A 5-Year Esthetic RCT Assessment of Anterior Maxillary Single-Tooth Implants with Different Abutment Interfaces

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Purpose: This study sought to define the tissue responses at different implant-abutment interfaces by studying bone and peri-implant mucosal changes using a 5-year prospective randomized clinical trial design study. The conus interface was compared with the flat-to-flat interface and platform-switched implant-abutment systems. ***Materials and Methods:*** One hundred forty-one subjects were recruited and randomized to the three treatment groups according to defined inclusion and exclusion criteria. Following implant placement and immediate provisionalization in healed alveolar ridges, clinical, photographic, and radiographic parameters were measured at 6 months and annually for 5 years. The calculated changes in marginal bone levels, peri-implant mucosal zenith location, papillae lengths, and peri-implant Plaque Index and bleeding on probing were statistically compared. ***Results:*** Forty-eight conus interface implants, 49 flat-to-flat interface implants, and 44 platform-switched implants were placed in 141 subjects. Six platform-switched interface and eight flat-to-flat interface implants failed, most of them within 3 months. After 5 years, 33 conical interface, 28 flat-to-flat interface, and 27 platform-switched interface implants remained for evaluation. Calculation of marginal bone level change showed a mean marginal bone loss of −0.16 ± 0.45 (−1.55 to 0.65), −0.92 ± 0.70 (−2.90 to 0.20), and −0.81 ± 1.06 (−3.35 to 1.35) mm for conical interface, flat-to-flat interface, and platform-switched interface implants, respectively ($P < .0005$). The peri-implant mucosal zenith changes were minimal for all three interface designs (0.10 mm and +0.08 mm, $P > .60$). Only 16% to 19% of the surfaces had presence of bleeding on probing, with no significant differences ($P > .81$) between groups. Interproximal tissue changes were positive and similar among the implant interface designs. ***Conclusion:*** Over 5 years, the immediate provisionalization protocol resulted in stable peri-implant mucosal responses for all three interfaces. Compared with the flat-to-flat and platform-switched interfaces, the conical interface implants demonstrated significantly less early marginal bone loss. The relationship of marginal bone responses and mucosal responses requires further experimental consideration. *Int J Oral Maxillofac Implants 2021;36:165–176. doi: 10.11607/jomi.8333*

Keywords: esthetics, immediate loading, marginal bone levels, peri-implant mucosa, randomized controlled clinical trial

Dental implant therapy includes a growing appreciation for the success of single-tooth implant therapy, anchored in the need for esthetic outcomes of care in what is now a predictable modality of treatment. Yet, there are biologic and technical complications impacting patients and clinicians. This is borne out in systematic reviews and large retrospective studies reporting on single-tooth implants.[1,2] Five-year implant survival rates of greater than 95% have been reported in association with technical complications, such as screw loosening, veneer fracture, and loss of retention, amounting to cumulative rates of approximately 9%. Regarding biologic complications including peri-implantitis and infection and soft tissue complications including soft tissue recession, a 7% incidence has been recorded. Thus, it may be concluded that biologic and technical complications are revealed during the first 5 years of single-tooth implant restoration function.

A common site for single-tooth implant therapy is the replacement of nonrestorable maxillary anterior teeth, as a result of aplasia, trauma or associated root resorption, recurrent caries, or recurrent infection. In this region of the mouth, esthetic outcomes are often the most important parameters for patient-oriented

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Submitted February 6, 2020; accepted September 1, 2020.

outcomes. This has been exemplified by the development of clinical scoring systems for the evaluation of dental implant esthetics including the pink esthetic score (PES),[3] related PES/white esthetic score (WES),[4] and the Implant Crown Aesthetic Index (ICAI),[5] among others.[6] The objective scoring of single-tooth implant esthetics is associated with patient satisfaction and the overall success of clinical implant practice. Although clinicians are more critical in evaluating implant esthetics, clinician measures are correlated with patient perceptions of peri-implant soft tissue.[7] The papilla and facial gingival margin represent key parameters affecting implant esthetic success,[8] and facial recession and the absence of papillae are reported. Thus, the biologic and technical foundations are important factors in the determination of single-tooth implant esthetics.

Assuming implant placement has been successfully planned and achieved,[9] peri-implant facial mucosal stability is associated with four risk factors: improper facial implant position, thin soft tissue biotype, a thin buccal bone plate, and smoking.[10] These factors, alone or separately, alert clinicians as to potential instability of the facial peri-implant mucosa and promote adjunctive therapies to enhance esthetic outcomes. The papilla architecture is dependent on the adjacent tooth connective tissue attachment levels. Many factors, including peri-implant tissue biotype, the facial bone thickness, the depth of implant placement, and the levels of the first-bone-to-implant contact, contribute to peri-implant mucosal stability or recession.[11] Other factors, such as the implant-abutment interface, have been suggested to influence the peri-implant bone levels[12] and, perhaps, peri-implant mucosa behavior over time.

The role of the implant-abutment design on biologic tissue responses in implant dentistry has been debated for many years.[13–16] While an assumed relationship of peri-implant mucosal changes related to peri-implant bone changes is suggested, there remains little data to support this supposition.[17] In this report, the results of a 5-year prospective randomized clinical trial compare the peri-implant tissue responses at three different implant-abutment systems.

MATERIALS AND METHODS

Overview

This report extends observations made in previously published 1- and 3-year reports.[18] This was a prospective, randomized, expertise-based trial designed to address the hypothesis that facial peri-implant mucosal stability and marginal bone responses at different implant-abutment systems differ over time. Participants requiring maxillary anterior or maxillary first premolar tooth replacement using a single dental implant protocol were recruited, referenced as the institutional review board (IRB) approved protocol (UNC 08-2024). Participants were screened based on defined inclusion and exclusion criteria typical of such studies but also requiring the alveolar site being edentulous for at least 5 months, of minimal 5.5-mm buccolingual dimension, 5.5-mm distance between adjacent teeth, keratinized midbuccal height of at least 2 mm, and an opposing fixed dentition.[18] Participants were treated for a single missing tooth using an immediate provisionalization protocol with one of three different implant systems: conical interface system (OsseoSpeed TX, Dentsply Sirona), a flat-to-flat interface system (NobelSpeedy, Nobel Biocare), or a platform-switched (platform-switched interface) system (NanoTite Certain PREVAIL, Biomet 3i).

Clinical Procedures

Following obtaining of informed consent, teeth were extracted, and ridge preservation was performed using recombinant human bone morphogenetic protein (rhBMP; Infuse, Medtronic); healed ridges were augmented using the same material. As described previously,[18] BMP-2/ACS collagen (Infuse) was used for grafting of 66 of 68 extraction sockets and 42 of 73 healed ridges. It was mixed with space-maintaining materials, including anorganic bone and mineralized bone products. Barrier (collagen) membranes were applied in 28 of 109 (25.6%) of grafted sites. Five months following, one of the three types of dental implants and related titanium abutments were placed according to the respective manufacturer's recommendation using an acrylic provisional crown in an immediate provisionalization protocol. Implants with primary stability as clinically defined by the absence of axial or rotational movement during abutment placement were provisionalized. Baseline periapical radiographs were made. At 8 weeks following implant placement, implant-level impressions were made of all implants. Zirconia abutments (Atlantis, Dentsply Sirona) and pressed lithium disilicate (IPS e.max, Ivoclar Vivadent) crowns were made by one laboratory. The crowns were cemented using a resin-based cement (RelyX, 3M ESPE). Participants returned at 6, 12, 36, and 60 months for clinical and periapical radiographic evaluations. The detailed clinical procedures have been reported previously.[19]

Evaluations

The primary outcome measure for this study was the peri-implant mucosal change from baseline to 1 year. The study sought to determine implant survival, marginal bone level alterations at the mesial and distal aspects of implants, soft tissue changes, Plaque Index, bleeding on probing, and probing depths. The study design also included esthetic assessments using the PES and patient-reported outcomes, both of which are subjects of separate reports.[20] Over the 5-year

Table 1 Participant Demographics

	Conical interface	Flat-to-flat interface	Platform-switched interface	Total subjects
Age (y), mean ± SD	43 ± 15	46 ± 17	46 ± 16	45 ± 16
Male/female, n (%)	25 (52%)/23 (48%)	14 (29%)/35 (71%)	22 (50%)/22 (50%)	61 (43%)/80 (57%)
Nonsmoker, n (%)	33 (69%)	35 (71%)	33 (75%)	101 (72%)
Bruxer, n (%)	15 (31%)	10 (20%)	7 (16%)	32 (23%)
Relevant medical hx, n (%)	31 (65%)	34 (69%)	28 (64%)	93 (66%)
Dentition (natural teeth/32)	70.90%	75.10%	71.20%	72.50%
Edentulous period (mo)	28 ± 46	28 ± 79	17 ± 25	25 ± 56
Periodontitis, n (%)	0	1 (2%)	0	1 (0.7%)
Tooth lost to trauma, n (%)	18 (37.5%)	16 (32.7%)	13 (29.5%)	47 (33.3%)

Table represents all patients enrolled. There were no significant differences among groups.

period, participants were scheduled for evaluations at 6 months and 1, 3, and 5 years.

Implant Survival

Every implant was categorized as surviving (in situ), failed (removed), or lost to follow-up. Implant failures and implant-related complications were recorded as adverse events.

Marginal Bone Levels

The vertical bone location relative to the implant-abutment reference point and changes in marginal bone levels was measured from digital periapical radiographs by a radiologist who was not involved in the clinical aspects of the study and was masked to the subject image being evaluated. The mean of the mesial and distal aspect measures at each implant was calculated, and the changes in the mean distances from baseline (implant placement) to up to 5 years was determined.

Soft Tissue Health Parameters

Bleeding on probing and peri-implant probing depth measures were made using standard methods with a calibrated UNC 15 probe.[18] Plaque scores, recorded at the 3-year recall, were low (approximately 10% of surfaces, and significantly reduced from baseline)[19] and were not recorded at the 5-year recall period.

Peri-implant Mucosal Linear Architectural Analyses

The position of the midfacial mucosal zenith and the papilla were recorded using the Canfield apparatus (Canfield Scientific), which positioned the region of interest to geometrically reproduce images over time.[18] All four centers used identical cameras and settings at all visits. A periodontal probe was included in images to calibrate all dimensions. The location of the peri-implant mucosal zenith and mesial and distal papillae were identified in .jpg images using ImageJ (National Institutes of Health) software. The changes in soft tissue positions from baseline (provisional and definitive crown delivery) were statistically analyzed.

Statistical Analyses

This study was analyzed using an intention-to-treat approach. Implant survival was evaluated by Fisher exact test. The within-group and between-group comparisons were calculated using nonparametric statistics (Wilcoxon signed-rank test and Mann-Whitney *U* test, respectively) using PASW Statistics for Windows, version 18.0 (Splatform switched interfaceS). A two-sided $P < .05$ was considered statistically significant. Demographics and other baseline characteristics are presented by means of descriptive statistics.

RESULTS

Recruitment and Retention of Participants

Forty-one participants were enrolled and randomized to receive conical interface implants (n = 48), flat-to-flat interface implants (n = 49), and platform-switched interface implants (n = 44). The implants were placed in regenerated rhBMP2 site preserved sockets (n = 66) and augmented alveolar ridges (n = 42).[18] Two extraction sites (deciduous teeth) did not require preservation, and 31 residual alveolar ridges did not require augmentation for implant placement. The demographic details of the recruited and retained participants (sex, smoking status, oral health status) are reported in Table 1.

One hundred forty-one participants were treated using 156 implants (conical interface = 48 subjects/53 implants; flat-to-flat interface = 49 subjects/53 implants; platform-switched interface = 44 subjects/50 implants). Fifteen implants were randomly excluded from analysis at the time of placement in order to achieve one study

Table 2 Disposition of Participants

	Implants evaluated	Implant failure	Lost to follow-up	Visit not performed	Not willing to continue
Conical interface					
Implant placement	48				
Postop 1 wk	47			1	
Postop 4 wk	47			1	
Impression	48				
Definitive restoration	48				
6 mo	43			5	
1 y	46		2		
2 y	45		1		
3 y	45			3	7
4 y	35				5
5 y	33				
Flat-to-flat interface					
Implant placement	49				
Postop 1 wk	49				
Postop 4 wk	46	3			
Impression	43	3		8	
Definitive restoration	43		3		
6 mo	32		1		
1 y	39		3		
2 y	36		1		1
3 y	34			2	5
4 y	27		1		
5 y	28				
Platform-switched interface					
Implant placement	44				
Postop 1 wk	43			1	
Postop 4 wk	44				
Impression	42	2			
Definitive restoration	39	3			
6 mo	34		2	5	
1 y	37		1		
2 y	34		3	1	
3 y	32				4
4 y	28		1		
5 y	27				

All participants were accounted for by implant failure, loss to follow-up, visit not performed, and not willing to continue (extending to 5-year evaluations under extended IRB protocol and consent).

implant/participant. Fourteen implants were lost during the first year due to failure of osseointegration, as noted by mobility without infection; an additional 17 participants refused to participate for an additional evaluation at 5 years upon re-consenting for this 5-year evaluation. Twenty-two participants were lost to follow-up. At the 5-year follow-up visit, 33 conical interface implants, 28 flat-to-flat interface implants, and 27 platform-switched interface implants were available for evaluation in the equivalent number of subjects (Table 2). The amount and type of preparatory grafting performed did not differ among the three study groups (Table 3). The average period of edentulism at the time of surgery was 28 ± 46 months for conical interface implants, 28 ± 79 months for flat-to-flat interface implants, and 17 ± 25 months for platform-switched interface implants. Immediate provisionalization was delayed for 10 conical interface (20.8%), 7 flat-to-flat interface (14.3%), and 9 platform-switched interface (20.5%) implants due to the lack of primary stability, as indicated by clinical

Table 3 Implant Site Procedural Characteristics

	Conical interface n = 48 (34%)		Flat-to-flat interface n = 49 (35%)		Platform-switched interface n = 44 (31%)		Total subjects n = 141 (100%)	
	Count	%	Count	%	Count	%	Count	%
Extraction only	0	0	1	2.0	1	2.2	2	1.4
Extraction with preservation	24	50.0	23	46.9	19	43.2	66	46.8
HR	10	20.8	13	26.5	8	18.2	31	22.0
HR with graft	14	29.2	11	22.4	13	29.5	38	27.0
HR with soft tissue graft	0	0	1	2.0	3	6.8	4	2.8
Flap procedure	21	43.8	18	36.7	18	40.9	57	40.4
Primary stability achieved[a]	45	93.8	48	98	40	90.9	133	94.3
Provisionalization								

Table represents all patients enrolled. There were no significant differences among groups. [a]Determined by clinician.
HR = healed ridge; Provisionalization = insertion of stock Ti abutment and cement-retained acrylic provisional crown free of occlusal contacts.

mobility (axial or rotational) of the implant at abutment attachment. No major protocol deviations were recorded, and minor protocol deviations were related to visit delays that did not impact study outcomes.

Implant Survival

No conical interface implants failed. In the flat-to-flat interface group, six implants failed to osseointegrate and were removed 3 to 8 weeks after implant placement. Two additional flat-to-flat implants were removed at the time of definitive crown placement due to lack of osseointegration. Regarding the platform-switched interface group, five implants failed to osseointegrate and were removed during the provisionalization period. Another platform-switched interface implant was removed at the time of placement of the definitive crown. All implants failed within the first year; no additional evaluated implants were lost during the 5-year follow-up period (Fig 1). When considering the effects of grafting, prior healed ridges vs extraction sockets, soft tissue augmentation, age, or sex, there was no statistically significant effect on the implant survival rates. The overall implant survival rates 5 years postloading were 100% (conical interface group), 83.7% (flat-to-flat group; $P = .0057$), and 86.4% (platform-switched interface group; $P = .0099$). It is noted that this study was not powered to discern difference in implant survival.

Marginal Bone Levels

A single radiologist evaluated the bone tissue responses at the mesial and distal aspects of the restored implants, and changes in marginal bone levels were calculated from baseline at implant insertion with specific reference points defined for each implant system (Fig 2). The overall mean marginal bone level was between 0.05 and 1.57 mm during the 5 years in function, with an overall mean marginal bone level of 0.78 ± 0.81 mm at the 5-year follow-up. Comparisons between the groups show statistically significant differences between the conical interface and flat-to-flat groups ($P \leq .0001$) and platform-switched interface group ($P \leq .006$) at all visits. There were no statistical differences between the flat-to-flat and platform-switched interface groups at any visit ($P > .24$). For conical interface implants, the overall mean marginal bone level change ranged between –0.09 and –0.22 mm, with a mean decrease (bone loss) of –0.16 ± 0.45 mm, relative to placement, at the 5-year follow-up. For flat-to-flat implants, the overall mean bone level change ranged between –0.88 and –1.20 mm, with a mean decrease (bone loss) of –0.92 ± 0.70 mm at the time of the 5-year follow-up. For platform-switched interface implants, the overall mean bone level change ranged between –0.81 and –1.32 mm, with a mean decrease (bone loss) of –0.81 ± 1.06 mm at the time of the 5-year follow-up. Significant changes in marginal bone levels within each group occurred between baseline and definitive crown placement (Fig 3).

Beyond the mean changes in marginal bone levels, the distribution of marginal bone level changes from placement to 5 years revealed notable and significant differences in the number of implants experiencing no bone loss (or bone gain) between the groups (Fig 4). It was also noted that three (9.1%) conical interface implants experienced > 1 mm marginal bone loss. Also, seven (39.3%) platform-switched interface and eight (33.3%) flat-to-flat interface implants had > 1 mm of marginal bone loss.

Peri-implant Mucosal Architecture

During the 5-year evaluation period, the peri-implant mucosal level relative to the implant crown incisal edge was 9.54 ± 1.56 mm at the time of the 5-year follow-up, ranging between 9.04 mm and 9.75 mm during the 5 years. Marked peri-implant mucosal recession

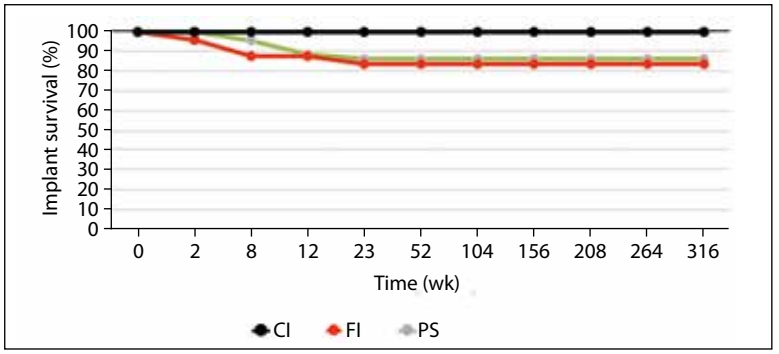


Fig 1 Implant survival. At 5 years, there were 15 conical interface, 13 flat-to-flat interface, and 11 platform-switched interface censored implants (lost to follow-up/no visit). Overall survival rates (intention to treat/per protocol): conical interface vs flat-to-flat interface ($P < .0057$); conical interface vs platform-switched interface ($P < .0099$); flat-to-flat interface vs platform-switched interface ($P < .5779$).

Fig 2 Defined reference point locations for the evaluated implant systems. *(a)* Conical interface. *(b)* Flat-to-flat interface. *(c)* Platform-switched interface. Arrow indicates reference point used in radiographic measurements of marginal bone levels.

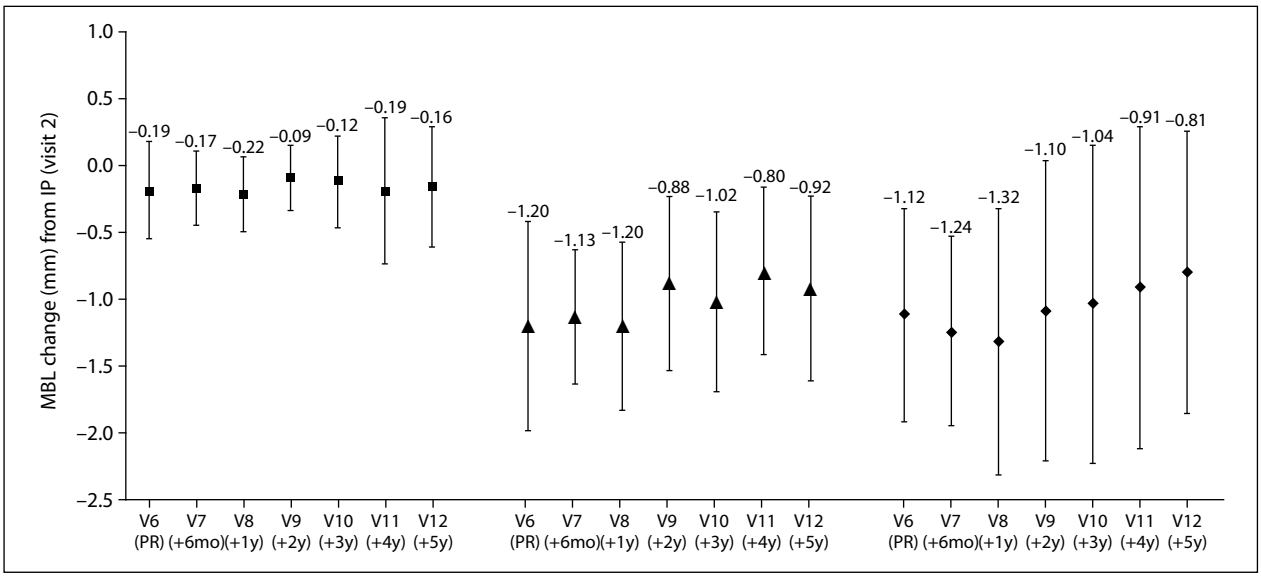
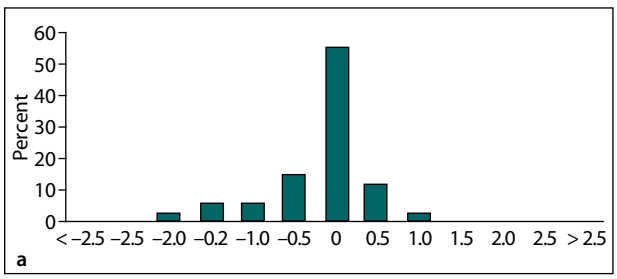
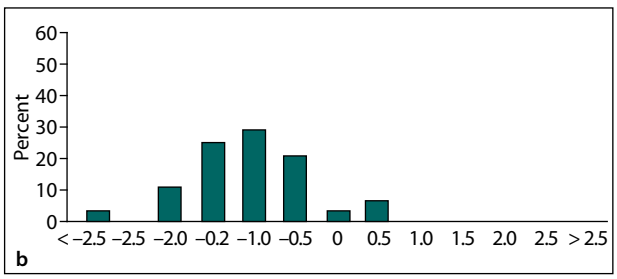


Fig 3 Mean marginal bone level (MBL) changes from baseline (implant placement) to evaluation period (6 months to 5 years). Conical interface = ■; flat-to-flat interface = ▲; platform-switched interface = ●. Conical interface vs flat-to-flat interface at all time points; $P < .0000$; conical interface vs platform-switched interface at all time points; $P < .0000$; flat-to-flat interface vs platform-switched interface at all time points (ns, $P < .3251$).





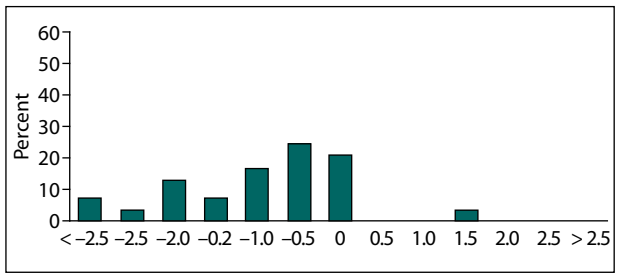


Fig 4 MBL change from implant placement to 5-year follow-up; cumulative proportion (#). The percentages of participants experiencing marginal bone level changes (mm) are plotted for *(a)* conical interface, *(b)* flat-to-flat interface, and *(c)* platform-switched interface implants. Note that at 5 years, there were 69.7% conical interface, 11% flat-to-flat interface, and 25% platform-switched interface implants with no bone loss or bone gain.

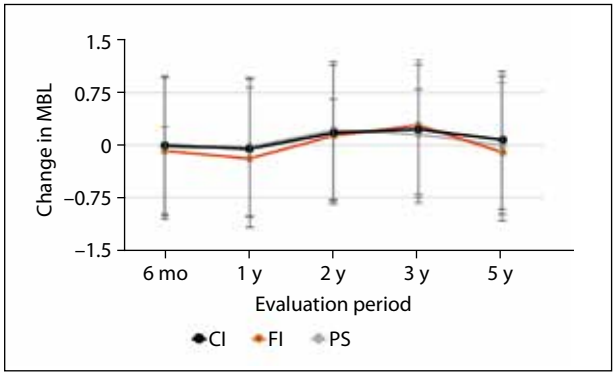


Fig 5 Changes in peri-implant mucosal zenith location following 6-month definitive crown placement (relative to incisal edge position measured using the Canfield apparatus). Changes in marginal bone level (MBL) are plotted as mean (mm) ± SD. There are no significant differences among groups.

Table 4 Papilla Distance (mm) from Incisal Edge from Crown Placement to 5 Years

	Provisional assessment		Definitive crown placement		6 mo		1 y		3 y		5 y	
	Mesial	Distal	Mesial	Distal	Mesial	Distal	Mesial	Distal	Mesial	Distal	Mesial	Distal
Conical interface												
n implants	46	46	43	43	47	47	46	46	45	45	32	32
Mean	3.91	3.21	4.15	3.39	4.16	3.46	4.02	3.38	3.89	3.33	4.03	3.32
SD	1.22	0.95	1.45	1.16	1.28	1.04	1.15	1.14	1.09	1.13	1.02	1.09
Flat-to-flat interface												
n implants	40	40	30	30	37	37	36	36	34	34	27	27
Mean	3.53	3.06	3.69	3.03	3.95	3.30	3.77	3.02	3.70	3.15	3.61	3.36
SD	1.02	1.05	0.89	1	0.96	0.99	0.89	1.02	0.90	0.95	0.93	1.01
Platform-switched interface												
n implants	38	38	32	32	34	34	34	34	31	31	26	26
Mean	3.97	3.60	4.14	3.55	4.20	3.71	3.99	3.71	3.94	3.76	4.16	3.68
SD	0.86	1.09	0.88	1	0.93	1.03	0.94	1.03	1.02	0.98	0.93	0.97
P values												
A vs B	.1248	.4507	.2297	.2096	.5891	.4856	.4373	.1757	.5983	.4450	.1548	.8979
A vs C	.5066	.082	.6374	.4194	.4736	.2157	.9268	.1779	.6800	.1207	.5193	.3489
B vs C	.0342*	.0271*	.0528	.0296*	.1887	.0546	.4232	.0072*	.3237	.0136*	.0405*	.0271*

*Mann-Whitney *U* test, Splatform switched interfaceS. A two-sided *P* value < .05 was considered statistically significant.

was not observed. Following delivery of the definitive crown, the changes in the peri-implant mucosal levels were small (mean 5-year changes of 0.05 mm, 0.02 mm, and 0.31 mm for conical interface, flat-to-flat interface, and platform-switched interface, respectively) and do not reflect clinical significance (Fig 5).

When the peri-implant mucosal changes were evaluated according to the incidence of no change or > 1 mm recession, the three groups displayed similar outcomes. The percentage of implants displaying > 1 mm of recession from definitive crown placement to 5-year recall were 22% for conical interface, 28% for flat-to-flat interface, and 23% for platform-switched interface implant groups. Twelve percent of flat-to-flat interface implants displayed > 1 mm of recession at this interval. This suggests that the risk for esthetic complications will be greater in this group, despite the lack of statistical significance in mean resorption values. Predictability may not readily be discerned by average values.

The interproximal peri-implant mucosa was evaluated by measurement of the papilla distance from the incisal edges using the Canfield apparatus. There were no significant changes in the papilla dimensions for any of the groups (Table 4). When measured from the time of definitive crown placement to 5 years, the average mesial and distal papilla changes were –0.04 (± 0.80; $P < .33$) mm and –0.17 (± 0.73; $P < .13$) mm, respectively.

Soft Tissue Parameters

The stable peri-implant mucosal responses were associated with only modest bleeding on probing at all implants. When reported as a proportion of the four probed surfaces, the percentage of surfaces was stable

Table 5 Proportion of Bleeding Surfaces (MDFL) Present Upon Examination Over Time

BoP average (%)	Provisional assessment	Definitive crown placement	6 mo	1 y	3 y	5 y
Conical interface						
n implants	46	48	43	47	45	33
Mean	16%*	28%	13%	14%	16%	16%
SD	25%	31%	18%	20%	18%	16%
Flat-to-flat interface						
n implants	45	43	32	39	34	28
Mean	30%	27%	25%	17%	18%	17%
SD	33%	27%	28%	24%	20%	23%
Platform switched interface						
n implants	43	39	34	36	32	27
Mean	27%	24%	17%	19%	10%	19%
SD	31%	24%	22%	24%	14%	26%
Total						
n implants	134	130	109	122	111	88
Mean	24%	26%	18%	16%	15%	17%
SD	30%	28%	23%	22%	18%	22%

Conical interface implants at provisional assessment were significantly lower than flat-to-flat implants ($P < .042$). The calculated reductions over time for flat-to-flat interface and platform-switched interface implants were significant at the 6-month, 1-year, and 3-year visits. BoP = bleeding on probing.

for the conical interface implant but decreasing from higher initial values for the flat-to-flat interface and platform-switched interface implant systems (Table 5). Overall, bleeding on probing as an indicator of inflammation was stable over the 1- to 5-year period of this investigation.

The average probing pocket depths observed at the three groups were between 2.26 mm and 3.05 mm, with an overall average of 2.64 ± 0.83 mm at the time of the 5-year follow-up. At 5 years, the pocket depths were 2.55 ± 0.67, 2.70 ± 0.92, and 2.69 ± 0.92 mm for the conical interface, flat-to-flat interface, and platform-switched interface implants, respectively ($P > .05$). There were minimal and insignificant changes in the probing pocket depths, with between –0.26 and +0.31 mm from definitive crown placement to 5 years in function, with an overall mean decrease in pocket depth of 0.02 ± 0.80 mm at the time of the 5-year follow-up.

DISCUSSION

In this 5-year prospective evaluation of three implant systems with differing implant-abutment designs placed by an immediate provisionalization procedure, four main observations were made. First, the conical interface implant demonstrated the relative absence of marginal bone loss. Second, stability of the peri-implant mucosal zenith was consistently observed among all groups and over time. Third, there was no observed association with changes in marginal bone levels and changes in peri-implant soft tissues. Finally, peri-implant tissue changes occurred in the initial phases (up to 6 months) of therapy, and bone and soft tissue stability was observed thereafter.

Regarding marginal bone loss, differences in marginal bone loss among the three groups were observed at the early time points of this study. The initial loss of approximately 1 mm of marginal bone at dental implants is well known. A marginal bone change of –1.5 mm in the first year was initially part of the accepted criteria for dental implant success.[21] Earlier cohort studies suggested that alternative implant designs were associated with minimal marginal bone changes.[22,23] Few prospective clinical studies have addressed this systematically; however, it is generally accepted that healthy implants demonstrate marginal bone stability following the first year in function.

Early or initial marginal bone loss is not correlated with bone changes later,[24] and the factors that influence early bone loss at dental implants may differ from those that influence late or delayed marginal bone loss.[25] Factors affecting early bone loss included clinical manipulation of components and tissue flap elevations associated with abutment, crown, or restoration placement. Additional factors beyond the impact of interfacial bacterial contamination on inflammation and its promotion of osteoclastogenesis are at play.

The presence of the implant-abutment interface or "microgap" has been implicated in marginal bone loss.

Bacterial contamination at the implant-abutment interface (microleakage) is often cited as a cause of peri-implant inflammation leading to bone loss. A systematic review that included 30 articles concluded that microleakage occurred at all implant-abutment interfaces, yet internal conical connections showed less microleakage.[26] In a human clinical study involving four different implant-abutment interfaces that included the conical interface implant used in this study, the use of microbiologic sampling and PCR analysis of select bacteria within the internal aspect of the implant after 5 years in function revealed that the conical interface implants demonstrated the lowest level of red complex bacteria and lower total bacterial load.[27]

Other prospective clinical studies have reported the absence of or minimal (< 0.5 mm) marginal bone loss at the conical interface implant system. In a 2- to 5-year prospective study, the marginal bone change recorded was a "gain" of 0.18 mm mesially and 0.34 mm distally.[28] In another 5-year prospective study, the mean marginal bone loss for the conical interface implant system was 0.29 ± 1.31 mm and 0.30 ± 0.91 mm.[29] The multivariate model suggested that immediate vs delayed loading, smoking, or tooth position did not influence the marginal bone levels. The presence of plaque and bleeding on probing did influence peri-implant bone loss. Other conical interface implant systems also demonstrate moderation of initial marginal bone loss.[30] In the present study, low plaque accumulation was recorded, and bleeding on probing was minimal among all groups. However, greater marginal bone loss occurred at the flat-to-flat interface and platform-switched interface implants. Additional factors, including implant design, likely influence incipient marginal bone changes.

A 5-year retrospective study investigating an implant with the flat-to-flat interface used here reported marginal bone level changes similar to those recorded presently. The marginal bone loss was 0.9 ± 1.6 mm after 1 year and an additional 0.1 ± 2.4 mm at 5 years; 14.8% of implants showed > 2 mm of bone loss, and 5.2% of implants showed > 3 mm of bone loss after 5 years.[31] Another 5-year report utilized a similar implant (NobelReplace Tapered Groovy, Nobel Biocare) and demonstrated 5-year marginal bone level changes of –1.21 ± 1.11 mm mesially and –1.19 ± 1.14 mm distally, and 16.1% of these implants experienced > 2 mm of bone loss. As reported here, the peri-implant mucosal zenith positions were little changed over 5 years, while mesial and distal papilla growth was observed.[32]

Platform switching is the process of utilizing an abutment with a smaller diameter to medially displace the implant-abutment interface from the bone. There is some support for its effect in reducing marginal bone loss following implant placement. This has been attributed to diverse factors including reduction of the inflammatory infiltrate at the bone crest, increasing the dimension of the biologic width or altering the biomechanics of the loaded implant-abutment system. A 5-year prospective study involving 68 participants with 31 platform-switched and 29 platform-matched implants revealed that both types of implant-abutment interfaces experienced approximately 1 mm of bone loss during this initial period. During the subsequent 5 years, similar and minimal bone changes were recorded. The mean difference after 5 years was 0.29 mm, resulting in a conclusion that these significant differences may not be clinically relevant.[33] The present experience using a platform-switched implant-abutment system closely parallels these results.

Several other studies have prospectively compared different implant designs in the context of peri-implant tissue responses.[34] Den Hartog et al reported the results of a 5-year randomized clinical trial comparing anterior single implants with different implant-abutment interface designs.[35] Ninety-three participants were randomized to treatment groups with a 1.5-mm smooth collar, a grooved collar, or a scalloped collar with grooves. They measured an average marginal bone loss of > 1.2 mm for all groups and > 2 mm for the scalloped implant design. The midfacial peri-implant mucosal levels demonstrated little change in the first year or thereafter. This is surprising, as the authors indicated that peri-implant mucosal inflammation was greater at the scalloped implants, as evidenced by higher bleeding scores and deeper pocket depths (related to greater bone loss over time). However, the dissociation of marginal bone changes (and inflammatory responses) from midfacial mucosal changes was also observed in the present investigation.

Other designs have not been included in this study. A 5-year report exemplified the use of a conical interface implant with a unique transcortical design for immediate provisionalization in the anterior maxilla. Interestingly, minimal marginal bone loss was associated with a statistically significant midfacial recession that progressed over 5 years.[36] These data again suggest that there is not a defined relationship of periapical radiographic marginal bone loss and the peri-implant mucosal tissue responses.

The present investigation did not include either external-hex or one-piece implant designs. A recent retrospective evaluation of external-hex implants in function 10 to 19 years demonstrated that after initial bone loss of approximately 1 mm, marginal bone levels were stable after 10 years.[37] This biologic response to external-hex implants has been confirmed by a systematic review and meta-analytic comparison of internal conus vs external-hex implants that stated that "internal-connection implants exhibited lower marginal bone loss than external-connection implants

($P < .00001$; mean difference [MD]: 0.44 mm; 95% confidence interval [conical interface]: 0.26 to 0.63 mm)."[38] External-hex implants are flat-to-flat interfaces that have perceptible micromotion and microleakage and are historically associated with initial marginal bone loss. Regarding the marginal bone responses at one- vs two-piece implants, recent systematic reviews have concluded that there was no difference among the two groups.[39,40] However, preclinical studies indicate that the absence of a microgap can influence the degree of inflammatory infiltrate and the extent of localized bone loss at a two-piece implant system.[41] Past investigations of external-hex and one-piece implants suggest that the implant-abutment interface is a factor influencing marginal bone responses.[42]

Implants in this study all possess enhanced surface topography. Rough surfaces may influence marginal bone responses at implants.[43] A recent clinical comparison of machined (n = 126) vs rough (n = 116) surface implants (mean period of 4.6 years) revealed 1.58 ± 0.73 mm vs 1.20 ± 0.52 mm for machined vs rough surface implants ($P = .007$).[44] A comprehensive systematic review including 87 studies reported on minimally rough (0.5 to 1.0 µm), moderately rough (1.0 to 2.0 µm), and rough (> 2 µm) implant surface designs. The study concluded that minimally rough surfaces presented statistically less bone loss. Yet, the analysis of bone loss was performed from the time of loading of the implant, not from the time of implant placement when the majority of bone loss has typically occurred. Irrespective of this key factor, the authors concluded that the various parameters affecting marginal bone have not been controlled in studies comparing different implant systems. In other words, there were no included studies comparing implants of equal design but only differing in surface topography.[45] Despite the same shortcoming in this study, the results in the present study including only implants with enhanced surface topographies demonstrated that a moderately rough surface alone was not sufficient to preclude incipient marginal bone loss that occurs following implant placement and that the presence of a rough surface was not associated with continued bone loss over time.

Mechanical loading of crestal bone is influenced by the implant-abutment interface design.[46] A conical interface may better distribute loads and avoid peak stresses that damage cortical bone that lead to crestal bone resorption. The loading environment may be critical to the crestal (cortical) bone responses that occur immediately following the surgical placement of an implant.

The other key observation made from this investigation is the stability of the peri-implant midfacial mucosal position and contour observed among all three groups. Similar midfacial stability was reported in a previous study comparing the marginal bone loss and midfacial mucosal changes that occurred at this conical interface implant following immediate provisionalization of implants placed into healed ridges vs extraction sockets.[47] Other groups have reported on dental implant midfacial mucosal stability following an immediate provisionalization protocol. In a study involving this conical interface implant, the 2- to 5-year (mean: 47 months) follow-up revealed 0.29 ± 0.74 mm peri-implant mucosal recession.[28] Similar results have been repeatedly observed.[29,48,49] Other supplemental procedures are implied to aid in mucosal outcomes. In a retrospective study of 90 implants with a mean follow-up of 55.9 months, only five patients presented with midfacial mucosal recession >1 mm.[50] The authors indicated that guided bone regeneration or connective tissue grafting techniques enabled optimal conditions and good dimensional stability. Here, in the relative absence of these supplemental procedures, a high degree of midfacial mucosal stability was observed.

Peri-implant mucosal dimensions are factors influencing peri-implant tissue responses. This study did not measure or investigate the impact of keratinized mucosal width, mucosal thickness, or biotype at the implant sites. A recent study concluded that the presence of keratinized mucosa was likely not relevant to the majority of single-tooth implant procedures.[51] Keratinized mucosal width may positively impact midfacial recession and inflammation.[52,53] Mucosal thickness (> 2 mm) positively impacts marginal bone responses, as indicated by both animal[54] and human interventional studies.[55,56] In this study, all clinicians were instructed in the placement of implants 3 mm below the mucosal crest, and postsurgical measurements affirmed that, on average, all three implant systems were positioned in this similar manner.[57] The tissue thickness or biotype are likely not factors affecting outcomes in this study.

Irrespective of tissue thickness, the height of an abutment may influence marginal bone loss. In a study involving platform-switched implants, the use of short abutments was associated with more early marginal bone loss.[58] In this study, stock titanium abutments from each manufacturer (1.5 mm [platform-switched interface], 2.0 mm [flat-to-flat interface], or 2.5 mm [conical interface]) were used for provisionalization. These dimensions were considered sufficient to permit supracrestal biologic width formation along titanium surfaces for each implant system tested. It remains to be determined if the abutment length was a factor contributing to differences in early marginal bone loss among the three groups.

This study involved immediate provisionalization, and there is speculation that the placement of a provisional crown may assist in directing esthetic tissue formation and its preservation following implant placement. This was not explored directly in the present study; however, a prospective clinical trial involving

immediate implant placement with or without provisionalization demonstrated that the midfacial mucosal marginal level changes were not different between the groups.[52] Further investigation is warranted.

The interproximal peri-implant mucosal responses following implant placement and provisionalization were minimal. The adjacent tooth connective tissue attachment apparatus offers predominant guidance to these tissues mesial and distal to the implant. The inclusion/exclusion criteria reduced the opportunity to include participants at risk for loss of attachment at adjacent teeth and, thus, risk of papilla dimension at the implant. In addition, papilla-sparing incisions or flapless approaches for implant placement were employed to reduce risk of reduced papilla dimension. The general stability of filled interproximal tissue spaces is reflected by the stable and relatively high PES scores (10.1 ± 1.9) previously reported.[59]

The multifactorial determinants of peri-implant bone and mucosal responses have been clearly enumerated and include, but may not be limited to, thin mucosa, a thin gingival biotype, limited keratinized mucosa, adjacent tooth connective tissue attachment loss, inadequate tooth-implant distance, deep implant placement, utilization of short abutments, and buccally positioned/oriented implants. Attempts were made to account for many of these factors by following the 3-mm depth of implant rule and use of patient-specific abutments that would not encroach transmucosally to bone. A predominating factor in the observed stability of the midfacial mucosa may be that implants were not placed in a facial orientation.

CONCLUSIONS

This 5-year prospective randomized clinical trial demonstrated that immediate provisionalization of anterior maxillary teeth with a conical implant-abutment interface system results in the relative absence of initial marginal bone loss compared with two other designs (flat-to-flat and platform-switched). There were minimal changes in the peri-implant mucosal positions over time among all three groups. The relationship of peri-implant mucosa and bone changes must be questioned. This 5-year evaluation supports the use of immediate provisionalization of implants to replace missing anterior teeth. The longer-term effects of differential marginal bone responses remain to be determined.

ACKNOWLEDGMENTS

L.F.C. receives research grants and honorarium from Dentsply Implants.

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