Clinical and Radiologic Outcomes after Submerged and Transmucosal Implant Placement with Two-Piece Implants in the Anterior Maxilla and Mandible: 3-Year Results of a Randomized Controlled Clinical Trial

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ABSTRACT

Purpose: The aim of this investigation was to evaluate the 3-year outcomes regarding crestal bone level, clinical parameters, and patient satisfaction, following submerged and transmucosal implant placement for two-piece implants in the anterior maxilla and mandible.

Materials and Methods: Patients requiring dental implants for single-tooth replacement in the anterior maxilla or mandible were enrolled in a randomized, controlled, multicenter clinical trial. The implants were randomized at placement to either submerged or transmucosal healing, with final restorations placed after 6 months. Radiographic and clinical parameters were recorded after 1, 2, and 3 years; a questionnaire was also used to assess patient satisfaction. A two-sided, unpaired T-test (significance level $p \leq .05$) was used to statistically evaluate the differences between the two groups.

Results: A total of 106 patients were included in the 3-year analysis. The mean change in crestal bone level from implant placement to 3 years was 0.68 ± 0.98 mm ($p < .001$) and 0.58 ± 0.77 mm ($p < .001$) in the submerged and transmucosal groups, respectively; the differences between the groups were not significant. Clinical parameters remained stable throughout the study, with no significant differences between the groups, and patient satisfaction was good or excellent for over 90% of subjects in both groups.

Conclusions: The results demonstrate excellent clinical and radiographic conditions after 3 years for implants supporting single-tooth restorations, regardless of whether a submerged or transmucosal surgical technique was used.

KEY WORDS: clinical and radiological outcomes, controlled clinical trial, dental implants, submerged, transmucosal placement

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INTRODUCTION

Implant therapy is a well-accepted solution for the replacement of missing anterior teeth, providing high survival rates (95–99%) when evaluated after 5 years in prospective studies.[1,2] This implant outcome, implant survival, has been reported as the main primary parameter to evaluate the performance of dental implants in 60.2% of all published studies. Implant success is the second most reported parameter (in 15.7%), although different success criteria have been used.[3] These parameters, although reporting the presence and functionality of the dental implant in the patient's mouth, do not reveal the status of the peri-implant tissues and hence are not currently considered as appropriate efficacy measures in clinical research. The focus has therefore switched to the evaluation of the long-term stability of peri-implant tissues by assessing radiological, aesthetic, and clinical parameters. The maintenance of the initially achieved peri-implant bone levels as coronally as possible is a key factor for long-term success and good aesthetic results of any implant treatment and, therefore, the maintenance of crestal bone levels has become one of the most critically appraised parameters.

Previously, crestal bone loss of less than 1 mm within the first year after implantation and less than 0.2 mm in subsequent years constituted an acceptable clinical standard.[4] With the advent of different implant designs currently available on the market and the use of new surgical protocols, there is a clear need to revise these success criteria and focus them on the existing demands of maintenance of aesthetics and function. A recently published meta-analysis evaluated the existing prospective studies of all implant systems available on the market reporting peri-implant marginal bone level changes with at least 5 years of follow-up.[1] Only three implant systems fulfilled the inclusion criteria: Astra Tech (Astra Tech AB, Mölndal, Sweden), Branemark (Nobel Biocare AB, Zürich, Switzerland), and Straumann dental implants (Institut Straumann AG, Basel, Switzerland). Mean marginal bone loss for all three systems amounted to well below 1 mm over a period of 5 years, placing them well within the success criteria suggested by Albrektsson and colleagues.[4]

Various factors have been identified as associated with crestal bone loss; some are related to the implant macrodesign and the connection between the implant and the abutment,[5] whereas others relate to the surgical technique, mainly the position of the most coronal rim of the implant in relation to the crest of the alveolar bone,[6,7] and whether the implants are submerged under the marginal mucosa during the healing period.[8] Furthermore, there are also methodological issues that may influence the outcome of the measurements, such as the use of different baseline measurements or different reference points.

Although many authors have provided evidence of successful osseointegration with one- or two-piece implants, as well as with either nonsubmerged or submerged installation protocols, there are a limited number of randomized, controlled clinical trials comparing both the submerged and transmucosal approaches of two-piece implant systems. Hammerle and colleagues[9] reported the 1-year results of a prospective, randomized, controlled multicenter clinical trial comparing two-piece bone level implants with either submerged or transmucosal healing placed in the anterior maxilla and mandible. The results demonstrated that submerged or transmucosal placement of these implants was equally successful in maintaining crestal bone levels. Less than 0.5 mm of crestal bone loss occurred in both groups, demonstrating that, irrespective of the surgical protocol used, implants placed in the anterior maxilla and mandible exhibited only a small amount of radiographic bone loss during the first year of function. These short-term results have not been evaluated over longer evaluation periods; therefore, the purpose of this publication is to report the 3-year outcome with respect to the same subject sample described by Hammerle and colleagues.[9]

MATERIALS AND METHODS

The detailed description of this clinical trial, including the sample population, experimental design, outcome measurement variables, and statistical analysis was described in the first publication reporting the 1-year results.[9] In brief, 145 patients were randomized to receive one implant in this controlled multicenter clinical trial, which was registered at Clinicaltrials.gov (http://clinicaltrials.gov/ct2/show/NCT00906425). The primary outcome measurement was the evaluation of the interproximal crestal bone levels by comparing the changes in these levels between placement of the implant (day of surgery) and 3 years postimplantation, between the transmucosal and the submerged implant groups. Secondary parameters were the determination of implant success and survival rates, periodontal and

peri-implant soft tissue parameters, patient satisfaction and safety outcomes. An independent statistician generated the randomization by providing randomization envelopes containing treatment allocations to each center. Eligible subjects were identified and randomly assigned to either the submerged or the transmucosal group after signing an informed consent form, previously approved by the respective Ethics Committees for each of the 12 participating centers.

All surgeons performing the implant surgeries were highly trained specialists, being different from the clinical investigators that collected all the measurements. They were trained to follow standardized procedures for measurement at one investigator meeting, although no calibration was performed. Immediately prior to the start of surgery, treatment allocation was carried out to either the submerged or the transmucosal treatment group. In both groups, two-piece implants (Straumann® Bone Level SLActive implant, intraosseous diameter 4.1 mm; Institut Straumann AG) were placed with sufficient primary stability according to the manufacturer's instructions.

In the submerged treatment group, a closure screw was placed and the mucosa was adapted and sutured over the implants for primary healing. These subjects underwent second stage surgery between 8 and 14 weeks later. The implant was then exposed, a healing abutment placed, and the mucosa adapted around the healing abutment.

In the transmucosal healing group, a healing abutment was placed and the mucosa was closely adapted to this abutment allowing for nonsubmerged healing. This abutment was removed 8 weeks after surgery when impressions were taken. Both closure screws and abutments were tightened to a torque of 15 Ncm. A temporary prosthesis was placed between weeks 8 and 14 after implant placement according to the treatment group. Thereafter, the treatment procedures were identical for both treatment groups with permanent reconstructions placed 26 weeks after implantation.

Standard periapical radiographs were taken immediately postoperatively and then once the permanent reconstruction was placed. At this time, radiographic, photographic, and clinical parameters were recorded. The same outcome measurements were measured at 1-, 2-, and 3-year postoperative visits.

Evaluation of crestal bone level changes was measured by standardized periapical radiographs. The changes at the mesial and distal crestal bone levels were used as reference, and the uppermost coronal edge of the implant platform and the length of the implant were used as an internal reference to adjust for distortion. The standardization was accomplished by using, for each patient, a custom-made bite block mounted on a film holder-beam aiming device (i.e., Rinn System [Dentsply International, York, PA, USA], RWT window X-ray system or similar). All the radiographs were collected and coded for a blinded analysis by two independent evaluators. If the differences between the two evaluators was >0.5 mm, the measurements were repeated and the conflict solved by agreement. Distal and mesial bone levels were measured and averaged for each implant.

Periodontal clinical parameters were recorded using a calibrated periodontal probe at the mesial and distal adjacent teeth and included probing pocket depths (PPD), bleeding on probing (BOP), and clinical attachment levels (CAL). These measurements were recorded at screening and at the 1-, 2-, and 3-year follow-up visits after implant placement.

The aesthetic appearance of the peri-implant soft tissue was visually assessed and recorded at final restoration, 1-, 2-, and 3-year follow-up examinations. Soft tissue measurements were taken starting 2 weeks post-surgery (Visit 3). These assessment parameters consisted of tissue form (normal or swollen), tissue colour (blue, pink, red, or white necrotic), and coverage (full coverage, dehiscence, or fenestration). The changes in the gingival/mucosal position and papilla height over time were measured on clinical photographs using a calibration mark attached to the implant. At these same follow-up visits, the patient completed a questionnaire in presence of the investigator for the assessment of the patient satisfaction on the performance of the final restoration.

The presence of adverse events (AEs) was assessed at each study visit, and if present, the appropriate treatment was initiated and subject continuation was reevaluated. Serious AEs were immediately reported to the trial coordination center and were monitored and followed up until the end of study treatment unless related to the device. The survival analysis was calculated by the percentage of implants in place at the different evaluation visits.

Statistical Analysis

Detailed information on the statistical analysis was reported in the one-year publication.[9] In brief, the sample size was calculated to detect differences in

marginal bone levels of 0.1 mm with a common standard deviation up to 0.2 mm. Based on these calculations, a sample of 134 subjects was required, homogeneously distributed among the 12 participating centers. Descriptive summary statistics were calculated separately for each treatment group and visit. For quantitative parameters, means, standard deviation, median, quartiles, minimum, and maximum were used, while for qualitative variables, absolute, and relative frequencies were calculated. The statistical analysis was based on the intent-to-treat (ITT) population by comparing the mean changes between the two implant groups at the 2- and 3-year evaluation visits, using the two-sided, unpaired *t*-test, with the significance level being set at $p \leq 0.05$.

RESULTS

Patient Demographics

From the total of 145 randomized patients that received an implant, 127 subjects attended the 1-year visit and 106 remained in the study until the 3-year evaluation visit (ITT analysis). The patient flow chart, including the reasons for patient dropout, is depicted in Figure 1.

Of these 106 subjects, 54 (51%) were included in the submerged treatment group and 52 (49%) in the transmucosal treatment group. The demographics of the subject cohort and treatment-specific details at 12 months were provided in the previous publication.[9]

Table 1 shows the distribution of implants by tooth position and arch. Most of the implants were placed in the maxilla, as only 14 out of 105 implants were placed in the mandible. The anterior maxillary teeth (from 13 to 23) accounted for most of the sample in both treatment groups.

Bone Level Changes

The efficacy analysis at 3-year postimplantation was performed on the ITT group (106 subjects). Crestal bone level change was also assessed between Visit 2 (1st stage) and Visit 7 (1-year follow-up), and Visit 8 (2-year follow-up) and Visit 9 (3-year follow-up). At 3 years, the submerged group lost 0.68 mm of crestal bone from baseline (SD ± 0.98 mm, $p < .001$, $n = 67$), whereas the transmucosal group lost 0.58 mm (SD ± 0.77 mm, $p < .001$). Differences between the treatment groups were not statistically significant. Figure 2A and B depict

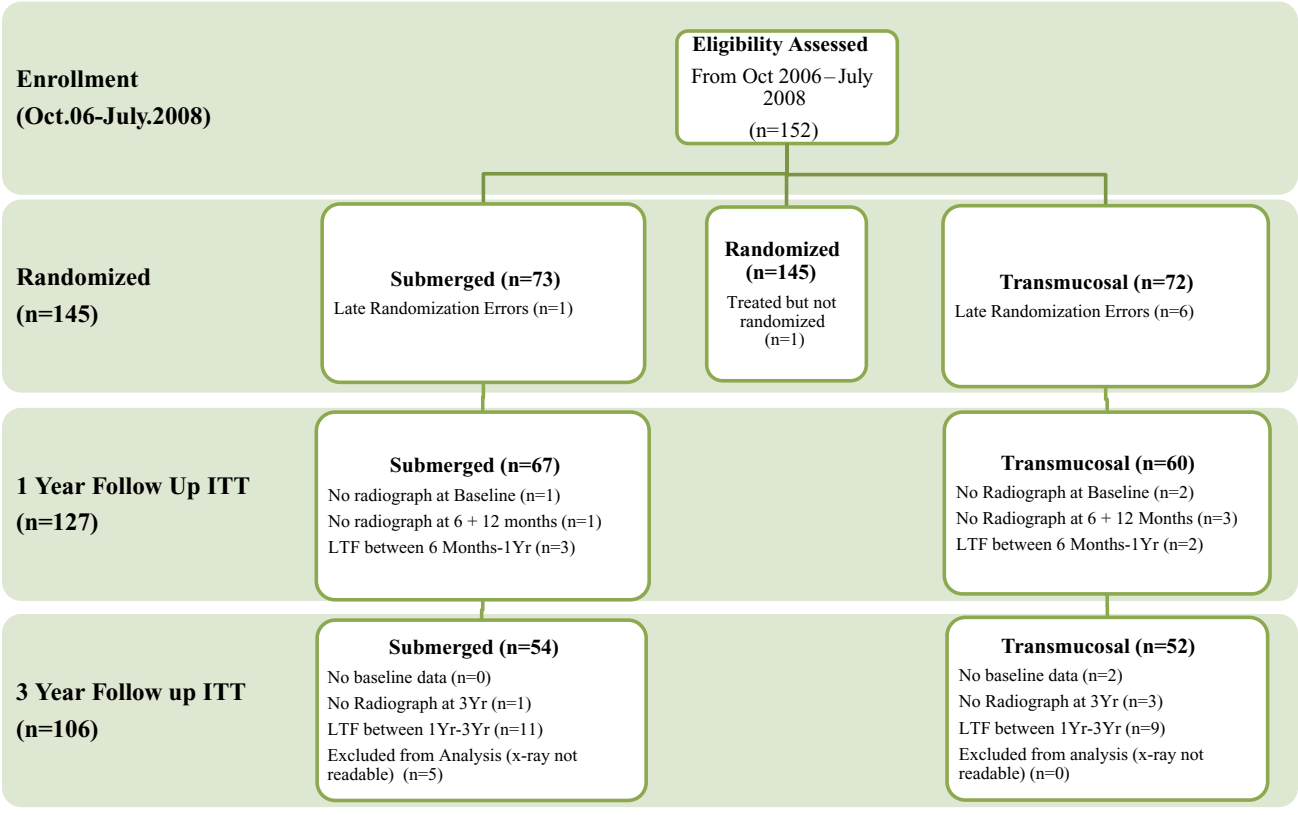

Figure 1 Study patient flow chart.

TABLE 1 Implant Position (FDI System) Categorized at First Stage Surgery (Visit 2)

	Submerged		Transmucosal		Total	
Implant Position	*n*	%	*n*	%	*n*	%
11	9	15.0	5	8.5	14	11.8
12	5	8.3	5	8.5	10	8.4
13	1	1.7	0	0.0	1	0.8
14	7	11.7	4	6.8	11	9.2
15	7	11.7	6	10.2	13	10.9
21	8	13.3	6	10.2	14	11.8
22	4	6.7	4	6.8	8	6.7
23	2	3.3	2	3.4	4	3.4
24	7	11.7	15	25.4	22	18.5
25	4	6.7	4	6.8	8	6.7
35	3	5.0	5	8.5	8	6.7
43	0	0.0	1	1.7	1	0.8
44	2	3.3		0.0	2	1.7
45	1	1.7	2	3.4	3	2.5
Patient total	60	100.0	59	100.0	119	100.0

FDI = Federation Dentaire Internationale.

changes in crestal bone level in millimeters, relative to the shoulder of the implant (mean of mesial and distal measurements per implant) from the implant placement surgery to 1, 2, and 3 years postoperatively for both the submerged and the transmucosal groups. In both groups, more than half of the total bone level change occurred during the first year (0.47 and 0.48 mm, respectively). From 1 to 3 years, there was a gradual but small loss of bone in both treatment groups (0.21 vs 0.10 mm in the submerged and transmucosal groups, respectively).

Figure 3 depicts the frequency distribution of the bone level changes at 3 years in both groups (mean of mesial and distal measurements per implant). In the transmucosal group, 59% of the sites were stable (within 0.5 mm), whereas the equivalent proportion in the submerged group was 49%. The percentage of sites losing more than 1.5 mm was similar in both treatment groups (19% in the submerged group and 18% in the transmucosal group).

Changes in the Periodontal Clinical Parameters at the Adjacent Teeth

Table 2 shows the percentages of BOP at the teeth adjacent to the implant site at implantation, permanent restoration, and at the 1-, 2-, and 3-year postimplantation visits in both the submerged and the transmucosal groups. At 1 year, the percentage of surfaces bleeding in both treatment groups was low (around 10%). These percentages did not change significantly during the 3 years of the study.

Figures 4 and 5 show the changes in CAL and PPD at teeth adjacent to the implant sties in both treatment groups. These clinical parameters remained unchanged during the 3 years of the study, demonstrating shallow PPD (2.0–2.5 mm) and stable CAL (within 0.5 mm) in both treatment groups.

Aesthetic Evaluation of the Permanent Restorations

At 1 year postimplantation, full tissue coverage was also observed in 97% and 100% of the subjects in the submerged and transmucosal groups, respectively (Figure 6). These percentages remained unchanged during the study. At 3 years, 98% of the implants demonstrated full tissue coverage in both the submerged and transmucosal groups. Figure 7 shows the outcome of tissue colour changes during the study. At 3 years, 90.2% in the transmucosal and 87% in the submerged group demonstrated healthy pink colour; only 9.4% and 7.8%, respectively, showed red tissue colour. In terms of tissue form, Figure 8 shows the evolution throughout the study. At 3 years, 92.5% in the transmucosal and 94.1% in the submerged group demonstrated normal tissue

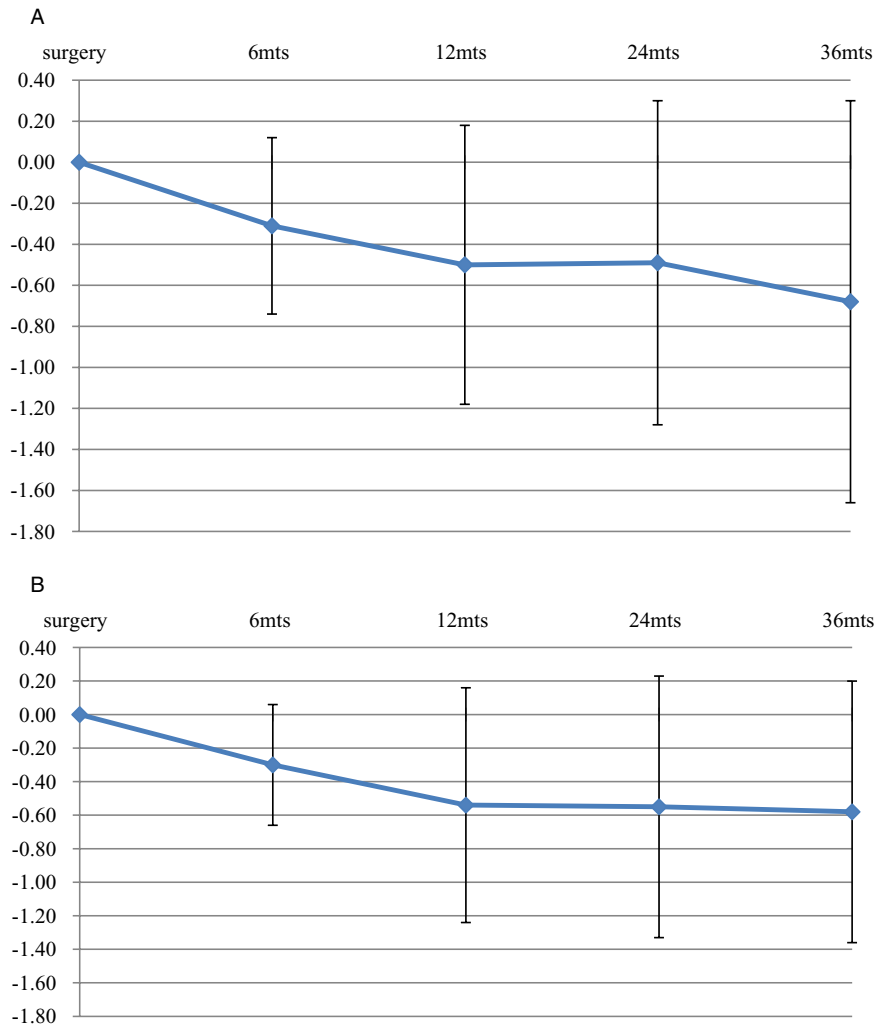

Figure 2 Changes in crestal bone level in millimeters, relative to the shoulder of the implant: *A*, submerged group; *B*, transmucosal group.

form; only 7.5% and 5.9%, respectively, showed swollen tissue form.

Patient Satisfaction

Figure 9 depicts the frequency distribution of the scores rated by the patients (excellent, good, fair, and poor) to the different aspects requested in the questionnaire (comfort, appearance, ability to chew, taste, and fit of the restoration). In general, 3 years after implant placement, the reported patient satisfaction was good to excellent in more than 90% of the subjects in both treatment groups for all the categories. It was quoted as excellent in a range between 70 and 80% for all categories (comfort, appearance, taste, ability to chew, and fit) in both treatment groups. In 11% of the patients from the submerged group, the level of satisfaction with the appearance was fair, whereas this score was only reported in 2% of the patients in the transmucosal group. No patient in any of the groups rated any of the tested categories as poor. The highest score in both groups was given for comfort (rated as excellent for 79% and 82% of patients in the submerged and transmucosal groups, respectively).

Implant Survival and Adverse Effects

Table 3 depicts the cumulative survival rate of implants in both treatment groups. At 3 years, 100% of the implants in the submerged group remained functional, whereas the corresponding percentage in the transmucosal group was 98.1% (one implant was lost). Differences between groups were not statistically significant. No serious adverse effects were reported during the study.

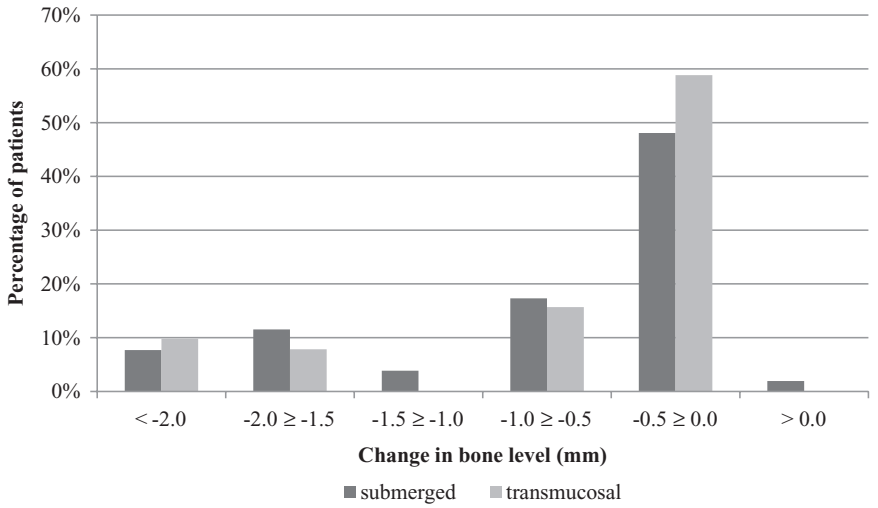

Figure 3 Frequency distribution of the bone level changes at 3 years.

DISCUSSION

The results of the present 3-year follow-up clinical study have demonstrated excellent clinical conditions at single-tooth implant-supported restorations irrespective of the surgical technique used for the implant installation, as both submerged and transmucosal placement of two-piece implants was equally successful in maintaining crestal bone levels. At 3 years, the submerged group lost 0.68 mm of crestal bone from baseline (SD ± 0.98 mm, $p < .001$, $n = 67$), whereas the transmucosal group lost 0.58 mm (SD ± 0.77 mm, $p < .001$). The difference in the change in bone level between the two treatment groups was not significant. Although the crestal bone levels were stable (within 0.5 mm) throughout the study in more sites in the transmucosal group (59%), when compared with the submerged group (49%), these differences were not statistically significant. In addition, the percentage of sites with bone loss ≥1.5 mm was similar in both treatment groups (19% in the submerged group and 18% in the transmucosal group). These results are in agreement with the results reported by Ericsson and colleagues[10] for implant-supported restorations in edentulous mandibles and those reported by Cecchinatto and colleagues for implants placed in the posterior maxilla and mandible.[8] In both studies, the reported crestal bone level changes at 5 years were small and did not differ between the submerged and transmucosal implants, although the

TABLE 2 Adjacent Teeth and Surfaces Examined That Exhibited Bleeding on Probing (Number and Percentage of Surfaces) at Both Test Sites for Each Adjacent Tooth for All Subjects

	Screen		Restoration		1 Year		2 Years		3 Years	
	Subm	Trans	Sub	Trans	Subm	Trans	Subm	Trans	Subm	Trans
Patients	54	52	54	52	54	51	54	51	53	51
Tooth No. 1										
Number of teeth examined	53	52	45	47	53	49	49	48	51	49
Number of Surfaces examined	105	103	89	94	106	98	98	96	101	98
Number of Surfaces Bleeding	4	3	9	9	9	10	4	10	4	11
Percentage (%) of surfaces bleeding	3.8	2.9	10.1	9.6	8.5	10.2	4.1	10.4	4.0	11.2
Tooth No. 2										
Number of teeth examined	52	52	45	46	52	48	49	48	49	49
Number of surfaces examined	104	104	90	91	103	96	97	96	98	98
Number of surfaces bleeding	9	8	6	9	7	9	7	10	8	9
Percentage (%) of surfaces bleeding	8.7	7.7	6.7	9.9	6.8	9.4	7.2	10.4	8.2	9.2

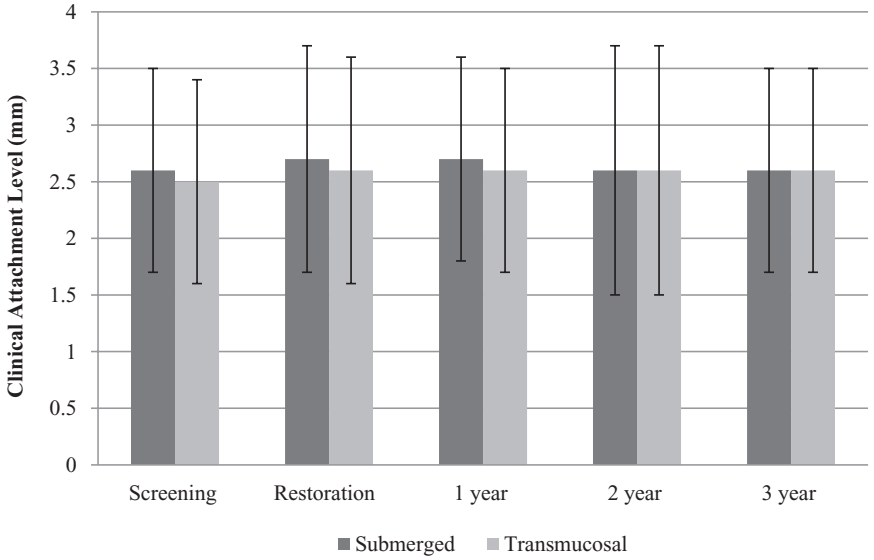

Figure 4 Changes in clinical attachment levels (CAL) at teeth adjacent to the implant sites in both treatment groups.

evaluation methodology was different in comparison with this study. In the Ericsson and colleagues[10] study, the bone level changes were reported between 18 months and 5 years, but not from the time the implant was installed. Similarly Cecchinato and colleagues reported the bone level changes from the time of placement of the bridge (FPD) to the 1- and 2-year reexaminations[11] and to the 5-year follow-up.[8]

In a subpopulation of a prospective multicenter, randomized clinical trial (RCT), Cordaro and colleagues[12] compared the clinical outcomes after 2 years with bone level implants placed to restore single missing teeth that needed simultaneous augmentation and were treated with a transmucosal or submerged approach. In both groups, small amounts of bone resorption were reported (0.37 ± 0.49 mm in the submerged group and 0.54 ± 0.76 in the nonsubmerged group), which are almost identical to those reported in this clinical trial. The authors concluded that single implants placed in the aesthetic zone in conjunction with bone augmentation will heal similarly, irrespective whether the surgical technique was submerged or transmucosal. Although experimental studies in nonloaded implants comparing submerged and nonsubmerged healing have shown that

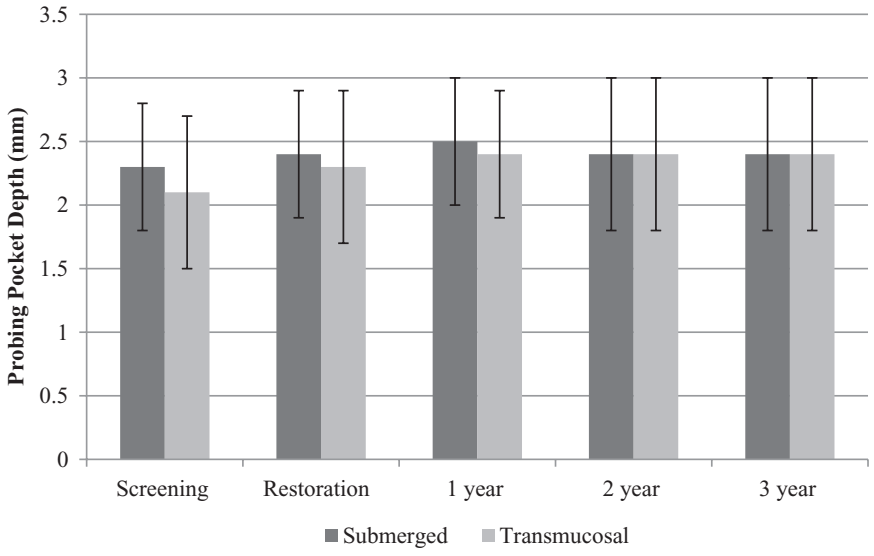

Figure 5 Changes in probing pocket depths (PPD) at teeth adjacent to the implant sites in both treatment groups.

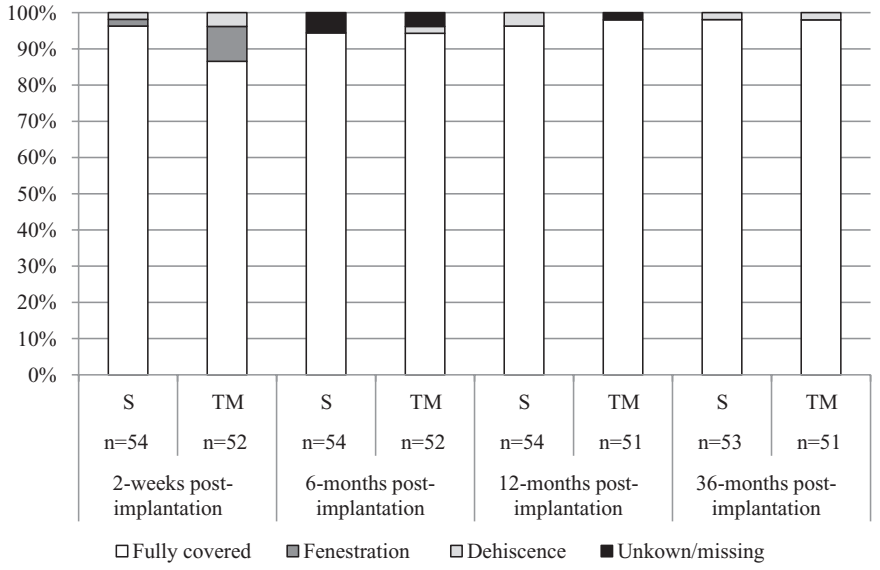

Figure 6 Aesthetic evaluation. Frequency distribution of soft tissue coverage.

the apical extension of the peri-implant epithelium was significantly greater and the attachment level significantly lower adjacent to submerged implants than in transmucosal implants,[13] the evaluation of the height of the mucosa and the percentage of bone-to-implant contact have rendered similar outcomes when the submerged and transmucosal groups were compared, thus demonstrating that the conditions for tissue integration were similar in both groups.[14]

Apart from the submerged or transmucosal healing conditions, other factors related to the implant surgical technique have been studied for their influence on the maintenance of crestal bone levels. The three-dimensional implant position with respect to the bone crest seems to influence the stability of the peri-implant marginal bone. Indeed, in experimental animals, increased bone loss has been reported when the implant shoulder has been placed 1 mm below the alveolar crest.[15] Similarly, in humans, an RCT using soft tissue level Straumann implants either placed with the shoulder at bone level or 1 mm below demonstrated more crestal bone loss with the lower placement.[16] These crestal changes have been explained by the need of the reestablishment of the peri-implant biological

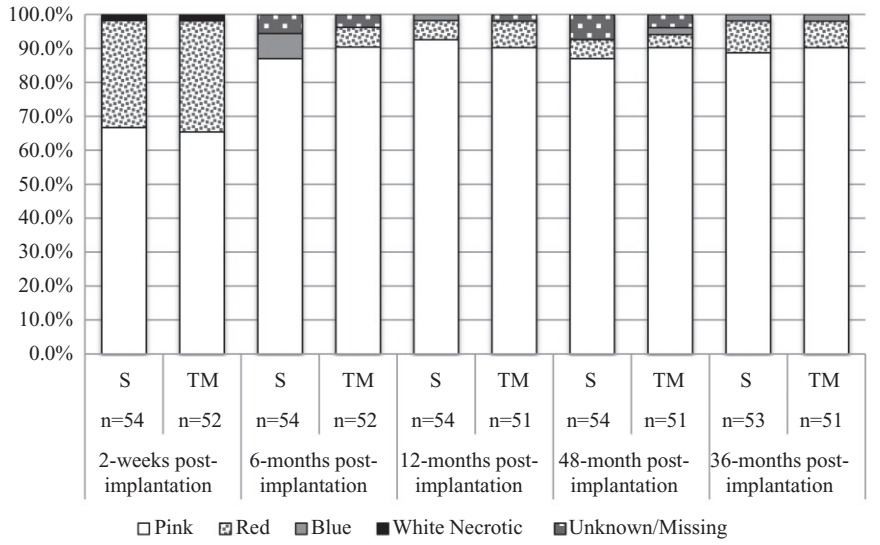

Figure 7 Aesthetic evaluation. Frequency distribution of the tissue color changes.

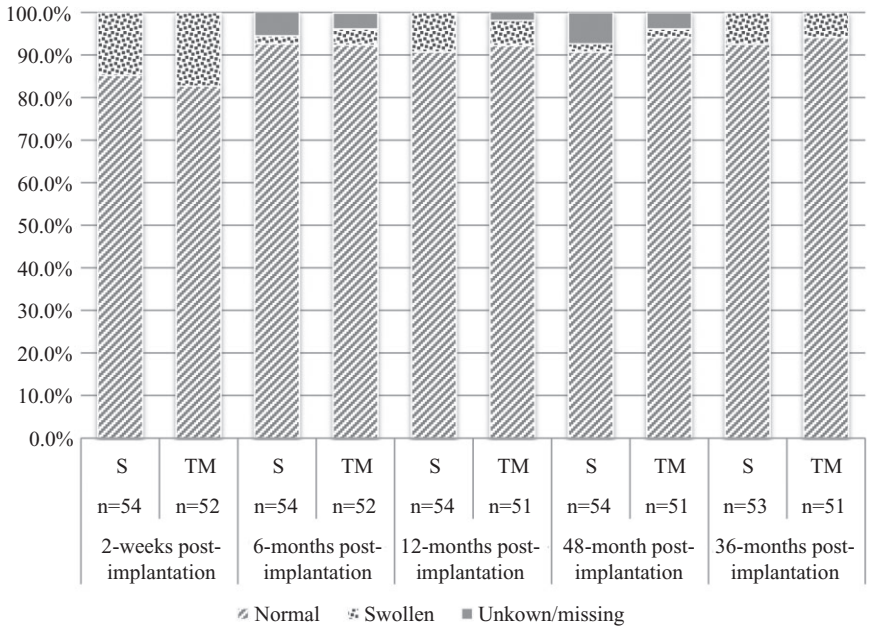

Figure 8 Aesthetic evaluation. Frequency distribution of the tissue form.

width,[17] which will occur physiologically regardless of the surgical technique[14,15] and implant system.[18] Moreover, if the implant is placed close to the adjacent teeth/implants[19] or to a thin residual buccal wall,[6] more crestal bone loss should be expected. Recently, the degree of mismatching between the implant and the abutment has also been demonstrated to significantly influence the maintenance of crestal bone levels.[20,21] The inward shifting of the implant-abutment interface apparently provides better spatial distribution of the biological width and diminishes the possible microbial leakage or micromovements[22,23] that may be associated with crestal bone level changes during the first stages of implant healing. A recent systematic review supports the efficacy of this concept by demonstrating a correlation between the degree of platform switching and the maintenance of crestal bone levels.[24]

The changes in the crestal bone levels reported in the present clinical trial are well below the values presented in previous studies. In a recent meta-analysis, only three implant systems showed mean values for marginal bone loss below 1 mm over a period of 5 years.[1] The pooled mean marginal bone level change

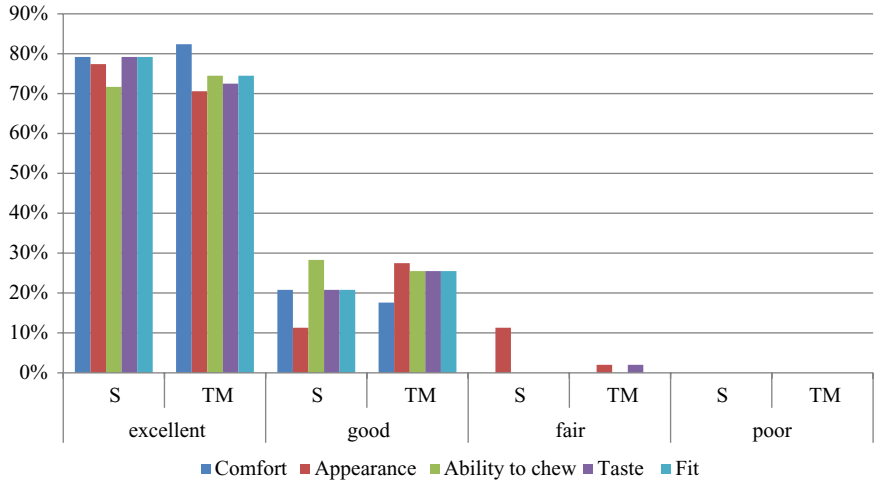

Figure 9 Patient satisfaction. Frequency distribution of the scores rated by patients (excellent, good, fair, and poor).

TABLE 3 Implant Survival (Missing Data Excluded) Based on All Patients at Second Stage Surgery, Temporary Prosthesis Placement, Final Restoration, and after 1, 2, and 3 Years

	Submerged		Transmucosal		Total	
	n	%	*n*	%	*n*	%
V4, 2nd stage surgery						
Surviving implant	54	100.0	36	100.0	90	100.0
Patients	54		36		90	
V5, temp. prosthesis placement						
Surviving implant	53	100.0	52	100.0	105	100.0
Patients	53		52		105	
V6, Final restoration						
Failing implant	0	0.0	1	2.0	1	1.0
Surviving implant	51	100.0	49	98.0	100	99.0
Patients	51		50		101	
V7, 1-year follow-up						
Surviving implant	54	100.0	50	100.0	104	100.0
Patients	54		50		104	
V8, 2-year follow-up						
Surviving implant	50	100.0	49	100.0	99	100.0
Patients	50		49		99	
V9, 3-year follow-up						
Surviving implant	53	100.0	51	100.0	104	100.0
Patients	53		51		104	
Cumulative survival						
Surviving implant	53	100.0	51	98.1	104	99.0
Failing implant	0		1	2.0	1	1.0
Patient total	53		52		105	

amounted to 0.48 mm over 5 years for the Straumann Dental Implant System, which is very similar to that obtained in this investigation. Similarly, prospective studies using the same implant type (Straumann Bone Level Implant) as that used in the present study have reported minimal bone loss and excellent aesthetic outcomes over 3 years follow-up (mean 0.18 mm) when using an early implant placement protocol.[25]

The immediate placement of dental implants has also been advocated as a likely risk factor for marginal bone loss, and a recent systematic review reported a mean crestal bone loss of about 0.8 to 1.0 mm, occurring mostly during the first year after implant placement.[26] The stability of the interproximal marginal bone levels, however, depends more on the presence of neighboring teeth than on the implant surgical protocol per se, which usually affects the buccal and lingual bone plates.[7,27] In fact, clinical trials comparing immediately placed implants with implants placed in healed ridges have not shown differences in marginal bone level changes, demonstrating minimal interproximal crestal bone level changes in both.[28]

In the present study, the periodontal and soft tissue parameters also demonstrated minimal changes over the 3-year follow-up. The patients in both treatment groups showed minimal gingival inflammation, shallow probing depths, and maintenance of CAL. The majority of subjects in both groups had normal tissue form and pink color, as well as full tissue coverage, indicating healthy peri-implant soft tissues. Over the 3 years, only one implant was lost in the transmucosal group at 6 months postimplantation, yielding very high implant survival rates in both groups, which is in agreement with a recent systematic review on the survival and incidence of complications of single-tooth implant restorations.[29]

In conclusion, the results of the present 3-year follow-up clinical study have demonstrated excellent

clinical and radiographic conditions at single-tooth implant-supported restorations irrespective of the surgical technique used for the implant installation.

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