

Pink Esthetic Score Outcomes Around Three Implant-Abutment Configurations: 3-Year Results

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Purpose: To evaluate the influence that three different implant-abutment interface designs had on peri-implant mucosal outcomes as assessed by the pink esthetic score (PES) 3 years after delayed implant placement and immediate provisionalization. **Materials and Methods:** Adult subjects ($n = 141$) requiring replacement of a bounded single tooth in the anterior maxilla as well as first premolar sites were randomized to receive one of three unique implant-abutment interface designs (conical interface [CI]; flat-to-flat interface [FI]; or platform-switch interface [PS]). Treatment included immediate provisionalization with prefabricated titanium abutments, followed by custom computer-aided design/computer-aided manufacturing (CAD/CAM) zirconia abutments and cement-retained, all-ceramic crowns delivered after 12 weeks. Bilateral (anterior sites) or unilateral (premolar sites) digital clinical photographs were made at 1, 3, 6, 12, 24, and 36 months post-implant placement. Five calibrated faculty evaluators who previously scored the 1-year PES image dataset scored the 24- and 36-month photographs using a digital, cloud-based tablet interface. **Results:** Six hundred ten clinical photographs were evaluated, resulting in a total of 3,050 sum PES values and 21,350 individual PES values. Faculty evaluator intrarater and interrater reliability were found to be “substantial,” with intraclass correlation coefficient (ICC) values of 0.76 and 0.77, respectively. All three implant-abutment interface groups demonstrated acceptable esthetics at 3 years (mean sum PES = 10.1 ± 1.9 , 4.0 to 13.2), with no single group demonstrating significantly greater mean sum PES values than another at the 3-year follow-up or at any recall interval in between. **Conclusion:** No significant differences were observed in mean sum PES scores for subjects randomized to one of three different implant-abutment interface geometries. Within the limitations of this study thus far, the first 6 months following definitive prosthesis delivery appear to still be the most significant with regard to improvement in PES outcomes for all three treatment groups. INT J ORAL MAXILLOFAC IMPLANTS 2018;33:1126–1135. doi: 10.11607/jomi.6659

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Single-tooth implant replacement therapy in the anterior maxilla has been shown to result in acceptable and stable treatment outcomes.^{1–4} Patient acceptance and improvement in quality-of-life measures also exemplify the relatively high potential success rates that this treatment regimen can engender.^{5,6}

A component of implant esthetics often correlated to both patient and clinician satisfaction with implant therapy outcomes is peri-implant mucosal appearance and stability.⁷ Peri-implant mucosal esthetics has increasingly become recognized as an important criterion for success, not only from a patient satisfaction perspective, but also from an outcomes perspective in applicable human clinical trials. As a result, evaluation rubrics by which to assess such subjective desirables have also become more systematic, resulting in several indices that seek to quantify mucosal

esthetic outcomes.^{8–10} Employing these indices, a variety of surgical and prosthetic factors, including timing of implant placement,^{11,12} prior need for bone augmentation,^{13,14} surgical access,¹⁵ timing of implant provisionalization,^{16,17} concomitant soft tissue augmentation,¹⁸ and transmucosal abutment biomaterial selection,^{19–21} among others, have been shown to have a significant impact on peri-implant mucosal esthetics and stability.

Of less clarity is the impact that heterogenous implant-abutment interfaces (represented by various implant manufacturers' proprietary designs) have on peri-implant mucosal stability and esthetics over time. Factors including implant-abutment interface geometries, marginal apico-coronal depth of the interface, and biomechanical stability of the interface have begun to be evaluated as potential modulating factors on peri-implant dynamics. Regarding interface geometries, recent analyses conducted on platform-switched implant-abutment interfaces have revealed significantly better marginal bone maintenance, when compared with non-platform-switched interfaces, which may also potentially influence long-term peri-implant mucosal responses.^{22–24} The depth of the implant-abutment interface relative to the crestal alveolar bone has also been postulated to influence the levels of interfacial inflammation; however, recent investigations have demonstrated variable outcomes based on the nature of the implant-abutment interface design, and require further documentation.^{25–27} Additionally, preservation of the biomechanical integrity of various implant-abutment interfaces has demonstrated significant differences when evaluated via finite element analysis,^{28–30} microbial *in vitro* assays,^{31,32} and animal studies,³³ and may significantly impact soft tissue dynamics and stability.

One-year outcomes of a multicenter, prospective clinical study to evaluate the role that heterogenous implant-abutment interfaces have on peri-implant mucosal dynamics were previously reported.³⁴ Here, the 3-year peri-implant mucosal esthetic outcomes of three distinct implant-abutment interface geometries, using a novel, calibrated cloud-based digital imaging interface are described.

MATERIALS AND METHODS

Study Overview and Treatment Protocols

The primary outcome of this multicenter, prospective, randomized clinical trial was the buccal soft tissue changes occurring around bounded single-tooth replacements in the maxilla in adult patients using three different implant-abutment interface geometries.³⁵ Peri-implant mucosal esthetic outcomes, as assessed

by the pink esthetic score (PES⁸) was a secondary outcome measure evaluated as part of this study. Additional secondary outcome measures evaluated as part of this study have been described previously.³⁵ Subjects participating in this study were enrolled based upon institutional review board (IRB)-approved guidelines (NCT00820235). The study was in compliance with CONSORT guidelines. The inclusion/exclusion criteria and details of this clinical protocol have been reported previously.^{34–36}

Subjects requiring replacement of single, bounded teeth in the anterior maxillary sextant, including first premolar sites, were recruited. Both healed-ridge sites possessing a minimum of 5.5-mm buccolingual width as well as preserved or augmented ridge sites possessing identical minimum ridge dimension thresholds after 5 months of healing were included so as to remove the residual alveolar morphology from influencing the mucosal dynamics. Patients enrolled were randomized according to a blinded statistical randomization scheme at the time of implant placement to one of three discrete implant categories, each representative of a distinct implant-abutment interface (conical interface [CI; OsseoSpeed, Astra Tech Implant System, Dentsply Implants]; flat-to-flat interface [FI; NobelSpeedy Replace, Nobel Biocare]; or horizontal platform-switch interface [PS; NanoTite Certain Preveil, Biomet 3i]) (Fig 1). While the surgical protocol involved flapless implant preparation and placement, mucoperiosteal flaps were elevated if deemed necessary by the surgeon. Surgical protocols to access the implant osteotomy have been previously summarized.³⁴ All implants were placed according to osteotomy preparation guidelines furnished by each implant manufacturer, with the distinct implant-abutment interface situated 3.0 mm apical to the desired future peri-implant mucosal zenith. Stability of the implant was confirmed by the absence mobility (axially or laterally) when placed at the torque values recommended by the manufacturer.

Subjects were immediately provisionalized using prefabricated titanium abutments specific to the particular manufacturer (CI = Direct Abutment, Dentsply Implants; FI = Snappy Abutment, Nobel Biocare; PS = GingiHue Abutment, Biomet 3i), and bisacryl crowns were custom-fabricated from diagnostic coronal matrices. Interim restoration fixation, subgingival contour morphology, and occlusal management during the provisional stage have been described previously.³⁴

Following 8 weeks of implant provisionalization, analogic implant-level impressions were obtained, along with shade selection and occlusal registration. Diagnostic and resultant definitive master models, along with all other relevant materials, were directed to a sole prosthetic laboratory (Studio32) for design and fabrication of a computer-aided design/computer-aided

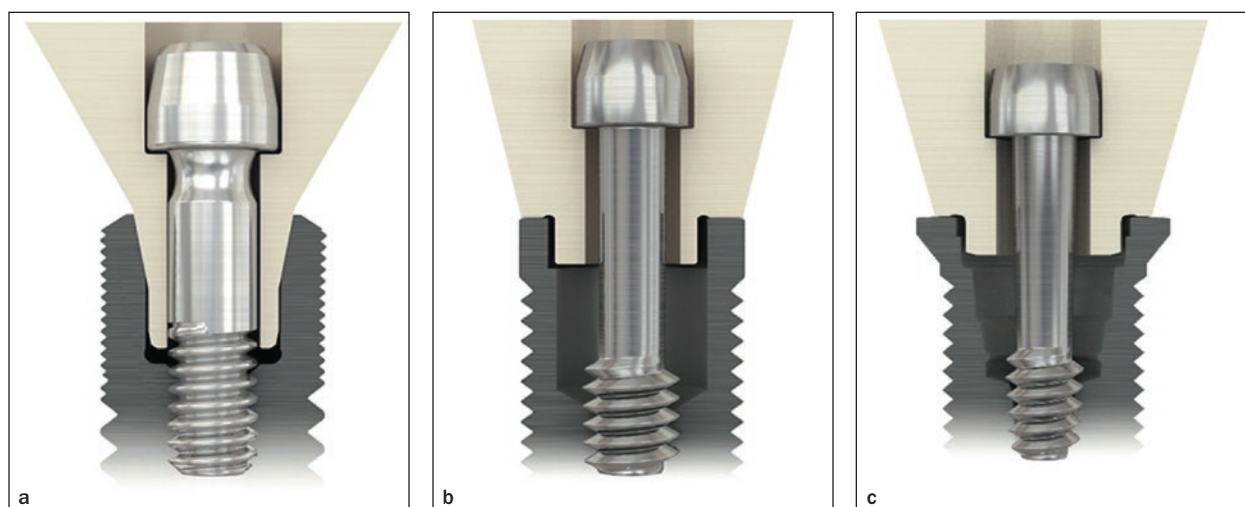


Fig 1 Implant-abutment interface geometries evaluated: (a) conical interface (CI, OsseoSpeed, Astra Tech Implant System, Dentsply Implants); (b) flat-to-flat interface (FI, NobelSpeedy Replace, Nobel Biocare); (c) horizontal platform-switch interface (PS, NanoTite Certain Prevail, Biomet 3i).

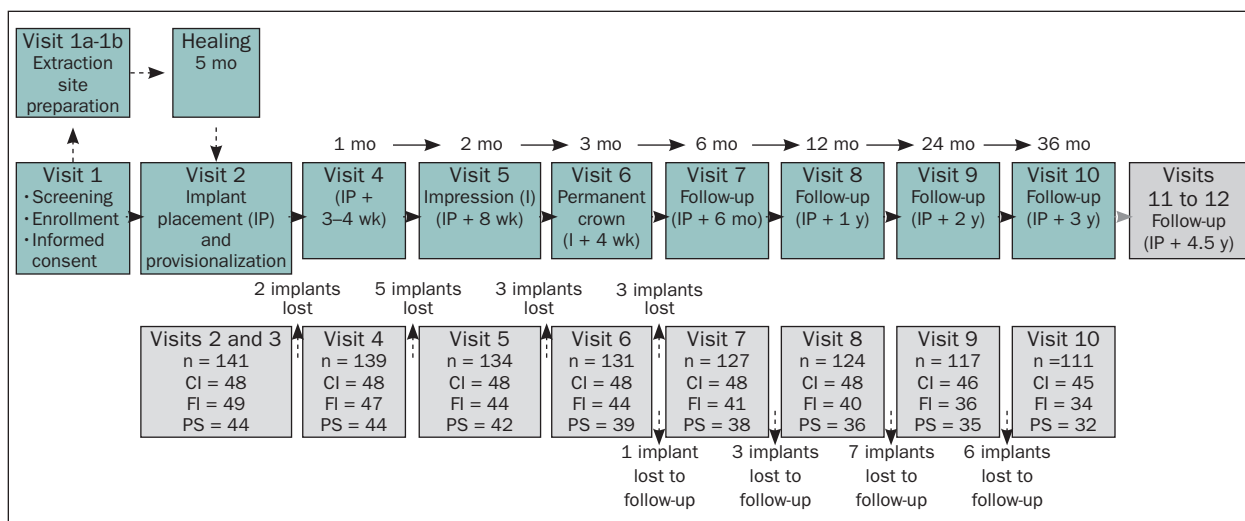


Fig 2 Clinical trial visit and study subject overview from baseline to 3 years. Subjects (n) requiring implant site development underwent a 5-month healing period prior to implant placement. The intervals of implant follow-up are demarcated according to time and visit number. PES scoring was initiated at visit 4 (1 month post-immediate provisionalization [IP]) and proceeded at each subsequent visit through visit 10 (3 years post-IP), with the exception of visit 5 (final impression).

manufacturing (CAD/CAM) zirconia abutment (Atlantis abutments, Dentsply Implants) and pressed lithium disilicate crown (IPS e-max, Ivoclar). Definitive restorations were placed 4 weeks post-impressioning and were fixated using cement retention (RelyX Unicem, 3M ESPE).

Evaluations

Subjects participating in this study through the 3-year timeframe had four scheduled recall visits following delivery (visit 6) of the permanent restoration, which occurred at 6 months post-implant placement (visit 7), 1 year post-implant placement (visit 8), 2 years post-implant placement (visit 9), and 3 years post-implant placement (visit 10) (Fig 2).

In addition to the buccal soft tissue changes occurring around bounded single-tooth replacements (primary outcome measure) at 3 years post-implant placement, several secondary outcome measures were evaluated (Table 1) and will be the subject of independent publications. Peri-implant mucosal results through the 3-year timeframe were evaluated via two methodologies: (1) employment of a stereotactic digital imaging camera (Canfield Scientific) to standardize intraoral images throughout the protocol's duration, and (2) using a tablet-based digital imaging format (iPad3 with retina display, Apple) to evaluate and score supplementary non-standardized intraoral images of implant sites according to the PES criteria (Fig 3). Methodology #1 results at 1 year have been published

Table 1 Summary of Study Variables and Frequency of Evaluation from Restoration Delivery to 3-year Recall

Variable	Visit 6 (Delivery) IP + 12 wk		Visit 7 (6 mo) IP + 6 mo	Visit 8 (1 y) IP + 12 mo	Visit 9 (2 y) IP + 24 mo	Visit 10 (3 y) IP + 36 mo
Crown	Prov	Perm	Perm	Perm	Perm	Perm
Patient questionnaire ^a	X		X	X	X	X
Peri-implant sulcular fluid (PISF) ^a	X			X	X	X
Gingival zenith and papilla: Canfield and clinical ^a	X	X	X	X	X	X
PES	X	X	X	X	X	X
PPD and BOP ^a	X		X	X	X	X
Radiograph ^a		X	X	X	X	X
Adverse device effects (complications) ^a	X	X	X	X	X	X

IP = implant placement; prov = provisional crown; perm = permanent crown; PES = pink esthetic score; PPD = probing pocket depth; BOP = bleeding on probing.

^aTopics of separate manuscripts.

previously,³⁵ and 3-year results of this methodology are currently unpublished; only methodology #2 at the 3-year timeframe will be reported here.

Pink Esthetic Score Assessment

Digital single-lens reflex (dSLR) camera systems (Nikon USA and Canon USA) were utilized to capture bilateral (anterior sites) or unilateral (premolar sites) intraoral clinical images of subjects throughout the duration of the study recall visits. To facilitate PES scoring, both the implant study site and the adjacent (premolar sites) or contralateral natural teeth (anterior sites) and their respective mucosa were captured in the digital images. Clinicians recorded photographic settings (eg, magnification factor, f-stop, shutter speed, etc) for each subject at the initial visit and repeated the identical photographic settings at later visits to standardize image rendering. The subsequent unaltered images from all study centers were electronically aggregated into a secure database designed specifically for this study, sorting the images by study subject number and recall appointment.

Five faculty evaluators from various clinical specialties (periodontics, prosthodontics, orthodontics, operative dentistry, general/restorative dentistry) at The University of Iowa College of Dentistry who were not involved with this clinical study volunteered to evaluate and score the PES images from visit 6 to visit 10. These five faculty evaluators were the same individuals who were previously calibrated and scored PES images from the baseline to 1-year follow-up. The methodology for calibration of all five faculty member evaluators, HIPAA electronic security compliance measures, electronic scoring methodology, and storage and retrieval of the images has been described in detail previously.³⁴

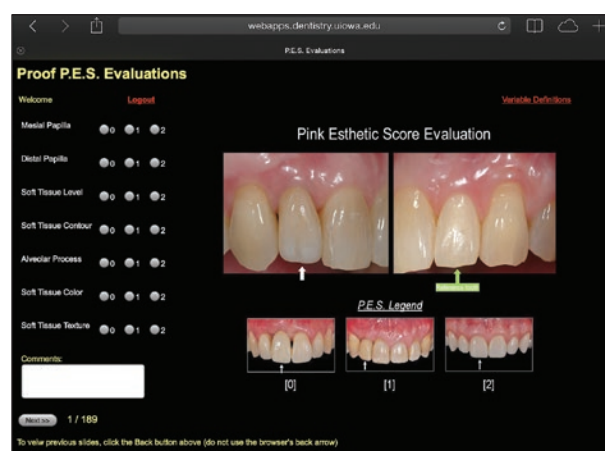


Fig 3 Screen capture example of a study subject implant site and the contralateral natural tooth (reference) for PES scoring on digital tablet.

All PES images were randomized by subject, study recall visit, and implant-abutment interface prior to being presented to the faculty evaluator to prevent evaluator bias. In order to assess intraobserver scoring agreement, 10% of the PES photographs were randomly selected by an individual not associated with this clinical study protocol for inclusion as duplicates within electronic scoring software.

Statistical Analyses

Assessment of evaluator reliability was completed using the intraclass correlation coefficient (ICC) to analyze both intraobserver agreement (eg, PES scores assigned for identical images at two different time points by the same evaluator) and interobserver agreement (eg, PES scores assigned for identical images by two different evaluators). The Wilcoxon signed-rank test was used as a nonparametric methodology to detect differences

Table 2 Initial Study Population Demographics

Variable	CI (OsseoSpeed)	FI (NobelSpeedy Replace)	PS (NanoTite Certain Prevail)	All
n	48 (34%)	49 (35%)	44 (31%)	141 (100%)
Age ([y] mean $\pm$ SD, range)	43 $\pm$ 15, 18 to 70	46 $\pm$ 17, 19 to 78	46 $\pm$ 16, 18 to 81	45 $\pm$ 16, 18 to 81
BMI (mean $\pm$ SD, range)	28 $\pm$ 7, 19 to 54	27 $\pm$ 6, 18 to 40	26 $\pm$ 5, 17 to 44	27 $\pm$ 6, 17 to 54
Sex (n)				
M	25 (52%)	14 (29%)	22 (50%)	61 (43%)
F	23 (48%)	35 (71%)	22 (50%)	80 (57%)
Periodontitis (n)				
M	0 (0%)	3 (6%)	0 (0%)	3 (2%)
F	48 (100%)	46 (94%)	44 (100%)	138 (98%)

in sum PES scores between two measurements for the same evaluator or between evaluators. A threshold P value of $P < .05$ was established to denote statistical significance.

Within-group and between-group (implant-abutment interface) 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 value of $P < .05$ was considered statistically significant.

RESULTS

Study Demographics

One hundred forty-one study participants, with a mean age of 45 ± 16 years (range: 18 to 81 years) entered the study. No significant differences in mean age existed between the three unique implant-abutment interface groups. Sixty-one ($n = 61$; 43%) male and 80 (57%) female subjects entered the study protocol, with fewer male than female subjects being randomized to the FI group. Similar body mass index (BMI) averages (mean = 27 ± 6 [range: 17 to 54]) existed among the groups. Three study subjects with a history of periodontitis were enrolled in the study, and were all randomly assigned to the FI group (Table 2).

Implant Follow-up

At the conclusion of the 3-year follow-up timeframe, 13 implants were lost due to failure (CI = 0, FI = 7, PS = 6) for a cumulative survival rate of 90.8% (CI = 100%, FI = 85.7%, PS = 86.4%) prior to the 6-month recall (visit 7), and 17 participants (with 17 implants) were lost to follow-up between the 3-month (visit 6) and 3-year (visit 10) recall, for a total of 111 (CI = 45, FI = 34, PS = 32) subjects completing the 3-year recall (Fig 2).

PES Measures

Six hundred ten clinical images were evaluated and scored by five faculty evaluators during a period of 4 weeks, resulting in 3,050 sum PES measures, and 21,350 individual PES measures.

Evaluator Reliability (Group Intraobserver Agreement)

The evidence was very strong that group ICC values differed from zero ($P < .0001$), and the ICC of 0.76 demonstrated substantial agreement among the faculty evaluators between the initial and subsequent recurrent measures (PES scores). Further, no significant difference was identified between the two ($P = .9278$, Wilcoxon signed-rank test). A mean = 0.04 and median = 0.00 difference between the two measurements was reported.

Evaluator Reliability (Individual Rater Intraobserver Agreement)

The first faculty evaluator (prosthodontist) demonstrated strong agreement (ICC = 0.81, $P < .0001$) between the recurring scoring intervals. No significant difference was observed between the two PES scores (Wilcoxon signed-rank test, $P = .2964$). A mean = 0.41 (SD = 1.78) and median = 0.50 difference between the two PES scores was reported.

The second faculty evaluator (orthodontist) demonstrated moderate agreement (ICC = 0.48, $P = .0483$) between the recurring scoring intervals. No significant difference was observed between the two PES scores (Wilcoxon signed-rank test, $P = .1244$). A mean = 0.71 (SD = 1.88) and median = 0.50 difference between the two PES scores was reported.

The third faculty evaluator (general dentist) demonstrated substantial agreement (ICC = 0.64, $P = .0029$) between the recurring scoring intervals. No significant difference was observed between the two PES scores

Table 3 Pink Esthetic Score Outcomes (Within-Group Changes Up to Year 3)

Time	Conical Interface (CI)	Flat Interface (FI)	Platform Switch (PS)	CI+FI+PS
PES Total (mean $\pm$ SD, range)^a				
Visit 6 (Delivery)	8.4 $\pm$ 2.1, 3.8 to 13.0	8.4 $\pm$ 1.5, 4.0 to 11.2	8.7 $\pm$ 2.1, 4.0 to 12.2	8.5 $\pm$ 1.9, 3.8 to 13.0
Visit 7 (6-mo recall)	10.0 $\pm$ 2.1, 4.6 to 13.6	9.9 $\pm$ 1.8, 5.4 to 13.2	10.0 $\pm$ 2.2, 4.4 to 12.8	10.0 $\pm$ 2.0, 4.4 to 13.6
Visit 8 (1-y recall)	10.2 $\pm$ 1.8, 6.0 to 13.4	9.7 $\pm$ 2.2, 4.4 to 13.4	10.1 $\pm$ 1.7, 6.4 to 12.6	10.0 $\pm$ 1.9, 4.4 to 13.4
Visit 9 (2-y recall)	10.2 $\pm$ 2.0, 4.4 to 13.0	10.1 $\pm$ 2.0, 3.8 to 13.2	10.1 $\pm$ 1.7, 7.0 to 13.6	10.2 $\pm$ 1.9, 3.8 to 13.6
Visit 10 (3-y recall)	10.1 $\pm$ 2.0, 4.6 to 13.0	10.2 $\pm$ 2.2, 4.0 to 13.2	9.9 $\pm$ 1.5, 6.6 to 12.8	10.1 $\pm$ 1.9, 4.0 to 13.2
Change (mean $\pm$ SD, range)^{a,b}				
Visit 6–Visit 7	1.7 $\pm$ 1.7, –0.4 to 5.6 (<i>P</i> = .000)	1.2 $\pm$ 1.4, –1.8 to 4.0 (<i>P</i> = .000)	1.3 $\pm$ 1.2, –1.0 to 3.6 (<i>P</i> = .000)	1.4 $\pm$ 1.4, –1.8 to 5.6 (<i>P</i> = .000)
Visit 6–Visit 8	1.8 $\pm$ 1.7, –3.8 to 5.4 (<i>P</i> = .000)	1.2 $\pm$ 1.9, –4.2 to 5.2 (<i>P</i> = .001)	1.4 $\pm$ 1.6, –1.6 to 4.6 (<i>P</i> = .000)	1.5 $\pm$ 1.8, –4.2 to 5.4 (<i>P</i> = .000)
Visit 6–Visit 9	1.8 $\pm$ 2.1, –2.6 to 6.6 (<i>P</i> = .000)	1.5 $\pm$ 2.0, –4.4 to 4.6 (<i>P</i> = .000)	1.5 $\pm$ 1.4, –2.0 to 4.2 (<i>P</i> = .000)	1.6 $\pm$ 1.9, –4.4 to 6.6 (<i>P</i> = .000)
Visit 6–Visit 10	1.7 $\pm$ 1.9, –2.2 to 7.4 (<i>P</i> = .000)	1.6 $\pm$ 2.3, –4.2 to 5.2 (<i>P</i> = .000)	1.1 $\pm$ 1.7, –2.2 to 4.0 (<i>P</i> = .002)	1.5 $\pm$ 2.0, –4.2 to 7.4 (<i>P</i> = .000)

^aImplant site value is the mean of the five evaluators.

^bNegative is worse; positive is improvement.

(Wilcoxon signed-rank test, *P* = .1495). A mean = 0.41 (SD = 1.64) and median = 0.50 difference between the two PES scores was reported.

The fourth faculty evaluator (periodontist) demonstrated substantial agreement (ICC = 0.76, *P* < .0001) between the recurring scoring intervals. A significant difference was observed between the two PES scores (Wilcoxon signed-rank test, *P* = .0169). A mean = 0.88 (SD = 1.62) and median = 1.00 difference between the two PES scores was reported.

The fifth faculty evaluator (operative dentist) demonstrated strong agreement (ICC = 0.82, *P* < .0001) between the recurring scoring intervals. No significant difference was observed between the two PES scores (Wilcoxon signed-rank test, *P* = .4900). A mean = 0.35 (SD = 1.72) and median = 0.00 difference between the two PES scores was reported.

Evaluator Reliability (Group Interobserver Agreement)

Analysis of group interobserver agreement demonstrated robust evidence that group ICC values deviated from zero (*P* < .0001), and the ICC = 0.77 established substantial interobserver agreement among all faculty evaluators after completion of pairwise interobserver analyses.

Pink Esthetic Score Outcomes (Within-Group Changes up to Year 3)

As reported previously, all three implant-abutment interface groups demonstrated satisfactory esthetics, with mean sum PES scores $\geq$ 7.0 for all groups from baseline through the 1-year recall visit, and the greatest

increase in mean sum PES scores transpiring between the 6-month and 1-year recall timeframe.³⁴ Following subjects further from the 1-year to the 3-year recall timeframe, mean sum PES scores remained largely static and unchanged for each treatment group (Table 3). Group CI subjects' mean sum PES scores spanned from 10.0 ($\pm$ 2.1, range = 4.6 to 13.6) at visit 7 (6-month recall) to 10.1 ($\pm$ 2.0, range = 4.6 to 13.0) at visit 10 (3-year recall) (Wilcoxon signed-rank test, *P* = .000). Group FI subjects' mean sum PES scores spanned from 9.9 ($\pm$ 1.8, range = 5.4 to 13.2) at visit 7 to 10.2 ($\pm$ 2.2, range = 4.0 to 13.2) at visit 10 (Wilcoxon signed-rank test, *P* = .000). Group PS subjects' mean sum PES scores spanned from 10.0 ($\pm$ 2.2, range = 4.4 to 12.8) at visit 7 to 9.9 ($\pm$ 1.5, range = 6.6 to 12.8) at visit 10 (Wilcoxon signed-rank test, *P* = .002). Evaluating the mean sum PES scores through the 3-year recall timeframe, the largest change (increase) in mean sum PES scores remained between the 6-month and 1-year window, behaving asymptotically thereafter (Fig 4).

Pink Esthetic Score Outcomes (Between-Group Changes up to Year 3)

Evaluation of between-group differences in mean sum PES scores for both single time point study recall visits, as well as for changes between study time point visits using nonparametric analyses (Mann-Whitney *U* test) failed to demonstrate significant disparities between groups (Table 4). Further analysis of the distribution of mean sum PES scores from visit 6 to visit 10 demonstrated stability or improvement in mean sum PES scores for 81% of both CI and FI groups, and 76% of PS groups (Fig 5).

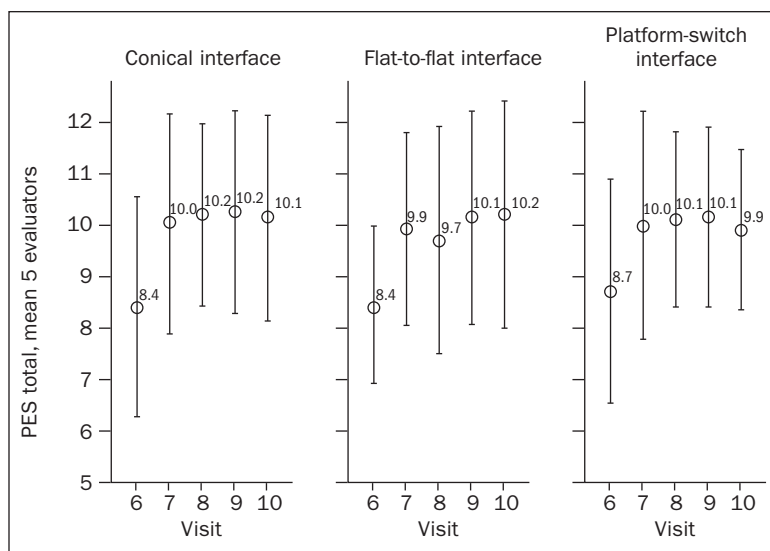


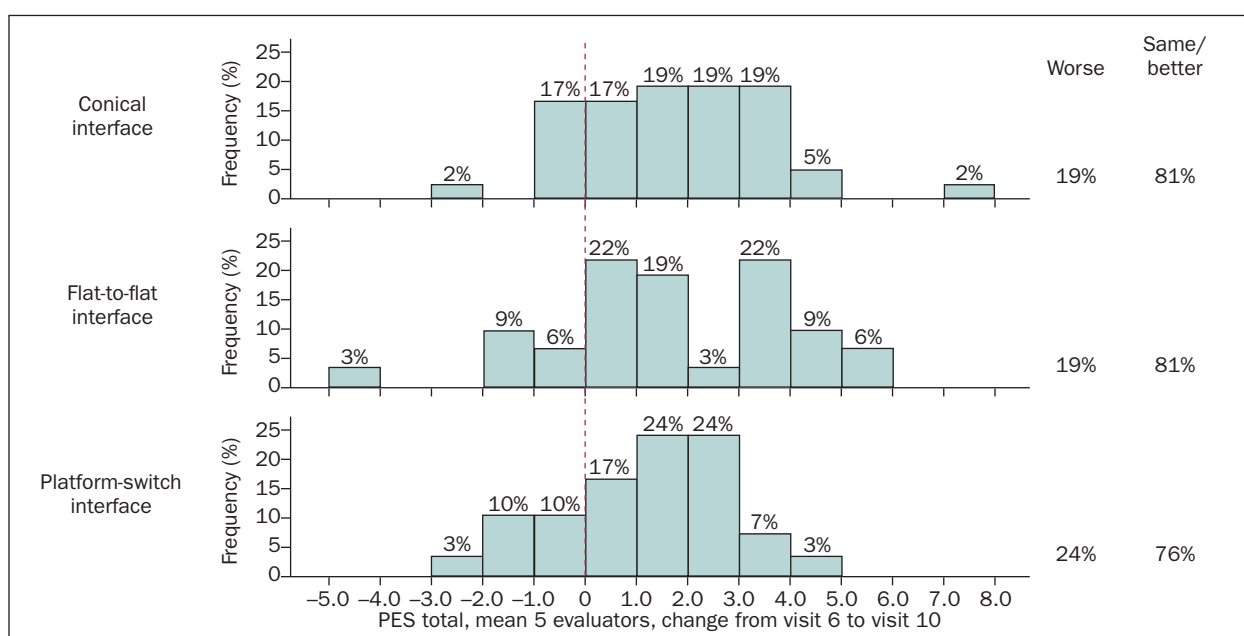
Fig 4 Mean sum PES scores (min = lower bar, max = higher bar) of all five faculty evaluators, by visit, for each implant-abutment interface.

Table 4 Pink Esthetic Score Outcomes (Between-Group Changes up to Year 3)

	CI vs FI	CI vs PS	FI vs PS
PES Total comparison (Mann-Whitney U test)			
Visit 6 (Delivery)	.837	.481	.391
Visit 7 (6-mo recall)	.679	.892	.594
Visit 8 (1-y recall)	.420	.904	.412
Visit 9 (2-year recall)	.701	.704	.900
Visit 10 (3-year recall)	.781	.336	.288
Change comparison			
Visit 6 – Visit 7	.495	.500	.935
Visit 6 – Visit 8	.138	.291	.746
Visit 6 – Visit 9	.781	.627	.781
Visit 6 – Visit 10	.937	.208	.319

All changes were not statistically significant.

Fig 5 (Below) Frequency of mean sum PES changes from definitive restoration delivery (visit 6) to 3 years (visit 10) for the three interface groups.



DISCUSSION

This multicenter, prospective, randomized clinical trial sought to investigate the impact that heterogeneous implant-abutment interfaces (represented by CI, FI, and PS geometries) yield for both hard and soft tissue outcomes at 3 years post-implant-placement and immediate provisionalization. One-year PES outcomes demonstrated that all three implant-abutment interface geometries yielded significant improvement in mean sum PES scores during the first 12 months following implant placement and immediate provisionalization, with the most dramatic improvement in sum PES scores occurring during the first 6-month time period after definitive abutment and crown connection. As was observed at the 1-year recall, the 3-year outcomes reported in this study demonstrate that no single implant-abutment interface design appears to yield superior mucosal esthetics when assessed by calibrated faculty employing the PES metric. From the 6-month post-definitive abutment and crown connection timeframe to the 3-year recall, all three groups demonstrated similar asymptotic stability of mean sum PES scores.

The 3-year mucosal PES outcomes of the present study correlate with other investigators' findings that demonstrate a level of dynamic plasticity and maturation of the peri-implant mucosa through the first year following prosthetic rehabilitation, after which time further maturation attenuates and can remain stable.^{37–39} Such peri-implant mucosal dynamics may be attributable to extended healing timeframes for implants, as compared with natural teeth.^{40,41}

Related to the findings of this study, additional factors associated with the stability and integrity of unique implant-abutment interfaces have been postulated to potentially mediate both peri-implant hard and soft tissue homeostasis. In vitro studies evaluating the biologic sealing capability of various two-piece implant-abutment interfaces have demonstrated that while no single implant-abutment interface can provide 100% absolute sealing capability, conical connection interfaces provide statistically significant decreases in the amount of saliva and bacteria penetrating the connection.^{42–44} Further, in a recent cross-sectional microbiologic evaluation of different implant-abutment interfaces 5 years after functional loading, Canullo and colleagues found that while four different implant-abutment connections all failed to exclude microbial penetrance through the implant-abutment microgap, conical connection interfaces had significantly fewer total bacterial counts in the peri-implant sulcus and within the implant-abutment connection, as compared with other connection types.⁴⁵ Such in vitro and in situ results may partially be substantiated by data

suggesting that conical connection interfaces appear to possess superior mechanical behavior under functional stress and strain.^{46–48} Additionally, a recent systematic review performed by Schmitt and colleagues summarized a large number of in vitro studies demonstrating that under vertical and oblique forces, conical interfaces demonstrated no enlargement of the implant-abutment microgap, yet external and internal hexagonal systems showed increased susceptibility to micromovement. Their systematic review also evaluated the limited number of animal and human studies available that compared conical and nonconical interfaces, and summarized that while implant survival and success rates are comparable between interfaces, the limited body of evidence seems to demonstrate that conical interfaces better maintain marginal bone levels than nonconical interfaces.⁴⁹

Despite demonstrating no significant differences in mean sum PES scores at both the 1- and 3-year post-immediate provisionalization timeframes among the three implant-abutment groups in this study, marginal bone level changes at the 1-year³⁵ and 3-year timeframes⁵⁰ were statistically significant, favoring the CI over the FI and PS interfaces. Similar trends of significant differences in crestal bone level maintenance between different implant-abutment interfaces, despite observing no difference in peri-implant mucosal outcomes between the interfaces, have been reported in another human randomized clinical trial evaluating single-tooth implants at 1 year.⁵¹ Potential explanations for the lack of correlation between bone and soft tissue outcomes in both this study and Pieri et al's study, despite different timing protocols, may be attributable to the fact that both studies evaluated outcomes of bounded single-tooth implant replacements. Such clinical parameters likely provide opportunity for the periodontal attachment levels of the adjacent teeth to significantly impact the peri-implant mucosal outcomes and may mask any influence that marginal bone maintenance, resulting from the unique interface, has on such outcomes.⁵² The authors recognize this as a potential limitation of the present study. To date, to the best of the authors' knowledge, no published prospective human clinical trials have been conducted on adjacent implants in the anterior maxilla utilizing heterogeneous implant-abutment interfaces. Such clinical trial data may potentially demonstrate a more substantial effect of the implant-abutment interface for peri-implant mucosal outcomes, as the periodontal attachment of an adjacent natural tooth would be removed from influencing interproximal and facial peri-implant mucosal outcomes.

The present study demonstrates the continued benefit of using a digital, cloud-based interface by which to collate and score a large subset of clinical images for

analysis in human clinical trials, enabling faculty or other calibrated examiners potentially located at different geographic locations to optimize and standardize viewing of the images at their convenience, unlike printed or projected images. The authors surmise that such advantages of digital interfaces also aid in reviewer calibration, which remained durable for this 3-year dataset.

CONCLUSIONS

The 3-year outcomes of this multicenter, prospective randomized clinical trial demonstrated that there was no significant difference in mean sum PES scores either within or between the three different implant-abutment interface groups, despite differences in maintenance of crestal bone levels. All three interfaces demonstrated acceptable esthetic outcomes and stability from the 1- to 3-year follow-up. Among all three groups, the most significant improvement in PES outcomes remained at the timeframe between prosthesis delivery and 6 months. Digital scoring interfaces based on cloud databases for storing and assessing PES outcomes continue to demonstrate reliability and standardization among calibrated faculty reviewers.

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