a higher GI, ie, greater marginal inflammation, to be significantly associated with  $\geq$  0.25 mm of annual attachment loss. Therefore, during function of single-tooth implants, good oral hygiene appears to be a requisite for long-term success.

The data on the effects of bone density are conflicting. Bone quality has been classified into 4 categories ranging from type 1, which consists of mostly cortical bone, to type 4, which is characterized by a thin layer of cortical bone surrounding a core of low density trabecular bone of poor strength.<sup>21</sup> In the present study, higher density bone was associated with decreased ALR. This is in agreement with a report that attributed a lower implant failure rate to implants placed in type 1 bone.<sup>34</sup> In contrast, other investigations conducted by the same authors found a higher failure rate to be associated with type 1 bone.<sup>35,36</sup> The inconsistencies may be the result of different implant coatings, the use of different surgical procedures, and most importantly, the lack of an objective grading protocol for bone density, ie, one that does not rely on the subjective "feel" of the surgeon.

Position of the implant shoulder in relation to the bony crest was statistically associated with increased ALR, suggesting that the proximity of the implantabutment interface to the crest of the bone affects ALR. All implant shoulders in group B were placed at the crest of the bone or supracrestally. In contrast, only 2 of 20 (10%) implants in group A were placed in those positions, whereas 18 (90%) were placed subcrestally. While reports in the literature<sup>14,18</sup> have

attributed the location of the microgap, or implantabutment interface, to early crestal bone loss around successfully integrated implants, none have linked this factor to continuance of attachment loss after loading. In a study conducted by Hermann and coworkers,<sup>37</sup> results showed that in submerged implants, where the microgap was located below the crest of the bone, the tip of the gingival margin was located more apically than in nonsubmerged implants. Again, that study was analyzed under nonloaded conditions. In another study<sup>38</sup> in which implants were loaded either immediately or early, bone levels were analyzed for 3 groups: subcrestal, crestal, and supracrestal placement. The subcrestal group had the greatest amount of bone loss, followed by the crestal group. The supracrestal group had a slight amount of bone gain. The differences between groups were statistically significant. The authors attributed the differences to the location of the microgap. Hämmerle and associates<sup>13</sup> investigated the effect of subcrestal placement of the polished surface. After 1 year of function, there was a statistically significant higher amount of bone loss around implants with a polished collar placed subcrestally compared to implants with a polished collar located at the crest. The results of the present study are consistent with these findings.

Yet another factor implicated in the initial bone loss is the type of implant-abutment interface,<sup>39</sup> eg, internal versus external connectors. In the present study, only 1 type of implant-abutment interface was evaluated.

Although some studies have shown that implant body design (cylindric, conical, stepped, hollow cylindric, screw-type) plays a role in attachment and bone loss patterns,<sup>40–42</sup> other studies have not supported such findings.<sup>2,43</sup> Other human<sup>5,7,9</sup> and nonhuman primate<sup>44</sup> models have shown that occlusal overload related to poor prosthesis fabrication, clenching, bruxing, and/or lack of anterior or posterior contact can result in marginal bone loss of successfully integrated implants.

Following restoration of the implant, soft tissue margins may recede, thereby exposing the titanium collar,<sup>45–47</sup> an outcome considered unacceptable in the esthetic zone. A 2-year longitudinal study by Bengazi and coworkers<sup>47</sup> showed that a difference of 1.1 mm can exist between the gingival margin level of an implant compared to that of an adjacent natural tooth. In a previously mentioned study,<sup>45</sup> mean recession around TPS implants, when it occurred, was 1.6 mm. In addition, it is important to point out that in Adell and associates' 1986 study, soft tissue remodeling did occur in the absence of any changes in the underlying bone levels. Human studies have shown

that marginal bone loss around implants is accompanied by recession of peri-implant soft tissues.<sup>48,49</sup> If bone loss and attachment loss are correlated, as shown by the present results and those of Weber and colleagues,<sup>24</sup> the significance of evaluating periimplant soft tissue stability along with hard tissue stability should be emphasized.

## CONCLUSIONS

Single-tooth replacement implants are an essential treatment modality in the practice of dentistry. Longitudinal studies evaluating clinical parameters of success and failure of such treatment are lacking. To the knowledge of the authors, this is the first study that analyzes clinical parameters of patients and implants in relation to long-term stability and maintenance of peri-implant soft-tissue attachment. Analysis of data from single-tooth externally hexed TPS cylindric implants between years 1 and 5 of function determined the following clinical parameters to be, to a statistically significant level, associated with less than 0.25 mm per year of attachment loss: longer implants, lower GI, higher bone density, and position of the implant shoulder at the crest or supracrestally. Furthermore, the ALR was strongly correlated to BLR.

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