Three-Year Prospective Randomized Comparative Assessment of Anterior Maxillary Single Implants with Different Abutment Interfaces

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Purpose: *The goal of this investigation was to define time-dependent peri-implant tissue changes at implants with different abutment interface designs.* ***Materials and Methods:*** *Participants requiring replacement of single maxillary anterior and first premolar teeth were recruited and treated under an institutional review board (IRB)-approved protocol. Implants, titanium abutments, and provisional crowns were placed in healed ridges 5 months following preservation after tooth extraction with recombinant human bone morphogenetic protein-2 (rhBMP-2). Twelve weeks later, permanent crowns were placed on patient-specific abutments and evaluated at 6, 12, and 36 months following implant placement. Clinical and radiographic assessments of abutments and crowns, peri-implant mucosa, and marginal bone levels were recorded.* ***Results:*** *The 3-year assessment included 45 conical interface (CI), 34 flat-to-flat interface (FI), and 32 platform-switched interface (PS) implants in 111 participants. At 3 years, the mean marginal bone level (MBL) change at CI, FI, and PS implants was –0.12, –1.02, and –1.04 mm, respectively (P = .014). "Zero" MBL loss or gain was measured over the 3-year period at 72.1% CI, 3.0% FI, and 16.6% PS implants. There was a minor change (0.0 to 0.3 mm) in peri-implant mucosal zenith positions over time and between groups. Eighty percent of CI implants, 61% of FI implants, and 84% of PS implants were observed to have a clinically stable peri-implant mucosal zenith position with less than 0.5 mm of measured recession. Over the 36-month period, there were no significant changes in the location of mesial or distal papilla in any group.* ***Conclusion:*** *Significant differences in MBLs were observed at different implant interfaces. Conical implant interfaces, but not flat-to-flat or platform-switched implant interfaces, were associated with no MBL changes over 3 years. Peri-implant mucosal stability was generally observed. The relationship of marginal bone responses and peri-implant mucosal stability requires further evaluation.* Int J Oral Maxillofac Implants 2019;34:150–158. doi: 10.11607/jomi.6810

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Dental implant therapy is widely recognized as a predictable method of tooth replacement for single missing anterior teeth.[1–3] Immediate provisionalization of single-tooth implants is associated with high success, favorable esthetic outcomes, and high patient satisfaction.

The peri-implant mucosal condition is regarded as one key to esthetic implant success. Objective assessment of implant outcomes using the pink esthetic score (PES) highlights the importance of peri-implant mucosal architecture in defining the esthetic success of single-tooth implant therapy.[4] Among the seven factors included in the PES, the peri-implant facial mucosal position ("soft tissue level") or peri-implant mucosal zenith prominently influences dental esthetics.[5] Mucosal recession is an unacceptable outcome associated with display of abutments, dehiscence revealing the implant, or extended and asymmetrical crown length that represent biologic and esthetic risks to the patient. Several investigators acknowledged that implant placement factors, particularly immediate placement or immediate provisionalization protocols, could negatively influence the tissue responses at implants.[6–8]

Many factors influence the peri-implant bone and mucosa. Kan et al[9] suggested that interproximal and facial mucosal tissues are affected differently. While interproximal tissue form (papillae) at implants may be strongly influenced by adjacent tooth connective tissue attachment levels, facial peri-implant mucosal levels are influenced by multiple factors. These include peri-implant biotype, facial bone crest level, implant fixture angle, the interproximal bone crest level, the depth of the implant platform, and the level of first bone-to-implant contact.[10] Facial mucosal recession at implants is associated with four risk factors that include: smoking, thin buccal bone plate (ie, < 1 mm thick), thin soft tissue biotype, and facial implant position.[11]

Among these factors, the position of buccal bone in relation to the desired peri-implant mucosal zenith and the implant-abutment interface is of particular interest. Kan et al demonstrated that a facial dehiscence results in mucosal recession of > 1.5 mm.[9] Other factors influencing buccal bone integrity include resorption following tooth extraction and post-implant loading marginal bone adaptation. Post-extraction alveolar bone resorption has been measured to be approximately 1.7 to 2.0 mm,[12] and post-implant loading marginal bone adaptation varies from less than 0.3 mm to greater than 1.5 mm and is implant system dependent.[13]

While it is widely accepted that bone changes around the implant influence peri-implant mucosal changes at dental implants, there are few prospective investigations that have attempted to correlate these tissue responses in the context of implant-abutment interface design. The aim of this 5-year prospective study was to compare the peri-implant tissue responses at three different implant-abutment interface designs following immediate provisionalization in healed alveolar ridges.

MATERIALS AND METHODS

Overview

Participants requiring maxillary anterior or first premolar dental implants were recruited and enrolled under an institutional review board (IRB)-approved protocol (08-2024) according to defined inclusion and exclusion criteria.[14] Participants were initially treated by extraction and/or ridge augmentation/socket preservation using recombinant human bone morphogenetic protein-2 (rhBMP-2; Infuse, Medtronic) and, 5 months later, a single dental implant and titanium abutment was placed into the healed alveolar ridge. After 8 weeks of provisional loading using an acrylic crown, impressions were made, and at 12 weeks following implant placement, a patient-specific zirconia abutment (Atlantis, Dentsply Sirona) and lithium disilicate crown (IPS e.max, Ivoclar Vivadent) was cemented. Clinical, biologic, and radiographic evaluations were performed at recall appointments at 6, 12, and 36 months after implant placement (Fig 1). This study was conducted in accordance with the standards of the IRB and the updated Helsinki Declaration.

Surgical and Implant Restorative Procedures

The detailed surgical and implant restorative procedures have been reported previously.[1] Ridge preservation and/or ridge augmentations were performed with rhBMP-2 with or without mineralized bone allograft for volumetric support. At 5 months, patients were randomized to three treatment groups reflecting different implant-abutment interfaces: *(1)* conus interface (CI) (OsseoSpeed Implants, Dentsply Sirona Implants), and *(2)* flat-to-flat interface (FI) (NobelSpeedy Replace, Nobel Biocare), and (PS) platform switched interface implants (NanoTite Certain Prevail; Biomet 3i Implants). Implants were placed according to manufacturers' recommended protocol, and the depth of implant placement was measured and recorded. Titanium abutments of the manufacturer's specification were placed (CI = Direct Abutments, Dentsply Sirona Implants; FI = Snappy Abutments, Nobel Biocare; PS = GingiHue Abutments, BIOMET 3i) as provisional abutments and bis-acryl provisional crowns were placed without occlusal contacts in centric or eccentric positions. Postoperative antibiotics (amoxicillin 500 mg/day or clindamycin 600 mg/day for 7 days), chlorhexidine mouthrinse, and analgesics as needed for pain were prescribed. Participants were evaluated at 1 and 4 weeks following treatment.

Eight weeks following implant placement and healing, provisional restorations and abutments were removed, implant stability was clinically assessed, and stable implants were impressed according to individual manufacturer's specifications. All clinical information was recorded and sent to a central dental laboratory for fabrication of definitive zirconia abutments (Atlantis abutments, Dentsply Sirona Implants) and pressed lithium disilicate (IPS e.max, Ivoclar Vivadent) crowns. The definitive crowns were cemented intraorally 4 weeks after impression using Rely X resin cement (3M ESPE). Participants were comprehensively evaluated at crown placement, and at 6, 12, and 36 months (Fig 1). Adverse events and adverse device events were recorded.

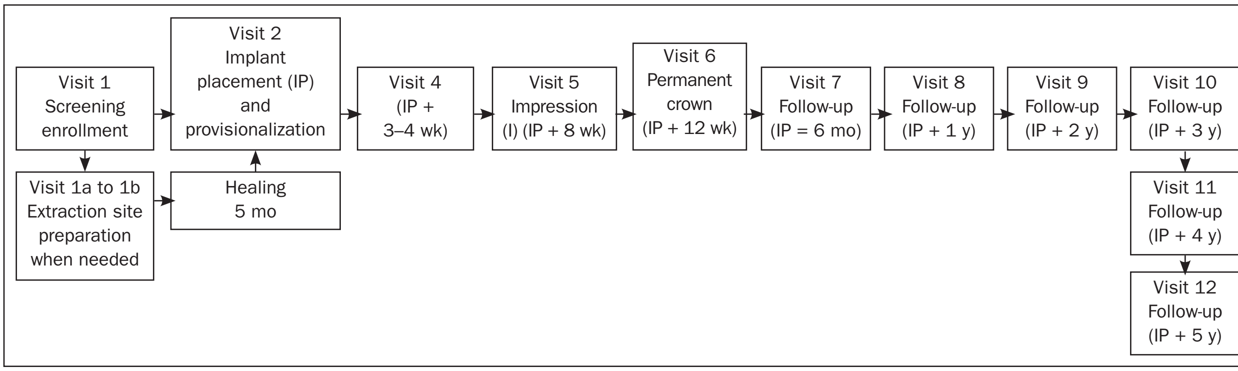

Fig 1 Timeline of study.

Implant Survival

Implants were categorized as surviving (present), failed (removed), or lost to follow-up (unaccounted for). Implant failure was recorded as an adverse device event. Survival was represented using Kaplan-Meier life table analysis.

Marginal Bone Levels

An independent radiologist measured the mesial and distal MBLs as the distance from the implant reference points (unique to each implant system) to the most coronal bone-to-implant contact on the implant. The mean of these two measures was calculated for each implant, and the changes from baseline (implant placement) to subsequent time points were calculated and statistically analyzed.

Peri-implant Mucosal Measurements

The mid-buccal peri-implant mucosal zenith and the mesial and distal papillae were evaluated by direct clinical measurement of the distance from the incisal edge to the zenith or papillae tip using a calibrated UNC 15 probe (Hu-Friedy). Additionally, serial standardized photographs were recorded with distances internally calibrated using a UNC 15 probe. The Canfield system (Canfield Scientific) assured geometrically reproduced image production from visit to visit. Linear measurements of photographs were made from unaltered .jpg images using ImageJ software. The changes in the distances to the mucosal zenith and papillae were recorded. Mesial and distal measures were averaged for each treatment group and compared statistically. The associated PES was evaluated using a digital image scoring format.[15]

Statistical Analyses

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 (SPSS). A two-sided $P < .05$ was considered statistically significant.

RESULTS

This study began with 48 CI, 49 FI, and 44 PS implants in 141 participants. The pre-operative oral health status and participant demographics are reported elsewhere.[14] The 1-year assessment included 48 CI, 40 FI, and 38 PS in 126 participants. This reflected the failure of eight FI implants before the final crown placement and the failure of five PS implants before and one PS implant after final crown placement. Five FI implants and three PS implants were additionally lost to follow-up. The 3-year assessment included 45 CI, 34 FI, and 32 PS implants in 111 participants; 3 CI, 6 FI, and 6 PS implant patients, in total, were lost to follow-up.

After the first year of this study, no further implant losses have been recorded. There were 36 Adverse Device Events (ADEs) reported as possibly, probably, or definitely device related. Seventeen ADEs were reported and resulted in 14 implant failures (FI: n = 8 PS; n = 6; Table 1; Kaplan-Meier survival analysis). The other reported 19 ADEs did not result in implant failures (CI: n = 5; FI: n = 10; PS: n = 4). Of the 14 failed implants, 6 were in sites where rhBMP-2 grafting was performed (no statistical difference [N.S.]). These failures were not related to individual medical history, surgical history, site augmentation, bone quantity, or bone quality.

MBL changes were calculated from marginal bone to reference point measures made from periapical radiographs taken at implant placement (visit 2) vs definitive restoration, 6-, 12-, and 36-month recall. At visit 2 (baseline), the mean MBL for all three groups was approximately 0.2 mm apical to the reference point. At the 6-month recall, while no change in MBL was observed for CI implants, there was 1.1 mm and 1.2 mm mean MBL loss at FI and PS implants (all $P < .001$). No further significant change in the mean MBL was observed at 12, 24, or 36 months (Fig 2). When considering the frequency of "stable" MBLs around individual implants, "zero" MBL loss or gain was measured over the 3-year period at 72.1% CI, 3.0% FI, and 16.6% PS implants (Fig 3).

Table 1 Implant Survival Rate

Interval	Group B					Group C				
	No. at risk	Lost	Censored	Interval survival probability	Survival proportion	No. at risk	Lost	Censored	Interval survival probability	Survival proportion
IP to visit 3 (IP + 2 wk)	48	0	0	1.000	1.000	44	0	0	1.000	1.000
Visit 3 to visit 4 (IP + 3 to 4 wk)	49	2	0	.9592	.9502	44	0	0	1.000	1.000
Visit 4 to visit 5 (IP + 8 wk)	47	4	0	.9149	.6776	44	2	0	.9545	.9545
Visit 5 to visit 6 (visit 5 + 4 wk)	43	0	0	1.000	.8776	42	3	0	.9286	.8864
Visit 6 to visit 7 (IP + 6 mo)	43	2	1	.9535	.8367	39	1	0	.9744	.8636
Visit 7 to visit 8 (IP + 1 y)	40	0	1	1.000	.8367	38	0	2	1.000	.8636
Visit 8 to visit 9 (IP + 2 y)	39	0	3	1.000	.8367	36	0	1	1.000	.8636
Visit 9 to visit 10 (IP + 3 y)	36	0	2	1.000	.8367	35	0	3	1.000	.8636
Visit 10 (IP + 3 y)	34	0	0	1.000	.8367	32	0	0	1.000	.8638
		Σ8	Σ7		83.7%		Σ6	Σ6		86.4%

Group A = 100 % survival; all implants surviving.
Group A = conical interface; group B = flat-to-flat interface; group C = platform-switched interface; IP = implant placement.

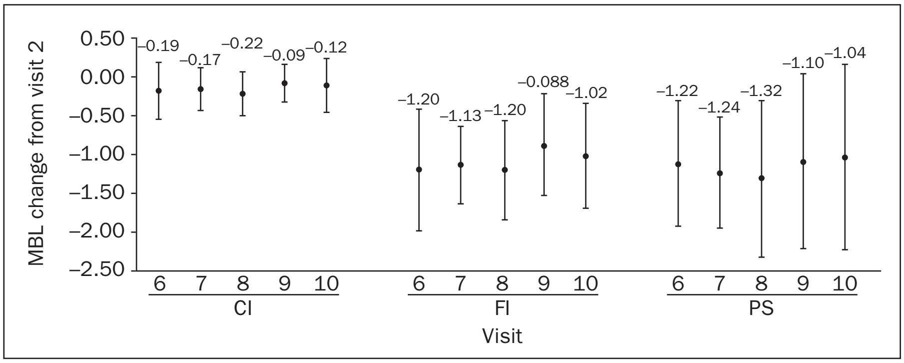

Fig 2 Marginal bone changes at sequential evaluations (0 to 3 years). Within-group comparisons were calculated using nonparametric statistics (Wilcoxon signed-rank test), $P < .000–.014$.

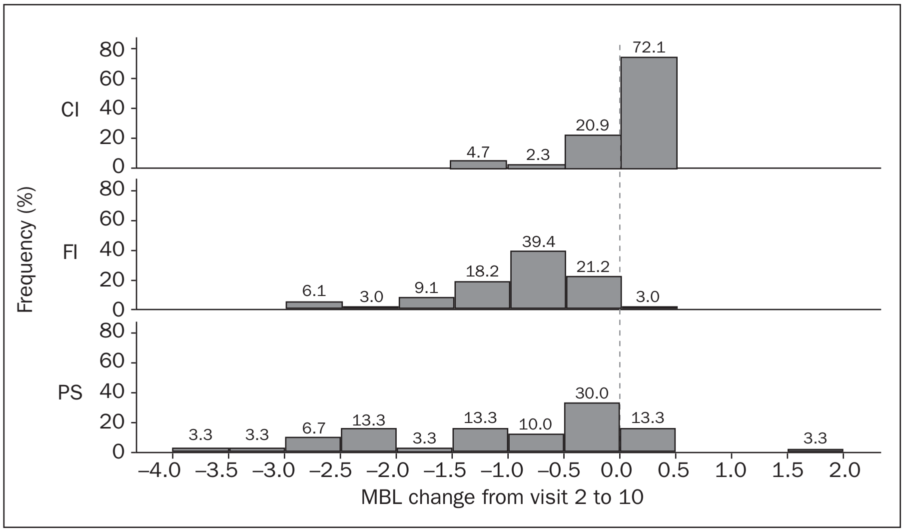

Fig 3 Distribution of MBL recorded from implant placement to 3 years within the treatment groups.

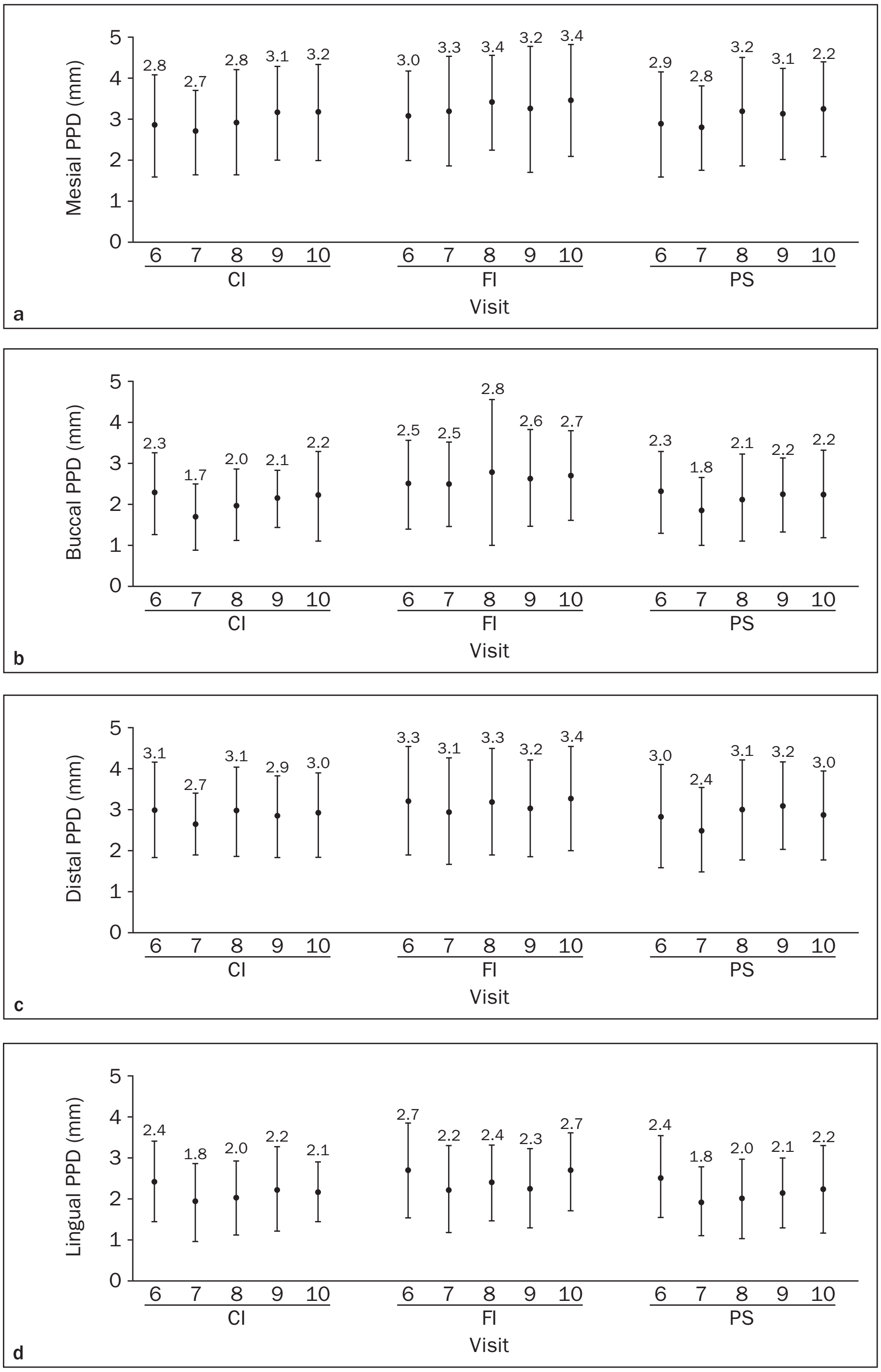

Fig 4 Probing pocket depths at sequential examinations (0 to 3 years). *(a)* Mesial. *(b)* Buccal. *(c)* Distal. *(d)* Lingual. CI: $P = .023$; FI: $P = .020$; PS: $P = .005$.

Differences in probing pocket depths (PPD) identified differences in peri-implant mucosal integration among the three different implant designs evaluated. Buccal probing depths were significantly smaller for CI implants vs FI implants at 6-, 12-, 24-, and 36-month recalls ($P < .001$, $P = .011$, $P = .038$, and $P = .023$, respectively) and for PS vs FI implants at 6 months ($P = .005$). Seven percent CI implants, 18% FI implants, and 9% PS implants possessed buccal PPD ≥ 4 mm at 36 months. At lingual aspects, PPD ≥ 4 mm was observed at 2%, 24%, and 12.5% of CI, FI, and PS implants, respectively (Fig 4).

Bleeding on probing (BOP) was similar among the different implant designs with the exception of greater BOP recorded at examination of FI implants vs CI implants ($P = .042$) at the 4-week evaluation where the provisional abutment and restorations were in place. During the 3-year period, the percentage of BOP surfaces was reduced on all surfaces and at 36 months, similar BOP measures were recorded at all implants (Table 2).

Table 2 Bleeding on Probing (% surfaces) Measured at Sequential Examinations

Time	CI	FI	PS
6 mo	13 ± 18, 0 to 75; median 0	25 ± 28, 0 to 100; median 25	17 ± 22, 0 to 75; median 0
1 y	14 ± 20, 0 to 50; median 0	17 ± 24, 0 to 100; median 0	19 ± 24, 0 to 75; median 0
2 y	23 ± 23, 0 to 75; median 25	23 ± 23, 0 to 100; median 25	22 ± 23, 0 to 75; median 25
3 y	16 ± 18, 0 to 50; median 0	18 ± 20, 0 to 50; median 25	10 ± 14, 0 to 50; median 0

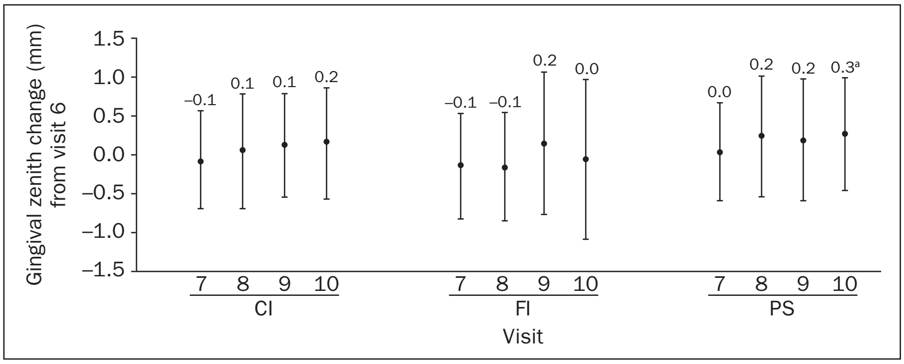

Fig 5 Peri-implant mucosal zenith location change from baseline at sequential evaluations (final crown to 3 years). a: $P = .0038$; all groups visits 6 to 10: $P < .049$.

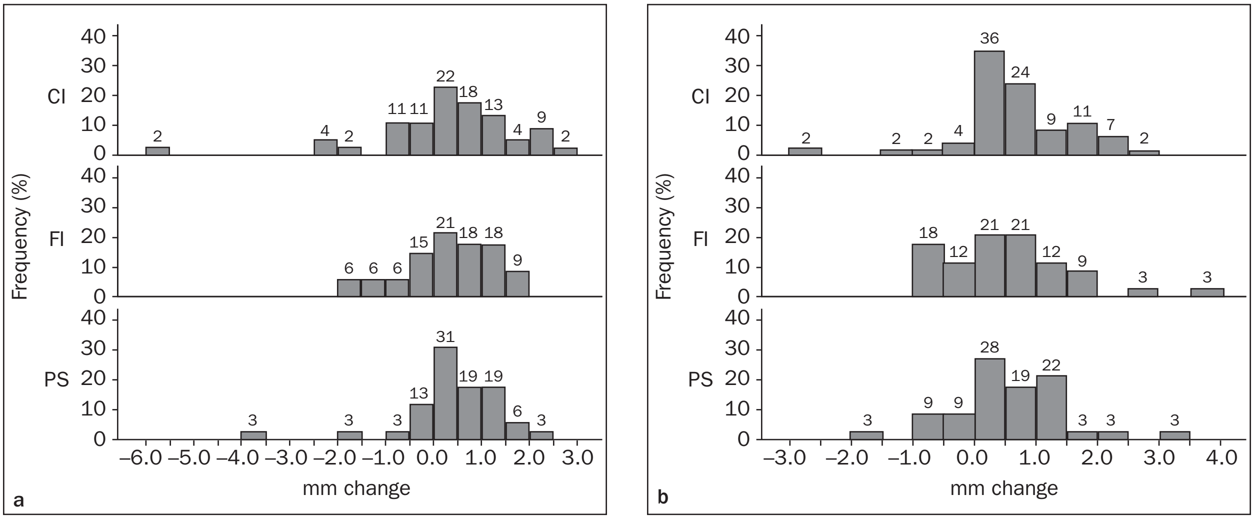

Fig 6 Papilla measurement changes from baseline at sequential evaluations (final crown to 3 years). *(a)* Mesial papillae. *(b)* Distal papillae. Papilla gains were of magnitude 0.2 to 0.4 mm; no significant differences were found between groups for visits 6 to 10.

Peri-implant mucosal architecture was measured at the peri-implant mucosal zenith and the mesial and distal papillae. The change in the clinically measured peri-implant mucosal zenith location from definitive restoration placement to 36 months was 0.2 ± 0.7 mm (–1.0 to 2.0) at CI implants, 0.0 ± 1.0 mm (–3.0 to 2.0) at FI implants, and 0.3 ± 0.7 mm (–1.5 to 2.0) at PS implants (N.S.). From 9 months to year 3, the change was significantly different for all groups ($P = .049$). Eighty percent of CI implants, 61% of FI implants, and 84% of PS implants were observed to have clinically stable peri-implant mucosal zenith position with less than 0.5 mm of measured recession (Fig 5). Peri-implant mucosal stability was also evident in the measurement of mesial and distal papillae locations. Over the 36-month observation period, there were no significant changes between the groups in average papillae locations (Fig 6).

A subjective assessment of peri-implant mucosa influence on implant restoration esthetics was performed using the PES. All PESs increased from a similar average baseline at the time of definitive abutment and crown placement to the 6-month evaluation. Continued assessments at 1, 2, and 3 years revealed no significant differences between the groups regarding the average PES scores. This is the subject of a related publication.[15]

DISCUSSION

This prospective study compared the bone and mucosal responses measured at CI, FI, and PS implant-abutment interfaces. The main observations at this interim 3-year period include system-dependent magnitude of initial marginal bone adaptation and a generalized absence of peri-implant mid-buccal mucosal changes in the measured vertical position. These data suggest that immediate provisionalization of implants in healed alveolar ridges is associated with favorable peri-implant tissue changes. The significantly different marginal bone changes revealed among the three implant-abutment interface designs were not associated with the absence of differences or time-dependent changes in peri-implant mucosal changes interproximally or facially.

This study demonstrated no change in peri-implant mucosal tissues over the 3-year period. While this may seem contradictory to earlier reports of facial mucosal recession,[6–8] recent investigations have demonstrated that peri-implant mucosal positions can be maintained.[13] The stability of the facial mucosal levels reported here may suggest an advantage for the immediate provisionalization protocol. However, a recent systematic review indicates that there are no significant differences in papilla or mid-buccal mucosal tissue responses following conventional or immediate loading protocols for single-tooth implants.[16]

In addition to the immediate provisionalization protocol, this study employed a flapless approach to implant placement in healed ridges. While it may be tempting to attribute peri-implant mucosal stability to this approach, comparative prospective studies fail to demonstrate for immediate placement and loading a benefit of flap or flapless surgery on buccal mucosal levels at 12 months.[17] No esthetic benefit has been attributed to flapless surgery in longer-term studies.[18] However, when considering placement of implants in healed ridges, a flapless approach may enhance buccal mucosal levels.[19]

Other factors beyond surgical protocols influence single-tooth implant esthetics. These include the material,[20,21] color,[22] and shape of abutments.[23] With the exception of color, abutment design variables have not influenced the esthetic outcomes in clinical studies. In this study, all implants were restored with patient-specific computer-aided design/computer-aided manufacturing (CAD/CAM) zirconia abutments without reported complications.[24] The use of one type of abutment in the study limited the abutment variables beyond the interface design.

Several directed implant-abutment design efforts to limit marginal bone loss and deleterious peri-implant mucosal changes at implants have been reported. These have included scalloped implants, platform-switched implants, and concave implant abutments. The conclusion of a recent systematic review addressing the impact of the implant-abutment interface on peri-implant tissues was that there was no evidence supporting the effectiveness of these designs in preventing marginal bone loss and soft tissue recession.[25] In contrast, the present study demonstrated that there is a relative absence of marginal bone loss at conical implant-abutment interfaces compared with both internal flat-to-flat and platform-switch interface designs. Further research regarding the influence of implant-abutment interface design is required. For example, recent studies of sloped implants demonstrating a positive impact on keratinized peri-implant mucosal dimension[26] suggest that implant-abutment interface may influence clinical mucosal outcomes.

Biologic mechanisms acting in the crestal region of bone (at the implant-abutment interface) may influence peri-implant bone and tissue responses.[13] This study affirms that peri-implant marginal bone changes occur shortly after implant-abutment connection. This likely does not reflect the immediate provisionalization protocol, as earlier studies have demonstrated that marginal bone adaptation occurs only following connection of abutments to implants. The magnitude of bone adaptation is consistent with other prospective measures of bone adaptation from implant placement to extended times of 3 to 5 years. Marginal bone loss of greater than 1 mm is not uncommon at flat-to-flat interfaces, and this is apparently not affected by the loading protocol in healed ridges.[27] For platform-switched implant-abutment interfaces, similar marginal bone loss of 1 mm or greater has also been reported by others.[28] The minimal bone adaptation observed at conical interface implants is also consistent with previous studies using this implant-abutment interface.[29] The magnitude of marginal bone changes in this comparative study is consistent with previous cohort studies involving these types of interfaces.

The results of the present study are consistent with the implant-abutment interface influence on marginal bone changes.[13] The conical interface system is associated with significantly less marginal bone loss following implant placement. However, some previous comparisons contradict this finding. In one series of comparisons, the depth of implant placement may not have been controlled.[30] Other studies measure marginal bone changes after implant loading, not implant placement.[31] However, when similar external hex and conical interface implants were compared and placement parameters were controlled, MBL changes again differed, with significantly less marginal bone adaptation (loss) occurring at the conical interface implants.[32] This prospective study, therefore, affirms that marginal bone adaptation is influenced by implant-abutment interface design and associated factors.

This study used pre-fabricated titanium abutments for provisionalization with relatively deep margins interproximally. Crowns were cemented with a zinc oxide-eugenol (ZOE) temporary cement. Definitive patient-specific abutments placed crown margins within 1 mm of the mucosal margin. Abutment contour was also consistent among patients and implant types ("support tissue"; Atlantis, Dentsply Sirona). No evidence of cement-related peri-implant inflammation was reported. This may reflect the use of a ZOE cement,[33] similar contours,[34] and the shallow margin placement of the definitive crowns.[35]

A limitation of this study is that these different implant systems with conical, flat-to- flat, and platform-switched interfaces also presented different surfaces, different transcortical design elements, and minor dimensional differences. Without manufacturing experimental implants and obtaining regulatory approval for use in a human clinical trial, it is not possible to isolate implant-abutment interface design as a single design variable. It is not possible to attribute these changes to one particular design feature of each implant system represented. Rather, the outcome may be interpreted in more generic terms.

Implant interface design can influence peri-implant inflammatory reactions and bone loss. Broggini et al[36] demonstrated that the implant design–associated inflammation levels influenced the MBLs at implants. Earlier studies demonstrated that the presence of a microgap and its mobility influenced marginal bone adaptation at implants in a canine model.[37] Here, the relative absence of marginal bone adaptation at the conical interface implants compared with either the flat-to-flat or platform-switched interfaces may reflect the predicted absence of micromotion at conical interfaces compared with internal sliding or external hex interfaces.[38]

Biomechanical factors may also impact MBLs. The distribution of stress to supporting bone in the crestal region is one factor considered a central determinant of marginal bone responses at implants.[39] Implant design factors (surface roughness, transcortical thread design) as represented by the CI implant studied here may further contribute to the relative marginal bone preservation observed at the CI implants.[40,41] Without isolation of the individual design parameters of implant-abutment interfaces in a clinical study, it is not possible to draw further conclusions from the present data.

This study did not consider biotype as a variable affecting possible outcomes. While biotype may influence several features of single-tooth implant esthetics,[42] it remains a controversial factor as a reproducible determinant of tissue architecture.

Biotype is a suggested co-variable influencing ultimate mid-buccal peri-implant mucosal levels.[43] However, the presurgical soft tissue thickness at dental implants (< 2 mm) may be a predictor of marginal bone loss.[44]

Time may be another factor affecting this outcome. When examining outcomes after 5 years, Cosyn et al[45] demonstrated that 3 of 17 single-tooth implants experienced greater than 1 mm of recession, and this was reflected in significant changes in the PESs. The clinician is another variable that influences esthetic outcomes; buccal soft tissue recession at 3 years following implant placement was greater for inexperienced vs experienced clinicians (0.58 ± 0.72 mm vs 1.52 ± 0.74 mm).[42] Here, experienced clinicians were calibrated and followed a strict protocol.

CONCLUSIONS

This 3-year prospective study of an immediate provisionalization protocol for anterior single-tooth implants revealed that different implant-abutment interface designs vary in their peri-implant marginal bone responses, with conical interface implants demonstrating a relative absence of marginal bone loss following implant placement. Associated with this protocol, the interproximal and mid-buccal peri-implant mucosal changes were minimal and did not differ among the different implant-abutment interface designs. It is possible that peri-implant mucosal architecture is dependent upon multiple factors that are not directly or solely linked to underlying MBLs. This study continues to monitor the peri-implant tissue responses.

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